Cost Effective, Reliable Implantation of Acetabular Cups in Total Hip Arthroplasty

Claire L. Young

Department of Biomedical Engineering

University of Strathclyde

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Signed: Clic Young

Date: 9th June 2016

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"*Now to Him who is able to do above and beyond all that we ask or think according to the power that works in us – to Him be glory in the church and in Christ Jesus to all generations, forever and ever."* Ephesians 3: 20 – 21

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To my parents, Joe and Lisbeth, thank you for all your support. For encouraging me to take this opportunity and for all your inspiration and input. To Megan, thank you for all the coffee, cake, chats and your wonderful friendship and to Andrew for your love and support, for being my helper and keeping me going to the finish line.

Abstract

Correct positioning of the acetabular cup is critical for success within Total Hip Arthroplasty. Malpositioning of the acetabular cup contributes to many complications, all of which lead to revision surgery. Despite recognition of the importance of correct orientation, there is no consensus on what the optimum orientation of the acetabular cup should be. The suggested orientations in the literature are contradictory and comparison between studies is difficult due to variations in angle definitions, measurement systems and reference systems. These contradictions, the lack of consensus in the literature and results from studies suggest that acetabular orientation must be patient specific.

Mechanical guides are the most commonly used device to assist surgeons in positioning the acetabular cup, both in cemented and uncemented arthroplasties. However, these devices have many limitations one of which is a fixed acetabular orientation which does not allow for any patient variability.

Using a combination of quantitative and qualitative product design techniques, Harrison User Centred Methodology was developed. This new methodology was adopted to design and develop a device to aid surgeons with positioning the acetabular cup in total hip arthroplasty. The aim was to design a device which could be used for both cemented and uncemented hip arthroplasty. The final device design was a novel positioning guide which addressed the lack of patient variability in current mechanical guides. The device simplified the positioning and limited the movement of the introducer. Feedback from surgeons demonstrated a positive response and with further development, a willingness to try the product.

Proof of concept testing was carried out to measure the accuracy of the device. An available (uncemented) introducer was used for testing which demonstrated the device can accurately position the acetabular cup. The accuracy of the developed device and current techniques was compared. The study showed less variation in the position over time using the novel device which highlights an added benefit for cemented procedures demonstrating stability as the cement cures.

Contents

Glossary of Terms

Term	Definition
Abdominopelvic Visera	Internal organs contained within the abdominal cavity.
Acetabular Axis	Centre of acetabular socket and perpindicular to the acetabular plane
Acetabular Cup	Component of hip prosthesis which replicates the acetabulum.
Acetabulum	The cup shaped cavity in the hipbone which articulates with the head of the femur.
Anterior Pelvic Plane (APP)	Plane which connects the anterior superior iliac spines and the pubic symphysis
Anterior Superior Iliac Spines	Bony landmark, anterior extremity of the iliac crest.
Anteversion	Angle used to describe the orientation of the acetabular cup.
Articular Cartilage	The cartilage which covers the articular surface of the bone.
Aseptic Loosening	Failure of the bond between the implant and bone in the absence of infection.
Coronal Plane	Plane which divides the body into dorsal and ventral parts.
CT	Computed tomography, radiography where a three dimensional image of a body structure is created.
Femoral Stem	Component of hip prosthesis which replicates the femur.
Femur	Thigh bone which extends from the pelvis to the knee. It articulates with the acetabulum.
Hip Dislocation	When the femoral head separates from the acetabular socket
Impingement	When the hip bone is abnormally shaped and as a result the hip bones rub together and cause damage to the hip.
Inclination	Angle used to describe the orientation of the acetabular cup.
Introducer	Surgical instrument that is used to position the acetabular cup in the pelvis.
Lateral Decubitus	Patient is positioned on the operating table on their left or right side.
Longitudinal Axis of the Patient	Axis running in the direction of the long axis of the body.
Mechanical Guide	Surgical instrument that is used to help the surgeon align the acetabular cup correctly.

Term	Definition
Osteoarthritis	Degeneration of joint cartilage and bone which causes pain and stiffness.
Osteolysis	Softening, absorption and destruction of bony tissue.
Palpate	To examine a part of the body by touch, pressing with palms of hands and fingers.
Pelvic Tilt	Rotation of the pelvis around a vertical axis.
Pelvic Visera	Internal organs contained within the pelvis.
Pubic Symphysis	Cartilaginous joint between the right and left pubic bones.
Radiographs	An image produced by x-ray.
Revision Surgery	Surgical procedure to replace a failed implant.
Supine	Patient is positioned on the operating table on their back.
Total Hip Arthroplasty (THA)	Surgical procedure to replace the hip joint with a prosthetic substitute.

List of Publications

The work presented in this thesis has been condensed and presented in the peer reviewed articles listed below:

1. Research synthesis of recommended acetabular cup orientations for total hip arthroplasty. Harrison CL, Thomson AI, Cutts S, Rowe PJ, Riches PE. J Arthroplasty. 2014 Feb;29(2):377-82. doi: 10.1016/j.arth.2013.06.026. Epub 2013 Aug 17.

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1

Objectives and Outline of Thesis

1.1 Introduction

"Let's make things better"

This motto summarises the purpose behind product design. Design happens anytime somebody changes an environment to make things better [151]. Tim Brown from IDEO stated, *"design is everywhere, inevitably everyone is a designer."* Product design is influential in many sectors such as commercial, engineering, automotive, defence and healthcare. Product design is particularly influential within healthcare as design can be used to directly improve patients' lives. It can be used to create innovative new treatments, to develop and improve current devices and to reduce use-related hazards and risks. Often within healthcare, product design is used to address a problem and improve the status quo. Using product design to provide solutions and make things better for the lives of patients is the motivation behind this work.

Total Hip Arthroplasty (THA) is one of the most successful operations in modern history. A prosthesis, consisting of an acetabular cup and femoral stem is implanted to replace the damaged hip joint. 708,311 primary procedures took place in England and Wales in 2014[1]. However 79,859 revision procedures[1], where the prosthesis needs replaced, also took place. Many factors increase the risk of revision surgery. The orientation of the prosthesis is critical to ensure both short term and long term success. Both components are important, however the acetabular cup has been shown to significantly influence the risk of aseptic

loosening and dislocation. 24% of revision surgeries are due to aseptic loosening while 17% are due to dislocation. Achieving correct orientation of the acetabular cup can also be difficult. For this reason, the orientation of the acetabular component, for both cemented and cementless arthroplasty, was focused on.

The clinical supervisor for this work, a consultant orthopaedic surgeon, identified a problem within current surgical technique for THA. There are many limitations with current devices which can lead to incorrect positioning of the acetabular cup. This identified problem was used as the basis for this research. From this problem, product design was used to try and create a solution.

Product design methodology was reviewed in respect to this problem and as a result a user-centred design approach, Harrison User Centred Methodology (HUCM), was developed. Using HUCM, many limitations with current devices and guidelines for optimum acetabular orientation were identified. The research identified the need for a device which could be patient specific and reduce errors in positioning. Using different design techniques, a simple positioning guide was developed to aid surgeons and improve the orientation of the acetabular cup. This guide was tested against current positioning devices to compare accuracy and user opinion was sought (tested with users) to assess if an appropriate solution had been created.

This thesis discusses the literature surrounding acetabular cup orientation, identifies key issues associated with THA and current positioning guides. These issues were addressed using HUCM. This work details the process of designing and testing a solution to help surgeons with acetabular orientation.

1.2 Objectives

The objectives set at the beginning of this project were as follows:

A. Review the literature and determine a universal method of reporting acetabular cup placement.

B. Analyse the literature and guidelines regarding acetabular cup orientation to determine if there is a consensus on optimum position using the identified universal reporting method.

C. Develop a Design Methodology to ensure a user-centred solution is developed.

D. Design and build a device to aid surgeons with positioning the acetabular cup during Total Hip Arthroplasty for both cemented and uncemented procedures.

E. Test the accuracy of the developed device against current techniques on both sawbones and cadaveric specimens.

1.3 Thesis Outline

Chapter 2 introduces Total Hip Arthroplasty and the incidence of revision surgery. The relationship between contributory factors leading to revision surgery and acetabular cup position is described in a review of the literature. Current methods used to aid with acetabular positioning and limitations with these techniques are discussed.

A research synthesis of the recommended acetabular orientations is explained in Chapter 3. Guidelines are converted to a single framework to allow for comparison between the literature, academic textbooks and manufacturers' guidelines.

Chapter 4 discusses Product Design theory and highlights the differences between several methodologies. Approaches and techniques for ensuring user-centred design are discussed. The theory discussed was used to develop a design methodology for use in this research.

Following on from the development of a design methodology, this methodology was used to design and develop a device to aid surgeons with positioning the acetabular cup within Total Hip Arthroplasty. Use of this methodology

is presented in Chapter 5, demonstrating the discussed techniques. The Chapter details the design process, starting from the initial research phase, building user understanding, detailing a design specification, concept generation, development and evaluation and reaching a final solution.

Testing the accuracy of the developed device in comparison to current techniques used to position the acetabular cup is detailed Chapter 6. Interviews with surgeons to gain feedback on the device are presented in Chapter 7.

The final chapter discusses the findings and the future developments of this work and summarises the research project. The objectives from the beginning of this chapter are also reviewed.

2

Total Hip Replacement

2.1 Chapter Contents

In this chapter the literature surrounding the alignment of the acetabular cup within total hip arthroplasty is expounded. Through discussion of the anatomy, the prosthesis used, purpose of the procedure and its incidence, total hip arthroplasty is explained. The position of the acetabular cup influences many factors which contribute to the risk of revision surgery. The relationship between the position of the acetabular cup and dislocation, cup wear, loosening, range of motion and impingement is assessed. The literature is reviewed to assess if an ideal orientation exists and current techniques used to position the acetabular cup will also be reviewed.

2.2 Anatomy

2.2.1 Pelvic Anatomy

The pelvis connects the axial skeleton to the lower limbs. The function of the pelvis is to:

- *"Transfer of weight from the upper axial skeleton to the lower appendicular components of the skeleton, especially during movement.*
- *Provide attachment for a number of muscles and ligaments used in locomotion.*
- *Contain and protect the abdominopelvic and pelvic visera.*" [2]

The pelvis is a bilaterally symmetrical structure which is constructed of two hip bones which are joined anteriorly via the pubic symphysis and posteriorly they articulate with the sacrum via the sacroiliac joint as shown in Figure 2-1[3].

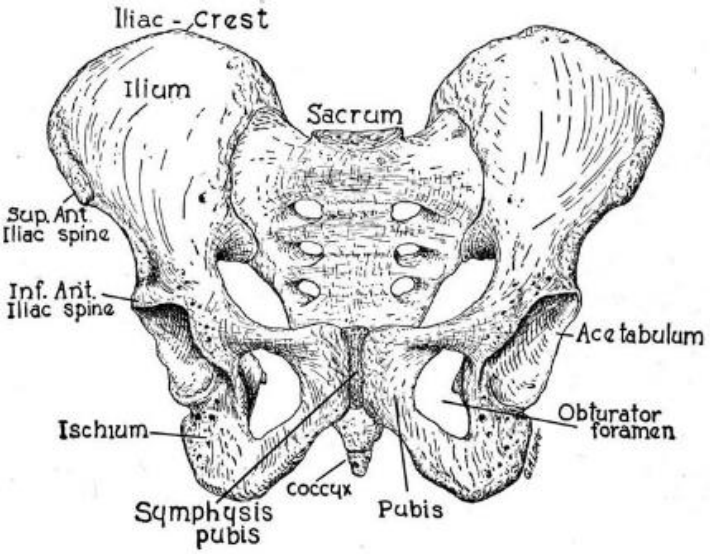


Figure 2-1 (left) Anatomy of the hip [171] (right)

Each hip bone is made up of three bones which are joined at the acetabulum; the ilium, the ischium and the pubis. The triradiate cartilage separates these bones until puberty when the bones fuse together. The fusion forms a cup-socket which is the acetabulum as shown in Figure 2-2. The head of the femur articulates with the acetabulum to form the hip joint [4].

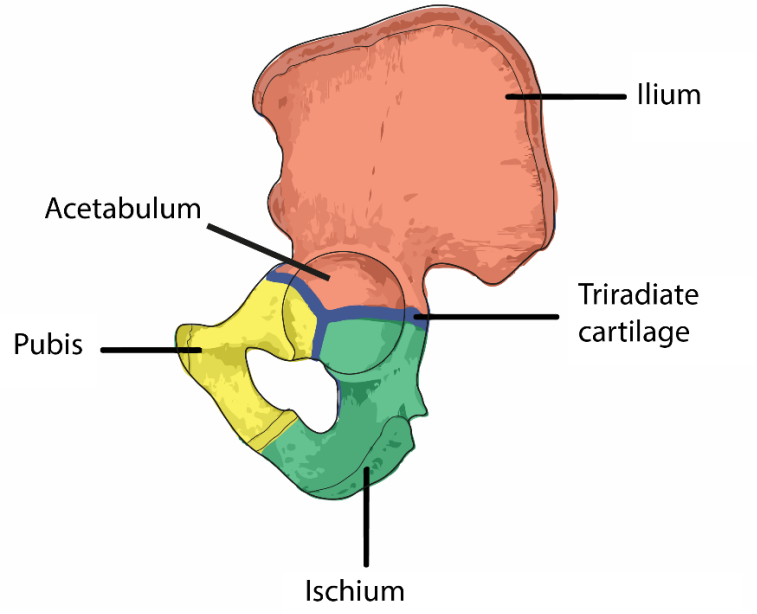


Figure 2-2 Anatomy of the pelvis [2]

2.2.2 Hip Joint Anatomy

The hip joint consists of a ball and deep socket synovial type joint which is formed by the femoral head and acetabulum as shown in Figure 2-3. The joint connects the pelvis to the lower limbs and is designed to be a stable weight bearing joint [5].

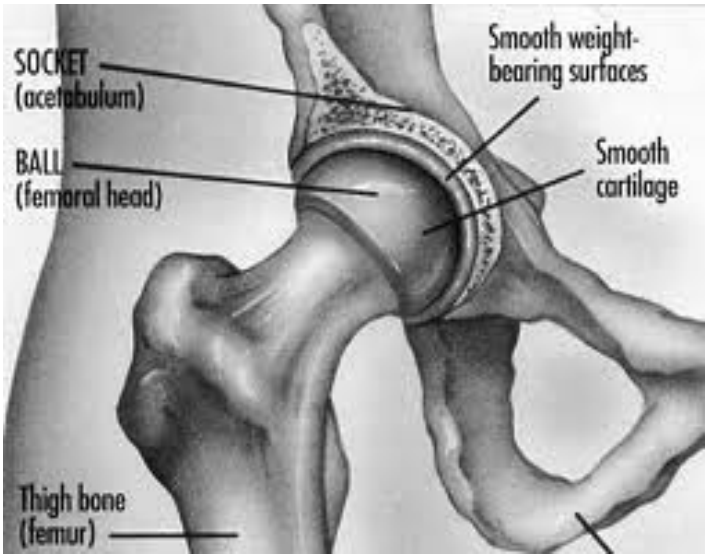


Figure 2-3 Hip Joint Anatomy [172]

The surfaces of the femoral head and acetabulum are covered with articular cartilage which is thicker at places of weight bearing and enables the joint to move easily. The leading causes of degeneration to the hip joint are osteoarthritis, rheumatoid arthritis, childhood disease and trauma [6]. These conditions can cause damage to the cartilage resulting in hip pain and stiffness which greatly restricts the patient's range of motion consequentially negatively impacting the patient's quality of life.

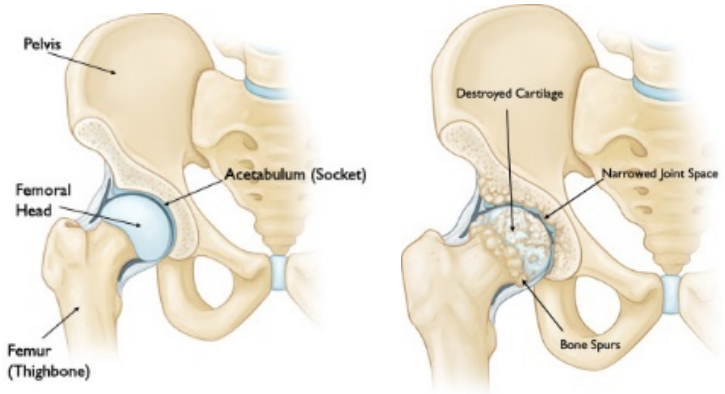


Figure 2-4 (left) Normal Hip (right) Damaged Hip [6]

2.3 Total Hip Arthroplasty

The most successful treatment for severely damaged joints is replacement by artificial parts [7]. Total hip arthroplasty (THA) replaces the damaged joint with a prosthesis. The prosthesis comprises of femoral and acetabular components which are discussed in greater detail in the following sections. It is colloquially referred to as a ball (femoral) and socket or cup (acetabular) device, where the femoral component contains a stem for integration with the existing patient femur.

There are several approaches that can be used to carry out THA due to factors such as the surgeon's preferred approach, the age of the patient, the type of prosthesis used and the position of the patient. There are many variations between these approaches, however all comprise of similar core steps. During the procedure, the surgeon will make an incision to gain access to the hip joint. The joint is dislocated to expose the acetabulum and the damaged femoral head is removed. The acetabulum is reamed (widened by a specialist tool) to prepare the socket for the new cup.

For uncemented, also known as cementless, procedures, the acetabular cup is hammered into place within the socket. Screws may be used to secure the cup in place. The plastic liner is then placed into the shell.

One key distinction with an uncemented acetabular cup is that it is often covered in a porous material conducive to natural bone regrowth so that the prosthesis is assimilated with the existing bone. This leads to a longer post-surgical recovery time, but for younger patients with good bone density, cementless can be favourable over the cemented alternative. The correct alignment of the acetabular component is critical, particularly for uncemented placement (versus cemented). This is because there is no room for adjusting the angle once in situ. Additionally, any movement of the prosthesis, particularly after it has been firmly hammered in place, has a higher risk of damaging the acetabulum, and impacting bone ingrowth.

For cemented procedures, bone cement is prepared and placed into the socket. The acetabular cup is aligned in the socket and held in place for typically around ten minutes, however this drying time varies depending on the properties of

the cement used. Polymethylmethacrylate cement is used due to the material properties during the working and setting phases. It is introduced in a dough-like state by hand or via a gun to the acetabulum. Once hardened, the cement has the ability to transfer loads in a natural manner from the femur to the acetabulum [8].

One of the key advantages of the cemented acetabulur cup is that the cement can be introduced into porous bone that has been damaged (e.g. by osteoporosis). The fact that the cement dries quickly means the surgeon can be confident that the prosthesis is securely in place. Unlike uncemented cups, this means that the patient can apply normal loads to the joint virtually immediately after surgery.

Where adjustment of the cementless acetabular cup can lead to damage as discussed above, the cemented prosthesis can be adjusted while the cement is drying. However, once the cement is set, it is difficult to realign, therefore, although for a different reason, angular alignment is critical for cemented acetabular cups, and due to the drying time, it can be suggested that a consistent angle throughout the procedure may be important to the integrity of the cement which may be compromised by unintentional movement.

A similar approach is taken to inserting the femoral component. The femur is reamed out and the new stem is inserted, either with or without (press fitted) cement. The positioning of the femoral component can be adjusted in relation to the acetabular component to ensure the optimal range of motion. The ball is placed on the stem (if separate) and seated within the cup so the joint is aligned and the incision is closed.

The components of the prosthesis are different for cemented and cementless THA. For cementless procedures, the femoral component of the prosthesis consists of a stem and head and the acetabular component is a shell and liner, as shown in Figure 2-5. The stem is formed from metal and the head is a ball which is placed onto the taper at the end of the stem. The liner is attached to the shell and is a bearing surface for the head. As movement causes friction between the head and liner, the material choice is critical to ensure wear is reduced. The head and liner can be manufactured from ceramic, plastic and metal to provide a hard wearing yet

smooth articulating surface. The shell is also made from metal and is attached to the acetabulum [9].

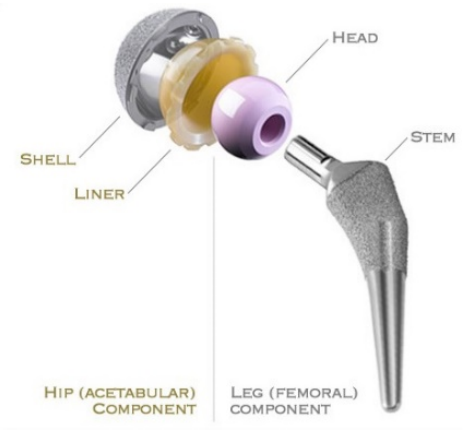


Figure 2-5 Cementless Prosthesis [9]

For cemented procedures, the prosthesis is slightly different, as shown in Figure 2-6. The acetabular component is a cup made from ultra-high molecular weight polyethylene (UHMWPe) which is anchored in the acetabulum in bone cement. The cup has a metal wire round the rim which enables the cup to be seen on x-rays.

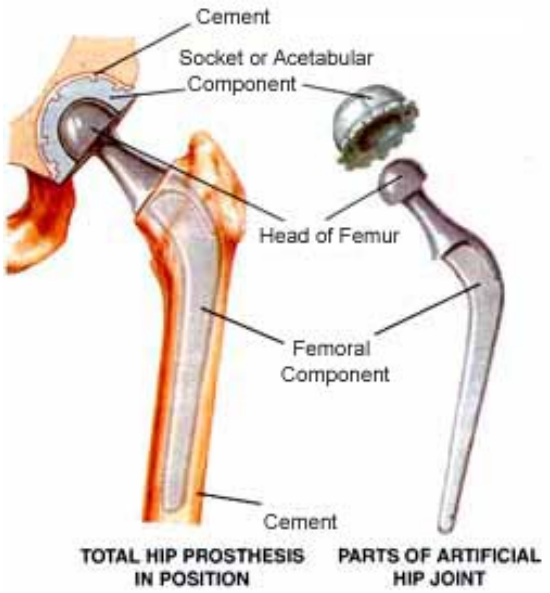


Figure 2-6 Cemented Prosthesis

The purpose of replacing the hip joint, as stated in NHS guidelines, [10] is to:

- Relieve pain
- Improve the function of the patient's hip

- Improve the patient's ability to move around
- Improve the patient's quality of life.

A study on patients with osteoarthritis agreed with this purpose, concluding a hip replacement, "improved the quality of life of patients and helpers, while also helping to reduce the demands for community health and welfare services" [11]. THA has been proven to be one of the most successful and cost effective operations in modern medicine [12].

2.3.1 Incidence

The prevalence of hip arthroplasty procedures being carried out has increased with the National Joint Registry recording 89,945 hip procedures in 2013. This is an 8% increase from 2012 [13]. This increase has been seen globally and as shown in Figure 2-7, the rate of hip replacements procedures has increased by over 25% between 2000 and 2013 [14]. The incidence rate is expected to continue to dramatically increase with the amount of procedures carried out estimated to have doubled by 2030 [15].

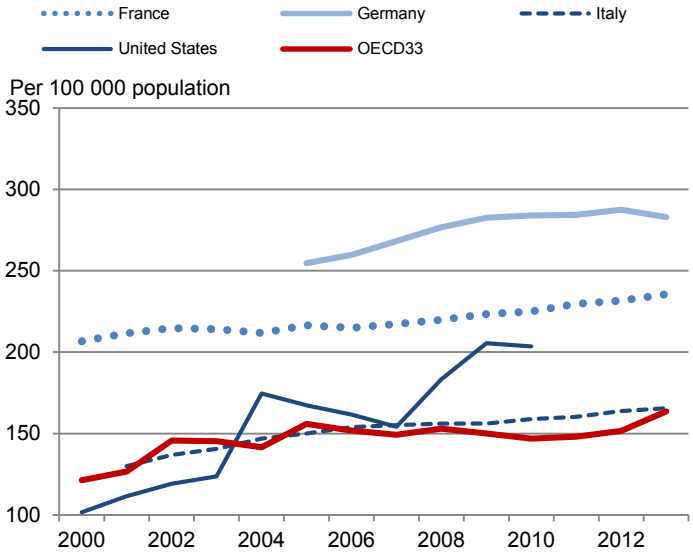


Figure 2-7 Trend in hip replacement surgery, selected OECD countries, 2000 to 2013 (or nearest years) [14]

This increase is a result of many socio economic factors. The number of people aged over 65 is due to double between 1971 and 2030. In the United

Kingdom, one-in-six of the population is currently aged 65 over but this will increase to one-in-four by 2050 [16]. The World Health Organisation (WHO) have warned this will pose a huge challenge on the health service as illnesses related to aging are predicted to rise [17].

Due to the aging population and the growing prevalence of obesity the number of people affected by osteoarthritis is likely to increase [18]. Osteoarthritis is named as the single largest indication for total hip arthroplasty, with osteoarthritis recorded in 91% of procedures [13]. This increase could be contributing to the current exponential growth of THA.

The incidence rate varies across countries with the highest rates in Germany, Switzerland and Austria, as shown in Figure 2-8. The variations between the countries may be due to differences in population structure. Age standardisation reduces the variations between countries however the country ranking does not change significantly [19]. The comparability of the data in the figure may be affected as classification practices vary across the countries. For example, most of the countries include data from partial hip replacements however some only consider the data from total hip replacements. Additionally some countries only includes procedures from publicly-funded hospitals. These factors may explain some of the surprising results of the country ranking and highlight the difficulty of accessing results within the literature.

In summarising the study, the Organisation for Economic Co-operation and Development have hypothesised that the varying rates could be due to:

i) differences in the prevalence of osteoarthritis problems;
ii) differences in the capacity to deliver and pay for these expensive procedures;
iii) differences in clinical treatment guidelines and practices [20].

All the above causes of variation are relevant to this investigation, however point three can be directly addressed by the current work, by redesigning the devices used in clinical treatment.

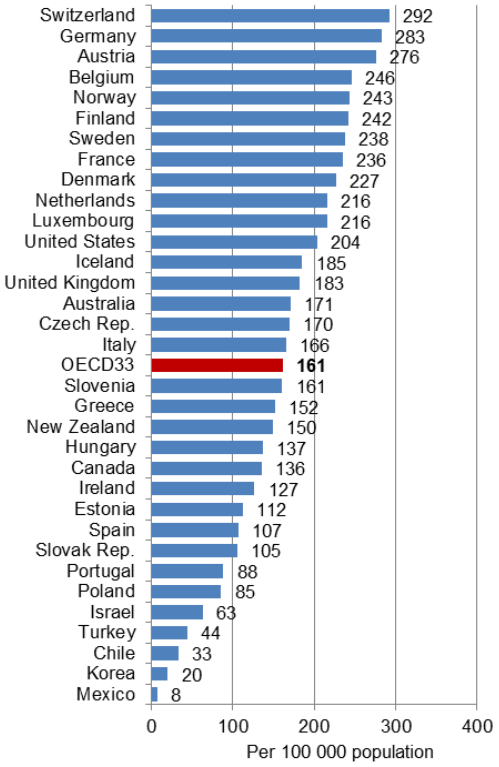


Figure 2-8 Hip Replacement Surgery, 2013 (or nearest year) [14]

2.3.2 Revision Surgery

Although THA is one of the most successful operations, the prosthesis may wear out or complications may occur which means revision surgery can be required. This involves the removal of the failing existing prosthesis and replacing it with new components. This can apply to both the acetabular or femoral components and both cemented and cementless variations. Revision surgery may be needed due to wear and loosening resulting in bone loss, dislocation, infection and additional impacts e.g. falling of elderly patients. In 2013, 12% of all hip procedures carried out were revision surgeries [15].

As the number of primary THA procedures carried out continues to grow, the amount of revision surgeries required to take place is predicted to rise from 40,800 in 2005 to 96,700 (137%) in 2030 [15]. The year on year projections are shown in Figure 2-9.

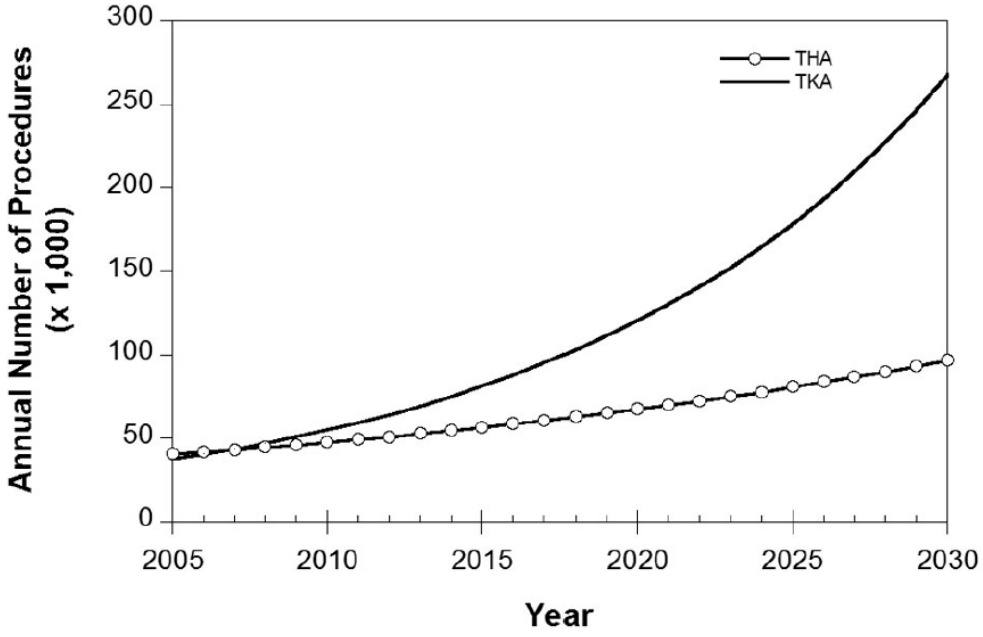


Figure 2-9 The projected number of revision total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures in the United States from 2005 to 2030 [15]**.**

This increase has a large implication on healthcare expenditure as revision arthroplasties consume greater economic resources than primary arthroplasties [21]. This is due to the increased costs of pre-operative planning, implants, instrumentation, medication and hospital stays [22]. In the United Kingdom, a revision procedure can cost from £11,000 to £22,000 [22] which results in costs to the NHS of up to £215 million pounds annually. Worldwide, the cost of a revision surgery varies with the cost highest in the United States [20]. In the United States, revision procedures cost between $15,000 and $40,000. If the revision burden in the US was reduced by 1% (a decrease of 2844 procedures) the potential cost savings could range from $42.5 million to $112.6 million [12].

The burden of revision surgery is going to continue to grow unless a *"limiting mechanism can be implemented to reduce the future burden"* [12]*.* Therefore as the amount of procedures continues to increase, a method to reduce revision surgery is becoming increasingly essential.

2.4 Orientation of the Implant

Correct orientation of the hip prosthesis is critical to ensure success of THA and reduce the risk of revision surgery. Correct orientation is one of the most important factors within the surgeon's control. Improper placement of the implant can lead to increased revision rates, increased dislocation rates, pelvic osteolysis, asceptic loosening, component impingement, increased surface wear and poor hip biomechanics [23]. The links between these complications and component positioning will be explained later in this section. In the post-operative period, these complications lead to increased costs, longer hospital stays, increased medical care, additional surgical procedures, increased litigation and patient dissatisfaction [24]. All of these are factors that directly contrast with fulfilling the purpose of the hip replacement, as set out in the NHS guidelines, of relieving pain, improving function of the hip, mobility of the patient and crucially the patient's quality of life.

Aseptic loosening is the most common indication for revision surgery and it has been reported that the loosening rate of the acetabular component is two to four times higher than the femoral component [2526,27]. The spatial relationship between the two prosthesis is critical to ensure a good range of motion of the hip however the correct alignment of the acetabular cup has proven to be more difficult than the stem [28]. Due to evidence such as this and input from clinical collaboration, the focus of this thesis will be placed on the positioning of the acetabular component.

2.4.1 Definition of Acetabular Orientation

The orientation of the acetabular cup is expressed relative to a specific reference system [29]. The orientation can be described in reference to the coronal plane or the anterior pelvic plane and the definition varies further if the observation is radiographic, operative or anatomical [30]. The position is described by two angles commonly described as inclination and anteversion. The names used to describe these angles vary throughout the literature. For example, inclination can be described as abduction or cover and anteversion is otherwise known as flexion, tilt or opening. For this thesis, the terms inclination and anteversion will be used in line with Murray's definitions.

The two reference planes that are commonly used to describe acetabular orientation are the coronal and anterior pelvic plane. The coronal plane is shown in Figure 2-10. Murray [31] classified three orientation definitions in reference to the coronal plane. These definitions describe acetabular orientation during the operation (operative), measuring from radiographs (radiographic) and the true anatomy (anatomic). The definitions describe, *"the orientation of the acetabular axis which passes through the centre of the socket and is perpendicular to the plane of the socket face"* [31]. Each of these definitions is explained in more detail in Chapter 3.

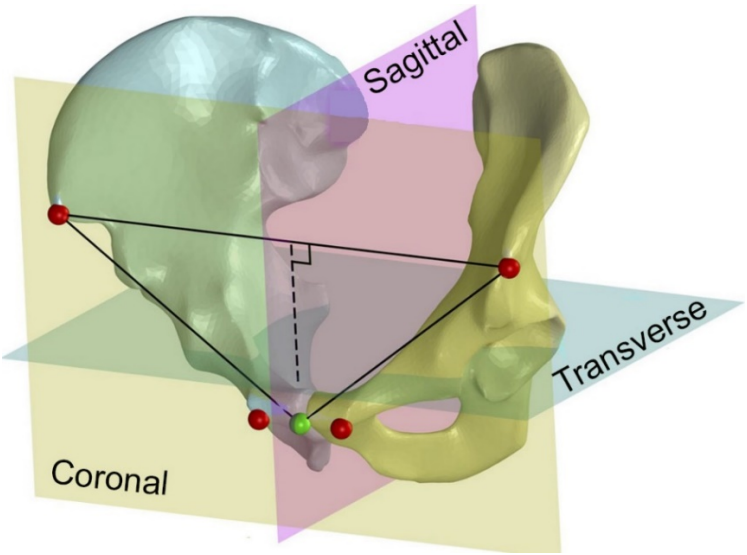


Figure 2-10 Anatomical Reference Planes and the Anterior Pelvic Plane in relation to the pelvis[32].

The anterior pelvic plane (APP) is the other reference plane commonly used. A line connecting the anterior superior iliac spine points is defined as the transverse axis. The anterior pelvic plane is defined by the transverse axis and the midpoint between the two pubic symphysis tubercles. These anatomical reference points are highlighted in Figure 2-10. The second axis of this plane is perpendicular to the transverse axis and the this axis of the plane is perpendicular to the anterior pelvic plane[29].

Cunningham [33] first defined the four key anatomical landmarks and Robinson first used it as the pelvic frontal plane in 1922 with Lewinnek describing the APP in 1978 [30]. The difference between the coronal plane and the anterior pelvic plane is defined as pelvic tilt (**Error! Reference source not found.**). When the distance between the midpoint of the anterior superior iliac spines and the coronal plane is

greater than the distance between the midpoint of the pubic symphysis and the coronal plane, pelvic tilt is defined as anterior and if the distance is shorter pelvic tilt is defined as posterior (Figure 2-11) [34]. Only when the patient has 0º pelvic tilt, the APP and coronal plane parallel and the reference systems are comparable. This comparison can be made with the patient in the supine or lateral decubitus position however this may need adjusted if the patient is standing. Current techniques for aiding surgeons in positioning the acetabular cup vary between using the coronal and anterior pelvic plane as a reference plane. Similarly to the radiographic, operative and anatomical definitions, it is critical to define the reference plane used to avoid error.

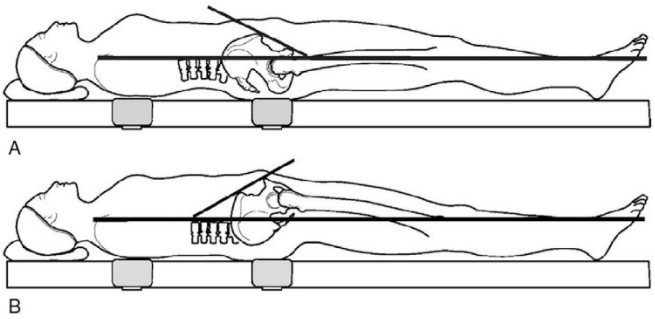


Figure 2-11 Pelvic Tilt A) Anterior B) Posterior [34]

2.4.2 Measurement Methods

The most commonly used diagnostic tool for measuring inclination and anteversion of the acetabular cup are plain radiographs [30]. Computer-aided tomography (CT) is the gold standard measurement technique however due to the simplicity, availability and low cost of radiographs, these are the standard measurement method [35].

A wide range of techniques are used to determine both the inclination and the anteversion angle from radiographs. When projected onto a radiograph, the circumferential wire of the acetabular cup appears as an ellipse from which the angles of the cup can be measured [36]. To accurately interpret the orientation of the prosthesis, both the patient and the X-ray machine need to be positioned correctly [37], ensuring the x-ray beam is centred over the hip [38]. If either is incorrect, an error is introduced in the measurement.

Inclination angles can be measured directly from the radiographs using the circumferential of the cup which appears as an ellipse and the teardrop line. As shown in Figure 2-12, the inclination angle can be defined as the angle between the teardrop line and the long axis of the ellipse [36].

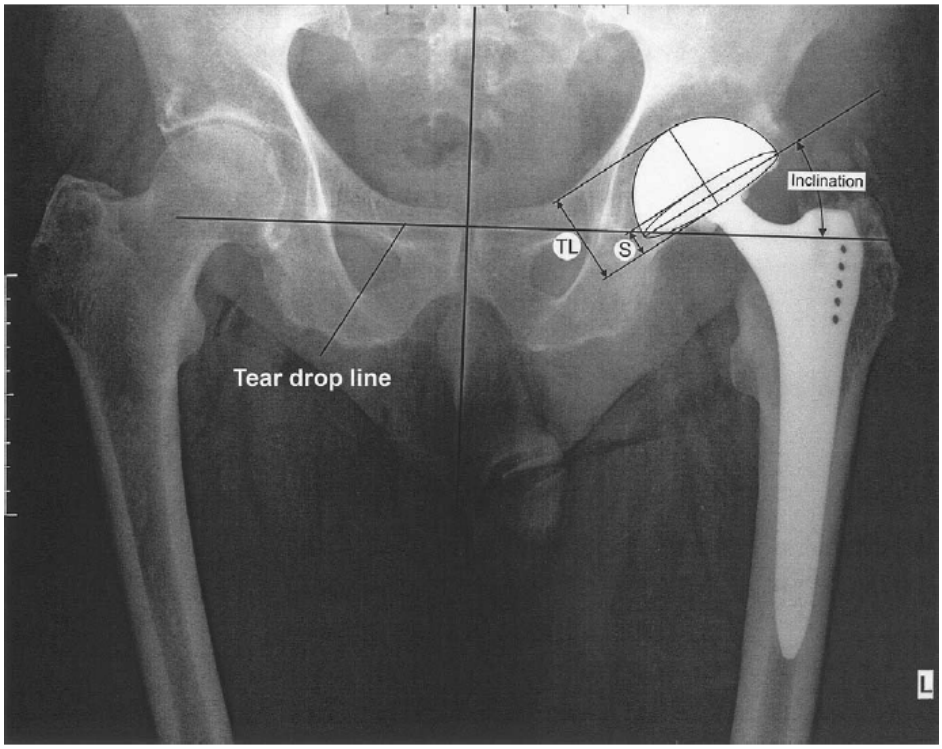


Figure 2-12 Radiographic inclination is the angle between the long axis of the ellipse and the tear drop line. Short axis (S) of projected ellipse and total length (TL) of projected cup cross-section along short axis.

Anteversion is considerably more difficult than inclination to measure from radiographs. The anteversion angle can also be calculated using the ellipse and can be calculated using the equation:

Anteversion = Arcsin (short axis of ellipse/ long axis of the ellipse)[36]

However due to the femoral component, part of the ellipse is obscured on the radiograph. Lewinnek at el. [39]used draughtsman's curves to complete the ellipse and calculate the long and short axis of the ellipse however using draughtsman's curves can introduce measurement error. Interpretation is also made hard by the fact that any movement in the pelvis is not recorded and it is difficult to distinguish between anteversion and retroversion on radiographs [30]. Hassan et al [38] illustrated there is a tendency to underestimate anteversion when reading radiographs.

Alternative methods that can be used to calculate anteversion from x-rays have been researched. Marx et al. [37] retrospectively reviewed the radiographs of 42 patients and utilised the mathematical algorithms of Pradhan [36], McLaren [40], Hassan [38], Ackland [41] and Widmer [42] to calculate the anteversion angles and to compare the accuracy of the techniques. All five algorithms displayed significant and clinically relevant differences to the CT while nearly all the calculated anteversion angles were lower than those measured using CT. Widmer's formula was shown to have the closest correlation to the recorded CT anteversion angles. Kalteis et al. [43] also compared Widmer's technique to CT data and similarly found there was a trend towards higher accuracy using CT. The CT technique was more exact for anteversion measurement however there was no significant difference for measuring inclination angles. However, this study did not give any consideration to pelvic tilt.

Pelvic tilt introduces an error to recorded measurement on radiographs. Only when the coronal plane and the APP are parallel, i.e. the patient has 0º pelvic tilt, will the angles measured on the radiographs correspond to the true angles. An assessment of pelvic tilt is therefore required to understand the true spatial orientation of the acetabular cup [44]. Babisch et al. [44] demonstrated that patient pelvic tilt pre-operatively and post-operatively was not neutral or centred around 0º. With the patient supine, pre-operative mean pelvic tilt was -8.9º ± 6.8º and post-operative mean pelvic tilt was -10.9º ± 7.6º.

Haenle et al. [45] stressed that patient position and the position of the pelvis should always be considered by establishing that tilting of the pelvis resulted in a variation between the radiographic and measured anteversion angles. Babisch et al. [44] recommended that for every 5º of pelvic tilt, the inclination angle should be adjusted 1.5º and the anteversion adjusted 4º. Malik et al. [34] constructed a phantom model to demonstrate that as pelvic tilt increased, there were larger differences between cup inclination and anteversion between the radiographic and anatomical definitions with 1º of pelvic tilt changing the anteversion angle by an average of 0.8º.

Although the importance of orientation of the prosthesis is widely known, there is little consensus as to the optimum orientation. Within literature, Lewinnek et

al.'s [39] coronal plane definition of 40° radiographic inclination and 15° radiographic anteversion with a safety zone of ± 10° for each angle is the most widely accepted. This safe zone is not universally accepted but it is a basis for most surgeons' desired positioning [46]. The work by Lewinnek et al. is described in greater detail in Figure 2.4.4. Due to these differences in reference planes, orientation definitions and measurement techniques used, direct comparison of literature and guidelines with regard to the optimum acetabular orientation is difficult. Due to the mixed definitions it is nearly impossible to directly compare reports [30].

Murray [31] has developed conversion equations to enable comparison between guidelines. To try and identify a common consensus on acetabular cup orientation, guidelines from literature, textbooks and manufacturer's guidelines were collated and converted to a single framework to enable comparison. The results and discussion of this comparison are discussed in greater detail in Chapter 3.

2.4.3 Natural orientation of the acetabular cup

Murtha et al.[47] examined the anatomy of the acetabulum using CT data to determine the native orientation of the acetabulum. The female acetabulum had a mean orientation of 57.1º inclination and 24.1º anteversion while the male acetabulum had a mean of 55.5º inclination and 1.3º anteversion. This highlights a significant variation based on gender. The native orientation does not align with Lewinnek's recommended orientation as natural inclination is significantly higher. The natural orientation of the acetabular cup also varies significantly between patients therefore aligning the acetabular cup to the acetabular rim may result in a wide range of cup orientations [48]. Frequently, the natural orientation of the acetabular cup is not complementary with the orientation of the femur therefore a compromise in prosthesis position must be achieved to ensure the best outcome [48].

2.4.4 Lewinnek safe zone

Lewinnek et al's recommended guideline of 40° radiographic inclination and 15° radiographic anteversion with a safety zone of ± 10° for each angle is not universally accepted but is a basis for most surgeons' desired positioning [46]. Lewinnek studied 300 total hip replacements that were carried out between the

years of 1972 and 1975. From these procedures, the dislocation incidence rate was 3%. Detailed information was not available for all the hips that did not dislocate, therefore information was obtained for 113 of the originally quoted 300 hips.

Orientation was determined from the elliptical appearance of the circular marker wire on the anteroposterior postoperative x-rays. Inclination (θ) was measured directly from the x-rays while anteversion (α) was calculated from the ratio between the lengths of the minor and major axes of the ellipse. Measurements were taken with the patient in the supine position and a device was used to make sure the pelvis was parallel to the x-ray film.

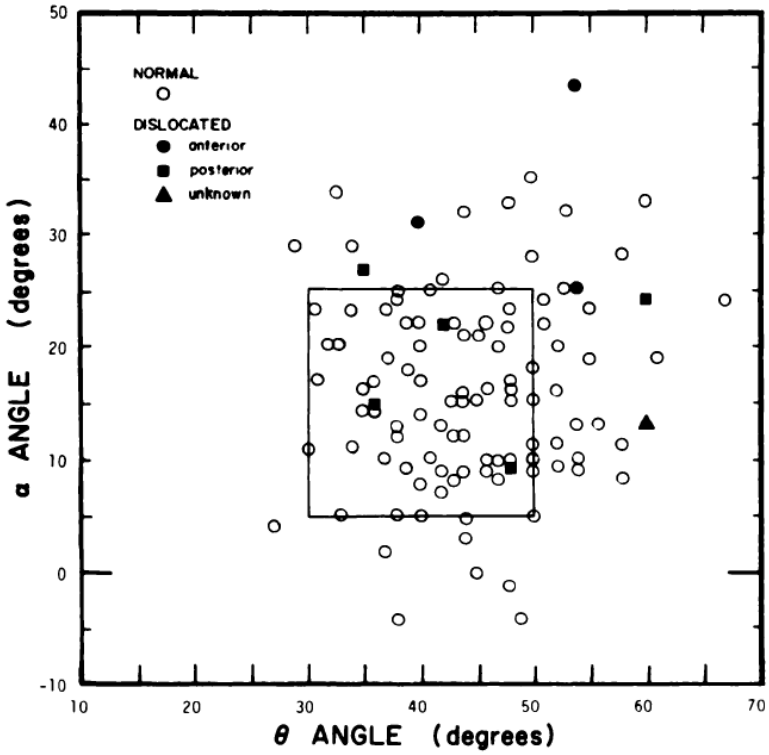


Figure 2-13 A scatter diagram summary of the orientation of the acetabular components [39].

The inclination and anteversion angles of the studied hips is shown in Figure 2-13. There was no significant difference between the average angles of the posterior dislocations and the average angles of the stable group. There was no significant difference between the inclination angles of the anterior dislocations and the stable group. However there was a significant difference between the anteversion angles. It is worth noting there were only three anterior dislocations and five posterior dislocation so the averages are not stated here.

When the dislocated hips were considered together as a group, there was a tendency for the dislocations to be associated with large deviations for the average angles. Lewinnek concluded that there is a "*relatively safe range of orientations*". After investigating a selection of ranges, 40° radiographic inclination and 15° radiographic anteversion with a safety zone of ± 10° provided the most satisfactory outcomes. The range was suggested to allow the surgeon "leeway" in the placement of the acetabular cup and allow for "adequate motion" in the implanted prosthesis.

The results were projected for the original cohort of 300. The predicted dislocation rate was 1.5% when the acetabular cup was positioned within the safe zone. The predicted dislocation rate outside the safety zone was 6.1%.

As discussed in the following section, the Lewinnek safety zone is often considered the ideal position for the acetabular cup however it is not universally accepted within the literature and other studies have been published which question this recommendation.

2.5 Malpositioning

Malalignment of the acetabular cup may be the single, most important variable under the surgeon's control with regard to success of THA [46]. In the following section literature which examines the relationship between component orientation and the following complications which increase the risk of revision will be discussed:

- Aseptic Loosening
- Cup Wear
- Dislocation
- Range of Motion
- Impingement

2.5.1 Aseptic Loosening

Aseptic loosening is the most common cause of revision surgery [13]. Wear from the prosthetic joint can be responsible for the loosening failure of the cups [26].

The wear creates debris particles which cause an immune system response. This response facilitates osteolysis which creates loosening between the implant and the bone [49]. Wear may also be influenced by high stress in the bone cement which may contribute to crack growth and debonding of the cement mantle. Many factors influence aseptic loosening but the position of the prosthesis is one of the most important [50].

Djerf et al. [50] monitored 138 patients annually over a 5 year period, using radiographs, to measure the loosening of acetabular cups. Two different prostheses were used, McKee-Farrar and Charnley, and the results were analysed separately. Within the McKee-Farrar group, acetabular cups with an inclination of more than 50º were associated with a higher loosening rate. The anteversion angle in when using either type of prosthesis, did not significantly influence the occurrence of loosening. Coudane [51] carried out a retrospective study of 711 prosthesis using radiographs to compare aseptic loosening and acetabular cup inclination. Results demonstrated that the prosthesis should be positioned with 44º inclination or less to avoid aseptic loosening however no mention is given to measurement technique and patient position.

The literature established that inclination angle of the acetabular cup is an influencing factor in aseptic loosening. High inclination angles have been shown to increase the risk of aseptic loosening.

2.5.2 Cup Wear

Acetabular cup wear is associated with both material and technical factors. Material factors such as the properties and quality of the material, femoral head size, fixation of the joint [52] and the relationship between the femoral head and the material, in particular polyethylene [53] are significant. Wear can be influenced by daily gait activities, any impact to the hip joint, age and sex of patient. One of the most important factors within the surgeon's control is the orientation of the acetabular cup as the orientation can be optimised to reduce contact stresses and minimise the wear [26].

Queiroz et al. [52] used a finite element model (FEM) to estimate the wear of acetabular cups made from high molecular weight polyethylene (HMWPE) and a femoral head made from Cobalt Crome (CoCr) alloy at varying incliations. The model consisted of an acetabular and femoral component which was programmed to perform flexion-extension movements and the load which was applied corresponded to the gait of a patient who had had a total hip replacement. Results showed that while wear rates did not vary for inclination angles between 30 and 45º, when the inclination was 60º the linear and volumetric wear rates were 42% and 53% greater.

A FEM was constructed by Oki et al. [54] to analyse the effect of varying inclination angles on relative motion between the acetabulum and the metal shell, shear stress at the bone–metal shell interface, and contact stress at the articulating surface. Increasing the inclination angle from 35º to 65º increased the maximum relative motion between the shell and acetabular cup (65.7 μm to 96.9μm), increased the maximum tilting shear stress (9.7MPa to 16.9MPa) and torsional shear stress (9.7MPa to 17.0MPa) at the bone-metal shell interface and increased the contact stress at the articulating surface of the polyethylene liner (23.4MPa to 26.8 MPa). This additional movement could be a cause of aseptic loosening and led to the conclusion that the inclination angle of the acetabular cup significantly influences wear generation [54].

Patil et al. [55] used a FEM to compute contact stresses and calculate wear during a gait cycle. The results were validated with a hip wear simulator study and subsequently a clinical trial of 56 patients. The FEM analysis showed increased inclination angles resulted in increased peak contact stresses while increased anteversion angles caused a reduction in peak contact stresses. The increased inclination angle also increased the linear wear rates. The hip wear simulator also showed increased wear between the angles of 45º and 55º inclination. The clinical study was carried out using radiographic analysis and also demonstrated a significant correlation between inclination angles and linear wear rates. The results from this study found that in acetabular cups with an inclination angle of over 40º then the wear rate was increased by 40%.

Hua et al [26] assessed the influence of the inclination angle on cup fixation, with respect to the cement mantle, using a FEM. A Charnley hip prosthesis was modelled and a fixed hip joint force was applied on the model through the centre of the femoral head to simulate the mid-to-terminal stance loading of the gait cycle. For the conditions tested, the cup inclination angle did not affect the contact mechanics or the fixation markedly. However it is predicted that beyond these conditions, if the inclination angle is increased further, an increase in the stress in the cement mantle would be observed.

Lusty et al. [56] studied retrieved alumina on alumina ceramic bearings which although known for being wear resistant the specimens displayed higher wear than anticipated. Angles were transformed into the operative reference system and the study demonstrated no correlation between the rate of wear and inclination angle of the acetabular component. A higher rate of wear of the femoral head was shown with lower acetabular anteversion and the highest rates of wear were observed in patients with cup anteversion of less than 15º.

Del Schutte et al. [53] conducted a study of 364 hips, quantifying the inclination angle from radiographs and measuring relative to the ischial tuberosity line. The mean inclination was 44.1° (sd 9.2°) and didn't show any correlation between acetabular inclination and polyethylene wear rates. The anteversion angle was not accounted for.

The revision rates for large diameter metal-on-metal (MoM) bearings are significantly higher than conventional total hip replacements. A reason for this is these implants have been associated with increased wear when the inclination or anteversion angle is too high. Elevated levels of cobalt and chromium in the urine and blood, pseudotumours, hypersensitivity and aseptic lymphocytic vasculitis associated lesions [57] have all been reported. These reactions indicate increased rates of wear.

The recommended guidelines for the position of the acetabular cup are based on studies carried out on low-friction metal-on-polyethylene (MoP) devices. Acetabular orientation is defined by the cup face, but the wear properties are influenced by position of the bearing edge. Large diameter MoM devices have a

similar external shape to traditional polyethylene cups however, significantly, the bearing surface is different. Due to this difference, the large diameter MoM operates at a steeper inclination angle from the bearing edge than is defined by the cup face.

Jeffers et al.[57] demonstrated that if a large diameter MoM is positioned at 45° inclination, the inclination at the bearing surface would be between 52° - 61°. Therefore the inclination angle for a large diameter MoM should be lower to achieve equivalent bearing surface positioning. High acetabular cup inclination can lead to edge loading, which causes an increase in pressure at the cup rim resulting in an increase of wear [58]. It can also cause a loss of lubrication resulting in an increase in frictional torque leading to aseptic loosening.

Mellon et al. calculated the risk of edge loading and impingement during gait, sit-to-stand, stair descent and standing. From this a safe zone of orientations for each participant was calculated and an optimal orientation was identified. The results demonstrated the mean optimal acetabular inclination angle was 39.7º (sd 6.6º) and the mean optimal anteversion orientation was 14.9º (sd 9.2º) The main conclusion of the study, however, was the need to identify patient-specific optimal acetabular cup orientation [59].

The literature highlights that increased inclination angles of the acetabular cup leads to increased wear rates. The angle at which the wear significantly increases is debated. Patil et al. [55] presented increased wear when the inclination of the acetabular cup was greater than 40º while Queiroz et al. [52] showed increased wear with an inclination angle of over 45º. A high inclination angle for large diameter MoM implants significantly increases wear rates causing many complications. The studies demonstrate the importance of patient-specific acetabular cup position based on design of the prosthesis used and patient anatomy.

2.5.3 Dislocation

Dislocation is one of the most common complications after THA [60] with an incidence rate ranging from 0.5-10% [61]. Dislocation is when the femoral head comes away from the acetabular socket as shown in Figure 2-14.

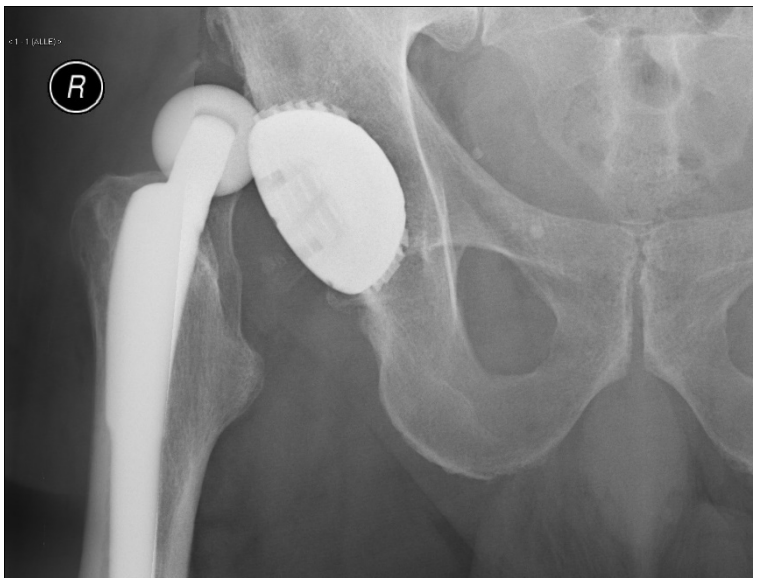


Figure 2-14 Dislocation of total hip arthroplasty [62]

Approximately $60-$75 million is spent annually in the United States to deal with dislocation [63]. There are many factors that lead to dislocation; patient related factors such as age, gender, osteoarthritis, lack of compliance with post-operative care, muscle weakness and technical factors such as head size, surgical experience, surgical technique. [64] Surgical orientation of the acetabular component is a leading cause of dislocation in THA [65,66].

Abdel et al. [67] compared the acetabular orientations of dislocated cups to the Lewinnek safe zone to test if the safe zone predicts dislocation in contemporary practice. Abdel et al identified that 58% of the dislocated cups were positioned within the Lewinnek safe zone and the mean inclination and anteversion angles were similar to the suggest target orientations provided by Lewinnek. Similarly, Esposito et al. [68] found 57% of the dislocated cups were positioned within the Lewinnek safe zone. The study found no orientation which could be considered safe, defining a safe zone as an area with two or three times fewer dislocations. Both studies demonstrate that dislocation has multiple causes and the Lewinnek safe zone is useful as a guide but not as a truly objective safe zone.

Biedermann et al. [69] proved a consistent relationship between the direction of dislocation and the position of the cup. Patients with anterior dislocation displayed significantly higher inclination and anteversion angles than the control group while patients with posterior dislocation displayed lower inclination and anteversion

angles. As shown in Figure 2-15 below there was a constant increase in the risk of anterior dislocation as the anteversion increased and a constant increase in the risk of posterior dislocation as the anteversion decreased.

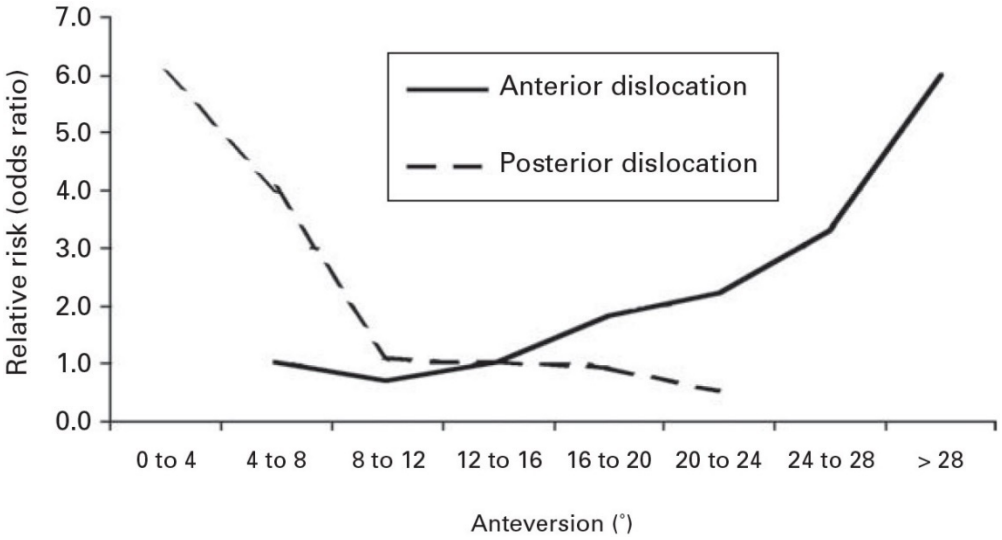


Figure 2-15 Anteversion angles and risk of revision [69]

Contrasting to the Lewinnek safe zone, the study recommended there is not a safe zone of recommended positions but when using the anterolateral approach, an orientation of 45º inclincation and 15º anteversion showed the lowest risk of dislocation.

Also varying from the Lewinnek guidelines is a study by Masaoka et al. [70] who studied a group of 317 patient with 10 dislocations (3.2%). 4 of the 10 dislocated hips were within Lewinnek's recommended zone suggesting the safe zone may not be appropriate in all cases. The recorded anteversion angle in the dislocated group was significantly different to the control group, suggesting the anteversion angle was a significant factor in dislocation and the safezone for the acetabular angle seemed to be between 20° and 30°. Similar to results by Biedermann [69], for posterior dislocations, the anteversion angle (4.5° ±6.6°) was smaller than the control group (15.5° ±11.9°) and for anterior dislocations the anteversion angle (42.0° ±12.7°) was considerably larger. Nishii [71] also identified a significant correlation between low cup anteversion and posterior dislocation. Yuan et al. [60] carried out a retrospective study of 62 dislocations and found that 48% of the dislocated hip were positioned outside of Lewinnek's safe zone and the degree of component malposition was directly related to the dislocation rate. These studies

verify that anteversion angle of the cup is the most important factor in determining the incidence of post-operative dislocation of the hip joint [69].

Studies have highlighted that a combined anteversion of the acetabular and femoral component should be considered. The anteversion angle of both the acetabular component and the femoral component is demonstrated in Figure 2-16.

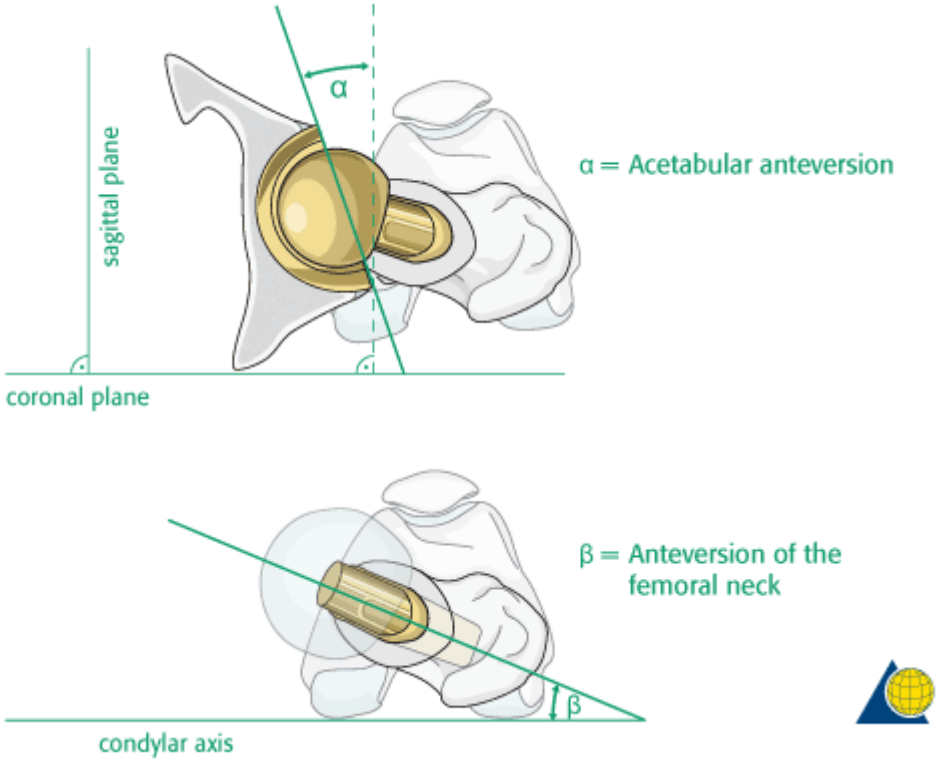


Figure 2-16 Anteversion angles of the acetabular and femoral components [72]

Masaoka et al. [70] found no dislocations were seen when the sum of the anteversion angle of the cup and the anteversion angle of the stem was between 45° and 65°. Jolles et al. [64] conducted a multivariate analysis on a study of 21 dislocated hips and demonstrated that a combined cup and stem anteversion of <40º or >60º was a statistically significant risk factor for dislocation (6.9 times). These results suggest that the acetabular cup safe zone could be extended to include the additive effect of anteversion angle of the stem [70].

He et al. [73] constructed a finite element analysis model which demonstrated that the interaction between the acetabular and femoral component positions was a key factor in improving joint stability. They also found that a larger anteversion angle

improved the stability of the joint and however this study was carried out on a healthy hip.

No statistical difference between the mean orientation of the cup and dislocation was shown by Pierchon et al. [74]. 38 total hip arthroplasties that had dislocated were compared to 14 uncomplicated arthroplasties. The mean cup inclination was 44.5º in the dislocated hips and 43.6º in the control group while mean cup anteversion was 24.4º in the dislocated group and 22.3º in the control group. The sum of acetabular and stem anteversion was also not significantly related to the number of episodes of dislocation. From the 38 dislocated hips that were studied, 11 of the hips were located within Lewinnek's safe zone. A variety of hip prosthesis and operative techniques were used within this study and no control for pelvic tilt has been described.

All the studies were in agreement that dislocation is a multifactorial issue. Muscle weakness, surgical approach, detachment of greater trochanter, head size, type of surgical approach and surgical experience are factors that should be considered, however these studies have shown that cup anteversion is an important factor in the occurrence of dislocation [71]. High cup anteversion correlated to an increased risk of anterior dislocation while low cup anteversion was associated with an increased risk of posterior dislocation. The most common dislocations are when the head dislocates posteriorly. Posterior dislocations account for 75% of cases [75] and is likely due to the anatomical and muscular differences associated with each. Therefore it is critical the surgeon avoids placing the cup at a low anteversion angle to reduce the risk of posterior dislocation.

2.5.4 Range of Motion

The purpose of THA is the restoration of a stable, well-functioning hip joint and relief of pain therefore ensuring an optimum range of motion for the hip joint is achieved is critical. The optimum range of motion is dependent on the stem/neck angle, cup opening plane design, offset, neck design, head/neck ratio, stem antetorsion, cup containment and inclination and anteversion of the cup [42]. The resulting range of motion is critically dependent on the relative orientation of both the femoral and acetabular components to each other.

Queiroz et al's [52] FEM study demonstrated that the orientation of the acetabular cup directly influenced the amplitude of the arc of movement and joint stability. D'Lima et al. [76] found that increasing the inclination angle increased hip flexion, extension and abduction and decreased adduction and axial rotation. The acetabular anteversion decreased hip abduction and the combined anteversion of the acetabular and femoral component had an additive effect. Figure 2-17 shows contour maps for range of motion. The white zones show orientations that gives an excellent range of motion, the black zones show orientations that would results in a poor range of motion due to prosthetic impingement and the grey zones show the orientations that would give a range of motion that would be borderline between excellent and poor. As shown in Figure 2-17 if the inclincation angle is 35º, there is only a small band of excellent range of motion while this potential for excellent range of motion increases as the inclination increases.

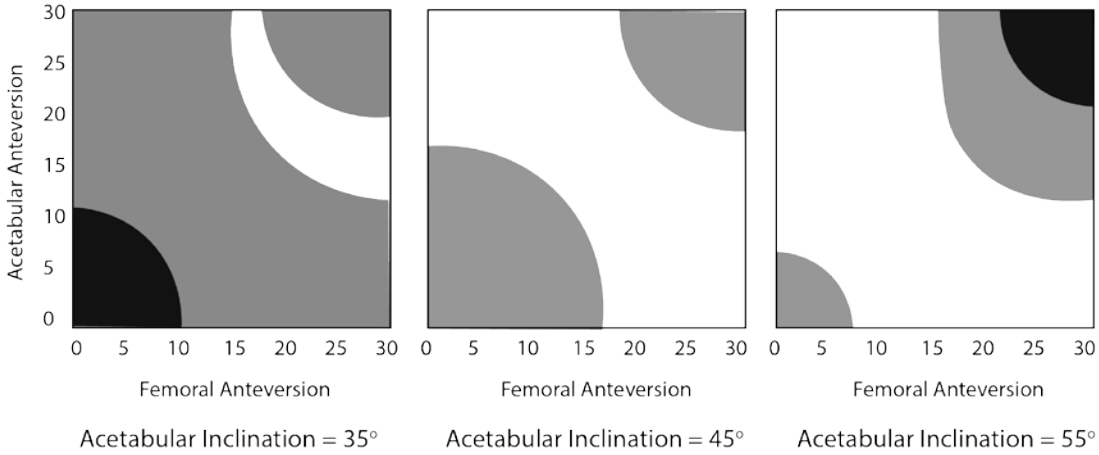


Figure 2-17 Anteversion and inclination and range of motion [76]

Kummer et al. [77] investigated acetabular cup orientations to determine the conditions for maximum internal and external rotations. Results showed that maximum internal and external rotations increased as inclination increased. It reached a maximum when the inclination was between 35º-45º before decreasing when the angle was above 45º. The anteversion angle had an opposite effect, with the maximum range of motion at 10º and as the cup anteversion was increased the range of motion decreased.

A three-dimensional computer model made from CT images of normal hips was used by Robinson et al. [78] to validate that the range of motion varies

significantly depending on the component positions. Hip flexion and external rotation increased as the acetabular inclination and anteversion and the femoral anteversion increased and external rotation increased as the anteversion of both the acetabular and femoral components decreased. Robinson recommended that the surgeon should decide how much hip motion is required for the individual patient and select the component orientation accordingly.

Widmer & Zurfluh [28] devised a mathematical model to determine the optimal combination of acetabular inclination and anteversion and stem anteversion which maximised the range of motion and minimised the risk of impingement. These results demonstrated that a low cup inclination was compatible with a small range of anteversion angles but a higher cup inclination could combine with a wider range of anteversion angles.

These studies display that the components of the acetabular anteversion and inclination and femoral antetorsion are very interdependent. The surgeon must determine the range of motion required by the patient prior to surgery and only then can the optimal orientation of the components for the patient be defined.

2.5.5 Impingement

Impingement within THA is contact between the femoral neck and the cup liner or bone to bone contact such as between the greater trochanter and the pelvis [79]. Types of impingement are shown in Figure 2-18. Impingement increases the risk of wear, loosening and dislocation as, *"the levering effect of the impingement forces the femoral head to slip over the rim"* [80].

Impingement can be both surgeon and device dependent as it can be due to the head/neck ratio, chamfer geometry of the liner, the presence of an extended rim liner and incorrect positioning of the liner. The risk of impingement is increased of the acetabular cup is in a lateralised horizontal positon [81].

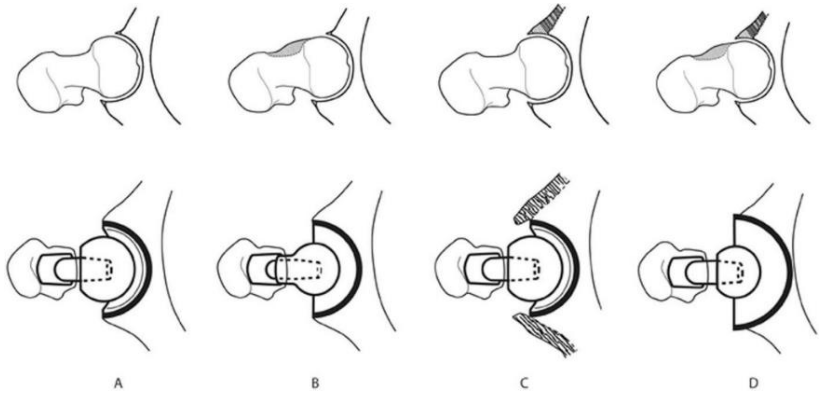


Figure 2-18 Impingement mechanisms in both normal hips and THA: A:Normal B:Cam-type impingement C:Pincer-type impingement D:Cam & pincer impingement with a liner with no chamfers [79]

Malik et al. [34] recommends instead of aiming for a target area or safe zone, the surgeon should concentrate on aligning the acetabular cup in relation to the femoral stem prosthesis. The best inclination angle for stability is under 45º therefore a position of 40º to allow for a margin of error in surgeon placement is recommended. Pedersen et al. [82] used finite element model to study the incidence of impingement with dislocation for a variety of different motion challenges. Results revealed occurrences of dislocations for most motion challenges. Dislocation occured in all cases of 30º inclination or 0º anteversion. Consequently Pedersen recommended that cup placement should be greater than 40º inclination and 10º anteversion. Based on calculated impingement risks for different acetabular component orientations during gait and varying standing positions, Mellon et al. [59] defined the optimal acetabular orientation free from impingement and edge loading as 39.7º inclination and 14.9º anteversion.

Shon et al. [80] conducted a study assessing 162 retrieved hip prosthesis to identify the prevalence of impingement, the relationship with dislocation any the influence of patient, design and surgical factors. They found no significant difference between inclination and anteversion angles of components that had impinged in comparison to those that hadn't. Three quarters of the cups had been placed within the recommended Lewinnek safe zone. Half had shown evidence of impingement demonstrating the, *"optimal acetabular position may be narrower than the ranges of acceptable acetabular position in literature"*. All the components that were assessed in this study had been retrieved from revision surgery, therefore consideration must

be given that the incidence of impingement may be higher than may be found in a general hip population .

The literature highlighted a compromise in acetabular orientation must be made to avoid impingement and the orientation should achieve good containment to avoid dislocation. These factors mean that the range of recommended orientation guidelines should be smaller than suggested in the literature.

2.5.6 Malpositioning summary

These studies demonstrate that although the factors that lead to revision surgery are multi-factorial, component orientation is important in all of them. Extreme angles of anteversion have been shown to increase the risk of dislocation, large inclination angles increase aseptic loosening, inclination angles over 40% increase polyethylene wear, the optimum range of motion is dependent on the relationship between the components and to avoid impingement, only a small range of orientations is acceptable. Although it is clear from the literature that orientation plays a contributing factor and is important, there is no consensus as to what the optimal orientation of the acetabular component is. Comparison between the conflicting guidelines is further studied in Chapter 3.

The literature has demonstrated that the orientation of the acetabular cup should be decided by the surgeon pre-operatively and consideration should be given to patient variability. Therefore it is vital to ensure that the acetabular cup can be easily and correctly placed at the angle of the surgeons choosing.

2.6 Current Techniques

There are two methods which are currently used to implant the acetabular cup and to guide the surgeon on the correct acetabular position:

- Mechanical guides
- Navigation Surgery
    - Imageless Navigation
    - Computer Aided Navigation

2.6.1 Mechanical Guides

The design of introducer, the surgical instrument, which is used to place the cup within the acetabulum, varies depending on the manufacturer and if the procedure is cemented or cementless.

For most cemented arthroplasties, the introducer is a similar design to that shown in Figure 2-19. The design of the introducer helps the surgeon achieve the correct angle. The inclination is achieved when the handle is at parallel to the table and the anteversion angle is defined by aligning the handle from above with the longitudinal axis of the patient. In cemented procedures, the introducer must be held in place for approximately 10 minutes while sufficient pressure is applied to permit the cement to set.

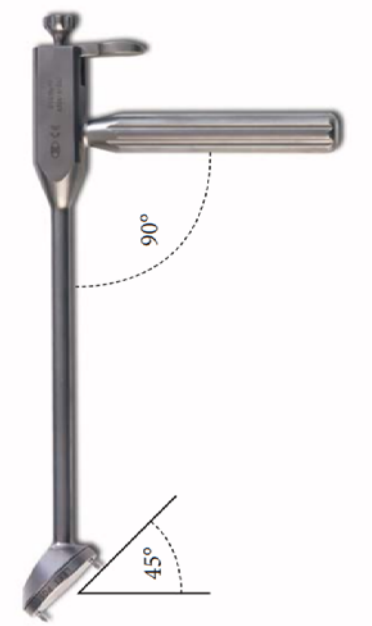


Figure 2-19 Cemented Introducer [174]

For cementless procedures, the introducer is a straight pole. A mechanical guide, as shown in Figure 2-19, can be attached to the introducer during surgery. The most common method used for implanting acetabular cups is the use of a mechanical guide [83]. Contrasting with the cemented introducer, the cementless introducer is hammered into place and is immediately set. Therefore there is no associated setting period.

Although this type of introducer is commonly used for cementless

procedures, this introducer design is also used for some cemented cups. For example, Smith and Nephew use this type of introducer for the Reflection cemented polyethylene component [84], as shown in Figure 2-20. The clinical supervisor involved in this research uses this type of introducer therefore this design of introducer was used for the project.

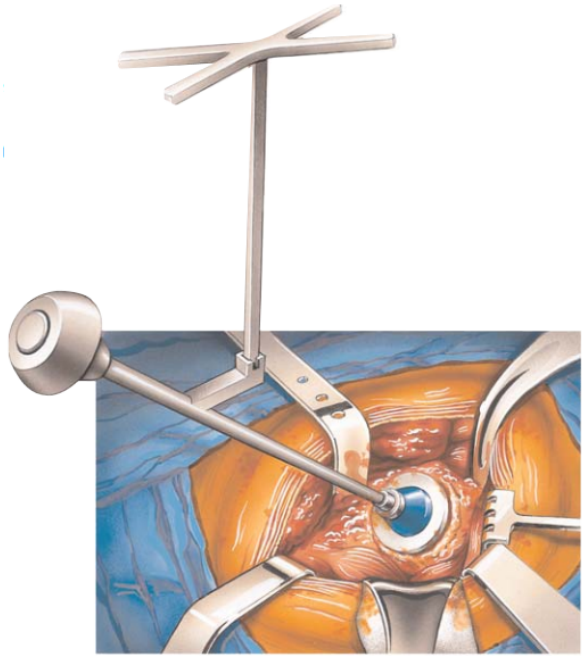


Figure 2-20 Smith and Nephew Acetabular Cup Introducer [84]

As shown in Figure 2-20, the device is constructed of metal rods which can be attached to the introducer during surgery. The metal rods guide the surgeon to show the correct position has been achieved. When the surgeon looks at the guide from the side, the metal rod should be parallel to the operating table to achieve the set inclination angle. When the surgeon looks at the guide from above, the metal rod should be parallel with the longitudinal axis of the patient to achieve the set anteversion angle. These devices are set prior to operation and provide a pre-determined orientation which means there is no allowance for no patient variability as they do not use an anatomical reference [85].

As the devices direct the surgeon to a given orientation, the accuracy of mechanical guides have a direct consequence on the postoperative acetabular cup alignment. Minoda et al. [83] assessed fifteen different mechanical guides by directly measuring the angles and showed that in all guides the angles indicated were different to those measured. The inclination was larger by a mean of 2º and

anteversion smaller with a mean of 6º which suggests that the alignment guide itself could be contributing to errors in component positioning, in particular the anteversion angle [83].

Mechanical guides have been shown to be inaccurate and imprecise as the surgeon is required to have precise visual control over two planes at once [86] and there is a tendency to underestimate both inclination and anteversion[87]. Bosker et al. [87] evaluated the accuracy of estimating cup position using a mechanical guide in comparison to measured outcomes from radiographs. In a study of 194 patients, 64.5% of cups were placed within 5º of the estimated inclination angle and 61% for anteversion angles. In comparison to the Lewinnek's safe zone, only 56.5% of acetabular cups were placed within this guideline. If the safe zone was reduced to +/- 5º and then +/-1º the accuracy of acetabular cups placed within these guidelines would reduce to 21.5% and 2.9% respectively. The study also highlighted a clear learning curve difference between residents & surgeon using a mechanical guide for inclination. Saxler et al. [88] used a CT scan to measure position. Results showed that only 27 of the 105 cups were positioned correctly within the Lewinnek safe zone. The mean inclination angle was 45.8º ± 10.1º and the mean anteversion angle was 27.3º ± 15.0º. DiGioia [89] demonstrated that none of the acetabular cups were correctly positioned with 45º inclination and 20º anteversion and 78% of the acetabular cups were placed outside the Lewinnek's safe zone. Results established that anteversion was much harder to judge as 58/74 cups were placed outside the desired anteversion position compared to only 1/74 for inclination. This study used the coronal plane as the reference plane for placement and the APP as the reference plane for measurement therefore error was introduced into the measurement [30].

Another significant limitation with mechanical guides is that they assume a fixed, predetermined pelvic orientation therefore the position of the patient in relation to the operating table is vital. When the patient is placed in the lateral decubitus position, the pelvis should be placed in the neutral position. Despite the variety of methods of positioning the pelvis, surgeons admit it is, "difficult to know precisely how the patient's pelvis is orientation during surgery" [89]. Therefore the orientation of the acetabular cup may considerably vary based on the position of the patient's pelvis on the operating table [29].

Consequently the surgeon must be aware of the pelvic position on the operating table and any motion that occurs during the operation [90]. Movement of the pelvis is inevitable during the operation due to factors such as the attachment of the pelvis to the operating table, hip dislocation, movement generated by the surgical procedure and range of movement testing [90]. Pelvic motion during surgery was assessed by Asayama et al. [90] using a pelvic tilt goniometer. The study showed that each of the pelvises studied rotated internally, associated with specific manoeuvres of positioning and tissue retraction and *"this universal internal rolling motion of the pelvis at this critical time during the operation may create risk for causing inadvertent decreases of cup anteversion"* [90]. As the hip is covered by surgical drapes during the operation, mechanical guides count on the surgeon's experience to correct for any movement in the pelvis during the operation [46].

Despite the limitations with mechanical guides, these devices are low cost and do not increase operating time so are still widely used [87]. Conversely some surgeons find it easier to estimate the position without specific guidance or feedback on position [87].

2.6.2 Navigation Surgery

Navigation systems have been developed to provide the surgeon with greater control during the operation and can be divided into two categories, computer navigated which are image based (based on CT scans) and imageless. Navigation surgery uses computer algorithms and tracking systems which use optical cameras and infrared light emitting diode (LED) markers to provide feedback to the surgeon on the 3D position of the prosthesis, surgical instruments and patient's pelvis intra-operatively [91].

2.6.2.1 Computer Navigated

Computer navigated systems can be used both in pre-operative planning, intra operatively and post-operative assessment (Figure 2-21).

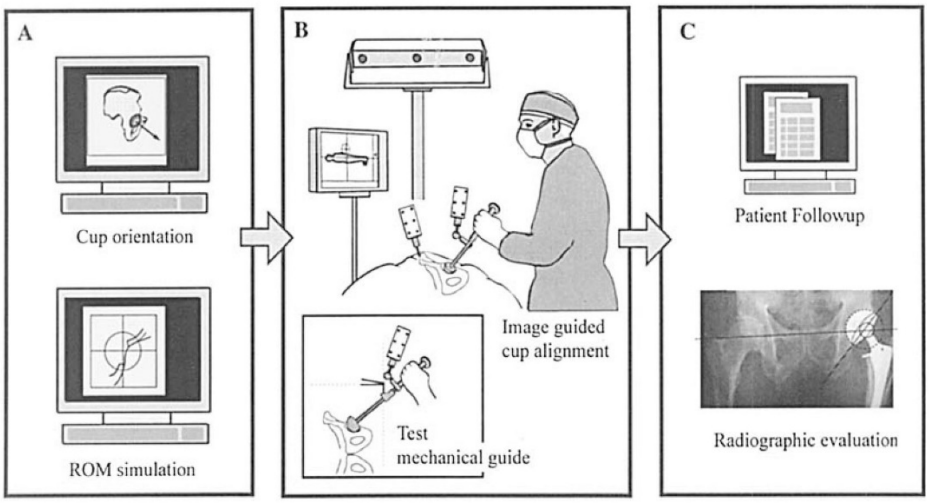


Figure 2-21 Computer Navigation A: Pre-operatively B: Intra-operatively C: Post-operatively [92]

To begin, computer navigation requires a pre-operative CT scan of the pelvis. This scan is used in pre-operative planning to determine the correct implant size, optimum orientation of the prosthesis and to test the range of motion. Infrared LED markers are rigidly attached to the patient's pelvis and the instrumentation. Optical cameras track the position of the markers resulting in the system knowing the position of the pelvis and instruments throughout the operation. The surgery starts with calibration of the system. This is to match the pre-operative scan with the patient on the operating table. Specific anatomical landmarks are marked using a probe which aligns the position of the pelvis on the table with the CT model of the pelvis. A computer interface helps with guiding the surgeon to the correct acetabular orientation. Based on the success of patient specific instrumentation for total knee arthroplasty, patient specific acetabular guides based on CT data is an active area of research. These guides are based on the bony anatomy of the patient's acetabulum, are created using a segmentation software and 3D printing, assisting the surgeon in accurately reproducing the preoperative plan [93].

Using computer-navigated techniques, the surgeon is able to increase accuracy and reliability as the position of the pelvis is monitored during surgery. The pre-operative scan provides the surgeon with considerably more information which helps prepare and plan for special situations [42]. Widmer [42] conducted a study using computer navigated surgery and demonstrated that surgeons were, "able to reach their planned position closely but there was a range of 6º". However the time required for surgery was increased, with the operating time increasing between

49.3% and 100% which resulted in higher blood loss (a loss of 140ml more than average procedures). Surgeons find the technique cumbersome and impractical [94] and the, *"time consuming intraoperative matching procedure is associated with a strong learning curve"* [95].

One of the limitations of using computer navigated techniques is the requirement of a CT before the operation which adds a significant radiation dose to the patient [96]. In patients with prior surgery, the image quality can sometimes be poor due to metallic artefacts [95]. The additional CT and related logistical chain with pre-operative planning represents extra costs resulting in the costs for the whole treatment becoming higher [95]. Therefore, CT based navigation techniques add a considerable overhead to the treatment from a clinical point of view [97]. Cost effectiveness of these systems in reducing the revision burden is yet to be proven [98].

2.6.2.2 Imageless Systems

Imageless navigation systems don't require a pre-operative CT scan and only require a few additional intra-operative steps so are more feasible for use in surgery [66]. Imageless systems require the surgeon to palpate the anatomical landmarks, iliac spines and pubic symphysis, to mark the anterior pelvic plane using a navigated stylus [99]. The positions of the stylus is recorded to mark the reference position and calibrated with the computer system.

Jenny et al. [100] compared the accuracy of an imageless navigation system in comparison to CT using the OrthoPilot system. Using the imageless system the inclination angle was recorded at a mean angle of 42º ± 4º while the inclination measured from CT the angle was 44º ± 5º. The anteversion angle using the imageless navigated system was recorded at a mean angle of 15º ± 3º and using the CT the angle was 19º ± 7º. This showed significant difference in both the inclination and the anteversion angle between the imageless system and CT measurement. 73% of the acetabular cups were positioned within Lewinnek's safe zone.

There is still a significant cost associated with imageless systems. The initial expense of the system can be $250,000. Recurring case costs for the tracking

arrays and pins are $473 per patient and the additional operating time required can cost approximately $1100 more per patient [101].

2.6.2.2 Calibration

The calibration of the pre-operative information to the position of the patient on the operating table is one of the most important steps in navigated surgery. [102] The accuracy in calibration accounts for the accuracy of the whole procedure [42] and computer navigation will only lead to correct implantation of the acetabular cup if the initial information inserted into the computer is accurate [99]. Navigated surgery uses the APP as the reference plane and correct definition of the plane comes from accurately identifying the anterior superior iliac spines and pubic tubercles. In total knee replacement, anatomical landmarks are directly exposed or easily palpated minimising risk. The bony landmarks in THA are much harder to correctly identify as they have to be palpated through tissue of varying thickness [99]. Wolf et al. [29] proved that even small errors (1-4mm) in anatomical landmark localisation could cause a large error in cup orientation, for example, if there was a 4mm error in measurement this could cause 2º inclination error and 7º anteversion error.

Spencer et al. [99] assessed the intra-and inter-observer reliability in establishing the anterior pelvic plan in imageless computer navigation systems using a cadaver. There was a significant difference between both the intra and inter observer recorded landmarks resulting in a significant difference between the inclination (intra SD 4.3º inter SD 5.9º) and anteversion angles (intra SD 6.3º inter SD 9.6º) and the anteversion angle was significantly larger for both cases. The cadaver used had a low body mass index (BMI) therefore it was easier to palpate. In reality the normal patients for THA have a larger BMI making it harder to correctly palpate bony landmarks. Parratte [103] highlighted that for patients with a BMI greater than 27, there was a poor correlation between the recorded intra-operative and post-operative measurements.

Although computer navigated systems are considerably more accurate than mechanical guides, the adoption of these systems for helping position the acetabular cup in total hip arthroplasty has been slow. This is for many reasons

such as the increased cost, increase to operating time, increased radiation for the patient and the associated learning curve for the surgeon [46].

2.6.3 Comparison between techniques

Direct comparison between the mechanical guides and navigation systems further highlight the differences between the systems. Wixson & MacDonald [104] compared the accuracy of imageless-computer assisted technique to using a mechanical guide for a posterior minimally invasive approach. 30% of the cups positioned using imageless navigation compared to 6% of the cups positioned using a mechanical guide were within their recommended guidelines of 40º -45º inclination and 17º -23º anteversion. The results from this study were measured from radiographs and there was a poor correlation between the anteversion angles measured from radiographs and the navigated surgery. Similarly Kalteis et al. [66] found that placement of the acetabular cup was significantly improved when using an imageless navigation system rather than a mechanical guide. The average inclination angle when using the imageless navigation was 45º and the average anteversion was 14.4º. When using a mechanical guide, the average inclination was 42.3º and the anteversion was 24.0º. Using the imageless navigation, 3 cups were outside of Lewinnek's safe zone while 11 of the cups placed using the mechanical guide were outside the recommend guidelines.

Using imageless navigation increased the duration of the surgical procedure by an average of 8 minutes. Najarian et al. [46] compared minimally invasive posterior approaches for imageless computer based surgical navigation to using a mechanical guide and included two navigation groups to test for any associated learning curve. The results showed a significant decrease in the number of outliers when using navigated surgery compared to mechanical guides. A significant difference between operating times was also recorded as the average operating time using a mechanical guide was 105 minutes. When using the navigated technique, the average times increased to 124 and 128 minutes. Parratte et al. [103] found no difference in the mean position of the acetabular cup between using mechanical and imageless navigation techniques. There was a significant difference in the percentage of outliers (57% freehand and 20% navigated) and the mean

additional operating time for imageless navigation was 12 minutes (range between 8-20 mins).

Leenders et al. [105] compared a completely freehand method (with no use of a mechanical guide) to a CT navigation method. Only the inclination angle was assessed with results showing the computer aided system reduced the variability in cup position.

Sugano et al. [106] compared CT-based navigation to THA performed using a mechanical guide. There was no significant difference in the mean inclination however the variance and the mean anteversion was greater in the mechanical guide group. Compared to the Lewinnek zone, none of the navigated group were outside of the safe zone while 31 placed by a mechanical guide were outside of the guidelines. There was also a statistically significant difference between the operating times. When using a mechanical guide the mean operating time was 111 mins compared to 169 mins when using CT-based navigation. Comparison of computer navigated surgery to mechanical guides by Haaker et al. [91] revealed a significant improvement in the desired surgical outcome however this study used different reference planes as the coronal plane was used for the mechanical guides while the APP was used for the computer navigation.

When comparing data measured from radiographs and CT it is critical to use the same reference plane or give consideration to pelvic tilt. Computer navigated systems use the anterior pelvic plane whilst radiographs and surgical instruments are based on the coronal plane. As shown in Figure 2-22 below, if using the separate reference planes, navigation systems will report the beta angle whilst clinicians report the alpha angle. Babisch et al [44] demonstrated that if a, *"patient has a pelvic tilt of 15° and the surgeon places the acetabular cup at 40° inclination and 15° anteversion then the computer navigated system will display 44° inclination and 26° of anteversion"* [44].

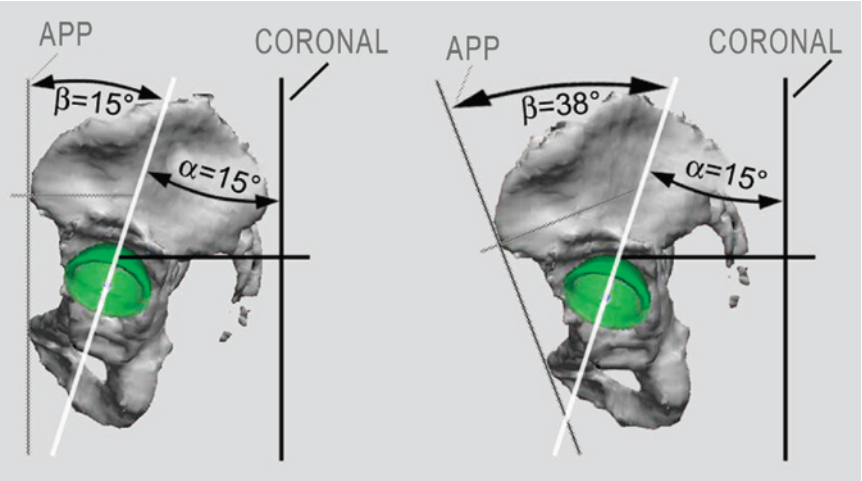


Figure 2-22 Difference between coronal and app measurements [44]

Guidelines such as Lewinnek's safe zone and Murray's definitions were defined in the coronal plane therefore cannot be directly applied to measurements taken from CT data unless pelvic tilt has been considered. If the pelvis is not in a neutral position then application of these guidelines to a navigation system is inaccurate [44] and any orientation system that refers to the APP without considering pelvic tilt must be regarded as imprecise [107]. Some studies [89,91,64,66,43,74] have not taken this into consideration [30]. Most navigation systems have not considered pelvic tilt [44] which means the acetabular cup is measured only relative to a known pelvic position and ignores the functional relation of the pelvis relative to the longitudinal axis of the patient. *"Acetabular anteversion reported relative to the coronal plane of the body provides a more functional cup position than the anatomic anteversion reported relative to the APP"* [34].

2.6.4 Alternative Methods

Many different methods have been developed to improve acetabular cup positioning. The following techniques will be discussed:

- Transverse Acetabular Ligament
- Hip Sextant
- Gravity Assisted Bubble Guide
- Smart Phones

2.6.4.1 Transverse Acetabular Ligament

The transverse acetabular ligament (TAL) when, “working normally acts as a tension band between the posteroinferior and anteroinferior aspects of the acetabulum, resisting anteroposterior widening during loading of the joint” [108]. Aligning the acetabular cup parallel to the ligament provides a guide based on the patient’s natural acetabular orientation.

Viste et al. [109] found in comparison to the APP, the anatomical anteversion of the TAL can range from -8º to +13.3º and is specific for individuals. The average antevesion angle of the TAL (1.9º) is outside the safezone defined by Lewinnek. Archbold et al. [108] found the anatomical anteversion angle of the TAL to range from 5.3º – 36.1º while Pearce et al. [110] measured the radiographic anteversion angle of the TAL from 11.3 – 24 º. Griffin et al. [111] carried out an in vivo study and discovered the mean TAL anteversion angle was 20.5 º +/- 7 º with a significant difference between genders. A significant amount had an anteversion angle greater than Lewinnek’s recommended safe zone.

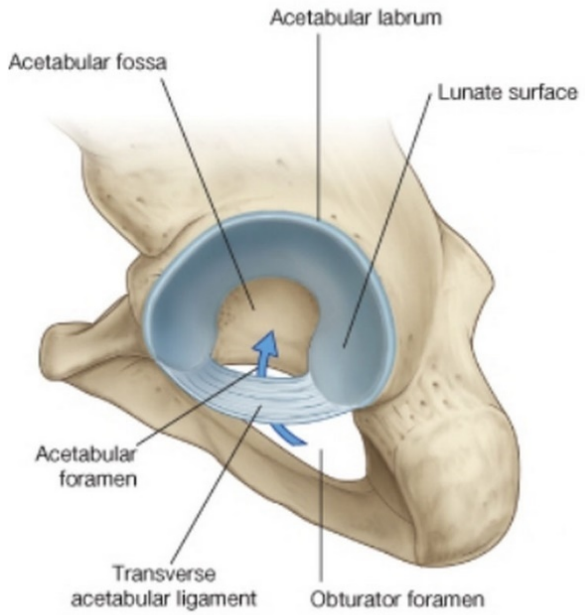


Figure 2-23 Transverse Acetabular Ligament Anatomy

Archbold et al. (2006) used the TAL as a guide in 1000 cases and the TAL was identified and exposed in 99.7% of cases. Using the technique, the dislocation rate was 0.6%. In comparison Miyoshi et al. [112] identified the TAL in 81.6% of cases while Epstein [113] in 47% of cases as identification of the TAL can be difficult. Beverland [114] found use of the TAL as a guide reduced the dislocation rate from 3.7% to 1% with the TAL immediately visible in 49% of cases.

The use of the TAL as a landmark is helpful with positioning the acetabular component, in particular with judging anteversion. The technique is a practical technique as it is patient specific, no extra instrumentation is required and is independent of the APP and patient position. Although helpful in estimating anteversion, the TAL provides no guide towards the inclination angle [114]. For this reason, the use of the TAL as a guide was not directly relevant to the design process but provided a useful verification of acetabular cup alignment for experienced surgeons.

2.6.4.2 Hip Sextant

Figure 2-24 Hip Sextant [115]

The Hip Sextant, as shown in Figure 2-24, is a navigation device which guides the surgeon to the pre-planned orientation. Based on a pre-operative CT, a patient-specific 3D model and plan is created. The Hip Sextant is attached to anatomical landmarks on the patient's pelvis (ischium, anterior superior iliac spine and the surface of the ilium) to provide a patient specific reference. The device points to the desired orientation and uses the APP as a reference plane [115]. The technique used to help the surgeon align the acetabular cup is shown in Figure 2-24 below.

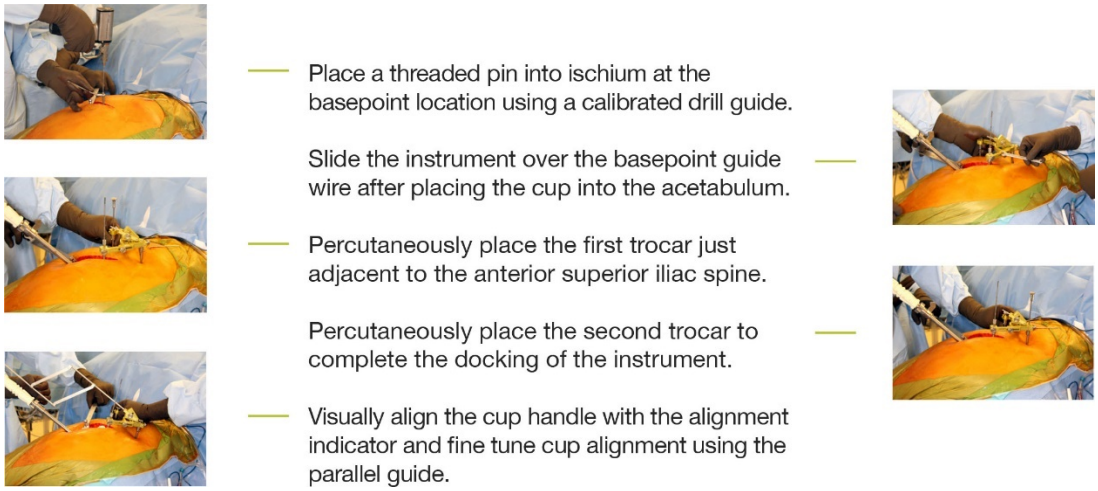


Figure 2-25 Hip Sextant Technique [116]

Steppacher et al. [117] assessed the accuracy of the Hip Sextant with CT based computer navigated THAs. Accuracy was measured against the pre-operative planned position for each prosthesis and the mean error of the Hip Sextant group was 1.3º +/- 3.4º for inclination and 1.0º +/- 4.1º for anteversion. In comparison the mean error using computer navigated techniques was 3.5º +/- 4.2º for inclination and 3.0º +/- 5.8º for anteversion. In comparison with CT-based navigation surgery, the mean length of operation was reduced. There were limitations in this study as the surgeon conducting the study was the inventor of the device so had previous experience of the tool.

The Hip Sextant improved the accuracy of placement of the acetabular cup however similar to imageless navigation techniques, the accuracy of the device is dependent on correct palpating of the anatomical landmarks. The device is based on pre-operative CT which would increase the cost of use and radiation to the patient.

2.6.4.3 Gravity Assisted Guidance System

Echeverri et al. [86] developed a gravity assisted guided system and technique to help with acetabular cup orientation. The device uses bull's eye bubble levels which guide the surgeon and display when the device is level in two perpendicular directions. The device consists of a bubble level which is pinned to the iliac crest to help the surgeon with correctly positioning the patient. This guides the surgeon

throughout the operation on any movement of the pelvis. The second bubble level is attached to the introducer and set to show the surgeon when the desired angle is achieved. In comparison to mechanical guides, the average error for the gravity assisted guide was 0.3 º for inclination and 0.4 º anteversion while the average error using a mechanical guide was -4.7º inclination and 10.4º anteversion.

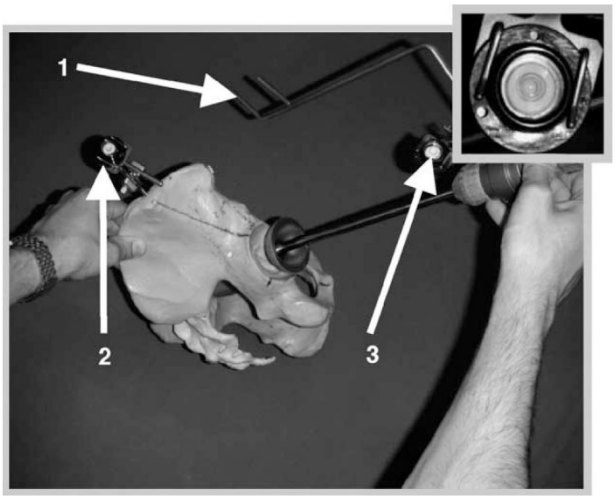


Figure 2-26 Gravity Assisted Guide 1: Anatomical reference point 2: Bubble control for pelvic Position 3: Bubble control for alignment [86]

2.6.4.4 Smart Phone Technology

Peters et al. [118] used the accelerometer and a camera protractor application on an iPhone to help with acetabular cup positioning as shown in Figure 2-27.

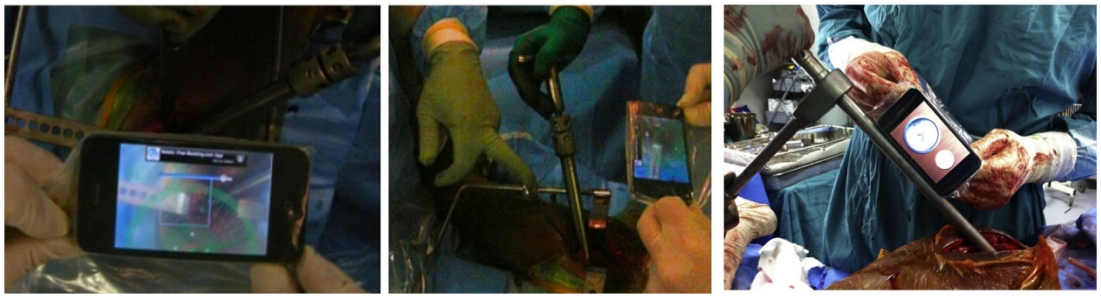


Figure 2-27 Smart Phone Technique A&B: Anteversion C:Inclination [118]

The angles from the iPhone were the only measurements intraoperatively. They were compared with measurements taken postoperatively for accuracy. The cups placed using this technique were all within the safe zone recommended by

Lewinnek however only 26% of the cups were placed at the desired anteversion angle. The technique is not limited to specific manufacturer's equipment and does not require a change to current surgical technique. However similar to mechanical guides, this technique requires the surgeon to have visual control over two planes at once and uses two separate functions which increases the difficulty and influences the accuracy [118].

2.7 Conclusion

There are many limitations within THA with regard to correct orientation of the acetabular cup. Although there is wide recognition that malpositioning increases the risk of many complications such as aseptic loosening, dislocation, impingement, wear and reduced range of motion there is no agreement on the optimum acetabular cup orientation. Limitations with the reference planes, orientation definitions and varying measurement techniques lead to confusion between the guidelines. In the following chapter, using Murray's developed equations, recommended orientation from textbooks, literature and manufacture's guidelines will be compared to try find a consensus.

Cup orientation should be specific for each patient rather than a universal standard [109,108,69;] therefore it is vital that the surgeon is able to correctly position the acetabular cup in line with the desired orientation. Many improvements have been made to improve the design of implants, material properties and fixation methods however little effort has been made to provide surgeons with more accurate tool guides or strategies to improve the reproducibility of alignment. Mechanical guides are inaccurate and imprecise and are positioned to a set orientation regardless of varying patient anatomy. Navigated techniques, although improved in accuracy, increase operating time, and are associated with a high learning curve and increased costs. Therefore the project aim of this thesis is to use product design methodologies to design, develop and test a low cost, reliable method of aiding surgeons in accurately positioning the acetabular cup in total hip arthroplasty.

3

Research Synthesis of Recommended Orientations of the Acetabular Cup

3.1 Chapter Contents

Comparisons between recommended orientations of the acetabular cup from literature, academic textbooks and manufacturers' guidelines are presented in this chapter. This chapter discusses the definitions of acetabular orientation, detailing the operative, radiographic and anatomical reference systems. Equations which can be used to convert between these definitions are derived and these are used to convert the recommended guidelines to a global reference system to enable a valid comparison. Results of these comparisons are discussed which highlights the current discrepancies in reference systems and recommended orientations.

Excerpts of this work have been published in the Journal of Arthroplasty. The presented work in this chapter expounds upon the work discussed in the paper.

3.2 Introduction

Correct component positioning is the major surgeon controlled variable which impacts the success of THA [101]. As discussed in the previous chapter, when the acetabular component is malpositioned, there is an increased risk of many complications which increase the risk of revision surgery. Despite extensive recognition towards the significance of positioning, there are disparities in the literature as to what the ideal orientation of the acetabular component is [119]. Objective comparison of the guidelines is difficult due to varying reference planes, orientation definitions, surgical technique, implants used and measurement methods.

Murray [31] defined three orientation definitions, anatomical, radiographic and operative, and provided equations to convert between definitions. Explanation of these definitions and the derivations of the conversion equations will be described in the following section of this chapter. Murray's definitions use the coronal plane of the patient as the reference plane.

Yoon et al. [120] conducted a study using some of the current recommendations from literature and converted these into a global reference system for comparison using Murray's equations. Each guideline was transformed to use the pelvic reference system as a reference plane and a pelvic tilt correction algorithm was used to ensure pelvic tilt was considered. As none of the literature reported the patient pelvic tilt angles, adjustments were made based on Lembeck's [107] study of assuming pelvic tilt angles of -8º standing and -4º supine.

The results gathered from literature demonstrated a varied range as shown in Table 3.1 however when Yoon et al. transformed to a global reference system there was less variation in the guidelines. The results listed in the table compare data from dislocated components against a control group. The number in the dislocated group in relationship to the control group is not representative of the incidence of dislocation. For example, Jolles et al.[64] performed 2,023 primary THAs between 1991 and 1998. The incidence of dislocation in this group was 1.48%. Due to a lack of available radiographs, some participants were excluded. To provide a fair comparison, 21 patients without any history of dislocation were compared to the 21 patients with dislocation.

Yoon et al. stressed that by using a common reference frame, studies can be directly compared and a common consensus could be found. A common consensus on the ideal orientation could be incorporated into surgical instrumentation to enable surgeons to achieve a specific orientation [120].

References	#dislocated	#control	Original				
			Inclination (degrees)		Anteversion (degrees)		Pelvic Tilt
Lewinnek et al. [39]	9	102	30-50	Radiographic	5-25	Radiographic	0
McCollum et al. [121]	5	436	30-50	Radiographic	20-40	Operative	-8
Dorr [94]	39	22	<55	Radiographic	10-25	Radiographic	-4
Seki et al. [122]			30-50	Radiographic	10-30	Radiographic	-8
Jolles et al. [64]	21	21	<50	Radiographic	20	Operative	-4
Widmer & Zurfluh [28]			40-45	Radiographic	20-28	Radiographic	-8
Yoshimine [123]			35-55	Radiographic	10-30	Radiographic	-8
Biedermann et al. [69]	127	114	35-55	Radiographic	5-25	Radiographic	-4
Masaoka et al. [70]	10	307			20-30 (RA)	Radiographic	-4

Table 3.1 Summary of recommended safe zones [120]

Yoon's study focused on resolving the inconsistencies within the literature and by converting the guidelines into the radiographic definition, studies which were carried out post-operatively could be compared. At the time of writing, there is no literature comparing intra-operative guidance. Therefore the aim of this chapter is to convert guidelines from literature, from surgical textbooks and from orthopaedic implant manufacturers' safety guidelines to a global reference system to enable comparison, highlight any disparities and to identify a common consensus of best practice. Any common consensus could be incorporated into the design of a device to help surgeons with accurate positioning of the acetabular cup.

3.3 Definitions

3.3.1 Acetabular Axis

The acetabular axis originates at the geometric centre of the acetabular socket and is perpendicular to the acetabular plane (Figure 3-1) [124]. The acetabular axis plane lies on the acetabular axis and is perpendicular to the acetabular plane.

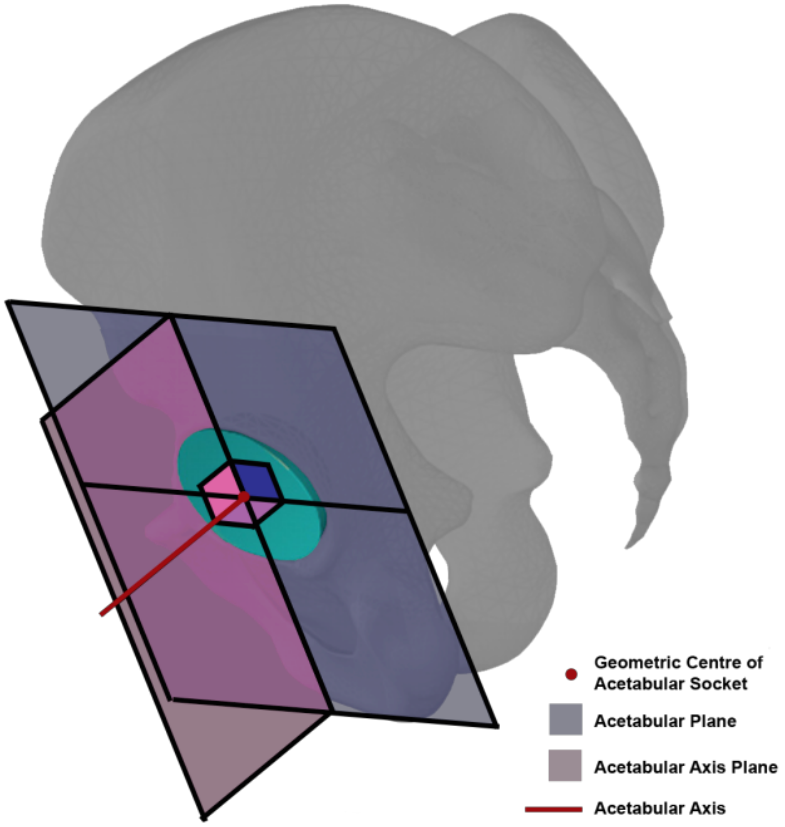


Figure 3-1 Acetabular Axis

The three different reference systems (operative, radiographic and anatomical), are used together with the acetabular axis to quantify acetabular orientation. These are outlined below.

3.3.2 Operative Reference System

The operative reference system is defined [125] by the intra-operative position of the patient on the operating table. Therefore, when the patient is in the ideal lateral decubitus orientation, with the sagittal plane horizontal, and coronal and transverse planes both vertically oriented, operative inclination (δ) is the angle between the acetabular axis and the sagittal plane whilst operative anteversion (ϕ) is the angle between acetabular axis as projected onto the sagittal plane and the longitudinal axis of the patient (Figure 3-2). The trignometric definition of each angle is shown while the derivation of each can be found in the Appendix.

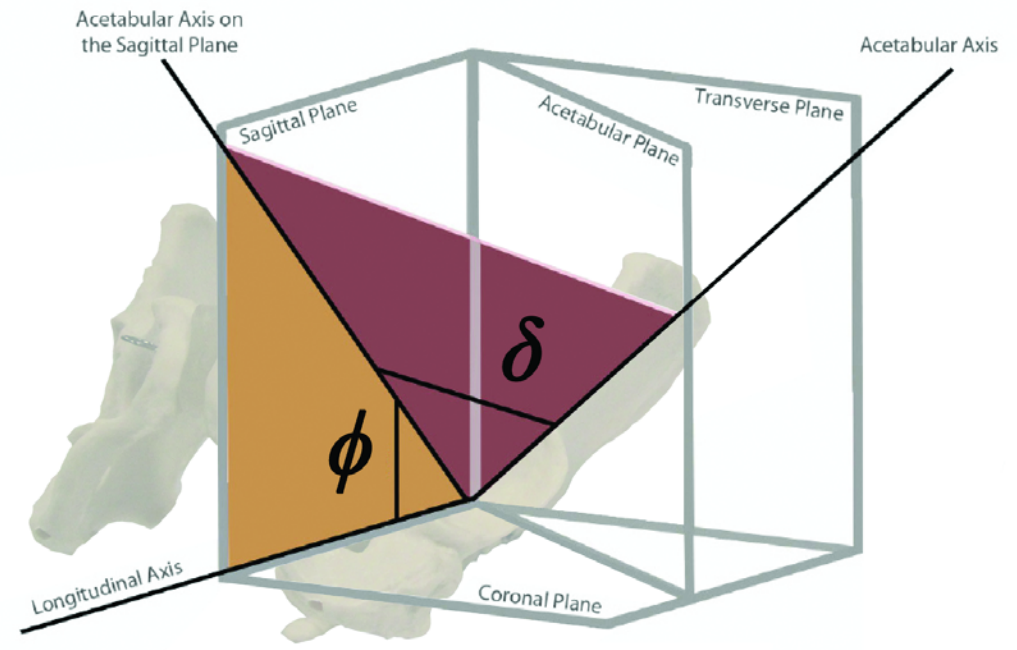


Figure 3-2 Operative Definition: Operative inclination (δ) and operative anteversion (ϕ)

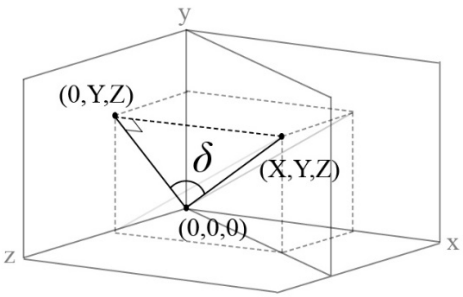


Figure 3-3 Operative Inclination (OI)

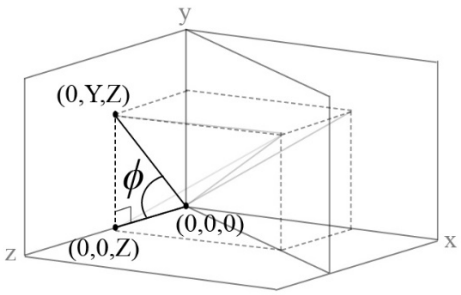
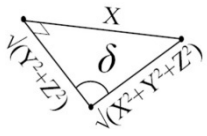
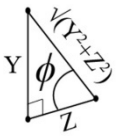


Figure 3-4 Operative Anteversion (OA)



$$\tan\delta = \frac{x}{\sqrt{y^2+z^2}} \qquad \sin\delta = \frac{x}{\sqrt{x^2+y^2+z^2}} \qquad \cos\delta = \frac{\sqrt{y^2+z^2}}{\sqrt{x^2+y^2+z^2}}$$



$$\tan\emptyset = \frac{y}{z} \qquad \sin\emptyset = \frac{y}{\sqrt{y^2+z^2}} \qquad \cos\emptyset = \frac{z}{\sqrt{y^2+z^2}}$$

3.3.3 Radiographic Reference System

The radiographic definition of inclination and anteversion relies on measurements taken from x-rays which are used for pre-operative planning and used post-operatively to measure the success of the procedure. This definition would also be used if the operation is carried out with the patient in the supine pose. The radiographic inclination angle (θ) is defined as the angle between the longitudinal axis of the body and projection of the acetabular axis in the coronal plane and the radiographic anteversion angle (α) is the angle between the acetabular axis and the coronal plane [31] (Figure 3.5). The trignometric definition of each angle is shown below.

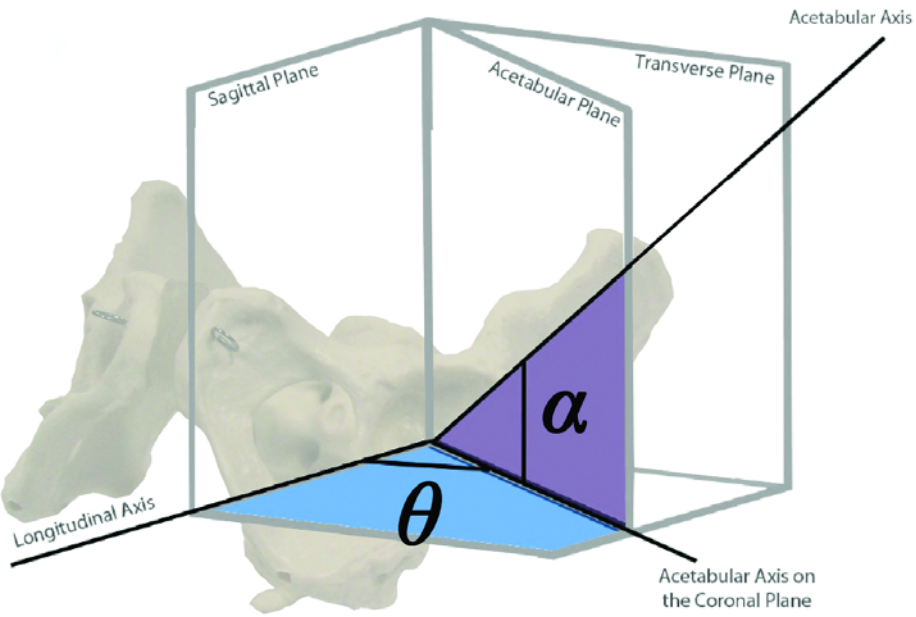


Figure 3-5 Radiographic Definition: Radiographic inclination (θ) and radiographic anteversion (α)

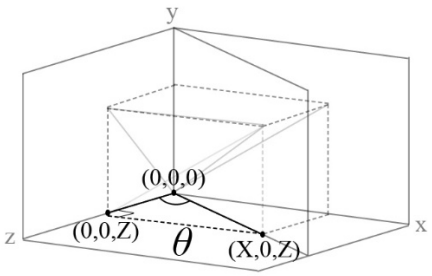


Figure 3-6 Radiographic Inclination (RI)

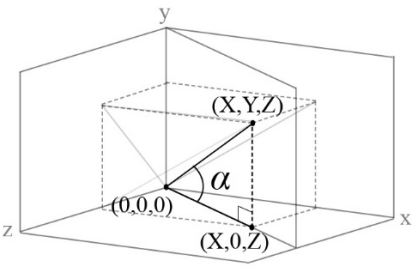
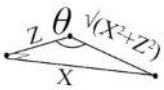
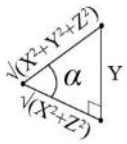


Figure 3-7 Radiographic Anteversion (RA)



$$\sin\theta = \frac{x}{\sqrt{x^2 + z^2}} \quad \cos\theta = \frac{z}{\sqrt{x^2 + z^2}} \quad \tan\theta = \frac{x}{z}$$



$$\tan\alpha = \frac{y}{\sqrt{x^2 + z^2}} \quad \sin\alpha = \frac{y}{\sqrt{x^2 + y^2 + z^2}} \quad \cos\alpha = \frac{\sqrt{x^2 + z^2}}{\sqrt{x^2 + y^2 + z^2}}$$

3.3.4 Anatomical Reference System

The anatomical reference [7] defines the anatomical inclination (β) as the angle between the acetabular axis and the longitudinal axis of the patient and the anatomical anteversion (γ) as the angle between the acetabular axis, as projected onto the transverse plane, and the transverse axis [31] as shown in Figure 3-8. Again the trignometric definition of each angle is shown below.

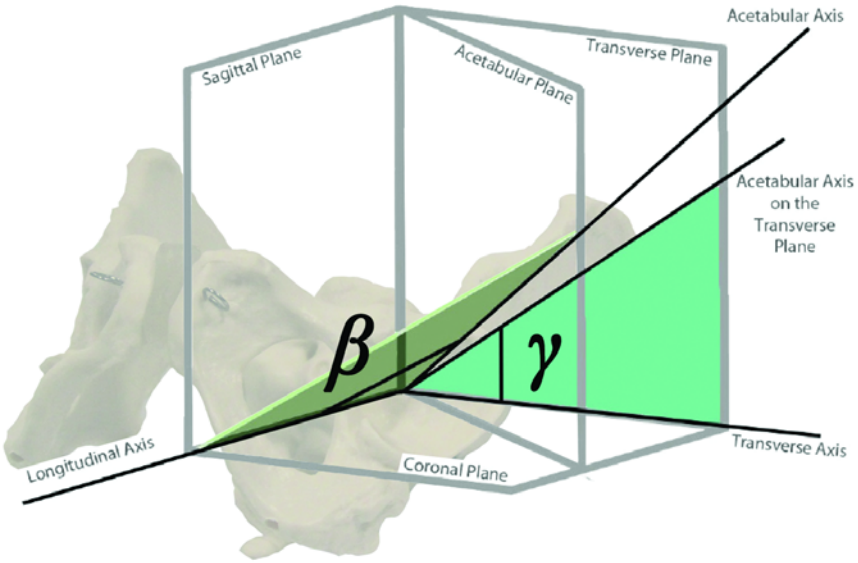


Figure 3-8 Anatomical Definition: Anatomical inclination (β) and anatomical anteversion (γ)

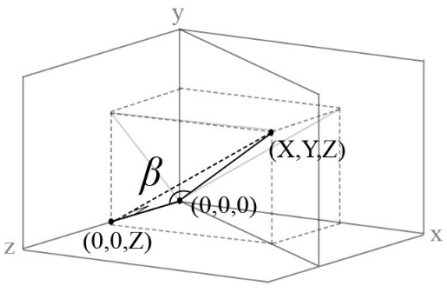


Figure 3-9 Anatomical Inclination (AI)

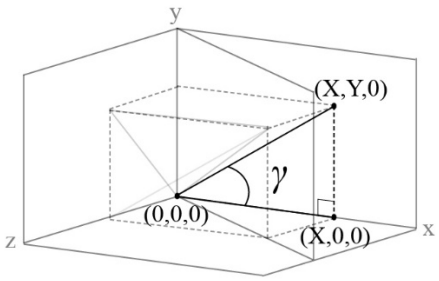
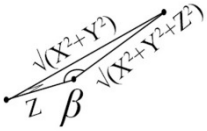
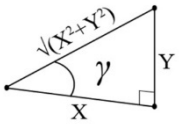


Figure 3-10 Anatomical Anteversion (AA)



$$\tan\beta = \frac{\sqrt{x^2+y^2}}{z} \qquad \sin\beta = \frac{\sqrt{x^2+y^2}}{\sqrt{x^2+y^2+z^2}} \qquad \cos\beta = \frac{z}{\sqrt{x^2+y^2+z^2}}$$



$$\tan\gamma = \frac{y}{x} \qquad \sin\gamma = \frac{y}{\sqrt{x^2+\ y^2}} \qquad \cos\gamma = \frac{x}{\sqrt{x^2+\ y^2}}$$

3.4 Methodology

The recommended position of the acetabular cup was collated from the literature [39,125,121,28,69,122] and academic textbooks [126,127,128]. Based on clinical input, the National Joint Registry for England and Wales [13] was used to identify the most commonly used uncemented implants, the surgical guidelines for which were subsequently selected for inclusion in the analysis [84,129–135]. All orientations were transformed to use the anterior pelvic plane as a reference. For studies which had no pelvic tilt control, a correction factor was used [107,44], adjusting 1.5º inclination and 4º anteversion for every 5º of pelvic tilt. The guidelines were all converted to the operative angle definition (δ,ϕ) for comparison using the equations [31]:

$$\sin(\delta)=\sin(\theta)\cos(\alpha)=\sin(\beta)\cos(\gamma)$$
$$\tan(\phi)=\tan(\alpha)/\cos(\theta)=\sin(\gamma)\tan(\beta)$$

3.5 Results

Comparison of the Lewinnek safe zone guidelines in each of the angle definitions demonstrated the difference between the definitions as shown in Figure 3-11.

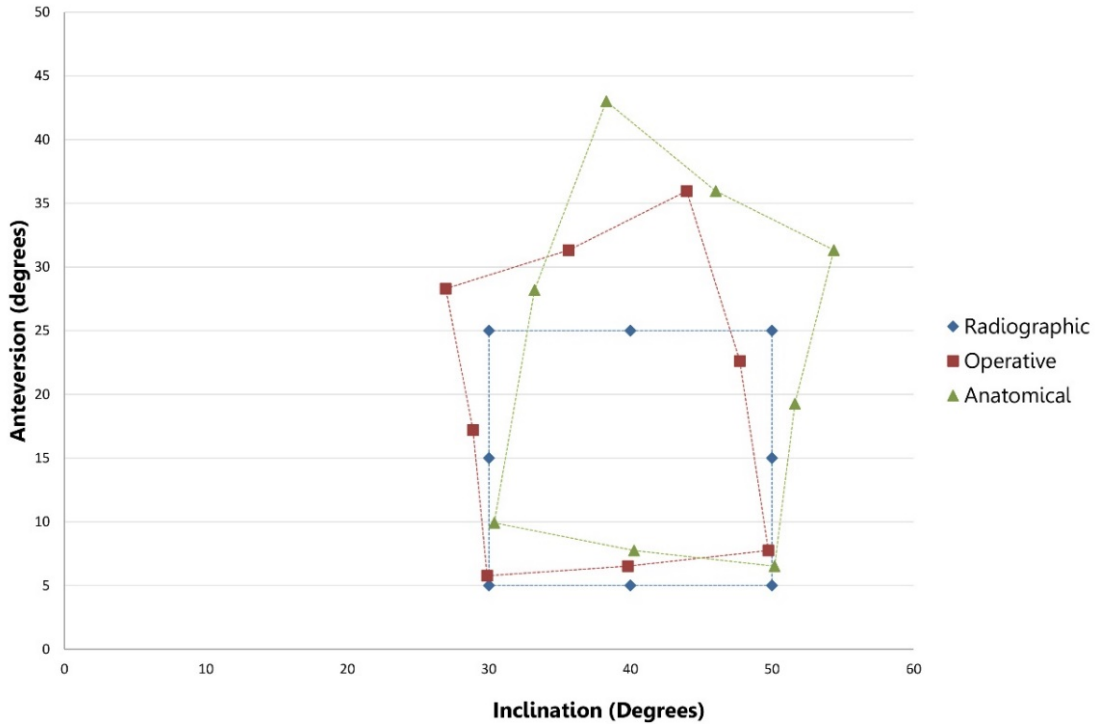


Figure 3-11 Lewinnek Safe zone: Radiographic, Operative & Anatomical Definitions

Compilation of the different recommended orientations of the acetabular cup from the literature showed a variety of orientations using different terms, angle definitions and reference planes. Table 3.2 and Table 3.3 display the different guidelines from the literature in the original definitions and converted operative, radiographic and anatomical inclination and anteversion definitions. In the operative definition, the suggested inclination angles ranged from between 27° – 50° and the suggested anteversion angles ranged from 3° – 40° demonstrating inconsistencies in recommendations found in the literatures.

Source	Inclination				
	Original Definitions Degrees (°)	Original Reference Frame	Operative Degrees (°)	Radiographic Degrees (°)	Anatomical Degrees (°)
Biedermann et al. [69]	45° Abduction	Radiographic	44	45	46
Harris [125]	30° Abduction	Radiographic	28	30	34
Lewinnek et al. [39]	30° - 50° Lateral Opening	Radiographic	27 - 49	30 - 50	30 - 54
McCollum & Gray [121]	30° - 50° Abduction	Radiographic	25 - 48	30 - 50	25 - 56
Seki et al. [122]	30° - 50° Abduction	Radiographic	27 - 43	30 - 50	29 - 51
Widmer & Zurfluh [28]	40° - 42° Inclination	Radiographic	35 - 37	40 – 42	40 - 44

Table 3.2 Safety Guidelines for Inclination Angles from the Literature

Source	Anteversion				
	Original Definitions Degrees (°)	Original Reference Frame	Operative Degrees (°)	Radiographic Degrees (°)	Anatomical Degrees (°)
Biedrmann et al. [69]	15° Anteversion	Radiographic	12	15	12
Harris [125]	20° Forward Flexion	Operative	20	18	32
Lewinnek et al. [39]	5° - 25° Anteversion	Radiographic	6 - 36	5 - 25	7 - 43
McCollum & Gray [121]	20° - 40° Flexion	Operative	20 - 40	14 - 36	17 - 55
Seki et al. [122]	1° - 30° Anteversion	Radiographic	3 - 27	1 - 30	2 - 38
Widmer & Zurfluh [28]	23° - 28° Anteversion	Radiographic	17 - 23	23 - 28	19 - 27

Table 3.3 Safety Guidelines for Anteversion Angles from the Literature

The recommended orientations of the acetabular cup from a range of surgical techniques found in academic textbooks also showed a variety of orientations which are displayed in Table 3.4 and Table 3.5. The majority of the orientations used the radiographic reference system to describe the inclination angle and the operative reference system to describe the anteversion angle. From the review of the literature there is no clear justification for this choice. The range, in the operative definition, was considerably smaller than the literature guidelines with

suggested inclination angles between 33.34° – 45° and the suggested anteversion angles ranging between 0° – 20°.

Source	Inclination				
	Original Definitions Degrees (°)	Original Reference Frame	Operative Degrees (°)	Radiographic Degrees (°)	Anatomical Degrees (°)
Total Hip Replacement [126]	45° Open	Radiographic	44	45	46
Campbell's Operative Orthopaedics [127]	35° - 45° Inclination	Radiographic	33 - 45	35 - 45	35 - 47
Charnley [128]	45°	Anatomical	45	45	45
Müller [128]	45° Facing Laterally	Radiographic	44	45	46

Table 3.4 Suggested Acetabular Cup Inclination Angles from Surgical Technique in Academic Textbooks

Source	Anteversion				
	Original Definitions Degrees (°)	Original Reference Frame	Operative Degrees (°)	Radiographic Degrees (°)	Anatomical Degrees (°)
Total Hip Replacement [126]	10° Anteversion	Operative	10	10	7
Campbell's Operative Orthopaedics [127]	10° - 20° Anteversion	Operative	10 - 20	7 - 17	10 - 28
Charnley [128]	0° Anteversion	Anatomical	0	0	0
Müller [128]	10°- 15° Anteversion	Operative	10 - 15	7 - 11	10 - 16

Table 3.5 Suggested Acetabular Cup Anteversion Angles from Surgical Technique in Academic Textbook

Figure 3-12 details the comparison of the recommended safety zones from the literature and textbooks in the operative reference frame. Most recommended implant orientations are contained within or overlap with Lewinneck's definition of the safe zone. Some of the recommended zones from literature describe a single position, some provide an ideal position with an area for error and others suggest a wider area.

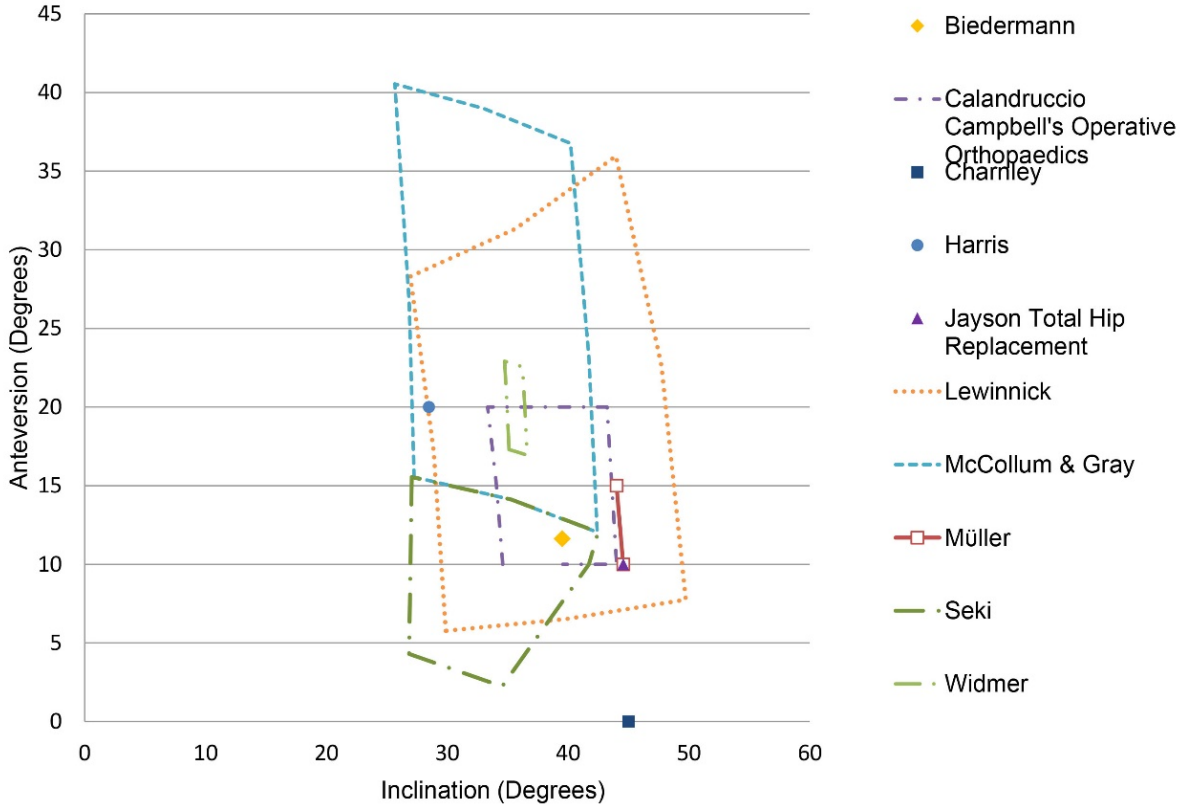


Figure 3-12 Recommended safe zone of the acetabular cup in the operative system

Suggested orientations, as per the manufacturers' instructions, showed less variability in the adopted reference system and recommended orientation. With the extra accuracy allowed from computer aided surgery, Widmer [28] recommended a smaller safe zone given there should be less variability however this value should be adjusted accordingly for patient anatomy. With the exception of DePuy, most manufacturers used the radiographic definition to describe the inclination angle and the operative definition to describe the anteversion angle. Table 3.6 and Table 3.7 display the range in the suggested positions of the implants in the original definition and the operative, radiographic and anatomical inclination and anteversion definitions. Results show that the suggested operative inclination angle range is between 29.8° - 49.6° and operative anteversion angle range is between 10° – 30.8°. The range for both operative inclination and operative anteversion is smaller than the safety guidelines from the literature.

Source	Inclination				
	Original Definitions Degrees (°)	Original Reference Frame	Operative Degrees (°)	Radiographic Degrees (°)	Anatomical Degrees (°)
Biomet: C2a Taper [133]	45° - 50° Inclination	Radiographic	44 - 49	45 – 50	45 – 51
DePuy: Duralock [134]	35° - 45° Abduction	Anatomical	33 - 43	34 - 44	35 - 45
DePuy: Pinnacle [135]	35° - 50° Abduction	Anatomical	30 - 48	31 - 49	35 - 50
Implanet: Mambo [132]	45° Abduction	Radiographic	44	45	46
Smith & Nephew: Reflection [84]	45° Abduction	Radiographic	43	45	47
Stryker: Trident [129]	45° Abduction	Radiographic	43	45	47
Wright Medical: Conserve [131]	45° Vertical	Radiographic	44	45	46
Zimmer: Trilogy [130]	45° Abduction	Radiographic	43	45	47

Table 3.6 Suggested Acetabular Cup Inclination Angles from Manufacturers' guidelines

Source	Anteversion				
	Original Definitions Degrees (°)	Original Reference Frame	Operative Degrees (°)	Radiographic Degrees (°)	Anatomical Degrees (°)
Biomet: C2a Taper [133]	10° - 15° Anteversion	Operative	10 - 15	7 - 12	12 ±3
DePuy: Duralock [134]	15° - 20° Anteversion	Anatomical	11 - 16	9 - 14	15 - 20
DePuy: Pinnacle [135]	15° – 30° Anteversion	Anatomical	11 - 31	8 - 23	15 - 30
Implanet: Mambo [132]	10° - 15° Anteversion	Operative	10 - 15	7 - 12	11 - 16
Smith & Nephew: Reflection [84]	20° Anteversion	Operative	20	14	20
Stryker: Trident [129]	20° Anteversion	Operative	20	14	20
Wright Medical: Conserve [131]	15° Anteversion	Operative	15	11	15
Zimmer: Trilogy [130]	20° Forward Flexion	Operative	20	14	20

Table 3.7 Suggested Acetabular Cup Anteversion Angles from Manufacturers' guidelines

Figure 3-13 details the manufacturers' recommended orientation of the acetabular cup in the operative reference system with respect to the Lewinnek and Campbell's Operative Orthopaedics recommended "safe zones". The majority suggest that the acetabular cup should be placed at an inclination angle of 45°. The recommended anteversion angle is more variable with most around 15° – 20°. A comparison of the suggested positions of the acetabular cup from the safety guidelines from literature and current surgical guidelines highlighted that 87.5% of the surgical guidelines are fully contained within the recommended Lewinnek "safe zone". However, 75% are concentrated in the bottom right quadrant. 62.5% of the suggested implant positions are on the border of the Campbell's Operative Orthopaedics "safe zone."

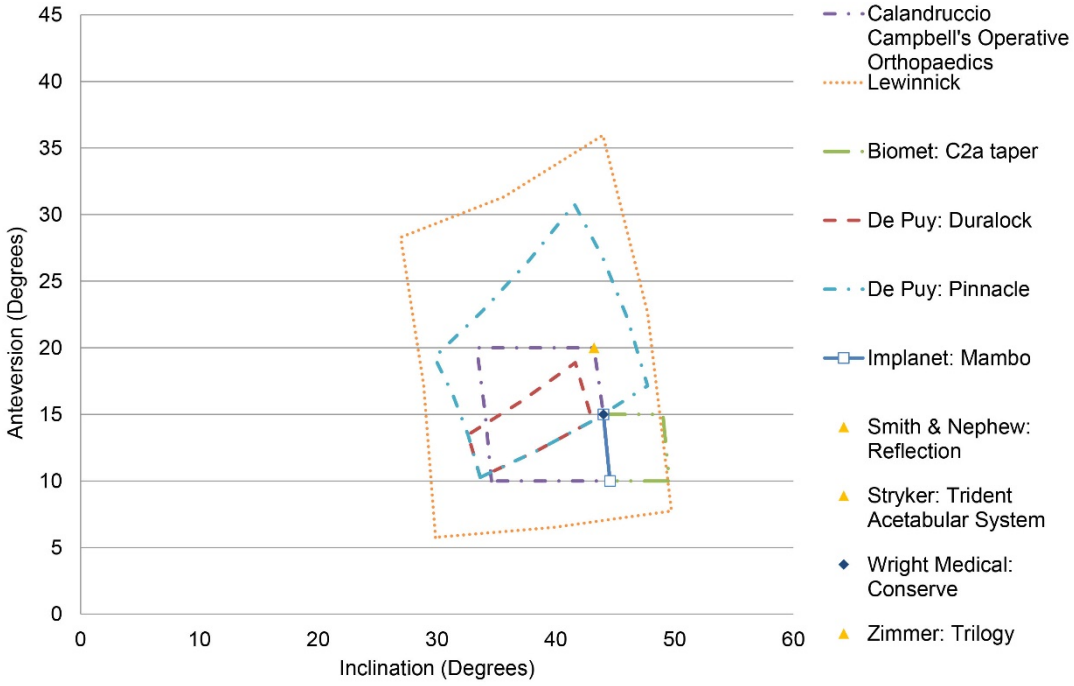


Figure 3-13 Comparison of desired orientations of the acetabular cup from the safety guidelines from literature and current surgical guidelines: operative definition

3.6 Discussion

The orientation of the acetabular cup is one of the most important factors under the surgeon's control [86] and as a result it is crucial that the surgeon has accurate and precise control over the position of the implanted acetabular cup [87].

There is no standardised measurement method or agreed orientation and this has resulted in variability of methods, safe zones and cup orientations [120,76,79,91,30]. Converting all literature and manufacturers' suggested guidelines into the operative reference system has enabled direct comparisons to be made. As highlighted in the results, there is a significant difference between definitions, no consensus on an optimum orientation and little overlap between definitions. This further emphasises the wide variability in the literature for the suggested position of the acetabular cup.

The results demonstrate a limitation with the use of the three definitions and suggest the need for a consensus. Current mechanical guides require the surgeon to have precise control of two planes at once as the inclination and anteversion angles are measured separately as shown below in Figure 3-14. This means intra-operatively the position suggested by the mechanical guide demonstrates the inclination angle on the coronal plane and the anteversion angle in the sagittal plane.

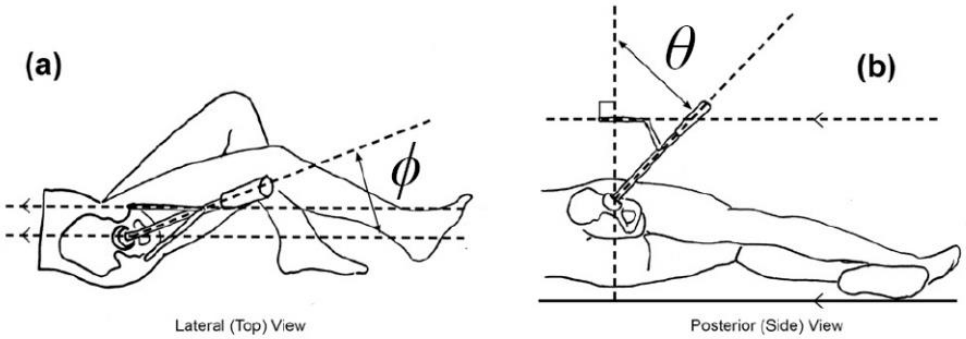


Figure 3-14 Surgical definition of anteversion (a) and inclination (b)

Using Murray's [31] definitions, mechanical guides show a radiographic inclination angle and an operative anteversion angle. Most of the manufacturer's safety guidelines and the surgical techniques from textbooks use this combination to define the suggested acetabular cup orientation. To overcome this discrepancy, this combination should be referred to as the Surgical Reference System. As demonstrated in Figure 3-15, inclination is the angle between the longitudinal axis of the patient and the acetabular axis as projected onto the coronal plane. Anteversion is the angle between the longitudinal axis of the patient and the acetabular axis as projected onto the sagittal plane.

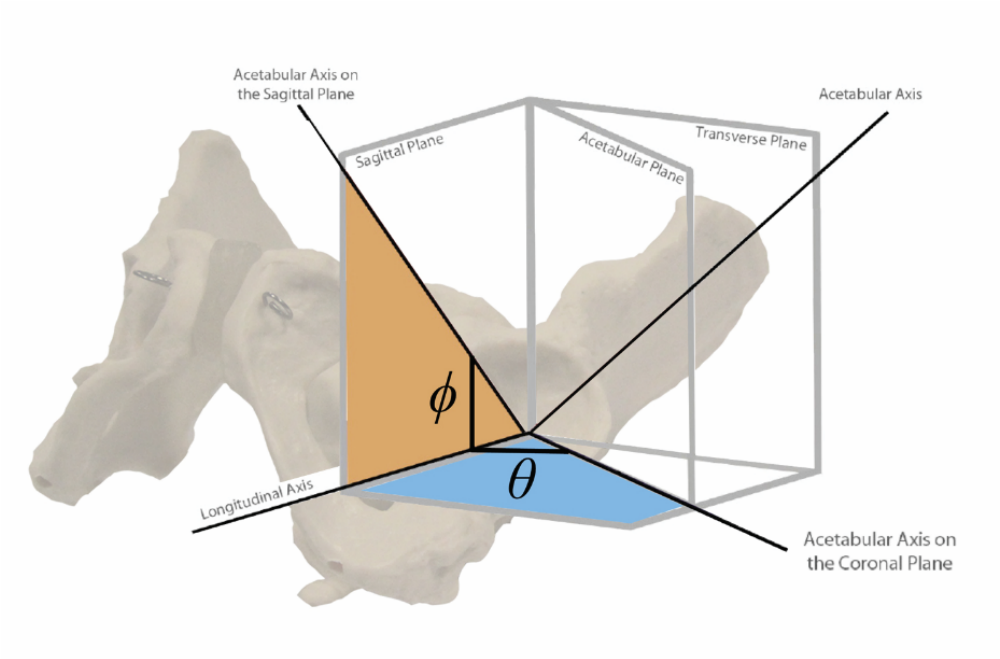


Figure 3-15 Surgical Reference System

Most of the manufacturer's use this surgical reference system, and when using a mechanical guide, this definition is used during the operation; however most of the literature is based on measurements taken post-operatively on radiographs. The implant is therefore positioned using the surgical definition but evaluated using a radiographic orientation. Using the surgical definition intra-operatively and a radiographic definition postoperatively can lead to further discrepancy and confusion.

Comparison of the results showed a larger range in the recommended anteversion angles compared to inclination angles. Anteversion is harder than inclination to evaluate using current techniques [41] which could account for this wide range; however, the anteversion angle is critical as it has been shown to be one of the biggest influencing factors that can lead to edge wear [26,58] and dislocation [70,71,73]. The significance of the anteversion angle along with the wide range of values found further emphasises the need for more clarity on position guidelines.

When reviewing the recommended implant positions in the surgical reference system, there is no suggested safe zone in the literature or the surgical techniques that corresponds with all the suggested implant positions from the manufacturers. Although 87.5% of the surgical guidelines are contained within the Lewinnek's safe

zone, they are congregated at the bottom right corner and the majority of the surgical guidelines within the Campbell's Operative Orthopaedics recommended position are on the edge of that zone. This puts a surgeon in a quandary: small deviations from the manufacturers' recommended position may place the cup in an orientation out with a safe zone, but contrastingly, aiming for the middle of the safe zone will contradict manufacturers' guidelines. Even ensuring the cup is placed within these zones does not completely remove the risk of failure.

In the surgical reference system, the Lewinnek safe zone is no longer square (Figure 3-16) which makes it difficult for the surgeon to ensure the implant is within the recommended area. A square was selected to provide surgeons with a simple upper and lower bound for each angle independently. We propose a new "Strathclyde Safety Zone" (SSZ) which is based on the current gold standard, the Lewinnek zone, and restricts anteversion angles to no less than 5° and no more than 30°. This square is centred on the bottom right hand corner of Lewinnek's zone at approximately 40° surgical inclination and 17-18° surgical anteversion.

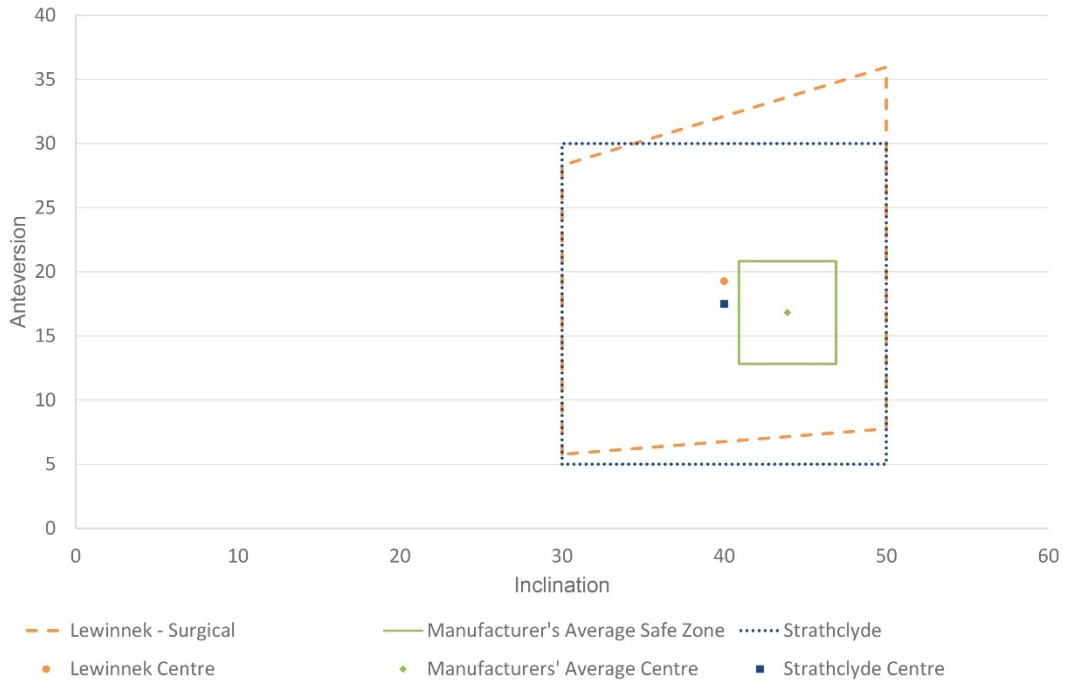


Figure 3-16 Strathclyde Safety Zone

The proposed Strathclyde Safe Zone ranges from 30° – 50° surgical inclination and 5° - 30° surgical anteversion. The inclination angle is in this range as

outside this range, wear rates have been shown to dramatically increase and large inclination angles have been demonstrated an increase the risk of aseptic loosening [50,51]. The anteversion angle ranges from 5°-30° as low anteversion angles have led to increased wear rates [56] and a correlation between low anteversion and dislocation has been demonstrated [69]. The centre of the recommended anteversion angle of the Strathclyde Safe Zone is closer to the average manufacturers' guideline of 17° ± 4° anteversion.

This proposed cup placement may be a simple target which could be used for all such arthroplasties irrespective of implant manufacturer. As this safe zone is defined in the surgical definition, it can be used with current surgical guidelines and used intra-operatively removing the need for surgeons to convert between definitions and the subsequent potential for error. The vast majority of the suggested acetabular cup positions from the safety guidelines are enclosed within this area (Figure 3-17).

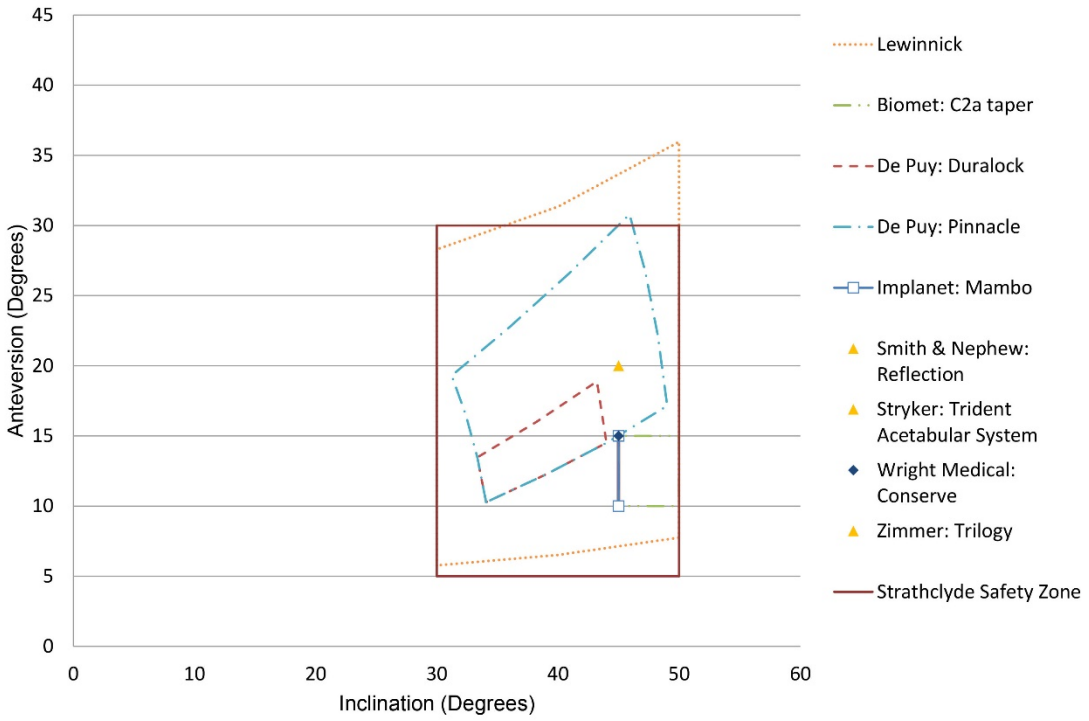


Figure 3-17 Comparison of desired orientation of the acetabular cup from current surgical guidelines and the proposed Strathclyde Safety Zone: surgical definition

The Strathclyde safe zone would require further study for validation. As a simple indication, converting the results from the Lewinnek study into the surgical

reference system demonstrated that if the actabular cup is placed outwith the Strathclyde Safe Zone there is a 5.8% increased chance of dislocation (Figure 3-18). This study is limited as only 57% of the placed cups were positioned within this safe zone and it is a small population of dislocations that were studied. A larger study would be required for validation.

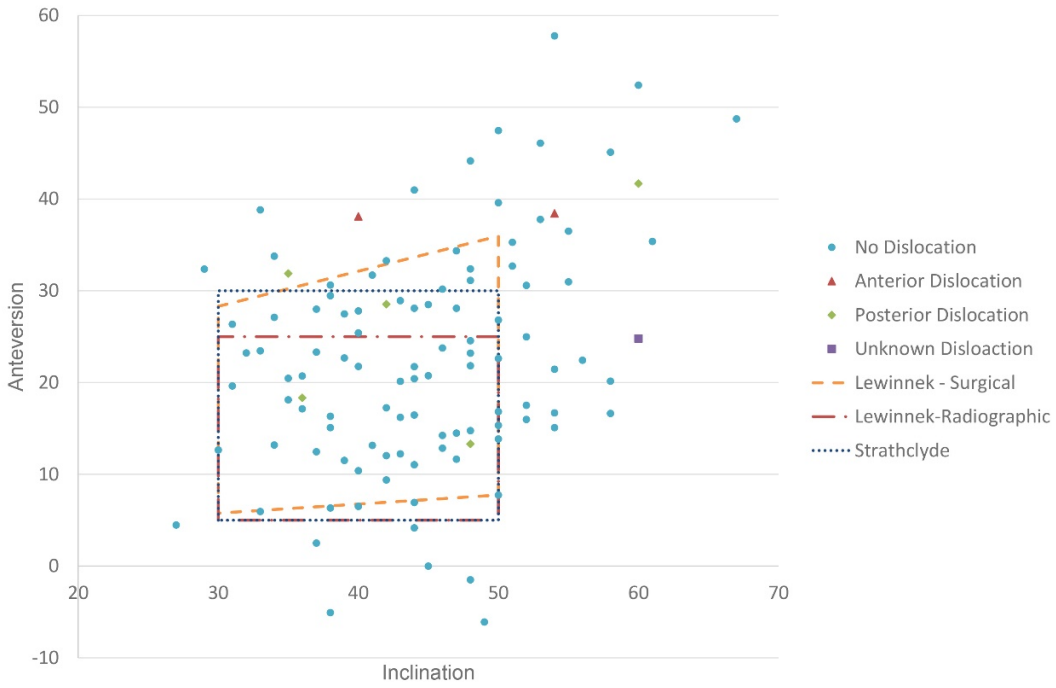


Figure 3-18 Acetabular component position and dislocation incidence

There are limitations with this research synthesis. In several of the studies from literature no mention was made of pelvic tilt angles. To correct this, assumptions were made to provide an estimation. When the patient is positioned in the lateral decubitus position, a neutral pelvic position has been presumed to be able to use the coronal plane as a reference system.

Widmer et al. [28] demonstrated that cup inclination, cup anteversion and stem anteversion are all interdependent in determining the optimal cup orientation. The anteversion angle should be considered as the combined sum of cup anteversion and stem anteversion. The risk of dislocation is 6.9 times higher if this combined value is outside the guidelines [64]. Wassilew [136] and Dorr [94] observed a broad range of stem anteversion angles. Therefore for this study a constant femoral stem

position has been assumed to allow for comparison.

3.7 Conclusion

This study demonstrates there is no consensus in the optimum orientation of the acetabular component in THA. Ensuring that all literature and guidelines are in the same definition would, at least, allow direct comparison to be made between the current approaches enabling further research to relate outcomes to cup position. This could lead to a reduction in the variability of recommended positions and the development of clearer definitions and better standards.

As no optimum orientation currently exists it is critical that the surgeon is able to decide on the desired orientation of the acetabular cup on an individual patient basis. Mechanical guides do not allow for variation and have been shown to be imprecise and inaccurate therefore development of a low cost method which enables the surgeon to accurately position the acetabular cup to their chosen orientation would be beneficial.

4

Product Design Process

4.1 Chapter Contents

To help surgeons correctly position the acetabular cup in total hip arthroplasty, product design methodology was used to create a solution. A review of current product design methodologies was conducted to develop a methodology that would be suitable for the development of a medical device. This chapter describes the literature and theory surrounding product design methodology and common techniques used. The application of this theory and details on how it was used to design a device to help surgeons position the acetabular cup can be found in the following chapter.

Many methodologies exist with varying processes used in design education in comparison to industry. Several examples, which highlight the range of design methodologies, have been selected for analysis and comparison. This chapter discusses product design theory through explanation and comparison of examples, such as Pugh, Ulrich & Eppinger, Design Council, IDEO and Wideblue.

Each section of the design process is discussed in further detail by describing techniques which can be used to carry out the methodology. This starts with qualitative and quantitative research methods. The influence of human factors on the design methodology is discussed, demonstrating how user-centred design can be used. Techniques to develop a product design specification are discussed and various approaches to concept generation, development and evaluation are highlighted.

Analysis of design methodologies enabled development of a design methodology which combines techniques from education and industry. This is explained at the end of this chapter and as further described in Chapter 5 was used to develop a product which helps surgeons correctly positioning the acetabular cup in total hip arthroplasty.

4.2 Product Design

Product design is a complex, multi-dimensional process which involves a range of people, a developing product, a process which requires a variety of activities, techniques and challenges and an expanding knowledge and understanding of the user, markets and micro and macro environments [137]. If aesthetics dictated design, products may be nice to look at but difficult use. Conversely, if usability is the key factor, products may be easy to use but unpleasant to look at. Equally products may not be aesthetically pleasing or functional if cost or manufacturing methods dominated the design. Each factor is important, however to ensure a successful product consideration must be given to all and a combination of design inputs is required [138]. Pugh [139] stated that, *"success in the market place requires total design rigour and engineering rigour of the highest order – never one without the other"*. This consideration of many different factors and subject areas leads to design engineers being at the centre of two intersecting cultural streams as shown in Figure 4-1.

The standard engineering design cultural streams (as shown in Figure 4-1) does not fully represent the scope of the design challenge faced for this thesis. This work must consider current surgical technique, the surgical environment, different users and any influence on the prosthesis. Therefore this design philosophy has been extended to include reference to medical devices and biomedical engineering. This extension creates a third cultural stream comprising of medicine, medical devices, biomedical engineering and biomedical science as shown in Figure 4-2.

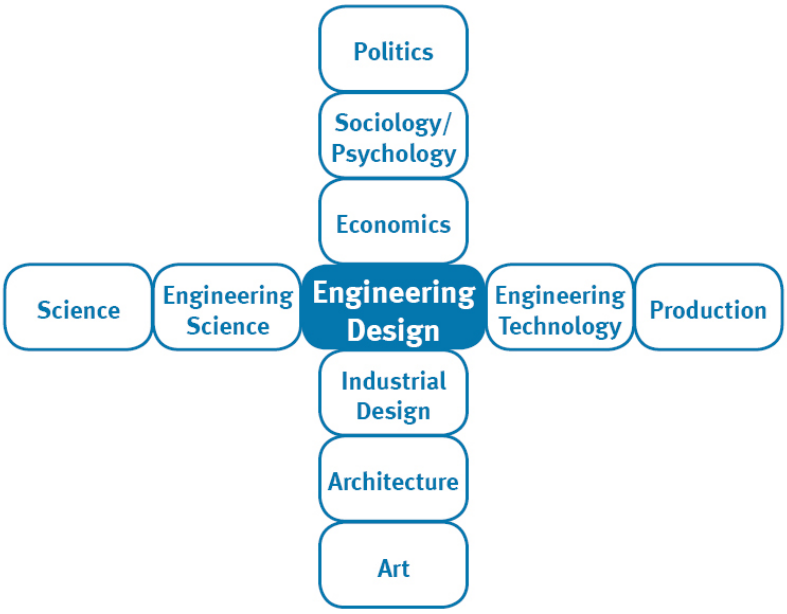


Figure 4-1 Engineering Design Cultural Streams [140]

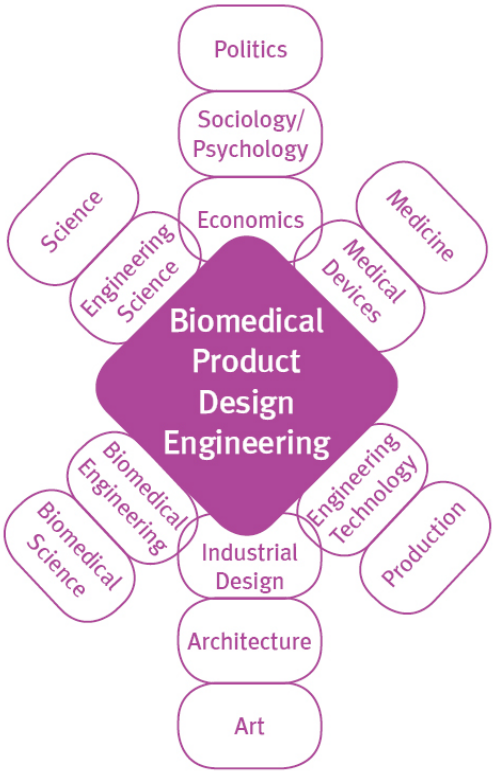


Figure 4-2 Biomedical Product Design Engineering Cultural Streams

Understanding the many aspects that are required for successful product design further highlights the importance of thinking about the whole process rather than individual sections. To ensure the whole process is considered and timely, efficient product development is achieved, it is important to have a defined design procedure that finds good solutions [140]. This process, design methodology, is defined as, *"the systematic activity necessary, from the identification of the market/user need, to the selling of the successful product to satisfy that need"* [139].

4.3 Design Methodology

Design methodology, can be defined as *"a set course of action for the design of technical systems that derives its knowledge from design science, cognitive psychology and from practical experience. It contains plans of action that work linking steps, strategies, rules and principles to achieve goals and methods to solve individual design tasks"* [140]. This procedure must be flexible yet provide a framework to guide designers, encourage creativity yet ensure objective evaluation of results and deliver a functional, cost effective product in a timely manner [140].

There are many different types of methodology with a stark difference existing between design methodology within education in comparison to industry. Design education focuses on teaching *"how to design"* where the focus of industrial design is *"the design of the products is design itself"* [141]. Methodologies range from structured detailed methods such as Pugh [139] and Ulrich and Eppinger [142] which guide the user through specific steps to more abstract theories such as the Design Council [143] and IDEO [144]. These methodologies do not explicitly state the sector or type of device that is to be designed using each process. They can be used in a wide range of sectors and could be easily applied to the development of medical devices.

4.3.1 Total Design: Stuart Pugh [139]

Total Design, which is often used within design education, splits the process into a central design of core of activities as shown in Figure 4-3. Pugh states that every design should start with a *"need that will fit into an existing market or create a market of its own"* [139]. Arising from this need, a product design specification (PDS) is

formulated which acts as the control, providing a reference, guidance and boundaries through the rest of the design process. This is an iterative process and iterations are depicted by vertical double-headed arrows in the figure. Techniques which are depicted as actions pointing inwards are used to enable the designer to operate the core activity and carry out the design.

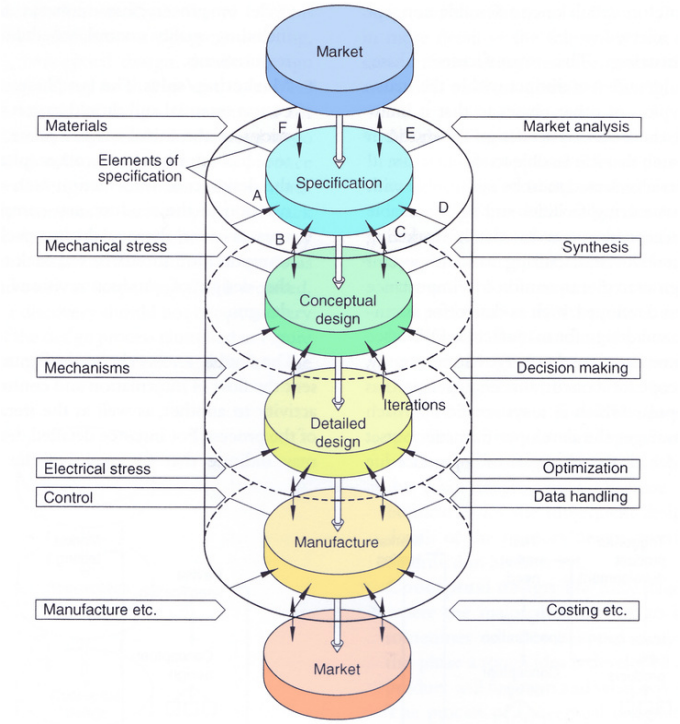


Figure 4-3 Pugh Design Process [139]

4.3.2 Ulrich & Eppinger [142]

Ulrich & Eppinger, also a technique used in design education, uses a converging/diverging model as shown in Figure 4-4 below. The process is split into six phases with tasks contained within each.

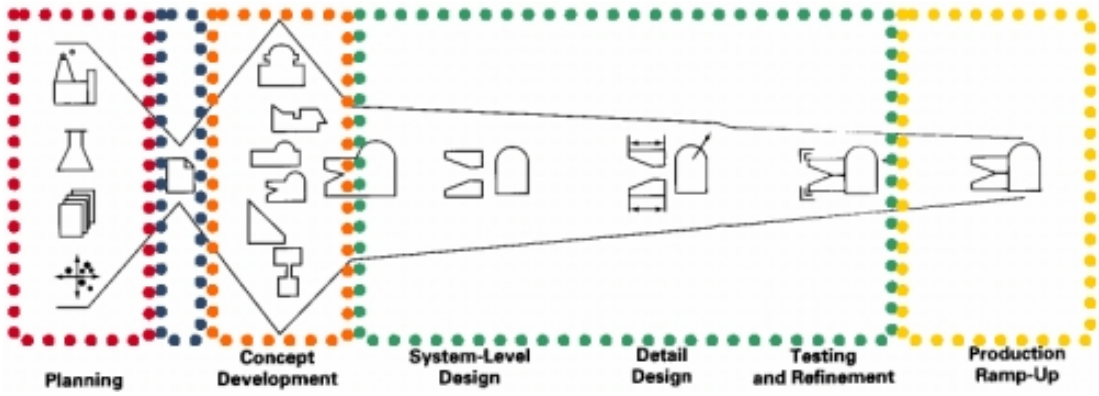


Figure 4-4 Ulrich & Eppinger Design Process [142]

The planning stage includes task such as corporate strategy, assessment of technological developments and market objectives. The process diverges as the research gathered from this task is culminated to generate a product mission statement. Using this statement, the process is widened for concept development where product concepts are generated, developed and evaluated. Following this, the process is narrowed where one or more concepts are selected for testing and development. The system level design phase is where the detailed definition of the product and components are considered and with a continual divergent process, the complete specification of geometry and parts is generated within the detail design phase. Testing and refinement of prototypes lead to the final phase of production ramp-up where the product is made using the intended production system [142].

4.3.3 Double Diamond Method: Design Council [143]

The Double Diamond Method is a hybrid between educational design tools and industry methods. The Design Council conducted a study of the design departments in eleven leading global companies:

Alessi	BSkyB	BT	LEGO	Microsoft	Sony
Starbucks	Virgin Atlantic Airways		Whirlpool	Xerox	Yahoo!

The study focused on different aspects of design within these companies. The combined insights were used to produce a design process based on industry practice. This method is split into 4 sections of Discover, Define, Develop and Deliver

(Figure 4-5) which contrast times when thinking is as broad as possible to situations with distinct objectives where thinking is deliberately narrowed down.

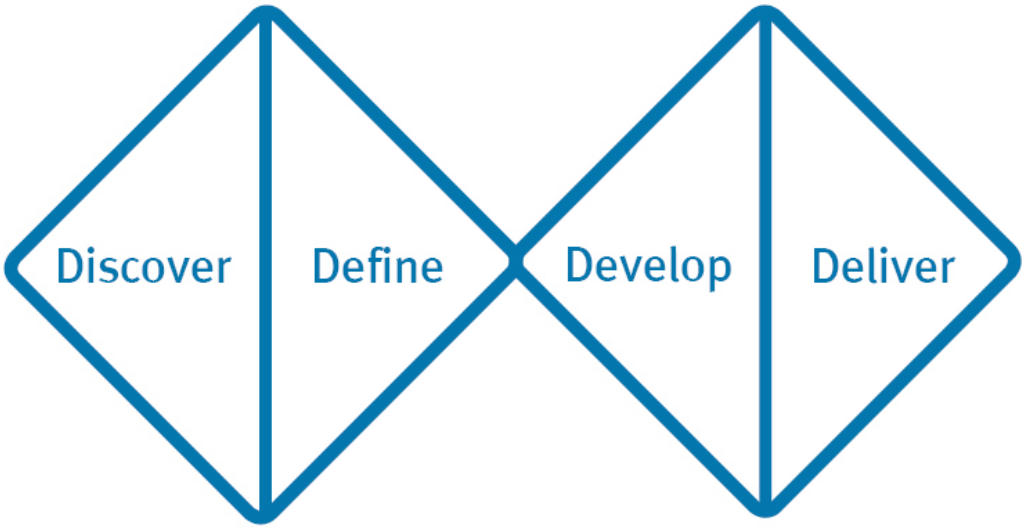


Figure 4-5 Design Council: Double Diamond Design Method [143]

Discovery is gathering inspiration, a rich understanding, insights, user needs and developing initial ideas with the objective to identify an opportunity or need to be addressed. Within the Define stage, designers identify the possibilities highlighted in the discovery stage and develop a clear project brief that marks out the design challenge for the company. Develop is the period when the brief is used to iteratively create, prototype and test concepts with end users until a final solution is reached. Finally Deliver is where the resulting product is approved, finalised and launched ensuring there are feedback mechanisms to enable lessons learnt to be fed back to the company [143].

4.3.4 IDEO [144] [145]

IDEO, an award winning design consultancy have a 5 step process as shown in Figure 4-6. Understand & Observe encourages the designer to start by building an understanding of the user first hand with emphasis placed on inspiration coming from observation [145]. Synthesize is an opportunity to gather all the research data and translate the information into design opportunities. Visualize is when

concepts and the customers are visualised leading to prototypes to shape ideas and finally implementation of the design.

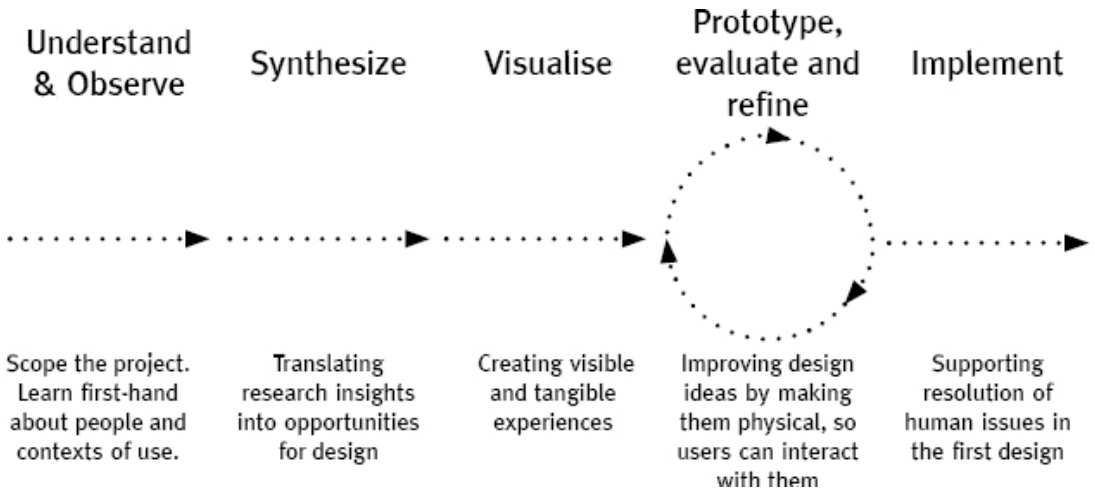


Figure 4-6 IDEO design process [145]

Instead of following a sequence of orderly steps, IDEO recommend throughout the process a system of overlapping spaces should be used.
The three lenses (Figure 4-7) that are used are desirability, feasibility and viability leading to the use of these questions to drive innovation,

- What do people desire?
- What is technically and organisationally feasible?
- What can be financially viable?

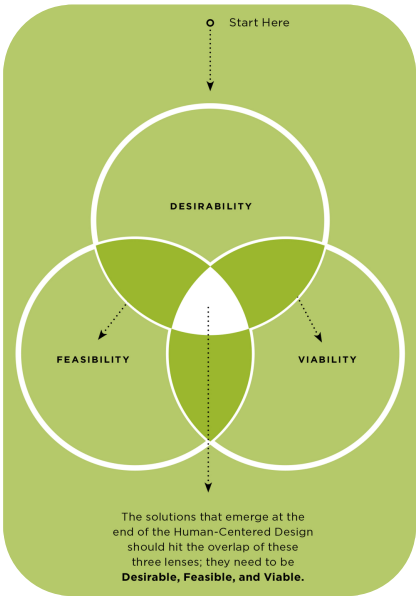


Figure 4-7 IDEO design lenses [144]

IDEO are also focused on a human centred design theory with Tim Brown, president and CEO explaining it as, "*a human-centred approach to design thinking that draws from the designers' toolkit to integrate the needs of people, the possibilities of technology, and the requirements for business success*". The Human Centred Design (HCD) toolkit guides the user through a process of Hear, Create and Deliver (Figure 4-8) ranging from abstract to concrete solutions.

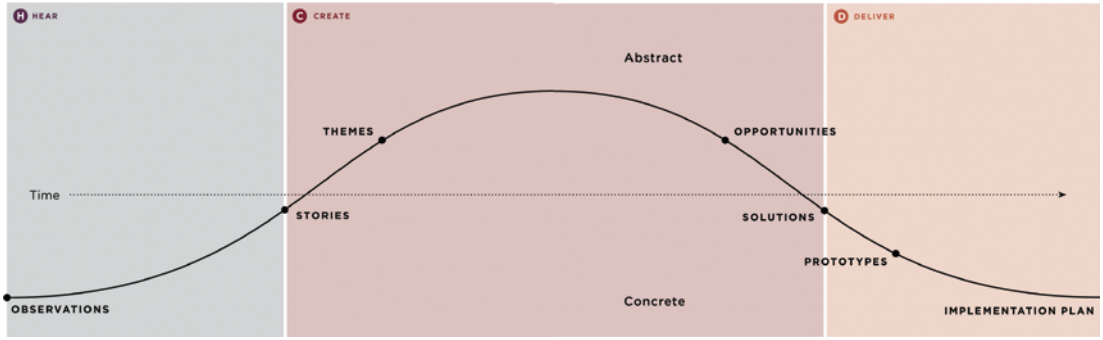


Figure 4-8 IDEO HCD Design Process [144]

The Hear phase is used to collect stories and inspiration from people through field research. The Create phase translates what is learnt through user interaction into frameworks, opportunities, solutions and prototypes. The process encourages looking at abstract ideas to identify opportunities but bringing it back to concrete solutions and prototypes. The deliver phase continues with development of solutions through cost modelling, capability assessment and implementation planning.

4.3.5 Wideblue: design process [146]

In contrast, Wideblue, a medical device design company have a more structured approach to design as shown in Figure 4-9. Final product requirements are considered from the beginning and the process is split into structured stages with more emphasis on the latter parts of the process. This approach provides strong control which is vital when approaching regulatory compliance and what Wideblue feel, *"maximises the probability of technical and commercial success"* [146].

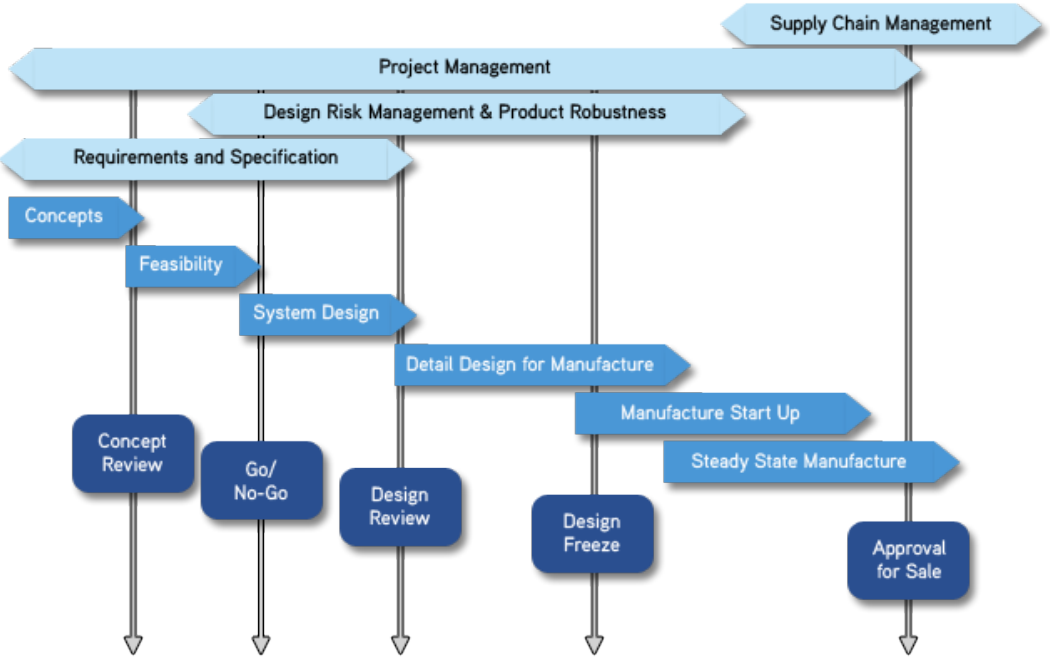


Figure 4-9 Wideblue Design Process [146]

4.3.6 Discussion

Although there appears to be many differing design methodologies, there are considerable similarities between them all. The overview and structure of the majority of design methodologies are similar with each creating phases of research, design specification, concept generation, development & evaluation and concept delivery. Most begin with a research phase, building an understanding of the problem, market and users. All the methodologies recommend spending time building a specification or clearly identifying design opportunities to be addressed. A phase of generating and developing several concepts is followed with all in agreement that using phases of convergent and divergent thought is vital before reaching a final solution. Each of the methodologies stressed the design process is an iterative process rather than a straightforward step by step.

The design methodologies differ when considering the techniques used within each phase. For example within the research phase, Pugh and Ulrich & Eppinger emphasise market research and literature understanding where IDEO stress the importance of user observation. In the following sections, techniques

within each phase are discussed highlighting the similarities and differences between methodologies.

4.4 Research

Research by the Design Council [143] showed that companies refer to this initial stage using different terms, LEGO call it *"Exploring"*, Microsoft *"Understand"* and Starbucks call it *"Concept Heights"* however all the above processes and many more are in agreement that any design process must start with building a rich understanding and knowledge of the subject area, current techniques and product market. In the context of this research, it is imperative to not only build an understanding of current techniques to position the acetabular cup but also an understanding of patient anatomy, conditions and surgical techniques and environment. Within industry, the research phase can be viewed as haphazard, risky and unpredictable which can result in innovation being limited to within the boundaries of current company practice [147]. This is particularly important within the medical sector due to financial and safety considerations. To avoid this limitation on innovation, an important factor identified throughout the leading companies is ensuring this research phases is a *"phase of divergent thought"* with *"perspectives wide enough to allow for a broad range of ideas and influences"* [143]. The time and budget must be created for divergent thinking before convergent thinking of prioritising solutions begins. This method (Figure 4-10) allows designers to think of new opportunities out with current boundaries and mind-sets [147].

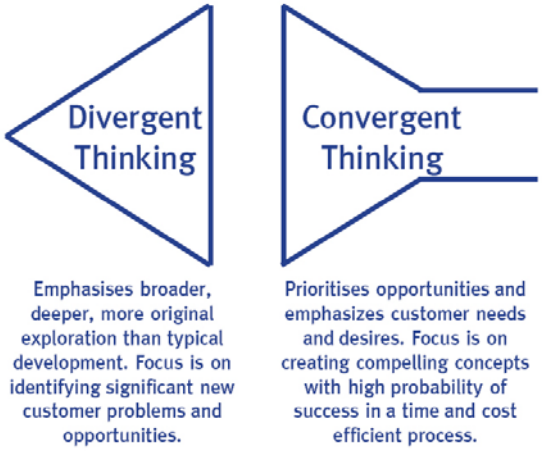


Figure 4-10 Divergent/ Convergent Thinking [147]

Pugh [139] states the starting point of any process much be establishing an understanding of the market/user need situation in considerable depth and to do this

requires the investigation into many areas as shown in Figure 4-11. At this stage, Pugh stresses the importance of understanding the relevant standards. Any applicable standards will have a considerable influence on the design process and may create restrictions on the design. In the context of this thesis, making sure the applicable standards for medical devices are met is critical for device safety and to gain approval.

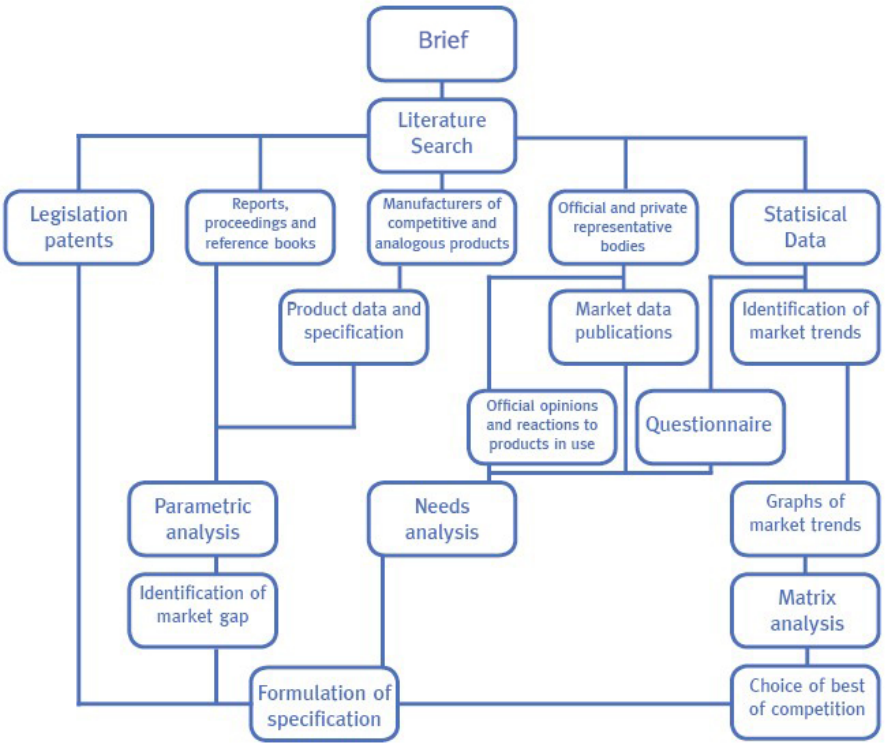


Figure 4-11 : Pugh Research Methods [139]

IDEO [144] use more qualitative research methods, encouraging the designer to use this research phase to gather people's stories, observe the users reality and build a deeper understanding of needs, barriers and constraints. Although this does not provide as broad coverage of the market, the advantage of qualitative research is it enables the designers to develop, *"deep empathy for people they are designing for, to question assumptions, and to inspire new solutions"* [144]. This data is useful in early stages as it inspires and helps identify opportunities but it is also beneficial in helping with evaluation in later stages.

Some of the techniques suggested by IDEO for the research phase are interviews, both individual and in groups, self-documentation, allowing the designer to see the problem from the user's perspective, and community driven discovery.

Inclusion of members of the community within the design team can provide valuable expertise and insight [144].

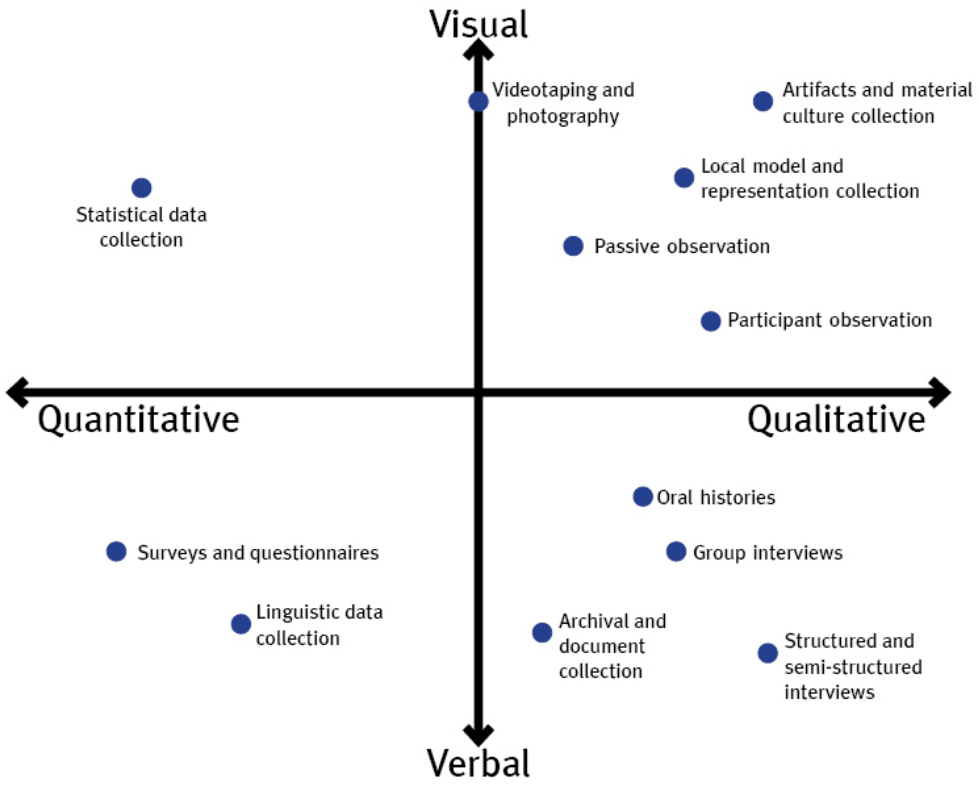


Figure 4-12 Ethnography Techniques [148]

A research technique called ethnography, originating from anthropology is becoming used more in qualitative research methods [148]. Bronislaw Malinowski described the purpose of his research work as studying the *"imponderabilia of actual life"* pursuing a perspective of understanding the, *"native's point of view, his relation to life, to realise his vision of the world"*[149]. Ethnography is the study of a small group in their own environment, "*attempting to get a deep detailed understanding of the life and circumstances of a few people as opposed to a small set of variables in among a large number of people*" [148].

Techniques used to carry out this practice are shown in Figure 4-12 which display the varied range of visual to verbal and quantitative to qualitative methods. In the context of this work, ethnography techniques would be used to fully understand the surgical environment and gather surgeons insight and opinions. The

biggest benefit of ethnography is it reveals new insights and unexpected opportunities as designers understand and empathise with users. Designers are able to differentiate between what users say they do and their actions. Ethnography results in design not just being on an intellectual level but also on an experiential level [144].

The Design Council found, *"the design process most commonly begins with teams finding their initial inspiration in information about user behaviour"* [143]. Although the focus of the companies varied, it was unanimous that all the companies analysed shared a user-driven mentality, *"which is apparent in the up-front phase of enquiry and gathering of initial research into the behaviours, needs and perceptions of users"*[143].

As a user-driven mentality is becoming increasingly integrated into the design process, the following sections explore the reasons why and techniques to ensure a user centred process is achieved in more detail.

4.4.1 User Centred Design

Due to continued increases in technology and manufacturing in many areas in product design, the competitive edge with regard to functionality, reliability and manufacturing is minimal. Many manufacturers' have recognised the importance of consideration of the user within design and human factors to gain advantage over competitors [150]. Consideration of the user is critical as although designers can often consider themselves as typical users, *"there is a big difference between the expertise required to be a designer and that require to be a user. Designers often become expert at the device they are using, users are often expert at the task they are trying to perform with the device"* [151].

Consideration of the user is also important for safety by reducing the risk of error and harm when using the device. This is particularly important within the medical device sector as many adverse events that occur are due to human error. The FDA specify that human factors must be included in the design process to

minimise use-related hazards and risks associated with the device and that users can use the device safely and effectively [152].

The discipline of human factors places the user as the centre of attention in product development [153]. Aside from use in the defence sector, historically within the manufacture of products, consideration towards human factors has not been present or is only an afterthought which is focused on the superficial interface design. Increasingly human factors is recognised as a subject which must be present at the beginning and continue throughout the design process with most major manufacturers now creating product development protocols [150].

The benefits of including human factors within the design process are highlighted in the international standard BS EN ISO 13407 Clause 4. Consideration to human factors ensures the product is,

- *"Easier to understand and use, thus reducing training and support costs*
- *Improves user satisfaction and reduce discomfort and stress*
- *Improves user productivity and operational efficiency of organisations*
- *Improves product quality, and provide a competitive advantage"*

Clause 5 of BS EN ISO 13407 identifies 4 principles which are vital for a human centred design approach:

- *"Encourage the active involvement of users in the design, and clearly understand the user and task requirements*
- *Establish the appropriate allocation of functions between users and technology*
- *Iterate design solutions*
- *Adopt a multi-disciplinary approach to system design"*

Consumers' attitudes towards human factors are also evolving; good human factors within a product are now becoming an expectation rather than a bonus [150]. Due to these changing expectations, users are no longer pleasantly surprised when products are easy to use but unpleasantly surprised by difficulty resulting in usability changing from being a satisfier to dissatisfier [150]. Consequentially, users no longer accept a product that is difficult to use just to put up with innovative technology [154].

4.4.1.1. User Needs

To be able to consider the needs of user with regard to product design, it is first important to understand basic human needs. Maslow's hierarchy of human needs (Figure 4.13) suggest that as soon as people have fulfilled one desire they want to fulfil the needs higher up the chain [155]. As people get used to having something, they keep going and look for something more. This is transferrable to product design. Based on Maslow's theory, Jordan [150] developed a hierarchy for needs for human factors both for manufacturers and consumers involving functionality, usability and pleasure as shown in Figure 4-13.

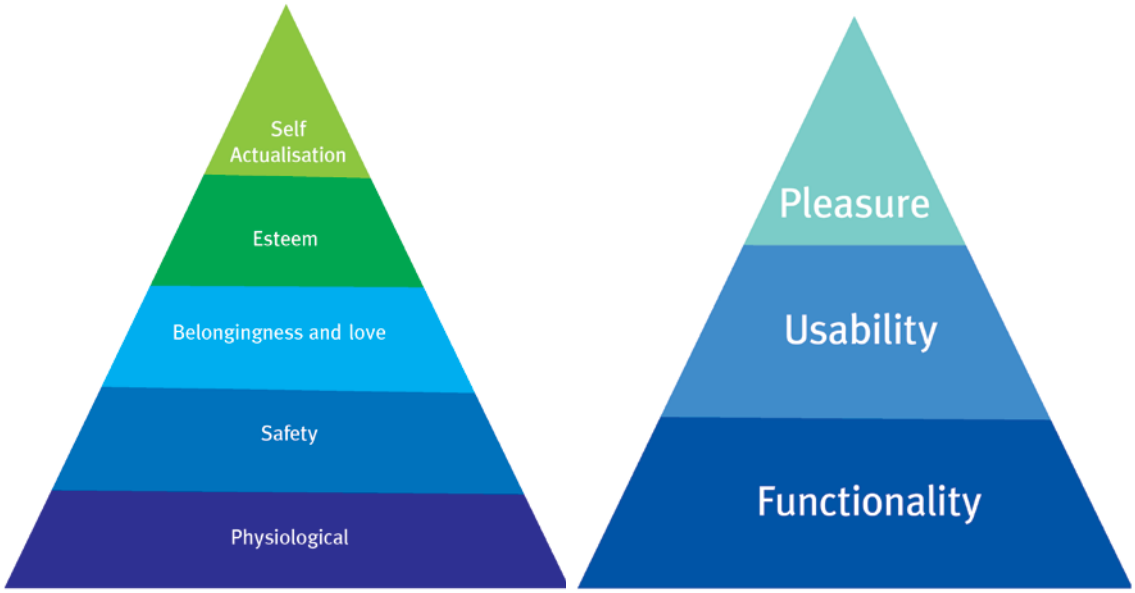


Figure 4-13 (a) Maslow's hierarchy of human needs (b) Jordan's hierarchy of product need [150]

The most important, basic need of a product is functionality, the device must be able to fulfil the users need to complete that task for which the product is created. It is therefore critical the designer has an understanding of the function of the product and the situation and environment of use.

Usability is reliant on functionality however good functionality does not guarantee usability. Usability is defined within the ISO 9241 standard as *"the extent to which a product or system can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use"* [153]. Usability provides increased revenue due to increased productivity, customer

satisfaction and brand image and reduces costs due to reduced user error, development time, user training and support [153].

The highest need in the hierarchy of needs is pleasure. With changing user expectations towards usable, functional products, it seems inevitable that users will soon want something more: products that offer something extra. User personalities influence how users respond and interact with products. Current human factor studies often just focus on physical factors such as age, gender, education and profession, and are only concerned with effectiveness, efficiency and satisfaction with how people perform tasks rather than an emotional response which limits how we think about users [150]. It is therefore critical the designer considers not the only functional benefits but also the emotional [150]. Emotional benefits for the user are directly linked to particular aspects of a product, for example: a product with high levels of reliability inspires feelings of security while poor reliability creates feelings of dissatisfaction and annoyance [150].

4.4.1.1 Designing Pleasurable Products

The Pursuit of Pleasure [156], created guidelines to aid the designer in consideration of pleasure when designing products. These pleasures come under four categories, physio-pleasure, socio-pleasure, psycho-pleasure and ideo-pleasure.

Physio-pleasure considers pleasures connected to the senses, which can be related to the physical aspects of the product. If anthropometrics of a product are incorrect, *"the user feels disconnected from the product but if dealt with well then user won't even notice the difference"* [150].

Socio-pleasure is connected to users' relationship with others or society as a whole. Status and image which are associated with types of products may form part of their social identity or products may help the user feel socially accepted within particular contexts [150]. Bourdieu identified two types of desired status, material and cultural [150]. Material status is achieved if the product conveys the user has a lot of wealth and cultural status when the product conveys the user is of great knowledge

and taste. Socio-pleasure can also be connected to the desire to avoid stigmatisation and negative connotations [150].

Psycho-pleasure is associated with cognitive and emotional reactions. Products which place a high cognitive demand on the user may create feelings of stress and frustration and a product which helps the user to avoid such feelings may be seen as fulfilling [150]. Features within the device can be included to reassure the user of quality and feelings of security as noises, clicks and switches can be used to reassure the user of correct assembly.

Ideo-pleasure relates to people's values. The ideals that users hold are important in defining their actions and how people would like to view themselves. For example a *"product that is bio-degradable may be seen as embodying the value of environmental responsibility- source of ideo-pleasure for those who are concerned about the environment"* [150].

Considering these four pleasures helps the designer to better understand the user and identify pleasure benefits which helps construct a better, deeper user profile. In the context of this work, understanding the needs of surgeons and patients who undergo a hip replacement helped with build detailed user profiles to help with development.

4.4.2 Using Design to Change User Behaviour

When considering the user, it may be in the user's best interest to use the product to change or modify their behaviour. In the context of this research, surgeons currently use a specific technique and any new device would require a modification of their current technique and behaviour. Understanding why users' behave in a certain way is critical before being to be able to change it and influence it. Lewin's equation [157] of:

$$\boldsymbol{B = f\ (P, E)}$$

describes behaviour $(\boldsymbol{B})$ as a function of the person $(\boldsymbol{P})$ and their environment $(\boldsymbol{E})$. However Ross and Nisbett's [158] fundamental attribution error found the degree to which other people's behaviours is due to their personal traits is over estimated

whilst the degree to which they are caused by the situation is underestimated. It is therefore important to recognise that a combination of attitudes and external conditions determine behaviour and to successfully change behaviour using design, the design must combine and consider both approaches. Products can be used to dictate behaviour as shown in Zachrisson et al.'s [159] 'distribution of control' spectrum.

Figure 4-14 Distribution of Control Spectrum [159]

Using products to change user behaviour is commonly seen within orthopaedics. Computer aided techniques are used to limit user behaviour by guiding the surgeon through the operation, therefore reducing human error. However despite the accuracy advantages this runs the risk of going too far along the spectrum leaving the user feeling disconnected with the feeling their skills is not being utilised. It is therefore vital when changing user behaviour to ensure the user still feels involved in the process.

4.4.3 Design With Intent

Lockton's [160] study on using design to change behaviour led to the development of a toolkit to advise designers on how to use design to change behaviour. From their research clear categories arose where *"all approaches to influencing behaviour are either about trying to get people to do something, or trying to get people not to do something; and the ways to do that are either about changing how easy or difficult it is to do, or making it so people want to do (or not to do) it"* [160].

These can be summarised to three categories of:

- **Motivating behaviour**
  Changing users behaviour by education, incentives etc.
- **Enabling behaviour**

Making the desired method easier to achieve over the alternatives.

- **Constraining behaviour**
  Making the alternatives difficult or impossible.

Dan Lockton developed the theory of Design With Intent which includes *"8 lenses"* which can be used to think about how design can be used to change user behaviour. Each of these lenses groups different methods and examples of using design to change behaviour. A more comprehensive explanation of each lens and examples can be found in Design With Intent toolkit [160].

The **ludic lens** influences user behaviour through games and playful interactions. This can include setting challenges and targets, creating achievable levels to engage users to feel as they are making progress or providing feedback and scores to provide a reference point.

The **interaction lens** focuses on how behaviour can be influenced through user interaction with the system. Real-time feedback can inform the user on their actions, alerts can be given at the right moment when they need to change their behaviour, a progress bar can help guide the user through the system or simulation could highlight to the user the results of different choices.

The **perceptual lens** utilises product semantics, semiotics and psychology about how users perceive patterns. Colour associations, implied sequence, prominence, proximity and metaphors can all guide users to use a system in a certain way. When things can't be made visible, sometimes sound can be used to show if the product is working correctly [138]. A benefit of using sound is it they can be detected even if the users' attention is applied elsewhere [138].

The **architectural lens** uses techniques in architecture, environment design and the structure of the system to influence behaviour. Angles, hiding features, positioning, material properties and affordances are some of the suggested techniques. Affordances provide the user with strong clues to the operations of the product, for example, *"Plates are for pushing. Knobs are for turning. Slots are for inserting things into. Balls are for throwing or bouncing"* [138]. The user should be able to know what to do and how the product works by looking at it with no need for instructions [138].

Errorproofing lens uses design to ensure that any potential error is impossible. User error is inevitable therefore designers should assume all possible errors will occur and consequentially design to reduce the chance of error or reduce the consequences [138]. Techniques to do this can include default settings, confirmation steps, conditional warnings, defaults, interlocking, feedback and forcing functions. Feedback is critical as if the result of the action is not visible, error cannot always be easily detected quickly.

Security lens is using countermeasures to deter undesired behaviour through surveillance, peerveillance, threat and coercive atmospherics.

Machiavellian lens embodies an "end justifies means" approach using techniques of bundling, degrading performance, first one free and lock-in/out format.

Cognitive lens focuses on behavioural economics and how people make decisions. User behaviour can be changed through desire for order, framing, commitment and consistency, decoys, emotional engagement, expert choice and user habits.

These lenses can be used to identify methods of changing behaviour which can be incorporated into a project brief. As discussed above, developing a new device would involve a change in surgical technique. Using the Design with Intent toolkit can help with identifying methods in which surgeon behaviour could be changed.

4.5 Product Design Specification

Mauer highlighted the feeling of excitement about learning about a new product/process/user/industry but those feelings soon turn to dread when facing the copious amount of data that has been collected in the research phase [161]. Data, which is often subjective and difficult to make sense of, must be turned into concept ideas therefore the next step in the process is to use this market and user research to write a project brief and define a clear design boundary.

IDEO define this stage as synthesis and recommend the designer spend time *"aggregating, editing and condensing what has been learned, to establish a*

new perspective and identify opportunities for innovation" [144]. This is done through identifying patterns, extracting key insights and creating frameworks. Frameworks allow for better visualisation of the process showing the relationship between insights.

Dym stressed the importance of using collected research to identify the function that the device must carry out. Product requirements can be formulated based on the performance of those functions [162].

Pugh [139] suggests the development of a product design specification or product design boundary model. At this stage in the process, this is a specification of the product to be designed rather than the product itself. This document remains dynamic rather than static as it develops and changes throughout the process. By highlighting a comprehensive range of areas as shown in Figure 4-15 to be considered it develops constraints relevant to the design of the product and leave no ambiguity.

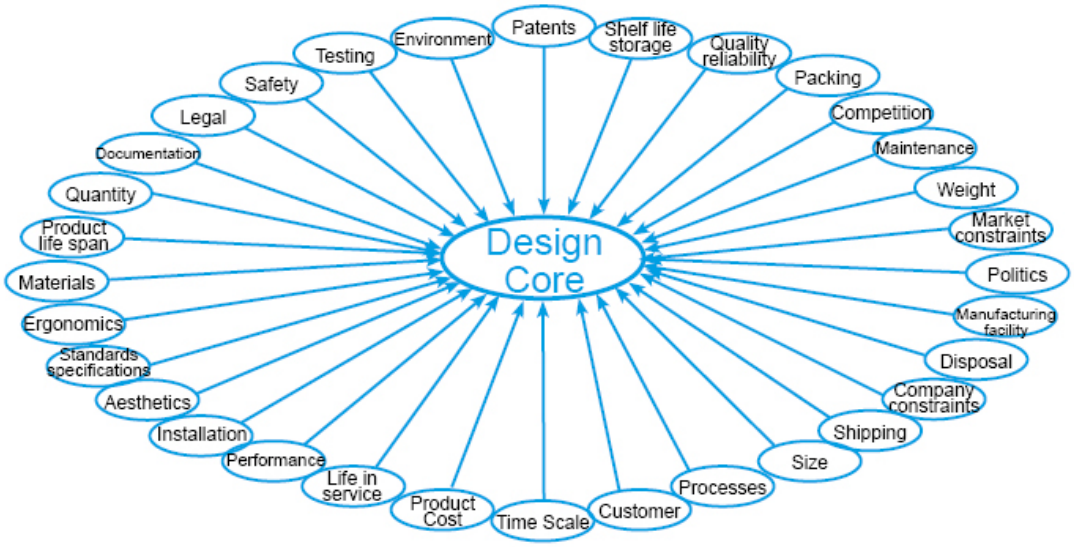


Figure 4-15 Product Design Boundary Model [139]

Another technique is to create a set of statements that list the functional requirements of the system by creating *"the product shall..."* statements [163]. These

statements create a picture of what the product is required to do which is useful for driving innovation and concept generation.

4.6 Concept Generation, Development and Evaluation

These next three phases of concept generation, development and evaluation work in an iterative loop as evaluation leads to further generation and development of existing and new concepts. This process is repeated until a final solution is decided and further repeated again for the individual components of the solution to ensure a successful and robust solution product which meets the product design specification.

4.6.1 Concept Generation

There are two extremes when approaching concept generation, solutions can be constrained to existing practice which can stifle innovation and creativity or there is complete freedom with a blank sheet of paper approach which can create unfeasible concepts [139]. The best method to encourage creative yet realistic thinking is to keep concept generation and concept evaluation and selection as separate activities [164].

The techniques, some of which are described below, used by most of the processes are similar. All highlight there is a spectrum of methods available for concept generation ranging from structured generation of morphological charts and function trees to more lateral thinking approaches of metaphors and analogies. However the difference is in how these techniques are carried out as Pugh suggests the best way of generating creative concepts is individually [139] and using groups for evaluation and selection however IDEO and The Design Council recommend a multi-disciplinary team involvement throughout the process [143].

Function trees and morphological charts are structured approaches towards concept generation. Function trees take the primary function, the designer asks the question *"How?"* and splits it into contributing functions. The process is continued with each of these contributing functions being split and so on. This results in functions on the lower level able to explain the above function. After reaching the

bottom, the designer goes the opposite way back up the function tree but asking the question *"Why?"*. The benefit of this technique is it helps the designer to work out the primary function of the product and the relationships with the subsidiary functions [164]. A morphological chart can be constructed using these functions. Solutions are devised for each separate function and concepts are generated by linking a solution of one function to a solution for another function creating many concept variations [162].

One of the most commonly used concept generation technique for is brainstorming. A tool popularised by Osborn (1957), brainstorming helps to think *"expansively and without constraints"* [144]. It is used to generate lots of ideas however it has been shown that although the technique may result in the production of more ideas, it can be at cost of creativity and quality [165]. There are several difficulties with this technique; creativity can be stifled as people are influenced by the opinion of others, people don't contribute or one individual dominates the group. Nijstad [166] found the biggest challenge was production blocking as, *"during a discussion, only one person can express his or her thoughts and ideas at any one time. Participants either disrupted another participant's train of thought or group discussion prevented participants from establishing a productive train of thought"* [167].

IDEO [144] developed seven brainstorming rules which can be used to avoid these problems:

- **Defer judgment**

  There are no bad ideas at this point. There will be plenty of time to judge ideas later.
- **Encourage wild ideas**

  It's the wild ideas that often create real innovation. It is always easy to bring ideas down to earth later!
- **Build on the ideas of others**

  Think in terms of 'and' instead of 'but.' If you dislike someone's idea, challenge yourself to build on it and make it better.
- **Stay focused on topic**

  You will get better output if everyone is disciplined.
- **Be visual**

Try to engage the logical and the creative sides of the brain.

- **One conversation at a time**

  Allow ideas to be heard and built upon.

- **Go for quantity**

  Set a big goal for number of ideas and surpass it! Remember there is no need to make a lengthy case for your idea since no one is judging. Ideas should flow quickly.

Another method to tackle some of the disadvantages of Brainstorming is to use a method called Brainwriting [164] or 6-3-5 [162]. Each participant communicates a limited number of ideas within a given time limit on a sheet of paper. This paper is passed to someone else in the group who can try improving or developing the ideas and this is continued until each sheet has been round every member of the group. This method uses the benefits of brainstorming whilst ensuring each individual is able to communicate their ideas.

On the opposite end of the spectrum is the use of metaphors to point out analogies which drive creativity. This method is *"a particular form of thinking or reasoning in which the properties of one object are thought of in terms of a second object which is different but has certain properties in common."* By looking at how the problem is solved in a different context the designer can completely change their perspective towards a problem or create new solutions. The Design With Intent toolkit [160] is useful for helping with this technique.

4.6.2 Concept Development

Following concept generation, IDEO stress the importance of turning ideas into prototypes so the concept so can be communicated to others and consequently refined. IDEO [144] describes 4 methods of prototyping: diagrams, storyboards, role play and models. Diagrams and storyboards are easy methods to express the process, the relationship between ideas and visualise the whole user experience from start to finish. Role play aides the designer in expressing the emotional experience of a product or service and constructing 3-dimensional models help make an idea just expressed on paper become tangible in a quick and cost effective manner.

Morris [168] encourages the designer to use simple sketching to develop ideas further. Although orthographic views are more commonly used for technical drawings, simple sketches can provide a, *"helpful tool in mapping out the basic features"* [168].

The Design Council are also in agreement with the importance of prototyping throughout the development stage. In the early stage of concept development, simple prototypes can be used to test key principles, function can be tested in working prototypes and aesthetic models are useful for testing form and ergonomics. Getting users to interact with prototypes highlights any problems which can be addressed and subsequently improve the design [143]. More and more companies are using virtual prototyping methods ranging from sketches to detailed 3-dimensional models to help with *"predicting the future of an idea, shaping the thinking behind the appearance and performance of a design"* [168].

Xerox ensure that Failure Mode and Effects Analysis (FMEA) is carried out on concepts to highlight any potential failures in the design. This method also helps with product evaluation [143].

Baxter [164] recommends designers must give consideration to many contribution factors such as product architecture, component design, general assembly, materials and manufacturing (Figure 4-16) at this stage which help when building prototypes and testing.

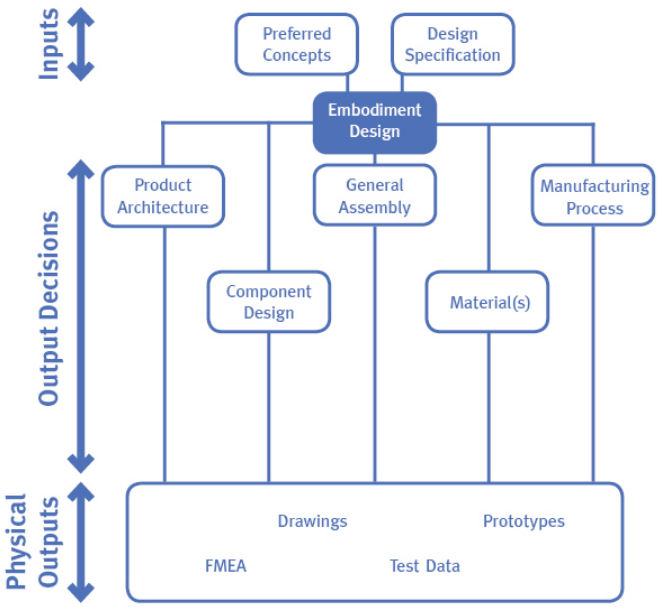


Figure 4-16 Embodiment Design Considerations [164]

Pugh highlights that as the converging, iterative process continues more detailed design of concepts is required and consideration to mechanisms and components must be given. The same techniques as described for concepts as a whole are used to generate mechanisms, develop the form of the concept and evaluate functions. Although components are, *"roughly defined at the conceptual stage, at the detailed design stage these may vary greatly at the detailed design stage due to methods of manufacture, detail, materials etc"* [139] therefore a more detailed product design specification and component design specifications are useful.

4.6.3 Concept Evaluation

After the generation of many concepts the designer is then faced with the task of selecting the best solution. It is not possible to develop all solutions therefore decisions must be made as to what solutions to take forward. It is critical to evaluate concepts to gain user feedback, to ensure the best solutions are moving forward and weaknesses in concepts are highlighted and refined resulting in robust solutions. Evaluation techniques range from qualitative to quantitative methods however the majority are qualitative [139].

Decisions can often be made by guesswork or are based on the designers' intuition and experience therefore Pugh stresses the importance that choices should

be made by a more rational procedure so developed a disciplined method of using an evaluation matrix [169] to aid in concept selection. Using a matrix compares the concepts against each other and against the criteria which is taken from the product design specification. For each criteria, each concept is compared to the industry standard. The concept is given a “+” if better than the standard, “-“ if the concept is worse than the standard or “s” if the concept is the same as the standard. This technique provides the designer with a better understanding of the concept with regard to strengths and weaknesses and a comparison to the industry standard. It also encourages new solutions which are a combination of the strengths of previous concepts [169]. As improved concepts are generated these can be developed further and the matrix can be repeated at a more detailed level. This technique can also be carried out using a numerical approach by weighting functions, scoring each concept on each function which results in a comparative score for the concepts [162].

IDEO [144] stress the importance of gaining feedback to bring the user directly back into the process as users often inspire further iterations. Baxter [164] suggests giving users the chance to vote on favourites as a great way to gather feedback and an opinion on solutions. A similar method is to use coloured post its, asking users to note things they like about a concept on green post its, things they don’t like on red post its and questions on yellow post its. The colour coding allows for quick and easy visualisation of the amount of advantages, disadvantage and questions for each concept.

As shown in Figure 4-17, a controlled convergence process [139] can be used until a final concept has been decided. This process alternates between convergent and divergent thinking as concepts are added throughout the process leading to improvements in concept generation, selection and most importantly better designs [139].

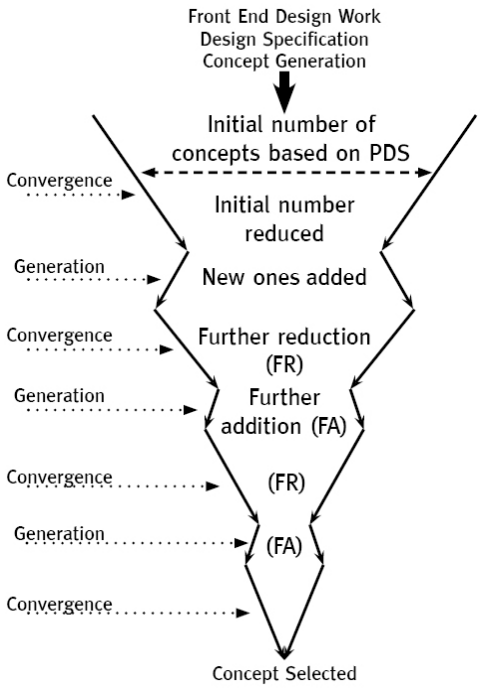


Figure 4-17 Controlled Convergence [139]

The Design Council [143] identified that this point is pivotal in the design process. Products are often at this stage either shelved or given the green light to go ahead with detailed design and manufacture. There was variation in the required level before this decision was made as Xerox required thorough review and testing while Yahoo! require a fully working prototype.

4.6 Concept Delivery

If it is decided to continue with the concept, it is tested and further refined using similar methods to the earlier development stage but this time the focus is preparing the product for manufacture. The Design Council found within most of the product design companies much of the manufacturing was outsourced [143].

All the processes are in agreement of the importance of product testing involving users before product launch. Xerox test using the Six Sigma principles in mind, Whirlpool carries out in-situ testing while Microsoft use a self-testing approach turning the project team into users [143]. IDEO recognise that launching a product is still an iterative process involving many prototypes and pilots to perfect the solution [144].

4.7 Harrison User Centred Methodology (HUCM)

Research into current product design literature highlighted the importance of using a design methodology which was centred on the user. Product design was used create a solution to help surgeons position the acetabular cup. This challenge required changing the current behaviour of surgeons therefore a user centred design methodology was critical. Although there are many similarities between the design methodologies, the reviewed methodologies put an emphasis on either quantitative or qualitative techniques. This demonstrated a gap for a process which was centred on the user and included both quantitative and qualitative techniques. Therefore for this research, a design methodology, Harrison User Centred Methodology (HUCM), was developed based on these methods and techniques researched. The methodology was developed with the medical sector in mind.

As can be seen throughout this chapter, the structure of the majority of the design methodologies are similar. The methodologies are split into phases involving building an understanding of the problem and user, defining a design specification and developing solutions in an iterative manner before reaching a solution. This structure has been the foundation for the design methodology used in this thesis. In line with these current methodologies, HUCM followed a similar structure, split into the following phases:

- Problem
- Understanding
- Design Specification
- Design Development
- Solution

Following IDEO's recommendation, the phases are not considered as distinct, orderly steps but a system of overlapping spaces. Some of the phases, such as understanding and design development, are split further into overlapping circles to additionally demonstrate these phases cannot be completed in a sequential manner but rather involve a combination of techniques. Each of these phases are not independent of each other but provide a basis for the next phase.

Although there are similarities in structure between the methodologies, the techniques used in each methodology, within each phase, range from structured, quantitative methods to subjective, lateral-thinking, qualitative approaches. The overlapping circles within the design methodology encourage a combination of both these quantitative and qualitative techniques within an iterative process. The design methodology of 8 overlapping circles within 5 phases, used for the rest of this thesis is shown in Figure 4-18 below.

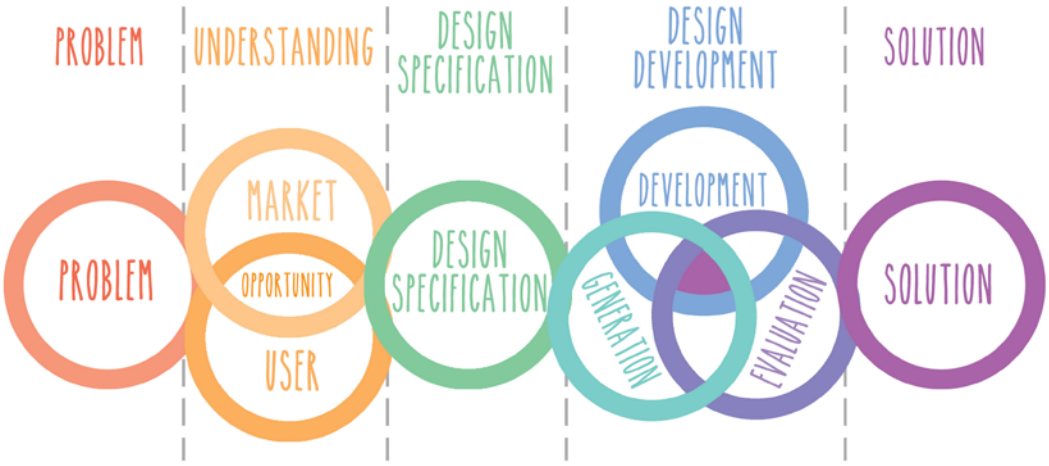


Figure 4-18 Harrison User Centred Methodology

Methodologies discussed in section 4.4, encourage a process of convergent and divergent thinking. This is important to allow the designer to build a rich understanding of the user, encourage innovation and ensure a wide range of solutions is pursued before improving and narrowing the process. As demonstrated in Figure 4-19, the methodology also encourages this pattern of divergent and convergent thinking. HUCM encourages divergent thinking when understanding the user, product market and when creating design solutions and divergent thinking when developing the design specification, developing solutions and reaching a final product solution.

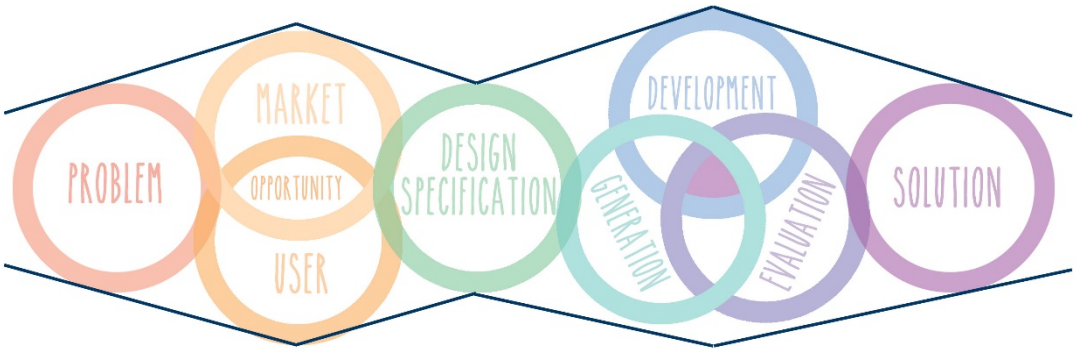


Figure 4-19 Convergent and Divergent thinking in HUCM

The 8 overlapping circles in the design methodology are based on the literature studied. HUCM starts with a defined problem, this is based on Pugh's theory which highlighted the importance to start with a specific need or problem that needs to be addressed.

The understanding phase is a combination of both qualitative and quantitative techniques. Combining Pugh's methods of building a clear understanding of the product market, IDEO's method of building an understanding of the user and giving consideration to human factors. Using the theory by the Design Council as a basis, the understanding developed during this phase can be combined to identify opportunities for product development. The understanding and opportunities phases identified help with developing a product design specification as described by Pugh and Ullrich and Eppinger. Similar to the other methodologies, HUCM converges as this point and the specification helps to provide a guide for the rest of the methodology. The design specification is used to drive the design development phase. In all the design methodologies studied, an iterative process between concept generation, development and evaluation is imperative to ensure a robust solution is achieved. This iterative loop is demonstrated in the methodology by the overlapping circles. Based on Pugh's theory, this is a phase of convergent and divergent thinking which leads to a final design solution.
Consideration of the user throughout the process is critical to ensure a successful product and to make sure the user is kept at the centre. This cannot be summed up in one step but must be present in all the phases, the designer must take the time to understand the context and problems, include the user in concept generation and gain vital feedback in concept evaluation and pilot testing.

Harrison User Centered Methodology was used to design a device to aid surgeon's with placing the acetabular cup in a desired position in total hip arthroplasty. The next chapter details the process of designing this device by explaining specific design techniques used within each of the phases.

5

Harrison User Centred Methodology

5.1 Chapter Contents

In this chapter the product design methodology developed for this research is elucidated through explanation of each of the 5 phases and a range of techniques. This methodology was used to design surgical instrumentation to help surgeons correctly position the acetabular cup in total hip arthroplasty therefore examples of how this process was used to reach a successful design is covered. HUCM starts at the initial problem, discusses the understanding of both the market and the intended users, details the product design specification, shows the iterative design development and explains the final design solution.

As a result of following the methodology, a positioning guide which can be used to aid surgeons with acetabular orientation was created. This device is a simple, mechanical low cost method. The device guides the surgeon to the correct angles by providing feedback, limits error and consistently holds the introducer in a steady position. A patent has been filed for this device to enable further development.

5.2 Design Methodology

As discussed in the previous chapter, after researching a variety of product design methodologies, a combination of these methods and techniques were used to develop the Harrison User Centred Methodology (HUCM). The methodology designed and developed for this project is shown in Figure 5.1.

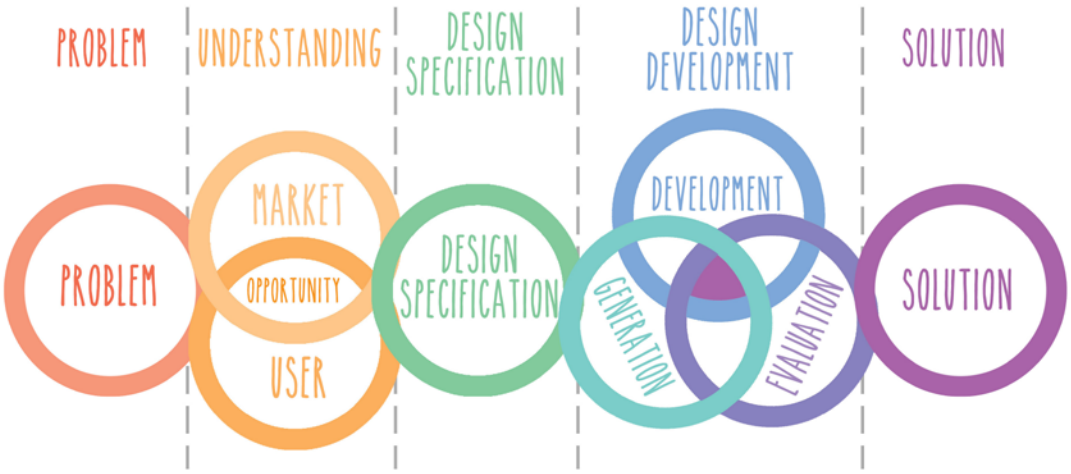


Figure 5-1 Harrison User Centred Methodology (HUCM)

This methodology was followed to design surgical instrumentation for aiding surgeons in achieving correct placement of the acetabular cup in total hip arthroplasty and the methodology and techniques used to create a successful solution will be explained throughout this chapter.

5.3 Problem

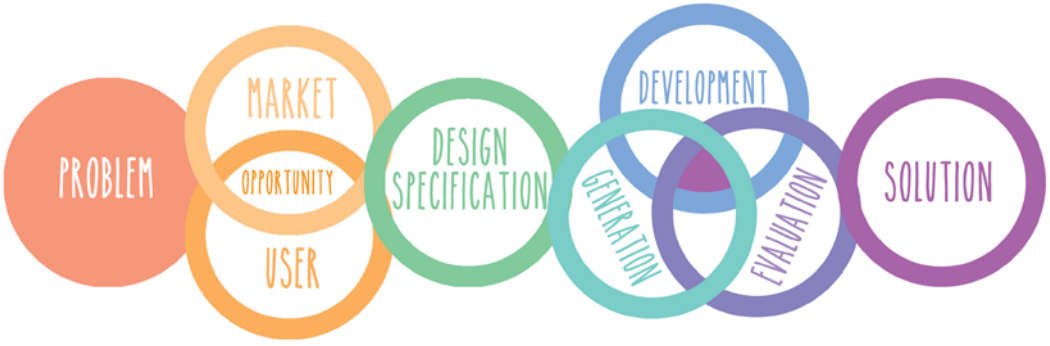


Figure 5-2 Problem Phase of HUCM

The initial identification of a problem and recognition of a need has been discussed in Chapter 2. As discussed previously, 86,478 cemented and cementless hip replacement procedures were carried out last year [13] and with the aging population, this number is expected to have doubled by 2030 [15]. 13% of these procedures are revision surgery and this revision burden is also expected to continue to increase [15]. Poor positioning of the acetabular cup leads to many complications, all which increase the risk of revision surgery, therefore correct

orientation is critical to ensure a successful operation. Current instruments to aid surgeons have many limitations with 78% of acetabular cups placed out with recommended positioning guidelines [89]. A device to help the surgeon position the acetabular cup could ensure the cup was at the correct orientation which would contribute to reducing the risk of revision surgery.

This desire, to aid surgeons in achieving accurate acetabular orientation for total hip arthroplasty, provided a clear start to the process. The defined problem led to many questions such as;

- Is orientation important?
- What are the current techniques?
- What are other contributing factors?

Research into these questions resulted in the research synthesis of acetabular orientations and has been described in Chapter 3.

The results from the problem phase identified the significant variation in the guidelines regarding acetabular orientation, limitations with current devices and the need for a device to aid surgeons with positioning of the acetabular cup.

5.4 Understanding

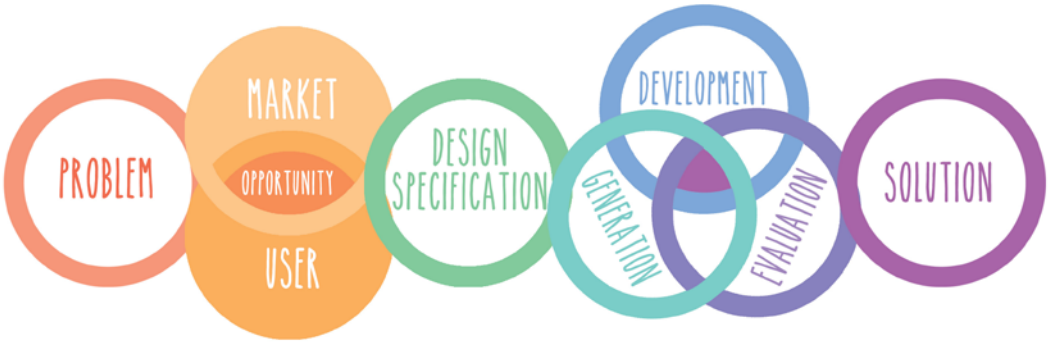


Figure 5-3 Understanding Phase of HUCM

As described earlier in this chapter, the understanding phase is an amalgamation of market and user research which is consequentially analysed to discover product opportunities. This section is split to discuss the results of market research, user research and how the gathered information was used to identify opportunities. The literature review as described in Chapter 2 is part of the market

understanding phase therefore as it has already been extensively explained more focus is placed on the user research results within this section.

Combinations of both quantitative and qualitative research techniques were vital to build an extensive knowledge of the subject area. Reading of surrounding literature, competitor and market analysis, user interviews and passive observation, user pleasure case studies and design with intent methodology were used to ensure a user centred approach was carried out. This provided a wide perspective which encouraged creativity when approaching design solutions.

5.4.1 Market Understanding

Quantitative research methods such as Pugh's techniques [139] (Chapter 4.3) provided a wealth of knowledge in the surrounding literature with regard to acetabular orientation. An extensive literature search involving reading of papers, reports, proceedings and reference books highlighted key problems such as the importance of correct acetabular orientation, competitor analysis, limitations with current techniques, the impact of pelvic tilt and the varying range of guidelines and reference systems used. The extent of this research has been documented and outputs have been reported in Chapters 2 and 3.

Pugh identified the importance of gaining understanding of the associated standards (Chapter 4.3). Following the Medical Device Directive 93/42/EEC and EN ISO 16061:2009, our device is categorised as a non-invasive instrument however due to the measuring function, is classified as Class 1m. As a result materials are standardized under ISO 5832-1 to ISO 5832-12.

Research into the manufacturers of competitive and analogous products highlighted the inadequacies and problems with current technologies, as mentioned in Chapter 2 & 3. To identify any gap in the product market, comparison was made between current methods. Najarian et al. [46] compared the accuracy of acetabular cup position and time added to the operation between mechanical guides, image-free systems and computer navigated systems. As shown in Figure 5.4, although the image-free and computer navigated system were considerably more accurate, the time added to the operation was significantly increased. Longer operating times

increase the risk to the patient and are considerably more expensive therefore are best avoided. Conversely, although mechanical guides did not add to the average operating time, the accuracy was reduced which highlighted a clear market opportunity (shown by the dotted red circle in **Figure 5-4**) for an accurate method which does not significantly increase operating time.

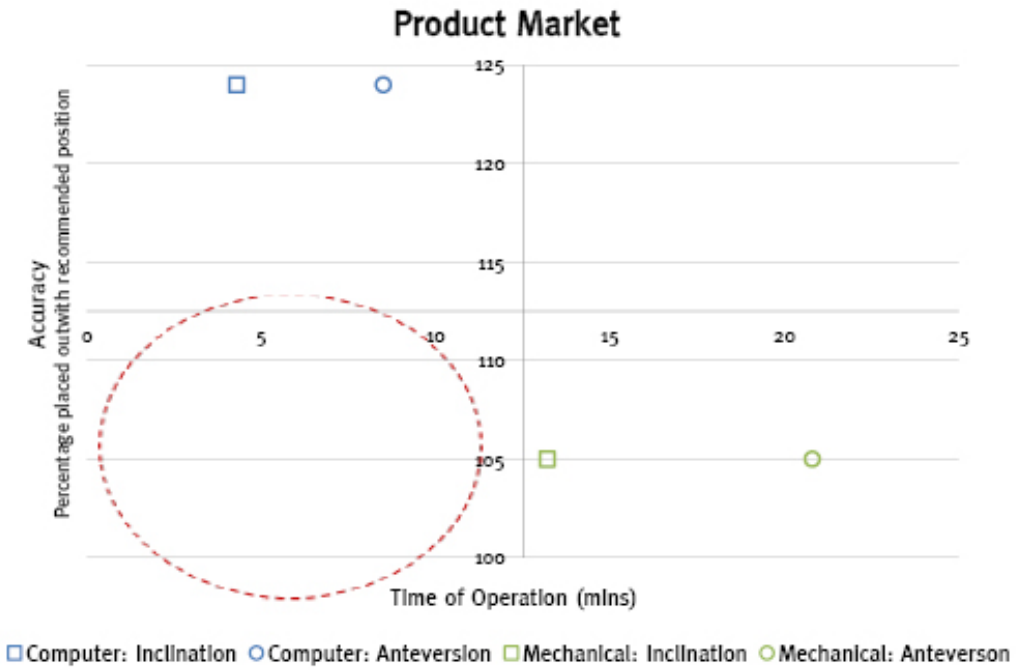


Figure 5-4 Comparison of current methods [46]

5.4.2 User Understanding

Qualitative research techniques suggested by IDEO [144] (Chapter 4.3) were used to gather users' stories through discussions and observation of users at James Paget University Hospital. Over a two day period, 4 total hip arthroplasties performed by different surgeons were observed. A combination of both cemented and cementless hip arthroplasties were observed and the introducer used was similar to a cementless introducer described in Section 2.6.1. Additional orthopaedic surgical procedures were observed to increase understanding of the surgical environment. Discussions were held with a variety of surgeons, both junior doctors and consultants, over the visit to build an understanding of user attitudes and issues they faced. This combined use of ethnographic techniques [148] (Chapter 4.3), in

particular passive observation and interviews, provided insights into how surgeons use positioning devices as opposed to how they claim to use positioning devices. The observation and conversations with surgeons enabled greater understanding of the problem, the surgical environment and unidentified contributing factors.

The insights gathered from this trip were:

- Alignment guides were difficult to use and from observations, some of the surgeons preferred not to.
- The anteversion angle was harder to judge than the inclination angle.
- There was no guide used when initially reaming the acetabulum.
- Guides do not allow for patient variability.
- There was no precise way of ensuring correct patient position.
- Surgeons would like real time feedback on the position of the guide and acetabular cup.

Each of these insights identified problems which could be addressed within the design of the new product.

Using the Designing Pleasurable Products methodology [150] (Chapter 4.3.2.2) to build a profile study for a surgeon helped identify pleasure benefits and develop an understandable user profile. The profile showed socio-pleasure, where new and novel techniques and technology are used, was important for encouraging surgeon use. Ensuring the device was an aide rather than removing the surgeon's skill or control was identified as important to meet psycho-pleasure needs.

Both ethnography techniques and the Designing Pleasurable Products methodologies highlighted the biggest user challenge was encouraging and engaging surgeons to use the device and change their current practice. This determined that the design of the product must challenge surgeons to alter their behaviour.

Mapping out the current procedure helped to envisage the whole process, as shown in Figure 5.5, led to the recognition of the importance of pre-operative procedures and correct patient positioning. It also identified opportunities within the current surgical technique for development, such as the reaming of the acetabulum.

Mapping the process encouraged creativity as focus shifted from the positioning of the acetabular cup to consider alternative opportunities during the procedure.

Harrison User Centred Methodology encouraged use of a combination of both quantitative and qualitative technique to build an understanding. The results demonstrated a difference between the outputs when using quantitative compared to qualitative research methods. Quantitative research methods determined many different opportunity areas such as reference systems, limitations in the accuracy of current mechanical guides and measurement methods however research gathered and opportunities identified were constrained within the limits of the initial given problem. Qualitative research methods identified wider problems outside the problem definition. Encouraging more divergent thinking resulted in understanding the influence of patient positioning leading to consideration of preventative measures and solving the wider problem.

Figure 5-5 Procedure Storyboard

5.5 Opportunity

Faced with the challenge of condensing and understanding the information gathered, as recommended by IDEO [144] (Chapter 4.4), time was spent identifying patterns, extracting key insights and creating techniques. As explained in this section, these techniques were used to identify problem areas within acetabular orientation, develop a framework of techniques which could be used to change surgeon behaviour and identify areas for product opportunity.

All of these research techniques indicated many limitations within correct orientation of the acetabular cup which were summarised into problem areas:

- Reference Systems
- Mechanical Guides
- Patient Positioning

Subsequently, addressing these three problem areas was a focus throughout the process when identifying product opportunities and concept generation.

As identified by the ethnographic studies and Designing Pleasure Products framework, the design of the product had to challenge surgeons to alter their behaviour. Design with Intent theory [160] (Chapter 4.4.3) was used to help identify methods where a product could be used to change user behaviour. The framework of motivating, enabling and constraining was altered (Figure 5-6) to create three techniques which could be used to change surgeon behaviour.

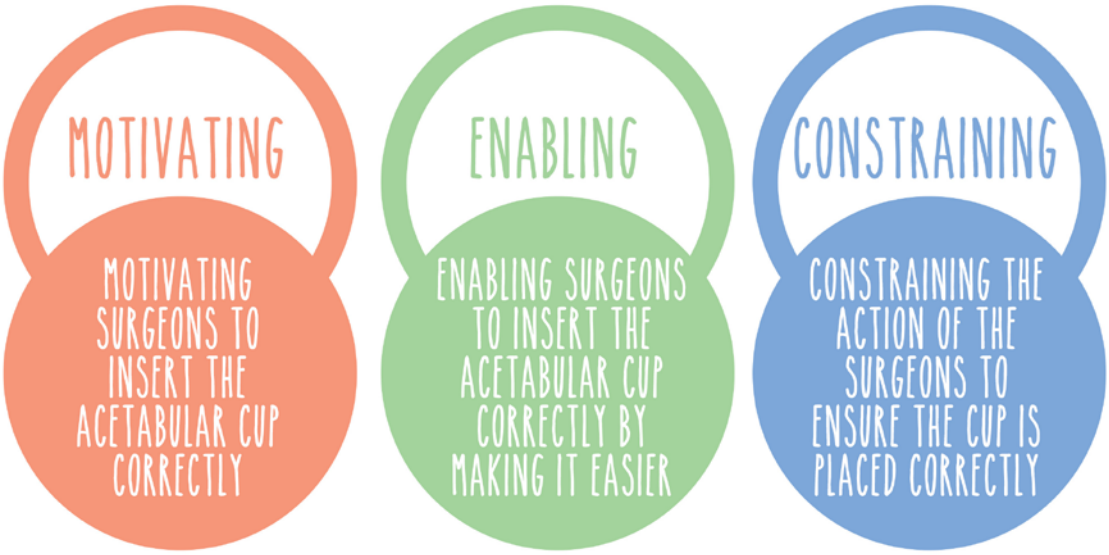


Figure 5-6 Altered Design with Intent - Motivating, Enabling and Constraining Aims

Using these three altered Motivating, Enabling and Constraining aims combined with the Design with Intent lenses [160] (Chapter 3.3.3.2) and considering the three recognised problem areas, different product opportunities were identified. Some of these opportunities are highlighted below:

Motivating Behaviour:

Motivating surgeons to insert the acetabular cup correctly

- **Teaching**
  - Make surgeons aware of the issues
  - Provide training on how to use the equipment
  - Provide better knowledge of discrepancies within orientation
- **Surveillance**
  - Monitoring surgeon technique: surgical statistics
  - Motivates surgeons to do better next time

Enabling Behaviour:

Enabling surgeons to insert the acetabular cup correctly by making it easier

- **Guidelines**
  - Rephrasing: make it obvious what the desired orientation is to be
  - Remove confusion over definitions and references
- **Cost**
  - Cheaper than alternative system
- **Computation**
  - Remove the need for the surgeon to align two planes at once
  - Device does the calculation for you
- **Skill level**
  - Provides a method that is not determined by the experience of the surgeon
- **Retrofitted**
  - Procedure fits into current surgical technique
  - Does not require the surgeon to go out of their way to complete

Constraining Behaviour:

Constraining the action of the surgeons to ensure the cup is placed correctly

- **Real-time feedback**
  - Surgeon is aware of implant position intra-operatively
  - Provides feedback loop to allow correction
- **Patient Positioning**
  - Pelvic position constrained
  - Pelvic position monitored
- **Alarms**
  - Tell the surgeon if the cup is placed outside of the safety zone
- **Error proof**
  - Does not work if aligned wrong
  - Device set at the desired angle
  - Cannot just avoid or remove the alignment guide

Combining the problem areas, insights gathered from the understanding phase and behavioural aims, a technique was created which identified areas of

product opportunity. This ranged from pre-operative to postoperative environments, as shown in Figure 5-7.

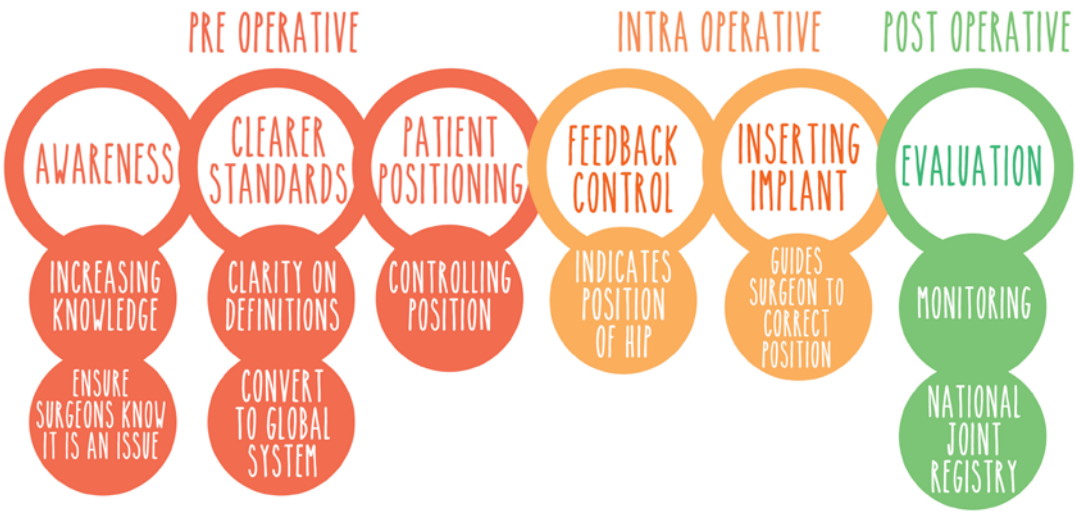


Figure 5-7 Product Opportunity Areas

Figure 5-7 demonstrates the wide range of opportunities available where products and/or services could be developed to help orthopaedic surgeons improve positioning of the acetabular cup within total hip arthroplasty. Consequently the design thinking had to be converged and therefore was focused on the intra-operative environment for the rest of the process. Consideration was given to pre-operative opportunities with clearer standards being discussed in Chapter 3. Patient positioning was identified as key influence on the device however as it required in-depth research to clarify the relationship between the position of the patient on the operating table, this would be looked into in more detail in future work.

5.6 Product Design Specification

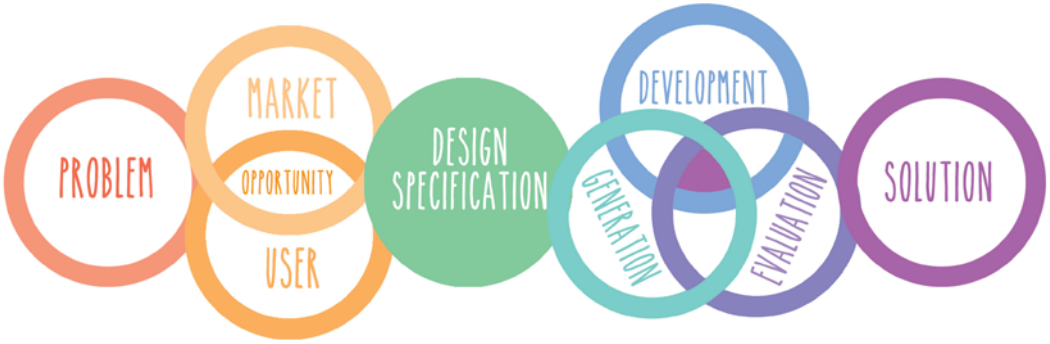


Figure 5-8 Design Specification Phase of HUCM

The insights gathered from the understanding phase were used to develop a list of product requirements or the Design Specification. The specification created a design space which was useful throughout the process as it helped drive innovation and provided a standard for evaluation.

Two techniques were used to develop the design specification. The first created a basic overview of the design space by using the 5Ws to ask the questions:

- Who?
- What?
- Where?
- Why?
- How?

The results are shown in Figure 5-9 and demonstrated that although the direct user is the surgeon consideration must also be given to the surgical assist who is setting up the instrument, the NHS health board who manage the associated costs and the patient who face the consequences if the device does not work correctly.

Figure 5-9 Design Specification 5Ws

Pugh's Total Design method [139] (Chapter 4.4) created a considerably more comprehensive design specification which caused thought to be given to important issues such as storage and sterilization and to create defined product aims. These aims prompted discussions regarding the type of patient positioning and surgical approach the device would be used for. The lateral decubitus was the decided patient position as it is used in 93% of operations [13]. It was decided that at this stage, both cemented and uncemented would continue to be considered as such a device could provide useful to either technique. The clinical supervisor uses a similar design of introducer for both cemented and uncemented therefore this design was used as a basis.

Although the design specification document was created at this stage, it was continually edited and adjusted throughout the design process. A detailed copy can be found in the appendix (section 9.1) however the key identified aspects from the design specification was the device must provide control, accuracy, real-time feedback, consistency and reliability.

5.7 Design Development

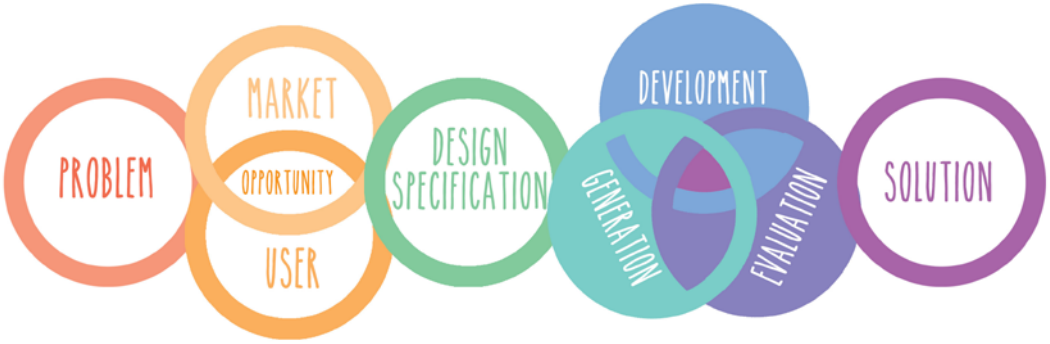


Figure 5-10 Design Development Phase HUCM

The next stage in the methodology was the Design Development phase consisting of the generation, development and evaluation of ideas which lead to a final solution. Although depicted as a Venn diagram with three overlapping circles, in reality this phase was repeated over and over again. Beginning with concept exploration, the process of generation, development and evaluation was repeated with many concepts, reduced to three concepts then decided on one final concept.

A range of techniques were used to generate, develop and evaluate concepts, details of which are provided in the following sections. Following the literature, to encourage creative thinking, generation and evaluation of ideas was separated. Concept generation was attempted in groups and individually and evaluation methods provided feedback which drove more concept generation and development.

5.7.1 Many concepts

The insights gathered, understanding built and product design specification were used to generate many concepts. To encourage creative thinking, these concepts were not limited by number but started with the generation of many ideas.

5.7.1.1 Concept Generation

Figure 5-11 Concept Generation a) Function Tree b) 6-3-5 session c) Individual brainstorming

Concept generation was started by developing a function tree (Chapter 4.5.2). Key aims from the PDS were noted on post-it notes and attached to the wall which provided a list of the significant functions (Figure 5-11a). Each function was categorised into either critical or desirable to determine the importance. The critical functions from the function tree were:

- Provides high levels of accuracy in a cost effective way
- Accuracy is not affected by high stresses subjected to the device during the operation
- Be able to be used with current surgical technique
- Be capable of withstanding sterile cleaning
- All angles are measured from one reference point
- Ensure the position of the implant and patient work on the same reference system

Ideas for solving each individual function were generated on separate post its. This created a morphological chart (Chapter 4.5.2) which produced a range of concept ideas.

Brainstorming was carried out both in group sessions and individually (Figure 5-11b). Three brainstorming sessions were carried out and an introductory presentation was given at the start of each session to set the problem and provide any necessary background. The principle investigator ran and organised these

sessions. The first session involved the clinical supervisor and postgraduate students who were not directly involved in this research. The second session involved a group from the University Biomechanics Focus Group. This included Professors, lecturers and students. The third session included a mix of people who had been present at either of the first two sessions. This was to be able to include lessons learned from the previous sessions.

Three sessions were run using a 6-3-5 method and IDEO's brainstorming rules [144] (Chapter 4.5.2) and the sessions provided many ideas. There were several limitations with these sessions as creativity was stifled with some ideas focused on one topic and due to the limited understanding of the focus group, concept generation was dependent on the success of the initial presentation describing the problem. Lessons learned from the sessions showed the most productive idea generation time was the discussion between participants afterwards. As a result, when the brainstorming sessions were repeated, group brainstorming, feedback and discussion were included in the process.

The group brainstorming enhanced individual brainstorming (Figure 5-11c) as questions were raised that had not been previously thought of. This encouraged creativity through searching for solutions to the questions. Rough ideas were generated using sketching.

Analogies (Chapter 4.5.2) were made using the Design With Intent methodology. Each suggested technique used to change behaviour was used to help create concepts for a surgical environment. Some examples of the generated ideas are given below:

- **Ludic lens**

  Create an obvious target for the surgeon to aim for
- **Interaction lens**

  Give real-time feedback on the orientation: allowing for correction during the operation
- **Perceptual lens**

  Use people's desire for symmetry and order within the design to help the surgeon line up angles

- **Architectural lens**

  Design of the guide means the device can only be used in a certain way
- **Errorproofing lens**

  Guide is set to default so that it automatically gives the correct orientation
- **Security lens**

  Angle needs to be logged into National Joint Registry which provides information for research
- **Machiavellian lens**

  Direct users to use a product in a particular way through example
- **Cognitive lens**

  Defined safe zone and gold standard

Similar to the Understanding phase, when using the developed design methodology, a range of quantitative and qualitative techniques were used. In the same way, comparison between the techniques showed more structured approaches created solutions that were within the design boundary however approaches such as brainstorming and analogies asked questions which encouraged more creative thinking.

Ideas were combined using IDEO's technique of identifying patterns [144] (Chapter 4.5.3). Ideas were grouped into concept areas of patient positioning, pelvic tilt, angle measurement, guidelines and real time feedback. These ideas which were taken forward for concept development are shown in Figure 5-12.

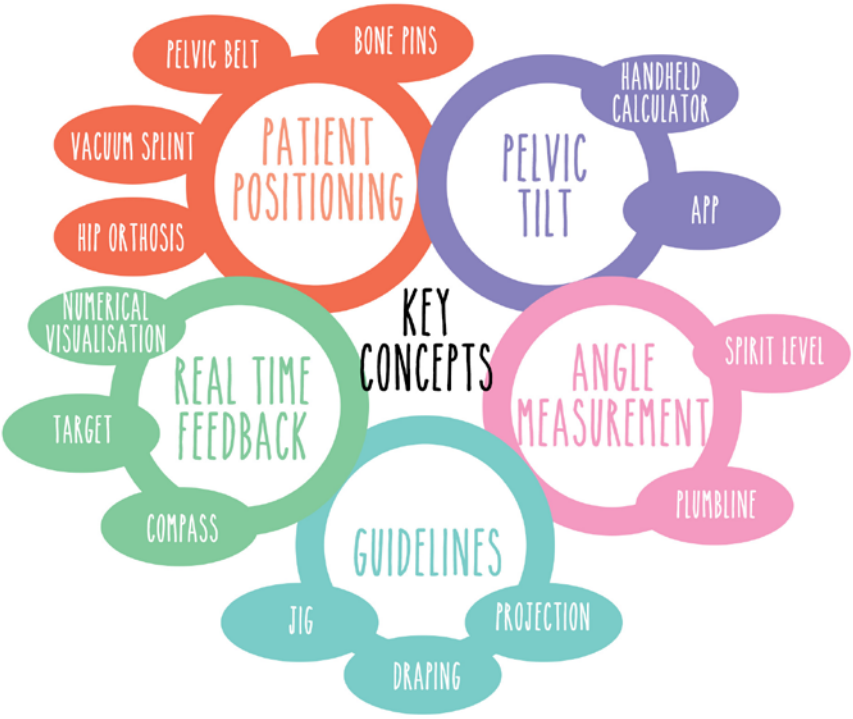


Figure 5-12 Concept Areas

5.7.1.2 Concept Development

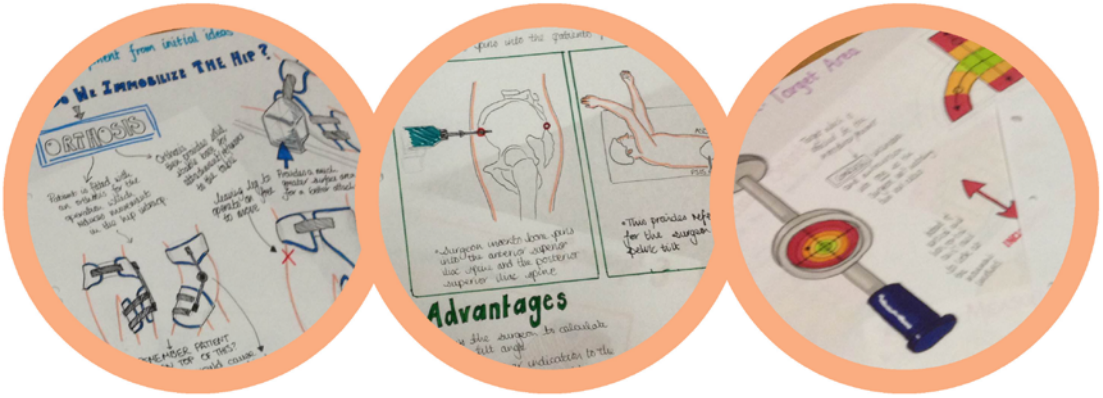


Figure 5-13 Concept Development sketching

At this initial stage, concepts were developed through combining ideas from the morphological chart, brainstorming sessions and analogies (Figure 5-13a). Sketching, simple storyboards, listing advantages and disadvantages (Figure 5-13b) and exploration and explanation of features (Figure 5-13c) helped visualise each concept on paper. 11 concepts were generated which are explained in Figure 5.15, Figure 5-14, Figure 5-16 and Figure 5-15.

As mentioned previously, the focus of the design was for an intra-operative device which reduced the concepts being developed during this research. The devices regarding positioning and pelvic tilt would be developed with further work.

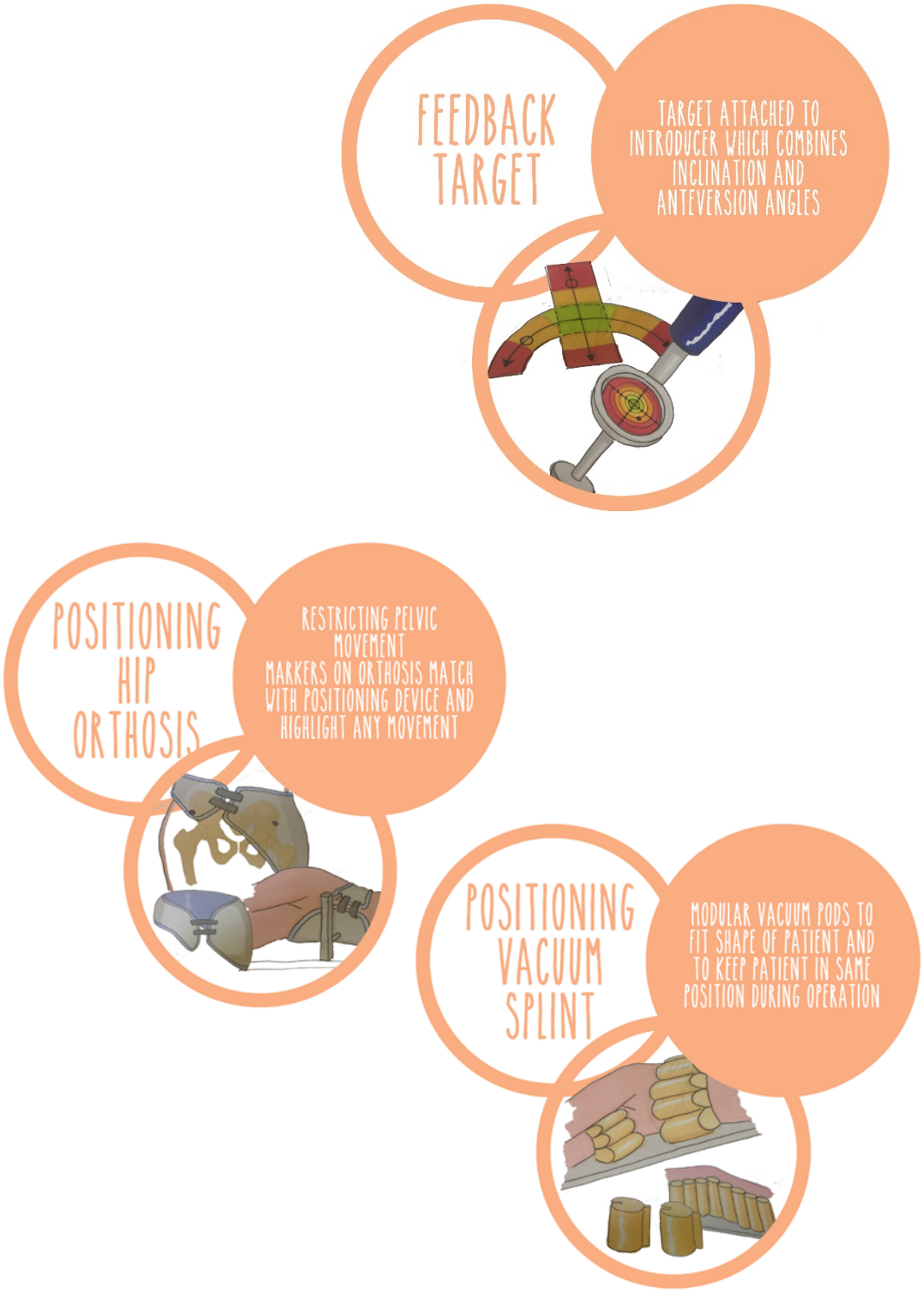


Figure 5-14 Concepts (a) Feedback target (b) Hip Orthosis (c) Vacuum Splint

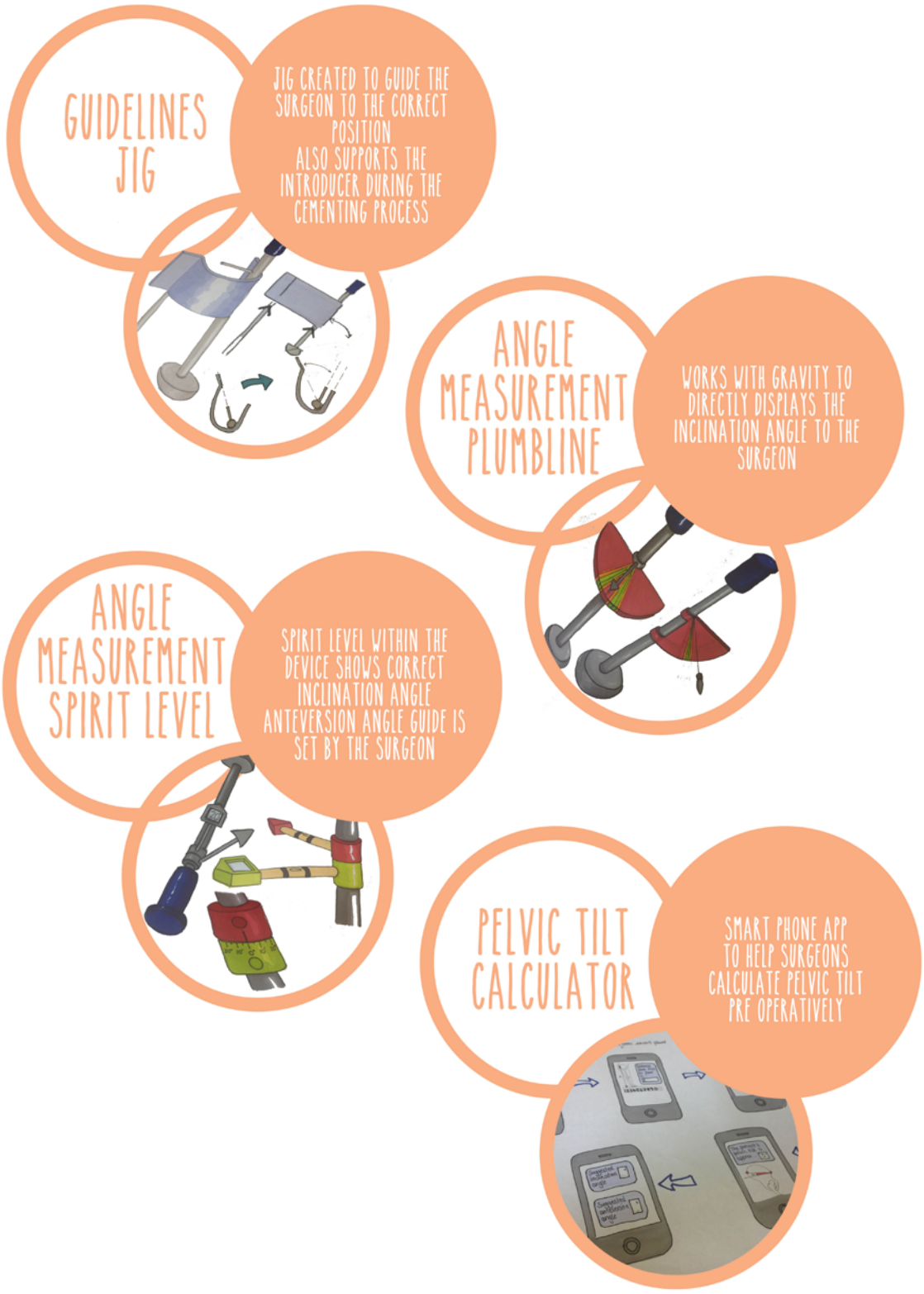


Figure 5-15 Concepts (f) Guidelines Jig (g) Angle Measurement Plumbline (h) Angle Measurement Spirit Level (i) Pelvic Tilt Calculator

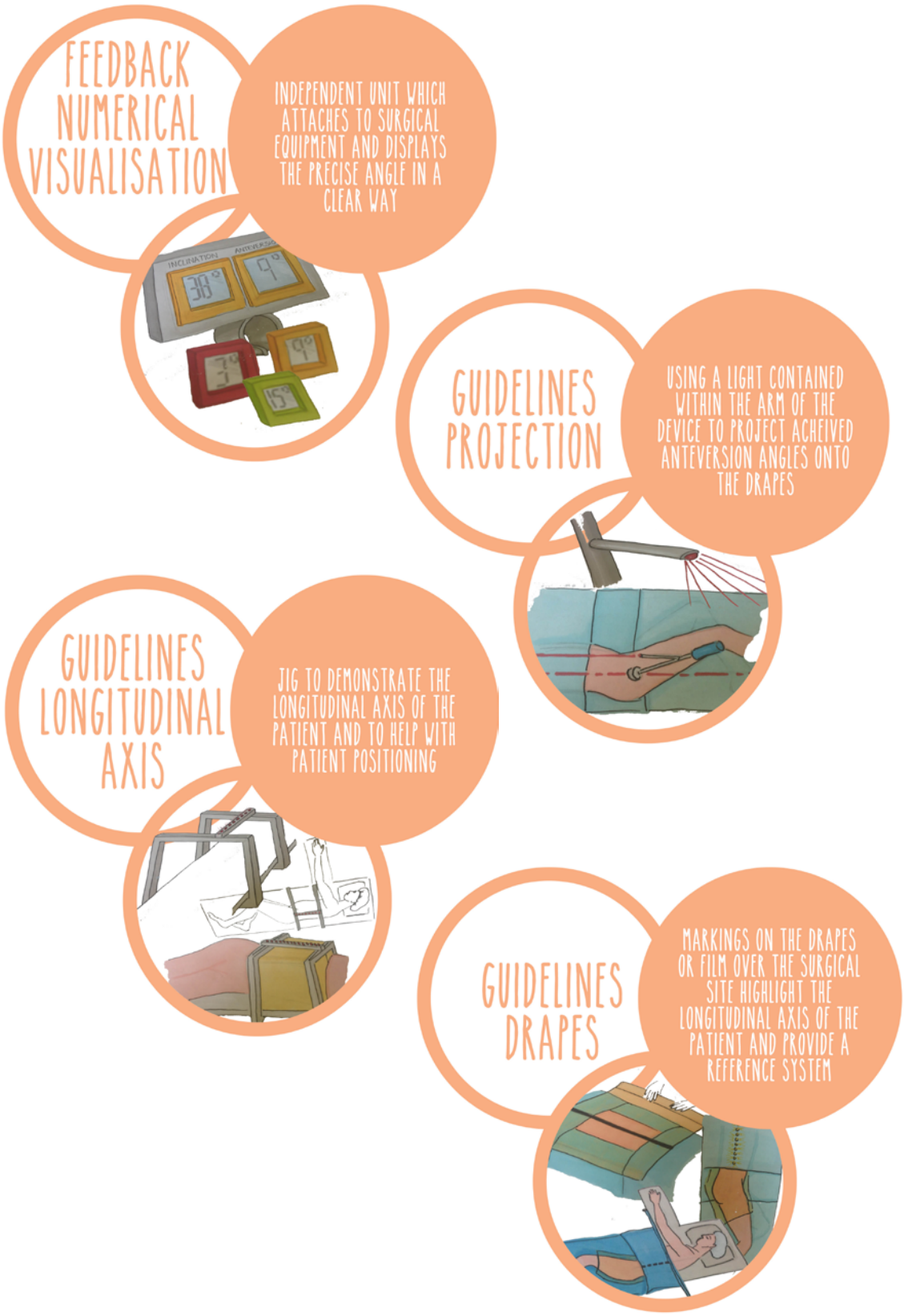


Figure 5-16 Concepts (b) Feedback Numerical Visualisation (c) Guidelines Projection (d) Guidelines Longitudinal axis (e) Guidelines drapes

5.7.1.2 Concept Evaluation

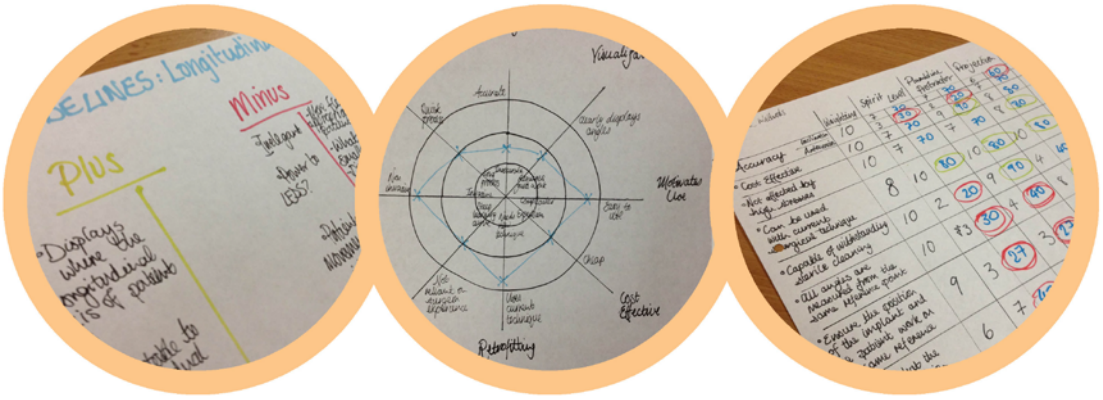


Figure 5-17 Concept Evaluation a) Plus/Minus/Same b) Target Graph c) Numerical Matrix

To aid with concept selection, the initial concepts were evaluated using a range of techniques. The disciplined method of Pugh's evaluation matrix [169] (Chapter 4.5.4) assessed concepts against the industry standard and the criteria from the design specification (Figure 5-17a). 22 criteria were used for assessment and the results, detailed in the Appendix, showed the Jig concept had the best outcome, with a score of 15. The Target and Numerical Visualisation both scored 14. The weakest concepts were the Projection, Plumbline and Spirit Level with scores of with 10, 9 and 7 respectively. This technique was limited as each criterion was treated with equal weighting. As a result, this method was repeated using a weighted numerical technique (Figure 5-17c). Using 30 criteria, this technique similarly ranked the Jig as the best solution. The results are listed in the Appendix. The Target was 2nd, Numerical Visualisation 3rd, Plumbline 4th, Projection 5th and again the weakest concept was the Spirit Level. Using target graph evaluation (Figure 5-17b) displayed clear strengths of each concept, and although it didn't produce a score it noticeably drew attention to weaker areas of each concept. This allowed for improvement in these areas. The target graphs generated are listed in the Appendix. These three techniques were useful for evaluation as they provided comparison against the design specification, helping ensure the concept which best met the design specification was identified. The techniques also clearly exhibited weak points in designs which could be improved by using the strengths from other concepts.

Feedback was gained by asking the brainstorming focus group to provide their opinion on the concepts. Each participant was given a selection of coloured post it notes and asked to add advantages, disadvantages and questions on each concept. This technique was constructive as it gave a variety of unbiased opinions rather than evaluation decisions to be prejudiced by the designer and also encouraged more questions to be asked. The results of this feedback was summarised and can be found in the Appendix.

Due to the techniques discussed above and the results detailed in the Appendix, weak points and strengths of each of these concepts were identified. Rather than completely removing concepts, ideas could be combined to strengthen concepts. Using the best attributes for the concepts, the ideas were combined to result in three concepts. The Numerical Visualisation and Target were combined to create a similar compass style device and the ideas from the Spirit level and Plumbline were incorporated into a Projection concept. The Jig/Positioning Guide came out as the best solution on every evaluation technique therefore was not combined with the other concepts.

5.7.2 Three Solutions

The generation, development and evaluation loop was repeated again for each of the winning concepts from the previous phase. The three concept solutions to be developed further were named Projection, Magnetic Compass and Positioning Guide.

5.7.2.1 Concept Generation

Figure 5-18 Concept Generation: a) Projection b) Magnetic Compass c) Positioning Guide

The results of the previous evaluation phase were used as feedback to improve each concept. The generation phase was repeated using similar techniques as described earlier and any weaknesses in the designs were replaced with strengths from other concepts.

Sketches from the generation stage are demonstrated in Figure 5.17 showing, Projection (Figure 5-18a), Magnetic Compass (Figure 5-18b) and Positioning Guide (Figure 5-18c).

Projection is made up of three lights, one on the patient marking out the longitudinal axis and two within arms which attach to the introducer. The weighted light on the base arm projects light down onto the introducer and markings display the achieved inclination angle. The light within the anteversion arm projects onto the drapes and the surgeon pivots the introducer until the projected line is parallel with the light marking the longitudinal axis of the patient.

Magnetic Compass is an independent unit which attaches to the introducer. The device demonstrates the angle to the surgeon in a clear way and provides continual feedback. The position is measured using accelerometers and gyroscopes as once the initial position of the device is measured, any displacement is calculated. LEDs surrounding the display change colour depending on the position showing the surgeon when they achieved the correct orientation.

Positioning guide is a simple, mechanical guide to aid surgeons. The cut away in the device ensures the introducer is held at the desired inclination angle and the markings on the device guide the surgeon to the correct anteversion angle. The guide is attached to a flexible arm which is attached to the operating table enabling a wide range of movement and a spirit level within the device ensures the guide is positioned correctly.

5.7.2.2 Concept Development

Similar to the earlier concept development phase, sketching was used to develop each concept with particular consideration for the technology required. Computer aided design was used to transform each concept from paper into 3-dimensional models (Figure 5-19). Storyboards (Chapter 4.5.3) of each concept were generated which gave a clearer understanding of the environment the device would be used in and raised issues concerned with the product life cycle. An example is shown in Figure 5-20.

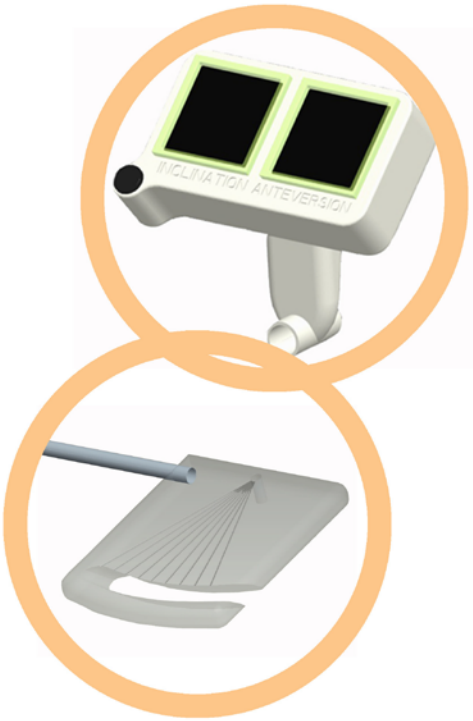


Figure 5-19 Concept Development: CAD of (a) Magnetic Compass (b) Positioning Guide

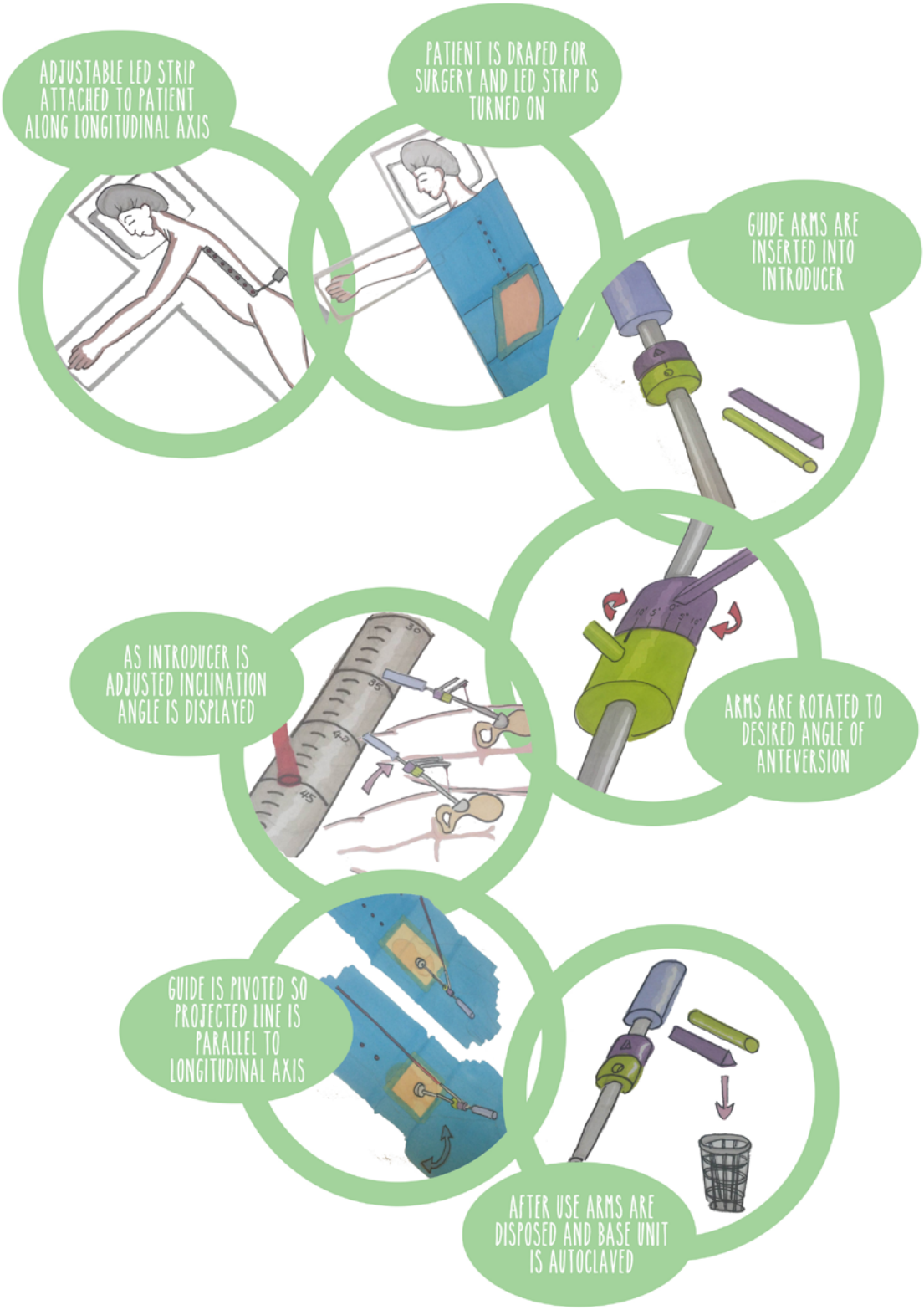


Figure 5-20 Storyboard of Projection Concept

5.7.2.3 Concept Evaluation

Similar evaluation techniques as described previously were used for each of these three concepts. User interviews were carried out with 4 consultant orthopaedic surgeons from a range of hospitals to gain feedback and opinions. This was useful however the responses gathered were varied in opinion. The positioning guide was popular as it provided a low-cost solution and the simplicity of this device was appreciated. Questions remained regarding the set-up of the device and influence on the rest of the operation was questioned. The Projection was described as a good idea but in practice the projection could be difficult to see in surgery and could cause a distraction. The Magnetic Compass was also viewed as a good idea however questions were raised regarding the reference system and interference with surrounding medical equipment. The challenge with this evaluation technique was each surgeon had a varying opinion which left no clear cut answer to the best solution. The opinions gathered were therefore used as contributing factors to help make a decision rather than providing a definitive answer.

One of the more experienced surgeons disagreed with the need of a device to help surgeons with acetabular cup positioning. This confirmed the challenge of encouraging surgeons to use the device as it was viewed as questioning his skill and experience. Further discussion showed he would however encourage younger, less experienced surgeon to use the device to build up skill. This is an invaluable insight and demonstrated that using the device as a training tool could be a potential product market.

Based on the results from the evaluation techniques and surgeon interviews, the Positioning Guide was chosen as the final design solution. The evaluation techniques consistently ranked the positioning guide above the other concepts and most importantly demonstrated it was the solution that best matched the design specification. The user feedback also ranked the positioning guide over the other concepts. The feedback was very positive and the simplicity and low cost of the device were attractive features. Discussions highlighted the positioning guide would be beneficial in aiding the surgeon by limiting movement and holding the introducer steady and could have the potential to aid with surgeon training. For these reasons the positioning guide was chosen as the final solution.

5.7.3 Final Solution

Although the final solution had been decided, the process of generation, development and evaluation was necessarily repeated. This was to ensure the concept was as robust as possible.

5.7.3.1 Concept Generation

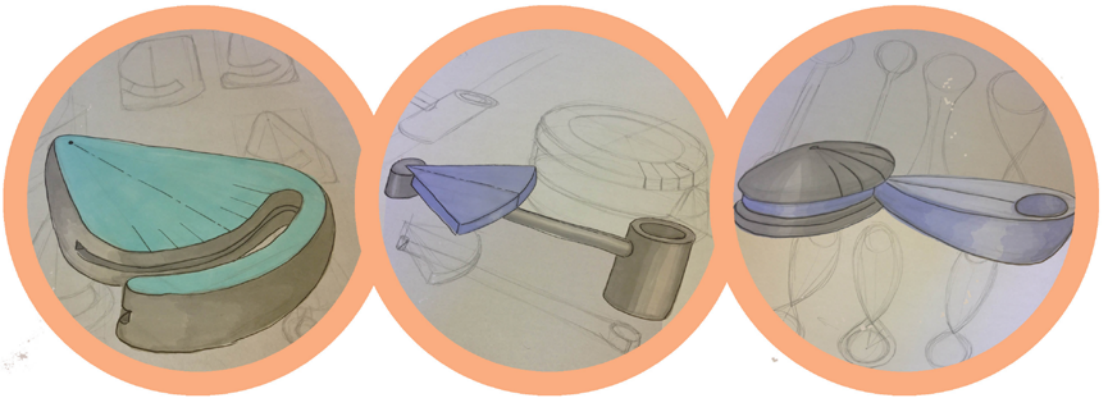


Figure 5-21 Concept Generation of form

At this stage, different orientations were generated (Figure 5-21) with each concept focused on different features. These features ranged from a solid base with no spare parts (Figure 5-21a), clear angle measurements (Figure 5-21b) or a pivoting arm (Figure 5-21c).

Figure 5-22 Sketches of Guide

Combination of the feature ideas shown above created a concept which is made up of three parts, a base unit, a rotating arm which locks the introducer into place and angle guide which provides a reference. As shown in Figure 5-23, the introducer is inserted into the rotating arm and the arm pivots the introducer round while the base unit ensures the inclination angle is achieved by limiting movement. The surgeon is able to

position the introducer at the desired angle by aligning the introducer to the angle guide and lock the introducer into place.

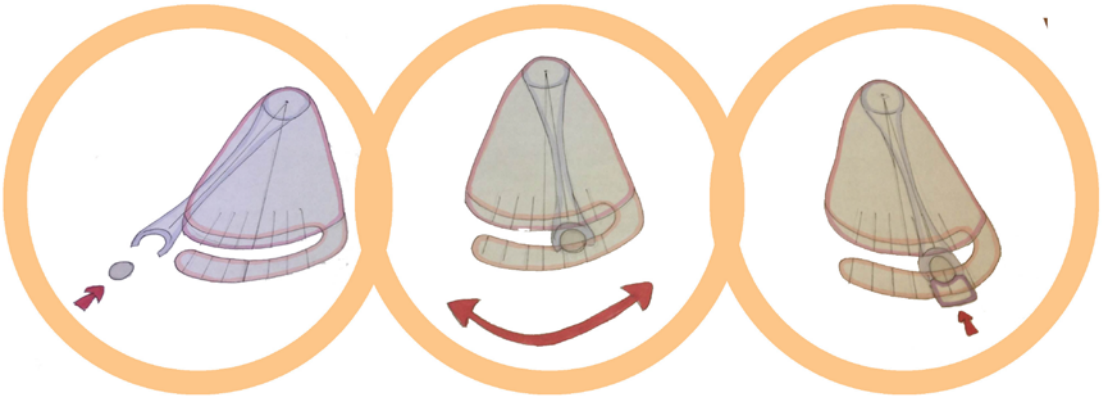


Figure 5-23 Storyboard sketches

5.5.3.2 Concept Development

Concept development was carried out using the same techniques as described previously however the focus of this development phase was on refining the product. Although the final solution had been decided it was critical to repeat the process again as details within the design created individual design problems that required solving.

Figure 5-24 Varying Introducers

An important aim from the design specification was the ability for the device to be retro-fitted to existing surgical equipment which removed the need for the development of a completely new instrumentation set. Dimensions of introducers vary in between different manufacturers as shown in Figure 5-24. The prototyped device was specifically designed for compatibility with a Corin uncemented introducer and guide as this instrumentation was available for testing. Although the developed device is designed for a specific introducer, the dimensions

of the device can be easily altered by using inserts to work with any manufacture. The introducer used to aid with design development was of a similar design to that commonly used by the clinical supervisor. For introducers which are of a different design, for example many introducers which are used for cemented procedures, further development is needed to adjust the device accordingly.

Defined product dimensions enabled accurate computer aided models to be developed which visualised product assembly, created technical drawings and enabled rapid prototyping. The engineering drawings can be found in the Appendix.

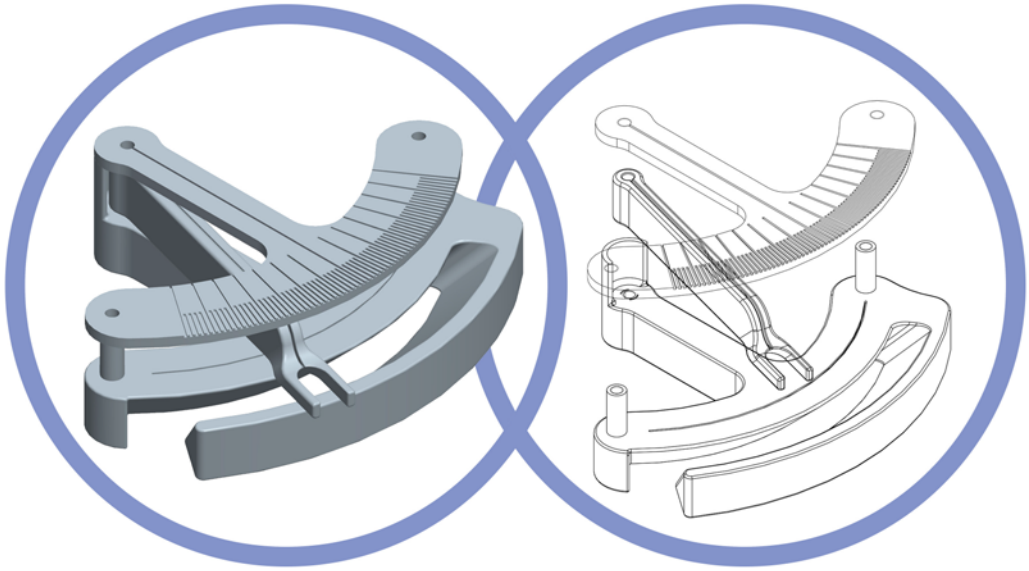


Figure 5-25 CAD of the assembled device

Creating more storyboards, as shown in Figure 5-26 on the following page, demonstrated the procedure the surgeon would have to go through when using the device. This further highlighted the consideration that must be given to the set-up of the positioning guide. A range of different concepts were generated, developed and user feedback was sought. Results of the user feedback suggested a flexible arm with lock appeared to be the best solution. Testing of these concepts demonstrated the flexible arm didn't provide the stability that was required. Testing demonstrated that although a flexible arm met apparent usability needs it didn't meet the initial functional needs. A key principle from the design specification was the stability of the arm and ability to hold the positioning guide steady. To meet this principle a solid

positioning arm was required for the remainder of this research to allow for testing. An appropriate device to aid with set-up would be developed with further work.

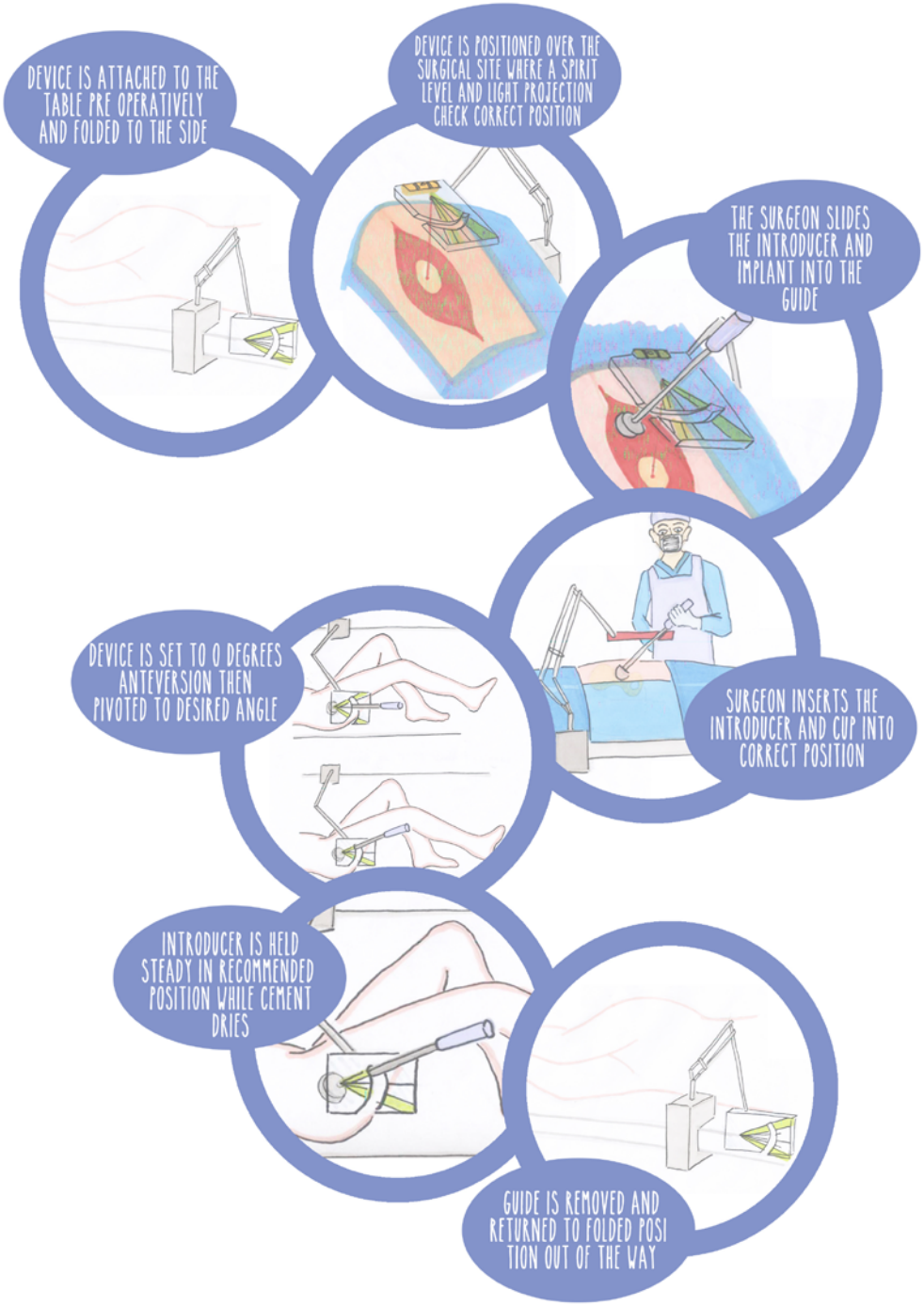


Figure 5-26 Storyboard of Positioning Guide

Prototyping was vital in the development of the form and function of the device. Simple prototypes from kappa board and foam (Figure 5-27a) were used to

easily test the form and dimensions. User feedback was conducted using prototypes which allowed the surgeons to see and interact with concepts. This demonstrated that a slimmer shape was required to avoid blocking the surgical site (Figure 5-27b). The Fused Deposition Modelling machine and laser cutter were used to rapid prototype more robust models to facilitate proof of concept testing (Figure 5-27c). The proof of concept testing results are discussed in Chapter 6.

Figure 5-27 Prototypes (a) Kappa board and Foam (b) Alternate Form Models (c) FDM models

Prototyping highlighted many problems within the design of the device. Early prototype models showed it was necessary to include a locking system for the rotational arm. Without a locking system, the introducer could easily move within the device which could create error in acetabular cup positioning. When using cemented acetabular cups, the locking system would hold the introducer steady as the cement dried and when using uncemented acetabular cups, the locking system would reduce movement as the cup is hammered into place. A similar process was followed of generating, developing and evaluating several ideas to solve this problem. A simple solution of using wing nuts to provide a friction fit was decided as this could be easily and quickly tightened and loosened in surgery as required.

Proof of concept testing of the prototype, as detailed in Chapter 6, further demonstrated the correct set up of the positioning guide over the surgical site was vital to ensure accurate acetabular positioning as incorrect set up would create measurement error. An error in the prototype dimensions caused an error in the

recorded position. A simple trigonometric correction factor could be applied as is discussed in Chapter 6. To reduce this error and aid the surgeon with correct set up, a mechanism is required to fix the dimension from the acetabular cup to the positioning guide. A variety of preliminary concepts were considered including using spirit levels and light projections. These concepts were developed further. To aid with development different light sources were tested on the acetabular cup from cadaveric specimens. This was to check if a light source firstly would be visible, whether a change in colour made a difference and if a patterned source was better than a single spot. These preliminary concept tests suggested a light source would be visible, and a single spot of blue light was clearest.

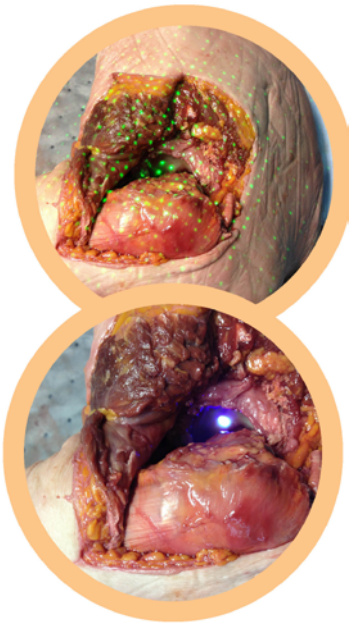


Figure 5-28 Cadaveric Light Testing

The testing discussed here is not presented in full due to their preliminary and conceptual nature. Using the results from the testing, a possible solution was devised using two light spots on the device. The lights could be positioned so they would intersect when the device is in the correct position. This work is presented to highlight the areas of the device (although were discovered during testing) that require more fundamental development as highlighted in the user interviews in Chapter 7. The volume of work required to develop this concept further was too extensive to pursue within this doctoral research project and is open to future development within the research department.

5.7.3.2 Concept Evaluation

Similarly to previous evaluation stages, user feedback was acquired to gain feedback on the design of the positioning guide. Qualitative opinion was gathered by conducting user interviews. The results of these discussions are discussed in Chapter 7.

5.8 Solution

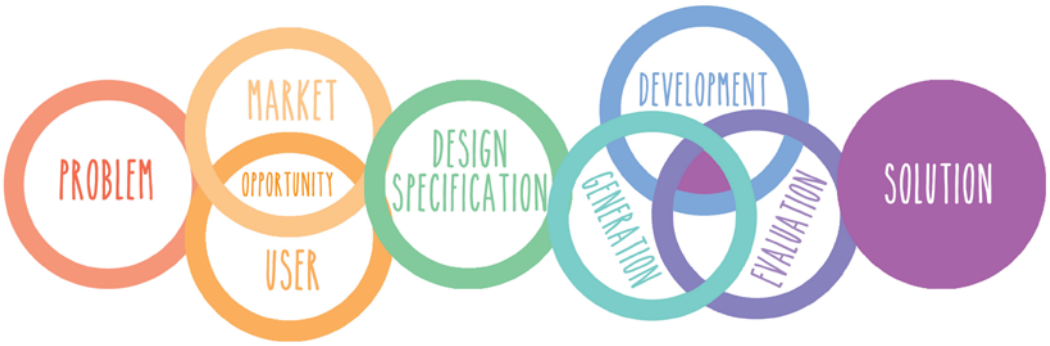


Figure 5-29 Solution Phase of the Developed Process

The proposed solution is a positioning guide which aids the surgeon in correctly positioning the acetabular cup in total hip arthroplasty. In this section, using the product design specification as a reference, the features of the device will be explained covering product function, environment, dimensions, materials, legislation and commercialisation.

5.8.1 Product Function

The positioning guide enables the surgeon to insert the acetabular cup into the acetabulum as the positioning guide holds the introducer steady, guiding the surgeon to the correct orientation. The shape of the positioning guide restricts the movement of the acetabular cup and introducer which limits the error of the inclination and anteversion angles.

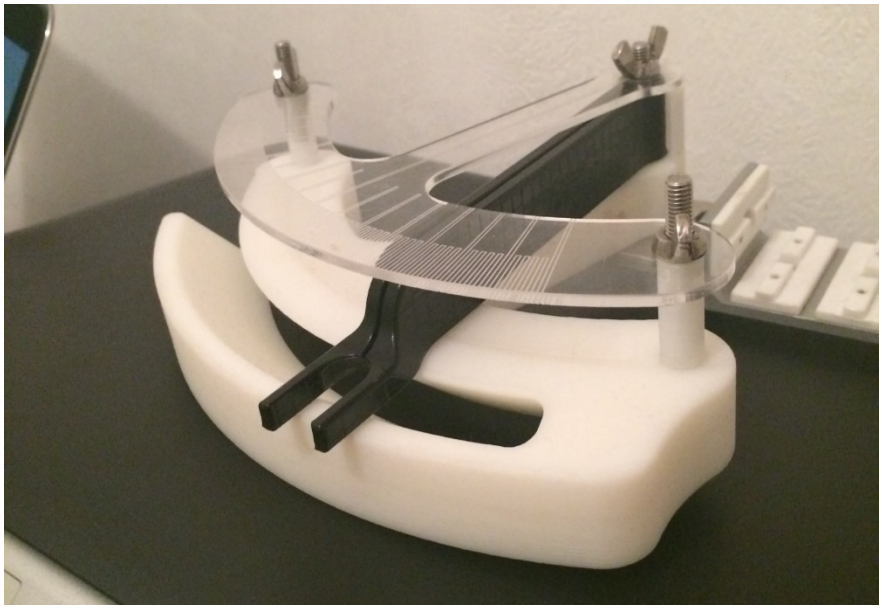


Figure 5-30 Prototype of final solution

Markings on the positioning guide display the anteversion angle as shown in Figure 5-31. This enables the surgeon to make a decision on the desired angles and provides feedback on the position.

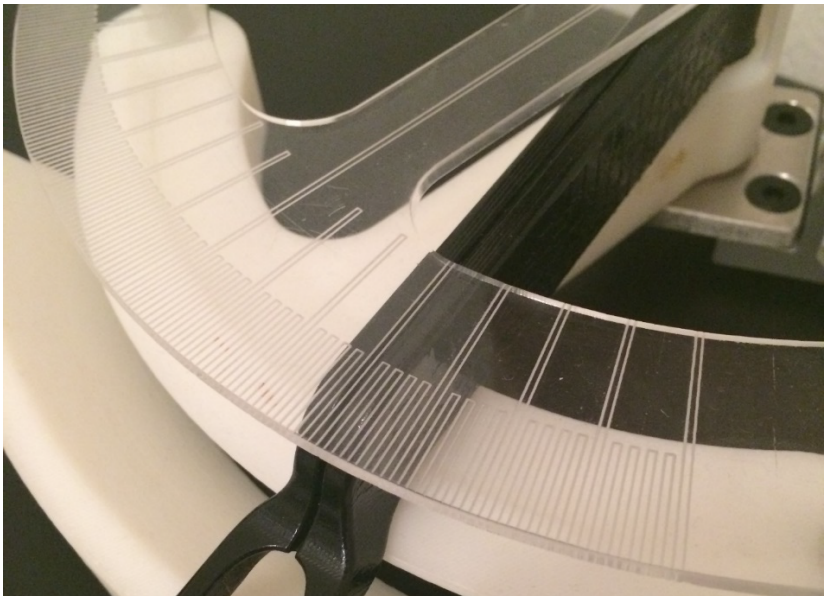


Figure 5-31 Markings demonstrating the anteversion angle

The surgeon is provided with control over the position of the acetabular cup and if the device is set up correctly, the cup is positioned within ± 2° of the surgeon's

desired orientation, as demonstrated by the testing and results discussed in Chapter 6.

The device ensures a consistent, reliable and steady acetabular cup position over the time period. This means the cup is in a stable position when the cup is first inserted and while the cement may be drying.

The device does not compromise the health and safety of the patient, as it is not invasive, should not significantly prolong operating times and can be retrofitted to existing medical equipment.
As the device is not dependent on surgeon experience, it can be used as a surgical training tool.

5.8.2 Product Environment

The positioning guide is compatible with existing surgical instrumentation allowing compliance with current equipment. Although the prototype is currently designed for compatibility with Corin instrumentation, the device can be easily altered for alternative manufactures by using device inserts.

The positioning guide is a sterile disposable device. The positioning arm is a reusable device which is able to withstand repeated sterile cleaning due to use in a sterile operating environment.

The positioning guide would be included as part of the orthopaedic instrumentation set.

5.8.3 Dimensions

As mentioned the device is currently designed for compatibility with Corin instrumentation. The positioning guide is made of three parts, the base unit, rotational arm and angle measurement guide. The assembled positioning guide has dimensions of 175mm (length) x 210mm (width) x 80mm (height) with a volume of 382.78 cm^3

Currently the inclination angle of the guide is set at 45 degrees. An insert can be created for the device which alters this angle depending on the surgeon's preference.

The positioning guide can also be available for both right and left hip arthroplasties.

5.8.4 Materials

BS EN ISO 16061:2015 categorises the device for non-invasive applications therefore the material must conform to ISO 5832-1 – 5832-12. The range of materials available are a selection of stainless steels, aluminium alloys and polymers.

Although not fully decided, it would be suggested the positioning guide would be made of a rigid polymer which is clear and the positioning arm would be made using a metal which is able to be sterilized.

5.8.5 Costing

To provide a simplified estimate of product costs, if the device was injection moulded using a polymer such as HDPE (high density polyethylene) the cost of producing each part would be estimated as follows:

To produce 100,000 units:

Base Unit

Materials:	$87, 271	
Production:	$67, 674	
Tooling:	$95,854	
Total Cost:	$250, 799	Cost per part: $2.51

Arm

Materials:	$14,708	
Production:	$48,889	
Tooling:	$41,582	
Total Cost:	$100,179	Cost per part: $1.00

Angle Guide

Materials:	$17,419	
Production:	$51,196	
Tooling:	$70,930	
Total Cost:	$139,545	Cost per part: $1.40

Assembled Unit

Manufacture of parts: $490,523

Cost of each device: $4.91

£3.05

This is an estimated cost of manufacturing the positioning guide. This estimate demonstrates the low cost of manufacturing the positioning guide affirming the feasibility of it as a disposable device. However this is limited as cost must still be added for the positioning arm, packaging, licenses and distribution and profit margins.

5.8.6 Legislation

In accordance with the EU Directive 93/42/EEC Medical Devices, the device is classified as a Class Im medical device

To gain a CE mark as a Class Im device:

I. The product must comply with the relevant essential requirements of the EU Directive 93/42/EEC Medical Devices
II. Compile the required technical file
III. As it is a sterile device, an application to a notified body must be completed for aspects of sterility and measurement requirements
IV. Register with the Competent Authority before affixing the CE mark
V. Post market surveillance

5.8.7 Commercialisation Strategy

An initial patent filing has been made for this device.

After obtaining guidance from the University commercialisation managers, the recommended commercialisation strategy is to license the device to an existing orthopaedic manufacturer.

If a licensing opportunity is pursued and if the University receives £20 every time the device is used, an example of potential generated income can be calculated using the increasing market projections by Kurtz [15]. These projections are based on historical data and improvements in technology and treatments may influence these numbers. Although an alternative method may be available by 2020, these numbers provide an estimation to allow for calculation. Presuming an increasing share in both the UK and US markets, by 2020 the income would be £1,645,080 and by 2030, £10,398,540 as shown in Table 5.1.

Year		2015	2020	2025	2030
UK	Market Share	1	3	5	10
	Income in thousands (£)	207.39	765.65	1570.34	3864.90
USA	Market Share		1	3	5
	Income in thousands (£)	0.00	879.44	3216.00	6533.63
Total Income in thousands (£)		**207.39**	**1645.08**	**4786.33**	**10398.54**

Table 5.1 Example of Potential Generated Income

5.9 Next Stages of Product Development

The next steps in the development of the device are to use the results gathered from the testing and user feedback to drive both prototype development and secure further funding. Testing and user feedback results will be fed into the iterative process to develop mechanisms for the set-up of the device. Although solutions have been generated, each of these problems created design projects of their own therefore require further work to ensure the best solution is created. Further work is required in understanding pelvic tilt and how the device can be best aligned to the position of the patient. Securing further funding enables the device to

be developed further, prototypes built, commercialisation opportunities pursued and a clinical trial to be conducted.

6

Proof of Concept Testing

6.1 Chapter Overview

To improve positioning of the acetabular cup within total hip arthroplasty, design methodology was used to develop a simple guide which can be used during surgery. This provides the surgeon with a clearer guide on position and real-time feedback on the angle achieved which could reduce error associated with acetabular component positioning. The detailed methodology used to develop this device is described in Chapter 5 however the key specification was to design a device which reliably and consistently placed the acetabular cup accurately in total hip arthroplasty. The aim of this study was to test if the developed device meets these product specifications. To do this, the Vicon motion analysis system was used to measure the position of the acetabular cup when placed using the developed device. The marker coordinate data was used to calculate the position of the acetabular cup and results were compared to the desired orientation to measure accuracy. The achieved orientation was also compared to results achieved when using current techniques, using a mechanical guide and positioning the cup freehand, to allow for comparison between the methods.

6.2 Pilot Study

A pilot study was conducted to evaluate feasibility, the experiment methodology, time, set up and identify any potential problems that may arise. The clinical supervisor, a consultant Orthopaedic surgeon, participated in the pilot study.

6.2.1 Methodology

A Sawbones model pelvis was attached to a base which was attached to a rigid table surface. The use of a sawbone reduces the complexity of the anatomy considerably however is necessary for simulation. The set up was clamped to a table to reduce any movement. A ring stand with clamps was also clamped to the table to hold the developed device to reduce positioning error.

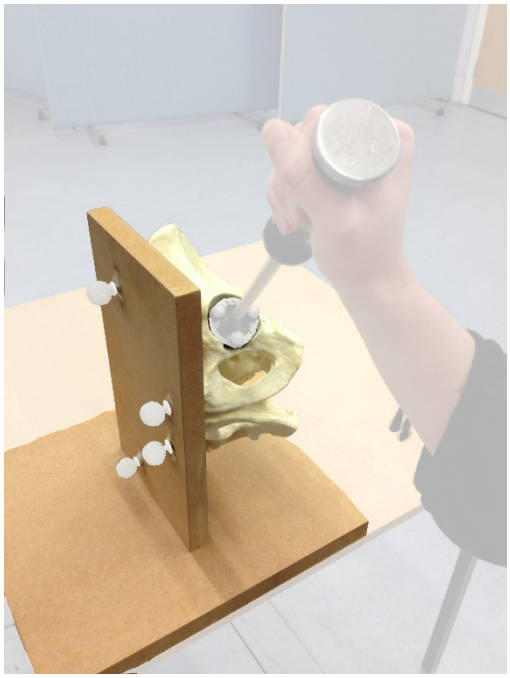


Figure 6-1 Testing Set-Up – Model Pelvis

A Trinity impactor (introducer), acetabular cup and anteversion guide were supplied by Corin. The Trinity impactor is designed for use in cementless operations. However, the design of this introducer is the similar to that used by the clinical supervisior for both cemented and cementless therefore it was used for this testing. The Vicon Nexus 1.8.2 motion analysis system was used to measure the position of the acetabular cup over the given time period.

The model was correctly positioned at the centreline of the table to ensure no pelvic tilt and that the anterior pelvic plane was on the vertical. The Vicon Nexus 1.8.2 system was used to calibrate the pelvic orientation defining the anterior pelvic plane as a reference. Four reflective markers were positioned on right and left anterior superior iliac spines and the right and left pubic tubercles to mark out the anterior pelvic plane and three reflective markers were placed the on rim of the acetabular cup.

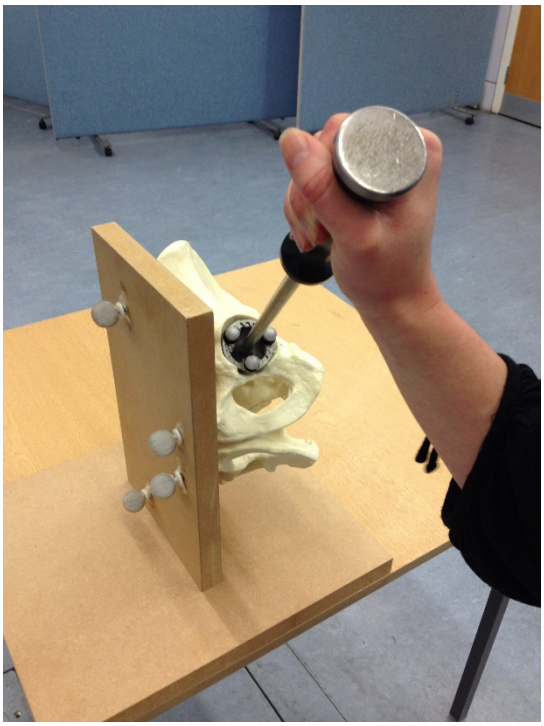


Figure 6-2 Testing set-up - Vicon markers

Using the impactor, the participant aligned the cup at 45° inclination and 15° anteversion in the acetabulum within a time of 1 minute. The set orientation of the guide provided by Corin dictated the orientation. When the participant was confident that they had achieved the correct orientation of the acetabular cup, measurements were taken.

The participant was asked to hold the acetabular cup in a steady position for 5 minutes. This was to replicate the time period that would exist when performing a cemented arthroplasty. Cement can take up to 10 minutes to harden in an arthroplasty. It can take several minutes to mix the cement and wait until it is malleable. There is a working period (2-4 minutes, depending on the type of the cement) when the cement can be inserted and the prosthesis can be positioned.

This is followed by a setting period, which can be a few minutes, where the cement hardens. Therefore a time period of 5 minutes was chosen to replicate the working and setting time.

Data was captured for 7 seconds at 100Hz at the start of each minute and the end of the last minute. Each consecutive reading corresponds with the epoch data presented in the results. Measurements were taken over the entire time period to measure any change in the cup orientation over the time period.

This protocol was carried out three times using different positioning techniques which were applied in a random order. Each technique was only carried out once. The first method was to position the acetabular cup freehand with no additional instrumentation or guides. The second was using a mechanical guide to aid in positioning and the third was to use the developed device to position the acetabular cup within the pelvis. Before testing began, training and a five minute practice time was given on each of the methods. Five minutes was provided between conditions to reduce fatigue.

Pelvic marker coordinate data was transformed to align with a standard Cartesian coordinate system, a global coordinate system. The marker data from the acetabular cup was rotated to align with this coordinate system. With respect to the global coordinate system, the orientation of the acetabular plane was computed and therefore the achieved inclination and anteversion angles were determined. The desired position of the acetabular cup was 45° inclination and 15° anteversion.

The average angle from each epoch is presented in the results. The mean average angle is the mean of the average angle within each epoch. This mean was calculated for each of the three techniques tested: freehand, using the mechanical guide and using the developed device. The key performance indicators identified and calculated were the mean inclination and anteversion angles (as defined above).

6.2.2 Results - Pilot Study

The results from the pilot study are split to demonstrate the changes in the average inclination angles and the average anteversion angles over the time period.

Following on, the average inclination and anteversion angles are visualised together to demonstrate the average position of the acetabular cup within the acetabulum.

6.2.2.1 Inclination

	Average		Average Epoch 1		Average Epoch 2		Average Epoch 3		Average Epoch 4		Average Epoch 5		Average Epoch 6	
	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD
Freehand	38.81	0.84	38.45	0.19	39.78	0.45	38.86	0.86	39.53	0.25	37.58	0.15	38.63	0.14
Mechanical Guide	38.27	1.76	38.65	0.50	39.38	0.44	40.16	0.25	39.60	0.08	35.70	0.12	36.10	0.13
Developed Device	42.48	0.08	42.62	0.06	42.49	0.01	42.47	0.01	42.44	0.01	42.44	0.01	42.39	0.01

Table 6.1 Average Inclination Angles - Pilot Study

Results of the pilot study demonstrated that the average inclination angle when positioning the acetabular cup freehand was 38.81° ± 0.84°, the average inclination angle when using angle a mechanical guide was 38.27° ± 1.76° and the average angle using the developed guide was 42.48° ± 0.08°. The developed device was closest to the desired inclination angle with the least variability in position over the time period as shown in Figure 6-3.

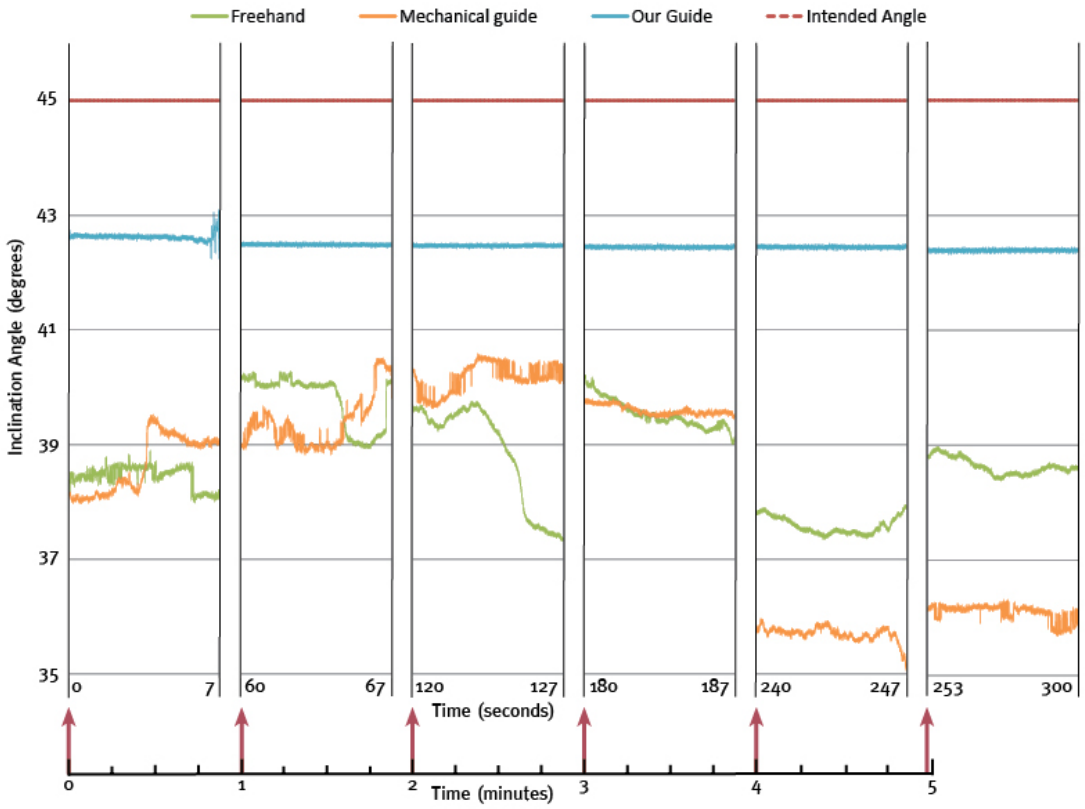


Figure 6-3 Inclination Angles over Time – Pilot Study

6.2.2.2 Anteversion

	Average		Average Epoch 1		Average Epoch 2		Average Epoch 3		Average Epoch 4		Average Epoch 5		Average Epoch 6	
	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD
Freehand	26.42	3.01	22.86	0.93	30.64	0.84	30.06	1.43	25.51	0.24	24.51	0.33	24.95	0.39
Mechanical Guide	20.16	2.72	15.55	0.66	19.60	0.64	22.49	0.47	23.75	0.05	21.02	0.52	18.57	0.14
Developed Device	19.34	0.24	19.82	0.19	19.32	0.03	19.29	0.02	19.25	0.03	19.25	0.03	19.14	0.03

Table 6.2 Average Anteversion Angles- Pilot Study

When aiming for an anteversion angle of 15°, the average angle using the freehand method was 26.42° ± 3.01° while the average anteversion angle using a mechanical guide was 20.16° ± 2.72° and the average angle when using the developed device was 19.34° ± 0.24°. Similarly to the inclination angle, the developed device was closest to the desired anteversion angle with the least variability. Although the anteversion angle when using the developed device was closest to the desired position, it was still out by 4°. When using a mechanical guide, the anteversion angle started at the desired position of 15° however as shown in

Figure 6-4, the angle deviated substantially from this during the 5 minute time period.

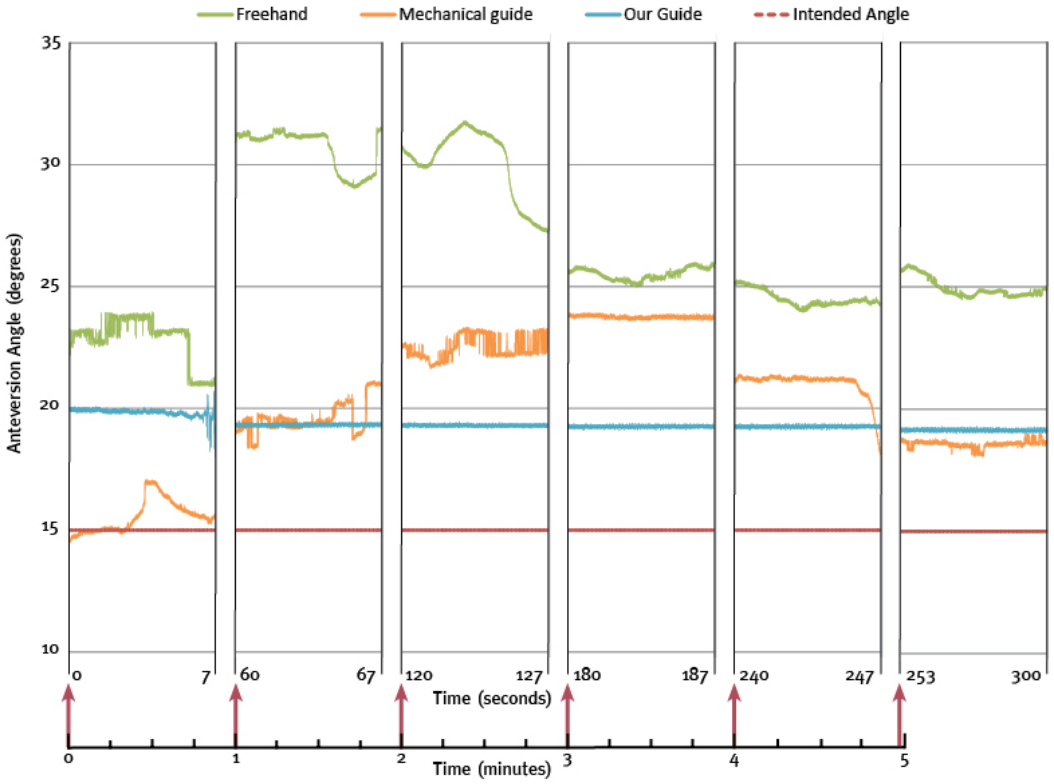


Figure 6-4 Anteversion Angles over Time – Pilot Study

6.2.3 Relationship between inclination and anteversion angles

The position of the acetabular cup when considering both inclination and anteversion angles is shown in Figure 6-5. When using a safe zone of ±5°error of the desired angles, only the developed device (including the standard deviation represented by the error bars) was positioned within the safe zone.

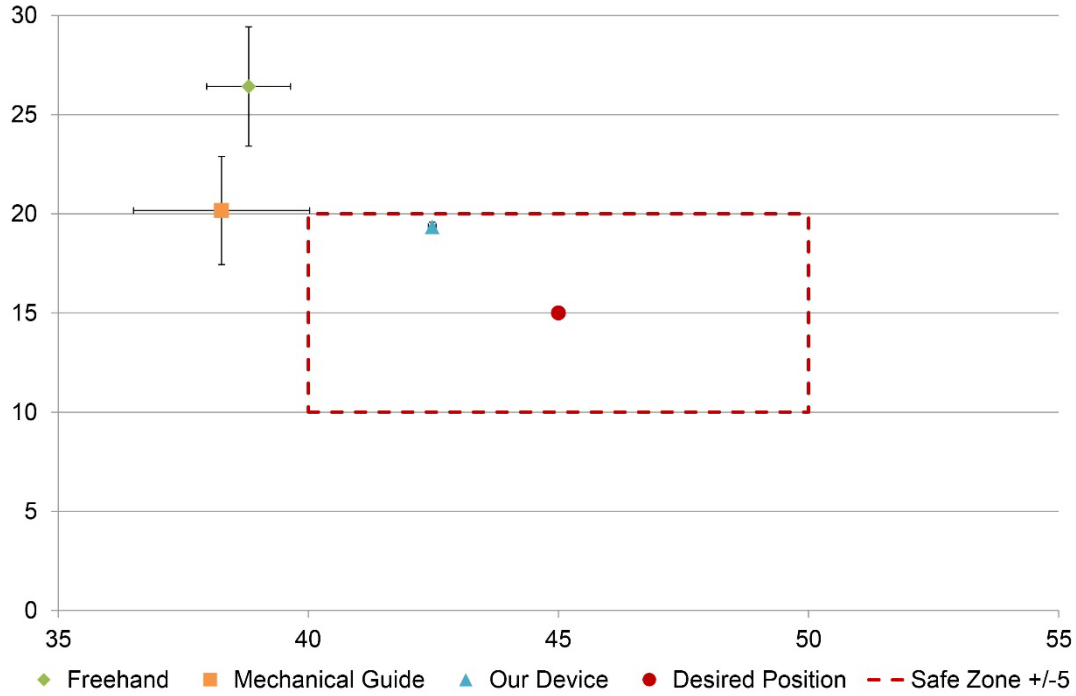


Figure 6-5 Combined Position of Acetabular Component – Pilot Study

The average error from the desired inclination angle of 45° and anteversion angle of 15° was smallest when the developed device was used to position the acetabular cup (2.52° inclination, 4.34° anteversion) in comparison to using a mechanical guide (6.73° inclination, 5.18° anteversion) or the freehand technique (6.21° inclination, 11.42° anteversion).

6.2.4 Discussion - Pilot Study

Results demonstrated that none of the techniques placed the acetabular cup in the desired position of 45° inclination and 15° anteversion. The developed device produced superior results than both the freehand and mechanical guide method with respect to position and variability over time. When considering a safe zone of ±5° error, only the developed device positioned the acetabular cup within this target.

However, one of the key aims from the product design specification was that the developed device was to have an error margin of ±2° from the desired acetabular position. The results have shown that all of the methods are outside of this error margin. Although the developed device is better than the current methods

tested, the device places the acetabular cup outside of the ideal safe zone therefore does not currently provide the strict desired accuracy required of a positioning guide.

Research into why this method did not provide accurate results suggested the initial set up and position of the developed guide is critical in achieving the correct angle placement. The set up used to hold the developed device in place was easily moved which could have introduced error. The angle reference point needs to be situated over the centre of the hip and the height of the positioning tool above the centre of the hip also needs to be fixed. During testing these factors were not fully taken into consideration which could have caused an error in the measured angles. To determine the effect of set up on the angle measurement further testing was done with a greater control on these factors.

The results demonstrated considerably more variation in movement over the time period of the freehand and mechanical guide in comparison to the developed guide. This was also highlighted in the marked difference in the standard deviation Erroin the average position. This difference was due to the participant treating the developed device as a guide that removed the need for him to continue to apply pressure on the introducer over the time period. As the developed device held the introducer steady, there was no need for the participant to hold it. During a cemented procedure, pressure would still have to be applied to the introducer to ensure a good cement fixation. Therefore to ensure a fair comparison for future studies, it was stipulated that the participant needs to apply pressure on the introducer throughout the time period. This explains why error bars are not visible on the Combined Position of the Acetabular Component in Figure 6-5.

There are limitations with this pilot study as the testing was carried out using a plastic sawbone. The operating theatre conditions and surgical procedure are not fully replicated which could contribute to error as it is a false environment. There was no cement within the socket which could have created more movement of the acetabular cup within the acetabulum. When positioning the cup, the surgeon did not have the same soft tissues and visible ligaments as references to help align the cup however the plastic sawbones enabled clear visualisation of the bony anatomy.

Results from this testing showed that the developed device did not provide an accurate positioning guide to ± 2° however, it was the only device to position the cup within a ± 5° safety zone. The initial pilot study demonstrated that the developed tool was more accurate and stable than current methods, therefore further testing with a wider population was required. Testing highlighted the importance of correct set up which was addressed and resolved as the device was further developed.

6.3 Experimental Evaluation of Device Design

Building on the results from pilot testing, experimental evaluation of the device design was conducted to measure the accuracy of positioning the acetabular cup to a desired position using the developed device in comparison to current techniques. Clinical and non-clinical participants participated in the study to test the effects of training and experience on accuracy of positioning the acetabular cup.

6.3.1 Methodology

Similarly to the pilot study, the intraoperative procedure of a THA was replicated using a Sawbones pelvis and a Trinity impactor (mechanical guide), acetabular cup and anteversion guide supplied by Corin. The Vicon Nexus 1.8.2 motion analysis system was used to measure the position of the acetabular cup over the given time period.

The model pelvis was positioned and attached to a rigid table surface ensuring the correct position to remove any pelvic tilt error, as shown in Figure 6-6. The set up was clamped to a table to reduce any movement of the system which could create errors. A sturdy, metal positioning arm was also clamped to the table to hold the developed device to reduced positioning error.

The Vicon Nexus 1.8.2 system was used to calibrate the pelvic orientation defining the anterior pelvic plane as a reference. Four reflective markers were positioned on right and left anterior superior iliac spines and the right and left pubic tubercles to mark out the anterior pelvic plane. No measurement of the movement of the model pelvis was taken as all measurements were taken relative to markers that were fixed to the model. There were no observed instances during testing of the reference

markers changing their relative position, which would have been observed and later validated had this occurred. Three reflective markers were placed the on rim of the acetabular cup as demonstrated in Figure 6-6.

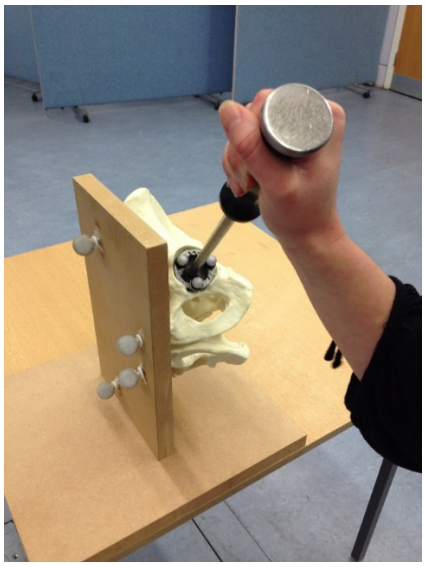


Figure 6-6 Testing set up

A 2mm layer of plasticine was placed within the socket to replicate the acrylic cement. Using the impactor, the participant aligned the cup at 45° inclination and 15° anteversion in the acetabulum within a time of 1 minute. This orientation was dictated by the set orientation of the mechanical guide. The measurement started when the participant indicated they believed they had achieved the correct position. Subsequently the participant was asked to hold the cup steady in the correct position for 5 minutes. Data was captured for 15 seconds at a frequency of 100Hz at the start of every minute and the end of the last minute to measure any displacement over this time. Each consecutive reading corresponds with the epoch data presented in the results.

This protocol was carried out three times using different positioning techniques which were applied in a random order. The first method was to position the acetabular cup freehand with no additional instrumentation or guides. The second was using a mechanical guide to aid in positioning and the third was to use the developed device to position the acetabular cup within the pelvis. The set-up of each technique is demonstrated in Figure 6-7. Before testing began, training and a five minute practice time was given on each of the methods. Five minutes was provided between conditions to reduce fatigue.

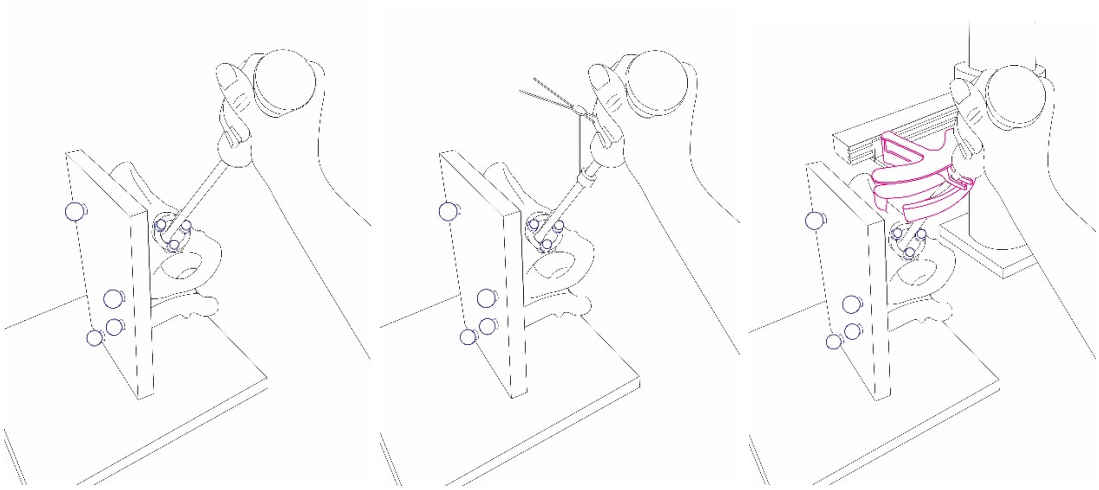


Figure 6-7 Positioning Technique A) Freehand B) Mechanical Guide C) Developed Device

University Departmental Ethics was granted and 14 participants were recruited (5 clinical experience and 9 non-clinical experience). To qualify for the clinical experience group the participant must have been a fully qualified orthopaedic surgeon with experience in conducting total hip arthroplasty. All 5 clinical participants who took part in the study were Consultant Orthopaedic surgeons. Participants were healthy volunteers of both genders between the age of 25 – 60. Exclusion criteria included any participants on any prescribed medicine, those who have had any recent arm injury or medical condition or those who have any difficulty holding and manipulating objects.

After testing by non-clinicians, an issue was discovered with the dimensions of the prototype. The geometry of the device had been miscalculated therefore a correction factor was applied to the results to correct this issue. The geometry had been based on the length of the whole introducer therefore there was an error in the anteversion angle markings. This has no influence on the inclination angle ($\alpha = \beta$) however this changes the anteversion angle as the angle is measured from a different point ($\gamma \neq \delta$), as shown in Figure 6-8. Therefore the angle the participant had been aiming for was not the angle measured.

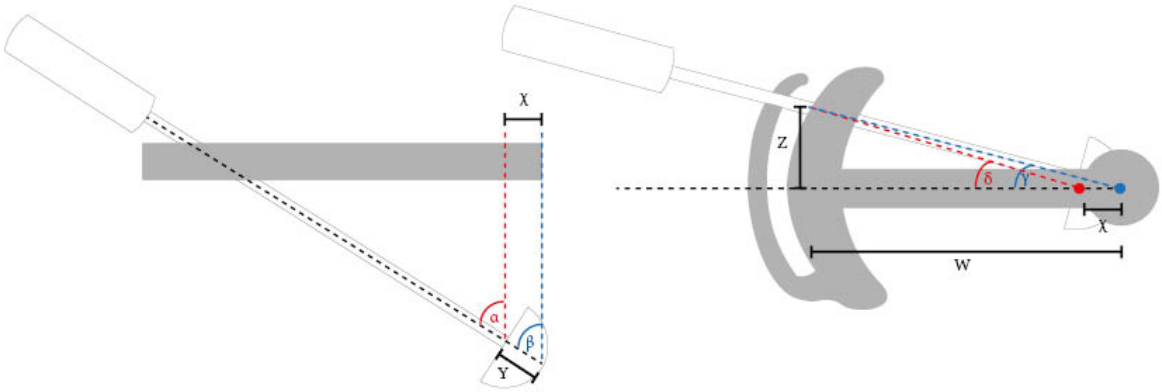


Figure 6-8 Influence of Geometry Error on Inclination and Anteversion Angles

To correct this, the anteversion angle the participant had been aiming for could be calculated using the following equations:

$$X = \sin\beta * Y$$

$$Z = \tan\delta * (W - X)$$

$$\gamma = \tan^{-1}(Z/W)$$

The average difference between the two anteversion angles was 2°. The device geometry was corrected before testing the device with clinicians.

Biomechanical marker data will inevitably contain noise within the signal therefore a Butterworth filter with of a cut off frequency of 2Hz was applied to process the raw marker coordinate data. The filtered data from the markers on the anterior pelvic plane was transformed to align with a standard Cartesian coordinate system, i.e. a global coordinate system. The data from the markers on the acetabular cup was rotated to align with this frame of reference. With respect to the global coordinate system, the orientation of the acetabular plane was computed and therefore the achieved anteversion and inclination angles were determined.

For each participant, the achieved angles at each reading were used to calculate the time averaged value both per epoch and the entire recording period of 5 minutes. The mean acetabular cup angles were determined by calculating the mean of each participant's time averaged angle. This mean was calculated for each of the three techniques tested: freehand, using the mechanical guide and using the developed device.

The key performance indicators identified and calculated were the mean inclination and anteversion angles (as defined above), the error from the desired orientation (defined as the difference between the achieved and desired angles) and the difference between the initial and final orientation of the acetabular cup (the deviation). The average error values were also computed using the same approach as for determining the average angle. The standard deviation of each participant's average was computed and was used to determine the pooled standard deviation for the mean acetabular cup angles.

A one way analysis of variation (ANOVA) F-test was used to determine whether a statistically significant difference between the three techniques existed. An F-test is used to test the assumption that the variation in observed averages was the same for all three techniques, a significant p-value would suggest that a difference in average between groups would be unaccounted for. An F-test was also carried out to test the difference between participant groups. These results demonstrated no significant difference between the groups therefore the data from the clinical and non-clinical participants was combined resulting in a larger cohort for analysis which is additionally presented in this chapter.

6.3.2 Results – Clinical experience

6.3.2.1 Inclination

	Average		Average Epoch 1		Average Epoch 2		Average Epoch 3		Average Epoch 4		Average Epoch 5		Average Epoch 6	
	Angle (°)	Pooled SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD
Freehand	39.72	1.89	40.82	0.14	40.80	0.19	38.50	0.21	39.00	0.22	39.59	0.11	39.59	0.16
Mechanical Guide	42.81	1.56	43.78	0.56	43.01	0.38	43.33	0.16	41.78	0.08	42.40	0.31	42.58	0.05
Our Device	47.27	0.34	46.80	0.06	46.87	0.14	47.64	0.07	47.64	0.06	47.33	0.04	47.31	0.07

Table 6.3 Average Inclination Angles - Clinical

The combined average inclination angles achieved when using the three techniques, aiming for an inclination of 45°, are displayed in Table 6.3. The average inclination angle of the mechanical guide and the developed device are closer to the desired orientation than using the freehand method. The pooled standard deviation was significantly smaller for the developed device ($p < 0.01$) demonstrating it is

more consistent in position. The average error from the desired position of 45° inclination for each of the participants is shown below in Table 6.5.

Method	Angle	Participant				
		1	2	3	4	5
		Error ±sd (°)	Error ±sd (°)	(Error ±sd (°)	Error ±sd (°)	Error ±sd (°)
Freehand	Inclination	10.01 ±2.98	1.29 ±0.75	6.96 ±2.02	5.51 ±0.88	2.90 ±1.51
Mechanical Guide	Inclination	3.06 ±0.77	3.66 ±1.01	3.60 ±0.71	1.98 ±4.27	1.99 ±1.52
Our Device	Inclination	0.75 ±0.28	0.73 ±0.15	8.33 ±0.23	0.30 ±0.27	2.17 ±0.47

Table 6.4 Deviation from desired position – Clinical

The combined average error of the inclination angle of the acetabular cup from the desired angle was 5.33°± 1.81° using the freehand method, 2.87°± 1.01° using the mechanical guide and 2.45°± 0.31° inclination using the developed device. The developed device showed the lowest deviation from the desired inclination however there was no significant difference in the inclination angle when positioned using the mechanical guide or when using a freehand method. The pooled standard deviation when using the developed device was significantly smaller than the freehand technique ($p < 0.01$) and the mechanical guide ($p < 0.05$). This highlights the consistency in the position amongst the participants when using the developed device.

The combined average inclination angle over the 5 minute time period is shown in Figure 6.4. This reveals variation in the inclination angle of the acetabular cup over the 5 minute period. There is variation in the inclination angle of the acetabular cup when using all three techniques. When using the developed device, there appears to be only two changes, between epoch 2 and 3 and between epoch 4 and 5. Within each epoch the inclination angle appears to remain constant. As can be seen in Figure 6-9, this was not the case in the inclination angle when using the mechanical guide and freehand method.

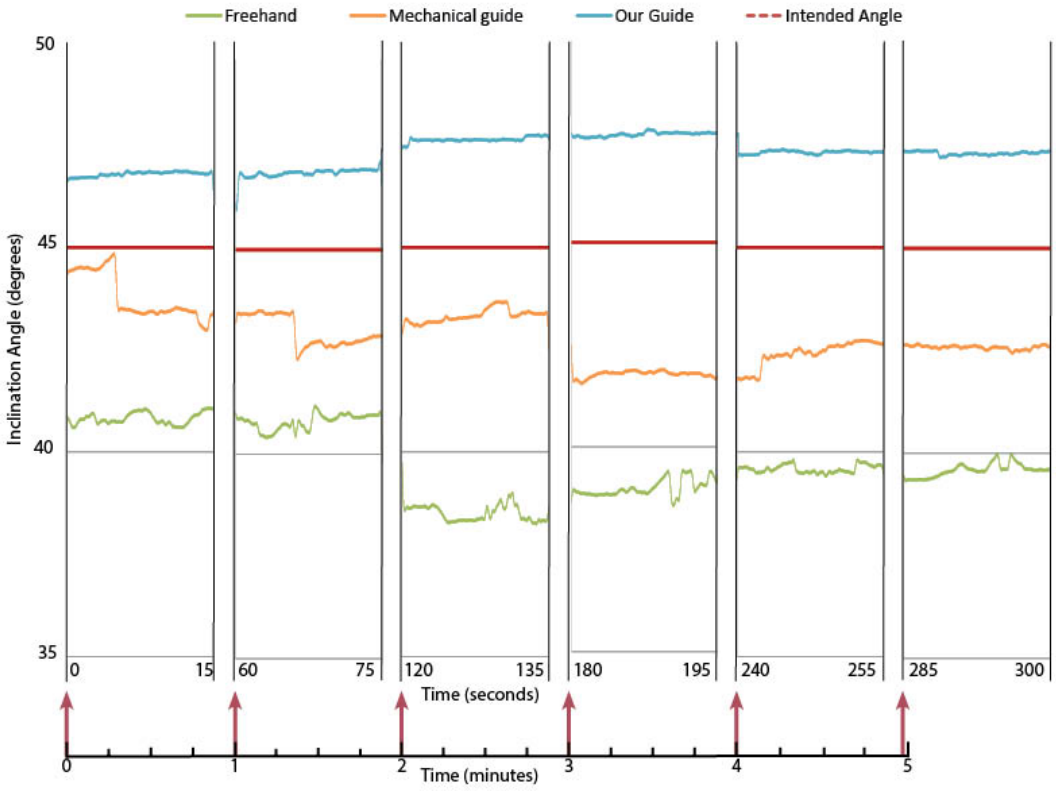


Figure 6-9 Inclination Angles Over Time - Clinical

6.3.3 Anteversion

	Average		Average Epoch 1		Average Epoch 2		Average Epoch 3		Average Epoch 4		Average Epoch 5		Average Epoch 6	
	Angle (°)	Pooled SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD
Freehand	12.42	3.12	14.15	0.22	12.29	0.22	13.40	0.25	11.88	0.12	11.45	0.08	11.33	0.13
Mechanical Guide	14.02	1.79	14.69	0.29	15.51	0.61	14.43	0.23	12.36	0.23	13.55	0.47	13.59	0.18
Our Device	14.07	0.61	14.08	0.19	14.06	0.35	14.04	0.12	14.06	0.09	14.27	0.10	13.92	0.13

Table 6.5 Average Anteversion Angles – Clinical

Similarly to the inclination angles, the combined average anteversion angles (Table 6.5) are closer to the desired anteversion angle of 15° when using the developed device (14.07° ± 0.61°) and the mechanical guide (14.02° ± 1.79°) rather than positioning the acetabular cup using the freehand technique (12.42° ± 3.12°). The pooled standard deviation is significantly smaller when using the developed device compared to the freehand ($p<0.01$) and mechanical guide ($p<0.05$) techniques demonstrating there is less variation between participants in the achieved anteversion angles of the acetabular cup.

The average error from the desired anteversion angle of 15° for each participant is shown in Table 6.6. The combined average error was less for the developed device (2.93°± 0.54°) than the freehand technique (4.23°± 2.19°) and when using a mechanical guide (4.07°± 1.01°) however there was no significant difference. The pooled standard deviation of the developed device was significantly smaller than the freehand technique ($p<0.01$) and although the pooled standard deviation was smaller there was no significant difference between the developed device and the mechanical guide.

		Participant				
		1	2	3	4	5
Method	Angle	Error ±sd (°)	Error ±sd (°)	(Error ±sd (°)	Error ±sd (°)	Error ±sd (°)
Freehand	Anteversion	3.48±1.70	8.87±1.01	0.94±0.69	0.68±0.68	7.14±4.39
Mechanical Guide	Anteversion	0.92±0.59	9.77±1.41	4.25±1.18	0.83±1.67	4.57±2.74
Our Device	Anteversion	3.26±0.71	7.49±0.28	1.38±0.33	0.73±0.73	1.78±0.40

Table 6.6 Deviation from desired position –Clinical

Figure 6-10 demonstrates the change in the combined average anteversion angle over the 5 minute time period and shows the anteversion angle of the acetabular cup was not constant over the time period. Similarly to the inclination angles, there is greater variation in the angle when using the mechanical guide and freehand than the developed device.

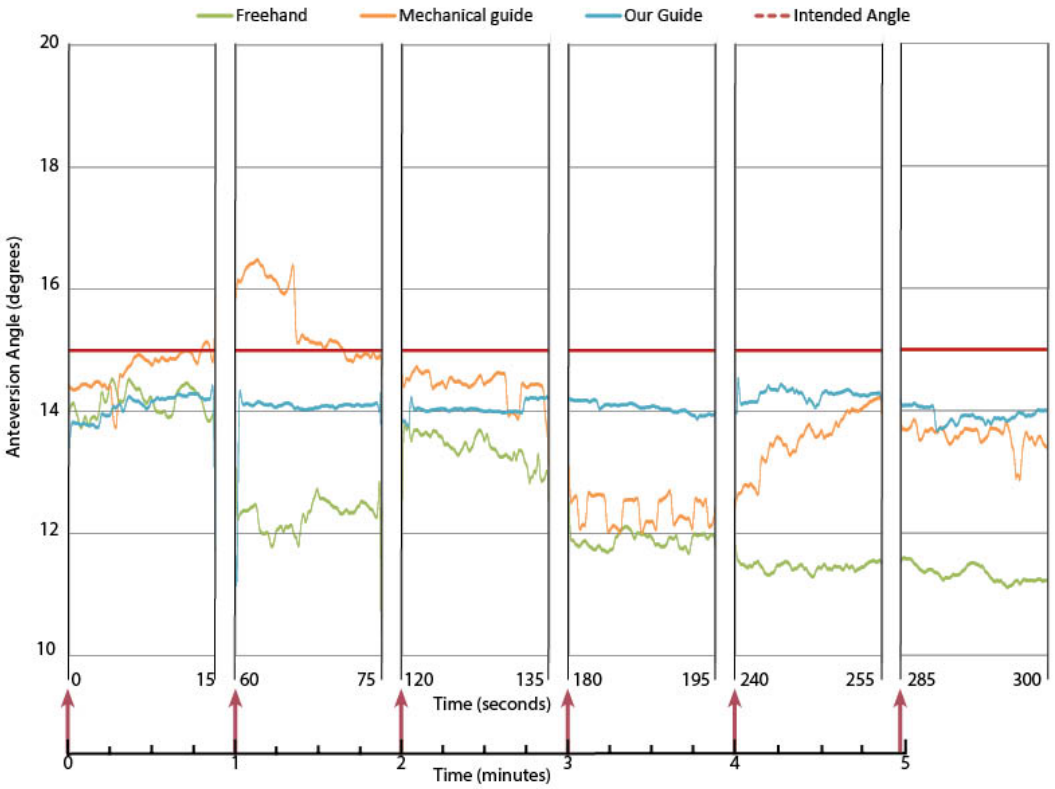


Figure 6-10 Anteversion Angles Over Time – Clinical

6.3.4 Relationship between inclination and anteversion angles

The combined average achieved position, considering both the inclination and anteversion angles, is shown in Figure 6-11. Both the mechanical guide and developed device method had an average acetabular cup position within the safe zone of ±5° and are just outside of the ideal safe zone of ±2°. The position of the acetabular cup when using the freehand method is outside of the safe zone of ±5°.

As recognised above, the pooled standard deviation when using the developed device to position the acetabular cup is significantly smaller showing the greater consistency in position amongst the participants. The average position of each participant is shown in Figure 6-12.

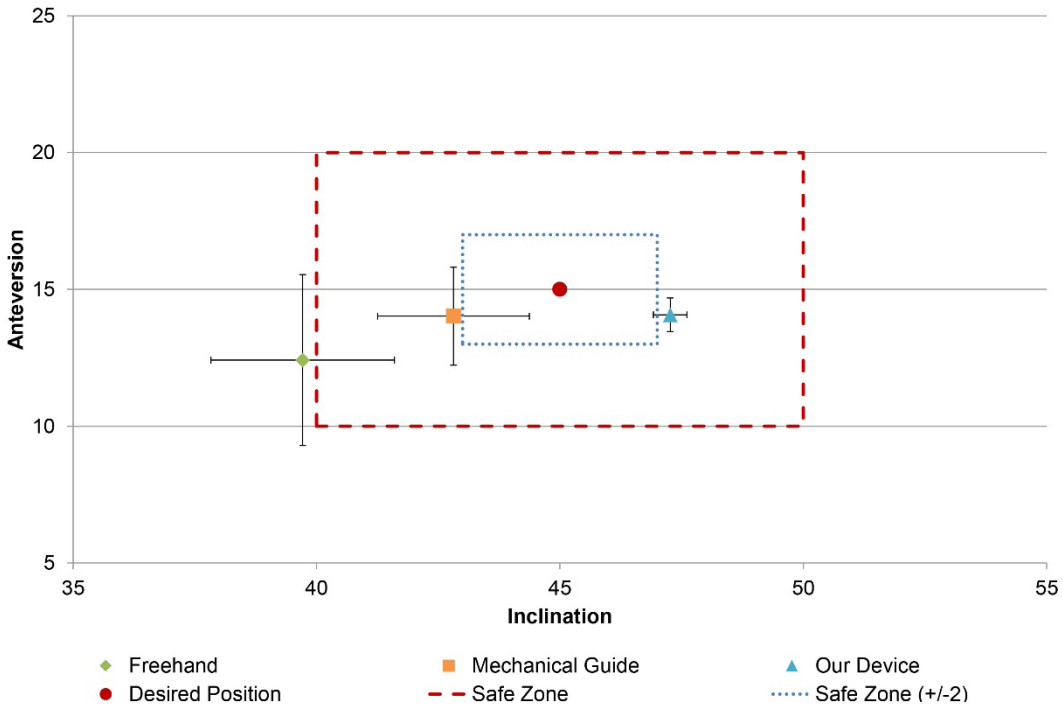


Figure 6-11 Combined Acetabular Position - Clinical

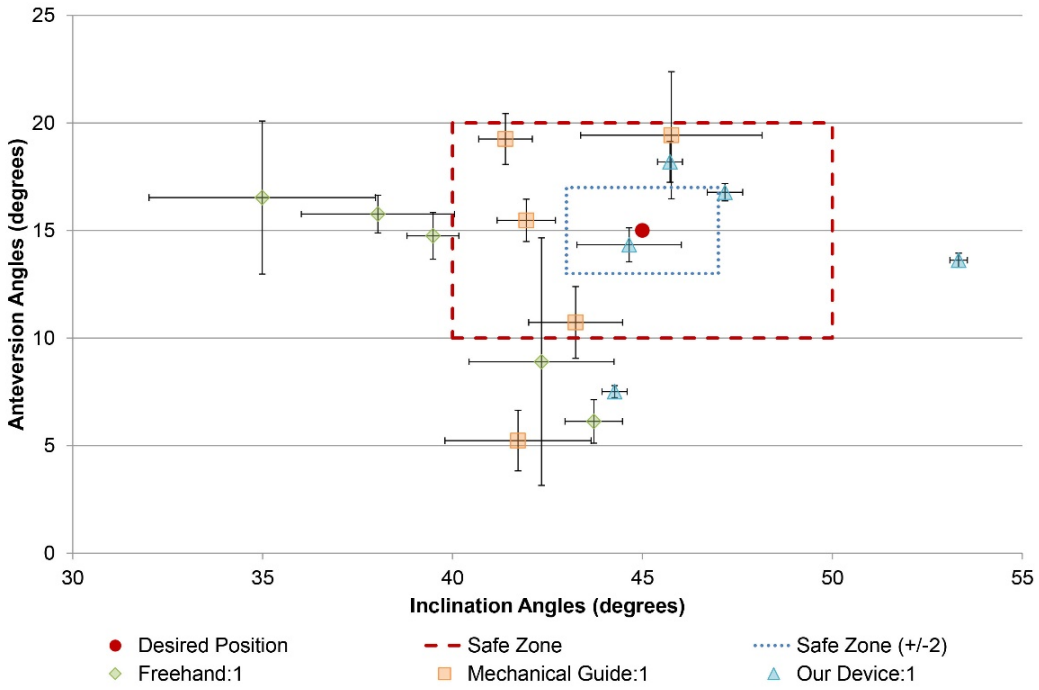


Figure 6-12 Individual Acetabular Position – Clinical

80% of the acetabular cups positioned using a mechanical guide are contained within or overlapping the safe zone of ±5° compared to 60% using the developed guide and 20% positioned freehand. 40% of the cups positioned using the developed guide are within or overlapping the safe zone of ±2° while only 20%

of the cups placed using the mechanical guide and none of cups positioned freehand were within this zone. The standard deviation of each of the participant's average position are smaller for the developed device than freehand and mechanical guide methods demonstrating less variation in position over the 5 minute time period.

To measure the variation in position over the 5 minute time period, the deviation from the start position for each participant was calculated with the results shown in Table 6.7. The results highlight that when using the developed device, the deviation from the start position (0.58° inclination, 0.90° anteversion) is significantly smaller than when using a mechanical guide (3.80° inclination, 3.26° anteversion)($p < 0.01, p < 0.05$) or freehand method (3.10° inclination, 4.22° anteversion)($p < 0.01$, $p < 0.01$). The pooled standard deviation is also significantly smaller ($p < 0.01$) when using the developed device rather than the mechanical guide and freehand technique showing that the smaller deviation is consistent among the participants.

Method	Angle	Average (°)	Standard Deviation (°)	Participant				
				1(°)	2(°)	3(°)	4(°)	5(°)
Freehand	Inclination	3.10	2.56	4.73	0.47	4.36	0.23	5.71
	Anteversion	4.22	7.00	2.86	0.69	0.41	0.52	16.60
Mechanical Guide	Inclination	3.80	3.04	1.28	8.98	2.28	3.87	2.57
	Anteversion	3.26	1.78	1.64	3.83	1.22	5.46	4.15
Our Device	Inclination	0.58	0.50	0.09	0.05	0.59	1.10	1.06
	Anteversion	0.90	0.31	0.45	0.85	1.12	1.24	0.84

Table 6.7 Difference between start and end position – Clinical

The initial placement of the acetabular cup is critical, however, to maintain the intended position at time of placement, the acetabular cup must stay in the same intended position while the cement dries. Any movement during this period is significant as it may cause the acetabular cup position to deviate from the intended position and may cause the cup to be out of the safe zone. The correct positioning of the acetabular cannot just be considered the initial placement position but must also consider the position of the acetabular cup throughout and at the end of the time period.

The orientation of the acetabular cup over the 5 minute time period of a single participant is shown in Figure 6-13. This demonstrates the movement and changing orientation of the acetabular cup over the time period. Although the participant positioned the acetabular cup within the safe zone of ±5° of the desired position to begin with, only the developed device remained within the safe zone throughout the time period. The final position of the acetabular cup at the end of the time period when using both the mechanical guide and freehand technique were out-with the safe zone of ±5°.

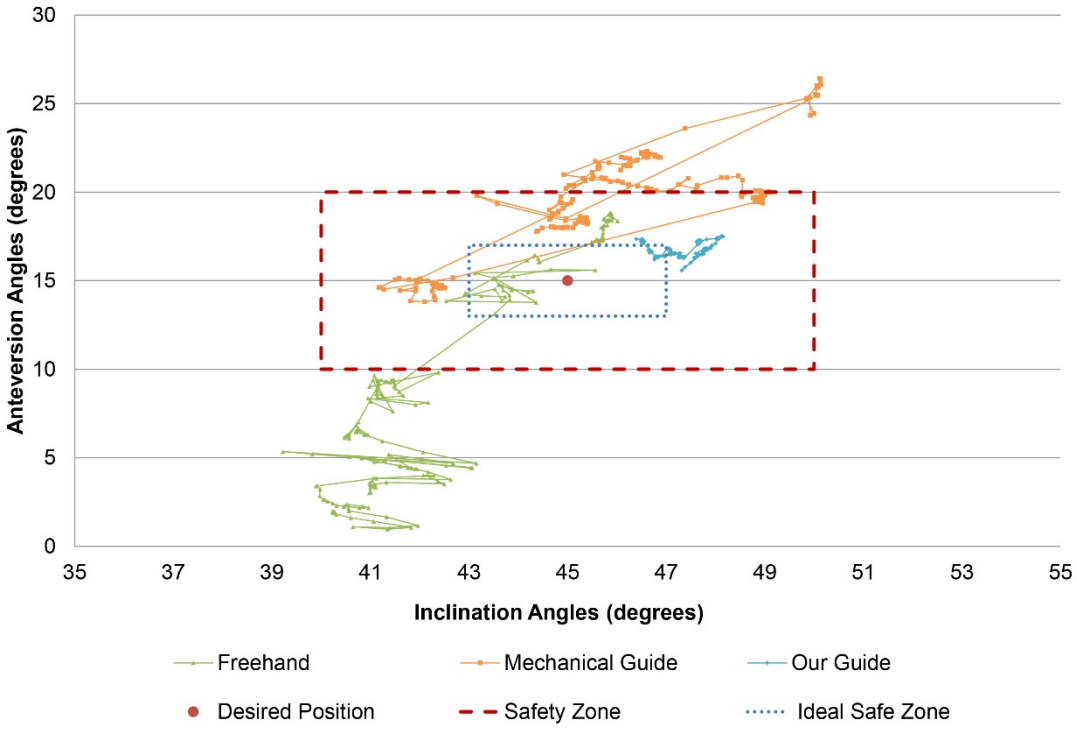


Figure 6-13 Movement in orientation over time – Clinical

The initial and final position of the acetabular cup for each participant is detailed in Table 6.8. For the initial position of the acetabular cup, 80% of the cups placed using a mechanical guide, 60% of cups using the developed device and 40% of cups using a freehand method are within a safe zone ±5°. The number of cups positioned within the safe zone for the final position are 60% when using the developed device, 40% when using a mechanical guide and 20% when placing the cup freehand.

Technique	Position	Angle	Participant Number

			1(°)	2(°)	3(°)	4(°)	5(°)
Freehand	Initial Position	Inclination	39	45	35	40	46
		Anteversion	15	6	16	15	19
	Final Position	Inclination	34	44	39	40	40
		Anteversion	18	5	16	15	2
Mechanical Guide	Initial Position	Inclination	44	48	40	46	44
		Anteversion	17	7	17	14	18
	Final Position	Inclination	42	39	43	42	47
		Anteversion	15	3	18	9	22
Developed Device	Initial Position	Inclination	45	44	53	44	47
		Anteversion	18	8	13	13	17
	Final Position	Inclination	46	44	54	45	48
		Anteversion	17	7	14	14	17

Table 6.8 Initial and Final Position of the Acetabular Cup - Clinical

6.3.5 Results – Non–clinical

6.3.5.1 Inclination

	Average		Average Epoch 1		Average Epoch 2		Average Epoch 3		Average Epoch 4		Average Epoch 5		Average Epoch 6	
	Angle (°)	Pooled SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD
Freehand	45.99	1.34	44.21	0.07	45.25	0.15	46.54	0.09	46.70	0.11	46.75	0.09	46.47	0.11
Mechanical Guide	44.20	1.31	43.43	0.16	44.79	0.23	43.90	0.37	44.09	0.15	44.62	0.10	44.37	0.13
Our Device	42.46	0.42	42.54	0.07	42.57	0.05	42.54	0.06	42.43	0.15	42.41	0.14	42.23	0.10

Table 6.9 Average Inclination Angles – Non-clinical

The average inclination angle (Table 6.9) when aiming for an inclination angle of 45° was 45.99° ± 1.34° (freehand), 44.20° ± 1.34° (mechanical guide) and 42.46° ± 0.42° (developed device). There was no significant difference between the inclination angles however the pooled standard deviation was significantly smaller for the developed device ($p < 0.01$) demonstrating a lower variability in inclination angles between the participants.

Each participant's average error from the desired inclination angle of 45° is shown in Table 6.10. The combined average error of the acetabular cup position from the desired position was 3.07°± 1.29° inclination using the freehand method, 2.11°± 1.09° inclination using the mechanical guide and 2.57°± 0.38° inclination

using the developed device. There is no significant difference between the average error in the inclination angle when using the different techniques. The pooled standard deviation when using the developed device was significantly smaller ($p < 0.01$) compared to using the mechanical guide or freehand technique showing greater consistency in the achieved inclination angles of the participants.

		Participant								
		1	2	3	4	5	6	7	8	9
Method	Angle	Error ±sd (°)	Error ±sd (°)	(Error ±sd (°)	Error ±sd (°)	Error ±sd (°)	Error ±sd (°)	Error ±sd (°)	Error ±sd (°)	Error ±sd (°)
Freehand	Inclination	5.9 ±1.8	1.2 ±0.9	8.7 ±1.8	0.8 ±2.4	2.8 ±1.2	0.4 ±0.3	4.5 ±1.9	2.4 ±1.4	0.9 ±0.6
Mechanical Guide	Inclination	1.5 ±0.7	2.1 ±2.6	3.1 ±1.5	3.2 ±5.1	1.3 ±1.0	5.0 ±0.8	1.5 ±0.8	0.4 ±0.2	0.9 ±0.6
Our Device	Inclination	2.0 ±0.0	2.7 ±0.1	3.0 ±0.2	0.9 ±4.8	2.5 ±0.2	5.1 ±0.2	3.3 ±0.1	1.7 ±0.1	2.0 ±1.0

Table 6.10 Average deviation from desired position – non-clinical

Figure 6-14 displays the change in the average inclination angle of the acetabular cup over the 5 minute time period. Similarly to the surgical group there is no constant inclination angle over the time period. There is less variation in the inclination angle when the acetabular cup is placed using the developed device rather than using the mechanical guide or freehand technique.

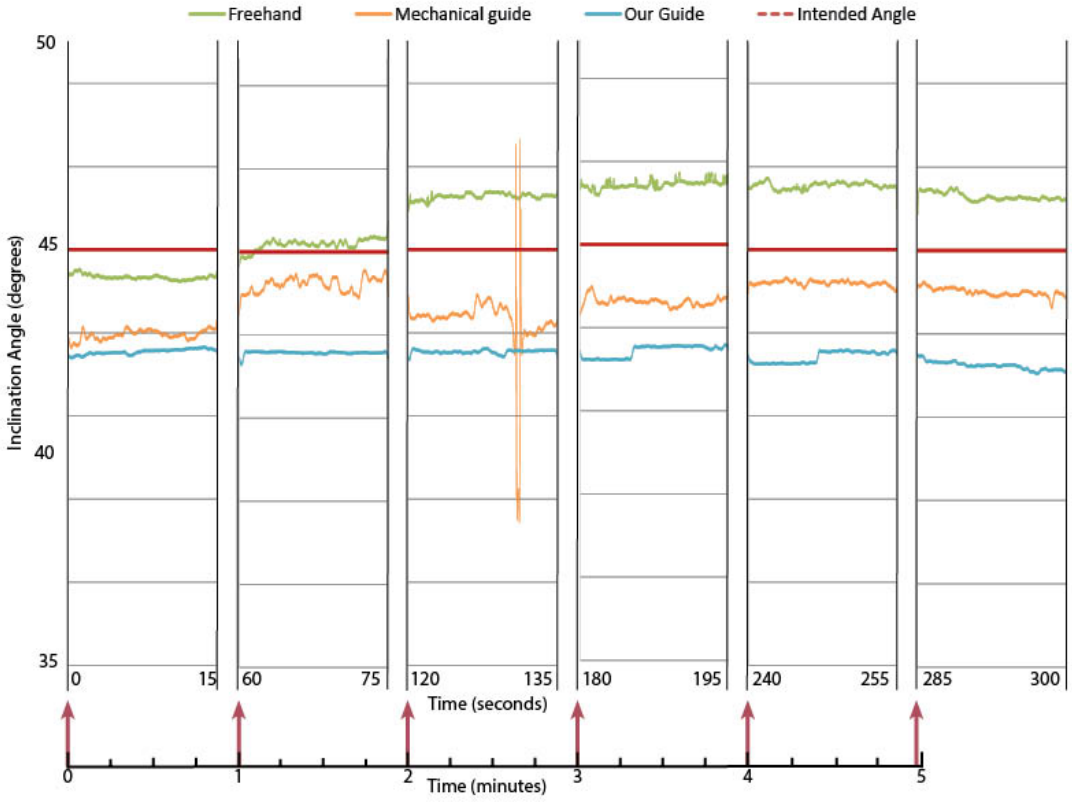


Figure 6-14 Inclination Angles Over Time – Non-clinical

6.3.5.2 Anteversion

	Average		Average Epoch 1		Average Epoch 2		Average Epoch 3		Average Epoch 4		Average Epoch 5		Average Epoch 6	
	Angle (°)	Pooled SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD
Freehand	16.73	2.33	14.67	0.13	15.53	0.30	16.73	0.15	18.24	0.15	17.30	0.10	17.92	0.38
Mechanical Guide	15.88	1.62	15.51	0.20	16.31	0.29	16.10	0.31	16.09	0.21	16.20	0.10	15.10	0.18
Our Device	15.57	0.43	15.63	0.07	15.65	0.05	15.65	0.13	15.80	0.10	15.84	0.10	15.85	0.17

Table 6.11 Average Anteversion Angles – Non-clinical

The combined average anteversion angle of the acetabular cup is shown in Table 6.11. The developed device helped the participant position the cup closest to the desired anteversion angle of 15° and the significantly smaller pooled standard deviation ($p < 0.01$) demonstrated the consistency among the participants.

The average error from the desired angle of 15° anteversion for each participant is shown in Table 6.12. The combined average error from the desired anteversion angle was 4.50°± 1.89° when using the freehand method, 6.27°± 1.61° anteversion when using the mechanical guide and 4.79°± 0.43° anteversion using the developed device. There was no significant difference between the average error from the desired anteversion angle when using the different techniques. The pooled standard deviation of the developed device was significantly smaller ($p < 0.01$) than the other techniques showing the greater consistency in the anteversion angles achieved amongst the participants when using the developed device.

Method	Angle	Participant								
		1	2	3	4	5	6	7	8	9
		Error ±sd (°)	Error ±sd (°)	(Error ±sd (°)	Error ±sd (°)	Error ±sd (°)	Error ±sd (°)	Error ±sd (°)	Error ±sd (°)	Error ±sd (°)
Freehand	Anteversion	1.7 ±1.3	4.2 ±0.8	5.1 ±4.1	0.3 ±1.0	1.3 ±0.8	7.1 ±0.8	9.1 ±1.1	6.9 ±2.9	4.7 ±1.0
Mechanical Guide	Anteversion	2.1 ±0.9	2.6 ±1.9	6.3 ±1.3	1.9 ±2.9	3.4 ±2.4	0.9 ±0.8	4.7 ±2.2	1.0 ±0.5	4.7 ±0.9
Our Device	Anteversion	1.0 ±0.1	2.6 ±0.2	0.6 ±0.3	1.0 ±1.2	0.2 ±0.2	1.2 ±0.1	3.8 ±0.2	1.0 ±0.2	1.6 ±0.2

Table 6.12 Average deviation from desired position – non-clinical

The change in the anteversion angles over the 5 minute period is shown in Figure 6-15 below. Similarly to the inclination angle, this demonstrates there is not a fixed anteversion angle over the time period. As shown there is less variation in the anteversion angle when the acetabular cup is placed using the developed device compared to when the participant is using the mechanical guide and freehand method.

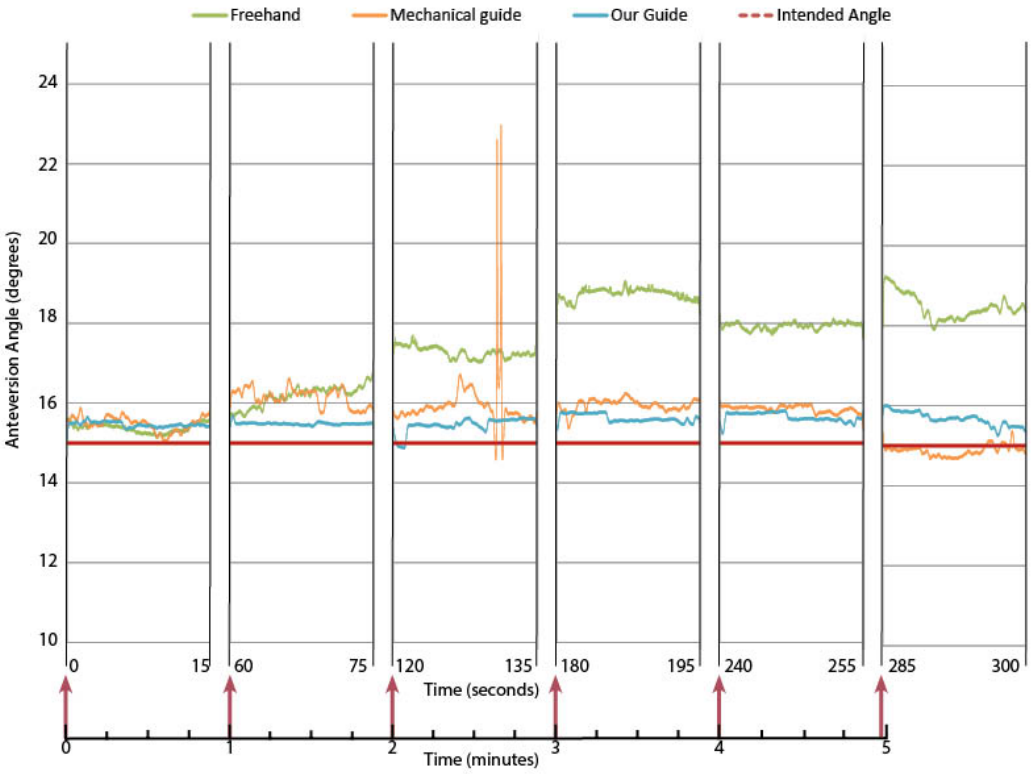


Figure 6-15 Anteversion Angles Over Time – Non-clinical

6.3.6 Relationship between inclination and anteversion angles

When considering both the inclination and anteversion angles, the average achieved position is shown in Figure 6-16. All the average positions are fully contained with the safe zone of ±5° but only the average position of the mechanical guide is within the ideal safe zone of ±2°. As discussed above, the pooled standard deviation when using the developed device is significantly smaller showing greater consistency in the position of the acetabular cup among the participants. The average position of each individual participant is shown in Figure 6-17.

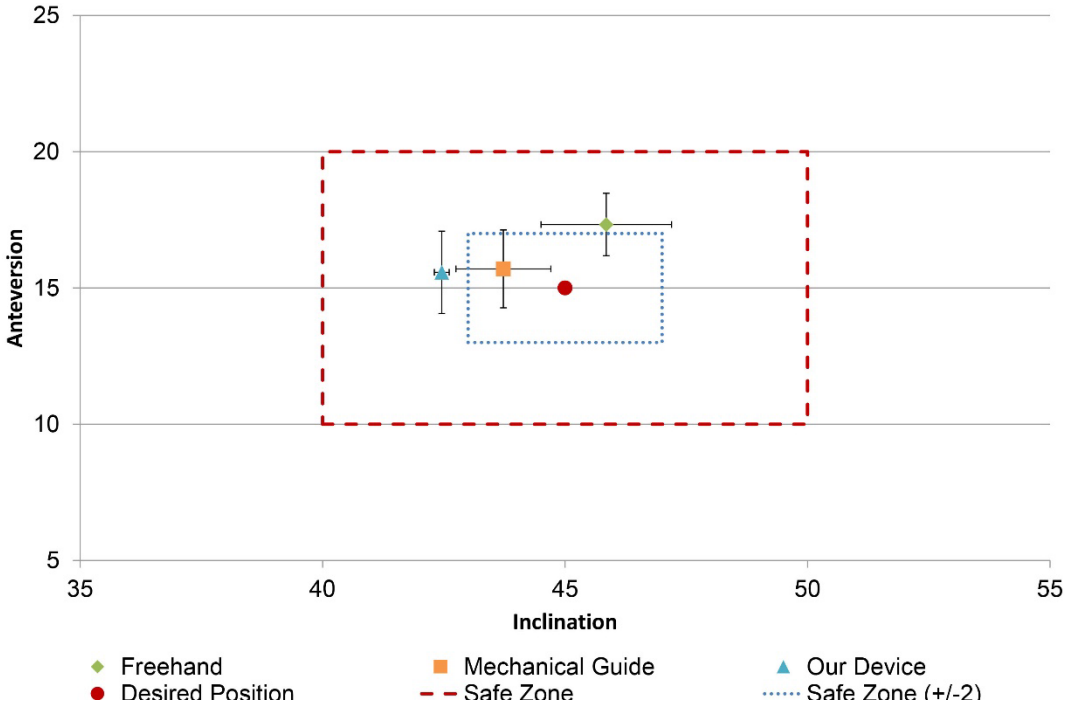


Figure 6-16 Combined Acetabular Position – Non-clinical

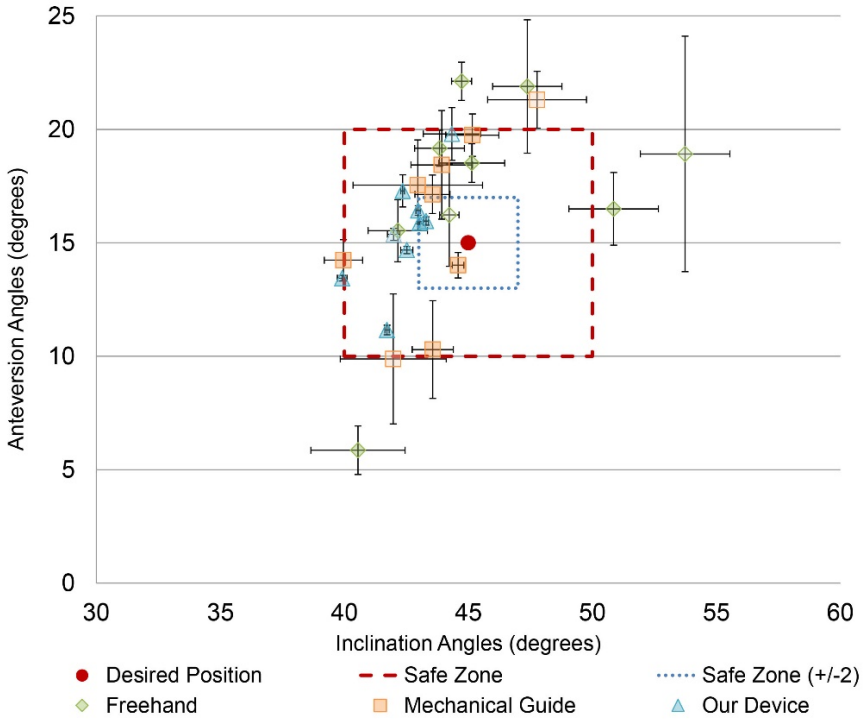


Figure 6-17 Individual Acetabular Position – Non-clinical

100% of the cups placed using the developed device are contained within or overlapping the safe zone of ±5°. 89% are within or overlapping this zone when the acetabular cup is positioned using a mechanical guide and 44% cups when

positioning freehand. When considering the safe zone of ±2°, 33% of the cups positioned using the developed guide are within or overlapping this zone compared to 22% of cups when using a mechanical guide and 11% when using the freehand technique.

The deviation from the start position to the end position for each participant is shown in the table below to demonstrate any change in the orientation of the acetabular cup over the time period.

Method	Angle	Average (°)	sd	Participant								
				1	2	3	4	5	6	7	8	9
				Angle (°)	Angle (°)	Angle (°)	Angle (°)	Angle (°)	Angle (°)	Angle (°)	Angle (°)	Angle (°)
Freehand	Inclination	2.25	1.76	5.91	1.05	0.87	0.88	2.37	0.83	4.17	1.72	2.48
	Anteversion	3.83	2.97	3.81	0.38	9.10	7.30	3.19	1.77	4.39	4.33	0.16
Mechanical Guide	Inclination	2.65	2.85	0.93	0.22	6.15	7.80	2.47	1.07	0.44	0.15	4.60
	Anteversion	2.56	1.90	1.59	0.17	2.85	6.68	1.87	3.47	3.62	1.54	1.23
Our Device	Inclination	0.58	0.97	0.03	0.16	0.71	3.12	0.39	0.24	0.15	0.35	0.10
	Anteversion	0.46	0.29	0.15	0.36	0.42	1.05	0.47	0.13	0.30	0.75	0.52

Table 6.13 Difference between start and end position – non-clinical

These results indicate that the average deviation between the acetabular orientation at the start and the end of the time period is significantly smaller ($p < 0.01$) when using the developed device. The pooled standard deviation was significantly smaller ($p < 0.01$) which demonstrates greater similarity amongst the participants when using the developed device in comparison to positioning the cup using the mechanical guide.

To demonstrate any change in the position of the acetabular cup and the path of the variation of the cup over time, the change in the cup position over the five minute period of an individual participant is shown in Figure 6-18.

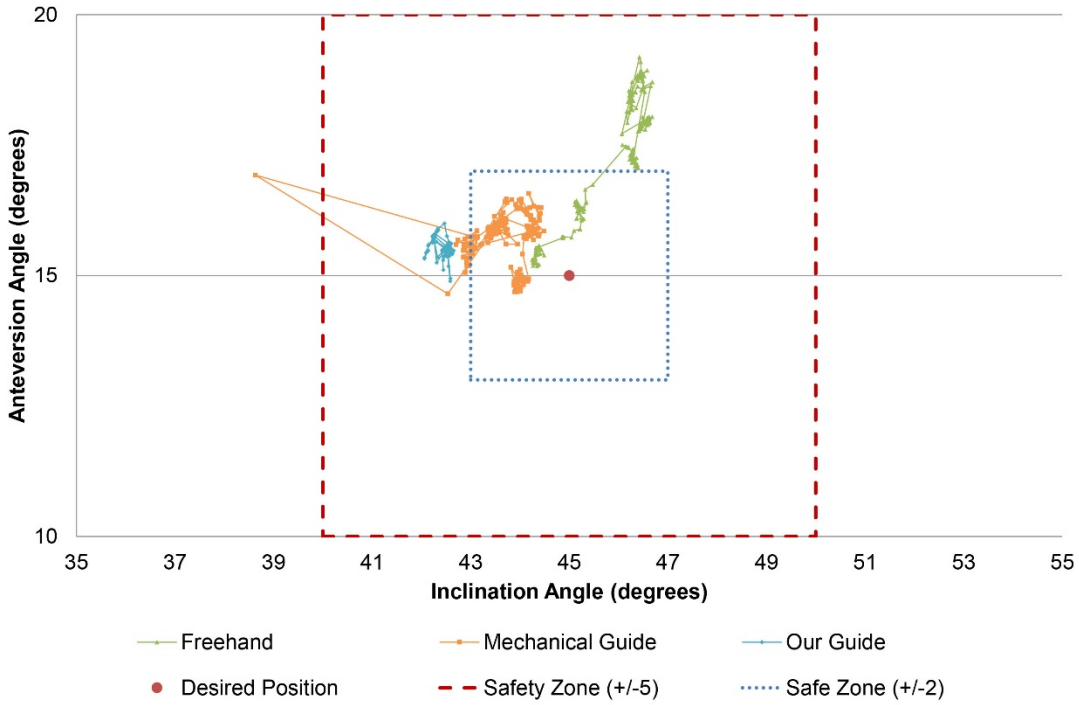


Figure 6-18 Movement in orientation over time – typical non-clinical participant

The initial and final position of the acetabular cup for each participant is detailed in Table 6.14. When considering a safe zone of ±5° and the initial position, 100% of the cups placed using the developed device are within this boundary. 78% of cups placed using the mechanical guide and 67% of cup placed freehand are within the safe zone. At the final cup position, 100% of cups placed using the developed device and 78% placed using the mechanical guide are within the safe zone however only 44% of cups placed freehand are within this zone.

Technique	Position	Angle	Participant Number								
			1(°)	2(°)	3(°)	4(°)	5(°)	6(°)	7(°)	8(°)	9(°)
Freehand	Initial Position	Inclination	47	42	53	44	40	46	38	47	43
		Anteversion	16	19	13	11	13	21	8	19	20
	Final Position	Inclination	53	43	52	45	43	45	42	49	45
		Anteversion	20	18	22	19	16	23	3	23	20
Mechanical Guide	Initial Position	Inclination	42	42	43	38	44	40	44	44	47
		Anteversion	16	17	19	12	17	16	9	14	19
	Final Position	Inclination	43	43	50	46	42	41	44	44	42
		Anteversion	17	17	22	5	15	13	13	13	17
Developed Device	Initial Position	Inclination	43	42	41	45	43	40	42	43	43
		Anteversion	16	18	16	19	14	13	11	16	16
	Final Position	Inclination	43	42	42	42	42	40	41	43	43
		Anteversion	16	17	15	20	15	13	11	15	16

Table 6.14 Initial and Final Positions of the Acetabular Cup – Non-clinical

6.3.7 Clinical Vs Non-clinical

Participants with both clinical and non-clinical experience contributed to this study to measure if the accuracy in positioning the acetabular cup was influenced by surgical experience. Results between the two groups were compared to test for any significant difference between the two groups.

Method	Angle	Non Clinical		Clinical	
		Angle (°)	Pooled SD	Angle (°)	Pooled SD
Freehand	Inclination	46	2.17	40	4.67
	Anteversion	17	9.66	12	15.86
Mechanical Guide	Inclination	44	1.51	43	1.55
	Anteversion	16	1.72	14	1.78
Developed Device	Inclination	43	0.41	47	0.33
	Anteversion	16	0.43	14	0.61

Table 6.15 Comparison of average position

The average inclination and anteversion angles achieved when using the three techniques to position the acetabular cup are shown in Table 6.15 above. There is no significant difference ($p>0.05$) between the achieved inclination and anteversion angles for the two groups as shown in Appendix 9.5.3.

The average error from the desired angles of 45° inclination and 15° anteversion and pooled standard deviations are shown in Table 6.16 below. This

highlights there is no significant difference (p>0.05) between the clinical and non-clinical participants, as shown in Appendix 9.5.3.

Method	Angle	Non Clinical		Clinical	
		Angle (°)	Pooled SD	Angle (°)	Pooled SD
Freehand	Inclination	3.07	1.29	5.33	1.81
	Anteversion	4.50	1.89	4.23	2.19
Mechanical Guide	Inclination	2.11	1.09	2.87	1.01
	Anteversion	6.27	1.61	4.07	1.68
Developed Device	Inclination	2.57	0.38	2.45	0.31
	Anteversion	4.76	0.43	2.93	0.54

Table 6.16 Comparison of average error from the desired orientation

Comparison was made between the two groups regarding any change in acetabular cup position from the beginning of the time period to the final measured position (Table 6.17). Similar to the previous results there is no significant difference (p>0.05) between the two groups in the deviation from the start point for most of the angles, as shown in Appendix 9.5.3. There is a significant difference in the standard deviation when placing the cup freehand ($p < 0.05$) however it is the non-clinical participants who have a smaller deviation.

Method	Angle	Non Clinical		Clinical	
		Angle (°)	Pooled SD	Angle (°)	Pooled SD
Freehand	Inclination	2.22	1.74	3.11	2.57
	Anteversion	3.69	3.00	4.17	6.90
Mechanical Guide	Inclination	2.66	2.73	3.77	2.91
	Anteversion	2.62	1.79	3.23	1.72
Developed Device	Inclination	0.62	0.96	0.72	0.60
	Anteversion	0.46	0.29	0.90	0.31

Table 6.17 Comparison of deviation between the start and end position

The comparison between the two groups established that for this testing, in the majority of results there is no significant difference (p>0.05) between participants with clinical experience and those without, as shown in Appendix 9.5.3.

As there is no significant difference between the results and in the case where there is, it is the non-clinical participants who are outperforming the clinical

participants, the data from each group can be combined for further evaluation. This allows for further analysis with a bigger sample size.

6.3.8 Results – both clinical and non-clinical combined

6.3.8.1 Inclination

	Average		Average Epoch 1		Average Epoch 2		Average Epoch 3		Average Epoch 4		Average Epoch 5		Average Epoch 6	
	Angle (°)	Pooled SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD
Freehand	43.66	1.56	43.08	0.07	43.62	0.11	43.51	0.08	43.79	0.12	44.06	0.06	43.90	0.05
Mechanical Guide	43.40	1.40	43.25	0.17	43.79	0.17	43.35	0.22	42.97	0.08	43.55	0.12	43.49	0.08
Our Device	44.08	0.39	44.05	0.07	44.12	0.08	44.09	0.05	44.01	0.12	44.16	0.10	44.03	0.07

Table 6.18 Average Inclination Angles - Combined

The combined average inclination angle of the acetabular cup was 43.66° ±1.56° when the participants placed the cup freehand, 43.40° ±1.40° when the participants used a mechanical guide to help and 44.08° ±0.39° when using the developed device. The developed device placed the acetabular cup closest to the desired position however there is no significant difference between the three techniques. The significant difference between the pooled standard deviation when using the developed device ($p < 0.01$) demonstrates greater consistency in the position of the acetabular cup between the participants.

The average error from the desired angle of 45° inclination is 3.1°±1.50° when using the freehand method, 2.1°± 1.06° using the mechanical guide and 2.6°±0.35° using the developed device. There is no significant difference between the error from the desired inclination angles using the developed device and both the mechanical guide and the freehand technique. The pooled standard deviation is significantly smaller when using the developed device ($p < 0.05$ freehand, $p < 0.01$ mechanical guide) further demonstrating the consistency in position achieved by the participants when using this device.

Figure 6-19 highlights the variation in the inclination angle over the 5 minute time period. The developed device is closest to the desired angle over the time period with less variation.

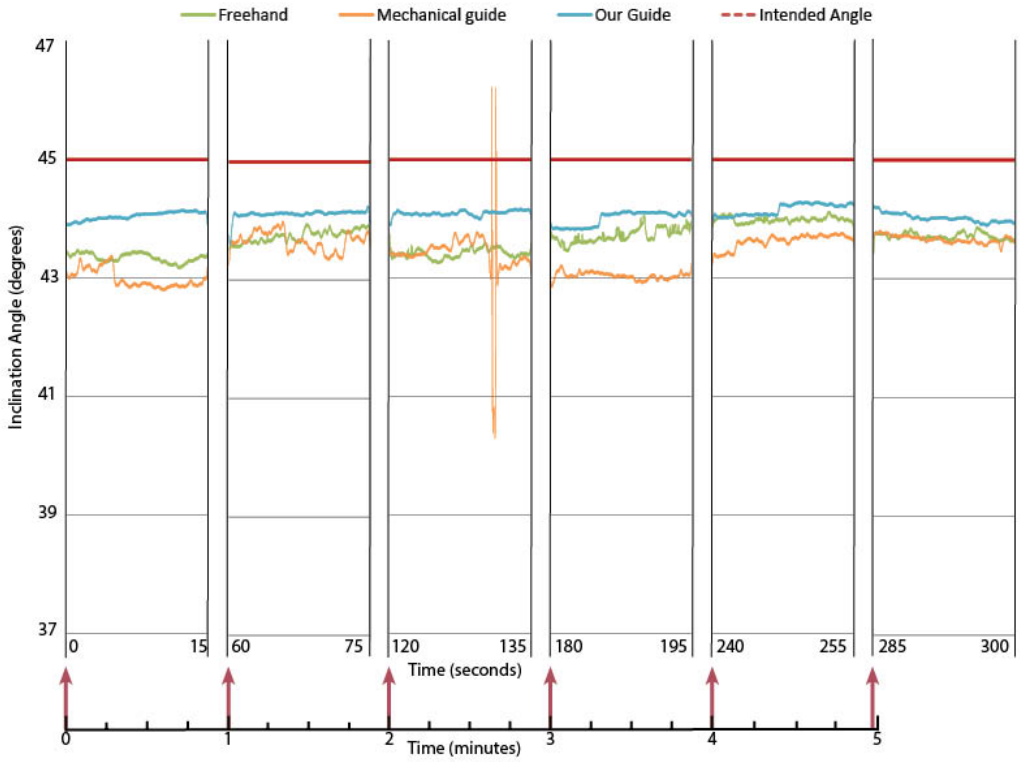


Figure 6-19 Inclination Angles Over Time - combined

6.3.8.2 Anteversion

	Average		Average Epoch 1		Average Epoch 2		Average Epoch 3		Average Epoch 4		Average Epoch 5		Average Epoch 6	
	Angle (°)	Pooled SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD	Angle (°)	SD
Freehand	15.58	2.64	14.94	0.10	14.79	0.20	15.89	0.15	16.29	0.10	15.62	0.07	15.92	0.23
Mechanical Guide	15.10	1.69	15.20	0.14	15.92	0.31	15.36	0.21	14.67	0.15	15.03	0.15	14.42	0.11
Our Device	14.13	0.52	14.07	0.05	14.08	0.11	14.07	0.10	14.18	0.08	14.26	0.07	14.15	0.12

Table 6.19 Average Anteversion Angles – Combined

The combined average anteversion angle when using the freehand method was 15.58° ±2.64°, 15.10° ±1.69° using the mechanical guide and 14.13° ±0.52° using the developed device. There was no significant difference between the average angles using each technique. Although the mechanical guide and freehand techniques positioned the device closer to the desired position, the pooled standard deviation was significantly smaller ($p < 0.01$) for the developed device demonstrating greater consistency among the participants in achieved acetabular cup position.

The average error from the desired anteversion angle of 15° was 4.4°± 2.01° using the freehand method, 5.48°±1.64° using the mechanical guide and 1.98°±0.48° using the developed device. Similarly as above, there was no significant difference between the three techniques when considering the error from the desired position. The pooled standard deviation when using the developed device was significantly smaller ($p < 0.01$) than when using the mechanical guide or freehand method showing greater similarity in achieved position of the acetabular cup between the participants.

Figure 6-20 shows the average anteversion angle over the 5 minute time period and demonstrates the variation in position over time. Similarly to the inclination angle that although there is no fixed anteversion angle and the developed device is the most consistent in position over the time period.

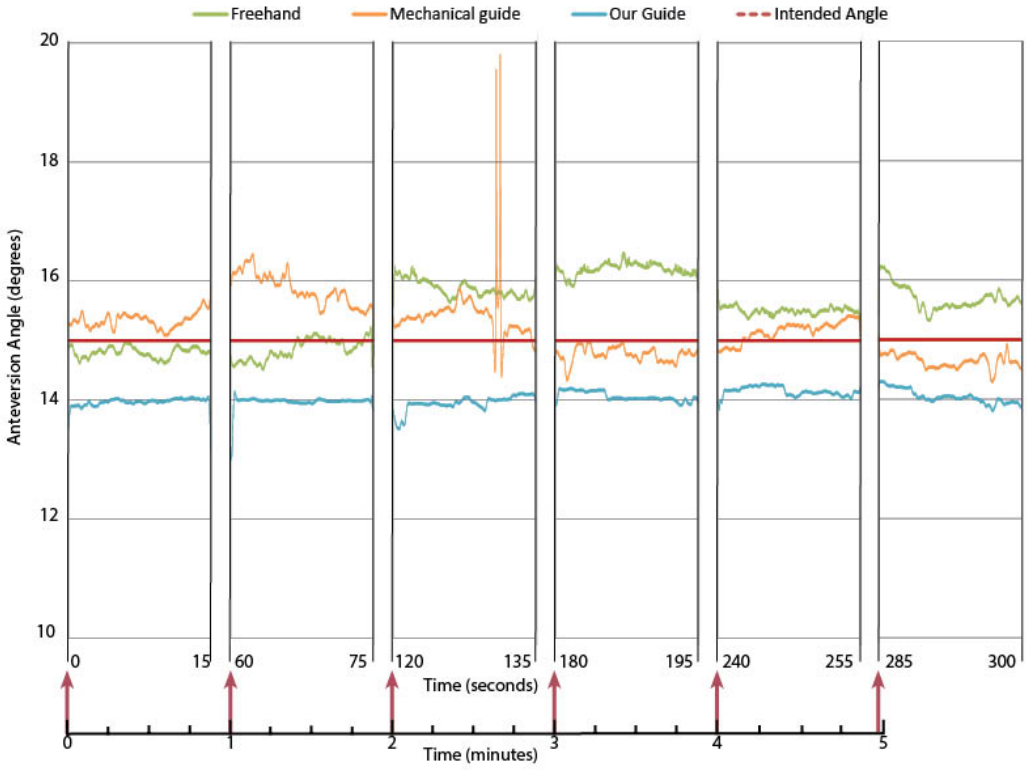


Figure 6-20 Anteversion Angles Over Time - combined

6.3.8.3 Combined position

The average position of the acetabular cup is shown in Figure 6-21 by considering both the inclination and anteversion angles. Although all three techniques have positioned the acetabular cup within the safe zone of ±5°, only the developed device is fully contained within the desired safe zone of ±2°. As

discussed previously, the pooled standard deviation when using the developed device is significantly smaller than when using a mechanical guide or freehand technique. This significant difference for both inclination and anteversion angles demonstrates that there is greater consistency in the achieved acetabular cup position when using the developed device.

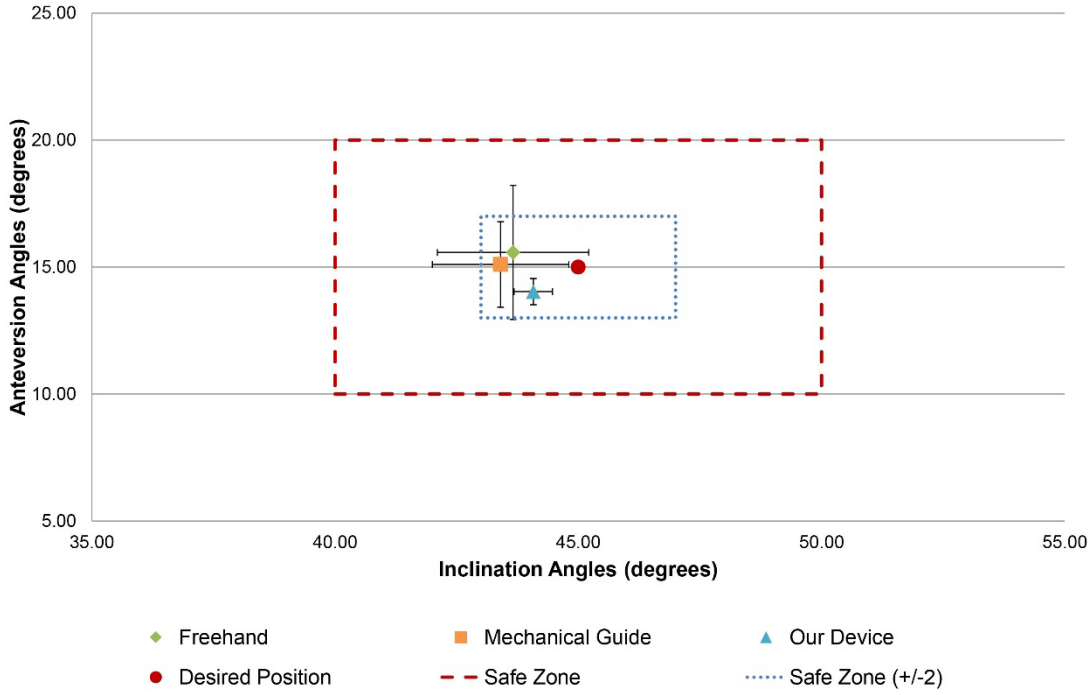


Figure 6-21 Combined Acetabular Position - combined

The average position of the acetabular cup for each participant is shown below in Figure 6-22. 80% of the acetabular cups positioned using the developed guide or the mechanical guide are contained within or overlapping the safe zone of ±5° compared to 47% when the acetabular cup is positioned freehand. There was a greater percentage of cups placed within the ideal safe zone of ±2° when using the developed device (33%) rather than using a mechanical guide (20%) or positioning the cup freehand (6%) The standard deviation for each participant's average position is smaller for the developed device than freehand and mechanical guide methods emphasising less variation in position of the acetabular cup over the 5 minute time period.

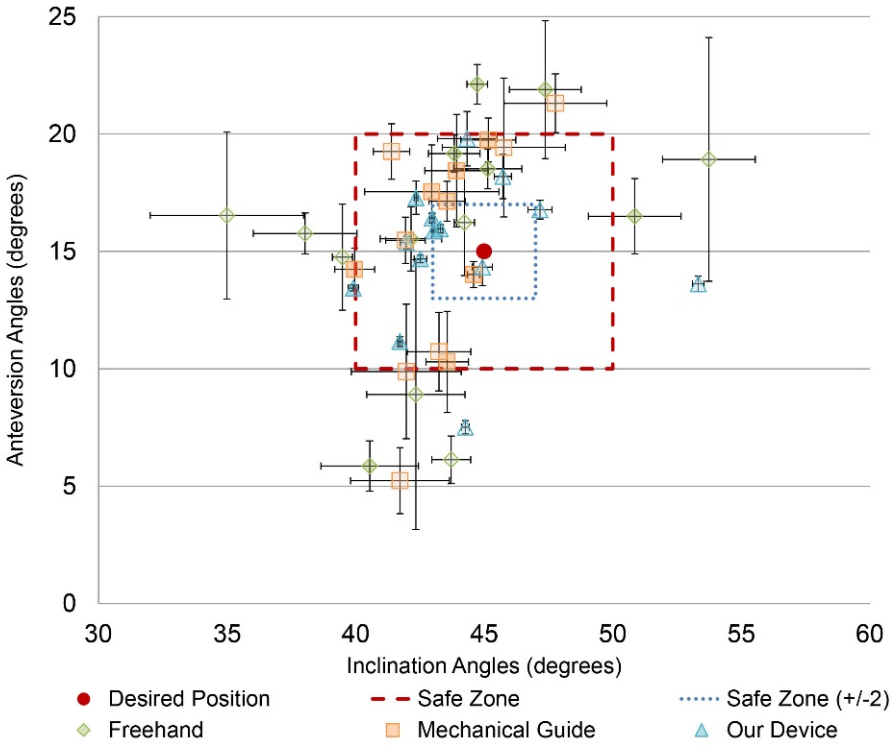


Figure 6-22 Average Participant Orientation - combined

Any deviation from the position of the acetabular cup to the position at the end of the time period is significantly smaller ($p < 0.01$) when using the developed device (0.58°±0.81 inclination, 0.62°±0.36 anteversion) compared to using the mechanical guide (3.06°±2.86 inclination, 2.81°±1.82 anteversion) or a freehand method (2.56°±2.02 inclination, 3.97°±4.53 anteversion). The significant difference ($p < 0.01$) in the pooled standard deviation when using the developed device further demonstrates lower variability in the achieved position of the acetabular cup over the time period.

When considering a safe zone of ±5° and the final position of the acetabular cup, 86% of cups placed using the developed device were within this range. This is in comparison to 64% when using a mechanical guide and 36% when using a freehand technique. If the safe zone is considered to be ±2°, 43% of cups placed using the developed device, 29% of cups placed using the mechanical guide and 14% using a freehand method are within this safe zone. In comparison, the starting position of the acetabular cup, when considering a safe zone of ±5°, 86% of cups placed using the developed device were within this range, 79% of cups when using the mechanical guide and 57% of cups when using a freehand technique. This

demonstrates that although some of the cups positioned using the mechanical guide and freehand technique were initially positioned within the acceptable zone, the final position shows they have moved over the time period.

6.4 Discussion

The product design specification stated the device must consistently and reliably position the acetabular cup accurately. The precise desired position of 45° inclination and 15° anteversion was not achieved by any of the three methods at any point over the 5 minute period. The average position of the acetabular cup, as shown in Figure 5.16 above, was within the defined safe zone of ±2° (set by the product design specification) for all three methods. Although the average positions fall within this critical space, only when using the developed device does the variation also lie within the acceptable safety zone. The product design specification stated the developed device must be able to achieve placement with ±2° of the desired angle therefore the testing demonstrated the design is meeting this criteria.

Several studies within the literature have provided comparable results when comparing the accuracy of current techniques. An in vitro study using a plastic pelvic model by Jolles et al.[170] compared the accuracy of placing an acetabular cup using freehand technique, mechanical guide and a computer aided technique. Results, assessed using an electromagnetic system, demonstrated the average error when placing the cup using the computer aided technique (2.5° inclination, 1.5°anteversion) was lower than when using the mechanical guide (4° inclination, 8°anteversion) and freehand technique (3.5° inclination, 10°anteversion). Clinical studies such as Bosker et al. [87] found the error from the estimated acetabular cup position when using the mechanical guide was 5.4° inclination and 5.5° anteversion. Saxler et al. [88] tested the accuracy when placing the acetabular cup using a freehand technique and found the average error to be 9.5° inclination and 15.5° anteversion. Kaletis et al. [66] established the error when positioning the acetabular cup using a freehand technique was 5.6° inclination and 13.7° anteversion and when using imageless navigation the average error was 2.3° inclination and 4° anteversion. The position of the acetabular cup was calculated from post-operative CT scans. The proof of concept results demonstrated similar results to the literature with the developed device demonstrating improved accuracy in comparison to cup

position when using the freehand and mechanical guide techniques. Similar to the study by Jolles et el. [170], the conditions of the study with regard to fixed placement of the patient makes positioning of the acetabular cup easier and the inaccuracy is likely to increase when in vivo.

Throughout the results, the developed device has a significantly lower pooled standard deviation in comparison to the mechanical guide and freehand technique. The smaller pooled standard deviation demonstrates consistency of the orientation over the given time period. The consistency among the participants suggests the developed device is not as dependent on the skill and experience of the user to achieve correct placement compared to using a mechanical guide or freehand technique. This suggests the developed device would be more dependable in achieving reliable results every time and demonstrates the consistency and reliability in positioning the acetabular cup when using the developed device.

Participants were instructed to position the acetabular cup at the desired orientation and hold the cup steady at this position for 5 minutes. This was to replicate intra-operative procedure as in a cemented total hip arthroplasty the surgeon/surgical assist is required to stand, hold the acetabular cup in the desired orientation and apply pressure as the cement hardens. The acetabular cup is initially positioned to the surgeon's desired orientation. Similar to intra-operative procedures, during testing, participants were allowed to self-correct their position if they felt the cup had wandered from the desired position over this time period. This means the measurements taken over the time period should be considered as the position the participant felt best matched the desired orientation and any movement in position should be minimal and would be for the pose of correcting any errors seen. Therefore any significant change over this time period would demonstrate deviation from their desired position. Deviation and changes in the position of the acetabular cup over this time could introduce error into the positioning. Achieving the correct orientation at initial placement has been shown to be near impossible therefore any further movement from this position could cause further inaccuracies and increase the risk of complications due to malpositioning. Movement in the acetabular cup as the cement is hardening may have an effect on the properties of the cement and weaken the bonding, these factors should be tested to discern any relationship between the two. A study should be designed to test whether any

movement *during* the setting process could weaken the structural integrity during the change of state, particularly during the hardening phase.

As discussed above, testing proved the position of the acetabular cup is not fixed over the 5 minute testing period as variation in the position in the acetabular cup was seen with all three techniques. This demonstrates the acetabular cup is likely to move intra-operatively between being placed in the acetabulum and the cement drying. The risk of the position of the acetabular cup changing within this time is increased further within an operating environment. During testing, holding the acetabular cup in the desired orientation was the participant's only task, whereas during surgery other distractions are also present. The time period during testing was taken as 5 minutes however during total hip arthroplasty this time can be longer which would increasing the time where movement can occur.

The testing demonstrated that the position of the acetabular cup at the end of the time period can be different to the initial placement. When the cup was placed using a mechanical guide or freehand technique, a higher percentage were within a safe zone of ±5° initially compared to the final position. The final acetabular position is critical as this position in which the cup is set. These results demonstrate movement in the position of the cup over the cement drying period, the consequences of which should be considered.

The developed device demonstrated a reduction in movement over time compared to the current methods. The deviation between the start and final position of the acetabular cup was significantly smaller which shows the developed device is better than the current techniques at ensuring the position of the acetabular cup is held steady over the time period, reducing the risk of movement and associated errors.

Testing revealed there was no significant difference in the accuracy of positioning the acetabular cup between participants with surgical experience and those without which suggests the developed device is independent of surgical experience. Therefore as the device is independent of surgical experience, it suggests the device could aid surgeons who are training or have recently completed training.

There are limitations to this proof of concept testing as the testing did not fully replicate surgical procedure. A plastic sawbone was used to simulate the surgical procedure within a Biomechanics laboratory. As a result there were no surrounding tissues and ligaments or anatomical landmarks other than the bony anatomy of the pelvis. The sawbone represents a healthy hip rather and does not consider bone degradation. This is different to what the surgeon would be used to within operating conditions. However unlike surgery, the bony anatomy of the pelvis was clearly visible during the testing. The pelvic mount provided a reference point and removed any pelvic tilt error and the mount also provided visual cues to the horizontal and vertical axis of the patient. These visual cues could have benefited both the freehand and mechanical guide method therefore the results recorded may have been better than they would be without these cues.

As testing was carried out in the Biomechanics laboratory, the pelvis was positioned on a rigid table rather than an operating table. The participants were asked to stand side on to the pelvis as if an operating table had been present. This was to replicate the procedure as best as possible however their stance may have been slightly different than they would be normally used to. The introducer and acetabular cup supplied by Corin which was used for the testing was for uncemented hips. The variations mean the surgeons may not have been used to holding this style of introducer steady for the time period. The same introducer and cup were always used during testing to reduce any effect this may have.

Plasticine was used to replicate bone cement during the testing, this is commonly used for surgical training purposes therefore is acceptable for the purpose of this research. The properties of plasticine meant that over the time period, as participants applied pressure to the introducer, the plasticine became more malleable. The change in properties could have caused the position of acetabular cup to drift over the time period introducing error. Error could also have been introduced due to the Vicon system and marker measurement. The calibration of the Vicon system, marker visibility and marker movement may all have contributed to error within testing.

6.5 Conclusion

Proof of concept testing demonstrated the hypothesis that the developed device can reliably and accurately position the acetabular cup within ±2° of the desired orientation is correct. The developed device reduced any movement of the acetabular cup position over the time period. The reliability of the device was highlighted as the developed device was more consistent in positioning the acetabular cup than the mechanical guide or freehand technique. Within this testing, the developed device was independent of surgical skill. This suggests it could provide a useful training device and reduce error associated with inexperience.

Although the position of the device was accurate with the design specification, it was not perfect and is heavily dependent on the initial set up of the device. Pelvic tilt was controlled within this experiment however during surgery this would not be the case. The results demonstrated the consistency and reliability in achieving acceptable acetabular cup orientations and if the device can be developed to improve the set-up and give consideration to the position of the pelvis, the developed device could provide reliable implantation of acetabular cups, independent of participant experience.

7

Surgical Interviews

7.1 Chapter Outline

A critical part of any product design process is the opinion of the target users. This chapter details the interviews held with the clinical participants after the testing sessions about the developed device. During the interviews, opinions towards the device in comparison to current methods, advantages and limitations of the device, the use of the device in training contexts and their own willingness to use the device were discussed. The results of the interviews are explained through this chapter.

7.2 Introduction

The role of the user is significant in the product design process. As detailed in Chapter 5, involving users in the development is vital to ensure a user-centred device is developed. Throughout the development of the device, the opinion of surgeons was sought. This opinion was obtained to gain understanding on initial ideas, on concept development, on the final solution provided invaluable insight into how the developed device may be received in the market.

7.3 Method

Similar to the proof of concept testing, University Departmental Ethics was granted to conduct interviews with the participants with clinical experience. 5 participants were recruited. Full qualification as an orthopaedic surgeon with experience in conducting total hip arthroplasty was a requirement for inclusion. Although an attempt was made to get surgeons with a range of experience, all participants were

Consultant orthopaedic surgeons. Participants were healthy volunteers of both genders between the age of 25 and 60.

Interviews were conducted after the proof of concept testing sessions. The interviews lasted no longer than 15 minutes and were informal with open ended questions to gather the participants' opinions on the devices. Surgeons were asked about their opinions on: the device in comparison to the other techniques; what they considered to be any benefits or challenges faced when using the device; if the device would be useful for training; and if they themselves would use the device.

7.4 Results

The results from the interviews were mostly positive towards the developed device, however this was not true of all interviewees. The key results from the interviews are detailed below while transcripts of the full interviews are available in the appendix.

7.4.1 Positive Feedback

In comparison to the other methods, surgeons found the device simple and easy to use. Surgeons stated they found it easier to hold the developed device steady resulting in the device being less tiring to use than the other techniques, *"it was very easy to use on the model, less tiring to use because it did allow you to lean on it a bit…seemed to work".*

The majority of surgeons agreed the greatest benefit of the device was the stability it provided in holding the acetabular cup at a constant position. Some of the comments made by the surgeons were, *"once you put it there, it's holding it for you. It's like having a very excellent medical student assisting or a registrar who doesn't ask any questions but just holds it as it should be"* and *"you choose that initial position and you are happy with it then it seems to hold which I think is a good feature."* As the device holds the acetabular cup in a constant position the variability is reduced enabling more reproducible results, *"basically takes all the variability out of it once you've set it."* The addition of the angles was seen as beneficial to reduce any error associated with malpositioning and allow the surgeon to have feedback on the position of the acetabular cup intraoperatively, *"it must take away that error and I think that on its own is advantageous"*.

7.4.2 Constructive Criticism

Challenges with using the device that were identified by the surgeons were mostly focused on the reference between the device and the patient. Some of the identified challenges are listed below:

- *"How are you going to fix it to the patient?"*
- *"How are you going to set the patient up to ensure that the positon you fix it to the patient is correct?"*
- *"How are you going to ensure that that position that it is telling you is the correct position?"*
- *"How you are going to get the alignment in the operating room*?"

One of the surgeons highlighted that the device could hold the acetabular cup steady and in the correct position however if the position of the pelvis is not known, the device is pointless. Questions surrounding the set-up of the device and the impact the device would have on the preparation pre-operatively and location of the device intra-operatively were also raised due to the concern around the hassle of set up and the obtrusiveness of the system in the operating theatre environment.

7.4.3 Concluding Opinions

The majority of the surgeons were in agreement that the device would be extremely beneficial with regarding to training. The device could aid trainees both on the dry bone model, cadaveric simulation and in surgery. This would be particularly beneficial in surgery because it would provide a safety check, *"Yes absolutely …is a good thing to have because it is like a safety check because it is one of the most important aspects of hip replacement"* and offer them reassurance when allowing less experienced surgeons to operate, *"I'm quite reluctant to let go and let them do it and so this is, this gives you that reassurance. That you can actually physically see what they are doing."*

During the interviews, the benefit of the developed device within cementless cups was highlighted by several surgeons, *"I could even see it being quite important in cementless cups… perhaps even being even more advantageous to a certain extent so because even if you are tapping it you can only go in the one trajectory with it"*.

As a concluding question, participants were asked whether they would consider adopting this device into their theatre practice. Most of the surgeons stated they would be keen to use it in surgery by saying, *"I would certainly be willing to use it and see how it was"*, and *"as I've said before it starts with the absolute precise positioning of the patient, you go to great lengths to, because it is so important I think it is something I would use"* but this is dependent on further development of the device and addressing the criticisms raised

7.5 Discussion

The majority (although not all) of the interviews were positive towards the design of the device and found it an interesting concept worth exploring further. Ensuring the device was simple and easy to use was a key aim of the product specification as stated in Chapter 5. The majority of the surgeons were in agreement that the device meets this aim. Finding the device easy to use and specifically easy to hold steady is a beneficial characteristic as within cemented total hip arthroplasties, the device needs to be held steady as the cement hardens. During surgery, as the cement in the acetabular cup dries, interruptions and distractions can occur therefore an aid to hold the acetabular cup steady is valuable.

The comments in the interviews demonstrated the surgeons were happy the device provided them with an aid to positioning the acetabular cup. The markings on the device was appreciated as the surgeons were able to gain feedback on the position of the device intra-operatively. The device allows the surgeon to choose an appropriate patient specific position and helps the surgeon maintain the desired position whilst still leaving the surgeon in control.

The challenges mentioned by the participants raised many good questions for discussion. The position of the pelvis on the operating table is critical to ensure correct acetabular positioning. To remove any error in the measurement due to pelvic tilt, the pelvis was in a fixed position for the testing which would not be the case during surgery. Further research is required into understanding the position of the pelvis on the operating table to enable the patient's anatomy to provide a reference for set up. The interviews highlighted that the current device does not

address this yet. Following further work, the device can be developed to use the patient's pelvic position as a reference.

Questions were also asked regarding the set-up of the device and the obtrusiveness of the system during the operation. The positioning arm used for the proof of concept testing was large and sturdy to provide the require support to hold the device steady as a control between participants. As mentioned in Chapter 5, the positioning arm requires further development and would address these concerns.

Surgeons felt the device would be beneficial as an aide to help with training less experienced surgeons. Surgeons also highlighted the device could be beneficial for acetabular cup placed using a cementless technique. The technique requires the surgeon to hammer the acetabular cup into place. Comments were made the device could be beneficial at this point as the device limits the movement of the introducer and could reduce any movement and change in positioning as the acetabular cup is hit into place.

Of the five interviews, one of the surgeons felt that the use of a cementless impactor and pelvic sawbone for the proof on concept testing was an unrealistic scenario. Based on the limitations with testing, he felt any comparison between techniques was insignificant which influenced his comments on the device. The content of the interview provided invaluable insights and highlighted limitations which should be addressed.

7.5.1 Conclusion

The interviews demonstrated a mostly positive attitude towards the developed device. The device was seen as simple and easy to use, and with further development, most surgeons would be happy to try using it in surgery. The biggest benefits of the device was the stability in acetabular position, helping reduce variability and providing an aide to the surgeon. The results demonstrate positive surgical opinion towards the device and a willingness to try. As discussed in Chapter 5, user research identified surgical opinion as one of the biggest barriers towards use. The device is designed to challenge and change their current behaviour whist still allowing the surgeon to be in control of the desired position. The positive attitude

from these interviews suggest the device meets this criteria from the product design specification criteria.

8

Discussion of Objectives, Limitations and Future Work

8.1 Chapter Overview

Within this thesis the goal of designing a cost-effective, reliable implantation method to aid surgeons with positioning the acetabular cup within total hip arthroplasty has been achieved.

This chapter discusses the objectives set at the beginning of this research and details the key outcomes from the work. The limitations from this study are explained and future work following the results of this research is described.

8.2 Objectives of research

A. *Review the literature and determine a universal method of reporting acetabular cup placement.*

Investigation into the literature identified many limitations regarding acetabular orientation. Despite wide recognition regarding the importance of the orientation of the acetabular cup, there were varying methods of defining and measuring acetabular cup orientation present in the literature. This lack of consensus is due to varying planes of reference, different definitions of acetabular orientation, a wide range of measurement methodologies and different measures used, if any, to account for pelvic tilt. These factors prevent it being possible to perform a valid like-for-like comparison of the literature.

Mechanical guides, which are currently used to position the acetabular cup, have been shown to have limitations as the surgeon is required to have visual control over the two planes at once. Using Murray's [31] definitions, during surgery mechanical guides show the surgeon a radiographic inclination angle and an operative anteversion angle. This combination, using different definitions for the inclination and anteversion angle is used by the majority of the manufacturers' in the product safety guidelines and in the surgical textbooks. To avoid using a combination of definitions, a unified Surgical Reference system was defined to reduce confusion and any potential misinterpretation regarding any reference to these angles within the literature.

B. *Analyse the literature and guidelines regarding acetabular cup orientation to determine if there is a consensus on optimum position using the identified universal reporting method.*

Following from Objective A which sought to clarify the definition of the angles, Objective B was to identify if there was a consensus amongst the literature, textbooks and manufacturers' guidelines on the optimal orientation of the acetabular cup within THA. Converting guidelines onto a global reference system defined by Murray [31] enabled comparison between the recommended orientations which demonstrated there is no common consensus amongst the literature and guidelines on the correct acetabular orientation. In comparison to the Lewinnek safe zone, the majority of the guidelines were concentrated in the bottom right-hand quadrant of the safe zone. This highlighted a problem for the surgeon as when deciding on the desired orientation they must decide to either follow the manufacturers' safety guidelines and position the cup on the edge of the Lewinnek safe zone or place the acetabular cup in the centre of the Lewinnek safe zone and ignore manufacturers' guidelines.

A review of the literature found that the optimal angle varied between patients. As discussed in Chapter 2, the optimal orientation of the acetabular is dependent on many factors and a "one size fits all" approach cannot be used. Consequentially, it is vital the surgeon is able to position the acetabular cup at an orientation that is appropriate for the patient rather than a fixed orientation. Mechanical guides which are used to position the acetabular cup do not allow for patient variability. To

improve the functionality of current devices, devices should allow for patient specific adjustments such as the influence of gender, individual anatomy, age and optimum range of motion.

C. *Develop a Design Methodology to ensure a user-centred solution is developed.*

Through understanding the literature and comparing design methodologies from education and industry, Harrison User Centred Methodology (HUCM) was developed during this research. HUCM, as was discussed fully in Chapter 4, combined both quantitative and qualitative techniques to ensure that when following the design process, a user-centred solution is produced.

The developed methodology was used to find a solution to improve acetabular cup placement within total hip arthroplasty. Following HUCM encouraged user insight from the start and the mix of techniques was beneficial in providing an understanding of the wider problems surrounding acetabular cup positioning whilst still providing structure to the development. The significance and influence of the user-centred design approach throughout the design process is apparent in Chapter 5. For example, the design approach helped identify that surgeon's opinion of the device was critical to encourage use and changing surgeons' opinions and current behaviours was one of the biggest challenges. The concluding interviews demonstrated an excitement and willingness to adopt the device which demonstrates the success of the user-centred design techniques.

D. *Design and build a device to aid surgeons with positioning the acetabular cup with Total Hip Arthroplasty.*

The design process developed during this research was used to design and build a device to aid surgeons with positioning the acetabular cup. Despite "designing a device" being an initial objective, the process did not start with concept ideas but with a phase of research which led to the identification of many contributory factors which influence acetabular cup positioning. Within these factors, areas where design could reduce the risk of malpositioning were identified. Unfortunately all the issues highlighted could not be addressed within this research

but provide areas for exploration for future work.

The process that was used to design and develop a device to aid surgeons is detailed in Chapter 5. The final device is a simple solution to help the surgeon position the acetabular cup within Total Hip Arthroplasty. A positioning guide directs the surgeon to the achieved acetabular cup angle intraoperatively. The jig limits the inclination angle and provides the surgeon with feedback on the anteversion angle removing the need for surgeons to have visual control over two planes at the exact same time. Device inserts and markings on the device enable the surgeon to place the acetabular cup at a patient specific angle rather a pre-set orientation. The influence of patient to patient variability was highlighted during the literature review, as the ideal acetabular component orientation was patient specific. Enabling the surgeon to position the acetabular cup at an anteversion angle of their choice helps in providing a solution that allows for patient variability. Rapid prototyping methods were used to create a prototype device suitable for testing.

E. Test the accuracy of the developed device against current techniques on both sawbones and cadaveric specimens.

A range of sawbone testing was conducted using the prototyped solution which is presented in Chapter 6. The tests demonstrate the device meets the criteria in the product design specification as the average position of the acetabular cup was within the defined safe zone of ±2° and the developed device held the acetabular cup in a steadier position over the time period as shown by the variance data presented in Chapter 6. The testing also demonstrated that the accuracy of acetabular cup placement when using the developed device was independent of surgical experience which would provide benefit for surgical training.

Testing identified the position of the acetabular cup varies significantly over the time period as the cement dries. The developed device reduces the movement over the time period in comparison to current techniques. The effect of this movement on the structural integrity of the cement is unknown and is a key area for further work.

Testing was not conducted on cadaveric specimens due to the time constraints of the project and is proposed as future work. The extensive sawbone testing provided sufficient data for the defence of this thesis and was taken into consideration before excluding cadaveric testing from this study.

8.3 Contributions to knowledge

This research has provided several contributions to knowledge. Differences between the positioning guidelines from literature and manufacturers have been identified, highlighting the lack of consensus on the optimum orientation of the acetabular cup. The discrepancies that exist when using different reference system were demonstrated and a surgical reference system was defined to reduce errors when converting between definitions.

A design methodology, focused on user-centred design techniques was developed. This methodology was used to design a simple positioning guide which could be used to aid surgeons during Total Hip Arthroplasty. The device developed through this work has been patented and will undergo further development.

A method of quantifying the performance of alignment guides has also been created. The methodology was used to test the accuracy of the developed device in comparison to current methods and has been detailed in the testing chapter.

8.4 Limitations

When considering joint stability, the orientation of the acetabular cup cannot be considered independently. As discussed in Chapter 2, the femoral stem component of the hip prosthesis has a significant influence on the stability and success of the joint therefore the two prosthesis must be placed in relation to each other. For the purpose of this research, as the scope was to focus on the acetabular component, it was assumed the femoral component was correctly positioned in relation to the acetabular component. Developing the device to provide a complete solution for both parts of the hip prosthesis by ensuring correct femoral orientation is the next stage in device development.

The methodology used for testing assumed a fixed pelvic tilt position to reduce error. The influence of pelvic tilt on acetabular cup orientation creates additional patient to patient variance. As it is difficult to know the precise position of the pelvis when the patient is on the operating table, the relationship between pelvic tilt and acetabular orientation is difficult to quantify. Further research is required to gain a deeper understanding of the position of the patient on the operating table and the influences this positioning has on acetabular cup orientation. The accuracy of the current design of the developed device would be dependent on the surgeon knowing the precise position of the patient. With a deeper understanding of the position of the patient on the operating table, the device can be set up with reference to the anatomical hip position and include consideration to pelvic tilt.

Several limitations existed within the experimental setup. As discussed in Chapter 6, testing was within a biomechanics laboratory using pelvic sawbones. Participants were asked to insert the acetabular cup into the acetabulum rather than complete the whole hip replacement procedure. Despite the limitations discussed in Chapter 6, the testing enabled a comparison between the accuracy of placing the acetabular cup using the developed device in comparison to current methods which was the aim of the study.

8.5 Future work

The results of this research have led to many questions and highlighted areas which should be explored further.

Testing highlighted the movement in the position of the acetabular cup over the time period as the cement would harden. The relationship between movement over this time and the properties of the cement as it hardens is something that should be explored further. If movement of the acetabular cup during the hardening period weakens the properties of the cement and the join between the hip prosthesis and the acetabulum, this may contribute to other factors which increase the risk of revision surgery.

Further development of the device is required. Ensuring the device is correctly positioned over the acetabulum is critical for accurate positioning. Although some

ideas to help with this have been generated, detailed design, development and testing of these concepts are required. Further research is required into understanding and controlling the position of the pelvis on the operating table to allow the device to be designed to ensure positioning in relation to the patient. The solution currently only considers the acetabular component of the hip prosthesis. Development of a solution which considers both components would ensure both components are placed in relation to each other.

Since this completing this research, experience has been gained developing medical devices as a human factors engineer. This experience provided further experience into user centred design process, in particular from a standard and regulatory perspective. Working to HE75 demonstrated the importance of following the usability design process throughout to ensure the device is safe and effective for use. Although the current design process included the early steps of this process, task analysis is required to identify any safety critical steps within the procedure. Usability testing studies would need to be conducted to verify there are no associated use errors with the design of the device and it is safe and effective use.

9

Appendix

9.1 Derivation of Comparison Equations

Conversion equations can be derived from each of the angle definitions to allow for comparison between reference systems.

Operative Inclination (δ)

$$\textbf{Sin OI = Sin RI * Cos RA}$$

$$\sin\delta = \sin\theta \times \cos\alpha$$

$$\frac{x}{\sqrt{x^2+y^2+z^2}} = \frac{x}{\sqrt{x^2+z^2}} \times \frac{\sqrt{x^2+z^2}}{\sqrt{x^2+y^2+z^2}}$$

$$\frac{x}{\sqrt{x^2+y^2+z^2}} = \frac{x(\sqrt{x^2+z^2})}{\sqrt{x^2+z^2}(\sqrt{x^2+y^2+z^2})}$$

$$\frac{x}{\sqrt{x^2+y^2+z^2}} = \frac{x}{\sqrt{x^2+y^2+z^2}}$$

$$\textbf{Sin OI = Sin AI * Cos AA}$$

$$\sin\delta = \sin\beta \times \cos\gamma$$

$$\frac{x}{\sqrt{x^2+y^2+z^2}} = \frac{\sqrt{x^2+y^2}}{\sqrt{x^2+y^2+z^2}} \times \frac{x}{\sqrt{x^2+y^2}}$$

$$\frac{x}{\sqrt{x^2+y^2+z^2}} = \frac{x(\sqrt{x^2+y^2})}{\sqrt{x^2+y^2}(\sqrt{x^2+y^2+z^2})}$$

$$\frac{x}{\sqrt{x^2+y^2+z^2}} = \frac{x}{\sqrt{x^2+y^2+z^2}}$$

Operative Anteversion

$$\textbf{Tan OA = Tan RA/ Cos RI}$$

$$\tan \emptyset = \frac{\tan \alpha}{\cos \theta}$$

$$\frac{y}{z} = \frac{\frac{y}{\sqrt{x^2 + z^2}}}{\frac{z}{\sqrt{x^2 + z^2}}}$$

$$\frac{y}{z} = \frac{y(\sqrt{x^2 + z^2})}{z(\sqrt{x^2 + z^2})}$$

$$\frac{y}{z} = \frac{y}{z}$$

$$\textbf{Tan OA = Sin AA * Tan AI}$$

$$\tan \emptyset = \sin \gamma \times \tan \beta$$

$$\frac{y}{z} = \frac{y}{\sqrt{x^2 + y^2}} \times \frac{\sqrt{x^2 + y^2}}{z}$$

$$\frac{y}{z} = \frac{y(\sqrt{x^2 + y^2})}{z\sqrt{x^2 + y^2}}$$

$$\frac{y}{z} = \frac{y}{z}$$

Radiographic Inclination

$$\textbf{Tan RI = Tan OI/ Cos OA}$$

$$\tan \theta = \frac{\tan \delta}{\cos \emptyset}$$

$$\frac{x}{z} = \frac{\frac{x}{\sqrt{y^2 + z^2}}}{\frac{z}{\sqrt{y^2 + z^2}}}$$

$$\frac{x}{z} = \frac{x(\sqrt{y^2 + z^2})}{z(\sqrt{y^2 + z^2})}$$

$$\frac{x}{z} = \frac{x}{z}$$

$$\textbf{Tan RI = Tan AI* Cos AA}$$

$$\tan \theta = \tan \beta \times \cos \gamma$$

$$\frac{x}{z} = \frac{\sqrt{x^2 + y^2}}{z} \times \frac{x}{\sqrt{x^2 + y^2}}$$

$$\frac{x}{z} = \frac{x(\sqrt{x^2+y^2})}{z(\sqrt{x^2+y^2})}$$

$$\frac{x}{z} = \frac{x}{z}$$

Radiographic Anteversion

Sin RA = Sin OA * Cos OI

$$\sin\alpha = \sin\emptyset \times \cos\delta$$

$$\frac{y}{\sqrt{x^2+y^2+z^2}} = \frac{y}{\sqrt{y^2+z^2}} \times \frac{\sqrt{y^2+z^2}}{\sqrt{x^2+y^2+z^2}}$$

$$\frac{y}{\sqrt{x^2+y^2+z^2}} = \frac{y(\sqrt{y^2+z^2})}{\sqrt{y^2+z^2}(\sqrt{x^2+y^2+z^2})}$$

$$\frac{y}{\sqrt{x^2+y^2+z^2}} = \frac{y}{\sqrt{x^2+y^2+z^2}}$$

Sin RA = Sin AA * Sin AI

$$\sin\alpha = \sin\gamma \times \sin\beta$$

$$\frac{y}{\sqrt{x^2+y^2+z^2}} = \frac{y}{\sqrt{x^2+y^2}} \times \frac{\sqrt{x^2+y^2}}{\sqrt{x^2+y^2+z^2}}$$

$$\frac{y}{\sqrt{x^2+y^2+z^2}} = \frac{y(\sqrt{x^2+y^2})}{\sqrt{x^2+y^2}(\sqrt{x^2+y^2+z^2})}$$

$$\frac{y}{\sqrt{x^2+y^2+z^2}} = \frac{y}{\sqrt{x^2+y^2+z^2}}$$

Anatomical Inclination

Cos AI = Cos OI * Cos OA

$$\cos\beta = \cos\delta \times \cos\emptyset$$

$$\frac{z}{\sqrt{x^2+y^2+z^2}} = \frac{\sqrt{y^2+z^2}}{\sqrt{x^2+y^2+z^2}} \times \frac{z}{\sqrt{y^2+z^2}}$$

$$\frac{z}{\sqrt{x^2+y^2+z^2}} = \frac{z(\sqrt{y^2+z^2})}{\sqrt{y^2+z^2}(\sqrt{x^2+y^2+z^2})}$$

$$\frac{z}{\sqrt{x^2+y^2+z^2}} = \frac{z}{\sqrt{x^2+y^2+z^2}}$$

Cos AI = Cos RI * Cos RA

$$\cos\beta = \cos\theta \times \cos\alpha$$

$$\frac{z}{\sqrt{x^2+y^2+z^2}} = \frac{z}{\sqrt{x^2+z^2}} \times \frac{\sqrt{x^2+z^2}}{\sqrt{x^2+y^2+z^2}}$$

$$\frac{z}{\sqrt{x^2+y^2+z^2}} = \frac{z(\sqrt{x^2+z^2})}{\sqrt{x^2+z^2}(\sqrt{x^2+y^2+z^2})}$$

$$\frac{z}{\sqrt{x^2+y^2+z^2}} = \frac{z}{\sqrt{x^2+y^2+z^2}}$$

Anatomical Anteversion

Tan AA = Sin OA/ Tan OI

$$\tan\gamma = \frac{\sin\emptyset}{\tan\delta}$$

$$\frac{y}{x} = \frac{\frac{y}{\sqrt{y^2+z^2}}}{\frac{x}{\sqrt{y^2+z^2}}}$$

$$\frac{y}{x} = \frac{y(\sqrt{y^2+z^2})}{x(\sqrt{y^2+z^2})}$$

$$\frac{y}{x} = \frac{y}{x}$$

Tan AA = Tan RA/ Sin RI

$$\tan\gamma = \frac{\tan\alpha}{\sin\theta}$$

$$\frac{y}{x} = \frac{\frac{y}{\sqrt{x^2+z^2}}}{\frac{x}{\sqrt{x^2+z^2}}}$$

$$\frac{y}{x} = \frac{y(\sqrt{x^2+z^2})}{x\sqrt{x^2+z^2}}$$

$$\frac{y}{x} = \frac{y}{x}$$

9.2 Product Design Specification

9.2.1 Performance

1.1 Device does not compromise the health and safety of the patient or the user.

1.2 Device must enable the surgeon to insert the acetabular cup implant into the acetabulum.

1.3 Provides the surgeon with control over the position of the acetabular cup, the cup is positioned within ± 2° of the surgeon's desired orientation.

1.4 Provides consistent and reliable accuracy with every operation.

1.5 Surgeon has real-time feedback on the position of implant during the operation.

1.6 Device guides surgeon in placing the acetabular cup in a desired orientation.

1.7 Device is easy to operate.

1.8 Performance is not affected if the surgeon is distracted during the operation.

1.9 Device does not prolong the operating time.

1.10 Performance of the device is not dependent on surgeon's skill or experience level.

1.11 Device can be used by either a left or right handed surgeon.

1.12 Device can be used for a right or left leg total hip arthroplasty.

1.13 The accuracy is not affected by high stresses which are subjected to the device during the operation.

1.14 Understanding of the stresses of the hammering process

9.2.2 Environment

1.15 Device will used within a sterile operating theatre environment.

1.16 Device must be compatible with existing orthopaedic instrumentation.

1.17 Device must be able to withstand sterile cleaning.

1.18 Temperature Range: device should perform and not be damaged by temperatures which would be determined during device testing

1.19 Pressure Range: device should perform and not be damaged by pressure levels which would be determined during device testing

1.20 Corrosion Resistance: device should be resistant to corrosion

1.21 Shock Loading: device must be able to withstand shock loading, levels which would be determined during device testing

9.2.3 Life In Service

1.22 The device would be disposable and one use only for sterility purposes.

1.23 The external positioning arm would be reused.

9.2.4 Maintenance

1.24 To compete with the competitors and to keep the product costs down, the design should:

1.25 Be maintenance free therefore reducing the need for the manufacture of spare parts.

1.26 Use British standards for screws, bolts and washers.

1.27 If any parts that may require lubrication or maintenance should be easily accessible and not need special tools to access.

9.2.5 Target Product Cost

1.28 The device must be cost effective.

1.29 Ensuring low cost must not influence the accuracy and precision of the device.

1.30 Aimed at the price range of current mechanical guides and rather than navigation systems.

9.2.6 Competition

1.31 Mechanical Guides.

1.32 Image Free Systems.

1.33 Computer Aided Systems.

Analysis of competitors is detailed in the research documentation.

9.2.7 Packing

1.34 Must conform to standard BS EN ISO 11602-1:2009 - 11607-2:2006 (see 16.0 Standards)

1.35 Must keep the device sterile.

1.36 Size, cost and weight must be kept to a minimum.

1.37 Should prevent damage from transportation and any shock loading.

1.38 Must be easily removed by the user when they are wearing surgical gloves.

1.39 Assembly and fitting instructions must be included.

1.40 Must display the information required by the EU Directive 93/42/EEC on Medical Devices (see 16.0 Standards)

9.2.8 Shipping/ Transport

1.41 Must comply with BS EN ISO 11607-1: 2009 - 11607-2: 2006 (see 16.0 Standards)

1.42 Device would be transported with current orthopaedic instrumentation sets

9.2.9 Quantity

1.43 Quantity is dependent on the commercialisation approach used.

9.2.10 Manufacturing Facility

1.44 The device must be manufactured in a sterile environment.

9.2.11 Size

1.45 Device must retrofit to existing implants.

1.46 Easy to handle and manoeuvre.

1.47 Surgeon can control the device using one hand.

1.48 Device must be small enough to be easily stored between uses.

9.2.12 Weight

1.49 Weight must be kept to a minimum.

1.50 However this must not reduce the strength of the device as it must be able to resist stresses applied during the operation.

9.2.13 Aesthetics

1.51 Design of device must encourage correct use.

1.52 Information displayed on the device must comply with the EU Directive 93/42/EEC on Medical Devices (see 16.0 Standards).

9.2.14 Materials

1.53 Materials for non-invasive device must conform to ISO 5832-1 – 5832-12 (see 16.0 Standards).

1.54 Material used must be biocompatible.

1.55 Material used must be cost effective.

1.56 Must withstand the environmental conditions (see 2.0 Environment).

1.57 Should be lightweight but must withstand the impact from hammer during implantation.

1.58 Material should be resistant to wear and corrosion.

1.59 Material must be easily used in production.

9.2.15 Standards/ Specifications

1.60 Device Guidelines

Essential requirements of EU Directive 93/42/EEC on Medical Devices

EN ISO 16062: 2014

BS EN 12011: 1998

1.61 Manufacture

Application of quality systems:

BS EN ISO 13485:2016

1.62 Materials

ISO 5832-1 to ISO 5832-12

1.63 Sterilization

Information to be provided by manufacturer:

BS EN ISO 17664: 2004

If provided sterile:

BS EN ISO 14937: 2001

BS EN 556-1: 2001

BS EN 556-2:2003

Ethylene Oxide:

BS EN 550

ISO 11135-1

Steam:

BS EN 554

ISO 17665-1

Irradiation:

BS EN 552

ISO 11137-1 – 11137-3

Estimation of microorganisms:

BS EN 1174

1.64 Testing

BS EN 60068-2-47: 2005

BS EN 60068-2-31: 2008

BS EN 60068-2-27: 2009

1.65 Risk Assessment

BS EN ISO 14971: 2009

1.66 Good Clinical Practice

BS EN ISO 141155:2011

1.67 Information to be supplied by the manufacturer

BS EN 1041: 2008

1.68 ISO 15223-1

Packaging & Transportation

BS EN ISO 11607-1: 2009

BS EN ISO 11607-2: 2006

1.69 Test Methods:

IEC 60068-2-27

IEC 60068-2-31

IEC 60068-2-47

9.2.16 Ergonomics

1.70 Device must be easy for the surgeon to interact with.

1.71 Design should dictate that the device cannot be used in the wrong way.

1.72 Design should be based on one handed operation.

1.73 Device will clearly demonstrate the anteversion and inclination angles to the surgeon.

1.74 Device must be able to be used regardless of the position of the surgeon.

9.2.17 Customer

1.75 Surgeon

1.76 Assisting Nurse

1.77 Patient

9.2.18 Quality and Reliability

1.78 The device must comply with the essential requirements of EU Directive 93/42/EEC (see 16.0 Standards).

1.79 The device must produce consistent accurate results to ±2°.

9.3 Design Evaluation Results

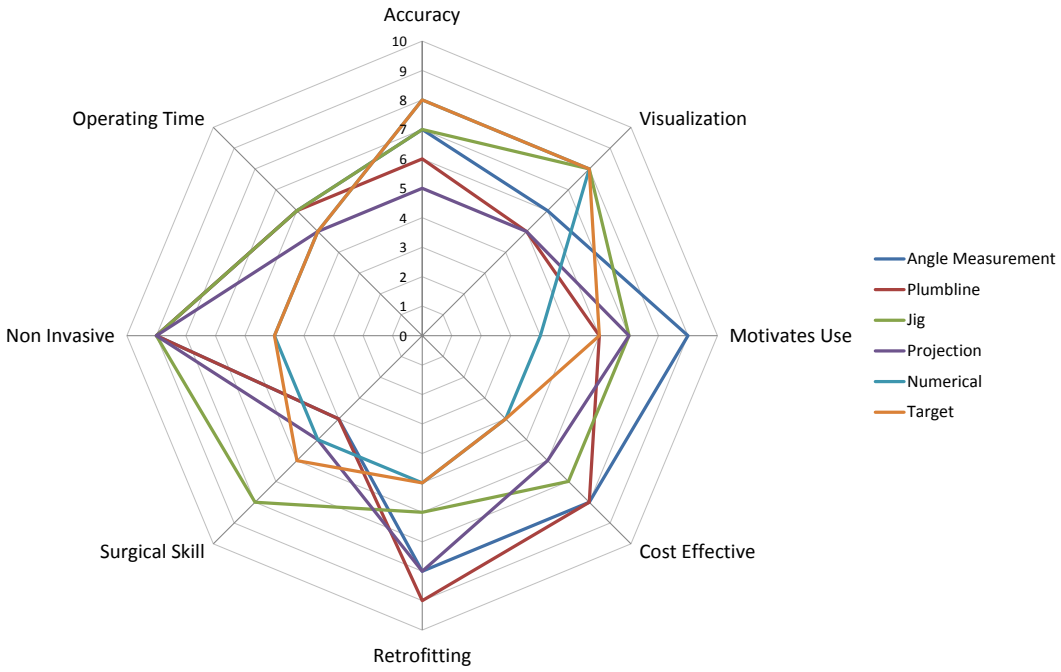
9.3.1 Results of Plus/ Minus/ Same Comparison

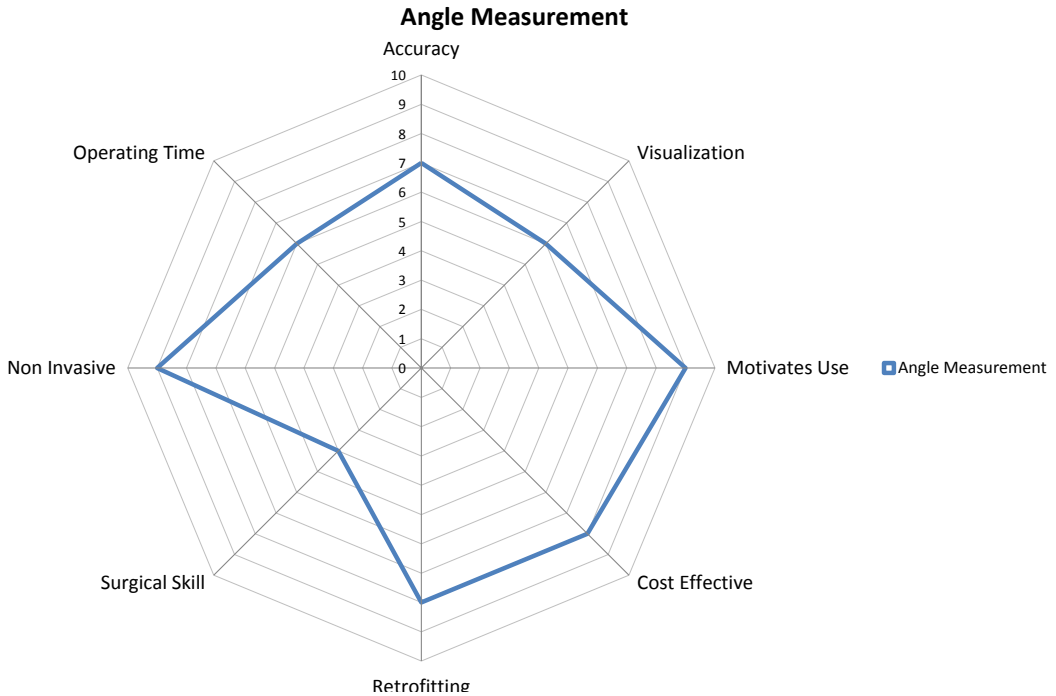
	Spirit Level	Plumbline Protractor	Projection	Numerical Visualisation	Target Area	Jig
Accuracy: Inclination	+	+	s	+	+	+
Accuracy: Anteversion	s	-	+	+	+	+
Cost Effective	+	+	+	+	+	+
Can be used with current surgical technique	s	s	s	+	+	+
Capable of withstanding sterile cleaning	-	-	-	-	-	-
All angles are measured from the same reference point	s	s	+	+	+	+
Ensure the position of the implant and patient work on same reference	s	s	+	+	+	+
Teaches what the correct orientation should be	+	+	+	+	+	+
Alerts the surgeon if the orientation wrong: Inclination	+	+	+	+	+	+
Alerts the surgeon if the orientation wrong: Anteversion	+	+	+	+	+	+
Provides realtime feedback to the surgeon on the position of the implant: Inclination	+	+	s	+	+	+
Provides realtime feedback to the surgeon on the position of the implant: Anteversion	-	+	+	+	+	+
Non Invasive	s	s	+	-	-	+
Allows surgeon to define angle: Inclination	s	+	s	+	+	s
Allows surgeon to define angle: Anteversion	+	+	s	+	+	+
Clearly demonstrates recommended angle: Inclination	+	+	s	+	+	s
Clearly demonstrates recommended angle: Anteversion	s	s	s	+	+	+
Independent of surgical skill level	+	+	+	+	+	+
Can be used with current surgical instrumentation	s	s	s	s	s	s
Doesn't prolong operating time	s	s	s	-	-	s
Easy to use	+	+	+	+	+	+
Easily stored between uses	s	s	+	+	+	+
Secure attachment	s	s	s	s	s	s
Total (+)	10	12	12	18	18	17
Total (s)	11	9	9	2	2	5
Total (-)	2	1	1	3	3	1
Total (+ - -)	8	11	11	15	15	16

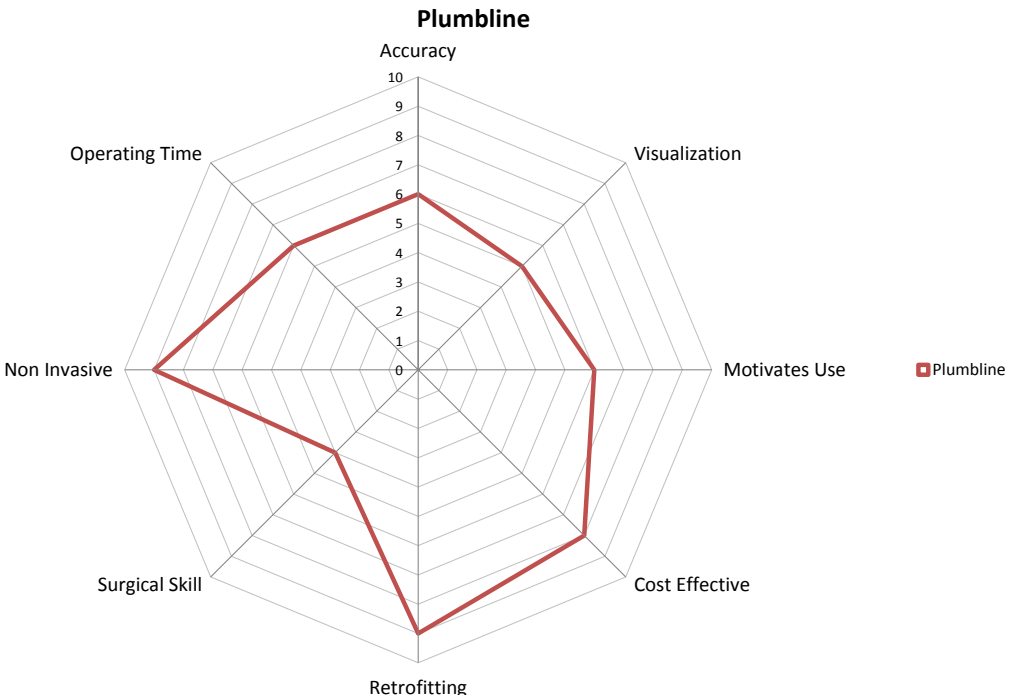
9.3.2 Results of Numerical Matrix Comparison

	Weighting	Spirit Level		Plumbline Protractor		Projection		Numerical Visualisation		Target Area		Jig	
		Score	S*W	Score	S*W	Score	S*W	Score	S*W	Score	S*W	Score	S*W
Accuracy: Inclination	10	7	70	7	70	6	60	9	90	8	80	7	70
Accuracy: Anteversion	10	3	30	2	20	7	70	9	90	8	80	7	70
Cost Effective	10	7	70	9	90	8	80	7	70	7	70	7	70
Not affected by high stresses	10	7	70	7	70	8	80	6	60	6	60	9	90
Can be used with current surgical technique	8	10	80	10	80	10	80	10	80	10	80	10	80
Capable of withstanding sterile cleaning	10	2	20	9	90	4	40	7	70	7	70	9	90
All angles are measured from the same reference point	10	3	30	4	40	8	80	6	60	6	60	8	80
Ensure the position of the implant and patient work on same reference	9	3	27	3	27	8	72	6	54	6	54	7	63
Teaches what the correct orientation should be	6	7	42	8	48	9	54	7	42	8	48	8	48
Motivates use compared to doing it by sight without a guide	8	6	48	7	56	7	56	7	56	7	56	7	56
Alerts the surgeon if the orientation wrong: Inclination	7	10	70	8	56	5	35	9	63	9	63	5	35
Alerts the surgeon if the orientation wrong: Anteversion	7	0	0	8	56	5	35	9	63	9	63	5	35
Provides realtime feedback to the surgeon on the position of the implant: Inclination	9	8	72	8	72	7	63	9	81	9	81	8	72
Provides realtime feedback to the surgeon on the position of the implant: Anteversion	9	4	36	6	54	7	63	9	81	9	81	8	72
Non Invasive	7	10	70	10	70	10	70	10	70	10	70	10	70
Allows surgeon to define angle: Inclination	6	4	24	7	42	3	18	8	48	7	42	8	48
Allows surgeon to define angle: Anteversion	6	9	54	7	42	3	18	8	48	7	42	8	48
Clearly demonstrates recommended angle: Inclination	10	10	100	9	90	7	70	8	80	9	90	8	80
Clearly demonstrates recommended angle: Anteversion	10	6	60	7	70	7	70	8	80	9	90	8	80
Independent of surgical skill level	5	5	25	5	25	6	30	7	35	8	40	9	45
Can be used with current surgical instrumentation	5	9	45	9	45	8	40	7	35	7	35	9	45
Doesn't prolong operating time	7	8	56	7	49	8	56	8	56	8	56	6	42
Device can be operated with one hand or free standing	5	8	40	8	40	8	40	8	40	8	40	10	50
Easy to use	7	5	35	6	42	7	49	6	42	7	49	8	56
Easily stored between uses	3	7	21	8	24	8	24	9	27	9	27	8	24
Secure attachment	6	5	30	5	30	7	42	3	18	4	24	7	42
			1225		1398		1395		1539		1551		1561

9.3.3 Target Graphs






Plumbline
Accuracy
Visualization
Motivates Use
Cost Effective
Retrofitting
Surgical Skill
Non Invasive
Operating Time
10
9
8
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2
1
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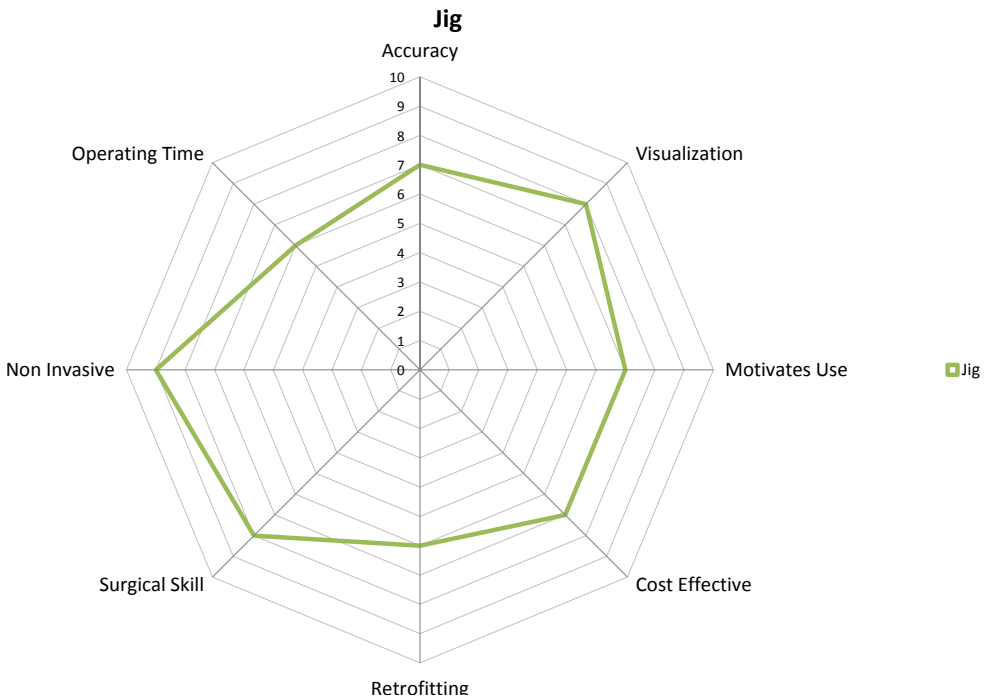
Plumbline


Jig
Accuracy
Visualization
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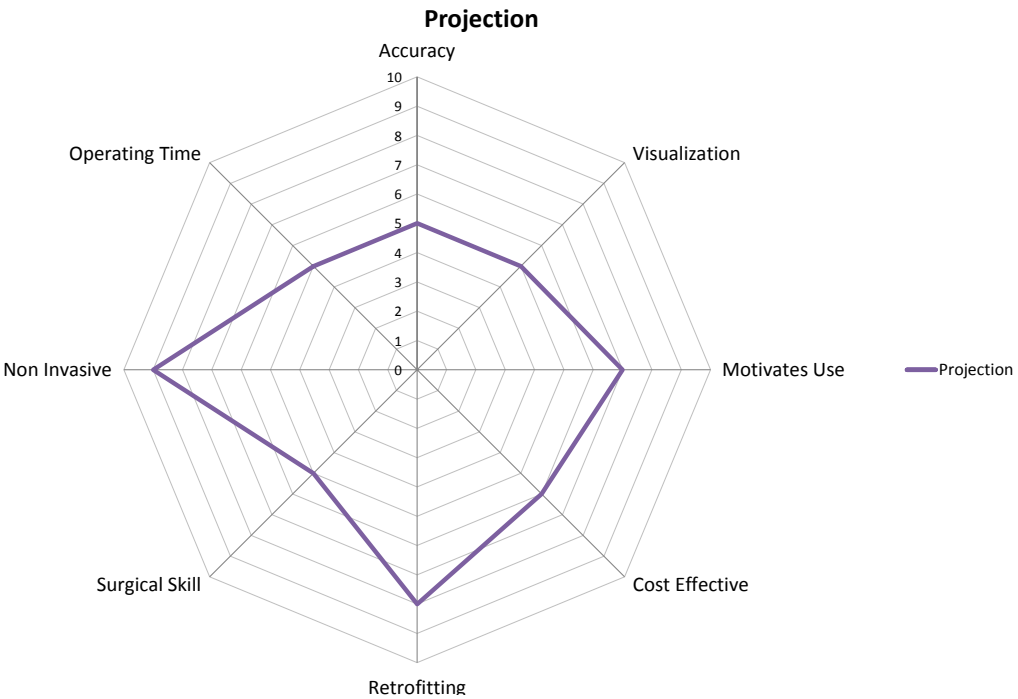
Projection
Accuracy
Visualization
Motivates Use
Cost Effective
Retrofitting
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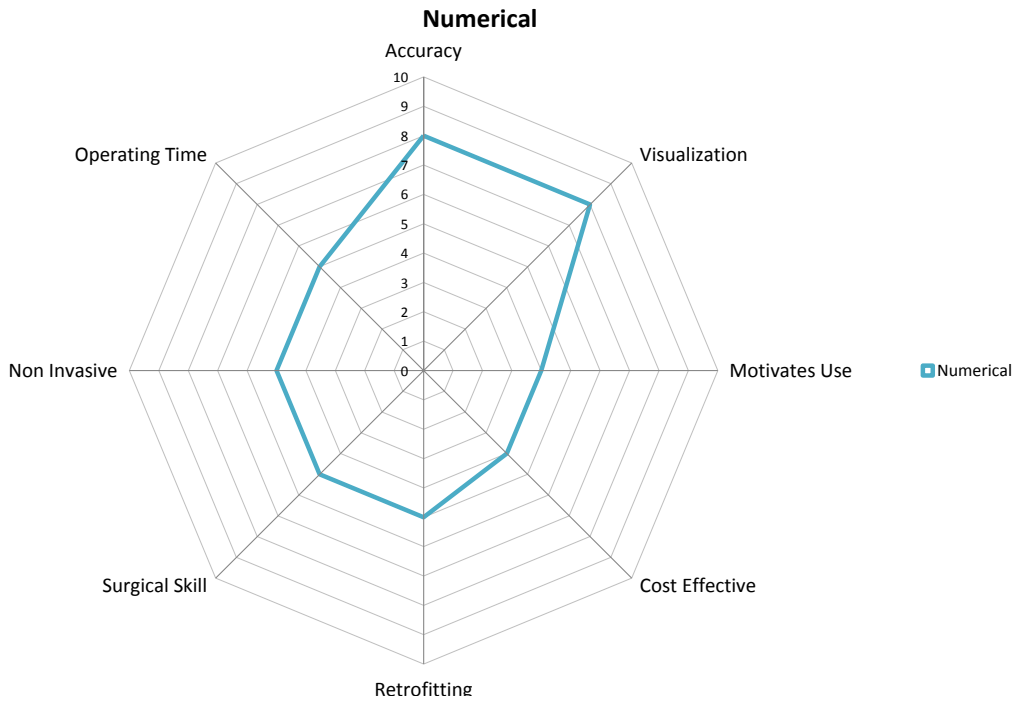
Numerical
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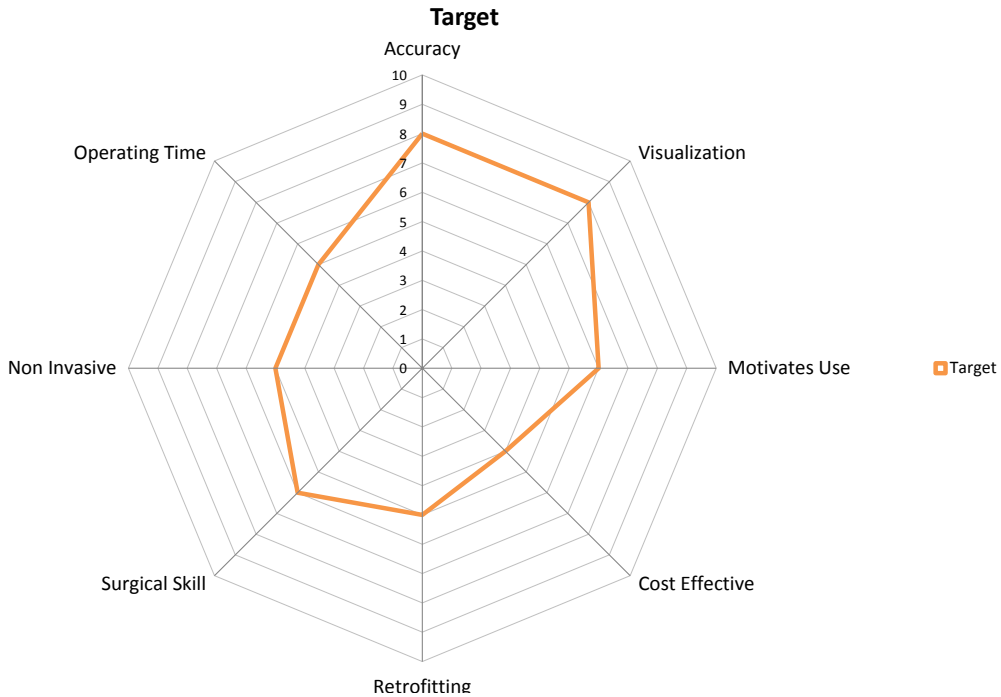
Numerical



9.3.4 Feedback on Individual Concepts

Jig	Target Area
Good for cemented	Shows the surgeon the correct position
Nice	Gives specific area to focus on
Could be used for the reamer & other instruments	Viewing the angles on the one plane
Surgeon just needs to focus on anteversion angles	Real-time feedback to surgeon on the positio
Focus off surgeon	Clear
Rests in the correct position	Unambiguous
Adjustable to desired angle	Easier to ignore green
Would leave surgeons hands free	Relying on the device, not surgical skill
Introducing more error into the measurement	Surgeon is looking at device NOT surgical site
Jig set up time	How do you measure the angle?
Movement of jig during operation	How do you calibrate the device?
Requires better design	Self monitoring
Could be in way during an emergency	Visual
Addition/ Obstruction to surgical technique?	Defauls
How would you position the jig correctly?	Cognitive
How is the jig held in place on the operating table?	
Steadiness?	
Could it be part set up before operation?	
Defaults	
Architechtural	

Projection

Using parallel lines rather than judging angles
Clearly shows the angle of the devvice

Simple and easy to use

Real time feedback
Easy and cheap
Independent of other factors

Needs to be at a set anteversion
Difficult to see the light

Requires a reference plane?
Separate projection of the longitudinal axis?

Requires projection straight down to show inclination?

The lighting in the room may influence visibility?
Can you have too perfect alignment??

Visual
Architechtural

Longitudinal Axis

Displays where the longitudinal axis of patient is
Adjustable to individual patient

Vacuum splint included to combine with patient position

Inelegant
Power for the LEDs
Patient movement intra-operatively
Could be in way during an emergency
Relative movement of frame and patient

Attachment to patient?
Do LEDs shine through the drapes?

Moved at an angle not 90 degrees to the patient position?

How and where will it be fixed to patient and table?
Drapes?

Visual
Architechtural

Drapes

Cheap
Easy

Using existing equipment

Can be clearly seen intraoperatively
Provides a clear guideline and reference

Reliant on the nurse setting up correctly
Accuracy
Movement of the draps
Adding to surgical procedure

How is this aligned to the patient?

What landmarks are used?
Reliant on accurate position may stop surgeon focusing on actual patient position?

Architechtural

Numerical Visualization

Colour coded indicator
There is an exact number to aim for

Shows the surgeon the precise angle

Wireless? How does this influence other equipment
Surgeon is looking at the device NOT the surgical site

Could record angles?
Is it necessary?
Attachment to device?
How do you measure the angles?
Could there be talking angles?

Persuasive

Social Proof
Surveillance

Vacuum Splint

Attachment for body and lower leg
Nurses control pressure

Adjustable

Good for patient variability

Needs to be easily moved away
Could get in the way in emergency
Attachment to the table

How do you control the pressure?
How do you ensure the correct position?
What impact on the spinal column?

Architechtural

Plumbline Protractor

Clear Visual
Using gravity

Good for inclination

Anteversion wrong
Displays angles on two separate planes
Deals with the two angles separately

Requires pivot, not rotation?
Needs external reference point?

Prominence & visibility
Self monitoring

Hip Orthosis

Reduces hip movement intra-operatively
Provides stable attachement

Discomfort for the patient

Patient individuality = high cost
Obstruction to surgery, may get in the way

Skin movement?
How will it be fixed?
How accurate can the markers to the ASIS and PSIS be?

Architechtural
Interlock

Spirit Level

Surgeon can set the desired angle
Clear indication of the angle is set to 45 degrees

Simple for inclination

Still displaying angles on two separate planes
Doesn't show the surgeon the angle the device is at
Aligning with the patient, not the table

Requires external reference?

Metaphors/ Visual
Self monitoring

Pelvic Tilt Calculator

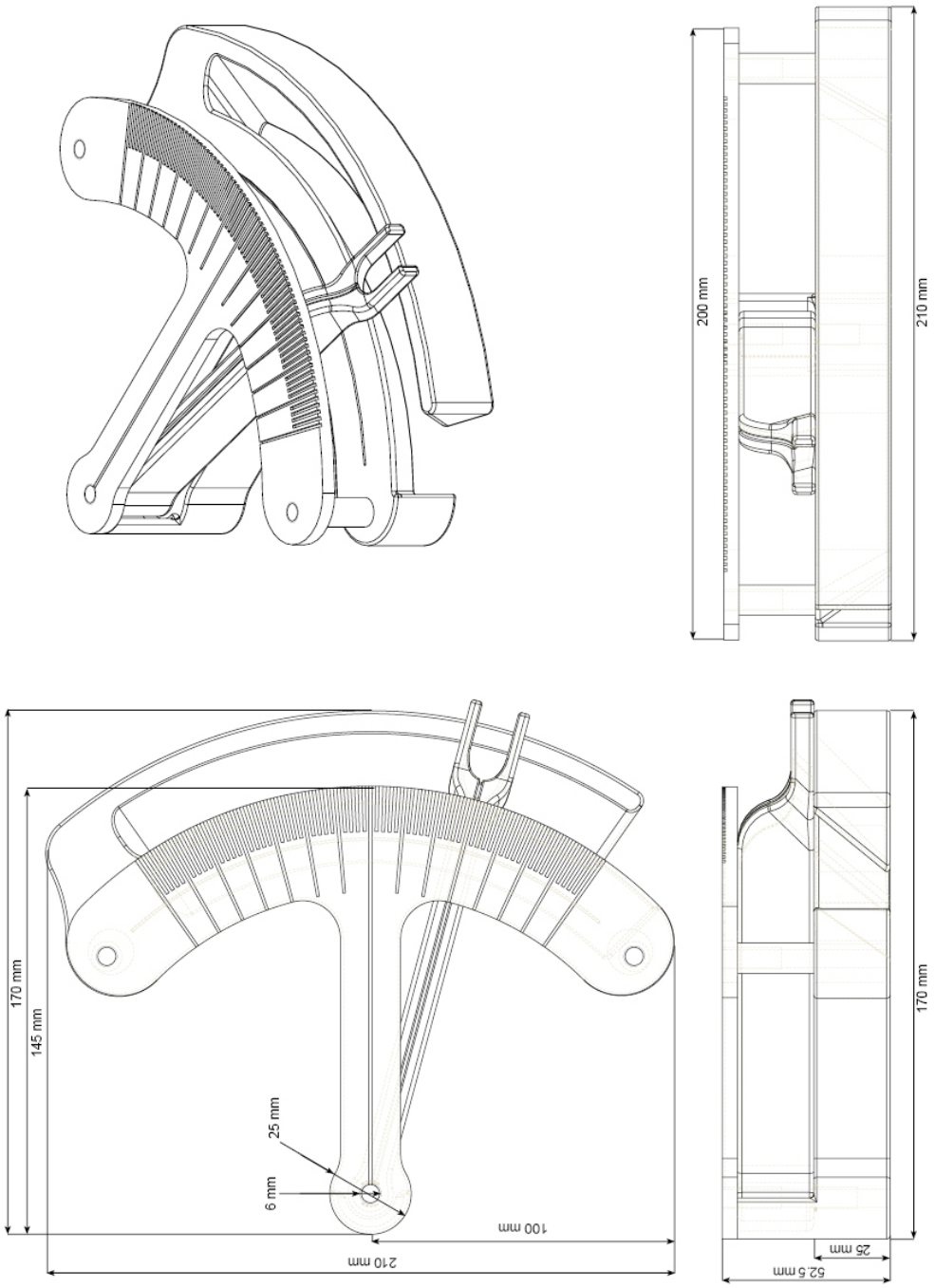
Pre-op assessment
Highlights the pelvic tilt angle

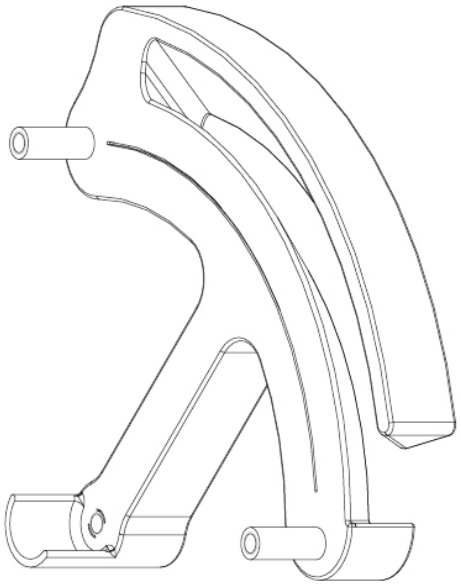
Patient privacy

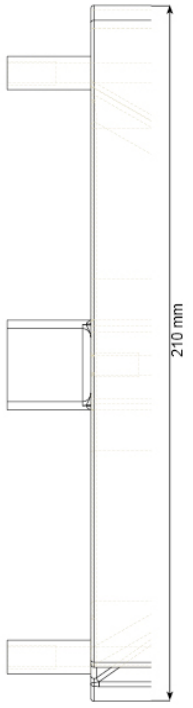
What happens to all the data?
Is a mobile phone always available?
Differences between PT standing and lying down
Accuracy - palpation?

How does the PT effect surgery?
How do you measure the distances?

9.4 Engineering Drawings of Device



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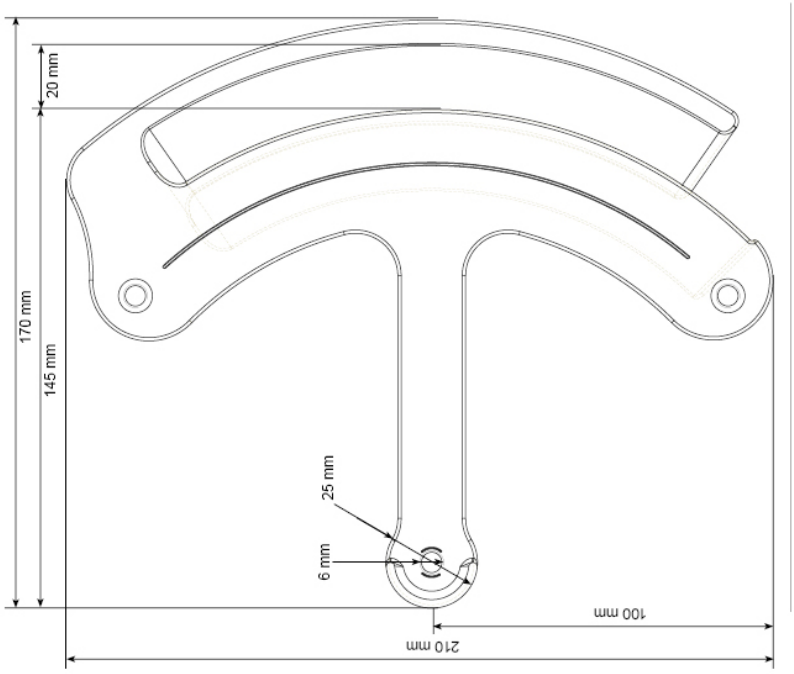
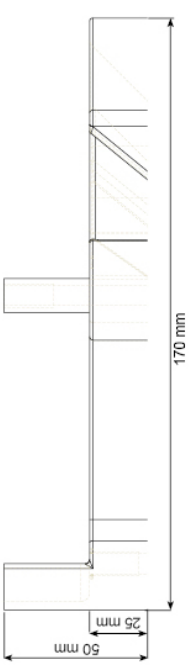
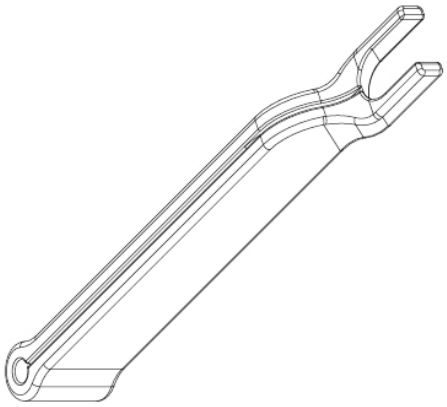
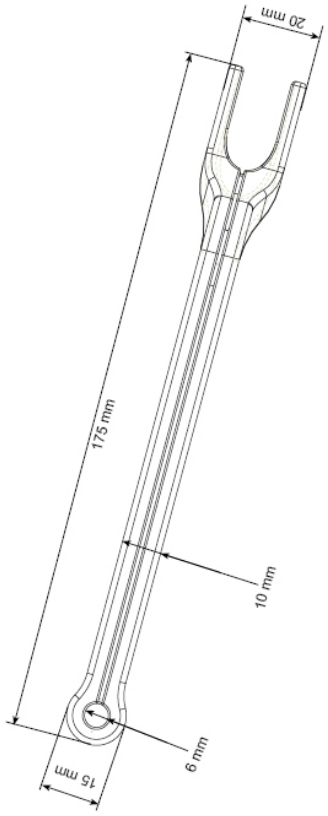
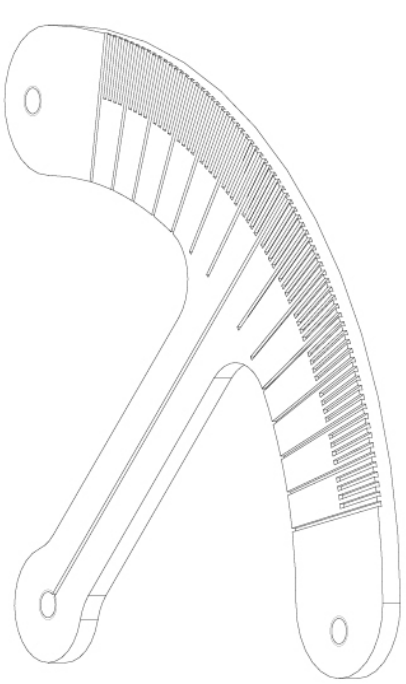

20 mm
170 mm
145 mm
25 mm
6 mm
100 mm
210 mm


170 mm
25 mm
50 mm

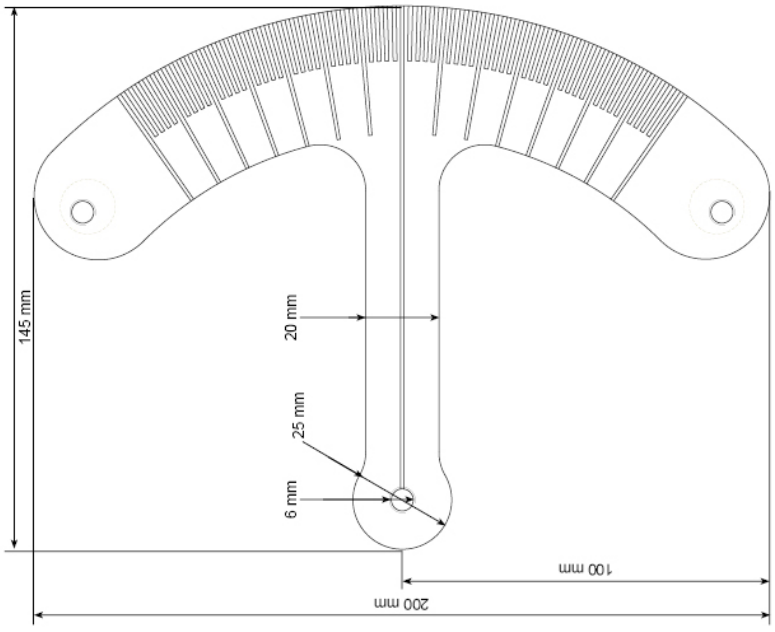


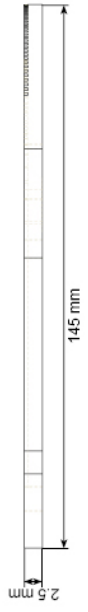

20 mm
175 mm
10 mm
6 mm
15 mm


7.5 mm
25 mm




200 mm
2.5 mm


145 mm
20 mm
25 mm
6 mm
100 mm
200 mm


145 mm
2.5 mm

9.5 Tables for Statistical Analysis

9.5.1 Clinical Experience

Variable	Compared Values	dof, dof	F1	Significance
Average Position	Freehand vs Developed Device	4,4	0.72	p > 0.05
	Mechanical Guide vs Developed Device	4,4	0.83	p > 0.05
Standard deviations	Freehand vs Developed Device	4,4	29.91	**p < 0.01**
	Mechanical Guide vs Developed Device	4,4	20.43	**p < 0.01**
$(4,4)F_{\alpha=0.10} = 4.11 \quad (4,4)F_{\alpha=0.05} = 6.39 \quad (4,4)F_{\alpha=0.01} = 15.98$				

Table 9.1 Standard Deviation – Average Inclination Angles - Clinical

Variable	Compared Values	dof, dof	F1	Significance
Error from desired position	Freehand vs Developed Device	4,4	4.72	p > 0.05
	Mechanical Guide vs Developed Device	4,4	1.36	p > 0.05
Standard deviations	Freehand vs Developed Device	4,4	33.83	**p < 0.01**
	Mechanical Guide vs Developed Device	4,4	10.50	**p < 0.05**
$(4,4)F_{\alpha=0.10} = 4.11 \quad (4,4)F_{\alpha=0.05} = 6.39 \quad (4,4)F_{\alpha=0.01} = 15.98$				

Table 9.2 Standard Deviation – Deviation from desired inclination position - Clinical

Variable	Compared Values	dof, dof	F1	Significance
Average Position	Freehand vs Developed Device	4,4	0.77	p > 0.05
	Mechanical Guide vs Developed Device	4,4	0.99	p > 0.05
Standard deviations	Freehand vs Developed Device	4,4	25.78	**p < 0.01**
	Mechanical Guide vs Developed Device	4,4	8.49	**p < 0.05**
$(4,4)F_{\alpha=0.10} = 4.11 \quad (4,4)F_{\alpha=0.05} = 6.39 \quad (4,4)F_{\alpha=0.01} = 15.98$				

Table 9.3 Standard Deviation – Average Anteversion Angles - Clinical

Variable	Compared Values	dof, dof	F1	Significance
Error from desired position	Freehand vs Developed Device	4,4	2.08	p > 0.05
	Mechanical Guide vs Developed Device	4,4	1.93	p > 0.05
Standard deviations	Freehand vs Developed Device	4,4	16.21	**p < 0.01**
	Mechanical Guide vs Developed Device	4,4	3.42	p > 0.05
$(4,4)F_{\alpha=0.10} = 4.11 \quad (4,4)F_{\alpha=0.05} = 6.39 \quad (4,4)F_{\alpha=0.01} = 15.98$				

Table 9.4 Standard Deviation – Deviation from desired anteversion position – Clinical

Inclination				
Variable	Compared Values	dof, dof	F1	Significance
Deviation (start to end)	Freehand vs Developed Device	4,4	28.54	**p < 0.01**
	Mechanical Guide vs Developed Device	4,4	42.78	**p < 0.01**
Standard deviations	Freehand vs Developed Device	4,4	25.83	**p < 0.01**
	Mechanical Guide vs Developed Device	4,4	36.43	**p < 0.01**
$(4,4)F_{\alpha=0.10} = 4.11 \quad (4,4)F_{\alpha=0.05} = 6.39 \quad (4,4)F_{\alpha=0.01} = 15.98$				

Table 9.5 Standard Deviation – Difference between start and end position – Inclination – Clinical

Anteversion				
Variable	Compared Values	dof, dof	F1	Significance
Deviation (start to end)	Freehand vs Developed Device	4,4	22.01	**p < 0.01**
	Mechanical Guide vs Developed Device	4,4	13.18	**p < 0.05**
Standard deviations	Freehand vs Developed Device	4,4	521.92	**p < 0.01**
	Mechanical Guide vs Developed Device	4,4	33.93	**p < 0.01**
$(4,4)F_{\alpha=0.10} = 4.11 \quad (4,4)F_{\alpha=0.05} = 6.39 \quad (4,4)F_{\alpha=0.01} = 15.98$				

Table 9.6 Standard Deviation –Difference between start and end position – Anteversion – Clinical

9.5.2 Non-clinical Experience

Variable	Compared Values	dof, dof	F1	Significance
Average Position	Freehand vs Developed Device	8,8	1.15	p > 0.05
	Mechanical Guide vs Developed Device	8,8	1.05	p > 0.05
Standard deviations	Freehand vs Developed Device	8,8	10.12	**p < 0.01**
	Mechanical Guide vs Developed Device	8,8	9.71	**p < 0.01**
$(8,8)F_{\alpha=0.10} = 2.59 \quad (8,8)F_{\alpha=0.05} = 3.44 \quad (8,8)F_{\alpha=0.01} = 6.03$				

Table 9.7 Standard Deviation – Average angles – Inclination – non clinical

Variable	Compared Values	dof, dof	F1	Significance
Error from desired position	Freehand vs Developed Device	8,8	1.43	p > 0.05
	Mechanical Guide vs Developed Device	8,8	0.67	p > 0.05
Standard deviations	Freehand vs Developed Device	8,8	11.78	**p < 0.01**
	Mechanical Guide vs Developed Device	8,8	8.42	**p < 0.01**
$(8,8)F_{\alpha=0.10} = 2.59 \quad (8,8)F_{\alpha=0.05} = 3.44 \quad (8,8)F_{\alpha=0.01} = 6.03$				

Table 9.8 Standard Deviation – Average deviation from desired position – Inclination – non-clinical

Variable	Compared Values	dof, dof	F1	Significance
Average Position	Freehand vs Developed Device	8,8	0.89	p > 0.05
	Mechanical Guide vs Developed Device	8,8	1.73	p > 0.05
Standard deviations	Freehand vs Developed Device	8,8	19.24	**p < 0.01**
	Mechanical Guide vs Developed Device	8,8	13.95	**p < 0.01**
$(8,8)F_{\alpha=0.10} = 2.59 \quad (8,8)F_{\alpha=0.05} = 3.44 \quad (8,8)F_{\alpha=0.01} = 6.03$				

Table 9.9 Standard Deviation – Average angles – Anteversion – Non-clinical

Variable	Compared Values	dof, dof	F1	Significance
Error from desired position	Freehand vs Developed Device	8,8	0.89	p > 0.05
	Mechanical Guide vs Developed Device	8,8	1.73	p > 0.05
Standard deviations	Freehand vs Developed Device	8,8	19.24	**p < 0.01**
	Mechanical Guide vs Developed Device	8,8	13.95	**p < 0.01**
$(8,8)F_{\alpha=0.10} = 2.59 \quad (8,8)F_{\alpha=0.05} = 3.44 \quad (8,8)F_{\alpha=0.01} = 6.03$				

Table 9.10 Standard Deviation – Average deviation from desired position – Anteversion – Non-clinical

Inclination				
Variable	Compared Values	dof, dof	F1	Significance
Deviation (start to end)	Freehand vs Developed Device	8,8	14.90	**p < 0.01**
	Mechanical Guide vs Developed Device	8,8	20.53	**p < 0.01**
Standard deviations	Freehand vs Developed Device	8,8	3.28	p > 0.05
	Mechanical Guide vs Developed Device	8,8	8.63	**p < 0.01**
$(8,8)F_{\alpha=0.10} = 2.59 \quad (8,8)F_{\alpha=0.05} = 3.44 \quad (8,8)F_{\alpha=0.01} = 6.03$				

Table 9.11 Standard Deviation –Difference between start and end position – Inclination – Non-clinical

Anteversion				
Variable	Compared Values	dof, dof	F1	Significance
Deviation (start to end)	Freehand vs Developed Device	8,8	71.98	**p < 0.01**
	Mechanical Guide vs Developed Device	8,8	32.13	**p < 0.01**
Standard deviations	Freehand vs Developed Device	8,8	104.72	**p < 0.01**
	Mechanical Guide vs Developed Device	8,8	43.08	**p < 0.01**
$(8,8)F_{\alpha=0.10} = 2.59 \quad (8,8)F_{\alpha=0.05} = 3.44 \quad (8,8)F_{\alpha=0.01} = 6.03$				

Table 9.12 Standard Deviation – Difference between start and end position – Anteversion – Non-clinical

9.5.3 Comparison between the groups

Inclination				
Variable	Compared Values	dof, dof	F1	Significance
Average angles	Freehand	4,8	0.75	p > 0.05
	Mechanical Guide	4,8	0.96	p > 0.05
	Developed Device	4,8	1.22	p > 0.05
Standard deviations	Freehand	4,8	1.98	p > 0.05
	Mechanical Guide	4,8	1.42	p > 0.05
	Developed Device	4,8	0.67	p > 0.05
	$(4,8)F_{\alpha=0.10} = 2.81$ $(4,8)F_{\alpha=0.05} = 3.84$ $(4,8)F_{\alpha=0.01} = 7.01$			

Table 9.13 Standard Deviation – Comparison of average angles - Inclination

Anteversion				
Variable	Compared Values	dof, dof	F1	Significance
Average angles	Freehand	4,8	0.51	p > 0.05
	Mechanical Guide	4,8	0.80	p > 0.05
	Developed Device	4,8	0.82	p > 0.05
Standard deviations	Freehand	4,8	1.80	p > 0.05
	Mechanical Guide	4,8	1.22	p > 0.05
	Developed Device	4,8	1.85	p > 0.05
	$(4,8)F_{\alpha=0.10} = 2.81$ $(4,8)F_{\alpha=0.05} = 3.84$ $(4,8)F_{\alpha=0.01} = 7.01$			

Table 9.14 Standard Deviation - Comparison of average angles - Anteversion

Inclination				
Variable	Compared Values	dof, dof	F1	Significance
Error from desired position	Freehand	4,8	3.02	p > 0.05
	Mechanical Guide	4,8	1.85	p > 0.05
	Developed Device	4,8	0.92	p > 0.05
Standard deviations	Freehand	4,8	1.96	p > 0.05
	Mechanical Guide	4,8	0.23	p > 0.05
	Developed Device	4,8	0.01	p > 0.05
	$(4,8)F_{\alpha=0.10} = 2.81$ $(4,8)F_{\alpha=0.05} = 3.84$ $(4,8)F_{\alpha=0.01} = 7.01$			

Table 9.15 Standard Deviation – Comparison of error from desired position – Inclination

Anteversion				
Variable	Compared Values	dof, dof	F1	Significance
Error from desired position	Freehand	4,8	0.88	p > 0.05
	Mechanical Guide	4,8	0.42	p > 0.05
	Developed Device	4,8	0.38	p > 0.05
Standard deviations	Freehand	4,8	1.34	p > 0.05
	Mechanical Guide	4,8	1.09	p > 0.05
	Developed Device	4,8	1.59	p > 0.05
$(4,8)F_{\alpha=0.10} = 2.81 \quad (4,8)F_{\alpha=0.05} = 3.84 \quad (4,8)F_{\alpha=0.01} = 7.01$				

Table 9.16 Standard Deviation - Comparison of error from desired position - Anteversion

Inclination				
Variable	Compared Values	dof, dof	F1	Significance
Deviation from start to end	Freehand	4,8	1.90	p > 0.05
	Mechanical Guide	4,8	2.06	p > 0.05
	Developed Device	4,8	0.99	p > 0.05
Standard deviations	Freehand	4,8	2.12	p > 0.05
	Mechanical Guide	4,8	1.14	p > 0.05
	Developed Device	4,8	0.30	p > 0.05
$(4,8)F_{\alpha=0.10} = 2.81 \quad (4,8)F_{\alpha=0.05} = 3.84 \quad (4,8)F_{\alpha=0.01} = 7.01$				

Table 9.17 Standard Deviation – Comparison between start and end - Inclination

Anteversion				
Variable	Compared Values	dof, dof	F1	Significance
Deviation from start to end	Freehand	4,8	1.21	p > 0.05
	Mechanical Guide	4,8	1.63	p > 0.05
	Developed Device	4,8	3.97	p > 0.05
Standard deviations	Freehand	4,8	5.56	**p < 0.05**
	Mechanical Guide	4,8	0.87	p > 0.05
	Developed Device	4,8	1.12	p > 0.05
$(4,8)F_{\alpha=0.10} = 2.81 \quad (4,8)F_{\alpha=0.05} = 3.84 \quad (4,8)F_{\alpha=0.01} = 7.01$				

Table 9.18 Standard Deviation – Comparison between start and end – Anteversion

9.5.4 Combined results

Variable	Compared Values	dof, dof	F1	Significance
Average Position	Freehand vs Developed Device	13,13	2.36	p > 0.05
	Mechanical Guide vs Developed Device	13,13	0.89	p > 0.05
Standard deviations	Freehand vs Developed Device	13,13	17.84	**p < 0.01**
	Mechanical Guide vs Developed Device	13,13	8.99	**p < 0.01**
$(13,13)F_{\alpha=0.05} = 2.58 \ (13,13)F_{\alpha=0.01} = 3.91$				

Table 9.19 Standard Deviation – Average angle – Inclination

Inclination				
Variable	Compared Values	dof, dof	F1	Significance
Error from desired position	Freehand vs Developed Device	13,13	2.35	p > 0.05
	Mechanical Guide vs Developed Device	13,13	0.89	p > 0.05
Standard deviations	Freehand vs Developed Device	13,13	3.28	**p < 0.05**
	Mechanical Guide vs Developed Device	13,13	8.63	**p < 0.01**
$(13,13)F_{\alpha=0.05} = 2.58\ (13,13)F_{\alpha=0.01} = 3.91$				

Table 9.20 Standard Deviation – Error from desired position - Inclination

Variable	Compared Values	dof, dof	F1	Significance
Average Position	Freehand vs Developed Device	13,13	1.15	p > 0.05
	Mechanical Guide vs Developed Device	13,13	1.78	p > 0.05
Standard deviations	Freehand vs Developed Device	13,13	17.81	**p < 0.01**
	Mechanical Guide vs Developed Device	13,13	11.88	**p < 0.01**
$(13,13)F_{\alpha=0.05} = 2.58\ (13,13)F_{\alpha=0.01} = 3.91$				

Table 9.21 Standard Deviation – Average angle - Anteversion

Anteversion				
Variable	Compared Values	dof, dof	F1	Significance
Error from desired position	Freehand vs Developed Device	13,13	1.15	p > 0.05
	Mechanical Guide vs Developed Device	13,13	1.78	p > 0.05
Standard deviations	Freehand vs Developed Device	13,13	17.82	**p < 0.01**
	Mechanical Guide vs Developed Device	13,13	11.88	**p < 0.01**
$(13,13)F_{\alpha=0.05} = 2.58\ (13,13)F_{\alpha=0.01} = 3.91$				

Table 9.22 Standard Deviation – Error from desired position - Anteversion

Inclination				
Variable	Compared Values	dof, dof	F1	Significance
Error from desired position	Freehand vs Developed Device	13,13	19.24	**p < 0.01**
	Mechanical Guide vs Developed Device	13,13	27.51	**p < 0.01**
Standard deviations	Freehand vs Developed Device	13,13	6.22	**p < 0.01**
	Mechanical Guide vs Developed Device	13,13	12.43	**p < 0.01**
$(13,13)F_{\alpha=0.05} = 2.58\ (13,13)F_{\alpha=0.01} = 3.91$				

Table 9.23 Standard Deviation – Start to end - Inclination

Anteversion				
Variable	Compared Values	dof, dof	F1	Significance
Error from desired position	Freehand vs Developed Device	13,13	42.15	**p < 0.01**
	Mechanical Guide vs Developed Device	13,13	21.14	**p < 0.01**
Standard deviations	Freehand vs Developed Device	13,13	157.77	**p < 0.01**
	Mechanical Guide vs Developed Device	13,13	25.61	**p < 0.01**
$(13,13)F_{\alpha=0.05} = 2.58 \ (13,13)F_{\alpha=0.01} = 3.91$				

Table 9.24 Standard Deviation – Start to end - Anteversion

9.6 Surgeon Interviews

9.6.1 Interview 1

C: Would mind telling me what you thought about the developed device. Did you find it useful? Which did you prefer out of the three?

S1: It basically takes all the variability out of it once you've set it. The main thing is obviously it's a bit unrealistic given that an operating theatre would need set up. Given things such as laminar flow, air coming down eh, how you would attach it to the eh actual operating table and obviously with the variability in patient sizes, eh, because you will have anything from eh BMI patients from 15 up to 40 and things like this also various pelvic widths. But from the actual point of when you actually slot it in and adjust it, it seemed to rigidly hold it. It did seem to take all the variability out of it so you were just applying the pressure on it. Erm, any others which maintain the force which maintains the pressurisation. You could see how it would help with trainees as well to help with thinking about it aswell. It's just going from the concept to the practicality that I can see as the challenge of it.

C: What do you think are the disadvantages of the device?

S1: I mean it doesn't block your view so that's good because some of the things. It's just, the disadvantage is just how are you going to get that to slot in because it's a bit cumbersome at the moment and your, with the wound, I can that you are going to have to look at cadaveric type things to see how the muscles get in the way aswell because at the moment you are having to slot it in to get into that bit outwith the arc that it's maintained like that so erm, yeah, that. It's really going to be how you initially introduce it. But there may be ways getting round that, you get, from some of the surgery we have done for minimally invasive, they've created handles, like introducing handles so it may be something that you could have that because you will want to have where the cup goes and that the bit where you are controlling it guided in. Whatever wee bit needs to be a straight line in between those, you may be able to do something that has a bend in it to accommodate the wound so that you are not catching on it to begin with so it's something that you can maybe look at. So maybe having a look at minimally invasive type introduction type handles because I say they are usually in the shape of a crank handle, to get past the wound so it might be something that. That's the principle thing.

C: What about advantages?

S1: Well the advantage is once you put it there, it's holding it for you. It's like having a very excellent medical student assisting or a registrar who doesn't ask any questions but just holds it as it should be. So, erm yeah, if the practicalities could be overcome it does have the advantage that you erm would be pretty much reproducible from what I can see because it doesn't feel like it's shifting at all and I'm sure you will be able to verify that with the results.
C: And would you use it in surgery if that was the case?
If the practicality of it, I could even see it being quite important in cementless cups particularly erm because the cemented ones obviously are probably going to come back in but the cementless one you are tapping them in and there is a little asperity in the bone and it throws you off at the last instant and that wouldn't allow you to do that so I could see perhaps even for the cementless ones being even more advantageous to a certain extent so because even if you are tapping it you can only go in the one trajectory with it so it could well be actually quite useful for the cementless ones so things like hip resurfacing where we don't, you can't do a cemented cup I can see it might be useful and hip resurfacing is one of the ones where orientation is critical because you get the high metal ions and stuff like that.
C:Thank you very much, that is great thanks

9.6.2 Interview 2

C: What did you think about the device, did it help you in positioning the acetabular cup?
S2: Yes it is quite simple to use which I think is important and it appears that it would be reproducible, erm I think particularly, I suppose it has to be referenced properly with respect to the patient positioning but erm I overall found it a simple and easy to use device.
C: Are there any clear advantages to the device that you can think of from using it as opposed to current methods?
S2: Erm I think the stability of it, because the current methods rely on, you've got on the introducer device you've got something that you are just having to eyeball and you are having to judge what is perpendicular and also 15 degrees or whatever you choose, whatever your target is. So human error in that so this feels more robust and also good because it gives some stability so once choose that position it is easy to maintain that and avoid drifting. You can actually go into significant error, once

you choose, you choose that initial position and you are happy with it then it seems to hold which I think is a good feature.
C: Any disadvantages, any issues that you think should be addressed?
S2: Erm I was trying to think of disadvantages as I was using it and erm without having seen the final device, I think the actual erm the bits that, erm the actual measurement guide, the attachment to it will be important so if you have some simple device that clamps onto the table is on some kind of arm and obviously not knowing what you are developing, that would be the key thing that has to be really easy to move around. You don't want it to be, often it can be an issue. When you are setting up a patient for hip replacement, most patients, most surgeons will have the patient on their side. You go to great lengths to get that position and there are various attachments front and back and there are also attachments the anaesthetists have to, so to then add an additional attachment it would, it can't be in any way cumbersome again or get in the way so I think. In a way in it's not really a disadvantage but have it, when you introduce something additional. It's not getting, I mean there are other things, there are assistants and you all have your space round the table.

C: What about do you think it would be useful for training less experienced surgeons?
S2: Yes absolutely because what trainees lack to begin with, is they don't have experience and erm so it's hard for them to judge and if you are assisting, sorry, if you are training a junior surgeon then it usually involves you have to switch sides and suddenly things look different. If you are used to standing in the one place and you kind of learn, you know roughly what is right and things look different when you change position so this in a way would be, is a good thing to have because it is like a safety check because it is one of the most important aspects of hip replacement in terms of dislocation. It's the acetabular cup orientation and I find that, as a relatively junior consultant, new consultant with trainees, I'm quite reluctant to let go and let them do it and so this is, this gives you that reassurance. That you can actually physically see what they are doing so yeah.
C: And would you use it?
S2: Yeah, I would as I'm sure most hip surgeons do, is put really, a lot of effort into , to position things accurately I mean that's, with the cup. As I've said before it starts with the absolute precise positioning of the patient, you go to great lengths to,

because it is so important I think it is something I would use. I would certainly be willing to use it and see how it was. Yeah, it's something I would try.
C:Thank you very much, thank you for all your help

9.6.3 Interview 3

C: How did you find the guide, in comparison to the other methods?
S3: It's easier to hold it steady I would guess but I think the whole set up is slightly false because it's not an introducer that you would use with a cemented cup. It's an uncemented introducer which has a different design so it's a false setting. I would never hold that introducer for more than about 10 seconds in an uncemented setting and two minutes in a cemented setting so to hold it for 5 minutes with a different setter is very arbitrary but yes it holds it steady.
C: Would you think it useful for uncemented cups in terms of limiting any movement of the introducer?
S3: Erm it might, some of the designs, they hold their direction very well. You hit it in that direction and it goes that way. With some of the other companies, it can tend to waver a small amount so it might help in that setting. But again, as you get more experienced that is probably a non issue for uncemented, I would argue. I think for somebody, the junior surgeons perhaps but I'm not convinced.
C: That was going to be my next question, do you think it would be helpful or useful for training purposes?
S3: Possibly in a cemented setting for the junior surgeons but again having an introducer in isolation without something telling you where the pelvis is, is meaningless. You can get it perfectly steady and in perfect position but if you don't know the position of the pelvis that's meaningless. So in isolation, it's pointless you have to know where the pelvis is.
C: Do you see any clear advantages or disadvantages to the developed device?
S3: I'm not convinced I can see obvious advantages to it erm because we only hold the introducer for barely two minutes. Once we've got the position, we take the introducer off and then we've got a pusher that's not attached to the socket, the position has been determined by that point. And the introducers are much easier to hold for that two minutes than that introducer is to hold for any length of time because they are designed with use with cement rather that that's designed for use with an uncemented socket. It's not designed to be held for 5 minutes.
C:Thank you very much for your time.

9.6.4 Interview 4

C: What did you think about the guide in comparison to the other methods?
S4: Erm, it was very easy to use on the model, less tiring to use because it did allow you to lean on it a bit so yip seemed to work but I have the question as to how you are going to get the alignment in the operating room. How you are going to fix that to the patient and also it does then fix you to put the cup in a position exactly where that says which might not always be the correct position for that patient. That is my only concern is that, like computer navigation and everything else you are prescribing a certain position for something that perhaps might not be appropriate for that position.
C: Is there any advantages you can see over current methods?
S4: Eh yeah, as I said it is easier to use and less tiring to use
C: Any disadvantages?
S4: How are you going to fix it to the patient? How are you going to set the patient up to ensure that the positon you fix it to the patient is correct and how are you going to ensure that that position that it is telling you is the correct position? Because if any of those two preceding things are incorrect then you will put it in where it tell you to go rather than where it should be.
C: Do you think, would you use it in surgery or do you think it would be useful for training less experienced surgeons?
S4: Training yes, I think that is very useful both actually on the dry bone model itself as you have done there and in cadaveric simulation and real life. But it's got to be cheap. It's got to be able to be cleaned and it's got to be disposable and it's got to be very very cheap and then you've got your pins and potential morbidity of pin sights.
C: Are there any additions that you would make to the device?
S4: No, erm not to the idea itself but it is everything else that goes along with that that we've discussed. Things behind it like how are you going to fix it to the patient?
C: Great, thank you very much for all your help.

9.6.5 Interview 5

C: How did you find using the guide?
S5: I thought that it was okay, I was a little bit worried about that little bit of vibration within the hole. It wobbled a bit in there. I'm a bit concerned about the breadth of the

arm might make it obtrusive in the operating theatre environment. If you had something more narrow but you might get more vibration. Having said that look at the distance the arm is from the clamps, that is much further than it would be in an operating theatre. It'd be about half that distance so the lever arm, you've got less vibration. I think the degree thing is obviously going to be extremely accurate if not perfect with the 15 and 45 degree thing. The main problem you are going to have is orientating it with respect to the table and getting the patient square on the table which is almost impossible to do with 100% confidence but eh it must take away that error and I think that on its own is advantageous which is what I've always thought from the beginning.

C: What advantages do you see the device having?
S5: Well the thing is, what happens is there will be an error in any system and when its set subjectively there will be, sometimes you get it wrong one way or the other yeah, so what happens then is eh sometimes there will be a tilt in the pelvis and the acetabular introducer will be tilted such that by accident it compensates for it yeah, 5 degree error in one direction but the acetabular introducer is leaning 5 degrees in that direction to compensate, sometimes it will lean 5 degrees in one direction and the introducer in the other way and you have a ten degree error yeah, even probably more than that, 10 degrees on the pelvis easily, 10 degrees on the introducer 20 degrees error which can become alarming yeah, so if you totally eliminate one of the areas although in some circumstances you wouldn't compensate for the error by accident, surely overall by average it must give you a better component positioning. I think the 45 degree thing will be y'know impeccable, eh, because that's an issue because the 45 degree is one of three angles. The 15 degree thing will be dependent on pelvic orientation on the table which you might be able to improve but you will never be able to get perfect.
C: What about any disadvantages that you can see?
S5: Erm, it may get in the way of the system. It may feel that it is obtrusive to them. Erm, people not like the hassle of setting up with the sterile technique and everything in theatre. Erm for research purposes it could to get a paper out of it. If you said to people , y'know, at the Jubilee you are the first people to use this and you can do 50 and get a paper out of it. Remember from their point of view a paper doesn't have to show it works. If it shows it doesn't, they've got a paper. Unless they have a vested interest in it, in terms of economic investment, you could publish

anyway, even if it doesn't work. To a certain extent they will all be supportive, I think, Glasgow research to do a new technique. Erm I think that eh, you probably have people of the opinion well I do that anyway, but even for people who are just beginning who tend to just have a high dislocation rate, say their first year as a consultant. I thought for those people it would em offer em, it would offer a genuine advantage because they don't actually think about that em the angle.
C: Would you want to use the device?
S5: You might want to use it in surgery, em, you might. The other thing I've just thought of for the first time is, can we go back to the model. Can I show you something? I tell you what could go wrong, is that sometimes the soft tissues extent there, when you have this thing you want to go 45 degrees, so at first you need to do this but sometimes what you end up doing is going in like this or like this. At an angle and then rotate it round and that is going to be harder if you've then got to. I suppose that you could swivel this round. You are going to have swivel it round to eh get your thing at 15 degrees that way. Or that is how you would have to do it. That is going to be a bit harder actually. You might have to do it sort of like that. See what I mean, sometimes you. Because just this rod on it's own, the rod you can actually ream that in but sometimes the hole. The access, if it's quite a large acetabular component, you might find it easier to go in like this and then turn over a bit so then you have to find a way to wiggle this into the holder. That might be a practical problem.
C: Finally are there any additions that you would make that you would suggest to the device?
S5: At the moment, I think see if in a lab based scenario, several other surgeons see if it is more precise. I presume it is and then you need someone crazy enough to volunteer to actually use it on patients.
C: Great, thank you.

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