

Minimising leg length inequality after total hip replacement.

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Abstract

The total hip replacement is one of the most effective medical interventions undertaken, with high reported rates of pain relief and patient satisfaction^{1,2}. Leg length inequality (LLI) following total hip replacement was first recognised by Charnley when the operation was popularised but has only recently increased in prominence in the literature. The definition of an unacceptable value of LLI is controversial and is complicated not only by the lack of agreement of significance but also by the fact that for any given magnitude of LLI, only a proportion will be symptomatic. This thesis begins by exploring the opinions of British Hip Society (BHS) members to generate an expert opinion on acceptable values. Findings were in broad agreement with the literature, with 67% of respondents stating they believed that LLI of less than 10mm would always be within the bounds of acceptable practice.

A second survey of BHS members regarding methods of minimising LLI intra-operatively identified that 77% of surgeons use the Shuck technique during every total hip replacement, and that 11% use a commercial device. Chapter four evaluated five commonly used intra-operative tests and concluded that when used in combination these tests could produce acceptable values of LLI. Most reliance was placed on the Shuck technique during decision making.

Results from this work identified scope for development of a novel device to be used as an adjunct to the Shuck test as an indirect measurement of leg length. A device was designed and manufactured and preliminary results from in vivo studies show a narrow range of both distraction distance and force applied during the Shuck test. These results indicate that the device could be developed further to standardise the Shuck test and use it as an adjunct to train junior surgeons how to assess leg length, minimising the requirement for subjective and invasive methods.

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Details of papers contributing to MD Thesis

Chapter 2. Literature review

Paper published in Orthopaedics and Trauma as;

Leg length inequality after primary total hip arthroplasty

Loughenbury FA, McWilliams AB, Smith M, Pandit H, Stone MH.

Orthopaedics and Trauma, Volume 32, Issue 1, 27 - 33

As the lead author, I performed a review of the literature and was involved in drafting and writing the paper.

Chapter 3. British Hip Surgeons and leg length inequality after primary total hip replacement

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As the lead author, I performed a review of the literature, designed the data collection questionnaire, collected and analysed data, and drafted, amended and submitted the paper.

List of abbreviations

Abbreviation	Term
AP	Anterior – Posterior
BHS	British Hip Society
BOA	British Orthopaedic Association
BMI	Body Mass Index
CI	Chief Investigator
CT	Computerised Tomography
GCP	Good Clinical Practice
GP	General Practitioner
ITB	Iliotibial band
IRAS	Integrated Research Application System
LIRMM	Leeds Institute of Rheumatic and Musculoskeletal Medicine
LLI	Leg Length Inequality
MRI	Magnetic Resonance Imaging
NHS	National Health Service
NHSLA	National Health Service Litigation Authority
NJR	National Joint Registry
QA	Quality Assurance
QALY	Quality Adjusted Life Years
REC	Research Ethics Committee
SD	Standard Deviation
THR	Total hip replacement
UHMWP	Ultra-high Molecular Weight Polyethylene

Chapter 1. Introduction

The first chapter introduces the subject of leg length inequality (LLI) following total hip replacement. This includes its definition, justification of the subject matter, hypothesis and a summary of how the hypothesis is explored by this thesis.

1.1. Definition of LLI inequality following total hip replacement

Anisomelia, or limb length inequality, is defined by Gurney as a condition in which paired limbs are noticeably unequal in length. The discrepancy can be described as relative lengthening or shortening of a limb when compared to the contralateral limb. When this occurs in the lower limb it is known as leg length inequality^{3,4}. There are many causes of LLI including congenital causes and trauma, which may result in a relative shortening or lengthening to any part of the lower limb. This research considers the changes that occur wholly as a result of hip replacement surgery.

Therefore, for the purposes of this thesis, LLI is defined as any change in leg length that results in discrepancy in length of the operated limb compared with the contralateral side that has arisen wholly as a result of a total hip replacement.

1.2. Justification of the subject matter

The total hip replacement is one of the most commonly performed and successful surgical interventions in the world, with high reported rates of pain relief and patient satisfaction^{1,2}. More than 102,000 total hip replacements were performed in the UK in 2016^{5,6} and over a million are performed worldwide every year. This figure is projected to double over the next twenty

years as the prevalence of degenerative hip disease continues to increase⁷⁻⁹.

The first successful total hip replacements were performed in the mid-twentieth century as salvage procedures for patients who were wheelchair bound due to pain. In the fifty years since their introduction, complication rates have fallen and survivorship has increased. This has led to broadening of the indications for total hip replacement. Now, younger, more physically demanding patients are undergoing total hip replacement and they have higher expectations from their surgery^{2,10,11}. For this reason, although recognised by Charnley when the operation was pioneered, LLI after total hip replacement has only recently risen to prominence in the literature¹².

LLI following total hip replacement is controversial topic which is not fully understood. It is complicated by a lack of consensus regarding definition and even clinical significance. Whilst the majority of published literature is in agreement that LLI following total hip replacement is significant, this is not a universal belief^{13,14}. A further confounding factor is that for any given magnitude of LLI, not everyone will be symptomatic. Symptomatic LLI can result in mechanical symptoms such as limp¹⁵, altered wear characteristics of associated native or replaced joints¹⁶⁻¹⁹, early fatigue and reduced walking distance²⁰. It has also been implicated in lower back pain^{21,22}, nerve palsy and total hip replacement instability²³. Authors disagree on the extent (if any) to which LLI causes these symptoms and what magnitude of LLI is necessary to generate these problems³. LLI following total hip replacement is now the fifth most frequently cited cause of litigation in the UK²⁴, and the most common cause in the USA²¹.

Methods of minimising LLI have been documented since the 1970s^{25,26} but there is still no single 'gold standard' method that has universal uptake and so the problem of LLI persists. Surgeons report using a variety of tests which assist with decision making intra-operatively but many of these are subjective

and reliant on surgical experience. Subjective tests may be effective in the hands of an experienced surgeon but they are difficult to teach and have a long learning curve. Following the introduction of the European working Time Directive in 1993, the practical time junior surgeons spend in theatre has fallen but the expectations to reach the same level of competency by the completion of training have remained the same. Alternative methods of acquiring operative skills have been explored such as computer simulation and devices to assist intra-operatively have become necessary. Although there are many publications promoting commercial devices that may assist in decreasing LLI following total hip replacement, many are expensive or are invasive techniques that require extra incisions or drill holes and therefore increase the risk of complications. A simple, validated device or technique that could accurately assess leg length intra-operatively without the need for invasive or expensive equipment would make a significant contribution to minimising LLI. LLI is an independent risk factor for the outcome of total hip replacement¹⁵ and reducing the magnitude and rate of the complication would lead to better patient outcomes and a decrease in LLI associated revisions and their costs and complications^{27,28}.

Presently to the author's knowledge there is no device that exists that may be used to assess soft tissue tension during total hip replacement. In 2010, a prototype device was manufactured and tested on an in-vitro shuck test model by four different surgeons, to assess loads applied during trial reduction for their left and right hands. The results showed a range of loads applied between surgeons from 35 – 82N. Feedback from the surgeons suggested that a device that could measure distraction forces would add significant value to hip arthroplasty²⁹.

This thesis aims to provide an expert opinion on the acceptable values of leg length, to explore techniques currently used to minimise LLI intra-operatively, and ascertain which, if any technique is the most effective. The overall aim of this thesis is to develop a traction-based device for minimising LLI that can be used intra-operatively to objectively test soft tissue tension, minimising the

requirement for subjective and invasive methods. If successful the novel device could reduce the resources required to treat this significant complication of hip replacement surgery.

1.3. Thesis hypothesis

The primary hypothesis to be tested is that using the novel device, which will involve employing a standardised level of force to perform the shuck test, will yield results that are in agreement with the findings of an experienced consultant surgeon.

1.4. Structure of this thesis

To explore the hypothesis this thesis will include the following sections.

Chapter two: Literature review

To provide context for this thesis, a review of the literature is undertaken. The history of the total hip replacement, current practice and complications are presented. The review then focuses on the development of understanding of LLI following total hip replacement as a complication, its classification and methods of quantification. Methods of minimising LLI pre- and intra-operatively are discussed. Finally, the opinions and strategies to manage LLI following total hip replacement are explored.

Chapter three: Survey of opinion regarding leg length inequality after total hip replacement

This chapter reports the results of two separate surveys of British Hip Society (BHS) members relating to LLI after primary hip replacement. There is currently no consensus regarding acceptable and unacceptable values of LLI following total hip replacement. It is therefore difficult to discuss definitions and

incidence of the complication. The first survey investigates the members' opinions on the effect of LLI on the outcome of total hip replacement in an attempt to generate an agreement of acceptable values from an expert body of surgeons. The second survey reports on the intra-operative techniques currently used by BHS members to minimise LLI after total hip replacement.

Chapter four: The accuracy of five intra-operative techniques to minimise leg length inequality during primary total hip replacement

This chapter reports the results of a study designed to establish whether an experienced hip surgeon can reproduce leg length using five intra-operative tests, without the use of a commercial device. The five tests were used in a cohort of 44 consecutive total hip replacements and the satisfaction of the outcome of each test was recorded. LLI was measured post operatively to ascertain which, if any test was the most effective.

Chapter five: Development of a novel device to minimise LLI

Chapter five documents the development of a novel device to be used as an adjunct to the Shuck test in order to produce a standardised force and distraction distance. The chapter includes details on design and development of the device and safety testing. The results of a preliminary proof of concept study are then presented.

Chapter 7: Discussion and conclusion

The final chapter draws together the conclusions from each chapter and provides a summary of their findings in the context of the hypothesis being explored by this thesis. Recommendations for future research in the study of LLI following total hip replacement are then proposed.

Chapter 2. Review of the literature

2.1 The total hip replacement

The total hip replacement is one of the most commonly performed surgical procedures in the western world with high reported rates of pain relief, patient satisfaction and excellent implant survivorship ^{1,2}. The number of total hip replacements performed each year in the UK has increased from 15,000 in 1978 to almost 102,000 in 2016 ^{5,6}. More than a million are performed worldwide every year, and this figure is projected to double over the next twenty years as the prevalence of degenerative hip disease continues to increase ⁷⁻⁹.

Symptomatic osteoarthritis is the indication for surgery in 90% of total hip replacements ⁶ and in most cases the hip joint will have been anatomically normal prior to the development of osteoarthritis. In these cases, the aim of total hip replacement is to restore the soft tissues around the hip to their pre-disease tension and position, which can only be achieved with knowledge of the anatomy and recognising the correct position of the implants.

In 2016, 80% of total hip replacements were performed on patients over the age of sixty ⁶ however the proportion of patients younger than 65 years is projected to increase to 50% of all total hip replacements by 2030 ³⁰. Today, an unacceptable compromise in quality of life constitutes a valid indication for total hip replacement, and patients have increasingly high expectations and aspirations from their surgery.

2.2 Background of the total hip replacement

Surgery for hip pain has progressed dramatically since its introduction in the 1800s. The first attempts at excision arthroplasty were performed by White in 1821. It became a popular operation due to its excellent pain relief but its results were unpredictable and it had an alarming mortality rate of 50% ^{31,32}. In the 1940s Girdlestone popularised resection of the femoral head for cases of infection and tuberculosis. The procedure bears his name and is still widely used today as a salvage operation ³².

The concept of interpositional arthroplasty was first described with the interposition of adipose tissue between the femoral and acetabular joint surfaces ³³ and over the next two decades surgeons experimented with various interpositional materials including muscle, celluloid, silver, rubber, magnesium, zinc, decalcified bones, wax, fascia lata and pigs bladder with mixed results ^{32,34,35}. The most successful interpositional material was a strip of gold foil which provided satisfactory pain free range of movement at twenty-one years of follow up ³⁶.

In 1925 Smith-Petersen created the first mould arthroplasty out of a hollow hemisphere of glass designed to fit over the femoral head with the objective of stimulating new smooth cartilage regeneration on both sides of the mould. Unfortunately the glass moulds were unable to withstand the large forces going through the hip joint and shattered ³⁷. Smith-Petersen subsequently experimented with celluloid, Bakelite and Pyrex and in 1937 introduced Vitallium, an alloy formed of cobalt, chrome and molybdenum. Interposition of the Vitallium mould, which covered the reshaped femoral head, heralded a new era of arthroplasty. It was the first implant to provide predictable results and has the longest reported follow up of any implant to date in one patient reaching 65 years survivorship before being revised in 2014 ³⁸.

The earliest documented attempt at total hip replacement was performed by Glück in 1891 and consisted of an ivory ball and socket joint fixed to bone with

nickel-plated screws³⁹. Later attempts included metal on metal components attached to bone with screws⁴⁰, acrylic⁴¹ and Vitallium prostheses⁴² but these were not successful. The McKee-Farrar cemented total hip replacement was the first widely used and successful total hip replacement. It consisted of a Thompson stem articulating with a three-claw acetabular socket. Survivorship analysis showed 84% of implants survived 20 years⁴³. The Ring total hip replacement consisted of cementless components with a metal on metal articulation and provided good results with excellent survivorship (97% at 17 years⁴⁴ and 74% at 28 years⁴⁵). The Ring prosthesis was only abandoned in the 1970s due to the success of Charnley's low friction arthroplasty.

Sir John Charnley from Wrightington is considered to be the father of the modern total hip replacement⁴⁶. Charnley predicted that the high frictional torque of the McKee-Farrar total hip replacement would lead to loosening and failure and this knowledge led to him researching polymers, including Polytetrafluoroethene (PTFE) or Teflon, which was found to have a coefficient of friction almost as low as cartilage⁴⁷. His first (Teflon on Teflon) and second (metal on Teflon) generation bearings showed high rates of wear which led to early and catastrophic failure^{5,48}. Charnley named his third generation total hip replacement, the 'low friction arthroplasty' as he believed the 22.25mm femoral head combined with the newly developed ultra-high molecular weight polyethylene (UHMWPE) acetabular cup would lead to lower wear rates⁴⁶. It showed excellent survivorship of 95% surviving ten years, 80% surviving 25 years and the longest follow up to date reaching over 45 years.^{2,49-54}. Charnley's low friction arthroplasty introduced in 1958 was a fully cemented, tapered, stainless steel intramedullary stem articulating with polyethylene socket which is identical in principle to the prostheses used today^{2,55,56} and whilst its use has declined in the UK it remains in widespread use elsewhere⁵⁷⁻⁵⁹.

2.3 Economics and survivorship

The effectiveness and cost utility of interventions in different disease areas are measured in quality adjusted life years (QALYS). QALYS allow incremental improvements in health to be compared, providing a “common currency”⁶⁰. The total hip replacement is one of the most cost effective operations performed throughout the world^{5,7,61-63}. One study comparing the cost utility of medical interventions concluded that the total hip replacement was the 7th most cost effective intervention^{64,65} and the mean cost per QALY has been calculated at £7,182. The mean cost per QALY in patients under 60 years of age was less than £6,000, demonstrating that total hip replacement has a high cost utility in younger patients⁶².

Revision surgery is fraught with technical difficulty and a higher risk of complications therefore there is significant potential benefit in decreasing complications such as LLI that may warrant revision surgery⁶⁶. Over the last five years there has been more focus on high quality value health care. In 2012, Professor Tim Briggs published a landmark report entitled ‘Getting it right first time’ (GIRFT) which aimed to improve patient outcomes by improving joint longevity, reducing complication rates, mortality and litigation leading to significant cost savings for the tax payer¹⁰.

The GIRFT report in 2015 built on the original work, investigating the variance in complication rates, implant choice and surgical volume. Analysis of surgical data found that 23.7% of surgeons performing total hip replacements undertook ten or fewer per annum⁶⁷. Surgical experience has a bearing on outcomes and the risk of complications such as LLI, instability and mortality are inversely related to the case volume of the operating surgeon⁶⁸. The report showed that between 2010 and 2015 the rate of revision total hip replacement increased by 49%, with an annual increase of 9.8%. The increase in revision rates coincides with the more recently introduced metal on metal hip replacements and hip resurfacings which have revision rates of up to 14% compared to revision rates for other bearing surfaces of 3.3 to 4.9%

The most common cause for revision total hip replacement is aseptic loosening which research has shown can be accelerated by LLI ⁷⁰⁻⁷⁴. Another common indication for revision surgery is instability due to component malpositioning and abductor deficiency which is also closely related to LLI. Revision surgery is more complex than primary joint replacement and is associated with a poorer prognosis, higher risk of failure ^{75,76} and a 32% increase in complication rates ⁷⁵. Revision total hip replacements are significantly more expensive than primary total hip replacements with a mean cost for revision surgery in aseptic cases of £11,897 ²⁷.

2.4 Current concepts in total hip replacement

There is no single universal system or philosophy for performing total hip replacement, current philosophies for methods of fixation, bearing surface, head size and surgical approach are detailed further in the following sections.

2.5 Methods of fixation

Total hip replacement components may be cemented, uncemented, hybrid (uncemented socket with cemented stem), or reverse hybrid (cemented socket with uncemented stem). The most common method of fixation in the UK in 2016 was uncemented, but this has fallen slightly to 39% from its peak of 46% in 2010. Hybrid fixation (including reverse hybrid) has risen from 15% in 2008 to overtake cemented fixation to 32% in 2016. Only 29% of all total hip replacements performed in the UK in 2016 were cemented. See Figure 2.1 ⁷⁷

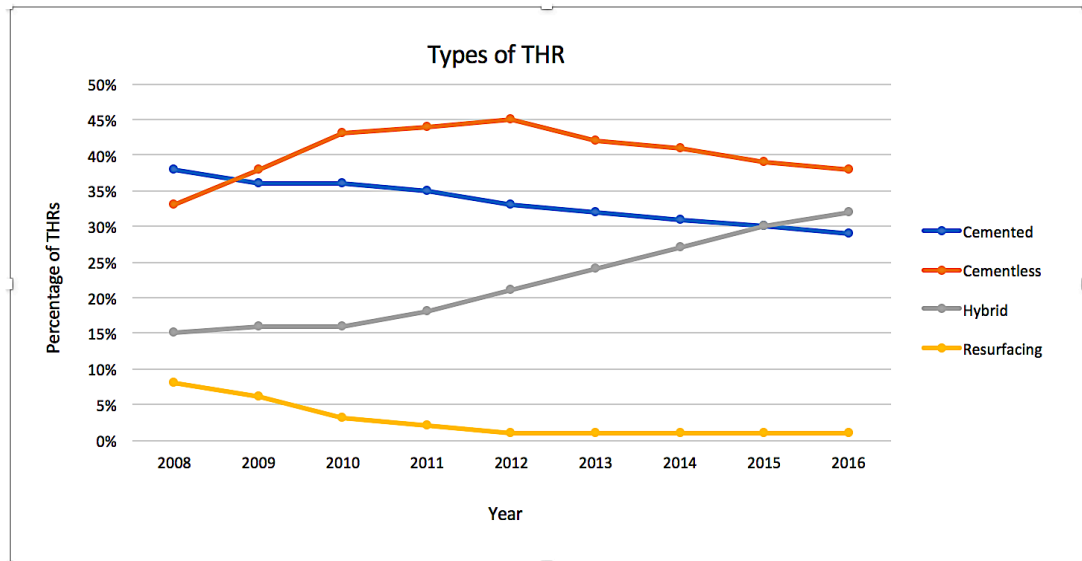


Figure 2.1. NJR figures showing trends in methods of fixation ^{6,77}

2.6 Cemented fixation

The name *bone cement* is a misnomer as it functions as a grout or space filler and has no intrinsic adhesive properties, but relies instead on close mechanical interlock between the irregular bone surface and the prosthesis ⁷⁸. Bone cement, or Polymethylmethacrylate (PMMA) is an acrylic polymer formed by mixing a liquid Methylmethacrylate monomer with a powdered Methylmethacrylate-styrene co-polymer ^{48,78}. Cementing is a technical skill which is highly technique dependent, as the surgeon manufactures the bone-cement-implant composite at the time of surgery. Cementing increases surgical time and if performed incorrectly can make the total hip replacement more vulnerable to failure from loosening or cement fractures ⁷⁹⁻⁸¹. In fractured neck of femur patients, cement pressurisation has been shown to lead to some degree of cardio-respiratory compromise (termed Bone Cement Implantation Syndrome) in up to 20% of patients undergoing cemented hemiarthroplasties ^{82,83}. Polished taper stems are associated with periprosthetic “log splitting” fractures, which arise due to hoop stresses arising from excess axial load leading to complex multifragmented fractures which necessitate extensive revision surgery ^{84,85}.

Fully cemented total hip replacements have decreased in popularity and are now the least popular type of total hip replacement used in the UK ⁷⁷. However, they have long term follow up available, have a predictable method of failure and allow a “custom fit” for all implants. The cemented femoral component gives better control of leg length as the surgeon is able to directly control how proud the stem is left. Pre-operative templating is more reliable in cemented total hip replacements and yields better agreement between the template and post-operative results ⁸⁶. Cemented total hip replacements carry a lower risk of revision ⁷⁷ and cost less than cementless implants ⁸⁷.

2.7 Uncemented fixation

Uncemented implants rely on osseointegration for stable fixation ^{88,89}, this may occur through bone on-growth where implants have a roughened surface allowing bone to grow on to it directly, or bone in-growth where implants have an osteoconductive coating (such as hydroxyapatite or bioactive glass), in to which bone can grow and bind directly to the host bone providing stability ⁹⁰.

Proponents of uncemented total hip replacements highlight the shorter operating time and ease of use. The technique is more simple and potentially more reproducible than that of cemented fixation ⁹¹. Cementless total hip replacements do not carry the risk of bone cement implantation syndrome but there is a higher risk of intra-operative and early post-operative fractures (1% within two days of surgery and 5% at one year ⁹¹) compared to cemented stems.

Templating sizes for uncemented total hip replacements show less agreement with final implant sizes ⁹². If rotational and axial stability is not achieved with the templated size stem, a larger implant may be required and this may result in inadvertent lengthening ⁹³. Lengthening of 10mm has been shown to occur in 53% of uncemented total hip replacements ⁹⁴. The converse may occur is stability is achieved with a smaller component. One study comparing implant

positions with final rasp positions showed that the average rasp-stem mismatch was within 2mm which the authors concluded to be of low clinical relevance⁹⁵ however any mismatch is misleading when performing a trial reduction to determine final implant size⁹⁶. Another study found no statistically significant difference in LLI, with a mean of 7.3mm (range -19 to +21mm) in the cemented group and 6.3mm (range -18 to +23mm) in the cementless group. However this study had many confounding variables including five different surgeons, mixed anaesthetic types and no account was taken of pre-operative LLI which can have a direct impact on post-operative LLI⁹⁶

Uncemented stems are more expensive and a recent cost effectiveness analysis concluded that uncemented stems do not improve health outcomes sufficiently to justify their higher costs⁸⁷.

2.8 Head size

The first generation of total hip replacements were monoblock components. The introduction of modern, highly modular hip prostheses now allows selection of the appropriate neck length, neck-shaft angle, neck offset, and head size in order to reproduce the patient's normal anatomy. It has also eliminated situations in which the surgeon is forced to 'upsized' the femoral stem in an attempt to increase stability, sacrificing leg length for stability.

Charnley's first generation of total hip replacement used a 41.5mm diameter femoral head which experienced early failure due to high volumetric wear rates⁴⁷. This failure led to the development of the low friction arthroplasty with a 22.25mm head, so called because Charnley believed a smaller head size caused less friction and wear¹². However smaller diameter femoral heads are inherently less stable and show less resistance to dislocation in a provocative position⁹⁷. One study showed a dislocation rate of 5.4% in 28mm heads and only 1.3% with 36mm heads⁹⁸. The larger head-neck ratio, combined with the increased jump distance of larger heads result in a greater arc of impingement free motion⁹⁷. Increasing the head diameter from 26mm

to 32mm increased their range of flexion by 10-11°^{99,100}, this is supported by mathematical formulae¹⁰¹. However larger heads have been implicated in causing groin pain and psoas impingement^{97,102}. Almost half (46%) of total hip replacements in 2016 used a size 32mm femoral head, compared to 2008 when 53% used a size 28mm⁶.

2.9 Femoral offset

The topic of femoral offset is introduced at this point as it is intimately related to LLI and the two are often discussed together. Femoral offset is defined as the distance from the centre of rotation of the femoral head to a line bisecting the long axis of the femur. Reconstruction of the femoral offset is important for restoring the biomechanics of the hip and specifically the abductor lever arm⁶³. LLI and incorrect offset should be corrected or will result in significant alteration of the biomechanics of the hip leading to dislocation, abnormal load reaction forces with increased wear, and early aseptic loosening¹⁰³.

Historically the assumption was that increased leg length translated to increased stability. Excessive limb lengthening may result when intra-operative instability due to inadequate offset is inappropriately addressed by increasing the neck length in an attempt to restore soft tissue tension⁶⁶. A high femoral neck resection can be combined with a short neck implant to yield the same leg length as provided by a low femoral neck resection combined with a long modular neck. However, the first option yields less femoral offset and may be appropriate in the presence of coxa valga. The second combination yields greater offset and is better option for patients with coxa vara. Varus and valgus malpositioning of the femoral stem can affect both offset and LLI. The introduction of modular femoral components allows adjustments to offset without significant effect on leg length⁶³.

2.10 Bearing surface and wear characteristics

Bearing surfaces can be broadly divided into hard-on-soft (metal on polyethylene, ceramic on polyethylene) and hard on hard (ceramic on ceramic, metal on metal) ⁶. Metal on polyethylene total hip replacements provide the most consistent results ¹⁰⁴ and this was the most frequently used bearing surface in the UK in 2016, followed by ceramic on polyethylene (59% and 29% respectively) ⁶. Hard on soft bearings provide a low friction articulation but are susceptible to wear and consequently osteolysis ^{12,105}.

Hard on hard bearings have lower wear rates. Ceramic on ceramic bearings potentially offer the surgeon a 'hard on hard' bearing surface exhibiting little wear, and any wear particles that are released are of low biological activity ^{105,106}. Earlier generations of ceramic components showed up to 13.4% fracture rate but recent studies with more modern ceramic shows this has fallen to 0.004% to 0.05% ¹⁰⁶⁻¹⁰⁸. The seemingly innocuous symptom of squeaking where the patient hears or feels a sensation as they move through the gait cycle is experienced by up to 4.2% ¹⁰⁹. 11% of total hip replacements in the UK in 2016 were ceramic on ceramic ⁶.

Metal on metal total hip replacements now account for less than 1% of all total hip replacements ^{6,110}. Early studies showed wear rates of sixty times less than conventional metal on polyethylene implants ¹¹¹ but adverse reactions to the highly biologically active metal debris released from the bearing surface as the implant wears has now led to their decline ¹¹⁰. The highly biologically active wear debris causes inflammatory changes in the surrounding soft tissues which have been termed pseudotumours and have been identified in 27%–32% of patients with metal on metal total hip replacements ^{112,113}.

LLI has been implicated in increased wear rates in total hip replacement through altered gait mechanics and edge loading ⁷⁰⁻⁷². A study comparing rates of aseptic loosening showed rates of 23.9% in cases of lengthening of 10-20mm, increasing to 50% in cases with a lengthening of 3-5cm ⁷³. Overtight

ligament tension can also have a negative effect on joint lubrication and increase wear⁷⁴.

2.11 Surgical approach

Surgical approach in total hip replacement is a constant area of debate as each approach has its own unique benefits and complications, including the risk of LLI. High-quality clinical comparisons amongst the approaches are lacking in the literature; therefore, surgeon preference is likely more a function of training and anecdotal success¹¹⁴. Four well known approaches are discussed below.

2.12 Trochanteric Osteotomy

The trochanteric osteotomy was the original approach described by Charnley⁴⁷ but is now used by fewer than 1% of surgeons in the UK⁶. After incising the iliotibial band and tensor fascia lata, the greater trochanter is osteotomised with its abductor insertions still attached and the hip capsule is exposed. After the components of the total hip replacement are inserted the greater trochanter is reduced and secured with cerclage wires¹¹⁵.

Trochanteric osteotomy allows excellent exposure to the femur and allows straight access to the femoral canal, therefore reducing the risk of varus or valgus positioning of the stem, improving offset and reducing the risk of LLI. As the abductors are not detached from the greater trochanter this approach has a low risk of dislocation¹¹⁵. A possible risk is non-union of the osteotomy site and breakage of reduction wires leading to “trochanteric escape” which may result in symptomatic abductor dysfunction and local irritation from the broken wires¹¹⁶. Following a trochanteric osteotomy patients must remain non-weight bearing for six weeks which is not necessary with a more modern approach.

2.13 Lateral Approach

The lateral approach is used by 25% of surgeons in the UK ⁶ and 42% of surgeons worldwide ¹¹⁷. The anterolateral approach to the hip was originally described in the supine position by Watson Jones in 1936 ¹¹⁸. After dissecting through the iliotibial band and tensor fascia lata the interval between the tensor fasciae lata and gluteus medius is developed to expose the capsule. The direct lateral approach was described by Hardinge in 1982 ¹¹⁹. This differs from the anterolateral approach as the abductors are dissected from their proximal femoral insertion to reveal the hip capsule ¹¹⁴. Anatomical repair of the abductors is essential to avoid complications. If they are reattached too proximally the muscles will not function properly and the patient will be left with a Trendelenburg gait. If they are reattached too distally, there will be iatrogenic abductor tightness which may lead to an apparent LLI ¹²⁰⁻¹²³.

Performing the lateral approach in the supine position allows direct measurement of limb lengths at the ankle or heel. The supine position also allows radiographs or fluoroscopy to confirm implant positioning and leg length intra-operatively if required ^{63,114}. Collectively the lateral approaches provide excellent exposure of the hip joint and have very low dislocation rates as the hip joint is dislocated anteriorly ¹²⁴, however symptomatic heterotopic ossification is more common in the lateral approach than any other approach ^{63,125}.

2.14 Posterior Approach

The posterior approach was popularised by Moore in the 1950s ¹¹⁴. It is the most common surgical approach used internationally ¹¹⁷ and in the UK 71% of total hip replacements are performed with this approach ⁶. The approach spares the abductor muscles during surgical exposure of the acetabulum and femur ^{4,115}. There is no true inter-nervous plane. The short external rotators are dissected close to their femoral insertion and retracted to protect the sciatic nerve ^{114,115}.

The posterior approach provides an unparalleled view of the acetabulum which decreases the risk of inadvertent incorrect orientation of implants and therefore the risk of type II LLI. It is possible to indirectly measure leg lengths using the soft tissue tests such as the Shuck test and the kick test in the lateral position, and directly measure leg lengths at the knees but this is reliant on precise positioning of the patient pre-operatively. Historically the posterior approach was associated with a high risk of dislocation and it was not uncommon for the extremity to be overlengthened during the total hip replacement with this approach, in an attempt to increase stability of the hip¹²⁶. With greater understanding of the role of the posterior capsule and short external rotators the dislocation rates have fallen to 1% to 5%^{114,124}. Failing to perform posterior soft tissue repair increases the relative risk of dislocation by eight times¹²⁴. The sciatic nerve is at risk with this approach as it lies at the inferior part of the surgical site as it exits the short external rotators, the risk of sciatic nerve palsy is reported to be 0.6 - 1.3%^{127,128}.

2.15 Anterior approach

The direct anterior approach to the hip was first described by Smith-Petersen in the 1940s, and was later modified by Heuter in the 1950s¹²⁹. The patient is positioned supine and the approach utilises the true internervous plane between the tensor fascia lata and the sartorius muscle superficially and between rectus femoris and vastus lateralis deeper^{129,130}. The major abductor attachments are preserved and the femur is delivered anteriorly. Studies have implicated excessive retraction in causing neuropraxia of the lateral femoral cutaneous nerve which has been reported in 15%–80% of patients undergoing total hip replacement through the direct anterior approach^{131,132}.

As with the lateral approach, one of the advantages of the direct anterior approach is the ability to directly measure limb lengths at the ankle or heel in the supine position, some advocate using the diathermy cord to measure from ASIS to lateral malleolus through the drapes¹³³. The supine position also

allows radiographs or fluoroscopy to confirm implant positioning and leg length intra-operatively if required ^{63,114}. Studies have shown an average mean LLI of 3.9mm with this approach making it one of the most accurate in terms of limb length reconstruction ^{134,135}

Other advantages of the direct anterior approach include the muscle sparing nature of its internervous intervals, earlier recovery with shorter inpatient stay, earlier restoration of gait kinematics and better cosmesis ¹³⁴⁻¹³⁷. Critics argue that incisions near the groin crease are at increased risk of infection, especially in obese patients ¹³⁸. There is a low rate of dislocation as the posterior capsule is not detached ¹³⁵ but there have been reports of intra-operative fracture during femoral elevation with a bone hook ^{135,139}. The approach is technically difficult with a steep learning curve ^{63,140}. In 2016, 3% of surgeons used the anterior approach in the UK ⁶ but its use in other countries is increasing ^{117,135}.

2.16 Complications of total hip replacement

Since the introduction of the total hip replacement in the 1950s there have been significant advances in surgical techniques and materials leading to improved outcomes in total hip replacement, however it is still a significant operation with considerable morbidity and more rarely, mortality. Optimum surgical results are obtained through careful patient selection. There is a 40% increased risk for any complication for every decade above the age of 65 years ¹⁴¹. Conversely, total hip replacements in patients younger than 50 years presents a unique set of challenges related to implant survivorship due to the possibility of increased wear and early implant failure in this group of more active patients ¹⁴¹. Pre-operative education is essential to align patient expectations with the risks and benefits of the procedure.

Reviewing litigation data for hip and knee arthroplasty highlights the recurrent theme of consent and clear communication ^{142,143}. This led the BOA to develop standardised consent forms with simple explanations of the procedure,

complications, with advice regarding alternative procedures and the consequences of taking no action. They graded risks as common, less common and rare ^{143,144}. These are listed in Table 2.1.

Table 2.1. List of complications of total hip replacement from BOA recommended consent form ¹⁴⁴

<p>Common (2-5%)</p>	<p>Blood Clots Bleeding Pain Prosthesis wear/loosening Altered leg length Joint dislocation</p>
<p>Less common (1-2%)</p>	<p>Infection</p>
<p>Rare (<1%)</p>	<p>Altered wound healing Nerve damage Bone damage Blood vessel damage Pulmonary embolus Death</p>

2.17 Leg length Inequality

The consequences of LLI following total hip replacement were recognised by Charnley when the technique was popularised in the 1950s but it was not until the 1990s that LLI following total hip replacement came to prominence in the literature. Total hip replacements were initially performed for pain relief but as the indications for total hip replacement have broadened to include younger, more physically demanding patients, the complication has risen in prominence.

Pain relief and improvement in function are the primary aims for total hip replacement but the maintenance or restoration of hip biomechanics, including leg length and femoral offset, is also highly desirable. Leg length is

strongly related to stability, and in order to achieve rotational and axial stability of a total hip replacement, the surgeon may be forced to sacrifice leg-length equality for stability and use a larger implant than was originally templated for, thus leading to lengthening of the operated limb ^{96,133,145}. LLI is therefore a common complication of total hip replacement, which, depending on the definition of LLI ranges from 5% ¹⁴⁶⁻¹⁴⁸ to almost 95% ^{26,149}.

LLI following total hip replacement documented in the literature ranges from -21mm to +70mm ¹⁴⁹⁻¹⁵². The literature has shown a gradual decrease in the range of LLI over the last two decades but it is still common, showing that although LLI can be minimised it is difficult to fully eliminate. Whilst LLI is now recognised as a complication of LLI it is complicated by the lack of consensus on what constitutes an “unacceptable value” of LLI ^{22,66}. Many studies have been performed in an attempt to determine the magnitude of LLI necessary to manifest complications and therefore to warrant treatment ^{153,154}. The threshold at which LLI is clinically important is controversial ¹⁵⁵, some investigators have tried to quantify an important value of LLI whereas others have defined an important discrepancy as one that affects function ²². The literature broadly agrees that less than 10mm is an acceptable goal ^{4,150,156-158}, however some think as little as 6-7 mm is significant ^{159,160}. There is some proof that up to 20mm is physiologically and subjectively tolerable by most adults ^{20,161,162} and greater than 30mm is not acceptable but the grey area in between these values is contentious. The literature does agree that steps should be taken to reduce LLI to as near to zero as possible.

The subject of what defines an unacceptable or even negligent LLI is complicated not only by the lack of agreement of significance but also by the fact that for any given magnitude of LLI, only a proportion of patients will be symptomatic. If a patient perceives LLI it can be termed ‘symptomatic LLI’. Patient perception of LLI and presence of radiographic LLI do not correlate well ¹⁶³ but as the difference in lengths increases the proportion that are symptomatic also increases. Symptomatic LLI post total hip replacement is reported in between 6% ¹⁴⁸ and 32% ¹⁵¹ of patients following total hip replacement. Sariali claimed it is universally perceived when shortening

exceeds 10mm and lengthening exceeds 6mm but this is disproved by many studies¹⁶⁴. A study of 68 patients with a mean LLI of 9.7mm reported that 32% of these patients were aware of their LLI and 50% were “disturbed” by it¹⁴⁸.

The associations between LLI and functional outcomes after total hip replacement are unclear in the literature. Many attempts have been made to determine the clinical effects of LLI following total hip replacement using objective methods of assessment such as the Oxford Hip Score (OHS) as a primary outcome measure although the individual variation amongst patients with LLI makes this difficult. The OHS is a joint specific outcome measure and is more sensitive to change than both generic and disease specific measures of health¹⁶⁵. Several studies have reported poorer OHS in patients with LLI, specifically with lengthening of the operated leg¹⁶⁶. Lengthening over 10mm is associated with having a significantly poorer outcome in terms of the clinical benefit of surgery but whether this difference in OHS is clinically important from a patient’s perspective remains less clear¹⁵⁸. A two-point change in the OHS has been described as the minimum clinical change perceived by patients as meaningful¹⁶⁷.

Patients who perceive leg lengthening have poorer OHS post operatively compared with patients who perceived equal leg length, even in the absence of true lengthening^{149,168} and this has been shown to influence function and satisfaction at long term follow up¹⁶⁹. One study showed that 30% of patients perceived LLI at five to eight years post-surgery, however only 36% of these patients had radiologically confirmed LLI. Of the patients with perceived LLI, 49% were bothered by the difference and 4% thought the surgery had not been worthwhile. In comparison, no patients who perceived their legs to be of equal length thought that the operation had not been worthwhile. However this study did not include any clinical or radiological magnitude of LLI¹⁶⁸. Regardless of whether LLI is clinically or radiographically measured, these studies provide evidence that perceived LLI influences function and satisfaction up to eight years after surgery¹⁶⁹.

It is generally agreed that all attempts should be made to minimise post total hip replacement LLI, however there are several studies to suggest that LLI is not as important as previously suggested. White and Dougal published a paper entitled 'Arthroplasty of the hip. Leg length is not important'. They prospectively followed up 200 patients undergoing unilateral total hip replacements. The range of post-operative LLI was -21mm to +35mm but they found no statistically significant association between post-operative LLI and comfort, function or satisfaction at six months following surgery ¹⁴. This length of follow up has been shown to be inadequate time for poor results in patients with LLI to be picked up by scoring systems ¹⁵¹. The paper also relies on the Harris hip score (HHS) and SF-36 questionnaires to assess outcome. The HHS is an insensitive scoring system conducted by the surgeon and there is considerable evidence demonstrating lack of agreement between surgeon and patient assessment of subjective domains such as pain ¹⁷⁰. The SF-36 is a generic tool and as such lacks the sensitivity and specificity of joint-specific questionnaires ¹⁷¹.

Whitehouse et al also stated that LLI following total hip replacement has no correlation with patient satisfaction or functional outcomes. However, their radiological measurements were calculated by subtracting the measurement of the acetabular component from the overall leg length which is not a recognised or accurate method of measuring leg length and therefore its results should be interpreted with caution ¹³.

A large percentage of the population are thought to have asymptomatic LLI; one study reported rates of 32% with LLI of 5 - 15mm, and 4% with LLI of over 15mm ¹⁷². A study of asymptomatic soldiers in the US army concluded that two thirds had asymptomatic LLI of up to 20mm, however, their methodology had significant limitations. Measurements were taken from the hip joint proximally to the bottom of the X-ray plate distally, instead of an anatomical landmark, and their mean LLI of 11.5mm was included in their 10 – 20mm subgroup therefore their conclusion claiming that 'LLI of up to 20mm can be asymptomatic' is misleading ¹⁷³.

Studies of marathon runners with asymptomatic LLI have concluded that discrepancies of 5 - 25mm are not a functional detriment to athletes ¹⁷⁴, and that individuals with a LLI of less than 20mm did not consider their short leg to be a problem in any way. However as the amount of discrepancy increased so too did their symptoms, although there was no critical cut off value ¹⁶¹. LLI is common in the general population and may be asymptomatic but LLI following total hip replacement is a more complex problem which leads to additional symptoms ¹⁷⁵. An acute change in leg length post-operatively does not allow time for compensatory strategies that may be present in idiopathic or congenital cases of LLI which may be well tolerated therefore these cases should not be used to provide evidence that LLI is insignificant ¹⁷⁶.

2.18 True and apparent leg length inequality

LLI can be conceptually divided into true (or structural), and apparent (or functional) LLI. This division is important as the diagnosis will inform the treatment, prognosis and success of various treatment options. Due to the technical and complex nature of the biomechanics of total hip replacement it is also possible to have a mixed picture where both true and apparent LLI exist. It is vital however to identify the major cause of symptomatic post total hip replacement LLI as misdiagnosis may result in unnecessary or inappropriate revision surgery. The two types of LLI are discussed below.

2.19 True leg length inequality

In true LLI the individually measured limbs are of different lengths and the cause of the inequality is intrinsic to the limb itself ^{150,177}. The causes may be pelvic, or infra-pelvic, for example when the femur, tibia or ankle is shortened due to trauma, surgery or a congenital condition. True leg length inequality may be caused by THR due to altered bony structures or component position ^{22,150,178}. True LLI can be further subdivided in to type I and type II:

Type I lengthening

Type I is lengthening due to the component size, for example if the acetabular cup is placed too low or the femoral stem is left proud.

Type II lengthening

Type II lengthening occurs when component malpositioning such as excess ante- or retroversion results in instability. In an effort to prevent dislocation the surgeon may increase length and or offset to increase soft tissue tension around the joint^{66,179,180}.

True LLI is usually caused by the femoral component, the position of the acetabular component has a much smaller impact on leg length, it has been shown that the cause of LLI was attributable to the position of the acetabular component in only 2% of cases¹⁶⁶, however incorrect positioning of the acetabular component first may lead to instability and inadvertent lengthening of the leg to attempt to counteract this.

2.20 Apparent leg length inequality

Apparent LLI occurs when the lower limbs appear to be of different lengths when measured from a fixed midline reference point (such as the xiphisternum) but when measured individually (from anterior superior iliac spine (ASIS) to medial malleolus (MM) or lateral malleolus (LM)) they are the same length. Apparent LLI occurs as a physiological response to altered mechanics along the kinetic chain anywhere from the foot to the lumbar spine giving the appearance of a shorter leg when bony asymmetry does not exist. Causes may therefore be supra-pelvic, pelvis or infra-pelvic. It can be caused by tightness of anterolateral soft tissues around the hip, (for example if the patient has had a “short” limb for a while), contractures of periarticular hip muscles including tensor fascia lata, gluteus minimus and medius, and the presence of pelvic obliquity¹⁵⁶ or degenerative disease with scoliosis of the spine causing obliquity of the pelvis¹⁸¹.

There are certain patient characteristics that are often identified in patients with apparent LLI, including short stature (< 5'6"), varus femoral necks, small and bony dimensions¹⁵⁶. Pre-operative fixed flexion deformity predisposes to apparent LLI as the anterior capsule remains tight after reconstruction, therefore limiting abduction and external rotation¹⁵⁶. Younger patients also seem to perceive LLI to a higher degree and are more likely to pursue treatment¹⁸².

True LLI has a weak relationship with functional outcome after total hip replacement while apparent LLI resulting from pelvic obliquity due to hip contracture or scoliosis is correlated with the short-term functional outcome after total hip replacement. Therefore, apparent LLI may be a better predictor of patient-perceived inequality and physical performance than true LLI¹⁸³. One study showed the presence of patient perceived LLI after total hip replacement in 41% of patients but 52% of these had LLI of 5mm or less¹⁸⁴. Another study showed that 14% of patients had perceived LLI but these patients had a mean radiological LLI of 3.4mm lengthening with no statistical difference in actual leg length change between the group with pelvic obliquity and the group without it¹⁵⁶. Apparent LLI can coexist with true LLI; Williamson et al found that 96% of patients with apparent LLI had a long operated limb²⁶ but the relationship is not fully understood.

The majority of cases of apparent LLI resolves with aggressive physiotherapy, soft tissue mobilisation techniques, orthoses and occasionally steroid or Botox injections within six months to a year^{156,180,185}. Ranawat identified nine patients with 'persistent apparent LLI' over a fifteen-year period. In these recalcitrant cases patients may benefit from soft tissue release or rarely revision of components¹⁵⁶.

2.21 Measurement of LLI

The use of accurate and reliable clinical and radiological imaging modalities for quantifying LLI is vital for planning appropriate treatment. Accuracy of a technique is defined as the variation of the measurement using the measurement method compared to the true measurement, whereas reliability of the technique is the variation between observers and within a single observer in obtaining measurements. When selecting an appropriate measurement technique, radiation dose, cost, convenience and patient acceptability must also be considered¹⁸⁶.

2.22 Clinical methods

There are both direct and indirect methods of measuring LLI clinically; the methods and a discussion of their relative benefits and limitations are discussed below.

Direct measurement

Direct measurement of LLI is performed using a measuring tape between two fixed points. This can measure both true and apparent leg length.

True leg length measures between two bony landmarks, commonly the anterior superior iliac spine (ASIS) to the medial malleolus (MM) or lateral malleolus (LM). Apparent leg length measures between a fixed midline point, usually the umbilicus to the medial malleolus. See Figure 2.2.

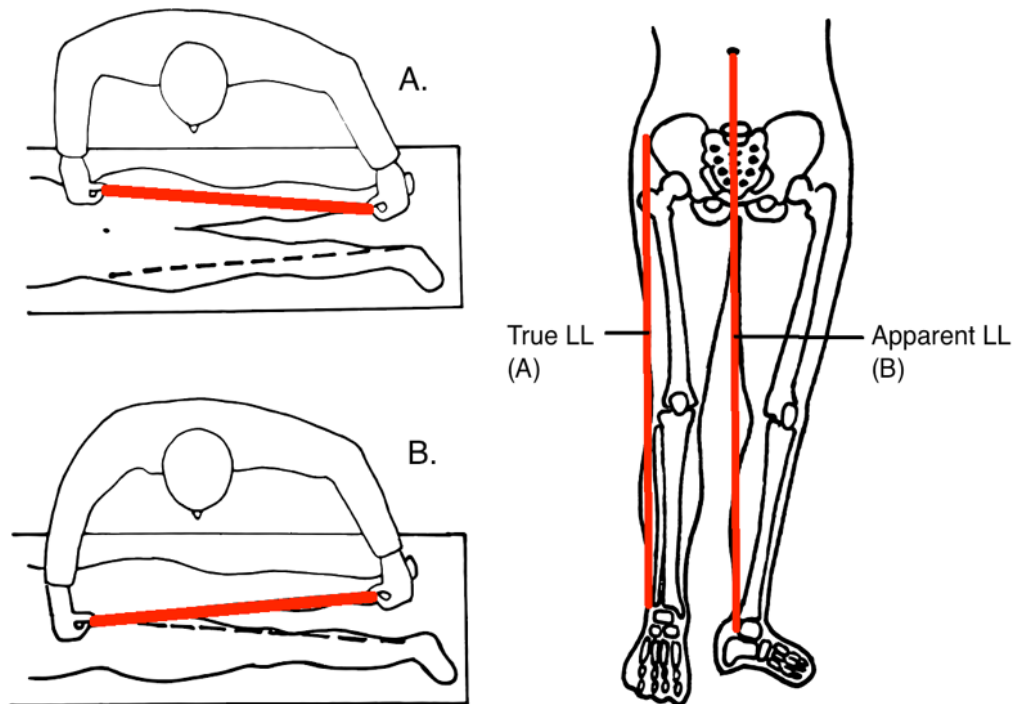


Figure 2.2. Measuring true leg length versus apparent leg length ¹⁸⁷

When measuring true leg length directly the pelvis must be squared to ensure identical positioning of the lower limbs. This is important because the upper reference point of the ASIS is outside the limb and any change in the position can affect the measurement. Thomas' test should also be performed to assess for any fixed flexion deformity of either hip which may contribute to apparent LLI. This is performed in the supine position by flexing the contralateral hip and knee. If a fixed flexion deformity of the opposite hip is present, the thigh will spontaneously elevate, thus indicating the amount of contracture present ¹⁸⁸.

Possible sources of error when using direct methods as a clinical measurement tool include asymmetry in the girth of the two limbs, angular deformities in the long axis of a limb following trauma, and difficulty in identifying bony prominences due to obesity. Direct methods may be more difficult to use in cases of fixed pelvic obliquity or joint contractures ¹⁸⁶. Techniques describe measuring from the ASIS to either the MM or the LM but studies have shown the ASIS to LM to be more accurate as it eliminates the contour of the thigh as a source of error ^{178,189}.

Several studies have compared direct clinical measurement with radiological values and showed poor to moderate correlation with the results ¹⁹⁰. One study comparing ASIS to MM measurements concluded that measurements differed by $\pm 8.6\text{mm}$ from standing radiographic measurement. The direct measurement method failed to determine any LLI in 27% of patients with LLI over 5mm ¹⁹¹. ASIS to MM measurements have been shown to be more accurate for post operate LLI measurements than for pre-operative LLI measurements, possibly due to the treatment of soft tissue contractures around the newly replaced hip joint no longer contributing to LLI¹⁹².

Beattie et al assessed the agreement between direct clinical measurements and those obtained radiologically and reported an intra-observer intraclass correlation coefficient (ICC) value of 0.68 and concluded that clinical measurement of LLI is a valid indicator of LLI ¹⁹³. Gogia supported these findings, reporting an ICC of 0.99 ¹⁹⁴ however both studies were very small cohorts (nineteen and thirty patients respectively).

The direct clinical method can be criticised as being subjective and some advocate using the average of two determinations to improve estimates of LLI ¹⁹³, however evaluator experience has been shown not to influence accuracy of measurements tested ¹⁷⁸. Morscher stated the degree of accuracy of the direct method is of the order of magnitude of $\pm 5 - 10\text{mm}$ ¹⁹⁵ and Paley reported ASIS to MM measurements were accurate to 10mm ¹⁹⁶, as this is often quoted as an 'acceptable' value of LLI it can be concluded that direct clinical measurements may be used as a screening tool for the presence of LLI but when precise accurate measurements are required other tests should be employed.

Indirect measurement

Placing blocks of known height beneath the heel of the short leg to level the pelvis allows “indirect” measurement of leg length discrepancy, see Figure 2.3. Not all types of LLI are amenable to this method of clinical measurement. Pelvic obliquity due to true LLI or flexion contractures of the hip or knee will correct with standing blocks, but pelvic obliquity in the presence of rigid scoliosis or hip abduction or adduction contracture will not ¹⁷⁶.

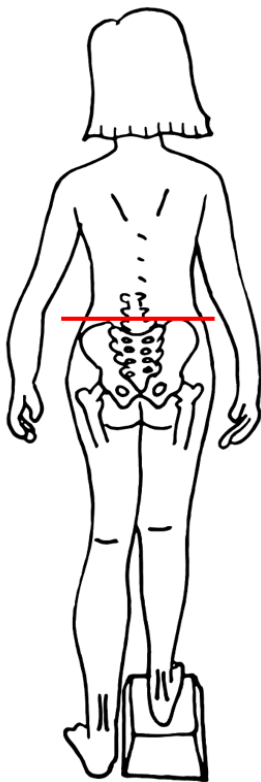


Figure 2.3. Indirect measurement of LLI using blocks of known size ¹⁸⁷

The indirect method is reported to be more accurate and reliable than the direct method. The indirect method includes the full length of the lower limb whereas the direct method only measures to the malleoli and therefore may fail to pick up causes of LLI inferior to this point. It is also less sensitive to errors in measurement caused by obesity.

The indirect method measures the extent of any LLI, whether true or apparent. A patient may display evidence of shortening in the weight bearing position

which was not appreciated in a non-weight bearing position and therefore would have not been detected using a direct clinical method. It can be argued that LLI in the weight bearing position has greater clinical value as it is the functional position.

Several studies have compared the indirect method with the direct method in patients with radiologically proven LLI and concluded that the indirect blocks test is the most accurate method¹⁷⁸ and that direct and indirect methods may differ in the range of 7.5 - 8.6mm^{195,197}. On study supporting the indirect method showed that 95% of clinical measurements with blocks were within -14 to +16mm of results made using orthoroentgenograms whereas the direct tape measure method produced significantly less agreement¹⁹⁸. A study by Johnson et al concluded that the indirect blocks test had high intra- and inter-observer reliability, with ICCs of 0.87 and 0.70 respectively¹⁷⁸.

Terry et al compared two direct methods (ASIS to lateral malleolus and ASIS to medial malleolus) with the indirect blocks test and concluded all three had high reliability with ICCs of 0.88, 0.78 and 0.86 respectively and inter-observer ICC of 0.83, 0.8 and 0.83 respectively¹⁸⁹.

Rondon et al. compared LLI measurements using direct and indirect clinical methods with radiographic methods and found high inter-observer reliability between the two clinical methods but low concordance between clinical and radiological measurements, with the indirect measurements showing less concordance than the direct measurement¹⁹⁹.

Clinical methods of measurement are useful screening tools, but not as accurate as imaging modalities¹⁸⁶ as patients with radiographic LLI of 10mm or greater have been shown to have equal leg lengths on clinical measurement¹⁷⁸. Some argue that clinical measurements are more important than radiological methods as they give a stronger idea of functional status. Harris et al stated that there was a strong correlation between the direct and indirect tests, and these correlated well with patient perceived LLI, whereas measurements obtained from CT scanogram did not¹⁸⁶.

2.23 Radiological methods

2.24 Plain radiographs

Radiographic measurements of LLI have been shown to have measurement errors in the range of 1-3mm¹⁸⁶. The frequently used methods are discussed below.

Plain AP pelvis radiograph

Many methods of measuring LLI on plain X-ray have been described in the literature but only the Williamson and the Woolson methods are used frequently in clinical practice. They both describe measurements on a plain AP radiograph of the pelvis.

The Williamson technique was described by Williamson and Reckling in 1978. Their method advocates using the inter-ischial line as a reference and measuring to the most prominent part of the lesser trochanter (Figure 2.4)²⁶.

The Woolson technique was described in 1985 by Woolson and Harris. They describe using the most inferior part of the acetabular teardrop as a reference and measuring to the most prominent part of the lesser trochanter²⁰⁰. The “teardrop” is a radiographic landmark in the antero-inferior portion of the acetabular fossa formed by the most distal part of the medial wall of the acetabulum and the tip of the anterior and posterior horn of the acetabulum²⁰¹. (Figure 2.5).

The Leeds method was developed from the Woolson technique by McWilliams et al in 2012 to divide measurements of LLI in to contributions from femoral stem malpositioning and acetabular malpositioning. The authors found this method to be similarly accurate for the measurement of LLI but with better repeatability than Williamson or Woolson. It can be particularly useful in the

audit of practice and in bilateral total hip replacement or revision total hip replacement setting. It involves drawing a reference line bisecting the centres of femoral rotation then drawing two further parallel lines; one at the level of the acetabular teardrop and one at the level of the midpoint of the lesser trochanter. The Leeds method provides three measurements per hip, the centre of femoral rotation to teardrop, which corresponds to any change in leg length associated with the cup, the center of femoral rotation to lesser trochanter, which corresponds to LLI due to the femoral stem and an overall measurement of leg length^{202,203}. Figure 2.6.

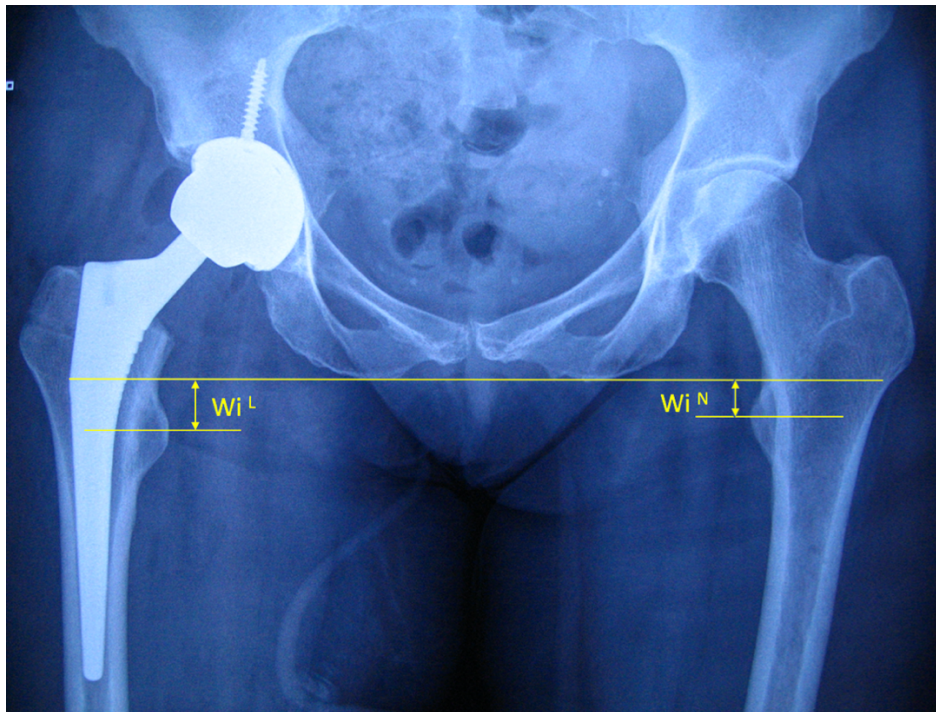


Figure 2.4. Williamson technique.

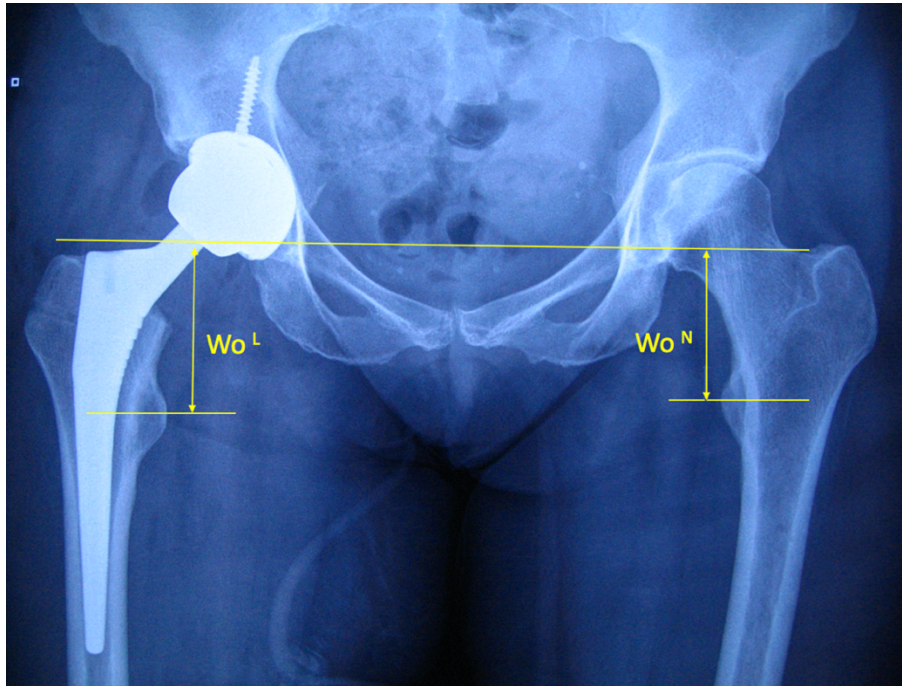


Figure 2.5. Woolson technique

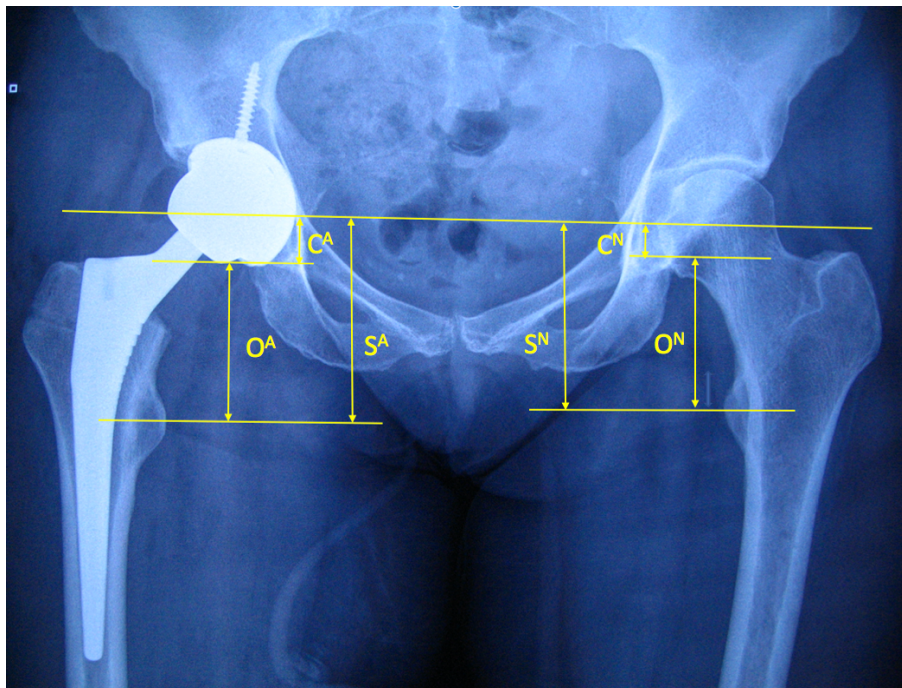


Figure 2.6. The Leeds technique.

C = LLI due to cup position,

S = LLI due to stem position,

O = overall measurement of LLI.

In this case, the S measurements are similar, C is greater on the arthroplasty side and the overall measurement, O is also greater. Therefore, the lengthening in this arthroplasty is predominantly due to the cup.

Any measurements taken from a radiograph of the pelvis will only provide information about LLI resulting from the hip joint. They are also subject to error and dependent on radiographer technique, position of the X-ray plate, tube, and calibration ball²⁰². They involve two dimensional measurements of a three dimensional structure and use two point measurement method, trigonometry dictates that a fixed flexion deformity of, for instance 25° will result in a reduction in measured LLI of approximately 10%²⁰².

Measurements taken from the acetabular teardrop are reported to be more accurate than those taken from the inter-ischial line. The teardrop comprises a well-defined, constant portion of the medial acetabular wall, less influenced by rotation of pelvis and most consistent in terms of sagittal or coronal rotation^{200,204,205} as it is closer to the centre of rotation of the hip²⁰⁴. The teardrop may be difficult to identify in patients with developmental dysplasia of the hip which is a common indication for total hip replacement. One study comparing the Woolson and Williamson methods with true LLI from full length radiographs found that the inter-teardrop measurement gave the true LLI whereas the inter-ischial line did not and concluded that the use of the bi-ischial line as a pelvic reference should be discouraged. However this study excluded all patients with functional LLI including cases of spinal deformity and soft tissue contractures which may be significant¹⁵⁵.

Reports claim the Woolson method to be as reliable as full length orthoroentgenograms¹⁶⁶, with inter-observer reliability of 0.5mm²⁰⁵ and intra-observer reliability giving a measurement error of ± 1 mm¹⁵¹.

Orthoroentgenogram

The orthoroentgenogram was initially described by Green in 1946²⁰⁶. It utilises three radiographic exposures over the hip, knee and ankle joints in order to minimise magnification error. A single large X-ray cassette is placed under the patient who remains lying supine next to a calibrated ruler between the three exposures. It requires the patient to lie very still between the three

exposures which may be uncomfortable for a patient with hip pain and is susceptible to error if the patient moves.

X-ray scanogram

The scanogram technique also utilises three radiographic exposures, one each centred over the hip, knee and ankle joint in order to minimise magnification error. The patient remains supine next to a calibrated ruler and unlike the orthoroentgenogram, the standard length radiographic cassette is moved between each of the three exposures¹⁸⁶. Merrill originally described this technique in 1942 using a specially constructed plywood grid with copper wires at one inch intervals and lead numbers placed on the even-numbered wires²⁰⁷.

The X-ray scanogram is one of most commonly used methods for measuring full lengths of the lower limbs. It is reported to have excellent reliability with minimal magnification error¹⁸⁶.

Teleoroentgenogram

The teleoroentgenogram is a full-length standing AP radiograph of the lower limbs. It is taken using a single long cassette placed behind the patient, while the X-ray beam is centred over the knee joint with the patellae pointing forward. Any LLI is corrected using blocks under the shorter limb to ensure the iliac crests are level¹⁸⁶. This avoids underestimation of any LLI that may occur with the patient using their compensatory methods to attempt to level the pelvis such as plantar flexing the ankle on the short side or flexing the contralateral knee.

The teleoroentgenogram exposes the patient to less radiation than the scanogram or orthoroentgenogram¹⁸⁶ and it allows detailed assessment of LLI and alignment²⁰⁸. Critics of this method claim that a single radiograph centred on the knee is sensitive to magnification error and the magnitude of this is dependent on various factors including the length and girth of the limb,

distance of the X-ray source to the cassette, and divergence of the X-ray beam^{206,209,210}. Teleoroentgenograms are more expensive than orthoroentgenograms or X-ray scanograms as they require extra equipment and processors. They do however measure the full length of the lower limb as the foot is included,

Computed radiography

Computed radiography is a relatively recent advance in the measurement of LLI that is gaining popularity. It involves digital manipulation of radiographs to produce a long leg view. The patient stands in front of a cassette at least 203cm away from the X-ray tube. A latent image is produced that is stored on a receptor contained in a standard radiographic cassette. Three images are taken and then stitched together to produce a high quality composite image^{209,211,212}. Studies have shown the mean radiation dose for computer radiography scanogram to be 1.6 to 3.8 times higher than for a teleoroentgenogram²⁰⁹. The magnification error for computer radiography is reported to be 5% but with the use of a marker ball and rule this can be further reduced¹⁸⁶.

Comparison of plain radiography methods

In all plain radiography methods magnification is a possible source of error, this may be as high as 129% in uncalibrated radiographs²¹³. Radiographic magnification can vary due to the patient's body habitus and templating enlarged by a uniform magnification factor may not be accurate. Errors can be reduced by using a ruler, marker ball or the known size of an implanted femoral head²¹⁴. There are still errors associated with marker balls as in patients with increased BMI it is difficult to palpate bony landmarks and ensure the marker ball is at the correct height. With the advent of digital templating and common use of a calibration tool, the error associated with varying magnification of solid film images should be reduced. Any error in magnification may lead to errors in templating and therefore could result in post-operative LLI.

Early comparisons of teleoroentgenograms, X-ray scanograms and orthoroentgenogram concluded that all three techniques gave equally accurate results but provided no data to support this view ¹⁹⁵. A comparison of teleoroentgenograms and orthoroentgenograms concluded that there was a threshold of 10mm for meaningful difference and accuracy was similar in the absence of significant mechanical axis deviation ¹⁹⁰. Teleoroentgenograms provide more information regarding underlying diagnosis and lower limb alignment and therefore are more clinically relevant than X-ray scanograms ²⁰⁸. A comparison of computed radiography scanogram and teleoroentgenography noted a 4.6% (33mm) magnification when measuring full limb length with the teleoroentgenogram but only a mean difference in LLI of 5mm ¹⁸⁶.

X-ray scanogram provides reliable measurements with minimal magnification but teleoroentgenography standing AP computed radiograph is a more comprehensive assessment technique, with similar costs and less radiation exposure. Orthoroentgenography has been shown to be the least accurate method ¹⁸⁶.

2.25 Computerised Tomography (CT)

In 1984, Helms claimed that the CT scanogram was the gold standard of measuring leg length. This is an anteroposterior (AP) scout view from iliac crest to ankles ¹⁸⁶. It has been suggested that CT scanograms are quicker, more accurate, and deliver 50-100 times less radiation than other current techniques ^{215,216}, other studies have supported these findings with values of 0.7mSv for teleoroentgenography compared to 0.1 - 0.2mSv for a CT scanogram ²¹⁷.

Single AP scout views may show erroneously low measurements in patients with flexion deformities and a lateral scout view may be performed rapidly and easily without changing the position of the patient in the presence of complex

deformities^{186,218-220}. CT also gives minimal magnification error and motion artefact is easily detected²²⁰

Two cadaveric studies by Temme and Aaron et al supported results for CT scanograms over orthoroentgenograms^{221,222}. Aaron et al stated that both methods gave accurate results for length of the femur at neutral, 15, 30 and 45° of flexion at the knee but stated that CT was significantly more accurate than orthoroentgenography in the measurements of length of the tibia and of total length of the limb when the knee was flexed to 30 degrees or more. Aaron stated the cost and time necessary to complete an examination were comparable for the two methods but that CT delivered only 20% of the radiation of orthoroentgenography. They concluded that CT is more accurate than orthoroentgenography for the measurement of LLI in patients who have a flexion deformity of the knee²²². CTs are more beneficial in defining anatomy and in patients who may require further surgery or interventions¹⁹². They also have excellent correlation in terms of inter- and intra-observer reliability^{223,224}.

Much of the early literature in support of CT scanograms is taken from case reports and cadaveric studies. Proponents of CT scanography cite accuracy, reproducibility, decreased exposure to radiation compared to other long leg views, as well as technical ease and speed of image acquisition³. Many authors use the CT scanogram as the 'gold standard' to which they compare all other methods^{225,226}. The limitations include the limited availability, they may not be readily available in clinic and may require a separate visit to hospital^{186,208}.

2.26 Magnetic Resonance Imaging (MRI)

MRI is traditionally used for soft tissue imaging but has recently emerged as a possible non-ionising method of measuring LLI. Images are obtained from T1 weighted spin echo sequence and coronal images are selected for

assessment of femoral length using the femoral head and medial femoral condyle as bony landmarks ¹⁸⁶.

A cadaveric study comparing MRI with traditional methods of measurement (radiographic scanogram and CT scanogram) showed very high intra- and inter observer reliability (ICC 0.99) for all three techniques but concluded MRI was the least accurate ²²⁷.

MRI is more expensive and less available than plain radiographs or CT but has the benefit of not requiring ionising radiation, enabling it to be used in children and in cases where repeated measurements are required. MRI scans may not be suitable for elderly patients who are unable to lie still for up to thirty minutes and are contraindicated in patients with certain implantable devices.

2.27 Ultrasonography

Ultrasound is not frequently used to measure LLI in the UK but it has been published by various authors in Europe, who cite its benefits as being a simple, non-invasive test which does not require ionising radiation, ²²⁸⁻²³¹. LLI is measured by using a transducer to identify the bony landmarks at the hip, knee, and ankle joints ²³⁰.

Krettek et al. and Junk et al performed two separate studies comparing ultrasonography with both direct and indirect clinical measurements and teleoroentgenogram. Their results showed that ultrasound measurements were more accurate than clinical methods but less accurate than the teleoroentgenograms ^{229 232}. Terjesen et al compared measurements of LLI using ultrasonography with results obtained using standing radiographs in 45 patients. There was a mean difference of -1.9mm difference between the techniques with ultrasound being less reliable ²³⁰.

Ultrasound is inexpensive, requires no radiation and in the hands of experienced users gives reliable results with high intra-observer reliability ²³³

but it does not allow comprehensive assessment of lower extremity including angular deformities²³⁰.

2.28 Conclusion

Clinical methods of measurement may be effective as a screening tool but if precise LLI measurements are required then radiological measurement is indicated for quantification of LLI^{189,190,198}. There is no consensus about which single method of radiological measurement is the most accurate and choice will depend on available facilities and patient factors. The published literature comparing radiological methods have many limitations; they are mostly retrospective, with multiple confounding variables and high quality non-cadaveric data is lacking due to ethical concerns about subjecting patients to several diagnostic modalities for direct comparison.

It can be concluded that for a simple primary total hip replacement with no previous history of trauma and no perceived LLI, a plain AP radiograph of the pelvis will be sufficient. Any factors that may lead to LLI or any perceived LLI should warrant further assessment with full length imaging.

2.29 Clinical presentation of LLI following total hip replacement

LLI is an independent risk factor in the outcome of total hip replacement and can result in a disappointing outcome despite an otherwise satisfactory operation¹⁵. The clinical presentation of LLI post total hip replacement varies between patients, even for the same magnitude of LLI. Not every patient with LLI will be symptomatic but the proportion increases as the LLI increases^{145,150}. Clinical symptoms are not mutually exclusive and may include one or a combination of mechanical symptoms such as limp or back pain, to localised hip pain or frank neurological deficit. Pain and neurological deficit caused by LLI is more likely to present earlier than mechanical symptoms.^{127,185}. The

common clinical presentations of LLI following total hip replacement are discussed in the following sections.

2.30 Pain

Patients with LLI may complain of pain around the hip or in other joints due to compensatory mechanisms which occur in an effort to accommodate the LLI. These mechanisms include knee flexion, increased hip flexion, equinus foot position and eversion of the calcaneum^{3,234}. Patients may present with a typical stance of the long leg flexed at the knee and hip (Figure 2.7).



Figure 2.7. Typical stance of patient with LLI.

Longer leg is flexed at the knee and hip.

There is evidence that pain and osteoarthritis may be present in the short or long limb. Golightly et al. concluded that the 'short' leg was at increased risk of developing osteoarthritis with LLI of greater than 20mm¹⁶⁻¹⁸ but other studies have shown this to be the case in the presence of as little as 5- 9 mm LLI^{3 235}. Gofton et al concluded that hip OA was 84% more common on the

side of the longer limb ²³⁶. Tallroth followed up 193 asymptomatic individuals for 29 years and concluded that patients with LLI were three times more likely to require arthroplasty on the 'long' leg ²³⁷.

Lower back pain arising from LLI is thought to be mechanical in nature due to pelvic tilt, followed by a compensatory functional scoliosis of the spine toward the shorter leg. Consequent abnormal loading of the lumbar spine has been suggested to be the cause of low back pain ⁷¹. Functional scoliosis can be detected with an LLI of 6mm ³.

2.31 Mechanical symptoms

Mechanical symptoms including gait disturbance, periarticular muscle spasm and fatigue, muscular tightness and alteration of wear characteristics of the total hip replacement are the commonest clinical presentation of LLI following total hip replacement ¹⁷⁶.

Mancuso reported that a limp is an independent risk factor for dissatisfaction following total hip replacement ¹⁵, and the commonest cause of limp post total hip replacement is LLI ¹³³. Edeen noted that up to 41% of patients with post-operative LLI walked with a noticeable limp ¹⁴⁸, one study concluded that patients with LLI greater than 10mm had twice the incidence of limping compared to those with LLI of less than 10mm ¹⁵⁸. There are links between perceived LLI and limp; with a limp being present in 31% of a group with perceived LLI and only 9% in a group with no perceived LLI ¹⁶⁸.

Observations of gait with artificial LLI revealed several compensatory strategies. The most common was a 'steppage' gait (increased hip and knee flexion), followed by circumduction (increased hip abduction during swing phase), vaulting (increased plantar flexion during step phase) and hip-hiking (increased ipsilateral lumbar side flexion during swing phase). Subjects often used more than one and as many as three compensatory mechanisms simultaneously ²⁰. Patients with LLI have may also exhibit lower gait velocity,

reduced stride length, decreased hip range of motion, reduced hip moment and greater asymmetry in hip contact force ²³⁸.

A LLI of 10 mm or more has been shown to result in altered activity in several muscle groups making it difficult to maintain a resting standing position ⁷¹. Mobilising with a LLI increases physiological demands, persistent knee flexion on the longer side during gait leads to overuse of the ipsilateral quadriceps and hamstring musculature ²³⁹ with lengthening of up to 30mm causing up to a 54% increase in quadriceps activity ²⁰. Patients with LLI have been shown to expend significantly more kinetic energy mobilising unaided than when wearing their corrective shoe ²⁴⁰. Gurney et al. suggested that the increasing physiological demands of mobilising with a LLI are measurably increased for LLI beyond 20mm in terms of oxygen consumption and perceived exertion. They found a 'breakpoint' between 20 and 30mm of leg lengthening in older patients above which causes significant quadriceps fatigue in the longer limb and difficulty in walking. They also noted that this breakpoint, beyond which the patient will fatigue, may be as small as 20mm in those with poor cardiorespiratory function or neuromuscular disease²⁰. Young people seem to be less physiologically affected by LLI, one study of young athletes showed no increase in physiological demand even with LLI of 60mm ²⁴¹. Most of these conclusions have been made from studies with artificial LLI and therefore only address acute changes in leg length. Chronic adaptations are possible and may reduce the amount of functional loss over time ²⁰.

It is broadly agreed that shortening is better tolerated than lengthening however some studies have shown mechanical symptoms may be worse with shortening as this leads to length tension disadvantage for the abductor muscles and subsequent decrease in strength ^{148,242}, see Figure 2.8.

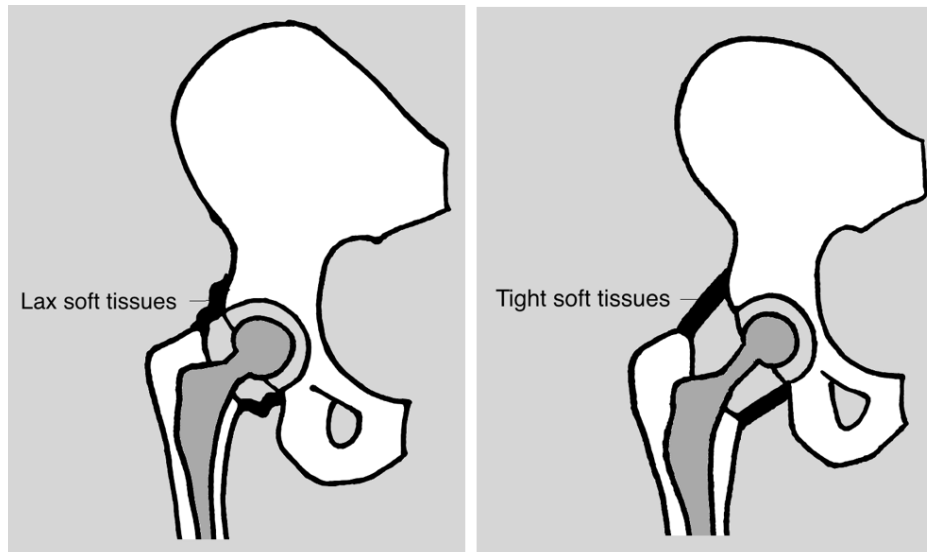


Figure 2.8. The effect of neck length on soft tissue tension.

One cohort study with matched controls showed that 10mm of shortening affected patients walking capacity significantly more than 10mm of lengthening, and shortening, although less common, had a stronger impact on the desired outcomes and on patient satisfaction than lengthening. However, this study had no standardised method of measurement, including both clinical and radiological methods, and measurements were made by the operating surgeon and therefore possibly subject to examiner bias²⁴³.

The literature agrees that LLI will result in altered wear properties of the arthroplasty but there is less agreement about the precise mechanism. Friberg proposed that as LLI patients develop a pelvic obliquity to compensate for LLI, the hip on the longer limb becomes adducted and the load bearing surface on that side will be reduced, therefore increasing the force per unit area⁷¹. Bhave et al. studied patients with a mean LLI of 49mm and concluded that the longer limb bears greater load for longer in the gait cycle than the shorter limb²³⁴. The altered biomechanics from altered gait may lead to edge loading, and in turn increased wear and loosening⁷⁰⁻⁷². Barnett et al. found no increase in wear rate. They studied five patients with LLI of 12 to 30mm found that although the hip in a long limb may be held in adduction, they showed a reduced range of motion which offset this. This analysis assumed that the contact remained within the cup, and that no edge loading was present¹⁹.

A study comparing rates of aseptic loosening showed rates of 23.9% in cases with a lengthening of 10 - 20mm which increasing to 50% in cases with a lengthening of 30 – 50mm⁷³. The work of Pauwels demonstrated that LLI of half an inch (12mm) can change the angle of Wiberg of the hip on the side of the LLI by as much as 2.3° which is significant enough to alter the normal gait mechanics and eventually lead to degenerative changes of that hip²⁴⁴. Overtight ligament tension can also have a negative effect on joint lubrication and increase wear. Subjectively patients with a 'tight' hip complain of joint pain and stiffness⁷⁴. LLI of as little as 10mm has also been implicated in a greater incidence of stress fractures¹⁵³.

2.32 Neurological symptoms

Nerve palsy is a recognised complication of total hip replacement with an overall prevalence of 0.6 - 2.5%^{128,245} in primary total hip replacement and 3 to 7% in revision total hip replacement. In 47% of cases the aetiology is unknown but in the remainder, the commonest cause is traction (20%)²⁴⁶. The sciatic nerve, or the peroneal division of the sciatic nerve, is involved in nearly 80% of cases²⁴⁷.

The risk of nerve palsy correlates with the amount of lengthening during total hip replacement but there is no known safe threshold. It has been shown to occur with as little as 13mm lengthening²⁴⁸ but it seems more likely when lengthening exceeds 25mm¹⁶⁰. Other studies have quoted much higher thresholds, with lengthening over 40mm associated with nerve palsy in 30% compared to 0% of cases in which lengthening was less than 40mm²⁴⁶. Edwards et al. reported an association between lengthening and nerve palsy and noted that peroneal palsy occurred with a mean LLI of 27mm (19mm to 37mm) lengthening and sciatic nerve palsy occurred at a mean LLI of 44mm (40mm to 51mm)¹²⁸.

The sciatic nerve is vulnerable to traction following limb lengthening, this may lead to motor weakness, sensory alterations or referred pain in the distribution

of an affected nerve ^{127,248-250}. Damage to the peroneal branch of the nerve leads to motor or sensory loss in the lateral compartment of the leg, including foot drop. Damage to the sciatic nerve before its division would also lead to sensory or motor loss in the posterior compartment of the leg, and loss of plantar flexion of the ankle and toes. It may also present as painful neuritis in the absence of any other motor or sensory loss ²⁵¹.

Females are at higher risk of developing symptoms due to their reduced femoral offset and a shorter stature increases the effect of any given magnitude of lengthening ^{127,128,248}. Other risk factors include the posterior approach, revision operations ¹²⁸ and total hip replacement for developmental dysplasia ¹²⁷. Patients with pre-existing degenerative disease around the spinal cord or exiting nerve roots may be more susceptible to neuropathic symptoms. Any resultant lengthening post total hip replacement may put these sensitive nerves under increased tension, resulting in a “double crush” syndrome ^{252,253}.

The role of electromyographic monitoring is controversial but in cases where lengthening of over 20 to 30mm is necessary or anticipated, it may be useful ^{254,255}. In these cases, patients should be counselled regarding the risks of symptomatic nerve injury.

Prognosis for recovery following nerve injury is variable. Early detection of traction injuries improves the prognosis ²⁴⁷. Patients with some residual motor function or who recover some motor function within two weeks of surgery have a good prognosis for recovery ²⁴⁷. At least 70-80% of cases can expect at least partial recovery ²⁵⁴. When indicated, surgical correction should be performed as soon as possible, thereby improving the chances of and shortening the time to complete recovery ²⁵⁰.

2.33 Litigation for LLI post total hip replacement

There is a paucity of reliable data indicating the frequency with which litigation following LLI occurs. Bhutta et al examined claims made to the National Health Service Litigation Authority (NHSLA) between 2002 and 2007 and identified an upward trend in malpractice claims within the UK. They reported a total of 352 claims made for total hip replacements with a total pay-out of £8,558,076. The mean pay out was £75,022 with a range of £1,000 to £448,335. LLI following total hip replacement was the fifth most common cause of litigation following total hip replacement with 41 claims made, comprising 11.6% of all claims regarding total hip replacement ²⁵⁶.

McWilliams et al performed a review of claims made to the NHSLA between 1995 and 2010. During this time, there were a total of 1,004 claims relating to total hip replacements which corresponded to 11% of orthopaedic claims and 10% of the total cost. LLI following total hip replacement was the fifth most frequently cited cause of claim (after neurological deficit, technical error, infection and miscellaneous causes). There were 100 claims made which comprised 8.7% of claims for total hip replacement, amounting to a total cost of £3,872,000. The highest single pay-out for LLI was £595,000 with a mean pay-out of £84,000 ²⁴. The absolute number of claims per annum has remained relatively stable between the two time periods (575 claims during 1995 to 2003, and 581 between 2003 and 2010), but has decreased as a proportion of the total procedures performed ²⁴.

In the USA LLI following total hip replacement has been cited as the most frequent cause of litigation following total hip replacement ²¹ and 7.9% of orthopaedic surgeons have been named as defendants in legal claims related to LLI ¹⁴². LLI following total hip replacement can ruin an otherwise satisfactory operation leaving the patient and surgeon frustrated. If the possibility of LLI has not been discussed pre-operatively, the patient may presume the surgeon has done something wrong, when, in fact from a technical perspective the total hip replacement may have been performed well. The only omission was to not counsel the patient regarding the risk of LLI. It is vital to document all

conversations with patients meticulously, this is especially important in patients at higher risk of developing or being sensitive to LLI ^{143,257,258}. Errors in information and of omission still lead to confused patients, leaving surgeons and Health Trusts open to litigation. This knowledge led to the development of standardised consent documents by the BOA (see section 2.5) ^{143,144}.

2.34 Patients at increased risk of developing symptomatic LLI

It is possible to categorise patients who are at increased risk of developing symptomatic LLI into patients who are more likely to have a symptomatic LLI and patients who are more sensitive to being symptomatic with any given magnitude of LLI. Identification of these 'at risk' patients will encourage increased care with leg lengths at the time of surgery.

2.35 Patients more prone to LLI

Any factors that increase the technical difficulty of a total hip replacement makes it more likely a patient will be left with a symptomatic LLI. Increased body mass index (BMI) leads to difficulty in positioning implants correctly and makes intra-operative assessment of LLI more difficult and less sensitive ¹⁷⁵.

Patients with atypical bony anatomy such as a narrow or bowed femur, or any anatomical variance following trauma or hip dysplasia makes alignment and positioning of implants more difficult ¹⁸⁰. Patients with pre-existing extra-articular LLI or a high hip centre are also more susceptible ²⁵⁹.

Patients who have bilateral hip disease resulting in shortening in both lower limbs should be made aware that following total hip replacement, which aims to restore 'normal' anatomy and the center of femoral rotation, is likely to cause a LLI until the second hip is replaced.

2.36 Patients more sensitive to LLI

Several patient characteristics have been identified which decrease the ability of a patient to compensate for any given magnitude of LLI. It is important to be aware of these groups as they may be sensitive to LLI at a magnitude that would not affect other patients. In patients of short stature (less than 5' 6"), any given amount of LLI will represent a greater percentage of the patient's overall height ¹⁵⁵. A taller person (around six feet) can tolerate LLI of 10mm without significant problems unless associated with pelvic tilt ¹⁴⁵. A narrow pelvis produces a greater pelvic obliquity for any given LLI ²⁶⁰ and patients with short, varus femoral necks may be inadvertently lengthened due to inaccurate implant selection ²⁶¹.

Younger people are able to detect artificial differences in LLI more accurately than older individuals, and there is a significant correlation between the decade of life and the ability to detect a limb length discrepancy ¹⁸². It has been proposed that 6.4mm of LLI in an athlete is as important pathologically as is 19mm in a non-athlete ¹⁵⁴. However younger patients will be more able to 'adapt' to LLI with compensatory methods such as pelvic tilt whereas in an older adult this compensation may not be possible due to decreased spinal motion ^{20,182}. Patients with pre-existing scoliosis or knee and ankle deformity of the opposite leg will be less able to compensate with added iatrogenic LLI ^{127,156}.

Patients with co-existing poor cardiorespiratory function and low physiological reserve may be unable to tolerate the increase in physical effort due to loss of efficient locomotion that occurs in a vaulting gait caused by LLI. Gurney concluded that elderly patients with substantial pulmonary, cardiac, or neuromuscular disease may have difficulty walking with a limb-length discrepancy as small as 20mm ²⁰.

Patients with a pre-existing asymptomatic LLI may be less likely to tolerate any increase in their leg length inequality as they are pushed over a threshold of what they are able to compensate for. Approximately 75% of patients with

end stage osteoarthritis present with a shortened leg due to loss of articular cartilage which allows superior migration of the femoral head^{148,155,156,205,262}. If the patient is already 'short' on the non-operative side (whether this is perceived or not), this may result in a relatively modest increase in leg length becoming symptomatic post-operatively. Patients should be advised that mild lengthening on the operated side often takes place, equalising it to the contralateral side in many cases but occasionally relatively lengthening it in others. Patients who feel that the arthritic hip is longer pre-operatively but actually have equal leg lengths are particularly at risk for perceiving that they have LLI post-operatively²⁶³. It is important to identify patients who are prone or sensitive to a symptomatic LLI and to counsel them appropriately^{249,259}.

2.37 Techniques to minimise LLI

There are multiple documented methods of techniques of measuring and minimising total hip replacement related LLI. They can be further subdivided into techniques employed pre-operatively and intra-operatively.

2.38 Preoperative techniques

The pre-operative evaluation of any patient undergoing total hip replacement should include an accurate assessment of pre-operative LLI including a detailed history and physical examination. The examination should include assessment of the patients' stance and gait to identify pelvic obliquity, weak abductors and dependence on walking aids. The levels of the iliac crests should be compared with the patient standing and the thoracic and lumbar spine assessed for coronal or sagittal deformity. If scoliosis is present it should be classified as structural or functional using techniques such as the Adam's forward bending test. It is important to identify the type of scoliosis as a structural scoliosis will render the patient potentially sensitive to any change in leg length, whereas a non-structural scoliosis may be caused by LLI and could be exacerbated by total hip replacement¹⁸⁰.

Measurement of pre-existing LLI should be carried out as a matter of routine. True leg length should be measured from the ASIS to LM or indirect blocks test. Apparent leg length should be measured from the xiphisternum to medial malleolus. If true LLI is present this can be further examined by using the Galeazzi test to identify whether the inequality is above or below the knee. If above the knee, examining Bryant's triangle will identify LLI at the level of the neck of the femur²⁶⁴. Clinical measurement is important in identifying LLI but should not be relied upon as a single qualitative measure.

A pre-operative AP radiograph of the pelvis should be examined for existing LLI from the hips, and to look for any factors that may affect component choices intra-operatively. The radiograph should be centered on the pubic symphysis with a marker ball, following local protocol. If there is pre-existing LLI it should be quantified. Of the two common methods of measuring radiographic LLI, the Woolson method is proven to be most accurate and reproducible¹⁸⁴.

Previous fractures, infection, physeal arrest and various dysplasias may result in LLI that may not be apparent on a simple radiograph of the pelvis so if there is anything indicating this in the history then further imaging should be performed. A lateral radiograph of the hip provides information about atypical bony anatomy in the hip or femoral shaft and full leg views yield information about LLI distal to the proximal femur.

Surgeons advocate meticulous pre-operative positioning of the patient to allow access for testing LLI intra-operatively and ensuring the table is level with the floor^{12,23}.

Müller introduced a templating technique in 1975 which remains remarkably unchanged today²⁶⁵. He advocated templating, stating

“templating forces the surgeon to think in three dimensions, greatly improves the precision of surgery, shortens the length of the procedure, and greatly reduces the incidence of complications”.

However, this assertion was not supported by any objective data^{25,266}

Templating identifies abnormal bony anatomy (such as acetabular roof deficiency, osteophytes or subchondral cysts), an estimation of component sizes, anticipated depth of seating of femoral component within the canal, the optimal level of femoral neck cut, and anticipated position of acetabular component. The aim is to reproduce the 'normal' anatomic center of rotation and restore femoral offset whilst maintaining equal leg lengths^{180,267}. Templating forces the surgeon to scrutinise the radiographs and anticipate difficulties such as resection of osteophytes or requirement for bone grafting,

Templating can be performed on the normal, contralateral hip and changes in limb length extrapolated to operative hip, or template on operative hip. With the advent of digital radiography, it is now common to use specialist software designed for implant specific pre-operative planning and digital templating^{268,269}.

Templating has the potential to reduce errors in component size and position in total hip replacement. If there is a large difference between the templated and the intra-operative implant size this will alert the surgeon to a potential problem²⁷⁰. Templating allows estimation of the femoral cut and size of implants. This is especially important with uncemented stems as fixation relies on a press fit. If the component is undersized it will not be stable and oversizing can lead to intra-operative fractures. If performed correctly, templating can minimise intra-operative guesswork, improve rates of LLI and decrease surgical time²⁷¹.

Standardised pre-operative radiographs and meticulous patient positioning are vital²⁶⁵. Hofmann advocated an AP pelvis radiograph distal to the iliac wings, focussed on the hip joints, with the feet pointing forwards to standardise rotation of the lower extremities, with the legs in neutral to prevent abduction or adduction of the limb¹⁶⁰. It has been argued that an arthritic hip frequently has an external rotation deformity therefore the AP pelvis radiograph should be made with the femurs in 20° of internal rotation to avoid underestimation of

femoral offset⁶³. Other studies have shown no improved results with a strictly standardised X-ray technique for positioning compared to non standardised techniques¹⁸⁴.

Pre-operative templating for predicting component size has demonstrated variable results. Unnanuntana et al evaluated the accuracy and clinical usefulness of pre-operative templating in 109 uncemented total hip replacements. They found that the size of the prosthesis was exactly predicted in 42.2% of acetabular and 68.8% of femoral components. The accuracy increased to greater than 90% if the prosthesis size was within one or two sizes for femoral component and acetabular components, respectively²⁷². Knight found that the correct implant size was predicted correctly for 62% of acetabular cups, 78% of cemented stems but only 42% of the cementless stems⁹². Other studies support the notion that cemented components are easier to template and yield better agreement between pre-operative plan and post-operative results⁸⁶. Egli published excellent results for their method of templating, stating the femoral and acetabular sizes were correctly predicted in 92% and 90% respectively. Their mean post-operative radiological LLI was 2 ± 1 mm and they claimed more than 80% of intra-operative difficulties were anticipated¹⁴⁶. In a study by Gonzales et al. the acetabular component size was predicted exactly in 83%, and to within +/-1 size in 99%; the femoral component size was predicted exactly in 78% and within +/-1 size in 99%. Their average post-operative LLI was 1.71 mm²¹³. A magnification error of 6% is sufficient to give a single step error in the size of the acetabular component but at least 30% error is required to produce one size error for femoral component¹⁴⁶.

Woolson et al published the results of their pre-operative planning technique. They measured the amount of head and neck to resect from a reference point on the superior aspect of the femoral head and chose the length of the femoral neck pre-operatively. Their mean post-operative LLI was 1mm, 97% had less than 10mm LLI and 86% had less than 6mm LLI. Statistical analysis of these results showed that the method is more accurate for patients with smaller LLI pre-operatively²⁰⁵.

It can be concluded that meticulous pre-operative templating aids in the restoration of limb length and prediction of appropriate implant types and sizes and should be performed as a matter of routine⁶³, however pre-operative templating alone has limitations when components are not placed exactly where pre-operative plans dictate⁹². Planning and execution are not synonymous and even in the presence of meticulous pre-operative plans, component malpositioning in any one plane during surgery may significantly alter the results achieved post-operatively and other intra-operative techniques should be employed¹⁶⁰.

2.39 Intra-operative techniques

There are numerous methods of assessing and correcting LLI that may be employed intra-operatively, these may be further sub-divided in to indirect and direct methods.

2.40 Indirect tests

Indirect methods of measuring LLI rely on the tension of the soft tissues around the implanted total hip replacement as a surrogate indicator of leg length. They guide accuracy of leg length and stability, assuming that the implanted total hip replacement constituents are a similar size to the native hip joint. In cases where total hip replacement is performed in a case of a chronically shortened lower limb in cases such as developmental dysplasia of the hip these tests may not be reliable. Indirect tests are typically performed with the trial components in situ and this enables the surgeon to make adjustments to length or offset by using various combinations of modular sizes and offset designs to obtain an optimal clinical result.

Four indirect methods of intra-operative assessment of LLI are discussed below.

The Shuck test

The Shuck test was first described by Charnley and allows assessment of soft tissue tension around the hip joint ^{12,267}. It is performed by placing a swab around the femoral neck and applying longitudinal traction in the direction of the femur. The soft tissue envelope surrounding the hip joint exerts a resistive force that allows a certain amount of distraction of the femoral head from the acetabulum but prevents it from dislocating completely ²⁷³. If the leg is “short”, the soft tissues will be too lax and it will be possible to distract the femoral head too far or even dislocate it. If the leg is ‘long’ then the soft tissues will be tight and it will not be possible to distract the femoral head far enough. The ideal amount of shuck and therefore the tension of the soft tissues around the hip is a subjective decision based on feel and surgical experience ¹⁷⁶; it is a very difficult skill to teach. By testing various combinations of neck offsets, neck lengths and possibly acetabular liners, the surgeon can assess which trial components provide optimal tensioning of the soft tissue structures and therefore leg length ²⁷⁴.

Rice et al performed a prospective randomised double blinded study of 81 consecutive total hip replacements and compared three techniques used at their institution. They concluded that the abductor shuck technique is the most reliable intra-operative indirect test but that the techniques should be used in combination ²⁷⁵. Woolson cautioned against solely relying on the Shuck test to determine intra-operative leg length as it frequently causes excessive lengthening ²⁷⁶. Others state that when performed incorrectly the Shuck test can lead to lengthening ²⁷⁷.

The kick test

The kick test utilises the tension in the quadriceps muscles to assess LLI intra-operatively. The test is performed in the lateral position, firstly whilst positioning the patient in the anaesthetic room to assess pre-operative tension, then repeated after the total hip replacement has been implanted.

The operated leg is lifted and held parallel to the contralateral leg and the leg is extended around 20° more than the contralateral leg so that the anterior edge of the patella is 10cm posterior to the anterior edge of the contralateral patella. The knee is then flexed to 90° and the ankle is released, if the leg is the correct length it will come to rest where it is placed^{259,278}. If the leg is too long the leg will passively kick forward due to increased tension within the rectus femoris. As an arthritic hip joint tends to be shorter owing to loss of cartilage and superior migration of the femoral head, lengthening may produce a kick, but excessive kick can mean significant lengthening^{160,259,279,280}.

The 'kick' occurs due to the anatomy of the rectus femoris muscle (Figure 2.9). The reflected head of rectus femoris arises at ilium, just superior to the acetabulum and inserts in to the quadriceps tendon before traversing the knee and inserting through the patellar tendon in to the anterior tibia²⁸¹. Its functions are to flex the hip and extend the knee therefore hyperextending the hip will force the knee to extend in cases of lengthening.

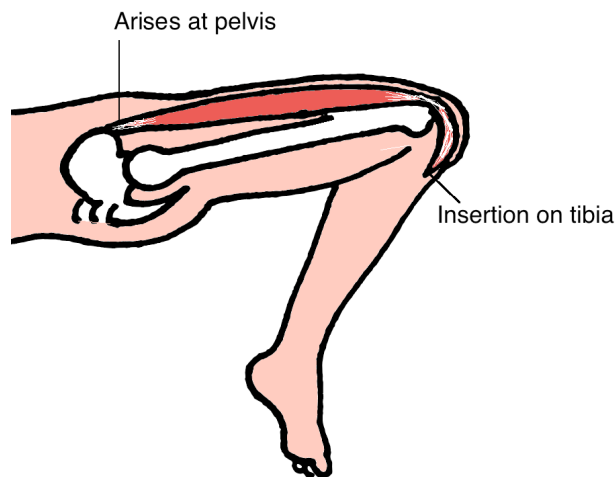


Figure 2.9. Rectus femoris muscle.

The Ober test

The Ober test is an assessment of iliotibial band (ITB) tension. It is performed in the lateral position with the lower, contralateral limb flexed at the hip to fix the lumbar spine. The knee of the operated leg is flexed to 90° and then the

hip is extended and abducted. If the leg is long, the ITB will be tight and the limb will remain in an abducted position (a positive test). If the leg is the correct length or short then the ITB will not be tight and the limb will return to the neutral position or in to adduction (a negative test)^{259,282,283}.

Short rotator apposition

If equal leg length has been attained after insertion of the total hip replacement components the soft tissues around the hip including the capsule and short external rotators should be well opposed and repair without too much tension or slack.

Indirect techniques of assessing LLI are an assessment of soft tissue balancing rather than direct tests of leg length. They are inherently subjective and are dependent on surgical skill and repeatability. They are difficult to teach to junior surgeons but they do not rely on expensive or invasive devices. Indirect tests may be misjudged in the presence of neuromuscular blockade such as local or regional anaesthetics. One study showed LLI was present in 87% of patients who received regional anaesthesia but only 47.6% of those who had a general anaesthetic¹⁵². Results from another study showed that patients who had had an epidural had decreased incidence of having an LLI greater than 10mm but there was no significant differences were associated with a general or spinal anaesthetic¹⁵⁸. It is thought that an epidural provides a less potent muscle relaxant effect compared with spinal or general anaesthetic²⁸⁴ and that with an epidural the patients muscles are in a more 'physiologically' normal state, therefore assessment of LLI intra-operatively will be more accurate¹⁷⁵.

Indirect tests are frequently used in conjunction, they are quick and simple to perform, and although they are subjective, an experienced arthroplasty surgeon will be able to reproduce the tests effectively as a useful surrogate evaluation of LLI. Soft tissue laxity can create a conflict between leg length equality and hip stability, in these situations, stability is more important, leg lengthening may be necessary to achieve the primary goal⁶⁶

2.41 Direct tests

Two simple direct measurements of leg length are measuring the calcar cut from the lesser trochanter using the index finger as a measure, and assessing the distance from the shoulder of the stem or rasp from the tip of the greater trochanter. These give a simple estimation of distance that can be compared to the position on pre-operative templates. Charnley advocated an intra-operative comparison of leg length by palpating the medial malleoli through the surgical drapes whilst in the supine position ¹². In the lateral position, it is possible to directly measure the length at the knees.

There have been more than 40 papers published since 1985 describing various intra-operative techniques or devices to directly measure leg length. Most of the earlier techniques rely on directly measuring between a stable fixed reference point such as a Steinmann pin, wire or screw in the pelvis to a fixed point on the femur before dislocation of the femoral head and attempting to recreate this same measurement with the new implanted hip joint. These methods are heavily reliant on accurate re-positioning of the leg between measurements. Small changes in adduction-abduction, flexion-extension or internal-external rotation between pre- and post-reconstruction measurements can lead to substantial errors in assessing leg length changes during surgery and can lead to the surgeon making poor decisions based on this inaccurate information. Sarin et al demonstrated that when combining acetabular and femoral height as a single measurement, 5° degrees of abduction or adduction malpositioning caused 8mm of apparent change in leg length and 10° of malpositioning resulted in 14-17mm error. The rotational malalignment between the pelvis and femur accentuates the effects of this, as the measurements are made away from the rotational center of the joint ¹⁶⁴.

The first documented intra-operative technique to measure LLI was by McGee et al in 1985. They used a fine guide wire inserted in to ilium and bent in to a 'U' shape to mark referencing points pre- and post-reduction. Their report claims to have been successful in 200 patients but they do not provide any radiological or clinical evidence of this. Intra-operative displacement of the

guidewire makes this technique sensitive to measurement error ²⁸⁵. In an attempt to reduce the risk of errors associated with displacement of a reference pin, Woolson and Harris designed a three pronged iliac reference device with adjustable caliper and had excellent results of less than 6mm LLI in 89% of patients. They also measured from the top of the femoral head instead of the lesser trochanter as they argue it is better visualised intra-operatively. Whilst the three prongs may lead to an increase in stability, it also risks propagating fractures through the three drill holes and requires a separate incision over the pelvis ²⁰⁰. Jasty et al used a similar calliper device in a consecutive series of 85 patients undergoing total hip replacement. They reported only 16% of their patients had LLI post operatively but their measurements were made clinically and there was no validation with radiological measures. It was a retrospective study and LLI was measured by the operating surgeon who was not blinded ¹⁷⁵.

In 1999 Naito described a technique using a Steinmann pin and adjustable straight caliper ¹⁹⁷, Figure 2.10. In 2004 the same group published results from a new L-shaped caliper device and showed that this showed significantly improved correlation between intra-operative and post-operative measurement ²⁸⁶. A major limitation with these studies is that the accuracy of measurement technique was not discussed and the correlation between predicted and actual lengthening was not noted.

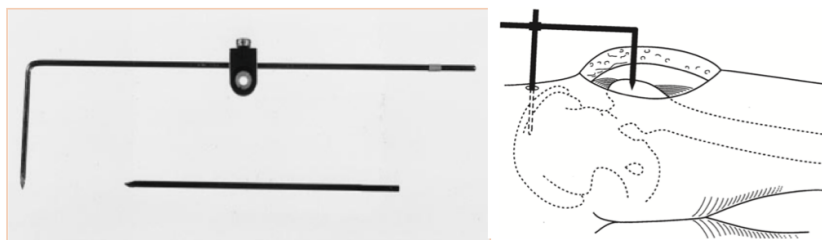


Figure 2.10. Naito et al's straight caliper ¹⁹⁷

In 2008 Takigami et al published positive results for their measuring device called the callipers dual pin retractor (CDPR). Their study consisted of 56 patients undergoing primary total hip replacement. Average post-operative LLI was 4.2 mm, all of whom were asymptomatic. Their dual pin minimised

the risk of loosening and the results were well validated by radiological and functional outcomes ²⁸⁷.

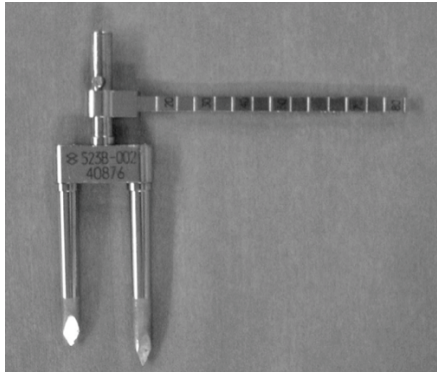


Figure 2.11. Takigami et al's calipers dual pin retractor.

Bal ²⁸⁸ and Huddleston described separate techniques of using a Steinmann pin fixed in the pelvis with good results but this technique is sensitive to error as the Steinmann pins have to be removed and replaced precisely in between measurements. Huddleston however did recognise the importance of reproducibility and introduced a VacPac to create a rigid molded cradle to allow placement of the leg back to or near its initial position at the time of measurement ¹²⁶.

Desai described placing a Judd in to the ilium just superior to the acetabulum to provide a stable reference point, tying a braided suture and marking a point on the greater trochanter with a diathermy mark before and after reconstruction. Again, this technique relies on the attitude of the operated leg maintaining the same position but it does improve upon previous techniques as the Judd pin stays does not have to be removed and replaced ^{70,289}.

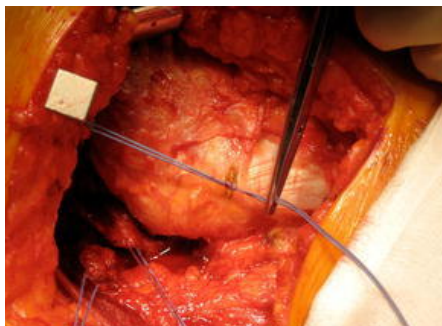


Figure 2.12. Desai et al's technique showing Judd pin and suture ²⁸⁹

Beverland's group recognised that previously discussed techniques of calipers correct LLI by combining the effects of both acetabular and femoral height to one single measurement and claimed that this was anatomically incorrect and that the contributions made by the acetabulum and the femur should be considered separately. They introduced their caliper in 1991 and after modifications in 2005 it has been used in over 9000 total hip replacements. The published results of a cohort of 200 total hip replacements, show a mean post-operative LLI of 0.38mm. 94% of patients had LLI of 6mm or less and a maximum LLI of $\pm 8\text{mm}$ ²⁹⁰. They validated the device in 2012 using a co-ordinate measuring machine and CT studies. Beverland advocated the use of the caliper to reduce reliance on templating and avoid inaccuracies that can occur from taking measurements from structures such as the lesser trochanter that has an indeterminate start point due to its curved profile. Although this method is one of the better validated techniques it is still susceptible to errors during measurement. The measuring bar of the caliper must be parallel to the coronal plane of the femur which is difficult to assess intra-operatively, and the technique is reliant on the femoral head being spherical and therefore not suitable for advanced stages of wear of superior femoral head in AVN, or in the presence of large medial osteophytes on the fovea of the femoral head²⁹¹.



Figure 2.13. The Belfast caliper^{290,291}

Both Ranawat¹⁴⁵ and Ritter²⁹² recognised that the current methods of pelvic reference points had potential for error due to their distance from the center of the hip and advocated using the infracotyloid groove as a pelvic reference point. They claimed that it was less sensitive to variations in measurement resulting from the position of the leg. Ranawat's mean post-operative LLI was 1.99 (range -7 to +8mm), and 87% had lengthening of 6mm or less. However, they also used strict templating and soft tissue tests intra-operatively so it cannot be concluded that the excellent results are entirely due to accuracy of the new landmark. Ritter's series of patients all had LLI of less than 3mm and 96% had LLI of less than 1mm. As with other techniques using Steinmann pins, this technique is sensitive to inaccuracies from inaccurate pin placement for example in the presence of large osteophytes.

Techniques selecting points of reference within the femur only, so as to negate the variations in measurements with different limb positions during surgery have been proposed¹⁰³. Bose and Rice attempted to negate the effect of variation in leg position by using a carpenter's spirit level to achieve correct limb positioning before hip dislocation and after trial reduction. Bose's study showed good results with a mean LLI of 3.4mm compared to 8.8mm when not using the device, and with 84% of patients achieving LLI of less than 6mm when using the device compared to 30% when the device was not used.²⁹³. Rice used a similar method with a spirit level but concluded that the Shuck test showed better results^{275,293}.

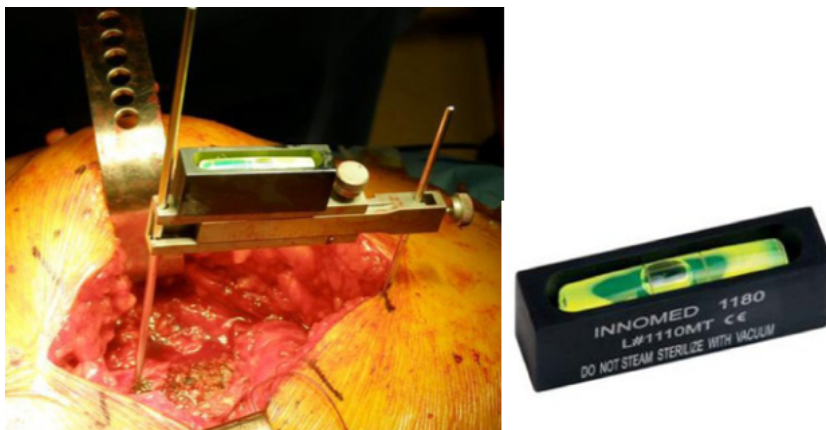


Figure 2.14. Bose's sterilisable spirit level²⁹³

Simple methods of measuring between bony landmarks have been suggested, including tape from the umbilicus with knots to reference the bony landmarks. These tests are sensitive to error as it is difficult to palpate bony prominences under surgical drapes especially in patients with high body mass index ²⁹⁴. One method described stitching a suture in to the skin superior to the surgical field and measuring its length to a fixed point on the lateral aspect of the greater trochanter marked with electrocautery. After insertion of trial implants the distance can be measured and compared to the measurement taken pre-dislocation. Readily apparent sources of error include the inherent mobility and inconsistency of the superficial soft tissues, particularly with multiple retractors in the wound and in obese patients, and in inconsistency in tensioning the suture between measurements ^{176,295}.

Kurtz published a novel method of in-situ femoral preparation where the modular femoral component is implanted before the femoral neck osteotomy and without dislocating the hip joint in a technique analogous to inserting an antegrade femoral nail. By inserting the femoral component before the anatomical relationship between the femur and pelvis is disrupted, the femoral component serves as the primary reference point in measuring pre- and post-operative LLI. In a prospective cohort of 100 total hip replacements, 92% of patients were within 3mm of predicted leg length. They did also use templating and intra-operative X-ray which may explain the favourable results, however this is a novel method which allows a single small incision ²⁹⁶.

Computer Assisted Surgery (CAS) was pioneered in the early 1990s. Computer navigated TKRs have become routine in some areas but computer navigated total hip replacements have been slow to take off in comparison. The first documented computer navigated total hip replacement in the literature was by Sarin et al in 2005 but their method only used a pelvic reference frame and digitized a landmark on the femur before and after reconstruction. This method was sensitive to inaccuracies as any change in position of the leg between pre-and post-reconstruction assessments would lead to large errors ¹⁶⁴. Murphy et al attempted to address this problem with a

method which measured the change in position of the femur relative to the pelvis using an algorithm. Femoral reference points were tracked before and after reconstruction, ensuring the leg is placed in the exact same orientation relative to the pelvis. However, measurements for the algorithm were taken from X-rays meaning they were still susceptible to error from pelvic tilt. The authors argued that even if the orientation of the pelvic coordinate system was achieved with an error of 5° this error would only affect leg length measurement by 1%²⁹⁷.

Many authors conclude that computer navigation is successful at decreasing LLI and publish excellent results for surgery with computer navigation. Nishio and Uvili published separate studies where they were able to reduce mean post-operative LLI to 0.9mm and 1.16mm respectively. Two meta-analyses by Gandhi and Xu^{298,299} also support computer navigated total hip replacement. Xu included 13 randomised controlled trials of over 1000 patients.

Other studies have compared computer navigated total hip replacement with simple device and found no statistically significant difference in post-operative LLI^{300,301}. Parratte et al performed a review and concluded no difference in functional outcome or LLI for computer assisted compared to traditional methods³⁰². Computer navigation may improve acetabular component positioning and therefore LLI but there is no long term clinical benefit in function or implant survivorship³⁰³. Further study is needed to establish whether potentially lower complication and revision rates would decrease lifetime costs³⁰⁴.

The use of computer navigation systems increases surgical time^{305,306 307,308} and theatre set up time, potentially decreasing hospital productivity which may be a significant obstacle to large scale uptake³⁰⁹. One study showed no statistically significant increase in surgical time but did show a narrowed range of surgical time taken, illustrating that the computer navigation system added time to the more straightforward operations but decreased the time for more complex operations^{297,310}. Another study found a mean increase of only four minutes when using computer navigation systems. This study also reported

that several of the total hip replacements patients in the navigation group had to be performed manually due to “technical difficulties”, showing the importance of being able to perform techniques to test leg length unaided ³¹¹.

As with all new techniques there is a learning curve, one study showed an increased time of thirty minutes but this decreased to only ten minutes after thirty procedures ^{28,309}. Though the measurements are calculated precisely, the precision largely depends upon mapping and referencing points, which are surgeon controlled, may be misplacement of tracking marker by the surgeon or the tracking marker may move or loosen in osteoporotic bone, both of which will introduce error, hence the possibility of LLI remains ³¹²

Computer navigation systems require expensive specialist equipment and currently their cost has prohibited widespread uptake. Some studies have implicated large computer navigation devices with increased rates of infection ³¹². Minimally invasive techniques usually lead to difficulties in assessing leg length but the use of a navigation system may allow for equal leg lengths and smaller incisions with accelerated recovery and potentially decreased rates of infection.

There has been one study published reporting the use of an ultrasound device to measure the distance between three points and the difference between the pre-operative and intra-operative measurements calculates leg length. This has only been used in vitro but published results of 0.4mm ³¹³

Intraoperative radiographs to directly visualise component position are frequently used in the USA. Kim produced results of 46 patients with a mean post-operative LLI of 0.3mm with a range of -5.8 mm to +5.9 mm ³¹⁴. Hofmann used intra-operative radiographs to assess LLI and guide any corrections to component position or neck cut necessary. Their mean post-operative LLI was 0.3mm (range -6 to +6mm). They claim that a change was made after the radiograph was taken in 50% of cases, supporting the role for X-ray, however they also employed intra-operative tests including soft tissue tension and the kick test to guide their final decision making, meaning they were not solely

relying on X-rays for information ¹⁶⁰. Beamer et al found that intra-operative fluoroscopy improved cup position but did not improve LLI. They also concluded that use of fluoroscopy had no increase in operative time and may have a role in complicated total hip replacements ³¹⁵. Bullock suggested an intra-operative radiograph with the addition of a guide rod to assess center of femoral rotation ³¹⁶

Intraoperative radiographs expose patients to extra, potentially unnecessary radiation and significantly increase the cost of the procedure as it requires machinery and a radiographer to be present during surgery. There is also concern about extrapolating two dimensional X-rays to three dimensional issue of LLI but with proper positioning and standardisation this can be minimised ¹⁶⁰.

Of the myriad of invasive and non-invasive techniques discussed there are promising results from small studies but none have universal uptake. Techniques reliant on direct measurements may provide precise measurements but are reliant on referencing points decided by the surgeon, and precise re-positioning of the hip between measurements, they are therefore still subject to error ²³. The majority of the techniques discussed require an extra, potentially cumbersome and invasive device, often requiring a larger or separate incision and the large pins have the potential for fracture propagation through the drill hole. ^{21,145,316}. The techniques that require expensive equipment may make them inaccessible in some centers and the purchase cost and required maintenance outweigh their utility ²¹. Many devices and techniques have been shown to reduce LLI but it has not been possible to eliminate it completely. Most recommend templating plus a combination of the above mentioned methods give best chance at minimising risk of LLI ²⁸⁹ but there is no single gold standard method.

2.42 Management of LLI following total hip replacement

Management of the patient with LLI post total hip replacement will depend on timing, type of symptoms, severity and cause. If LLI is suspected post-operatively it should be assessed and measured radiologically to ascertain diagnosis of true, apparent or mixed picture of LLI to inform treatment.

1.6.1. Non-operative management

One of the challenges in evaluating the management of LLI following total hip replacement is the body of evidence that mechanical symptoms improve spontaneously over time without any surgical intervention. Patients should be made aware of this and counselled appropriately ²². Konyves et al followed up a group of fifty-six patients with a mean LLI of 9mm. At three months only 43% of patients were symptomatic and by twelve months this had fallen further to 33% ¹⁶⁶.

Several studies advocate intensive physiotherapy to improve symptoms caused by LLI. Ranawat et al found that 14% of patients had pelvic obliquity at one month post-operatively but that all cases resolved within three to six months following stretching exercises ¹⁵⁶. Bhave et al reported that at a mean of 61 months follow up 94% of their patients had either a “good” or “excellent” improvement in symptoms following six months of intensive non-operative therapy ³¹⁷. Clark et al suggested waiting at least six months for an improvement in symptoms ²¹, and Goldstein et al advocated twelve months ⁴, Similarly Zhang noted improvement in terms of pain and kinematics in all patients, (n=92) including a cohort of greater than 20mm, when studied over the course of a year ³¹⁸, others state no improvement in functional outcomes between their three and twelve months follow up ³¹⁹.

The mainstay of non-operative treatment for structural LLI is the heel insert or shoe raise, this option alone can result in improvement of symptoms of between 44 and 90% ^{19,248}. Shoe inserts can provide as much as 9.5mm of

height without requiring shoe modifications ²¹. Friberg concluded that corrective orthoses resulted in complete resolution of symptoms in up to 75% of patients with LLI and a further 15.7% reported some alleviation in their symptoms⁷¹. Gurney found up to 100% improvement in lower back pain symptoms with shoe raises³. D'Amico et al showed that an appropriate size shoe wedge caused a symmetrical gait and postural rebalancing in 90%, whereas those with no treatment had worsening of postural balancing and back pain ³²⁰. One study showed a shoe raise improved symptoms after 12 months for their groups of 10mm LLI and 10mm-20mm but made no difference to their cohort of patients with LLI over 20mm ³¹⁸.

Shoe raises are non-invasive, inexpensive and can be prepared and adjusted by physiotherapists ²³³. Although they seem to be an unobtrusive treatment method there are issues with patient non-compliance. A small lift can be placed inside the shoe, but larger ones must be on the outside and may be unsightly. They only address the problem when wearing shoes.

One study advocated the use of heel lifts in the early post-operative period, claiming these produced relevant changes in functional LLI after total hip replacement, however they did not support this with any long term results ^{321,322}. Most of the literature agrees that functional LLI should not be aggressively treated with orthoses as they may limit spontaneous correction of soft tissue deformity, they may be introduced at least six months after surgery when most of the soft-tissue contributors have healed ^{21,317,323}. Physiotherapy may be attempted in the interim ¹⁸⁰.

Post-operative functional LLI can be treated with aggressive physiotherapy in the form of stretching exercises, massage and soft tissue mobilisation techniques occasionally supplemented with steroid or Botox injection ¹⁸⁵. Iversen et al noted that six years after surgery, patients with perceived LLI still had lower Harris hip scores. Regardless of whether limb length inequality is clinically or radiographically measured, perceived LLD influences function and satisfaction up to six years after surgery ¹⁶⁹. These studies do not mention whether there was any attempt at management or treatment of symptomatic

LLI. It could be concluded from these studies that any improvement in symptoms resulting from non-operative management will become apparent by 12 months and there will be little or no improvement in symptoms after this time period. Therefore, it appears that non-operative treatment of an uncomplicated LLI may be safely continued while nature is allowed time to compensate for the LLI. A trial of conservative management, depending on the severity and type of symptoms or deformity, of six months to a year could be considered appropriate.

In cases of structural LLI, physiotherapy has a much more limited role as no amount of rehabilitation will correct the discrepancy. If there are persistent symptoms following attempt at conservative treatment with shoe raises or there is gross instability of the total hip replacement, revision surgery is an option ⁶⁶.

1.6.2. Operative management

The decision to proceed with surgical intervention is dependent on timing, clinical features and diagnosis. In cases of true LLI a trial of conservative management will be attempted before proceeding to surgery except in rare circumstances. If the surgeon notices a significant LLI at the end of the operation, a radiograph should be taken and advice from a second surgeon should be sought. If the LLI is greater than 30mm, consideration should be given to immediate revision surgery to correct the problem. The action taken will depend on facilities and experience of the surgeon ¹⁸⁰.

Neurological symptoms will tend to present sooner than mechanical symptoms. If true LLI is confirmed on post-operative radiographs other causes of nerve palsy such as ischaemia, thermal injury, direct trauma or compression from haematoma should be excluded before it is presumed they are entirely due to lengthening ^{127,249}. With mild to moderate neurological symptoms it is acceptable to attempt conservative management as these symptoms may resolve without surgical treatment however severe dysesthesias are unlikely to improve without correcting the LLI ²⁴⁸.

The extent of a nerve palsy guides how it should be managed, with mild to moderate deficits usually resolving spontaneously and severe palsy unlikely to resolve without revision surgery ¹²⁷. Retention of motor function or early return post operatively show a greater likelihood of full recovery ¹²⁷. Peroneal nerve palsy in patients with LLI less than 6mm may resolve spontaneously.

Improvement of neurological symptoms following revision surgery are unpredictable ^{248,324}. In Pritchett's series of nineteen patients, seventeen went on to revision surgery for nerve deficit. There was a mean lengthening of 24 mm (13 to 41mm), nine patients had an excellent result, two had partial improvement and 6 had no improvement. Time from recognition of symptoms to revision surgery ranged from four hours to four months and the mean time from primary to revision surgery was ten weeks (eight hours to twenty- six weeks). The mean shortening at revision surgery was 15mm and residual LLI was less than 5mm in all patients. Of the seventeen patients, two acetabular cups were repositioned, five modular femoral heads were changed, and in ten patients the femoral stem had to be revised. Eight of these hips were found to be unstable, four had trochanteric advancement and four had constrained acetabular prostheses ²⁴⁸.

Parvizi et al. reported a retrospective review of the results of twenty-one revisions for symptomatic LLI (hip pain, back pain, pain with foot drop and dislocation) with a mean LLI of 40mm (20 to 70mm). In fifteen cases the acetabular cup was revised, in three the femoral stem and in three cases both the femur and the acetabulum were revised. Fifteen patients had equalisation of limb length at revision surgery and the mean improvement of LLI was to 10mm (5 to 20mm). Nineteen of the twenty-one patients were satisfied with the outcome of the revision, including three patients with neurological pain (two sciatic and one femoral) and four cases of heterotopic ossification. Of the remaining two, one had persistent lower back and hip pain while the other had ongoing problems with instability. 9.5% of patients were still not satisfied with their results following revision, this further emphasises the importance of counselling patients about this risk pre-operatively. A limitation of this study

was that data was taken from a retrospective review of the patient notes and therefore uncertainty exists regarding the accuracy and detail of the documentation. It is noteworthy that this represented a cohort of patients where two of the twenty-one patients (9.5%) were not satisfied that the surgery had achieved what it had set out to do. The study highlights therefore the importance of counselling patients. They have demonstrated that despite cases of nerve damage and heterotopic ossification, revision for LLI following total hip replacement can provide symptom relief and leave patients satisfied with their outcome⁶⁶. Parvizi reported revising the cup in only fifteen cases, the stem in only three cases and both components in the remaining three⁶⁶. These findings are in contrast to Konyves et al. who attributed lengthening to the femoral stem in 55 of 56 patients¹⁶⁶

Stone et al. reported a study involving a cohort of patients suffering from lengthening following total hip replacement that was refractory to conservative treatments.. All patients presented with pain plus mechanical symptoms of lengthening. The fourteen patients had a mean pre-operative LLI of 17mm (range 8 to 30mm). The mean time between primary and revision surgery was 32 months (8 to 72). Many patients commented that it was difficult to get anyone to understand the problems that they had. Of the fourteen patients, thirteen had the stem revised and four had the acetabular component revised. Mean improvement of LLI was 15.3mm (8 to 24mm) and thirteen of the fourteen patients were satisfied with the surgery in terms of correction of the symptoms of LLI. Two had complete resolution; five patients had persistent pain. The post-operative complications were one sciatic nerve palsy, improving at one year; two further revisions for dislocation; one stem which subsequently became loose and following further revisions became infected; and finally, one operation to remove broken trochanteric osteotomy wires. Stone's report recognised that the pain and mechanical symptoms of LLI following total hip replacement were not the same problem and noted that while revision can be a useful in relieving the latter it will not necessarily be the case for the former, although despite this patients were generally satisfied with their operation³²⁴.

Although the majority of patients with an apparent LLI have satisfactory outcomes with non-operative management, Bhave et al identified a sub group of patients that may benefit from surgery. The group published the results for a small cohort of patients with adductor tightness where only one of the four in this study responded well. Of the remaining three, one required muscle relaxation using botulinum toxin and the other two improved following surgery adductor lengthening or revision surgery ¹⁸⁵.

Ranawat found that two of nine patients with persistent apparent LLI required operative intervention (one soft tissue release only and one soft tissue release and stem shortening) before symptoms resolved. While it is difficult to draw many conclusions from such small studies, they both agree that there are occasions where surgery, though not revision of implants, is an option for some types of recalcitrant true or apparent LLI.

There are some cases in the literature where surgical intervention is required but the primary total hip replacement is functioning well and has not been straightforward it may be preferable to resolve the LLI by operating on the contralateral side. Cases in the literature include contralateral distal femoral shortening osteotomy with fixation with an external fixator assisted blade plate ³²⁵, lengthening over a femoral nail with an external fixator or an intramedullary kinetic skeletal distractor ³²⁶, and ipsilateral distal femoral metaphyseal shortening ³²⁶. These are unusual examples with small case series of five cases or fewer and would only be considered in very rare circumstances.

The patient must be made aware before revision surgery that hip stability is of paramount importance and attempts at 'shortening' a long leg should not compromise this. The surgeon must be prepared to revise both the acetabular and femoral components and have the option of constrained liners available if decreased limb length, despite appropriate component positioning, results in soft tissue laxity and instability. No guarantee of leg length equality should be given to the patient, and the risk of instability should also be explained. When offering revision surgery for nerve palsy related to lengthening, patient expectations should be tempered ³²⁴.

2.43 Summary

Over 102,000 total hip replacements were performed in the UK in 2016⁶ and more than a million are performed worldwide every year. This figure is projected to double over the next twenty years as the prevalence of degenerative hip disease continues to increase⁷⁻⁹. Total hip replacements have evolved from a salvage procedure with poor long term outcomes reserved for the most infirm patients, to one of the most successful and frequently undertaken elective operations.

LLI post total hip replacement was first recognised by Charnley when the operation was popularised in the 1960s but has only recently increased in prominence in the literature possibly due to younger, more physically demanding patients undergoing total hip replacement and having greater expectations post-operatively, requiring more function from an arthroplasty as opposed to simply pain relief.

LLI following total hip replacement is an independent risk factor in the outcome of total hip replacement. LLI can spoil the result of an otherwise technically perfect operation and is frustrating for both the patient and the surgeon. LLI post total hip replacement is now the fifth most frequently cited claim in the UK²⁴ and the most common in the USA²¹.

Patients with LLI post total hip replacement may present with pain, neurological symptoms or mechanical symptoms including a limp. Patients are more troubled by a “longer” leg but shortening can lead to instability which may necessitate revision surgery. Although any patient undergoing total hip replacement is at risk of symptomatic LLI, there are identifiable populations who are less likely to tolerate what would otherwise be considered an acceptable deformity. LLI can be true, apparent, or a mixed picture. It is important to correctly diagnose the main cause of symptomatic LLI to be able to pursue correct conservative or surgical management.

The boundary between acceptable and unacceptable levels of disparity remains undefined. The subject of what defines an unacceptable or even negligent LLI is controversial and is complicated not only by the lack of agreement of significance but also by the fact that for any given magnitude of LLI, only a proportion will be symptomatic. The literature broadly agrees that less than 10mm is acceptable and that greater than 30mm is not acceptable but the grey area in between these values is contentious.

The intra-operative challenge of achieving stability and equal limb lengths post total hip replacement starts with pre-operative planning including physical examination, radiological evaluation, templating and aligning patient and surgeon expectations. There are numerous intra-operative devices that claim to decrease LLI and some advocate the use of computer navigation and intra-operative radiographs, but there is no single gold standard technique and problem persists.

A multimodal model should be followed with pre-operative detailed discussion with the patient, clinical history to assess sensitivity to LLI, counselling for realistic expectations especially in those with pre-existing LLI.

Table 2.2. Peri-operative considerations for LLI

Pre-operative	History and examination
	Appropriate radiographs
	Patient education and expectations
	Identify 'at risk' patients
	Templating / implant selection
Intra-operative	Establish baseline measurements
	Reproducible technique of measuring change
	Balance between soft tissue tension, stability and leg length
Post-operative	Clinical evaluation and radiographs
	Quantify LLI
	Early intervention versus observation

Revision surgery to correct symptomatic LLI is fraught with technical difficulty and has a high risk of complications therefore there is significant potential benefit to 'getting it right first time'.⁶⁶ If LLI is suspected post operatively it should be confirmed radiologically. If a true LLI of less than 10mm is suspected then an expectant course of management should be sought. If greater than 10mm then the options should be discussed with the patient including a trial of conservative management with the possibility of revision surgery if this fails. In terms of management, for uncomplicated LLI with no neurological symptoms a trial of conservative management of six to twelve months may be considered appropriate.

LLI following total hip replacement is an independent risk factor in the outcome of total hip replacement. The definition of an unacceptable or even negligent value of LLI is controversial and is complicated not only by the lack of agreement of significance but also by the fact that for any given magnitude of LLI, only a proportion will be symptomatic. Symptomatic LLI may present with pain, neurological deficit, limp, back pain and may lead to altered wear characteristics of the total hip replacement. LLI post total hip replacement is the fifth most commonly cited cause of litigation in the UK and causes frustration for the patient and surgeon. There are multiple gaps in the literature including a gold standard intra-operative method of minimising LLI. Patients should be made aware of the risk of developing symptomatic LLI and counselled appropriately.

Chapter 3. British Hip Surgeons and leg length inequality after primary total hip replacement

There have been several papers published regarding leg length inequality (LLI) following total hip replacement but there is very little consensus in the literature regarding measurement, a 'cut off' which constitutes an acceptable amount of LLI, nor is there a gold standard technique to minimise LLI intra-operatively.

The British Hip Society (BHS) is the largest body of surgeons with a specialist interest in hip arthroplasty in the UK, with approximately 400 members. To be elected as a member, surgeons must have evidence of performing research in the field of hip arthroplasty and be proposed and seconded by current members, therefore BHS members should represent an expert opinion in the field of hip arthroplasty.

This chapter reports the results of two separate surveys of British Hip Society (BHS) members relating to LLI after primary hip replacement. The first survey investigates the members' opinions on the effect of LLI on the outcome of total hip replacement and explores expert opinions of acceptable limits of LLI after primary total hip replacement. The second survey reports on the intra-operative techniques currently used by BHS members to minimise LLI after total hip replacement.

The results of this work have been published in Hip International as;
Loughenbury FA, McWilliams AB, Stewart TD, Redmond AC, Stone MH.
'Hip Surgeons and Leg Length Inequality after primary total hip replacement'.
Accepted 21 Jan 2018.

<https://doi.org/10.1177%2F1120700018777858>

The first part of this chapter was presented as a poster at the British Hip Society annual meeting in Norwich in March 2016 as;
McWilliams AB, Barnett FA, Stewart TD, Redmond AC, Stone MH.

‘Does Leg Length matter after hip replacement? Survey of Opinion Regarding Leg Length Inequality Following Total Hip Replacement’.

The second part of this work was presented as a poster at the British Hip Society annual meeting in London in March 2015 as;

Barnett, FA, Stewart TD, Redmond AC, Stone MH.

‘Methods used to assess leg length inequality during total hip replacement – a survey of British Hip Society surgeons’.

3.1 Survey of opinion regarding leg length inequality after total hip replacement

3.2 Introduction

Many studies have been performed in an attempt to determine the magnitude of LLI necessary to manifest complications and therefore to warrant treatment^{153,154} but the threshold at which LLI becomes clinically important is controversial¹⁵⁵. There has been no published work that has attempted to demonstrate a consensus, or indeed lack thereof, for significance and quantification of LLI following total hip replacement. A study to gauge the opinions of sub-specialist hip replacement surgeons is warranted and any data obtained would provide important information. While the investigation may identify a body of opinion agreeing on limits of acceptability, it is also possible that there will be no agreement. While this latter result would not clarify LLI following total hip replacement it would be significant in that it would provide the first examination of opinion and provide a range of magnitudes of LLI following total hip replacement which themselves could be investigated further.

This chapter presents a survey of current opinion from the membership of the BHS on the effect of LLI on outcome of surgery, and an expert opinion on currently acceptable values after hip replacement.

3.3 Methods

A five-question survey was created and piloted at the lead authors institution (Appendix 1). The pilot questionnaire was completed by six hip arthroplasty consultants at the end of a weekly governance meeting and feedback was provided. Following this some minor modifications to the layout and phrasing were made to make the survey more straightforward to complete.

The survey was focused on uncomplicated unilateral total hip replacement for osteoarthritis without any other confounding factors. The option of including free text boxes to provide qualitative information was discussed but for ease of analysis these were not included.

The survey began by asking whether the respondent believed that LLI had a bearing on outcomes of total hip replacement, if they did they were then guided to offer a magnitude. Questions one, two and four offered yes/no options but questions three and five were numerical free text boxes, allowing any value to be entered. See Table 3.1 and Appendix 2.

Table 3.1. Survey 1 questions

Question 1	Do you feel that post-operative leg length inequality has a bearing on outcomes following total hip replacement?
Question 2	Do you feel that there is a value of post-operative leg length inequality, below which would always be considered within the bounds of acceptable practice?
Question 3	If yes, please specify (in mm)
Question 4	Do you feel that there is a value of post-operative leg length inequality, above which would always be considered excessive?
Question 5	If yes please specify (in mm)

Following approval from the board of the BHS, (Appendix 3), an email was sent out to 394 members of the BHS explaining the aim of the work and containing a link to the survey using the Survey Monkey email platform. The introduction explained that the survey was focused on “uncomplicated primary total hip replacement in a patient with single joint osteoarthritis who has no other confounding factors”.

A reminder email was sent after one month. The survey was not incentivised and all answers were anonymous. All surveys were included in the analysis including incomplete responses. There was an option to include the responder’s email address if they wished to receive the results.

3.4 Results

A total of 156 of BHS members responded, giving a response rate of 40%. 97% of responding surgeons felt that post-operative leg length inequality has a bearing on outcomes following total hip replacement. 89% of respondents felt that there is a value of post-operative LLI below which would always be considered within the bounds of acceptable practice and 90% felt that there is a value of post-operative LLI above which would always be considered excessive. Respondents were then prompted to give values.

Question three received 129 responses. The results are shown in Figures 3.1 and 3.2.

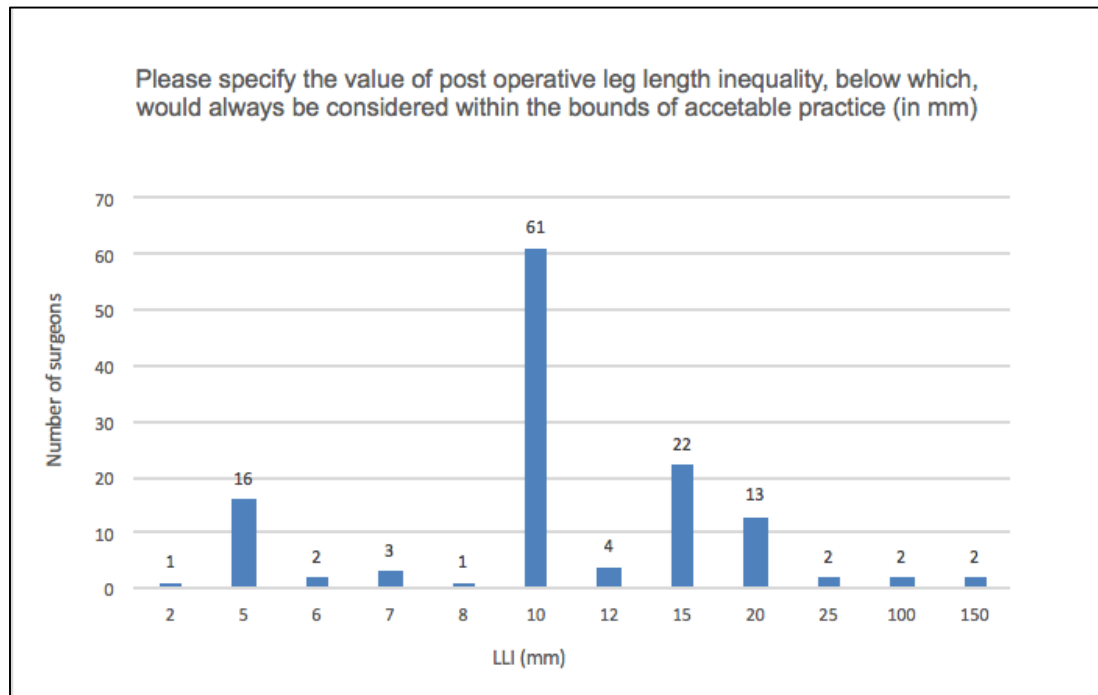


Figure 3.1. Question three results. Values below which would always be considered acceptable.

The most frequent value of LLI that respondents feel would always be within the bounds of acceptable practice was 10mm, with 47% of respondents giving this value. The median value was also 10. The range of values was 2mm to 150mm and the calculated mean response was 14.9mm.

Four responses were thought to be excessively high (100mm, 100mm, 150mm, 150mm) and it is assumed that these values were entered using incorrect multiples of 10. These values have been excluded in the results below.

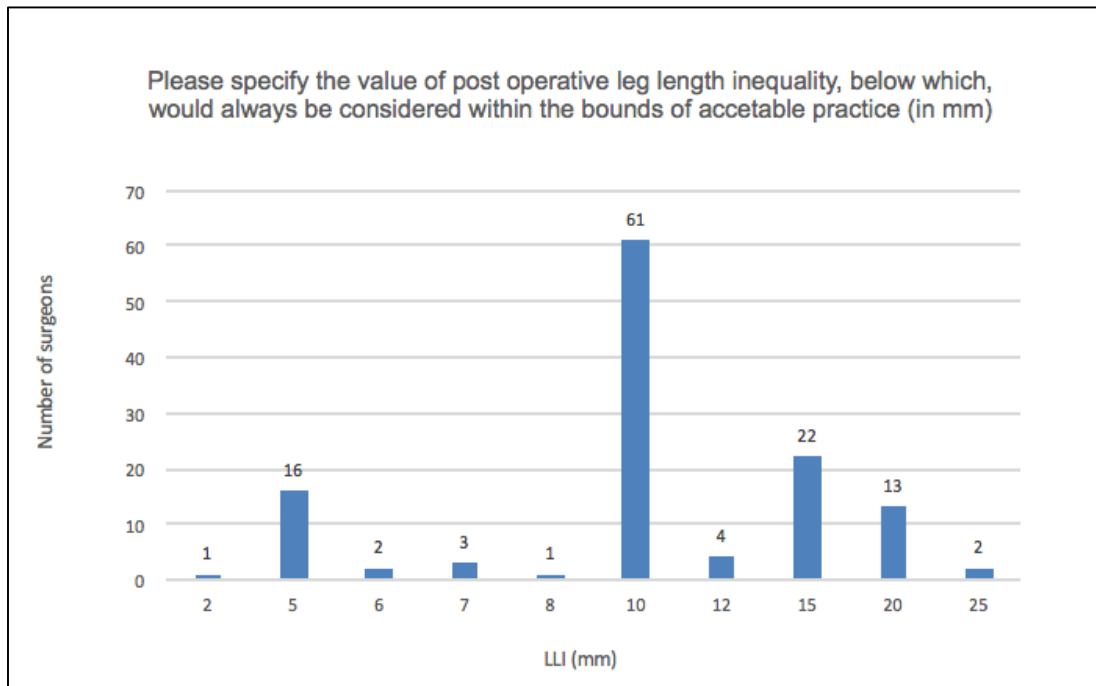


Figure 3.2. Question three results. Values below which would always be considered acceptable (with excessively high values excluded).

After excluding the excessively high values the median and mode values remain the same at 10mm, with a decreased range of 2 to 25mm. The mean decreased to 11.4mm. 67% of respondents thought that a value of 10mm or less was always acceptable and 88% of respondents entered values of 15mm or less. Almost all respondents (98%) gave a value of 20mm or less. 90% of all responses were in multiples of five.

There were 130 responses to question five. The results are shown in Figures 3.3 and 3.4.

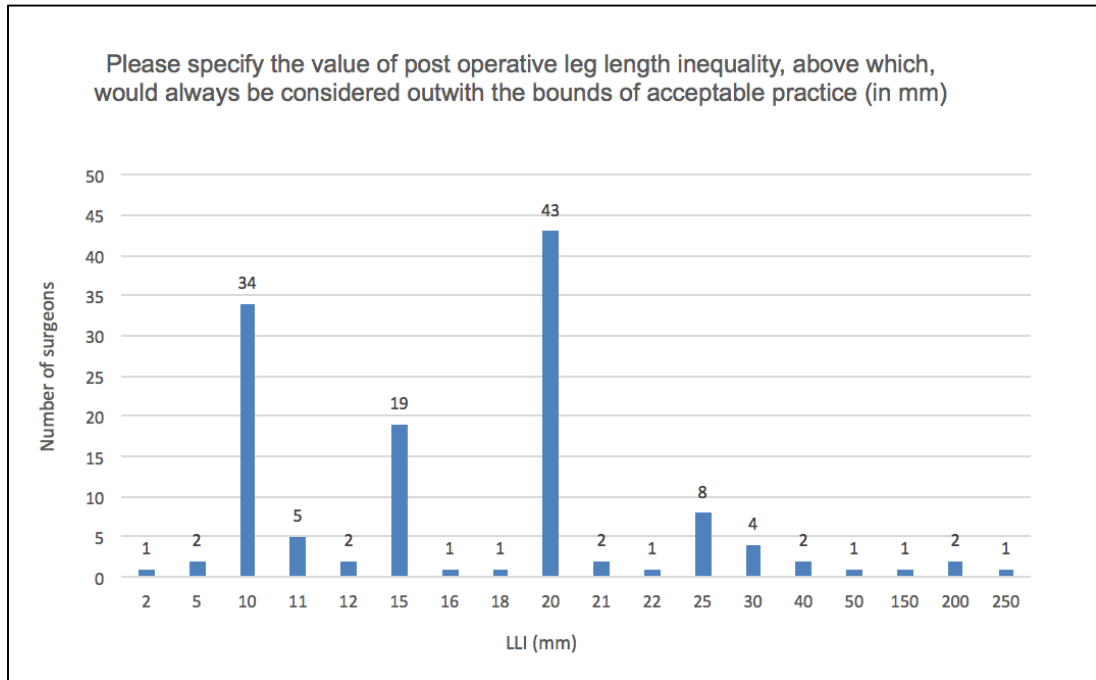


Figure 3.3. Question five results. Values above which would always be above the range of acceptable practice.

The most frequent value of LLI that respondents feel would always be above the bounds of acceptable practice was 20mm, with 33% of respondents giving this value. The median value was 19mm. The range of values was 2mm to 250mm and the calculated mean response was 22.5mm.

Again, four responses were thought to be excessively high (150mm, 200mm, 200mm, 250mm) and it is assumed that these values were entered using incorrect multiples of 10. These values have been excluded from analysis in the results below.

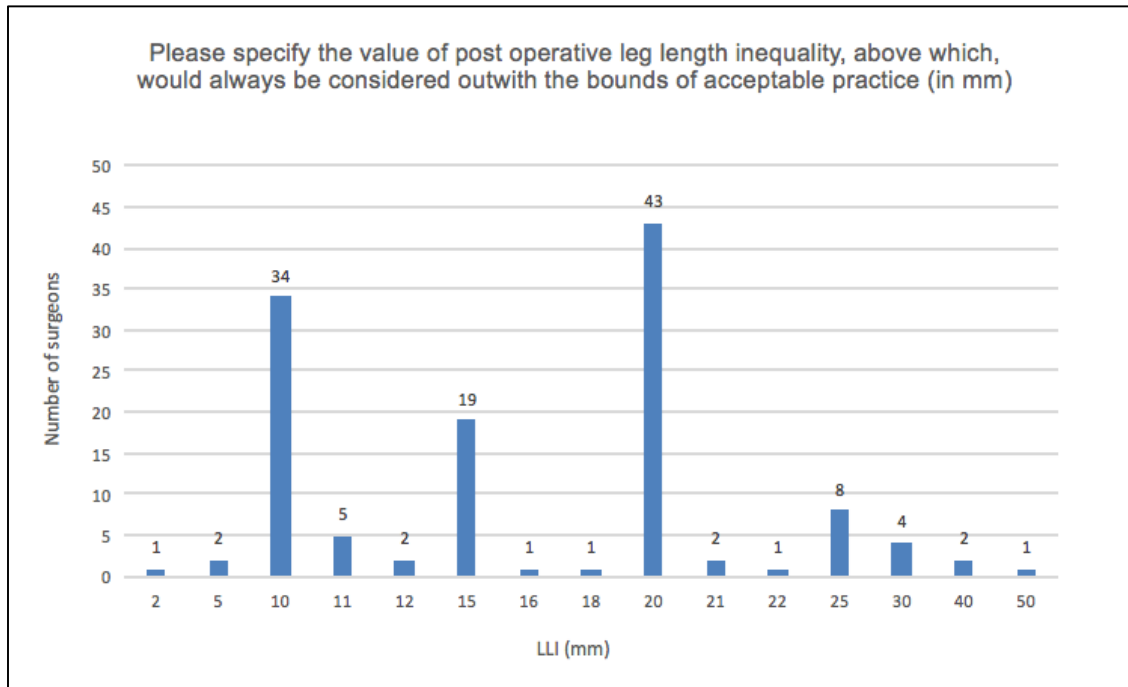


Figure 3.4. Question five results. Values above which would always be above the range of acceptable practice (with excessively high values excluded).

After excluding the excessively high values the median decreased to 15.5mm. The mode remained the same at 20mm, with a decreased range of 2 to 25mm. The calculated mean decreased to 16.5mm. 48% of 126 respondents thought that a value of 20mm or greater would always be above an acceptable limit of LLI, 65% indicated that 15mm or greater would always be above acceptable limits and 98% indicated that 10mm or greater would always be above acceptable limits. As with question three, 90% of responses were values in multiples of five.

3.5 Discussion

There is broad agreement in the literature that less than 10mm LLI following total hip replacement is acceptable^{4,12,150,156-158} but reaching a consensus for an upper limit of acceptability has proved difficult as the threshold at which LLI becomes clinically significant varies between patients¹⁵³⁻¹⁵⁵. 97% of surgeons answering this survey believe that LLI does have a bearing on the outcome of

total hip replacement. Although there is broad agreement in the literature it is not a universal belief and some surgeons have publicly stated that they do not believe LLI has any effect on outcomes of total hip replacement^{151 13}. Whilst almost all respondents were in agreement that LLI does have a bearing on outcome of total hip replacement, fewer agreed that there was a value below or above which was always within the bounds of acceptable practice (89% and 90% respectively). This is mirrored in the literature, with studies presenting results of widely ranging values of LLI with varied outcomes.

In this study, the most frequently cited value for an amount of LLI below which would always be acceptable was 10mm, with 47% of respondents giving this answer. This 'cut off' of 10mm is in broad agreement with the literature. Bhave et al concluded that equalisation to within 10mm was critical in normalising gait and improving the symptoms of LLI²³⁴. O'Brien et al. found that when simulating LLI using wooden blocks, twenty nine out of the thirty subjects perceived a difference at 10mm and all were aware at 20mm and 25mm with increasing numbers in the cohort complaining of discomfort¹⁵⁷. Sariali claimed LLI was perceived by all when shortening exceeds 10mm and lengthening 6mm¹⁶⁴. Edeen et al interviewed sixty-eight patients with a mean LLI of 9.7mm. 32% of these patients were aware of their LLI and 50% were "disturbed" by it¹⁴⁸.

The most frequent value of LLI above which would always be unacceptable was 20mm, with 33% of all respondents giving this value. There was a larger variance in values for the upper limit of acceptability (2mm to 50mm), compared to the lower limit of acceptability (2mm to 25mm), suggesting there is less agreement in terms of upper levels of acceptable LLI values than with a lower value which again is mirrored in the literature. After exclusion of the excessively high values, the highest response for the upper limit of acceptability was 50mm but the most commonly cited upper limit in literature is 30mm^{20,161,162}. Only seven of 126 respondents (5%) indicated they thought that an LLI of above 30mm would be acceptable.

Questions three and five were numerical free text boxes with no restrictions on answers but despite this there was a predilection for values to be given in multiples of five, with 90% of values ending in zero or five. Although this seems simplistic, LLI in the literature is often referred to in multiples of five so these values are often used as broad divisions.

This survey received a response rate of 40%, which is acceptable for an electronic survey. Reported response rates of email based surveys range from 25% to 39.6% in the literature ³²⁷⁻³²⁹. Response rates could have been improved by allowing a multimode method of returning surveys, studies comparing postal, email and web-based surveys concluded that offering multimodal methods of responding improved response rates to up to 70% ³²⁸. The possibility of including interim results in the “prompt’ email that was sent at one month was discussed but decided against as it is thought that responses made after publishing interim results are susceptible to bias ³³⁰. In addition to this, it is possible that the surgeons who did respond had particularly strong opinions (either positive or negative) about the importance of LLI following total hip replacement and therefore their responses may not be entirely representative of the opinions of all arthroplasty surgeons. However, the results do provide us with an insight into a range of opinions.

The survey was sent to members of the British Hip Society in an attempt to gain the expert opinion of high volume hip surgeons. As the topic of LLI is controversial, no demographics were requested in the survey to prevent respondents being discouraged from giving truthful responses for fear of reprimand or ridicule, or encouraging participant bias, where responders provide results that they think the researcher wants to receive.

The results do not provide concrete values of acceptable leg length inequality following total hip replacement however this is the first study of its kind aiming to generate a body of opinion from an expert group. Care must be taken when interpreting the results of this survey due to the relatively small number of respondents and the simplistic nature of the questions. The authors did

receive one email suggesting that the questions were too simplistic but it would not be possible to extend the survey to encompass all situations.

Possibilities for further research would be extending the survey to include European or North American arthroplasty surgeons, which may provide interesting geographical variation, and including a request for demographics. It is possible that younger surgeons may have different opinions on LLI than more senior consultants, as the topic has only come in to prominence in the 1990s it is possible that the more senior consultants are less aware of its significance. Patterns in geography may become clear, or large volume centres such as Wrightington or Exeter may have differing opinions on acceptable LLI than lower volume centres. Alternative methods of survey including phone calls, or postal surveys may have increased response rates³²⁹ however this would have removed anonymity which may have conceivably resulted in different conclusions and would have taken a significant amount of time.

3.6 Conclusion

The boundary between acceptable and unacceptable levels of LLI remains undefined¹⁵¹. This is the first study examining the expert opinion on LLI following total hip replacement. 97% of those completing the survey felt that LLI affected the outcome of hip replacement. The results of this survey are in broad agreement with the literature with 10mm being the most commonly cited value of acceptability and 20mm being the most common value of upper limit of acceptability, with a grey area in between. This study demonstrates a strong agreement that LLI following total hip replacement can affect outcome. Additionally, there is a strong agreement for limits of acceptability.

3.7 Survey of intra-operative techniques used by British Hip Surgeons to minimise LLI

3.8 Introduction

As the prominence of LLI has risen in the literature so too has the number of publications promoting various devices and techniques to ensure equal leg length, yet none have reached universal uptake or managed to eliminate LLI. In an attempt to minimise LLI and its associated complications, surgeons employ a range of techniques pre- and intra-operatively. Direct methods of assessment involve measurement between two points, and indirect methods rely on surrogate tests of soft tissue tension during surgery. The indirect methods are particularly subjective and depend on several factors including anaesthetic type, patient positioning, pre-existing comorbidities and whether the patient had a pre-existing LLI. In the hands of an experienced arthroplasty surgeon, it is reported that a combination of these techniques can achieve acceptable levels of LLI ^{70,275}. Apart from the previously discussed myriad of published small series' promoting a new and novel device, there is very little high quality data to show the frequency and indeed which intra-operative tests for assessing LLI are used in the UK.

3.9 Methods

The aim of this study was to identify which intra-operative techniques are currently utilised by specialist hip surgeon representatives attending the British Hip Society annual scientific meeting, and members of a regional arthroplasty group to identify the most commonly used techniques and establish whether practice differs across the country.

A questionnaire consisting of three questions was developed at a round table discussion of the senior authors. It was kept deliberately short to encourage

participation. The questionnaire was piloted at Chapel Allerton Orthopaedic Hospital by distributing paper copies of the questionnaire to the six hip arthroplasty surgeons at the end of a weekly arthroplasty governance meeting. All six surgeons completed the questionnaire and returned it the same day.

Following feedback from the first pilot study, question three was modified to include options of 'always', 'sometimes' or 'never', instead of simple 'yes' or 'no' options. It was suggested that these options were too simplistic as surgeons may use different techniques depending on the complexity of the total hip replacement, or in certain circumstances. Two out of six surgeons completing the CHOC pilot questionnaire utilised short rotator apposition as an extra intra-operative test so this was added as an extra test at this stage.

The first group surveyed was the Yorkshire Arthroplasty Group (YAG), now called the Regional Hip and Knee group. Emails were sent to 82 members of the YAG explaining the aim of the work and a link to the survey using the Survey Monkey email platform on 2nd March 2014. A reminder email was sent on the 28th March but no interim results were provided. No changes were made to the questionnaire following the YAG survey.

The questionnaires were then distributed on the final day of the British Hip Society Annual Meeting on Friday 7th March 2014 in Exeter. (Figure 3.5.) Questionnaires were placed on all 300 chairs in the main hall during a poster session on the final day of the meeting and an announcement was made by Mr Martin Stone, explaining the background and purpose of the study. Respondents were requested to leave their completed questionnaires on their chairs and they were collected after the last presentation, leaving approximately two hours for completion. There were no incentives for completing the survey and no prompts were made to encourage completion.

1. Approximately how many total hip replacements do you perform per year?
2. What percentage of A) the cups and B) the stems you insert are cemented?
3. Which of the following techniques do you routinely use to assess for leg length during a primary THR? *Surgeons were asked to indicate whether they use each technique always, sometimes, or never.*
 - a. Measurement of leg length at knees.
 - b. Measure the remaining length of the calcar after cutting the femoral neck.
 - c. Measurement of the height of femoral stem collar to tip of the greater trochanter.
 - d. The Kick test.
 - e. The Shuck test.
 - f. Use of a skin suture for measurement.
 - g. Assessment of short rotator apposition.
 - h. Assessment of a general feeling of happiness.
 - i. Other technique. Please specify and name any commercial device used.

Figure 3.5. YAG and BHS questionnaire.

3.10 Results

There were 32 responses to the YAG questionnaire giving a response rate of 39%. For the survey of BHS members, a questionnaire was placed on each of the three hundred seats in the main hall at the BHS meeting and 129 were returned completed, giving a notional response rate of 43%. It is not possible to calculate an exact response rate as there is no way of knowing how many delegates attended the session.

The results from the two surveys were initially analysed separately and then assessed to look for similarities. The results for each question showed no

significant differences in trends and therefore the results of the two surveys were combined for the final analysis.

Question 1. Approximately how many total hip replacements do you perform per year?

There were 160 responses to this question. Surgeons completing this question report a median of 100 total hip replacements per year with a range of 10 to 400. The mode was 100 total hip replacements per year which was reported by 20% of all respondents. The calculated mean was 123 total hip replacements per year. Where a range (e.g. 100 – 150) was offered, the middle number was selected and entered in to the analysis. Figure 3.6.

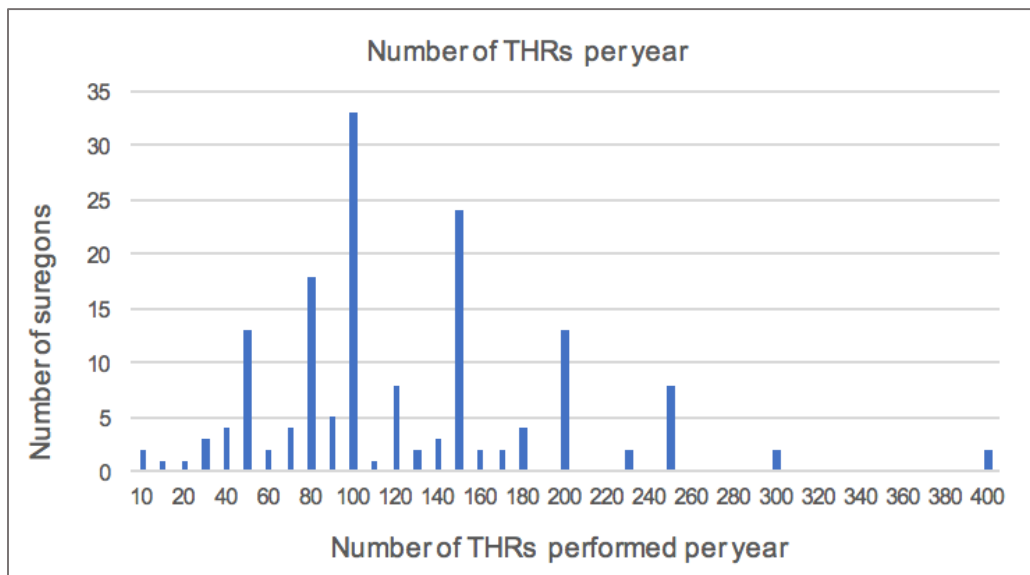


Figure 3.6. Number of total hip replacements performed per year.

Question 2 - What percentage of A) cups and B) stems you insert are cemented?

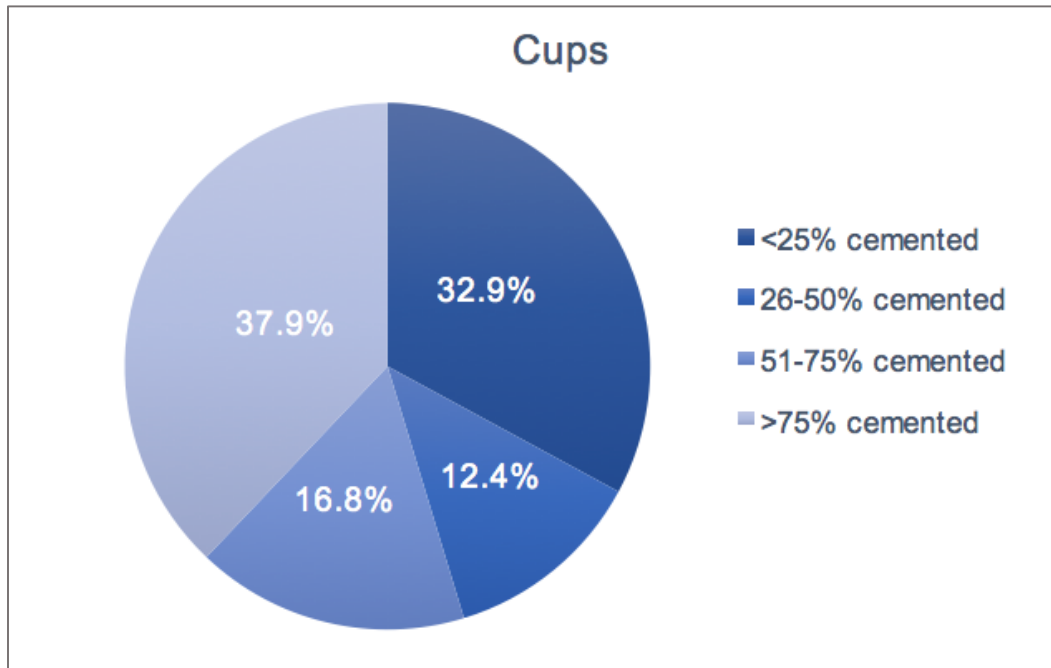


Figure 3.7. Cup fixation methods.

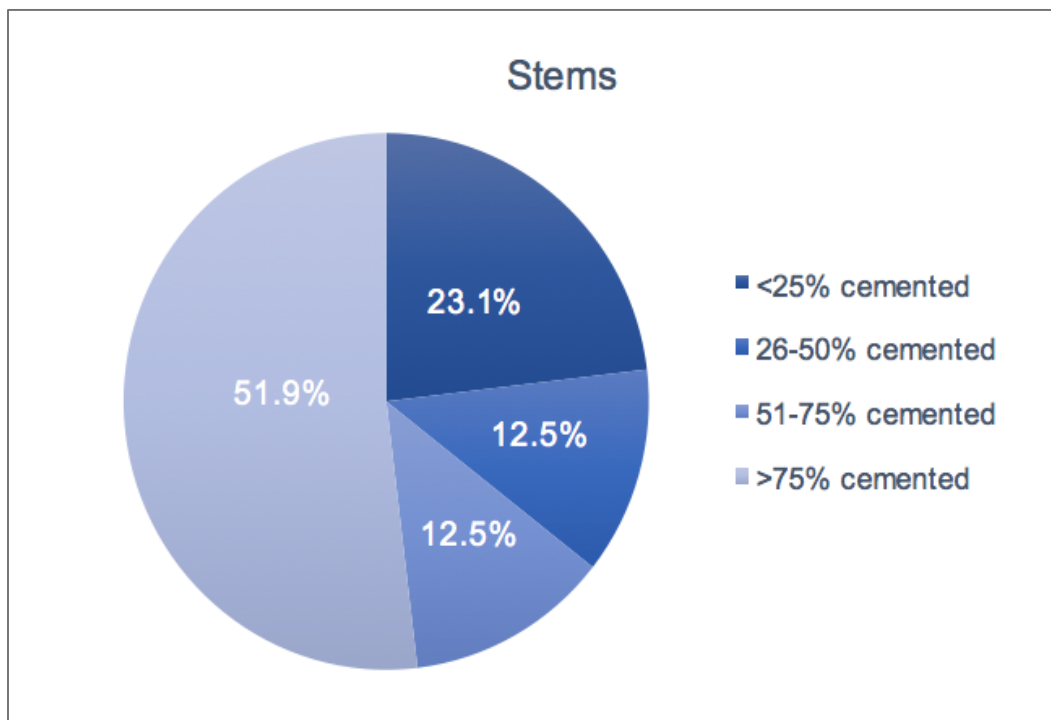


Figure 3.8. Stem fixation methods.

Cemented cups and cemented stems were the most commonly used implants. (Figures 3.7 and 3.8). 55% of surgeons use cemented cups in more than half of all total hip replacements and 38% report using cemented cups in three quarters of their total hip replacements. 33% report using cemented cups less in less than a quarter of total hip replacements, and therefore must use cementless cups in three quarters of total hip replacements. 64% of surgeons reported using cemented stems in more than half of their total hip replacements and 52% report using cemented stems in three quarters of their total hip replacements. 23% use cemented stems in less than a quarter of total hip replacements, and therefore must use cementless stems in three quarters of their total hip replacements.

Question 3 - Which of the following techniques do you routinely use to assess for leg length during a primary total hip replacement?

The most commonly employed technique is measuring leg length at the knees, utilised by 90.6% of surgeons during every total hip replacement. A ‘general feeling of happiness’ and the Shuck test are both commonly used (77.5% and 77.3% respectively). 66.2% of surgeons measure the height of the collar to the tip of the greater trochanter, 64.5% measure the neck cut on the calcar, 59.3% of surgeons use the Kick test, 53.5% assess short rotator apposition and 7.9% of surgeons use a skin suture technique. Figure 3.9.

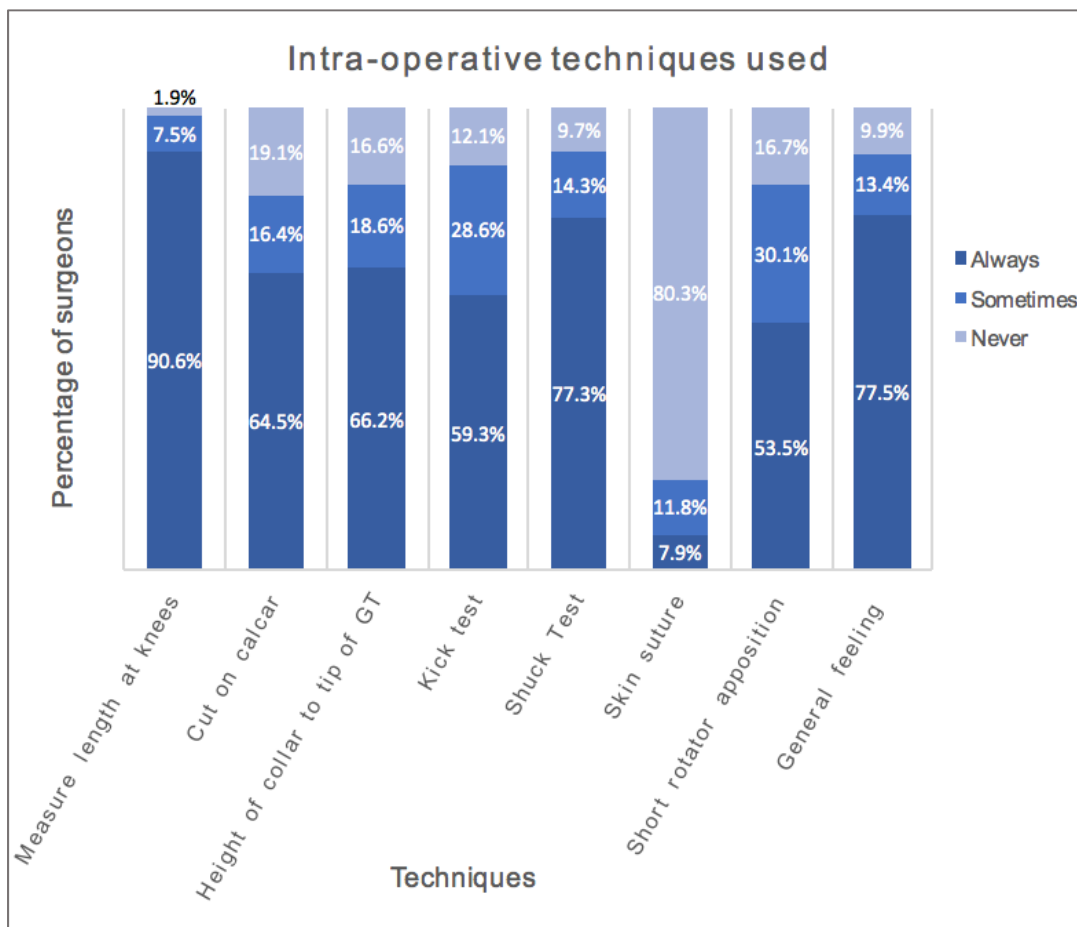


Figure 3.9. Question three - Intra-operative techniques used.

Overall, the 161 surgeons reported “always using” 738 techniques, giving a mean of five techniques employed in combination per surgeon. Seventeen surgeons (11%) completing the questionnaire report using commercial devices, as shown in Table 3.2.

Table 3.2. Commercial devices used.

Commercial device	Number of surgeons
Burns jig	2
Iliac pin	6
Charnley pin	2
Judd pin	1
Supra-acetabular pin	1
Caliper	2
Smith & Nephew leg length / offset guide	3

The results were then analysed according to methods of fixation. The type of total hip replacement utilised did not have any effect on the number of techniques used for assessing LLI, with an average of 4.7 techniques used by surgeon using fully cementless and 4.4 techniques used by surgeons using fully cemented total hip replacements. The type of techniques used did not differ according to methods of fixation either. The surgeons who report using commercial devices did show a tendency towards cementless or hybrid fixation. No surgeon that reported using fully cemented total hip replacements used a commercial device. 50% of those that reported using a commercial device used a full cementless total hip replacement and 50% describe using a hybrid total hip replacement.

3.11 Discussion

The questionnaires were distributed to members of a regional arthroplasty group and to members of the British Hip Society at the largest hip arthroplasty meeting in the UK so it is expected that all consultants completing the questionnaires were relatively high volume primary hip surgeons. Taking this in to consideration there is a very large range (10 – 400) in the numbers of total hip replacements performed per year. The median number reported was 100, which is a much larger figure than 54 reported in the NJR 14th annual report. This may reflect the high-volume surgeons who are members of arthroplasty groups and attend conferences such as the BHS there is also a chance that surgeons may be over-reporting volume due to recall bias, or rounding up numbers, compared to the 'true' NJR activity.

There were no instructions to prevent junior surgeons who were in attendance at the BHS from completing the questionnaire, the inclusion of their responses may have skewed results. For a more representative sample a sentence could have been added in the introduction requesting that only arthroplasty consultants complete the survey.

The surgeons at the BHS mainly use cemented implants, (55% cement over half of their cups and 64% cement over half of their stems), compared to data taken from the NJR which shows that only 30% of surgeons use fully cemented implants. According to the NJR the most popular method of fixation is fully cementless, at 39%. 28% of total hip replacements in the NJR are hybrid and 3% reverse hybrid implants (Figure 3.10)⁶. The larger proportion of cemented implants seen at the BHS perhaps represents experienced surgeons who may be more conservative with their implant choices, favouring the cemented implants with long term results over the newer, cementless implants with shorter-term follow up.

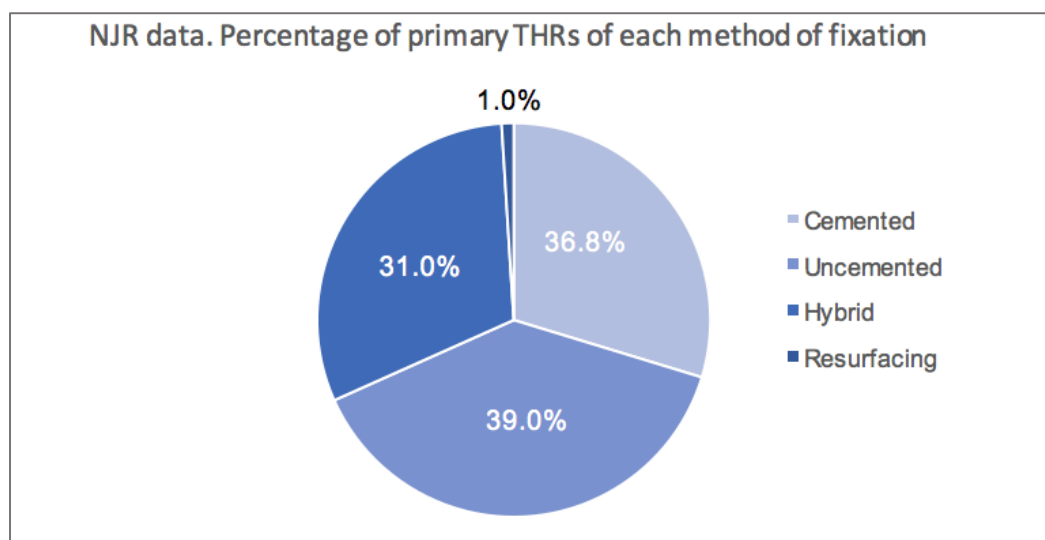


Figure 3.10. 2017 NJR data - Percentage of THR for each method of fixation⁶

It is not possible to compare the results of the percentage of cemented and uncemented implants from this study with the NJR data directly because of the way the survey question was phrased. The options provided (<25% cemented, 26-50% cemented, 51-75% cemented or >75% cemented) were quite difficult to comprehend. At the time of writing the questionnaire this seemed to be a simple way of providing the options and this was not mentioned as an issue in the pilot questionnaire, it only became apparent on analysis of the data. A simpler way of displaying the options in the questionnaire would have been how the data is presented in the NJR, offering

options for fully cemented, uncemented, hybrid or reverse hybrid. This would have made the question easier to complete and simplified analysis of the data.

In the BHS study, all surgeons use at least one intra-operative technique to minimise LLI during hip replacement, the most commonly utilised are measuring length at the knees (used by 90.6% of surgeons during every operation), the Shuck test (77.3%) and relying on a general feeling of happiness or unhappiness (77.5%). Surgeons used a mean of five techniques which suggests that no one technique is completely accurate and that surgeons feel that employing a combination of techniques gives better accuracy than using a single technique. This is supported by the literature^{275,331}. Seventeen surgeons report using commercial devices, an iliac pin was used by six surgeons, three report using a branded offset / leg length gauge and the rest use varieties of pins or callipers. This shows that there is no single gold standard device that has reached universal uptake.

The questionnaire did not ask about surgical approach. The technique of measuring length at the knees only applies to surgeons operating in the lateral position. Surgeons using an antero-lateral approach in the supine position may measure length at the ankles instead. This question should have included an option for measuring length at the knees and ankles or included a question about approach.

Analysis of the questionnaires of the respondents who reported using a commercial device showed that these were surgeons who reported either using a fully cementless or a hybrid total hip replacement the majority of the time. No surgeon who favoured a fully cemented total hip replacement reported using a commercial device. The fully cemented total hip replacement is a more traditional method of fixation and it may be the case that more senior surgeons do not feel it necessary to use a commercial device, whereas more junior or newer surgeons are more aware of or concerned about LLI and are more likely to use a commercial device in an attempt to minimise it.

This is a questionnaire based study and therefore has limitations based on the questions asked. In order to encourage participation, the questionnaire was kept deliberately short, with closed questions for ease of analysis. This may have led to losing qualitative data. An option for adding free text comments was included to try and minimise this.

With any questionnaire, there is a level of researcher “imposition”, when developing the questionnaire, it is possible that assumptions are made about the more important techniques. In order to minimise the effects of this the questionnaire was piloted at a local arthroplasty governance meeting. The method of distribution may have meant that only surgeons with strong views responded and this may have led to bias in the answers. An alternative method of distribution would have been to circulate in between sessions and ask the attendees the questions face to face. This may have improved response rates but would have been time consuming and would have removed the anonymity, possibly leading to surgeons giving different answers than they would have done if the survey was confidential. Including demographics in the survey would have yielded further information which may have revealed patterns in practice between high and lower volume surgeons or different practice between junior and more experienced arthroplasty consultants.

3.12 Conclusion

Whilst this study had some limitations it yielded some important information. There is currently very little in the literature about which techniques surgeons use to assess leg length intra-operatively. This study showed that directly measuring length at the knees, the Shuck test and a ‘general feeling’ were the most frequently utilised techniques. It also concludes that the majority of surgeons feel that using a variety of methods improves their results as no one technique is 100% reliable. This supports the requirement for the development of an objective assessment tool to decrease the incidence of LLI and increase patient outcomes.

3.13 Acknowledgements

We are very grateful to the British Hip Society for allowing us to survey their members and particularly to the members who took the time to respond to the surveys.

Chapter 4. The accuracy of five intra-operative techniques to minimise leg length inequality during primary total hip replacement.

4.1 Introduction

It is difficult for inexperienced junior arthroplasty surgeons to learn how to accurately reproduce leg length at the time of hip replacement surgery. A recent survey by the author at the British Hip Society, discussed in chapter three, identified the five most commonly utilised tests to be the Shuck test, the kick test, measuring leg length at the knees, measuring from the tip of the greater trochanter to the shoulder of the trial stem, measuring the cut on the calcar and a 'general feeling' of leg length equality but there is a paucity of literature providing validation for these tests, or identifying which, if any, are the most effective.

4.2 Aim

This study set out to establish whether an experienced hip surgeon can reproduce leg length using the five intra-operative tests described, without the use of a commercial device. In order to achieve this aim, a validated method of measuring LLI was required to reference the tests against. The Woolson method of quantifying LLI from plain film X-rays was considered the most appropriate as it is widely used in clinical practice and is reported to be more consistent than other methods in the literature ²⁷⁶. Prior to employing the Woolson technique as a reference standard the inter- and intra-observer reliability of the measure was investigated. Through the analysis of pre-operative radiographs of patients in this study this phase also served to define a cohort of patients to be included in the next phase of this thesis.

4.3 Assessing inter- and intra-observer reliability of the Woolson technique

Accurate quantification of LLI is important for both pre-operative planning and post-operative assessment. Failure to accurately assess LLI pre-operatively may lead to an under-appreciated and perhaps asymptomatic LLI causing symptoms post-operatively, or post-operative symptoms of LLI being ascribed inappropriately to another cause. The Woolson and Williamson techniques appear in the literature consistently. The Woolson technique is reported to be more reliable as the teardrop is a more discrete radiological landmark than the inferior ischium, and is less prone to errors due to pelvic tilt²⁷⁶. The Woolson technique has therefore been selected for use as the reference standard in this study. See section 2.7.2.1.

There has been very little validation in the literature for the Woolson technique. Woolson et al quote an inter-observer variation of 0.5mm but do not support this with data²⁷⁶. McWilliams et al reported inter-reader reliability ICC of 0.91^{202,332}, and Meermans et al reported the inter-teardrop line to be statistically significantly more reliable than the Williamson technique and proposed an intra-observer reliability ICC of greater than 0.8¹⁵⁵.

4.4 Methods

All patients referred to Mr M H Stone for consideration for a total hip replacement were identified for inclusion in the study and underwent pre-and post-operative radiographs. All radiographs were taken at Chapel Allerton Hospital (Leeds Teaching Hospitals NHS Trust). Radiographs were taken according to the local standardised operating protocol, with the patient in a supine position with both hips resting in internal rotation. Radiographs were centred on the pubic symphysis. Calibration of images was performed to standard hospital protocol. With a source-to-plate distance of 1150mm aiming for a source-to-hip distance of 1000mm. A 25mm calibration ball (AGFA,

Wilmington, MA, U.S.A.) was placed in the groin at the level as the greater trochanter. The images were acquired, stored and retrieved using the Leeds Teaching Hospitals NHS Trust picture archiving and communication system (PACS) (AGFA, Wilmington, MA, U.S.A.). All measurements were made to the nearest millimetre. Measurements of LLI were corrected for magnification using the 25mm marker ball on pre-operative radiographs.

Limits of difference

Acceptable limits of difference in LLI measurements between sessions or between examiners needed to be defined. For measurements to be useful they should give consistent results between examiners at least to a level that provides clinical utility. Discussion with six senior arthroplasty consultant colleagues during an arthroplasty governance meeting led to the conclusion that a measurement technique would be considered adequately useful in routine clinical practice if the limits of difference in LLI measurement between examiners was 5mm or less.

Inter-observer reliability

Radiographs were measured by two observers (the candidate and the Senior Hip Fellow at Chapel Allerton Orthopaedic Centre) using calibrated digital X-rays. The observers were blinded to each other's results. The results were then compared for inter-observer reliability.

Intra-observer reliability

LLI was measured by a single observer (the candidate) on two separate occasions with a minimum of one week in between measurements. The candidate was not allowed to refer to the original readings at the time that the second set of readings was made.

Data analysis

Data were analysed using SPSS and reliability was quantified through the generation of Intra-Class Correlation Coefficients (ICC) and mean difference. ICC model 3,1 was used to determine inter-reader reliability and ICC model 1,1 was used to evaluate consistency in measurement from serial images.

Explanation of cohorts

Throughout this chapter, three cohorts are introduced. Cohorts one and two had pre-operative radiographs examined and cohort three had both pre- and post-operative radiographs examined. The cohorts were generated as follows:

Pre-operative cohorts

Cohort one

Cohort one consists of 'unfiltered' patients. All consecutive patients referred for consideration of a total hip replacement were included before examination of the radiographs and therefore this cohort includes patients with a wide range of pathologies including advanced osteoarthritis with contractures, pelvic trauma and cases of DDH with significant LLI.

Cohort two

Cohort two was generated after the analysis of radiographs and the exclusion of patients with pathology other than primary osteoarthritis. Any radiographs showing significant malpositioning were also excluded. This generated a small but highly selective cohort which represented patients who would be suitable for entry in to the main part of the study. The generation of these strict exclusion criteria were also used in the selection of patients for chapter 5 which required 'simple' total hip replacements for the development of the device and use of the device as a teaching tool.

Pre- and Post-operative cohort

Cohort three

Cohort three was formed by adding patients to cohort two, using the refined inclusion and exclusion criteria. This generated a larger refined cohort to increase the significance of results. Patients in cohort three had pre-operative LLI measured to assess inter- and intra-observer reliability, were then included in the main part of the study, undergoing intra-operative assessment, and post-operative LLI measurement.

4.5 Results

Cohort one – pre-operative LLI (N=42)

Cohort one consisted of 42 consecutive patients referred to Mr M Stone for consideration of a total hip replacement. The LLI measurements for the two examiners using the Woolson technique for cohort one are shown in Table 4.1.

Table 4.1. Cohort one. Results of pre-operative LLI.

Cohort one, n=42				
	Mean (mm)	Range (mm)	SD	Intra-observer ICC
Examiner one	- 4.5	- 23.6 to +11.4	8.2	0.98
Examiner two	- 4.3	- 21.8 to +12.2	7.1	

The mean pre-operative LLI was – 4.5mm for examiner one, and – 4.3mm for examiner two. Both examiners reported a surprisingly wide range of results and reported difficulty in assessing some the original films with a degree of certainty. Examination of the radiographs revealed that many of the patients included in this cohort had abnormal positioning of the pelvis, including fixed

contractures or pelvic obliquity. To enable accurate validation of measurement methods and to define a cohort of patients suitable to be included in the main part of this chapter, all patients with obvious malpositioning of the pelvis or femora were excluded from the analysis, and were re-analysed as cohort two.

Cohort two – pre-operative LLI (N=16)

Cohort two consisted therefore of 16 patients due to undergo total hip replacement for uncomplicated, primary osteoarthritis with a radiographically well-centred pelvis without significant contractures or pelvic tilt. The results for pre-operative LLI are displayed in Table 4.2.

Table 4.2. Cohort two. Results of pre-operative LLI.

Cohort two, n=16			
	Mean (mm)	Range (mm)	SD
Examiner one	- 2.8	- 13.9 to +4.0	4.7
Examiner two	- 2.9	- 16.1 to +12.2	7.5

The mean LLI was - 2.9mm for examiner one and – 2.8mm for examiner two, with a smaller range of LLI values than shown in cohort two. In this refined cohort of patients, the mean value for LLI was within the pre-specified acceptable value of 5mm therefore this cohort was investigated further by assessing inter-observer reliability. The ICCs for inter-observer reliability are summarised in Table 4.3.

Table 4.3. Inter-observer reliability of LLI measurements (N=16).

Inter-observer ICC	Mean difference (mm)	95% confidence interval	
		Lower bound	Upper bound
0.93	0.1	0.78	0.97

These results show excellent inter-observer agreement of 0.93. This refined group showed more promising reliability therefore, but the cohort of 16 was deemed insufficient for further analysis. In order to adequately power the final analysis a further 27 patients were recruited for analysis following the previously defined inclusion and exclusion criteria, providing a third cohort of N=44. Prior to entering this cohort in to the main study, an intra-observer reliability analysis was performed, the results are presented in Table 4.4.

Table 4.4. Intra-observer reliability of LLI measurements (N=44).

Intra-observer CC	Mean difference (mm)	95% confidence interval	
		Lower bound	Upper bound
0.97	0.5	0.95	0.99

4.6 Discussion

The wide variance in pre-operative measurement from two examiners in cohort one was difficult to interpret. In order to validate the five intra-operative techniques in the main part of the chapter, this study required a cohort that would provide reliable and accurate measurements of LLI. Examination of the radiographs in cohort one revealed many of the patients had abnormal positioning of the pelvis due to fixed deformities which are often present in end stage osteoarthritis of the hip³³³. The most common deformity seen is a combination of flexion and adduction, as seen in Figure 4.1.

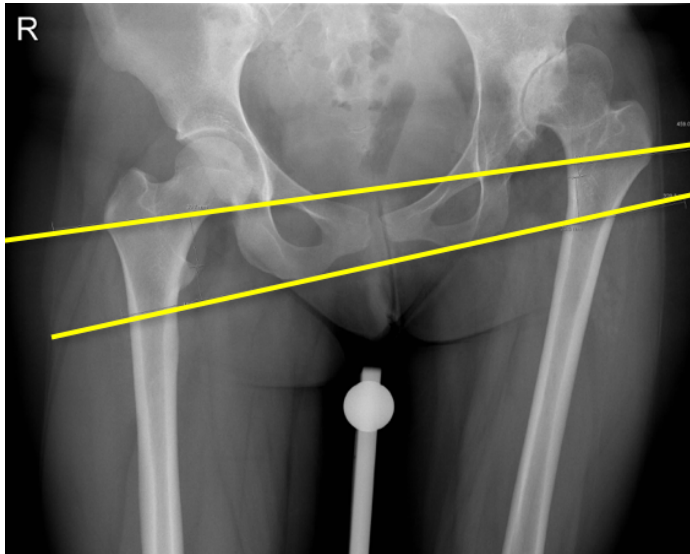


Figure 4.1. Adduction contracture leading to Williamson and Woolson reference lines converging.

Each of these deformities affects visualisation of one or both of the radiographic landmarks required for measuring LLI using the Woolson technique. External rotation of the femur changed the profile of the lesser trochanter on one or both hips making its use as a measurement landmark difficult or impossible. Flexion of the hip affected the rotation of the pelvis which changed the profile of both the lesser trochanter and the acetabular teardrop, and adduction at the hip either caused a pelvic tilt or if unilateral, made the measurement of LLI unreliable. After removing all cases with significant contractures, pelvic tilt and all cases without standardised X-rays, the variance between measurements decreased.

The range of LLI measurements in cohort one was – 23.6 to +11.4mm and - 21.8 to +12.2mm for examiners one and two respectively, this decreased to - 13.9 to +4.0mm and – 16.1 to +12.2mm in cohort two. The inter-observer ICC in cohorts one and two were 0.98 and 0.93 respectively. This excellent inter-observer agreement confirms that the wide range of values in this cohort was due to the scatter of the actual measurements in these cases, and not resulting from lack of agreement between the examiners. Analysis of results of LLI from cohorts one and two demonstrate that for both observers the mean

differences are smaller in cohort two than in cohort one and the variance of the results is less in cohort two than in cohort one.

The inter-observer reliability of measurements taken using the Woolson technique for cohort two showed excellent results, comparable with those in the literature^{155,202,332}. The intra-observer reliability was also excellent for the highly refined cohort three.

The strict exclusion criteria of malpositioning of the pelvis and fixed contractures excluded a large percentage of the 50 patients who were initially identified to be included, and therefore excluded common presentations of end-stage osteoarthritis. This was intended to produce a cohort of simple radiographs for analysis inter-and intra-observer reliability, and to produce a cohort without significant confounding variables to be included in the next part of this chapter. The exclusion criteria also served to generate a cohort of 'simple' cases to be included in chapter 5, which required patients with minimal pre-operative LLI and no clinical deformity, for the development of the device to be used as a teaching tool.

4.7 The accuracy of five intra-operative techniques to minimise leg length inequality during primary total hip replacement

The main part of this chapter focused on assessing the effectiveness of the five displayed techniques for minimising LLI intra-operatively.

4.8 Methods

This study used the 44 patients in cohort three defined as per section 4.3. The patients all met the stringent criteria for accurate measurement of LLI from their pre-operative radiographs, with no pelvic obliquity or fixed joint contractures ensuring that their post-operative LLI measurements would be

an accurate representation of the LLI that could be obtained by using the five intra-operative tests, without any significant confounding leading to inaccurate radiological measurements of leg length. The indication for total hip replacement was primary osteoarthritis in all cases and only first side total hip replacements were included. A single orthopaedic hip surgeon with over 20 years' experience as a consultant operated on all patients following the same procedure.

The patient was positioned in the lateral position and the posterior approach was used. The total hip replacement was a reverse hybrid consisting of a Marathon (DePuy) cemented cup and an uncemented Corail (DePuy) femoral component. The hip replacement was carried out as per the surgeon's standard surgical practice. Once the trial total hip replacement components were in place the surgeon performed the five intra-operative tests to determine the correct leg length. The intra-operative tests reference a number of anatomical landmarks including the tip of the greater trochanter, the lesser trochanter, the teardrop, the ischial tuberosity and the medial side of the femoral neck which is referred to as the calcar. These structures are illustrated in Figure 4.3.

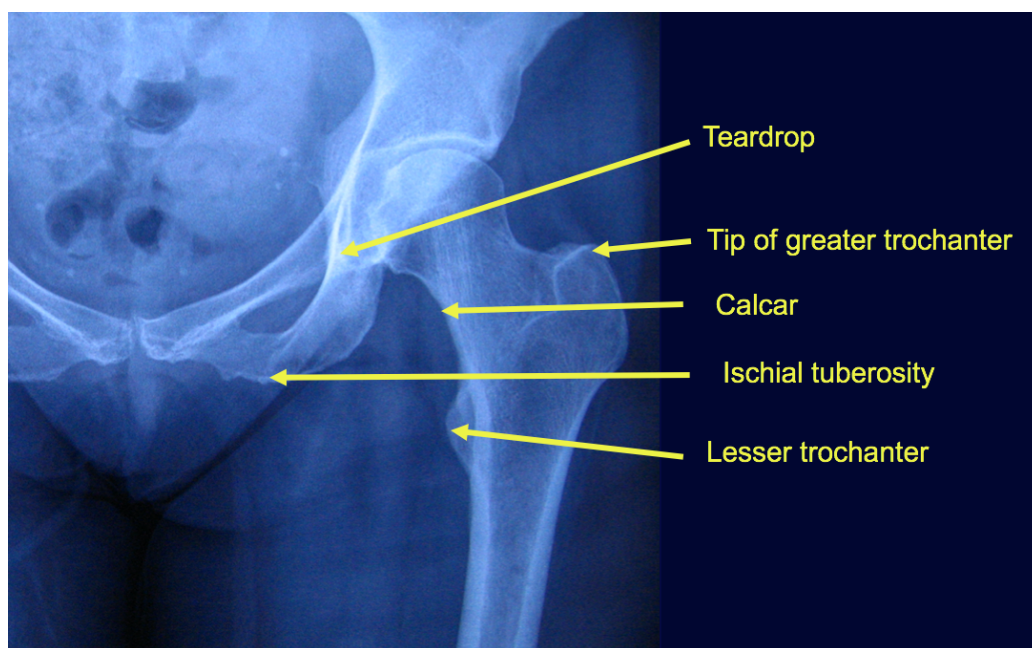


Figure 4.3. Anatomy of the proximal femur including anatomical landmarks used to assess leg length intra-operatively.

After each of the five intra-operative tests was performed, the surgeon recorded his satisfaction with the outcome. as 'equal', 'long' or 'short'. Depending on the outcome, the surgeon made a number of alterations to the trial components before selecting the final implant.

The options to decrease leg length included using a shorter femoral head, impacting the stem further in to the femur or re-cutting the femoral neck. Options to increase leg length included using a larger femoral head or increasing the size of the femoral component. It was not possible to alter leg length by changing the position of the acetabular component at this point as it had already been cemented in place. After an alteration was made to any component the five tests were repeated again until the surgeon was satisfied that leg lengths were as close to equal as possible.

A record was made of each intra-operative test, any changes made and an overall summary of satisfaction with the five tests was also made. In total, six records of test satisfaction were collected for each patient.

The five intra-operative tests

The five intra-operative tests included a variety of direct and indirect methods. The direct methods take a simple estimation of distance between two reference points that can be compared to the position on pre-operative templates. The indirect tests measure soft tissue tension of muscles and ligaments around the hip joint and are therefore a surrogate measure of leg length. They guide accuracy of leg length and stability, assuming that the implanted total hip replacement constituents are a similar size to the native hip joint. In cases where total hip replacement is performed in a case of a chronically shortened lower limb in cases such as DDH these tests may not be reliable. Indirect tests are typically performed with the trial components in situ and this enables the surgeon to make adjustments to length or offset by using various combinations of modular sizes and offset designs to obtain an optimal clinical result, Figure 4.3.

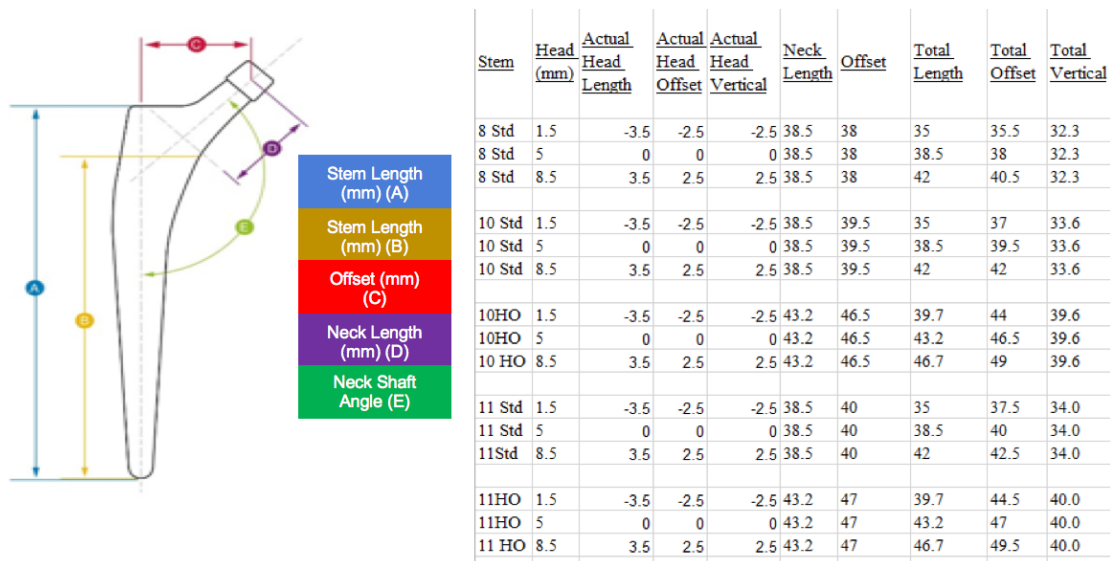


Figure 4.2. Corail implant options showing effect on leg length.

Using the five tests in conjunction gives the surgeon an overall measure of LLI. The five tests are described below in the order they would be carried out intra-operatively.

Test one. Measuring the cut on the calcar

The first test aims to accurately position the femoral neck resection. The level of the resection has a large bearing on the outcome of leg length and if the resection is at the incorrect level the patient will be left with a significant LLI. The level of the resection is planned on pre-operative templates using the lesser trochanter as a reference point. Each implant has its own correct neck resection line placement. For a Corail stem this line is approximately 8-10mm more distal than the neck resection for a cemented stem.

After planning the resection line this measurement is recreated intra-operatively. Firstly, the hip is dislocated and the femur is internally rotated by 45° to enable the lesser trochanter to be palpated through the soft tissue attachments, the lesser trochanter is not dissected out. The surgeon uses his index finger as a measuring guide to measure the predicted resection line 8-10mm above the lesser trochanter. In Figure 4.4 the measurement is

approximately two thirds of the width of the surgeon's index finger but each surgeon will develop a modified measurement based on the width of their finger. The planned femoral resection is then marked with a diathermy line before the neck resection is made. After inserting the trial stem the distance is measured again and if necessary a further resection can be made.

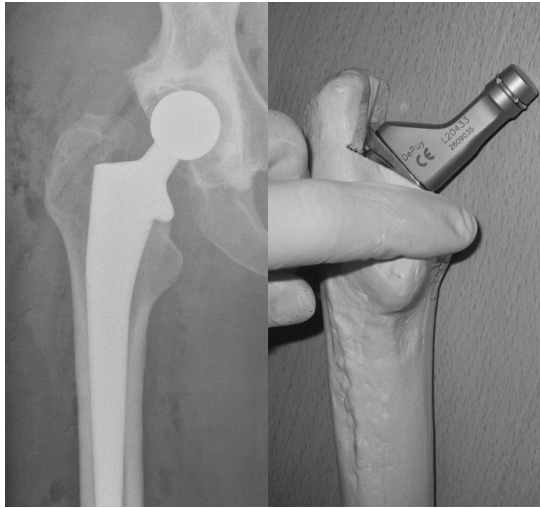


Figure 4.3. Measuring the cut on the calcar.

Test two. Measuring the tip of the greater trochanter to the shoulder of the rasp or trial stem

The second test measures the level of the femoral neck resection after the cut has been made and the trial stem is in position. It is a measurement of the distance from the lateral shoulder of the femoral rasp or trial stem to the tip of the greater trochanter. To carry out this test, the surgeon places the index finger along the medial aspect of the trochanter to assess the height of the tip of the greater trochanter from the shoulder of the rasp as shown in Figure 4.5.



Figure 4.4. Measuring the tip of the greater trochanter to the shoulder of the femoral rasp.

This test can also be performed with the trial neck removed from the stem and the measurement is again measured using a pre-determined measurement from the width of the surgeon's index finger. A similar technique has also been described by locating the tip of the greater trochanter with the tip of a white hypodermic needle and using this as a reference point from which to measure to the shoulder of the trial stem with a ruler³³⁴.

Test three. Measuring length at the knees

The third test is a direct measurement of leg length made by comparing the level of the knees. This is first performed pre-operatively whilst positioning the patient in the anaesthetic room. It is reliant on meticulous positioning of the patient in the lateral position with the pelvis held perpendicular to the floor with supports, and any adduction removed by placing a pillow between the legs. The knees are flexed to approximately 90° and the heels and knees are lined up. The leg lengths are compared by palpating the levels of the patellae as shown in Figure 4.6. The test is then repeated intra-operatively after the trial components are in situ and the new leg length is compared to the pre-operative measurement by palpating through the surgical drapes. A similar

test can be performed if the patient is in the supine position. This was originally described by Charnley and involves measuring leg length at the medial malleoli ¹².



Figure 4.5. Pre-operative direct measurement of leg length at the knees.

Test four. The kick test

The Kick test is an indirect assessment of leg length performed when the trial components are in place ²⁷⁸⁻²⁸⁰. It tests the tension in the rectus femoris muscle after the hip has been reduced. The surgeon holds the operated leg with the knee in flexion then extends the hip by an additional 10-20° whilst the knee remains flexed. If the leg is the correct length it will rest exactly where the surgeon places it on top of the lower leg. If the operated leg is 'long' then the tibia will kick forward on releasing the foot. This occurs as the rectus femoris arises in the pelvis and inserts into the tibia, crossing both the hip and the knee joint. If the leg is lengthened by the total hip replacement then the rectus femoris will be under tension and will 'kick', bringing the tibia forward to decrease tension and shorten its length.

Test five. The Shuck test

The Shuck test is the final test performed. It is another indirect test of leg length performed after the trial components are in place. The soft tissue envelope surrounding the new total hip replacement exerts a resistive force that allows a certain amount of distraction of the femoral head from the acetabulum but prevents it from subluxing completely²⁷³. The Shuck test is performed by placing a swab around the femoral neck and applying longitudinal traction in the direction of the femur, perpendicular to the face of the acetabular socket, see Figure 4.7. For the left hip, the surgeon supports the left leg with his left arm under the tibia and knee. The leg is then abducted and internally rotated about 20°. The leg is abducted to remove any adduction created by the patient being in the lateral position and square the pelvis, bringing the femur parallel to the floor. The leg is internally rotated by 20° to recreate the femoral neck shaft angle and bring the shaft-implant-head-socket complex in to a neutral and stable position. Any force applied along the femoral neck in this position is a pure distraction force. If the Shuck test was performed without internally rotating the femur then there would be a combination of distraction plus external rotation. Internally rotating the femur by 20 degrees during every test allows a reproducible test of distraction alone³³⁵.

Traction is applied with the swab and the amount of distraction or “shuck” of the trial femoral head from the acetabulum is assessed. If the leg is “short”, the soft tissues will be too lax and it will be possible to distract the femoral head too far or even dislocate it. If the leg is “long” then the soft tissues will be tight and it will not be possible to distract the femoral head far enough. The ideal amount of shuck and therefore the tension of the soft tissues around the hip is a subjective decision based on feel and surgical experience^{176,274,336}.

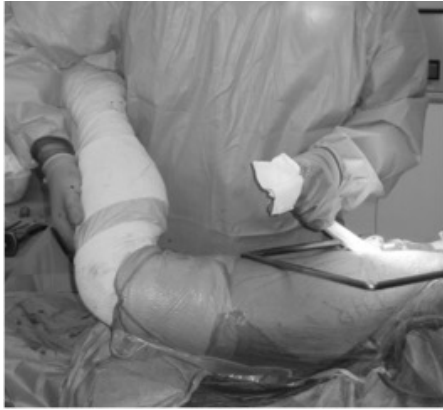


Figure 4.6. The surgeon applies longitudinal traction in line with the femur in the Shuck test.

After the surgeon was satisfied with the outcome of leg length using the trial components, the total hip replacement was completed as normal.

Post-operative radiograph

As part of normal clinical practice, all patients had a standardised AP radiograph of the pelvis on day two following their surgery. LLI was measured using the Woolson technique by a single observer (the candidate) making two measurements on separate occasions and calculating the mean LLI for each case.

4.9 Results

44 patients were included in this study. There were 27 females and 17 males. The mean patient age was 62 with a range of 40 to 83 years.

4.10 Post-operative LLI

The mean post-operative LLI was +3.1mm, with a range of – 10.5 to 14.2mm. The standard deviation was 4.60

4.11 Five intra-operative test results

There were 44 patients each with five test results, plus a test of overall satisfaction with the leg length. This resulted in a total of 264 test results before any adjustments to the implant or neck cut were made, as shown in Table 4.5.

Table 4.5. Satisfaction of individual test results and overall satisfaction of leg length before any adjustments

First check result	Test 1 LT/Calcar	Test 2 Collar/GT	Test 3 Knees	Test 4 Shuck	Test 5 Kick	Overall Feeling
Equal	43	44	34	15	25	14
Long	1	0	7	22	18	22
Short	0	0	3	7	1	8

In 15 patients, all five tests were recorded as 'equal' and no further adjustments were made. The kick test and the Shuck test led to more adjustments than the other three tests. In several patients, more than one test was unsatisfactory.

In 10 patients, tests three (measuring length at the knees), four (Shuck test) and five (Kick test) suggested the leg was long. In 14 patients test four (Shuck test) and five (Kick test) signified 'unequal' and felt long, however in this group test three (measuring length at the knees) was normal. In three patients, test four (Shuck test) and five (Kick test) felt short however the measurement at the knees was normal. In one patient test three (measuring length at the knees) felt short however tests four (Shuck test) and five (Kick test) felt equal. In one patient test three (measuring length at the knees), four (Shuck test) and five (Kick test) all felt short.

In cases where the test results were not equal the surgeon made adjustments either in the implant selection or the femoral neck resection cut. The five tests

were then repeated and the results of each test after any adjustment of the implants are shown in Table 4.6.

Table 4.6. Individual five test results after adjustment

Second check result	Test 1 LT/Calcar	Test 2 collar/GT	Test 3 Knees	Test 4 Shuck	Test 5 Kick	Overall Feeling
Equal	44	44	36	44	44	37
Long	0	0	4	0	0	5
Short	0	0	4	0	0	2

In most cases adjusting the LL for any one abnormal test corrected all the other tests without further adjustment. Only test three (measuring length at the knees) still had eight cases that were not recorded as 'equal' after adjustments. All other test results were recorded as equal before final implant insertion.

Cases with persisting LLI intra-operatively

There were seven cases that had an overall feeling after all subjective tests and adjustments were made, that the surgeon felt were still unequal but it was not possible to improve on this. Test three (length at the knees) and the overall feeling suggested lengthening, but the remaining tests were satisfactory. Seven of the eight cases with an unsatisfactory test three were the same cases as the seven abnormal overall feeling results.

Descriptive presentation of the residual LLI cases.

The mean LLI between the two measurements for the seven unequal results in test three (measuring length at the knees) after adjustments are shown in Table 4.7. The results are the mean of two measurements taken by the same examiner on separate occasions. The case in which test three (measuring length at the knees) alone suggested the leg was short resulted in a LLI of -5.7mm.

Table 4.7. The mean LLI for the seven 'unsatisfactory' results in test three after adjustment.

Test 3 long	LLI in mm
1	+8.2
2	+4.7
3	+13.2
4	+7.0
Test 3 short	LLI in mm
1	-10.0
2	-6.3
3	-0.8

The mean LLI measurements of six out of the seven cases which were identified as unequal by test three are above the mean LLI of the 'satisfactory' patients in cohort three (+ 2.69mm).

Comparison of 'satisfactory' and 'unsatisfactory' outcomes of five tests

The mean LLI in the 'equal' group was +2.7mm, the mean LLI in the unsatisfactory group (long or short) was +2.3mm. Statistical analysis was performed to compare the means of the two groups. The t-test was selected as the data was normally distributed. While there was a trend towards a greater residual LLI in the group deemed unsatisfactory by the five tests, the difference did not reach statistical significance ($t=-0.529$, $P=0.600$). See Figure 4.8.

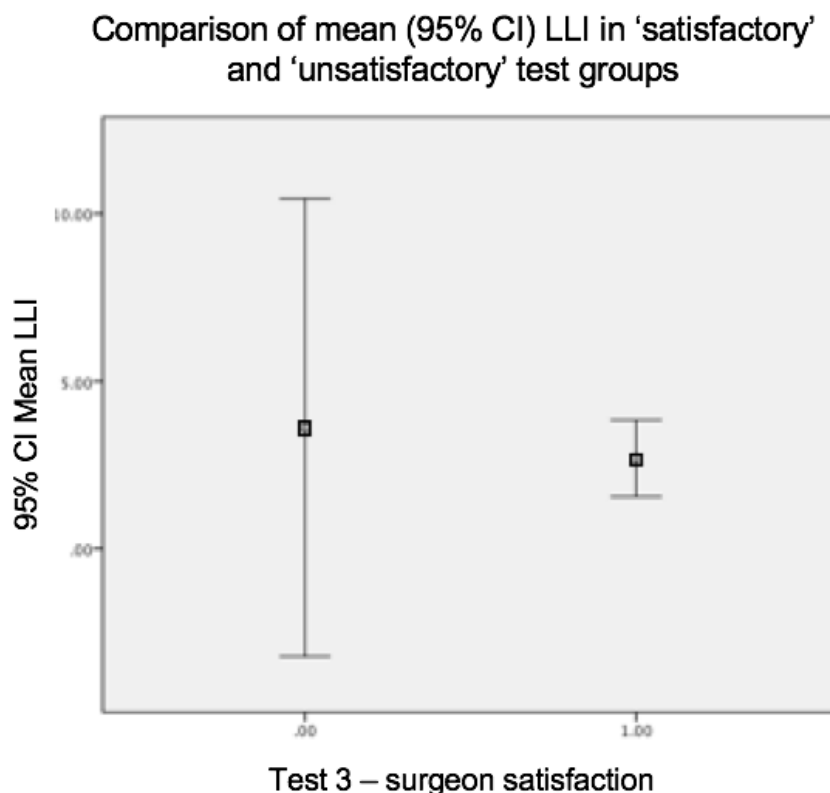


Figure 4.7. Error bars for 95% confidence intervals comparing 'satisfactory' and 'unsatisfactory' outcomes of test three and 'general feeling'.

It is broadly agreed that shortening is better tolerated than lengthening^{166,276} and revision for LLI is generally for lengthening. Therefore, we attempted to find whether the tests were more sensitive for lengthening than shortening.

The total hip replacements which after final adjustments and tests still indicated 'long' were evaluated. The mean (SD) LLI in the 'equal' group remained at 2.7mm, the mean LLI in the 'long group' was 8.3mm. A t-test was conducted to compare the groups which indicated that the difference was systematic ($t=-3.105$, $P=0.004$). See Figure 4.9.

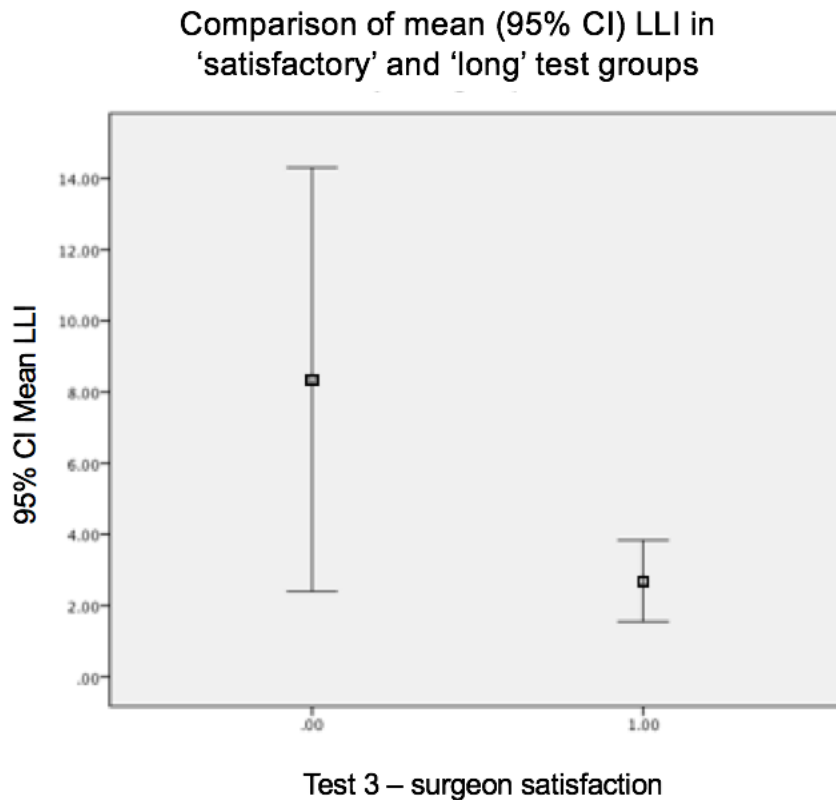


Figure 4.8. Error bars for 95% confidence intervals comparing 'satisfactory' versus 'long' outcomes of test three and 'general feeling'.

4.12 Changes in measurement of LLI with time

Introduction

It has been suggested anecdotally that the immediate post-operative radiograph does not give a true reflection of post-operative LLI. This is perhaps due to post-operative pain and the inability to lie in the required position required for the radiograph, and because any residual apparent LLI has not yet had time to correct itself. The literature agrees that most apparent LLI has resolved by six months following total hip replacement therefore it is possible that radiographs taken after this time will show smaller values of LLI than the patients immediate post-operative radiograph. This sub-study aimed to assess any difference in LLI between the immediate post operate

radiographs and second radiographs taken at an average of 12 months post-operatively.

Methods

All patients from cohort 3 have now reached 12 months since their total hip replacement. Patients attended their normal follow up at 12 months and repeat AP pelvic radiographs were taken using the previously documented standardised protocol. The LLI was measured by a single examiner using the Woolson technique.

Results

40 out of the 44 patients from cohort 3 attended their one year follow up. The mean and range of LLI from the immediately post-operative radiograph and the 12 month X-ray are shown in Table 4.8

Table 4.8. LLI measurements immediately post-operative, and at 12 months.

Immediate Post op LLI	12 month LLI	Difference (mm)
Mean and Range (mm)	Mean and range (mm)	
+3.1 (-10.5 to 14.2)	-0.1 (-12.5 to 12.6)	3.2 (- 2.0 to +1.6)

At 12 months post-operatively the mean LLI has fallen from +3.1 to -0.1mm. The range of difference is slightly higher at 12 months (25.1mm compared to 24.7mm) but the results are very similar.

Discussion

Although the mean LLI is smaller in the radiographs taken 12 months post-operatively it is very difficult to draw any conclusions from this small study as the cohort included in the initial study had already excluded any patients with contractures and pelvic malpositioning. It is obvious perhaps that these are

the more difficult radiographs to interpret and are more likely to show differences in LLI over time as any contractures may improve post-operatively.

Repeating a similar study with a larger cohort and fewer exclusion criteria would be likely to show larger differences in LLI between immediate post-operative and radiographs repeated at at least six months post-operatively.

4.13 Discussion

This study set out to assess the effectiveness of the five intra-operative techniques used by an experienced hip surgeon to minimise LLI after primary total hip replacement by measuring the post-operative leg lengths on X-rays of the previously defined cohort of consecutive total hip replacements. The use of the five intra-operative tests in combination resulted in a mean LLI of +3.1mm with a range of -10 to +14.2mm which is within the range of LLI that would always be acceptable, as supported by the literature and a recent survey of BHS surgeons ^{4,150,156-158}.

Tests which, when an unsatisfactory result was obtained, led to more adjustments tended to be more subjective tests such as the Shuck test. When the tests using direct measurements from the greater trochanter or the cut on the calcar indicated an LLI these were often ignored in favour of the result of the Shuck test. This is perhaps because the surgeon recognised that a small variation in the direct tests is normal due to the patient's anatomy but these small differences would not have a significant impact on LLI. The first two tests (measuring the cut on the calcar and measuring tip of greater trochanter to the shoulder of the trial stem) are relied upon when planning the insertion of the femoral stem, and final adjustments to LLI are made with the modular head and neck selection. Only when a significant LLI was noticed and could not be corrected with a different modular head and neck combination was the femoral resection changed. We can therefore conclude that final decisions regarding implant selection rely more on the outcome of the Shuck and kick tests than the other three tests.

The outcome of satisfaction from test three (measuring the leg length at the knees), gave the same result (long or short) as the 'general feeling'. This suggests that test three is the most accurate of the five tests but this is not the case. When this test suggested unequal leg lengths, but the Shuck and kick tests were satisfactory, the results of the Shuck and kick test were favoured and the total hip replacement was completed. The surgeon never completed the total hip replacement when the outcome of the Shuck or the kick test indicted LLI. The Shuck and the kick tests are relied upon in decision making during a total hip replacement as they indicate stability of the hip as well leg length. A short leg indicated by too much 'shuck' would mean the hip was potentially unstable and liable to dislocate. This would therefore never be accepted. If the Shuck test indicated a short leg but other tests indicated the leg was long then the surgeon would be more likely to be directed by the Shuck test. Soft tissue laxity can create a conflict between leg length equality and hip stability, in these situations, stability is more important, leg lengthening may be necessary to achieve the primary goal ⁶⁶.

In all cases when the 'overall feeling' was of unequal leg lengths this was reflected by increased post-operative LLI. This is the most subjective test of all which relies partly on information from the five tests but mainly relies on surgical experience and skill. This demonstrates why the myriad of commercial devices and computer navigated surgery are unable to completely eliminate LLI ²⁵⁹.

Indirect tests may be misjudged in the presence of neuromuscular blockade such as local or regional anaesthetics. One study showed LLI was present in 87% of patients who received regional anaesthesia but only 47.6% of those who had a general anaesthetic ¹⁵². Results from another study showed that patients who had had an epidural had decreased incidence of having an LLI of greater than 10mm but there was no significant differences were associated with a general or spinal anaesthetic. ¹⁵⁸. To minimise any possible effect of anaesthetic type on soft tissue tension all patients included in the trial had spinal anaesthesia. This is the surgeon's anaesthetic of choice. It is possible

that repeating this study with a cohort of patients who had received a general anaesthetic would give different results but this has not been explored.

There are many publications in the literature reporting results of intra-operative techniques and devices to decrease LLI post total hip replacement ^{103,145,151,197,282,287,293,297,337-339}. The range of LLI from 11 papers varied from 20mm shortening to 35mm lengthening with a range of 55mm. Six of the eleven papers reported mean LLIs ranging from 0.3mm to 12mm ^{160,282}. This study has shown that reporting LLI as a root mean square value gives more accurate presentation of results.

This study had several limitations. In order to reduce the variance caused by significant LLI pre-operatively in the results of the five tests, all complicated cases such as bilateral disease, DDH or previous trauma or surgery were excluded from the post-operative analysis leading to a small final cohort of 44 patients. This is a limitation of the study as the conclusions regarding the effectiveness of the five intra-operative tests can only be applied to simple primary total hip replacements with previously normal anatomy and cannot be extrapolated to include more complex cases. It could be argued that these more complicated total hip replacements are the ones at increased risk of post-operative LLI and therefore would benefit from proven techniques for assessing LLI. To make this study more clinically relevant it could be repeated with a larger cohort and without the exclusion of complicated total hip replacements.

This study was performed by a single experienced arthroplasty surgeon and it could be argued that the excellent LLI results are down to surgical experience rather than the five tests used. The study could be repeated with a more junior arthroplasty surgeon and a decrease in LLI after the introduction of the five tests would further validate the results.

It is not possible to conclude which, if any, of the five tests is the most effective at minimising LLI or could be used alone as a single technique as it would not be ethical to complete the operation leaving any of the tests with

unsatisfactory results in order to make conclusions about their contribution. This study reports a mean LLI of +3.1mm which is superior to many reports in the published literature and within the reported range of LLI which would always be considered acceptable according to a recent survey of the British Hip Society³⁴⁰, as discussed in chapter three.

4.14 Conclusion

This study set out to establish whether an experienced hip surgeon can reproduce leg length using the five intra-operative tests described, without the use of commercial devices. The results of post-operative leg length show this is possible. The mean LLI obtained by using these techniques was +3.1mm with a range of -10.5 to +14.2. The mean and the majority of values were within the range that is considered acceptable by the literature with the exception of four cases^{4,150,156-158,340}. This is the first study to report these five tests being used in combination and validated by results. However, the cohort of patients included only unilateral total hip replacements for primary osteoarthritis and the results are therefore only applicable to these cases.

It is not possible to prove which of the five tests is the most effective, however more adjustments to components were made when the Shuck test and the kick test indicated LLI. This suggests the surgeon favours these subjective tests and is more dependent on them. The five tests used in conjunction give excellent results.

The complex deformities that are often present in patients presenting with end stage osteoarthritis present a difficult challenge to surgeons and radiologists measuring leg length. It is clear that despite standardised protocols for AP pelvic radiographs, it is impossible to completely eliminate any inaccuracies resulting from fixed contractures and pelvic obliquity. Direct comparison of LLI using any method should be interpreted with caution, especially for serial imaging. Greater accuracy, particularly in the presence of complex deformity

can be achieved using CT scanograms, however this study explored the more commonly used, more economical plain film radiographic techniques.

Chapter 5. Development of a novel device to minimise leg length inequality during primary total hip replacement

5.1 Introduction

There are many well-known pre- and intra-operative methods of minimising total hip replacement related LLI. Preoperative templating assists surgeons in making decisions about size and placement of implants, neck length, offset, level of femoral osteotomy and restoration of limb length required. Although careful pre-operative planning is vital, it does not replace the requirement for intra-operative assessment. There are multiple ways of assessing leg length intra-operatively, ranging from simple tests to commercial devices. Most commercial devices recommended in the literature are based on measuring between two fixed points, for example a K-wire or Steinman pin in the acetabulum and measuring to a set point on the femur. These devices are often invasive, requiring an extra or longer incision or inserting a large pin which can potentially propagate fractures. They may be expensive and are heavily reliant on exact replication of positioning of the operated limb to be reliable. Indirect methods of assessing leg length rely on the tension of the soft tissues around the implanted total hip replacement as a surrogate indicator of leg length. They guide accuracy of leg length and stability, assuming that the implanted total hip replacement constituents are a similar size to the native hip joint.

Following the introduction of the European Working Time Directive in 1993, the practical time junior surgeons spend in theatre has fallen but the expectations to reach the same level of competency by the completion of training have remained the same. Alternative methods of acquiring operative skills have been explored such as computer simulation and devices to assist

intra-operatively have become necessary. Previous work from this thesis showed that the Shuck test is utilised by approximately 77% of surgeons surveyed and there is scope for development for an adjunct to this test to improve reproducibility. The Shuck is an inherently subjective test and is dependent on factors such as anaesthetic type ^{152,158}, body habitus and hip anatomy. It is heavily dependent on technique ²⁷⁴ and its subjective nature means it is a difficult skill to teach to junior arthroplasty surgeons as there is no objective method of measuring it. It is a skill that is acquired with experience and feedback. Presently, the Shuck test takes place first during the trial reduction phase. The surgeon makes an assessment of soft tissue tension by applying longitudinal traction on the femur and attempting to displace the replaced femoral head from the socket. See Figures 5.1 and 5.75.



Figure 5.1. total hip replacement in situ showing Shuck test. Swab (not pictured) distracting replaced femoral head from socket.

Lines on femoral head have been added by the author to quantify distraction.

The surgeons' decision as to whether the soft tissues are providing the correct stability is based broadly on experience and judgement as no actual measurements of force, angle of pull, or distraction distance are taken. Hence, from their judgement alone, the surgeon adjusts the soft tissue forces by changing the size of the stem, the femoral neck offset or the femoral head offset; all of these options directly affect the subsequent leg length. The handedness of the surgeon is additionally important as the surgeon uses his right hand to assess the stability of a right leg, and left hand to assess a left

leg and it is possible to inadvertently apply more traction with the dominant hand.

Presently to the author's knowledge there is no device that exists that may be used to assess soft tissue tension during total hip replacement. In 2010, a prototype device was manufactured and tested on an in-vitro shuck test model for four different surgeons to assess loads applied during trial reduction for their left and right hands. The results in Figure 5.2 showed a range of loads applied (35-82 N) with variability from left to right hand of the surgeon ranging from 46N to 29N respectively. Feedback from the surgeons suggested that a device that could measure distraction forces would add significant value to hip arthroplasty ²⁹.

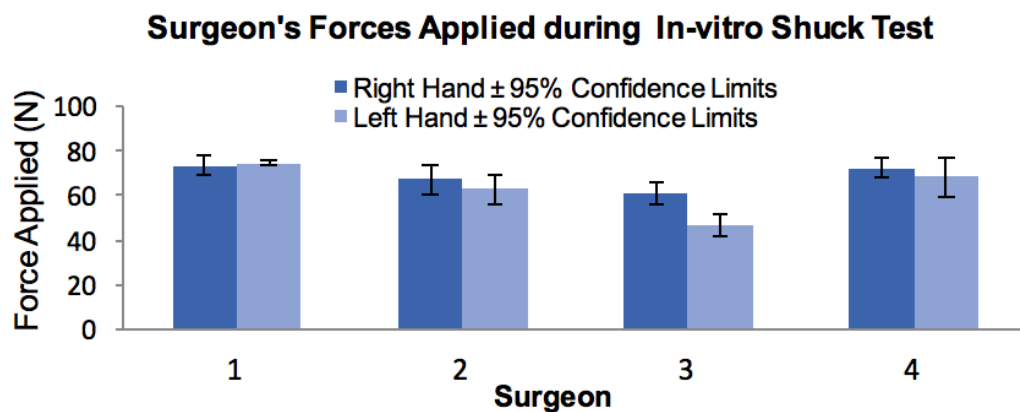


Figure 5.2. Forces applied during simulated Shuck test ²⁹

5.2 Study aim

The aim of this chapter was to develop a novel approach to objectively assess in vivo soft tissue tension, minimising the requirement for subjective and invasive methods.

A device was designed to measure the amount of force applied during the Shuck test and to measure the amount of displacement produced in a correctly tensioned total hip replacement. When developed further this device

could be used intra-operatively to objectively test soft tissue tension and therefore LLI. If successful the device could then be used to teach junior arthroplasty surgeons how to perform the Shuck test correctly, potentially reducing the learning curve by a significant amount of time.

The device was to be used in NHS theatres and therefore needed to fulfil NHS requirements for new medical devices including materials and sterilisation guidelines and was thus developed in conjunction with Leeds NHS Trust's Medical Physics department, St James' Hospital, Leeds.

5.3 Development of novel device

5.4 Concept

The initial concept of the device was discussed with a consultant arthroplasty surgeon (MHS) and a medical engineer (TDS). The original model proposed was similar in nature to a mechanical luggage scale with a hook to connect to a surgical swab and a modified handle to apply traction (Figure 5.3 A.). Although this would have been simple to read intra-operatively, the mechanical nature meant it would be difficult to sterilise.



Figure 5.3. A. Mechanical luggage scale and B. Electronic luggage scale

The idea of an electronic luggage scale (Figure 5.3 B) was also explored but it was concluded that the difficulties in sterilisation and increased price to

produce would lead this to be prohibitive to uptake. However, the ergonomics of this design were promising. The shape of the grip handle was comfortable, an appropriate size and allowed tactile feedback.

Soft tissue knee surgeons use a tensioning device for anterior cruciate ligament repair surgery made by DePuy (Leeds, UK) (Figure 5.4). Whilst this device was not a suitable shape, the stainless-steel components including a spring were already proven to be suitable for intra-operative use and sterilisation.



Figure 5.4. ACL tensioning device. Intrafix, DePuy, Leeds, UK

The developed device needed to be cheap to produce so that cost would not be prohibitive to uptake. It also needed to be simple to use so it would give repeatable results and not add on significant time to surgery. Initial plans were drawn up with the mechanical engineers. An entirely stainless steel design was decided upon with a simple spring and plunger design to enable easy disassembly for sterilisation. The barrel to be held in the surgeon's hand to apply traction was designed to be made from smooth stainless steel for comfort and good grip. This was designed to attach to a plunger with etched markings to show force. The initial design included a maximum force of 80N which was the maximal force of Shuck identified in a previous study²⁹. The option of numbered force markings was discussed but it was thought that the small etched numbers would be too small to read across the operating table. After the initial plans were established, CAD images were produced by the mechanical engineers and the prototype device was produced.

5.5 Device design

The device was designed to fit in the surgeon's hand and attach to a swab as an adjunct to the Shuck test, (instead of the surgeon holding the swab directly as in an unaided Shuck test) but still allow tactile feedback. It was designed to deliver a standardised amount of tension or "shuck" which is measurable and repeatable.

A prototype device was subsequently designed and manufactured by orthopaedic, engineering and medical physics teams from Leeds Teaching Hospitals and the University of Leeds. The device was named 'TrueTense'. The device was designed to be used in conjunction with etched femoral heads and therefore comprises of two parts:

- Part A is the handheld tensioning device used to measure the force and
- Part B is a customised femoral head trial implant

Part A- TrueTense device

Part A will from here on be referred to as the TrueTense device. It is made from medical grade 316L stainless steel and comprises of a handle for the surgeon to grip enclosing a spring connected to a T-handle that the swab will be wrapped around. There are major and minor lines etched on the T-handle to indicate the force pulled in Newtons. In the prototype device, each bold line corresponds with 20 Newtons and each thin line corresponds with 10 Newtons. See Figures 5.5 and 5.15.



Figure 5.5. Part A. Prototype TrueTense device.

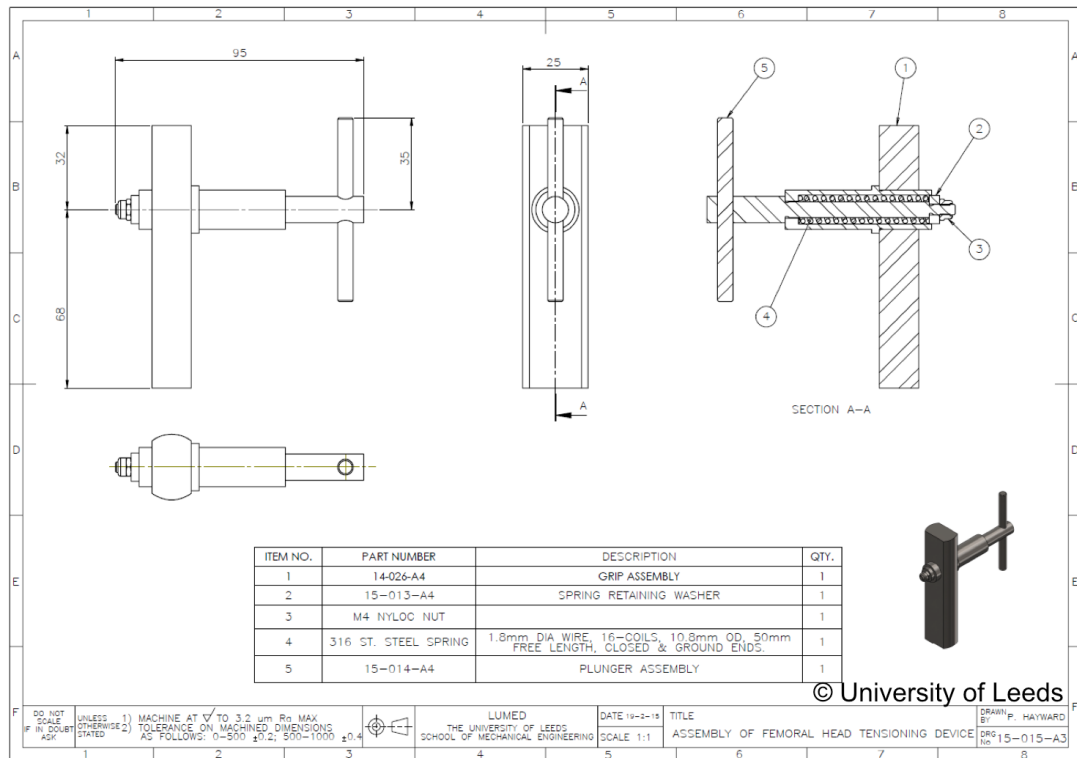


Figure 5.6. Schematic of TrueTense prototype device.

The TrueTense device consists of the components shown in Figure 5.6. Two assembly options and two stiffness options were manufactured to assess the user requirements of the device.



- ① Stainless steel plunger assembly
- ② Stainless steel grip assembly
- ③ 50mm stainless steel spring
- ④ TrueTense 7mm stainless steel spanner
- ⑤ TrueTense 28mm calibration ball black
- ⑥ TrueTense 28mm calibration ball blue
- ⑦ TrueTense 28mm calibration ball brown
- ⑧ TrueTense 28mm calibration ball green
- ⑨ Separately packed Nylock nut

Figure 5.7. TrueTense device components in sterilisation tray (Nylock)

The TrueTense circlip option is assembled by following the five steps outlined below:

1. Place T-handle in to longer side of grip assembly



2. Place spring inside shorter side

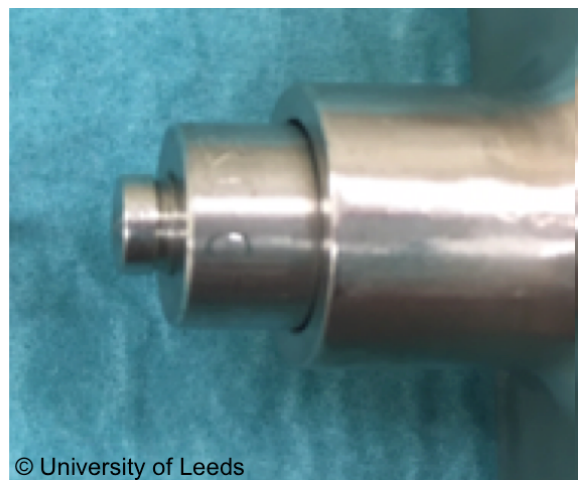


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3. Place spring retainer ring over spring



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4. Grip circlip using circlip pliers



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5. Squeeze pliers to open circlip and place in groove to hold spring retainer ring in place



Part B – modified femoral heads

The femoral heads used were a modified version of the existing trial DePuy femoral heads (DePuy Synthes, Leeds, UK) that are used in the trial reduction stage of surgery and were used in conjunction with the TrueTense device. The heads were additionally modified by etching markings at 3.5mm intervals which allows the surgeon to measure the distance of distraction of the replaced femoral head from the socket to facilitate force measurement (Figure 5.8 and 5.9).



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Figure 5.8. Modified trial femoral heads

Circumferential lines spaced at 3.5mm intervals.

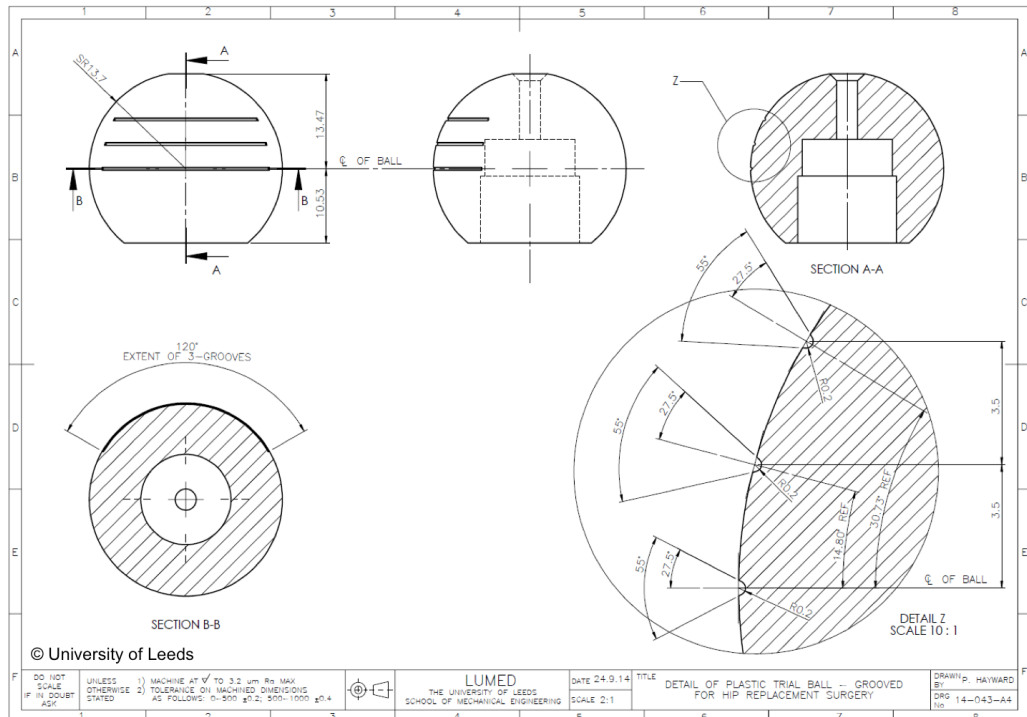


Figure 5.9. Schematic of etched trial femoral heads

Twelve TrueTense devices were produced. The devices were made in accordance with British Standards Institution (BSI) guidelines for production of medical devices. There are two versions of the TrueTense device, A-S (Short) and A-L, (Long). The short device A-S, has a shorter stiffer spring whilst the long device has a longer softer spring. The devices were made specifically in this manner to provide the surgeon with a variable stiffness of spring to evaluate.

The short and long TrueTense devices have different size barrels with springs containing different displacement scales. By making them different lengths

avoids the potential confusion in assembly with the incorrect spring. The devices had either a short or a long barrel with a short or a long spring.

Additionally, the TrueTense device has two fixation versions, a circlip option and a Nylock nut option, hereby labelled Part A-SC, Part A-SN, Part A-LC and Part A-LN. The proof of concept trial of the device is intended to determine which option is preferred by both the surgeon during usage and scrub nurse during assembly and thus provide the most convenient option. On initial in-vitro testing it was possible to overload and deform the circlip which weakened the design. The pliers were then modified to reduce the risk of overstretching the circlip. The circlip and Nylock nut options which secure the spring are shown in Figure 5.10 and the device options are shown in Table 5.1.



Figure 5.10. Stainless steel 5mm circlip and stainless steel self-locking nylon insert 'Nylock' nut.

Table 5.1. Device options.

Load	Quantity	Description	Stiffness	Distraction (mm)
Part A-SC	2	Short, Circlip	6.94N/mm	7, 10.5, 14
Part A-SN	4	Short, Nylock	6.94N/mm	7, 10.5, 14
Part A-LC	1	Long, Circlip	4.68 N/mm	7, 10.5, 14
Part A-LN	5	Long, Nylock	4.68 N/mm	7, 10.5, 14

5.6 Device testing

The devices were safety tested according to the Failure Mode Effects Analysis (FMEA) table (Appendix 4).

The devices were tested in a laboratory using an Instron E3000 universal testing machine. The devices were tested in four stages

1. Device calibrated to compare Instron load vs applied load
2. Devices tested to failure
3. Spring accuracy tested

(Device introduced and force found to be not large enough. Springs exchanged)

4. New spring accuracy tested

5.7 Device calibrated

The test machine was calibrated over the load range, with results shown in Figure 5.11. The measured load versus applied load was shown to have an excellent regression with a coefficient of 0.996 indicating the calibration of the device was accurate.

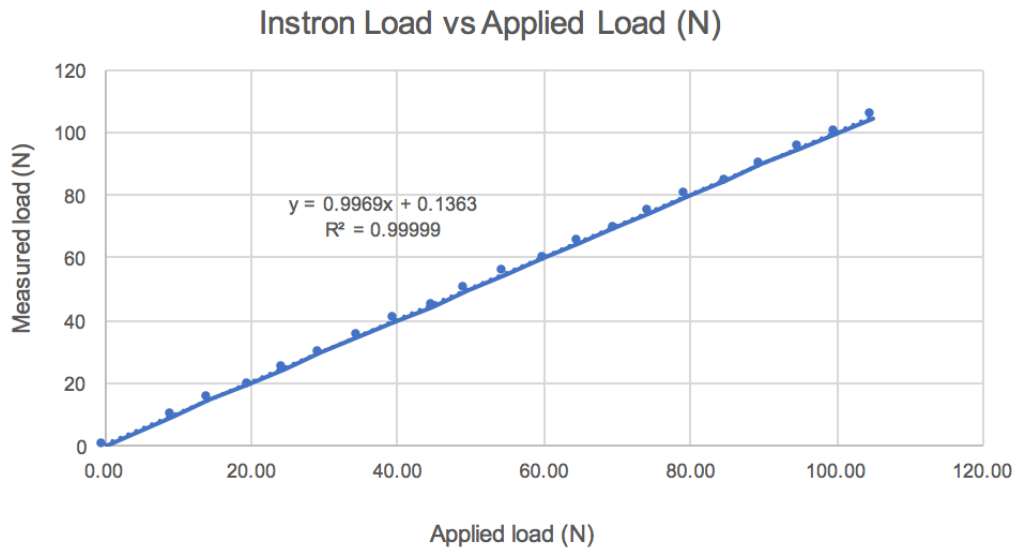


Figure 5.11. Device calibration.

5.8 Devices tested to failure

The devices were tested to failure, with a 600N max force applied to ensure that the device would not fail under a load that was ten times greater than the intended target load (60N)²⁹. No device failures were observed at 600N. The load was then increased to investigate the failure load of the device. The cotton surgical swab was found to break at around 600 - 650N (Figure 5.13), with no damage to the device, hence the risk of device failure was minimised. See Figure 5.12.

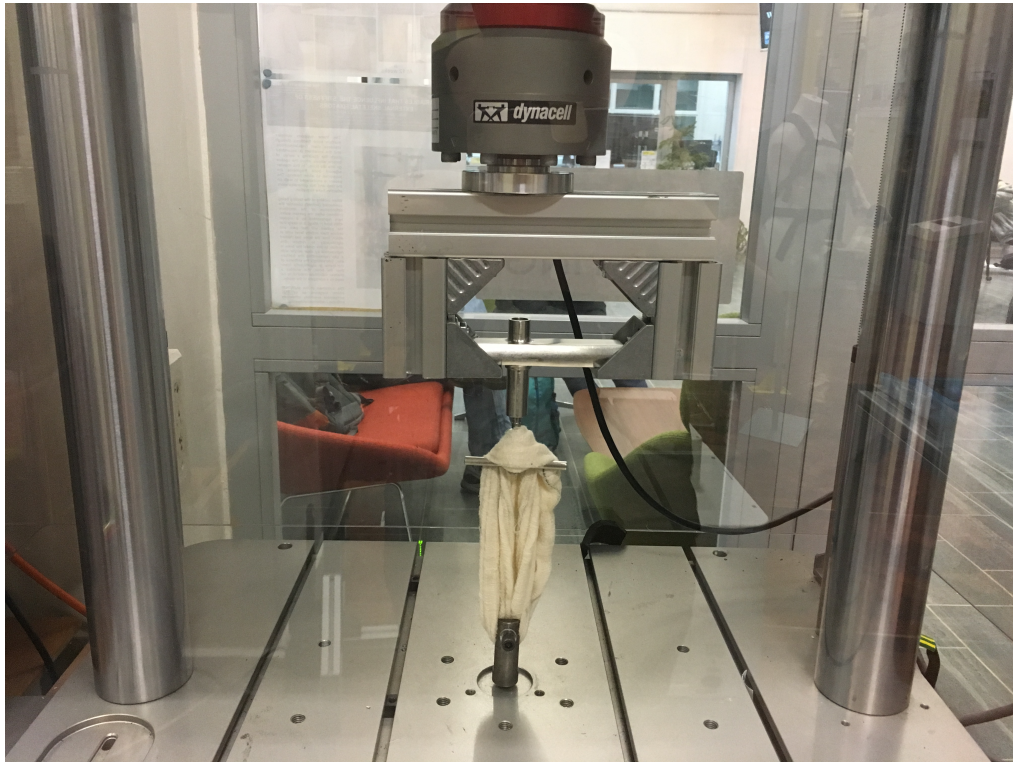
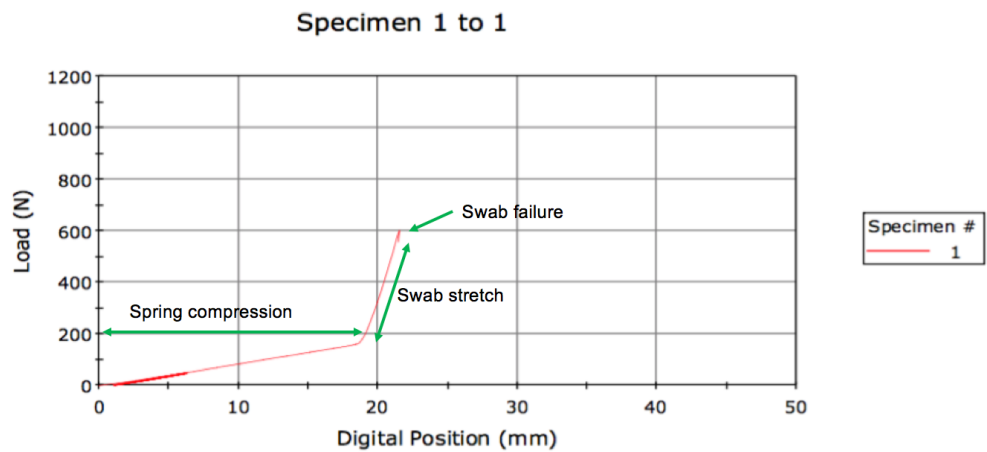


Figure 5.12. Instron E3000 calibration



	Custom text input 1	Start Date	Load at Break (Standard) (N)
1	s1	08/12/2014 14:36	600.59

	Digital Position at Break (Standard) (mm)
1	21.5

Figure 5.13. Testing device to failure

5.9 Spring accuracy tested

The devices and springs were tested for accuracy, to ensure the actual stiffness was in keeping with the manufacturers advertised stiffness. The load was applied and compared to the individual scale increments of the device, as shown in Figure 5.14.

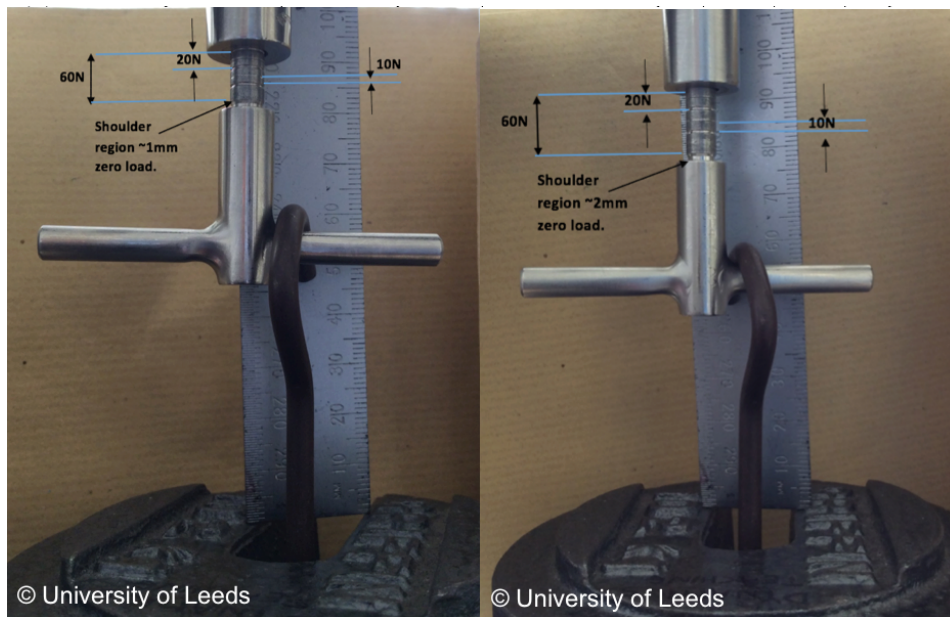


Figure 5.14. TrueTense device under 60N load

- a) TrueTense short - distracts ~9mm
- b) TrueTense long - distracts ~14mm

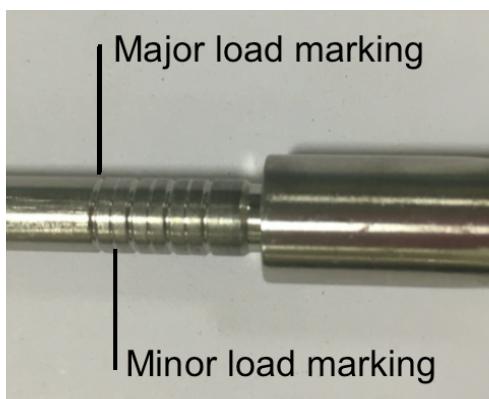


Figure 5.15. Etched load markings.

Major load scale marks were initially marked for 20N, and minor marks for 10N for both long and short barrelled devices.

The springs were tested to 60N using the Instron E3000 with an additional RDP 60N calibrated load cell. This was repeated in samples to determine losses in length with use. Each spring was tested in one of the twelve devices, three times with the Instron machine re-set to zero in between each test. There was no change to the length of the springs after use. The results are shown Tables 5.2 to 5.14 and Figures 5.16 to 5.71 below.

Device S1

Table 5.2. Device S1

Loading trial and Load (N)			Average Load vs Displacement			Load		Repeatability of loading trials 1-3
1	2	3	Average load (N)	Trial load (N)	Instron load (N)	% difference to target	% difference to Instron	SD
19.2	19.5	18.8	19.2	20	19.1	4.2	0.6	0.4
30.0	30.4	30.9	30.4	30	29.9	1.4	0.3	0.5
39.6	39.9	39.8	39.8	40	39.4	0.6	0.5	0.2
48.2	51.7	51.2	50.4	50	47.9	0.7	0.6	1.9
60.7	60.9	61.1	60.9	60	60.3	1.5	0.7	0.2

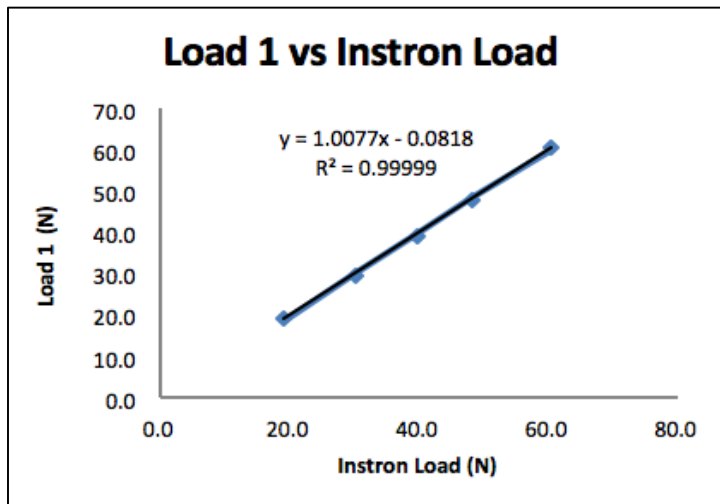


Figure 5.16. S1 Load 1 vs Instron load

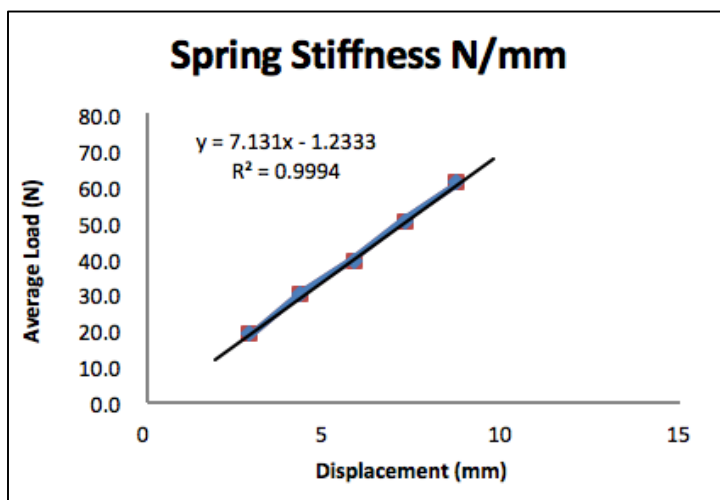


Figure 5.17. S1 Spring stiffness

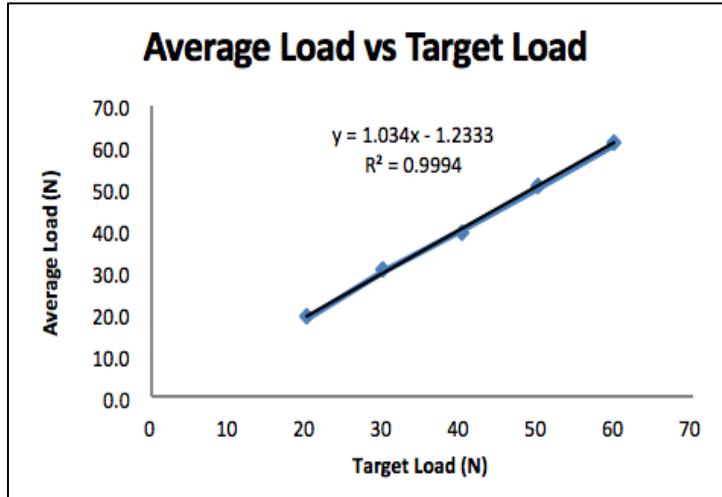


Figure 5.18. S1 Average load vs target load

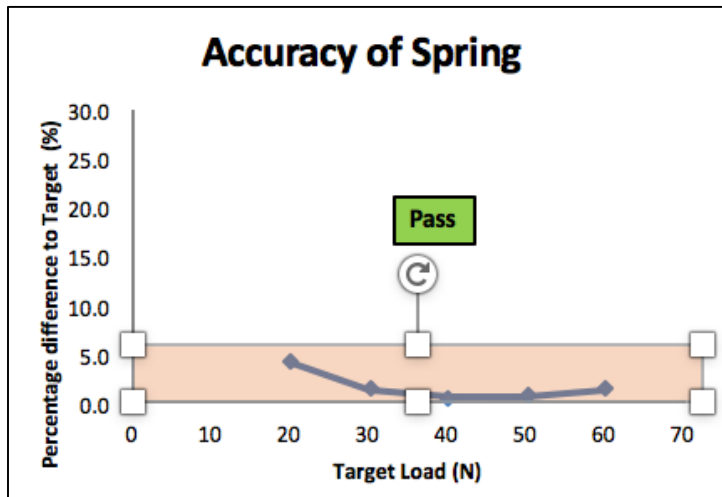


Figure 5.19. S1 Accuracy of spring

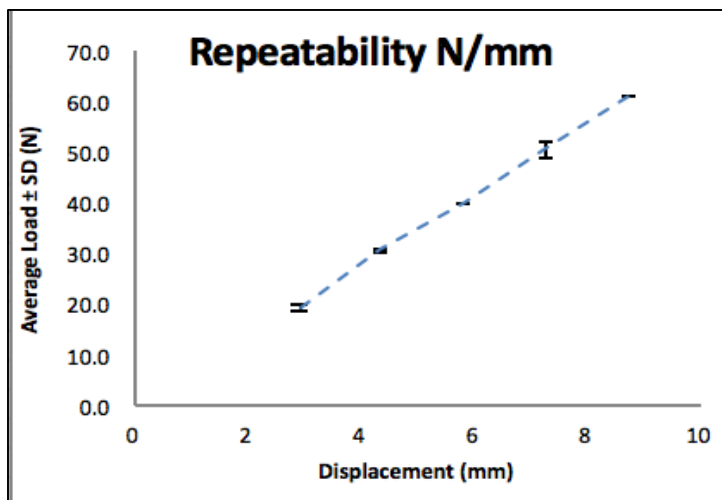


Figure 5.20. S1 Repeatability

Device S2

Table 5.3. Device S2.

Loading trial and Load (N)			Average Load vs Displacement			Load		Repeatability of loading trials 1-3
1	2	3	Average load (N)	Trial load (N)	Instron load (N)	% difference to target	% difference to Instron	SD
17.0	18.0	16.9	17.3	20	16.9	13.6	0.5	0.6
27.3	27.8	28.1	27.7	30	27.1	7.6	0.7	0.4
38.1	38.8	39.8	38.9	40	37.9	2.8	0.5	0.9
47	48.8	49.0	48.2	50	46.7	3.5	0.7	1.0
58.7	58.9	59.1	58.9	60	58.3	1.9	0.8	0.2

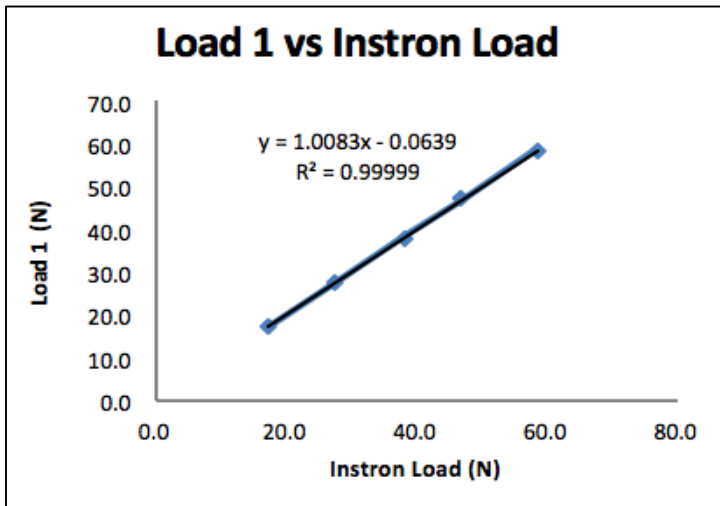


Figure 5.21. S2 Load 1 vs Instron load

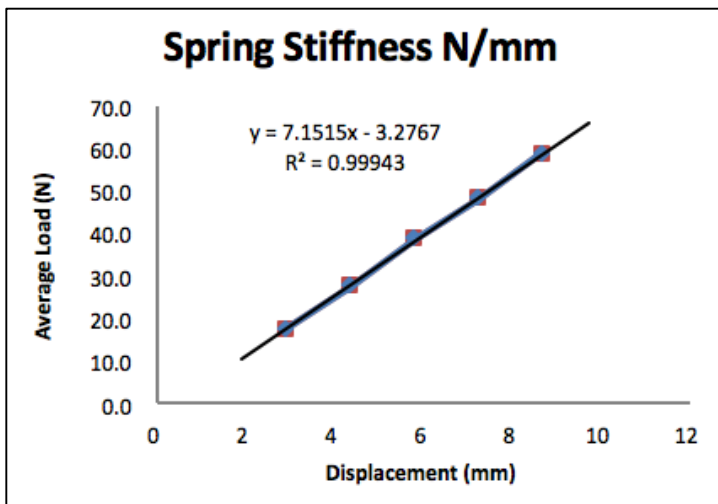


Figure 5.22. S2 spring stiffness

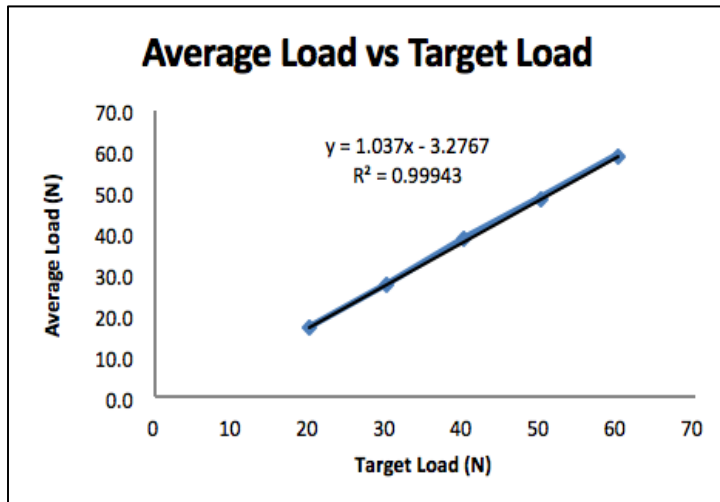


Figure 5.23. S2 average load vs target load

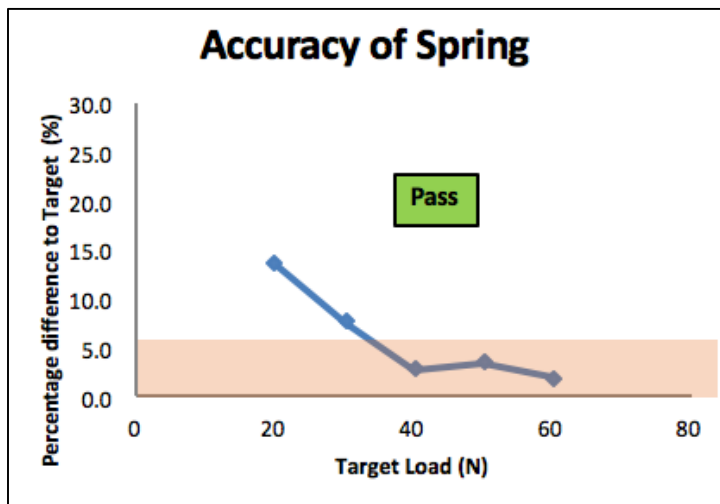


Figure 5.24. S2 Accuracy of spring

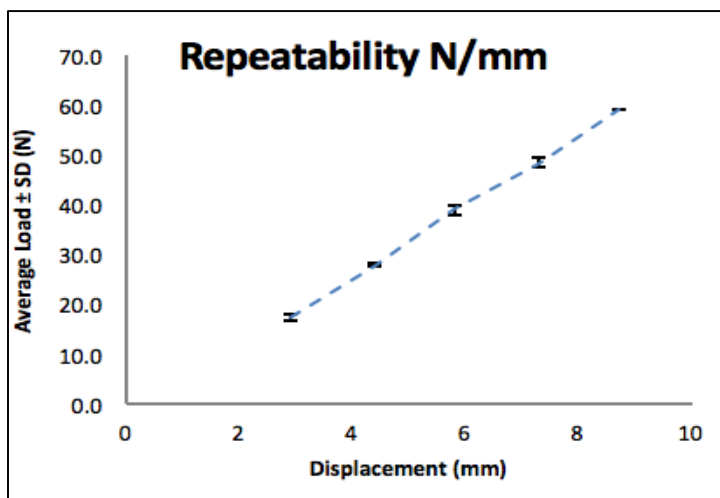


Figure 5.25. S2 repeatability

Device S3

Table 5.4. Device S3.

Loading trial and Load (N)			Average Load vs Displacement			Load		Repeatability of loading trials 1-3
1	2	3	Average load (N)	Target load (N)	Instron load (N)	% difference to target	% difference to Instron	SD
20.9	21.0	20.9	20.9	20	20.9	4.6	0.2	0.1
32.7	32.2	28.1	31.0	30	32.7	3.3	0.0	2.5
42.0	41.4	41.2	41.5	40	41.9	3.8	0.4	0.4
52.6	52.1	52.6	52.4	50	52.5	4.8	0.2	0.3
62.4	62.7	60.0	61.7	60	62.0	2.8	0.5	1.5

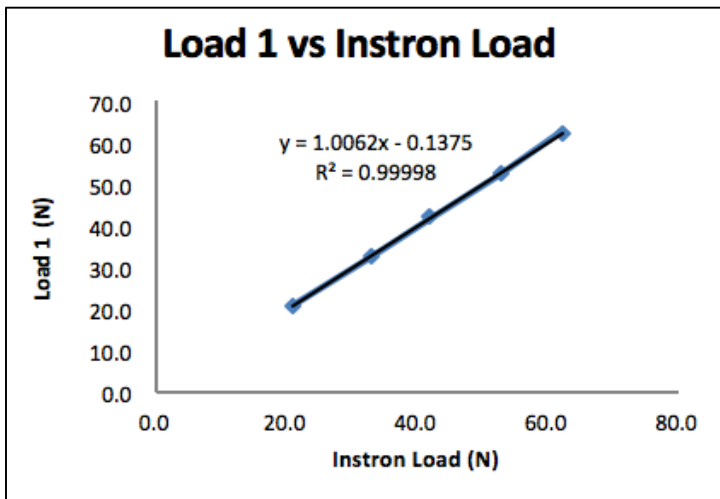


Figure 5.26. S3 load 1 vs Instron load

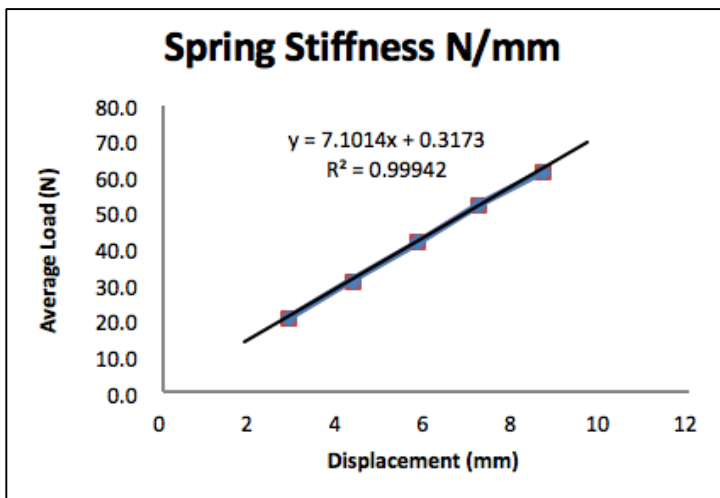


Figure 5.27. S3 spring stiffness

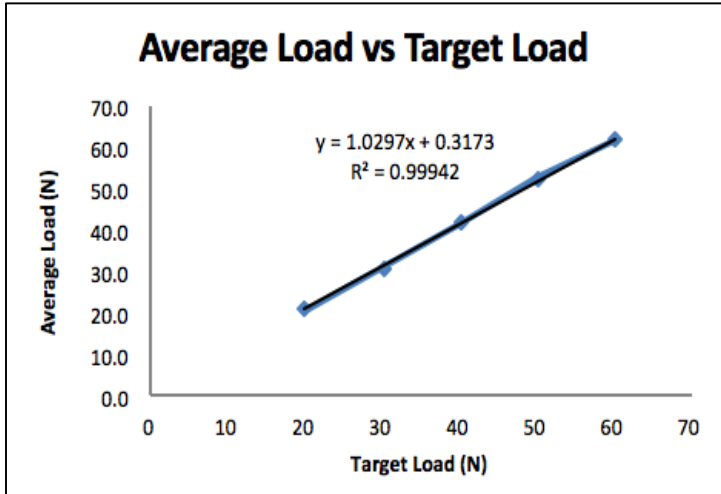


Figure 5.28. S3 average load vs target load

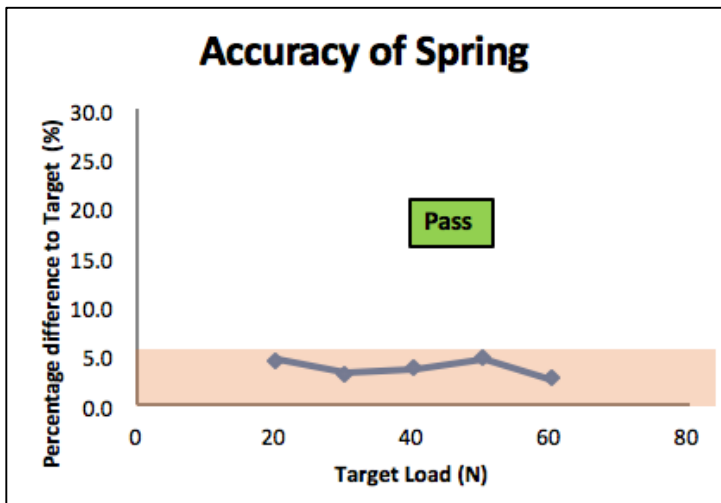


Figure 5.29. S3 Accuracy of spring

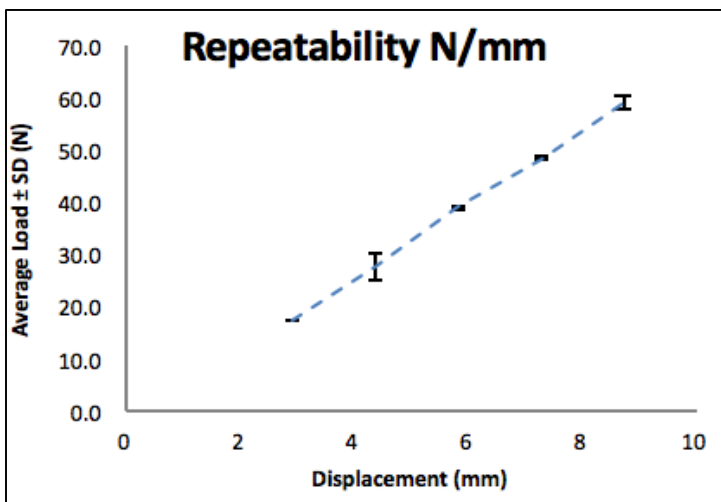


Figure 5.30. S3 repeatability

Device S4

Table 5.5. Device S4.

Loading trial and Load (N)			Average Load vs Displacement			Load		Repeatability of loading trials 1-3
1	2	3	Average load (N)	Target load (N)	Instron load (N)	% difference to target	% difference to Instron	SD
18.4	18.1	18.8	18.4	20	18.4	7.9	0.2	0.4
29.0	28.6	29.0	28.9	30	29.3	3.8	0.8	0.3
39.3	39.4	39.9	39.5	40	39.1	1.2	0.5	0.3
48.8	50.2	51.3	50.1	50	48.6	0.2	0.4	1.3
60.3	60.7	61.0	60.7	60	59.9	1.1	0.7	0.4

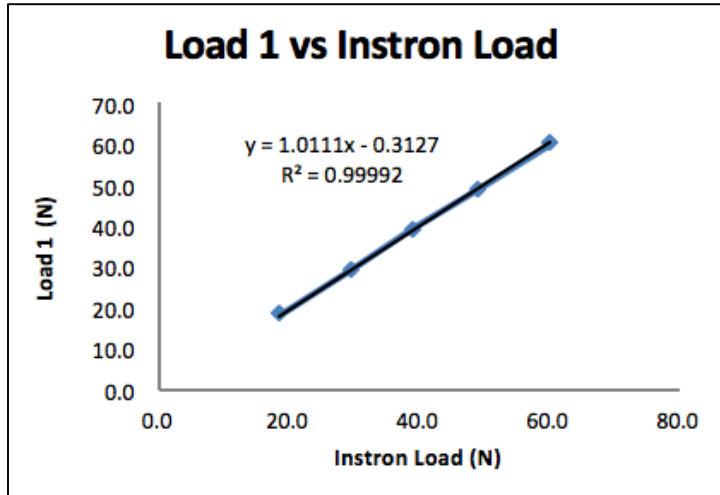


Figure 5.31. S4 load 1 vs Instron load

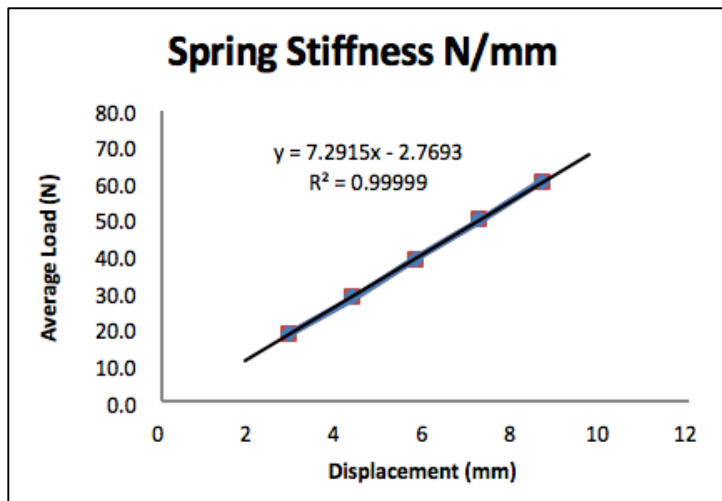


Figure 5.32. S4 spring stiffness

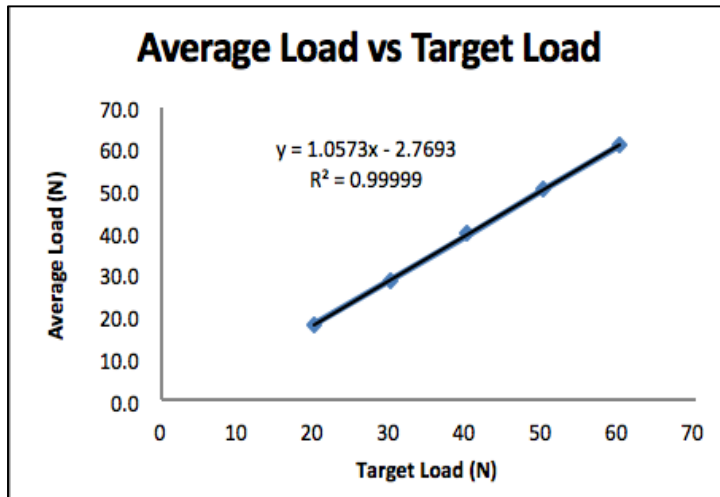


Figure 5.33. S4 average load vs target load

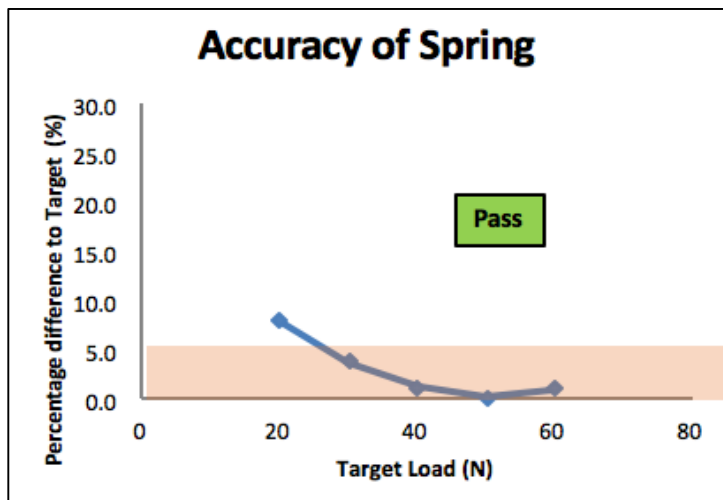


Figure 5.34. S4 accuracy of spring

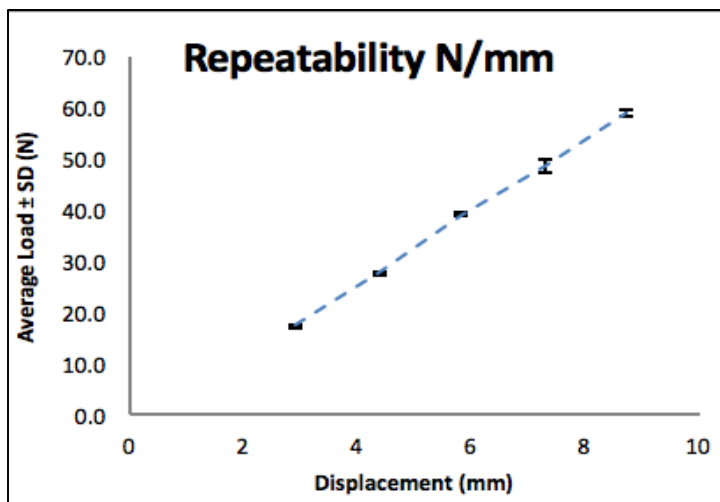


Figure 5.35. S4 repeatability

Device S5

Table 5.6. Device S5.

Loading trial and Load (N)			Average Load vs Displacement			Load		Repeatability of loading trials 1-3
1	2	3	Average load (N)	Target load (N)	Instron load (N)	% difference to target	% difference to Instron	SD
16.3	20.2	17.2	17.9	20	16.2	10.5	0.6	2.0
30.7	29.6	28.1	29.5	30	30.3	1.8	1.3	1.3
42.2	38.6	39.8	40.2	40	41.6	0.5	1.4	1.8
49.4	49.0	51.5	50.0	50	48.9	0.1	0.9	1.3
61.2	59.2	61.2	60.5	60	60.7	0.9	0.8	1.2

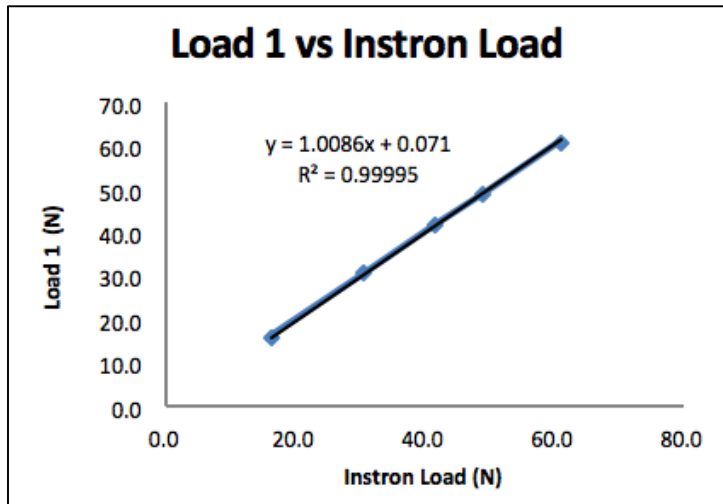


Figure 5.36. S5 load 1 vs Instron load

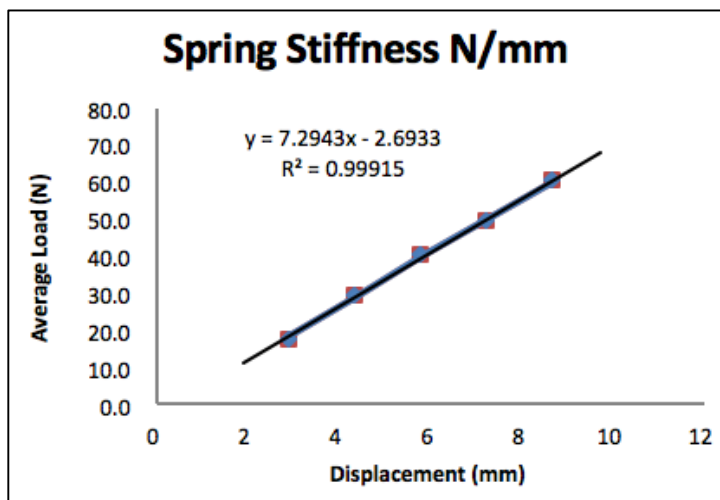


Figure 5.37. S5 spring stiffness

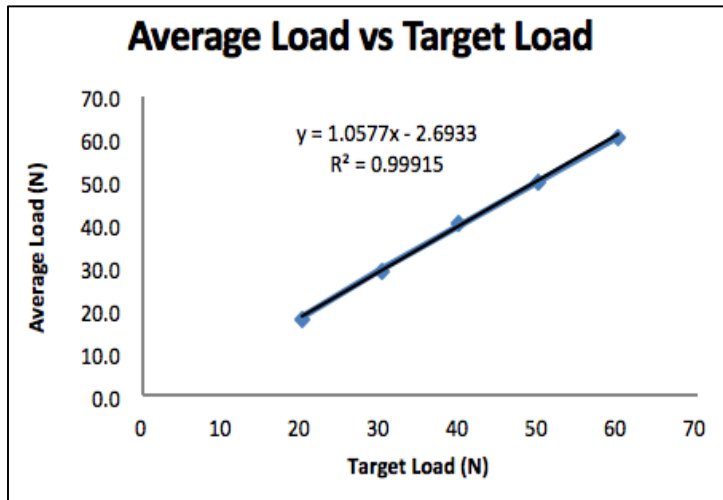


Figure 5.38. S5 average load vs target load

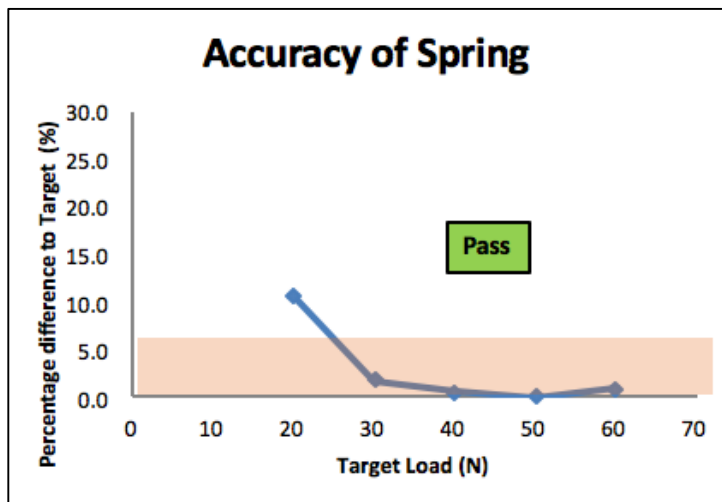


Figure 5.39. S5 accuracy of spring

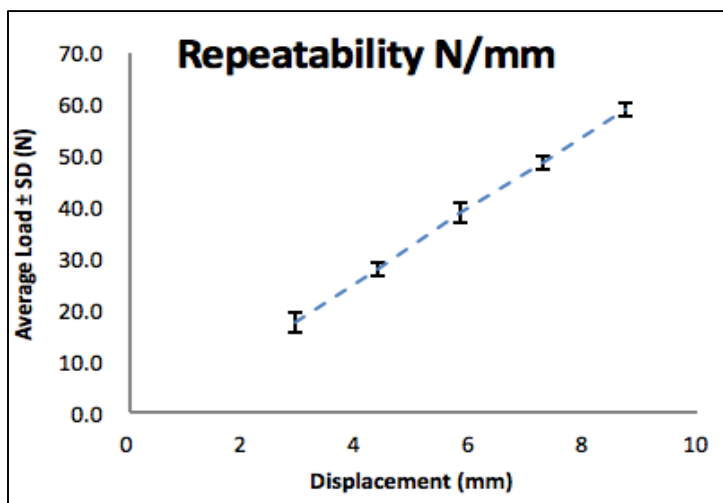


Figure 5.40. S5 repeatability

Device S6

Table 5.7. Device S6.

Loading trial and Load (N)			Average Load vs Displacement			Load		Repeatability of loading trials 1-3
1	2	3	Average load (N)	Target load (N)	Instron load (N)	% difference to target	% difference to Instron	SD
21.4	19.7	20.8	20.6	20	21.2	3.1	0.8	0.8
32.9	31.7	31.7	31.9	30	32.7	6.3	0.6	0.9
41.3	40.9	41.5	41.2	40	41.0	3.1	0.7	0.3
52.1	52.1	51.5	51.9	50	51.8	3.8	0.5	0.3
62.0	62.3	62.3	62.2	60	61.6	3.6	0.6	0.2

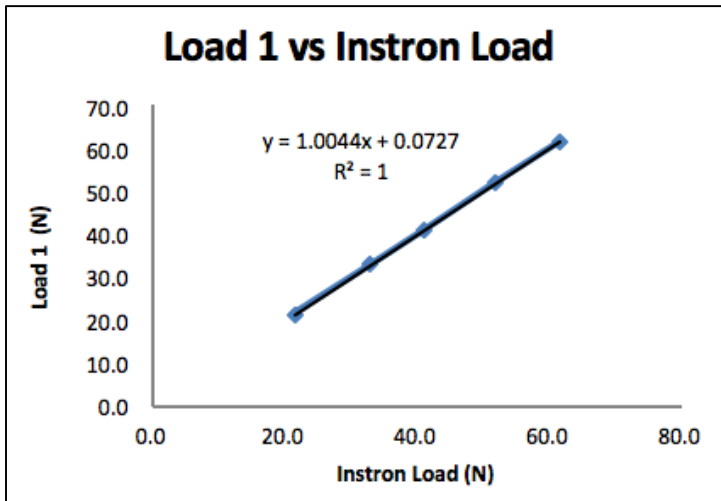


Figure 5.41. S6 load 1 vs Instron load

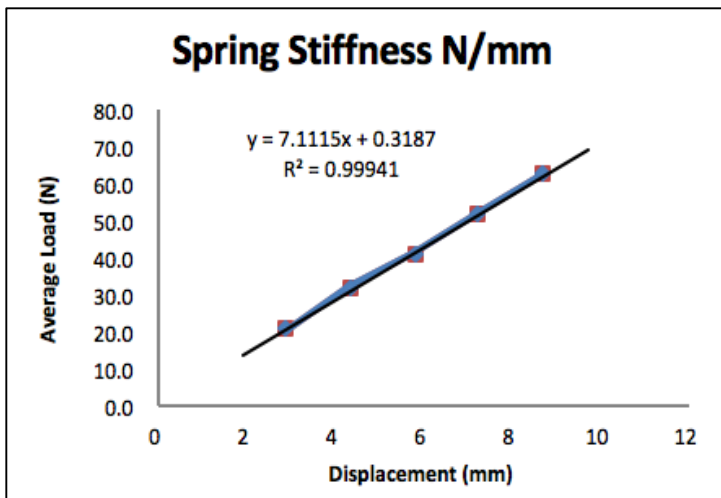


Figure 5.42. S6 spring stiffness

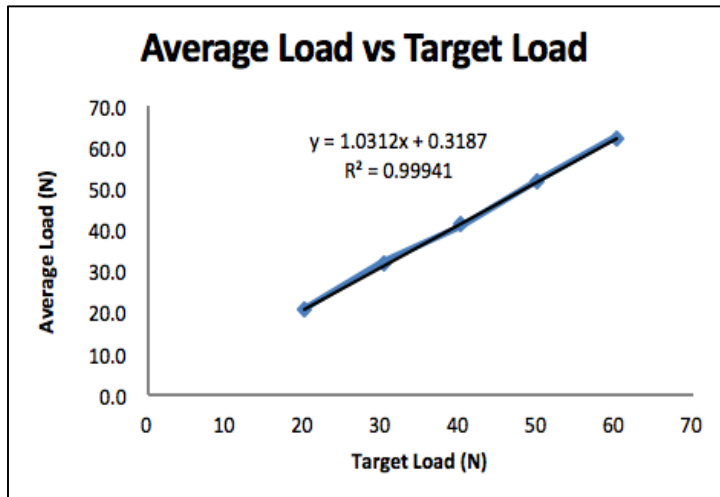


Figure 5.43. S6 average load vs target load

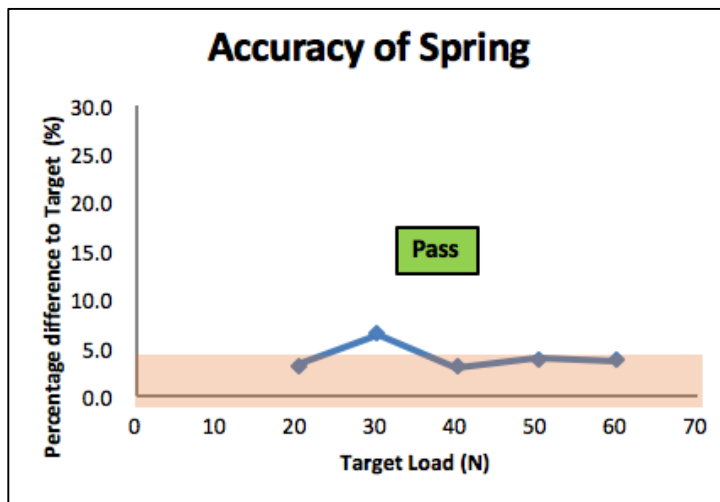


Figure 5.44. S6 accuracy of spring

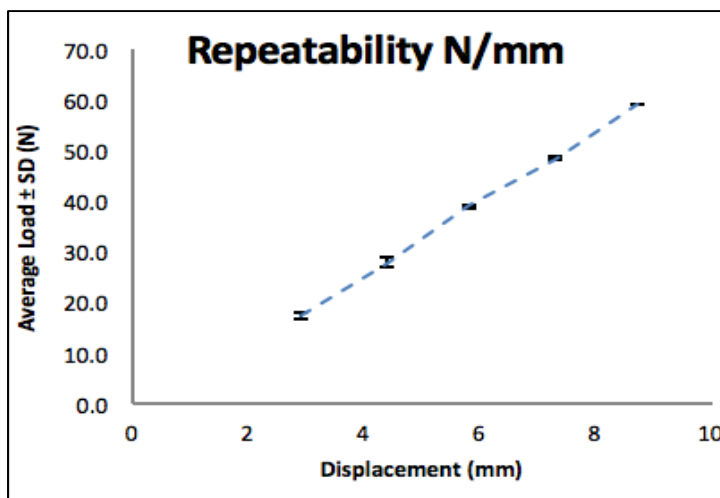


Figure 5.45. S6 repeatability

Device L1

Table 5.8. Device L1.

Loading trial and Load (N)			Average Load vs Displacement			Load		Repeatability of loading trials 1-3
1	2	3	Average load (N)	Target load (N)	Instron load (N)	% difference to target	% difference to Instron	SD
17.6	17.1	19.0	17.9	20	17.5	10.5	0.6	1.0
28.4	30.2	29.6	29.4	30	28.2	2.0	0.7	0.9
39.7	40.2	43.1	41.0	40	39.4	2.5	0.8	1.8
47.4	50.3	51.2	49.6	50	47.0	0.7	0.9	2.0
60.8	60.9	60.6	60.8	60	60.4	1.3	0.6	0.2

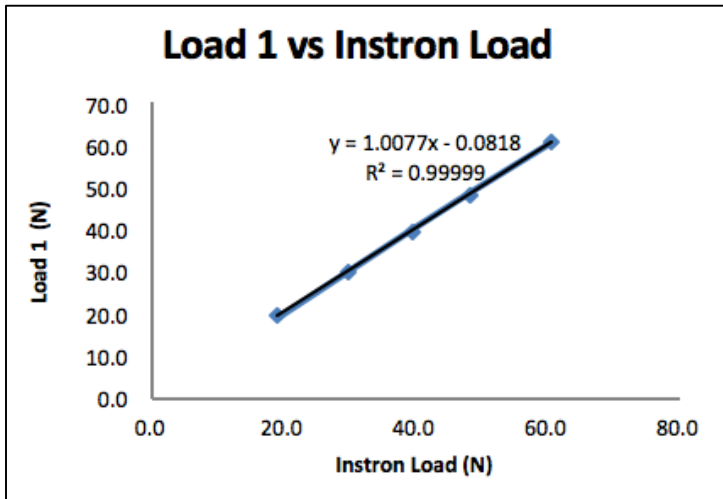


Figure 5.46. L1 load 1 vs Instron load

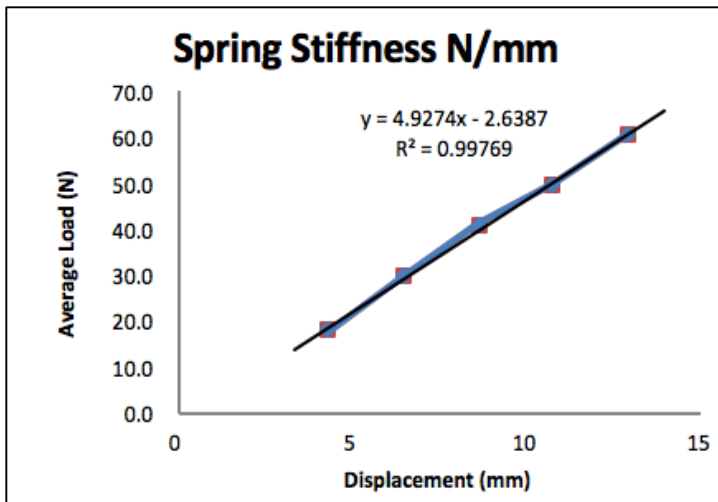


Figure 5.47. L1 spring stiffness

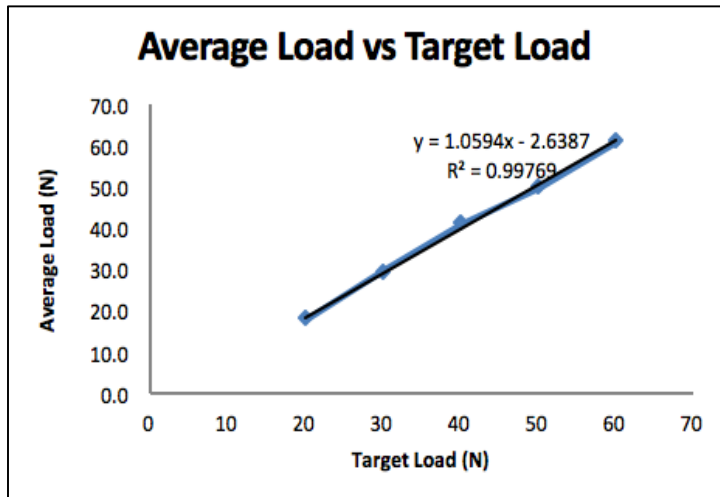


Figure 5.48. L1 average load vs target load

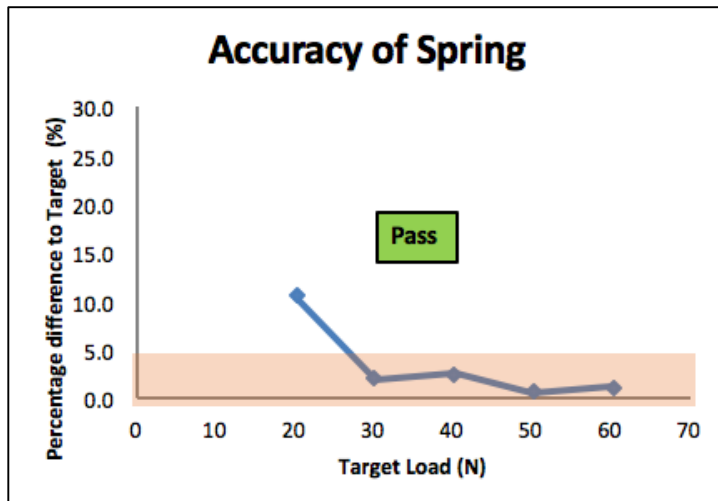


Figure 5.49. L1 accuracy of spring

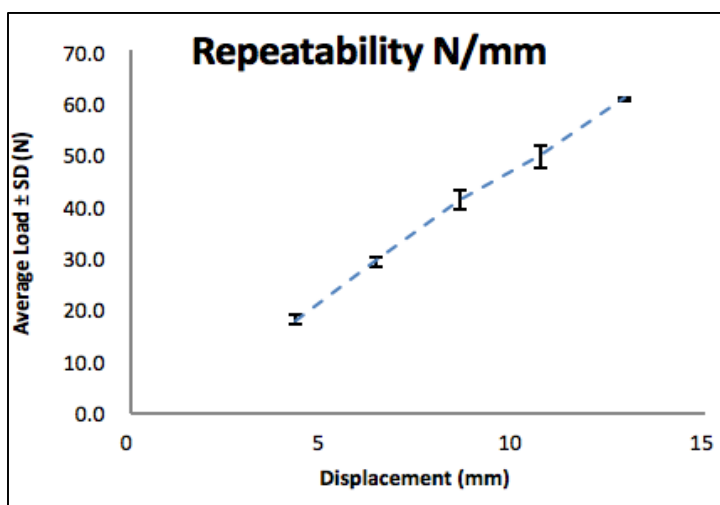


Figure 5.50. L1 repeatability

Device L2

Table 5.9. Device L2.

Loading trial and Load (N)			Average Load vs Displacement			Load		Repeatability of loading trials 1-3
1	2	3	Average load (N)	Target load (N)	Instron load (N)	% difference to target	% difference to Instron	SD
18.6	17.7	19.2	18.5	20	18.5	7.5	0.6	0.8
30.0	30.2	30.2	30.1	30	29.9	0.4	0.4	0.1
39.5	39.2	40.2	39.6	40	39.2	1.0	0.6	0.6
52.6	50.6	50.4	51.2	50	52.3	2.4	0.5	1.2
61.6	59.7	62.3	61.2	60	61.3	2.0	0.5	1.3

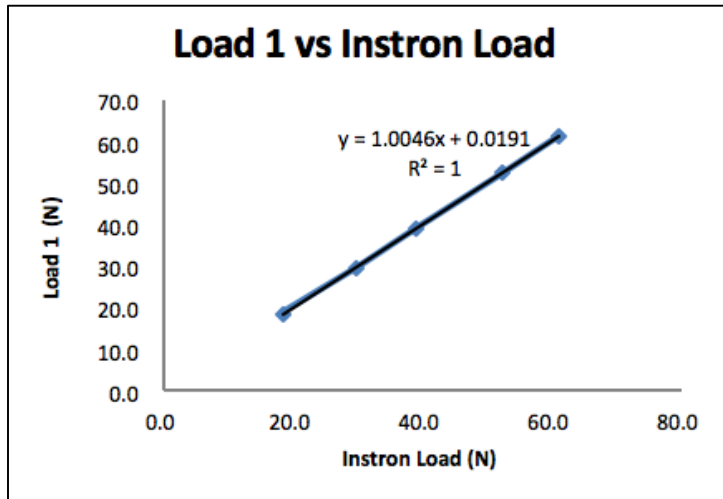


Figure 5.51. L2 load 1 vs Instron load

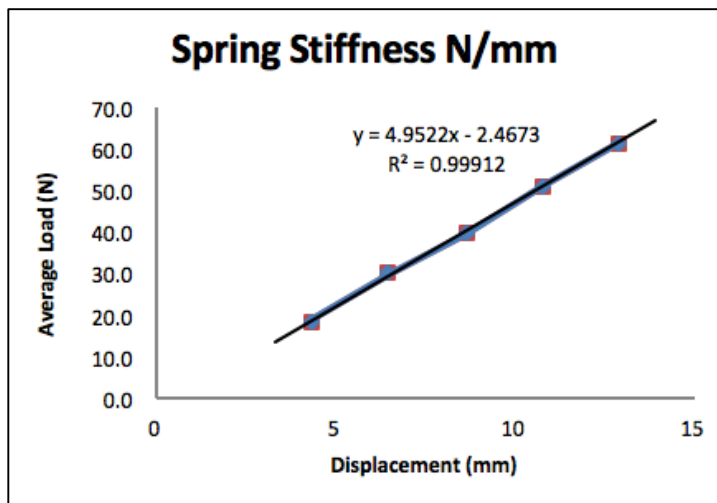


Figure 5.52. L2 spring stiffness

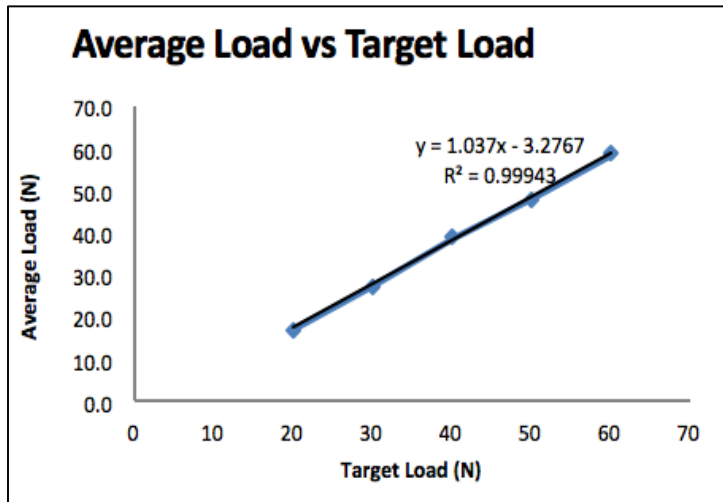


Figure 5.53. L2 average load vs target load

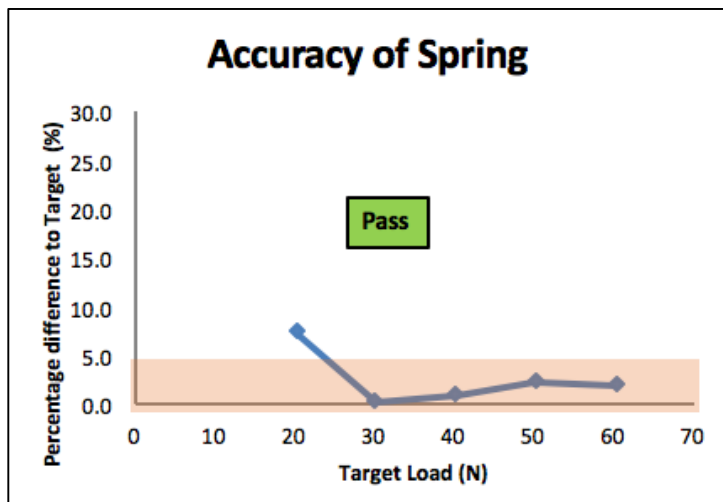


Figure 5.54. L2 accuracy of spring

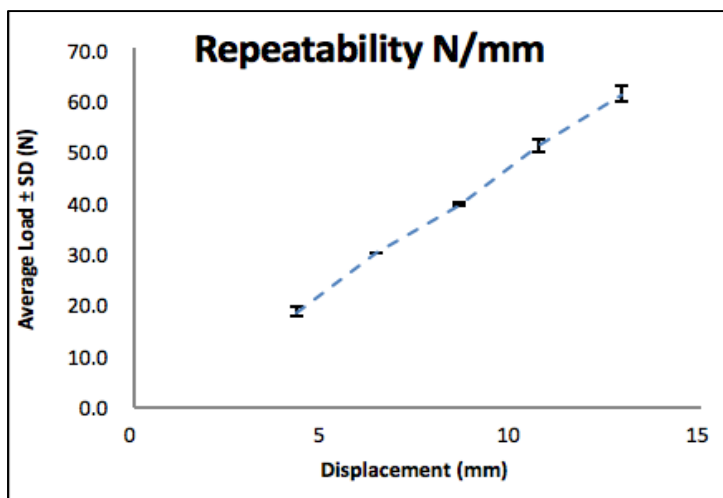


Figure 5.55. L2 repeatability

Device L3

Table 5.10. Device L3.

Loading trial and Load (N)			Average Load vs Displacement			Load		Repeatability of loading trials 1-3
1	2	3	Average load (N)	Target load (N)	Instron load (N)	% difference to target	% difference to Instron	SD
19.8	18.9	18.1	18.9	20	19.7	5.4	0.3	0.9
29.1	30.5	30.3	30.0	30	28.9	0.1	0.7	0.8
40.4	40.6	40.3	40.4	40	40.2	1.1	0.6	0.2
51.4	49.8	50.4	50.5	50	51.2	1.0	0.4	0.8
59.0	59.6	60.9	59.8	60	58.9	0.3	0.3	1.0

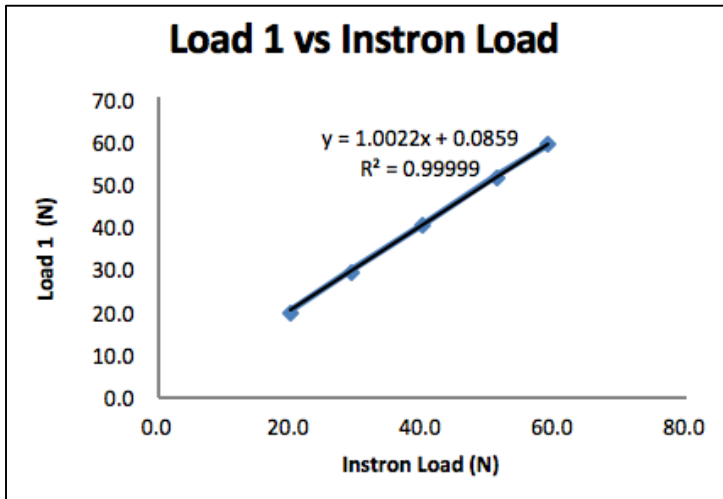


Figure 5.56. L3 load 1 vs Instron load

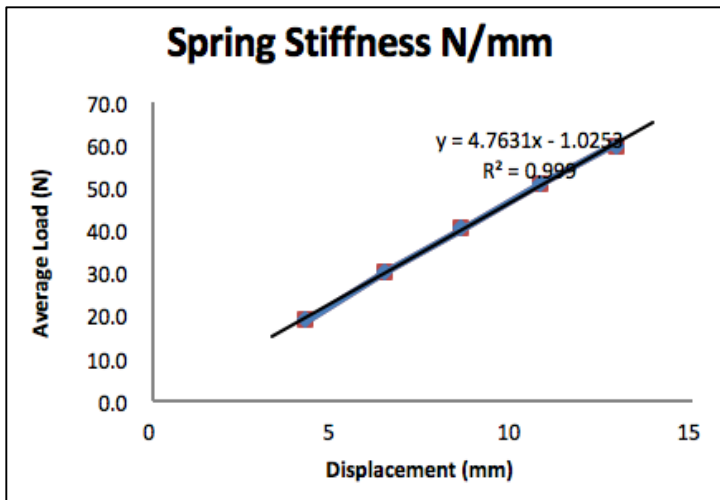


Figure 5.57. L3 spring stiffness

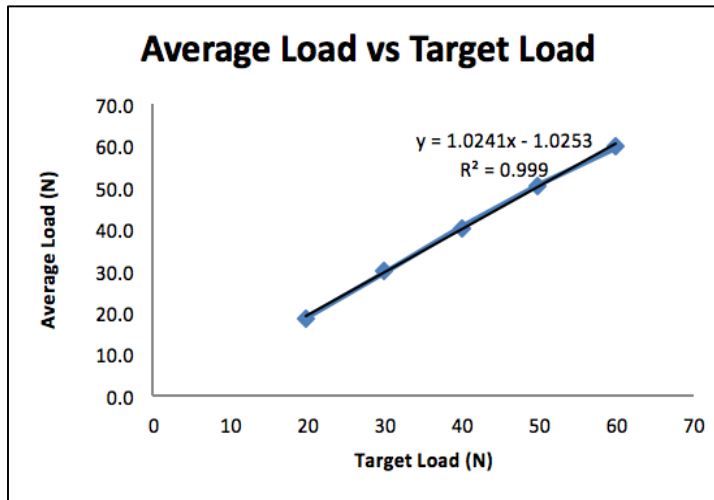


Figure 5.58. L3 average load vs target load

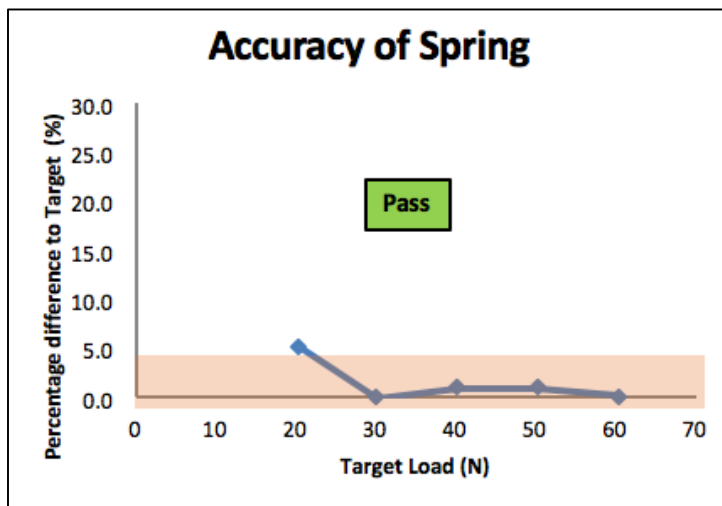


Figure 5.59. L3 accuracy of spring

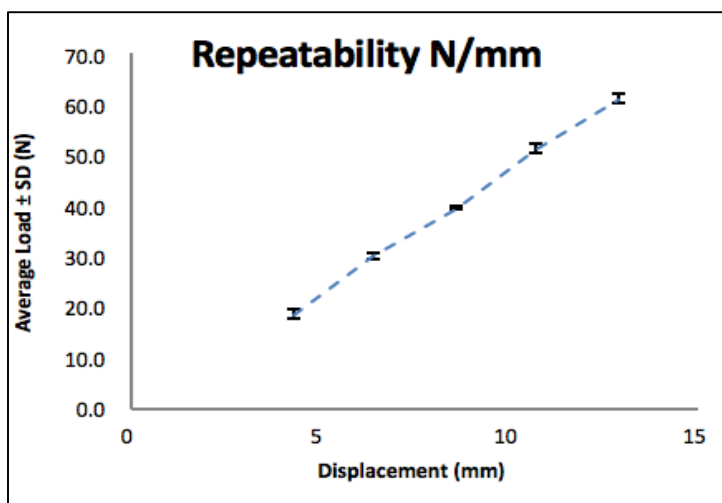


Figure 5.60. L3 repeatability

Device L4

Table 5.11. Device L4.

Loading trial and Load (N)			Average Load vs Displacement			Load		Repeatability of loading trials 1-3
1	2	3	Average load (N)	Target load (N)	Instron load (N)	% difference to target	% difference to Instron	SD
21.9	21.2	20.4	21.2	20	21.8	5.8	0.7	0.8
32.5	31.4	32.9	32.3	30	32.4	7.6	0.3	0.8
42.2	42.6	42.7	42.5	40	42.1	6.3	0.2	0.3
51.6	51.9	52.5	52.0	50	51.4	4.0	0.4	0.5
61.2	61.7	62.5	61.8	60	60.9	3.0	0.5	0.7

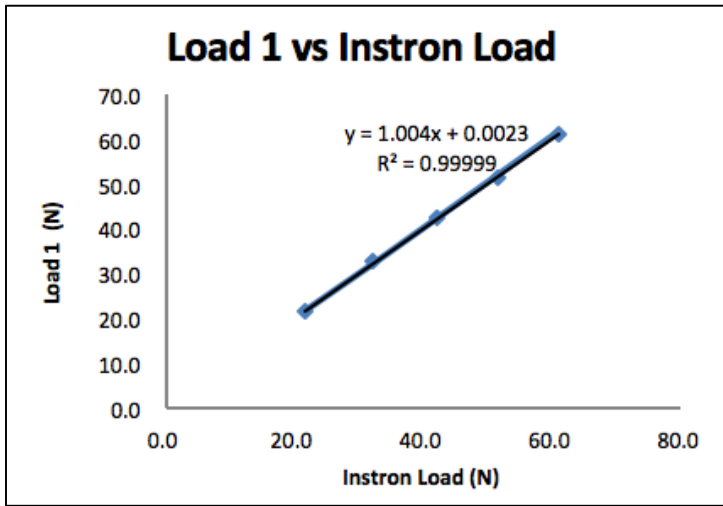


Figure 5.61. L4 load 1 vs Instron load

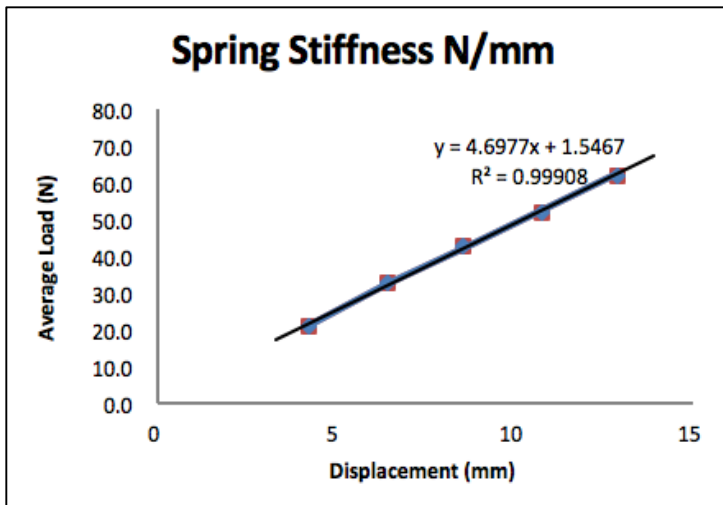


Figure 5.62. L4 spring stiffness

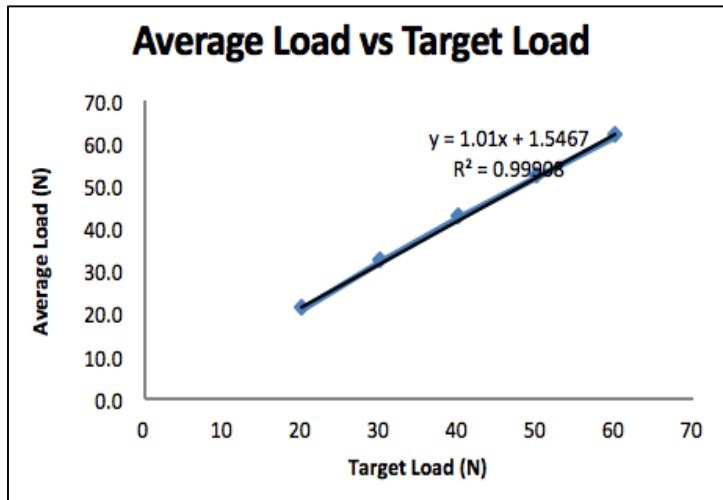


Figure 5.63. L4 average load vs target load

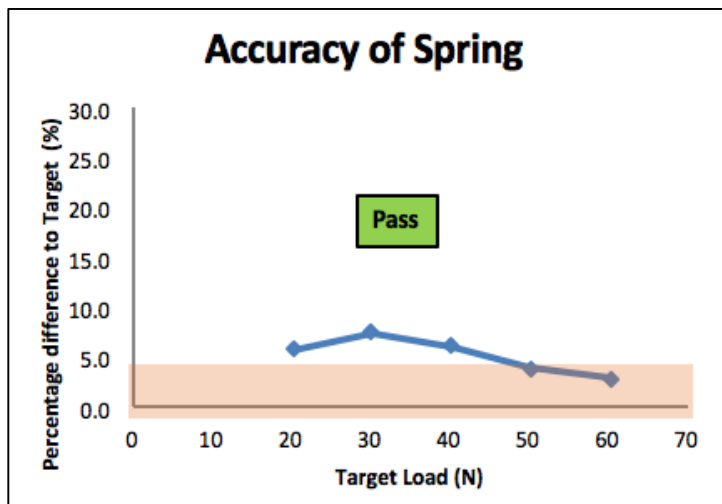


Figure 5.64. L4 accuracy of spring

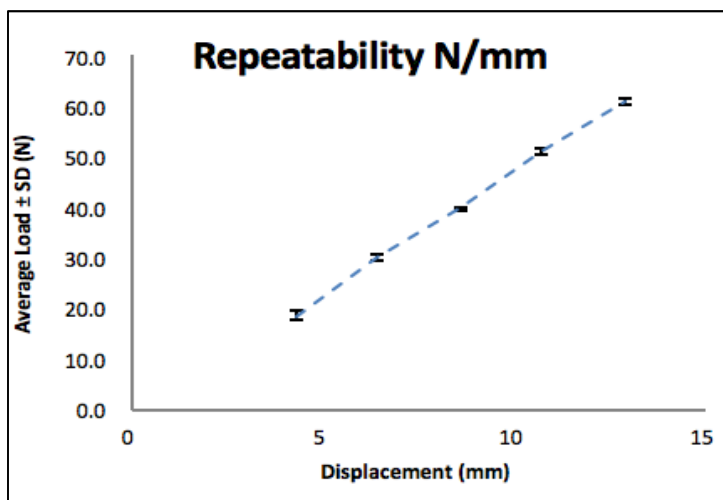


Figure 5.65. L4 repeatability

Device L6

Table 5.12. Device L6.

Loading trial and Load (N)			Average Load vs Displacement			Load		Repeatability of loading trials 1-3
1	2	3	Average load (N)	Target load (N)	Instron load (N)	% difference to target	% difference to Instron	SD
18.4	20.1	20.4	19.6	20	18.2	1.8	1.1	1.1
31.1	32.4	33.2	32.2	30	31.1	7.4	0.0	1.1
40.4	42.3	41.0	41.2	40	40.2	3.1	0.5	1.0
52.9	52.3	52.7	52.6	50	52.7	5.3	0.4	0.3
60.9	60.7	59.0	60.2	60	60.6	0.4	0.5	1.0

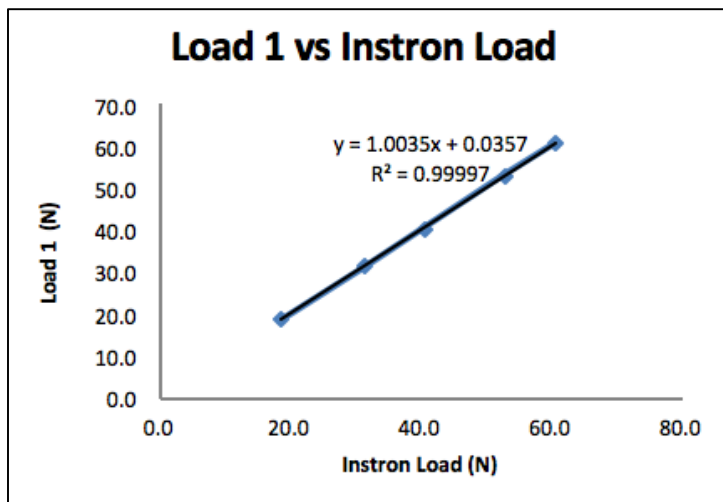


Figure 5.66. L6 load 1 vs Instron load

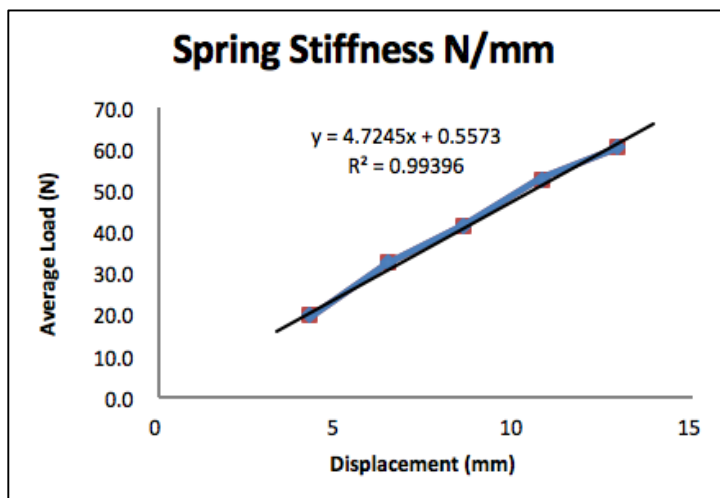


Figure 5.67. L6 spring stiffness

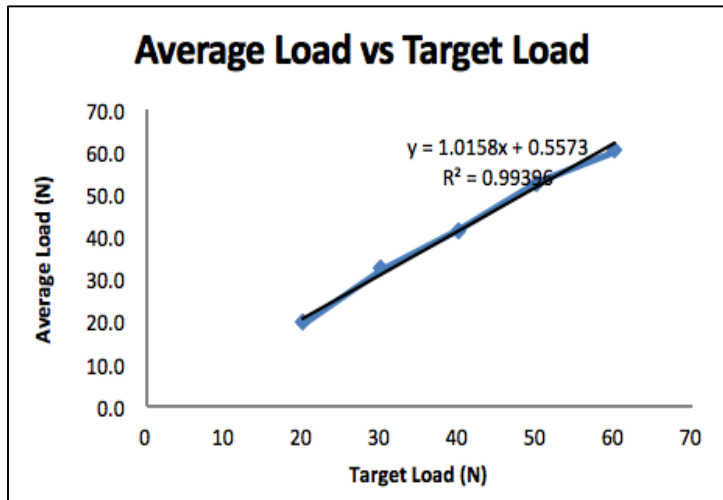


Figure 5.68. L6 average load vs target load

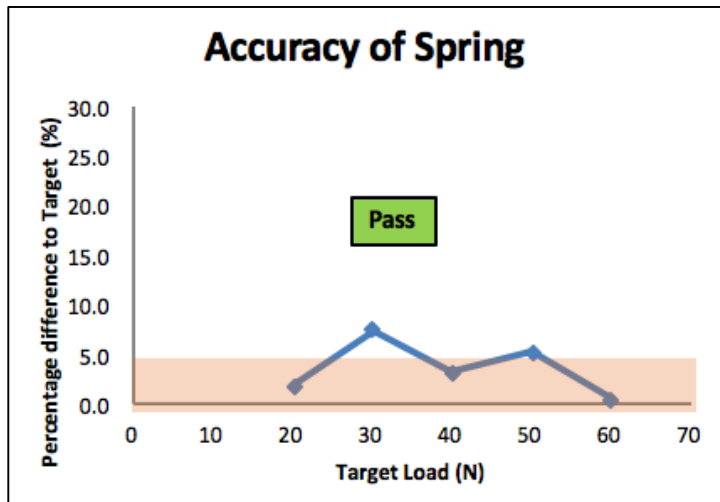


Figure 5.69. L6 accuracy of spring

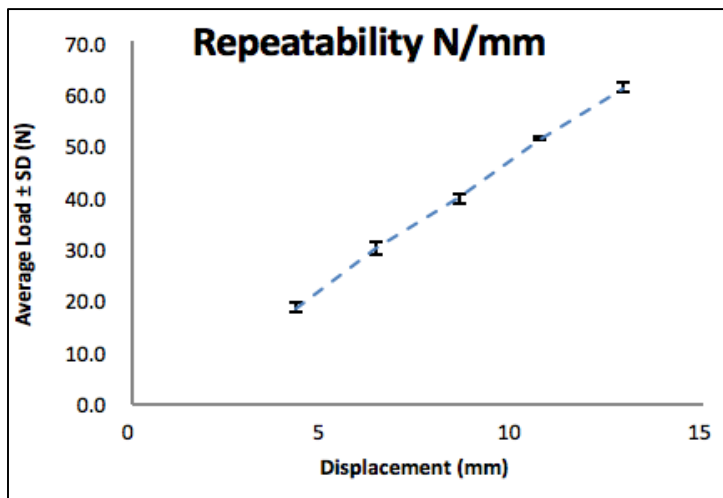


Figure 5.70. L6 repeatability

Overall average spring stiffness

Table 5.13. Summary of spring accuracy testing for long springs

	N/mm			Average	
	Long	% difference	Pass / fail	60 N Load	SD
L1	4.93	5.3	Pass	60.8	0.2
L2	4.95	5.8	Pass	61.2	1.3
L3	4.76	1.7	Pass	59.8	1.0
L4	4.69	0.2	Pass	61.8	0.7
L5	4.75	1.5	Pass	59.7	1.2
L6	4.72	0.9	Pass	60.2	1.0

Table 5.14. Summary of spring accuracy testing for short springs

	N/mm			Average	
	Short	% difference	Pass / fail	60 N Load	SD
S1	7.13	2.7	Pass	60.9	0.2
S2	7.15	3.0	Pass	58.9	0.2
S3	7.10	2.3	Pass	61.7	1.5
S4	7.29	5.0	Pass	60.7	0.4
S5	7.29	5.0	Pass	60.5	1.2
S6	7.11	2.4	Pass	62.2	0.2

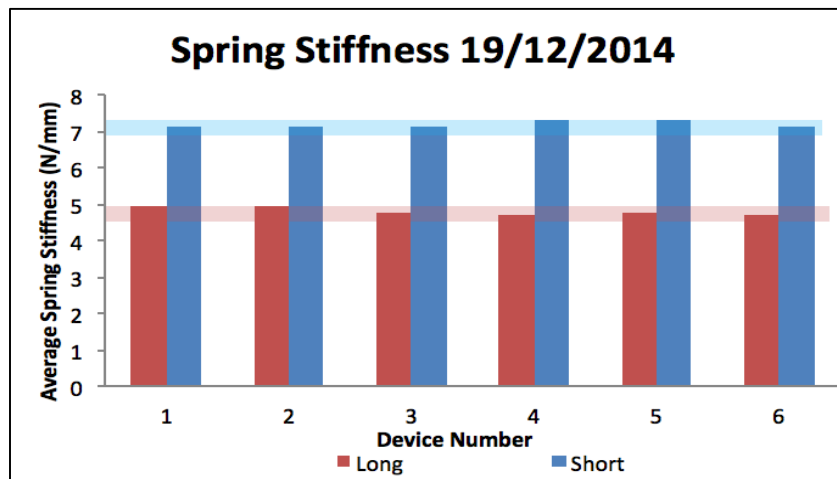


Figure 5.71. Average spring stiffness for short and long devices

The specified spring stiffness for the short spring was 6.94 N/mm and for the long spring was 4.68 N/mm. No springs failed accuracy testing. Both short and long springs were deemed acceptable and the testing was considered complete.

5.10 Assembly and cleaning

Assembly instructions were produced in conjunction with advice from NHS Medical Physics and device sterilisation staff and displayed in theatre for scrub staff unfamiliar with the device. See Appendix 11.

Sterilisation instructions were produced in conjunction with the NHS contractor B-Braun. Appendices 13 to 15. The device is disassembled at the end of each case, Nylock nuts and circlips are single use and are discarded after the final instrument count. The device is replaced in the tray (Figure 5.72) and subsequently sterilised by B-Braun.



Figure 5.72. TrueTense sterilisation tray.

5.11 Device optimisation

The device was introduced in to theatre for the first trial patient. When performing the device assisted Shuck test the force applied exceeded the maximum range of the device of 10-80 Newtons and it was therefore not possible to measure it.

The springs were subsequently exchanged for stiffer springs with approximately 20% greater maximum load capacity for the long and short devices. This increased the spring maximum load to 104N. The springs were then re-calibrated following previous methods outlined in section 5.3.3.3. The summarised results are shown in Figures 5.73 and 5.74 The new springs were accurate when tested up to 104N.

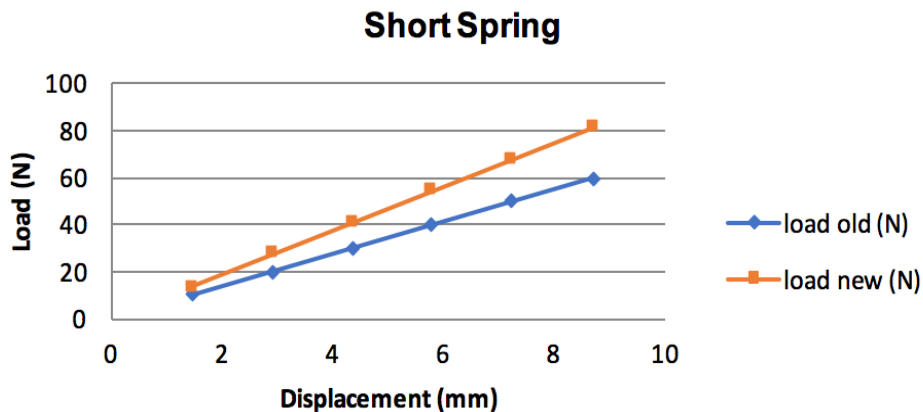


Figure 5.73. Re-calibration of short springs

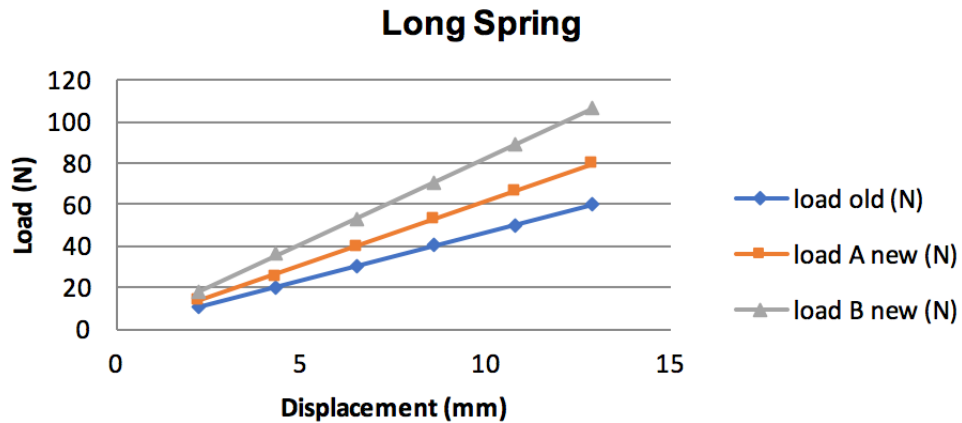


Figure 5.74. Re-calibration of long springs.

The revised properties of the devices are listed in Table 5.15.

Table 5.15. Updated device options

Load	Quantity	Description	Stiffness	Trial heads	Distraction (mm)
Part A-SC	2	Short, Circlip	10.2 N/mm	+12, +8.5, +4, +1.5	7, 10.5, 14
Part A-SN	4	Short, Nylock	10.2 N/mm	+12, +8.5, +4, +1.5	7, 10.5, 14
Part A-LC	1	Long, Circlip	8.65 N/mm	+12, +8.5, +4, +1.5	7, 10.5, 14
Part A-LN	5	Long, Nylock	8.65 N/mm	+12, +8.5, +4, +1.5	7, 10.5, 14

The major and minor markings on the T-handle of the device correspond with the values shown in Table 5.16.

Table 5.16. Forces corresponding with major and minor etched markings

	Major markings	Minor markings
Short device	35 N	17.5 N
Long device	27 N	13.5 N

The device was retested in theatre with satisfactory results and then the proof of concept study was performed.

5.12 Proof of concept study

5.13 Aims

The aim of this proof of concept study was to examine the range of distraction and force required when using the device on a correctly tensioned total hip replacement. It also aimed to ascertain the preferred options for use intra-operatively (long or short, Nylock or circlip) and identify any technical or logistical problems that may arise with the device in theatre or complications that may occur post-operatively.

5.14 Methods

Ethical approval was sought from the Research Ethics Committee (REC) and approval was granted. Patients attended Chapel Allerton Hospital (CAH) on the day of their surgery as usual. They had received an information leaflet about the study in their pre-assessment appointment. On the morning of their operation the study was explained again and the patient was given the opportunity to ask any questions at this point. If they were happy to proceed they signed the consent form.

Patients with primary osteoarthritis were included in the study. The exclusion criteria are shown in Table 5.17.

Table 5.17. Exclusion criteria.

Developmental dysplasia of the hip
Previous ipsilateral pelvic trauma or surgery
Contraindication to spinal anaesthesia
Patient declined or unable to consent to being part of study
Second side in bilateral total hip replacements

All patients had spinal anaesthesia. All patients were positioned in the lateral position and underwent total hip replacement through the posterior approach. The surgeon completed the total hip replacement as normal, performing the

five intra-operative tests to assess LLI. Once the surgeon had made any adjustments necessary and was happy that leg lengths were equal, the device was used. Only the Nylock versions of the device were used but a long or short barrelled device was selected at random.

The device was used in two stages. First the etched trial head was exchanged for the standard trial head and the surgeon performed the Shuck test again. The swab was wrapped around the femoral neck and the device and the device was pulled. The number of rings the femoral head was displaced out of the socket was recorded by the assistant. See Figure 5.75.



Figure 5.75. The device assisted Shuck test.

The device was then used to repeat this previously identified amount of distraction from the socket. The surgeon pulls on the TrueTense device which pulls on the swab and distracts the lower plunger, allowing the amount of force on the TrueTense device to be viewed and recorded in Newtons by the

assistant. This was repeated three times. The implants were then inserted and the total hip replacement completed as normal.

Patients had a pelvic radiograph taken on day two post-surgery, this is normal procedure following total hip replacement and patients were not subjected to any further radiation for this study. LLI was calculated from this radiograph using the Woolson method.

To perform a radiological measurement of LLI using the Woolson method a line is drawn through the most inferior part of the acetabular teardrops. A perpendicular line is then drawn through the mid-point of each lesser trochanter and the distance between the inter-teardrop and each lesser trochanter line is measured. The smaller value is subtracted from the larger value and this gives a value of LLI in mm. Lengthening is expressed as a positive number and shortening is expressed as a negative number. The diameter of the 28mm implanted femoral head is measured and this value is used to calculate magnification and hence true LLI. Two measurements were taken by the same examiner with an interval of seven days and the mean of these two values was used.

Patients were followed up at their scheduled appointment three months post-surgery where they answered questions about symptomatic leg length inequality. If any patient felt that their operated leg had been lengthened or shortened post-operatively then they underwent a physical examination to assess true and apparent leg length inequality and if necessary had pelvic radiograph. Patients only had a further radiograph if clinically required due to pain or LLI symptoms. Any complications or adverse events were noted from post-operative notes at this point.

5.15 Results

Eight consecutive patients were identified to be included in the study. One patient was excluded as her total hip replacement was the second side in bilateral procedures, leaving a cohort of 7. The results for LLI are shown in Table 5.18.

Table 5.18. LLI and magnification

Patient	LLI 1 (mm)	LLI 2 (mm)	Mean LLI (mm)	Size of 28mm head (mm)	Magnification factor	Corrected LLI (mm)
001	- 1.6	- 1.4	- 1.5	33.8	1.2	- 1.3
002	- 4.5	- 4.6	- 4.55	33.7	1.2	- 3.8
003	+1.7	+1.6	+1.65	33.0	1.2	+1.4
004	+6.9	+7.2	+7.05	32.1	1.1	+6.6
005	+2.9	+2.7	+2.8	34.4	1.2	+2.3
006	- 3.4	- 3.8	- 3.6	33.3	1.2	- 3.2
007	+3.5	+3.5	+3.5	37.7	1.3	+2.7

The mean LLI after correction for magnification was +0.7mm. The range was -3.8mm to +6.6mm. All LLI measurements were less than 5mm except for patient 004. The X-rays for this patient revealed bilateral end stage osteoarthritis with significant shortening in the non-operative hip. The total hip replacement has corrected the shortening on the operated side which explains why this measurement of LLI is higher than the others.

The amount of distraction of the femoral head from the socket, the measured force required and the post-operative LLI are shown in Tables 5.19 and 5.20.

Table 5.19. Calculation of force

Patient	BMI	Force (lines)	Device (short or long)	Force (Newtons)
001	34	3	Short	105
002	29	3.5	Long	94.5
003	35	3	Long	81
004	20	2.5	Short	87.5
005	22	3	Long	81
006	29	3	Long	81
007	22	3.5	Long	94.5

Table 5.20. Distraction distance, force and LLI.

Patient	Distraction distance (number of rings)	Force (Newtons)	LLI (mm)
001	3	87.5	- 1.3
002	3	94.5	- 3.8
003	3	81	1.4
004	2	87.5	6.6
005	3	81	2.3
006	3	81	- 3.2
007	2	94.5	2.7

The amount of distraction of the femoral head from the socket was two or three rings in every case. This equates to a 3.5mm range of distraction.

The force required to repeat the Shuck test and distract the femoral head to the previously identified number of rings ranged from 81 to 105 Newtons. Six out seven of the values were within a 13.5 Newton range.

The distraction force and distraction distance were then analysed according to the patient's body mass index (BMI), as shown in Table 5.21 and Table 5.22..

Table 5.21. BMI and mean distraction force

BMI	Distraction force (lines)	Mean distraction force
20 - 25	87.5	87.7
	81	
	94.5	
26 - 30	94.5	87.8
	81	
31 - 35	105	93.0
	81	

Table 5.22. BMI and mean distraction distance

BMI	Distraction distance (rings)	Mean distraction distance
20 - 25	2.5	3.0
	3.0	
	3.5	
26-30	3.5	3.25
	3.0	
31 - 35	3.0	3.0
	3.0	

At the three month follow up no patient complained of symptomatic LLI therefore no repeat radiographs were required.

Comparison of LLI results with cohort 3 LLI results

The mean post-operative LLI measurements from cohort three (chapter four) and the cohort of seven patients in this chapter have been compared in Table 5.23

Table 5.23. Table comparing mean post-operative LLI measurements of cohort 3 and cohort of 7 patients

Cohort	Mean LLI	Range	SD
Cohort 3 (Chapter 4) (N=44)	+3.1mm	-10.5 to 14.2mm	4.60
Chapter 5 (N=7)	+0.7mm	-3.8 to +6.6mm	3.41

The mean, range and standard deviation are all lower for the cohort of seven patients from the TrueTense proof of concept study. Although this is interesting to note, no conclusions can be drawn from these results due to the unequal groups and small number of patients. It cannot be used as proof that use of the TrueTense device decreases LLI as the device was only used once all decision making had been completed.

5.16 Discussion

When the correct size components were in situ in the presence of minimal LLI (confirmed on X-ray), the amount of distraction of the femoral head from the socket and the force required to achieve this were always within the range of distance and force provided by the TrueTense device and modified femoral heads. These results show that it is possible to produce a device to standardise the force and distraction required for the Shuck test.

The results show narrow ranges for both the distraction distance and the force required. This suggests that it might be possible to produce a range of 'acceptable' Shuck distance and force values that indicate acceptable soft tissue tension, rather than a single measurement. This is the first study to attempt standardisation of the Shuck test in the literature.

The sub-group analysis of distraction force according to patient BMI seems to show an increased force required for the patients with BMIs of 26-30 compared to the groups of 20 – 25, and 26 – 30, however the groups are too small to draw any conclusions from and have not been analysed further.

All study patients had spinal anaesthesia. It has been noted in previous chapters that regional anaesthesia including spinal anaesthetics can affect tissue tension. Some studies showed it did and some showed it had no effect. To minimise any possible effect of anaesthetic type on soft tissue tension all patients included in the trial had spinal anaesthesia and patients with contraindications to spinal anaesthetic would have been excluded. A spinal anaesthetic is the surgeons preferred anaesthetic technique and this is mirrored in the literature. Spinal anaesthetics have been shown to lead to lower complication rates and it has been suggested they may be the new 'gold standard' of arthroplasty anaesthesia ^{341,342}. Therefore, the options for calculating a range of force required for a general anaesthetic compared to a spinal anaesthetic have not been explored further.

The device was simple to use intra-operatively, with no surgical errors and added on approximately two minutes to surgical time. If used only to test tension as a decision-making tool it is anticipated that it would add on less than one minute which is much less than other devices in the literature.

There were no adverse events in theatre, the device proved simple to assemble and disassemble. The size of the long-barrelled device made reading measurements easier for the observer and the Nylock nut option was

preferred over the circlip option. Whilst 'double-gloved' in theatre the delicate circlip was difficult to assemble and this risks losing it intra-operatively.

The results of the Yorkshire Arthroplasty Group and British Hip Society surveys in chapter three reported that over 77% of surgeons use the Shuck test in every total hip replacement, and 11% of surgeons used some type of commercial device for assessing leg length intra-operatively, therefore an adjunct to the Shuck test which improved its objectivity may be well received. Feedback from surgeons in a separate study suggested that a device that could measure distraction forces would add significant value to hip arthroplasty²⁹. Chapter four of this thesis concluded that the Shuck test is one of the most effective tests in assessing leg length. The Shuck assesses stability as well as leg length and it is therefore possible that the device could be developed to standardise the Shuck test and perform an assessment of stability.

Each prototype TrueTense device cost approximately £2,000 to produce and it is estimated that if the developed devices were to be produced in larger numbers this price would reduce to approximately £200 each. The TrueTense device can be re-used an unlimited amount of times after sterilisation and the Nylock nuts are single use but cost a maximum of £1 per case. This is significantly less than other devices in literature, meaning cost would not be prohibitive to uptake. One study concluded that the cost of computer navigation systems including capital costs of up to \$250,000 before factoring for software and service contracts. The Intelijoint computer navigated system by Gross was reported to cost \$500-995 per case²⁸. Severe LLI can lead to revision surgery in extreme cases^{66,248,324}, which has an average cost of £11,897 per case²⁷ and which has a complication rate of up to 32%⁷⁵, therefore there is a significant value in avoiding this complication.

The TrueTense device is non-invasive when compared with other devices in the literature. There is no risk of fracture from an acetabular pin, no sharps risk and no increased risk of infection from an extra, or larger incision. It is a reproducible method, and is not reliant on meticulous re-positioning of the hip

so can be used by different surgeons without variability. It is reliant on one single test rather than reproducing two tests and risking errors in measurement due to incorrect second measurements due to inaccurate replacement of the pin or inaccurate leg positioning.

The device does not come in to contact with the patient or incision therefore there is theoretically no increased risk of infection. At the six week follow up phone call there were no cases of infection and for the cases patients that have reached their three month follow up appointment this is also the case.

This study shows the successful introduction of a novel device in to theatre but it is not possible to draw any conclusions from the results as the device was not used in decision making, it was only used once all surgical decisions had been made. The cohort of seven patients was also too small to be able to draw any conclusions.

The indication for total hip replacement in this study was primary osteoarthritis in all cases. Any patients with DDH or previous surgery or trauma to the pelvis were excluded to enable accurate assessment of soft tissue tension and post-operative measurement of LLI. Indirect methods of testing leg length are most appropriate for 'simple' total hip replacements for primary osteoarthritis and minimal pre-operative LLI. In a complex total hip replacement for DDH, or advanced arthritis where the limb has been 'short' for some time there will be contractures and tight soft tissues and in these cases, the indirect tests of soft tissue as a surrogate test for leg length will not be accurate and should not be relied upon. Therefore, it would not be possible to use the TrueTense device in cases where leg lengthening was expected or intentional and it would only be reliable in 'straightforward total hip replacements' with minimal pre-operative LLI. It could be argued that it is the more complex total hip replacements that require additional tools to assist with equalisation of leg length rather than the simple ones.

The next stage in this work will include three larger studies to standardise a range of values for force and displacement. The circlip version of the

TrueTense device will be discontinued and the Nylock version will be used in all future trials. Future trials would include identification of any patient characteristics that may influence the degree of force required in order to create a reference range for the force required. It would be possible to develop the device further with markings to show ranges for 'acceptable', 'unacceptable' force, and 'special cases', as shown in Figure 5.77. These special cases may include patients with increased higher, advanced OA and significant shortening pre-operatively or patients with diagnoses of ligamentous laxity.

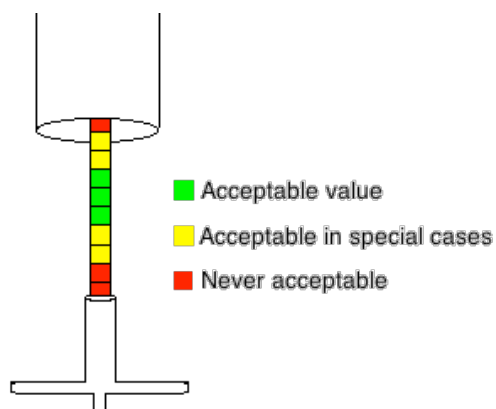


Figure 5.76. Developed TrueTense device showing markings to indicate acceptable range of values

After standardisation of force and distance reference ranges and calibration of the TrueTense device, it could then be used to improve the total hip replacement training model further to develop a more realistic Shuck test and allow junior arthroplasty surgeons to learn how to recreate the sensation of the correct soft tissue tension in vitro.

5.17 Conclusion

The proof of concept study showed satisfactory results following its introduction in to theatre. The mean post-operative LLI was +0.7mm. The results show narrow ranges for both the distraction distance and the force required. When the correct size components were in situ in the presence of minimal LLI (confirmed on post-operative X-ray), the amount of distraction of

the femoral head from the socket and the force required to achieve this were always within the range of distance and force provided by the TrueTense device and modified femoral heads. These results show that it is possible to produce a device to standardise the force and distraction required for the Shuck test.

The device was simple to use intra-operatively, with no surgical errors and added on approximately two minutes to surgical time. If used only to test tension as a decision-making tool it is anticipated that it would add on less than one minute which is much less than other devices in the literature.

This is the first study to attempt standardisation of the Shuck test in the literature. This study shows the successful introduction of a novel device in to theatre but it is not possible to draw any conclusions from the results as the device was not used in decision making, it was only used once all surgical decisions had been made. The cohort of seven patients was also too small to be able to draw any conclusions. Further work is required to understand the relationship between force and patient factors.

After standardisation of force and distance reference ranges and calibration of the TrueTense device, it could then be used to improve the total hip replacement training model further to develop a more realistic Shuck test and allow junior arthroplasty surgeons to learn how to recreate the sensation of the correct soft tissue tension in vitro.

Chapter 6. Summary and Conclusion

This chapter reviews the main findings from the preceding chapters in this thesis. It draws together the main conclusions from each section and considers them as a whole. In chapter 6 there is also consideration for future research in this field.

6.1 Overview of LLI in the literature

The review of the literature presented in chapter two of this thesis has provided an overview of the subject of leg length inequality following total hip replacement. The first successful total hip replacements were performed in the mid-twentieth century as salvage procedures for patients who were wheelchair bound due to pain. In the fifty years since their introduction, complication rates have fallen and survivorship has increased. This has led to broadening of the indications for total hip replacement. Now, younger, more physically demanding patients are undergoing total hip replacement and they have higher expectations from their surgery^{2,10,11}. For this reason, although recognised by Charnley when the operation was pioneered, LLI after total hip replacement has only recently risen to prominence in the literature¹². Revision surgery to correct symptomatic LLI is fraught with technical difficulty and has a higher risk of complications therefore there is significant potential benefit to 'getting it right first time'.⁶⁶

Opinions regarding the significance of LLI following total hip replacement are wide-ranging. Issues such as incidence, cause and quantification have yet to reach broad agreement. Additionally, without an accepted definition of what magnitude of LLI following total hip replacement actually causes symptoms, it is difficult to achieve any consensus. The definition of an unacceptable value of LLI is controversial and is complicated not only by the lack of agreement of significance but also by the fact that for any given magnitude of LLI, only a proportion will be symptomatic. The literature broadly agrees that less than

10mm is an acceptable goal ^{4,150,156-158}, up to 20mm is physiologically and subjectively tolerable by most adults ^{20,161,162} and greater than 30mm is not acceptable but the grey area in between these values is contentious.

LLI is an independent risk factor in the outcome of total hip replacement and can result in a disappointing outcome despite an otherwise satisfactory operation ¹⁵. The clinical presentation of LLI post total hip replacement varies between patients, even for the same magnitude of LLI. Not every patient with LLI will be symptomatic but the proportion increases as the LLI increases ^{145,150}. Clinical symptoms are not mutually exclusive and may include one or a combination of mechanical symptoms such as limp or back pain, to localised hip pain or frank neurological deficit.

Clinical methods of measurement have been shown to be an effective screening tool but differences between clinical and radiological measurements can be up to 10mm ^{20,195,196} therefore when precise measurements are required radiological measurements should be employed. The Williamson and the Woolson techniques are used frequently in clinical practice ^{26,200}. They both describe measurements on a plain AP radiograph of the pelvis and are subject to error and dependent on radiographer technique, position of the X-ray plate, tube, and calibration ball ²⁰². In complex cases of deformity, other radiological methods of measurement may be considered ¹⁸⁶.

The methods of minimising LLI begin pre-operatively with a thorough history and examination, and templating ^{25,146,265}. Of the myriad of invasive and non-invasive techniques discussed there are promising results from small studies but none have universal uptake.

This thesis therefore set out to generate a body of opinion on limits of acceptability from a group of experts, assess the effectiveness of five intra-operative techniques of minimising LLI, used by this group of experts, and develop a device to standardise the Shuck test, minimising the requirement for subjective and invasive tests.

6.2 Thesis synopsis

6.3 Chapter three: British Hip Surgeons and LLI after primary THR

Chapter three reports the results of two separate surveys of British Hip Society (BHS) members relating to LLI after primary hip replacement. The first survey investigates the members' opinions on the effect of LLI on the outcome of total hip replacement and explores expert opinions of acceptable limits of LLI after primary total hip replacement. The second survey reports on the intra-operative techniques currently used by BHS members to minimise LLI after total hip replacement.

6.4 Survey of opinion regarding LLI after THR

The aim of this study was to generate an opinion on acceptable values of LLI from a large body of experts in the field of hip surgery. To achieve this, 394 members of the British Hip Society members were surveyed via email. There was a 40% response rate. 97% of respondents believed that LLI does have a bearing on outcome of total hip replacement. 89% felt there was a value, below which would always be within the bounds of acceptable practice and 90% felt there was a value above which would always be unacceptable. These respondents were then prompted to provide a value. In this study 67% of respondents thought that a value of 10mm or less would always be acceptable. This 'cut off' point of 10mm is in broad agreement with the literature^{148,157,164,234}.

The most frequent value of LLI above which would always be unacceptable was 20mm, with 34% of all respondents giving this value. 65% of all respondent provided values of 15mm or above. There was a larger variance in values for the upper limit of acceptability (2mm to 50mm), compared to the lower limit of acceptability (2mm to 25mm), suggesting there is less agreement

in terms of upper levels of acceptable LLI values than with a lower value which again is mirrored in the literature. The highest response for the upper limit of acceptability was 50mm. The most commonly cited upper limit in literature is 30mm^{20,161,162}, only seven of 130 respondents (5%) indicated they thought that an LLI of above 30mm would be acceptable.

Reaching a consensus that encompasses all patients is contentious. Surgeons may be hesitant to state a “cut off value” of what is unacceptable for fear of being criticised. Many experts feel that one value for all patients and all situations is too simplistic and that individual outcomes are more important³⁴³. The results of this study do not provide concrete values of acceptable leg length inequality following total hip replacement however this is the first study of its kind aiming to generate a body of opinion from an expert group. This study demonstrates a strong agreement that LLI following total hip replacement can affect outcome and there is a strong agreement for limits of acceptability.

6.5 Survey of intra-operative techniques used by British Hip surgeons to minimise LLI

There is currently very little in the literature about which techniques surgeons use to assess leg length intra-operatively. The aim of this study was to identify which intra-operative techniques are currently utilised by specialist hip surgeon representatives in a regional arthroplasty meeting and those attending the British Hip Society annual scientific meeting.

All surgeons surveyed describe using at least one intra-operative technique to minimise LLI during hip replacement. Directly measuring length at the knees, the Shuck test and a ‘general feeling’ were the most frequently utilised techniques. Surgeons used an average of five techniques which suggests that that no one technique is completely accurate and that surgeons feel that employing a combination of techniques gives better accuracy than using a single technique. This is supported by the literature^{275,331}.

6.6 Chapter four: The accuracy of five intra-operative techniques to minimise LLI during primary THR

This chapter set out to establish whether an experienced hip surgeon can reproduce leg length using the five intra-operative tests described, without the use of a commercial device. In order to achieve this aim, a validated method of measuring LLI was required to reference the tests against. The Woolson method of quantifying LLI from plain film X-rays was considered the most appropriate as it is widely used in clinical practice and is reported to be more consistent than other methods in the literature ²⁷⁶. Prior to employing the Woolson technique as a reference standard the inter- and intra-observer reliability of the measure was investigated. The results showed excellent inter- and intra-observer agreement, with ICCs of 0.98 and 0.99 respectively.

This study set out to establish whether an experienced hip surgeon can reproduce leg length using five intra-operative tests, without the use of a commercial device. The use of the five intra-operative tests in combination resulted in a mean LLI of +3.1mm which is within the range of LLI that would always be acceptable, as supported by the literature and a recent survey of BHS surgeons ^{4,150,156-158}.

It is not possible to prove which of the five tests is the most effective, however more adjustments to components were made when the Shuck test and the kick test indicated LLI. This suggests the surgeon favours these subjective tests and is more dependent on them. In all cases when the 'overall feeling' was of unequal leg lengths this was reflected by increased post-operative LLI. This is the most subjective test of all which relies partly on information from the five tests but mainly relies on surgical experience and skill. This demonstrates why the myriad of commercial devices and computer navigated surgery are unable to completely eliminate LLI ²⁵⁹. This is the first study to report these five tests being used in combination and validated by results.

6.7 Chapter five: Development of a novel device to minimise LLI during primary THR

Previous work from this thesis has identified the Shuck test to be an effective indirect test of measuring leg length intra-operatively that is used by a large percentage of surgeons in the UK. Feedback from surgeons in a separate study suggested that a device that could measure distraction forces would add significant value to hip arthroplasty²⁹. Presently to the author's knowledge there is no device that exists that may be used to assess soft tissue tension during total hip replacement.

A device was designed and developed to measure the amount of force applied during the Shuck test and to measure the amount of displacement produced in a correctly tensioned total hip replacement. The device was then used in a proof of concept study to examine the range of distraction and force required when using the device on a correctly tensioned total hip replacement. The results show narrow ranges for both the distraction distance and the force required. When the correct size components were in situ in the presence of minimal LLI (confirmed on post-operative X-ray), the amount of distraction of the femoral head from the socket and the force required to achieve this were always within the range of distance and force provided by the TrueTense device and modified femoral heads. These results show that it is possible to produce a device to standardise the force and distraction required for the Shuck test.

This is the first study to attempt standardisation of the Shuck test in the literature. This study shows the successful introduction of a novel device in to theatre but it is not possible to draw any conclusions from the results as the device was not used in decision making, it was only used once all surgical decisions had been made.

6.8 Thesis discussion

The subject of LLI following total hip replacement is complicated by the lack of consensus regarding many of the issues surrounding it including an acceptable value, a definition and gold standard methods of minimising LLI intra-operatively, and quantifying LLI post-operatively.

The hypothesis stated in chapter one was:

Using the novel device, which will involve employing a standardised level of force to perform the shuck test, will yield results that are in agreement with the findings of an experienced consultant surgeon.

To explore this hypothesis, a review of the published literature was presented in chapter two, detailing the lack of consensus for many of the aspects of LLI following total hip replacement. The literature reveals a wide range of opinions regarding clinical significance and limits of acceptability. The majority of authors are in agreement that LLI following total hip replacement is clinically important but this is not a universal belief¹⁴. The first BHS survey provided results that 97% of surgeons believe that LLI does have a bearing on the outcome of total hip replacement and the published records of successful litigation claims provide further support that it is a significant source of dissatisfaction and establishes a link between LLI and its symptoms.

Publications presenting results for LLI following total hip replacement each have their own methodologies in terms of approach, technique, implants, and follow up, therefore little direct comparison can be drawn from the literature in terms of evidence of LLI following total hip replacement. Without a definition of a clinically significant value of LLI following total hip replacement there will be little progress towards greater understanding. The earliest published single value of LLI was provided by Charnley in 1979 who stated that for an uncomplicated primary total hip replacement a LLI of less than 10mm is acceptable¹². Since this statement there has been hesitance to provide a “cut off” value and there is no universally agreed ‘limit of acceptability’, a point

below which any LLI following total hip replacement would always be considered within the bounds of reasonable practice and above which would always be considered unacceptable. There has been no published work that has attempted to demonstrate a consensus, or indeed lack thereof, for significance and quantification of LLI following total hip replacement. Chapter three presents the results of a study to gauge the opinions of sub-specialist arthroplasty surgeons. 67% of respondents agreed that a value of 10mm or less would always be within the range of acceptability, and this is in keeping with the majority of the literature^{4,150,156-158}, therefore this value was used throughout the rest of this thesis. Although it cannot be claimed that a consensus has been reached, this survey provided important information and a broad agreement on limits of acceptability was reached. This is a significant finding as it is the first examination of opinion and provides a range of magnitudes of LLI following total hip replacement which themselves could be investigated further. It is unlikely that a single value for the magnitude of acceptable LLI for all patients and all situations will be attained as there is a range of measurements suggested in the literature where symptoms may present and at any given magnitude of LLI not everyone will be symptomatic. The breadth of published post-operative values of LLI suggests that instead there may be a range of post-operative LLI and that cases must be judged on a case by case basis, taking individual patient factors in to account.

A significant barrier to decreasing the magnitude of LLI following total hip replacement is the lack of a gold standard method of minimising it intra-operatively. There have been over forty publications describing novel techniques but large scale, prospective, blinded studies are lacking. The commercial devices promoted in the literature show promising results in small scale studies but have associated negatives, including expensive devices or software, or invasive techniques requiring extra drill holes or incisions. No device has been fully validated and reached universal uptake. There is a paucity of data in the literature regarding the effectiveness of the simple, unaided tests that a surgeon may perform intra-operatively to assess leg length. The second survey of British Hip Society members provided further weight that a body of experts consider LLI to be clinically significant as all

surveyed members use at least one technique in an attempt to minimise it. The 161 surgeons surveyed describe using a collective total of 738 tests during every total hip replacement, giving an average of five tests used per surgeon. The three most commonly utilised tests were found to be directly measuring leg length at the knees, the Shuck test and a 'general feeling' of satisfaction, used by 91%, 78% and 77% of surgeons respectively. Measuring length at the knees is a direct measurement which is simple and provides immediate feedback, but the Shuck test and 'general feeling' of satisfaction are both subjective tests which proves problematic for junior arthroplasty surgeons when trying to learn how to perform and interpret these tests. It may take years of experience to understand how the soft tissue tension around the hip translates to leg length. Alternative methods of acquiring operative skills have been explored such as computer simulation and devices to assist intra-operatively have become necessary. The study also suggests that surgeons feel that employing a combination of techniques gives better results than using just one, which is in agreement with the literature³³¹. The major finding of these combined surveys indicates that an expert body of surgeons consider LLI following total hip replacement to be a significant problem. There is a broad agreement of an acceptable value, and attempts are made to minimise LLI intra-operatively.

Chapter four presents the results of a study assessing the effectiveness of the five intra-operative techniques used by an experienced hip surgeon to minimise LLI after primary total hip replacement. In order to achieve this, a record of the outcome of each test was made and post-operative LLI was measured on the radiographs of a previously defined cohort of consecutive total hip replacements. The use of the five intra-operative tests in combination resulted in LLI of 4.1mm which is within the range of LLI that would always be acceptable, as supported by the literature and a recent survey of BHS surgeons^{4,150,156-158}. This is the first study to report these five tests being used in combination and validated by results. However, the cohort of patients included only unilateral total hip replacements for primary osteoarthritis and had strict exclusion criteria therefore the results of this study are only applicable to these cases.

It is not possible to prove which of the five tests is the most effective, however more adjustments to components were made when the Shuck test and the kick test indicated LLI. This suggests the surgeon favours these subjective tests and is more dependent on them. When the tests using direct measurements from the greater trochanter or the cut on the calcar indicated an LLI these were often ignored in favour of the result of the Shuck test. We can therefore conclude that final decisions regarding implant selection rely more on the outcome of the Shuck and Kick tests than the other three tests. There were seven cases that had an overall feeling after all subjective tests and adjustments were made, that the surgeon felt were still unequal but it was not possible to improve on this. The direct measurement of leg length at the knees and the 'overall feeling' of satisfaction suggested lengthening, but the remaining tests were satisfactory. Seven of the eight cases with an unsatisfactory outcome to measuring length at the knees were the same cases as the seven abnormal overall feeling results. Analysis of post-operative leg lengths in these cases showed a trend towards a greater residual LLI in the group deemed unsatisfactory by the five tests but the difference did not reach statistical significance. Of these seven cases with an 'unsatisfactory' outcome from the five tests, four indicated that they had been lengthened and three indicated shortening. Lengthening is reported to be less well tolerated than shortening, therefore the t-test was repeated using the four 'long' cases to assess whether the tests were more sensitive at picking up lengthening. For this group the difference did reach statistical significance. It is not possible to make conclusions from this cohort of four patients but the results show possibility for future research.

Through the analysis of pre-operative radiographs used to assess inter- and intra-reader reliability of Woolson techniques, a cohort of radiographs were identified which proved difficult to measure due to abnormal positioning of the pelvis due to fixed deformities. These fixed deformities confound two-dimensional measurements making LLI measurements unreliable.

There have been many attempts to calculate to correct for tilt in the literature³⁴⁴. Van der Bom found that any more than $\pm 4^\circ$ of pelvic tilt would cause an unacceptable error in measurement³⁴⁵. Flexion and adduction contractures, often seen in end stage arthritis, often lead to pelvic obliquity, as seen in Figure 6.1.

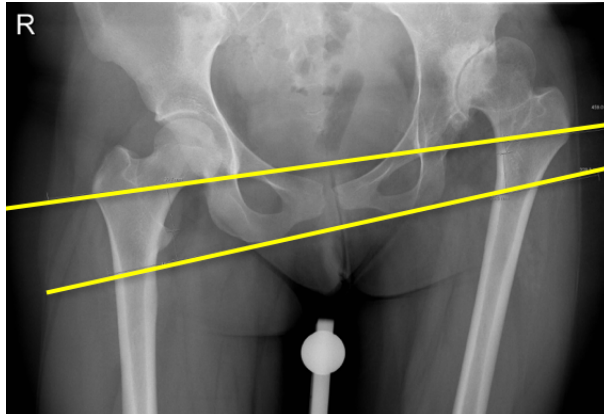


Figure 6.1. Adduction contracture leading to Williamson and Woolson reference lines converging.

Femoral positioning can also lead to inaccurate measurements. Sarin et al concluded that adduction/abduction malpositioning gave the greatest error in measurement, up to 17.4mm at 10° ¹⁶⁴. The most prominent part of the lesser trochanter is used as the femoral reference point for the Woolson technique, which is also affected by femoral malposition and may affect measurements taken from this point, as seen in Figure 6.2.

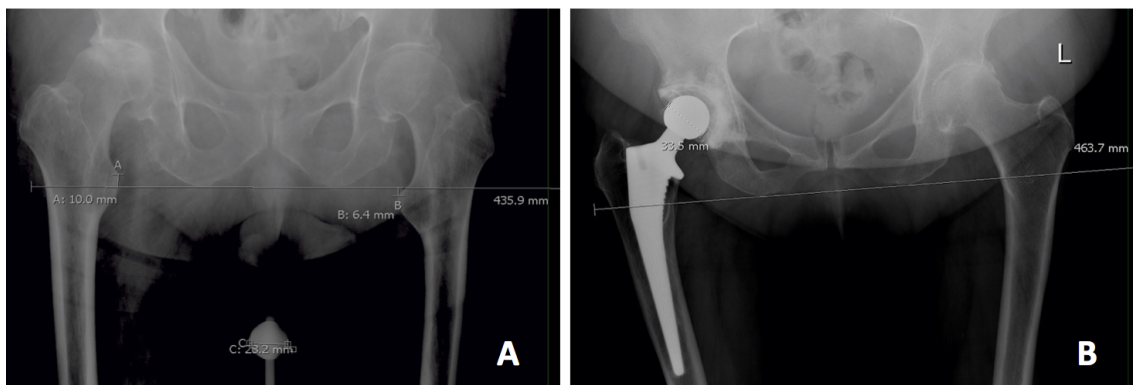


Figure 6.2. A. Asymmetrical lesser trochanters leading to inaccurate leg length measurement, B. Lesser trochanters not visible due to femoral rotation.

These studies highlight the error that may be introduced by variations in femoral position when using plain AP radiographs of the pelvis. Trigonometry dictates that a fixed flexion deformity, of for instance, 20° will result in a reduction in measured LLI of approximately 6%, as seen in Figure 6.3. A femur with a true length of 400mm will, on an AP projection, have an apparent length of 375mm ($400 \cos 20$) when projected on to the X-ray receiving plate³³².

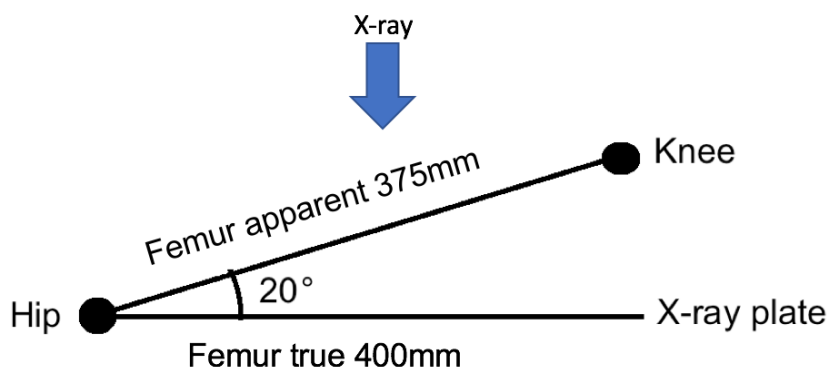


Figure 6.3. Illustration of the effect of 20° of fixed flexion.

These trigonometrical estimations provide a theoretical estimate of error in a measurement between two points in a single plane malposition, when combinations of fixed deformities are introduced such as flexion-adduction contractures, the resultant multiplanar malposition becomes more complex as the sum of the movement in single planes does not reproduce the same magnitude of error when they are combined³³².

After excluding all cases with significant contractures or pelvic malpositioning evident on X-ray, the range and mean LLI measurements decreased. The strict exclusion criteria were intended to produce a cohort of simple radiographs for analysis of agreement and inter-reader reliability however this excluded a large proportion of the typical patients with hip disease requiring total hip replacement. This study showed patients with complex fixed deformities present a difficult challenge to surgeons and radiologists measuring leg length. The study not only highlights the importance of a standardised protocol for patient positioning for pelvic radiographs but also highlights the need for a technique to reduce measurement errors associated

with malpositioning, as despite standardised protocols, it is impossible to completely eliminate the malpositions in this cohort of patients. Direct comparison of LLI using any method should be interpreted with caution, especially for serial imaging. Greater accuracy, particularly in the presence of complex deformity can be achieved using CT scanograms, however this study explored the more commonly used, more economical plain film radiographic techniques.

Methods of minimising LLI have been documented since the 1970s^{25,26} but there is still no single 'gold standard' method that has reached universal uptake. Subjective tests may be effective in the hands of an experienced surgeon but they are difficult to teach and have a long learning curve. Following the introduction of the European working Time Directive in 1993, the practical time junior surgeons spend in theatre has fallen but the expectations to reach the same level of competency by the completion of training have remained the same. A simple, validated device that could accurately assess leg length intra-operatively without the need for invasive or expensive equipment would make a significant contribution to minimising LLI. As the Shuck test is widely used by surgeons across the UK, and heavily relied upon during intra-operative decision making, this test showed the most opportunity for development. This led to the development of a novel traction based device to standardise the Shuck test and use as a teaching aid.

Preliminary results of an in-vivo study show that acceptable tissue tension, defined by surgeon satisfaction, and confirmed on post-operative radiographs, when using the device, produced small range of distraction distance and force exerted, which indicates that it would be possible to further define a range of values in order to produce a standardised device for use in theatre. It is likely that there is not one magnitude for all patients, and more likely that a range will be produced. It seems probable that older, less muscular individuals will require less distraction force than younger people. It is also possible that the type of anaesthetic would alter the range required. Further research is required to reach these conclusions.

The hypothesis set out in this thesis has been explored by:

- i) Investigating the opinions of experts in the field of arthroplasty regarding acceptable values of LLI post total hip replacement. This was the first study to generate a broad agreement of acceptable values of LLI post total hip replacement.
- ii) Defining the five most commonly used techniques for minimising LLI intra-operatively that are used by arthroplasty surgeons in the UK.
- iii) Presenting results showing that when used in combination these five intra-operative tests can produce a range of LLI than is within an acceptable range, as defined by the literature and the previous opinion of expert surgeons. This study also suggested that an unsatisfactory result of the Shuck test led to the most changes in component size and position, suggesting the most dependence on this test for decision making.
- iv) Designing and manufacturing a device to be used as an adjunct to the Shuck test. Preliminary results show a narrow range of distraction distance and force exerted which indicates the possibility of developing the device further to standardise the force produced during the Shuck test and to be used as a teaching aid to decrease the steep learning curve associated with equalising leg length during total hip replacement.

6.9 Further research

This thesis has raised questions that should be considered for future research and should help provide further clarity to the problems associated with LLI following total hip replacement

6.10 Validation of TrueTense device.

The results from chapter five provided promising results for a narrow range of both force and distraction distance for the device assisted Shuck test. These preliminary results cannot be used as proof that the device works however as it was only used after all decisions had been made. The next stage in this work will include three larger studies to standardise force and displacement. The primary hypothesis to be tested will remain the same;

The standardised TrueTense device will yield results that are in agreement with the findings of an experienced consultant surgeon.

The next phases of studies will take place as outlined below.

Study 1i: Number of rings exposed

In a small group of patients (n=30), once the consultant surgeon is happy with the implant, the head will be swapped for one that is ring-marked on one side to indicate the extent to which it is pulled from the socket during the Shuck test. The surgeon will then perform the shuck test as usual; the surgeon will be unable to see the ring markings during the test, but the assistant will note the number of rings exposed.

These data will be analysed to establish whether the head is exposed to a consistent degree during the Shuck test when a satisfactory result has been achieved, and will inform the next stage of development.

Study 1ii: Force used

Having established the number of rings typically exposed during the test, we will conduct a larger observational trial (n=120) examining the force used by the consultant surgeon during the shuck test. Once the surgeon is happy with the result, the shuck test will be repeated using a prototype of the novel device in conjunction with a fully ring-marked head. The prototype device will record the force used by the surgeon but the force will only be displayed to the assistant during the test. The surgeon will expose the appropriate number of rings determined in stage 1i, and the assistant will record the force used. This procedure will be repeated three times to ascertain the repeatability of the force used. Regression modelling will be used to determine a reference range for the force to be used, dependent on any patient characteristics found to influence this variable.

Stage 2: Validation of device

Having determined the procedure for using the device during the development phase (force to be used/number of implant marker rings to be exposed at this force for acceptable result) we will conduct a single-group proof-of-concept study (n=50) to obtain preliminary data on the performance of the finalised device when used in this standardised manner. The finalised device will allow the surgeon to read the level of force used during the test. The device-assisted shuck test will be performed once the surgeon is happy with the implant, then the implant head will be replaced with a head one size too large. The surgeon will then perform an unassisted shuck test, and repeat the test using the device and marked head. The correct sized head will then be replaced. Agreement between the two tests as to whether the implant is acceptable will be quantified. LLI will be determined from the post-operative radiographs.

Secondary outcomes from this study will include identification of patient characteristics that may influence the degree of force required in order to create a reference range for the force required.

If these trials prove successful in validating the device it is possible that it may be used in the education of junior arthroplasty surgeons to teach them about soft tissue tension.

6.11 New technique for minimising LLI intra-operatively

During assessment of the effectiveness of the five intra-operative tests, the possibility of a new test was noted. This new test uses both the Shuck and the kick test in combination and is performed with the trial components in situ, after the other five intra-operative tests have been completed. The trial femoral head is then exchanged for one, one size bigger. For example, if using the Corail hip, if the surgeon has initially selected a brown 5mm trial head as the correct size, the brown 5mm trial head is exchanged for a blue 8.5mm trial head. The kick test is then repeated. In all cases noted during this study the kick test was now positive. The trial head is then exchanged for a trial head one size smaller from the selected head, (in this case a green 1.5mm trial head). Repeating the Shuck test now leads to dislocation.

To assess the accuracy of this test, it was performed in the 44 patients in cohort three. This cohort consisted of patients with primary osteoarthritis and the anaesthetic and surgical technique was standardised.

The post-operative LLI from this cohort was analysed in chapter 4. Mean LLI was +3.1mm. This shows promising results for the newly described test but larger scale trials would be needed to make any conclusions from the results.

6.12 Conclusion

LLI following total hip replacement has been identified as a cause of post-operative dissatisfaction since the operation was pioneered in the 1950's but it has only recently risen in prominence in the literature.

One of the major inhibitions to greater understanding of LLI following total hip replacement is the lack of any consensus regarding limits of acceptability, a point below which any LLI following total hip replacement would be considered within the bounds of reasonable practice and above which would always be considered unacceptable. The results from this thesis suggest strong agreement for LLI below 10mm to be acceptable and above 20mm to be unacceptable.

This thesis explored the five most commonly used tests for minimising LLI intra-operatively. The Shuck test was used by 77% of surveyed members of the British Hip Society, the largest body of arthroplasty surgeons in the UK. Assessment of the effectiveness of the Shuck test suggested it is one of the most reliable tests for minimising LLI intra-operatively. These findings led to the development of a novel device to be used as an adjunct to the Shuck test. Presently to the author's knowledge there is no device that exists that may be used to assess soft tissue tension during total hip replacement. A proof of concept study was performed and preliminary results of a cohort of 7 patients showed a very narrow range of both distraction distance and force exerted when the total hip replacement was correctly tensioned, as confirmed by post-operative radiographs showing a mean LLI of 3.1mm. The device was simple to use and there were no associated complications. Unlike other commercial devices in the literature the device is non-invasive and cheap to produce. With further development and validation, the device could be used to standardise the Shuck test and be used as an adjunct to train junior surgeons how to assess leg length, minimising the requirement for subjective and invasive methods.

The initial hypothesis was formed with the intention of testing the agreement of the device as outlined in section 6.4.1, however due to time constraints this was not possible. It would not be appropriate to perform a formal assessment of agreement with the results from this preliminary study due to its small sample size, however the results do show the possibility for standardising the device to produce a narrow range of force. At present, it is not possible to confirm the hypothesis stated in chapter one. Further work is required to understand the relationship between range of force and the Shuck technique. In the meantime, we can conclude that there is no substitute for experience.

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Appendices

Appendix 1 - Pilot questionnaire

Pilot primary total hip replacement Questionnaire - CHOC

This is a questionnaire targeted at arthroplasty surgeons performing total hip replacements. It is part of a bigger study in to minimising leg-length inequality following total hip replacements. There are a variety of methods for assessing leg length intra-operatively, ranging from simple tests to commercial devices. This is a pilot questionnaire to find out which methods are most commonly used in CHOC.

I would be grateful if you could fill in the details below.

- Do you template pre-operatively? **Yes / No**
- Which of the following techniques do you **routinely** use to assess for leg length during a primary total hip replacement: (Tick all that apply)
 1. Measure length at knees
 2. Cut on calcar
 3. Height of collar to tip of GT
 4. Kick test
 5. Shuck Test
 6. Commercial device
 7. General feeling of happiness / unhappiness
 8. Other, please specify:

Thank you for your time,
Faye Barnett
CRF

Appendix 2 - YAG and BHS Questionnaire

Dear Colleague,

I am doing an MD looking at **intraoperative** methods of minimising limb length inequality during total hip replacements. My name is Dr Faye Barnett; I am an Orthopaedic clinical research fellow working with Mr Martin Stone and the Leeds Musculoskeletal Biomedical Research Unit (LMBRU) at Chapel Allerton Hospital in Leeds.

This is a three question study which will take 1-2 minutes to complete. The aim of the survey is to find out which methods are most commonly used by arthroplasty surgeons in the UK.

I would be grateful if you could fill in the details below:

Approximately how many total hip replacements do you perform per year?

What percentage of: A. the cups and B. the stems you insert are cemented?

	<25% cemented	26-50% cemented	51-75% cemented	>75% cemented
Cups				
Stems				

Which of the following techniques do you routinely use to assess for leg length during a primary THR: (Tick all that apply)

	Always	Never	Sometimes
Measure length at knees			
Cut on calcar			
Height of collar to tip of GT			
Kick test			
Shuck test			
Skin suture			
Short rotator apposition			
General feeling of happiness / unhappiness			
Other (please specify, including commercial device)			

If you would like a summary of the results please provide an email address in the comments box above.

Please leave your completed questionnaire in the box by the door as you exit.

Thank you for your time,

Faye Barnett
fayebarnett@doctors.org.uk

Appendix 3 - Request for e-survey to members of the BHS

Request for e-survey to the members of the British Hip Society

Survey of opinions regarding leg length inequality following total hip replacements

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Project Proposal

This group has been active in researching issues surrounding leg length inequality following total hip replacement and has had multiple presentations of the work at the British Hip Society on the podium and as poster. The senior surgeon, Mr Martin Stone, is a long standing member of the British Hip Society and has an active research interest.

One of the many issues when considering leg length inequality following total hip replacement is that there is very little agreement in the literature. In our published papers^{24,163,180,202,346} we have had to make clear that there are various opinions ranging for White and Dougal¹⁵¹, who found no link between outcomes and leg length inequality to others who feel that refractory cases are suitable for revision^{66,149,248}. While, in all but the most extreme cases, there may not be a direct correlation, there has not, to the author's knowledge, been any publication of any data regarding the opinions of a body of orthopaedic surgeons who specialise in total hip replacements.

This group would therefore propose an electronic survey of the opinion of the member of the British Hip Society. The aim is to gauge consensus, if any, regarding the significance of leg length inequality following total hip replacement. As this would be a novel piece of work and any result, be it consensus for, against or no consensus at all, would be a significant finding. The results of the survey would be offered for presentation to the British Hip Society in the first instance. The group is hoping to conduct a 3 question survey, to investigate the breadth of hip surgeon's opinions about the link between post-operative leg length inequality and outcomes. It is deliberately brief as electronic surveys can sometimes have a bad reputation and term such as negligence have been consciously avoided.

These questions have been put to and discussed with senior surgeons in Chapel Allerton, Wrightington and Exeter. There has been broad approval of the tone and positive feedback as to the aim of the research.

The questions are:

All the questions below are when considering an otherwise standard, uncomplicated primary unilateral hip replacement for osteoarthritis, where the patient has no co-morbidities or other confounding factors (e.g. back pain)

Q1 *Under normal circumstances, do you feel that leg length inequality has a bearing on outcomes following total hip replacement?*

Y go to question 2.

N ends survey

Q2 *Do you feel that there is a limit, below which, and under normal circumstances, would be considered within the bounds of acceptable practice?*

Y - and give number

N

Q3 *Do you feel that there is a limit, above which, and under normal circumstances, would be considered excessive?*

Y – and give number

N

If this is considered acceptable for distribution to the membership of the British Hip Society, a link to surveymonkey would be emailed.

FMEA Assessment

<u>O = OCCURRENCE</u>		<u>S = SEVERITY</u>	<u>D = DETECTION</u>
Qualitative	Quantitative		
1. Improbable	<1 in 1,000,000	1. Negligible – Inconvenience or temporary	1. Frequently
2. Remote	<1 in 100,000	2. Minor – Results in temporary injury or	2. Reasonably Likely
3. Occasional	<1 in 10,000	3. Serious - Results in injury or impairment	3. Occasionally
4. Probable	<1 in 1,000	4. Critical – Results in permanent	4. Remote Chance
5. Frequent	<1 in 100	5. catastrophic – Results in death.	5. Extremely Unlikely

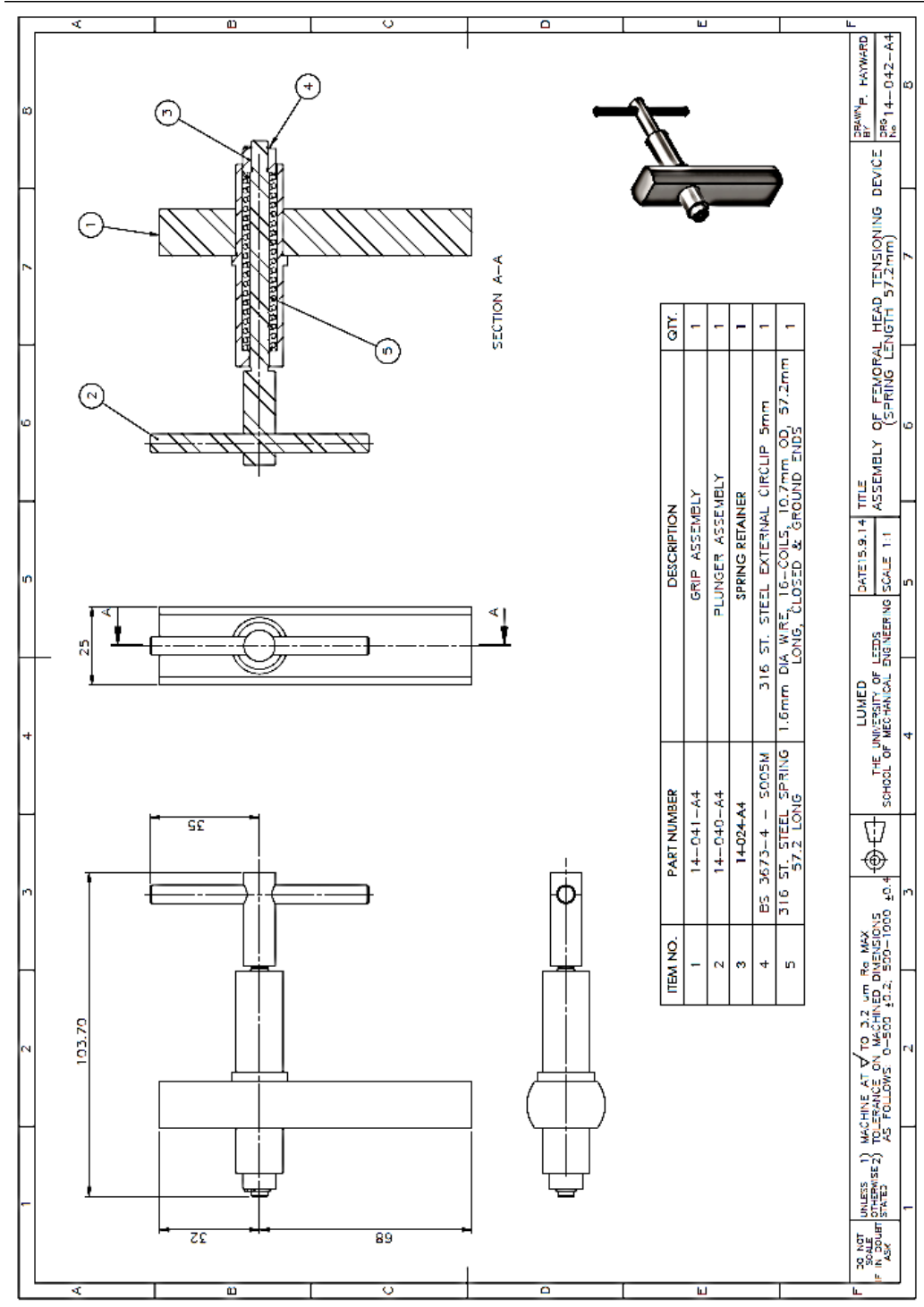
<u>RPN = O x S x D</u>		<u>Action</u>
<u>Qualitative</u>	<u>Quantitative</u>	
1. Low	1 – 20	No action required, current process controls adequate.
2. Medium	21- 44	Action required within a planned schedule.
3. High	45 - 125	Immediate action required.

Notes

Occurrence frequencies are related to the failure of an individual product.
 Severity is the effect of the failure on the user.
 Detection of the failure is by the end user,

Ref	Sub Title	Link
1	ISO 14971 Medical devices — Application of risk management to medical devices	http://www.isosert.ru/isosert_iso_14971.pdf
2	IEC/TR 80002-1 Part 1: Guidance on the application of ISO 14971 to medical device software	http://webstore.iec.ch/preview/info_iec80002-1%7Bed1.0%7Den.pdf
3	What's Different in ISO 14971:2007?	http://www.captrak.com/Files/PresH%20-%20ISO%2014971.pdf
4	ISO 14971, 2007 Risk Management for all Medical Devices The New Global Era	http://www.ghf.org/meetings/conferences/11thconference/D/02DOLAN.pdf
5	Risk management for medical devices and ISO 14971	http://www.gantus.com/courses/risk-management-for-medical-devices-and-iso-
6		

Appendix 5 - Plan of device



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	14-041-A4	GRIP ASSEMBLY	1
2	14-040-A4	PLUNGER ASSEMBLY	1
3	14-024-A4	SPRING RETAINER	1
4	BS 3673-4 - 5005M	316 ST. STEEL EXTERNAL CIRCLIP 5mm	1
5	316 ST. STEEL SPRING	1.6mm DIA. WIRE, 16 COILS, 10.7mm OD, 57.2mm LONG, CLOSED & GROUND ENDS	1

DO NOT UNLESS OTHERWISE STATED ASK

1) MACHINE AT $\sqrt{}$ TO 3.2 μ m R_a MAX TO-FRANCE ON MACHINED DIMENSIONS AS FOLLOWS: 0-500 \pm 0.2, 500-1000 \pm 0.4

LUMED THE UNIVERSITY OF LEEDS SCHOOL OF MECHANICAL ENGINEERING

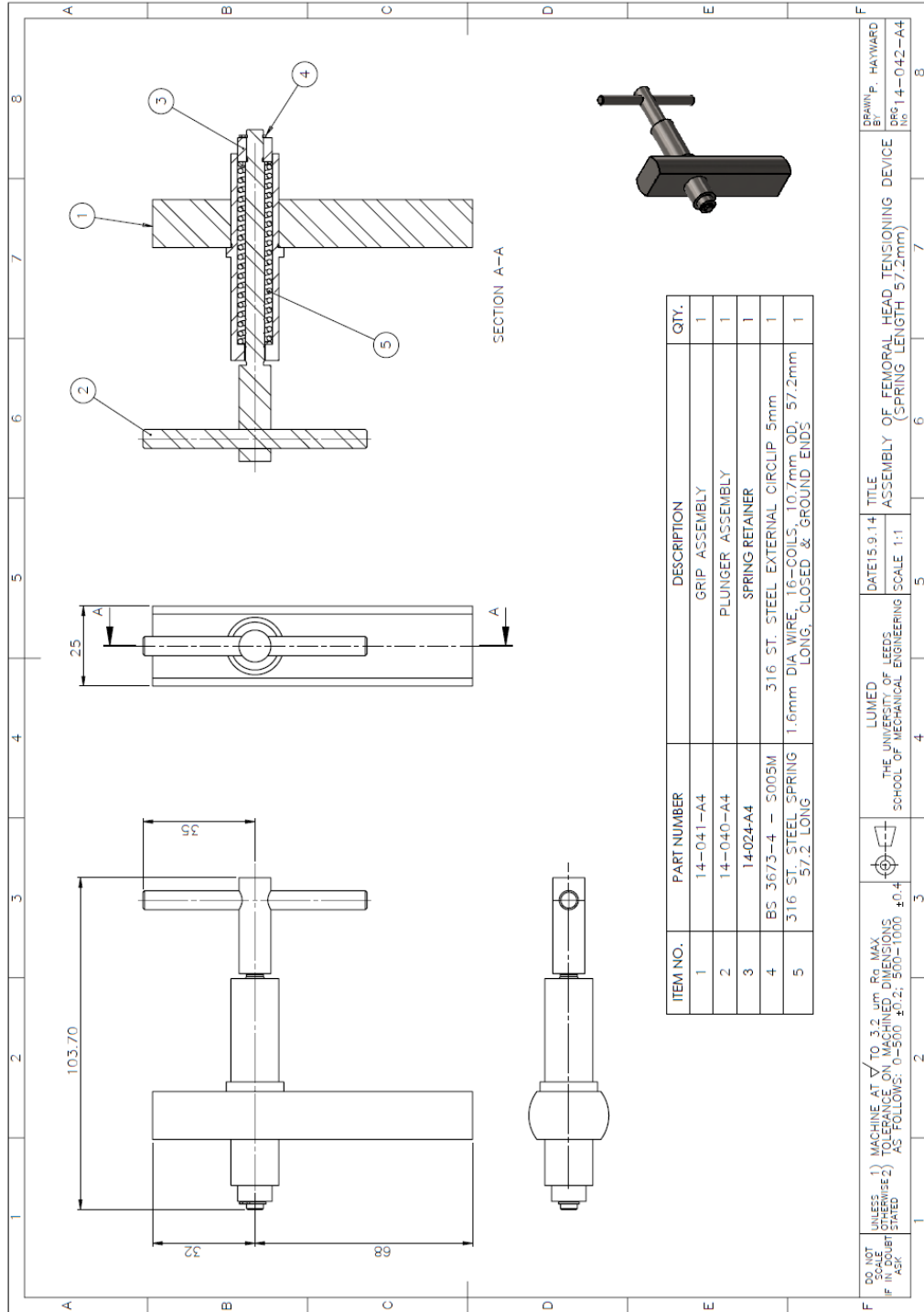
DATE: 19.9.14

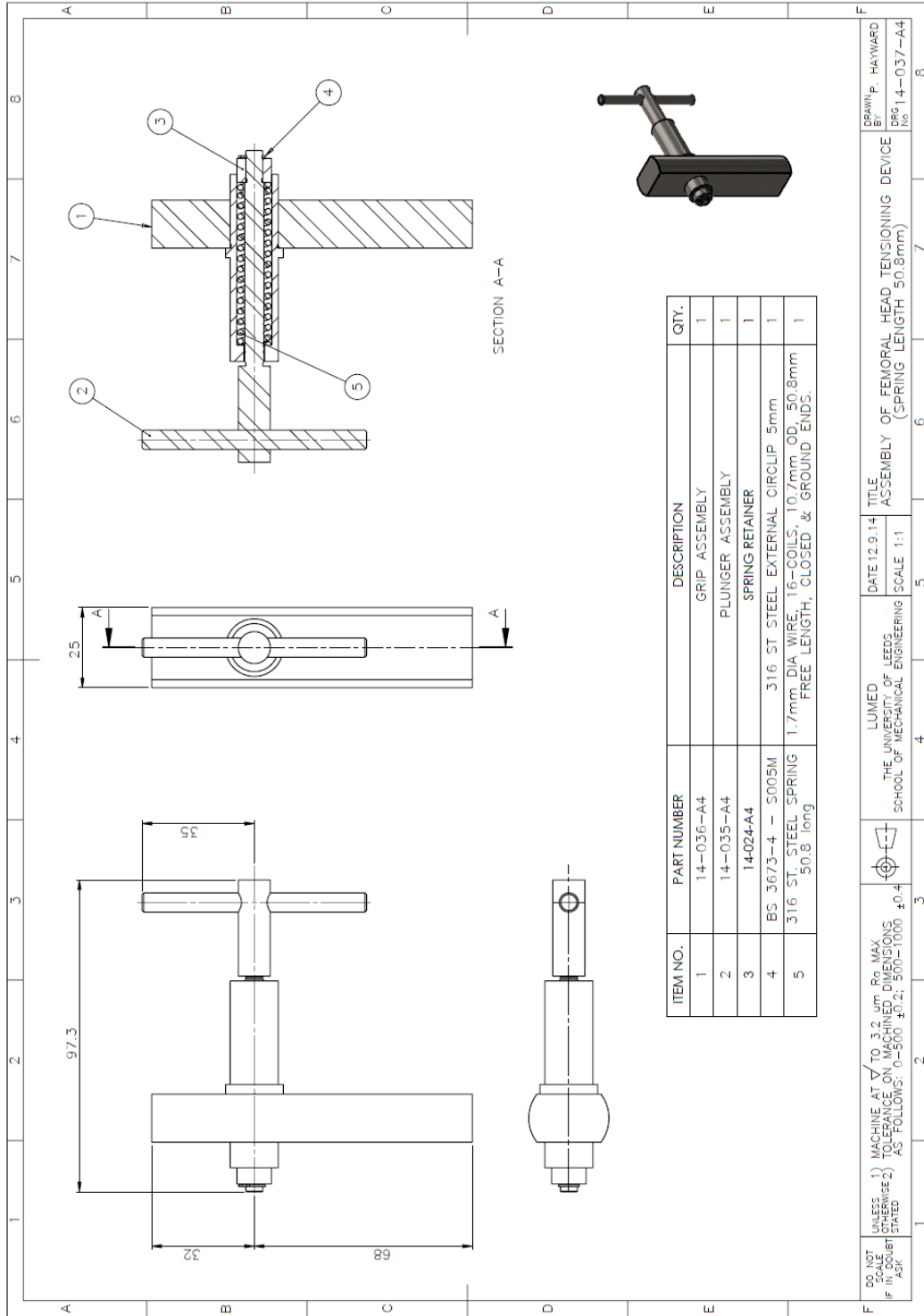
TITLE: ASSEMBLY OF FEMORAL HEAD TENSIONING DEVICE (SPRING LENGTH 57.2mm)

DRAWN BY: P. HAYWARD

PROJ: 14-042-A4

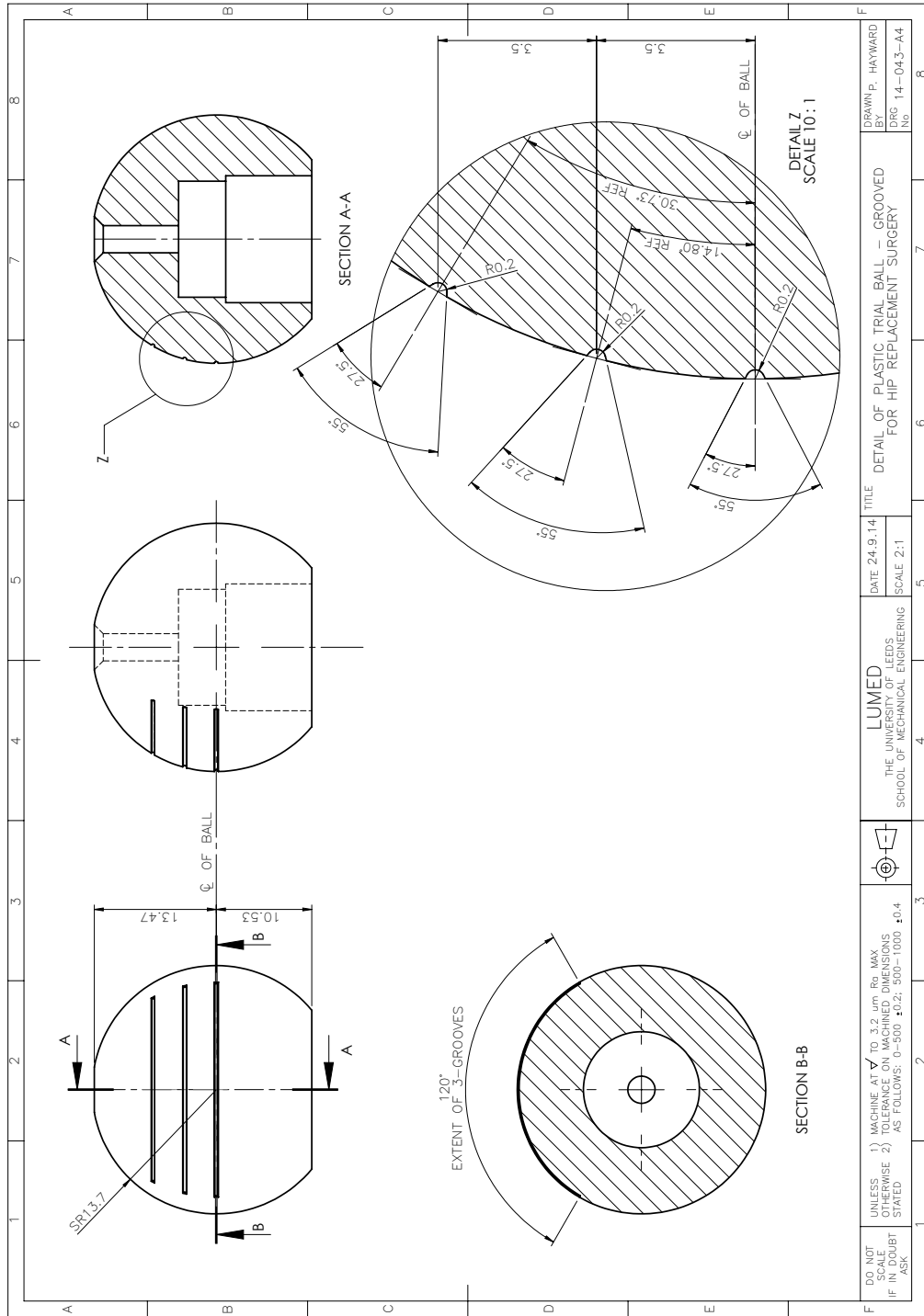
Appendix 6 – CAD Assembly drawing of Part A – Circlip options short and long





DO NOT SCALE UNLESS OTHERWISE STATED
 UNLESS OTHERWISE STATED
 MACHINING TO 3.2 μm Ra MAX
 FINISHING TO 0.4 μm Ra MAX
 AS FOLLOWS: 0-500 ±0.2, 500-1000 ±0.4

Appendix 7 – CAD drawings of etched trial femoral head



Appendix 8 – Marking guide

A device to measure soft tissue tension during trial reduction of hip arthroplasty surgery.

Faye Barnett^{1,2}, Tim Clarkson³, David Brettle³
 , Peter Hayward², Mr. Martin Stone¹, Dr Todd D Stewart²

¹Orthopaedics Leeds Teaching Hospitals Trust
²Mechanical Engineering, The University of Leeds
³Medical Physics Leeds Teaching Hospitals Trust

Device Engraving/Marking Guide

There are 12 devices in total. 6 are shorter with a 6.9 N/mm spring (50.8mm spring length) and 6 are longer with a 4.7N/mm spring (57.2mm spring length). 9 of the 12 have ~~nylock~~ fixation, and 3 of the 12 have circlip fixation. Details are outlined in Table 1 and 2.

Table 1. Details of Device

ID	Quantity	Description	Stiffness / Scale	Distraction (trial heads)
TrueTense SC-01,2	1	Short, Circlip	6.94N/mm @10, 20N	+12, +8.5, +4, +1.5
TrueTense SN-01 to 04	5	Short, Nylock	6.94N/mm @10, 20N	+12, +8.5, +4, +1.5
TrueTense LC-01	2	Long, Circlip	4.68 N/mm @10, 20N	+12, +8.5, +4, +1.5
TrueTense LN-01 to 05	4	Long, Nylock	4.68 N/mm @10, 20N	+12, +8.5, +4, +1.5



Table 2. Engraving Detail (Part A)

ID	Parts – CAD ID	Quantity	Description	Spring Length	Scale	Engraving
TrueTense SC-01,2	Grip, Plunger	1	Short, Circlip	50.8 mm	@10N minor @20N major	TrueTense TT50SC-01 TrueTense TT50SC-02
TrueTense SN-01 to 04	Grip, Plunger	5	Short, Nylock	50.8 mm	@10N minor @20N major	TrueTense TT50SN-01 TrueTense TT50SN-02 TrueTense TT50SN-03 TrueTense TT50SN-04
TrueTense LC-01	Grip, Plunger	2	Long, Circlip	57.2 mm	@10N minor @20N major	TrueTense TT57LC-01
TrueTense LN-01 to 05	Grip, Plunger	4	Long, Nylock	57.2 mm	@10N minor @20N major	TrueTense TT57LN-01 TrueTense TT57LN-02 TrueTense TT57LN-03 TrueTense TT57LN-04 TrueTense TT57LN-05
Spring Retainer	Spring Retainer (very small)	9	Nylock	All	Could be marked "TT-N" If space insufficient.	TT SN-01 TT SN-02 TT SN-03 TT SN-04 TT LN-01 TT LN-02 TT LN-03 TT LN-04 TT LN-05
Spring Retainer	Spring Retainer (very small)	3	Circlip	All	Could be marked "TT-C" If space insufficient.	TT SC-01 TT SC-02 TT LC-01
Nylock Spanner	Nylock Spanner	11	7mm Spanner	All		True Tense 7mm

Appendix 9 – Laxity device failure testing results

Laxity Device Failure testing results

Whom	Date	Location	Method 20mm/min extension to failure	Device	Load (N)	Failure mechanism
T Stewart, F Barnett	25/09/2014	Mechanical Engineering	20mm/min extension to failure	S1	644	No damage, swab fracture. Swabs replaced until no fracture at Load>600N.
T Stewart, F Barnett	25/09/2014	Mechanical Engineering	20mm/min extension to failure	S2	600	No Damage, Swabs replaced until no fracture at Load=600N.
T Stewart, F Barnett	25/09/2014	Mechanical Engineering	20mm/min extension to failure	S3	600	No Damage, Swabs replaced until no fracture at Load=600N.
T Stewart, F Barnett	25/09/2014	Mechanical Engineering	20mm/min extension to failure	S4	600	No Damage, Swabs replaced until no fracture at Load=600N.
T Stewart, F Barnett	25/09/2014	Mechanical Engineering	20mm/min extension to failure	S5	600	No Damage, Swabs replaced until no fracture at Load=600N.
T Stewart, F Barnett	25/09/2014	Mechanical Engineering	20mm/min extension to failure	S6	600	No Damage, Swabs replaced until no fracture at Load=600N.
T Stewart, F Barnett	25/09/2014	Mechanical Engineering	20mm/min extension to failure	L1	600	No Damage, Swabs replaced until no fracture at Load=600N.
T Stewart, F Barnett	25/09/2014	Mechanical Engineering	20mm/min extension to failure	L2	600	No Damage, Swabs replaced until no fracture at Load=600N.
T Stewart, F Barnett	25/09/2014	Mechanical Engineering	20mm/min extension to failure	L3	600	No Damage, Swabs replaced until no fracture at Load=600N.
T Stewart, F Barnett	25/09/2014	Mechanical Engineering	20mm/min extension to failure	L4	600	No Damage, Swabs replaced until no fracture at Load=600N.
T Stewart, F Barnett	25/09/2014	Mechanical Engineering	20mm/min extension to failure	L5	600	No Damage, Swabs replaced until no fracture at Load=600N.
T Stewart, F Barnett	25/09/2014	Mechanical Engineering	20mm/min extension to failure	L6	600	No Damage, Swabs replaced until no fracture at Load=600N.

Appendix 10 - Off label use of Medical Device Proposal Form

Off Label Use of Medical Device Proposal Form

In normal circumstances the form should be completed prior to any off-label use of a medical device in LTHT.

If there is an unforeseen urgent requirement for off label use, the plan must be discussed with another clinician and the form submitted within 5-days of usage.

1) Contact Details

Consultant Name:	Mr Martin Stone
Position:	Consultant Orthopaedic Surgeon
Department:	Orthopaedics, Chapel Allerton Orthopaedic Centre
Clinical Director:	Jacqueline Andrews
CSU Manager:	Chris Jones
Business Manager:	Andrea Burnell

2) Clinical Application

<p>Treatment pathway including proposed medical device (MD) application:</p>	<p>Leg length following total hip replacement is dependent on several factors including the size and position of the hip implant. To get this correct a surgeon relies on several tests, the most important one being the Shuck test. This takes place after insertion of the hip implant. The surgeon tests the muscles around the implant by seeing how much it moves out of the cup when traction is applied to the leg. If the muscles are too tight then the leg has been made too long, if the muscles are too slack then the leg has been made too short. This test is usually repeated several times with different size implants and the correct size is decided on.</p> <p>The shuck test is entirely subjective and decisions are made based on the surgeon's experience. It is a difficult skill to teach to</p>
--	--

	<p>junior surgeons who are learning how to perform hip replacements. The aim of the study is to develop a device to objectively test the soft tissues and gives the same results as an experienced orthopaedic surgeon when assessing leg length during total hip replacement.</p> <p>The device aims to deliver a standardized amount of tension or “shuck”. It is made from medical grade stainless steel and comprises of a handle for the surgeon to grip enclosing a spring connected to a T-handle that the swab will be wrapped around. The device has a scale on the handle to show the force pulled in Newtons. Each line has been calculated to represent 10 Newtons. Previous studies have shown that the force pulled during the shuck test is around 60 Newtons. Each device has been tested up to 600 Newtons without failure. There will be 12 devices which will be sent for sterilization following each use. The device will be used in conjunction with an etched trial femoral head.</p>
Are there any MDs on the market for this application ?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Don't Know <input type="checkbox"/>
If Yes, please describe what they are and why they are not suitable	N/A
Consequence of not proceeding with proposed application of MD ?	The MD is intended to improve clinical practise.
Is this proposal part of a research study (give R&D reference number)?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> R&D number awaited.
Is this research with a non-CE marked device?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Please indicate the Clinical Investigation number issued by the MHRA for this Clinical Investigation with a non-CE marked device.	Awaited.

3) Proposed MD Summary

Name of MD:	TrueTense
Manufacturer:	The University of Leeds and Medical Physics Leeds
Supplier:	The University of Leeds and Medical Physics Leeds
Original scope of intended use of MD (licenced use):	Medical Device Trial N=30 patients
Is the device intended for single use ?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Does this MD have a CE mark?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Proposed variation of use of MD:	None – currently no device is used.
Does the MD manufacturer agree to the proposed application ?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Are you aware of other healthcare organisations using the MD for this proposed application (give details)?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is the proposed variation already LTHT practice (give details) ?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>

4) Evidence

Provide any published evidence for the use of this variation of MD use including evidence of effectiveness:	<p>There is currently no medical device of this kind. Past research by the applicants [1-3] suggests that surgeon variation and handedness may lead to a variation in the assessment of ligament tension around the hip and the subsequent sizing of the implant that may contribute to leg length inequality.</p> <p>Pennington N; Redmond A; Stewart T; Stone M <i>The impact of surgeon handedness in total hip replacement. Annals of the Royal College of Surgeons of England</i>, vol. 96, pp.437-441. 2014.</p> <p>Li J; Redmond AC; Jin Z; Fisher J; Stone MH; Stewart TD <i>Hip contact forces in</i></p>
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	<p><i>asymptomatic total hip replacement patients differ from normal healthy individuals: Implications for preclinical testing. Clinical Biomechanics, vol. 29, pp.747-751. 2014. Li J; McWilliams AB, Redmond AC; Jin Z; Fisher J; Stone MH; Stewart TD Unilateral total hip replacement patients with symptomatic leg length inequality have abnormal hip biomechanics during walking. Clinical Biomechanics, Available online 28 February 2015.</i></p>
<p>Provide a summary of adverse effects/events associated with this specific variation of MD use:</p>	<p>The device will increase operative time by a maximum of 5 minutes. In the study the device will be used to gather information about current clinical practise but not to subscribe surgical practise.</p>
<p>Provide a summary of adverse effects/events generally associated with this type of MD:</p>	<p>Infection. Similar MD's are used currently in knee surgery to prescribe soft tissue forces.</p>

5) Managing Operational and Information Hazards

<p>What steps are you proposing to take to ensure that patients are fully informed of the status of the procedure (i.e. off label use) ?</p>	<p>Potential participants will be approached in outpatient clinic after they have been booked for a hip replacement. The study will be explained to them and they will receive a patient information sheet to take home to read and discuss with their family and friends.</p> <p>On the day they attend for their hip replacement they will be asked if they want to enter the study. They will have the opportunity to ask any questions they have.</p>
<p>Plan for training users of the devices for this application (give details) ?</p>	<p>The MD will only be used by one consultant orthopaedic surgeon who was involved with the design of the MD and will receive full instructions for use from the manufacturer.</p>

CCXXXVIII

Are there implications of the proposed variation for Maintenance/service/warrantee calibration Infection prevention	The device is composed of medical grade stainless steel and will be autoclaved with other theatre equipment following Leeds Teaching Hospitals Trust sterilisation protocols.
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6) Hazard Evaluation of Variation in Use

Are there energy hazards ?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Not sure <input type="checkbox"/>
Are there biological or chemical hazards ?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Not sure <input type="checkbox"/>
Are there operational hazards?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Not sure <input type="checkbox"/>
Are there information hazards	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Not sure <input type="checkbox"/>

See examples of hazard in supporting information at end of form

7) Risks of Failure of the Variation of use of MD

Identify at least the 3 highest risk consequences of MD usage in this application?		Quantify the likelihood and severity of each of these risks below.		Risk Score
	Risk consequence	Likelihood L (1-5)	Severity S (1-5)	L x S
1	Biological -infection	1	2	2
2	Mechanical	1	1	1
3	Labelling	1	1	1

See risk matrix in supporting information at end of form

8) Control Measures

For each of the amber or red risks above (risk score >6), identify additional control measures to reduce risks

Control measure required ?	Control measure (consent, patient information, use training.....)	Reassess the likelihood and severity of each risk	Risk Score
----------------------------	---	---	------------

CCXXXIX

			with the control measure in place		
			Likelihood L (1-5)	Severity S (1-5)	L x S
1	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Consent MD sterilised in the same manner as current MD's used in the operation. Device does not come in direct contact with the body. Manufactured from medical grade materials.	1	1	1
2	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Device Tested at 10 times anticipated load. All devices laboratory tested and calibrated.	1	1	1
3	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	All components labelled by Medical Physics. User limited to 1, and trained for use.	1	1	1

9) Submission

<i>Clinician Proposing the Procedure</i>	
Name: MARTIN STONE <i>(Print)</i>	Signature:
Post: Consultant Orthopaedic Surgeon	Contact number: E-mail:
Department: Orthopaedics	Date:

<i>CSU Clinical Governance Approval</i>	
<p>The above evidence has been reviewed by the CSU Clinical Governance Group. The benefits outweigh the residual risk of using this medical device off licence.</p> <p>Name: Signature:Clinical Governance chair Date:</p>	
<i>Medical Physics and Engineering Approval</i>	
<p>The above evidence has been reviewed by a senior manager in Physics and Engineering. It is line with Trust policy to ensure medical devices are safe and used correctly for the benefit.</p> <p>Name: Signature:Senior Manager Date:</p> <p>Additional RA completed? Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<i>Infection Prevention and Control Approval</i>	
<p>The above evidence has been reviewed by Infection Prevention and Control. It is line with Trust policy to ensure medical devices are safe and used correctly for the benefit of patients.</p> <p>Name: Signature:Senior Clinician Date:</p> <p>Additional RA completed? Yes <input type="checkbox"/> No <input type="checkbox"/></p>	

governances group. Also send an electronic copy to Medical Physics at riskassessment@medphysics.leeds.ac.uk and to Infection Prevention at InfectionPrevention@leedsth.nhs.uk

10) Approval

Supporting Information

Examples of Hazards

CCXLI

Energy	Biological or Chemical	Operational	Information
Electromagnetic energy	Biological	Function	Labelling
Line voltage	Bacteria	Incorrect or inappropriate output or functionality	Incomplete instructions for use
Leakage current – enclosure leakage current – earth leakage current – patient leakage current	Viruses	Incorrect measurement	Inadequate description of performance characteristics
Electric fields	Other agents (e.g. prions)	Erroneous data transfer	Inadequate specification of intended use
Magnetic fields	Re- or cross-infection	Loss or deterioration of function	Inadequate disclosure of limitations
Radiation energy	Chemical	Use error	Operating instructions
Ionizing radiation	Exposure of airway, tissues, environment or property, e.g. to foreign materials:	Attentional failure	Inadequate specification of accessories to be used with the medical device
Non-ionizing radiation	– acids or alkalis	Memory failure	Inadequate specification of pre-use checks
Thermal energy	– residues	Rule-based failure	Over-complicated operating instructions
High temperature	– contaminants	Knowledge-based failure	
Low temperature	– additives or processing aids	Routine violation	
Mechanical energy	– cleaning, disinfecting or testing agents		Warnings
Gravity – falling – suspended masses	– degradation products		Of side effects
Vibration	– medical gasses		Of hazards likely with re-use of single-use medical devices
Stored energy	– anaesthetic products		
Moving parts	Biocompatibility		Specification of service and maintenance
	Toxicity of chemical constituents, e.g.:		
	– allergenicity/irritancy		
	– pyrogenicity		

<p>Torsion, shear and tensile force</p> <p>Moving and positioning of patient</p> <p>Acoustic energy</p> <ul style="list-style-type: none"> – ultrasonic energy – infrasound energy – sound <p>High pressure fluid injection</p>			
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Standard Risk Matrix

SEVERITY INDEX		LIKELIHOOD INDEX		
5	Multiple deaths caused by an event; ≥£5m loss; May result in Special Administration or Suspension of CQC Registration; Hospital closure; Total loss of public confidence	5	Very Likely	No effective control ≥80% chance
4	Severe permanent harm or death caused by an event; £1m - £5m loss; Prolonged adverse publicity; Prolonged disruption to one or more CSU's; Extended service closure	4	Somewhat Likely	Weak control; or ≥10% chance
3	Moderate harm – medical treatment required up to 1 year; £100k – £1m loss; Temporary disruption to one or more CSU's; Service closure	3	Possible	Limited effective control ≥1% chance
2	Minor harm – first aid treatment required up to 1 month; £50k - £100K loss; or Temporary service restriction	2	Unlikely	Good control ≥0.1% chance
1	No harm; 0 - £50K loss; or No disruption – service continues without impact	1	Extremely Unlikely	Very good control <0.1% chance (or less)

Appendix 12 - Assembly instructions (Circlip)

TrueTense Laxity Device Assembly Instructions (1) **TT57LC (circlip)**

Packs:



Contents:

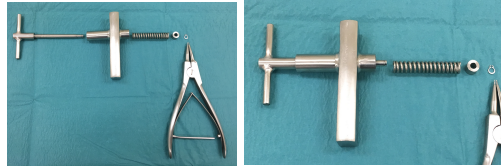
- 1 Stainless steel plunger assembly ①
- 1 Stainless steel grip assembly ②
- 1 Stainless steel 7mm spring retainer ③
- 1 57mm stainless steel spring ④
- 1 stainless steel circlip plier ⑤
- 1 Truetense 28mm calibration ball black ⑥
- 1 Truetense 28mm calibration ball blue ⑦
- 1 Truetense 28mm calibration ball brown ⑧
- 1 Truetense 28mm calibration ball green ⑨

Also require separately packed circlips ⑩



Assembly Instructions:

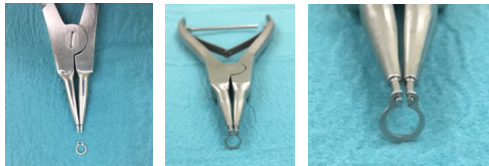
1. Place T-handle in to longer side of grip assembly



2. Place spring inside shorter side and place spring retainer over spring



3. Grip circlip using circlip pliers as shown:



4. Squeeze pliers to open circlip and place in groove to hold spring retainer ring in place



Please disassemble and replace in tray after use.

Circlips are single use and may be disposed of in sharps bin after final count

Assembly instructions (Nylock)

TrueTense Laxity Device Assembly Instructions (2) **TT57LC (nut)**

Packs:



Contents:

- 1 Stainless steel plunger assembly ①
- 1 Stainless steel grip assembly ②
- 1 50mm stainless steel spring ③
- 1 TrueTense 7mm stainless steel spanner ④
- 1 Truetense 28mm calibration ball black ⑤
- 1 Truetense 28mm calibration ball blue ⑥
- 1 Truetense 28mm calibration ball brown ⑦
- 1 Truetense 28mm calibration ball green ⑧

Also require separately packed nuts ⑨



Assembly Instructions:

1. Place T-handle in to longer side of grip assembly



2. Place spring inside shorter side



3. Place nut over spring



4. Tighten nut with spanner until end of nut is flush



Please disassemble and replace in tray after use.

Nuts are single use and may be disposed of in sharps bin after final count

Appendix 13 - Disassembly instructions

Disassembly Instructions in preparation for cleaning for *TrueTense* Surgical Tension Device (Circlip Type - Short) & Associated Equipment

Manufacturer; Radiotherapy Technical Services (RTS)

Device; These instructions apply to the *TrueTense* Surgical Tension Device and Associated Equipment only

Device ID; these devices will be labelled **TT50SC-01 and TT50SC-02** (TT50SC-xx).

This document corresponds to the attached diagram [14-037-A4] illustrating the fully assembled device and Figure 1. illustrating the disassembled device within a cleaning tray.

To disassemble TT50SC-xx use the following instructions(Reference Figure 2-4):

1. Using the circlip plier **TT-C** remove the circlip retainer from the groove at the end of the plunger assembly. Note: *TrueTense* Circlips are disposed after use.
2. Remove the spring retainer, spring and plunger **TT50SC-xx** from the grip assembly.

Sterilisation Tray Contents:

One of **TT50SC-xx** 316L Stainless Steel grip assembly

One of **TT50SC-xx** 316L Stainless Steel plunger assembly

One of **TT50SC-xx** 316L Stainless Steel 7mm spring retainer

One 50mm 316L Stainless Steel spring

One **TT-C** 316L Stainless Steel Circlip Plier

One set Nylon *TrueTense* 28mm **TT** Calibration Balls (Green, Brown, Blue, Black; 4 in total)



Figure 1. Disassembled device in cleaning tray, and assembled device.

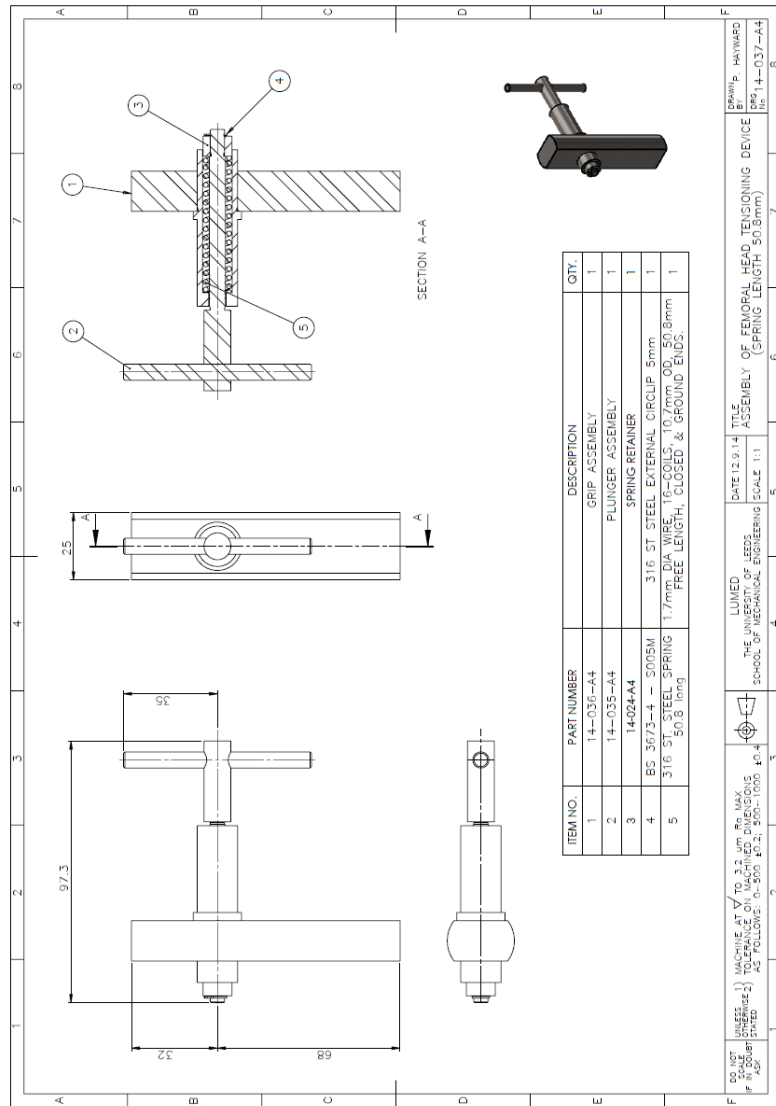


Figure 2. Assembly Detail

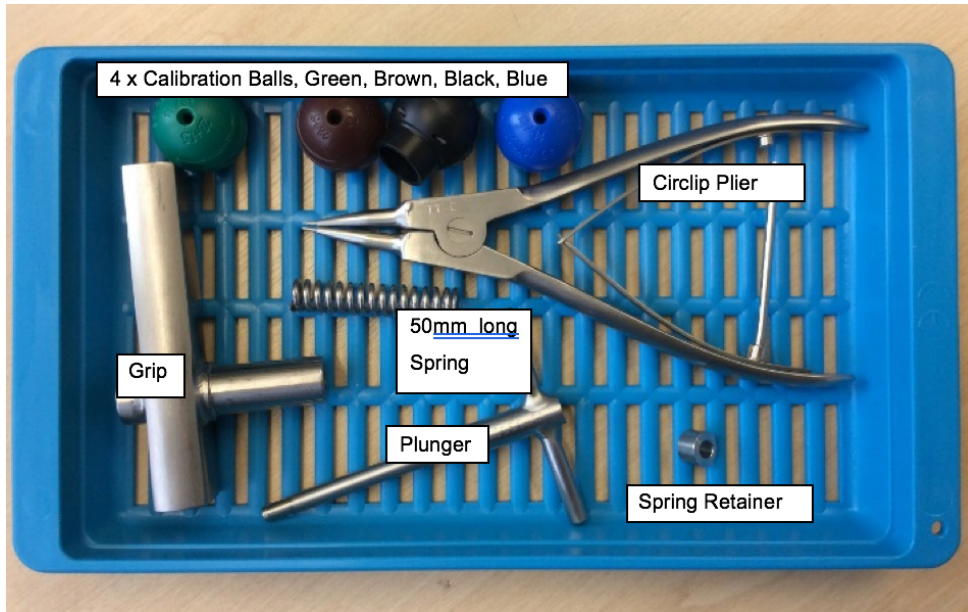


Figure 3. Parts Detail.

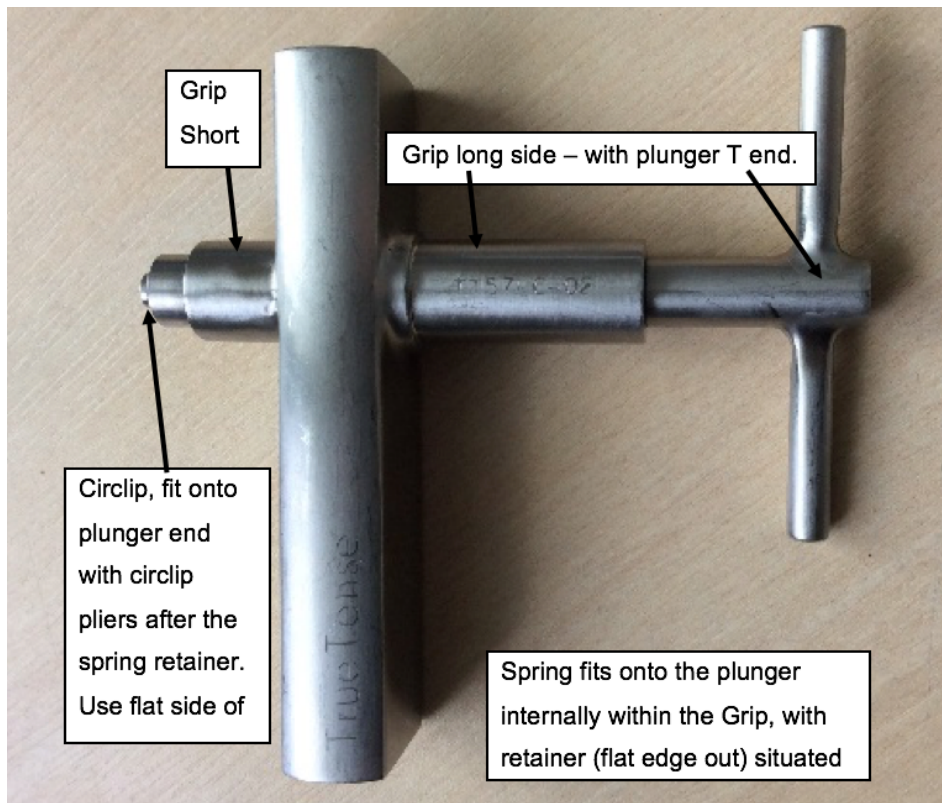


Figure 4. Assembled Device

**Disassembly Instructions in preparation for cleaning
for *TrueTense* Surgical Tension Device
(Nut Type - Short) & Associated Equipment**

Manufacturer; Radiotherapy Technical Services (RTS)

Device; These instructions apply to the *TrueTense* Surgical Tension Device and Associated Equipment only

Device ID; these devices will be labelled **TT50SN-01 thru to TT50SN-04** (TT50SN-xx).

This document corresponds to the attached diagram [15-015-A3] illustrating the fully assembled device and Figure 1. illustrating the disassembled device within a cleaning tray.

To disassemble TT50SN-xx use the following instructions (Reference Figure 2-4):

3. Using the **TrueTense 7mm** spanner unscrew the Nylock Nut by turning the spanner counter-clockwise. Note: *TrueTense* Nylock Nuts are disposed after use.
4. Remove the spring retainer, spring and plunger **TT50SN-xx** from the grip assembly.
5. Take special care with the spring retainer this is to be sterilised separately in a pouch.

Sterilisation Tray Contents:

One of **TT50SN-xx** 316L Stainless Steel grip assembly

One of **TT50SN-xx** 316L Stainless Steel plunger assembly

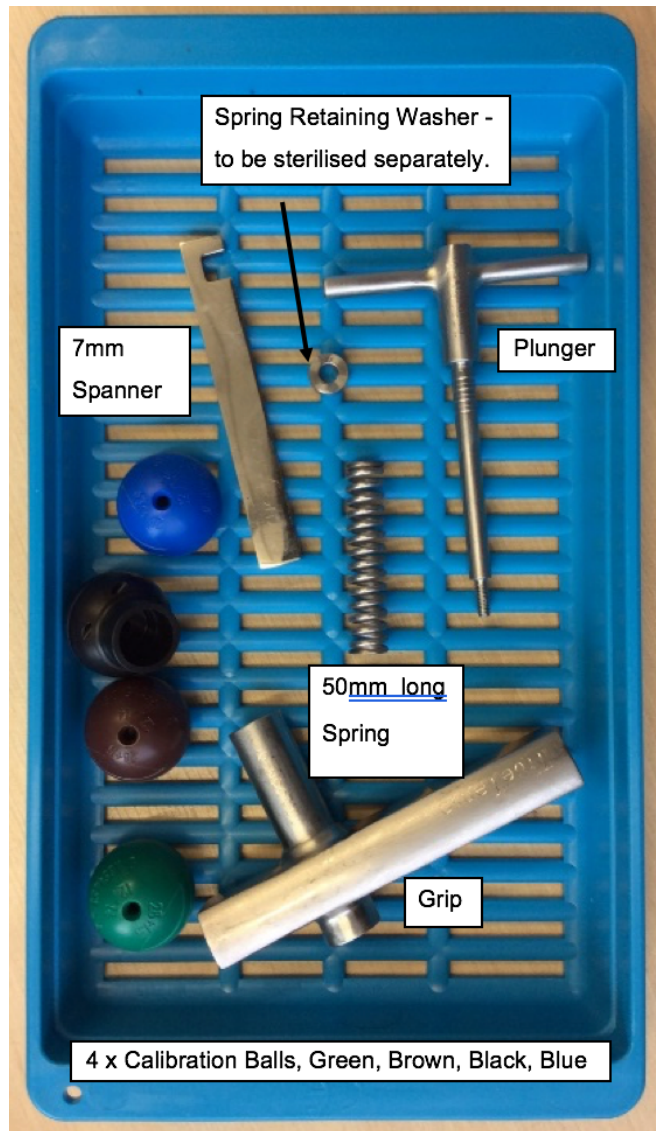
One of **TT50SN-xx** 316L Stainless Steel 4mm spring retaining washer (sterilised in a pouch separately)

One 50mm 316L Stainless Steel spring

One **TrueTense 7mm** 316L Stainless Steel Spanner

One set Nylon *TrueTense* 28mm **TT** Calibration Balls (Green, Brown, Blue, Black; 4 in total)

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Appendix 14 – Re-processing instructions for TrueTense

Reprocessing Instructions for *TrueTense* Surgical Tension Device (Nut Type-Short) & Associated Equipment

Manufacturer; Radiotherapy Technical Services (RTS)

Device; These instructions apply to the *TrueTense* Surgical Tension Device and Associated Equipment only. The Device has four versions with long, short, Circlip, Nylock Nut options.

Device ID; these devices will be labelled **TT50SN-01 thru to TT50SN-04** (TT50SN-xx).

Sterilisation Tray Contents:

One of **TT50SN-xx** 316L Stainless Steel grip assembly

One of **TT50SN-xx** 316L Stainless Steel plunger assembly

One of **TT50SN-xx** 316L Stainless Steel 4mm spring retaining washer (sterilised in a pouch separately)

One 57mm 316L Stainless Steel spring

One **TrueTense 7mm** 316L Stainless Steel Spanner

One set Nylon *TrueTense* 28mm TT Calibration Balls (Green, Brown, Blue, Black; 4 in total)

Figure 1.Outlines the **TrueTense Surgical Tension Device (Nut Type-Short)** as supplied for reprocessing. The ID of this device is **TT50SN-xx**.

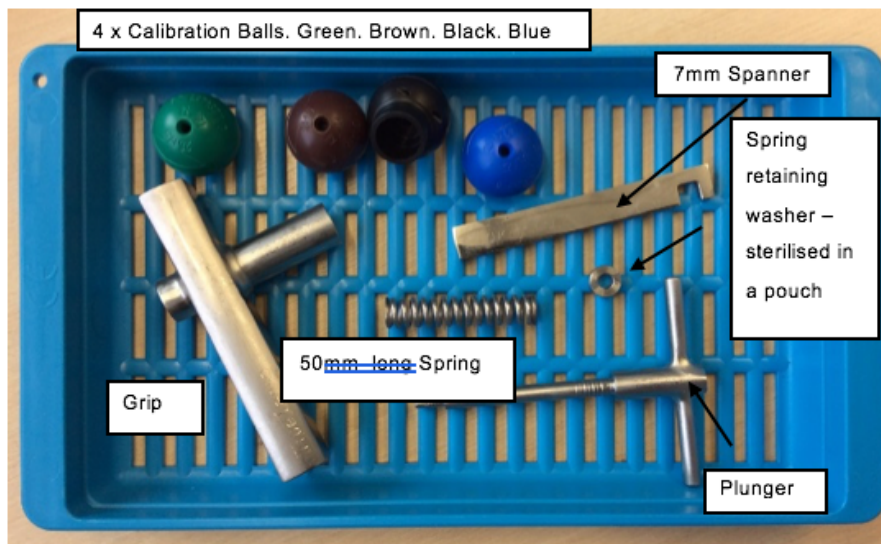


Figure 1. Disassembled *TrueTense Surgical Tension Device (Nut Type-Short) TT50SN-xx*.

Cleaning and sterilization equipment varies in performance characteristics and must be validated accordingly. The reprocessing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of preparing the *TrueTense Surgical Tension Device* and associated equipment for reuse. Any deviation from these procedures must be evaluated for efficiency by the reprocessing facility.

WARNINGS	<p>These instructions <u>have not</u> been proven effective for sterilizing this instrument if contaminated with unconventional transmissible agents (prions) such as the causative agents of Creutzfeldt-Jakob Disease (CJD) and Bovine Spongiform Encephalopathy (BSE). It <u>should not</u> be assumed that the methods described are effective against such agents.</p> <p>Cleaning is an essential pre-requisite to ensure effective sterilization. Blind holes, cavities, serrations and joints require particular attention during cleaning. Failure to completely remove organic debris and/or cleaning residues may lead to inadequate sterilization and result in an increased probability of infection.</p> <p>Failure to thoroughly remove cleaning agents may lead to sensitivity and/or allergic reactions.</p> <p>Wear appropriate protective equipment and follow local infection control policies while handling contaminated instruments. This includes, but is not limited to, waterproof clothing, robust gloves and eye protection. Avoid splashing and creation of aerosols.</p> <p>Caustic substances and those containing make-up of highly acidic or alkaline-based solutions may cause corrosion and shorten instrument life. Exposure to temperatures above 137°C (279°F) may accelerate instrument degradation. Water impurities, such as alkali metal, metal and chloride ions may discolour or corrode instruments.</p> <p>Use purified water for final rinsing and steam sterilization cycles. Saline may cause deterioration of instrument surfaces. Corrosion,</p>
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	<p>rusting and pitting may occur when blood and debris are allowed to dry on surgical instruments.</p> <p>Only legally marketed medical equipment, solutions and accessories should be used for reprocessing surgical instruments. Do not use non-absorbent tray accessories as these may cause condensation to pool and extend drying times.</p> <p>All non-sterile instruments must be thoroughly cleaned and sterilized prior to use. Always clean and sterilize surgical instruments before returning to RTS.</p>
<p>LIMITATIONS ON REPROCESSING</p>	<p>Repeated reprocessing according to these instructions has minimal effect on the instrument and associated equipment. The useful life is normally determined by a visual and/or functional evaluation prior to use.</p>
<p>INSTRUCTIONS</p>	
<p>POINT OF USE</p>	<ul style="list-style-type: none"> • Remove gross debris immediately after use. • Disassemble the assembly into its component parts (See Assembly/Disassembly Instructions). • Remove excess soil with surgical wipes/sponges moistened with sterile water. • Irrigate blind holes, cavities, serrations and joints with sterile water • In order to ensure effective cleaning, do not allow soil to dry on instruments. • A 2% solution of hydrogen peroxide (which bubbles when it comes into contact with blood or protein) may be used to verify removal of protein debris.
<p>PREPARATION BEFORE CLEANING</p>	<p>No Particular requirements.</p>
<p>CLEANING - GENERAL INSTRUCTIONS</p>	<p>The following cleaning guidelines are intended to supplement those supplied by equipment and solution manufacturers and local policies. Operate equipment in accordance with the equipment manufacturer's instructions and in consideration of any limitations of use. This includes characteristics of certain types of instruments that require special handling or which may not be adequately cleaned by the equipment. Select, prepare and use cleaning solutions in</p>

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	<p>accordance with the equipment manufacturer's instructions. Special attention should be paid to specifications for detergent concentration, water temperature, water quality and maintenance schedules.</p> <p>In order to prevent damage to instruments, use only neutral enzymatic detergents (pH 7 - 9)</p> <p>During ultrasonic cleaning, combine only instruments made of similar metals in order to avoid ion transfer, which may result in etching and/or pitting.</p> <p>Ensure rinsing process removes all cleaning residues. Removal of cleaning residues is an essential prerequisite for effective steam sterilization.</p> <p>Ensure cleaning equipment achieves and maintains the proper process parameters (e.g. time, temperature, water pressure, fluid flow rates, concentration and delivery of accessory solutions etc.)</p>
<p>CLEANING - MANUAL</p>	<p>Equipment: Ultrasonic Cleaner, Cleaning Brush, Enzymatic Detergent (Neutral pH), Running Water (Tap, Purified)</p> <ul style="list-style-type: none"> • Pre-rinse under warm running water for a minimum of two (2) minutes to remove debris. • Completely immerse in an Ultra Sonic cleaning bath filled with neutral (pH 7 - 9) enzymatic detergent solution prepared according to the manufacturers instructions. • Ultrasonicate for a minimum of ten (10) minutes at or below 35°C (95°F). • Remove any remaining debris from crevices using a Cleaning Brush. • Rinse for at least two (2) minutes under purified running water to remove cleaning residue. • Carefully dry using an absorbent, non-shedding cloth or industrial hot dryer, or place into a drying cabinet until all moisture is removed.,
<p>CLEANING - AUTOMATED</p>	<ul style="list-style-type: none"> • An automated cleaning process of equal effectiveness to the manual cleaning method may be used. Manual pre-cleaning is recommended in cases of dried-on organic material. Follow instructions provided by the washer manufacturer and detergent manufacturer as well as local policies. • Arrange instruments in the washer such that all surfaces are exposed to the action of the automated washer. • Sequencing, number and type of stages may vary among washer manufacturers. Washers may use single chamber for rinsing, cleaning and drying or may use multiple chambers, one for each cycle. Typical wash cycles may include the following; cool water rinse, enzymatic soak, detergent wash, ultrasonic cleaning, sustained hot water rinse and drying. It is recommended to perform a neutralizing rinse after use of strong alkaline or acidic cleaning solutions. Use purified water for the final rinse.

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<p>CLEANING - INSPECTION</p>	<ul style="list-style-type: none"> • After cleaning, visually inspect for cleanliness • Removal of all visible organic material and other residue is required prior to steam sterilization. • Repeat automated cleaning or perform manual cleaning as required. 						
<p>PACKAGING</p>	<ul style="list-style-type: none"> • Wrap entire tray in sterilization wrap material and apply label to indicate contents. Sterilization wraps must allow adequate steam penetration, aeration and protection against microbial penetration. Sterilization wraps should be approved for clinical use. 						
<p>STERILIZATION</p>	<p>Equipment: Pre-vacuum Steam Autoclave, Purified Water, Sterilization Wrap.</p> <p>Perform a pre-vacuum steam cycle using one of the following cycles:</p> <table border="1" data-bbox="587 875 1402 1016"> <thead> <tr> <th>TEMPRATURE RANGE</th> <th>MINIMUM EXPOSURE TIME</th> </tr> </thead> <tbody> <tr> <td>132 - 135° (270 - 275°F)</td> <td>Four (4) Minutes</td> </tr> <tr> <td>134 - 137°C (273 - 279°F)</td> <td>Three (3) Minutes</td> </tr> </tbody> </table> <ul style="list-style-type: none"> • Ensure Autoclave equipment achieves and maintains the proper time, temperature and pressure. • Operate equipment in accordance with the equipment manufacturers instructions. • When sterilizing multiple instrument sets in one autoclave cycle ensure the maximum load stated by the equipment manufacturer is not exceeded. • Use Purified Water for steam sterilization. 	TEMPRATURE RANGE	MINIMUM EXPOSURE TIME	132 - 135° (270 - 275°F)	Four (4) Minutes	134 - 137°C (273 - 279°F)	Three (3) Minutes
TEMPRATURE RANGE	MINIMUM EXPOSURE TIME						
132 - 135° (270 - 275°F)	Four (4) Minutes						
134 - 137°C (273 - 279°F)	Three (3) Minutes						
<p>STORAGE</p>	<ul style="list-style-type: none"> • Store and transport sterile instruments in such a way as to maintain sterility and functional integrity. • Store instruments in dry, clean, well-ventilated environments away from floors, ceilings and outside walls. • If sterilization is performed by an outside contract facility, protect the wrapped devices from contamination by additional coverings. • Segregate sterile instruments from non-sterile items. Label sterile instruments to identify sterility status and ensure use in a first in, first out (FIFO) order. • Do not use instruments if the sterilization wrap is opened, damaged or wet. 						
<p>Manufacturer Contact Information</p>	<p>For additional Information contact;</p> <p>Radiotherapy Engineering Services Level B1 Bexley Wing St. James's Hospital Leeds LS15 9TF</p> <p>Email: rts.lth@nhs.net</p>						

Appendix 15 – Reprocessing instructions - Circlips

Reprocessing Instructions for *TrueTense* Surgical Tension Device (Circlips)

Manufacturer; Radiotherapy Technical Services (RTS)

Device; These instructions apply to the *TrueTense* Surgical Tension Device and Associated Equipment only

Figure 1.Outlines the ***TrueTense* Circlips** as supplied loose. These will be packaged in groups of 2 in pouches for reprocessing. An additional image is present to allow the size to be assessed.

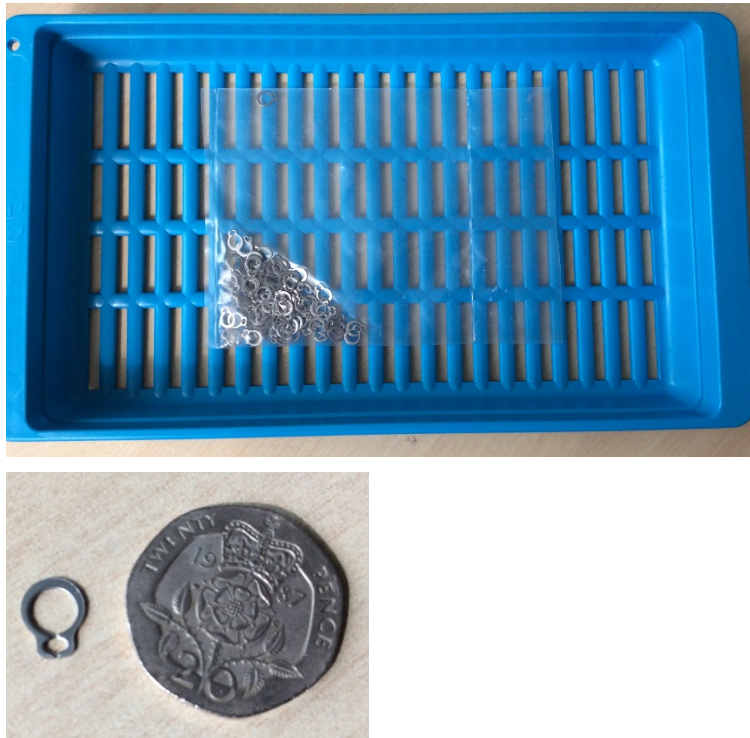


Figure 1. Circlips (100) and size reference image.

Cleaning and sterilization equipment varies in performance characteristics and must be validated accordingly. The reprocessing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of preparing the *TrueTense* Surgical Tension Device and associated equipment for reuse. Any deviation from these procedures must be evaluated for efficiency by the reprocessing facility.

WARNINGS	<p>These instructions <u>have not</u> been proven effective for sterilizing this instrument if contaminated with unconventional transmissible agents (prions) such as the causative agents of Creutzfeldt-Jakob Disease (CJD) and Bovine Spongiform Encephalopathy (BSE). It <u>should not</u> be assumed that the methods described are effective against such agents.</p> <p>Cleaning is an essential pre-requisite to ensure effective sterilization. Blind holes, cavities, serrations and joints require particular attention during cleaning. Failure to completely remove organic debris and/or cleaning residues may lead to inadequate sterilization and result in an increased probability of infection.</p> <p>Failure to thoroughly remove cleaning agents may lead to sensitivity and/or allergic reactions.</p> <p>Wear appropriate protective equipment and follow local infection control policies while handling contaminated instruments. This includes, but is not limited to, waterproof clothing, robust gloves and eye protection. Avoid splashing and creation of aerosols.</p> <p>Caustic substances and those containing make-up of highly acidic or alkaline-based solutions may cause corrosion and shorten instrument life. Exposure to temperatures above 137°C (279°F) may accelerate instrument degradation. Water impurities, such as alkali metal, metal and chloride ions may discolour or corrode instruments.</p> <p>Use purified water for final rinsing and steam sterilization cycles. Saline may cause deterioration of instrument surfaces. Corrosion, rusting and pitting may occur when blood and debris are allowed to dry on surgical instruments.</p> <p>Only legally marketed medical equipment, solutions and accessories should be used for reprocessing surgical instruments. Do not use non-absorbent tray accessories as these may cause condensation to pool and extend drying times.</p> <p>All non-sterile instruments must be thoroughly cleaned and sterilized prior to use. Always clean and sterilize surgical instruments before returning to RTS.</p>
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<p>LIMITATIONS ON REPROCESSING</p>	<p>Repeated reprocessing according to these instructions has minimal effect on the instrument and associated equipment. The useful life is normally determined by a visual and/or functional evaluation prior to use.</p>
<p>INSTRUCTIONS</p>	
<p>POINT OF USE</p>	<ul style="list-style-type: none"> • Remove gross debris immediately after use. • Disassemble the assembly into its component parts (See Assembly/Disassembly Instructions). • Remove excess soil with surgical wipes/sponges moistened with sterile water. • Irrigate blind holes, cavities, serrations and joints with sterile water • In order to ensure effective cleaning, do not allow soil to dry on instruments. • A 2% solution of hydrogen peroxide (which bubbles when it comes into contact with blood or protein) may be used to verify removal of protein debris.
<p>PREPARATION BEFORE CLEANING</p>	<p>No Particular requirements.</p>
<p>CLEANING - GENERAL INSTRUCTIONS</p>	<p>The following cleaning guidelines are intended to supplement those supplied by equipment and solution manufacturers and local policies.</p> <p>Operate equipment in accordance with the equipment manufacturer's instructions and in consideration of any limitations of use. This includes characteristics of certain types of instruments that require special handling or which may not be adequately cleaned by the equipment. Select, prepare and use cleaning solutions in accordance with the equipment manufacturer's instructions. Special attention should be paid to specifications for detergent concentration, water temperature, water quality and maintenance schedules.</p> <p>In order to prevent damage to instruments, use only neutral enzymatic detergents (pH 7 - 9)</p> <p>During ultrasonic cleaning, combine only instruments made of similar metals in order to avoid ion transfer, which may result in etching and/or pitting.</p>

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	<p>Ensure rinsing process removes all cleaning residues. Removal of cleaning residues is an essential prerequisite for effective steam sterilization.</p> <p>Ensure cleaning equipment achieves and maintains the proper process parameters (e.g. time, temperature, water pressure, fluid flow rates, concentration and delivery of accessory solutions etc.)</p>
CLEANING - MANUAL	<p>Equipment: Ultrasonic Cleaner, Cleaning Brush, Enzymatic Detergent (Neutral pH), Running Water (Tap, Purified)</p> <ul style="list-style-type: none"> • Pre-rinse under warm running water for a minimum of two (2) minutes to remove debris. • Completely immerse in an Ultra Sonic cleaning bath filled with neutral (pH 7 - 9) enzymatic detergent solution prepared according to the manufacturers instructions. • Ultrasonicate for a minimum of ten (10) minutes at or below 35°C (95°F). • Remove any remaining debris from crevices using a Cleaning Brush. • Rinse for at least two (2) minutes under purified running water to remove cleaning residue. • Carefully dry using an absorbent, non-shedding cloth or industrial hot dryer, or place into a drying cabinet until all moisture is removed.,
CLEANING - AUTOMATED	<ul style="list-style-type: none"> • An automated cleaning process of equal effectiveness to the manual cleaning method may be used. Manual pre-cleaning is recommended in cases of dried-on organic material. Follow instructions provided by the washer manufacturer and detergent manufacturer as well as local policies. • Arrange instruments in the washer such that all surfaces are exposed to the action of the automated washer. • Sequencing, number and type of stages may vary among washer manufacturers. Washers may use single chamber for rinsing, cleaning and drying or may use multiple chambers, one for each cycle. Typical wash cycles may include the following; cool water rinse, enzymatic soak, detergent wash, ultrasonic cleaning, sustained hot water rinse and drying. It is recommended to perform a neutralizing rinse after use of strong alkaline or acidic cleaning solutions. Use purified water for the final rinse.
CLEANING - INSPECTION	<ul style="list-style-type: none"> • After cleaning, visually inspect for cleanliness • Removal of all visible organic material and other residue is required prior to steam sterilization. • Repeat automated cleaning or perform manual cleaning as required.
PACKAGING	

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	<ul style="list-style-type: none"> • Wrap entire tray in sterilization wrap material and apply label to indicate contents. Sterilization wraps must allow adequate steam penetration, aeration and protection against microbial penetration. Sterilization wraps should be approved for clinical use. 						
<p>STERILIZATION</p>	<p>Equipment: Pre-vacuum Steam Autoclave, Purified Water, Sterilization Wrap.</p> <p>Perform a pre-vacuum steam cycle using one of the following cycles:</p> <table border="1" data-bbox="587 622 1406 766"> <thead> <tr> <th>TEMPRATURE RANGE</th> <th>MINIMUM EXPOSURE TIME</th> </tr> </thead> <tbody> <tr> <td>132 - 135° (270 - 275°F)</td> <td>Four (4) Minutes</td> </tr> <tr> <td>134 - 137°C (273 - 279°F)</td> <td>Three (3) Minutes</td> </tr> </tbody> </table> <ul style="list-style-type: none"> • Ensure Autoclave equipment achieves and maintains the proper time, temperature and pressure. • Operate equipment in accordance with the equipment manufacturers instructions. • When sterilizing multiple instrument sets in one autoclave cycle ensure the maximum load stated by the equipment manufacturer is not exceeded. • Use Purified Water for steam sterilization. 	TEMPRATURE RANGE	MINIMUM EXPOSURE TIME	132 - 135° (270 - 275°F)	Four (4) Minutes	134 - 137°C (273 - 279°F)	Three (3) Minutes
TEMPRATURE RANGE	MINIMUM EXPOSURE TIME						
132 - 135° (270 - 275°F)	Four (4) Minutes						
134 - 137°C (273 - 279°F)	Three (3) Minutes						
<p>STORAGE</p>	<ul style="list-style-type: none"> • Store and transport sterile instruments in such a way as to maintain sterility and functional integrity. • Store instruments in dry, clean, well-ventilated environments away from floors, ceilings and outside walls. • If sterilization is performed by an outside contract facility, protect the wrapped devices from contamination by additional coverings. • Segregate sterile instruments from non-sterile items. Label sterile instruments to identify sterility status and ensure use in a first in, first out (FIFO) order. • Do not use instruments if the sterilization wrap is opened, damaged or wet. 						
<p>Manufacturer Contact Information</p>	<p>For additional Information contact;</p> <p>Radiotherapy Engineering Services Level B1 Bexley Wing St. James's Hospital Leeds LS15 9TF</p> <p>Email: rts.lth@nhs.net</p>						

Reprocessing instructions for True Tense Nylock nuts

Reprocessing Instructions for *TrueTense* Surgical Tension Device (Nylock Nuts)

Manufacturer; Radiotherapy Technical Services (RTS)

Device; These instructions apply to the *TrueTense* Surgical Tension Device and Associated Equipment only.

Figure 1. Outlines the ***TrueTense* Nylock Nuts** as supplied loose. These will be packaged in groups of 2 in pouches for reprocessing. An additional image is present to allow the size to be assessed.



Figure 1. Nylock Nuts (100) and size reference image.

Cleaning and sterilization equipment varies in performance characteristics and must be validated accordingly. The reprocessing facility is responsible for the routine validation and

monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of preparing the *TrueTense* Surgical Tension Device and associated equipment for reuse. Any deviation from these procedures must be evaluated for efficiency by the reprocessing facility.

<p>WARNINGS</p>	<p>These instructions <u>have not</u> been proven effective for sterilizing this instrument if contaminated with unconventional transmissible agents (prions) such as the causative agents of Creutzfeldt-Jakob Disease (CJD) and Bovine Spongiform Encephalopathy (BSE). It <u>should not</u> be assumed that the methods described are effective against such agents.</p> <p>Cleaning is an essential pre-requisite to ensure effective sterilization. Blind holes, cavities, serrations and joints require particular attention during cleaning. Failure to completely remove organic debris and/or cleaning residues may lead to inadequate sterilization and result in an increased probability of infection.</p> <p>Failure to thoroughly remove cleaning agents may lead to sensitivity and/or allergic reactions.</p> <p>Wear appropriate protective equipment and follow local infection control policies while handling contaminated instruments. This includes, but is not limited to, waterproof clothing, robust gloves and eye protection. Avoid splashing and creation of aerosols.</p> <p>Caustic substances and those containing make-up of highly acidic or alkaline-based solutions may cause corrosion and shorten instrument life. Exposure to temperatures above 137°C (279°F) may accelerate instrument degradation. Water impurities, such as alkali metal, metal and chloride ions may discolour or corrode instruments.</p> <p>Use purified water for final rinsing and steam sterilization cycles. Saline may cause deterioration of instrument surfaces. Corrosion, rusting and pitting may occur when blood and debris are allowed to dry on surgical instruments.</p>
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	<p>Only legally marketed medical equipment, solutions and accessories should be used for reprocessing surgical instruments. Do not use non-absorbent tray accessories as these may cause condensation to pool and extend drying times.</p> <p>All non-sterile instruments must be thoroughly cleaned and sterilized prior to use. Always clean and sterilize surgical instruments before returning to RTS.</p>
LIMITATIONS ON REPROCESSING	Repeated reprocessing according to these instructions has minimal effect on the instrument and associated equipment. The useful life is normally determined by a visual and/or functional evaluation prior to use.
INSTRUCTIONS	
POINT OF USE	<ul style="list-style-type: none"> • Remove gross debris immediately after use. • Disassemble the assembly into its component parts (See Assembly/Disassembly Instructions). • Remove excess soil with surgical wipes/sponges moistened with sterile water. • Irrigate blind holes, cavities, serrations and joints with sterile water • In order to ensure effective cleaning, do not allow soil to dry on instruments. • A 2% solution of hydrogen peroxide (which bubbles when it comes into contact with blood or protein) may be used to verify removal of protein debris.
PREPARATION BEFORE CLEANING	No Particular requirements.
CLEANING - GENERAL INSTRUCTIONS	<p>The following cleaning guidelines are intended to supplement those supplied by equipment and solution manufacturers and local policies.</p> <p>Operate equipment in accordance with the equipment manufacturer's instructions and in consideration of any limitations of use. This includes characteristics of certain types of instruments that require special handling or which may not be adequately cleaned by the equipment. Select, prepare and use cleaning solutions in accordance with the equipment manufacturer's instructions. Special</p>

	<p>attention should be paid to specifications for detergent concentration, water temperature, water quality and maintenance schedules.</p> <p>In order to prevent damage to instruments, use only neutral enzymatic detergents (pH 7 - 9)</p> <p>During ultrasonic cleaning, combine only instruments made of similar metals in order to avoid ion transfer, which may result in etching and/or pitting.</p> <p>Ensure rinsing process removes all cleaning residues. Removal of cleaning residues is an essential prerequisite for effective steam sterilization.</p> <p>Ensure cleaning equipment achieves and maintains the proper process parameters (e.g. time, temperature, water pressure, fluid flow rates, concentration and delivery of accessory solutions etc.)</p>
<p>CLEANING - MANUAL</p>	<p>Equipment: Ultrasonic Cleaner, Cleaning Brush, Enzymatic Detergent (Neutral pH), Running Water (Tap, Purified)</p> <ul style="list-style-type: none"> • Pre-rinse under warm running water for a minimum of two (2) minutes to remove debris. • Completely immerse in an Ultra Sonic cleaning bath filled with neutral (pH 7 - 9) enzymatic detergent solution prepared according to the manufacturers instructions. • Ultrasonicate for a minimum of ten (10) minutes at or below 35°C (95°F). • Remove any remaining debris from crevices using a Cleaning Brush. • Rinse for at least two (2) minutes under purified running water to remove cleaning residue. • Carefully dry using an absorbent, non-shedding cloth or industrial hot dryer, or place into a drying cabinet until all moisture is removed.,
<p>CLEANING - AUTOMATED</p>	<ul style="list-style-type: none"> • An automated cleaning process of equal effectiveness to the manual cleaning method may be used. Manual pre-cleaning is recommended in cases of dried-on organic material. Follow instructions provided by the washer manufacturer and detergent manufacturer as well as local policies. • Arrange instruments in the washer such that all surfaces are exposed to the action of the automated washer. • Sequencing, number and type of stages may vary among washer manufacturers. Washers may use single chamber for rinsing, cleaning and drying or may use multiple chambers, one for each cycle. Typical wash cycles may include the following; cool water rinse, enzymatic soak, detergent wash, ultrasonic cleaning, sustained hot water rinse and drying. It is recommended to perform a

	neutralizing rinse after use of strong alkaline or acidic cleaning solutions. Use purified water for the final rinse.						
CLEANING - INSPECTION	<ul style="list-style-type: none"> • After cleaning, visually inspect for cleanliness • Removal of all visible organic material and other residue is required prior to steam sterilization. • Repeat automated cleaning or perform manual cleaning as required. 						
PACKAGING	<ul style="list-style-type: none"> • Wrap entire tray in sterilization wrap material and apply label to indicate contents. Sterilization wraps must allow adequate steam penetration, aeration and protection against microbial penetration. Sterilization wraps should be approved for clinical use. 						
STERILIZATION	<p>Equipment: Pre-vacuum Steam Autoclave, Purified Water, Sterilization Wrap.</p> <p>Perform a pre-vacuum steam cycle using one of the following cycles:</p> <table border="1"> <thead> <tr> <th>TEMPRATURE RANGE</th> <th>MINIMUM EXPOSURE TIME</th> </tr> </thead> <tbody> <tr> <td>132 - 135° (270 - 275°F)</td> <td>Four (4) Minutes</td> </tr> <tr> <td>134 - 137°C (273 - 279°F)</td> <td>Three (3) Minutes</td> </tr> </tbody> </table> <ul style="list-style-type: none"> • Ensure Autoclave equipment achieves and maintains the proper time, temperature and pressure. • Operate equipment in accordance with the equipment manufacturers instructions. • When sterilizing multiple instrument sets in one autoclave cycle ensure the maximum load stated by the equipment manufacturer is not exceeded. • Use Purified Water for steam sterilization. 	TEMPRATURE RANGE	MINIMUM EXPOSURE TIME	132 - 135° (270 - 275°F)	Four (4) Minutes	134 - 137°C (273 - 279°F)	Three (3) Minutes
TEMPRATURE RANGE	MINIMUM EXPOSURE TIME						
132 - 135° (270 - 275°F)	Four (4) Minutes						
134 - 137°C (273 - 279°F)	Three (3) Minutes						
STORAGE	<ul style="list-style-type: none"> • Store and transport sterile instruments in such a way as to maintain sterility and functional integrity. • Store instruments in dry, clean, well-ventilated environments away from floors, ceilings and outside walls. • If sterilization is performed by an outside contract facility, protect the wrapped devices from contamination by additional coverings. • Segregate sterile instruments from non-sterile items. Label sterile instruments to identify sterility status and ensure use in a first in, first out (FIFO) order. • Do not use instruments if the sterilization wrap is opened, damaged or wet. 						
Manufacturer Contact Information	<p>For additional Information contact; Radiotherapy Engineering Services Level B1 Bexley Wing St. James's Hospital Leeds LS15 9TF</p> <p>Email: rts.lth@nhs.net</p>						