NAVIGATION IN TOTAL HIP ARTHROPLASTY

Does it improve the accuracy of desired leg length and offset achievement, and does this result in better patient outcomes?

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ADVANCED MEDICAL SCIENCE

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May 2011

Statement from Supervisor

This research project has been approved and is ready for submission.

A/Prof Andrew Bucknill Supervisor	**Date**

"However beautiful the strategy, you should occasionally look at the results."

- Winston Churchill

“I cannot walk. And if you can’t walk, you can’t do much”

- Mr B.P (Study Cohort) during pre-operative evaluation

Acknowledgements

There are a number of people I would like to acknowledge, whose support and assistance made this project possible. Firstly, I wish to thank my supervisors, A/Prof Andrew Bucknill and Mr Bob Jennings, for their advice, patience, guidance and generosity over the past year. I would like to extend that gratitude to the rest of the Orthopaedic Department at the Royal Melbourne Hospital who together have made my year truly fantastic.

I would also like to acknowledge Dr Julie Miller and Dr Anita Skandarajah for their support and running of weekly tutorial sessions, which were of immense help. Many thanks must also go to Dr Alexandra Gorelik, who ran the statistics sessions and was of great assistance during the statistical analysis of my data.

Thank you to the team members of Health Information Services who were very helpful when records were needed.

Declaration

I declare that all material presented in this thesis is my own work unless otherwise specified. No other person's work has been used without due acknowledgement. Direction and feedback were received for this thesis from A/Prof Andrew Bucknill and Mr Bob Jennings.

Abstract

Introduction

Stability of the reconstructed joint and adequate component fixation are essential in total hip arthroplasty (THA). Advances in technology and surgical technique have enabled surgeons to effectively address these parameters; however, whilst consideration of leg length and offset are not the primary aims of THA, they both influence surgical outcome. There is paucity in the literature of studies comparing leg length or offset restoration with controlled, non-navigated groups. This controlled study compares the accuracy of achieving pre-operative targets of leg length and offset change with and without the use of surgical navigation.

Aims

This study aims to investigate if target leg length and offset changes are better achieved with the use of navigation. A secondary aim was to determine if achievement of leg length and offset targets improved functional outcomes.

Methods

Following ethics committee approval, a prospective, consecutive series of patients undergoing navigated surgery over a five-month period were identified. The navigated series was compared to an historic, consecutive series of patients who underwent total hip arthroplasty without the use of navigation. Leg length and offset changes were measured from pre- and post-operative digital radiographs, and target changes were recorded from saved pre-operative digital

templating sessions. For the navigated group, measurements of leg length and offset change made by the navigation system intra-operatively were recorded, as well as modified Oxford Hip Scores pre-operatively, six weeks post-operatively, and three months post-operatively.

Results

Differences in terms of age, sex and body mass index between the groups were not statistically significant (P>0.05). All but two of the procedures were performed using a standard posterior approach. The difference in achievement of target leg length changes between the navigated and control groups was not shown to be significantly significant (P=0.775). Femoral offset targets were more likely to be achieved in the navigated group (P=0.037). Measurements made by the navigation system showed a high correlation with radiographic measurements for leg length change (R=0.766, P<0.0001) and good correlation was found between navigated and radiographic measurements of total offset change (R=0.47, P=0.021). When the navigation system was employed, procedure time was longer by a mean of 6 minutes, however this was not statistically significant (P=0.084).

Conclusion

This research demonstrates that computer navigation can be a reliable tool of intra-operative leg length and offset measurement. However, this reliability only translated to statistically significant improvements for the achievement of target offset change. Research using greater study numbers and long-term follow up is required to demonstrate true cost-effectiveness and outcome improvement in navigated THA procedures.

Abbreviations

A number of abbreviations have been used in this paper:

ASIS	Anterior Superior Iliac Spine
AOS	Acetabular Offset
BMI	Body Mass Index
BW	Body Weight
CI	Confidence Interval
CT	Computed Tomography
DHS	Dynamic Hip Screw
DRB	Dynamic Reference Base
Fab	Abductor Force
FAOS	Femoral to Acetabular Offset
FOS	Femoral Offset
GT	Greater trochanter
JRF	Joint Reaction Force
LL	Leg Length
LLD	Leg Length Discrepancy
LOS	Length of Stay
MIS	Minimal Incision Surgery
OHS	Oxford Hip Score
OS	Offset
PE	Polyethylene
ROM	Range of Motion
SD	Standard Deviation
SER's	Short External Rotators
THA	Total Hip Arthroplasty
TOS	Total Offset

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CHAPTER 1: Background

1.01 Indications for Total Hip Arthroplasty

Previously, the main indication of primary total hip arthroplasty (THA) has been osteoarthritis in the elderly. Today, a high success rate, advancements in prosthetic technology and improved prosthetic longevity have extended the umbrella of candidates to incorporate younger patients and patients with varying diagnoses [1-3]. Patients undergoing THA will have experienced limited success with non-operative measures [1].

1.02 Aims of Total Hip Arthroplasty

The aims of a total hip arthroplasty are to [4]:

- Restore normal biomechanics of the hip
- Introduce a durable, low friction artificial joint surface to replace the damaged native joint
- Achieve adequate biological fixation of the prosthetic components
- Maintain longevity by achieving correct component positioning.

The primary aims are to achieve well-fixed acetabular and femoral components. Second to this, the hip needs to be dynamically stable through an adequate range of motion. Equalisation of limb lengths and offset restoration follow these two as tertiary goals [5].

1.03 Navigation

Computer aided surgery is an ever-expanding and revolutionary field covering many surgical specialties [6-9]. Research in the field is ongoing [10-12], however, the widespread acceptance of navigation is hampered by increased costs, increased time, and a lack of evidence that demonstrates long-term benefit with relatively minor improvements in component positioning.

1.03.1 Classification of Computer Systems

Computer systems in surgery are classified according to the degree to which they can perform tasks independently. Passive systems provide additional information to assist the surgeon during a procedure and the surgeon remains in control of both the computer system and the surgery [13]. The terms 'passive systems' and 'navigation systems' are used interchangeably, and this convention will be followed in this paper. An active system is one which is capable of performing individual tasks autonomously [14], such as robots [15-18]. Semi-active systems involve constraint or adjustment of surgical actions, but final control still lies with the surgeon [14].

Navigation systems may be further categorised with respect to the imaging modality required to register the patient to the computer system. A navigation system may be image-free, CT-based, fluoroscopy-based or employ a combination of CT scans and fluoroscopic images (hybrid CT-fluoroscopic navigation) [19-23]. The system used in this study is a passive, image-free computer system.

1.03.2 A Brief History of Navigation

Stereotactic surgical techniques were first developed in animal experimentation by the pioneering work of Robert Henry Clarke and Sir Victor Horsley [24]. In orthopaedics, navigation was first used in spinal surgery for pedicle screw placement [25], and the first navigated total hip replacement was performed in 1992 [14]. By mid-2004 there were already 30 active systems developed to assist orthopaedic procedures [9].

Semi-active and passive navigation systems were also developed [13, 25], and have become popular due to lower cost, ease of use, and the fact that surgeons retain ultimate control is still offered to the surgeon [14]. However, human error still limits the accuracy and reproducibility of navigated procedures [16].

Over the last decade, navigated orthopaedic operations have expanded to include periacetabular osteotomy, sacro-iliac screw insertion, pelvic fracture treatment, long bone fracture reduction, high tibial osteotomy, ACL replacement and distal radius osteotomy [25-30].

Additionally, the application of navigation to the total hip arthroplasty has expanded, and navigation systems are now capable of providing information on prosthetic range of motion, femoral stem and acetabular cup position during placement, changes made to leg length and offset, and navigation of hip resurfacing procedures [31-38].

1.03.3 Tracking Reference Frames and Registering the Patient

There are two methods of reference recognition available for navigated surgery: optical and electromagnetic [20, 21]. A T-shaped optical reference array fixed to the iliac crest is visible in Figure 1.01. In both cases, rigid fixation of the reference frames is crucial for accurate results [39-41].

Figure 1.01: A T-shaped iliac reference array (used with infrared optical tracking)

Once the navigation system is set-up the patient's anatomy needs to be registered. For image-free navigation, landmarks are acquired, or 'digitised', with a pointer that is visible to the navigation system, to register the patient. For image-based systems, the patient's anatomy needs to be registered to the computer model. This is typically achieved using a combination of paired-point matching (points registered on the patients bone are matched to the equivalent point on the computer model shown on the screen) and surface matching (a group of points on the cortical surface of the bone are digitised and allied to the computer model).

1.03.4 Benefits and Pitfalls of Navigation

Undoubtedly, computer navigation adds expense and significantly increases the time of the surgical procedure [33, 38, 42-47], although the increase in surgical time tapers as the surgeon becomes more experienced [48]. The use of navigation also necessitates the presence of more equipment in the operating room [31].

Furthermore, navigation introduces the possibility of novel complications, such as reference screw retention (Figure 1.02), infection of a wound used for percutaneous reference frame attachment, fracture around the site of reference pin, pin or drill bit breakage, and soft-tissue injury [49-55]. Cutting errors due to inadequate fixation of the reference frames is another navigated-related complication [56].

Figure 1.02: The temporary reference screw (left greater trochanter) may be left behind unintentionally

It is believed the pitfalls of navigation will be mitigated by the putative short- and long-term advantages of correct implant placement, such as shorter hospital stay, fewer revisions, and more rapid functional improvement. In addition, the surgeon is provided with intra-operative feedback concerning the suitability of trial components, or similarly the position and orientation of the acetabular and/or femoral components. Previously, a placement error would not be realized until post-operative radiographs had become available, at times necessitating another operation.

1.05 Leg Length

Leg length is an important to consider during THA. Causing a significant post-operative leg length discrepancy (LLD) can result in lower back pain, sciatic nerve palsy, instability, gait abnormalities, stress fractures, limp, patient dissatisfaction and litigation [57-64]. Only one study has published contradictory results showing that post-operative LLD had no correlation with post-operative outcome or patient satisfaction [65].

It is difficult to identify when an LLD becomes significant, and patient awareness has a major influence. Whilst the size of the leg length inequality correlates with awareness [66, 67], varying perception of discrepancy has been described by patients [67-70]. Up to 10 mm is the generally accepted size of LLD.

To address LLD, pre-operative assessment is vital [71-75]. The surgeon must also consider the patient's perception of discrepancy and if the discrepancy is apparent or true. A reliable method of radiographically or clinically evaluating leg length is then employed [76]. Failure to discuss the possibility of a residual

LLD, perceived or true, may lead to litigation. Patient dissatisfaction with discrepancy is the most common cause of orthopaedic litigation [64, 67, 77, 78].

Treatment of LLD following total hip arthroplasty is usually conservative, and symptoms resolve with time and therapy in most instances. A heel raise may required in 15% to 20% of the patients with a residual discrepancy of ≥1 cm [79]. If the inequality is disabling due to pain or loss of function then revision surgery is a last resort [80].

1.06 Femoral and Acetabular Offset

Femoral offset is defined as the perpendicular distance from the centre of rotation of the hip (the centre of the femoral head) to the anatomical axis of the femur [81] and usually lies between 40 and 45 mm [81-87]. The major factors that influence femoral offset are neck-shaft angle and femoral size [88, 89]. Acetabular offset is less clearly defined. For this study acetabular offset was defined in accordance with the methods of Asayama *et al* as the perpendicular distance from the midline to the centre of rotation of the hip (Figure A1.2) [90]. Additionally, the term 'total offset' will be used to refer to the sum of the acetabular and femoral offset.

Femoral offset has been shown to influence polyethylene wear (prosthetic longevity), hip stability, soft tissue tensioning, abductor muscle function, joint reaction forces, prosthetic micromotion, prosthetic and interface stresses, and range of motion [82, 85, 86, 89-108]. A lack of offset restoration has also been correlated with an increased risk of post-operative limp and need for walking aids [94, 100, 109]. The majority of evidence supports the restoration of native femoral offset [71, 82, 84, 89, 91, 94, 110, 111].

However, femoral offset, the lever arm for the abductor muscles (Fab), needs to be considered in combination with changes made to the body weight lever arm (acetabular offset) (Figure 1.03).

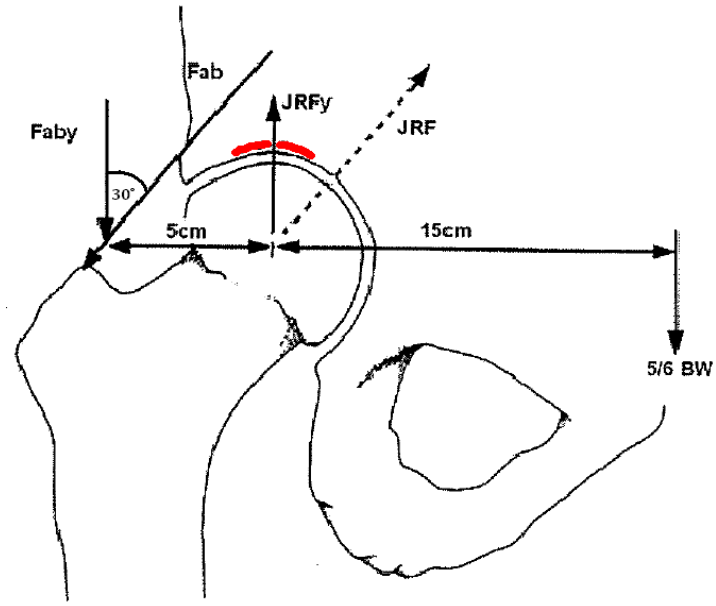

Figure 1.03: A free-body diagram of the right hip (anterior view) in single-leg stance. JRF – joint reaction force, JRF_y – vertical component of JRF, Fab – abductor muscle force, Fab_y – vertical component of Fab, BW – body weight (Adapted from Miller, Review of Orthopaedics [112])

If femoral offset is increased, or acetabular offset is reduced, less abductor muscle force is required to balance the pelvis in single-leg stance. Accordingly, less force (JRF_y) is transmitted through the joint. The 'see-saw'-like relationship between femoral and acetabular offsets is simplified in Figure 1.02.

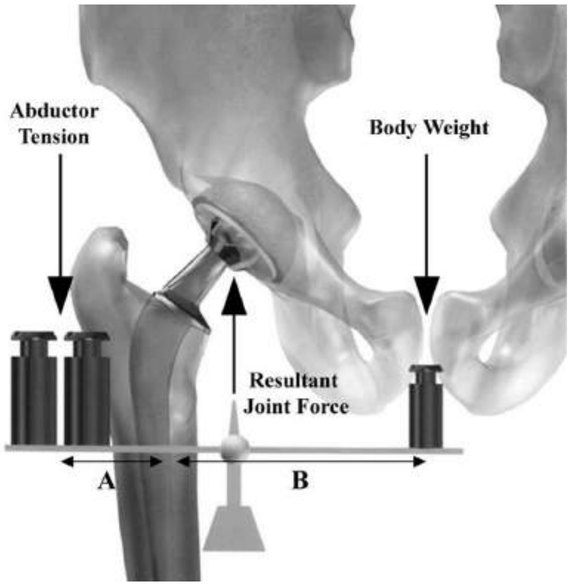

Figure 1.04: Balance at the hip joint during single-leg stance (Image obtained with permission from "Soft-Tissue Balancing of the Hip," J Bone Joint Surg, [89]).

Consequently, the ratio of femoral to acetabular offset (FAOS ratio) is of particular relevance. Asayama *et al* demonstrated improved abductor muscle function when the FAOS ratio was enhanced [90, 113]. Poor management of the biomechanical relationship between femoral and acetabular offsets can lead to abductor muscle insufficiency. When this occurs, the pelvis sags and a Trendelenburg gait may result [4, 114-117]. In order to maintain soft tissue tension and optimise hip biomechanics, the aim of the surgeons of this study when performing a THA is not to simply restore femoral offset, but improve the FAOS ratio.

1.07 Leg Length and Offset Measurements

Femoral offset and leg length discrepancy are usually calculated using plain antero-posterior pelvic radiographs, but can also be made using CT scans. Alternatively, leg length discrepancy can be calculated clinically by placing blocks of known thickness under the shorter limb until the pelvis appears horizontal, or by comparing the distance on both sides from the ASIS to the medial malleolus [118].

From radiographs, LLD is measured by drawing a line between two points on the pelvis, and then measuring the perpendicular distance from this line to a specified point on each femur [73, 119, 120]. The points normally used are the inferior aspect of the ischial tuberosities or acetabular teardrops, and the lesser trochanter on the femora. For femoral offset, a line is drawn through the centre of the medullary cavity and the perpendicular distance to the centre of the femoral head is measured [81, 84, 121, 122]. The techniques used in this study are described in Appendix 1.

However, the accuracy of linear measurements from radiographs has been criticised [121, 123-126]. The inaccuracies stem from the unpredictability of pelvic position relative to the x-ray beam (pelvic tilt), magnification errors due to divergent x-rays, femoral rotation and also the plane of the film [124, 127-132]. Nevertheless, Robb *et al.* demonstrated the trans-acetabular teardrop line, which was used in this study, to be an accurate and reliable reference point [123].

1.08 Intra-operative Assessments

Methods of measuring leg length, offset and other parameters intraoperatively can be categorised as belonging to one of navigation systems, jigs or rulers. One author describes the use of an intra-operative radiograph for leg length assessment [133]. Special tests are also able to provide general feedback but give no direct measurement.

1.08.1 Navigation systems

Several navigation systems are capable of providing intra-operative feedback on changes made to leg length and offset (Figures 1.05 and 1.06). This is usually achieved by calculating changes made to the relative positions of reference arrays or a reference point before and after arthroplasty.

Figure 1.05: The surgeons assess leg length changes using the navigation system

Intraoperative measurements of leg length and offset made by navigation systems in both experimental and patient studies show varying reliability [21, 34, 35, 134-139]. The study that was most comparable to this project was an experimental assessment of the same navigation software in cadavers. Comparing measurements made using navigation and CT scans, Renkawitz *et al* demonstrated a mean difference of 0.50 mm (95% CI, -0.37 to 1.37 mm) for leg length measurements, and 0.49 mm (95% CI, -0.2 to 1.17 mm) for offset measurements [35]. This study showed a very high and statistically significant correlation between navigation and CT measurement for both leg length (R=0.92) and offset (R=0.97). However, a major limitation of the study by Renkawitz *et al* is that cadaveric models don't entirely mimic the *in vivo* scenario. Ease of landmark registration, tissue properties, and several other variables differ significantly between operations on living patients and on cadavers. It was deemed of interest that an investigation into the accuracy of the BrainLAB Hip 5.1 navigation system was carried out in a clinical study.

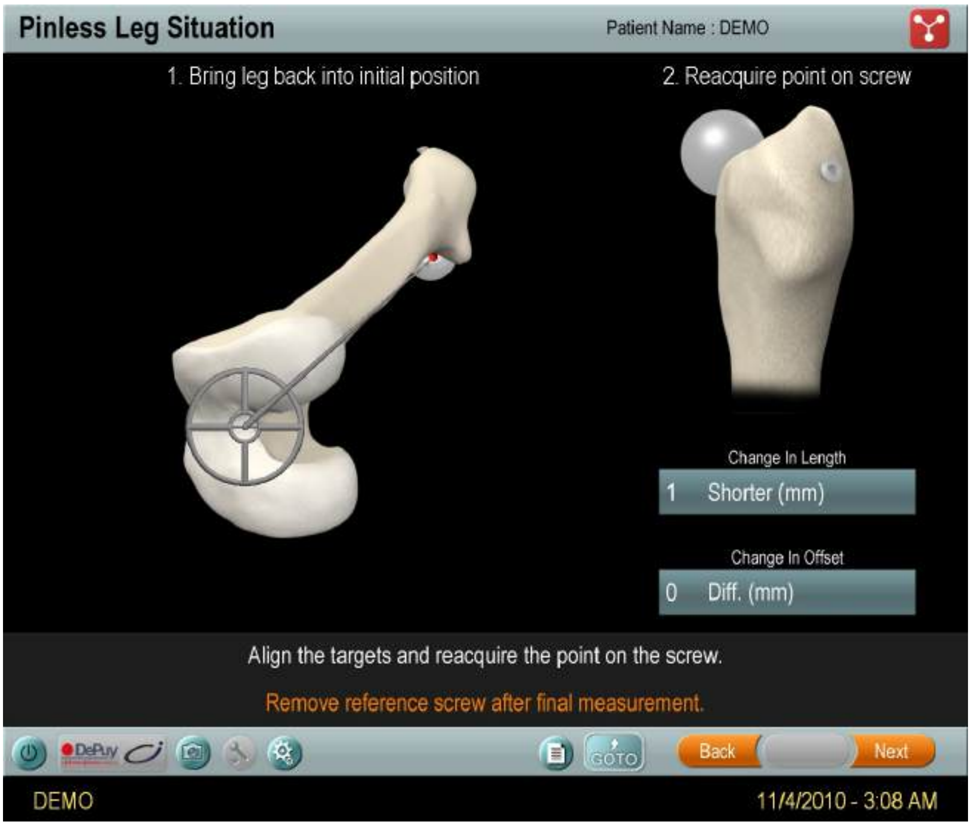

Figure 1.06: Leg length and offset change results are provided intra-operatively by the BrainLAB navigation system

Other studies employing a variety of workflows and operating systems have been undertaken both experimentally and *in vivo*. A mean difference between measurements made by navigation and a reference (radiographs, CT scans, millimeter paper) ranged from 0.2 to 1.3 mm [21, 134-136, 138, 139] for leg length and 0.5 to 1.3 mm for femoral offset [135, 138-140]. In one analysis, Kiefer *et al* showed that measurements of leg length change made by the OrthoPilot navigation system (B.Braun-Aesculap, Tuttlingen, Germany) were accurate within ±5 mm of the radiographic value for 83 to 85% of the cohort [34, 137].

Currently available navigation systems have a good ability to intra-operatively evaluate changes made to leg length and offset. Whilst the navigation system investigated in this study has been tested in an experimental setting, so far no results have been published from a clinical study. It is also important to consider that many of these studies compare the results to radiographic measurements, which may in fact be a source of error.

1.08.2 Jigs and Rulers

Although navigation systems exist that are capable of offset measurements, non-computerised methods of measuring change in leg length and offset have been described [141-151]. These methods use a specialized jig, ruler or caliper to measure the distance before and after implantation between two fixed points.

Whilst these methods indeed reduce the likelihood of causing an LLD they are not infallible, and mean post-operative discrepancies of 2 to 8 mm are still reported [141-152].

1.08.3 Femoral Repositioning

During intra-operative measurements of changes to leg length and offset, the accuracy of the results are dependent on the accuracy of femoral repositioning. The importance has been highlighted for both manual [142, 150] and navigational [153] methods. Sarin *et al* demonstrated that re-positioning error of as little as 5° introduced 8 mm of error for measurements of leg length change.

In the workflow of the navigation system used in this study, a neutral position (0° of flexion/extension and internal/external rotation) is required for registrations, and this is facilitated by an on-screen guide (Figures 2.02 and 2.03).

1.08.4 Special Tests

There are several clinical tests that can be performed intraoperatively to assess the artificial joint reconstruction, including the shuck test, drop-kick test, leg-to-leg comparison test, and assessment of stability and range of motion [69, 89, 96, 148, 151, 154]. Through performing the tests the surgeon is able to examine soft tissue tensioning, leg length changes, joint stability and range of motion. The tests are applied following each trial reduction to determine the suitability of the components used. Despite these tests not being incredibly very precise, no one method of intra-operative assessment is 100% accurate. Thus, even when navigation is used, the tests should still be performed to compare the results with the navigational measurements.

1.09 Navigation and the Ability to Restore Leg Length and Femoral Offset

Much research has been performed to investigate the effect of navigation systems on the ability of the surgeon to restoring leg length and femoral offset. Some studies describe the ease with which such variables are adjusted intra-operatively with the use of navigation, however these provide no manual cohort for comparison [21, 34, 36, 134, 137, 140]. Controlled studies that compare leg length and offset restoration between navigated and non-navigated cohorts are relatively rare [33, 155], and no studies have as yet made this comparison using the BrainLAB Hip 5.0 navigation system.

Dastane *et al* described femoral offset discrepancy as the difference in femoral offset from the contralateral hip. The study alluded to the proximity of the post-operative discrepancy of offset from the contralateral hip (mean 1.7 mm) to the desired offset change (1.5 mm) when navigation was used [140]. In this study, 95% of patients had a post-operative radiographic offset within 6 mm of the contralateral leg, and for leg length, 99% had a post-operative radiographic discrepancy of 6 mm or less. Similarly, using navigation, Ecker and Murphy described a mean post-operative LLD of 1.2 mm, and Nishio *et al* demonstrated a mean post-operative LLD of 0.9 mm [21, 156].

As many surgeons make a definitive shift to using navigation, studies that compare leg length and offset results with a controlled non-navigated group are relatively rare. Confalonieri *et al* conducted a study using the OrthoPilot 3.0 navigation system (B.Braun-Aesculap, Tuttlingen, Germany) [33]. The post-operative leg length discrepancy was significantly reduced in the navigated group (mean 4.1 mm), compared to the free-hand group (mean 7.9 mm). Likewise, femoral offset was significantly better restored in the navigated group, who showed a mean change of 2.8 mm compared to the non-navigated group (mean change, 5.1 mm).

Manzotti *et al* conducted a similar controlled study with greater numbers and produced comparable results, using BrainLAB's VectorVision software (BrainLAB, Feldkirchen, Germany). The study demonstrated a significant reduction in post-operative leg length discrepancy in the navigated group; mean 5.1 mm, when compared to a non-navigated group; mean 7.65 mm [155].

From the limited number of controlled studies examining femoral offset and leg length changes using navigation systems, a preliminary conclusion may be that leg length and offset restoration are enhanced with navigation use. This conclusion needs to be supported with larger randomised controlled trials for results to be more conclusive. Further to this, it remains unclear if the slight improvements shown to occur in leg length and offset changes translate to better patient outcomes and implant survivability in the medium- and long-term.

1.10 Pre-operative Planning

Before navigation may be employed, the surgeon must know what changes to leg length and offset are desired, by pre-operatively estimating the size and position of hip prosthetic components in a process known as templating. Templating facilitates accurate restoration of normal hip biomechanics, helps to predict the level of femoral neck osteotomy and leg length changes, allows suitable implant selection, potentially decreases surgical time and helps to ensure that the appropriate prostheses are available for the operation [72, 74, 157, 158].

Initially, analogue templating was performed using hard copy radiographs and bulky prosthetic acetate overlays [72, 75, 110, 159]. Although overlays are criticised for an inability to correct for varying magnification between individual radiographs [159].

A modern and more practical solution is digital templating (Figure 1.07). The transition to digital templating has been encouraged by an increased availability of digital radiographs and the introduction of Picture Archiving Communications Systems (PACS). The surgeon maneuvers digital template overlays of the prosthetic components into the desired position on a scaled digital radiograph [157, 158, 160, 161]. The surgeon may select from a range of different manufacturer's prostheses that can be downloaded onto the software, allowing the surgeon to more easily make a decision on the appropriate implant system [72, 110].

Although early assessments of digital templating were critical [162-164], recent studies are showing at the very least equal accuracy between analogue and digital methods, several studies even demonstrating significant benefit with digital templating when compared to analogue methods [165-167].

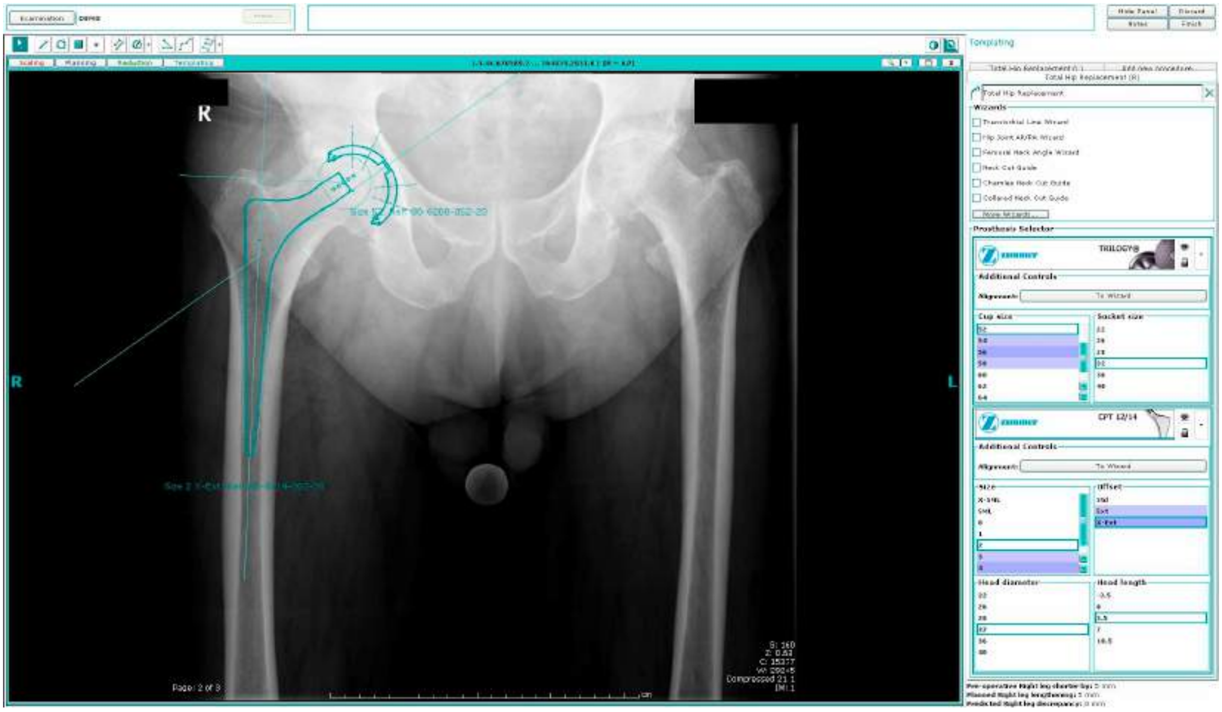

Figure 1.07: An example of digital templating software (OrthoView; Orthoview LLC, Florida, USA).

1.11 Surgical Time

The duration of surgery is important, as it will then have downstream effects on the financial efficiency of the surgeon and/or hospital. With increased operating time, there is also the potential for increased risk of infection. The use of navigation has been demonstrated to increase surgical time, although this increase diminishes as the surgeon becomes more experienced with the procedure [168]. The amount of added time to the procedure will also vary with the different navigation options decided upon, such as the imaging modality (CT, fluoroscopy or imageless) and the choice of navigation workflow (leg length and offset, cup, stem, combinations or all).

Both Manzotti *et al* and Confalonieri *et al* found a significant ($Ps \leq 0.0001$) increase in operative time when imageless navigation was used in controlled studies, with a mean difference of 16.2 and 14.9 minutes respectively [33, 155]. Other authors describe an increased surgical time ranging from 8 to 15 minutes for image free navigation and up to 17 minutes for CT-based navigation [46, 169, 170].

1.12 The Oxford Hip Score

1.12.1 Background

The Oxford Hip Score (OHS) is a patient-reported outcomes measurement tool used to assess function and pain in patients with poor hip function. It is also used to evaluate post-operative recovery. Studies have shown that it is reliable, valid, easy to administer and a feasible tool for evaluating the need for a total hip replacement from the perspective of the patient [171-173]. However, a small number of studies have also described criticism of one or more aspects of the questionnaire [173, 174]. In this study the modified Oxford hip score result was recorded, where the scores range from a 0 (poor) to 48 (good).

1.12.2 Role of Obesity

Interestingly, there is little evidence in the literature to suggest that patients with a higher body mass index (BMI) will have worse post-operative outcomes. Although Arden *et al* described an association between lower BMI and patient satisfaction, Andrew *et al* rebuted such evidence in a study of 1421 hip replacements, in which no difference was observed of change in Oxford hip score between non-obese, obese and morbidly obese patients [175, 176].

CHAPTER 2: Methods

2.01 Ethics

The Royal Melbourne Hospital Research and Ethics Committee (HREC) approved this study.

2.02 Cohorts

The study group consisted of a prospective, consecutive group of 24 navigated total hip arthroplasties and a retrospective, consecutive group of 37 non-navigated total hip arthroplasties. All procedures were performed at either the Royal Melbourne Hospital or Melbourne Private hospital.

One patient in the navigated group lacked an adequate pre-operative radiograph for planning purposes and was not included in the study. For the navigated group, an imageless navigation system (Hip 5.1; BrainLAB, Feldkirchen, Germany) provided intra-operative information on leg length and offset changes.

The lead surgeon was A/Prof Andrew Bucknill, or one of his three fellows. As all three fellows applied the technique learned from the one consultant, the standard posterior surgical technique was consistent.

2.03 How The Navigation System Works

The navigation system used in this study operated the Hip 5.1 software (BrainLAB, Feldkirchen, Germany). A pelvic array is fixed to the iliac crest and a pinless femoral array placed on the distal lateral thigh area (Figure 1.01).

During the procedure, a point on the greater trochanter of the operative femur is acquired before the hip is replaced ($\sigma_{pre\ op}$) and once more following prosthetic reconstruction ($\sigma_{post\ op}$) (Figure 2.03). The alignment of the leg for the acquisition of the first point (a process called primary registration) is in a 'neutral' position of 0° of flexion, abduction and internal/external rotation (Figure 2.01).

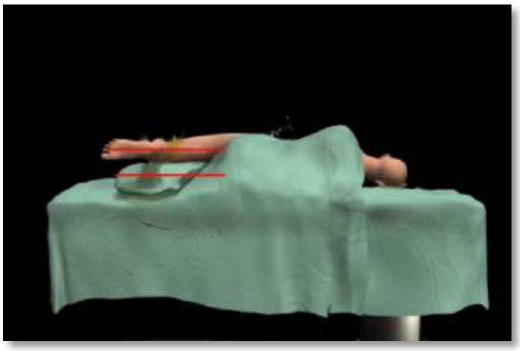

Figure 2.01: Positioning of leg for initial registration (Image courtesy of BrainLAB, Feldkirchen, Germany)

The surgeon is aided to precisely reposition the leg by a target produced on the screen (Figure 2.02). For accuracy reasons, it is only possible to reacquire the reference point when the leg is brought within 5° of the position it was in for primary registration. When this occurs, the target changes from yellow to green (Figure 2.03).

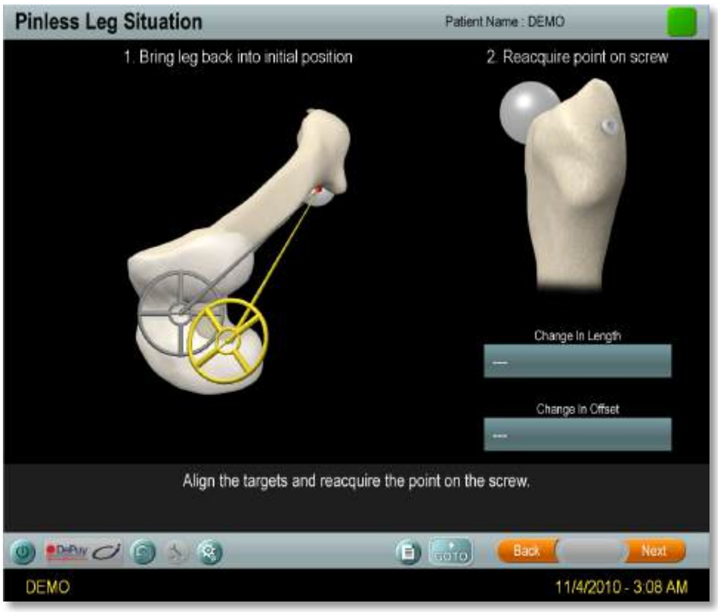

Figure 2.02: Navigation system guides the leg into the original neutral position.

Figure 2.03: Leg successfully returned to initial position and changes to leg length and offset displayed.

The software creates a reference axis of the femur (α) by simulating a line drawn that extends from the centre of the acetabulum (the middle of two opposing points, $\beta_{anterior}$ and $\beta_{posterior}$) and passes 5 cm below the pinless array (Figure 2.04). This axis is essentially the mechanical axis of the femur.

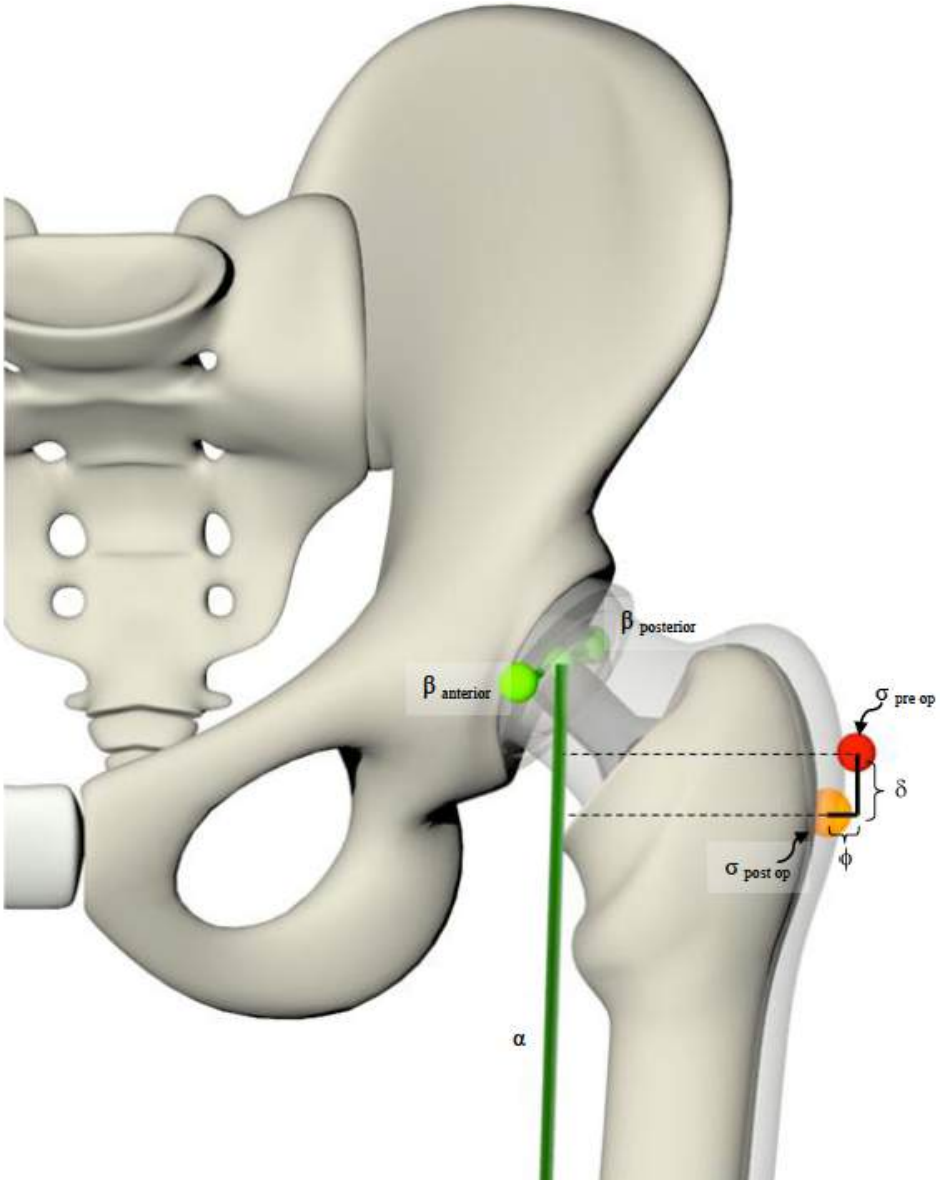

Figure 2.04: Calculation of leg length and offset changes following reduction of the hip and neutral positioning of the leg (Image courtesy of BrainLAB, Feldkirchen, Germany)

The difference in location between the two points is reduced to a two-dimensional vector. The vector is then separated into two component vectors that are mutually orthogonal. The vertical component runs parallel to the reference axis and this value (δ) is provided on screen as the change made to leg length, along with the direction of change (lengthening or shortening). The horizontal component is perpendicular to the reference axis and this value (ϕ) is provided on screen as the change made to offset, along with its direction (medialisation or lateralisation).

As no secondary registration takes place following implantation of the prosthetic cup, the calculation for change in offset does not take into account changes made to the centre of rotation of the hip joint. Consequently, the value provided for offset change represents the change in total offset (femoral plus acetabular offset). Some orthopaedic surgeons seek to medialise the cup by one or two millimeters in the course of the operation with the aim of improving hip biomechanics in order to reduce the lever arm of body weight. If the cup is medialised then the measurement given by the navigation system will be under-reading the change made to the true femoral offset.

For example, a 3 mm cup medialisation (which is the surgeon's average) with no change to femoral offset will produce a reading of a 3 mm reduction in offset. Alternatively, a 2 mm cup medialisation and a 2 mm increase in femoral offset would be interpreted as no change in offset. It is important that the surgeon is aware of this method of offset calculation.

2.04 Surgical Technique

The standard posterior approach employed by the lead surgeon and used in the vast majority of cases is described:

1. Patient is positioned in the lateral decubitus position, undergoes a preparatory wash and is draped
2. A skin incision is made through the skin extending from 5 cm above the tip of the greater trochanter (GT) to approximately 3 cm below the GT along the axis of the femoral shaft
3. The fascia lata is exposed and incised parallel to the skin incision
4. The fibres of gluteus maximus are split
5. The greater trochanter is exposed
6. The sciatic nerve is identified and looped as a precautionary measure
7. The piriformis tendon and short external rotators (SERs) are reflected from their attachment
8. A posterior capsulotomy is performed
9. The hip is dislocated
10. A femoral neck osteotomy is executed
11. The femoral head and neck are removed to expose the acetabulum
12. The acetabulum is reamed to the true floor
13. An offset reamer completes acetabular preparation, reaming the cavity to the desired size
14. The definitive acetabular cup is impacted by press-fit with appropriate orientation
15. If adequate fixation is not achieved, 2 to 3 screws are used to provide further fixation
16. A lipped polyethylene liner is inserted, with the lip positioned postero-inferiorly

17. The femoral shaft is prepared using a compaction broach of increasing size until adequate rotational stability and fit is achieved
18. Appropriate trial necks and heads are applied and the hip is then reduced
19. Once enlocated, the hip joint and leg is clinically examined for stability, range of motion and leg length discrepancy using the tests described in Section 1.08.4
20. The surgeon combines all of this available information and decides upon the appropriateness of the particular components used in the trial reduction
21. When a satisfactory result is achieved the definitive stem is impacted and is re-trialed with different trial heads
22. Once the appropriate head size is chosen and attached the hip is enlocated and the joint is assessed one final time with all definitive components in place
23. The SERs and piriformis tendon are re-attached to the GT with transosseous sutures
24. A reinfusion drain is placed
25. Fascia lata is repaired using sutures
26. The wounds are closed using absorbable sutures, superficially in conjunction with tissue glue

In the navigated cases, several additional steps are required. Firstly, the navigation equipment (Kolibri™ platform, BrainLAB, Feldkirchen, Germany) is set up in theatre (Figure 2.05).

Figure 2.05: BrainLAB imageless navigation system set-up

Prior to making the main incision (step 2), two percutaneous stab incisions are made in the skin overlying the anterior superior iliac crest. Two 125x4 mm Schanz screws are drilled into the iliac bone through the perforations and the Dynamic Reference Base (DRB) used for navigation is fixed to these two screws (Figure 1.01). A reference plate is then placed on the lateral thigh distal to the proposed incision site (Figure 1.01), and is affixed using an adhesive antimicrobial drape (Ioban™; 3M healthcare, Minnesota, USA). A second DRB is then attached to this plate.

After the GT is exposed (step 5) a 10 mm cortical screw is applied to its most lateral aspect. The surgeon then brings the patient's leg into a neutral position of

0° of flexion, abduction, and internal/external rotation (Figure 2.01 above), the tip of the digitiser is placed in the depression on the head of the screw and primary registration takes place (Figure 2.06)

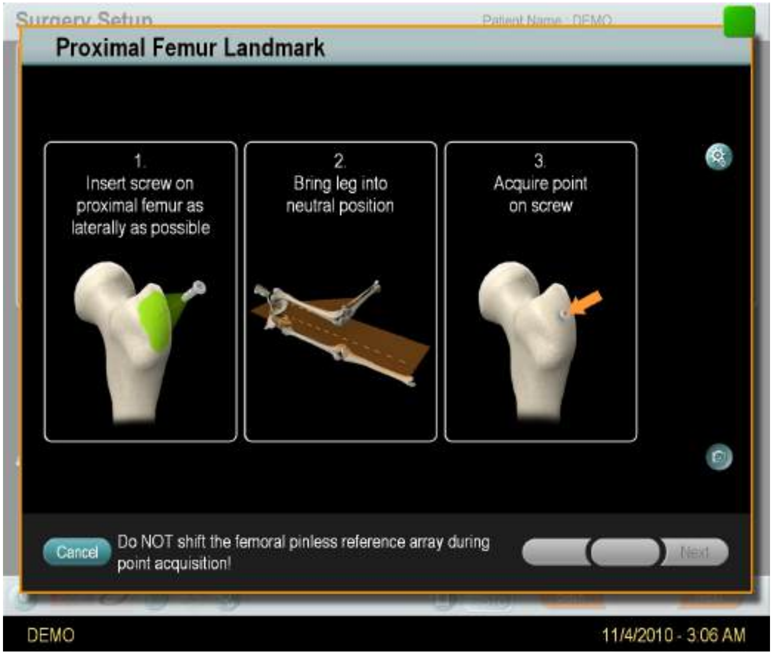

Figure 2.06: The steps of primary registration

Once the acetabulum is exposed (step 11) two opposite points on the acetabular rim are registered with the navigation system (Figure 2.07)

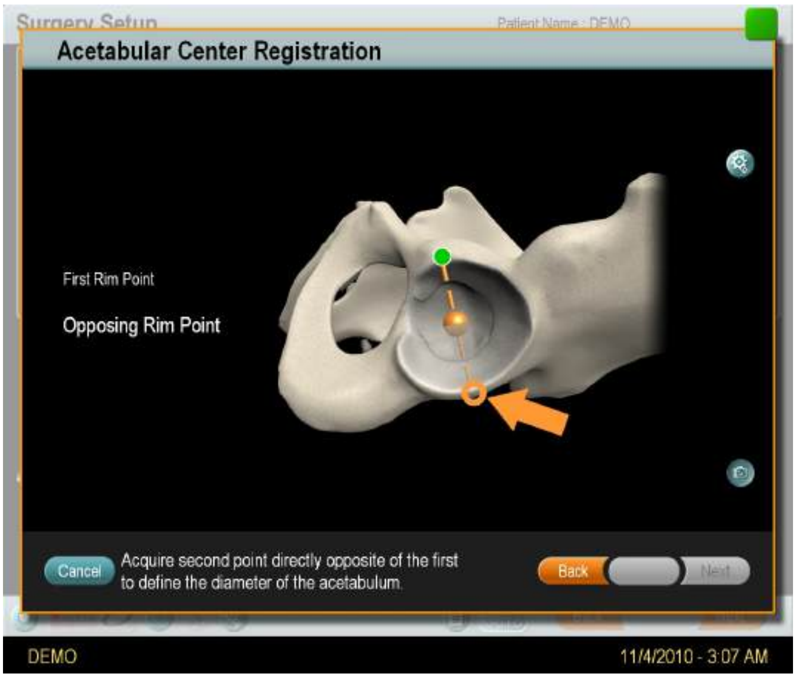

Figure 2.08: acquisition of opposing acetabular rim points

When a trial reduction takes place (step 19) the surgeon realigns the patient's leg in the neutral position, guided by an image on the computer screen (Figure 2.02), and touches the depression in the 10 mm screw with the pointer once more. The navigation system will then provide the changes made to leg length and offset from the primary registration in mm (Figure 2.03).

At the completion of surgery the 10 mm cancellous screw, the two Schanz pins and the dynamic reference bases are removed from the patient (Figure 2.08). The wound used for the fixation of the iliac reference array is sutured.

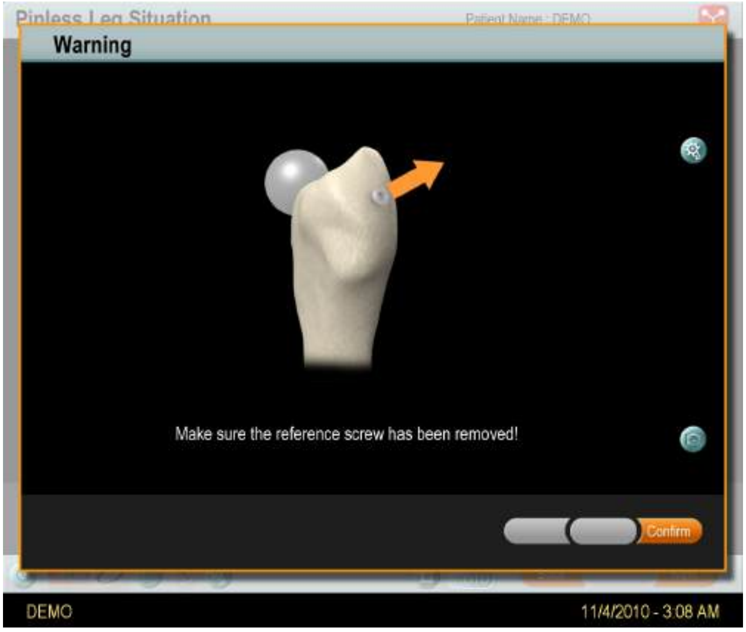

Figure 2.08: Reminder to remove the reference screw prior to closure

2.05 Data Collection

Baseline demographic data were documented, including patient age, sex, body mass index (BMI) and pre-operative diagnosis.

Pre- and post-operative plain pelvic radiographs were available for all patients and were analysed for leg length discrepancy, femoral offset and acetabular offset. Pre- and post-operative leg length discrepancy was analysed as an absolute measure because of a relatively even spread of values on either side of zero. Acetabular offset was defined as the perpendicular distance between the centre of the femoral head and the midline. Femoral offset was defined as the perpendicular distance from the centre of the femoral head to the anatomical axis of the femur.

From the pre-and post-operative measurements for leg length and offset, change in leg length and offset was determined. The pre- and post-operative ratio of femoral offset to acetabular offset was also calculated from this data. The pre-operative targets for changes to leg length and offset were recorded from the saved pre-operative planning session. For a detailed description of how leg length, offset and templating goals were measured, see Appendix 1.

Data on surgical variables were collected, including the lead surgeon's experience grade, the prosthetic components used, the duration of the surgical procedure, operative side, if the operation was a primary or revision and whether the contralateral side had been replaced or not. The length of post-operative hospital stay, or recovery time, was also recorded. For the collection of data on the duration of the surgical procedure, the revision and resurfacing cases were omitted, as these procedures are know to take more time and would introduce bias into the results.

For the prospective study group alone, results for final intra-operative leg length and offset changes were recorded from the BrainLAB navigation system. Furthermore, the study group was assessed using the Oxford Hip Score (modified score), which is a well-recognised tool for providing information on patient-reported pain and functional status. The pre-operative questionnaire was compared to scores collected subsequently at six weeks and three months post-operatively.

All data was entered into a spreadsheet (Microsoft Excel 2008 for mac, Microsoft Corporation, USA). Statistical analysis was carried out using STATA 10 (StataCorp LP, Texas, USA).

CHAPTER 3: Results

3.01 Patient Demographics

A total of 24 consecutive patients (24 hips) attending two hospitals for navigated total hip replacement were recruited into the study group. The control group comprised of 34 consecutive patients (37 hips) who attended the Royal Melbourne Hospital and underwent non-navigated total hip arthroplasty. All arthroplasties were unilateral.

The two groups were found to have no statistically significant differences in terms of sex, age or body mass index.

	Control Group n=37	Study Group n=24	*P*
Age (years): mean ± SD	60.3 ± 14.9	59.5 ± 14.4	0.845
Gender: *n* male, (% male)	14 (37.8%)	15 (62.5%)	0.072
BMI (kg m^{-2}): mean ± SD	29.9 ± 5.6	29.9 ± 5.1	0.995

Abbreviations used: BMI; body mass index, SD: standard deviation

Table 3.01: Demographic Data

3.02 Surgical Parameters

The data on surgical parameters that were collected during the study are summarised (Table 3.02).

	Control Group (n=37)	Study Group (n=24)	*P*
Surgical Approach	35 Posterior 1 Modified Hardinge 1 Watson-Jones	24 Posterior	0.511
Operative Side: *n* Right (% Right)	18 (48.65%)	13 (54.17%)	0.674
Operation Type	37 Primary THA	20 Primary THA 1 Hip Resurfacing 3 Revision	0.020
Previous Contralateral THA: *n* Yes (% Yes)	10 (27.03%)	6 (25.00%)	0.860
Hospital Class	37 Public	22 Public 2 Private	0.074
Primary Diagnosis	26 Osteoarthritis 9 Avascular Necrosis 1 Ankylosing Spondylitis 1 Failure of DHS	17 Osteoarthritis 3 Avascular Necrosis 3 Revised Arthroplasties 1 Trauma	0.197
Surgeon Grade	13 Consultant 24 Fellow	13 Consultant 11 Fellow	0.142
Prosthetic Cup: Model (Company)	7 Pinnacle (DePuy) 24 Trilogy (Zimmer) 4 ZCA (Zimmer) 2 EP-Fit (Smith&Nephew)	18 Pinnacle (DePuy) 3 Trilogy (Zimmer) 2 Trabecular Metal (Zimmer) 1 Birmingham (Smith&Nephew) 1 Trident (Zimmer)	<0.001
Prosthetic Stem: Model (Company)	5 Corail (DePuy) 3 S-ROM (DePuy) 13 Alloclassic (Zimmer) 8 M/L Taper (Zimmer) 6 CPT (Zimmer) 2 SL-Plus (Smith&Nephew)	18 Corail (DePuy) 1 S-ROM (DePuy) 3 Not Revised 1 Birmingham (Smith&Nephew) 1 Exeter V40 (Stryker)	<0.001
Cemented Cups: *n* (%)	2 (5.4%)	0 (0%)	0.515
Cemented Stems: *n* (%)	4 (10.8%)	1 (4.2%)	0.640

Abbreviations used: DHS, Dynamic Hip Screw

Table 3.02: Data describing surgical parameters

The diagnoses in both groups were presented as pie charts

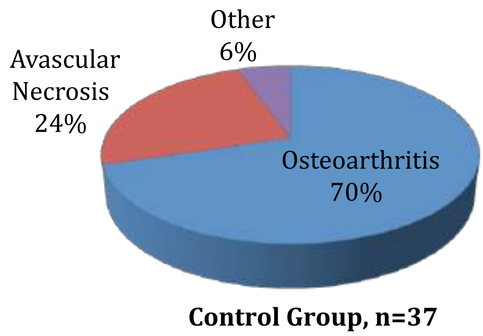

Figure 3.01: Primary diagnoses in the control group patients

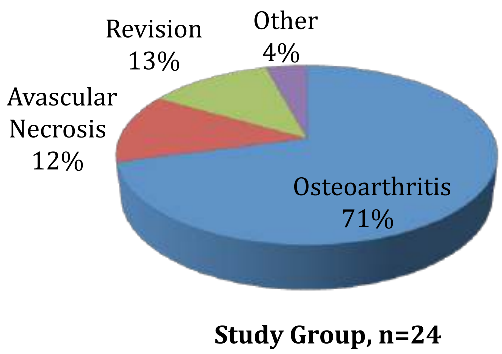

Figure 3.02: Primary diagnoses in the study group patients

3.04 Leg Length Discrepancy

3.04.1 Overall Changes

There was no statistically significant difference in pre- or post-operative leg length discrepancy between the study and control groups (*P*=0.829). The mean absolute post-operative discrepancy was 4.42 mm in the study group and 4.34 mm in the control group. In the study group 17 cases (70.83%) had leg length restored to within 6 mm, compared to 27 cases (72.97%) in the control group, but this was not statistically significant (*P*=0.858).

	Control Group	Study Group	*P*
Pre-Operative LLD: mean ± SD (mm; range)	8.48 ± 7.99 (0.0 to 33.0)	4.38 ± 2.93 (1.0 to 12.0)	0.087
Post-Operative LLD: mean ± SD (mm; range)	4.34 ± 3.90 (0.0 to 20.0)	4.42 ± 3.27 (0.0 to 10.0)	0.829
Change in LLD: mean ± SD (mm; range)	-4.05 ± 7.35 (-23.0 to 9.0)	0.04 ± 5.80 (-12.0 to 7.0)	0.019
Post-Operative LLD of 6mm or less: *n* (%)	27 (72.97%)	17 (70.83%)	0.858

Note: pre- and post-operative LLD values are absolute

Table 3.03: Pre- and post-operative leg length discrepancies and the size of change

3.04.2 Achievement of Target Leg Length Change

When compared to the pre-operative goals, the study group showed a small, but not statistically significant (P=0.775), reduction in the mean deviation from the desired leg length change.

	Control Group	Study Group	*P*
Absolute difference between target and resulting LLD: mean ± SD (mm; range)	4.23 ± 3.44 (0.0 to 16.0)	3.90 ± 2.91 (0.0 to 9.0)	0.775
Change of LL within 6mm of target: *n* (%)	27 (73.0%)	18 (75.0%)	0.862

Table 3.04: Deviation from pre-operative leg length change goals

These results are interpreted graphically as a box plot (Figure 3.03) and as a column graph (Figure 3.04), the latter of which shows the direction of deviation. In these figures it can graphically appreciated that there was little difference between the two groups in terms of achievement of pre-operative targets.

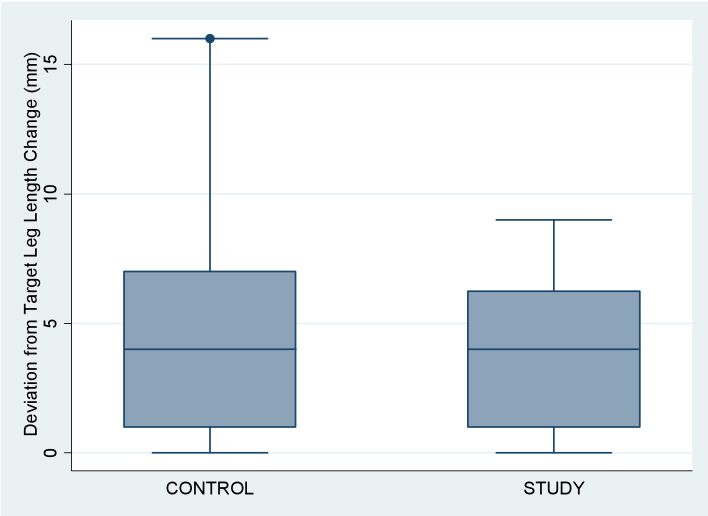

Figure 3.03: Box plot depicting the absolute deviation from the desired leg length change (bars: minimum and maximum; box: inter-quartile range; line in box: mean)

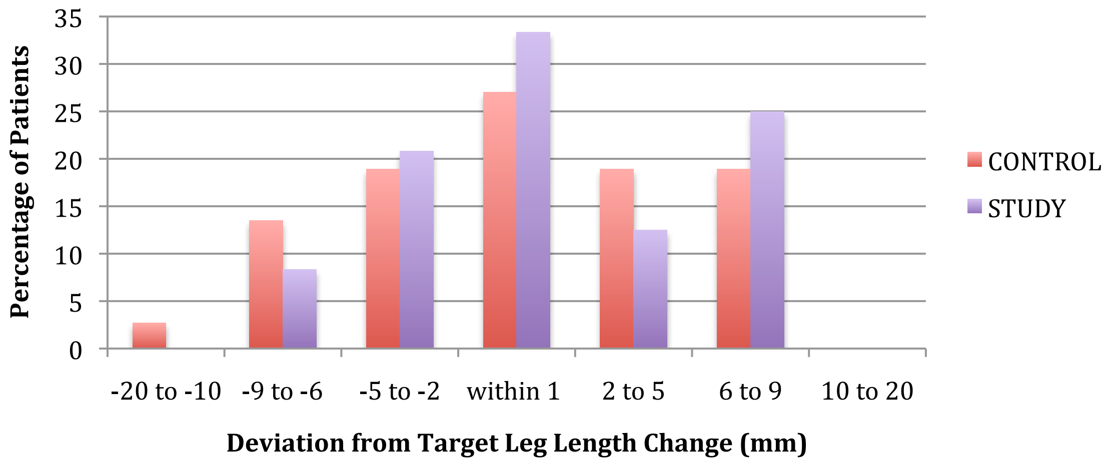

Figure 3.04: Graph of the size of deviations from target leg length change

3.05 Femoral Offset

3.05.1 Overall Changes:

Femoral offset (FOS) was well restored in both groups. Femoral offset was increased by a mean of 2.33 mm in the study group and by a mean of 3.20 mm in the control group. A statistically significant difference between the two groups was observed for the ability to create a post-operative femoral offset within 6 mm of the pre-operative value (*P*=0.046), suggesting that femoral offset was more likely to be restored in the navigation group.

	Control Group	Study Group	*P*
Pre-Operative FOS: mean ± SD (mm; range)	38.54 ± 9.64 (18.0 to 58.5)	40.94 ± 6.75 (25.0 to 52.5)	0.294
Post-Operative FOS: mean ± SD (mm; range)	41.74 ± 7.78 (26.0 to 59.0)	43.27 ± 7.03 (25.5 to 58.0)	0.440
Change in FOS: mean ± SD (mm; range)	3.20 ± 9.06 (-19.5 to 27.5)	2.33 ± 4.05 (-4.0 to 14.0)	0.326
Change in FOS of 6mm or less: *n* (%)	20 (54.05%)	19 (79.17%)	0.046

Table 3.05: Pre- and post-operative femoral offset values and size of change

3.05.2 Achievement of Target Offset Change:

When comparing the change in femoral offset to the templating goals, the study group showed a statistically significant reduction in the deviation from the desired change (*P*=0.037).

	Control Group	Study Group	*P*
Absolute difference between target and resulting FOS: mean ± SD (mm; range)	5.09 ± 4.61 (0.0 to 18.5)	2.85 ± 2.66 (0.5 to 11.0)	0.037
Change of FOS within 6mm of target: *n* (%)	27 (72.97%)	21 (87.5%)	0.177

Table 3.06: Deviation from pre-operative femoral offset change goals

These results are once more interpreted graphically as a box plot (Figure 3.05), and as a column graph (Figure 3.06). From these graphs it can be seen that target femoral offset was more closely achieved in the study group where navigation was used.

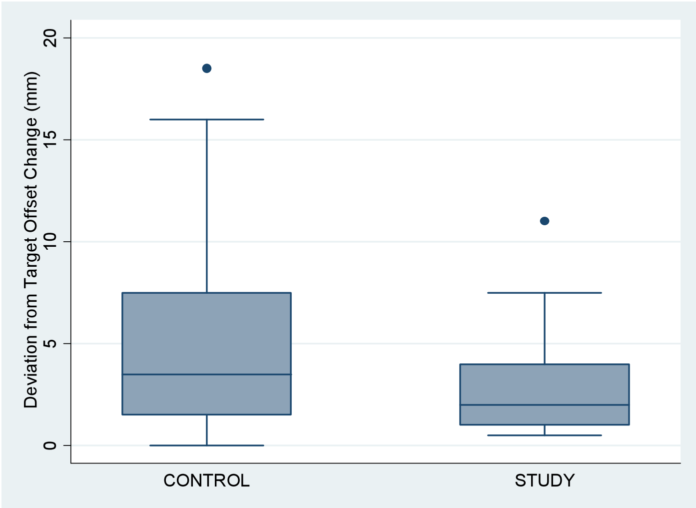

Figure 3.05: Box plot depicting for each group the absolute deviation from desired femoral offset change (bars: minimum and maximum; box: inter-quartile range; line in box: mean)

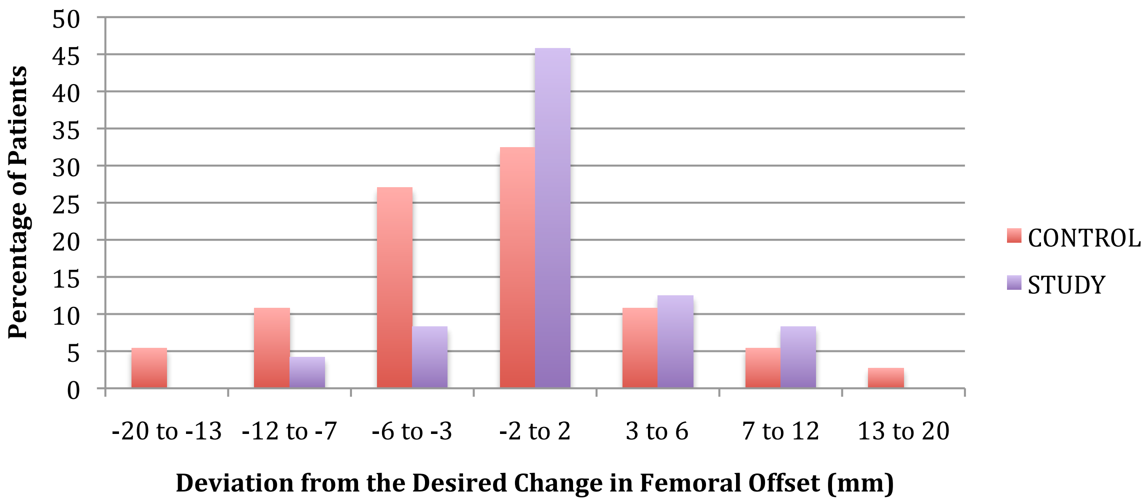

Figure 3.06: Graph of the size of deviations from the target femoral offset change

3.06 Acetabular Offset

There was no significant difference between the two groups in terms of pre-operative, post-operative, or change made to acetabular offset. Overall the data shows a tendency to medialise the centre of rotation of the hip by an average of 3.5 mm in the study group and 4.2 mm in the control group.

	Control Group	Study Group	*P*
Pre-Operative AOS: mean ± SD (mm; range)	91.54 ± 8.22 (77.0 to 110.5)	91.31 ± 7.63 (77.0 to 106.0)	0.914
Post-Operative AOS: mean ± SD (mm; range)	87.30 ± 5.97 (74.0 to 103.0)	87.83 ± 4.94 (78.0 to 98.0)	0.716
Change in AOS: mean ± SD (mm; range)	-4.24 ± 6.35 (-20.0 to 11.5)	-3.48 ± 7.17 (-24.0 to 6.5)	0.664

AOS: Acetabular Offset

Table 3.07: pre- and post-operative acetabular offset values and the size of the change

3.07 Femoral to Acetabular Offset Ratio

There was no statistically significant difference between the two groups pre- or post-operatively in terms of femoral to acetabular offset ratio (FAOS). Additionally, no significant difference was observed between the two groups in terms of change made to FAOS caused by the operation (P=0.512). However, the study group had a greater proportion of participants where an increase in the FAOS ratio was observed (33.3% compared to 24.3%), but this finding was not statistically significant (P=0.443).

	Control Group	Study Group	*P*
Pre-Operative FAOS Ratio: mean ± SD ($x10^{-2}$; range)	41.95 ± 9.50 (21.89 to 57.64)	45.05 ± 7.97 (30.34 to 66.29)	0.193
Post-Operative FAOS Ratio: mean ± SD ($x10^{-2}$; range)	47.94 ± 8.96 (30.34 to 66.29)	49.39 ± 8.38 (29.48 to 69.46)	0.526
Change in FAOS Ratio: mean ± SD ($x10^{-2}$; range)	5.97 ± 10.77 (-18.04 to 34.37)	4.34 ± 6.83 (-5.18 to 19.20)	0.512
Proportion with Increased Ratio (≥0): *n* (%)	9 (24.3%)	8 (33.3%)	0.443

FAOS: Femoral to Acetabular Offset

Table 3.08: Data describing pre- and post operative femoral to acetabular offset ratios and the changes made as a result of surgery

3.08 Length of Stay

The number of days of post-operative recovery was also noted. The study group showed a marginal reduction in length of stay (LOS) by a mean of 1.2 days, which was just beyond statistical significance (P=0.067).

	Control Group	Study Group	*P*
Post-operative Length of Stay: mean ± SD (days; range)	5.96 ± 2.89 (3 to 17)	4.75 ± 1.62 (3 to 9)	0.067

Table 3.09: Length of post-operative stay for the two cohorts

This data is also presented as a box plot for further comparison. It can be seen that lengths of stay of the two groups were very similar.

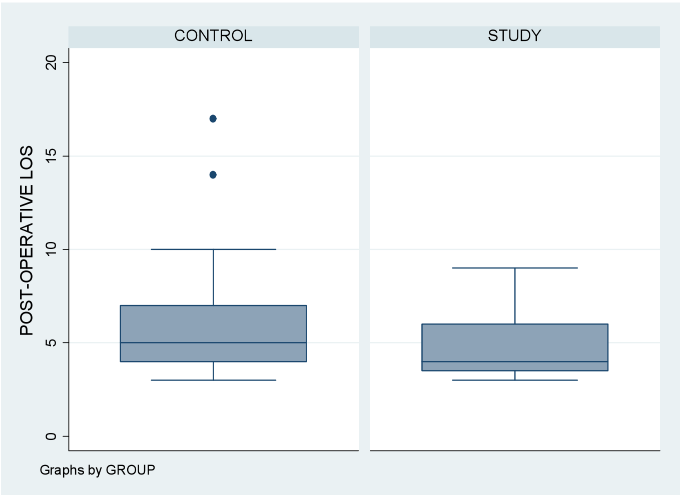

Figure 3.07: Box plot showing post-operative length of stay (bars: minimum and maximum; box: inter-quartile range; line in box: mean)

3.03 Time Considerations

For analysis of surgical time, the three revisions and one hip resurfacing procedures in the study group were omitted. Only primary total hip arthroplasties remained in both groups. The procedure in the navigated group lasted a mean of 6 minutes longer than when navigation was not used, however this was not statistically significant (*P*=0.084).

Measurement, minutes	Mean	SD	Min.	Max.	Percentile 25th	Percentile 75th	*P*
Study	153.7	23.0	102.0	200.0	135.0	170.0	0.084
Control	147.7	47.0	75.0	325.0	116.0	165.0	

SD; standard deviation, Min; minimum, Max; maximum

Table 3.10: Duration of surgery

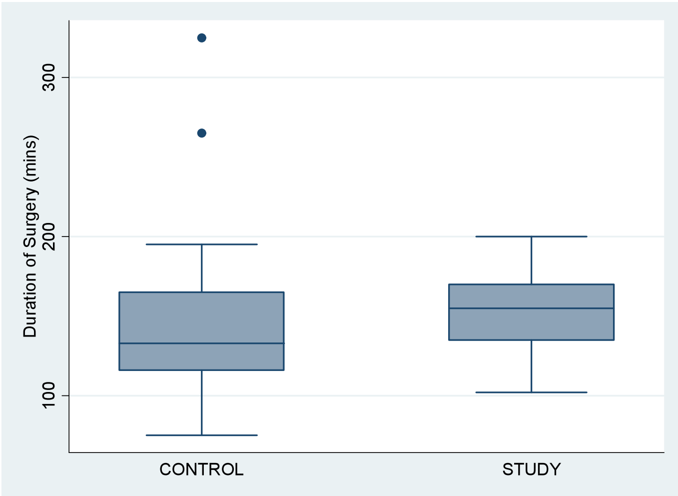

Figure 3.08: Box plot showing differences in length of surgery (bars: minimum and maximum; box: inter-quartile range; line in box: mean)

3.09 Navigation Accuracy

The data recorded from the navigation system was compared to changes measured radiographically to assess the accuracy of the system.

3.09.1 Leg Length

A strong and statistically significant correlation was shown between radiographic measurements of leg length (LL) changes and the changes calculated intra-operatively by the navigation system was observed (R=0.766, P < 0.0001). The mean difference between the two measurements was +0.42 mm (95% CI, -0.72 to 1.55 mm) though it was not statistically significant (*P*=0.723).

					Percentile	
Measurement, mm	Mean	SD	Min.	Max.	25th	75th
Radiographic	4.13	4.16	-3.0	12.0	2.0	7.0
Navigational	4.54	4.15	-3.0	13.0	0.8	7.0
Difference	0.42	2.84	-5.0	7.0	-1.0	2.0

SD; standard deviation, Min; minimum, Max; maximum

Table 3.12: Comparison of leg length measurements by navigational and radiographic methods

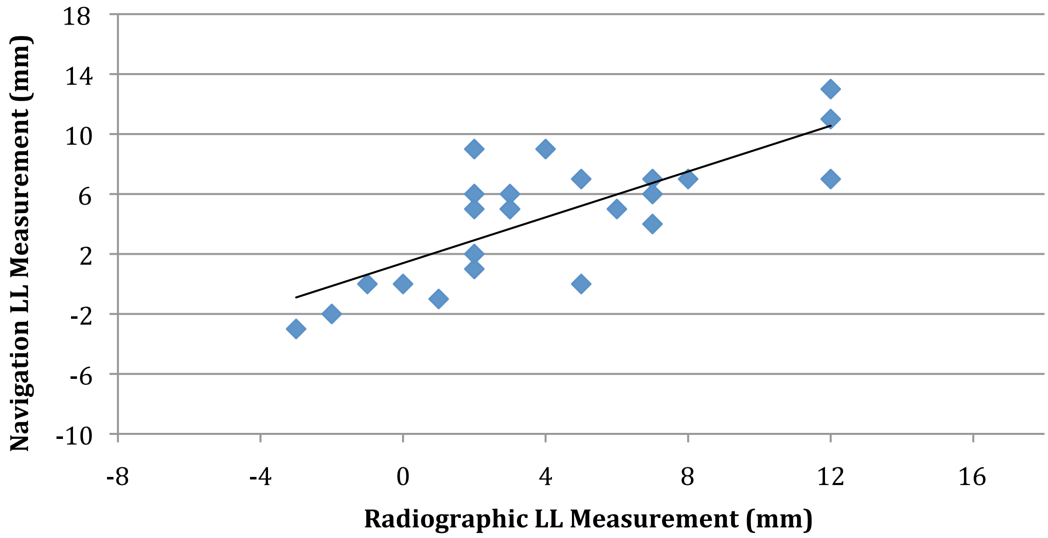

Figure 3.10: Scatter-plot of leg length (LL) change measurements made by the navigation system and as measured from scaled digital radiographs

The navigation system was within 5 mm or less for 23 (95.8%) cases.

Difference from Radiographic Measurement:	≤1 mm	≤2 mm	≤5 mm
n:	12	16	23
%:	50.0	66.7	95.8

Table 3.13: Accuracy of the navigation system in calculating leg length changes intra-operatively

3.09.2 Femoral Offset

Radiographic change of femoral offset was compared to navigational measurements of offset change (R=0.323, *P*=0.123). The mean difference between the two measurements was -2.13 mm (95% CI, -4.23 to -0.02 mm), and this difference showed no statistical significance (*P*=0.109).

3.09.3 Total Offset

The navigation systems measurement of offset (OS) showed a good correlation with total offset (TOF) change (change in femoral offset plus change in acetabular offset). This comparison showed a good and statistically significant correlation (R=0.468, *P*=0.021). Furthermore, the mean difference between the navigation and radiographic measurements was +1.35 mm (95% CI, -1.22 to 3.93 mm), and this difference was shown have no statistical significance (*P*=0.4446).

Measurement, mm	Mean	SD	Min.	Max.	Percentile 25th	Percentile 75th
Radiographic	-1.15	7.06	-25.0	8.5	-3.5	3.0
Navigational	0.21	4.92	-9.0	13.0	-2.3	1.5
Difference	1.35	6.44	-10.5	16.0	-3.1	3.8

SD; standard deviation, Min; minimum, Max; maximum

Table 3.16: Comparison of femoral offset measurements by navigation and combined offset measured by radiographic methods

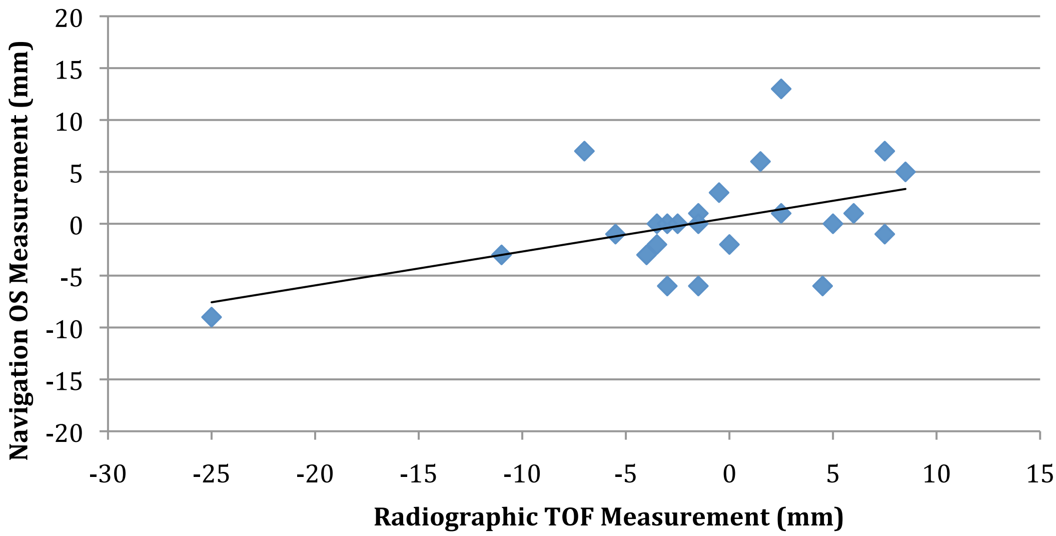

Figure 3.12: Scatter-plot of offset (OS) change as measured by navigation compared to the change in total offset (TOF) measured from digital radiographs

The navigation system was within 5 mm or less in 18 (75%) cases.

Difference from Radiographic Measurement:	≤1 mm	≤2 mm	≤5 mm
n:	2	6	18
%:	8.3	25.0	75.0

Table 3.17: Accuracy of the navigation system in calculating offset changes intra-operatively (compared to radiographic measurement of combined femoral and acetabular offset)

3.10 Oxford Hip Scores

In this study the modified Oxford Hip Score result was used, with scores ranging from 0 (poor) to 48 (good). These results were only available for the study group.

3.10.1 Changes Following the Operation

Statistically significant improvements were observed of the Oxford Hip Score results at six weeks and three months post-operatively.

Time Point:	Score: mean ± SD (range)	Improvement from t_0: mean ± SD (range)	*P*
Pre-operative (t_0):	13.96 ± 7.43 (2 to 34)	-	-
Six Weeks Post-operative:	31.04 ± 9.63 (16 to 47)	17.09 ± 11.40 (-8 to 38)	<0.0001
Three Months Post-operative:	38.57 ± 7.50 (24 to 48)	24.61 ± 10.08 (3 to 43)	<0.0001

Table 3.18: Summary of Oxford Hip Score results

Figure 3.13: Box plot depicting Oxford Hip Score pre-operatively, at six weeks post-operatively, and at three months post-operatively (bars: minimum and maximum; box: inter-quartile range; line in box: mean)

3.10.2 Oxford Hip Scores and Accuracy of Leg Length Achievement

No correlation was found between six-week Oxford Hip Score improvement and accuracy of leg length achievement (R=0.07, *P*=0.745).

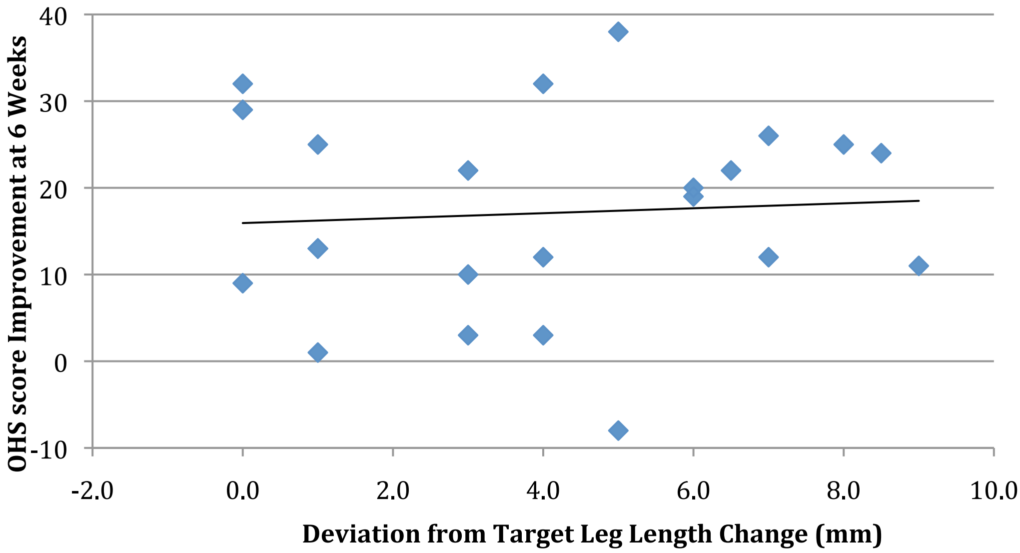

Figure 3.14: Scatter plot comparing 6-week Oxford Hip Score (OHS) improvement and the accuracy of leg length change

A positive correlation was shown between leg length target achievement and three-month oxford hip score improvement, however this was not statistically significant (R=0.31, *P*=0.154).

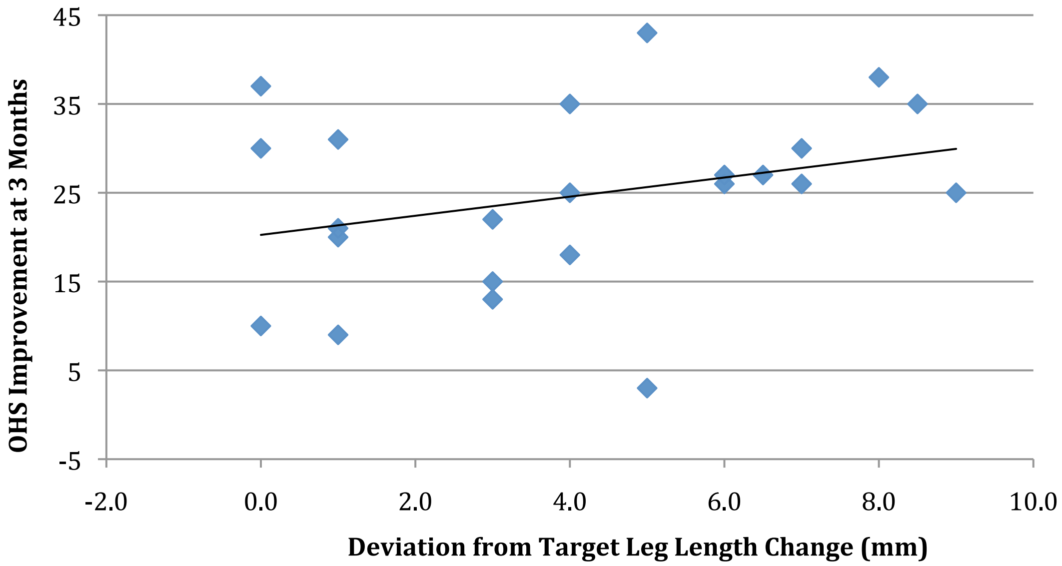

Figure 3.15: Scatter plot comparing 3-month Oxford Hip Score (OHS) improvement and the accuracy of leg length change

3.10.3 Oxford Hip Scores and Accuracy of Offset Achievement

A correlation was found between the accuracy of femoral offset achievement and six-week OHS improvement; once more this finding was not statistically significant (R=0.31, *P*=0.151).

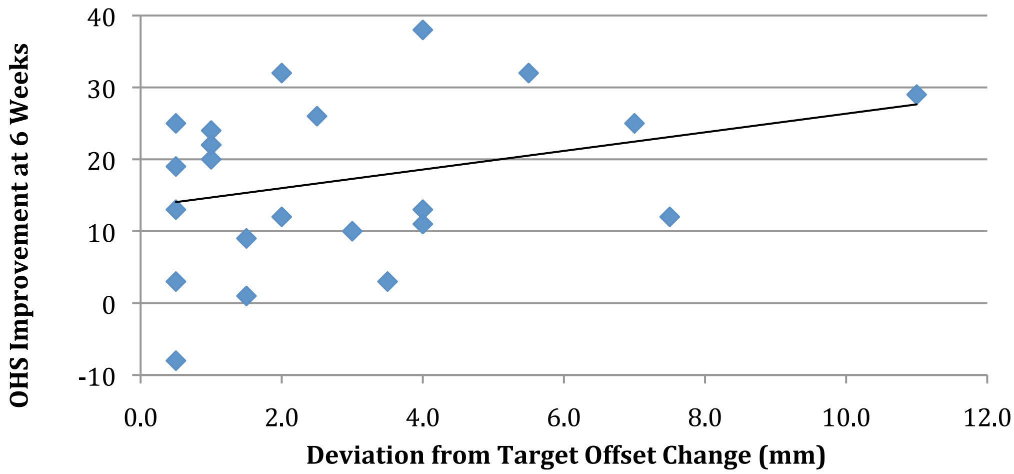

Figure 3.16: Scatter plot comparing 6-week Oxford Hip Score (OHS) improvement and the accuracy of femoral offset change

A medium correlation was found between the accuracy of femoral offset achievement and three-month OHS improvement (R=0.31, *P*=0.147)

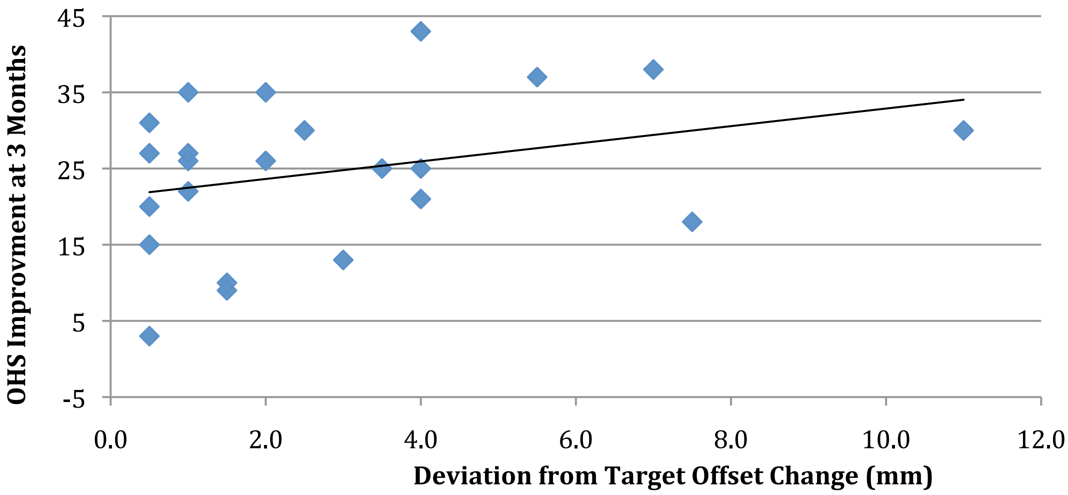

Figure 3.17: Scatter plot comparing 3-month Oxford Hip Score (OHS) improvement and the accuracy of femoral offset change

3.10.4 Oxford Hip Scores and BMI

Body mass index (BMI) was shown to have a negative correlation with pre-operative Oxford Hip Score (OHS) (R=-0.37, *P*=0.084).

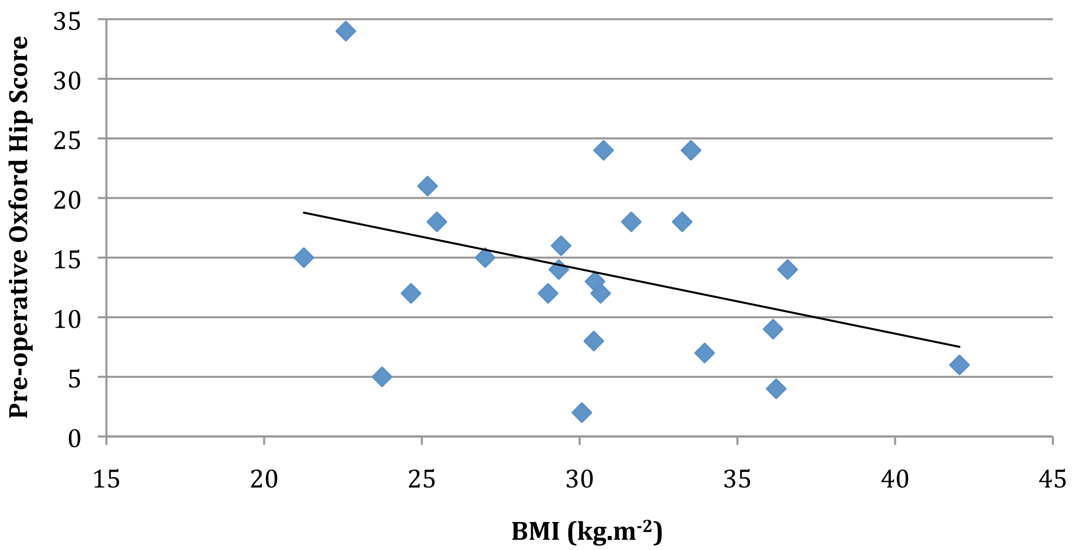

Figure 3.18: A scatter-plot depicting patient's body mass index (BMI) and pre-operative oxford hip score (OHS)

A small correlation was found between patient BMI and Oxford Hip Score improvement at six weeks (R=0.26, *P*=0.240).

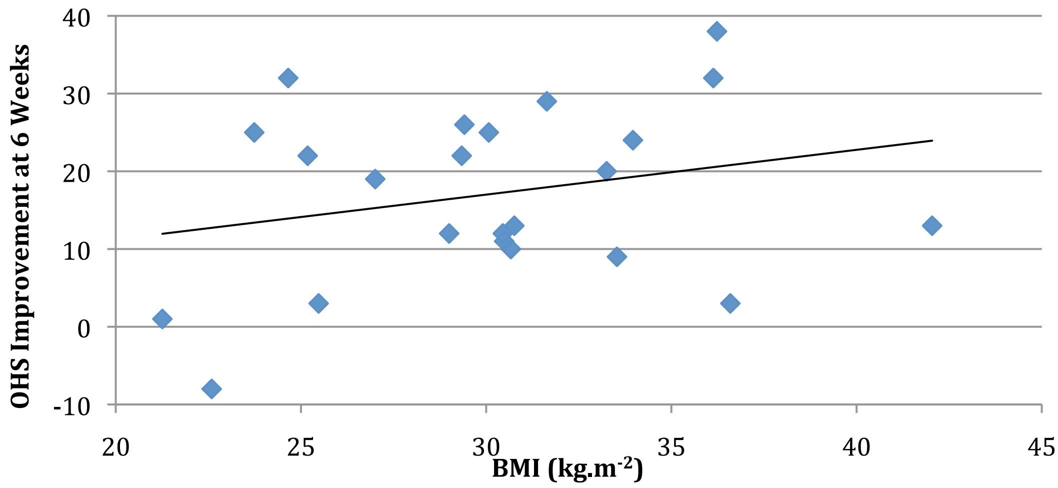

Figure 3.19: Scatter plot comparing 6-week Oxford Hip Score (OHS) improvement and patient body mass index (BMI)

At three months a positive correlation that was not statistically significant was found between BMI and OHS improvement (R=0.33, P=0.122).

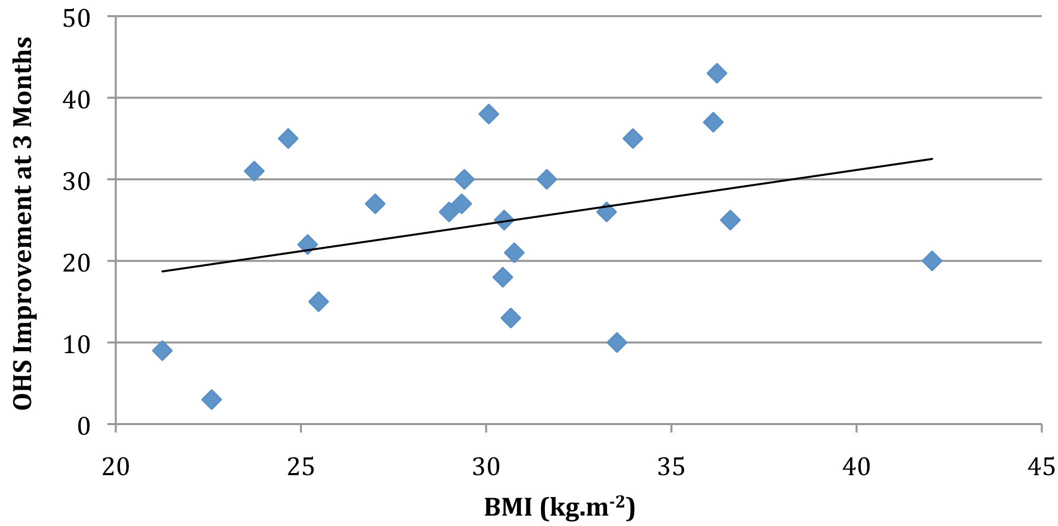

Figure 3.20: Scatter plot comparing 3-month Oxford Hip Score (OHS) improvement and patient Body Mass Index (BMI)

3.10.5 Oxford Hip Scores and FAOS Ratio Change

A small correlation was found between the change made to the FAOS ratio and improvement of Oxford Hip Scores at six weeks (R=0.23, *P*=0.302) and three months (R=0.12, *P*=0.577) post-operatively.

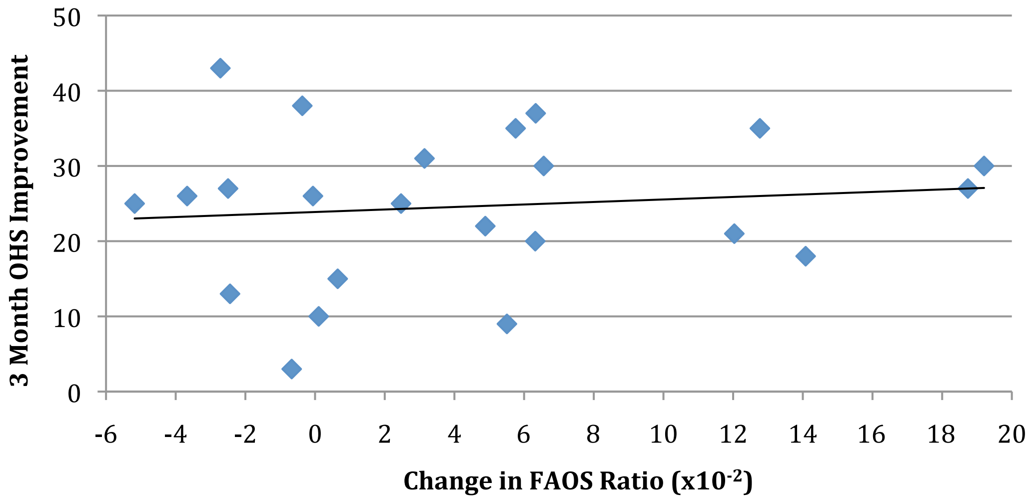

Figure 3.21: Scatter plot and trendline of the change in the FAOS ratio and 6 week OHS improvement

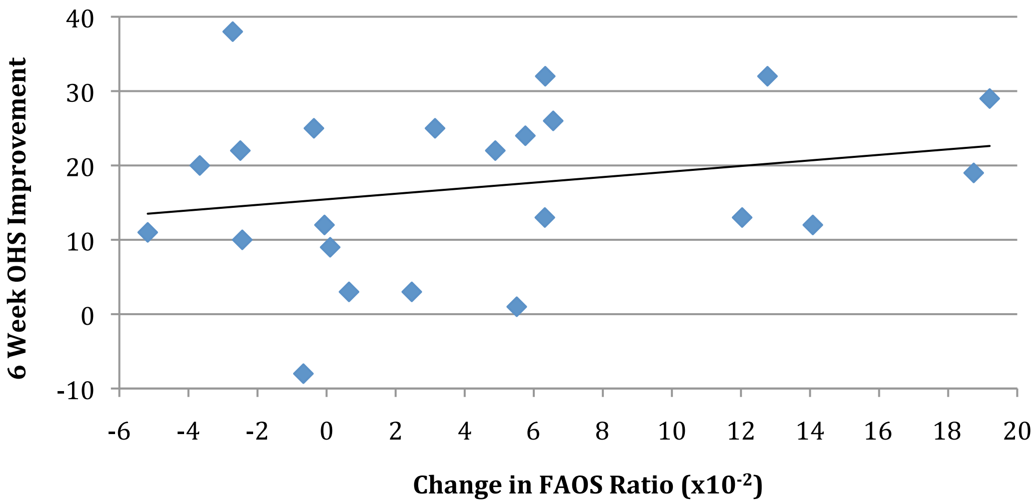

Figure 3.22: Scatter plot and trendline of the change in the FAOS ratio and 3 month OHS improvement

CHAPTER 4: Discussion

The primary aim of this study was to identify whether or not the use of navigation improves the achievement of target offset and leg length in total hip arthroplasty. Secondary aims included an assessment of the correlation between navigational measurements and radiographic measurements, and to assess the influence of navigation use on procedure times, theatre times and length of surgery.

4.01 Leg Length

Failure to achieve desired post-operative limb length can result in back pain, sciatic nerve palsy, instability, gait abnormalities, limp, patient dissatisfaction and litigation [57, 60-64]. Navigation of leg length change aims to increase the frequency with which target leg lengths are achieved and our study evaluated its efficacy in that regard.

Contrary to the hypothesis of this study, no statistically significant difference in post-operative leg length discrepancy was observed between the navigated and non-navigated cohorts (Table 3.03). This contradicts the findings of Confalonieri *et al* and Manzotti *et al*., who found a post-operative discrepancy of 4 mm in the navigated cohort and 8 mm in the control group, and 5 mm for navigated patients and 8 mm for control patients respectively [33, 155]. The post-operative leg length discrepancies described in this study (mean 4 mm in both groups) thus compare favourably to those described in the literature. However, the mean pre-operative discrepancies were larger in the studies by Confalonieri *et al* and

Manzotti *et al*. The proportion of patients with residual inequalities of 6 mm or less showed no significant difference (control group, 73%; study group, 71%). and were slightly lower than results described from other authors (range, 84% to 99%) [140, 150, 177]

In some cases, it is the surgeon's plan not to fully equalise leg length, perhaps due to severe pre-operative discrepancy or contralateral disease. Consequently, the more relevant outcome measure for leg length changes is to compare the end result with the surgeon's pre-operative plan. No previously published studies employing this method of comparison were identified in the literature search. Navigated cases presented a closer correlation between target and actual leg length changes than control cases, but this finding was not statistically significant (Table 3.04). Similarly, no significant difference was found between the proportion of patients in each group where leg length change was within 6 mm of the target (Table 3.04).

In summary, this study did not show statistically improved accuracy in achieving leg length targets with the use of navigation.

4.02 Offset

Femoral offset has been shown to be of significant importance through its influence on stability, polyethylene wear rates, abductor muscle function, range of motion, bone stresses and micromotion [82, 89, 92, 94, 96, 100, 108]. Research has also shown that restoring femoral offset is important in achieving optimal hip biomechanics and to prevent some of the complications listed above

[81, 89, 90, 110]. Other studies have gone further to describe how the femoral to acetabular offset (FAOS) ratio can be manipulated to improve abductor function and reduce wear rates [90, 113].

Our study demonstrated good restoration of femoral offset in both the study and control groups (mean increase of 2.3 and 3.2 mm respectively). It was found that navigated groups were more likely to have femoral offset restored within 6 mm of the pre-operative value (79% of patients) compared to the control group (54% of patients), which was statistically significant (P=0.046). Once more the offset changes were also gauged against the surgeon's aims.

A statistically significant reduction in the deviation from target offset change was shown for the navigated group when compared to the control group. This finding suggests that the navigation system successfully aided the surgeon in achieving their pre-operative targets, which aligns well with studies by Dastane *et al* and Confalonieri *et al* [33, 140]. In addition, the proportion of patients with a post-operative femoral offset within 6 mm of the target was slightly higher in the study group (87.5% compared to 73.0%) but this result was not statistically significant. A graphical overview of the results (Figure 3.06) depicts what the smaller standard deviation statistically suggests; that there is a reduced error and increased likelihood of target achievement in the navigated group.

4.03 Accuracy of the Navigation System

For reasons described previously, it is important to address leg length and offset during total hip arthroplasty. For navigation to be useful, the system's intra-operative measurements must be accurate.

The navigation system employed in this study has been assessed in experimental studies by Renkawitz *et al* in the past, using cadavers and saw-bone models [35, 135, 138, 139, 178]. There are no published studies evaluating the accuracy of BrainLAB navigation *in vivo*.

4.03.1 Leg Length

The navigation system's leg length measurements showed excellent results (Figure 3.10), with a strong and statistically significant correlation between radiographic and navigational methods ($R=0.77$, $P < 0.0001$). In addition, the difference between the two methods of measurements showed a low mean and standard deviation (0.4 mm and 2.8 mm respectively), further supporting this finding (Table 3.12). The mean difference of 0.4 mm found in this study is concordant with differences between navigational and radiographic or manual measurements of leg length described in the literature, which range from 0.2 to 1.3 mm [21, 35, 134-136, 138, 139]. Furthermore, the mean difference in this study (0.4 mm) compared favourably with the experimental mean difference of 0.5 mm using the same navigation system in a cadaveric study, showing that the measurements are just as accurate *in vivo* [35].

Table 3.13 also supports the accuracy of navigational measurement of leg length change, showing that the system was accurate within 5 mm 96% of the time. This finding improves upon the observations of Kiefer *et al* where a different navigation system was studied and was found to be accurate within 5 mm 83-85% of the time [34, 137].

It was noted that the correlation between navigation and radiographic measurements of leg length change was not as strong in this study (R=0.77) when compared with the findings of Renkawitz *et al* (R=0.92) [35]. A potential explanation for this is the use of CT imaging to measure the changes of leg length in the experimental study, which is more accurate than measurements from radiographs used in this study. However, due to added radiation exposure and extra cost the use of CT imaging could not be ethically or financially justified. There are also many other variables that are more easily controlled in a cadaver lab compared to in a live surgical patient.

4.03.2 Offset

Considering femoral offset alone (as opposed to total offset), a correlation of 0.32 was found between radiographic measurement and the navigational offset value, and this was not statistically significant. The mean difference between navigational and radiographic measurements was a navigation under-reading of 2.1 mm, which was somewhat greater than the values described in the literature, which range from 0.5 to 1.3 mm [135, 138-140]. When compared to results from a cadaveric study using the same navigation system, the difference was greater in this study (2.1 mm versus 0.5 mm) and the correlation was significantly lower

(0.32 versus 0.97) [35]. This may be explained by medialisation of the acetabular cup in this study (Table 3.07 shows a mean reduction in acetabular offset), which would introduce error into the comparison. Furthermore, femoral rotation and inaccuracies related to a divergent x-ray beam are a source of error in measuring femoral offset from plain AP radiographs. The experimental study employed CT imaging in its assessment, which is known to be more accurate [121, 122, 124].

When change in total offset was considered (acetabular plus femoral offset) a good and statistically significant correlation was shown (R=0.47, *P*=0.021). Comparing this correlation and significance to those for when femoral offset alone was used for comparison (R=0.32, *P*=0.123) provided strong support of our hypothesis that the navigation measurement of offset was more closely related to total offset. The correlation found (R=0.47) still did not compare with the results described by Renkawitz *et al* in their cadaver study, and this may once more be explained by differences in measurement technique and the conditions under which the surgeries were performed. A finding that further supports our hypothesis is the comparison of a mean change to acetabular offset of -3.5 mm (Table 3.07) to a mean under-reading when navigation was compared to femoral offset alone of -2.1 mm (Table 3.14), which also points to a summation of offsets. It is then evident that the measurement for offset change provided by the navigation system is more an evaluation of the change to total offset than it is of change to femoral offset alone.

The navigation system used in this study is highly accurate, as has been shown in experimental studies [35]. Leg length measures were shown in this *in vivo* study to show high accuracy, closely followed by good correlation for offset measurements.

4.04 Length of Stay

It is believed that the use of navigation systems will provide better component placement and thus improve patient recovery and reduce post-operative stay [179]. In this study minimal difference was observed between the cohorts (post-operative stay was 1.2 days shorter for the navigated group), which was very close to showing no statistically significant difference (P=0.07). It is important to also consider that the use of an historic control group may have resulted in difference in post-operative protocol that could influence the length of stay.

4.05 Time Considerations

It has been demonstrated in the literature that procedural time is greater with the use of navigation. Increases of 8 to 17 minutes have been reported [46, 169, 170]. The findings of this analysis are similar, demonstrating a mean increase in time of 6 minutes for navigated procedures. For this analysis we accounted for potential confounding caused by differing surgical difficulty between the groups by omitting 3 revision cases and a hip resurfacing from the study group.

4.06 Patient Functional Outcome

This study further supported the well-known success of total hip arthroplasty. Evaluation using the Oxford Hip Score (OHS) showed statistically significant increases from pre-operative results at both the six-weeks and three-months post-operatively (Table 3.18, Figure 3.13). The study provided little support of hypotheses regarding the influence of achieving leg length and offset targets, and

BMI. Low study numbers in this cohort where the Oxford hip scores were available (n=24), is a potential explanation for this lack of conclusive results.

The basis of navigation is that by enhancing component positioning the patient will experience better patient outcomes. One objective of the study was to investigate if improvement in component positioning would translate to better functional outcomes, however no significant correlation was observed between target leg length and offset achievement and hip score improvements.

Whilst the relationships between target achievement and OHS improvements are not statistically significant, the trendlines pointed to an overall enhanced patient outcome with poorer achievement of pre-operative aims (Figures 3.14 - 3.17). This contradictory finding has a simple explanation. Patients that presented with larger pre-operative deformities were both more likely to present with a lower hip score and more likely to have a bigger target change to achieve. As a result, patients in whom targets were easier to fall short of (patients with greater pre-operative deformities) had more scope to improve their Oxford Hip Scores.

The influence of body mass index on the patient outcomes was likewise investigated. It was predicted that overweight and obese patients would experience poorer improvements in outcome measures. The results demonstrated no statistically significant relationship between body mass index and Oxford hip score changes, which is concordant with the findings of Andrew *et al* [175]. Although the correlations discovered were not of statistical significance, there was a clear positive relationship between increasing BMI and

Oxford hip score improvements (Figures 3.19 and 3.20). This result was initially surprising, and contradicted what was expected. Figure 3.18 provides some insight. Patients with a greater BMI presented with a lower pre-operative hip score (Figure 3.18) and, as a result, for these patients there was a greater opportunity for this score to be ameliorated.

It was finally predicted that by improving the femoral to acetabular offset ratio, hip biomechanics would be improved and this would enhance post-operative function and OHS results, as exemplified by the findings of Asayama *et al* [90, 113]. In this study, no significant relationship was shown between improvements to femoral to acetabular offset ratio and change in Oxford hip score, although the trendlines generated in suggest this relationship (Figures 3.21 and 3.22).

4.07 Limitations

This study had several limitations that need to be identified.

Firstly, a greater sample population may have provided more confidence in some of the results. In addition, measurements of leg length and offset were obtained using plain AP pelvic radiographs. Using plain AP pelvic radiographs for linear measurements is a known source of error, caused by divergent x-ray beams, magnification errors, pelvic tilt or rotation, and femoral rotation [122-125, 127, 129]. For the purposes of this study, where CT imaging of total hip arthroplasty patients was not standard of care, obtaining CT images for the purposes of leg length and offset measurements could not be ethically or financially justified.

Furthermore, potential loosening and resultant movement of navigational arrays or reference screws is known to be possible [40, 41], and may have inadvertently occurred and introduced error to the navigation system readings.

All total hip arthroplasty cases performed by the surgeons were navigated from the point of the introduction of navigational tools. As a result, the control group could not be prospectively recruited and Oxford hip scores were not available, which would have been a valuable tool of comparison between the two groups. Furthermore, insight made into changes to length of post-operative stay cannot be conclusive as other factors that surround post-operative care, such as protocol and rehabilitation methods, were likely to be different between the two groups.

In terms of evaluating leg length changes, the mean discrepancy of control patients pre-operatively was close to being larger than the study group at a statistically significant level, which may have introduced bias when evaluating outcomes in terms of post-operative change.

4.08 Scope for Further Research

As previously mentioned, it would be interesting to compare the results of CT-derived measurements of leg length and offset changes with navigational measurements in an *in-vivo* context.

Further opportunity to build on this study would be to compare long-term functional outcomes, dislocations and revision rates between navigated and non-navigated procedures, which wasn’t possible in the given time frame of one year.

CHAPTER 5: Conclusion

The application of surgical navigation in total hip arthroplasty will remain a controversial issue for some time. At the crux of the debate lies the question of whether or not improved component positioning facilitated by navigational systems will correlate to better patient outcomes and prosthetic longevity.

This study comprised of two primary aims, to assess the accuracy f the navigation system and to evaluate if the navigation system influenced the achievement of pre-operative targets for leg length and offset changes. The navigation system was showed high reliability for leg length measurements, and good reliability for measurement of change to total offset. The achievement of leg length targets was no different between the two groups, but the group that used navigation was shown to come closer to achieving offset change targets.

Larger, long-term studies are needed to demonstrate that enhanced accuracy of component positioning does indeed correlate to better functional outcomes and prosthetic longevity.

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Appendix I – Radiographical Assessment

The pre- and post-operative radiographs were assessed using Orthoview, a templating software program (Orthoview LLC, Florida, USA).

Magnification

Due to divergent beams from the x-ray source and variable pelvic positions relative to the plate, it is necessary to correct digital radiographs for magnification if accurate measurements are to be drawn. The pre-operative radiographs were all performed with a 25 mm templating marker ball positioned at the level of the hip joint, and this was used to scale the radiograph. For all post-operative images, the known diameter of the prosthetic femoral head was used to correct for magnification.

Leg Length Discrepancy

Both pre- and post-operatively, Leg Length Discrepancy (LLD) was measured using the difference in the orthogonal distance from the inter-teardrop line to the lesser trochanters on the scaled radiographs (see Figures A1.1 and A1.2). When the acetabular teardrops or lesser trochanters were not clearly identifiable, other bony landmarks on the pelvis and femora were used, such as the ischial tuberosity and greater trochanter respectively. This method and variants are well described in the literature [75, 110, 180].

Femoral Offset

Femoral offset is defined as the perpendicular distance from the anatomical axis of the femur to the centre of the femoral head [81]. This was directly taken from the AP radiograph using the Hip Joint AP/PA Wizard on OrthoView, whereby the operator simply places a circle around the femoral head and positions a maneuverable rectangle over the femoral medulla. (Figures A1.1 and A1.2).

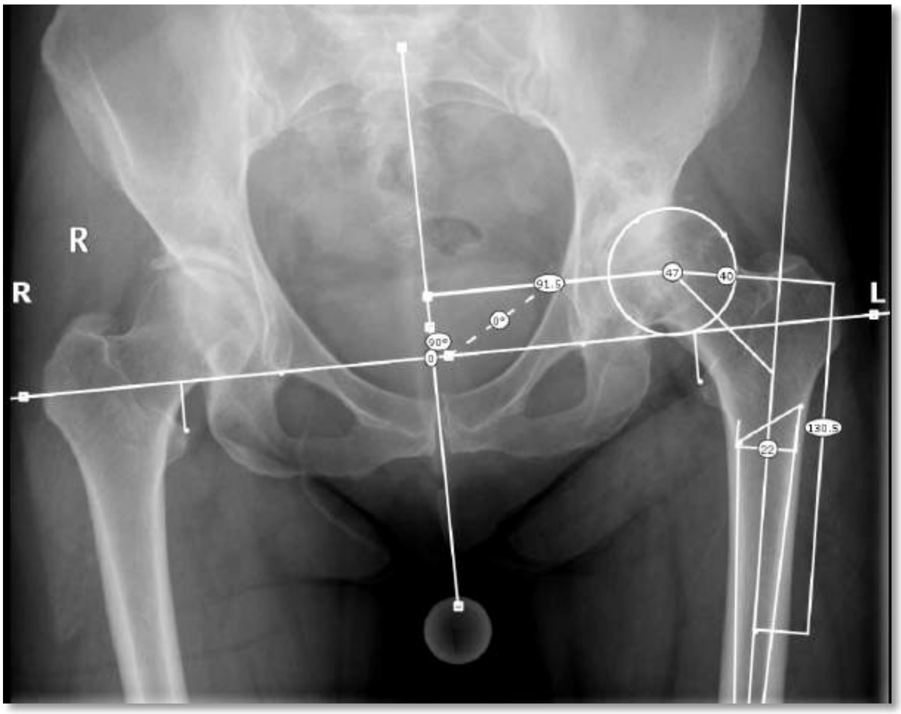

Figure A1.1: OrthoView screenshot of the pre-operative measurements (Femoral Offset; 40, Acetabular Offset; 91.5). Note also the presence of the 25 mm radio-opaque marker ball.

Acetabular Offset

For the purpose of this study acetabular offset was defined as the perpendicular distance from the centre of the femoral head to the midline. This midline was created by drawing a line perpendicular to the trans-teardrop line that also passed through the centre of the pubic symphysis. (Figures A1.1 and A1.2).

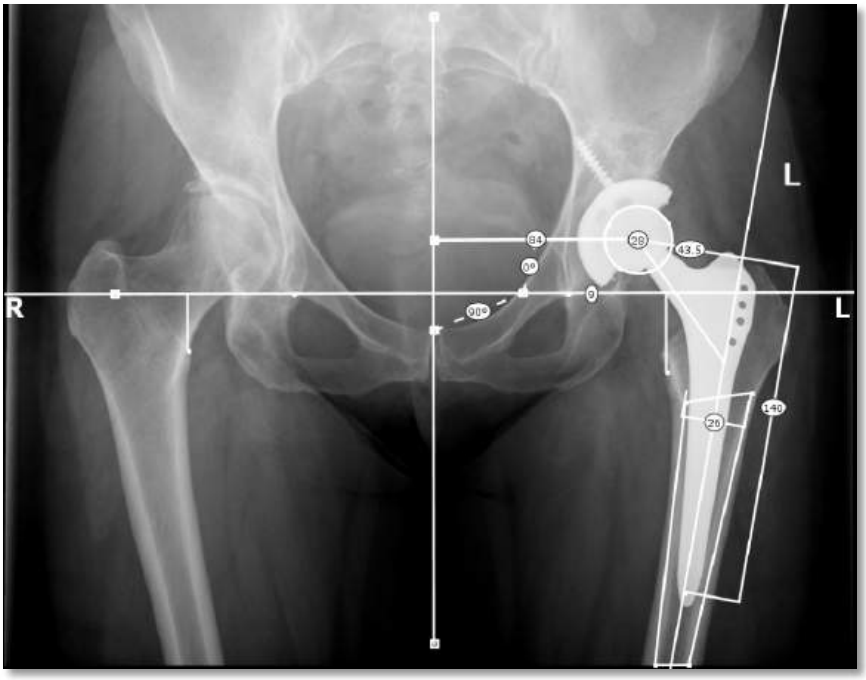

Figure A1.2: On the patient from figure 4, the same measurements are made post-operatively (Femoral offset; 43.5 mm, Acetabular offset; 84 mm, Leg length discrepancy, +9 mm).

Templated Changes to Offset

Prior to the operation the surgeon places a template of the prosthetic components overlaying the scaled digital radiograph. At the Royal Melbourne Hospital, pre-operative surgical planning for hip arthroplasties is carried out using a templating software program called OrthoView. In order to ascertain the desired change in offset the distance between the centre of the native femoral head and the centre of the proposed prosthetic head was measured. This measurement needed to be perpendicular to the anatomical axis of the femur in order to give an accurate reading (see figure A1.3).

Figure A1.3: On another patient the femoral stem is templated. The surgical plan here is to increase femoral offset by 9 mm. The two vertical lines drawn are parallel to the femoral anatomical axis.

Templated Changes to Leg Length

The OrthoView pre-operative templating program provided a measurement of the pre-operative leg length discrepancy, the proposed lengthening or shortening of the leg, and the predicted resultant discrepancy (Figure A1.4). These measurements are performed automatically using the relative positions of the centre of the prosthetic acetabular component and the centre of the prosthetic femoral head, both in their respective proposed implantation locations.

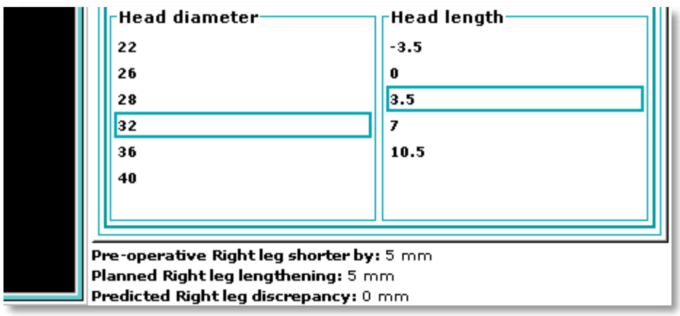

Figure A1.4: A screenshot of the bottom right corner of OrthoView program showing leg length changes.