

**A COMPARISON OF THE EFFECTIVENESS OF THREE
METHODS OF ANCHORAGE REINFORCEMENT IN THE
TREATMENT OF MAXIMUM ANCHORAGE PATIENTS -
A RANDOMISED CLINICAL TRIAL**

Paul Jonathan Sandler

Thesis submitted for the degree of

Doctor of Philosophy

School of Clinical Dentistry

The University of Sheffield



October 2013

ABSTRACT

A COMPARISON OF THE EFFECTIVENESS OF THREE METHODS OF ANCHORAGE REINFORCEMENT IN THE TREATMENT OF MAXIMUM ANCHORAGE PATIENTS: A RANDOMISED CLINICAL TRIAL.

The primary intention of this study was to add to the body of scientific evidence by determining whether a recently introduced method of anchorage reinforcement, namely Temporary Anchorage Devices (TADs), is effective. It is clear that there are several commonly used methods for anchorage support but some of these are totally dependent for success upon good patient compliance. Orthodontic clinicians would enthusiastically welcome as an alternative, an effective and efficient method that is less dependent upon patient co-operation.

The introduction of new orthodontic techniques is rarely supported by high quality evidence on efficiency or effectiveness, in advance of them being promoted for widespread clinical use. New appliances and techniques are often promoted based upon very low levels of clinical evidence.

Temporary Anchorage Devices were first introduced in 1983. Since then many papers have referred to Temporary Anchorage Devices as a source of stationary anchorage yet to date, few Randomised Clinical Trials (RCTs) have been carried out into this treatment method.

AIMS

To evaluate the effectiveness of Temporary Anchorage Devices for orthodontic anchorage when compared with the Nance button palatal arch and to Headgear.

METHOD

The TADs assessment trial is a prospective, dual-centre RCT involving 78 'maximum anchorage' patients between 12 and 18 years of age with 39 males and 39 females. The three treatment arms of the study were Headgear, a Nance button palatal arch and TADs. Outcomes recorded included: anchorage loss measured both on lateral cephalometric radiographs and 3D model scanning, length of treatment, number of visits, quality of the outcome and the patients' perception of the various treatment methods.

RESULTS

Sample summary showed the groups to be matched in terms of age, start PAR score and SNA.

There was a statistically significant ($p=0.002$) overall effect of treatment when the right molar position was assessed on cephalograms. The Nance group lost 2.03mm (0.81-3.25) more anchorage than the Headgear group. No other statistically and clinically significant results were recorded between the groups on the cephalograms or on the superimposed digital models.

Mean treatment times in months varied from 26.83 (SD 9.35) to 28.01(SD 5.38) and the total number of visits from 18.38 (SD 5.95) to 21.77 (SD 4.41).

Casual visits and DNAs were almost identical between the groups but PAR scores were nearly 4 points better with TADs than Headgear and Nance. This result was statistically and clinically significant.

From the patient questionnaires, the comfort levels both on placement and removal were similar with TADs and the Nance, and both techniques were highly recommended by the patients. Headgear was more troublesome and much less popular with the patients.

CONCLUSIONS

- 1) There is no difference in the effectiveness of temporary anchorage devices, Nance button palatal arches and headgear in reinforcing anchorage in orthodontic treatment.
- 2) Patients' perceptions suggest that there were greater problems with headgear and Nance buttons, than with temporary anchorage devices.
- 3) The quality of treatment as measured by PAR scores was significantly better with TADs than with headgear
- 4) Temporary anchorage devices may be the preferred method of choice for reinforcing orthodontic anchorage

ABSTRACT	ii
CONTENTS LIST	v
DECLARATION	x
COPYRIGHT STATEMENT	xi
DEDICATION	xii
LIST OF FIGURES	xiii
LIST OF TABLES	xvii
ACKNOWLEDGEMENTS	xviii
SECTION 1 INTRODUCTION AND LITERATURE REVIEW	1
1.0 GENERAL INTRODUCTION	
1.1 THE UNAVOIDABLE NEED FOR ANCHORAGE	2
2.0 LITERATURE REVIEW	
2.1 HISTORY OF HEADGEAR	4
2.2 STUDIES OF HEADGEAR	6
2.3 SUMMARY OF HEADGEAR FINDINGS	15
2.4 THE NANCE PALATAL ARCH	16
2.5 MINI-IMPLANTS	20
2.5.1 FAILURE RATE OF TADS	22
2.5.2 CONCLUSIONS ON TADS FAILURES	25
2.6 UPDATE OF THE COCHRANE REVIEW ON TADS	26
2.6.1 COMPARISON 1: MESIAL MOVEMENT OF THE UPPER FIRST MOLAR BETWEEN SURGICAL AND CONVENTIONAL ANCHORAGE	33
2.6.2 COMPARISON 2: MESIAL MOVEMENT OF THE UPPER FIRST MOLAR BETWEEN MID-PALATAL IMPLANT AND HEADGEAR	34
2.7 SUMMARY OF THE LITERATURE ON SURGICALLY ASSISTED ANCHORAGE SUPPORT	36
2.8 CONCLUSIONS ON SURGICALLY ASSISTED ANCHORAGE	41
2.9 3D MEASUREMENTS AND ORTHODONTICS	43
2.10 SUPERIMPOSITION OF 3D MODELS	46
2.11 LASER SCANNING IN ORTHODONTICS	50

3.0 AIMS AND OBJECTIVES	
3.1 AIMS	62
3.2 OBJECTIVES	62
3.3 NULL HYPOTHESES	63
SECTION 2 – MATERIAL AND METHODS	64
4.0 METHODOLOGY	
4.1 INTRODUCTION	65
4.2 STUDY DESIGN	65
4.3 OUTCOME MEASURES	65
4.4 CENTRES INVOLVED	66
4.5 SUBJECTS	66
4.5.1 INCLUSION CRITERIA	67
4.5.2 EXCLUSION CRITERIA	67
4.5.3 RECRUITMENT OF SUBJECTS	67
4.6 ENROLMENT OF PARTICIPANTS	68
4.7 CONSENT PROCESS	69
4.8 METHOD OF RANDOM ALLOCATION	69
5.0 CLINICAL TREATMENT	71
5.1 TREATMENT PROTOCOLS	75
5.1.1 HEADGEAR DESIGN	75
5.1.2 NANCE BUTTON ON A PALATAL ARCH	76
5.1.3 TADS	77
5.2 PROTOCOL DEVIATIONS	79
5.3 OUTCOME ASSESSMENT	80
5.4 RECORDS AND DATA COLLECTED	80
5.5 OPERATOR STANDARDISATION	81
5.6 PROGRESS OF TREATMENT	81
5.7 QUESTIONNAIRES	83
5.8 STATISTICAL ANALYSIS	85
6.0 RECORD ANALYSIS - 3D MODELS	
6.1 SCANNING THE MODELS	86
6.2 ASSESSING TOOTH MOVEMENT USING 3D SCANS	89
6.3 IDENTIFYING MOLAR MOVEMENTS	94

6.4 REPRODUCIBILITY OF THE 3D METHOD	96
6.4.1 HISTOGRAMS	100
6.4.2 INTRACLASS CORRELATION SCATTERGRAMS	103
6.5 LIMITS OF AGREEMENT	106
6.6 ERROR OF THE METHOD	110
7.0 RECORD ANALYSIS - CEPHALOGRAMS	
7.1 ASSESSING ANCHORAGE LOSS ON CEPHALOGRAMS	111
7.2 RELIABILITY OF MEASUREMENT OF MOLAR MOVEMENT ON THE CEPHALOMETRIC RADIOGRAPHS	111
7.3 TOOTH MOVEMENT AS ASSESSED ON CEPHALOGRAMS - RESULTS FOR THE CLINICAL VALIDATION STUDY	113
7.3.1 HISTOGRAMS	116
7.3.2 INTRACLASS CORRELATION SCATTERGRAMS	117
7.4 LIMITS OF AGREEMENT	119
SECTION 3 RESULTS	121
8.0 RESULTS	
8.1 SAMPLE SUMMARY STATISTICS	124
8.2 ANCHORAGE LOSS ON LATERAL CEPHALOGRAMS	124
8.3 ANCHORAGE LOSS AS ASSESSED BY 3D SCANS	126
9.0 SECONDARY OUTCOME MEASURES	127
9.1 TREATMENT DURATION AND NUMBER OF VISITS	127
9.2 CASUAL VISITS AND FAILED APPOINTMENTS	128
9.3 DENTO-OCCLUSAL CHANGE	128
9.4 IMPACT OF ‘ANCHORAGE SUPPLEMENTATION METHOD’ QUESTIONNAIRES	129
9.5 FREE TEXT COMMENTS ON THE ANCHORAGE SUPPLEMENTATION METHOD	
9.5.1 FREE TEXT ABOUT TADs	130
9.5.2 FREE TEXT - PROBLEMS WITH NANCE BUTTONS	131
9.5.3 FREE TEXT ABOUT REMOVAL OF NANCE BUTTONS	131
9.6 QUESTIONNAIRES ABOUT HEADGEAR	132
9.6.1 FREE TEXT ABOUT HEADGEAR PROBLEMS	132

9.6.2	FREE TEXT – FINAL COMMENTS ABOUT HEADGEAR	133
9.7	EXTRACTION DECISIONS IN MAXIMUM ANCHORAGE CASES	134
9.8	MORPHOLOGICAL CHARACTERISTICS OF THE SAMPLE	134
9.9	SUBJECTS WHO DECLINED TO BE INCLUDED IN THE STUDY	135
9.10	DETAILS OF DROPOUTS	136
9.11	TAD FAILURES IN THE STUDY	138
SECTION 4 – DISCUSSION AND CONCLUSIONS		141
10.0	DISCUSSION	142
10.1	MEASUREMENT OF TOOTH MOVEMENT	142
10.2	SECONDARY OUTCOME MEASURES	146
10.2.1	TREATMENT TIME AND NUMBER OF VISITS	146
10.2.2	DENTO-OCCLUSAL CHANGE	148
10.2.3	PATIENT QUESTIONNAIRES	149
10.2.3.1	HEADGEAR QUESTIONNAIRES	149
10.2.3.2	NANCE QUESTIONNAIRES	150
10.2.3.3	TAD QUESTIONNAIRES	152
10.3	USE OF PROXIMAL OUTCOME MEASURES	153
10.4	PREPARATORY PHASE OF TREATMENT	154
10.5	TRIAL DESIGN AND SAMPLE SIZE	155
10.5.1	SUBJECTS INCLUDED IN THE STUDY	155
10.5.2	PATIENTS DECLINING TO ENTER THE STUDY	156
10.6	RISK OF BIAS IN THE STUDY	156
10.6.1	SELECTION BIAS	157
10.6.2	RANDOMISATION LEADING TO GENDER IMBALANCE	158
10.6.3	PERFORMANCE BIAS	159
10.6.4	DETECTION BIAS	160
10.6.5	ATTRITION BIAS	161
10.6.6	REPORTING BIAS	162
10.7	INCLUSION/EXCLUSION CRITERIA	162
10.8	SAMPLE SIZE CALCULATION	164
10.9	VALIDITY AND REPRODUCIBILITY OF THE 3D METHOD	164
10.9.1	ITERATIVE CLOSEST POINT	165
10.10	VALIDITY OF THE CEPHALOMETRIC METHOD	175
10.11	REPRODUCIBILITY OF THE CEPHALOMETRIC METHOD	176

10.12 EFFECT OF TIP OR ROTATION ON ANCHORAGE ASSESSMENT	177
10.13 ACCURACY OF IMPRESSIONS AND JAW REGISTRATION	178
10.14 EXTRACTION PATTERNS OF PATIENTS IN THE STUDY	180
10.15 TAD FAILURES IN THIS STUDY	182
10.16 HOW COULD STUDY BE IMPROVED?	183
10.16.1 HORIZONTAL ‘CROSSHAIR’ ON THE RIGHT AND LEFT MOLAR MARKERS	184
10.16.2 TRANSPALATAL ARCH INSTEAD OF NANCE	184
10.17 IDEAS FOR FUTURE STUDIES	185
10.18 CLINICAL IMPLICATIONS OF THIS STUDY	186
11.0 CONCLUSIONS	187
12.0 REFERENCES	188

APPENDICES	196
APPENDIX 1 Search strategy used in electronic searching of databases	197
APPENDIX 2 Form 1 to decide if abstract can be included or not	198
APPENDIX 3 Form 2: Agreement Between 2 Reviewers After Initial Screening	199
APPENDIX 4 Form 3: Study eligibility form: Surgical anchorage update	201
APPENDIX 5 Form 4: Data extraction form	202
APPENDIX 6 Application for funding from the BOSF	203
APPENDIX 7 Ethical approval	217
APPENDIX 8 Patient information pack	218
APPENDIX 9 Patient Consent form	223
APPENDIX 10 Parent Consent form	224
APPENDIX 11 Letter to General Dental Practitioner	225
APPENDIX 12 Log-in instructions	226
APPENDIX 13 Final randomisation table	227
APPENDIX 14: Flow diagram of patients through the study	231
APPENDIX 15 Nance Questionnaire	232
APPENDIX 16 TADs Questionnaire	234
APPENDIX 17 Headgear Questionnaire	236
APPENDIX 18 Radiographic measurement techniques	238
APPENDIX 19 Permission to use figures from Elsevier and Wiley	242
APPENDIX 20 ‘The Long and Winding Road’	243

DECLARATION

No portion of the work referred to in this thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning

A handwritten signature in black ink that reads "Jonathan Sandler". The signature is written in a cursive style and is underlined with a single horizontal stroke.

Jonathan Sandler

October 2013

COPYRIGHT STATEMENT

- 1) The author of this thesis (including any appendices and/or schedules to this thesis) owns any copyright in it (the "Copyright") and he has given The University of Sheffield the right to use such Copyright for any administrative, promotional, educational and/or teaching purposes.
- 2) Copies of this thesis, either in full or in extracts, may be made only in accordance with the regulations of the University Library of Sheffield. Details of these regulations may be obtained from the Librarian. This page must form part of any such copies made.
- 3) The ownership of any patents, designs, trade marks and any and all other intellectual property rights except for the Copyright (the "Intellectual Property Rights") and any reproductions of copyright works, for example graphs and tables ("Reproductions"), which may be described in this thesis, may not be owned by the author and may be owned by third parties. Such Intellectual Property Rights and Reproductions cannot and must not be made available for use without the prior written permission of the owner(s) of the relevant Intellectual Property Rights and/or Reproductions.

Further information on the conditions under which disclosure, publication and exploitation of this thesis, the Copyright and any Intellectual Property Rights and/or Reproductions described in it may take place is available from the Head of School of Dentistry (or the Vice-President) and the Dean of the Faculty Dentistry

A handwritten signature in black ink that reads "Jonathan Sandler". The signature is written in a cursive style and is underlined with a thick, dark stroke.

Jonathan Sandler

October 2013

DEDICATION

*This thesis is dedicated to Ella and Gerry
for setting an example
for us all to follow*

LIST OF FIGURES

Figure 1.1 Principia Mathematica	2
Figure 2.1 Historical versions of orthodontic headgear used in the 19 th C.	4
Figure 2.1 Acrylic Nance button added to the palatal arch to supplement anchorage	17
Figure 2.3 Flow diagram of Cochrane update of TADs for anchorage	30
Figure 2.4 Mid-palatal implants are seen to be more effective than conventional methods in reinforcing anchorage, although there was moderate heterogeneity	34
Figure 2.5 Orthosystem mid-palatal implant provides excellent anchorage support	35
Figure 2.6 Forest plot demonstrates that the mid palatal implants are more effective than conventional methods	36
Figure 2.7 The Bolton Orientator - 3D representation of 2D points	43
Figure 2.8 All models orientated in the same plane X-Y represented AP direction and bucco-lingual direction and the Z-axis indicates vertical direction.	47
Figure 2.9 Slit ray laser projector and two CCD devices capture images	50
Figure 2.10 Virtual set-up teeth moved to the 'ideal' position, on the computer	51
Figure 2.11 Three-dimensional computerised models proved to be very accurate	53
Figure 2.12 Landmarks identified for reproducible dental cast superimposition. R3M = Right 3 rd rugae medial, L3M = Left 3 rd Rugae medial, point A bisector	55
Figure 2.13 Palatal rugae identified on start and end of treatment models	56
Figure 2.14 Unloaded implants allowed stable area of palate to be identified (blue)	60
Figure 4.1 The pattern of recruitment can be seen over a 28-month period	68
Figure 5.1 Sectional appliances removed, molar markers prepared in 19/25	71
Figure 5.2 and 5.3 Right and Left molar markers held in place with elastics for the radiograph	73

Figure 5.4. Lateral cephalometric radiograph with molar markers in place, allowing the left molar to be clearly distinguished from the right molar.	74
Figure 5.5 Occipital pull safety headgear and safety Ni-Tom, Kloehn bow	75
Figure 5.6 Nance button palatal arch	76
Figure 5.7 Aarhus 8mm x 1.6mm TAD	79
Figure 6.1 3D scanner connected to two PCs, to allow image capture and manipulation	86
Figure 6.2 Mounted models placed in scanner to register the occlusion	87
Figure 6.3 Individual model, mounted on scanning plate	88
Figure 6.4 Models held in occlusion with a clamp to allow scanning to be performed	88
Figure 6.5 3D polygon mesh comprised > 300,000 data points	89
Figure 6.6 Virtual model re-orientated to show the occlusal view, then converted to solid colour	89
Figure 6.7 Superimposed images - gold selected for pre-treatment model, crimson for post-anchorage supplementation model	90
Figure 6.8 Both models palatal rugae to be simultaneously viewed on the split screen	91
Figure 6.9 The corresponding anatomical points are indicated by the same coloured dots	91
Figure 6.10 Colour of the model represents the accuracy of the superimposition	92
Figure 6.11 Blue 'mushroom' covering points of known stability for regional superimposition	93
Figure 6.12 Start model moved around to allow the entire occlusal, buccal and palatal surfaces to be highlighted forming the molar shell	94
Figure 6.13 Occlusal surface identified on end of anchorage supplementation model	95

Figure 6.14 Movement of molar shells seen and measurements in all 3 planes	96
Figure 6.15 Rapidform files show the molar movement and the measurements	97
Figure 6.16-6.21 Histograms for assessing normal distribution of Differences between 1 st and 2 nd measurements on Right and Left molars in three planes of space	100
Figure 6.22-6.27 Intraclass correlation scattergrams for double determinations of molar movement in all three planes of space	103
Figure 6.28-6.33 Bland Altman plots of the differences in 3D scan measurements for double determinations of molar movement in all three planes of space	107
Figure 7.1 Difference between 1 st and 2 nd measurement of left molar	116
Figure 7.2 Difference between 1 st and 2 nd measurement of right molar	117
Figures 7.3 Scatterplots showing Intraclass Correlation Coefficient between 1 st and 2 nd differences between measurements	118
Figure 7.5 and 7.6 Bland and Altman plots for measurements from the cephalograms	119
Figure 8.1 CONSORT flow diagram for patients through the study	123
Figure 9.1 Successive TAD sites separated by 2mm	139
Figure 9.2 No similar problems experienced on the right side of the arch	139
Figure 9.3 TAD has loosened but still useful for canine retraction	140
Figure 9.4 Head of TAD sheared off during placement	140
Figure 9.5 Fractured head of the screw placed on cotton wool roll	140
Figure 10.1 Movements required to superimpose source cloud on target cloud	167
Figure 10.2 6 degrees of freedom involves translation about the X, Y and Z axes and rotation around the X (pitch), Y (roll) and Z (yaw) axes. From Wikipedia http://en.wikipedia.org/wiki/Six_degrees_of_freedom	168

Figure 10.3 Correspondences need to be identified on both the source and the target clouds	169
Figure 10.4 After one ICP iteration translation brings clouds into contact	170
Figure 10.5 After a second ICP iteration, rotation makes clouds approximately parallel	171
Figure 10.6 After a third ICP iteration, further translation brings correspondences much closer, small further rotation clearly required and further translation	171
Figure 10.7 Second TAD, inserted 2mm occlusal to the sheared screw	182
Figure 10.8 Fractured part of screw clearly visible between two radiographic markers	183
Figure a Computer setup allowed two radiographs to be viewed side by side	238
Figure b Constructed 'vertical' marked on both radiographs @ 97° to SN	239
Figure c Linear measurements from Left and Right molar markers to the vertical, millimeter scale can be clearly seen above the molar markers	241

LIST OF TABLES

Table 4.1 Sample size calculation: One-way analysis of variance (equal n's)	66
Table 6.1 Double determination of movement of the Centres of Mass of upper molar teeth on two occasions. 1 st and 2 nd set of measurements	98
Table 6.2 Differences between the 1st and 2nd determinations and means of the differences of movement	99
Table 6.3 Relationship between first and second measurements of each movement	105
Table 6.4 Paired Sample T test for the mean errors in measurements of movement of molars on two occasions, to assess method error	110
Table 7.1 Intraclass correlation – Sample size calculation for number of cephalograms on which to perform double determination	112
Table 7.2 Double determination on 20 randomly selected Cephalograms – distances from left and right molar markers to constructed vertical	114
Table 7.3 Difference between the two measurements, therefore anchorage loss plus the error in measurement, plus mean of the measurement on two occasions	115
Table 7.4 Intraclass correlation coefficient to assess intra-rater reliability	119
Table 8.1 Sample summary statistics at start of treatment, by treatment group and for total sample (mean and standard deviation)	124
Table 8.2 Measurement of left and right molar position at start (DC1) and end (DC2) of anchorage supplementation, by treatment group and for total sample (mean and standard deviation)	125
Table 8.3 Linear regression model for the effects of treatment and initial values on the end of anchorage supplementation outcomes.	125
Table 8.4 Anchorage loss demonstrated on 3D models	126
Table 8.5 Linear regression model for the effects of treatment on the anchorage loss, as measured on digital models as the outcome	126

Table 9.1 The mean total treatment time and standard deviations from the initial placement of appliances, to debond of all attachments	127
Table 9.2 Linear regression model for total treatment time and number of visits during treatment	127
Table 9.3 Casual visits and failed appointments	128
Table 9.4 Start and finish PAR scores for all three groups and reduction of PAR	128
Table 9.5 Linear regression models for the effects of treatment on the finish PAR	129
Table 9.6. Questionnaire results about comfort on placement and removal, mean scores and standard deviations	129
Table 9.7 Headgear questionnaires results about headgear wear, comfort and convenience, mean scores and standard deviations.	132
Table 9.8. Extraction patterns – frequency distribution table	134
Table 9.9. Features of malocclusion in frequency distribution chart	135

ACKNOWLEDGEMENTS

I would like to express sincere thanks to Prof Kevin O'Brien, my friend and colleague for the past 37 years and PhD supervisor for the past 6 years, for his guidance, patience, incisive wit and constant support throughout my professional life. His contributions to this project, detailed comments and insight have been invaluable.

Paul Speight my co-supervisor has also been a close friend for 37 years. He has helped guide my early career and has supported me in all my professional endeavours. His assistance and support with this PhD thesis have been both enjoyed and enormously appreciated.

Alison Murray deserves the next mention, as my life companion, role model, co-researcher and very best friend. Without her enthusiasm and unquestioning support for the past 30 years nothing would have been achieved.

David DiBiase was the professional role model *par excellence*: arguably the county's finest clinician of his day. He was my boss, my mentor and my dear friend, during my five formative years as a Senior Registrar. Bob Lee deserves a mention for 'bringing me in from the cold' and Ray Reed was the first clinician who introduced me to both the wonders of clinical photography and the pleasures of scientific writing. This mapped out a path for me to follow for the next 27 years.

The Angle Society of Europe has inspired me to strive for greater heights in both my clinical and academic work, and I will always be grateful to Dr Neville Bass for introducing me to this group at such an early stage in my career.

Phil Benson has very kindly chaired the Data Monitoring Committee and helped with my upgrade viva, and Professor Helen Rodd has been assiduous in her task as my pastoral supervisor.

Badri, my former student turned teacher, has helped and encouraged me with many aspects of this study and Rodrigo, my research assistant, has assisted me greatly with all aspects of the 3D scanning. Adrian Smith at Chesterfield Hospital has been brilliant in accommodating all my requests for ‘special case’ privileges, with the Chesterfield PACS system.

Debbie Barker has been with me on this entire journey as my primary Research Assistant, and has meticulously cared for all the paperwork in both Chesterfield and Derby, ensuring nothing was out of place at any stage in the process.

Malcolm and Viv in the Chesterfield laboratory and the technicians in Derby have done sterling work throughout the study, producing the necessary models and lab work, and also Jane who has helped keep track of everything throughout the trial.

My sincere thanks to all the nursing, clinical and administrative staff at Chesterfield and Derby Royal Hospitals. Only the Chesterfield nurses, and particularly Anne McTighe, know what a roller coaster ride it has been over the past 20 years!

To Jon and Dave, I extend my sincere thanks: the ‘dynamic duo’ at Chesterfield Royal Hospital who, when faced with recruitment obstacles thrown at me by the PCT, just ‘made it happen’.

Dan Wolstenholme, Research Nurse at Chesterfield played a vital part in obtaining ethical approval and steering paperwork through the COREC process.

Thanks are also due to Dan Simpkins of the Nottingham Clinical Trials Unit who setup the randomisation for the study and was extremely helpful in overcoming my PC vs Mac tussle, when later trying to retrieve the database.

I am grateful for the commitment from all of the patients who took part in the study and thanks are also due to their parents for their patience with the scientific process.

Ian Hollier of ‘American Orthodontics’ deserves a mention as a loyal friend for 27 years. He and his team have supported all my teaching and research endeavours for which I am extremely grateful. American Orthodontics supplied all the implant equipment and materials required for this study.

Luke, Cara and Ben, my three wonderful children, have also been extremely patient when work just had to be done. I hope they have been inspired by what they have seen, but if not . . . thanks for not complaining.

A British Orthodontic Society Foundation grant supported this work.

Section 1

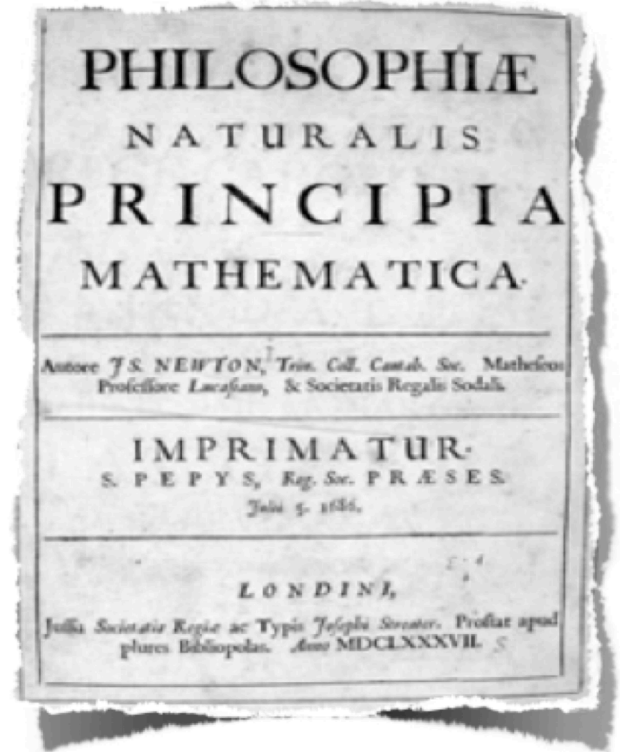
INTRODUCTION AND LITERATURE REVIEW

Chapter 1 GENERAL INTRODUCTION

1.1 THE UNAVOIDABLE NEED FOR ANCHORAGE

Actioni contrarium semper et aequalem esse reactionem: sive corporum duorum actions in se muoto semper esse aequales et in partes contrarias dirige

Fig 1.1 Principia Mathematica



Newton's third law of motion was published in Principia Mathematica (Figure 1.1) in 1687, (Smith, 2008) and is translated as 'For every action there is an equal and opposite reaction'. The teeth naturally obey this basic law of physics, which means that when practicing orthodontics we have to learn to manage forces to obtain optimum tooth movement as part orthodontic care. This is termed 'anchorage management'.

One of the fundamental keys to successful orthodontic care is to build into the treatment plan sufficient anchorage, to allow all the required tooth movements to be efficiently and effectively achieved. Since the advent of modern orthodontic therapy in the 19th century, many suggestions have been made as to the most effective method of holding the posterior teeth in position, whilst correction of the position of anterior teeth is carried out. Despite much heated debate about these

methods for well over a hundred years, consensus has not yet been reached. This has resulted in a plethora of ‘anchorage supplementation’ devices, each having the aim of distalisation or stationary anchorage.

The key to accurate assessment of the anchorage requirements, in almost every orthodontic treatment is a full appreciation of the patient’s canine relationship when in the retruded contact position. In most adolescent orthodontic treatments, the upper and lower permanent canine teeth will form an integral part of the final dentition and in most patients a class 1 canine relationship will be the ideal outcome for a satisfactory static and functional occlusion. The clinician providing the orthodontic care needs to understand where the lower canines will need to be moved to, to allow full correction of the position and alignment of the lower labial segment. This should be carried out as a mental exercise, before orthodontic treatment commences, then a second assessment is necessary of the initial upper canine position relative to the ‘corrected’ lower canine tooth. The evaluation of the canine relationship, in this hypothetical situation, will then allow determination of whether anchorage needs to be reinforced in any particular case.

A number of different methods of supplementing anchorage by controlling the posterior teeth are currently used and I will discuss these in subsequent sections.

Chapter 2 LITERATURE REVIEW

2.1 HISTORY OF HEADGEAR

Edward Angle, the father of modern orthodontics, was quoted in 1887 as saying that *'the occipital bandage, as part of orthodontic treatment, was becoming more and more appreciated'* when used for maxillary protrusion cases and it was one of the oldest methods described for controlling the position of the teeth (Figure 2.1). Angle felt, following his experience of having used it only 16 times, that it was *'more satisfactory than any of the few devices described in the literature'* Graber (1955).

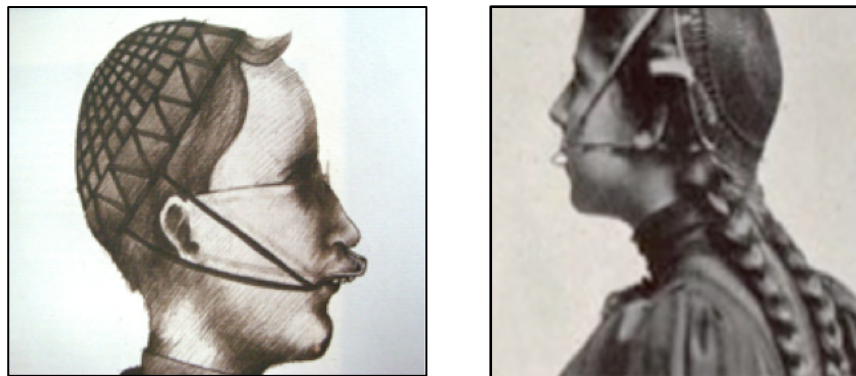


Figure 2.1 Historical versions of orthodontic headgear used in the 19th C.

Whilst this was a small number of cases on which to form an opinion, it was probably more than any other clinicians of the day had performed with this particular anchorage supplementation technique.

Similarly the use of an orthodontic headcap to distalise the buccal segment teeth was described by Oppenheim (1936). He felt that by creating space in the appropriate area of the dentition, this would allow *'biologic'* correction, particularly of aberrant canine teeth. Interestingly, he was against the use of

constant elastic force to correct malpositioned teeth and he preferred using elastics sparingly at night, and then ideally not even every night. He stated, “In his vast experience, constant forces on teeth would ultimately lead to loss of vitality of these teeth, even if this was many years after the event”. Also if the distal movement of the teeth was occurring too rapidly, as would be evidenced by unwanted spacing opening up between the premolar teeth, he advised alternate nights with the headcap rather than every night. This approach to headgear therapy is completely contrary to the commonly held belief that the more hours the headgear is in place, the more chance there is of achieving the desired effect, therefore daily use is strongly recommended currently by most practitioners.

The use of occipital headgear was advocated in many cases almost as soon as the upper first molars had fully erupted, by Kloehn (1947), who was an enthusiastic supporter of this ‘biologic orthodontic therapy’. He was keen to instigate this treatment early, because of the declining rate of growth of the jaws and the alveolar process, as the child gets older. This general approach to providing early treatment to children persists to this day in the United States of America, where patients are commonly called in for their first assessment, as early as 7 or 8 years of age as evidenced by the article in the Wall St. Journal by Keates (2010).

Kloehn’s work was followed by that of Graber (1955) who described a retrospective study of the treatment of 150 Class II division 1 patients. Even at this early stage in the formation of an ‘evidence base’ for orthodontic treatment he acknowledged the need to report on all the cases treated, not just the ones that responded well to treatment. This may be one of the earliest references to an ‘intention to treat analysis’. All cases in the study were treated with cervical

headgear and standardised records were used to allow comparison of treatment effects on three different age groups: 3-6 years, 7-10 years and 11-19 years. He concluded that extra-oral headgear forces could efficiently correct Class II division 1 malocclusions. To be successful not only was patient co-operation essential, but coordination of the treatment with the pubertal growth spurt would also significantly increase the likelihood of a successful outcome. The most favourable treatment results in this study were seen when the headgear was provided for 10-12 year old females and 12-17 year old males. Graber also recognised that associated with this headgear treatment were some undesirable but unavoidable sequelae; such as incomplete correction of the malocclusion, marked lingual tipping of upper incisors and excessive molar tipping, leading to second and sometimes third molar impaction.

2.2 STUDIES OF HEADGEAR

Randomised clinical trials (RCTs) are now accepted as one of the highest levels of investigation that can be carried out into any particular medical or surgical intervention. As a result, from this point onward, I will confine this review to studies that can be judged as being at this high level of scientific evidence.

Jakobsson (1967) carried out one of the first high quality studies in 1967 where he and his co-workers divided sixty 8-9 year old children into 'triples', matched for dental development and malocclusion traits. One of the triples received treatment with an activator 11.5 hours per day for 18 months, the second of the triples with a Kloehn bow cervical pull headgear, 12 hours per day, for 18 months and the third triple received no active orthodontic treatment but acted as a control. They reported that the headgear group demonstrated a posterior repositioning of the

molar teeth, by nearly 4mm. Unfortunately there was no mention of how much of this movement could have been due to distal tipping, rather than actual bodily movement of the teeth. The authors felt that, as a direct result of the headgear treatment, there was a definite effect upon the basal parts of the maxilla, as well as the effect on the dentition.

A fascinating, but unrepeatable randomised clinical study, was described by Melsen (1978) in which 20 Scandinavian children aged between 8 and 10 had four maxillary permanent metal implants and five mandibular permanent metal implants placed to act as fixed reference points. Lateral cephalometric radiographs were taken at the start of treatment, then again after 3 months to check the implants had not moved, and once again after 8 months of headgear treatment. All of the children “wore their headgear for exactly 12 hours per day” for the 8 months of the study.

One strength of this study was that the movement of the respective jaws, represented by the implant lines to the cranial base, could be separated from movement of the teeth within the jaws, i.e. the intra-maxillary tooth movements. In one group, where the cervical headgear was applied using a downward pointing extra-oral bow, the average distal movement of the teeth was 3.5mm, and was described as purely distal tilting. This would have been expected with the particular bow design, as the applied force was so far below the centre of resistance of the tooth that little else could have occurred. Where the extra-oral bow was tilted up by 20° to the inner bow, the distal movement was a much more modest 1.5mm, and in this group there was insignificant tilting of the teeth.

One unexpected finding was that extrusion of the molars was seen in both groups to a similar extent. It was thought that the upward tilted outer bow would extrude the teeth more than the downward facing bow. The author proposed that the occlusal forces and the occlusal contacts may have a role in determining the overall effects of treatment and that mathematical calculations alone, cannot solely be used to predict the results of headgear treatment. Individual adjustments were, and always will be, necessary depending upon each patient's response to the therapy. The patients were all followed up with a further cephalometric radiograph when facial growth had largely ceased. In all but two of the cases the change in growth direction, thought to be induced by the headgear, reverted back to the original, anterior growth direction.

A RCT to examine the anteroposterior skeletal and dental effects of a Bionator functional appliance and a Headgear/biteplane combination on groups of nine year olds with a Class II malocclusion was carried out by Keeling et al. (1998). They compared the effects of both of these appliance systems with a control group. The recommended headgear was either cervical pull or high pull, and 450gm of force per side was recommended for 14 hours per day. The patients were instructed to wear the Bionator for 22 hours per day, the appliance only being removed for eating, cleaning and contact sports. A dentist, who was part of the research team, removed all appliances at each data collection point therefore it was claimed that the orthodontist doing the measurements will have been 'blinded' to the treatment method. It should however have been obvious to the examiners, which of the patients had recently had first molar bands removed (the headgear group), therefore some bias could have been introduced at this point. The Johnson 'Pitchfork' type analysis was carried out, which allowed separation of the effects

on the upper and the lower jaws and also separation of skeletal from the dental effects, of any particular treatment.

This was a large study in which 325 patients were enrolled, however unfortunately 49 of the patients did not reach the third data collection point. The Bionator and the headgear group both showed more Class II correction than the controls when mandibular and apical base measurements were made. The headgear group also showed significant dental Class II correction. In this study, the main effect was enhancement of mandibular growth in both groups and it is thought that the biteplane was a major contributory component in the headgear group, however the specific nature of this contribution to mandibular advancement was unclear. The authors could not find a convincing effect on maxillary growth with either treatment modality, which was counter to commonly held opinion that some distalisation of the maxillary teeth is seen with both headgear and functional appliances.

This sample of patients was analysed further by Ashmore et al. (2002), when they compared a control group from one particular study with a treatment group from a second study. The investigators used the palatal rugae on which to superimpose sequentially taken models. They found that in the headgear group the molars moved distally by over 2mm during the 24-month treatment period, compared with a molar mesialisation of 0.76mm in the control group. It has to be stressed again that these patients were not randomly assigned to treatment or control groups, but were brought together from two unconnected studies. It was therefore considered important to test the baseline groups and this was done using 't' tests, which indeed confirmed the pre-assessment equivalence. Despite this overall

‘confirmation of equivalence’, there was a significant difference between the groups pre-treatment ANB measurement, thought to be due to the inclusion stipulation of $>4.5^\circ$ ANB for one study, but not the other.

Overall the 3mm molar difference between the headgear group and the control group over the 2-year period was felt by the authors to be in agreement with the findings of other researchers. They also felt that despite the fact there could be a change in the distance between rugae of up to 2% over the 2-year treatment period, this was not sufficient to materially effect the measured molar movement. Model superimposition was therefore recommended as the method of assessment, as serial models could be taken regularly, with no detriment to the patient, compared to the potential harm caused by repeated exposures to ionising radiation with each cephalogram taken.

An unusual study was carried out by Sari et al. (2003), involving a rather unique Jasper Jumper (JJ)/removable plate system, whereby the active JJ pre-formed component or the occipital pull headgear, was attached to the removable appliances. The patient was then asked to wear the appliance for 18 hours per day and heavy headgear forces of 700gm per side were applied. The other study group in this RCT were treated with a Headgear-Activator appliance and again a heavy headgear force of 700gm was applied. Both groups were treated for an average of 8.5 months.

In both treatment groups there was significant molar distalisation compared to the slight molar mesialisation in the control group. The final difference was 2.6mm in the Activator HG group and 3.1mm in the JJ/HG group. The authors reported that

in every single case a Class I skeletal pattern was achieved. The activator group was felt to have more effect on the mandible and the mandibular dentition, whereas the JJ group showed a greater effect on the maxillary teeth and the maxilla.

In a further study Altug et al. (2005) took a sample of Class II patients requiring unilateral molar distalisation and randomly assigned 10 patients to a group with asymmetric headgear attached to a removable plate and the other group were fitted with cervical headgear also applied to a removable plate. They used radiographic markers on molar teeth to identify molar tooth movement and to enable them to separate the molars being actively distalised from the molars on the passive side.

They did not report any data on the duration of headgear wear, or the duration of treatment. However they reported that distalisation was achieved in all patients, and they recorded 6.6mm of molar distalisation in both treatment groups, which represents highly successful treatment.

It was unsurprising in this study that a number of significant findings were reported, as the method included something of a 'ceph fest'. Twelve radiographic measures were used on the lateral cephalogram and thirteen measures on the somewhat unconventional analysis. When reporting the statistically significant results, there was no reference to the magnitude of the movements so their clinical significance could not easily be ascertained, the tables did not include units of measurement (mms or degrees) and different levels of statistical significance were used for the various reported measurements with no apparent consistency. It was

also noted that there were statistically significant rotations and distal tipping of the molar and premolar teeth, between 8 and 12 degrees. If these patients subsequently moved to fixed appliances, and full sized archwires were employed, much of the apparent molar distalisation would be lost, as the molars would upright and derotate.

Efstratiadis et al. (2005) analysed the results of a RCT involving either straight pull headgear or Function Regulator (FR) treatment. The investigators looked at both conventional cephalometry and at regional superimposition of radiographs on the cranial base and the maxilla. The 84 patients in the study were allocated to wear headgear for 14 hours per day, or the Frankel FR appliance for 16 hours per day. The authors judged 19 of the patients as 'non-compliant' and only included the 65 'compliant' patients in their final data set. This would certainly seem to contravene best practice of an 'intention to treat analysis' (ITT).

The concept underpinning the regional superimpositions was to allow a better understanding of conventional measurements, by including the effects of structural displacements. They quite rightly pointed out that a decrease in SNA after headgear use would leave the reader with the impression that point A had moved backwards, however a large contribution to this reduction was from a downward movement of point A, i.e. maxillary rotation. Forward growth of Nasion could also be the cause of the observed SNA decrease. They concluded that the main effect of the straight pull headgear, as used in their study, was on the maxilla and the maxillary molars, as opposed to the Function regulator that mainly affected the mandibular position, as well as affecting the maxillary

incisors, the mandibular molars and incisors. In this study the average distal movement of the upper first molars was less than 2mm.

Another RCT into anchorage methods was conducted by Bondemark and Karlsson (2005) where they randomised 40 11-year-old Scandinavian children. The children were allocated to treatment either with a cervical headgear or an intra-oral appliance comprising NiTi springs on a palatal wire between molar and premolar or second deciduous molar bands. The children were compliant with headgear and wore this with an average force of 400-500gm for 10.8 hours per day. The intra-oral appliance (IOA) was only activated once on insertion, and required no further adjustments. There were no dropouts after randomisation, although the authors noted there were four patients who refused to be included into the study at the outset.

The results of the study were that there was effective distalisation of the molars of 3mm, occurring over a significantly shorter time period of 5.2 months with the IOA, compared to a distalisation of 1.7mm over 6.4 months with the headgear. Interestingly the overjet increased by 1mm in the IOA because the Nance button clearly failed to provide complete anchorage support. In the headgear group the overjet actually decreased by 1mm and this would be a distinct advantage of this approach.

The cephalometric findings of a RCT comparing two different methods of anchorage reinforcement, in a series of 'maximum anchorage' cases were described by Benson et al. (2007). The study involved 51 orthodontic patients who were randomised for either Headgear, as the method of anchorage

supplementation, or placement of a mid-palatal implant under local anaesthesia. Following a 3-month healing period, to allow osseointegration of the implant, forces were applied to the anchor unit via a custom made palatal arch. The authors found that all the skeletal and dental cephalometric points moved mesially during treatment, more in the headgear group than in the implant group. The range of mesial movement of these landmarks was between 0.5mm and 1.5mm. None of the treatment changes between the groups were found to be statistically significant. They concluded that mid-palatal implants were as effective as headgear in reinforcing anchorage.

One criticism of this study is the failure to use molar markers to accurately identify the left and right molars. This would have allowed more accurate measurement of the effect of each treatment modality upon the molar teeth.

Sandler et al. (2008) described in detail all the clinical aspects of the above study. They pointed out that headgear and mid-palatal implants were equally effective in providing anchorage support and that despite the greater number of visits with the implant group, the overall treatment times were almost identical. This was the first time that palatal implants had been included in an RCT and though they reported a surgical success rate of only 75%, they reported an orthodontic success rate of 90%, which was in accordance with other studies looking at success of this particular method.

There were also no statistically significant differences in the Peer Assessment Rating (PAR) scores at the end of treatment between the two groups demonstrating an equally high standard of treatment in both groups of patients.

Once again, taking into account all the clinical aspects of treatment, it was concluded that there was little to choose between the two techniques, when considering the effectiveness of anchorage supplementation with mid-palatal or extra-oral anchorage. The factors that might determine the treatment choice therefore, will be patient preference for an implant or headgear.

2.3 SUMMARY OF HEADGEAR FINDINGS

It can be seen from the 8 RCTs described above, that a small amount of distal movement of the maxillary first molar teeth can be achieved with headgear. Usually the success of headgear is thought to be due to a combination of the force applied and the number of hours the headgear is actually worn.

Most clinical researchers applied a force of between 400 and 500gm, although one group used a force of 250gm and another group used 700gm per side. The requested duration of wear in study patients was generally 12-14 hours per day, and it is likely that the hours of wear is at least as important as the actual magnitude of the force applied. This aspect of the orthodontic treatment was generally continued for a minimum of 6 months and in one study for the entire treatment time that averaged 24 months.

In all but one study the movements achieved with the headgear were less than 4mm and in most studies the average movement was less than 2.2mm. In the one study that claimed over 6mm of molar correction, (Altug et al. (2005)), it was accepted that a significant amount of this movement was from molar tipping,

which is of little clinical use because as soon as the fixed appliances are placed, the teeth upright again, thus losing much of the apparent 'distalisation'.

It can be concluded from these studies that one could reasonably expect headgear in a cooperative patient, to at least provide stationary anchorage. This means that in 'maximum anchorage' cases, providing the patient was cooperative with all the reasonable demands made of them, it should be possible to avoid a significant amount of mesial molar movement during the anchorage supplementation phase of treatment.

2.4 THE NANCE PALATAL ARCH

In the United Kingdom at this current time, amongst both patients and clinicians, there is a general dislike of headgear and all reasonable alternatives are usually explored. This was illustrated by the results of a survey of specialist orthodontists carried out by Banks et al. (2010). In this study they gathered the opinions of 935 practicing specialists on all aspects of fixed appliance treatment and the authors had a 66% response rate. When asked specifically about anchorage supplementation techniques, only 38% of respondents said they were using headgear routinely. When broken down on a regional basis, 45% in the North of England responded positively to the routine headgear query. In this study, 20% of respondents confided that they did not use headgear at all.

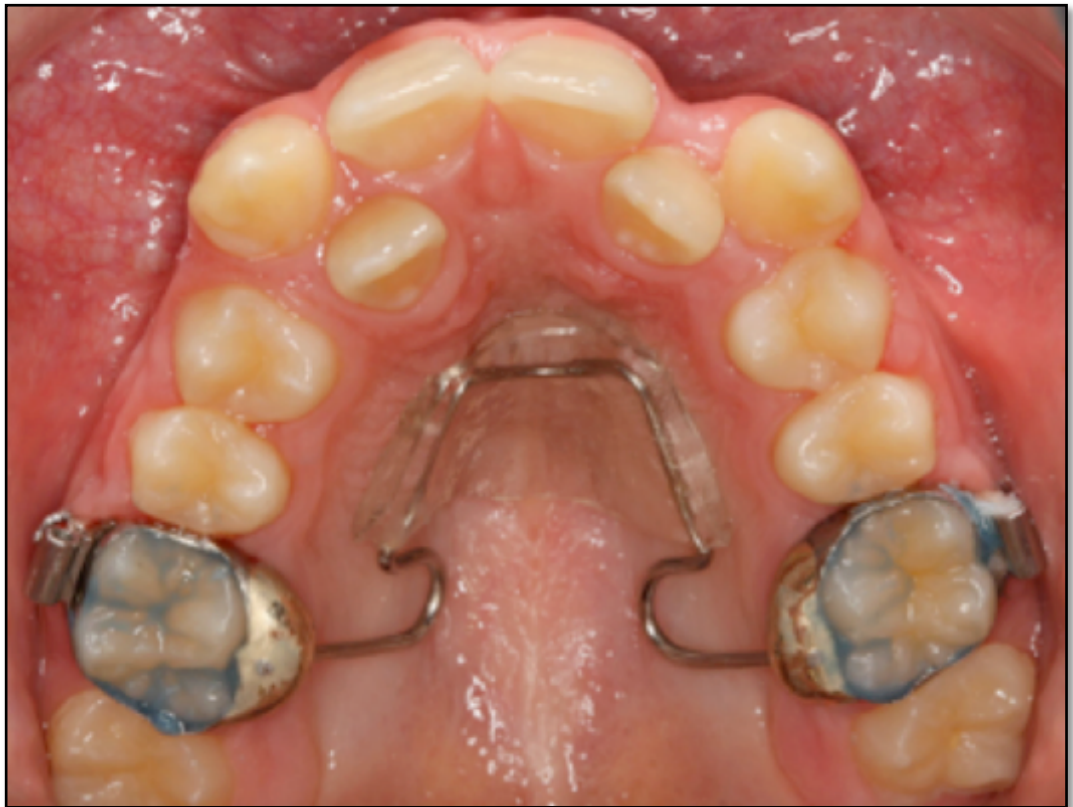


Figure 2.2 Acrylic Nance button added to the palatal arch to supplement anchorage

A commonly used alternative to headgear is the use of a palatal arch either with or without a large acrylic Nance button (Figure 2.2) Dr Hays Nance first described this modification to the simple palatal arch in 1947. The theory behind the palatal arch is that the 0.9mm stainless steel wire connecting the two teeth fixes the intermolar distance. This means that if the molars were to move mesially the buccal roots would press on the cortical bone, as the arch became narrower as they moved forward, thus providing 'cortical anchorage'. Even if there was a slight tendency for mesial movement of the molar teeth, this would be further resisted by the acrylic button added onto the anterior part of the palatal arch referred to as the 'Nance button'. This is meant to cover the vertical part of the hard palate and to be kept 2-3mm clear of the gingival margins to minimise the chances of any irritation.

Clinical problems with the Nance button have been listed in a recent article by Singh and Cox (2009) and include: breakage, irritation of the gingival tissues, poor oral hygiene under the button and more seriously deep embedding in the tissues leading to soft tissue overgrowth, denudation of palatal bone and damage to the palatal roots of the incisor teeth. Treatment to correct one adverse event involved immediate removal of the appliance, prescription of antibiotics and periodontal flap surgery. Fortunately reports of problems with Nance buttons are rare and in a response to this particular case Morris (2010) implied that an inappropriate treatment plan by an inexperienced operator, using a poorly designed appliance was the probable cause of the problem, rather than any inherent problem with the Nance button.

There have been several studies that have investigated the effectiveness of palatal arches and most of these have been retrospective. There has only been one RCT (Stivaros et al. (2010)). This was a two-centre trial evaluating the effectiveness of the Goshgarian and the Nance palatal arches. They also evaluated patient comfort and ease of removal.

A sample size calculation indicated 57 patients should be included in the study and 86% of these patients completed the trial period. The molar movements were assessed using a sophisticated method of 3D scanning of the T1 and T2 plaster models of the upper dental arch. The results showed that there were no statistically significant differences between the two interventions in terms of mesial drift or distal tipping however the Goshgarian palatal arch allowed more disto-palatal molar rotation than the Nance arch. This was despite neither

appliance having been activated in any way or form. Pain scores, which had been recorded by the patients on a 7-point Likert scale, also differed with the Goshgarian being more comfortable than the Nance palatal arch. The authors concluded there was no preference of one type of palatal arch over the other, unless the slightly increased discomfort with the Nance was considered significant.

While the results of this study were interesting the study is of doubtful clinical relevance because they only evaluated tooth movement during the levelling and aligning stage of treatment. As a result, they did not evaluate tooth movement during the application of force to the molar teeth when retracting canines and/or reducing the overjet. This is important because when we consider anchorage reinforcement, it is during this stage that the need to prevent mesial molar movement is the most critical.

2.5 MINI-IMPLANTS

Titanium dental implants were developed in Sweden during the 1970s and since this time they have been used extensively in the USA and Europe mainly to replace missing teeth. They offered an acceptable solution to both single and multiple edentulous spaces where the general dental health was of a good standard. For implants to be successful in general dentistry, the titanium surface must form a mechanical bond with the bone and become osseointegrated. As a result it appeared that osseointegrated implants might have a role to play in reinforcing orthodontic anchorage as they provide a stable point from which force can be applied and may therefore be a viable alternative to headgear. If these implants were placed in the mid-palate and could be satisfactorily attached to buccal segment teeth they could act as anchorage devices.

As long ago as 1983 Creekmore and Eklund described a technique of anchorage reinforcement using small, non-osseointegrating 'mini-implants'. These small screws were placed in a patient's maxilla above the upper anterior teeth and were successfully used to intrude these teeth. Since then many case reports and case series have been published in the orthodontic literature.

Skeggs et al. (2007) published a Cochrane review on mini-implants or Temporary Anchorage Devices (TADs) in which they examined all the randomised or quasi-randomised studies purporting to investigate surgically assisted anchorage supplementation. They only found one study, by Benson et al. (2007), that could be considered to be of 'Cochrane Quality' from which they concluded that there was limited evidence to suggest mid palatal implants are effective in assisting

anchorage support. The quality of all other studies before 2007 was considered poor and their recommendation was that more RCTs are required.

A RCT using osseointegrated implants for anchorage supplementation was carried out in Chesterfield by Sandler et al. (2008). This study described the treatment process in detail and demonstrated that both headgear and mid-palatal implants were successful for anchorage supplementation and also that the palatal implants were well accepted by the patients. Sadly, at the end of 2008, the mid-palatal implants were taken out of production, despite the fact that they had been scientifically proven to work effectively. The manufacturers (the Straumann Company) felt they would never appeal to anything more than a 'niche market'.

A systematic review of the literature by Reynders et al. (2009) using the subject heading 'orthodontics', and keywords: implant, screw, mini-implant, mini-screw, micro-implant, screw implant, and temporary anchorage device revealed 3364 abstracts, all of which were read to identify high quality scientific studies. At the initial assessment stage of the review 3312 were excluded from the review having fallen foul of general selection criteria leaving 52 abstracts for further review. These 52 papers were analysed and a further 21 were excluded, again on the general selection criteria (they were only interested in miniscrews for orthodontic anchorage, human studies, minimum of 10 patients, implants <2.5mm diameter, studies not involving miniplates). Another 12 were then excluded on specific selection criteria (success not defined, force duration not specified, study < 3 months, studies that failed to measured success at predetermined time).

This, therefore, left only 19 articles of which fewer than 50% were prospective studies. The validity of the conclusions from these studies were rated as clear (5), partially clear (8) and unclear (6), and detailed explanations were offered of the grading given. None of the 3364 articles was a RCT, and the authors noted, agreeing with Skeggs et al. (2007), that high quality studies in this area of orthodontic research were absolutely essential, and that scientific study into this area, really was in its infancy.

2.5.1 FAILURE RATE OF TADS

Mini-implants have become extremely popular over the past couple of decades as they are considered to be a simple and cheap way of offering an alternative to more traditional methods of anchorage reinforcement that often rely heavily on patient compliance. The ability of these small implants to remain stationary within the bone and the lack of significant disadvantages or problems with the technique was discussed by Liou et al. (2004).

Complications with TADs have however been described by Melsen and Verna (2005) and efforts have been made by these authors to iron out some of the potential problems by modifying both the implant and the technique. The Aarhus system was eventually the one proposed by Dr Melsen and is the one used in this current study.

Many factors have been suggested as possible contributors to the failure of TADs, for example injury to adjacent structures (periodontal membrane, roots, blood vessels and nerves) can lead to inflammation and infection.

The site of TAD placement has been suggested as an important issue and the recommendation was made that attached gingivae is more appropriate than moveable mucosa (Miyawaki et al. (2003)). The time period after loading was suggested to be important by Weichmann et al. (2007), who found most failures in their studies occurred within 5 months of loading.

Papageorgiou et al. (2012) carried out a meta-analysis following guidelines covered in the PRISMA statement detailed in the Cochrane Handbook for Systematic Reviews of Interventions. (Version 5.1.0). The authors not only included RCTs but also prospective controlled trials and prospective cohort studies. The meta analysis was aimed at identifying possible risk factors affecting mini-implant failure and a minimum of five studies covering the same specific aspect of treatment was required for inclusion in the analysis. Any comparisons that occurred with less than five studies to back them up were merely described as exploratory analyses.

Their initial search revealed 4491 articles that were reduced to 4115 once the duplicates had been removed. 3954 of these articles were then removed as the title and abstract indicated their inadmissibility and 109 articles were also removed after the full text revealed flaws. The 52 remaining studies were categorized into 5 RCTs, 8 prospective controlled clinical trials and 39 prospective cohort studies.

The total included 4987 implants placed to supplement anchorage in 2281 patients, which revealed an overall failure rate of 13.5% (95% CI, 11.5–15.8). A meta-analysis limited to trials of over 100 miniscrew implants yielded a failure rate of 14% (9.5-17). No difference in failure rates were observed when gender or

age were used, nor was thread diameter or length shown to play a part. Side of implant placement (left vs right) and site of placement (buccal vs lingual) was also irrelevant. However jaw of placement showed differing success rates, mandibular implants failed in 19.3% of cases and maxillary implants in 12%.

Exploratory analyses (those with fewer than 5 studies to support them) must be viewed with caution, but there was no effect of self-drilling vs no self-drilling, the type of tissue into which the implant was placed made no difference i.e. attached vs moveable mucosa, and the time of loading (immediate vs > 2 weeks) appeared not to effect the success of the technique. Root contact during insertion increased the failure rate from <8% to 29% so this is clearly one event to be avoided.

The overall miniscrew implant failure rate is similar to that found in the previous systematic review (16.4%) carried out by Schaeztle et al. (2009). Only one paper, Cheng et al. (2004) made reference to the possibility of overheating when drilling sites of dense cortical bone and these authors recommended constant irrigation with saline throughout the placement to prevent necrosis.

The higher failure rate in the mandible (19.3%) compared to the maxilla (12%) was attributed to: (1) greater density of bone requiring greater insertion torque, (2) overheating, (3) less cortical bone around the implant, and (4) narrower vestibule leading to inadequate cleaning.

The strength of the above meta-analysis is that despite strict inclusion and exclusion criteria it included a large number (52) of published studies. Where

possible between-studies heterogeneity and publication bias was minimized and the robustness of the failure estimates were checked and only risk-factor studies were included. The arbitrary level of five studies was chosen; any factors studied with fewer than five supporting studies was listed under ‘exploratory’ comparisons which require further RCTs before their effect can be verified.

2.5.2 CONCLUSIONS ON TADS FAILURES

The modest mean failure rate of 13.5% indicates the usefulness of this technique in orthodontic practice. Many of the previously held beliefs about the age and gender of the patient, or the site of the implant, or the method of drilling or timing of force placement, were all found not to affect the success or failure of the technique.

This meta-analysis reiterates the assertion of the previous systematic review of Reynders et al. and the conclusions of the previous Cochrane review by Skeggs et al. (2007) that more RCTs need to be carried out into this area.

2.6 UPDATE OF THE COCHRANE REVIEW

The most relevant piece of work pertinent to my study was the systematic review of the literature carried out by Skeggs et al. (2007), which had the aim of evaluating the effectiveness of surgical methods of reinforcing anchorage compared with more conventional methods. Other objectives were to report on failure rates, discomfort and patient acceptance of the particular techniques.

The authors examined all randomised and quasi-randomised clinical trials using surgically assisted anchorage reinforcement techniques and two reviewers independently assessed the data. The results were collated then entered into RevMan. Analysis of mean differences and 95% confidence intervals for continuous data was reported along with risk ratios and 95% confidence intervals for dichotomous data. Only one study was judged of sufficient quality for a scientific assessment of effectiveness of surgically enhanced anchorage: Benson et al. (2007).

In 2009 the original Cochrane review of Skeggs et al. (2007) was updated. I participated in this update together with Dr Safi Jambi and Professor Kevin O'Brien of Manchester University. Following the Cochrane guidelines the same search criteria and Medline search strategy as used by the original authors was used, the details of which can be seen in Appendix 1 of this thesis. The aim of the update was once again to identify any randomised clinical trials that used surgically assisted anchorage reinforcement.

Electronic searching of the following databases was carried out: Cochrane Oral Health Group Trials Register (searched 1 February 2006), Cochrane Central

Register of Controlled Trials (CENTRAL), The Cochrane Library 2006, Issue 1, MEDLINE (1966 to 31 January 2006) and EMBASE (1980 to 1 February 2006).

The journals that were hand searched included: American Journal of Orthodontics and Dentofacial Orthopedics, Angle Orthodontist, European Journal of Orthodontics, Journal of Orthodontics, Orthodontics and Craniofacial Research, Journal of Dental Research, Journal of Dentistry, Journal of Clinical Orthodontics, Clinical Oral Implant Research, Orthodontics and Craniofacial Research International, Journal of Oral and Maxillofacial Implants, Clinical Implant Dentistry and Related Research, and Implant Dentistry.

The results of the initial electronic and hand search of the relevant literature revealed 108 initial reports. The titles and abstracts of each report were reviewed by two reviewers (PJS and SJ) and the decisions recorded on the 'surgical reinforcement of anchorage during brace treatment' form. Two basic questions were asked: was it a clinical trial, case controlled study or case series involving humans and is surgical anchorage involved? If the answer was yes to both of these questions then it was deemed worthy of further investigation and the outcome of each assessment of all 108 papers was recorded on the initial assessment sheet (Appendix 2).

Each author assessed the forms individually and recorded the result on a basic inclusion sheet. The results from both reviewers were then tabulated listing the 108 papers initially picked up by the search. A note was made if each reviewer put the study down for inclusion or exclusion and a third column listed whether the two reviewers agreed or disagreed on the outcome. Where there was agreement

the studies were either included or excluded accordingly and when there was an area of disagreement the paper was discussed and a consensus view agreed and recorded. In the case of on-going disagreement then a third assessor (KO'B) arbitrated.

There was agreement that further data extraction was required on 10 of the 25 papers and that 7 could be excluded at that stage. Both reviewers felt that 2 papers were 'unclear' and further clarification was required and on five papers there was disagreement and further discussion was required. It was felt that there was missing data from one paper and an attempt would be made to retrieve the data.

A final column was agreed upon that then listed at the top, the 25 papers that were to be investigated further and the 83 papers that were going to be excluded from further assessment, (Appendix 3).

The 25 papers still in the study were then obtained and printed in full and sent to each of the reviewers for the next stage of the process. The 'Study Eligibility Form' (Appendix 4) applied to all 25 papers included four questions:

Is the study a RCT?

Are the participants having brace treatment?

Are there two groups of patients, at least one with surgical anchorage?

Were outcome measures reported?

The answers to each question could be Yes, Unclear or No

If the answers to the four questions were 'Yes' the author would decide to include the study in the list for further investigation. If a decisive 'No' was recorded for

any of the four questions then the study was excluded and the reason for excluding the study was listed. At this stage 11 of the 25 reports were excluded: four because of non-random assignment of patients to particular treatment modalities, three because the method of patient treatment was not relevant to our study and four because the outcome measures were not relevant.

Three reports were still unclear and I attempted to contact the three authors to obtain further clarification. One author replied stating that there was non-random allocation of patients and therefore this study was excluded. One author failed to reply, and it proved impossible to track down the contact details of the third author. These final two papers were therefore also excluded from further investigation. A flow diagram of progression of the papers through the study can be seen in Figure 2.3.

Eleven reports from the original 108 papers were deemed worthy of comprehensive data extraction. Each reviewer, on three selected papers, independently piloted a data extraction form and after discussion further modifications of the form were made (Appendix 5). This final form was then used to perform data extraction on the 8 studies, which represented the 11 reports still included in the sample. One of these papers was written in Chinese and it was not possible to obtain a satisfactory translation, to allow adequate data extraction.

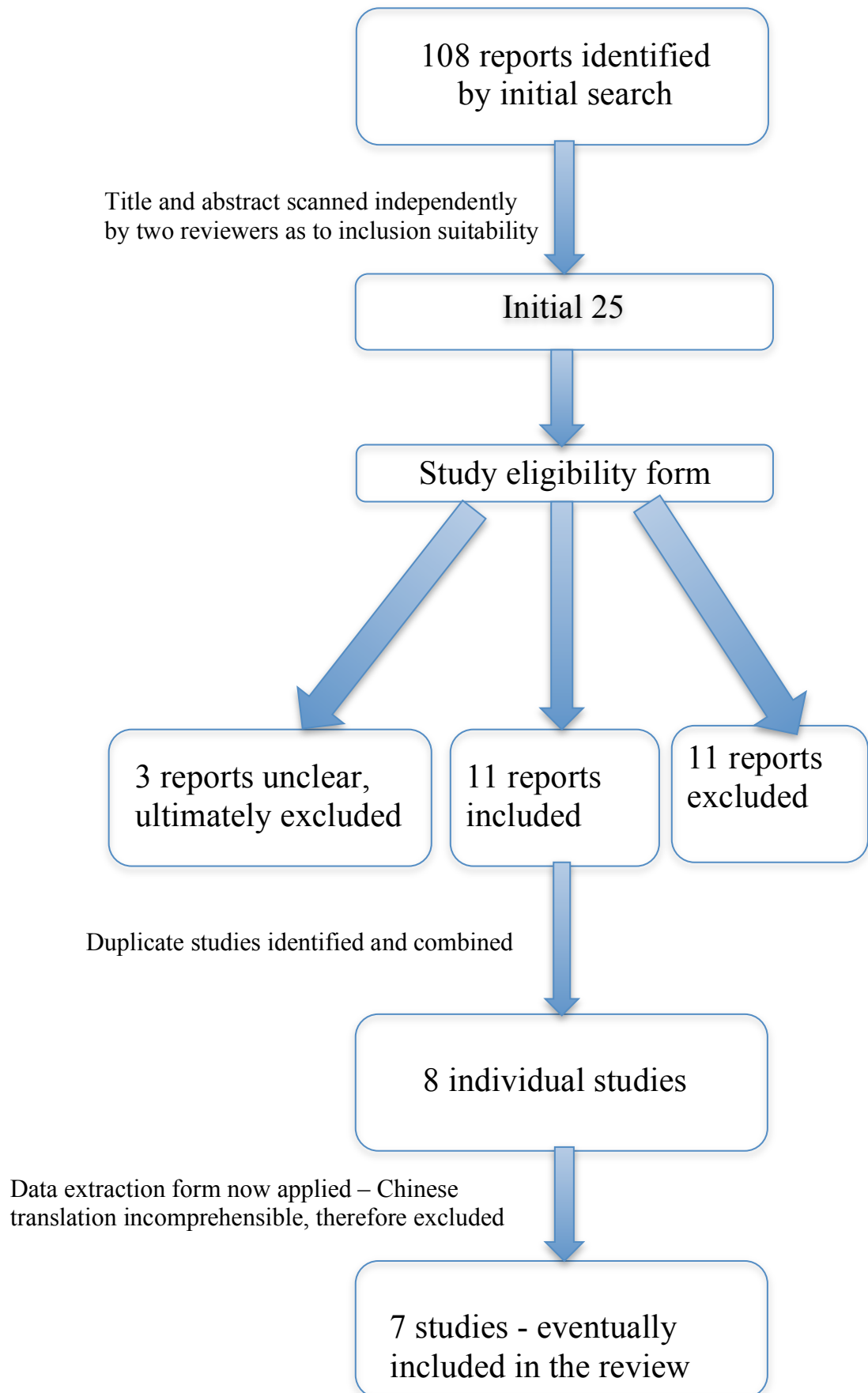


Figure 2.3. Flow diagram of |Cochrane update of TADs for anchorage 30

Seven studies were therefore found to be appropriate for adequate data extraction and therefore inclusion in this review. These were Benson et al. (2007), Feldmann and Bondemark (2008), Garfinkle et al. (2008), Jackson et al. (2008), Upadhyay et al. (2008a), Upadhyay et al. (2008b) and Jung et al. (2010).

Primary outcome measures were looked for in these seven studies. We wanted to identify those that recorded mesial movement of maxillary molars, measured in millimetres. Studies recording these primary outcomes were Benson et al. (2007), Feldmann et al. (2008), Upadhyay et al. (2008a) and Upadhyay et al. (2008b). At least one of the secondary outcome measures of interest was referred to in the other three studies namely: success rate, pain and discomfort, number of visits, treatment duration and acceptability of the anchorage device.

Due consideration was given to the quality of all of the studies and it was generally felt that the quality was not very high. We took into account allocation concealment, blinding and information given on the subjects who withdrew from the studies. In only one study did the two independent assessors rate the methodology 'A' and that was the study by Benson et al. (2007).

The main source of bias was inadequate concealment of the allocation sequence. The Benson et al. (2007) study suffered from the fact that the person generating the sequence was actually involved in treating a few of the patients. Envelopes were also kept at the treatment centres and theoretically could be tampered with.

The same criticism could be made of the Feldmann (2008) study. In the Upadhyay¹ (2008a) study a statistician generated the allocation sequence and the operators were blinded, but no details were given as to how the sequence was kept. In the Upadhyay² (2008b) study the allocation sequence and concealment were not specifically mentioned.

The flip of a coin was used in Garfinkle et al. (2008), for sequence generation that is considered an inadequate method for allocation by the CONSORT group as it can apparently be manipulated.

Jackson et al. (2008) used computer generated permuted blocks, which were sealed in a brown envelope by a third party and only opened immediately before implant placement. Again centralised storage of the envelopes and tamper proof envelopes lined with foil or thick paper would have been the ideal method.

Blinding of the person doing the radiographic assessment of the various treatment groups is thought to be important. Only in the Benson et al. (2007) study can it be said with confidence that blinding was definitely performed. In the other studies blinding was either clearly not performed, or it was unclear as to whether it had been carried out.

2.6.1 Comparison 1: Mesial movement of the upper first molar between surgical and conventional anchorage

When examining maxillary molar movement in the TAD group Upadhyay et al.(2008a) reported a net distal movement of the molar (-0.78 ± 1.35)($p<0.05$). These differences were significant when compared to conventional methods of anchorage reinforcement such as palatal arches, headgear, banding of second molars and application of differential moments, all of which were applied as necessary. Anchorage loss when conventional anchorage methods were used was measured as mesial movement (3.22 ± 1.06 mm) ($p<0.001$). From this RCT the authors concluded that mini-implants provided a stable source of absolute anchorage for en-masse retraction of the anterior teeth. The success rate was high (93%) but no statistically significant shortening of the treatment time was found. Molars were actually distalised and intruded when TADs were used as opposed to the horizontal and vertical anchorage loss seen with conventional methods of anchorage reinforcement.

The same group of authors conducted a second RCT, this time on maximum anchorage cases requiring just upper premolar extraction, instead of upper and lower arch extractions (Upadhyay et al. (2008b)). En-masse retraction of the anterior teeth was once again assisted by TADs or by conventional methods of anchorage support such as headgear, palatal arches and inclusion of second molars, depending upon the needs of the case. Comparing lateral cephalometric radiographs before retraction started, with radiographs after all extraction space was closed, allowed assessment of mesial molar movement. Maxillary molars moved distally (-0.55 ± 0.98 mm) in the TAD group compared with anchorage

loss seen as mesial movement (1.95 ± 1.19) in the non-TAD group relying on conventional methods. The success rate of the implants was slightly lower in this study (87%), however each one that was lost was replaced after 6 weeks of healing. Treatment times for space closure were similar in the two groups. Upadhyay et al. (2008b) concluded that TADs prevented loss of anchorage both in the vertical and horizontal plane compared to conventional methods of anchorage reinforcement, however a decrease in intermolar width was noted.

The results of the four studies recording this primary outcome measure of interest are shown on the Forest plot (Figure 2.4).

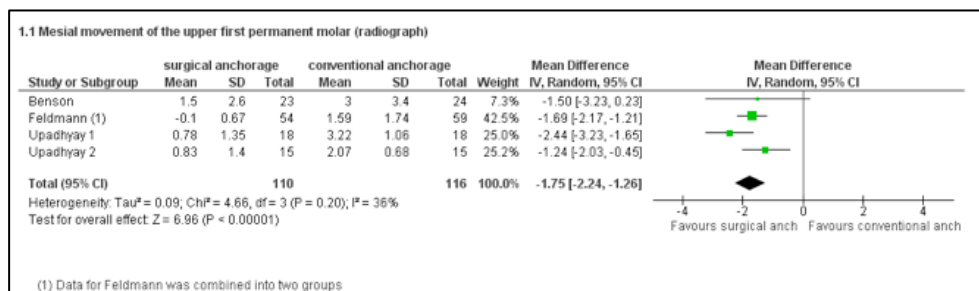


Figure 2.4. Mid-palatal implants are seen to be more effective than conventional methods in reinforcing anchorage, although there was moderate heterogeneity, (Cochrane Review on TADs Safa, Sandler, O'Brien, in Press).

2.6.2 Comparison 2: Mesial movement of the upper first molar between mid-palatal implant and headgear.

Feldmann and Bondemark (2008) conducted the world's first study that compared two osseointegrated palatal anchorage systems as to their anchorage reinforcement capabilities. They were compared with headgear and a trans-palatal arch in cases requiring upper premolar extractions. The onplant allowed very slight mesialisation of the maxillary molars (0.1mm; S.D. 0.42) and using the

Orthosystem implant the molars exhibited very slight distalisation (-0.1mm; S.D. 0.82). Both of the conventional methods allowed anchorage loss and this was smaller with the headgear group (1.2mm; S.D. 1.96) compared with the palatal arch group (2.0mm; S.D. 1.39).

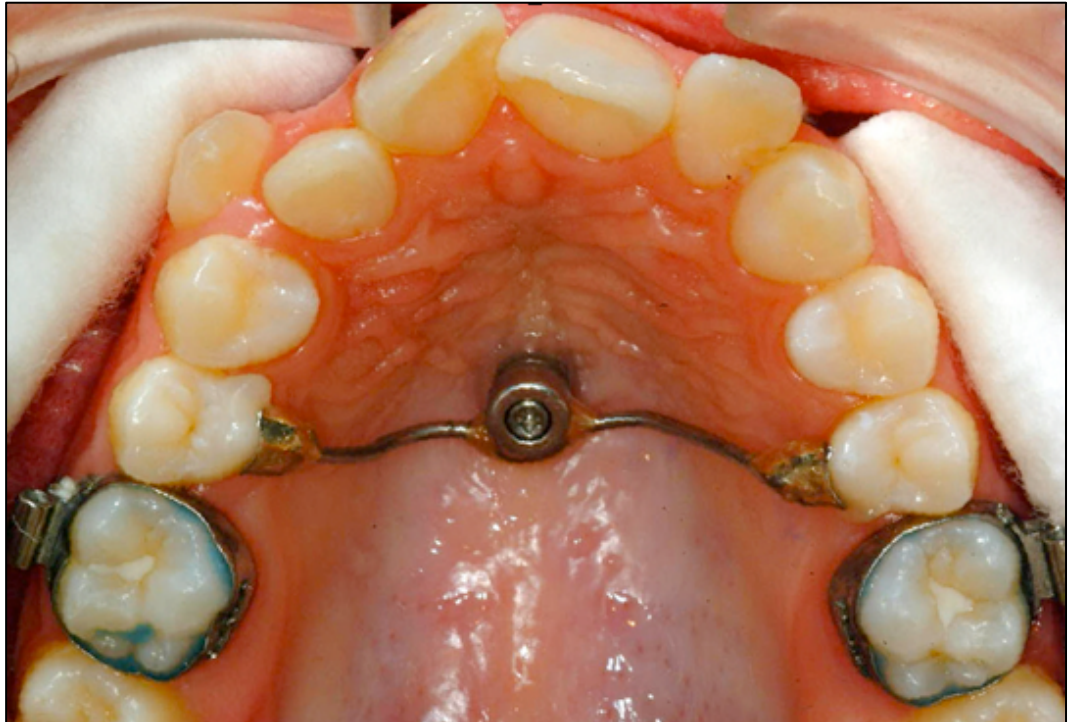


Figure 2.5. Orthosystem mid-palatal implant provides excellent anchorage support

They defined unacceptable anchorage loss as greater than 1 mm of mesial molar movement and therefore concluded that the Orthosystem implant was the one to use if maximum anchorage was required (Figure 2.5).

The Feldman and Bondemark (2008), and the Benson et al. (2007) study both compare these two methods of anchorage reinforcement. A fixed effects meta-analysis was used to combine these two studies (Figure 2.6).

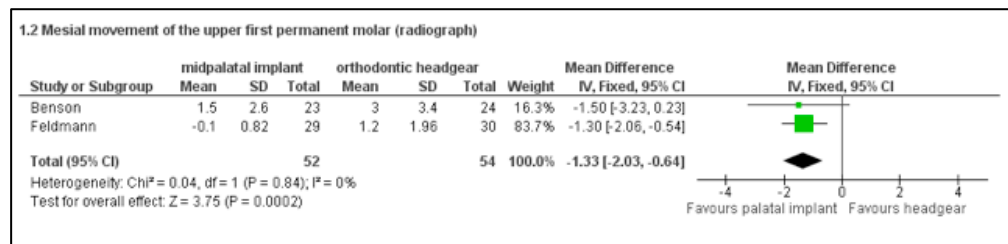


Figure 2.6. Forest plot demonstrates that the mid palatal implants are more effective than conventional methods, (Cochrane Review on TADs Safa, Sandler, O'Brien, in Press).

2.7 SUMMARY OF THE LITERATURE ON SURGICALLY ASSISTED ANCHORAGE SUPPORT

In the studies analysed in this systematic review the primary outcome measure was anchorage loss, however the methods of measuring this aspect of treatment were not identical in each study. Benson et al. (2007), in their study of mid-palatal implants versus headgear, when assessing anchorage loss concentrated on the maxillary molar position comparing the start of treatment position with that at the end of anchorage supplementation. In this study no statistically significant differences were identified between the two groups.

Three time points were used by the Feldman group when measuring anchorage loss, comparing two types of mid-palatal implant with headgear and palatal arches. Combining the two surgical methods and likewise combining the two conventional methods of anchorage supplementation allowed the four different interventions to be handled. They first measured the molar position at the start of treatment to the end of leveling and alignment, and then again measured molar position from this point to the end of space closure, and finally calculated the overall anchorage loss. The difference in anchorage loss between cases using

implants and cases relying on conventional methods of anchorage support did reach statistical significance, and the difference was in favour of palatal implants.

The Upadhyay studies (2008a & b) compared TADs with conventional anchorage comprising headgear, palatal arches and banding of second molars 'where necessary'. Both studies measured the maxillary molar position from the start of treatment to the end of space closure and both found in favour of TADs, the results being statistically significant. They gave no clear indication however, in either study, how many patients required each of the specific conventional anchorage supplementation interventions. It was also a slightly spurious comparison between whether to use TADs or band the second molars, as it is normal practice to include second molars unless there is an indication not to do so.

Secondary outcome measures included the success rate of the anchorage supplementation technique, as well as specific aspects of the treatment process including: length of treatment, number of visits and the patients' perception of the particular treatment they received. The problem with comparing success rates is that the different groups measured success in different ways. The Feldmann group reported surgical and conventional anchorage success but the other studies merely recorded the success rates of the surgical anchorage technique.

Surgical success was defined by Sandler et al. (2008), as whether or not the palatal implant osseointegrated successfully and, using this definition, approximately 25% of the implants failed. Orthodontic success of the implant however, was defined by whether or not anchorage supplementation was ultimately provided by palatal implants or not (the original or a subsequent

replacement), in which case the success rate was closer to 90%.

Upadhyay et al. (2008a) and (2007)) defined success as when the TADs were stable throughout the space closure phase of treatment, but if they loosened and fell out they were deemed to have failed. Their final success rates were reported in the two studies as 93% and 87% respectively.

Anchorage loss of less than 1mm, with no failure of osseointegration, was a definition of success by the Feldmann group, when comparing their two palatal implants with headgear and palatal arches. An 83% success rate was recorded with the Nobel Biocare onplant compared with a 93% success rate with the Straumann, Orthosystem implant. These were in stark comparison to the 47% success with the headgear group and 28% success recorded with the palatal arch group. The large failure rate with the latter two groups were recorded because there was > 1mm anchorage loss.

Had this definition, depending upon <1mm of anchorage loss for success, been used for the Benson et al. (2007) study, then their reported failure rate would have been much higher, as the mean average anchorage loss was 1.5mm in the implant group and 3.0mm in the headgear group.

Early loading of the implants was compared to delayed loading in the Garfinkle et al. (2008) and the Jackson et al. (2008) study, with the former looking at TADs and the latter studying mid-palatal implants. They both defined success as the ability to use the implant for anchorage supplementation throughout the treatment. Success rate of TADs was reported at 80% both for the early loaded and the

delayed loaded implants and for both types of palatal implants the success rate was greater, at 95%.

Sandler et al. (2008) was the only study to report on the number of patient visits, which was 26.21 (SD 7.41) in the implant group, compared with 19.29 (SD 4.58) in the headgear group. This difference was statistically significant, but could be explained by the additional number of visits the patient required specifically for issues surrounding the surgical assessment, subsequent placement and follow up of the implant, and then subsequent surgical removal of the mid-palatal implant and associated follow up appointment.

Despite the additional visits required by the patients having surgical anchorage supplementation, the mean duration of active treatment was not significantly different: 2.15 and 2.23 years for the implant and headgear groups respectively. The additional 3 months taken for osseointegration was, of course, not included within the record of active treatment time.

Treatment duration was also considered in both of the Upadhyay studies, however they only looked at the time taken for space closure, with the TAD group compared to the headgear group. In their first study (Upadhyay et al. 2008a), time for space closure was measured at 8.6 months for the group requiring surgical anchorage supplementation compared to 9.4 months when conventional anchorage was employed. This difference in treatment timings was not statistically significant. In their second study (Upadhyay et al. 2008b) the mean time for space closure was 9.2 months in the surgical anchorage group compared to 10.6 months when conventional anchorage was used. The missing standard

deviations in the Upadhyay et al. (2008b) study meant these results could not be combined to be included in the meta-analysis.

Patient perception of treatment is an increasingly important factor to be studied. In these investigations the authors included questions on the pain and discomfort associated with placement and removal of the anchorage device. This was a secondary outcome measure reported by Sandler et al. (2008), Feldmann et al. (2007) and Garfinkle et al. (2008). The latter two groups used visual analogue scales ranging from no pain (0) to very painful (100).

Feldmann et al. (2007) measured pain at a number of stages; including at injection, on implant placement and after extractions both the evening after the surgery and also one week after the surgery had been carried out. In their study pain during anaesthetic placement was similar with a median score of 15 (0-72) for Nobel Biocare onplant, 16 (0-84) Orthosystem and 10 (0-55) for premolar extractions. Thankfully, the pain during the actual surgery was much less, with scores of 3(0-14), 3(0-16) and 4 (9-28) respectively. The evening after the surgery pain levels were high with Nobel Biocare (38; 0-100), low with Orthosystem (5; 0-90) and intermediate with premolar extractions (28; 0-100). One week after surgery the pain was insignificant in all three groups.

In the Garfinkle et al. (2008) study the patients were asked to record the pain 1) on TAD placement, 2) during treatment, and 3) on TAD removal. The scores again on a range of 0-100 were recorded as 54.77 (SD 35.1), 35.92 (SD 28.53) and 27.1 (SD22.78) respectively.

The assessment of pain was simpler in the Sandler et al. (2008) study as a six-point scale was used where 1 indicated maximum discomfort and 6 was totally comfortable. The questionnaire was completed on placement, after 3 days and on removal of the implant. 75% of the respondents listed the score 4-6 both on placement and after 3 days however on removal more discomfort was recorded, with 20% scoring 1 and 40% scoring 3. Only 40% scored the palatal implant removal as a comfortable procedure.

Li et al. (2011) published a systematic review looking at all the studies that compared the anchorage capacity of implants and headgear, when looking at anterior segment retraction. Whilst the initial search revealed 35 articles, only 8 studies met all the inclusion criteria. Two of the studies (Huang and Han (2007) and Qin and Mao (2008)) reported significantly less mesial movement of the molar teeth in the mini-implant group than with the headgear group.

2.8 CONCLUSIONS ON SURGICALLY ASSISTED ANCHORAGE

There are only a few studies of high quality with low risk of bias identified in the literature, comparing surgical reinforcement of anchorage with more conventional methods.

When data was combined using Cochrane guidelines in a meta-analysis, a statistically significant result favouring the surgically assisted anchorage was obtained.

There is still a need for more RCTs to strengthen the evidence to allow us to make

even more reliable recommendations about the anchorage supplementation value of TADs, compared with more conventional methods of anchorage support.

2.9 THREE DIMENSIONAL MEASUREMENTS AND ORTHODONTICS

Three-dimensional measurements have always been a goal of orthodontists. Since the introduction of the cephalostat by Broadbent (1931), in an attempt to standardise lateral cephalometric radiographs, suggestions were made that 3D measurements had more value than the traditional 2D measurements. These pioneers attempted to introduce coordination of lateral and posterior-anterior (PA) radiographs to the orthodontic community using ‘the Orientator’, Figure 2.7. The patient was placed in the cephalostat, which after taking the lateral cephalogram was rotated through 90 degrees to allow a PA cephalogram to be obtained, without the patient having moved at all. Points were then identified on both views and corresponded on ‘the Orientator’ which could be then said to be a two dimensional representation of the three dimensional position of the landmarks. The aim was to compensate for the inherent distortions due to the spread of the x-ray beam.

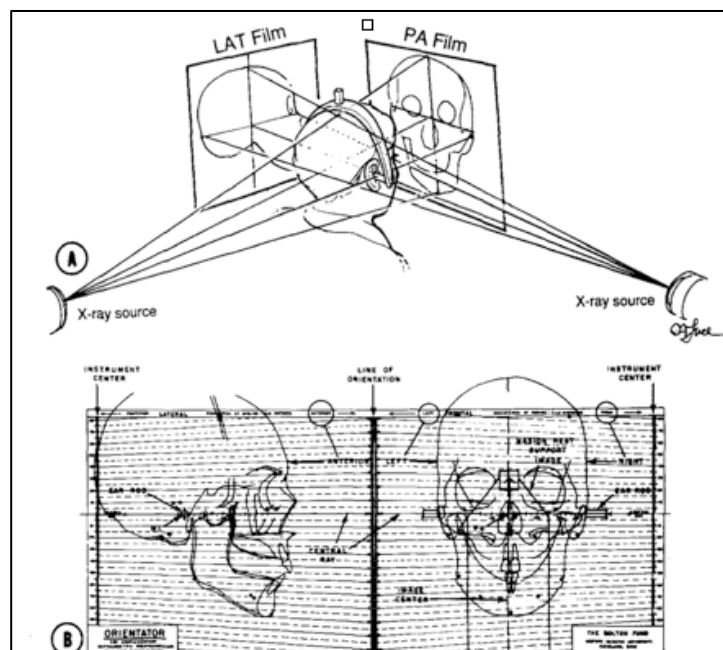


Figure 2.7 The Bolton Orientator - 3D representation of 2D points from Broadbent (1931)

This development was not accepted into routine practice by orthodontists because they maintained that orthodontic problems were usually symmetrical and there was no need for a PA view. Furthermore if there were distortions on a lateral cephalogram, these were the same for all patients, as a result they could be largely ignored. This perception remains today as evidenced by the fact that most cephalometric projects are based on averaging out the position of the right and left upper first molar.

Other workers such as Baumrind, Moffet and Curry (1983), have used true three-dimensional cephalograms using coplanar cephalometric stereo pairs but the disadvantage of needing expensive machinery for visualising the reconstructed form was highlighted. The other recognised problem with all the new techniques was an absence of normative data.

When considering the technique of three-dimensional cephalograms Grayson et al. (1988), pointed out that the technique will proceed more accurately if bilateral landmarks on the lateral film have not been averaged.

Burstone et al. (1982) made early attempts at measurement of tooth movement in three dimensions. They used pulsed laser hologram interferometry to measure the effect of axially directed forces on maxillary central incisors. The technique involved splitting the laser beam into two to allow one beam to illuminate the subject and the other to be steered towards the high-resolution photographic plate to produce the hologram that allowed reconstruction of a 3D image of the subject. The pulsed laser had extremely short exposure times hence eliminating the effects

of movement, and holograms were repeated 4 times at 30-second intervals to see the immediate effects of the axial loading. Four subjects were tested with forces of 200gm and 300gm, which produced measurable tooth movement over the two-minute time interval and the translation and rotation allowed calculation of centres of rotation that were found to lie at a vertical level coincident with the root centroid.

In 1985 the first publications started to appear detailing attempts to use laser scanning as a tool for prediction and planning in maxillofacial surgery. For example Arridge et al. (1985) listed the potential benefits of this approach including integration of soft tissue scans with the information obtained from CT scans of the underlying hard tissues. They gave details of the early attempts at data acquisition along with how the two data sets were subsequently managed. The main limiting factor was the processing speeds of the computers and the choice of hardware to manage even a few thousand triangular surface elements was critical. The need to set up a database was stressed so that the simulated tissue behaviour following reconstructive 'surgery' bore some relation to reality.

An attempt to start compiling a database of 3D facial form was made by Ferrario et al. (1995). They used an automated infrared photogrammetry system to record 22 standardised soft-tissue facial landmarks on 40 men and 40 women selected for their dento-facial 'normality'. Facial volumes were calculated and sample variability described. They felt that in the future non-invasive surface measurements would be employed with or without conventional radiographic data to allow classification of facial types.

2.10 SUPERIMPOSITION OF 3D MODELS

An early attempt to make 3D measurements on dental casts was described by Le Bret (1962) who found inter-rugae distances to be constant, particularly those near the midline. Peavy and Kendrick (1967) found the lateral ends of the rugae were affected by tooth movement, but they looked at movement of canines and second premolars only, not the molar movement and also failed to study the medial ends of the rugae.

In 1978, van der Linden reported on 65 cases that had been studied over a 10-year period. He found the canine distance to the lateral end of the first rugae to be a stable measurement but the first molars moved mesially, relative to the lateral ends of the third rugae in these untreated cases over a 10-year period. He didn't study the medial ends of the rugae in great detail, but he finally concluded that the palatal rugae could be used as stable points against which movement of molar teeth could be measured, agreeing with his other researchers such as Moyers et al. (1976)

Almeida et al. (1995) looked at 94 patients involved in a Class 2 study and identified that the lateral ends of the rugae moved with treatment. She concluded that the medial ends of the rugae could be used for model superimposition.

It is clear from these studies that possible drawbacks of using palatal landmarks include that the lateral ends of the rugae could be effected by both headgear treatment (Almeida et al. (1995)), by maxillary premolar extraction (Bailey et al. 1996) and by large amounts of maxillary expansion (Damstra et al. (2009)). However it appears that the medial part of the palatal rugae are sufficiently stable

to allow reliable superimposition of maxillary models, from which accurate measurements can be taken.

Another study that looked at the stability of the palatal rugae was that by Ashmore et al. (2002). These authors were trying to develop a technique to superimpose 3D data taken from selected landmarks on serial models to allow them to assess first molar movement in patients subjected to two years of headgear therapy, Figure 2.8.

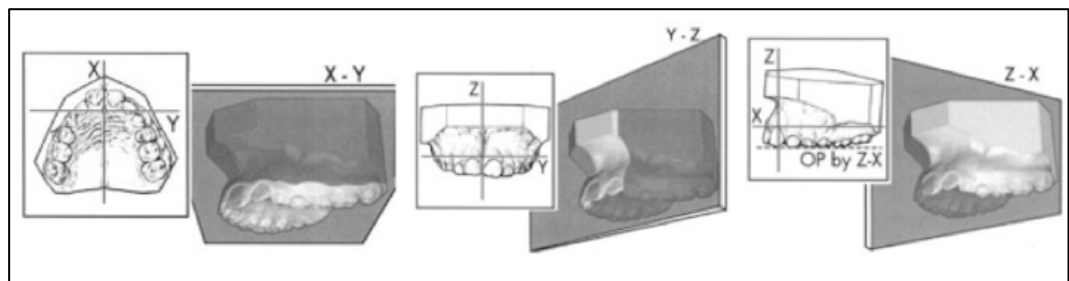


Figure 2.8 All models orientated in the same plane X-Y represented AP direction and bucco-lingual direction and the Z-axis indicates vertical direction, from Ashmore et al. (2002).

This study was carried out because it was recognised that, up until that point, most of the conclusions about the anterior and vertical effects of headgear had been derived from superimposing serial lateral cephalometric films with all the attendant drawbacks. These problems with cephalograms include exposure of the patients to potentially harmful radiation limiting the number of films which can be taken, the necessary annualisation of changes, because of the varying interval between films, may mask the true dynamic change, superimposition of bilateral landmarks can lead to interpretational inaccuracies, and errors in patient

positioning and in identification of stable structures, may lead to misrepresentation of the actual clinical effect.

Ashmore et al. (2002) therefore aimed to measure the molar movement using a 3D digitiser to measure landmarks on stable maxillary structures from bi-monthly maxillary casts. A desktop mechanical 3D digitiser comprised a stylus tip on a mechanical arm, which allowed movement in all 3 planes of space. On activation of a foot pedal the X, Y and Z coordinates of the stylus tip were captured and fed to a computer.

The authors found statistically detectable changes in the shape of the palatal rugae in both the control and the headgear group but these amounted to only 2% of the distance between measured rugae. It was felt this was insufficient to effect the conclusions drawn in the study. In future studies the authors suggested using a weighting superimposition method that would put greater statistical emphasis on the most stable parts of the rugae (medial ends) and less emphasis on the moveable parts of the rugae (anterior and lateral parts). Using their 3D method of study model measurement they concluded that headgear treatment could lead to up to 3mm of distalisation of first molars compared to an untreated control.

Vertical growth changes in the position of the palatal rugae were studied in detail by Christou and Kiliaridis (2008). Whilst it was accepted that palatal rugae are reliable points against which short-term anteroposterior dental changes can be measured, they found that significant vertical changes in the rugae occur, having observed 10 adults and 13 adolescents over a four-year period. They felt that only

the third rugae can be reliably used to assess dental changes, as vertical and anteroposterior growth changes around the third rugae are almost negligible.

2.11 LASER SCANNING IN ORTHODONTICS

The use of lasers in the head and neck region was another step forward to allow more accurate 3D assessment of the clinical situation. Colour stereo lithography has been put to good use in preoperative planning when working up patients with complex maxillofacial tumours (Kermer et al. (1998)). Colouring of the area affected by tumour is produced by slowing the rate of scanning thus exposing the area to a larger dose of laser that solidifies the resin and changes its colour to a deep red. Greater accuracy in planning the resection can be achieved as well as enhanced preparation of the plates needed in the reconstruction.

The first investigator to use surface laser scanning of study models was Kuroda et al. (1996). They used a slit-ray laser and two charged coupled devices within video cameras to record the images, Figure 2.9 Two cameras were needed to allow a record to be made of undercuts and it took about 40 minutes to record a dental cast.

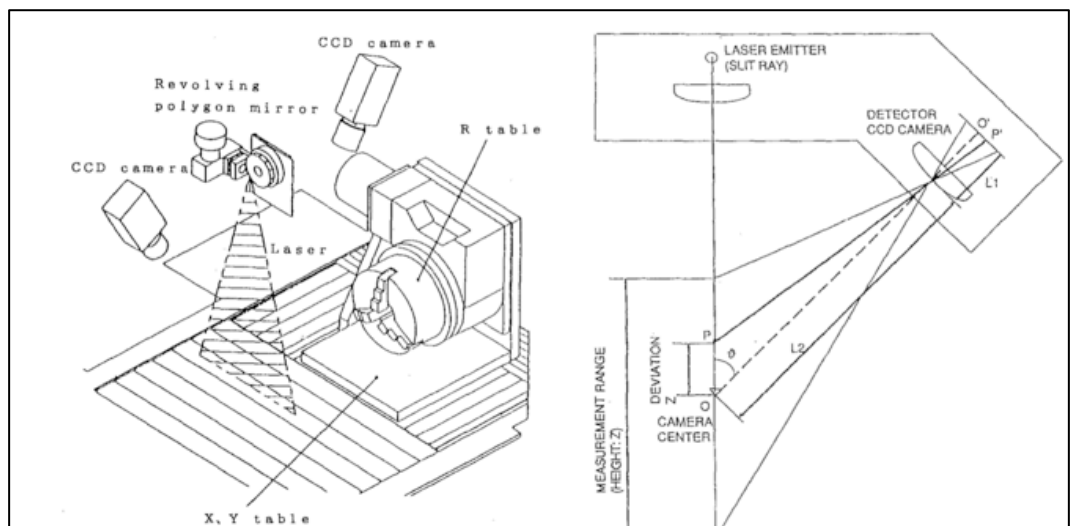


Figure 2.9 Slit ray laser projector and two CCD devices capture images (from Kuroda et al. (1996))

The computer stored 90,000 sets of X, Y and Z coordinates and the measurement error was found to be less than 0.05mm. They felt that an important advantage was the ability to measure both the palatal area and the volume of the oral cavity and suggested that time consuming mock surgery on models will eventually be replaced by virtual set-ups on laser-generated models, Figure 2.10.

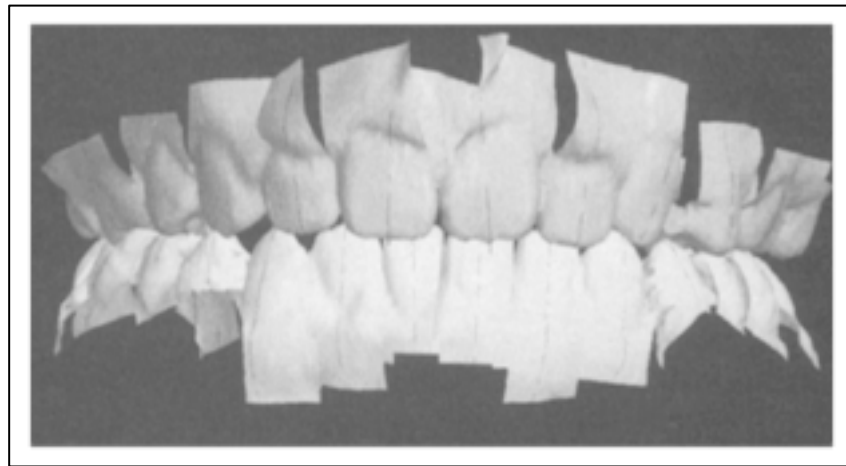


Figure 2.10 Virtual set-up teeth moved to the 'ideal' position, on the computer (from Kuroda et al. (1996))

In a more recent investigation the commercially available Minolta Vivid 700 scanner was used by Sohamura et al. (2000), to evaluate if accurate 3D scans of models could be produced for diagnosis and treatment planning. They developed a 'goniometer' that held the study models in 4 different positions to allow scanning even of the undercut areas on the models. Each scan took 0.6 seconds and the computer connected the data from the four scans to reconstruct the model. They showed that data connections were accurate for flat surfaces, but less so for inclined surfaces. It proved possible to reconstruct the patient's occlusion and they predicted that despite its current shortcomings, 3D models would replace the traditional stone alternatives in the future.

Using scanner technology Hoggan and Sadowsky (2001) studied 33 patients who had upper first premolars extracted and subsequent orthodontic treatment. Anteroposterior molar and incisor movement was assessed on 2 cephalometric variables and 6 study model variables. Models in this study were scanned with a simple flat bed scanner and a mm rule was placed on the models to allow magnification to be checked. The molar points on the cephalogram were averaged and on the scans the right and left molar points were also averaged. There were no statistically significant differences whatsoever between the tooth movements measured cephalometrically and measured from the medial and lateral ends of the first or second rugae, or the medial end of the third ruga. The authors therefore concluded that rugae landmarks are as reliable as cephalometric superimposition, to assess anteroposterior molar movement.

Another experiment to assess the reliability of scanning, for measuring the 3D position of landmarks, was carried out by Kusnoto and Evans (2002). They pointed out that it was already possible to obtain 3D information on all patients using CT scans, but felt the level of radiation was unacceptably high for them to be used routinely. Their investigation also used the Minolta Vivid700 laser surface scanner which in 0.6 seconds could produce a surface lattice of 380,000 points allowing models to be cross sectioned and superimposed and subsequently measured on the computer screen (Figure 2.11).

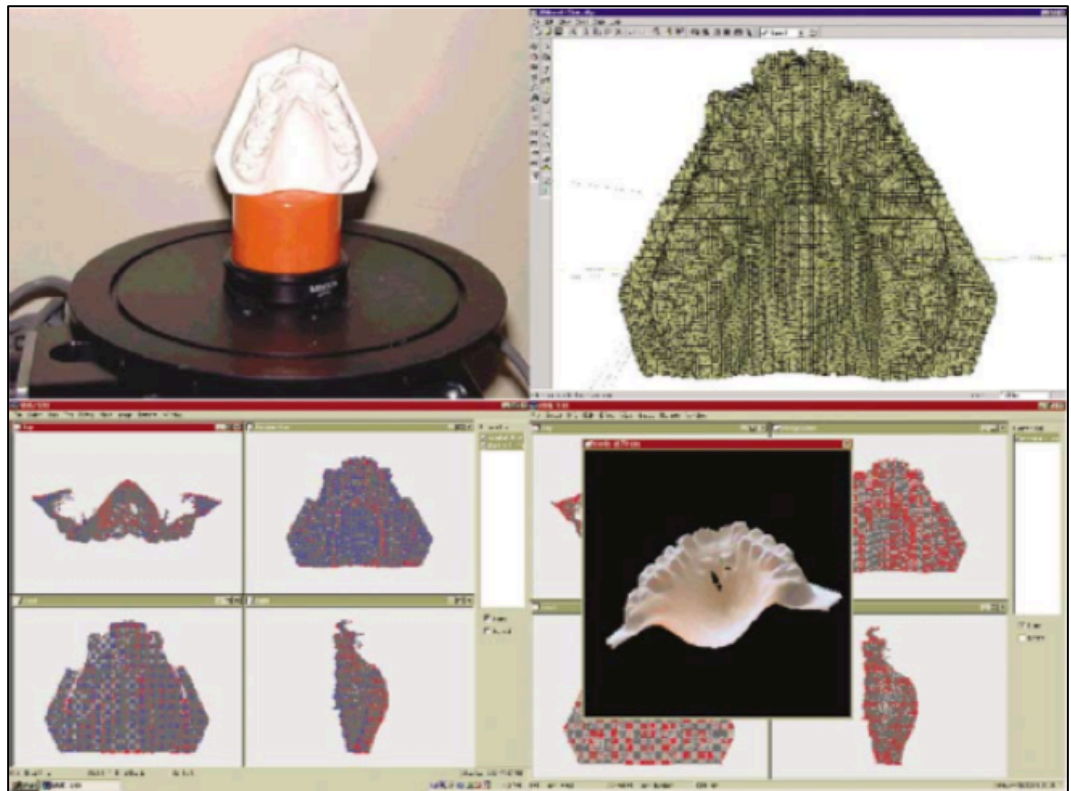


Figure 2.11 Three-dimensional computerised models proved to be very accurate (from Kusnoto and Evans (2002))

The errors they found were between 0.2 and 0.7mm and in a similar way to other investigators they had problems scanning undercuts necessitating 3 separate scans with model repositioning in between. They demonstrated the technique to be more accurate in measuring height and width aspects of the study models mainly due to the units horizontal beam source however the time discrepancy when measuring depth led to a slight enlargement in this dimension. A correction factor was introduced to minimise errors of magnification and modifications made to subsequent laser units to avoid this problem.

Since these early experiments with digital models many researchers have investigated the validity and precision with which measurements can be made

recognising the plethora of advantages including storage and retrieval as well as communication, transfer of records, and long distance diagnosis and treatment planning (Kusnoto and Evans (2002), Zilberman et al. (2003), Quimby et al. (2004), Redlich et al. (2008) and Fleming et al. (2011)).

An interesting study was carried out by Jang et al. (2009). On 10 patients an oral surgeon placed 3 miniscrews in the palate prior to the extraction of upper first premolars and comprehensive orthodontic treatment. The miniscrews were ligated to a palatal arch so they were used primarily to supplement anchorage but were also used as landmarks for superimposition. They accurately identified the medial and lateral ends of the first three rugae thus identifying twelve palatal landmarks in all. The 3D images were superimposed with the 'best-fit' method on the three implants, which were considered stationary landmarks. A co-ordinate system as described by Cha et al. (2007) was used to measure the displacement of the rugae in three planes of space.

They were therefore able to compare tooth movement measured by superimposing 3D scans on the three implants, with tooth movement measured by superimposing on the palatal rugae. They found that the medial point of the third rugae, which in the experiment was furthest from the retracted anterior teeth, was the most stable thus agreeing with the work of Frans van der Linden (1978) (Figure 2.12). The contour of the posterior region of the palatal vault was also particularly stable and Jang et al. (2009) concluded that these landmarks can be reliably used as stable points from which tooth movement can be measured.

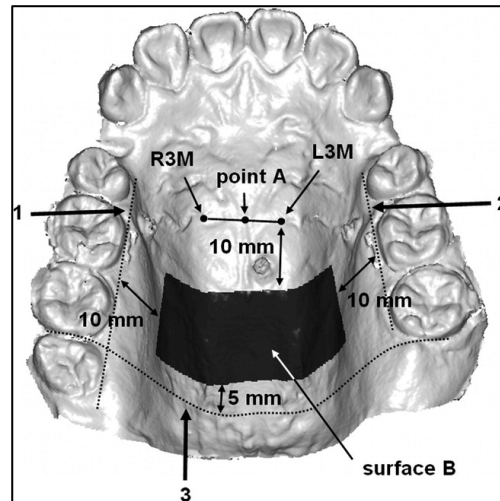


Figure 2.12 Landmarks identified for reproducible dental cast superimposition. R3M = Right 3rd rugae medial, L3M = Left 3rd Rugae medial, point A bisector (from Jang et al. (2009))

Their superimposition method was based upon point A, the mid-point of the line connecting medial points of the 3rd rugae, and surface B on the palatal vault delineated by a line 10mm behind point A and 5mm ahead of a line connecting the distal surfaces of the second molar teeth. Laterally the line was 10mm from a line connecting the gingival margins of the posterior teeth. Movement of both the upper incisors and the molars, measured using the rugae-palate-superimposition were not significantly different from the movements measured using the three fixed screws.

This method was not considered necessarily appropriate for superimposing maxillary casts in growing children as the dimensions of the alveolus have been shown to change with growth (Simmons et al. (1987)).

A subsequent model of the laser scanner used by Kusnoto and Evans (2002), the Minolta Vivid 910i, was tested by Thiruvengkatachari et al. (2009). They also

wanted to test the accuracy of the 3D scanner and to compare it with measurements from cephalometric radiographs. They developed a method of superimposing scans from pre- and post-treatment models using primarily stable points on the palatal rugae and a stable area in the centre of the hard palate (Figure 2.13).

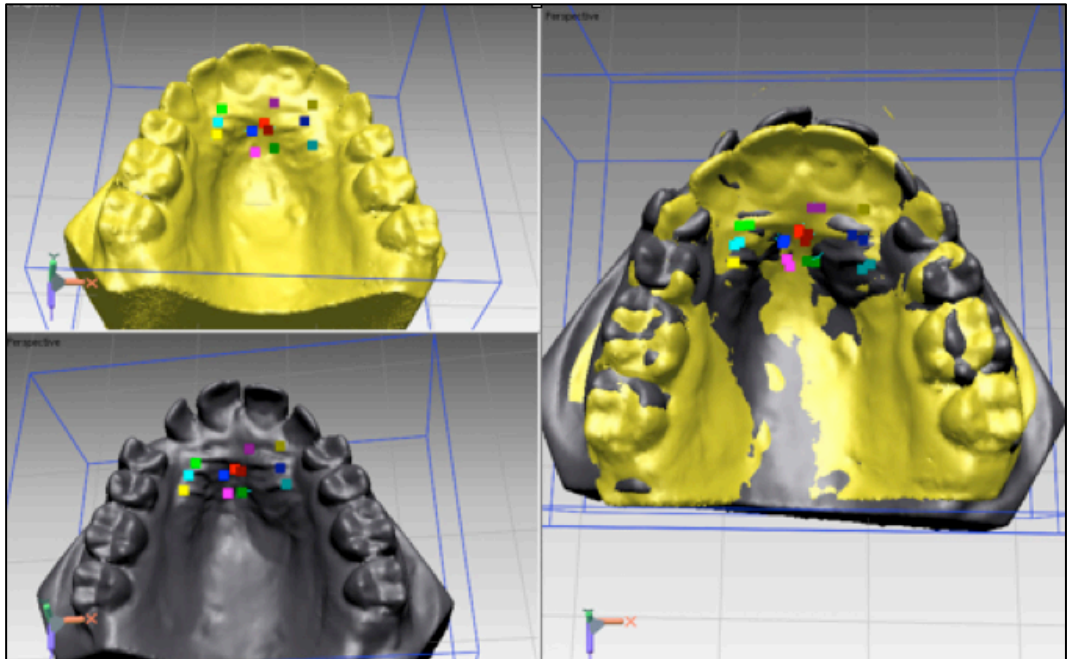


Figure 2.13. Palatal rugae identified on start and end of treatment models (from Thiruvengkatachari et al. (2009))

This newly designed hardware and improved measurement algorithms provide four times the measurement accuracy of previous models. The model on a rotating platform was scanned and light reflected from the surface is recorded on the charged-couple device in a camera. The computer, using the Rapidform 2006 software, then triangulates the 300,000 points making a 3D polygon mesh. The models are then aligned with their occlusal planes parallel to the horizontal then superimposed on the prominent rugae. A stable mushroom shaped area on the palate is then selected for final superimposition. Differences between the pre and

post treatment models were then assessed and accepted if they were found to be less than 0.8mm.

The next stage involved tracing the clinical crown of the molar, which then allowed the software to calculate the centre of mass of the crown of the tooth. When this was done for both molars, on both pre- and post-treatment models, movement of the centre of mass in all 3 planes of space can be measured. The whole procedure took 30 minutes for each set of models.

The accuracy of the computer measurements were compared with hand measurements with digital callipers and with an experimental jig where the molar crown could be moved bucco-lingually and mesio-distally in 0.5mm increments. There were no statistically significant differences between the calliper and the computer measurements. The scanner was accurate to 0.023mm for AP and 0.007mm for bucco-lingual movements when comparing it to the predetermined (0.5mm increments) jig movements. The final part of the study was comparing the movements measured by the scanner with those measured by cephalometric radiographs and there were, once again, no statistically significant differences.

This study therefore showed that 3D scanning is accurate and is an acceptable alternative to cephalometric measurements when assessing molar movement. The main advantage is the avoidance of patient exposure to potentially harmful ionizing radiation. It also meant that the movement of the individual molar teeth in all 3 planes could be measured with great accuracy, which is not the case with cephalometric radiographs. The disadvantage of this technique is the time

required for scanning of each set of models, which is currently 20-30 minutes, and the initial cost of the hardware and software (\$40,000).

Choi et al. (2010) carried out a study on 20 sets of plaster models whereby 3D scans were taken and then the teeth were randomly moved having been sectioned from the models. A second 3D scan was made with the teeth in the new position and measurements were made having superimposed the scans on the palatal tissues and also directly on the plaster model. Anteroposterior, vertical and transverse movements were measured using both methods and the means did not differ significantly. There were also very high correlations between the two types of models demonstrating that the method of measurement on 3D scans was precise and reproducible

Another study aimed at identifying a stable and reproducible reference region on which 3D scans could be superimposed was carried out by Chen et al. (2011). This study was carried out on fifteen patients who required reduction of maxillary protrusion involving bilateral first premolar extractions. Six miniscrews were placed but only two were loaded and used for anchorage reinforcement. The other four miniscrews were left unloaded, which allowed confirmation that the unloaded miniscrews were in fact stable. Impressions were taken 1 week after screw placement, and then at 17 months when the active tooth movement was complete. This methodology allowed a comparison between loaded and unloaded miniscrews. The maxillary models were registered using iterative closest point (ICP) methodology. 'Iterative Closest Point' is an algorithm employed to minimise the difference between two clouds of points. It is used to reconstruct two or three-dimensional surfaces from different scans. The algorithm iteratively

revises the transformation (which comprises rotation and translation) needed to minimise the distance between the points of the two raw scans.

The initial rotation and translation matrices were estimated using the unloaded miniscrews, considered to be stationary implants. First, they investigated if the unloaded screws remained stable by measuring the distances between the screws at T1 and T2. All successful miniscrews were stationary i.e. displaced $< 0.5\text{mm}$. Displacements of all the loaded miniscrews was also $< 0.5\text{mm}$. Mean displacement of the unloaded miniscrews was $0.23 \pm 0.1\text{mm}$ while the loaded screws was $0.24 \pm 0.13\text{mm}$. There was no significant difference between the two.

Using the stable (unloaded) miniscrews as reference points, a stable palatal region between the T1 and T2 models (deviation $< 0.5\text{mm}$) was also identified. It was the area delineated anteriorly, by the curve of the anterior outline of the 3rd rugae and a line connecting the medial points of the right and left 3rd rugae, posteriorly by a line connecting the first molars distal surface and laterally by a line connecting the lateral 1/3 point of the 3rd rugae parallel to a line through the central groove of the molars on the same side. The stable palatal region is therefore defined as the medial 2/3 of the 3rd rugae and the regional palatal vault dorsal to it (Figure 2.14).

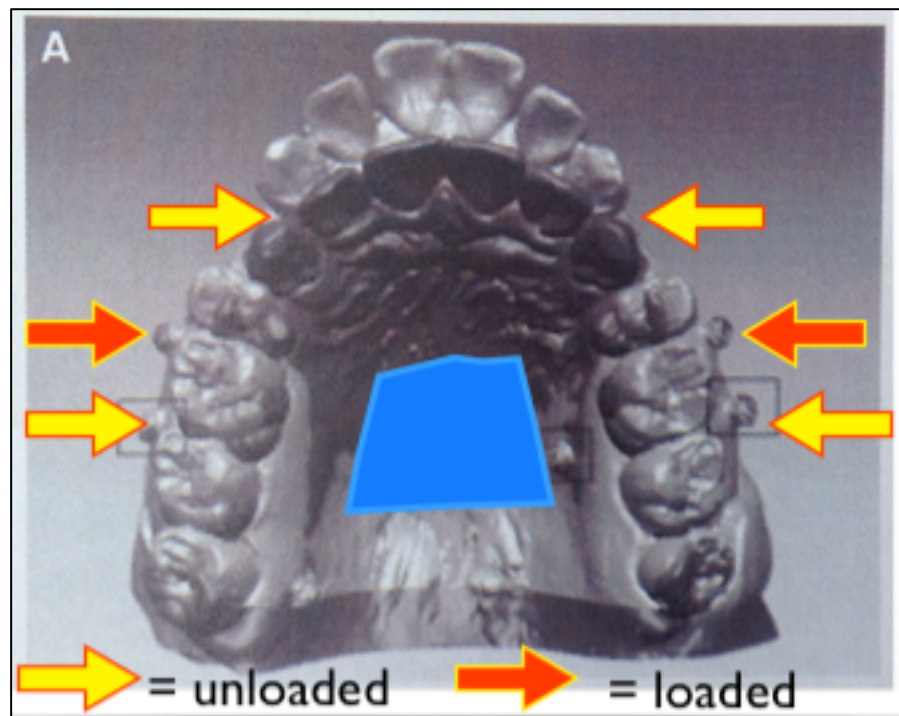


Figure 2.14 Unloaded implants allowed the stable area of the palate to be identified (blue), whilst the loaded implants facilitate retraction of the incisor teeth (from Chen et al. (2011)).

A comparison was now drawn between the molar and incisor movements during treatment, as measured using the miniscrews, and then measured again using the palatal vault method. There was no statistically significant difference between the two measurements. The palatal vault method was considered to be valid and therefore there would be little need to place implants in future patients to allow precise regional superimposition of T1 and T2 models.

In summary, the weight of evidence indicates that the medial ends are the more stable parts of the major rugae and are least affected by extractions and subsequent orthodontic tooth movement. The third rugae in particular appears to be the most reliable area for superimposition particularly when combined with an area stretching backwards over the hard palate, extending either side of the

midline. This area should ideally be selected when ‘helping’ the computer find correspondences, using algorithms such as ‘Iterative Closest Point’.

Chapter 3.0 AIMS AND OBJECTIVES

3.1 AIMS

The aims of this study were:

- To compare the anchorage supplementation effectiveness of TADs with both headgear and Nance button palatal arches
- To compare the patient perception of the above three methods of anchorage supplementation

3.2 OBJECTIVES

Specific objectives were:

1) To determine if there is a difference in the amount of upper molar movement when reinforcing anchorage in 'maximum anchorage cases' using:

- (a) Headgear
- (b) Nance button palatal arches or
- (c) TADs.

2) To determine if there is a difference in the treatment process:

- duration of anchorage reinforcement
- total number of visits
- total treatment time
- number of casual appointments or number of failed appointments

when comparing the above three methods of anchorage reinforcement.

3) To determine if there is a difference in the quality of the final outcome, as measured by PAR, when reinforcing anchorage in ‘maximum anchorage cases’ using: (a) Headgear, (b) Nance button palatal arches or (c) TADs.

4) To determine if there are differences in patients perceptions of the three methods of anchorage reinforcement

3.3 NULL HYPOTHESIS

There is no difference in the effects of TADs, Headgear or Nance button palatal arches when used to reinforce orthodontic anchorage with respect to:

1. The amount of molar tooth movement.
2. Duration of treatment
3. Number of treatment visits
4. Dento-occlusal change (PAR Index) and final PAR score
5. Impact of anchorage supplementation method questionnaire

Section 2

MATERIALS AND METHODS

CHAPTER 4.0 METHODOLOGY

4.1 INTRODUCTION

The TADs assessment trial was a dual-centre prospective randomized controlled trial to evaluate the effectiveness of three different methods of supplementing anchorage in a group of ‘maximum anchorage cases’. The study was made possible following a successful grant application to the British Orthodontic Society Foundation (Appendix 6)

The study and clinical treatment was carried out in two centres: Chesterfield and North Derbyshire Royal Hospital (CNDRH) and Royal Derby Hospital (RDH). The research team consisted of three members: the author of this thesis from CNDRH (Mr Jonathan Sandler) from RDH (Ms Alison Murray) and the project supervisor from Manchester (Professor Kevin O'Brien).

4.2 STUDY DESIGN

This was a two-centre randomised clinical trial and was approved by Derbyshire Research Ethics Committee REC reference 07/Q2401/50 (Appendix 7)

4.3 OUTCOME MEASURES

The following primary outcome measures were used in the trial:

Amount of movement of the upper molar teeth as measured by:

- Restricted cephalometric analysis
- Three-dimensional tooth movement using a laser scanner on study models

The following secondary outcome measures were used in the trial:

- Duration of anchorage reinforcement
- Number of treatment visits
- Number of casual (emergency) visits and failed appointments

- Total treatment time
- Dento-occlusal outcome – final PAR score
- Patient impact of anchorage supplementation method (questionnaires)

4.4 CENTRES INVOLVED

The study was coordinated from Chesterfield and North Derbyshire Royal Hospital Foundation Trust and some patients were also treated at the Royal Derby Hospital. Both of these centres are District General Hospital orthodontic departments, primarily concerned with the delivery of high quality orthodontic care for patients and for the clinical training of orthodontic registrars.

4.5 SUBJECTS

Comparison of experimental and control group

The sample size calculation was based on a clinically meaningful difference in anchorage loss from a previous investigation into the effectiveness of mid-palatal implants and headgear (O'Brien and Fleming, 1979). If we consider that a variance of means to be 1.5mm (Common SD – 3.035) then for a trial with a power of 80% and an alpha of 0.05 a sample of 25 patients was needed in each group, assuming an estimate of non-compliance of 20%. The table from the nQuery Advisor statistical software is included for reference (Table 4.1).

Table 4.1 Sample size calculation: One-way analysis of variance (equal n's)

	1	2	3
<i>Test Significance level, α</i>	0.05	0.05	0.05
<i>Number of groups</i>	3	3	3
<i>Variance of means $V = \Sigma(\mu_i - \mu)^2 / G$</i>	1.50	0.50	0.72
<i>Common standard deviation, σ</i>	3.04	3.04	3.04
<i>Effect size, $\Delta^2 = V / \sigma^2$</i>	0.16	0.05	0.08
<i>N per group</i>	21	61	42

4.5.1 INCLUSION CRITERIA

- Patients aged between 12-18 years
- Patients who desired orthodontic treatment for correction of their malocclusion
- No previous experience of orthodontic treatment
- Patients who satisfy the ‘absolute anchorage’ requirement. Absolute anchorage was determined on the need to prevent any mesial movement of the molar teeth, until the anterior teeth had been moved to an appropriate position.
- Clinical examination confirmed a functional appliance was not indicated
- Orthognathic surgery not considered appropriate

4.5.2 EXCLUSION CRITERIA

- Clinical indication that the patient would benefit from a functional appliance approach
- Previous orthodontic treatment and/or tooth extraction, for orthodontic purposes
- Hypodontia of more than one tooth, in any quadrant, excluding third molars
- Inadequate level of oral hygiene or persistent gingival disease
- Orthognathic treatment indicated, or may be required in the future
- Presence of a cleft or craniofacial anomaly

4.5.3 RECRUITMENT OF SUBJECTS

Patients were initially selected from the new patients referred to CNDRH and RDH for orthodontic treatment.

The pattern of recruitment can be seen in Figure 15.

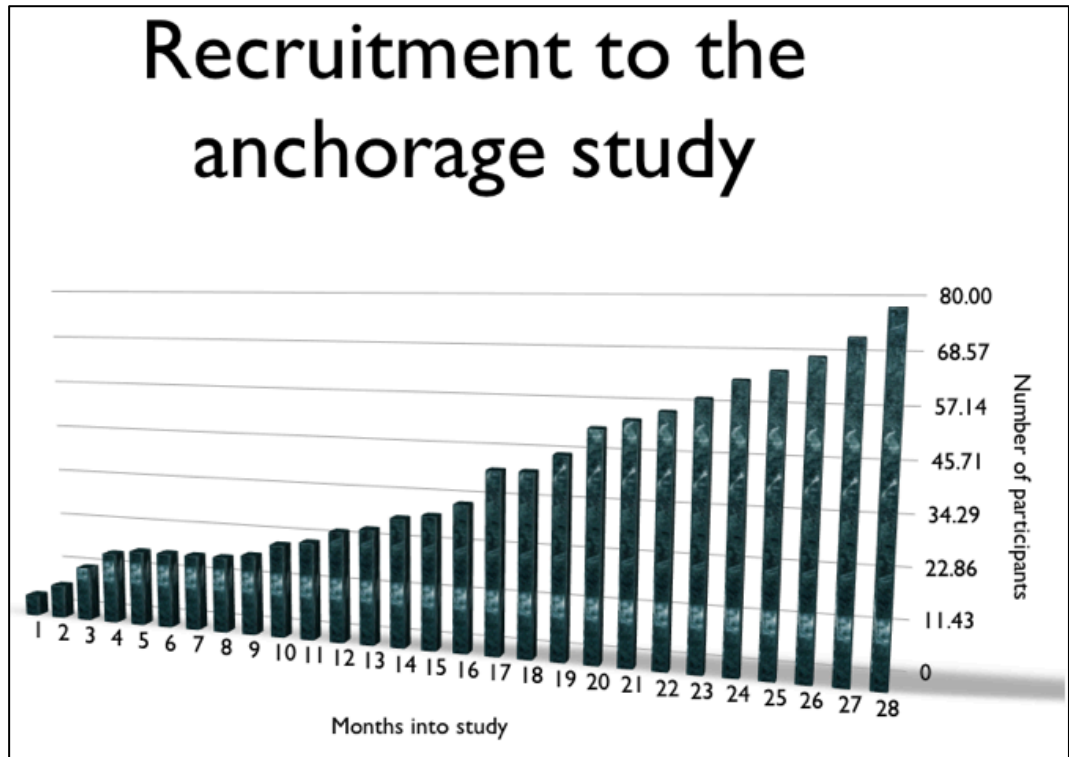


Figure 4.1 The pattern of recruitment can be seen over a 28-month period.

4.6 ENROLMENT OF PARTICIPANTS

If a patient satisfied the eligibility criteria, they met with the clinician who would be performing the orthodontic treatment. The study was explained to both the patients and their parents and they were given comprehensive verbal and written information. They were given the opportunity to ask any questions that they might have. In addition, they were given leaflets that fully explained all aspects of the study: one document was written for the parents and a second document specifically written for the patients (Appendix 8).

The patients and parents were then given a ‘cooling off’ period of at least 7 days, to consider whether they wished to be involved in this RCT. A subsequent appointment was made at least one week after the orientation meeting, to allow

written consent to be obtained for inclusion in the study if they chose to participate.

4.7 CONSENT PROCESS

The parents and patients each had three copies of the consent form to sign (Appendix 9 & Appendix 10). They consent gave permission for clinical photographs and radiographs to be used in future presentations. One copy of each form was then given to the parent; a second placed in the research file and the original copy was kept in the patient's medical notes.

If they declined to participate in the study but were still keen on correction of their problem they were still offered orthodontic treatment. Under these circumstances we used the default method of anchorage supplementation, which was the provision of headgear, extractions as appropriate and upper and lower fixed appliances.

The patients General Dental Practitioner was also informed that their patient had been enrolled into a trial (Appendix 11) which has full ethical approval and is supported by the British Orthodontic Society Foundation (BOSF) and by Chesterfield Royal Hospital NHS Foundation Trust.

4.8 METHOD OF RANDOM ALLOCATION

Randomisation was performed by The University of Nottingham, Clinical Trials Unit thereby separating the process of patient recruitment and randomisation.

When the patient and parent had consented to be in the study, the randomisation centre at The University of Nottingham, Clinical Trials Unit was contacted via the Internet address: <http://www.ctsu.nottingham.ac.uk/0822/login.asp>

The clinician was instructed to enter their login name and preset password (Appendix 12). The clinician then entered the following data: (i) patient's initials, (ii) gender (iii) date of birth. Once confirmation of the patient details was given, the computer instantly randomised the patient to one of three groups.

The randomisation was based on a computer generated pseudo-random code using random permuted blocks of randomly varying size. This random sequence was created by the Nottingham Clinical Trials Unit and held on a secure server in accordance with their standard operating procedure.

The clinicians and the patients were blinded to the allocation sequence.

Once randomisation was complete we printed out the page as verification of the group to which the patient was randomised. In addition, a sticker was placed on the front of the patient's notes that indicated which group the patient was in. This served as a visual prompt to any other clinicians who happen to see the patient for an emergency appointment, that they are part of the TADs trial.

At the end of the study the full randomisation list was printed out (Appendix 13) to be referred to during the data analysis stage.

CHAPTER 5.0 CLINICAL TREATMENT

Once the patient had been randomised they were given specific details about their particular treatment protocol and arrangements were made to start clinical treatment.

Molar derotation was carried out before the anchorage supplementation method was fitted. This was done by fitting a sectional fixed appliance on the premolars and molars. We progressed through a standard archwire sequence of 016 Sentalloy, 18/25 Neo-Sentalloy and 19/25 Stainless Steel. Once this wire had been in place for at least 4 weeks, and the molars were seen to be fully uprighted and derotated an appointment was made for debond of the sectional appliance (Figure 5.1), and collection of further records.

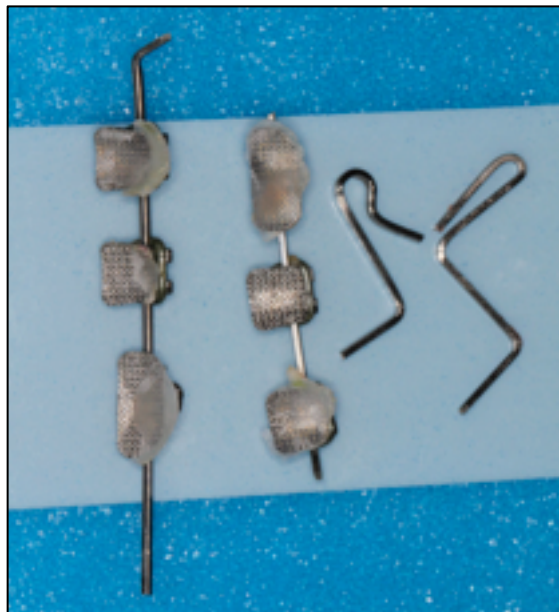


Figure 5.1 Sectional appliances removed, molar markers prepared in 19/25

Up until this point all three patient groups were treated identically but from this visit onwards, three distinctly different paths were followed. To aid efficient and effective completion of subsequent visits, to ensure nothing was overlooked and all necessary records were taken at the appropriate stage, a single laminated sheet

was provided for all the assistants involved in the study (Appendix 14). The assistants were instructed to familiarise themselves with the contents of the sheet appropriate to the patients they were dealing with on each anchorage clinic. Wherever possible the patients were booked onto the same treatment day for the whole of their treatment. Apart from the occasional emergency visit, all treatments were carried out by a single operator (PJS or AMM).

Different coloured folders were given to the three groups of patients:

- red = TADs
- green = Headgear (HG)
- yellow = Nance button

This allowed both the operator and the assistant to instantly identify research patients. This would then ensure that the required paperwork was completed with meticulous precision at every visit.

Silicone impressions, alginate impressions and two wax bites were taken to allow subsequent assessment of the molar position at the start of anchorage supplementation. Molar bands were then fitted to the upper molars and cephalometric markers were placed prior to an initial lateral cephalometric radiograph. This allowed the 'base-line' antero-posterior position of the upper left and right molar teeth to be identified on the cephalogram taken at the start of treatment.

In order to allow the right molar tooth to be differentiated from the left molar tooth on the lateral cephalometric radiograph, 'molar markers' were bent up in

0.019" x 0.025" stainless steel arch wire. These markers were bent into the shape of an 'R' or an 'L' to indicate their respective sides; these were held hard up against the mesial edge of the molar band using a separating module (Figures 5.2 and 5.3).



Figure 5.2 and 5.3 Right and Left molar markers held in place with elastics for the radiograph

After the lateral cephalometric radiograph had been taken (Figure 5.4), checked for errors and approved as acceptable, the markers were removed from the molar bands. These were then placed in a small plastic bag that was subsequently stapled to the patients' orthodontic treatment sheet. These markers would be required for use at the end of the anchorage supplementation period, at which point the second lateral cephalogram would be taken.



Figure 5.4 Lateral cephalometric radiograph with molar markers in place, allowing the left molar to be clearly distinguished from the right molar.

5.1 TREATMENT PROTOCOLS

5.1.1 HEADGEAR DESIGN

It was felt that the specific choice of headgear (High-pull, Combination-pull or Low-pull) would be determined by the many clinical aspects of the case. For example, if a significant vertical pull (intrusion) was required, as well as the need to prevent forward movement of the molars, then occipital pull headgear would be most appropriate (Figure 5.5). The converse situation might be a low angle deep bite case where some extrusion of the upper molars may be more appropriate; in which case a neck strap in combination with a head cap may be used.



Figure 5.5 Occipital pull safety headgear and safety Ni-Tom, Kloehn bow

The important feature for headgear success was to use a force of 250gm per side, and to achieve at least 100 hours per week; therefore this was requested right from the outset. To help encourage the patients to comply with the headgear treatment, they were also asked to complete a headgear diary chart on a daily basis. Both

operators involved in the study resolved to take an active and enthusiastic interest in these headgear charts every time the patients attended an appointment. Patients were also asked to demonstrate placement and removal of their headgear at every visit, to ensure they could do this with ease and ideally without the aid of a mirror. As well as checking the headgear charts, the magnitude of the force on the headgear was also checked and adjusted where necessary.

Before patients were allowed to leave the department they had to demonstrate their ability to safely and efficiently place and remove the headgear. In addition, they had to show that they fully understood all the safety features of their appliance, as well as understanding when they should and should not wear the headgear. Once the patients demonstrated satisfactory headgear placement and removal both to their parents and the clinicians, an extraction letter was given to them for their General Dental Practitioner.

5.1.2 NANCE BUTTON ON A PALATAL ARCH

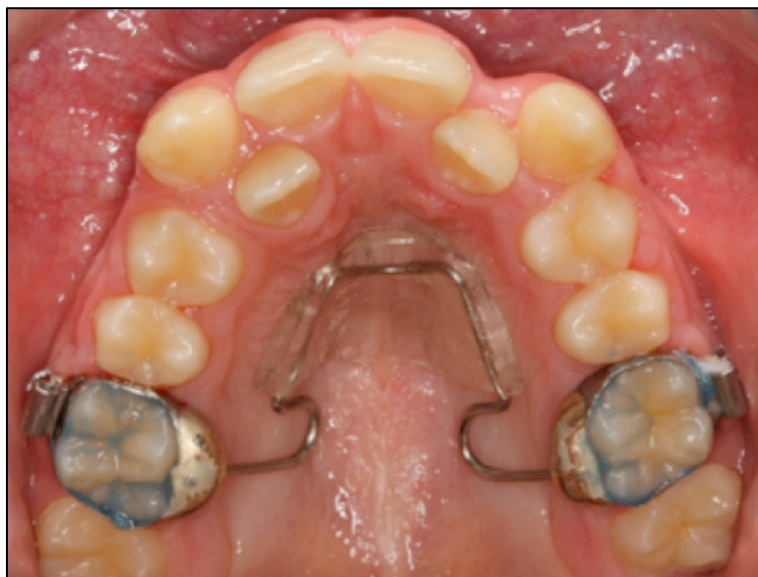


Figure 5.6 Nance button palatal arch

Molar bands were selected and fitted, and an alginate impression was taken over the molar bands. The bands were then removed and placed accurately in the impression. This was then taken to the laboratory to allow working models to be cast, on which the Nance button palatal arch was fabricated (Figure 5.6). A 1mm stainless steel wire was formed to the palatal surface of the upper first molars and then bent over the posterior palate and across the anterior palate. Much of the vertical part of the anterior hard palate was covered with cold cured acrylic that, after curing, was polished smooth to minimise patient irritation.

No separation was required during the initial placement of the molar bands, as these teeth had been moved over the previous 3-4 months with sectional wires. Once molar bands had been fitted and subsequently removed, a further pair of bands was placed to help keep the space until the Nance arch had been constructed and was ready to fit. Once the Nance arch was cemented in place, the patient could take the extraction letter to their General Dental Practitioner.

5.1.3 TADs

The upper and lower straight wire appliances were placed and an appointment was made for the extractions to be carried out by the General Dental Practitioner. The TADs were to be placed for anchorage supplementation, prior to straining the anchorage unit. In this group of cases no canine lacebacks were used from the molar bands and no initial canine retraction was performed in advance of TAD placement. Soon after the extraction sockets had healed the patients were booked in for placement of the TADs.

If the patients were particularly nervous about TAD placement, they would first have some topical anaesthetic gel placed on the mucosa, immediately mesial to the molar tooth in the upper arch. A small amount of lignocaine was then carefully infiltrated into the reflected mucosa, immediately mesial to the molar tooth and this was digitally massaged into the tissues. A few minutes later, further anaesthetic was infiltrated and three or four minutes later the area was tested with a sharp probe to ensure complete soft tissue anaesthesia. A 2mm biopsy punch was then used to remove a small cylinder of mucosa, where possible at the junction of the attached and reflected mucosa.

The 8mm x 1.6mm Aarhus screw (Figure 22) was lifted from the screw rack in the Aarhus kit, using the custom made screwdriver. Using copious water irrigation and narrow bore suction the screw was gently but firmly screwed into place over a 60-90 second period. Water irrigation was continued throughout this period of screw placement. The TAD was tightened until there was minimal space between the collar and the mucosa and each screw was checked for primary stability. Occasionally undue resistance was felt as attempts were made to pierce the buccal plate of bone. In this situation the screw was removed and a site at least 2-3mm distant from the original site was selected for a subsequent attempt at screw placement.

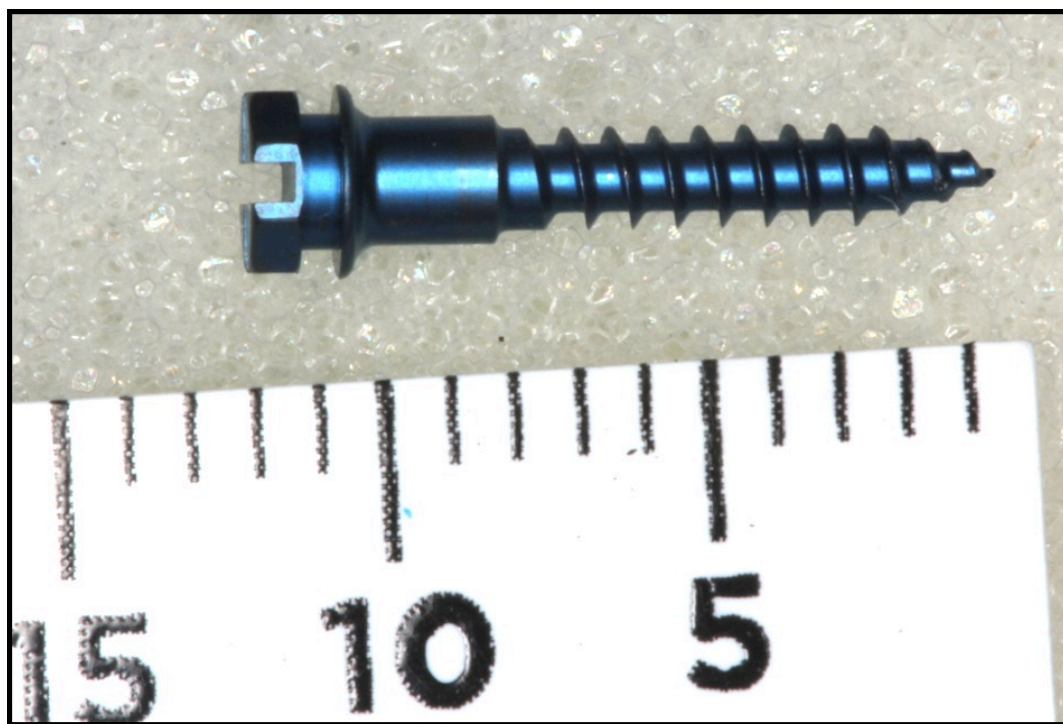


Figure 5.7 Aarhus 8mm x 1.6mm TAD

The TADs were loaded immediately via a 6mm NiTi coil spring that had metal ligatures attached to both ends. One ligature was threaded through an internal hole in the head of the screw and the other ligature tied around the bracket on the tooth to be distalised. A gentle pressure of 80-100gm was immediately applied from the TAD to the canine teeth that required distalisation.

5.2 PROTOCOL DEVIATIONS

- Any patient who failed an appointment was sent another in the near future
- Patients failing two appointments, were contacted by telephone and encouraged to attend
- Patients were allowed to withdraw from the study at any point, they were assured that this would not have a detrimental effect on their subsequent treatment in the department

- Patients withdrawing from the study had records taken at the point of withdrawal
- If there was a casual appointment, an attempt was made for the patient to be seen by their regular clinician, although in an emergency other operators would do the necessary treatment

5.3 OUTCOME ASSESSMENT

Data collection was carried out at the following points

- 1- DC1 – After initial molar derotation prior to the anchorage supplementation
- 2- DC2 - At the point where anchorage supplementation was no longer required
- 3- DC3 - At the end of all active orthodontic treatment

5.4 RECORDS AND DATA COLLECTED

- Upper and lower impressions (silicone) to allow accurate models to be cast for analysis by 3D laser scanner (DC1, DC2, DC3) and alginate impressions as a back up
- Lateral cephalometric radiographs with markers on Right and Left molars (DC1, DC2, DC3)
- Photographs – the standard 4 extraoral and 5 intraoral photographs (DC1, DC2, DC3)
- Orthopantomogram (DC1, DC3)
- TADs questionnaire (2 weeks after placement and removal)
- Headgear questionnaire (2 weeks after cessation of headgear)
- Nance questionnaire (2 weeks after placement and removal)
- PAR scores (DC1, DC3)

Data collected from patient notes

- Number of attendances
- Number of visits DC1-DC2 and DC2-DC3
- Duration of overall treatment
- Number of failed or cancelled appointments
- Frequency and reason for additional attendance for appliance breakages

5.5 OPERATOR STANDARDISATION

The following factors were standardised:

- The design of the Nance button palatal arch
- The magnitude of force on the headgear
- The number of hours of headgear wear requested
- The headgear charts that were given to the patients
- The timing of microscrew placement
- The site and type of microscrew placed

5.6 PROGRESS OF TREATMENT

A standard approach was taken to treatment in that three archwires are used in the vast majority of cases. Initial alignment was carried out with a 0.016” Sentalloy wire using its properties of low flexural rigidity and high elastic recovery. After one or two visits involving re-tying, progression was made to a Neo-Sentalloy 018x025” archwire, again left in place for at least two visits. If malaligned canines were a significant problem, a piggyback of 0.016” Sentalloy was used on

a base archwire of 0.018” stainless steel, until the canines could be included in the 0.018x0.025” Neo-Sentalloy. Progressive alignment allowed eventual placement of the 0.019x0.025” stainless steel working archwire.

In this study the exception to this approach was in the TAD cases where initial retraction of the displaced canines was sometimes carried out directly to the TAD which had been placed mesial to the upper molars.

The main indicator for when anchorage supplementation was no longer required was when the upper canines were in a Class 1 relationship with the lower canines which in turn were positioned behind a perfectly aligned lower labial segment. There also had to be sufficient anchorage in the upper arch to allow completion of anterior tooth alignment and reduction of the overjet.

Once it was judged that no further anchorage supplementation would be required, the particular method of supplementing anchorage was stopped so the headgear use could be stopped or the springs attached to the TADs could be removed. Further records including impressions, a cephalogram and photographs could be taken immediately and a questionnaire was handed to the headgear patients for the first time and to the TADs patient for the second time.

In the case of the Nance button on a palatal arch, this was removed and the palatal tissues were given at least 2 weeks to recover before any further records were taken. The patient was scheduled for a records appointment and this involved a post anchorage questionnaire, impressions and a lateral Cephalogram, (DC2).

In all three groups the original markers, which had been stored in the notes, were replaced in the molar slots and the lateral cephalogram was repeated. On confirmation of securing an adequate lateral cephalogram the markers were removed, upper molar bands were also removed and following cleaning of any cement remnants, another double set of impressions were taken of the upper and lower arches as well as two wax bites to record the jaw relationship.

Alginate impressions were taken to allow fabrication of the routine study models, as this is standard practice in both of the departments involved in the study. To enable the intricate anatomical detail of the palatal rugae to be accurately recorded, impressions were taken using both heavy bodied and light bodied silicone impression material in a two-stage technique. This allowed for subsequent production of the accurate and detailed study models that were to be used in the 3D scanning process.

5.7 QUESTIONNAIRES

Questionnaires were used at DC1 and DC2 for both the Nance and the TADs groups to determine the patient's views on the placement and removal of these two anchorage supplementation devices. There was a six-point Likert scale to complete, with numeric scores ranging from 1, representing significantly uncomfortable, to 6 if the process was judged as being completely comfortable. The scoring was done 2 weeks after fitting of the appliances and questions were asked specifically on the levels of comfort during fitting, the level of discomfort experienced over the first few days and for how long this discomfort lasted. Similar questions were again asked 2 weeks after the end of treatment. The questionnaires can be seen as Appendix 15 and Appendix 16.

The headgear patients were given a single questionnaire, 2 weeks after they had been asked to stop wearing the headgear, and this time the patient views and experiences of headgear were recorded (Appendix 17).

5.8 STATISTICAL ANALYSIS

The primary outcome measures of molar tooth movement as measured both on lateral cephalometric radiographs and on superimposed 3D scans are continuous variables. Summary statistics were derived for the data at the start and finish points of the study. The data were checked for normality and, once found to be normally distributed, parametric tests were deemed appropriate.

An intention to treat analysis was appropriate for this study and all patients that had been enrolled in the study were either included in the final data analysis or, if they had dropped out, were reported on individually.

The study design involved the measurement of the same dependent variable (mesial molar movement, as a measure of anchorage loss) in three independent groups (Nance, Headgear and TADs) over two time points (start and finish of anchorage supplementation). It was also important to consider the effect of any co variates, for example, gender. As a result, the data were analysed with analysis of covariance (ANCOVA), which is a variant of linear regression analysis. This allowed the fitting of gender as a covariate and also adjusted for the baseline scores.

CHAPTER 6.0 RECORD ANALYSIS - 3D MODELS

6.1 SCANNING THE MODELS

To allow 3D digital scan of the models to be produced, the high quality study models were sent to Bioprecision Diagnostics (Yeovil, Somerset) where they were placed in a 3D scanner to allow image capture. The scanner used was supplied by 3Shape (www.3shape.com). It is conveniently sized for worktop use, approximately 46cm x 54cm x 32cm (Figure 6.1).

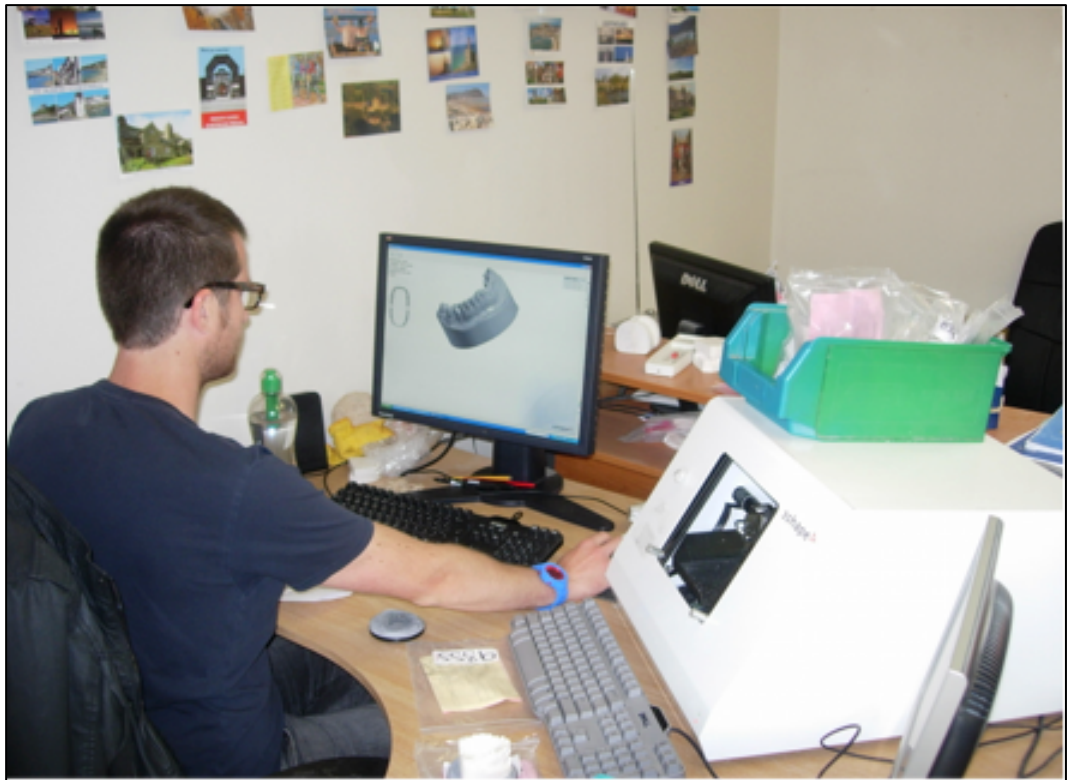


Figure 6.1 3D scanner connected to two PCs, to allow image capture and manipulation

The scanner was linked to two personal computers; the first controlled the movement of the scanner and the second was required for processing the

information in the scanned file. The programmes used by the scanner include "3Shape Scanserver" and "3Shape ScanItOrthodontics" software packages.

The scanner had an opening on the front behind two small sliding doors into which the plaster models were positioned for scanning (Figure 6.2). A laser and two cameras were used to obtain the images, using the principle of laser triangulation. The study models were scanned with laser stripes and the charge couple devices of the two cameras received the reflected light from the surface of the model. Surface shape measurements of the model were recorded through triangulation and the computer then converted this information into a 3D polygon mesh.

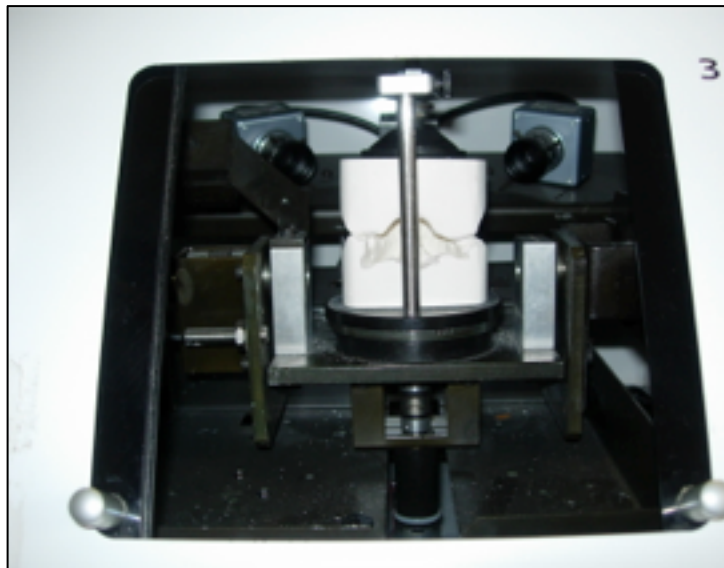


Figure 6.2. Mounted models placed in scanner to register the occlusion

When scanning the arches, the individual models were mounted on a plate before placing in the scanner (Figure 6.3). When scanning pairs of arches in occlusion, they were mounted in a clamp stand that had a maximum height capacity of about 6.5cm (Figure 6.4). The scanning process for a set of models involved making

detailed scans of each arch individually, and a slightly less detailed scan of both arches positioned in occlusion. The operator was presented with a view of both the detailed scans of the arches and of the occlusal scan. By indicating common areas on both the detailed models and occlusal scans, the operator manipulated the software to align the detailed scans in the correct occlusion.



Figure 6.3 Individual model, mounted on scanning plate, Figure 6.4 Models held in occlusion with a clamp to allow scanning to be performed

The detailed scans were saved and loaded into another piece of software ("Rhinceros" CAD, www.rhino3d.com) to allow the operator to 'trim' the digital models by removing excess plaster and making the tops and bottoms parallel, before finally being returned to the investigating team.

Within 3 or 4 weeks the batch of models were returned to Chesterfield Hospital, along with the 3D scans for each patient and each set of models, recorded as digital information on compact discs.

6.2. ASSESSING TOOTH MOVEMENT USING 3D SCANS

The following steps were used to measure molar tooth movement on the scans:

1) Each scan was made up of approximately 300,000 points which when imported resulted in a 3D polygon mesh appearing in the computer screen as an ill-defined grey mesh image (Figure 6.5).

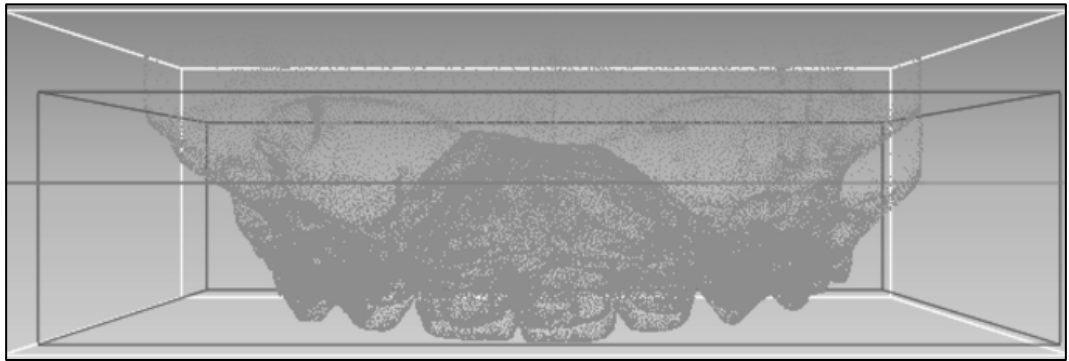


Figure 6.5 3D polygon mesh comprised > 300,000 data points

2) The orientation of the scans was then adjusted to give an occlusal view of the model (Figure 6.6).

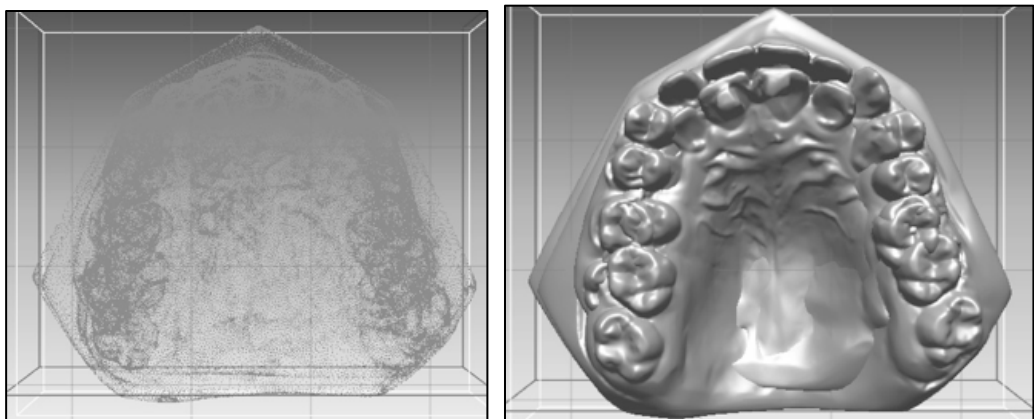


Figure 6.6 Virtual model re-orientated to show the occlusal view, then converted to solid colour

3) The mesh was changed to a solid colour: the scans of start models (M_s) were coloured gold and the scans of the ‘finish’ models (M_f) crimson (Figure 6.7). This convention was adhered to throughout the study

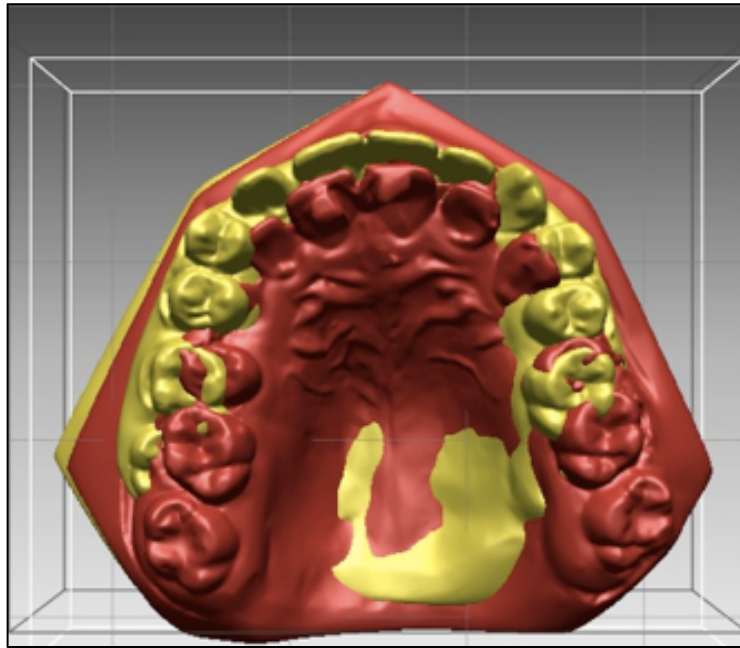


Figure 6.7 Superimposed images - gold selected for pre-treatment model, crimson for post-anchorage supplementation model

4) The preliminary superimposition of M_s and M_f was carried out on landmarks identified on the palatal rugae. Each of the 3D scans was manipulated independently, primarily to enlarge the area showing the detailed anatomy of the palatal rugae. The image of each model was enlarged to fit into half of the computer screen and the split computer screen allowed simultaneous visualization of both M_s and M_f . This enabled the specific anatomical detail of the rugae to be seen simultaneously on both models, to ensure identical anatomical points were identified and subsequently selected on both scanned images. It was a simple operation to adjust the viewing angle or alternatively the magnification as necessary, at any stage, to improve visualization of anatomical detail of the palatal rugae on both scans (Figure 6.8).

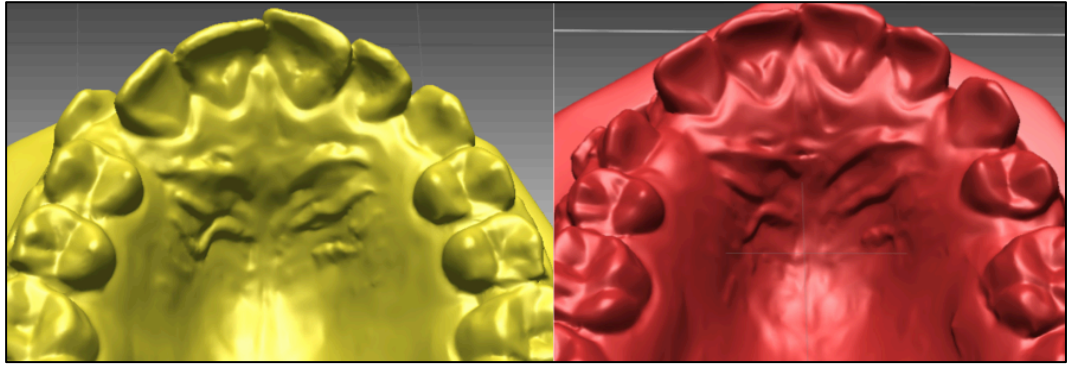


Figure 6.8 The palatal rugae of both models could be simultaneously viewed on the split screen.

Landmarks were now alternately selected between M_s and M_f and the same colour dots were used on both images to identify identical anatomical points. Ideally, points on a minimum of 3 of the major rugae were identified on either side of the midline. The most notable points on the rugae were usually selected at their medial and lateral extremities. The points were highlighted on the surface of both of the models by identical coloured dots on M_s and M_f . Once a sufficient number of anatomical points were identified the programme was instructed to carry out an initial superimposition of the two 3D images based upon those anatomical points (Figure 6.9).

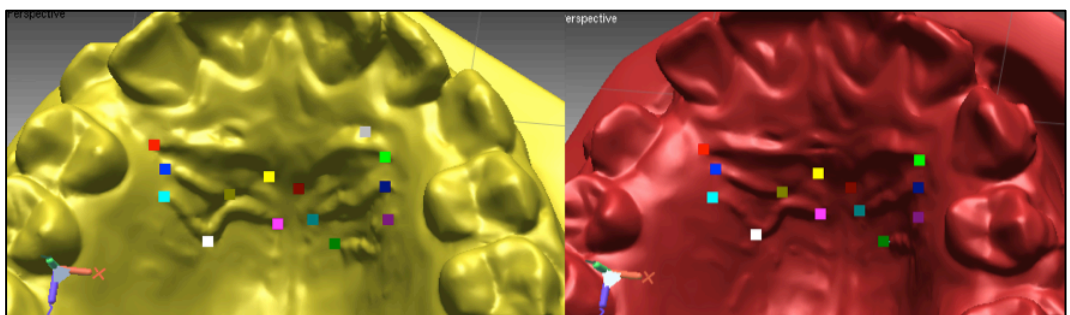


Figure 6.9 The corresponding anatomical points are indicated by the same coloured dots

The accuracy of the superimposition was then visualized on a histogram, and also on the coloured upper model, the colours of which indicate the magnitude of the

discrepancy (Figure 6.10). A ‘perfect fit’ of any superimposition resulted in a totally blue colouration of the soft tissues. Slight discrepancies move through cyan to green which both still indicated an acceptable level of accuracy of fit. Larger discrepancies were indicated towards the yellow, orange and red end of the spectrum.

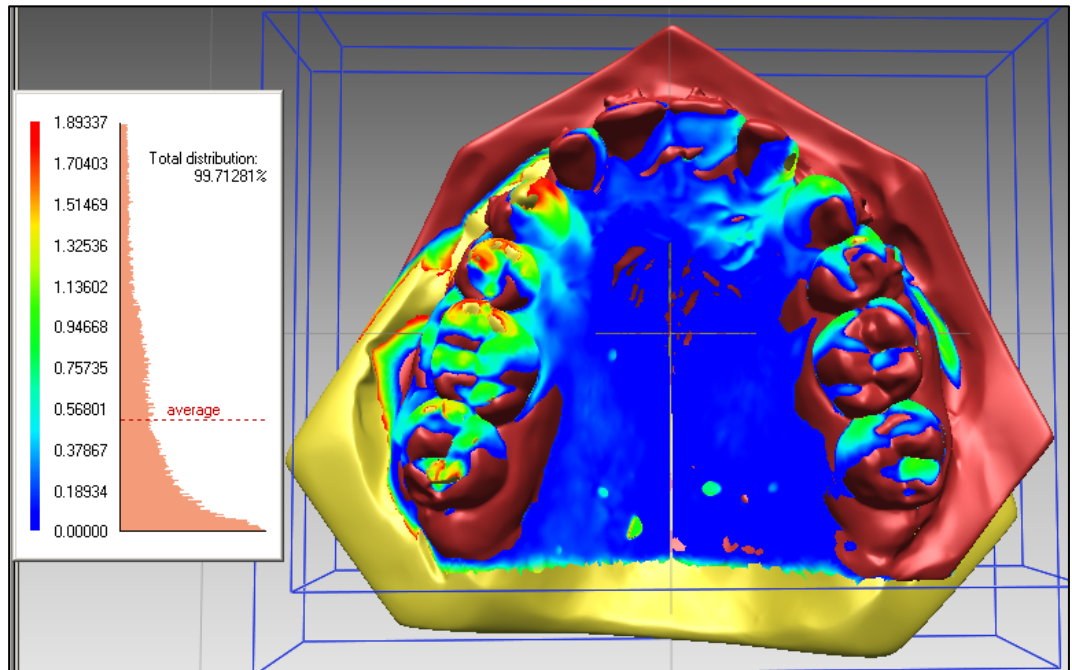


Figure 6.10 Colour of the model represents the accuracy of the superimposition

From the various colours representing the different degrees of ‘fit’ of the two 3D scans the computer calculated an ‘average value’ for the discrepancy of the preliminary superimposition.

Any superimpositions that revealed an average discrepancy of $> 0.8\text{mm}$, required that the whole identification of landmarks and subsequent superimposition process was repeated, until an acceptable level of $< 0.8\text{mm}$ was achieved.

Once the accuracy of the initial superimposition was within the acceptable levels, a more accurate ‘regional superimposition’ was performed. An area of known

stability was selected, involving a ‘mushroom’ shaped area plus the ‘mushroom stalk’ extending posteriorly on the hard palate for a few millimeters either side of the midline palatal raphe (Figure 6.11).

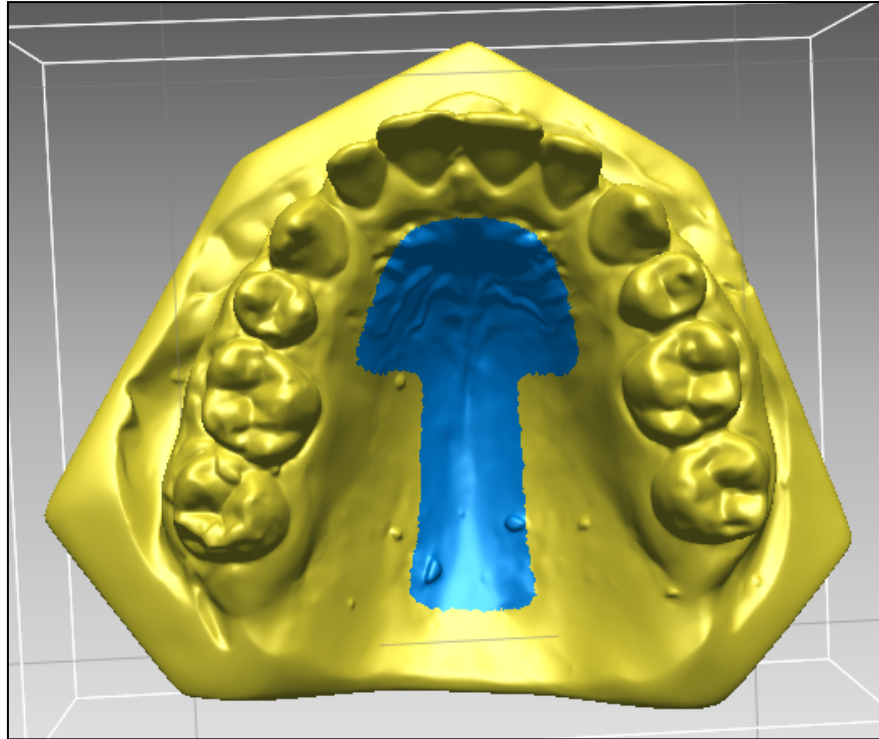


Figure 6.11 Blue ‘mushroom’ covering points of known stability for regional superimposition

The mushroom was centered on the medial ends of the first three major rugae which are known to be relatively stable (Van der Linden (1978), Bailey et al. (1996), Almeida et al. (1995)), avoiding the lateral ends of the rugae.

After this second ‘regional superimposition’ the computer software again calculated the accuracy of superimposition. A histogram again indicated with colours the degree of deviation from ideal and when the calculated average discrepancy was $<0.8\text{mm}$ the superimposition was considered acceptable.

6.3. IDENTIFYING MOLAR MOVEMENTS

The next stage in the procedure was to mark the ‘shell’ of the left and right molar teeth, as it is these shells whose movement was ultimately to be measured. In most of the maximum anchorage patients enrolled in the study we used the upper first molars, however in a small number of cases the first molars were extracted and the second molars were selected to detect anchorage loss. The crowns of the selected molars were identified and, with careful use of the mouse, were highlighted in blue. Marking started with the occlusal surface then, after tilting the model, the buccal and the palatal surface were marked. Eventually the entire ‘shell’ of the crown had been selected (Figure 6.12).

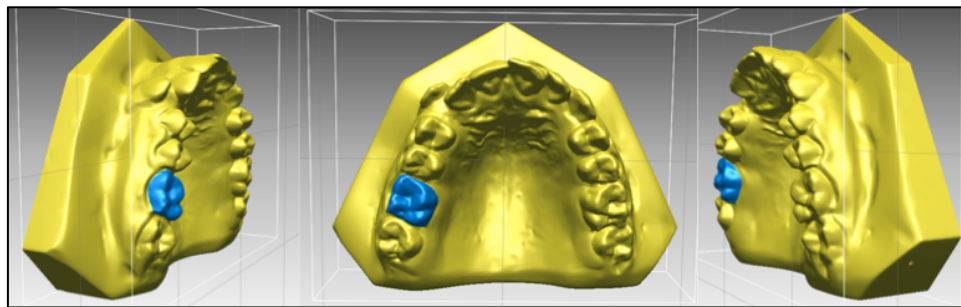


Figure 6.12 Start model rotated to allow the entire occlusal, buccal and palatal surfaces to be highlighted, forming the start of treatment molar shell.

This highlighted molar shell could then be copied, named to allow later selection (e.g. UL6s) and ultimately saved as a freestanding shell. This entire process was then repeated for the other side of the arch on M_s and then once again repeated for both molar crowns on the final models, M_f (Figure 6.13)

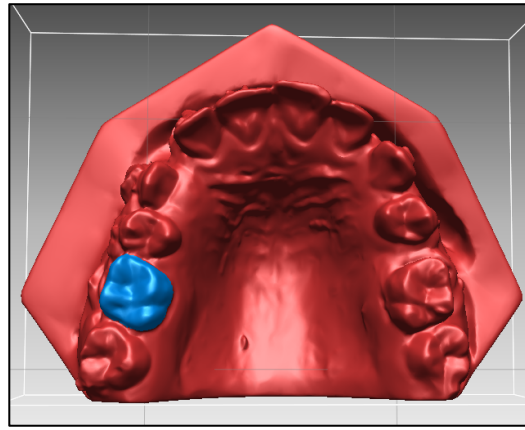


Figure 6.13 Occlusal surface identified on the end of anchorage model (M_f)

The freestanding shell of the upper left first molar on M_s was then superimposed exactly on the shell of the upper left first molar on M_f , using the fine superimposition function. This superimposition was done using only the anatomy of the occlusal surface of the tooth to ensure very accurate superimposition. The original buccal and palatal surface outlines from the start of treatment molar shell, were the ones actually used on the final molar shell. Using this clever substitution technique any possible gingival impingement on the post treatment molar (e.g. gingival irritation, overgrowth or hyperplasia), which would affect the calculation of the Centre of Mass of the crown, is taken out of consideration. The computer programme was then instructed to calculate the Centre of Mass of both the upper first molar shell from the start of treatment model and also of the ‘adjusted’ upper first molar shell from the post-treatment model.

The computer then calculated the physical distances between the Centres of Mass on the regionally superimposed M_s and M_f and presented a diagrammatic representation of the tooth movement that had occurred and gives the linear distances (Figure 6.14).

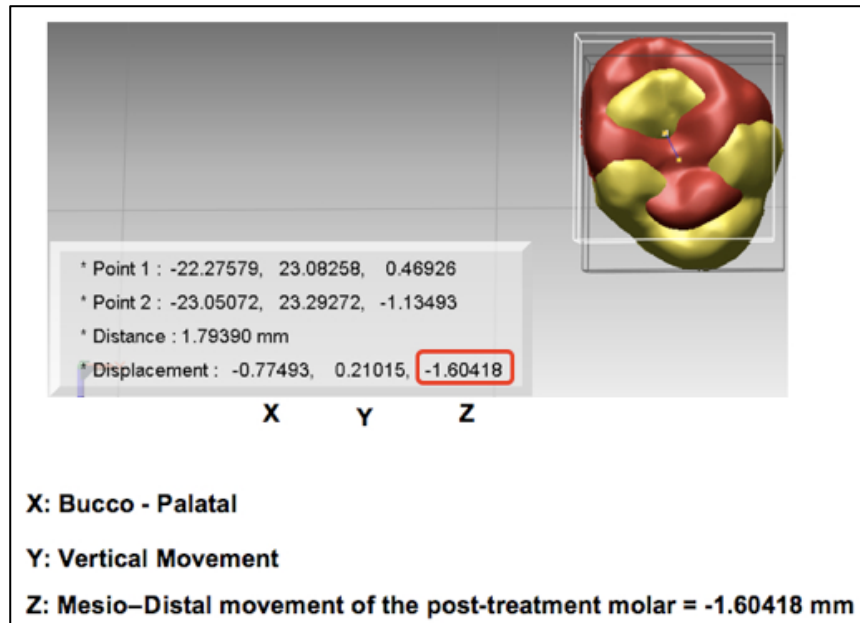


Figure 6.14 Movement of molar shell and measurements in all 3 planes

Movement in a bucco-palatal direction is seen in the X-axis figure, movement in a vertical direction by the Y-axis, and the Z-axis is an indication of mesio-distal movement of the molar tooth. The positive or negative notation of the figure could vary according to the order of superimposition of the models. A convention was adopted to superimpose the later model on the earlier model and this ensured that any mesial molar movement would be represented by a negative figure.

6.4 REPRODUCIBILITY OF THE 3D METHOD

Double determinations were carried out to investigate whether this method of superimposition was reproducible. Twenty randomly selected pairs of 3D scans, where superimposition had already been carried out, were chosen and the whole process of superimposition was repeated. This investigation was undertaken to detect any intra-operator error and to ensure consistency in the methodology. Repeated measurements of molar movement from successive superimpositions were carried out at least two weeks apart.

On each occasion the start scans (M_s) and the end of anchorage supplementation scan (M_f) were superimposed using the technique described previously (Section 6.3). The movement of the centres of mass of the molars was calculated by the computer in all 3 planes of space, for both the right and left molars. The data was stored firstly as a Rapidform file, which gives visual presentation of the molar movement and also shows the actual measurements for movement that allowed crosschecking for accurate data entry (Figure 6.15). Secondly the information was stored as an excel file which could be directly imported into SPSS 19 for Mac, to enable subsequent statistical analysis.

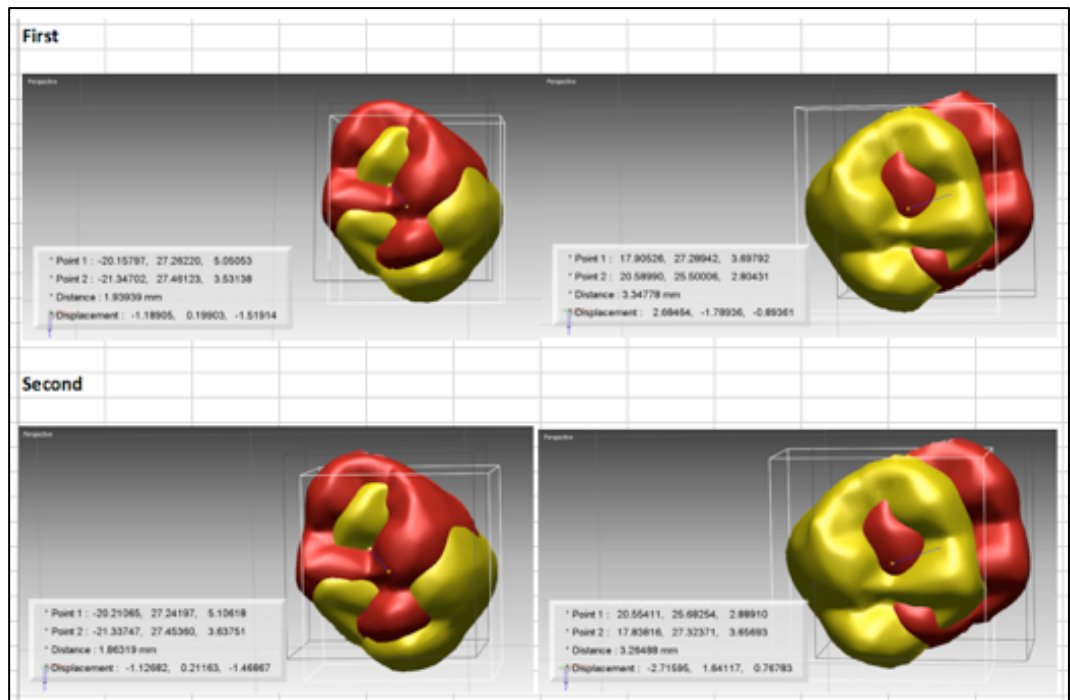


Figure 6.15 Rapidform files show the molar movement and the measurements

A file was produced which listed the values of the movement of the centre of mass of the molars for each of the 20 cases studied as part of the reproducibility study (Table 6.1). Movement was listed for the right and left molar teeth in all

three planes of space. In subsequent tables acronyms were used; URMZ1 identified the first measurement for the upper right molar in the Z direction, which was the anterior posterior movement of interest when measuring anchorage loss. The second occasion of measurement of this particular variable was listed under the acronym URMZ2.

Upper Right Molar 1 st Z (URMZ1) mm	Upper Left molar 1 st Z (ULMZ1) mm	Upper Right Molar 2 nd Z (URMZ2) mm	Upper Left Molar 2 nd Z (ULMZ2) mm
1.52	-0.89	1.47	-0.77
0.55	4.30	0.57	4.18
1.00	-0.41	0.95	-0.68
0.16	0.82	0.37	0.70
2.89	1.18	2.82	1.26
0.39	1.82	0.41	1.41
0.83	1.29	0.99	1.44
3.60	1.61	3.13	1.88
2.35	3.20	2.12	3.28
1.88	1.91	1.70	1.75
-0.56	1.51	-0.89	1.44
0.93	1.39	1.16	1.83
0.35	0.52	0.58	0.51
0.16	-0.06	0.30	-0.31
0.047	2.95	0.48	2.35
0.29	2.20	0.71	1.78
0.08	1.95	0.20	2.20
1.91	2.41	2.44	1.61
1.26	-0.57	1.53	-0.59

Table 6.1 - Double determination of movement of the Centres of Mass of upper molar teeth on two occasions. 1st and 2nd set of measurements

Z = Mesial-Distal or antero-posterior movement

The figures of particular interest were the differences between the molar movement measured on first and second superimposition and the mean of these differences, which were calculated by the computer using SPSS 19 for Mac, (Table 6.2).

Differences between URMZ1 and URMZ2 mm	Differences between ULMZ1 and ULMZ2 mm	Mean of URMZ1 and URMZ2 mm	Mean of ULMZ1 and ULMZ2 mm
0.05	-0.13	1.49	-0.83
-0.02	0.13	0.56	4.24
0.05	0.28	0.97	-0.54
-0.21	0.11	0.27	0.76
0.07	-0.07	2.85	1.22
-0.02	0.42	0.40	1.62
-0.16	-0.15	0.91	1.36
0.48	-0.27	3.37	1.75
0.24	-0.08	2.24	3.24
0.18	0.15	1.79	1.83
0.26	0.07	-0.69	1.47
-0.23	-0.44	1.05	1.61
-0.23	0.01	0.47	0.52
-0.14	0.25	0.23	-0.18
-0.43	0.60	0.26	2.65
-0.42	0.42	0.50	1.99
-0.12	-0.24	0.14	2.08
-0.53	0.80	2.17	2.01
-0.28	0.03	1.39	-0.58
-1.07	-2.32	2.78	3.46

Table 6.2 Differences between the 1st and 2nd determinations and means of the differences of movement

6.4.1 HISTOGRAMS

Before applying any statistical tests the data was first tested for normal distribution that, once confirmed, allowed parametric statistical tests to be employed for further analysis (Figs 6.16 to 6.22)

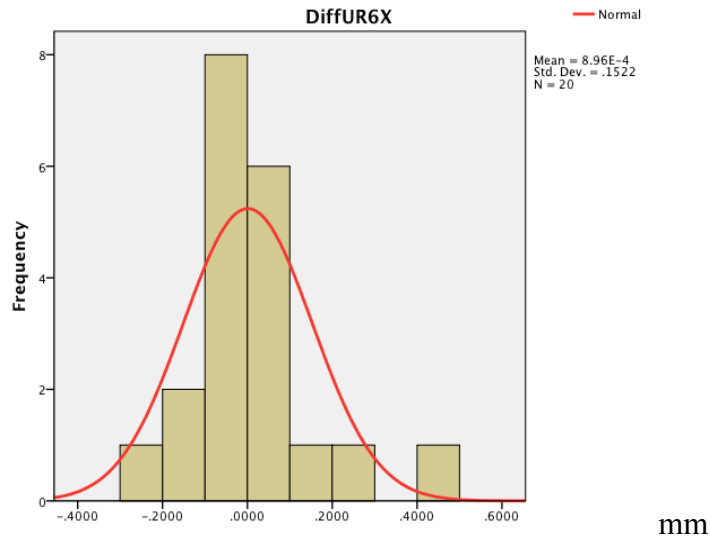


Figure 6.16 Differences between 1st and 2nd measurements for upper right molar in the bucco-palatal direction

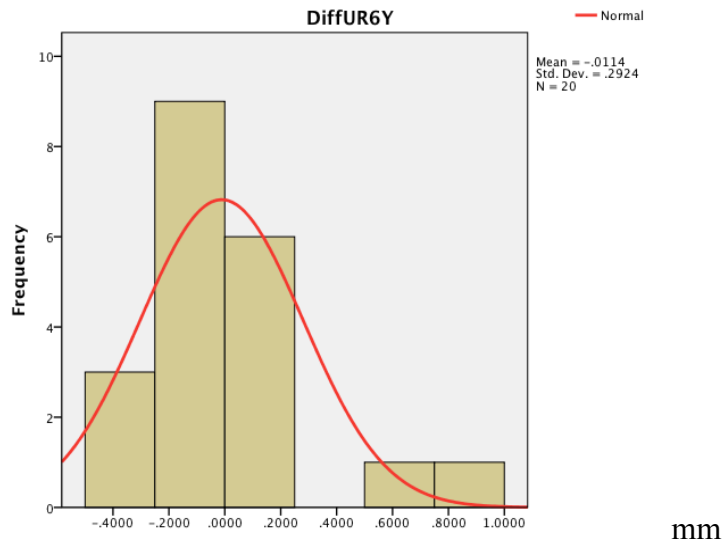


Figure 6.17 Differences between 1st and 2nd measurements for upper right molar in the vertical direction

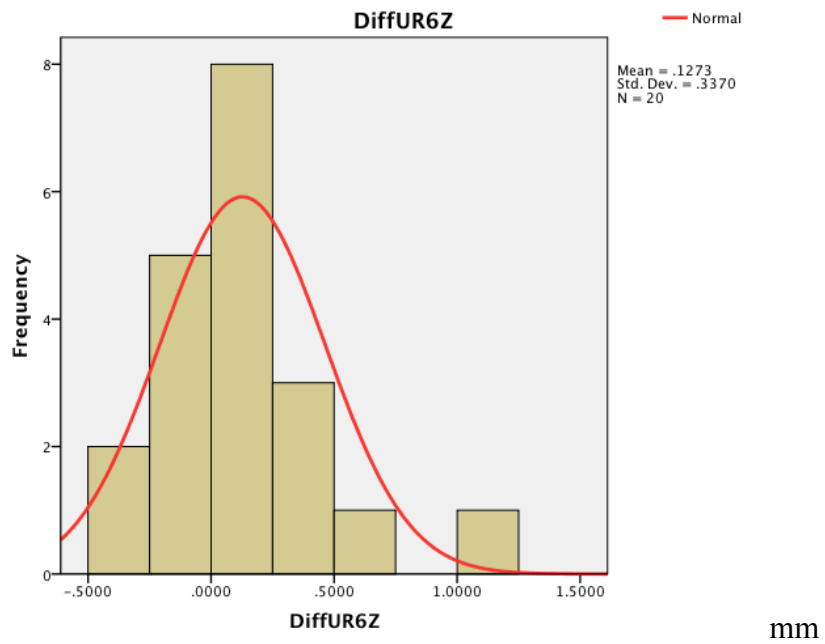


Figure 6.18 Differences between 1st and 2nd measurements for upper right molar in the mesio-distal direction

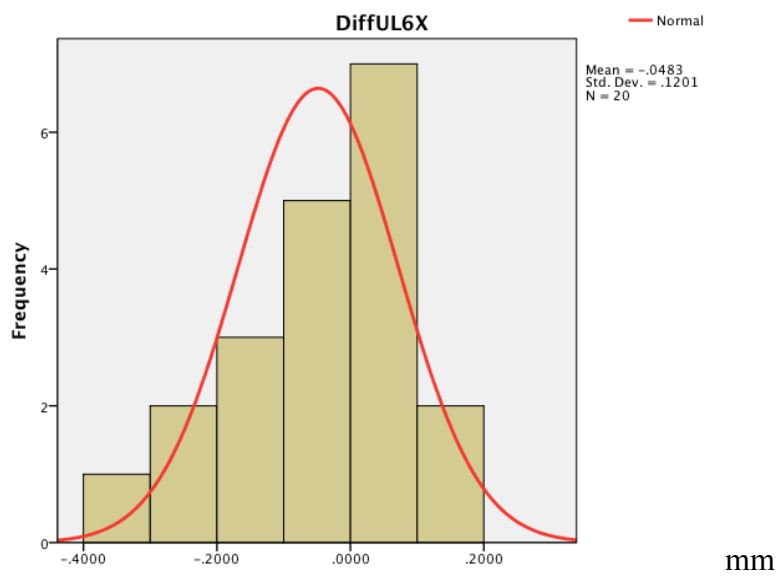


Figure 6.19 Differences between 1st and 2nd measurements for upper left molar in the bucco-palatal direction

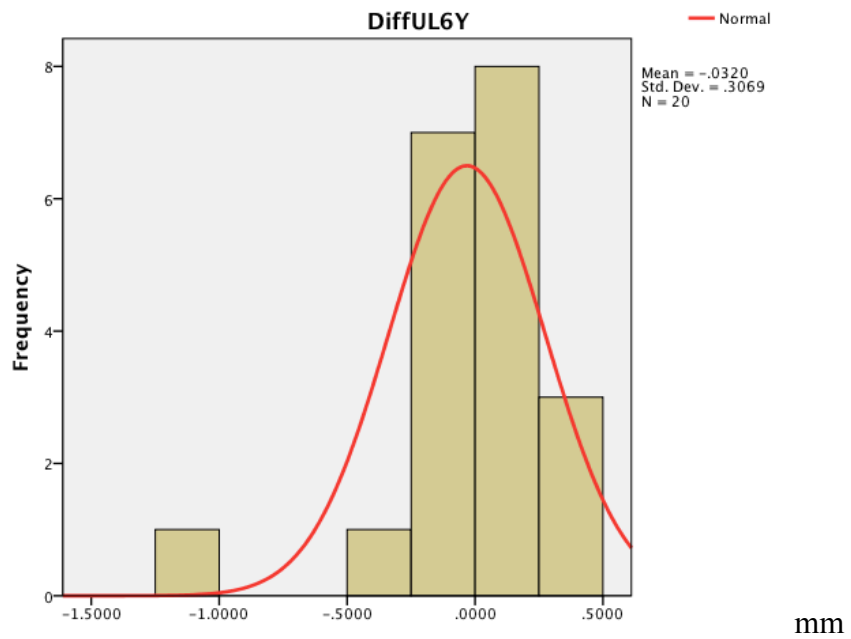


Figure 6.20 Differences between 1st and 2nd measurements for upper left molar in the vertical direction

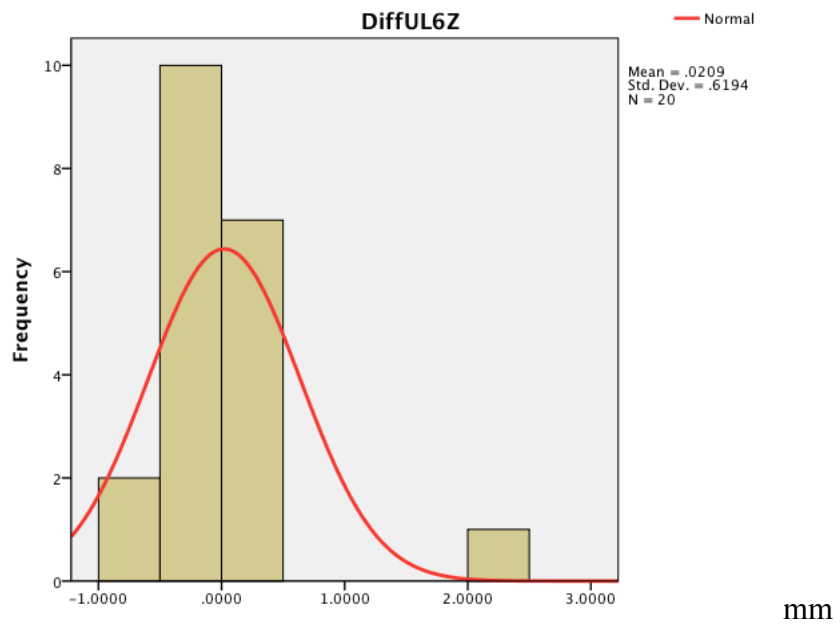


Figure 6.21 Differences between 1st and 2nd measurements for upper left molar in the mesio-distal direction

6.4.2 INTRACLASS CORRELATION SCATTERGRAMS

As a result of demonstrating the normal distribution of the data, the relationship between the two determinations was investigated using Intraclass correlation coefficients, which can be seen in Figures 6.22-6.27.

Figure 6.22 to 6.27 Intraclass correlation scattergrams for double determinations of molar movement in all three planes of space

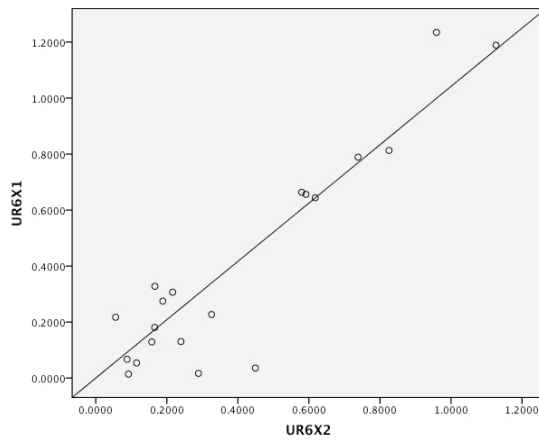


Figure 6.22 Bucco-palatal movement of right molar on first measuring, plotted against that on second measuring

mm

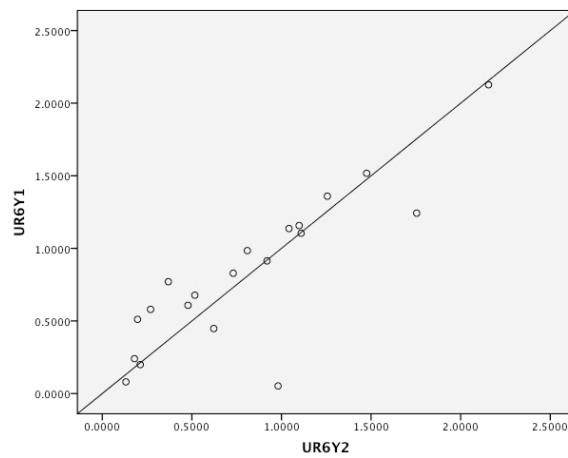


Figure 6.23 Vertical movement of right molar on first measuring, plotted against that on second measuring

mm

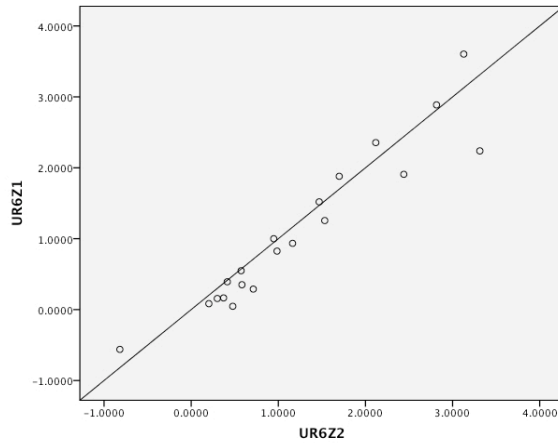


Figure 6.24 Mesio-distal movement of right molar on first measuring, plotted against that on second measuring

mm

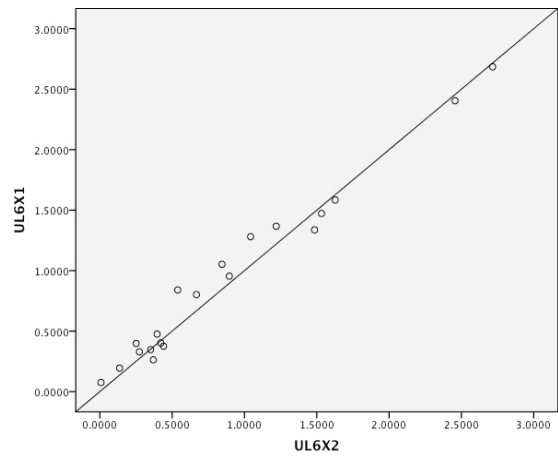


Figure 6.25 Bucco-palatal movement of left molar on first measuring, plotted against that on second measuring

mm

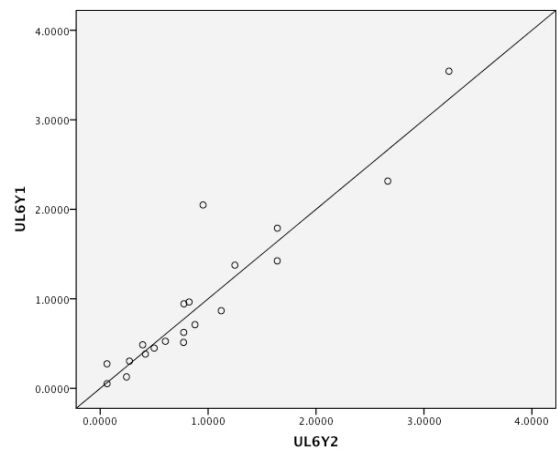


Figure 6.26 Vertical movement of left molar on first measuring, plotted against that on second measuring

mm

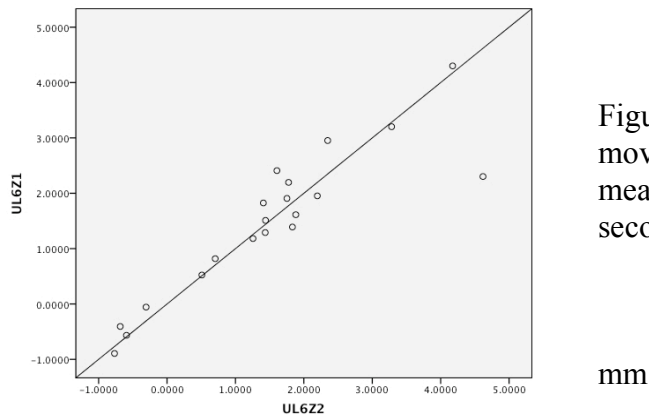


Figure 6.27 Mesio-distal movement of right molar on first measuring, plotted against that on second measuring

mm

The linearity between the two determinations can be clearly seen. It was therefore deemed appropriate to calculate the intraclass correlation coefficient that varied between 0.93 and 0.99, Table 6.3. This indicated a very strong correlation between the repeated measurements of all the molar movements.

Tooth movement mm	Cronbach's alpha	Intraclass correlation	95% Confidence Interval		P-value
UR6X	0.99	0.95	0.89	0.98	<0.001
UR6Y	0.92	0.93	0.81	0.97	<0.001
UR6Z	0.98	0.97	0.93	0.99	<0.001
UL6X	0.93	0.99	0.98	0.99	<0.001
UL6Y	0.97	0.97	0.92	0.98	<0.001
UL6Z	0.95	0.95	0.88	0.98	<0.001

Table 6.3 Relationship between first and second measurements of each movement

The association between the repeated measurements was confirmed using a two-tailed T-test, which measured whether the correlation coefficient was statistically significantly different from zero. The correlation coefficients were all found to be highly significantly different from zero ($p < 0.001$).

6.5 LIMITS OF AGREEMENT

Systematic error or bias was then investigated, using plots recommended by Bland Altman (1986), carried out for each of the pairs of determinations, Figure 6.28-6.33. The Bland Altman plot illustrates the difference (d) between the subsequent readings of a particular variable (y-axis), plotted against the average of those two readings (x-axis). The horizontal lines above and below the zero line indicate \pm two standard deviations (the upper and lower lines giving the limits of agreement – 95% confidence intervals).

The error in the measurements follows a normal distribution; therefore 95% of the points lie between the lines defining $d \pm 2$ standard deviations. The Bland Altman plots are not formally measured, but are generally subjected to informal interpretation bearing in mind the following three questions: 1) How large is the discrepancy between the double determinations and is this magnitude of discrepancy of importance clinically? 2) Is there a trend seen? 3) Is the variability of points plotted, reasonably consistent across the plot?

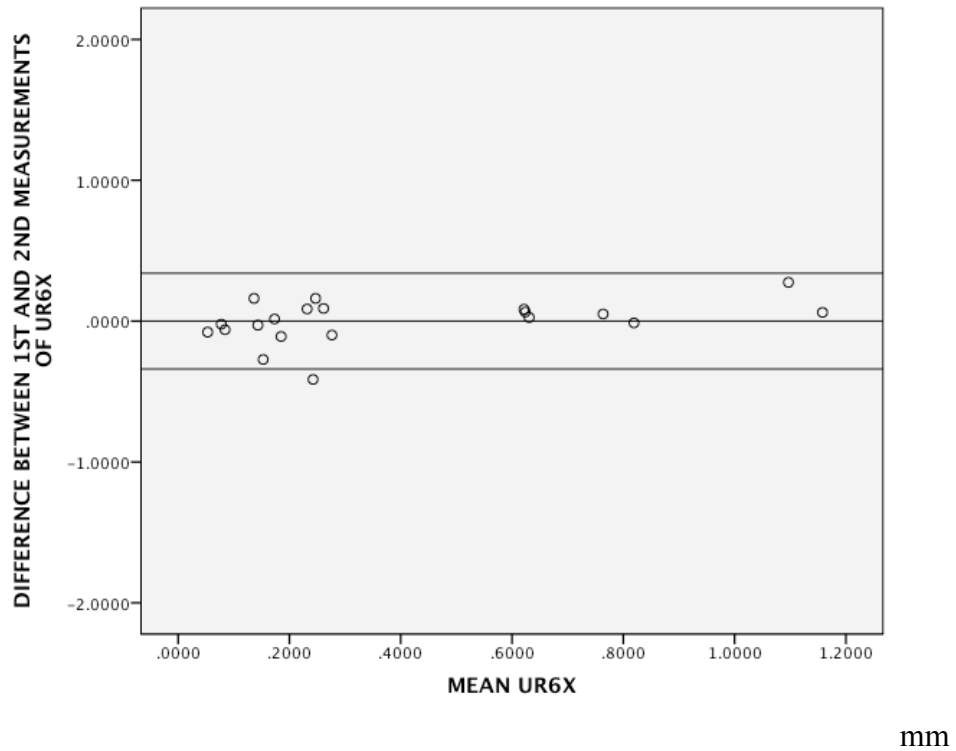


Figure 6.28 Bland Altman plots of the differences in 3D scan measurements of the upper right molar in the bucco palatal direction

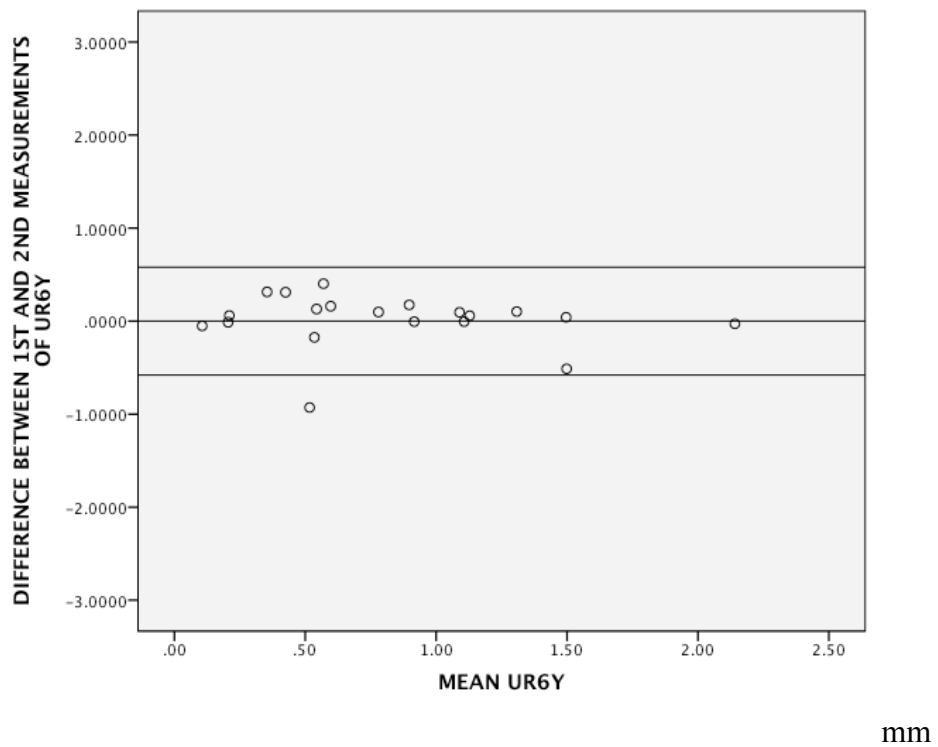
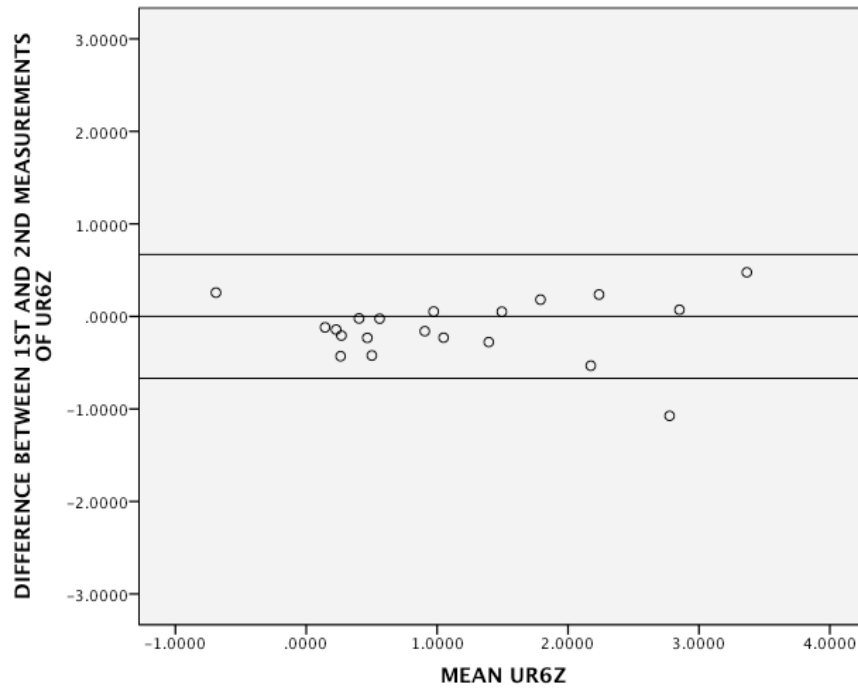
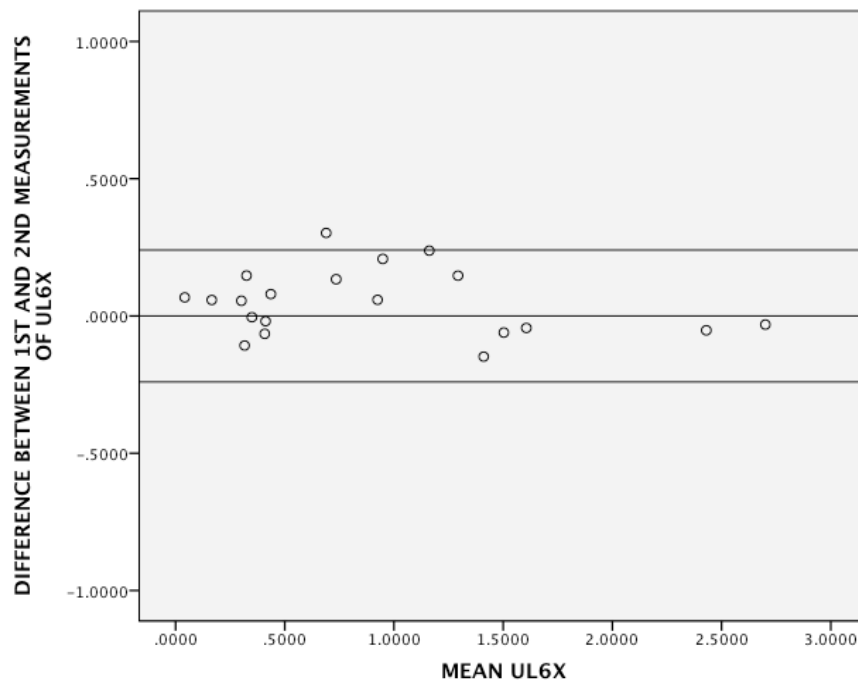


Figure 6.29 Bland Altman plots of the differences in 3D scan measurements of the upper right molar in the vertical direction



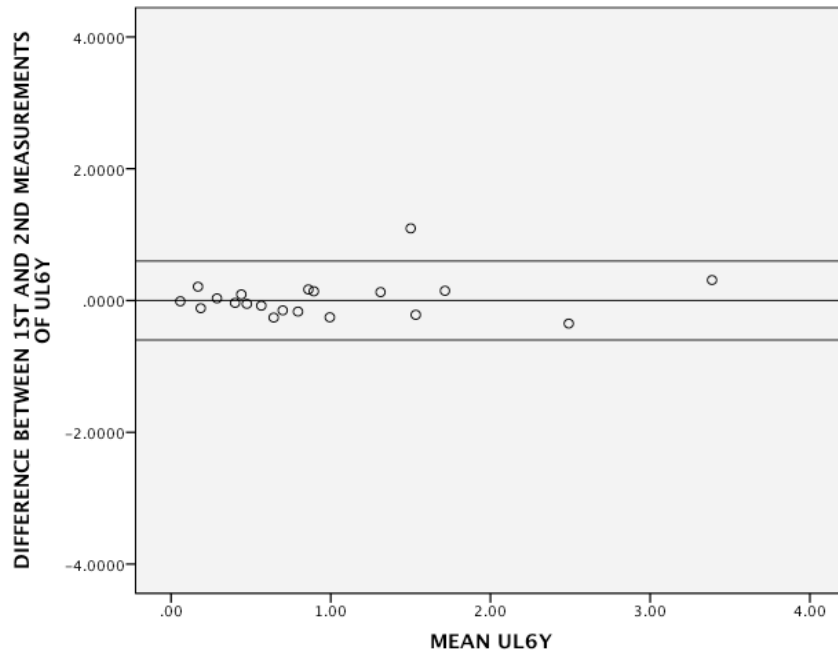
mm

Figure 6.30 Bland Altman plots of the differences in 3D scan measurements of the upper right molar in the mesio-distal direction



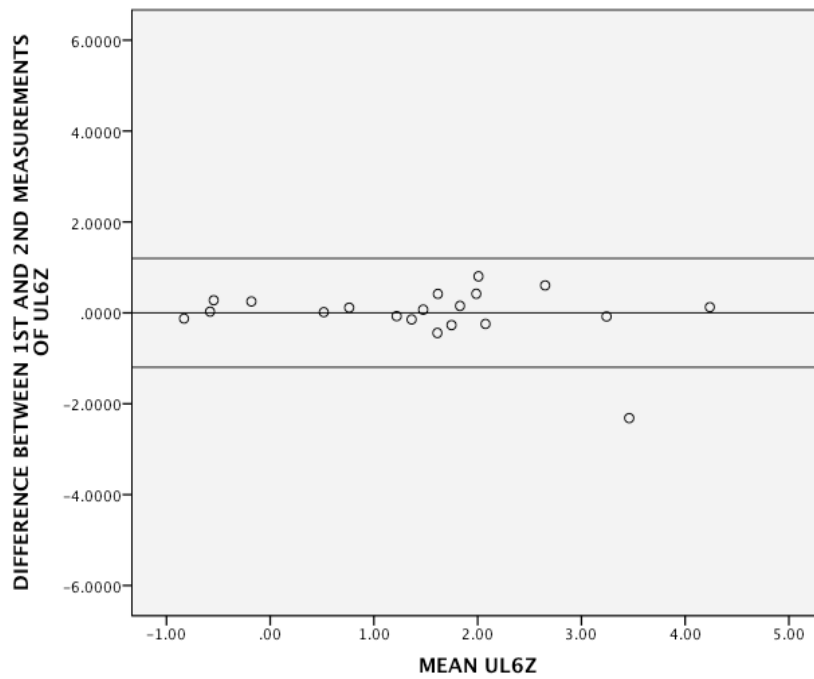
mm

Figure 6.31 Bland Altman plots of the differences in 3D scan measurements of the upper left molar in the bucco palatal direction



mm

Figure 6.32 Bland Altman plots of the differences in 3D scan measurements of the upper left molar in the vertical direction



mm

Figure 6.33 Bland Altman plots of the differences in 3D scan measurements of the upper left molar in the mesio-distal direction

The Bland-Altman analyses, for the six sets of double determinations of the movements of the centres of mass of the molars, following superimposition, consistently provide similar measures. The level of agreement did not include any clinically important discrepancies.

6.6. ERROR OF METHOD

The means of the differences between the measurements on the first and second occasion were all compared using a paired sample t-test. Means, standard deviations and standard errors of the mean are shown in Table 6.4. None of the measurements showed statistically significant differences; for each of the six measurements $p > 0.05$. The mean error values were all less than 0.05mm with the exception of measurement of the upper right molar movement in the antero-posterior plane, which only amounted to 0.14mm. The method of superimposing digital models to measure anchorage loss is therefore reproducible and has acceptable levels of error.

Tooth and direction of movement n = 20	Mean of the difference (mm)	Standard deviation	Standard Error of mean	95% confidence interval of the difference		P-value
				Lower	Upper	
Upper right molar transverse (X)	-.02	.15	.03	-.07	.07	.98
Upper right molar vertical (Y)	.01	.29	.065	-.13	.15	.86
Upper right antero-posterior (Z)	-.14	.34	.08	-.29	.03	.11
Upper left molar transverse (X)	.05	.12	.03	-.01	.10	.09
Upper left molar vertical (Y)	.03	.31	.07	-.11	.18	.65
Upper left antero-posterior (Z)	-.02	.62	.14	-.31	.27	.88

Table 6.4 Paired Sample T test for the mean errors in measurements of movement of molars on two occasions, to assess method error. Data from table 6

Chapter 7.0 RECORD ANALYSES – CEPHALOGRAMS

7.1. ASSESSING ANCHORAGE LOSS ON CEPHALOGRAMS

For the purposes of assessing the anchorage loss we required a limited cephalometric analysis similar to the analysis described by Pancherz (1982). A constructed vertical was dropped through Sella, at 97 degrees to the SN plane, both on the start and the end of anchorage supplementation films. Horizontal measurements were taken from this vertical line, to both the left and right molar markers both at DC1 and DC2 and the difference between the two measurements represented the molar movement in the antero-posterior direction. For details of the Cephalometric technique see Appendix 18.

7.2. RELIABILITY OF MEASUREMENT OF MOLAR MOVEMENT ON THE CEPHALOMETRIC RADIOGRAPHS

To test the reproducibility of the cephalometric measurements, double determinations were necessary for selected pairs of cephalograms. A sample size calculation (Table 6) revealed the need for assessment of twenty pairs of cephalograms for reliability analysis. An internet based, random number sequence generator was used to identify 20 random cases, between 1 and 78, <http://www.randomizer.org/form.htm>, for repeat analysis.

The aim of this part of the investigation was to detect any differences in the measurements of molar teeth movement, measured on pairs of radiographs, on two separate occasions at least two weeks apart.

Pre-treatment and post-treatment cephalograms were assessed and the molar movement was measured relative to the constructed vertical line, which passed through Sella. The same pairs of radiographs were remeasured 2 or more weeks later, and differences between the measurements were calculated. The data was analysed statistically using SPSS 19.0.0 for Mac software.

	1	2	3
Confidence level, 1-a	0.95	0.95	0.95
1 or 2-sided interval?	2	2	2
Number of measurements, k	2	2	2
Expected intraclass correlation, r	0.90	0.90	0.85
Distance from correlation to limit, w	0.10	0.09	0.13
n	15	20	20

Table 7.1 Intraclass correlation – Sample size calculation for number of cephalograms on which to perform double determination

1. When the sample size is 15, a two-sided 95.0% confidence interval computed using the large sample normal approximation for an intraclass correlation based on 2 measurements will extend about 0.1 from the observed intraclass correlation when the expected intraclass correlation is 0.9.

2. When the sample size is 20, a two-sided 95.0% confidence interval computed using the large sample normal approximation for an intraclass correlation based on 2 measurements will extend about 0.09 from the observed intraclass correlation when the expected intraclass correlation is 0.9.

3. When the sample size is 20, a two-sided 95.0% confidence interval computed using the large sample normal approximation for an intraclass correlation based on 2 measurements will extend about 0.13 from the observed intraclass correlation when the expected intraclass correlation is 0.85.

7.3. TOOTH MOVEMENT AS ASSESSED ON CEPHALOGRAMS - RESULTS FOR THE RELIABILITY STUDY

The acronym heading each column, indicates the tooth, the measurement taken, whether it is pre-treatment or post-treatment and whether it is the first occasion of measurement or the second occasion of measurement e.g. Upper left molar Z1-1st. This figure indicates the distance in millimetres from the constructed vertical, of the upper left molar tooth, pre-treatment, on the first occasion it was measured. The Z2 acronym means post anchorage supplementation, and 2nd indicates the measurement on the second occasion it was measured.

The molars were usually first molars although a few of the cases involved extraction of the first molars and the second molars were used for measurement instead. For the sake of convention the acronym still included the figure 6, to indicate the molar tooth.

The difference between the pre-treatment and the post anchorage supplementation measurements indicated the amount of mesial or distal movement that has occurred during this stage of treatment, which represents the anchorage loss or

gain. The movement indicating the anchorage loss or gain was measured on two separate occasions. There were no statistically significant differences between the repeated measurements of tooth movement.

Upper Left Molar Z1 1 st mm	Upper Right Molar Z1 1 st mm	Upper Left Molar Z2 1 st mm	Upper Right Molar Z2 1 st mm	Upper Left Molar Z1 2 nd mm	Upper Right Molar Z1 2 nd mm	Upper Left Molar Z2 2 nd mm	Upper Right Molar Z2 2 nd mm
41.47	42.88	42.96	45.7	39.76	41.26	40.98	43.55
36.12	39.14	44.36	43	32.14	35.19	40.55	39.4
40.55	40.55	42.78	44.88	40.82	40.82	42.97	45.13
44.08	46.45	45.74	47.46	44.57	47.32	46.25	47.68
33.1	31.91	31.54	30.37	34.3	33.33	32.9	32.08
22.89	26.92	27.21	32.24	23.99	28.35	27.83	33.48
34.43	34.43	37.12	37.78	35	35.38	36.75	37.24
26.61	28.06	31.78	32.12	26.43	27.83	33.64	33.91
38.14	39.12	37.76	41.09	37.72	38.6	38.36	39.77
38.2	40.66	38.97	41.64	39.32	42.3	39.1	42.33
41.03	43.56	44.78	46.01	42.16	44.91	44.14	45.33
37.49	39.38	38.2	38.68	35.81	37.46	37.33	37.89
32.31	32.28	34.42	33.74	31.71	33.84	32.4	33.95
44.24	44.77	46.97	46.53	45.78	44.99	46	46
39.56	41.27	40.72	41.67	39.8	41.61	41	41.94
43.03	47.36	48.05	51.45	43.32	47.71	48.2	51.9
43.59	49.5	45.45	50.38	44.02	50.39	46.14	51.06
37.25	39.21	42.53	42.53	38.09	40	41.8	41.8
39.3	39.3	36.98	36.98	39.38	39.38	36.99	36.99
40.77	43.98	40.57	43.8	41.97	45.91	40.99	44.45

Table 7.2 Double determination on 20 randomly selected Cephalograms – distances from left and right molar markers to the constructed vertical

L DIFF 2 mm	L DIFF 1 mm	L2 - 1 (error)	R DIFF 2 mm	R DIFF 1 mm	R2 - 1 (error)	MEAN L mm	MEAN R mm
-1.22	-1.49	0.27	-2.29	-2.82	0.53	-1.36	-2.56
-8.41	-8.24	-0.17	-4.21	-3.86	-0.35	-8.33	-4.04
-2.15	-2.23	0.08	-4.31	-4.33	0.02	-2.19	-4.32
-1.68	-1.66	-0.02	-0.36	-1.01	0.65	-1.67	-0.69
1.40	1.56	-0.16	1.25	1.54	-0.29	1.48	1.40
-3.84	-4.32	0.48	-5.13	-5.32	0.19	-4.08	-5.23
-1.75	-2.69	0.94	-1.86	-3.35	1.49	-2.22	-2.61
-7.21	-5.17	-2.04	-6.08	-4.06	-2.02	-6.19	-5.07
-0.64	0.38	-1.02	-1.17	-1.97	0.80	-0.13	-1.57
0.22	-0.77	0.99	-0.03	-0.98	0.95	-0.28	-0.51
-1.98	-3.75	1.77	-0.42	-2.45	2.03	-2.87	-1.44
-1.52	-0.71	-0.81	-0.43	0.70	-1.13	-1.12	0.14
-0.69	-2.11	1.42	-0.11	-1.46	1.35	-1.40	-0.79
-0.22	-2.73	2.51	-1.01	-1.76	0.75	-1.48	-1.39
-1.20	-1.16	-0.04	-0.33	-0.40	0.07	-1.18	-0.37
-4.88	-5.02	0.14	-4.19	-4.09	-0.10	-4.95	-4.14
-2.12	-1.86	-0.26	-0.67	-0.88	0.21	-1.99	-0.78
-3.71	-5.28	1.57	-1.80	-3.32	1.52	-4.50	-2.56
2.39	2.32	0.07	2.39	2.32	0.07	2.36	2.36
0.98	0.20	0.78	1.46	0.18	1.28	0.59	0.82

Table 7.3. Difference between the two measurements, therefore the anchorage loss (or gain) plus the error in measurement, plus mean of the measurement on two occasions

7.3.1 HISTOGRAMS

The normality of the data was assessed using histograms for the difference between the first and second sets of measurements. The results clearly demonstrated normal distribution of the measurements in question, allowing parametric statistical analyses to be used (Figure 7.1 and 7.2).

Histogram charts for the assessing the normality of the difference between the first and second set of measurements

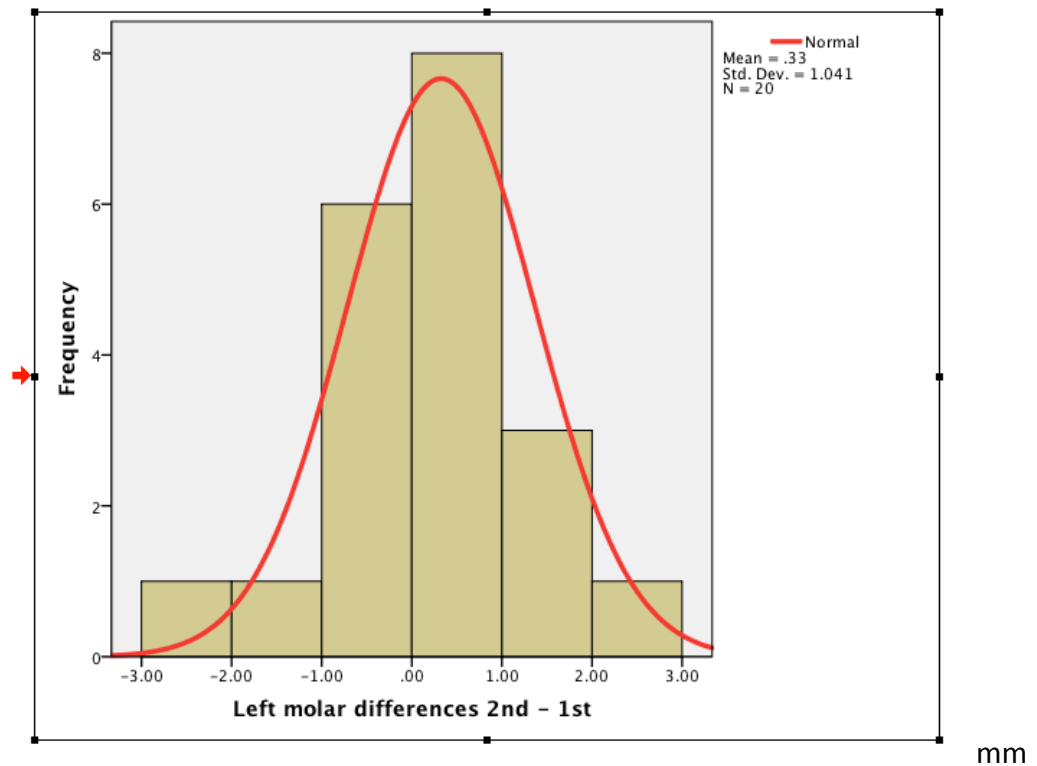


Figure 7.1 Difference between 1st and 2nd measurement of left molar movement

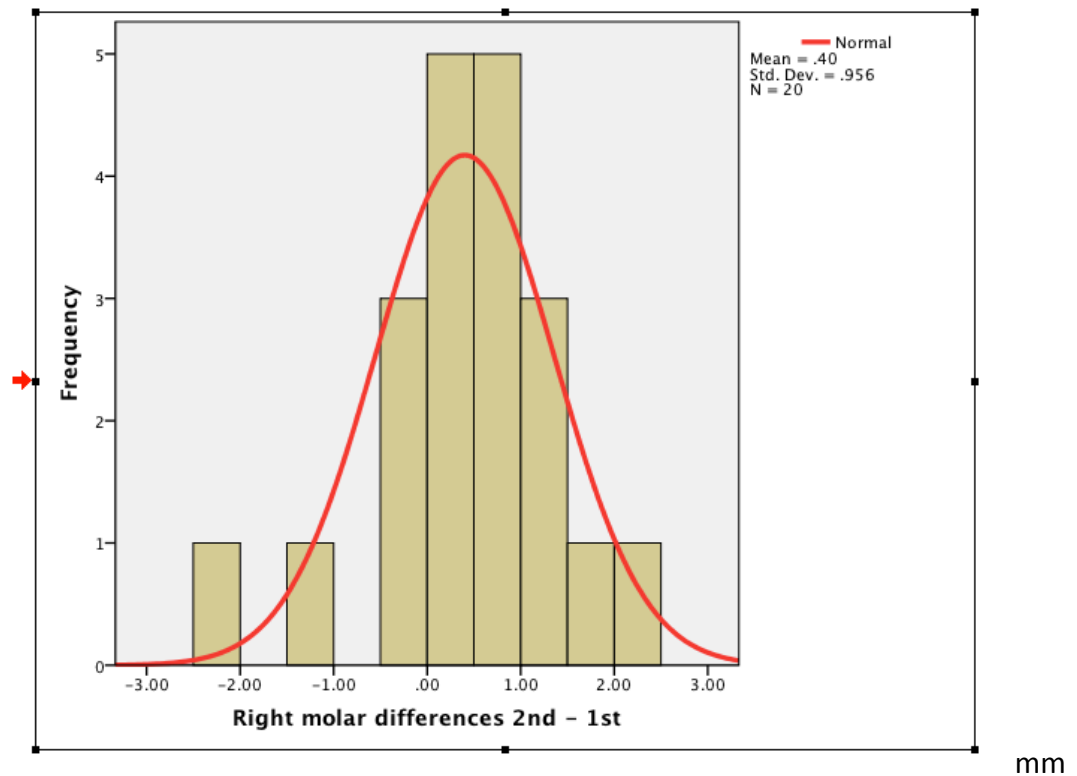
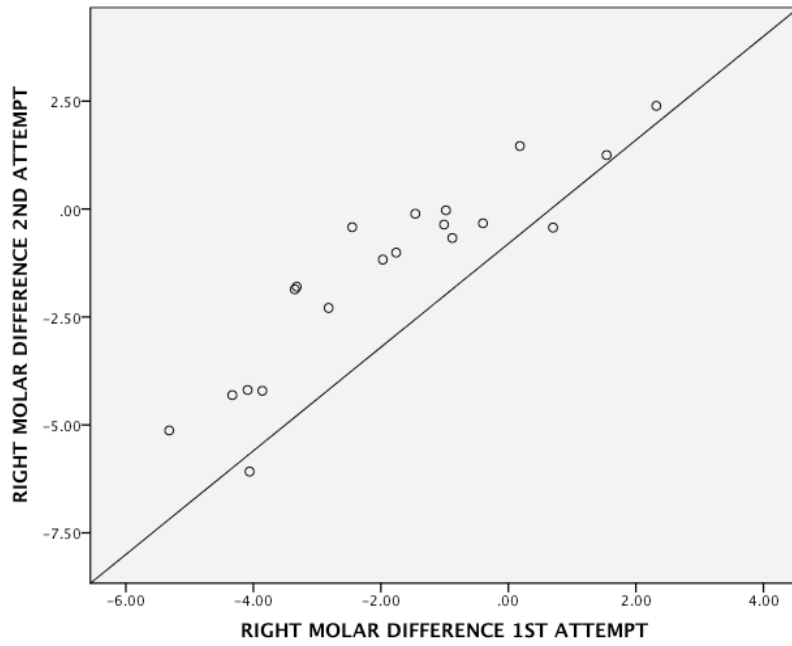


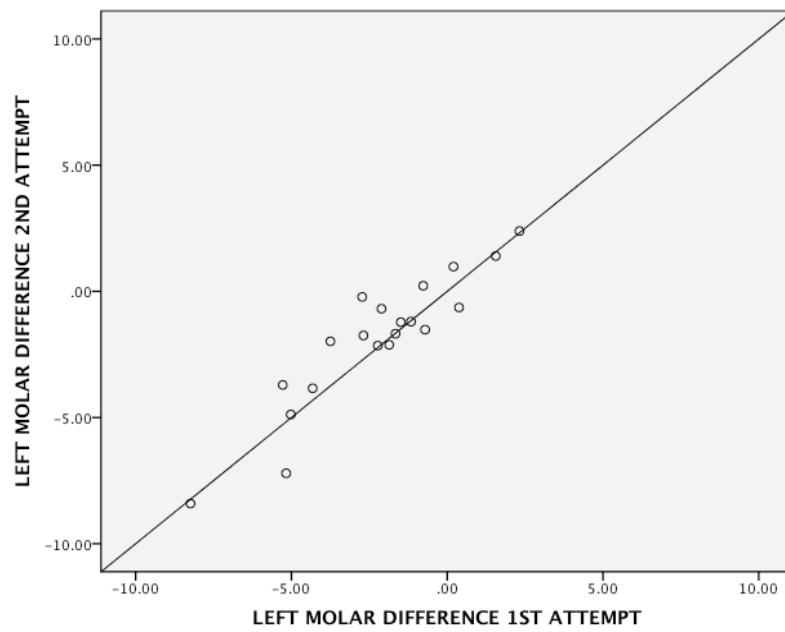
Figure 7.2 Difference between 1st and 2nd measurement of right molar movement

7.3.2 INTRACLASS CORRELATION SCATTERGRAMS

The scatter plots were used to demonstrate the strength of association between the first and second measurement of the antero-posterior movement of the molar teeth. The results using the Intraclass correlation (Figures 7.3 and 7.4 Table 7.4) demonstrated a strong positive correlation for all the variables (Shrout and Fleiss (1979). The results show that this cephalometric method was reproducible and showed a high intraclass level of reliability.



mm



mm

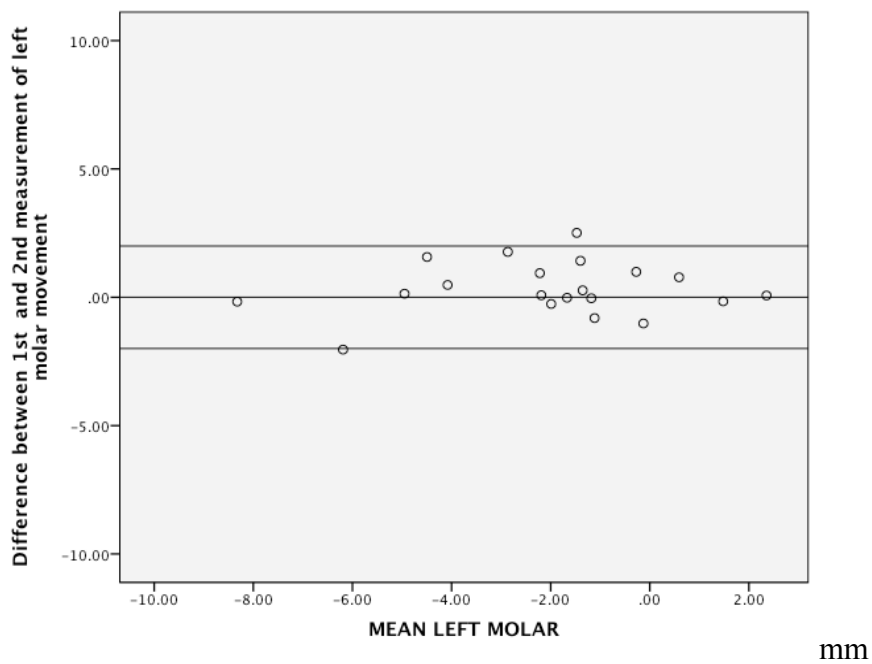
Figures 7.3 Scatterplots showing Intraclass Correlation Coefficient between 1st and 2nd differences between measurements

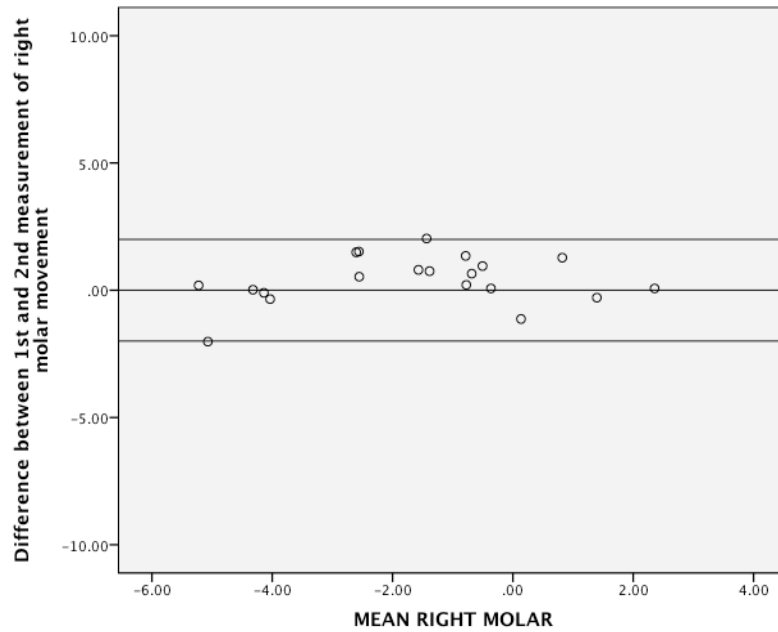
Tooth movement	Cronbach's alpha	Intraclass correlation	95% Confidence Interval		P-Value
			Lower	Upper	
Upper left molar 1st and 2nd	0.96	0.96	0.89	0.98	0.00
Upper right molar 1st and 2nd	0.95	0.94	0.86	0.98	0.00

Table 7.4 Intraclass correlation coefficient to assess intra-rater reliability

7.4 LIMITS OF AGREEMENT

Random error or bias was then again investigated, using Bland Altman plots, carried out for each of the pairs of determinations Figure 7.5 and 7.6.





Figures 7.5 and 7.6. Bland and Altman plots for measurements from the cephalograms.

The Bland-Altman analysis, for the two sets of double determinations of the movements of the molars, measured cephalometrically consistently provides similar measures. The level of agreement did not include any clinically important discrepancies.

Section 3

RESULTS

CHAPTER 8.0 RESULTS

Full ethical approval for the amended protocol was granted on 23rd March 2008. Recruitment of patients started in August 2008 and the final patient was recruited on December 24th 2010.

Ninety patients were eligible for inclusion in the study. All were given the relevant information to give consent to take part. Twelve patients declined to participate in the trial. As a result, seventy-eight patients were recruited. Of these, seventy-three were enrolled at Chesterfield Royal Hospital and five at the Royal Derby Hospital.

The CONSORT flow diagram (Figure 8.1) illustrates the flow of the patients through the study. Twenty-seven (16 female and 11 male) were allocated to the TADs group, twenty -six patients (7 female and 19 male) to the Nance button palatal arch group and twenty-five (14 female and 11 male) to the headgear group.

Throughout the study only seven patients discontinued treatment. Of these, 2 females and 3 males had been allocated to the TAD group and 1 female and 1 male had been allocated to the headgear group. The two discontinued patients in the headgear group were from the Royal Derby Hospital and the five in the TADs group were from the Chesterfield Royal Hospital.

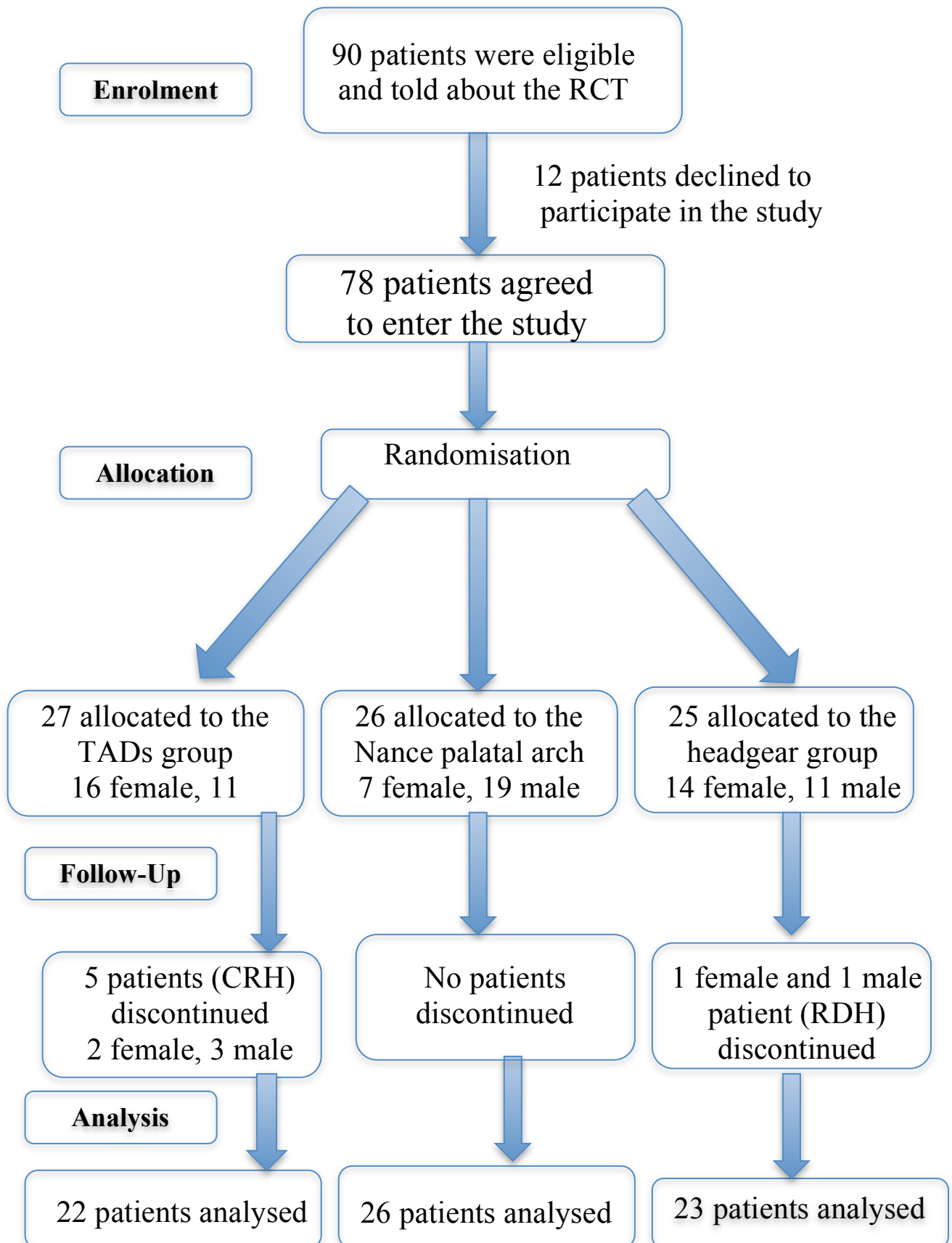


Figure 8.1. CONSORT flow diagram for patients through the study

8.1 SAMPLE SUMMARY STATISTICS

Sample summary statistics in Table 8.1 demonstrate that the groups are comparable at baseline for age, PAR scores and SNA. The proportion of females was lower in the Nance group than the Headgear and TAD groups.

Patient details	HG	Nance	TAD	Total
Age in years	14.38(1.67) n=25	14.14(1.48) n=26	14.15(1.25) n=27	14.22(1.46) n=78
PAR	33.13(13.40) n = 23	36.92(12.52) n=26	34.86(13.39) n=22	35.06(12.99) n=71
SNA	80.99(3.43) n=23	81.40(5.13) n=26	82.12(3.31) n=24	81.51(4.06) n=73
Female (n,%)	14/25 (56%)	7/26 (27%)	16/27 (59%)	37/78 (47%)

Table 8.1 Sample summary statistics at start of treatment, by treatment group and for total sample (mean and standard deviation)

8.2 ANCHORAGE LOSS ASSESSED ON CEPHALOGRAMS

The means and standard deviations for the measurements of the right and left molar teeth and the total mesial molar movement, recorded on the cephalogram, are given in Table 8.2

Horizontal distance (mm) of molar from constructed vertical, on cephalograms	HG (n=23)	Nance (n=26)	TAD (n=22)
Right molar distance, before treatment - DC1	38.37(4.20)	40.84(6.15)	40.13(4.74)
Right molar distance, after treatment, DC2	39.26(3.73)	43.71(5.80)	40.96(5.54)
Right molar movement (DC2-DC1)	0.89(2.34)	2.87(2.00)	0.83(1.92)
Left molar distance, before treatment - DC1	36.94(4.05)	39.57(6.48)	38.51(4.82)
Left molar distance, after treatment, - DC2	38.29(3.97)	41.92(6.08)	39.46(5.17)
Left molar movement (DC2-DC1)	1.35(2.44)	2.35(2.09)	0.95(2.07)

Table 8.2 Measurement of right and left molar position at start (DC1) and end (DC2) of anchorage supplementation, by treatment group (mean and SD)

The linear regression models for molar tooth movement are shown in Table 8.3

Outcome	Effect of each treatment (95% CI)*	Overall effect of treatment	R ²	Covariates
Right molar position - DC2	Nance 2.03 (0.81 to 3.25) TAD 0.17 (-1.07 to 1.40)	F(2,66) = 6.70 P = 0.002	0.86	Right molar position DC1 Gender
Left molar position - DC2	Nance 0.86 (-0.35 to 2.07) TAD -0.09 (-1.31 to 1.12)	F(2,66) = 1.47 P = 0.24	0.85	Left molar position DC1 Gender

*Reference category is headgear

Table 8.3 Linear regression models for the effects of treatment and initial values on the end of anchorage supplementation outcomes.

This revealed that there was significantly greater anchorage loss (2.03mm) for the Nance group compared to headgear, for the right molar tooth, having accounted for the other covariates. There was no significant effect when considering the use of TADS.

When we considered the movement of the molar on the left side of the mouth also shown in Table 8.3, the regression did not reveal any significant effect of treatment (P=0.24).

8.3 ANCHORAGE LOSS AS ASSESSED BY 3D SCANS OF MODELS

The mean and standard deviation for the mesial molar movement, recorded from the superimposed three-dimensional digital models, for the upper right molar and the upper left molars are seen in Table 8.4

Molar movement on 3D models	HG (n=23)	Nance (n=26)	TAD (n=22)
Upper right molar (z)	1.36(1.83)	1.84(1.32)	0.80(1.60)
Upper left molar (z)	1.99(2.09)	2.09(1.32)	0.99(1.15)

Table 8.4 Anchorage loss demonstrated on 3D models (mean and SD)

Outcome	Effect of each treatment (95% CI)*	Overall effect of treatment	R²	Covariates
Upper right molar (z)	Nance 0.62 (-0.32 to 1.55) TAD -0.58 (-1.53 to 0.36)	F(2,67) = 3.10 P = 0.05	0.07	Gender
Upper left molar (z)	Nance -0.09 (-1.00 to 0.83) TAD -0.96 (-1.89 to -0.04)	F(2,67) = 2.58 P = 0.08	0.09	Gender

*Reference category is headgear

Table 8.5 Linear regression models for the effects of treatment on the anchorage loss, as measured on digital models as the outcome.

Evaluation of these models (Table 8.5) reveals that there was an effect of treatment, (P=0.05). Nevertheless, the mean differences were small and are not likely to be clinically significant. Furthermore, evaluation of the confidence intervals and the amount of variation explained by the model (R²= 0.07 and 0.09 respectively) suggest that no single treatment was more effective than the other, in terms of maintaining molar tooth position.

Chapter 9 SECONDARY OUTCOME MEASURES

Listed below are the data (means and standard deviations) of the secondary outcome measures used in this study.

9.1 TREATMENT DURATION AND NUMBER OF VISITS

Data for the total treatment time and the relevant regression analyses are shown in Tables 9.1 and 9.2

Process of treatment	HG (n=23)	Nance (n=26)	TAD (n=22)	Total (n=71)
Total treatment time (months)	28.01(5.38)	27.43(6.33)	26.83(9.35)	27.42(7.10)
Total number of visits	19.24(6.42)	21.77(4.41)	18.38(5.95)	19.84(5.75)

Table 9.1 The total treatment time and number of visits (mean and standard deviation) from the initial placement of appliances, to debond of all attachments

The regression analysis model investigating total treatment time between start and finish treatment (start to DC3).

Outcome	Effect of each treatment (95% CI)*	Overall effect of treatment	R ²	Covariates
Total treatment time (months)	Nance -0.58 (-4.68 to 3.52) TAD -1.18 (-5.41 to 3.04)	F(2,69) = 0.16 P = 0.87	0.01	None
Total number of visits	Nance 2.53 (-0.62 to 5.68) TAD -0.87 (-4.08 to 2.35)	F(2,72) = 2.47 P = 0.09	0.06	None

Table 9.2 Linear regression models for total treatment time and number of visits during treatment

There were no significant effects of treatment on either the total treatment time or number of visits.

9.2 CASUAL VISITS AND FAILED APPOINTMENTS

Appointments	HG	Nance	TAD	Total
Number of casual appointments (median (min, max))	1(0,6) (n=25)	1(0,7) (n=26)	1(0,7) (n=23)	1.82 (1.83) (n=74)
Number of failed appointments (median (min, max))	0(0,7) (n=25)	1(0,4) (n=25)	0(0,7) (n=23)	0(0,7) (n=73)

Table 9.3 Casual visits and failed appointments, (median (min, max))

There were no statistically significant differences in the number of either emergency visits, or the number of failed appointments between the three different treatment groups

9.3 DENTO-OCCLUSAL CHANGE

The Peer Assessment Rating (PAR) scores are included in Table 9.4

PAR scores	HG (n=23)	Nance (n=26)	TAD (n=22)	Total (n=71)
PAR start	33.13 (13.40)	36.92 (12.52)	34.86 (13.39)	35.06 (12.99)
PAR finish	11.91 (7.39)	11.38 (5.73)	8.27 (4.13)	10.59 (6.04)
PAR reduction	21.26 (10.61)	25.69 (11.47)	26.59 (13.82)	24.54 (12.04)

Table 9.4 Start and finish PAR scores for all three groups and reduction of PAR (means and standard deviations)

Outcome	Effect of each treatment (95% CI)*	Overall effect of treatment	R ²	Covariates
PAR finish	Nance -1.24 (-4.36 to 1.89) TAD -3.97 (-7.20 to -0.73)	F(2,67) = 3.13 P = 0.05	0.23	PAR start

*Reference category is headgear

Table 9.5 Linear regression model for the effects of treatment on the finish PAR

The linear regression analysis indicates a significant effect of treatment ($\alpha = 0.05$) on PAR finish, with the TADs group being nearly 4 points lower than headgear, which is clinically significant.

9.4 'IMPACT OF ANCHORAGE SUPPLEMENTATION METHOD' QUESTIONNAIRES

This section is concerned with the results derived from the impact of anchorage supplementation questionnaires.

Anchorage method	Placement comfort	Comfort during 1 st 3 days	No. of discomfort days	Removal comfort	Discomfort after 3 days	Discomfort duration in days
TADs	4.41(1.1)	3.73(1.55)	2.82(2.11)	4.25(1.41)	4.81(1.54)	1.00(1.4)
Nance	4.62(1.3)	3.46(1.48)	2.65(2.04)	4.31(1.44)	4.92(1.06)	1.12(1.73)

Table 9.6. Questionnaire results about comfort on placement and removal, (mean scores and standard deviations)

The data above in table 9.6 was derived from the 6-point Likert scale, measuring the patients' perceptions of discomfort with 1 representing uncomfortable and 6 comfortable.

9.5 FREE TEXT COMMENTS ON THE ANCHORAGE SUPPLEMENTATION METHOD

When we consider the overall comments that were collected, it appears that almost all the patients who had been fitted with TADs had a positive experience and would recommend this particular method of anchorage supplementation to a friend.

9.5.1 FREE TEXT ABOUT TADs

Free text comments from TADs group included:

“uncomfortable at first, but all worth while”

“didn’t know he had removed screw”

“after a couple of days of hurting, I couldn’t feel anything”

“microscrews pain free, tightening braces very painful worked well, comfortable”

“bit of discomfort taking screws out”

“tender for a bit after, but all ok 24hrs later”

“very impressive on how the screws work”

Seventeen patients in the TADs group stated ‘No’ when asked if they had problems with their method of anchorage supplementation and 12 made no comment whatsoever in the free text section at the end. All but two of the TADs patients would recommend this method of anchorage supplementation.

9.5.2 FREE TEXT ABOUT PROBLEMS WITH NANCE BUTTONS

Patients were invited to add free text about specific problems they had during the use of the Nance button palatal arch and they listed:

“food got stuck under arch”

“sometimes it would catch roof of mouth”

“it felt like it was dislodged into the gums behind teeth”

“a little inflammation”

“concerned how to clean under it”

“catching skin on roof of mouth”

The other 20 patients recorded “No”, when asked specifically whether they had experienced problems from the Nance palatal arch so again it was overall a positive experience. All but two patients in the Nance group would recommend Nance buttons to a friend needing anchorage supplementation.

9.5.3 FREE TEXT ABOUT REMOVAL OF NANCE BUTTONS

Free text after Nance removal included:

“it was comfortable when fitted and easy to get used to”

“not very painful and easy to get on with”

“good and comfortable treatment”

“very effective”

“no particular discomfort in removal, other than the novelty”

“the area tickled and was tender”

9.6 QUESTIONNAIRES ABOUT HEADGEAR

The data below in table 9.7 were derived from 6-point Likert scales, recording the patients understanding of the instructions, actual headgear wear, and perceptions of comfort, convenience and interference with social life.

Headgear	Hrs. request	Actually worn HG	Months	Comfort	Convenience	Social interference	Did it bother you?
Mean	13.87	10.87	9.89	2.87	2.91	3.78	2.76
SD	3.31	4.01	4.73	1.39	1.41	1.51	1.55

Table 9.7 Headgear questionnaires results about headgear wear, comfort and convenience, mean scores and standard deviations.

9.6.1 FREE TEXT ABOUT HEADGEAR PROBLEMS

The patients were also asked to add free text documenting the problems they experienced using headgear and these included:

“hard to sleep”

“pain sometimes”

“at beginning getting used to fitting in right slots”

“broke whilst on holiday, pain sometimes”

“uncomfortable at night when sleeping, also when putting in”

“left mark on hair”

“difficult to eat and drink, rubbed cheek”

“impracticable” (sic)

“hurt to lay down on pillow”

9.6.2 FREE TEXT – FINAL COMMENTS ABOUT HEADGEAR

The patients were also asked to add final comments on the headgear as free text, and the following comments were made:

“I was happy to wear headgear to do my treatment”

“wouldn’t rec(commend) if alternative”

“very happy with teeth afterwards”

“hard to sleep at night”

“uncomfortable to sleep, but got used to it”

“makes you very conscious”

“I wear my headgear at all times in the day and night”

“got used to it but glad not to wear now”

“it works but embarrassing to wear”

“don’t understand how people can wear it,”

“even in sleep I would take it off”

“not as bad as expected”

Thirteen patients said they would recommend headgear, and ten patients stated they would definitely not recommend headgear as a method of anchorage supplementation.

9.7 EXTRACTION DECISIONS IN MAXIMUM ANCHORAGE CASES

Maximum anchorage cases require careful extraction decisions to ensure effective and efficient treatment. The choice of teeth extracted is illustrated in Table 9.8.

Upper first premolars	38
Upper first and lower second premolars	9
Four first premolars	7
One first and three second premolars	5
One first premolar and one other tooth	3
One first premolar and three other teeth	3
Four first molars	3
Other extraction pattern	9
Non-extraction	1

Table 9.8. Extraction patterns – frequency distribution table

Most of the extraction cases involved the upper first premolar at least on the side where there was a maximum anchorage requirement. Occasionally molars were considered the appropriate teeth for extraction because of poor long-term prognosis.

9.8 MORPHOLOGICAL CHARACTERISTICS OF THE SAMPLE

The morphological characteristics of the sample are listed in Table 9.9. Most of the patients, 48/78 (61.5%), had a Class 2 skeletal pattern and 27/78 (34.6%) had a Class 1 skeletal pattern. Only three patients had a Class 3 skeletal pattern (3.8%) This split into the various skeletal groupings would reasonably reflect the types of patients referred in to secondary care, for diagnosis and treatment planning.

When we considered the British Standards Institute definitions the incisor classifications of the seventy-eight patients are shown in Table 9.9.

Only four patients (5.1%) were listed as having a Class 3 incisor relationship. Once again these groupings would be reasonably representative of what is referred into the secondary care service from primary care, with the majority of the patients being Class 2 division one incisor relationship on a Class 2 skeletal base.

British Standards Classifications BS4492, 1983	N (%)
Incisor classification	
Class I	27 (34.6%)
Class II Division 1	48 (61.5%)
Class 2 Division 2	10 (12.8%)
Class III	4 (5.1%)
Skeletal Pattern	
Class 1	27 (34.6%)
Class 2	48 (61.5%)
Class 3	3 (3.8%)

Table 9.9. Features of malocclusion in frequency distribution chart

9.9 SUBJECTS WHO DECLINED TO BE INCLUDED IN THE STUDY

Analysis of the questionnaires from the 12 patients who declined to take part in the study revealed the following reasons for their decision

KC – patient failed the follow-up appointment, and we subsequently heard she was pregnant, and that she didn't want to be involved

SS – “nervous of both the TADs and the palatal arch” and therefore

declined randomisation

AS – “they didn’t want orthodontic treatment after all”

CMcC – “couldn’t accept headgear” as an option, so declined randomisation

CV – “didn’t want a palatal arch in the roof of their mouth”

DS – “wouldn’t wear headgear under any circumstances”

JJ – “didn’t want to be in an experimental study”

HB – “didn’t want a palatal arch”

EJ – “wanted her own dentist to do her orthodontic treatment”

SD – “didn’t want to be in this specific study”

RS – patient declined to “be in any experimental study”

JS – “uneasy about randomisation, as was particularly worried about headgear”

9.10 DETAILS OF DROPOUTS

The following reasons were given for discontinuation:

Case No. 6 had completed the initial alignment of the buccal segment teeth prior to DC1 records and extraction of the first molars. The patient then decided he did not want to continue with fixed appliance therapy. He was debonded before the anchorage supplementation technique (TADs) was implemented.

Case No 11. was a female TADs patient who attended for the first three visits after which decided she would like her own General Dental Practitioner to continue the orthodontic treatment.

Case No. 28 had 3 routine appointments, one casual appointment and 3 DNAs. Due to an administrative error, the surgeons removed the teeth and had reflected a full palatal flap for exposure of an impacted tooth, before any initial impressions had been taken of the case and before any anchorage support had been fitted. As a consequence of the lack of high quality records and the fact anchorage could well have already been lost, this female patient, who had been randomised to the headgear group, was withdrawn from the study.

Case No.29 was a male patient allocated to the TADs group. After 4 regular appointments, during which initial alignment of the buccal segments was performed, and 3 casual appointments for repair of his broken braces, he decided he neither wanted to proceed with extraction of four teeth, nor have a further course of orthodontic treatment.

Case No. 32 was a male patient allocated to the headgear group. He had 8 regular appointments 2 casual appointments and 7 DNAs. He traumatised his front teeth whilst skateboarding, and as a consequence of this accident the treatment plan was changed to include extraction of the fractured upper lateral incisors. He was consequently taken out of the study as the maximum anchorage classification had

been somewhat compromised.

Case No.74 had 6 regular appointments but in addition 5 DNAs, 3 of which were scheduled for the placement of TADs. This female patient had a number of domestic issues in her life that made treatment difficult.

Case No. 76 was a male patient assigned to the TAD group. He only attended for the randomisation visit and subsequently withdrew from the study.

9.11 TAD FAILURES IN THIS STUDY

In the TAD group there were 26 patients. Fifteen had TADs placed bilaterally, distal to the second premolar tooth. On 4 patients TADs were only inserted distal to the right second premolar and on one patient a TAD was placed distal to the left second premolar.

An allowance was made for this asymmetric placement on the spreadsheet, whereby mesial movement of any molar tooth that did not have a TAD placed was listed as N/A, as no attempt was being made to prevent mesial movement of that particular molar. In total 35 TADs were placed for anchorage supplementation.

In one case (BH) placement of the TAD proved to be problematic, in that the buccal plate of bone was exceedingly dense, necessitating two unsuccessful attempts at TAD placement, followed by a third successful attempt. On the two

previous occasions, an attempt was made over a period of two or three minutes, to drive the tip of the implant through the dense outer cortical plate of bone. After a number of unsuccessful rotations of the screw it was assumed that the tip of the TAD had been blunted, and therefore a fresh TAD was used.

On each subsequent attempt the site for placement was moved a couple of millimeters distant from the previous attempt, (Figure 9.1)

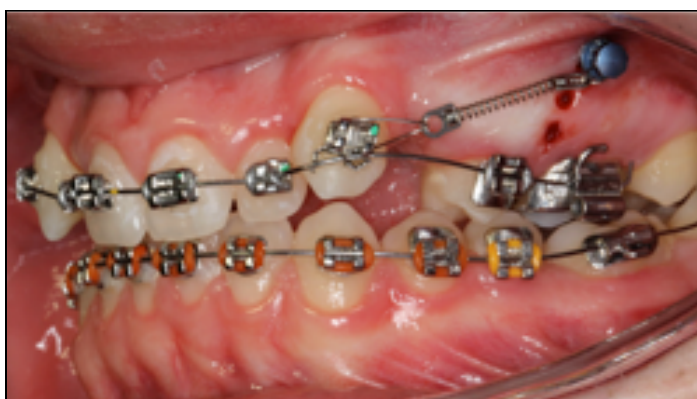


Figure 9.1 Successive TAD sites separated by 2mm

This resulted in a TAD on the left side that was 2mm apical to the attached gingivae/ moveable mucosa junction. Clearly it was a localized issue as no problems were experienced on the right hand side, (Figure 9.2).



Figure 9.2 No similar problems experienced on the right

The second patient (TP) in whom there was a potential problem involved an implant becoming loose during the canine retraction phase of treatment. TADs are

not designed to achieve full osseointegration, however primary stability after placement was usually achieved. Occasionally the TADs move some distance during the anchorage supplementation phase. In this particular case despite some obvious movement, the TAD provided sufficient anchorage to complete canine retraction (Figure 9.3).



Figure 9.3 TAD loosened, but still provided anchorage for canine retraction

The third, and only other problem, encountered with a TAD patient was when, on attempted insertion of an implant distal to an upper second premolar tooth, there was significant resistance to further insertion. Once the TAD was $\frac{3}{4}$ inserted further rotation sheared the head, together with the final screw thread of the rest of the thread (Figure 9.4 and 9.5).



Figure 9.4 and 9.5 Head of TAD and final thread of screw, sheared off during placement, placed on cotton wool roll

SECTION 4 – DISCUSSION AND CONCLUSIONS

CHAPTER 10 DISCUSSION

The results of this study reveal that anchorage loss occurred with all three methods of anchorage supplementation. When the relative effectiveness of the interventions is considered, it was evident that while some differences were detected, TADs were equally as effective as headgear or Nance palatal arches. If this finding is then combined with the patients' satisfaction with the methods of anchorage reinforcement it is suggested that the use of TADs is to be recommended in preference to headgear or Nance palatal arches.

I will now expand on the information that was used to come to this conclusion.

10.1 MEASUREMENT OF TOOTH MOVEMENT.

When I considered the results of the statistical analysis for 3D molar tooth movement (Table 8.5) it was clear that the amount of variance explained by the statistical models was low. Any differences between the interventions were small, not clinically significant and had comparatively wide confidence intervals.

Similarly, when the data derived from the cephalometric measurement was analysed (Table 8.3) this model had a good fit ($R^2 = 0.85$) however, this was because the start tooth positions was fitted as a variable. Apart from movement of the right molar all other differences were small with wide confidence intervals and this reinforces the conclusion derived from the analysis of the 3D tooth measurement.

Taking both assessments of molar movement into consideration our findings are not in agreement with Feldmann and Bondemark (2008) who demonstrated no loss of anchorage with either of their osseointegrated methods (mid palatal implant and onplant) through levelling and aligning and space closure, compared with 1mm of anchorage loss in the palatal arch group during levelling and aligning and a further 1mm loss during space closure and just 1.6mm of anchorage loss in the headgear group during the space closure phase of treatment.

A similar difference of 1.5mm greater anchorage loss in the headgear group than the mid palatal implant group was reported by Benson et al. (2007), however the authors reported that the study was underpowered, and this difference did not reach statistical significance

There may be several reasons for the different findings between these previous studies and the current study. The most likely reason is that both previous studies used a method of surgically assisted anchorage that relied upon osseointegration of the implant into the mid palatal bone. This may have resulted in more effective anchorage reinforcement than with TADs, because the TADs do not osseointegrate. While this may be an advantage it is clear that the placement and removal of mid palatal implants requires more invasive surgery than TADs.

Another reason for the different conclusions may originate from the method of measurement, in that both of these studies used measurements derived from lateral cephalograms. It is well established that cephalometric measurements have inherent errors in patient positioning, differing levels of magnification and landmark identification. Furthermore, when we consider the study by Feldmann (2007) measurements were only made to the nearest 0.5mm, which must have led to a certain amount of rounding out of the differences. In addition the lead author, was not blinded to the treatment method and recorded all the measurements. This would lead to at least moderate risk of bias at this stage in the study.

When we consider the Benson et al. (2007) study this was based on cephalometrics with the inherent patient positioning errors, and they also relied on superimposition of bilateral molars, thus introducing a further degree of inaccuracy. As with all orthodontic studies it was impossible during the treatment phase to blind the clinicians to the method of treatment and some risk of performance bias must have been present. Nevertheless, when the measurement were recorded this was done blind as the mid palatal area of the cephalograms were blanked out.

In the two studies carried out by Upadhyay et al. (2008a) they reported 0.78 ± 1.35 mm of molar distalisation in the TADs group, which they attributed to leaving the closing coils on for a few months after upper arch space closure was

complete. This was in comparison to mesial molar movement of $3.22 \pm 1.06\text{mm}$ when conventional anchorage methods were used. We did not observe any distalisation in our TADs group nor did we see this large amount of anchorage loss with the headgear group. It was claimed that the measurements were performed blindly but it is unclear if the TADs were present on any of the lateral cephalograms.

In a second RCT, Upadhyay et al. (2008b) again reported a net distal movement of 0.55mm in the TADs group and a net mesial movement of 1.95mm in the conventional anchorage group. They concluded once again, that there was no horizontal anchorage loss when mini implants were used, a situation which could not be replicated in our RCT.

In all four of the previously discussed RCTs (Feldmann and Bondemark (2007), Benson et al. (2007), Upadhyay et al. (2008a) and Upadhyay et al. (2008b)) no attempt was made to distinguish between the left and the right first molar. Midpoints between the greatest mesial and distal convexities of molar crowns were used on tracings to 'determine' centroids of molar teeth, bilateral points and bilateral structures on the lateral cephalogram were also bisected to represent a 'mean' position. All this averaging, rounding out and approximating on these 'imprecise sketchings', must lead to less meaningful measurements than with the meticulous methodology of identifying individual molar teeth and measuring from identifiable metal markers or preferably from identifiable points

on 3D scans.

In our study, using as accurate a measurement process as possible, the evidence from the primary outcome measures demonstrates little to chose between the methods as far as anchorage supplementation is concerned.

10.2 SECONDARY OUTCOME MEASURES

This section is concerned with an analysis of the secondary outcomes used in this study.

10.2.1 TREATMENT TIME AND NUMBER OF VISITS

Treatment times and number of visits were in keeping with the treatment times reported in our previous RCT (Sandler et al. (2008). We reported 2.15 years (\pm 0.59) for the mid-palatal implant and 2.23 years (\pm 0.62) for the headgear group. No statistically significant differences were found between the two groups. The total number of visits was 19.2 (\pm 4.58) with the Headgear group, in keeping with the number of visits in all three treatment groups in the current study. This figure was statistically significantly lower than the mid-palatal implant group (26.21 ± 7.41 , $P < 0.001$). This was explained however, by the additional visits needed for the maxillofacial surgeons to assess, operate and review the case both at placement and removal of the mid-palatal implant. Surgical procedures involving the mid-palatal implant are far more serious procedures, requiring

profound anaesthesia of much of the hard palate, compared with placement or removal of TADs, the latter not even requiring local anaesthesia.

No significant differences between the groups studied, as regards the length of the levelling and aligning phase and no differences between the groups in the space-closing phase were reported in the Feldmann and Bondemark (2007) study. They did not however report the treatment times to the end of treatment, despite producing four papers from their study, but the authors promise to report the end of treatment figures in a follow up study, which will include a cost-effectiveness analysis.

Unfortunately the Upadhyay et al. studies (2008a) and (2008b) also did not report total treatment times for the cases they followed. The radiographs, from which they made their assessments of anchorage loss, were taken immediately before retraction commenced and as soon as space closure was complete. It was therefore not possible to make a comparison of the total length of treatment time, or the number of visits, with these two studies and our current study.

From the information gained from the current study we can conclude that the method of anchorage supplementation did not influence either the number of visits or the total length of orthodontic treatment.

10.2.2 DENTO-OCCLUSAL CHANGE

The amount of molar tooth movement was an important outcome for this study, in that it provided information on the intended effect of the interventions under test. However, it may only be considered to be a proximal outcome, since it is important to consider the final outcome of treatment. This was measured in terms of the alignment and occlusion of the teeth by using the PAR index.

In this study the final PAR score was influenced by the treatment method: the use of TADs resulted in a statistically and clinically significantly greater improvement than with headgear, whereas there was little difference between the PAR scores of the Nance group and the Headgear group. This certainly strengthens the argument for the use of TADs as a method of supplementing anchorage in maximum anchorage cases, rather than headgear.

Only one other study investigating methods of anchorage has used PAR as an outcome (Sandler et al. (2008)) This study showed that there were no significant difference between mid-palatal implants and HG, when assessing PAR scores. As the patient groups were likely to be similar between these two studies this may be a reflection of the natural variability that occurs between groups with time.

10.2.3 PATIENT QUESTIONNAIRES

One of the most important aspects of orthodontic treatment is the patients' perception of, and satisfaction with, their treatment and the findings from the patient questionnaires are very relevant to the overall conclusions of this study

10.2.3.1 HEADGEAR QUESTIONNAIRES

The results revealed that most of the patients understood that wearing headgear was a requirement for the majority of the day, but unfortunately five patients felt that it had only to be worn for half the day or less. This demonstrates that, even with very careful planning and explanations of treatment, mixed messages can still arise. The need to provide a written explanation to patients and parents, of what specifically is required of them, to maximize the chance of success in treatment is clear; as well as explicit verbal instructions on keeping a headgear calendar which should be repeated at every available opportunity.

The average 'hours requested' with headgear was reported by the patients as being almost 14 which would be sufficient to provide the 'stationary anchorage' required in this group of absolute anchorage cases. Patients were asked to report truthfully how many hours they actually wore their headgear, and the mean wear reported was some 3 hours short of the actual hours requested. There was once again a wide variety of responses in the reported hours worn, from none whatsoever, to three reports of 15 hours per day on average. Cureton et al. (1993) demonstrated that simply asking the patients to keep a headgear diary increases the compliance with headgear by between 2-3 hours per day in almost

every age group of patients and this approach was therefore routinely followed in this study.

While there were few real differences in the scores derived from the Likert scales, the free text sections revealed several important clinically relevant findings.

When asked specifically whether they had problems with headgear, only three patients mentioned that headgear interfered with sleep, whilst another three mentioned some pain, discomfort or rubbing experienced whilst wearing the headgear. One further patient said it was just “impracticable”(sic) and another complained “it messed up their hair”. Eleven of the patients indicated that they had had no problems with headgear.

The free comments that patients added to the end of the form contained seven generally positive comments about headgear, but three comments suggested headgear made them self-conscious or embarrassed.

These data suggest that whilst thirteen of the patients said they would recommend headgear for anchorage supplementation ten gave a contrary view, clearly stating that they would not recommend this approach for anchorage supplementation.

None of the other four studies that also involved headgear (Benson et al. (2007), Feldmann and Bondemark (2007), Upadhyay et al. (2008a) and (2008b)) took

any account of the patient's perceptions of the headgear aspect of the treatment, so there was nothing to compare with the results of the present study.

10.2.3.2 NANCE QUESTIONNAIRES

The questionnaires completed by the group who had the palatal arch and Nance buttons, generally indicated that these were comfortable appliances to fit. During the first three days of appliance wear the score was at the comfortable end of the scale, and the discomfort was recorded as lasting just over two and a half days. On removing the Nance similarly positive scores were recorded for comfort and the slight discomfort lasted a little over 24 hours on average and was almost gone by 3 days.

Twenty of the Nance patients indicated they had absolutely no problems with the appliance at all, whereas the remaining six mentioned gum irritation or inflammation, or problems with cleaning or food getting under the arch. This group were much more positive about their method of anchorage supplementation with 24/26 saying they would recommend this particular method to a friend.

In the free text section there were six positive comments and two comments mentioning that the area 'tickles' once the Nance button palatal arch is removed, so this is certainly something that the patients can be warned about before appliance removal, in the future.

10.2.3.3 TAD QUESTIONNAIRES

The questionnaires filled in by the group randomised to TADs, scored the level of comfort on placement of the TADs at a slightly lower level than the scores given to the placement of the Nance button palatal arch. The comfort level over the first three days was however slightly greater than the level scored by those in the Nance group. Discomfort was reported to last slightly longer than in the Nance group.

Feldmann and Bondemark (2007) investigated pain intensity, discomfort and analgesia consumption when comparing the mid-palatal implants with the onplant system and reported significantly fewer concerns with the implants. They concluded that as the onplant required additional surgery to uncover the onplant and place abutments, the mid-palatal implant was a far preferable system, the anchorage value of both being almost identical.

Surgical anchorage placement was also scored for comfort in the Sandler et al. (2008) study that used Straumann mid-palatal implants. A similar six-point Likert scale was used in this study, and 75% of the patients scored placement between 4-6, i.e. at the comfortable end of the scale demonstrating that patient acceptance was good.

On removal of the TADs comfort was scored similarly to removal of the Nance, and after three days the comfort level was very slightly less than the Nance. On average, only one day of discomfort was recorded after TAD removal. Again the

overwhelming majority (20/22) would recommend this method of anchorage supplementation to their friends.

The free text responses were also very valuable in giving an insight into their perceptions. Seventeen of the patients recorded no problems in free text, when asked if they experienced any problems after placement of the TADs. One respondent noted that one of the TADs became loose and another reported occasional discomfort but then added that they were 'very impressed with how the screws work'. Twelve of the respondents chose to add 'none' to the final opportunity to leave feedback and six positive comments were included.

Again this is important information gained from the patients that TADs were 'no big deal' for patients to have placed, with similar comfort levels to Nance and there was some evidence to show they were the most effective anchorage supplementation method in this study.

10.3 USE OF PROXIMAL OUTCOME MEASURES

The main question in this study was concerned with effectiveness of the treatment interventions to reduce or prevent anchorage loss represented by mesial movement of molars. This was a simple proximal outcome measure evaluated at the end of the anchorage reinforcement phase of treatment. It could be suggested that the molar tooth position should have been evaluated at the end of the treatments, as this reflects the final result of the intervention. However, because of the nature of orthodontic treatment mechanics in the finishing phase of treatment, it was decided that the most relevant point to measure molar

position was at this interim point, as this was the point of interest for anchorage loss. It is, of course, necessary to consider the final treatment outcome and the most relevant outcome measure was the PAR index. This was measured at the conclusion of all treatment.

This was exactly the approach to the observation period used by Feldmann and Bondemark (2007) who conceded that after the space closure phase some patients needed mesial movement of molars whilst others may require Class 2 elastics to get the best occlusal result.

10.4 PREPARATORY PHASE OF TREATMENT

The protocol for this study was developed to reflect information on treatment mechanics that were derived from our previous study on the effectiveness of mid-palatal implants (Sandler et al. (2008)). In this study we recognised that it was necessary to align the posterior teeth to allow free sliding of archwires, particularly if a palatal arch was used.

Whilst this preparatory phase of treatment is not carried out as a matter of routine it certainly offered advantages. There is of course the risk of this extra stage introducing systematic error or bias to the results, in that a minimum of three or four extra visits are required before the full fixed appliance can be placed. The additional visits are however applied across all three groups of patients so it is unlikely to introduce any significant bias.

The total length of treatment in this study was also very similar to that reported in the other high quality RCTs involving surgical anchorage (Benson et al.

(2007), Feldmann and Bondemark (2007), Upadhyay et al. (2008a) and (2008b)).

10.5 TRIAL DESIGN AND SAMPLE SIZE

10.5.1 SUBJECTS INCLUDED IN THE STUDY

In any prospective study there will be a number of patients who decline to take part. This could be due to concern about one or more of the particular treatment regimes to which they may be randomised. Other patients may decide, after the first few months of treatment, that they are not suited to the treatment using the particular technique to which they have been randomised.

Our sample size calculation indicated we needed to recruit at least 21 patients in each group. A similar RCT, (Sandler et al. (2008)), showed a 20% dropout rate; therefore we aimed at enrolling 25 patients per group. In the end 78 patients were randomised, instead of the 75 originally planned.

Interestingly, in the similar RCT carried out by Feldmann and Bondemark (2007) they based their sample size calculation on an alpha of 0.05 and a beta of 0.1 to achieve 90% power, to detect a clinically meaningful difference of 1.5mm (SD 1.5mm) in anchorage loss, between the four groups they studied. These authors also arrived at the figure of 21 patients in each group, however they anticipated a larger number of dropouts, so these authors aimed to enroll 30 patients in each of their four groups.

10.5.2 PATIENTS DECLINING TO ENTER THE STUDY

Twelve patients decided not to continue with the study and their specific reasons for this decision are included in the results section of this thesis. Only one patient mentioned concern about TADs, compared with three who specifically cited the headgear as the deterrent factor and a further three cited the palatal arches as the aspect of treatment that felt they could not accept, if randomised to that particular group. This suggests that the thought of minor surgery for the placement and removal of the small implants is not a major concern for the teenagers of today. Four times as many patients refused to enter the Feldmann and Bondemark (2007) study, which was only 50% larger than ours. In the Upadhyay et al. (2008a) study, which was half the size of ours, seven patients refused to enter. The take up rate of patients is clearly different between studies and is dependent upon how well the concept of the study is 'sold' to the prospective patients.

10.6 RISK OF BIAS IN THE STUDY

With any study there is always the risk of bias or systematic error in the results, meaning that the effect of the particular intervention will either be over or underestimated. It is, therefore, essential to assess all studies for bias. This may be done by using a checklist against which the study can be appraised. The Cochrane Handbook for Systematic Reviews of Interventions (2008) outlines all the factors that need to be taken into consideration. The basic four questions required of any study are:

- 1) Was the randomisation method acceptable?
- 2) Was concealment of treatment method performed?
- 3) Were the outcome assessors blinded to the intervention?
- 4) Were dropouts explained?

If three or more ‘Yes’ answers are obtained after full assessment of the study then bias risk is deemed to be low, if two ‘Yes’ answers then it is considered to have ‘moderate’ risk of bias, and if one or zero ‘yes’ answers then there is a high risk of bias. Of the four RCTs used for the large part of this discussion, only Benson et al. (2007) and Feldmann and Bondemark (2008) were considered to have a low risk of bias, in the systematic review of anchorage capacity of implants versus headgear, carried out by Li et al. (2011).

10.6.1 SELECTION BIAS

This occurs if there are systematic differences in the characteristics of the groups and may be minimised by adequate randomisation. As a result, it is necessary to pay close attention to sequence generation and allocation concealment.

In this study the randomisation was based on a computer generated pseudo-random code, using random permuted blocks of randomly varying size. The use of a computer based random number generator, as was used in this study, can be considered to have a ‘low risk of bias’.

Furthermore there was no possibility of the operators having prior knowledge of

the likely allocation of interventions. This is because the random sequence was generated by the Nottingham Clinical Trials Unit and held on a secure server in accordance with their standard operating procedure. The group allocation was passed to the treating centre over the Internet, the moment the patient details were entered into a computer following obtaining written consent. As a result, we can conclude that this study had a low risk of selection bias

10.6.2 RANDOMISATION LEADING TO GENDER IMBALANCE

Despite using a computer generated pseudo random code, to produce random permuted blocks of randomly varying size, we ended up with uneven numbers of females and males in the three groups as stratification had not been included within the randomisation on the basis of gender.

With the benefit of hindsight this would be one area that could have been improved upon in this study and certainly if done again, we would have asked for gender stratification during the randomisation. It would have been helpful had each of the three groups contained similar proportions of males and females especially as the questionnaires contained questions about comfort versus discomfort, and how the patients actually felt about the process of treatment, which might have been reported differently by the two genders.

An account was taken of this imbalance however, when carrying out the linear regression models for the overall effects of treatment on the end of treatment molar position, in that gender was added as a covariate. In future studies gender imbalance should be a consideration when planning the randomisation process, and every effort should be made to ensure similar numbers of males and females in each of the groups to be studied.

10.6.3 PERFORMANCE BIAS

This may occur if operators in the study know which particular treatment modality is being provided to the patient. This is usually avoided by blinding. Unfortunately, in orthodontic trials it is not possible to conceal the type of treatment from the treating clinician. Both clinicians were in a position of equipoise at the outset of the study, therefore the outcome measures were unlikely to be influenced in a major way by the lack of blinding; however when giving consideration to performance bias in this study because the clinicians clearly knew the groups it was considered that there was a ‘moderate risk of bias’.

The participants could also not be blinded to the anchorage supplementation method either, as their co-operation was required to place headgear, to keep their Nance button palatal arch clean or to allow the minor surgery to place the TADs. The patients were presumably in a position of ‘equipoise’ at the outset as one of the conditions for inclusion was no previous experience of orthodontic treatment. Therefore when giving consideration to performance bias in this study because of a lack of blinding of the patients, it was considered that there was this

time a ‘low risk of bias’.

10.6.4 DETECTION BIAS

To achieve the blinding of outcome assessment, a member of the Chesterfield Hospital IT staff, who was otherwise unconnected with the study, anonymised all the patients’ lateral cephalograms by assigning random numbers to individual patients. The person tracing and measuring the cephalograms (JS) had no way of knowing which treatment modality was used to treat that particular patient, as no patient identifiers were attached to the radiographs. The key to the patient’s identities was held by the hospital IT staff and was not revealed until all the cephalograms had been traced and measured.

With the 3D scans and manipulation of the digital models, the research assistant who carried out the superimpositions (RG), had no knowledge of the method of treatment used with each particular patient as he was otherwise unconnected with the study.

Both measurers in the study were, therefore, blinded to the treatment modality when they were making their measurements and assessments, and there was no possibility that the blinding could have been broken. It was therefore considered that in this study that because the blinding was effective, and there was a ‘low risk of detection bias’.

10.6.5 ATTRITION BIAS

Where the study might end up with incomplete outcome data because of differences in the number of dropouts in each group of the study, another risk of bias exists. The dropouts in this study were; five patients from the TADs group, all from Chesterfield Royal Hospital and two from the Headgear group, both from the Royal Derby Hospital. No patients dropped out from the Nance group and there were no exclusions in the study. All losses to follow up were disclosed and the analyses conducted using firstly, a modified intention to treat analysis and secondly, on an observed basis.

Having five Chesterfield patients drop out of the study could potentially have caused problems. The initial sample size calculation had fortunately made allowances for a 20% dropout rate and the overall dropout rate in this study was only 9%. The estimate was based upon a previous implant anchorage RCT, Sandler et al. (2008), carried out on a group of Chesterfield patients, so a more relevant sample could not have been selected. The 20% anticipated dropout rate was in fact almost reached when the TADs group was considered separately. Luckily the TADs group already had two more participants than the headgear group.

Therefore after dropouts, the numbers in each group were still in excess of the 21 required by the sample size calculation, and each of the 78 patients was reported on at the end of the study. There were no missing patient data at all, therefore it was felt that the attrition rate was reasonable and not expected to affect the results. Therefore there was a low 'risk of bias'.

10.6.6 REPORTING BIAS

Selective reporting bias was minimised because the study was registered at the outset <http://clinicaltrials.gov/ct2/show/NCT00995436?term=anchorage&rank=1> and the study protocol was explicit. The primary and secondary outcomes were specifically defined, measured, documented and reported in the pre-specified way. All dropouts from the study were explained. Reporting bias was therefore also judged as having a low ‘risk of bias’

10.7 INCLUSION/EXCLUSION CRITERIA

The patients enrolled in the study were adolescents between 12 and 18 years of age who desired orthodontic treatment, but had no previous experience of treatment, had an absolute anchorage requirement and for whom functional appliance therapy or orthognathic surgery was not indicated.

The ‘absolute anchorage’ assessment was met when, on assessment of the sagittal relationship of the dentition, no forward movement of the molar teeth could be deemed acceptable.

In the study we were aiming to test the ability of each of the three methods of anchorage supplementation to resist the forward movement of the molar teeth. On most occasions the absolute anchorage requirement was a bilateral consideration however on a few occasions it was only a unilateral situation.

Patients deemed ineligible for inclusion in the study are listed below and the reasons for their inadmissibility are discussed:

- 1) Any patients for whom a Twin Block was thought to be the most appropriate appliance as, despite their absolute anchorage classification, it was felt unfair to deny these patients the treatment that had the greatest chance of producing the most aesthetically acceptable result.
- 2) Patients who had previously experienced orthodontic treatment, as we felt their potential co-operation may be affected. They may have pre-existing views on treatment methods having had a bad experience of headgear for example, thus were certainly not in a position of equipoise.
- 3) Patients with hypodontia involving more than one tooth per quadrant, were also deemed ineligible. We felt the many dental compromises necessary in these cases, because of this deficit in tooth size or number, will complicate the treatment decisions and the mechanotherapy necessary to provide a solution.
- 4) Patients with inadequate oral hygiene were not enrolled as in this situation the disadvantages of treatment far outweigh any potential benefit. Inadequate cleaning almost always precludes any form of serious orthodontic intervention.
- 5) Patients for whom orthognathic treatment may be required in the future. In this group of patients the method of dealing with the malocclusion may differ markedly from appliance only patients, for example severe anchorage loss in the upper arch may indeed be a desirable feature in this particular group.
- 6) Presence of a cleft or craniofacial anomaly was also a precluding factor because of the many compromises that have to be considered in managing this group of patients.

10.8 SAMPLE SIZE CALCULATION

These calculations were reported both for the original sample size and for the double determination necessary when looking at the measurements on the cephalograms.

10.9 VALIDITY AND REPRODUCIBILITY OF THE 3D METHOD

Cephalometric superimposition is the tried and tested method for comparing molar tooth movement, however this technique has a number of inherent disadvantages. Firstly it involves exposing the patient to potentially harmful radiation and unnecessary exposure. Secondly, errors in identification of radiographic landmarks compounded by additional errors when making linear and angular measurements have been well documented in the landmark papers by Baumrind and Frantz (1971a, 1971b, 1976). Whilst every effort can be made by researchers to minimise these errors, they will never be eliminated completely. Thirdly, a lateral cephalogram will always be a two-dimensional projection of a three-dimensional object. Bilateral landmarks are subject to differing magnifications and their already blurred outlines, due to overlapping anatomical structures, are usually 'averaged' to represent a 'mean molar' tooth. By the time the magnifications and the averaging on the start and finish radiographs are all considered one has to wonder how much of the actual molar tooth movement is really represented on these rather imprecise measurements.

Over half a century ago Hixon (1960) suggested that to reduce errors in landmark identification, all the radiographs of a particular patient should be

viewed side by side, and the landmarks decided upon and marked with ‘pin pricks through the emulsion’ on the actual film. This ‘side by side’ technique is what was done with the cephalograms in this study, to ensure we were looking at the same landmarks in the limited cephalometric analysis used.

Over the past decade there has been a search for a digital solution to assessment of tooth movement and many researchers have investigated the superimposition of 3D digital models. In this study the digital equivalent of this ‘side by side’ technique was also done, when identifying the palatal rugae on models before and after anchorage supplementation, as the particular anatomical points were viewed together, precisely identified and duly marked.

10.9.1 ITERATIVE CLOSEST POINT

The assessment of molar tooth movement in this study is predicated upon an accurate superimposition algorithm. Firstly the start and finish models had to be superimposed and the next requirement was relating the centre of mass of the pretreatment molar shell, which had to be superimposed upon the posttreatment molar occlusal surface. The computer used a sophisticated programme, Rapidform 2006, which contains the necessary algorithm to carry out the series of steps to allow the precise superimposition of the models and of the molar occlusal surfaces.

This algorithm used in this case to superimpose three-dimensional objects, otherwise known as ‘point clouds’, on one another is known as the Iterative Closest Point (ICP) algorithm.. The three-dimensional objects involved (3D

digital models, in the case of this study) are considered to be a collection of points in 3D space that have X, Y and Z dimensions. The third dimension of 'depth' is the difference between a three-dimensional object and one with only X and Y coordinates, which would appear in two dimensions.

The laser scanner is the tool we used in this particular study to create the 3D objects, and the method that allows the laser to carry out this task has been described in detail (Thiruvengkatacharti, PhD Thesis, 2009).

To allow me to make appropriate measurements of anchorage loss from the 3D models it was necessary to precisely and reliably superimpose the 'start of anchorage reinforcement' model (Ms) on the 'end of anchorage supplementation' model (Mf). The difference between the stable parts of two point clouds in this study (Ms and Mf), excluding the area that has changed due to growth or active orthodontic treatment, is that one of them has been 'transformed' relative to the other.

This transformation required for perfect superimposition of the source and target clouds is necessarily a combination of rotation of the second point cloud around an axis and translation along the axis, with respect to the original first point cloud. This can be represented simply in two dimensions in the diagram below (Figure 10.1).

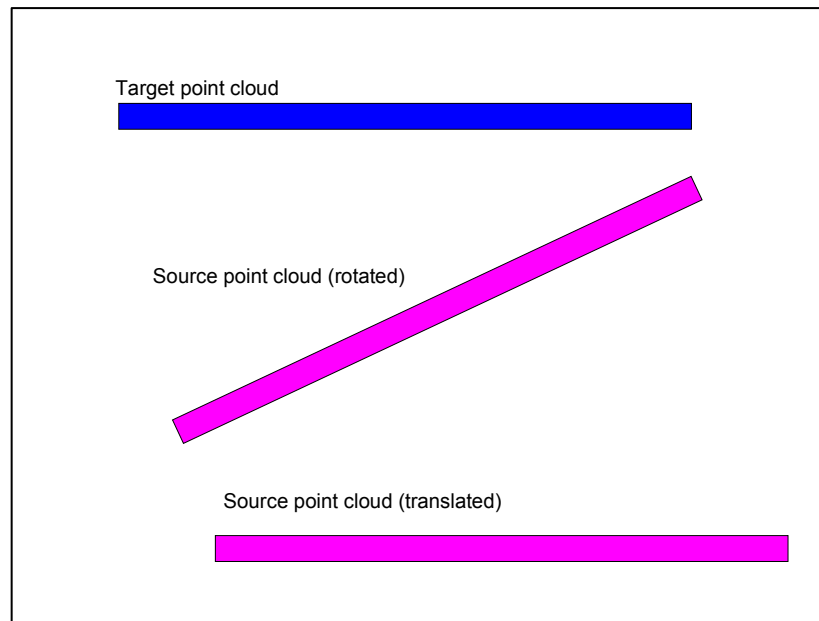


Figure 10.1 Movements required to superimpose source cloud on target cloud

If we identify stable structures on which to superimpose the point clouds (digital models), then the movements of specific areas of the source point clouds relative to corresponding points on the target point cloud can be accurately measured.

The Iterative Closest Point (ICP) algorithm is a registration technique that uses the information about the points (X, Y and Z co-ordinate geometry) to carry out the accurate superimposition of the 3D objects. The steps involved include:

- (i) From initial complete malalignment 'n' iterations are performed to bring the objects into the 'ballpark' position (rotation improved, but not perfect)
- (ii) After more iterations ('n' ± 'k') alignment is satisfactory with regards to rotation
- (iii) Even more iterations ('n' ± 'k' ± 't') are required for the translation to be perfected as well

This technique allows convergence of the target and source with 6 degrees of freedom illustrated below, Fig 10.2.

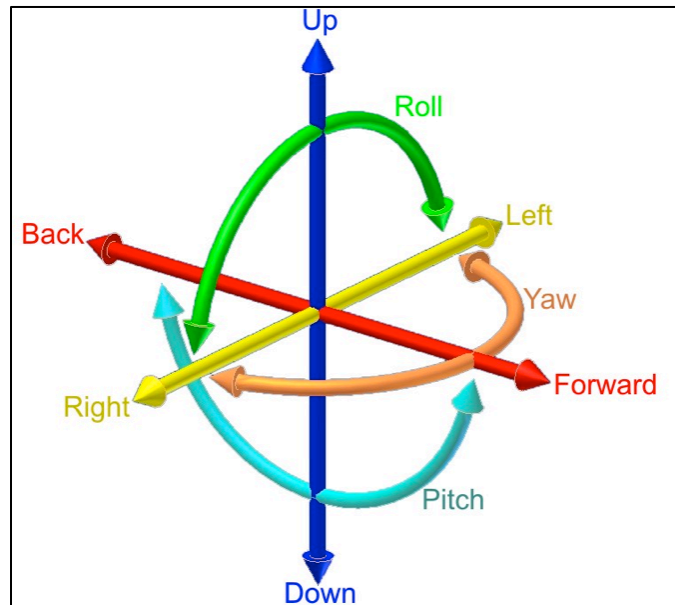


Figure 10.2 6 degrees of freedom involves translation about the X, Y and Z axes and rotation around the X (pitch), Y (roll) and Z (yaw) axes. From Wikipedia http://en.wikipedia.org/wiki/Six_degrees_of_freedom

To understand what occurs in the sequential iterations, it helps to consider the clouds as individual points, which allow corresponding points to be identified. This is the first step to ICP matching and in the current study was by identifying the lateral and medial anatomical points of at least the three major palatal rugae to allow us to do the initial superimposition. These ‘identical’ anatomical points were marked consecutively on the two close-up views of the palatal rugae on adjacent windows of the computer screen.

These pairs of points are called correspondences (Figure 10.3) and if we knew all the correspondences within the cloud, we could let the computer calculate how each point is transformed from the target, and the transformation would perfectly superimpose the two clouds, producing perfect alignment.

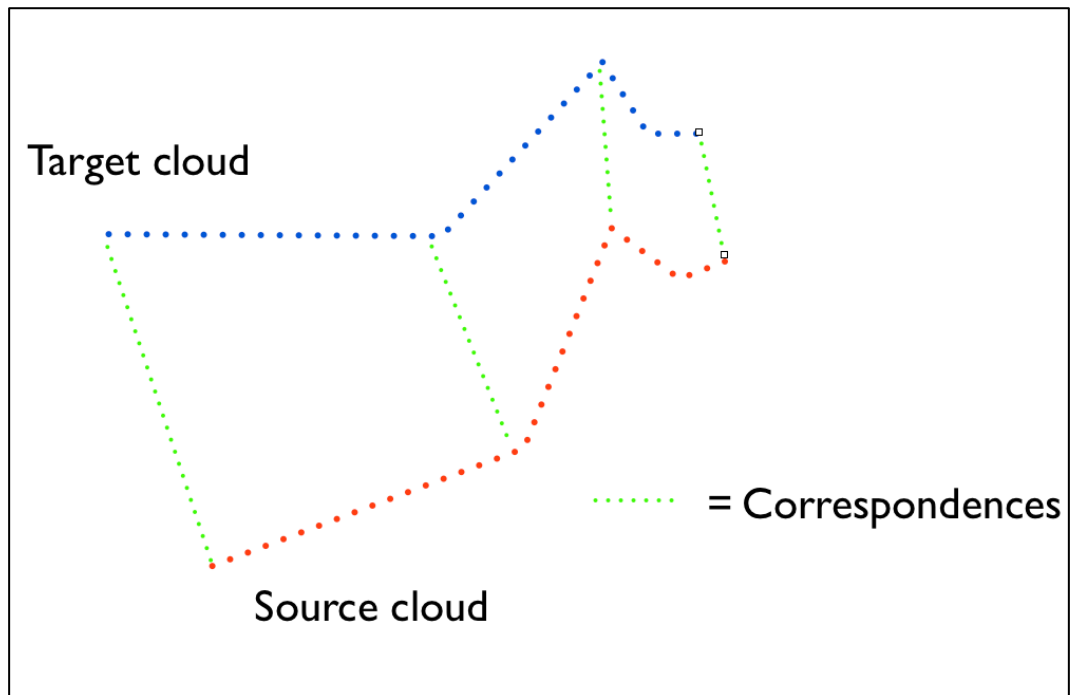


Figure 10.3 Correspondences need to be identified on both the source and the target clouds

In my study certain areas of the 3D model have moved between the two scans, so a perfect match would never be possible. An arbitrary 'acceptable' figure, of 0.8mm for the overall 'accuracy' of the initial superimposition, was chosen. This takes into consideration that many of the points in the cloud will not have moved significantly, but some of the points, e.g. 1st molars, may have moved a number of millimeters. The overall figure is just an average value for movement of all the points.

Within the ICP algorithm, the assumption is made that the closest points are ‘correspondences’. This is a reasonable assumption as the points with the smallest Euclidean distances between them, are very close to the true correspondences.

Iterative closest point is therefore a ‘minimisation’ problem. When doing the superimposition for each pair of points from the source to the target cloud, the Euclidean distance is squared and the mean is taken. Each subsequent iteration may involve translations (Figures 10.4, 10.6) or further rotations (Figure 10.5), each trying to reduce that mean squared distance, to as close to zero as possible.

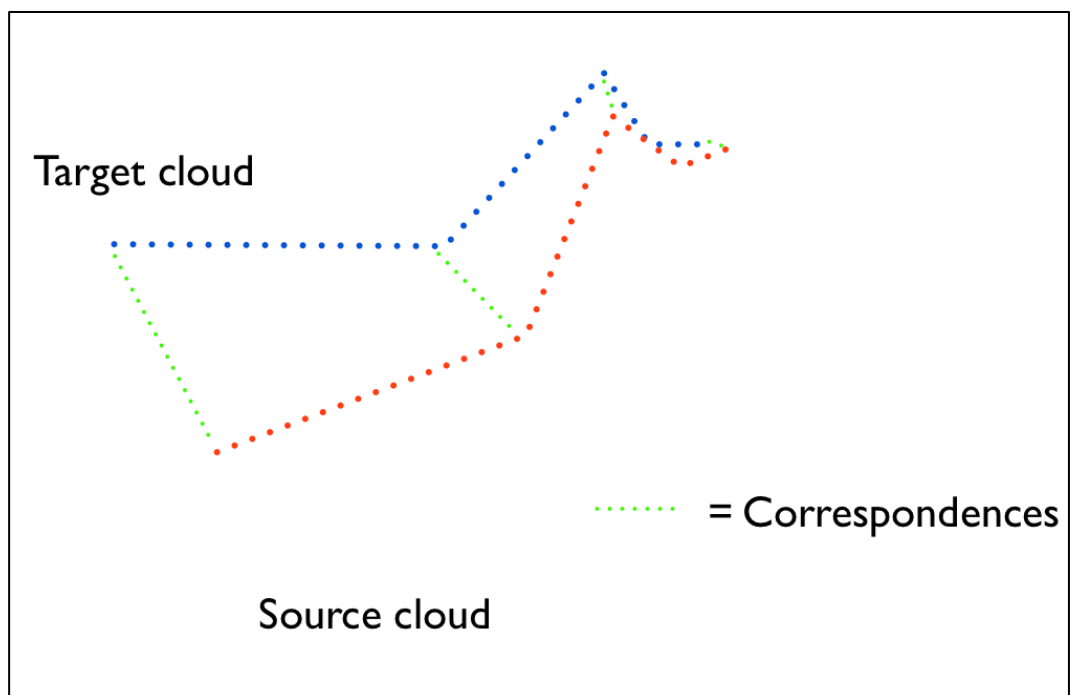


Figure 10.4 After one ICP iteration, translation brings clouds into contact

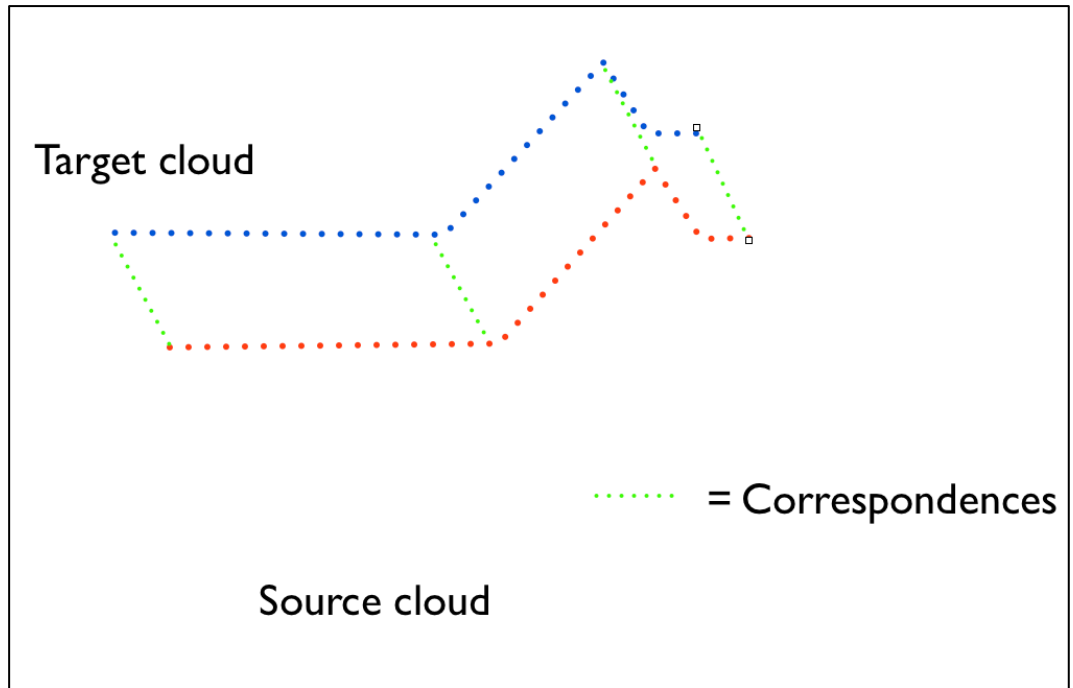


Figure 10.5 After a second ICP iteration, rotation makes clouds approximately parallel

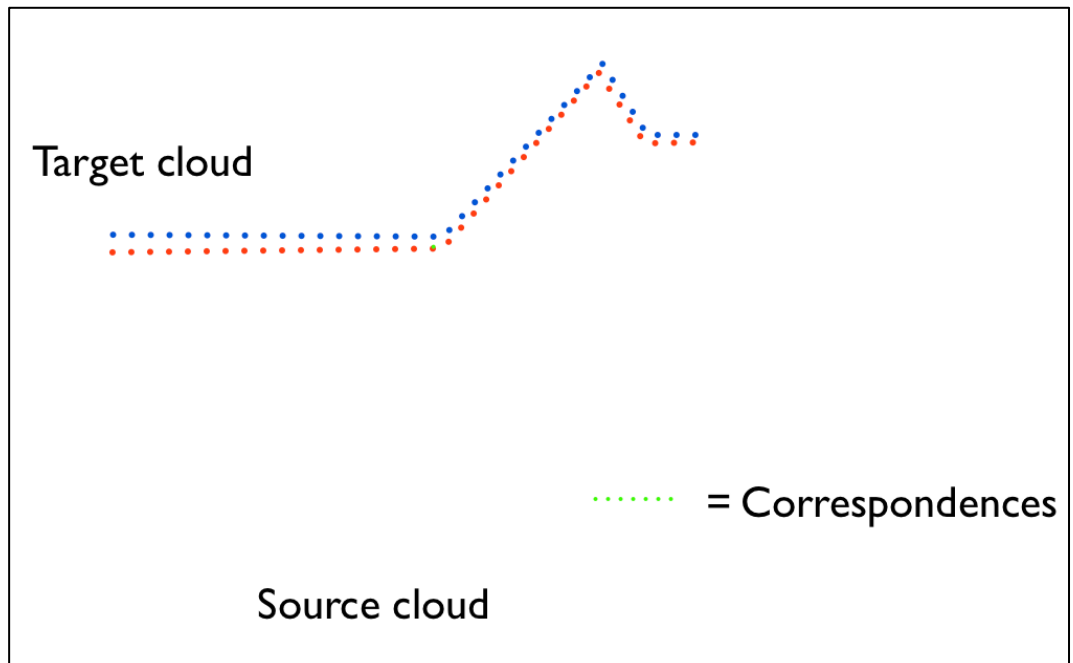


Figure 10.6 After a third ICP iteration, further translation brings correspondences much closer

Once the initial superimposition was deemed to be 'accurate' by virtue of the blue colouration to the palate, and average discrepancy figure $< 0.8\text{mm}$, a 'Regional superimposition' was then performed. This involved outlining the blue 'mushroom-shaped' area of stability (Figure 6.11), which included the medial ends of the three major rugae, and a stable area of the hard palate either side of the midline. The superimposition is then carried out largely on this specific area. Movement of the 'centre of mass' of the molar shell, M_s , was then calculated relative to overlapping point clouds, superimposed as precisely as possible using the stable reproducible areas, as the corresponding points.

Outlining the molar shells was crucial to this particular technique. Magnifying and subsequently rotating the 3D models, allowed highlighting of the entire occlusal surface of the molars and most of the buccal and palatal surfaces of the molar teeth on the pre-anchorage model, M_s . Of course it was impossible to accurately identify the mesial and distal surface of the molar teeth, but there was already sufficient information captured to allow the computer to calculate a 'centre of mass' of the molar shell on the start model. This same molar shell, and therefore the same 'centre of mass' from the start model, was superimposed on the occlusal surface of the molar, from the end of anchorage supplementation model. The idea of using the same original molar shell was to remove any possible effects of gingival recession or more likely gingival hyperplasia that could have a significant effect upon the identified centre of mass.

Extremely accurate three-dimensional scans of models have become a reality as a result of modern laser technology. Many investigations have been carried out

to check the accuracy of these digital study models including those of Stevens et al. (2006) and Okunami et al. (2007). Measurements taken on these digital models have been shown to be comparable to those taken on conventional study models.

Part of this study was aimed at investigating whether we had a reliable technique of superimposing 3D digital models, taken at two different time points in treatment, upon landmarks that were believed to be stable. The purpose was to determine if molar tooth movements could be accurately measured in 3 planes of space.

Because this method proved to be reliable and reproducible, it offers a number of potential advantages over the previously used methods of measuring tooth movement. One major benefit is the potential to markedly reduce the use of potentially harmful radiation. Assessments of tooth position can be made as often as is thought to be useful, to allow much more detailed information to be gained about the rate and nature of tooth movement.

Another major advantage of the use of three-dimensional scans instead of standard cephalometry is the ability to separate movements of the left from the right molar, thus allowing a greater understanding of how the various biomechanical systems used on an everyday basis, really affect the position of the molar teeth. It is also possible to assess the molar movement not only antero-posteriorly but also in the transverse plane, which may be of great interest in

maxillary expansion cases and in other popular types of treatment involving significant 'arch development'.

Vertical tooth movements can also be identified using this technique; however Christou and Kiliardis (2008), pointed out that vertical changes in the rugae are quite marked in adolescent patients compared to adults, and this could cause problems when superimposing and subsequently interpreting the individual tooth movements.

Calculation of intraclass correlation coefficients in the error study (Table 6.3) confirmed the strong correlation between all the repeated measurements. Subsequent use of Bland-Altman plots indicated no random error or bias within the method of measurement that should cause any concern. Paired sample T-tests finally confirmed that there were no significant differences between the repeated measurements of the movement of the centres of mass of the molar teeth, in all three planes of space.

The conclusion reached is that the method described for superimposition of the three-dimensional scans taken of repeated digital models to assess molar tooth movement, is both reliable and reproducible. This technique should therefore be considered for use, perhaps alongside cephalometric measures, in all future biomechanical orthodontic studies investigating the nature, efficiency and effectiveness of tooth moving systems.

The burgeoning popularity of three-dimensional digital models has offered many other advantages to the orthodontic community. Primarily they overcome the problem of storage of all these study models, which, as practitioners go through their career, can become an ever-increasing logistical problem. Now that 3D images of models have been shown to be just as accurate as traditional plaster models, the vast numbers of garages and attics, full of tons of dental plaster should certainly become a thing of the past.

10.10 VALIDITY OF THE CEPHALOMETRIC METHOD

Validating the digital x-ray method for measurement was a difficult task, as there was no 'gold standard' method of measuring the tooth movements using the Picture Archiving and Communication System (PACS). The limited cephalometric analysis used on PACS was designed purely to measure mesial movement of the left and right molars individually, on screen. The molar markers were used to identify separately the left and right molars, and a measurement was taken perpendicular to a constructed vertical, created at 97 degrees to the SN plane. Two computer screens were used simultaneously, in a darkened room, to allow side-by-side identification of identical anatomical structures. To check the reproducibility of the measurements double determinations were done at least 2 weeks apart.

Based on Bland's recommendation, a sample size calculation to test the validity of this method revealed the need for 20 pairs of radiographs to be subjected to double determination.

10.11 REPRODUCIBILITY OF THE CEPHALOMETRIC METHOD

Intraclass correlations (ICC) are typically used to assess inter-rater reliability. In the context of this particular study, the double determinations done at least 2 weeks apart, on the differences between measurements of molar movement, are considered to be two 'raters'.

The 'one-way random' setting within the ICC makes the assumption that the two measurements are indistinguishable, which is the case in our model, as the measured distances are identical.

The absolute agreement setting was also used for the ICC as using Consistency setting just identifies a linear agreement, somewhat similar to using the Pearson's Correlation Coefficient, with all the attendant shortcomings. Absolute agreement gives an accurate assessment of whether the two measurements exactly match.

The average measures reading, assesses the agreement across two raters or time points, so this was relevant in this error study.

In the Social Sciences the benchmark for ICC is typically 0.72 to indicate relatively good agreement between two measurements however an ICC of higher than 0.8 is preferred, for a conclusion of excellent reliability.

When obtaining measurements using a particular technique it is important to know that the technique will result in consistent and reliable results. When the

technique returns a stable result, the measurements are said to be reliable. Cronbach's alpha is an index of reliability associated with the variation accounted for by the true score of the "underlying construct." Construct is the hypothetical variable that is being measured (Hatcher, 1994).

For the repeated measurements for the left molar movement the Cronbach's alpha was 0.959 and the ICC was 0.957 on the one-way random effects model (REM). The 95% Confidence intervals were 0.892-0.938 indicating a very high level of reliability.

For the right molar movement the Cronbach's alpha was 0.950 and the ICC was 0.943 on the one-way random effects model (REM). The 95% Confidence intervals were 0.859-0.977, once again indicating a very high level of reliability.

It is therefore recommended that any future cephalometric studies purporting to measure anchorage loss, consider using right and left metal molar markers as an indicator of molar position. Also recommended is that they also consider using a dual video card that will allow 'side by side' on screen digitisation and measurement to ensure identical cephalometric landmarks are identified and measured on pre- and post-treatment films.

10.12 EFFECT OF TIP OR ROTATION ON ANCHORAGE ASSESSMENT

It could also be suggested that tipping and rotational effects, not measured in this particular study, could have a bearing on the real anchorage loss or gain. Often

in studies involving removable appliances such as the pendulum or 'nudger', authors speak about the distalising effect of the appliance. They are purely speaking about the mesio-distal position of the molar crown and completely ignore the fact that the teeth are tilted distally often by 5-10 degrees or more. As soon as the fixed appliances are placed the molars upright again, and most of the apparent anchorage gain is almost immediately lost, unless measures are taken to prevent the molar crowns moving mesially.

With this study these criticisms are rejected, as efforts were taken to minimise any tipping or rotational effects at two stages. Both with the large rectangular sectional wires when initially aligning the molar teeth, and again before the end of anchorage supplementation the patients were in 19/25 stainless steel archwires in an 022"x028" slot, for a number of weeks. This effectively 'full sized' rectangular stainless steel archwire allows very little deviation of the molar teeth in terms either of rotation or of mesio-distal tip. It is therefore assumed that these effects are minimal and therefore the measurements made on the movement of the centres of mass of the molar teeth truly give an indication of the preservation or loss of anchorage.

10.13 ACCURACY OF IMPRESSIONS AND JAW REGISTRATION

For the purposes of this study silicone impressions were taken in stock impression trays, initially using the heavy bodied material, then subsequently a second 'wash' of light bodied material was used to record the fine detail. Thongthammachat et al. (2002) demonstrated that accurate casts can be taken in

stock trays and that addition silicone impression material had better dimensional stability than polyether.

Chen et al. (2004), tested 10 different types of impression material including 3 alginates and 7 silicones, and concluded that the addition type silicones were the ones that produced the greatest accuracy and the best stability.

Debate continues amongst prosthodontists about the relative merits of one-step versus two-step impression techniques. Al-Bakri et al. (2007), when testing four different techniques of taking silicone impressions, found fewer inaccuracies using the two-stage, heavy base followed by a wash technique, and this was therefore the method used in our study.

When studying methods of recording jaw relationships the greatest accuracy, to within 0.33mm, was found using unrefined wax registrations, (Utz et al. (2002)). Two simple wax bites were therefore taken to record the relative position of the lower to the upper dentition in maximum intercuspation. In both hospitals involved in this study, the impressions and the wax bites were taken immediately to the dental laboratories, which in both cases were adjacent to the clinic and, following the appropriate disinfection procedures, two pairs of study models were immediately cast.

The aim was to limit any time delay, to minimise the potential shrinkage of the alginate impression material, to ensure that both sets of models accurately reflected the true clinical situation. Silicone impression material with its known

hydrophobic properties was felt to be the appropriate material to record the most anatomical details of the palatal soft tissues.

10.14 EXTRACTION PATTERNS OF PATIENTS IN THE STUDY

All of the cases included in the study were by definition ‘maximum anchorage cases implying that no mesial movement of the molar teeth would be acceptable. Clearly there was a space requirement in all of these cases and a number of different extraction patterns were adopted to attempt successful management of the malocclusions. Whilst the space requirement is often the major factor determining which teeth are to be extracted, there are often other factors that have to be taken into consideration. This list would include the health of the other teeth, the total amount of space required and the specific site of the crowding as well as an assessment of the anchorage value of the remaining units.

Seventeen different extraction patterns were identified although most of these patterns had low single figures of cases within their group. By far the most popular approach to extractions involved the removal of upper first premolars only, that was prescribed as a solution in 38 patients (49%). This was unsurprising as all these cases had a significant anchorage requirement, and most involved severe crowding in the upper labial segment but were deemed unsuitable for functional appliance treatment or orthognathic surgery. It was therefore considered that extractions and fixed appliances could offer a solution in these high anchorage cases. Extracting in the lower arch can often compound

the problems of anchorage, if care is not taken over controlling the position of the lower labial segment.

The second most popular approach to treatment was removal of upper first premolars and lower second premolars, carried out in 9 patients and then upper and lower first premolar extractions were carried out on 7 patients.

It can be seen from the frequency distribution table (Table 9.8) that 54/78 (69%) of patients required extraction of both upper first premolars and 68/78 (87%) of patients had extraction of one upper first premolar, along with a combination of other teeth.

First molars were only considered the appropriate teeth for extraction on five occasions (6.5%) and this was largely due to their long-term prognosis being compromised because of extensive dental disease or enamel hypoplasia. The potential problems and pitfalls of removing first molars have been discussed in the literature (Sandler et al. (2000)) and careful anchorage management in these cases is essential to ensure success of treatment.

Three of the patients required extraction of deciduous teeth only and one of the patients required no extractions whatsoever. This latter group of four patients all had congenital absence of upper lateral incisors and space was being recreated to provide space to allow osseointegrated implants to be placed in the lateral incisor area. The canines were usually one unit further anteriorly than their

normal position and had to be returned to their Class 1 canine relationship without any mesial movement of the upper posterior segments whatsoever.

10.15 TAD FAILURES IN THIS STUDY

Out of the 35 TADs placed in the study only one fractured, which represents a 2.8% failure rate. This compares extremely well with the failure figures reported in a meta-analysis carried by Papageorgiou et al. (2012) These authors included many prospective studies involving 4987 miniscrews in 2281 patients, which demonstrated an overall failure rate of 12% in the maxilla. It also compares well with the other RCTs using TADs as Upadhyay et al. (2008a) reported a 7% failure rate and Upadhyay et al. (2008b) a 13% failure rate.

We decided that surgical removal of the fractured 7mm TAD would be counterproductive. The area was already anaesthetized, so it was a simple matter to place a second screw 2mm more occlusal to the first TAD, (Figure 10.7).



Figure 10.7 Second TAD, inserted 2mm occlusal to the sheared screw

Healing was uneventful over the next couple of weeks and the epithelium grew over the fractured screw. An opinion was sought from a maxillofacial colleague who advised to leave this ‘implant’ in place, as it was felt that more harm than good would result from attempted removal. The decision was therefore taken

together with the surgeons and the patient, to leave the screw in place for as long as it remains asymptomatic. The remaining part of the screw can clearly be seen between the two radiographic markers on the final cephalometric radiograph (Figure 10.8) and the General Dental Practitioner has been asked to keep this area under periodic review.



Figure 10.8 Fractured part of screw clearly visible between two radiographic markers

All the other implants were placed without incident and all were removed from all the patients in the study, again without incident. On no occasions was local anaesthetic required for TAD removal.

10.16 HOW COULD THE STUDY BE IMPROVED?

As with any research project, it is not until the study has been carried out that one realises ways in which the methodology could have been significantly improved.

10.16.1 HORIZONTAL ‘CROSSHAIR’ ON THE RIGHT AND LEFT MOLAR MARKERS

One concept for future studies is to have a horizontal marker or ‘crosshair’ on the vertical part of the metal marker, to allow identification of a reproducible point, from which measurements could have easily been taken. This crosshair should be positioned gingival to the cervical margin of the molar band, on the vertical leg of the metal marker. This would be particularly useful if vertical measurements were to be taken in addition to antero-posterior movements. Without this horizontal reference point, it was a matter of trying to identify the point at which the vertical part of the metal marker crosses the horizontal part of the molar band. This is a reasonably easy thing to do in many of the cases, but in a few cases, where the outlines of the left and right molar bands coincide, this can be quite problematic.

10.16.2 TRANSPALATAL ARCH INSTEAD OF NANCE

The introduction of the Nance button on the palatal arch was in response to one arm of my study being jeopardised, as we were told mid-palatal implants would not be available. There was sometimes quite a marked reaction of the palatal mucosa under the acrylic of the Nance button. This might have led to more difficulty identifying the morphological points on the palatal rugae or ‘correspondences’ than otherwise would have been the case. To avoid this potential problem a trans-palatal arch relieved by 1.5mm from the palatal tissues, and nowhere near any of the palatal rugae would be a preferable anchorage supplementation method to test.

10.17 IDEAS FOR FUTURE STUDIES

The literature would seem to suggest that mid-palatal implants are an excellent form of anchorage with a high success rate (Feldmann and Bondemark, 2007). The Straumann Company originally informed me that production was going to cease. They however reversed this decision and they are now back in production. I think it would be worth comparing traditional TADs with the mid-palatal implant to see how each performs in maximum anchorage cases. A pilot study would have to be performed to see if 3D scans can still be used to assess molar movement when the implants are placed on the palatal side of the arch.

There are more and more papers in the literature suggesting that TADs should be placed in the anterior palate offering advantages over the traditional buccal placement (Karagkiolidou et al. (2013)). Again this is something that should be scientifically tested with a high quality RCT once it has been established that the method can be used without jeopardizing the use of 3D scans to assess molar movement.

Headgear clearly has a use in cases that require active distalisation of molars. Upadhyay et al. (2008a, 2008b) reported active distalisation and intrusion of molar teeth using TADs. If these results can be reliably reproduced then it would beg the question as to whether there was any place at all for headgear in clinical orthodontics in the 21st Century.

10.18 CLINICAL IMPLICATIONS OF THIS STUDY

This study adds to the body of evidence that TADs are an efficient and effective method of supplementing anchorage. The technique is definitely recommended by patients and is at least as effective in supplementing anchorage as the other methods on the market. TADs also allow achievement of a higher quality orthodontic result.

Headgear is generally unpopular with UK clinicians providing orthodontic treatment and most certainly with patients in the UK. Now that we have an alternative method of anchorage supplementation there can be little or no need to consider the use of headgear, unless active distalisation of the molar teeth is required. Even then, the current popular techniques involving TADs, particularly when placed in the anterior palate, may well mean that the ‘writing is on the wall’ for this antediluvian approach.

There should be much greater emphasis in all postgraduate training establishments, to ensure all the clinicians providing instruction to the students, are up to speed with the various techniques to surgically reinforce anchorage. Arrangements should be made for postgraduates to get hands-on experience with placing and removing TADs on a variety of patients with a range of clinical problems, to ensure that on completion of their training they are comfortable with this contemporary technique.

CHAPTER 11.0 CONCLUSIONS

1. There is no difference in the effectiveness of temporary anchorage devices, Nance button palatal arches and headgear in reinforcing anchorage in orthodontic treatment.
2. Patients perception suggest that there were greater problems with headgear and Nance buttons than with temporary anchorage devices.
3. The quality of treatment as measured by PAR scores was significantly better with TADs than with headgear.
4. Temporary anchorage devices may be the preferred method of choice for reinforcing orthodontic anchorage.

REFERENCES

AL-BAKRI, I., HUSSEY, D. & W, A.L-OMARI. 2007. The dimensional accuracy of four impression techniques with the use of addition silicone impression materials. *The Journal of Clinical Dentistry*, 18, 29-33.

ALMEIDA, M. A., PHILLIPS, C., KULA, K. & TULLOCH, C. 1995. Stability of the palatal rugae as landmarks for analysis of dental casts. *Angle Orthodontist*, 65, 43-8.

ALTUG, H., BENGI, A. O., AKIN, E. & KARACAY, S. 2005. Dentofacial effects of asymmetric headgear and cervical headgear with removable plate on unilateral molar distalization. *Angle Orthodontist*, 75, 584-92.

ANGLE, E. 1887. New System of Dental Regulation and Retention. *Dental Register*, 41, 597-603.

ARRIDGE, S., MOSS, J., LINNEY, A. & JAMES, D. 1985. Three Dimensional Digitization of the Face and Skull. *Journal of Maxillofacial Surgery*, 13, 136-143.

ASHMORE, J. L., KURLAND, B. F., KING, G. J., WHEELER, T., GHAFARI, J. & RAMSAY, D. S. 2002. A three-dimensional analysis of molar movement during headgear treatment. *American Journal of Orthodontics and Dentofacial Orthopedics*, 121, 18.

BAILEY, L., ESMAILNEJAD, A. & ALMEIDA, M. 1996. Stability of the palatal rugae as landmarks for analysis of dental casts in extraction and nonextraction cases. *Angle Orthodontist*, 66, 73-8.

BANKS, P., ELTON, V., JONES, Y., RICE, P., DERWENT, S. & ODONDI, L. 2010. The use of fixed appliances in the UK : a survey of Specialist Orthodontists. *Journal of Orthodontics*, 37, 43-55.

BAUMRIND, S. & FRANTZ, R. 1971b. The reliability of head film measurements 2. Conventional angular and linear measures. *American Journal of Orthodontics and Dentofacial Orthopedics*, 60, 505-517.

BAUMRIND, S. & FRANTZ, R. 1971a. The reliability of head film measurements. 1. Landmark identification. *American Journal of Orthodontics and Dentofacial Orthopedics*, 60, 111-127.

BAUMRIND, S. & FRANTZ, R. 1976. The Reliability of headfilm measurements. 3. Tracing superimposition. *American Journal of Orthodontics and Dentofacial Orthopedics*, 70, 617-44.

BAUMRIND, S., MOFFITT, F. & CURRY, S. 1983. The geometry of three dimensional stereometry from paired coplanar images. *American Journal of Orthodontics and Dentofacial Orthopedics*, 84, 313.

- BENSON, P., TINSLEY, D., O'DWYER, J., MAJUMDAR, A., DOYLE, P. & SANDLER, J. 2007. Midpalatal implants vs headgear for orthodontic anchorage - a randomized clinical trial: Cephalometric results. *American Journal of Orthodontics and Dentofacial Orthopedics*, 132, 606-615.
- BONDEMARK, L. & KARLSSON, I. 2005. Extraoral vs Intraoral Appliance for Distal Movement of Maxillary First Molars: A Randomised Controlled Trial. *Angle Orthodontist*, 75, 699-706.
- BROADBENT, B. H. 1931. A new xray technique and its application to orthodontia. *Angle Orthodontist*, 1, 45.
- BURSTONE, C. J., EVERY, T. W. & PRYPUTNIEWICZ, R. J. 1982. Holographic measurement of incisoor extrusion. *American Journal of Orthodontics and Dentofacial Orthopedics*, 82, 1-9.
- CHA, B., LEE, J., JOST-BRINKMANN, P. & YOSHIDA, N. 2007. Analysis of tooth movement in extraction cases using three-dimensional reverse engineering technology. *European Journal of Orthodontics*, 29, 325-331.
- CHEN, G., CHEN, S., ZHANG, X., JIANG, R., LIU, Y., SHI, F. & XU, T. 2011. Stable region for maxillary dental cast superimposition in adults, studied with the aid of stable miniscrews. *Orthodontics and Craniofacial Research*, 14, 70-79.
- CHEN, S., LIANG, W. & CHEN, F. 2004. Factors affecting the accuracy of elastometric impression materials. *Journal of Dentistry*, 32, 603-609.
- CHENG, S., TSENG, T., LEE, J., KOK, S. 2004 A prospective study of the risk factors associated with failure of mini-implants used for orthodontic anchorage. *International Journal of Oral and Maxillofacial Implants*; 19: 100-6.
- CHOI, D., JEONG, Y., JANG, I., JOST-BRINKMAN, J. & CHA, B. 2010. Accuracy and Reliability of palatal superimposition of three-dimensional digital models. *Angle Orthodontist*, 80, 685-691.
- CHRISTOU, P. & KILIARIDIS, S. 2008. Vertical growth-related changes in the positions of the palatal rugae and maxillary incisors. *American Journal of Orthodontics and Dentofacial Orthopedics*, 133, 81-6.
- COCHRANE HANDBOOK FOR SYSTEMATIC REVIEWS OF INTERVENTIONS 2008 Ed Higgins J and Green S, Wiley Blackwell
- CREEKMORE, T. & EKLUND, M. 1983. The possibility of skeletal anchorage. *Journal of Clinical Orthodontics*, 04, 266 - 269.
- CURETON, S., REGENNITTER, F.J. & YANCEY, J. 1993 The role of the headgear calendar in headgear compliance. *American Journal of Orthodontics & Dentofacial Orthopedics*, 104, 4 387-394

- DAMSTRA, J., MISTRY, D., CRUZ, C. & REN, Y. 2009. Antero-posterior and transverse changes in the position of the palatal rugae after rapid palatal expansion. *European Journal of Orthodontics*, 31, 327-32.
- EFSTRATIADIS, S., BAUMRIND, S., SHOFER, F., JACOBSSON-HUNT, U., LASTER, L. & GHAFARI, J. 2005. Evaluation of Class II treatment by cephalometric regional superimpositions versus conventional measurements. *American Journal of Orthodontics and Dentofacial Orthopedics*, 128, 607-618.
- FELDMANN, I. 2007. Orthodontic anchorage; Evidence based evaluation of anchorage capacity and patients' perceptions. *Swedish Dental Journal - supplement*, 1-132.
- FELDMANN, I. & BONDEMARK, L. 2008. Anchorage capacity of osseointegrated and conventional anchorage systems; A randomized controlled trial. *American Journal of Orthodontics and Dentofacial Orthopedics*, 133, 339.e19-339.e28.
- FELDMANN, I., LIST, T., FELDMANN, H. & BONDEMARK, L. 2007. Pain Intensity and Discomfort Following Surgical Placement of Orthodontic Anchoring Units and Premolar Extraction. *Angle Orthodontist*, 77, 578-585.
- FERRARIO, V., SFORZA, C., SERRAO, G. & MIANI, A. 1995. A computerized non-invasive method for the assessment of human facial volume. *Journal of Cranio Maxillo-Facial Surgery*, 23, 280-286.
- FLEMING, P., MARINHO, V. & JOHAL, A. 2011. Orthodontic measurements on digital study models compared with plaster models: a systematic review. *Orthodontics and Craniofacial Research*, 14, 1-16.
- GARFINKLE, J., CUNNINGHAM, L., BEEMAN, C., KLUEMPER, T., HICKS, P. & KIM, M. 2008. Evaluation of orthodontic mini-implant anchorage in premolar extraction therapy in adolescents. *American Journal of Orthodontics and Dentofacial Orthopedics*, 133, 642-653.
- GRABER, T. 1955. Extraoral force - facts and fallacies. *American Journal of Orthodontics and Dentofacial Orthopedics*, 41, 490-505.
- GRAYSON, B., CUTTING, C., BOOKSTEIN, F., KIM, H. & MCCARTHY, J. 1988. The three-dimensional cephalogram: Theory, technique and clinical application. *American Journal of Orthodontics and Dentofacial Orthopedics*, 94, 327-37.
- HATCHER, L. C., NC: SAS INSTITUTE. 1994. A step-by-step approach to using the SAS(R) system for factor analysis and structural equation modeling. Cary, NC: SAS Institute.
- HIXON, E. 1960. Cephalometrics and longitudinal research *American Journal of Orthodontics and Dentofacial Orthopedics*, 46, 36-42.

- HOGGAN, B. R. & SADOWSKY, C. 2001. The use of palatal rugae for the assessment of anteroposterior tooth movements. *American Journal of Orthodontics and Dentofacial Orthopedics*, 119, 482-88.
- HUANG, X. & HAN, P. 2007. Comparison of clinical effects between screw-implant and extra-oral force as anchorage. *Beijing Journal of Stomatology*, 15, 213-215.
- JACKSON, A., LEMKE, R., HATCH, J., SALOME, N., GAKUNGA, P. & COCHRAN, D. 2008. A Comparison of Stability between Delayed versus Immediately Loaded Orthodontic Palatal Implants. *Journal of Esthetic and Restorative dentistry*, 20, 174-184.
- JAKOBSSON, S. O. 1967. Cephalometric evaluation of treatment effect on Class II, Division I malocclusions. *American Journal of Orthodontics and Dentofacial Orthopedics*, 53, 446-57.
- JANG, I., TANAKA, M., KOGA, Y., IJIMA, S., YOZGATIAN, J., CHA, B. & YOSHIDA, N. 2009. A Novel Method for the Assessment of Three-Dimensional Tooth Movement during Orthodontic Treatment. *Angle Orthodontist*, 79, 447-453.
- JUNG, B., HARZER, W., WEHRBEIN, H., GEDRANGE, T., HOPFENMULLER, W., LUDICKE, G., MOERGEL, M., DIEDRICH, P. & KUNKEL, M. 2011. Immediate versus conventional loading of palatal implants in humans: A first report of a multicentre trial. *Clinical Oral Investigations*: 15: 495-502
- KARAGKIOLIDOU, A., LUDWIG, B., PAZERA, P., GKANTIDIS, N., PANDIS, N. & KATSAROS, C. 2013. Survival of palatal miniscrews used for orthodontic appliance anchorage: A retrospective cohort study *American Journal of Orthodontics and Dentofacial Orthopedics* 2013;143:767-72
- KEATES, N. 2010. The 8-Year-Old With a Perfect Smile. *Wall Street Journal*, November 16th, 2010.
- KEELING, S. D., WHEELER, T. T., KING, G. J., GARVAN, C. W., COHEN, D. A., CABASSA, S., MCGORRAY, S. P. & TAYLOR, M. G. 1998. Anteroposterior skeletal and dental changes after early Class II treatment with bionators and headgear. *American Journal of Orthodontics and Dentofacial Orthopedics*, 113, 40-50.
- KERMER, C., RASSE, M., LAGOIANNIS, G., UNDT, G., WAGNER, A. & MILLESI, W. 1998. Colour stereolithography for planning complex maxillofacial tumour surgery. *Journal of Cranio Maxillo-Facial Surgery*, 26, 360-362.
- KLOEHN, S. 1947. Guiding alveolar growth and eruption of teeth to reduce treatment time and produce a more balanced denture and face. *Angle Orthodontist*, 17, 10-33.

- KURODA, T., MOTOHASHI, N., TOMINAGA, R. & IWATA, K. 1996. Three-dimensional dental cast analyzing system using laser scanning. *American Journal of Orthodontics and Dentofacial Orthopedics*, 110, 365-9.
- KUSNOTO, B. & EVANS, C. 2002. Reliability of a 3D surface laser scanner for orthodontic applications. *American Journal of Orthodontics and Dentofacial Orthopedics*, 122, 342-8.
- LEBRET, L. 1962. Growth changes of the palate. *Journal of Dental Research*, 41, 1391-1404.
- LI, F., HU, H., CHEN, J., LIU, Z., LI, G., HE, S., ZOU, S. & YE, Q. 2011. Comparison of the anchorage capacity between implant and headgear during anterior segment retraction - A Systematic Review. *Angle Orthodontist*, 81, 915-922.
- LIU, E., PAI, B. & LIN, J. 2004. Do miniscrews remain stationary under orthodontic forces? *American Journal of Orthodontics and Dentofacial Orthopedics*, 16, 42-47.
- MELSEN, B. 1978. Effects of cervical anchorage during and after treatment an implant study. *American Journal of Orthodontics and Dentofacial Orthopedics*, 73, 526-40.
- MELSEN, B., VERNA, C. 2005. Miniscrew implants: the Aarhus anchorage system. *Seminars in Orthodontics*, 11, 24-31.
- MIYAWAKI, S., KOYAMA, I., INOUE, M., MISHIMA, K., SUGAHARA, T. & TAKANO-YAMAMOTO, T. 2003. Factors associated with the stability of titanium screws placed in the posterior region for orthodontic anchorage. *American Journal of Orthodontics and Dentofacial Orthopedics*, 124, 373-378.
- MORRIS, D. 2010. Letters to the Editor. *Journal of Orthodontics*, 37, 139.
- MOYERS, R., VAN DER LINDEN, F., RIOLO, M. & MCNAMARA, J. 1976. Standards of Human Occlusal Development. . Monograph No. 5, Craniofacial Growth Series, Ann Arbor: The Centre for Human Growth and Development, the University of Michigan, 187.
- NANCE, H. 1947. The limitations of orthodontic treatment1: mixed dentition diagnosis and treatment. *American Journal of Orthodontics and Oral Surgery*, 33, 177-223.
- O'BRIEN, P. & FLEMING, T. R. 1979. A multiple testing procedure for clinical trials. *Biometrics*, 35, 549-556.
- OKUNAMI, T., KUSNOTO, B., BEGOLE, E., EVANS, C., SADOWSKY, C. & FADAVI, S. 2007. Assessing the American Board of Orthodontics objective grading system Digital vs plaster dental casts. *American Journal of Orthodontics and Dentofacial Orthopedics*, 131, 51-56.

- OPPENHEIM, A. 1936. Biologic Orthodontic Therapy and Reality. *Angle Orthodontist*, 6, 153-183.
- PANCHERZ, H. 1982. The mechanism of Class II correction in Herbst appliance treatment. *American Journal of Orthodontics and Dentofacial Orthopedics*, 82, 104-113.
- PAPAGEORGIYOU, S., ZOGAKIS, I. & PAPADOPOULOS, M. 2012. Failure rates and associated risk factors of orthodontic miniscrew implants: A meta-analysis. *American Journal of Orthodontics and Dentofacial Orthopedics*, 142, 577-595.e7.
- PEAVY, D. C. & KENDRICK, G. S. 1967. The effects of tooth movement on the palatine rugae. *Journal of Prosthetic Dentistry*, 18, 536-42.
- QIN, M. & MAO, J. 2008. Micro implant versus extraoral J hook for Angle Class II division 1 malocclusion. *Journal Clinical Rehabilitative Tissue Engineering Research* 12, 8705-8708.
- QUIMBY, M., VIG, C., RASHID, R. & FIRESTONE, A. 2004. The accuracy and reliability of measurements made on computer-based digital models. *Angle Orthodontist*, 74, 298-303.
- REDLICH, M., WEINSTOCK, T., ABED, Y., SCHNEOR, R., HOLDSTEIN, Y. & FISCHER, A. 2008. A new system for scanning, measuring and analyzing dental casts based on a 3D holographic sensor. *Orthodontics and Craniofacial Research*, 11, 90-5.
- REYNDERS, R., RONCHI, L. & BIPAT, S. 2009. Mini-implants in Orthodontics: A systematic review of the literature. *American Journal of Orthodontics and Dentofacial Orthopedics*, 135, 564. e1-564.e19.
- SANDLER, J., BENSON, P., DOYLE, P., MAJUMDAR, A., O'DWYER, J., SPEIGHT, P., THIRUVENKATACHARI, B. & TINSLEY, D. 2008. Palatal implants are a good alternative to headgear; A randomized trial. *American Journal of Orthodontics and Dentofacial Orthopedics*, 133, 51-57.
- SANDLER, P. J., ATKINSON, R. & MURRAY, A. M. 2000. For four sixes. *American Journal of Orthodontics and Dentofacial Orthopedics*, 117, 418-34.
- SARI, Z., GOYENC, Y., DORUK, C. & USEMEZ, S. 2003. Comparative evaluation of a new removable Jasper Jumper functional appliance vs an activator-headgear combination. *Angle Orthodontist*, 73, 286-93.
- SCHÄTZLE, M., MÄNNCHEN, R., ZWAHLEN, M., LAND, N. 2009 Survival and failure rates of orthodontic temporary anchorage devices; a systematic review. *Clinical Oral Implants Research*, 20: 1351-9

- SIMMONS, J., MOORE, R. & ERICKSON, L. 1987. A longitudinal study of anteroposterior growth changes in the palatine rugae. *Journal of Dental Research*, 66, 1512-1515.
- SINGH, P. & COX, S. 2009. Nance palatal arch : a cautionary tale. *Journal of Orthodontics*, 36, 272-276.
- SKEGGS, R. M., BENSON, P. E., DYER, F. & JAMBI, S. 2007. Reinforcement of anchorage during orthodontic brace treatment with implants or other surgical methods. *Cochrane Database of Systematic Reviews* 2007.
- SMITH, G. 2008. Newton's *Philosophiae Naturalis Principia Mathematica* ("Mathematical Principles of Natural Philosophy"). *The Stanford Encyclopedia of Philosophy* (Winter 2008 Edition), Edward N Zalta (ed.).
- SOHMURA, T., KOJIMA, T., WAKABAYASHI, K. & TAKAHASHI, J. 2000. Use of ultrahigh-speed laser scanner for constructing three-dimensional shapes of dentition and occlusion. *The Journal of Prosthetic Dentistry*, 84, 345-52.
- STEVENS, D., FLORES-MIR, C., NEBBE, B., RABOUD, D., HEO, G. & MAJOR, P. 2006. Validity, reliability, and reproducibility of plaster vs digital study models: Comparison of peer assessment rating and Bolton analysis and their constituent measurements. *American Journal of Orthodontics and Dentofacial Orthopedics*, 129, 794-803.
- STIVAROS, N., LOWE, C., DANDY, N., DOHERTY, B. & MANDALL, N. A. 2010. A randomized clinical trial to compare the Goshgarian and Nance palatal arch. *European Journal of Orthodontics*, 32, 171-176.
- THIRUVENKATACHARI, B. 2009 A comparison of the effectiveness of the twin block and the dynamax appliances for the treatment of Class I division 1 malocclusion patients: a randomised controlled trial. PhD Thesis, University of Manchester.
- THIRUVENKATACHARI, B., AL-ABDALLAH, M., AKRAM, N., SANDLER, J. & O'BRIEN, K. 2009. Measuring 3Dimensional tooth movement with a 3Dimensional surface laser scanner. *American Journal of Orthodontics and Dentofacial Orthopedics*, 135, 480-5.
- THONGTHAMMACHAT, S., MOORE, K., BARCO, M., HOVIJITRA, S., BROWN, D. & ANDRES, C. 2002. Dimensional accuracy of dental casts: Influence of tray material, impression material and time. *Journal of Prosthetic Dentistry*, 11, 98-101.
- UPADHYAY, M., YADAV, S., NAGARAJ, K. & PATIL, S. 2008a. Treatment effects of mini-implants for en-masse retraction of anterior teeth in bialveolar dental protrusion patients: A randomized controlled trial. . *American Journal of Orthodontics and Dentofacial Orthopedics*, 134, 18-29.

UPADHYAY, M., YADAV, S. & PATIL, S. 2008b. Mini-implant anchorage for en-masse retraction of maxillary anterior teeth: A clinical cephalometric study. *American Journal of Orthodontics and Dentofacial Orthopedics*, 134, 803-810.

UTZ, K., MÜLLER, F., LÜCKERATH, W., FUSS, E. & KOECK, B. 2002. Accuracy of check-bite registration and centric condylar position. *Journal of Oral Rehabilitation*, 29, 458-466.

VAN DER LINDEN, F. P. 1978. Changes in the position of the posterior teeth in relation to the ruga points. *American Journal of Orthodontics and Dentofacial Orthopedics*, 74, 142-61.

WEICHMANN, D., MEYER, U. & BÜCHTER, A. 2007. Success rate of mini- and micro-implants used for orthodontic anchorage: a prospective clinical study. *Clinical Oral Implants Research*, 18, 263-267.

ZILBERMAN, O., HUGGARE, J. & PARIKAKIS, K. 2003. Evaluation of the validity of tooth size and arch width measurements using conventional and three-dimensional virtual orthodontic models. *Angle Orthodontist*, 73, 301-6.

APPENDICES

APPENDIX 1 : Search strategy used in electronic searching of databases

1 MEDLINE search strategy

#1 exp ORTHODONTICS/ ME
#2 orthodontic\$.mp.
#3 OR/1-2
#4 exp Dental Implants/
#5 exp Dental Implantation
#6 ((Dental adj4 implant\$) or (oral adj4 implant\$) or (titanium adj4 implant\$) or (palatal adj4 implant\$) or (endosseous adj4 implant\$).mp. [mp=title, abstract,name of substance, mesh subject heading]
#7 osseointegration.mp[mp=title, abstract,name of substance, mesh subject heading]
#8 titanium plate\$.mp [mp=title, abstract,name of substance, mesh subject heading]
#9 zygoma\$ wire\$.mp [mp=title, abstract,name of substance, mesh subject heading]
#10 (miniscrew\$ or miniscrew\$ or microscrew\$ or spiderscrew\$).[mp=title, abstract,name of substance, mesh subject heading]
#11 (surgical\$ or surgery).mp. [mp=title, abstract,name of substance, mesh subject heading]
#12 onplant\$.mp. [mp=title, abstract,name of substance, mesh subject heading]
#13 OR/4-12
#14 anchor\$.mp. [mp=title, abstract,name of substance, mesh subject heading]
#15 3 AND 13 AND 14

APPENDIX 2: Form 1 to decide if abstract can be included or not

Reviewer:

Surgical reinforcement of anchorage during brace treatment

Author:	
---------	--

Title, Keywords or Abstract	Yes	No	Not clear	Comments
Is this a clinical trial, case-control study or case series. involving humans?				
Is a surgical method of anchorage reinforcement used?				

Is this to be included in the systematic review?				
--	--	--	--	--

Author:	
---------	--

Title, Keywords or Abstract	Yes	No	Not clear	Comments
Is this a clinical trial, case-control study or case series. involving humans?				
Is a surgical method of anchorage reinforcement used?				

Is this to be included in the systematic review?				
--	--	--	--	--

Author:	
---------	--

Title, Keywords or Abstract	Yes	No	Not clear	Comments
Is this a clinical trial, case-control study or case series. involving humans?				
Is a surgical method of anchorage reinforcement?				

Is this to be included in the systematic review?				
--	--	--	--	--

APPENDIX 3: FORM 2: AGREEMENT BETWEEN 2 REVIEWERS AFTER INITIAL SCREENING

1= include citation, 2= exclude citation

studyID	SJ after screeni ng	JS after screeni ng	agreement and JS independent screening	SJ after discussion	opinion2: SJ and JS after discussion	agreed citations after screening and discussion
Gelgor 2007	1	1	1			1
Bondemark 2005	1	2	2		1	1
Altug-Atac 2008	1	2	2		1	1
Jung 2007	1	1	1			1
Thiruvengkatachari 2008	1	1	1			1
Upadhyay 2008	1	2	2		1	1
Shi 2008	1	1	1			1
Melsen 2007	1	1	1			1
Benson 2007	1	1	1			1
Borsos 2008	1	1	1			1
Cheng 2004	1	2	2		1	1
Deguchi 2008	1	1	1			1
Feldmann 2008	1	1	1			1
Feldmann 2007	1	1	1			1
Feldmann 2007_2	1	1	1			1
Garfinkle 2008	1	2	2		1	1
Jackson 2008	1	1	1			1
Kadioglu 2008	1	2	2		1	1
Ma 2008	1	1	1			1
Moon 2008	1	2	2		1	1
Motoyoshi 2007	1	2	2		1	1
Sandler 2008	1	1	1			1
Schatzle 2009	1	1	1			1
Upadhyay 2008_2	1	1	1			1
Zhou 2009	1	1	1			1
Bokas 2006	2	2	1			2
Pandis 2006	2	2	1			2
Garib 2006	2	2	1			2
Mossaz 2007	2	2	1			2
Sjoholm 1994	2	2	1			2
Schutze 2007	2	2	1			2
Polat-Ozsoy 2008	2	2	1			2
Lin 2007	2	1	2		2	2
Zhang 2004	2	2	1			2
Ingervall 1995	2	2	1			2
Odenrick 1991	2	2	1			2
Andreasen 1980	2	2	1			2
Witt 1999	2	2	1			2
Du 2002	2	2	1			2
Wieslander 1984	2	2	1			2
Schneidman 1990	2	2	1			2
Michelotti 1999	2	2	1			2
Favero 2002	2	2	1			2
Hagg 2002	2	2	1			2
Weschler 2005	2	2	1			2
Ohashi 2006	2	2	1			2
Cornelis 2007/04	2	2	1			2
Heo 2007	2	2	1			2
Germec 2008	2	2	1			2
Oncag 2007	2	1	2		2	2

Lee 2007	2	2	1		2
Irvine 2004	2	2	1		2
Lotzof 1996	2	2	1		2
Chen 2009	2	2	1		2
Chun 2009	2	2	1		2
Eliades 2009	2	2	1		2
Favero 2007	2	2	2	2	2
Garino 2003	2	2	1		2
Goncalves 2008	2	2	1		2
Gracco 2008	2	2	1		2
Han 2009	2	2	1		2
Hassan 2003	2	2	1		2
Hedayati 2007	2	2	1		2
Janssen 2008	2	2	1		2
Kaufmann 2009	2	2	1		2
Kim 2006	2	2	1		2
Kokitsawat 2008	2	2	1		2
Korbmacher 2005	2	2	1		2
Koudstaal 2009	2	2	1		2
Krey 2008	2	2	1		2
Kuroda 2007	2	2	1		2
Lai 2008	2	2	1		2
Livas 2006	2	2	1		2
Miethke 1990	2	2	1		2
Morarend 2009	2	1	2	2	2
Motoyoshi 2007_2	2	2	1		2
Proff 2006	2	2	1		2
Sari 2007	2	2	1		2
Willems 1999	2	2	1		2
Wu 2006	2	2	1		2
Yao 2008	2	2	1		2
Aloise 2007	2	2	1		2
Bardach 1992	2	2	1		2
Bartonova 2005	2	2	1		2
Bongaarts 2004	2	2	1		2
Cousley 2004	2	2	1		2
Davilla 2005	2	2	1		2
Danesh 2006	2	2	1		2
Hassan 2007	2	2	1		2
Keeling 1996	2	2	1		2
Korbmacher 2007	2	2	1		2
Koudstaal 2006	2	2	1		2
Koijpers-Jagtman 2006	2	2	1		2
Kurkcu 2005	2	2	1		2
Lux 2002	2	2	1		2
Main 2009	2	2	1		2
O'Ryan 1983	2	2	1		2
Ortiz_Posadas 2004	2	2	1		2
Owens 2003	2	2	1		2
Peled 2005	2	2	1		2
Pinto de Moura 2005	2	2	1		2
Provatidis 2007	2	2	1		2
Schlegel 1997	2	2	1		2
Sensi 2005	2	2	1		2
Trawitzki 2006	2	2	1		2
Valiathan 2000	2	2	1		2
Vasconcelos 2006	2	2	1		2

APPENDIX 4 : Form 3: Study eligibility form: Surgical anchorage update

Study ID:

Completed by:

Type of study:

Q1: Is the study a randomised clinical trial?

Yes



Unclear



No



Go to next question

Exclude

Type of participants:

Q2: Are the participants undergoing orthodontic treatment with braces?

Yes



Unclear



No



Go to next question

Exclude

Interventions in the study:

Q3: Did the study contain at least two groups, each receiving a different form of surgical anchorage OR surgical anchorage compared to conventional anchorage?

Yes



Unclear



No



Go to next question

Exclude

Outcomes in the study:

Q4: Did the study report at least one of the following outcome measures:

Mesial movement of the upper first permanent molar, residual overjet at the end of treatment, patient perceptions of pain, discomfort, acceptability, treatment time, number of visits, failure of anchorage appliance, compliance, incomplete treatment such as failure to finish, adverse effects, or economic factors.

Yes



Unclear



No



Final decision

Include

Include subject to clarification of 'Unclear' Exclude

APPENDIX 5: Form 4: Data extraction form

Study ID _____

Assessor _____

Study Eligible: Yes _____ No _____ Reason:.....

METHODS

Study design	
Total study duration	
Sequence generation	
Allocation sequence concealment	
Blinding	
Other concerns about bias	

PARTICIPANTS

Total number	
Setting	
Inclusion and exclusion criteria	
Age	
Gender	
Country	

INTERVENTIONS

Total number of interventions	Name of intervention	Description
Intervention 1		
Intervention 2		
Intervention 3		
Intervention 4		

OUTCOMES

Mesial molar movement			
Residual OJ			
Success/failure of anchorage device			
Patient perception (pain/discomfort)			
Acceptability			
No. of visits			
Duration of treatment			
Compliance			
Incomplete treatment			
Economic factors			

APPENDIX 6: APPLICATION FOR FUNDING FROM THE BOSF

1. APPLICANT

Surname Sandler
Forenames Paul Jonathan

Qualifications (with dates) BDS(Hons) 79, FDSRCPS 83, MSc 84,
DOrth.RCS 84 MOrthRCS 86 European Board Certification 2000

Address for correspondence
Orthodontic Department, Chesterfield Royal Hospital, Chesterfield
S445BL

Daytime telephone 01246 513346

Email address Jonsandler@AOL.com

Present appointment Consultant Orthodontist, Chesterfield Royal
Hospital, Senior Clinical Lecturer, Charles Clifford Dental Hospital,
University of Sheffield.

(Please also provide a brief curriculum vitae at Appendix 1)

2. DETAILS OF CENTRE WHERE RESEARCH IS TO BE CARRIED OUT

Name Paul Jonathan Sandler

Address Orthodontic Department, Chesterfield Royal Hospital,
Calow, Chesterfield

Name of Head of Department
Mr Paul Jonathan Sandler (Chesterfield),

Permission been granted in writing Preliminary authorization
given by Clinical director. Formal hospital management committee
approval to follow.

(Please enclose copy)

Please note six copies of this form should be submitted

Closing date for application 31st May 2006 but please indicate in
writing by the 30th April 2006 if you are planning to submit an
application with brief details of topic area and funding required.

3. **PROJECT** Efficiency and effectiveness of three methods of anchorage reinforcement in orthodontics

Title Orthodontic anchorage reinforcement – An RCT comparing methods

Proposed starting date January 2007

Proposed duration 4 years

Abstract (200 words)

Research problem

Anchorage reinforcement is effective with headgear provided patient compliance is optimal. Mid palatal implants have also been shown to be effective. Microscrews despite their popularity however have no scientific evidence to support their use.

Aim

To compare the effectiveness of 3 methods of anchorage reinforcement 1) headgear 2) an off-centred palatal implant 3) orthodontic micro-screws.

Hypothesis

There is no difference in the amount of anchorage loss between the three methods of anchorage reinforcement.

Design

Randomized clinical trial.

Setting: District General Hospital orthodontic department

Participants: 75 patients requiring “absolute anchorage”.

Interventions: The subjects will be randomized into 3 groups. In group 1 headgear will be requested 12-14 hours per day. In group 2 an off-centred palatal implant will be placed for use as intra oral anchorage reinforcement. In group 3, orthodontic micro-screws will be used for anchorage.

Method of investigation

The study will be of 75 ‘absolute anchorage’ patients older than 12 years randomly assigned to one of three groups of anchorage reinforcement

Outcome measures:

1. Anchorage loss measured from lateral Cephalometric radiographs and 3D model scanning, records will be taken at three points
2. Patient perception of the different treatment methods, including surgical experience

Data analysis: The data will be analysed on an intention to treat basis. Basic descriptive statistics and uni-variate tests will initially be done to explore the data. Final data analysis will involve the relevant multi-variate statistical modeling.

Dissemination: Conference proceedings, journal papers and the Cochrane oral health group.

SUMMARY OF SUPPORT REQUEST TO BOSF FOUNDATION

	Year ending March 31		
	2007	2008	2009
Personal support of applicant			
Apparatus and equipment			
Materials and consumables	£13277.56		
Other expenses Research assistant	£4962	£5505	£6096
Total support requested	£18,239.56	£5005	£6096

Please explain the request in Appendix 3

Is this support request currently being submitted elsewhere?

YES _____ NO X _____

If yes, please indicate the organisation concerned and the date by which a decision is expected.

Has this support request been submitted elsewhere over the past year?

YES _____ NO X _____

If yes, to which organisation and what was the result?

Funding was requested last year but the request was unsuccessful

Is additional support needed, from another source, for the project to go ahead?

YES _____ NO X _____

If yes, please give details.

3. ETHICAL STATUS

Does the project require local Ethical Committee approval?

YES _____ NO _____

If yes, have you already applied for ethical approval?

YES _____ NO _____

N.B. Previous RCT on Mid-Palatal Implants at Chesterfield received local Ethical Committee approval. The COREC form is being submitted at the moment

If yes, have you received ethical approval?

YES _____ NO _____

Note: All clinical and animal research should have ethical approval. You are advised to seek advice from the Chairman of your local Ethical Committee, at the earliest opportunity.

SIGNATURES

A. ADMINISTRATOR or FINANCE OFFICER:

I have seen this estimate of costs and I agree that any prize money will be administered by this Institution. Please note that no overheads charge is applicable.

Signature..... W.C.Lambert, Director of
Research Date.....

Institution Chesterfield and North Derbyshire Royal Hospital
Foundation Trust

HEAD of DEPARTMENT or EMPLOYER:

I have seen this application and agree to this research being carried out.

Signature..... W.C.Lambert, Medical
Director Date.....

B. APPLICANT:

I agree to abide by any regulations governing the award by the British Orthodontic Society Foundation and agree that the results of this research will be presented initially to the British Orthodontic Society.

Signature.....
Date.....

**Please complete and return this form to:
Chairman, Scholarship Committee
British Orthodontic Society
12 Bridwell Place
London, EC4V 6AP**

BRIEF CURRICULUM VITAE OF APPLICANT

SURNAME: Sandler		FORENAMES: Paul Jonathan	
DATE OF BIRTH: 21-05-57			
DEGREES/PRIZES/HONOURS:			
	B.D.S. (Hons)	University of Manchester	1979
	F.D.S.R.C.P.S.	Glasgow	1983
	MSc	University of London	1986
	D. Orth.	Royal College of Surgeons (Eng)	1986
	M. Orth.	Royal College of Surgeons (Eng)	1988
	European Board Certification		2000
Prizes:	University Gold Medal, Charles H. Preston Prize		
Awards	<p>Orodent Scholarship 1988 -£2750 awarded to investigate the uses of NIB Magnets</p> <p>T.C.White Travel Award 1990 - £750 contribution towards a study trip in Australia.</p> <p>Probe Photographic Competition,1992-£500 award for photographic documentation</p> <p>Forestadent Travel Award - £2000 for visiting Orthodontic Centres in the USA</p> <p>Probe Photographic Competition, 1994 - £250 award for photographic documentation</p> <p>Trent Regional Postgraduate Dental Dean's Award - £7500 awarded for the purchase of hardware and software for up-to-date cephalometric analysis. Soroptomists of Chesterfield and District Millenium Award - £5000 presented to the Department for the purchase of computer equipment for the department</p> <p>Chesterfield Research Bursary 2004 - £6500 awarded the the Implant Team to finance analysis of the results of the Implant Research</p> <p>NEDSCAN award of £70.000 to fund a digital x-ray facility in the maxillofacial unit</p>		
RECENT PUBLICATIONS:			
Yip L, McKeown HF, Sandler PJ (2003) Two cases of Molar Root Resorprtion Dental Update 2003; 30: 200-204			
Usmani T, O'Brien KD, Worthington S, Derwent S, Fox D, Harrison S, Sandler PJ, Mandall NA (2003) A randomised clinical trial to compare the effectiveness of canine lacebacks with reference to the canine tip Journal of Orthodontics 29: 281- 286			
Popat H and Sandler PJ (2003) A magnetic fixation and orientation system for orthognathic surgery planning models Grand Rounds Vol 3 pp 1-3, http://www.grandrounds-e-med.com			
O'Brien K, Wright J, Conboy F, Sanjie YeW, Mandall N, Chadwick S, Connolly I, Cook P, Birnie D, Hammond M, Harradine N, Lewis D, McDade C, Mitchell L, Murray A, O'Neill J, Read M, Robinson S, Roberts-Harry D, Sandler J, Shaw (2003) Effectiveness of treatment for Class II with the Herbst or Twin Block appliance: A randomized, controlled trial American Journal of Orthodontics			

and Dentofacial Orthopedics 2003;124: 128-37

O'Brien K, Wright J, Conboy F, Sanjie YeW, Mandall N, Chadwick S, Connolly I, Cook P, Birnie D, Hammond M, Harradine N, Lewis D, McDade C, Mitchell L, Murray A, O'Neill J, Read M, Robinson S, Roberts-Harry D, Sandler J, Shaw (2003)

Effectiveness of early orthodontic treatment with the Twin Block appliance: A multicenter, randomized, controlled trial. Part 1 : Dental and skeletal effects
American Journal of Orthodontics and Dentofacial Orthopedics 2003;124: 234-43

Sandler PJ (2003) Ask us – Palatal Implants American Journal of Orthodontics and Dentofacial Orthopedics 2003;124: 17A

Sandler PJ and Dutterloo HS (2003)

The European Board of Orthodontics: a professional challenge
Journal of Orthodontics 30; 59-71

O'Brien K, Wright J, Conboy F, Sanjie YeW, Mandall N, Chadwick S, Connolly I, Cook P, Birnie D, Hammond M, Harradine N, Lewis D, McDade C, Mitchell L, Murray A, O'Neill J, Read M, Robinson S, Roberts-Harry D, Sandler J, Shaw (2003)

Effectiveness of early orthodontic treatment with the Twin Block appliance: A multicenter, randomized, controlled trial. Part 2 : Psychosocial effects

American Journal of Orthodontics and Dentofacial Orthopedics 2003;124: 488-95

Tinsley D, O'Dwyer JJ, Benson PE, Doyle PT, and Sandler PJ (2004)

Orthodontic palatal implants: clinical technique

Journal of Orthodontics 31; 1-6

Dutterloo HS and Sandler PJ (2004) A Comparison of Current Orthodontic Board Examinations Journal of Orthodontics 31: 98 - 104.

Shetty R and Sandler PJ (2004) Keeping your eye on the ball Dental Update - 31: 398 - 402

Patel A, Brennan J A and Sandler PJ (2004) Auto-transplantation of an Impacted Third Molar – an Orthodontic Case Report Dental Update - December 2004 31: 596- 601

Patel A, Davies SJ, Sandler PJ. (2004) A potentially fatal vascular anomaly and orthodontic treatment – a case report Dent Update. 2004 May;31(4):230-2, 235-6.

Majumdar A, Tinsley D, O'Dwyer J, Doyle P, Sandler J, Benson P, Davies S The 'Chesterfield Stent': an aid to placement of Midpalatal implants (2005) British Journal of Oral and Maxillofacial Surgery 43, 36-39

McKeown H.F., Sandler P.J. , Murray A.M (2005) How to avoid errors in clinical photography Journal of Orthodontics 32: 43-54

Sandler P.J. , Sira S. Murray A.M (2005) A photographic 'Kesling' Setup Journal of Orthodontics 32: 85-88

Shah A A., Sandler P.J. , Murray A.M (2005) How to place a lower bonded retainer Journal of Orthodontics 32: 206-210

PROPOSED INVESTIGATION (up to 3000 words)

1. Title
2. Purpose of proposed investigation
3. Background and literature review
4. Plan of investigation
5. Detailed justification for support

Title

A comparison of three methods of orthodontic anchorage reinforcement: A randomized clinical trial.

Purpose of the proposed investigation

To strengthen the evidence base around the use of palatal implants and micro-screws in the supplementation of orthodontic anchorage.

BACKGROUND OF THE PROJECT AND LITERATURE REVIEW

An important component of any orthodontic treatment plan is the control or reinforcement of anchorage. This is commonly achieved by the use of orthodontic headgear. However, this method of treatment relies on patient compliance and carries with it the risk of ocular and facial damage. As a result, alternative methods have been developed. These include the use of titanium implants and small metal screws.

Titanium dental implants were developed in Sweden during the 1970's. Since this time they have been used extensively in the USA and Europe to treat patients with edentulous spaces¹⁻⁷. For implants to be successful, their titanium surface must form a mechanical bond with the bone and become osseointegrated. It appears that implants may have a role to play in reinforcing orthodontic anchorage and be an alternative to headgear. This is because their use may not require patient compliance and do not carry the well documented risk of facial and ocular damage that occasionally occurs with headgear⁸⁻¹⁰.

Recently a specially designed endosseous implant (Straumann Orthosystem) has been introduced onto the market for this purpose (figure 4).



Figure 1 – The Straumann mid-palatal implant in this case connected to the molars.

The implants are short (4 and 6mm) root-formed and placed into the mid-sagittal area of the palate. Once osseointegration is complete they can be loaded and incorporated into fixed orthodontic appliances and used to temporarily reinforce anchorage.

To date there are several case reports and case series but no studies assessing implants for this application^{11,12,13,14}.

Another method of anchorage supplementation is with the use of small metal screws and this is gaining popularity. Many case reports have been described detailing their use in retracting, protracting, intruding and extruding teeth¹⁵⁻²⁰.

A systematic review by Skeggs²¹ (2005) documented 157 papers on implant reinforcement of anchorage. Every single one of these papers was excluded from the review and where appropriate the reasons for exclusion were listed. The conclusions were that there was no evidence currently available to firmly support the use of implants for orthodontic anchorage reinforcement.

The effectiveness of these treatment methods has not been evaluated using randomised clinical trial methodology and well designed RCTs are most definitely required.

PLAN OF THE INVESTIGATION

AIMS

The aims of this trial are:

To evaluate:

1. the effectiveness of 3 different methods of anchorage reinforcement
2. The patient perception of their treatment, including surgical procedures.
- 3.

NULL HYPOTHESES

1. There is no difference in the amount of upper molar tooth movement when using (i) palatal implant, (ii) miniscrews or (iii) Headgear as part of orthodontic anchorage reinforcement
2. There are no differences in patient perceptions of the three methods of anchorage reinforcement.

Design

A longitudinal, prospective randomised clinical trial

Setting

A district hospital orthodontic department

Intervention

Seventy-five children aged over 12 referred from the General Dental Service to Chesterfield Royal Hospital will be selected to take part in this study. Informed consent will be obtained. They will then be randomly allocated using block randomisation into 3 groups. In group 1 the anchorage required for orthodontic treatment will be reinforced with extra-oral headgear worn for 12-14 hours each day. For group 2 An off-centred palatal implant will be surgically placed and following integration (12 weeks) used to reinforce the anchorage of the upper molars by means of a trans-palatal arch. In group 3, miniscrews placed in the buccal alveolus will be used for anchorage supplementation.

The patients will be treated according to the normal treatment protocols of the operators. In all groups bands will be placed onto the 1st molars and pre-adjusted edgewise orthodontic brackets on the premolars and anterior teeth. The aim of treatment will be to finish to a similar standard of ideal occlusion in all groups. At the end of treatment the implants and screws will be removed.

Data collection

Data will be collected at the following stages of treatment;

1. The start of treatment (DC1)
2. At the point that the operator decides that anchorage reinforcement is no longer required (DC2)
3. At the end of treatment (DC3)

We will collect the following records

- Study casts (DC 1,2,3)
- Lateral cephalograms (DC 1,2 3)
- Treatment process data; number of attendances, duration of treatment, number of failed or cancelled appointments and frequency and reason for additional attendance for appliance breakage or debonds.

The study casts will be scanned with a Minolta 3D surface laser scanner, the pre and post-treatment casts will be superimposed on stable palatal rugae and tooth movement will be measured using Rapid form software. The study casts will also be analysed with the PAR index. The radiographs will be digitized and molar and incisor tooth movement will be evaluated with the Pancherz analysis.

A questionnaire will be developed using a two stage approach to measure the subjects perception of their appliances and surgical experiences. This will be given to the patients at DC2 and DC3.

Statistics

Sample size calculation

We carried out a sample size calculation using data derived from a study that used the Pitchfork analysis (Luecke & Johnston²²). Their results suggest that the molars moved forward 3.2mm (sd 1.5mm). Altman²³ describes a sample size calculation for three independent groups with continuous data.

$$\begin{aligned}
 \text{Standard deviation of variable (s)} &= 1.5\text{mm} \\
 \text{Clinically relevant difference } (\delta) &= 2.0\text{mm} \\
 \text{Standard difference} &= \delta/s \\
 &= 2.0/1.5 \\
 &= 1.33
 \end{aligned}$$

Using the nomogram (p 456 Altman 1991) with a standardized difference of 1.33 a sample size of 20 in each group will give a power of

0.85 with a significance level of 0.05. An assumption of 20% dropout means 25 patients need to be recruited into each of the 3 groups.

Statistical methods to be used

The primary outcome measures of tooth movement and PAR scores are continuous variables and the data will be checked for normality and any transformations that may be necessary will be carried out. We will carry out an intention to treat analysis and all patients will be included in the study. Initially, we will carry out a comparison of the groups for the end of the study using “t” tests or Mann Whitney tests (as appropriate) on outcome variables. This will then be followed by relevant multivariate analysis depending upon any associations identified between the independent variables.

The data analysis will be carried out at the end of the study.

Ability of the investigators to carry out this project

The orthodontic department at Chesterfield hospital has already taken part in two large randomized trials of Class II therapy and prospective investigations of the effectiveness of orthognathic surgery.

All the operators in the study will have ownership of the investigation, and as a result, they will have motivation to complete the investigation. The trial will be co-ordinated by the trials co-ordinating centre of the Research Unit of Orthodontics at the University of Manchester.

This unit has a history of 15 years Medical Research Council funding and has been involved in the running of 10 randomized controlled trials in the last ten years. Currently, they co-ordinate the only RCT funded by the MRC in clinical dentistry.

The unit is staffed by 5 research assistants and has contemporary computer and data collection support. Present research grants are from the Medical Research Council, European Union, National Health Service R&D and the British Orthodontic Society Foundation. Over the last 10 years the Unit has attracted over £3million research funds.

Detailed justification of the support

Surgical starter Kit Dentos Abso Anchor Micro-implants – 1126.48 ± VAT 2 Kits required

Miniscrews currently cost £29.14 ± VAT per screw and we have estimated we may need up to 4 screws per patient. Personal communication with orthodontists using a significant number of miniscrews indicates a failure rate with the miniscrews of up to 40%. We therefore are budgeting for 140 screws = £4793.54

Palatal Implant equipment

TOTAL for 25 palatal implant cases
= £7098.40 ± VAT = £8340.62

The cost of the research assistant has been provided by the Research Team of Manchester University and is detailed below:

QUOTATION RA1B4

INCREMENT MONTH 9 SEPTEMBER
INFLATION MONTH 8 AUGUST
DURATION (MONTHS) 36 MONTHS
START MONTH 9 SEPTEMBER 2006
CONV. RATE ##### £ = 1 0

INFLATION MONTH YEAR 0 YEAR 1 YEAR 2 YEAR 3 YEAR 4 YEAR 5
 0.00% 0.00% 0.00% 0.00% 0.00% 0.00%
PART TIME % 's 20.00% 20.00% 20.00% 100.00% 100.00%

SCALE	YEAR	YEAR	YEAR	YEAR	YEAR	YEAR
RA1B4	1	2	3	4	5	6
SALARY	3892	4108	4328	0	0	0
SUPERAN.	545	575	606	0	0	0
NAT. INS.	269	289	310	0	0	0
TOTAL	4706	4973	5244	0	0	0

5% Inflation Included

QUOTATION RA1B4

INCREMENT MONTH 9 SEPTEMBER
INFLATION MONTH 8 AUGUST
DURATION (MONTHS) 36 MONTHS
START MONTH 9 SEPTEMBER 2006
CONV. RATE ##### £ = 1 0

INFLATION MONTH YEAR 0 YEAR 1 YEAR 2 YEAR 3 YEAR 4 YEAR 5
 5.00% 5.00% 5.00% 5.00% 0.00% 0.00%
PART TIME % 's 20.00% 20.00% 20.00% 100.00% 100.00%

SCALE	YEAR	YEAR	YEAR	YEAR	YEAR	YEAR
RA1B4	1	2	3	4	5	6
SALARY	4104	4548	5031	0	0	0
SUPERAN.	575	637	704	0	0	0
NAT. INS.	284	320	360	0	0	0
TOTAL	4962	5505	6096	0	0	0


1. **Adell R, Lekholm U, Rockler B, Brånemark P-I (1981).** A 15-year study of osseointegrated implants in the treatment of the edentulous jaw. *Int. J. Oral Surg*, **10**: 387-416.
2. **Brånemark P-I, Zarb GA, Albrektsson T (1985).** *Tissue-Integrated Prostheses*. Quintessence Publishing Co. Inc. Chicago.
3. **Albrektsson T, Brånemark PI, Hansson HA, Lindstrom J (1981).** Osseointegrated titanium implants. Requirements for ensuring a long-lasting, direct bone-to-implant anchorage in man. *Acta Orthopaedica Scandinavica*, **52(2)**: 155-70.
4. **Albrektsson T, Zarb G, Worthington P, Eriksson AR (1986).** The long-term efficacy of currently used dental implants: a review and proposed criteria of success. *International Journal of Oral & Maxillofacial Implants*, **1(1)**: 11-25.
5. **Sennerby L, Roos J (1998).** Surgical determinants of clinical success of osseointegrated oral implants: a review of the literature. *International Journal of Prosthodontics*, **11(5)**: 408-20.
6. **Smith DE, Zarb GA (1989).** Criteria for success of osseointegrated endosseous implants. *Journal of Prosthetic Dentistry*, **62(5)**: 567-72.
7. **Watson CJ, Tinsley D, Ogden AR, Mulay S, Davidson E (1999).** A 3 to 4 year study of single tooth HA coated endosseous dental implants. *Brit Dent J*, **187(2)**: 90-94.
8. **Samuels RHA et al. (1996)** A national survey of orthodontic facebow injuries in the UK and Eire. *BJO* **23**: 11-20.
9. **Samuels RHA and Jones ML (1994)** Orthodontic injuries and safety equipment. *EJO*, **16**: 385 –394.
10. **Cureton SL et al. (1993)** Clinical versus quantitative assessment of headgear compliance. *Am J Orthod Dentofacial Orthop*, **104**: 277-284.
11. **Celenza F. Hochman MN. (2000)** Absolute anchorage in orthodontics: Direct and indirect implant assisted modalities. *J C O*, **34**: 397-402.
12. **Wehrbein H. Feifel H. Diedrich P.(1999)** Palatal implant anchorage reinforcement of posterior teeth: A prospective study. *Am J Orthod Dentofacial Orthop* , **116**: 678-86.
13. **Wehrbein H. Merz BR. Diedrich P. Glatzmaier J. (1996)** The use of palatal implants for orthodontic anchorage. *Clin Oral Impl Res* , **7**: 410-416.
14. **Creekmore T Eklund MK (1983)** The possibility of skeletal anchorage *JCO* **17**:266-269
15. **Park YC, Lee SY, Kim DH, Jee SH (2003)** Intrusion of posterior teeth using miniscrew implants *Am J Orthod Dentofacial Orthop***123**:690-694
16. **Kyung HM, Park HS, Bae SM, Sung JH, Kim IB (2003)** Development of orthodontic mini-implants for intra-oral anchorage *JCO* **37**:321-328
17. **Kanimi R (1997)** Mini-implant for orthodontic anchorage *JCO* **31**:763-767
18. **Costa A Raffiani M , Melsen B (1998)** Miniscrews as orthodontic anchorage A preliminary report *Int J Adult Orthod Orthog Surg* **13**:201-209
19. **Park HS, Bae SM, Kyung HM, Sung JH, (2001)** Micro-Implant Anchorage for treatment of skeletal Class 1 bialveolar protrusion *JCO* **35**:417-428
20. **Bae SM, Park HS, Kyung HM, Kwon OWSung JH, (2002)** Clinical applications of Micro-Implant anchorage *JCO* **36**: 298-302
21. **Skeggs R.M.** A systematic review of surgical reinforcement of anchorage during orthodontic treatment M.C.Dent University of Sheffield

FINANCIAL DETAILS OF GRANT REQUEST

Personal support	Research 1 day per week over 3 years = £16,563
Apparatus and equipment	<p>Straumann Palatal implant setup</p> <p>Orthosystem cassette complete 040.162 Sales price £830 x 2 = £1660 ± VAT Implants 3.3mm x 6mm x 2.5mm neck 25 @ 134.10 = £3352 ± VAT Emergency Implants 4mm x 6mm x 2.5mm neck 5 @ 134.10 = £670.50 ± VAT Ortho healing cap 25 @ 15.30 = £382.50 ± VAT Ortho analogue 25 @ £11.10 = £277.50 ± VAT Ortho explantation drill 2 @ £43.10 = £86.20 ± VAT Ortho guide cylinder 2 @ £11.10 = £22.20 ± VAT Ortho post cap 25 @ £25.90 = £647.50 TOTAL for 25 palatal implant cases = £7098.40 ± VAT = £8340.62 Lingual Hinge cap assembly from ORMCO 50 @ £6 = £300 ± VAT = £352.50</p>
Materials and consumables	<p>Xantopen and Optosil to take impressions of palatal implant cases. £24.90 ± £14.35 ± £39.25 ± VAT = 46.11 for 15 impressions Sufficient for 60 impressions =£184.44</p>
Other expenses	<p>Extra clinics for the surgeons to place palatal implants in 25 patients and microscrews in another 25 patients Four patients per clinic Thirteen clinics @ £300 per clinic = £3900 TOTAL =£8340.62± £352.50 ± £184.44 ± £3900 ± £16563 = £ 29,340.56</p>
TOTAL GRANT	= £ 29,340.56

BOSF FUNDING APPLICATION FORM

Efficiency and Effectiveness of Three Methods of Anchorage Reinforcement in Orthodontics


National Research Ethics Service

Derbyshire Research Ethics Committee
3rd Floor
Laurie House
Colyear Street
Derby
DE1 1LJ

Telephone: 01332 868765
Facsimile: 01332 868785

22 May 2008

Mr Jonathan Sandler
Consultant Orthodontist
Orthodontic Department
Chesterfield Royal Hospital NHS Foundation Trust
Calow
Chesterfield
S44 5BL

Dear Mr Sandler

Full title of study: Efficiency and effectiveness of three methods of anchorage reinforcement in orthodontics
REC reference number: 07/Q2401/50

The REC gave a favourable ethical opinion to this study on 29 June 2007.

Further notification(s) have been received from local site assessor(s) following site-specific assessment. On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s). I attach an updated version of the site approval form, listing all sites with a favourable ethical opinion to conduct the research.

R&D approval


The Chief Investigator or sponsor should inform the local Principal Investigator at each site of the favourable opinion by sending a copy of this letter and the attached form. The research should not commence at any NHS site until approval from the R&D office for the relevant NHS care organisation has been confirmed.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

07/Q2401/50	Please quote this number on all correspondence
--------------------	---

Yours sincerely


Jenny Hancock
Committee Co-ordinator

This Research Ethics Committee is an advisory committee to East Midlands Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the
National Patient Safety Agency and Research Ethics Committees in England

WPH 1370

APPENDIX 8: Patient information pack

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

Chesterfield Royal Hospital 
NHS Foundation Trust

A STUDY TO DETERMINE THE EFFICIENCY AND EFFECTIVENESS OF THREE METHODS OF ANCHORAGE REINFORCEMENT IN ORTHODONTICS

INFORMATION FOR PATIENTS

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET AND A SIGNED CONSENT FORM TO KEEP.

You are 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 friends, relatives and your dentist. Ask us if there is anything that is not clear or if you would like more information.

Introduction

This study is a randomised clinical trial. What this means is that patients are asked to take part in a clinical study where three methods of treatment are compared. The patients are randomly allocated to one of three treatment groups using a computer and not by the dentist. Therefore there is a one in three chance of getting a particular treatment. Apart from the 'methods' under test the patients are treated exactly the same (i.e. using the same type of braces etc). In this study the 'methods' being compared are Transpalatal arch, Microscrews and Headgear (these are explained in more detail in the next sections) and their clinical effectiveness in keeping the back teeth anchored. It is important to stress that until this study is completed the researchers do not know which of the three methods under test is the best.

What is involved?

To enable the orthodontist to straighten teeth and to pull them back if they stick out we first need to create space. This is achieved by extracting teeth, normally the premolars (side teeth). However problems can arise following the extraction of these teeth as the molars (back teeth) can move forward and fill the space that has just been created. This will 'use up' the available space and prevent the orthodontic treatment from being a success.

To 'hold' the back teeth in position a piece of equipment called *headgear* is used. This must be worn 12-14 hours a day for as long as a year to maintain the molars in position during the orthodontic treatment period.



Figure 1 – Headgear

One alternative to wearing ‘*headgear*’ is using a Transpalatal arch combined with a Nance button (TPA/Nance). The transpalatal arch is a thin stainless steel wire (less than a millimetre thick) which goes across the roof of the mouth and is fastened to metal bands on the first molar (Big teeth). The front part of the arch is covered with acrylic (Nance Button, clear plastic) which keeps the arch secure against the roof of your mouth and keeps the back teeth still. This appliance does not require you to do anything above keeping your teeth clean, it causes little discomfort and has no bad effects on how you talk.

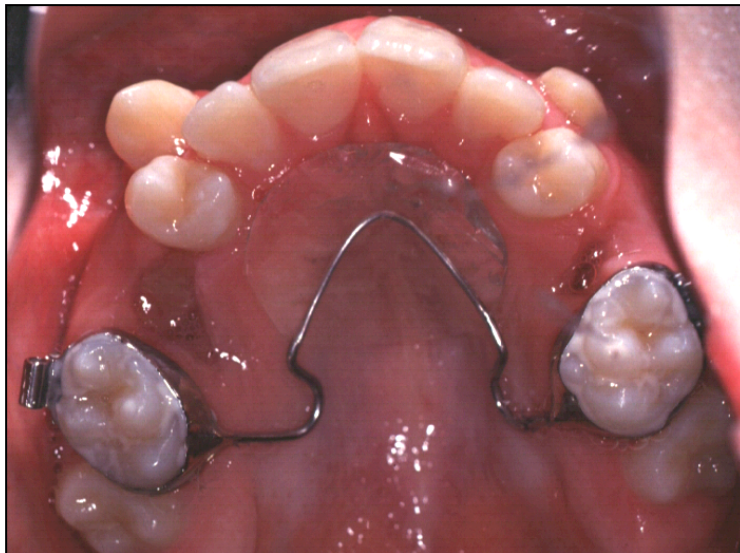
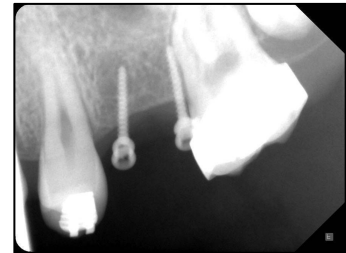
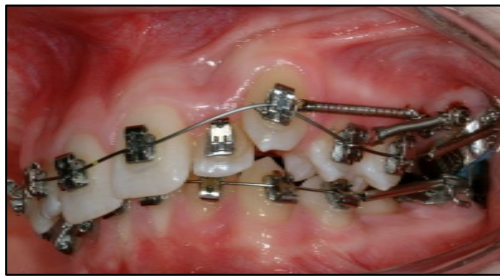


Figure 2 – Nance button attached to the molar teeth via the palatal arch

A second alternative to wearing ‘*headgear*’ is using a microscrew which is another form of dental implant. These are placed into the bone alongside the back teeth during a very simple and quick procedure under a local anaesthetic. The

microscrews are very small, 6 or 8mm long, and about 1.5mm in diameter and made of titanium.



These microscrews don't usually bond with bone, but provide a fixed, stationary anchor point. They are then connected to the other teeth with wires or elastics and stop the back teeth moving forward.

The study is designed to ascertain the most effective method of reinforcing the anchorage or holding the back teeth in position whilst the rest of the teeth are straightened.

Why have you been chosen?

In total 75 patients will be selected to take part in the study. All patients have the same degree of crowding of their teeth and all require the back teeth to be held back by one of the methods.

Do all patients have to take part?

No, participation is voluntary. Patients are entitled to decline or to withdraw from the study at any time, without having to give a reason and without this affecting future treatment. If you do not take part in the study you will receive the standard current practice of headgear and extractions.

What will happen if I take part in the study?

Treatment will take about 2 years regardless of whether an implant (arch or micro-screw) is used or not. Patients who enter the study will require 2 extra visits to place and then remove the implant. Apart from this no extra procedures will be necessary other than the routine 4-6 week visits to adjust the brace. X-rays are required for orthodontic treatment and one extra X-ray will be required for the study. This X-Ray is to allow the researchers to measure how far the teeth have moved from the beginning to the end of the project. One extra X-Ray is equivalent to less than half an hour's natural background radiation. The risk arising from this is negligible

You will be asked to fill in a couple of questionnaires, one after the implant is inserted and one after it is removed, these questionnaires will not be anonymous

but only the Dentists working in the study will know who the responses are from. If you are in the headgear group there will only be one questionnaire to complete.

The trial will be randomised. Because we do not know which way of treating people is better we need to make comparisons. The 3 groups (headgear/transpalatal arch/microscrew) are selected by computer, which has no information about the individual. Patients in each group then have a different treatment, which is subsequently compared.

Are there any risks?

There are no known risks to the patient's general health, as the procedure of placing and removing the microscrews will be carried out using a normal dental anaesthetic. Slight discomfort can be expected for the patients having microscrews placed and removed, again usually controllable by painkillers. Occasionally there are reports of minor tooth tenderness after good/effective headgear wear. The whole procedure is considered to be as safe as any general dental surgical procedure.

What are the possible benefits of taking part?

We hope the treatment will benefit the patient. However, this cannot be guaranteed as to-date there have been no comparisons made between the 3 treatments. However, the research team is hoping that the information we get may help us to treat orthodontic patients quicker, safer and more reliably in the future.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research dentist will tell you about it and discuss whether you want to continue in the study. If you decide to withdraw we will make arrangements for the treatment to continue.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If the harm is due to someone's negligence, then you may have grounds for legal action but may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

Will taking part in this study be kept confidential?

All information collected during the course of the research will be kept strictly confidential. The Data protection act will be complied with. We would however like to seek your agreement to use some of your clinical photographs and x-rays in future presentations of the study. These would be fully anonymised and you could and would not be identified or identifiable from these images.

What will happen to the results?

The study will be published in a medical journal (details unknown at present time) however individual patients will not be identified in any way.

Who is organising and funding the research?

The Orthodontic and Oral Surgery department within the Chesterfield Royal is organising the study. It is to be funded by a Grant from the British Orthodontic Society Foundation.

Who has reviewed the study?

Derbyshire Research Ethics Committee

When do I need to decide?

If possible, we would like you to decide by the time of your next appointment. If you agree to take part in the trial, we will ask you to sign a consent form.

Contact for further information?

IMPORTANT

Please remember; if you prefer not take part in the trial, this will not affect treatment in any way.

If there is anything in this leaflet that you do not understand, or if you need further information about the trial, please contact:

Mr P Sandler - Telephone Number: 01246 552103

If you wish to contact someone outside the study please contact

Julie Lyons (complaints manager at Chesterfield Royal Hospital NHS Foundation Trust) on 01246 512640

Or

Patient Advice and Liason Service (PALS) on 01246 513742.

Thank you for considering taking part in this study.

APPENDIX 9: Patient Consent form

Patient Identification Number for this trial:

CONSENT FORM (Patient)

Efficiency and effectiveness of three methods of anchorage reinforcement in orthodontics

Name of Researcher: Mr Jonathan Sandler

PLEASE INITIAL BOX

- 1 I confirm that I have read and understand the information sheet dated February 2008 (version 4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily
- 2 I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
- 3 I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by responsible individuals from regulatory authorities or from the NHS Trust, where it is relevant my taking part in this research. I give permission for these individuals to have access to my records.
- 4 I understand that clinical photographs / x-rays of me may be used in future presentations of results of this study. I will not be identifiable from such images.
- 5 I agree to take part in the above study

Name of Person giving consent Date Signature

Name of Person taking consent Date Signature
(if different from researcher)

Researcher Date Signature

APPENDIX 10: Parent consent form

Patient Identification Number for this trial:

CONSENT FORM (Parent / Guardian)

Efficiency and effectiveness of three methods of anchorage reinforcement in orthodontics

Name of Researcher: Mr Jonathan Sandler

PLEASE INITIAL BOX

- 1 I confirm that I have read and understand the information sheet dated February 08 (version 4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily
- 2 I understand that my child's participation is voluntary and that he/she is free to withdraw at any time, without giving any reason, without their medical care or legal rights being affected.
- 3 I understand that relevant sections of any of my child's medical notes and data collected during the study, may be looked at by responsible individuals from regulatory authorities or from the NHS Trust, where it is relevant to my child taking part in this research. I give permission for these individuals to have access to my child's records.
- 4 I understand that clinical photographs / x-rays of my child may be used in future presentations of results of this study. My child will not be identifiable from such images.
- 5 I agree that my child may take part in the above study

Name of Person giving consent Date Signature

Name of Person taking consent Date Signature
(if different from researcher)

Researcher Date Signature

APPENDIX 11: GDP LETTER

Chesterfield Royal Hospital 
NHS Foundation Trust

Calow
Chesterfield
S44 5BL

Tel: 01246 277271
Minicom: 01246 512611
www.chesterfieldroyal.nhs.uk

Department of Orthodontics
Direct line: 01246 512105

Date:

Dear Dr

FOR YOUR RECORDS

Your patienthas been enrolled into a trial during their planned attendance at Chesterfield Royal Hospital for elective orthodontic treatment.

The trial is designed to assess the Efficiency and effectiveness of three methods of anchorage reinforcement in orthodontics.

The trial is sponsored by the host Trust and funded by a grant from the British Orthodontic Society Foundation. It has full ethical and Chesterfield Royal Hospital NHS Foundation Trust Hospital Management Committee approval. All patients entered into the trial will have provided written informed consent or assent, in line with the principles of International Conference on Harmonisation Good Clinical Practice (ICH-GCP).

This letter is for information purposes. If you require further information do not hesitate to contact me.

Yours sincerely

PJ Sandler
Consultant in Orthodontics
(Principal Investigator)

APPENDIX 12: Log-in instructions

WEB ADDRESS:

<HTTPS://CTSU.NOTTINGHAM.AC.UK/0822/LOGIN.ASP>

User name: p_sandler

Password: brassband

TO RANDOMISE PATIENTS

- To enrol patients onto the system – by entering:-
 - Gender
 - D.O.B.
 - Initials
- Press the submit button
- If submitted data has been accepted, click on ‘next form’ link
- Check both boxes and click on the randomise button
- The screen will now show you an allocated randomisation number and treatment
- You will then receive an automated email confirming the randomisation/allocation – sent to Jonsandler@aol.com

Any problems or questions contact:-

Dan Simpkins

IT/Data Manager

Tel: 0115 8230508 ext: 30508

<http://ctu.nottingham.ac.uk>

APPENDIX 13: Final randomisation table

Chesterfield Royal Hospital NHSFT	1	Y-D	male	24-Aug-96	05/08/2008 09:03	B.T.	1	palatal arch
Chesterfield Royal Hospital NHSFT	2	T-W	male	22-Nov-92	05/08/2008 13:58	B.T.	2	headgear
Chesterfield Royal Hospital NHSFT	3	K-H	female	08-Nov-92	05/08/2008 14:39	B.T.	3	headgear
Chesterfield Royal Hospital NHSFT	4	K-G	female	06-Aug-95	20/08/2008 17:10	A.P.	4	miniscrews
Chesterfield Royal Hospital NHSFT	5	CJL	male	09-Apr-94	21/08/2008 15:25	A.P.	5	palatal arch
Chesterfield Royal Hospital NHSFT	6	J-G	male	17-Aug-94	09/09/2008 09:58	D.B.	6	miniscrews
Chesterfield Royal Hospital NHSFT	7	L-F	female	20-Sep-93	09/09/2008 15:06	D.B.	7	headgear
Chesterfield Royal Hospital NHSFT	8	B-G	male	13-Aug-94	23/09/2008 10:23	D.B.	8	palatal arch
Chesterfield Royal Hospital NHSFT	9	M-S	male	24-Feb-92	20/10/2008 11:49	D.B.	9	palatal arch
Chesterfield Royal Hospital NHSFT	10	N-F	female	28-Nov-95	20/10/2008 11:51	D.B.	10	miniscrews
Chesterfield Royal Hospital NHSFT	11	C-S	female	28-Sep-94	20/10/2008 11:53	D.B.	11	miniscrews
Chesterfield Royal Hospital NHSFT	12	L-C	male	10-Jul-94	29/10/2008 09:45	PJS	12	headgear
Chesterfield Royal Hospital NHSFT	13	R-H	male	04-Sep-93	29/10/2008 14:51	D.B.	13	headgear
Chesterfield Royal Hospital NHSFT	14	T-P	male	27-Mar-97	24/11/2008 09:03	D.B.	14	miniscrews
Chesterfield Royal Hospital NHSFT	15	L-P	female	21-Nov-96	24/11/2008 11:27	D.B.	15	headgear
Chesterfield Royal Hospital NHSFT	16	S-R	female	31-Oct-95	27/11/2008 14:34	D.B.	16	palatal arch
Chesterfield Royal Hospital NHSFT	17	C-G	male	01-Mar-95	27/11/2008 15:14	D.B.	17	palatal arch
Chesterfield Royal Hospital NHSFT	18	P-C	female	16-May-95	22/12/2008 11:47	D.B.	18	miniscrews
Chesterfield Royal Hospital NHSFT	23	M-B	female	01-Jan-97	02/06/2009 17:33	D.B.	23	miniscrews
Chesterfield Royal Hospital NHSFT	19	C-G	female	06-May-96	22/04/2009 14:37	D.B.	19	palatal arch
Chesterfield Royal Hospital NHSFT	21	L.D	female	11-Jan-92	20/05/2009 10:37	AMM	21	headgear
Chesterfield Royal Hospital NHSFT	22	N-P	male	07-Aug-96	21/05/2009 15:46	D.B.	22	palatal arch

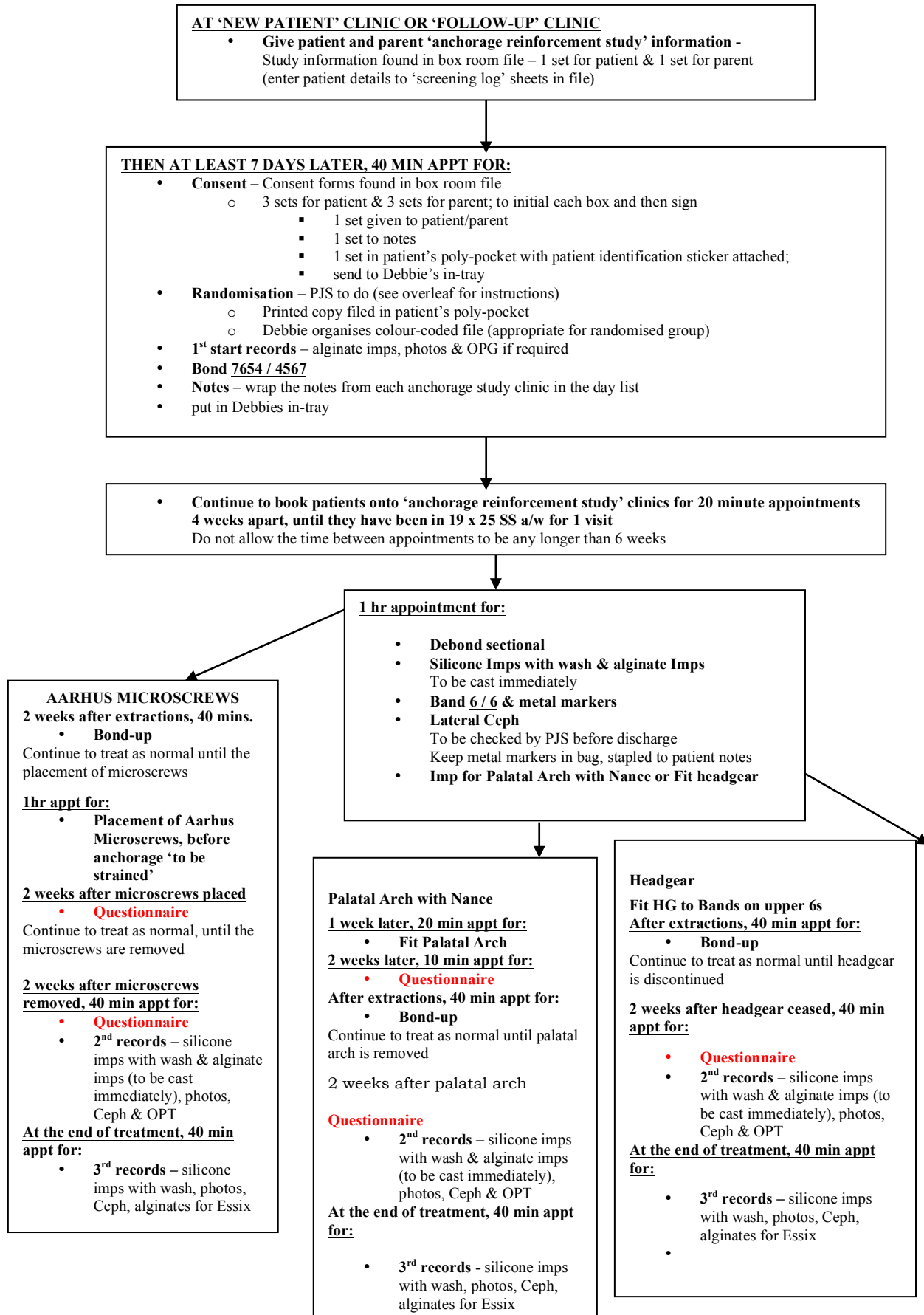
Chesterfield Royal Hospital NHSFT	20	C-J	male	09-May-94	06/05/2009 15:49	D.B.	20	headgear
Chesterfield Royal Hospital NHSFT	28	S-P	female	02-Oct-94	06/10/2009 10:19	AMM	28	headgear
Chesterfield Royal Hospital NHSFT	29	B-I	male	18-May-94	07/10/2009 09:47	PJS	29	miniscrews
Chesterfield Royal Hospital NHSFT	25	T-W	male	04-Oct-93	15/07/2009 11:24	PJS	25	palatal arch
Chesterfield Royal Hospital NHSFT	26	C-N	male	02-Aug-93	22/07/2009 10:17	PJS	26	palatal arch
Chesterfield Royal Hospital NHSFT	24	C-T	female	26-Nov-93	08/07/2009 14:38	D.B.	24	miniscrews
Chesterfield Royal Hospital NHSFT	30	A-R	female	05-Dec-95	28/10/2009 15:23	PJS	30	miniscrews
Chesterfield Royal Hospital NHSFT	31	L-M	female	02-Jun-96	18/11/2009 11:49	PJS	31	palatal arch
Chesterfield Royal Hospital NHSFT	27	KWS	male	17-Jan-95	12/08/2009 10:14	PJS	27	miniscrews
Chesterfield Royal Hospital NHSFT	32	M-S	male	25-Jul-96	15/12/2009 12:29	AMM	32	headgear
Chesterfield Royal Hospital NHSFT	33	H-G	female	30-Mar-94	24/12/2009 11:05	A.P.	33	headgear
Chesterfield Royal Hospital NHSFT	34	P.L	female	21-Feb-97	31/12/2009 16:43	PJS	34	headgear
Chesterfield Royal Hospital NHSFT	69	G-D	male	09-Sep-96	01/11/2010 09:05	PJS	69	palatal arch
Chesterfield Royal Hospital NHSFT	70	A-K	male	11-Oct-94	01/11/2010 11:04	PJS	70	miniscrews
Chesterfield Royal Hospital NHSFT	35	L-B	female	22-Mar-97	19/01/2010 09:22	PJS	35	miniscrews
Chesterfield Royal Hospital NHSFT	36	H-J	female	04-Sep-93	19/01/2010 09:56	PJS	36	palatal arch
Chesterfield Royal Hospital NHSFT	37	O-J	male	20-Mar-96	19/01/2010 10:22	PJS	37	palatal arch
Chesterfield Royal Hospital NHSFT	38	A-T	male	28-Mar-95	19/01/2010 10:48	PJS	38	headgear
Chesterfield Royal Hospital NHSFT	39	P-M	female	12-Oct-97	19/01/2010 11:28	PJS	39	miniscrews
Chesterfield Royal Hospital NHSFT	40	E-S	female	30-Nov-93	19/01/2010 11:56	PJS	40	palatal arch
Chesterfield Royal Hospital NHSFT	41	A-L	female	01-Apr-97	19/01/2010 12:00	PJS	41	palatal arch
Chesterfield Royal Hospital NHSFT	42	S-V	female	07-Apr-95	19/01/2010 12:23	PJS	42	miniscrews
Chesterfield Royal Hospital NHSFT	55	C-J	male	26-Oct-93	03/06/2010 13:53	PJS	55	headgear

Chesterfield Royal Hospital NHSFT	60	NJL	female	05-Dec-93	03/08/2010 15:10	PJS	60	miniscrews
Chesterfield Royal Hospital NHSFT	44	S-A	male	01-Jan-96	30/03/2010 14:53	D.B.	44	headgear
Chesterfield Royal Hospital NHSFT	45	K-P	female	01-Mar-97	30/03/2010 15:13	D.B.	45	headgear
Chesterfield Royal Hospital NHSFT	46	E-S	female	10-Jan-96	30/03/2010 16:00	D.B.	46	headgear
Chesterfield Royal Hospital NHSFT	43	L-T	female	15-May-96	04/03/2010 13:01	AMM	43	miniscrews
Chesterfield Royal Hospital NHSFT	47	A-G	male	21-Oct-96	14/04/2010 15:47	PJS	47	palatal arch
Chesterfield Royal Hospital NHSFT	48	C-E	male	03-Nov-96	20/04/2010 09:18	PJS	48	miniscrews
Chesterfield Royal Hospital NHSFT	49	R-W	male	18-Jan-96	20/04/2010 09:22	PJS	49	miniscrews
Chesterfield Royal Hospital NHSFT	50	H-T	female	03-Jun-97	20/04/2010 10:33	PJS	50	headgear
Chesterfield Royal Hospital NHSFT	51	J-D	female	30-Nov-95	20/04/2010 11:39	PJS	51	palatal arch
Chesterfield Royal Hospital NHSFT	52	J-C	female	19-Jul-95	20/04/2010 14:08	PJS	52	miniscrews
Chesterfield Royal Hospital NHSFT	53	R-M	male	17-Nov-94	18/05/2010 11:28	PJS	53	palatal arch
Chesterfield Royal Hospital NHSFT	54	C-H	female	23-Mar-96	26/05/2010 14:37	PJS	54	headgear
Chesterfield Royal Hospital NHSFT	66	B-H	male	05-Oct-95	06/10/2010 16:22	PJS	66	miniscrews
Chesterfield Royal Hospital NHSFT	56	M-W	male	05-Aug-93	29/06/2010 10:34	PJS	56	palatal arch
Chesterfield Royal Hospital NHSFT	57	D-W	male	04-Jun-97	07/07/2010 10:25	PJS	57	headgear
Chesterfield Royal Hospital NHSFT	59	O-C	male	18-Dec-97	27/07/2010 11:57	PJS	59	palatal arch
Chesterfield Royal Hospital NHSFT	58	S-C	male	03-Jan-97	08/07/2010 14:57	PJS	58	miniscrews
Chesterfield Royal Hospital NHSFT	74	L-H	female	10-Oct-95	08/12/2010 15:03	PJS	74	miniscrews
Chesterfield Royal Hospital NHSFT	71	M-A	male	01-Dec-97	09/11/2010 13:29	AMM	71	palatal arch
Chesterfield Royal Hospital NHSFT	64	D-R	female	24-Mar-97	16/09/2010 15:35	PJS	64	headgear
Chesterfield Royal Hospital NHSFT	65	J-H	male	04-Mar-97	29/09/2010 09:52	PJS	65	palatal arch
Chesterfield Royal Hospital NHSFT	61	R-Y	female	22-Dec-92	10/08/2010 11:34	PJS	61	headgear
Chesterfield Royal Hospital	62	HAN	female	24-Mar-98	10/08/2010 15:29	PJS	62	miniscrews

NHSFT								
Chesterfield Royal Hospital NHSFT	67	J-D	male	27-Sep-99	21/10/2010 15:37	PJS	67	headgear
Chesterfield Royal Hospital NHSFT	68	S-V	male	03-Feb-97	27/10/2010 09:57	PJS	68	miniscrews
Chesterfield Royal Hospital NHSFT	63	D.M	male	27-Mar-95	11/08/2010 15:13	PJS	63	palatal arch
Chesterfield Royal Hospital NHSFT	72	A-T	male	20-May-96	24/11/2010 09:46	PJS	72	palatal arch
Chesterfield Royal Hospital NHSFT	73	R-W	female	14-Jun-97	24/11/2010 16:25	PJS	73	headgear
Chesterfield Royal Hospital NHSFT	75	M.G	male	17-Mar-98	21/12/2010 10:09	PJS	75	headgear
Chesterfield Royal Hospital NHSFT	76	A-H	male	06-Jul-97	21/12/2010 16:09	PJS	76	miniscrews
Chesterfield Royal Hospital NHSFT	77	S-H	male	27-Oct-97	22/12/2010 09:08	PJS	77	palatal arch
Chesterfield Royal Hospital NHSFT	78	THG	female	12-Dec-95	22/12/2010 11:32	PJS	78	miniscrews

APPENDIX 14: Flow diagram of patients through the study Efficiency and Effectiveness of Three Methods of Anchorage Reinforcement in Orthodontics

- | | |
|----------------------------|-----------------------|
| 1. Aarhus microscrews | red patient folder |
| 2. Palatal arch with Nance | yellow patient folder |
| 3. Headgear | green patient folder |



APPENDIX 15: Nance Questionnaire

A study to determine the efficiency and effectiveness of three methods of anchorage reinforcement in orthodontics

PLEASE ANSWER THE FOLLOWING QUESTIONS ACCURATELY AND HONESTLY. YOUR DOCTORS WILL KNOW THAT IT IS YOU ANSWERING THE QUESTIONS, BUT YOUR ANSWERS WILL BE CONFIDENTIAL LIKE ANYTHING ELSE YOU TELL THE DOCTOR. YOUR ANSWERS WILL NOT AFFECT YOUR TREATMENT.

Unique number _____/a

2 weeks

IF YOU HAVE THE PALATAL ARCH

Q1. What was the placement of your palatal arch like?

Uncomfortable						Comfortable
1	2	3	4	5		6

Q2. What was the palatal arch like during the first 3 days?

Uncomfortable						Comfortable
1	2	3	4	5		6

Q3. If you had any discomfort after placement of your palatal arch, for how many days did it last?

Days

Thanks very much for taking the time to fill this in

A study to determine the efficiency and effectiveness of three methods of anchorage reinforcement in orthodontics

PLEASE ANSWER THE FOLLOWING QUESTIONS ACCURATELY AND HONESTLY. YOUR DOCTORS WILL KNOW THAT IT IS YOU ANSWERING THE QUESTIONS, BUT YOUR ANSWERS WILL BE CONFIDENTIAL LIKE ANYTHING ELSE YOU TELL THE DOCTOR. YOUR ANSWERS WILL NOT AFFECT YOUR TREATMENT.

Unique number _____/a

2 weeks after removal

IF YOU HAVE THE PALATAL ARCH

Q4. Did you have any problems from the palatal arch during the treatment period?

Q5. What was removal of the palatal arch like?

Uncomfortable						Comfortable
1	2	3	4	5		6

Q6. What was it like 3 days after removal of the palatal arch?

Uncomfortable						Comfortable
1	2	3	4	5		6

Q7. If you had any discomfort following removal of the palatal arch for how many days did it last?

Days

Q8. Would you recommend the palatal arch to a friend requiring similar treatment?

Yes / No

Q9. Any comments

Thanks very much for taking the time to fill this in

APPENDIX 16: TADs Questionnaire

A study to determine the efficiency and effectiveness of three methods of anchorage reinforcement in orthodontics

PLEASE ANSWER THE FOLLOWING QUESTIONS ACCURATELY AND HONESTLY. YOUR DOCTORS WILL KNOW THAT IT IS YOU ANSWERING THE QUESTIONS, BUT YOUR ANSWERS WILL BE CONFIDENTIAL LIKE ANYTHING ELSE YOU TELL THE DOCTOR. YOUR ANSWERS WILL NOT AFFECT YOUR TREATMENT.

Unique number _____/b

2 weeks

IF YOU HAVE THE MICROSCREWS

Q1. What was the placement of your Microscrew like?

Uncomfortable						Comfortable
1	2	3	4	5		6

Q2. What was the Microscrew like during the first 3 days?

Uncomfortable						Comfortable
1	2	3	4	5		6

Q3. If you had any discomfort after placement of your Microscrew, for how many days did it last?

Days

Thanks very much for taking the time to fill this in

A study to determine the efficiency and effectiveness of three methods of anchorage reinforcement in orthodontics

PLEASE ANSWER THE FOLLOWING QUESTIONS ACCURATELY AND HONESTLY. YOUR DOCTORS WILL KNOW THAT IT IS YOU ANSWERING THE QUESTIONS, BUT YOUR ANSWERS WILL BE CONFIDENTIAL LIKE ANYTHING ELSE YOU TELL THE DOCTOR. YOUR ANSWERS WILL NOT AFFECT YOUR TREATMENT.

Unique number _____/b

2 weeks after removal

IF YOU HAVE THE MICROSCREWS

Q4. Did you have any problems from the Microscrew during the treatment period?

Q5. What was removal of the Microscrew like?

Uncomfortable						Comfortable
1	2	3	4	5	6	

Q6. What was it like 3 days after removal of the Microscrew?

Uncomfortable						Comfortable
1	2	3	4	5	6	

Q7. If you had any discomfort following removal of the Microscrew for how many days did it last?

Days

Q8. Would you recommend the Microscrew to a friend requiring similar treatment?

Yes / No

9. Any comments

Thanks very much for taking the time to fill this in

APPENDIX 17: Headgear Questionnaire

Chesterfield Royal Hospital 
NHS Foundation Trust

A study to determine the efficiency and effectiveness of three methods of anchorage reinforcement in orthodontics

PLEASE ANSWER THE FOLLOWING QUESTIONS ACCURATELY AND HONESTLY. YOUR DOCTORS WILL KNOW THAT IT IS YOU ANSWERING THE QUESTIONS, BUT YOUR ANSWERS WILL BE CONFIDENTIAL LIKE ANYTHING ELSE YOU TELL THE DOCTOR. YOUR ANSWERS WILL NOT AFFECT YOUR TREATMENT.

Unique number _____/c

2 weeks after discontinuation

IF YOU HAVE THE HEADGEAR

Q1 HOW MANY HOURS A DAY, WERE YOU ASKED TO WEAR YOUR HEADGEAR?

 Hours

Q2 ON AVERAGE HOW MANY HOURS A DAY DID YOU WEAR YOUR HEADGEAR?

 Hours

Q3 DID YOU WEAR YOUR HEADGEAR FOR LESS TIME THAN INSTRUCTED?

Yes / No

Q3 For how many months did you wear the Headgear?

 Months

Q4. What was wearing headgear like?

Uncomfortable 1 2 3 4 5 Comfortable 6

Q5. How convenient was your headgear to wear?

Inconvenient 1 2 3 4 5 6 Convenient

Q6. How did wearing headgear interfere with your social life?

Large effect
1 2 3 4 5 6 No effect

Q7. Did wearing headgear bother you?

Bothered
1 2 3 4 5 6 Did not mind

Q8. Did you have any problems from the headgear during treatment?

Q9. Would you recommend the headgear to a friend requiring similar treatment?

Yes / No

Q10 Any comments

Thanks very much for taking the time to fill this in

APPENDIX 18: Radiographic measurement technique

To enable blinding of the operator when assessing the cephalograms for anchorage loss, the 78 patients in the study were anonymised by a member of the hospital IT staff. This was carried out prior to loading the anonymised radiographs to the hospital Picture Archive and Communications System (PACS). The cases were assigned a number between 1 and 78, but this number did not correspond to the order in which the patients were enrolled into the study. The key to decode the patient identification was kept by the IT staff member. The key was not used to break the code until after all the cephalograms had been analysed.

The cases were analysed on a computer setup devised to replicate the setup used for superimposing the three-dimensional scans of the models. This largely followed the recommendations of Hixon (1960), who said the landmarks should be viewed side by side to ensure similar cephalometric points were chosen. To enable this to be done a dual head video card was fitted to my hospital computer, which allowed two large format, high quality, 19" DVI monitors to be used simultaneously (Figure a).

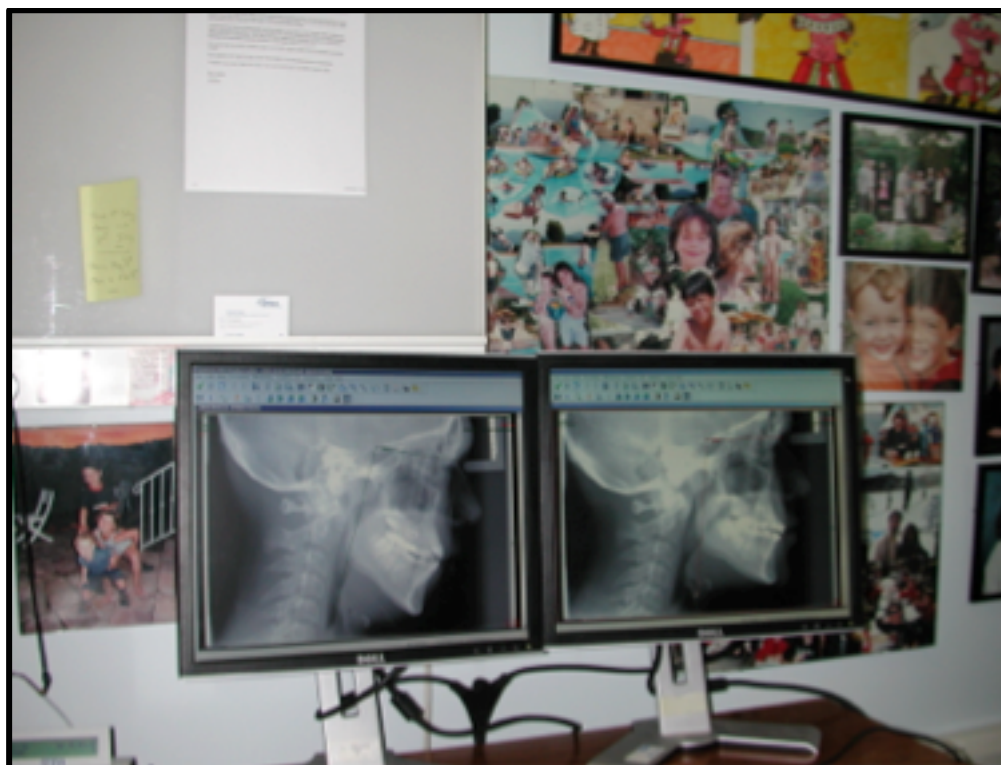


Figure a. Computer setup allowed two radiographs to be viewed side by side

Radiographs taken at two time points could be viewed simultaneously and edited on the PACS system. Appropriate angular and linear measurements were taken and these were saved to a new image which was stored within the PACS system. These new images with measurements could be recalled at any point in the future if necessary, to allow checking of accuracy of data entry.

The main measurement of interest for this study, to assess whether anchorage had been lost or not, was that which determined whether the molar teeth had moved mesially during treatment. The PACS system on the computer allowed the patients start of anchorage cephalogram C_s , and end of anchorage supplementation cephalogram C_f to be selected individually, each image being placed to fill a high quality monitor. These images were viewed in a darkened room, simultaneously, on the two high quality monitors.

CEPHALOMETRIC MEASUREMENTS USED

The tool system within PACS allowed both linear and angular on-screen measurements to be carried out. The first requirement was to construct an angular measurement involving the Sella-Nasion (SN) plane but including a ‘vertical’ line to which horizontal measurements could be made. This cephalometric assessment was a similar method of measurement to that used by Pancherz (1982). The angle formed began at Nasion (N) and included a constructed ‘vertical’ line, which started in the centre of the Sella Turcica (S), whose internal angle was 97 degrees to the Sella-Nasion plane (Figure b).

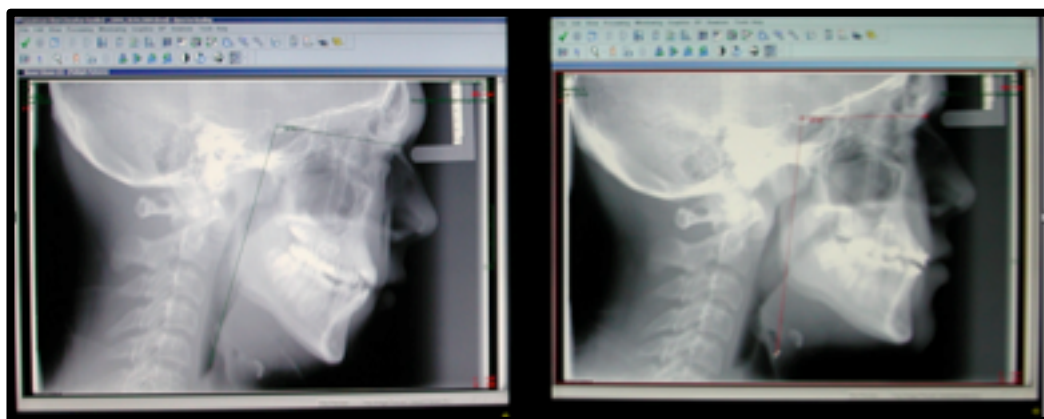


Figure b. Constructed ‘vertical’ marked on both radiographs @ 97° to SN

This vertical line was created by first clicking left mouse button with the cursor on the digital image at Nasion (N), then moving the cursor to S point and making a second left mouse click, then dropping the cursor 'vertically' to a point well below Gonion. This internal angular measurement changed as the cursor point was moved from left to right on the screen. The cursor trigger was only released, to make the third point of the angular measurement, when the internal angle was as close to 97.0 degrees as possible.

The pretreatment cephalogram C_s was marked first and on many occasions it proved to be difficult to hit 97.0 degrees exactly. Any measurement from 96.8 degrees to 97.2 degrees was considered acceptable for demarcation of the first angular measurement. The angular measurement on the post treatment radiograph C_f , using exactly the same process, had to be within 0.2 degrees of the first angular measurement recorded, before the cursor trigger was released.

LINEAR MEASUREMENTS TO ASSESS ANCHORAGE LOSS

Metal markers had been inserted into the molar arch wire slots on both the left and the right molar bands and held in place with an elastic module, while the cephalogram C_s , was taken. These markers were stapled to the patient's treatment card and kept there throughout the duration of treatment. At the appropriate point in treatment these markers were replaced in the molar arch wire slots and held in place once again, whilst the second cephalogram C_f was recorded. These molar markers greatly aided identification of the mesial of the individual left and right molar teeth (Figure c).

Prior to making the linear measurements the radiographic images were enlarged significantly, so that the area of interest from the constructed vertical line to the left and right molar markers could be easily viewed. This linear distance, which was between 25 and 45mm occupied 200mm of the 19" monitors. This 4-8x magnification allowed easier identification of the appropriate points on the radiographs. The point at which the left molar marker overlapped the edge of the molar band was used to start the linear measurement and the mouse cursor was depressed here.

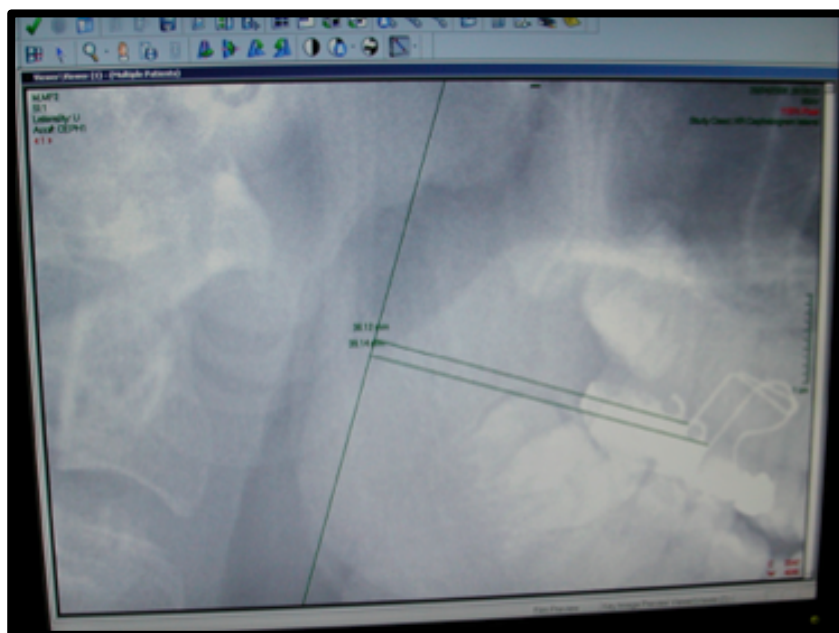


Figure c. Linear measurements from Left and Right molar markers to the vertical, millimeter scale can be clearly seen above the molar markers

The cursor was then moved to form a perpendicular line with the 'constructed vertical' (Figure c). The millimeter measurement of the distance between the molar tooth and the constructed vertical was clearly visible on the screen. The accuracy of each magnification could also be checked at any time, as a millimeter scale was automatically positioned by the PACS system on the right hand side of the screen after each change to the magnification was carried out. For peace of mind, this millimeter scale was checked on a regular basis during the tracing process.

This linear measurement was made on both screens for both the left and the right molar markers and the measurements were transferred directly into an Excel spreadsheet on a second laptop computer positioned on the same desk.

Finally the images containing the SN plane, the constructed verticals at 97° to SN and both of the linear measurements, were saved to the hard disc on the PACS system. This then served as a permanent record of the measurements that could be checked at a later date if required.

APPENDIX 19: Permission to from Elsevier use figures in AJODO, from Wiley for Orthodontics and Craniofacial Research, and from the Angle Orthodontist

The screenshot shows the RightsLink interface with a search filter for the date range 24-Feb-2013 to 24-May-2013. The results table is as follows:

Order Date	Article Title	Publication	Type Of Use	Order Status	Order Number
24-May-2013	Stable region for maxillary dental cast superimposition in adults, studied with the aid of stable miniscrews	Orthodontics & Craniofacial Research	Dissertation/Thesis	Completed	3155440194352
24-May-2013	Measuring 3-dimensional tooth movement with a 3-dimensional surface laser scanner	American Journal of Orthodontics and Dentofacial Orthopedics	reuse in a thesis/dissertation	Completed	3155310113204
24-May-2013	Reliability of a 3D surface laser scanner for orthodontic applications	American Journal of Orthodontics and Dentofacial Orthopedics	reuse in a thesis/dissertation	Completed	3155301464624
24-May-2013	Three-dimensional dental cast analyzing system using laser scanning	American Journal of Orthodontics and Dentofacial Orthopedics	reuse in a thesis/dissertation	Completed	3155301027084
24-May-2013	The three-dimensional cephalogram: Theory, techniques, and clinical application	American Journal of Orthodontics and Dentofacial Orthopedics	reuse in a thesis/dissertation	Completed	3155300838089
24-May-2013	The three-dimensional cephalogram: Theory, techniques, and clinical application	American Journal of Orthodontics and Dentofacial Orthopedics	reuse in a thesis/dissertation	Completed	3155300569643
24-May-2013	A 3-dimensional analysis of molar movement during headgear treatment	American Journal of Orthodontics and Dentofacial Orthopedics	reuse in a thesis/dissertation	Completed	3155300386042

Angle Permission [Inbox](#)

☆ **Steven J Lindauer** <sjlindau@vcu.edu> Tue, May 28, 2013
 To: jonsandler57@gmail.com

[Reply](#) | [Reply to all](#) | [Forward](#) | [Print](#) | [Delete](#) | [Show original](#)

Dear Jonathan Sandler,

Permission is hereby granted for you to reproduce the following for a PhD thesis:

Figure 5 from: A Novel Method for the Assessment of Three-Dimensional Tooth Movement during Orthodontic Treatment
 Insan Jang, Motohiro Tanaka, Yoshiyuki Koga, Seiko Iijima, Joseph H. Yozgatian, Bong Kuen Cha, and Noriaki Yoshida
 The Angle Orthodontist 2009 79:3, 447-453

The journal appreciates that you cite the source when using the figure.

Sincerely,

Steven J Lindauer, DMD, MDSc
 Editor, The Angle Orthodontist

