ACCURACY IN HIP ARTHROPLASTY: 
ASSESSMENT, CONSEQUENCE AND SOLUTION

A dissertation submitted to Imperial College 
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Declaration

I, Kinner Davda, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis
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Abstract

Hip arthroplasty is the most common and successful surgical treatment for the management of hip osteoarthrosis. However, complications arising from technical error in analysing the native hip, as well as the position of the hip prosthesis can result in a suboptimal outcome for the patient.

This thesis principally examines acetabular component orientation, investigating the use of technology in this critical aspect of hip arthroplasty surgery.

In the first study, navigation technology is used to assess the performance of a current cohort of training and senior orthopaedic surgeons in a simulated surgical setting. A wide range of error in orientating an acetabular cup orientation to a target position is demonstrated. The second study seeks to establish a novel method of delineating the femoral neck axis in 3D using a sample of normal hip CT scans. Using such a proximal femoral frame of reference allows a standardised approach to assessing normal and abnormal hip morphology. The articular margin of the femoral head is shown to have a wave like pattern that consists of an anterior and posterior facet. The third study compares 2D and 3D measurements of inclination and version of acetabular components, finding a critical difference between the two in version measurements and that 3D measurements are more reliable. The thesis continues by examining the current methodology of analysing the concentration of cobalt and chromium metal ions in the joint fluid from a cohort of symptomatic patients with a metal on metal hip arthroplasty. A more robust laboratory method of processing fluid samples using a digestive oxidative method is presented. The relationship between concentrations of metal ion levels in joint fluid and several clinical parameters is investigated with no clear association shown, suggesting joint fluid in itself cannot be used as a marker for a failing metal on metal hip. The thesis concludes by comparing navigation technology to conventional ‘freehand’ method in orientating an acetabular component in a group of patients undergoing metal on metal hip resurfacing. The results suggest that navigation technology may substantially improve surgeon error in this task.

Technology and three dimensional imaging can play a vital role in improving the accuracy of orientating an acetabular component in hip surgery. It can be employed in the pre-operative stages to assess trainee performance, intra-operatively to reduce surgical error and post-operatively to investigate surgeon accuracy on CT imaging.
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I am especially thankful to my family. My wife, Sonal, has encouraged and supported my endeavours often facing weekends and evenings alone with a husband buried in amongst journals or learning the finer points of SPSS statistical software. My children, Shriya, and Rohan, were born as the data collection of this thesis was completed. I hope in years to come that when they reach up to a book shelf for a dusty copy of this thesis, that they are pleasantly surprised that their father was able to do more than fix and replace bones.

I would also like to thank the following people, without whom this work would not have been possible. I am indebted to you for your help and kindness:

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This thesis is dedicated to my wife, Sonal (forever 21), and children Shriya (3 ½ years) and Rohan (2 years)
Contents

List of Figures 8
List of Tables 12
List of Abbreviations 14

Chapter 1  Introduction 15
  1.1  Epidemiology of Hip Arthroplasty 15
  1.2  Femoro-Acetabular Impingement 15
  1.3  Overview of Hip Arthroplasty Types 17
  1.4  Definition of a Frame of Reference 21
  1.5  The Safe Zone 22
  1.6  Complications of Total Hip Arthroplasty 23
  1.7  Metal on Metal Hip Resurfacing 24
  1.8  Achieving acetabular cup orientation 29
  1.9  Thesis Aims 36

Chapter 2  Assessing Surgeon Error in Cup Orientation 37
  2.1  Abstract 37
  2.2  Introduction 38
  2.3  Method 39
  2.4  Results 44
  2.5  Discussion 48

Chapter 3  The 3D Femoral Neck Axis and Morphometric Analysis of the Head Neck Junction in the Normal Hip 53
  3.1  Abstract 53
  3.2  Introduction 54
  3.3  Method 55
<table>
<thead>
<tr>
<th>Chapter</th>
<th>Title</th>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.4</td>
<td>Results</td>
<td></td>
<td>60</td>
</tr>
<tr>
<td>3.5</td>
<td>Discussion</td>
<td></td>
<td>63</td>
</tr>
<tr>
<td><strong>Chapter 4</strong></td>
<td>Comparing the Difference between 2D and 3D Measurements of Cup Orientation in Metal on Metal Hip Arthroplasty</td>
<td>4.1 Abstract</td>
<td>66</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.2 Introduction</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.3 Method</td>
<td>67</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.4 Results</td>
<td>68</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.5 Discussion</td>
<td>73</td>
</tr>
<tr>
<td><strong>Chapter 5</strong></td>
<td>An Analysis of Metal Ion Levels in the Joint Fluid of Symptomatic Patients with Metal on Metal Hip Arthroplasty</td>
<td>5.1 Abstract</td>
<td>84</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.2 Introduction</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.3 Method</td>
<td>85</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.4 Results</td>
<td>86</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.5 Discussion</td>
<td>88</td>
</tr>
<tr>
<td><strong>Chapter 6</strong></td>
<td>The Accuracy of CT Based Navigation Versus Freehand Hip Resurfacing: An Analysis of Acetabular Component Orientation</td>
<td>6.1 Abstract</td>
<td>103</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.2 Introduction</td>
<td>104</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.3 Method</td>
<td>105</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.4 Results</td>
<td>109</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.5 Discussion</td>
<td>112</td>
</tr>
<tr>
<td><strong>Chapter 7</strong></td>
<td>Discussion</td>
<td>7.1 General Discussion</td>
<td>116</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7.2 Thesis Limitations</td>
<td>118</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7.3 Personal Perspective</td>
<td>120</td>
</tr>
<tr>
<td>Section</td>
<td>Page</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publications Of Work From This Thesis</td>
<td>123</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presentations Of Work From This Thesis</td>
<td>124</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posters of Work From This Thesis</td>
<td>125</td>
<td></td>
<td></td>
</tr>
<tr>
<td>References</td>
<td>126</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.1.</td>
<td>Schematic representation of cam FAI. In cam FAI ........................................... 16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.2.</td>
<td>A plain radiograph of a cam hip, ....................................................................... 16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.3.</td>
<td>Schematic representation of pincer FAI ........................................................... 17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.4.</td>
<td>Typical radiographic appearance of a pincer hip .............................................. 17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.5.</td>
<td>Pelvic radiograph of an uncemented left total hip arthroplasty, with metal on polyethylene articulation (Implanted by author) ................................................ 18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.6.</td>
<td>Pelvic radiograph showing a left hip resurfacing .............................................. 18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.7.</td>
<td>The differing definitions of inclination ............................................................. 19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.8.</td>
<td>The different definitions of version ................................................................... 20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.9.</td>
<td>A frame of reference consists of an origin, O, and three orthogonal axes (x,y,z) ................................................................. 21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.10.</td>
<td>The anterior pelvic plane ................................................................................... 22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.11.</td>
<td>Illustration of the functional articular arc of an acetabular cup. ....................... 27</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.12.</td>
<td>Head size versus functional articular arc (degrees) for differing manufacturers. ................................................................................................................................. 28</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.13.</td>
<td>Illustration of the ‘Hipsextant’ mechanical guide for acetabular orientation ................................................................................................................................. 31</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.14.</td>
<td>Illustration of the steps in ‘segmentation’ of a CT scan to produce a three dimension pelvic bone model ........................................................................................................... 32</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.15.</td>
<td>Illustration of an optical tracking computer navigation system. ....................... 33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 1.16.</td>
<td>Illustration of a spatial linkage computer navigation system. ......................... 34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 2.1.</td>
<td>Dry bone pelvis (without surgical draping) orientated to the neutral pelvic tilt – Pelvis A. .................................................................................................................. 40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 2.2.</td>
<td>Synthetic dry bone ‘osteoarthritic’acetabulum implanted in both Pelvis B and C. ................................................................................................................................. 40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 2.3.</td>
<td>Surgical simulation of a posterior approach to the hip joint. ............................. 41</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 2.4. A 3D virtual plan with an acetabular component orientated to the target position of 40° inclination and 20° version. ................................................................. 42

Figure 2.5. Photo demonstrating the set up for Pelvis C, including the screen shot that is available to the assessor. .................................................................................. 43

Figure 2.6. Box and whiskers plots demonstrating the cup inclination achieved by senior and trainee orthopaedic surgeons across the three pelvic stations. ............. 45

Figure 2.7. Box and whiskers plots demonstrating the cup version achieved by senior and trainee orthopaedic surgeons across the three pelvic stations. ............... 46

Figure 2.8. Pelvis A. Scatter graph plotting inclination error (x axis) against version error (y axis). ........................................................................................................ 46

Figure 2.9. Pelvis B. Scatter graph plotting inclination error (x axis) against version error (y axis). ........................................................................................................ 47

Figure 2.10. Pelvis C. Scatter graph plotting inclination error against version error .......... 47

Figure 3.1. Diagram showing the construction of the alpha angle in the normal hip. ...... 54

Figure 3.2. Diagram showing the construction of the alpha angle in the cam hip. .......... 55

Figure 3.3. Illustration of the method used to determine the femoral neck axis. ............. 57

Figure 3.4. Best fit spheres applied to the femoral head, lesser trochanter and piriform fossa.................................................................................................................. 58

Figure 3.5. Illustration of the local coordinate system used to orientate the proximal femur. ................................................................................................................. 58

Figure 3.6. a Orientation of the proximal femur used to conduct morphometry analysis. b Schematic of femoral head showing clock face values.............. 59

Figure 3.7. Diagram representing the head neck offset. ................................................ 60

Figure 3.8. The articular margin between the femoral head and neck is marked from anterior to posterior. ............................................................................................. 60

Figure 3.9. Scatter plot illustrating the x and y distance between the head centre and neck axis for each hip analysed. ................................................................. 61

Figure 4.1. Screen shot illustrating the EBRA analysis of a left MoM hip. ............. 69

Figure 4.2. Illustration of the Imperial hip CT scanning protocol............................. 70

Figure 4.3. Screen shot of 3D-CT analysis of an acetabular component in the coronal view. .............................................................................................................. 71
Figure 4.4. Screen shot of 3D-CT analysis of an acetabular component in the axial view..................................................................................................................71

Figure 4.5. Simultaneous coronal, sagittal and axial views of an acetabular component ........................................................................................................72

Figure 4.6. Bland Altman plots of agreement between EBRA and 3D-CT version with the pelvis in the supine position.................................................................74

Figure 4.7. Bland Altman plots of agreement between EBRA and 3D-CT version with the pelvis in the APP position .......................................................................74

Figure 4.8. Bland Altman plots of agreement between EBRA and 3D-CT inclination with the pelvis in the supine position.................................................................75

Figure 4.9. Bland Altman plots of agreement between EBRA and 3D-CT version with the pelvis in the APP position ........................................................................75

Figure 4.10 Bland Altman plots of agreement in version between 3D CT in the APP and supine pelvic position................................................................................76

Figure 4.11 Bland Altman plots of agreement in inclination between 3D CT in the APP and supine pelvic position ........................................................................76

Figure 4.12 Scatter graph of cup inclination (x axis) against cup version (y axis) measured using 3D-CT with the pelvis in the supine position..............................77

Figure 5.1. Bland Altman analysis of agreement of Chromium (Cr) ion levels in digested versus undigested joint fluid.................................................................90

Figure 5.2. Bland Altman analysis of agreement of Cobalt (Co) ion levels in digested versus undigested joint fluid .................................................................90

Figure 5.3. Box and whiskers plots demonstrating the Cr and Co joint fluid levels (Log 10 values) in 64 patients categorised according to failure. .......................91

Figure 5.4. The Cr and Co joint fluid levels categorised according to manufacturer of MoM prosthesis .........................................................................................92

Figure 5.5. Box and whiskers plots demonstrating the Cr and Co joint fluid levels categorised according to femoral head size .................................................93

Figure 5.6. Scatter plot of 3D CT acetabular inclination versus Cr levels .................................................................................................................................94

Figure 5.7. Scatter plot of 3D CT acetabular inclination versus Co levels .................................................................................................................................94

Figure 5.8. Scatter plot of Cr ion levels in the whole blood and joint fluid of 30 paired samples ..............................................................................................95

Figure 5.9. Scatter plot of Co ion levels in the whole blood and joint fluid of 30 paired samples ..............................................................................................96
Figure 6.1. Illustration of key steps involved in planning and executed a navigated hip resurfacing case. .......................................................... 108

Figure 6.2. Scatter graph demonstrating the number of hips falling within 5° and 10° of the planned cup orientation. .................................................. 112
List of Tables

Table 2.1. Summary of the year of training and number of hip arthroplasty procedures performed by the trainees surgeon group ............................................. 43

Table 2.2. The study group stratified by levels of experience in number of hip arthroplasty procedures performed ............................................................ 44

Table 2.3. Descriptive statistics summarising error in performance in inclination and version across all three stations ......................................................... 45

Table 2.4. The number of trainees and consultants able to orientate the acetabular component to the desired safe zone in each task ........................................ 45

Table 2.5. Differing types of validity required in surgical simulation .................. 51

Table 3.1. Results table summarising the distance of the femoral head centre from the neck axis .................................................................................................. 61

Table 3.2. Results table showing the articular margin angle for each hip measured .... 62

Table 3.3. Suggested mean and upper limit of the reference interval values for the alpha angle in the current literature, from studies of asymptomatic individuals, with a lateral (or equivalent) radiological projection .................. 64

Table 4.1. Safe zone analysis of cups measured using EBRA and 3D-CT .................. 77

Table 4.2. Intra observer reliability for cup orientation measurements using EBRA and 3D CT ................................................................................................. 79

Table 4.3. Inter observer reliability for cup orientation measurements using EBRA and 3D CT ................................................................................................. 79

Table 5.1. Table of descriptive statistics comparing chromium and cobalt levels against several clinical variables ................................................................. 89

Table 5.2. Comparison of the median (range) metal ion concentrations between the current study and those previous ................................................................. 98

Table 6.1. Patient demographics of the freehand navigated hip resurfacing group .... 110

Table 6.2. The inter and intra observer reliability of cup orientation measurements using 3D CT on thirty randomly selected hips ........................................... 110

Table 6.3. Summary of the planned and achieved cup orientation in the freehand and navigated hip resurfacing group .............................................................. 110
Table 6.4. The error in inclination and version between the freehand and navigated hip resurfacing group; the number of hips falling within a 5 and 10 degrees of the surgical plan.
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>2D</td>
<td>Two dimensional</td>
</tr>
<tr>
<td>3D</td>
<td>Three dimensional</td>
</tr>
<tr>
<td>AMA</td>
<td>Articular margin angle</td>
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<tr>
<td>ANOVA</td>
<td>Analysis of Variance</td>
</tr>
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<td>AP</td>
<td>Antero-posterior</td>
</tr>
<tr>
<td>APP</td>
<td>Anterior Pelvic Plane</td>
</tr>
<tr>
<td>ASIS</td>
<td>Anterior Superior Iliac Spine</td>
</tr>
<tr>
<td>CAAA</td>
<td>Cup articular arc angle</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>Co</td>
<td>Cobalt</td>
</tr>
<tr>
<td>CoC</td>
<td>Ceramic on Ceramic</td>
</tr>
<tr>
<td>Cr</td>
<td>Chromium</td>
</tr>
<tr>
<td>CT</td>
<td>Computed Tomography</td>
</tr>
<tr>
<td>FAI</td>
<td>Femoro-Acetabular Impingement</td>
</tr>
<tr>
<td>FoR</td>
<td>Frame of Reference</td>
</tr>
<tr>
<td>HA</td>
<td>Hip Arthroplasty</td>
</tr>
<tr>
<td>Inc</td>
<td>Inclination</td>
</tr>
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<td>ICC</td>
<td>Intraclass Coefficient</td>
</tr>
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<td>MHRA</td>
<td>Medicines and Health Regulatory Authority</td>
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<td>MoM</td>
<td>Metal on Metal</td>
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<td>MoP</td>
<td>Metal on Polyethylene</td>
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<td>Mo</td>
<td>Molybedanum</td>
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<td>Min</td>
<td>Minimum</td>
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<td>Max</td>
<td>Maximum</td>
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<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>QUALYS</td>
<td>Quality of Adjusted Life Years</td>
</tr>
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<td>SD</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>THA</td>
<td>Total hip Arthroplasty</td>
</tr>
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<td>THR</td>
<td>Total Hip Replacement</td>
</tr>
</tbody>
</table>
CHAPTER 1

Introduction

1.1 Epidemiology of Hip Arthroplasty

Hip arthroplasty is the most common and successful elective surgical treatment for the management of hip osteoarthrosis. It relieves pain, restores function and mobility as measured by validated health related outcome tools [1]. In the UK approximately 70,000 total hip arthroplasty procedures are performed per year in the NHS [2], whilst the annual figure in the USA is 300,000 [3]. Demand in the USA alone will rise to 570,000 primary and 97,000 revision THA procedures by 2030 [4].

The increase in hip arthroplasty procedures performed, not only reflects the growth of the population as a whole, but also that indications have evolved. Total hip arthroplasty was initially restricted to either elderly or infirm patients, or individuals with locomotor limitations associated with other comorbidities, such as rheumatoid arthritis. However, today an acceptable compromise in the quality of life constitutes a valid indication for hip arthroplasty, with patients seeking high performance hips, not only to be pain free, but to deliver their expectations and aspirations [5-7]. Over the last two decades, new bearing couples and resurfacing implants have been introduced to meet the requirements of a younger more active arthritic population. These have demanded a greater level of technical proficiency and accuracy from the surgeons who implant them. Furthermore, an improved understanding of the shape and morphometry of the hip joint that contributes to degenerative joint disease has been gained, enabling the surgeon to refine the surgical strategy used to treat this condition.

1.2 Femoro-Acetabular Impingement

Now recognised as a cause of osteoarthrosis, impingement refers to the patho-mechanical process whereby the femoral head and/or neck abuts against the acetabular rim, from reduced joint clearance. The joint clearance is influenced by the head neck ratio and the excursion curve of the femoral neck before contact with the acetabular rim. Two patterns of hip
morphology are now recognised that lead to repetitive femoral acetabular impingement (FAI), a term popularized by Ganz et al [8]. Commonly occurring in males, the ‘cam’ hip is typified by an aspherical femoral head, characterised by an osseous bump present at the anterior femoral head neck junction, hence decreasing the head neck offset [9]. In hip flexion, adduction and internal rotation the anterior neck abuts against the antero-superior acetabular rim leading to labral damage (Figure 1.1 and Figure 1.2), increased shear forces on articular cartilage and early osteoarthritic wear [8]. The second pattern, ‘profunda’ is seen more commonly in females. Here the acetabular rim is functionally excessive causing a pincer FAI (Figure 1.3 and Figure 1.4). The hip levers against the anterior rim causing labral damage anteriorly, and subsequent ‘contre-coup’ wear in the posteroinferior acetabulum [10]. As our understanding of these pathomechanical processes has evolved, early modes of surgical intervention and patient specific treatments have been developed.

**Figure 1.1.** Schematic representation of cam FAI. In cam FAI, there is repetitive abutment of the anterior femoral head neck against the acetabular rim (shown by the red margin), leading to antero-superior wear. (Figure 1.1 and Figure 1.3 reproduced with permission from Lavigne et al [10]).

**Figure 1.2.** A plain radiograph of a cam hip, demonstrating the loss of femoral neck offset and the presence anterior osseous neck bump shown by the white arrow.
Figure 1.3. Schematic representation of pincer FAI. Persistent anterior abutment with chronic leverage of the head in the acetabulum results in chondral injury in the ‘contre-coup’ region of the posterior – inferior acetabulum.

Figure 1.4. Typical radiographic appearance of a pincer hip. The femoral head protrudes beyond the ilio-schial line and is seated deeply within the acetabulum.

1.3 Overview of Hip Arthroplasty Types

Hip arthroplasty can be broadly categorised according to the bearing surface used as the articulation between prosthetic femoral head and acetabular cup. The most common types are metal on polyethylene (MoP, Figure 1.5), ceramic on ceramic (CoC) and metal on metal (MoM). For MoM hips, the femoral component can be either modular using a large diameter head (> 36mm) head on a traditional femoral steam or a resurfacing, whereby the femoral head can be capped rather than removed (Figure 1.6). In both situations the acetabular component is uncemented, with the back surface coated with hydroxyapatite to integrate with the host bone. The acetabular and femoral orientation is critical to the function and stability of the bearing surface.
Figure 1.5. Pelvic radiograph of an uncemented left total hip arthroplasty, with metal on polyethylene articulation (Implanted by author).

Figure 1.6. Pelvic radiograph showing a left hip resurfacing composed of a metal on metal bearing couple (Implanted by the author).

The orientation of the acetabular component is described by its two constituents: ‘inclination’ and ‘version’. In 1993, Murray [11] demonstrated that each could be assessed anatomically, radiographically and by direct observation at operation.

The definitions are as follows:

1.3.1 The Definitions of Inclination

Anatomic

- The angle between the plane of the face of the acetabulum and the transverse plane, which is equivalent to the angle between the acetabular axis and the longitudinal axis.
Radiographic

- The angle between the face of the cup and the transverse axis, that is the angle between the longitudinal axis and the acetabular axis when projected on to the coronal plane.

Operative

- The angle between the acetabular axis and the saggital plane. It is the angle of abduction of the acetabular axis.

These definitions are shown in Figure 1.7 below.

Figure 1.7. The differing definitions of inclination (Figure reproduced with permission from Murray et al [11]).

1.3.2 The Definitions of Version

Anatomic

- The angle between the transverse axis and the acetabular axis when this is projected on to the transverse plan

Radiographic

- The angle between the acetabular axis and the coronal plane
Operative

- The angle between longitudinal axis of the patient and the acetabular axis as projected onto the sagittal plane.

The differing definitions of version are illustrated in Figure 1.8 below.

**Figure 1.8.** The different definitions of version (Figure reproduced with permission from Murray et al [11]).

Murray et al produced comprehensive trigonometric equations and nomograms that allowed for conversion of one orientation value to another. To the present time, these definitions remain the standard for quantifying and reporting acetabular cup orientation.
1.4  **Definition of a Frame of Reference**

A frame of reference (FoR) consists of an origin and three orthogonal axes. It is based on a coordinate system with which the position, orientation and movement of any object can be defined and standardised (Figure 1.9). Two frames of reference are commonly employed in the literature when describing cup orientation: ground based and pelvic.

![Figure 1.9. A frame of reference consists of an origin, O, and three orthogonal axes (x,y,z)](image)

The body orientation is often used to define a ground based axis system, namely the superoinferior, anteroposterior, and mediolateral axes. However, the pelvic orientation is not fixed because of variations in lumbar lordosis [12] and pelvic tilt. As cup orientation relative to the floor changes with pelvic position, plain radiographic measurements will be inconsistent due to inter and intra-patient variability.

First described by Cunningham in 1918 [13], the anterior pelvic plane (APP) is delineated by the two anterior superior iliac spines (ASIS) and pubic tubercles, and serves as the most commonly used anatomic pelvic FoR. The plane defines the pelvic position in the erect human. The concept has gained popularity as a means of standardising the pelvic position for the purposes of radiographic analysis. In 1998, Jaramaz and DiGioia first introduced the concept for computer assisted cup insertion [14-16] and thus it remains today as the frame of reference in most hip navigation systems.
Figure 1.10. The anterior pelvic plane as demonstrated by the blue rectangle between the two ASISs and pubic tubercles. (Image reproduced from Google Images – copyright free)

1.5 The Safe Zone

In a seminal paper during the late 1970’s, Lewinnek et al [17] introduced the notion of the ‘safe zone’. The acetabular cup orientation was measured radiographically in a series 122 patients, in whom nine hips had dislocated. In all cases, the pelvic position was standardised at the time of xray with the use of a handheld spirit level placed on the ASISs and symphysis pubis, that is the anterior pelvic plane. Cup inclination and version were measured from the ellipse of a circular marker wire found along the cup rim, and plotted on a scatter graph. Lewinnek demonstrated that the dislocation rate was three times higher when the cups were placed outside of a ten degree zone of 40° inclination and 15° anteversion. The study clearly showed for the first time, that the position of the acetabular component relative to the body axis was associated with the risk of dislocation. In doing so, Lewinnek created not only a target zone for cup orientation that remains common in orthopaedic practice to this day, but demonstrated the need for a surgeon to critically analyse postoperative radiographs for technical error.

Numerous studies have shown that the task of achieving optimal cup orientation within the safe zone is challenging [18-21]. High angles of inclination are linked to higher rates of dislocation [22], wear through edge loading, and instability. Highly anteverted cups correlate
with an increased incidence of anterior dislocation and conversely, posterior dislocation in retroverted cups [23, 24].

Impingement is also associated with cup malorientation, and may result not only in dislocation but unexplained pain from periprosthetic soft tissue inflammation [25] and liner damage [26, 27]. Retrieval studies have shown impingement to be contributory to both linear [22] and volumetric wear, with resulting osteolysis and component loosening [28-30].

1.6 Complications of Total Hip Arthroplasty

Total hip arthroplasty gained popularity during the 1960s, as Sir John Charnley introduced the use of polymethylmethacrylate to secure the acetabular and femoral component to bone. The cup was made of polyethylene and the femoral component composed of a monoblock stem with a 22.25mm diameter head. The enduring success of this MoP bearing is evident today as being the most commonly used in the UK [2]. Total hip replacement is a highly successful treatment for advanced osteoarthritis in terms of pain relief, quality of life scores and cost effectiveness [31-35]. The benefits have been shown over thirty years following the index procedure in the Swedish Joint Registry [36]. However, the commonest cause of failure in this bearing couple is loosening caused by macrophagial phagocytosis of polyethylene wear particles [37]. This induces an osteolytic reaction involving several inflammatory mediators [38]. This proves problematic in the young arthritic population who wish to maintain a high level of function following THR. Reports in the early 1990s demonstrated an unacceptably high failure rate in patients aged 40 years at the time of surgery [39, 40].

1.6.1 Dislocation

Dislocation is a significant and one of the most common complications in THR, with rates varying between 0.5 and 5% [41-43], with up to 50% occurring within the first three months [41, 44]. In a recent study of over 50,000 revision THA procedures, the most common indication for surgery was dislocation (22.5%), with the average cost per case in excess of $54,000 [45]. Each closed reduction represents 20% of the cost of a primary THR, while revision surgery to obtain hip stability can cost an additional 150% [46]. Impingement between the prosthetic cup rim and femoral neck is an important mechanism in causing dislocation. While bone to bone impingement is addressed by the offset of the prosthesis, component to component impingement is highly dependent on design parameters and
component orientation. The risk of dislocation and impingement is thus multifactorial and related to patient, surgeon and device.

1.6.2 Patient Related Factors

Neuromuscular disorders and cognitive impairment were shown to be present in 22% of patients with a single dislocation and 75% in those with a recurrent episode [47]. The underlying indication for hip arthroplasty may also affect the risk of dislocation, with increased rates seen in neck of femur fracture [48], which may lack the stabilizing effect of capsular fibrosis and hypertrophy found in osteoarthritic hips.

1.6.3 Surgical Factors

Several elements of surgical technique may influence the occurrence of dislocation. These include the surgical approach and soft tissue tension. Several studies have demonstrated a higher incidence of dislocation with a posterolateral approach as compared with the anterolateral or transtrochanteric approach [41, 49, 50]. These findings have been further supported in a meta analysis of over 13,000 patients, where the dislocation rate was found to be 3.23% when utilising a posterior approach, but only 0.55% after a direct lateral approach [51].

1.6.4 Device Related Factors

The choice of design and positioning of implants are critical in mitigating the risk of dislocation and impingement. The variable factors in femoral prosthesis design are head size, modular head design, offset, neck geometry and neck version. With regard to the acetabulum, several features can affect the stability and range of motion: location of the bore [52], an acetabular liner larger than a hemisphere [53] and a bevelled liner edge [54, 55]. While designs have evolved, it is the orientation of the cup that significantly determines hip stability and is under the immediate control of the surgeon.

1.7 Metal on Metal Hip Resurfacing

Hip resurfacing arthroplasty evolved from the mould arthroplasty of Smith Petersen during the 1970’s and had been performed with a variety of materials, designs and fixation methods [56-59]. This was initially viewed as a technical advance in the treatment of early arthritis in the young and active patient [60], until it became clear that there was an unacceptably high
failure rate. The thin polyethylene liner and large diameter head used, resulted in high frictional torque producing catastrophic wear, osteolysis and implant loosening. Early and mid-term failure rates of up 33% were reported [58, 61-64]. The lack of standardisation in patient selection, operative approach and surgical technique, led to the first generation resurfacing prostheses being abandoned.

It was in the early 1950s that McKee and Watson-Farrar [65] utilised a MoM bearing couple with a modified Thompson THR stem; this was proceeded by Ring in the 1960s with a similar concept [66]. It was not until the late 1990s, did the concept of hip resurfacing using a MoM articulation as an alternative to MoP re-emerge, with improved bearing tribology and wear resistance.

There are many suggested advantages of hip resurfacing arthroplasty. MoM articulations are associated with low wear rates, which unlike traditional MoP, improves as femoral head size increases. Further advantages include bone conservation [67], restoration of native hip biomechanics [68, 69], normal femoral loading and reduced stress shielding [70] as well as lower dislocation rates [71, 72]. Thus, hip resurfacing was popularised as a viable alternative to THR particularly in the young active patient. Pailhe et al recently conducted a meta analysis of HRA literature between 2005 and 2012 [73], examining 26,456 resurfacings spanning three randomised studies and eight cohort studies. The average survival rate of HRA at 5 years was 94.84% (range 89.1-100%), with a mean postoperative functional score of 91.2 (range 68.3-98.6, 100 representing excellent function). The revision rate was 4.4%, mainly attributed to aspetic loosening and femoral fracture.

After initial popularity in the later 1990s and early 2000’s, numerous issues over the MoM bearing have come to light. Concerns were initially directed at the tribology of the bearing couple, position of the femoral prosthesis, and latterly at the orientation of the acetabular cup

1.7.1 The Bearing Couple and Generation of Metal Ions

Current Metal on Metal (MoM) bearing surfaces are manufactured from a high carbon (0.20% to 0.25%) cobalt (Co)-chromium (Cr)-molybdenum (Mo) alloy. The ratio of Co to Cr is approximately 2 to 1 and makes up 80% of the alloy content. These trace metals are naturally acquired in the diet, required for normal physiology and excreted in the urine.
Deposition of cobalt–chrome wear particles within the peri-prosthetic tissue induces a spectrum of inflammatory and necrotic change [74]. These have been described with various qualitative terms including metallosis [75], pseudotumour [76], aspetic lymphocytic vasculitis associated lesions (ALVAL) [77] and adverse reaction to metal debris (ARMD) [78]. It has been suggested that these abnormal soft tissue reactions may be attributed to wear related cellular cytotoxicity and hypersensitivity [79].

All MoM bearings demonstrate a period of run in wear during a bedding phase within the first 6-12 months. The concentration of metal ions in blood increases and remains elevated throughout the period the implant remains in situ. Levels appear grossly raised when the implant loosens and measuring these levels now forms the basis of monitoring the function of the MoM bearing. Systemic exposure to Co and Cr has been associated with DNA change and genotoxicity, as well as reduction of circulating T and B lymphocytes [80, 81].

1.7.2 Femoral Component Failure

In a meta analysis of 53 HRA studies of 26, 456 patients, Pailhe et al illustrated that femoral neck fracture was amongst the common complication occurring in 26% of patients [73]. The rate of fracture in women is twice that of men and maybe related to the reduced bone quality and relative osteoporosity that occurs post menopause. Technique associated factors include notching of the superior femoral neck and varus placement relative to the anatomical neck. This is consistent with the biomechanical principles suggested by Freeman et al [82] as early as in 1978. The compressive strength of the femoral head depends upon the medial trabecular system which runs through the head at approximately 20 degrees to the vertical i.e. the plane of the resultant of the major loads borne by the hip. A varus component position results in increased tensile forces in the superior –lateral portion of the neck, shear stresses at the head neck junction and increased compressive forces. Thus it has been recommended that the femoral peg be placed in 5-10° of relative valgus to the neck shaft angle. Achieving this level of accuracy appears problematic using conventional jigs [83, 84], with a significant learning curve required even among expert hip surgeons.

1.7.3 Acetabular Component Orientation and MoM Failure

High inclination angles result in edge loading of the acetabular component, thought to cause a failure of fluid film lubrication and strongly implicated in accelerating wear particle generation [85]. Metal particles are smaller and appear to be released two orders of
magnitude higher than that of conventional MoP bearings. The wear debris appears to invoke an intracellular corrosion reaction resulting in the release cobalt, causing cell death. Following phagocytosis of metal particles, osteoblastic activity is impaired and may contribute to aspetic loosening [86], associated with increased rates of revision among MoM patients [87-89].

The effect of version on wear and failure is more difficult to study, in part as it more difficult to measure [88]. Radiographic analysis suggests that periprosthetic soft tissue is associated with higher anteversion angles [78], and that this may differ according to the specific designs [90]. The association between increased version angles and wear, and blood metal ions, has not been confirmed however, when cup orientation has been measured using 3D-CT [91, 92].

The optimal position of the acetabular component in resurfacing has been suggested to be approximately 45° inclination and 20° anteversion [93, 94]. When the cup has been placed within 10° of this orientation, a fourfold reduction in the incidence of pseudotumours has been reported [93].

De Haan et al showed elevated metal ion release correlates with the effective coverage of the head in the metal shell or the cup’s functional articular arc [87]. The cup articular arc angle (CAAA) is a function of the component design, component size, and the inclination angle of the cup (Figure 1.11). The authors noted that surgeons need to be aware of the functional arcs of the acetabular components they implant.

![Figure 1.11. Illustration of the functional articular arc of an acetabular cup. The functional articular arc ‘a’ is a function of the radius ‘r’ and depth of the cup ‘d’. When implanted, the amount of coverage laterally over the head is therefore a function of the inclination angle the cup is implanted in and the articular surface. (Reproduced with permission from De Haan et al[87] )](image)
Griffin et al calculated the CAAA of 33 differing metal shells using the measurements of cup depth and internal cup radius.[95] The arc of the articular surface varied widely among manufacturers, generally decreasing shell diameter (Figure 1.12). The mean articular arc angle was 160.5° (range 151.8° - 165.8°) which is less than the 180° angle of conventional acetabular component designs. In general, the Conserve cup (Wright Medical, Arlington, Tennesse,) had the largest functional arcs, whereas the Birmingham Hip Resurfacing (BHR; Smith and Nephew, Warwick, United Kingdom) had the smallest across the range of cup sizes. Of all the cups measured, the 44mm Articular Surface Replacement (ASR; Depuy, Leeds, United Kingdom) had the smallest functional arc.

![Figure 1.12. Head size versus functional articular arc (degrees) for differing manufacturers. (Reproduced with permission from Griffin et al [95].)](image)

In a single centre study of 660 MoM resurfacings, Langton et al [78] reported failures from adverse reaction to metal debris in patients with an ASR hips, but none in those with a BHR. The authors suggested the increased metal debris resulted from the reduced CAAA of the ASR compared to the BHR. As previously noted, the amount of functional arc available is in
part a function of the inclination angle the acetabular component is implanted at. For example, a cup with a CAAA of 151° implanted at 55° inclination will behave like a 180° cup implanted at 70°. Surgeons should thus be aware of these subtle design features that can compromise the outcome of surgery and lead to premature bearing failure. The traditionally accepted 45° angle of cup implantation in non hemispheric metal cups leaves little room for error, demanding a greater level of surgical accuracy from the operator.

As a consequence of the high failure rates and suboptimal functional results of MoM hips, the UK Medicine and Health Regulatory Authority (MHRA) now recommends that all MoM hips undergo annual surveillance by the surgeon who carried out the procedure [96]. In symptomatic cases, patients undergo blood tests for Cr and Co levels, and if necessary imaging for periprosthetic soft tissue reaction [96]. Similarly, the US Food and Drug Administration (FDA) issued a public health communication and ordered manufacturers to conduct post market surveillance on total MoM hip replacement devices to monitor adverse events. The US economic burden for revision hip surgery is projected to be $4 billion by 2015 [97] whilst it is estimated that $17 billion will be spent on primary hip arthroplasty. These costs reflect the demand for primary hip procedures, which is set to grow by 174% by 2030, with a doubling of hip revision procedures by 2026 [98]. The impact on the health economy is significant with the cost of revision surgery ranging from £12,000 to £22,000 [99]. The cost of revising a MoM hip specifically is unclear with no study in the literature at the present time.

1.8 Achieving acetabular cup orientation
Attaining correct orientation using external alignment guides or freehand methods is inconsistent and inaccurate [16, 100-103]. Several techniques have evolved to minimise surgeon error in this task, including the use of anatomic landmarks, improved mechanical jigs and computer technology.

1.8.1 Anatomic Landmarks
Bony, soft tissue or a combination of both, have been described to guide acetabular component placement. McCollum and Gray [12] described an intra-operative method of orientating the cup perpendicular to a line drawn from the sciatic notch and ASIS in order to achieve a version angle of 20°. Sotereanos [104] used the lowest point of the acetabular sulcus of the ischium, prominence of the superior pubic ramus and most superior point of the
acetabular rim, to define an acetabular plane from which the cup could be positioned. Maruyma [105] proposed the ‘acetabular notch angle’, calculated from the intersection of a line from the sciatic notch along the posterior acetabular rim, and a line from the posterior to anterior acetabular wall. This angle, nearly always perpendicular according to the authors, may provide a means of improving cup version. Austin and Rothman [106] reported a means of using reference points from the acetabular rim and pelvis and the relationship when operating on a patient in the supine position. The inferomedial edge of the cup is positioned at the inferior margin of the acetabular notch, and the superolateral edge of the cup at the outer rim of the native acetabulum in order to achieve 40° of cup inclination.

However, potential drawbacks to using bony landmarks include difficulty in exposing and delineating certain osseous features, particularly in diseased hips where osteophyte formation and bony remodelling have occurred.

Archbold et al [107] proposed using the ‘transverse acetabular ligament’ (TAL), that spans the inferior aspect of the acetabular notch. The authors suggest that this method can be used regardless of patient position and surgical approach, eliminating the need for external jigs and guides. Version is controlled by keeping the face of the acetabular component parallel and encircled by the TAL; inclination is maintained by keeping the cup flush with the residual labrum. Using the TAL as a landmark, Archbold reported a dislocation rate of 0.6% in 1000 consecutive THAs. This is lower than comparative registry data, and in spite of using a posterior approach, neutral acetabular liners and 28 mm femoral heads, all of which are associated with a higher risk of dislocation. However, the authors acknowledge that the use of the TAL may not be applicable in where the acetabulum is dysplastic or distorted by pelvic trauma. In a later study, Archbold examined the native orientation of the TAL in MRI studies of non arthritic hips, reporting a mean of 23° version (range 5.3° - 36.1°) and 45.6° inclination (range 38.4° - 50.3°) [108]. It is unclear however whether using TAL as a surgical landmark improves radiographic measurements of acetabular orientation. Furthermore, the ligament may be difficult to visualise being obscured in 50% of cases, a finding highlighted by Epstein et al [109].

Merle et al [110] retrospectively evaluated the native acetabular orientation according to Lewinnek’s safe zone in a consecutive series of 131 preoperative CT scans of patients with primary end-stage hip osteoarthritis. Ninety-five percent of the native acetabula were classified as being within the safe anteversion zone, whereas only 15% were classified as
being within the safe inclination zone. However, when both parameters were combined on a scatter plot, only 8% of cases met the criteria of “safe zone”. Whilst acetabular anteversion may provide a anatomical reference for cup orientation, native acetabular inclination may not.

### 1.8.2 Mechanical Navigation

Steppacher et al [111] have recently introduced a novel mechanical navigation device (Hip Sextant, Surgical Planning Associates, Medford, USA) to aid cup orientation. This is a jig composed of two adjustable protractors and arms. A direction indicator points in the direction of the planned cup orientation. The Sextant is fixed to pelvis, overlying the acetabulum and the APP defined. Protractor angles are adjusted for each patient based on patient specific three dimensional models from CT imaging using preoperative planning software (Figure 1.13), and the cup introduced using the direction tool. The cup orientation in a group of THR s performed with the HipSextant was compared to a historic control group of hips performed using the CT based computer navigation. Using the mechanical device, a decrease in inclination and version errors was observed. Furthermore, none of the acetabular cups were outside of +/- 5° of the planned orientation.

![Figure 1.13. Illustration of the ‘Hipsextant’ mechanical guide for acetabular orientation. The Hipsextant guide is pinned to the acetabular roof, and ischium via percutaneous incisions. (Figure used with consent from personal communication with Dr SB Murphy, Hip Surgeon and designer of the Hipsextant)](image)

Although the results are promising, the authors acknowledge the study is limited by it being a single surgeon series, where the lead clinician is the device designer significantly advanced in the learning curve of its use.
1.8.3  Computer Assisted Hip Arthroplasty

Computer assisted surgery (CAS) has progressed from the first generation systems of the 1990s to the present third generation systems for the implantation of a knee or hip prosthesis. It has grown in popularity to minimise errors in cup placement. Two types of CAS exist for hip arthroplasty: an active system, using a robot to implant the cup [112], and a passive system, whereby during surgery the operator navigates calibrated instruments, and components, within a virtual picture. Passive systems can either be image based or image free. Image based systems utilise anatomical data sought from pre-operative computed tomography (CT) or magnetic resonance imaged (MRI); or intra-operatively from fluoroscopic imaging. The imaging is ‘segmented’ and the osseous anatomy delineated from surrounding soft tissue structures. A preoperative plan tailored to the patient’s anatomy is devised with the hip arthroplasty placed in the desired position and orientation. This is uploaded into the computer navigation system in preparation for intra-operative execution. In contrast, imageless systems utilise a virtual hip model ‘averaged’ from an atlas of hip scans that is refined intra-operatively by registering the native anatomy.

The use of either system requires the operator to link the patients’ osseous anatomy intra-operatively to the virtual model. Static trackers are mounted to the pelvis and specific anatomical landmarks, typically the ASISs and local hip joint, are ‘registered’ to the virtual model. The navigation computer can thus establish where the pelvis lies in space, and determine a frame of reference, such as the APP, from which component orientation can be referenced.

![Figure 1.14. Illustration of the steps in ‘segmentation’ of a CT scan to produce a three dimension pelvic bone model. Image based navigation systems require the patient’s bone anatomy, in this case from a pelvic CT, to be ‘segmented’ from the surrounding soft tissue to create a bone 3D model. (Acrobot Planner and Modeller version 1.16, The Acrobot Company Ltd, London, UK)](image)

During surgery, the surgeon uses instruments modified to hold a ‘tracking’ element that enables the position and orientation of the instrument tip to be determined by the navigation
system. Several types of position sensing device are available and are essentially composed of two parts: a tracking system that is placed near the patient in the operating room, and a tracker attached to an instrument or to the patient.

1.8.4 Tracking Technologies

Optical Tracking System

These use two main technologies: active and passive. Active systems utilise infrared light emitting diodes (LEDs) that are detected by a camera near the operative field, enabling the position of the patient or instrument to be calculated. Passive systems employ either retroreflective markers (such as spheres or disks) or special printed patterns (e.g. checkerboard) placed on the trackers. Infrared LEDs form an array around the lens of the camera. Light generated by the illuminators is reflected by each retroreflective target back to the camera lens. Clusters of at least three reflectors are attached to the tracker. (Figure 1.15) Retroreflective spheres are now widely used in image free navigation systems.

Figure 1.15. Illustration of an optical tracking computer navigation system. An optical tracking system (Vectorvision Hip Navigation System, BrainLab. Feldkirchen, Germany). Light emitted from a LED cluster around the camera is reflected from the trackers attached to the patient and surgical instrumentation back to the camera lens. The orientation of the femoral and acetabular component is displayed on the navigation system.
**Spatial Linkage System**

Mechanical linkage systems consist of passive, multi-jointed arms containing encoders that determine the orientation and location of calibrated instruments placed at the end of the arm. During the course of this thesis, such a system was used (Acrobot Wayfinder, Stanmore Implants Worldwide, Stanmore, England) [113].

![Figure 1.16](image)

**Figure 1.16.** Illustration of a spatial linkage computer navigation system. The Acrobot Wayfinder Navigation system (Stanmore Implants Worldwide, Stanmore, England) uses two mechanical arms. One is static and attached with pins to the ischium and the other connected to calibrated surgical instrument, such as an acetabular reamer.

### 1.8.5 Navigation of the Acetabular Cup in Hip Arthroplasty

In recent years, computer assisted surgery has grown in popularity to minimise error in acetabular cup orientation. A good number of observer studies [114-121] have been published but selection bias and variations in methodology have limited the applicability of the results. In 2009, Gandhi et al [122] conducted a meta-analysis of the use of navigation in total hip arthroplasty. Three randomised controlled trials were identified [20, 100, 101] that compared freehand cup orientation to either image free or CT based navigation (or both). All showed significantly greater accuracy in acetabular component orientation when navigation was employed. Gandhi notes that the numbers in all three studies are small and that the
intervention used were not consistent, in that free hand technique has been compared with both CT based and image free systems. Nevertheless, the number of outliers away from the target safe zone was 13/110 (11%) in the navigation group compared to 46/110 (42%) in the freehand group. Gandhi reported a beneficial odds ratio for the number of outliers outliers of 0.285 (95% CI 0.143 to 0.569, p<0.001).

While the benefits of navigated cup placement have been demonstrated, there remain a number of issues: pin site fracture and infection; accuracy in registering and establishing anatomic frames of reference; line of sight when using infrared systems; training theatre personnel and surgeons to use navigation; increased operating time; and lastly, the expense of hardware and software.

While the benefit of CAS is now well reported in total hip arthroplasty, there remains relatively limited literature in its use for hip resurfacing. Several papers have clearly shown the substantial improvement in surgeon accuracy in positioning the femoral component [83, 84, 123-126]; a technically demanding step that has been attributed to early failure due to femoral neck notching and fracture. At the time of writing, only one study could be identified that reported the accuracy of cup orientation in HRA. Romanowski et al [127] reported a series on 71 consecutive patients who underwent image free navigated hip resurfacing. Post-operative cup inclination angles were measured on radiographs and compared to intraoperative values. No significant differences were found and the authors conclude that this form of navigation is accurate for navigation of cup inclination. However, the study is limited as cup version was not measured, orientation analysis was not blinded and only conducted with the use of plain radiographs. At the time of conducting this thesis, a study examining the accuracy of image based navigation for cup orientation in HRA had not been reported in the literature.
1.9 Thesis Aims

Hip replacement surgery is the commonest orthopaedic procedure in the UK and rates one of the highest in patient satisfaction and cost effectiveness amongst all types of operation [128]. There are, however, areas for improving the accuracy of surgery, with the ultimate aim of delivering improved functional outcome. As a training orthopaedic surgeon, I was keen to understand where technology might be utilised in the patient pathway from the pre-operative, intra operative to finally the post-operative stages, for what is one of the commonest orthopaedic procedures that trainees will be involved in at an early stage in their career: total hip replacement. This coincided with the rising popularity of Metal on Metal hip arthroplasty, a new bearing technology that might improve the function for the young active arthritic hip population. The adverse effects of component malorientation in total and resurfacing arthroplasty have been outlined. This thesis therefore will examine the various sources of error and inaccuracy faced by the hip surgeon in managing and treating patients with hip osteoarthritis. This project will be directed to areas where there is a paucity of data and study in the literature, and will focus primarily on one part of the hip arthroplasty prosthesis, the acetabular component. The aims of this work are:

- Establish a means of assessing surgical performance in acetabular cup orientation
- Establish a method of delineating the femoral neck axis in three dimensions
- Compare measurements of acetabular cup orientation using two dimensional radiographs and three dimensional CT
- Investigate the accuracy of current laboratory methods of assessing metal ion levels in symptomatic metal on metal hips.
- Compare the accuracy of conventional free hand surgery to navigated computer technology in acetabular cup placement.
CHAPTER 2

Assessing Surgeon Error in Cup Orientation

2.1 Abstract

Total hip arthroplasty is one of the core operations an orthopaedic trainee is first exposed to and taught. Implanting an acetabular cup is an integral stage, requiring optimal orientation to ensure component longevity and problem free function. Mal-orientation beyond a ‘safe zone’ of +/-10° of the target can result in wear [176], impingement [177], and dislocation [178], ultimately leading to premature device failure. This is of detriment to the functional outcome of the patient and may lead to costly revision surgery.

We measured the ability of a group of orthopaedic surgeons in achieving a target acetabular cup orientation. Forty nine orthopaedic trainees and 18 senior surgeons orientated an acetabular component to a target of 40° inclination and 20° anteversion in three dry bone pelvic models. Pelvis A contained a featureless smooth acetabulum. Pelvis B and C contained an arthritic acetabulum, with Pelvis C housed in a silicone mould simulating a human hip. Three exercises of increasing difficulty were presented: neutral pelvic tilt (A), anteriorly tilted and adducted system (B and C). A wide range of inclination and version error was demonstrated in all scenarios. 59% of trainees were within 10° of the target in A, 25% in B, and 8% in C. 72% of seniors achieved the target zone in A, 61% in B and 17% in C.

There is opportunity to improve the accuracy of trainees in cup orientation. A moderate distortion in the position of the pelvis leads to a substantial deterioration in performance. Accuracy does not improve with experience. The use of computer assistance systems as an educational adjunct must be explored further.
2.2 Introduction

Over 200,000 primary hip arthroplasty procedures were performed in the United States of America [4] and over 70,000 in the United Kingdom in 2010 [2]. It is one of the core operations an orthopaedic trainee is first exposed to and taught. Implanting an acetabular cup is an integral stage, requiring optimal orientation to ensure component longevity and problem-free function. Mal-orientation beyond a ‘safe zone’ of +/-10° of the target can result in wear [176], impingement [177], and dislocation [178], ultimately leading to premature device failure. This is of detriment to the functional outcome of the patient and the health economy, with reduction of a dislocated primary THR costing 20%, and revision hip surgery approaching 150% of the primary procedure [46].

Ideal cup orientation relies on a clear understanding of its two constituents, the concepts of inclination and version [11], as well as appreciation of the variations in native acetabular morphology [135] and differences in cup design [95]. Local anatomical cues such as the transverse acetabular ligament have been shown to improve surgeon accuracy [107], but can be difficult to visualise [109]. Mechanical alignment jigs have been shown to be unreliable [179]. Thus, teaching this key skill is difficult, with no clear standardised method of achieving optimal orientation.

The traditional concept of ‘apprenticeship’ surgical training has been increasing exposure to invasive procedures in order to gain proficiency. The quality of this training is now deteriorating with a reduction in working hours [180], where the demands on a trainee, and trainer, to meet a target driven service compromise the educational opportunities available. Surgical competence as assessed by the trainer using an arbitrary grading scale has been shown to be subjective, not fit for purpose and prone to bias [181, 182]. In hip arthroplasty, the pelvic radiograph provides a further measure of technical performance, but is only available postoperatively. This imaging modality is prone to errors in magnification and pelvic tilt, that can render measurements of cup orientation less accurate and less reliable than using CT scans [162, 165].

The current literature comparing trainee to senior surgeon performance in hip arthroplasty is limited. The use of functional outcome scores [183] and surveys of postoperative morbidity are indirect, unspecific measures of aptitude, confounded by patient and surgeon related factors. In any orthopaedic procedure, objectively assessing technical skill that requires a high level of accuracy and precision must remain the de facto standard. Technology may
facilitate this. Virtual reality simulation of shoulder and knee arthroscopy, for example [184, 185], is now a well established means of discriminating expert from novice surgeons that provide real time feedback of surgical performance. In hip arthroplasty, several studies have demonstrated the impact of navigation technology as an assessment tool and aid in reducing the learning curve of novice surgeons, unfamiliar to surgery, in technically demanding procedures [83, 84, 186].

However, there is a hiatus in the literature regarding the baseline ability of trainee orthopaedic surgeons in orientating an acetabular cup, particularly in surgical scenarios of evolving difficulty.

The aims of this study were to investigate the accuracy of a group of trainee orthopaedic surgeons in implanting an acetabular component to target cup inclination and version.

2.3 Method

Three surgical scenarios were created each using a synthetic pelvic model fitted with dry bone acetabulum. The first scenario, ‘Pelvis A’, (Figure 2.1, Medical Models Ltd, Twickenham, UK) featured a smooth acetabulum with a featureless rim contour. The second and third scenarios, ‘Pelvis B’ and ‘Pelvis C’, contained the same acetabular model produced anonymised CT scan data from a consented patients with hip osteoarthritis undergoing navigated arthroplasty surgery. This is shown in Figure 2.2. The texture and firmness of the model was similar to bone. All three pelvises were carefully placed in the lateral decubitus position and covered in surgical drapes leaving the acetabulum exposed, in a manner similar to that of conventional hip surgery.
Figure 2.1. Dry bone pelvis (without surgical draping) orientated to the neutral pelvic tilt – Pelvis A.

Figure 2.2. Synthetic dry bone ‘osteoarthritic’ acetabulum implanted in both Pelvis B and C.

The first model, Pelvis A, was orientated to neutral pelvic tilt representing the ‘ideal’ position used during hip surgery. The second model, Pelvis B, was anteriorly tilted and adducted by 20°. The third model, Pelvis C, was orientated in precisely the same position as ‘B’, but housed in a periacetabular silicone mould giving the look of soft tissue. A posterior hip approach was simulated (by a senior surgeon) and a Charnley retractor placed to maintain exposure of the acetabulum (Figure 2.3).
Figure 2.3. Surgical simulation of a posterior approach to the hip joint. Pelvis C: Dry bone pelvis housed in synthetic soft tissue, with a simulated posterior approach to the hip.

The scan data utilised to create the synthetic acetabulae was reconstructed to a produce a three dimensional (3D) virtual model, using commercial available software (Acrobot Software Version 1.6.1, The Acrobot Company Ltd, London, UK). The anterior pelvic plane (APP) was applied by selecting the most anteriorly prominent aspects of the two anterior superior iliac spines and the most anterior prominence of the pubic symphsis. An acetabular component (CSF Plus, JRI Ltd, Sheffield, UK) was seated in the virtual acetabulum to an orientation of 40° inclination and 20° anteversion (Figure 2.4).
This 3D surgical template was loaded onto a virtual reality simulator, that used an image based navigation system as a platform (Navigator, The Acrobot Company Ltd, London, UK), validated to an accuracy of 1° and 1 mm [113]. A simulator was linked to each pelvic station using two digitising arms, one firmly attached to the pelvis and the other free to connect to hip instrumentation. The acetabulum was matched, by way of ‘registration’ to its virtual model to a root mean square error of less than 1mm. A custom designed cup introducer with a 52 mm acetabular cup (CSF Plus, JRI Ltd, Sheffield, UK) was connected to the system. By registering the virtual acetabulum to the corresponding model, any real time movement of the ‘tool’ arm would be simultaneously visible on screen. The cup orientation chosen by the user was thus accurately measured and logged (Figure 2.5).
Forty nine orthopaedic trainees and 18 senior surgeons from a single training region were available to participate during the study. This was a random collection of participants with no selection criteria applied. The year of training and total number of hip arthroplasty procedures (either total hip or hip resurfacing) performed by each participant was recorded. (Table 2.1), and stratified into several levels of experience: novice (0-10 procedures), intermediate (11-50), advanced (51-100) and expert (100+). The trainee group was broadly composed of registrars from year 1-5, with 34 participants having performed a hip arthroplasty procedure at least ten times before the study. Fifteen of the consultant surgeon group had an expert level of experience of hip arthroplasty, with the remaining three having performed at least 50 procedures. (Table 2.2)

**Table 2.1.** Summary of the year of training and number of hip arthroplasty procedures performed by the trainees surgeon group

<table>
<thead>
<tr>
<th>Year Of Training</th>
<th>Trainees (n = 49)</th>
<th>Number of Procedures Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>1</td>
<td>11</td>
<td>16</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>38</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>46</td>
</tr>
<tr>
<td>4</td>
<td>10</td>
<td>84</td>
</tr>
<tr>
<td>5</td>
<td>12</td>
<td>78</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>89</td>
</tr>
</tbody>
</table>
Table 2.2. The study group stratified by levels of experience in number of hip arthroplasty procedures performed.

<table>
<thead>
<tr>
<th>Experience (Number of Procedures Performed)</th>
<th>Trainees (n=49)</th>
<th>Consultants (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novice (0-10)</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Intermediate (11-50)</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>Advanced (51-100)</td>
<td>17</td>
<td>3</td>
</tr>
<tr>
<td>Expert (100+)</td>
<td>7</td>
<td>15</td>
</tr>
</tbody>
</table>

Each individual was asked to orientate an acetabular cup to a target inclination of 40° and anteversion of 20°, reflective of current clinical practice. Prior to the beginning of the study, two expert hip surgeons (Professors Justin Cobb and Alister Hart) trialled each test pelvis to ensure no system errors were present.

Individuals were free to check the position of each test pelvis before orientation of the cup. There was no time restriction imposed on the task. Participants were informed that the acetabular morphology differed between the first surgical scenario and the second two, as well as that the pelvis position may be suboptimal and altered. No reaming of the dry bone acetabulum or excision of peripheral osteophytes was performed. Participants were blind to the measurements made by the navigation system. Participants moved sequentially from pelvic models A, to B, to C; hence only three cup implantations were performed by each person.

2.3.1 Statistical Analysis

Results were statistically analysed using SPSS Version 16.0 for Windows (SPSS Inc., Chicago, Illinois). The results express cup orientation angles as radiological values. The significance level was set to a p<0.05.

2.4 Results

The performance in each test pelvis is summarised as descriptive statistics in Table 2.3. The results for both inclination and version are displayed as box and whiskers plots in Figure 2.6 and Figure 2.7. Scatter plots of inclination (x axis) and version (y axis) error demonstrating the number of individuals within 10° of the target orientation are illustrated in Table 2.4 and Figure 2.8 to Figure 2.10.
Table 2.3. Descriptive statistics summarising error in performance in inclination and version across all three stations

<table>
<thead>
<tr>
<th></th>
<th>TRAINEES (n=49)</th>
<th>EXPERTS (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inclination Error</td>
<td>Version Error</td>
</tr>
<tr>
<td></td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Mean</td>
<td>-4</td>
<td>-1</td>
</tr>
<tr>
<td>95% CI</td>
<td>-7</td>
<td>-1</td>
</tr>
<tr>
<td>Maximum</td>
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<td>19</td>
</tr>
<tr>
<td>Range</td>
<td>29</td>
<td>41</td>
</tr>
</tbody>
</table>

Table 2.4. The number of trainees and consultants able to orientate the acetabular component to the desired safe zone in each task

<table>
<thead>
<tr>
<th>Pelvis</th>
<th>Within +/- 10° of target orientation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trainees (n=49)</td>
</tr>
<tr>
<td>A</td>
<td>65</td>
</tr>
<tr>
<td>B</td>
<td>25</td>
</tr>
<tr>
<td>C</td>
<td>10</td>
</tr>
</tbody>
</table>

Figure 2.6. Box and whiskers plots demonstrating the cup inclination achieved by senior and trainee orthopaedic surgeons across the three pelvic stations. Absolute values (degrees) are expressed. The inferior, middle and superior horizontal lines of the box represent the first, median and last quartile respectively. The ends of the whisker correspond to the limits of the data.
Figure 2.7. Box and whiskers plots demonstrating the cup version achieved by senior and trainee orthopaedic surgeons across the three pelvic stations. Absolute values (degrees) are expressed. The inferior, middle and superior horizontal lines of the box represent the first, median and last quartile respectively. The ends of the whisker correspond to the limits of the data.

Figure 2.8. Pelvis A. Scatter graph plotting inclination error (x axis) against version error (y axis). The black square represents a ten degree zone about zero degrees of error. The trainee group is represented by the red triangles and consultant group by the green circles.
Figure 2.9. Pelvis B. Scatter graph plotting inclination error (x axis) against version error (y axis).

Figure 2.10. Pelvis C. Scatter graph plotting inclination error against version error.
2.5 Discussion

We asked a group of trainee and senior orthopaedic surgeons to orientate an acetabular cup to a target orientation of 40° inclination and 20° version in three surgical simulations.

The study group was composed of 49 orthopaedic trainees from years 1 to 6, with approximately 10 trainees represented from each year group (Table 2.1). This sample can be considered typical of the number and experience of registrars in current UK national training programmes [187]. Although 8 of the 47 participants were novice in hip arthroplasty, the majority had an intermediate to advanced level of operative experience of hip arthroplasty. It can be assumed that they all possessed a practical understanding of cup implantation, as well as the concepts of inclination and version. The consultant cohort was mixed in subspecialist interest but all had advanced levels of experience.

Amongst our trainee group, a large variation in accuracy was found in the three tasks. A wide range of error was observed, even in the most basic task, Pelvis A, where the range was 29° and 40° for inclination and version respectively.

The version error increased between Pelvis A and B, with most trainees orientating the cup in a retroverted position. The change in pelvic tilt was unlikely to have been accounted for, suggesting that trainees were continuing to use gross parameters such as the orientation of the cup introducer to the plane of the floor and pelvis, rather than local cues such as the relationship of the cup edge to the acetabular rim. A change in body position due to the loss of an anterior pelvic support is not an uncommon event during surgery and may leave the pelvis anteriorly or posteriorly tilted. The effect of pelvic tilt on the surgeon’s perception was investigated in 477 clinical cases by Zhu et al [188], who reported a 10° magnitude of tilt creates an absolute error in cup orientation of 8°.

Error in inclination was greatest in Pelvis C, with trainees and senior surgeons orientating the cup in an open, highly abducted, position. The addition of soft tissue appears to further disrupt the surgeon’s estimation of true pelvic tilt and orientation, leading to a substantial drop in performance. This trend of cups abducted beyond a target orientation is reflected by reports of CT analysed cup orientation [102, 121]. The relative improvement in version error from Pelvis B to Pelvis C suggests either a learning curve or reflects the relationship between inclination and version, which is not mutually exclusive, but inter related. Inclination is commonly thought of the angle between cup introducer and the horizontal plane of the floor. Version is
Judged by the longitudinal axis of the body. We suggest that participants were likely to be correcting the cup orientation in a step wise manner, judging each parameter of orientation as a separate movement. However, it is likely that as the operator brings the cup into anteversion, the cup face opens, hence the measured inclination increases. In this situation, an active effort to close the cup should be made once the appropriate version is achieved.

Performance in Pelvis C, the task most realistic of surgery, was considerably worse than Pelvis A or B. Only 17% of senior surgeons and 10% of trainees were within the 10° safe zone of the target. Given the seemingly poor results, the registration of the synthetic model, navigation hardware and software was systematically checked immediately following the study to ensure there were no faults. No equipment error was found, and the readings appeared to be an accurate recording of the task in Pelvis C. This level of error does correspond with numerous clinical studies that have analysed free hand cup orientation in hip arthroplasty: Saxler et al [102] found only 26% of cups in their series of 105 hips were within a safe zone, reporting a wide range of values for both inclination (23-71°) and version (-23°-59°). In a prospective randomised study, Parratte et al [20] reported 57% of cups orientated by expert surgeons using a free hand technique were outside a safe zone.

Consultants appeared to perform with no substantially greater level of accuracy than trainees, particularly in the task most realistic of surgery, Pelvis C. This suggests that even expert levels of experience in hip surgery, does not correspond with accuracy in cup orientation. However, were this the case clinically, one would expect a considerable higher number of hips to fail, or have greater level of complications such as dislocations were the safe zone a clinically relevant standard.

The ‘safe zone’ concept introduced by Lewinnek et al [17] can be considered outmoded for the current generation of hard bearings, which demand an even greater level of accuracy with a narrower margin of error than more traditional bearing couples. This concept, while providing a now commonly accepted standard, does not communicate a surgeon’s own angular preferences in cup orientation nor describe their precision or accuracy. In comparing many individuals on the same scatter graph, similar to Figure 2.7, surgeons may appear worse or better than they actually are.

The Six Sigma concept evaluates quality control processes in the manufacturing industry, where it has successfully minimised human and machine error to near zero. The process
capability index determines an acceptable range of values in the form a bell distribution curve where 95% of values fall within +/- 3 standard deviations of the mean [189]. Heck et al [190] successfully applied this in hip surgery, comparing conventional freehand to image free navigation in the task of cup orientation. Such concepts may provide a better means of quantifying surgical performance and make for fairer inter and intra subject comparisons.

Our study demonstrates that technology can be used to investigate a core skill in hip arthroplasty. The behaviour and subsequent response by trainees to a challenging but clinically relevant scenario can be studied. Such technology can identify outlying surgical performance, reproduce common clinical scenarios and may assist trainees to avoid clinical errors. Furthermore, trainers can track and potentially accelerate a trainee’s learning curve in an educational environment that augments, rather than replaces the clinical experience.

2.5.1 Limitations

For any assessment tool to be fit for purpose in an education setting, four different types of validity have to be met (Table 2.5) [191, 192]. Navigation technology has been validated in numerous clinical studies [20, 100, 102] for accuracy and precision and meets the criteria for construct and content validity. It is an assessment tool that can discriminate between high and low levels of accuracy.

The face validity, that is the fidelity of the test in resembling actual surgery, was limited however for several reasons. Although the synthetic pelvis used resembled bone, it was not appropriate for the step of reaming, which often allows the surgeon to gain a ‘feel’ for the acetabulum, the level of bony coverage and the presence of rim osteophytes. The silicone mould used to resemble soft tissue lacked the elasticity and texture of real muscle. In a normal clinical scenario, the surgeon has access to preoperative radiographs for templating; positions the patient on the operating table to the desired orientation; and may use local bone and soft tissue anatomical cues to aid cup orientation.

This investigation was a one-time assessment, giving a snapshot of an individual’s technical ability. The tools, equipment and even simulated approach to the artificial hip joint may not have been familiar to the participants. To measure precision and accuracy, this study would be improved by repeating the task not only on the same day, but re-testing the participants at regular time intervals (e.g. 6, 12 and 24 weeks) in a longitudinal investigation. A series of different scenarios could be simulated from differing types of hip morphology (such as
dysplastic) to various surgical approaches such as the anterior and lateral approach. Following a course in the laboratory, it would be necessary to examine the transfer validity of the test [192], by assessing a participants cup orientation in an actual operating environment on real patients. This would measure skill retention and an individual’s learning curve. Lastly, formal feedback by way of survey or questionnaire is a vital means of exploring the participants’ attitudes toward the assessment. This has been advocated as an integral stage in validating any assessment tool and is included for future work.

Table 2.5. Differing types of validity required in surgical simulation

<table>
<thead>
<tr>
<th>Type of Validity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Construct</td>
<td>The ability of a test to assess what it is designed for OR The degree to which a test measures the underlying concepts that are being assessed.</td>
</tr>
<tr>
<td>Content</td>
<td>The ability of a test to reflect the content of the domain tested</td>
</tr>
<tr>
<td>Face</td>
<td>The ability of a test to resemble the real situation</td>
</tr>
<tr>
<td>Predicative</td>
<td>The ability of a test to predict performance</td>
</tr>
</tbody>
</table>

This exercise required only one goal to be met: angular accuracy. Other metrics that have been used in the field of general surgery to discriminate between levels of surgical performance such as time taken, hand movements and total path length, were considered unnecessary. Indeed, acetabular component orientation forms only one step in performing a successful hip arthroplasty procedure. A total assessment of a trainees’ ability might include several key stages of this operation from pelvis positioning, surgical approach, to component implantation. This would ideally be performed in a dry laboratory environment before progressing to a cadaveric model. The costs related to material, infrastructure and navigation hardware are currently prohibitive to perform such an investigation.

Surgeons are likely to be held increasingly accountable by the public and professional bodies for the results of their procedures. The advent of professional revalidation and a trend toward patient reported outcomes [193] will inevitably result in surgical performance being scrutinised. It is not unrealistic to expect that some form of simulator based credential will be encouraged; it is already a requirement to gain specialist certification in other disciplines [194]. In anticipation, orthopaedic trainees should now be assessed using objective measures on standardised procedures, and only allowed to progress if a required level of proficiency is gained, thus ensuring quality remains the key focus in training. At the current time, navigation technology is available to test the accuracy of trainees, and even senior surgeons, in the task of cup orientation. As the demand for hip arthroplasty is likely to double in the
coming decades, the use of such systems in training surgeons must be explored further to avoid future clinical complications.
CHAPTER 3

The 3D Femoral Neck Axis and Morphometric Analysis of the Head Neck Junction in the Normal Hip

3.1 Abstract
A robust frame of reference is required to accurately characterize pathoanatomy in the proximal femur and quantify the femoral head-neck relationship. A three dimensional (3D) femoral neck axis (FNA) could serve such a purpose, but has not yet been established in the current literature.

Forty nine normal hips were retrieved from a CT scan database and segmented to create a 3D digital model. The neck axis was estimated using a custom written algorithm evaluating the centre of gravity of 1mm cross sections of the femoral neck. A line of best fit was calculated along these central points using a continuous iterative process until the angle between two subsequent axes was less than one degree. The rotation and orientation of the proximal femur was fixed using a novel frame of reference. The distance in space between the femoral head centre and neck axis was measured. The extent of the articular surface was marked along the head neck margin and the subtended articular margin angle measured.

The head centre is near collinear with the neck axis, with a mean offset in the x axis of 0 mm and 1mm in the y axis. However, a large range is noted, particularly in the y axis, where the head centre can be translated from the neck superiorly by up to 9 mm. The mean articular margin angle is 64° (range 55-72°). The articular surface of the normal hip appears to have a wide anterior and posterior extension.

These results suggest that normal hip head centre is not always collinear with the femoral neck. The normal femoral head appears to have a shape consisting of both a flexion and extension ‘facet’ to aid impingement free motion. The results of this study may have use in improving current prosthesis design and charactering abnormal hip shapes.
3.2 Introduction

Surgical strategies to treat cam FAI are directed toward restoring normal hip anatomy by resection of anterior osseous bump and increasing femoral head-neck offset. In order to improve the understanding of the condition and its treatment, accurate quantification of ‘normal’ and ‘abnormal’ hip morphology is required.

Radiographic imaging is a valuable screening tool in diagnosing femoro-acetabular impingement. Using 2D axial images of the hip from MRI, Notzli et al proposed the ‘alpha angle’ as a measure of the severity of the cam lesion [129]. This angle is defined by the angle subtended between the femoral neck axis and the point at which the femoral head becomes aspheric (Figure 3.1). The average alpha angle for the cam group was 74° and 42° for ‘normal’ control group. Notzli proposed a non gender specific cut off of 50° to differentiate between the two.

However flaws in using this technique are evident as measurements are highly sensitive to the rotation of the hip at the time of imaging. Eijer et al suggested that the proximal femur has greater offset anteromedially than anterolaterally, resulting in an apparent increase in the alpha angle and decrease in offset with progressive internal rotation [130]. Further measurements of the angle are prone to error from the radiographic projection utilised and variations in observer reliability [131, 132].

Figure 3.1. Diagram showing the construction of the alpha angle in the normal hip. Point A is the anterior point where the distance from the centre of the head (hc) exceeds the radius r of the femoral head. The alpha angle is then measured as the angle between A-hc and hc-nc, nc being the centre of the neck at the narrowest point. (Figure reproduced from Notzli et al [129])
Several studies have attempted to improve on 2D techniques that are susceptible to variations in hip position. Beaule et al measured the alpha angle on multiple 2D axial slices from 3D CT volumetric reconstructions where the hip was rotated about a subjectively placed neck axis. [133] In the asymptomatic control subjects, the mean alpha angle measured was 44° and in those with a cam lesion 66°. Similar results were found by Pfirmann et al performed in a MRI investigation of non-spherical shape of the femur in eight positions around the femoral head neck junction [134]. Three dimensional analysis of the hip may offer an improvement of 2D techniques but requires a frame of reference to standardise the position of the hip in space. A method of defining the femoral neck axis in 3D, a component of the frame of reference, does not yet exist in the literature. By establishing such a reference, further study of the differences in shape between hip specimens may be conducted, the orientation of the hip fixed to a standardised position in space allowing the alpha angle to be measured in 3D.

The aims of this study were to firstly define a robust 3D method of acquiring the femoral neck axis in a normal hip; secondly, to quantify the offset between head centre and neck axis; lastly to characterise the morphology of the articular margin of the femoral head.

3.3 Method

The specimens used for this study were available from a database that had been grouped according to morphology by one of the supervisors of this thesis (Professor Justin P Cobb, JPC) from a previous study [135]. These had been collected from standardised antero-posterior (AP) and lateral radiographs of the pelvis as well as CT imaging of the same
patient. These were available from patients undergoing navigated lower limb arthroplasty, CT colonography or pelvic fractures. Scans had been performed using the Siemens Sensation 64 slice scanner (Siemens Medical Solutions, Erlangen, Germany). Cam, profunda, and dysplastic hip morphology types based on established radiological parameters [136]. Cam hips were identified by the presence of an osseous bump along the anterior femoral head-neck junction, and reduced head neck offset as seen on the cross table lateral and anteroposterior hip radiograph[129] [133, 136]. Profunda hips were defined by the acetabular socket having a lateral centre angle of greater than 39° and dysplastic sockets as those less than 20° [136]. Hips with evidence of osteoarthritis, as graded by a Tönnis score [137] greater than 1 or narrowed joint space were excluded to ensure that all bony landmarks were preserved. By excluding cam, profunda and dysplastic hip types, a total of forty nine hips of ‘normal’ morphology were available based on these criteria. The proximal femur of each hip was segmented from DICOM images using validated commercial software (Robins 3D, Cavendish Medical, London, UK [138-140]) and converted to 3D stereolith (STL) models. Each model was exported to image processing software (3-Matics, Materialise Group, Leuven, Belgium) in preparation for further analysis. In order to standardise measurements, all femoral head specimens were scaled to a diameter of 54mm.

3.3.1 Defining the femoral neck axis

In order to standardise the position of each femur in virtual space, a proximal femoral frame of reference based on a local coordinate system was developed. To do this a method of determining the axis of the femoral neck, that is required to make up a femoral reference plane, was sought.

In 3-Matics imaging software, the femoral neck waist was marked. A cone of best fit was applied, with its central axis providing the first iteration of the neck axis. A datum plane transecting the width of the neck was applied perpendicular to the cone axis at every 1mm interval along its length, dividing the neck into a series of slices. The centre of gravity (CoG) for each slice was computed, resulting in a series of central points running the length of the femoral neck. These coordinates were exported into an algorithm in Matlab software (The Mathworks Incorporated®, USA), custom written by a post doctorate bioengineering fellow (Dr. Milad Masjedi) within the Musculoskeletal research laboratory of Imperial College. The initial axis was refined by applying a least –squares fit on these centroid points to produce a
new axis. This process was repeated until the iteration converged such that the angle between two subsequent axes was less than one degree (Figure 3.3).

![Figure 3.3](image)

**Figure 3.3.** Illustration of the method used to determine the femoral neck axis. 

- **A** A 15mm area of the femoral neck is marked circumferentially; 
- **B** The central axis of a best fit cone provides the first estimate of a neck axis; 
- **C** The neck is divided into slices of 1mm thickness; 
- **D** the central point of each is calculated and a best fit line fitted to give the final neck axis.

Next, a sphere of best fit was applied to the femoral head, lesser trochanter and piriform fossa to a root mean square error of less than 0.5 mm (Figure 3.4) and the centre of each sphere defined. A vector between the centre of piriform fossa (superiorly) and the lesser trochanter (inferiorly) defined the ‘y’ axis, and the femoral neck axis defined as the ‘z’ axis. The normal product of the intersection of these two axes provided the ‘x’ axis. The intersection of all three axes was set as the zero point (Figure 3.5).
Figure 3.4. Best fit spheres applied to the femoral head, lesser trochanter and piriform fossa.

Figure 3.5. Illustration of the local coordinate system used to orientate the proximal femur.

Using this local frame of reference, each proximal femur was re-orientated such that the neck was viewed down its barrel. In this projection, the axis of the femoral neck appeared end on and the femoral head in 2D as a circle (Figure 3.6a). The anterior aspect of the femur head-neck junction thus occupied the arc between 0 and 180 degrees (analogous to 12 and 6 o’clock on a clock face), and the posterior aspect between 180 and 360 degrees. The most inferior aspect of the head neck junction could be delineated at 180° and the most superior aspect at 360 degrees (Figure 3.6b). The rotation of each specimen was fixed such that the y
axis ran from the 12 to 6 o’clock position. The coordinates for the centres of the spheres approximated to the femoral head, piriform fossa and lesser trochanter were recorded.

Figure 3.6. a Orientation of the proximal femur used to conduct morphometry analysis.  
   b Schematic of femoral head showing clock face values as if viewed end on, looking down the neck axis. The vertical blue line in both Figure 3.6a and b represents the y axis running from the 12 to 6 o’clock position. This is also shown in Figure 3.5 earlier.

3.3.2 Morphometric Analysis

The perpendicular distance between the centre of the femoral head and the neck axis was calculated and termed the ‘head-neck offset’ (Figure 3.7). Secondly, the shape of the articular margin of the femoral head was determined. Approximately 40 points were marked along the perimeter of the femoral head articular surface starting antero-superiorly (Figure 3.8). Termed the ‘articular margin angle’ (AMA), the subtended angle between the line created from the origin to the articular margin and a normal vector to head centre were calculated.

Results were analysed with the use of Microsoft Excel (Microsoft Office 2010, Microsoft Corp, USA), and SPSS Version 16.0 for Windows (SPSS Inc., Chicago, Illinois). All measurements were rounded to integer values.
Figure 3.7. Diagram representing the head neck offset. The two rings represent the superior and inferior aspect of the femoral neck. The central green line represents the neck axis. The blue circle represents the femoral head and its centre. The perpendicular distance (light green line) between head centre and axis is calculated; in this instance it is 3.34mm.

Figure 3.8 The articular margin between the femoral head and neck is marked from anterior to posterior.

3.4 Results

The mean offset values, range and standard deviation in the offset and AMA are presented in Table 3.1. The head centre is near collinear with the neck axis, with a mean offset in the x axis of 0 mm and 1mm in the y axis. A large range is noted in these values, particularly in the y axis, where the head centre can be displaced superiorly by up to 9 mm (Figure 3.9)
Table 3.1. Results table summarising the distance of the femoral head centre from the neck axis.

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Range</th>
<th>SD</th>
</tr>
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<tbody>
<tr>
<td>X distance of head centre from neck</td>
<td>0</td>
<td>-4</td>
<td>4</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>axis (mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Y distance of head centre from neck</td>
<td>1</td>
<td>-5</td>
<td>9</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>axis (mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 3.9. Scatter plot illustrating the x and y distance between the head centre and neck axis for each hip analysed. The graph is best interpreted as if viewing the femoral head end on, down the barrel of the femoral neck centre at 0,0

3.4.1 The articular margin

The articular margin of the normal hip was not a constant hemisphere, but rather found to have two extensions. One found anteriorly, between 80 and 100° along the ‘clock face’ of the femoral head and a second extension posteriorly, between 240° and 280°. The mean AMA was 64° (SD 4°, range 55-72°). Results for each individual hip are shown in Table 3.2 and are charted in Figure 3.10. The average of these angles is illustrated in Figure 3.11.
Table 3.2. Results table showing the articular margin angle for each hip measured.

<table>
<thead>
<tr>
<th>Hip</th>
<th>Average AMA (degrees)</th>
<th>Hip</th>
<th>Average AMA (degrees)</th>
<th>Hip</th>
<th>Average AMA (degrees)</th>
<th>Hip</th>
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</tr>
</thead>
<tbody>
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<td>71</td>
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<td>63</td>
<td>45</td>
<td>70</td>
<td>SD</td>
<td>63-65</td>
</tr>
</tbody>
</table>

Figure 3.10. Line plot of the subtended angle between head centre and articular margin in our sample of 49 hips
3.5 Discussion

A standardised means of quantifying the morphology of the head–neck junction in the normal hip is required to provide a baseline reference from which an abnormal hip can be described. This was a small CT based study where the objective was to develop a methodology to determine the neck axis that would allow for a local frame of reference to orientate the hip.

The alpha angle of Notzli in the ‘normal’ hip population is variable and dependent on the imaging modality used and the position of the hip at the time of imaging, as shown in Table 3.3. Lack of standardisation in orientating the proximal femur and the use of 2D imaging have contributed to the error in measuring this angle. The use of 3D imaging and delineating a proximal frame of reference presented in this study may overcome these issues and provide a robust methodology of describing the normal and abnormal hip shape. Following on from the present study, Masjedi et al [141, 142] has successfully employed this methodology in

![Figure 3.11. Scatter plot of the mean subtended angle between the centre of the femoral head and the articular margin for a normal hip. An annotation is presented in the top right of the graph, showing a femoral head viewed end on. The anterior aspect of the head is at 90°, inferior at 180° and posterior at 270°.](image)
measuring the difference in the articular margin and head/neck ratio between normal and cam hips. The articular margin angle measured in this study is distinct and different from the alpha angle measured by Notzli, which measures the articular margin that is not within the sphericity of the femoral head. The 3D neck axis described in this study is novel and could be employed into the 3D analysis of differing hip types and may offer a standardised means of quantifying cam hips.

Table 3.3. Suggested mean and upper limit of the reference interval values for the alpha angle in the current literature, from studies of asymptomatic individuals, with a lateral (or equivalent) radiological projection.

<table>
<thead>
<tr>
<th>Author</th>
<th>Imaging Modality</th>
<th>Number of Hips</th>
<th>Alpha Angle (degrees)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mean</td>
<td>Standard Deviation</td>
<td>Range</td>
<td>Upper limit 95% reference interval</td>
</tr>
<tr>
<td>Beaule et al (2005)[133]</td>
<td>CT</td>
<td>20</td>
<td>44</td>
<td>5</td>
<td>36-50</td>
<td>53</td>
</tr>
<tr>
<td>Clohisy et al (2007)[143]</td>
<td>Cross table lateral radiograph (neutral rotation)</td>
<td>24</td>
<td>47</td>
<td>15</td>
<td>31-76</td>
<td>77</td>
</tr>
<tr>
<td>Pollard et al (2010)[144]</td>
<td>Cross table lateral radiograph (15° internal rotation)</td>
<td>83</td>
<td>47</td>
<td>8</td>
<td>30-70</td>
<td>62</td>
</tr>
</tbody>
</table>

Based on the results of this study, the articular margin of the normal head follows a wave like pattern, consisting of an anterior and posterior extension (Figure 3.11). These have been termed the flexion and extension facet respectively. The ‘anterior’ flexion facet is likely to provide a large surface area for articulation with the overlying psoas tendon and may act as a fulcrum to assist in hip flexion. The ‘posterior’ extension facet may articulate with the iliac eminence creating a fulcrum for the hip to extend. It may also be reasonable to suggest that these extensions are in direct contrast and reciprocal to the troughs found in the acetabular rim, which in itself does not have a constant equatorial rim. Earlier work by Vandenbussche et al [145] and Cobb et al [135] has shown that the acetabulum rim is composed of an asymmetric succession of three peaks and troughs. The anterior flexion facet of the femoral head appears to correspond to the anterior ‘psoas trough’, while the posterior extension facet appears to correspond to the ‘ischial trough’. These features may allow for impingement free rotation of the hip within the acetabulum, particular when the
pelvis is in the functional supine position. These suppositions would require further investigation using computer modelling and cadaveric study.

Femoral components of current generation hip resurfacings have failed to replicate the shape of the normal femur articular margin. These deviations from normal hip shape have been postulated to cause psoas impingement, providing a possible reason for the unexplained pain experienced by a number of HRA patients [146]. A prosthesis more faithful in shape and design to the normal femoral head may contribute to better biomechanics and avoid such complications. The methodology described in this study may have use in software applications for surgical planning and execution in both navigated and robotic hip surgery [147].

3.5.1 Limitations

There were several limitations to this study. Firstly the hips analysed were sourced from an anonymised dataset and therefore the sample could not be stratified according to gender or age (though all were adults over the age of 18 years). It has been assumed that the database used to source the images for analysis in this study was robust in defining normal from abnormal hip shapes. It would be worthwhile extending the analysis of the present study to a much larger sample size to ensure the findings are consistent.

The rotation of each proximal femur was standardised by modelling a sphere on the piriformis fossa and lesser trochanter. The position of these two anatomical structures will vary between individuals, but the consistency of using these landmarks to produce the y axis of the coordinate system is reflected in the similarity of the wave forms between the specimens. The reliability in developing the x, y and z axes from these landmarks was shown to be less than 1° in a validation study by Majedi et al in a study subsequent to this work [148]. Furthermore, these local landmarks were utilised to create a proximal frame of reference as the CT scans used did not extend to the knee. A femoral frame of reference accounting for variations in morphometry such as anterior bowing and femoral neck shaft version may offer a future direction of work [105]. Lastly, a formal power analysis was not conducted as this study is not comparative in nature.

This small CT based study has attempted to define a novel method of determining the femoral neck axis. This may aid 3D analysis of differing hip shapes and provide threshold values for the alpha angle of normal and cam hips. The shape of the femoral head described has use in prosthesis design and computer modelling for navigation and simulation software.
CHAPTER 4

Comparing the Difference between 2D and 3D Measurements of Cup Orientation in Metal on Metal Hip Arthroplasty

4.1 Abstract

Several highly cited studies [89, 93, 149-151] have investigated the cup orientation of over 5000 MoM HA patients using two dimensional (2D) pelvic radiographs with one commercial software package, Ein Bild Roentgen Analyse (EBRA Version 10, University of Innsbruck, Austria) to examine associations with outcome and complications. Recently, three dimensional (3D) evaluation of hip and knee arthroplasty imaging for component orientation has been shown to be more accurate than that using 2D [152]. However, there is no comparison between 2D EBRA and 3D-CT analysis for MoM HA.

The primary aim of this study was to compare measurements of cup version of large diameter MoM hips between EBRA and 3D CT. The secondary aim was to compare cup inclination and lastly to determine the inter and intra observer reliability of both methods.

Eighty seven MoM hip radiographs were analysed for cup orientation using EBRA; CT scans were analysed for 3D cup orientation with the pelvis in the plane of the scanner as well as aligned to the APP.

Results demonstrated a substantial difference in version measurement between EBRA and 3D-CT of -6° with the supine pelvis, and -8° with the pelvis orientated to the APP. The difference for inclination was no more than 1° irrespective of pelvic position, but with large standard deviations. When inclination and version for each cup were plotted on scatter graphs, 53% of hips were within the ten degree safe zone when measured by 3D CT pelvis supine and 54% with the pelvis in the APP. This compared to 24% when measured by EBRA. This difference was statistically significant. Inter and intra observer reliability of cup version is poorer using 2D analysis than 3D-CT. Retroversion was evident in 3 hips on 3D CT, but not on plain radiographs.

Errors in 2D version were likely to be due to the difficulty of delineating the cup rim, obscured by a large diameter metal head of same radio opacity. This study demonstrates that using 3D CT is a more accurate tool for measuring cup version and inclination in the MoM HA patient.
4.2 Introduction

Reports of high failure rates with large diameter Metal on Metal Hip Arthroplasty (MoM HA)[149, 153, 154] and the international recall of the Articular Surface Replacement prosthesis (ASR, Depuy International Ltd, Leeds, UK)[155] have resulted in increased numbers of patients being assessed for revision hip surgery. It is uncertain what proportion of these failures result from suboptimal cup version and inclination, both associated with poorly functioning hips [87, 89, 91-93]. Several studies have shown that antero posterior (AP), pelvic and lateral hip radiographs, two commonly used radiographic projections, are neither accurate nor precise for these measurements. The position, and orientation of the patient’s pelvis changes, with variations in pelvic tilt, obliquity and rotation [152, 156-158], when taking serial radiographs In addition, plain radiographs are prone to errors in magnification and perspective distortion. These factors can lead to an alteration in the cup appearance and errors in the subsequent measurements of orientation made.

Designed originally to measure migration and wear of the cup in total hip replacement (THR), [159, 160] Ein Bild Roentgen Analyse (EBRA Version 10, University of Innsbruck, Austria) software has been an increasingly common used measuring tool in MoM HA,[89, 93, 149-151] to improve on the limitations of plain radiographic assessment. Numerous studies have drawn conclusions based on these analyses, suggesting that abnormal cup inclination and version results in increased wear rates, [78] metal ions levels [89] and an adverse reaction to metal debris (ARMD) [150]. These reports are of significant importance to many hip surgeons treating patients with a symptomatic MoM HA as well as researchers examining the causes of failure in this bearing couple. While EBRA has been shown to measure socket version in non MoM THR with sufficient accuracy [18], its validity for this application in MoM hips is based on a single laboratory study [161] with controlled conditions and without a metal head in situ. Its accuracy in the clinical setting when both components are present is unclear; particularly as a large diameter metal head has been shown to obscure the cup margins on plain xray [162], making measurements of version in particular difficult to ascertain.

More recently, three dimensional computer tomography (3D-CT) has emerged as a robust method in providing objective measurements of component alignment in hip and knee arthroplasty. Specifically, it has been shown to be more accurate and reliable than xrays [152] and axial CT [163] in determining the three dimensional spatial orientation of the acetabular
cup. This is because the radiographic method is dependent on a 2D coordinate system that by definition cannot simulate the sagittal plane required to calculate the angle of version [11]; the coronal plane is analogous to the radiographic plane and is fixed at the time of exposure. EBRA offers the advantage of using complex geometric calculations to simulate the 3D position of the acetabular cup [164]. In 3D – CT variations in pelvic tilt can be controlled by fixing the pelvis to a standardised frame of reference that allows the use of x, y and z coordinates to generate the planes necessary to measure version and inclination. It is unclear from the current literature of what, if any, difference exists between the highly used EBRA technique and 3D-CT. Indeed given the disadvantages of radiation exposure and cost, it is not known if 3D-CT offers any greater accuracy than the EBRA method of cup analysis in MoM HA.

The primary aim of this study was to compare measurements of cup version of large diameter MOM hips using two methods: EBRA and 3D CT. The secondary aim was to compare measurements of cup inclination. The last aim was to determine the inter and intra observer reliability of both methods.

4.3 Method

This was a retrospective analysis of prospectively collected data. We retrieved the AP pelvic and lateral hip radiographs, as well as low radiation pelvis CT scans of 100 consecutive patients that had attended our hip arthroplasty clinics between 2009 and 2010. These imaging studies were taken within 6 weeks of each other. Radiographs of nineteen patients were excluded as the entire pelvis had not been captured on the plain radiographs and could therefore not been amenable to EBRA measurements. Hence, a total of 87 hips were analysed in a sample consisting of 81 patients, each with a current generation large diameter MoM HA (84 hip resurfacings and 3 modular total hips in total). Sizes of the femoral and acetabular components used were retrieved from the operation note. There were 26 females and 55 males, with a mean age 56 years (range 26-74). All patients had consented for their imaging to be used for research purposes.

4.3.1 Two dimensional radiographic analysis

Digital supine pelvic radiographs (Axiom Aristos FX Plus, Siemens , Erlangen, Germany) were taken in standardised fashion with the anterior superior iliac spines (ASISs) included, a symmetrical appearance of both obturator foramen, and the coccyx appearing directly in line
with the pubic symphysis [165]. The xray beam was centred in the midline and directed on the pubic symphysis.

Analysis of cup orientation was conducted by importing the radiograph into EBRA software. The image was first calibrated to the specific head and cup size. Six gridlines (three vertical and three horizontal) were generated by the marking specific bone landmarks on the pelvis. The cup dome was marked with 4 points; in addition the rim was delineated either by marking three specific points (supero lateral apex, infero-medial apex, arbitrary point) or a minimum of five evenly distributed points along the anterior or posterior outline of the rim (Figure 4.1). From these points, a best fit ellipse representing the cup rim was created. Lateral radiographs were used to determine ante or retroversion [93, 161].

The software calculates inclination in the plane of the radiograph, as the angle between the EBRA base line (tangent to the oburator foramina) and the longer axis of symmetry of the ellipse. Version is defined in space as the slope angle of the cup axis with respect to the film plane.

Figure 4.1. Screen shot illustrating the EBRA analysis of a left MoM hip. EBRA analysis of an antero-posterior pelvic radiograph with a left MoM HRA in situ. A frontal plane is developed as represented by the central red square. The cup dome (best fit circle shown in red) and rim (best fit ellipse shown in red) are marked out by the user in order to calculate inclination and version.
4.3.2 3D CT Analysis

All post-operative CT scans (Somatom Sensation 64 bit, Siemens, Erlangen, Germany) were performed with an extended Hounsfield range of 16,000 units using the Imperial hip protocol [166] (Figure 4.2) with 0.75mm collimation (high resolution), allowing clear imaging of the implanted components with minimal metal artefact. The data was reformatted to 3D models and analysed using commercially available software (Robins 3D, Robin Richards London, UK [138-140]). In each case, the cup orientation was measured first in the frame of reference of the CT scanner and secondly, the anterior pelvic plane (APP) developed from the anterior most prominence of the ASISs and pubic tubercles (Figure 4.3 and Figure 4.4). From this, transverse, coronal and parasagittal planes were established. Using simultaneous coronal, sagittal and axial views, a plane across the cup face was produced by setting points along the rim of the acetabular component (Figure 4.5). The acetabular cup axis was defined by a vector passing through the cup centre and perpendicular to the cup face. Radiological inclination and version were calculated by the software based on the nomograms and equations stated by Murray [11].

**Figure 4.2.** Illustration of the Imperial hip CT scanning protocol.

<table>
<thead>
<tr>
<th>ASIS:</th>
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<tbody>
<tr>
<td>Must include the most anterior part of both ASIS</td>
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<tr>
<td>kV</td>
<td>100</td>
</tr>
<tr>
<td>mA</td>
<td>80</td>
</tr>
<tr>
<td>Scan Length</td>
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<table>
<thead>
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<td>From 5 mm above acetabulum to just below mid-point of lesser trochanter</td>
<td></td>
</tr>
<tr>
<td>kV</td>
<td>100</td>
</tr>
<tr>
<td>mA</td>
<td>100</td>
</tr>
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<tr>
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<tr>
<td>mA</td>
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<tr>
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Figure 4.3. Screen shot of 3D-CT analysis of an acetabular component in the coronal view. The pelvis is orientated in the APP as shown by the red triangle that connects 3 out of the 4 points that describe the APP: two anterior superior iliac spines and two pubic tubercles. The pelvis can be viewed coronally to calculate inclination and version.

Figure 4.4. Screen shot of 3D-CT analysis of an acetabular component in the axial view. The pelvis can be viewed axially to calculate inclination and version. The bone anatomy has been removed from this picture to better illustrate the prosthetic components.
Measurements were conducted by the author (KD) and a second orthopaedic research fellow (Dr. Niall Smyth, NS), who had both previously used EBRA and 3D-CT in over fifty cases prior to this study. For tests of reliability, thirty randomly selected hips were measured in random order using both imaging modalities, three times at two weekly intervals. The imaging was anonymised to any patient identifiers.

### 4.3.3 Statistical Analysis

To quantify the level of agreement for cup version and inclination radiographic angles, a Bland-Altman analysis [167] was carried out comparing EBRA with 3D CT values (Figure 4.6 –Figure 4.9 ).

To demonstrate the clinical significance of the two imaging methods, a scatter graph was created where each plot represented the inclination (x axis) and version (y axis) of each hip measured.
(Figure 4.10 –Figure 4.12 ). The number of hips within 10° of 45° inclination and 20° version was determined, converted to dichotomous data and compared by Fisher’s exact test. These specific values were selected as being representative of what is considered a safe zone target for MoM cup placement [93]. A p value of less than 0.05 was considered statistically significant.

To quantify the intra and inter observer reliability of our measurements, the Intra Class Coefficient (ICC) was calculated. This measures repeatability and reproducibility between pairs of observations, whereby an ICC of ‘1’ indicates perfect agreement, while ‘0’ indicates no agreement [168]. Based on previously published work examining similar criteria, a power analysis determined a sample size of 30 hips was sufficient for an alpha error of 0.05 and beta error of 0.20. The ICC of three observations was calculated to describe the intra-observer reliability. Inter-observer reliability was calculated by comparing the mean of the three observations of the two investigators (KD and NS).

Data was analysed using Windows SPSS software Version 20 (SPSS Inc, Chicago, Illinois, USA).

4.4 Results

Bland-Altman analysis demonstrated a mean difference of - 6° when measuring version between EBRA and 3D –CT analysis of the supine pelvis (Figure 4.6) and - 8° when the pelvis orientated to the APP (Figure 4.7). The two standard deviation limits of agreement were pronounced with EBRA underestimating cup version by up to 22° with the pelvis in the APP position.

The mean difference between cup inclination measured by EBRA or by 3D-CT was less pronounced than for cup version, irrespective of pelvic position. This was 1°, when EBRA was compared to 3D-CT with the pelvis supine, and 0° with pelvis adjusted to the APP. There was, however, a substantial difference in the two standard deviation limits of agreement as illustrated in Figure 4.8 and Figure 4.9.

The difference in version between the pelvis in the supine position and APP position was 3°, with a two standard deviation difference at the upper limit of 14° and -9° at the lower limit (Figure 4.10). The difference in inclination between the pelvis in the supine position and APP position was 1°, with a two standard deviation difference at the upper limit of 9° and -7° at the lower limit (Figure 4.11).
Figure 4.6. Bland Altman plots of agreement between EBRA and 3D-CT version with the pelvis in the supine position. The horizontal solid represents the mean difference for the two methods. The horizontal hatched lines represent the two standard deviation limits of agreement about the mean.

Figure 4.7. Bland Altman plots of agreement between EBRA and 3D-CT version with the pelvis in the APP position.
Figure 4.8. Bland Altman plots of agreement between EBRA and 3D-CT inclination with the pelvis in the supine position.

Figure 4.9. Bland Altman plots of agreement between EBRA and 3D-CT version with the pelvis in the APP position.
Figure 4.10 Bland Altman plots of agreement in version between 3D CT in the APP and supine pelvic position.

Figure 4.11 Bland Altman plots of agreement in inclination between 3D CT in the APP and supine pelvic position.
4.4.1 Safe Zone Analysis

When inclination and version for each cup were plotted on scatter graphs, 53% of hips were within the ten degree safe zone when measured by 3D CT pelvis supine and 54% with the pelvis in the APP. (Figure 4.12 and Figure 4.13). This compared to 24% when measured by EBRA (Figure 4.14). This difference was statistically significant (Table 4.1).

<table>
<thead>
<tr>
<th>Table 4.1. Safe zone analysis of cups measured using EBRA and 3D-CT</th>
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</thead>
<tbody>
<tr>
<td><strong>Within Safe Zone</strong></td>
</tr>
<tr>
<td>EBRA</td>
</tr>
<tr>
<td>CT Supine</td>
</tr>
<tr>
<td>CT APP</td>
</tr>
</tbody>
</table>

Figure 4.12 Scatter graph of cup inclination (x axis) against cup version (y axis) measured using 3D-CT with the pelvis in the supine position. The red square highlights a notional safe zone with ten degrees of 45° inclination and 20° anteversion.
**Figure 4.13** Scatter graph of cup inclination against cup version measured using 3D-CT with the pelvis in the APP position.

**Figure 4.14** Scatter graph of cup inclination (x axis) against cup version (y axis) measured using EBRA software.
4.4.2 Observer Reliability

Although EBRA measurements showed good intra-observer reliability (ICC 0.89), 3D-CT of version was near perfect (0.99) having a narrower 95% confidence interval (0.99-1.0 vs 0.76-0.96). EBRA and 3D CT measurements of inclination both demonstrated excellent intra observer reliability (ICC 0.99, 95% CI 0.99-1.0).

In testing inter-observer reliability, 3D CT gave near perfect agreement in version values compared to EBRA (0.98 vs 0.79), with a narrower confidence interval (0.96-0.99 vs 0.51-0.90). The reliability of inclination was values was also high whether measured by EBRA or 3D CT (0.99 vs 0.97). These results are summarized in Table 4.2 and Table 4.3.

Table 4.2. Intra observer reliability for cup orientation measurements using EBRA and 3D CT

<table>
<thead>
<tr>
<th></th>
<th>Intra Class Coefficient</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBRA version</td>
<td>0.89</td>
<td>0.76 - 0.96</td>
</tr>
<tr>
<td>3D-CT version</td>
<td>0.99</td>
<td>0.99 – 1.0</td>
</tr>
<tr>
<td>EBRA inclination</td>
<td>0.99</td>
<td>0.99 – 1.0</td>
</tr>
<tr>
<td>3D-CT inclination</td>
<td>0.99</td>
<td>0.99 – 1.0</td>
</tr>
</tbody>
</table>

Table 4.3. Inter observer reliability for cup orientation measurements using EBRA and 3D CT

<table>
<thead>
<tr>
<th></th>
<th>Intra Class Coefficient</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBRA version</td>
<td>0.79</td>
<td>0.51-0.90</td>
</tr>
<tr>
<td>3D-CT version</td>
<td>0.98</td>
<td>0.96-0.99</td>
</tr>
<tr>
<td>EBRA inclination</td>
<td>0.97</td>
<td>0.94-0.99</td>
</tr>
<tr>
<td>3D-CT inclination</td>
<td>0.99</td>
<td>0.98-1.0</td>
</tr>
</tbody>
</table>

4.5 Discussion

The influence of cup version and inclination on MoM bearing failure has been mainly investigated using 2D analysis of plain radiographs with EBRA software [78, 89, 93, 149-151]. These studies represent the greatest body of work in the literature and included a series of over 5000 MoM hips. The difference in orientation values between 2D measurements with EBRA and 3D-CT has not been established, and the present study appears to be the only one to have been conducted. This study shows EBRA measurements of cup orientation, particularly version, have poor agreement and are relatively less reliable than that with 3D – CT. The differences between the two modalities may be sufficiently large to affect the validity of conclusions based on 2D measurements.
4.5.1 Version

There was a mean difference of -6° between EBRA and 3D-CT measurements with the pelvis supine, and -8° with the pelvis orientated to the APP. More importantly the Bland-Altman two SD limits of agreement were wide at 8° to -20°, and 6° to -22° respectively. These results suggest that using EBRA is inaccurate and tends to underestimate cup version. Our EBRA measurements were highly reliable suggesting that the poor agreement with 3D CT is attributable to the method of measurement rather than the learning curve of the observers in this study. The version value calculated by EBRA is a function of the users’ ability to accurately mark the cup contour for the cup axis to be generated from a best fit ellipse. The anterior and posterior cup rim are often obscured by a large metal femoral head [162], which is of similar radio-opacity, rendering the central portion of the rim difficult to visualise. This may have contributed to the relatively poor inter and intra observer reliability found in this study. The difference in version between the pelvis in the supine position and APP position when measured with 3D CT was 3°, with a two standard deviation difference at the upper limit of 14° and -9° at the lower limit. Whilst the mean difference of 3° is lower than that when measured with EBRA. The wide limits of agreement highlights that measurements of version are likely to be variable depending on the position of the pelvis that the image is taken. Where the rim is more easily identified, such as in polyethylene cups in total hip arthroplasty, EBRA has been shown to have greater accuracy [18]. By comparison, 3D-CT enables the user not only to generate an axial and sagittal plane but also to visualise the entire circumference of the cup when an extended Hounsfield scale is used to minimise metal artefact (Figure 4.3 – Figure 4.5). Both are likely to contribute to better accuracy, and reproducibility reflected in the near perfect intra- and inter- observer reliability.

There were 3 patients in whom retroversion was evident on 3D CT, but not on EBRA. Lateral radiographs were assessed according to the method reported by Grammatopolous et al, but retroversion could not be detected according to their criteria [93]. These findings reflect those of Langton et al in the only study in the literature validating EBRA in MoM hips using a controlled laboratory setting [161]. Fifty radiographs of current generation metal cups were mounted in a synthetic pelvis without a femoral head in situ to a pre-determined orientation. Only one of several cups placed in a retroverted position was identified by EBRA. This result was excluded from the validation analysis, and is a limitation of the software acknowledged by the authors. This is clinically relevant as a recent study showed that 10 out 100 MoM hips
were found to be retroverted on 3D-CT analysis [92]. The inability of EBRA software to measure retroversion, was further highlighted in a lab based study by Derbyshire et al [169].

4.5.2 Inclination

The error between inclination values for the two techniques were substantially less when compared to version, probably because the superior and inferior margins of the cup are readily identified on plain radiographs, even with a large diameter metal heads. The discrepancy is probably related to the disadvantage of two rather than three dimensional measurement [157]. The radiographic plane from which inclination is calculated is prone to errors from variations in pelvic tilt, rotation and obliquity that occur not only between subjects but also when the same subject is serially assessed [152, 170-172]. A critical advantage of 3D-CT is that the pelvis is corrected to the anterior pelvic plane, eliminating the variability of patient position at the time of scanning, thus allowing objective measurements of cup placement to be made between different subjects. The difference in inclination between the pelvis in the supine position and APP position was 1°, with a two standard deviation difference at the upper limit of 9° and -7° at the lower limit. The mean difference of 1° is similar to that when compared to EBRA measurements, suggesting that pelvic position has less of an impact on the accuracy of cup inclination measurements than in version measurements. Nevertheless there remains a wide range in agreement between 9° and -7°, further illustrating that pelvic position will contribute to error in cup measurements, unless fixed to a standardised position such as the APP.

4.5.3 ‘Safe Zone’ Scatter graphs

Safe zone graphs have been popularised in the hip arthroplasty literature since the time of Lewinnek et al [17] as a means of determining surgical accuracy and examining problems associated with a particular device. In this analysis, the difference in the number of hips falling with the safe zone was substantial. This may have implications towards any study using the EBRA method to investigate outcomes related to MoM HA cup mal-orientation. The incidence of complications, such as pseudotumour, as well as an individual’s surgical performance may be under or over reported depending whether EBRA or 3D-CT orientation values are used to plot safe zone graphs.
4.5.4 Limitations

There are several limitations to this study, in part due to its retrospective nature. Firstly, supine pelvic radiographs were used, in contrast with a large number of MoM studies utilising the standing position. There is substantial variability in pelvic orientation in both the supine and standing position when measured in the same patient over time. The appearance of the pelvis and an acetabular component can therefore be inconsistent on successive radiographs. Standing films are thus no more accurate for the purpose of determining cup orientation than the pelvis in the supine position, as neither can be truly standardised [156, 172-174].

Secondly, it was assumed that there had not been a substantial change in the pelvic tilt or cup position in the time interval between the radiograph and CT scan being taken. It would have been ideal to perform both investigations sequentially on the same day, but this was not possible logistically in a busy urban hospital. Indeed an improvement to the current study design would be to perform a controlled laboratory based investigation. Cup position could be set within a synthetic pelvis to a series of known orientations to a standardised pelvic position and measured with both EBRA and 3D-CT. This could be performed with a metal femoral head in situ to give a better representation of the clinical setting.

Thirdly, different acetabular components with variable cup articular arc angles (CAAA) were studied [170]. De Haan [87] and Langton et al [89] demonstrated the importance of the functional articular arc as it relates to wear complications with large diameter MoM hips. The amount of articular arc available is a function of not only of the size, but the inclination angle of the cup. Studies seeking to quantify the performance of a specific cup design with regard to its CAAA must therefore rely on robust measurements of cup orientation.

Fourthly, the manufacturers of EBRA recommend that the accuracy of the software may be improved by measuring cup orientation on sequential radiographs and calculating an average of both version and inclination. Given the retrospective nature of this study, this would not have been possible.

Lastly, there may be concerns regarding the radiation dosage of CT. The scanning protocol in our study exposes the patient to 1.7 millisieverts (mSV) [175], the equivalent of 3 pelvic radiographs and less than the 10 mSv of a traditional pelvic CT. With current guidelines recommending the long term clinical surveillance of MoM hips, the radiation exposure of one
low dose CT scan is likely to be offset by that of the successive radiographs a patient will require for EBRA measurements.

Understanding the effect of cup orientation on outcome and modes of failure in MoM arthroplasty is dependent on an objective tool that allows the user to accurately and reliably measure these values regardless of pelvic position at the time of radiographic exposure. This study has shown a large, and clinically relevant, difference in cup version values when using 3D-CT. Surgeons and researchers should be aware of these differences when interpreting the orientation of MoM cups measured with the EBRA 2D technique.
CHAPTER 5

An Analysis of Metal Ion Levels in the Joint Fluid of Symptomatic Patients with Metal on Metal Hip Arthroplasty

5.1 Abstract

Concentrations of chromium and cobalt ions in samples of joint fluid and whole blood in ninety two patients with failed current generation metal-on-metal hip arthroplasties were analysed. An acid oxidative digestion process was applied to the metal analysis protocol resulting in significantly higher levels of metal ion concentrations. Patients were sub categorised by mode of failure, either ‘unexplained pain’ or ‘defined causes’ (eg aseptic loosening, cup malorientation and infection). Using this classification, chromium and cobalt were present over a wider range in joint fluid and not as strongly correlated with blood as reported previously in the literature. There was no significant difference between metal ion concentrations and manufacturer nor femoral head size below or above 50mm. There was a moderate positive correlation between metal ion levels and cup inclination as measured on 3D CT. The wide range of levels reported will provide a reference to surgeons following up patients with MoM hips, and researchers performing mechanistic studies on the periprosthetic tissue reactions following this type of arthroplasty.
5.2 Introduction

Wear debris from Metal on Metal (MoM) hip arthroplasty is now thought to cause a local soft tissue inflammatory response leading to premature implant failure [76]. Higher wear rates have been linked to this mode of failure, when compared to other causes [195], and has been shown to result in raised systemic levels of chromium (Cr) and cobalt (Co) [196]. Whether blood concentrations of these ions truly reflect joint fluid levels, and hence act as a surrogate marker of failure in the symptomatic MoM patients remains ill defined, with only a few reports in the literature.

With the advent of 2010 MHRA recommendation to all hip surgeons to investigate symptomatic MoM patients with blood metal ion analysis [96], the need to examine the relationship to joint fluid levels is more pertinent. The clinical relevance of joint fluid analysis is not clear and the resulting metal ion values difficult to interpret.

Sampling fluid from the hip joint is technically, and logistically, more difficult than the relative simplicity of retrieving venous blood, and its value as a diagnostic investigation must therefore be considered carefully. Given the paucity of current literature, more information on relationships that may influence joint fluid concentrations of metal ions and hence affect blood levels may prove useful to the clinician and contribute to a better understanding of the mechanisms of failure in this patient group.

Two studies have investigated in vivo concentrations of Cr and Co in the joint fluid of failed MoM hips with a total of 43 patients [78, 196]. De Smet et al [196] demonstrated a strong positive correlation between hip wear rates and joint fluid concentrations, with serum metal ion levels in 26 patients (7 of which were bilateral). Additionally, they showed patients at revision surgery had median joint fluid levels of Cr and Co approximately twenty times greater in those with metallosis than those without. Langton et al [78] examined joint fluid metal ion levels in seventeen patients with Adverse Reaction to Metal Debris (ARMD) finding a wide range in Cr (~1000 to 46,000 micrograms per litre [μg/L]) and Co (~1000-10,000 μ/L). While both reports have contributed to the current knowledge in the field, the large variation in metal ion levels between the two studies and the low number of patients in both studies limits the universal applicability of the conclusions drawn.

In order to investigate precise relationships with metal ion levels, a method to ascertain and analyse sample fluid that is robust and avoids inaccurate measurements is required. Firstly,
intra-operative sampling of joint fluid should be free of blood contaminant from the surgical dissection. Secondly, metal ions should be liberated from their molecular bounds, such as Cr in red blood cells [197], into free ionic form through acid oxidative digestion in the laboratory.

The primary aim of this study was to validate a method of metal ion analysis in the joint fluid of symptomatic MoM hip joints, and, to investigate the relationship of these values to several clinical variables.

5.3 Method

This study was a retrospective analysis of prospectively collected data, approved by the research ethics committee of Charing Cross Hospital (REC number 07/Q0401/25). All patients with joint fluid metal ion levels that had been referred to the arthroplasty service of Charing Cross Hospital (London, UK) for problematic MoM hips over a two year period were included.

All patients underwent conventional hip assessment in the form of clinical history and examination, infection screen using routine blood tests including C-reactive protein, as well as plain antero-posterior and lateral radiographs. The cause of pain was investigated further using 3D CT data for anatomic acetabular component orientation [198], and metal artefact reduction sequences magnetic resonance imaging (MARS MRI) to investigate the presence of any soft tissue abnormality [199]. To exclude infection, sterile hip aspiration was performed and joint fluid sent for microscopy and culture. A diagnosis of non-infection was made if either the C-reactive protein was less than 10 milligrams per litre and microbiology results were negative. All patients had a current generation large diameter (>36 mm) prosthesis either MoM hip resurfacing or total hip arthroplasty. Intra-operative findings such as loosening were recorded. Hence, patients were categorised into two cohorts by diagnosis: ‘defined cause of failure’ and ‘unexplained pain’. The latter had no evidence of infection, cup mal-orientation, head and cup component size mismatch, loosening, dislocation, or periprosthetic fracture.

Patients in whom there were bilateral hip prostheses or other metal devices that could affect blood levels of metal ions were excluded; as well as those requiring revision surgery within 12 months of the primary procedure where steady state levels of metal ions would not have been reached [200-202] and in patients with abnormal renal function [203, 204]. Control
whole blood (WB) and joint fluid (JF) samples were taken from five consented patients undergoing hip arthroscopy, or hip arthroplasty, in whom there were no metal implants present.

Hip joint fluid and whole blood samples were taken within 6 hours of each other. Blood samples were taken from the antecubital vein. Joint fluid was sampled either intra-operatively prior to hip capsulotomy (carefully avoiding dilution with blood from the surgical dissection) or under fluoroscopic guidance during hip aspiration. Samples were drawn using a stainless steel needle into a trace element vacutainer (BD, Oxford, United Kingdom) containing sodium ethylenediaminetetraacetate (EDTA) for blood, or sterile universal plastic containers for joint fluid. Fluids were stored at -80°C until analysis, where upon the sample was thawed to room temperature and resuspended using a vortex mixer in preparation for further processing. The Cr and Co ion levels in WB and JF samples were compared, using two differing processing methods.

The first method involved simple dilution of the sample fluid in a diluent containing tetramethyl ammonium hydroxide (TMAH, final concentration 0.5%, electronic grade, Alfa Aesar, Ward Hill, MA, USA), Triton-X100 (final concentration 0.001%, ultrapure grade, Merck, Darmstadt, Germany) and butan-1-ol (final concentration 0.1%, SPS grade, Romil, Cambridge, UK). The diluent also contained inductively coupled plasma mass spectrometer (ICPMS) internal standard (Gallium, 1μg/L). Lastly, 0.15 millilitres (ml) of sample fluid was diluted to a final volume of 4.80 ml for ICPMS analysis. The isotopes measured were 52 Cr and 59 Co. Samples beyond the calibration range were diluted appropriately with deionised water and re-analysed.

The second method utilized acid oxidative digestion, a process that liberates metal ions bound to proteins in red blood cells, as well as insoluble material and metal nano particles found in the fluid of MoM hips. A 0.5ml aliquot of synovial fluid was digested with 5 ml of nitric acid (SPS grade, Romil, Cambridge) at 100° for 240 minutes, using a dry heating block (DigiPrep, SCP Scince, Quebec, Canada). With each batch, two additional ‘blank’ samples were processed, whereby the joint fluid component was substituted with 0.5ml of 18 Ohm deionised water. Post digestion, the remaining fluid in each tube was further diluted to 50 ml with deionised water and analysed with high resolution ICPMS (Element2, Thermo Finigan, Bremen, Germany). The blank samples were used to correct for any contamination for each batch. The concentration of metal ions was expressed as micrograms per litre (μg/L), rather
than parts per billion (ppb) which is primarily used in North America. The two are interchangeable in that 1 μg/L is equivalent to 1ppb.

5.3.1 Statistical methods
For the initial 25 samples, Bland-Altman plots of Cr and Co values were performed in order to analyse the level of agreement between the two methods of sample processing. Based on these results, acid oxidative digestion was used for all subsequent measurements.

For statistical analysis, SPSS Version 16.0 for Windows (SPSS Inc., Chicago, Illinois) was used. Significance was set at a p value <0.05. Mann Whitney U test was used to test for differences between JF ion levels in patients categorised according to cause of failure and femoral head size. ANOVA with Tukey Post Hoc analysis was used to test differences between manufacturer type. Scatter plots, Spearman’s Rank correlation and linear regression were used to examine the relationship of JF metal ion levels with cup inclination, and paired whole blood samples. A logarithmic (base 10) conversion of joint fluid values was performed to allow certain results to be illustrated as box plots.

5.4 Results
Ninety-two consecutive hip joint fluid samples were available for analysis (female = 62, male = 30). The mean patient age at the time of revision of the primary MoM arthroplasty was 60 years (30 to 87). The mean number of months the primary prosthesis was in situ was 36 months (12 to 137).

Cobalt and chromium Levels Pre and Post Acid Digestion
Descriptive statistical results are summarised in Table 5.1. Bland Altman analysis (Figure 5.1 and Figure 5.2) demonstrated the mean difference between digested and undigested synovial fluid was significantly greater for Cr (12, 744 μg/L, p=0.002) than for Co (1249 μg/L, p=0.083). Regardless of processing method, Cr and Co levels in the joint fluid of our control group were below the limits of detection of the mass spectrometer, which was 0.3 μg/L for both ions.
Table 5.1.  Table of descriptive statistics comparing chromium and cobalt levels against several clinical variables.

<table>
<thead>
<tr>
<th>Variable (Number of patients in analysis)</th>
<th>Chromium (µg/L)</th>
<th>Cobalt (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (95% CI)</td>
<td>Median</td>
</tr>
<tr>
<td>Undigested (25)</td>
<td>7849 (3340-12358)</td>
<td>1844</td>
</tr>
<tr>
<td></td>
<td>p=0.002</td>
<td></td>
</tr>
<tr>
<td>Acid Digested (25)</td>
<td>20593 (3863-37324)</td>
<td>5072</td>
</tr>
<tr>
<td></td>
<td>P = 0.083</td>
<td></td>
</tr>
<tr>
<td>Unexplained Pain (35)</td>
<td>10276 (-766-21318)</td>
<td>1337</td>
</tr>
<tr>
<td></td>
<td>p=0.681</td>
<td></td>
</tr>
<tr>
<td>Defined Cause of Failure (29)</td>
<td>17397 (-2061-36856)</td>
<td>1512</td>
</tr>
<tr>
<td></td>
<td>P=0.377</td>
<td></td>
</tr>
<tr>
<td>BHR (36)</td>
<td>12360 (2829-21890)</td>
<td>1388</td>
</tr>
<tr>
<td></td>
<td>p=0.163</td>
<td></td>
</tr>
<tr>
<td>ASR (18)</td>
<td>28347 (-8218-64912)</td>
<td>1779</td>
</tr>
<tr>
<td></td>
<td>P=0.377</td>
<td></td>
</tr>
<tr>
<td>Cormet (16)</td>
<td>1955 (73-3836)</td>
<td>756</td>
</tr>
<tr>
<td>Other (22)</td>
<td>5762 (989-10534)</td>
<td>1655</td>
</tr>
<tr>
<td>&lt;50mm head (56)</td>
<td>8446 (1316-15575)</td>
<td>1139</td>
</tr>
<tr>
<td></td>
<td>p=0.610</td>
<td></td>
</tr>
<tr>
<td>≥50mm head (31)</td>
<td>16025 (-2139-34190)</td>
<td>1064</td>
</tr>
</tbody>
</table>
Figure 5.1. Bland Altman analysis of agreement of Chromium (Cr) ion levels in digested versus undigested joint fluid. The horizontal solid line represents the mean difference between values for the two methods. The dashed lines represent two standard deviations about the mean.

Figure 5.2. Bland Altman analysis of agreement of Cobalt (Co) ion levels in digested versus undigested joint fluid.
Joint fluid levels and category of failure

Of the ninety two patients in the study, sixty-four patients had been categorised at the time of treatment according to their cause of failure into ‘unexplained pain’ (n=35) and ‘defined cause of failure’ (n=29) (Table 5.1 and Figure 5.3). Twenty eight patients had not been assigned a cause of failure at the time of investigation and were excluded from the analysis. There was no significant difference in either Cr (p = 0.681) or Co (p = 0.475) between the two groups.

![Figure 5.3](image-url)

**Figure 5.3.** Box and whiskers plots demonstrating the Cr and Co joint fluid levels (Log 10 values) in 64 patients categorised according to failure. The inferior, middle and superior horizontal lines represent the first, median and last quartile respectively. The ends of the whiskers correspond to the limits of the data. Anomalous results considered outliers are represented by the black crosses x.
Joint fluid levels and manufacturer hip type

Ninety two samples were investigated according according to the manufacturer of the prosthesis. The three largest groups were composed of the Birmingham Hip Resurfacing (BHR, Smith & Nephew, Warwick, United Kingdom), Articular Surface Replacements (ASR, DePuy International Ltd, Leeds, United Kingdom) and Cormet (Corin Group PLC, Cirencester, United Kingdom). The further hip types were nine Durom (Zimmer Ltd, Swindon, United Kingdom); six Adept (Finsbury Orthopaedics, Leatherhead, United Kingdom); four Recap (Biomet UK Ltd, Swindon, United Kingdom); and three Mitch (Stryker Ltd, Newbury, United Kingdom). These latter 22 patients were combined into a single group labelled as ‘Other’, to allow for statistical comparison (Table 5.1 and Figure 5.4). There was no significant difference for either Cr (p=0.163) or Co (p=0.377) between different manufacturers.

![Figure 5.4. The Cr and Co joint fluid levels categorised according to manufacturer of MoM prosthesis.](image)

Joint fluid levels and femoral head size

Eighty-seven femoral component sizes were available for analysis. The mean head diameter was 47 millimetres (mm) (range 39 - 54). We divided the sample into two groups: below 50
mm (n= 56), and, above or equal to 50 mm (n=31) (Table 5.1 and Figure 5.5). There was no significant difference in either Cr (p=0.610) or Co (p=0.620) levels between the groups.

**Figure 5.5.** Box and whiskers plots demonstrating the Cr and Co joint fluid levels categorised according to femoral head size

**Joint fluid levels radiographic cup inclination angle**

The correlation between inclination angle and joint fluid metal ion levels was weakly positive for Cr (Spearman’s rho = 0.213, p = 0.114) and Co (Spearman’s rho = 0.286, p = 0.032) (Figure 5.6 and Figure 5.7)
**Figure 5.6.** Scatter plot of 3D CT acetabular inclination versus Cr levels

**Figure 5.7.** Scatter plot of 3D CT acetabular inclination versus Co levels
**Relationship between joint fluid and blood metal ion levels**

Of the 92 joint fluid samples analysed, 30 had paired whole blood samples. There was a significant and moderately positive correlation between the levels in whole blood and joint fluid for Cr (Spearman’s rho = 0.48, p=0.007) and Co (Spearman’s rho = 0.412, p=0.024) (Figure 5.8 and Figure 5.9). The linear regression analysis was as follows:

Joint fluid cobalt = 4.1 * Blood cobalt + 0.01 (95%CI, -4.1 to 12.2)

Joint fluid chromium = 7.5 * Blood chromium + 0.003 (95%CI, 1.8 to 13.2)

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**Figure 5.8.** Scatter plot of Cr ion levels in the whole blood and joint fluid of 30 paired samples
5.5 Discussion

This study primarily focused on hip joint fluid levels in symptomatic patients following MoM hip arthroplasty. The results have demonstrated the effect of acid oxidative digestion and shown this causes a significant increase in metal ions measured in both blood and joint fluid samples, thus providing the most accurate reflection of actual concentrations present. Interestingly the effect of protein digestion on liberation of metal ions was greater for Cr when compared to Co, suggesting that more chromium is bound to protein. Depending on the processing used, clinical studies in the current literature may be under or over reporting these levels and therefore demonstrates the need for a standardised laboratory protocol that is universally applied. It is only then that meaningful comparisons between studies examining metal ion concentrations can be made.

In comparison to other prominent studies in this field, a wider range of Cr and Co levels. (Table 5.2) was found. De Smet et al [196] analysed the joint fluid of failed MoM hips differentiating between those with and without metallosis observed at revision surgery. In patients with no metallosis, median Cr and Co levels of 179.5μg/l and 106.25μg/l respectively are reported. These values appear an order of magnitude lower than the ‘unexplained pain’ cohort (1137 vs 1127 μg/L) in this study. The demographics of their study sample appear similar to the present study in terms of gender composition (approximately 2
females: 1 male), manufacturer type (predominantly the BHR), femoral head size (>36mm) and mean time the implant was in situ prior to revision surgery (3 years). Thus, it would reasonable to assume the differences in results between this study and theirs relate to the laboratory processing of fluid samples, or possibly the effect of blood contamination quoted in their paper. Further interpretation is limited as they categorise their results by the term ‘metallosis’ (defined as a ‘gray discolouration’ at the time of surgery). This is an intra-operative description open to observer variation. Langton et al [78] report a series of seventeen failed MoM hips diagnosed with ARMD (encompassing the term ‘metallosis’) with metal levels approximately six times greater than either of two diagnostic groups in this study. This again may be related to the laboratory treatment of their joint fluid samples. These much higher levels may also represent a group of outliers as the predominant hip type in their study sample was the ASR (DePuy International Ltd, Leeds, United Kingdom). The group of patients available for this study may be considered more representative of the general population presenting to hip surgeons in terms of age, gender and the variety of hip types. The results of both studies do however echo the current study, in that a wide range of metal ion concentrations exists in the joint fluid of a failed MoM hip.
Table 5.2. Comparison of the median (range) metal ion concentrations between the current study and those previous

<table>
<thead>
<tr>
<th>Authors (number of patients in analysis)</th>
<th>Cause of Failure</th>
<th>Number of Patients</th>
<th>Joint Fluid Levels (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Chromium</td>
</tr>
<tr>
<td>Current Study (n=64)</td>
<td>Unexplained Pain</td>
<td>35</td>
<td>1337 (0-19,0416)</td>
</tr>
<tr>
<td></td>
<td>Defined Cause of Failure</td>
<td>29</td>
<td>1512 (0-263,298)</td>
</tr>
<tr>
<td>DeSmet et al[192] (n=26, of which 7 are bilateral)</td>
<td>Without Metallosis</td>
<td>N/A</td>
<td>179.5 (19-661)</td>
</tr>
<tr>
<td></td>
<td>With Metallosis</td>
<td>N/A</td>
<td>5136.5 (155-29,080)</td>
</tr>
<tr>
<td>Langton et al[78] (n=17)</td>
<td>Adverse Reaction to Metal Debris (ARMD)</td>
<td>17</td>
<td>~8,000 (1,000-46,000)</td>
</tr>
</tbody>
</table>

Joint fluid metal ions and category of failure

Joint fluid metal ion levels were examined according to modes of failure, which may help a surgeon looking for a reference range when treating MoM hip patients according to a specific diagnosis. No significant difference was found in joint fluid levels between those patients who present with unexplained pain and or those who fail by a definable cause. Fourteen patients in the latter group failed through aseptic loosening of either the acetabular or femoral component. The median values are not substantially different to those patients with unexplained pain (and who had well fixed components at the time of revision) for either log Cr (3.2 vs 3.1 µg/L) or log Co (3.1 vs 3.1 µg/L). The highest joint fluid Cr ion levels were noted in patients where the failure was attributed to a size mismatch between head and cup (log Cr 3.8 µg/L) or cup malorientation (log Cr 4 µg/L), compared to the unexplained group (log Cr 3.1 µg/L). While the numbers of patients in these groups are too low to draw any definitive conclusions, it is likely that these increased levels are due to higher wear rates where the mechanics of the MoM bearing are suboptimal. Irrespective of cause of failure, the range of Cr and Co levels in the joint fluid of failing MoM hips is too wide to establish a discrete threshold that would indicate toxic level. A limitation of this analysis is that other possible causes of MoM failure such as hypersensitivity [205, 206] or corrosion have not been examined for.

Manufacturer

No significant difference in the concentration of metal ion levels of failed MoM joints was found when related to manufacturer. This is likely to be explained by a relative uniformity in the alloy composition of most commercially available implants, consisting of cobalt to chromium ratio of 2:1. The manufacturing process, whether casted (e.g. such as the BHR) or
forged (e.g. Durom), does not appear to have influenced the local concentrations of metal ions. A wide range of metal ion values were observed, particularly in the ASR group, where two patients had joint fluid concentrations above 200,000μg/L. Both had steeply inclined cups on 3D-CT analysis and can be considered outliers. (The ASR component has since been discontinued).

**Head Size and Cup Inclination**

Femoral head size did not have an effect on local metal ion levels, with no difference between those above and below a 50mm cut-off. There is no available comparative data in the literature. Previously published studies have suggested that compared to larger diameter heads, smaller diameter hip resurfacing (<51mm) and total hip arthroplasty (<36mm) have greater metal ion levels as measured in either blood or serum [78, 89]. The findings of the present study does not support this hypothesis; the results suggest that of the two components of the MoM bearing couple, the orientation of the acetabular component, not head size [207, 208] is the primary determinant of wear particle generation. Edge loading of a steeply inclined acetabular cup continues to be the most likely mechanical explanation for this phenomena [87, 89]. Indeed, a significant positive correlation was demonstrated between anatomic cup inclination and the concentration of Co ion; but unlike other studies, no failed significant correlation was detected with Cr ion levels [87, 89]. This may relate to the method that was used to assess cup inclination. Two dimensional plain radiographs are prone to rotational and magnification error and are likely to suffer from observer variation when compared to 3D CT which has been shown to be more accurate for measurements of cup orientation [162].

**Correlation with blood metal ion levels**

Joint fluid has higher levels of Cr ions than Co with a failing MoM in situ, an unexpected finding given that hip resurfacing designs are composed of a metal alloy composition of 2:1 Co to Cr. These concentrations also reflect findings of in vitro studies that suggest raised levels of Cr and Co inhibit osteoblastic activity [209], induce osteocytic apoptosis [210], and upregulate osteoclastic cell [211], and may ultimately contribute to ‘component loosening’ as the mode of MoM failure. The reverse trend is true however in whole blood of the same patients, where Co is the predominant ion. This pattern has been recognised previously [78]
and suggests that the chromium is sequestered within the joint at far higher concentrations than cobalt which appears to be more readily disseminated into the circulation.

Four outlying results were noted with high Cr and Co concentrations in both joint fluid and blood samples. All had ASR components in situ, with two failures attributed to cup malorientation and two from unexplained pain.

In general, joint fluid levels had a wide range in vivo and were only moderately correlated with blood. The association is not as strong as previously reported by De Smet et al [196] who demonstrated a high correlation coefficient between serum and joint fluid samples for Cr (r=0.92) and Co (r=0.88). However, there are several differences between the current study and theirs. In this study, whole blood, rather than serum, was used in order to provide a more complete analysis of the concentrations of circulating ions. Daniel et al [212] demonstrated the variability and lack of agreement between values in concurrent serum and whole blood samples, recommending the latter as a more accurate measure of systemic metal ion levels. In a study measuring the distribution of Cr and Co ions in various blood fractions after MoM hip resurfacing, Walter et al [197] demonstrated that metal ion values are twice in serum than if whole blood were measured in the same sample and may explain the far higher correlation De Smet et al found. Secondly, it is not clear from De Smet et al whether an acid oxidation protocol was utilized during sample processing, which as demonstrated earlier in this study, will increase the variation in the results.

Several patients were noted to have relatively high joint fluid levels, despite blood levels in the normal range. This may illustrate that some patients have an increased renal excretion rate. These findings highlight the need to measure metal ion concentrations in the hip joint of symptomatic patients, particularly in the presence of other normal investigations, in order to determine a poorly functioning hip.

For clinical purposes, blood is easier to ascertain from a patient rather than joint fluid, and its use for metal ion levels continues to be investigated. There does not appear to be consensus in the literature as to whether serum or whole blood should be used as both continue to be utilised in clinical studies, and appear to have correlation with joint fluid levels [213-215]. Hart et al [216] performed a pair-matched, case-control study to investigate the sensitivity and specificity of whole blood metal ion levels for diagnosing failure in 176 patients with a unilateral MoM joint. They investigated the 7 parts per billion cut-off level recommended by
the MHRA and a specificity of 89% and sensitivity 52% for detecting a pre-operative unexplained failed MoM replacement. Although this study suggests blood metal ions had good discriminant ability to separate failed from well-functioning hip replacements, a subsequent study by the same author [217], suggested there was a lack of sensitivity and positive predictive value for these to be used alone in the clinical management of failing MoM hips. Blood metal ion levels remains one of several investigation that can be used in investigating the painful MoM hip.

5.5.1 Limitations

First, the amount of Cr and Co in the joint fluid measured may have not necessarily quantified the amount of physiologically active material in vivo, because this will also depend upon whether the metal ions are derived from particles. The trigger for soft tissue inflammatory reactions is not yet known. Although cobalt ions have been implicated [218], the relative contribution of the different debris species remains speculative. Secondly, not all of the factors likely to influence joint fluid concentrations such as total fluid volume within the hip have been examined, making it impossible to determine the total amount of metal ions present in the joint. It has been assumed that metal ion concentrations are uniform throughout the joint and that is reflected in the aspirate obtained. It is likely that if volume differences were accounted for, a smaller variation in total metal ion levels would be found and a stronger correlation between these levels and blood, or category of failure, could be determined. Indeed, this study failed to detect a significant difference in metal ion levels in several of the analyses performed, such as between types of failure or head size. It may have been insufficiently powered to demonstrate a difference, however it is the largest by number in the field currently. This type of multivariate analysis would require hundreds of fluid samples, and are beyond the scope of this study. Fourthly, although all patients in this study had haemoglobin (Hb) and haemtocrit (Hct) values within the normal range, the impact of parameters on the concentration of ions measured in the whole blood analysis was not accounted for. Lastly, corrosion, as well as wear, can contribute to metal ion levels in the joint fluid of failing MoM hips. Both fretting and passive corrosion is evident in modular MoM total hip components at the taper junction [219]. A further limitation of this study is that a comparison between hip resurfacing devices and modular components has not been performed, as the number of the latter in the sample of 92 hips analysed was only nine. The differing metal ion levels that could arise from either wear or corrosion have not been examined.
Following a recent MHRA device alert, metal ion analysis of blood and joint fluid is likely to grow, particularly as the cause of failure in a substantial portion of these patients remains ‘unexplained’ [2]. This study on hip joint fluid levels following MoM hip arthroplasty has attempted to provide new information, relevant to surgeons, and to researchers performing mechanistic studies on the periprosthetic tissue reactions following this type of arthroplasty. First, acid digestion of joint fluid samples is required to accurately determine metal ion concentrations such that meaningful comparisons can be made between clinical studies adhering to a standardised laboratory protocols. Secondly, joint fluid levels are present in vivo over a wider range of values and are not as strongly correlated with whole blood levels as previously thought. Lastly, this study, currently the largest by number of joint fluid samples in the literature, provides a reference range to surgeons following up patients with MoM hip arthroplasties looking to interpret the results of fluid analysis.
CHAPTER 6

The Accuracy of CT Based Navigation Versus Freehand Hip Resurfacing: An Analysis of Acetabular Component Orientation

6.1 Abstract

The accuracy of cup orientation in Metal on Metal (MoM) hip resurfacing arthroplasty performed by either freehand technique or CT based navigation was compared. Seventy five patients (81 hips) underwent either freehand (n=42) or navigation (n=39) surgery, both requiring a three dimensional (3D) CT plan. Surgery was conducted by hip specialists blind to the method of cup implantation until the operation. Deviation in inclination and version from the planned orientation, as well as, number of cups within a 10° safe zone and 5° optimal zone of the target position was calculated using post operative 3D CT analysis.

Error in inclination was significantly reduced with navigation compared to freehand technique (4° vs 6°, p=0.02). We could not detect a difference between the two groups for version error (5° vs 7°, p=0.06). There was significantly greater number of hips within a 10° (87% vs 67%, p=0.04) and 5° (50% vs 20%, p=0.06) safe zone when navigated.

Image based navigation can substantially improve accuracy in cup orientation. The results of the freehand group appear better than historic controls, suggesting the use of a 3D plan may help to reduce technical error. The results of this study suggest the use of image based navigation in MoM hip resurfacing arthroplasty may be of benefit.
6.2 Introduction

Metal on metal (MoM) hip resurfacing may offer similar or better functional outcome for the young arthritic population when compared to total hip replacement [220-222], with the proposed advantages of preserving acetabular and femoral bone stock and retaining native biomechanics. However, errors in cup orientation have lead to adverse outcomes affecting implant survival: high inclination (abduction) angles have been shown to cause edge loading with subsequent increase in wear and raised circulating metal ions [223-225]; while errors in version have been associated with pseudotumour formation [226] and impingement [227]. Such complications have been recorded by registry data [228, 229], causing concern regarding the continued used of resurfacing arthroplasty.

Established by Lewinnek et al [230] over 30 years ago, the de facto standard for cup orientation remains a ten degree ‘safe zone’ around 40° inclination and 15° anteversion. A safe zone based on absolute values of inclination and version has not been universally accepted. This standard fails to account for variations in hip morphology [231], the surgeons own preference in cup orientation and specific features of cup design [232].

Aids to assist the surgeon in achieving the required cup orientation such as mechanical jigs have been developed but are inconsistent and unreliable [233-235], failing to provide the necessary level accuracy required by MoM couples. These guides cannot account for the spatial orientation of the acetabulum in the pelvis [236], nor changes in pelvic tilt that occur during surgery [237].

The last decade has seen a growing interest in computer assisted orthopaedic surgery (CAOS) systems as a means of improving technical performance. This technology provides real time intra operative feedback to the operator. Two types of navigation technology exist: either ‘image based’ or ‘image free’. Both require a virtual three dimensional (3D) reconstructed model of the hip joint to apply a pelvic frame of reference and plan surgery. Image based technology utilises a fluoroscopic image or computed tomographic (CT) scan of the patient’s hip, allowing anatomical parameters to be determined pre-operatively. Image free devices rely on a hip shape approximated from an atlas of randomised scans, refined intra-operatively by acquisition of the bone surface. The virtual model is matched to the native anatomy intra operatively, a process termed ‘registration’, and the component implanted to the desired position.
Recent studies have suggested that the development of hip osteoarthritis is associated with a morphological abnormality of either the proximal femur or acetabulum [238, 239]. ‘Femoracetabular impingement’ encompasses two of these patterns: the ‘cam’ lesion, typically seen in males, and the ‘profunda’ pattern, found predominantly in females. Morphometric analyses of both reveals subtle differences in the inclination, version and acetabular rim profile [231, 240] which may influence a surgeon’s judgement of cup orientation during implantation. Such variations in native hip morphology cannot be accounted for, nor appreciated preoperatively by the surgeon developing a patient specific strategy, if using an image free system.

While there are numerous studies examining the accuracy of image free navigation systems in total hip arthroplasty, reports of image based systems, particularly in hip resurfacing, are limited. The aim of this study was to compare the accuracy of cup orientation using a CT based navigation system to freehand surgery in hip resurfacing arthroplasty.

6.3 Method

This was a retrospective analysis of prospectively collected data in a cohort of MoM hip resurfacing patients performed by two surgeons in two hospitals, part of a single institution. Using 3D CT analysis, the accuracy of acetabular cup orientation was investigated in two concurrent groups of patients: one performed by freehand technique using conventional instruments and another performed using image based navigation. The use of CT pre and post operatively was approved by the Charing Cross Hospital research ethics committee prior to the study commencing (REC number 04/0002). Consented patients were recruited over a 30 month period, between January 2008 and June 2010, and were blind to the mode of surgery performed.

Randomisation

One navigation system with calibrated hip instrumentation was available, as well as one conventional hip resurfacing set. Thus a maximum of two resurfacing procedures could be performed on any one operating list. The order of cases and mode of surgery were assigned randomly by a blinded booking clerk. There was no pre-emptive selection for navigation by the operating surgeon, who was blind to the mode of surgery until the day of operation. This allowed an analysis on 75 consecutive patients who had arbitrarily fallen into two cohorts, either freehand or navigated, of approximately equal size.
**Inclusion and Exclusion Criteria**

Males and female subjects aged over 18 years of age requiring HR on clinical and radiological grounds fulfilled the inclusion criteria. Hip specific criteria were radiological evidence of good acetabular and femoral bone quality with minimal cystic change. All patients consented to pre and post-operative low radiation dosage CT scans, the imaging from which had been approved for several studies. There were no patients lost to follow up. Patients over the age of 75 years were excluded.

**Pre-Operative Planning**

All patients underwent a pre and post-operative low dose CT scan developed at Charing Cross Hospital in London [241]. Sections were taken through the ASIS and hip at 4mm and 1mm slice thickness respectively, and 4 mm through the knee. The radiation exposure was 2 mSV per scan; this is equivalent to two long leg radiographs [241]. This data was saved as Digital Imaging and Communications in Medicine (DICOM) files, from which bone anatomy was extracted using a semi automated segmentation process using commercially available software (Acrobot Planner and Modeller version 1.16, The Acrobot Company Ltd, London, UK).[242] Bone surfaces were reformatted to produce a three dimensional (3D) virtual model of the patient’s pelvis and hip. The APP frame of reference was applied by selecting the anterior most prominences of the ASISs and pubic tubercles. By placing 30 data points on the acetabular floor and rim, the native socket orientation was calculated by fitting a best fit plane across the cup face,. A hip resurfacing cup (Cormet, Corin plc, Cirencester, UK) of appropriate size was seated initially to the appropriate depth and planned to 40° inclination and 20° anteversion.Cup version was refined by aligning the anterior edge of the cup with the psoas valley of the acetabular rim, leaving the posterior edge proud of the ilio-ischial valley. Inclination was adjusted such that the superior edge of the cup was adequately covered by the iliac eminence. Having planned the position of the femoral component, the full range of motion of the HR was simulated on the surgical plan, carefully examining for neck on cup impingement. The preoperative plan served as a guide for the surgeon to be refined intraoperatively as local bone condition allowed (Figure 6.1). For freehand cases, cup orientation was judged based on the relationship of the cup edge to the acetabulum rim as described above.
Operative procedure

For each procedure, the surgical plan was uploaded to an image-based navigation system (The Acrobot Wayfinder, Stanmore Implants Worldwide, Stanmore, UK). The system is composed of a monitor, central processing unit and two digitising arms; one that securely attaches to the pelvis and the other to custom-made hip instrumentation (Corin plc, Cirencester, UK) calibrated for purpose. All patients were placed in the lateral decubitus position and the hip exposed via a posterior approach. In navigated cases, the pelvis digitising arm was interlocked with a custom adapter to two half-threaded bone pins drilled into the roof of the acetabulum. Any change in pelvic position could now be recorded and compensated for by the second ‘tool’ arm. Using a ball tip probe, pair point matching was performed for initial registration, followed by surface registration of 32 data points acquired on the acetabular floor and rim. Bone anatomy was thus matched to the virtual model to an accuracy of less than 1 millimetre (mm) root mean square error. A final ‘reality’ check comparing the real time motion of the tool arm on the monitor to the actual hip was performed by running the probe over readily identifiable bony landmarks such as the ischial eminence and cotyloid fossa. No registration of the ASISs was required and any rim osteophytes were removed. The acetabulum was reamed and the cup initially impacted into the desired preoperative orientation with the tool arm connected to a calibrated impactor. Cup orientation was refined as local anatomical conditions allowed. To ensure sound press fit of the acetabular component used, the arm was disconnected for final impaction before being reconnected to record the final cup orientation. This was logged as a snapshot on the system and recorded in the operation summary. It was these values that were used to compare the achieved cup orientation on postoperative CT.

When non-navigated, hip resurfacing arthroplasty was carried out as per the operation technique described by the manufacturer (Cormet, Corin plc, Cirencester, UK).

All surgery was performed by senior hip surgeons (Professor Alister Hart and Professor Justin Cobb), having performed 30 computer navigated hip arthroplasty procedures prior.
Figure 6.1. Illustration of key steps involved in planning and executed a navigated hip resurfacing case. A 46 year old male presented with a severely degenerate left hip joint. He was randomised to have navigated surgery and underwent the following key steps: a) Pre-operative antero-posterior and lateral radiographs b) 3D reconstruction of the pelvis following segmentation. The cup is planned to the desired orientation accounting for the grossly distorted hip anatomy c) The virtual acetabulum is ‘registered’ to the native bone and the cup implanted to the target position d) Post-operative 3D CT measurements performed reveal a final cup orientation of 41°inclination and 19° anteversion.
Postoperative Analysis

A post-operative CT scan was performed at a minimum of 6 weeks after surgery, allowing the patient enough time to recover and re-ambulate. An extended Hounsfield range of up to 16,000 units was used, allowing clear image capture of the implanted components with minimal metal artefact. The data was reformatted to 3D models and analysed using previously validated software (Robins 3D, London, UK). The APP was reapplied and the transverse and parasagittal planes were established. A plane across the cup face was produced by setting points along the rim of the acetabular component. The anatomical inclination was defined as the angle to the transverse plane and anatomical version as the angle to the parasagittal plane.

The intra class coefficient was calculated to examine intra-observer reliability of cup measurements between the primary researcher (KD) and a blinded researcher (Dr Niall Smyth). To do this, the anonymised CT scans of thirty patients were randomly selected and the component orientation in both inclination and version measured. For inter-observer variability, the measurements for the same thirty patients were conducted after a two week interval.

The primary outcome measure was the change in cup orientation, defined as the difference between the planned and achieved inclination and version angles. This difference was expressed as ‘angle error’ and is presented as radiological values. The secondary outcome was the number of cups within 5° and 10° of the surgeons intended cup orientation.

6.3.1 Statistical Analysis

Data was analysed using SPSS software (SPSS inc, Chicago, Illinois). Normal distribution was demonstrated on Kolgomorov- Smirnov test. Hence any difference between the freehand and navigated group was investigated using two tailed Student’s T test. A significance level was set to a p value of less than 0.05. The number of cases within 10°,and 5°, of the planned orientation was converted to dichotomous data and compared by Fisher’s exact test.

6.4 Results

A total of 81 hips (in 75 patients) were investigated. Forty two cups were implanted using the freehand technique and thirty nine using CT navigation. The epidemiological characteristics of each group are presented in Table 6.1
Table 6.1.  Patient demographics of the freehand navigated hip resurfacing group

<table>
<thead>
<tr>
<th></th>
<th>Freehand</th>
<th>Navigated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>26</td>
<td>31</td>
</tr>
<tr>
<td>Females</td>
<td>16</td>
<td>8</td>
</tr>
<tr>
<td>Side</td>
<td>L = 16, R = 26</td>
<td>L = 12, R = 19</td>
</tr>
<tr>
<td>Mean age at time of surgery (years)</td>
<td>53 (range 26-68)</td>
<td>56 (30-74)</td>
</tr>
</tbody>
</table>

Table 6.2.  The inter and intra observer reliability of cup orientation measurements using 3D CT on thirty randomly selected hips.

<table>
<thead>
<tr>
<th></th>
<th>Inclination</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inter-observer ICC</td>
<td>0.99 (95% CI 0.98-1.0)</td>
<td>0.98 (95% CI 0.96-0.99)</td>
</tr>
<tr>
<td>Intra-observer ICC</td>
<td>0.99 (95% CI 0.98 – 0.99)</td>
<td>0.99 (95% CI 0.99 – 0.99)</td>
</tr>
</tbody>
</table>

A summary of the absolute orientation values for both study groups is given in Table 6.3. The angular error in cup orientation between the freehand (n=42) and navigation (n=39) groups was compared and summarised in Table 6.4.

Table 6.3.  Summary of the planned and achieved cup orientation in the freehand and navigated hip resurfacing group (‘Inc’ = inclination, ‘Ver’ = version).

<table>
<thead>
<tr>
<th></th>
<th>Freehand</th>
<th>Navigated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Planned</td>
<td>Achieved</td>
</tr>
<tr>
<td>Mean 95% CI</td>
<td>Inc  (39-41) Ver (13-14)</td>
<td>Inc  (36-41) Ver (15-20)</td>
</tr>
<tr>
<td>Median</td>
<td>38</td>
<td>38</td>
</tr>
<tr>
<td>Range</td>
<td>37-43</td>
<td>10-20</td>
</tr>
</tbody>
</table>
Table 6.4. The error in inclination and version between the freehand and navigated hip resurfacing group; the number of hips falling within a 5 and 10 degrees of the surgical plan

<table>
<thead>
<tr>
<th></th>
<th>Freehand (n=42)</th>
<th>Navigated (n=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inclination Error</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (95% CI)</td>
<td>6 (4-7)</td>
<td>4 (3-5)</td>
</tr>
<tr>
<td>Median</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Range</td>
<td>0-24</td>
<td>0-18</td>
</tr>
<tr>
<td><strong>Version Error</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (95% CI)</td>
<td>7 (5-8)</td>
<td>5 (4-6)</td>
</tr>
<tr>
<td>Median</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Range</td>
<td>0-20</td>
<td>0-18</td>
</tr>
<tr>
<td><strong>Safe Zone Placement</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 10°</td>
<td>28 (67%)</td>
<td>34 (87%)</td>
</tr>
<tr>
<td>Within 5°</td>
<td>9 (20%)</td>
<td>20 (51%)</td>
</tr>
</tbody>
</table>

The use of a navigation system significantly reduced inclination error when compared to freehand technique (p=0.02). There was no difference in version error between the two groups (p=0.06). However, the range of error for both inclination and version was lower in the navigated group.

The difference in accuracy between the navigated and freehand group is further illustrated when applying a 5°, and 10°, safe zone on a scatter graph of inclination against version error (Figure 6.2). Eighty seven percent of hips were within 10° of the planned cup orientation, compared to 67% in the freehand group (p=0.04), with 51% of those navigated within 5° of the plan (p=0.006).
Figure 6.2. Scatter graph demonstrating the number of hips falling within 5° and 10° of the planned cup orientation.

6.5 Discussion

To date there appears to be no study in the current literature investigating the use of an image based COAS system for MoM hip resurfacing. The results demonstrate that inclination error in particular is significantly reduced with a CT based system. A significantly higher number of cups were within 10° of the surgeons planned orientation, whilst 51% of cups were within 5°.

Numerous studies investigate the accuracy of cup placement in total hip arthroplasty with only one study examining this subject in the context of hip resurfacing. Romanowski et al [243] examined the accuracy of cup inclination using an imageless system (VectorVision hip SR 1.0, Brainlab, Feldkirchen, Germany) and found postoperative inclination ranged from 43-46° from a preoperative target of 40, as measured on plain two dimensional radiographs. There is no data regarding the version accuracy or number of hips within a target zone reported in this paper.
Indeed, as demonstrated in a previous chapter, radiographic analysis of cup position is prone to errors in pelvic tilt and rotation as well as observer variation when compared to 3D CT [244]. The x-ray beam in an antero–posterior pelvic radiograph is not perpendicular to the socket, with resulting divergence causing error in magnification and angular measurements. Measurements of cup version in particular are difficult as the cup rim is difficult to visualise when superimposed on a metal head [245]. Postoperative analysis with 3D-CT should remain the measuring tool in order to make standardised comparisons amongst studies reporting angular accuracy as an outcome measure.

6.5.1 Limitations

Two extreme outliers were noted in the navigated group, one with 18° of inclination error and the other with 18° of version error. Deviations in cup placement could be related to impaction of a press fit component, because of oversizing, under or over reaming.

A relatively high level of accuracy in cup orientation is evident in the freehand group, with 67% of patients within a ten degree safe zone of the planned position. This is substantially better than several other studies examining freehand cup placement [246-248]. These results may be confounded by several factors: Firstly, both surgeons had the 3D preoperative virtual plan available during surgery allowing comparison to their real time orientation. This may have improved their visual-spatial perception of the relationship of the cup within the bony socket. This has been illustrated by Gofton et al [249] who demonstrated that novice surgeons performed cup orientation significantly better with the use of a virtual surgical plan. Secondly, both surgeons may have experienced an accelerated learning curve that improved their freehand performance while concurrently using navigation, an effect demonstrated in both hip and knee arthroplasty [243, 250-252]. This study may be improved by comparing surgeons with access to CT navigation to those with none, in an independent centre. It is likely that the accuracy of navigation compared to freehand would have been shown to be greater in this case.

A 40° inclination and 20° anteversion target was selected for this study as it was recommended by the manufacturers for the functional CAAA of the Cormet cup. These values may differ depending on the particular cup preferred by the surgeon, requiring relatively simple calibration by the navigation system. There is a lack of consensus in recent clinical studies as to the target cup orientation surgeons should aim for. This will vary
according to the particular cup used and manufacturer recommendation, as well as whether the orientation has been defined according to anatomical, operative and radiographic values. Not all surgeons will choose to implant a cup at the absolute values of 40° inclination and 20° version, choosing instead to orientate relative to the local anatomy which can be appreciated on an image based plan. Native hip version, socket inclination and acetabular rim pattern vary according to hip morphology [135] and may influence the depth of reaming, as well as cup orientation selected during surgery. Thus the target orientation will vary from individual to individual [253]. With image based analysis, hip shape, size and anatomical aberrations can be appreciated, facilitating preoperative planning of difficult cases.

The safe zone used in this study of ten degrees about the target orientation is a commonly accepted range, based on Lewinnek’s original paper [17]. There is no single study in the current literature that defines the optimal range or whether it should narrower or wider than the ten degrees used currently. Only one study has examined this issue in the total hip arthroplasty literature with reference to hard on soft bearings. Grammatopoulos et al [254] assessed the orientation of the acetabular component in 1070 primary total hip arthroplasties aiming to determine the size and site of the target zone that optimises outcome. Outcome measures included complications, dislocations, revisions and the difference between the Oxford Hip Scores pre-operatively and five years post-operatively. Placing the component within Lewinnek’s zone was not associated with improved outcome. Of the different zone sizes tested (± 5°, ± 10° and ± 15°), only ± 15° was associated with a decreased rate of dislocation. The dislocation rate with acetabular components inside an inclination/anteversion zone of 40°/15° ± 15° was four times lower than those outside. The only zone size associated with statistically significant and clinically important improvement in the Oxford hip score was ± 5°. This study demonstrated that with traditional technology surgeons can only reliably achieve a target zone of ±15°. As the optimal zone to diminish the risk of dislocation is also ±15°, surgeons should be able to achieve this. However, the study does conclude that the target zone of ± 5°is small and cannot, with current technology, be consistently achieved. A future avenue for work from this thesis would be to define outcome related to a target safe zone for MoM bearings.

The system used in the study offers several advantages to image free systems. Though a preoperative CT scan is required for image based systems, the radiation dosage is low, equivalent to several long leg radiographs, while maintaining bone detail to a slice thickness
of 1mm. Indeed, low radiation dosage scanners are now available commercially and with time it is likely will grow in popularity, negating the need for the existing scanning protocol. Secondly, image free systems require the APP to be registered with the patient supine, prior to formal prepping, via percutaneous incisions over the relevant bony prominence. This is prone to surgeon error and variability and [255, 256], presenting unnecessary morbidity to the patient. Lastly, intra-operative changes in pelvic tilt cannot be detected nor compensated for by these systems.

Metal on metal hip resurfacing can be a viable surgical option for the arthritic hip in a patient group that have high functional demands and are likely to outlive their prosthesis. The risk of complications arising from surgeon error associated with cup orientation may be negated with the use of modern technology. In order to offer a patient specific strategy that is highly accurate and accounts for individual variations in hip morphology, the results of the current study suggest the use of CT based navigation should be strongly considered.
CHAPTER 7

Discussion

7.1 General Discussion

The number of hip arthroplasty procedures performed worldwide is rapidly growing. Patients requiring hip arthroplasty are not only the elderly and infirm, but a younger cohort with greater functional requirements. The complications of hip arthroplasty are well documented and include impingement, dislocation and wear. Newer bearing couples such as metal on metal initially offered an advance on traditional couples, but have lost favour due to problems of wear, local soft tissue masses and unexplained pain resulting in premature failure. The premise of this thesis was to examine the various aspects of accuracy and error associated with hip arthroplasty surgery from an investigation of proximal femoral morphology, to evaluating a means of improving surgeon accuracy in acetabular cup orientation.

A drive toward transparency and better clinical governance has resulted in the NJR of England and Wales publishing the clinical results of surgeons performing hip arthroplasty as of 2013. Whilst there has been criticism of the nature and accuracy of the data recorded in the registry, there is no doubt that in this era of revalidation, the technical performance of individual surgeons will be closely examined and outliers scrutinised. Surgeons will need to demonstrate objective measures of their ability. In the UK, the Joint Committee of Surgical Training (JSCT) has recognised this, producing a mandate to integrate simulation into training for orthopaedic surgeons. Navigation technology, as demonstrated in Chapter 2 of this thesis, is a useful resource to objectively measure trainees in achieving a target cup orientation. The sample of trainees tested in this was small and their performance was recorded only as a snapshot. The study did demonstrate the wide and varying range of cup orientation achieved, despite the number of hip procedures previously performed. Further work is required to develop this pilot study into a robust and validated model suitable for a competency based assessment in hip arthroplasty.
Variations in femoral orientation at the time of imaging are likely to have contributed to the error and range of alpha angles reported in the literature in the analysis of cam hips. A means of standardising the orientation and position of each femur is this important when investigating normal and abnormal hip morphology and may overcome such issues. A novel means of determining the femoral neck axis based on the neck shape was developed in Chapter 3 using a customised mathematical algorithm. A unique frame of reference based on a sphere applied to the femoral head, piriform fossa and lesser trochanter was created. The centre of the femoral head was shown not to be collinear in x and y space with the femoral neck axis in normal hips. The articular surface extends further anteriorly and posteriorly and appears reciprocal to the shape of the acetabulum at these points as described by others [135, 145]. These anatomical features may aid femoral head device design. The development of a three dimensional neck axis may have use in computer navigation software for pre-operative surgical planning in head resurfacing. Subsequent to this study, Masjedi et al have utilised this 3D femoral neck axis to describe various anatomical parameters in normal and abnormal hips [141, 142].

Plain radiographs are the standard imaging used by surgeons to measure hip arthroplasty orientation. However, these images are prone to errors in pelvic orientation and magnification distortion that contribute to observer reliability. Several seminal papers have utilised EBRA software to measure the orientation of cups in MoM arthroplasty and relate these to complications. The study conducted in Chapter 4 demonstrated a substantial difference in cup version measurements between 2D EBRA analysis and 3D CT. The acetabular rim is obscured and cannot be delineated against the metal shell of the femoral head on a normal hip radiograph. The accuracy of measuring MoM cup orientation can thus be increased with the use of 3D-CT when the appropriate Hounsfield setting to demarcate the cup rim is used. The findings of Chapter 4 suggest that studies utilising EBRA software investigating MoM hips may have drawn conclusions on erroneous cup version measurements.

With the growing number of failing MoM hips, government guidelines were produced in 2010 requiring surgeons to monitor patients with a MoM hip in situ and if necessary measure the metal ions levels in blood and synovial fluid. In Chapter 5, the concentrations of chromium and cobalt ions in the joint fluid and whole blood of ninety two patients with failed current generation MoM hips was analysed. An acid oxidative digestion was utilised in the trace metal analysis protocol resulting in significantly higher levels of metal ion
concentrations. Patients were sub categorised by mode of failure, either ‘unexplained pain’ or ‘defined causes’ (eg aseptic loosening, cup malorientation and infection). Using this classification, chromium and cobalt were present over a wider range in joint fluid and not as strongly correlated with blood as reported previously in the literature. There was no significant difference between metal ion concentrations and manufacturer nor femoral head size below or above 50mm. There was a moderate positive correlation between metal ion levels and cup inclination as measured on 3D CT. This chapter demonstrated a substantial difference between an acid and non acid digestion protocol, suggesting that a standardised laboratory protocol be used by surgeons and researchers investigating metal ion levels and periprosthetic tissue reaction in this type of arthroplasty. A further avenue of study would be the analysis of the relationship between cup version and joint fluid metal ion levels. Establishing a base line of joint fluid metal ion levels in the asymptomatic patient with a metal on metal bearing would also be of value, but may difficult from an ethical standpoint as the risk of infection in aspirating the joint too high for the potential scientific benefit.

In the last chapter, the difficulty of achieving the ideal cup orientation was addressed, with the use of image based computer navigation technology in a cohort patients undergoing MoM hip resurfacing. Error in inclination was significantly reduced with navigation compared to freehand technique. Postoperative measurements were carried out on 3D-CT reconstructions, which as previously demonstrated, is a more robust tool for this purpose. Furthermore, there was a significantly greater number of hips within a 10° safe zone of the target cup orientation when navigated. The results of this study suggest that CT based navigation technology may help improve accuracy in the technically demanding step of orientating a metal cup.

7.2 Thesis Limitations

Increasing reports of complications, premature failure and early revision of MoM hips has had a demonstrable impact on usage: the number of MoM hip resurfacings performed as the primary arthroplasty in England and Wales has steadily declined from 10% in 2006 to 1% in 2012 [257]. Furthermore, computer navigation was used in only 0.3% of any type of hip arthroplasty case. Thus, the results of chapter 5 are unlikely to have any significant impact amongst hip surgeons in the current climate. However, the use of uncemented sockets is outpacing that of cemented cups with over 47,000 implanted in 2012, and it is for this use that navigation technology may yet still have a purpose. In a time of revalidation where hip surgeons will need to show objective measures of technical performance, navigation remains
a validated tool. In the NHS, cost of hardware, pressures of delivering a target driven service, and lack of support to train surgeons and nurses are the likely barriers to widespread adoption.

**The Use of CT**

Computed tomographic scans were used extensively in this thesis in order to measure cup orientation and produce preoperative surgical plans for computer assisted surgery. The radiation dosages involved may be of concern, but it should be stressed that these were low. The scanning protocol used in this study exposes the patient to 1.7 mSv, the equivalent of 3 pelvic radiographs and less than the 10 mSv of a traditional pelvic CT. The scans, both pre and postoperative have been utilised for several research studies within the MSK laboratory of Imperial College and form part of an extensive image database. Two studies have shown that CT appears as accurate as MRI in detecting and demonstrating the geometry of articular cartilage [258] [259]. It has a higher resolution than MRI and will produce better 3D images, thus allowing for more accurate measurements in multiple planes. The repeatable of measurements is further improved by the use of Hounsfield units set to a standard value to identify bony limits.

**The Safe Zone Is Variable**

In order to define the accuracy of acetabular cup orientation, the concept of the safe zone was utilised in this thesis. This is a commonly used reference standard and has provided a means of expressing surgeon error. It relies on the use of the APP as a reference plane and accurate measures of cup orientation, be it two or three dimensional. However, different conventions used to describe cup orientation have produced substantial variations in the recommendations for correct positioning, making it difficult for clinicians to properly interpret and apply previously reported studies. Yoon et al examined nine articles recommending target safe zones, and showed that the choice of reference frame and definition of cup orientation angle significantly altered the target orientation [260].

Outcome following hip surgery can be measured according to patient satisfaction with the use of validated questionnaires, as well as objective measures of function such as gait analysis. Determining a correlation between the accuracy of component orientation and these outcome measures requires further investigation and provides an interesting avenue for future work.
The Femoral Stem

The successful function of a hip arthroplasty relies on not just the cup orientation but that of the accuracy femoral stem position, which has not been considered in this thesis. A finite element study has suggested that the optimal ‘combined version’ of both femur and acetabulum prostheses is 37° [261] to ensure impingement free motion. Clinically, Ranawat et al defined a target combined version of between 25° and 35° for men and up to 45° for women [262]. Several studies have shown that achieving this orientation with cementless stems is inaccurate [263, 264]. Gaining a stable press fit demands a compromise between the geometry of the stem and that of the proximal femur, in particular the anteversion and the anteroposterior dimension of the femoral isthmus. As the use of cementless stems grows, the study of achieving accurate femoral stem orientation provides another avenue of research that continues from this thesis.

7.3 Personal Perspective

As a training Orthopaedic surgeon, I examined my own practice and those of the senior surgeons I worked for. The first formal Orthopaedic procedure that I learnt was the total hip replacement. This is a transformational procedure that delivers amongst the highest level of satisfaction amongst patients of any surgical discipline. It is a procedure that will dramatically alleviate pain, and allow patients to return to a much improved level of function and quality of life. Yet it was clear to me that there were areas of surgery where my performance could improve, in particular that of cup orientation. This seemed to me an almost arbitrary step, where the simple instruction of most trainers was to point the acetabular cup introducer to the ‘corner of the room’. I initially had no concept of local anatomical references, or indeed that various hip morphologies could influence my orientation. Hence this thesis has focussed primarily on cup orientation: how it can be assessed both in real time during implantation, as well as post operatively with current imaging modalities. This provided the motivation for Chapters 2 and 4. The start of this work coincided with some of the early reports of metal on metal hip failure. This provided further incentive to examine the consequences of acetabular malorientation with this new bearing surface. From this initial concept, grew Chapter 5 where I could examine the association of joint fluid metal ion levels with multiple variables and not just cup inclination. The relationship with cup version was not possible during the study and is an avenue for further work.
Since the late 2000’s, the use of metal on metal hips has dwindled as evidenced by recent National Joint Registry data. Thus, I would suggest the impact of Chapter 6 and navigation technology in improving acetabular orientation for this bearing type, is minimal. Using an image based navigation platform such as that available for this thesis is costly, requires additional personnel and equipment that is unlikely to be funded by the National Health Service. The accuracy of image free platforms for cup orientation in total hip arthroplasty has been established in the literature as outlined in the Introduction of this thesis and may yet have a role to play. With the advent of professional revalidation and the requirement to show objective measures of surgical performance, hip surgeons may be more motivated and encouraged to adopt technology that can document their accuracy. It should also be remembered that the cup orientation measured by navigation is perhaps a static snapshot taken with the pelvis in a fixed position. The orientation of the cup is dynamic: version and inclination change at any one time as the pelvis moves and rotates during the gait cycle. The functional safe zone and how it relates to different hip morphologies, as well as bearing types, requires further analysis and investigation.

It is, however, training the Orthopaedic surgeons of tomorrow where I believe the greatest potential of navigation technology lies, and may indeed provide the most fruitful area of future work from this thesis. Surgical simulation of hip surgery remains in the embryonic stages. Establishing a frame work and validating a synthetic bone model that will satisfactorily test a participant’s performance has yet to be developed. Ensuring transfer validity from the laboratory to the actual operating theatre is the ultimate goal of any teaching simulation package. It is a complex and engaging area of interest and one that would provide the basis for another thesis.

I hope that I am a far better hip surgeon now that I was at the beginning of this journey. Understanding local acetabular anatomy and an increased visual spatial awareness of the pelvis has allowed me to refine my technique of cup orientation. The process of research in itself and writing this thesis has had as much impact on my practice as the material I studied. I am far better equipped to critique and analyse the literature that contributes to the evidence base of my practice.

The question of accuracy in component orientation and its relationship to functional outcome remains ultimately unanswered. If the number of acetabular components being implanted were as malorientated as the results of Chapter 2 suggest, then it is likely we would see a far
higher number of hips failing than actually occurs. Functional outcome therefore is multifactorial, based on the dynamics and characteristics of the patient, the devices and bearings used and ultimately the surgeon who implants them. Whilst technology may help, hip surgery remains as much art and fine craft, as it is science.
Publications Of Work From This Thesis


Cobb JP, Davda K, Ahmed A, Hart AJ Why large head metal on metal hip replacements are painful: The anatomical basis of psoas impingement on the femoral head junction

Presentations Of Work From This Thesis

Davda K., Smyth N, Henckel, J, Cobb JP, Hart AJ EBRA software is inaccurate for measurements of cup orientation in MoM hips compared to 3D-CT. AAOS, San Francisco, USA, February 2012;

Joined At The Hip – Meeting of Surgeons and Engineers, Institute of Mechanical Engineers, London, November 2011; BOA/ IOA Combined Meeting, Dublin, Ireland, September 2011


Posters of Work From This Thesis


References


