Leg Length Inequality Following Total Hip Replacement.

A Little Understood Complication.

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Intellectual Property and Publication Statements

The candidate confirms that the work submitted is his own, except where work which has formed part of jointly-authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below[9]. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others. Full Details are given on pages XII and XIII.

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Details of papers published that are contributing to MD Thesis

Chapter 2 – Review of the Literature

Leg length inequality following total hip replacement

Anthony McWilliams, Todd D. Stewart, Andrew J. Grainger, Philip J. O'Connor, Derrick White, Anthony Redmond, Martin H. Stone

Orthopaedics and Trauma, Volume 25, Issue 1, February 2011, Pages 37–42

Associated Corrigendum in press

A review of symptomatic leg length inequality following total hip arthroplasty.
McWilliams AB, Grainger AJ, O'Connor PJ, Redmond AC, Stewart TD, Stone MH
Hip International 2013, 23(1):6-14(PMID:23397200)

Involvement

As the principal author and researcher for both papers, I performed the full literature search, drafted, amended and submitted the papers.

Chapter 3 Litigation For Leg Length Inequality Following Total Hip Replacement

Litigation after hip and knee replacement in the National Health Service.
McWilliams AB, Douglas SL, Redmond AC, Grainger AJ, O'Connor PJ, Stewart TD, Stone MH.
Bone Joint J. 2013 Jan;95-B(1):122-6. PMID: 23307685

Involvement

As the principal author and researcher for the paper, I obtained the data for the NHLA under a freedom of information request. Created the protocols for analysis and categorising. Jointly responsible for going through and sorting the data as well as the statistical analysis. I wrote, amended and submitted the paper.

Chapter 4 Reproducibility of Methods for Radiographic Measurement of Leg Length Inequality Following Total Hip Replacement

Assessing reproducibility for radiographic measurement of leg length inequality after total hip replacement.
McWilliams AB, Grainger AJ, O'Connor PJ, Redmond AC, Stewart TD, Stone MH.
Hip Int. 2012 Sep-Oct;22(5):539-44. PMID: 23100154

Erratum in press

Involvement

As principal researcher I co-ordinated this study. Outlining the four methods for measuring leg length inequality following total hip replacement, presenting the information to the two senior musculoskeletal radiologists in the study. Presenting the data to the statistician, Dr L Hensor. As the principal author of the paper I drafted, amended and submitted the paper.

Chapter 5 The effect of femoral malposition on the measurement of Leg Length Inequality on Plain AP Radiographs

Paper in preparation

Work formed part of a BORS/ORUK/BHS prize winning presentation at the British Hip Society Annual Meeting, Exeter, 2013

Work also formed part of M.Eng project for students of the Institute of Mechanical and Biological Engineering, University of Leeds.

As the principal medical researcher, and in forming a concluding part to the MD project, I was responsible for the projects conception and protocol, jointly responsible for a pilot study. Limitations of the pilot study mandated further engineering input, particularly with accurate positioning of the artificial skeleton in free space for the radiographic part, as a result was the main medical contributor to the formal part study. I was also responsible for the medical interpretation of the results.

Acknowledgements

I would like to acknowledge and thank the following for their help and assistance:

Chapter 3

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Finally, I would like to thank my wife, Helen and children, Katherine, Jonathan Matthew. Without their support, encouragement and understanding this would not have been possible.

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The ultimate goal of any operation is to give the patient a perfect result. However sometimes this is not always possible. When everything is conspiring against you, there is usually a safer side to fall on.

Abstract

Total hip replacement (THR) is one of the most effective medical interventions undertaken. Leg length inequality (LLI) following total hip replacement is a recognised complication and although recognized when the operation was pioneered, has only more recently come to prominence in the literature. Understanding of LLI following THR is impeded by there being little consensus regarding definition, incidence, measurement, symptoms, treatment or even clinical significance.

The thesis begins by outlining the extent of LLI using an analysis of litigation data for orthopaedic operations covered by the National Health Service Litigation Authority. The data found that LLI following THR was cited in 100 claims, 44 of which were successful and at a total cost of nearly £3.9 million. During the same time period, nearly 800,000 THRs were performed.

The thesis then studies techniques to measure LLI following THR on plain radiograph. The four techniques studied were comparable in terms of inter and intra reader reliability as well as for the image acquisition protocol. The CFH-TD-LT method, has an advantage of providing information regarding the contribution of any LLI due to the components of the joint replacement.

The final part of this work employs a computational model and a radiographic experiment to study the effect of femoral malposition has on the measurement of LLI using the CFH-TD-LT technique. Results indicate that errors associated with flexion and abduction are small when in isolation. However, when the malpositions are combined there is an additive effect this is not predicted by the malpositions in isolation. Extension and adduction result in a greater error of interpretation both in isolation and when combined with internal rotation, and while clinically less common, should be viewed with caution when being interpreted on plain radiograph. Perhaps just as significantly, it is only in the extremes of malposition that there is any major difference in the contribution that the cup measurement makes to the limb length.

In summary, this thesis presents data regarding the validation for measurement on plain radiographs. It provides evidence to suggest that should a patient present with an LLI following THR, then a plain x-ray will give all the necessary information, even in the presence of larger angles of the clinically relevant deformities of flexion and abduction.

Abbreviations

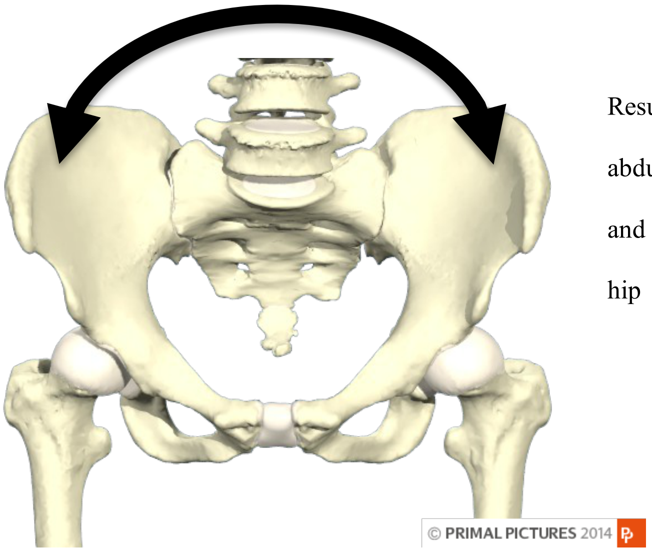
AP	Anterior posterior (regarding radiographs)
BOA	British Orthopaedic Association
CAD	Computer Aided Design
CI	Confidence interval
CNST	Clinical Negligence Scheme for Trusts
CFH	Centre of femoral rotation
CT	Computer Tomography (Scan)
HES	Hospital Episode Statistics
II	Interischial Line
ISTC	Independent Sector Treatment Centre
LLI	Leg length inequality
LT	Lesser Trochanter

LOA	Limits of agreement
LOR	Limits of repeatability
MRI	Magnetic resonance imaging
NHS	National Health Service
NHSLA	National Health Service litigation authority
NJR	National Joint Registry for England and Wales
QALY	Quality of life adjusted year
TD	Teardrop
THR	Total hip replacement
UHMWPE	Ultra-High Molecular Weight Polyethylene
U.K.	United Kingdom
XLPE	Cross-linked Polyethylene

Glossary - Rotation of the Pelvis

<u>Pelvic Obliquity –</u> Occurs in the coronal plane and around an antero-posterior axis

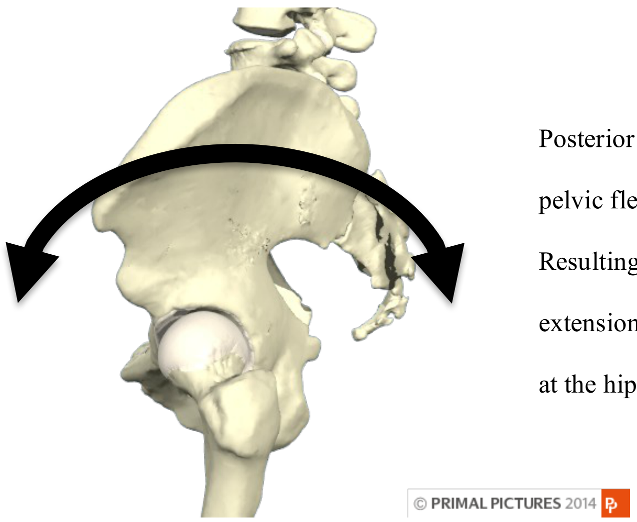
Resulting in relative abduction of the right hip and adduction of the left hip



Resulting in relative abduction of the left hip and adduction of the right hip

<u>Pelvic Tilt -</u> Occurs in the saggital plane and around a medio-lateral axis

Anterior pelvic tilt or pelvic extension. Resulting in relative flexion of the femur at the hip joint

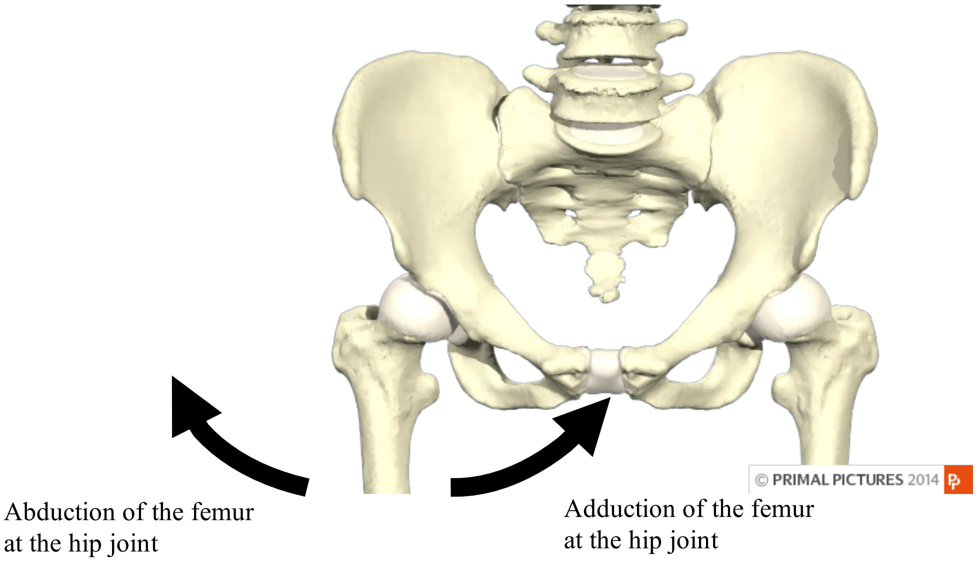


Posterior pelvic tilt or pelvic flexion. Resulting in relative extension of the femur at the hip joint

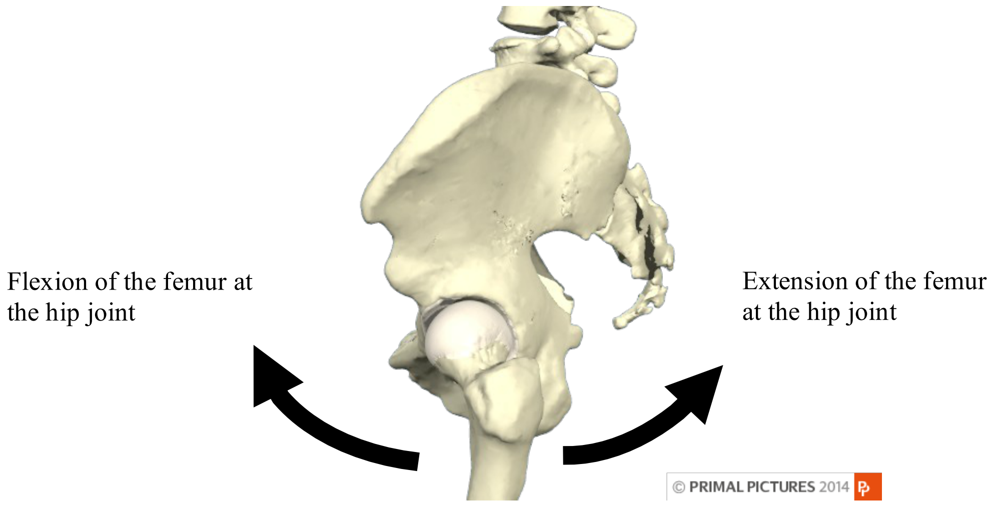
Images used with the permission of primal pictures/ Anantomy.TV

Glossary – Movement of the Femur at the Hip

<u>Abduction and Adduction of the femur at the hip</u> – Occurs in the coronal plane and around an antero-posterior or Z axis

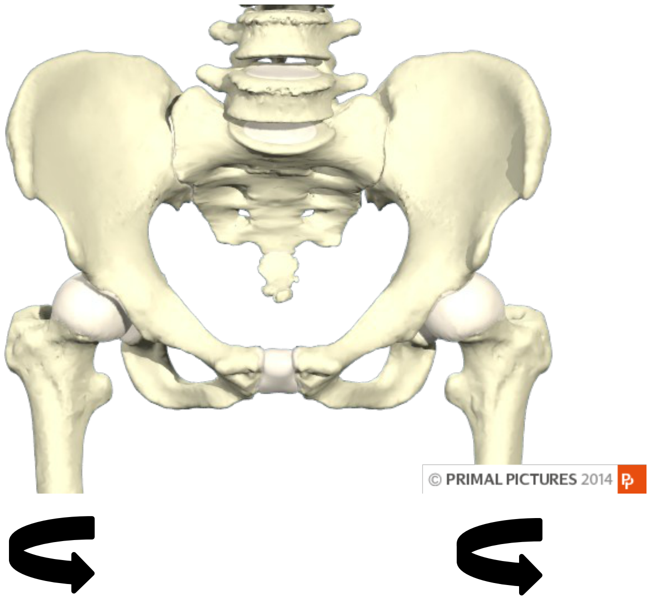


<u>Flexion and extension of the femur at the hip</u>- Occurs in the saggital plane and around a medio-lateral X axis



Images used with the permission of primal pictures/ Anantomy.TV

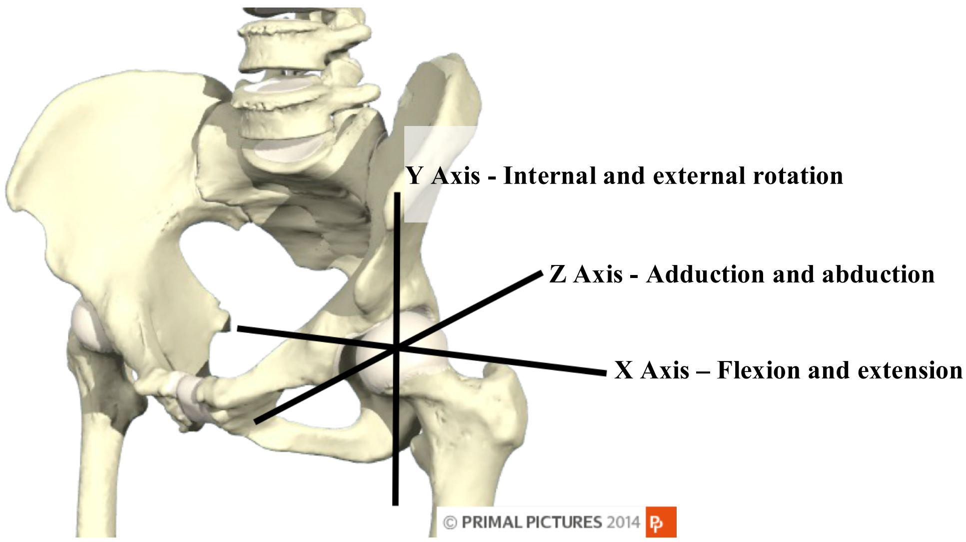
<u>Rotation of the femur at the hip -</u> Occurs in the transverse plane on the superior-inferior or Y axis



Internal rotation of the right femur at the right hip joint

External rotation of the left femur at the left hip joint

<u>Axes of rotation of the hip joint</u>



Images used with the permission of primal pictures/ Anantomy.TV

Chapter 1. Introduction

The first chapter provides an introduction to the subject of leg length inequality (LLI) following total hip replacement(THR). This includes a historical background, justification of the subject matter, hypothesis and a summary of how the hypothesis is explored by this thesis.

1.1. Definition of leg length inequality following total hip replacement

Limb length inequality, or anisomelia, is defined by Gurney as a condition in which paired limbs are noticeably unequal in length. When this occurs in the lower limb it is known as leg length inequality. The inequality can be described as a relative lengthening or shortening of a lower limb when compared to the contra-lateral side[1 2].

While there are many other aetiologies that can result in a LLI, such as trauma, or congenital causes either of which result in either a relative lengthening or shortening to any part of the lower limb, this research considers the particular changes that occur wholly as a result of hip replacement surgery.

Therefore, for the purposes of this work LLI is defined as any change in leg length that results in a lower limb inequality when compared with the contra-lateral side that has arisen wholly as a result of a total hip replacement. An example of an LLI following THR is given in Figure 1-1.

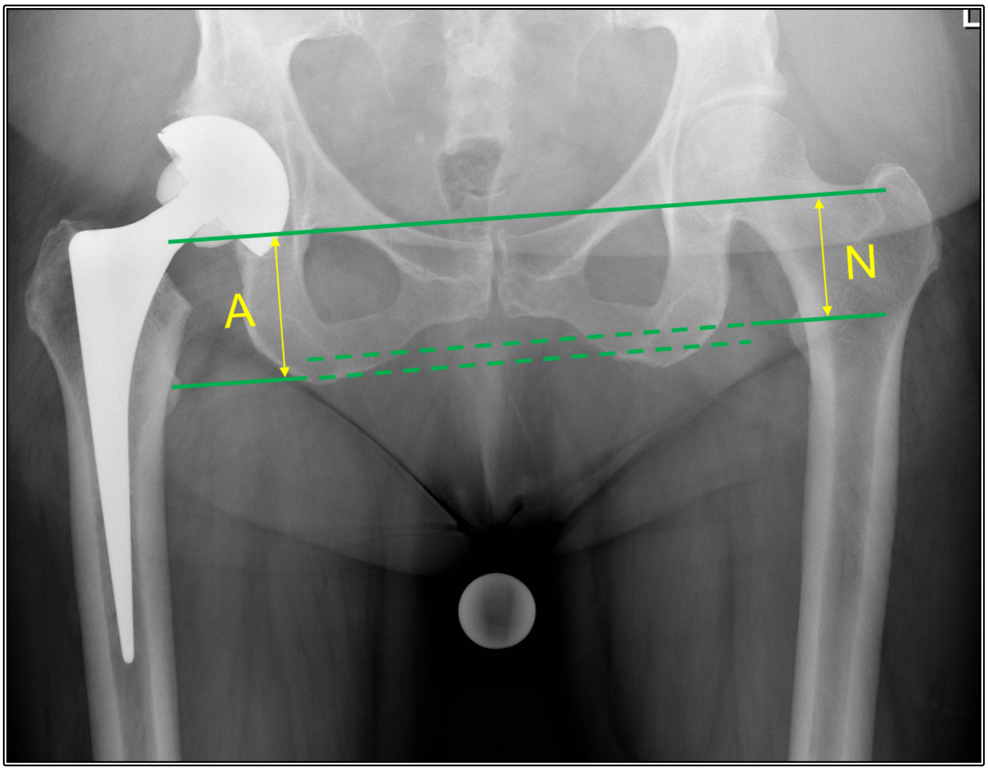


Figure 1-1 An example of an LLI following THR.
This is a radiograph of an LLI following THR and the assessment of the extent of the LLI is performed using the method described by Woolson et al[3]. The uppermost line on this radiograph references an intra-pelvic marker, the acetabular teardrops on the side of the arthroplasty (A) and on the side of the native (N) or un-replaced hip. Further lines as then drawn at the level of the most medial part of the corresponding lesser trochanter. For the purposes of illustration on this radiograph, these lesser trochanter reference lines have been extended with dashed lines. The image demonstrates that the distance between the intra-pelvic reference and femoral reference is greater on the arthroplasty side than the native side. Therefore, there is a lengthening inequality following this right sided THR.

1.1. Justification of the subject matter

Though the surgical treatment for hip pain had been described in the early 19th century, it was not until the mid-twentieth century that the first successful total hip replacements were performed[4 5]. Since Professor Charnley's early work with the low friction arthroplasty, there has been a dramatic rise in the numbers of primary total hip replacements performed. In the latest data from the 13th National Joint Registry (NJR) report for England, Wales, Northern Ireland and the Isle of Man 89,288 primary total hip replacements were performed[6]. Worldwide the current figure of 1 million primary hip replacements a year is set to double by 2030[7].

Although it has been described as 'the operation of the century'[8], total hip replacement is major surgery which can result in major morbidity and more rarely, mortality. In the early days of the successful THR, infection rates were reported to be as high as 12%[9]. However with modern techniques, the current practice of THR is associated with a 3% to 5% overall complication rate[10].

Possibly due to the reduction in overall complication rate and a proven durability, there has been a broadening of indications for THR to include a more demanding patient group[11-14].

For this reason, LLI, although recognised when the operation was pioneered, has only more recently come to prominence in the literature[15].

The understanding of LLI following THR is complicated by lack of agreement regarding clinical significance. White and Dougal[16], Whitehouse et al[17] and Mahmood[18] found no association between LLI and THR. Whereas Mancuso et al found the symptoms associated with LLI following THR to be an independent risk factor for outcome of the operation[16 19]. Many other papers also associated poor results of THR in the presence of an LLI[20-30].

A confounding factor is that not everyone with any given LLI following THR will be symptomatic. However LLI, when symptomatic, can result in: mechanical symptoms such limp (itself a manifestation of chronic disease[19]), altered wear characteristics of associated native or replaced joints[31-34], early fatigue or reduced walking distance[35], and ultimately instability of the THR resulting in dislocation[36]. Patients may also complain of pain[37 38] and nerve palsy[36]. LLI can also result in significant medico-legal consequences[39].

Difficulty in diagnosing LLI as the cause of post-THR symptoms may be due to symptoms that can be the result of other complications during the operation i.e. failure to obtain full haemostasis intraoperatively can result in an expanding haematoma which results in pain and direct compression on the sciatic nerve.

Lack of consensus regarding many of the issues surrounding LLI following THR and difficulty in diagnosis as a cause of symptoms, results in a paucity of literature to indicate its true incidence.

Many patients who do have symptoms caused by a post-THR LLI are amenable to non-operative treatments[1 39-41]. However, there are a small group of patients that are refractory to non-operative treatment and have been treated by revision of the THR to correct LLI[28 29 42]. The extent of the revision THR to be performed requires a clear understanding of how it has arisen and if the acetabular cup, femoral stem or both are contributing[28].

Therefore, despite nearly 60 years since the pioneering work of Professor Charnley, significant improvement in complication rates and excellent long term results, LLI after THR is still the subject of debate[4 9 12 43].

The process of diagnosing an LLI following THR starts with the patient's presenting history. Thereafter clinical examination is performed but this can be notoriously inaccurate when quantifying an LLI[44]. A plain AP radiograph will provide significant information regarding the presence of a post-THR LLI but there is no single or universally adopted method to measure the LLI on plain AP radiographs. The two that are used most widely in the literature have little published validation[3 45]. The reference imaging technique, computerised tomography (CT), is impractical to use on a routine basis and subjects the patient to additional radiation[46].

A reproducible method to measure LLI following THR on a plain AP pelvis radiograph which is associated with an understanding of the potentials for inaccuracy, would make a significant contribution to the understanding of the problem of LLI following THR. It may lead to an agreed definition of LLI and better treatment outcomes for the patient.

This thesis aims to provide greater understanding of the scale of LLI following THR, to investigate the methods of measurement of LLI following THR and understand the errors that can occur on plain radiograph measurement.

1.2. Thesis hypothesis

A significant obstacle to the greater understanding of LLI after hip replacement is a lack of a validated technique to measure LLI on plain AP pelvis radiograph. Therefore, the hypothesis to be explored by this is:

It is possible to optimise measurement of leg length inequality following total hip replacement on plain AP pelvis radiographs and therefore aid understanding of this clinically and legally significant complication.

The work in this thesis will study: the background literature regarding LLI following total hip replacement, the incidence of LLI following THR using litigation data, the validity of the measurement of LLI following THR on plain AP pelvis radiograph and the error that can arise from malposition of the femur.

1.3. Structure of the thesis

To explore the hypothesis this work will take the following steps.

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 THR as a complication, its classification the literature, attempts to quantify and methods to prevent LLI following THR are then discussed. Finally, the published results are detailed and strategies to manage LLI as a complication following THR are explored.

Chapter Three: Litigation for leg length inequality following total hip replacement in the National Health Service

There is little data regarding incidence of LLI following THR. This is partly due to the lack of agreement regarding many of the issues surrounding LLI following THR including the definition and clinical symptoms which could be attributed to other causes. To provide some scale to the problem an estimation of the total number of THRs performed over the time period in the study was made. In order to provide a greater understanding of the scope of LLI as a problem in England and Wales, a study using litigation as a surrogate marker was performed. Data obtained from the National Health Service Litigation Authority (NHSLA) was obtained and those complaints regarding THR were analysed per cause of complaint. The study reports the overall number and success of the complaints by cause, as well as an analysis of change in litigation practice over time.

Chapter Four: Reproducibility of Methods of Radiographic Measurement of Leg Length Inequality Following Total Hip Replacement.

This chapter investigates four methods of measurement of LLI on plain AP radiographs. The study compares two techniques that are prominent in the literature and two methods less prominent in the literature. In chapter four, data for the intra and inter observer reliability and reliability of image acquisition is considered.

Chapter Five: The Effect of Malpositioning of the Femur on the Measurement of LLI on Plain Radiograph

Chapter five presents the results of a study designed to explore the error that fixed deformity both in isolation and in combination can have on the measurement of LLI on plain AP radiograph using the CFH-TD-LT technique. A computational model and radiographic study are compared in this chapter so that a better understanding of the accuracy of this component based measurement system is presented.

Chapter Six: Conclusions and future directions

The final part 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 THR are then proposed.

Chapter 2. Review of the literature

This chapter explores the published literature associated with LLI following THR and the current understanding of the issues surrounding the problem. It also reviews the established practice in the measurement of, and technique to minimise LLI following THA.

Two papers have been published as a result of this work (Appendix A);

1) Leg length inequality following total hip replacement.

McWilliams A., Stewart T.D., Grainger A.J., O'Connor P.J., White D., Redmond A., Stone M.H. (2011).

Orthopaedics and Trauma 25:37-42

2) A review of symptomatic leg length inequality following total hip arthroplasty.
McWilliams AB, Grainger AJ, O'Connor PJ, Redmond AC, Stewart TD, Stone MH.

Hip Int. 2013 Feb 21;23(1):6-14. doi: 10.5301/HIP.2013.10631.

2.1. Introduction

2.1.1. History of the total hip replacement

The first documented attempt at a surgical treatment of hip pain and deformity was performed in 1822 by Anthony White in Westminster Hospital. The patient was a 9-year-old boy who, having previously suffered major trauma underwent excision of the proximal femur. The deformity was corrected and movement restored[4 5].

Later in the same decade, Barton was one of the first surgeons to intentionally perform an arthroplasty of the femur in a 21-year-old sailor suffering with ankylosis. Without the benefit of anaesthetic and in under 7 minutes, Barton was able to approach and excise the femur, just above the lesser trochanter, leaving the wound to heal by secondary intention. Passive movements were performed once the ‘irritation of the operation shall have passed away’ with the purpose of preventing bony union and establishing a fibrous non-union and seen in un-united fractures. The patient was able to mobilise with a stick at around three and a half months[5 47].

Performed in the 1891, the first documented attempt to replace the whole hip joint[48] was undertaken in Berlin by Professor Thermistocles Gluck, who used an ivory ball and socket, fixed with ‘bone glue’ (a form of cement composed of colophony, pumice powder and plaster). Although fixation of the implant to the bone was later changed to nickel plated bone screws, Gluck noted that the marrow cavity had an almost unlimited tolerance to aseptic implantation, walling off the cement in a similar manner to that which occurred following imbedding of a bullet. These joint replacements however suffered extrusion after some months[4 5 11 48]

Noting the problems that arose from Gluck’s operation, British Surgeon Robert Jones interposed gold foil around an excised joint and contoured proximal femur in 1895. However, the first reported replacement of a head of femur (following an un-united fracture) was performed by Hey-Groves from Bristol in work that he presented whilst giving the Bradshaw lecture to the Royal College of Surgeons of England in 1926. The operation used an ivory ball on a stem with autograft from the contralateral femur[4 5 11 49 50].

Smith-Peterson of Boston USA noted that a piece of glass that was removed from a patient's back after about a year was surrounded by a smooth synovial membrane and minimal fibrous tissue. Noting this benign reaction, he conceived the technique of contouring the femur and acetabulum and interposing an inert material so that a natural repair process would generate a new articulation, the mould being later removed. Thus, in 1923 the concept of the floating hip replacement was born. In initial attempts, although the glass mould broke, on its removal the desired 'glistening lining' was noted. Further work was done and subsequent operations employed Bakelite, pyrex and vitalium (cobalt, chrome and molybdenum alloy). The latter was used on the Smith-Petersen mould prosthesis which, in 1938, showed initial promise, however analysis of the outcomes showed only around 50% pain relief and re-absorption of the femoral head[4 5 49]. Aufranc presented 1000 cases of this form of surgery reporting it to be the operation of choice for many disorders of the hip and acetabulum[51].

Also in 1938 U.K surgeon, Peter Wiles of the Middlesex hospital, was the first to use stainless steel for both the femur and the acetabulum, and therefore should be considered the originator of the metal on metal total hip replacement. However, World War II was a distraction and further development was delayed. 1946 saw the Judet brothers develop the acrylic stem. In 1951, Haboush of New York, United States of America (USA) used vitalium components fixed with acrylic cement. He had previously noted the association with diameter of the femoral head/acetabulum and the contact pressure[5 11 49 50 52]. At around the same time McBride, Moore, Thompson, McKeever, Wilson and further work from the Judet brothers, all attempted to solve the various surgical and biomechanical problems associated with replacement of the hip. While many reported encouraging results, they were all susceptible to early loosening and failure[4 5 49].

McKee, a surgeon from Norwich, U.K, building on previous work, arrived in 1956 at what could be considered the basic configuration of the modern total hip replacement. He used a stemmed femoral component, articulating in a hemispherical acetabular cup, both of vitalium. These were however prone to failure associated with metal wear debris[4].

None of these prostheses met what would later be described by Elloy, Wright and Cavendish as the fundamental requirements for joint arthroplasty and implant design[53] (Table 2.1)

Thus up until the 1960s the only widely accepted and available surgical treatments for hip arthritis were osteotomy, excision arthroplasty (with or without interposition of soft tissue) or fusion[54]. While these techniques could, if successful, bring some pain relief there was a significant price to pay in terms of long term function, mobility and in the particular case of fusion back and other joint pain[4 11 49 50 52]

It was at Wrightington, a tuberculosis hospital near Wigan in Lancashire, U.K., from 1958 that John Charnley combined the use of cold curing acrylic cement (similar to that employed by dentists at the time) and a polymer acetabular cup. His efforts were also not without setback. Initially the acetabular component was fabricated from polytetrofluroethene (PTFE) or Teflon, a polymer noted for being one of the few solids with a co-efficient of friction nearly as low as cartilage[54]. Unfortunately, PTFE was found to have very poor wear characteristics and this resulted in early and catastrophic failure due to susceptibility to linear wear. Were it not for Charnley's

Table 2-1 Describing the requirements for a joint arthroplasty and the design criteria need to meet them according to Elloy et al.[53]

Requirements	Design criteria
Relief of pain	Appropriate Articulation
Adequate function	Good stability
Correction of deformity	Adequate strength
Durability	Good fixation
Satisfactory Salvage potential	Correct choice of materials
Chemical passivity	Low frictional forces
Sterility	Acceptable wear rate
Appropriate size	Good salvage potential
Simple operative procedure	Fail safe feature
Minimal operative trauma	Standardisation
Early mobilization	Sterilisation
Not subcutaneous	Cost effectiveness
Universality	Surgical Instrumentation
Convenient packaging	
Reasonable cost	

insistence on meticulous follow up and limited diffusion of technique, instruments and implants, there would have been considerably more than the 300 patients with the PTFE cup and he would have repeated the mistakes of the Judet hip[4 54 55]. Subsequently and still conscious of the failure of PTFE, Charnley was presented with a newly developed polymer, high density polyethylene, otherwise known as ultrahigh molecular weight polyethylene (UHMWPE). After being persuaded by his engineers, he experimented with this new material, and found it to be remarkably successfully. In so doing, he introduced the first successful; all cemented, tapered, stainless steel intramedullary stem, on polyethylene, low frictional torque total hip replacement, Figure 2-1 [11 49 50 52 55].

Figure 2-1 Father of the Modern Hip Replacement.
Professor Sir John Charnley with an example of his low friction arthroplasty. Images courtesy of the Charnley Trust

Many papers report excellent long term survivorship and currently the longest surviving patient has had cup and stem in situ for 45 years[11 43 56-60]. Many of the principles of this work remain the gold standard. Indeed, while the use of the Charnley Low Friction Arthroplasty hip replacement has declined in the U.K. in favour of the polished taper stem and uncemented stems, it and similar prostheses remain in widespread use[61 62].

2.1.2. Current practice in total hip replacements

2.1.2.1. Economics and success of THR

Since the successful introduction of THR just over 50 years ago, the hip replacement has provided long term pain relief to many. There are more than a million performed worldwide every year, and this figure is projected to double over the next 20 years[7].

Not only is THR a successful operation for pain relief, it is one of the most cost effective[4 7 60 63]. One method of quantifying this cost effectiveness is the quality adjusted life year (QALY).

By taking a measure of time in any given health state, the QALY takes into account both quantity and quality of life generated by any given healthcare intervention[64 65]. QALY data can be combined with the cost of the particular intervention to provide a cost-utility ratio and make an assessment of the cost per year of perfect health generated. Therefore, QALY (and cost per QALY) has become the common currency in health economics to review the relative benefits of healthcare [64 65]. This measure is gaining particular significance as a tool for resource allocation in austere economic times.

Mason et al. in 1993 studied a broad range of medical interventions and found that (in 1990 prices) that the cost per QALY for THR was £1,180 and was the seventh most cost effective intervention overall, but additionally, the most-cost effective of the elective operations in the review[65]. To give some perspective, the same study found cholesterol testing to have the lowest cost per QALY at £220, breast cancer screening £5,780 per QALY and erythropoietin up to £126,290 per QALY. Other studies have demonstrated a similarly affirmative view of the cost effectiveness of THR when compared to other interventions[66-69].

Rasanen et al. more recently reviewed cost per QALY for THR and found it to be €6,710 (approx. £5,300 GBP)[63].

It has been well established therefore that THR is a successful operation in terms of excellent outcomes, long term survival and cost effectiveness. Hence its description by Coventry as 'the operation of the century'[8]

There are many different methods of performing THR, reflecting individual surgeons' philosophies about which works best in their hands. A summary of the principal philosophies for many of the aspects for total hip replacement are detailed further in the following subsections.

2.1.2.2. Philosophies for THR fixation

The basic stages and components of the operation would still be recognized by the pioneers of THR. The philosophies for the fixation of the implants are: Cemented, Uncemented and a combination of the two, the Hybrid and reverse Hybrid[70].

2.1.2.2.1. Cemented Fixation

In a cemented hip, a polymethylmethacylate cement is used essentially as a grout or space filler. This provides a stable bed for the implant and also good inter-digitation with the host bone, allowing load transmission[71]. The original Charnley hip used the cement to provide a rigid hold on the implant and create a composite beam construct. Another form of cemented implant is the polished taper, e.g. the Exeter stem. This relies on the viscoelastic properties of the cement for the continuation of the weight bearing longitudinal forces being converted into hoop stresses, which the host bone is able to tolerate[71]. Both of these systems rely on the cement to provide a stable bed for the acetabular component without movement at the cement-bone or cement-implant interface.

Supporters of cemented stems point to the long-term experience, the fact that every stem is a ‘custom’ fit, the stability of the implant once the cement has set, as well as the predictability of any failure. However, cementation adds time to the operation and the technique of cementing is an additional skill for the surgeon to acquire and the material itself is vulnerable to cement fractures[52 71 72]. Cement has also been linked with morbidity directly. Cement pressurisation can result in cardio-respiratory compromise as a result of emboli arising from blood clots, fat or cement directly[73 74]. Much of the research surrounding cement morbidity has come from studying fractured neck of femur patients and the use of cemented hemiarthroplasties, however, and with conflicting opinions, some have linked cement use with increasing early post-operative mortality[74-76].

The increasing use of polished taper stems has also resulted in the phenomenon of ‘log splitting’ fractures. Where the hoop stresses arising for excess axial load results in multi-fragmentary fractures which are difficult to treat without extensive revision surgery[77 78]

Notwithstanding, the literature remains clear in support of the use of cemented stems including the UK NJR which indicates that cemented implants carry the lowest risk of revision.[79-86]

2.1.2.2.2. Uncemented Fixation

Uncemented prostheses rely either on bone on-growth or bone in-growth. On-growth of host bone occurs when an uncemented implant has a roughened surface which provides a high friction interface and thus stability when host bone grows onto it. In-growth occurs when the implant has either some form of metal trabeculations, hydroxyappetite coating or bioactive glass, into which host bone can grow, providing stability for the implant[52 72 87].

Hydroxyapatite and bioactive glass (glass material which dissolves in the body leaving hydroxycarbonate apatite which bonds with bone) are osteoconductive and if doped with growth factors can be osteoinductive and thus able to gain stability by binding directly to the host bone[87 88].

Supporters of uncemented components highlight the ease of use, shorter operating time, lack of cement implantation syndrome, biological fixation, and the ability to alter any unsatisfactory component position at the time of the first operation with relative ease[89]. The addition of a bioactive coating accelerates osteointergration, can prevent proximal stress shielding. With circumferential bone ingrowth, the bioactive coating can also resists wear particle migration[87 90].

Exponents also find that without the technical skills required for cementation, uncemented implants are easier to teach to trainees. Uncemented stems are however generally more expensive, are associated with higher risk of intra-operative fracture and have a greater risk of leg length inequality when compared with cemented stems[52 72 91]. Ahmad studied this last issue, uncemented stems and lengthening, and found that 53% of the 100 patients treated with an uncemented stem (Corail, DePuy, Warsaw, IN, U.S.A.) had a lengthening of greater than 10mm, although without any correlation to the grade of surgeon or approach to the hip[91]. It is possible that this lengthening occurs when a surgeon, in an effort to ensure good stability, leaves the stem proud.

Hybrid THR involves the surgeon using an uncemented acetabular component and a cemented stem. The reverse hybrid construct is when a cemented cup is used along with an uncemented stem. The reverse hybrid is popular in Norway where is used in 25% of THRs[92]. Proponents highlight the 'best of both worlds' for each component[93].

2.1.2.3. Philosophies for the bearing surface

The ideal bearing for a total hip replacement is an articulating surface that has minimum wear, is immunologically passive, chemically stable, has low friction, allows modularity, is noise free, is tough (to minimize fracture risk) and hard enough to minimise scratching and third body wear.[94]

Currently no single or combined bearing fulfils all these ideals. Options for the material for the head of the THR are metal (stainless steel or cobalt/chrome) or ceramic. In terms of the acetabulum, the options are plastic (typically ultra-high molecular weight polyethylene UHMWPE) or crosslinked polyethylene (XLPE), ceramic or metal acetabular liners[6].

Hard on soft bearings such as either metal or ceramic on UHMWPE or XLPE provide a low friction articulation but are susceptible to wear and the consequences of wear debris such as osteolysis[95]. However, encouraging results have been obtained with XLPE which has shown reduced wear when compared with UHMWPE[96]. A thick acetabular component is desirable to accommodate this wear, but can be a limit to the head size of the femoral stem.

Metal on metal articulations have been the subject of much recent debate and study. A 'hard on hard' bearing has the advantage of low wear, meaning that potentially thinner acetabular component which would allow a greater size of femoral head can be used. Improvements in material science, in conjunction with a better understanding of implant design as well as lubrication, led to the re-visitation of prostheses such as the Smith-Peterson metal on metal hip replacement.

However clinical experience, particularly the DePuy (Warsaw, IN, U.S.A.) ASR, either in the resurfacing or stemmed hip replacement, found that the larger, metal-on-metal bearing surface produced low volumes of highly biologically active wear debris[97 98]. As a result, there has a significant reduction in the use of this combination in recent times [99-101].

Ceramic on ceramic bearings potentially offer the surgeon a 'hard on hard' bearing surface with little wear, which itself is of low biological activity[94 102-104]. However these bearings are susceptible to fracture, up to 13.4% with earlier ceramics[105], although more modern 4th generation ceramics have reduced this problem[103 106-108]. An additional problem, associated with ceramic on ceramic bearings is squeaking, in that there will either be an audible or (to the patient palpable) noise as they move through the gait cycle. While this in the majority of patients is intermittent it can still result in a small number of patients seeking revision surgery[102 104 109 110]. Owen et al in a review of 43 studies, detailing 16,828 ceramic on ceramic hip replacements found the revision rate for squeaking to be 0.2%[111].

Ceramic on metal articulations in total hip replacement have also been used but the concerns regarding metal ions and wear debris have limited their use. The 13th annual NJR reported this bearing combination being used in only one case[6 112 113].

2.1.2.4. Philosophies for head size

The original Charnley monoblock prosthesis was manufactured with a 22.225mm head size. This was found to provide the optimum characteristics for frictional torque, linear and volumetric wear, thus maximizing the survival of the implant.

However, biomechanics dictates that a smaller head size has a smaller sliding distance. Sliding distance is the measure impingement free range of motion a hip replacement. It is reduced in smaller prosthetic head sizes when compared to the larger head sizes Figure 2.2[114-116]. Smaller head sizes also have a lower volumetric wear at the cost of a higher linear wear. Additionally, a smaller femoral component head size will allow thicker acetabular component, which when combined with lower volumetric wear increase the longevity potential of the joint replacement[116].

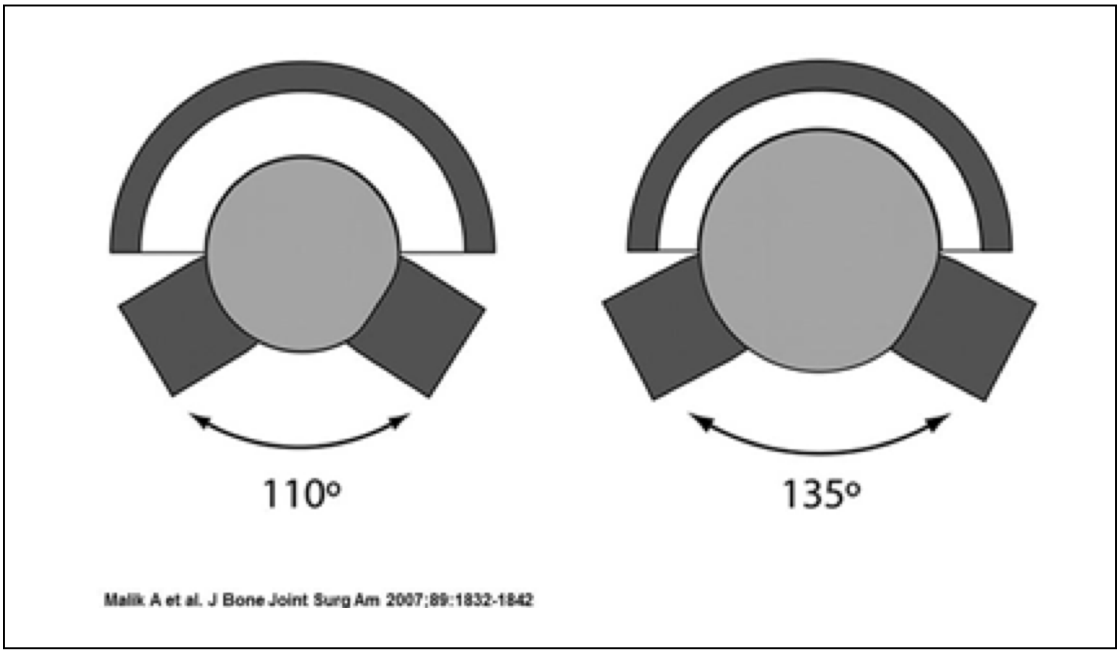


Figure 2-2 Illustration of the effect of head size on sliding distance.
The joint on the left has a smaller head and a lower arc of movement when compared with the larger articulation on the right, when the neck diameter remains constant[114].

The converse becomes true as the head size increases, with the theoretical advantage of a reduced dislocation rate. The larger the size of the articulation though, either the greater the bone loss at operation or the thinner the bearing surfaces become, and therefore the lifespan of the THR might be reduced[114 117].

2.1.2.5. Philosophies for approach to the hip joint

Many approaches to the hip joint have been described. They are named anatomically and in relation to the greater trochanter. Charnley originally used a trochanteric osteotomy, more recently the posterior and lateral approaches have come to prominence. [70 118]. These methods require an incision on the outer or lateral part of the thigh, using the greater trochanter as the main landmark for the incision. The subsequent sections detail these approaches, though many surgeons will have their ‘own modifications’ or subtleties in their interpretation of them. All three approaches then require dissection through the iliotibial band and tensor fascia lata. This delivers the proximal femur and its muscular attachments into the wound[119].

2.1.2.5.1. Trochanteric osteotomy

This approach to the hip joint was employed by Professor Sir John Charnley who employed trochanteric osteotomy to gain access to the femur for stem implantation. Once through the iliotibial band/tensior fascia lata, the greater trochanter (including the abductor insertions) is detached from the proximal femur and the capsule of the hip joint is exposed. After insertion of the hip replacement, the osteotomy is reduced and fixed with wire[119]. Advantages of the trochanteric osteotomy are that bone is one of the only tissues that heal without scarring; it allows excellent exposure in even the most difficult of cases and provides straight line access to the femoral canal, thus reducing the risk of varus or valgus positioning of the stem and a very low dislocation and nerve palsy risk. The main disadvantage of this approach is trochanteric escape. This occurs after the operation when there is non-union of the trochanteric fragment and the reduction wires break. The patient has symptomatic abductor dysfunction and or pain due to the metalware[118]

2.1.2.5.2. Posterior approach

The posterior approach gained greater popularity with increasing understanding of techniques allowing access to the femoral canal. For the posterior approach the patient is placed in the true lateral position. There is no true inter-nervous plane and superficial dissection includes part of gluteus maximus. The short external rotator of the hip (piriformis, obturator internus, superior and inferior gamellus and occasionally part of quadratus femoris) are dissected from the bone and employed to protect the sciatic nerve which is at the inferior part of the surgical site. Some surgeons use a piriformis sparing approach leaving the piriformis tendon attached to the trochanter. The capsule is opened to reveal the posterior hip joint[119 120].

The posterior approach provides good access to the femur and acetabulum, particularly for complex primary and revision purposes, has a reduced rate of heterotopic ossification when compared to the lateral approach and does not violate the abductors.

Historically though, this approach was associated with a higher risk of dislocation, with more experience of the technique and possibly due to greater understanding of the role of the posterior capsule and short external rotators in stabilising the joint, this has been reduced[121]. Furthermore, the posterior approach was historically associated with an increased risk of sciatic nerve and inferior gluteal artery injury[52 118 120]. Failure to carefully restore the anatomy can also lead to gait problems with the posterior approach. If, when reattaching the posterior structures, these are over tightened, particularly in the presence of lengthening, then the patient can mobilise with an externally rotated gait, which in extremes can present with an abduction deformity which, in turn, would result in an apparent or functional LLI following THR [122].

2.1.2.5.3. Lateral approaches.

The patient may be supine or in the lateral position for the lateral approaches. The lateral (also known as Watson Jones) antero-lateral (also known as the Hardinge) approaches differ in that, once dissection through the iliotibial band and tensor fascia lata has been achieved, the hip joint is exposed by advancing anterior to the gluteus medius for the lateral approach, or by dissecting the abductors from their proximal femoral insertion and revealing the capsule of the hip joint. The direct lateral and the anterolateral approached can provide an excellent exposure of the hip joint and a very low dislocation rate, but both risk heterotopic ossification and (particularly the latter) violation of the abductors[52 120 123]. An additional risk associated with any approach that requires dissection of the abductors is that there is a risk of reattachment either too proximally or too distally. This can be compounded by the positioning of the patient. At the time of the repair of the abductors the limb should be held in neutral. This can be difficult to achieve in the lateral decubitus position and without careful technique, the limb can be held in abduction, the abductors reattached distally leading to iatrogenic abductor tightness and an apparent of functional LLI. This can be compounded if there is also a lengthening due to the positioning of the hip replacement that may ultimately result in failure of the reattachment an associated lurching gait[120 124-127].

Conversely, when the approach is performed in the supine position, and in order to maintain a clear field of view during the operation, the lower limb is adducted. Failure to appreciate the limb position in this instance can risk more proximal reattachment of the abductors and in effect defunctioning the muscles, giving the patient a limping gait[120 124-127].

2.1.2.5.4. Anterior approach

The direct anterior approach for THR utilises the true internervous plane between the tensor fascia lata (superior gluteal nerve) and the sartorius muscle (femoral nerve) superficially and between rectus femoris (superior gluteal nerve) and vastus lateralis deep (femoral nerve)[128 129]. Capsulotomy can then be performed to deliver the joint into the surgical site. The technique is a modification of the Smith-Petersen and the Heuter approach to the anterior approach to the hip[129]. Typically, the patient is placed on a fracture table that will allow traction for surgical dislocation, the ipsilateral hip to be extended for exposure of the acetabulum and the contralateral abducted to allow relative adduction exposure of the femur[129 130]. Intra-operative image intensifiers can also be used to confirm implant positioning[130].

Advocates of the direct anterior approach cite that as a true inter-nervous and muscle sparing approach, the recovery following the operation and inpatient stay are reduced. The approach was further refined to employ a minimally invasive technique that has allowed THR to be performed as day case surgery[131]. While there is an advantage in terms of early mobilisation, however by the two year post-operative point there is no difference between the approaches[129 131-134]

Others have raised concerns regarding the risk of femur fracture during retraction and palsy to lateral femoral cutaneous nerve as well as increasing wound problems attributed to retraction of soft tissues and incision placement near the groin crease, particularly in the obese patient[128 131].

2.1.3. United Kingdom current practice

According to the 13th report of the NJR report for England, Wales and Northern Ireland, which presents data for 2015, there were 89,288 primary hip replacement procedures performed[6]. Of the 39% of these that were uncemented, the most commonly used combination was the Corail stem and Pinnacle cup (both DePuy, Warsaw, IN, U.S.A.). Of the 31% of primary THR that were cemented, the most commonly used implants were the Exeter V40 stem and contemporary cup (both Stryker, Kalamazoo, MI, U.S.A,). The majority of the remaining were hybrid (including reverse) at 29% of the total hip replacements, the final 1% were resurfacing and metal on metal THR[135-137].

For the bearing coupling, the majority were metal on polyethylene at around 59%, followed by ceramic on ceramic at circa 16% and ceramic on polyethylene at circa 22%. The hip articulations of metal on metal and ceramic on metal contribute cumulatively less than 1% and the remaining 2% were described as 'unclear or unsure' by the NJR[138].

Regarding head sizes, in THR the most commonly used are 32mm (42%) 28mm (31%), and 36mm (24%)[139].

The most common surgical approach to the hip is posterior (69%), followed by lateral, including Hardinge (27%), trochanteric osteotomy(<1%) and the anterior approach (<1%)[135 140].

2.1.4. Summary of current practice

THR is an operation that can provide significant and long lasting patient benefit[8 57 141]. However, there is no single, universal system or philosophy. The decision about which approach, type of hip replacement, bearing coupling and head size, is dependent on the individual circumstances of the patient and especially on the training and experience of the operating surgeon. This latter point has been the subject of interest in the literature, with surgeons who perform more THRs generally having better outcomes than lower volume surgeons[141-145]. With a trend in the United Kingdom (U.K.) towards sub-specialisation and consultant-delivered service it is likely that this trend will continue.

2.2. Complications of total hip replacement

The utility of THR to improve outcomes for patients has been established. However, it must also be borne in mind that THR as with any major surgery is associated with considerable morbidity, or more rarely mortality.

Briggs et al in 'Getting it right first time' in 2012 and reviewed in 2015 focused on the benefits of raising the level of practice to that of the best performing in the units[12 146]. The report brings into focus issues surrounding surgical practice, activity levels, implant selection that can lead to variance in complication rates. Elevation to the practice of the exemplar units can therefore realise a reduction in complication rates following THR and therefore reduced patient morbidity. Additionally, with austerity affecting healthcare, reduction in complication of surgery can lead to a reduction in overall costs. [12 146].

The consequences of poor health care are also highlighted by Upadhyay et al in 2007 when they reviewed litigation data for hip and knee surgery [147]. Atrey et al in 2010 performed a more global review of the medico-legal consequences in the wider orthopaedic specialty[148]. Both papers concluded that while litigation occurs for many reasons, one recurring theme is the consent process and re-enforces the importance of clear communication.

The most recent paper by Mead in 2014, analysed litigation across all surgical specialties excluding obstetrics and gynaecology. The study found that orthopaedics, at 49%, was associated with the largest number of claims. Mead et al also found that claims are rising. Although breaking down by subspecialty claims increased from 953 in 2008/2009 to 1,588 in 2012/2013[149].

Therefore, as part of the process of obtaining informed consent, the surgeon must clearly counsel the patient regarding the reasons why the procedure is being offered, details of the intervention, alternatives and complications prior to the operation[150 151]

These complications are summarized in Table 2.1[10] from the British Orthopaedic Association (BOA).

Table 2-2 Complications of THR listed on the BOA recommended consent form[10]

Common, 2-5%
Blood Clots Pain Prosthesis wear/loosening Altered leg length Joint dislocation
Less Common, 1-2%
Infection
Rare, 1%
Altered wound healing Nerve damage Bone damage Blood vessel damage Pulmonary embolus Death

2.3. Leg length inequality following total hip replacement

The potential for residual leg length inequality was recognized by Professor Sir John Charnley when the operation was popularized in the 1960s, however other complications were of greater prominence and considerably more catastrophic. In the early years of the modern THR, infection rates were reported by Charnley to be 8% and by Wilson as 12%[9 152]. This has been reduced in recent times using various techniques such as improved theatre design including ultra clean air, lamina flow, antibiotics as pre-operative prophylaxis and included in the cement, as well as an increased awareness, which have combined to reduce infection rates to as low as 0.2% [12].

Since the inception of THR there have been changes in the patient population. Initially THR was indicated only in those patients considered elderly, infirm or so severely disabled that the historically greater risks of THR were considered acceptable. Charnley's patients were usually already on maximal doses of opiate analgesia and every other medical treatment had failed them. They had generally suffered with prolonged and severe disability with limited pre-operative function, and post-operative rehabilitation and function restoration was less important to the patient than having been relieved of a great deal of pain.

More recently, perhaps associated with reduced complication rates of primary THR, increasing experience of revision THR and proven longevity, the indications for total hip replacement have broadened[11 12 57 153 154].

While THR remains a pain relieving operation primarily, an unacceptable compromise in quality of life due to associated functional restriction can also constitute a reason to proceed[11]. Patients are therefore presenting earlier and with higher expectation for functional outcome than was historically the case.[7 11 14 48 155]. Kurtz et al. predicted that as a consequence of raised expectation regarding function, greater than 50% of THRs will be in patients under 65years of age in the U.S.A. by 2030[156]. All of this means that complications that affect function have come to prominence in more recent times.

LLI, specifically following total hip replacement is an example of this. It can be a significant cause of dysfunction and dissatisfaction, and is the focus of this work.

Charnley first noted in *low friction arthroplasty,* that LLI was a complication of THR but that patients usually tolerated up to 10mm[15]. However, it is important to note that there is no universal consensus in the literature regarding either the definition or quantification of LLI following THR as well as disagreement about the link between LLI and symptoms.

The most well recognized paper is by White and Dougall, who in 2002, published a prospective study on two hundred patients who had total hip replacements via the anterolateral approach. The group presented an analysis of post-operative symptoms and leg length. This cohort of patients had a radiological LLI ranging from 21mm shortening to 35mm lengthening. They found no statistically significant association between post-operative LLI and comfort, function or satisfaction at six months post-operation[16]. The relatively short time period of follow-up is however a limitation of this paper. The antero-lateral approach involves division of at least part of the insertion of the abductors from the greater trochanter. Abductor dysfunction has been noted in the early post-operative period and can take up to two years to normalise[120 157-161]. It is therefore possible that data in the White and Dougall study was collected too early for any dysfunction or dissatisfaction due to LLI to become apparent or to be distinguished from that of the abductor weakness.

Additionally, White and Dougall did not consider patient characteristics. There are identifiable groups of patients that can confound the results of any study of LLI following THR. There those patients who are more prone to a LLI, an example being the obese patient where which presents greater technical difficulty at the time of surgery. There are also those patients that are more sensitive to LLI following THR an example being the short stature patient.[23 162 163]. These groups are further considered in Section 2.5.

More recently, two further papers have questioned the link between LLI following THR and outcomes. Mahmood et al performed a prospective study involving 174 patients based on function and quality of life questionnaires (WOMAC and EQ-5d) up to twelve to fifteen months post-operation. While they found that the lengthening group (≥9mm and up to 20mm) showed less improvement, more use of a shoe raise and more pain; there was no statistically significant difference in outcomes when compared to the group with a shortened limb (-6mm to 20mm) and restoration to normal (-5mm to 9mm)[18].

Whitehouse et al also presented an outcome-based study (Oxford Hip Score, MOS Short Form 12) and found no correlation between LLI following THR and outcomes at a mean 3.8 years follow up. They only gave general details of the LLI however, stating that 21.5% were lengthened by more than 10mm. There was no specific mention of a range other than a graph which suggests that 5 patients (or 25% of the lengthened group) were greater than 16mm. The group also potentially misinterpret the measurements as their technique uses the centre of the femoral head to the lesser trochanter. This would be an indication of any LLI due to the stem but does not take into account any LLI due to the cup placement. This point that was reinforced in their results where they note that there was good correlation between the centre of the femoral head to the lesser trochanter and the teardrop to lesser trochanter but there was poor correlation with their method and the centre of the femoral head and the tear drop. The tear drop to lesser trochanter method was described by Woolson et al and is a measure of the total or overall LLI from the hip replacement[3 17].

There are however limitations in patient reported outcome measure based studies. Whitehouse et al and Mahmood et al both acknowledge the ceiling effect as a source of error. The ceiling effect occurs when there is poorer discrimination between groups of patients in the presence of very good outcomes. It becomes hard to distinguish between those who get high post-op absolute scores and those who still gain benefit from an operation, despite not scoring near the maximum for other reasons, in this case perhaps an LLI [164].

While both of these papers include patients that have been lengthened by up to 23mm, the majority were under 20mm and the greater part of the sample reported in Whitehouse et al were 16mm or less. As will be discussed in further detail below and in Sections 2.10 and 2.11, many studies present results that fall within these parameters. It is possible therefore, that the paucity of data for the greater LLIs following THR is overshadowed by the large pool of results for samples with relatively smaller LLIs.

Many papers in the literature agree that while there are many aspects of LLI following THR about which there is little understanding, it is clear that there is a connection between the technical complication of residual LLI and the symptoms experienced by patients[19-22 24 25 30]

Mancuso et al. found that symptoms associated with LLI following total hip replacement were an independent risk factor for the successful outcome of total hip replacement[19]. Hoffman et al. titled their paper ‘Leg-length inequality and nerve palsy in total hip arthroplasty: a lawyer awaits!' and noted that LLI is the biggest single cause of litigation surrounding total hip replacements in the U.S.A.[39].

A confounding factor in the understanding of LLI is the incidence of LLI in the general population and in those in whom it is present for reasons other than THR. Friberg noted in 1983 that some consider LLI common enough to be a normal variation, though the magnitude of this could vary from a few millimetres up to 25mm[165]. Rush and Steiner explored the association of LLI and back pain in soldiers in the United States Army and found that in a group of 100 asymptomatic soldiers there was a subgroup of four with a pre-existing LLI of greater than 10mm. This group had a mean LLI of 11.5mm. However, this categorisation of the group, 10 to 20mm has resulted in this paper being misquoted as demonstrating LLI up to 20mm[20 166]. It is of note that in this paper, published in 1946, the methodology (standing radiograph, measurements made to the bottom of the radiographic plate) demonstrates the limits of understanding of LLI at that time. It was not until 1978 that Williamson and Recking published the use of a technique for the measurement of LLI following THR on plain AP pelvis radiograph that was regularly used in the subsequent literature. The method uses measurements from a reference line at the level of the ischial tuberosities and measures to the lesser trochanters[45 166].

Hult, in the Monkfors Investigation of the aetiology of spinal pain in forestry and industrial workers found that 30% of the labourers in this group had a leg length inequality up to 25mm, though most were 10 to 15mm. However the study did not discuss the method used to measure LLI[167]. Nichols in a review of papers noting LLI in the general population noted 8% had an LLI of greater than ½ inch (12.7mm), this rose to 22% in patients with lower back pain[168].

It is important to consider the circumstances that are unique to the patient with an LLI following THR. The typical patient undergoing THR is likely to have been pre-operatively asymptomatic, (in terms of LLI) and to have undergone, intra-operatively and instantaneously, a change in leg length during THR. They are typically in their 7th decade[70], and are therefore a different population of patients to those who have had long standing or congenital LLI[20]

Due to the overlap of symptoms associated with LLI and other causes, such as pain, limited walking distance and nerve deficit, as well as the lack of consensus or recognition of this as a problem, it is impossible to know with any accuracy the total number of patients who develop an LLI following THR.

Edeen et al. reported that with a mean lengthening of 9.7mm, 32% of their patients were symptomatic[20]. Love et al. reported a lower incidence of 18% of patients with a post-operative lengthening of greater than 15mm%[169]. Beard et al. found that 6% of 987 cases had an LLI of greater than 20mm[25].

An additional cause for lack of consensus on diagnosis and treatment is that not everyone with any given magnitude of LLI will be symptomatic[38]. There is little agreement regarding what constitutes a significant LLI. This, coupled with the multifactorial nature of post-operative symptoms can make definitive diagnosis of LLI difficult and LLI must be considered along with the other major causes of pain following total hip replacement.

2.4. Definition of LLI by Aetiology

LLI of any cause is primarily divided into two categories, true and apparent according to aetiology:

True or structural leg length inequality occurs when the cause of the inequality is intrinsic to the limb itself, e.g. when the femur, tibia or ankle is shortened due to trauma, surgery or a congenital condition such as hip dysplasia. The individually measured limbs will be of different lengths[170-172]. This may occur following arthroplasty when a true LLI is present due to altered bony structures or component position[1 38 170 172 173].

Apparent or functional leg length inequality exists when, despite the individual limbs being the same length, they are found to be unequal when measured from a fixed midline reference point[171]. An example would pelvic deformity. When there is a fixed pelvic obliquity where the right side is higher, in an effort to maintain the position of the head over the centre of mass, the deformity could be accommodated by adduction at the right hip, and abduction of the left. This would give the appearance of a short right lower limb and a longer left lower limb. In the context of total hip replacement this can occur if there is tight capsular tissue that can cause fixed deformity such as flexion or as discussed in Section 2.1.2.5.3 the abductors are attached distally[1 38 172] (Figure 2.3).

2.5. Classification of LLI following THR

When a true LLI follows THR it can be further sub-classified either clinically or by the surgical factors contributing to the LLI.

2.5.1. Clinical classification

The clinical classification in based on whether the patient is either symptomatic or asymptomatic with regard to the inequality[38]. LLI being the direct cause of morbidity is sometimes difficult to ascertain as, while a large inequality can be more obviously associated with, say, a vaulting gait, early fatigue or back pain, these symptoms may have other associations in the presence of a more modest LLI, and occasionally arise due to other causes. For example a low grade infection can lead to pain around the operative site[174], or a patient can have back pain for other reasons[175]

2.5.2. Classification by cause

Type 1 or primary symptomatic LLI following THR is due directly to component mal-positioning, i.e. where the stem is proud, Figure 2.4, the femoral cut is too high or the cup has been placed too low[28].

Type 2 or secondary symptomatic LLI occurs when component malposition leads indirectly to a limb length discrepancy. For example, if acetabular component has been placed in a position where the reduced hip replacement would be unstable, such as in an excessively open position where there is a risk of dislocation. To improve stability, the surgeon may then increase the soft tissue tension, generally by increasing the femoral offset by choosing a longer neck length for the stem, which in turn can create an LLI[28] [176], Figure 2-5.

It is important to recognize this distinction between these types of LLI prior to revision surgery because simple revision of the femoral component in the above case may result in inadequate tissue tension and an unstable total hip replacement. A combination of types 1 and 2 is often seen.

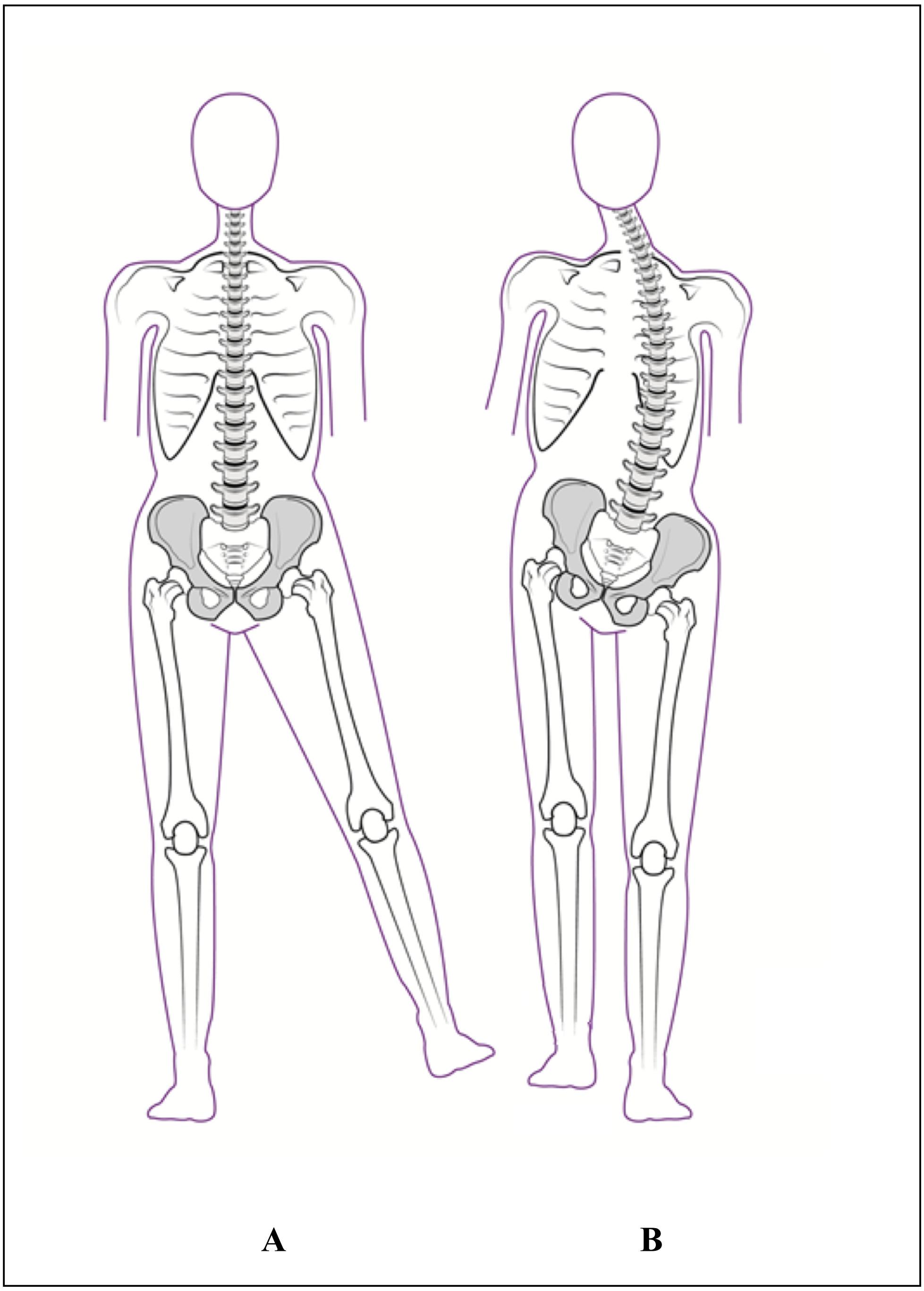


Figure 2-3 Effect of abduction
Illustrating that abduction and resulting pelvic obliquity which can result in an apparent LLI. In this figure, A has an abduction contracture of the left hip as a result of (for example) tight abductors. To compensate for this and in order to place the left foot flat on the ground the patient has to bring their pelvis into obliquity, B causing an apparent LLI. Therefore, caution must be taken as even a minor addition of a true LLI following THR may result in significant morbidity.

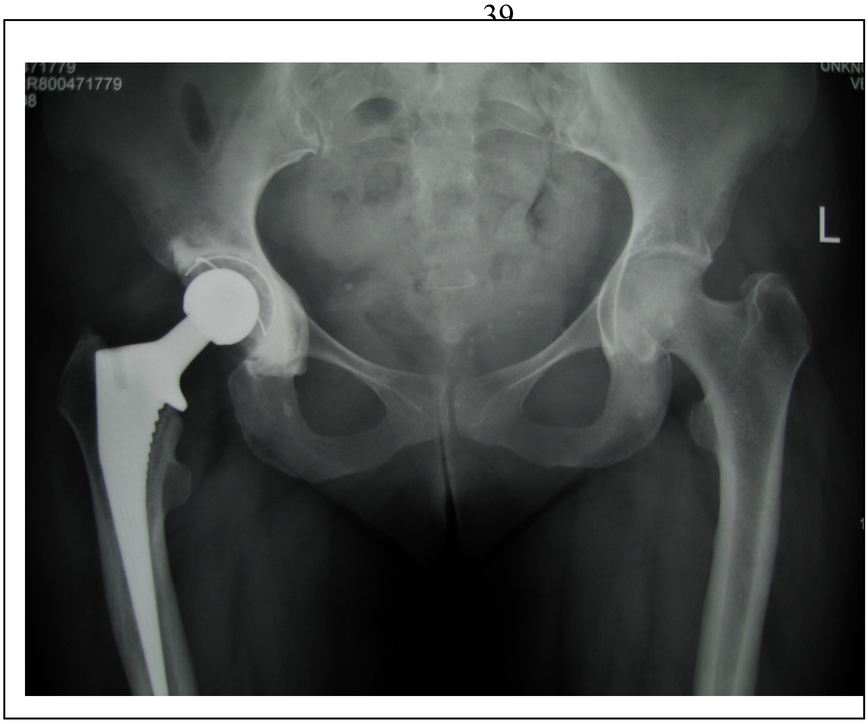


Figure 2-4 Type I Error. A radiograph of a total hip replacement where the femoral stem is too long resulting in a type 1 true leg length inequality

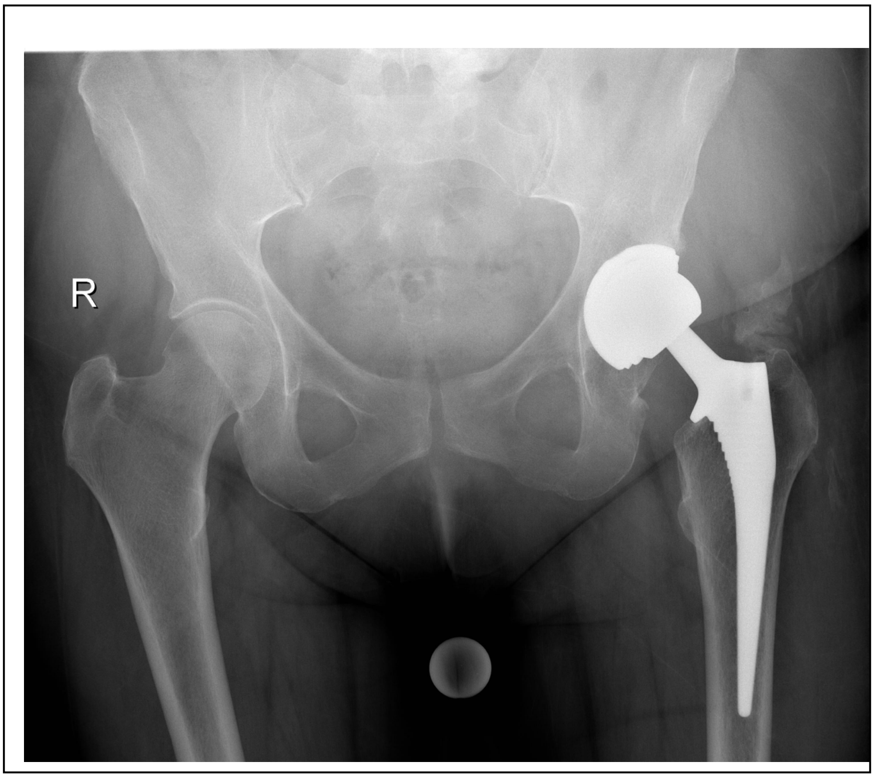


Figure 2-5 Type 2 Error. The acetabular component has been malpositioned and risks dislocation. Therefore, to achieve stability the femoral component has been inserted to produce lengthening due to the stem.

2.6. Patients most at risk of developing a symptomatic LLI following THR

The population of patients at risk of symptomatic LLI can be divided into those patients who are more prone to a LLI and patients who are more sensitive to a given magnitude of LLI

2.6.1. Patients more Prone to LLI

Patients who are more prone to LLI are those with bony abnormalities (i.e. dysplasia or previous trauma) that inhibit proper stem insertion, alignment or positioning of the components. Similarly in patients who are morbidly obese, body habitus presents a technical challenge to preforming THR[163]. The use of an uncemented femoral stem also increases the risk of LLI possibly due to inexperience or where the surgeon over-sizes the stem to ensure the implant has primary stability[91] (Table 2.3).

Table 2-3 Patients that are more prone to leg length inequality.

Narrow femoral canal
Abnormal femoral diaphysis
Acetabular abnormality
High BMI
Uncemented Stem

2.6.2. Patients more Sensitive to LLI

Several identifiable patient groups are particularly sensitive to leg length inequality and are summarised in Table 2-4. This is important because they are sensitive to a relatively small amount of lengthening that may pass unnoticed by other patients. These groups include the short stature female patient (tendency to smaller femoral offset and narrower pelvis), patients with pre-existing scoliosis, or those with knee and ankle deformity of the opposite leg[23 162]. This latter problem causes a true shortening of the opposite leg which is often symptomatic for the patient. These groups all appear less able to compensate for any given LLI

Table 2-4 Patient Groups that are more sensitive to Symptomatic LLI

Short Stature
Female
Pre-existing Scoliosis
Ipsi and Contra lateral knee and ankle pathology
Short, Varus Femoral Neck
Narrow pelvic width
Low Physiological Reserve
Pre-existing shortening of abductors
Pre-existing LLI
Developmental dysplasia of the hip

The patient with a short, varus neck of femur may be lengthened at surgery due to implant selection. In these cases, particularly where the femoral neck is short, there may be oversizing of the stem, either through lack of appreciation of the anatomy or where the suitable implant is not available. This group of patients is very sensitive to even a small amount of lengthening. This may be as a result of stretching of the abductors, causing an abduction deformity and a pelvic obliquity with the operated side lower[170].

In short stature patients, any given amount of lengthening will represent a greater percentage of the patient's overall height. In addition, smaller patients tend to have a narrower pelvis, which through basic geometry can be shown to produce a greater pelvic obliquity for any given LLI[177], Figures 2.6 and 2.7.

Furthermore, those patients with low physiological reserve, such as those with poor cardiac or respiratory function, are also less able to tolerate the increase in physical effort due to loss of efficient locomotion that occurs in a vaulting gait for any given level of mobility[35].

The legs of patients with pre-existing shortened gluteals will tend to lie pre-operatively in an abducted and externally rotated position, resulting in an apparent lengthening. If these patients then exhibit true lengthening as a result of total hip replacement they either have to increase their pelvic obliquity or, if the required compensation is too great, will have to pivot on the shorter leg to be able to place the longer leg on the ground[1] Figure 2-7. As noted above this effect is further compounded in the short stature patient.

$$Pelvic\ Obliquity\ (degrees) = tan^{-1} \frac{\textbf{LLI}}{\textbf{Horizontal distance between the Head centres}}$$

(Where LLI is a vertical distance measured as a perpendicular from the horizontal line defining the pelvic width)

Figure 2-7 The relationship between pelvic width LLI and pelvic obliquity.

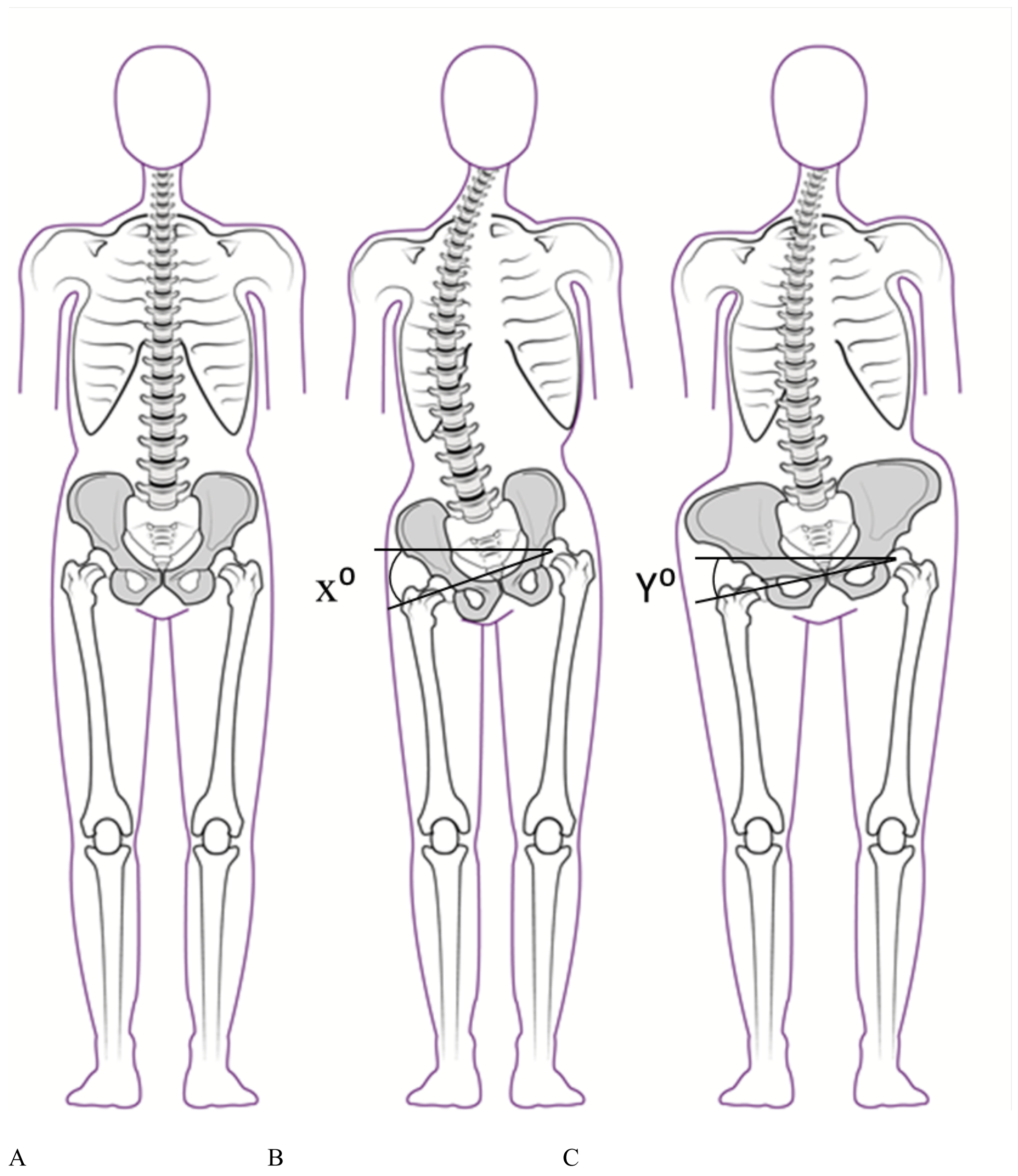


Figure 2-6 An illustration of the effect that pelvic obliquity can have for the accommodation of an LLI. Patient A is unaffected. Both patient B and C have a similar LLI, but B with the narrower pelvis has to adopt a greater scoliosis thus angle x° is greater than y°.

Finally, patients who have a pre-existing but asymptomatic LLI may be less likely to tolerate any increase in their leg length inequality and can experience significantly worse morbidity than would be associated with a similar inequality in other patients.

It is important, prior to either primary or revision surgery, to identity patients who are prone or sensitive to a symptomatic LLI and to counsel them appropriately.[39 178]

2.7. Clinical Presentation of LLI Following THR

Patients with significant symptomatic LLI (whether it be true, apparent or a combination of the two) may be immediately aware of this on recovering from the anaesthetic or on taking their first steps after hip replacement. Other patients do not notice any change in leg length until this is brought to their notice by the physiotherapist or partner. Patients tend to tolerate shortening better than lengthening, and an apparent LLI may resolve in the early post-operative period[179 180].

Clinical presentation varies from mechanical problems such as limp, increased fatigue and pain, or more rarely frank nerve damage. These symptoms are not mutually exclusive and they can have complex associations, however, pain and palsy will tend to present earlier than mechanical and gait associated symptoms[40 162]

2.7.1. Mechanical Symptoms

The mechanical symptoms are associated with limp and associated vaulting gait, muscular pain and tightness, along with alteration of the wear characteristics of the

THR. Mancuso reported that a limp after a hip replacement, one of the cardinal signs of an uncompensated LLI, is an independent risk factor for the outcome of THR[19]

Gurney et al. suggested that the increasing physiological demands of mobilizing 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 there may be 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 disease[35].

The compensations for LLI are complex and variable. As LLI patients develop a pelvic obliquity, 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 area [165 180].

Bhave et al. studied patients with a LLI of all causes (mean 49mm) and found that the longer limb bears greater load for longer in the gait cycle than the shorter limb[180]. Barnett et al. found that although the hip in a long limb may be held in adduction (in five patients with LLI 12mm to 30mm), concomitant gait abnormality (reduced range of motion) would tend to offset this and the wear rate was predicted not to increase [34]. This analysis assumed that the contact remained within the cup, and that no edge loading was present. An additional consideration is that if a patient has a symptomatic LLI that reduces mobility, then the wear through both hips will be reduced through a reduction in sliding distance. This latter point may be counterbalanced by the compromised lubrication of the hip joint that can be associated with reduced and abnormal mobility[72 181]. The varus and valgus gait alterations to accommodate a post-arthroplasty LLI may also cause increased edge loading, and in turn, increasing wear or loosening.

2.7.2. Pain as a result of LLI

Patients with a symptomatic leg length inequality may complain of pain in other joints due to compensatory mechanisms which occur in an attempt to accommodate the LLI. These include increased knee flexion, increased flexion at the hip, equinus foot position, eversion of the calcaneum on the longer side and decreased walking speed [1 180]. Golightly et al. in a series of papers studied the effect that LLI (of all causes not just arthroplasty) is associated with progressive pain and osteoarthritis in the knee and the hip generally in the short limb, when the inequality is greater than 20mm[31 33 182]

These changes can be visualised in clinic and studied in detail in a gait laboratory. Many patients with leg length inequality adopt the typical stance of the long leg flexed at the hip and knee, a pathognomonic sign of symptomatic leg length inequality (Figure 2.8).

Although lower back pain, pelvic obliquity and altered gait are common in many patients attending orthopaedic clinics, a greater percentage of those with leg length inequality have lower back pain [179 183 184]. This is thought to be mechanical in nature resulting from the presence of a functional scoliosis in the LLI patients. A leg length inequality 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 [165].

Figure 2-8 The typical stance of a patient with LLI.
Note that the long limb is flexed at the hip and the knee to produce an apparent shortening and equalised leg length.

2.7.3. Neurological symptoms

The sciatic nerve is vulnerable to limb lengthening, leading to motor impairment by sensory alterations or referred pain in the distribution of the nerve[29 39 162 185]. Nerve injuries have been reported in 1% to 3% of primary THA and 3% to 7% of revision arthroplasties[29 39 45 162]. Motor loss is typically due to injury of the peroneal part of the sciatic nerve with or without tibial nerve involvement. The former would result in loss of or reduced function of the anterior and lateral compartment of the leg (in this case the lower leg the being an anatomical region below the knee and is as opposed to the thigh) most noticeably causing a foot drop. The latter, due to loss or reduced function to the posterior compartments of the leg, a deficit in plantar flexion of the ankle, great and lesser toes.

Motor function can be quantified using the Medical Research Council grading of motor function ranging from: 0 where there is no function to 5 where there is normal power. A similar Medical Research Council grading can be used for sensory loss, where 0 is absolute anaesthesia and 5 is complete recovery. Pain, though subjective, can be quantified by systems such as a visual analogue or numerical rating scale, where 0 is no pain and 10 is their worst pain. Additionally, nerve conduction studies can provide objective diagnostic and prognostic information[29 39 185 186].

Females are at higher risk than males, due to their reduced femoral offset and the closer proximity of the nerve to the surgical site [29 162]. In terms of post-operative neurological deficit, Pritchett presented a cohort of 19 patients with severe neurological impairment following primary uncomplicated THA. These patients had been lengthened between 13 mm and 41 mm [29]. 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)[187]

There are another group of patients who may be more susceptible to pain or neuropathy. This cohort has a pre-existing, perhaps even pre-symptomatic degenerative disease around the spinal cord or exiting nerve roots. Should they suffer an LLI following THR that places any nerve under increased tension, there may be a danger of a 'double crush' syndrome.[188 189]

2.8. Measurement of LLI

2.8.1. Clinical

During clinical assessment, leg length inequality may be quantified directly by physical examination [23 171 190-192], as a direct measurement of the true leg length inequality (anterior superior iliac spine to the medial malleolus [1 20 163 192]), as an apparent leg length inequality (fixed midline point usually the xyphoid or the umbilicus[20]) or using indirect measurement. The indirect measurement technique stands the patient on increasing thickness of blocks under the short foot until the pelvis becomes level [1 20 36 163].

Clinical measurements are notoriously inaccurate. Two studies comparing clinical and x-ray measurements of LLI found that the direct and indirect methods differed by a mean of 8.6mm and 7.5mm respectively. Furthermore patients with equal leg lengths on clinical measurement have been reported to have a radiographic LLI of 10 mm or more[1 44 192].

2.8.2. Radiological methods

2.8.2.1. Plain X-ray

Though various methods have been described, two radiological techniques for measuring LLI are commonly found in the literature and are widely used in clinical practice. Using a plain AP pelvis radiograph, Williamson et al. used the interischial line as a reference and measured the perpendicular distance to the most prominent part of the lesser trochanter [45], Figure 2.9. Woolson et al., constructed a line drawn through the most inferior part of the acetabular teardrop and measured to the perpendicular distance to the most prominent part of the lesser trochanter [3], Figure 2.10. The Woolson technique has a reported inter-observer variation of 0.5 mm [3]. Advocates of the teardrop as a reference, cite that this is a more discreet anatomical structure and less affected by rotation[3 193].

All of these methods measure inequality only at the hip on plain AP pelvis radiograph and do not take into account other discrepancies, that will alter the leg length, such as hip flexion at the time of the x-ray (which may reduce the measured LLI) or any causes of a LLI not involving the hip.[30 194]

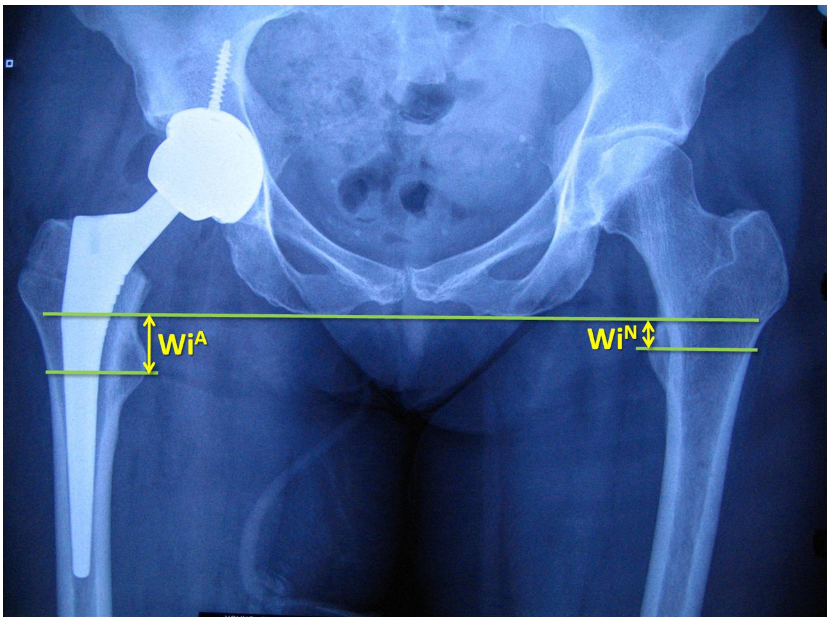


Figure 2-10 The Williamson method.
A reference line tangential and parallel to the most inferior portion of the Ischia is constructed. Two further parallel lines are drawn through the most prominent part of the lesser trochanter and the perpendicular distance between the lines measured. The difference between the left and right sides is the measure of LLI.

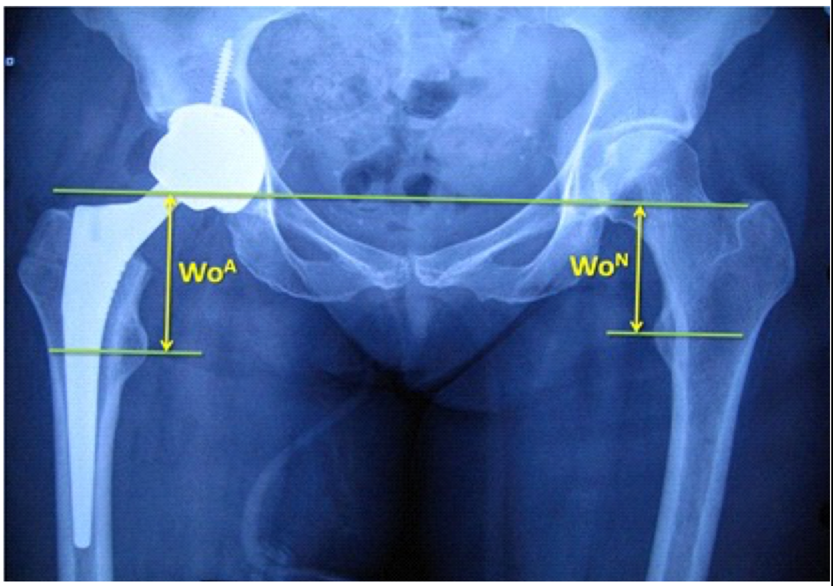


Figure 2-9 The Woolson method.
A reference line is drawn through the most inferior part of the acetabular teardrop. Two lines parallel to this are drawn through the centres of the lesser trochanter. The difference in the perpendicular distance between the left and right sides is defined as the LLI

Another source of error on plain radiographs at the pre-operative stage (particularly hard copies) is the magnification error if the films are not calibrated, or where the size either the calibration ball or the femoral head of the THR are not known, can be up to 129%[195]. Khanduja et al. quantified magnification by measuring the size of the femoral component, using its known dimensions for calibration purposes[194]. Similarly, Suh et al. employed magnification markers to aid calibration of the radiographs[196]. The known size of the replaced femoral head is a useful calibration maker for a post-operative x-ray. With the advent of digital imaging in conjunction with the use of calibration, the error associated with varying magnification of solid film images should be reduced.

Other techniques have been used to measure LLI on x-ray but are not commonly used in clinical practice. Turula et al. used standing AP films with blocks and mercury as a radio opaque spirit level [24]. Jasty et al. and Knight measured using x-ray scanograms [163] [197]. Williamson et al. reported their methods for measuring LLI (interischial line to lesser trochanter) to be of similar accuracy as these long leg views [45].

Morscher and Figner presented a review of three methods they studied, teleradiography (whole of both lower limbs on a single, large, radiographic plate using a single static X-ray tube), scanography (single, large plate, X-ray beam moved over the distance to be measured) and orthoroentgenography (multiple standard x-ray plates on a calibrated frame). They highlighted limitations of all three methods such as; technical difficulty of image acquisition, the requirement for the patient to remain static during the imaging and loss of accuracy in the presence of contractures. The group concluded that they favoured orthoroentgenography though accepted that these radiographic techniques, were ‘more or less equally accurate’. They did not however present any data to support this view[192].

In a more objective paper, Sabharwal and Kumar 2008 also reviewed methods of measurement of LLI. When comparing the plain film techniques for the measurement of LLI found that teleoroentgenograms, x-ray scanograms and computed radiography (digital manipulation of radiographs to form a long leg view) they found that three methods were comparable for reliability and accuracy. They found, contrary to the opinion of Morcher and Finger, that orthoroentgenography, did not have as good reliability as the other plain film techniques studied.

2.8.2.2. Computerised Tomography

The computerised tomography (CT) scanogram was noted as early as 1984 by Helms et al to have utility in the measurement of LLI, (all causes, not just as a result of THR) as the group found it to be more accurate, quicker and requiring less radiation exposure than other techniques[198]. Further work later in the 1980s yielded a similar view regarding the use of CT for LLI. Glass et al found CT scanograms to be accurate but in the presence complex deformity a lateral scout view was also needed [199]. O’Connor et al in 1987, published two case reports where CT scanograms were used and coming to a similar conclusion, also noting that a lateral view was needed in complex deformity [200]. Aitken et al found that when compared to spot radiography (calibrated radiographs of the hip, knee and ankle), CT was just as accurate with a radiation dose was three to six times lower[201]. In 1987 Temme et al compared CT scanograms with orthoroentgenograph when measuring dried femora and found the former to be more accurate [202]. Aaron et al compared CT scanograms versus orthoroentengography on twenty cadaveric lower limbs, again finding that CT was accurate and required less radiation exposure[203].

Tokarowski et al investigated CT scanograms on 34 patients and demonstrated a sensitivity of 1mm and described the technique as ‘precise and trust worthy’ and repeated some of the findings in the previous work highlighting the lower dose of irradiation, reproducibility and ease of use[204].

In 1987 Huurman et al published a series of thirty consecutive patients and six dried bones. The group found that CT scanograms were accurate and had an advantage over the previously used plain radiographs in that motion artefact is easily detected and the scan easily re-done and there was minimal magnification error [205]. This report does highlight a limitation of the use of CT scanograms in clinical practice, in that even in a facility with a CT scanner, there are problems scheduling patients for these studies and they cannot typically be done at the same time as the visit to the orthopaedic clinic.

While the early literature has limitations, case reports and a relatively few studies, there is a common theme; accuracy and reduced radiation dose when compared with the more typically used methods to radiographically measure LLI following THR.

The more recent literature includes consideration of the use of CT. Gurney in 2002 published an extensive review of LLI, highlighting the flaws of clinical measurement as well as finding CT scanography to be superior to magnetic resonance imaging (MRI) and ultrasound, albeit accepting that these techniques do not require irradiation[1].

Machen et al published a review of imaging for LLI in their paediatric practice and concluded that CT scanograms ‘are more precise and accurate than (x-ray) scanograms’ but accepted that they are not always convenient nor readily available to the ‘general orthopaedist’[206].

In 2008 Sabharwal and Kumar published a review measurement of LLI for all causes where they considered clinical measurements, plain and digitised radiographs, as well as MRI and ultrasound. They found that CT scanograms were superior when considering reliability and accuracy, with only a ‘minimal’ influence of magnification. There was consideration of the additional radiation dose (60mrads) which was less than scanograms performed using plain x-ray but also accepting that this was not an ‘office’ (clinic) based investigation that incurred additional costs. They noted that greater accuracy in the presence of contractures around the hip or knee when the supine CT scanogram was combined with a lateral scanogram.[46]

Sayed-Noor et al published work in the same year comparing clinical and radiological (plain x-ray) measurements in one hundred and thirty-nine patients both pre-operatively and post-operatively. In recommending the radiological methods, particularly in the post-operative period, they conclude by advocating CT scanograms in those cases that may give rise to any further interventions or surgery [207].

Poutawera published a more detailed examination of the accuracy of CT scanograms. Where twenty-six films were measured by seven physicians and then re-measured at least eight weeks later. They yielded high correlation (0.96) across all sections of the study[208].

When considering LLI following intra-medullary fixation of femoral trauma, Vaidya held CT scanograms (supine AP films and lateral where there is 3 dimensional deformity) to be the imaging of choice, with a strong degree of correlation between the two observers in the study[209].

Kjellberg et al used CT scanograms as the gold standard when they compared with plain film. In their study, four readers measured the imaging of ten patients with LLI following THR. Although noting that their study was small, they found that plain radiographs had 'limited accuracy' when compared with CT scanograms [210].

Other modalities have shown some promise. Guggenberger performed a comparison study using CT scanogram as the gold standard versus standing films and a newer technique that uses 3-dimension modelling software and bi-planar linear (full length) radiographs. This was performed on fifty-one consecutive patients with two independent readers. They found the three techniques to be comparable but that there was better inter-reader agreement with their novel technique. They noted that Supine AP CT scanography produced a two-dimensional image of a three-dimensional structure but made no comment upon, or use of, the concurrent lateral CT scanogram, a limitation that had been discussed in the 1980s. Additionally, they did not consider radiation dose, an advantage that CT scanograms have over some of the other techniques[211].

Radiological measurement has been shown to be more accurate than clinical assessment for LLI (of all causes)[1 46 207]. In terms of which imaging modality might be best, there is support for the use of CT scanograms which have a distinct combination of advantages including accuracy, reproducibility, lower radiation exposure than other radiographic techniques for whole limb LLI measure, as well as technical ease and speed of image acquisition. There are limitations to the technique in that there is additional cost to perform and they are less convenient than other modalities that can be performed at the time of visit to the orthopaedic clinic. Additionally, both in review and original work, no other imaging technique has been show to consistently outperform CT scanograms for the assessment of LLI following THR when CT scanograms have been used as the reference comparator[1 207 210].

2.9. Techniques available to the surgeon to minimize LLI

2.9.1. Pre-operative techniques to minimise LLI

Twenty papers, published between 1988 and 2015 reported pre-operative measures that can be used to reduce LLI[2 3 17 171 195 196 212-225]. Typically, these employed some form of overlay template, and followed the method described by Muller [2 3 36 171 196 213 214 223]. Initially the techniques involved the assessment of size and position of the acetabular component. Next the centre of rotation was determined, followed by consideration of any osteophytes to be excised. The femoral component was then templated, the appropriate stem size and neck length determined and [225]the femoral resection planned[223 226]. Woolson et al. published a technique where these overlay templates were only used to determine the level of the femoral neck resection [3].

The advantage of pre-operative planning, as advocated by Muller, is that it allows the surgeon the opportunity to plan resections and consider any likely difficulties and indicate which implants are to be used. The latter is particularly important for uncemented prostheses where under-sizing can result in a loose stem and over sizing can result in fractures [215].

Another technique described in the literature uses direct measurements from the radiographs intra-operatively (i.e. Measuring the distance from the superior part of the femoral head to the planned neck resection on the radiograph) and then using that reading during the preparation of the femur [3 212 227].

With the advent of digital radiograph papers detail use of specialist software designed for pre-operative planning and digital templating, replacing the more established plain film and overlay templates. [216 217 222 224 17 221 222].

2.9.2. Intra-operative techniques to minimise LLI

The common intra-operative techniques used by the surgeon can be classified as indirect tests (mainly those using soft tissue tension testing) and detailed in Section 2.8.2.1. or those using direct measurement or direct comparison which are considered in section 2.8.2.2 which are called direct tests.

2.9.2.1. Indirect Tests

Indirect tests, also known as the soft tissue tests, are used intra-operatively, and while they are primarily a measure of stability of the arthroplasty they can also guide the accuracy of leg length. They are primarily a function of the tension in the soft tissue and may be vulnerable to misinterpretation in the presence of muscular blockade, as seen with spinal anaesthesia[228]

The shuck test, described by Charnley, allows assessment of the soft tissue tension by applying traction to the reduced hip replacement[15 178 229]. With the trial implants in place, the surgeon attempts to sublux the hip joint by applying traction in the line of the neck of the stem, whilst abducting the limb and the tibia horizontal to the floor. In the ‘correct’ length hip the prosthetic femoral head should be able to sublux out of the socket with moderate traction, commonly 5mm to10mm. If the prosthetic head cannot be made to sublux then the limb length may be too long.

The Ober test is an assessment of iliotibial band (ITB) tension. To perform this test, the patient is in the lateral position. The lower, contralateral limb is flexed at the hip to fix the lumbar spine. The knee of the lower limb that is being examined is then flexed to ninety degrees, the hip is then extended and abducted. If positive (if the ITB is tight) the limb will tend to remain in an abducted position. If the ITB is not tight the limb will return to the neutral position or into adduction and the Ober test will be negative.[21 178 230 231].

The Kick Test is an assessment of quadriceps length and tension. This is due to the reflected head of rectus femoris crossing the hip joint before inserting into quadriceps tendon, traversing the knee and then through the patellar tendon into the tibia. The test is performed in the lateral position by holding the leg parallel to the contralateral lower limb, then extending the limb in question so that the anterior edge of the patella is 10cm posterior to the anterior edge of the contralateral patella. During the manoeuvre the knee is flexed to ninety degrees and if the leg has been overly lengthened the knee will swing passively into extension due to the increased tension within the rectus[178 190 229].

Limb stability as a function of soft tissue balance is tested within the full range of motion, with anterior impingement tested at full internal rotation and anterior capsule tightness tested at full extension and external rotation [178 190 229].

These soft tissue tests are inherently subjective and are dependent on the surgeon making a judgment about the repeatability of the force applied and the position that the limb is placed for the assessment.

2.9.2.2. Direct Tests.

Some Forty papers published between 1983 and 2015 describe intra-operative techniques to minimise leg length inequality LLI following THR[21 22 30 44 163 169 190 191 197 227 232-261].

Many of the earlier papers involve the measurement from a fixed reference such as a Steinman, K-wire or screw in the ilium to a fixed point on the greater trochanter [21 22 44 163 169 191 197 233 235 238-243 248].

Five of the papers recognised the potential for error with a simple two-point method. The line of measurement (reference point to greater trochanter) is not parallel to the limb lengthening axis, and therefore close attention must be paid to the rotation and limb position when assessing any change in LLI. These techniques included the placement of the proximal reference on a fixed point at the posterior rim of the acetabulum, close to the centre of rotation [22], and using an ' L' shaped calliper[238] or spirit level[191] to ensure horizontal positioning. Two papers addressed the loosening of the reference point by using 'Callipers Dual Pin Retractor' [235 239].

Maratt et al described a novel technique which employed a trial head which had been modified with a slot at the level of the centre of rotation. During the trial of the femoral construct, a guide plate is placed in the slotted groove and the position relative to the greater trochanter is assessed[250].

Two papers, Hill et al and Pooler Archbold et al emphasises the importance of anatomical restoration of the hip joint following total hip replacement. The transverse acetabular ligament is used as a reference for the position of the cup component of the THR. A graduated calliper is used to perform measurements of the femoral head for vertical height and offset in relation to reference marks distal to the neck cut on the femur. In doing so the authors advocate a technique which restores the patient specific morphology[246 253].

Other techniques, more typically described in the earlier literature are; direct comparison of femoral length with the contra-lateral limb by comparing the position of the tibial tubercles during surgery[190] intra-operative radiographic assessment with either plain films or fluoroscopy[190 244 247], direct measurement with a ruler (with or without reference to pre-op templating [234]), comparison of the trial implant with the resected femoral head[245], use of a proprietary measuring device and a carpenter's spirit level[191] or direct measurement using a knotted piece of 36 inch umbilical tape[236].

As with the pre-operative techniques, with the advancement of technology. Nine papers, published between 2007 and 2015, have described the use of various versions of computer aided navigation to reduce the incidence and magnitude of LLI following THR[237 254-261]. Four of these nine papers used CT based navigation systems[237 256-258] and the remaining five used intraoperative arrays to calculate the correct positioning of the implants[254 255 259-261].

Many surgeons measure the distance either of the femoral neck resection to the lesser trochanter or the level of the shoulder of the femoral stem trial to the greater trochanter. These particular measurements vary with each hip prosthesis although they are easy to learn and use surgically. Another technique described by surgeons who use the posterior approach is to gauge the change in leg length by the ease of the reduction of the short external rotators. Similarly, although the approach is in decline[62 70], surgeons who employ a trochanteric osteotomy can gauge change in leg length by the reduction position of the osteotomised greater trochanter on the trochanteric bed.

While it is encouraging that these intra-operative techniques can reduce the number of patients with LLI, there is no one technique which will accurately provide the surgeon with the assurance of an equal leg length in every case.

2.10. Accuracy of Techniques to Minimize LLI

Mahmood et al noted the limitations with many of the papers that have published results of LLI following THR[18]. Of the sixty three papers discussed in Section 2.8, fifteen were either instructional or technical notes[15 178 197 215 224 229 232 233 236 239-242 245 249], nine papers did not state in their methodology whether they were prospective or retrospective[3 21 30 190 220 227 235 237 238 247] twenty eight were retrospective studies[2 36 44 163 169 171 196 212 213 216-219 221 222 225 243 244 250 252-256 258-261] and ten were prospective [17 22 191 214 223 234 248 251 257].

There may be a form of publication bias. Only surgeons with an interest in LLI following THR are likely to publish work on this specific part of a sub-specialist orthopaedic field. The fact that these surgeons have paid particular attention to LLI following THR may mean that the published results are likely better than for others performing the operation. It is also possible that surgeons who have poorer results for LLI following THR are less likely to publish those results. These papers therefore may not be representative to the wider body of orthopaedic surgeons performing hip replacements.

In this section, the reported accuracy of the papers that have published results for their stated techniques are considered with specific regard to the results of LLI following total hip replacements.

2.10.1. Accuracy of Pre-Operative techniques to minimise LLI

Of the twenty papers that detailed pre-operative techniques, three papers were prospective[17 214 223], two were instructional/technical notes[215 224], thirteen were retrospective[2 36 171 196 212 213 216-219 221 222 225] and two were unclear from their methodology[3 220].

One limitation of the papers reviewing the pre-operative techniques is that some of the studies were relatively small. Seventeen papers published data regarding patient numbers, the mean for these publications was 129 patients, range 42 to 410 patients[3 17 36 171 196 212-214 216-223 225]. Two of the studies, Woolson et al and Iagulli et al were notably much bigger than the other studies with 351 and 410 patients respectively. While there are clear difficulties drawing many firm conclusions from heterogeneous data and the studies' limitations as discussed there are some consistent themes throughout the literature.

Pre-operative techniques alone are unsatisfactory determinants of leg length and stability. Hofmann et al., noted the importance of intra-operative techniques to minimize LLI, however he also reported that despite his careful preoperative planning, in 50% of his cases the pre-operative plan was changed intra-operatively [190]. Konyves et al. stated that templating made no significant difference to LLI in his series [30]. X-ray magnification can affect pre-operative planning. Particularly with the use and accurate positioning of a calibration marker. Knight et al. noted that the magnification error was greater than 3mm in 17% of subjects, a magnitude which equated to more than a component size [214].

The use of digital images and templating were only detailed in three studies, Jassim et al, Lim et al and Halai et al[216 217 222]. The range of LLI following THR was -20mm to 10mm, 0 to 19mm and a maximum of 9.2mm in their series.

Knight et al., using meticulous pre-operative planning, reported 92% of patients with post op leg length who were within ± 5mm. Della Valle et al. Eggli et al. used a similar method and 99% of hips were within one component size for both the stem and the cup. Eggli et al. also published 92% accuracy for the stem and 90% for the cup also using templating only. Woolson and Hartford et al., using radiographs to plan a direct measure to guide the neck resection, reported 86% of patients within 6mm and 97% of patients within 10mm [3 214]. Despite their careful planning, however, 3% of patients had a LLI of greater than 1 cm.

Halai et al used a technique previously published as a technical note by Wilson [217 224]. Using digital templating to plan the placement of the stem relative to the distance between the shoulder of the implant and the greater trochanter. The resulting LLIs form this process were among the lowest reported in the literature. The cohort had a mean post-THR LLI of 1.3mm and a maximum of 9.2mm.

The presentation of the data varied between the studies. Fifteen of the eighteen scientific papers published a mean LLI following THR[2 3 212 221 17 36 171 196 213 217 218 220 222 223 225]. This mean LLI ranged from 0.9mm to 6.2mm. Eleven of the eighteen papers published detailed ranges (as a specific measurement as opposed to percentage above or below a certain level) with their data[17 36 171 196 213 216 217 220 222 223 225]. This mean varied from -20mm to +21.3mm. It is obvious therefore that despite enthusiastic adoption by the authors of these techniques the results remain variable.

2.10.2. Accuracy of Intra-Operative techniques to minimise LLI

Thirty of the forty-three papers that discussed intra-operative techniques published original research. Of these, eight were prospective, seventeen retrospective and the remaining four did not give details in their methodology. The mean number of patients in all of these studies was, at 102 patients (range 37 to 344), lower than the papers studying pre-operative techniques to reduce LLI following THR.

The soft tissue techniques on their own (Shuck, Kick, Ober tests, tightness of the anterior capsule anterior impingement) have been primarily developed and used for assessing stability rather than leg length. There are many factors out of the surgeons' control which can adversely affect his ability to measure the LLI using soft tissue methods during hip replacement. The accuracy of the soft tissue balancing test is dependent on the amount of force applied as well as the soft tissue relaxation [163 229 262]. The type of anaesthesia can also interfere with the surgeon's intra-operative tests of leg length. The muscular relaxation as a result of the motor blockade seen with spinal anaesthesia can increase the perceived laxity and give a false sense of shortening due to prosthesis size and position. To compensate for this artefactual assessment of shortening and potential for instability, a surgeon may inadvertently increase the limb length during the THR[228].

Sathappan et al published a retrospective study of one hundred and thirty-two patients, exploring spinal anaesthesia versus general anaesthesia without muscular paralysis. The group found a statistically significant difference between the two groups for post-operative LLI. The 63 patients who underwent spinal anaesthesia, 87% had an LLI of some measureable magnitude, as opposed to 20% (14/69) in the general anaesthetic group. Additionally, in the spinal anaesthetic group 52% (33/63) were greater than 10mm as opposed to 1% (1/69) in the general anaesthetic [228].

Soft tissue balancing can also be subject to patient-specific factors such as fixed flexion contractures or a tight anterior capsule [236].

Sathappan's data agree with those published by Rice et al and Naito et al who found that use of the shuck test resulted in a statistically significant increase in lengthening when compared to the direct intra-operative fixed references[44 251].

The importance of the accurate patient positioning is highlighted by Sarin et al., as reported in a test bench study using dry bone models. Sarin found that as little as 5° of mal-positioning of the leg in adduction/abduction intra-operatively can cause as much as 8mm error in leg length measurement, and 10° of adduction/abduction can cause a 14mm to 17mm error in leg length measurement. It is difficult to position the leg to an accuracy within 5° in all but the thinnest of patients. Flexion/extension mal-positioning results in much less pronounced errors [263]. The magnitude of error associated with what would be considered a relatively modest variation in the coronal and sagittal plane position highlights the complexity of the anatomy in this region. Basic trigonometry would predict that abduction of 10° would result in an error in length measurement of 7mm.

With regard to surgical approach to the hip, Nam et al published retrospective study comparing the anterio-lateral, posterior and posterior with navigation approaches and found no statistical difference in post-THR LLI between the groups [255]. Similarly, in a review, Konyves et al discussed LLI with reference to surgical approach and again found no statistically significant difference between the antero-lateral and posterior approach. In addition, Konyves et al found that there were fewer long limbs with the CPT (Zimmer, Warsaw, IN, U.S.A.) than the other stems used in the paper; Exeter (Stryker, Kalamazoo, MI, U.S.A.) , C Stem, (DePuy, Warsaw, IN, U.S.A) Charnley (DePuy) and IPS (DePuy)), although there was no differences in Oxford hip scores at 3 and 12 months[30].

White et al. reported that more patients with Charnley monoblock prostheses had a post-operative LLI under 10mm than the Elite plus modular stem via the anterolateral approach [16]. While they did not discuss possible causes for this finding, it is possible that, given the availability of modularity, the surgeons opted to lengthen to improve stability.

While many of the papers discussing intra-operative techniques look at the total LLI following THR, only, Pooler Archbold et al and later form the same group, Hill et al and Beamer et al uncoupled the component parts of the THR. They emphasised the importance of cup and stem placement and published techniques for both the cup and the stem[244 246 264].

Beamer et al used intra-operative fluoroscopy for positioning of both cup and stem in 57 patients versus 52 positioned free-hand. The group were not able to demonstrate a difference in LLI following THR, however in a separate element of the investigation found improved version of cup placement.

One of the larger studies publishing the results of a specific technique for LLI following THR, was presented by Pooler Archbold et al[246 253]. This group demonstrated, in their retrospective review of 200 patients that attention to the transverse acetabular ligament in conjunction with the use of a calliper to control the positioning of the femoral component yielded a mean LLI following THR of 0.38mm (-8mm to 8mm) for uncemented Duraloc (DePuy, Warsaw, IN, U.S.A) cups and a custom cemented stem (DePuy).

The use of this form of calliper was then validated by Hill et al in a laboratory study, using a co-ordinate measuring machine on nine Sawbone femoral specimens[246]. The work was then followed by a prospective study using CT analysis of 38 patients. The results indicated a mean LLI of -0.6mm (95% C.I -1.4mm to 0.2mm) for the co-ordinate measurement element of the work and mean of 4mm (range -3mm to 14mm, SD 3mm). The authors did note that the calliper required some training to prevent technical error, but once expertise was achieved the method was inexpensive and quick although the author note that it must be used with caution where the femoral head has lost sphericity.

Eight papers considered computer aided navigation, using various systems, to assist in the prevention of LLI and eight published both mean LLI and range[237 252 255 256 259 260]. These mean post-THR LLI ranged from 0.3mm to 6.1mm however the overall range of inequality was broad, -29.8mm to 12mm. Manzotti et al, Ogawa et al and Licini et al presented work comparing navigation with their previous methodology. Of this group, only Ogawa and Licini were able to demonstrate any significant improvement in LLI following THR. Thirteen papers presented data for techniques that, with nuances, were based on the use of a fixed reference point and measurement during the operation[22 44 163 169 191 235 238 246 248 251 253 255 256]. The mean LLIs arising out of these approaches were between 2.1mm to 7.6mm and the maximum upper and lower ranges were -8mm to 16mm.

In all, twenty-nine papers presented data for an intra-operative method for minimising LLI following total hip replacement detailing mean differences from 0.3mm to 9.0mm. Therefore, if the premise made by Charnley is considered acceptable and that patients tolerate up to 10mm, then these results would indicate that the majority of patients are being well served by the technique published in the literature. It is a testament to the complexity of the issue of LLI following total hip replacement, that within the body of literature published by authors who have an interest in LLI following THR, only eleven of these papers publish ranges that are also below 10mm[21 22 163 190 234 237 238 250 256 258 259].

The range of LLI reported across all twenty-nine papers varies from -29.8mm to 16mm, which is substantial and includes magnitudes at which symptoms would be expected to occur.

2.11. What is an acceptable LLI?

It is always disappointing for the surgeon and the patient when an otherwise well performed hip replacement has a poor clinical result due to LLI. There are many steps during a hip replacement and as noted previously, several of these affect the final leg length. At present, there is no fool-proof method to guarantee equal leg lengths after hip replacement. Sir John Charnley stated that in an uncomplicated primary THA an increase in LLI of less than 10mm is acceptable, although others surgeons have considered the individual clinical outcome more important[15 169].

The variation in the published range and mean values for LLI following total hip replacement poses the question as to what is acceptable? It is striking that in the studies detailed in the previous sections, residual LLIs that have followed THR of greater than 10mm have been reported consistently, despite a specific focus on LLI and the adoption of pre-operative and intra-operative techniques to minimize LLI.

While recognizing the consequences of LLI in respect of patient morbidity, dissatisfaction and litigation, patients and surgeons should be aware that it is not always possible to ensure that the final leg lengths will match within 10mm. Furthermore, as the indications for hip arthroplasty have broadened and a more demanding population are undergoing total hip replacement, what may have been considered an acceptable outcome previously would not necessarily be adequate today.

LLI of greater than 20mm (of all causes, not just arthroplasty) is known to be associated with progressive pain and osteoarthritis in the knee and the hip generally in the short limb[31 33 182]. Bhave et al. found that equalization to within 10mm was critical in normalizing gait and improving the symptoms of LLI although patients appear to be able to tolerate shortening better than lengthening of the operated side.[180]. Gurney, in a review of the literature suggested that scoliosis was detectable once LLI exceeds 6mm LLI, pelvic tilt from 6.3mm and 'pain/arthritic changes' from 9mm[1]. O'Brien et al. found that in young healthy adults, 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 discomfort[265].

Conversely in a study of 20 patients with a mean LLI post THR of 11mm, who were at least one year follow up, Benedetti et al found that, at least in terms of gait laboratory obtained data, that there was no detectable difference in the kinematics of the hips. They concede though that they only looked at hip kinematics in a group of patients who had already demonstrated high post-operative outcome scores.

Zhang et al published a retrospective study in which a group of 96 patients were followed over the course of a year. Patients with an LLI following THR of greater than 20mm did less well in term of kinematics and also had a greater incidence of lower back pain[266].

In addition to the papers that published a technique to minimise LLI with or without data, there were thirteen papers that presented data for LLI following THR[16 18 20 23 24 27 45 194 262 266-269]. Of these thirteen papers, seven published mean LLI, which ranged from 1.1mm to 15.91mm[20 24 27 45 194 262 268]. The overall range of LLI reported across all of the papers ranged between 38mm of shortening to over 23mm of lengthening. While few direct conclusions or comparisons can be drawn from a diverse range of literature, it is clear that in general, patients are being well served by THR.

In all, sixty-one papers published data detailing LLI post total hip replacement. Of these, fifteen papers reported ranges whose maximum lengthening was at or below 10 mm[237 256 21-23 163 190 213 217 223 234 238 250 258 259]. It is evident therefore that even using techniques specifically designed to equalise leg length after hip replacement, achieving equality of length is not always possible in practice. There is perhaps broad but not universal consensus in the literature and amongst many surgeons, that less than 10mm LLI is acceptable, although there is little agreement about an upper limit of acceptable and this lack of consensus can make dealing with a symptomatic LLI following THR controversial. Ultimately patients must be considered on their individual merits as to the best way of managing their inequality.

2.12. Plans for Management of the Patient with Symptomatic LLI

In the immediate post-operative period, if the surgeon suspects a LLI without nerve palsy, radiographic confirmation of an LLI following THR should be sought. If a true LLI of less than 10mm is suspected, then an expectant course of management should be followed. If the LLI is greater than this, then the patient should be counselled regarding conservative management with the possibility of operative correction of these techniques fail.

2.12.1. Non-Operative Management

One of the difficulties in evaluating the treatment of LLI is the well reported improvement in symptoms over time and in the absence of treatment[38]. Konyves et al. found that of 56 patients with LLI (mean 9mm), only 43% at 3 months and 33% at 12 months perceived the inequality (mean LLI of 9mm)[30] .

The effect of a shoe raise has been extensively reported in the literature. A simple shoe raise can result in improvement of symptoms of between 44 and 90 % of patients with symptomatic LLI of all causes. Friberg found that corrective orthoses resulted in complete symptom resolution in up to 75% of patients with LLI and a further 15.7% had symptoms alleviated [165]. D'Amico et al. demonstrated that more than 90% of patients with an appropriate size wedge to correct the LLI had symmetrical gait and postural rebalancing, whereas those who did not have this correction had worsening of postural balancing and increased back pain [41]. Gurney at al, in a review paper, found up to 100% improvement of symptoms in patients with lower back pain[1]. While shoe raises and orthoses are obviously helpful in many cases they must be used with some caution, as early and injudicious use can prevent an apparent LLI from correcting [37 270] spontaneously.

If the cause of the LLI is apparent, Bhave et al reported that up to 94% of patients had a good or excellent outcome following up to 6 months of intensive non-operative therapy[40 270]. Ranawat et al found that all patients with apparent LLI and pelvic obliquity had resolution of symptoms at 6 months with stretching exercises, and that seven of nine 'persistent functional (apparent) LLI' improved with further physiotherapy and orthotics. Clark et al advocated a similar timescale, while Goldstein et al stated that most symptomatic issues resolve at one year[2 23 37]. Similarly Zhang noted improvement in terms of pain and kinematics in all patients, (n92) including a cohort of greater than 20mm, when studied over the course of a year[266]. 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.

2.12.2. Operative Correction of LLI

Surgical options for correction of post replacement leg length inequality are dependent on the clinical presentation. Early revision is more likely to be required when there is a nerve palsy compared to cases where mechanical symptoms[162] predominate, although when considering management of nerve palsy it must be remembered that there are many other potential causes of post-operative nerve dysfunction including laceration, compression, traction, ischaemia and thermal damage. There is a risk that any surgery would further endanger these structures[39 233 271].

Revision of prostheses for mechanical reasons should be considered when confirmed as a true structural LLI and following failure of non-operative management.

Although the majority of patients with an apparent leg length inequality tend to have a good outcome 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 arthroplasty)[40]. Ranawat found that two of nine patients with persistent apparent LLI required operative intervention (one soft tissue release only and the other soft tissue release and stem shortening) before symptoms resolved. While 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.

One of the additional problems surgeons face in 2016, is that of a cohort of patients, in particular the younger female, who do not consider a shoe raise acceptable. This has prompted an emerging body of work aimed at preserving a well-functioning hip replacement by resolving the inequality on the contra-lateral side. These cases remain small in number though, and this is not yet considered a mainstream approach.

Bhaskar et al presented a case series of five patients with well-functioning THRs but with an LLI typically associated with management of developmental dysplasia of the hip, and with a mean lengthening of 28mm (25mm to 32mm)[272]. These patients underwent distal metaphyseal shortening osteotomy and fixation with a plate. They reported this to be a viable option providing pain relief in this very carefully selected group of patients for whom a shoe raise was not a tolerable option[272]. Kasis et al published a single case report under similar circumstances where a shortening osteotomy was performed for an LLI of 5cm again as a result of contra-lateral THR as a consequence of developmental dysplasia and where the fixation was performed with a blade plate [273].

In a three-patient series, Thakral et al approached the LLI where the operated hip was longer by greater than 25mm with a contra-lateral lengthening[274]. One patient underwent external fixation and intramedullary nailing and the other two underwent treatment with an intramedullary kinetic skeletal distractor. All three patients progressed to union at the distraction site, without loss of joint function and all patients were reported as being satisfied with the surgery[273].

Mild to moderate neurological injuries may resolve without further treatment. Severe dysesthesias (15% to 20%) are unlikely to improve without surgical correction of LLI[29]. Patients with retention or early return of motor function post-operatively show a greater likelihood of good recovery [162].

The results of surgery for symptomatic leg length inequality do offer the potential for improvement to those refractory to non-operative measures, even when accompanied by a nerve palsy. In Pritchett's series of 19 patients, 17 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 0 to 5mm in all patients. Of the 17 patients, two acetabular cups were repositioned, five modular femoral heads were changed, and in 10 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[29].

Parvisi et al. reported a retrospective review of the results of 21 revisions for symptomatic leg length inequality (hip pain, back pain, pain with foot drop and dislocation) with a mean LLI of 40mm (20 to 70mm)[28]. In 15 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). Mean time to surgery was eight months (six days to six years). Nineteen of 21 patients were satisfied with the outcome of the revision, including three patients with nerve pain (two sciatic and one femoral) and four cases of heterotopic ossification. Of the remaining two, one had persistent back and hip pain while the other continued to sublux and dislocate. 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 THR can provide symptom relief and leave patients satisfied with their outcome. [28].

The level of revisions required also warrants a comment. In the Parvisi et al study they report that they had to revise the cup only in fifteen cases, stem only in three and both components in the remaining three[28]. These findings are in contrast to Konyves et al. who attributed lengthening to the femoral stem in 55 of 56 patients[30].

Stone et al. reported a study involving a cohort of patients suffering from lengthening following total hip replacement that was refractory to non-operative intervention[42]. All patients presented with pain after the hip surgery, as well as symptoms associated with the mechanical features of lengthening. The fourteen patients had a mean pre-operative inequality 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 these fourteen patients who underwent revision for LLI, thirteen had the stem revised and of these thirteen, ten were uncemented stems. Four of the fourteen had the acetabular component revised. Mean improvement of inequality 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 majority of which was back 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 recognized that the pain and mechanical symptoms of LLI following THR 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 operation[42].

A proposed pathway for the management of SLLI is summarized in Figure 2-11.

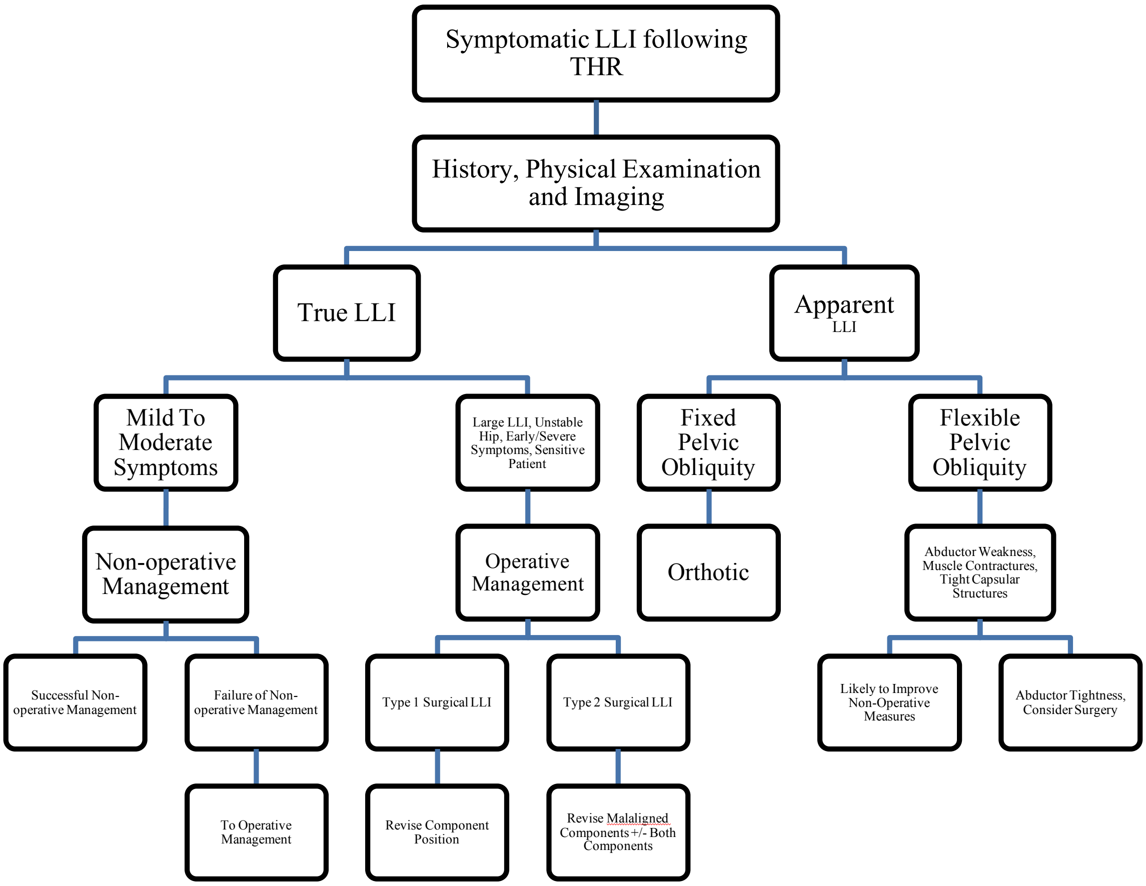


Figure 2-11 A schematic of the pathway for management of a patient with a symptomatic LLI following THR.

2.13. Summary

There has been documented correction of hip disease for nearly 200 years, but it is only in the last 60 years or so that the modern successful hip replacement has been performed. Long term studies demonstrate the excellent outcomes that are possible from the operation.

Through various mechanisms, the complication rate has significantly reduced over the years. This combination of lower complications and better outcomes may be the reason that the indications for THR have broadened to include younger, less debilitated patients. Thus hip replacements are now offered to patients who have higher expectations and with greater demands than before. Consequently, complications such as LLI, which were recognised when the operation was pioneered, but considered less important, have come to greater prominence.

LLI can compromise what would otherwise be a successful operation and result in serious patient morbidity. Patients are more likely to complain of a long leg than a short leg although, a shortened leg can lead to an unstable hip which may itself be cause for revision.

The issue of LLI is clouded by the fact that there is little agreement in the literature regarding the impact of LLI on outcome following total hip replacement, since for any given inequality only a proportion of patients will be symptomatic. Additionally, there is no globally adopted LLI measurement technique, leading to differences in reported values and definitions. While the consensus from the literature appears to be that 10 mm or less is likely to be acceptable, there is little agreement about the importance of LLIs above this value and at what point LLI becomes definitively unacceptable.

A multimodal approach should be employed in both the pre and peri-operative setting, as well as a greater understanding and recognition being given to the symptoms that arise from an LLI following THR in the post-operative review. It is vital that from the beginning patients are made aware of the overall risks of LLI and any factors suggesting that the patient is either prone or sensitive to LLI should be highlighted.

Despite careful surgery, precise matching of the native leg length is at best difficult to achieve in a reproducible fashion. Additionally, without any accepted agreement regarding some of the fundamental issues surrounding LLI following THR, such as validated and practical measurement techniques, definition and understanding of the clinical problem, it continues to be difficult to make progress in understanding and mitigating the issues.

Chapter 3. Litigation for leg length inequality following total hip replacement in the National Health Service

This chapter explores the frequency with which patients litigate against surgeons for LLI following total hip replacement in the NHS.

The results of this work have been published in the Bone and Joint Journal (formerly Journal of Bone and Joint Surgery British Edition) as; McWilliams AB, Douglas SL, Redmond AC, Grainger AJ, O'Connor PJ, Stewart TD, Stone MH. 'Litigation after hip and knee replacement in the National Health Service.' Bone Joint J. 2013 Jan;95-B(1):122-6.

3.1. Introduction

3.1.1. Background

One of the major factors preventing greater understanding of LLI following THR, whether symptomatic or otherwise, is that the incidence is difficult to gauge. Some put it as high as 30%[26]. This is partly due to the absence of an agreed definition. Despite the multi-factorial nature of the causes of morbidity recorded following THR there is little in the literature or registry data regarding the incidence LLI specifically as a direct cause for post-operative problems.

One method of assessing the extent of the current patients' perception of the problem is to study data regarding litigation following total hip replacement. In the United States of America, LLI had been reported to be the single biggest cause of litigation for hip replacement surgery[37].

The National Health Service (NHS) is the major healthcare provider in the United Kingdom. In the 8th NJR report, which published data for 2010, of the 68,907 primary total hip replacement performed in England and Wales, 51,071 (67%) were performed in NHS hospitals, 19,669 (26%) were performed in Independent sector Hospitals, 3, 627 (5%) were performed in Independent Sector Treatment Centres and 2,221 (3%) were performed at NHS treatment centres[275]. Within the latter two groups of centres it is likely that a considerable number of the primary THRs will be funded by, although is not necessarily the direct responsibility of, the NHS. Therefore, any data held by the NHS is likely to take into account at least two thirds of THRs performed in the UK.

The wider issue surrounding the variance of practice that can be associated with litigation has been considered by Briggs et al. First published in 2012 and reviewed in 2015, ‘Getting it Right First Time’ focuses attention of the consequences for patients and the NHS when orthopaedic surgery falls below accepted standards. There is particular concern regarding the increased risk of complications associated with surgeons performing fewer than ten THRs a year. The group also draw attention to the benefits of raising standards to the best in the country. An example being the difference in the national thirty day mortality rate for hip and knee replacements which is ‘4 to 4.5 times greater’ than that seen at Wrightington, a specialist orthopaedic centre[12 146].

Jurisprudence in the U.K., in terms of litigation for medical negligence, is based on the concepts of negligence and causation. Negligence refers to circumstances where a duty of care, either by commission or omission is breached. The ‘Bolitho Test’ is typically applied, which is a refinement of the ‘Bolam Test’, and requires that there is no ‘respectable body of professional opinion’ to support the event. Once this has been ascertained then, for damages to be awarded, a direct causal link, on the balance of probabilities, must be demonstrated between the negligence and the harm that has been suffered[276].

3.1.2. The National Health Service Litigation Authority

There is limited data in the private sector and from medical indemnity insurers[277] regarding litigation for LLI following THR. The National Health Service Litigation Authority (NHSLA) only assumes responsibility for the NHS in England. As the NHS and therefore the NHSLA is a central government funded organization it is subject to the freedom of information act 2000[278] and publishes data regarding the number and value of claims made against it[279-281].

The NHSLA was created in November 1995 to indemnify NHS Trusts in England. From its inception to April 2002 the NHSLA took responsibility only for larger claims. Claims of a clinical nature are handled though the Clinical Negligence Scheme for Trusts (CNST). This was a voluntary risk-pooling scheme where the threshold for NHSLA involvement depended on the CNST excess threshold, ranging from £10,000 to £500,000 GBP depending on the NHS Trust. From April 2002 the NHSLA took over all claims, removing the responsibility from the NHS Trust for the smaller liabilities[279-281].

From November 1995 to March 2010 the NHSLA handled more than 57,000 claims for clinical negligence of all types. Of these 22,400 were related to surgery excluding obstetrics and gynaecology, with a resultant total cost of 1.82 billion, Figure 3-1 and 3-2[279 280]. The NHSLA estimates its' potential liabilities for clinical negligence are in the region of £16.6 billion GBP[279 280].

Figure 3-1 Cumulative Claims Per Medical Specialty from April 1995 to March 2010[280]

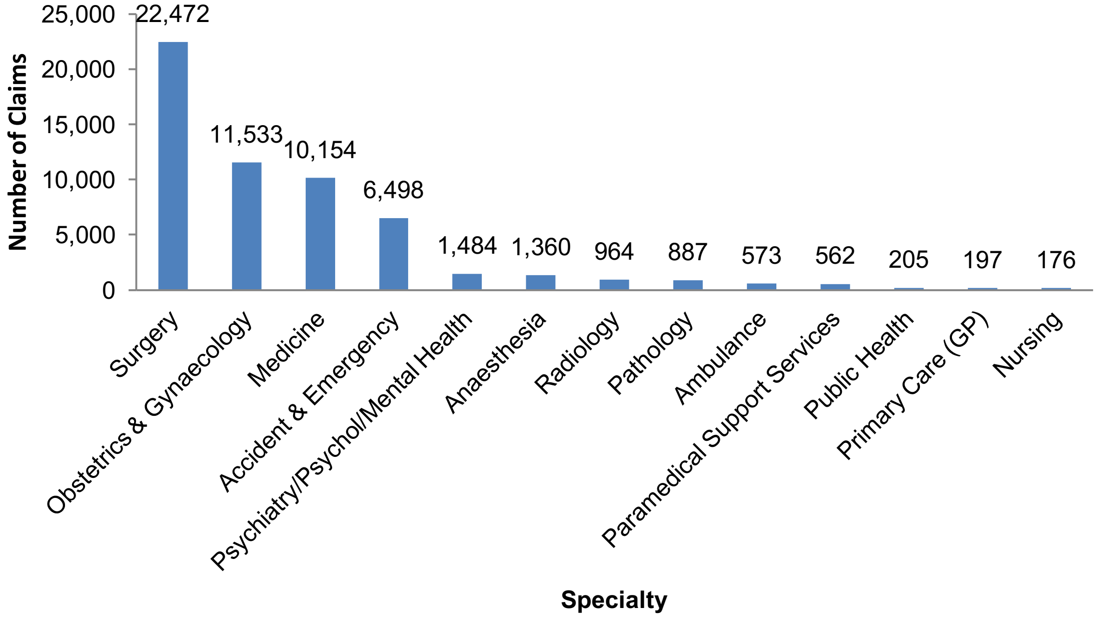
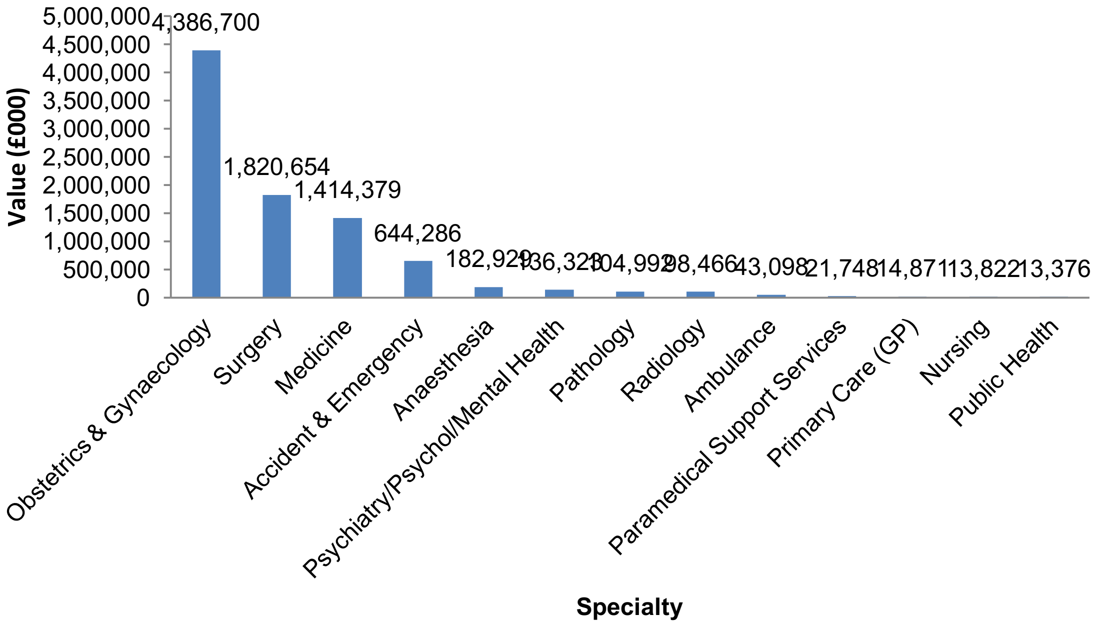


Figure 3-2 Total Value of Claims made to the NHSLA Per Medical Specialty From April 1995 to March 2010[280]



*April 1995 to April 2002 the NHSLA was only responsible for claims above CNST excess

3.1.3. Litigation and Defensive Medicine

Mead studied litigation behaviour between 2008 and 2013. The data showed that orthopaedics (all sub-specialties) accounted for 49% of all claims The number of claims involving orthopaedics and rose by 61%, from 953 in 2008/2009 to 1,588 in 2012/2013[149]. However, over the same time period the NJR reported a 19% increase in the number of primary total hip replacements being performed, with 70,699 in 2008 rising to 84,372 in 2013.[138]. While the litigation data from Mead considered orthopaedics as a whole, not just hip replacements, it does provide some support for the impression that litigation is rising disproportionately faster than the increase in surgical activity.

The perception of rising litigation can lead to an increase in defensive medicine. Defensive medicine occurs when a doctor modifies their practice to act in a way least likely to be sued. While this generally ensures practice within the bounds of safety, it can be at the expense of best-practice and may result in patients being either over investigated or over treated[147 282-284]. It is therefore useful to consider the change in litigation hip replacements over time.

Prior to the work by Mead, both Atrey et al and Upadhyay et al have published work looking at litigation in orthopaedics[148 147]. However, there has been no detailed study of the causes of litigation following THR in the UK.

While LLI following THA was first described clinically by Charnley and Muller when the operation was popularised in the 1960s, LLI has only come to wider prominence more recently[15 226]. It is not clear whether this has been reflected in the pattern of litigation within the NHS.

3.1.4. Total Hip Replacements Performed 1995/1996 to 2009/2010

If litigation is to be considered during a period of time, then it is useful to consider the total number of hip replacements that were performed during that time period. Sheldon et al that noted from the Hospital Episode Statistics (HES) data that in 1994/1995 over 38,000 total hip replacements were carried out in the NHS, with over three quarters being primary[285].

The HES database was conceived in 1987 and since 1989 has been recoding in patient data for NHS England[90]. Since 1999/2000 HES has published details of THRs performed in England under the Office of Population Censuses and Surveys Codes W37, W38 and W39. Prior to this point, although data is recorded, it was not published to distinguish data for a particular operation. Data prior to this is only available via formal written request and incurs substantial fee for data retrieval that is beyond requirements of this work. From the published data between 1999/2000 and 2002/2003 the HES data records that 204,681 primary THRs were performed[286-289].

Since 2003 the NJR has been publishing data for the number of total hips performed along with an overall response rates. The 6th annual NJR reports that from 2003/2004 to 2007/2008 the cumulative response rate was 78% and the total number of THRs declared in the data set were 264,724. This would equate to a total of 339,000 THRs actually performed in that four-year time period or an average of 84,750/year [290]. For the years 2008/2009 and 2009/2010 the sum total recorded by the NJR and adjusted for response rate (91.5% and 92.4% respectively) was 153,000 THRs[291 292].

Therefore, if a linear increase in the number of THRs performed between 1994/1995 to 1998/1999 were assumed, the cumulative total for this missing period would be

173,000. The sum total of THRs performed between 1999 and 2010 – the period covered by this chapter – can therefore be estimated to be 795,000 THRs.

3.1.5. Study Aims

The aim of the work in this chapter is to assess the patterns of litigation for hip replacement surgery against the NHSLA. This study will evaluate the extent of the problem associated with LLI following THR and will be undertaken in three parts to evaluate three aims.

To identify the main causes of complaint leading to litigation and how frequently these are conceded by the NHSLA.

To establish the costs associated with any particular cause of complaint in cases that the NHSLA has conceded.

To explore any a change in the pattern of litigation against the NHSLA over time.

3.2. Methods

3.2.1. Data Collection

A request to the NHSLA was made under the freedom of information act 2000[278] on 4th of August 2010 for data regarding all trauma and orthopaedic related complaints including; year of incident, year of claim and the nature of claim. Additional fields included details of costs arising from the claim and the cause of the costs i.e. whether they are defence costs, claimant costs or damages awarded. The data provided covered the period 1995/96 to 2009/10 and was received on 8th September 2010.

The data was presented electronically on a spreadsheet (Microsoft Excel). A search for all claims using the terms ‘hip’, hip replacement’ and ‘total hip replacement’ was made to identify the relevant cases from the original data. Each claim was then further filtered for pertinence to hip replacement surgery. Terms such as ‘hip operation’ were deemed too ambiguous and as such were not included in this analysis. As each claim included only a brief explanation of the nature of the claim, it was impossible to distinguish the various types of THR (such as resurfacing, minimally invasive, manufacturer etc.) in most cases.

THR cases were further analysed for the specific causes for the litigation according to the groups summarized in Table 3-1.

Table 3-1 Definition of causes for claims made for hip replacement surgery

Neurological Deficit	Any nerve damage cited in claim
Technical Errors	Claims relating to the technical aspects of the operation such as incorrect components/incorrectly inserted, and retained cement
Local Infection	Infection of the surgical site only. (Pneumonia etc. included in miscellaneous)
Miscellaneous	Claims where not specific cause detailed. Also included are low number and rarer causes of claims.
Leg Length Inequality	Claims for leg length inequality
Peri-operative injury	Injuries sustained during the operation such as fractures, burns, lacerations and injuries during transfer.
Pain	Any reference made to pain were included in this category in addition to the cause if detailed
Wrong side surgery	Any surgery mistakenly performed on the contra lateral side
DVT/PE	Where reference to deep vein thrombosis (DVT) or Pulmonary Embolus (PE) was made in the claim
Post-operative care	This group includes all aspects of post-op care such as falls and issues surrounding nursing and physiotherapy care as well as post-op renal failure
Fatality	Where there was death of any cause
Dislocation	All claims citing dislocation
Vascular complications	Any vascular insult including vessel injury and compartment syndrome, some of which resulted in amputation or directly resulted in a death.
Delay	Where there was delay of any cause cited
3M	Claims relating to the 3M total hip replacement[293]
Prosthetic Failure	Including ceramic fracture or where a specific allegation of failure of prosthesis was made

As a suit for negligence may arise from cumulative dissatisfaction, many claims referred to more than one cause of complaint, meaning that there are more ‘causes’ discussed than individual claims. Consequently, an individual’s claim may appear more than once in the data as each cause will be included separately.

3.2.2. Cumulative Causes

Data provided by the NHSLA described claims as open or closed. Claims that are defined as “open” were ongoing at the time of disclosure and had not reached final settlement. Claims that are closed have reached their final conclusion and no further financial consequences anticipated.

In this part of the study only the closed cases were reviewed. These cases were then arranged by cause (as opposed to whole claim). The cumulative totals for each complaint as detailed in Table 3-1 were then calculated.

These totals by cause were further divided into paid out and not paid out. Not paid out claims were taken to those claims that were taken to completion and where the NHSLA has only had to cover its’ own costs. Claims that were ‘paid-out’ were those where the NHSLA assumed not only its own costs but also conceded claimant’s cost, damages or both. This very specific definition was used so that in cases where, for instance, any morbidity was self-evident, responsibility was immediately assumed by the NHSLA and settlement was reached without the defendant having to recourse to their own legal team.

No data were provided by the NHSLA in terms of outcome in law. It is important to state that there is no information in the data regarding circumstances of settlements, court proceedings or judgements, so the definitions used here are provided for the purposes of interpreting this research and not in any strict legal sense. Terms referring to cases being 'won' or 'lost' as well as extent of liability or co-liability were avoided as the data would not support such conclusions with specific legal meanings.

3.2.3. Costs of Litigation

The sub-group of those closed claims, arranged by cause, that were paid out were then further analysed. The total costs of each cause of claim was the sum of the defence costs, claimant's costs and damages paid. This allowed an arithmetic mean of the total costs to be obtained as well as a maximum total cost. Additionally, the total cost of each cause was calculated by the sum of all associated costs (defence's, claimant's and damages).

3.2.4. Pattern of Litigation Over Time

For the third part of this study, these data for the causes (as opposed to claims) was reorganized. A chronological half way point divided the data into two periods, 1995/96 to 2002/03 and 2003/04 to 2009/10, this latter time period including both open and closed cases. The cumulative numbers for each cause were analysed for each time period and those for the same cause compared in the first versus second time period and providing an indication of any chronological change in litigation behaviour.

3.3. Results

3.3.1. General results

From 1995 to 2011, the NHSLA dealt with 22,500 claims relating to surgery (excluding obstetrics and gynaecology) with costs in excess of £1.8 billion. Some 8,950 (40%) of these claims were related to trauma and orthopaedics with a cost of £402 million (22% of the total in this group of surgery).

Of these trauma and orthopaedic related claims, 1,004 (11%) claims were associated with hip replacement surgery and within these 1,004 claims, a total of 1,156 causes of complaint were cited. The total cost of these hip replacement claims was just over £41 million (10% of the overall cost).

At the time the data were obtained there were 136 claims still ‘open’, representing approximately 13% of all the lodged claims.

3.3.2. Causes cited in claims

The results for the causes of cited claims versus claims paid out are summarised in Table 3.2. Neurological deficit was the most commonly cited, being involved in 136 claims, although with only 46% of these being paid out it is amongst the lowest in terms of proportions of successful litigation on the part of the claimant. Conversely the two least frequently cited causes of litigation, vascular injury and wrong-site surgery have the highest proportion of claims paid out. LLI following THR is the fifth most commonly cited cause at 44%, is, alongside pain in terms of percentage paid out.

Table 3-2 Total number of times an individual cause is cited in the complaint and the number paid out.

Category	Total Closed Claims	Number Paid Out	% Paid out
Neurological Deficit	138	63	46
Technical Errors	123	84	68
Infection	113	52	46
Miscellaneous	101	38	38
Leg Length Inequality	100	44	44
Dislocation	71	36	51
Peri-operative Injury	68	38	56
Post-op Care	63	39	62
Delay	55	25	45
Pain	43	19	44
3M	34	1	3
DVT/PE	32	16	50
Prosthetic Failure	32	16	50
Fatality	31	21	68
Vascular Injury	10	7	70
Wrong Side	4	3	75

3.3.3. Costs associated with litigation

Details of the costs associated with litigation are detailed in Table 3.3. The mean total cost of contested cases was £98,000 (£1,050 to £1,052,500). Vascular surgery has both the highest mean cost (for claims that have been defended then paid out) as well as the highest cost for an individual claim. In terms of the total costs for all claims involving a particular cause, technical error is the most expensive at just over £9.5 million. Wrong-site surgery is the cited cause of claim that resulted in the lowest cost in terms of mean claim, for individual claims and for total claims.

LLI following THR at eighth out of the 16 causes of claims, was mid-way in terms of mean cost per defended-and-subsequently-lost claims, but is fourth for cost of its highest value claim. Claims that have cited LLI following THR have, to date, a total cost of nearly £3.9 million.

3.3.4. Pattern of litigation over time

The changes in litigation patterns over time are summarised in Table 3.4 and includes details of the number of THR performed during the two time periods using the HES/NJR data from Section 3.1.4. The most commonly cited cause of litigation over the two time periods changes from technical error to neurological deficit. Over the same period, the number of peri-operative injury claims doubled from five to 10%. There was no change in the proportion of claims for LLI in the pre and post 2003 groups.

Table 3-3 Summary of Claims data for Hip Replacement Surgery

Cause of Claim	Mean Cost*** £ GBP (nearest £100)	Highest Cost** £ GBP (nearest £100)	Total Cost for all claims
Neurological Deficit	116,800	384,500	7,470,000
Technical Error	111,700	814,500	9,531,000
Infection	138,600	639,700	7,466,000
Miscellaneous	107,000	531,600	4,007,000
Leg Length Inequality	84,000	595,000	3,872,000
Peri-op Injury	48,200	131,900	1,907,000
Dislocation	105,200	448,300	3,867,000
Post-op Care	59,500	466,900	2,380,000
Delay	39,100	324,300	1,030,800
Pain	111,700	448,300	2,161,000
Fatality	49,300	207,800	1,072,000
DVT/PE	58,300	292,000	969,000
Prosthetic failure	81,000	354,800	1,327,000
3M	46,600	46,600	56,000
Vascular	375,800	1,052,500	2,631,000
Wrong Site	17,400	24,400	52,000

* refers to % of total claims that incurred claimants cost and or damages
** includes all costs, defence, claimants and damages
***mean cost of contested claims subsequently lost

Table 3-4 Comparison of data pre and post 2002/3 for hip replacements %(n)

Cause of complaint	1995/96 to 2002/03	2003/04 to 2009/10
Number of THRs performed	303,000	492,000
All causes	575	581
Technical Error	13(72)	11(66)
Neurological Deficit	12(71)	15(88)
Infection	11(65)	12(68)
Miscellaneous	10(55)	12(69)
Leg Length inequality	9(49)	9(51)
Post-operative Care	6(36)	6(35)
Delay	6(34)	4(25)
3M	6(34)	0(0)
Dislocation	6(34)	8(45)
Peri-operative injury	5(29)	10(57)
Pain	5(27)	4(22)
DVT/PE	4(22)	2(14)
Prosthetic Failure	4(22)	2(14)
Fatality	3(17)	3(19)
Vascular Injury	1(8)	1(5)
Wrong site	0(1)	1(3)

3.4. Discussion

3.4.1. General

Due to the inherent difficulties in definition and lack of consensus surrounding LLI following THR there is little reliable data indicating the frequency with which this complication occurs. Additionally, some of the signs and symptoms associated with LLI following THR can have other causes. For example, a LLI that results in a traction injury to the sciatic nerve might result in a complaint relating to either pain and or neurological deficit that is not necessarily attributed directly to the LLI. There is difficulty therefore in assessing the extent of the problem for patients with symptoms. In this study litigation following hip replacement surgery was used as a surrogate for comprehensive clinical or epidemiological data.

The NHSLA has been responsible for managing just over 1000 claims regarding hip replacement surgery - since its inception in 1995 for the larger claims, and from 2002 for all claims. Accounting for 11% of the total number of claims and 10% of the total cost, hip replacement surgery constitutes a considerable part of the litigation in orthopaedics.

While there are limitations in the methods used to estimate of the total number of THRs performed there has been an assumption of a steady progression from 1995/1996 to 1999/2000. The HES data is limited in that it is collected by NHS England only and does not include joint replacements performed in the private sector. The NJR data has a wider catchment and also provides an estimation of response rates. The total number of THRs performed over the time period covered in this chapter should be considered an estimate only and because of the conservative approach taken is likely to represent a lower estimate.

Therefore, this study has demonstrated that just over 1000 claims involving hip replacement surgery were made between 1995 to 2010 and over the same time period an estimate of nearly 800,000 THRs were performed. This equates to litigation arising from 0.0126% or 1 in every 8000 hip replacements performed.

3.4.2. Cumulative Claims

The results for the closed claims provides an interesting perspective on the causes of claims and the associated likelihood of success. While the act of making a claim is not evidence of negligence, those claims more likely to be self-evidently negligent represent the largest proportion paid out. The top four are wrong-site surgery, vascular, technical error and fatality. It is of interest that the most frequent cause cited in claims, neurological deficit, is amongst the lowest individual causes for numbers paid out.

Neurological deficit can be a devastating post- operative complication that can result in lifelong disability and pain. It is however a well-recognised post-operative complication that should be discussed with the patient prior to any decision to proceed to surgery and is included in the standard consent process[294]. It is possible that because it is well recognised as a complication and that it is associated with multiple possible causes, it is relatively difficult to establish negligence, which may in turn account for the lower rate of claims paid out.

The second most commonly cited cause, and one of the most consistently paid out, is technical error. While this is not a homogenous group, a major theme was incorrect positioning of the implants. There are two important factors that coincide in this group to make as often cited and paid out as it is. Many of the causes of technical error are identifiable on imaging. For instance, an incorrectly positioned implant diagnosable on plain radiograph. In circumstances such as this, there is little room to dispute causation. Also, while technical error does happen, it is rarely something that could be considered a 'recognised complication', where a complication occurs despite the surgeon's best effort. Therefore, technical error, as defined in this study, often occurs in circumstances that fall below recognised standards of care. Thus, negligence is less in dispute. These data further highlight the importance of avoiding technical error and is one of the major themes of "getting it right first time" [12].

In this study LLI following THR was the fifth highest mean cost cause of claim, if the category "miscellaneous" is disregarded due being regarded as a 'multiple reason' category, LLI lies fourth. At 44% of cases paid-out, LLI, along with pain is the second lowest cause for pay-out lying behind the 3M capital hip. The circumstances of the 3M capital are now historical and were associated with specific problems surrounding the design of the hip system. As such 3M assumed much of the costs associated with the matter, hence the very low (3%), pay-out for the NHS[293]. If this category is set aside, then LLI following THR has the lowest rate of pay-out, alongside pain, of all the causes of litigation in this study. It is likely that the previously highlighted issues surrounding poor understanding of the issues and lack of consensus regarding LLI definition following THR are a major contributing factor to the difficulty in establishing, on the balance of probabilities, that there was both negligence and causation.

3.4.3. Costs incurred

When reviewing the cost of claims per cause, this includes claims that have multiple causes for complaint. An example is a case that cited a combination of pain, LLI and dislocation, that resulted in it being the highest cost case in two of the three categories (pain and dislocation). It is impossible from the NHSLA data to disentangle the individual cost of each contributing factor. This illustrates the multifactorial nature of morbidity resulting in some claims. This has a similar effect in the total cost category. The data from this part of the study allows some conclusions regarding the cost of a successfully brought case for each category.

It is not surprising that the more devastating and long lasting symptoms associated with any given cause result in the greatest mean and highest total pay-outs. In this study, vascular complications, though rare, were more expensive than the next costliest by nearly £240,000 for both the mean and the highest cost.

What might be surprising is the relatively low cost of wrong-site surgery. Wrong site surgery is described by the UK department of health as a 'never event' which is defined as 'serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers'[295]. It is difficult to defend and is reassuring therefore that this is the lowest occurring cause of claim. Conversely it is surprising that, with the potential to cause lifelong problems, wrong site surgery is the least expensive in terms of mean and highest cost.

The average pay-out for LLI following THR was just below the overall mean at £97,000. This may reflect the difficulty in ascribing a causal relationship to particulars of the complaint. The most significant finding however was the fact that LLI resulted in the fourth highest single case cost. The case that resulted in that total cost was for LLI only, with no other causes cited. This establishes the fact that, although difficult to define and demonstrate a link to the symptoms, where it is clear that the symptoms are associated with an LLI following THR, the symptoms can be devastating for the patient and result in major disability and loss resulting in a requirement of substantial damages. This may explain why legal teams go to so much effort to defend these cases.

3.4.4. Pattern of Litigation over time

When comparing the patterns of litigation over time, despite a near doubling of the numbers of THRs performed over the course of the study, there has not been a marked increase in litigation between the 1995/96 to 2002/03 and 2003/04 to 2009/10 time periods. These results therefore do not support the assertion made by Mead, that litigation is increasing in frequency relative to the increase in orthopaedic activity[149].

The pattern of litigation over time in this study, in relative terms, indicates that there has been a sizeable decrease in cases brought to the NHSLA. If the total number of claims considered alongside the number of hip replacements performed the rate of litigation reduces from 1 claim per 530 THRs in the 1995/96 to 2002/03 time period, to 1 claim per 850 THRs in the 2003/04 to 2009/10 period. This may reflect the increasing experience with the operation, increasing subspecialisation and an increasing awareness of the issues that consistently arise in litigation.

Looking specifically at LLI, there has been an increase of only two claims, from first to last time point. The change in litigation for LLI between the two time periods has reduced, from 1 per 6,200 THRs performed in the 1995/05 to 2002/03 period, to 1 claim per 9,600 THRs performed in the 2003/04 to 2009/10 time period. Although there are many issues in identifying negligence and causation with LLI following THR, this relative reduction in claims over the investigation lends further weight to the argument that surgeons are making increasing efforts to reduce the incidence of this complication.

There have been some notable changes in cited causes of claims in the two time periods. Peri-operative injury increased from 5% (71) to 10% (88) and Neurological deficit (increase from 12% to 15%). This may be associated with a more active and a more aware patient population who would be find their typical pastimes and activities of daily living affected by any given complication than in the earlier, 1995/1996 to 2002/2003 time period.

3.4.5. Limitations

A limitation of this work is the use of litigation data as a surrogate for gauging the extent and impact of complications around THR. Litigation will only highlight those patients who are so dissatisfied that they to seek medico-legal redress. It will not include those patients who are symptomatic as a result of an LLI following THR and are successfully managed by physiotherapy or a shoe raise. The likelihood of litigation may be a reflection of the severity of the perceived level of injury. For instance, a total hip replacement that causes a vascular injury that results in an amputation is perhaps more likely to end in litigation and if proven, greater settlement, than a straightforward LLI with mechanical symptoms even when problematic enough to seek redress. Litigation data may be skewed towards these more consequential problems, particularly in the time period before 2002 when the NHSLA assumed responsibility for all claims. Prior to a claim being dealt with by the NHSLA, an attempt to deal with this will be made at a local level. This may result in a complaint not proceeding to a claim and could also result in the data under- representing the problem.

From the above, the use of litigation data alone is likely to underestimate the data relating to extent of LLI after THR.

A greater level of scrutiny of dis-satisfaction would only be identified using patient reported satisfaction and outcome scores and, for the purposes of studying LLI following THR would have to be linked to an agreed method of measurement of LLI. Currently there are no published studies that have identified this level of dissatisfaction due to LLI and as such, while litigation data has clear limitations, over the time period in question, it is the only data available that reflects the practice of the hospitals covered by NHS England. The relative infrequency of litigation as a whole and LLI in particular, any survey data would require a large patient cohort to provide meaningful results.

While the NHS is responsible for the majority of hip replacement operations in the UK, some one-third of THRs are performed in either the private sector or in independent sector treatment centres. Approximately half of the hip replacements performed in the independent sector were funded from outside the NHS[296]. These non-NHS funded operations will not be covered by the NHSLA scheme, nor the freedom of information act, and do not appear in the NHSLA data. It is likely therefore that the figures presented in this work would represent an under estimation of the total extent of litigation for hip replacements in England.

One limitation of this study relates to the information attached to each claim. The NHSLA data is intended primarily for claims management rather than for clinical analysis. The comments attached are limited therefore to the main points of the claim. It is impossible therefore to differentiate between the various types of hip replacement operation, such as for example, resurfacing arthroplasty using a metal on metal bearing, an operation that underwent a rise in popularity followed by a dramatic decline when it became clear that there were major specific complications arising[297].

Additionally, it is not possible to ascertain the particulars of the claim with reference to a sequence of events. There are a number of reasons that LLI following THR can result in a claim. LLI can be the only cause of dissatisfaction following what would have otherwise been a successful operation. Also, an LLI that although unsatisfactory, might not itself lead to a claim, but subsequent revision surgery performed to correct the inequality may result, either in failure to achieve its aim leaving a persistent LLI, or the operation may have resulted in a different complication that, but for the initial LLI would not have happened. Furthermore, a revision THR may have been performed for another reason (e.g. aseptic loosening) and the patient has an LLI following this revision surgery. None of these more nuanced associations are discernible from the short summary, other than to say that LLI was involved as a cause for claim.

Time delay of the claims may be an issue in this study. While the change over time identifies only a small increase in total numbers of litigation, it does not take into account claims that have not yet been made. Under normal circumstances there is a time limit of three years between incident (or the patient becoming aware of the problem) and a claim being brought[298]. This will mean there are likely to be further claims for this time period that were not included in these data. While this additional level of litigation is hard to predict, as there has been a near doubling of the numbers of THR being performed in the time frame of this study, there would have to be a substantial increase in claims for the data to support an increase in litigation behaviour relative to the numbers of hip replacements performed.

In NHSLA litigation data there is there is no information regarding co-liability. It is possible that that there were confounding factors whereby a patient had a reasonable claim but other external factors resulted in the NHS not being deemed wholly liable. An example of this would be claims associated with the 3M capital hip, where significant liability was borne by a third party.

The U.K. operates an adversarial system whereby, for a claim to be successful, both negligence and causation must be established. Other countries such as New Zealand have a 'no-fault' system where this is not required[299]. It is possible therefore that under the U.K. arrangements, a recognisable complication can arise as a result of surgery but if either negligence or causation are not be established then this may result in a claim failing or indeed never being taken forward.

3.5. Conclusion

The aim of this study was to use litigation data to gain further insight into LLI following THR. While using litigation has significant limitations, in the absence of prospective studies or epidemiological datasets there is much that can be drawn from this study. This study also provides an interesting insight into the more general state of litigation surrounding hip replacement surgery within the NHS.

The main conclusions are: Litigation following THR is not common with only 1,004 cases stemming from approximately 800,000 THRs performed between 1995/1996 to 2009/2010. Of these 1004 claims, 100 were in relation to leg length issues which equate to 1 in every 8,000 cases. The top four 'single cause' categories i.e. causes that have not been grouped together such as miscellaneous or post-operative care, were neurological deficit, infection, LLI, and dislocation. These four would be well recognised by any specialist hip replacement surgeons since the operation was pioneered in the 1960s and are specifically detailed in the BOA consent form[294]. The persistence of technical error remains one of the most consistently cited and paid out causes for claim. Although patients can be counselled prior to any operation that a good result cannot be guaranteed, technical errors cannot be considered nor defended as a recognised complication. While no surgeon would set out to perform such a mistake, it provides further evidence to support a safe and reproducible practice.[12].

This study does not support the common assertion that litigation has increased dramatically since 1995. The results show that although the total number of claims is approximately the same between the two time periods, there has been an increase in the number of THRs performed. Therefore, litigation arising following THR has actually decreased between the two time periods[300 301].

This study confirms that, within the claims relating to hip replacement, LLI following THR is a significant problem. 10% of all causes of litigation for hip replacements were associated with the complication and, while relatively speaking the rate of successful claims was amongst the lowest and mean cost of claims was just below the average for all causes in the study, LLI can be associated with a huge cost for an individual claim. Total costs for claims citing LLI following THR between 1995/1996 and 2009/2010 are approaching £3.9 million.

LLI is an important cause of morbidity following THR and it can be potentially devastating. This study, using litigation as an indirect indicator of the prevalence and impact of LLI following THR lends weight to the view that this complication can be a source of harm to patients while also presenting a financial liability burden to the NHSLA. Good prospective and epidemiological studies are required to provide better detail on the prevalence and consequences of this complication following hip replacement.

Chapter 4. Reproducibility of Methods of Radiographic Measurement of Leg Length Inequality Following Total Hip Replacement

This chapter explores the methods employed to measure LLI following total hip replacement. The work compares the two most common techniques in the literature with two novel methods.

One paper has been published as a result of this work (Appendix C);

Assessment of the reproducibility for radiographic measurement of LLI following THR

McWilliams AB, Grainger AJ, O'Connor PJ, Redmond AC, Stewart TD, Stone MH.

Hip Int. 2012 Sep-Oct;22(5):539-44. doi: 10.5301/HIP.2012.9751.PMID:23100154

4.1. Introduction

4.1.1. Background

Residual LLI following an otherwise successful arthroplasty can result in considerable morbidity, patient dissatisfaction and the potential for litigation [19 26 28 39]. This can manifest as mechanical symptoms, pain or neurological compromise[25 31 32 34 35 39 183]. Ultimately, symptomatic leg length inequality as a result of a total hip replacement may require a revision operation, with all of the associated risk and further morbidity[39].

It is evident from the literature however, that the association between LLI following total hip replacement and symptoms is neither clear nor absolute[16-18]. There is little consensus regarding definition, measurement, extent, significance or patient perception of LLI[16 26 302 303]

4.1.2. Measurement of LLI

Although a clinical suspicion of LLI would normally be first raised when taking a history, quantitative assessment occurs initially during the physical examination. This can be undertaken clinically by tape, ruler, or block measurement of true and apparent leg length, followed by clinical assessment to ascertain in which part of the lower limb the inequality arises. This is in a context of multiple studies showing clinical measurement to be inaccurate by 10mm or more[1 20 163 304].

It is important therefore, particularly if informing surgical decisions, that any LLI is quantified accurately. Typically, this is done through radiology either via plain X ray or where there are greater concerns using CT or other modalities.

A plain AP radiograph of the pelvis and both hips is usually ordered as a routine part of the consultation so it is the usual initial method of radiological assessment of LLI. [202]

As explored in the review of the literature in Section 2.8.2.2, CT scanography has advantages of lower dose of ionising radiation when compared with the other methods of radiographic measurement of whole limb LLI such as, teleorentgenogram (standing full length AP radiograph), orthoroentgenogram (three calibrated radiographic exposures at the hips knee and ankles), scanogram (plain radiographic technique similar to orthoroentgenogram but where the whole limb, not just the joints are imaged)[46]. CT scanography also has better reproducibility and, particularly when combined with a lateral scan for fixed deformity, at least comparable accuracy[46 199 201]. The technique has been used as the gold standard in research and is considered the imaging modality of choice in complicated cases[46 204 209 210].

However, it is impractical from a clinical point of view to perform CT routinely as it requires the patient to be referred to the local radiology service, attend for the imaging and return to the orthopaedic clinic for a further appointment to discuss the results[46 206].

Plain X ray remains therefore, a key approach to quantifying LLI in the early stages of post-operative clinical decision making.

4.1.3. Importance of assessment of LLI following THR

Accurate assessment of LLI is important for both preoperative planning and post-operative assessment. Failure to do either adequately may risk an underappreciated and perhaps asymptomatic LLI becoming a problem, or post-operative symptoms being ascribed inappropriately to another cause. Additionally, as has been demonstrated in the last chapter, LLI following total hip replacement can have significant medico-legal consequences[305].

As detailed in Chapter 2 of this work, Parvizi et al. describe a classification of LLI following THR based on the likely cause. Type 1 arises where the components or their positioning are directly responsible for the inequality, Figure 4-1. Type 2 occurs when the lengthening is secondary to a problem with the component position, which is causing instability. One of the intra-operative methods to improve stability is for the surgeon to increase soft tissue tension by deliberately lengthening across the hip joint by not completely inserting the stem, Figure 4-2[28]. Failure to appreciate the fact that the stem is proud in the femur to compensate for a stability problem arising from the cup being sited high, could result in revision of only one of the components and risks further instability and dislocation of the revised hip[262]. It is for this reason that a method that is able to distinguish between post-THR LLI arising from the cup or the stem, individually or in combination, would be an advantage.

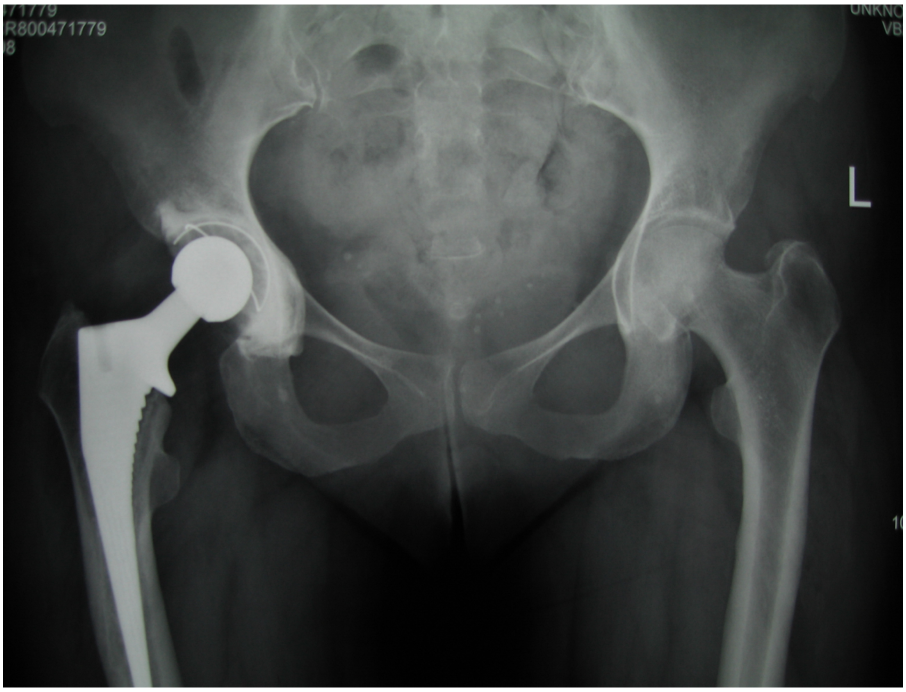


Figure 4-1 radiograph of a total hip replacement where the femoral stem is too long resulting in a type 1 true leg length inequality.

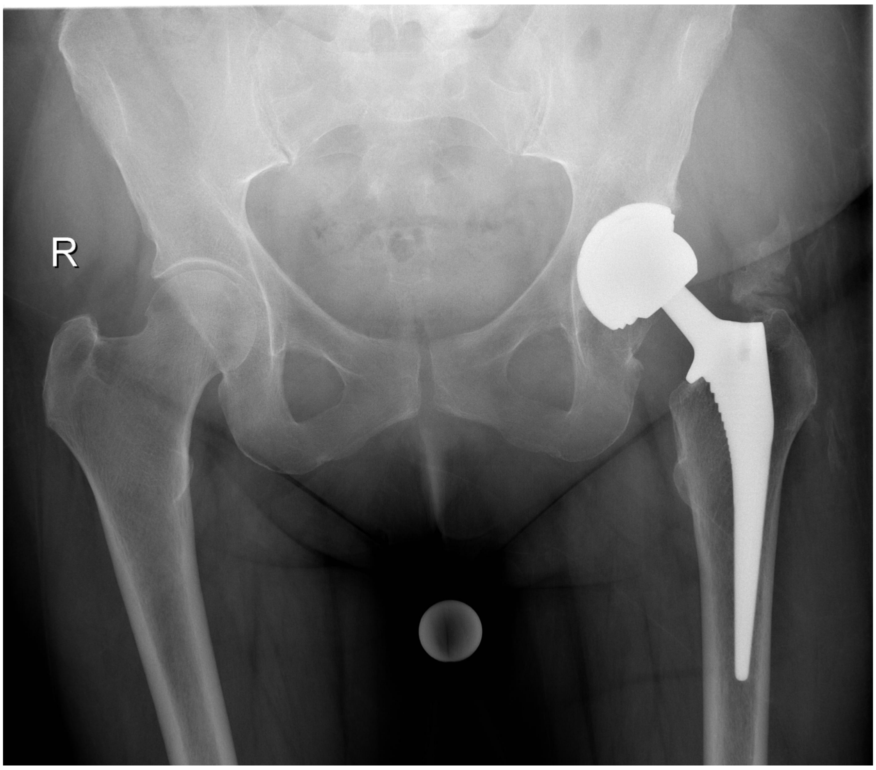


Figure 4-2 Example of a type two LLI. The acetabular component has been malpositioned and risks dislocation. Therefore, to obtain satisfactory ‘on table’ stability the femoral stem has been positioned to produce a lengthening, increasing the soft tissue tension and thus reducing risk of dislocation.

4.1.4. Methods used to measure LLI on plain radiograph

While many methods of measuring LLI following THR have been detailed, two methods appear in the literature consistently. Method one, first published by Williamson and Reckling in 1978 describes a technique in which the interischial line (II) is used as a reference to adjust for pelvic obliquity. The perpendicular distance from this line to the most medial projection of the lesser trochanter (LT) is measured and the distance between the two used to assess any inequality around the hip, Figure 4.3[45]. For the purposes of this study this will be referred to as the II-LT method. The second, described by Woolson, Hartford and Sawyer, creates a reference from the inter-teardrop (TD) line and uses a perpendicular measurement to the most prominent part of the lesser trochanter, Figure 4-4[3], the TD-LT method. The authors of this second method suggest that the TD is preferable to the inferior ischium as it is a more discrete radiological landmark and less prone to errors due to pelvic tilt[3 193].

In the review of the literature, of the fifty-six papers that detailed the method of measuring LLI following THR. Seventeen employed the Williamson (Il-LT) method [20 26 28 29 44 45 171 190 191 196 215 225 233 235 247 251 252 262 267] and thirty two, the Woolson (TD-LT) method[3 16 22 23 194 195 212 214 216-218 220 222 223 225 228 234 237 238 244 248 256 257 259 260 266 268 269 306 307]. The remaining papers in the review used either varying techniques such as CT[246], x-ray scanogram[163 197], a mercury spirit level[24], or a range of different radiographic points[17 30 213 227 302].

It is relevant to note that while both the TD-LT and II-LT methods have been described as “validated”, there is little evidence published of any process to demonstrate this. Woolson et al. quotes an inter-observer “variation” of 0.5mm but does not support this

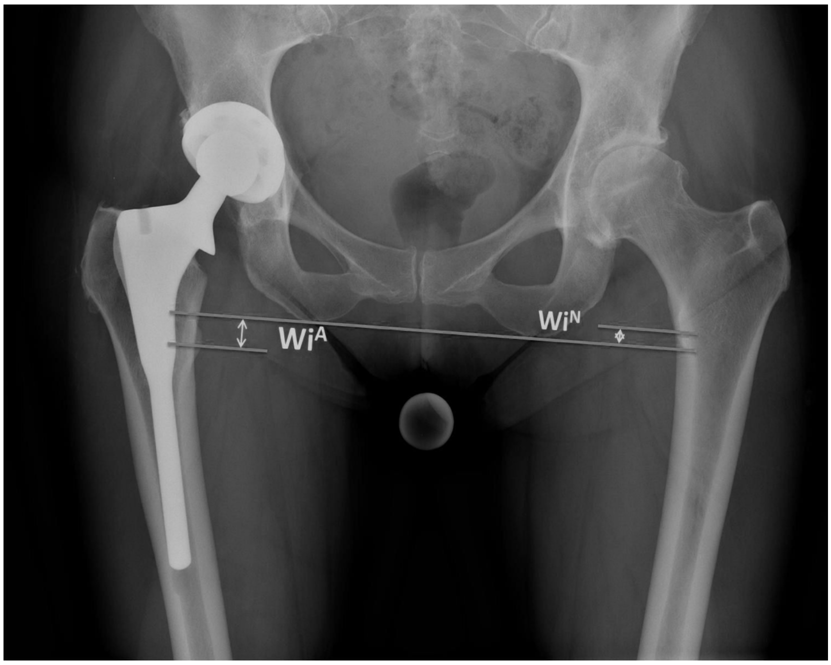


Figure 4-3 The II – LT method.
Described by Williamson et al., reference line tangential and parallel to the most inferior portion of the ischia. Two further parallel lines are drawn and the perpendicular distance between the lines measured, the difference between the two measurements (WiA – WiN) is the LLI.

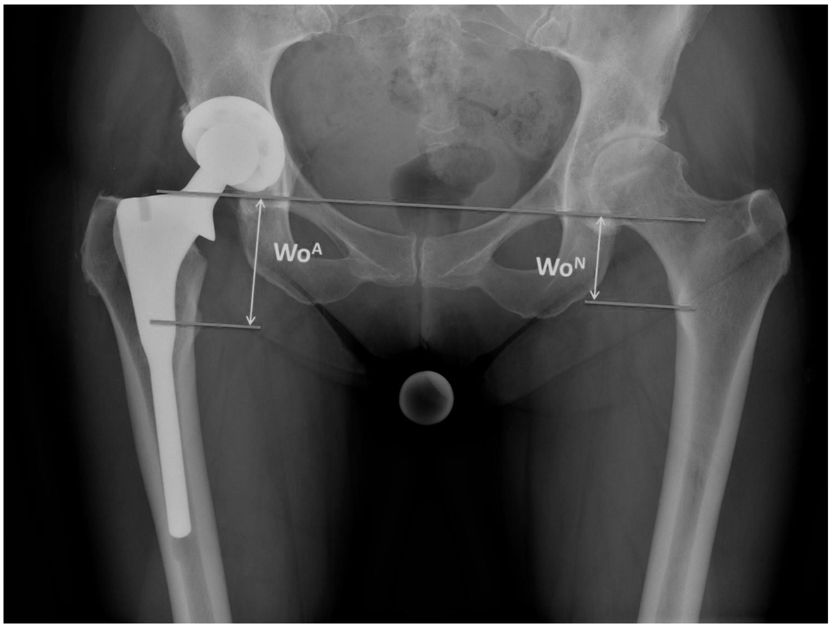


Figure 4-4 The TD-LT method.
Described by Woolson et al., a reference line is drawn through the most inferior part of the acetabular teardrops (T). Two lines parallel to this are drawn through the centre of the lesser trochanter (LT). The difference in the perpendicular distance between the two lines (Wo^A – Wo^N) is defined as the leg length inequality

with data[3]. Williamson tested the II-LT method by re-measuring the un-operated side and reported that there was no statistically significant difference in these measurements. There is little detail regarding how this study was constructed.[45]

It is only more recently and, subsequent to the studies reported in this thesis, that other groups have published work investigating the reproducibility of different methods of plain radiograph measurement of LLI.

Meermans et al. studied four radiographic landmarks, the centre of femoral head and lesser trochanter as femoral references, and the inter-teardrop and the inter-ischial lines as pelvic references. The group found the inter-ischial line to be statistically significantly less reliable as a pelvic reference, compared to the inter-teardrop line. There were no significant differences between the two femoral references. All measurements made with these points yielded intra-class correlation co-efficients for intra-observer reproducibility of greater than 0.8. All performed less well in terms of inter-observer error with the II-CFH measure being best performing[308].

Heaver et al. analysed 100 pelvic radiographs using four intra-pelvic references; teardrops, ischial spines, inferior sacroiliac joint and the ischial tuberosities. Measurements were made at both the greater and lesser trochanter. In disagreement with Meermans et al. however, Heaver et al. found the inter-ischial line to be the best performing of the pelvic reference points and the lesser trochanter the best landmark for the femora. In their study the II-LT approach also yielded the narrowest standard deviation[308 309].

In addition to the methods detailed above, two other methods have been used in Leeds Teaching Hospital NHS trust to measure LLI following THR. First, a method which does not use perpendicular lines but which measures the straight line distance between the centre of femoral head (CFH) to the medial apex of the lesser trochanter (LT) – the CFH-LT method, Figure 4-5. As this method requires no reference line, it is a technically a little easier and quicker to perform.

As this method is a function of i) the vertical distance between the centre of the femoral head and lesser trochanter and ii) the femoral offset, it cannot however be accurately described as a true measurement of the LLI in this context. In reality it is a measure of any change in length and offset due to the femoral stem and not the acetabular cup. For instance, a large change in the offset, even without any change in the CFH to LT distance, will still register as an increased leg length in this measure. Its utility is based on its ease of use for a 'quick estimate' which is predicated on no major change in the femoral offset following the THR and, as this method only assess changes to the femur, it will not account for any effect of the positioning of the acetabular component. It is therefore not a true measure of an LLI due to THR and as such it should be used with caution.

The second method identifies the contributions of the cup and stem to the overall LLI. The cup position is assessed by the CFH to TD distance and the stem component from and the stem contribution by the CFH to LT distance.

This second method uses an initial reference line drawn between the two centres of femoral head, then measures the perpendicular distance to the teardrop (TD) on each side and the distance to the centre of the lesser trochanter, thus referred to as the CFH-LT-TD method Figure 4-6. These reference points on the radiograph have previously been described by Knoyves and Bannister in 2005 as well as Eggli in 1998[30 213].

This component based CFH-TD-LT measurement was developed because it can be used to differentiate the contribution to any LLI following THR, of either or both of the acetabular component or the femoral component. For example; if the replaced limb is lengthened (and therefore the TD-LT measure will be greater) and it is due to the stem, then measurement CFH-LT component of the CFH-TD-LT method in particular, will be greater in the operated limb.

If, however, the acetabular component has been placed ‘high’, then the CFH-TD distance will be greater. If this was the only source inequality i.e. the CFH-TD measurements were the same on both sides, there will be an overall shortening and the TD-LT measure will be shorter on the operated side.

Although slightly more complicated, it is helpful when using this method to consider each component part with the corresponding measure on the contra-lateral side and not to simply compare the overall TD-LT measurements. It is possible with this method, where the component parts can be independent of each other, that the two can neutralise each other i.e. that the acetabular component is placed ‘high’ (and the CFH-TD measure greater than the non-operated side), but that the stem is used to lengthen the CFR-LT measure so that the overall result demonstrates little or no LLI.

This method has the particular advantage of aiding discrimination of the cause of any lengthening, a nuance not provided by the other methods in this study. However, the validity of this component based measurement technique has not been demonstrated as the CFH-TD-LT method, along with the CFH-LT, has not been subject to any comprehensive process of validation.

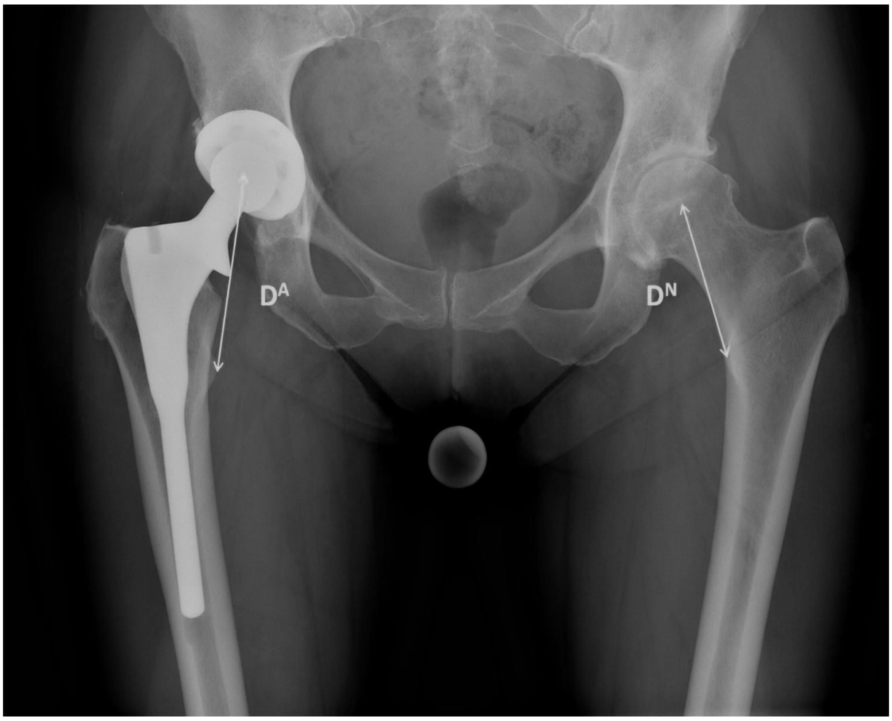


Figure 4-5 The CFH-LT method

The CFH-LT method is a measure of the straight-line distance between the centre of femoral head and the lesser trochanter.

These are the same reference points as used in the CFH-LT component of the CFH-TD-LT method. However, the CFH-TD-LT measures the perpendicular distance between the reference points which are on both the pelvis and femur, as such it can give a measure of the LLI following THR.

The CFH-LT measurement method is a function of both the change in femoral offset and vertical positioning of the stem. No account is made for any change in leg length due to the acetabular component and therefore the CFH-LT method is not a measure of LLI following THR. The CFH-LT method's ability to accurately assess change in leg length is based on the conclusion, made by Konyves et al, that lengthening is predominantly due to the stem and therefore any change in the leg length due to the acetabulum would be small[29]. When this is combined with the CFH-LT methods ease of use, the utility of the technique is as a 'quick check' assessment of inequality.

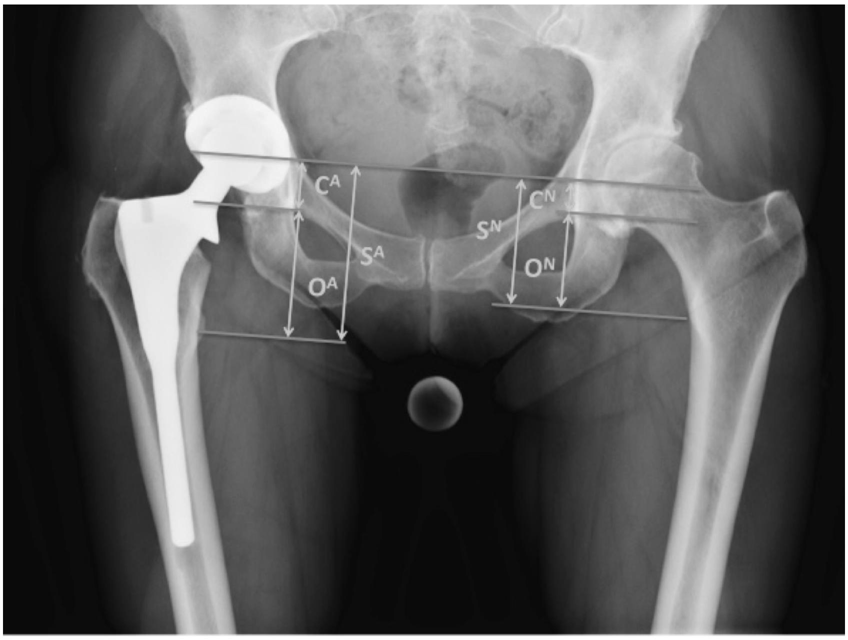


Figure 4-6 The CFH-TD-LT Method
An initial reference line is drawn between the centres of the two femoral heads. Two further line are drawn parallel to this. The first at the level of the most inferior part of the acetabular teardrop to give measurement C, which corresponds to any inequality (C^A-C^N) due to the position of the cup. The second is at the level of the centre of the lesser trochanter to give measurement S, which corresponds to inequality (S^A-S^N) due to position of the stem. The third measurement is O which corresponds to the overall measurement (O^A-O^N). The elements in this technique, C and S can be independent of each other, it is therefore important that for any given LLI following THR the constituent parts are considered.

4.1.5. Study Aims

This study aimed to assess formally the reliability of the methods for quantifying post THR leg length inequality described previously in the literature, the II-LT and the TD-LT methods; as well as the two novel methods used locally, the CFH-LT, as a measure of the LLI of attributable to the femoral component only and CFH-TD-LT methods.

The study was conducted in three parts.

Assessment of the inter-reader reliability

Assessment of the intra-reader reliability

Assessment of reliability of the acquisition protocol

The overarching aim therefore is to be able to present data for the validity of these techniques and their ability to reproducibly measure LLI on plain AP radiograph. The information obtained would be expected to improve surgeon confidence when discussing LLI with the patient at the first clinic appointment.

4.2. Methods

Ethical approval was provided by the Leeds West NHS ethics committee and all images were obtained from patients who had given prior consent for use for research purposes.

Thirty-five sequential cases referred to Mr M H stone for consideration of further, possibly surgical intervention for LLI, were enrolled in the study. All patients had been seen by Mr M H Stone who confirmed the clinical suspicion of LLI. Four patients had not had previous hip replacement but had an LLI at the hip.

All radiographs were taken at Chapel Allerton Hospital (Leeds Teaching Hospitals NHS Trust. The equipment in the suite was AXIOM Arisitos MX/MV (Siemens, Munich, Germany) consisting of a solid state detector and a stationary grid. Tube assembly consisted of an OPTILIX 150/30/50 HC-100 (150kV maximum voltage). A Polydoros LX50 Lite (Siemens, Munich, Germany) generator was employed.

Radiographs were taken according to the local standardized operating protocol, with the patient in a supine position with both hips resting in internal rotation. Calibration of images was performed to the standard hospital protocol. With a source-to-plate distance of 1150mm aiming for a source-to-hip distance of 1000mm. AP pelvic radiographs were centred on the pubic symphysis.

A 25mm calibration ball (AGFA, Wilmington, MA, U.S.A.) was placed in the groin at the same height above the table as the greater trochanter and the image centred on the pubic symphysis. This calibration ball, which was used either in the patients where there was not THR in situ or where the prosthetic femoral head size was not known, can be seen in Figures 4-1 to 4-4 lying below the midline of the pelvis.

To obtain the most valid data, two senior musculoskeletal radiologists (Reader 1 and Reader 2) performed both the new and established measurement sets. Both have an interest in research and are experienced in reviewing, interpreting and performing measurements on musculoskeletal radiographs for many indications including LLI following THR.

The candidate obtained the details of the patients in the cohort, co-ordinated the data gathering, identified the measurement methods used in the study, co-ordinated the statistical interpretation as well as drawing together the resulting information and forming the conclusions detailed in this work.

The digital 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.). The software allows measurements to be made on the image and subsequently deleted so as not the bias the study. All measurements were made to the nearest millimetre.

4.2.1. Inter-reader reliability

A total of 35 radiographs, one for each of the patients in the study, were measured using the four techniques by two experienced musculoskeletal specialist radiologists. Both radiologists were blinded to the other's results. The results were then compared for inter-reader reliability.

4.2.2. Intra-reader reliability

To assess intra-reader reliability, 10 of these radiographs were re-read (both hips) after three months. These readings were compared with the original readings. The radiologists were not allowed to refer to the original readings at the time that the second set of readings was made.

4.2.3. Reliability of the acquisition protocol.

Finally, to explore the reliability of the acquisition protocol in addition to reader consistency, in 24 radiographs of patients who had undergone serial imaging but no further surgery in the interim, follow-up images were also measured and compared with baseline radiographs.

Data were analysed using SPSS v16 and reliability was quantified through the generation of Intra-Class Correlation Coefficients (ICC), mean difference and limits of Agreement (LOA) or limits of repeatability (LOR) respectively. ICC model 3,1 was used to determine inter-reader reliability and ICC model 1,1 was used to evaluate between-day reliability and consistency in measurement from serial images.

4.3. Results

Of the 35 patients in our sample, five patients (14%) had native hips 21 patients (60%) had undergone unilateral total hip replacement and nine patients (26%) had received bilateral hip replacements.

For the subset of 24 in whom serial radiographs were obtained and had no further surgery, the mean time between the first and second x-ray was 393 days (0-7052 days).

4.3.1. Inter-reader reliability study

The ICCs for inter-reader reliability are summarized in Table 4.1. All four methods show high ICCs for inter-reader agreement (>0.9) and were essentially comparable. Mean difference ranges between -0.8 and 1.00. In this case, the lowest mean difference was for the II-LT method. Limits of agreement between raters of <8.3mm, the narrowest being for the CFH-LT method of LLI measurement attributable to the femoral stem.

Table 4-1 Inter-reader reliability of leg length inequality measurement

Leg Length Ineq. Measure	Inter-reader $ICC_{(3,1)}$	Mean difference (mm)	95% LOA (mm)
CFH-LT	0.91 (0.83/0.96)	1.00	±5.31
CFH-TD-LT	0.90 (0.81/0.95)	0.60	±6.02
II-LT	0.90 (0.81/0.95)	0.26	±7.68
TD-LT	0.91 (0.82/0.95)	-0.80	±8.26

4.3.2. Intra-reader reliability

The results for measuring intra-reader reliability are presented in Table 4. 2 and 4.3. When measuring ICC for the same radiograph to study intra-reader reliability, Reader 1 and Reader 2 found the best performing method was CFH-LT. Reader 1 also found the same method to have a zero mean difference. Similarly, both readers had the narrowest LOR for this method.

Table 4-2 Results for intra-reader reliability for Reader 1

Leg Length Ineq. Measure	Intra-reader ICC	Mean difference (mm)	95% LOR (mm)
CFH-LT	0.96 (0.84/0.99)	0.00	±3.61
CFH-TD-LT	0.95 (0.83/0.99)	0.20	±4.11
II-LT	0.87 (0.58/0.97)	-1.90	±6.41
TD-LT	0.65 (0.10/0.90)	-1.60	±14.97

Table 4-3 Intra-reader reliability for Reader 2

Leg Length Ineq. Measure	Intra-reader ICC	Mean difference (mm)	95% LOR (mm)
CFH-LT	0.97 (0.88/0.99)	0.60	±3.03
CFH-TD-LT	0.90 (0.67/0.97)	-0.90	±5.51
II-LT	0.88 (0.62/0.97)	-1.40	±5.68
TD-LT	0.89 (0.63/0.97)	-0.50	±6.53

4.3.3. Reliability of the acquisition protocol.

The results of the reliability of the acquisition protocol section of this study are presented in Table 4.4 and 4.5. Both Reader 1 and Reader 2 found the CFH-LT and CFH-TD-LT methods to have a lower ICC than the two methods established in the literature. Reader 1 found that all four methods have similar mean differences and LOR. Reader 2 found the TD-LT method to have the smallest mean difference and narrowest LOR, the others presenting similar results.

Table 4-4 Results for the reliability of acquisition study, Reader 1

Leg Length Ineq. Measure	Intra-reader ICC	Mean difference (mm)	95% LOR (mm)
CFH-LT	0.63 (0.31/0.82)	-4.71	±15.24
CFH-TD-LT	0.63 (0.32/0.82)	-4.75	±15.43
II-LT	0.77 (0.54/0.89)	-4.42	±14.19
TD-LT	0.77 (0.53/0.89)	-4.17	±14.57

Table 4-5 Results for the reliability of acquisition study, Reader 2.

Leg Length Ineq. Measure	Intra-reader $ICC_{(1,1)}$	Mean difference (mm)	95% LOR (mm)
CFH-LT	0.53 (0.17/0.76)	-4.08	±15.87
CFH-TD-LT	0.50 (0.14/0.75)	-3.42	±15.87
II-LT	0.76 (0.53/0.89)	-4.92	±14.69
TD-LT	0.71 (0.44/0.86)	-1.42	±13.13

4.4. Discussion

4.4.1. General

The precise nature of the association between LLI following total hip replacement and symptoms remains unclear, with some studies producing inconclusive or conflicting results [16 25 28 302]. The aim of this study was to aid understanding of LLI following THR by assessing the reliability of several methods used for measuring inequality on plain AP radiographs.

The literature review identified two methods that are prominent in the literature, Williamson et al. published their work in 1978 and Woolson et al. in 1999. However, not until the candidate's current work and two studies published since 2012 was there any meaningful investigation of inter and intra-observer variation. It is a testament to the complex nature of the problem of LLI and measurement on radiograph that Meermans at al. and Heaver et al. published conflicting results about the most useful method[3 45 308 309]. The work detailed in this chapter therefore appears to be among a small number of papers in the literature to study the methods of measuring LLI due to THR on plain radiograph, and is the first study to do so using a three reference point method.

4.4.2. Inter-reader reliability

The first part of this work was to assess the inter-reader reliability across the four methods for measuring LLI on plain AP radiographs. There was very high agreement, across the 35 sets of films analysed with the mean values and ranges being similar.

Essentially this part of the study found all four methods broadly comparable. All methods had similar mean differences and clinically acceptable LOAs. No method demonstrated significantly better inter-reader reliability than the others.

In interpreting the agreement data, the radiologists commented that it was occasionally difficult to identify the acetabular tear drop, for instance, where a cemented cup was used. Additionally, it was felt more difficult to accurately identify the centre of rotation in the native, generally arthropathic, femoral head.

Another limitation of this study was that no allowance was made for the tilt or obliquity of the pelvis, nor for flexion, abduction, adduction at the hip. While rotation is largely controlled for by the standardized radiographic acquisition protocol at Chapel Allerton Hospital it cannot be entirely excluded and will remain a limitation.

Fixed deformity is often evident in the later stages in osteoarthritis of the hip [310], commonly a combination of flexion with adduction, which causes confounding of two-dimensional measures. With two-point measurement methods, trigonometry dictates that a fixed flexion deformity of for instance, 25° will result in a reduction in measured LLI of approximately 10%. When using the centre of the femoral head as the centre of rotation of the hip joint, adduction and abduction deformities or malpositions, when occurring in isolation should introduce only minimal error in measures relative to the fixed reference on the femur. This would not necessarily be true in combination, multi-planar deformities/malpositions where errors can be compounded.

These trignometrical estimates provide only a theoretical estimate of error in a measurement between two points. Three of the four methods in this study (II-LT, TD-LT and CFH-TD-LT) rely on a reference line to mitigate against inaccuracy due to pelvic obliquity, and all four methods rely on a comparison of one side of the pelvis to the other. Thus, the additional level of complexity means that the underlying mathematical theory has only limited use in indicating potential inaccuracy when applied in the clinical setting. Consequently, the actual interpretation error due to either fixed deformity or patient malposition remains an undefined source of error. The effect of single and multiple plane patient-position error on resulting radiographic measures are further studied in Chapter five of this thesis.

Factors such as patient position when supine for the radiograph and the relative positions of the calibration ball, tube and radiographic plate are all potential sources of reduced reliability.

Therefore, the inter-reader reliability section of this work indicated that all four methods demonstrated high agreement between observers, comparable mean differences and that the two methods based on the centre of the femoral head had the narrowest limits of agreement.

Additionally, as one of these four methods, the CFH-TD method, only measures changes associated with the femoral stem, the fact that there is broad comparability would suggest that the position of the femoral component is the major contributor to LLI in this study.

While this does not suggest that one is superior to another, it does point to the fact that the CFH-TD-LT method is at least comparable to the other three methods and is the only technique that provides information regarding both the position of the cup (CFH-TD), the stem (CFH-LT) and as well as the resultant or overall LLI (TD-LT).

4.4.3. Intra-reader reliability

To assess intra-reader reliability, 10 radiographs were re-measured after a one-month interval. Both readers found the CFH-LT and CFH-TD-LT methods to have intraclass correlation coefficients for intra-reader reliability greater than 0.90. For both readers it was found that the IL-LT method performed marginally less well. Reader 1 and 2 then differed regarding the TD-LT method. Reader 1's ICC was 0.65 (and with a much broader range) and for Reader 2, 0.89. It was in this method that Reader 1 had a much higher LOR at ±14.97 than any other method for either reader in this part of the study. Reader 2 found all methods comparable, with the CFH-LT method of measuring inequality due to the femoral component, generally performing better.

In addition to the general limitations discussed in 4.5.2.2, this sub-study, which involved repeat measurements by the same reader over period of time, was limited by the inability to safely alter patient details on clinical radiographs. It was therefore not practical to formally blind the radiologists to the identity of the radiographs that were being measured. There is therefore some risk of bias although is it likely to be low due to the relatively long time period between the two sets of readings, that neither radiologists had any access to other data, and the complexity of the measurements with multiple measurements being made for each hip.

There is no obvious explanation for the poorer TD-LT results of Reader 1 who produced generally comparable results for the other three methods and which were themselves comparable with all four for Reader 2. This may be a result of difficulty identifying the teardrop in cemented acetabulae, which would be consistent with the finding of a wide range for ICC and LOR.

The intra-reader reliability study demonstrates that with overlapping intervals for ICC there is not one overtly superior method. The two methods which use the centre of the femoral head do appear to be better performing however, than the II-LT and the TD-LT methods. This reinforces that the CFH-TD-LT is at least comparable to the other three methods and, as noted earlier, offers more information regarding the causes for any LLI.

4.4.4. Reliability of the acquisition protocol

The aim of this part of the study was to assess how much agreement there was between measurements made on radiographs taken between two time points when there had been either no, or no additional surgery, i.e. a native hip had remained un-operated or a replaced hip remained unrevised.

All four methods performed less well when compared with the earlier results. All had a lower ICC, higher mean differences and wider LOR than the majority of the other results in the study as a whole, although this would be expected as the measures were derived from different sets of images. Even so there remained an acceptable ICC for all four methods for Reader 1 and for the II-LT and TD-LT methods for Reader 2.

While all measures did not, in general perform as well in this part of the project, the two established methods, II-LT and TD-LT, tended to perform marginally better for both Reader 1 and 2 in terms of ICC (though with overlapping ranges) and LOR, compared to the CFH-LT and CFH-TD-LT methods.

The acquisition protocol study was similarly subject to the limitations described in section 4.5.2. A likely explanation for an 'across the board' poorer intra-reader reliability is that there were over time. The confounding factors of subtle differences in the patient characteristics including habitus and minor variations in the acquisition protocol, such as rotation of the lower limb would introduce error. Over one year the patient's body habitus may have changed or the position of the patient may have been slightly different.

In those cases, where there had been no operation (so no femoral head of the arthroplasty to measure) the calibration ball may not have been in the same AP position leading to and over or under measurement of error, or the patients may not have had the radiograph taken in the same suite in the department, possibly introducing a difference in radiograph due to slight differences in the equipment.

These subtler differences, such as minor positional changes, may not be apparent when the radiographs are compared visually, but as this work demonstrates, when taking measurements for LLI over time, some caution must be shown if there are unexplained differences.

In summary, the findings of the third part of this study, which was designed to assess the utility of these four methods on serial radiographs, established that while the mean differences and LORs were all broadly comparable, both readers demonstrated a trend towards better reliability associated with the two established methods compared to the two novel methods.

4.5. Conclusion

It is clear that despite standardized clinical protocols for AP Pelvic/Hip radiography, direct comparison of measurements for LLI for any method should be interpreted with caution especially for serial imaging over time. Greater accuracy, particularly in the presence of complex deformity can be achieved using CT scanograms, however this study explored the real-world reliability of the more commonplace and economical plain-film radiographic techniques for LLI assessment.

All four methods investigated were broadly comparable for inter-reader and intra-reader reliability of measures taken from the same films. The study also yielded similar findings for the third part of the study looking at serial radiographs, but with the caveat that all four methods did not perform as well, and that the II-LT and the TD-LT were marginally better in terms of agreement than the CFH-LT and CFH-TD-LT methods. There are however many more potential confounding factors in this part of the study.

While all of the methods in this study, the three methods for measuring LLI (II-LT, TD-LT and CFH-TD-LT), and the fourth (CFH-LT) method for inequality solely due to the femoral component, proved satisfactorily reliable. The two locally used methods have something to offer the clinician in allowing assessment of inequality, albeit not necessarily due to the whole of the hip replacement.

The CFH-LT method has demonstrated comparability with the established methods, and requires no parallel lines to be drawn. This could be considered useful if a ‘snap shot’ of any inequality is required as it is technically quicker. It must however be used with a little caution as it is affected by changes in femoral offset so may be subject to inaccuracy where this is an issue.

The CFH-TD-LT method, which also demonstrated comparable reliability to the two more established methods, has the potential extra advantage of being able to distinguish between LLI caused by cup position and LLI caused by stem position, thus potentially avoiding inappropriate revision of only one component if both are contributing to the problem such as is seem in a Parvizi type 2 LLI [28].

The most significant limitation in this study, one which has also been noted as a limitation of AP only scanogram views[200], is that it remains unclear as to the level of inaccuracy that arises from fixed deformity and malposition of the patient at the time of acquiring the radiograph. A better understanding of the interpretation errors associated with malpositioning of the femur on plain radiograph would provide the clinician the ability to make a judgment about whether or not further imaging is required.

In conclusion, the data provide support for the reliability of measurement of inequality on plain radiographs for the three methods of measuring LLI following THR, the II-LT, TD-LT and CFH-TD-LT, as well as the fourth technique in this study, the CFH-LT method which assess inequality due to the femoral component only.

This study has provided the first direct comparison of the methods currently in common use and we can conclude that all the methods described previously, plus the new methods, demonstrate broadly comparable reliability. The CFH-TD-LT method has the added advantage of differentiating between cup or stem position as the cause of any LLI.

Chapter 5. The Effect of Malpositioning of the Femur on the Measurement of LLI on Plain Radiograph

This chapter investigates to what extent malpositioning or fixed deformity affects the apparent measurement on plain radiograph. An understanding of the extent of the error will allow the surgeon to come to a conclusion about the accuracy of the plain films; either accepting them or sending the patient for further imaging as appropriate.

Part of this work was presented at the British Hip Society Annual Meeting in Exeter in 2014, and jointly won the British Hip Society/British Orthopaedic Research Society/ Orthopaedic Research UK Prize for the best presentation. (Appendix D)

5.1. Introduction

5.1.1. Background

The previous chapter explored four methods of measuring LLI on plain AP radiograph. It found all four to be essentially equivalent for inter and intra-observer error. That being that case, there is an argument for the use of the CFH-TD-LT method for its extra utility in providing additional information regarding the contribution to any LLI made by the cup and the stem separately. What is unknown is the amount of error that malposition due to fixed deformity, can have on the acquisition of the underlying images and the effect on subsequent measurement of an LLI.

For clarity, as each part of this component-based method corresponds to the elements of a hip replacement, the constituent parts will be referred to as CFH-TD(Cup), CFH-LT(Stem) and TD-LT(Overall) measurements.

In a more straightforward two-point measurement system, where one point is also the axis about which the malposition occurs, then trigonometry could be used to quantify any error. In the example shown in Figure 5.1, a 20^0 fixed flexion deformity can be predicted to result in a 6% measurement error.

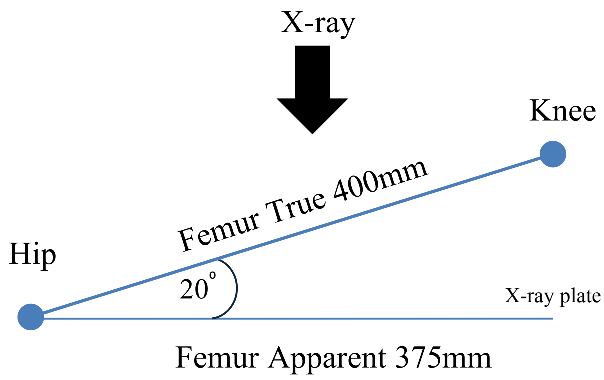


Figure 5-1 Illustration of the effect of 20 degrees of fixed flexion.
A femur with a true length of 400mm will, on an anterior to posterior projection, have an apparent length of 375mm (400 Cos 20) when projected onto an x-ray receiver plate.

The CFH-TD-LT is a more nuanced measurement method which has three reference points; the centre of femoral rotation as the axis of movement of the hip joint, the teardrop (an intra-pelvic marker point) and the lesser trochanter on the femur. These are used to generate three measurements per hip.

Simple trigonometry would not be able to predict how the component parts of the CFH-TD-LT method would be altered, nor could it calculate how these changes would affect the relative contributions of each part to the overall. This is illustrated in Figure 5-2

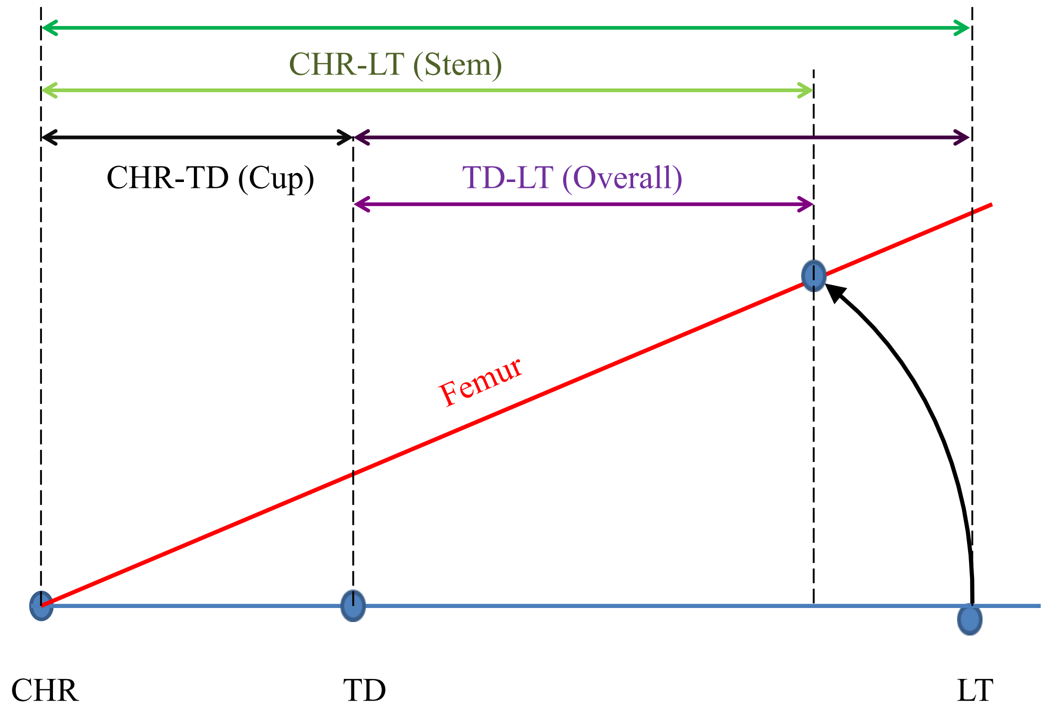


Figure 5-2 Illustrates why simple trigonometry cannot be used to predict the error associated with malposition when using the CFH-TD-LT method.
In the diagram the intra-pelvic TD reference will not move when the femur is flexed through an arc of movement. Therefore, there is potential for measurement error in the TD-LT (Overall) measurement and the CFH-LT (stem measurement). The relative magnitude of the error will be greater for the TD-LT (Overall) measure.

For instance, if considering a deformity that would result in an under-interpretation of the TD-LT(Overall) measurement but leaves the CFH-TD(Cup) measurement unaltered, this would cause a corresponding reduction in the CFH-LT(Stem) measurement, but perhaps crucially, would increase the relative contribution of the cup component of the stem and by definition, the overall length. If these errors are not understood, the effect of this in quantifying deformity has the potential to result in a misinterpretation of the

Parvizi classification of LLI following THR and may result in inappropriate revision surgery[28].

To study the interactions of the individual parts of the CFH-TD-LT method, a more complex model is therefore required.

5.1.2. Published Studies

There has been little work published regarding the errors associated with femoral malposition and its effect on the AP radiograph. The majority have concerned the pelvis and acetabulum, exploring the effect on subtle pelvic land marks or on the measurement of the acetabular index[311 312]

In an attempt to find a parameter that could be used to correct for pelvic tilt on plain radiographs, Tannast et al.[313] found that the most reliable measure in the study was the distance between the upper edge of the pubis to the mid-sacrococcygeal joint. Even this parameter had only a moderately strong correlation (r=0.65, P=<0.001) with pelvic tilt however. In discussing this finding of limited accuracy of even their most reliable measure, the group acknowledged the complex nature of the problem. Additionally they highlighted the importance of a standardised protocol for radiographs[313].

While measuring acetabular index, van der Bom et al. found that any more than $\pm 4^0$ of pelvic obliquity and tilt would cause an unacceptable error in measurement[312].

Similarly, Foss et al. and Muller et al, analysed pelvic tilt on radiographs and noted it as a source of inaccuracy and also highlighted that other factors such as radiographic focussing and central beam positions represent additional sources of error[314 315].

Sarin et al. studied the effect of malposition of the femur when measuring LLI using a test-bench simulation of a patient in the lateral position. Markers used in computerised navigation were placed on the greater trochanter and superior to the acetabulum. LLI was then studied through a range of malpositions, and measurements made using computerised surgical navigation equipment. They found the greatest error to occur with adduction/abduction. In this plane, the error induced was up to 8.4mm at 5^{o} and up to 17.4mm at 10^{o}. This study also found that flexion and extension had relatively little effect. Sarin et al. did not however consider the effect of internal or external rotation of the femur[263].

While these studies in the published literature cannot translate directly to the use of the CFH-TD-LT method in assessing LLI, they do highlight that a significant amount of error can be introduced by variations in femoral position when using plain AP radiographs.

5.1.3. Clinical Relevance of Understanding Malposition Error

Chapter four of this work has highlighted the importance of accurately quantifying any LLI. Any assessment must include a detailed history, examination and appropriate imaging. In current practice, if there is a major concern regarding a LLI either pre-operatively or post-operatively, then the current gold-standard examination would be considered to be CT scanograms[46]. Deformity around the hip joint can be part of the presentation both pre-operatively[1 38 54 236] or post-operatively, particularly where the latter involves a lengthening leading to (for example) abduction or flexion contractures, as seen in those patients considered to be sensitive to any lengthening.[170]

A surgeon who has a patient with such a deformity and who requires imaging of a known leg length inequality may therefore order a CT scanogram as a way of quantifying this problem. This would involve all the associated issues discussed in Section 2.7.2.2. such as exposing the patient to additional ionising radiation, as well as the associated costs in terms of resources and additional clinic time required[46].

This could be avoided if the surgeon is able with greater confidence to: i) quantify the extent of fixed deformity around the hip, ii) confirm that the LLI is due to problems around the hip and iii) understand the amount of error that the level of fixed deformity is likely to produce on plain AP pelvis radiograph. As has been shown above there has been little work to quantify this in these circumstances and none that considers a more complex method of measuring LLI such as the CFH-TD-LT method.

5.1.4. Pilot Study

Prior to the full experiment detailed in this chapter, a pilot study was performed to assess the feasibility and accuracy of this experiment. For the pilot study, all four methods detailed in chapter 4 were compared, as well as the effect of vertical position of the beam generator over the model.

5.1.4.1. Pilot methods

The computational part of the pilot study used SOLIDWORKS 2010 (Dassult Sytémes SOLIDWORKS Corp, MA, USA) Computer aided design (CAD) software package. The pelvis and hip models to be used were downloaded from a public domain library of three-dimensional anatomical and engineering structures derived from real-world data. http://3dcontentcentral.com/search.aspx?arg=pelvis and http://3dcontentcentral.com/search.aspx?arg=hip.

The radiographic study was performed using an anatomical male skeletal model (Sawbones, Pacific Research Laboratories, U.S.A). The reference points used in the CFH-TD-LT method were attached to the pelvis (TD) and femur (LT) using radiolucent tape. The model pelvis was placed on the bed of the radiographic equipment to mimic the position of a patient undergoing AP pelvis/hips radiograph. Angles of deformity of the femur at the hip joint were measured with a digital inclinometer which had two degrees of freedom (inclination and rotation about the same axis) for flexion and extension, as well as internal and external rotation. Femoral adduction and abduction at the hip joint were measured initially using a digital compass, and then subsequently an orthopaedic goniometer, more typically used in clinic.

5.1.4.2. Pilot findings

The results of the pilot phase experiment did provide some useful insight into the relationship between the position of the lower limb and the potential for error in the assessment of LLI following THR, although some limitations of the approach were highlighted.

The combination of the CAD software and the model of the skeleton used were difficult to manipulate in 3D space, and the final study employed a simplified model. Much work was required to adapt the models, particularly in terms of sizing and dimensions to validate the accuracy of the model.

There were also limitations in the radiological component of the pilot. The model pelvis was placed directly onto the bed of the radiographic equipment. This meant that it was difficult to stabilise the pelvis through the range of deformities being explored and also meant that it was not possible to assess extension. It was not possible to analyse internal/external rotation of the femur in total isolation as, at any angle of rotation, for the distal femur to clear the bed, an element of flexion was required. This study also found that external rotation of the femur was limited by impingement of the model. These reflect real-world constraints but did impact on the theoretical modelling profile.

During the experiment, it became clear that the digital compass that was used to assess angle of femoral adduction and abduction was not accurate or reproducible. This was most likely due to the amount of ferrous metal in the vicinity of the experiment. The compass was therefore abandoned and the abduction/adduction of the femur was measured using a goniometer which has the same obvious limitations as any clinical instrument. The reference abduction/adduction positions of the femur should therefore be interpreted with caution. In any future study, a more accurate and more reproducible method of measuring abduction/adduction would be required.

5.1.5. Main Study Aims

The aim of this part of the project was to quantify the error in measurement using the CFH-TD-LT method on plain radiograph when associated with malposition of the femur. To achieve this, a two-part experiment was performed:

A computational model was created to simulate an anatomical hip model which can then be placed into various (mal)positions to assess the errors that would result when translated to an AP pelvis projection.

To validate the computational model an experiment was performed in a radiographic suite in which an anatomical skeletal model was placed into incremental malpositions and the CFH-TD-LT measurements were acquired to provide an assessment of the real world applicability of the theoretical computational model.

5.2. Methods

With the aim of quantifying the error on the measurement of LLI on a plain AP pelvis radiograph when using the CFH-TD-LT method, an experimental study was carried out in two parts, Figure 5.3. This study specifically focused on the CFH-TD-LT method as it was shown to have comparable utility to the other methods explored in chapter four, but was able distinguish between the LLI due to the components of the THR. Also, as this method has three reference points per side that are not co-planar it is the most difficult method of the four to predict using simple trigonometry.

The first was a computational model which was then validated against a second experimental model performed in a radiographic suite.

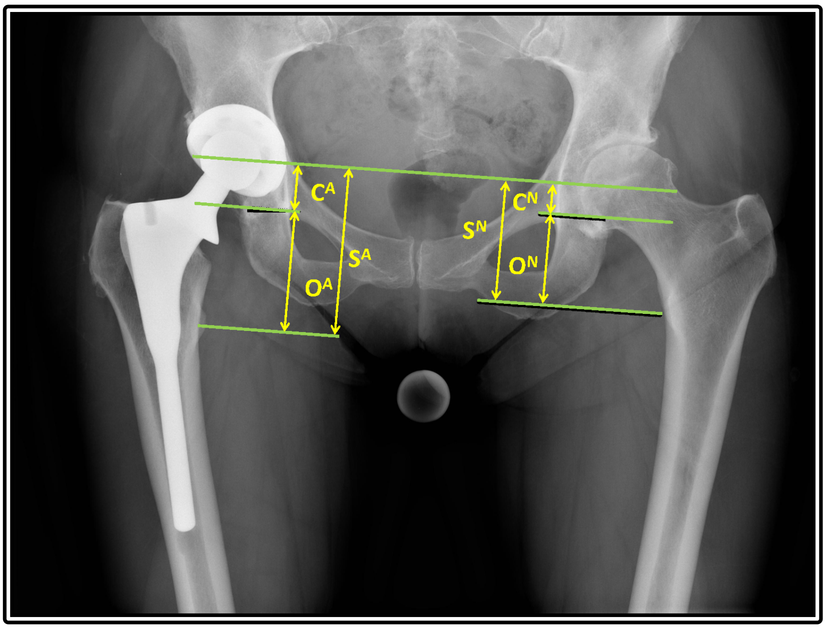


Figure 5-3 The CFH-TD-LT Method.
An initial reference line is drawn between the centres of femoral rotation (CFH). Two further lines are drawn parallel to this. The first at the level of the most inferior part of the acetabular teardrop(TD). This is labelled C and corresponds to the CFH-TD(Cup) measurement. The second is at the level of the centre of the lesser trochanter. The measurement between these two latter points is labelled O and corresponds to the TD-LT(Overall) or the total LLI measurement for the THR. The measurement CFH-LT(Stem) corresponds to the contribution of any given LLI made by the stem. In this image, the measurements are labelled ^{A} for the arthroplasty side and ^{N} for the native side. This radiograph illustrates a post THR LLI predominantly associated with an increase in the CFH-LT(Stem) measurement.

In this study, all angles (and therefore malpositions) discussed describe the position that the femur has been placed into while the pelvis remains in neutral.

5.2.1. Computational Study

To create the model used in the computational component of this study, an anatomical male skeletal model (Sawbones, Pacific Research Laboratories, U.S.A) was obtained.

This underwent computerised tomographic (CT) scanning (Siemens, Munich, Germany) at Leeds General Infirmary. The high-density scan allowed 1mm slice images to be obtained and therefore accurate identification of the anatomical landmarks.

The CT was then manually segmented in Endpoint software (IMORPHICS, Manchester, U.K.) to generate a three-dimensional computer model of the pelvis and hips, Figure 5.4.

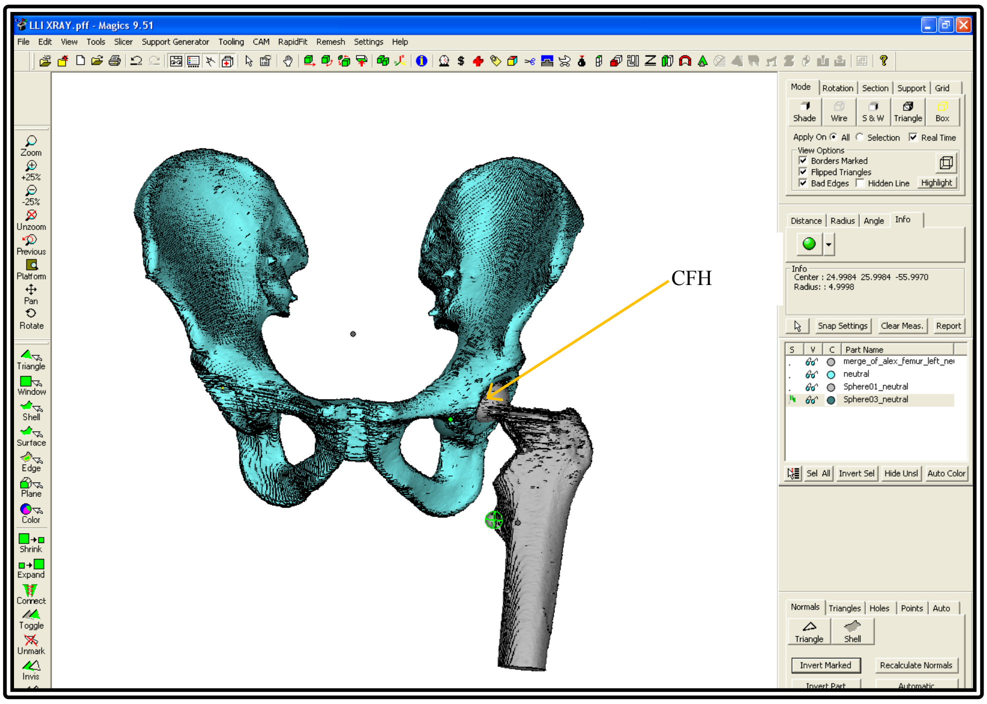


Figure 5-4 Screen shot of the computer model of the skeleton used in the study. Rotation occurred around the centre of femoral head, CFH.

The computer version of the skeletal model was then transferred to the MAGICS image analysis programme (MATERIALISE, Leuven, Belgium) where a workspace was created. This software allowed independent movement of the component of the model. In this workspace, a 28mm sphere was created in the centre (0,0,0) to overlay the 28mm femoral head of the left hip prosthesis. With the femur positioned and centred in free space, the acetabular cup of the pelvis model was reduced onto the femoral head and the hip joint was defined within the computer programme. The long axis of the femur was used as a reference and was positioned parallel to the McKibbin plane of the pelvis.

The MAGICS application allows location of further marker spheres within in the three-dimensional workspace. These were placed at the acetabular teardrop and the midpoint of the lesser trochanter, which alongside the centre point of the model corresponding to the centre of femoral rotation, allowed the measurements for the CFH-TD-LT method to be performed.

In this programme, movement about the centre of femoral rotation in the X- axis recreated flexion and extension, Y-axis for femoral abduction and adduction and the Z-axis, internal and external rotation of the femur[316]. The simulation was then moved at 5 degree intervals for each plain in isolation. The total arcs of movement are summarised in Table 5.1

At each of these 5^0 increments the co-ordinates of the points of interest and the corresponding distances were measured.

It was the role of this candidate to frame the research question, with particular reference to the limitations of this part of the study, outline the methodology of the measurement technique used in this study, identify the radiographic marker points in three-dimensional space, identify the various malpositions and combined malpostions in the study and directly supervise the data capture process. Thereafter it was the role of this candidate to provide clinical background, correlation and interpretation for the results.

Table 5-1 Total arc angles analysed in effect of femoral malposition study

Arc of hip movement
30^0 Flexion to 30^0 Extension
30^0 Abduction to 30^0Adduction
30^0 Internal Rotation to 20^0 External rotation

In addition to the single-plane deformities in this part of the study, two further computational models were considered. It has been noted clinically that in patients who are in the early to moderate stages of osteoarthritis of the hip, flexion from neutral may be accompanied by external rotation due to the typical morphological and functional changes within the ball and socket joint.

Therefore, the computational model was also used to analyse the error in the measurement of LLI that arises as a result of flexion when it is combined increasing levels of external rotation, Table 5-2.

The final part of the computational modelling combined deformity in all three planes in their clinically most likely combinations (flexion, external rotation and abduction) as well as their reciprocals (extension with internal rotation and adduction). All deformities were incrementally increased at equivalent magnitudes i.e.10º of flexion was combined with 10º external rotation and 10º of abduction, Table 5-3.

Table 5-2 Angles of femoral malposition studied in the combined flexion external rotation element of the computational model.

Range of Flexion	Angle of External Rotation
0º to 30º	0º
0º to 30º	5º
0º to 30º	10º
0º to 30º	15º
0º to 30º	20º
0º to 30º	25º
0º to 30º	30º

Table 5-3 Angle of combined deformity analysed in the computational model of femoral deformity in the saggital plane (Ext – Extension, Flex – Flexion), coronal plane (Add – Adduction, Abd – Abduction) and the transverse plane (Int Rot – Internal rotation, Ext Rot – External Rotation).

Angle of malposition	**30^{o}**	**25^{o}**	**20^{o}**	**15^{o}**	**10^{o}**	**5^{o}**	**0^{o}**	**5^{o}**	**10^{o}**	**15^{o}**	**20^{o}**	**25^{o}**	**30^{o}**
Saggital Plane (X-axis)	30^{o} Ext	25^{o} Ext	20^{o} Ext	15^{o} Ext	10^{o} Ext	5^{o} Ext	0^{o}	5^{o} Flex	10^{o} Flex	15^{o} Flex	20^{o} Flex	25^{o} Flex	30^{o} Flex
Coronal Plane (Z axis)	30^{o} Add	25^{o} Add	20^{o} Add	15^{o} Add	10^{o} Add	5^{o} Add	0^{o}	5^{o} Abd	10^{o} Abd	15^{o} Abd	20^{o} Abd	25^{o} Abd	30^{o} Abd
Transverse Plane (Y Axis)	30^{o} Int Rot	25^{o} Int Rot	20^{o} Int Rot	15^{o} Int Rot	10^{o} Int Rot	5^{o} Int Rot	0^{o}	5^{o} Ext Rot	10^{o} Ext Rot	15^{o} Ext Rot	20^{o} Ext Rot	25^{o} Ext Rot	30^{o} Ext Rot

5.2.2. Radiographic Study

The same anatomical skeletal model used in the initial part of the computational study, was used in this experiment and image acquisition was performed in a radiographic suite in Chapel Allerton Hospital, Leeds, U.K.

To avoid errors associated with repeated assembly and disassembly of the construct, and to accommodate the limited time available for the study using a radiographic suite in a busy tertiary referral centre this element of the study was performed in a single session.

The skeletal model used in this study is only partially radio-opaque, and so to aid radiographic identification of the three points of interest; teardrop and the lesser trochanter, 5mm ball bearings were attached to the corresponding points on the skeletal model. The centre of femoral rotation was identifiable as the centre of the head of the total hip replacement implanted in the model

The model was secured to a tilt table and the pelvis was positioned anatomically in the McKibbin plane, where the antero-superior part of the pubic ramus is in the same coronal plane as the anterior superior iliac spines and both anterior superior iliac spines lie in the same transverse plane[317].

To simulate the conditions of a standard symphysis-centred AP pelvis film taken clinically, a standard protocol was followed. The distance between the x-ray emitter and the digital receiving plate was 115cm and the distance from the emitter to the pubic symphysis of the skeletal model was 100cm, Figure 5.5. As is the standard clinical practice, a 25mm stainless steel ball bearing was used as a calibration marker and was placed at the level of the greater trochanter.

Radiographic equipment in the suite was AXIOM Aristos MX/VX / (Siemens, Munich, Germany) incorporating a table with a solid-state detector with a stationary grid. The X-ray tube assembly consisted of an OPTILIX 150/30/50 HC-100 (maximum voltage: 150kv). A Polydoros LX50 Lite (Siemens, Munich, Germany) generator was employed.

Angles of malposition in this part of the study were determined using a tilt sensor and a bevelled protractor. The digital inclinometer sensor had been calibrated to an accuracy of ±0.5^0 by being placed on a table at 0^0 and then, using two blocks of known angles of 45^0 and 90^0. The tilt sensor was therefore able to reproduce the position of the long axis of the femur in the horizontal, or in this experiment, the neutral position whilst the pelvis remained in the McKibbin plane. The tilt sensor was then used to determine the angle of flexion/extension and rotation. The tilt meter was able to measure in two degrees of freedom. In addition to being able to indicate angle of inclination, the tilt meter was also, with the same accuracy, able to indicate rotation. This allowed the measurements to be made in the particular deformity in isolation, without any additional rotation which may have confounded the results. To avoid the problems with the digital compass and the goniometer, a bevelled protractor was used to confirm the abduction angle.

Despite the use of a purpose-built frame, the skeletal model would not allow more than 20^0 of femoral external rotation without acetabular impingement compared to the 30^0 notionally evaluated in the computational model. Also, due to time-limitations for experimental access to an NHS radiographic suite the experimental angles were measured at 10^0 increments compared to the 5^0 increments employed in the computational model.

The femur was held in position manually by the researcher, Miss Jennifer Barlow, Master of Engineering student, as the use of external devices such as clamps were found to obstruct the radiograph. During acquisition a protective lead apron was worn, with a 0.35mm lead rubber equivalent value. To minimise error as a result of the femur being held in place and not fixed, each radiograph was repeated three times and particular attention paid to the rotation information provided by the tilt meter, an example of which is given in Figure 5.6.

The radiographs were saved directly to the hospital's version of the PACS, IMPAX (AGFA Healthcare). In real time, each was annotated and subsequently uploaded to a digital versatile disc in digital imaging and communication in medicine (DICOM) format.

Matlab mathworks software was used to convert the DICOM images into a portable network graphics (PNG) file that could then be analysed with Imatri Medical Online Software Measurements using the CFH-TD-LT method were made and corrected for magnification. Data were collected in Microsoft Excel (2010, Microsoft Corp, Etc) for analysis.

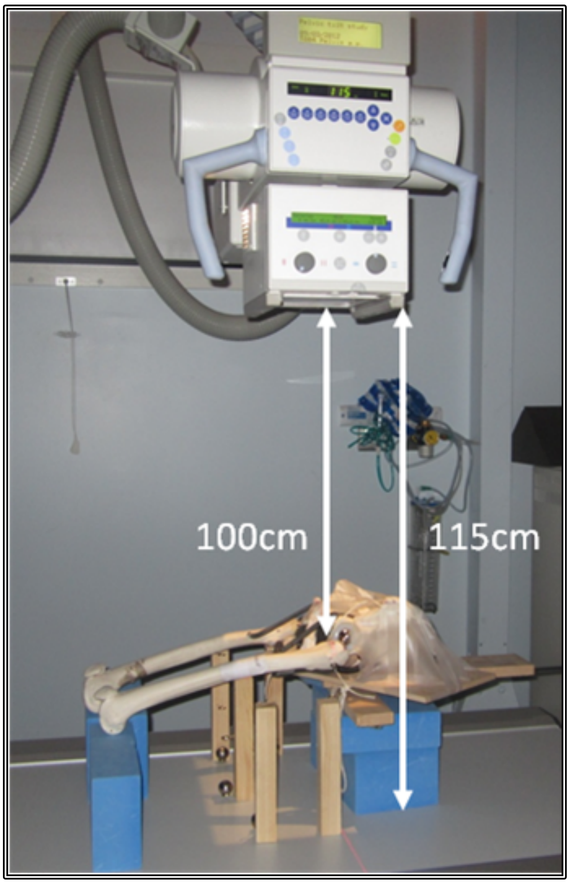


Figure 5-5 Image of the skeletal model in the radiographic suite.
Photograph to illustrate the skeletal model in the radiographic suite at Chapel Allerton Hospital. During the radiographic experiment the pelvis was placed in the position for a plain AP pelvis. Also, illustrated (on the left of the image at the pelvis), is the frame to allow stable and reproducible positioning of the pelvis. Note this image and the labelled distances are for illustrative purposes only and may not reflect the precise values.

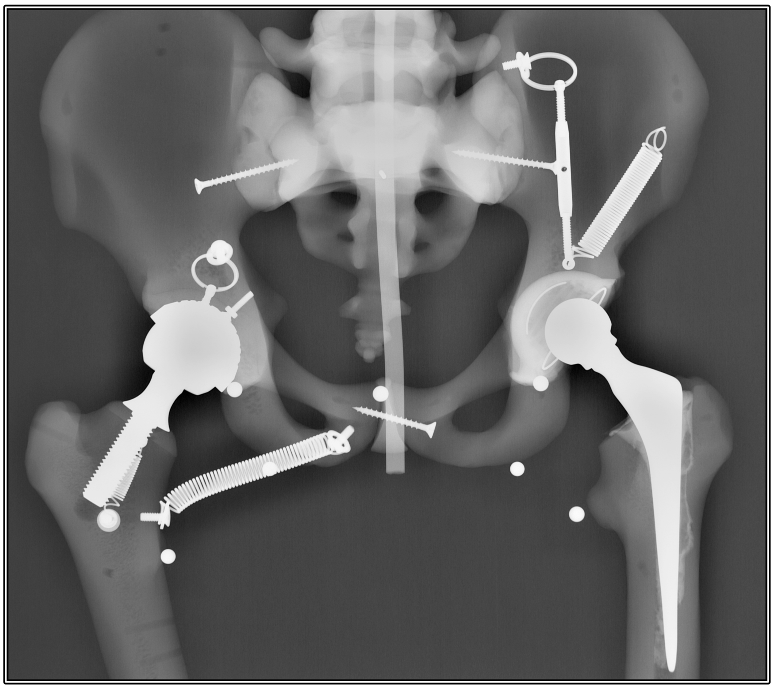


Figure 5-6 The acetabular teardrop and the lesser trochanters are highlighted with 5mm ball bearings. The centre of femoral rotation was taken to be the centre of the head of the total hip replacement. In the neutral position.

5.3. Results

5.3.1. Computational Model

In the computational model, the measurements of the left hip when in neutral were: CFH-TD(Cup) =15mm, the TD-LT (Overall) =70mm, and the resultant CFH-LT (Stem) =85mm. In this position, the CFH-TD(Cup) position constituted 18% (15mm/85mm x 100) of the TD-LT(Overall)length.

In the computational model, when the femur was moved though the arcs of malposition it was clear that there was no change in the CFH-TD(Cup) measurement that corresponds to any change in LLI due to cup placement.

As the TD-LT (Overall) is a function of both the CFH-TD(Cup) and the CFH-LT (Stem), it is a measure of an LLI following THR. As such it is typically the first measurement referred to in any discussion of inequality.

While any change in interpreted LLI in the computational study would be a reflection of the CFH-LT(Stem) measurement, as the CFH-TD(Cup) measure is a constant in the element of the study, any change would also be correspondingly reflected in the TD-LT(Overall) measure. Additionally, as the magnitude of the TD-LT(Overall) measure will always be of smaller magnitude than the CFH-TD(Stem) measure, any given interpretation error would have a greater proportional effect.

Therefore, Figures 5-7, to 5-11detail only the actual measurement difference for the TD-LT (Overall) component. Where the actual difference is given as a positive value, the radiographic measurement at that angle was greater than the original, and where it is negative then the measurement was less than the original.

5.3.1.1. Flexion and Extension Malposition

The results for flexion and extension malposition in the computational model are presented in Figure 5-7. While not clinically relevant in terms of the patient (mal)positioning when taking a plain radiograph, the greatest technical potential for error is in extension. The maximum error at 30^0 extension is a 15.38mm under-interpretation, which represents a 22% error in the TD-LT (Overall) measurement and a 18% error in the CFH-LT (Stem) measurement. The CFH-TD(Cup) goes from being responsible for 18% of the CFH-LT (Stem) measure to 22% (15/ (85 -15.38) x 100).

When progressing through the arc of flexion there is an initial over-interpretation error. At 10^0 the TD-LT (Overall) measurement peaks at 1.02mm greater than at the neutral point. Thereafter a trend towards under-interpretation occurs and is at its maximum in 30^0 flexion, where the TD-LT (Overall) measurement is 3.38mm shorter than the neutral measure. This represents a 5% error in the TD-LT (Overall) measurement and a 4% error in the CFH-LT (Stem) measurement. At this point the CFH-TD(Cup) measure contributes the same 18% to the CFH-LT (Stem)measure as when in neutral.

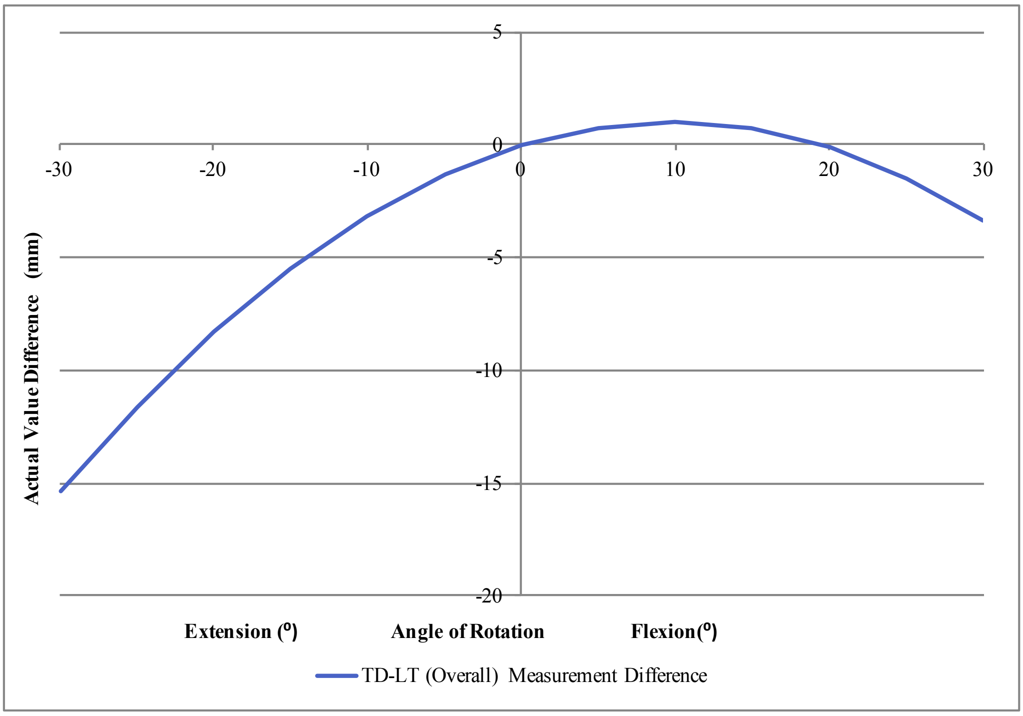


Figure 5-7 The results for the actual value difference in the measurement of the stem component of the CFH-TD-LT method when brought through extension and flexion in the computational model.

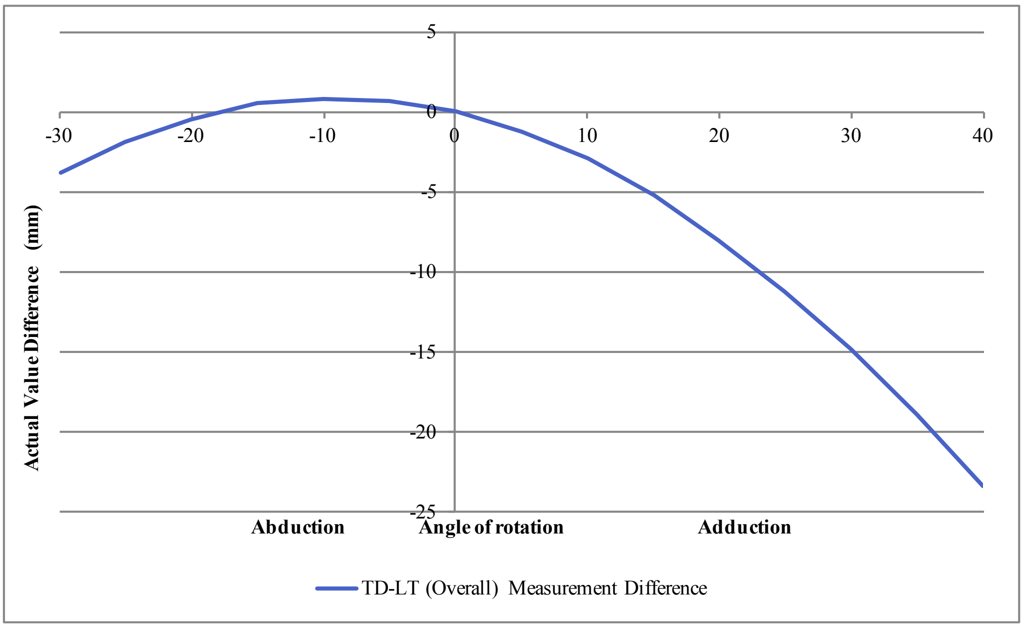


Figure 5-8 The results for the actual value difference in the measurement of the stem component of the CFH-TD-LT method when brought through abduction and adduction in the computational model.

5.3.1.2. Abduction and Adduction Malposition

The results for abduction and adduction malposition for the computational model are presented in Figure 5-8. The greatest error occurs in adduction where at 30^0 the TD-LT (Overall) measurement is under-interpretation of 14.88mm. This causes represents a 21% error in the TD-LT (Overall) measurement and an 18% error in the CFH-LT (Stem). measurement. At 30^0 adduction the CFH-TD(Cup) measurement comprises 21% of the CFH-LT (Stem), as opposed to 18% of the overall when in neutral.

The error arising from abduction from neutral is less the error associated with adduction. Abduction initially causes an over-interpretation of the TD-LT length, peaking at 10^0 and resulting in a 0.84mm error, corresponding to a 1% error of the TD-LT (Overall) measurement and 1% of the CFH-LT (Stem). Following this peak, it trends towards an under-interpretation, and at 30^0 abduction the error becomes maximal at 3.88mm of shortening. This causes a 6% error for the TD-LT (Overall) measurement and a 5% error in the CFH-LT (Stem). measurement. At this angle, the cup contributes the same 18% of the CFH-LT (Stem) measurement as when in neutral.

5.3.1.3. Internal and External Rotation

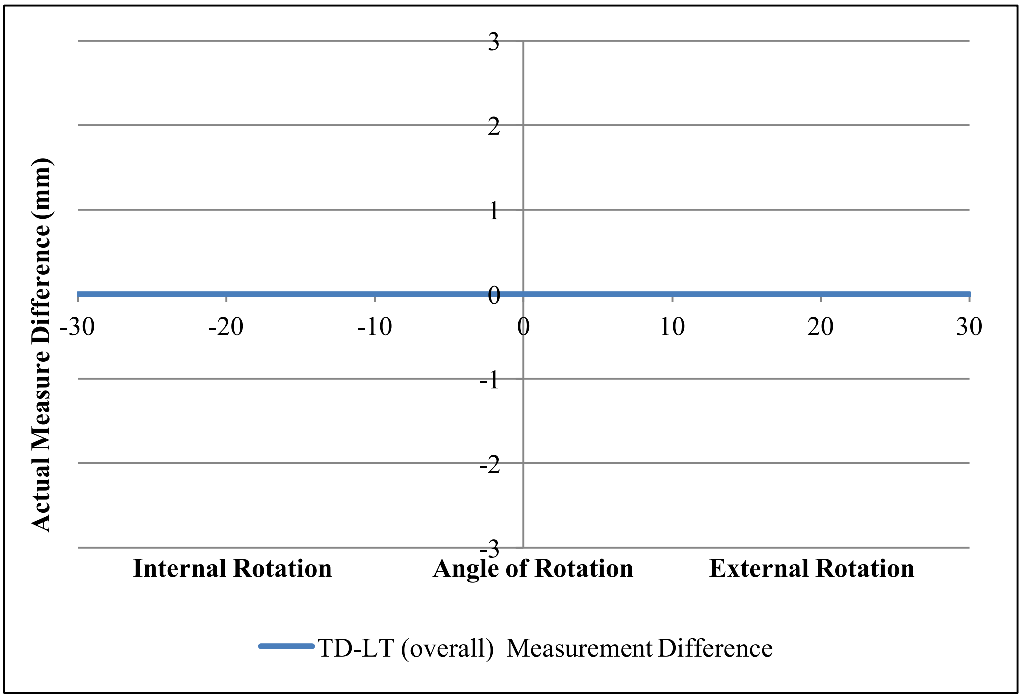


Figure 5-9 The results for the actual value difference in the measurement of the stem component of the CFH-TD-LT method when brought through internal and external rotation in the computational model.

The results for single-plane internal and external rotation malposition in the computational model are presented in Figure 5-8. There was no error resulting from either external or internal rotation across the whole arc of movement.

5.3.1.4. Flexion and External Rotation

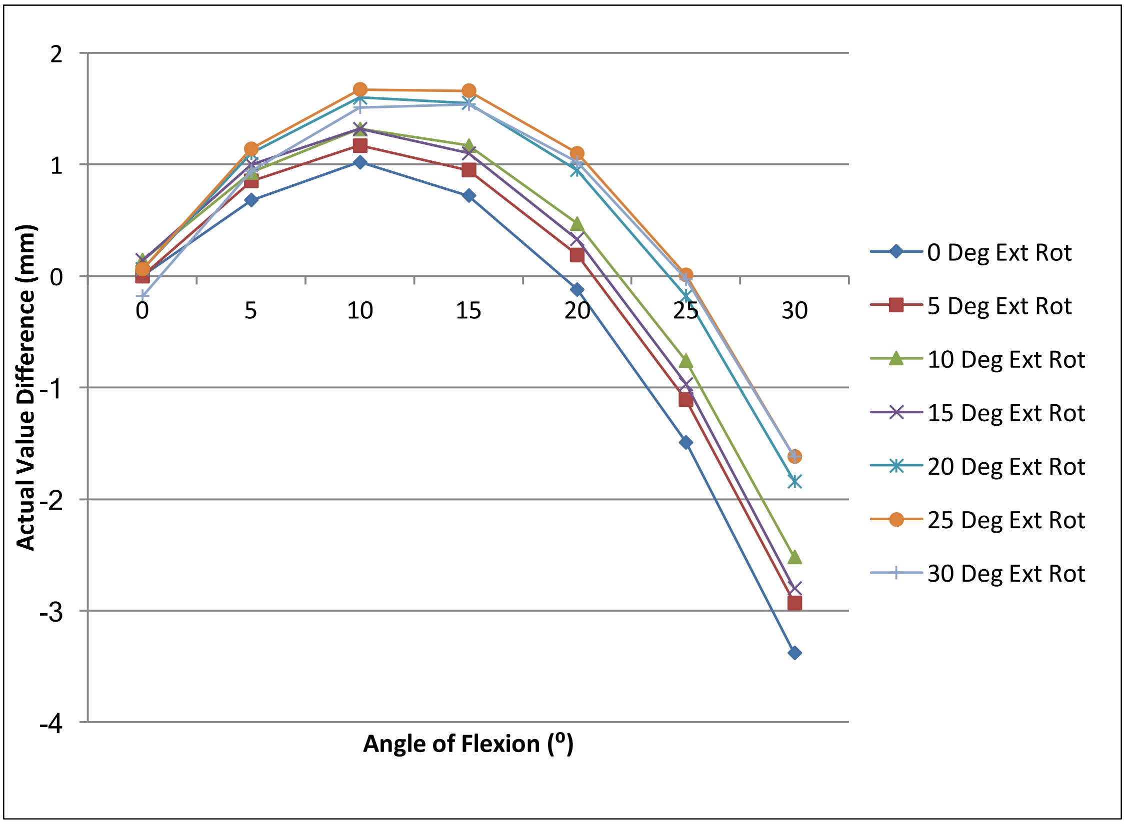


Figure 5-10 The results of the combined flexion with external rotation as an actual value difference using the CFH-TD-LT method.

The results for the computational experiment for the extent of error associated with flexion when it is combined with external rotation are shown in Figure 5-10. There is additional error when the external rotation is combined with any given degree of flexion. The actual value difference increases as the external rotation increases for all malpositions except when increasing from 10º to 15º external rotation. The actual value difference decreases after 10º flexion for 15º external rotation, a trend that continues The actual value difference is greatest the extremes of flexion and rotation where it the difference is -1.5mm. This represents a 1.8% error of the CFH-LT (Stem) measurement.

While the actual value difference increase throughout the range of this work, all malpositions with a degree external rotation of pass through the null point after 20º, whereas flexion without any external rotation for flexion crosses before this point. Therefore, when there is a flexion malposition above 20˚, while the actual value difference will increase, the associated error of measurement reduces with increasing external rotation.

5.3.1.5. Combined malpositions

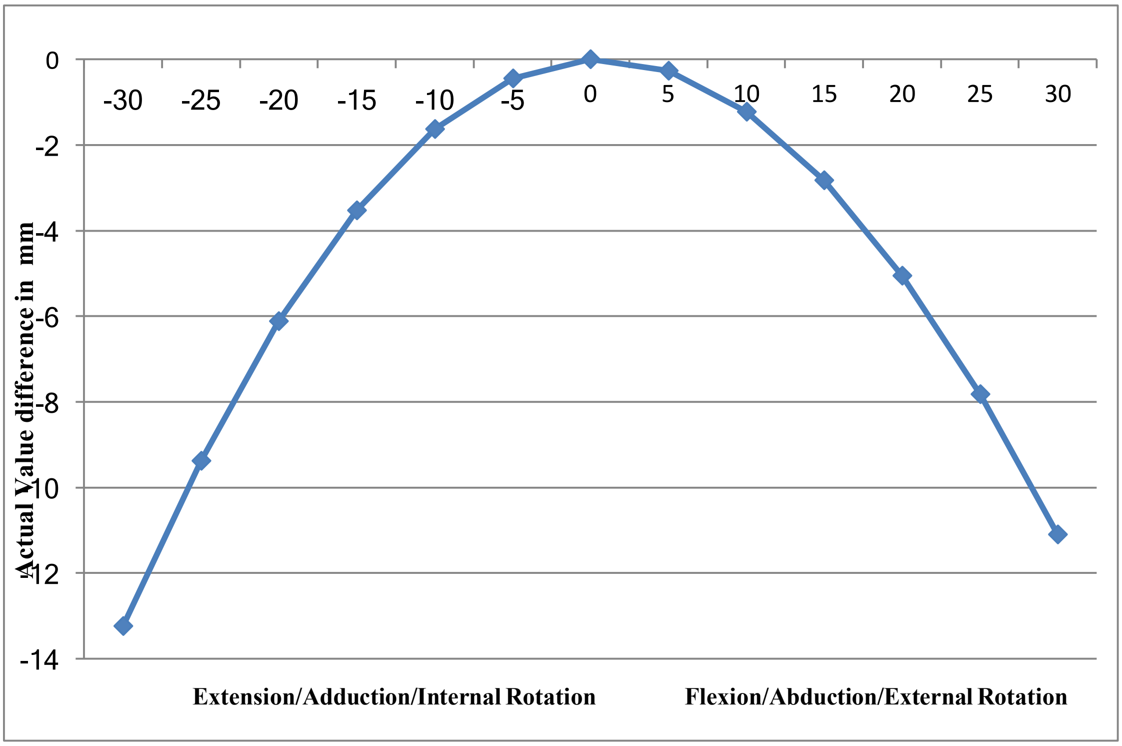


Figure 5-11 The results for the computational modelling of actual value difference of the CFH-TD-LT method when the femur is placed in the combined deformities extension adduction and internal rotation through to flexion, adduction and external rotation.

The results for the computational modelling of deformity in all planes are detailed in Figure 5-11. The actual value for the calculated error increases with greater magnitudes of positional variation in either direction. Variation from neutral positions results is an under-interpretation error, which when taken to its maximum is -13mm for extension/adduction/internal rotation, which equates to a 15% measurement error of the

CFH-LT(Stem) and 19% error of the TD-LT(Overall). The error is smaller in flexion/external rotation/abduction, where, at 30º in all is 11mm and is equivalent to 16% of the TD-LT(Overall)measurement and 13% of the CFH-LT(Stem). Unlike the all the previous malpositions, both single plane and combined in the computational study, at no stage do these results cross the 0mm error line.

5.3.2. Radiographic Measurements

The reference measurements in neutral for the hip of the skeletal model were; CFH-TD(Cup) =15 mm, TD-LT (Overall) =62mm and the CFH-LT (Stem) =77mm. In this position, the CFH-TD(Cup) constituted 19% (15mm/75mm x 100) of the overall length.

The results of the radiographic experiment are summarised in Figures 5-12, to 5-15 and are presented as the difference between the reference measurements for LLI on the skeletal model and the measurements taken from the radiograph. Where the actual difference is given as a positive value, the radiographic measurement at that angle was greater than the original, and where it is negative then the measurement was less than the original.

In this experiment model, unlike in the computational model, there were recorded differences in the cup measurements and as such these are also included in the results.

5.3.2.1. Flexion and Extension Malposition

Figure 5-12 details the results for isolated flexion and extension. As the CFH-TD(Cup) measurement is intra-pelvic, it is not specifically affected by the position of the femur. The difference throughout the whole 60^0 arc of motion for the CFH-TD(Cup) measurement; the greatest error is -2.71mm at 30^0 of extension and is an indication of experimental error in the radiographic component of this investigation. 95% confidence intervals are at their broadest at 10^0 extension where they are ± 0.96mm and narrowest at 20^0 extension where they are ± 0.53mm.

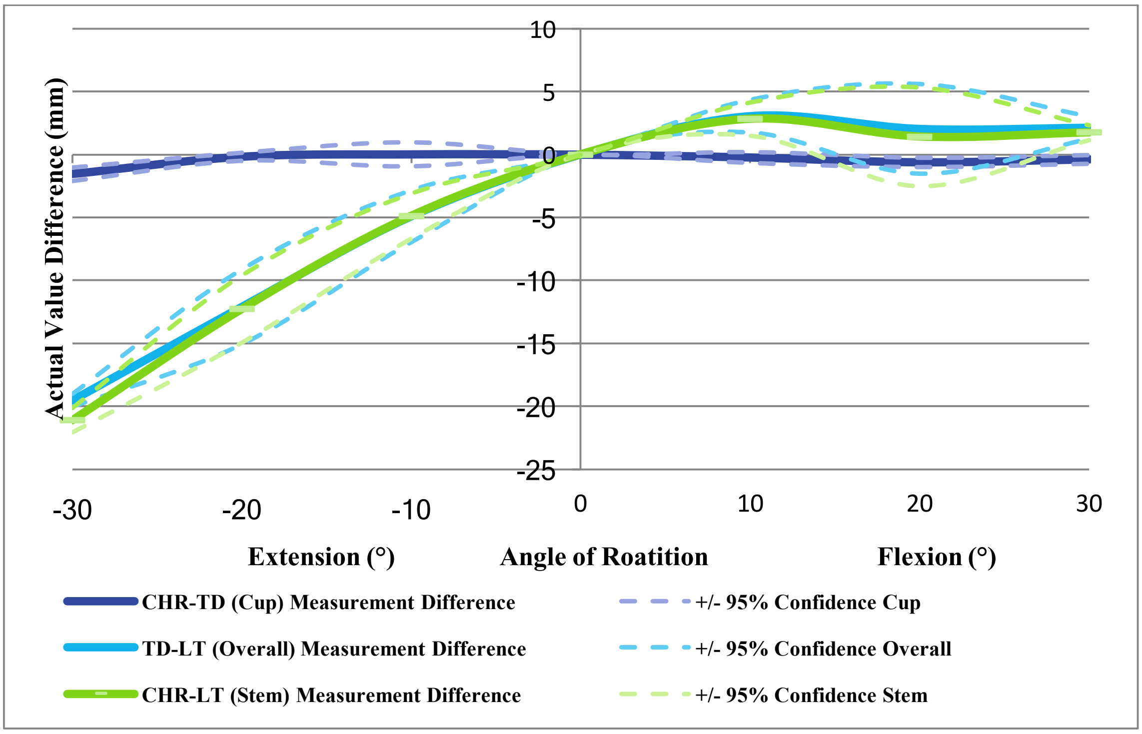


Figure 5-12 The results for the actual value difference in the measurement of CFH-TD-LT method when brought through extension and flexion in the radiographic study.

The largest difference is seen for the TD-LT (Overall) measurement at the limits of extension, where a 19.53mm under-interpretation was observed. This equates to a 32% error in the TD-LT (Overall) measurement and a 25% error in the CFH-LT (Stem)measurement. At this angle, the CFH-TD(Cup) contributes 26% to the CFH-LT (Stem) as opposed to 19% of the CFH-LT (Stem) when in the neutral position.

The maximum error in flexion for the TD-LT (Overall) measurements is at 10^0 where there is a 3.04mm over-interpretation which corresponds to a 5% error for the TD-LT (Overall) and a 4% error in the CFH-LT (Stem)measurements. At 10^0 flexion, the CFH-TD(Cup) measurement increases to 20% of the CFH-LT (Stem). Beyond 10^0 of flexion the error due to malposition levels at around 2mm TD-LT (Overall) measurement error.

The 95% confidence intervals for the TD-LT (Overall) measurement were greatest at 20^0 flexion and were ±3.57mm and least at 30^0 extension and were ±0.53mm

5.3.2.2. Abduction and Adduction Malposition

The results for the analysis of abduction and adduction malposition for the radiographic experiment are presented in Figures 5-13 and 5-14

The CFH-TD(Cup) measurement does not deviate from zero by more than 0.66mm (4% of the cup measurement) in across the full arc of positions evaluated in of this study. The confidence intervals are at their narrowest at 20^0 adduction at ± 0.03mm and greatest at 30^0 abduction where they are 0.56mm.

Adduction causes the greatest error in the TD-LT (Overall) measurement at the maximum of 30^0. This causes a 31.83mm under-interpretation which equates to a 51% error in the TD-LT (Overall) measurement and a 42% error in the overall measurement. At this angle, the cup contributes 33% of the overall measurement.

Abduction causes less error than adduction. The greatest error is at 10^0 where the TD-LT (Overall) measurement is over-interpreted by 2.38mm, or 4% of the TD-LT (Overall) measurement and 3% of the CFH-LT (Stem). At 10^o the CFH-TD(Cup) contribution to the CFH-LT (Stem) increases to 20% from 19% when in neutral.

Confidence intervals for this arc of malposition are narrowest a 30^0 adduction at ± 1.33mm and broadest at 20^0 adduction where they are ± 4.04mm.

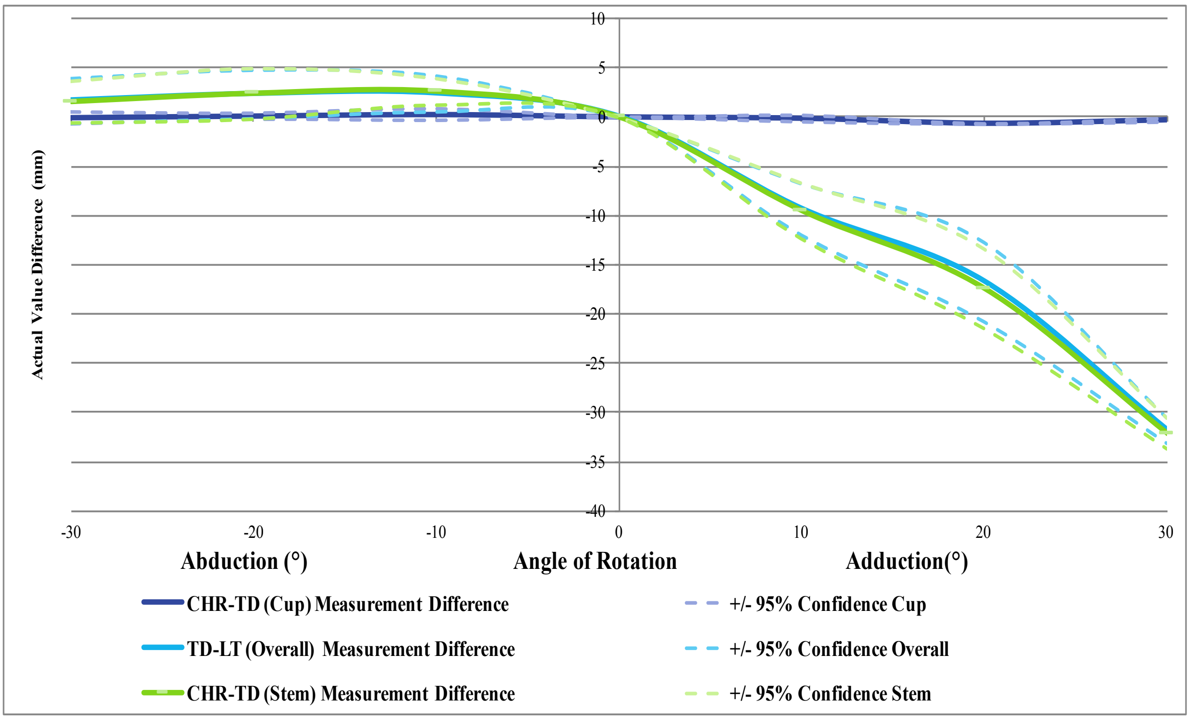


Figure 5-13 The results for the actual value difference in the measurement of CFH-TD-LT method when brought through abduction and adduction in the radiographic study.

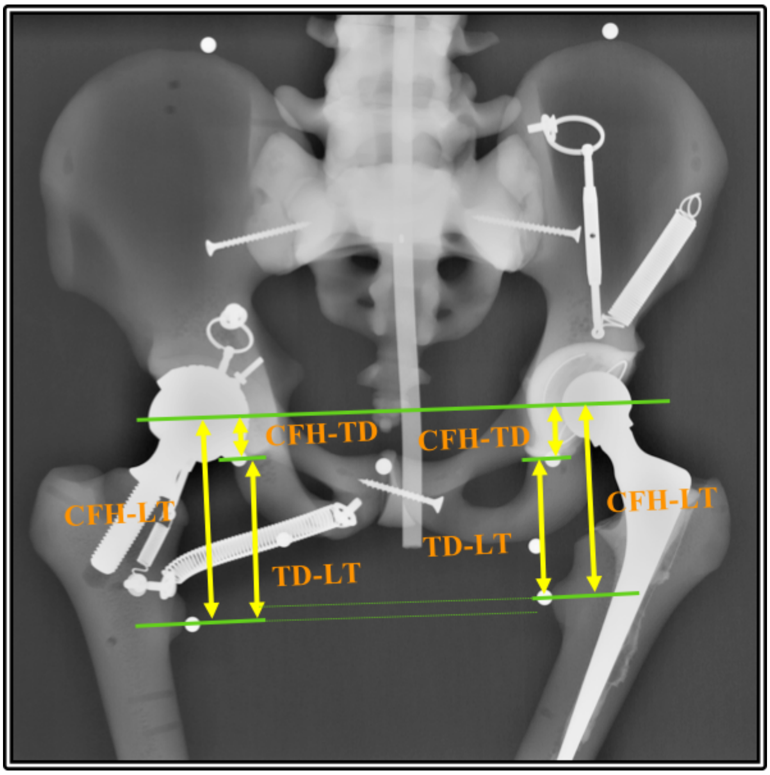


Figure 5-14 Radiograph of the model in adduction. Image has been marked up using the CFR-TD-LT method and the dotted lines illustrates reduction in the magnitude of the in the vertical measurement of the TD-LT (Overall) and the CFH-TD (Stem) measurements.

5.3.2.3. Internal and External Rotation Malposition

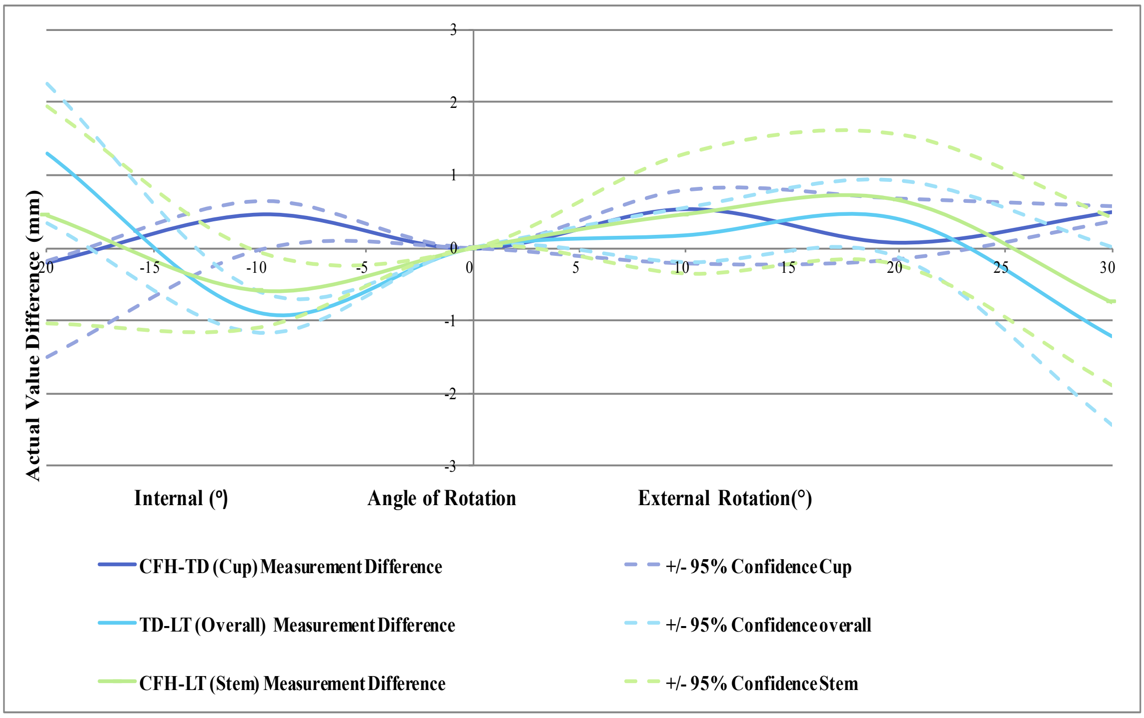


Figure 5-15 The results for the actual value difference in the measurement of CFH-TD-LT method when acquired through a range of internal and external rotation positions in the radiographic study.

The results for internal and external rotation malposition in the radiographic study are presented in Figure 5-15. Data collection at 30^0 internal rotation was not possible due to impingement of the skeletal model femur on the wooden frame securing the pelvis.

The CFH-TD(Cup) measurement does not deviate from zero by more than 0.54mm (4% of the CFH-TD(Cup) measurement and 1% of the CFH-LT (Stem)) and does not follow a linear relationship. Confidence intervals were narrowest at 30^0 external rotation and were ±0.10mm and were at their broadest at 20^0 where they were ±0.65mm.

Errors associated with the TD-LT (Overall) measurement were small but were non-linear for internal and external rotation and were without clear pattern. The magnitude of error was smaller than in the flexion/extension and adduction/abduction part of the radiographic study.

Maximum error in internal rotation corresponded to a 1.29mm over-interpretation compared to the true length which equates to a 2% error for the TD-LT (Overall) measurement and a 2% error in the CFH-LT (Stem) measurement. In internal rotation the CFH-TD(Cup) increases to 20% of the CFH-LT (Stem).

The greatest error in external rotation was at 30^0. At this point there was a 1.21mm under-interpretation, resulting in a 2% error in the TD-LT (Overall) measurement and a 2% error in the CFH-LT (Stem) measurement. The CFH-TD(Cup) contributes 20% of the CFH-LT (Stem) measurement

As the magnitudes of the TD-LT (Overall) measurements were different in the computational and the radiographic studies, further analysis of the data has been performed. To provide further comparability, the change in the TD-LT (Overall) measurement as a percentage of the CFH-LT (Stem) has been calculated.

The linear errors in measuring LLI for different positions of internal and external rotation were zero in the computational model and were small enough to be clinically irrelevant in the radiographic study, therefore only flexion/extension and abduction/adduction have been compared in detail.

5.3.2.4. Comparison of Computational and Radiological studies in Flexion and Extension

The results for the comparison of percentage change in the TD-LT (Overall) measurement when in flexion/extension malposition are presented in Figure 5-16.

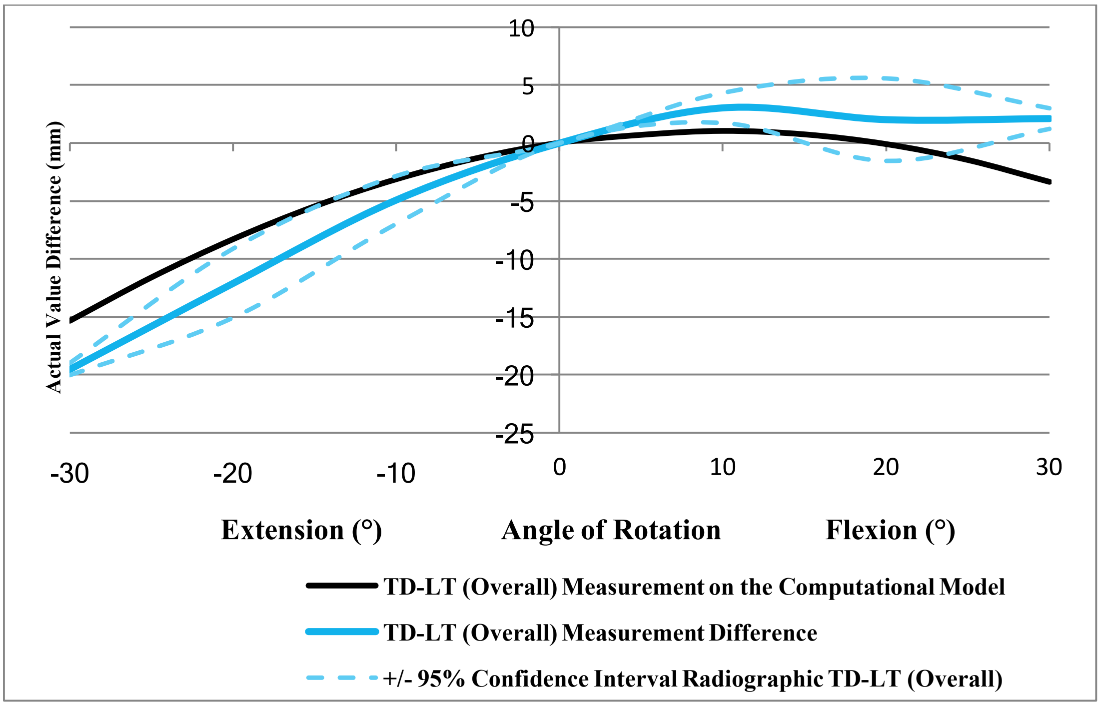


Figure 5-16 The results for the comparison of the percentage error in the stem measurement for the computational and radiographic study for flexion/extension malposition.

Both the computational study and the radiographic study show a similar trend in extension, although the magnitudes are different with the radiographic study producing a greater magnitude of resultant error than the computational study for similar magnitudes of malposition. At the maximum angle of extension of 30^0 in the computational model, there is a 22% under-interpretation of the TD-LT (Overall) measurement, whereas the radiographic model finds it to be 32% (C.I. ± 1%). The confidence intervals for the LLI values obtained from the radiographic study cease to include those from the computational model once extension exceeds 10^0.

In flexion, the computational model shows an over-interpretation, resulting in a 1% error in the TD-LT (Overall) measurement and then trends towards under-interpretation, crossing zero before 20^0 flexion and progressing to a maximum of 5% under-interpretation at 30^0. The radiographic method demonstrated an over- error throughout the range of flexion, also peaking at 10^0 which produced a 5% (C.I. ± 2%) error in the TD-LT (Overall) measurement, the error then levels at 3% to the maximum flexion, though at 20^0 flexion the 95% confidence intervals are at their broadest at ± 5%.

5.3.2.5. Comparison of Computational and Radiological studies in Abduction and Adduction

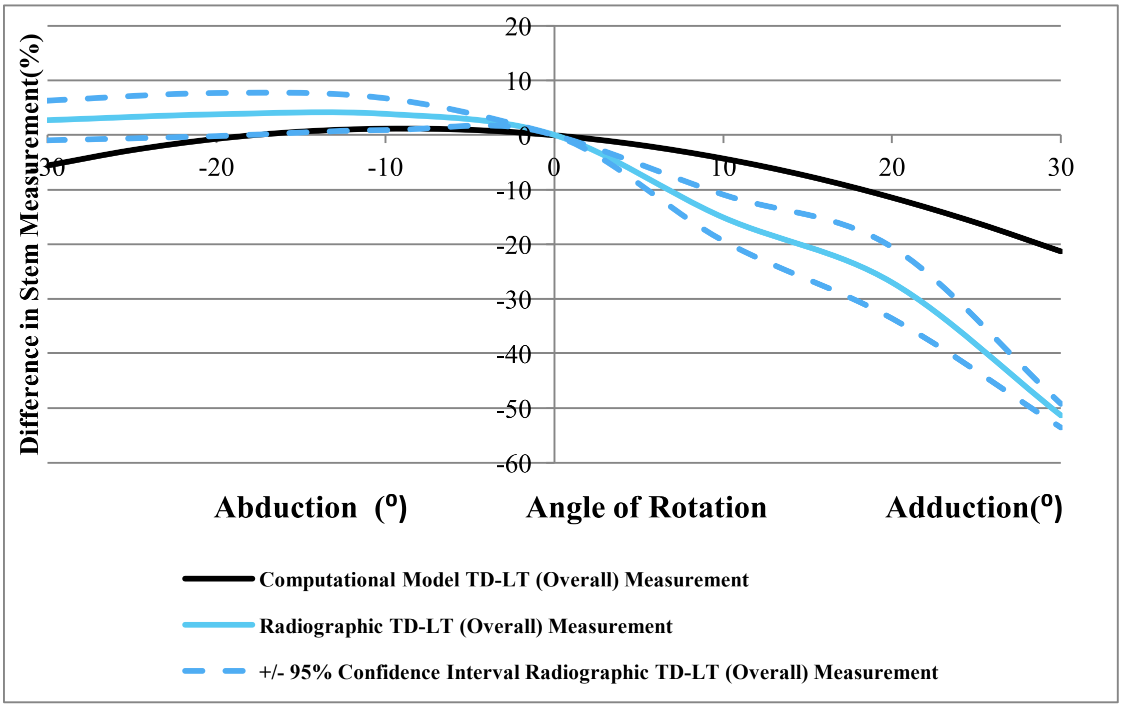


Figure 5-17 The results for the comparison of the percentage error in the stem measurement for the computational and radiographic study for Abduction/Adduction malposition.

The results for the comparison of percentage change in the TD-LT (Overall) measurement when in abduction/adduction malposition are presented in Figure 5-17.

Malposition in abduction in the computational model causes an over-interpretation peak at 10^0 of 1.2% error in the TD-LT (Overall) measurement, which then becomes an under-interpretation error once malposition exceeds 15^0. This under-interpretation is greatest at 30^0 of abduction where it results in 6% error. In the radiographic experiment, the peak error in abduction was at 10^0 and resulted in 4% error. Thereafter there was a trend down to 3% over-interpretation at 30^0. In abduction, the confidence interval is broadest at 20^0 at ± 3.9mm and is at this point the confidence intervals for the experimental model results no longer include the mean for the computational model.

Malposition in adduction causes a larger error than abduction through the range of angles in both the computational and radiographic studies. The maximum error for the computational study is at 30^o of adduction, which causes a 21% under-interpretation of the TD-LT (Overall) measurement. The results in adduction for the radiographic study also demonstrate a greater magnitude of error than those for the computational study. The greatest error occurs at 30^o malposition causing a 53% under-interpretation error in the TD-LT (Overall) measurement. The widest confidence intervals occur at 20^o adduction and are ± 6.5mm. At no point in the adduction arc do the confidence intervals for the radiographic data overlap the values obtained from the computational study.

5.4. Discussion

5.4.1. General

As noted previously the CFH-TD-LT method of measuring LLI radiograph holds an advantage over other plain AP pelvic techniques in that it allows separate analysis of the position of the cup and stem. This becomes particularly important if considering revision surgery where failure to appreciate the underlying causes for an LLI following THR, such as in a Parvizi type 2, can risk instability of the hip.

It is therefore important to consider the error that can occur with plain radiograph measurement using the CFH-TD-LT method in the presence of malposition of the femur, not only for the overall LLI but also for each of the component measurements with respect to one another.

In the CFH-TD-LT method there is a point of axis, fixed points on the pelvis and the femur, and while the radiograph is a two-dimensional image, the points are not co-planar. Therefore, any assumptions based on trigonometry would not be valid.

This work aimed therefore, to describe via a computational model and a radiographic experiment the extent of error in measurement using this technique in the presence of malposition of the femur.

While there are studies that have considered malposition and the errors associated with it, this is the first work to quantify the effect of femoral position, in three arcs of rotation, on a three reference point method.

5.4.2. Computational study

As the computational model was able to fix the pelvis, this allowed movement of the femur around the centre of rotation only, and in the plane of movement being studied. As such the CFH-TD(Cup) measure, which is the perpendicular distance between the fixed axis point, the centre of rotation and the unmoved, intra-pelvic tear trop, does not change throughout all arcs of movement, both in single plane and combined-plane malposition. Any error due to malpositioning is a result therefore of the TD-LT (Overall) measurement and thus in the computational model this is the only variable of relevance for the overall measure of LLI.

Similarly, in terms of this computer model, it is not surprising that, when internal/external rotation is studied in isolation, there was no resulting measurement error as the rotation did not alter the perpendicular distance between the measurement points.

The results for both flexion/extension and abduction/adduction form an arc, the apex of which is a 10^{o} flexion and 10^{o} abduction. This can be explained by the femoral anatomy in which the lesser trochanter, due to femoral anteversion, is posterior to the centre of rotation and medial to the centre of rotation.

The overall effect demonstrated by these results is that error due to malpositioning is greater in extension or adduction than in flexion and abduction.

For the purposes of discussion in this part of the work, a notional level of acceptable accuracy of 10%, which corresponds 8.5mm error in the computational model (and 7.7mm error in the radiographic study) is suggested as the benchmark for acceptable error. Ultimately however it is for each individual surgeon to conclude what they feel is an acceptable, and a notional 10% limit is utilised purely for discussion.

In this study, neither flexion nor abduction malpositioning result in errors reaching this limit. Extension and adduction malposition error were found to cause >10% error after malposition exceeded 20^{o}. At this 10% hypothetical limit of acceptability the CFH-TD(Cup) measurement would only increase to 20% of the CFH-LT (Stem) measure from 18% in neutral position.

The result for extension also must also be considered in a clinical context. The typical extension at the hip is up to 20^{o}[318 319]. However, and particularly in the case of patients presenting with osteoarthritis, there is more likely to be an element of fixed flexion and therefore a loss of extension at the hip in question. Additionally, when a AP pelvis radiograph is taken, the patient is supine and as such extension of the femur at the hip does not occur in routine practice. Therefore, while this study does demonstrate an increasing error with increasing extension, the likelihood is that this will not be part of the presentation of the typical osteoarthritis patient.

A limitation of this part of the study is that the computer model was able to isolate each arc of movement individually. While this is important for a theoretical study in providing data to compare to a radiographic study, the precision associated with a computer model may have only limited translatability to a clinical setting, where there are other confounding factors such as patient body habitus or position on the x-ray table.

It is also not initially clear why, when using the anatomical model of the pelvis, which was digitised using a CT scanner and then modulated in a software programme, the associated measurements of CFH-TD, TD-LT and CFH-LT were observed to be 15mm, 70mm and 85mm respectively when these were not the directly measured equivalents of the same skeletal model (15mm, 62mm and 77mm) from the reference in the radiographic experiment. In both cases the CFH-TD(Cup) measurement is the same, therefore it is most likely that the differences in the TD-LT (Overall), and the resulting CFH-LT (Stem) measurements are due to the positioning of the stem in free space on the computer model.

One of the main aims of this study was to assess not only the more general errors associated with malposition but also how any given angle would affect the more detailed analysis of the particular cause of an LLI following total hip replacement. This work does demonstrate that there is an associated error when comparing the CFH-TD(Cup) measurement (which did not change) with the CFH-LT (Stem).

However, even at the extremes of flexion and abduction, where the more general error was relatively small, at <5% and 6% respectively, there were only minor changes to the contribution of the CFH-TD(Cup) component. Similarly, despite the errors associated with extension and adduction being greater at the extremes at a maximum of 18% under interpretation of the CFH-LT(Stem), there were only relatively small changes in the contribution made by the CFH-TD(Cup), which increased from 18% to 22% of the CFH-LT(Stem)

From a clinical point of view this is reassuring as this study has demonstrated that, even when considering large malpositions of the lower limb resulting in larger measurement errors, there is not a large change in the relative contributions of the component parts of the measurement. Therefore, the chances of an error when considering the Parvizi[28]classification is low, particularly in the more typical clinical presentations.

The flexion with external rotation part of the computational model highlights the complex nature of the anatomy in this region. If the individual components of the single plane study were combined then, it would be reasonable to assume that there would be little difference in the measurement error with increasing external rotation. This however is not the case. There is a discernible difference in the measurement error through the range of malposition. This can be explained when the detailed femoral anatomy is considered.

The results demonstrate what the effect of an additional degree of freedom, flexion, can have when measuring to the lesser trochanter reference which is displaced from the axis of rotation due to anatomical reasons. The long axis of the femur is displaced from the centre of femoral rotation, resulting in the femoral offset and the femur itself not being perpendicular to the mechanical axis of the limb. Additionally the lesser trochanter is medial to the long axis of the femur but also, as also shown by the results for adduction and abduction, lateral to the mechanical axis of the lower limb[320 321]. This is also the most likely cause of the seemingly unexpected change in error with the higher angles of external rotation with flexion.

This complex anatomical arrangement around the hip joint is further demonstrated by the combined malposition study. When taken as the sum of the individual results in the earlier part of this study, there should be a small over-interpretation error at the initial stages of flexion/abduction/external rotation. This however is not confirmed in the results where, when combined, there is always an under-interpretation. In concordance with the results for the rest of this part of the study, errors associated with extension/adduction/internal rotation are greater than the errors associated with flexion/abduction/external rotation, which were 19% and 16% of the TD-LT(Overall) respectively.

The combined deformity results add to the results in this section which establish that malposition does cause an error in the measurement of LLI on plain radiograph, but that a large and likely noticeable level of deformity around the hip is required for these measurement errors to make a clinical difference in the quantification of a LLI and the contribution of each of the component parts.

5.4.3. Radiographic study

Unlike in the computational model, on radiographic evaluation there was deviation observed in the CFH-TD(Cup) measurement. The finding that an exclusively intra-pelvic measurement, which should not be altered by the position of the femur, is an indication of the experimental error that has occurred in this, physical, as opposed to computational, investigation. However, these errors are comparatively small and the main cause of error is associated directly with the TD-LT (Overall) measurement.

The results for internal and external rotation demonstrate no clear trend and the error due to malposition in this arc is difficult to predict. Even when taken at their maximum however, the errors remain small at around 2% of the overall.

As the error is small in magnitude and as the computational study found that there should be no change in the measurements it is likely that the errors seen in for internal and external rotation are due to random, sampling and human errors. This would therefore provide an interesting insight in to the errors that could have occurred throughout the radiographic part of the study.

The results for flexion/extension and abduction/adduction both show similar trends throughout the arc of movement. Both demonstrate a linear increase in under-interpretation error in extension and adduction, though of different magnitude. This under interpretation error, which was greatest at 30° was 40% of the CFH-LT (Stem) in adduction and 25% error in extension. As a result, the contribution to the overall length made by the CFH-TD(Cup) measurement, increases from 19% to 33% for adduction and 26% for extension.

However, and as discussed in the previous section 5.4.2, extension must be taken in a context of a patient undergoing supine plain AP radiograph. In a healthy individual the femur can extend to 20° at the hip joint (16% interpretation error of the CFH-LT(Stem) measurement), but any malposition of the femur would be neutralised when lying supine and positioned the image. Therefore, while potential errors associated with extension have been quantified in this work, in reality they would rarely occur in the clinical setting.

Flexion and abduction both plateau, with a small peak at 3.04mm and 2.38mm of over-interpretation respectively. These relatively small errors have little effect on the overall measurement or the contribution made by CFH-TD(Cup) measurement.

When in flexion, where the results indicate a continuing over-interpretation error, the radiographic study does not follow the same trend as seen in the computational study, where the trend progresses to an under-interpretation error. Additionally, the C.I. at 10° and 30° are narrow at a maximum of ± 0.53mm would indicate that there is another factor than human or random error. Abduction follows a similar trend, albeit with overlap of the C.I. with the 0mm error. Both sets of results indicate a trend of continuing over-interpretation error, which is counter-intuitive if taken to extremes. There are a number of possible, and not mutually exclusive explanations.

It is possible that the reference of the lesser trochanter was not placed centrally. When the femur moves through the arc of malposition the position of the marker, the lesser trochanter marker would have a subtly different relative position when the radiograph is taken. This may also be a truer reflection of the radiological anatomy of the lesser trochanter. As the results in this case are of the order of 0.5mm, any small error such as these is unlikely to have a profound effect in these data.

The skeletal model is designed to be anatomically accurate but the use of a physical model can introduce limitations. The left hip of the model is a cemented 28mm metal on polyethylene total hip replacement and the joint is prevented from dislocation by the use of springs which maintain tension across the joint. A potential for error may occur as the construct, though anatomical, may not completely reproduce the effects of movement that occur in the patient. While the model was the most accurate available for this project, there have been no studies to assess how accurately such models can reproduce subtlety of movement in all planes that occur in either a native or replaced hip joint *in vivo*.

For the radiographic study, the tilt sensor used to measure flexion and extension, was calibrated to be accurate to within 0.5^{o} in two degrees of freedom, flexion angle and internal rotation about the hip, however it was not possible to use the pre-prepared jig to hold the limb in the required position as it obscured the markings on the skeletal model, and because of this, the researcher (Miss Jennifer Barlow) was required to hold the limb in free space. This could therefore be a source of inaccuracy that would be difficult to precisely define. The bevelled protractor, used to measure abduction and adduction, had graduations every 5° which may also have limited the accuracy of this part of the research.

As the results from the internal and external rotation part of the radiographic study indicate, it is impossible to entirely exclude error. Random and human errors will occur, for example; identifying the markers when measuring or inaccurate positioning of the limb at the required angle. There will also be experimental errors such as the computational model not fully reproducing the movements found in a human hip. The radiographic experiment cannot isolate the limb in the same manner as the computational study, for instance when the limb is adducted there may be a component of flexion to allow clearance of the contralateral limb. The errors associated with the radiographic study may be reflective of those that would appear in the real world.

If, as in section 5.4.2., the notional 10% level of acceptability is used for the purposes of discussion, it corresponds to a 7.7mm error in this radiographic study. This limit is not reached in flexion and abduction, either by the mean value or the C.I. in this experiment. Even when both are taken at their peak error, there is only a small change in the contribution of the CFH-TD(Cup) component, which increases by no more than 1% of the overall measurement.

While this study demonstrates that extension and adduction are a greater source of error than flexion and abduction, when they are taken to the limit of acceptability there is only a relatively minor change in the contribution that the CFH-TD(Cup) makes to the CFH-LT (Stem). If the theoretical limit of acceptability is again taken to be 10% then the contribution of the CFH-TD(Cup)measure increases from 19% to 23% for both extension and adduction. At the maximum malposition this contribution increases to 26% in extension and 33% in adduction. These results would indicate that while at their maximum angle there can be an important change in the contribution that the CFH-TD(Cup) measurement makes to the CFH-LT (Stem) measure, they remain relatively minor at the point when the error in the other measures would indicate an unacceptable interpretation error.

The radiographic part of this study has indicated that malposition error associated with flexion and abduction cause only relatively minor errors in the resulting measurements. Even at the greatest magnitude of error, the mean error in reported X-ray measurement does not exceed 5%. Internal and external rotation also do not appear to be a major or systematic source of error in this experiment. The positions of extension and adduction give rise to much more potential for error, and malposition in either of these directions should cause concern regarding accuracy of plain film measurements in any patient with anything more than a minor fixed deformity. Additionally, although the relative CFH-TD(Cup) contribution to the CFH-LT (Stem) measurement can increase in these malposition, any error in this part would be secondary to greater concerns about the accuracy of the TD-LT (Overall) and therefore CFH-LT (Stem) measurements.

5.4.4. Radiological versus computational comparison study

The magnitude of the TD-LT (Overall) component measurements in neutral were different for the radiological and computational models (62mm vs 70mm). These results for the two experiments were given as actual value differences in the measurements. Therefore, for the final part of this chapter, and to provide further comparability, a calculation of the TD-LT (Overall) measurement at the corresponding angles as a percentage of the CFH-LT (Stem) in neutral was made.

These data for flexion show some similarities in trend for both experiments. Both the radiological and computational studies agree that at 10^{o} of flexion, an error exists in the direction of over-interpretation but of no more than 5% (equivalent to 3.8mm in the radiographic study). Thereafter the results diverge, though the percentage error in the TD-LT (Overall) measurements remain relatively small. At 30^{o} flexion, the errors are a 3.4% over-interpretation for the radiographic study and a 5% under-interpretation for the computational study

Abduction malposition error follows a similar trend to that of the results for flexion. Both the radiographic and computational studies suggest a maximum over-interpretation at 10^{o} abduction resulting in a maximum error of 4% (equivalent to 3.1mm in the radiographic study). Thereafter the two studies differ in that the computational model indicates a maximum error of 6% under-interpretation at 30^{o} abduction, whereas the radiographic study indicates an over-interpretation of 3% at the same angle

Extension and adduction error due to malposition was greater than flexion and abduction. For both extension and adduction, both studies demonstrated a linear decrease in accuracy with increasing angle of malposition. While these trends follow a similar pattern, the magnitude of error associated with any given angle was greater in the radiographic study with a 10% difference between the two experiments at 30^{o}.

The divergence in magnitude of predicted error was greater for adduction, 21% for the computational study and 53% for the radiological. Both maximum errors, which are equivalent to 19mm and 41mm respectively, are likely to be considered unacceptably large and they highlight the uncertainty, and thus the caution that should be shown when considering this large malposition and LLI measurement on plain radiograph.

The degree to which the 95% C.I.s from the radiographic study overlap with the results for the computational study vary. While there is overlap up to 20^{o} abduction, flexion is much less clear. At 10° and 30° the C.I.s are relatively narrow and do not include the computational study. Conversely at 20° flexion the C.I.s broaden significantly.

One limitation of the radiographic study that has already been mentioned was that the femur was held in free space. Although errors should have been reduced to a degree but the methodology of multiple readings at any given position, it is possible that, despite the use of a tilt meter there was an element of this additional malposition in the uniplanar study.

The combined elements of the computational demonstrated the additive effect that even a relatively minor degree of rotation, which had previously indicated no interpretation error in the uniplanar study, can cause. This may well therefore be a contributing factor to the divergent confidence intervals due to experimental error. The interpretation errors were further demonstrated when flexion, external rotation and abduction were combined and compared with their reciprocals.

The 95% C.I. for flexion at 10º and 30º are narrow at 1.5%, and do not overlap with the means from the computational study. This suggests that at these points, there is an additional source of experimental error. This is most likely due to factors such as impingement, an element of additional planar deformity in combination with flexion, as well as change in the relative position of the trochanteric marker moving through the arc of malposition.

Conversely the C.I. at 20º, which at 5% is larger than at the other flexion angles, suggests that in this position, there is greater experimental error. This may arise from a mechanical factor such as possible impingement of the anatomical model or difficulty in maintaining the limb in that particular position.

The 95% C.I. for the radiographic study arc no longer includes the mean for the computational model after 10^{o} extension and the findings in adduction for the computational study are not overlapping with corresponding positions from the radiographic study at any point. The results for adduction are more divergent than any of the others in the comparison study. These data suggest therefore that there is a limitation to this study other than experimental error. It is possible that for adduction in particular, the computational model does not accurately reflect the movements of the anatomical model. When the pelvis is fixed and there is increasing adduction, in an effort to accommodate the adduction there is also flexion at the hip. This specifically would not occur in the computational model which is fixed in five degrees of freedom.

As this part of the study compared the results of both previous arms of this work, it is subject to limitations arising from both the computational and radiographic experiments. The difference in the TD-LT (Overall) measurement, which produces a corresponding difference in the CFH-LT (Stem) measurement, is one potential source of conflict between the two studies as the computational model yields a TD-LT (Overall) measurement at 70mm, whereas the radiographic experiment yields a TD-LT (Overall) length of 62mm. Theoretically, in a hip where the LLI is of greater magnitude, the error should be correspondingly greater. However, as the computational study tends to result in a smaller error than the radiographic study, this is not likely to be the cause of the difference in magnitude of the findings.

The divergent nature of the findings in this study suggest that there are other factors involved in the disagreement over magnitude. It is possible that a rigid computer model, modelling motions confined to a single plane, while indicating a theoretically precise magnitude of error, does not entirely reproduce the movements that actually occur in real life. It is also possible that the skeletal model, which is designed to be anatomically accurate was not able to entirely isolate rotation to a single plane.

Additionally, despite the pelvis being fixed via a wooden bracket Figure 5.5, it is possible that there was an element of pelvic tilt or impingement introduced during extremes of malposition. This could add to the error in the radiological study and be an explanation for the variation in the intra-pelvic CFR-TD(Cup) measurement which, as the computational model suggested should not be affected by the positioning of the femur.

Although minor errors do confound the picture it remains clear that positional errors in the direction of adduction and extension a are source of greater error than equivalent positional errors in abduction or flexion.

The range of movement of the hip joint has been well described in texts, as has the association of arthropathy and reduced range of motion[322 323]. There is however little data to quantitatively indicate the incidence and magnitude of malposition of the hip joint that arise due to fixed deformity of the lower limb and spine, possibly due to the difficulties in the ability to attribute or reliably measure a single cause for the deformity in a group of patients that may have multiple joint problems.

Both studies indicate that the resulting error in LLI estimation due to malposition for the measurements made using the CFH-TD-LT technique is relatively small when in flexion and abduction, even for angles of up to 30°. Similarly, the computational and radiographic experiments agree that adduction and extension result in greater error for any given angle and as such caution should be exercised when reviewing radiographs under these circumstances.

5.5. Conclusion

This work, in accordance with other published work, identifies that malposition can be a significant source of error when interpreting complex three-dimensional anatomy on plain AP pelvis radiographs. The literature also emphasises that deformity around the hip is not the only source of error when it comes to taking radiographs and their subsequent interpretation. This is however the first to study systematically identify the errors that occur due to femoral malposition when using the CFH-TD-LT methods.

These computational and experimental results concur that there is considerably less error associated with flexion and abduction malposition than there is with extension and adduction. The study also underlines the complexity of the femoro-acetabular anatomy. The sum of movement in single planes does not reproduce the same magnitudes of error when they are combined.

Ultimately the limit of acceptable accuracy is a judgement that must be made by the surgeon. For the purposes of the discussion herein, a notional 10% limit of accuracy was used. This study shows that in patients who have flexion and adduction deformity of up to 30^0 there is likely to be a maximum inaccuracy of 5% of the CFH-TD-LT (overall measurement), which equates to 4.3mm in the computational study and 3.9mm for the radiographic study. Perhaps just significantly, the percentage that the CFH-TD(Cup) contributes to the CFH-LT (Stem) measure is unaffected. Thus, the risk of misinterpretation of the causes of an LLI is low.

Extension and adduction are a greater source of error. The radiographic study found a 10% error equating to 7.7mm at around 10^o of extension and adduction. The computational study found this 10% point at around 20^o extension or adduction. At these points of larger measurement error, the contribution to the CFH-LT (Stem) made by the CFH-TD(Cup) increases by a maximum of 3% (or 2.6mm) of the overall measure. This suggests that, in concordance with the results for flexion and abduction, the risks of incorrectly ascribing a post THR LLI to (say) only one component is low. Any angle of extension or adduction great enough to cause for malposition error tends to cause the most significant error in the TD-LT (Overall) measurement and thus the CFH-LT (Stem), before any major change in the contribution of the CFH-TD(Cup) measurement to the CFH-LT (Stem).

When considered in a more clinically typical presentation, with flexion and external rotation combined, there is an additional error that is not predicted by the sum of the two in isolation. The additional error however remains relatively small.

When these errors are considered in the context of Charnley's longstanding and widely accepted assertion that up to 10mm LLI is accepted by the patient[15], then a surgeon must be cautious in interpreting the measurements taken on plain AP radiograph when using the CFH-TD-LT method when the patient has an extension or adduction deformity. Conversely if the patient has a mild to moderate flexion or abduction deformity then a relatively small error in LLI estimation is predicted. This study also demonstrates that when the patient has a deformity likely to result in an acceptable error of measurement, then there is little change in the contribution to the total made by the CFH-TD(Cup) measurement.

If the patient falls within these limits, particularly in flexion or adduction, and a good quality, well centred and positioned film is taken in a patient in whom the surgeon is satisfied that the LLI in any given lower limb is above the lesser trochanter, then this work suggests that any further imaging, such as CT scanograms, to quantify the discrepancy may not be required.

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 part and considers them as a whole. In Chapter 6 there is also consideration for future research in this field.

6.1. Overview

The literature review presented in Chapter two of this thesis has provided an overview of the subject of LLI following total hip replacement.

As a treatment for hip pain, THR has been successfully performed since the operation was pioneered in the later part of the twentieth century. It is however a major surgery and although much successful work has been done to reduce the associated complications, there remain significant risks associated with the operation.

LLI as a complication following THR was recognised by Charnley from the early days of the operation. In more recent times however, and possibly due to generally excellent long term results, combined with a more demanding and possibly more litigious patient population, there has been greater emphasis on complications such as LLI that can be a cause of dissatisfaction, pain and poor functional outcome.

As noted previously, LLI can arise from a number of other causes, such as trauma or paediatric dysplasias, but patients who do most poorly with LLI post THR are a different group in many ways. Generally, they are an older population, likely to have lower physiological reserves, are attending for an elective orthopaedic operation that has the aim of relieving pain and improving function and, if left with an LLI, they undergo an essentially instantaneous change in leg length around the hip.

Opinions regarding the importance of LLI following THR are varied. Matters such as clinical significance, incidence, cause and quantification have yet to find broad agreement. Additionally, without an accepted definition of what magnitude of limb length difference following THR actually constitutes true LLI, it is difficult to achieve any consensus.

White and Dougal, Whitehouse et al and Mahmood et al found no association between LLI and outcome, while Mancuso and many others fundamentally disagree with that finding[16 17 19 25 28-30 39 190 307]. An understanding of the incidence of LLI following THR becomes difficult without a standardised definition and with the aforementioned complexities in diagnosis. Beard et al. found that 20% of the patients in their study had an LLI of greater than 10mm and 6% had greater than 20mm[25]. Love et al. reported that 18% of patients had an inequality of more than 15mm, but that only 6% were symptomatic[169]. Edeen et al. published work reporting that 32% of 68 patients were aware of an inequality following THR, and in this sub-group the mean lengthening was 14.9mm[20]. Konyves et found 43% of 90 patients perceived an LLI for a mean lengthening 9mm at three months post-operation[30]. Reports of incidence of LLI in the (non THR) general public also vary. Nichols published a review of “short leg syndrome” and detailed idiopathic short leg of ½ inch (12.7mm) can be found in 8% of the general population and 22% in patients with lower back pain[168]. Hult in the Monkfors investigation found a higher figure of 30% of 277 labourers who had an LLI of between 10mm and 25mm, and that 78% (64 of 82) of this group had ‘lumbar spine trouble[167].

The literature review also considered the techniques used to measure LLI. Clinical measurement during the physical examination has been shown to be less accurate than methods that use imaging. This difference between the clinical and radiographic methods can be up to 10mm[35 44 192].

Plain radiographic methods for the measurement of LLI following THR have been described. The two most prominent in the literature for are those detailed by Williamson et al and Woolson et al[3 45]. These measurements are made on plain AP pelvis radiograph which can be vulnerable to interpretation errors due to deformity around the hip or malpositioning of the patient at the time of radiography.

Accurate measurement of LLI, of all causes, has been considered in the literature. Methods such as teleradiography, orthoroentgenography, computed radiography as well as the non-irradiating techniques of ultrasound and MRI scanning have all been considered. However, the technique that has consistently provided accurate and reliable results is CT scanography [46 192 204 324]. While it does involve additional exposure to ionising radiation, the dose is less than the other radiographic measurements for assessing whole limb LLI[46]. In the presence of complex deformity, the AP scanogram can be combined with a lateral scanogram at the same time[199 200]. As such, CT scanograms have been used as the comparator technique in published studies[207 210].

The point at which an inequality becomes clinically relevant, though also dependent on the associated symptoms, is also debated in the literature. Charnley suggested that up to 10mm was tolerated although made this assertion without formal justification[15].

Bhave similarly asserted in a 1999 paper that equalisation to 10mm was important to normalise gait and reduce the risk of a residual limp when studying 18 patients who had subsequently undergone correction of leg lengthening via Ilizarov distraction osteogenesis. This group had a relatively low mean age of 24yrs (range=11 to 42yrs) and had presented with LLI due to congenital, developmental or traumatic cases. Mean pre-operative LLI of 49mm was corrected to within a 10mm[180].

O'Brien et al. found that 97% of 30 undergraduate students (mean age 23yrs) with simulated inequality, perceived LLIs exceeding 10mm. When this simulated LLI was increased to 20 mm, all participants progressed to a subjective feeling of either 'definitely longer' or 'longer and uncomfortable'. When the study reached the maximum simulated LLI of 25mm, more than half were uncomfortable when standing for 30 seconds[265].

While the result from Bhave and O'Brien would not necessarily translate to the post-THR group directly, it does demonstrate that there are detectable changes in gait at an LLI magnitude well within those published for post-operative results found in the literature review. Additionally, it is likely that, as the cohort of patients in both studies study were younger, they would be more able to tolerate any given LLI than the more typical arthroplasty patient[180 265]

Gurney et al., in a 2001 paper presented results for a study of gait economy in subjects with a mean age of 72.8 years. The subjects had a simulated LLI and walked on a treadmill while indirect calorimetry, oxygen consumption and minute ventilation were measured. The authors reported significant increases in perceived exertion and oxygen consumption with magnitudes of LLI above 20mm and at 30mm there was significant quadriceps fatigue. They concluded by describing a physiological breakpoint for LLI, above which there can be a significant impact on economy thorough the gait cycle, and postulated that it could be as low as 20 to 30mm in patients with lower physiological reserve such as the older patient[35]. In studying the subjects that would be more typical of the patient presenting for a THR, giving them an 'instantaneous' inequality and testing walking, Gurney et al have published work most likely to simulate a post-THR LLI[35]. This study provides important data to indicate the level at which an LLI becomes unacceptable and why. By suggesting a relatively broad range, of between 20 and 30mm, there is also an acceptance that there are individual patient related factors to be considered that may mean that a universal single magnitude of LLI would be always acceptable if below and always unacceptable if above.

It is difficult therefore to state from the literature where the boundary of acceptability will lie. Added to this is the range of LLI found in routine clinical practice. There have been many techniques, both pre and intra-operatively which aim to reduce the risk of a large leg length change, but despite this, only fifteen papers [21-23 163 190 213 217 223 234 238 250 256 258] reported ranges below 10mm.

In the broadest terms, the literature may indicate what is considered an acceptable LLI and what is considered unacceptable. Most studies indicate that anything below 10mm to be within the bounds of acceptable practice. Similarly, as noted above there is a broad understanding that LLI following THR becomes clinically unacceptable and perhaps functionally intolerable at the 20mm to 30mm level. While the upper and lower limits of the published ranges of data for LLI following THR are outside these margins, the means are comfortably within this range. The point at which an LLI moves from being within the bounds of conventional practice to without remains the subject of much discussion however. Ultimately symptoms would principally dictate how an LLI following THR is managed and would guide what is considered acceptable on a patient by patient basis.

This thesis therefore set out to further study LLI following THR by using litigation data to give perspective to the extent of the problem, and then to study reproducibility of measurement techniques on plain AP radiographs and finally to quantify possible errors due to malposition of the femur when taking a radiograph.

6.2. Thesis synopsis

6.2.1. Chapter three: Litigation for leg length inequality following total hip replacement in the National Health Service

Due to the lack of agreement regarding many of the aspects of LLI following THR and the 'cross-over' of the associated symptoms which can be of other causes, as well as the fact that for any given LLI following THR not everyone will be symptomatic, there was little in the existing literature to indicate the incidence of LLI following THR.

The aim of Chapter three was to provide an evaluation of the scale of the problem. To achieve this, Chapter three proposed using litigation as an indirect indicator, to provide an assessment of the magnitude of the problem of LLI following THR.

An estimation of the number of THRs during the same time period of the study was made. Using published literature, HES data and NJR data, there were approximately 795,000 THRs performed between 1995 and 2010.

Data obtained from the NHSLA found 1004 claims relating to hip replacement surgery of which 100 cited LLI following THR which is equivalent to approximately 1 claim for LLI following per 8,000 operations. The total cost for all closed cases involving LLI following THR was nearly £3.9 million and is 9% of the £41 million for the total cost of litigation for hip replacement surgery.

The information given by the NHSLA only included a brief summary of the complaint. Furthermore, no data from the private sector was included. Although preceding papers have studied a more general review of litigation associated with trauma and orthopaedics, this was the first work to study hip replacements specifically[148 283].

LLI is among the commonly cited ‘single’ causes for litigation; as such it is a notable cause for dissatisfaction in this study. It is also a reflection of the potential severity of the complaint that the maximum total cost was substantial. The largest single settlement, at a total cost of £595,000 meant that LLI was fourth highest cost cause of litigation. It is a reflection of the controversial nature of LLI following THR that these 100 claims, corresponding to 100 of the 1004 complainants, had the second lowest success rate, only 44% cases won either damages or claimant costs.

This work is able to conclude that dissatisfaction with THR that leads to litigation is rare when compared with the number of THRs performed. When dissatisfaction occurs, LLI is involved around 10% of the time. However, due to the lack of consensus regarding many of the issues surround the complication, it is difficult to establish, on the balance of probabilities, that this is both negligent and the cause of the problem.

This broader theme is recurrent in the literature. Many papers recognise that LLI is a complication following THR and is associated with a range of symptoms. While there are papers which suggest a level of acceptability, or where symptoms are likely to become intolerable, no paper suggests a specific limit beyond which, even under routine circumstances, would be classified as negligent surgery.

The results of this study did not support the view that claims involving THR in the NHS was increasing. If fact, when the number of claims made is considered alongside the number of THRs performed during the two time periods, there has been a reduction in the number of claims, from 1 claim for every 530 THRs performed in between 1995/95 and 2002/03, to 1 claim for every 850 THRs performed between 2003/04 to 2009/10. Although over differing time periods, these data indicate a contrary view to that of

Mead et al who noted that claims for orthopaedics as a whole has risen by nearly 50% between 2008 and 2013.

When these data were divided by date of incidence, there was no particular increase in claims, which when considering the increase in the number of operations being performed year on year should be considered a reduction in litigation claims.

Chapter three has demonstrated that LLI following THR is a factor in 10% of the claims brought to the NHSLA, in England and Wales. It is therefore one of the more frequent causes of complaint in this study but also one of the most difficult to prove. While the mean costs of 'lost' cases suggest a less catastrophic outcome than pain or dislocation, the fact that, on occasion, LLI following THR can result in substantial total costs, amongst some of the most devastating complications, is an indication of the potential for severity when at its' most extreme.

This work is the first to use litigation data to frame the extent of the problems associated with LLI following THR, and concludes that, when using the definition of symptomatic LLI following total hip replacement as that which will lead to litigation, it constitutes a notable component of dissatisfaction following total hip replacement. The study also adds evidence to the observation that LLI is poorly understood which may contribute to its being amongst the least successful cause of claims.

6.2.2. Chapter four: Reproducibility of Methods of Radiographic Measurement of Leg Length Inequality Following Total Hip Replacement

One barrier to greater understanding and consensus for LLI following THR is that there is no single agreed method of measurement on plain AP radiograph. The two methods used to quantify LLI following THR that are prominent in the literature are the II-LT method described by Williamson et al.[45] , the TD-LT method by Woolson et al.[3]. Although these two methods have been cited in fifty-six papers in the literature, there have been little published regarding the validity of the techniques.

Chapter four in this thesis studied these two methods from the literature, alongside two less prominent techniques. The first, the CFH-LT method, which is not a true measure of LLI following THR as it only assesses any change in leg length due to the femoral stem, not the whole of the THR construct. The second, a component based method of measuring LLI following THR, the CFH-TD-LT method.

The aim of the research was to produce data for the intra and inter-observer reproducibility of the various techniques, as well as a study of the image acquisition protocol for the films.

This study analysed the results of the measurements made on the thirty-five radiographs of the entire cohort of patients referred for a specialist opinion regarding LLI. The data provided results for intra and inter-observer reproducibility as well as for the protocol used for image acquisition. Clinical images were used and the readers were not blinded to the patient names. There was also difficulty identifying the teardrop in some cemented THRs.

A major limitation in Chapter four was that there was no allowance for femoral malposition that may occur as a result of fixed deformity of the hip. The potential magnitude of this was undefined and as such became the premise for the study detailed in Chapter five.

The study found that the three methods for measuring LLI (II-LT, TD-LT and CFH-TD-LT methods) and the CFH-LT methods for measuring LLI due to the femoral component, analysed had comparable results, with good intra and inter-observer agreement.

This was the first study to publish results for the comparison of techniques to measure LLI on plain AP pelvis radiographs. It is an indication of the complexity of the issue that two subsequent papers published conflicting results regarding the best performing measurements[308 309].

The work detailed in Chapter four found that the four methods for measuring LLI flowing THR on plain AP radiograph were comparable for reliability and no one was found to have superior reliability to any other. While all methods are as useful as each other in the measurement of an LLI following THR on plain AP radiograph, the CFH-TD-LT technique can provide more information regarding the contributions of the acetabular and femoral components to the inequality.

6.2.3. Chapter five: The Effect of Malpositioning of the Femur on the Measurement of LLI on Plain Radiograph

Chapter five investigates the main limitation highlighted in Chapter four in order to better understand the effect of position on radiographic error. The skeletal anatomy around the hip joint forms a complex three-dimensional arrangement and the plain AP pelvis radiograph is a two-dimensional projection of this structure. It has previously been unclear what effect malposition of the femur, which can arise as a result of fixed deformity around the hip, can have on the measurement of LLI following THR on plain AP pelvis radiograph. Based on the results of Chapter four, the CFH-TD-LT method was chosen as the preferred technique as it is able to provide information about each of the components of the THR as well as an overall.

Trigonometry can be used to predict the error associated with a method that uses two co-planar reference points where one of these is the axis of rotation. The CFH-TD-LT is more nuanced, having three reference points that are not coplanar. The first is the centre of rotation of the femoral head, the second, the acetabular teardrop is fixed in the pelvis and the third is the lesser trochanter which is susceptible to femoral malposition. As this method indicates the relative positions of the acetabular cup and the stem, an understanding of not just the overall error, but how these measurements change in respect to each other can be made.

It is important therefore, when using a component based technique to measure LLI following THR, to understand not just the effect on the overall measurement of the inequality but to know what would be the effect on the measurements relative to each other. Poor understanding of this inter-relationship may result in the surgeon, when treating a patient that is refractory to non-operative treatments, inappropriately limiting surgery to a single component of the THR and therefore risking instability of the prosthesis.

To investigate the potential for error as a result of malposition a computational and radiological study was performed.

Malpositions of up to 30^{o} in uniplanar displacement and with combined deformity were simulated and the CFH-TD-LT technique used for all measurements. Both experiments were subject to limitations. The computer model, which was fixed in 5 degrees of freedom, is likely to isolate each malposition in a manner that does not occur in real life. The radiographic study, in addition to being subject to human error, may also not reproduce malpositions seen in clinical practice.

The results detailed in Chapter five demonstrate that the error when placed in up to 30^{0} of isolated flexion or abduction malposition is a maximum of 5% of the CFH-LT(Stem) measure with minimal change in the CFH-TD(Cup) contribution. Internal and external rotation malposition resulted in no more than 2% of the CFH-LT(Stem), with no change in the CFH-TD(Cup) contribution. Extension and adduction malpositions were a much greater source of error. Although differing in magnitude, both the computational and radiographic experiment demonstrated a similar progression of interpretation error. The maximum misreading error was 42% of the CFH-LT(Stem) in abduction and 25% in extension. The CFH-TD(Cup) contribution increased to 33% and 26% respectively. The interpretation errors due to adduction and extension must however be taken in context as the maximum angle of malposition in the study is beyond that typically seen clinically.

The computer analysis also considered combined malpositions as can be seen clinically in joints osteoarthritis. Flexion when combined with external rotation demonstrates an additive effect that would not be predicted by the uniplanar studies. The maximum additional error introduced resulted in an under-interpretation equivalent to over 2% of the TD-LT(Overall) measurement.

The complex interrelationship between these three-dimensional non-coplanar anatomical references is further highlighted when all three malpositions are combined. The uniplanar element would predict that flexion, abduction and external rotation would cause less measurement error that extension, adduction and internal rotation, and this has been borne out by this element of the study. What might not have been expected when analysing the uniplanar study was that the malposition errors would combine to produce an under interpretation of the measurements made around the hip. At maximum malposition angle this equated to 16% error of the TD-LT(Overall) measurement in flexion, abduction with external rotation.

The study in Chapter five has therefore quantified systematically for the first time, the error associated with measurement of LLI following THR using the CFH-TD-LT method on plain AP pelvis radiograph in the presence of malposition of the femur.

Although ultimately the assessment of what is considered to be an acceptable error is for the judgement of the individual surgeon, this study has demonstrated that flexion, abduction, internal and external rotation when taken individually result in smaller errors than their reciprocals. When flexion with external rotation are combined and then with abduction added, this results additional error in clinical radiographical interpretation that might not be predicted by the individual components.

The ability of the CFH-TD-LT method to distinguish between lengthening associated with the position of the cup or the stem of the THR is one of this technique's unique advantages. Therefore, just as significant as the total error associated with malposition, is the change in contribution to the CFH- LT(Stem) measurement made by the CFH-TD(Cup) measure. This study demonstrates that there is minimal change in the percentage contribution that the CFH-TD(Cup) makes to the CFH -LT(Stem) even at maximum error. The errors associated with extension and adduction are greater, and while these malpositions are relatively uncommon clinically, this work indicates the caution that should be taken when considering a patient with these deformities.

6.3. Thesis discussion

The hypothesis stated in Chapter one was:

It is possible to optimise measurement of leg length inequality following total hip replacement on plain AP pelvis radiograph and therefore aid understanding of this clinically and legally significant complication.

To explore this hypothesis, a literature search was presented in Chapter two, detailing the lack of consensus for many of the aspects of LLI following total hip replacement. There was little agreement about definition, extent of clinical significance, limits of acceptability, quantification and management. Chapter two therefore establishes that the body of literature indicates that LLI following THR is clinically important but largely unreconciled particularly for many of the most important issues. In particular, there will be little progress toward greater understanding without a definition of what is a clinically significant LLI following THR. It is not likely that any agreement will coalesce around a particular magnitude of LLI following THR as; i) there is a range of measurements suggested in the literature where symptoms may present, ii) at any given LLI not everyone will be symptomatic and iii) that there are identifiable characteristics that make certain patients more prone of sensitive to an LLI. Additionally, the breadth of the published results around primary THR in terms of post-operative LLI suggests that there will always be a range of post-op LLI that will still be part of acceptable practice.

Without an agreed definition however, there is little ability to obtain even basic epidemiological data for LLI following THR. Papers suggest up to 43% of patients have a perception of LLI in the early post-operative period. This reduces to 32% of all patients in the longer term [30]. As any paper that discusses their own results for LLI following THR has their own methodologies in terms of approach, implants, follow up and rehabilitation, there is little direct comparability to be draw from the literature in terms of incidence of LLI following THR. Therefore, to determine the importance of LLI following THR from a clinical and medico-legal point of view data from the NHSLA was obtained.

Chapter three defined the complication as 'any LLI following hip replacement surgery that was significant enough to warrant litigation, whether successful or otherwise'. The work found that LLI is a factor in 10% of the claims made to the NHSLA following hip replacement surgery, making it one of the most common 'single' causes of complaint. During the same period (1995 to 2010) that these 1004 claims were made, it is estimated that nearly 800,000 THRs were performed. The overall rate of number of claims for LLI per number of THRs performed across this study was 1 claim per 8,000 THRs performed. When the rate of litigation for LLI following THR is considered over the two time periods, there was a decrease in the number of claims, from 1 LLI related claim per 6,200 THRs performed between 1995/96 to 2002/03, to 1 LLI related claim per 9,600 THRs performed.

The fact that LLI following THR is relatively common in the litigation data is also a reflection of not only the lack of clarity in the literature, but also a lack of understanding in the body of hip surgeons in total. Khan et al.[27] demonstrated that a simple checklist can be effective in reducing LLI following THR. Should a surgeon recognise therefore that LLI is leading to poor outcomes within their own practice, then relatively straight forward steps can be taken to reduce the incidence of the complication.

That litigation for LLI succeeds at all indicates a body of opinion differing from White and Dougal, Whitehouse et al and Mahmood et al, and is more consistent with Charnley[15], Mancuso[19] and others[10 28 30] in that there is recognition of this complication as a source of dissatisfaction. This would establish the link of causation between LLI and symptoms.

Thereafter, no definition of a point at which a LLI becomes significant or negligent, has found popular support. Not only is there breadth in the opinion about at what point symptoms could be expected to be attributable to LLI, but many of the published studies include these magnitudes in their results. To be found on the 'balance of probabilities' to be negligent, any LLI following THR would have to be outwith the practice of a respectable body of opinion. If, however, that body of opinion includes a large range of possible LLIs then establishing negligence becomes difficult. The added factors of lack of definition, plus the absence of agreed and validated measurement techniques would further cloud the issue.

A significant barrier to an agreed definition of LLI following total hip replacement is therefore, the lack of a technique to reproducibly make an assessment of it on the most commonly used clinical investigation, the AP pelvis radiograph. Chapter four uses the two methods established in the literature studying them alongside two further techniques, the CFH-LT measure of inequality due to the femoral component, and the three point CFH-TD-LT measure of LLI following THR. The main finding was that these were comparable with no single technique consistently demonstrating superior results.

That being the case, the fact that the CFH-TD-LT technique is able to divide any given inequality between the constituent parts, and so has distinct advantages over the other methods studied. Firstly, for clinical governance and audit purposes, it would conceptually allow a surgeon to understand that, should they be regularly causing the complication, then they might be able to deduce which particular part of the operation is more consistently responsible for then LLI. This would allow the surgeon to amend their practice, though not at the expense of stability of the hip and perhaps lead to better outcomes for patients and greater awareness of the problem.

Secondly, if a patient has an intolerable LLI following THR, which is refractory to non-operative interventions, then the surgeon will be able to make clearer plan for any revision surgery. Thirdly, from a medico-legal perspective, any surgeon performing revision hip replacement would be able to use the CFH-LT-TD measurements to defend a course of action should some of the more significant complications occur. This is particularly important for a subject such as LLI following THR where there is such a diversity of opinions regarding most of the major issues surrounding the subject.

A disadvantage of the CFH-TD-LT method is that it is more complicated to perform than the others assessed in Chapter four. The CFH-LT-TD method also requires a clear understanding of what each particular measure means as a vector quantity, not just a scalar.

For example, should, for any given LLI, the CFH-TD(Cup) measurement be large, if taken in isolation this would mean that the TD-LT(Overall) was smaller than the contralateral side and there would be a shortening. To compensate for this shortening the surgeon may excessively lengthen with the stem, making the CFH-LT(Stem) measure much longer. This could result in, should the patient undergo operative correction revising only the stem, a risk of instability of the hip and dislocation.

There is a distinct advantage in teasing out the effect of both components, while Konyves[30] suggested that the fault lay with the stem, Parvizi[28] and Stone[42] published data for LLI when both components had to be revised. While there may be other reasons for cup revision such as avoiding mismatched, worn or malaligned components, it is vital to understand the contribution that each component has made to any inequality if further complications, either persistence of LLI, pain or dislocation are to be avoided. Failure to do so may result in a worse outcome for the patient than if they had simply accepted the inequality in the first place.

Chapter five adds further clarity to the techniques of measurement of LLI on plain AP pelvis radiograph by quantifying the errors that are associated by malposition of the femur when the image is taken. The study found that flexion, abduction and both internal and external rotation resulted in relatively small errors in the total measurement, as well of the component parts when viewed in isolation. Extension, albeit in clinical terms not relevant, if occurring along with adduction would have the potential to cause much greater error, particularly at the maximum angles of deformity in this study, and when identified, measurement on radiograph should be performed with caution.

In addition to the single plane studies, chapter five also considered the more common combined deformities seen clinically, initially when flexion was combined with external rotation, and then when flexion and external rotation was combined with abduction and studied alongside their reciprocal, extension with adduction and internal rotation.

The major finding of these combined studies indicates that these more complex malpositions result in additional interpretation error. The results provide some assurance that the errors associated with these combined deformities, which can be found in patients presenting for THR, still have to be greater than 20º before the misinterpretation becomes greater than 10%. However, after this level of combined malposition the clinician may require further imaging to quantify any LLI following THR.

Deformity resulting in femoral malposition on radiograph is further complicated by the fact that is can be driven by other joints. Stiffness preventing full extension at the knee can result in flexion of the hip when supine. Similarly, fixed deformity of the spine may also prevent comfortable supine positioning for the radiograph. While radiographic departments, particularly those associated with elective orthopaedic clinics will have a standard protocol for patient positioning of the radiograph, they may not be able to correct for such positional issues completely.

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

i) Investigating litigation data highlighting the extent of the complaint in terms of clinical and medico-legal terms and placing it in the context of the total number of THRs performed.

ii) The work has also aided optimisation of the measurement of LLI following THR by comparing the established technique to; firstly, a method that measures the inequality due to the femoral stem and secondly, a component based method of measuring LLI follow THR. The study found that they produced comparable results and therefore demonstrated reproducibility. Specifically, the CFH-TD-LT method was found to be similar for intra and inter-reader reliability. With this added understanding of the contribution to an LLI from the component parts, it is possible that, should an LLI following THR require revision surgery, the likelihood of inappropriate surgery may be reduced.

iii) The final part quantified the error associated with malposition. This allows a surgeon to better understand the limits of accuracy of the plain film measurement of LLI due to THR and then only request further imaging if it is clinically warranted.

6.4. 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.

6.4.1. Assessment of consensus

One of the major inhibitions to greater understanding of LLI following THR is the lack of any consensus around the subject. While LLI has been recognised as a complication since the operation was pioneered, there are conflicting opinions in the literature regarding clinical significance and magnitude. As discussed previously there is no universally agreed ‘limit of acceptability’, a point below which any LLI following THR would be considered within the bounds of reasonable practice and above which would be considered unacceptable. It is possible that these are two points and that always acceptable and always not, correspond to different magnitudes of LLI.

There has been no published work that has attempted to demonstrate a consensus, or indeed lack thereof, for significance and quantification of LLI following THR. A study to gauge the opinions of sub-specialist hip replacement surgeons is warranted. 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 is no broad consensus. 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 THR which themselves could be investigated further.

6.4.2. Analysis of other sources of error when taking radiographs

This thesis has quantified the error associated with malposition associated with LLI following THR, finding that is can be considerable in certain positions.

These post-THR patients have a replacement femoral head of a known size which can subsequently be used to calibrate measurements on plain films. However, what has not been widely understood is, in the pre-operative patient, what influence malpositioning of the calibration ball and beam positioning in relation to the patient's anatomy.

Further work is therefore proposed to investigate and quantify these errors. The study would be performed in a radiographic suite and could use two radiopaque markers of known size. One would be positioned to simulate the position of the hip according to the standard protocol and the other would be placed in various positions in the antero-posterior and medio-lateral plane. The mobile reference would be used to measure the apparent size of the fixed reference and errors defined.

The result would, in a similar fashion to Chapter five in this thesis, allow a quantification of associated error and mean that a surgeon can make a judgement regarding the acceptability of accuracy of measurements made on plain films.

6.4.3. Error associated with malposition when taking a CT scanogram

One of the main elements of this work is to provide an understanding of the accuracy and reliability of measuring LLI following THR on plain radiograph. Current practice also accepts that when these factors are not clear then further investigation is warranted, in most cases a CT scanogram[46]. As the results in Chapter four and five have demonstrated, assessment on plain radiograph has good inter and intra-observer reproducibility and the potential for error has been quantified.

What is not clear is the accuracy of the reference examination in cases of deformity around the hip which lead to malposition. Others have studied the accuracy of CT scanograms for whole limb LLI and not secondary to THR and advocate the use of a lateral scout view in addition to the AP CT scanogram. CT scanograms have been shown to be accurate and subsequently used as the reference modality in comparative studies[46 200]. However, there is little quantification in the literature regarding the accuracy of CT scanograms in patients who have an LLI following THR.

Work in this thesis has provided data describing potential for error associated with plain film measurement and it is possible, that from a that CT scanograms do not provided much additional, clinically relevant, information.

A future project to investigate this relationship could be performed using much of the equipment and methodology used in the radiographic study element of Chapter five in this work. It would however require the use of a CT scanner and associated operational staff. The risks associated with ionising radiation exposure may mandate a solution to the problems encountered in maintaining the skeletal model in the various angles of deformity. It is not clear whether the relatively small gain in clinical interpretation would justify the cost and risk associated with such a technical study.

6.5. Conclusions

LLI following THR has been identified as a cause of post-operative dissatisfaction since the operation was popularised in the later part of the twentieth century and it has more recently come to prominence in the literature.

This thesis has explored NHS litigation data to indicate the extent of the problem. Taken in the context of the number of THRs performed over the same time period, litigation for THR is relatively rare. However, LLI following total hip replacement appears to be among the more cited complaints in litigation for total hip replacement. It is therefore a relevant source of dissatisfaction following THR and warrants consideration.

Data has also been presented for the reproducibility of the established techniques for measuring LLI following THR on plain AP pelvis radiographs. One method, the CFH-TD-LT method, which demonstrated comparability with the other techniques studied, had the advantage of providing more information of the cause an LLI. The final part of this work has provided an understanding of the error associated with malposition when taking the radiograph. The results indicate that isolated flexion and abduction result in relatively small errors in measurement of LLI. However, the measurement of LLI following THR using the CRF-TD-LT method should be interpreted with caution in the presence of greater degrees of combined deformity.

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Appendices

Appendix A: Published papers arising from the work in Chapter 2.

Leg length inequality following total hip replacement

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Abstract

Total hip replacement is a technical and demanding operation and subsequent leg length inequality (LLI) is a recognized complication. Although noted when the operation was popularized in the 1960s it was in the 1990s that it increased in prominence. LLI following total hip replacement is an independent risk factor in the outcome of total hip replacement. While not everyone with a post-total hip replacement LLI will be symptomatic, those who are can complain of mechanical problems, pain and neurological deficit. LLI also has increasing medico-legal consequences. Although any patient undergoing total hip replacement is at risk of a symptomatic LLI there are identifiable populations who are less likely to tolerate what would be otherwise considered an acceptable deformity. This paper focuses on the important elements in the history, examination and investigation with relevance to LLI and total hip replacement, particularly considering those at greater risk of symptoms. The paper also discusses the background, definitions as well as the management strategies for an unacceptable LLI.

Keywords arthroplasty; hip; leg length inequality; replacement

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Introduction

After a hip replacement many patients have a small difference in their leg lengths. Most remain unaware of this. As the difference in the leg lengths increases the proportion of patients who are both aware of the difference and are unhappy with it increases. Leg length inequality (LLI) is an independent risk factor in the outcome of total hip replacement (THR) and can result in a disappointing result despite an otherwise satisfactory operation.[1] It is important to remember though that not everyone with an inequality will be symptomatic, though the proportion increases with increasing inequality.[2,3]

Although the consequences of leg lengthening were recognized by Charnley when the technique of arthroplasty was popularized and subsequent papers were published during the 1970s and 1980s, it was not until the 1990s that LLI following total hip replacement came to prominence in the literature. This may be due the indications for arthroplasty broadening to include a more demanding and younger population who require more function from an arthroplasty as opposed to simple pain relief.

This article focuses on LLI following THR particularly in the identification of those likely to result in a symptomatic LLI, mechanisms to minimize the deformity and treatment options in those identified with a post-operative LLI. It also highlights important parts of the history, examination and investigation that would typically take place in an arthroplasty clinic but are of particular relevance to LLI.

While both shortening and lengthening are issues with THR, patients tend to tolerate shortening more than lengthening.[2] As a result the bulk of this paper primarily concerned with lengthening of the post-operative limb.

As well as the associated morbidity, LLI following total hip replacement is having increasing medico-legal consequences.

Definitions

LLI after THR, as with any other cause of LLI, may be divided into true and apparent inequality.

Apparent, sometimes called functional LLI, occurs when the lower limbs appear to be of different lengths when measured from a fixed midline reference point but are the same length when measured individually. An example of an apparent/functional LLI is when tight anterior structures result in a flexion deformity. True or structural LLI occurs when the limb length is either shortened or lengthened due to the implant itself.[3,4]

True or structural LLI can be further subdivided. Type I is lengthening directly due to the component, i.e. if the femoral stem is proud or the cup has been placed too low (Figure 1). Type

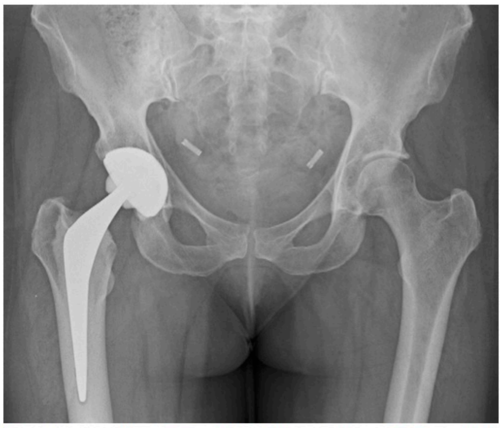

Figure 1 An example of a Type I LLI. In this case the stem is incompletely inserted, which is directly leading to the inequality.

II lengthening occurs when component mal-positioning (such as excess ante- or retroversion) results in instability. In an effort to stop the hip dislocation the surgeon may increase length and offset to increase soft tissue tension (Figure 2).[5,6]

Due to the technical and complex nature of the biomechanics of arthroplasty it is also possible to have a mixed picture of true and apparent LLI. It is vital however that the major cause of a symptomatic post-operative LLI is identified as misdiagnosis may result in unnecessary or inappropriate revision surgery.

The issue of what defines an unacceptable and perhaps even negligent LLI is more difficult and is not only clouded by the lack of agreement of significance but also by the fact that for any given LLI only a proportion will be symptomatic. Within the literature the consensus is that less than 10 mm is acceptable and that greater than 30 mm is, under normal circumstances, definitely not. However, there remains a grey area in-between that is contentious.

Figure 2 This radiograph demonstrates a Type 2 structural LLI. In this case the cup has been inserted in an open position, which causes instability of the joint replacement. In an effort to increase soft tissue tension, a stem with increased neck length and offset has been inserted, resulting in an LLI.

Background

The morbidity associated with a post-THR LLI can vary from the patient only becoming aware of the problem when noticed by others (often the physiotherapist or spouse), to other patients who experience unpleasant symptoms on recovering from the anaesthetic. Patients can complain of mechanical problems or pain or may suffer nerve damage.[7,8]

The mechanical symptoms of LLI range from instability and dislocation to a limp. Limping is itself a manifestation of disability and the resulting gait abnormality can increase the physiological demands of mobility. A breakpoint around 40 mm in healthy individuals has been reported at which this occurs; however, in those with reduced physiological reserve this may be as low as 20 mm of LLI or less. This is important as although the limit for a healthy patient would be considered a rare and unacceptably high inequality, 20 mm is well within the 'grey area' and is within the range of some of the post-operative LLI published.[9] While patients tend to notice lengthening more than shortening, it is important to remember that an excessively shortened limb may result in loss of soft tissue support, instability and dislocation as well as many other of the mechanical complaints.

Lower back pain is more common in patients with an LLI and is thought to be largely due to the resulting functional scoliosis which, along with altered muscle action, can make it difficult to stand erect even with an inequality of 10 mm.[10] Scoliosis can be detected with an LLI of 6 mm.[4] Similarly, both ipsi and contralateral hip, knee and ankle joint pain can arise due to compensatory mechanisms. Golightly et al. demonstrated that an LLI of greater than 20 mm (of all causes, not just arthroplasty) is associated with progressive pain and osteoarthritis in the knee and hip, generally in the short limb.[11,12] Pain and arthritic changes may be present following as little as 9 mm LLI.[4]

Nerve damage due to surgical limb lengthening tends to present earlier than mechanical symptoms. These patients complain of immediate paraesthesiae or pain on recovery from the anaesthesia. The sciatic nerve is particularly vulnerable, resulting in potential motor and sensory deficit.

As well as the problems for the patient detailed above, there are mechanical consequences of LLI for the articulation of the hip joint itself. While there is an agreement of the concept that LLI will result in altered wear properties of the arthroplasty, there is disagreement about the precise mechanisms. Behave et al. noted that with an LLI (of any cause) the longer limb bears greater load for longer in the gait cycle than the shorter limb.[8] However, Barnett et al. found that lengthening resulted in a varus deformity causing reduced range of motion at the hip, leading to predictably lower wear rates.[13] In addition, even if LLI does result in an increased wear rate per million steps, if a patient has a significantly symptomatic LLI they are likely to be less mobile, with a corresponding reduction in wear associated with the reduction in activity.

The patient in the clinical setting

Identification of the patient at particular risk

Heightened awareness by the surgeon of an 'at risk' patient for LLI will encourage increased care with leg lengths at the time of surgery. There are specific sub-groups of patients who are more likely to suffer a symptomatic LLI and if these can be identified before hip replacement this can be discussed with them at that stage. The populations can be divided into those susceptible and those sensitive.

Patients who are susceptible to an LLI are those with atypical bony anatomy such as a narrow or bowed femur or poor acetabular bone stock. These anatomical problems make insertion and alignment of the components difficult. Due to the increased technical demands and the difficulty in performing intra-operative checks, patients with very high BMI may also be at greater risk of an LLI.

The patients that are more sensitive to LLI are those who have a decreased ability to cope with or compensate for any given inequality. The assessment prior to any decision to operate must identify this group as they may not even tolerate what would otherwise be considered an acceptable LLI. This group includes patients with a pre-existing scoliosis, contra-lateral leg shortening for any reason, females and patients with a short stature.[14] Contractures around either hip, such as fixed flexion, abduction or adduction, not only affect the patient's gait pre-operatively, but also additionally can cause an apparent LLI. Hence, contractures can potentially reduce the patient's ability to compensate for any change in leg length. A short varus femoral neck may not only predispose a patient to be susceptible, but also, with stretching of previously short and tight abductors, can result in an abduction contracture. The resulting pelvic tilt exaggerates any lengthening.

Any history of a limp or LLI should be cause for further enquiry. Questions such as: 'When did it start?, How was it first noticed?, Any obvious cause (e.g. trauma)?, Which leg feels longer?, What are the present symptoms? and Are there other symptoms, such as lower back pain, that can be caused by an unidentified LLI?' should also be discussed with the patient.

Pre-existing LLI of either leg must be documented. If the patient already is 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. In addition, any patient who has bilateral hip disease resulting in 'equal' shortening on both sides should be made aware that the process of arthroplasty, which aims to restore the centre of rotation, is likely to cause an inequality until such time as the other hip is replaced.

Pre-operative physical examination

The patient's stance and then gait must be examined and documented. A patient with an LLI of any cause is likely to flex the knee of the longer limb in an attempt to correct pelvic tilt (Figure 3). Particularly of interest is the long leg gait, indicating a pre-existing inequality, which can be the result of a true LLI in any part of either leg or be the result of a functional nature. A Trendelenburg gait may indicate abnormal abductor function and thus a patient with a Trendelenburg gait may be susceptible to LLI, which must be considered when planning surgery. Gait abnormalities due to previous arthropathy on either side must also be recognized. The footwear should be examined for raises, asymmetric wear or the presence of orthotics.

While the patient is still standing the spine should be assessed for any scoliosis, and if present it should be identified as being structural or non-structural using techniques such as the Adam's forward bending test. It is particularly important to identify the

Figure 3 The typical stance adopted by a patient with an LLI. The knee of the longer leg is flexed to assist in the maintenance of a level pelvis.

type of deformity 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 injudicious surgery.

Examination of the resting position of the leg and comparison of the range of movement of the hips, as well as employing techniques such as the Thomas test, should provide information regarding the presence of soft tissue contracture, though the picture can be blurred by both pain inhibition and reduced range of movement due to arthropathy, which are typical in the patients presenting to an arthroplasty clinic. Adduction and abduction contractures should be tested for fixed deformity and its cause must be identified as it can be a source of pre-operative LLI and associated symptoms as well as a cause of post-operative functional LLI and resulting morbidity.

Assessment of pre-existing LLI should be carried out as a matter of routine. In the general population LLI has been found to be as great as 20 mm in asymptomatic individuals.[4,15] This can be performed while the patient remains standing using the 'indirect method'. This is accomplished by placing blocks of known height underneath the shorter leg until the pelvis is square. The leg lengths may also be measured directly: prior to employing this method the pelvis must be levelled and the legs placed in a symmetrical position. Apparent LLI should be measured using a fixed midline reference to the medial malleoli and true LLI measured from the greater trochanter to the medial mallioli. The latter can be further examined 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 femur.[16] Clinical measurement is important in identifying LLI, however, it can be inaccurate and therefore must not be relied upon to be the single quantitative measure. A radiographic LLI of 10 mm or more can appear equal on clinical examination.

Investigations

The primary investigation in the arthroplasty clinic is the plain AP radiograph, centered at the symphysis, to include the pelvis and both hips. Ideally this should be performed in a standardized way. Typically this can done with the pelvis square (using blocks if required) and the hips in either neutral or internally rotated to allow adequate views of the hip/pelvic anatomy.[17]

Two methods of measurement of LLI on plain AP radiographs are common in the literature. Williamson et al. describes using an inferior interischial line as a reference, then drawing a line parallel to this at the level of the most prominent part of the lesser trochanter and measuring the perpendicular distance between the two lines. This is repeated for the other hip and the two measurements are compared (Figure 4).[18] The second method (Woolson et al.) is similar but uses a line at the level of the inferior part of the acetabular teardrop as a reference and a parallel line at the level of the middle of the lesser trochanter (Figure 5).[19]

To separate femoral mal-positioning from acetabular cup mal-positioning, the authors have presented work comparing these methods to other methods and advocate the use of the 'Leeds method' of measuring LLI on plane AP pelvis radiographs. The Leeds method uses an initial reference at the level of the centre of femoral rotation (CFR), two further parallel lines are drawn, one at the level of the inferior acetabular teardrop and the other at the midpoint of the lesser trochanter, and repeated for the other hip. This provides three measurements per hip, the CFR to teardrop, which corresponds to any change in leg length associated with the cup, the teardrop to trochanter for LLI due to the stem and an overall measurement of leg length; these can be of particular use in the audit of practice and in the bilateral or revision setting. The authors have found the Leeds method to be similarly accurate for the measurement of LLI but with better repeatability than the two prominent methods in the literature (Figure 6).[20] The authors recommend that a lateral hip radiograph should also be obtained to check for any atypical bony anatomy in the hip or femoral shaft.

More complex investigations such as CT scans or use of a gait lab tend to be either for the investigation of a large or unexplained LLI or in the revision arthroplasty setting.

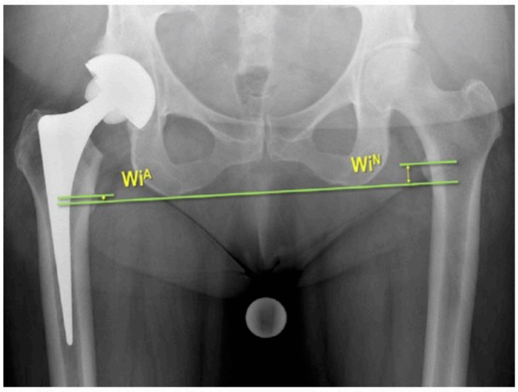

Figure 4 The Williamson et al. method of measuring LLI on a radiograph. The reference line is at the inferior interischial line and two further parallel lines are drawn through the most prominent part of the lesser trochanters. The perpendicular distance between is measured and compared. In this case the distance Wi^A for the arthroplasty is *smaller* than Wi^N for the native hip, indicating that the operated side has been lengthened.

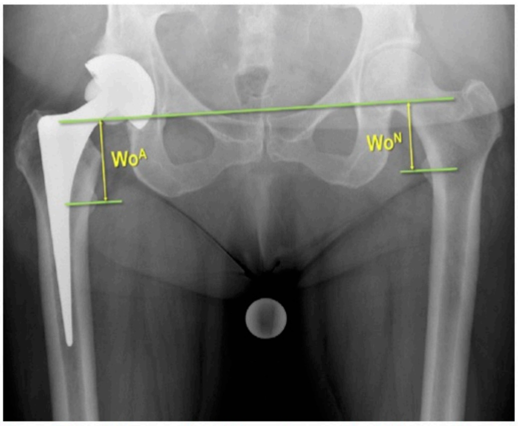

Figure 5 The Woolson et al. technique for measuring LLI on an AP pelvis radiograph. The reference line is at the level of the inferior part of the acetabular teardrop. The two further parallel lines are at the level of the midpoint of the lesser trochanter. Measurement Wo^A for the arthroplasty side is *greater* than the Wo^N, indicating that the arthroplasty side is longer. Note the contrast with the Williamson et al. method.

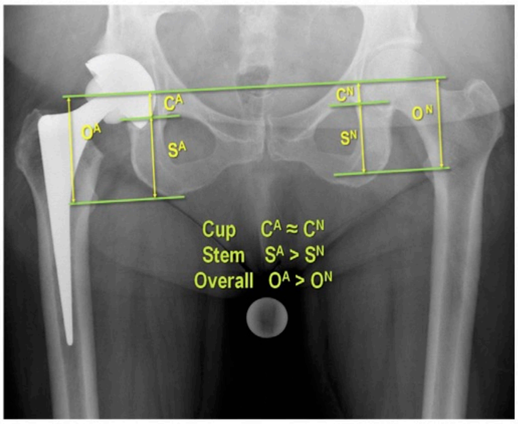

Figure 6 The Leeds method for measuring LLI on a radiograph. The reference line bisects the centres of femoral rotation. Two further parallel lines per hip are then drawn, the first at the level of the acetabular teardrop and the second at the level of the midpoint of the lesser trochanter. This produces three measurements per hip, C equating to any LLI due to the cup position, S any LLI due to the stem and overall measurement O. In this case the C measurements are similar, S is greater on the arthroplasty side and the overall measurement, O, is greater. Therefore the lengthening in this arthroplasty is predominantly due to the stem.

Techniques to minimize LLI

Current literature separates techniques employed to minimize LLI at the time of surgery into pre-operative and intra-operative techniques.

The main pre-operative technique is to use templates as described by Muller[21]; originally using overlay templates but more recently with computerized templating for digital films. Using this technique the acetabulum is analyzed for version, size and abnormal bony anatomy (such as roof deficiency, osteophytes or subchondral cysts), allowing the surgeon to determine the planned size of acetabular component. The femur is then similarly assessed for abnormal anatomy and planning of the neck resection and size and offset of stem.

Intra-operative techniques to assess and minimize LLI can be subdivided into indirect and direct methods. Indirect techniques are either those to assess soft tissue tension or direct comparison with the contra-lateral lower limb. The indirect techniques are an assessment of soft tissue balancing more than specifically of LLI; as such they are subjective and dependant on other factors such as the patient positioning, the type of anaesthetic and the amount of muscle relaxation achieved. However, in the hands of an experienced arthroplasty surgeon intra-operative techniques can be a useful 'surrogate' evaluation of LLI.

A number of direct measurement techniques have been published with varying clinical success. These direct measurement techniques are broadly based around using a fixed reference on the pelvis and measuring to a marker usually on the greater trochanter (typically either a suture or electrocautery mark). The devices vary from either a Steinman pin or K-wire bent to act as a marker or caliper, to specific proprietary devices. Other published methods include the use of an 'L' shaped caliper to allow measurement of the long axis of the femur,[17] a carpenter's or spirit level for horizontal alignment,[22] dual pin calipers to minimize loosening[23] or direct measurement with a ruler.[24] The authors found a mean LLI for all published techniques of 0.3–9.0 mm and the total range of all results for LLI was −22 to +35 mm.[24–27] A major difficulty with all of these techniques results from the significant change in leg length that results from changes in adduction or abduction of the leg between measurements. Up to 17 mm error in the measurement of leg length can be caused by 10° of adduction or abduction malpositioning.[28] Many surgeons measure the calcar cut from the lesser trochanter using the surgeon's index finger as the measuring ruler. The distance from the shoulder of the stem or stem rasp from the tip of the greater trochanter is also used as a good reference distance.

Clinical success in the reporting of intra-operative techniques are varied; Hofmann et al. reported that in 50% of cases the pre-operative plan was altered intra-operatively. Others report good series with 97% of cases with a post-surgery LLI within 1 cm.[19] Radiographic errors can also cause a problem pre-operatively as the image magnification may be up to 129% in error, resulting in sizing issues.[29] Advocates of templating state that it formalizes a process of thought in which the surgeon plans the operation, components and likely obstacles.

Management of the patient with a post-operative LLI

The management of the patient with a symptomatic LLI will depend on the timing, type of symptoms, severity, and cause. If the surgeon notices a significant LLI at the end of the operation an X-ray should be taken and advice from a second surgeon should be sought before the patient is woken from the anaesthetic. If the LLI is greater than 3 cm, consideration should be given to an immediate re-operation to correct this problem. The action taken will depend on the facilities and the competence and experience of the staff available at the time. For an LLI of less than 3 cm, a wait and see approach may be considered more appropriate. Each case must be decided on its merits.

Neurological deficit will tend to present sooner than pain or mechanical symptoms. Nerve palsy in severe LLI can present in the immediate post-operative period and must be investigated with a plain X-ray. Other causes of nerve palsy should be excluded, such as direct trauma intra-operatively, traction, ischaemia, thermal injury or compression due to haematoma or cement. Extent of the palsy is a useful indicator as mild to moderate deficits may resolve, however, severe palsy in the presence of significant LLI is unlikely to improve without surgical correction. Retention of the prostheses or early return of motor function has a better prognosis for recovery in these patients.[30,31]

Patients presenting after hip replacement with pain or mechanical symptoms should be assessed to ensure that the LLI is the likely cause of the symptoms. These are much more likely to be functional or structural as opposed to nerve palsies which, especially in earlier/severe presentation, would tend to be purely structural.

The mainstay of non-operative treatment of a structural LLI is the shoe raise. Over 90% of patients can have gait correction and significant improvement with this option alone.[13,31] However, functional LLI should not be aggressively treated with orthoses as correction of the soft tissue deformity could be limited by them; physiotherapy is more appropriate for these patients.

Operative management in LLI should be considered a last resort for most patients and is usually carried out in specialist centres. Many patients' perception of the LLI will improve and often resolve in the first year after the surgery. Surgery in cases of functional LLI predominantly involves soft tissue release or soft tissue advancement. The management of structural LLI would tend to be revision arthroplasty. It is therefore important that prior to any surgery the classification of the structural LLI is known. Without this the patient may undergo extensive and unnecessary surgery. If the problem is due to a Type I structural LLI, where the lengthening is directly due the prosthesis, then the individual component or, with modular systems just part of the component (e.g. changing to a reduced offset head in a proud stem), may be revised.

In a Type II structural LLI the surgeon has lengthened the leg to provide compensatory tightening of the soft tissues at the time of the initial hip replacement for a mal-aligned component, usually the cup. This malpositioned component must be revised initially and the other component reviewed on the table. Simple correction of the alignment may not take into account the extra lengthening factored into the other component to maintain stability, causing a greater instability.

Summary

LLI following total hip replacement, though not always symptomatic, can be a cause of major dissatisfaction despite an otherwise successful operation. It is likely that with the broadening indications for hip replacement surgery and an increasingly demanding population the prominence of LLI is going to increase.

The morbidity associated with LLI ranges from mechanical symptoms to pain and nerve palsy. While LLI is a recognized risk following total hip replacement, there are populations of patients that are more likely to be symptomatic following total hip replacement. It is vital that these are identified pre-operatively and counselled appropriately.

Post-operative LLI following total hip replacement is becoming more prominent in the literature and increasingly recognized as having medico-legal consequences.

This paper aims to highlight those steps of a normal consultation that are of particular importance in the consideration of LLI and provide some background in terms of definition and management. ◆

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CORRIGENDUM

Corrigendum to “Leg length inequality following total hip replacement” [Orthopaed Trauma 25 (2011) 37–42]

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Philip J O’Connor
Derrick White
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Martin H Stone

ORTHOPAEDICS AND TRAUMA 2016; ■ ■:■.

The authors of this article would like to draw attention to an error in the investigations section on page 40. In the third paragraph, the sentence starting ‘This provides three measurements per hip…’ should read:

“This provides three measurements per hip, the CFR to teardrop, which corresponds to any change in leg length associated with the cup, the CFR to trochanter for LLI due to the stem and an overall measurement of leg length the teardrop to lesser trochanter; these can be of particular use in the audit of practice and in the bilateral or revision setting.”

A corrected version of Figure 6 is also reproduced below.

The authors would like to apologise for any inconvenience caused.

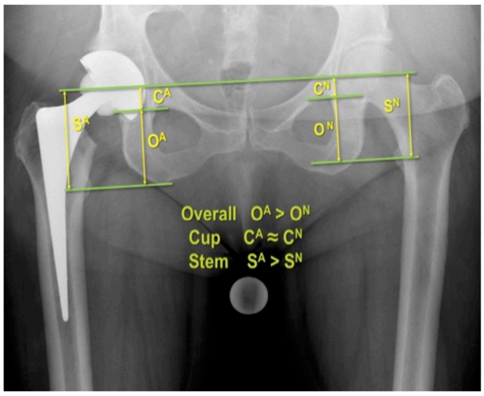

Figure 6 caption:
The Leeds method for measuring LLI on a radiograph. The reference line bisects the centres of femoral rotation. Two further parallel lines per hip are then drawn, the first at the level of the acetabular teardrop and the second at the level of the midpoint of the lesser trochanter. This produces three measurements per hip, C equating to any LLI due to the cup position, S any LLI due to the stem and overall measurement O. In this case the C measurements are similar, S is greater on the arthroplasty side and the overall measurement, O, is greater. Therefore the lengthening in this arthroplasty is predominantly due to the stem.

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REVIEW

A review of symptomatic leg length inequality following total hip arthroplasty

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ABSTRACT: *Leg length inequality (LLI) following total hip replacement is a complication which features increasingly in the recent literature. The definition of LLI is complicated by lack of consensus regarding radiological measurement, clinical measurement and the incomplete relationship between LLI and associated symptoms. This paper reviews 79 reports relating to LLI post hip replacement, detailing definitions and classification and highlighting patient populations prone to symptomatic LLI.*

While there is no universal definition of LLI, there is a broad consensus that less than 10 mm of difference on AP view plain radiographs is clinically acceptable. There are few techniques described that consistently produce a postoperative LLI of less than this magnitude. Where postoperative LLI exists, lengthening appears to cause more problems than shortening.

In cases of mild LLI, non-surgical management produces adequate outcomes in the majority of cases, with functional LLI cases doing better than those with true LLI. Operative correction is effective in half of cases, even where nerve palsy is present, and remains an important option of last resort. Poor outcomes in patients with LLI may be minimised if individuals at risk are identified and counselled appropriately.

KEY WORDS: *Hip replacement, Leg length inequality, Arthroplasty*

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INTRODUCTION

It was not until the 1990s that postoperative leg length inequality (LLI) came to prominence in the literature (1). Though many cases are asymptomatic, residual LLI following hip replacement surgery can result in limp, unremitting pain, neurological complications or recurrent dislocations (2). LLI is the most common cause of litigation against orthopaedic surgeons in the United States and is now the fourth most common for hip replacements in the UK (3-5). The cost to the National Health Service Litigation Authority of litigation specifically citing LLI is greater than £3.8 million GBP (6).

There is a lack of agreement in the literature about what constitutes a significant LLI both pre and postoperatively, and for any given magnitude of inequality only a proportion of cases will be symptomatic. Asymptomatic leg length inequality of 2 cm or more is relatively common in the general population who have not undergone hip replacement arthroplasty (7, 8) and it is well recognised that both lengthening and shortening of this magnitude can occur with hip replacement arthroplasty. Consequently there are patients who remain satisfied with their arthroplasty despite having an LLI which might be symptomatic in others, while others appear to experience symptoms or functional compromise with relatively small inequalities. This occurs against a backdrop of a poor understanding of why this is the case.

Currently, there is no globally accepted LLI measurement protocol and so there are differences in both definitions and reported normative values. While the consensus from the literature appears to be that post operative LLI of 10 mm or less is likely to be acceptable, there is little agreement about an upper limit of LLI that would be considered definitively unacceptable. While one study has reported a prevalence of LLI following THR of some 30% (9) the absence of agreed definitions has led to a paucity of good quality epidemiological data on the scale of the problem.

Furthermore, while the preceding section has focused on radiologically confirmed LLI, it is clear that patient perception of LLI and presence of a radiographic LLI do not correlate well (9, 10). In one study of THR outcomes at 5 to 8 years post-op follow-up, some 30% of patients (329 of 1114) perceived an LLI following total hip replacement, while radiographic analysis of a section of this sub group of patients indicated that only 36% (27 of 75) had a LLI of ≥5 mm (9).

Multiple studies have demonstrated the benefits of total hip replacement and have shown that satisfaction and dissatisfaction is multi-factorial (11-13). There is, however, disagreement about clinical significance of radiologically evident LLI following total hip replacement. White et al found no association between LLI (21 mm shortening to 35 mm lengthening) and either functional outcome or patient satisfaction (14). Another study found no association between pre-operative and post-operative LLI (15).

Conversely, a link between LLI following total hip replacement and poorer outcomes has been proposed (2, 8, 16), however even relatively small magnitudes of LLI can be associated with limping and pain (2), and one third of all THR patients were reported to perceive differences in limb length to the point where they 'annoyed' by it (8). To-date there has been no formal study attempting to set a scientifically derived threshold for magnitude of LLI that may relate to a level of clinical significance. Using a cut point of 10 mm, Beard et al found that patients with LLI >10 mm at follow up of up to three years had significantly worse Oxford hip scores (17). Mancuso found that symptoms associated with LLI to be an independent risk factor for the outcome for total hip replacement (13). This

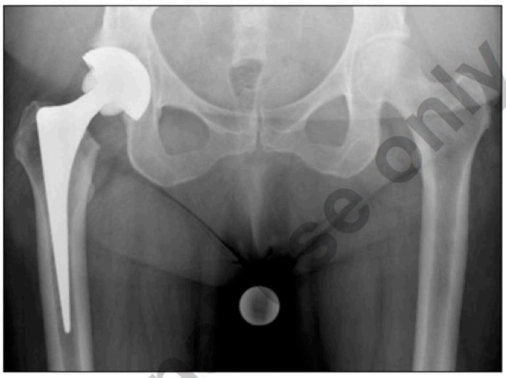

Fig. 1 - *A radiograph of a total hip replacement where the femoral cut is too proximal resulting in a type 1 true leg length inequality.*

review of nearly 80 papers aimed to examine the literature relating to LLI following total hip arthroplasty and to highlight causes, consequences and techniques to minimise the problem.

DEFINITIONS

LLI can be described as true or apparent (also described as structural and functional respectively) (7, 18).

True or structural LLI can be further subdivided according to aetiology. Type 1 or primary symptomatic LLI is due directly to component mal-positioning (Fig. 1) i.e. where a narrow femoral canal or high femoral cut leads to in incomplete stem insertion resulting in a stem which sits too proud, or where the acetabular cup has been placed too low (5).

Type 2 or secondary symptomatic LLI occurs when a limb length discrepancy is accompanied by component malposition. For example, when poor version of the acetabular component requires increased soft tissue tension to prevent dislocation. The surgeon achieves this by increasing the femoral length (Fig. 2) (5, 19).

It is important to distinguish between the types of LLI prior to any revision surgery. Revising only one component of a type 1 LLI may correct the problem, however in a type 2 LLI a single component revision is likely to result in an unstable arthroplasty.

Fig. 2 - *Example of a type two LLI, the cup is malpositioned and stability has been achieved by lengthening at the stem.*

DIAGNOSIS OF SYMPTOMATIC LLI FOLLOWING TOTAL HIP REPLACEMENT

Clinical presentation

The clinical presentation of problematic LLI varies and can include limp, fatigue, pain, or nerve damage. Patients tend to tolerate shortening better than lengthening (20, 21). Symptoms can occur immediately in the postoperative period or develop at a later date. Although not mutually exclusive, nerve pain and palsy will tend to present earlier than mechanical and gait associated symptoms (22, 23).

Patients may also complain of symptoms in other joints due to compensation mechanisms including hip or knee flexion, equinus and decreased walking speed (7, 21). Many patients adopt the pathognomonic stance of LLI, with the long leg flexed at the hip and knee (Fig. 3). Back pain is commonly reported, likely due to the development of a functional scoliosis (20, 24, 25).

The pelvic tilt associated with a LLI can also result in the longer limb becoming abducted, changing the load distribution in the lower limbs, which may contribute to progressive pain and osteoarthritis in the healthy contralateral knee and the hip, or to edge loading and accelerated wear in prosthetic joints (21, 26-29). The biomechanical changes associated with post replacement

Fig. 3 - *The typical stance of a patient with LLI. Note that the long limb is flexed at the hip and the knee to produce an apparent shortening and equalised leg length.*

LLI are complex and have not however been extensively investigated (21).

In the presence of limb lengthening the sciatic nerve is especially vulnerable, with damage leading to motor impairment, sensory alterations or referred pain (22, 30-32). Nerve injuries (of all causes) have been reported in 1% to 3% in primary and 3% to 7% of revision arthroplasties (22, 30, 31, 33). Females are at higher risk, due to their

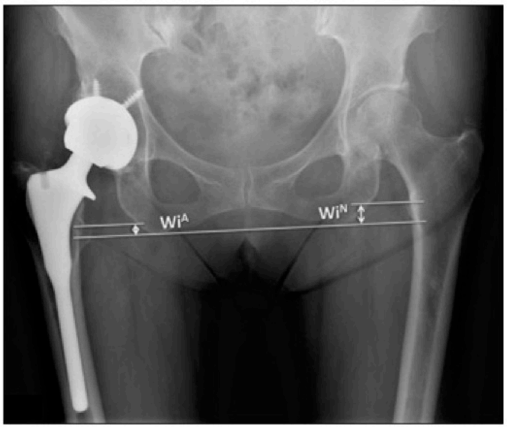

Fig. 4 - *The method described by Williamson and Reckling (33). A reference line tangential and parallel to the most inferior portion of the Ischia is constructed. Two further parallel lines are drawn through the most prominent part of the lesser trochanter and the perpendicular distance between the lines measured. The difference between the left and right sides is the measure of LLI.*

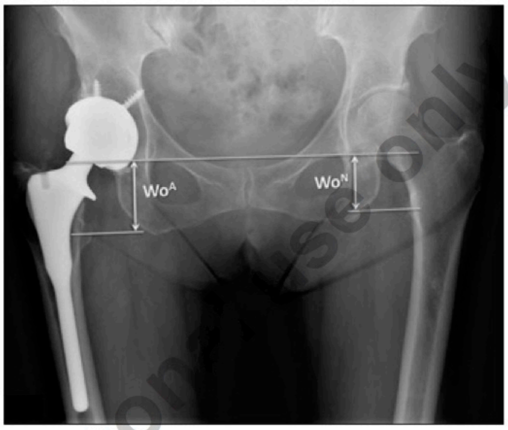

Fig. 5 - *The method described by Woolson et al (38). A reference line is drawn through the most inferior part of the acetabular teardrop. Two lines parallel to this are drawn through the centres of the lesser trochanter. The difference in the perpendicular distance between the left and right sides is defined as the LLI.*

reduced femoral offset and the closer proximity of the nerve to the surgical site (22, 31). Various studies have found postoperative nerve palsy associated with lengthening of between 13 mm and 51 mm (31, 34).

Clinical and radiological measurement of LLI

During physical examination LLI can be quantified clinically (1, 18, 35, 36) although clinical measurements can be inaccurate by 10 mm or more (7, 37) and confirmatory radiological investigation is often required. Two radiological techniques predominate in the literature and are widely used in clinical practice. The methods described by Williamson and Reckling (Fig. 4) and by Woolson et al (Fig. 5), the latter has a reported mean inter-observer variation of 0.5 mm (33, 38). Neither method takes into account however, deformities such as hip flexion or abduction at the time of the x-ray (which will tend to reduce the measured LLI) or any causes of LLI not involving the hip (16, 39). A more recent study of various methods found that the Williamson and Reckling technique was the more reproducible but was still associated with 4-5 mm error in measurements derived from plain x-ray (40).

APPROACH TO MINIMISING SYMPTOMATIC LLI

Identification of patients most at risk

There are several identifiable factors that increase the risk of a patient suffering a symptomatic LLI (Tab. I). Atypical anatomy, such as excessive femoral bowing, narrow femoral canal or poor bone stock can cause difficulties in obtaining proper alignment or insertion of the components. This can be further complicated when using an uncemented femoral stem (41) or in the obese patient.

The patient with a short varus neck of femur is sensitive to stretching of the abductor muscles, resulting in a tilted hemi-pelvis with the operated side lower (functional LLI) (36). In short stature patients, any lengthening will represent a greater percentage of the patients overall height. In addition, smaller patients tend to have a narrower pelvis, which produces a greater amount of pelvic tilt for any given LLI (42).

The legs of patients with pre-existing gluteal shortening will tend to lie preoperatively in an abducted and externally rotated position, resulting in an apparent lengthening. If these patients are then lengthened as a result of THR they

TABLE I - RISK FACTORS FOR SYMPTOMATIC LLI FOLLOWING TOTAL HIP REPLACEMENT

Narrow femoral canal	Female gender
Abnormal femoral diaphysis	Pre-existing Scoliosis
Acetabular abnormality	Ipsi and contra lateral knee and ankle pathology
Poor bone stock	Short, varus femoral neck
High BMI	Narrow pelvic width
Uncemented stem	Pre-existing shortening of abductors
Short stature	Pre-existing LLI

will consequently either increase their pelvic tilt or, if the required compensation is too great, will have to pivot on the shorter leg to place the longer leg on the ground.
Furthermore, patients with low physiological reserve are less able to tolerate the increased demands that a vaulting gait requires for any given level of mobility (26).
Finally, patients with pre-existing but asymptomatic LLI may be less likely to tolerate any increase in their leg length inequality and can experience worse morbidity than would be associated with a similar LLI in other patients (30, 43).

Preoperative techniques to minimise LLI

Preoperative techniques typically involve some form of overlay template (18, 38, 44-51) While highlighting the importance of templating, Hofmann also noted that the plan was changed intraoperatively in 50% of cases (1). Others found that templating made no difference and another found errors associated with magnification of >3 mm in 17% of subjects' x-rays, equating to more than one component size and making effective preoperative planning difficult (16, 49).
Five papers have reported preoperative measures to minimise LLI following THA and provided operative data for leg length. The mean lengthening observed was 2.7 mm (-22 - 27 mm) (18, 48, 52-54) and the most successful studies report 92% of cases with LLI within ±5 mm, 99% within one component size and 92% and 90% accuracy for the stem and the cup respectively (45, 48, 49). Woolson et al using radiographs to plan the neck resection, reported that 86% of patients were level to within 6 mm and 97% of patients within 10 mm (38).

Intraoperative techniques to minimise LLI

Twenty two papers described intraoperative techniques attempting to minimise LLI (1, 14, 15, 35, 37, 55-71) most of which have involved measuring from a fixed reference such as a Steinman or K-wire in the ilium and a fixed point on the greater trochanter (15, 35, 37, 56, 58, 61-71). Five papers described methods that take into account rotation, measurement of length parallel to the limb axis or single pin loosening. They describe using a proximal reference on a fixed point at the posterior rim of the acetabulum, close to the centre of rotation (62), and using an 'L' shaped calliper (61) or spirit level (35) or a 'calliper dual pin retractor (58, 63).
Limb position is a known source of error, with five degrees of adduction or abduction intraoperatively causing as much as 8 mm error in leg length measurement and ten degrees of abduction/adduction causing up to 17 mm error in length (72).
Other techniques described in the literature are; direct comparison of leg length with the contra-lateral limb (1), intraoperative radiographs (1), direct measurement either with a ruler (57), or with knotted umbilical tape (59) or meticulous attention to the originally described technique of arthroplasty and soft tissue assessment (14). One paper was able to demonstrate that a system of computer navigation was able to provide accurate assessment of the intraoperative change in leg length (60). Twelve papers reported the results of their own intraoperative techniques (1, 14, 15, 35, 37, 57, 58, 60-62, 64, 69). The range of LLI across all eleven studies varied from 20 mm shortening to 35 mm lengthening, a range of 55 mm. Seven of the 12 papers published means which ranged from 0.3 mm to 12 mm (1, 15, 37, 58, 61, 62, 64).
The techniques employing evaluation of soft tissues are primarily assessing stability and the accuracy of any soft tissue balancing test is dependent on the force applied and the soft tissue relaxation (64, 73). Soft tissues are affected by preoperative contractures and by anaesthetic type and Sathappen et al found that more than half (33/63) of the patients with a spinal anaesthesia had greater than 10 mm LLI while of the corresponding group under general anaesthesia only one patient of 69 had an LLI over 10 mm (59, 74).
The shuck test assesses soft tissue tension by applying traction to the reduced hip replacement. If tension is correct, the prosthetic femur should sublux by 10 mm (43, 75).
The Ober Test estimates iliotibial band (ITB) tension. The

hip is extended and abducted, and if positive (if the ITB is tight) the limb will tend to remain extended and abducted (43, 69). The Kick Test for quadriceps tension is performed in the lateral position by holding the leg parallel to the contralateral limb, with some extension. The knee is flexed and if the limb has been lengthened it will swing passively into extension (1, 43).

MANAGEMENT OF THE PATIENT WITH SYMPTOMATIC LLI

Non-operative management of symptomatic LLI

One of the difficulties in evaluating the treatment of LLI, is the well reported improvement in symptoms over time even in the absence of treatment. Konyves et al found that of 56 patients with LLI (mean 9 mm), only 33% at 12 months perceived the inequality (16). The prognosis for recovery from functional LLI can be good, especially where not due to component malposition, with 94% of patients reporting a good or excellent outcome following intensive non-operative therapy (23, 76). Ranawat et al found that all patients with functional LLI and pelvic obliquity had resolution of symptoms after six-months of stretching exercises and that seven of nine 'persistent functional LLI' improved with further physiotherapy and orthotics, Goldstein et al further stated that most symptomatic issues resolve by one year (36, 51).
The use of a shoe raise has been extensively reported in the literature and most if not all patients with a symptomatic LLI are likely to gain at least some improvement in symptoms and posture, with some going on to complete resolution of symptoms (7, 28, 77). While orthoses are helpful, they must be used with some caution as early and injudicious use can prevent a functional LLI from correcting spontaneously (3, 76, 78).

Operative correction of LLI

The results of surgery to correct symptomatic LLI are encouraging, even when associated with nerve palsy (31). In a series of 17 patients undergoing revision surgery for nerve deficit (mean lengthening 24 mm, range 13 - 41 mm), nine patients had an excellent result, two had partial improvement and six had no improvement. Time from recognition of symptoms to revision surgery ranged from 4 hours to 4 months and the mean time from primary to revision surgery was 10 weeks (8 hours to 26 weeks). Of the 17 patients reported, two acetabular cups were repositioned, five modular femoral heads were changed, and in 10 patients the femoral stem was revised. Eight hips were found to be unstable, four had trochanteric advancement and four had constrained acetabular prostheses (31).
Parvizi et al reported the results of 21 revisions for symptomatic leg length with a mean LLI of 40 mm (range 20 - 70 mm). In 15 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 10 mm (5 - 20 mm). Nineteen of 21 patients were satisfied with the outcome of the revision. Of the remaining two, one had persistent back and hip pain, the other continued to sublux (5). This contrasts Konyves et al who attributed almost all his LLI to lengthening on the femoral side in 55 of 56 patients (16). The importance of patient selection was recently highlighted in a study by McMurray et al in which 12 of 13 patients with a mean LLI of 12 mm (6 - 22 mm) with disabling leg pain preoperatively, were very satisfied following revision surgery (79).

CONCLUSION

Leg Length Inequality can result in serious patient morbidity although the correlation between magnitude of radiology measured LLI and symptoms is weak. Patients are more likely to complain of a long leg than a short leg, although shortening can result in instability which may itself be cause for revision. In total, thirty papers reported specific data on LLI following THR. The overall range varied from 38 mm shortening to 35 mm of lengthening. Only eight papers reported ranges in which maximum lengthening was below 10 mm (1, 18, 48, 53, 57, 61, 62, 69). It is evident, therefore, that even using techniques specifically designed to equalise leg length after THR, achieving equality of length is not always possible. Furthermore, as the indications for arthroplasty broaden and a more demanding population are undergoing THR, what may have been considered an acceptable outcome previously, may not be thought adequate today.
There is a broad consensus in the literature that any residual LLI of less than 10 mm on AP radiographs is clinically acceptable, but there is no agreement over an upper limit that would be considered clearly unacceptable. Many surgeons highlight the importance of considering clinical

outcome (68, 75) although this is subjective, variable and even more difficult to define than a radiological diagnosis.

Despite a specific focus on, and the adoption of preoperative and intraoperative techniques to minimise LLI, postoperative values greater than 10 mm appear still to be common. In cases where mild LLI persists postoperatively, non-surgical management produces adequate outcomes in the majority of cases, and operative correction is also effective in approximately half of more severe cases, even where nerve palsy is present. Poor outcomes in patients with LLI may be minimised if individuals at risk are identified and counselled appropriately.

Informed consent: All radiographs used were of patients who had given informed consent for the images to be used in research.
The project was part of a larger study for which ethical approval was obtained from the Leeds West National Health Service Ethics Committee. Ref: 09/H1307/63.

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Appendix B: Published paper arising from the work in Chapter 3.

■ ARTHROPLASTY

Litigation after hip and knee replacement in the National Health Service

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The results of hip and knee replacement surgery are generally regarded as positive for patients. Nonetheless, they are both major operations and have recognised complications. We present a review of relevant claims made to the National Health Service Litigation Authority. Between 1995 and 2010 there were 1004 claims to a value of £41.5 million following hip replacement surgery and 523 claims to a value of £21 million for knee replacement. The most common complaint after hip surgery was related to residual neurological deficit, whereas after knee replacement it was related to infection. Vascular complications resulted in the highest costs per case in each group.

Although there has been a large increase in the number of operations performed, there has not been a corresponding relative increase in litigation. The reasons for litigation have remained largely unchanged over time after hip replacement. In the case of knee replacement, although there has been a reduction in claims for infection, there has been an increase in claims for technical errors. There has also been a rise in claims for non-specified dissatisfaction. This information is of value to surgeons and can be used to minimise the potential mismatch between patient expectation, informed consent and outcome.

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The National Health Service Litigation Authority (NHSLA) was created in 1995 to indemnify National Health Service Trusts in England. Initially it was only responsible for larger claims, but since 2002 has kept data on all claims made against the NHS. Up to March 2010 the NHSLA has handled more than 57 000 claims for negligence of all types, of which more than 22 400 were related to surgery (excluding obstetrics and gynaecology), at a total cost of £1.82 billion.[1,2] In the year 2010/2011 it made payments of more than £729 million for clinical negligence.[3] The NHSLA estimates that its potential liabilities for all clinical negligence are in the region of £16.6 billion.[3] This aim of this study was to review claims made through the NHSLA relating to hip and knee replacement surgery, to explore the reasons for litigation and to explore trends over time.

Hip and knee replacement surgery produce some of the highest health gains, both in terms of improvement in quality of life and in cost-effectiveness.[4-6] Both are major procedures, however, and are associated with well-recognised morbidity and, rarely, mortality.[7,8]

The National Joint Registry for England and Wales reported that > 163 000 hip and knee replacement operations were performed in the year 2009/2010,[9] nearly double the 90 000 operations noted in the first annual report of September 2004.[10] It takes the total number of hip and knee replacements to > 900 000 since the registry began collecting data in 2003.[9,10]

When total claims for negligence are considered year on year, based on the year of incident as opposed to the year in which the claim was made, the number of claims recorded by the NHSLA has remained relatively stable. Between 1995/1996 and 2005/2006 the mean number of claims per year was 5792 (5190 to 6643) though owing to the varying time interval between incident and claim it cannot be determined with any certainty how this trend has evolved in recent years.[1] There is, however, a general perception that litigation for alleged medical negligence is increasing.[11] This perception has led to concern that surgeons are practising defensively at the expense of best practice.[11-13]

Although previous studies have reviewed the general state of litigation for orthopaedics within the NHS[14] and others within the private sector,[15] it is not clear whether in the United Kingdom there is evidence of any trend towards increasing litigation associated with hip or knee replacement.

Table I. Causes attributed to claims made for hip replacement surgery

Cause	Description
Neurological deficit	Any nerve damage cited in claim
Technical errors	Claims relating to the technical aspects of the operation such as incorrect components/incorrectly inserted, and retained cement
Local infection	Infection of the surgical site only (pneumonia etc. included in miscellaneous)
Miscellaneous	Claims either non-specific or inclusive of a low number of rarer causes of claims
Leg-length inequality	Claims for leg-length inequality
Peri-operative injury	Injuries sustained during the operation, such as fractures, burns, lacerations and injuries during transfer
Pain	Any reference made to pain were included in this category in addition to the cause if detailed
Wrong-side surgery	Any surgery mistakenly performed on the contralateral side
DVT/PE	Where reference to deep-vein thrombosis (DVT) or pulmonary embolus (PE) was made in the claim
Post-operative care	This group includes all aspects of post-operative care, such as falls and issues surrounding nursing and physiotherapy care as well as post-operative renal failure
Fatality	Where there was death from any cause
Dislocation	All claims citing dislocation
Vascular complications	Any vascular insult including vessel injury and compartment syndrome
Delay	Where there was delay from any cause cited
3M	Claims relating to the 3M total hip replacement
Prosthetic failure	Including ceramic fracture or where a specific allegation of prosthesis failure was made

Table II. Causes attributed to claims made for knee replacement surgery

Cause	Description
Local infection	Infection of the surgical site only (pneumonia etc. included in miscellaneous)
Technical error – component	All allegations relating to the technical aspects of the implant and the operation; incorrect implant, wrong size or poor alignment.
Alleged negligence	This term was commonly and specifically used without reference to another cause
Miscellaneous	Claims either non-specific or inclusive of a low number of rarer causes of claims
Post-operative care	This group includes all aspects of post-operative care, such as falls and issues surrounding nursing and physiotherapy care as well as post-operative renal failure
Pain	Any reference made to pain were included in this category in addition to the cause if detailed
Technical error – other	Technical issues during the operation that did not relate to the components, such as cementophytes, retained drains and allegations that the symptoms were associated with the patella not being resurfaced
Neurological deficit	Any nerve damage cited in claim
Vascular complications	Any vascular insult including vessel injury and compartment syndrome
Peri-operative injury	Injuries sustained during the operation, such as fractures, burns, lacerations and injuries during transfer.
DVT/PE	Where reference to deep-vein thrombosis (DVT) or pulmonary embolus (PE) was made in the claim
Poor range of movement	Restriction of range of movement
Fatality	Where there was death from any cause
Delay	Where there was delay due to any cause cited
Prosthetic failure	Where there was failure of a component, e.g. the modular rotating platform, or the whole prosthesis
Dislocation	All claims citing dislocation

Materials and Methods

In 2011, a freedom of information request was made to the NHSLA asking for data about all claims involving orthopaedics and trauma, to include year of incident, the year the claim was made, the nature of the claim and, where applicable, the costs incurred (defence costs, claimant costs and damages paid). Data were provided by NHSLA from the period 1995/96 to 2009/10. These data were then filtered to include only those cases involving hip and knee replacement. Definitions such as 'hip operation' or 'knee operation' were considered ambiguous and therefore excluded from this analysis. The details of each claim were then categorised and are summarised in Tables I and II.

Owing to the nature of the descriptions attached to a given claim, no distinction was made between the various types of hip and knee replacements. As a claim for negligence may arise from cumulative dissatisfaction, many claims attribute more than one cause for complaint, meaning that there are more 'causes' discussed than individual claims. Consequently, an individual claim may appear more than once in the data as each cause is included separately. Where either 'no costs' or only 'defence costs' were incurred, this was taken to mean that the case was successfully defended (provided the case was closed). Where either claimant's costs or damages were paid, this was interpreted as the NHS having lost the case. The data were then sorted to compare, for each cause of claim, the total number of claims closed and the total number of these claims that were paid out.

The data were divided into two periods, 1995/96 to 2002/03 and 2003/04 to 2009/10 (the approximate halfway point) to allow analysis of any change in the nature and number of claims between the two periods. The second period included both open and closed claims.

Table III. Summary of claims data for hip replacement surgery (DVT, deep-vein thrombosis; PE, pulmonary embolism)

Cause of claim	Total number of cases (%)	Cases closed	Percentage paid (%)*	Highest cost (nearest £100)†	Mean cost (nearest £100)‡
Neurological deficit	159 (*13.8*)	138	46	£384 500	£116 800
Technical error	138 (*11.9*)	123	68	£814 500	£111 700
Infection	133 (*11.5*)	113	46	£639 700	£138 600
Miscellaneous	124 (*10.7*)	101	38	£531 600	£107 000
Leg-length inequality	100 (*8.7*)	100	44	£595 000	£84 000
Peri-operative injury	86 (*7.4*)	68	56	£131 900	£48 200
Dislocation	78 (*6.7*)	71	51	£448 300	£105 200
Post-operative care	71 (*6.1*)	63	62	£466 900	£59 500
Delay	59 (*5.1*)	55	45	£324 300	£39 100
Pain	49 (*4.2*)	43	44	£448 300	£111 700
Fatality	36 (*3.1*)	31	68	£207 800	£49 300
DVT/PE	36 (*3.1*)	32	50	£292 000	£58 300
Prosthetic failure	36 (*3.1*)	32	50	£354 800	£81 000
3M system	34 (*2.9*)	34	3	£46 600	£46 600
Vascular	13 (*1.1*)	10	70	£1 052 500	£375 800
Wrong site	4 (*0.3*)	4	75	£24 400	£17 400

* refers to % of total claims that incurred claimant's cost and/or damages
† includes all costs, defence, claimants and damages
‡ mean cost of contested claims subsequently lost

Results

Over the study period a total of 22 500 claims were made to the NHSLA relating to surgery (excluding obstetrics and gynaecology), with costs > £1.8 billion. Of these, 8950 (40%) involved orthopaedics at a cost of £402 million (22%).

Of the orthopaedic claims, 1527 (17%) were related to hip or knee replacement surgery. The value of these claims to date exceeds £62 million, or 15.5% of the total awards made in relation to orthopaedic surgery. Of the claims, 224 (14.6%) remain 'open' or unsettled at the time of writing (136 hips and 88 knees).

Hip replacement surgery accounted for 1004 of the claims, at a current cost of over £41.5 million. This corresponds to 11% of orthopaedic claims and 10% of the overall cost. After knee replacement surgery 523 claims had been made, at a cost of £21 million, which represented 6% of all orthopaedic claims and 5% of the total cost.

Causes of claims data. A summary of claims relating to hip replacement surgery is detailed in Table III. A total of 413 of 1004 claims were paid out. The mean total cost of contested cases that were subsequently lost and where damages were paid was £98 000 (£1050 to £1 052 500).

The highest single cost, at > £1.05 million, arose from a case of vascular injury in which the involvement of the vascular surgeons was delayed, resulting in compartment syndrome. Although cited as a cause in only 13 (1.1%) of claims, vascular injury resulted in the highest mean payouts. A further four of the 13 claims resulted in compensation > £100 000, one of which was > £1 million. These four claims addressed major vessel injury, compartment syndrome, amputation and one death.

Other causes of litigation that resulted in compensation above the mean of £98 000 were infection, neurological deficit, technical error, pain and dislocation. A 'miscellaneous' group included 13 paid claims that cost more than £100 000, 12 of which were non-specified 'dissatisfaction' with outcome.

Comparable data on claims for knee replacement surgery are summarised in Table IV. A total of 218 of 523 claims were paid out, with a mean cost for cases contested and lost of £93 000. The highest single cost was for a vascular injury that resulted in compartment syndrome and subsequent amputation. Vascular injuries accounted for 4.2% of claims but generated the highest mean cost (£232 900 (£1000 to £779 000)). There were ten further vascular associated claims that resulted in payments of more than the mean figure for knee replacements (£93 000). Seven of these involved compartment syndrome, amputation or both, and the remaining three cases were for vascular injury or ischaemia.

Other causes that resulted in mean costs greater than average were prosthesis failure, infection, neurological deficit, dislocation and DVT/PE.

Trends. For hip replacements, the total number of claims per annum has changed little between the two time periods. There were 575 claims in the period 1995/96 to 2002/03 and 581 between 2003/04 and 2009/10 (Table V). Although the absolute number of claims after hip replacement was relatively stable, there was an increase over the two time periods in the proportion of claims for injury resulting in neurological deficit, which is now the commonest cause of litigation for hip replacement surgery.

The time trend data for knee replacement show a 46% increase in the total number of claims, from 232 to the end of 2002/03 to 337 in 2009/10 (Table VI).

Within the individual categories there is evidence of considerable change in the cited reason for bringing a case. 'Alleged negligence' increased from 5% to 16%, 'technical error – component' and 'technical error – other' increased by 5% and 4%, respectively. Conversely, the proportion of claims associated with infection dropped from 20% to detail. This may be due to the way in which the data were recorded, or may simply reflect claims that relate to more general dissatisfaction with the outcome of knee replacement surgery. What cannot be ignored, however, is that between 2002/03 and 2009/10 this group underwent the largest relative increase in claims for knee replacement surgery. The non-specific nature of this type of claim, in which it is difficult to isolate the nature of the complaint and therefore the resulting loss, may be the cause of the low rate of pay-out, with only some 28% of all cases being closed.

Within this dataset there are limitations in the description that accompanies each claim. The NHSLA information is intended primarily for claims management. The data are not structured for clinical purposes, and the clinical detail within the claim is limited to the major points of the claim. Furthermore, before April 2002 the NHSLA did not specifically collect data on cases below a certain level (varying between £10 000 and £50 000), so it is not possible to draw specific conclusions about trends before this date.

One assumption we were required to make in this analysis was the absence of co-liability. It is possible that there were other unknown and confounding factors whereby a patient had a reasonable claim for an NHS operation but the NHSLA was not found to be liable. An example of this would be the claims associated with the 3M hip (3M Health Care Ltd, Loughborough, United Kingdom), in which the liability for costs was passed to the third party.

The current analysis also only addresses legal challenges that followed alleged negligence, and there are likely to be occasions where clinical negligence has occurred but litigation has not been pursued, and conversely, cases where clinical negligence has not been proven or admitted but a settlement has been agreed.

Although the current data provide an overview of the causes of litigation, it has not been possible to distinguish between the different types of joint replacement operation performed, such as hip resurfacing, unicondylar knee replacement, patellofemoral joint and more established total replacements. Further work on the patterns of poor outcome and legal intervention associated with specific techniques would be instructive.

This study shows that over the last decade or so the absolute number of claims made against the NHSLA for hip replacement surgery has remained fairly stable, but has decreased as a proportion of the total procedures performed. Furthermore, the reasons for the claims are consistent and generally well recognised by surgeons.

There have, however, been changes in the pattern of litigation for knee replacement surgery, and although cases of infection have reduced in number, a previously small and non-specific category where there is simply 'alleged negligence' has notably increased. This is of concern for surgeons, as it is difficult to plan against such a non-specific allegation and it does not help refine techniques or improve outcomes.

Of equal concern is that there are three categories ('technical error – component', 'technical error – other' and 'post-operative care'), which appear on nearly a third of the claims but are not specifically discussed on the British Orthopaedic Association's consent form. We therefore suggest that the pre-operative consenting process might be refined to include a discussion of the possibility of these complications as a cause of an unsatisfactory outcome.

It is encouraging that litigation for infection has diminished after both THR and TKR: this may reflect improvement in practice. There remains a large group of patients who sue the NHS for poorly specified reasons, but the NHSLA data provide no evidence to suggest that orthopaedic surgeons are, within the bounds of the NHS, subject to a more litigious culture.

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Appendix C: Published paper arising from the work in Chapter 4.

Hip Int 2012; 00 (00): 000 - 000

ORIGINAL ARTICLE

Assessing reproducibility for radiographic measurement of leg length inequality after total hip replacement

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ABSTRACT: *Leg length inequality (LLI) as a result of total hip replacement can cause considerable morbidity. Although LLI was described when the technique was popularised in the 1960s, it remains a significant challenge to arthroplasty surgeons. This study reviews the established practice for the measurement of LLI on plain antero-posterior radiograph, and compares these techniques to two methods used locally. The radiographs of 35 patients were measured using four techniques. All four methods yielded an interclass correlation co-efficient of ≥0.90 for inter reader reliability. This study shows that the four methods are comparable for reliability, while a composite method, measuring from the centre of femoral rotation to the inferior teardrop and then to the lesser trochanter, has the added advantage of providing extra information on component position as well as an overall measure of LLI.*

KEY WORDS: *Hip, Leg length inequality, Radiographic measurement*

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INTRODUCTION

Leg length inequality (LLI) following an otherwise successful arthroplasty can result in considerable morbidity and patient dissatisfaction (1-3). The association between LLI following total hip replacement is neither clear nor absolute however and there is little consensus regarding definition, measurement, extent, significance or patient perception (3-6). Although many cases are asymptomatic, complications, when they occur, include mechanical symptoms such as limp and early fatigue, lower back pain, pelvic tilt, other joint pain, nerve palsy, increased wear of the implant and dislocation (7-13). Ultimately, symptomatic leg length inequality as a result of a total hip replacement may require a revision operation, with all of the associated risk and further morbidity (11).

Initial assessment of leg length inequality is typically undertaken clinically by tape, ruler or block measurement of true and apparent leg length, followed by clinical assessment of where in the lower limb the inequality arises. This is in the context of multiple studies showing clinical measurement to only be accurate to within 10 mm or more (14-16). It is important therefore that any LLI is quantified accurately, this is usually achieved through radiology. While computed tomography (CT) is considered the gold standard for the radiologic measurement of leg length inequality, the cost and increased exposure to ionizing radiation make CT use unsafe and impractical to perform routinely. A plain antero-posterior (AP) radiograph of the pelvis and both hips is usually performed.

Postoperative LLI has been classified according to underlying cause by Parvizi et al. A type 1 structural LLI, exists where the components are directly responsible for the lengthening, for example when a stem has not been fully inserted and is proud. A type 2 structural LLI occurs when lengthening is accompanied by component malposition, for example when poor component version mandates increased soft tissue tension for stability with resulting

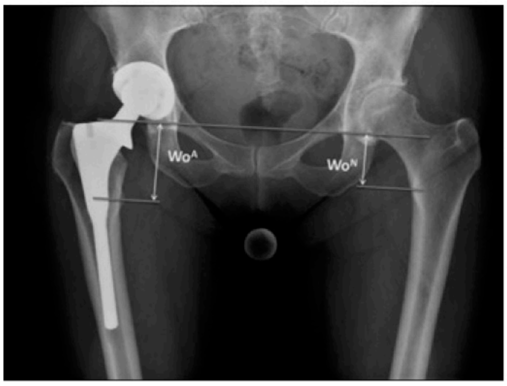

Fig. 1 - *The T-LT (Woolson) method. Described by Woolson et al, reference line is drawn through the most inferior part of the acetabular teardrops (T). Two lines parallel to this are drawn through the centre of the lesser trochanter (LT). The difference in the perpendicular distance between the two lines (Wo^A – Wo^N) is defined as the leg length inequality.*

Fig. 2 - *The II-LT (Williamson) method. Described by Williamson et al, reference line tangential and parallel to the most inferior portion of the ischia. Two further parallel lines are drawn and the perpendicular distance between the lines measure, the difference between the two measurements (Wi^A – Wi^N) is the LLI.*

lengthening (2). It is vital to accurately identify the cause of the LLI, as revision of the either the wrong component in a type 1 or a single component in a type 2 can result in an unstable prosthesis, which will require further revision surgery.

A literature review identified 35 papers that specifically discussed the radiographic measurement of LLI. Thirteen of the 35 papers (5, 17-28) described a method that creates a reference between the most inferior part of the acetabular teardrop (T) and measures the perpendicular distance to the centre of the lesser trochanter (LT) (24) (Fig. 1). A further 15 of the 35 (2, 3, 14, 29-40) described a method of measuring LLI by creating a bisecting inter-ischial line (II) through the inferior part of the ischial tuberosities and measured the perpendicular distance to the most medial portion of the lesser trochanter 'II-LT method' (34) (Fig. 2). While both methods were regularly described as 'validated' there was very little documentation of the validation process.

The remaining papers in the review either used varying techniques such as scanogram (15, 41), a mercury spirit level (42), and different radiographic markers including the method used in this study (4, 43-45).

This study aimed to assess formally the reliability of methods for quantifying post total hip replacement (THR) leg length inequality described in the literature and compare them with methods used in our unit.

METHODS

The radiographs of 35 patients, originally taken as part of the routine follow-up, were extracted from the case notes of patients attending the senior author's (MHS) outpatient arthroplasty clinic. Ethical approval was provided by the Leeds West NHS ethics committee and all images were obtained from patients who had given prior consent for use for research purposes. Radiographs were taken according to the local standardised operating protocol, with the patient in a supine position with both hips resting in internal rotation. A 25 mm calibration ball (AGFA, Wilmington, MA) was placed in the groin at the same height above the table as the greater trochanter and the image centred on the pubic symphysis.

Four methods of quantifying LLI from AP radiograph were used. The two methods prominent in the literature (T-LT and the II-LT) and two further methods, the first which utilises described radiographic markers, the centre of femoral rotation (CFR), the teardrop and the centre of the lesser trochanter (43, 44) using a method where by the reference line bisects the centre of femoral rotation described in (46) (Fig. 3). The fourth method used CFR and LT references, but instead of constructing parallel line, was derived as a simple, direct measure of the distance between the two points (Fig. 4).

Fig. 3 - *The CFR-LT method. This is a measurement of the straight line distance between the femoral centre of rotation and the apex of the lesser trochanter. The difference in the measurement for both hips is the leg length discrepancy.*

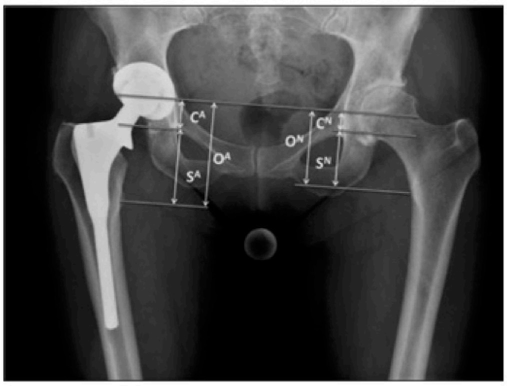

Fig 4 - *The CFR-T-LT Method. An initial reference line is drawn between the centres of femoral rotation. Two further lines are drawn parallel to this. The first at the level of the most inferior part of the acetabular teardrop to give measurement C, which corresponds to any inequality (C^A-C^N) due to the position of the cup. The second is at the level of the centre of the lesser trochanter to give measurement S, which corresponds to inequality (S^A-S^N) due to position of the stem. The sum of the two is measurement O which corresponds to the overall leg length inequality (O^A-O^N).*

The measurements, to the nearest millimeter, were made by two senior consultant musculoskeletal radiologists (AJG and PJO) using a PACS system (AGFA, Wilmington, MA). The original 35 radiographs were measured using the four methods. Subsequently 10 of these radiographs were picked at random and re-read after at least three months. Finally, to explore the reliability of the acquisition protocol in addition to reader consistency, in 24 radiographs of patients who had undergone serial imaging but no further surgery in the interim, follow-up images were also measured and compared with baseline radiographs.

Data were analysed using SPSS v16 (IBM, New York, USA) and reliability was quantified through the generation of Intra Class Correlation Coefficients (ICC) and Limits of Agreement. ICC model 3,1 was used to determine inter-reader reliability and ICC model 1,1 was used to evaluate between-day reliability and consistency in measurement from serial images.

RESULTS

Of the 35 patients in our sample, five patients (14%) had native hips 21 patients 60% had a undergone unilateral total hip replacement and nine patients (26%) had received bilateral hip replacements.

For the subset of 24 in whom serial radiographs were obtained, the mean time between the first and second x-ray was 393 days (0-7052 days).

The ICCs for inter-reader reliability are summarised in Table I. All four methods show high ICCs for inter-reader agreement (>0.9) and limits of agreement between raters of <10 mm.

When measuring intra-reader reliability for the same radiograph when assessed at two different time points, the Direct CFR-LT and the CFR-T-LT methods performed slightly better than the II-LT and T-LT methods (Tab. II).

In the subset of 24 radiographs taken on two different occasions (Tab. III), the variability of the acquisition protocol combined with reader variation increased error such that all four techniques exhibited only moderate reliability.

TABLE I - INTER-READER RELIABILITY OF LEG LENGTH INEQUALITY MEASUREMENT

Method	Inter-reader $ICC_{(3,1)}$	Mean difference (mm)	95% LOA (mm)
CFR -LT	0.91	1.00	±5.31
CFR-T-LT	0.90	0.60	±6.02
II-LT	0.90	0.26	±7.68
T-LT	0.91	-0.80	±8.26

TABLE II - INTRA-READER RELIABILITY OF LEG LENGTH INEQUALITY MEASUREMENT, SAME RADIOGRAPHS RE-MEASURED AFTER THREE MONTHS

Method	Intra-reader $ICC_{(1,1)}$ (Reader 1) n = 10	Intra-reader $ICC_{(1,1)}$ (Reader 2) n = 10
CFR -LT	0.96	0.97
CFR-T-LT	0.95	0.90
II-LT	0.87	0.88
T-LT	0.65	0.89

TABLE III - INTRA-READER RELIABILITY OF LEG LENGTH INEQUALITY MEASUREMENT, RADIOGRAPHS TAKEN AT DIFFERENT OCCASIONS

Method	Intra-reader $ICC_{(1,1)}$ (Reader 1) n = 24	Intra-reader $ICC_{(1,1)}$ (Reader 2) n = 24
CFR-LT	0.63	0.53
CFR-T-LT	0.63	0.50
II-LT	0.77	0.76
T-LT	0.77	0.71

DISCUSSION

With the broadening of the indications for THR and increase in patient expectation, leg length inequality following total hip replacement is likely to receive more attention. The precise nature of the association between LLI following total hip replacement and symptoms remains unclear, with a range of studies producing inconclusive or conflicting results (2, 4, 5, 13). This variability is due, at least in part, to a lack of consensus over measurement techniques and resulting definitions. The current study focuses on the error in radiological measurements made around the hip that can confound the identification of leg length inequality. While there is no single agreed method for the measurement of LLI on a plain AP radiograph, the literature has focused primarily on two methods, the Teardrop to Lesser Trochanter (T-LT) and the Inferior Ischia to Lesser Trochanter (II-LT) methods, often referred to as the Woolson and Willamson methods respectively. Despite the widespread use of these techniques in clinical practice and research there is little published validation of the method. We found no substantive data in the literature describing the error or reliability of these widely used techniques and, to our knowledge, ours is the first study to compare techniques directly.

In interpreting the agreement data, the radiologists commented that it was occasionally difficult to identify the acetabular tear drop where, for instance, a cemented cup was used. Additionally it was felt harder to accurately identify the centre of rotation in the native, generally arthropathic, femoral head. In this study, no allowance was made for the rotation of the pelvis, or for flexion, abduction or adduction and all measures were acquired and measured according to standard clinical protocols. With two point measurement methods, trigonometry dictates that a fixed flexion deformity of, for instance, 25° will result in a reduction in measured LLI of approximately 10%. Conversely, when using the centre of femoral rotation as a reference, adduction and abduction deformities will introduce only minimal error when measuring relative to a fixed reference on the femur. Factors such as patient position when supine for the radiograph and the relative positions of the calibration ball, tube and radiographic plate are all potential sources of reduced reliability. It is clear that despite clinical protocols for AP pelvic/hip radiography direct comparison of measurements for LLI for any method should be made with caution. Greater accuracy can be achieved using more detailed CT or MRI imaging, however, this study explored the real-world reliability of the more common place and economical radiographic techniques for LLI assessment.

All four methods investigated were comparable for inter-reader and intra-reader reliability of measures taken from the same films, and for intra-reader reliability of radiographs taken at different occasions. While all methods proved satisfactory for assessing LLI overall, the CFR-T-LT method has the potential extra advantage of being able to distinguish between LLI caused by cup position and LLI caused by stem position. If the limb is left long (i.e. O^A is greater than O^N) and it is due to the stem, measurement S^A will be greater than S^N. However if the lengthening is due to the cup position, the measurement C^A will be smaller than C^N. The authors propose that using the method of measuring from the centre of femoral rotation to the inferior teardrop and then to the lesser trochanter (CFR-T-LT method) for the assessment of leg length inequality provides comparable accuracy to existing methods and is able to differentiate problems caused by the cup, stem or both, which aids discrimination between a type 1 and 2 structural LLI.

CONCLUSION

In conclusion, the data provide support for measurement from the centre of femoral rotation to the inferior teardrop and then to the lesser trochanter (CFR-T-LT method) as a suitable method to quantify post THR limb length inequality. We have provided the first direct comparison of the methods currently in common use and conclude that all the methods described previously, including the new method, demonstrate comparable reliability. The CFR-T-LT method has the added advantage of differentiating between cup or stem position as the cause of any LLI.

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ERRATUM

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Hip Int. 2012 Sep-Oct;22(5):539-544.
Assessing reproducibility for radiographic measurement of leg length inequality after total hip replacement.
McWilliams AB, Grainger AJ, O'Connor PJ, Redmond AC, Stewart TD, Stone MH.
PMID: 23100154 DOI:10.5301/HIP.2012.9751 [PubMed - indexed for MEDLINE]

In the article "Assessing reproducibility for radiographic measurement of leg length inequality after total hip replacement", by Anthony B. McWilliams, Andrew J. Grainger, Philip J. O'Connor, Anthony C. Redmond, Todd D. Stewart, Martin H. Stone, published in Hip International 2012; 22 (5): 539-544, there is an error in the labelling of Figure 4. The radiograph of the CFR-T-LT method is incorrectly labelled. The S (or stem) measurement and the O (or overall) measurement should be switched. The text in the caption is corrected below:

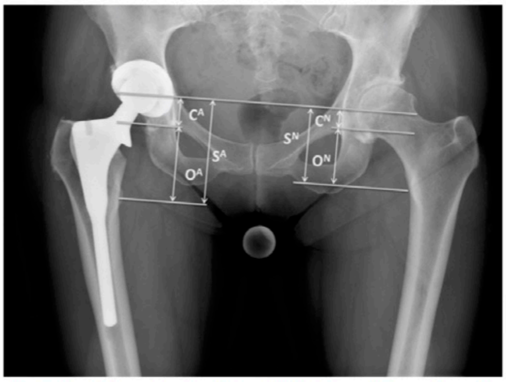

Fig. 4 - The CFR-T-LT Method. An initial reference line is drawn between the centres of femoral rotation. Two further lines are drawn parallel to this. The first at the level of the most inferior part of the acetabular teardrop to give measurement C, which corresponds to any inequality (C^A-C^N) due to the position of the cup. The second is at the level of the centre of the lesser trochanter to give measurement S, which corresponds to inequality (S^A-S^N) due to position of the stem. The measurement between these two additional lines is the overall LLI, (O^A-O^N).

This is an error in labelling and makes no difference to the results of the study; the measurements and methodology remain unchanged and the authors stand by the results.

Appendix D: Abstract for presentation arising from the work in Chapter 5

The Effect of Patient Positioning on Measurement of Leg Length Inequality Following Total Hip Replacement on Plain Radiographs Using the CFR-TD-LT Method.

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Introduction

Leg length inequality (LLI) as a result of a total hip replacement (THR) is a recognised complication which can result in significant patient morbidity as well as having medico-legal consequences. Symptoms resulting from an LLI are an independent risk factor in the outcome of THR.

While CT Scanograms would be considered the gold standard for measurement of leg length inequality, they expose the patient to radiation as well as being an additional resource burden in terms of radiology and orthopaedic attendances.

This study investigates the extent of inaccuracy that results from fixed deformity of the femur and pelvis when measuring LLI following THR using a previously validated method on plain x-ray. The aim being to assess the possibility of defining a set of parameters within which any inaccuracy on measurement of LLI following THR would be predictable and reducing the need for scanograms under these circumstances

Method

The method of assessing LLI following THR on plain film uses the centre of femoral rotation, the acetabular teardrop and the lesser trochanter (CFR-TD-LT).

A radiographic experiment was performed in an X-ray suit using a plastic skeleton and a calibrated jig to accurately assess deformity. Radiographs and readings were repeated three times and an average taken.

Parallel to this work a computational experiment was created using a CT scan of the plastic skeleton and IMORPHICS and MAGICS software used to generate a 3D model.

Deformities were modelled up to 10 degrees in extension, adduction and external rotation and up to 20 degrees in all others.

Results

The mean overall CRF to LT measurement for the limb in neutral was 62.4mm.

For femoral deformity in the saggital plain, the maximum inaccuracy for both the radiographic computational study was at around10 degrees of flexion at up to 2.8mm (5%) reducing thereafter. Error in extension was greatest at the maximal extension in this study of up to 4.9mm (8%) at 10 degrees.

Abduction of the femur had a more profound effect with up to a 17.4mm (28%) error at 20 degrees than adduction. Rotation resulted in virtually no recordable difference.

In terms of pelvic deformity, the results were much more linear. Vertical tilt resulted in a maximum inaccuracy of 4.7mm (8%) at 20 degrees. Lateral tilt resulted in greater error with 7.2mm (12%) at 20 degrees.

Discussion

The effect of fixed deformity on the measurement of LLI following THR using the CFR-TD-LT method is highly dependent on the plain in which it is. In this study, femoral rotation and transverse pelvic tilt resulted in negligible error.

The greatest errors were seen at 20 degrees of femoral abduction and lateral pelvic tilt. All other deformities within the parameter of this study were less than 10%.

This work suggests that the CRF-TD-LT can give an acceptable level of accuracy over a range of fixed deformities of the pelvis and femur, potentially reducing the need for CT scanograms for this purpose.