A cross-over randomised controlled trial of selective pressure impressions for lower complete dentures and laboratory investigations into impression pressure variation.

Mr T Paul Hyde

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The candidate confirms that the work submitted is his own, except where work which has formed part of jointly-authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below* (page ii). The candidate confirms that appropriate credit has been given within the Thesis where reference has been made to the work of others.

* There are three published papers which draw on the work of this Thesis:

The first was entitled 'The effect of seating velocity on pressure within impressions' (Hyde, T.P. Craddock, H. Brunton, PA., 2008. *Journal of Prosthetic Dentistry*, 100(5), 384-9.). This paper was written by the candidate, T Paul Hyde, with his PhD supervisors, Prof Paul Brunton and Dr Helen Craddock. The contribution of Prof Brunton and Dr Craddock is acknowledged as that of PhD supervisors and was advisory and editorial in nature. The paper forms part of chapter 5 of Part II of the Thesis.

The second paper was entitled 'A Technique to Construct Duplicate Dentures for Clinical Research' (Dillon, S. Hyde T.P. Brunton P. 2008 *Quintessence Journal of Dental Technology*, 6 (1), 30–39). The introduction and background were written by T Paul Hyde (pages 31-32 of the published article). The laboratory technique was devised and written by Mr Sean Dillon in discussion with T Paul Hyde (most of pages 33-36). The clinical stages were written by T Paul Hyde (interspersed in pages 34-37) as was the conclusion (pages 37-38). Mr Dillon provided all the illustrations and technical work for the paper. The paper forms part of Chapter 3 of Part IV of the Thesis. The contribution of Prof Brunton is acknowledged as that of PhD supervisor and was advisory and editorial in nature.

The final paper which drew on the work of this Thesis was entitled 'A cross-over Randomised Controlled Trial of selective pressure impressions for lower complete dentures' (Hyde, T.P. Craddock, H.L. Blance, A. Brunton, P.A., 2010. *Journal of Dentistry*, 38(11), 853-8.). This was again written with supervisory input and editorial advice from Prof Brunton and Dr Craddock; in addition the statistics analysing the results of the RCT were devised and undertaken by Mr Andrew Blance of the University of Leeds. Andrew Blance is a statistician who was also a joint applicant (with Prof Brunton and T Paul Hyde) on the grant funding for the clinical study. He wrote the presentation of the data in both the results and the discussion sections of the paper.

In addition to the papers above which draw exclusively on the work of this Thesis there are two papers that pre date the work of the Thesis. These papers were undertaken while the candidate was not a registered PhD student; both are the work of the candidate. They are relevant to the work of the Thesis and they are quoted (with appropriate references) throughout the Thesis. These are firstly a paper entitled 'Case report: differential pressure impressions for complete dentures'

(Hyde, T.P. 2003. *European Journal of Prosthodontics and Restorative Dentistry*, 11(1), 5-8) which was written exclusively by T Paul Hyde as sole author. Secondly, the paper entitled 'Survey of prosthodontic impression procedures for complete dentures in general dental practice in the United Kingdom' (Hyde, T.P. McCord, J.F. 1999.. *Journal of Prosthetic Dentistry*. 81(3), 295-9) which was written by T Paul Hyde while employed by the University of Manchester in the Prosthetics department of Prof McCord.

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I would like to acknowledge the help of Mr Sean Dillon who has acted as dental technician for the construction of all the dentures used throughout the randomised controlled clinical trial which was conducted as part of this Thesis. Sean's ability and technical excellence in producing the dentures has been central to the success of that trial. The laboratory technique for the duplication of dentures was devised by Sean and the candidate in close co-operation.

The manufacture of the brass components for the in-vitro studies of Part II of this Thesis is the work of Mr D Foakes who I would like to thank for his craftsmanship and patience.

Finally, I would like to thank my wife Hilary for all her encouragement and support. We both look forward to a time when we will no longer use the words ‘after the PhD’ to anticipate the future.

Abstract

Part I of this Thesis gives a brief outline of the history and evidence for impression techniques for complete dentures. The literature review suggested there was a paucity of high quality evidence for impression techniques for complete dentures, especially in the form of randomised controlled trials (Jokstad et al 2002, Harwood 2008).

The literature review from Part I suggested that selective pressure impressions for complete dentures required evidence on three levels; firstly, in-vitro evidence on the numerous factors that affect pressure, secondly evidence that within a specific impression technique the pressure is re-distributed, and thirdly evidence that the specific impression technique provides patient benefit. Part II, III and IV of this Thesis address each of these issues in turn. Part II of the Thesis uses laboratory based in-vitro impression pressure research to investigate new issues and re-address old controversies where the evidence in the literature was conflicting or deficient. Part III investigates the specific distribution of pressure within the impression technique used for the clinical trial of Part IV, concluding that the pressure was distributed in a specific and useful way, which was clinically significant.

The Clinical Trial reported in Part IV of this Thesis, had the primary objective of assessing patient preference for a specific selective pressure impression for complete dentures. The cross-over, randomised, controlled, clinical trial (RCT) was performed comparing a selective pressure impression with a placebo and an alternative method of redistributing pressure. Patients who had shown a specific pressure related clinical problem were recruited for the study. The results show that the preference for the selective pressure impression was greater than that of the other two techniques.

The work of this Thesis introduces dentists to a successful impression technique and provides them with clear, clinically relevant and useful evidence for that impression technique.

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Part I

Background

Chapter 1
Introduction

Selective pressure impression techniques have been widely advocated for complete dentures (see literature review below). They aim to distribute load under dentures. They are said to achieve this by applying different loads within different areas of the same impression. Although widely advocated the evidence base for the techniques is limited. To fill the gap in the evidence base, research was required on three levels. First a series of 11 laboratory experiments were required to investigate individual variables that may affect the pressure. Secondly a laboratory investigation was required to simultaneously measure the pressure at two points within a selective pressure impression; one point located where the pressure was designed to be higher and another where the pressure was intended to be lower. Thirdly an RCT of the selective impression technique was required to investigate the benefit to patients of the impression technique. These three areas of investigation are presented in Parts II, III and IV of this Thesis. Part II investigates the factors that affect the pressure within prosthodontic impressions. Part III investigates the differential pressure within a specific selective pressure impression technique. Part IV reports a randomised clinical trial of the selective pressure technique.

The overall research question for the Thesis is, ‘Is a specifically designed selective pressure impression technique effective?’ This over all research question is then divided into the three parts. In Part II the primary research question is, ‘What factors alter pressure within impressions in-vitro?’ In Part III the primary research question is, ‘Is the intended pressure differential physically produced within a selective pressure impression in-vitro?’. In Part IV the primary research question is ‘Do patients receive a benefit from the selective pressure impression?’. However, before these investigations began we needed to consider the academic background to the research project. The review of the academic literature forms the basis of Part I of the Thesis.

Chapter 2
Review of the development of impression techniques with reference to pressures within impressions

In 1951 Carl Boucher, who was well known for his prosthodontic text book and who many consider an authority within prosthodontics in the 20th century, stated 'There are far too many impression techniques to consider each one separately.' (Boucher 1951). Since that date further impression techniques and many more variations on impression techniques have been reported in the literature. Boucher in his paper (Boucher 1951) showed profound insight into the subject of denture impressions and went on to discuss the problems associated with the classification of impression techniques. Taking a lead from Boucher, this literature review does not attempt to review all the expounded variations in the techniques for impressions for complete dentures; rather, it looks at the origins of the various types of impressions (or impressions 'philosophies') with particular reference to the pressure within the impression.

Impressions for dentures have a long history. Lufkin (1948, p 294-297) stated that 'Plaster of Paris was first suggested for impressions in 1844 and was soon in general use'. Later beeswax, other waxes, resins and various modelling compounds were developed to overcome the 'many disadvantages of plaster' (Lufkin 1948). It wasn't until 1925 that materials flexible enough to be removed undistorted from undercuts (the colloid agar-agar) became available (Lufkin 1948). The contemporary list of available impression materials was completed by the introduction of Zinc oxide/eugenol, irreversible hydrocolloids (alginates), polysulphides, polyethers and polyvinylsiloxanes (silicones).

In addition to the numerous variations of available materials, impressions can be classified by the relative amount and distribution of pressure exerted on the underlying tissues. Impressions may be described as 'selective pressure', 'mucodisplasive', 'mucostatic', or 'functional occlusal pressure'. It is instructive to look at the origins of these four types of impression.

2.1 Origins of selective pressure impressions

The early paper by Stansbery (1925) introduces selective pressure impressions and gives an insight to the understanding at that time of the pressures within impressions. Stansbery's (1925) elegant demonstration of high pressure at the centre of approximated discs influenced future discussions over pressure distribution. The high central pressure has been partially confirmed by direct observation in in-vivo experiments (Douglas et al 1964, and Rihani 1981). However some in-vitro experiments seem to partially contradict Stansbery's prediction; for example Masri in 2002 and Frank in 1969 are both reported to have found the reverse but only with unperforated close fitting special trays (see later discussion in chapter 4 below and Part II chapter 7). Stansbery's (1925) paper describes a method specifically designed to selectively load mucosa under an impression. Although the published scientific evidence for selective pressure techniques was (and is still) limited the paper demonstrates that the concept of a selective pressure impression was one of the earliest impression philosophies to be defined and advocated.

The technique described by Stansbery (1925) was a two phase impression. Phase 1 was a compound impression which was cut back in specific areas and followed by a plaster of Paris wash (phase 2). The technique was specifically designed to preferentially load the residual alveolar ridges and the post dam areas. Although the clinical impression technique advocated by Stansbery (1925) may seem over complicated, the principles it expounds lay a basis for much of the academic debate over the next half century; discussions of 'palatal rock' and the eventual development of 'palatal relief chambers' may be traced back to this paper. Unfortunately the paper presents no hard evidence of the clinical success (or otherwise) of the clinical technique. The successful redistribution of the pressure is not physically demonstrated within an impression; it is assumed. Furthermore the assumptions that it is right to distribute pressure to the residual ridge and that doing so will result in a better denture are not tested. It is only later, with the development of the methodology of Randomised Controlled Trials (RCTs) that an adequate tool became available for a comparison to be made between impression techniques. This paper by Stansbery (1925) remains the forerunner of 'selective pressure' impression techniques and stands the test of time where contemporary papers seem dated.

2.2 Origins of high pressure, mucodisplasive impressions

In contrast to Stansbery (1925) the paper by Fournet and Tuller in 1936 advocates a high pressure impression technique. A modern day clinician reading the original paper today will be struck by how far academic writing has progressed over the last 74 years. The blatant advocacy of a technique in this way would not be acceptable in a modern academic journal. However the paper is of its time and an important contribution to the debate on impression pressures. The technique advocated by the paper involved high pressure. The technique was described by others as 'muco-compressive' until the inherent error within this term was brought to the professions attention by Addison's paper of 1944. The technically correct term of 'mucodisplasive' was suggested as an alternative by Addison (1944). In current day practice true mucodisplasive impression techniques are thought to restrict blood supply to bone, increase alveolar resorption and are no longer routinely advocated for complete dentures (El-Khodary et al 1985). The 'altered cast' technique for free end saddle partial dentures is perhaps the best known contemporary use of deliberately high pressure impressions.

2.3 Origins of mucostatic impressions

Addison's 'Mucostatic' paper (1944) is again written without formal experimental or clinical evidence; it is argued from first principles in the rhetorical style of the era. The assumptions and assertions of the paper need to be challenged; in modern terms the paper lacks evidence. Addison (1944) advocates a low pressure or 'Mucostatic' technique. Although there are no known papers published by Page until 1946, he is credited by Addison (1944) with being the originator of the mucostatic impression 'principle'. Page was a physicist and engineer who was reputed to have presented his mucostatic principle to the profession as early as 1937 (Lee 1980). By 1951 Page's mucostatic principle reads 'Lasting stability demands an impression and denture base that are accurate negatives of the ridge tissues in their natural passive form' (Page 1951). As a principle this has much to commend it. Page does not suggest or endorse any particular impression technique to achieve his principle and so appears to leave how the mucostatic principle is actually achieved in the mouth to the dentists he taught. The irreconcilable Mucostatic/Mucodisplasive argument became the focus for academic prosthodontic

debate for some considerable time. As late as 1980 the Mucostatic paper by Robert E Lee echoes this debate.

The idea of taking an impression of the tissues 'at rest' is central to the concept of 'mucostatics'. This requires that the visco-elastic mucosa (Kydd 1974 & 1976) is allowed to return to its undistorted shape prior to taking an impression. Lee (1980) states this aspect of mucostatics succinctly 'A mucostatic impression should be taken in a well healed mouth that is free from inflammation. Should the patient be wearing an old denture with resulting inflammation, the denture should be left out of the mouth until the inflammatory condition has subsided. If this not be convenient, a tissue conditioner might be used under the existing denture to reduce inflammation'. Lee (1980) does not say that the use of a tissue conditioner returns the tissues to 'rest'; there is an implication that the use of a tissue conditioner is second best to leaving the denture out.

2.4 Origins of functional impressions

Lytle's' 1957 paper points out the importance of the 'management of abused oral tissues' and points out that neither dentists from the mucostatic school nor the mucodisplasive camp would want to take an impression of 'deformed tissues' (Lytle 1957 p32-33). This concept of preparation or 'conditioning' of the mouth prior to definitive impressions is taken up in prosthodontic text books (Boucher 14th edition p219; and Basker and Davenport 2002, chapter 8).

Chase 1961 takes the concept of tissue conditioning further. He gives details of a technique for tissue conditioning and then uses the impression within the tissue conditioned denture for the definitive cast for the new dentures. He used a material called Hydrocast which is described as an acrylic powder mixed with a plasticizer. The conditioner was placed under dentures and left in-stitu for a period of 2-3 days (this step was repeated until the denture were satisfactory for the patient); then a final wash with the same material worn for 4-5 hours, after which the definitive casts was poured from the impression in the dentures. Chase (1961) called this the 'dynamic adaptive stress' method of taking impressions. Chase (1961) paper points out that 'the oral tissues assume a different contour under treatment' but could only claim that 'we assume it is beneficial'. In his discussion Chase (1961) states that 'Dentures made on casts poured in these dynamic impressions were, in general,

superior to those made from our usual impressions'. Chase (1961) gives no details of his 'usual impressions' technique. It is worth saying again that it is only later, with the development and application of the methodology of Randomised Controlled Trials (RCTs) that an adequate tool has become available for a comparison to be made between impression techniques. The technique has been adapted by others (Vig 1965) and has become known as 'functional occlusal pressure' impressions or just simply as 'Functional' impressions.

2.5 Contemporary impression procedures

Most modern British standard textbooks recognize the variation in academic opinion on impressions. Each offers various materials and techniques for different clinical situations. Watt and McGregor (1986) described both impression compound and irreversible hydrocolloid (alginate) primary impressions and four basic materials for secondary impressions and an additional five 'special' techniques. Basker and Davenport (2002) advocated a compound and alginate primary impression with the same basic materials and techniques for final impressions as McGregor. Grant et al (1994) recommended three primary impression materials and a total of 7 techniques for definitive or secondary impressions. In contrast to the variety given in most modern British text books the standard American textbook, originally written by Boucher, is unique among the major textbooks in only advocating one standard impression technique for final impressions and not recommending any specific impressions materials. The phrase 'the impression material of choice' is now used when the final impression technique is described. Although Boucher discusses plaster, zinc oxide/eugenol, irreversible hydrocolloid and elastomeric impression materials, in the 13th edition (Boucher 1997) of the text book the editors defer the choice of impression materials saying 'The reader should refer to a textbook on dental materials science for a detailed description of impression materials'. They go on to emphasize custom tray construction and adaptation, implying (perhaps correctly) that this is more important than the choice of impression material. In the 14th edition (Boucher 2004) the deferring sentence on the choice of materials was removed, but rather than any firm new guidance, the phrase 'the impression material of choice' is still used. Practitioners still make their own choice; in the UK, Hyde's survey of 1999 showed the choice of material was often alginate (Hyde 1999).

The British prosthodontic textbooks do give useful advice on which clinical situation each technique is best suited and on appropriate details for special trays. The variety of recommendations in these textbooks suggests no one technique is satisfactory for all clinical situations. Indeed, different clinicians offer different solutions to the same problem.

2.6 Developing consensus or continuing controversy?

While new developments in materials and techniques for impressions continued to contribute to the sum of academic knowledge, Firtell and Koumjian pointed out in 1992 that: 'recent reports in the literature agree that selective pressure is the best method of making impressions for complete dentures'. This developing consensus towards selective pressure impressions did not stop new applications for materials and variations in selective pressure impressions techniques being advocated in the literature (Klein and Broner 1985, Hyde 2003, Duncan et al 2004, Lynch and Allen 2006, Massad et al 2006 & 2007 etc). However, with this academic development of selective pressure impressions comes the accompanying repetition of untested assumptions and over time it has become the accepted proposition that the pressure within impressions can be controlled and redistributed by an impression technique. Fundamental basic research was needed to confirm this assumption.

2.7 Different opinions on the clinical application of selective pressure

As more academic authors took up the 'selective pressure' theme, it becomes unclear on what basis a clinician should select areas for low or high pressure. The dental literature reveals different opinions as to where pressure should be exerted during the taking of an impression. It is useful to classify these opinions. Some authors advocate placing pressure to effect *retention*; others to distribute *support*; others for *occlusal stability*, and (later) others to prevent *resorption*. These four differing priorities for placing pressure partly explain the numerous differing techniques for impressions advocated in the literature. It is instructive to look at these four possible reasons for placing pressure in turn.

2.7.1. Priority retention

If one's priority was *retention* then one would perhaps advocate placing some pressure at the periphery (Frank 1970 p 457) to give an improved 'peripheral seal' (later known as 'border seal'). Peripheral seal was considered important but it should be noted that the work of Rihani (1981) seems to question if it is possible to achieve peripheral pressure that is high relative to central palate pressure in a situation where the special tray has no other vents (perforations) for the impression material (see discussion below page 21). Frank (1970) makes the assumption that tissue distortion (via increased impression pressure) is possible at the periphery of the special tray. This may or may not be true. The assumption that a close fitting adaptation of the tray at the periphery produces a relatively higher pressure at the periphery is not tested; nor can it be assumed to be the case from the in-vitro work of Frank (1969).

It could be argued that at the periphery of a denture all that is needed (and maybe all that is actually achieved via Frank's 1970 technique) is a close adaptation to the mucosal reflection at the functional depth of the sulcus. Such close adaptation alone may be sufficient to gain retention by the cohesive and adhesive forces manifest in the surface tension of the meniscus of a thin film of saliva. It remains unclear whether high pressure at the periphery of a denture is obtainable or desirable for retention. Further research is required to investigate this. High peripheral pressure may also restrict blood flow to the periosteum of the buccal alveolar ridge and increase alveolar resorption. Further research is required to investigate this possibility.

2.7.2. Priority occlusal stability

If one's priority for selective pressure distribution was occlusal *stability* one may advocate low pressure over the relatively non compressible tissue of the palatal mid-line to avoid a 'palatal rocking' motion on this tissue in the final denture. As we have seen this was first suggested by Stansbery 1925, taken up by Boucher (1944, 1951) and widely held to be true by academics over many years. In 1970 Collett (p259) debated the validity of this hypothesis based on the experimental in-vitro work of Frank (1969) but after this discussion, Collett concluded and advocated a 'large hole in the palatal part of the tray' to 'allow excess materials… to escape' and 'reduce unwanted pressure in this area' (Collett 1970, p260). The

relevance, accuracy and possible errors of experimental measurements of palatal pressure versus ridge pressure are discussed further under chapter 4 below and in Part II chapter 7.

2.7.3. Priority support

If one was using a selective pressure technique in order to gain the best *support* then one may choose to put the pressure on minimally compressible tissues. The original window technique of Watson (1970) and the variations in the technique (e.g. Lynch and Allen 2006) aim to achieve this effect. Alternatively one may routinely choose to load the so called 'primary support' areas. The reasons why certain areas are designated as 'primary support areas' are difficult to trace back in the literature. In the upper arch it appears many authorities ultimately base their assumptions on avoiding palatal rock and/or pressure on central palate or incisive foramen. This ultimately links to discussion above on occlusal stability. There has been some debate in the literature as to the precise position of these 'primary support' areas. Stansbery 1925 says 'the residual ridge must bear the burden of mastication'; Boucher 1951 p 477 agrees that the residual ridge is the 'primary denture bearing area' but only in the upper arch and for the lower arch Boucher suggests 'the buccal shelf …is ideal for carrying the stresses of occlusion' (Boucher 1951, p 478); Collett (1970) agrees and says the lower buccal shelf, not the residual ridge, can be the ideal primary support area in the lower arch. Frank (1970) states that the lower residual ridge is the primary support area until the ridge is resorbed when the buccal shelf becomes the primary support area. He appears to miss the irony that preferentially loading the ridge (as the 'primary support area') may cause resorption. Into the late 1970's there seems to be an emerging consensus that the primary support area of choice in the upper arch is the ridge and in the lower arch the ridge and/or the buccal shelf; albeit this consensus was developing without proven research based evidence of any benefit to the patient of preferentially loading these 'primary support areas'. However in 1983 Jacobson and Krol challenged the consensus by saying that the sloping palate (but not mid line or incisive papillae) is the primary support area (Jacobson and Krol 1983a, Jacobson and Krol 1983b, Jacobson and Krol 1983c).

2.7.4. Consideration of alveolar resorption

Although Boucher had advocated relief of the incisive papillae 'to protect the blood and nerve supply that emerges there' (Boucher 1951 p477), the selective placing of impression pressure specifically to protect the blood supply or prevent *resorption* is a relatively modern concept. Jacobson and Krol (1983c) concludes 'those [regions] that are less resistant to long term changes or are unable to tolerate stress should be relieved of excessive contact with the denture base.' (Jacobson and Krol 1983 p 312). His description of 'primary support areas' is consequently at variance to the developing consensus. Few would disagree with the aim of using areas that are resistant to resorption to support dentures, however, research is required to show where these areas are to be found. Jacobson and Krol's diagram of upper primary support area (Jacobson and Krol 1983, Figure 9, p 311) suggests loading the area of the emergence and distribution of the greater palatine artery. Research is still required to show the benefit of such a policy. Basic research was also required to confirm that selectively loading any particular area is physically achieved under any advocated impression procedure. Part III of this Thesis may represent the first publication to give evidence of deliberate and successful pressure variation within an impression; Part IV of this Thesis presents original research to demonstrate the patient benefit of pressure distribution.

As Collett (1970) points out 'All techniques have advantages and disadvantages. None will accomplish the objective completely. When an advantage is introduced, often a disadvantage is introduced at the same time. Each technique is of necessity a compromise'. This statement is wise; it has echoes of the old philosopher's statement that 'what has been will be again, what has been done will be done again; there is nothing new under the sun' (Eccles.1:9 RSV). However it is not used by Collett (1970) as a reason for no further enquiry. Indeed in his critical analysis of the areas of ignorance and prejudice in prosthodontics, Collett (1970) highlighted the need for more robust scientific enquiry.

2.8 Evidence required

The debate of how, where and why to put pressure should continue but it must be backed by evidence. The evidence required is on two levels. First the advocated impression techniques must be shown to be effective in delivering a selective

pressure. This is fundamental and to date has only been assumed to be achieved by any advocated impression technique. The alleged pressure distribution of an advocated impression technique should be demonstrated. This may be achieved by simultaneously measuring the pressure within these impressions at high and low pressure points. In the first instance this may be done to a basic level in-vitro. Secondly, evidence is required on the outcome of any advocated impression technique. The fact that an impression technique re-distributes pressure does not automatically mean that the impression technique produces a better denture for the patient. An impression technique must be shown to be advantageous to the patient in a double blind randomized controlled clinical trial.

This author developed and published a selective pressure impression technique to relieve sharp bony ridges under a lower complete denture (Hyde 2003). The paper detailed how the author had attempted to relieve an area by the use of a novel development of selective pressure impression techniques using polyvinylsiloxane (silicone) materials (Hyde 2003). The technique for distributing pressure has been further developed and reported by Lynch and Allen (2006) in a new application. However the published paper (Hyde 2003) lacked the fundamental evidence detailed above. As we have seen this is unfortunately not unusual in the field of reporting clinical impression techniques. The overall aim of this PhD is to investigate the effectiveness of a selective pressure impression technique (Hyde 2003) in delivering differential pressure and patient benefit.

Chapter 3
Anatomy of the denture bearing area and physical properties of the oral mucosa.

3.1 Anatomy

The paper by the late Carl Boucher in 1944 entitled 'Complete denture impressions based on the anatomy of the mouth' was the seminal work on the applied anatomy of the so called 'denture bearing areas'. The 1944 paper (Boucher 1944) follows the joint anatomical paper he wrote with anatomist L F Edward on the anatomy of the mouth in relation to complete dentures (Edward and Boucher 1942). Boucher's definition of the denture bearing area (Boucher 1944) is still used in contemporary textbooks. His use of the anatomical landmarks including muscle insertion and the mucosal reflection to define the extent of the sulci is still fundamental to a good understanding of prosthodontics. The classic anatomical dissection photographs used in Boucher's work (Boucher 1951) help to define the detail of the structure and features of the denture bearing areas of the upper and lower jaws.

References that report dissections to investigate the applied anatomy of the edentulous denture bearing area are few in the literature. A review of the dental literature has yielded no other paper which reports anatomical dissections of the whole denture bearing area. After Boucher the applied anatomy is investigated by dissection only in relation to specific areas (i.e. not the whole). For example Nairn (1965) shows a dissection of the retro molar pad and histopathology of a transverse section of the posterior lingual sulcus; Preiskei (1968) gives a detailed discussion of the gross anatomy of the posterior lingual sulcus; Shannon's dissection of 50 cadavers is instructive to examine the mentalis insertion (Shannon 1972). These papers illuminate understanding of specific aspects of the denture bearing area as defined by Boucher. Edwards and Boucher's work and Boucher's use of it (Edwards and Boucher 1942, Boucher 1944, Boucher 1951) remain the standard references for the applied anatomy of the normal, edentulous 'denture bearing' area.

Although they do not discuss the denture bearing area as a distinct entity, modern anatomy textbooks illuminate the underlying general anatomy. Foremost

amongst these, Berkovitz et al (Berkovitz et al 2002) discusses the gross anatomy, innervations, vasculature and mucosal histology of the area and the adjacent structures with good illustrations, dissections and a clear writing style. Norton (2007) and Johnson (1989) also give good groundings in the subject.

Prosthodontic textbooks are more helpful in confirming the outline of the denture bearing area. The latest edition of Basker's textbook (Basker et al 4th edition, 2011) concurs with Boucher on the outline of the area and gives clear anatomical diagrams to illustrate its extent (Basker et al 4th edition pages 130-135).

Although Boucher is credited here for his anatomical work, it is important for the reader to distinguish Boucher's presentations of fact from his opinions because they are delivered in the same authoritarian style of writing. For example his description of the histology of the palatal mucosa (Boucher 1951, page 476) is detailed and accurate; however his statement that 'relief {*of the incisive papilla*} is absolutely essential because the incisive papilla is found on or near the crest of the alveolar ridge, and is very soft…..pressure on it will interfere with blood supply…..this relief must be made mechanically' has been deduced and advocated by Boucher with little or no direct evidence to support it. It would not be considered best practice in the 21st century dentistry; but this is minor criticism of the immense contribution to Prosthodontic dentistry by Carl Boucher. Overall, he advocated understanding and knowledge to inform appropriate decision making for individuals; for example in 1951 he stated 'There is no single ('best') impression technique. The variety of impression materials and the range of working characteristics of these materials, make possible the development of impression procedure best suited for the specific conditions in each area in a mouth. Blindly following a technique will not produce the results which are possible by critical analysis of the requirements of the patient….'. In this he was ahead of his time.

Designing an impression technique to deal with a specific problem was rewarding (Hyde 2003); investigating such a technique by laboratory studies and a cross over Randomised Clinical Trial is the subject of this Thesis, with the aim of providing evidence for clinical practice.

3.2 Physical properties of the oral mucosa

Standard textbooks give good descriptions of the histology of the denture bearing area. The reader is referred to Berkovitz et al (2002) and to Johnson and Moore (1998) for details of the mucoperiosteum, the masticatory mucosa and the lining mucosa of the denture bearing area. The ability of the mucosa to bear the denture relies on the physical properties of the oral mucosa.

As Kydd (1967) says, 'All complete and most removable partial prostheses must rest upon the mucoperiosteum of the residual ridge and palate'. On occlusal load, complete dentures are supported by mucosa; therefore, it is important to understand the nature and physical properties of the mucosa of the denture bearing area. The work of Kydd (1967, 1969, 1974, 1976 and 1982) forms much of the basis of our current understanding of the physical properties of the oral mucosa, although Kydd himself acknowledges the earlier work of Sohm (written in German in 1934), and Lytle (1962).

Sohm (1934) as cited by Kydd (1967) is reported to have tested the palatal mucosa under compression of a rounded 9mm steel ball bearing. This is the direct translation of the classic test of the modulus of elasticity of a material, brought from the materials laboratory, and applied to oral mucosa. Sohm (1934) is cited by Kydd (1967) as reporting differences in compression of oral mucosa under a standard force at differing sites around the mouth.

Lytle (1962) made casts 'from hydrocolloid impression of twenty five partially edentulous ridges that had been supporting partial dentures. The partial dentures then were removed for a period of sometime. Casts were made from hydrocolloid impressions of the same ridges after the soft tissues had recovered their normal form', quoted from Lytle (1962). Although the paper concentrated on the displacement of tissues under a functioning denture rather than the recovery of the tissue shape and the nature of the mucoperiosteum, he does refer to a 'tendency for soft tissue to return to their normal form will be referred to as tissue recovery.' To the modern reader the paper was, amongst other things, an early demonstration of the visco elastic recovery of oral muco-periosteum.

Prior to Kydd (1967), all the testing of the physical properties of mucosa was undertaken in compression, for the first time in 1967 Kydd published the tensile results of fresh sample of mucosa in-vitro alongside the compressive test results.

His results ‘found that human gingival gave an anisotrophic response, therefore the results are given as *low moduli* and *high moduli*. When plotted this tissue generated an S-shaped curve’ (Kydd 1967). This was the first indication that the complex compound biological tissue mucosa could not be assessed by a simple, single, modulus of elasticity.

The classic 1971 paper by Kydd plotted the thickness of the oral mucoperiosteum using an intraoral ultrasonic depth gauge in-vivo. The thinner mucoperiosteum over the midline of the palate and thicker mucoperiosteum elsewhere in the palate was shown clearly in this early in-vivo work of Kydd (1971). The Figures obtained still represent the best evidence of in the vivo depth of denture bearing area despite some later and cruder attempts at in-vivo depth measurements using sharp probes (Wara-Aswapati N, 2001).

Kydd’s 1974 paper built on his earlier work and demonstrated the visco-elastic nature of human soft tissue. The delayed recovery time and the effect of aging were clearly shown.

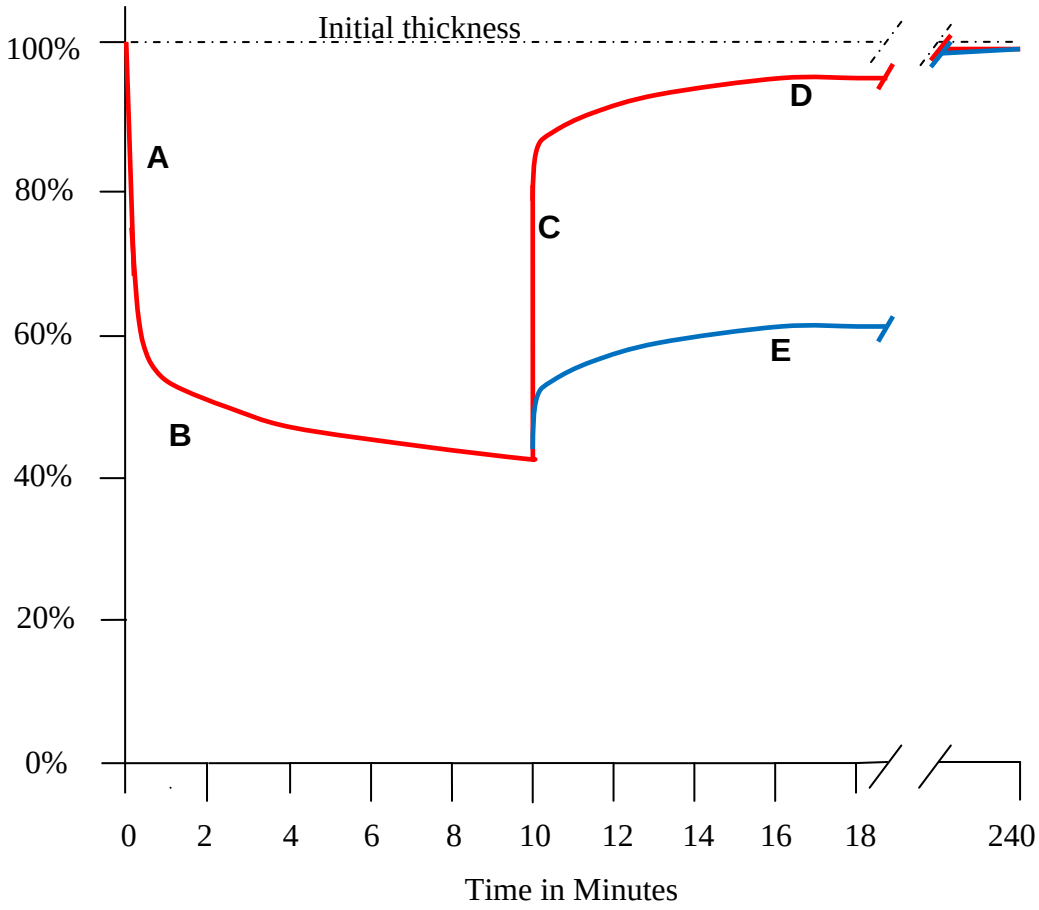

Figure 1 Reporting Kydd's findings in the style of the summary diagram of the 'typical' results published by Kydd (1974). The compression of mucosa is followed by the release of load; the graph follows the resulting mucosal thickness as a percentage of total mucosal thickness.

Figure 1 shows a classic summary diagram in the style of Kydd (1974); it demonstrates the physical properties of mucosa and the viscoelastic nature of the mucoperiosteum under load and following release from load. Of particular interest for the studies in Part II of this Thesis is the demonstration of the speed of tissue distortion under load (section marked A on the diagram) and its age dependant, slow recovery (the sections marked D and E on the diagram). The blue line (marked E) represented the 'typical' recovery in older patients and the section marked C & D represented the 'typical' recovery in a young patient. The tissues initially recover quickly but only to a maximum of 85% of their original depth (in the older patients there was much less 'initial' elastic recovery). Eventually the tissues do recover to their full (pre-load) height but this is several hours later.

This slow viscoelastic nature of the recovery of the full mucosal thickness is relevant to this study of pressure within impressions. A high initial pressure can be expected to distort the mucosa instantaneously, but release from that pressure will not give recovery to the full mucosal depth within the timescale of the impression itself. In these circumstances the pressures at the end of an impression become less important that the high peak pressures that occur during impression making.

The 1982 paper by Kydd on the effects of stress on the oral mucosa looks at histopathology of mucosal stress and provides a useful summary of his findings and philosophy derived from many years of research on the subject.

El-Khodary et al (1985) took the histopathology further in his 1985 paper and looked at the effect of high pressure impressions, and the subsequent wearing of dentures made from them, on the histology of the mucoperiosteum. He found increased numbers of osteoclasts under denture made from high pressure impressions; implying that high pressure impressions increase bone resorption. This work is significant as it draws together the themes of the nature of the denture bearing mucosa and impression pressure; showing the effects of impression pressure on the mucosa under the subsequent dentures. It reminds prosthodontists of the importance in modern prosthodontic practice of avoiding high pressure under impressions wherever it is possible to do so.

Chapter 4
Measuring pressure in impressions

The papers which directly measure impression pressure require critical review. Wain (1961) was the first to use a pressure transducer to measure directly the intra oral pressure under a denture during insertion, rest and removal. However the first author to report the direct measurement of the pressure of an impression was Douglas et al (1964). Douglas et al (1964) found intra oral pressure with zinc oxide eugenol impressions on insertion varied from 1.4 pound/square inch (9.65 kilopascal) to 4 pound/square inch (27.58 kilopascal). Many papers prior to this had speculated on the pressure under impressions but this short early paper was the first that physically measured impression pressure and so was the forerunner of this line of research. In their discussion the authors suggest that 'the behaviour of the pastes should be assessed in the laboratory'. Other workers have taken this advice and studied impression pressure in-vitro (Frank 1969, Masri 2002, Komiyama et al 2004, Al-Ahmad et al 2006, Hyde 2008).

Douglas et al (1964) reported results from only two patients (albeit that each patient had a total of 7 impressions with different proprietary brands of Zinc oxide impression pastes). The lack of sufficient numbers and the lack of control of the numerous variables make firm conclusions difficult. Higher central pressure compared to lateral pressure is found (but on different patients) and it is useful to have this limited confirmation of the expected pressure distribution in an in-vivo direct measurement (see later discussion on this issues Part II chapter 7). The inconsistency of the ranking of insertion pressure of the 7 pastes between the two different patients is remarked upon within the paper. This may be because variables were not understood or controlled; for example the hand held insertion was not at a controlled velocity, this alone would be enough to explain the differences between the pressures (Hyde 2008). The custom constructed analogue pressure transducer used by Douglas et al had a '0.004inch thick brass diaphragm'. The response time of the transducer pressure readings was not calibrated. It is not know what dampening effect the brass diaphragm had on the response time of the sensor. If the response time was long, any resultant dampening of short duration peak pressure

readings would be constant across the study; but the study may then underestimate all the 'peak' pressures.

Frank's 1969 paper requires detailed consideration since it is the definitive work of the 20th century on impression pressures. 21st century papers (Masri 2002, Komiyama et al 2004, Al-Ahmad et al 2006 and Hyde 2008) all refer back to this original work and advance knowledge with modern impression materials.

Frank's in-vitro experiments used an 'oral analogue' which consisted of an edentulous cast constructed in silicone rubber. The validity of the 'oral analogue' was tested by comparing pressure readings taken on it with those obtained with the same measuring apparatus used in-vivo on the patient from whose dental cast the analogue was constructed. Frank (1969) used a constant velocity motor which later Komiyama et al (2004) tells was set at 120mm/min. The measuring apparatus used by Frank (1969) was completed by 'an unbounded wire strain gauge' connected to plastic tubing then to brass tubing which was covered at one end by a 'thin flexible rubber membrane'. The tubing was filled with water. This arrangement, particularly the 'flexible rubber membrane', is likely to dampen the sharpness of the peak recording of pressure on the oscilloscope.

Frank's (1969) methodology can be compared favourably to contemporary papers. For example in those pre-digital days he used analogue equipment. An analogue pressure transducer connected to an oscilloscope gave a continuous read out of pressure. The capture of the oscilloscope image allowed the pressure to be determined at any point in the making of the impression. This gives a superior capture of data than the human observation of a visual meter used by Masri (2002) and Al-Ahmad et al (2006). Masri and Al-Ahmad et al could only observe the pressure meters every 10 seconds and so may have missed peak pressures. Even the digital capture of data by Komiyama et al (2004) may be inferior since it used a low digital sample rate of the analogue signal (at 5Hz) which may be too slow to capture accurately the true peak pressure. A 5Hz sample rate (Komiyama et al 2004) is likely to have resulted in a lower recorded peak pressure mean (with a higher variance).

Frank's (1969) results were presented in four sections; determined by whether they were 'initial' pressures or 'end' pressures, mechanically produced pressure or manually produced. 'Initial' pressure is the peak pressure on seating an impression.

These ‘initial’ pressures are significant since the work of Kydd (1967, 1969, 1974 & 1976) tells us that once distorted the viscoelastic mucosa will not rebound to its full depth or original shape for hours. ‘Initial’ pressures are always greater than ‘end’ pressures. ‘End’ pressure is the residual pressure at which the impression material does not overcome the frictional resistance to movement over the analogue. In Frank’s (1969) paper the results for the ‘Initial’ pressures showed a variation in pressure was obtained with the various impression materials. The results suggest a possible correlation between the pressure and the viscosity of the materials. Perforations reduced ‘initial’ pressure. Spacing of the trays reduced ‘initial’ pressure. The figures for spacing may reflect the larger peripheral vent in a spaced tray on the in-vitro model; this may or may not happen in-vivo and is discussed later (see Part II Chapters 14 &15).

In Frank’s (1969) paper the manual seating of impressions failed to give consistent results between dentists. One dentist in particular was able to make impressions with all four impression materials and produce the same pressure. It may be that he achieved this by simply varying the speed of seating (Hyde 2008).

When Collect (1970) discusses the theory that the centre of the palate has high pressure relative to the residual ridge, he states that Frank’s (1969) ‘research opens this belief to question’. Rihani (1981) goes further and says ‘Frank found that the ridge crest received much more pressure than did the palate’. It is worth noting that Frank’s paper shows no statistical difference between ridge and palate except in unperforated close fitting trays. Furthermore Frank is actually contradictory on this point, during the section on the ‘validity of the analogue’ he states ‘higher forces were recorded in the palatal area than in the ridge crest area’ (Frank 1969, p403). This issue of high palatal pressure relative to ridge pressure was unresolved. The lower palatal pressure with close fitting trays in Frank’s main in-vitro study (1969) may be explained by unaccounted venting of the impression material. In Frank’s in-vitro model the pressure was lower, that is relieved more, or vented more, in the palate. A venting of impression material across the post dam rather than sideways across the residual ridge is one possible explanation of how the palatal pressure could be lower. Whether post dam venting was the cause of Frank’s results and, more crucially, whether post dam venting occurs in-vivo is currently unknown and would require further investigation. This reminds us that ultimately in-vitro models only tell us about in-vitro impressions. As we have seen (page 18 above) Douglas et

al (1964) had already compared palatal verse ridge pressure in-vivo. He found palatal pressure higher, but his study was only on two patients and so it was severely underpowered. Comparisons of palatal v ridge pressure needed to be conducted in-vivo to deliver clinically useful information. Rihani attempted this in 1981.

Rihani 1981, studied relative pressure across the palate in-vivo. He placed flexible hollow plastic tubing in 7 separate anterior to posterior strands across the palate of a special tray. One strand was central, then the left and right borders of the tray each had a strand, similarly the left and right edentulous ridges each had a strand, and the final two strands were placed on the left and right sloping palate. The flexible hollow plastic tubes were filled with water and connected to vertical glass tubes. The displacement of the water within the tubes was measured when the special tray impression was inserted in-vivo. This allowed the relative pressure across the palate, measured as displaced mm of water, to be recorded. He measured pressure on three patients with an open mouth impression and one patient with a closed mouth impression.

Rihani's equipment was cumbersome with an extra-oral face bow, spirit levels and 7 vertical monometers all physically attached to the intra oral, close fitting, upper special tray. The equipment does not seem to have been calibrated, and so was not capable of recording either absolute or gauge pressure, only the change in pressure (in mm of displaced water) is recorded. The results were presented in tabulated form and are worth reporting in full see Table 1 below.

Displacement of water (mm) Open mouth impressions							
Subject	Left border	Left ridge	Left slope	Centre of	Right slope	Right ridge	Right border
A	-	8	-	12	-	10	-
B	-	10	13	18	12	9	-
C	-	9	14	19	15	7	-
Closed mouth impression							
C	-	6	8	10	7	5	-

Table 1 reporting Rihani's results in the style of the table from Rihani's paper 1981.

Rihani concludes that these results show the pressure is not even across the palate, that it is greater at the centre, that it was (with this equipment) undetectable along the tray borders and that the shape of the patients palate did not affect the pressure distribution. The pressure distribution found by Rihani in the upper impression was predicted by Stansbery in 1925 and shown to be expected by Bikerman (1961, p54) from the first principles of hydraulics. Bikerman's equation showed that if the assumption that viscosity is independent of the rate of flow is correct (i.e. the fluid is not non-Newtonian), then Pressure = $K(X^2 - x^2)$ where K is a constant, X is width of the disc and x is distance from centre. This assumption that viscosity is independent of flow rate is discussed and partially investigated in Part II chapter 13 below. A literature search has revealed no evidence of an investigation of the assumption that setting dental impression materials behave as 'Newtonian liquids'. The debate on the distribution of pressure within the impression 'disc' continued in some papers but the distribution demonstrated by Rihani was assumed to be the correct pressure distribution in much of the 20^{th} century denture literature. Rihani's paper was a useful confirmation.

Later papers re-ignite this issue of ridge versus central palate pressure. Masri 2002 found that 'pressures….were always lower on the palate when compared to the pressure on the right and left ridges'. In 2004 Komiyama et al found the reverse stating 'mid palatal impression pressure ….was significantly higher ($p<001$) than or similar to the pressure at the ridge crest'. The fundamental laws of fluid mechanics

have not changed, so the explanation of such contradictions lies in the introduction of uncontrolled, unknown variables. These later in-vitro studies of impression pressure used oral analogues to simulate clinical conditions; by doing so, the investigators may have introduced confounding variables. It is probable that the introduction of these variables resulted in the contradictory findings found between the studies. This particular contradiction is again potentially explained by post dam venting with the analogue and special tray combination used by Masri. Further research was required to determine whether clinical impression materials did indeed produce higher central pressure if uneven peripheral venting was eliminated from the model.

Masri (2002) investigated, 'the pressure exerted by maxillary edentulous impressions composed of three commonly used impression materials using four different impression tray configurations'. Masri's (2002) work was in-vitro with an oral analogue. The oral analogue consisted of a model of an edentulous upper arch made with a silicone rubber surface layer backed by dental stone. Pressure was sampled at three points; left and right edentulous ridges and the central palate. Pressure was measured via water filled tubes connected to pressure transducers the output of which, quote, 'were recorded by three operators at three locations on the oral analogue…..The resultant pressure was recorded every 10 seconds until no change in pressure was detected and the impression material was completely set' (Masri 2002). This method of manually recording the output of the transducers every 10 seconds may lose important data and so reduce the value of the collected data; in particular the peak of the pressure may be missed.

There is some initial confusion over the impression materials Masri tested. In the abstract we are told the '3 impression materials tested were irreversible hydrocolloid, light-body and medium-body polyvinylsiloxane, and polysulfide' (Masri 2002). However, in the method section (Masri 2002, Table 1, p157) Masri reports that the three materials tested were 'Polyether, vinylpolysiloxane, medium and light body and Polysulfide' (Masri 2002). In the results and conclusion sections Polyether is not reported.

Masri (2002) found tray perforations and relief beneath the special tray (space) did not affect pressure. In his conclusion Masri (2002) states 'Tray modification was not important in changing the amount of pressure produced during impression

making'. The role of perforations in reducing pressure is discussed elsewhere (Part II chapters 8 to 11), but it is worth noting here that Masri (2002) used small perforations which were some distance from the pressure sensors. It is possible the perforations used were too small and/or too far away to show a statistically significant pressure difference. Further research was required to show the effect of perforation size and distance to a perforation on impression pressure. The main thrust of the Masri (2002) conclusions were that the material used in taking the impression was the most important factor for changes to the pressure of the impression, concluding 'The impression materials used had more effect on the pressure produced than the tray design. The use of light-body vinyl polysiloxane or polysulfide is recommended for minimum pressure production in maxillary edentulous impressions. The fact that they produce the least pressure is important in the production of accurate impressions of minimally displaced mucosa' (Masri 2002).

Masri (2002) states 'A Satec universal testing machine was used to deliver a constant pressure of 2 kg/cm, seating the loaded custom tray onto the oral analogue'. This is fundamentally different from other studies which used a constant speed motor to seat the impression (Frank 1969, Hyde 2008, and probably Komiyama et al 2004, see below). In constant pressure testing, as the impression is seated and resistance encountered, the universal testing machine reduces the velocity of approximation to maintain the constant pressure on the special tray. If on seating, the pressure changes within the impression material were even and produced instantaneous macro changes in the overall pressure of seating, and if it is assumed the Satec machine reacts instantaneously to those changes, then the overall recorded localised pressure would not be expected to change. However the Masri (2002) results did show differential changes; therefore (since the speed of reaction of the Satec machine was a constant across all the Masri 2002 experiments) the recorded results maybe expected to be due to the differences in the ability of the various materials/tray combinations to 'cushion' the micro pressure changes. Alternatively they may represent high and low pressure points within the impression which together, on average, result in the constant macro pressure of approximation but which are also constantly changing in their distribution during the impression procedure. Clearly this methodology, using a 'constant pressure of seating', needs particular care in the interpretation of the clinical relevance of the results. The

ability of the material/tray combinations to cushion pressure against mucosa may be different than against the oral analogue.

Later Komiyama et al (2004) also looked at in-vitro impression pressure. Unfortunately there is some confusion in the reported methodology. In the abstract Komiyama et al states 'The cast and tray were attached to a rheometer for applying a continuous isotonic force of 5.0 Kgf and compressive speed of 120 mm/min'. The expression 'continuous isotonic force' is repeated later in the Method section and again, in the method section the paper states: 'The compression force was set at 5.0kgf and the press speed at 120mm/min as reported by Frank'. It is known from first principles that as the plates approximate and resistance is encountered either the force of approximation must increase or the approximation must slow down. Clearly, it is not possible to have both a constant velocity and a constant force. One must therefore assume that these Komiyama et al (2004) figures for velocity and force of seating represent either the maximum force of approximation or the maximum velocity of approximation entered as settings on the rheometer used by Komiyama et al. It seems likely that 5kgf is the maximum force of approximation and 120mm/min is the constant velocity of approximation, but this is currently unconfirmed. Correspondence with the author has not received a reply.

Komiyama et al (2004) investigated the effect of a single perforation in the impression tray on pressure within the impression. The single perforation was placed directly opposite the palate sensor. The perforation showed a significant effect on both 'initial' and 'end' pressure. Palatal pressure was affected more than ridge pressure. An increase in the size of the hole showed a larger effect in pressure reduction.

Komiyama et al investigated the effect of spacing beneath the impression tray on pressure within the impression. Quote: 'Three types of tray relief were used: no wax spacer ..; sheet wax (... 0.36 mm thick) …, or base plate wax (...1.40 mm thick)'. Broadly, Komiyama et al found that the larger the space ('relief') the lower the pressure. Komiyama et al concludes that space beneath the impression tray reduces pressure. This effect is presumably due to a larger peripheral vent if the space is extended to the periphery. On the clinic this vent may be wholly or partially blocked by the addition of 'greenstick' border moulding. Further research

was required to confirm the effect of a close fitting periphery on impression trays with variable space under the remainder of the impression tray.

Komiyama et al's (2004) paper contains a misleading error in the published 'Figure 4'. As Komiyama et al's 'Figure 5' and 'Table 3' (Komiyama et al 2003) show, the end pressures in the BS20H groups, point P (palatal) had a significantly lower pressure than point R (ridge). Figure 5 and Table 3 (Komiyama et al 2003) show this palatal versus ridge 'end pressure' result is reversed for special trays with no space and no perforations (NSNH). Thus Figure 4 is incorrect for BS20H but is correct for NSNH.

For 'initial pressure' Komiyama et al's results support Stanberry's (1925) theory of high palatal pressure. Komiyama et al (2004) states 'data obtained at point-P showed significantly higher values ……than corresponding values at point-R'. However for 'end pressure' some of these results are reversed. The 'end pressure' results of Komiyama et al (2004) add further confusion to the long standing ridge pressure versus palate pressure debate; overall the results are different (and different in different ways) from both Frank's and Masri's in-vitro work. As noted above the fundamental laws of fluid mechanics have not changed, so the explanation of such contradictions lies in the introduction of uncontrolled, unknown variables from the use of so-called 'oral analogues'. In particular this confusion may be due to the differential in palatal venting across the post dam compared to the venting around the rest of the periphery between and within the studies. Further research is needed to confirm this.

Since mucosa has different properties from the surface of any oral analogue and the lips and cheeks affect peripheral venting in-vivo, the peripheral venting at the post dam and the buccal reflection in the clinic on patients will be different to that of any 'oral analogue'. As this author said (Hyde 2008) 'Uncontrolled and unknown variables are introduced when attempting, and perhaps failing, to simulate the oral environment.'

Al-Ahmad et al (2006) used very similar methodology to Masri 2002; Masri was a co-author on Al-Ahmad et al's 2006 paper. Al-Ahmad et al (2006) looked at the pressure generated under lower arch impressions in-vitro. As Al-Ahmad et al (2006) states: 'The main difference between the two studies is the arch tested. In addition, the pressure transducer used in Al-Ahmad et al's study was a different

model than that used in the Masri study, and this may have played a role in the difference between the recorded numbers. Also, due to the fracture of the oral analogue when the applied force was at 2 kg/cm2, the Satec machine force was reduced from 2 kg/cm^2 to 1 kg/cm^2'. Al-Ahmad et al's (2006) study appears to have used a constant pressure of approximation rather than a constant speed of approximation. Similar problems to Masri's study occur with the time gap of 10 seconds between the sampling of the pressure. The results and the conclusion are distinct from those of Masri (2002). Firstly, in agreement with Masri (2002), Al-Ahmad et al (2006) concludes that the materials used affect pressure; this is very similar to Masri (2002) with materials that appear to be the most viscous producing the highest pressure. However, in contrast to Masri (2002), Al-Ahmad et al (2006) shows that tray modification (perforations and relief space) significantly affects pressure when viscous impression materials are used (but not with 'light bodied' materials). Al-Ahmad et al's (2006) result is the 'expected' result from the first principles of fluid mechanics. The question is not why did Al-Ahmad et al (2006) conclude this but rather why didn't Masri (2002) produce similar results and conclusions? The answer is probably because the perforations in Masri's special trays were far away from the sensors whereas Al-Ahmad et al's perforations were either directly over the sensor (in the mid line of the model) or very close to the sensor in the region of the posterior ridges. Further research was required to confirm the effect of the distance of a special tray perforation from the pressure sensor on the pressure recorded by the sensor.

This literature review has revealed six papers which measured impression pressure; Douglas et al (1964), Frank (1969), Rihani (1981), Masri (2002), Komiyama et al (2004) and Al-Ahmad et al (2006). Each paper progressed academic knowledge and each paper raised further questions. There are contradictions between the conclusions of the papers. In particular the evidence was contradictory whether tray modification (via perforations and relief space) effected changes in impression pressure, and whether palate pressure was higher than ridge pressure. These contradictions required further investigation.

In 2003 Hyde proposed a selective pressure technique (Hyde 2003). It was proposed to use that technique in the RCT incorporated in this PhD. Hyde's (2003) impression technique advocated space and perforations to reduce pressure in certain

areas of an impression. Because of the contradictions in the literature on the effect of space and perforations in reducing pressure, further in-vitro research was needed.

Chapter 5
Randomised controlled clinical trials of impression techniques

Randomised Clinical Trials (RCTs) are accepted as the 'gold standard' for the assessment of treatment modalities. The conduct and reporting of RCTs is governed by the standards outlined in the CONSORT statement (CONSORT group, 2010). In 2002 Jokstad et al published a critical review of RCTs in prosthetic dentistry. They reviewed 92 papers reporting Prosthodontics RCTs. In the discussion section they state: 'The result of this investigation causes concern, since it points out the lack of sound evidence on a number of common procedures in prosthodontics, e.g., differences between impression materials …… …Moreover, the number of actual RCTs is low, and the methodological quality of the reporting of these trials seems highly variable…… Thus, in conclusion, there seem to be multiple areas within prosthodontics where well-designed and reported RCTs may document therapeutic gains of new materials, techniques, and procedures compared to traditional interventions.' Jokstad et al 2002.

Carlsson has addressed the evidence for best practice for prosthodontics within 3 papers which give an overview of the subject (Carlsson 2006, 2009 and 2010). The brief sections on impression techniques for complete dentures are relevant to this thesis.

In 2006 Carlsson correctly states that (at that time) "among the hundreds of articles on impression materials and methods, only one RCT was found", referencing the paper of Firtell and Koumjian (1992) which is reported below in this chapter. However, Carlsson (2006) then appears to question the potential for the success of RCT's of impressions. He states that "although impression materials differ in many respects and there is a wide variety of techniques in taking the impressions, it is not probable that comparisons between dentures made with varying materials and methods would lead to significant differences in clinical long term results." This secondary opinion may or may not be true. He does not cite evidence for this opinion. Caution is needed here; the lack of RCT evidence should not lead to an assumption that RCT evidence cannot be obtained nor an assumption of equivalence in treatment modalities. Elsewhere Carlsson (2006, 2009) uses good

quality RCT evidence to refute the dogmatic opinion of experts. It is ironic that for this section on impression materials and methods Carlsson uses his own expert opinion to declare that 'it is not probable' that good quality evidence can be gathered.

In his 2009 review Carlsson (2009) uses very similar referenced material to his 2006 paper adding McCord et al's study as the only new RCT on impressions for complete dentures (McCord et al 2009).

In 2009 Carlsson goes on to cite (again) the work of the candidate (Hyde 1999) and uses Hyde's paper to report that dentures made with alginate impressions were at that time normal practice in the UK. Having quoted good evidence that it was normal practice, he then goes on to imply that because it is normal practice to use alginate, it is equivalent to (or better than) other materials. In contrast to this opinion, the paper he quotes (|Hyde and McCord 1999) takes the opposite view, saying in the discussion section that the impressions techniques used by the GDPs in the survey "have to be viewed with concern", implying the techniques used by the GDPs in the survey will not be equivalent to those recommended by contemporary expert opinion.

As Carlsson (2009) correctly points out, it is indeed unfortunate that in much of Prosthodontics (including impressions for complete dentures) the level of expert opinion has been the best available evidence. Carlsson is right to point this out. However this low level of evidence (expert opinion) should not be dismissed without higher quality contrary evidence. In this context the lack of high quality RCT evidence is best used as a spur to more high quality (RCT) research. New research may confirm expert opinion or the expert opinion may indeed be shown to be the errant 'dogma' Carlsson suggests it may be (Carlsson 2009); but only high quality research (including RCT's) will illuminate the discussion.

Harwood 2008 looked in detail at the RCT evidence base for current practice in Prosthodontics. Harwood (2008) did not differentiate between partial and complete denture impression techniques and found: 'Five RCTs focus on impression materials and techniques, only two compared materials'

Thus in prosthetic dentistry generally the evidence from RCT's is limited (Jokstad et al 2002, Carlsson 2006,2009 and 2010, Harwood 2008); the authority for clinical practice has been based on expert opinion backed by the anecdotal evidence

of case histories. These form a lower level of evidence than a RCT. The situation is worse when looking at the specific subject of impression procedures for complete dentures; here the evidence base from RCTs is very limited indeed. A review of the literature has revealed only two Randomised Controlled Trials (RCTs) which have investigated clinical impressions for complete dentures.

Firtell and Koumjian 1992 reported a randomised clinical trial of clinical impression materials for complete dentures. The trial recruited 30 patients, the study design was parallel; 15 patients received dentures made from impressions with light bodied polysulphide and 15 from fluid wax impressions. The fluid wax impression material is largely defunct as a commercially available material; it is not currently taught by any US dental school (Petropoulos et al 2003), although 1% of specialist prosthodontists in the USA reported using it in 2005 (Petrie et al 2005). Polysulphide rubber is widely advocated in the USA; Petrie et al (2005) reports that 64% of dental schools use polysulphide 'most often' for secondary impressions for complete dentures.

The outcome of treatment was assessed in Firtell and Koumjian's paper (1992) by counting the number of adjustments to the finished dentures that were required for each side of the trial. No statistical difference was found between the two impression materials using this assessment tool. Firtell and Koumjian (1992) concludes, 'fluid wax… can be used as well as light bodied polysulfide rubber impression material for making impressions of edentulous mouths'.

Firtell and Koumjian's (1992) paper is to be commended as the first RCT of impression techniques; for this alone it ground breaking research. When the paper is compared to modern CONSORT standards of reporting RCTs it falls short of the standard required in several areas (Jokstad et al 2002). The assessment of Firtell and Koumjian's paper (1992) by Jokstad et al (2002) is given in tabular form and summarized in Table 2 below by the same criteria Jokstad et al used. Jokstad et al (2002) reports the number of patients incorrectly as 22; there were 30 (3 of whom withdrew).

Paper	Funding	Setting	Study Design	No. of patients	Power calculation
Firtell and Koumjian	Independent	Unclear	Parallel	22	Not mentioned

Randomization description	Incl/excl criteria	Withdrawal described	Compared at entry	Blinding attempt
Inadequate	Unclear	Yes	No	No

Table 2 above giving the summary in the style used by Jokstad et al (2002) of compliance with CONSORT guidelines.

In comparison to the accepted CONSORT standards for reporting RCTs, Jokstad et al (2002) makes valid criticisms of Firtell and Koumjian's (1992) description of the power calculation, of the randomisation, of the inclusion/exclusion criteria, of the comparison of the groups at entry and of the attempt at blinding. The lack of a reported power calculation may have contributed to the inability of the study to differentiate between the assessed impression materials. With hindsight the use of the number of post insertion adjustments visits as the primary outcome measure may have been inadequate and therefore inappropriate to detect a difference between the groups. Notwithstanding this criticism, Firtell and Koumjian's 1992 paper remains a landmark attempt to move beyond expert opinion as the prime source of evidence for the assessment of the benefits of impression materials.

McCord et al in 2005 reported a double blind cross over randomized controlled trial in 11 patients looking at three impression materials. Each patient received three lower dentures, each constructed from a different impression material. The paper post dates Jokstad et al (2002) and so is not assessed in that review. It is however useful to evaluate McCord et al's (2005) paper in the manner and style outlined by Jokstad et al (20002) with reference to the CONSORT guidelines (CONSORT group, 2010); this is summarized in Table 3 below.

Paper	Funding	Setting	Study Design	No. of patients	Power calculation
McCord et al	Unclear	University	Cross Over	11	Not mentioned

Randomization description	Incl/excl criteria	Withdrawal described	Compared at entry	Blinding attempt
Inadequate	Unclear	Yes	No	No

Table 3 Summary of McCord et al (2005) paper compared to Consort standards in the style of Jokstad et al (2002).

A power calculation is not mentioned in McCord et al's (2005) paper; 11 patients were inadequate to delineate the preferred impression material of the three used in the study. There were particular problems with randomization method which produced a lop-sided distribution of the order in which the dentures were given to the patient. McCord et al describes a prejudice amongst the patients against the first denture, stating: 'it was a clinically significant finding that the first worn denture initially caused most discomfort'. Since the 'Provil' denture was given first in six out of the eleven patients (54%) there was clear potential for bias against Provil in this study. The dentures made from the compound 'Admix' was provided first on two out of eleven patients; there is clear potential for bias in favour of the 'Admix' dentures in this study.

The results of McCord et al's study (2005) showed the dentures made from Zinc Oxide/Eugenol impression material were never the most preferred denture. There was no detected difference between the other two impression materials. McCord et al (2005) concludes 'The need for larger randomized clinical trials is clear from the findings of this study and, the basis that the first-worn denture always produced most discomfort , the need for robust statistical planning is apparent'.

Part II

Laboratory investigations of variables that affect the pressure of impressions

Chapter 1
Outline and background

1.1 Introduction

Chapter 4 of Part I of this Thesis reviews the academic literature on the experimental evidence of pressure, and pressure variation, within impressions. From that literature review, it was clear that there were two broad issues that needed to be addressed; two areas where further investigation was needed. Firstly there were variables that hadn't been investigated. Secondly there were areas where variables had been investigated but the investigations resulted in a dichotomy of opinion in the literature.

There was a lack of basic research on variables which have the capacity to affect pressure. These included: the effect of velocity of approximation on pressure; the effect of delays in seating an impression on pressure; and the effect on pressure of border moulding the impression tray to develop border and facial seal.

The inconsistencies in the literature which indicated the necessity for further research included: a dichotomy of opinion over the effect of tray perforation and tray spacing on impression pressure (Masri 2002 and Komiyama et al 2004); an on-going controversy over ridge pressure versus palatal pressure in the upper arch (Frank 1969, Masri 2002, Komiyama et al 2004); and a lack of clinically relevant knowledge on the effect of space beneath an impression tray. As noted above (Part I, chapter 4) and in a published paper from the work of this Thesis (Hyde 2008) the fundamental laws of fluid mechanics do not change to create the above inconsistencies and controversies. The most plausible explanation of such controversies lies in the introduction of uncontrolled, unknown variables from the use of so-called 'oral analogues'. Uncontrolled and unknown variables are introduced when attempting, and perhaps failing, to simulate the oral environment. Rather than attempt, and fail, to produce 'life like' oral analogues and intra oral in-vivo conditions, the series of experiments in Part II has taken a deliberate and different approach.

The approach for Part II follows the classic scientific methodology to study the effect of a single variable in each separate experiment. Thus the approach adopted

for Part II laboratory studies, was to eliminate or control unknown variables. Such potential confounding variables included, surface topography of casts, mucosal viscoelasticity, variable peripheral venting, variable border adaptation of the impression tray, and 'lifelike' compressible silicone casts. In this section of the Thesis experiments were specifically designed to isolate the individual variable under investigation. Potential confounding variables were either eliminated or controlled.

To eliminate the potentially confounding variables a flat, hard, circular surface was used to carry the setting impression material. Photographs of an example of a flat brass discs used in Part II of this Thesis are shown below in section 1.3 (Figure 3 below). The experiments were carried out in an environmentally controlled laboratory with a constant temperature of 21 degrees centigrade. The impression materials used in Part IV of this Thesis were tested; thus a single type of impression material (polyvinylsiloxane) was used throughout. A list of potential variables to be investigated was drawn up (see objectives below in section 1.2.2). While one of these potential variables was being tested the remaining potential variables were usually set at a default setting. The default settings for these variables are listed in the Table 4 below. An exception to the use of default setting was the size of the disc used in the experiment that looked at the position of the sensor within an impression. That experiment necessitated the use of a brass disc of a larger diameter in order to attach the sensors at specific points.

The individual variables isolated and investigated by this methodology in Part II of this Thesis included, velocity of approximation, delays in seating, position of sensor, perforation position, perforation number, perforation size, space under the special tray, of border moulding of the impression tray (to develop border and facial seal), viscosity of the impression material and speed of set of the impression material. One variable was investigated at any one time.

Variable	Default Setting
Velocity of approximation	120 mm/min
Delay in seating impression	20 seconds
Position of sensor	Centre
Number of perforations	None
Size of perforations	2mm
Position of perforations	10mm from central sensor
Space beneath the impression ‘tray’.	0.5mm
Border adaptation	None
Diameter of discs	70mm
Viscosity of impression material	Light bodied (regular set), Express 3M
Speed of set of impression material	Regular set (Express 3M)

Table 4 the default setting of variables assessed in Part II of this Thesis

1.2 Aims and objective of the laboratory studies

1.2.1 Aims

1. To establish the experimental methodology.
2. To eliminate or control unknown and unwanted variables.
3. To investigate the relationship between each potential variable and the impression pressure.
4. To disseminate the results of the investigations.

1.2.2 Objectives

The objectives of Part II of this Thesis were to investigate;

1. The accuracy and precision of the integrated pressure measurement system

2. The effect of the amount of impression material on impression pressure

3. The effect of velocity of approximation on impression pressure

4. The effect of delays in approximation on impression pressure

5. The effect of the position of the sensor within the impression on impression pressure

6. The effect of the distance of a tray perforation to the pressure sensor, on impression pressure

7. The effect of the number of perforations on impression pressure

8. The effect of the size of a perforation on impression pressure

9. The effect of the space under a special tray, where there is no border adaptation, on impression pressure

10. The effect of the space under a special tray with a constant peripheral gap on impression pressure.

11. The effect of the viscosity of the impression material on impression pressure.

12. The effect of the speed of set of an impression material on impression pressure

1.3 The equipment used to carry the impression material and the objects impressed

The brass disc shown in Figure 2 below is a standard impression ‘object’ used in many of the experiments described in Chapters 5 to 15 below. This is the ‘object’ of which an impression was taken. This particular ‘object’ has a central perforation connected to a pressure sensor. The central hole is the point at which the pressure within the impression material was recorded when this ‘object’ was used. The space from the surface of the central hole to the sensor diaphragm was filled with tap water. It was necessary to eliminate any air bubbles in this water filled chamber; failure to do so dampened (reduced) the peak pressure recorded. The elimination of air was initially found to be a difficult task, but with experience the operator became an expert in the procedure.

Figure 2 the ‘object’ which is to have an ‘impression’ taken.

Figure 3 An ‘impression tray’ used to carry impression material note the stainless steel ‘spacers’ made from engineers’ ‘feeler gauges’.

The disc above (Figure 3) is an example of an ‘impression tray’ used to carry impression material into contact with the ‘object’ which was to have an impression taken. The steel ‘stops’ used to space the tray can be seen; in this case they are 0.5mm sections cut from an engineer’s ‘feeler’ gauge, held in position with superglue. The three steel stops and the unset superglue were compressed under load on a Lloyd Universal Testing machine to ensure intimate contact between the steel spacer and the brass disc and so ensure even spacing. Variation in the impression trays affects pressure (see chapters 8, 9, 10, 11, 14 & 15 below). The size, number and position of perforations in an ‘impression tray’ are examples of the factors which were investigated for the effect they had on the recorded pressure; see Chapters 8-11 below.

1.4 The motor used to approximate the discs

A Lloyd Universal Testing machine was selected to provide the means to approximate the impression material on the 'impression tray' to the 'object'. This gave precise control of the distance travelled, the alignment of the discs, the velocity of approximation, and the range of force of approximation. Figure 4 below shows the Lloyd machine with the discs in place. Figure 5 shows a closer view of the discs mounted on the Lloyd machine with a pressure sensor attached.

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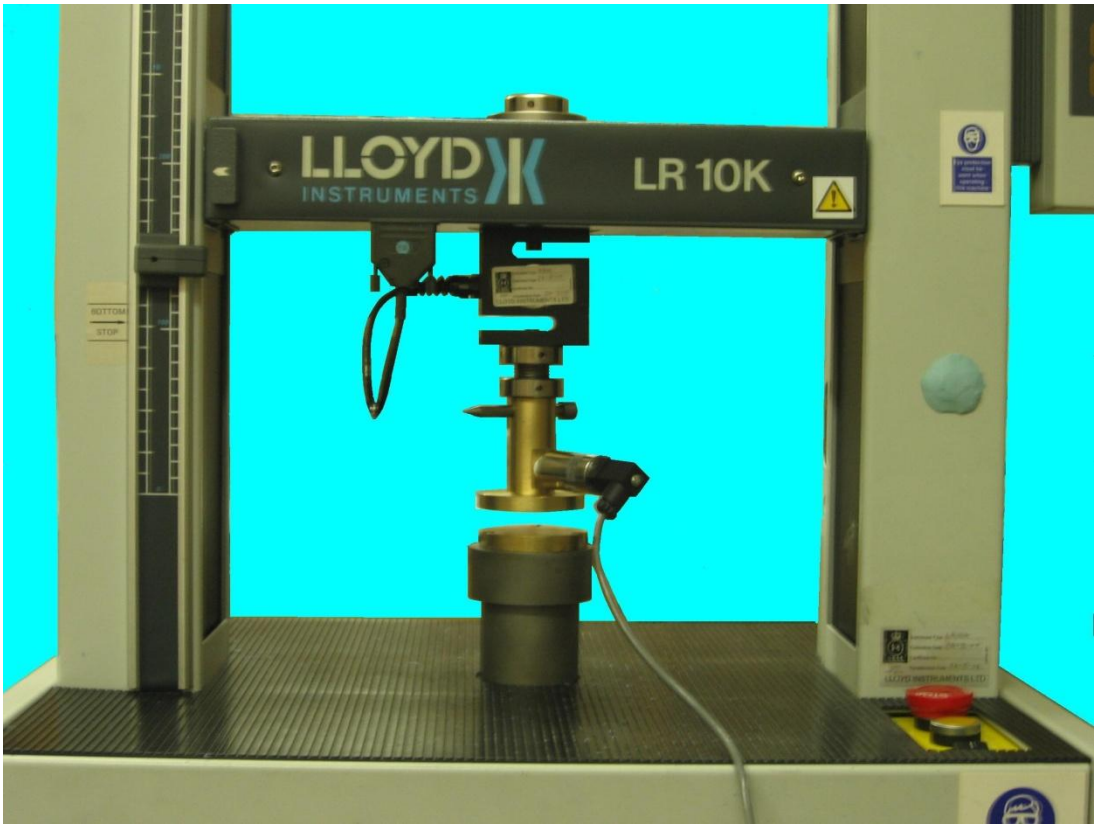


Figure 4 the Lloyd machine with the brass discs mounted

Figure 5 close up of the brass discs on the Lloyd machine

Chapter 2
Calibration of pressure measurement

2.1 Introduction

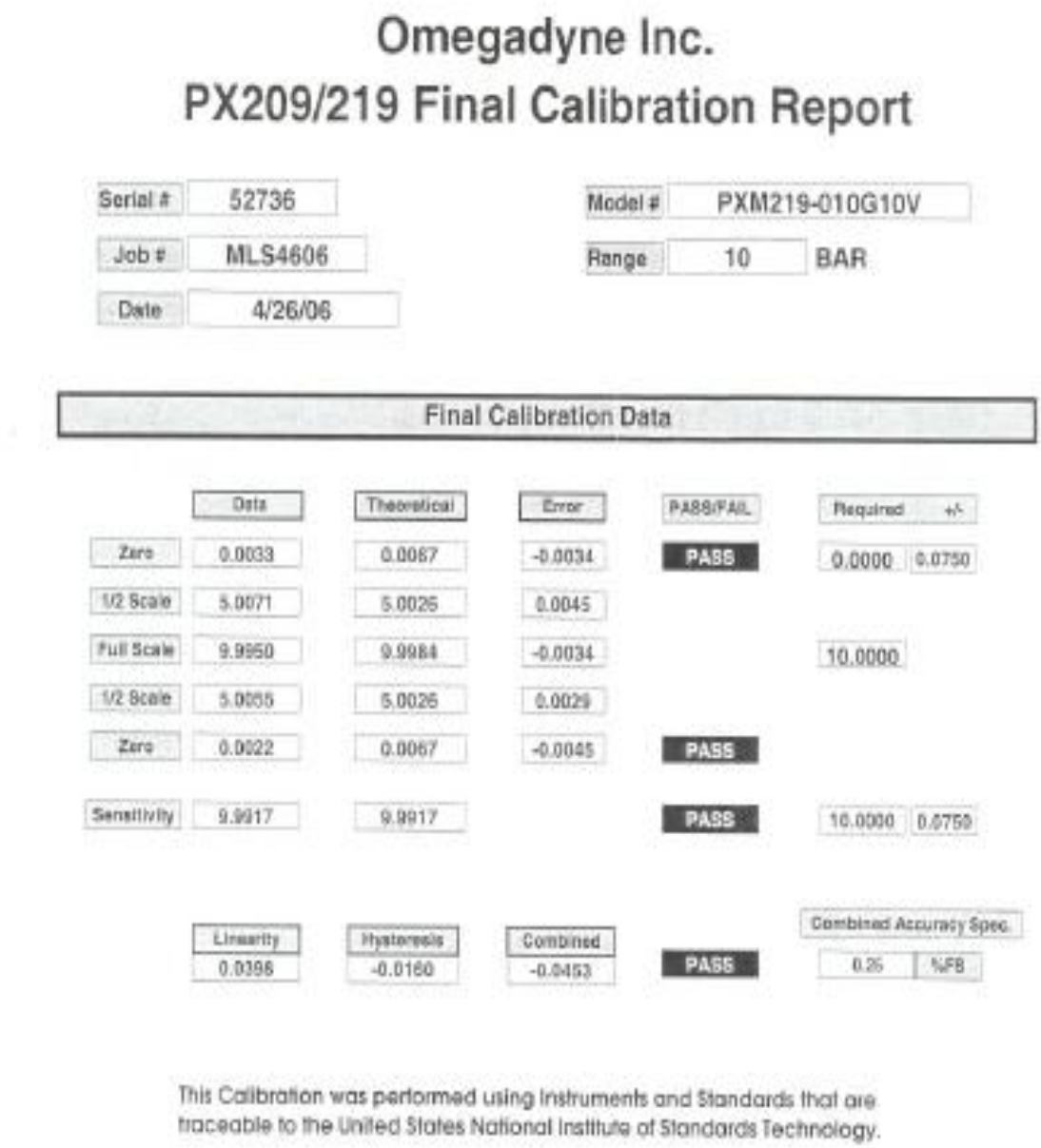
This chapter details the measurements taken to calibrate the integrated pressure recording system used for the experiments of Part II of this Thesis.

2.2 The pressure sensor

In preliminary experiments to look at the range of pressure generated in these experiments, two sensors with a range of 0-100KPa (0-1 Bar) were unexpectedly over-loaded and destroyed. Therefore the sensor chosen for Part II of this Thesis had a range of 0 to 1000 KPa which is 0-10 Bar (the American calibration report shown in Figure 6 uses a scale expressed in Bar units to measure pressure). For all the experiments in Part II of the Thesis this single sensor was used. The sensor was an analogue pressure transducer; catalogue number PXM209-010G10V from Omega Engineering, Inc, Stamford, Conn., USA and the calibration certificate was referenced to standards traceable to United States National Institute of Standards Technology.

2.3 The certification of accuracy

The pressure sensor purchased for the laboratory work of this Thesis was supplied with a calibration certificate (Figure 6). The report gave details of the linearity, hysteresis and combined error.



Omegadyne Inc.

PX209/219 Final Calibration Report

Serial #	52736	Model #	PXM219-010G10V
Job #	MLS4606	Range	10 BAR
Date	4/26/06		

Final Calibration Data

	Data	Theoretical	Error	PASS/FAIL	Required	+/-
Zero	0.0033	0.0067	-0.0034	PASS	0.0000	0.0750
1/2 Scale	5.0071	5.0026	0.0045			
Full Scale	9.9950	9.9984	-0.0034		10.0000	
1/2 Scale	5.0055	5.0026	0.0029			
Zero	0.0022	0.0067	-0.0045	PASS		
Sensitivity	9.9917	9.9917		PASS	10.0000	0.0750

Linearity	Hysteresis	Combined		Combined Accuracy Spec.	
0.0396	-0.0160	-0.0453	PASS	0.25	%FS

This Calibration was performed using instruments and Standards that are traceable to the United States National Institute of Standards Technology.

Figure 6 the calibration certificate for the sensor used throughout in Part II of the Thesis.

The Linearity variation is best described as the difference between the straight line representing the true pressure values and the line of the recorded output. Hysteresis error in this situation is best described as the difference in given pressure between that obtained with an ascending pressure and that obtained with a descending pressure. The standard specified when purchasing the transducers was a Combined Accuracy Specification of +/- 0.25% Full Scale. However, the data

sheet for this transducer shows the combined error to be well within the specified limits. The linearity error was 0.0398%FS, the Hysteresis error was -0.0160% FS giving a combined error of -0.0453%FS. The full scale is 0-1000KPa; the sensor underestimates the pressure by 0.453KPa. A simple linear transformation was performed; 'true pressure' is 'given pressure' minus 0.453KPa. It was possible to achieve this linear transformation with the software supplied with the digital sampler purchased with the pressure transducer.

The simple transformation produced a figure for 'true' pressure which, on average, could be said to be accurate. However with the range of pressure output shown on the data sheet there was potential for 'imprecision' of the data. Further investigation of the 'precision' of the sensor was required. In addition to the sensor there were other potential sources of 'imprecision'. The output from the sensor is analogue; it is transformed to a digital signal by the digital sampler (labelled B in Figure 8 below). This transformation of the 'pure' analogue signal to a digital signal may introduce a 'precision' error (see below).

2.4 Definition of ‘accuracy’ and ‘precision’

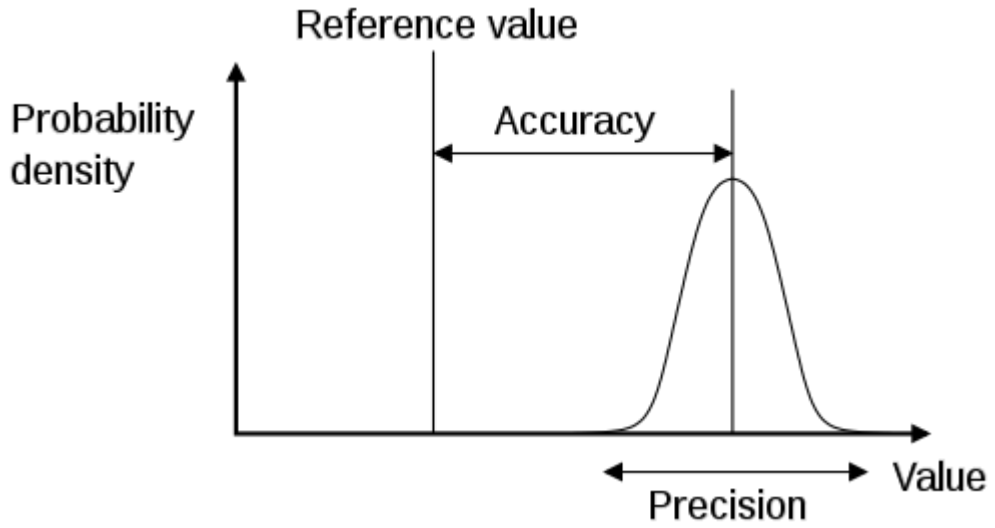


Figure 7 A diagrammatic representation of the definitions of accuracy and precision

The term ‘accuracy’ is defined as “the nearness of an observed value to its true value” (Day 1999). The term ‘precision’ is defined as “the extent to which the replicated measurements agree with one another” (Day, 1999). It is possible for a measurement system to be accurate but not precise, precise but not accurate, neither, or both. Figure 7 gives a clear illustration of these basic definitions. The copyright graph (Figure 7) reproduced above is licensed under the GFDL by the original author; and released here under the same GNU Free Documentation License. It was sourced from the Wikipedia website on 17.8.10 2.5 Data collection for the precision calculation

As described above, the accuracy of the pressure sensor was certified to a satisfactory level; however the sensors only formed one part of the proposed integrated data acquisition system. The remaining components for data acquisition included the analogue to digital converter, the computer hardware and the programme software. There was potential for the other components in the data acquisition system to introduce precision errors in the measurement of the pressure. Therefore an assessment of the precision of the whole integrated data acquisition system was indicated.

2.5.1 Components of the integrated pressure data acquisition system

The components of the data collection system are shown in Figure 8 below. They consisted of A, the analogue pressure sensor; B the digital sampler of the analogue output from the sensor; C the transformer (DC power source); and D the computer with specialist software (Omegadyne Inc).

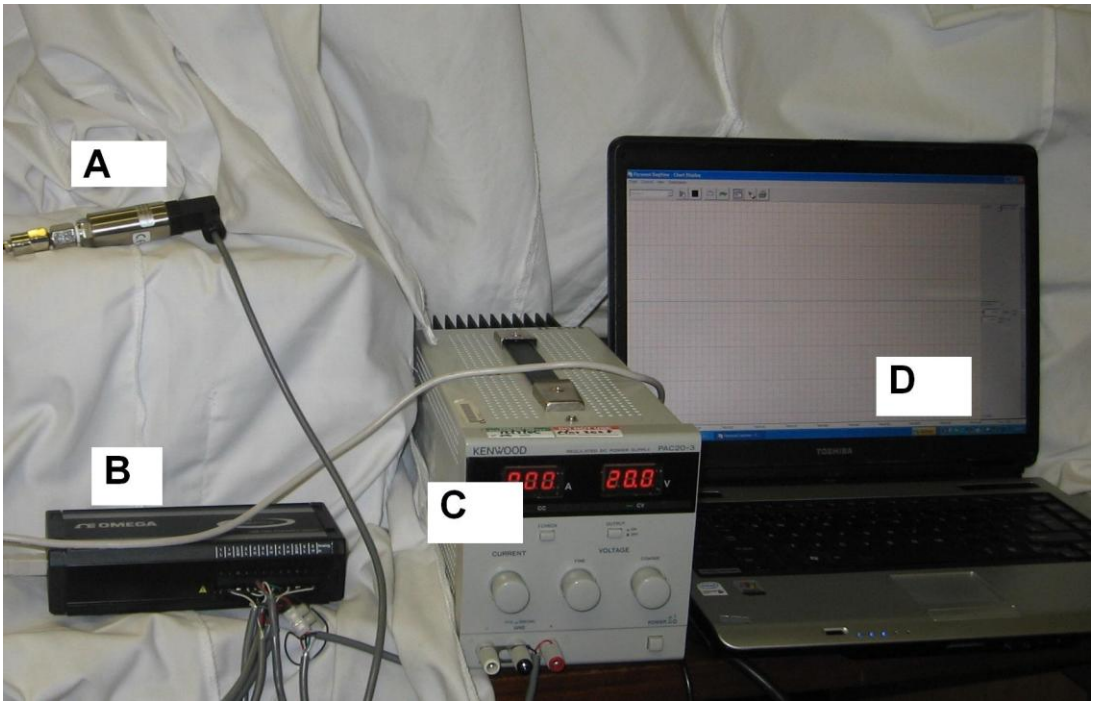


Figure 8 Components of the pressure recording equipment.

To estimate the precision of the integrated measurement system a 100 pressure readings were taken at 10 different pressure settings. The pressure sensor was held in turn at the nominal pressure of approximately 1000KPa, 900KPa, 800KPa, 700KPa, 600KPa, 500KPa, 400KPa, 300KPa, 200KPa, and 100KPa. The pressure gauge used is shown in Figure 9 below.

Figure 9 Combined pressure gauge and pneumatic hand pump used to hold the sensor at standard pressures for the precision data collection.

The pressure gauge shown in Figure 9 above was certified as accurate to the standard pressure reference held at the British Standards Institute. Although this gauge was certified it could only read the pressure to the nearest Kilopascal (the reading in Figure 9 above is 0.99Bar which is 99KPa). Thus the 'gauge' reading of

pressure was only an approximation to the nearest kilopascal. The purpose of the gauge was to hold the pressure steady at a nominal but constant pressure. The pressure was approximate (not accurate) but constant (precise). With the pressure held steady at a nominal pressure, the output from the sensor was captured via the digital sampler and the software to the computer hard drive. At each nominal pressure 100 datum points were sampled. The 10 nominal 'gauge' pressures used were 100, 200, 300, 400, 500, 600, 700, 800, 900, and 1000 Kilopascals. Figure 10 below is a graph of the collected data from the 10 nominal pressures with 100 data points for each pressure shown.

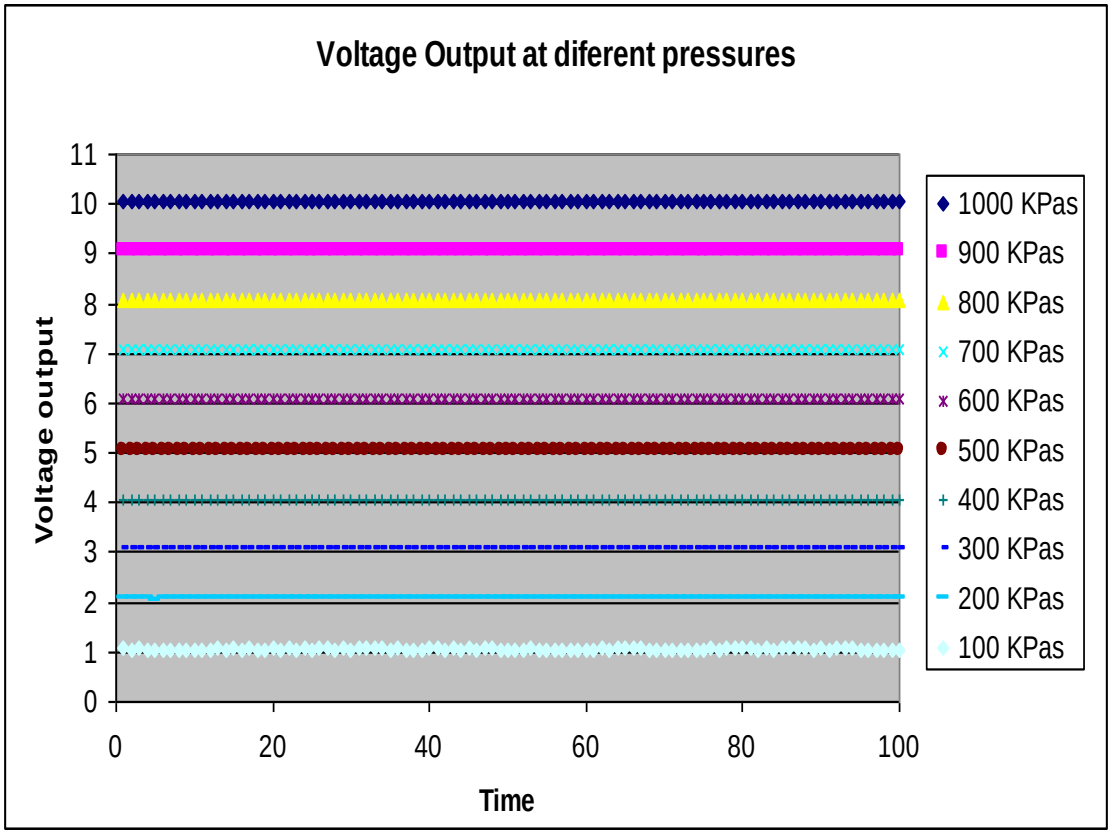


Figure 10 Output from sensor at 10 nominal pressures.

2.6 Analysis of the output and estimation of precision error.

The 10 lines on the graph (Figure 10) above appear to be straight but on closer inspection they are in fact fluctuating. In the graph (Figure 11) below the 'Y' axis of the graph for 400KPa nominal pressure is expanded. The expanded graph demonstrates the variation in output from the sensor; this is the imprecision of the pressure measurement.

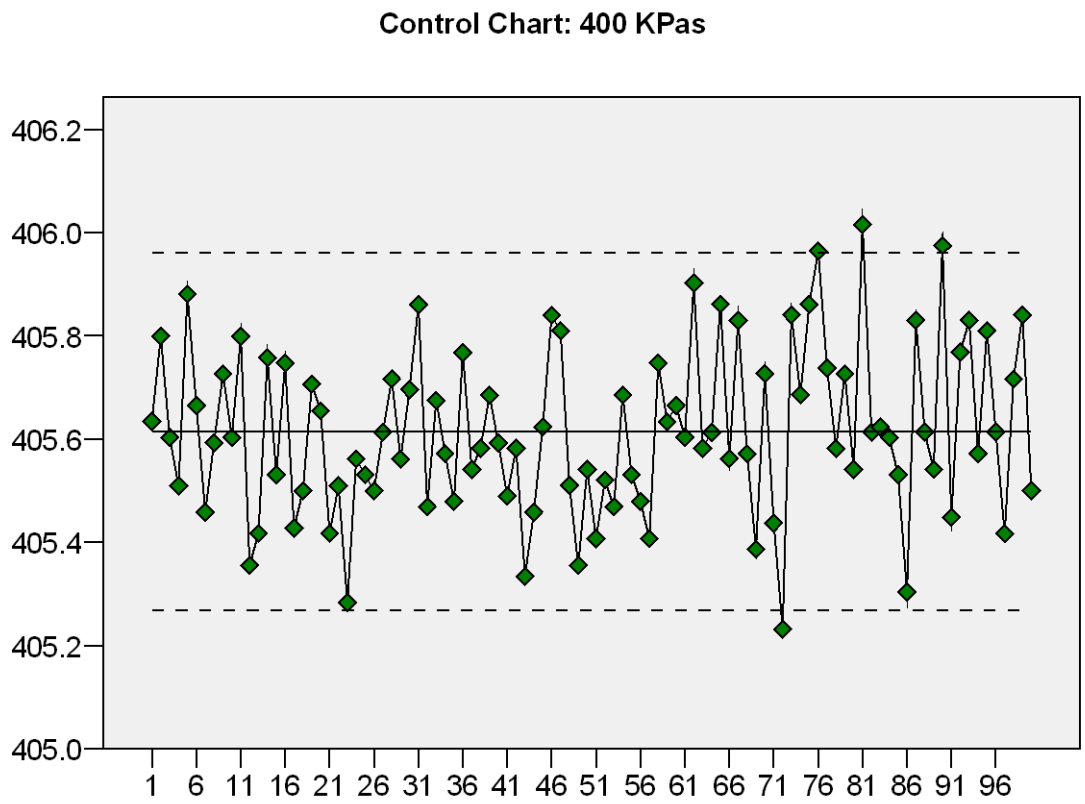


Figure 11 Variation in digital output when sensor held at a nominal 400KPa The bold horizontal line indicate mean and 2Standard deviation from the mean (above and below).

The variation in output in Figure 11 above is given by the integrated pressure measuring system and it demonstrates the precision error. A frequency histogram (SPSS legacy histogram) of the 100 data points shown in Figure 11 above is shown below in Figure 12; it is instructive to see the distribution of the data points about the mean (see Figure 12 below). Compare this to the illustration of precision error in Figure 7 in section 2.3 above.

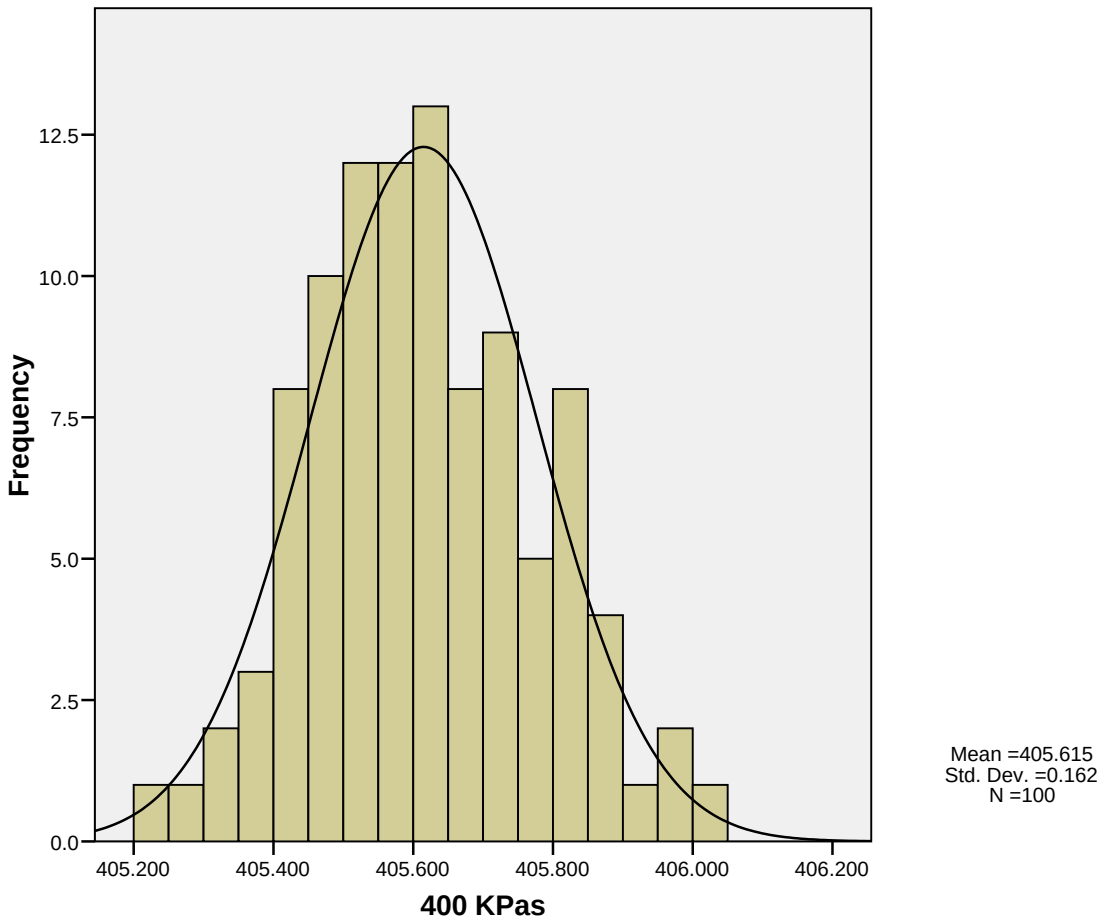


Figure 12 Precision error at a nominal 400KPa; a SPSS legacy histogram of 100 output data with the normal distribution curve superimposed.

The mean of the distribution shown in Figure 12 above is 405.615KPa, the Standard Deviation is 0.162KPa. Since the data forms a normal distribution we know from statistical theory that 95% of the observed values lie within $\pm$ 1.96 times the Standard Deviation of the mean. Thus if we pick a single datum output from this sensor when it is held at a nominal 400KPa, we can estimate with 95% certainty that it lies within $\pm$ 0.318 KPa of the sample mean.

The summary statistics of the 100 data points for all the 10 nominal pressures are shown in Table 5 below. The minimum, maximum, mean and standard deviation are included together with the coefficient of variance (S.D. / Mean) which

is a measure of the dispersion of the data. The small value of the coefficient of variance shows little dispersion.

Nominal Pressure	N	Minimum	Maximum	Mean	Std. Dev	Coefficient of variance
1000 KPa	100	1004.007	1004.915	1004.459	.2012	0.000200
900 KPa	100	904.030	904.784	904.441	.1814	0.000201
800 KPa	100	803.899	804.683	804.302	.1796	0.000223
700 KPa	100	705.120	705.956	705.496	.1613	0.000229
600 KPa	100	604.937	605.701	605.360	.1781	0.000294
500 KPa	100	504.939	505.776	505.475	.1767	0.000350
400 KPa	100	405.232	406.015	405.615	.1624	0.000400
300 KPa	100	305.307	306.194	305.707	.2016	0.000660
200 KPa	100	205.742	206.507	206.137	.1831	0.000888
100KPa	100	105.839	106.675	106.246	.1742	0.001639

Table 5 Output statistics of 100 datum points for each of the 10 nominal pressures.

The classic SPSS generated frequency distributions (similar to Figure 12 above) for the remaining nominal pressures are appended to the Thesis (see Appendix 1). The graphs suggest normal distributions. The Shapiro-Wilk Test of Normality for each of the ten data sets is shown in Table 6 below. The results for reference pressure 500 KPa shows a skewed distribution (skewness statistic -0.413 with a standard error of 0.241), but the remaining distributions cannot be shown to be significantly different from Normal at the 0.05 level.

Nominal Pressure	Shapiro-Wilk		
	Statistic	Df	Sig.
1000	.989	100	.567
900	.980	100	.136
800	.986	100	.366
700	.986	100	.356
600	.980	100	.128
500	.966	100	.012
400	.989	100	.566
300	.982	100	.199
200	.978	100	.100
100	.993	100	.882

Table 6 Shapiro-Wilk Test for the data of each nominal pressure

Similar calculations can be performed for each of the 10 nominal pressures. Table 7 below gives the values, for the interval in which 95% of the observed values lie at each nominal pressure.

Nominal Pressure	N	Mean	Std. Dev	1.96 times SD
1000 KPa	100	1004.45909	.201227	+/- 0.3947205
900 KPa	100	904.44052	.181381	+/- 0.3565848
800 KPa	100	804.30216	.179567	+/- 0.3515319
700 KPa	100	705.49649	.161251	+/- 0.3155012
600 KPa	100	605.36009	.178139	+/- 0.3486389
500 KPa	100	505.47489	.176677	+/- 0.3463555
400 KPa	100	405.61477	.162389	+/- 0.3182726
300 KPa	100	305.70670	.201636	+/- 0.3941893
200 KPa	100	206.13658	.183109	+/- 0.3585095
100KPa	100	106.24599	.174184	+/- 0.3412144

Table 7 Raw data with a calculation of 95% Confidence Interval for the data

The average value, for the 10 intervals in which 95% of the observed values lie, is +/- 0.353 Kilopascals. If this data is rounded to the nearest whole Kilopascal the data may be said to be precise at that level.

2.7 Calibration and rounding used for the investigation of impression pressure

The linear transformation of the output from the transducer proposed in section 2.2 above, corrected the known accuracy error of the transducer. The rounding of the recorded digital data to the nearest whole kilopascal produced data that is precise at that level.

For the investigation of impression pressure the output data was rounded to the nearest kilopascal for all experiments throughout Part II and Part III. Where, in Part III, two sensors were used simultaneously to measure pressure the data was transformed by applying the average accuracy error prior to rounding.

Chapter 3
Cut-off force on the Lloyd universal testing machine (UTM)

3.1 The problem

The Lloyd Universal Testing machine (Figure 4 above) has an automatic overload cut-off fitted. The 'cut-off' force can be set at a desired level and triggers an immediate halt to the movement of the Lloyd machine. The cut-off force is the force at which and above which the machine comes to an immediate stop. The force is sensed by a transducer mounted above the experimental equipment; this transducer can be seen in Figure 4 above.

As an impression is seated, an increased resistance would be expected from the moment when the impression material comes into contact with the brass discs. As the discs approximate at a constant velocity (set on the Lloyd machine) the force required to overcome the resistance increases when more impression material comes into contact.

It became apparent during preliminary tests that a low cut-off level (50 Newton) for the seating force on the Lloyd Universal Testing machine resulted in a failure of the impression to seat down to the 0.5 mm stops; see Figure 13 below.

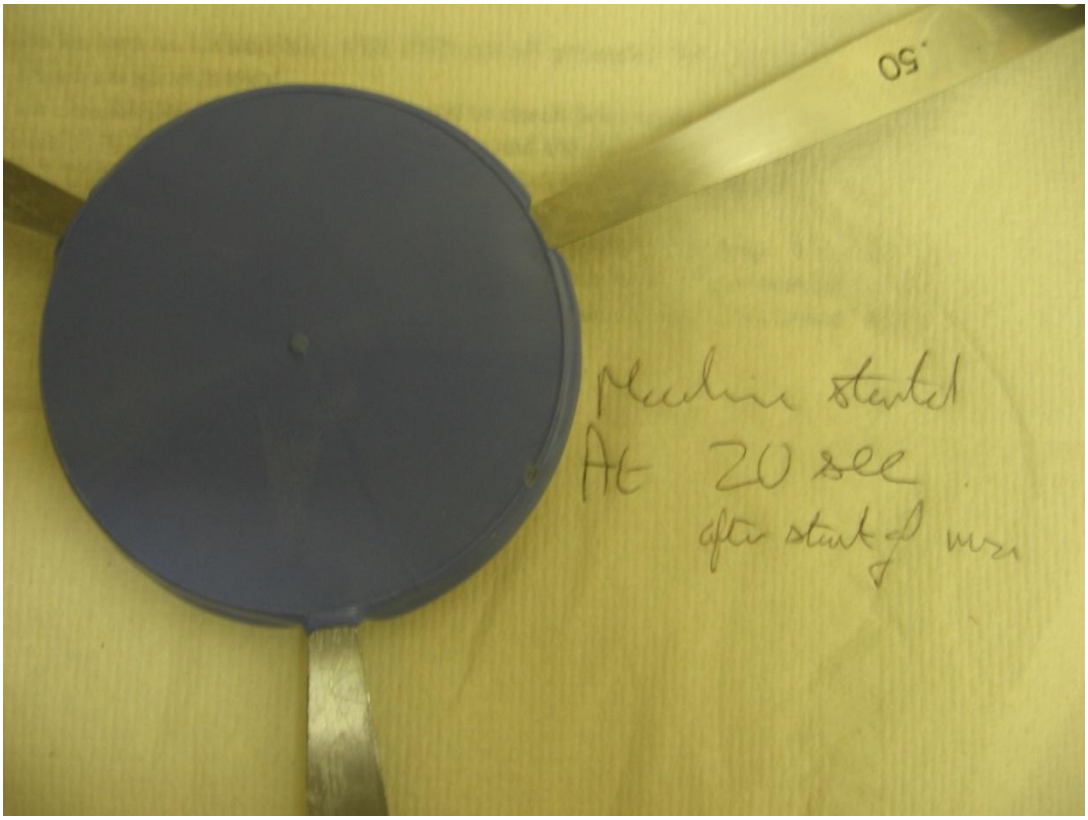


Figure 13 above shows the silicone impression material covering the surface of the steel stops at the end of the experiment.

3.2 Background

The early work of Frank (Frank 1969) had shown impression tray spacing to be significant in varying the pressure of an impression in-vitro. In Frank's experiments (Frank 1969) he found that the greater the space beneath the impression tray, the lower the recorded pressure. The intention in the experiments of Section II of this Thesis was to control the depth of silicone by the use of steel spacers of known depth (0.5mm). The picture above (Figure 13) shows a failure to achieve this objective. This failure to seat down onto the steel spacers meant that the space between the brass discs was not directly controlled. Frank's work suggests that this lack of depth control could lead directly to variable pressure and so introduce a potentially confounding variable; this was therefore unacceptable. The proposed solution was to increase the cut-off force setting on the Lloyd machine until the impression seated, i.e. the stops show through. The research question for the experiment in this chapter was, 'At what cut-off force do the steel spacers show though the silicone?'

3.3 Method

A series of experiments was carried out increasing the cut-off force on the Lloyd machine until the steel spacers showed through the impression material. The series of photographs below (Figures 14-18 below) show typical results from the series of experiments. The experiment was repeated three times at each setting of the cut of force.

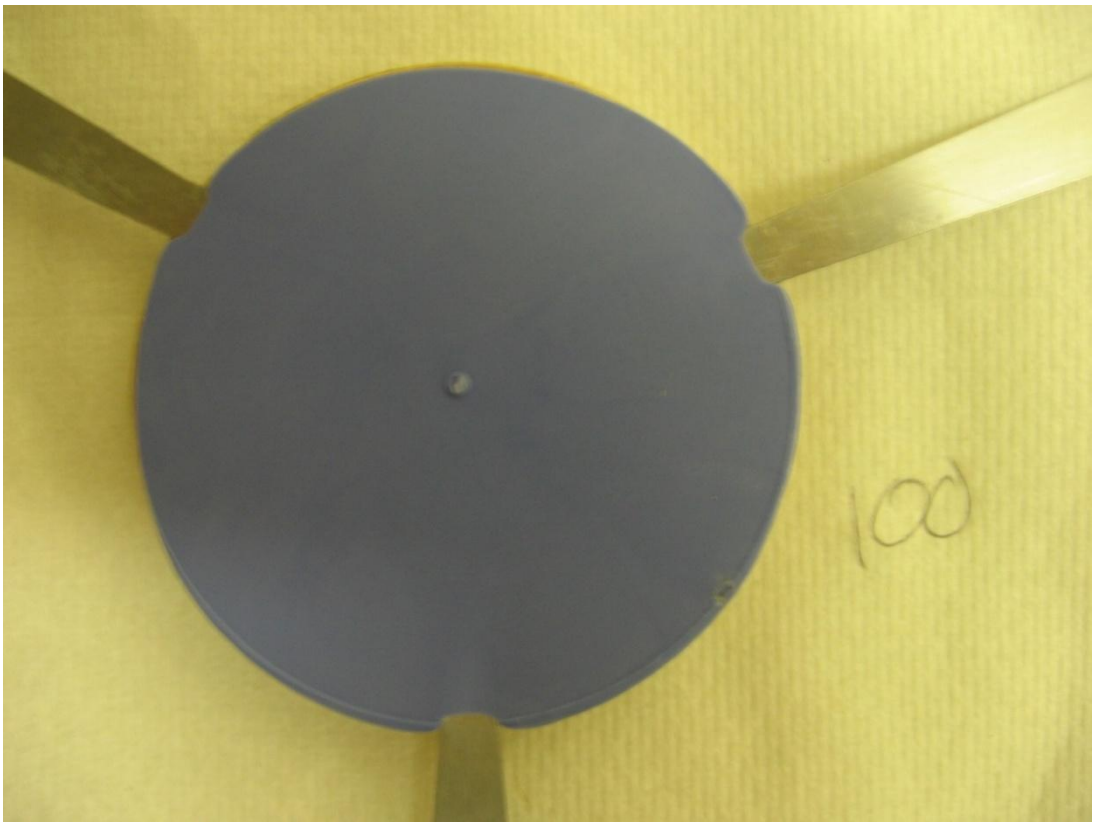


Figure 14 Cut-off force 100 Newton

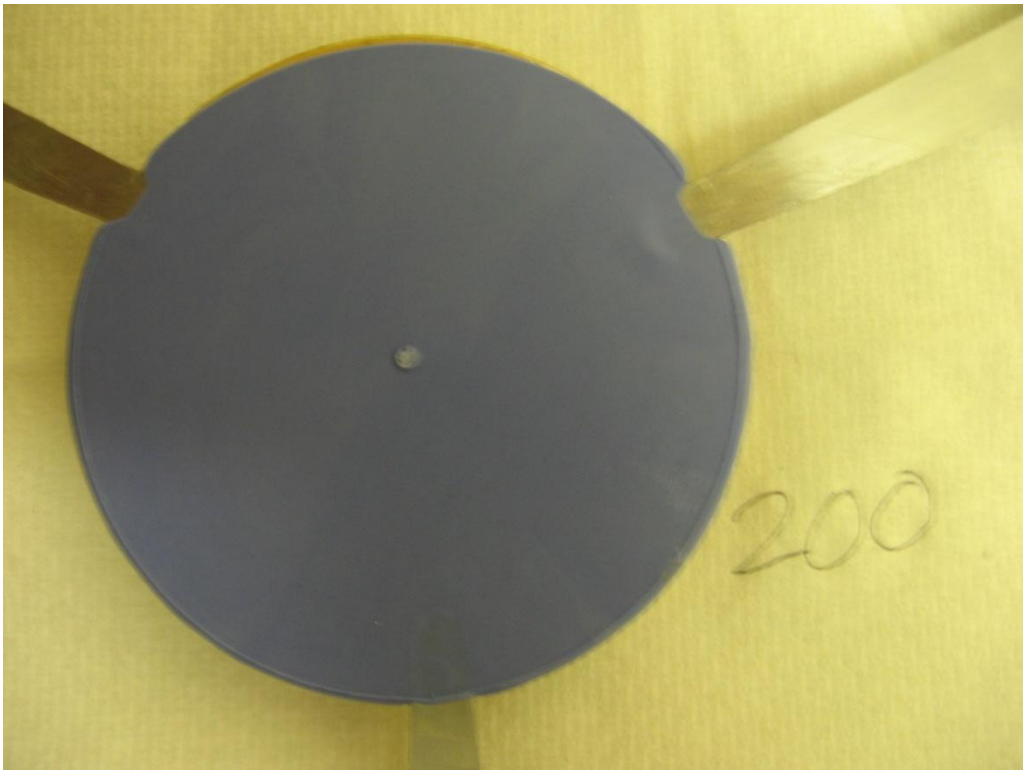


Figure 15 Cut-off force 200 Newton

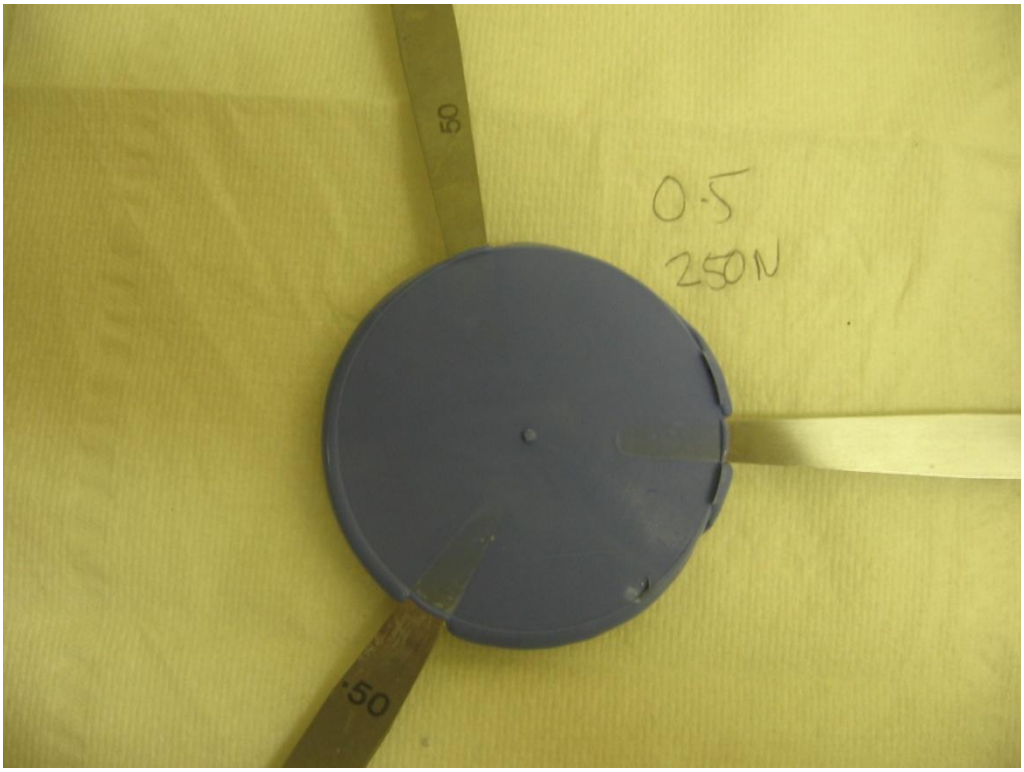


Figure 16 Cut-off force 250 Newton

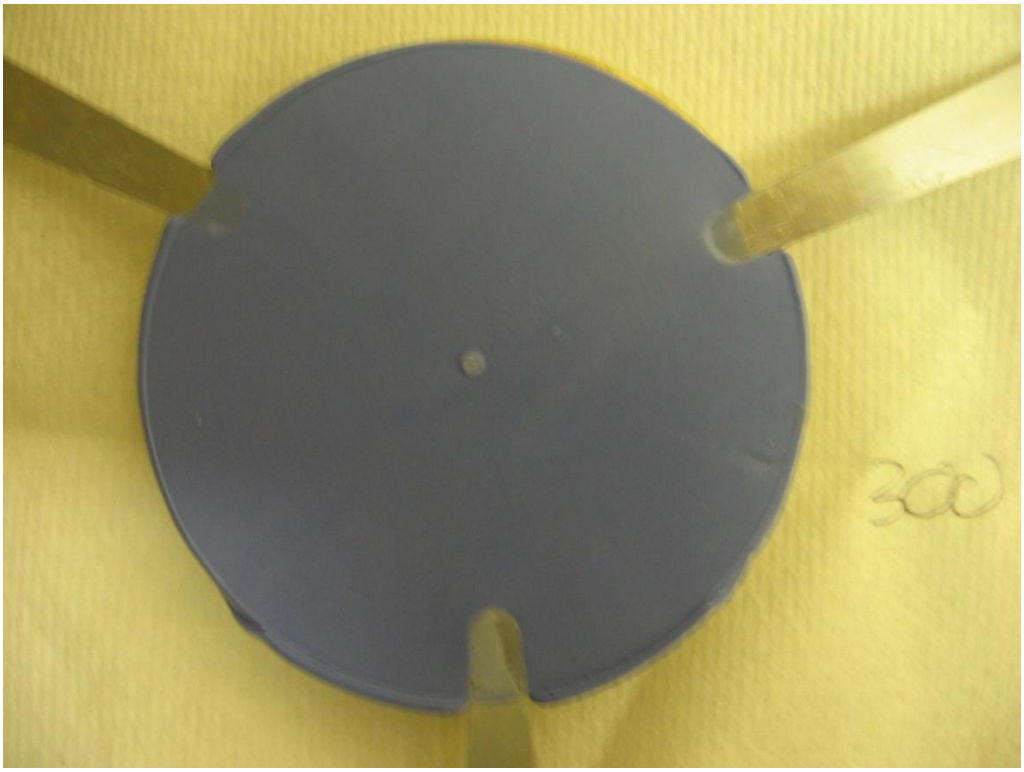


Figure 17 Cut-off force 300Newton

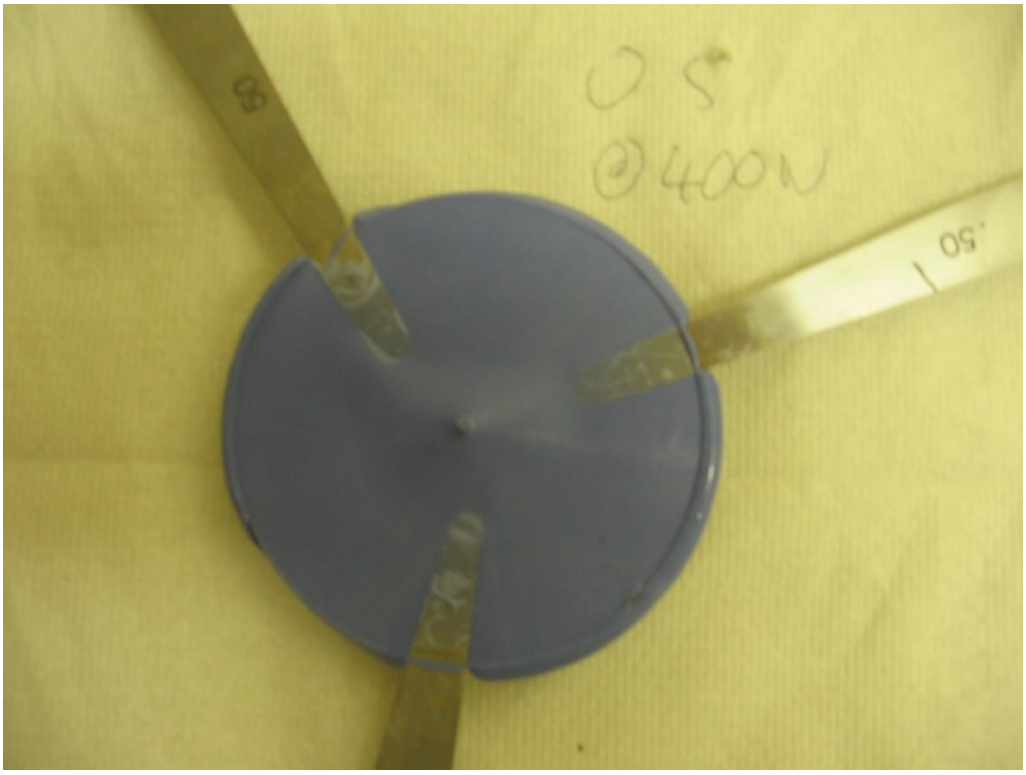


Figure 18 Cut-off force 400Newton

3.4 Discussion and conclusions

This experiment was simple and basic. It formed an early investigation into the problems of measuring impression pressure in-vitro. Later in Part II, experiments led to a greater understanding of the force required to eliminate silicone from beneath the parallel surfaces of the steel spacer and the brass disc; at this early stage in the experiments that understanding was absent. The drive here was to have a known space between the brass discs; the solution proposed below achieves that objective.

The purpose of this experiment was to determine at what cut-off force the steel spacers showed though the silicone. The metal spacers were just visible at 200 Newton (Figure 15) and are clearly showing (with no silicone covering some of the steel) at a cut-off setting of 300 Newton force (Figure 17). In order to eliminate this potentially confounding variable it was postulated that an increase in the cut-off force to a significantly higher level (1000 Newton) would have an advantage; it would also have a disadvantage (see below).

In discussing the advantages and disadvantages, it is important to point out that if steel hits brass at a certain cut-off force, increasing the cut-off force beyond that level, does not alter the pressure recorded within the impression material. If a cut-off force of 1000 Newton is used, the steel stops were expected to clearly show through the impression material from when the force was 300 Newton and to be in contact with the steel up until the force is cut at 1000 Newton. The increased force, above 300 Newton, was expected to be taken by hard contact on the steel stops. Since the steel cannot be compressed at these pressures, the space between the brass discs does not decrease and so the pressure within the impression does not increase. An increase to 1000 Newton for the cut-off force was not expected to affect the recorded pressure within the impression material (above that recorded when the steel stops first come into contact with brass). The Lloyd machine will still stop with the brass plates 0.5mm apart.

There is a potential advantage in increasing the cut of force to 1000 Newton for some experiments in Part II. With the conditions used in the pictures above (light bodied silicone on a disc of 7cm), it wasn’t necessary to increase the cut-off force above 300 Newton in order to seat the discs down to the steel stops. However, the planned experiments in Part II include those where the viscosity of the impression

material would be increased, where there would be a delay in seating the impression material, where the impression material would be seated at a higher velocity and include an experiment using a disc of wider diameter (10cm). In these planned experiments the resistance to seating was expected to be higher than that shown above. A higher cut-off force may be required to fully seat the impression. It was estimated that a cut-off force of 1000 Newton would provide ample seating force to accommodate all the conditions in the planned experiments of Part II. It was considered an advantage to set the same cut-off force (1000 Newton) for all experiments in Part II. It is important to state again this increase (above 300N) in the cut-off force does not increase the pressure on or within the silicone impression material, just the force on the steel stops.

A high cut-off force has a possible perceived disadvantage. 1000 Newton is more force than would be used clinically to seat an impression. In setting a 1000 Newton cut-off force, the experiments could be open to the criticism that they are not relevant to the clinical situation. This is partly a misunderstanding, it does not take 1000 Newton to seat these impressions; the steel stops show through at just 300 Newton (as above). However, the criticism still holds since it is also true to say that 300 Newton is more force than that normally used clinically to seat an impression.

It should be stated here that Part II of this Thesis attempts to eliminate potentially confounding variables to investigate single issues; it does not attempt to directly mimic the clinical situation (Part III does partially, see below). The design of Part II experiments to eliminate these potentially confounding variables led to (among other things) the use of dry, flat, hard discs made of brass. The clinical situation is wet, soft, compressive, visco-elastic, contoured mucoperiosteum. When compared to the complex clinical situation, the use of the controlled conditions has apparently led to a higher resistance to flow of the silicone impression material in the narrowing gap between the approximating surfaces. This has necessitated a higher seating force than used clinically. Indeed, if the cut-off force was set to a clinical level when this high resistance to flow was encountered, the approximation of the discs would stop before the discs seated onto the steel. With no steel contact the seating force is entirely taken by the silicone. The approximating discs would always stop at the same force (the cut-off) and so be likely to stop at the same average pressure within the silicone (with no steel stop contact).

The high seating force is necessary to eliminate confounding variables but it limits the *clinical* claims that can be made from any single experiment in Part II of this Thesis. To look at a specific, more clinically relevant situation would require a different approach; in Part III of this Thesis a different approach is used.

In Part III of this Thesis, a specific clinical impression technique is investigated and the maximum seating force in that situation could be reduced to lower levels (50 Newton). The limited aim of Part III of this Thesis was to demonstrate a differential pressure across the experimental impression technique used in Part IV of this Thesis. To achieve this limited aim, the force used to seat the impression was kept near clinical levels, and the differential pressure within the impression recorded. In Part III it became important to keep the overall seating force to clinical levels to avoid the criticism that the results were not clinically relevant. This is discussed further in Part III (Chapter 3, section 3.8, page 265).

Chapter 4
Weight of impression material used in an experiment

4.1 The problem

The weight of silicone used in the experiments of Part II of this Thesis represents a potentially confounding variable which is difficult to control as the silicone is dispensed. The manufacturers of the silicone give guidance that it is to be seated within 30 seconds of mixing. It proved impossible to mix the silicone in the usual manner (with a hand held dispensing gun) weight it, and then position the silicone within the Lloyd UTM to seat over a distance of 15mm at a constant speed (usually120mm/min). To travel the 15mm at 120mm/min takes 7.5seconds, to mix the silicone 10-15sec; there was no time to weight the silicone.

It would not be easy or convenient to control the amount of silicone with precision prior to an experiment. Therefore it became important to understand the effect of the weight of silicone in order to design an appropriate experimental protocol. Alternative approaches to the protocol were possible. For example it may have been possible to separate the base and the catalyst of the silicone and weigh them individually before the experiment then mix the silicone by hand; but hand mixing is imprecise and wasteful so the weight of the silicone actually used would still vary. Alternatively a protocol involving weighing the actual silicone used after the experiment was completed may have been possible; but this would necessitate using a higher number of repeated experiments together with more complex analysis (ANOVA with a factorial treatment structure) to account for the variation in weight of silicone used within each arm of each experiment. Both these alternatives were considered and both have disadvantages and some advantages.

The research question for this chapter was, ‘Does the weight of silicone affect the pressure of impression with the in-vitro conditions used in this study?’ The Null Hypothesis was that weight of silicone does not affect the pressure; the alternative hypothesis was that weight of silicone does affect pressure. Subsequently subsets of the data was analysed to test the Null Hypothesis that when the silicone overflows the edge of the brass discs there is no effect of weight of silicone on pressure.

4.2 Aim

The aim of the experiment was to investigate the effect of the weight of silicone on the pressure at the centre of the impression.

4.3 Method

In this preliminary experiment a simple methodology was adopted. Differing amounts of silicone were dispensed from a clinical hand-held dispensing pump. The brass discs were approximated at 120mm/min, until they were 0.5mm apart and the peak pressure recorded. After the silicone was set, it was removed and weighed on a digital scale certified as accurate to four decimal places of grams. A note was made of any overflow of the silicone beyond the edge of the brass discs. The results are presented below in Table 8 and the graph in Figure 19.

For this early experiment the 'measurement duration' of the analogue to digital sampler was set at the default for the equipment. Figure 8 shows the analogue to digital sampler. No change in the frequency of sampling was made before the experiment was performed; and the output of the experiments showed a sample rate of 10Hz. Although this was twice the frequency of the sampling rate used by Komiyama et al (2004) and 100 times more frequent than the manual sampling of Masri (2002) and Al Ahmad (2006), it is below the sampling rate (67Hz) used in the later pressure experiments of Part II of this Thesis; with a short duration of peak pressure this may reduce the precision of the data. With hindsight it would have been better to adjust the frequency of sampling to the faster rate used in the rest of Part II of this Thesis. Failure to do so may have reduced the peak of recorded pressure and may have been expected to produce a higher than normal variance in the output readings for this experiment.

4.4 Results

4.4.1 Raw data

Nominal number of squeezes on silicone gun	Voltage output	Silicone weight in grams	Full overflow of silicone?
0.5	1.81	1.5786	No
0.5	1.89	1.9790	No
0.5	1.82	1.5595	No
0.5	1.63	1.4288	No
0.5	1.74	1.3338	No
1	3.26	3.7999	No
1	2.96	3.4921	No
1	2.63	3.5234	No
1	3.43	3.5876	No
1	2.98	3.5328	No
1.5	3.83	3.9550	Yes
1.5	3.59	3.8322	Yes
1.5	2.61	3.2524	No
1.5	3.53	4.1835	Yes
1.5	2.98	3.8125	No
2	3.89	8.6494	Yes
2	3.72	5.9866	Yes
2	3.67	6.0756	Yes
2	4.07	5.9696	Yes
2	3.96	6.1422	Yes
3	3.86	8.5363	Yes
3	3.65	8.4138	Yes
3	3.7	6.5264	Yes
3	3.8	8.4009	Yes
3	3.88	8.4916	Yes
4	3.8	10.9143	Yes
4	3.9	10.8797	Yes
4	3.75	10.6114	Yes
4	3.74	8.8548	Yes
4	3.91	10.7720	Yes

Table 8 Raw data

4.5 Analysis of data.

4.5.1 Exploration of the Raw data

The results are tabulated above (Table 8) and explored by the scatter plot (Figure 19) below.

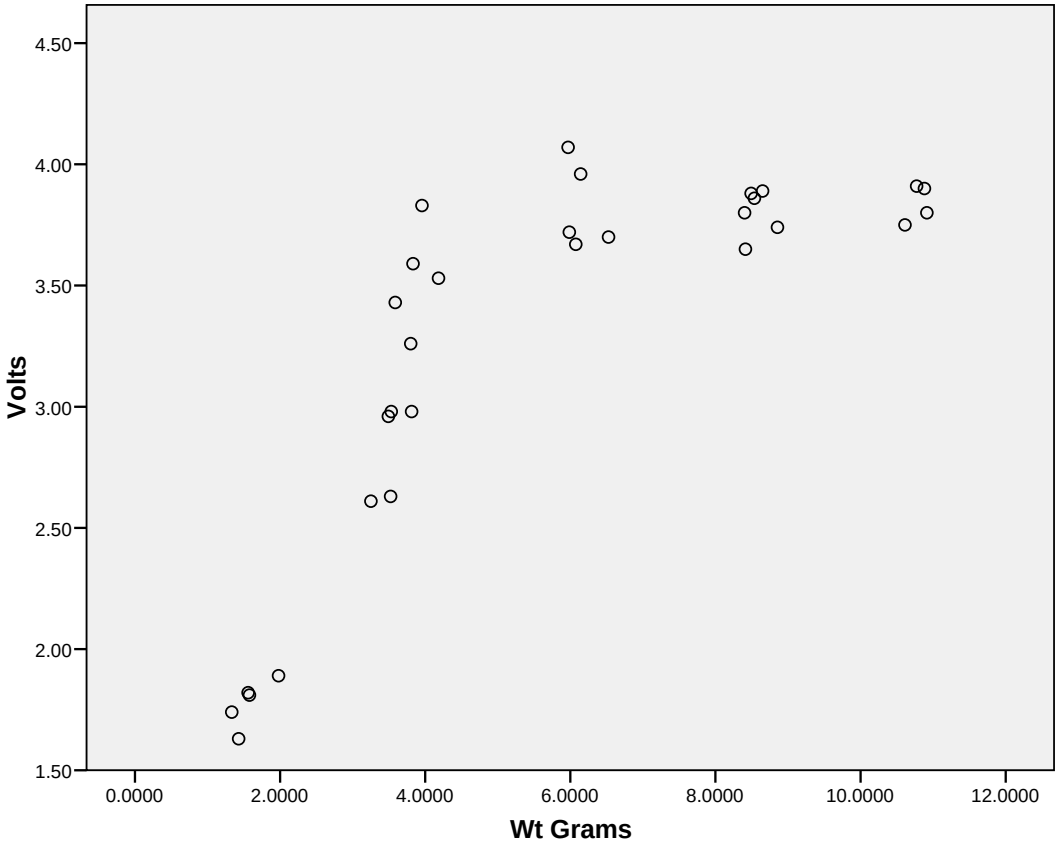


Figure 19 scatter plot of weight versus output of pressure sensor

Overall, Figure 19 shows a non-linear relationship between voltage and weight.

4.5.2 Correlation for overall weight and pressure

There was no expectation that the frequency distribution of the variable of weight would be distributed normally. This was formally confirmed by Shapiro-Wilk Test (Table 9 below).

Shapiro-Wilk			
	Statistic	**df**	**Sig.**
Volts	.801	30	.000
Wt Grams	.914	30	.019

Table 9 Shapiro-Wilk Test of normality for the variables weight and output voltage.

Since the distribution was not a normal distribution, Spearman's correlation was performed.

ALL			**Volts**	**Wt Grams**
Spearman's rho	Volts	Correlation Coefficient	1.000	.857(**)
		Sig. (2-tailed)	.	.000
		N	30	30
	Wt Grams	Correlation Coefficient	.857(**)	1.000
		Sig. (2-tailed)	.000	.
		N	30	30

Table 10 Spearman correlation for all the data. ** Correlation is significant at the 0.01 level (2-tailed).

Taking all the results there is a significant positive correlation between pressure and weight of silicone; Spearman correlation coefficient = 0.857 ($p<0.001$).

4.5.3 Further exploration of the data

Exploration of the data by scatter plot of weight against output voltage of the pressure sensor is shown above (Figure 19). About the weight of 5 grams and above the graph appeared to flatten out.

The data was separated into those pressure recordings where the silicone overflowed the entire circumference of the lower brass disc and those results where the silicone did not overflow. Table 10 above gives this information for the raw data; this has been divided into the data sets in Tables 11 & 12 below. The scatter plot of weight versus voltage output for each subset can be seen in Figures 20 and 21 below.

Nominal number of squeezes	**Voltage output**	**Silicone weight**	**Overflow of silicone**
1.5	3.83	3.9550	Yes
1.5	3.59	3.8322	Yes
1.5	3.53	4.1835	Yes
2	3.89	8.6494	Yes
2	3.72	5.9866	Yes
2	3.67	6.0756	Yes
2	4.07	5.9696	Yes
2	3.96	6.1422	Yes
3	3.86	8.5363	Yes
3	3.65	8.4138	Yes
3	3.70	6.5264	Yes
3	3.80	8.4009	Yes
3	3.88	8.4916	Yes
4	3.80	10.9143	Yes
4	3.90	10.8797	Yes
4	3.75	10.6114	Yes
4	3.74	8.8548	Yes
4	3.91	10.7720	Yes

Table 11 Data with silicone overflow

Nominal number of squeezes	Voltage output	Silicone weight	Overflow of silicone?
0.5	1.81	1.5786	No
0.5	1.89	1.9790	No
0.5	1.82	1.5595	No
0.5	1.63	1.4288	No
0.5	1.74	1.3338	No
1	3.26	3.7999	No
1	2.96	3.4921	No
1	2.63	3.5234	No
1	3.43	3.5876	No
1	2.98	3.5328	No
1.5	2.61	3.2524	No
1.5	2.98	3.8125	No

Table 12 Data with no silicone overflow

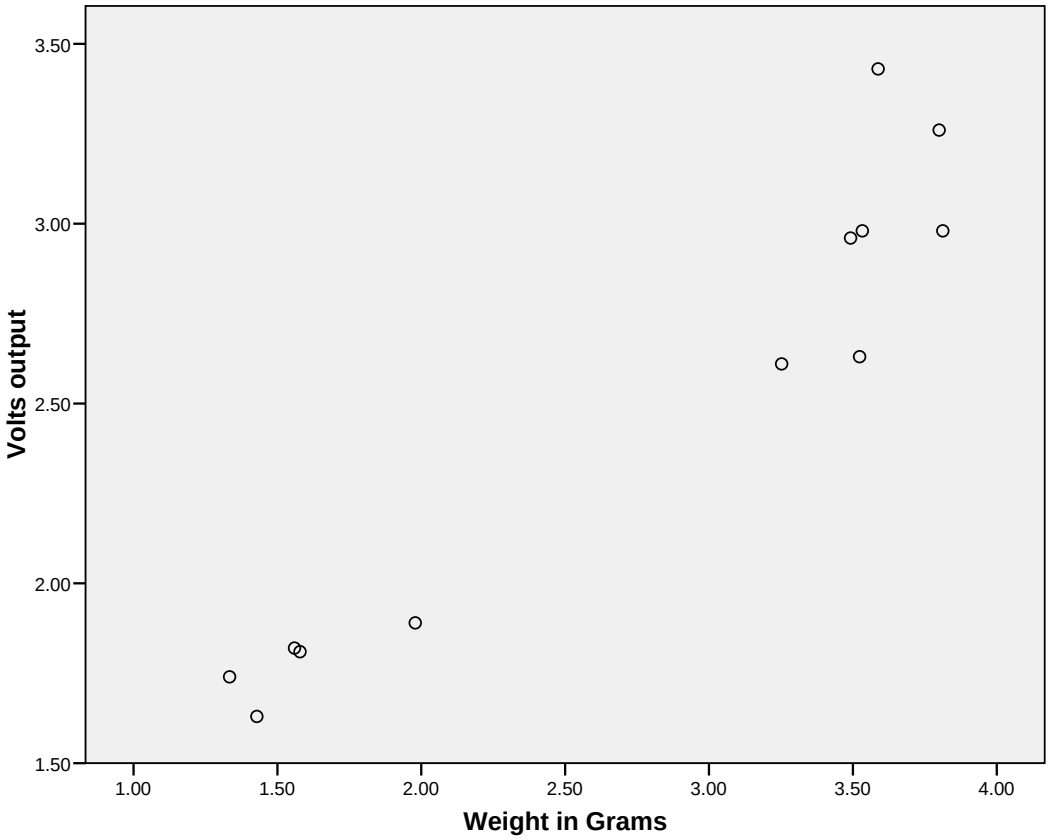


Figure 20 Scatter Plot of weight versus output voltage where there was no overflow of silicone.

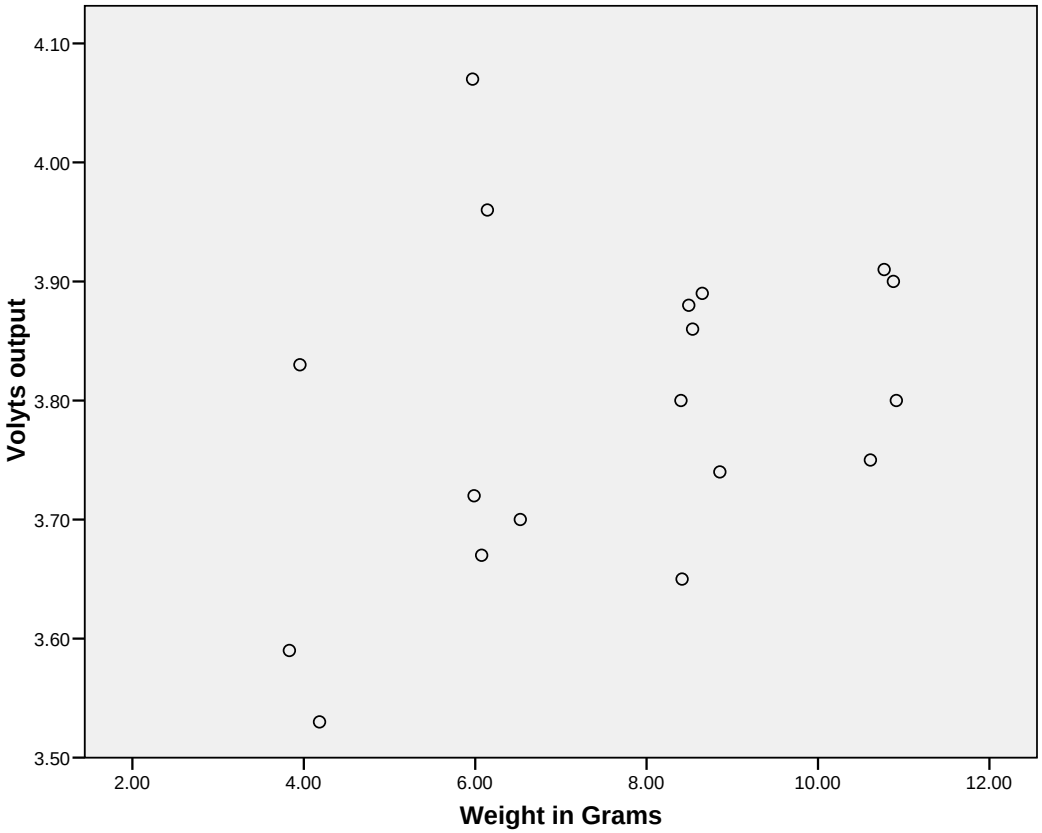


Figure 21 Scatter Plot of weight v output voltage where was an overflow of silicone.

While the scatter plot where there is no overflow of silicone is suggestive of a correlation, in contrast the scatter plot where there is an overflow of silicone appears random. The two data sets were subjected to data analysis for correlation. Frequency plots of the weight of silicone and the voltage output did not have a normal distribution. Shapiro–Wilk test of normality for the subset of data showed a significant difference from a normal distribution (Table 13 below). Therefore Spearman's correlation was used for the analysis of a correlation.

Shapiro-Wilk			
Variable	**Statistic**	**df**	**Sig.**
Volts	.801	30	.000
Wt Grams	.914	30	.019

Table 13 Shapiro-Wilk test

4.5.4 Correlation

Two data sets were defined by whether the silicone over ran the whole of the circumference of the lower brass disc or not. These two data sets were analysed by Spearman correlations; the correlation tables are shown below (Table 14 and 15).

WITH NO OVERFLOW			**Volts output**	**Weight in Grams**
Spearman's rho	Volts output	Correlation	1.000	.942(**)
		Sig. (2-tailed)	.	.000
		N	12	12
	Weight in Grams	Correlation	.942(**)	1.000
		Sig. (2-tailed)	.000	.
		N	12	12

** Correlation is significant at the 0.01 level (2-tailed).

Table 14 Spearman correlation table when there is no overflow of silicone.

WITH OVERFLOW			**Volts output**	**Weight in Grams**
Spearman's rho	Volts output	Correlation	1.000	.355
		Sig. (2-tailed)	.	.148
		N	18	18
	Weight in Grams	Correlation	.355	1.000
		Sig. (2-tailed)	.148	.
		N	18	18

** Correlation is significant at the 0.01 level (2-tailed).

Table 15 Spearman correlation table when there is silicone overflowing the brass disc

As can be seen above there is a statistically significant correlation when there is no overflow of silicone over the brass; Spearman Correlation 0. 942 ($p<0.001$). In contrast when the silicone overflows the brass there is no significant correlation; Spearman Correlation 0. 355 ($p=0. 148$).

4.5.5 The Relationship between the number of squeezes on the silicone gun and weight of silicone

The weight of silicone dispensed from the hand held silicone 'gun' may be expected to be proportional to the number of squeezes of the gun trigger. The scatter plot, Figure 22, below explores this.

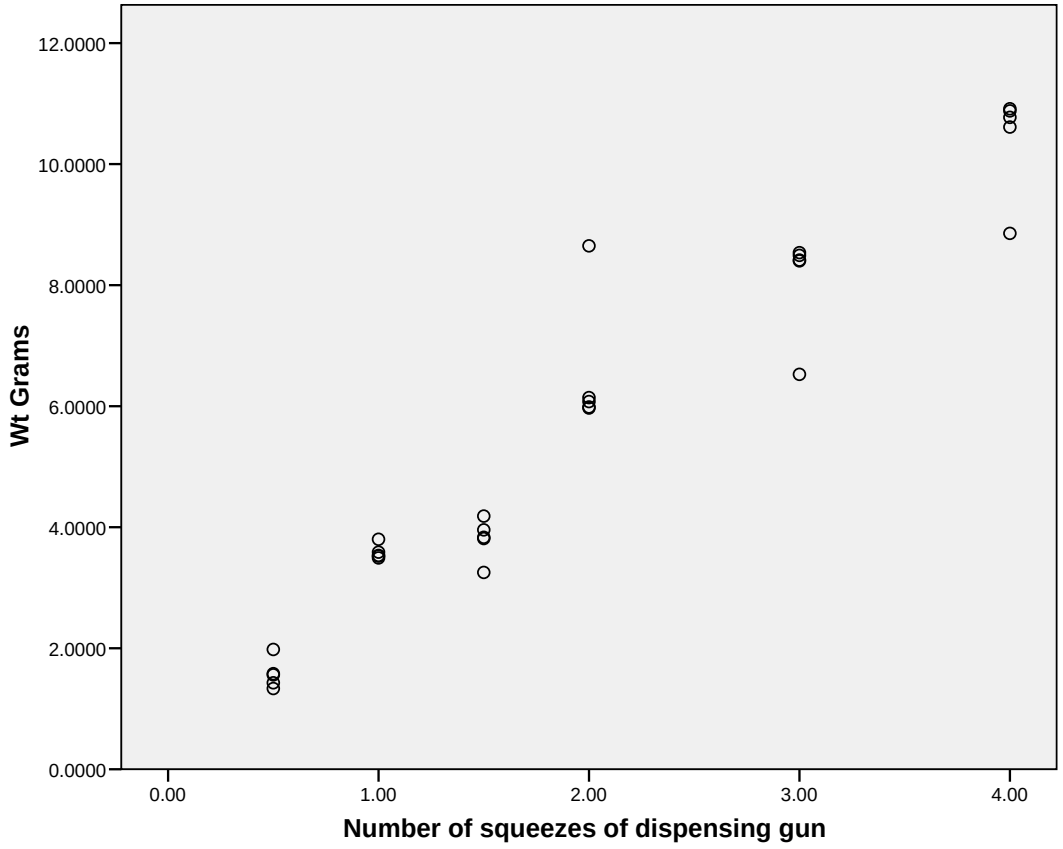


Figure 22 Scatter plot of weight versus number of squeezes on the dispensing gun trigger

As may be expected the graph of number of squeezes against weight of silicone suggests a linear relationship. A linear regression model was fitted with dependant variable weight and explanatory variable number of squeezes. With the assumption that weight equals zero when number of squeezes equals zero (no constant in the equation) then the analysis by linear regression gave a relationship of weight equals 2.74 times the number of squeezes with R^2 for this model of 0.98,

p<0.001 and the 95% Confidence Interval for the parameter estimate of +/- 0.146. This is relationship is depicted in the Stata Graph below (Figure 23 below).

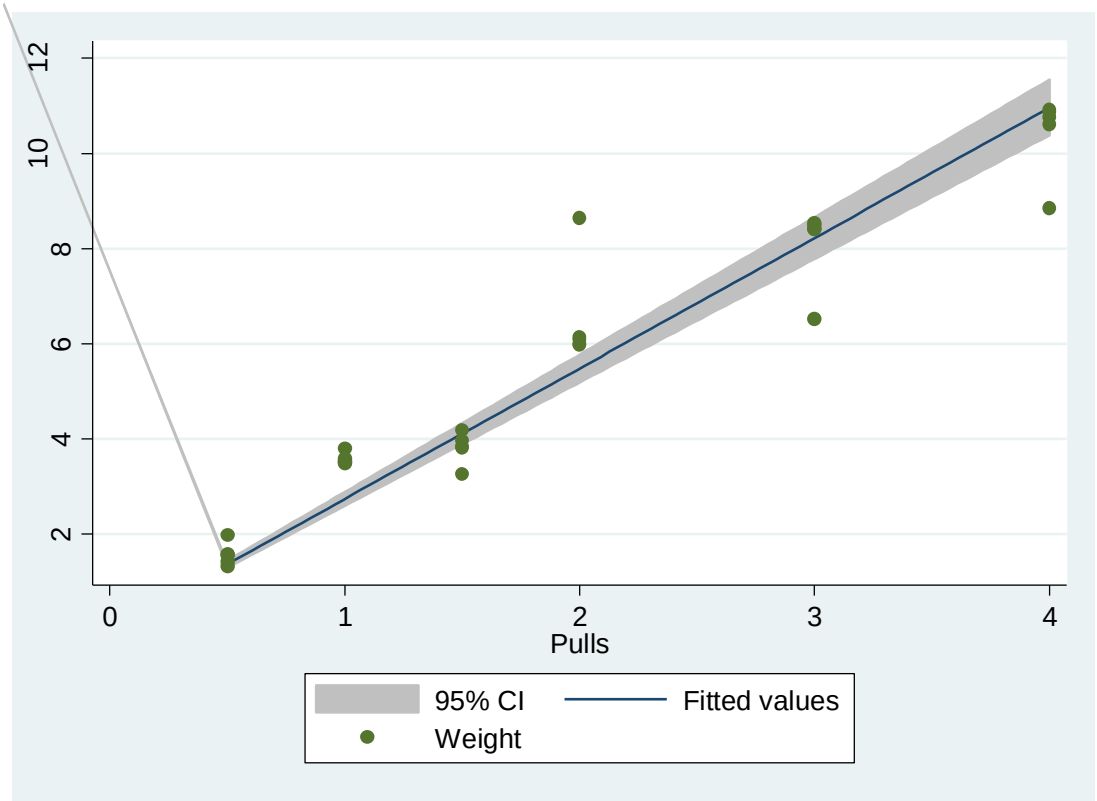


Figure 23 linear regression of weight by the number of squeezes of dispensing gun trigger.

As may have been expected the regression data confirms a reasonable linear relationship between the number of squeezes of the dispensing gun and the weight of silicone. The relationship is not perfect but an estimate of weight can be made from the number of squeezes of the gun trigger handle and the model with number of squeezes as the predictor variable explains 98% of the variation in weight. For practical purposes it would be useful to have as a guide, how many squeezes of the trigger of the gun produces a predictable overflow of the silicone over the brass disc. From the raw data above it is clear this occurs when the number of squeezes on the trigger is two or more.

The analysis of weight versus number of squeezes above, suggests that the possibility of using the number of squeezes of the dispensing gun trigger as a proxy for weight in future experiments. This possibility was investigated. The relationship between the number of squeezes of the trigger and the output voltage was explored (Box plot Figure 24 below. The Null Hypothesis was that, for two or more squeezes

of the trigger of the dispensing gun, the number of squeezes does not affect the pressure of impression.

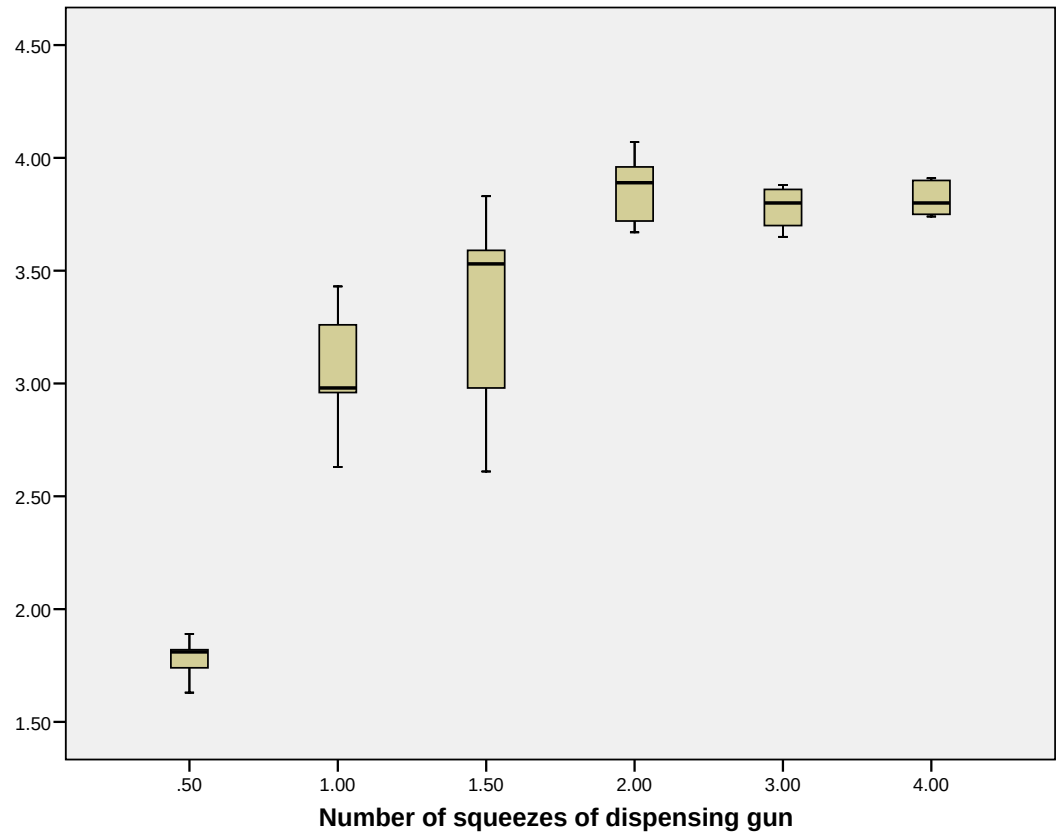


Figure 24 Box and whisker plot of voltage output from the pressure sensor versus number of pull of dispensing gun trigger

Figure 24 shows that median voltage increases as number of squeezes increases up to two squeezes and then remains stable. Further analysis of the data was now performed to test the correlation between the number of squeezes of the trigger of the silicone gun and the output pressure. The research question was ‘if two or more squeezes of the trigger on the silicone dispensing gun are used is there a correlation between the number of squeezes on the trigger and the pressure?’. The Null Hypothesis was that there was no correlation. The alternative was that there was a correlation. The data where there were two or more squeezes on the trigger

was separated out from the raw data to form a new data set. The data was explored with a scatter plot (see Figure 25 below) and a Spearman correlation test.

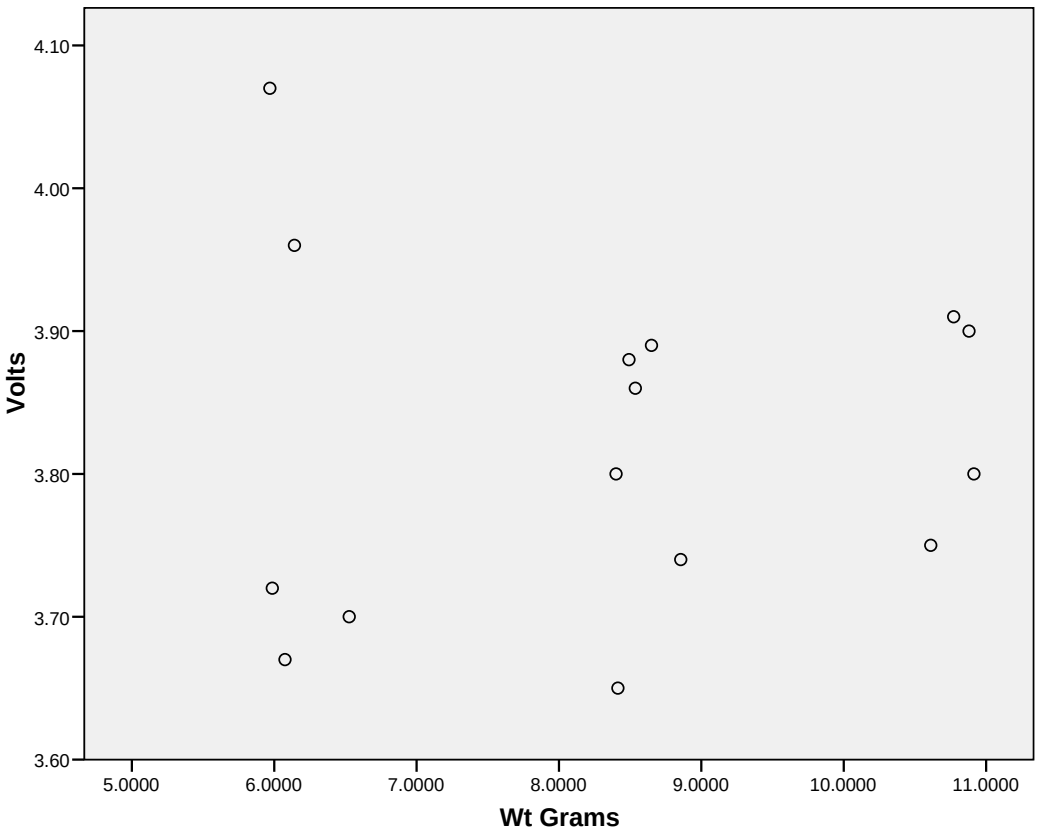


Figure 25 scatter plot of weight versus voltage output from the pressure sensor when more than two squeezes of the trigger of the silicone dispensing gun were used.

Two or more squeezes			Volts	Wt Grams
Spearman's rho	Volts	Correlation Coefficient	1.000	.141
		Sig. (2-tailed)	.	.616
		N	15	15
	Wt Grams	Correlation Coefficient	.141	1.000
		Sig. (2-tailed)	.616	.
		N	15	15

Table 16 The Spearman correlation output of weight versus voltage output when two or more squeezes of the trigger were performed.

As can be seen from the Spearman correlation table above there is no significant correlation between weight and pressure (Spearman correlation 0. 141, p=0. 616) when two or more squeezes of the trigger of the silicone dispensing gun were used confirming the pattern shown in fig 24. The Null Hypothesis, that there was no correlation between voltage and number of squeezes with two or more squeezes could not be disproved by this set of data.

4.5.6 ANOVA

Having failed to show a correlation between pressure and silicone weight (when number of squeezes $\geq$ 2) the final research question of this chapter was, 'Could the data show a significant difference in pressure between two squeezes, three squeezes, and four squeezes of the dispensing gun?'

Since the aim was to compare voltages in three groups with an outcome that is normally distributed, ANOVA was used to test the Null Hypothesis that there is no significant difference between the three levels. The grouping variable was number of squeezes of the trigger of the dispensing gun. All groups where there were two or more squeezes were included in the analysis. Data from all three groups could not

be shown to deviate from normality assumption using Shapiro-Wilk tests. A Levene test was conducted to check the homogeneity assumption for ANOVA.

4.5.6.1 ANOVA results of groups where two or more squeezes of the dispensing gun were used

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	.018	2	.009	.598	.565
Within Groups	.177	12	.015		
Total	.195	14			

Table 17 Results

No significant difference could be shown between the groups when two or more squeezes of the trigger were used (F=0.598, P=0.565).

4.5.6.2 ANOVA results of groups where less than two squeezes of the dispensing gun were used

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	6.716	2	3.358	28.525	.000
Within Groups	1.413	12	.118		
Total	8.128	14			

Table 18 Results

A significant difference could be shown between the groups (F= 28.525, $p<0.001$) when less than two squeezes of the trigger were used.

4.6 Discussion

The research question for this chapter was ‘does the weight of silicone affect the pressure of impression with the in-vitro conditions used in this study?’. The

Null Hypothesis was that weight of silicone does not affect the pressure; the alternative hypothesis was that weight of silicone does affect pressure. Overall, the weight of silicone does affect pressure and the Null Hypothesis is rejected. However, for the data recorded when the silicone overflowed the brass disc the Null Hypothesis could NOT be rejected.

It is pertinent to consider the philosophical statement that it is not possible to prove a negative when considering these results. The experiments in the data subset where silicone overflowed were unable to show there was a correlation between pressure and weight; also, in the overflow subset, the experiments were unable to prove there was a pressure difference between the groups defined by numbers of squeezes of the trigger. Of course this does not mean there wasn't a difference; just that the experiment couldn't show it.

While it is tempting to say that once the silicone overflows the brass disc there is no difference in pressure brought about by the additional weight of silicone, this chapter has not proved that; just suggested it.

The positive findings of this chapter are:

1. There is a significant correlation shown between pressure and weight when the silicone does not overflow the brass discs.

2. Similarly there is a significant difference in the pressure of impression between experimental runs when less than two squeezes on the silicone gun are used to dispense the silicone.

If consistent results are to be achieved in the experiments in Part II of this Thesis it is important that conditions where the silicone does not overflow the brass discs are avoided; when the separation between the discs is 0.5mm this can happen when less than two squeezes of the silicone gun are used.

4.7 Conclusions

1. In these in-vitro experiments, inconsistent pressure readings may be expected if the silicone does not overflow the brass discs at the end of the experimental run.

2. When there is 0.5mm gap between the discs at the end of the run, more than two squeezes of the trigger of the silicone dispensing gun are required to achieve consistent results.

3. In this in-vitro experiment, the weight of silicone was not demonstrated to be correlated to pressure once the silicone overflowed the brass discs.

4. The number of squeezes of the trigger of the dispensing gun is a reasonable proxy for the weight of silicone dispensed.

5. In all future experiments the amount of silicone used should be chosen to easily overflow the edge of the discs.

4.8 Potential explanation for the results and implications for further protocol designs

It is suggested that an explanation for these results may be found in considering the resistance to the flow of the silicone before and after overflowing the edge of the brass disc. The resistance from surface tension between the silicone and the brass is expected to be proportional to the surface area of brass in contact with the silicone; once the silicone reaches the edge of the disc and falls away there is no further increase in area of brass in contact with the silicone. Adding more silicone just means more overflows, it does not produce more silicone in contact with more brass and so it does not increase resistance to flow and so does not produce a higher pressure. This explanation is suggested by the experiments, but it remains a hypothesis and further experimentation would be needed to prove or disprove the hypothesis. The results do not prove the hypothesis; but they do suggest it.

From a purely practical point of view it was clear from this experiment that dispensing silicone from three squeezes of the trigger of the dispensing gun, when the gap between the brass plates was 0.5mm, should produce consistent pressure. Therefore the protocol for the experiments in Chapters 5 to 13 used this simple practical empirical guideline to ensure adequate control of the potentially confounding variable of the amount of silicone dispensed. When the protocol required differing gaps between the brass discs or different diameters of brass discs

(Chapter 14 &15), the practical approach adopted was to ensure ample silicone was dispensed and it overflowed the edge of the brass discs.

Purely as a precaution, the prudent step was taken of recording the weight of the silicone for the next experiment (Chapter 5). The later (much later in time, during the write up of this Thesis) retrospective analysis of weight as an independent variable was performed by factorial ANOVA together with the independent variable under consideration (velocity). This is reported below (in Chapter 5, section 5.7, pages 103-107).

Chapter 5
Velocity of approximation

In 2008 the subject and result shown in this chapter were reported by the author of this Thesis with his PhD supervisors and published in the Journal of Prosthetic Dentistry (Hyde 2008). The issues discussed, and the work presented, in the previous four chapters have facilitated the presentation of the work in the published paper (the full article is Hyde 2008).

The author has chosen to re-use his own words from the published paper here, but using the reference system and headings which conform to the Leeds Thesis template and returning to English spelling (correcting the American spelling). Where quotation marks are shown the words are reproduced from the published paper.

5.1 Introduction

'The amount and distribution of pressure beneath prosthodontic impressions has been the subject of academic debate and research. Mucodisplasive (Fournet and Tuller 1936), mucostatic (Addison 1944, Page 1951), functional (Chase 1961, Vig 1964) and differential pressure (Boucher, 9th edition, 1990) techniques have been advocated. Many contemporary complete denture impression techniques aim to reduce or control pressure. In this era of evidence-based dentistry, re-evaluation of the evidence-based literature supporting clinical techniques is needed. Kydd et al (Kydd 1967, 1969, 1971, 1974) demonstrated the physical properties of oral mucosa. The importance of controlling pressure under complete denture impressions is a consequence of these physical properties. The viscoelastic mucosa will distort during the making of an impression; once distorted, the mucosa takes hours to return to the rest position (Kydd 1967, 1974). An impression of distorted mucosa may result in a denture that will load that mucosa in an unpredictable and potentially undesirable way. For example, overloaded mucosa may be traumatized or uncomfortable for the patient. Constant overload of mucosa may increase the rate of bone resorption. El-Khodary et al et al (El-Khodary et al 1985) demonstrated that dentures fabricated from impressions made under pressure are associated with an

increased number of osteoclasts in the mucoperiosteum. Methods of controlling pressure under impressions have been investigated. (Frank 1969, Masri 2002, Komiyama et al 2004, Al Ahmad 2006). Frank (Frank 1969) demonstrated that, in-vitro, the introduction of spacing and perforations reduced pressure under impressions. Frank's findings have largely been confirmed by Komiyama et al's work (Komiyama et al 2004) using modern impression materials. These practical, in-vitro results provide an evidence base to validate current clinical practices. Masri et al (Masri 2002) and Al-Ahmad et al et al (Al-Ahmad et al 2006) have investigated impression pressures in-vitro in the maxilla and mandible, respectively. The authors used oral analogue models and manual recording of the pressures. Previous studies (Frank 1969, Komiyama et al 2004) have used a constant velocity motor. Komiyama et al et al (Komiyama et al 2004) reported using a press velocity at 120mm/min, as reported by Frank (Frank 1969). A review of the literature revealed no previously published data on the relationship between seating velocity and the pressures produced by an impression. The purpose of this study was to assess the relationship between pressure and seating velocity when an impression material is seated onto a die. The Null Hypothesis was that the seating velocity has no effect on pressure produced.'

5.2 Materials and methods

'Pressure was measured when silicone impression material was compressed at different velocities. Vinyl polysiloxane impression material (Express, fast set, light body; 3M ESPE, St. Paul, Minn.) was placed between two 7-cm-diameter brass discs. At the centre of the upper disc, a 2mm diameter hole led to an analogue pressure transducer (PXM209-010G10V; Omega Engineering Inc, Stamford, Conn). The pressure transducer was directly connected to the brass disc via a one-quarter-inch British Standard Pipe (BSP) screw thread sealed with plumber's tape. The connection to the pressure transducer was filled with water (Figures 26 & 27).

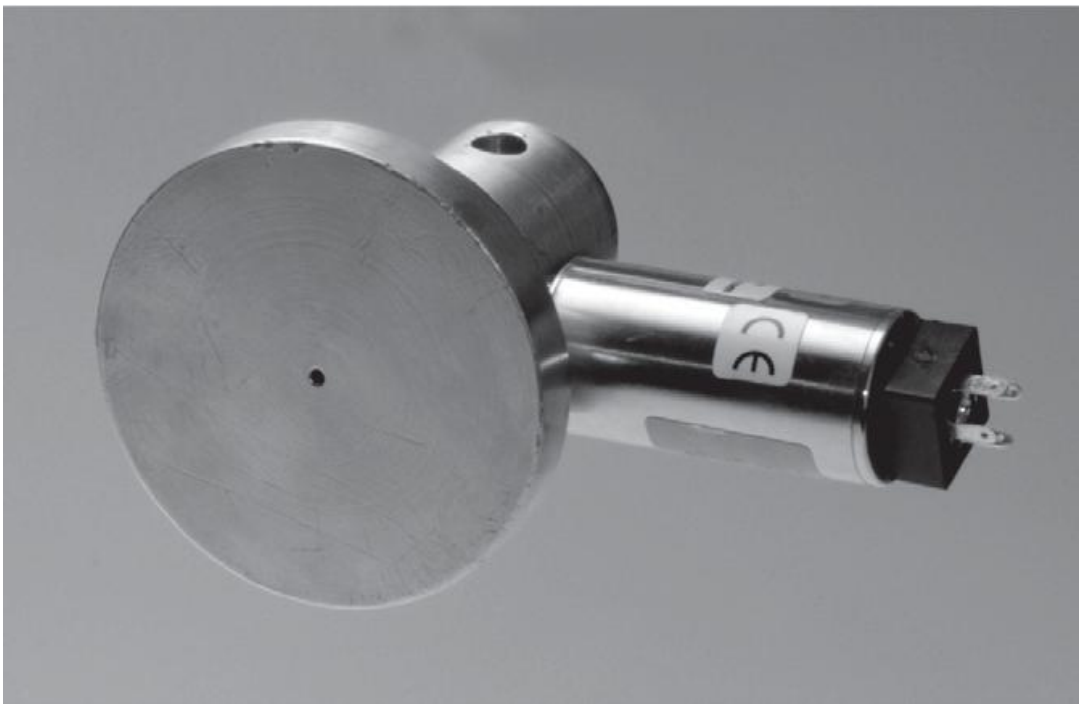


Figure 26 Sensor attached to brass disc with 2mm hole at centre.

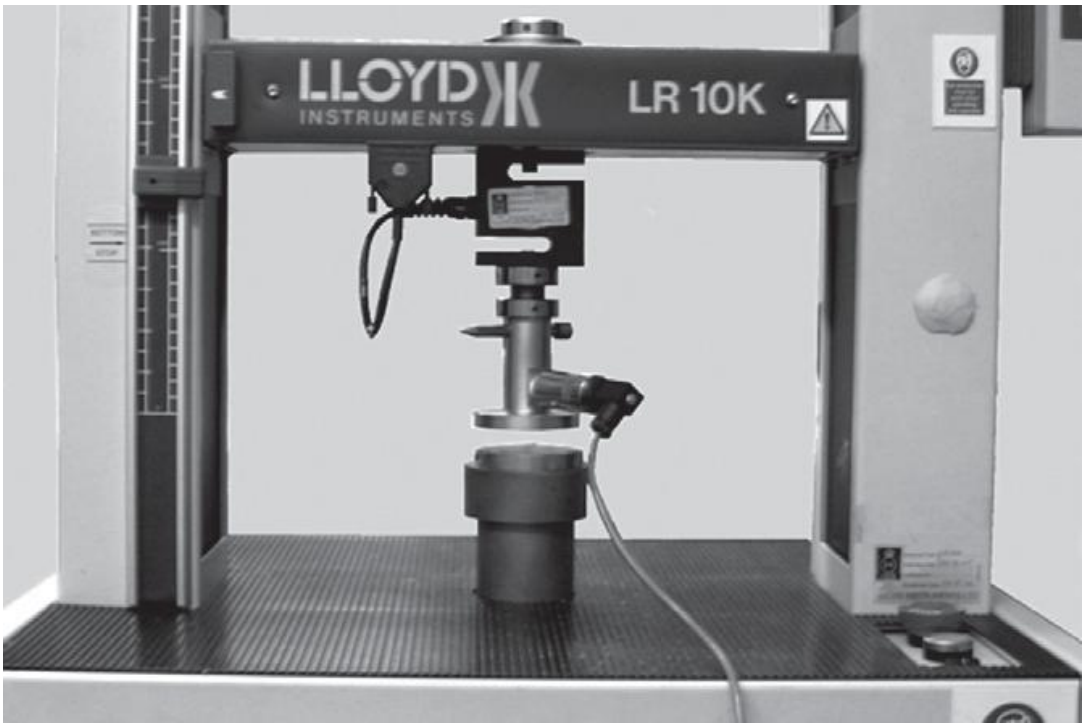


Figure 27 Lloyd Universal Testing Machine with brass discs and sensors attached.

The brass components of the experimental apparatus were manufactured by Leeds Dental Institute (University of Leeds, Leeds, UK). The amount of material used for each experiment was that dispensed by three full squeezes on the

manufacturer's mixing gun. After the material was polymerized, the weight of impression material in each experiment was measured and recorded. The range of the weight of impression material used was 4.3 g to 6.4 g, with a mean (SD) of 5.48 (0.53) g. A preliminary study indicated that within this range, there was little correlation between the weight of impression material and the pressure recorded when using this equipment (Pearson correlation = -0.301, P=.342). Three squeezes on the dispensing gun provided ample impression material to overflow the edge of the brass disc. The impression material was dispensed to the centre of the lower disc from the manufacturer's mixing gun over a period of approximately six seconds. Data from the transducer was logged at a rate of 67 samples/s via a USB data acquisition module (OMBDAQ- 55; Omega Engineering, Inc) to a computer using associated software (Omega Engineering, Inc). The brass plates were approximated at seven different velocities in a universal testing machine (Lloyd LR10K UTM; Lloyd Instruments Ltd, Fareham, UK). The velocities were: 45mm/min (0.75mm/s), 60mm/min (1mm/s), 75mm/min (1.25mm/s), 90mm/min (1.5mm/s), 120mm/min (2mm/s), 150mm/min (2.5mm/s) and 180mm/min (3mm/s). The initial spacing of the brass discs was 15 mm. The approximation of the plates was carefully coordinated to finish 30 seconds after the commencement of mixing the impression material. This complies with the manufacturer's recommendation that the impression should be seated within 30 seconds of mixing. Completing seating of the impression at a constant point in time ensured that the peak recorded pressure occurred at the same time (relative to mixing) for all of the different velocities of approximation. This allowed the peak pressures to be recorded with material at a similar state of polymerization and, thus, a similar viscosity. The plates were approximated until they were 0.5 mm apart, consistent separation was ensured by the use of three steel spacers made from engineering feeler gauges (Safe and Sure Feeler Gauge; Moore & Wright, Sheffield, UK) placed around the periphery of the brass discs. The steel spacers prevented the brass discs from closing beyond 0.5mm. Pressure sampling at 67Hz was continued for 5 minutes, after which the material was polymerized to touch. Data was collected from five repeated experiments for each of the groups. The sample size was determined based on the previously mentioned preliminary study, which examined weight of impression material versus peak pressure and showed a low variance in recorded pressure. A formal power analysis was not performed. The peak pressure from each run was noted and

recorded. Data was entered into a spreadsheet (SPSS 14.0; SPSS, Inc, Chicago, Ill). Mean and standard deviation were computed for each seating velocity. Data were analyzed with a 1-way ANOVA. When a significant group difference was found, the homogeneity of the variances was tested using the Levene statistic. Levene's test of equality of error variance, tests that the Null Hypothesis that the error variance of the dependent variable is equal across groups. The Levene test had a P value of 0.076 suggesting possible marginal significance but not within the usual 0.05 level. Subsequent post hoc testing used both Tukey B tests (which assume equal variance) and Dunnett's T3 tests (which do not assume equal variance) at the .05 level of significance. Calibration of the sensor was certified by the manufacturers to have used instruments and standards that are traceable to the United States National Institute of Standards Technology (NIST). The assembled system, including the data-logging via the software onto the computer, was tested for accuracy in-house and compared to a pressure standard traceable to the British Standards Institute (BSI).'

5.3 Results

Approximation velocity (mm/s)	Mean (KPa)	Standard Deviation
0.75	239.66*	06.67
1.00	273.75*	14.89
1.25	347.27*	11.97
1.50	424.56*	19.73
2.00	487.32*	17.84
2.50	547.00*	21.25
3.00	623.76*	32.60

Table 19 Mean and standard deviation at each velocity; *indicates that difference was significant for p<.05

‘Table 19 provides the mean and standard deviation of the peak pressures for each seating velocity. As the velocity increases, so does the recorded pressure (P<.001). The highest pressure values are seen in the 180 mm/min (3 mm/s) group. Typical time-pressure graphs from the 60 mm/min (1 mm/s), 120 mm/min (2 mm/s), and 180 mm/min (3 mm/s) groups are shown in Figures 28 through 30, respectively.

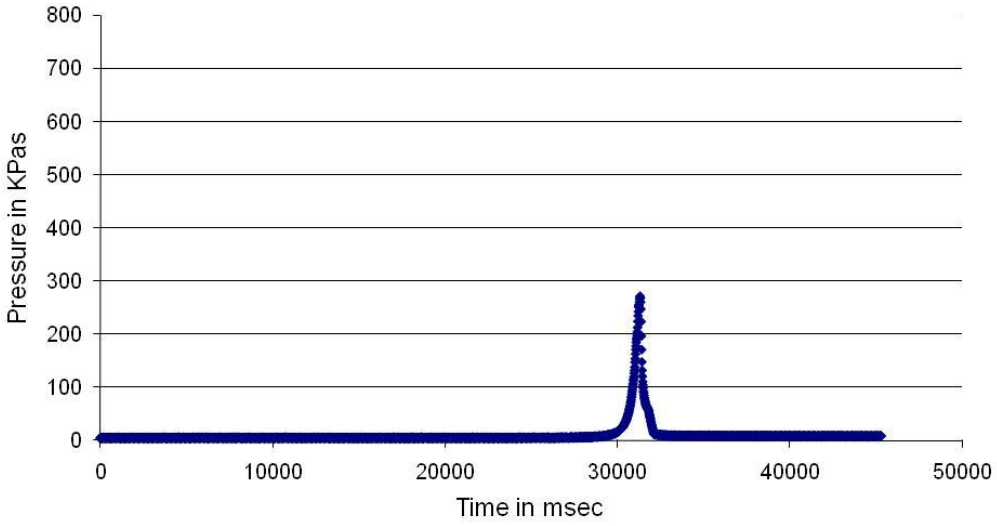


Figure 28 Single run showing time plotted against pressure at 1mm/s

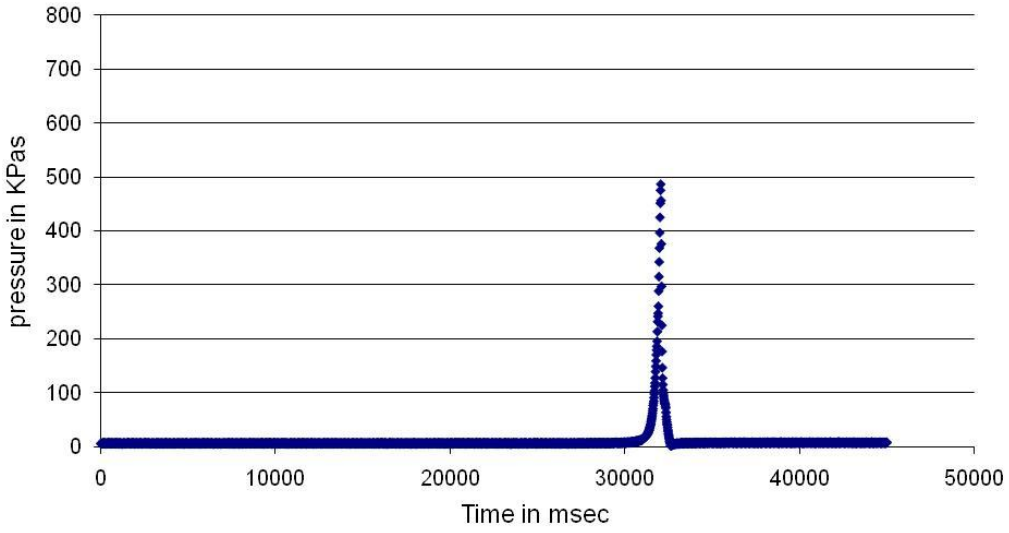


Figure 29 Single run showing time plotted against pressure at 2mm/s

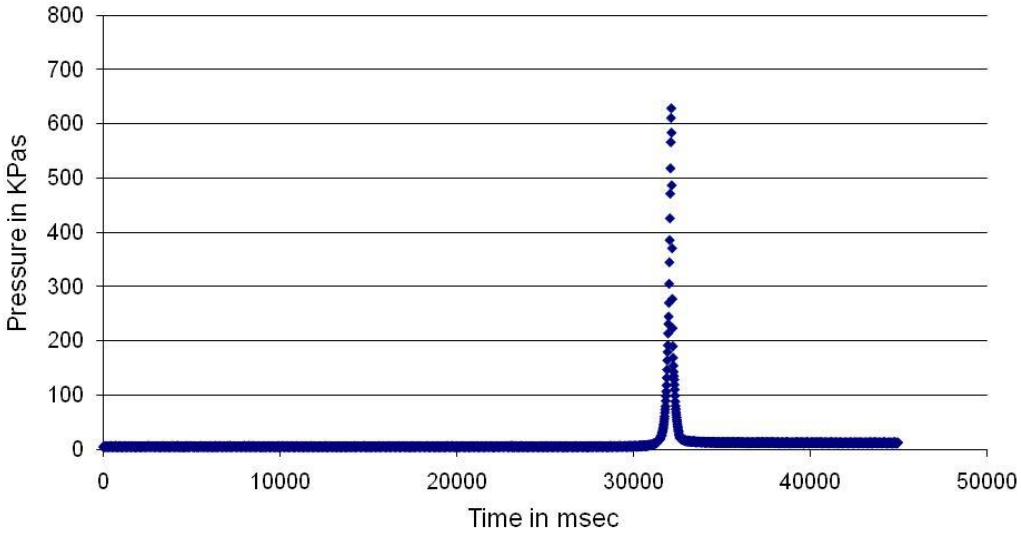


Figure 30 Single run showing time plotted against pressure at 3mm/s

These graphs represent individual experiments from each of the groups. These particular graphs are chosen for illustration because the peak pressure measurements are the closest to the mean for the group. Thus, they are representative of the pressure-velocity relationship of the group. In this study, the recorded pressure returned to a lower but sustained level (Figures 28 through 30) after the high of the peak pressure. The pressure drops to a range within 3-12 KPa. For example, in Figure 28, the end pressure recorded at 5 minutes was 10.62 KPa.

The 1-way ANOVA test was significant ($P<.001$). Both Dunnett's T3 and Tukey B post hoc tests showed that the difference of the means was significant at the .05 level for all mean pairs ($P\leq.045$).'

5.4 Discussion

'The results indicate that the Null Hypothesis should be rejected. In rejecting the Null Hypothesis that the seating velocity has no effect on pressure produced, the alternative hypothesis that velocity affects pressure is favoured. The results concur with a hypothesis that an increase in pressure occurs when the velocity of compression is increased.

The previous in-vitro studies of impression pressure (Frank 1969, Masri 2002, Komiyama et al 2004, Al Ahmad 2006) all used oral analogues to simulate clinical conditions; by doing so, the investigators introduced many confounding variables. It is probable that the introduction of variables resulted in the contradictory findings found between the studies. An obvious example of a contradiction would be the difference in effect of impression tray perforations on pressure between studies by Masri et al (Masri 2002) and Komiyama et al et al (Komiyama et al 2004). It is probable that these different results occurred because the perforations in the two experiments were different. The results are most likely explained by the different position of the holes relative to the sensor, together with the different number and size of the holes. Further experimentation is required to confirm this explanation. It is more speculative to attempt to identify the confounding variables that explain some of the other contradictions. For example, Masri et al (Masri 2002) found that with unperforated, close-fitting impression trays and light-bodied vinyl polysiloxane, palatal pressure was lower than ridge pressure; with a similar material and conditions, Komiyama et al et al (Komiyama et al 2004) reported contradictory results. The fundamental laws of fluid mechanics have not changed, so the explanation of such contradictions lies in the introduction of uncontrolled, unknown variables. Perhaps this particular contradiction is explained by post dam venting in the analogue used by Masri et al (Masri 2002), but again, further experimentation would be required to confirm this speculative explanation. Uncontrolled and unknown variables are introduced when attempting, and perhaps failing, to simulate the oral environment. The experimental design of the current study took a different approach. The authors have eliminated known variables to allow a single issue to be addressed, the velocity of approximation. The factors of uncontrolled topography, of variable of border moulding of the impression tray (to develop border and facial seal), ‘lifelike’ compressible silicone casts, perforations of variable size, position, or number, variable space, and different impression materials were eliminated. By eliminating these variables, the study was able to draw a single conclusion. Further study is needed to understand the effect of each of these variables on the pressure produced during impressions with different velocities.

It was known from the preliminary studies that the peak pressure occurred at the last moment of approximation. The current study was designed so that the time that approximation ended was the same in all the groups. By setting the same finish

time for all the groups, the investigators ensured that the material in all groups was at a similar point in the polymerization reaction, and, therefore, a similar viscosity, at the final moment of seating. This allows for a true comparison of the effect of velocity on peak pressure without the complicating variable of degree of polymerization (viscosity). In order to end approximation at the same time, seating was started at different times for the different groups. Further research is required to investigate the effect of delays in seating on the pressure within impressions. In the current study, the end pressure dropped to a range within 3-12 KPa. End pressures reported in the literature range from approximately 0.1 KPa, as taken from Frank's graph (Frank 1969), to 517 KPa (Al-Ahmad et al 2006). This variation in end pressures in the previous studies is not unexpected; it reflects the variations in different models and equipment used. Impression material flows if the pressure is sufficient to overcome the resistance. It stops flowing when the pressure is insufficient to overcome the resistance. The reported end pressures are the residual pressures at which the impression material stops flowing. If the oral analogues used in the previous studies had a high resistance to flow, then the end pressure was high, and vice versa. It would seem likely that uncontrolled variables within the previous studies caused variations in the resistance to flow and, therefore, variations in the recorded end pressures. For example, it is possible to speculate that the dry, hydrophobic vinyl polysiloxane models used in some previous studies (Masri 2002, Komiyama et al 2004, and Al-Ahmad et al 2006) have a high resistance to flow of the impression material. Further studies are needed to confirm this explanation.

The work of Kydd et al (Kydd 1967, 1969, 1971, 1974, 1976, 1982) elucidates the viscoelastic nature of oral mucosa. It is clear that once distorted by pressure, the mucosa takes time to recover; this is especially true for older patients (Kydd 1974). The recovery time for the mucosa is longer than the time it takes to complete an impression (Kydd 1974). The mucosa is unlikely to recover before the impression is removed. This implies that peak pressure is the most relevant, definitive measure to determine how 'mucostatic' an impression is. The end pressures found with oral analogues (or between brass plates) are unlikely to be as relevant clinically. Peak pressure was the selected outcome measure for this study. The peak pressure recorded in these experiments was of short duration. It is worth noting that the high sample rate of the equipment used in this study (67 Hz) enabled accurate capture of this peak pressure. Previous studies used lower sample rates. Masri et al (Masri

2002) sampled the pressure every 10 seconds. If a similar sample rate of once every 10 seconds had been used for this experiment, the peak pressure would have been missed. Even the 15Hz sample rate used by Komiyama et al et al (Komiyama et al 2004) would have been likely to result in a lower recorded peak pressure (with a higher variance) if used for the current study.

An intriguing aspect of Frank's study (Frank 1969) was the brief section on the measurement of pressure during the manual seating of the impression. Various colleagues were asked to seat impressions. Some of those colleagues managed to seat the impressions at a consistent pressure when using materials of different viscosities and in different types of impression trays. This suggests that individual operator technique may be important. In view of the results presented in this article, it is suggested that the colleagues mentioned in Frank's study (Frank 1969) produced consistent pressure by possibly varying the velocity of seating.

This study has limitations; most notably, it was an in-vitro study and only one impression material was evaluated. However, many of the variables which are introduced with intraoral impressions were absent. The in-vivo peak pressures may be higher or lower than those produced here. Further research is required to investigate this issue. The study design did not use a formal power analysis, and with hindsight, this is regretted. The preliminary study indicated a low variance, and the results of this study demonstrate a significant result. The estimation of the sample size that was used was sufficient for this experiment; however, a formal power analysis should have been performed.

It is intuitive for a clinician to assume that slower seating of an impression material produces less pressure. This study demonstrates the truth of that clinical assumption. In view of these findings, clinicians should consider and adjust the velocity at which the impression is seated in order to control the overall pressure of a particular impression technique. The results from this study may provide clinical insight for dentists. It is important that the velocity of seating is controlled. If the pressures produced by seating at 2mm/s are considered acceptable, then the guideline for dentists should be to seat to the depth required for the impression (which could be 10 mm) over an appropriate time (5 seconds). As a dentist becomes more experienced, encouragement to feel the resistance to seating at this standard velocity should be given to help develop the technique while controlling the overall

pressure as the impression is seated. Ultimately, the dentist may be able control the overall pressure by varying the velocity of approximation during impression seating.'

5.5 Conclusions

'Within the limitations of this in-vitro study, it was observed that varying the velocity of compression has a significant effect on the peak pressure produced in the impression material. A faster velocity of compression results in a significantly higher pressure.'

Please note that the quotation from the published paper ends at this point in the Thesis.

5.6 Further details of the statistical analysis

The details of the statistical exploration and analysis are given below these details were not published in the paper (Hyde 2008).

5.6.1 Raw data

At each velocity of approximation five individual experimental runs were performed. Each experimental run recorded the pressure via an analogue sensor with digital sampling of the pressure 67 times a second for 5 minutes. The individual experiments produced data for 5 minutes and peak pressure was recorded. The table below lists the individual readings recorded for the different velocities of approximation. These are the peak pressure data recorded from each of the experiments. Each result listed in the table is one datum point (the peak) taken from 5 minutes of recording the data of the pressure at 67Hz. A sample of the raw data from an individual experimental runs is printed out from the excel file and presented in Appendix 2. This is a sample of 100 data points that include the peak pressure of that experiment and a graph of the pressure variation. This is the data from which the typical graph (Figure 29 above) is taken.

The peak pressure from each experiment was recorded and is presented in Table 20.

Velocity	Peak pressure in kilopascals (rounded)	Velocity	Peak pressure in kilopascals (rounded)
45	241	120	486
45	247	120	490
45	239	120	502
45	229	120	501
45	242	120	458
60	258	150	550
60	262	150	532
60	282	150	574
60	273	150	521
60	295	150	558
75	345	180	602
75	340	180	629
75	355	180	581
75	363	180	662
75	333	180	646
90	390		
90	439		
90	433		
90	432		
90	429		

Table 20 Raw data

5.6.2 Data exploration

The data was explored using SPSS. The descriptive statistics are summarized in Table 21.

5.6.2.1 Descriptives

Pressure in kilopascals

	N	Mean	Std. Dev	Std. Error	95% Confidence Interval for Mean		Mini	Maxi
					Lower Bound	Upper Bound		
.75	5	239.60	6.618	2.960	231.38	247.82	229	247
1.00	5	274.00	15.050	6.731	255.31	292.69	258	295
1.25	5	347.20	11.925	5.333	332.39	362.01	333	363
1.50	5	424.60	19.680	8.801	400.16	449.04	390	439
2.00	5	487.40	17.827	7.972	465.26	509.54	458	502
2.50	5	547.00	20.976	9.381	520.95	573.05	521	574
3.00	5	624.00	32.734	14.639	583.36	664.64	581	662
Total	35	420.54	134.804	22.786	374.24	466.85	229	662

Table 21 Descriptives

In the Table 21 above the Confidence Intervals for the means of each velocity can be seen. There is no overlap seen between the 95% C.I.'s of the means for each group.

5.6.2.2 Shapiro-Wilk

The result of Shapiro-Wilk tests of normality for each velocity group is shown in Table 22. All the velocity groups showed no significant difference from a normal distribution except the velocity group 1.5mm/sec. It is not known why the experiment at velocity 1.5mm/sec produced a non-normal distribution; but it was speculated that perhaps it is a combination of the small sample size with the outlier shown in the box plot (Figure 31 below). The Shapiro-Wilk test of normality was repeated without the outlier and the results are shown below in Table 23.

		Shapiro-Wilk		
	Velocity in mm/sec	**Statistic**	**df**	**Sig.**
Pressure in KPa	.75	.919	5	.522
	1.00	.955	5	.775
	1.25	.976	5	.911
	1.50	.726	5	.017
	2.00	.850	5	.193
	2.50	.979	5	.927
	3.00	.969	5	.871

Table 22 Shapiro-Wilk tests of normality of distribution of each velocity group

	Shapiro-Wilk		
	Statistic	**df**	**Sig.**
Pressure KPa at 1.5mm/min eliminating outlier	.939	4	.650

Table 23 Shapiro-Wilk tests of normality of distribution for velocity 1.5mm/min eliminating the low outlier.

When the outlier is eliminated the data cannot be shown to have a significantly different distribution to that of a normal distribution.

5.6.2.3 Box and whisker plots

Box and whisker plots of the results are shown below. Figure 31

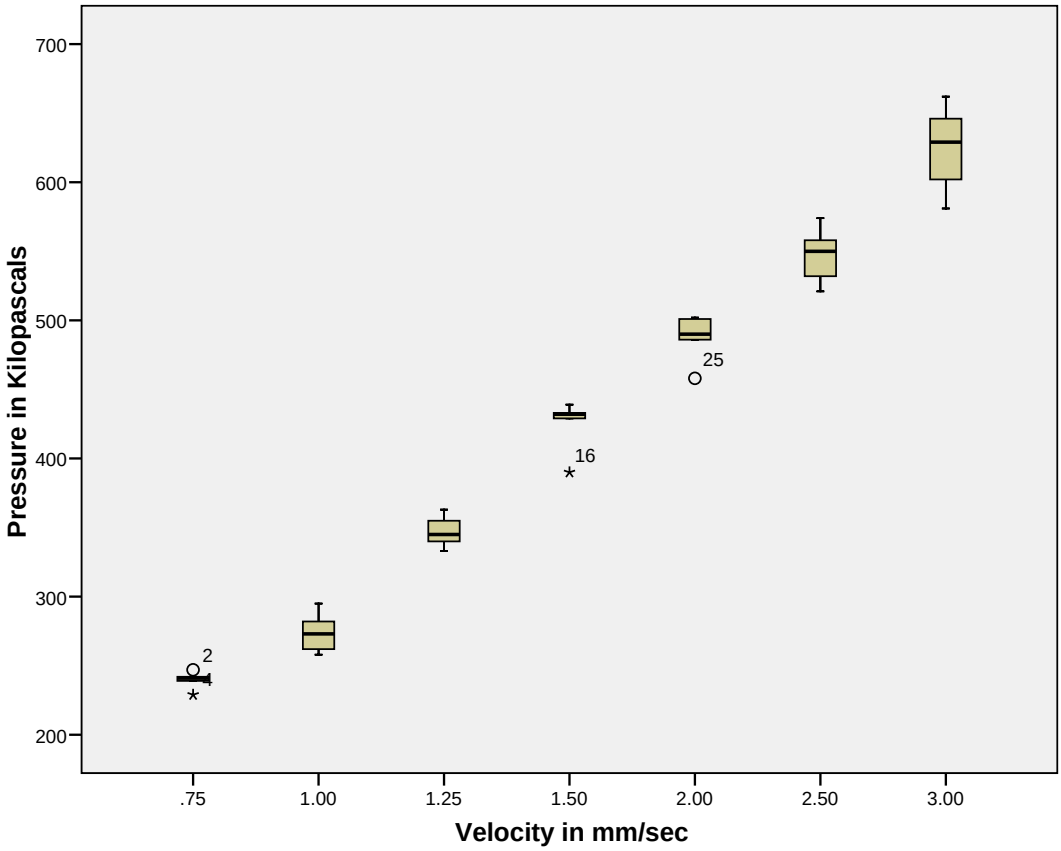


Figure 31 Box and Whisker plot of velocity versus pressure

Each box plot gives a summary that describes the data of the variable by plotting five numbers; the minimum of the range, the maximum, border of the lower quartile, the medium and the border of the upper quartile.

5.6.2.4 Levene test

Levene's test of equality of error variance, tests that the Null Hypothesis that the error variance of the dependent variable is equal across groups and is shown in Table 24

Levene Statistic	df1	df2	Sig.
2.186	6	28	.075

Table 24 Levene test statistic, pressure in kilopascals

The significance of the Levene statistic was above the usual 0.05 threshold. The Null Hypothesis was not disproved and this prerequisite for an ANOVA analysis fulfilled. However, for post hoc analysis it was decided, for prudence sake, to use two types of post hoc tests, one (Bonferroni) which relied on homogeneity of variance and corrects for multiple comparisons and one (Dunnett T3) which did not rely on the homogeneity of variance.

5.6.3 Analysis

5.6.3.1 ANOVA

Pressure in kilopascals

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	607334.29	6	101222.381	269.505	.000
Within Groups	10516.40	28	375.586		
Total	617850.69	34			

Table 25 ANOVA results

The overall ANOVA analysis shows a significant difference between the groups ($F=269.5$, $p<0.001$)

5.6.3.2 Post hoc

Post hoc Analysis showed significant differences between all the groups with both Bonferroni and Dunnett T3 test. Please note that SPSS produces post hoc tables

with each comparison produced twice once as A compared to B and then B compared to A; for the sake of space the duplicated results have been removed throughout this thesis.

5.6.3.2.1 Bonferroni correction at the 0.05 level

(I) Velocity in mm/sec	(J) Velocity in mm/sec	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Upper Bound	Lower Bound
.75	1.00	-34.400	12.257	.189	-75.34	6.54
	1.25	-107.600(*)	12.257	.000	-148.54	-66.66
	1.50	-185.000(*)	12.257	.000	-225.94	-144.06
	2.00	-247.800(*)	12.257	.000	-288.74	-206.86
	2.50	-307.400(*)	12.257	.000	-348.34	-266.46
	3.00	-384.400(*)	12.257	.000	-425.34	-343.46
1.00	1.25	-73.200(*)	12.257	.000	-114.14	-32.26
	1.50	-150.600(*)	12.257	.000	-191.54	-109.66
	2.00	-213.400(*)	12.257	.000	-254.34	-172.46
	2.50	-273.000(*)	12.257	.000	-313.94	-232.06
	3.00	-350.000(*)	12.257	.000	-390.94	-309.06
1.25	1.50	-77.400(*)	12.257	.000	-118.34	-36.46
	2.00	-140.200(*)	12.257	.000	-181.14	-99.26
	2.50	-199.800(*)	12.257	.000	-240.74	-158.86
	3.00	-276.800(*)	12.257	.000	-317.74	-235.86
1.50	2.00	-62.800(*)	12.257	.000	-103.74	-21.86
	2.50	-122.400(*)	12.257	.000	-163.34	-81.46
	3.00	-199.400(*)	12.257	.000	-240.34	-158.46
2.00	2.50	-59.600(*)	12.257	.001	-100.54	-18.66
	3.00	-136.600(*)	12.257	.000	-177.54	-95.66
2.50	3.00	-77.000(*)	12.257	.000	-117.94	-36.06

Table 26 Bonferroni post hoc tests: * the mean difference is significant with the Bonferroni correction at the .05 level.

5.6.3.2.2 Dunnett T3

(I) Velocity in mm/sec	(J) Velocity in mm/sec	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Upper Bound	Lower Bound
.75	1.00	-34.400(*)	7.353	.049	-68.64	-.16
	1.25	-107.600(*)	6.099	.000	-134.58	-80.62
	1.50	-185.000(*)	9.285	.000	-230.52	-139.48
	2.00	-247.800(*)	8.504	.000	-288.77	-206.83
	2.50	-307.400(*)	9.837	.000	-356.13	-258.67
	3.00	-384.400(*)	14.935	.000	-462.30	-306.50
1.00	1.25	-73.200(*)	8.587	.001	-108.76	-37.64
	1.50	-150.600(*)	11.080	.000	-196.70	-104.50
	2.00	-213.400(*)	10.434	.000	-256.31	-170.49
	2.50	-273.000(*)	11.546	.000	-321.52	-224.48
	3.00	-350.000(*)	16.112	.000	-424.31	-275.69
1.25	1.50	-77.400(*)	10.291	.003	-122.07	-32.73
	2.00	-140.200(*)	9.592	.000	-181.02	-99.38
	2.50	-199.800(*)	10.791	.000	-247.29	-152.31
	3.00	-276.800(*)	15.580	.000	-352.12	-201.48
1.50	2.00	-62.800(*)	11.875	.012	-111.38	-14.22
	2.50	-122.400(*)	12.863	.000	-174.93	-69.87
	3.00	-199.400(*)	17.081	.000	-273.67	-125.13
2.00	2.50	-59.600(*)	12.311	.020	-110.20	-9.00
	3.00	-136.600(*)	16.669	.002	-210.65	-62.55
2.50	3.00	-77.000(*)	17.387	.043	-151.61	-2.39

Table 27 Dunnett's T3 post hoc tests; * the mean difference is significant at the 0.05 level (continued from previous page)

5.7 Retrospective review of the potentially confounding variable of the weight of silicone used

The previous chapter investigated the effect of weight on impression pressure and for those experiments where the silicone overflowed the edge of the brass discs, were unable to show a significant correlation between weight and pressure. The experiment in this chapter above ensured that there was sufficient silicone dispensed to overflow the brass disc. The assumption was made that the weight of the silicone would not affect pressure. The published paper from the work of chapter 5 made no further analysis of the weight.

However the weight of silicone was actually recorded for this experiment. Retrospective analysis of the affect of weight was therefore possible via factorial ANOVA; it would seem sensible to return and retrospectively check the effect of weight in a live experiment. After the use of ANOVA with a factorial treatment structure became familiar to the writer (factorial ANOVA was first used later in chapters 12-15 below) it was decided to re-analyse the data to reinvestigate the effect of weight within this velocity experiment. The Null Hypothesis was that weight had no effect on the pressure. The alternative hypothesis was that weight affected pressure.

5.7.1 Raw data

The variable of weight was divided into two groups; those values above the median and those values at the median or below.

5.7.2 Normality test

The histogram (Figure 32 below) shows the frequency distribution of the weight of silicone used with a superimposed normal distribution curve. The histogram is suggestive of an overall normal distribution of the weight of silicone.

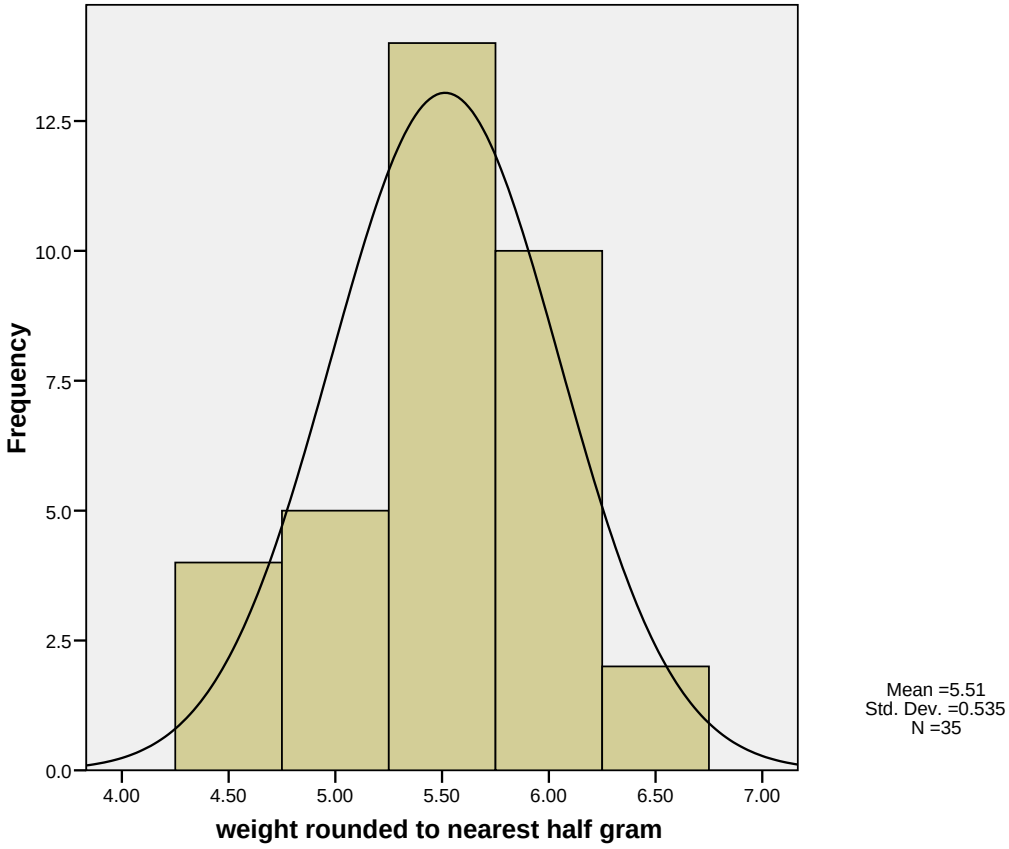


Figure 32 Plot of frequency versus weight categories (SPSS legacy histogram)

Shapiro-Wilk test of normality was unable to show a difference from normal for the distribution of weight (Table 28 below).

	Shapiro-Wilk		
	Statistic	**df**	**Sig.**
Weight in Grams	.965	35	.320

Table 28 Shapiro-Wilk test of normality for the distribution of weight.

5.7.3 Analysis with factorial ANOVA

The results of the Factorial ANOVA analysis of the significance of the independent variables of Velocity and Weight are given in Table 29 below.

Source	Type III Sum of Squares	Df	Mean Square	F	Sig.	Obs Power (a)
Corrected Model	608869.44(b)	10	60886.94	162.704	.000	1.000
Intercept	5729254.80	1	5729254.79	15309.908	.000	1.000
Velocity	528089.88	6	88014.98	235.197	.000	1.000
Weight	530.05	1	530.05	1.416	.246	.208
Velocity * Weight	1011.51	3	337.17	.901	.455	.217
Error	8981.25	24	374.22			
Total	6807821.00	35				
Corrected Total	617850.69	34				

Table 29 Factorial ANOVA, Dependent Variable: Pressure in kilopascals, ‘a’
Computed using alpha = .05

These results indicate that the overall model is statistically significant ($F = 162.704$, $p < 0.001$). The main effects of velocity is statistically significant ($F = 235.197$, $p < 0.001$). These results show the different velocities produce significantly different pressures when ignoring the weight of the silicone used.

The variable weight and the interaction between velocity and weight cannot be shown to be significant ($F = 1.416$, $p = 0.246$ and $F = 0.901$, $p = 0.455$ respectively). The different values of weight cannot be shown to affect pressure; furthermore, the interaction between velocity and weight cannot be shown to be significant so that, within each velocity groupings, the weight used cannot be shown to have a significant effect on pressure. The lack of interaction also shows that the effect of velocity does not depend on weight.

5.7.4 Conclusions for retrospective review of the potential confounding variable of weight

The Null Hypothesis was that weight makes no difference to the pressure of impression. The Null Hypothesis cannot be shown to be untrue by this experiment. This confirms the findings of Chapter 4. Weight of silicone cannot be shown to be significant when the silicone overflows the edge of the brass discs.

This retrospective confirmation is reassuring; weight cannot be shown to affect pressure in this experiment. For the remainder of the experiments in Part II of this Thesis the silicone overflowed the edge of the brass discs and the weight of silicone was not considered as a confounding variable.

5.8 The next experiment

The paper (Hyde 2008) raised questions about other variables involved in the pressure of impressions. Among these was the time delay after mixing of the impression material which in turn is related to the viscosity of the material. As the paper (Hyde 2008) says, 'the experiment was carefully designed so that the time that approximation ended was the same in all the groups. All the groups finished seating at 30 seconds. By ensuring that the groups finished at the same time we ensured that they were at the same point of set and so the same viscosity. This allows a true comparison of speed on peak pressure without the complicating variable of degree of set (viscosity).'

In order to end approximation at the same time, seating was started at different times for the different groups. A separate experiment was now required to investigate the effect of delays in seating on the pressure within impressions.

Chapter 6
Delay

6.1 Introduction

The protocol for the laboratory experiments that was discussed and developed in Chapters 1-4 above, became established in the work related in Chapter 5, and could be adapted and applied to investigate other variables involved in the pressure generated within prosthodontic impressions. The next variable to be investigated was the effect of delay in seating the prosthodontic impression.

6.2 Background

The setting reaction of an impression material means that a delay in seating an impression may be expected to increase the viscosity of the impression material. An increase in the viscosity of the impression material is expected to cause an increase in the force required to seat that impression. Most manufacturers give a working time for impression materials. At the end of the working time, it is expected that the impression material will be viscous and unusable. Advice is given by manufacturers that an impression should not be seated after the working time has been exceeded. This experiment quantifies the change in pressure when there is a delay in seating an impression material both within and immediately after the working time.

6.3 Aim

The aim of this study is to assess the relationship between pressure and the timing of the seating of the impression. A search of the available literature has not revealed published data on the effect of delays on the pressure within impressions. The Null Hypothesis was that a delay in seating did not affect the pressure of impression.

6.4 Materials and method

Impression material was placed between two discs (Figures 34 & 35 below) on a Universal testing Machine. The arrangement of the discs was similar to the set up for the velocity experiment (Chapter 5). At the centre of the upper disc, a 2mm diameter hole led to an analogue pressure transducer (PXM209-010G10V; Omega Engineering, Inc, Stamford, Conn). The pressure transducer was directly connected to the brass disc via a one-quarter-inch British Standard Pipe (BSP) screw-thread sealed with plumber's tape. The connection to the pressure transducer was filled with water.

The discs were 15 mm apart at the start of the experiment and were set to approximate at 2mm/sec. It would take 7.5 seconds to approximate the discs. The seven groups had delay times of 15secs, 30secs, 45secs, 60secs, 75secs, 90secs, and 105secs. The peak pressure within the impression was recorded. At each timed delay, five individual experiments were performed.

Figure 33 The disc used for the 'delay' impressions with the pressure sensor attached.

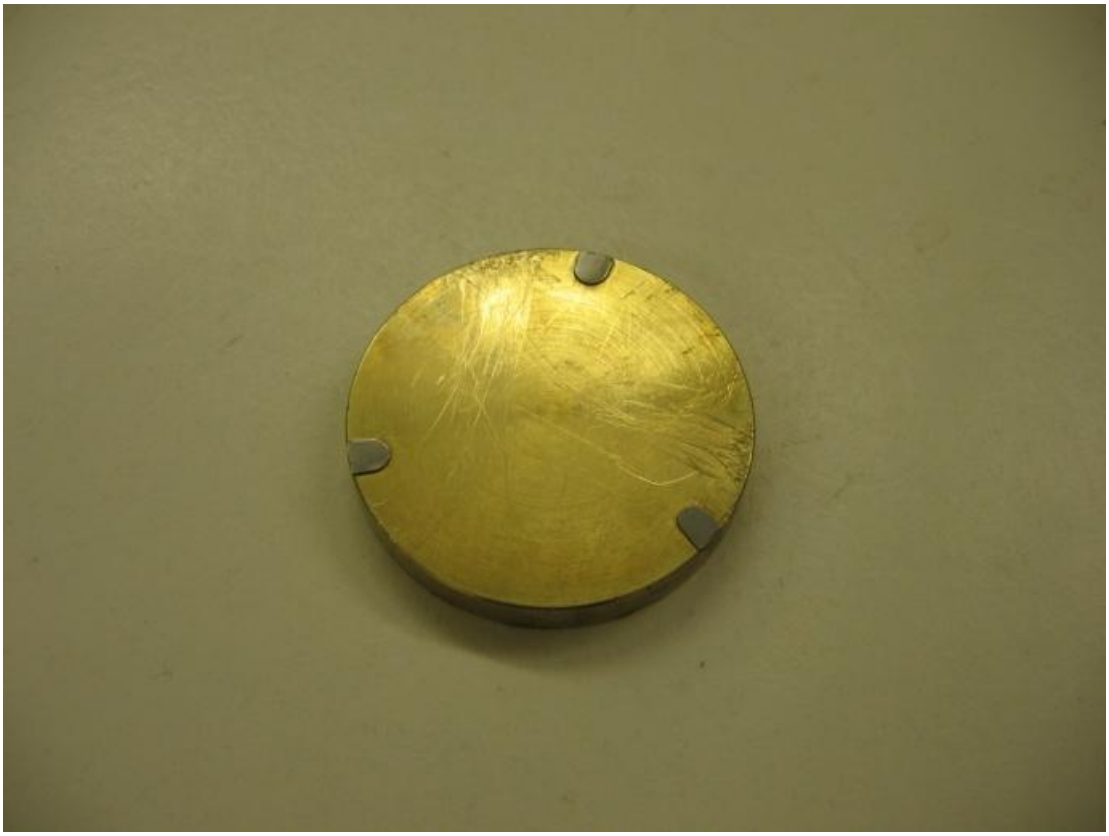


Figure 34 The ‘impression tray’ for the ‘delay’ experiment, note the steel spacers.

6.5 Detail of statistical analysis

6.5.1 Raw data

Each experimental run recorded the pressure via an analogue sensor with digital sampling of the pressure 67 times a second for five minutes. The individual experiments recorded data for five minutes; the peak datum pressure points were used for analysis. The peak pressure from each experiment was recorded and is presented in Table 30.

Delay Seconds	Pressure Kilopascals		Delay Seconds	Pressure Kilopascals
15	507		60	601
15	504		60	633
15	499		60	591
15	496		60	634
15	490		60	592
30	514		75	663
30	521		75	674
30	522		75	661
30	528		75	651
30	514		75	660
45	561		90	700
45	565		90	714
45	563		90	720
45	561		90	761
45	572		90	801
			105	926
			105	934
			105	1250*
			105	1750*

Table 30 Raw data; * Data is outside the calibrated range of the sensor

The recording at 105 seconds delay exceeded the calibrated range (and the safe operating range) of pressure for the transducer. The viscosity of the silicone increases as it sets. The experiment was stopped after three runs due to concerns

over possible damage to the sensor (again). The 105 second delay group was not included in the analysis. A graph of all the recorded data including the 105 second delay results is shown below (Figure 35). It demonstrates the increasing pressure (and the trend of increasing variance of the groups).

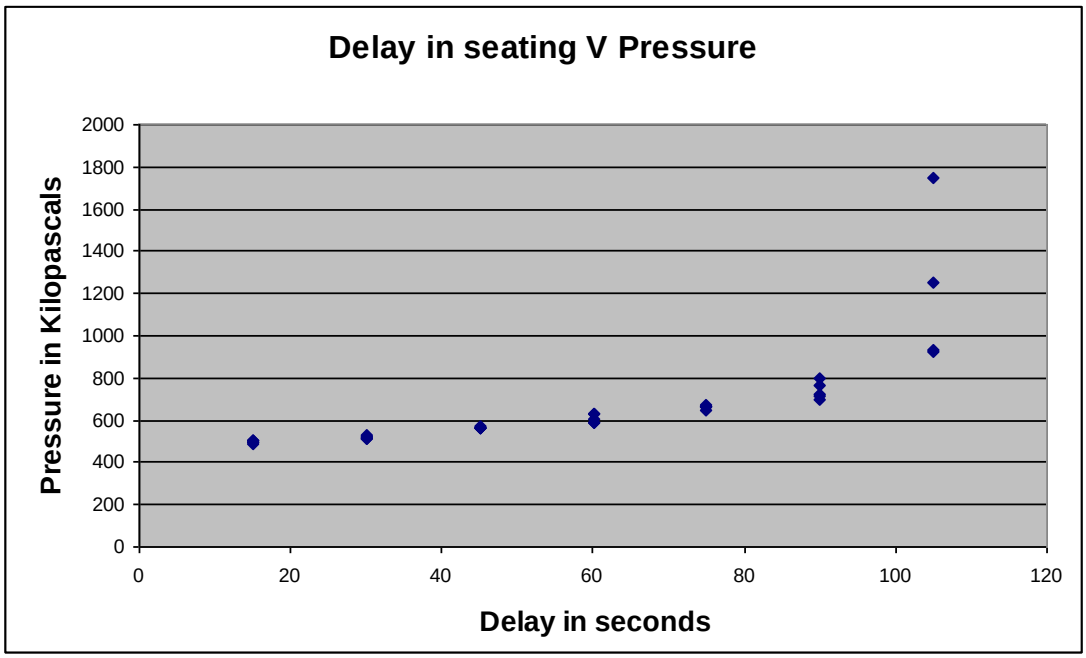


Figure 35 All the results from the 'delay' experiment; delay versus pressure

The choice of method for the statistical analysis was determined first by the exploration of the data; specifically by a test of normality (Shapiro-Wilks) followed by the Levene test of homogeneity of the error variance of the dependant; ANOVA and Bonferroni were planned if there was homogeneity, Kruskal Wallis and Dunnett T3 if not.

6.5.2 Data exploration

The data was explored using SPSS. The descriptive statistics, Box plots, Shapiro-Wilk and Levene tests are summarized below.

6.5.2.1 Descriptives

Delay secs	N	Mean	Std. Dev	Std. Error	95% Confidence Interval for Mean		Mini	Max
					Upper Bound	Lower Bound		
15	5	499.20	6.686	2.990	490.90	507.50	490	507
30	5	519.80	5.933	2.653	512.43	527.17	514	528
45	5	564.40	4.561	2.040	558.74	570.06	561	572
60	5	610.20	21.626	9.672	583.35	637.05	591	634
75	5	661.80	8.228	3.680	651.58	672.02	651	674
90	5	739.20	41.336	18.486	687.87	790.53	700	801
Total	30	599.10	86.134	15.726	566.94	631.26	490	801

Table 31 Descriptives

6.5.2.2 Shapiro-Wilk

The result of Shapiro-Wilk tests of normality for each velocity group is shown in Table 32.

	Delay from start of mixing	Shapiro-Wilk		
		Statistic	df	Sig.
Pressure in kilopascals	15.00	.979	5	.929
	30.00	.897	5	.391
	45.00	.823	5	.124
	60.00	.791	5	.069
	75.00	.947	5	.713
	90.00	.901	5	.415

Table 32 Shapiro-Wilk tests of normality of distribution of each group

The Shapiro-Wilk test for each group was unable to demonstrate a deviation from normality at the 0.05 level. Normality of variances for each group could therefore be assumed; this fulfils one criterion for the use of ANOVA as an appropriate test to compare the means of the groups. The other prerequisite for ANOVA is an equality of dependant variance across the groups, for this the variance shown visually by the Box and Whisker plot together with Levene's statistical test was used.

6.5.2.3 Box and whisker plots

Box and whisker plots of the results are shown below (Figure 36).

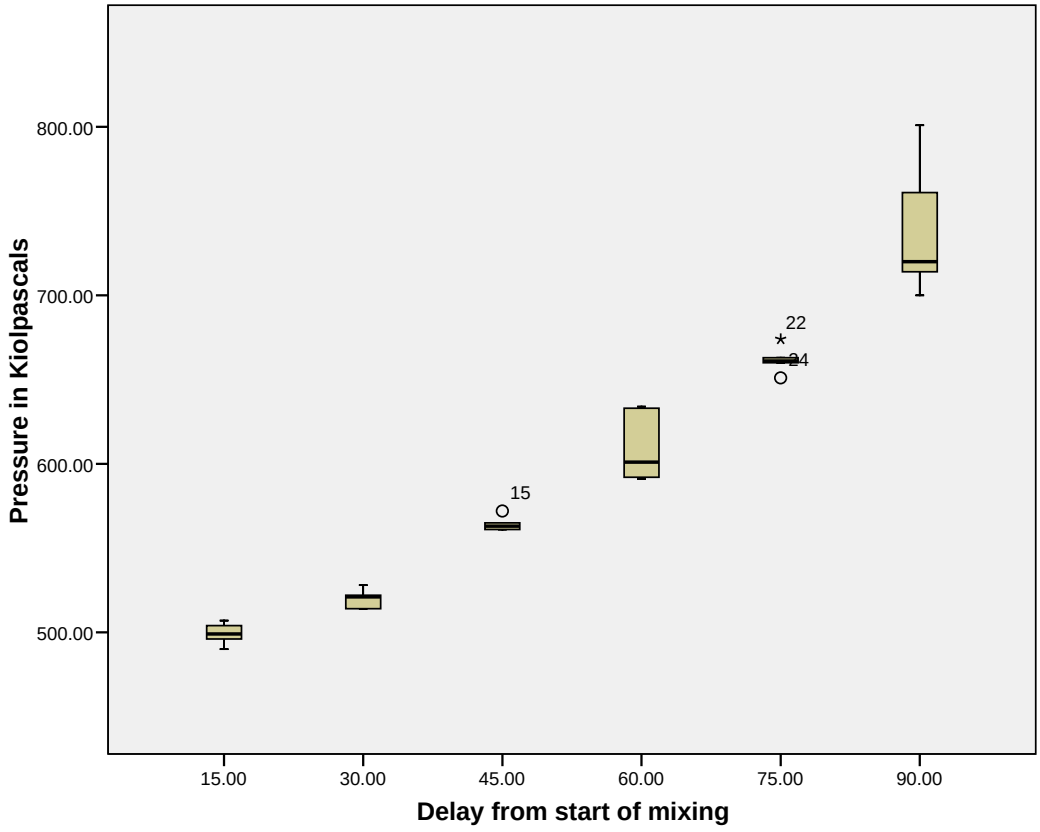


Figure 36 Box and whisker plot of each group for the delay in seating

The two groups at 60 and 90 appear to have a greater variance than the other groups. This required further analysis with Levene's test of equality of error variance.

6.5.2.4 Levene test

Levene's test of equality of error variance, tests that the Null Hypothesis that the error variance of the dependent variable is equal across groups; it is shown in Table 33.

Levene Statistic	df1	df2	Sig.
10.765	5	24	.000016

Table 33 Levene test, pressure in kilopascals

The Homogeneity of variances of the groups is not shown; therefore the overall assessment of the statistics was performed with a non-parametric, Kruskal Wallis test and the post hoc tests used the robust Dunnett T3 analysis, both of which do not require or assume equivalence of variance.

6.5.3. Analysis

6.5.3.1 Kruskal Wallis test

	Pressure in Kilopascals
Chi-Square	28.238
Df	5
Asymp. Sig.	.000033

Table 34 Kruskal Wallis test, grouping variable: delay from start of mixing

The overall significance of the Kruskal Wallis non parametric test gives a p value of less 0.0001. There is a significant difference in the pressure outcome within the data from the different delay times in the experiment. Further analysis with the robust post hoc Dunnett's T3 was performed to investigate where the differences lay.

6.5.3.2 Post hoc

Post hoc analysis showed significant differences between all the groups with Dunnett T3 tests, except between the 45 & 60 second delay groups and the 75 & 90 second delay groups (see Table 35 below).

(I) Delay from start of mixing	(J) Delay from start of mixing	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence	
					Upper Bound	Lower Bound
15	30	-20.600(*)	3.997	.011	-36.22	-4.98
	45	-65.200(*)	3.619	.000	-79.82	-50.58
	60	-111.000(*)	10.123	.001	-158.76	-63.24
	75	-162.600(*)	4.741	.000	-181.27	-143.93
	90	-240.000(*)	18.726	.001	-334.04	-145.96
30	45	-44.600(*)	3.347	.000	-57.87	-31.33
	60	-90.400(*)	10.029	.004	-138.51	-42.29
	75	-142.000(*)	4.537	.000	-160.15	-123.85
	90	-219.400(*)	18.676	.002	-313.73	-125.07
45	60	-45.800	9.884	.062	-94.54	2.94
	75	-97.400(*)	4.207	.000	-115.12	-79.68
	90	-174.800(*)	18.598	.005	-269.59	-80.01
60	75	-51.600(*)	10.348	.035	-98.75	-4.45
	90	-129.000(*)	20.863	.008	-217.99	-40.01
75	90	-77.400	18.849	.096	-170.79	15.99

Table 35 Post hoc with Dunnett's T3; * denotes significance, with the Dunnett T3 test at $p < 0.05$.

6.6 Summary of results

The mean pressures for each group were 499KPa, 520KPa, 564KPa, 610KPa, 662KPa, 739KPa, and 1215KPa. The Kruskal Wallis test was significant ($P<0.001$) with all individual results showing significant difference with the post hoc Dunnett T3 correction ($p<0.05$), except between the 45 & 60 second delay groups and the 75 & 90 second delay groups.

6.7 Discussion

The Kruskal Wallis test (6.5.3.1 above) demonstrated a significant difference ($p<0.0001$). The Null Hypothesis is rejected; in rejected the Null Hypothesis, the alternative hypothesis is proposed that the delay in seating the impression affected the pressure of impression.

The high variability of the pressure after a delay of 105 seconds is presumed to be due to the final 'snap' set of the material. The working time designated by the manufacturers (30 seconds) appears to be adequate; but it must be remembered that this experiment was conducted in-vitro at a specific, environmentally controlled, room temperature of 21^0c.

The ranges of values for the indirect variables in the previous chapter and this (velocity and delay) were chosen to represent the extremes of clinical possibility. The dependent variable was the same, the experimental conditions were similar but never reproduced (see chapter 11 below). Direct comparisons between the results in each chapter are therefore uncertain (also see the discussion at the end of chapters 10 & 11).

6.7.1 Comment on the comparison of similar data points obtained in the velocity study and the delay study

There is a reasonable correlation between the output of this study and the previous velocity study, but it is important to note that there is no experimental run which causes a repetition of recording pressure at exactly the same delay timing *and* velocity. The nearest correlation would be the datum points from the velocity study result of 2mm/second, with the delay results of 15 seconds or 30 seconds delay. The relevant figures are a mean of 499KPa for the delay of 15 seconds, and a mean of 520KPa for the delay of 30 seconds, compared with the velocity experiment result where the mean was 487.32KPa for the 2mm/second approximation.

6.8 Clinical implications

Taken together this study and the previous velocity study suggests that, if an impression is delayed after mixing, it should be seated even more slowly to produce an acceptable (lower) impression pressure; the clinical advice should be rush to get it there but seat it slowly.

The start of approximation in the 2mm/min velocity study was at 22.5 seconds (to ensure the final moment of seating was co-ordinated within the velocity study to happen at 30 seconds). It would be expected that the figure for 22.5 second delay would lie between the figure for the 15 second and 30 second delay. It is disappointing that the independent experiments do not have a directly comparable set of results. In later studies (looking at perforations) this apparent inconsistency is greater. This issue of an apparent inconsistency in the results is discussed in greater detail in Chapter 11 below.

Chapter 7
The position within an impression of the measurement of the pressure

7.1 Background

The dichotomy of opinion in the literature is epitomized by the following quotes:

Quote Komiyama et al (2004) : 'Within the limitations of this in-vitro study, it was found that initially, mid-palatal impression pressure using a tray with no spacer, a sheet wax spacer and no hole, or an escape hole 0.5 mm in diameter, was significantly higher ($P< 0.001$) than or similar to the pressure at the ridge crest.'

Quote Masri (2002): 'Pressures produced by light-body vinyl polysiloxane and polysulfide impression materials were always lower on the palate when compared to the pressure produced on the right and left ridges with a tray that had no holes and no relief.'

The ridge verse palate pressure was first discussed in the early paper by Stansbery (1925). His elegant demonstration of high pressure at the centre of approximated discs influenced future discussions over pressure distribution. This next experiment was a mere confirmation of his results, nearly 90 years later, with modern impression materials, digital equipment and statistical techniques.

7.2 Statement of problem

Many dentures are mucosa supported. Clinicians often aim to distribute occlusal pressure from these dentures as evenly as possible across the denture bearing area. In order to achieve this, they hope to have a uniform pressure across the working impression. The laws of fluid mechanics suggest that uniform pressure is unlikely to be achieved spontaneously.

The research question for this chapter is, 'if all confounding variables are removed or controlled, is the pressure of impression even across the width of the impression'. The Null Hypothesis is that it is not possible to detect a difference

across the impression. The alternative hypothesis is that it is possible to detect a difference in pressure across the impression.

7.3 Aim

The purpose of this study is to investigate the distribution of pressure across an impression.

7.4 Materials and method

Impression material was placed between two approximating discs on a Universal Testing Machine. The pressure within the impression was recorded at five evenly distributed points across the discs (Figure 37 below).

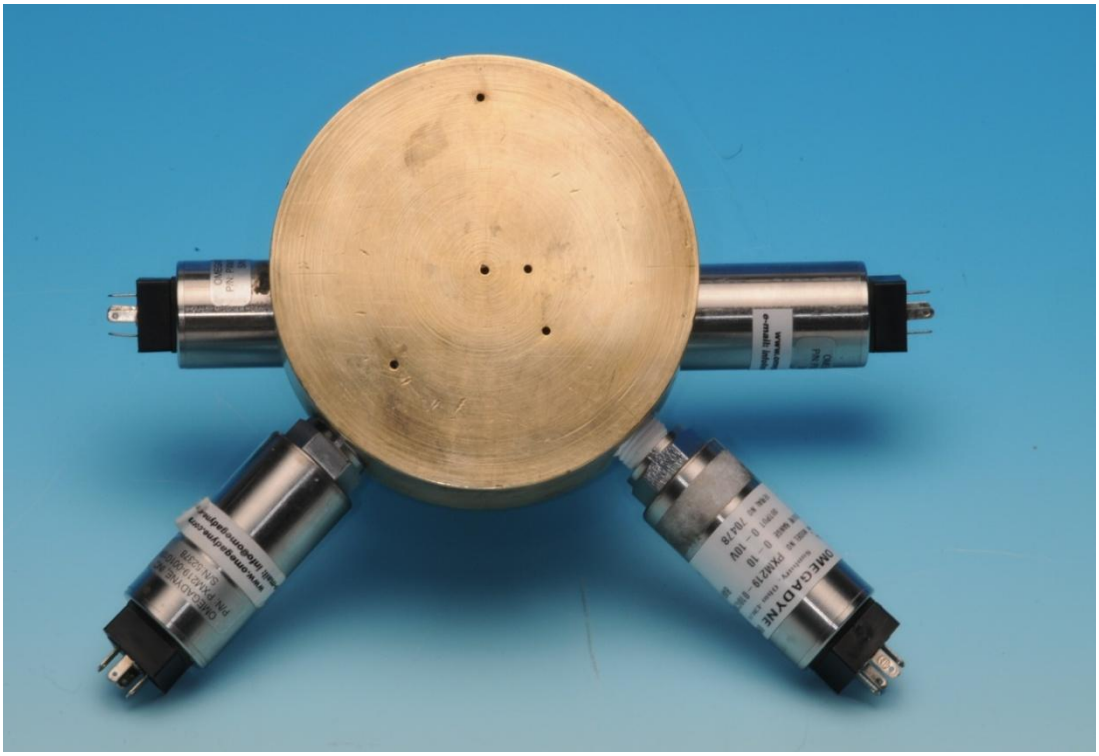


Figure 37 disc used for the experiment to investigate the position of the pressure sensor within the impression

Five separate recordings were made at each position. Statistical analysis was performed using SPSS.

7.5 Statistical analysis

7.5.1 Raw data

Distance from edge of disc in mm	Pressure KPa	Distance from edge of disc in mm	Pressure KPa
10	250	40	588
10	256	40	590
10	198	40	593
10	199	40	601
10	267	40	597
20	448	50	631
20	441	50	630
20	454	50	649
20	423	50	627
20	426	50	614
30	485		
30	496		
30	492		
30	492		
30	502		

Table 36 Raw data

7.5.2 Data exploration

7.5.2.1 Descriptives

Mm	N	Mean KPa	Std. Dev	Std. Error	95% Confidence Interval for Mean		Mini	Max
					Lower Bound	Upper Bound		
10	5	234.00	32.977	14.748	193.05	274.95	198	267
20	5	438.40	13.539	6.055	421.59	455.21	423	454
30	5	493.40	6.229	2.786	485.67	501.13	485	502
40	5	593.80	5.263	2.354	587.27	600.33	588	601
50	5	630.20	12.518	5.598	614.66	645.74	614	649
Total	25	477.96	143.695	28.739	418.65	537.27	198	649

Table 37 Descriptives

7.5.2.2 Shapiro-Wilk

No statistically significant difference from a normal distribution for any of the groups could be demonstrated by the Shapiro Wilks statistic at the 0.05 level.

	Distance from edge of disc	Shapiro-Wilks		
		Statistic	Df	Sig.
Pressure	10.00	.817	5	.111
	20.00	.916	5	.504
	30.00	.969	5	.870
	40.00	.963	5	.829
	50.00	.936	5	.641

Table 38 Shapiro-Wilk

7.5.2.3 Box plot

The box plots (Figure 38) suggest that the group 10mm from the edge of the disc has a higher range or spread than the other groups.

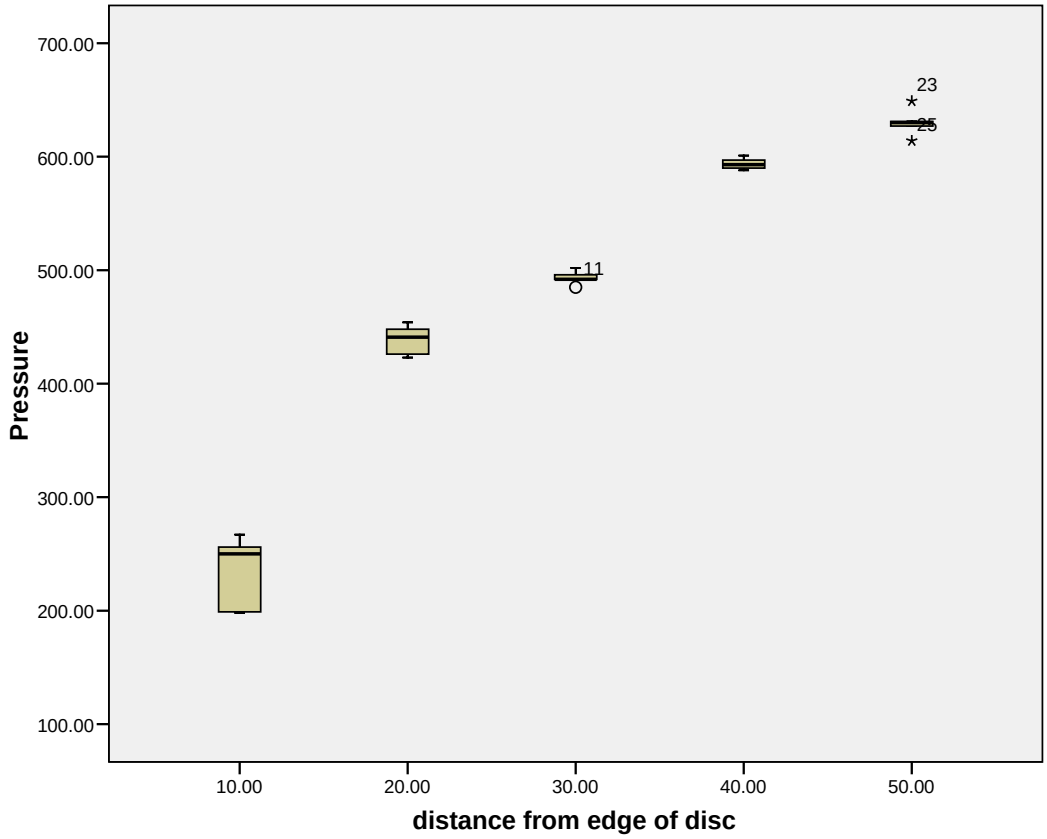


Figure 38 Box plot of results; distance from the edge of the disc against pressure.

7.5.2.4 Levene test

Levene Statistic	df1	df2	Sig.
12.094	4	20	.000

Table 39 The Levene test of Homogeneity of variances.

The Levene test of homogeneity of variances is shown above in Table 39. The Homogeneity of variances of the groups is not shown; therefore the overall assessment of the statistics was performed with a Non-Parametric Kruskal Wallis test and the post hoc tests used the robust Dunnett T3 analysis both of which do not require or assume equivalence of variance.

7.5.3 Data analysis

7.5.3.1 Kruskal Wallis

	Pressure
Chi-Square	23.086
Df	4
Asymp. Sig.	0.000122

Table 40 Kruskal Wallis test; grouping variable: distance from edge of disc

Kruskal Wallis analysis demonstrates a significant difference between the groups ($p<0.0001$). Further analysis was indicated to investigate precisely where the differences occurred.

7.5.3.2 Post hoc

Dunnett T3 test showed a significant mean difference between all groups at the 0.05 level, see Table 41 below.

(I) distance from edge of disc	(J) distance from edge of disc	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
10	20	-204.400(*)	15.942	.000	-271.39	-137.41
	30	-259.400(*)	15.009	.000	-329.07	-189.73
	40	-359.800(*)	14.935	.000	-429.82	-289.78
	50	-396.200(*)	15.775	.000	-463.46	-328.94
20	30	-55.000(*)	6.665	.002	-82.38	-27.62
	40	-155.400(*)	6.496	.000	-182.98	-127.82
	50	-191.800(*)	8.246	.000	-222.03	-161.57
30	40	-100.400(*)	3.647	.000	-113.85	-86.95
	50	-136.800(*)	6.253	.000	-162.07	-111.53
40	50	-36.400(*)	6.073	.010	-61.80	-11.00

Table 41 Dunnett T3 post hoc Analysis; *the mean difference is significant at the .05 level.

7.6 Summary of results.

The mean of the recorded pressures for each position was 231KPa, 438KPa, 493KPa, 594KPa, and 630KPa (see Figure 39 below). These results are, respectively, at 10mm, 20mm, 30mm, 40mm and 50mm from the periphery of the 100mm disc (the 50mm result is at the centre of the disc). These results show a significant difference at the 5% level of significance (with Kruskal Wallis and with all Dunnett T3 comparisons). The Null Hypothesis is rejected; in rejecting the Null Hypothesis, the alternative hypothesis is proposed that it is possible to detect a difference in pressure across the disc.

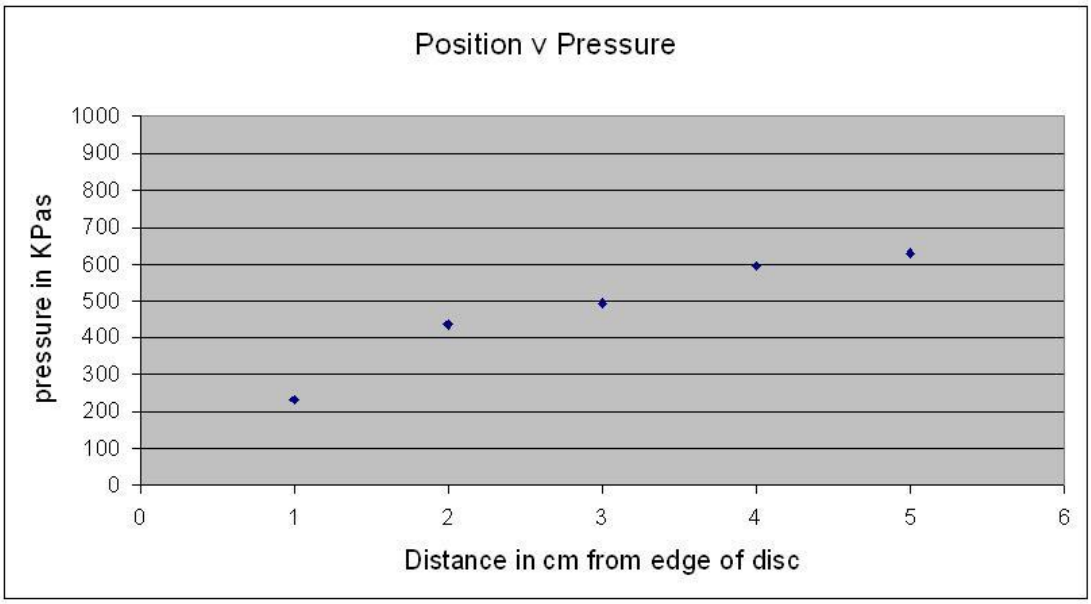


Figure 39 The mean of pressure recorded at each position

7.7 Conclusion.

If all other variables are equal, the tissues at the centre of an impression will endure a higher pressure than those at the periphery

7.8 Clinical implications.

This in-vitro study demonstrates a gradient in pressure from the centre of an impression towards the peripheral vent. This uneven loading may distort the mucosa and the distortion may be transferred via the cast into the shape of the fitting surface of the subsequent denture. Clinicians may wish to have a more even distribution of impression pressure in order to achieve a more even distribution of occlusal load under the denture.

7.9 Next experiment

To distribute pressure more evenly, one possible solution is the introduction of additional venting, in the form of perforations in the special tray. These perforations may change the impression pressure. Further experiments were required to determine the effect of perforations, including the effect of the different properties of those perforations.

Chapter 8
Perforation position

8.1 Background

The research literature differs on the importance of special tray perforations in reducing impression pressure. One in-vitro study (Komiyama et al 2004) reported that perforations in special trays reduce pressure, however another (Masri 2002) found that perforations in special trays have little effect on pressure. Tray perforations vary and it is likely that the variations in the tray perforations explain the difference between the results reported in the literature. Perforations have a number of variables and these include; the distance of a perforation to a pressure sensor, the size of a perforation and the total number of perforations. This study looks at the perforation position relative to the pressure sensor.

8.2 Objectives

The aim of the study is to investigate the pressure of an impression when a perforation in the 'tray' is at different, set distances. The Null Hypothesis is that the position of perforation does not affect the pressure of an impression. The Alternative Hypothesis is that the position of perforation affects the pressure of an impression.

8.3 Method

Vinyl polysiloxane impression material (express 3M) was placed between two approximating discs on a universal testing machine and the pressure generated at the centre of the upper disc was recorded (see Figure 40). The lower disc was perforated at the centre and at 3, 6, 9, 12, 15, 18, 21, & 24mm from the centre with 2mm perforations (see Figure 41). The perforations were sealed. Each perforation, in turn, was unsealed and the peak impression pressure as the discs were approximated was recorded for five approximations. Data was analyzed by ANOVA with post hoc multiple comparisons (Bonferroni) at the 0.05 level of significance.

Figure 40 The standard disc with sensor attached

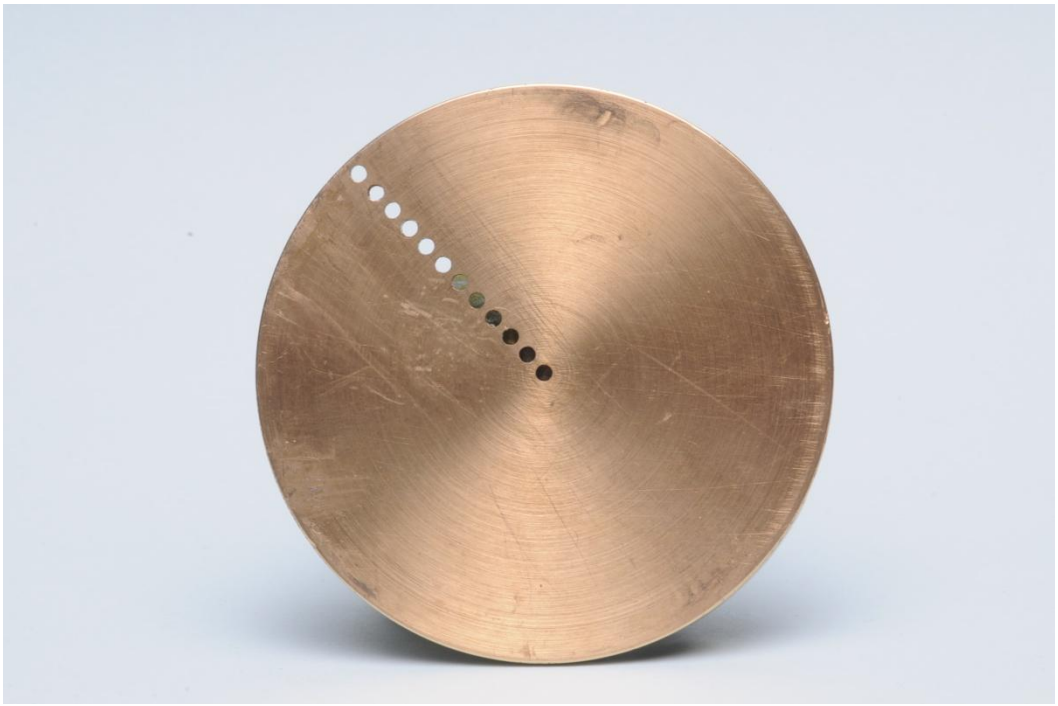


Figure 41 The ‘impression tray’ for the distance to a perforation experiment

8.4 Statistical analysis

8.4.1Raw data

Distance to a perforation mm	Pressure KPa	Distance to a perforation mm	Pressure KPa
0	67	15	320
0	75	15	326
0	72	15	311
0	86	15	306
0	85	15	318
3	166	18	340
3	182	18	348
3	186	18	341
3	185	18	334
3	164	18	340
6	224	21	372
6	213	21	365
6	207	21	348
6	225	21	356
6	206	21	346
9	255	24	385
9	259	24	395
9	247	24	378
9	255	24	366
9	268	24	370
12	304	none, 35mm to edge	381
12	294	none, 35mm to edge	420
12	279	none, 35mm to edge	353
12	290	none, 35mm to edge	380
12	282	none, 35mm to edge	357

Table 42 Raw data

8.4.2 Data exploration

8.4.2.1 Descriptives

mm to a perforation	N	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
0	5	77.00	8.276	3.701	66.72	87.28	67	86
3	5	176.60	10.714	4.792	163.30	189.90	164	186
6	5	215.00	9.083	4.062	203.72	226.28	206	225
9	5	256.80	7.629	3.412	247.33	266.27	247	268
12	5	289.80	9.960	4.454	277.43	302.17	279	304
15	5	316.20	7.823	3.499	306.49	325.91	306	326
18	5	340.60	4.980	2.227	334.42	346.78	334	348
21	5	357.40	11.082	4.956	343.64	371.16	346	372
24	5	378.80	11.649	5.210	364.34	393.26	366	395
no perfor. 35	5	378.20	26.659	11.922	345.10	411.30	353	420
Total	50	278.64	94.923	13.424	251.66	305.62	67	420

Table 43 Descriptives

8.4.2.2 Shapiro-Wilk

Shapiro-Wilks tests show no significance from normal distributions of the groups. The SPSS table is shown below Table 44.

		Shapiro-Wilk		
	Distance to a perforation mm	**Statistic**	**df**	**Sig.**
Pressure KPa	0	.907	5	.451
	3	.803	5	.086
	6	.848	5	.189
	9	.957	5	.784
	12	.960	5	.805
	15	.977	5	.918
	18	.919	5	.521
	21	.931	5	.603
	24	.966	5	.847
	no perforation; 35 mm to edge	.891	5	.361

Table 44 Shapiro-Wilk

8.4.2.3 Box plot

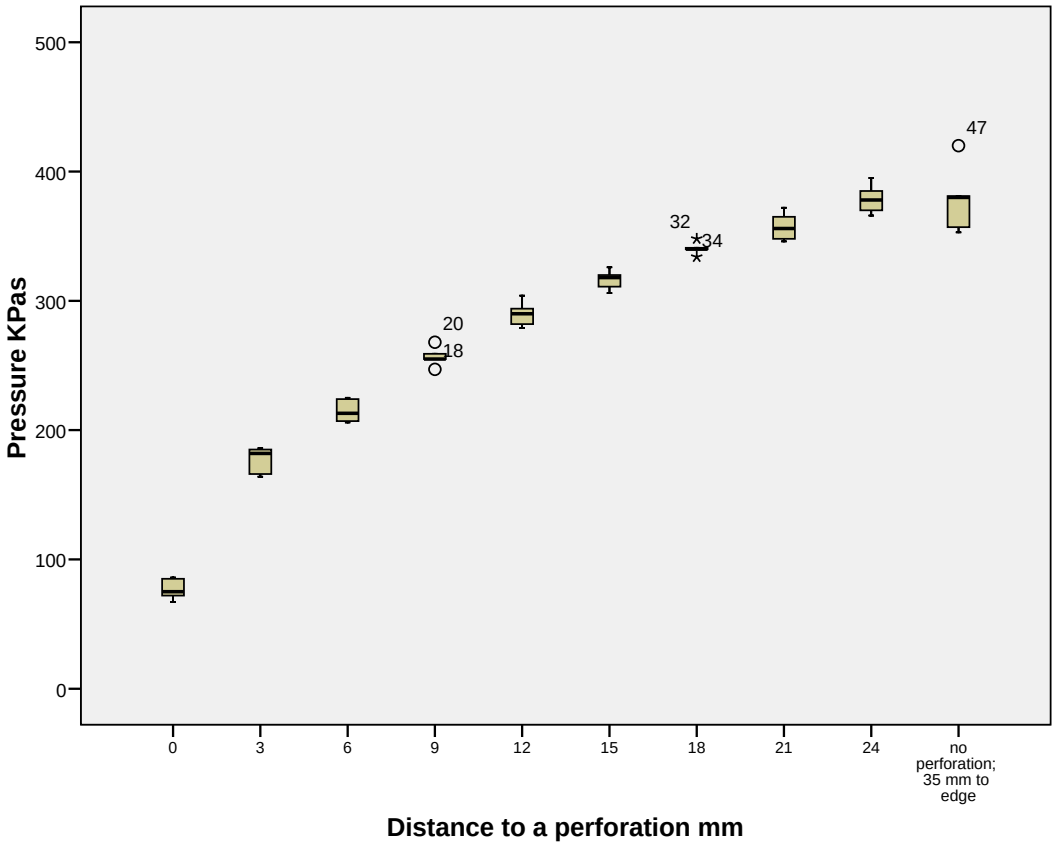


Figure 42 Box plot of results for the ‘distance to a perforation’ experiment

8.4.2.4 Levene test

Levene Statistic	df1	df2	Sig.
1.872	9	40	.085

Table 45 Levene Statistic

The Levene statistic was unable to show a significant variation in the variance of the dependant within the groups ($p>0.05$). Therefore it was decided to use ANOVA for the overall results and the Bonferroni correction for post hoc analysis both of which assume homogeneity of variance.

8.4.3 Data analysis

8.4.3.1 ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	435597.920	9	48399.769	327.379	.000
Within Groups	5913.600	40	147.840		
Total	441511.520	49			

Table 46 ANOVA output

The ANOVA analysis shows the significance of the overall difference between the groups ($p<0.001$). We reject the Null Hypothesis that there is no difference in pressure with an increase in the distance to the sensor. The alternative hypothesis is proposed that distance to the perforation affects the pressure; the further the perforation is from the sensor the higher the pressure.

8.4.3.2 Post hoc

Bonferroni post hoc Analysis shows a significant difference between ALL groups up to the perforation at 12mm from the sensor. Thereafter the Bonferroni tests show significance summarized below.

Bonferroni shows no significant difference between:

12mm and 15mm

15mm and either 12mm or 18mm

18 mm and either 15mm or 21mm

21mm and 18mm or 24mm or no perforation

24mm and either 21mm or no perforation

No perforation and either 21mm or 24mm.

Looking at the Confidence Intervals (Table 46 above) and the post hoc analysis, the trend appears to be that there is little or no difference between groups when the perforation is more than 18mm or 21mm from the sensor. It is useful in these circumstances to turn to Tukey's B post hoc test, a test which groups the similar variables into homogeneous subsets. Tukey's B analysis of this data is shown below (Table 47). With Tukey's B analysis the groups with perforations more than 21mm from the sensor form a homogeneous subgroup. It would appear that (for a perforation of this size with this material in these in-vitro experimental conditions) when the perforation is more than 21mm from the sensor there is little or no effect on the pressure

Distance to perfor. mm	subset for alpha = 0.05								
	N	2	3	4	5	6	7	8	1
0	5	77.0							
3	5		176.6						
6	5			215.0					
9	5				256.8				
12	5					289.8			
15	5						316.2		
18	5							340.6	
21	5							357.4	357.4
no perfor	5								378.2
24	5								378.8

Table 47 Tukey’s B analysis of distance to a perforation in mm, using SPSS

8.5 Summary of results

Distance to a perforation	Mean	Std. Deviation
Opposite sensor	77.00	8.276
3 mm	176.60	10.714
6 mm	215.00	9.083
9 mm	256.80	7.629
12 mm	289.80	9.960
15 mm	316.20	7.823
18 mm	340.60	4.980
21 mm	357.40	11.082
24 mm	378.80	11.649
no perforation; 35 mm to edge	378.20	26.659

Table 48 Summary of results

The peak pressure means (S.D.) were 77 (S.D. 8), 177 (11), 215 (9), 257 (9), 290 (8), 316 (8), 341 (5), 357 (11), 379 (11), and 378 (27) KPa (see Figure 43 below). There was a significant difference between the groups ($p<0.001$). The Tukey-B showed significant difference for each of the holes up to and including the hole 15mm from the centre (alpha=0.05). The holes at 18 and 21mm and the holes at 21, 24mm & 'no hole' formed homogenous subsets.

8.5.1 Graph of means of groups

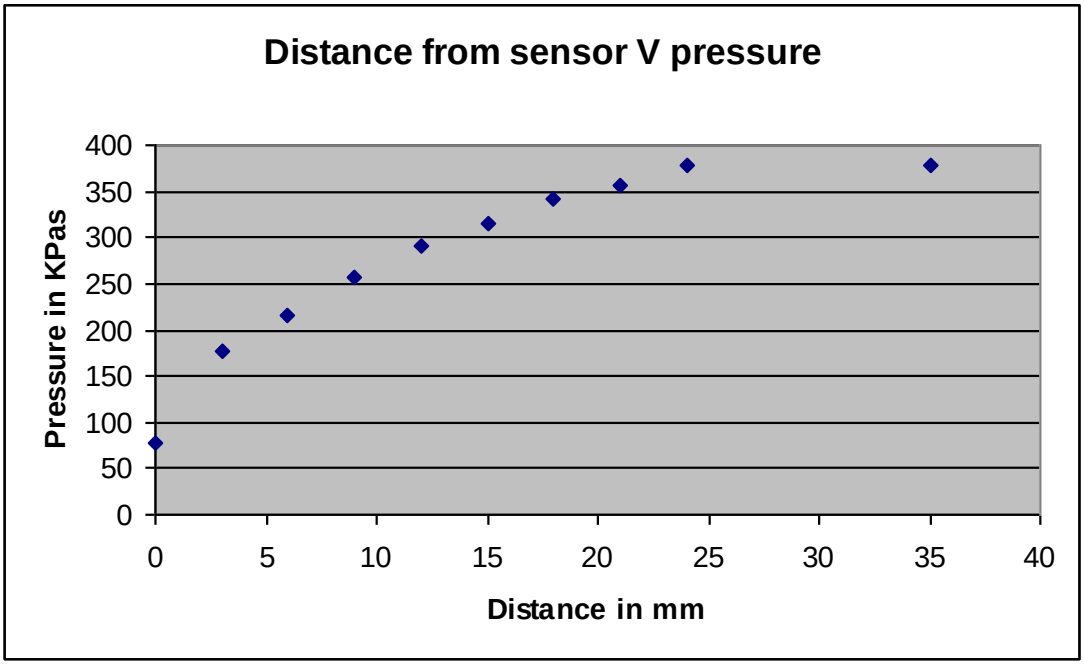


Figure 43 plot of means of the results

8.6 Conclusion

In this in-vitro experiment, perforations have a decreasing effect on impression pressure as they become more distant from the sensor. At distances greater than 21mm the effect of the perforation is not statistically different from no perforations.

8.7 Clinical implications

The nearer to a perforation, the lower was the impression pressure. Thus, although a perforation reduced impression pressure, it also introduced a new pressure gradient.

8.8 Next experiment

A clinician wishing to have a more even distribution of impression pressure may wish to introduce multiple perforations. Further experimentation was therefore indicated to investigate the effect on pressure of multiple perforations.

Chapter 9
Perforation number

9.1 Background

The research literature differs on the importance of special tray perforations in reducing impression pressure. Both Frank (Frank 1969) and Komiyama et al (Komiyama et al 2004) reported that perforations in special trays reduce pressure; however Masri (Masri 2002) found that placing perforations in special trays had little effect on pressure. Tray perforations vary and it is likely that the variations in the tray perforations explain the difference between the results reported in the literature. Perforations have a number of variables and these include the distance of a perforation to a pressure sensor, the size of a perforation and the total number of perforations. The aim of this study is to investigate the effect of number of tray perforations on impression pressure. The Hypothesis is that the number of perforation affects the pressure of an impression. The Null Hypothesis is that the number of perforation does not affect the pressure of an impression.

9.2 Objectives

The research literature differs on the importance of special tray perforations in reducing impression pressure. One in-vitro study reported that perforations in special trays reduce pressure; however another found that perforations in special trays have little effect on pressure. The aim of the study is to investigate the effect of increasing the number of tray perforations on impression pressure.

9.3 Method

Vinyl polysiloxane impression material (express 3M) was placed between two approximating discs on a universal testing machine and the pressure generated at the centre of the upper disc was recorded (see Figure 44). The lower disc had 12 perforations located equidistant from the centre in the position of the numbers of a clock face (see Figure 45). The perforations were sealed. First one perforation then 2, 3, 4, 6, and 12 perforations were uncovered and the impression pressure as the discs were approximated was recorded for five approximations. Data was analyzed

by ANOVA with post hoc comparisons using the Bonferroni correction at the 0.05 level of significance.

Figure 44 standard impressed disc with sensor attached

Figure 45 ‘impression tray’ for the number of holes experiment

9.4 Statistical analysis

9.4.1 Raw data

Number of holes	Pressure Kilopascals	Number of holes	Pressure Kilopascals
0	238	4	115
0	229	4	103
0	232	4	104
0	226	4	113
0	227	4	113
1	218	6	87
1	186	6	91
1	195	6	89
1	193	6	87
1	220	6	91
2	148	12	64
2	156	12	58
2	143	12	62
2	145	12	62
2	163	12	57
3	136		
3	138		
3	135		
3	133		
3	141		

Table 49 Raw data

9.4.2 Data exploration

9.4.2.1 Descriptives

No. of perfor.	N	Mean	Std. Dev	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
0	5	230.40	4.827	2.159	224.41	236.39	226	238
1	5	202.40	15.534	6.947	183.11	221.69	186	220
2	5	151.00	8.337	3.728	140.65	161.35	143	163
3	5	136.60	3.050	1.364	132.81	140.39	133	141
4	5	109.60	5.639	2.522	102.60	116.60	103	115
6	5	89.00	2.000	0.894	86.52	91.48	87	91
12	5	60.60	2.966	1.327	56.92	64.28	57	64
Total	35	139.94	57.315	9.688	120.25	159.63	57	238

Table 50 Descriptives

9.4.2.2 Shapiro-Wilk

No significance difference from a normal distribution was shown at the 0.05 level for any group.

	Number of perforations	Shapiro-Wilk		
		Statistic	df	Sig.
Pressure	0	.905	5	.436
	1	.849	5	.192
	2	.915	5	.497
	3	.981	5	.940
	4	.810	5	.097
	6	.821	5	.119
	12	.897	5	.391

Table 51 Shapiro-Wilk

9.4.2.3 Box plot

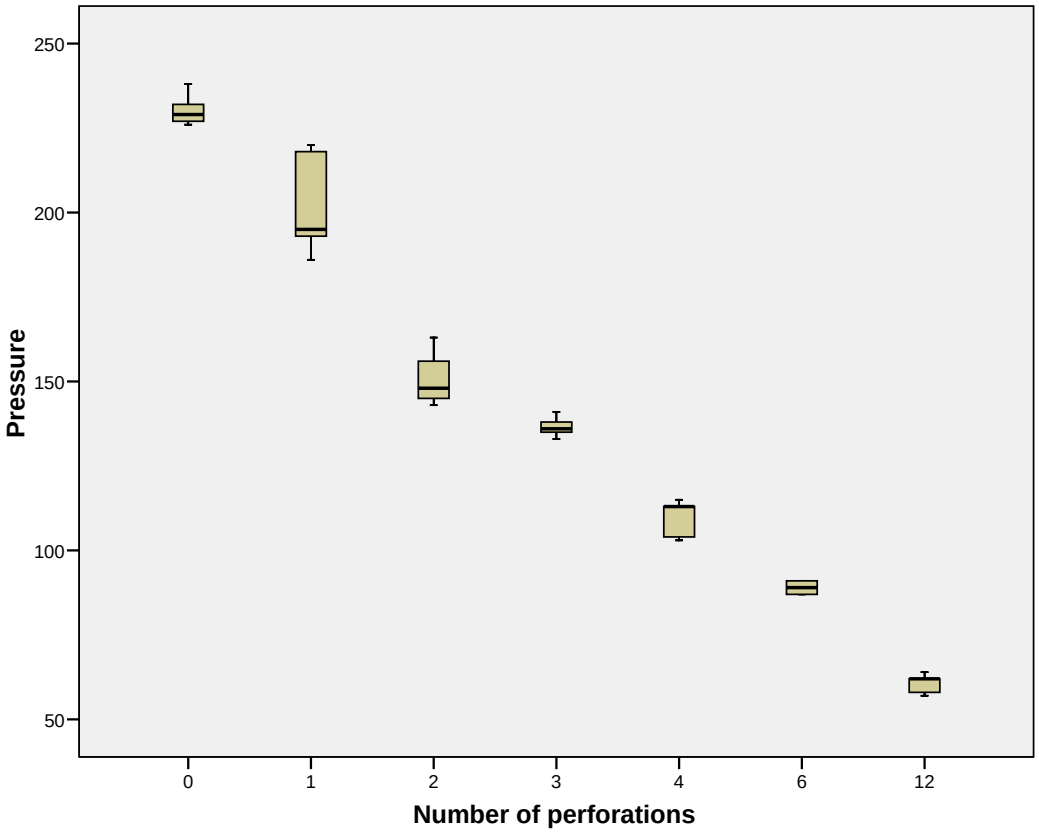


Figure 46 Box plots of results for the number of perforations experiment

9.4.2.4 Levene test

Levene Statistic	df1	df2	Sig.
12.664	6	28	.000

Table 52 Levene

The Homogeneity of variances of the groups is not shown; therefore the overall assessment of the statistics was performed with a Non-Parametric Kruskal Wallis test and the post hoc tests used the robust Dunnett T3 analysis both of which do not require or assume equivalence of variance.

9.4.3 Data analysis

9.4.3.1 Kruskal Wallis

	Pressure
Chi-Square	33.352
Df	6
Asymp. Sig.	.000009

Table 53 Kruskal Wallis test, grouping variable: Number of perforations,

Overall Kruskal Wallis analysis showed a significant difference between the groups ($p<0.001$). Further analysis was indicated to investigate precisely where the differences occurred.

9.4.3.2 Post hoc

Post hoc DunnettT3 tests show significant differences; the significance results are summarized below Table 54.

(I) Number of perfor.	(J) Number of perfor.	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
0	1	28.000	7.275	.126	-8.12	64.12
	2	79.400(*)	4.308	.000	60.52	98.28
	3	93.800(*)	2.553	.000	82.81	104.79
	4	120.800(*)	3.320	.000	107.17	134.43
	6	141.400(*)	2.337	.000	130.38	152.42
	12	169.800(*)	2.534	.000	158.83	180.77
1	2	51.400(*)	7.884	.008	16.26	86.54
	3	65.800(*)	7.080	.005	28.79	102.81
	4	92.800(*)	7.391	.001	57.05	128.55
	6	113.400(*)	7.004	.001	75.93	150.87
	12	141.800(*)	7.072	.000	104.75	178.85
2	3	14.400	3.970	.145	-4.78	33.58
	4	41.400(*)	4.501	.001	22.29	60.51
	6	62.000(*)	3.834	.000	42.32	81.68
	12	90.400(*)	3.957	.000	71.19	109.61
3	4	27.000(*)	2.867	.001	14.24	39.76
	6	47.600(*)	1.631	.000	40.63	54.57
	12	76.000(*)	1.903	.000	68.24	83.76
4	6	20.600(*)	2.676	.007	7.60	33.60
	12	49.000(*)	2.850	.000	36.24	61.76
6	12	28.400(*)	1.600	.000	21.60	35.20

Table 54 Post hoc Dunnett's T3; * the mean difference is significant at the .05 level.

Post hoc tests showed significant differences ($p<0.05$) between the groups except between no perforation and one perforation and between groups with two and three perforations.

9.5 Summary of results

The peak pressure means (S.D.) were 230(S.D. 5), 202(16), 151(8), 137(3), 110(6), 90(2) and 61(3) respectively. In a non parametric test, Kruskal Wallis showed a significant difference between the results ($p<0.001$). Post hoc tests with Dunnett's T3 showed a statistically significant difference between all the groups ($p<0.005$) with the exceptions of between two holes and three holes and between 0 and 1 hole. The Null Hypothesis is rejected; in rejecting the Null Hypothesis the alternative hypothesis is proposed that number of perforations affects pressure of the impression.

Number of perforations	Mean Pressure KPa	Std. Deviation
0	230	5
1	202	16
2	151	8
3	137	3
4	110	6
6	90	2
12	61	3

Table 55 Summary of results

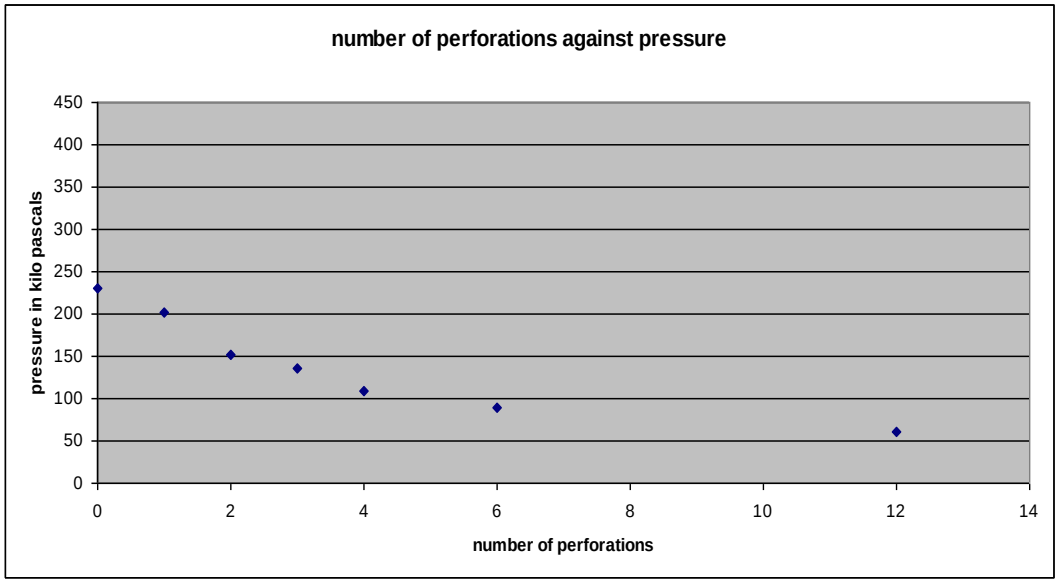


Figure 47 plot of means of results

9.6 Conclusion

In this in-vitro experiment, the impression pressure decreased as the number of perforations increased.

9.7 Clinical implications

The more perforations there are in an impression tray, the lower the impression pressure. If a clinician wishes to reduce the impression pressure multiple perforations are a valid method of achieving that aim.

Chapter 10
Perforation size

10.1 Background

It is often recommended to place perforations in custom impression trays for prosthodontic impressions. One reason for doing so is to reduce the pressure of the impression.

However, the research literature differs on the importance of special tray perforations in reducing impression pressure. Both Frank and Komiyama et al reported that perforations in special trays reduce pressure; however Masri found that placing perforations in special trays had little effect on pressure. Tray perforations vary and it is likely that the variations in the tray perforations explain the difference between the results reported in the literature. Perforations have a number of variables and these include; the distance of a perforation to a pressure sensor, the size of a perforation and the total number of perforations. This study investigated perforation size.

10.2 Aims and Objectives

The aim of this study is to investigate the effect of size of tray perforations on impression pressure. The Hypothesis is that the size of perforation affects the pressure of an impression. The Null Hypothesis is that the size of perforation does not affect the pressure of an impression.

10.3 Method

Vinyl polysiloxane impression material (express 3M) was placed between two approximating discs on a universal testing machine and the pressure generated at the centre of the upper disc was recorded. The lower disc had six perforations located so that the centre of each perforation was equidistant from the centre of the disc (see Figure 49 below). The perforations were 0.5 mm, 1mm, 1.5mm, 2mm, 2.5mm and 3mm in diameter. The perforations were sealed. Each perforation in turn was

uncovered and the impression pressure as the discs were approximated was recorded for five approximations. Data was analyzed by ANOVA with post hoc comparisons using the Bonferroni correction at the 0.05 level of significance.

Figure 48 The standard upper disc with sensor attached

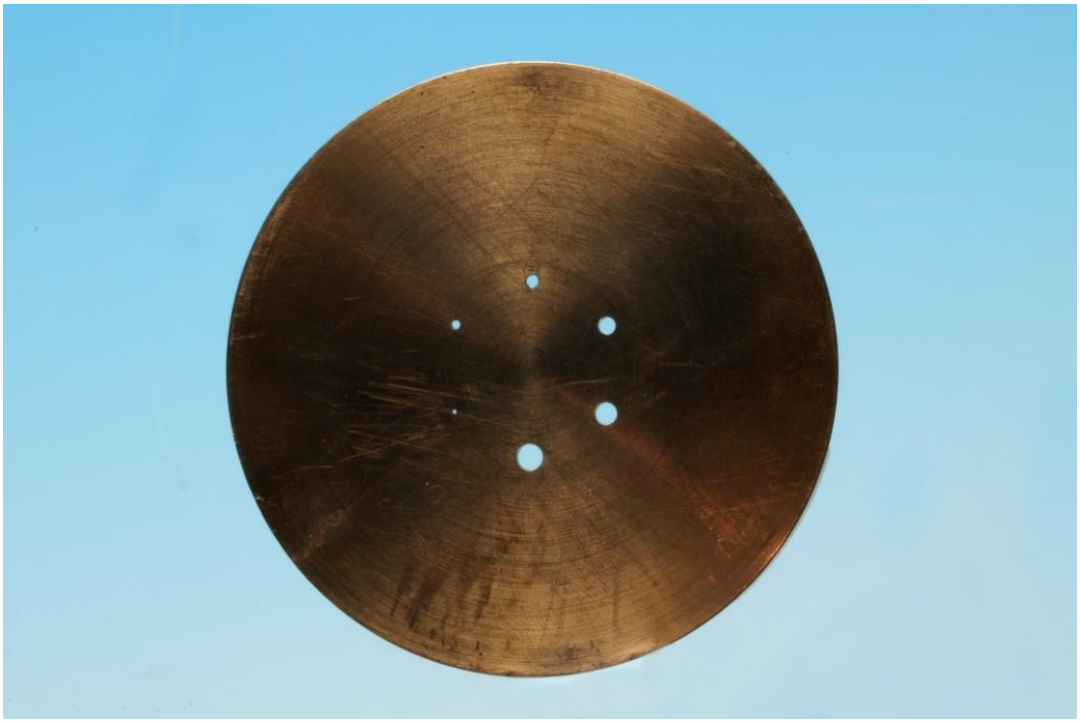


Figure 49 the ‘impression tray’ for the perforation size experiment

10.4 Statistical analysis

10.4.1 Raw data

Perforation size	Peak pressure KPa		Perforation size	Peak pressure KPa
3.0	219		1.5	243
3.0	203		1.5	238
3.0	203		1.5	218
3.0	191		1.5	261
3.0	202		1.5	260
2.5	212		1.0	298
2.5	192		1.0	275
2.5	196		1.0	275
2.5	214		1.0	280
2.5	195		1.0	274
2.0	219		0.5	291
2.0	235		0.5	291
2.0	206		0.5	288
2.0	215		0.5	288
2.0	226		0.5	297
			0.0	296
			0.0	302
			0.0	302
			0.0	292
			0.0	294

Table 56 Raw data

10.4.2 Data exploration

10.4.2.1 Descriptives

Size	N	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean		Mini	Max
					Lower Bound	Upper Bound		
.0	5	297.20	4.604	2.059	291.48	302.92	292	302
.5	5	291.00	3.674	1.643	286.44	295.56	288	297
1.0	5	280.40	10.114	4.523	267.84	292.96	274	298
1.5	5	244.00	17.734	7.931	221.98	266.02	218	261
2.0	5	220.20	10.986	4.913	206.56	233.84	206	235
2.5	5	201.80	10.354	4.630	188.94	214.66	192	214
3.0	5	203.60	9.990	4.468	191.20	216.00	191	219
Total	35	248.31	39.920	6.748	234.60	262.03	191	302

Table 57 Descriptives

10.4.2.2 Shapiro-Wilk test of normality

All the perforation size groups showed no significant difference from a normal distribution except the group with a perforation size of 1mm. It is not known why the experiment with 1mm diameter perforations produced a non normal distribution; but it was speculated that perhaps it is a combination of the small sample size with the outlier shown in the box plot (Figure 50 below). The Shapiro-Wilk test of normality was repeated without the outlier and the results are shown below Table 58 with outlier without.

	Size of perforation in mm	Shapiro-Wilk		
		Statistic	Df	Sig.
Pressure in KPa	0.0	.868	5	.257
	0.5	.833	5	.146
	1.0	.719	5	.015
	1.5	.913	5	.486
	2.0	.996	5	.996
	2.5	.818	5	.112
	3.0	.890	5	.358

		Shapiro-Wilk		
		Statistic	Df	Sig.
Pressure in KPa	1.0 outlier eliminated	.773	4	.062

Table 58 Shapiro-Wilk repeated eliminating outlier in the 1mm group

10.4.2.3 Box plot

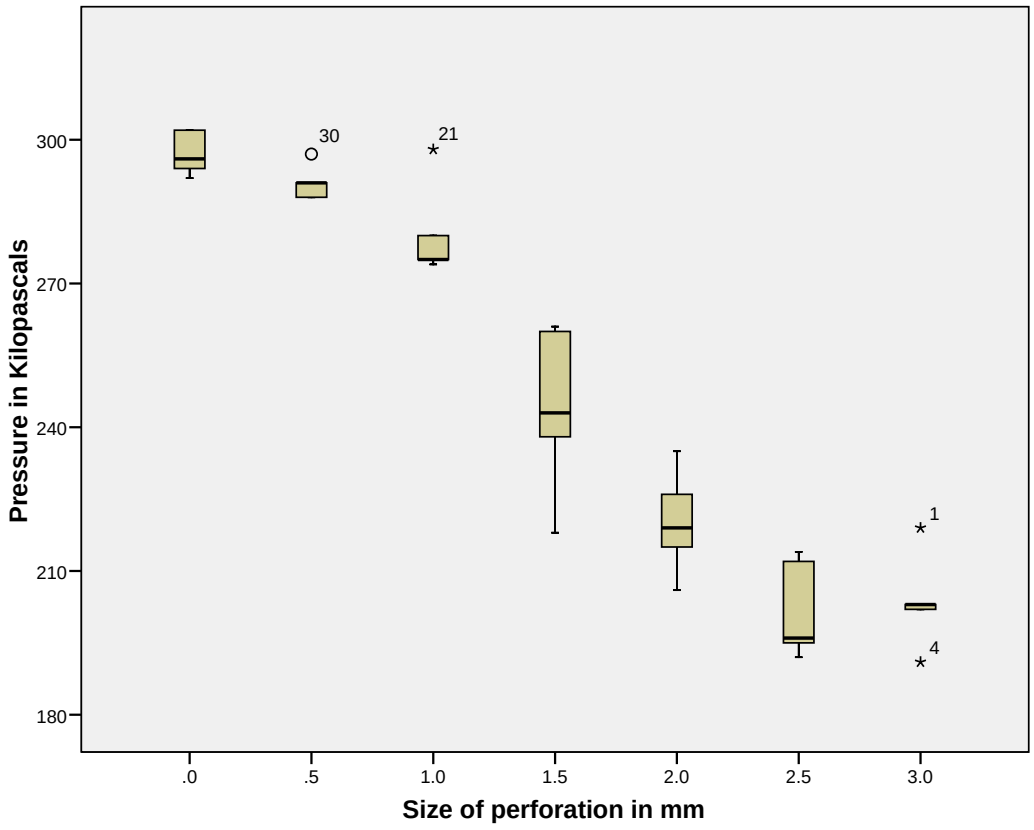


Figure 50 Box plots of results for the perforation size experiment

10.4.2.4 Levene test

Levene's test of equality of error variance, tests that the Null Hypothesis that the error variance of the dependent variable is equal across groups. The Levene statistic showed no statistically significant difference in homogeneity of variance therefore ANOVA was used for the overall assessment and the Bonferroni correction was used in post hoc analysis to correct for multiple testing.

Levene Statistic	df1	df2	Sig.
1.828	6	28	.130

Table 59 Levene test output

10.4.3 Data analysis

10.4.3.1 ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	51066.743	6	8511.124	76.460	.000
Within Groups	3116.800	28	111.314		
Total	54183.543	34			

Table 60 ANOVA Output

Overall ANOVA analysis showed a significant difference between the groups. Further analysis was indicated to investigate precisely where the differences occurred.

10.4.3.2 Post hoc

Post hoc analysis with Bonferroni correction showed mean differences of significance at the 0.05 level as detailed in Table 61 below.

(I) Size of perforation in mm	(J) Size of perforation in mm	Mean Diff. (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
.0	.5	6.2	6.673	1.000	-16.09	28.49
	1.0	16.8	6.673	0.374	-5.49	39.09
	1.5	53.2(*)	6.673	0.000	30.91	75.49
	2.0	77.0(*)	6.673	0.000	54.71	99.29
	2.5	95.4(*)	6.673	0.000	73.11	117.69
	3.0	93.6(*)	6.673	0.000	71.31	115.89
.5	1.0	10.6	6.673	1.000	-11.69	32.89
	1.5	47.0(*)	6.673	0.000	24.71	69.29
	2.0	70.8(*)	6.673	0.000	48.51	93.09
	2.5	89.2(*)	6.673	0.000	66.91	111.49
	3.0	87.4(*)	6.673	0.000	65.11	109.69
1.0	1.5	36.4(*)	6.673	0.000	14.11	58.69
	2.0	60.2(*)	6.673	0.000	37.91	82.49
	2.5	78.6(*)	6.673	0.000	56.31	100.89
	3.0	76.8(*)	6.673	0.000	54.51	99.09
1.5	2.0	23.8(*)	6.673	0.028	1.51	46.09
	2.5	42.2(*)	6.673	0.000	19.91	64.49
	3.0	40.4(*)	6.673	0.000	18.11	62.69
2.0	2.5	18.4	6.673	0.213	-3.89	40.69
	3.0	16.6	6.673	0.401	-5.69	38.89
2.5	3.0	-1.8	6.673	1.000	-24.09	20.49

Table 61 Post hoc with Bonferroni correction, * the mean difference is significant at the .05 level

10.5 Summary of results

The peak pressure means (S.D.) were 297 (5) for no perforation, 291 (4) with a 0.5mm perforation, 280 (10) for 1mm, 244 (18) for 1.5mm, 220 (11) for 2mm, 212 (11) for 2.5mm, and 203 (10) for 3mm (see Table 62 and Figure 51 below). ANOVA showed a significant difference between the results ($p<0.0001$). The Null Hypothesis is rejected in rejecting the Null Hypothesis the alternative hypothesis is proposed that the size of the perforation affects the pressure of impression.

Size of perforation	Mean pressure KPa	Std. Deviation
None	297	5
.5 mm	291	4
1.0 mm	280	10
1.5 mm	244	18
2.0 mm	220	11
2.5 mm	202	10
3.0 mm	204	10

Table 62 Summary of results

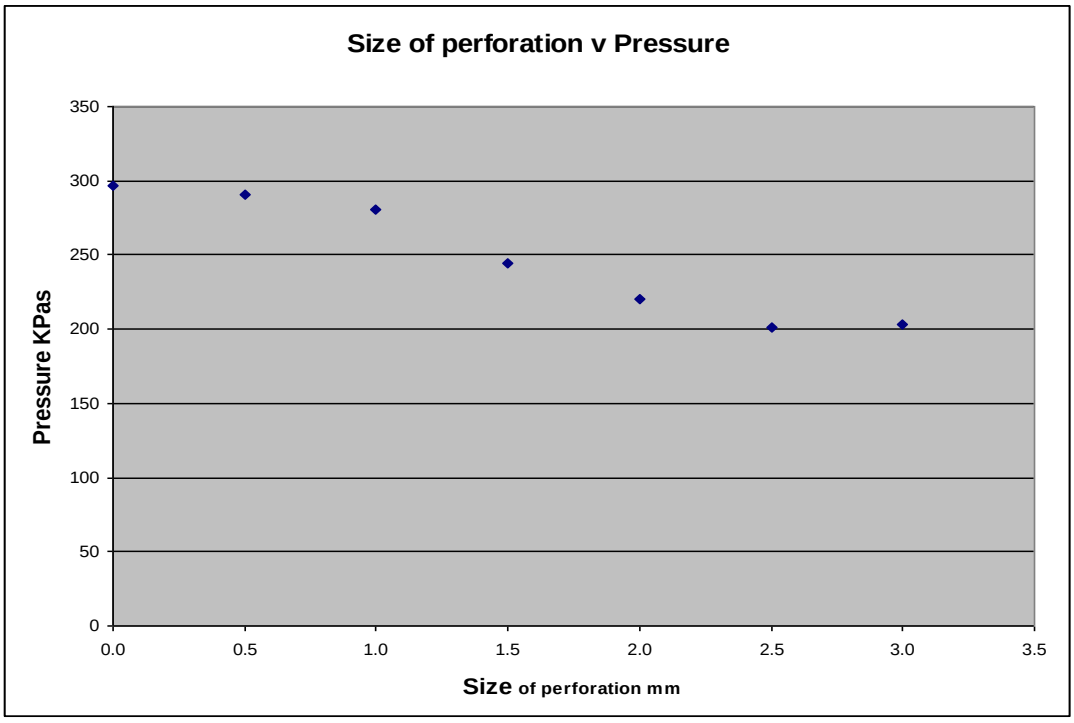


Figure 51 Plot of means of results for the perforation size experiment

10.6 Discussion

Previous results in this series of experiments have shown a reduction in pressure when the numbers of perforations increase and when the distance from a perforation to the pressure sensor decreased. The results from this series of experiments are sufficient to explain the differences between the results reported in the literature. When compared to Komiyama et al and Frank the perforations reported by Masri appear to be smaller, further away from the sensor and fewer in number than those in the other studies. Impression pressures remain important when constructing mucosal borne restorations. Clinically dentists need to be aware of these factors when attempting to control impression pressure. It is particularly relevant when developing differential pressure techniques for complex prosthodontic cases.

Within the confines of this in-vitro experiment there appears to be a limited range of perforation sizes which are effective in changing the pressure. A decrease in perforation size below 1mm does not increase pressure significantly. An increase in perforation size above 2mm does decrease pressure significantly.

10.7 Conclusion

In this in-vitro experiment, the impression pressure decreased as the size of perforations increased.

10.8 Clinical implications

Within the confines of this in-vitro experiment, a perforation size of 2mm would appear to be sufficient to reduce the impression pressure to an optimum for a relatively mucostatic impression. Although clinical in-vivo experiments would be required to confirm the precise figure; it is reasonable to suggest from this evidence that, for this impression material, 2mm perforations may be optimum for in-vivo pressure reduction.

Chapter 11
Reducing inconsistencies in perforation studies

11.1 Background and statement of problem

The experiments that have investigation the effect of perforations on impression pressure have used similar methodology. This is by design with the aim that the results would be consistent and comparable. The individual experiments have an internal consistency and are valid for the limited in-vitro experimental conditions that prevailed in each experiment. It was expected that there would be a consistency across the experiments such that where each experiment looked the same conditions similar pressure would be recorded. This has not occurred. There is an obvious inconsistency in the results with no perforations. Mean pressure with no perforations, in the disc used for the size study was 297KPa, for the number of perforation study it was 230 KPa and for the disc used for the position of the perforations it was a remarkable 378 KPa.

There are less obvious but important further inconsistencies across the results, for example in the size study a single perforation 10 mm from the central sensors had a mean pressure of 220KPa, whereas in the number study a similar single hole had a mean pressure of 202 KPa. The Table below (Tables 63) has these inconsistencies highlighted.

The laboratory experiments in Part II of this work have taken a deliberate approach which aimed to eliminate uncontrolled variables for each experiment. This has been successful within individual experiments but not for comparisons between experiments. These inconsistencies required investigation.

Number of 2mm perforations	Mean Pressure KPa		Distance to a 2mm perforation	Mean pressure KPa		Size of Perforation	Mean Pressure KPa
No perforation	**230**		**No perforation**	**378**		**No perforation**	**297**
1	**202**		24	379		.5 mm	291
2	151		21	357		1.0 mm	280
3	137		18	341		1.5 mm	244
4	110		15	316		**2.0 mm**	**220**
6	89		12	290		2.5 mm	202
12	61		9	257		3.0 mm	204
			6	215			
			3	177			
			0	77			

Table 63 Summary raw data of data from the previous 3 chapters

11.2 Aims and objectives

11.2.1 Aim

The aim of this chapter was to identify a feasible hypothesis for the differences highlighted in the introduction and test the hypothesis.

11.2.2 Objectives

1. Identify a feasible uncontrolled variable
2. Eliminate that uncontrolled variable
3. Re-run perforation experiments and re-assess outcomes to test hypothesis

11.3 Method

The impression material, upper brass discs, the pressure sensing equipment, the timing of the approximation, the recorded room temperature and the Lloyd universal testing machine were identical in all the three perforation studies. The

‘trays’ (the brass discs which carried the impression material) were different between the three perforation studies. The three discs used in the different perforation studies are shown in Figures 54 and 55 below.

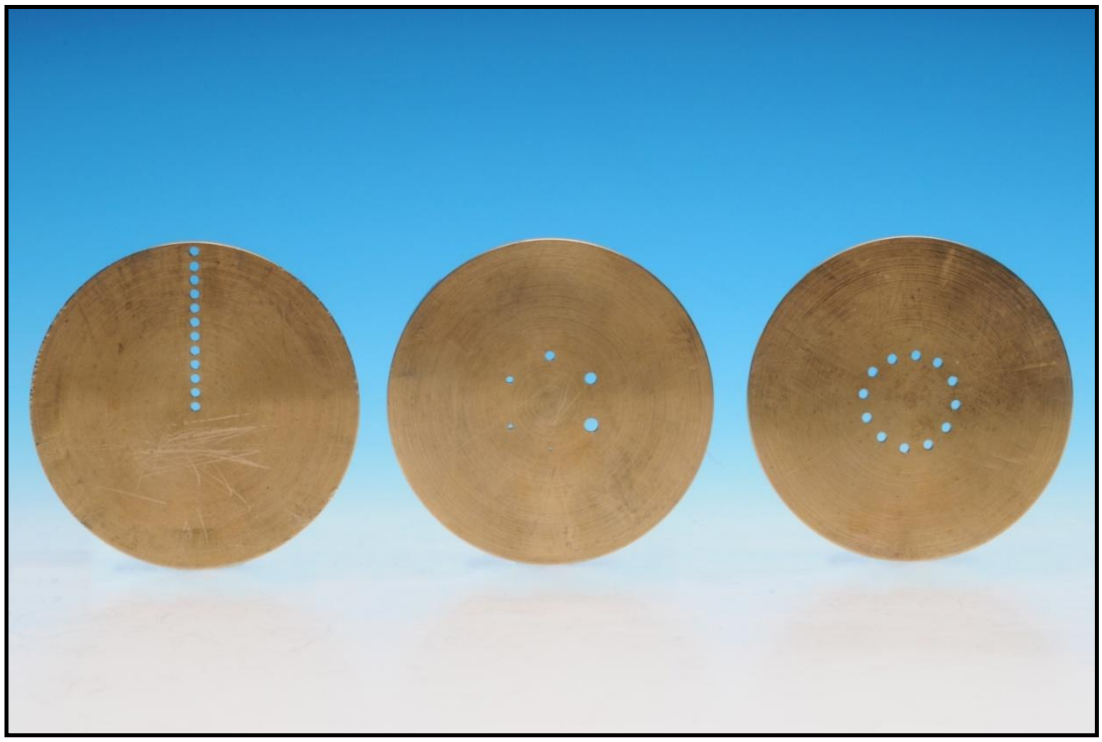


Figure 52 The disc for the distance study is on the left the disc for the size study is in the centre and the number study on the right.

From above (Figure 52) the discs appear to be very similar, apart from the configuration of the various holes. However when viewed from the side, Figure 53, there were apparent differences. The ‘distance’ disc appeared to be more substantial in construction with more robust supports. The technician whose considerable skill was used to construct the discs had taken the precaution of constructing more careful support for the ‘distance’ disc because of a perceived inherent weakness caused by the pattern of the perforations. On measuring the thickness of the top platform of the discs with a micrometer the discs were similar but with the ‘numbers’ disc just marginally thinner.

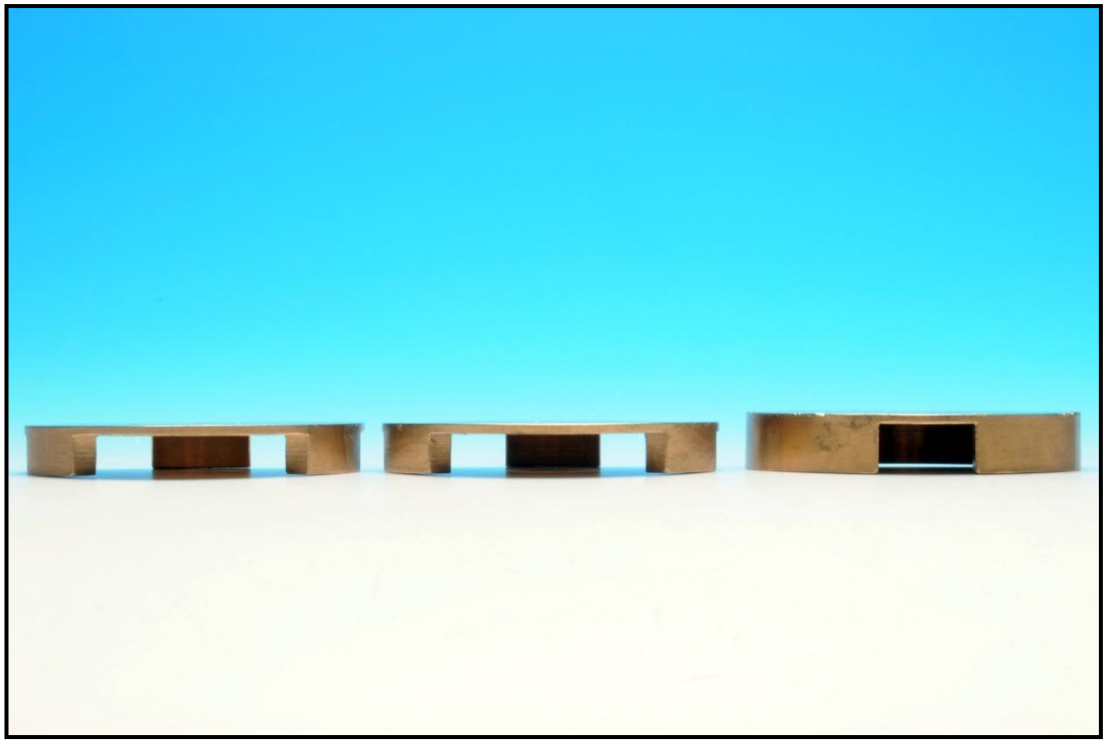


Figure 53 The disc for the number study is on the left, the size study is in the centre and the distance study is on the right.

The hypothesis was proposed that the differences in the construction of the lower brass discs had resulted in the recorded differences in the recorded pressure between the three studies. To test the hypothesis the three discs were re-engineered, and the experiments in chapter 7, 8 & 9 were repeated. Since the purpose of the repeated experiments was to test the hypothesis above, only five factors (5 different levels of variable e.g. number of holes used or the size of the holes used) were required for each experiment. The previous results were used to choose appropriate levels for the factors used for each disc.

The chosen factors for the experiment for the ‘distance’ disc were 3mm 9mm 15mm 21mm and no perforation. The chosen factors for the ‘size’ disc were no perforation, 1mm, 1.5mm 2mm and 3mm. The chosen factors for the ‘number of perforation’ discs were no perforations, one perforation, two perforations, four perforations and six perforations. The re-engineered discs can be seen in Figures56 to 59 below.

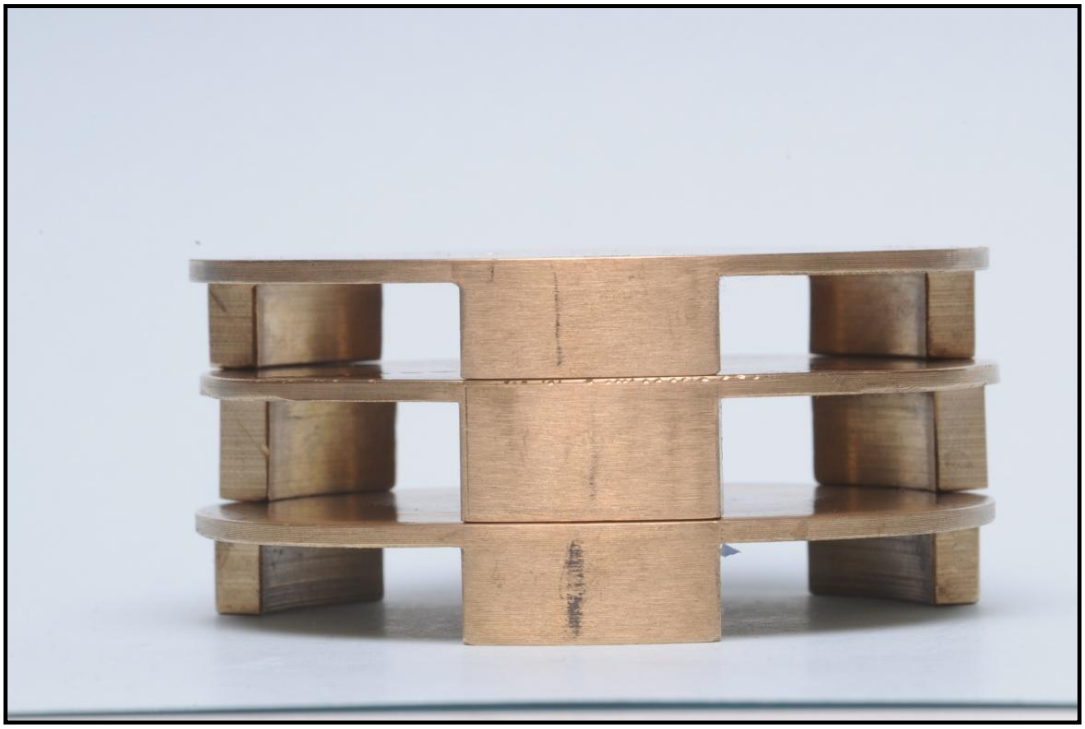


Figure 55 The three discs after alteration.

Figure 55 Disc for the distance to a perforation study.

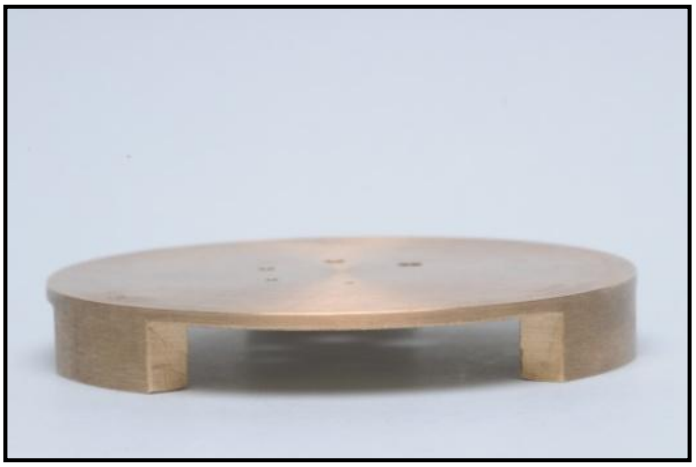


Figure 56 Disc for the size of a perforation study.

Figure 57 Disc for the number of perforations study.

11.4 Statistical analysis

The choice of method for the statistical analysis was determined first by a test of normality (Shapiro-Wilks) followed by the Levene test homogeneity of the error variance of the dependant. ANOVA followed by post hoc tests with Bonferroni correction for multiple testing were used if there was normality and homogeneity of variance. Kruskal Wallis and Dunnett T3 were only used if the conditions required for ANOVA were not satisfied.

11.4.1 Results, raw data

Number study			**Study of perforation position from central sensor**			**Size study**	
Number of 2mm Perforations	**Pressure KPa**		**Distance to a 2mm perforation**	**Pressure KPa**		**Size of the perforation**	**Pressure KPa**
No perforation	**232**		**No perforation**	**234**		**No perforation**	**252**
1	**174**		21 mm	233		1 mm	237
2	119		15 mm	202		1.5 mm	218
4	75		9 mm	163		**2 mm**	**180**
6	73		3 mm	135		3 mm	166

Table 64 Means of the new experiment with the altered discs.

11.4.2 Data exploration

11.4.2.1 Descriptives

11.4.2.1.1 Descriptives for distance to a perforation from the central sensor

Dist. in mm	N	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean		Mini	Max
					Lower Bound	Upper Bound		
3	5	134.80	5.805	2.596	127.59	142.01	126	141
9	5	163.00	13.058	5.840	146.79	179.21	151	177
15	5	201.60	7.021	3.140	192.88	210.32	194	213
21	5	232.60	3.286	1.470	228.52	236.68	230	238
35	5	233.80	7.596	3.397	224.37	243.23	225	246
Total	25	193.16	40.444	8.089	176.47	209.85	126	246

Table 65 Descriptives for distance

11.4.2.1.2 Descriptives for number of perforations

Num.	N	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean		Mini	Max
					Lower Bound	Upper Bound		
0	5	232.20	10.474	4.684	219.20	245.20	216	245
1	5	174.20	13.846	6.192	157.01	191.39	159	189
2	5	118.80	4.087	1.828	113.73	123.87	112	122
4	5	74.80	2.387	1.068	71.84	77.76	72	78
6	5	72.80	4.764	2.131	66.88	78.72	67	79
Total	25	134.56	62.942	12.588	108.58	160.54	67	245

Table 66 Descriptives for number

11.4.2.1.3 Descriptives for size of perforations

Size mm	N	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean		Mini	Max
					Lower Bound	Upper Bound		
.0	5	252.00	11.314	5.060	237.95	266.05	237	267
1.0	5	237.20	17.297	7.736	215.72	258.68	208	252
1.5	5	218.20	10.498	4.695	205.17	231.23	210	236
2.0	5	180.40	13.993	6.258	163.03	197.77	166	199
3.0	5	162.00	11.832	5.292	147.31	176.69	148	177
Total	25	209.96	36.657	7.331	194.83	225.09	148	267

Table 67 Descriptives for size

11.4.2.2. Shapiro-Wilk

11.4.2.2.1 Shapiro-Wilk for distance to a perforation from the central sensor

		Shapiro-Wilk		
	Distance	**Statistic**	**df**	**Sig.**
Pressure in KPa	3.00	.927	5	.574
	9.00	.797	5	.077
	15.00	.904	5	.433
	21.00	.845	5	.179
	35.00	.874	5	.281

Table 68 Shapiro-Wilk for distance

11.4.2.2.2 Shapiro-Wilk for number of perforations

	Number of perforations	Shapiro-Wilk		
		Statistic	**df**	**Sig.**
Pressure in KPa	0	.934	5	.621
	1	.880	5	.308
	2	.813	5	.103
	4	.974	5	.899
	6	.978	5	.924

Table 69 Shapiro-Wilk for number

11.4.2.2.3 Shapiro-Wilk for size of perforation

	Size of perforation	Shapiro-Wilk		
		Statistic	df	Sig.
Pressure in KPa	.0	.997	5	.998
	1.0	.837	5	.158
	1.5	.816	5	.109
	2.0	.914	5	.494
	3.0	.956	5	.779

Table 70 Shapiro-Wilk for size

11.4.2.3. Box plots

11.4.2.3.1 Distance to a perforation from the central sensor

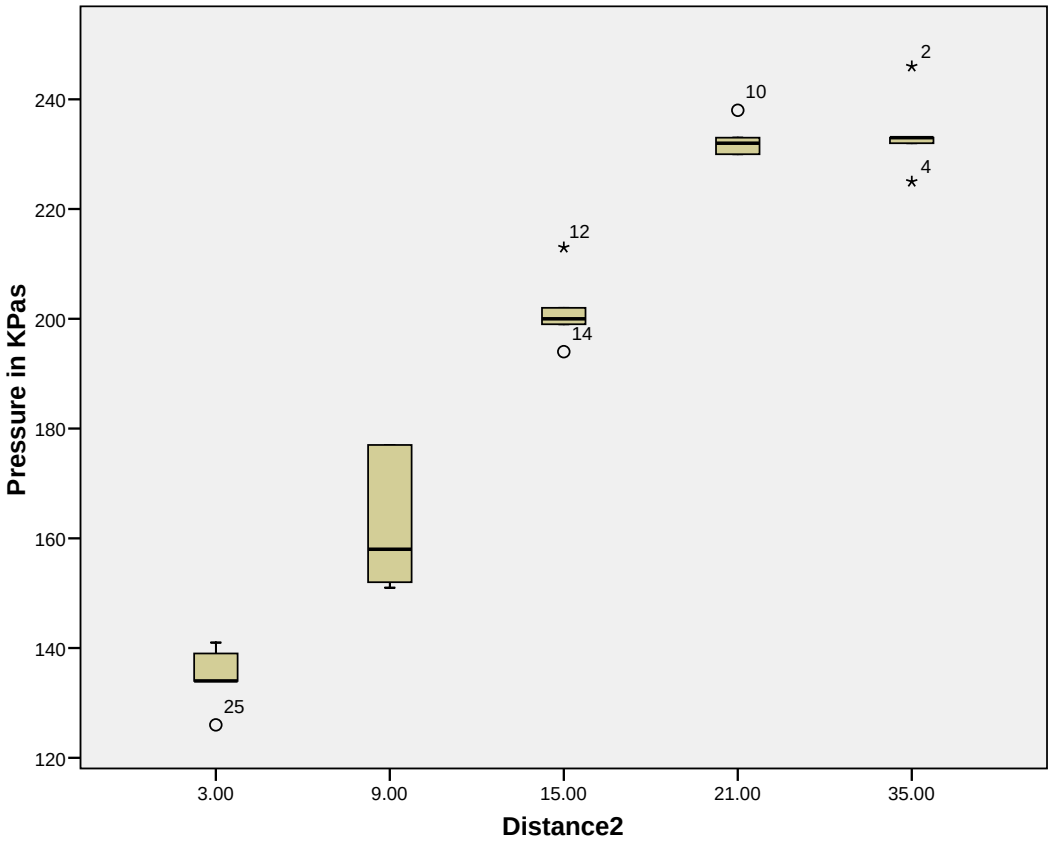


Figure 58 Box plots of results for the distance to a perforation

11.4.2.3.2 Number of perforations

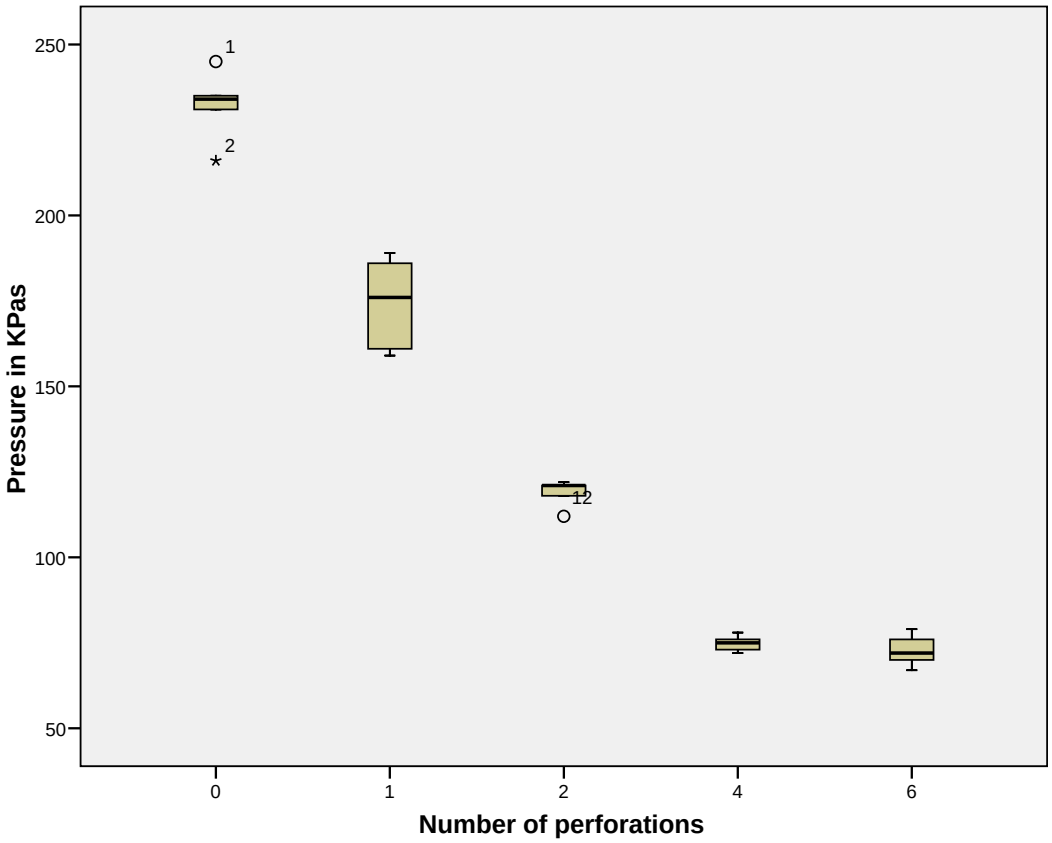


Figure 59 Box plots of results for the number of perforations

11.4.2.3.3 Size of perforation

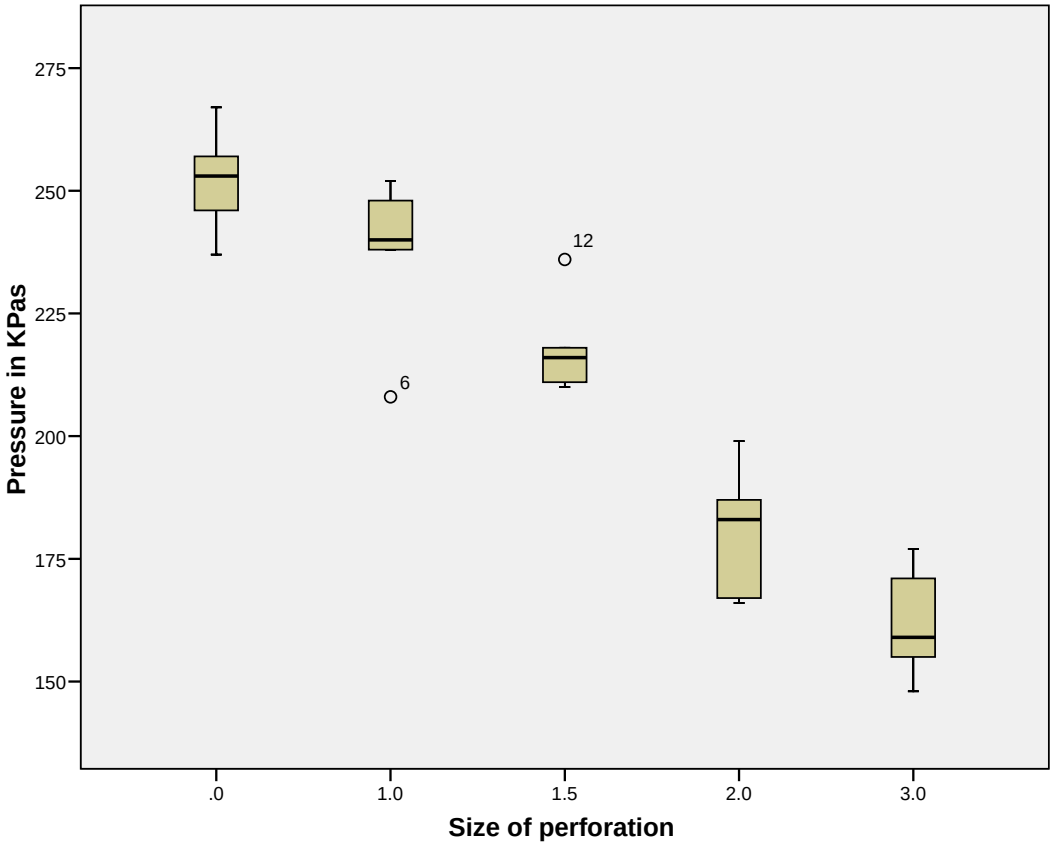


Figure 60 Box plots of results for the size of a perforation

11.4.2.4 Levene test

Levene's test of equality of error variance, tests that the Null Hypothesis that the error variance of the dependent variable is equal across groups.

11.4.1.4.1 Distance to a perforation from the central sensor

Levene Statistic	df1	df2	Sig.
3.580	4	20	.023

Table 71 Levene, distance to a perforation

Table 71 above shows the Levene test for the 'Distance' data. The Homogeneity of variances of the groups is not shown; therefore the overall assessment of the statistics was performed with a Non-Parametric Kruskal Wallis test and the post hoc tests used the robust Dunnett T3 analysis both of which do not require or assume equivalence of variance.

11.4.2.4.2 Number of perforations

Levene Statistic	df1	df2	Sig.
4.036	4	20	.015

Table 72 Levene, number of perforations

Table 72 above shows the Levene test for the 'Number' data. The Homogeneity of variances of the groups is not shown; therefore the overall assessment of the statistics was performed with a non-parametric Kruskal Wallis test and the post hoc tests used the robust Dunnett T3 analysis both of which do not require or assume equivalence of variance.

11.4.2.4.3 Size of perforation

Levene Statistic	df1	df2	Sig.
.316	4	20	.864

Table 73 Levene, size of perforations

Table 73 above shows the Levene test for the 'size' data. There is no evidence of a significant difference in homogeneity of variance between the groups; therefore ANOVA was used for the overall results and post hoc analysis was with the Bonferroni correction.

11.4.3 Data analysis

11.4.3.1 ANOVA and Kruskal Wallis test of overall significance

11.4.3.1.1 Kruskal Wallis; distance to a perforation from the central sensor

	Pressure in KPa
Chi-Square	22.020
Df	4
Asymp. Sig.	.000199

Table 74 Kruskal Wallis; distance to a perforation

Table 74 shows an overall statistical significance $p<0.001$, Kruskal Wallis test, grouping variable: distance.

11.4.3.1.2 Kruskal Wallis, number of perforations

	Pressure in KPa
Chi-Square	22.039
Df	4
Asymp. Sig.	.000197

Table 75 Kruskal Wallis, number of perforations

Table 75 shows an overall statistical significance $p<0.001$, Kruskal Wallis test, grouping variable: number of perforations.

11.4.3.1.3 ANOVA size of perforation

	Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**
Between Groups	28756.160	4	7189.040	41.165	.000
Within Groups	3492.800	20	174.640		
Total	32248.960	24			

Table 76 ANOVA size of perforation

Table 76 above shows an overall statistical significance $p<0.001$

For each variable investigated the overall analysis (by Kruskal Wallis or ANOVA) showed a significant difference between the groups. Further analysis was indicated to investigate precisely where the differences occurred.

11.4.3.2 Post hoc

11.4.3.2.1 Distance to a perforation from the central sensor, Dunnett T3

(I) Distance to pref.	(J) Distance to perf.	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower bound	Upper bound
3.00	9.00	-28.200(*)	6.391	.038	-54.63	-1.77
	15.00	-66.800(*)	4.074	.000	-81.86	-51.74
	21.00	-97.800(*)	2.983	.000	-109.53	-86.07
	35.00	-99.000(*)	4.276	.000	-114.94	-83.06
9.00	15.00	-38.600(*)	6.630	.008	-64.96	-12.24
	21.00	-69.600(*)	6.022	.001	-96.85	-42.35
	35.00	-70.800(*)	6.756	.000	-97.22	-44.38
15.00	21.00	-31.000(*)	3.467	.001	-45.19	-16.81
	35.00	-32.200(*)	4.626	.001	-49.16	-15.24
21.00	35.00	-1.200	3.701	1.000	-16.59	14.19

Table 77 Post hoc test with Dunnett T3; * denotes that the mean difference is significant at the .05 level.

11.4.3.2.2 Number of perforations, Dunnett T3

(I) Number of perfs.	(J) Number of perfs.	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Upper Bound	Lower Bound
0	1	58.000(*)	7.764	.001	29.01	86.99
	2	113.400(*)	5.028	.000	92.07	134.73
	4	157.400(*)	4.804	.000	135.44	179.36
	6	159.400(*)	5.146	.000	138.21	180.59
1	2	55.400(*)	6.456	.003	26.75	84.05
	4	99.400(*)	6.283	.000	70.06	128.74
	6	101.400(*)	6.548	.000	73.00	129.80
2	4	44.000(*)	2.117	.000	35.73	52.27
	6	46.000(*)	2.807	.000	35.66	56.34
4	6	2.000	2.383	.983	-7.62	11.62

Table 78 Post hoc test with Dunnett T3; * denotes that the mean difference is significant at the .05 level.

11.4.3.2.3 Size of perforation Bonferroni

(I) Size of perfs.	(J) Size of perfs	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Upper Bound	Lower Bound
.0	1.0	14.800	8.358	.918	-11.56	41.16
	1.5	33.800(*)	8.358	.006	7.44	60.16
	2.0	71.600(*)	8.358	.000	45.24	97.96
	3.0	90.000(*)	8.358	.000	63.64	116.36
1.0	1.5	19.000	8.358	.342	-7.36	45.36
	2.0	56.800(*)	8.358	.000	30.44	83.16
	3.0	75.200(*)	8.358	.000	48.84	101.56
1.5	2.0	37.800(*)	8.358	.002	11.44	64.16
	3.0	56.200(*)	8.358	.000	29.84	82.56
2.0	3.0	18.400	8.358	.396	-7.96	44.76

Table 79 Post hoc test with Bonferroni correction; * denotes that the mean difference is significant at the .05 level.

11.5 Summary of results

11.5.1 Summary of the results obtained before trimming the discs (chap 8 to 10 above)

Number of 2mm perforations	Mean Pressure KPa		Distance to a 2mm perforation	Mean pressure KPa		Size of Perforation	Mean Pressure KPa
No perforation	**230**		**No perforation**	**378**		**No perforation**	**297**
1	**202**		24	379		.5 mm	291
2	151		21	357		1.0 mm	280
3	137		18	341		1.5 mm	244
4	110		15	316		**2.0 mm**	**220**
6	89		12	290		2.5 mm	202
12	61		9	257		3.0 mm	204
			6	215			
			3	177			
			0	77			

Table 80 Previous results

11.5.2 Summary of the results obtained after trimming the discs

Number of 2mm perforations	Mean Pressure	Distance to 2mm perforation	Mean Pressure	Size of the perforation	Mean Pressure
No perforation	**232**	**No perforation**	**234**	**No perforation**	**252**
1	**174**	21 mm	233	1 mm	237
2	119	15 mm	202	1.5 mm	218
4	75	9 mm	163	**2 mm**	**180**
6	73	3 mm	135	3 mm	166

Table 81 New results

11.5.3. Analysis of the results when there were no perforations open on the three discs

The Table 81 above highlights in blue, three means which are the results from the three separate experiments when all the perforations on the three discs were sealed (no perforations). These means each come from five 'runs' (i.e. experiments) where the peak pressure was recorded. These results have been explored and analysed for comparison of the means using ANOVA in SPSS (Appendix 3).

No significant difference can be seen between the mean pressure generated on the 'numbers' disc and the 'distance' disc, however there is a statistically significant difference in the mean pressure generated between the 'size' disc and both the 'number' disc and the 'distance' disc ($P<0.05$) (see Appendix 3).

11.5.4. Analysis of the results with one 2mm perforation at 10 mm from the sensor

The Table 81 above highlights in red, two means which are the results from the two separate experiments when there was one 2mm perforation 10mm from the pressure sensor. These means each come from five 'runs' (i.e. experiments) where the peak pressure was recorded. These results have been explored and analysed for comparison of the means using independent t-test in SPSS (Appendix 4).

There is a statistically significant difference in the mean pressure generated between the 'size' disc and the 'number' disc ($p<0.05$) (see Appendix 4).

11.6 Discussion

The conclusions of chapters 8 to 10 are confirmed by these repeated experiments. That is to say in these in-vitro experiments the increase in the size, and the number of perforations decreases the pressure of impression and an increase in the distance to a perforation increases the pressure of an impression. The aim of the experiments of this chapter was to identify a feasible hypothesis for the differences highlighted in the introduction (11.1 above) and test that hypothesis. The hypothesis tested was that the differences in the construction of the lower brass discs had resulted in the recorded differences in the recorded peak pressure between the three studies. To test the hypothesis the discs were made as near identical as was possible with the engineering equipment and technical skill available at Leeds Dental Institute.

The results outlined above show a greater degree of inter experiment consistency after the lower 'impression tray' discs had each been machined to similar thicknesses and given similar supporting 'legs'. The machining of the original discs reduced the thickness of each disc and the width of the three 'leg' supports on each disc. The machining of each disc may also have reduced the surface roughness of each disc.

The results do not show complete conformity of results between the discs. While the 'numbers' and 'distance' discs give similar results (see section 11.5.3 above) the 'size' disc does not (see section 11.5.3 and 11.5.4 above). Although the re-machining of the 'size' disc has reduced the mean of the readings from the original 'size' disc experiment ($p<0.05$), it does not reduce the mean pressures to be similar to the other discs when similar circumstances occur.

This partial success in eliminating the differences between the discs was frustrating but illuminating. It is instructive to note that minor differences between the experimental conditions prevalent in these in-vitro experiments can affect the recorded pressures. It did not prove possible to eliminate uncontrolled variables. It would seem likely that any vitro experiment would have such variables, unknown and possibly uncontrolled.

In 1964 Douglas et al carried out ground breaking in-vivo experiments investigating pressure within impressions. In his discussion in his paper he says 'the behaviour of {impression} pastes should be investigated in the laboratory.' At the

time this was good advice but the results from these in-vitro experiments and other in-vitro studies (Komiyama et al Masri and Ahmad) suggest this advice should be re-considered; if further studies on impression pressure are to be clinically meaningful it is now time to go back to intra oral measurements. It would seem unlikely that in-vitro experiments can quantify the exact in-vivo pressure of impressions; the in-vitro work only shows the trends that *may* occur in-vivo (or only identify variables that *may* have an effect in-vivo). The work in this chapter reinforces the view that the inconsistencies in the literature on in-vitro impression pressure may be caused by unknown confounding variables.

On a more positive note the clear trends that size, number and position of perforations have an effect on the pressure of an impression is consistent across these experiments.

11.7 Conclusions

Within the limitations of these in-vitro experiments the size, number and relative position of impression tray perforations affect the pressure within impressions.

In-vitro experiments only quantify the effect of variables in the very specific in-vitro conditions prevalent during the experiment.

Chapter 12
Category of silicone; viscosity and speed of set

12.1 Background

The paper of Frank from 1969 identified differences in the pressure of impressions when different impression materials were used (in-vitro). The materials used were very different in composition and chemistry; they had different rates of set, different surface tensions and differences in affinity for the (in-vitro) model used by Frank in his experiments. Perhaps the most significant difference between the impression materials used was the viscosity of the materials. The reported results place the impression materials in an order which clinical experience would suggest is the order of their increasing viscosity.

While it would be of interest to investigate the pressures created in-vitro with all clinically available impression materials, it is clearly beyond the scope of this Thesis. As we have seen in chapter 11 above, unknown and uncontrolled variables confound in-vitro experiments. When the chemistry of the materials is also variable, further physical differences occur between materials; in particular, the varying affinity of different materials for moist oral mucosa may make any dry in-vitro experiments irrelevant to the clinical situation.

This Thesis has as it central aim the investigation of a specific impression technique used in Part IV for a randomised controlled clinical trial. The clinical trial in Part IV used a particular brand (Express from 3M) of polyvinylsiloxane (silicone) as the impression material of choice (Hyde 2003 and Hyde 2010). In these circumstances it was reasonable to limit the investigation of Part II and Part III of this Thesis to that brand of impression material. Therefore, all the in-vitro experiments of part II and III of this Thesis used the brand of polyvinylsiloxane material used in Part IV of this Thesis, namely Express 3M. The use of a single brand of impression material (Express 3M) reduces variables for all the experiments but also allows an investigation of differences introduced by the particular type or 'category' of material within that brand.

The broader problems with the relevance of in-vitro testing to the clinical situation will still apply in this study. However variables are reduced by keeping to

one brand of impression material. The chemistry of a brand is likely to be similar for all categories (of viscosity and speed of set) of the single brand. Similarly the chemical affinity of the branded polyvinylsiloxane for the impressed object (moist oral mucosa for Part IV, brass for Part II, acrylic for Part III) may be similar for all viscosities of the material. By keeping to a single brand and so a similar chemistry of the tested materials, it is anticipated (or perhaps hoped) that ranking (but not the magnitude) of particular materials in-vitro are likely to reflect the in-vivo situation (but see discussion section 11.6).

12.2 Statement of problem

Most dental materials manufacturers produce a range of viscosities and a choice of the speed of set of their particular brand of impression materials. The impression materials are usually said to be 'light bodied', 'medium bodied', 'heavy bodied' or 'putty'. These terms describe the viscosity of the materials; although there does not appear to be any standard range of viscosity for these descriptive terms. In addition there is usually a choice of 'regular set' or 'fast set'; these terms describe the speed of the chemical setting reaction. These are different 'catalogue types' or 'categories' of an impression brand. The differences between these categories of viscosity and speed of set have potential to change the impression pressure.

In part II of this Thesis we have used light bodied, regular set Express from 3M as the standard material. The clinical trial in Part IV used medium bodied, regular set Express and light bodied, regular set Express both from 3M ESPE. An investigation was indicated to investigate the effect on pressure of these different types or 'categories' of the same brand of impression material on impression pressure.

12.3 Aim and hypothesis

12.3.1 Aim

The aim of the experiment was to investigate the effect of the category (as defined by viscosity and speed of set) of the same brand of impression material, on the pressure produced by a standard in-vitro impression.

12.3.2 Hypothesis

The Null Hypothesis was that impression pressure is unaffected by the category of the impression material used. The alternative hypothesis was that the impression pressure was affected by the category of the impression material.

12.4 Materials and method

Impression material was placed between two brass discs on a Universal Testing Machine. The arrangement of the discs was similar to the set up for the velocity experiment (Chapter 5). At the centre of the upper disc, a 2-mm-diameter hole led to an analogue pressure transducer (PXM209-010G10V; Omega Engineering, Inc, Stamford, Conn). The pressure transducer was directly connected to the brass disc via a one-quarter-inch British standard pipe (BSP) screw thread sealed with plumber's tape. The connection to the pressure transducer was filled with water. The discs were 15 mm apart at the start of the experiment and were set to approximate at 2mm/sec. Approximation of the discs was started 20 seconds after the start of mixing of the impression material. The peak pressure within the impression was recorded. Impression materials of three different catalogue types or 'categories' were tested. They were; 'medium bodied, regular set'; 'light bodied, fast set'; and 'light bodied, regular set' of Express from 3M ESPE. For each impression material, five individual experiments were performed.

Variable	Setting for viscosity experiment
Velocity of approximation	120 mm/min
Delay in seating impression	20 seconds
Number of perforations	None
Border adaptation	None
Diameter of discs	70mm
Position of pressure sensor	centre of disc
Height of stops; space beneath the tray	0.5mm

Table 82 default settings

12.5 Statistical analysis

12.5.1 Raw data

Impression material	Pressure KPa
light bodied regular set	426
light bodied regular set	437
light bodied regular set	423
light bodied regular set	435
light bodied regular set	451
light bodied fast set	486
light bodied fast set	490
light bodied fast set	502
light bodied fast set	501
light bodied fast set	458
medium bodied	526
medium bodied	535
medium bodied	547
medium bodied	562
medium bodied	536

Table 83 Raw data

12.5.2 Data exploration

12.5.2.1 Descriptives

Peak pressure in kilopascals

	N	Mean	Std. Dev	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
Light, regular set	5	434.4	10.991	4.915	420.75	448.05	423	451
Light, fast set	5	487.4	17.827	7.972	465.26	509.54	458	502
medium bodied	5	541.2	13.809	6.176	524.05	558.35	526	562
Total	15	487.7	47.081	12.156	461.59	513.74	423	562

Table 84 Descriptives

12.5.2.2. Shapiro-Wilk

	Category of impression material	Shapiro-Wilk		
		Statistic	Df	Sig.
Peak pressure in kilopascals	Light, regular set	.936	5	.637
	Light fast set	.850	5	.193
	medium bodied	.943	5	.689

Table 85 Shapiro-Wilk

Shapiro-Wilks tests shows that data is normally distributed at the 0.05 level (Table 85).

12.5.2.3. Box plot

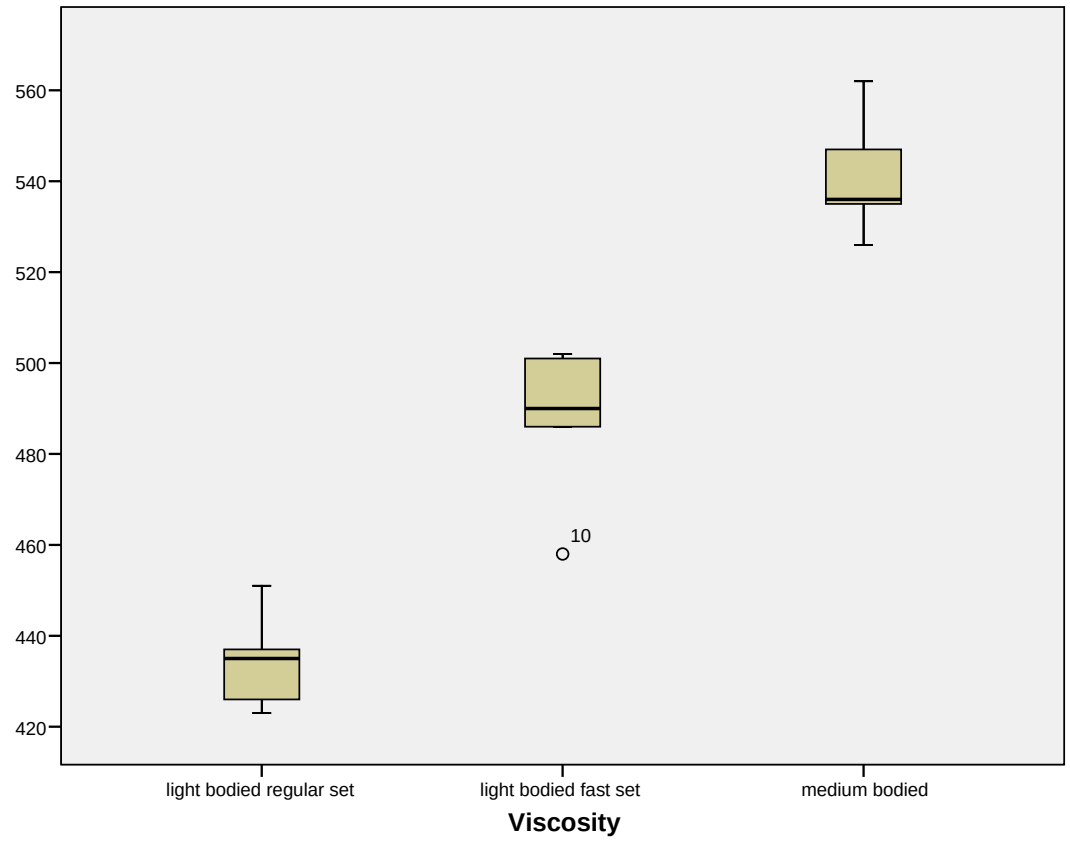


Figure 61 Box plot of the results; category of material against pressure

12.5.2.4 Levene test

Levene's test of equality of error variance, tests that the Null Hypothesis that the error variance of the dependent variable is equal across groups.

Levene Statistic	df1	df2	Sig.
.337	2	12	.721

Table 86 Levene

The Levene statistic shows no violations of the homogeneity of variance assumption since the p value greater than 0.05 therefore ANOVA was used for the overall results and post hoc tests used the Bonferroni corrected p values for multiple testing.

12.5.3 Data analysis

12.5.3.1 ANOVA

Peak pressure in kilopascals

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	28516.133	2	14258.067	67.971	.000
Within Groups	2517.200	12	209.767		
Total	31033.333	14			

Table 87 ANOVA output

Overall ANOVA analysis showed a significant difference between the groups ($p<0.001$). Further analysis was indicated to investigate precisely where the differences occurred.

12.5.3.2 Post hoc analysis

(I) Category of material	(J) Category of material	Mean Diff. (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Upper Bound	Lower Bound
light reg. set	Light, fast set	-53.0(*)	9.160	.000	-78.46	-27.54
light reg. set	Medium	-106.8(*)	9.160	.000	-132.26	-81.34
Light, fast set	Medium	-53.8(*)	9.160	.000	-79.26	-28.34

Table 88 Post hoc Bonferroni; * denotes that the mean difference is significant at the .05 level.

12.6 Summary of results.

Viscosity	Mean Pressure KPa	SD
light bodied regular set	434.40 *	10.991
light bodied fast set	487.40 *	17.827
medium bodied	541.20 *	13.809

Table 89 Summary of results; * denotes that the mean difference is significant at the .05 level.

12.7 Discussion

The results show statistically significant differences ($p<0.05$) in impression pressure between the three different types of silicone impression material used in this in-vitro study. The Null Hypothesis is therefore rejected; in rejecting the Null Hypothesis, the alternative hypothesis is proposed that the category of the impression material affects impression pressure. Specifically it is suggested that increasing either the viscosity or the speed of set of this brand of impression material increases the impression pressure.

The results for the increase in pressure with the increase in viscosity are as expected and most clinicians may be expected to know this intuitively. However the increased pressure with the 'fast set' material of the same viscosity category was not expected. The effect size was large in these in-vitro experiments and there is therefore potential for this to be clinically significant.

Before this experiment was performed the result expected by many clinicians, would have been that both light bodied materials would have a similar impression pressure and the medium bodied material to have a higher pressure. While the experiment confirms the expected result for the viscosity of the material, the significantly higher pressure for the faster setting material is an important finding.

12.8 Clinical implications.

The results of this in-vitro experiment confirm that increasing the viscosity of an impression material increases impression pressure. It is reassuring to know that a clinician wishing to change the pressure of impression may choose a suitable viscosity of impression material.

The choice of speed of set of the impression material also changed the pressure of an impression in this in-vitro experiment. Clinicians should be aware of this unexpected issue.

12.9 Conclusion.

In this in-vitro experiment increasing the viscosity of an impression material and increasing the speed of set of an impression material increased the pressure of impression.

12.10 Further investigation

These results are achieved at under standardised conditions. Altering the standard conditions is likely to change the pressures involved. Flow rate and viscosity are related. It is worth considering if an increase or decrease in flow rate of the impression material, brought about by an increase in the velocity of approximation may change the ranking order of the categories of impression material. Does variation in velocity of approximation vary the results of pressure ranking order for these impression materials? Further investigation was indicated.

Chapter 13
Category of silicone with velocity of approximation

13.1 Background

'Sheer thinning' and 'sheer thickening' are terms which describe the changing viscosity of a fluid at different rates of sheer. This happens in complex (also called Non- Newtonian) liquids. With sheer thickening the liquid becomes more viscous with a higher rate of sheer, and with sheer thinning the opposite. In such fluids a constant coefficient of viscosity cannot be given. It is said to be a common property among polymers. The silicone materials used clinically in dentistry may be susceptible to viscosity changes with different rates of sheer; this phenomenon may be independent of but complicated by the setting reaction of the impression material.

If such a material is made to flow faster, for example with different velocities of approximation, and so different rates of sheer, the viscosity of the liquid may change. Such a change in viscosity may affect the pressure of a dental impression. In chapter 12 above the differences in the pressure of different categories of a brand of impression material were only compared at a constant velocity of approximation.

The focus of this Thesis is clinical; material science is fascinating and useful in gaining understanding, but the clinical effects are the prime interest here. Further investigations are limited to the potential clinically relevant effects to impression pressure. If they are Non-Newtonian the relative viscosity of impression materials may change with rate of sheer. Clinically this has the potential to alter the ranking order of the materials when it is defined by the viscosity (and so pressure produced) at different rates of sheer. This would be unfortunate since it would make the properties of the impression material unpredictable.

13.2 Statement of problem

The previous chapter ranked the categories of the impression material by the pressure they created during a standard in-vitro impression at a single velocity of approximation. A ranking order can be given to the materials; that material demonstrating the highest pressure of impression can be ranked 1, the material demonstrating the lowest pressure of impression ranked 3, and the other ranked 2.

The research question for this chapter is, ‘does changing the velocity of approximation change the ranking order of the categories of impression material’. The Null Hypothesis is that changing the velocity of approximation does not change the ranking order of the materials. The alternative hypothesis is that changing the velocity of approximation does change the ranking order of the impressions.

The clinical significance of the experiment is that if ranking order changed at different velocities, the relative pressures from each category of material would be unpredictable in clinical use.

13.3 Aim

The aim of the experiment was to investigate the changes in pressure within each category of impression material as the velocity of approximation changed.

13.4 Materials and method

Standard set up of the experimental equipment was used for this experiment. The three materials used in the previous chapter were tested with the standard equipment under standardized conditions (see Table 90 below). Each of the three materials was tested at 7 different velocities of approximation (as used in chapter 5 above). The output data from the experiments was entered into an SPSS spreadsheet and explored to deduce the suitability of further statistical analysis.

13.5 Results

13.5.1 Raw data

Light bodied fast set		Medium bodied reg set		Light bodied reg set	
Velocity	**Pressure**	**Velocity**	**Pressure**	**Velocity**	**Pressure**
45	241	45	264	45	214
45	247	45	272	45	244
45	239	45	230	45	212
45	229	45	263	45	201
45	242	45	240	45	222
60	258	60	317	60	278
60	262	60	297	60	270
60	282	60	317	60	278
60	273	60	325	60	258
60	295	60	320	60	260
75	345	75	380	75	297
75	340	75	398	75	304
75	355	75	371	75	309
75	363	75	379	75	311
75	333	75	379	75	299
90	390	90	427	90	393
90	439	90	425	90	380
90	433	90	437	90	349
90	432	90	431	90	340
90	429	90	429	90	352
120	486	120	526	120	426
120	490	120	535	120	437
120	502	120	547	120	423
120	501	120	562	120	435
120	458	120	536	120	451
150	550	150	617	150	470
150	532	150	614	150	464
150	574	150	616	150	468
150	521	150	626	150	464
150	558	150	630	150	491
180	602	180	733	180	550
180	629	180	717	180	538
180	581	180	702	180	537
180	662	180	745	180	541
180	646	180	730	180	560

Table 90 Raw data

13.5.2 Data exploration

13.5.2.1 Descriptives

Material	Velocity	N	Pressure KPa		95% Confidence Interval for Mean	
			Mean	S.D.	Lower Bound	Upper Bound
Light bodied fast set	45.00	5	239.6	6.61816	231.3825	247.8175
	60.00	5	274.0	15.04992	255.3131	292.6869
	75.00	5	347.2	11.92476	332.3934	362.0066
	90.00	5	424.6	19.679939	400.1641	449.0359
	120.00	5	487.4	17.82695	465.2649	509.5351
	150.00	5	547.0	20.97618	520.9546	573.0454
	180.00	5	624.0	32.73377	583.3557	664.6443
Medium bodied regular set	45.00	5	253.8	17.86617	231.6162	275.9838
	60.00	5	315.2	10.68644	301.9310	328.4690
	75.00	5	381.4	9.96494	369.0269	393.7731
	90.00	5	429.8	4.60435	424.0829	435.5171
	120.00	5	541.2	13.80942	524.0533	558.3467
	150.00	5	620.6	6.98570	611.9261	629.2739
	180.00	5	725.4	16.44080	704.9860	745.8140
Light bodied regular set	45.00	5	218.6	16.05615	198.6637	238.5363
	60.00	5	268.8	9.54987	256.9423	280.6577
	75.00	5	304.0	6.08276	296.4473	311.5527
	90.00	5	362.8	22.55438	334.7950	390.8050
	120.00	5	434.4	10.99091	420.7530	448.0470
	150.00	5	471.4	11.26055	457.4182	485.3818
	180.00	5	545.2	9.73139	533.1169	557.2831

Table 91 Descriptives

In the descriptive Table 91 above; within each material category, there is no overlap in the 95% Confidence Intervals of the means of the pressure produced by the 7 different velocities used.

13.5.2.2. Shapiro-Wilk test of normality

Material Category	Velocity of approximation mm/min	Shapiro-Wilk		
		Statistic	df	Sig.
Light bodied fast set	45.00	.919	5	.522
	60.00	.955	5	.775
	75.00	.976	5	.911
	90.00	.726	5	.017
	120.00	.850	5	.193
	150.00	.979	5	.927
	180.00	.969	5	.871
Medium bodied regular	45.00	.890	5	.356
	60.00	.818	5	.113
	75.00	.833	5	.146
	90.00	.943	5	.685
	120.00	.943	5	.689
	150.00	.872	5	.275
	180.00	.973	5	.897
Light bodied regular	45.00	.932	5	.607
	60.00	.853	5	.203
	75.00	.928	5	.582
	90.00	.896	5	.390
	120.00	.936	5	.637
	150.00	.742	5	.025
	180.00	.873	5	.278

Table 92 Shapiro-Wilk

The results of the Shapiro-Wilk test show no significant deviation from a normal distribution except for the results of light bodied regular set silicone at 150mm/min and light bodied fast set silicone at 90mm/min. Both of these data sets

have outliers (see box plots below); the outliers were eliminated for the figures and the Shapiro-Wilk test re-run. The results of eliminating the outliers are shown in Table 93 below.

	Shapiro-Wilk		
	Statistic	**df**	**Sig.**
light bodied fast set 90mm/min no outlier	.939	4	.650
light bodied reg set 150mm/min no outlier	.732	4	.026

Table 93 Shapiro-Wilk without outliers

These results show that there remains a significant difference at the 0.05 level from a normal distribution with the results of the light bodied, regular set silicone approximated at 150mm.min even when the outlier is eliminated. This is disappointing but not unexpected given the 21 categories and the test level of 0.05 (1 in 20).

13.5.2.3 Box plots

13.5.2.3.1 Light bodied regular set

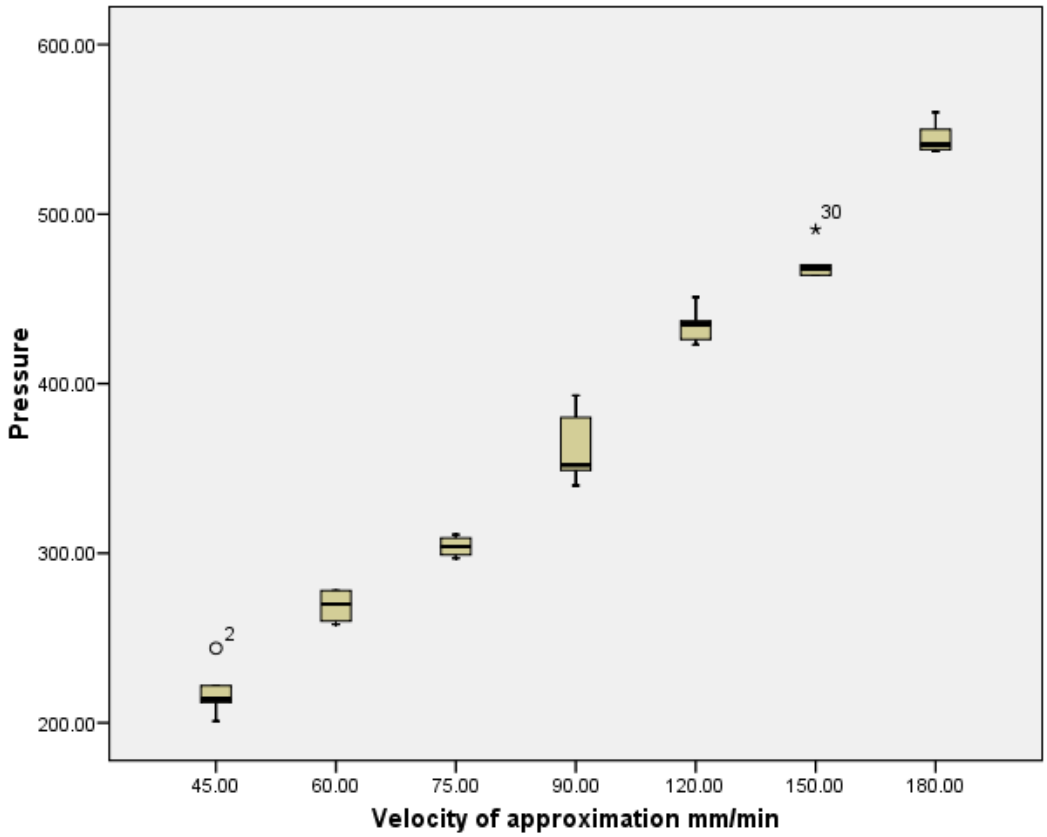


Figure 62 Box plot of results for the light bodied regular set silicone; velocity against pressure

13.5.2.3.2 Medium bodied regular set

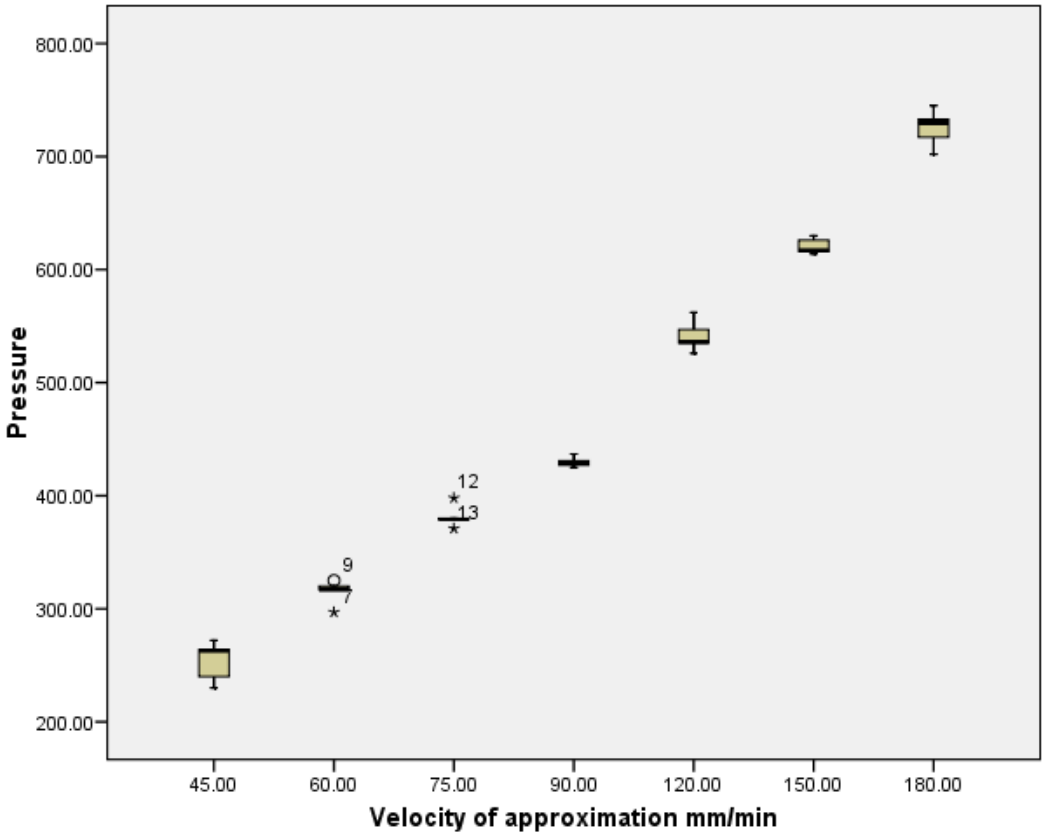


Figure 63 Box plot of results for the medium bodied regular set silicone; velocity against pressure

13.5.2.3.3 Light bodied fast set

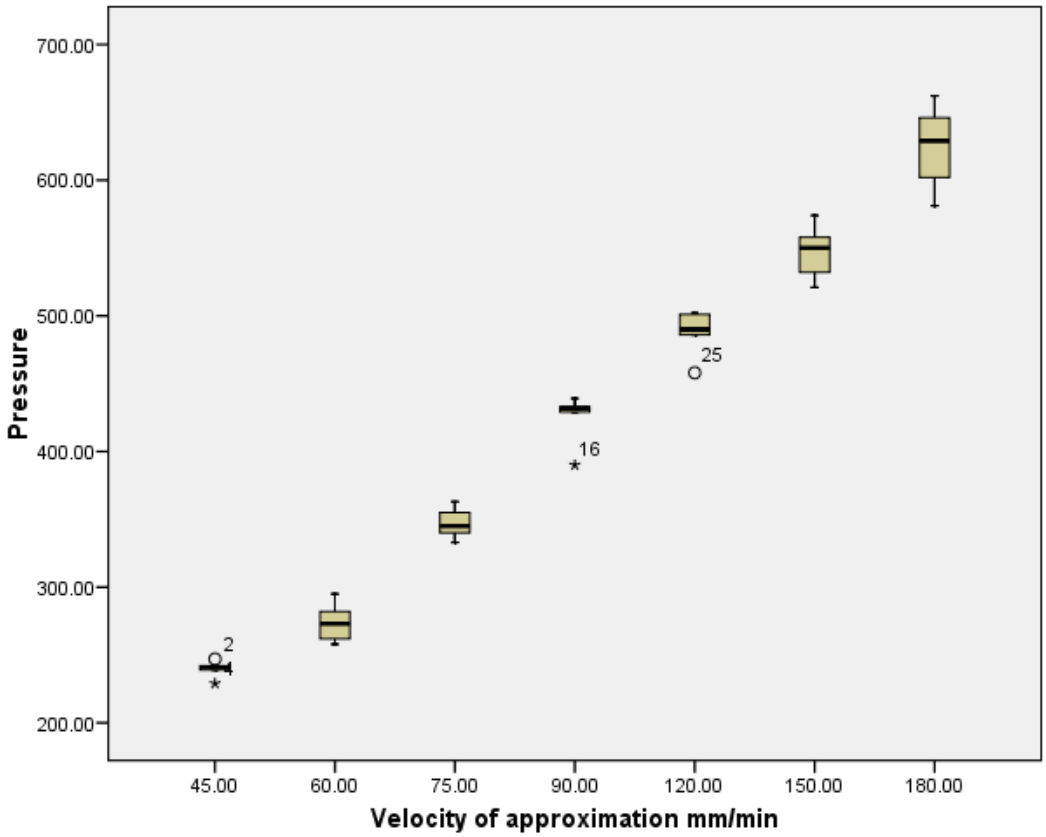


Figure 64 Box plot of results for the light bodied fast set silicone; velocity against pressure

13.5.3 Data analysis

Data analysis is by Factorial ANOVA. 'A factorial ANOVA has two or more categorical independent variables (either with or without the interactions) and a single normally distributed interval dependent variable.' Quoted from: Introduction to SAS UCLA: Academic Technology Services, Statistical Consulting Group. Accessed October 10 2010 from: http://www.ats.ucla.edu/stat/sas/notes2/.

SPSS output of data analysis is in Table 94 below:

Source	Type III Sum of Squares	Df	Mean Square	F	Sig.
Corrected Model	2042671.714(a)	20	102133.586	435.069	.000
Intercept	18506883.086	1	18506883.086	78835.76	.000
Velocity	1838359.848	6	306393.308	1305.177	.000
Category	156637.086	2	78318.543	333.622	.000
Velocity * Category	47674.781	12	3972.898	16.924	.000
Error	19719.200	84	234.752		
Total	20569274.000	105			
Corrected Total	2062390.914	104			

Table 94 Tests of between-subjects effects, dependent variable: pressure in KPa 'a'
R Squared = .990 (Adjusted R Squared = .988)

These results indicate that the overall model is statistically significant ($F = 435.069$, $p < 0.001$). The variables velocity and category are also independently statistically significant ($F = 1305.177$, $p < 0.001$ and $F = 333.622$, $p < 0.001$, respectively). The interaction between velocity and category is statistically significant ($F = 16.924$, $p < 0.001$). These results show the different velocities produce significantly different pressures, even when ignoring the material (i.e. when the mean values of the different material categories are used). Similarly the different materials produce significantly different pressures even when ignoring the velocity. Having a significant interaction also shows that the effect of velocity alters with category and vice versa.

The significant value of the interaction of velocity and category requires further investigation. Pairwise comparisons were used to determine where the differences lay. First the comparison was made of the different velocities with each

of the other velocities within each category of material. The resultant Pairwise table is large and therefore it is appended to the Thesis (Appendix 5). Suffice to say here that every comparison produced a significant result at the 0.05 level.

The second Pairwise comparison is between categories of material at each of the velocities used. The results are shown below (see Table 95). Differences could not be detected between just three sets of results: medium-bodied-regular-set silicone and light-bodied-fast-set at both 45 and 90 mm per minute; and the two light-bodied silicones at 60mm per minute. All other results show a significant difference.

On the graph of the means (Figure 65) below, the three non significant results are the three points where the lines approach (but do not cross) each other.

Dependent variable: pressure in KPa

Vel. mm per min	(I) Category	(J) Category	Mean Diff (I-J)	Std. Err.	Sig.	95% Confidence Interval for Difference(a)	
						Lower Bound	Upper Bound
45	Medium	Light fast	14.2	9.69	.147	-5.07	33.47
	Medium	Light reg	35.2(*)	9.69	.000	15.93	54.47
	Light fast	Light reg	21.0(*)	9.69	.033	1.73	40.27
60	Medium	Light fast	41.2(*)	9.69	.000	21.93	60.47
	Medium	Light reg	46.4(*)	9.69	.000	27.13	65.67
	Light fast	Light reg	5.20	9.69	.593	-14.07	24.47
75	Medium	Light fast	34.2(*)	9.69	.001	14.93	53.47
	Medium	Light reg	77.4(*)	9.69	.000	58.13	96.67
	Light fast	Light reg	43.2(*)	9.69	.000	23.93	62.47
90	Medium	Light fast	5.2	9.69	.593	-14.07	24.47
	Medium	Light reg	67.0(*)	9.69	.000	47.73	86.27
	Light fast	Light reg	61.8(*)	9.69	.000	42.53	81.07
120	Medium	Light fast	53.8(*)	9.69	.000	34.53	73.07
	Medium	Light reg	106.8(*	9.69	.000	87.53	126.07
	Light fast	Light reg	53.0(*)	9.69	.000	33.73	72.27
150	Medium	Light fast	73.6(*)	9.69	.000	54.33	92.87
	Medium	Light reg	149.2(*	9.69	.000	129.93	168.47
	Light fast	Light reg	75.6(*)	9.69	.000	56.33	94.87
180	Medium	Light fast	101.4(*	9.69	.000	82.13	120.67
	Medium	Light reg	180.2(*	9.69	.000	160.93	199.47
	Light fast	Light reg	78.8(*)	9.69	.000	59.53	98.07

Table 95 Pairwise comparisons of the results. Based on estimated marginal means; * denotes that the mean difference is significant at the 0.05 level. a Adjustments for multiple comparisons were carried with Least Significant Difference (LSD, equivalent to no adjustments)

In the Table 95 above Least Significant Difference is used to calculate the significance of multiple comparisons at the 0.05 level. A more robust analysis may be had by applying Bonferroni correction on these p values. After applying a

Bonferroni correction for multiple comparisons, the results still demonstrate significance at the 0.05 level.

13.6 Summary of results.

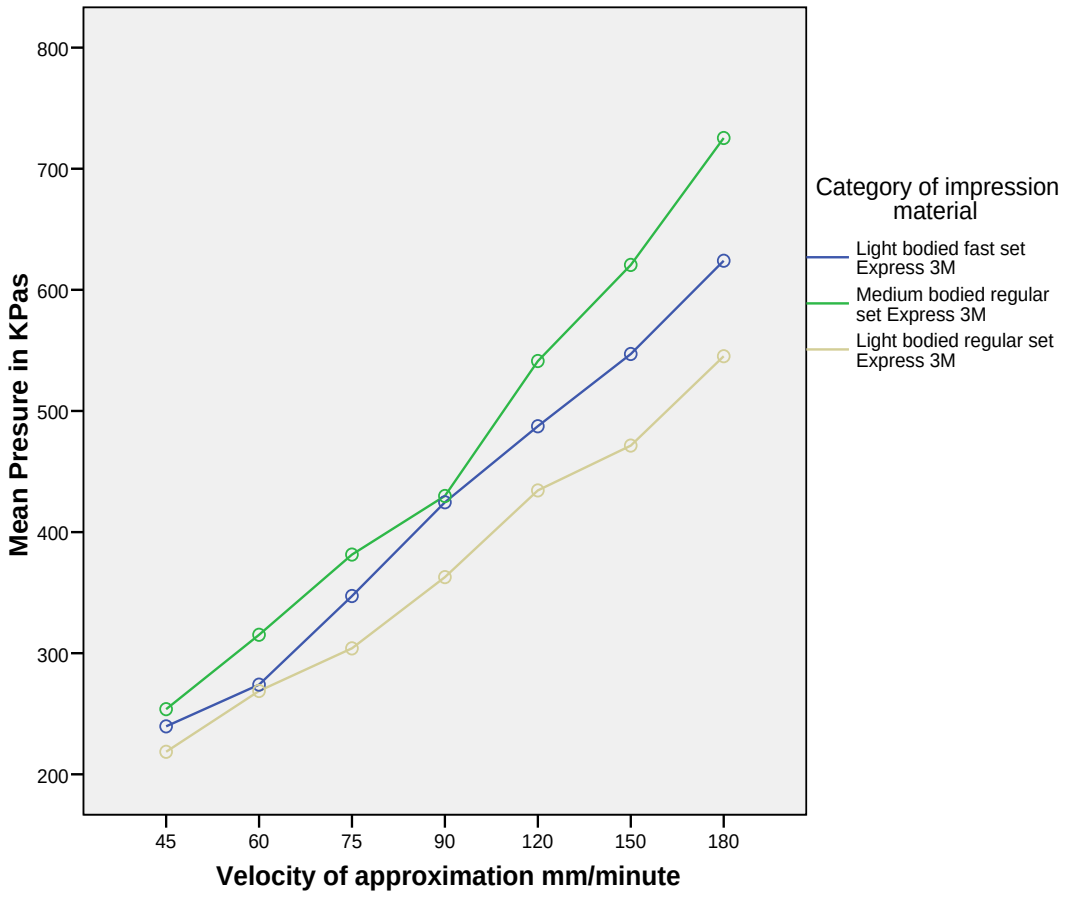


Figure 65 graph of means

The graph above illustrates the results; the predictable response of each impression category to different velocities of approximation is seen. The analysis of the results with factorial ANOVA confirms the statistical significance of the results.

At any given velocity of approximation, the medium bodied material produces the highest pressure and the light bodied regular set material the lowest pressure.

13.7 Conclusions.

1. In this in-vitro experiment both the category of impression material and the velocity of approximation produce a significant effect on the outcome pressure.

2. The materials behaved in a predictable way; the ranking order (as defined by pressure produced) did not change with velocity of approximation. The Null Hypothesis is not disproved. The alternative hypothesis that the different velocity of approximation changes the ranking order of the pressure generated by the impressions is rejected.

13.8 Clinical implications.

Since the velocity of approximation does not change the ranking order of the materials, the materials can be said to behave in a predictable way. For example medium bodied silicone can be expected to produce a higher impression pressure (no matter what the speed of approximation) than either light bodied fast set silicone or light bodied regular set silicone. Similarly light bodied regular set silicone can be expected to produce a lower pressure of impression (no matter what the speed of approximation) than either medium bodied silicone or light bodied fast set silicone.

Clinically it is useful to know that the materials behaved in this predictable manner.

Chapter 14
Space with no border adaptation of the impression tray

14.1 Background

Frank (1969) had shown that 'space' beneath an impression tray reduced impression pressure in his in-vitro experiments. Masri found that the design of the impression tray did not significantly affect the pressure in his in-vitro experiments; he says 'In this study, we believe that the tray design was not clinically important in controlling the pressure produced, contrary to Frank's findings' (Masri 2002).

14.2 Statement of problem

There is a contradiction in the literature on the importance of tray design on impression pressure. An experiment to investigate the effect of space beneath a tray was indicated.

14.3 Aim and hypothesis

14.3.1 Aim

The aim of this study was to investigate in-vitro the effect of the space beneath the impression tray on the pressure of an impression.

14.3.2 Hypothesis

The Null Hypothesis was that the space beneath an impression tray would not affect the pressure of impression. The alternative hypothesis was that the space beneath an impression tray would affect the pressure of impression.

14.4 Materials and method

Impression material was placed between two brass discs on a Universal Testing Machine. The arrangement of the discs was similar to the set up for the velocity experiment (Chapter 5). The disc used for the 'impression tray' is shown above (Figure 3 in Part II Section 1.3 above). At the centre of the upper disc, a 2-mm-diameter hole led to an analogue pressure transducer (PXM209-010G10V; Omega Engineering, Inc, Stamford, Conn). The pressure transducer was directly connected to the brass disc via a one-quarter-inch British standard pipe (BSP) screw thread sealed with plumber's tape. The connection to the pressure transducer was filled with water. The discs were 15 mm apart at the start of the experiment and

were set to approximate at 2mm/sec. Approximation of the discs was started at 20 seconds after the start of mixing of the impression material. The peak pressure within the impression was recorded. The space beneath the impression tray was determined by the use of metal ‘spacer’ or ‘stops’. The approximation of the discs was stopped at four different heights, 0.5mm, 1mm, 1.5mm and 2mm. At each height, five experiments were performed. The peak pressure from each experiment was recorded for analysis. Statistical analysis was determined by the Levene test homogeneity of the dependant (ANOVA and Bonferroni if there was homogeneity, Kruskal Wallis and Dunnett T3 if not).

Variable	Setting for space experiment
Velocity of approximation	120 mm/min
Delay in seating impression	20 seconds
Number of perforations	None
Border adaptation	None
Diameter of discs	70mm
Position of pressure sensor	centre of disc
Category of impression material	light bodied, reg. set Express, 3M ESPE

Table 96 default settings

14.5 Results

14.5.1 Raw data

Nominal Space (mm)	Pressure KPa
0.5	384
0.5	367
0.5	359
0.5	362
0.5	352
1	100
1	102
1	104
1	108
1	94
1.5	48
1.5	50
1.5	49
1.5	45
1.5	46
2	27
2	26
2	28
2	24
2	26

Table 97 Raw data

14.5.2 Data exploration

14.5.2.1 Descriptives

Pressure in KPa

Nom. Space mm	N	Mean	Std. Dev.	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
.5	5	364.80	12.029	5.380	349.86	379.74	352	384
1.0	5	101.60	5.177	2.315	95.17	108.03	94	108
1.5	5	47.60	2.074	.927	45.03	50.17	45	50
2.0	5	26.20	1.483	.663	24.36	28.04	24	28
Total	20	135.05	139.116	31.107	69.94	200.16	24	384

14.5.2.2. Shapiro-Wilk

	Nominal Space in mm	Shapiro-Wilks		
		Statistic	Df	Sig.
Pressure in KPa	0.5	.930	5	.595
	1.0	.984	5	.955
	1.5	.952	5	.754
	2.0	.956	5	.777

Table 99 Shapiro-Wilk

Shapiro-Wilk test did not show a significance deviation from a normal distribution.

14.5.2.3. Box plot

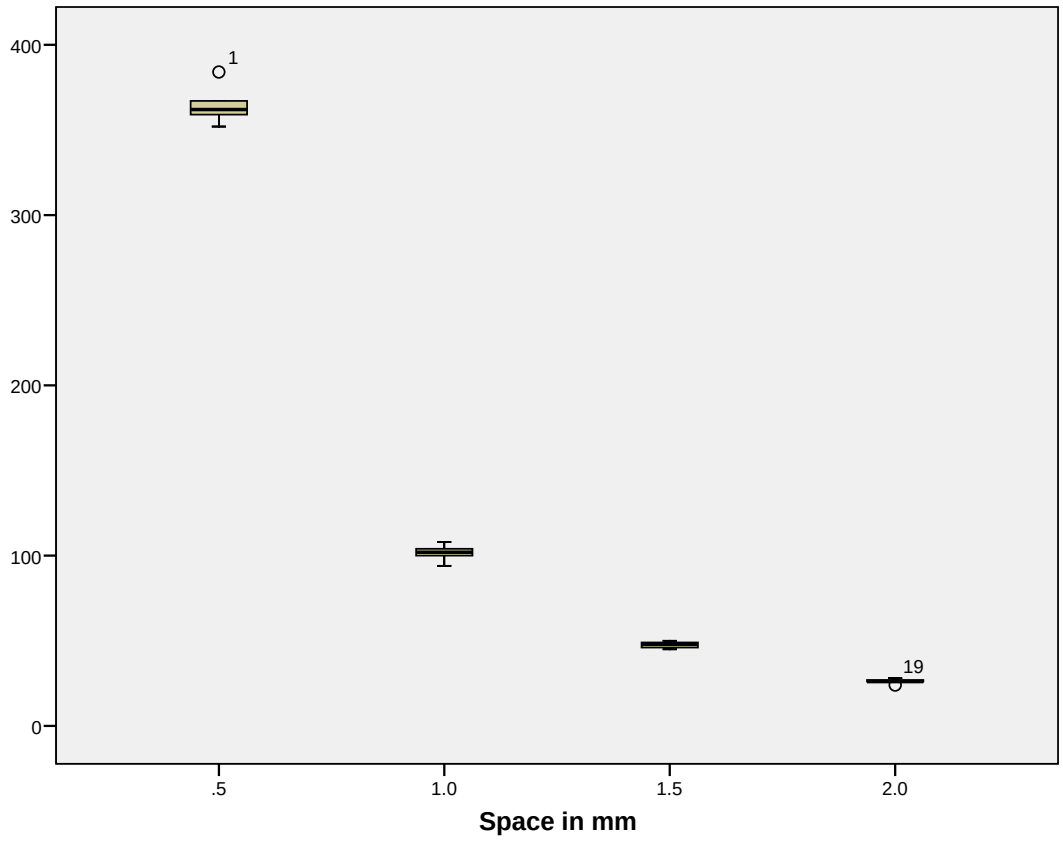


Figure 66 Box plot of results space under the impression tray against pressure

14.5.2.4 Levene test

Levene's test of equality of error variance, tests that the Null Hypothesis that the error variance of the dependent variable is equal across groups.

Pressure in KPa

Levene Statistic	df1	df2	Sig.
3.588	3	16	.037

Table 100 Levene test

Table 100 The Levene test was statistically significant at the 0.05 level.

The Homogeneity of variances of the groups is not shown; therefore the overall assessment of the statistics was performed with a Non-Parametric Kruskal Wallis test and the post hoc tests used the robust Dunnett T3 analysis; both of which do not require or assume equivalence of variance.

14.5.3 Data analysis

14.5.3.1 Kruskal Wallis

	Pressure in KPa
Chi-Square	14.296
Df	1
Asymp. Sig.	.000

Table 101 Kruskal Wallis test; grouping variable, space in mm

The between group analysis Kruskal Wallis demonstrates a statistically significant difference ($p < 0.001$). Further analysis was indicated to investigate precisely where the differences occurred.

14.5.3.2 Post hoc

Dependent variable: pressure in KPa Dunnett T3

(I) Nominal Space in mm	(J) Space in mm	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					lower bound	upper bound
.5	1.0	263.200(*)	5.857	.000	240.95	285.45
	1.5	317.200(*)	5.459	.000	294.07	340.33
	2.0	338.600(*)	5.420	.000	315.30	361.90
1.0	1.5	54.000(*)	2.494	.000	44.40	63.60
	2.0	75.400(*)	2.408	.000	65.64	85.16
1.5	2.0	21.400(*)	1.140	.000	17.46	25.34

Table 102 Post hoc Dunnett's T3; * denotes that the mean difference is significant at the .05 level.

Dunnett T3 post hoc analysis demonstrates a statistically significant difference between all the groups ($p<0.001$).

14.6 Summary of results.

Space mm	Mean	Std. Deviation
.5	364.80 (*)	12.029
1.0	101.60 (*)	5.177
1.5	47.60 (*)	2.074
2.0	26.20 (*)	1.483

Table 103 Summary statistics; * denotes that the mean difference is significant at the .05 level.

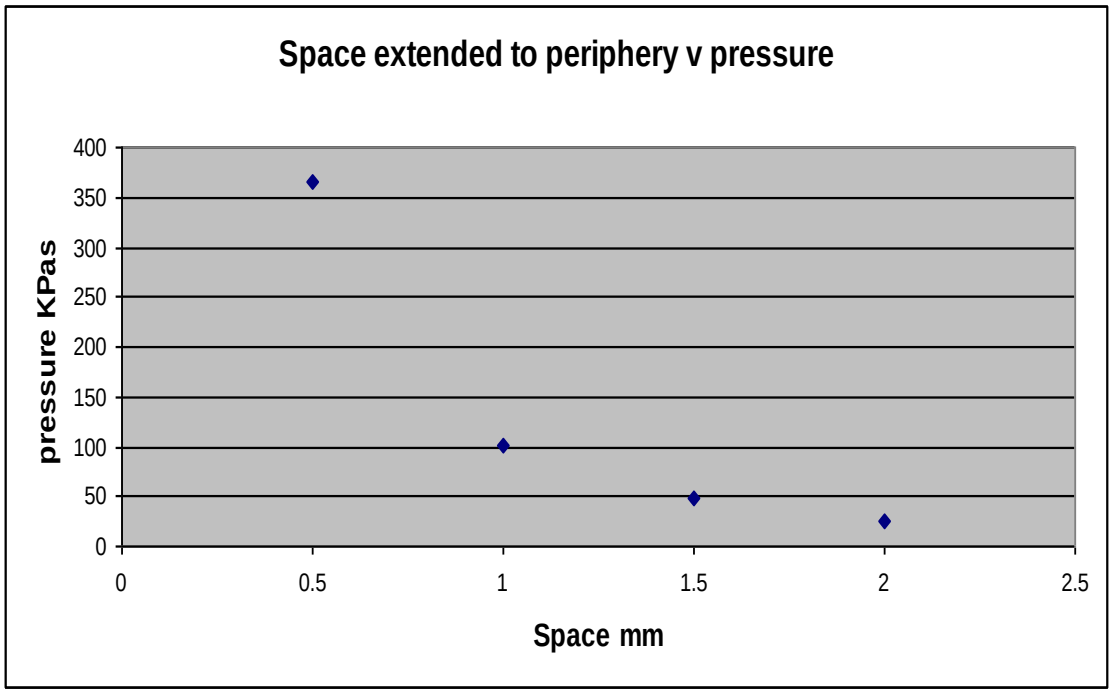


Figure 67 Plot of mean pressure at various levels of variable ‘space’.

14.7 Conclusion.

In this in-vitro experiment an increase in the unrestricted space beneath the impression tray decreased the pressure of impression

14.8 Discussion and clinical implications.

On the basis of these results the Null Hypothesis is rejected and the alternative hypothesis is therefore proposed that in this in-vitro experiment increasing the space beneath the tray decreases the pressure of impression.

On the face of this evidence Frank (1969) and Komiyama et al (2004) assertions that space beneath the tray reduces pressure are confirmed by this experiment. However caution should again be expressed when drawing clinical implications from this in-vitro experiment. In this case foremost among concerns was the unrestricted venting of the impression material at the periphery of the in-vitro models. Is this re-produced in-vivo?

Certainly in-vitro, it is clear that increasing the space beneath the tray dramatically increases the size of the peripheral vent. The increase in the surface area of the peripheral vent would be expected to follow a simple mathematical transformation from the original vent size present at 0.5mm. Two questions now arose. The first question was, does this reduction in impression pressure, when there was an increase in the space beneath the impression tray, still occur with the common clinical practice of 'border moulding', with a stiff resilient material, on the periphery of an impression tray (see chapter 15 below); or does border moulding block the peripheral vent and increase pressure? The second question that arose was, 'is there likely to be unrestricted flow in-vivo when the soft tissues of the sulci are in close proximity to the peripheral vent of the tray?'. Unfortunately this second question can only be tested in a relevant way by in-vivo measurements, and is beyond the scope of this PhD. The first question of the affect of border moulding on pressure is investigated in-vitro in chapter 15.

14.9 Regression analysis

In the graph of the results Figure 67 above, as space increases so pressure decreases and vice aversa; this is suggestive of an inverse relationship between the space and the pressure. To test the hypothesis of a predictable inverse relationship the results require a regression analysis. The Levene test above (section 14.5.2.4)

demonstrates the variance of errors differs at different values of the 'Space' this is called heteroscedasticity. Classically an assumption of homoscedasticity is desired for regression analysis.

There are two differing ways to approach the use of regression where there is heteroscedasticity; accept or transform. It was instructive to look at the divergence of opinion. According to Berry and Feldman (1985) and Tabachnick and Fidell (1996) a slight heteroscedasticity has little effect on significance. The 'p' value from the Levene test from this data was not extreme (p=0.037); this approach has therefore been followed in section 14.9.1 below.

An alternative approach was to perform a suitable transformation of the data to reduce the heteroscedasticity. This approach was followed in Appendix 6. A natural log transformation produced homoscedasticity, allowing a linear regression to be performed. The results may then be back transformed in the usual way. This approach was acceptable but it was less clinically relevant. It is therefore appended to the Thesis rather than used as the main analysis (see Appendix 6). The Appendix 6 holds the results of the linear regression of the log transformed data and demonstrates a significance of $p<0.001$.

14.9.1 Regression using pressure.

A regression was performed on the untransformed data (accepting the slight heteroscedasticity). To test the hypothesis of a predictable inverse relationship the results were therefore assessed using the SPSS regression curve estimation facility. SPSS software provides a facility to eliminate the constant from the predicted equations; this function effectively derives the best equation to fit the results which does not have a constant in the equation. It allows estimation of the best fit equation where the prediction does not cross the axis. It is useful to use this facility where it is known that a negative values of y (in this case pressure) or x (in this case space) are not feasible.

The SPSS output for the predicted curves are reproduced in Table 104 below (these are all the types of predictive equations that are available in SPSS).

Equation	Model Summary					Parameter Estimates		
	R Sqd.	F	df1	df2	Sig.	b1	b2	b3
Linear	.151	3.389	1	19	.081	54.373		
Log	.281	7.442	1	19	.013	-191.414		
Inverse	.920	218.347	1	19	.000	153.840		
Quadratic	.551	11.041	2	18	.001	409.169	-212.877	
Cubic	.897	49.537	3	17	.000	1259.457	-1519.896	450.195
Comp.	.646	34.606	1	19	.000	14.185		
Power	.001	.014	1	19	.907	-.231		
S	.914	202.186	1	19	.000	3.622		
Growth	.646	34.606	1	19	.000	2.652		
Expon.	.646	34.606	1	19	.000	2.652		
Logistic	.646	34.606	1	19	.000	.070		

Table 104 Output of the SPSS ‘regression curve estimation’. The independent variable is Space in mm. Dependent variable: pressure in KPa.

The best fit (as shown by R^2 values) is the inverse equation with an R^2 value of 0.920 ($p < 0.001$) and a formula of ‘Pressure’ = 154 divided by ‘Space’. The graph of the fit of predicted curve against the actual results is shown in Figure 68 below.

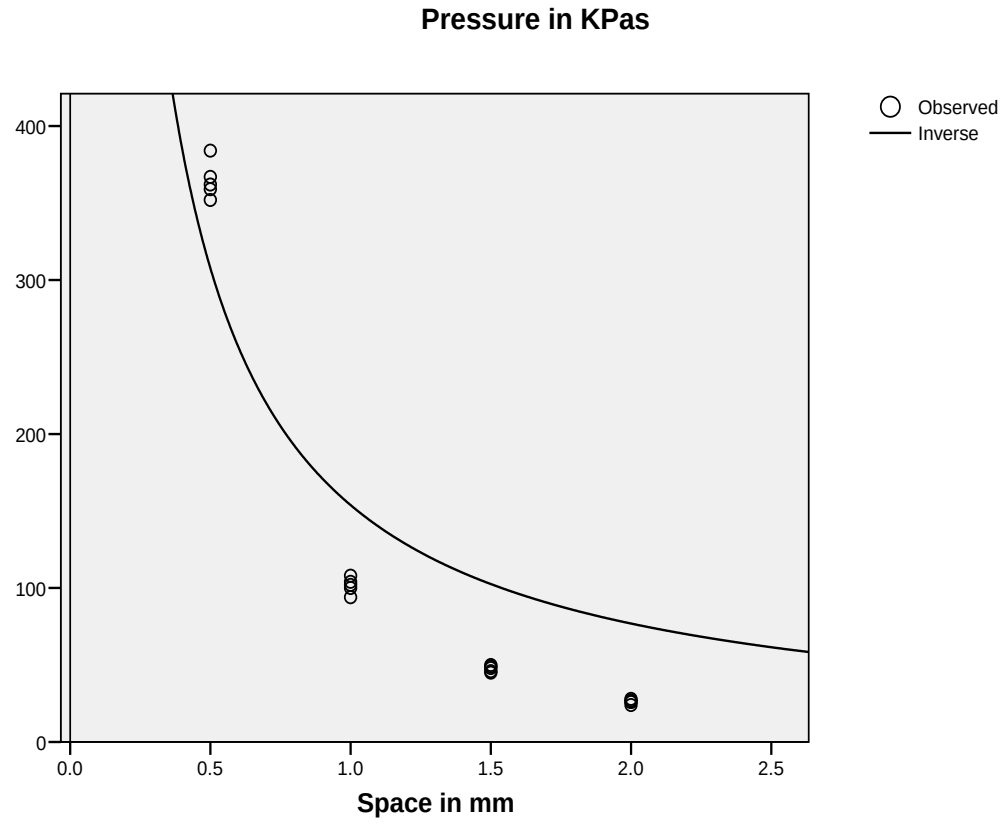


Figure 68 Scatter plot of pressure with the inverse regression curve superimposed; the independent variable is Space in mm.

14.10 Conclusion of regression analysis of space beneath the impression tray

The regression curve estimation by SPSS demonstrates that the data is not inconsistent with an inverse association of the space between the brass discs and the resultant recorded pressure. This has important clinical implications see section 14.11.2 below.

14.11 Discussion of regression analysis

Regression analysis is possible with the data from most of the experiments in Part II of this Thesis. For example the velocity study has a reasonable fit for a linear

relationship between the factor and the pressure (R^2=0.957). The remainder of the studies show factor v pressure graphs with a variety of different curves suggesting more complex relationships.

A poster, entitled 'Impression pressure and the distance to a tray perforation' and derived from the work of Chapter 8 of this Thesis was presented at PEF IADR, London, 2008. It was entered into the poster competition of that society in order to obtain maximum available peer review of the work. It was suggested by a judging dentist (who had an interest in statistics) that the study depicted on the poster should (indeed must) be subjected to a regression analysis as the assumptions for regression were fulfilled in the data from the experiment. It was a useful exercise to subject the work of the Thesis to such peer review. The advice was considered in detail and in consultation with expert statisticians at Leeds University. The advice to use regression analysis for the 'distance to a perforation' study was rejected (see section 14.11.1 below for reasons). Furthermore, having assessed the advantages and disadvantages of regression analysis, the decision was taken not to use regression analysis for the majority of the chapters in Part II. The reasons for the decision not to use regression analysis for other chapters in Part II are listed below (see section 14.11.1).

This chapter, detailing the investigation into space beneath an impression tray, is an exception to that general decision. The relationship between pressure and 'space' has been analysed by regression because the results of the analysis had potential for a prediction with a *clinical* significance (see section 14.11.2 below for details). In reaching this decision I was aware that this is a clinical PhD Thesis and clinical significance is central to the enquiries; therefore an exception to the general avoidance of regression analysis was indicated for this chapter.

14.11.1 Advantages and disadvantages of regression analysis for the remainder of Part II of this Thesis

Regression models of relationships between variables can be illuminating in specific incidences. Regressions are useful where predictions are required or where the significance of potentially confounding variables needs to be taken into account. Where a regression analysis results in an insight which is *clinically* revealing it is to be commended. However there are sound reasons NOT to subject all data in this

Thesis to analysis by regression; just because we can, doesn't mean we should. The reasons why regression analysis has not been used in all the experiments in Part II and III of this Thesis are perhaps best understood by considering an example.

For example, it is possible to express the relationship between pressure and the distance to a perforation by the best fit regression of a cubic transformation thus:

$P= 115.885 + 4.9919d^3 + 0.123d^2 -0.005d$ where P equals pressure and d is the distance to a perforation. This regression produces a $R^2 =0.963$, suggesting that this regression formula accurately describes over 96% of the results.

The methodology of producing this regression is accurate and not incorrect but there are sound reasons not to do so:

1 There is no reason to predict pressure values beyond the experimental limits; and projection of the results beyond the limits is bad statistical practice.

2 There is no reason to predict pressure values within the experimental limits. For example in the example above there is no reason to wish to calculate a prediction of the pressure that results when a perforation is at a distance of 8mm.

3 There is no reason to define a precise mathematical equation of the relationship between pressure and perforations, since it will only predict the pressure in these precise specific in-vitro experimental conditions. These in-vitro experiments show the trend or ability for a variable to affect pressure, but we have seen in the series of experiments on perforations that even minimal variations in conditions affect the results. These experiments do not precisely predict the clinical situation merely show the trend or possible effect.

4 Complicated statistics may not be understood by target clinical audience for this research (GDP's).

5 Compared to the regression analysis and the predictive equations, the one way ANOVA statistics are easier to explain to the target audience of GDP's who may be expected to have some

understanding of p values, and may even understand Confidence Intervals.

6 Mathematically the ANOVA uses the same mathematical assumptions and indeed many of the same equations as the regression modelling (the Generalised Linear Model). It is equally accurate and robust.

7 Many of the experiments in the Thesis do not show homoscedasticity and complex transformations would be required. The transformations are less easily understood by the target audience.

14.11.2 Discussion of the potential clinical significance of results of the regression analysis of 'space'

The regression analysis of the space study above suggests an inverse relationship between pressure and space, so that as the space underneath the impression tray approaches to zero, the pressure of an impression tends to infinity. This is easy to understand in the in-vitro environment since as the 'space' beneath the tray reduces so the peripheral vent for the impression material reduces in size. The smaller the vent the larger resistance to flow of the impression material through it and the higher the pressure required to move the impression material through it.

Many clinicians use close fitting special tray for prosthodontic impressions. A typical and common example would be zinc oxide eugenol impression material in a close fitting, unperforated tray for a lower complete denture. If such an impression is fully seated, the analysis above suggests the pressures of impression will be high. Of course clinically this would distort the mucosa; indeed if the mucosa (and the special tray) was incapable of distortion, it would require an infinite pressure to seat a close fitting tray; clearly this does not happen. Further investigation of the pressure in-vivo of close fitting trays is required.

Three working hypothesises are suggested to explain the clinical situation with close fitting trays; first it may be that the tray made from a primary impression is not a close fit to the shape of the relaxed mucosa (allowing venting to occur where it

does not fit), or secondly the mucosa may distort as the impression is seated and so the distorted shape of the mucosa is no longer ‘close fitting’ to the shape of the tray (allowing venting to occur where it does not touch) or finally the tray is not ‘fully’ seated by the clinician, that is tray approximation is stopped before the gap from the tray to the mucosa is too small. In practice all these explanations may be expected to happen at the same time. Of the three hypothesis perhaps the third explanation is the ‘preferred compromise’ in order to obtain a final impression of relatively undistorted mucosa (that may go on to provide a comfortable prosthesis).

In any prosthodontic impression of mucosa there are two topographical surfaces that can change shape, that of the impression material and that of the mucosa. If all other factors are constant and an unrestricted peripheral vent, a close fitting special tray may result in higher pressure and more mucosal distortion than a spaced tray if they are both ‘fully seated’.

Chapter 15
Space with border adaptation of the impression tray

15.1 Background

Frank's 1970 paper, describing his clinical impression technique, followed on from his in-vitro experiments presented in his scientific paper of 1969. In the 1970 paper he advocates the use of border moulding with greenstick. Border moulding of the impression tray (carried out to develop border and facial seal) may affect the size of the peripheral vent for escaping impression material. If it does this may in turn affect impression pressure. The use of border moulding by Frank (1970) may negate the affect of spacing the tray to reduce the impression pressure. Border moulding is considered good practice and widely advocated (Basker and Davenport 2002, Basker et al 2011, Watt and MacGregor 1996, Grant et al 1994, McCord and Grant 2000, Boucher 2004); the effect of border moulding on impression pressure has not been investigated in the prosthodontic literature. Further investigation was therefore indicated.

15.2 Statement of problem

In-vitro experiments of Frank and Komiyama et al suggest that space under impression trays reduces the pressure of impression. However the experiments which found this outcome did not use any border moulding which can affect the size of the peripheral vent in-vitro. It is common practice to border mould prosthodontic impressions with compound or silicone (Drago 2003). The research question for this chapter is 'does the border moulding affect the impression pressure?'. The Null Hypothesis is that border moulding the periphery does not affect the impression pressure; the alternative hypothesis is that border moulding the periphery affects the impression pressure.

15.3 Aim

To investigate the effect of 'border moulding' the peripheral vent on the impression pressure when the space under the tray varies.

15.4 Materials and method

15.4.1 Background to methodology adopted for this study

Preliminary in-vitro experiments, using green stick border moulding of the 'impression tray' discs for this investigation, proved to be difficult. The major problem was the manipulation of the green stick to a precise uniform height at the periphery of the trays. Compressing the green stick to a uniform height was possible using the Lloyd machine set with a high cut-off force and steel spacers. However the difficult heating of the green stick and application onto a cold and heat conductive metallic surfaces was time consuming. The green stick needed to be applied fresh for each experimental run since during each run it frequently fractured or adhered to the silicone and/or the opposing disc. Although this was a purely practical, mechanical problem it led to difficult and time consuming problems with the reproducibility of experimental conditions. The use of greenstick to border mould the impression disc was considered impractical for these in-vitro experiments.

Polyvinylsiloxane (silicone) has been proposed as an alternative impression material for border moulding of the impression tray (to develop border and facial seal) and investigated in-vivo by Drago (Drago 2003). A retrospective clinical study of the silicone border moulding technique showed no difference in the number and complexity of post treatment denture adjustments from the use of green stick (Drago 2003). A survey by Petrie et al (2005) of American experts in prosthodontics (ACP members) shows 1 in 5 prosthodontists advocating silicone or polyether as the primary material of choice for border moulding and a further 29% of ACP members using these materials as an alternative border moulding material (Petrie et al 2005).

Preliminary studies showed the use of silicone as the border moulding material for this experiment to be simple and efficient. This use of set silicone for the restriction of the peripheral vent simplified the experimental design and improved the precision (and so the reproducibility) of the results.

The methodology used for this experiment (see section 15.4.3 below) required the disc used for the 'impression tray' in this study to be repeatedly aligned in an exact position for each sequential experiment. The disc used for the simple unrestricted 'space' experiments of chapter 14 (Figure 3 in Part II Chapter 1.3 above) was freestanding and unsuitable because the precision of re-alignment

proved to be impossible. Therefore a new ‘impression tray’ was constructed which was directly attached to the Lloyd machine to give the necessary reproducibility of alignment. We have seen how a slight alteration in the impression trays affects the pressure in the perforation studies above (chapter 8 to 11). It was therefore anticipated that the results from the unrestricted space studies to these new border moulded studies would not be directly comparable.

15.4.2 Standardised experimental methodology.

Variable	Setting for space experiment
Velocity of approximation	120 mm/min
Delay in seating impression	20 seconds
Number of perforations	None
Diameter of discs	70mm
Position of pressure sensor	centre of disc
Category of impression material	light bodied, reg set Express 3M ESPE

Table 105 default settings

15.4.3 Sequential acquisition of data

Data collection was conveniently facilitated by sequential building of the border adaptation. Initial impression was taken with 0.5mm spacers between the discs; this is similar to the other experiments above (as seen in Figure 3 above). The pressure of this initial impression was recorded but it did not form part of the experimental analysis for reason given below (section 15.5.11). After the initial impression was taken, the resulting silicone was 0.5mm thick and spread across the disc. This silicone was cut back so that only the silicone at the periphery remained. This peripheral silicone was 4mm across; this was achieved by cutting around a template with a scalpel blade. With the silicone border adaptation in place three additional 0.5mm spacer where placed on top of the original 0.5mm spacers to create 1mm space between the discs and 0.5mm peripheral silicone. The first experimental impression was taken and the pressure recorded.

After the first experimental impression was taken the depth of the silicone over the brass was 1mm. This silicone was cut back so that only the silicone at the periphery remained. This peripheral silicone was 4mm across; this was achieved by cutting around a template with a scalpel blade. With the silicone border adaptation in place three additional 0.5mm spacer where placed on top of the original 0.5mm spacers to create 1.5mm space between the discs and 1mm peripheral silicone. The second experimental impression was taken and the pressure recorded.

After the second experimental impression the silicone was again cut back, additional 0.5mm stops placed and a third impression taken with a 1.5mm periphery and 2mm space between the discs.

After the third experimental impression all the silicone was removed the forth impression taken at 2mm space without peripheral silicone. After the forth impression, the silicone was again removed and the top 0.5mm steel spacer was removed for the fifth impression at 1.5 mm space and no peripheral silicone, the sixth impression followed at 1mm space with no peripheral silicone.

The sequential acquisition of data described above was repeated five times to produce the raw data of peak pressure listed in Table 106 below

15.4.4 Statistical methods

The data collected will be explored with SPSS including test of normality and equivalence of variance. Following exploration appropriate statistical instruments will be used to analyse and evaluate the main effects of the independent variables ‘space’ and ‘gap’ together with the interactions (if any) of ‘space’ and ‘gap’.

15.5 Results

15.5.1 Raw data

Pressure in KPa:

	0.5mm gap 1mm space	0.5mm gap 1.5mm space	0.5mm gap 2mm space	no border 2mm space	no border 1.5mm space	no border 1mm space
Run 1	192	140	147	26	32	81
Run 2	173	121	104	21	35	40
Run 3	185	144	139	24	34	75
Run 4	172	143	101	28	44	61
Run 5	219	139	137	24	29	55

Table 106 Raw data of peak pressure from five runs of sequential data collection.

15.5.1.1 Chart of means of pressure data for each group

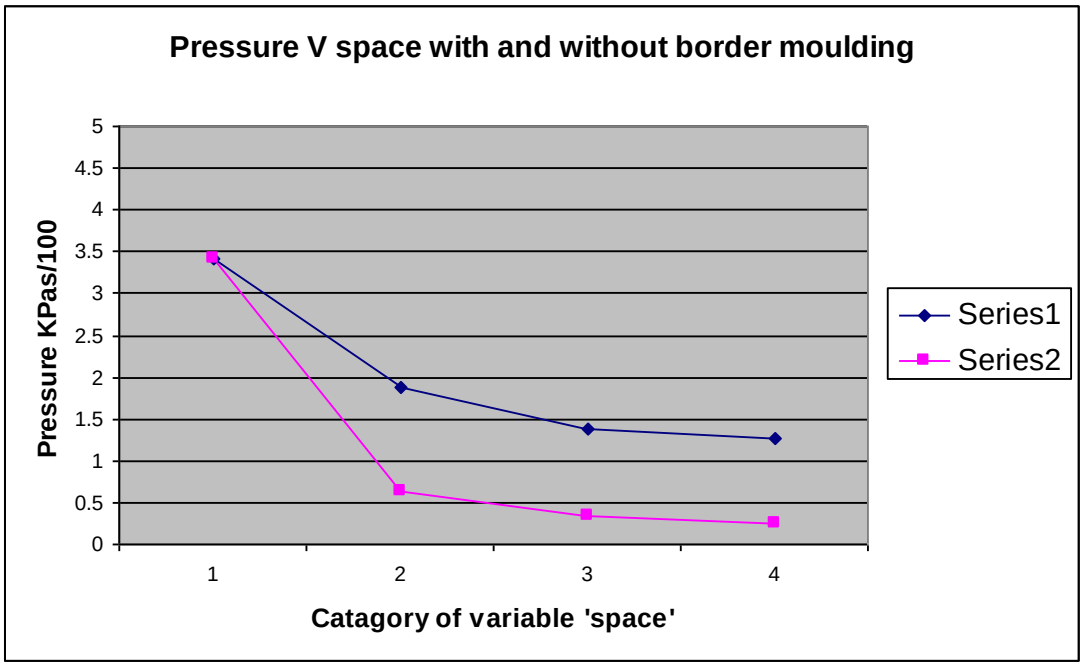


Figure 69 Series 1 is results from impressions with border adaptation to create peripheral gap of 0.5mm; series 2 is with an unrestricted periphery.

In the graph above the series 2 is equivalent to the data in Chapter 14 above. It is a collection of similar data; as mentioned above in section 15.4.1 the data in chapter 14 uses a different impression 'tray' and so the data is not directly comparable, however the trends and values are similar. The categories of space are 1 = 0.5mm, 2 = 1mm, 3 =1.5mm and 4 = 2mm. The results for the 0.5mm space are without any border adaptation and therefore fit into series 2. These results for 0.5mm space are also have a 0.5mm peripheral gap and so could be said to fit into series 1. However the peripheral gap is with brass rather than silicone; the contact angle between the materials will be different. Furthermore the brass is inflexible and unlike the silicone will have no 'give'. This makes the flow of the impression material over the peripheral vent dissimilar; these results for 0.5mm space and no border adaptation are therefore eliminated from the further analysis.

15.5.2 Data exploration

15.5.2.1 Descriptives

Group	N	Mean	Std. Dev.	Std. Err.	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
Space 1mm, peripheral gap 0.5mm.	5	188.2	19.149	8.564	164.42	211.98	172	219
Space 1.5mm, peripheral gap 0.5mm	5	137.4	9.397	4.202	125.73	149.07	121	144
Space 2mm, peripheral gap 0.5mm	5	125.6	21.443	9.590	98.98	152.22	101	147
Space 1mm, gap unrestricted	5	62.4	16.303	7.291	42.16	82.64	40	81
Space 1.5mm, gap unrestricted	5	34.8	5.630	2.518	27.81	41.79	29	44
Space 2mm, gap unrestricted	5	24.6	2.608	1.166	21.36	27.84	21	28
Total	30	95.5	61.640	11.254	72.48	118.52	21	219

Table 107 Descriptives

15.5.2.2 Box plot

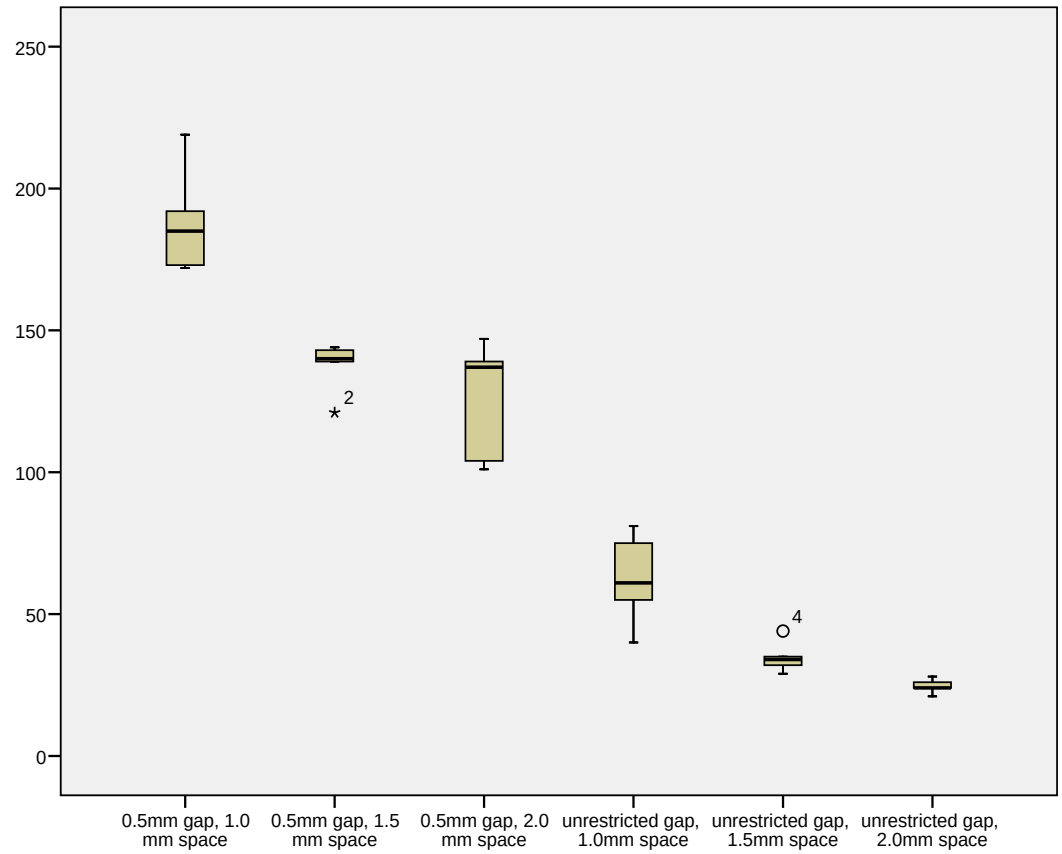


Figure 70 Box plots of results

The box plot above (Figure 70) suggests that there may be a difference in the variance of the dependant variable pressure with the different categories of space and gap. A Levene test of equality of error variance was therefore performed.

15.5.2.3 Levene test

Levene's test of equality of error variance, tests that the Null Hypothesis that the error variance of the dependent variable is equal across groups.

F	df1	df2	Sig.
4.413	5	24	.005

Table 108 Levene test

The results shown in Table 108 above show that there is a statistically significant difference from Homogeneity of the dependant variable (pressure) across the groups.

ANOVA with a factorial treatment structure assumes equality of variance and should not be used where equality is not demonstrated. In the general linear model, the residuals can be plotted (see graph Figure 71 below). The divergence of the residuals as the pressure increases suggests an increasing variance of the dependant pressure. In these circumstances a logarithmic transformation of the dependant variable pressure can often achieve an equality of variance of the dependant. A log transformation of the dependant was therefore performed the results are shown below. A non parametric equivalent to Factorial ANOVA is not available; a transformation of the data was indicated.

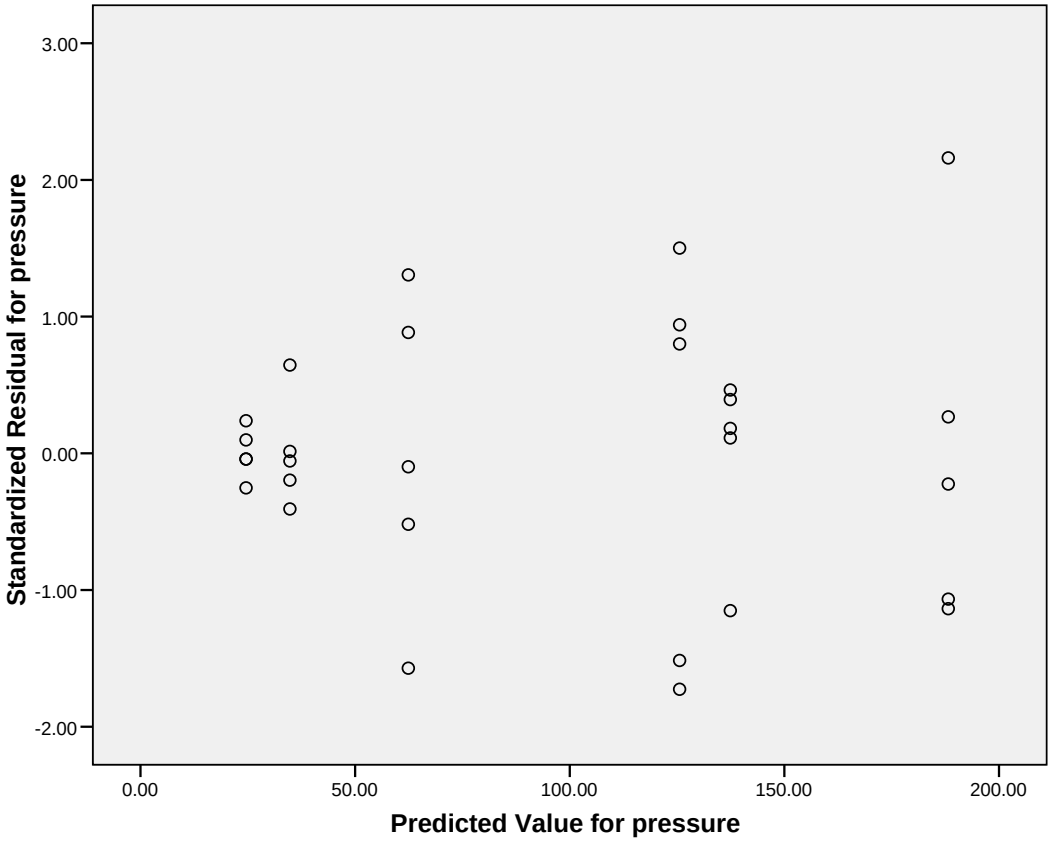


Figure 71 Residuals against predicted pressure using the SPSS factorial ANOVA general linear model (glm) software.

15.5.2.4 Log transformation of pressure

The results of the log transformation of pressure are shown in Table 109 below

	0.5mm gap, 1mm space	**0.5mm gap, 1.5mm Space**	**0.5mm gap, 2mm Space**	**No border, 2mm space**	**Mo border, 1.5mm space**	**No border, 1mm Space**
Run 1	5.26	4.94	4.99	3.26	3.47	4.39
Run 2	5.15	4.80	4.64	3.04	3.56	3.69
Run 3	5.22	4.97	4.93	3.18	3.53	4.32
Run 4	5.15	4.96	4.62	3.33	3.78	4.11
Run 5	5.39	4.93	4.92	3.18	3.37	4.01

Table 109 Results of log transformation of the variable pressure

15.5.2.5 Levene test of transformed data

The Levene test of equality of the transformed data was explored. The results are shown in Table 110 below.

F	df1	df2	Sig.
2.153	5	24	.093

Table 110 Levene test of the equality of the error variance with the dependent variable: log of pressure.

The error variance of log of pressure cannot be shown to be different from homogenous across the groups.

15.5.2 6 Shapiro-Wilk test of normality for log of pressure.

ANOVA also requires a normal distribution; therefore a Shapiro–Wilk test of normality was performed the results are shown in Table 111 below.

Category	Shapiro-Wilk		
	Statistic	df	Sig.
space 1mm, gap 0.5mm	.889	5	.354
space 1.5mm, gap0.5mm	.735	5	.022
space2mm, gap 0.5mm	.817	5	.110
space1mm, gap unrestricted	.949	5	.729
space 1.5mm, gap unrestricted	.935	5	.634
space 2mm, gap unrestricted	.964	5	.836

Table 111 Shapiro-Wilk of the log of pressure

The Shapiro-Wilk test of normality shows no statistically significant variation from normality for any group except the ‘0.5mm gap, 1.5mm space’ group. This group had an outlying result (see box plot below). The Shapiro-Wilk test was re-run without the outlier; the results are shown below in Table 112.

		Shapiro-Wilk		
		Statistic	**df**	**Sig.**
Log pressure with no outlier	space 1.5mm, gap0.5mm	.911	4	.488

Table 112 Shapiro-Wilk without outlier

15.5.3 Data analysis

The prerequisite tests for ANOVA are found to be acceptable for the log transformation of the dependant variable of the log of pressure. Analysis of the results was therefore performed by Factorial ANOVA of the dependant 'log of pressure' with the factor of space and peripheral gap.

15.5.3.1 Main effects

The results of Factorial ANOVA analysis (via SPSS Univariate General Linear Model with two fixed Factors of 'space' and 'gap' and dependant variable of log of pressure) are shown in Table 113 below.

Source	**Type III Sum of Squares**	**Df**	**Mean Square**	**F**	**Sig.**
Corrected Model	16.794(b)	5	3.359	126.510	.0000
Intercept	555.436	1	555.436	20921.105	.0000
Space	2.251	2	1.126	42.397	.0000
Gap	14.239	1	14.239	536.312	.0000
space * gap	.304	2	.152	5.721	.0093
Error	.637	24	.027		
Total	572.867	30			
Corrected Total	17.431	29			

Table 113 Factorial ANOVA, dependent variable: log of pressure, computed using alpha = .05; 'b' R squared = 0.963 (adjusted R squared = 0.956)

These results (table 113) indicate that the overall model is statistically significant ($F = 126.510$, $p < 0.001$). The variables 'space' and 'gap' are also statistically significant ($F = 42.397$, $p < 0.001$ and $F = 536.312$, $p < 0.001$, respectively). The interaction between space and gap is also statistically significant ($F = 5.721$, $p < 0.01$). Since the interaction is significant, the effect of space depends on peripheral gap and vice versa. Pairwise comparisons of two way means are indicated.

Further analysis was indicated to show where the significant differences lay.

15.5.3.2 Pairwise comparisons of 'gap' within 'space' groups

Pairwise comparison was used to analyse the effect on impression pressure of the presence or absence of a restricted peripheral gap at different values of the variable 'space'.

Space under the tray	(I) Peripheral gap	(J) Peripheral gap	Mean Diff. (I-J)	Std. Err.	Sig. (a)	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
1mm	0.5mm gap at periphery	unrestricted periphery	1.130(*)	.103	.000	.917	1.342
1.5mm	0.5mm gap at periphery	unrestricted periphery	1.381(*)	.103	.000	1.168	1.594
2mm	0.5mm gap at periphery	unrestricted periphery	1.623(*)	.103	.000	1.410	1.835

Table 114 Pairwise comparisons

Table 114 has the dependent variable of log of pressure. The table shows a Pairwise assessment of the difference in the means of the different peripheral gap at each of the values for space under the tray. * indicates where the mean difference is significant at the 0.001 level (also note that the 95% confidence intervals do not cross zero).

The results in Pairwise Table 114 above show that within the groups shown (1mm space, 1.5mm space, and 2mm of space) the presence or absence of a restricted periphery always has a statistically significant effect on log of pressure ($p<0.001$).

Subsequent application of a Bonferroni correction to these figures was indicated to correct for multiple comparisons. The Bonferroni correction is applied by taking the level of significance and dividing by the number of comparisons. If the p value of the test is less than this figure the test is said to be significant at the original level of significance 'with a Bonferroni correction'. In this case the Bonferroni correction is $p=0.05$ divided by 3 comparisons equals 0.0166. All the p values obtained in Table 114 are below this level. Therefore, after applying a Bonferroni correction for multiple comparisons, the results still demonstrate statistical significance (at the 0.05 level, with a Bonferroni correction).

15.5.3.3 Pairwise comparison 'space' within 'gap' groups

Pairwise comparison was used to analyse the effect on pressure of the space beneath the tray within the groups defined by the presence or not of the peripheral silicone.

Peri-pheral gap	(I) Space under the tray	(J) Space under the tray	Mean Diff. (I-J)	Std. Err	Sig. (a)	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
0.5mm gap	1mm space	1.5mm space	.313(*)	.103	.006	.100	.525
	1mm space	2mm space	.413(*)	.103	.001	.200	.625
	1.5mm space	2mm space	.100	.103	.341	-.113	.313
Un-restricted gap	1mm space	1.5mm space	.564(*)	.103	.000	.351	.777
	1mm space	2mm space	.906(*)	.103	.000	.693	1.118
	1.5mm space	2mm space	.342(*)	.103	.003	.129	.554

Table 115 Pairwise comparison, dependent variable: log of pressure. * indicates where the mean difference is significant at the 0.05 level.

The Table 115 shows a Pairwise assessment of the difference in the means of the values for 'space' for each of the different categories of peripheral gaps.

The results in Pairwise Table 115 above show that within the groups shown (restricted or unrestricted periphery) the 'space' is significant for log of pressure for all groups except when 1.5mm and 2mm space are compared in the unrestricted peripheral gap group.

Subsequent application of a Bonferroni correction to these figures was indicated to correct for multiple comparisons. After applying a Bonferroni correction for multiple comparisons, the results that are marked by * in the table still demonstrate statistical significance (at the 0.05 level).

15.5.3.4 Post hoc analysis of space (without differentiating out and considering the peripheral gap)

(I) Space under the tray	(J) Space under the tray	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
1mm space under the tray	1,5mm space under the tray	0.4383(*)	.07287	.00001	.2508	.6259
1mm space under the tray	2mm space under the tray	0.6591(*)	.07287	.00000	.4716	.8467
1,5mm space under the tray	2mm space under the tray	0.2208(*)	.07287	.01732	.0333	.4084

Table 116 Post hoc analysis with Bonferroni; dependent variable: log of pressure, based on observed means. * indicates the mean difference is significant at the 0.05 level

The results for post hoc test of the variable space by Dunnett T3 test are shown in the table above (Table 116). This analysis does not take into account whether there was a restricted periphery present or not. That is to say no account is taken as to the presence of ‘border moulding’; all the results for each value of ‘space’ are compared with all the results of each of the other values for ‘space’. The results are all significant at the 0.05 level. This confirms the findings of the main effect of the factorial ANOVA section 15.5.3.1 above.

15.5.3.5 Independent t-test of variable 'gap' (without considering space)

The dependant variable for this analysis is pressure measured in KPa. In the raw data half the runs have a 0.5mm gap at the border and half the runs have no peripheral border restriction. For clarity the data are rearranged in Table 117 below.

Pressure with border (0.5mm gap)	Pressure with no border (unrestricted periphery)
81	192
40	173
75	185
61	172
55	219
32	140
35	121
34	144
44	143
29	139
26	147
21	104
24	139
28	101
24	137

Table 117 This data was analysed with an independent t-test.

Levene test for equality of Variances did not show a significant difference See Table 118 below.

Levene's test for Equality of Variances	
F	Sig.
3.155	.087

Table 118 Levene

Independent samples t-test, dependant variable pressure:

		T	Df	Sig.2-tailed	Mean Diff.	Std. Err. Diff.	95% Confidence Interval of the Difference	
							Lower Bound	Upper Bound
Pres. in KPa	Equal variances assumed	11.318	28	.0000	109.8	9.702	89.927	129.673
	Equal variances not assumed	11.318	22.58	.0000	109.8	9.702	89.710	129.890

Table 119 Independent samples t-test

The analysis in the Table 119 above shows a statistically significant difference between a restricted and an unrestricted periphery ($p<0.001$). This analysis was performed without considering the space between the discs.

15.6 Summary of results.

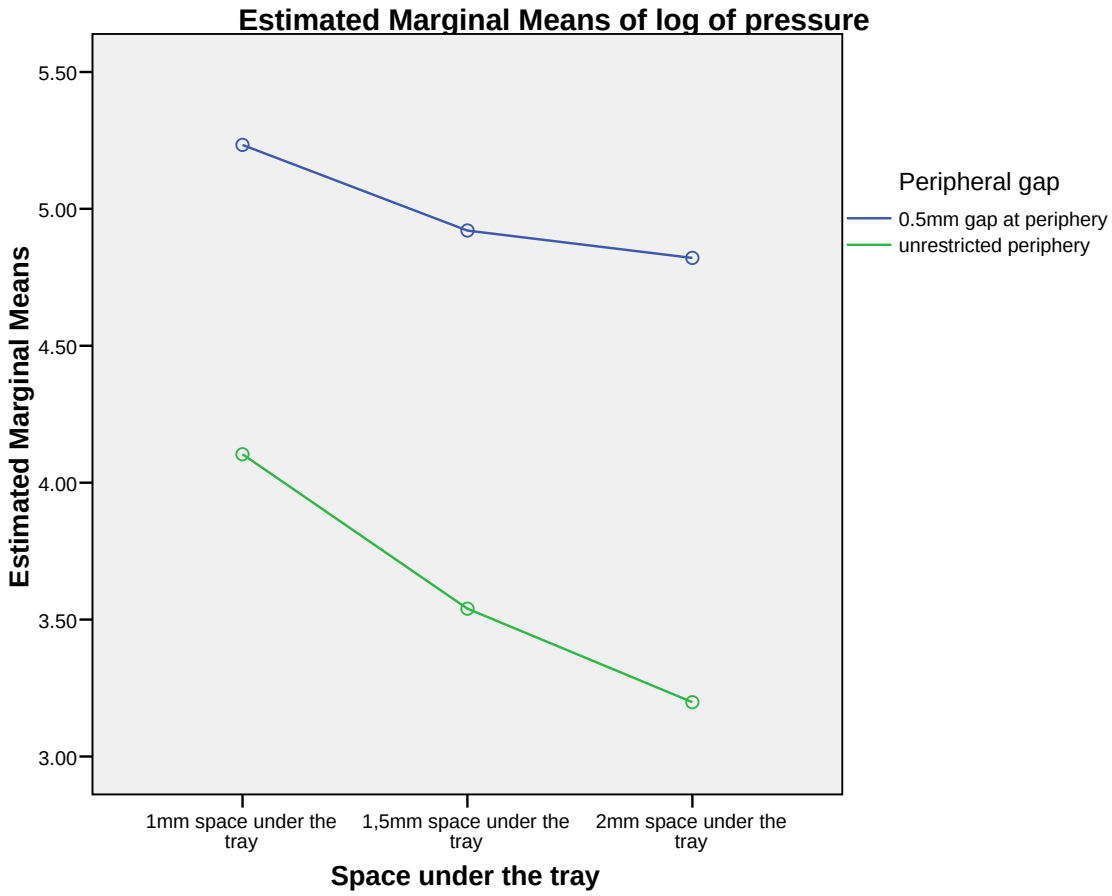


Figure 72 Estimated marginal means

The plot above gives a summary of the results for border adaptation. There is a significant difference between the results of the top line (with border adaptation) and the results of the bottom line (no border adaptation). Furthermore each of the three vertically related pairs of points (one from each line) shows a statistically significant difference in pressure.

15.7 Statistical significance.

The conclusions that can be made from this in-vitro experiment are:

1. Looking at the overall model from the factorial ANOVA (section 15.5.3.1)
    a. The overall model is statistically significant ($F = 126.510$, $p < 0.001$).
    b. The variable 'space under the impression tray' is statistically significant ($F = 42.397$, $p < 0.001$).
    c. The variable 'peripheral gap' is statistically significant ($F = 536.312$, $p < 0.001$).
    d. The interaction between space and gap is statistically significant ($F = 5.721$, $p = 0.009$).

2. Looking at the variable 'Peripheral gap':
    a. There was a statistically significant difference in the pressure between the two specific values for 'peripheral gap' when level of the variable space was not taken into account (i.e. without considering the different spaces between the discs) (section 15.5.3.5, $p<0.001$).
    b. For each level of 'space beneath the impression tray' the log of the pressure of impression showed a significant difference with each different type of 'peripheral gap' (section 15.5.3.2, $p<0.001$).

3. Looking at the variable of 'space beneath the impression tray':
    a. Analysis of the mean of the log of pressure showed that there was a significant difference between each level of 'space' whatever the peripheral gap (section 15.5.3.4, $p < 0.05$).
    b. Space affects pressure, but when the border adaptation was absence a significant difference was not detected in this experiment between the means of the 1.5mm space group and the means of the 2mm space group.

15.8 Conclusion

The Null Hypothesis that border adaptation of the periphery does not affect the impression pressure is rejected ($p < 0.001$). In rejecting the Null Hypothesis the alternative hypothesis that border adaptation of the periphery affects the impression pressure is proposed.

15.9 Clinical implications.

The border adaptation of the impression tray increases the internal pressure of the impression in-vitro. The in-vivo situation is more complicated with the lips, tongue and cheeks having potential to further restrict the peripheral vent of the impression. In-vivo the trend will be similar but the actual in-vivo effect size cannot be deduced from these in-vitro experiments. Further in-vivo experiments would be required to investigate the in-vivo effect of spacing and border moulding on impression pressure.

These experiments suggest that decreasing the space beneath the impression tray will increase the pressure of impression. This trend was shown even when the peripheral vent was kept at a constant 0.5mm. Clinicians will note that these experiments confirm the traditional practice of spacing impression trays to reduce impression pressure; however the effect size of the peripheral vent (restricted by border adaptation) is much larger and produces a more consistent effect in these experiments than the space beneath the tray. This has not been shown before.

Clinicians should note the potentially clinically relevant information that border moulding will reduce the peripheral vent, and so increase the pressure of impressions. This has not been shown before. Adaptation of special trays may be desirable clinically to enhance border and facial seal. However, if a low pressure (mucostatic) impression is required and the impression tray is border moulded, care must be taken to reduce the impression pressure in other ways for example perforations and/or the use of a lower viscosity impression material.

Part III

An investigation of the pressure differential within a specific impression technique

Chapter 1 Outline and background

Part II of this Thesis investigated the effect of individual variables on impression pressure. The variables investigated where chosen because they were considered relevant to clinical dentistry. Each of the variables investigated are relevant to clinical impressions and were shown to affect impression pressure in the in-vitro environment used in the studies. Part IV of the Thesis goes on to investigate a specific impression technique (Hyde 2003) which was said to distribute pressure unevenly within the clinical impression.

The clinical impression technique investigated in Part IV of this Thesis used a two stage impression (see Part IV chapter 3, section 3.2, page 316). The final wash of that impression was designed to selectively distribute the impression pressure. Three features of the final wash impression aimed to give the desired selective pressure. Firstly the tray was spaced over the area where low pressure was desired and close fitting in areas where a higher load was required; chapter 14 of Part II demonstrated that increased spacing reduces pressure. Secondly the area of low pressure had an unrestricted periphery; chapter 15 of Part II demonstrated that lack of border adaptation reduces pressure. Thirdly the tray was perforated in the area where low pressure was required and unperforated in areas where a higher load was desired; chapters 8 to 11 of Part II demonstrated that perforations reduce pressure.

Part II of the Thesis demonstrated that the features introduced for the clinical selective pressure impression of Part IV have the potential to redistribute pressure, but with flat brass discs in the restricted in-vitro environment of the laboratory studies. The in-vitro studies of Part II eliminated or controlled potentially confounding variables (see Part II section 1.1). This was undertaken deliberately in order to avoid the conflicting evidence found in earlier studies (Masri 2002, Komiyama et al 2004, Frank 1969; see Part II section 1.1). A direct consequence of the methodology used in Part II is the minimal amount of evidence of the effect of *combinations* of the known variables which were shown to affect pressure.

In the oral environment all the variables investigated in Part II have the potential to simultaneously affect the impression pressure; they have an effect in

combination with each other. In addition within the oral environment there are more potentially confounding variables such as the force of approximation, the overall topography of the area, the surface detail, the visco elastic nature of the mucosa, the amount of moisture on the mucosal surface, the nature of each individual patient's saliva, the surface tension of mucosa (which affects contact angle and 'wetability' of the impression material). As discussed (Part II Chapter 11, section 11.6 page 189) ultimately the only way to investigate the total combination of all variables is to measure the impression pressure in-vivo, however, it remained possible to investigate the combination of some of these variables in-vitro.

In Part III of this Thesis the variables investigated in Part II are combined and fixed into the specific combination used for the impressions in Part IV. In addition the variables of force of approximation, overall topography and surface detail are fixed to the conditions experienced in the clinical situation encountered in Part IV. Where the potentially confounding variables encountered in-vivo could not be duplicated they were controlled by fixing them to a known but nominal state. For example, the investigation could not duplicate the in-vivo conditions of the visco elastic nature of the mucosa, the moisture on the mucosal surface, the nature of saliva, nor the surface tension of mucosa. These conditions were not duplicated; the conditions that were not duplicated were fixed at a nominal level. Failure to duplicate requires limitations to be expressed for the clinical relevance of the investigation.

Part III of this Thesis investigates the pressure distribution of the clinical impression used in Part IV of this Thesis. Where it is possible Part III, replicates the conditions used in the clinical impression, where it is not possible to duplicate the in-vivo conditions they are fixed at a known but nominal level.

The research question for Part III of this Thesis is 'does the impression technique used in Part IV of this Thesis produce, in-vitro, a differential in the impression pressure between the areas in the impression that are designed to be high pressure and the areas that are designed to be low pressure?'.

Chapter 2 Aims and objectives of the study

2.2 Aims

To investigate, in-vitro, the distribution of pressure within an impression which has been taken following the clinical methodology used in Part IV of this Thesis.

2.2 Objectives

To produce a cast which replicates the surface topography and surface detail of the lower denture bearing area of a patient who has a palpable mental foramen on the denture bearing surface of the lower ridge.

To use a spaced unperforated acrylic special tray to take a medium bodied silicone impression of the test cast, recording the pressure of that impression as a secondary comparative outcome measure.

To simultaneously measure the pressure of the final light bodied silicone wash impression in the areas of the mental foramen and of the buccal shelf.

Chapter 3 Methods and materials

3.1 The cast of the edentulous area

Part III of the Thesis introduces three new independent variables to be considered in the assessment of impression pressure. These are the force of approximation, the overall topography of the lower denture bearing area and the surface detail of the area. See section 3.8 below for discussion of the maximum force of approximation. For the other two new variables, it is possible, with careful methodology, to reproduce the clinical conditions of these variables by using dental casts. A dental cast from the clinical study in Part IV of this Thesis was selected for this study; it was considered to be typical of the natural topography of the patients treated in the clinical trial. The cast was duplicated in heat cured acrylic.

3.2 Pressure sensors attached

Following the reproduction of the clinical cast, two pressure sensing points were developed in the cast. These were positioned over the area of the mental foramen and over the buccal shelf. The sensor points were 2mm in diameter and drilled into the model parallel to the path of approximation used during when making an impression. One half inch British Standard Pipe (BSP) couplings were tapped into the side of the acrylic casts' perpendicular to the 2mm pressure sensing holes and communicating with them. Pressure transducers were inserted in to the half inch BSP couplings. During the experiments, water filled the pressure sensing hole, the BSP couplings and the transducer, up to the sensor diaphragm.

3.3 The pressure recording apparatus

The pressure recording equipment used in Part II of this Thesis was adapted for this study. The components of the data collection system are shown in Figure 73 below. They consisted of A, the analogue pressure sensors; B the digital sampler of the analogue output from the sensor; C the transformer (DC power source); and D the computer with specialist software (Omegadyne Inc).

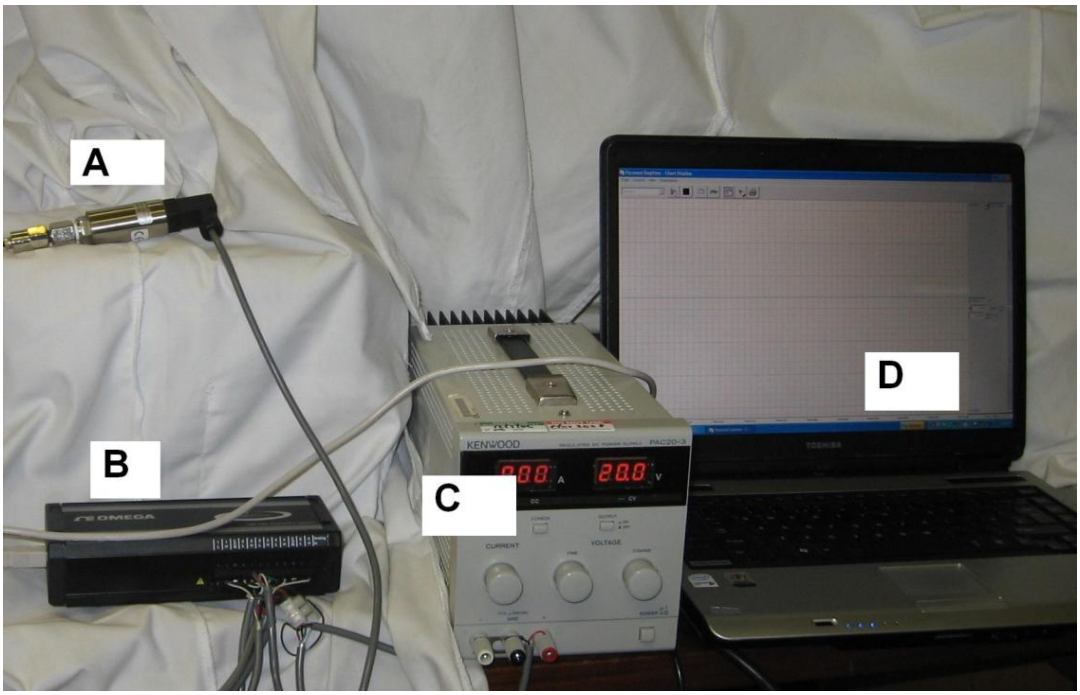


Figure 73 the pressure sensing equipment

For Part III of this Thesis two pressure sensors were used simultaneously to measure the pressure of impression. One measured the pressure at the mental foramen area and the other on the buccal shelf area. In order to use two pressure sensors the digital sampler (of the analogue signal from the sensor) used a sample rate of 37 Hz. This was the maximum frequency of sampling possible with this system when two sensors were used simultaneously. This is less than that used in Part II where only one sensor was used. With this reduced sampling frequency there is potential for the recorded peak of pressure to average a lower value with a higher variance (as discussed in the velocity study in part II). In order to compensate for a possible increase in variance of the output of peak pressure, it was felt prudent to increase the sample size of the study from five impressions (used throughout part II) to 10.

3.4 The special tray

A 2mm spaced unperforated special tray with acrylic stops was made from light cured acrylic on a cast of the edentulous lower ridge. The construction of the special tray followed normal clinical practice. The tray had no handle.

3.5 Articulation

The Lloyd Universal Testing Machine (UTM) used in Part II of this Thesis was used as a constant speed motor to approximate a special impression tray to a dental cast. The special tray and the edentulous cast were articulated onto brass discs on the Lloyd machine by the use of light cured acrylic.

Initially, light cured acrylic (used for the construction of clinical special trays) was cured and so chemically bonded to the special tray. The acrylic was simultaneously adapted to the shape of the brass disc. The acrylic did not chemically bond to the brass, so the cured acrylic was attached with superglue to the upper brass disc. The brass discs used here were those used as the 'impressed objects' (i.e. not the 'impression trays') in Part II of this Thesis (as shown in Figure 2 of Part II), they, in their turn, attached by a bolt and screw mechanism to the Lloyd machine. The brass attachment was screwed onto the Lloyd machine in the usual way.

The lower edentulous cast was then attached under the special tray with sticky wax in the desired (clinical) position. The brass disc was attached to the lower arm of the Lloyd machine in the usual way. The brass disc was covered with unset light cured acrylic material. The two arms of the Lloyd machine were then approximated until the base of the edentulous cast seated into the unset acrylic and the automatic cut-off of the Lloyd machine was triggered. With the cast held securely, embedded in the light cured acrylic, on the lower arm of the Lloyd machine; a hand held curing light was used to cure the acrylic. After curing the acrylic, the sticky wax which held the special tray to the cast was removed and the arms of the Lloyd machine opened, taking the special tray away from the cast on a designed predetermined linear vector.

3.6 The medium bodied base impression

3.6.1 Background

The impression technique used in part IV of this Thesis was a two stage impression. The first stage was to take an impression that was designed to be relatively mucostatic (that is low pressure) in medium bodied silicone. The medium bodied impression was then adapted (see Part IV, chapter 3, section 3.2 page 316)

and a final light bodied silicone wash impression was taken. The final wash impression used the first stage medium bodied silicone as a close fitting special tray (apart from the small area of the medium bodied impression that was cut away).

The medium bodied silicone was designed to be a relatively low pressure, relatively mucostatic impression (see discussion section 6.3 below for the reasons behind this). To test the assertion that the first stage impression is relatively low pressure, the pressure of impression within the medium bodied silicone was measured as a secondary outcome measure for this study.

3.6.2 The control of variables for the medium bodied silicone base impression

Part II of this Thesis determined several variables which affected pressure. For this in-vitro assessment of the clinical impression technique these variables were controlled. The setting for each of these variables is given in the Table 120 below.

Variable	Setting for in-vitro assessment of the clinical wash impression
Velocity of approximation	120 mm/min
Delay in seating impression	20 seconds
Position of sensors	Over mental foramen and the buccal shelf
Number of perforations in special tray	None
Space beneath the impression ‘tray’.	2mm
Border adaptation	None
Viscosity of impression material	Medium bodied, Express 3M
Speed of set of impression material	Regular set, Express, 3M

Table 120 Default settings used

3.6.3 The measurement of pressure

The pressure of impression was simultaneously measured at the position of the mental foramen and the posterior buccal shelf, during the taking of the medium bodied silicone impression, using the equipment methodology given in sections 3.1

to 3.5 above. It was expected the medium bodied silicone impression would be low pressure; new lower pressure, 100KPa (1 bar) pressure sensors were used to measure the pressure of this impression. The calibration of the sensors is reported below (Part III, Chapter 4, Section 4.2, page 270).

3.7 The control of variables for the final wash impression

Part II of this Thesis determined several variables which affected pressure. For this in-vitro assessment of the clinical impression technique these variables were controlled. The setting for each of these variables is given in the Table 121 below.

Variable	Setting for in-vitro assessment of the clinical wash impression
Velocity of approximation	120 mm/min
Delay in seating impression	20 seconds
Position of sensors	Over mental foramen and the buccal shelf
Number of perforations in special tray	One
Size of perforation	2mm
Position of perforations	Mental foramen
Space beneath the impression 'tray'.	2mm space over the mental foramen but 'close fitting' elsewhere (see section 3.8)
Border adaptation	None
Viscosity of impression material	Light bodied, Express 3M
Speed of set of impression material	Regular set, Express, 3M

Table 121 Default settings used

3.8 The cut-off force used for the final wash impression

Chapter 3 of Part II discusses the issues of the setting of the cut-off force of approximation on the Lloyd machine. The cut-off force is the force at which the Lloyd UTM trips out and ceases to approximate the two arms of the machine. As two objects with impression material between them approximate, resistance to the approximation is encountered. In this situation either the force of approximation has to increase or the velocity of approximation slows down (until the impression material spreads and the resistance reduces). In all the work of this Thesis, the Lloyd UTM acted as a constant speed motor, that is to say as the resistance to approximation increased the velocity of approximation remained constant. To keep the velocity constant, the force of approximation increased.

As discussed in Chapter 3 of Part II of this Thesis in order to keep the final space between the approximating discs at a known and constant level, a high setting for the cut-off force was used for all the experiments of Part II. The majority of experiments in Part II also used a set 'space' between impression 'tray' and 'object' of 0.5mm. In contrast in Part III we use a 'close fitting', wash impression as the final impression of the edentulous cast.

As we saw in Chapter 8 of Part II as the distance between the 'tray' and object tends to zero the force of approximation and pressure of impression tend to infinity. The use of a close fitting special tray can lead to higher impression pressures (Chapter 14, Part II above,). To fully seat a close fitting tray may take a high seating force.

Part III of this Thesis investigates the clinical impression technique. To be relevant to the clinical situation the cut-off force for the Lloyd UTM was set at the value of the estimated maximum clinical force of approximation. This was deemed to be 50 Newton (5.1Kgf). This setting was compared to the forces used in the literature for in-vitro testing of impression pressure.

The force used (50N) was approximately equal to the setting reported by Komiyama et al (2004) which was 5Kgf. This contrasts with Frank (Frank 1969) who did not report a cut-off setting for the motor he used. Since Frank did not use a Universal Testing Machine it is assumed the motor did not have a known maximum force or an automatic cut-off facility. In these circumstances the modest force proposed here in Part III (50 Newton) is likely to be considerably less than the force

used by Frank (Frank 1969). In contrast again 50 Newton is likely to be more than the force resulting from the motor used by Masri (2002). Masri set his motor at '2Kg/cm^2' (196.1KPa) (which is a constant pressure rather than constant force); we do not know the size of the surface on which this pressure acted, but given the size of the dental cast Masri used, and assuming this is spread over the whole, this may be approximately equivalent to a force of 0.2Kgf (2 Newton) or less. It may take a longer time to seat such an impression and, because there is a time limit with the changing viscosity of a setting impression material, Masri's results require careful interpretation (see chapter 4 Part I above).

3.8.1 Consequences of setting a low cut-off force.

The depth of the final wash impression will be a direct consequence of the height at which the Lloyd machine halts. The impression depth will therefore be determined by the setting of the cut-off force on the Lloyd UTM at 50 Newton. The depth of the final wash impression was not predetermined in this experiment. This has advantages and disadvantages; on one hand this introduces a potential confounding variable, on the other hand it reproduces the clinical situation. It is important to assess these disadvantages while accepting the advantages.

The risk of introducing a potentially confounding variable was thought to be minimal; the height of the final wash was determined by the same cut-off setting in all experiments, therefore, it was likely to be consistent and therefore at a controlled value as a variable within the experimental design. Even though it is not predetermined, if it is consistent, it would be a controlled variable (albeit indirectly controlled) and not a confounding variable. To assess the potential for the depth of the wash impression to be a confounding variable the depth of the final wash impression was recorded for all the experiments in Part III. This was achieved using the position sensor on the Lloyd UTM.

The Lloyd UTM automatically recorded the height of the finished position of the approximation. Using this information the heights of the medium bodied base impression, and the corresponding final wash impression were recorded. The depth of the final wash impression was the difference between these two recorded heights. The depth of the final wash impression was measured and analysed to determine if it was constant across the experiments (see results and discussion below).

Clinically an impression is seated until the clinician is happy with the position. This is clinical judgement; it will vary from one clinician to another. The force a clinician uses to seat the impression is also an individual judgement. Clinically, in close fitting trays, where there is no 'stop', the clinicians chosen force of seating will determine the depth of the impression. If the cut-off force is set at the maximum clinical level of the expected force of seating then the depth of the wash silicone will be minimum and determined by similar criteria to the clinical situation. It was considered an advantage to reproduce in this way, the clinical situation encountered with the final wash impression.

3.9 Pressure sensors

The light bodied silicone wash was expected to be higher pressure in the posterior buccal shelf and lower pressure in the mental foramen area. A pressure sensor with a range of 0-100KPa was used for the mental foramen sensor and a sensor with a range of 0-1000KPa was used for the posterior buccal shelf.

3.10 Sequence of impressions

The 10 impressions for the medium bodied silicone base impressions were made first, recording the pressure simultaneously at two points; one point over the mental foramen and one over the buccal shelf. After each impression the silicone was carefully removed from the Lloyd machine marked with a reference number and stored. No silicone adhesive was used.

After all the base impressions were made, the posterior sensor was changed to the 10 bar sensor (the same sensor used in Part II of this Thesis). This was in anticipation of high pressures under the posterior wash impression. Following the re-mounting of the impression tray and lower model on the Lloyd machine, the silicone from the first run was returned onto the special tray and the first wash impression taken. Each subsequent wash impression was taken using the numbered sequence of base impressions.

The fifth wash impression to be taken had trapped air within the chamber of the sensor; this results in a dampening of the output pressure. The recording from this experiment was discarded without reading. After all the air had been removed from the system, a new medium bodied silicone base impression was taken (without

pressure recording) and the new base impression produced was used for the new wash impression pressure recording.

3.11 Statistical analysis

3.11.1 Primary outcome

The primary outcome was the differential pressure within the final wash impression. The pressure was measured simultaneously at two points for each of 10 impressions. The data was explored and analysed with SPSS software using paired t-tests for the final analysis.

3.11.2 Secondary outcome

The results of all the recorded pressures within both the base impression and the final wash impression were explored and analysed with SPSS software using either one-way ANOVA or Kruskal -Wallis (as indicated by the result of the tests of normality and for the equality of the error of variance of the dependant). Post hoc tests were to be with either Bonferroni or Dunnett T3 (also as appropriate).

Chapter 4 Accuracy and precision; the calibration of the new sensors

4.1 Introduction

The clinical impression under investigation was a lower arch impression; no single point is further than 10mm from the periphery of the impression. Chapter 7 of Part II above demonstrated the distribution of pressure across an impression; the nearer the peripheral vent, the lower the pressure. The initial base impression was in a 2mm spaced custom tray. Chapter 14 of Part II above demonstrated that the larger the space beneath a tray the lower the pressure of impression. The impressions used were not initially border moulded; one of the purposes of the base impression was to provide the border moulding. Chapter 15 of Part II above showed that without border moulding the pressure of impression is lower. Taking all these factors into account, it was anticipated that the pressure of impression in the initial (base) impression would be low.

The final wash impression was ‘close fitting’ in the majority of the impression, but spaced 2mm and perforated over the mental foramen area. Chapters 7 to 15 of Part II demonstrated the expected consequences of these conditions. It was anticipated that the final wash impression would be low pressure over the mental foramen and higher pressure elsewhere.

As a consequence of the anticipated pressures, two new pressure sensors were purchased for the experiments in Part III. The new pressure sensors had a range of 0-100KPa (0-1Bar). The new sensors were used for both sensor points in the initial (base) impression and in the mental foramen area in the final wash impression. The second sensor for the final wash (placed in the buccal shelf area) was the 0-1000KPa (0-10 bar) sensor used in Part II, and was calibrated above (chapter 2 Part II).

4.2 Calibration of the sensors

The new sensors were calibrated. The methodology of the accuracy and precision calculations followed that of Chapter 2 in Part II of this Thesis, for a full explanation of the methodology please refer back to that chapter.

4.2.1 Accuracy and precision definitions

The definitions of accuracy and precision are given in chapter 2.3.2 of Part II of this Thesis. The graph below summarizes the definitions (Figure 74). It is reproduced below (Licensed under the GFDL by the original author; and released here under the same GNU Free Documentation License) is sourced from the 17.8.10 Wikipedia website.

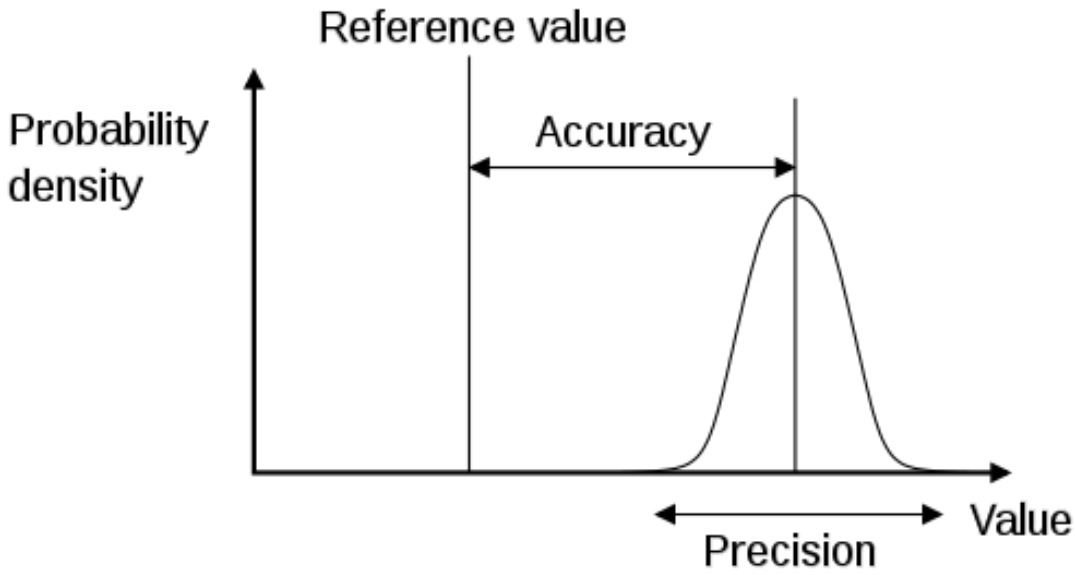


Figure 74 Summary of accuracy and precision of measurement.

4.2.2 The certification of accuracy

4.2.2.1 Sensor used over the mental foramen in all tests for Part III

An example of the certificate purchased with the transducer is shown in Figure 6 above (Part I, Chapter 2, section 2.3, page 42). The data sheet for this transducer gave the combined error as 0.0879% FS (Full Scale =1bar or 100KPa) so this is 0.0879KPa. A simple linear transformation was performed; 'true pressure' is 'given pressure' plus 0.0879KPa. It was possible to achieve this linear transformation with the software supplied with the digital sampler purchased with the pressure transducer.

4.2.2.2 Sensor used over the buccal shelf in the base impressions

The data sheet for this transducer gives the combined error as 0.0946% FS (Full Scale =1bar or 100KPa) so this is 0.0946KPa. A simple linear transformation was performed; 'true pressure' is 'given pressure' plus 0.0946KPa. It was possible to achieve this linear transformation with the software supplied with the digital sampler purchased with the pressure transducer.

4.2.3 Precision assessment

4.2.3.1 Sensor used over the mental foramen in all impressions for Part III

Nominal pressure	N	Mean	Std. Deviation	1.96 times SD	Coefficient of variance (SD/Mean)
100KPa	100	100.2739	0.043904	0.086051	0.000438
90KPa	100	91.14288	0.049333	0.096693	0.000541
80KPa	100	80.77134	0.050588	0.099153	0.000626
70KPa	100	70.78103	0.048321	0.094708	0.000683
60KPa	100	60.83168	0.049139	0.096312	0.000808
50KPa	100	50.83587	0.050071	0.098139	0.000985
40KPa	100	41.49663	0.048369	0.094803	0.001166
30KPa	100	31.26238	0.049103	0.096241	0.001571
20KPa	100	21.25019	0.048561	0.095179	0.002285
10KPa	100	11.22957	0.046411	0.090965	0.004133

Table 122 mean and standard deviation from 100 data point with pressure held at approximately the nominal pressure

Shapiro-Wilk test of normality did not detect a variation from Normality for the data that gave the means listed in Table 122 above. Therefore the method detailed in Part II Chapter 2 was used to calculate the average of the 95% Confidence Intervals of the means for the 10 data sets in Table 122 above; for the mental foramen sensor this was +/- 0.094KPa.

It is reasonable to round the output from the mental foramen sensor to the nearest tenth of a Kilopascal.

4.2.3.2 Sensor used over the buccal shelf for the base impression in Part III

Nominal pressure	N	Mean	Std. Deviation	1.96 times SD	Coefficient of variance (SD/Mean)
100KPa	100	100.1373	0.040333	0.079053	0.000403
90KPa	100	90.35629	0.040488	0.079357	0.000448
80KPa	100	80.6041	0.043593	0.085442	0.000541
70KPa	100	70.42262	0.044517	0.087253	0.000632
60KPa	100	60.56266	0.038995	0.076431	0.000644
50KPa	100	50.70966	0.044113	0.086461	0.00087
40KPa	100	40.98024	0.041749	0.081827	0.001019
30KPa	100	31.26497	0.04357	0.085397	0.001394
20KPa	100	21.03702	0.040506	0.079392	0.001925
10KPa	100	10.79018	0.041803	0.081934	0.003874

Table 123 mean and standard deviation from 100 data point with pressure held at approximately the nominal pressure

Shapiro-Wilk test of normality did not detect a variation from Normality for the data that gave the means listed in Table 123 above. Therefore the method detailed in Part II Chapter 2 was used to calculate the average of the 95% Confidence Intervals of the means for the 10 data sets in Table 123 above; for the mental foramen sensor this was +/- 0.084KPa (with the maximum recoded 95% C.I of +/- 0.087KPa).

It is reasonable to round the output from the mental foramen sensor to the nearest tenth of a Kilopascal.

Chapter 5 Results

5.1 Depth of the wash impression

The results of monitoring the depth of silicone under the final wash impression were an average silicone depth of 0.087mm, standard deviation (0.029mm)

5.2 Primary outcome

The primary outcome was the differential pressure within the final wash impression. The pressure was measured simultaneously at the mental foramen region and on the buccal shelf. 10 sets of observations were obtained within 10 impressions of light bodied silicone.

5.2.1 Raw data

The results, corrected for accuracy and rounded for precision are shown below.

Position	KPa		**Position**	KPa
Wash mental foramen	3.5		Wash buccal shelf	16
Wash mental foramen	3.8		Wash buccal shelf	12
Wash mental foramen	3.4		Wash buccal shelf	13
Wash mental foramen	3.3		Wash buccal shelf	11
Wash mental foramen	7.3		Wash buccal shelf	13
Wash mental foramen	3.3		Wash buccal shelf	13
Wash mental foramen	3.5		Wash buccal shelf	17
Wash mental foramen	3.4		Wash buccal shelf	11
Wash mental foramen	3.8		Wash buccal shelf	18
Wash mental foramen	2.8		Wash buccal shelf	12
Wash mental foramen	3.5		Wash buccal shelf	16

Table 124 Primary results, raw data

5.2.2 Exploration of data

5.2.2.1 Descriptives

	N	Minimum	Maximum	Mean	Std. Dev.
wash mental foramen	10	2.8	7.3	3.810	1.2583
wash posterior	10	11.0	18.0	13.600	2.5033

Table 125 Descriptives

5.2.2.3 Box plots

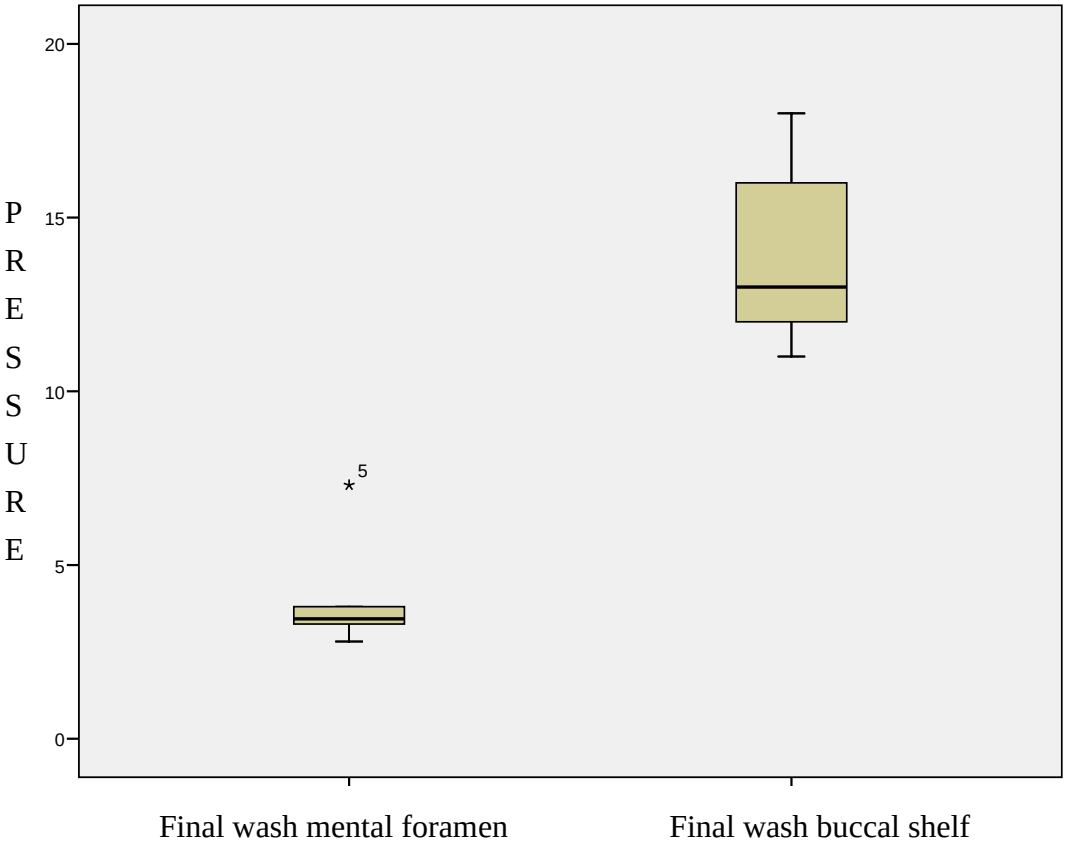


Figure 75 Box plots of the pressures from the final wash at mental foramen and the buccal shelf

The box plot (Figure 75) suggested an outlier in the data for the pressure at the mental foramen.

5.2.2.4 Shapiro-Wilk test of normality

Shapiro-Wilks was used to test if the distribution differed from normality.

5.2.2.4.1 All results

The initial; assessment included the outlier and are presented in Table 126 below

Shapiro-Wilk			
	Statistic	**df**	**Sig.**
Wash mental foramen	.578	10	.000
Wash posterior	.861	10	.079

Table 126 Shapiro–Wilks of primary outcome (outlier included)

The results of Shapiro-Wilk test suggests that the distribution of the pressure recorded over the posterior sensor did not differ from normal. However the pressure over the mental foramen sensor showed a significant difference from normal. As mentioned above the box plots suggested an outlier, this was now removed from the calculation and the Shapiro-Wilk test repeated.

5.2.2.4.2 Shapiro-Wilk without outlier

Shapiro-Wilk			
	Statistic	**Df**	**Sig.**
Wash mental foramen (without outlier)	.894	9	.221

Table 127 Shapiro-Wilk test of primary outcome without outlier.

Without the outlier the distribution of the pressures recorded over the mental foramen cannot be shown to differ from a normal distribution with the Shapiro-Wilk test.

5.2.3 Analysis

		Mean	Std. Dev	Std. Err. Mean	95% Confidence Interval of the Difference		t	df	Sig. 2-tailed
					Lower Bound	Upper Bound			
Pair 1	Mental foramen – Posterior	-9.79	2.78	.88	-11.776	-7.804	-11.15	9	.000

Table 128 Students paired t-test for equality of means

There is a statistically significant difference ($p<0.01$) between the pressures recorded at the mental foramen and the pressures recorded at the buccal shelf.

5.3 Secondary outcome

5.3.1 Raw data

Position	KPa		**Position**	KPa
Base mental foramen	11.5		Base buccal shelf	11.1
Base mental foramen	12.2		Base buccal shelf	11.5
Base mental foramen	13.3		Base buccal shelf	10.7
Base mental foramen	12.0		Base buccal shelf	12.3
Base mental foramen	12.7		Base buccal shelf	12.1
Base mental foramen	12.0		Base buccal shelf	10.4
Base mental foramen	12.0		Base buccal shelf	10.4
Base mental foramen	12.3		Base buccal shelf	11.3
Base mental foramen	10.3		Base buccal shelf	11.2
Base mental foramen	11.8		Base buccal shelf	10.1
Position	KPa		**Position**	KPa
Wash mental foramen	3.5		Wash buccal shelf	16
Wash mental foramen	3.8		Wash buccal shelf	12
Wash mental foramen	3.4		Wash buccal shelf	13
Wash mental foramen	3.3		Wash buccal shelf	11
Wash mental foramen	7.3		Wash buccal shelf	13
Wash mental foramen	3.3		Wash buccal shelf	13
Wash mental foramen	3.5		Wash buccal shelf	17
Wash mental foramen	3.4		Wash buccal shelf	11
Wash mental foramen	3.8		Wash buccal shelf	18
Wash mental foramen	2.8		Wash buccal shelf	12

Table 129 the raw data for the base and wash impressions

5.3.2 Exploration of data

5.3.2.1 Descriptives

	N	Mean	Std. Dev	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
Base mental foramen	10	12.01	.781	.247	11.45	12.57	10.3	13.3
Base posterior	10	11.11	.730	.231	10.59	11.63	10.1	12.3
Wash mental foramen	10	3.81	1.258	.398	2.91	4.71	2.8	7.3
Wash posterior	10	13.60	2.503	.792	11.81	15.39	11.0	18.0
Total	40	10.13	4.069	.643	8.83	11.43	2.8	18.0

Table 130 Descriptives

5.3.2.2 Box plot

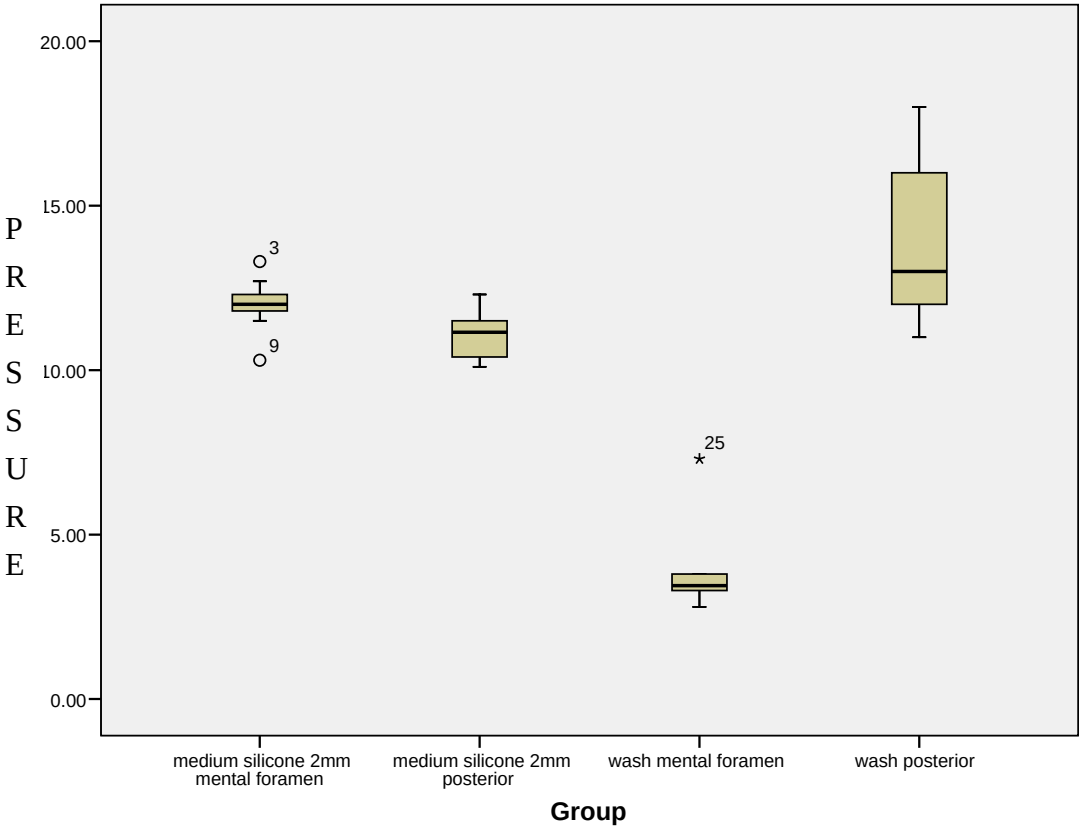


Figure 76 Box plots of the pressures from the base impression and the final wash.

5.3.2.3 Shapiro-Wilk

Shapiro-Wilk tests were used to assess the normality of the distribution of the results.

Shapiro-Wilk			
	Statistic	**df**	**Sig.**
Base mental foramen	.920	10	.360
Base posterior	.952	10	.689
Wash mental foramen	.578	10	.000
Wash posterior	.861	10	.079

Table 131 Shapiro-Wilk test of normality

The mental foramen wash had an outlier (see Box plot above). The outlier was above the remaining 9 results. It was eliminated and the Shapiro-Wilk test repeated (see below).

Shapiro-Wilk			
	Statistic	**df**	**Sig.**
Wash mental foramen (without outlier)	.894	9	.221

Table 132 Shapiro-Wilk test of normality without outlier.

5.3.2.4 Levene test

Levene Statistic	df1	df2	Sig.
6.698	3	36	.001

Table 133 Levene test for equality of variance

Levene test was unable to demonstrate equality of variance, therefore K-Wallis was used for the overall significance and Dunnett's T3 for post hoc tests.

5.3.3 Analysis

5.3.3.1 Main effect; Kruskal -Wallis non parametric

	Pressure KPa
Chi-Square	22.393
Df	2
Asymp. Sig.	.000

Table 134 Kruskal Wallis test

The Kruskal-Wallis test showed a statistically significance difference in the overall effect. Further analysis was indicated to determine where the differences lay. Dunnett's T3 was used.

5.3.3.2 Post hoc Dunnett's T3

(I) Group	(J) Group	Mean Diff. (I-J)	Std. Err.	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Base mental foramen	Base posterior	0.900	.33793	.0863	-.0904	1.8904
	Wash mental	8.200(*)	.46831	.0000	6.7984	9.6016
	Wash posterior	-1.590	.82925	.3586	-4.2069	1.0269
Base posterior	Base mental	-0.900	.33793	.0863	-1.8904	.0904
	Wash mental	7.300(*)	.45993	.0000	5.9159	8.6841
	Wash posterior	-2.490	.82455	.0640	-5.1021	.1221
Wash mental foramen	Base mental	-8.200(*)	.46831	.0000	-9.6016	-6.7984
	Base posterior	-7.300(*)	.45993	.0000	-8.6841	-5.9159
	Wash posterior	-9.790(*)	.88600	.0000	-12.4885	-7.0915
Wash posterior	Base mental	1.590	.82925	.3586	-1.0269	4.2069
	Base posterior	2.490	.82455	.0640	-.1221	5.1021
	Wash mental	9.790(*)	.88600	.0000	7.0915	12.488

Table 135 Post hoc Dunnett's T3; secondary outcome, dependent variable: pressure KPa; * denotes that the mean difference is significant at the .05 level.

The Dunnett's T3 results show that the results for the pressure of the wash impression at the mental foramen are significantly different than the other impression pressures. They are significantly lower. No significant differences can be shown between the other impression pressures in this analysis.

Chapter 6 Discussion

6.1 Historical lack of evidence

Differential pressures within a prosthodontic impression have been advocated from the earliest times. Stansbery's (1925) paper describes a method specifically designed to selectively load mucosa under an impression. Although the scientific evidence presented by Stansbery for his selective pressure technique was limited, the paper demonstrated that the concept of a selective pressure impression was one of the earliest impression philosophies to be defined and advocated (see section 2.1 of Part I for further discussion of Stansbury).

Selective pressures have been advocated continually since this time and it has been considered the impression technique of choice by many experts. In 1992 Firtell and Koumjian says 'recent reports in the literature agree that selective pressure is the best method of making impressions for complete dentures'. Moving into the 21st century the established practice of selective pressures impressions is still being developed for modern materials and advocated in the academic literature: Hyde 2003, Duncan et al 2004, Lynch and Allen 2006, and Massad et al 2006.

Despite the many clinical reports and case histories a literature search has not provided any actual evidence (since the early limited demonstration by Stansbury in 1925) of differential pressures that may occur within any of the advocated impression techniques. Do these advocated techniques produce a differential in pressure across an impression? Evidence was required; this investigation (Part III) is an attempt (perhaps the first) to do so within any particular impression technique.

6.2 Cut-off force and variance in depth

The setting for the cut-off force on the Lloyd Universal Testing machine was 50N throughout Part III of this study. This was considered the maximum force that could be exerted clinically for any impression. The depth of the wash impression was not directly controlled; this mimics the clinical situation. The depth of silicone was measured and the results show an average depth of 0.087mm (S.D. 0.039).

Compared to the designed space difference between the mental foramen and the buccal shelf (2mm), the variation in the depth of the wash is small. However, if the pressure to space relationship is inverse (as in Chapter 14 of Part II) such small variation has the potential to make a large difference to the pressure. It is noted that the variation in the recorded pressure of the close fitting area of the final wash impression on the buccal shelf is larger than elsewhere. If the buccal shelf figures are removed from analysis a Levene test for the equality of variance changes in significance from p=0.001 to p=0.831 demonstrating that the buccal shelf is responsible for the non conformity of variance. This can be visualised in box plot Figure 76 section 5.3.2.2 above. In these circumstances, an hypothesis may be suggested that the variation of the buccal shelf pressure may be caused by the lack of control of the depth of impression.

An hypothesis could be proposed that the buccal shelf variation may be due to the 'close fitting' nature of the wash impression in this area; further investigations would be required to test this hypothesis. The important question here was, does this buccal shelf variance matter? In answer to that question three points were considered. Firstly, the differences demonstrated by the primary outcome are large in comparison to the difference shown within the buccal shelf pressure readings (which may or may not be caused by a variation in the depth of silicone). Secondly, the variation experienced has not rendered it impossible to analyse the results. Finally, the use of the cut-off level to determine the depth of silicone mimics the clinical technique. Taking these three points into consideration, it was considered that the variation in the depth of silicone was neither an important nor a statistically significant confounding variable.

6.3 The base impression

The results suggest the base impression is clinically adequate; it has the following desirable properties:

1. It is relatively low pressure, relatively mucostatic.

It is important the base impression does not produce a highly mucodisplasive impression since we know from the work of Kydd (1974) (see section 3.2, Part I above) that viscoelastic recovery will not occur within the timescale of the impression appointment. The results suggest the pressure of impression for the

medium bodied base impression is not significantly different from the low pressure of the light bodied silicone wash impression over the buccal shelf (see section 5.3.3.2, Post hoc Dunnett's T3 above).

2. It loads the mucosa relatively evenly

The differential pressures within the base impression are not significantly different from each other (see section 5.3.3.2); this suggests relatively even loading of the mucosa under the impression.

3. It provides adequate border moulding of the impression tray to develop border and facial seal.

The use of silicone to border mould impressions is becoming more popular among specialists (Petrie et al 2005) (although not yet the dental schools who lag behind) as an alternative to traditional green stick tracing compound. It requires a different technique to adapt the border of an impression tray with silicone. The border moulding may be best applied in different ways in the upper and the lower arches. In the upper arch placing the silicone on the periphery is easy and quick. In the lower arch, if one restricts the application of the silicone to the borders of the special tray, it inevitably spreads to cover much of the mucosal surface of the denture bearing area during the moulding. In the hands of this operator, the easiest technique to border mould with silicone in the lower arch is to spread the silicone over the entire lower impression and take the border moulding impression. The final impression is then a wash impression, using the set silicone of the base impression as the border moulding.

4. It provides a close fitting special tray that is not made from a poorly adapted (potentially high pressure) primary impression.

The base impression carried out in a spaced special tray is relatively mucostatic with even loading and good border moulding. This provides a surface upon which a close fitting wash can be taken. This surface for the wash impression is expected to be superior to that of a close fitting special tray made from a primary impression. As discussed in section 14.11.2 of Part II above, a special tray from a primary impression is unlikely to be a good fit, it has potential therefore to preferentially load and distort the mucosa. The surface from the medium bodied silicone impression is likely to be superior in the three ways shown above.

5. It was easy to adapt.

6.4 The primary outcome

The paired student t-test shows a statistically significant difference between the mental foramen pressure and the buccal shelf pressure. The mental foramen pressure is lower. This is in contrast to the base impression where the same pressure points showed no statistical difference with the Dunnett T3 post hoc test in section 5.3.3.2. This is the desired pressure differential that the impression technique was designed to produce.

6.5 Limitations on interpretation

The usual limitations of in-vitro experiments need to be emphasized for the interpretation of these results. Within the oral environment there are more potentially confounding variables such as the visco elastic nature of the mucosa, the amount of moisture on the mucosal surface, the nature of each individual patient's saliva, the surface tension of mucosa (which affects contact angle and 'wetability' of the impression material). As discussed (Part II section 11.6 above) ultimately the only way to investigate the total combination of all variables is to measure the impression pressure in-vivo.

Chapter 7 Conclusion of Part III

Within the limitations of this in-vitro experiment there is a differential pressure between the buccal shelf and the mental foramen in this impression technique. The lower pressure is recorded over the mental foramen.

Part IV

The clinical assessment of an impression technique

Chapter 1
Aims and objectives

1.1 Aim

The aim of Part IV was to conduct a Randomized Controlled Clinical Trial to determine patient preference for treatment modalities which distribute pressure under a lower denture.

1.2 Objectives

The objectives of Part IV are:

1. To identify appropriate research participants with a specific clinical need.

2. To adapt Hyde's 2003 method of selective pressure impression (Hyde 2003) to the clinical problem.

4. To choose an appropriate primary outcome measure for the trial.

5. To devise a method of producing three dentures for each patient which are very similar apart from the impression surface.

6. To test, for accuracy, the method of reproducing the occlusion of the three dentures.

7. To design an appropriate protocol for the conduct of the trial.

8. To run the trial, collect data and undertake appropriate statistical analysis of the results.

9. To disseminate the results for the trial.

Chapter 2
Introduction; the background to trial specific issues

2.1 Identifying a specific clinical need

The Adult Dental Health Survey for the UK (Kelly 1998) showed that 34% of patients over 64 years of age were edentulous. In northern England, in patients over the age of 75 years, in social class *IV* and *V*, the edentulous figure rose to 63% for men and 73% for women. Many of these patients have been edentulous for decades. There are particular problems providing dentures for patients who have been edentulous for many years. These problems are associated with severe alveolar bone resorption (Budtz-Jørgensen 1999). It is the lower edentulous arch, and so the lower denture, where these problems are more pronounced. In some patients, as the mandible resorbes down to basal bone the mental foramen becomes involved in the denture bearing area (Boucher 2004). The subsequent crushing of the emerging nerve by a functioning lower denture can cause pain and discomfort (Basker and Davenport 2002). These patients may benefit from the use of a selective pressure impression which reduces impression pressure in the area of the mental foramen and ultimately reduces the pressure from occlusal load under the subsequent denture.

"A survey by the candidate and the local consultants of the clinics at Leeds in 2005 suggested that there were high numbers of patients with mental foramen problems in Leeds. The high numbers of patients with mental foramen problems in the audit may have been due to a concentration of these patients within the Leeds Dental Institute or alternatively the sample used for the audit may be reflective of an under diagnosis of mental foramen problems in the edentulous population.

Leeds Dental Institute is a centre of excellence and a referral centre for the region. Referrals of 'chronic' denture patients may have resulted in a high concentration of these technically more difficult complete denture patients on the Institute waiting lists. However it remains possible that the mental foramen problem is prevalent in larger numbers within the edentulous population than has been hereto realised. Further research would be useful on this topic. Whatever the cause, the high numbers of patients with a mental foramen problems in Leeds in 2005 was sufficient for further research to be considered.

2.2 Treatment options for patients with mental foramen problems

The McGill consensus statement (Feine et al 2002) for the treatment of the edentulous mandible states that the minimum standard of care for the treatment of the edentulous mandible should be the provision of osteo-integrated dental implants to support and retain the complete lower denture. This approach is supported, as far as finances allow, within Leeds Dental Institute. In the UK the 2008 conference of the BSSPD fully debated the advantages imparted by implant supported lower complete dentures. The resulting York Consensus as published by Thomason et al (2009) strongly advocated the use of implants (Thomason 2008). The author of this Thesis is credited as a co-author of the Thomason et al paper (but please note, it is a joint paper with many credited authors and is not the sole work of any author; it does not form any part of this Thesis, and it is mentioned for reference only).

There are, however, barriers to treatment with implants; notably cost and surgical risk. Esfandiari et al (2009) provides insight into the effect of financial cost in deterring patients from accepting implants. Walton and MacEntee (2005) showed that even when there is no cost, a proportion of patients' still refused implants. The most common and highly rated reason for this refusal was the perceived surgical risks (Walton and MacEntee 2005, Esfandiari et al 2009).

Patients, who have a mental foramen within the denture bearing area, necessarily have very little height to their mandible. This lack of bone would usually indicate bone enhancement prior to implant provision. Medical and social problems may counter indicate autogenous bone transplants for many of the more frail older patients. Others may refuse because they do not accept the cost or surgical risk (Esfandiari et al 2009, Walton and MacEntee 2005). In patients for who implant treatment is counter indicated or refused, conventional complete dentures remain the best option for treatment.

If conventional dentures are to be provided and the problem is undiagnosed it is common for a conventional impression to be used. When the problem is diagnosed, a traditional way of relieving pressure over the mental foramen has been advocated in standard textbooks (McCord and Grant 2000). A metallic foil placed on the working cast, over the area of the mental foramen, provides space under the lower denture in this area. The space is said to provide local relief from pressure on

occlusal load. An alternative way of dealing with the problem, by a selective pressure impression, was now proposed by Hyde.

2.3 The need for a randomised clinical trial

Jokstad et al (2002) stated: 'A randomized controlled trial (RCT) is the most scientifically sound method to detect small therapeutic gains, as long as it has been properly designed to minimize bias (systematic error)'. As reported in the literature review (Part I, Chapter 5, Page 28), within the prosthodontic literature, there is a paucity of high quality evidence in the form of Randomised Controlled Trials (RCTs) for any specific impression technique for complete dentures. A new development of selective pressure impressions has been advocated by Hyde (Hyde, 2003). Evidence was required to validate the technique. An RCT of the impression technique was therefore proposed using, as subjects, patients who had a problem with an emerging mental nerve on the denture bearing area of the lower edentulous ridge.

2.4 Grant application and funding

Clinical trials are expensive to run. Studies which are underfunded run the risk of having too few patients and so being underpowered. For example, McCord's 2005 paper appears to fall into this trap. It was necessary to apply for and obtain appropriate resources for the project. Funding for the trial was applied for from Dunhill Medical Trust (Appendix 7). As the PhD supervisor, Prof Brunton kindly agreed to be the Principle Investigator (PI) for the grant application. However, as the application was written by Mr T Paul Hyde as the principle author (with assistance from PhD supervisors) it is appended to this Thesis. The referees for Dunhill Medical Trust made several helpful suggestions (see section 2.5.3). These were addressed, and additional funding for a quality of life assessment (OHIP-14) was included in the final grant.

2.5 Selection of an appropriate primary outcome measure.

In order to avoid an indiscriminate outcome of the trial, particular care was needed in the selection of the primary outcome measure. Some previous studies have been unable to detect a difference (Firtell and Koumjian 1992, Frank 2004).

This inability to differentiate maybe because there was really no clinically significant difference or this failure to differentiate may be because the outcome measure used was insufficiently sensitive to be able to detect the difference. Equally important is that the chosen outcome measure is able to correctly select negative outcomes. The outcome measure should be sensitive (i.e. not miss positive results) but it should also be selective (i.e. not give false positives). It was appropriate to review outcome measures used in previous studies.

To facilitate selection of an appropriate outcome measure two strategies were proposed. First, the evaluation of the primary outcome measure in previous RCT's of impressions (see section 2.5.1) and second, evaluating the use of OHIP's as primary outcome measures in the papers that used OHIPs in any RCTs (see section 2.5.2). The summary and conclusion are discussed in section 2.5.3. below.

2.5.1. Evaluation of primary outcome measures used in five papers reporting RCTs involving dental impressions

2.5.1.1. Firtell and Koumjian (1992)

Firtell and Koumjian's (1992) study has been discussed previously (Part I, chapter 5) it is one of only two papers that investigate complete denture impressions with RCTs. He used the number of adjustments to the finished denture as the primary outcome assessment for the study. He was unable to detect a difference between the impression materials. The study also appears to be underpowered with only 15 patients for each side of the parallel RCT. As Jokstad (2002) reports Firtell and Koumjian's (1992) study was not blinded (see Part 1, Chapter 5 and Table 2). The under powering and the weak outcome measure may both have contributed to the inability to detect a difference in this study. The number of adjustments was rejected as an outcome measure for the RCT in this Thesis.

2.5.1.2 Millar et al (1996)

Millar et al (1996) investigated the use of a topical surfactant on the quality of polyvinylsiloxane impressions in-vivo in a split mouth RCT of dentate patients. He assessed the quality of the impressions by subjective examination by three 'experts'. A statistically significant difference was found between the treated and untreated sides of the impressions. The assessment was reported to be blind. Reproducibility in the form of intra and inter examiner agreement was not reported. This study

suggests that expert opinion is sufficiently discriminatory in assessing perceived quality of impressions. However for the proposed RCT of selective pressure impressions in this Thesis the visual assessment of the impression by experts would not be enough to establish that the subsequent denture was beneficial.

2.5.1.3. Hochman and Yaniv (1998)

Hochman and Yaniv (1998) looked at the 'fit' of cobalt chrome frameworks constructed on casts made from either irreversible hydrocolloid or condensation cured polyvinylsiloxane impressions. Customized special trays do not seem to have been used in the study. The study design was cross over with 22 patients. The technicians who made the two frameworks were blind, the patients were blind; it is unclear whether the dentists performing the assessments were blind. The assessment was stated as: 'the examiner selected the better frame work'. This was achieved by assessing the framework on the cast (with numerous criteria), in the mouth (with numerous criteria) and by asking the patient about comfort. It is unclear how the numerous assessments were correlated to arrive at the final decision of the examiner. Nevertheless the opinion of the examiner produced a statistically significant result which was that the alginate impressions were superior. Reproducibility of the assessment was not tested. Although (structured) dentist opinion has (again) produced a clear outcome for this study, it was felt dentist opinion was not an appropriate primary outcome measure for the RCT of this Thesis since it would not establish the benefit to the patient, nor be respected for reproducibility.

2.5.1.4. Frank et al (2004)

Frank et al (2004) conducted a parallel, double blind, randomised, controlled, clinical trial to compare altered cast impressions of free end saddles with secondary impressions in well fitting, customised, border moulded, special tray using polyether material (Impregum). Frank et al does not specify a 'primary' outcome measure. There were at least 16 different assessment criteria listed in the method section in addition to a questionnaire given to the patient that lists four distinct questions and two 'open ended' questions. Two of the outcome measures used gave statistically significant results; the remainder gave no statistical difference. There is a problem with statistical analysis which uses multiple testing. If 20 outcomes are analysed in a study, each at a 95% significance level, then it would be expected that on average (over a large number of such studies) the tests would yield one out of the 20 as a

false positive result. In Frank et al's study (2004) 2 out of 20 gave a positive result; further statistical analysis would be necessary to determine if such a result is within a reasonable confidence interval of a chance occurrence. Frank et al does not comment on this statistical dilemma. Frank et al concludes that the two positive results were not *clinically* significant.

It is good practice when establishing any outcome measure, to set the level of a 'clinically significant' result before the RCT commences and use the set level for the power calculation; retrospective setting of the value of clinical significance is respected less. It is unclear when the level of 'clinical significance' was set in Frank et al's study (2004).

The use of multiple assessment tools can be useful if used in a preliminary study where they can be evaluated for their role as primary outcome measures in the definitive study. However such 'fishing trips' need careful statistical analysis. Consideration should be given to whether Frank et al's (2004) study can be used (as a 'fishing trip') to evaluate sensitive and selective outcome measures for future studies.

The two measures which gave positive results in Frank et al's paper (2004) were considered as potential outcome measures for this PhD. They were the measurement of the depth of fit checker beneath the acrylic fitting surface of the dentures, and the visual assessment of the position of the border of the denture by an expert. For the RCT in this Thesis the visual assessment of the border of the lower complete dentures was considered too subjective, too difficult in the lingual sulcus, and largely irrelevant to the success of the dentures in patients with mental foramen problems. It was therefore dismissed.

In Frank et al's study (2004), the depth of 'fit checker' over the ridge was greater in dentures which were not made from altered cast impressions. The use of 'fit checker' under the free end saddle cobalt chrome denture was appropriate as an assessment tool for Frank et al's study because the metal framework could be fully seated on the anterior teeth, and any gap posterior to the last abutment assessed. However for complete dentures this method of assessment has problems. There is no tooth borne 'stop' in complete dentures and the thickness of fit checker would be dependant (among other variables) on the pressure of seating placed on the denture. This method of assessment had potential for relevance for patients with mental

foramen problems. However the inability to reproduce consistent pressure between different dentures and amongst different patients could not be overcome easily. That is to say intra and inter patient reproducibility were expected to be low. The method was therefore rejected for use in this Thesis.

2.5.1.5. McCord et al (2005)

McCord et al's study (2005) has been discussed previously in Part I, chapter 5; it is one of only two papers that investigate complete denture impressions with RCTs. The study was underpowered and because of a lack of control of the order of delivery it was potentially bias in favour of 'admix' and against 'Provil'. It failed to discriminate the best impression material of the three used but elucidated the worst material (zinc oxide eugenol) with a statistically significant result. The primary outcome measure was the patients' preference for the dentures. It is remarkable that so simple an outcome measure could discriminate a statistically significant result with just 11 subjects in the trial.

Patient preference appeared to be a sensitive assessment tool. For patients with mental foramen problems, the patient is the best (and only) one to determine the comfort of the denture. As an outcome measure, patient preference is relevant for the RCT of this Thesis.

2.5.2. Evaluation of OHIPs as primary outcome measures

Oral Health Impact Profile (OHIP) questionnaires have been established as one of the more widely used patient centred, quality of life (QoL) assessment tools available in dentistry. Over 230 published papers mention OHIP questionnaires in the dental literature. The number of papers mentioning 'OHIP' within 'dental journals' by year of publication can be seen in Table 136 below. Many of these papers are cross sectional studies or use OHIPs for an overall view of a study rather than as a primary outcome. If the literature search is limited to 'Randomised Clinical Trials' only 29 published papers mentioned 'OHIP'.

Year	Number of published dental papers mentioning OHIPs		Year	Number of published dental papers mentioning OHIPs
1993	1		2002	9
1994	2		2003	18
1995	1		2004	16
1996	0		2005	17
1997	2		2006	23
1998	1		2007	33
1999	4		2008	37
2000	2		2009	35
2001	6		2010*	29

Table 136 Number of published papers mentioning OHIPs by year; * year to December

A survey of the published papers that use OHIP's is indicated. This is divided here into two sections. Firstly those papers published prior to the protocol design. Secondly those papers published after the protocol had been written but within the period where the trial was underway. The second part of this review was undertaken to monitor the use and progress of OHIPs within the research community. Only papers reporting the use of OHIPs as the primary (or equal first) outcome measure in Randomised Clinical Trials are reported here.

2.5.2.1 OHIP evaluation prior to protocol design

2.5.2.1.1 Wolfart et al (2005)

Wolfart et al (2005) reports the pilot study of a multi centre, randomised clinical trial of two treatment modalities of the shortened dental arch using OHIPs as an assessment tool. For statistical methodology Wolfart et al reports: 'The items were scaled using 6-point scales: 'never', 'rarely', 'occasionally', 'often', 'very often' and 'all of the time'. Consequently, higher scores indicate a higher impact. Subscale and sum-scores were calculated by adding the item scores with weighting'.

However in the statistical analysis section he states that pair wise analysis with Wilcoxon was also used. Thus he appears to use both common methods of assessing OHIPs. Wolfart et al reports: 'No significant difference could be reported between the two therapy concepts'. There may be no difference or the OHIP failed to detect any difference.

2.5.2.1.2. The Papers which have JS Feine as the corresponding author

The papers of Awad et al (2000 & 2003) and, Heydecke et al (2003 & 2005) report trials conducted in Montreal and share authorship with JS Feine who is the corresponding author for all papers. All the papers report parallel sided RCTs looking at the difference between lower conventional complete dentures (CD) and implant retained lower complete dentures (IOD).

Taking the earliest paper first, Awad et al (2000) reports 102 patients (ages 35 to 65 yrs) with 54 in the implant (IOD) group, and 48 in the conventional denture (CD) group. They use OHIP as the outcome measure. For analysis they manufactured a dichotomous variable. To achieve this those patients who answered 'rarely' or 'never' were said to have 'no negative impact' from the dentures; they then compared numbers of patients with 'no negative impact' 'before' and 'after' for both the IOD group and the CD group. T-tests were used for each OHIP 'domain' with Bonferroni correction for multiple testing. They conclude: 'patients who receive implant treatment experience more improvement in their perceived oral health than do patients who receive conventional treatment'. This was a positive result for the use of OHIP's as a primary outcome measure.

In 2003 Awad et al reports a similar study; this time with just 60 older patients aged 65-70 (30 per group). They used general satisfaction with a visual analogue scale (VAS) as the primary outcome measure and both OHIP-49 and OHIP-EDENT as secondary outcome measures. The treatment assessment was carried out at two months. They gave the six possible answers to the OHIP questions arbitrary score of 1-6 and performed analysis on the scores with independent t-tests. They conclude: patients 'who received a mandibular overdenture retained by ball attachments on two implants opposed by a maxillary conventional denture had significantly better oral function than those who were given mandibular and

maxillary conventional dentures'. This was a positive result for the use of OHIP's as a primary outcome measure.

Heydecke et al (2003) appears to report the same trial as Awad et al (2003), 60 patients aged 65-70 divided into two groups. This time the study is reported using a 20 item version of the OHIP (OHIP-20) and the study measured post treatment assessment at 6 months, alongside a general 'SF-36' questionnaire. Analysis was by adding up the OHIP 'scores' (1-6) which represented the standard answers to the questions. Paired t-tests were used to compare the baseline with the six month post treatment scores. They also manufactured a dichotomous outcome, by comparing the number of patients who answer 'no impact' between the IOD and CD groups. They conclude: 'senior patients in this trial who received mandibular implant overdentures six months before had significantly better oral health status than patients given conventional removable dentures. This was a positive result for the use of OHIP's as a primary outcome measure.

Heydecke et al (2005) investigated 102 patients in a parallel RCT looking at removable complete lower dentures with and without implants. This appears to be the same study as Awad et al (2000). They report results of using a separate 'Social Impact Questionnaire' (SIQ) for the 'main outcomes' and the OHIP 49. They report correlations between the two surveys using Spearman's correlation. For example, they found that if the denture were rated as unstable (via OHIP) there was a correlation with a negative impact on sexual activities (via SIQ). Both types of survey conveyed a significant improvement in overall patient wellbeing post treatment (for both the implants group and no-implants group). For sexual activities 'kissing' and 'sexual relations' the SIQ rated implant retained dentures as better. They do not report whether there were any significant findings using the OHIP for the difference between the implant group and non implant group. However, this appears to be reported separately in the Awad et al (2000) paper (see above). They conclude 'The impact of conventional and implant dentures on social and sexual activities is not fully captured by an existing OHQoL measure, the OHIP'. They are emphasizing that the SIQ is better at differentiating improvements in sexual quality of life than the OHIP, rather than saying that the OHIP is ineffective.

2.5.2.2 Monitoring the performance of OHIPs in using publications post 2005 (during the running of the trial)

In late 2008, a search of the dental literature for the terms 'OHIP' and 'RCT' revealed five further papers that had been published during the course of the trial and that assessed therapeutic interventions with OHIPs as the primary outcome. These studies cover all areas of dentistry. An evaluation of the effectiveness of the OHIP's as an outcome measure in these studies was indicated.

2.5.2.2.1 Gil-Montoya et al (2008)

Gil-Montoya et al (2008) carried out a randomised, double blind, cross-over pilot study. This study evaluated the clinical efficacy of a mouthwash and an oral gel in elderly individuals with dry mouth. An OHIP-14 was used as one of five outcome assessments. The OHIP was the only outcome measure to record any significant result. However, the OHIP 'found the impact greater in the placebo group in both interventional periods'. They conclude that the study 'yielded no positive results'; they state this was in contrast to simi lar published studies. It is difficult to see this study as a validation of using OHIP's as a primary outcome measure.

2.5.2.2.2. Ozcelik et al (2007)

Ozcelik et al (2007) found that an OHIP could discriminate the difference in the quality of a patient's life in the week following treatment by periodontal surgery or non surgical treatment. Patients who had surgical intervention had a worse quality of life in the week after treatment. This is a positive result for the use of OHIP's as a primary outcome measure.

2.5.2.2.3. Sutton and McCord(2007)

Sutton and McCord (2007) used OHIP-20 to assess patient quality of life in a cross over trial following treatment with three different arrangements of occlusal form. The Wilcoxon test was used to assess the median values of the OHIP scores. Wilcoxon found statistically significant differences in 5 out of 60 assessments; however the issue of multiple testing clouds these results. At a 95% confidence level it would be expected that three out of 60 results would return a statistically significant result by random choice. As the CONSORT Statement says, 'A common but misleading approach is to compare P values for separate analyses of the

treatment effect in each group. It is incorrect to infer a subgroup effect (interaction) from one significant and one non-significant P value. Such inferences have a high false positive rate.' (Consort Group, 2010, Methods section, 3-12b, additional analysis).

It is interesting to note that the other paper by Sutton et al (2007a) published in the Journal of Dental Research reporting this same (PhD) study and with the respected statistician Helen Worthington as a co-author does not report the OHIP results. The Journal of Dental Research paper (Sutton et al, 2007a) used patient preference expressed in Visual Analogue Scales (VASs) using ANOVA and appropriate statistical treatment of repeated measures. For the purpose of this discussion on OHIPs as primary outcome measures, it is instructive to note from Sutton's PhD papers (2007 & 2007a) that the patient preference outcome assessed by Visual Analogue Scales (VAS's) produced the clearer outcome and was reported in a high quality journal.

2.5.2.2.4. Baker et al (2006)

Baker et al (2006) investigated a short form OHIP-14 compared to another questionnaire (OIDP) as part of a RCT of reservoir bite guard in patients with xerostomia. This study did not use an OHIP as an outcome measure in a RCT, and is therefore irrelevant to an evaluation of OHIPs for primary outcome measurement, but of interest in assessing the value of OHIPs compared to other measures of outcome.

Quantifiable measurements of the severity of the xerostomia were obtained from the patients together with symptoms seen on clinical examination. The patients were then given the questionnaire to take home and fill in during a one week period. 'This study aimed to evaluate the validity of two OHRQoL measures in a specific clinical context: patients with xerostomia' (Baker et al 2006); they conclude: 'The findings suggest that both OHIP-14 and OIDP have good psychometric properties and are useful measures of OHRQoL in xerostomia. Overall, however, the OHIP-14 performed better than did OIDP'. This study did not report an OHIP as a primary outcome measure in a RCT, however the superiority of the OHIP-14 over another quality of life assessment tool was worthy of note.

2.5.2.2.5. Allen et al (2006)

Allen et al (2006) compared implant and conventional mandibular dentures within a parallel designed, randomised clinical controlled trial using OHIP as the primary outcome measure'. Allen et al states: 'There were no significant post-treatment differences between the groups, but a treatment effect may be masked by application of 'intention to treat' analysis'.

This trial (Allen et al 2006) used the 'intention to treat' philosophy for analysis; it would be interesting to know the results of an analysis based on actual treatment received. Asking for analysis on the basis of actual treatment received would be against normal convention for an RCT and such an analysis needs to be carefully interpreted. The CONSORT guidelines state 'One widely recommended way to handle such issues is to analyze all participants according to their original group assignment, regardless of what subsequently occurred. This 'intention-to-treat' strategy is not always straightforward to implement. It is common for some patients not to complete a study (they may drop out or be withdrawn from active treatment) and thus not be assessed at the end. Although those participants cannot be included in the analysis, it is customary still to refer to analysis of all available participants as an intention-to-treat analysis.' and goes on to say 'Conversely, analysis can be restricted to only participants who fulfil the protocol in terms of eligibility, interventions, and outcome assessment. This analysis is known as an 'on-treatment' or 'per protocol' analysis. Sometimes both types of analysis are presented.' end quote (CONSORT 2010). Perhaps both types of analysis would have improved the Allen et al (2006) paper.

In the end there was no difference detected; there may be no difference or the OHIP failed to detect any difference.

2.5.3. Discussion of the assessment of possible primary outcome measures

Section 2.5.1 above looked at various outcome measures in previous RCT of impressions. Five Papers highlighted some possible outcome measures. two of the papers, Firtell and Koumjian (1992) and Frank et al (2004) failed to elucidate any difference. After careful consideration, the outcome measures used in these two papers were dismissed as unsuitable for this study.

Three papers produced a significant outcome for RCTs; Millar et al (1996), Hochman and Yaniv (1998), and McCord et al (2005). Both Millar et al (1996) and

Hochman and Yaniv (1998) used careful assessment by experts as outcome measures. There were concerns that 'expert opinion' had potential problems of bias in the proposed study. Of more concern was the consideration that the purpose of performing an RCT was to provide a standard of evidence for clinical practice that was above the level of 'expert opinion'. Even with well intended, well structured and effective 'expert opinion', use of 'expert opinion' seemed counter to the ethos of an RCT. 'Expert opinion' was considered inappropriate as a primary outcome measure for this study.

McCord et al (2005) used patient preference for the finished denture as the primary assessment tool. This simple measure was, at least partially, effective. It was also considered sensitive, given the small number of participants in the trial (McCord et al 2005).

The two papers by Sutton in 2007 contrast (within the same PhD study) the use of patient preference (Sutton et al 2007a) and the use of an OHIP (Sutton and McCord 2007) as outcome measures. Patient preference was decisive as an outcome measure, the OHIP was indecisive.

Section 2.5.2 considers the use of OHIP's as outcome measurements. Out of the 9 papers that used OHIPs, three papers of the papers, namely Gil-Montoya et al (2008), Allen et al (2006), and Wolfart et al (2005), found no evidence of a difference, 1 paper (Sutton and McCord 2007) used multiple analysis and may therefore have made errors in the statistical analysis. 1 paper does not fully report the results for the OHIP (Heydecke et al 2005) and four papers Ozcelik et al (2007), Awad et al (2000), Awad et al (2003), and Heydecke et al (2003) report positive results for the use of OHIPs.

The studies with positive outcomes have in common dramatic differences between the two sides of the trials. Surgical intervention against no surgical intervention, and measured during the week after surgery (Ozcelik et al 2007) is a dramatic difference between the two treatment modalities. Similarly lower implant retained over dentures against conventional lower dentures is a dramatic difference between the two treatment modalities. Maybe where there is a dramatic difference between to two side of the trial, OHIPs are able to detect the difference. However an hypothesis that only a dramatic difference can be detected by an OHIP is speculative and should be tested; it must also be considered that Allen et al in 2006

failed to detect such a difference between traditional dentures and implant retained dentures with an OHIP.

The four papers which had JS Feine as the corresponding author are noteworthy. The three earlier papers, Awad et al (2003 & 2000) and Heydecke et al (2003) had results which were able to discriminate between 2 sides of the trial using an OHIP and yet this group of researchers felt it necessary to investigate an alternative to OHIPs in their later paper (Heydecke et al 2005). This is not unreasonable since the OHIP was not designed to directly assess sexual well being. They conclude that the difference they were trying to measure 'is not fully captured by an existing OHQoL measure, the OHIP' (Heydecke et al 2005).

Statistical 'regression to the mean' is a reported potential problem with OHIP questionnaires (Heydeck 2003, Slade 1998). Heydeck (2003) says 'Regression to the mean can be observed if an outcome measurement is repeated, often resulting in values closer to the population mean. This phenomenon has also been reported for the OHIP questionnaire (Slade 1998).' Heydeck goes on to say about his own results 'It is possible that regression to the mean may be the explanation for the fact that mean subscale and total OHIP-20 scores in both groups were lower than at the 2-month follow-up.'. Although the term 'regression to the mean' has specific technical definitions in statistics, it may have different interpretations in different contexts. It is usual to use the term to explain an artificial difference occurring between two non random samples that are imperfectly correlated; if the original sample is skewed a repeated sample may be expected to regress toward the population mean. The question that is more perhaps more relevant is, 'what made a sample skewed?' Or, expressed in non technical terms 'if there is a shift in patient response, why was there a shift in the response?' The problem expressed by Heydeck (2003) and Slade (1998) as 'regression to the mean' represents a potential complication for the use of OHIPs for outcome measures in the proposed study.

The related problem of questionnaire fatigue also needed to be considered; if we were to use OHIP questionnaires as a primary or secondary outcome measure for the proposed study, we would need a total of four OHIPs (a baseline OHIP and three trial denture OHIPs). This may cause questionnaire fatigue. The patient would also need to wear each denture for a sufficiently long period prior to the OHIP assessment; this would lengthen the trial.

It should be noted that in the study design stage of the planning for the RCT, this Thesis did not have the benefit of the later papers published after 2005 (later papers were not available during the planning stages). These later papers are more negative in their evidence for the ability of OHIPs to provide useful outcomes. Overall, the evidence from the literature for the effectiveness of OHIPs as a primary outcome measure in clinical trials is ambivalent.

2.5.4. Decision over the primary outcome measure

The Randomised Clinical Trial (RCT) for this Thesis chose the use of 'patient preference' as the primary outcome. This gave a patient centred outcome, involving the patients in the decision making process. The evidence suggested that patient preference was sensitive and easy to use. It also required a short assessment period, which was considered an advantage.

The use of an OHIP as the primary outcome measure was rejected for this study. However, the referees of the grant funding agency (Dunhill Medical Trust) asked us to re-consider the use of an OHIP as an additional outcome measure. Aware of the issues discussed above and in particular that the sensitivity of the measure may be low there were reservations. Furthermore to have included an assessment of the impact of each denture on a patient's quality of life (i.e. the use of an OHIP) would have required a lengthening of the assessment period for each denture to a minimum of 8 weeks. Unless adjustments could be made to the fitting surface of the dentures, this would have potential to be uncomfortable (impossible) for at least some of the participants. It would be unethical to ask the patients to wear a denture for 8 weeks if it caused ulceration. However, adjustments to the dentures before the patient's choice of denture would negate the purpose of the study since it would alter the impression surface. Consideration was given to whether an adjustment could be made to one denture and the same change made to each of the other dentures, but this seemed impractical. The lengthy assessment period required for an OHIP, and the necessity not to change the fitting surface prior to the choice of preferred denture by the patient, made the use of an OHIP as an outcome measure impractical for this study. The request from the Dunhill reviewers for an OHIP remained a potential obstacle to funding.

A compromise was reached; changes were made to the protocol to include an OHIP-14 to monitor the overall changes in the research participants quality of life

brought about by their participation in the trial. This was not the use of the OHIP-14 as an additional, albeit secondary, outcome measure. The baseline OHIP-14 was completed before any intervention, and the second OHIP-14 was returned three months after the patient had chosen, and had started wearing, their preferred denture. The OHIP score was not a direct outcome measure. Rather it was used to assess the patients overall improvement or deterioration in quality of life. It was also possible to use the before and after scores of the OHIPs in a multinomial logistic regression to check for parity between the experimental groups.

At the time of the design of the protocol for the clinical trial, the OHIP-edent and the OHIP-14 were both considered as potential candidates for the assessment of the overall outcome. The OHIP-edent had been introduced in 2002 (Allen 2002) but had only been reported to have been used in one other publication (Awad 2003) at that time. In contrast the OHIP-14 had been reported as being used in 31 published papers at that time. For the overall assessment it was preferred to have a well reported assessment tool. The OHIP-14 was chosen for the assessment of the overall outcome of the trial. At the time of this thesis being written up there are 11 published papers which report use of the Ohip-edent. With this hindsight the decision over which Ohip to use would have needed more careful consideration; it may have been reversed.

The Randomised Clinical Trial for this Thesis chose to aim to gain sensitivity from the use of the 'patient preference' as the primary outcome. The useful addition of an OHIP questionnaire was made in the final planning stages at the suggestion of the Dunhill Reviewers (with additional funding granted for the inclusion of the OHIP, see 2.4 above). This addition of the OHIP was used as an assessment of overall impact of the trial on participant's quality of life.

2.6 The decision to use a cross over or parallel design for the trial.

It is (again) useful at this point to review the literature on previous trials (see Part 1 chapter 5) with more attention to the exact study design that was used in each study. Firtell and Koumjian (1992) used a parallel design Randomised Controlled Trial (RCT) for the first RCT study of removable prosthodontic impressions. With this type of study design, an intervention is applied to the two separate groups of patients on the two sides of a trial and they are statistically compared. The Firtell

and Koumjian (1992) study failed to differentiate a statistically significant result. The parallel RCT protocol has elucidated significant differences in other areas of research, but has disadvantages. The two major disadvantages of a parallel design are with ensuring that the two sides of the study are carried out on similar subjects and providing enough subjects to have a satisfactory statistical power for the study. If the two sides of the study are not similar then any detected significant outcome between the two sides may be due to the difference between the participating groups and not due to the variable under investigation. For this reason, a protocol with a parallel design may need to have large numbers of randomised research participants (to reduce this potential for bias) or require the careful matching (pairing) of the two groups of patients or require allocation by Stratification or Minimization (with large numbers) rather than simple randomisation. The analysis of a parallel designed study should also include an analysis of potential co-variants to exclude the possibility that a co-variant has influenced any detected statistical significance between the two sides of the study.

Sutton et al (2007a) and McCord et al (2005) have used a modified research protocol for prosthodontic research, using a cross over design. This type of protocol has some advantages and some disadvantages. A classic problem with a cross over design is the potential requirement for a ‘wash out period’ to ensure the influence of the first treatment has ceased prior to the assessment of the second treatment. This is a particular problem with drug trials. For RCT’s of dentures, the wash out procedure is simplified, but not entirely eliminated, by the removal of the dentures from the patients’ mouth; this removal takes a short time. However the influence of the first denture is not entirely eliminated since it is thought a patient may ‘habituate’ to first denture. The second denture will have the benefit of this habituation. The first denture will not have the benefit of habituation to a similar denture. Therefore the first denture may be disliked by the patient more than the second denture (McCord et al 2005). This potential problem is highlighted in the study by McCord et al (2005) who describes that his study found a prejudice amongst the patients against the first denture, stating: ’it was a clinically significant finding that the first worn denture initially caused most discomfort’. It is important to overcome this potential problem by ensuring that the dentures are given to the patients in a random order; McCord et al (2005) failed to achieve this. Even with good randomisation the problem caused by habituation are not entirely eliminated.

If some patients choose second denture because of the have become habituated to the shape of the first denture (rather than the variable under investigation) then there will be a reduction in the sensitivity of the study. It is hard to accommodate this dilution of sensitivity other than by increasing the numbers of participants. A cross over study of dentures should always monitor the potential for bias against the first denture.

A further disadvantage of the cross over design is the need to keep both sets of dentures very similar in all features and dimension apart from the variable under consideration (in this case the impression surface). This is important since if they are not the same a patient may choose a set of dentures because they prefer a certain difference other than the difference under investigation. A cross over design therefore introduces the need for careful duplication of the dentures (see section 3.3-3.5).

The major advantage of a cross over design is that the patients participate as their own 'control' group; they do not need to be 'matched'. This simplifies analysis and has potential to increase the selectivity of the outcome measure and has some potential to reduce the numbers of participants required to produce a significant result. After due consideration of the advantages and disadvantages of trial design, a decision was taken to use a cross over design for the trial, with the primary outcome as patient preference.

2.7 Secondary assessment

The OHIP-14 was introduced into the study as an overall assessment of change in the patients' perception of the impact of oral health on general health, see section 2.5.4 above. The OHIP was not suggested as an assessment of the success of the different dentures.

It was also suggested as good practice to have a secondary outcome tool which would be independent of the primary outcome. The literature review gave no suggestion of a suitable tool for secondary analysis. A simple questionnaire was developed to assess the comfort, stability and masticatory efficiency of each denture. The questionnaire is appended to the Thesis (Appendix 8). The questionnaire was used by the research participants to record their views on the comfort stability and masticatory efficiency of each denture in turn.

Chapter 3
Materials and methods

3.1 Trial design.

3.1.1 The study participants

As discussed in Section 2.1 of part IV of this Thesis, patients who had a mental foramen within the denture bearing area of a lower complete denture had a particular problem with the distribution of pressure under the lower denture. Those patients with this problem, who attended Leeds Dental Institute for treatment, were selected and recruited for this study.

The inclusion criteria were subjects who were able to attend, edentulous in the lower arch, with the mental foramen apparent clinically (palpable) or radiographically on the denture bearing area of the lower residual alveolar ridge. Exclusion criteria were subjects who were allergic to acrylic or silicone rubber. (see Appendix 8)

3.1.2 The study intervention

Each research participant was provided with three lower dentures labelled A, B and C. The dentures were as close as possible identical except for the fitting surface (see Part IV, section 3.3).

Type A denture was constructed on a model from a secondary impression made in a spaced, perforated acrylic special tray with a medium bodied silicone impression which had a light bodied silicone wash (see Part IV, section 3.2.2). This was the ‘control’ denture constructed by conventional methods.

Type B denture was constructed on a duplicate of the Type A model on which the area of the mental foramen had been coated with tin foil to provide a space beneath the finished denture (see Part IV section 3.2.3).

Type C denture was constructed on a model from a ‘differential pressure’ impression. A spaced, perforated acrylic special tray was used to make a medium bodied silicone impression with a light bodied wash. The silicone in the area of the mental foramen was removed with a scalpel blade, and the tray perforated in this

area. A second wash impression was then made with a light bodied silicone impression material (see Part IV section 3.2.4).

3.1.3 The trial aims and objectives

3.1.3.1 Aims of the clinical trial

Aim of the clinical trial was to determine which impression procedure produced the denture that was preferred by the research participants.

3.1.3.2 Objectives

The objectives of the clinical trial were:

1. To provide three lower dentures for each research participant, each one identical except for the manner in which the fitting surface had been contoured.

2. To allow the research participant to assess each denture for comfort, stability and masticatory efficiency (secondary outcome).

3. To allow the research participant to choose the denture they prefer (primary outcome).

4. To assess impact on the patients oral health related quality of life before and after treatment.

5. To carry out appropriate statistical analysis of the results.

6. To disseminate the study results to General Dental Practitioners

3.1.3.3 Hypothesis

The Null Hypothesis was that none of the dentures will be preferred more than by chance by the patients. The alternative hypothesis was that one of the dentures would be preferred by the patients.

3.1.4 The study outcomes

The academic background to the choice of the primary study outcome is discussed in Part IV, chapter 2.

Chronologically the first assessment of each denture was the secondary assessment of comfort, stability and masticatory efficiency. The research participants were given each denture in random order for 1 week. After 1 week of wearing a denture the research participant was asked to assess the denture (for

comfort, stability and masticatory efficiency) using a four point Likert scale. This secondary assessment was made by a structured questionnaire (see Appendix 8 for the paperwork used).

The fitting surface of the dentures is moulded and formed against a stone cast of the impression. Any adjustment to the fitting surface would alter the topography of the surface determined by that impression. Since we were investigating an impression technique it was preferable to fit the dentures with no adjustments to avoid the introduction of the adjustment as a confounding variable. This left a perceived ethical dilemma. There was a possibility that the unadjusted dentures may have caused a sore mouth. Because of the possibility that the unadjusted denture would cause a sore mouth, it was deemed desirable from an ethical viewpoint to keep the assessment period to just one week.

Fortunately patients who have clinically palpable mental foramina also have flat alveolar ridges; there was no complicating 'bony undercut' about residual alveolar ridges. This made it easier to fit the lower dentures without any adjustment. The technician was asked to process the denture and remove acrylic 'pearls'. No adjustment was made to the fitting surface of the denture by the clinician prior to the delivery of the lower dentures to the patients.

After assessing each denture individually the research participants were given all three dentures for 1 week. After 1 week the research participants were asked which denture they preferred. This was the primary outcome of the trial (see Appendix 8 for the paper work used to record this assessment).

All assessments were carried out by the research participant with assistance from a research nurse who was blind to the denture identity.. Thus the trial was 'double blind'; the research participant and the person conducting the assessment procedure did not know which denture was being assessed.

The impact of the participants' oral health on their overall Quality of Life was assessed prior to treatment by an Oral Health Impact Profile (OHIP-14), Appendix 8. Three months following treatment the research participants were asked to complete a further Oral Health Impact Profile (see Appendix 8).

3.1.5 Sample size

For the initial grant application, statistical advice was sought from co-applicant Mr Andrew Blance of Division of Biostatistics, Leeds Institute of Genetics, Health & Therapeutics. For the determination of the required sample size, the assumption was made that the control denture (Type A) will not be chosen. This was a reasonable assumption if the estimated prevalence for such was very low; a standard text book and the research literature (Grant et al 1994, McCord and Grant 2000) implied lack of success would occur with the control impression. We then had the situation of estimating the precision of a binary proportion. We hypothesised that 60% will prefer denture Type C and wish to estimate this to within 20% of its anticipated value. An appropriate formula for determining the sample size was thus:

$$N = \frac{(1-\pi) z^2_{1-\alpha/2}}{\pi \varepsilon^2}$$

Where $z1\text{-}\alpha/2 = 1.96$

$\pi = 0.6$

$\varepsilon = 0.2$

This yielded a required sample size of 65. In order to allow for some tolerance of the estimates and allow for potential dropouts, the sample size suggested was 75.

3.1.6 Randomization generation, allocation concealment and randomization implementation.

In this cross over trial, the order in which the treatments were given to the patients was randomly assigned. The order was determined by a blocked randomisation procedure.

With three treatments under review there are six possible orders in which the treatments could be delivered. The possible orders can be summarised as ABC, ACB, BAC, BCA, CAB and CBA. The sample size calculation resulted in an aim of recruiting 75 participants in order to have 65 patients complete the study. 75 does not divide by 6 to leave a whole number. The research nurse drew up a distribution to the groups so that 13 participants would be assigned to the ABC, BCA and CAB groups and 12 participants to the remaining groups. The research nurse was blind to

which treatments ware to be designated ‘A’ ‘B’ or ‘C’. The 75 assignments were placed in sealed envelopes and shuffled.

Allocation of the patients to these six groups took place when the three lower dentures had been constructed. The envelope was opened by the research nurse on the day of delivery of the first lower denture. Thus during the construction of the dentures the allocation of the randomisation was concealed from the operator, nurse and patient.

In parallel sided RCTs the concealment of allocation remains very important, with particular issues of treatment selection (i.e. which side of the trial is allocated) either by patients or medical staff. In a cross over trial all groups receive all treatments and so there are fewer such issues. Even so in this trial the concealment of the allocation was an integral part of the study design.

3.1.7 Blinding or masking

During the construction phase (after impressions) the cast on which the dentures were made were labelled by the dental technician as 1, 2 & 3. The dentist did not label the casts. The dental technician kept the secure record of the coding of which cast came from which impression. The patient and the research nurse were blind at all times to the identity of the casts (& dentures).

After processing the dentures, before the assessment phase, the dentures were re-labelled A, B, & C by the dental technician. The dental technician kept this secondary record of the coding (of which denture came from which impression) secure. The dentist was ‘blind’ to the secondary coding (& also not involved in recording outcome assessments). The assessments were carried out by the ‘blind’ patient with assistance from ‘blind’ research nurse.

‘Blinding’ or ‘masking’ is an important feature of RCT’s. When the assessment takes place the assessor must be blind to the identity of the three trial dentures. In this trial the assessor of the primary outcome was the patient. They were blind at all times to which denture came from which impression. The research nurse who was present during the assessments was also blind to the denture identity.

The dentist constructing the dentures was initially blind to which cast was which. Throughout the trial the dentist was not informed which denture was which, but because the casts were visibly different it was not possible to be certain that the

dentist remained blind during the denture construction process of the trial. Any such insight by the dentist may have been a source of unconscious bias (or indeed leave the trial open to criticism of conscious bias). It was important to guard against such bias; this was anticipated and safeguards put in place.

The safeguards were threefold, firstly, the trial was designed so that the completed dentures were re-coded and re-labelled. The casts on which the three dentures were constructed were initially labelled 1, 2 and 3 during the construction process. Following processing, the dentures were re-coded and re-labelled A, B and C. The knowledge of which cast (1, 2 or3) produced which denture (A, B or C) was kept hidden from the clinical team. Following this recoding, the dentist, research nurse and patients remained blind to the coding of the processed dentures. Secondly, the patients, who performed all the assessments, were blind throughout the trial. Thirdly, the methodology used in this trial to produce very similar dentures (see section 3.3 below) deliberately reduces the chance that potentially biased actions by the dentist can affect denture shape. It is therefore considered unlikely that intentional or unintentional bias could have been introduced by the dentist constructing the dentures.

3.1.8 Other considerations

The three dentures needed to be as near as possible identical (see Part IV, section 3.3); except for the fitting surface of each denture. The fitting surface of the three dentures was to be designed and constructed in three different ways. The control denture was to be made from a standard, relatively low pressure impression (see Part IV, section 3.3.2). The second denture was to be made from a duplicate of the control cast in which metal foils had been placed over the mental foramen area on the cast (see Figure 77 below). The third denture was to be constructed from a novel selective pressure impression (see Part IV, section 3.3.3).

3.1.9 Statistical methods

Multinomial logistic regression was used to analyze the effect size and significance of possible confounding variables. Subsequent analysis of patient preference was performed using bootstrapped 95% confidence intervals[30].

3.1.10 Summary of trial design

The selection of appropriate and effective outcome measures is discussed in detail in Section 1.5 of Part IV of this Thesis. The choice of primary outcome was

patient preference for a denture. The patient decides which denture is best; this reduces operator bias, simplifies assessment, and ensures a patient centred approach. Secondary outcome measure was the assessment of comfort, stability and masticatory efficiency of individual dentures by Likert scales. An OHIP-14 questionnaire was used to assess the effect of the treatment of the patients' perception of quality of life.

A cross over, randomised, controlled, clinical trial was deigned to investigate patient preference for their choice of one of three dentures.

3.2 Impression procedures for production of the three working casts.

3.2.1 The primary impression and special tray

The primary impression was taken in silicone putty. The outline of the special tray and the position of the 'stops' was drawn by the clinician on the impression with an 'indelible' pencil. A single, spaced, unperforated, light cured acrylic, special tray with stub handle and acrylic stops was constructed. The same tray was used for control and differential pressure impression, and so the same tray was used for all three lower dentures.

3.2.2 The control impression and cast

The control secondary impression used medium bodied silicone (Express 3M) with a light bodied silicone wash (Express 3M). The details follow.

3.2.2.1 Choice of control impression material and technique

The choice of the material and technique for the control impression was important. This trial was an investigation of the differential pressure generated by the Hyde (2003) impression technique. It was not a trial of the impression material. To have used a different material would have introduced an additional confounding variable. It was therefore decided to use addition cured polyvinylsiloxane (silicone) for the control impression.

Border moulding of the impression tray to develop border and facial seal with greenstick is normal practice in the UK, however the work of Drago (2003) suggested that there is no detectable difference in the resultant dentures if the border adaptation is performed with silicone. It was important to avoid areas, within the

control lower impression, of high and lower pressure following the border moulding. If traditional greenstick was used in the traditional way there was potential for the impression tray to be effectively close fitting in some areas and spaced in others. This may lead to an undesirable, undesigned, unknown, differential in the pressure across the final impression. The border moulding material was chosen to be medium bodied silicone (Express 3M) and the technique used for the border moulding avoided alternating areas of 'space' and 'close fit' within the special tray (see section 3.2.2.2).

3.2.2.2 Clinical technique of the control impression

Spaced, unperforated, light cured, acrylic special trays with stub handles and finger rests were constructed on the primary casts. The spacers, stub handles and finger rests were acrylic and constructed in the denture laboratory. Placing the spacers in the laboratory ensures consistency of space beneath the trays.

The tray was trimmed intra orally to remove over extension and border moulded with medium bodied silicone (Express 3M). In the lower arch, because of the minimal dimensions of the edentulous ridge, border adaptation with silicone usually produces a complete lower impression. Rather than have voids in the border moulded silicone, a full lower impression in medium bodied silicone was used to achieve consistent border moulding. It is important that the special tray is not under extended by more than 2mm for this technique to be successful.

Following border moulding with medium bodied silicone, any overextended tray showing through on the periphery was reduced with an acrylic trimming bur in a straight handpiece. If such reduction of the tray border was required the border moulding was removed (after the tray was adjusted with a bur) and then repeated. Following the successful border moulding, the occlusal stops were reduced to the height of the surrounding silicone. This was to eliminate high pressure areas which Hyde has called 'stop dimples' (BSSPD Conference paper, Hyde 2008a) on the fitting surface of the impression. The definitive wash impression was then taken in the usual way with light bodied silicone (Express 3M).

3.2.3 The traditional relief of a cast

The relief of high pressure under complete dentures has traditionally been achieved by the use of ‘relief chambers’. These are areas where the denture fitting surface has been designed to have a space or hollow of known height in a specific area (ref McCord and Grant 2000). Relief chambers are made by placing a metallic foil of the required thickness on the definitive dental cast in the area where pressure relief is required. The denture is then processed on a duplicate of the relieved cast and a ‘relief chamber’ is left on the fitting surface in the area where the foil was placed. For this study the relief chambers were constructed in the areas of the mental foramen (Figure 77).

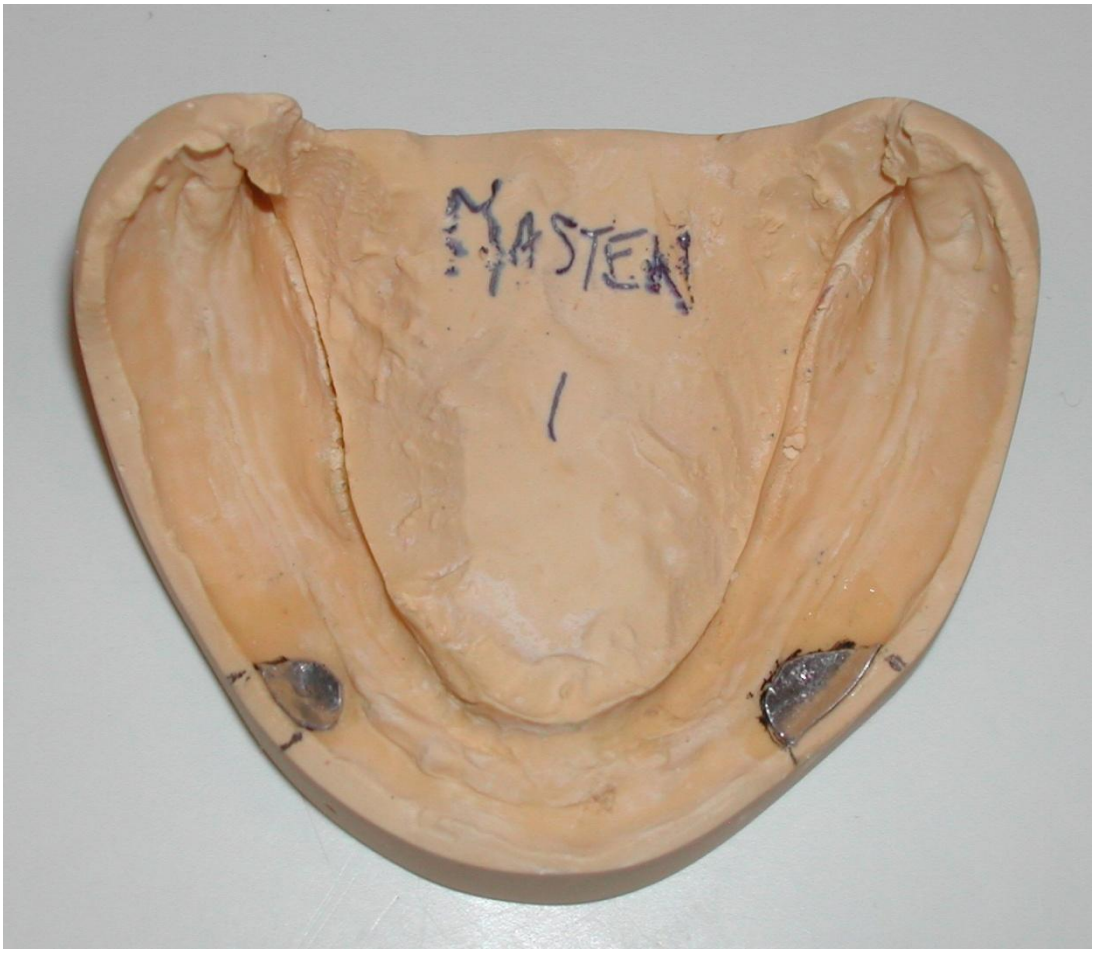


Figure 77 metal foil spacers over the mental foramen of the lower cast

3.2.4 The selective pressure impression.

The impression procedure for the third trial denture was an adaptation of the technique advocated by Hyde (2003). An impression of the lower edentulous arch

was taken in a spaced, acrylic, special tray using medium bodied silicone impression material (express 3M ESPE) with a light bodied wash (express 3M ESPE).

Figure 78 The base impression is marked in the areas of the mental foramen

The mental foramen was palpated intra orally and the position of the mental foramen area on the impression identified and marked (Figure 78).

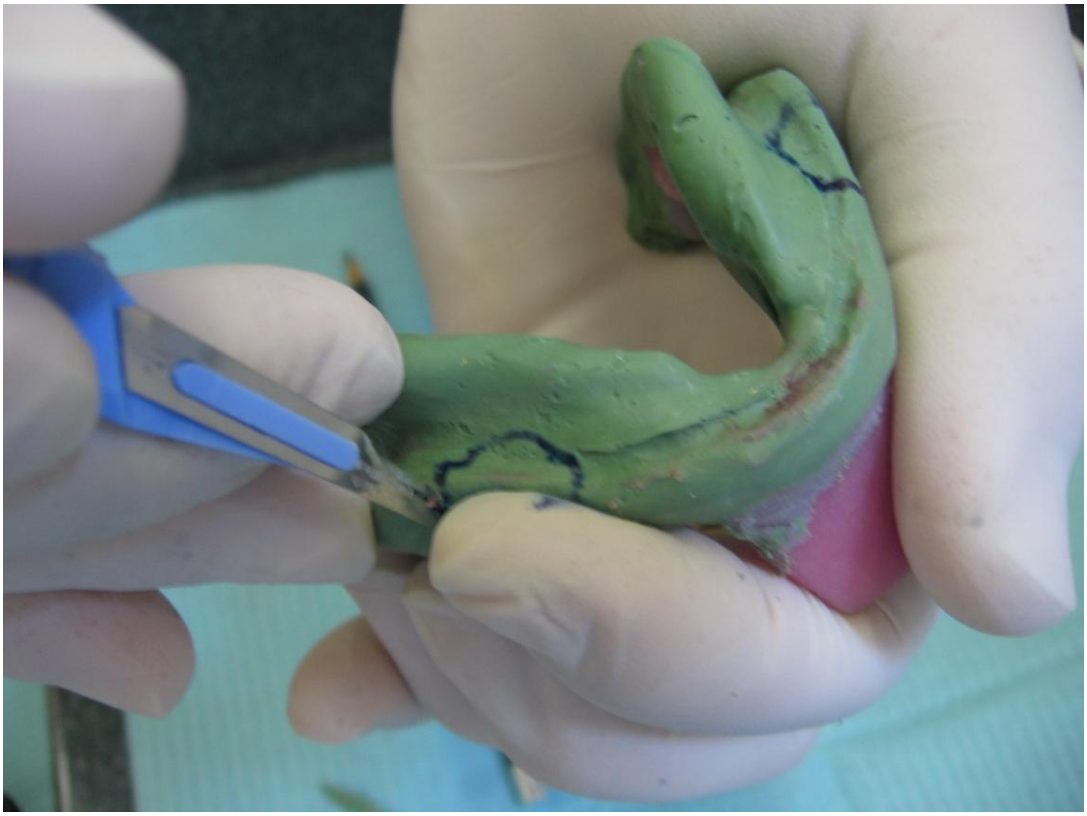


Figure 79 A scalpel blade is used the cut through the silicone along the marked lines.

The full depth of the silicone impression material in the area of the mental foramen was removed with a scalpel blade (Figures 81 and 82).

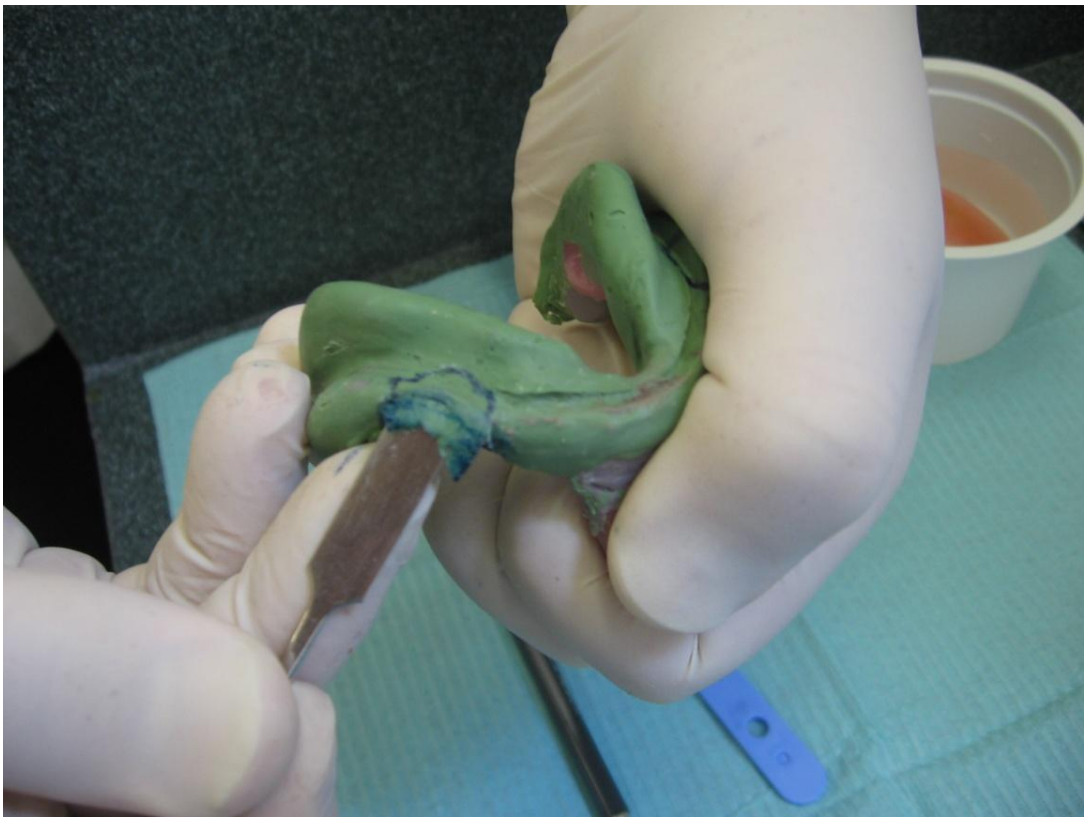


Figure 80 The cut silicone is carefully lifted and removed

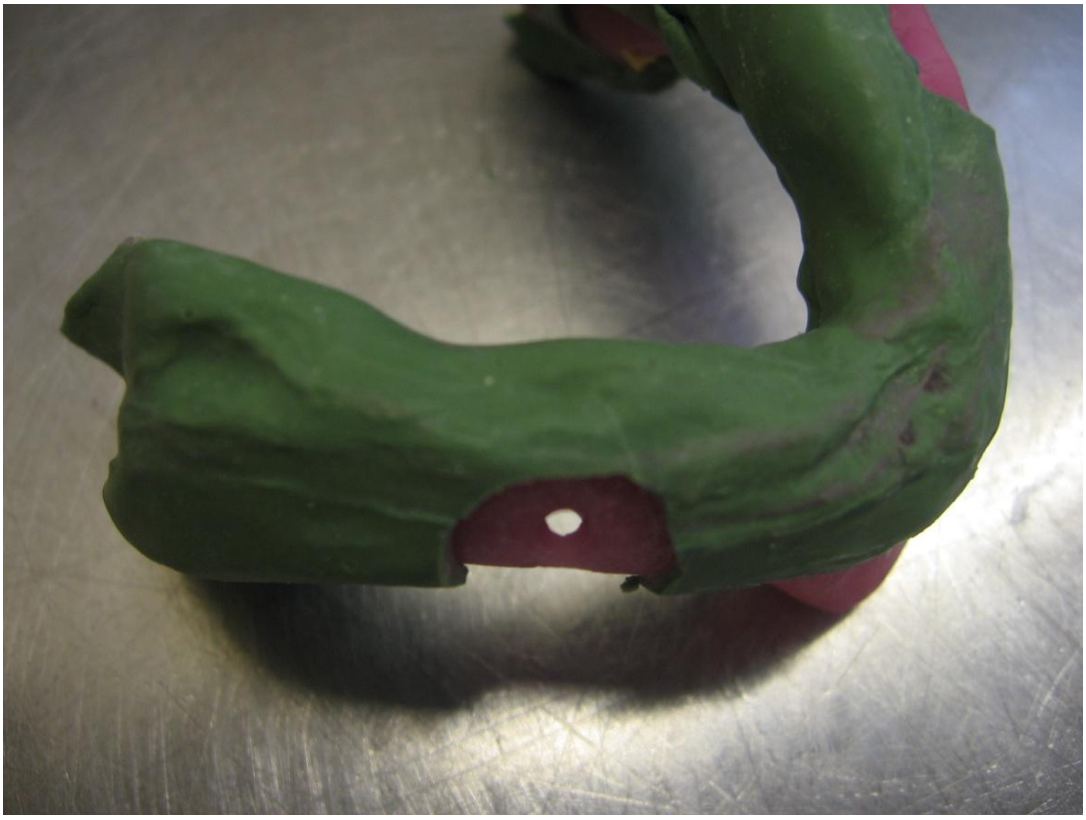


Figure 81 The tray was perforated in the area of the mental foramen

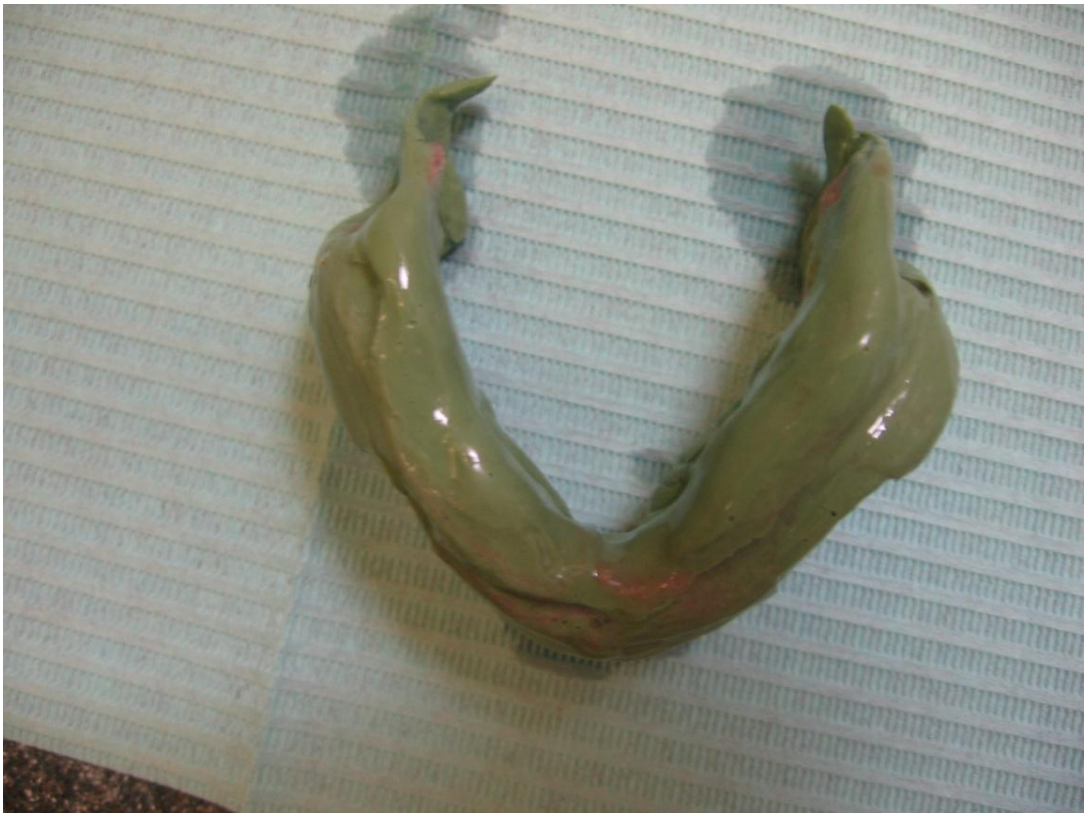


Figure 82 The final wash impression is taken is light bodied silicone

A final wash impression was taken using light bodied silicone impression material (Express 3M) Figure 82.

Figure 83 A close up of the typical topography in the area of lighter pressure.

On the impression surface, the area of the pressure relief is seen (Figure 83).

3.3 The production of three similar dentures.

3.3.1 The need for similar dentures

The double blind, cross over, randomised, controlled, clinical trial was designed to investigate patient preference for their choice of one of three dentures. This type of protocol is not without potential problems. Prominent among these was the need to keep all the dentures (that were given to the patient for assessment) as

near as possible the same. This was a challenge for the dental team. During their construction, dentures are individually made and there will always be small differences between each of them. While great care may be taken to ensure that the polished and occlusal surfaces are similar, it is not possible to get these surfaces exactly the same. The normal waxing-up techniques, combined with finishing and polishing techniques, can lead to significant differences between dentures.

To understand how this affects this type of research it is perhaps best to give an example: if a project were investigating occlusal schemes (e.g. Sutton et al 2007a) it would be no good if the dentures given to the patient had polished surfaces that were vastly different. Clearly, if they did, then the patient might choose a particular denture, not because of the particular occlusal scheme, but because they found the polished surfaces better. This would have the effect of diluting the sensitivity of the outcome measure. It was clearly important to minimise the differences between dentures used in the research.

A search of the literature revealed no papers that describe how to minimise differences between the dentures used in cross over trials. As a consequence the dental team found it necessary to develop a protocol which enabled the production of very similar mandibular dentures. The details of the methodological protocol that was developed for this study in Leeds were published by Dillon and Hyde, 2008.

3.3.2 Technical methodology of production of three similar dentures

The three impression techniques investigated by this study produced three secondary casts. On each of the secondary casts a denture was constructed. The production of similar shapes to the polished surfaces of the three dentures was achieved by the adaptation of a standard denture duplication technique using silicone putty moulds (see below and Dillon and Hyde 2008). The production of similar occlusions can be broken down into the duplication of tooth shape and mould, together with the more problematic duplication of the three dimensional orientation of the lower cast to the upper dentition.

The positioning of the three lower casts on an articulator in the same precise position was achieved by the use of two clinical visits (and two sets of occlusal rims) to record the occlusion. The first clinical visit ensured the occlusal vertical dimension (OVD) was similar in all three dentures; the second ensured the orientation was similar.

To record the occlusal vertical dimension a single lower occlusal record rim was used for all three lower casts. The clinical (intra oral) height was recorded using the single occlusal record rim in the usual way. The single rim was then used to position the three lower casts at the same height in relation to the upper teeth on the articulator. The lower occlusal record rim was constructed so that it seated well on all the lower casts.

The problems associated with the seating of the single record rim on three casts are similar to that reported by Atkinson and Johnson in 1972 on the use of an instrument to compare the contour of different dental casts. Atkinson and Johnson (1972) overcame the orientation problem by identifying an area on the upper dental cast (in the mid line, mid palate) where the different casts had a similar shape. Atkinson and Johnson's (1972) 'Frog' locating device has been used in further research to locate upper casts. In this study areas were identified on the lower cast which did not appear to have changed shape with the different impression techniques. These were on the buccal shelf area. These areas were used to provide posterior support for the primary occlusal record rim. Anterior support was also required to give a 'tripod' of support for the lower occlusal record rim. It was more difficult to find an area in the anterior region where the three casts were likely to be similar. The anterior support for the lower primary occlusal record rim was therefore a compromise and had potential to distort the orientation of the underlying casts. The typical areas used for support are shown in Figure 86.

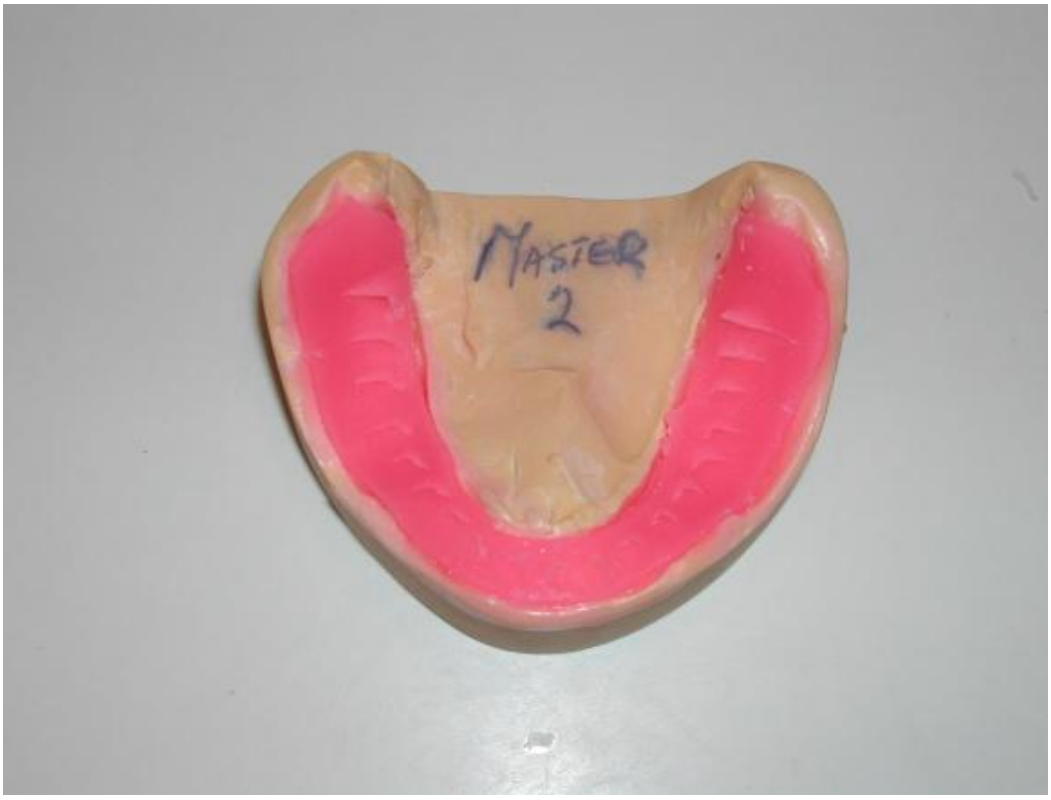


Figure 84 Base wax laid down to ‘space’ the primary occlusal record rim, shown prior to providing areas for support of the rim

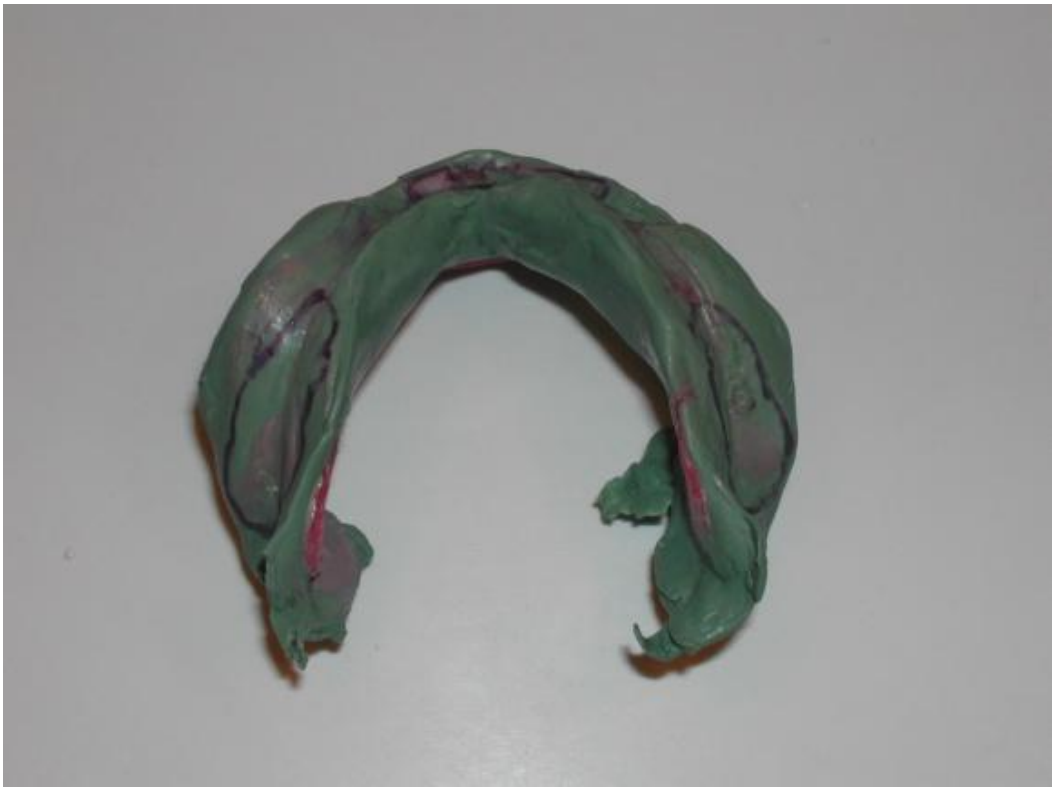


Figure 85 Areas to be used the support the primary occlusal record rim, marked by the clinician.

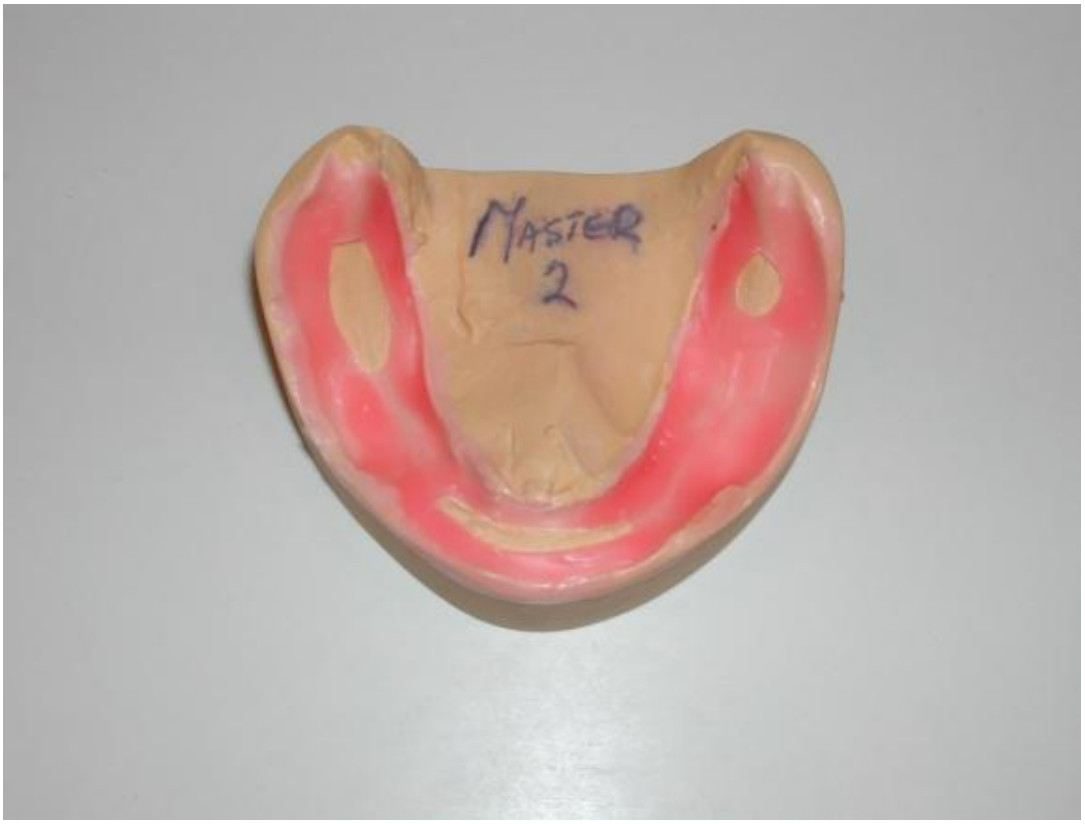


Figure 86 The areas to be used for support have been cut out of the wax spacer

Once the areas for support were identified spacing wax was applied to the cast and the wax was cut out from the areas designated for support (Figure 86).

A light cured acrylic base plate was then constructed which had ‘stops’ for support in the designated areas. A modified ‘Manchester’ occlusal record rim was constructed on the base plate. The completed rim was positioned in turn on each of the three lower casts and the fit of the rim to the cast was checked. If the rim did not seat on any of the casts the rim was adjusted. Once the rim seated so that the three areas designated for support seated on each of the casts the rim was returned to the clinic for the clinical stage of jaw registration.

In the upper arch a traditional occlusal record rim was constructed. On the clinic the upper rim was trimmed and marked as detailed in Basker and Davenport (2002). The lower rim was trimmed until the required height was achieved and then the upper and lower rims were sealed into position using blue mouse.

In the laboratory, the upper rim was used to position the upper cast on an average value articulator. Each lower cast was positioned in turn using the single lower occlusal record rim. Figure 87 below shows the three lower casts positioned

with the single lower jaw registration block against the same single upper block and cast.

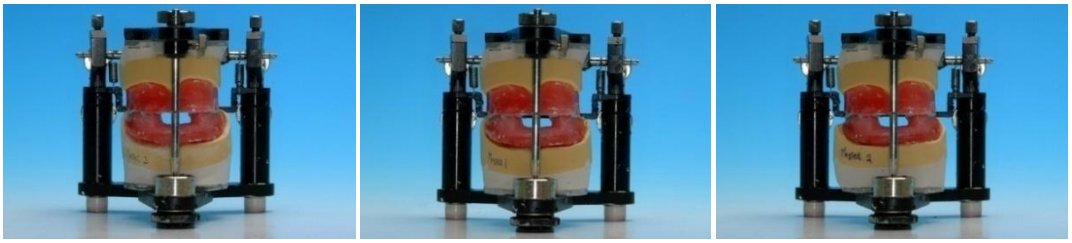


Figure 87 The primary occlusal registration was used to mount the three lower casts against the singular upper cast on an articulator.

Once each lower cast was mounted, the upper try-in was constructed (only one upper denture was constructed for the patients in the trial) and three new modified lower Manchester occlusal record rims were constructed, one on each of the articulated casts (Figure 88).

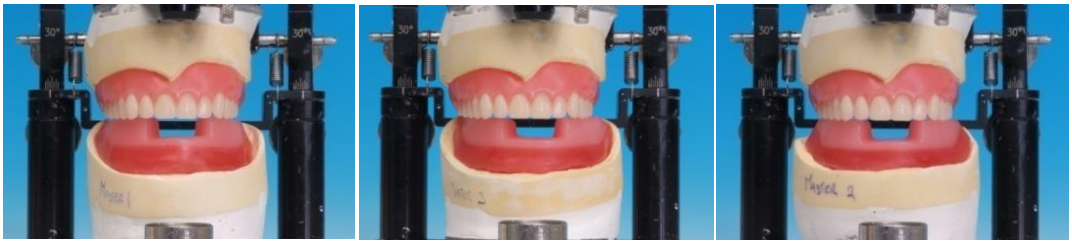


Figure 88 Secondary occlusal record rims constructed to the height of the primary jaw registration and articulated against the same upper denture (it was moved between the photos!)

The upper try in and the three lower modified Manchester rims were returned to the clinic. Once the upper try-in was acceptable, each of the lower occlusal record rims was used to record the occasion against the upper rim. It was essential that the occlusal vertical dimension (OVD) and the retruded contact position (RCP) were recorded identically on all three casts. If modification of the any of the three lower rims was required in a given case, all three rims were re-inserted, one at a time, and the position of the patient and the rims carefully checked. When the same OVD and RCP was obtained with all three occlusal record rims the rims were reinserted one at a time and sealed intraorally into the correct position using blue silicone moose. The

upper try in and lower rims were returned to the dental laboratory and each lower cast was re-articulated with the new jaw registration (Figure 89)

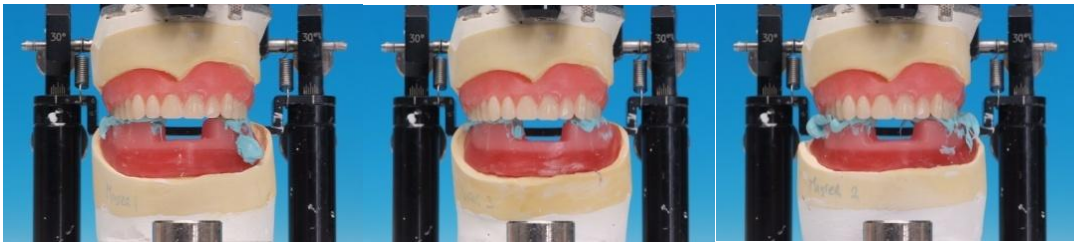


Figure 89 Rearticulation with the secondary jaw registration

A randomly selected lower cast was then used to construct the first lower try-in (Figure 90).

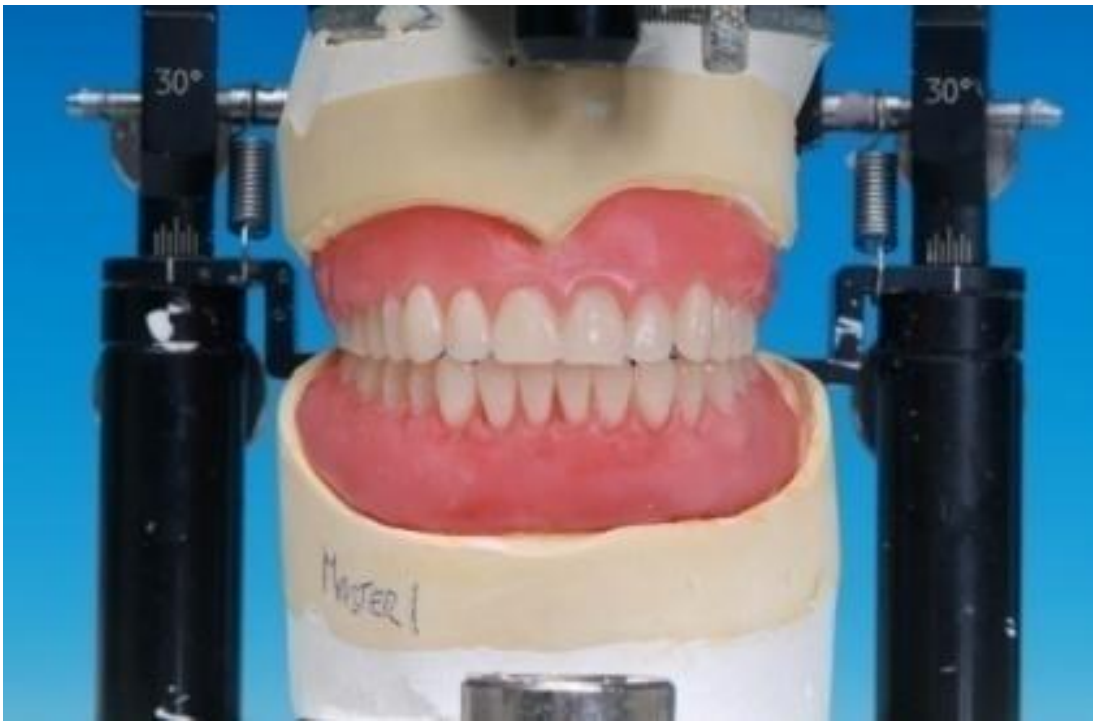


Figure 90 The first lower wax trial denture was constructed in the conventional way

A laboratory putty matrix was constructed by making an impression of the occlusal and polished surfaces of the first lower try-in. (Figure 91 below)

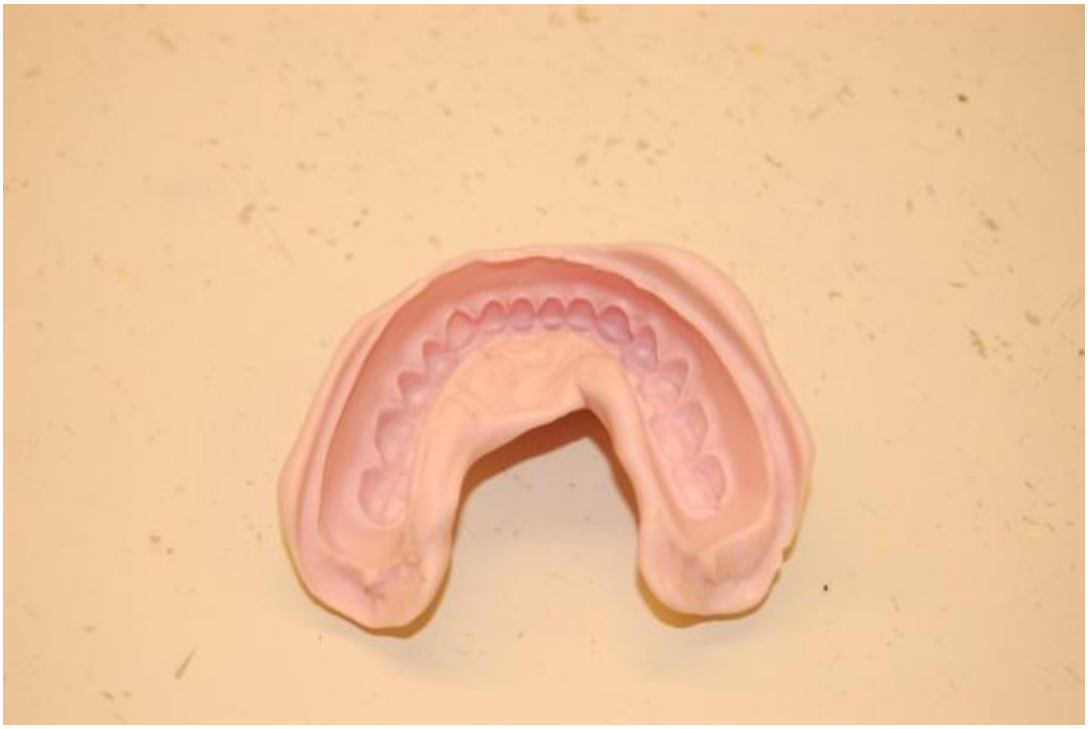


Figure 91 The silicone matrix of the first lower trial insertion

Individual teeth were inserted into the matrix. The individual teeth were taken from the same manufacturers mould as the first lower try in. Denture wax was then heated and poured in the mould. (Figure 92)

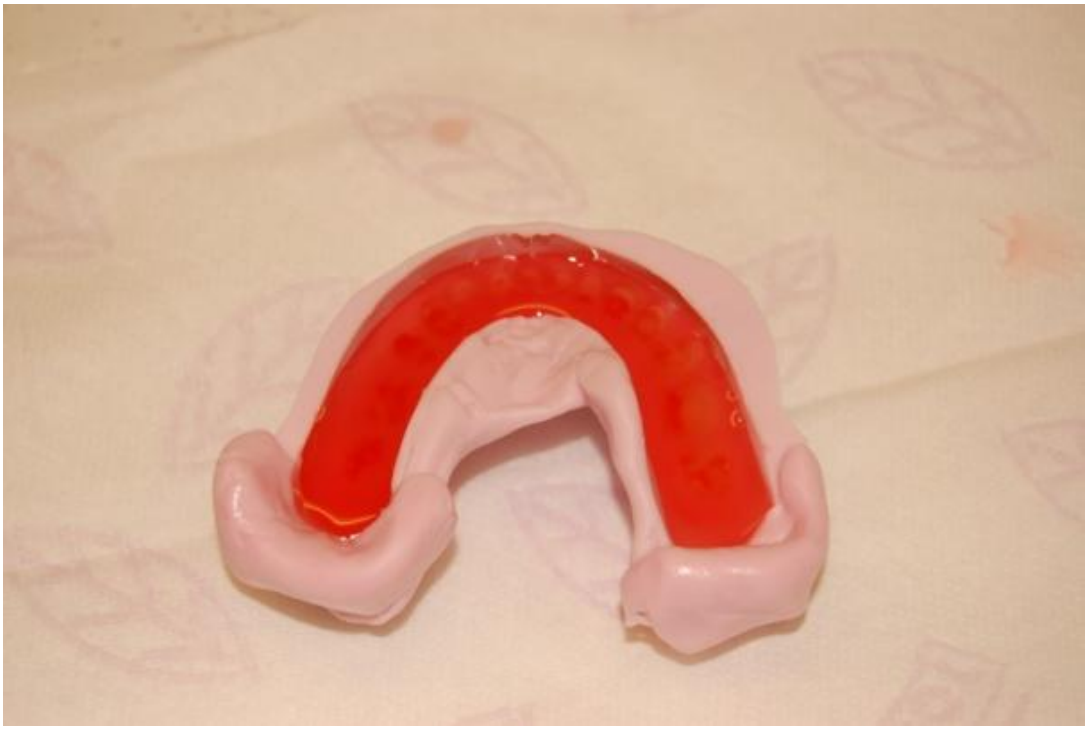


Figure 92 Duplicating the occlusal form of the first trial insertion

The tooth and wax duplicate was then articulated against the upper trial denture (Figure 93) and wax to attach to the lower base plate.

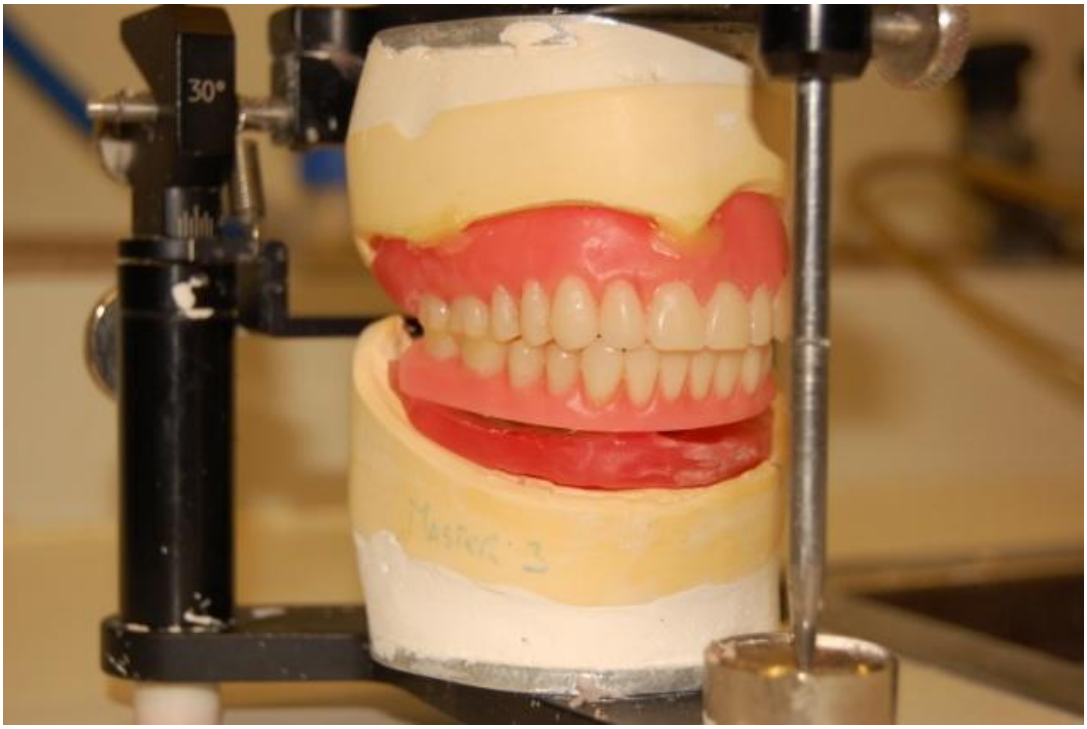


Figure 93 The duplicated occlusal form positioned against the upper denture and orientated relative to the lower cast on a semi adjustable articulator.

Thus each lower trial denture had teeth and part of the smooth surfaces duplicated to be (as near as possible) identical (Figure 94 and 97).

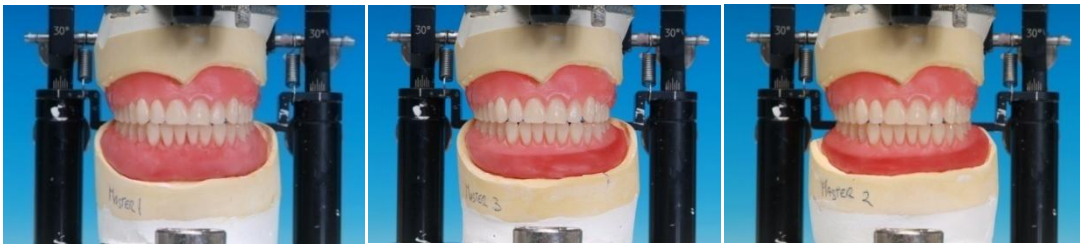


Figure 94 Three similar lower dentures articulated against the same upper denture

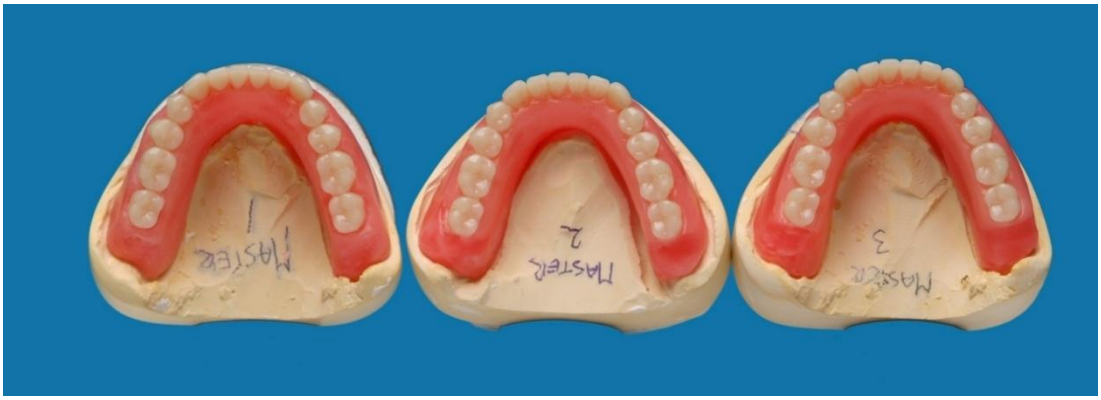


Figure 95 Three similar lower trial insertions

Following successful clinical trial insertion of all three dentures they were each processed in the traditional way.

3.4 Summary of trial method and clinical arrangements

A sample size calculation based on the difference in proportions of preferring the selective impression technique compared to not preferring it, yielded a required sample size of 65. Recruitment ceased when 69 participants had completed or were about to complete the primary outcome assessment of the study. The trial was conducted at Leeds Dental Institute, University of Leeds, UK. Ethical approval was sought and obtained from the appropriate Medical Ethical Committee. All participants gave written, signed, informed consent. Participants were recruited between November 2006 and November 2008 from the waiting lists at the institute. The last assessment (a three monthly follow up OHIP questionnaire) was completed and the trial finished in June 2009. The inclusion criteria were subjects who are able to attend, were edentulous in the lower arch, and had the mental foramen apparent clinically or radiographically on the denture bearing area of the lower ridge. Exclusion criteria were subjects who are allergic to acrylic or silicone rubber. Immediately after a patient had consented to treatment and before treatment commenced, the patient was asked to complete an OHIP-14 questionnaire to identify a base line for the secondary outcome measure of the impact of new dentures on their quality of life.

Three lower dentures were produced for each trial participant, using the duplication method developed by the research team at Leeds. The first denture was a

control, constructed on a cast made form a standard, relatively mucostatic, impression procedure. The second denture was constructed by a traditional method of dealing with problems of the mental foramen. This traditional method used metal foils, placed over the area of the mental foramina and processed the finished denture on the spaced cast. The third denture was constructed from a selective pressure impression technique (the technique reported in Hyde's 2003 case history was adapted to relieve pressure over the area of the mental foramen).

The three dentures were given to each patient; the order in which the dentures were assessed by the patient was determined by a blocked randomization procedure. The order the encoded dentures were to be worn was revealed on the day of delivery of the first denture by a designated research nurse, without the prior knowledge of the clinician. They wore each denture for one week and assessed the denture individually. When they had assessed each denture individually they were given all three dentures together and asked to assess their preferred denture over a period of one to two weeks. The stated preference by the patient for a denture was the pre-determined primary outcome measure for the study. All the outcome assessments were performed by the patients; they were recorded by the research nurse and the dentist remained blind to the choice. After the patients had worn their preferred denture for three months they were asked to complete a post treatment OHIP-14 questionnaire to assess the impact of their new dentures on their quality of life following treatment.

3.5 The testing of the accuracy of the replication of the occlusal of the three trial dentures.

3.5.1. The attempt to use the laser scanner

An initial investigation to scan the finished dentures with the laser scanner in Manchester proved unsuccessful due to reflection of the laser beam on the polished surfaces of the dentures.

For the initial laser scanner investigation, the dentures were orientated in the scanner on the cast they were constructed on, which in turn was held in the lower half of the articulator used during construction. This enabled the same orientation of the three dentures during scanning. The intention was that the three dimensional position of any point on the occlusal surface or polished surface of the dentures could be known, relative to the reference articulator. The digitalised images of dentures could then be compared for consistency. Unfortunately this approach ran into a major problem.

The major problem was that the dentures did not scan well. This was because they were red and polished. Consideration was given to looking at unpolished (but still mostly red) dentures, but this was considered less relevant since the act of polishing acrylic changes its shape. Furthermore the acrylic teeth were already polished by the manufacturers and would reflect the beam. It was suggested that the dentures could be dusted with metallic (titanium) dust to eliminate the reflective surface, however the removal of the metallic dust proved problematic. The clinical dentures needed to be re-polished to remove the dust prior to delivery to the patients; this altered the shape. The results of scanning are seen in Figure 96 below. Further use of the scanner for this research was rejected.

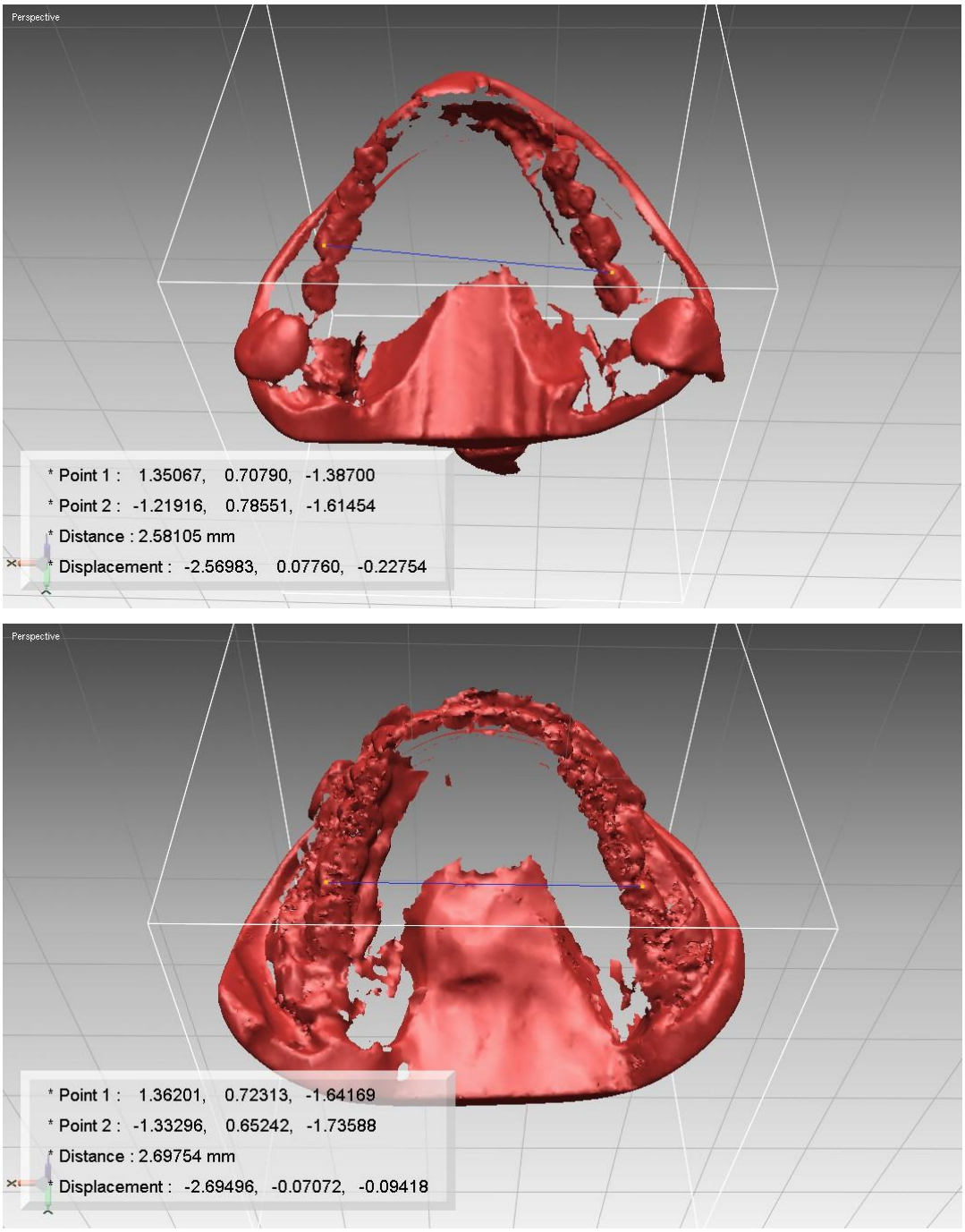


Figure 96 Results of scanning two dentures using the scanner at Manchester DH.

3.5.1. The use of physical measurements

Following the disappointing results from the scanner, a re-appraisal was required. Rather than use virtual (scanned) models of the dentures, an attempt was made to produce physical models of the dentures for comparison.

The protocol for the first attempt at a physical measurement accuracy study was drawn up involving;

1. The duplication of denture shape using an Agar mould.

2. The production of stone casts of the agar mould.

3. The use of a clinical microscope to mark same position on the denture teeth on each model (the same mould of tooth is used for each denture).

4. The use of a digital micrometer to measure the distance between the set points

The process is pictured in Figure 97 below.

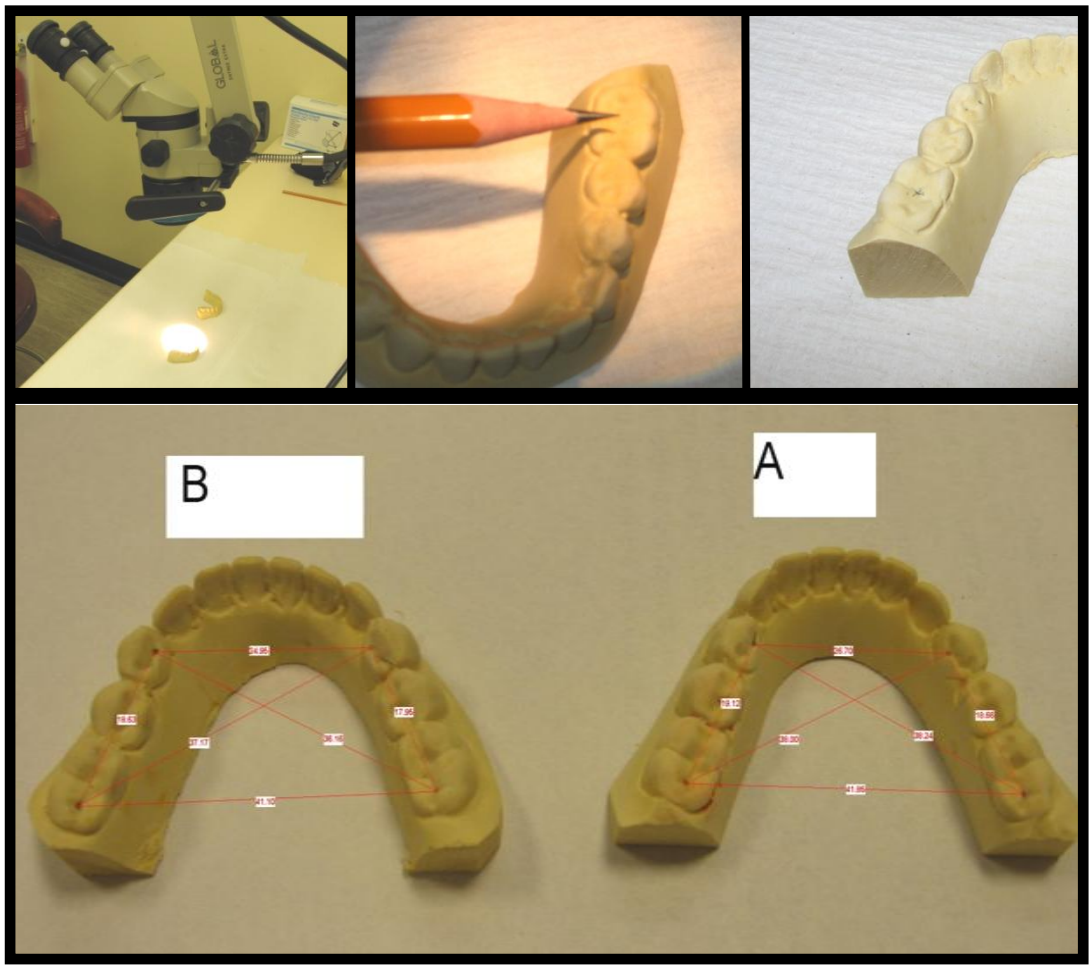


Figure 97 The use of clinical microscope to mark and measure the six chosen dimensions of the occlusion.

The results of a preliminary case (see Table 137 below) were initially considered promising. Two sets of duplicated dentures (these were not study dentures) were produced which had slight differences between the sets. However

the results for this case suggested that there can be large differences (up to 1.15mm across the arch) in tooth position.

Results of from the measurement of the dentures:

	7-/-7	**4-/-4**	**4-/-7**	**7-/-4**	**7—4/**	**/4—7**
DentureA	41.85	26.70	38.00	38.24	18.66	19.12
DentureB	41.10	24.95	37.17	36.16	17.95	18.63
Difference	00.75	01.15	00.83	01.08	00.71	00.49

Table 137 Results of measurements of dentures A and B

The highlighted red results (in the Table 137 above) are variations which were considered unacceptable as a clinical variation between the trial dentures. At the time this was thought to be caused by a mal-positioned lower left first premolar on one of the dentures. Alternative explanations were; either the inaccurate manufacture of the mould of the lower right first premolar, or the incorrect (different) position of the point drawn on the lower left first premolar on the two casts. With hindsight this third explanation is the more likely.

Further investigation of this method of comparing the three dentures was warranted. A set of clinical trial dentures were tested. Each denture was measured by the method above (using stone casts) on two separate occasions to look at intra observer reliability. The results are below in Table 138.

	First assessment			Second assessment		
	Denture A	**Denture B**	**Denture C**	**Denture A**	**Denture B**	**Denture C**
Premolars	26.50	26.16	25.42	26.50	26.09	25.40
Molars	49.60	49.42	50.00	49.43	49.43	49.87
X-arch left	44.31	44.59	43.23	44.38	44.54	43.60
X-arch right	43.89	43.18	44.03	43.99	43.30	44.28
Right side	25.19	25.18	25.56	25.23	25.21	25.68
Left side	25.44	25.60	25.46	25.64	25.53	25.69

Table 138 Intra observer reliability

At first sight these results also appeared promising but with a little consideration there were clearly still some problems. If the reading for each of the two observations are averaged, then the results show significant differences between the dentures, see Table 139 below.

	Apparent average differences between the dentures in mm		
	A&B	**A&C**	**B&C**
Premolars	0.375	1.090	0.715
Molars	0.090	0.420	0.510
X-arch left	0.220	0.930	1.150
X-arch right	0.700	0.21	0.915
Right side	0.015	0.410	0.425
Left side	0.025	0.035	0.010

Table 139 Differences between dentures

These apparent differences between the dentures are of a magnitude which would make a difference clinically. Furthermore there were problems with intra observer reproducibility. The difference between the first time the dentures were measured and the second occasion are shown in the Table 140 below:

	The differences between the two observations the dentures in mm		
	Denture A	**Denture B**	**Denture C**
Premolars	0.00	0.07	0.02
Molars	0.17	0.01	0.13
X-arch left	0.07	0.05	0.37
X-arch right	0.10	0.12	0.25
Right side	0.04	0.03	0.12
Left side	0.20	0.07	0.23

Table 140 Differences between two observations

This intra observer reliability was not perfect but the size of the differences between the observations on the same dentures was less than the differences between the three trial dentures. With hindsight this too was misleading; the two occasions when the dentures were measured for intra observer reliability used the same pencil marks on the models. The differences observed were caused by the variation in the use of the measuring devise only. Later it was realised that far greater errors may be introduced by the marking of the dentures.

3.5.3. The direct physical measurement of the dentures

At the time of this experiment a possible explanation for differences between the dentures was thought to be the errors introduced by the duplication of the shape of the denture by the agar duplication and the pouring of the stone casts. It was therefore decided to eliminate the duplication of the dentures, mark the dentures directly and make the measurements on the dentures themselves. A trial of this methodology was undertaken using the trial dentures. This assessment of the methodology of testing the accuracy of the reproduction of the dentures was concurrent with the main clinical trial. As dentures were produced for the patients so they were measured.

The assessment was done on clinic with the clinical operating microscope used to position the pencil marks on the three newly processed lower dentures for 50 cases (out of a total of 66 cases assessed by the trial). The microscope magnification was then reduced and a digital micrometer was then used to make the measurements between the pencil marks. The results were record on data collection sheets, and collated on an Excel spreadsheet. The results of this assessment are given in Table 141 below.

Measurement	**Mean and S.D of A-B**	**Mean and S.D. of A-C**	**Mean and S.D. of B-C**
4-4 (50cases)	0.05(0.36)	0.08(0.40)	-0.13(0.45)
7-7 (50cases)	0.06(0.40)	0.09(0.39)	0.15(0.42)
4/7 (50cases)	0.14(0.35)	0.06(0.36)	-0.09(0.32)
7/4 (50cases)	0.10(0.44)	-0.03(0.49)	-0.13(0.40)
/74 (50cases)	0.02(0.35)	-0.01(0.35)	-0.03(0.38)
/47 (50cases)	0.02(0.30)	-0.07(0.29)	-0.09(0.30)

Table 141 These results are the means of the 50 cases where the differences between the measuring points on the three dentures were recorded

In Table 141 above the figure for the standard deviation is the more important figure since it represents the spread of the difference between the dentures. We know from statistical theory that if data is normally distributed 95% of the results lie within +/- 1.96 times the standard deviation of the mean. The 'precision' of this data can be described by this measurement (See Part II chapter 2.4). We know that 95% of the data lie within a maximum range of approximately 1mm (1.96 times 0.49mm) from the mean measured difference. Such variance was considered large and clinically significant; a millimetre is a long way in dentistry.

These results do show variation between the measurements of the three dentures. During the assessment of these cases it became apparent to the operator that the consistent positioning of the pencil marks on the three dentures was a problem. Even with the use of the operating microscope and the marking of one

position on all the three dentures before moving on to another, it was difficult to find a precise reproducible position in the fissures of the artificial teeth.

Because of the concerns about the reproducibility of the position of the marked pencil points for the physical measurements, an alternative measuring point was devised. The new measuring point did not depend on locating a precise point on the occlusal fissure pattern.

3.5.4. The final direct cross arch physical measurement

The new measurement was the cross arch width between the lingual surfaces of the second molar at the gingival margin just below the line on the tooth moulds between the two lingual cusps. Using this position the reproducibility of the measuring point on the three dentures became far easier. For the final 21 dentures both the original positions and the new position were measured. Thus the measurement of the width of the denture across the arch was made by two different methods. The original method measured the width across the arch from points on the occlusal fissures of the second molars. The new way measured the x-arch width against the hard lingual side of the same teeth. Because of the similarity of the dimensions resulting from of these two measurements, it is appropriate to look at the differences in the variance obtained from the two methods of measurement.

The comparison of the accuracy of the two ways measuring the reproduction of the dentures was made, by comparing the standard deviation of the difference between the dentures when each method of measurement was used. Table 142 below shows the standard deviation of the cross arch measurements on the 21 dentures for which both methods of measuring the cross arch width was used. These figures show a lower variance when the measurements are made against the side of the tooth. Since the standard deviation of the measurements was lower in the side of tooth measurements it was decided to use these measurements alone to observe the size and effect of differences between the dentures.

Measurement	S.D. of A-B in mm	S.D. of A-C in mm	S.D. of B-C in mm
7-7 occlusal fissures	0.45	0.26	0.47
X-arch side of teeth	0.17	0.23	0.18

Table 142 A summary and comparison of the difference measured across the arch by the two methods; the new method of the side of the tooth and the measurement to the marks on the fissure.

3.5.5. Results

The results below are from the final method of measurement. They are the measurements of the cross arch width against the hard lingual surface of the lower second premolar. The differences (in the designated dimension) between denture A and denture B, between denture A and denture C and between denture B and denture C are the raw statistics explored below.

The results of the study which looked at the accuracy of the duplication of the dentures are represented below in the three graphs below. The graphs show the frequency distribution of the differences in the measurements between each of the dentures. Figure 98 shows the frequency distribution of the differences between dentures A and B; Figure 99 the distribution of differences between denture A and C, and Figure 100 between denture B and C.

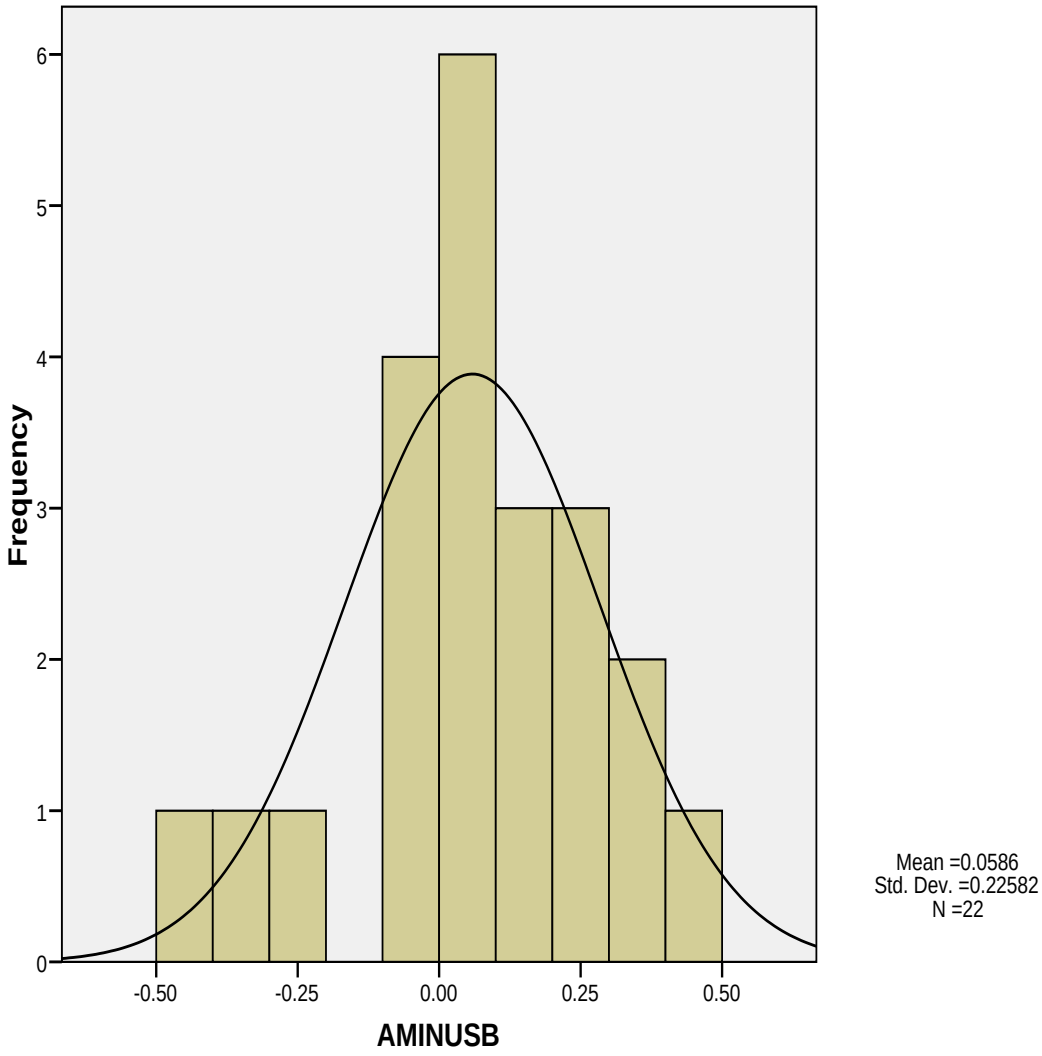


Figure 98 A SPSS legacy graph of the frequency distribution of the difference between denture A and B

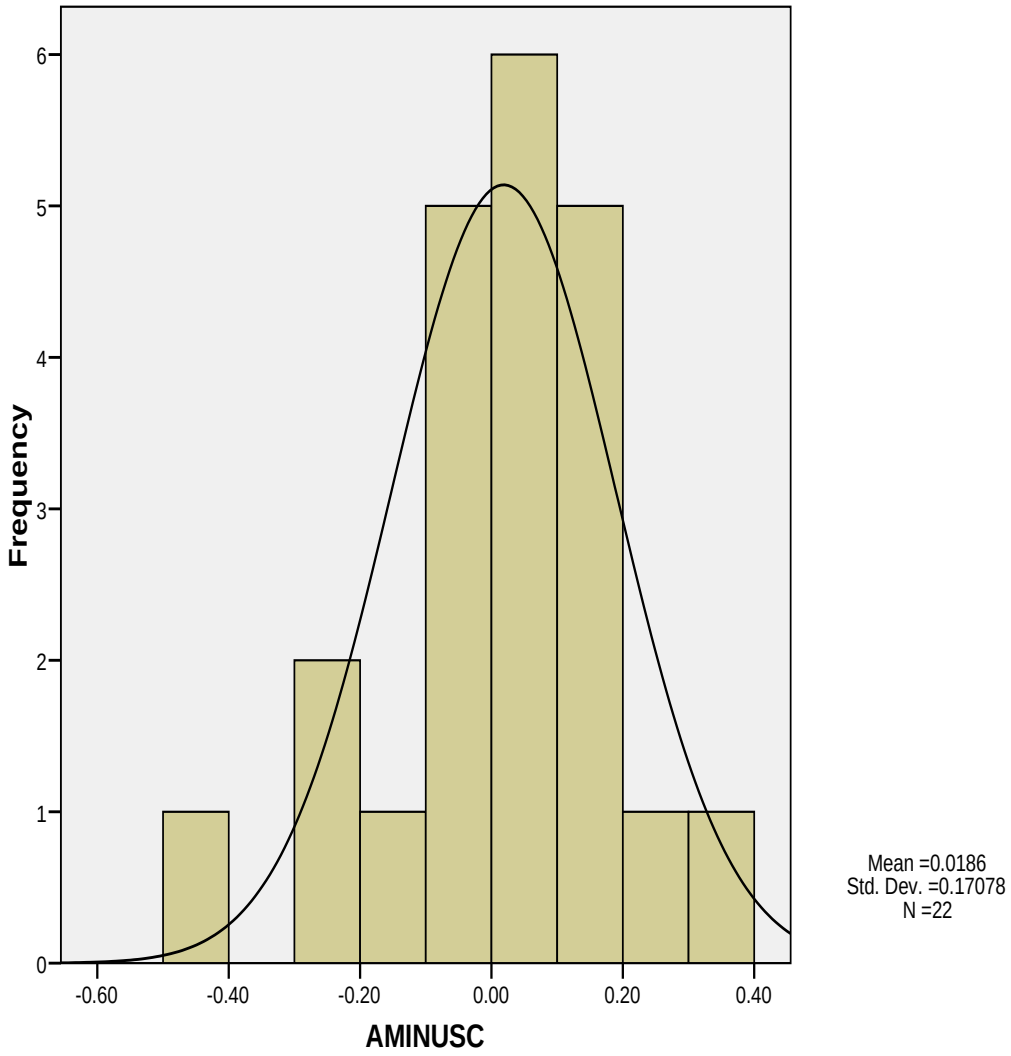


Figure 99 A SPSS legacy graph of the frequency distribution of the difference between denture A and C

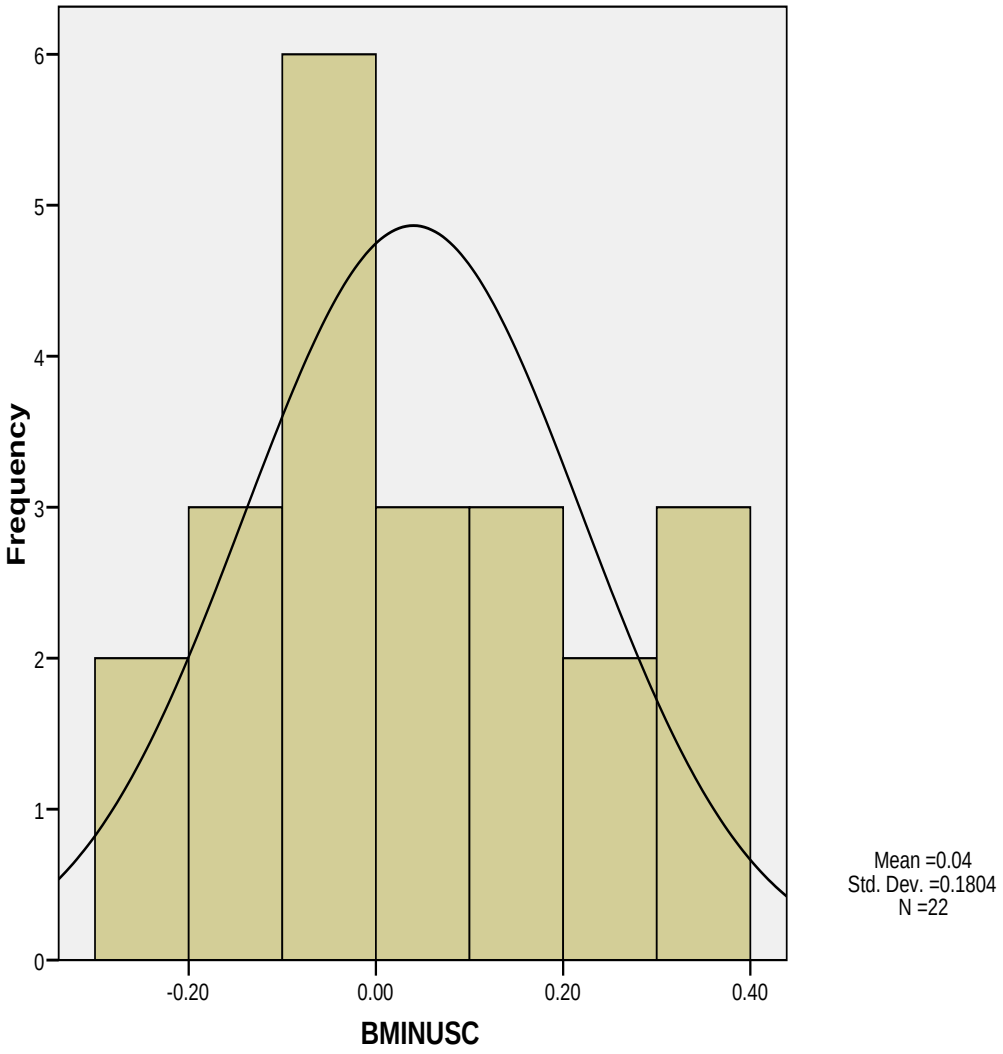


Figure 100 A SPSS legacy graph of the frequency distribution of the difference between denture B and C

Paired sample t-test of the difference between the dentures showed no significant difference detected, Table 143 below.

Paired Differences									
		Mean	Std. Dev	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. 2 tail
					Lower	Upper			
Pair 1	Denture A Denture B	.0186	.1708	.0364	-.0570	.0944	.512	21	.614
Pair 2	Denture A Denture C	.0586	.2258	.0481	-.0415	.1588	1.218	21	.237
Pair 3	Denture B Denture C	.0400	.1804	.0385	-.0400	.1200	1.040	21	.310

Table 143 Paired t-test of differences between dentures: no significant differences detected.

3.5.6 Discussion

The devising of a technique to measure the accuracy of the reproduction of the dentures proved to be a problem. A reasonable method of checking cross arch tooth width was finally devised; however this final method of checking reproducibility was not without problems. With hindsight the methodology used should have been tested for accuracy and precision well before the trial started.

It was desirable to eliminate the possibility of clinically relevant discrepancies being introduced between individual dentures. A physical difference between the dentures introduces a potential confounding variable. A significant number of similar confounding variables could cause a Type I error (an erroneous 'false positive') if the errors occurred preferentially in one type of denture (one side of the trial) or a Type II error (a ‘false negative’ conclusion) if high numbers of significantly dissimilar dentures are randomly distributed.

As a result of the analysis of the dimensions recorded in the study (see results section above) we can say that in this study there is no evidence that any type of denture had greater differences in dimensions (giving rise to a potentially confounding variable) than another type of denture. That is to say the differences in dimensions were randomly distributed between the dentures.

Given that the differences between the dentures in this study are randomly distributed between the types of denture, the effect of the differences between the dentures is likely to result in a reduction in the power of the trial to detect a difference. The greater the differences between the dentures the greater will be the effect on the power of the study. If, for example, just one patient chooses a denture because they preferred the occlusion of the denture rather than the fitting surface (the independent variable) the power of the trial would be reduced, but the effect would be small. The more patients who base their decision for preference on a randomly distributed difference in denture production, the more the power of the study is reduced. One way of dealing with this reduction in power due to problems of randomly distributed variables would be to increase the number of trial participants. It would therefore have been preferable to have known these potential problems prior to the start of the trial as they have the potential to affect the sample size calculation.

For the purposes of planning future trials, it would also have been useful to record and classify why a patient choose a certain denture. If many patients were choosing on the basis of an introduced variable (other than the designated independent variable of denture fitting surface) future trials could use this information to estimate effect size and sample size for the planned trial.

It remained important to make every effort during denture construction to keep the three lower dentures as close as possible in shape and occlusion. The technical

method that was devised for producing three similar dentures (Dillon and Hyde 2008) was important for the ability of the primary outcome of the trial to differentiate between the dentures.. If there had been no attention to this problem then similar dentures would not have been produced. Participants may have chosen dentures because of the other differences between the dentures (randomly distributed variables). This would have led to a dilution of the precision of all the outcome measures in the trial, and the possibility of a result of ‘no difference detected’ between the dentures. This problem for denture trials may explain why some previous trials have struggled to detect a difference (McCord et al 2005). Future denture trials need to consider the methodology of denture reproduction.

Chapter 4
Clinical trial: timings and procedures

The trial took place in the (old) Prosthetics Staff Surgery, on Level 5 of the Leeds Dental Institute, University of Leeds, Clarendon Way, Leeds. The clinics where the dental work of the trial occurred were under the supervision of Prof Brunton as the NHS Honorary Consultant. The clinical work for the trial was carried out by a single dentist assisted by a research dental nurse. The outcome assessments for the trial were made by the patients with assistance (if needed) from the research nurse.

Recruitment for the trial started in November 2006 and the final OHIP questionnaire was returned in June 2009. At the start of the trial, patients who were on the student waiting list for treatment at the LDI were called in to be assessed for suitability for the trial. Later in the trial, patients were referred for assessment for suitability for the trial by the local NHS consultants in restorative dentistry. Mr T Paul Hyde carried out these initial assessments of suitability of the patients according to the designated inclusion and exclusion criteria. The data collection sheets used to record the assessment of suitability of research participants are appended to the Thesis (Appendix 8).

When a patient was found to be suitable, the patient was given an explanation of the trial and a Patient Information Sheet (Appendix 8); they were then asked to return for an appointment one week later to discuss the trial tell us their decision whether to take part and, potentially, to give their formal consent to the trial. The suitable, willing patients were consented and recruited using the trial consent form (Appendix 8). Following consent, at the same visit, the primary impressions were taken.

There followed a minimum of five further appointments for denture construction. These were appointments for secondary impression, followed by primary jaw registration, followed by secondary jaw registration, followed by trial insertion and finally fit of dentures. After the fit of the dentures, four further appointments took place for denture assessment. The first three appointments assessed the randomly selected dentures in turn with the secondary outcome

questionnaire (Appendix 8 and chapter 9 below), the 4th assessment appointment assessed all three dentures in the pre determined primary outcome assessment (Appendix 8 and chapters 5 & 6 below). Finally an appointment was offered three months later to assess the overall treatment success by the OHIP-14 questionnaire (Appendix 8 and chapter 8 below). If patients were reluctant to return to fill in the OHIP-14 they were asked to return the completed questionnaire by post. All the assessment tools are appended to the Thesis (Appendix 8).

Chapter 5
The results for the primary outcome patient preference.

66 patients completed the trial (Figure 101 and 102). Three patients failed to complete; one deceased, one who's spouse deceased, and one who was unable to continue because he required unrelated surgery. The Consort flow diagram (below) reports the numbers in each arm of the trial.

The primary outcome measure was patient preference for the denture. 33 patients (50%) chose the denture from the selective pressure impression; 19 (29%) chose the denture from the traditional method of relieving pressure on the mental foramen; and 14 (21%) preferred the control denture.

5.1 Age and age distribution of participants

The average age of research participants was 72.5 years with a standard deviation of. 8.9 years. The youngest research participant was 50 and the oldest 94. The distribution of age is shown in the SPSS legacy histogram below (Figure 101).

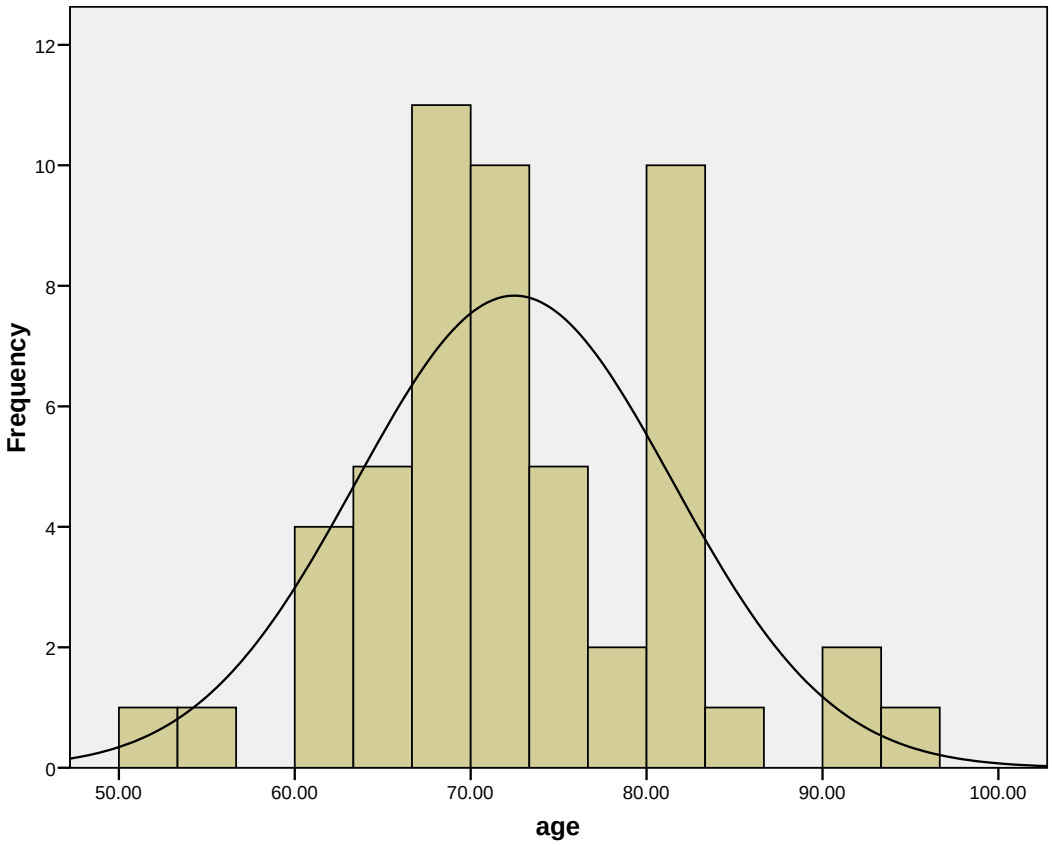


Figure 101, A SSPS legacy histogram of the age distribution of research participants.

5.2 Consort flow diagram

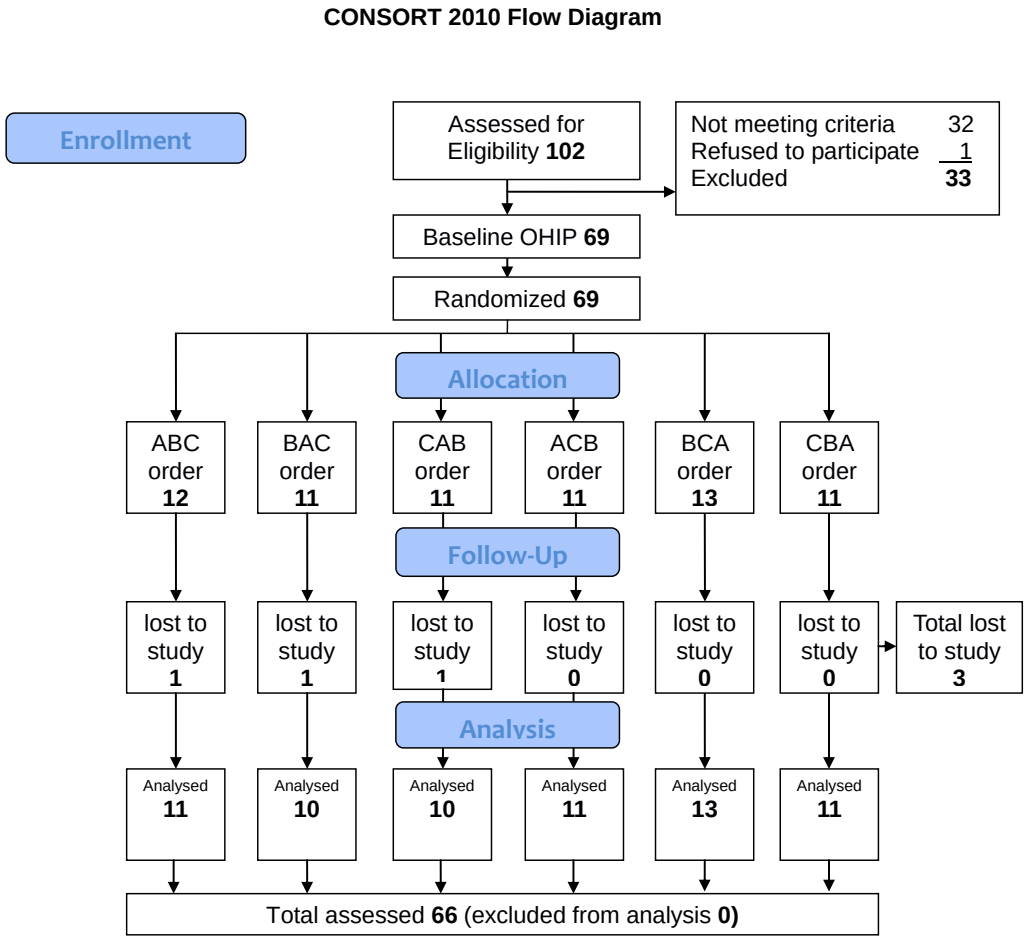


Figure 102 Consort flow diagram for the cross over controlled clinical trial

5.3 Multinomial logistic regression

The statistical analysis of the multinomial logistic regression and the bootstrap were carried out by Andrew Blance of the Division of Biostatistics, Leeds Institute of Genetics. Andrew was a co-applicant on the original Dunhill grant and a co-author on the published paper (Hyde 2010). His work is fully acknowledged.

The Table 144 below gives the output from SPSS of a multinomial logistic regression of the final choice of the denture with the variables of sex, order, OHIP before, OHIP after, and age. The table is produced by SPSS software, but it should be noted that the original analysis for the paper was made by Andrew Blance (the trial statistician) who preferred to use a different software package to produce the regression.

Final choice of denture: The reference category is Denture C.		**B**	**Std. Error**	**Wald**	**Df**	**Sig.**	**Exp(B)**	**95% Confidence Interval for Exp(B)**	
								Lower Bound	**Upper Bound**
Denture A	Intercept	6.141	3.955	2.411	1	.120			
	Sex	.775	.912	.722	1	.396	2.170	.363	12.95
	Order	-.085	.259	.107	1	.743	.919	.553	1.527
	OHIP 1	.031	.038	.670	1	.413	1.032	.957	1.112
	OHIP 2	-.050	.032	2.445	1	.118	.951	.893	1.013
	Age	-.070	.047	2.239	1	.135	.933	.851	1.022
Denture B	Intercept	7.508	4.665	2.590	1	.108			
	Sex	.037	1.128	.001	1	.974	1.038	.114	9.473
	Order	.061	.299	.041	1	.839	1.062	.592	1.908
	OHIP 1	.022	.043	.263	1	.608	1.022	.940	1.111
	OHIP 2	-.031	.035	.800	1	.371	.969	.905	1.038
	Age	-.106	.056	3.561	1	.059	.899	.805	1.004

Table 144 Multinomial logistic regression with the control denture as the base.

Quoting from the published paper (Hyde 2010); ‘Multinomial logistic regression showed no evidence of a sizable or important effect of the potential confounding variables’

5.4 Bootstrap results

Quoting from the paper Hyde 2010; ‘Multinomial logistic regression showed no evidence of a sizable or important effect of the potential confounding variables. Consequently, bootstrapped 95% confidence intervals were preferred to the Null model and were used for analysis. Bootstrapped 95% confidence intervals were used to analyze patient preference for

1. the selective pressure method over the control

2. the selective pressure over the traditional foil relief

3. the traditional foil relief over the control

The difference in preference for the selective pressure method over the control method was 29% with a 95% Confidence Interval of (9, 47)%. The difference in preference for the selective pressure over the traditional foil method was 21% and of borderline significance with a 95% Confidence Interval of (-1, 47)%. The preference of the traditional method over the control was not statistically significant.’

Chapter 6
Discussion of the primary outcome, patient preference.

6.1. Multinomial logistic regression and statistical support

The statistician (Mr Andrew Blance) was a co-author of the paper which reported this study (Hyde 2010). He is acknowledged in this Thesis for his work; he devised the statistical analysis of the clinical study used here and in the published paper (Hyde 2010). That paper (Hyde 2010) expresses the results of the statistical analysis thus: 'The possible confounding variables of age, sex, order of delivery of the dentures, initial OHIP score, and final OHIP score were investigated by multinomial logistic regression. No evidence of a sizable or important effect of these potential confounding variables was indicated. Therefore it was considered unnecessary to adjust the model for these variables.'

Table 144 above shows the output of the multinomial logistic regression performed for the published paper (Hyde 2010) in consultation with co-author Andrew Blance. Multinomial logistic regression produces a measure, the regression coefficient; it is the logarithm of the odds that an independent variable is correlated to the dependant variable. The value of log of the odds is shown in the Table 144 above, it is labelled B. The exponential of B, Exp (B) above, is the odds of correlation. Each of the 95% Confidence Intervals (C.I.) of the odds value of B includes the value 1, that is to say odds of 1 (equal odds). Since the 95%C.I. includes 1, no significant difference can be shown to be attributable to the variable investigated. The Table 144 above therefore shows no significant difference for any of the potentially confounding variables; the significance values (column marked 'Sig' above) are always more than 0.05.

6.2 Bootstrap

Bootstrap was a statistical method recommended by the statistician (Andrew Blance) who was a co-applicant of the Dunhill grant that funded the study and a co-author of the published paper (Hyde 2010) of this study. Bootstrap takes the pool of raw results and randomly, selects a case from the pool of results. After selecting a case from the pool of results that selection is reinserted into the data pool before the

next random selection is made. The process is continued until N results are selected and a new data set is produced. N is usually the number of variable in the original dataset, in this case N=66. After each data set of N results is composed the process is repeated to produce a large number of data sets each with N results. In this study 100,000 data sets (each of N data points of patient final choice of denture) were produced in this way before the final analysis was performed.

6.3 Rejection of the Null Hypothesis

'The Null Hypothesis was that none of the dentures would be preferred more than random chance by the patients. The results of this study show 95% confidence intervals indicating preference for the dentures constructed from the selective pressure impression. The Null Hypothesis is rejected. In rejecting the Null Hypothesis, the alternative hypothesis is proposed that in this patient group there was a preference for denture made by the selective pressure impression.' (Hyde 2010).

6.4 Clinical considerations

This study provides evidence from a RCT of a preference for a particular impression technique for complete dentures in this patient group. This is the first randomized controlled trial to provide such evidence. Given the history and size of the academic literature for impressions for complete dentures this is remarkable. In the opinion of the author there are four factors which have been particularly important in providing a clear outcome for the trial: firstly, the adequate size of the sample; secondly, the methodology used in the duplication of the shape and occlusion of the three trial dentures; third, the selection of the primary outcome as patient preference; fourth, the selection of a group of patients who all had a single specific clinical condition. The last three of these factors were concerned with reducing confounding variables while providing a sensitive and specific outcome measure. Future RCTs in this area may benefit from adopting a similar strategy.

The denture produced from the new selective pressure technique is preferred in this study. It is reasonable to postulate that the designed selective pressure of the impression translates into preferential loading under the resultant denture, and explains the patient preference for that denture.

Chapter 7 OHIP-14 results and analysis

7.1 Introduction to OHIP-14 results and methods of analysis

The traditional method of analysis of OHIP-14 was mentioned in the original OHIP-14 validation paper (Slade, 1997) who said 'Descriptive statistics were created by computing the mean of the coded response for each item'. Steele et al (Steele et al 2004) explains the assignment of values to the Likert scales further saying 'for analysis ordinal responses were coded 0 for 'never' through to 4 for 'very often', and all 14 ordinal responses were summed to produce an overall OHIP score that could range from 0 to 56, with higher scores indicating poorer oral health related quality of life.' (Steele et al 2004).

An alternative method of analysing OHIP questionnaires is to assess the Ranks by Likert score within each level of the 'grouping variable'. The grouping variable in this case was before or after the treatment.

The traditional method of analysis has the benefit that it is easy to use and has been widely reported in the literature but it makes the statistical assumption that the Likert scale of the OHIP is continuous. If the Likert scale of the OHIP is continuous then a true mean can be calculated. However if the scale is discrete but ordered a mean would be inappropriate, since it can cannot be assumed that the distance between the levels of the Likert scale is always the same value.

A paper published from the work of this Thesis (Hyde 2010) used the traditional method of analysis for assessment of the OHIP questionnaire. The details of the traditional analysis are therefore included in section 7.3 below. The non parametric analyses are shown in section 7.4 below.

7.2 Results: raw data of the before and after OHIP-14 questionnaires

The raw data for the OHIP scores are appended (Appendix 9).

7.3 Traditional OHIP analysis

The Null Hypothesis for this analysis is that the treatment does not result in a change in the traditional OHIP-14 score. The alternative hypothesis is that the treatment does affect the traditional OHIP-14 score.

7.3.1 Before and after summed OHIP-14 scores

The means and standard deviations of both the before and the after, traditional, summed OHIP-14 scores are shown in Table 145 below. All of a research participants answers were eliminated from the total if they missed more than 1 answer (Steele et al 2004). In this study no research participant missed just one question. These are the means from all the remaining answers, from all participants, before treatment and then after treatment.

	N	**Mean**	**Std. Deviation**
Before	686	3.04	1.450
After	686	2.43	1.420

Table 145 descriptive statistics of traditional OHIP-14 scores before and after treatment.

The OHIP-14 before score is higher than the OHIP-14 after score indicating an improvement in the patients' perception of their oral health related quality of life. An analysis of the statistical significance of the decrease in the traditional OHIP score was indicated.

7.3.2 Paired students t-test of overall OHIP

For the overall assessment of the traditional OHIP scores, if any data was missing from a before or after question all that research participants data was eliminated from the analysis.

The result of paired t-test of comparing the means of all OHIP question scores from all research participants before treatment with the scores after treatment is shown below in Table 146.

OHIP-14	Mean	Std. Dev.	Std. Error Mean	95% Confidence Interval of the Difference		T	df	Sig. (2-tailed)
				Lower	Upper			
Before – After	.606	1.567	.060	.489	.724	10.137	685	.0000

Table 146 Overall paired samples students' t-test of traditional summed OHIP scores

The results of the t-test reveal a statistically significant result ($p < 0.001$). See chapter 8 for further discussion of the results.

7.3.3 Traditional OHIP means scores for individual questions

The mean and standard deviation of the score for each individual OHIP question are shown in Table 147 below. Any unanswered question was eliminated together with the corresponding (before or after) question from the same patient; thus only matching data where the same patient answered the same question before and after treatment was included.

		Mean	N	Std. Deviation
Pair 1	question 1 before	2.59	56	1.345
	question 1 after	2.27	56	1.300
Pair 2	question 2 before	2.18	56	1.281
	question 2 after	1.80	56	1.086
Pair 3	question 3 before	3.64	56	1.354
	question 3 after	3.18	56	1.515
Pair 4	question 4 before	4.39	56	0.908
	question 4 after	3.79	56	1.275
Pair 5	question 5 before	3.46	54	1.397
	question 5 after	2.69	54	1.540
Pair 6	question 6 before	3.41	54	1.296
	question 6 after	2.70	54	1.327
Pair 7	question 7 before	3.51	53	1.449
	question 7 after	2.81	53	1.455
Pair 8	question 8 before	3.59	54	1.158
	question 8 after	3.04	54	1.345
Pair 9	question 9 before	3.15	55	1.353
	question 9 after	2.33	55	1.402
Pair 10	question 10 before	3.41	54	1.237
	question 10 after	2.39	54	1.352
Pair 11	question 11 before	2.61	54	1.352
	question 11 after	2.04	54	1.317
Pair 12	question 12 before	1.69	54	0.968
	question 12 after	1.65	54	1.152
Pair 13	question 13 before	3.07	54	1.385
	question 13 after	2.33	54	1.427
Pair 14	question 14 before	1.98	54	1.173
	question 14 after	1.72	54	1.265

Table 147 Traditional OHIP means scores for individual questions

For each question the average traditional OHIP ‘before’ score is higher than the OHIP ‘after’ score, indicating an improvement in the patients’ perception of their oral health related quality of life. An analysis of the statistical significance of

this decrease in the traditional OHIP score was indicated. This was achieved by paired sample t-tests.

7.3.4 Paired sample t-tests for each OHIP question

		Paired Differences					T	df	Sig. (2-tailed)
		Mean	Std. Dev.	Std. Err. Mean	95% CI of the Difference Lower	Upper			
Pair 1	Q 1 before Q 1after	0.321	1.454	.194	-.068	.711	1.66	55	.104
Pair 2	Q 2 before Q 2 after	0.375	1.383	.185	.005	.745	2.03	55	.047
Pair 3	Q 3 before Q 3 after	0.464	1.618	.216	.031	.898	2.15	55	.036
Pair 4	Q 4 before Q 4 after	0.607	1.397	.187	.233	.981	3.25	55	.002 B
Pair 5	Q 5 before Q 5 after	0.778	1.890	.257	.262	1.294	3.02	53	.004
Pair 6	Q 6 before Q 6 after	0.704	1.513	.206	.291	1.117	3.42	53	.001 B
Pair 7	Q 7 before Q 7 after	0.698	1.671	.230	.238	1.159	3.04	52	.004
Pair 8	Q 8 before Q 8 after	0.556	1.501	.204	.146	.965	2.72	53	.009
Pair 9	Q 9 before Q 9 after	0.818	1.712	.231	.355	1.281	3.55	54	.001 B
Pair 10	Q 10before Q 10 after	1.019	1.677	.228	.561	1.476	4.46	53	.000 B
Pair 11	Q 11 before Q 11 after	0.574	1.655	.225	.122	1.026	2.55	53	.014
Pair 12	Q 12 before Q 12 after	0.037	1.258	.171	-.306	.381	0.21	53	.830
Pair 13	Q 13 before Q 13 after	0.741	1.761	.240	.260	1.221	3.09	53	.003 B
Pair 14	Q 14 before Q 14 after	0.259	1.568	.213	-.169	.687	1.22	53	.230

Table 148 Paired t-tests of before and after traditional OHIP scores for each question

The paired t-test of each question demonstrates statistically significant differences in 11 out of the 14 OHIP questions before and after treatment. The five results marked **B** above show significance with Bonferroni correction of the 0.05 significance level (see discussion below section 8.5).

7.4 Non Parametric analysis of OHIP questionnaires.

In order to compare traditional analysis with non parametric analysis, the same data sets used for 7.3 above were now used for non parametric analysis.

7.4.1 Non parametric overall assessment of before and after

For the non parametric overall assessment if any data was missing from a before or after question all that research participants data was eliminated from the analysis.

The data was entered into SPSS and analysed with non parametric related Wilcoxon sign rank test. The results are shown in Table 149 and Table 150 below.

OHIP-14	N	Mean Rank	Sum of Ranks
Negative Ranks (After < Before)	323	231.23	74687.00
Positive Ranks (After > Before)	120	197.16	23659.00
Ties (After = Before)	243		
Total	686		

Table 149 Mean ranks; there are more negative ranks than positive ranks; participants answer more questions with a higher before-treatment rank-score than vice a versa.

Wilcoxon Signed Ranks test	After - Before
Z	-9.614
Exact Sig. (2-tailed)	0.0000

Table 150 Overall Non parametric Related Wilcoxon sign rank test

The results show a statistically significant result with Exact Sig (2 tailed) less than 0.001 (see discussion below)

7.4.2 Non parametric exploration of individual questions

The same dataset as in section 7.3.4 above was used for a non parametric related sample analysis; this is the equivalent non parametric test to the paired t-test above. Only matching data where the same patient answered the same question before and after treatment was included.

Wilcoxon sign rank tests were used to assess the significance of the data. The results are shown for each question below in Table 151 which shows Mean Ranks of related (same question same patient) before and after OHIP questions using SPSS.

		N	Mean Rank	Sum of Ranks
Q1 after - before	Negative Ranks	20(a)	15.65	313.00
	Positive Ranks	10(b)	15.20	152.00
	Ties	26(c)		
	Total	56		
Q2 after - before	Negative Ranks	19(a)	14.82	281.50
	Positive Ranks	9(b)	13.83	124.50
	Ties	28(c)		
	Total	56		
Q3 after – before	Negative Ranks	24(a)	18.92	454.00
	Positive Ranks	12(b)	17.67	212.00
	Ties	20(c)		
	Total	56		
Q4 after – before	Negative Ranks	27(a)	18.96	512.00
	Positive Ranks	9(b)	17.11	154.00
	Ties	20(c)		
	Total	56		
Q5 after – before	Negative Ranks	35(a)	23.06	807.00
	Positive Ranks	11(b)	24.91	274.00
	Ties	8(c)		
	Total	54		
Q6 after – before	Negative Ranks	27(a)	23.96	647.00
	Positive Ranks	13(b)	13.31	173.00
	Ties	14(c)		
	Total	54		
Q7 after – before	Negative Ranks	26(a)	20.83	541.50
	Positive Ranks	11(b)	14.68	161.50
	Ties	16(c)		
	Total	53		

Table 151 (continued below)

		N	Mean Rank	Sum of Ranks
Q8 after – before	Negative Ranks Positive Ranks Ties Total	22(a) 8(b) 24(c) 54	15.95 14.25	351.00 114.00
Q9 after – before	Negative Ranks Positive Ranks Ties Total	29(a) 10(b) 16(c) 55	21.22 16.45	615.50 164.50
Q10 after – before	Negative Ranks Positive Ranks Ties Total	37(a) 9(b) 8(c) 54	24.43 19.67	904.00 177.00
Q11 after – before	Negative Ranks Positive Ranks Ties Total	30(a) 10(b) 14(c) 54	19.63 23.10	589.00 231.00
Q12 after – before	Negative Ranks Positive Ranks Ties Total	13(a) 10(b) 31(c) 54	11.08 13.20	144.00 132.00
Q13 after – before	Negative Ranks Positive Ranks Ties Total	28(a) 10(b) 16(c) 54	20.43 16.90	572.00 169.00
Q14 after – before	Negative Ranks Positive Ranks Ties Total	18(a) 13(b) 23(c) 54	17.42 14.04	313.50 182.50

Table 151 (continued) Mean ranks and sum of ranks for questions; a after question< before question, b after question> before question, c after question= before question

As can be seen by the variation in the totals in the N column above (Table 151) some patients missed out some questions. Table 151 above always showed more

negative ranks than positive ranks for every question. That is to say the number of participants who ranked the answer to each question lower afterwards was always greater than the number of participants who ranked the answers higher after treatment. This suggests that there was an improvement in the patents perception of their oral health related quality of life after treatment. Further analysis was required to test the significance of the difference for each question.

7.4.3 Non parametric analysis

The Wilcoxon signed rank test was performed on the same data set as section 7.3 above (i.e. the data set where all question where included where the before and after questions had been completed by the research participants).

Wilcoxon sign rank	**Q 1 after - before**	**Q 2 after - before**	**Q 3 after - before**	**Q 4 after- before**	**Q 5 after - before**	**Q 6 after - before**	**Q 7 after - before**
Z(Based on positive ranks)	-1.684	-1.815	-1.929	-2.880	-2.951	-3.243	-2.906
Asymp. Sig. (2-tailed)	.092	.069	.054	.004	.003	.001	.004
Exact Sig. (2-tailed)	.094	.070	.054	.003 **B**	.003 **B**	.001 **B**	.003 **B**
	Q 8 after - before	**Q 9 after - before**	**Q 10 after - before**	**Q 11 after - before**	**Q 12 after - before**	**Q 13 after - before**	**Q 14 after- before**
Z(Based on positive ranks)	-2.479	-3.184	-4.032	-2.452	-.186	-2.955	-1.303
Asymp. Sig. (2-tailed)	.013	.001	.000	.014	.853	.003	.193
Exact Sig. (2-tailed)	.012	.001 **B**	.000 **B**	.013	.900	.002 **B**	.196

Table 152 Wilcoxon sign rank tests for each question in the OHIP-14 questionnaire

The results for the non parametric analysis show a statistically significant result in 9 out of the 14 questions (exact 2-tailed) at the 0.05 level. 7 of the fourteen questions (marked **B** above) were significant with the Bonferroni correction of multiple analysis (see chapter 8 below for a discussion of this).

Chapter 8 Discussion of assessment by OHIPs

8.1 Raw data for OHIPs

There is some missing data for both before and after OHIP scores. The data missing for the before scores are largely due to patients missing a page of questions when filling in the OHIP questionnaire. Where more than one question was missed the OHIP score was deleted from all calculations as described by Steel (2004).

There were more 'after' OHIP scores missing than 'before' OHIP scores. This was due to patient failing to return the questionnaires. The 'after' OHIP score were completed three months after all other aspects of the trial were completed. When the patient could not return for an appointment to fill in the questionnaire patients were contacted by post with an OHIP questionnaire to the last known address and were telephoned (where possible) to encourage completion. The cut-off point for waiting for OHIP scores to be returned was late June 2009.

8.2 Paired samples students t-test of overall traditional OHIP-14 scores

The results of analysis (shown in Table 146, section 7.3.2 above) show a statistically significant difference between the 'before' and 'after' OHIP scores ($p<0.001$). The Null Hypothesis that the treatment did not affect the OHIP score is rejected. In rejecting the Null Hypothesis the alternative hypothesis is proposed that the treatment provided affected the patients' perception of oral health related quality of life.

The reduction in the OHIP score demonstrates an improvement in the patients' perception of the oral health related quality of life.

8.3 Traditional OHIP scores for individual OHIP-14 questions

Taking the mean OHIP score for each question (from all the patients) all individual OHIP question showed a decrease in mean OHIP score after treatment (Table 147 above). Subsequent paired t-tests demonstrated this difference to be statistically significant in 11 out of the 14 OHIP questions before and after treatment.

OHIP questionnaires are designed to assess 7 ‘dimensions’ of a patient’s quality of life. These ‘dimensions are ‘Functional limitation’, ‘Physical pain’, ‘Psychological discomfort’, ‘Physical disability’, ‘Psychological disability’, ‘Social disability’ and ‘Handicap’. For the OHIP-14, two questions are allocated sequentially to each of these 7 dimensions; the first two questions to the first dimension listed above, the second two questions are related to the second dimension listed above, etc until the last questions, 13 and 14, are allocated to the last dimension of ‘handicap’.

Each OHIP dimension has at least one question where there is a statistically significant result. The dimensions of ‘Physical pain’, ‘Psychological discomfort’, ‘Physical disability’ and ‘Psychological disability’ have both allocated questions showing a significant result. The dimensions where both questions showed a significant difference can be said to demonstrate a clear improvement in that aspect of the patients’ perceived oral health related quality of life.

Bonferroni correction for multiple testing was subsequently applied to the data. Bonferroni is a conservative estimate of significance when the numbers of multiple tests are increased. In the Bonferroni correction for multiple testing, the level of significance is divided by the number of tests. In this case there are 14 individual tests so the correction of the level of significance is 0.05/14= 0.00357. Five of the 14 results (marked **B** in Table 148 above) show significance with Bonferroni correction of the 0.05 significant level.

Dimensions that have a significance difference between before and after treatment when the Bonferroni correction is used are: Physical pain (One out of two possible questions significant), Psychological discomfort (one out of two questions), Psychological disability (both questions), and Handicap (one question).

8.4 Non parametric analysis for the overall OHIP-14 questions

The results of analysis (shown in Table 150, section 7.4.1 above) show a statistically significant difference between the 'before' and 'after' OHIP-14 ranks ($p<0.001$). The Null Hypothesis that the treatment did not affect the OHIP score is rejected. In rejecting the Null Hypothesis the alternative hypothesis is proposed that the treatment provided affected the patients' perception of oral health related quality of life.

The reduction in the OHIP-14 ranks demonstrates an improvement in the patients' perception of the oral health related quality of life.

8.5 Non parametric analysis for the individual OHIP-14 questions

In Table 151 above, the mean rank of the before OHIP-14 questions were always higher than the mean rank of the after questions. This suggested a difference. The subsequent non parametric analysis showed a significant difference in 9 of the 14 questions, alpha =0.05 (Table 152).

The dimensions of 'Psychological discomfort', 'Physical disability' and 'Psychological disability' have both allocated questions showing a significant result. The dimensions of 'physical pain' and 'disability' have a statistically significant difference in one of the two questions for the dimension. The dimension of 'Functional limitation' does not show a statistically significant difference with this analysis (no difference detected).

The Bonferroni correction for multiple testing was subsequently applied to the data. In the Bonferroni correction for multiple testing, the level of significance is divided by the number of tests. In this case there are 14 individual tests so the correction of the level of significance is 0.05/14= 0.00357. Severn of the 14 results (marked **B** in Table 152 above) show significance with Bonferroni correction of the 0.05 significant level.

Dimensions that have a significance difference between before and after treatment when the Bonferroni correction is used are: Physical pain (one out of a possible two questions significant), Psychological discomfort (both questions significant), Physical disability (one out of two questions), Psychological disability (both questions), and Handicap (one question significant).

8.6 Summary of OHIP-14 and the analysis used in this study

A lengthy discussion of the advantages and disadvantages of the alternative methods of analysis for OHIP type questionnaire is a matter for statistical experts and beyond the scope of this clinical Thesis. Suffice to say here that the analysis of the OHIP-14 showed improvement after treatment, by both the traditional and non parametric analysis of the OHIP-14.

The OHIP-14 was not used in this study to provide a tool for differentiation of the patient benefit from each side of the trial; that is, each individual denture (see section 2.5.4 of chapter 2, Part IV above). It was used instead to show the overall benefit of treatment. Whichever analysis is used, the conclusion that patients benefitted from this provision of new dentures can be made.

The analysis of the individual questions of the OHIP involves multiple comparisons. It is good statistical practice to use a conservative correction of the significance level in these circumstances. The Bonferroni correction suggested here is robust.

When Bonferroni was used in this study the non parametric analysis had more questions showing a significant difference than the paired t-test (the same data set was used for both analyses). Suffice to say here that the traditional summed OHIP analysis did not produce as robust an outcome; it would be speculative to suggest that this is because the assumptions required for the traditional statistical analysis were violated. This study suggests the non parametric analysis was more robust; but further statistical research is required before further conclusions can be made as different data sets may show different trends.

The trend in papers published throughout 2009-2010 in the scientific literature was towards non parametric analysis of the OHIP questionnaires, either by Wilcoxon (for example Bihan 2010) or a suitable (non parametric) form of regression (for example Sanders et al 2009, Russanen 2010). The correction for multiple testing that has been used here has not been carried out often in the literature; although as this was being written, papers have been published that report the use of Bonferroni corrections (Sanders et al 2009).

The papers that report multiple ‘p’ values often report p values as less than a certain amount (rather than the figure itself). This makes it difficult for the reader to

retrospectively apply a correction for multiple testing. There is a notable exception and Sutton and McCord (2007) is an example in the literature where a correction for multiple testing has not been carried out, yet in all but one domain, the actual p value was quoted. This allows the inquisitive reader to perform manually a Bonferroni correction of the significance level. If the results in Sutton and McCord (2007) were subjected to Bonferroni correction there would be only one domain which gives a statistically significant result (the domain is 'sore spots in the mouth' where the p value was quoted as $p<0.001$ and the Bonferroni correction would require a p value <0.002).

In summary, the traditional summed OHIP-14 score uses a non continuous, ordinal, variable and yet it compares means; expert statisticians are aware of the potential problems with this type of analysis. In contrast the more correct non parametric analysis presented here is easy to use and can be described in an understandable way. A suitable correction of multiple testing (with either traditional or non parametric analysis) should always be applied to analysis of multiple OHIP domains.

For the type of overall analysis required for the work of this Thesis, the non parametric, Bonferroni corrected analysis is preferred.

Chapter 9 The secondary outcome questionnaire

9.1 Introduction

The assessment of the dentures by the secondary outcome questionnaire took place after the research participants had worn each new denture for two weeks. The assessments were sequential. Each denture was assessed separately, with two weeks between each assessment.

The secondary outcome questionnaire (see Appendix 8) asked three questions. In answer to each question the research participant was given the option of four Likert-like boxes to tick. The outcome measures are ordinal; four outcome responses for each assessment ranging from the very positive, through positive and negative, to the very negative. For the comfort question responses were labelled very comfortable, comfortable, uncomfortable and very uncomfortable. For the stability question they were labelled very stable, stable, unstable and very unstable. For the masticatory efficiency question they were labelled very efficient, efficient, inefficient, and very inefficient.

The answers to the three questions were each given the numbering of 1 for the very positive response, two for the positive response, three for the negative response and four for the very negative response. Thus the higher the number of the response the worse was the patients' assessment of the outcome.

Two independent variables were recorded at each assessment. They were the denture being reviewed (denture A, denture B or denture C) and the order of delivery (first denture to be delivered and assessed, or second denture or third denture).

9.2 Research questions and Null Hypothesis for secondary outcomes

Research questions were raised for each of the independent factor variables. For each independent factor variables of 'Denture' (A, B or C) and 'Order' (1^{st} 2^{nd} or 3^{rd}), the research questions were;

Was there a significant difference in comfort rating between the levels of the independent variables?

Was there a significant difference in stability rating between the levels of the independent variables?

Was there a significant difference in masticatory efficiency rating between the levels of the independent variables?

The corresponding Null Hypothesis for each research question was 'there was no difference between the levels of the factor variable'. Thus there were a total of three Null Hypothesis related to each factor of 'denture' and of 'order'. The initial analysis of the results was designed to test each of these six Null Hypotheses in turn. The initial analysis was by related non parametric analysis with Wilcoxon signed ranks test (section 9.5 below). Further modelling was carried out using ordinal logistic regression (see appendix 11 below).

9.3 Raw data

The raw data for the assessment of comfort, stability and chewing efficiency is appended in Appendix 10.

Since all research participants completed the secondary assessment at the clinical visits, there was no missing data; all 66 patients who completed the trial completed the secondary outcome assessment questionnaires after wearing each denture.

9.4 Exploration

The outcome is not continuous so it was considered inappropriate to calculate the means and standard deviations of the number attached to the order of the variables. Mean ranks are used for the analysis. The medians of the overall data sets for comfort, stability and masticatory efficiency scores, from all the questionnaires, are listed in Table 153 below.

		Comfort	Stability	Mastication
N	Valid	198	198	198
	Missing	0	0	0
	Median	3	2	3

Table 153. The medians of dependant outcomes from all the questionnaires (before and after).

The bar charts showing the frequency of each answer to the three questions are shown below (Figures 105, 106 and 107).

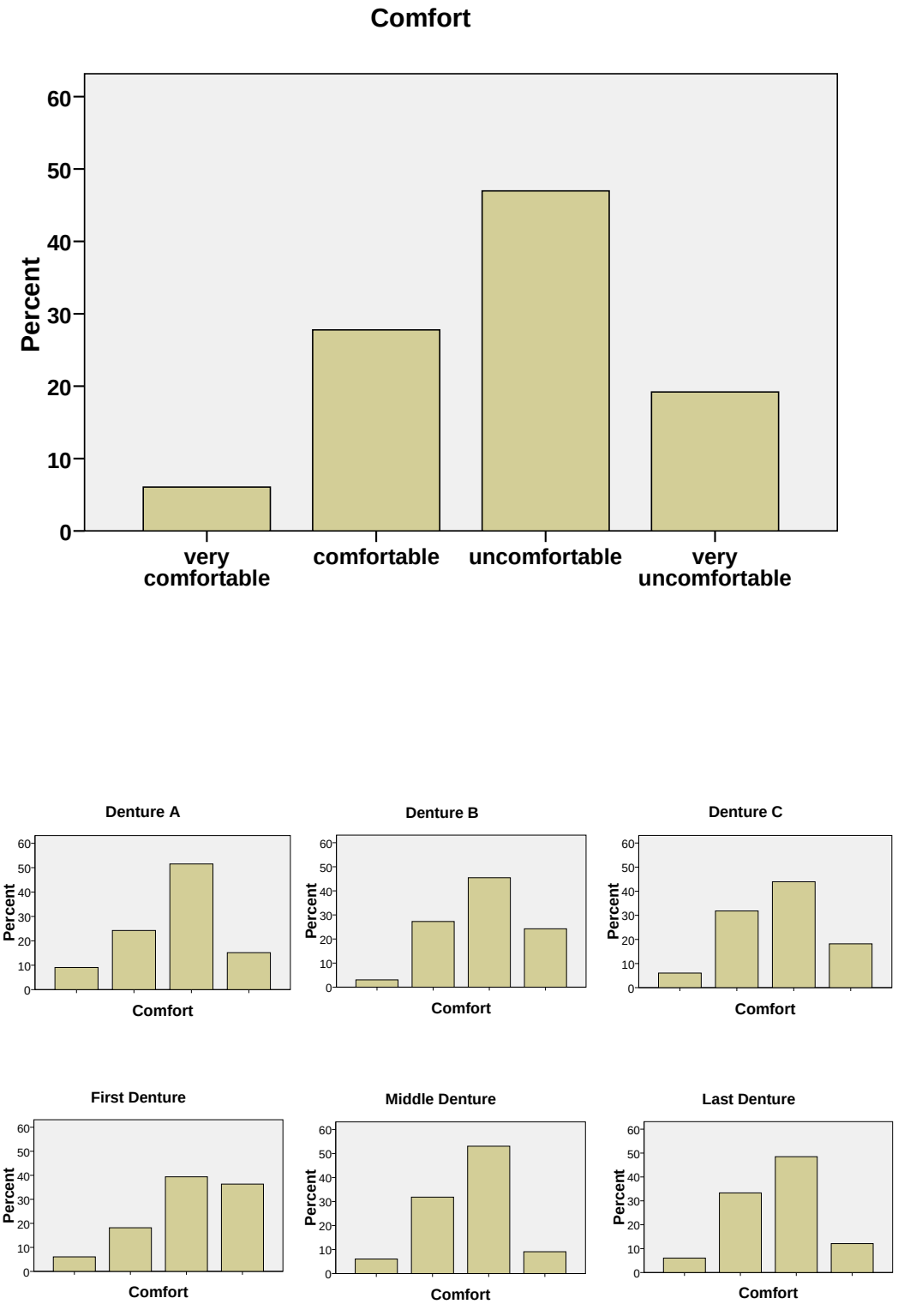


Figure 103 frequency chart of the dependant variable ‘comfort’. Main chart above shows all the results for the unadjusted dentures, and then smaller histograms are for each of the three dentures followed by three histogram for the order of delivery.

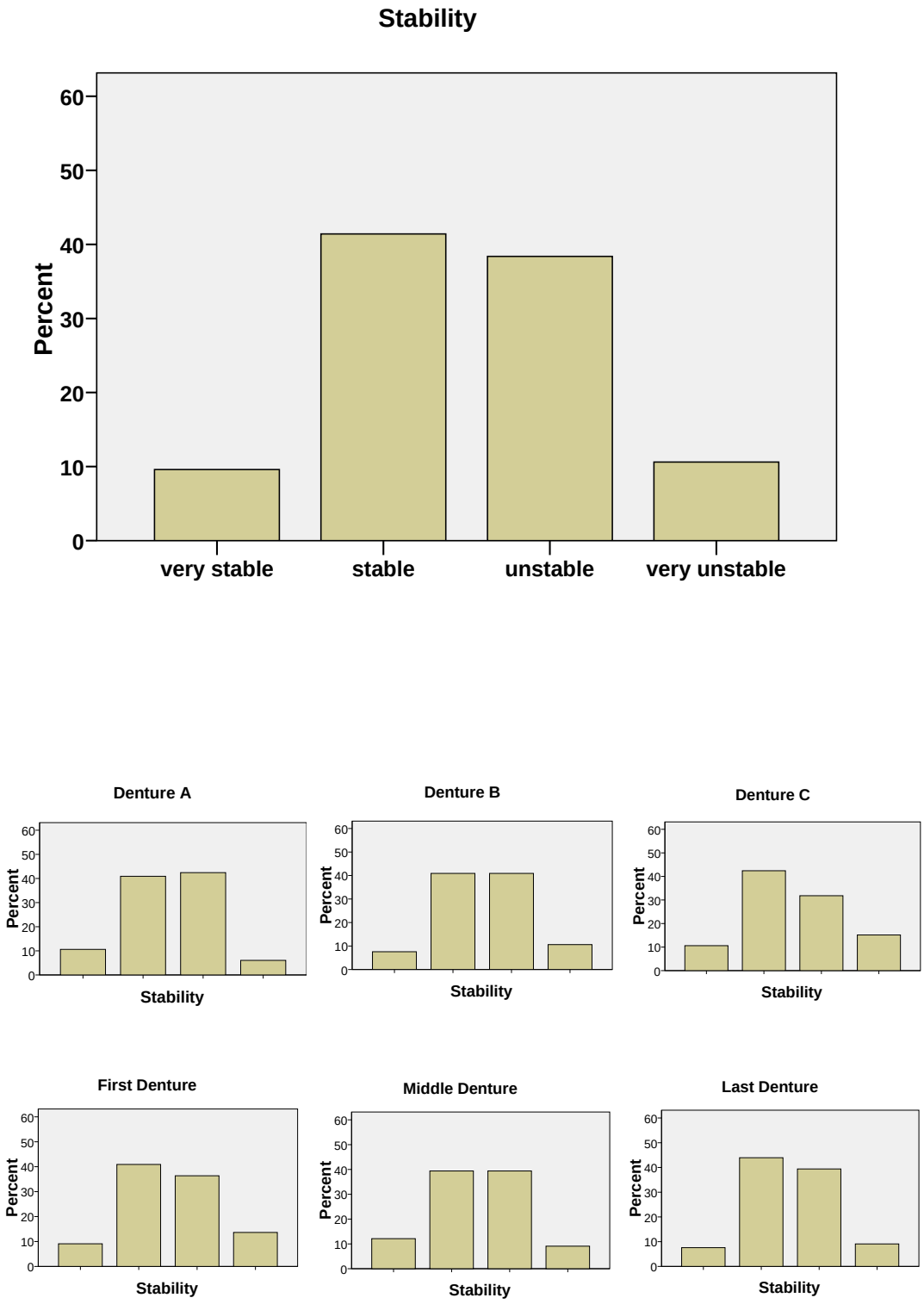


Figure 104 frequency chart of the dependant variable ‘stability’. Main chart above shows all the results for the unadjusted dentures, and then smaller histograms are for each of the three dentures followed by three histogram for the order of delivery.

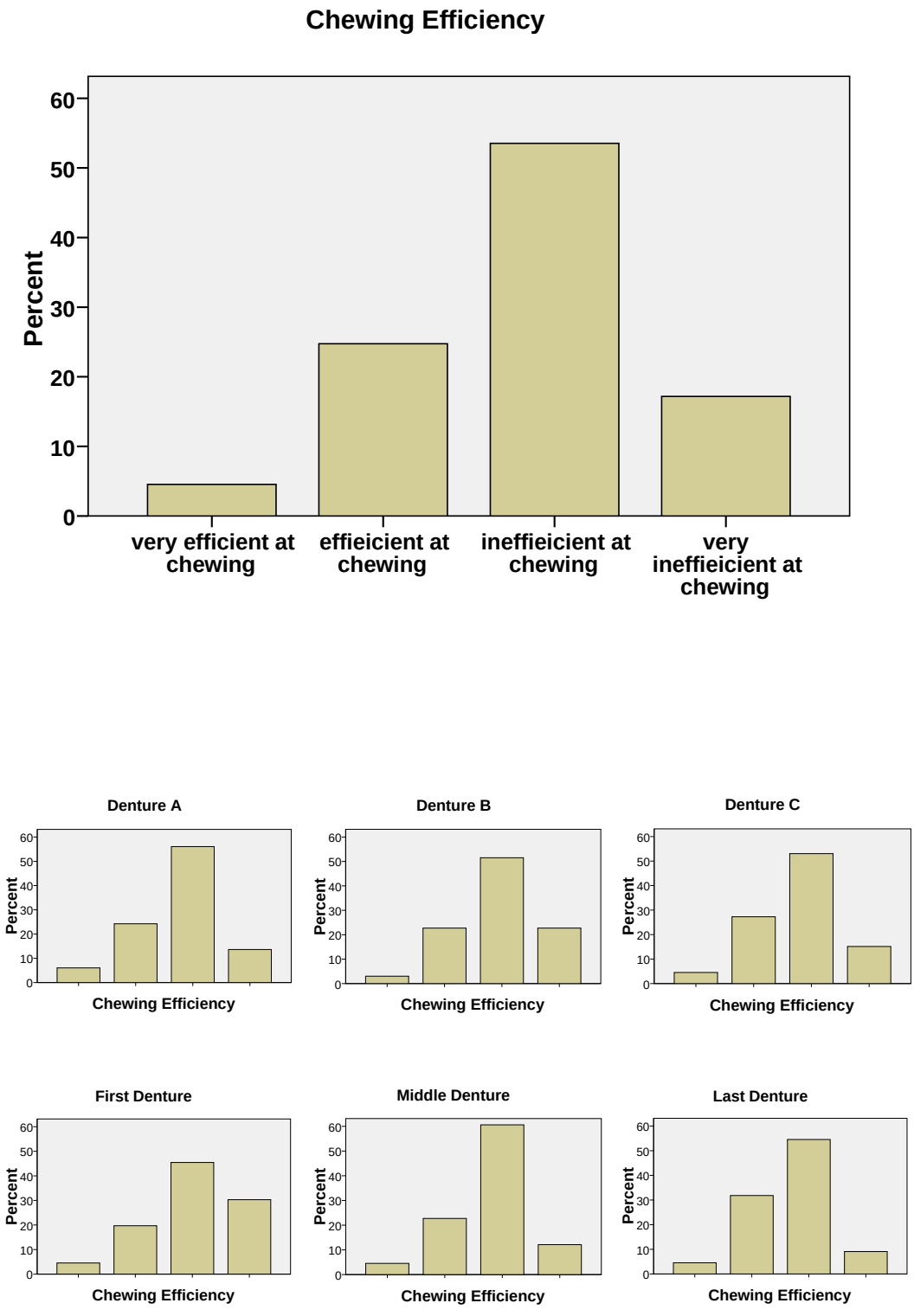


Figure 105 frequency chart of the dependant variable ‘chewing efficiency’. Main chart above shows all the results for the unadjusted dentures, and then smaller histograms are for each of the three dentures followed by three histogram for the order of delivery.

9.5 Analysis of the secondary outcome by Wilcoxon signed ranks test

9.5.1 Comfort assessed between the dentures by the secondary outcome questionnaire with Wilcoxon signed ranks test

Comfort by denture			
Wilcoxon Signed Ranks test	**Dentures B – A**	**Dentures C – A**	**Dentures C – B**
Z	-1.577(a)	-.107(b)	-1.580(b)
Asymp. Sig. (2-tailed)	.115	.915	.114
Exact Sig. (2-tailed)	.130	.936	.125

Table 154. Related 2 sample Wilcoxon signed rank test of comfort; (a) Z based on negative ranks, (b) Z based on positive ranks.

No difference was detected between the three dentures for the research participants' rating of comfort using the secondary outcome questionnaire. Bonferroni correction was not applied as the results were not significant at the uncorrected 0.05 level.

9.5.2 Stability assessed between the dentures by the secondary outcome questionnaire with Wilcoxon signed ranks test

Stability by denture			
Wilcoxon Signed Ranks test	**Dentures B – A**	**Dentures C – A**	**Dentures C – B**
Z	-.788(a)	-.441(a)	-.435(b)
Asymp. Sig. (2-tailed)	.431	.659	.664
Exact Sig. (2-tailed)	.436	.672	.670

Table 155. Related 2 sample Wilcoxon signed rank test of stability; (a) Z based on negative ranks, (b) Z based on positive ranks.

No difference was detected between the three dentures for the research participants' rating of Stability using the secondary outcome questionnaire. Bonferroni correction was not applied as the results were not significant at the uncorrected 0.05 level.

9.5.3 Masticatory efficiency assessed between the dentures by the secondary outcome questionnaire with Wilcoxon signed ranks test

Masticatory efficiency by denture			
Wilcoxon Signed Ranks test	**Dentures B – A**	**Dentures C – A**	**Dentures C – B**
Z	-1.304(a)	-.319(b)	-1.754(b)
Asymp. Sig. (2-tailed)	.192	.750	.079
Exact Sig. (2-tailed)	.209	.755	.096

Table 156. Related 2 sample Wilcoxon signed rank test of masticatory efficiency; (a) Z based on negative ranks, (b) Z based on positive ranks.

No difference was detected between the three dentures for the research participants' rating of masticatory efficiency using the secondary outcome questionnaire. Bonferroni correction was not applied as the results were not significant at the uncorrected 0.05 level.

9.5.4 Comfort assessed between the order of delivery by the secondary outcome with Wilcoxon signed ranks test

Comfort by order of delivery			
Wilcoxon Signed Ranks test	**Second – first**	**Third - first**	**Third- second**
Z	-3.108(a)	-3.143(a)	-.042(b)
Asymp. Sig. (2-tailed)	.002	.002	.966
Exact Sig. (2-tailed)	.002 B	.002 B	.959

Table 157. Related 2 sample Wilcoxon signed rank test of comfort by order of delivery; (a) Z based on negative ranks, (b) Z based on positive ranks.

The exact 2-tailed test is significant at 0.05 level for the research participants' rating of the first denture against both the second and the third denture. Multiple testing requires a conservative correction of the significance level. Bonferroni correction is applied and in this case the Bonferroni correction of the 0.05 level is 0.05/3 = 0.0167. With the Bonferroni correction the exact 2 tailed p value shows a statistical significant difference between the first denture and both of the other dentures.

9.5.5 Stability assessed between the order of delivery by the secondary outcome with Wilcoxon signed ranks test

Stability by order delivered			
Wilcoxon Signed Ranks test	**Second- first**	**Third – first**	**Third – second**
Z	-.902(a)	-.415(a)	-.607(b)
Asymp. Sig. (2-tailed)	.367	.678	.544
Exact Sig. (2-tailed)	.390	.686	.645

Table 158. Related 2 sample Wilcoxon signed rank test of stability by order of delivery; (a) Z based on negative ranks, (b) Z based on positive ranks.

No difference was detected between the order of delivery of the dentures for the patient recorded stability of the dentures using the secondary outcome questionnaire. Bonferroni correction was not applied as the results were not significant at the uncorrected 0.05 level.

9.5.6 Masticatory efficiency assessed between the order of delivery by the secondary outcome with Wilcoxon signed ranks test

Masticatory efficiency by order delivered			
Wilcoxon Signed Ranks test	**Second-first**	**Third – first**	**Third – second**
Z	-1.909(a)	-2.674(a)	-1.110(a)
Asymp. Sig. (2-tailed)	.056	.007	.267
Exact Sig. (2-tailed)	.063	.006 B	.242

Table 159. Related 2 sample Wilcoxon signed rank test of masticatory efficiency by order of delivery; (a) Z based on positive ranks.

The exact 2-tailed test is significant at 0.05 level for the research participants' rating of the first denture against third denture. Multiple testing requires a conservative correction of the significance level. The Bonferroni correction was applied and in this case the Bonferroni correction of the 0.05 level gave significance at the p=0.05/3 = 0.0167 level. With the Bonferroni correction the exact 2 tailed result shows statistical significance between the first denture and the third of the other dentures.

9.6 Discussion of secondary outcome questionnaire

9.6.1 Overall result

With the secondary outcome, the trial participants express overall dissatisfaction with the new dentures in their assessment of comfort and chewing efficiency. This is well illustrated in Figures 103 and 105 above. At one week post insertion, the majority of patients found the unadjusted dentures uncomfortable or very uncomfortable and inefficient or very inefficient at chewing.

As discussed in section 3.1.4 above, the adjustment of the fitting surface before the assessment of the fitting surface would have introduced a confounding variable into the study. The assessment of the unadjusted dentures was therefore considered desirable. The secondary outcome measure was timed to assess the dentures after each unadjusted denture had been worn for 1 week. While it may not be considered surprising by experienced clinicians that an unadjusted denture was assessed by the patients as uncomfortable, it is important not to dismiss this result as unimportant. The patients were uncomfortable. The discomfort of the patient highlights an important ethical consideration for future denture trial protocols. This result confirms as correct the caution within this trial protocol which restricted the assessment period for the unadjusted dentures to just one week (see section 3.1.4 above).

In a similar way the assessment of chewing efficiency at one week by the secondary assessment tool reflects the patients' inability to adapt to the unadjusted dentures within this period. Habituation to dentures is well recognized and discussed elsewhere (see sections 9.6.4 to 9.6.6 below). Because the dentures were constructed to be similar in the shape of their polished and occlusal surfaces it was expected that the patients would habituate to the second and third dentures more easily. This is one possible explanation for the difference in the assessment of chewing efficiency between the first and third denture seen in section 9.5.6 above. This order related bias is discussed below (section 9.6.4). It highlights the need for randomization in cross over clinical trials.

Following the assessment in the primary outcome (which followed after the assessment by the secondary outcome) the dentures were adjusted for the patients, if necessarily repeatedly, until they were satisfactory. The patients were able to habituate to the adjusted dentures over the following 3 months before the final OHIP

assessment. The OHIP (see Chapters 7 & 8 above) reflects patient satisfaction with the dentures after the adjustment and habituation periods. At this time the overall assessment of the dentures by the patients reflects satisfaction. The reduction in traditional OHIP score compares well with other trials and the minimum important difference (MID) in prosthodontics determined for the OHIP 49 by John et al (2009).

9.6.2 Outcome differences

The primary result (Chapter 5, Part IV) was able to demonstrate a significant difference between the dentures (A, B or C), and yet the secondary outcome failed to detect a difference. Consideration needs to be given to why there is this dichotomy of results between the primary outcome and the secondary questionnaire. There are two possibilities; the primary outcome has wrongly detected a difference or the secondary outcome failed to detect a real difference. A Type I error or a Type 2 error; consideration and judgement is required to assess these possibilities.

9.6.3 'No difference detected' and experimental power

An insignificant outcome (as found with the secondary outcome) is often erroneously portrayed as a confirmation of the Null Hypothesis, whereas it should be more carefully worded as 'no difference detected' and an inability to reject the Null Hypothesis.

It is normal practice for clinical trials to calculate the number of subjects required by a power calculation based on the assessment tool to be used for the primary outcome. This clinical trial was powered for the primary output. The secondary outcome was not considered in the power calculation. A retrospective consideration of the power of the secondary outcome was therefore indicated.

An assessment of the secondary outcome by ordinal logistic regression is appended to the Thesis (Appendix 11). Guidance with the statistics involved in the ordinal logistic regression analysis was given by Theresa Munyombwe of the department of Biostatistics, University of Leeds whose help is acknowledged here and in the Thesis acknowledgements. The overall results of the Ordinal Logistic

Regression confirmed the significances provided by the simpler Wilcoxon sign rank tests above; exactly matching those occasions when significance was shown.

For an analysis involving Odds Ratios, the power of the calculation may be estimated retrospectively from the reduced formula below (Machin et al, 1987, page 23)

$m= 6(k)/(\log OR)^2$

where 'm' is the number of participants in the trial, 'k' is a value from which the power may be assessed using standard statistical tables, and 'log OR' is the log of the Odds Ratio (Machin et al1987).

In this study m=66 so we can solve the equation above for 'k' thus:

$k=11(\log OR)^2$

From standard statistical tables, when k= 7.849 the power of the calculation is 0.08 (80%); if k is less than 7.849 then the power of the calculation is less than 80% (i.e. insufficient). For k to be less than 7.849 then the log of the odds ratio would be lie between + 0.8447 and - 0.8447. The exponentials of 0.8447 and -0.8447 are 6.994 and 0.143 respectively; therefore the odds ratio for Power to be less than 0.8 would be less than 6.994 but more than 0.143. The odds ratios from an ordinal logistic regression of the secondary assessment (performed by the statistical software 'STATA') are given in Appendix 11. All 12 Odds Ratios from the Ordinal Logistic Regression return the power of the calculation as less than 0.8 (beta < 80%). The power for the secondary outcome was less than 80%. Low power for the secondary outcome may lead to type 2 errors.

A conclusion of 'no difference detected' does not mean there was a certainty of no real difference but that a difference could not be detected by the experiment with analysis used. One possible explanation for the different conclusions between primary and secondary outcomes (significant difference v no difference detected) would be that the secondary outcome has insufficient power.

The primary outcome was powered; the secondary was not. An assessment of possible explanations for the insufficient power of the secondary outcome was indicated. The different conclusions between primary and secondary outcomes may be explained by a 'type 2' error due to insufficient power; but what caused the insufficient power?

The primary outcome was designed to be simple and explicit. It asked the research participant to name the denture they preferred. Crucially the primary outcome was comparative, the research participants were given all the dentures to take home for two weeks and they could swap and change to compare the dentures as much as they liked. The primary outcome was not directed to be sequential but directly comparative. In contrast, the secondary outcome assessments were sequential and not directly comparative; for the secondary outcomes research participants only had one denture at a time. This raises the possibility of response shift (see below).

It was suggested as an initial working hypothesis that the nature of the secondary assessment introduced a confounding variable which masked the real difference between the dentures.

9.6.4 Order related confounding variable

For the primary outcome, we know from the multinomial logistic regression above (section 6.1, Chapter 6, Part IV) that the order of delivery of the dentures did not affect the primary outcome. For the secondary assessment, the analysis by the Wilcoxon signed rank tests above show that the first denture delivered was perceived to be worse than the others for comfort, and worse than the third denture for masticatory efficiency. For the comfort and masticatory efficiency assessments the Null Hypothesis is rejected and the alternative proposed that there is a significant difference in outcome related to the order of delivery of the dentures. The alternative hypothesis that the order of delivery affects the outcome of the secondary assessment tool is proposed. This finding of the potential for the order of delivery to affect an outcome measure in cross over denture trials confirms the opinion expressed by McCord (McCord 2005). Future trials should be careful to include appropriate randomisation within the protocol.

For both the comfort group and the masticatory efficiency group there appears to be a bias against the first denture delivered. The effect size of this potential confounder was large. It was suggested as a revision to the working hypothesis (raised in section 9.6.3 above) that the confounding variable was the order of delivery.

Dentists will be familiar with the concept of 'habituation' to new dentures (Basker and Davenport 2002). The order related bias seen with the secondary assessment may be explained by the habituation of the patient to the shape of the new (first) denture. Since the second and third dentures are deliberately made to have polished and occlusal surfaces very similar in shape to the first denture, the patient will be habituated to second and third dentures shape before they are worn. In these circumstances it is no surprise that the second and third dentures do not cause such a negative reaction as the first denture. Although McCord et al (2005) does not mention 'habituation' by name, he found a similar bias against the first denture in his limited study (McCord et al 2005). For the denture research of this Thesis, habituation is a useful hypothesis for the cause of the order related bias in the secondary outcome.

The variable of order of delivery of the dentures was significant for the secondary outcome. It was possible that the order of delivery has confounded the results to mask the effect for which denture was being assessed. A mechanism (habituation) for the potential cause of this possible confounding variable is well known to clinicians.

9.6.5 Response shift

'Habituation' is a potentially useful and familiar term for dentists to gain an understanding of these confounded results. To express the problem to a non dental audience it is preferable to say that in this trial, there is a problem caused by the repeated treatment (and repeated assessment) creating a bias in the objectivity of the self assessment of the therapeutic effect of a treatment. The second time a similar treatment was offered it was not assessed by the patient as having the same magnitude of effect by the subjective assessment tool. There is potential for the same type of 'response shift' to happen in other research where similar treatments are assessed by patient centred questionnaires.

In the wider research community this phenomenon of patient centred quality of life assessments has been recently discussed (Barclay-Goddard et al 2009, Nolte et al 2009, Gillison et al 2008, Ring et al 2005, Ahmed et al 2005). Some papers found small effects of response shift with no overall recalibration needed (Gillison et al 2008); others found that response shift masks results (Ring 2005), others that it has

the potential to ‘enhance’ results with a false positive finding (Ahmed et al 2005). Methods of overcoming response shift within studies have been suggested. Both the ‘pre-test/post test’ and the ‘then-test/post test’ were investigated by Nolte et al (2009) who suggested for his area of study, the pre-test post test data appear to be the more robust method. In future research designs, sequential patient centred outcome questionnaires must always be considered to have a potential for a response shift. Because of this potential, response shift and ways of controlling for a potential response shift still require further research.

9.6.6 Overcoming order related bias for denture trials

There is a specific explanation for the response shift in denture research (‘habituation’ see above). More generally, when all or most research participants show a similar tendency in the direction of the response shift to a question, the result is an order related bias in assessment. This consistent directional response shift for patients in a trial has the potential to effectively confound the results.

If it is strong enough, the order related response shift in patient-centred, self assessment has potential to mask benefits of treatment in any cross over RCT; it becomes an effective confounding variable which masks the clinical effect of the different treatments.

As with all confounding variables one traditional solution to the problem is to increase the number of participants to show the effective treatment hidden by the confounders. For denture trials this traditional solution may be financially prohibitive. Other solutions are possible, for instance, a parallel sided (instead of cross over) study may be considered, but this solution (for denture research) would also introduce many more confounding variables (some are more obvious than others and they are too numerous to mention them all, obvious examples would be age and sex distributions, less obvious potential confounders would be things like the ridge shape, biting force, tooth size, occlusal scheme, skeletal relationship, incisal overjet overbite, etc).

The trial presented in this Thesis had no order related bias shown for the primary outcome. This has been achieved by an almost simultaneous comparative assessment of the dentures using the patients’ choice as the pre-planned primary outcome (see the detailed discussion in chapter 2 above). This comparative,

decisive choice by the patient for one of the dentures has negated the order related bias inherent in the secondary outcome measure. This was demonstrated for the primary analysis of this trial by the multi nominal logistic regression analysis of the order related bias (see section 6.1 above). There was no order related bias shown for the primary outcome.

9.6.7 Denture research as a tool for the assessment of response shift in research design

Further work on the problem of order related bias for patient assessed outcome questionnaires is needed. Patient centred research has many benefits but a shift in the response to questionnaires may explain some of the inherent difficulties with sequential assessments. Denture research provides a useful environment to study patient centred assessments in cross over trials. Two advantages are apparent for denture research as an environment in which to analyse the problems for patient centred assessment tools in cross over medical trials. First, with denture research there is no pharmacological wash out period needed. Secondly denture research also has the ability for the patient to first use sequential assessment (as for the secondary outcome above) and then provide on a separate occasion, a comparative assessment which is almost simultaneous by switching freely from one denture to another.

If the same questionnaire is used for both the sequential assessment and the almost simultaneous, comparative assessment then it should be possible to assess and possibly quantify the response shift. Unfortunately in this Thesis the same assessment tool was not used for the sequential (secondary outcome) and the comparative assessment of the dentures (primary outcome). The protocol of the current RfPB NIHR grant funded research ‘IMPROVDENT’ (NIHR grant number PB-PG-0408-16300) for which the candidate (Paul Hyde) is grant holder and CI, includes a facility to pursue this issue further, by using the same tool as a secondary outcome for both sequential and comparative assessments.

Chapter 10 Randomised controlled clinical trial conclusion and future work

10.1 Conclusion for the RCT

It is concluded that the patient group in this trial had a preference for the selective pressure impression technique. This provides a validation of this selective pressure impression technique.

10.2 Clinical implications

Within the hierarchy of clinical evidence for 'best practice', randomised controlled trials are considered as the highest standard available from a single trial. The validation of the clinical impression technique by the RCT reported in this thesis provides clinicians with high quality of evidence for best practice. This impression technique for patients with palpable mental foramen should now be considered as the 'best practice'.

The impression technique was originally described for sharp bony ridges (Hyde 2003). Clinicians should consider the evidence from this RCT (and the remainder of the thesis) in cases where a re-distribution of pressure is deemed desirable. The evidence presented in the RCT should be evaluated for relevance by clinicians when considering impression techniques for other clinical conditions.

10.3 Future work

Several writers (Jokstad et al 2002, Carlsson 2006 2009 & 2010, Harwood 2008) have all reviewed the evidence for modern prosthodontics and commented on lack of high level evidence for prosthodontic procedures and practices. The candidate is taking up the challenge of producing high quality evidence for best practice in prosthodontics by initiating further RCT research of materials and methods of denture construction.

Following the completion of the clinical trial reported in this thesis the candidate has obtained funding and commenced a new RCT of complete denture impressions. The new trial investigates patient preference and overall cost effectiveness of dentures constructed with alginate and silicone impression materials. At the time of submission of this PhD half the required numbers of patients have been recruited. The trial is expecting to report results in 2012. This new trial is the first 'IMPROVDENT' trial. The protocol used for 'IMPROVDENT' has been adapted from the successful protocol used in this thesis.

Chapter 11 A brief overview of the Thesis

Clinical research forms the basis of this Thesis; the randomised controlled clinical trial (RCT) at the centre of the Thesis has successfully investigated the effectiveness of a clinical impression technique. The laboratory research supplements the clinical trial. The laboratory work became necessary when the original literature review for the clinical study demonstrated conflicts or deficiencies in the published evidence. The review highlighted the need for new investigations of the factors which affect pressure within impressions. Those factors had the potential to alter impression pressure and so the potential to confound or enable selective pressure impressions. The subsequent laboratory investigations became an important aspect of the Thesis. Part II of the Thesis records these investigations.

Part II details the background, procedures, methods, and results of in-vitro experiments of factors which affect impression pressure. The work highlights some factors which have not been investigated or reported previously. Examples of this original research include; the effect on pressure of border moulding of the impression tray to develop border and facial seal, the effect on pressure of the velocity of approximation, the effect of delays in seating an impression and the effect of viscosity and speed of set of an impression material. The investigations in Part II have also confirmed some previous work and illuminated the academic discussion where there was previously a conflict of opinion in the literature. Examples of this include chapter 7 (where it was shown that if all other factors are equal, the centre of an impression will receive a higher pressure) and chapters 8-11 (where aspects of perforations in special trays were investigated in more detail than previously reported). As well as the new evidence obtained by these investigations, the limitations of in-vitro measurements of pressure have become apparent and are discussed within the Thesis.

Part III of the Thesis demonstrates the differential pressure, in-vitro, within a selective pressure impression. The impression technique investigated was that used for the RCT in Part IV. The simultaneous measurement of pressure at different points within the same impression has not been previously reported.

Part IV of the Thesis reports the background, procedures, methods, and results of running a RCT of the impression procedure in-vivo. The detailed planning and the systematic methodology were important for the success of the RCT. Part IV of the Thesis provides evidence from a RCT of a preference for a particular impression technique for lower complete dentures in the patient group investigated. This is the first randomized controlled trial to provide such evidence. Given the history and size of the academic literature for impressions for complete dentures this is remarkable. Possible reasons for the positive evidential outcome of this RCT are discussed in detail in the Thesis and it is hoped these will be useful for future RCT's in this area of research.

Part I Chapter 1 of this Thesis gave the overall research question for the Thesis it was 'Is a specifically designed selective pressure impression technique effective?' The answer to the research question is given by the investigations contained in this Thesis; the answer is yes.

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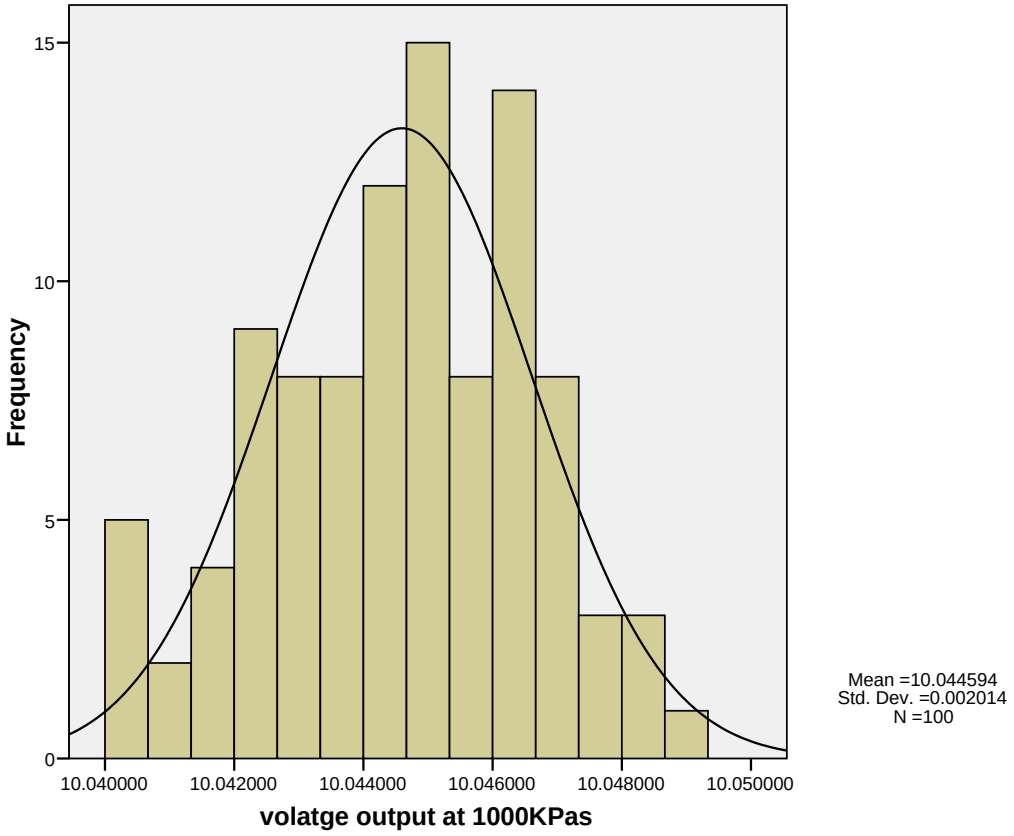
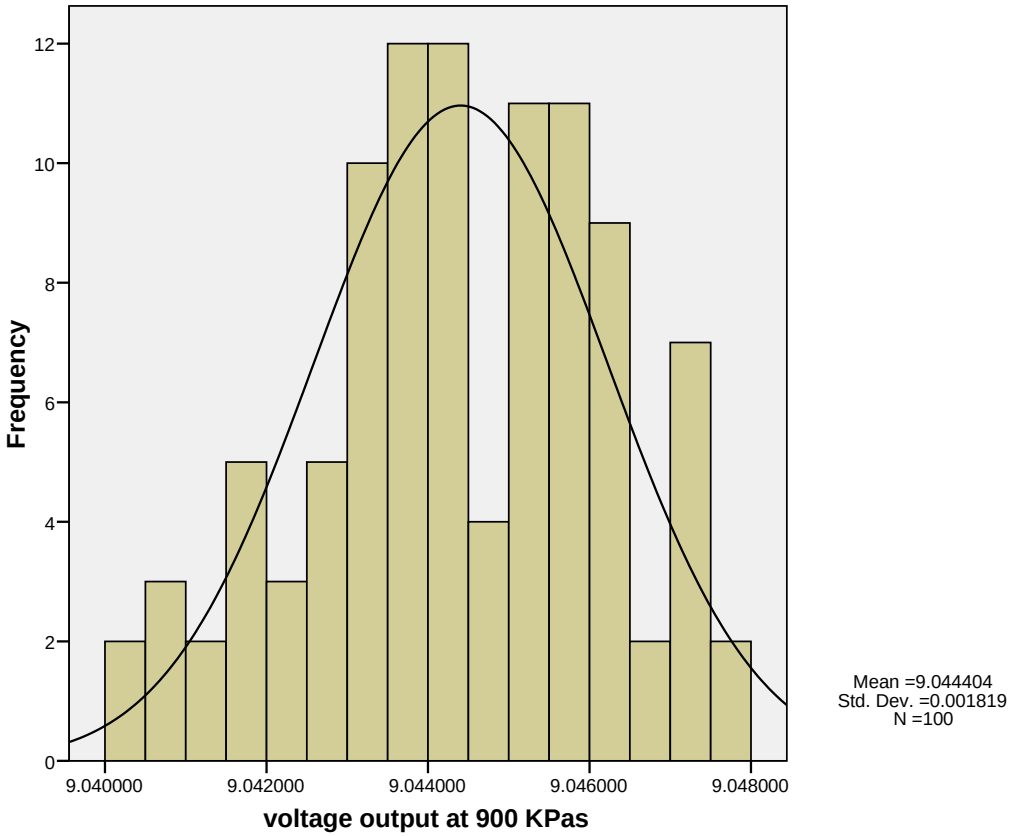
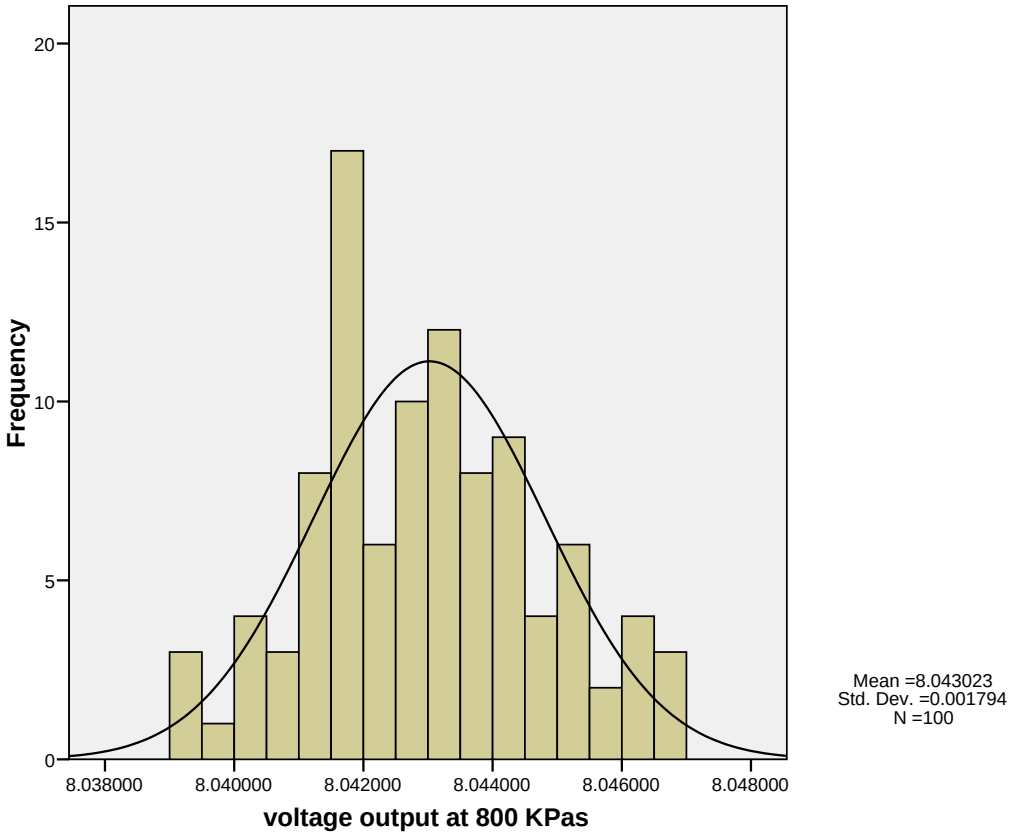
Index of Appendices

Appendix 1 Precision of sensor output; graphically illustrated by SPSS legacy histograms.




Frequency
12
10
8
6
4
2
0
9.040000
9.042000
9.044000
9.046000
9.048000
voltage output at 900 KPas
Mean =9.044404
Std. Dev. =0.001819
N =100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15
10
5
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8.040000
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8.048000
voltage output at 800 KPas
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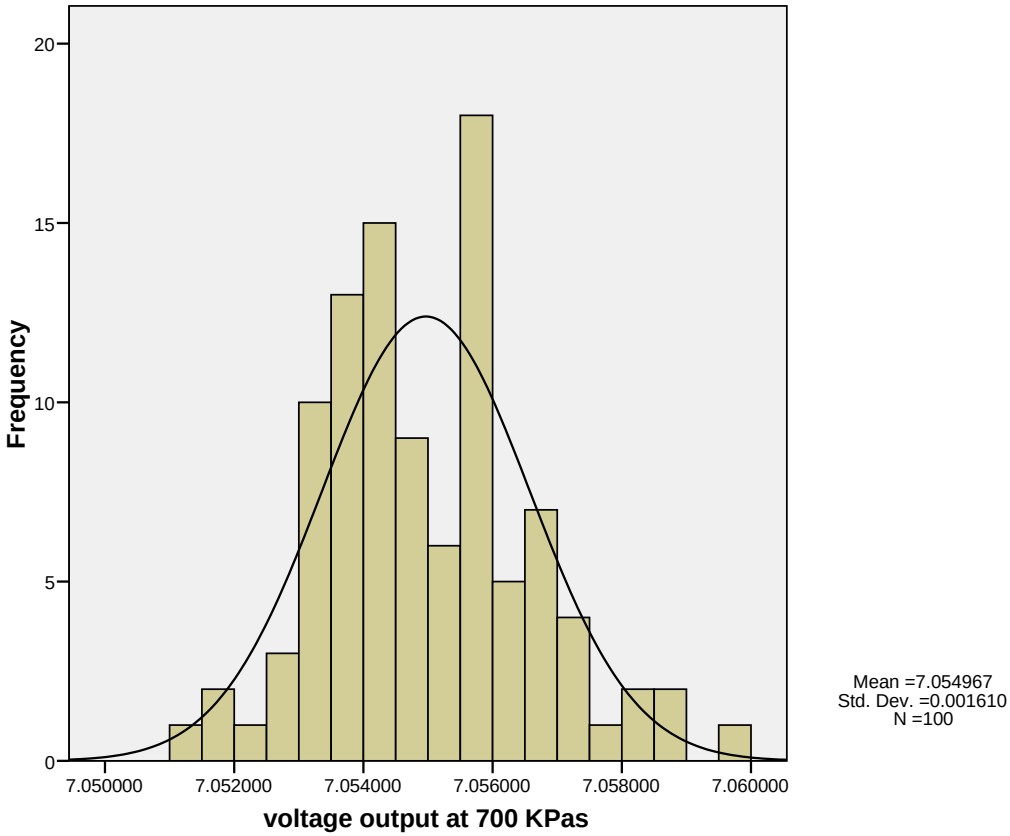
N =100


Frequency
20
15
10
5
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7.050000
7.052000
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7.058000
7.060000
voltage output at 700 KPas
Mean =7.054967
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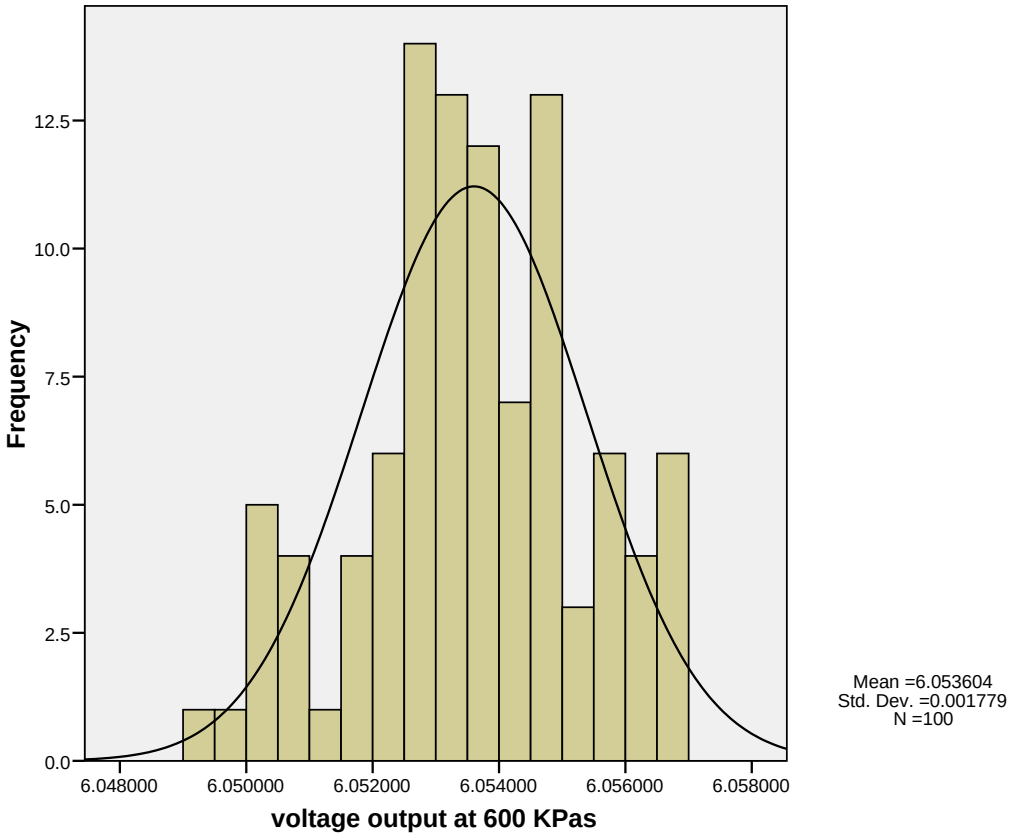
N =100


Frequency
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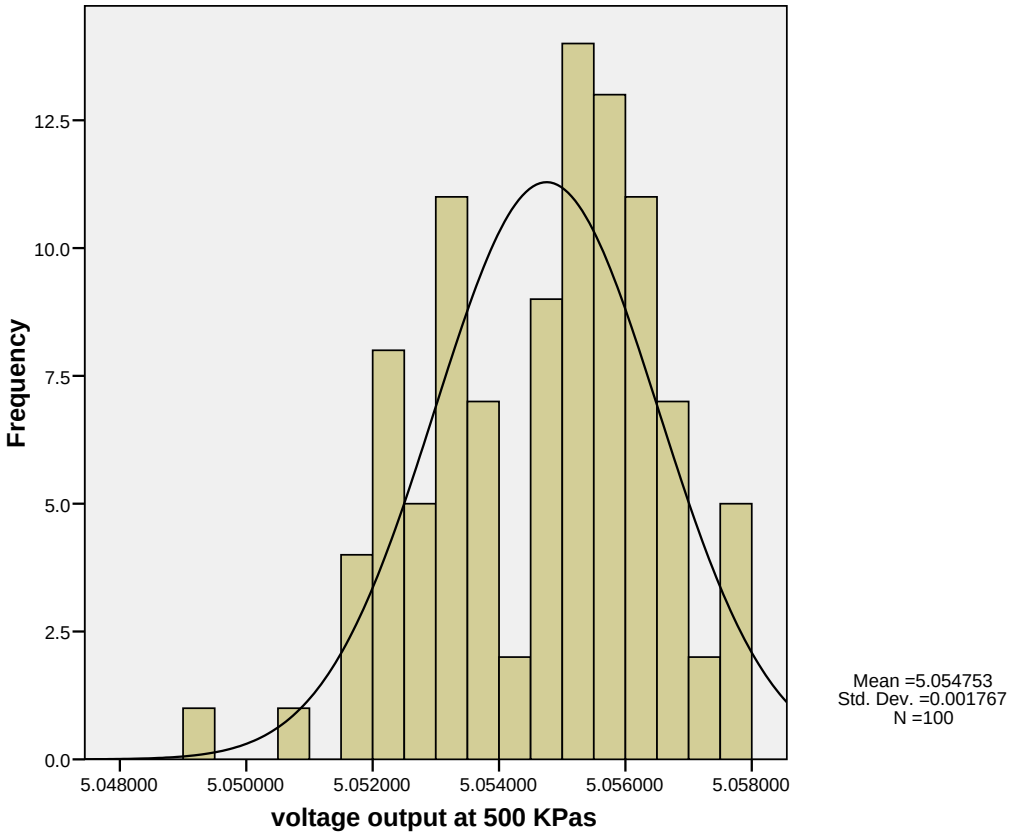
10.0
7.5
5.0
2.5
0.0
6.048000
6.050000
6.052000
6.054000
6.056000
6.058000
voltage output at 600 KPas
Mean =6.053604
Std. Dev. =0.001779
N =100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10.0
7.5
5.0
2.5
0.0
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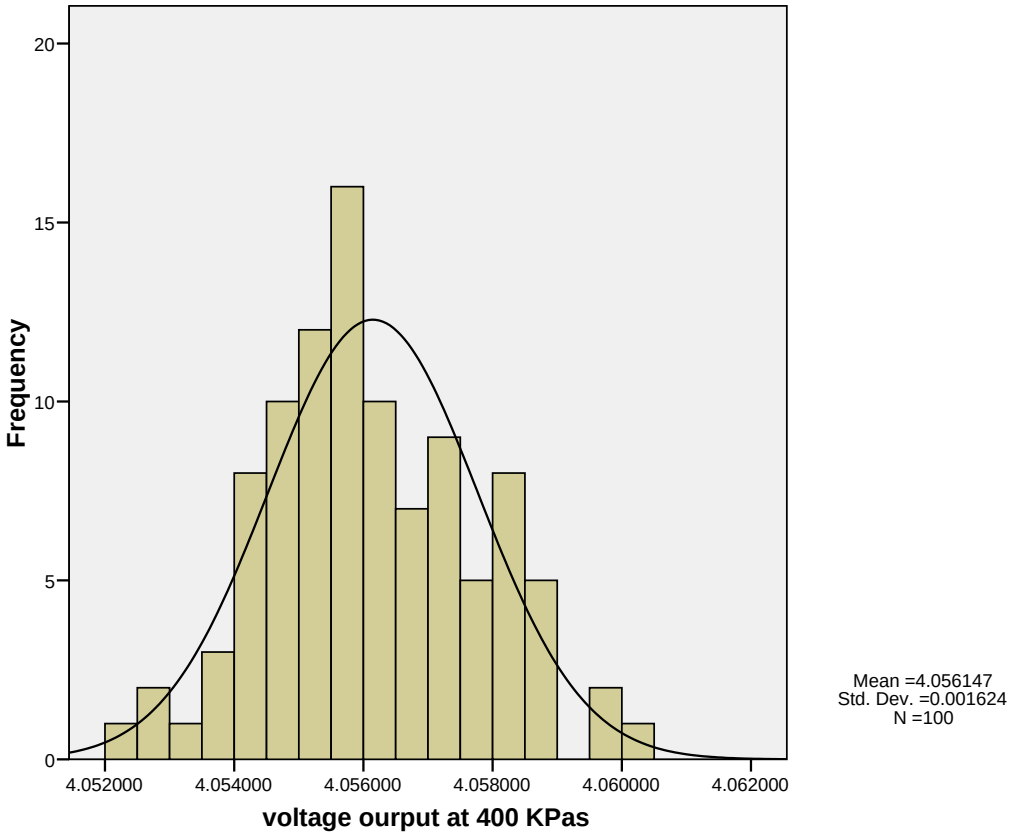
5.050000
5.052000
5.054000
5.056000
5.058000
voltage output at 500 KPas
Mean =5.054753
Std. Dev. =0.001767
N =100


Frequency
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10
5
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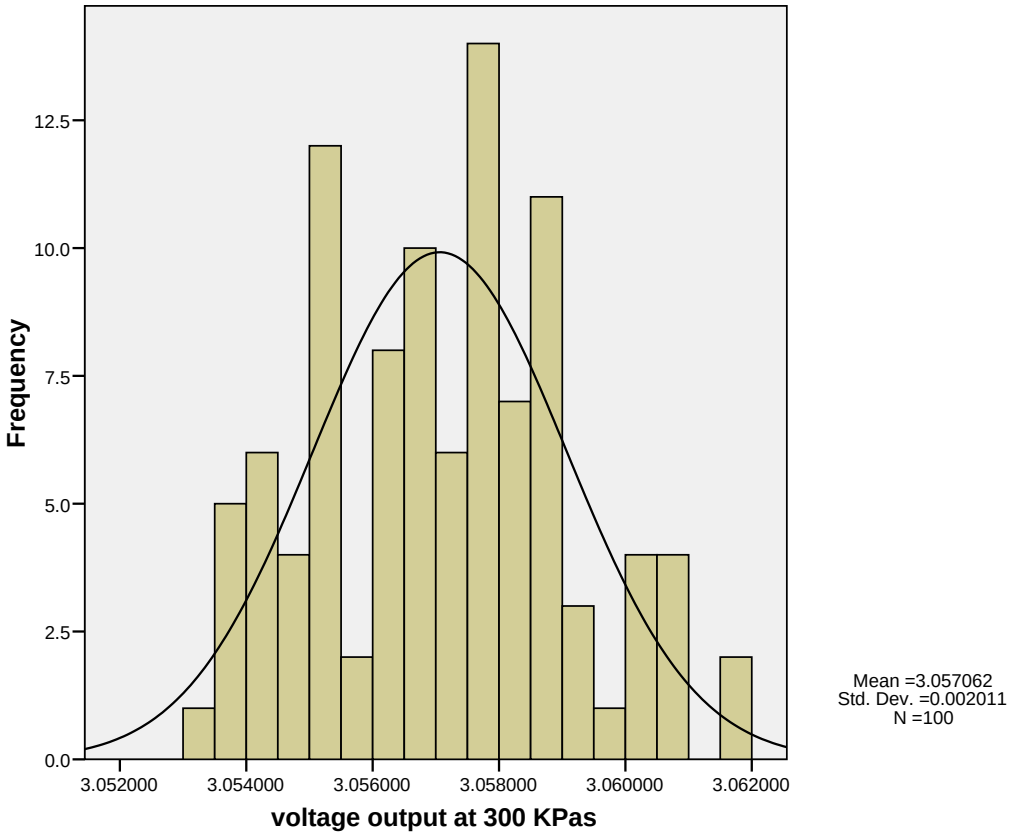
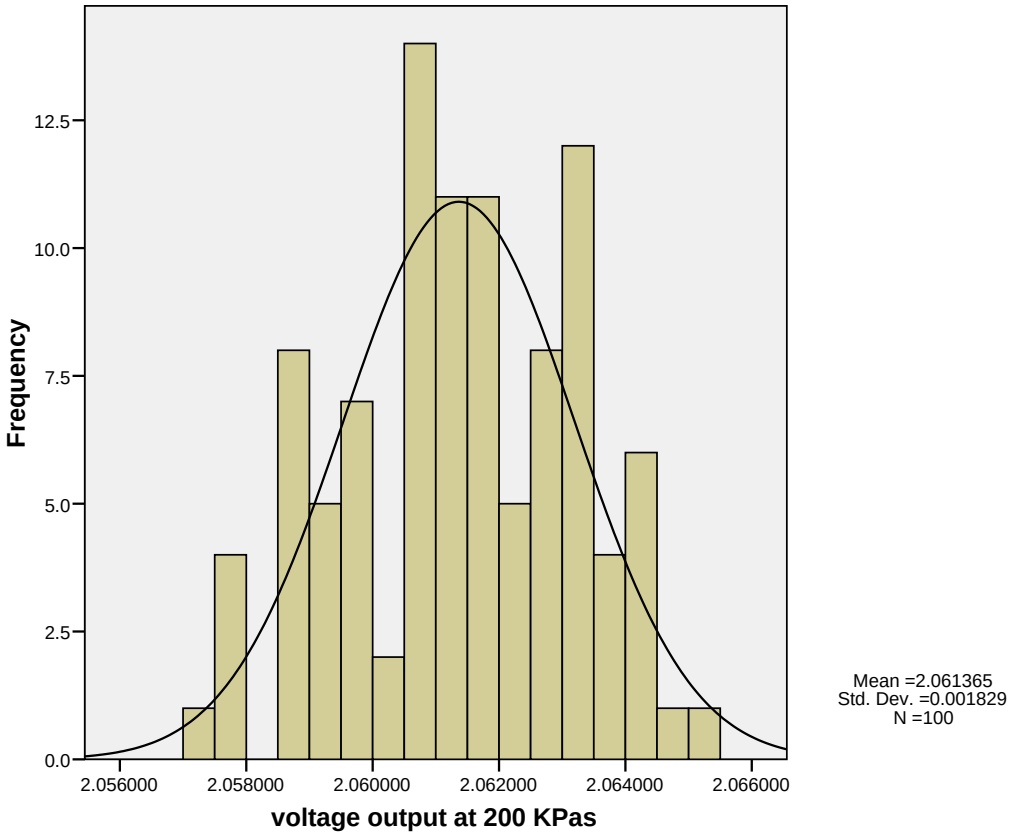
4.060000
4.062000
voltage ourput at 400 KPas
Mean =4.056147
Std. Dev. =0.001624
N =100


Frequency
12.5
10.0
7.5
5.0
2.5
0.0
3.052000
3.054000
3.056000
3.058000
3.060000
3.062000
voltage output at 300 KPas
Mean =3.057062
Std. Dev. =0.002011
N =100


Frequency
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10.0
7.5
5.0
2.5
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2.056000
2.058000
2.060000
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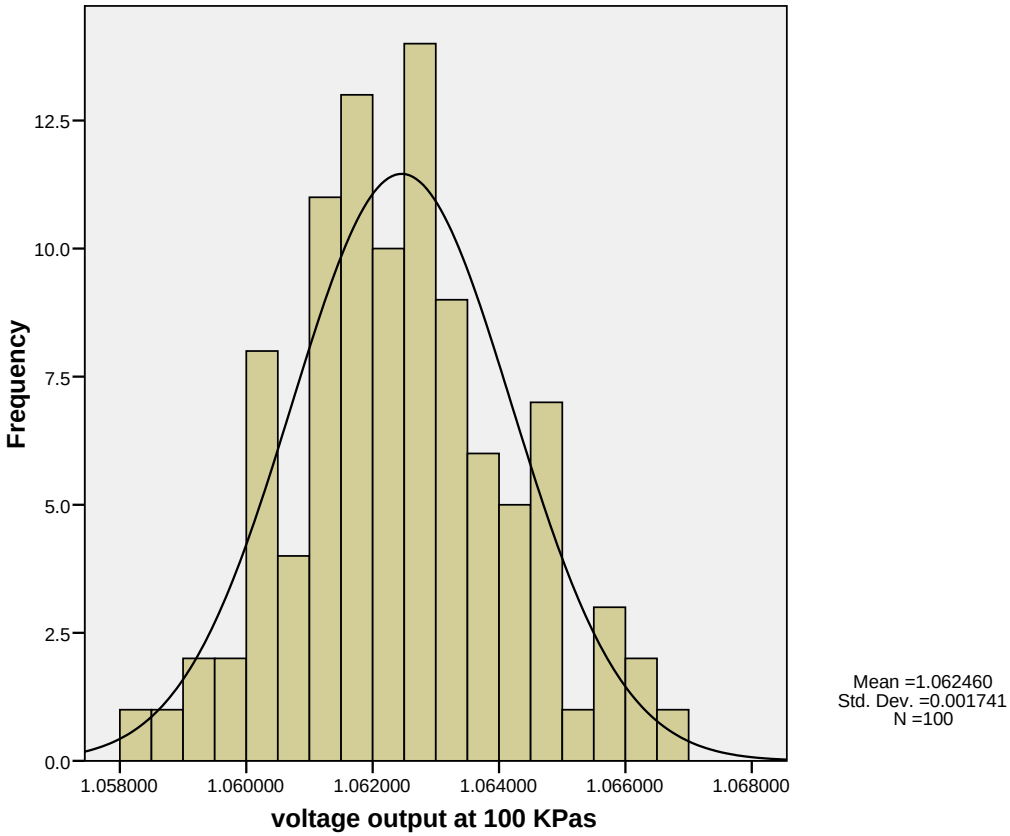
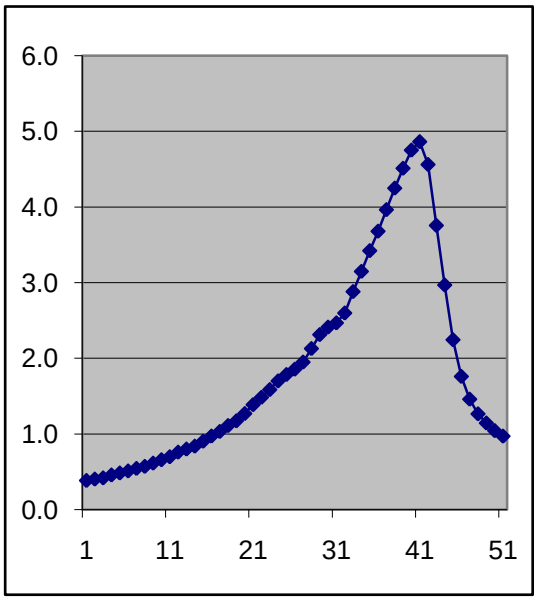
2.064000
2.066000
voltage output at 200 KPas
Mean =2.061365
Std. Dev. =0.001829
N =100


Frequency
12.5
10.0
7.5
5.0
2.5
0.0
1.058000
1.060000
1.062000
1.064000
1.066000
1.068000
voltage output at 100 KPas
Mean =1.062460
Std. Dev. =0.001741
N =100

Appendix 2 An example of the raw data from laboratory studies

09:50:45	26/10/2007	0.135803
09:50:45	26/10/2007	0.147154
09:50:45	26/10/2007	0.150869
09:50:45	26/10/2007	0.152107
09:50:45	26/10/2007	0.156035
09:50:45	26/10/2007	0.163665
09:50:45	26/10/2007	0.164703
09:50:45	26/10/2007	0.170063
09:50:45	26/10/2007	0.177906
09:50:45	26/10/2007	0.175023
09:50:45	26/10/2007	0.191946
09:50:45	26/10/2007	0.193385
09:50:45	26/10/2007	0.189670
09:50:45	26/10/2007	0.220628
09:50:45	26/10/2007	0.213617
09:50:45	26/10/2007	0.213611
09:50:45	26/10/2007	0.233224
09:50:45	26/10/2007	0.234049
09:50:45	26/10/2007	0.240647
09:50:45	26/10/2007	0.262737
09:50:45	26/10/2007	0.259016
09:50:45	26/10/2007	0.282757
09:50:45	26/10/2007	0.301531
09:50:45	26/10/2007	0.297816
09:50:45	26/10/2007	0.329806
09:50:45	26/10/2007	0.346737
09:50:45	26/10/2007	0.362835
09:50:45	26/10/2007	0.382029
09:50:45	26/10/2007	0.400597
09:50:45	26/10/2007	0.416283
09:50:45	26/10/2007	0.454780
09:50:46	26/10/2007	0.481198
09:50:46	26/10/2007	0.508022
09:50:46	26/10/2007	0.541456
09:50:46	26/10/2007	0.568293
09:50:46	26/10/2007	0.611428
09:50:46	26/10/2007	0.656111
09:50:46	26/10/2007	0.695634
09:50:46	26/10/2007	0.756408
09:50:46	26/10/2007	0.797692
09:50:46	26/10/2007	0.835764

09:50:46	26/10/2007	0.900673
09:50:46	26/10/2007	0.969406
09:50:46	26/10/2007	1.029768
09:50:46	26/10/2007	1.107995
09:50:46	26/10/2007	1.170730
09:50:46	26/10/2007	1.267016
09:50:46	26/10/2007	1.384244
09:50:46	26/10/2007	1.481452
09:50:46	26/10/2007	1.583717
09:50:46	26/10/2007	1.698159
09:50:46	26/10/2007	1.783080
09:50:46	26/10/2007	1.853052
09:50:46	26/10/2007	1.947784
09:50:46	26/10/2007	2.126715
09:50:46	26/10/2007	2.310921
09:50:46	26/10/2007	2.410187
09:50:46	26/10/2007	2.466228
09:50:46	26/10/2007	2.596348
09:50:46	26/10/2007	2.879827
09:50:46	26/10/2007	3.146995
09:50:46	26/10/2007	3.420864
09:50:46	26/10/2007	3.678442
09:50:46	26/10/2007	3.962946
09:50:46	26/10/2007	4.247863
09:50:46	26/10/2007	4.510484
09:50:46	26/10/2007	4.750003
09:50:46	26/10/2007	4.862278
09:50:46	26/10/2007	4.560643
09:50:46	26/10/2007	3.755011
09:50:46	26/10/2007	2.967026
09:50:46	26/10/2007	2.243020
09:50:46	26/10/2007	1.757804
09:50:46	26/10/2007	1.457195
09:50:46	26/10/2007	1.262882
09:50:46	26/10/2007	1.142152
09:50:46	26/10/2007	1.041429
09:50:46	26/10/2007	0.968477
09:50:46	26/10/2007	0.928226
09:50:46	26/10/2007	0.883859
09:50:46	26/10/2007	0.848251
09:50:46	26/10/2007	0.826070
09:50:46	26/10/2007	0.796041
09:50:46	26/10/2007	0.788921
09:50:46	26/10/2007	0.772403
09:50:46	26/10/2007	0.742477



Appendix 3 SPSS exploration of differences in the perforations study

```
EXAMINE
  VARIABLES=presKPa BY nopreferation
  /PLOT BOXPLOT NPPLOT
  /COMPARE GROUP
  /STATISTICS DESCRIPTIVES
  /CINTERVAL 95
  /MISSING LISTWISE
  /NOTOTAL.
```

Explore

```
[DataSet2] E:\My Documents\research project\Lab study\11b combined
perforations with similar discs\raw data.sav
```

nopreferation

Case Processing Summary

		Cases					
		Valid		Missing		Total	
	nopreferation	N	Percent	N	Percent	N	Percent
Pressure in KPas	Number	5	100.0%	0	.0%	5	100.0%
	Distance	5	100.0%	0	.0%	5	100.0%
	Size	5	100.0%	0	.0%	5	100.0%

Descriptives

	nopreferation			Statistic	Std. Error
Pressure in KPas	Number	Mean		232.20	4.684
		95% Confidence Interval for Mean	Lower Bound	219.20	
			Upper Bound	245.20	
		5% Trimmed Mean		232.39	
		Median		234.00	
		Variance		109.700	
		Std. Deviation		10.474	
		Minimum		216	
		Maximum		245	
		Range		29	
		Interquartile Range		17	
		Skewness		-.772	.913
		Kurtosis		1.950	2.000
	Distance	Mean		233.80	3.397
		95% Confidence Interval for Mean	Lower Bound	224.37	
			Upper Bound	243.23	
		5% Trimmed Mean		233.61	
		Median		233.00	
		Variance		57.700	
		Std. Deviation		7.596	
		Minimum		225	
		Maximum		246	
		Range		21	
		Interquartile Range		11	
		Skewness		1.072	.913
		Kurtosis		2.573	2.000
	Size	Mean		252.00	5.060
		95% Confidence Interval for Mean	Lower Bound	237.95	
			Upper Bound	266.05	
		5% Trimmed Mean		252.00	
		Median		253.00	
		Variance		128.000	
		Std. Deviation		11.314	
		Minimum		237	
		Maximum		267	
		Range		30	
		Interquartile Range		21	
		Skewness		-.026	.913
		Kurtosis		-.129	2.000

Tests of Normality

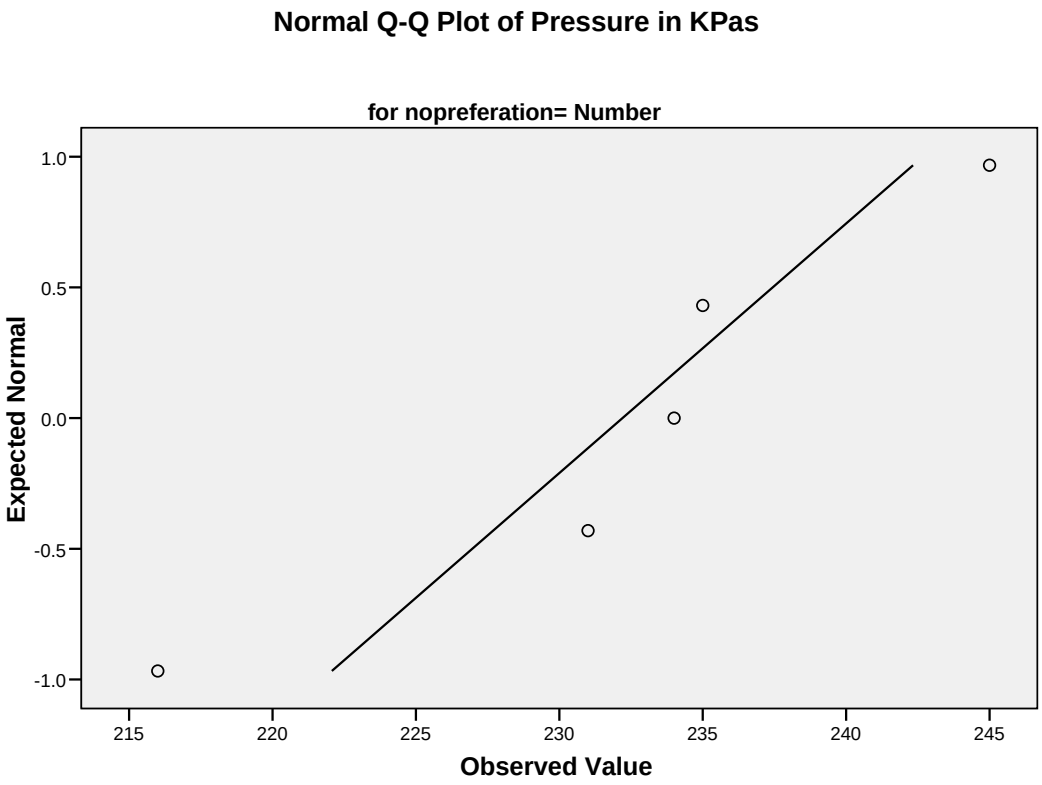
		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	nopreferation	Statistic	df	Sig.	Statistic	df	Sig.
Pressure in KPas	Number	.254	5	.200*	.934	5	.621
	Distance	.342	5	.057	.874	5	.281
	Size	.135	5	.200*	.997	5	.998

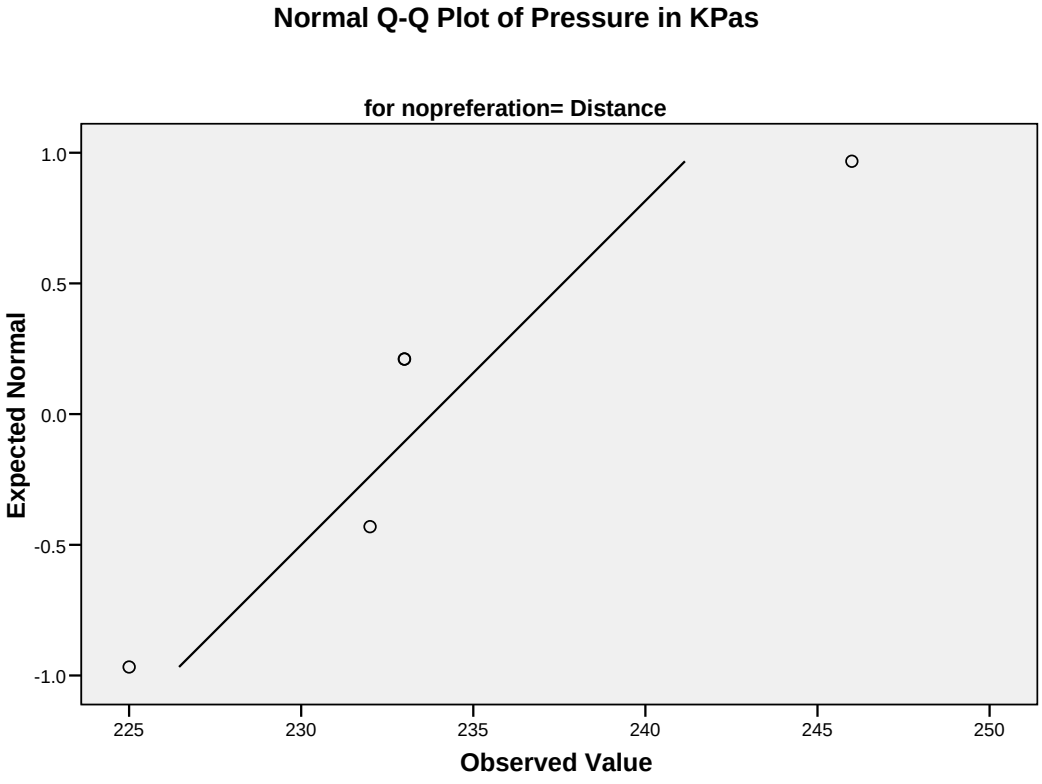
*. This is a lower bound of the true significance.

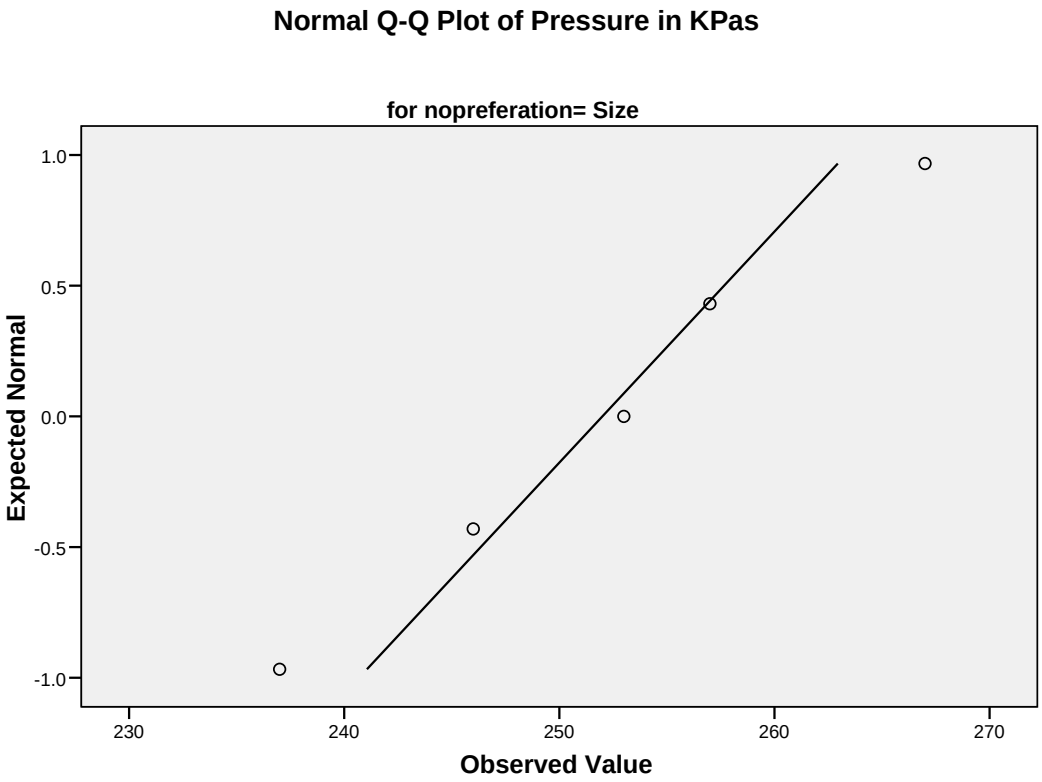
a. Lilliefors Significance Correction

Pressure in KPa

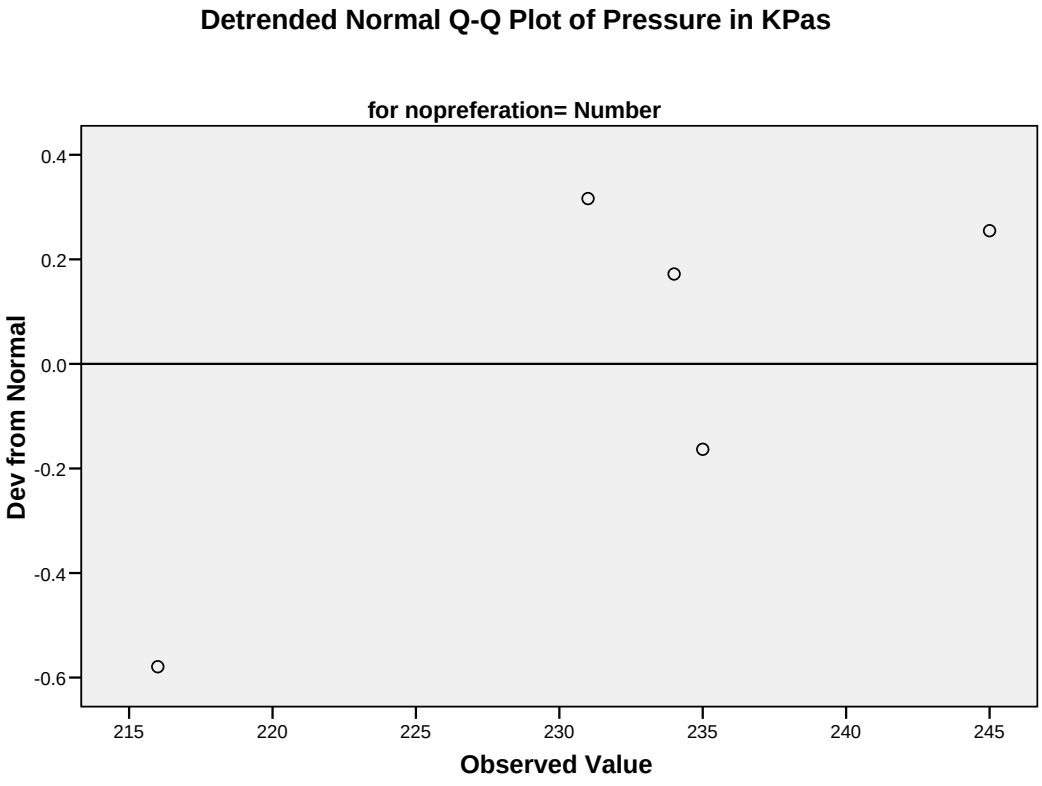
Normal Q-Q Plots



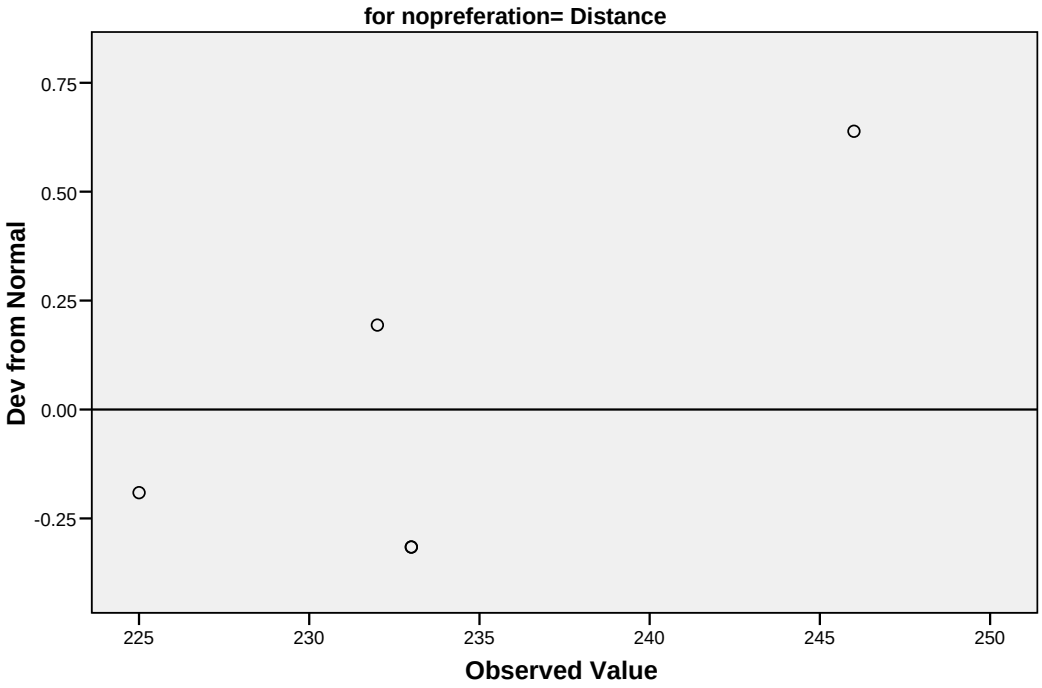




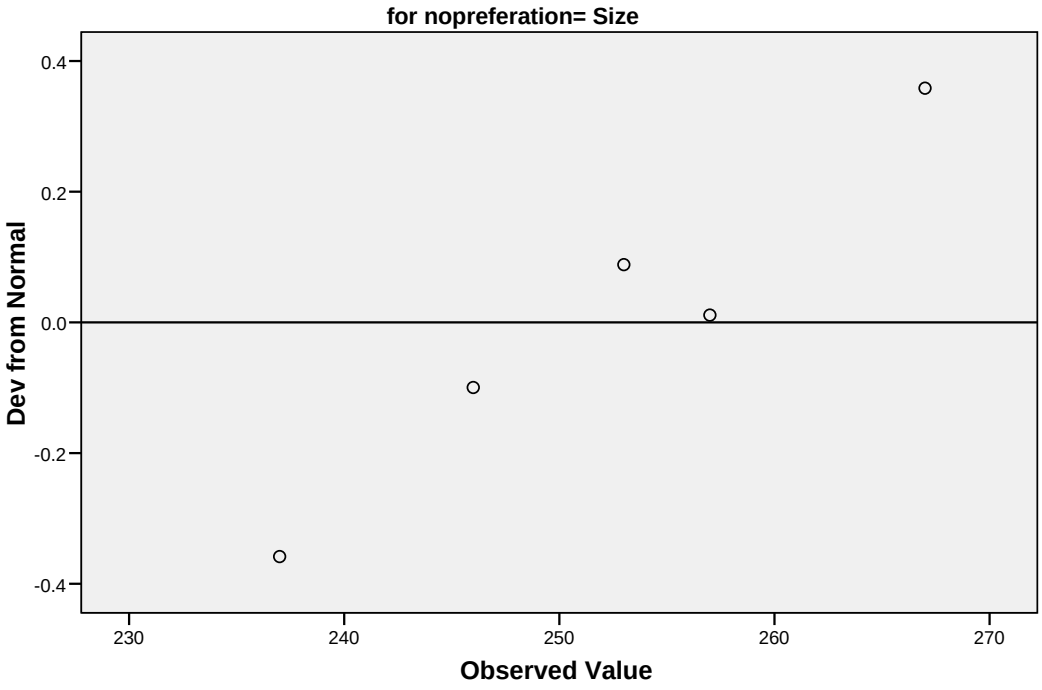
Detrended Normal Q-Q Plots

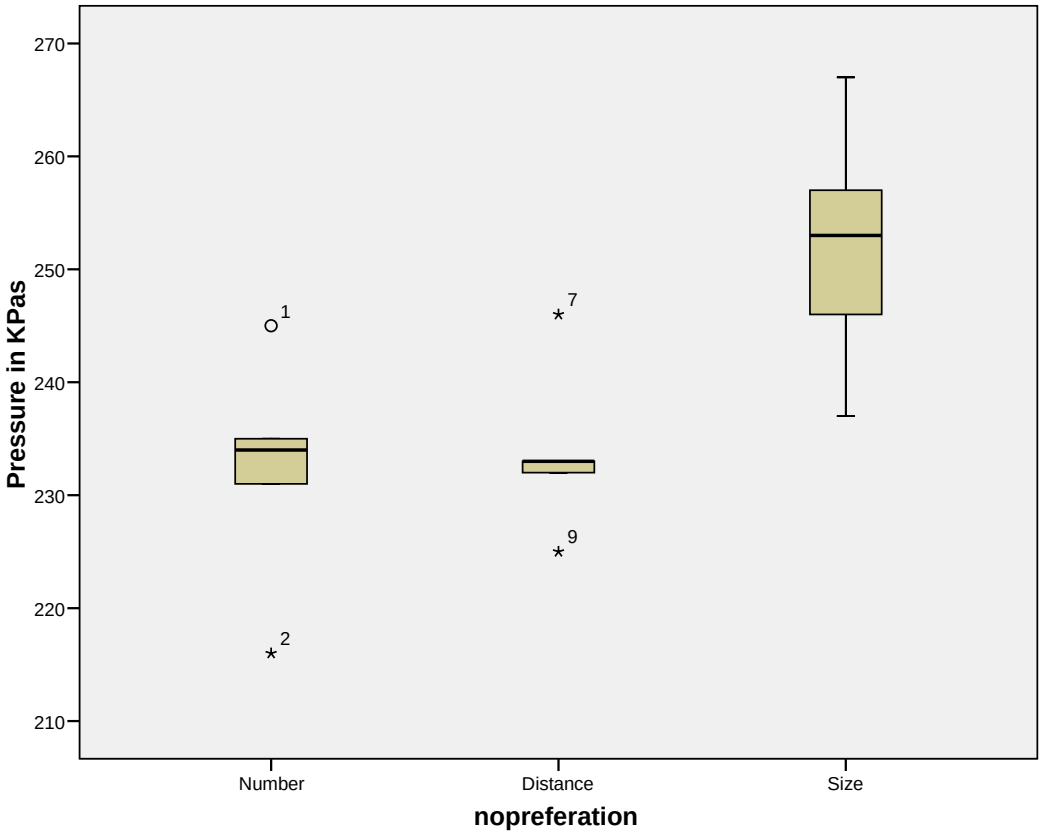


Detrended Normal Q-Q Plot of Pressure in KPas



Detrended Normal Q-Q Plot of Pressure in KPas






```
ONEWAY
  presKPa BY nopreferation
  /STATISTICS DESCRIPTIVES HOMOGENEITY
  /MISSING ANALYSIS
  /POSTHOC = BONFERRONI ALPHA(.05).
```

Oneway

```
[DataSet2] E:\My Documents\research project\Lab study\11b combined
perforations with similar discs\raw data.sav
```

Descriptives

Pressure in KPas

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
Number	5	232.20	10.474	4.684	219.20	245.20	216	245
Distance	5	233.80	7.596	3.397	224.37	243.23	225	246
Size	5	252.00	11.314	5.060	237.95	266.05	237	267
Total	15	239.33	13.069	3.375	232.10	246.57	216	267

Test of Homogeneity of Variances

Pressure in KPas

Levene Statistic	df1	df2	Sig.
.402	2	12	.678

ANOVA

Pressure in KPas

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1209.733	2	604.867	6.143	.015
Within Groups	1181.600	12	98.467		
Total	2391.333	14			

Post hoc tests

Multiple Comparisons

Dependent Variable: Pressure in KPas

Bonferroni

(I) nopreferation	(J) nopreferation	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Number	Distance	-1.600	6.276	1.000	-19.04	15.84
	Size	-19.800*	6.276	.025	-37.24	-2.36
Distance	Number	1.600	6.276	1.000	-15.84	19.04
	Size	-18.200*	6.276	.040	-35.64	-.76
Size	Number	19.800*	6.276	.025	2.36	37.24
	Distance	18.200*	6.276	.040	.76	35.64

*. The mean difference is significant at the .05 level.

Appendix 4 t-test of differences in the perforation study

```
EXAMINE
  VARIABLES=VAR00004 BY oneprefat10mm
  /PLOT BOXPLOT NPPLOT
  /COMPARE GROUP
  /STATISTICS DESCRIPTIVES
  /CINTERVAL 95
  /MISSING LISTWISE
  /NOTOTAL.
```

Explore

[DataSet2] E:\My Documents\research project\Lab study\11b combined perforations with similar discs\raw data.sav

Single perforation at 10mm

Case Processing Summary

		Cases					
		Valid		Missing		Total	
	Single perforation at 10mm	N	Percent	N	Percent	N	Percent
Pressure in KPas	from number study	5	100.0%	0	.0%	5	100.0%
	from size study	5	100.0%	0	.0%	5	100.0%

Descriptives

	Single perforation			Statistic	Std. Error
Pressure in KPas	from number study	Mean		174.2000	6.19193
		95% Confidence Interval for Mean	Lower Bound	157.0084	
			Upper Bound	191.3916	
		5% Trimmed Mean		174.2222	
		Median		176.0000	
		Variance		191.700	
		Std. Deviation		13.84558	
		Minimum		159.00	
		Maximum		189.00	
		Range		30.00	
		Interquartile Range		27.50	
		Skewness		-.145	.913
		Kurtosis		-2.860	2.000
	from size study	Mean		180.4000	6.25780
		95% Confidence Interval for Mean	Lower Bound	163.0256	
			Upper Bound	197.7744	
		5% Trimmed Mean		180.1667	
		Median		183.0000	
		Variance		195.800	
		Std. Deviation		13.99286	
		Minimum		166.00	
		Maximum		199.00	
		Range		33.00	
		Interquartile Range		26.50	
		Skewness		.205	.913
		Kurtosis		-1.581	2.000

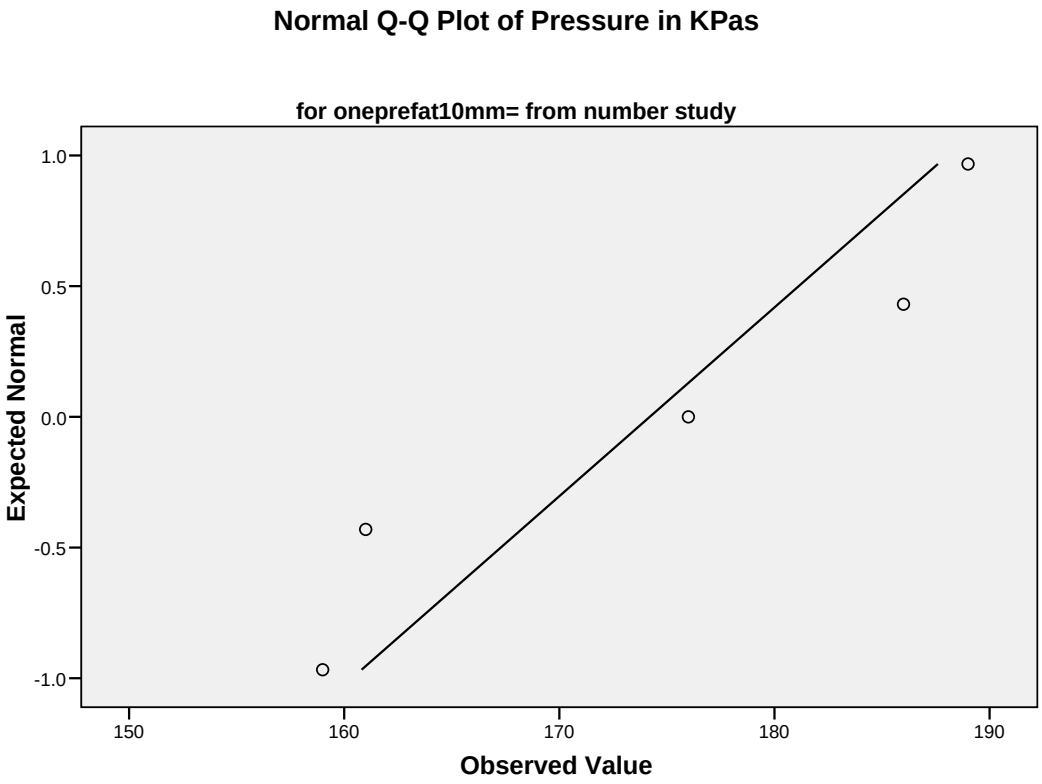
Tests of Normality

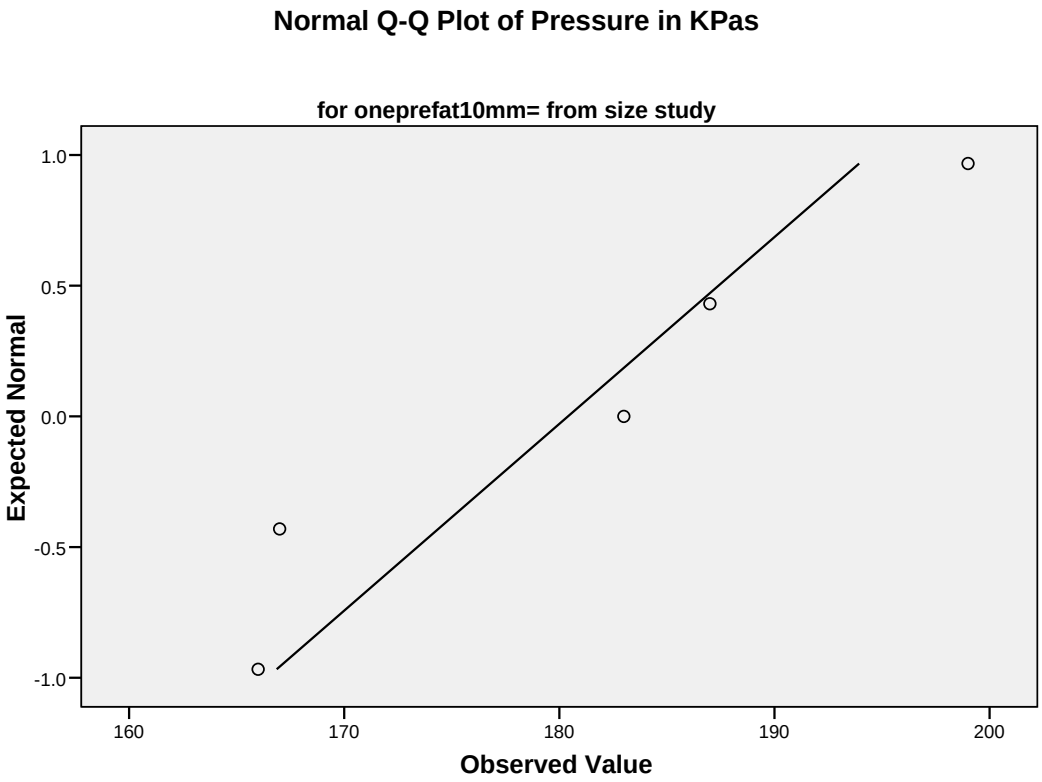
	Single perforation at 10mm	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
Pressure in KPas	from number study	.230	5	.200*	.880	5	.308
	from size study	.231	5	.200*	.914	5	.494

*. This is a lower bound of the true significance.

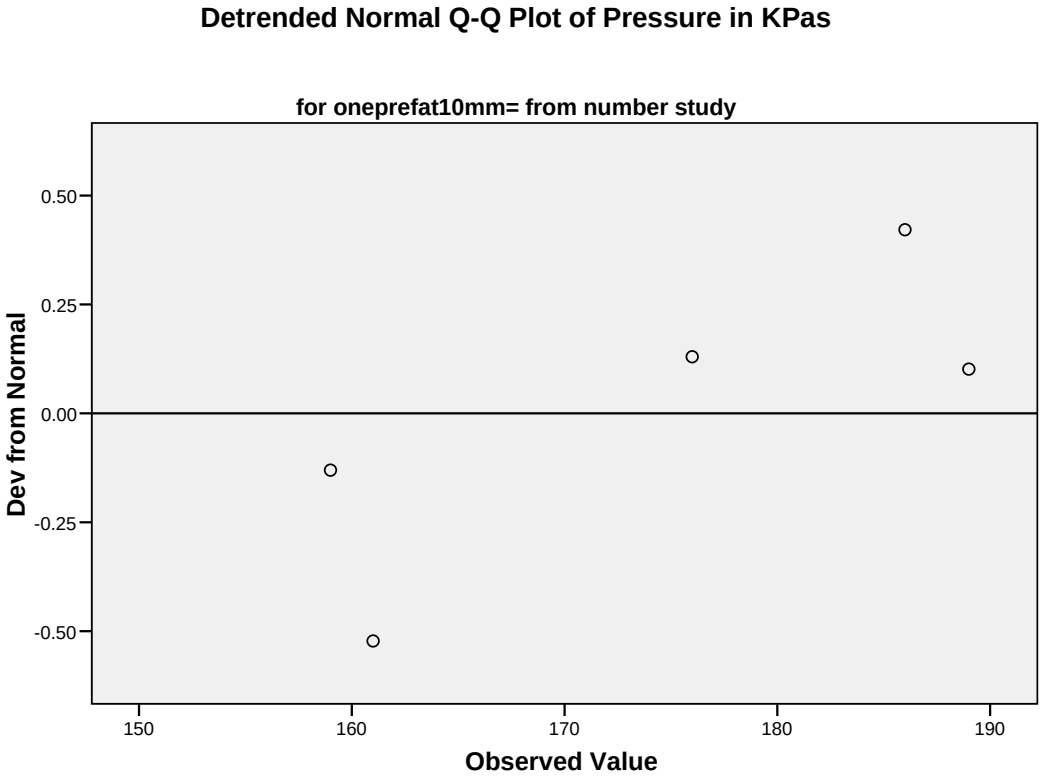
a. Lilliefors Significance Correction

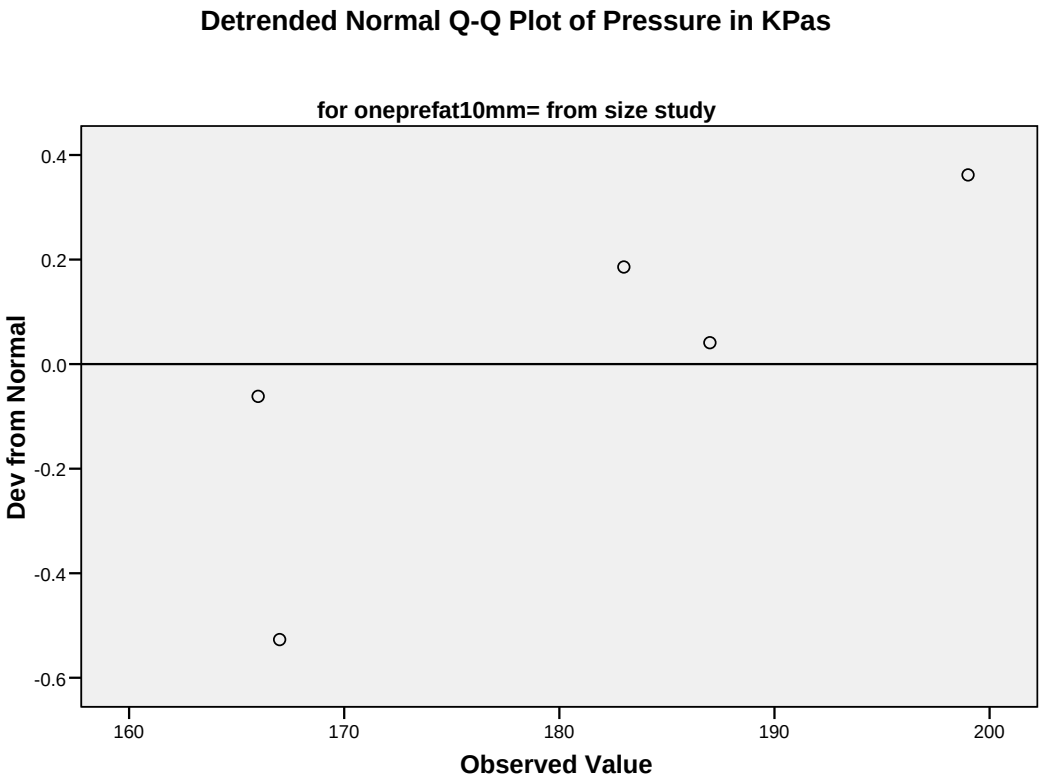
Pressure in KPa
Normal Q-Q Plots

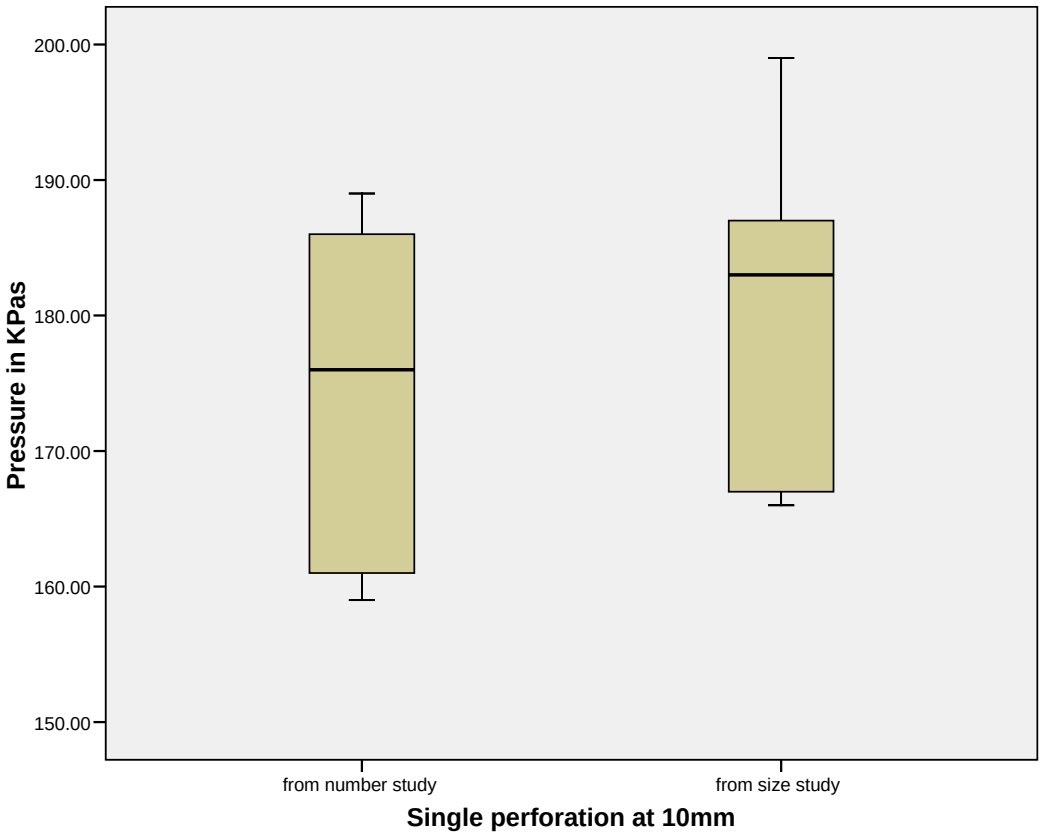




Detrended Normal Q-Q Plots




Detrended Normal Q-Q Plot of Pressure in KPas
for oneprefat10mm= from size study
Dev from Normal
0.4
0.2
0.0
-0.2
-0.4
-0.6
160
170
180
190
200
Observed Value


Pressure in KPas
200.00
190.00
180.00
170.00
160.00
150.00
from number study
from size study
Single perforation at 10mm

```
T-TEST
  GROUPS = oneprefat10mm(1 2)
  /MISSING = ANALYSIS
  /VARIABLES = VAR00004
  /CRITERIA = CI(.95) .
[DataSet2] E:\My Documents\research project\Lab study\11b combined
perforations with similar discs\raw data.sav
```

Group Statistics

	Single perforation at 10mm	N	Mean	Std. Deviation	Std. Error Mean
Pressure in KPas	from number study	5	174.2000	13.84558	6.19193
	from size study	5	180.4000	13.99286	6.25780

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Pressure in KPas	Equal variances assumed	.004	.951	-.704	8	.501	-6.20000	8.80341	-26.50070	14.10070
	Equal variances not assumed			-.704	7.999	.501	-6.20000	8.80341	-26.50109	14.10109

Appendix 5 Pairwise table velocity and category

```
glm pressure by velocity category
 /emmeans = tables(velocity*category)compare(velocity)
 /emmeans = tables(velocity*category)compare(category).
```

General Linear Model

```
[DataSet1] E:\My Documents\research project\Lab study\14.viscosity
studies\raw data basic viscosity study.sav
```

Between-Subjects Factors

		Value Label	N
Velocity of approximation mm/minute	45		15
	60		15
	75		15
	90		15
	120		15
	150		15
	180		15
Category of impression material	1	Light bodied fast set Express 3M	35
	2	Medium bodied regular set Express 3M	35
	3	Light bodied regular set Express 3M	35

Tests of Between-Subjects Effects

Dependent Variable: Pressure in KPas

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	2042671.714[a]	20	102133.586	435.069	.000
Intercept	18506883.1	1	18506883.09	78835.763	.000
Velocity	1838359.848	6	306393.308	1305.177	.000
Category	156637.086	2	78318.543	333.622	.000
Velocity * Category	47674.781	12	3972.898	16.924	.000
Error	19719.200	84	234.752		
Total	20569274.0	105			
Corrected Total	2062390.914	104			

a. R Squared = .990 (Adjusted R Squared = .988)

Estimated Marginal Means
1. Velocity of approximation mm/minute * Category of impression material

Estimates

Dependent Variable: Pressure in KPas

Velocity of approximation mm/minute	Category of impression material	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
45	Light bodied fast set Express 3M	239.600	6.852	225.974	253.226
	Medium bodied regular set Express 3M	253.800	6.852	240.174	267.426
	Light bodied regular set Express 3M	218.600	6.852	204.974	232.226
60	Light bodied fast set Express 3M	274.000	6.852	260.374	287.626
	Medium bodied regular set Express 3M	315.200	6.852	301.574	328.826
	Light bodied regular set Express 3M	268.800	6.852	255.174	282.426
75	Light bodied fast set Express 3M	347.200	6.852	333.574	360.826
	Medium bodied regular set Express 3M	381.400	6.852	367.774	395.026
	Light bodied regular set Express 3M	304.000	6.852	290.374	317.626
90	Light bodied fast set Express 3M	424.600	6.852	410.974	438.226
	Medium bodied regular set Express 3M	429.800	6.852	416.174	443.426
	Light bodied regular set Express 3M	362.800	6.852	349.174	376.426
120	Light bodied fast set Express 3M	487.400	6.852	473.774	501.026
	Medium bodied regular set Express 3M	541.200	6.852	527.574	554.826
	Light bodied regular set Express 3M	434.400	6.852	420.774	448.026
150	Light bodied fast set Express 3M	547.000	6.852	533.374	560.626
	Medium bodied regular set Express 3M	620.600	6.852	606.974	634.226
	Light bodied regular set Express 3M	471.400	6.852	457.774	485.026
180	Light bodied fast set Express 3M	624.000	6.852	610.374	637.626
	Medium bodied regular set Express 3M	725.400	6.852	711.774	739.026
	Light bodied regular set Express 3M	545.200	6.852	531.574	558.826

Pairwise Comparisons

Dependent Variable: Pressure in KPas

Category of impression material	(I) Velocity of approximation mm/minute	(J) Velocity of approximation mm/minute	Mean Difference (I-J)	Std. Error	Sig.[a]
Light bodied fast set Express 3M	45	60	-34.400*	9.690	.001
		75	-107.600*	9.690	.000
		90	-185.000*	9.690	.000
		120	-247.800*	9.690	.000
		150	-307.400*	9.690	.000
		180	-384.400*	9.690	.000
	60	45	34.400*	9.690	.001
		75	-73.200*	9.690	.000
		90	-150.600*	9.690	.000
		120	-213.400*	9.690	.000
		150	-273.000*	9.690	.000
		180	-350.000*	9.690	.000
	75	45	107.600*	9.690	.000
		60	73.200*	9.690	.000
		90	-77.400*	9.690	.000
		120	-140.200*	9.690	.000
		150	-199.800*	9.690	.000
		180	-276.800*	9.690	.000
	90	45	185.000*	9.690	.000
		60	150.600*	9.690	.000
		75	77.400*	9.690	.000
		120	-62.800*	9.690	.000
		150	-122.400*	9.690	.000
		180	-199.400*	9.690	.000
	120	45	247.800*	9.690	.000
		60	213.400*	9.690	.000
		75	140.200*	9.690	.000
		90	62.800*	9.690	.000
		150	-59.600*	9.690	.000
		180	-136.600*	9.690	.000
	150	45	307.400*	9.690	.000
		60	273.000*	9.690	.000
		75	199.800*	9.690	.000
		90	122.400*	9.690	.000
		120	59.600*	9.690	.000
		180	-77.000*	9.690	.000
	180	45	384.400*	9.690	.000
		60	350.000*	9.690	.000
		75	276.800*	9.690	.000
		90	199.400*	9.690	.000
		120	136.600*	9.690	.000
		150	77.000*	9.690	.000
Medium bodied regular set Express 3M	45	60	-61.400*	9.690	.000
		75	-127.600*	9.690	.000
		90	-176.000*	9.690	.000
		120	-287.400*	9.690	.000
		150	-366.800*	9.690	.000
		180	-471.600*	9.690	.000

Based on estimated marginal means

continued

Pairwise Comparisons

Dependent Variable: Pressure in KPas

Category of impression material	(I) Velocity of approximation mm/minute	(J) Velocity of approximation mm/minute	Mean Difference (I-J)	Std. Error	Sig.[a]
Medium bodied regular set Express 3M	60	45	61.400*	9.690	.000
		75	-66.200*	9.690	.000
		90	-114.600*	9.690	.000
		120	-226.000*	9.690	.000
		150	-305.400*	9.690	.000
		180	-410.200*	9.690	.000
	75	45	127.600*	9.690	.000
		60	66.200*	9.690	.000
		90	-48.400*	9.690	.000
		120	-159.800*	9.690	.000
		150	-239.200*	9.690	.000
		180	-344.000*	9.690	.000
	90	45	176.000*	9.690	.000
		60	114.600*	9.690	.000
		75	48.400*	9.690	.000
		120	-111.400*	9.690	.000
		150	-190.800*	9.690	.000
		180	-295.600*	9.690	.000
	120	45	287.400*	9.690	.000
		60	226.000*	9.690	.000
		75	159.800*	9.690	.000
		90	111.400*	9.690	.000
		150	-79.400*	9.690	.000
		180	-184.200*	9.690	.000
	150	45	366.800*	9.690	.000
		60	305.400*	9.690	.000
		75	239.200*	9.690	.000
		90	190.800*	9.690	.000
		120	79.400*	9.690	.000
		180	-104.800*	9.690	.000
	180	45	471.600*	9.690	.000
		60	410.200*	9.690	.000
		75	344.000*	9.690	.000
		90	295.600*	9.690	.000
		120	184.200*	9.690	.000
		150	104.800*	9.690	.000
Light bodied regular set Express 3M	45	60	-50.200*	9.690	.000
		75	-85.400*	9.690	.000
		90	-144.200*	9.690	.000
		120	-215.800*	9.690	.000
		150	-252.800*	9.690	.000
		180	-326.600*	9.690	.000
	60	45	50.200*	9.690	.000
		75	-35.200*	9.690	.000
		90	-94.000*	9.690	.000
		120	-165.600*	9.690	.000
		150	-202.600*	9.690	.000
		180	-276.400*	9.690	.000

Based on estimated marginal means

continued

Pairwise Comparisons

Dependent Variable: Pressure in KPas

Category of impression material	(I) Velocity of approximation mm/minute	(J) Velocity of approximation mm/minute	Mean Difference (I-J)	Std. Error	Sig.[a]
Light bodied regular set Express 3M	75	45	85.400*	9.690	.000
		60	35.200*	9.690	.000
		90	-68.800*	9.690	.000
		120	-130.400*	9.690	.000
		150	-167.400*	9.690	.000
		180	-241.200*	9.690	.000
	90	45	144.200*	9.690	.000
		60	94.000*	9.690	.000
		75	58.800*	9.690	.000
		120	-71.600*	9.690	.000
		150	-108.600*	9.690	.000
		180	-182.400*	9.690	.000
	120	45	215.800*	9.690	.000
		60	165.600*	9.690	.000
		75	130.400*	9.690	.000
		90	71.600*	9.690	.000
		150	-37.000*	9.690	.000
		180	-110.800*	9.690	.000
	150	45	252.800*	9.690	.000
		60	202.600*	9.690	.000
		75	167.400*	9.690	.000
		90	108.600*	9.690	.000
		120	37.000*	9.690	.000
		180	-73.800*	9.690	.000
	180	45	326.600*	9.690	.000
		60	276.400*	9.690	.000
		75	241.200*	9.690	.000
		90	182.400*	9.690	.000
		120	110.800*	9.690	.000
		150	73.800*	9.690	.000

Based on estimated marginal means

Univariate Tests

Dependent Variable: Pressure in KPas

Category of impression material		Sum of Squares	df	Mean Square	F	Sig.
Light bodied fast set Express 3M	Contrast	607334.3	6	101222.381	431.188	.000
	Error	19719.200	84	234.752		
Medium bodied regular set Express 3M	Contrast	865387.4	6	144231.229	614.397	.000
	Error	19719.200	84	234.752		
Light bodied regular set Express 3M	Contrast	413313.0	6	68885.495	293.439	.000
	Error	19719.200	84	234.752		

Each F tests the simple effects of Velocity of approximation mm/minute within each level combination of the other effects shown. These tests are based on the linearly independent pairwise comparisons among the estimated marginal means.

2. Velocity of approximation mm/minute * Category of impression material

Estimates

Dependent Variable: Pressure in KPas

Velocity of approximation mm/minute	Category of impression material	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
45	Light bodied fast set Express 3M	239.600	6.852	225.974	253.226
	Medium bodied regular set Express 3M	253.800	6.852	240.174	267.426
	Light bodied regular set Express 3M	218.600	6.852	204.974	232.226
60	Light bodied fast set Express 3M	274.000	6.852	260.374	287.626
	Medium bodied regular set Express 3M	315.200	6.852	301.574	328.826
	Light bodied regular set Express 3M	268.800	6.852	255.174	282.426
75	Light bodied fast set Express 3M	347.200	6.852	333.574	360.826
	Medium bodied regular set Express 3M	381.400	6.852	367.774	395.026
	Light bodied regular set Express 3M	304.000	6.852	290.374	317.626
90	Light bodied fast set Express 3M	424.600	6.852	410.974	438.226
	Medium bodied regular set Express 3M	429.800	6.852	416.174	443.426
	Light bodied regular set Express 3M	362.800	6.852	349.174	376.426
120	Light bodied fast set Express 3M	487.400	6.852	473.774	501.026
	Medium bodied regular set Express 3M	541.200	6.852	527.574	554.826
	Light bodied regular set Express 3M	434.400	6.852	420.774	448.026
150	Light bodied fast set Express 3M	547.000	6.852	533.374	560.626
	Medium bodied regular set Express 3M	620.600	6.852	606.974	634.226
	Light bodied regular set Express 3M	471.400	6.852	457.774	485.026
180	Light bodied fast set Express 3M	624.000	6.852	610.374	637.626
	Medium bodied regular set Express 3M	725.400	6.852	711.774	739.026
	Light bodied regular set Express 3M	545.200	6.852	531.574	558.826

Pairwise Comparisons

Dependent Variable: Pressure in KPas

Velocity of approximation mm/minute	(I) Category of impression material	(J) Category of impression material	Mean Difference (I-J)	Std. Error
45	Light bodied fast set Express 3M	Medium bodied regular set Express 3M	-14.200	9.690
		Light bodied regular set Express 3M	21.000*	9.690
	Medium bodied regular set Express 3M	Light bodied fast set Express 3M	14.200	9.690
		Light bodied regular set Express 3M	35.200*	9.690
	Light bodied regular set Express 3M	Light bodied fast set Express 3M	-21.000*	9.690
		Medium bodied regular set Express 3M	-35.200*	9.690
60	Light bodied fast set Express 3M	Medium bodied regular set Express 3M	-41.200*	9.690
		Light bodied regular set Express 3M	5.200	9.690
	Medium bodied regular set Express 3M	Light bodied fast set Express 3M	41.200*	9.690
		Light bodied regular set Express 3M	46.400*	9.690
	Light bodied regular set Express 3M	Light bodied fast set Express 3M	-5.200	9.690
		Medium bodied regular set Express 3M	-46.400*	9.690
75	Light bodied fast set Express 3M	Medium bodied regular set Express 3M	-34.200*	9.690
		Light bodied regular set Express 3M	43.200*	9.690
	Medium bodied regular set Express 3M	Light bodied fast set Express 3M	34.200*	9.690
		Light bodied regular set Express 3M	77.400*	9.690
	Light bodied regular set Express 3M	Light bodied fast set Express 3M	-43.200*	9.690
		Medium bodied regular set Express 3M	-77.400*	9.690
90	Light bodied fast set Express 3M	Medium bodied regular set Express 3M	-5.200	9.690
		Light bodied regular set Express 3M	61.800*	9.690
	Medium bodied regular set Express 3M	Light bodied fast set Express 3M	5.200	9.690
		Light bodied regular set Express 3M	67.000*	9.690
	Light bodied regular set Express 3M	Light bodied fast set Express 3M	-61.800*	9.690
		Medium bodied regular set Express 3M	-67.000*	9.690
120	Light bodied fast set Express 3M	Medium bodied regular set Express 3M	-53.800*	9.690
		Light bodied regular set Express 3M	53.000*	9.690
	Medium bodied regular set Express 3M	Light bodied fast set Express 3M	53.800*	9.690
		Light bodied regular set Express 3M	106.800*	9.690

Based on estimated marginal means

continued

Pairwise Comparisons

Dependent Variable: Pressure in KPas

Velocity of approximation mm/minute	(I) Category of impression material	(J) Category of impression material	Mean Difference (I-J)	Std. Error
120	Light bodied regular set Express 3M	Light bodied fast set Express 3M	-53.000*	9.690
		Medium bodied regular set Express 3M	-106.800*	9.690
150	Light bodied fast set Express 3M	Medium bodied regular set Express 3M	-73.600*	9.690
		Light bodied regular set Express 3M	75.600*	9.690
	Medium bodied regular set Express 3M	Light bodied fast set Express 3M	73.600*	9.690
		Light bodied regular set Express 3M	149.200*	9.690
	Light bodied regular set Express 3M	Light bodied fast set Express 3M	-75.600*	9.690
		Medium bodied regular set Express 3M	-149.200*	9.690
180	Light bodied fast set Express 3M	Medium bodied regular set Express 3M	-101.400*	9.690
		Light bodied regular set Express 3M	78.800*	9.690
	Medium bodied regular set Express 3M	Light bodied fast set Express 3M	101.400*	9.690
		Light bodied regular set Express 3M	180.200*	9.690
	Light bodied regular set Express 3M	Light bodied fast set Express 3M	-78.800*	9.690
		Medium bodied regular set Express 3M	-180.200*	9.690

Based on estimated marginal means

Univariate Tests

Dependent Variable: Pressure in KPas

Velocity of approximation mm/minute		Sum of Squares	df	Mean Square	F	Sig.
45	Contrast	3136.133	2	1568.067	6.680	.002
	Error	19719.200	84	234.752		
60	Contrast	6462.400	2	3231.200	13.764	.000
	Error	19719.200	84	234.752		
75	Contrast	15044.400	2	7522.200	32.043	.000
	Error	19719.200	84	234.752		
90	Contrast	13892.133	2	6946.067	29.589	.000
	Error	19719.200	84	234.752		
120	Contrast	28516.133	2	14258.067	60.737	.000
	Error	19719.200	84	234.752		
150	Contrast	55654.933	2	27827.467	118.540	.000
	Error	19719.200	84	234.752		
180	Contrast	81605.733	2	40802.867	173.812	.000
	Error	19719.200	84	234.752		

Each F tests the simple effects of Category of impression material within each level combination of the oth effects shown. These tests are based on the linearly independent pairwise comparisons among the estimated marginal means.

Appendix 6 Regression using a log transformation of pressure.

Residual plots:

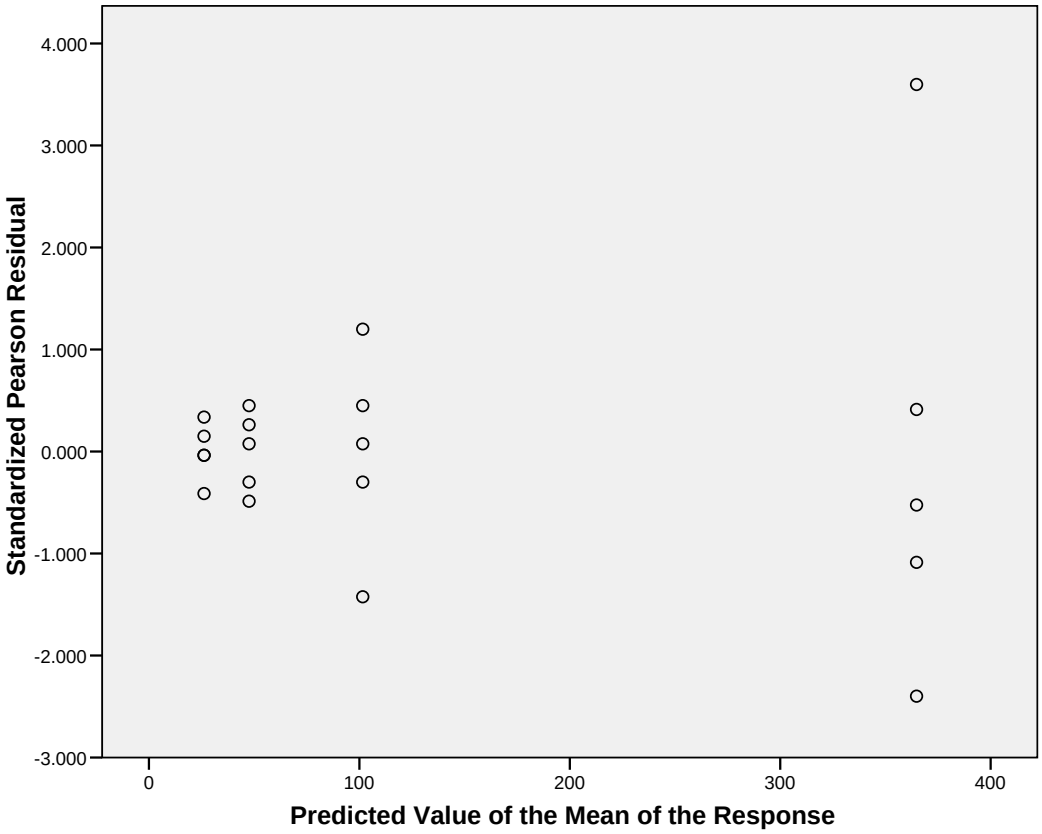


Figure 1 standardized residuals v predicted means

The divergence of the residuals of the raw data for pressure as the pressure increases suggests an increasing variance of the dependant pressure. In these circumstances a logarithmic transformation of the dependant variable pressure can often achieve an equality of variance of the dependant.

Log transformation of the Raw data

Space	Pressure	log of Pressure
0.5	384	5.95
0.5	367	5.91
0.5	359	5.88
0.5	362	5.89
0.5	352	5.86
1	100	4.61
1	102	4.62
1	104	4.64
1	108	4.68
1	94	4.54
1.5	48	3.87
1.5	50	3.91
1.5	49	3.89
1.5	45	3.81
1.5	46	3.83
2	27	3.3
2	26	3.26
2	28	3.33
2	24	3.18
2	26	3.26

Exploration of the natural log transformed data

Shapiro-Wilk				
	Space in mm	**Statistic**	**df**	**Sig.**
Ln of Pressure	.5	.937	5	.642
	1.0	.978	5	.924
	1.5	.950	5	.740
	2.0	.949	5	.727

Table xx Shapiro-Wilk test of normality of the groups

There was no deviation from normality shown to the distribution of the data by the Shapiro-Wilk tests.

Levene			
F	**df1**	**df2**	**Sig.**
.346	3	16	.793

Table xx Levene's test of the error variance of the dependent variable across groups.

Levene's test detected no error variance across the transformed groups. The prerequisites for regression are met following the log transformation of the data.

SPSS output of the Linear regression of transformed data

Model Summary(b)

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.983(a)	.967	.965	.18979

a Predictors: (Constant), Space in mm, b Dependent Variable: logpressure

ANOVA(b)

Model		Sum of Squares	Df	Mean Square	F	Sig.
1	Regression	18.755	1	18.755	520.656	.000(a)
	Residual	.648	18	.036		
	Total	19.403	19			

a Predictors: (Constant), Space in mm, b Dependent Variable: logpressure

Coefficients(a)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	6.577	.104		63.266	.000
	Space in mm	-1.732	.076	-.983	-22.818	.000

a Dependent Variable: logpressure

Appendix 7 Grant application form and protocol

DUNHILL MEDICAL TRUST

(Charity Registration No 294286)

3rd Floor, 16-18 Marshalsea Rd, London SE1 1HL; Tel: 020 7403 3299; Fax: 020 7403 3277

e-mail: admin@dunhillmedical.org.uk

APPLICATION FOR A DUNHILL RESEARCH GRANT

Applicants must read, and comply with the regulations contained in the GRANT MAKING POLICY AND TERMS AND CONDITIONS before completing this form. Completed applications should be sent to the Secretary to the Trustees at the above address. Please note that ALL sections of the application form must be completed. Failure to do so will mean that your application cannot be considered.

Surname of applicant(s)	Title	Forename(s)	Qualifications
Brunton	Prof	Paul Anthony	BChD;MSc; FDS RCS; PhD
Hyde	Mr	Timothy Paul	BChD;DGDP (UK);MGDS RCS.
Blance	Mr	Andrew	BSc MSC

Present Appointment(s)/Role(s) in organisation/charity

Professor of Restorative Dentistry

Name of organisation and official address for correspondence *(inc. postcode, telephone, fax, e-mail address & charity number where applicable)*	Contact details of organisation to administer grant *(if different from 3)*
Prof Paul Brunton Leeds Dental Institute Clarendon Way University of Leeds LEEDS LS2 9LU	Mrs RB Kayman Research Office, Worsley Building, Leeds Dental Institute Clarendon Way LEEDS LS2 9LU

Brief description of aims and objectives of organisation/charity applying for the grant

We are a research-intensive University which strives to create, advance and disseminate knowledge, develop outstanding graduates/scholars and to make a major impact upon global society.

To be world leaders in dental research through excellence in basic and clinical dental science and promotion of the unique Leeds brand.

TITLE OF PROPOSED RESEARCH *(25 words max)*

Randomized controlled clinical trial of impression techniques designed to alleviate the pain of lower dentures in patients with severely resorbed mandibles

ABSTRACT *(150 words max)*

As the mandible resorbes down to basal bone the mental foramen becomes involved in the superior buccal aspect of the denture bearing area[1]. The subsequent crushing of the emerging nerve by a functioning lower denture can cause pain and discomfort. It has been suggested that this and similar conditions may be relieved by the use of differential pressure impressions[2]. An older but not evidence based method of dealing with this and similar problems has been advanced[3]. This research investigates two clinical procedure advocated for dealing with this problem and a control procedure within the structure of a randomized, blind clinical trial.

References:

1. Basker, R. M. & J.C. Davenport. Prosthetic treatment of the edentulous patient. Oxford: Blackwell, 2002. 4th ed. p281.

2. Hyde TP. *Case report: differential pressure impressions for complete dentures.* Eur J Prosthodont Restor Dent. 2003 Mar; 11(1): 5-8.

3. McCord, J. Fraser. Phillip Smith, Nicholas Grey**.** Treatment of edentulous patients. Edinburgh: Churchill Livingstone, 2004. p 63.

NOTE: A full protocol for the proposed research, and a CV for each applicant should be attached to this form

LAY STATEMENT: explanation of the proposed research, the aims of the project and the outcomes envisaged

(150 words max)

Pain and discomfort under a lower denture is common in elderly people. A major cause of this discomfort is the resorbtion of bone in the lower jaw. After bone resorbtion, dentures are supported by the gum over thin jaw bone. In this area of bone under the lower denture a nerve (the mental nerve) emerges from a hole in the bone. The subsequent crushing of the emerging nerve by a functioning lower denture can cause pain and discomfort. The value of this discomfort is such that a patient might not be able to wear a denture leading to social embarrassment and isolation. This research aims to compare, a traditional method of addressing this problem with a method reported by one of our research team and a control.

The aim of the study is to determine which procedure produces the most comfortable denture. We hope and expect to show that the new method will be superior. The results will help dentists make more comfortable dentures for people with this problem.

How does this application fit in with the current priorities for funding of the Dunhill Medical Trust?

(please tick as appropriate)

Care of older people	☐ yes
Disease(s)/Issue(s)of particular relevance to older people	☐ yes
Disabilities	☐ yes
Rehabilitation	☐ yes
None of the above	☐

If NONE, what are the key words which describe the population group(s) and issue(s) you are addressing?

(eg. children, cancer)

……..

10. TOTAL AMOUNT OF FUNDING APPLIED FOR:

£56,429

TIMESCALE FOR THE PROJECT: *Please insert dates below:*

Start……01/09/2006

End……01/03/2009

DATE WHEN THE GRANT WILL BE REQUIRED AND DATE BY WHICH IT WILL BE SPENT. *Please insert dates below:*

NB. You will be monitored on this, therefore the dates given should be realistic. Any subsequent change will require justification.

Start……01/09/2006

End……01/03/2009

OTHER SUPPORT:

(i) Is this research currently supported by any other outside body? NO

If YES, please indicate the organisation(s), amount and timescale of support

(ii) Is this application being submitted elsewhere? NO

If YES, to what organisation(s) and when is a decision expected?

Does this project require the approval of a Research Ethics Committee? YES

If YES, please attach Ethical Approval letter

Ethics approval has been applied for. We anticipate no problems with ethical approval.

Does this project require Home Office licences and certificates under the provision of the Animals (Scientific Procedures) Act 1986? NO

If YES, please state the appropriate Home Office licence no(s)

…….

Please specify the organisation acting as Research Sponsor for this project (as required by the terms of the NHS Research Governance Framework)

University of Leeds

DETAILS OF SUPPORT REQUESTED					
Basic salary (including increments) must be shown separately from on-costs (National Insurance, Superannuation and London Allowance (if applicable). A provision for nationally agreed pay awards during the term of the grant must be included.					
RESEARCH STAFF SALARIES					
Name Mr TP Hyde Basic Salary:	Grade Clinical Academic	1st Year £ xxxx	2nd Year £ xxxx	3rd year £ -	TOTAL £ xxxx
On-costs: NI & Superann London Allowance Pay award provision		xxxx	xxxx	-	xxxx
Total A:		**xxxx**	**xxxx**	**-**	**xxxx**
Name Mr A Blance Basic Salary	Lecturer	xxxx	xxxx	xxxx	xxxx
On-costs: NI & Superann London Allowance Pay award provision		xxxx	xxxx	x	xxxx
Total B:		**xxx**	**xxx**	-	**xxx**
Name Mrs G Dukanovic Basic Salary	Research Dental Nurse	Year 1 £ xxx	Year 2 £ xxx	Year 3 £ -	Total £ xxx

On-costs: NI & Superann London Allowance Pay award provision		xxx	xxx	-	xxx
Total C:		**xxx**	**xxx**	-	**xxx**
Name Dental Nurse (TBA) Basic Salary	Dental Nurse	xxxx	xxxx		xxxx
On-costs: NI & Superann London Allowance Pay award provision		xxx	xxx	-	xxx
Total D:		**xxxx**	**xxxx**	-	**xxxx**
CONSUMABLES		**10,649**	**10,649**	-	**21,298**
MINOR EQUIPMENT		-	-	-	-
GRAND TOTAL		**27,904**	**28,525**		**56,429**

If the application is successful, to whom should the Dunhill Medical Trust cheque be made payable?

UNIVERSITY OF LEEDS

DECLARATION

I have received and read a copy of the Dunhill Medical Trust Grant Making Policy and Terms and Conditions before making this application and I understand and agree that my application is subject to the requirements and conditions contained therein and that in accepting any offer of a grant which is made by the Trust I will be accepting and agreeing to be bound by them. I also understand that no alteration or waiver of those conditions can occur without written approval from the Trust.

I agree that the personal data relating to me shown on this form, or otherwise made known to the Dunhill Medical Trust for the purposes of a grant or grants by it, may be recorded by the Dunhill Medical Trust and used by it for the purposes of evaluating, monitoring and administering any such grant and for reference in connection with it and may be passed by it to individuals and/or organ isations consulted by the Dunhill Medical Trust when assessing applications and monitoring grants and to the Trust's auditors.

Names of Applicant (s)
Signature
Date

Professor P Brunton

I confirm on behalf of my organisation that in signing and supporting this application I am making a declaration in the same terms as the applicant himself as a proposed grant holder and I also confirm that I have the accommodation and facilities in my department necessary for the grant project and that, unless applied for here, the salary of the applicant/principal or investigator is guaranteed during the term of the grant

Name of Organisation and
Signature
Date
Chief Executive/Head of Department

Professor Jennifer Kirkham
Director of Research
Leeds Dental Institute
Worlsey Building, Level 6
Clarendon Way, Leeds LS2 9LU

I confirm on behalf of my organisation that I have read and accept the conditions under which grants are awarded and that the salary details given are correct and include a provision for nationally agreed pay awards.

Name of Finance Officer
Signature
Date
Mrs K Brownridge
University of Leeds, Research Support Unit
3 Cavendish Road
Leeds LS2 9LU

Protocol

Randomized controlled clinical trial of impression techniques designed to alleviate the pain of lower dentures in patients with severely resorbed mandibles

Principle Investigators

Professor Paul Brunton
Leeds Dental Institute
University of Leeds

Mr Paul Hyde
Leeds Dental Institute
University of Leeds

Mr Andrew Blance
Leeds Dental Institute
Biostatistics Unit
University of Leeds

Author Paul Hyde
Leeds Dental Institute
Leeds, UK

Background to the proposal

People who have no natural teeth are said to be 'edentulous'. The percentage of the population who are edentulous increases with age. The 1998 Adult Dental Health Survey of the UK showed that 34% of patients over 64 were edentulous.[1] A Strategic Review[2], commissioned and funded by the Department of Health in December 2005, estimated that 'in 20 years time one fifth of older people will still have no teeth'. Life expectancy is increasing. Furthermore, there is a large generational cohort of the population which is related to the increase in birth rate between the 1940's and the 1960's. That is the 'baby boomers bulge'. When these factors are coupled together it is clear that a significant proportion of older patients will be without natural teeth for many years. In particular, we may expect to see an increase in the number of elderly patients who have been edentulous for 2 or more decades.

There are particular problems providing dentures for patients who have been edentulous for many years. Most of these problems are associated with severe alveolar bone resorption[3]. It is the lower edentulous arch, and so the lower denture, where these problems are more pronounced. The flat mandibular arch causes problems for support, comfort, stability and retention of the lower denture. This research seeks to deal with a major well-defined problem of the severely resorbed mandibular arch. This typically prevents elderly patients from wearing their lower denture.

As the mandible resorbes down to basal bone the mental foramen becomes involved in the superior buccal aspect of the denture bearing area[4]. The subsequent crushing of the emerging nerve by a functioning lower denture can cause pain and discomfort[5]. This research looks at 2 clinical ways of dealing with this problem and a control procedure within the structure of a randomized, blind clinical trial.

According to the WHO[6] definition a person who is edentulous is deemed to have a 'physical impairment'. The problems associated with the resorbed mandible present current and real difficulties for both patients and dentists. Patients who have the additional problems associated with a prominent mental foramen can find that a conventional lower denture is intolerable. This is especially true when trying to eat certain kinds of food and consequently nutritional deficiency is associated with poor fitting and well-fitting-but-painful dentures[7]. It is common for patients to leave out dentures and modify their behaviour so that they do not eat or venture out in public. This withdrawal is considered a 'handicap' (social integration handicap scale 1) within WHO definitions[6].

Aim of the study

The aim of the study is to determine which impression procedure produces the most comfortable denture.

Objectives

The objectives of the study are:

- to provide 3 lower dentures for each research participant, each one identical except for the manner in which the fitting surface has been contoured.
- to allow the research participant to assess each denture.
- to allow the research participant to choose the denture they find the most comfortable.
- to disseminate the study results to General Dental Practitioners

Study design

A randomized, controlled, clinical trial, in which the assessment is 'blind'.

Method

Research participants will be selected from the waiting lists at Leeds Dental Institute.

The selection criteria are detailed on the initial selection form (Appendix 5). The inclusion criteria will be subjects who are able to attend, edentulous in the lower arch, with the mental foramen apparent clinically or radiographically on the denture bearing area of the lower residual alveolar ridge. Exclusion criteria will be subjects who are allergic to acrylic or silicone rubber.

Clinical treatment will be provided by Paul Hyde under the supervision of Prof P. Brunton.

Each research participant will be provided with three lower dentures A B and C. The dentures will be identical except for the fitting surface.

Type A denture will be constructed on a model from a secondary impression made in a spaced, perforated acrylic special tray with a medium bodied silicone impression. This will be the 'control' denture constructed by conventional methods.

Type B denture will be constructed on a duplicate of the Type A model on which the area of the mental foramen has been coated with tin foil to provide a space beneath the finished denture. This basic method is presented by McCord[8].

Type C denture will be constructed on a model from a 'differential pressure' impression. A spaced, perforated acrylic special tray will be used to make a medium bodied silicone impression of the edentulous arch. It is intended to use the same impression used for Type A and B but modified as follows. The silicone in the area of the mental foramen will be removed with a scalpel blade, and the tray perforated in this area. A second wash impression will then be made with a light bodied silicone impression material. The technique has recently been described in a case study by Hyde[9].

Each denture will be marked with the research participants name and a coded number. The coded number will be put on by the dental technician and will encode whether the denture is type A, B or C. Neither the research participant nor the dentist providing the denture will know which type of denture (A B or C) is being provided. The research participant will be given each denture sequentially. The order in which research participants are given the dentures will be decided by random allocation (Latin square).

The research participants will be given each denture for 1 week. After 1 week of wearing a denture the research participant will be asked to assess the denture for comfort, stability and masticatory efficiency using a 4 point Likert scale[10] (see Appendix 3). A Dental Nurse will be recruited and trained to guide the research participants through the assessment procedure. The assessment will be made by a structured interview. Thus the trial will be 'double blind' since the research participant and the person conducting the assessment procedure will not know which denture (A, B or C) is being assessed.

After assessing each denture individually the research participants will be given all 3 dentures for 1 week. After 1 week the research participants will be asked which denture they prefer (see appendix 4).

When the research participant has expressed a preference the marking code will be broken and the preferences recorded in the results.

Sample Size Calculation

For the determination of the required sample size, we make the assumption that the control denture (Type A) will not be chosen (reasonable assumption since the estimated prevalence for such is very low[11]). We then have the situation of estimating the precision of a binary proportion. We hypothesise that 60% will prefer denture Type C and wish to estimate this to within 20% of its anticipated value. An appropriate formula for determining the sample size is thus

$$N = \frac{(1-\pi) z_{1-\alpha/2}^2}{\pi \varepsilon^2}$$

(Ref 12)

Where $z_{1-\alpha/2}$ = 1.96

π = 0.6

ε = 0.2

This yields a required sample size of 65. In order to allow for some tolerance of the estimates and allow for potential dropouts, the suggested sample size is 75.

Expected outcomes

We expect that the innovative method of a 'selective pressure' impression technique previously reported by a member of this team[9], will be of benefit to research participants. We expect the control method of a simple 'normal' impression to be rejected by the research participants, and we expect the older established yet not evidence-based method to be of some small advantage over the control.

For patients who have problems because of a prominent mental foramen, we hope to show which is the best method of taking a lower denture impression. Our aim is to enable all dentists to produce more comfortable lower dentures for these patients.

Timetable and milestones

Ethical approval will be sought for this study and the application procedure has been started. As and when funding has been obtained ethical approval will be forthcoming from Leeds East Research and Ethics Committee.

Once funding is forthcoming and ethics approval is acquired, screening clinics will be arranged to find suitable research participants. Working one day a week it is anticipated that we will need up to 10 weeks to screen sufficient patients.

A power calculation (above) suggests that we will need to include 65 research participants to produce meaningful results. To allow for loss to follow-up it is intended to recruit 75 research participants. It will take 10 visits for each research participant to construct and assess the dentures. In all 750 research-participant visits will be required. We estimate therefore that it will take 20 months to complete the clinical proportion of the project.

Justification of the costs

We believe that this research sits well within the published aims and objectives of the Dunhill Medical Trust. It is peer reviewed clinical research which aims to provide care by improving the rehabilitation of an impairment[6] that is associated with aging. Dissemination of the results of this research will enable General Dental Practitioners to improve the treatment of their patients. This innovative research is also in an 'unfashionable' area for clinical research grants. Even within dentistry, Prosthodontics (false teeth) is a 'Cinderella' area. Research priorities are generally in more high profile areas and yet the issue of comfortable and usable dentures is a major concern for many older people. Good dentures not only improve a person's nutritional status[7] but also their social confidence and appearance.

The grant will pay for the time of

1. Mr Paul Hyde to assess and select research participants and undertake the clinical work,
2. Mr Andrew Blance to perform the statistical analysis,
3. A dental nurse to assist at chairside during the clinical treatment,
4. A research nurse (Mrs G Dukanovic) to assist in the selection of research participants and to take the research participants though the assessment process,

The grant will pay for consumables and laboratory materials including

1. The commercial cost of the production of the additional 2 lower dentures for each research participant. This amounts to £18,298

(Note: An upper denture, if needed, and 1 lower denture for each patient will be paid for by the NHS and NOT charged to Dunhill, this is to conform with the stated Dunhill Medical Trust grant making policy of excluding provision of services usually provided by the NHS)

2. The cost of additional silicone impression materials and other clinical consumables. This amounts to £3.000.

In total the contribution from Dunhill Medical Trust will be £56,429

Informed consent

Patients will have the research protocol explained to them by Paul Hyde. They will be given the information sheet (appendix 1) to take away with them. Paul Hyde will be available for questions. At their next visit, they will be asked if they wish to take part in the project, if they do, they will be asked to sign the consent form (appendix 2).

References

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5. Basker, R. M. & J.C. Davenport. Prosthetic treatment of the edentulous patient. Oxford: Blackwell, 2002. 4th ed. page 281.
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8. McCord, J. Fraser. Treatment of edentulous patients / J. Fraser McCord, Phillip Smith, Nicholas Grey**.** Edinburgh: Churchill Livingstone, 2004. page 63.
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11. McCord, J., McNally L.M., Smith P.W., Grey N.J.A. Does the Nature of the Definitive Impression Material Influence the Outcome of (Mandibular) Complete Dentures? European Journal of Prosthodontics and Restorative Dentistry, (2005); 13, pp105-108.
12. Machin D, Campbell M, Fayers P, Pinol A. Sample size tables for clinical studies (2nd Ed.) Blackwell Science, London (1997), page 132.

Appendix 8 Ethical committee approved paperwork for the trial

Headed note paper

Initial selection form

Subject initials_____ Subject study number_____

Age _____ Sex_____

1. Is the subject available for 10 visits, each visit a week apart? YES___ NO___

2. Is the subject edentulous in the lower jaw? YES___ NO___

If the answer to EITHER question 1 or 2 is NO then the subject is ineligible. If ineligible the subject should be dismissed and question 7 completed. If subject is eligible, continue questions 3-4.

3. Is the mental foramen visible on the denture bearing surface of the lower jaw on an existing radiograph? YES___ NO___

4. Is the mental foramen clinically palpable on the denture bearing area of the lower jaw? YES___ NO___

If the answer to BOTH 3 and 4 is NO then the subject is ineligible. If ineligible the subject should be dismissed and question 7 completed. If subject is eligible, continue questions 5-6.

5. Is the subject allergic to acrylic? YES___ NO___

6. Is the subject allergic to silicone rubber? YES___ NO___

If the answer to EITHER question 5 or 6 is YES then the subject is ineligible. Subject should be dismissed and question 7 completed.

7. IS THE SUBJECT ELIGIBLE FOR ENTRY INTO THIS STUDY? YES___ NO___

Date_____ SIGNITURE OF EXAMINER_____

Headed note paper

Information sheet

A study to determine which impression technique gives the best lower denture

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?
The aim of the study is to determine which procedure produces the most comfortable lower denture.

Why have I been chosen?
We wish to include patients who:
1. need a complete lower denture
2. have a flat lower jaw, which has a pressure point (known as a mental foramen) on the denture bearing area.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect access to or provision of the dental care you receive.

What will happen to me if I take part?
If you decide to participate in this research project we intend to make 3 lower dentures for you. Each lower denture will be made by a slightly different impression technique. When the dentures are made you will be given each denture in turn and asked your opinion of fit, comfort and chewing ability. Then you will be given all 3 lower dentures and asked to tell us which denture you prefer.

What do I have to do?
Allow us to make three lower dentures for you and then tell us which is best for you. We will also ask you to score each denture for comfort, fit and chewing efficiency. Before the

start of the research we will ask you to complete a questionnaire on how your dentures affect you. We will ask you to repeat the questionnaire 3 months after the dentures are fitted.

What are the possible disadvantages taking part?
It is usual to take 6 visits to construct dentures. Although the construction of the dentures will not take any more visits, each visit will take up to 30 minutes longer. Furthermore, after the dentures are made you will be asked to return for 4 visits to tell us about each denture in turn. Reasonable travelling expenses can be claimed for the 4 extra visits. It is usual to have 1 week between visits.

What are the possible benefits of taking part?
You are given a choice of 3 lower dentures and you are able to choose which denture you prefer. You keep all 3 lower dentures and can choose to use the best one. Your participation will help in developing an evidence-based treatment for the benefit of people who have your condition.

Will my taking part in this study be kept confidential?
During the study only your study number will be used to identify you. When the results of the study are published your identity will be kept confidential.

As part of the clinical trial we will be collecting and processing personal information about you including your name and age as well as information about your general and oral health. This information will be used for the purpose of conducting the clinical trial and for the consequent evaluation and research findings.

If you have any queries about the personal data we hold, please contact us at any time.

What will happen to the results of the research study?
The results of this study may be published in a scientific journal. If you would like to discuss the results of the study with someone your dentist will be provided with a copy of the study report. Information about the study can also be obtained by calling Professor Paul Brunton 0113 343 6182 the Principle Investigator for this study.

If you have any questions about this research, Paul Hyde will also be happy to answer your questions when you return for your next appointment. In addition he may be contacted at the address above.

Your participation will help us to improve our treatment of future patients.

If you decide to participate then you will be asked to sign a consent form at your next appointment. Participation is entirely voluntary and if you decline to participate your treatment will not be affected in any way.

Headed note paper

Consent form

Title of Project: Randomized controlled clinical trial of impression techniques designed to alleviate the pain of lower dentures in patients with severely resorbed mandibles

Name of Person taking consent……

Please initial box

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐

3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my clinical care or legal rights being affected. ☐

4. I understand that the information collected during this study be looked at by responsible individuals and their agents or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to this information. ☐

5. I consent to the collection, use and processing of my personal data as described in the information sheet. ☐

6. I have been given a copy of the information sheet and consent form. ☐

7. I consent to my general dental practitioner being informed of my involvement in this study. ☐

8. I agree to take part in the above study. ☐

Name of Patient	Date	Signature
Name of Person taking consent (If different from Dental Examiner)	Date	Signature
Mr Paul Hyde Dental Examiner	Date	Signature

OHIP-14 assessment questionnaire

Please mark the box that most closely applies:

1 Have you had trouble pronouncing any words because of problems with your mouth or dentures?

never	hardly ever.	occasionally	fairly often,	very often.

2 Have you felt that your sense of taste has worsened because of problems with your mouth or dentures?

never	hardly ever.	occasionally	fairly often,	very often.

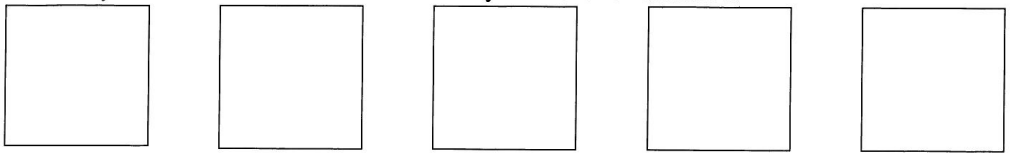
3 Have you had painful aching in your mouth?

never	hardly ever.	occasionally	fairly often,	very often.

4 Have you found it uncomfortable to eat any foods because of problems with your mouth or dentures?

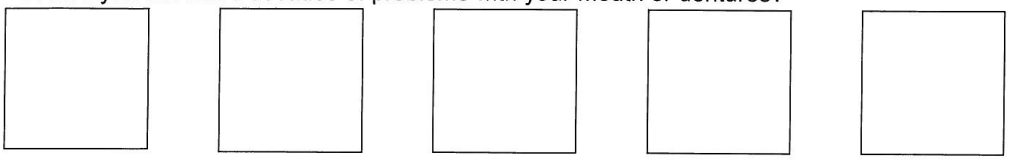
never	hardly ever.	occasionally	fairly often,	very often.

5 Have you been self-conscious because of your mouth or dentures?



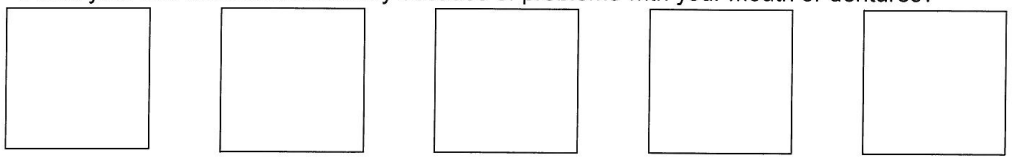
never hardly ever. occasionally fairly often, very often.

6 Have you felt tense because of problems with your mouth or dentures?



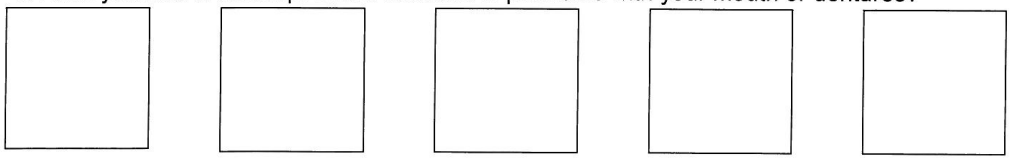
never hardly ever. occasionally fairly often, very often.

7 Has your diet been unsatisfactory because of problems with your mouth or dentures?



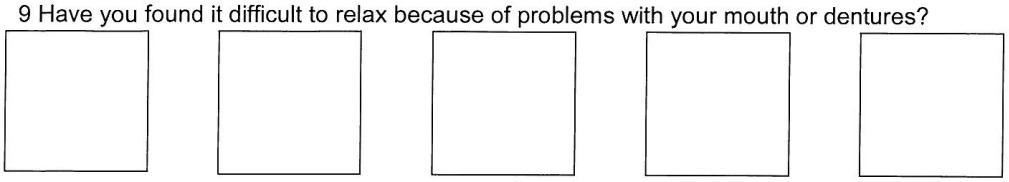
never hardly ever. occasionally fairly often, very often.

8 Have you had to interrupt meals because of problems with your mouth or dentures?



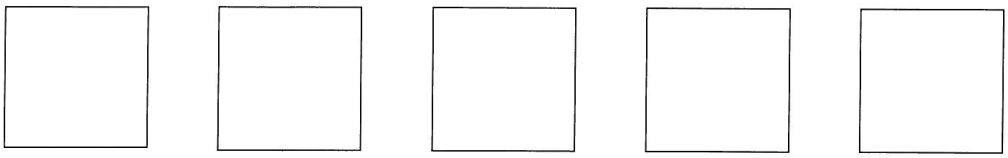
never hardly ever. occasionally fairly often, very often.

9 Have you found it difficult to relax because of problems with your mouth or dentures?



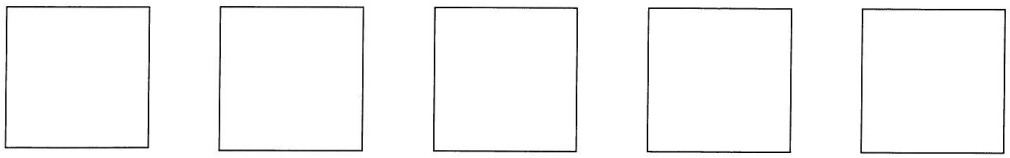
never hardly ever. occasionally fairly often, very often.

10 Have you been a bit embarrassed because of problems with your mouth or dentures?



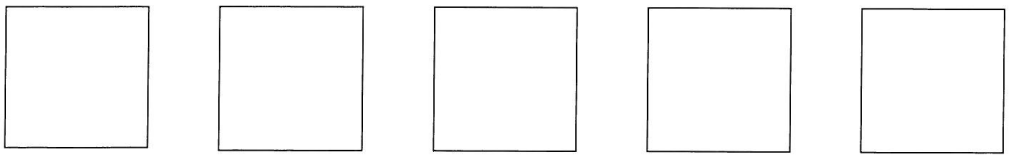
never hardly ever. occasionally fairly often, very often.

11 Have you been a bit irritable with other people because of problems with your mouth or dentures?



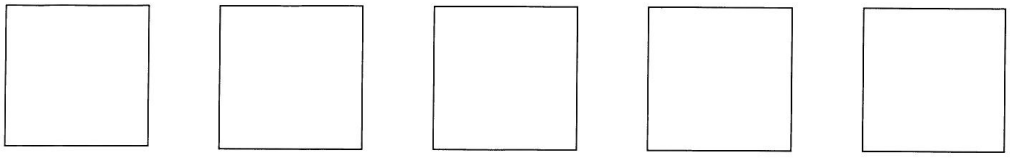
never hardly ever. occasionally fairly often, very often.

12 Have you had difficulty doing your usual jobs because of problems with your mouth or dentures?



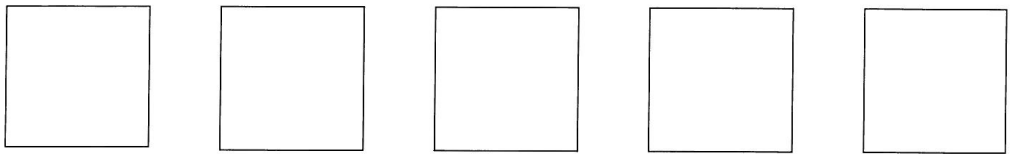
never hardly ever. occasionally fairly often, very often.

13 Have you felt that life in general was less satisfying because of problems with your mouth or dentures?



never hardly ever. occasionally fairly often, very often.

14 Have you been totally unable to function because of problems with your mouth or dentures?



never hardly ever. occasionally fairly often, very often.

Secondary Assessment form for each lower denture

Subject initials_____ Subject study number_____

Denture Code_____ Age _____ Sex_____

Please answer the following questions by ticking the box that you feel best reflects your experience with your lower denture.

Q1. How comfortable did you find the lower denture?

☐ Very Comfortable ☐ Comfortable ☐ Uncomfortable ☐ Very uncomfortable

Q2 How stable did you find the lower denture?

☐ Very Stable ☐ Stable ☐ Unstable ☐ Very Unstable

Q3 How efficient was your denture at chewing your food?

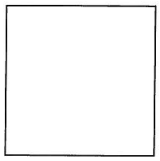
☐ Very efficient ☐ Efficient ☐ Not efficient ☐ Very inefficient

Final Assessment Form

Subject initials_____ Subject study number_____

Age _____ Sex_____

Please write the code of the denture that the patient prefers to use in the box blow.



Appendix 9 Raw data of OHIPs

Traditional ohip scores				Before																					After																			
	Date consent	Pt ID	Initials	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	pt's average	sum before	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	pt's average	sum after	Score	
1	06/12/2006	6/1017(	SS	2	3	4	4	2	4	4	4	4	2	4	2	4	1	3.14	44	0	0	3	4	0	1	1	0	0	0	0	0	1	0	0.71	10	0	Never
2	06/12/2006	6/1132(	CH	2	3	3	3	4	4	3	0	3	3	1	0	4	0	2.36	33	1	2	1	2	2	1	1	0	1	1	0	0	1	0	0.93	13	1	Hardly ever
3	06/12/2006	6/0753(	EM	0	0	4	4	4	4	4	1	.	.	.	.	3	3			0	0	3	3	0	2	3	0	2	0	0	0	0	0	0.93	13	2	Occasionall
4	06/12/2006	5/0609(	MA	4	1	4	4	4	1	1	4	4	3	4	1	1	1	2.64	37	0	3	4	0	1	3	2	2	2	0	2	0	0	0	1.36	19	3	Fairly often
5	29/11/2006	9/0383(	EVD	2	2	4	3	2	2	2	3	2	2	3	2	1	2	2.29	32	2	2	3	3	2	3	3	3	2	3	2	2	2	2	2.43	34	4	Very often
6	29/11/2006	9/0787(	CP	3	2	3	4	4	3	2	4	3	3	2	2	2	1	2.71	38	4	1	4	4	4	4	4	4	4	4	4	4	4	3	3.71	52		
7	22/10/2006	85/0699	RR	1	0	2	2	0	0	2	2	0	.	.	.	1	0			2	2	4	4	1	2	4	2	2	3	1	1	3	0	2.21	31		
8	29/11/2006	7/0204(	NH	4	3	4	4	4	4	3	3	3	3	2	2	2	1	3.00	42	4	3	4	4	4	3	3	3	2	2	2	2	2	3	2.93	41		
9	06/12/2006	3/1238(	EL	2	1	2	4	3	2	4	4	2	4	1	1	4	2	2.57	36	2	1	0	2	2	1	0	2	0	2	0	0	1	0	0.93	13		
10	10/01/2007	6/0917(	RC	2	0	1	4	3	3	0	2	0	3	0	0	0	0	1.29	18	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0.14	2		
11	31/01/2007	2/0894(	RN	2	1	2	2	4	3	4	4	4	4	1	1	2	1	2.50	35	3	3	4	4	4	3	4	4	4	4	3	3	3	3	3.50	49		
12	21/02/2007	6/0787(	SM	3	2	4	4	4	4	4	4	3	3	0	2	3	2	3.00	42	.	.	.	.	.	.	.	.	.	.	.	.	.	.			sent no reply	
13	06/12/2006	7/1444(	JIB	2	0	4	4	0	2	4	4	2	0	0	0	0	0	1.57	22	0	0	4	3	0	2	2	2	2	0	2	0	0	0	1.21	17		
14	21/02/2007	8/0894(	EG	0	0	2	0	0	0	0	2	0	0	0	0	0	0	0.29	4	.	.	.	.	.	.	.	.	.	.	.	.	.	.			deceased during c	
15	28/02/2007	6/1309(	DM	2	0	0	4	4	3	4	3	1	2	2	0	4	0	2.07	29	0	2	2	3	2	2	2	2	1	2	2	1	2	0	1.64	23		
16	07/03/2007	3/1286(	KI	1	0	3	4	4	2	3	4	3	4	2	0	3	1	2.43	34	2	0	0	2	0	0	2	2	0	0	0	0	0	0	0.57	8		
17	21/03/2007	8/1227(	SH	2	0	4	4	3	2	0	2	2	2	2	0	2	0	1.79	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.			2 sent no reply	
18	21/03/2007	6/1461(	GB	3	4	4	4	4	3	4	4	4	3	2	2	4	3	3.43	48	2	3	0	4	2	2	3	3	2	2	2	2	3	0	2.14	30		
19	21/03/2007	6/1418(	MT	3	3	4	4	4	4	4	4	3	4	2	2	4	2	3.36	47	3	0	3	4	4	3	2	3	2	3	0	0	3	0	2.14	30		
20	18/04/2007	9/0366(	LB	0	0	3	4	2	3	3	3	2	2	0	0	0	0	1.57	22	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0.14	2		
21	18/04/2007	96/1682	KBH	2	3	3	4	3	3	3	4	3	3	2	3	3	2	2.93	41	2	3	3	2	2	3	3	4	0	1	3	0	3	1	2.21	31		
22	25/04/2007	6/1341(	CL	0	0	0	2	4	2	0	2	0	2	0	0	0	0	0.86	12	0	0	0	2	2	0	0	2	0	0	0	0	0	0	0.43	6		
23	02/05/2007	7/1576(	FP	0	0	0	4	3	2	2	1	0	2	2	0	3	0	1.36	19	.	.	.	.	.	.	.	.	.	.	.	.	.	.			deceased after re	
24	09/05/2007	6/1358(	SB	4	2	0	4	3	2	3	4	2	3	4	2	3	2	2.71	38	1	0	0	2	0	2	0	0	0	0	1	0	0	0	0.43	6		
25	09/05/2007	6/1341(	ES	2	3	0	2	2	2	2	2	0	2	2	1	2	2	1.71	24	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0.14	2		
26	20/06/2007	4/1011(	JB	2	1	3	4	2	3	4	3	2	2	2	0	3	2	2.36	33	2	1	3	4	4	3	4	3	1	1	1	1	0	3	2.21	31		
27	27/06/2007	6/0707(	ME	0	0	3	4	4	4	4	2	4	4	4	0	2	3	2.71	38	0	0	2	3	2	2	2	2	1	1	2	0	1	0	1.29	18		
28	27/06/2007	6/1426(	JC	0	0	4	4	2	1	4	2	2	3	2	0	3	0	1.93	27	0	0	0	3	0	2	3	2	0	2	0	0	2	0	1.00	14		
29	27/06/2007	7/0568(	JL	3	2	4	4	3	2	2	3	3	3	4	2	3	0	2.71	38	3	2	2	4	2	0	2	2	1	2	1	0	0	0	1.50	21		
30	27/06/2007	7/0221(	PS	2	1	4	4	4	4	4	4	4	4	4	0	2	0	2.93	41	1	0	4	4	2	2	3	4	0	2	1	0	0	0	1.64	23		
31	07/02/2007	94/8736	KMG	1	0	2	3	0	3	2	2	2	2	0	0	1	2	1.43	20	3	1	4	4	4	4	3	3	3	3	2	2	2	3	2.93	41		
32	01/08/2007	7E+05	JB2	4	0	4	3	1	4	0	2	3	2	1	1	1	1	1.93	27	1	0	2	1	1	2	1	0	0	1	0	1	1	0	0.79	11		
33	05/09/2007	5/1129(	JS	0	0	4	4	2	2	4	4	4	2	3	1	4	2	2.57	36	0	0	4	4	.	.	.	.	4	4	4	4	4	4				
34	20/06/2007	4/1011(	JLB	2	1	3	4	2	3	4	3	2	2	2	0	3	2	2.36	33	2	1	3	4	4	3	4	3	1	1	1	1	0	3	2.21	31		
35	26/09/2007	9E+06	ME2	3	0	3	2	0	2	0	2	2	2	0	0	2	0	1.29	18	1	0	1	2	1	2	0	1	1	0	0	0	0	0	0.64	9		
36	26/09/2007	7E+05	DM2	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0.07	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00	0		
37	03/10/2007	81/5978	LS	0	0	3	4	0	3	3	4	0	0	0	0	0	0	1.21	17	0	0	4	4	4	4	4	4	3	4	4	0	4	0	2.79	39		
38	24/10/2007	96/1403	DM3	0	0	4	4	3	4	4	4	4	4	0	2	4	0	2.64	37	.	.	.	.	.	.	.	.	.	.	.	.	.	.			sent no reply	
39	31/10/2007	7/0861(	ES2	0	3	4	4	3	4	4	4	4	3	3	0	4	4	3.14	44	0	2	1	3	0	1	1	0	1	0	1	0	.	.	0.83	10		
40	07/11/2007	4/0480(	MD	0	0	3	4	0	0	1	2	0	0	0	0	0	0	0.71	10	0	0	3	4	4	0	0	4	0	1	0	0	1	0	1.21	17		
41	28/11/2007	7/0416(	LMC	1	1	2	3	4	3	2	2	2	3	3	2	2	1	2.21	31	.	.	.	.	.	.	.	.	.	.	.	.	.	.			pt DNA	
42	19/12/2007	1/1032(	DS	2	0	2	3	3	1	3	1	2	3	1	0	3	3	1.93	27	2	0	4	4	2	1	4	4	3	1	0	0	1	1	1.93	27		
43	19/12/2007	4/1485(	EP	0	0	2	4	1	3	4	2	2	2	2	0	4	0	1.86	26	0	1	3	3	0	2	2	2	1	0	2	1	3	1	1.50	21		
44	23/01/2008	6/0068(	NH2	0	2	3	3	3	3	3	3	2	2	0	0	1	0	1.79	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.			withdrawn partner	
45	23/01/2008	7/0846(	PB	2	0	3	3	1	3	2	1	0	2	0	0	2	0	1.36	19	1	0	2	2	0	0	2	2	0	0	0	0	.	.		9		
46	21/01/2008	99/600	JN	0	0	3	4	1	1	3	3	3	1	1	0	2	0	1.57	22	0	0	3	3	0	0	0	2	0	0	0	0	2	0	0.71	10		
47	30/01/2008	7/0922(	HI	2	0	2	1	4	4	1	2	2	4	3	1	4	2	2.29	32	.	.	.	.	.	.	.	.	.	.	.	.	.	.			pt cancelled	
48	30/01/2008	7/1218(	JWB	0	0	2	2	1	2	0	2	1	0	0	0	0	0	0.71	10	4	2	4	4	4	3	4	4	3	4	4	3	4	4	3.64	51		
49	27/02/2008	7E+05	DB	1	2	2	4	3	3	4	3	1	3	3	2	3	2	2.57	36	.	.	.	.	.	.	.	.	.	.	.	.	.	.			sent no reply	
50	27/02/2008	7E+05	ACH	2	2	3	2	4	4	2	1	4	4	4	2	4	4	3.00	42	0	1	3	4	4	2	2	4	4	2	1	4	1	1	2.57	36		
51	20/02/2008	8E+06	SB2	0	3	4	4	4	2	4	4	2	4	2	0	4	0	2.64	37	0	0	1	2	1	0	1	0	0	0	0	0	0	0	0.36	5		
52	05/03/2008	5/1230(	DM4	3	2	0	2	0	0	2	1	1	1	1	1	2	0	1.14	16	2	0	0	3	1	1	2	1	4	0	0	0	0	0	1.00	14		
53	06/02/2008	7/1372(	TR	3	2	4	4	3	3	3	2	3	3	2	1	2	1	2.57	36	4	4	4	4	4	4	.	4	4	4	4	4	4	4	4.00	52		
54	06/02/2008	7E+05	DT	0	3	0	3	0	0	1	2	1	2	0	0	3	0	1.07	15	.	.	.	.	.	.	.	.	.	.	.	.	.	.			pt in hospital leg a	
55	07/05/2008	8/0079(	GG	0	3	2	2	3	2	0	2	1	2	0	0	2	0	1.36	19	2	0	2	3	4	3	0	2	3	2	0	0	3	0	1.71	24		
56	17/04/2008	4/0542(	CB	2	1	2	3	3	2	0	2	3	4	2	1	2	2	2.07	29	2	1	2	3	2	1	2	1	0	2	1	0	2	0	1.36	19		
57	11/06/2008	3E+05	JMS	2	2	2	4	3	4	4	3	2	3	2	0	2	0	2.36	33	0	0	3	4	1	2	4	4	0	1	0	0	0	0	1.36	19		
58	12/06/2008	8E+06	ID	3	2	4	4	2	0	3	3	2	2	0	0	2	0	1.93	27	2	1	3	2	1	2	3	3	1	2	1	0	1	1	1.64	23		
59	05/06/2008	7E+05	AW	0	0	0	4	4	4	3	2	2	4	2	0	0	0	1.79	25	0	0	3	2	3	0	0	0	2	0	0	0	0	0	0.71	10		
60	10/04/2008	9E+06	LB2	1	0	4	3	.	.	.	.	4	2	1	1	2	1			0	0	2	2	0	1	0	2	4	1	0	0	0	0	0.86	12		
61	18/06/2008	9E+07	KG	0	0	0	2	1	0	0	1	0	0	0	0	0	0	0.29	4	2	1	0	1	0	0	1	1	1	1	0	0	0	1	0.64	9		
62	03/07/2008	1E+07	RM	0	0	2	3	2	2	2	2	2	3	2	0	0	2	1.57	22	3	0	4	4	0	2	1	2	1	1	0	0	0	0	1.29	18		
63	09/07/2008	6E+05	LC	2	4	4	4	4	4	4	2	4	4	2	2	4	2	3.29	46	.	.	.	.	.	.	.	.	.	.	.	.	.	.			pt DNA	
64	24/07/2008	8E+05	PR	3	2	3	4	3	2	3	3	2	3	1	2	2	0	2.36	33	3	1	2	4	2	3	2	3	1	2	0	2	2	1	2.00	28		
65	13/08/2008	8E+05	KR	2	2	2	3	2	2	1	1	1	2	1	0	2	0	1.50	21	1	1	1	2	1	0	0	1	1	1	0	0	1	0	0.71	10		
66	21/08/2008	1E+07	JL2	0	2	2	4	2	0	2	2	0	0	0	0	2	0	1.14	16	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0.14	2		
67	08/10/2008	#####	SH2	1	3	4	4	4	3	4	4	4	4	4	3	4	4	3.57	50	.	.	.	.	.	.	.	.	.	.	.	.	.	.			blank	
68	26/11/2008	1E+05	GP	.	.	.	.	.	.	.	.	.	.	.	.	.	.			.	.	.	.	.	.	.	.	.	.	.	.	.	.			blank	
69	11/12/2008	8E+05	CB2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4.00	56	1	0	1	2	1	2	0	2	0	1	2	1	2	0	1.07	15		
																		pt average per q	pt average total															pt average per q	pt average total		
																	before	2.08	29.18461538														after	1.47	20.2		
																	rounded		42														rounded		42		
																	st dev	0.845427028	11.8359784														st dev	0.992427506	13.69157622		

Appendix 10 Raw data of secondary outcome

Initials	Date consent	Age	Sex	OHIP			1st	Comfort	tabilit	Mast.	2nd	Comfort	tabilit	Mast.	3rd	Comfort	tabilit	Mast.	Date choice	refere	Final OHIP due
SS	06/12/2006	69	F	Y		1	A	3	2	4	B	3	2	3	C	3	2	3	28/02/2007	B	28/05/2007
CH	06/12/2006	64	F	Y		2	C	4	2	4	B	3	3	4	A	2	2	2	01/12/2007	A	01/02/2008
EM	06/12/2006	80	F	Y		3	B	3	2	3	C	2	1	3	A	1	2	3	13/06/2007	A	13/06/2007
MA	06/12/2006	66	M	Y		4	B	4	3	4	C	4	4	4	A	3	3	3	12/09/2007	A	12/12/2007
EVD	29/11/2006	72	M	Y		5	A	3	3	3	B	3	2	3	C	3	3	3	25/04/2007	A	25/07/2007
CP	29/11/2006	54	F	Y		6	A	4	3	2	C	2	1	2	B	3	1	2	02/05/2007	B	02/08/2007
RR	22/10/2006	92	F	Y		7	B	4	3	3	A	3	3	3	C	3	3	3	11/04/2007	C	11/06/2007
NH	29/11/2006	82	F	Y		8	C	2	2	2	B	3	2	3	A	3	3	3	28/02/2007	C	28/05/2007
EL	06/12/2006	81	F	Y		9	C	3	2	4	A	3	2	3	B	3	2	3	13/06/2007	A	13/09/2007
RC	10/01/2007	75	F	Y		10	C	1	1	1	A	1	1	1	B	2	2	2	25/04/2007	A	25/07/2007
RN	31/01/2007	72	F	Y		11	C	3	3	3	A	3	3	3	B	4	3	4	?12/9/7	B	12/12/7?
SM	21/02/2007	72	F	Y		12	A	3	3	3	B	1	1	2	C	3	3	3	01/08/2007	B	01/11/2007
JIB	06/12/2006	67	F	Y		13	B	4	4	4	C	3	3	3	A	3	2	2	27/06/2007	B	27/09/2007
EG	21/02/2007	69	F	Y	Pt deceased	14	A	3	3	3	B	1	1	2	C						
DM	28/02/2007	82	M	Y		15	C	2	4	4	A	2	2	2	B	2	2	3	12/09/2007	C	12/12/2007
KI	07/03/2007	69	F	Y		16	C	2	2	2	B	2	3	2	A	2	2	3	27/06/2007	C	27/09/2007
SH	21/03/2007	82	F	Y		17	B	4	4	4	C	4	3	4	A	3	3	4	12/12/2007	A	12/03/2008
GB	21/03/2007	61	M	Y		18	C	4	3	3	A	3	3	3	B	4	4	4	10/10/2007	A	10/01/2008
MT	21/03/2007	71	F	Y		19	A	2	3	3	C	2	2	3	B	2	2	3	10/04/2008	A	10/07/2008
LB	18/04/2007	81	F	Y		20	A	2	2	4	C	1	1	1	B	1	1	1	23/01/2008	B	23/04/2008
KBH	18/04/2007	83	M	Y		21	C	4	3	4	A	3	2	3	B	3	3	4	22/08/2007	A	22/11/2007
CL	25/04/2007	62	F	Y		22	B	3	2	3	A	2	3	3	C	2	2	2	19/12/2007	A	19/03/2008
FP	02/05/2007	81	F	Y		23	A	3	2	3	C	2	2	3	B	3	2	3	03/10/2007	A	03/10/2008
SB	09/05/2007	64	F	Y		24	C	4	1	3	A	4	1	4	B	3	2	3	23/04/2008	B	23/07/2008
ES	09/05/2007	69	F	Y		25	B	4	3	3	A	2	1	1	C	3	2	2	03/10/2007	A	03/01/2008
JB	20/06/2007	74	F	Y		26	B	4	4	4	A	3	3	3	C	3	3	3	19/12/2007	C	19/03/2008
ME	27/06/2007	73	F	Y		27	B	3	3	3	C	3	4	3	A	3	3	3	16/01/2008	A	16/04/2008
JC	27/06/2007	67	F	Y		28	C	4	3	4	A	2	2	4	B	2	2	1	28/05/2008	C	28/08/2008
JL	27/06/2007	71	M	Y		29	C	4	2	4	B	3	2	2	A	3	2	3	13/02/2008	A	13/05/2008
PS	27/06/2007	60	F	Y		30	C	3	2	2	A	3	2	2	B	3	2	2	12/03/2008	A	12/06/2008
KMG	07/02/2007	83	M	Y		31	B	3	2	3	A	3	2	3	C	3	2	3	17/10/2007	A	17/01/2008
JB2	01/08/2007	50	F	Y		32	A	1	2	2	C	3	3	3	B	3	3	3	17/05/2008	A	17/08/2008
JS	05/09/2007	78	M	Y		33	B	4	4	4	A	4	2	4	C	2	2	2	20/02/2008	B	20/05/2008
JLB	20/06/2007	74	F	Y		34	B	4	4	4	A	3	3	3	C	3	3	3	19/12/2007	C	19/03/2008
ME2	26/09/2007	71	F	Y		35	B	3	3	2	A	2	2	2	C	2	2	2	15/05/2008	C	15/08/2008
DM2	26/09/2007	71	M	Y		36	A	1	2	1	B	3	3	2	C	3	2	2	27/03/2008	A	27/05/2008
LS	03/10/2007		F	Y		37	A	4	2	3	C	1	4	4	B	4	3	4	26/03/2008	A	26/06/2008
DM3	24/10/2007		F	Y		38	C	4	3	3	B	3	3	2	A	3	4	3	14/05/2008	A	14/08/2008
ES2	31/10/2007	78	F	Y		39	B	3	2	3	C	3	2	4	A	4	3	3	30/04/2008	B	30/07/2008
MD	07/11/2007	80	F	Y		40	A	4	3	3	C	2	3	3	B	2	2	4	29/05/2008	A	29/08/2008
LMC	28/11/2007		F	Y		41	A	2	3	3	B	3	3	3	C	2	3	2	14/05/2008	B	14/08/2008
DS	19/12/2007	67	M	Y		42	A	3	1	4	B	2	1	3	C	2	2	2	21/08/2008	C	21/11/2008
EP	19/12/2007	86	F	Y		43	B	3	3	3	C	3	3	3	A	3	3	3	21/05/2008	C	21/08/2008
NH2	23/01/2008	91	M	Y	pt's wife died treat	44															
PB	23/01/2008	69	F	Y		45	C	3	2	3	B	2	3	3	A	2	3	3	23/07/2008	B	23/10/2008
JN	21/01/2008	94	M	Y		46	B	2	2	3	C	3	2	3	A	2	3	3	02/07/2008	C	02/10/2008
HI	30/01/2008	61	F	Y		47	C	1	1	2	B	2	2	2	A	1	1	2	25/06/2008	A	25/09/2008
JWB	30/01/2008	75	F	Y		48	A	3	2	2	B	4	3	3	C	3	2	2	25/02/2009	C	25/05/2009
DB	27/02/2008		F	Y		49	B	4	3	4	C	3	3	3	A	3	4	3	16/10/2008	B	16/01/2009
ACH	27/02/2008	64	F	Y		50	B	4	2	4	C	2	2	3	A	4	3	2	23/07/2008	B	23/10/2008
SB2	20/02/2008	71	F	Y		51	A	2	3	2	C	3	4	3	B	2	3	3	14/08/2008	A	14/08/2008
DM4	05/03/2008	67	M	Y		52	A	3	2	2	B	3	3	2	C	4	4	3	27/08/2008	B	27/11/2008
TR	06/02/2008		F	Y		53	A	4	4	4	C	4	4	3	B	3	3	3	20/11/2008	B	20/02/2009
DT	06/02/2008		M	Y	pt lost leg; treatme	54															
GG	07/05/2008		F	Y		55	C	3	2	3	B	2	2	3	A	3	1	3		B	
CB	17/04/2008		M	Y		56	B	2	2	2	C	2	2	3	A	2	3	2	16/10/2008	A	16/01/2009
JMS	11/06/2008		F	Y		57	A	3	3	3	B	2	2	3	C	2	2	2	17/09/2008	A	17/12/2008
ID	12/06/2008	91	F	Y		58	A	3	2	3	B	3	3	3	C	4	4	3	12/10/2008	A	12/01/2009
AW	05/06/2008		F	Y		59	A	3	3	3	C	2	2	2	B	2	2	2		B	
LB2	10/04/2008		F	Y		60	C	3	2	2	A	3	2	2	B	3	3	3		A	
KG	18/06/2008	68	F	Y		61	B	2	1	3	C	2	2	2	A	3	2	3		A	14/01/2009
RM	03/07/2008		F	Y		62	B	3	2	3	A	3	3	3	C	2	3	2		B	
LC	09/07/2008	67	F	Y		63	B	4	3	4	A	3	3	3	C	3	4	3	04/03/2009	A	04/06/2009
PR	24/07/2008	72	F	Y		64	B	4	3	3	C	3	3	3	A	3	2	3		C	
KR	13/08/2008	66	M	Y		65	C	3	3	3	B	2	2	2	A	2	2	2	05/02/2009	B	05/05/2009
JL2	21/08/2008		F	Y		66	A	2	2	2	C	3	2	3	B	2	2	2	12/02/2009	A	12/05/2009
SH2	08/10/2008	75	F	Y		67	A	4	4	4	B	3	3	3	C	2	3	3	19/03/2009	C	19/06/2009
GP	26/11/2008		F	Y		68	C	3	4	3	B	3	3	3	A	4	3	3	19/03/2009	A	19/06/2009
CB2	11/12/2008	68	F	Y		69	C	2	1	1	B	3	4	3	A	1	1	1	19/03/2009	A	19/06/2009

Appendix 11 Secondary outcome ordinal logistic regression

Stata output of an ordinal logistic regression of the secondary outcome questionnaire. The three dependant variables (Comfort, Stability and Chewing efficiency) are each looked at in turn. They are regressed against the independent variables of 'order of delivery' (1st, 2nd or 3rd) and the 'denture' (A, B or C). The STATA software uses the first independent as the base variable for the regression. With the codes entered for this regression the two base variables for the two independent variables, were the first denture and the control denture (denture C). The log ratios (highlighted below) of the regression are used in section 9.6.3 of Part IV of the Thesis to retrospectively assess the power of the secondary outcome assessment.

```
xi:ologit  comfort i.Recodenture i.orderdelivered, or
i.Recodenture     _IRecodentu_1-3     (naturally coded; _IRecodentu_1 omitted)
i.orderdelive~d   _Iorderdeli_1-3     (naturally coded; _Iorderdeli_1 omitted)

Iteration 0:   log likelihood = -237.09464
Iteration 1:   log likelihood = -229.99185
Iteration 2:   log likelihood = -229.92771
Iteration 3:   log likelihood = -229.92766

Ordered logistic regression                       Number of obs   =        198
                                                  LR chi2(4)      =      14.33
                                                  Prob > chi2     =     0.0063
Log likelihood = -229.92766                       Pseudo R2       =     0.0302

------------------------------------------------------------------------------
     comfort | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
_IRecodent~2 |   1.416393    .461525     1.07   0.285     .7478659    2.682525
_IRecodent~3 |   .9813683   .3209652    -0.06   0.954     .5169386    1.863052
_Iorderdel~2 |    .344747   .1169209    -3.14   0.002     .1773436    .6701708
_Iorderdel~3 |   .3567153   .1216563    -3.02   0.003     .1828197     .696018
-------------+----------------------------------------------------------------
       /cut1 |  -3.442094   .4263734                     -4.277771   -2.606418
       /cut2 |  -1.337362   .3347461                     -1.993453   -.6812722
       /cut3 |   .9062855   .3226155                      .2739708      1.5386
------------------------------------------------------------------------------
r; t=0.23 17:09:37

.
. xi:ologit  stablility i.Recodenture i.orderdelivered, or
i.Recodenture     _IRecodentu_1-3     (naturally coded; _IRecodentu_1 omitted)
i.orderdelive~d   _Iorderdeli_1-3     (naturally coded; _Iorderdeli_1 omitted)

Iteration 0:   log likelihood = -236.71085
Iteration 1:   log likelihood = -236.34436
Iteration 2:   log likelihood = -236.34425

Ordered logistic regression                       Number of obs   =        198
                                                  LR chi2(4)      =       0.73
                                                  Prob > chi2     =     0.9472
Log likelihood = -236.34425                       Pseudo R2       =     0.0015
```

```
------------------------------------------------------------------------------
  stablility | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
_IRecodent~2 |    1.103407   .3599536     0.30   0.763     .5821791    2.091293
_IRecodent~3 |    .8915057   .2902877    -0.35   0.724      .470934    1.687673
_Iorderdel~2 |     .834804   .2721175    -0.55   0.580     .4406786    1.581419
_Iorderdel~3 |     .911339   .2943409    -0.29   0.774     .4839071    1.716318
-------------+----------------------------------------------------------------
       /cut1 |  -2.343813   .3659724                     -3.061105    -1.62652
       /cut2 |  -.0571916    .310178                     -.6651292    .5507461
       /cut3 |   2.037953   .3567295                      1.338776     2.73713
------------------------------------------------------------------------------
r; t=0.16 17:09:38

.
. xi:ologit  efficiency i.Recodenture i.orderdelivered, or
i.Recodenture     _IRecodentu_1-3     (naturally coded; _IRecodentu_1 omitted)
i.orderdelive~d   _Iorderdeli_1-3     (naturally coded; _Iorderdeli_1 omitted)

Iteration 0:   log likelihood = -222.38185
Iteration 1:   log likelihood = -217.87796
Iteration 2:   log likelihood = -217.84588
Iteration 3:   log likelihood = -217.84587

Ordered logistic regression                       Number of obs   =        198
                                                  LR chi2(4)      =       9.07
                                                  Prob > chi2     =     0.0593
Log likelihood = -217.84587                       Pseudo R2       =     0.0204

------------------------------------------------------------------------------
  efficiency | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
_IRecodent~2 |    1.390399   .4663101     0.98   0.326     .7205507     2.68296
_IRecodent~3 |    .9771572   .3249066    -0.07   0.945     .5092586    1.874954
_Iorderdel~2 |    .5460768   .1873759    -1.76   0.078     .2787277    1.069861
_Iorderdel~3 |    .4045046   .1395687    -2.62   0.009     .2056971    .7954608
-------------+----------------------------------------------------------------
       /cut1 |  -3.523434   .4586336                     -4.422339   -2.624528
       /cut2 |  -1.339826   .3405824                     -2.007356   -.6722972
       /cut3 |   1.210977   .3356996                      .5530182    1.868936
------------------------------------------------------------------------------
r; t=0.14 17:09:38
```

Appendix 12 Posters and oral communications derived from the work of the Thesis and presented at academic conferences

Title	Type	Society	Venue	Year	Thesis chapter
The effect of seating speed on pressure within impressions	Poster	BSSPD	Exeter	2008	Part II Ch. 5
The effect of delayed seating on impression pressure	Oral	BSSPD	Exeter	2008	Part II Ch.6
A demonstration of the pressure gradient across prosthodontic impressions	Poster	BSRD	London	2008	Part II Ch. 7
Impression Pressure and the Distance to a Tray Perforation	Poster	BSDR	London	2008	Part II Ch.8
Impression Pressure and the Number of Custom Tray Perforations	Poster	IADR	Miami	2009	Part II Ch. 9
Impression Pressure and the Size of Custom Tray Perforations	Poster	BSRD	Edinburgh	2009	Part II Ch.10
A Cross Over Randomised Controlled Trial of Selective Pressure Impressions	Oral	BSDR	Glasgow	2009	Part IV Ch. 2-6

Appendix 13 Candidate's relevant papers

Relevant papers	Page first mentioned in the Thesis
Hyde, T.P. McCord, J.F. 1999. Survey of prosthodontic impression procedures for complete dentures in general dental practice in the United Kingdom. *Journal of Prosthetic Dentistry*. 81(3), 295-9.	PAGE 7
Hyde, T.P. 2003. Case report: differential pressure impressions for complete dentures. *European Journal of Prosthodontics and Restorative Dentistry*, 11(1), 5-8.	PAGE 12
Hyde, T.P. Craddock, H. Brunton, PA., 2008. The effect of seating velocity on pressure within impressions. *Journal of Prosthetic Dentistry*, 100(5), 384-9.	PAGE 81
Dillon, S. Hyde T.P. Brunton P. 2008 A Technique to Construct Duplicate Dentures for Clinical Research *Quintessence Journal of Dental Technology*, 6 (1), 30–39.	PAGE 324
Thomason, J.M. Feine, J. Exley, C. Moynihan, P. Müller, F. Naert, I. Ellis. J.S. Barclay, C. Butterworth, C. Scott, B. Lynch, C. Stewardson, D. Smith, P. Welfare, R. Hyde, P. McAndrew, R. Fenlon, M. Barclay, S. Barker, D., 2009. Mandibular two implant-supported overdentures as the first choice standard of care for edentulous patients--the York Consensus Statement. *British Dental Journal*, 207(4), 185-6.	PAGE 293
Hyde, T.P. Craddock, H.L. Blance, A. Brunton, P.A., 2010. A cross-over Randomised Controlled Trial of selective pressure impressions for lower complete dentures. *Journal of Dentistry*, 38(11), 853-8.	PAGE 355