

# **MINIMALLY INVASIVE APPROACH FOR SURGICAL TREATMENT OF PROXIMAL FEMUR FRACTURES**

*by*

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# **ABSTRACT**

Minimally invasive surgery (MIS) is fast becoming a preferred choice for patients and surgeons, due to its biological, aesthetic and commercial benefits. The dynamic hip screw (DHS) is the standard implant for the treatment of fractures of the proximal femur, which is considered to be the most frequent injury in the elderly. The aim of this research was to develop MIS for the treatment of these fractures utilising the principle and surgical technique of the DHS implant. During the research, a thorough medical device design process was conducted to develop three new medical devices – a new angle guide, a new ergonomic T-handle and a new implant. The design process for each of the new medical devices conformed to requirements of the relevant standards. The designs of the new medical devices were verified using methods such as risk analysis, finite element analysis and mechanical testing of manufactured prototype. Finally, an operative technique applying a minimally invasive approach with the new medical devices was developed to treat the fractures of the proximal femur.

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# CHAPTER 1

## INTRODUCTION

Studies have established that hip fractures, also known as fractures of the proximal femur, are considered to be frequent injuries in the elderly (Canale, 2002), and carry a lifetime risk of 15 to 17% amongst women and 5 to 6% in men (Wong *et al.*, 2009; Jewell *et al.*, 2007; Van Staa *et al.*, 2001). Surgery using a dynamic hip screw (DHS) implant is the standard treatment option for the treatment of such fractures (Chirodian *et al.*, 2005; Harrington *et al.*, 2002; Esser *et al.*, 1986).

Minimally invasive surgery (MIS) has proved to be beneficial for a variety of reasons including reduced peri-operative blood loss and aesthetic appeal to the patient due to less scarring (Ho *et al.*, 2008; Peyser *et al.*, 2005). Although it is currently possible to administer MIS for treatment of such fractures, several problems exist in implementing the approach including a steep learning curve for the surgeons (Scuderi and Tria, 2010) and an increase of hospital inventory due to additional instrumentation.

The purpose of this research, initiated by Professor Nicola Maffulli (Professor of Trauma and Orthopaedic Surgery, and Consultant orthopaedic surgeon, The London Independent Hospital, London, UK), was to develop a minimally invasive approach for the treatment of proximal femur fractures. The specific objectives of this research, realised after the feasibility study, were to develop medical devices capable of conducting the MIS procedure with an incision length of not more than 30 mm, and to utilise an operative technique that would be similar to the conventional method used to implant the DHS.

Chapter 2 begins with a description of the stages of a design process of any product. The chapter goes on to present the methodology of the design approach used in this thesis for the development of the new medical devices. This thesis is structured according to the core stages of the design process used in this research.

Chapter 3 presents a feasibility study to identify the specific medical devices that would be redesigned during the course of this research. The study identifies three medical devices, namely the angle guide, the T-handle and the DHS implant, which would aid in establishing a MIS for the proximal femur fractures. This chapter also serves as a background chapter for all three design processes in this thesis.

Chapter 4 marks the beginning of the actual design of the medical devices. Following that, the structure of the thesis is divided into four parts – Chapters 4 to 6 are for the design process of a new angle guide, Chapter 7 describes the development of a new ergonomic T-handle, the new implant design is presented in Chapters 8 and 9, and finally all the new devices are brought together for exhibition in the operative technique for the new implant in Chapter 10, followed by conclusions in Chapter 11.

This research involved three experiments, and they are described in detail in Chapter 5, Chapter 9 and in Appendix A. The results of a test presented in Chapter 5 were useful in selecting the new base material for the new angle guide. The experiment in Chapter 9 follows the guidelines laid out in ASTM F-384 (2006) to assess the strength of the new implant. Appendix A presents a survey conducted at the City General Hospital (Stoke-on-Trent, UK) to assess the surgeon's perspective on the T-handle and the base material of a bone interfacing instrument such as the angle guide. However, due to inconclusive results, the findings were not incorporated into the design process of the new angle guide.

Appendix B provides engineering drawings of model 1 of the new implant, and Appendix C presents the engineering drawings of two additional instruments that were used in the surgical technique for the new implant in Chapter 10.



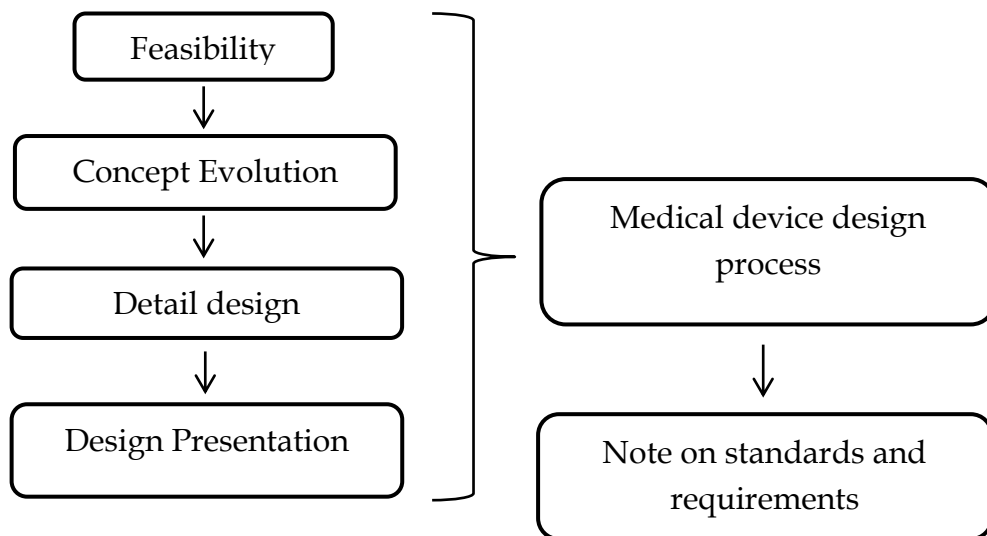
# CHAPTER 2

## MEDICAL DEVICE DESIGN PROCESS

### 2.1 Chapter at a glance

#### 2.1.1. Chapter overview

Figure 2.1 shows the chapter overview in the form of a flowchart.



**Figure 2.1: Flowchart of the chapter structure**

#### 2.1.2. Keywords

Concept design; design verification; medical device design; product design specification; total design approach

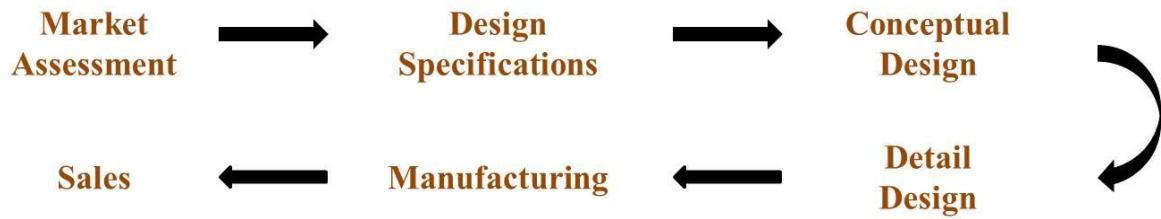
## 2. 2. Introduction

The stages of a medical device design process have to conform to certain requirements as directed by the regulating standard (such as the Medical Device Directive for Europe; Food and Drug Administration (FDA) for USA) to ensure the safety of patients and healthcare staff. The purpose of this chapter is to explain in detail the methodology of the design approach used during the development of three medical devices in this research. The references used to compile the general information in this chapter were Aitchison *et al.* (2009), Childs (2004), O’Leary (2004), Wallace and Clarkson (1999), and Hill (1998).

## 2. 3. Design process

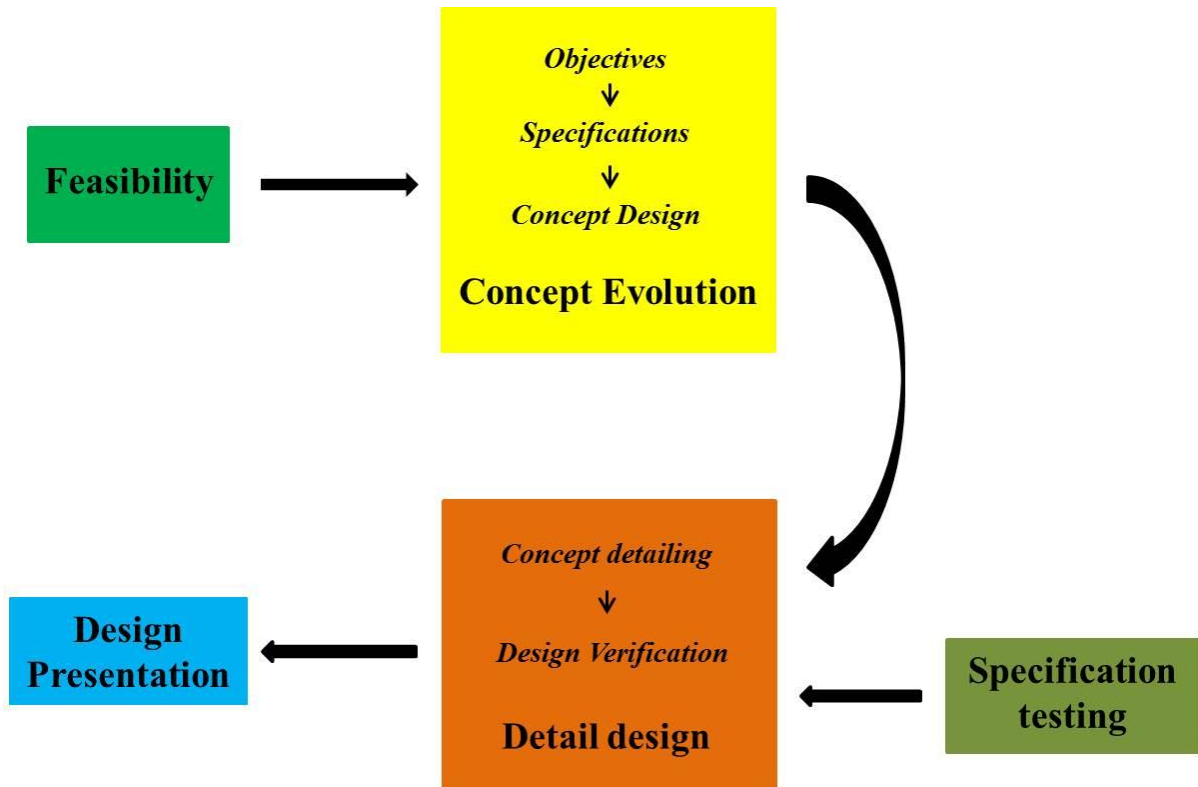
### 2.3.1. Overview

The core activities of the ‘total design’ approach to a generic design process as proposed by Pugh in 1985 are shown in Figure 2.2. The steps of this approach include market assessment, design specifications, conceptual design, detail design, manufacturing and finally sales. It is important to review and revert back to previous stages of the design process to achieve a superior design.



**Figure 2.2: Total design approach proposed by Pugh in 1985**

The purpose of this research was to design new medical devices, and hence the total design approach was modified to implement the structure of this thesis. This research covered design processes of three new medical devices to be used in the same surgery. The design approach used during the development of the medical devices is illustrated schematically in Figure 2.3. The core stages of the design approach used in the thesis were feasibility, concept evolution, detail design and design presentation. Furthermore, “specification testing” stage was added to the above to include experiments conducted for evaluation of certain specifications used in the detail design. In effect, the stages of design specifications and conceptual design from the ‘total design’ approach were combined to form concept evolution; manufacturing and sales from ‘total design’ approach was replaced with design presentation for the context of this thesis. As seen in Figure 2.3, the different stages of the design approach are distinguished by unique colours. Each chapter in this thesis is marked by one of the five representative colours, which facilitates identification of the design stage discussed by the respective chapter.



**Figure 2.3: Design approach utilised for the research presented in this thesis**

The following sections will discuss the design approach used in the thesis in more detail, and will also explain the methodologies that were used during each of the stages and sub-stages.

### 2.3.2. Feasibility

The starting point for any design process is to identify a requirement to be fulfilled. For a medical device, the idea for a new, or an improved product may come from medical staff or from a variety of other sources including the marketing department of a medical device manufacturer. The feasibility study begins with an

assessment of the market for that particular medical device. It is important to establish that the product is commercially viable and to research the market for competition. The feasibility study should also identify the main aspects of the idea, and determine the actual requirements of the product by the market. The study yields the identification of medical devices and their general objectives to achieve a solution for the requirement to be fulfilled.

The feasibility study for the new medical devices is discussed in Chapter 3 of this thesis.

### **2.3.3. Concept Evolution**

#### **2.3.3.1. Overview**

The feasibility stage identifies the market need and general requirements of a medical device. The next step is to transform the general requirements into terse objectives and specifications (often termed as the product design specification) of the new medical device. Several concepts, which are able to combine the set specifications, are generated through brain-storming. The concept which is most effective in achieving the requirements is selected and taken up for further detail design, either through scoring methods or by a panel of experts through feasibility discussions based on factors such as performance and cost. The details of the sub-

stages of stating the specifications and selecting a concept are discussed in the following sections.

Although the step of stating the product design specifications is generally a part of the feasibility study (Aitchison et al., 2009), it was more appropriate for the structure of this thesis to include it in the concept stage, as this research dealt with three medical devices and their respective regulations, but with the same general feasibility study. Specific feasibility studies were carried out, when required, to gather more information for the design process (for example, the new T-handle in Chapter 7) during the research.

#### ***2.3.3.2. Design Objectives***

This step of the process is used to outline specific objectives that are expected of the new medical device. The objectives are used as general guidelines, which are to be adhered by all the specifications of the new concept. For example, the objectives of the new implant designed in Chapters 8 to 10 were to allow for incision of less than 30 mm, retain the principle mechanism of the dynamic hip screw (DHS) implant and retrieve the experience of surgeons by designing a similar surgical procedure as the DHS.

### ***2.3.3.3. Design specifications***

It is an extremely important task to prepare an elaborate and quantified (wherever possible) product design specification (PDS) statement. The PDS captures a framework of the exact requirements, through research and consultation, of the medical device to be designed. The PDS is often referred to throughout the remainder of the process to verify the design.

There are specific standards that were utilised as guides for laying out the specifications for the medical devices designed in this research. The standard BS EN 12011 (1998) has been produced to help identify the requirements for surgical devices which include the intended performance, design attributes and materials amongst other important headings. BS EN ISO 14630 (2009) was used to identify the general requirements of the new implant designed in this research. Furthermore, BS EN ISO 14602 (2010) and BS 3531-15 (1992) state the particular requirements for implants to be used for osteosynthesis and for devices used for fixation of ends of adult femurs. These and additional standards, that will be discussed in later chapters, were used in developing PDS for the new medical devices designed in this research.

#### **2.3.3.4. Concept design**

The first step in this stage involves generation of all the possible solutions that concur with the design specifications laid out. It may be possible that some concepts do not meet all the design requirements. However, these concept designs are not to be discouraged at this point and effective brain-storming could be used to search for the best idea. The concepts are reviewed against the requirements laid out in the PDS to select the final concept either through a scoring method or through discussion on the designs' strengths and weaknesses.

During the design process of the medical devices in this research, some of the generated concepts were considered stepping stones rather than feasible ideas and were excluded from the write-up to maintain the flow and limit the length of this thesis. The concepts were then evaluated subjectively by engineers and a consultant surgeon, Professor N. Maffulli, and chosen on the basis of their suitability and conformity to the PDS and the design objectives.

#### **2.3.4. Specification testing**

Although most specifications for the detailing were obtained through research of publications and existing medical devices, it was also necessary to verify certain solutions to solve a design requirement. During the development of a new angle guide in this thesis, a new base material for the bone-instrument interface was



decided upon through an *in vitro* experiment. The materials and methods of the experiment are discussed in detail in Chapter 5.

### **2.3.5. Detail design**

#### **2.3.5.1. Overview**

The selected final concept should be fully defined during this stage. The detailed design is verified using methods including finite element analysis, risk analysis and mechanical testing. The following sections discuss the sub-stages of developing a detail design and verifying the same.

#### **2.3.5.2. Concept detailing**

The framework developed during the product design specification is reviewed, and the requirements are given specific values and solutions at this stage. Factors that are confirmed at this juncture include specifications of material and drafting of engineering drawing resulting in a detailed concept design with confirmed dimensions and tolerances.

### 2. 3. 5. 3. Design verification

During the design process, the detailed concept could be verified using – a) risk analysis, b) finite element analysis, and c) prototyping.

#### a. Risk Analysis

Risk analysis, a key part of the medical device design process (Shepherd, 2002), aims to identify the hazards associated with the device, and control measures to prevent the hazards. Failure mode and effects analysis (FMEA) is a method that considers all the potential hazards of each component, sub-assembly and final product assembly (Hill, 1998), and was selected for the risk analyses in this research. BS EN ISO 14971 (2009) standard was used as guidance for the application of risk management to the medical devices in this research.

**Table 2.1: Ratings as indicated by occurrence, severity and detection**

Rating	Occurrence, <i>O</i>	Severity, <i>S</i>	Detection, <i>D</i>
1	<1 in 10 <sup>6</sup>	No harm caused	Always visible
2			
3		Not noticed by customer	
4			
5	1 in 100	Noticed by customer	Easily spotted
6			
7		Complain by customer	
8			
9	1 in 2		No detection
10		Product stops functioning	

A risk priority number (RPN), which can be considered as a way of ranking hazards, is calculated by scoring three elements – the frequency of occurrence, O, severity of failure, S, and an ability to detect the failure, D, on a scale of 1 to 10 (Table 2.1) and then multiplying the numbers together (Hill, 1998). The data for estimating risks could be obtained from the literature, clinical evidence, and results of testing or expert opinion. Steps are taken at a further stage of the design process to address the high risks that were identified during this stage. The standard does not define a risk as high or low based on the RPN. It is up to the individual/ company to decide and show that the identified hazards have been reduced to an acceptable risk.

#### *b. Finite Element Analysis*

Finite Element Analysis is a widely used, computer-based, numerical analysis method to understand the mechanics (stresses, displacements, strains) of a physical system (Wayne, 2008). A variety of commercially available packages are able to analyse and process a meshed computer aided design (CAD) model very quickly and economically. In biomedical engineering, the method could be used to verify the load bearing capacity of implants and prosthetic systems. The FEA studies in this project, like the traditional method, followed three stages – pre-processing, analysis and post-processing (Avallone et al., 2007). The process is explained while simultaneously discussing the FEA on the new concept of angle guide in section 5.5.

This method was used in this research to check for presence of excessive bending in the new angle guide (Chapter 6); and to verify if the new implant designed will have sufficient strength to withstand the loading conditions in the human body (Chapter 9).

### c. Prototyping

Manufacture of a prototype is a very effective technique for visually verifying the design of the medical device. Prototypes also enhance and simplify communication between surgeons and engineers.

During this research, a rapid prototyped model of the new angle guide was manufactured to verify the design with surgeons. A prototype of the new implant was also manufactured for verification of the design through static loading and fatigue tests. The presentation of the new angle guide to the surgeons (Chapter 4) and the mechanical tests performed on the new implant (Chapter 9) were able to augment and verify the specifications of the design of the respective medical devices.

#### **2.3.6. Design presentation**

This stage was added to the design process specifically for the purpose of this thesis. The medical devices that were designed in this thesis are presented in

Chapter 10. The presentation highlights the features and states the final detailed specifications of the new medical devices. The chapter also includes an illustrative guide to the surgical technique for the new implant and associated instruments including the new angle guide and the new ergonomic T-handle.

## **2. 4. Note on standards and requirements**

All medical devices should ideally conform to standards, and must have regulatory approval before they can be released into the market. During the design process of the medical devices in this thesis, the standards that the particular medical device is expected to comply with, were mentioned in the product design specification. However, there were certain requirements and standards that have not undergone elaborate explanation owing to the scope of the project. The requirements of manufacturing, packaging and the information to be supplied by the manufacturer were not stated in each of the design processes discussed in the thesis. However, care was taken during the design process so that the medical device would not fail any of the requirements of the standards for manufacturing, packaging or information to be supplied. The medical devices adhered to all the relevant standards stated in their respective requirements.

## **2. 5. Summary**

The summarising points of the chapter are stated below.

- i. The total design approach to a generic design process consists of six stages: market assessment, design specifications, conceptual design, detail design, manufacturing and finally sales.
- ii. The design process used in this thesis was modified to suit medical devices and the structure of this research. The stages of the process include feasibility, concept evolution, detail design and design presentation. The sub-stages were explained in detail in this chapter.
- iii. The stages were assigned a unique colour to help the reader identify each stage of the design process that the chapter deals with. Feasibility is green, concept evolution is yellow, detail design is orange and design presentation is blue.

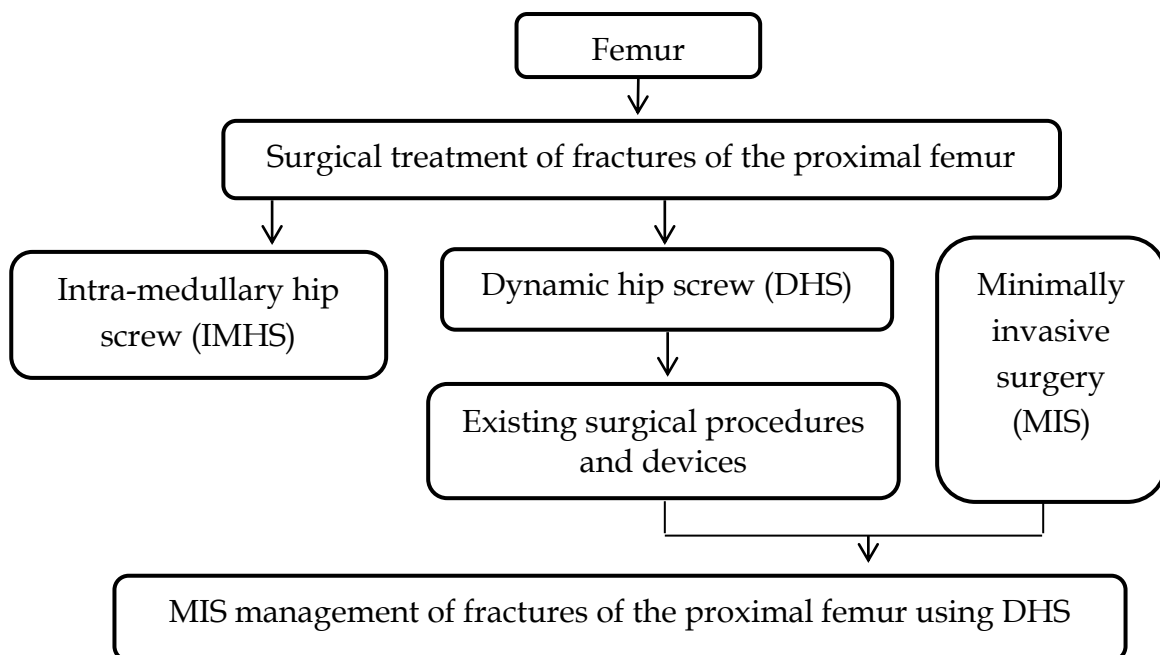
# CHAPTER 3

## FEASIBILITY OF NEW MEDICAL DEVICES FOR HIP FRACTURES

### 3.1 Chapter at a glance

#### 3.1.1. Chapter overview

Figure 3.1 shows the chapter overview in the form of a flowchart.



**Figure 3.1: Flowchart of the chapter structure**

#### 3.1.2. Keywords

Dynamic hip screw; femur; fractures of proximal femur; intra-medullary hip screw; minimally invasive surgery

### 3. 2. Introduction

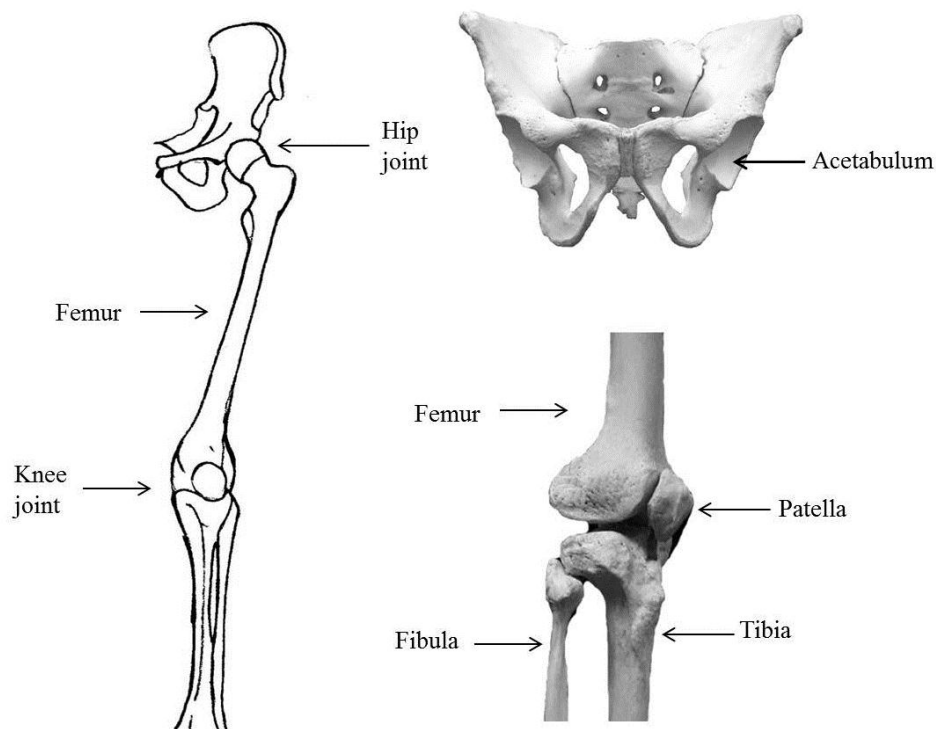
Fractures of the proximal femur, more commonly known as hip fractures are frequent injuries in the elderly (Canale, 2002); surgical management is considered to be the standard treatment for these fractures (Ahn and Bernstein, 2010). Intramedullary devices or dynamic hip screws are used for surgical treatments of fractures of the proximal femur. Amongst them the dynamic hip screw (DHS), first introduced in 1941 by Dr. E. Pohl (Dittel and Rapp, 2008), is considered the standard fixation device for the treatment of such fractures (Chirodian *et al.*, 2005; Harrington *et al.*, 2002; Esser *et al.*, 1986).

In recent years, there has been an increase in the popularity of minimally invasive surgeries (MIS) due to apparent advantages to the hospital and patients. These include relatively reduced perioperative blood loss, shorter hospital stay and aesthetic appeal due to lesser scarring (Ho *et al.*, 2008; Yeung, 2008; Lee *et al.*, 2007). The objective of this research was to design medical devices, which would aid the implementation of MIS for the implantation of the DHS. A feasibility study for new devices is important to identify the potential market share, similar devices produced by competitor companies and the potential market value of devices (Aitchison *et al.*, 2009). The feasibility study presented in this chapter concluded with the identification of devices that had to be redesigned/ developed to enable MIS treatment of proximal femur fractures using the DHS.



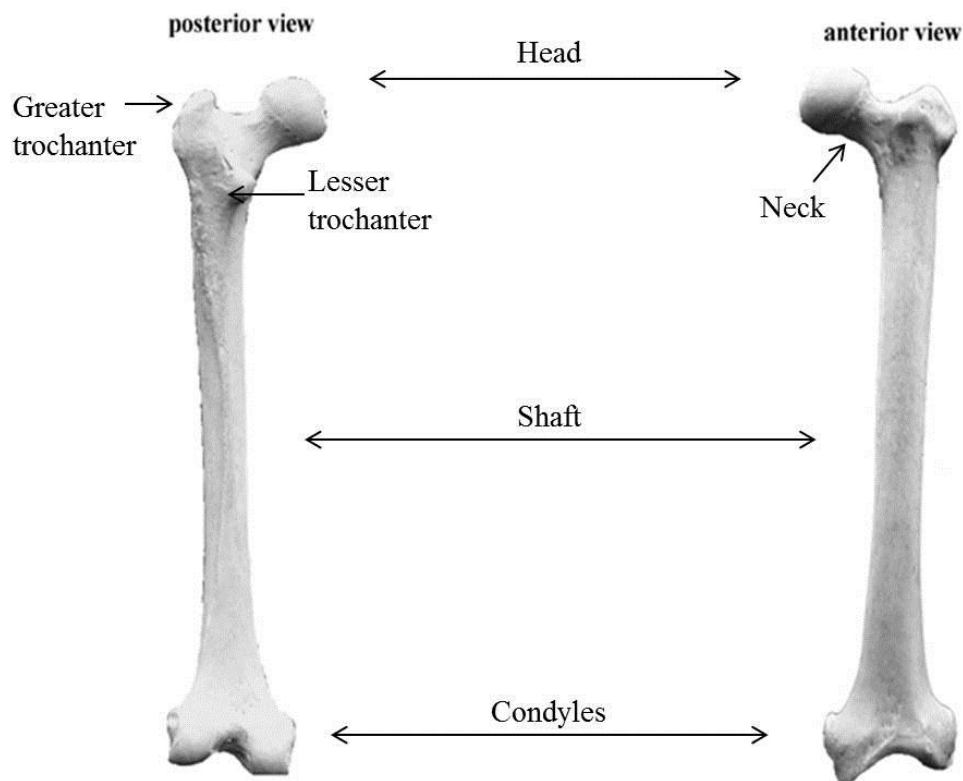
### 3. 3. The Femur

The femur, also called the thigh bone, is the longest, heaviest and one of the strongest bones in the body. Studies and findings described by Standring (2008) and Callaghan *et al.* (2007) were used to state the structure and function of the femur that are discussed in this section, unless otherwise cited. It articulates with the acetabulum of the pelvis (socket of the “ball – socket” hip joint) superiorly, and with the tibia and the patella (knee cap) inferiorly, thus forming a part of both the hip and the knee joint (Figure 3.2). The femur is the skeletal support for the thigh.



**Figure 3.2: Location of femur relative to the bones of the lower extremity. Images of pelvis and knee joint reproduced with kind permission from Sawchuck, L.A. and J. Padiak, Department of Anthropology, University of Toronto, Scarborough**

The proximal end of the femur consists of a head, a neck, and a greater and lesser trochanter. The neck connects the head to the trochanters and in turn to the shaft. The femoral neck forms an angle of about 135 degrees with the shaft in adults. The shaft of the femur is roughly cylindrical and inclines medially and downwards. The shaft is broader at the extremities than in the centre, and is the broadest at the distal extremity. The tibia and the fibula descends vertically from the knee joint to the ankles, and hence the inclination in the shaft of the femur permits the ankles to be aligned with the body. The various regions of femur are shown in Figure 3.3.



**Figure 3.3: Anatomy of the femur.** *Images reproduced with kind permission from Sawchuck, L.A. and J. Padiak, Department of Anthropology, University of Toronto, Scarborough*

Bone can either be cortical or cancellous. Cortical, also known as compact bone, comprises 80% of the human skeleton and is formed of tightly assembled osteons. It is mainly found in the outer aspects of long bones. On the other hand, cancellous (trabecular) bone is formed of less densely assembled osteons. Cancellous bone is mainly found towards the ends of long bones (Tsiridis and Schizas, 2008). Rho *et al.* (1993) has shown that the Young's modulus of cortical bone ( $18.6 \pm 3.5$  GPa) is relatively higher than that of cancellous bone ( $10.4 \pm 3.5$  GPa). The femoral shaft consists predominantly of cortical bone with a large medullary cavity running axially along the length of the bone. The wall is thickest at the middle of the shaft and gets thinner towards the extremities; and the cavity is progressively filled with cancellous bone. The proximal and distal ends of the femur have a thin shell of cortical bone with the cancellous bone arranged along lines of greatest stress. The combination of spongy extremities and hard middle allows the bone to transmit the forces of body weight and muscles efficiently.

The attributes and structure of the femur allow the bone to perform its significant functions, which are to support and transmit the weight of the body and to assist in gait.

### 3. 4. Fractures of the Proximal Femur

#### 3. 4. 1. Overview

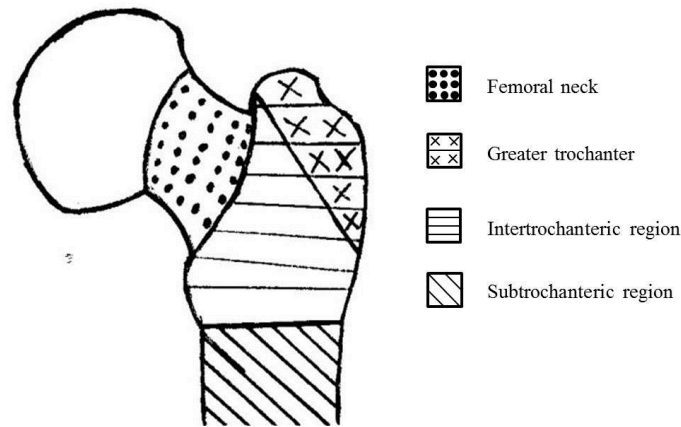
The fractures of the proximal femur are the most frequent injuries in the elderly population (Jewell *et al.*, 2007). Along with the increase in life expectancy of the world's population, it is likely that the incidence of these fractures may keep rising. The following sections discuss the classification and cause of the fracture, and the statistics associated with the fracture.

#### 3. 4. 2. Anatomical Locations of the Fractures

The fractures are divided into four main categories, classified by the region of the femur affected. The information collected in this section was retrieved from a publication by Evans and Mcgrory (2002) and from Campbell's operative orthopaedics 10<sup>th</sup> edition (Canale, 2002). A graphical representation of the anatomic regions of the proximal femur relating to the areas of fractures is shown in Figure 3.4.

- i. *Femoral neck fracture* involves the fractures that occur between the femoral head and the greater trochanter, and are prominent in elderly patients. The fractures are intracapsular and the synovial fluid may interfere with the healing. These fractures are either treated with insertion and placement of

parallel cannulated screws to achieve compression and anatomic reduction or by hemiarthroplasty of the hip, where only the ball (femoral head) of the hip joint is replaced by an implant. The treatment of choice depends on the age of the patient and the characteristics of the fracture.



**Figure 3.4: Anatomical regions of the proximal femur.**

ii. *Greater trochanter fractures* are not very common and are usually a cause of direct trauma to the trochanter. A non-operative treatment, like the use of crutches, is preferred for the management of these fractures.

iii. *Intertrochanteric fracture* involves the fractures in a line between the femoral neck and the femoral shaft. They may involve both the trochanters. These fractures are classified based on the stability of the fracture pattern and usually occur in patients over 70 years of age. Surgery is the treatment of choice and the dynamic hip screw is the most common form of fixation device used.

iv. *Subtrochanteric fractures* occur between the lesser trochanter and the isthmus of the diaphysis (shaft) of the femur. These fractures have a bimodal age distribution and can be treated operatively or non-operatively.

### **3. 4. 3. Cause of the fracture**

Femoral fractures in young patients are rare and mostly are a result of high energy physical traumas like car accidents, whereas in the elderly population it is a very frequent injury and is caused due to low impact accidents like falls (Holt et al., 2008; Marks, 2010). Age is a major factor for the fracture as the bone mineral density decreases with increasing age, leading to a weaker bone (Evans and McGrory, 2002). Sex, apart from age, is another major risk factor for hip fractures, as post-menopausal women are more prone to osteoporosis, which causes weaker bones; resulting in the risk of fracture being 2 to 3 times higher than in men (Marks, 2010). Other factors that cause hip fractures include ethnicity, malnutrition, less physical activity, low body mass index, smoking, and excessive intake of caffeine and alcohol. The fractures are frequently pathologic in the elderly (Lefauveau and Fardellone, 2004).

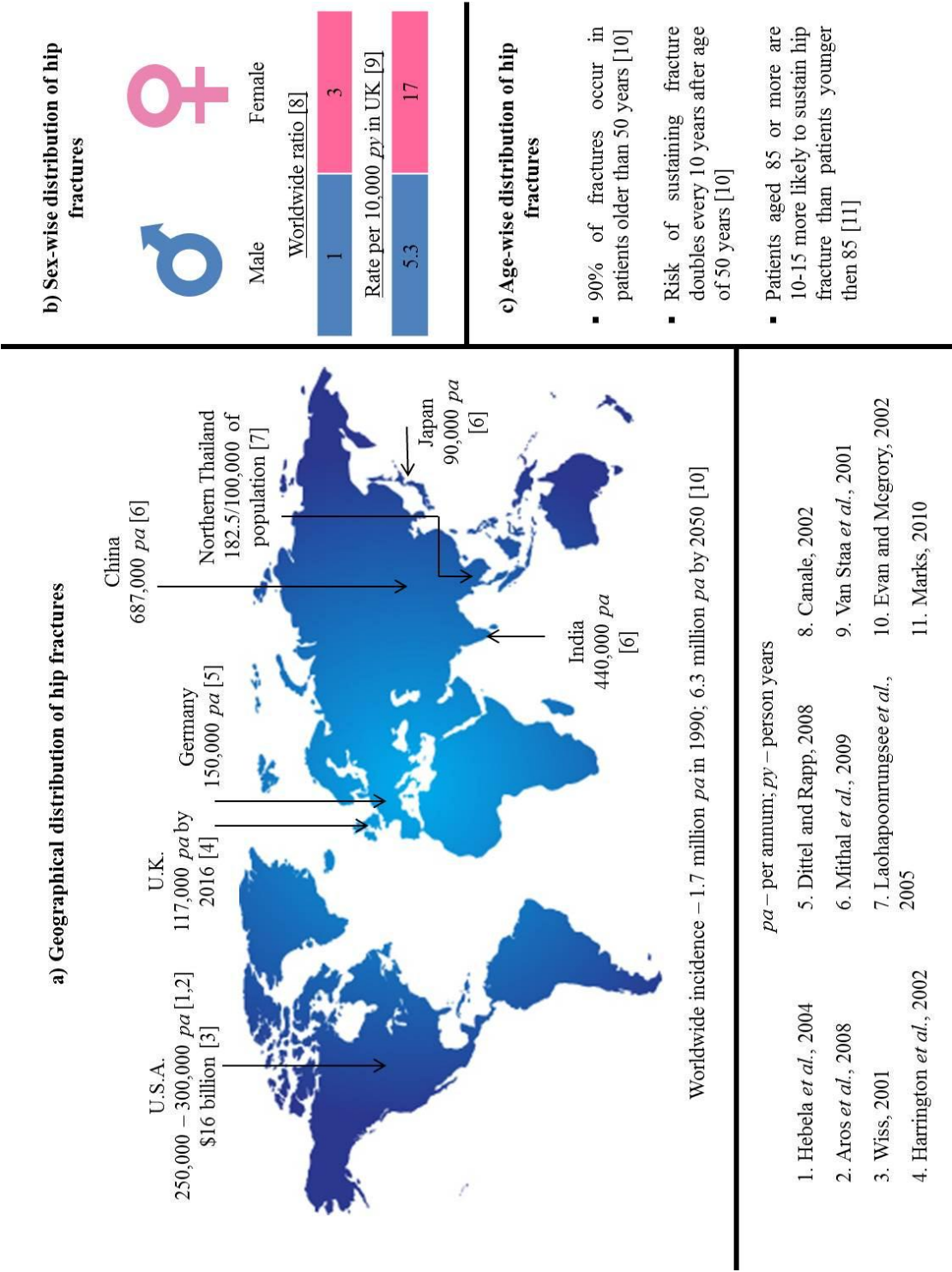
### **3. 4. 4. Epidemiology of the fracture**

Hip fractures represent a substantial burden socially, medically and financially, and studies suggest a steady increase in hip fractures along with the ageing

population. The lifetime risk of a hip fracture in industrialised nations is 15 to 17% for women and 5 to 6% for men (Wong *et al.*, 2009; Jewell *et al.*, 2007; Van Staa *et al.*, 2001). The risk of enduring a hip fracture doubles every decade after the age of 50 years in both men and women (Evans and Mcgrory, 2002). There are 250,000 to 300,000 hip fractures annually and account for 30% of all hospitalised patients in the USA (Aros *et al.*, 2008; Wiss, 2001)

There were 1.6 million cases worldwide and 560,000 cases in Europe in 1992 (Lefauveau and Fardellone, 2004). Medicare cost for hip fractures in 1991 in the USA was estimated at \$2.9 billion, and the cost was estimated at \$16 billion in 2001 (Lee *et al.*, 2007). It has been estimated that it may affect 117,000 people in the UK in the year 2016 (Wiss, 2001), and the worldwide incidences have been predicted to rise to 6.26 million by 2050 (Evan and Mcgrory, 2002). The epidemiology of hip fractures is shown in Figure 3.5.

Intertrochanteric fractures account for approximately 50% of the proximal femoral fractures in the elderly (Peyser *et al.*, 2005; Gotfried, 2000). They usually occur in patients over 70 years of age. Subtrochanteric fractures appear commonly in patients between 20 to 40 years of age and in those over 60 years of age (Canale, 2002).



**Figure 3.5: Epidemiology of hip fractures – a) Geographical distribution, b) sex-wise distribution, and c) age wise distribution. Royalty free image of world map courtesy of Maps for design (www.mapsfordesign.com)**



### **3. 4. 5. Morbidity and mortality due to the fracture**

Hip fractures are associated with a high rate of mortality and morbidity, with mortality ranging from 11% to 23% after six months, and 22% to 29% after a year (Haleem *et al.*, 2008; Jewell *et al.*, 2008; Roder *et al.*, 2003); the rate increases with the age at which the fracture was sustained. The mortality rates due to intertrochanteric femoral fractures range from 15% to 20%. However, after a year, it seems that the rate adjusts as per the age of the patient (Canale, 2002).

## **3. 5. Treatment of Intertrochanteric Fractures of the Proximal Femur**

### **3. 5. 1. Overview**

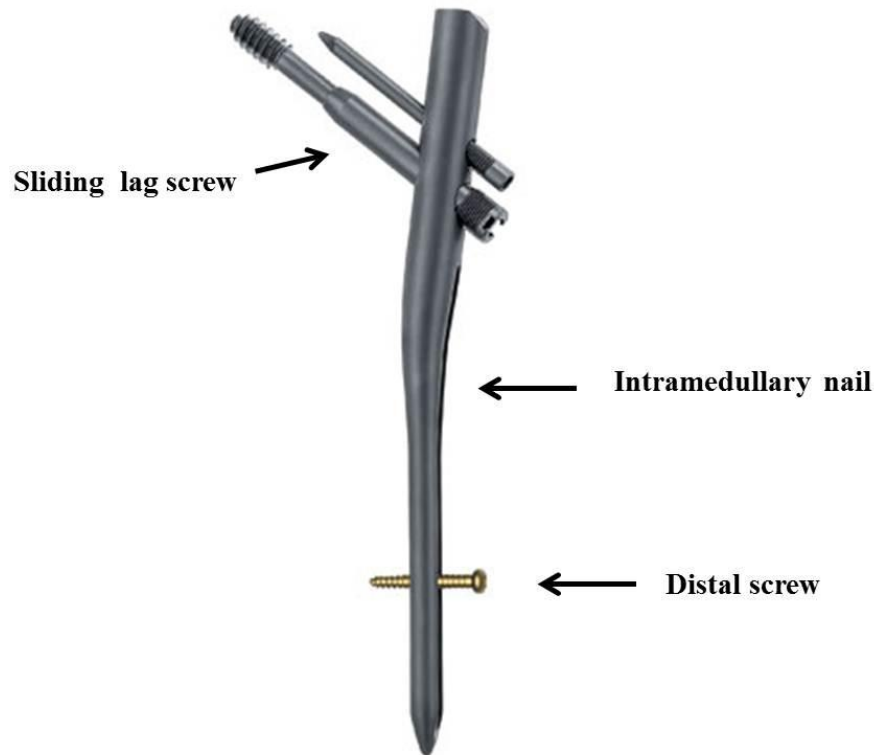
The purpose of hip fracture treatment is to alleviate pain and to achieve maximum possible anatomical union of the fracture to assist restoration of the patient's lower extremity to pre-injury activity level. Surgery is considered to be the standard treatment for management of intertrochanteric fractures. Surgical treatment allows for early mobilization of the patient, with partial weight-bearing, as well as reducing mortality and morbidity (Steinberg *et al.*, 2005).

### 3. 5. 2. Surgical treatment of hip fractures

The fixation devices for the treatment of these fractures can be broadly classified into two groups, namely i) dynamic hip screws (DHS) and ii) intra-medullary fixation devices (Canale, 2002).

i. *Dynamic hip screw (DHS)*: The implant is used along with an angled side plate. A collapsible lag screw is inserted into the neck and head of the femur. The lag screw is then attached with the angled side plate, which is then screwed to the lateral shaft of the femur. The device will be discussed in more detail in section 3.6

ii. *Intra-Medullary fixation devices*: These fixation devices, shown in Figure 3.6, have evolved from a simple intra-medullary nail to modern intra-medullary implants such as the Gamma nail (Stryker, Kalamazoo, Michigan, USA), IMHS (Smith & Nephew, London, UK) and others. The principle of the modern intra-medullary fixation implant is to combine a sliding lag screw with an intra-medullary nail. The assembly consists of an intra-medullary rod inserted through the greater trochanter and a sliding screw that passes through the rod to be inserted into the femoral head and neck (Rosenblum *et al.*, 1992). The intra-medullary rod is locked distally with screws.



**Figure 3.6: Targon® PF intra-medullary nail (B. Braun Melsungen AG, Melsungen, Germany) for proximal femur fractures. Image reproduced with kind permission of B. Braun Melsungen AG**

These devices could be utilized for stable or unstable intertrochanteric hip fractures and are ideal for subtrochanteric and reverse obliquity fractures (Canale, 2002). The design of the implant allows for a shorter lever arm than the DHS due to the medial placement of the shaft fixation. It requires a closed insertion technique and hence results in a smaller incision and less intra and post-operative blood loss (Steinberg *et al.*, 2005; Harrington *et al.*, 2002).

According to Canale (2002), intra-medullary fixation cannot be used for femoral neck fractures and in patients with femoral shaft deformities as the nail of the

implant needs to be inserted into the medullary canal of the shaft, which may cause further injuries. The implant is also not recommended for younger patients as it requires a large amount of cancellous bone to be removed from the trochanteric block. The insertion of the nail into the medullary cavity could result in trauma for the bone and could lead to further fractures. Canale (2002) also reports a complication rate of 3% to 6% of secondary fractures of the femoral shaft during the insertion of these devices and the surgery is also regarded as a more technically demanding procedure for the surgeon.

### 3. 5. 3. Intra-Medullary or DHS?

The two fixation methods to treat the fractures of the proximal femur offer their own sets of advantages. Although intra-medullary fixation offers biological benefits due to the percutaneous method of implantation, the DHS implant has a simpler surgical technique for insertion (Canale, 2002). Butt *et al.* (1995) reported no significant difference in operating time and blood loss in their study to evaluate the difference between a DHS and a Gamma nail. In addition, no significant differences were recorded for the time the fracture took to heal. However, it has been discovered that in some cases, intra-medullary fixation causes secondary fracture of the shaft of the femur (Aros *et al.*, 2008; Harrington *et al.*, 2001; Butt *et al.*, 1995). The DHS surgical technique is also a bone-saving procedure as the stabilising plate is fixed to the exterior of the bone. In comparison, intra-medullary implants cause damage to the cancellous bone. Trials conducted by Parker and

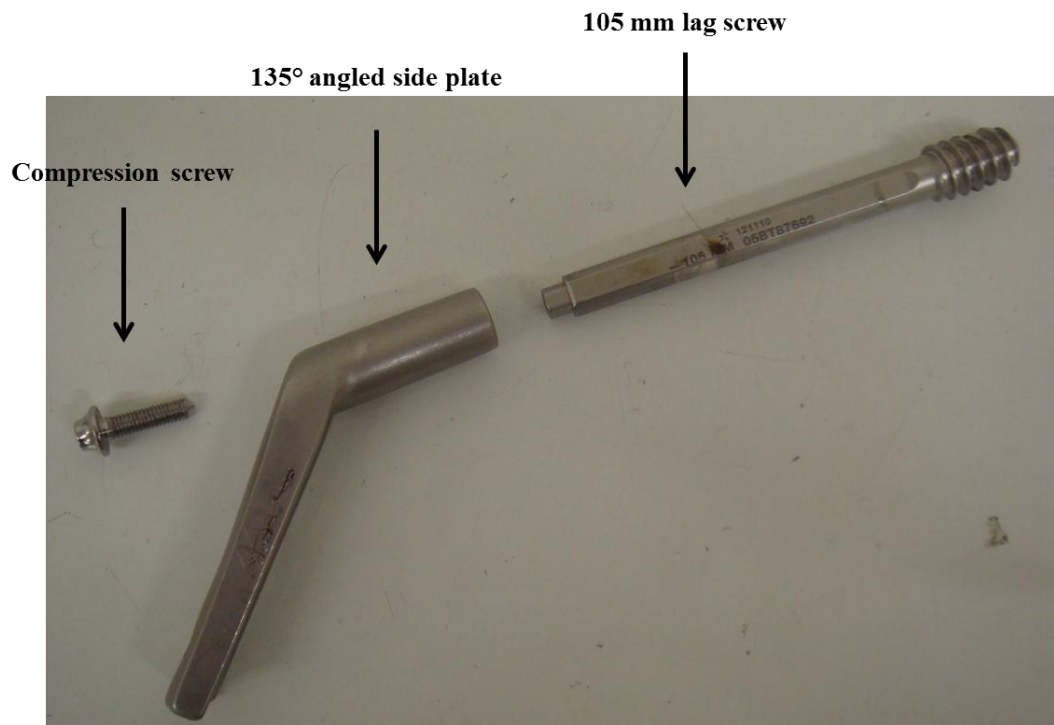
Handoll (2009) concluded that the DHS had lower complication rates than that of intra-medullary nails. However, intra-medullary fixations are preferred to the DHS for unstable trochanteric fractures, subtrochanteric fractures and reverse obliquity fractures (Hamilton and Kelly, 2003). There are continual improvements in both types of fixation, but as indicated by the literature, currently the dynamic hip screw is the standard and most common type of fixation for intertrochanteric fractures.

### **3. 6. Dynamic Hip Screw (DHS)**

#### **3. 6. 1. The implant**

The DHS, also called the sliding hip screw, is an extra-medullary fixation device used for the treatment of fractures of the proximal femur. The DHS assembly consists of a lag screw and a side plate. The fundamental principle of this implant is to promote compression of the fractured bone fragments by allowing the lag screw, inserted into the femoral head, to form a sliding connection with side plate attached to the lateral femoral shaft. The impaction increases bone-on-bone contact, which aids in healing while decreasing implant stress (Evans and McGrory, 2002). The screw/plate angle is selected depending on the femoral anatomy of the patient and the type of fracture. The implant also provides rotational stability to the fracture as the lag screw is unable to rotate within the

side plate due to corresponding flattened surfaces. The DHS is usually indicated for most fractures of the proximal femur including intertrochanteric fractures, intracapsular and basal neck fractures and for subtrochanteric fractures (Canale, 2002).



**Figure 3.7: Exploded view of a generic dynamic hip screw manufactured by Smith & Nephew plc. (London, UK)**

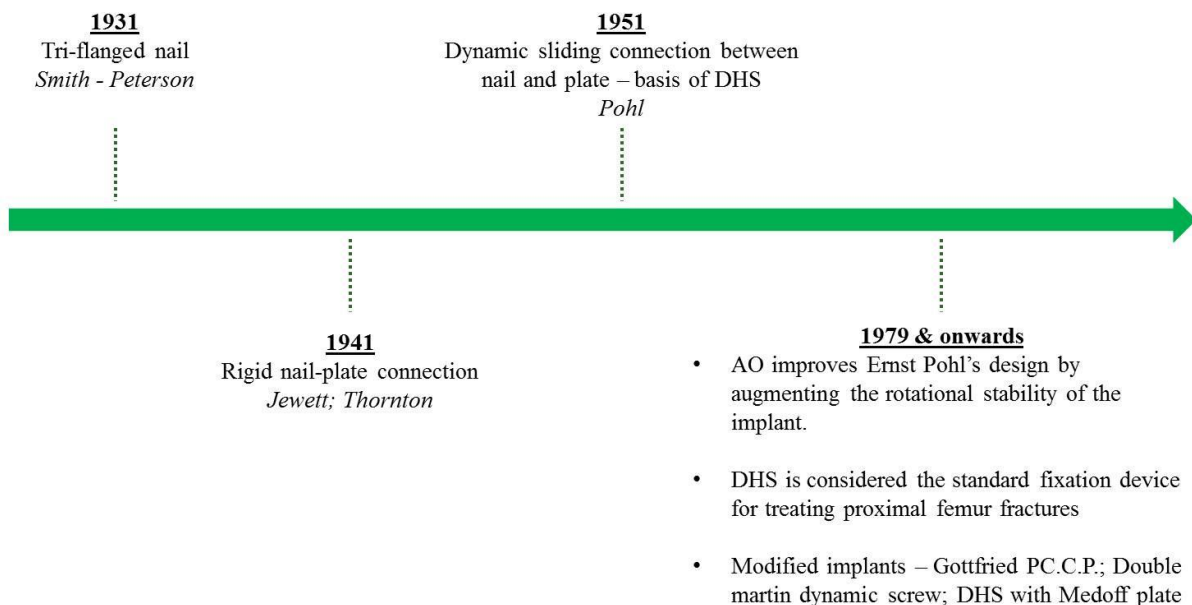
The femoral neck forms an average angle of 135 degrees with the femoral shaft in adults (Canale, 2002; Hoaglund and Low, 1980). However, the neck/shaft angle depends on race and sex. The neck/shaft angles reported in publications include  $129^{\circ} \pm 6^{\circ}$  (375 femurs from Caucasians and African-Americans populations, Toogood *et.al.*, 2009),  $126^{\circ} \pm 7^{\circ}$  (56 femurs from Chinese population, Liang, J. *et.al.*, 2009), and  $123^{\circ} \pm 4^{\circ}$  (150 femurs from Indian population, Siwach and Dahiya,

2003). The angled side plate of the generic DHS is supplied in angles of 120 degrees to 150 degrees in increments of 5 degrees to cater to the differing neck/shaft angles of the global population. Although newer implant - Gotfried PC.C.P. (section 3.8.2) only caters to the most common angle (135 degrees), it is criticised for not offering variability in the neck/shaft angle (Peyser *et.al.*, 2005).

The failure rate of DHS has been reported to range from 16 % to 23% (Kumar *et al.*, 2007; Gundle *et al.*, 1995). The implant requires adequate purchase in the bone for the fixation to be stable, and hence the position of the lag screw in the femoral head and strength of the cancellous bone is crucial (Gundle *et al.*, 1995; Baumgaertner *et al.*, 1995). Osteoporotic bones and incorrect placement of the lag screw are two factors that may cause cut-out of the screw from the femoral head (Evans and McGrory, 2002). Screw cut-out is the most common cause of failure of fixation and incidence rates have been reported to range from 5.3% to 16.8% (Kumar *et al.*, 2007). The complications of the DHS also include non-union, shortening of the affected limb, and displacement of fracture (Laohapoonrungssee *et al.*, 2005; Peyser *et al.*, 2005; Kim *et al.*, 2001). Causes of these complications could be excessive slide of the lag screw and/or lack of anatomic reduction. Kim *et al.* (2001) suggested that the instability of the fracture is the most important cause of fixation failure. Nevertheless, DHS is currently considered the standard device for the treatment of fractures of the proximal femur.

### 3. 6. 2. Evolution of the DHS implant

Surgical fixation of proximal femur fractures gained popularity with the introduction of the tri-flanged nail by M. Smith Peterson in 1931. The design was enhanced in 1941 by Jewett, when the femoral nail was given a rigid connection with a plate attached to the lateral side of the femur. The high rate of complications concerning this design and parallel developments of the era by Thornton (also with a rigid connection) included leg length discrepancy and external rotation. The data on the evolution of the DHS implant was taken from a publication by Dittel and Rapp (2008) and the timeline is shown in Figure 3.8.



**Figure 3.8: Timeline of evolution of DHS**

The first implant with the principle of a sliding connection between the femoral nail and side plate was designed and introduced by Ernst Pohl in 1951. The design



is the basis of the DHS implants till date and the design has not evolved much from the original. The design was improved in 1979 by AO (Davos, Switzerland). The round cross-section of the lag screw was replaced by a lag screw which had been flattened on the sides; the barrel was also flattened on two sides to provide corresponding sliding surfaces. This design augmented the rotational stability of the implant.

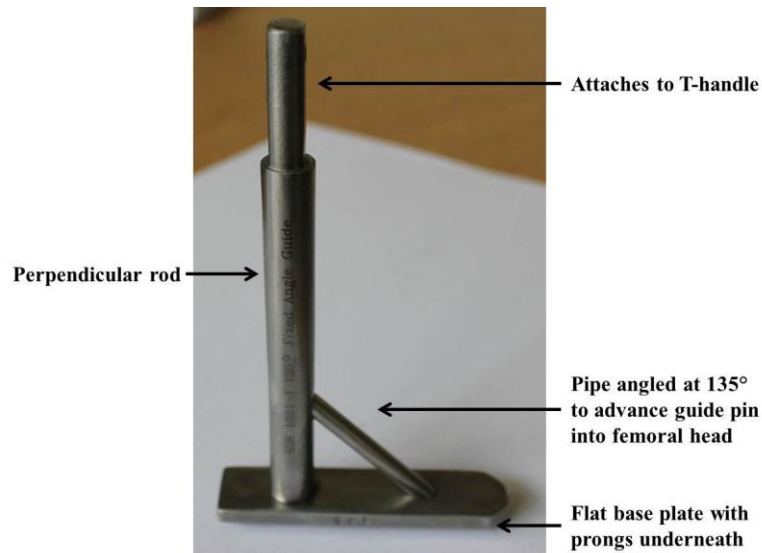
Since the introduction of the DHS, there have been some modified versions of the basic principle like the DHS with a Medoff plate, Gotfried PCCP and the Double Dynamic Martin screw. The generic DHS is still the preferred implant because of its simple surgical technique and promising results.

### **3. 6. 3. Surgical procedure for implanting a DHS implant**

#### ***3. 6. 3. 1. Surgical instruments***

There are seven key instruments used during the implantation of a DHS using the conventional surgical procedure. The functions of the instruments were taken from Campbell's Operative Orthopaedics (Canale, 2002) and the surgical technique manual for compression hip screw plates (Smith & Nephew plc., London, UK). The instruments are shown in Figures 3.9 to 3.15, and were all manufactured by Sushrut Surgicals Pvt. Ltd. (Pune, Maharashtra, India)

- i. *Angle guide* (Figure 3.9) is temporarily attached to the upper end of the femur, to accurately provide both horizontal and vertical reference required by the surgeon to insert the guide pin into the femoral head.



**Figure 3.9: Generic DHS angle guide**

- ii. *Guide pin* (Figure 3.10) is inserted at the start of the surgery, and is retained until the end of the surgical procedure. It acts as a guide regarding the angle and the length required of the lag screw. It also serves a secondary purpose of reducing the fracture at the start of the surgery.



**Figure 3.10: Guide pins (diameter – 3mm)**

iii. *Measuring gauge* (Figure 3.11) is used to measure the length of the lag screw required.



**Figure 3.11: Generic measuring gauge**

iv. *Triple reamer* (Figure 3.12) is length-adjustable, and is used to make a tunnel where the lag screw and the angle plate are later placed in. The triple reamer is a special drill which would create a tunnel with three different diameters - one for the screw, one for the plate barrel and one for the junctions between the plate and the barrel.



**Figure 3.12: Generic triple reamer to make tunnel of three different diameters**

v. *Tap* (Figure 3.13): tapping is an optional step during the procedure and is not deemed necessary in osteoporotic bones. This is because the lag screw will be able to cut through the softer bone without any need of excess force.

However, it is required in younger patients and cases with strong bones, to avoid torque exertion on the insertion wrench and rotation of the fracture.



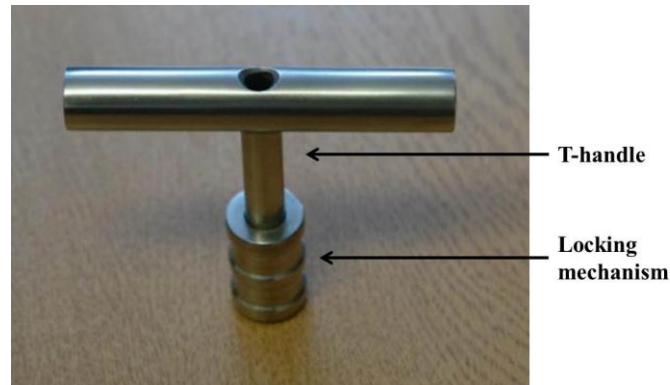
**Figure 3.13: Generic tap**

vi. *Insertion wrench* (Figure 3.14) is used to assemble the lag screw, centre sleeve and angle plate to be inserted into the femur.



**Figure 3.14: Generic insertion wrench**

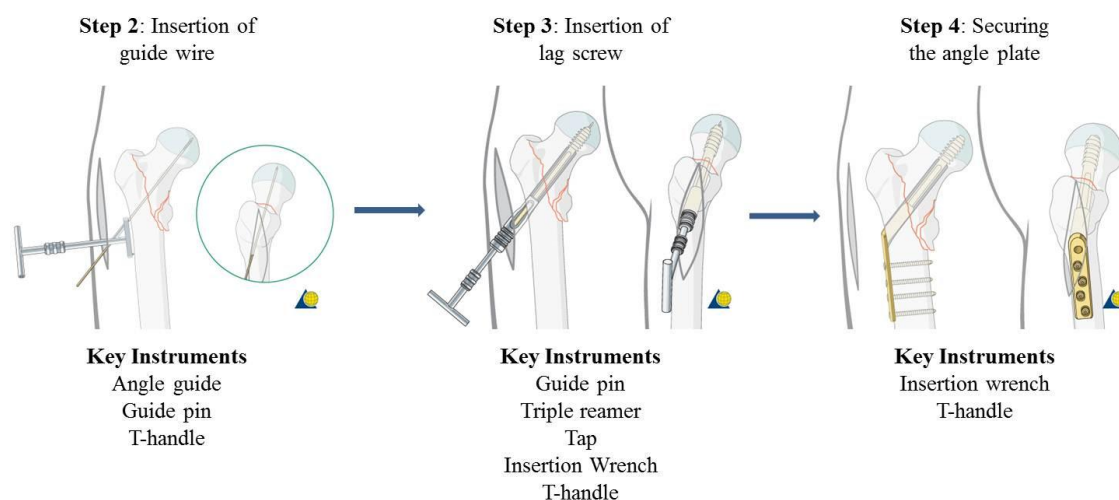
vii. *T-handle* (Figure 3.15) is detachable and is used at various points of the surgery. First, it is used to hold the angle guide and later, to insert the lag screw.



**Figure 3.15: Generic T-handle for use with different instruments in the DHS surgery**

### 3. 6. 3. 2. Surgical Technique

A conventional DHS technique that uses the instruments described in section 3.6.3.1 could be divided into four steps described below. Steps 2 to 4 are summarized in an illustration shown in Figure 3.16. The surgical technique was taken from Campbell's Operative Orthopaedics (Canale, 2002), as recommended by AO Foundation (Davos, Switzerland), and surgical technique manual for compression hip screw plates (Smith & Nephew plc., London).

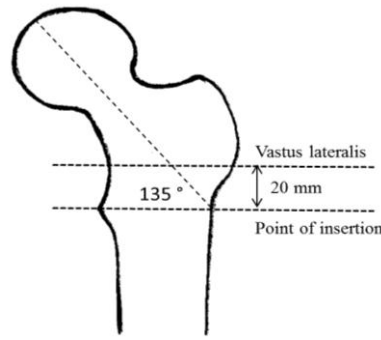


**Figure 3.16: Illustrated summary of surgical steps 2 to 4 to implant a DHS and angled plate. Images reproduced with kind permission of AO Foundation (Davos, Switzerland)**

i. *Reduction and exposure:* the patient is anaesthetised and placed in a supine position. The legs are also placed in a traction extension. A closed reduction is performed on the fracture. An incision is then made extending distally from the greater trochanter. The length of the incision, generally between 100 and 150 mm, depends on the length of the side plate being used. The fracture is then reduced with the traction extensions.

ii. *Placing the guide wire and determination of length of screw:* the angle of insertion of the guide pin varies with the angle of the plate to be used, which is decided prior to the surgery. The 135 degrees angle plate is most commonly used for these surgeries, and thus they will be used to describe the rest of the procedure. A good point to locate the entry of the guide wire is approximately 20 mm below the *vastus lateralis* ridge (inferior border of the greater trochanter), as shown in Figure 3.17. The entrance site is moved 5 mm distally for each 5 degrees increase in the barrel angle thereof. The guide pin is then inserted into the femoral head using a Fixed Angle Guide.

The depth of the guide pin inserted is measured using a measuring gauge, and then a lag screw which is 10 mm shorter than the reading is selected. (For example, if the measuring gauge reads 115 mm, then the lag screw should be 105 mm.)



**Figure 3.17: Insertion point of guide pin in context to vastus lateralis**

iii. *Insertion of the DHS screw:* once the guide wire is in place, the DHS triple reamer is used to make a tunnel. This reamer creates a tunnel with three different diameters, i.e. one for the screw, one for the plate barrel and one for the junctions between the plate and the barrel. The tunnel is then tapped, if deemed necessary, to avoid excess torque application while inserting the screw. It is usually advisable to tap in younger patients as the bone is much stronger. The screw is then inserted using a wrench and centring T-handle. The plate can only be installed and aligned correctly if the T-handle is turned perpendicular to the axis of the femoral shaft at the end of this step.

iv. *Mounting and securing the plate:* once the screw is set in place, the DHS plate on the insertion wrench is slid over the guide wire. The guide wire can now be removed. The plate is hammered into the tunnel with an instrument called the DHS impactor. The plate is then secured distally with a number of cortex screws of required lengths. The fracture can also be compressed by inserting a compression screw at this point. However, the compression screw could be

avoided as the sliding mechanism of the implant will allow the fracture to impact and compress as the patient bears weight.

### **3. 7. Minimally Invasive Surgeries (MIS)**

There has been an increase in popularity of minimally invasive surgeries in recent years. The foremost purpose of a MIS is to promote or maintain the benefits of an existing surgical treatment while combining the advantages of a smaller incision. The advantages of a smaller incision are aesthetical, biological and commercial, which may include reduction in soft tissue trauma surrounding the fracture repair site, relatively less perioperative blood loss and better cosmetic results to the patient due to reduced scarring. (Chong *et al.*, 2006) Other benefits of the less invasive technique also include reduced post-operative pain and reduced morbidity (Ho *et al.*, 2008; Peyser *et al.*, 2005). All these advantages could lead to reduced hospital stay, which may be beneficial to the patient and reduce the hospital costs.

A prominent criticism against MIS is the learning curve for the surgeons. Teaching of the new techniques could not only lead to a relatively greater rate of complications initially, but also prove difficult to learn due to the reduced visibility and feedback signals (Scuderi and Tria, 2010). MIS is a relatively new innovation in the surgical field and the concerns stated could be solved with developments in surgical techniques and implant designs.



MIS procedures vary according to the medical discipline. However, for broad classification, the author of this thesis has divided them into two categories of surgical approaches – Alternative and Similar. Alternative surgical approaches, like the recently developed two-incision hip replacement techniques or robotic surgeries involves an entirely new surgical procedure, implant and associated instruments to facilitate a small incision entry for the treatment of the injury. Similar surgical approach attempts to emulate the existing surgical procedure with minor modifications and may also include amendments to the design of the implant and/or inclusion of new instruments to achieve implantation through a smaller incision.

### **3. 8. Review of existing MIS techniques for proximal femur fractures**

#### **3. 8. 1. Overview**

DHS as the standard choice and the rising popularity of MIS procedures have encouraged proximal femur fracture treatment techniques discussed in this section. They were grouped according to their surgical approach. It should be noted that intra-medullary devices can be considered as MIS option for treatment of proximal femur fractures. However, the following review is intended to discuss the MIS options that are based or were initiated by the principle of the DHS implant.

### 3. 8. 2. Alternative Surgical Approach

The devices mentioned in this section were developed using the sliding principle of DHS and are indicated for fracture management of the proximal femur. The devices mentioned in this section are compared with the generic DHS implant to form a competitor review in Table 3.1

- i. *Mini invasive screw system (MISS)* is a three part implant system consisting of a long five-hole femoral plate, a large cephalic screw and a barrel which is locked on to the femoral plate to allow the screw a maximum slide of 15 mm once implanted. The incision required to implant the device is 50 mm to 70 mm long (Burdin et al., 2006)
- ii. *Percutaneous compression plate (P.C.P.)* was introduced by Gotfried in the late 1990 (Gotfried, 2000). The wide range of studies (Peyser et al., 2007; Brandt et al., 2006; Peyser et al., 2005) conducted on the device suggests the popularity it has gained over a short period. The device consists of a femoral plate which is first introduced to slide along the femoral shaft. This is followed by insertion of two telescoping neck screws into the femoral neck and head to compress the fracture. The device requires two incisions of 20 mm each for implantation. The purpose of two neck screws is to provide rotational stability to the fracture (Gotfried, 2000). The device is superior to the DHS in terms of blood loss, soft tissue healing and operation time and similar in terms of fracture stability and device failure. However, the device demands a steep learning curve as the

surgical procedure is perceived as technically demanding (Peyser *et al.*, 2005). The device also requires new instruments and other inventory and hence may not prove cost effective for the hospital until it is selected as the standard implant for the treatment of fractures of the proximal femur.



**Figure 3.18: Gotfried PC.C.P (Orthofix srl, Italy). Image reproduced with kind permission of Orthofix srl.**

iii. The Targon® FN (B. Braun Melsungen AG, Melsungen, Germany) implant, made of titanium alloy, consists of a small femoral plate with six locking screw holes. The two distal holes fix the plate onto the femoral shaft. The proximal holes allow four telescoping sliding screws to be advanced into the femoral head. The device requires a special rig for insertion of the implant, and needs 60 mm of incision for insertion (Brandt *et al.*, 2010). The information was also collected personally by the author at the product launch held at Stamford, UK in October 2007.



**Figure 3.19: Targon® FN (B. Braun Melsungen AG, Melsungen, Germany) for proximal femur fractures. Image reproduced with kind permission of B. Braun Melsungen AG**

### 3. 8. 3. Similar Surgical Approach

The similar surgical approaches practiced at present, attempts minor modifications to the actual surgical approach to perform a smaller incision while using existing fixation devices. This requires a smaller learning curve and prevents stocking of new equipment. It could possibly promote faster inclusion of a minimally invasive approach and their advantages to the surgical treatment. A review of current surgical techniques presented procedures which could be broadly classified into two kinds – with and without the use of angle guide.

i. *With angle guide*: the minimally invasive surgeries conducted with an angle guide included trials by Ho *et al.* (2008), and by Leung and Tsang (2008). The incision used in these procedures ranged from 40 mm to 50 mm in length. The lag screw is advanced after the insertion of the guide wire, as with the conventional procedure. The side plate is inserted with the barrel facing laterally and then rotated until it lies under the skin and the fascia. The skin is retracted to secure the plate with distal screws. The deep layer and skin incision closure are performed in the usual fashion.

ii. *Without angle guide*: the distance between the front end and bar of the generic angle guide is 40 mm (Leung and Tsang, 2008), and thus it is the minimum required incision for utilizing this instrument during the surgery. The function of the angle guide to insert the guide wire at an angle of 135 degrees or as required based on the patient's anatomy, could be performed by use of fluoroscopy and estimation using landmarks (Waters *et al.*, 2006). This would enable the incision to be reduced to a range of 20 mm to 30 mm. This review included trials by Wong *et al.* (2009), Lee *et al.* (2007) and Waters *et al.* (2006). All the studies reviewed inserted the guide wire percutaneously by placing the angle guide parallel to the femoral shaft externally and then using fluoroscopy imaging to ensure satisfactory alignment. The incision is made distally from the guide wire. The remaining procedure is the same as mentioned previously with the use of an angle guide.

Table 3.1: Comparison of implants

	<b>Generic DHS implant</b>	<b>Gotfried PC.C.P.</b>	<b>Targon FN</b>
<b>Manufacturer</b>	Many including Smith & Nephew plc (London, UK) and Synthes GmbH (Solothurn, Switzerland)	Orthofix srl, Italy	B. Braun Melsungen AG, Melsungen, Germany
<b>Year of Introduction</b>	Previous generic design update in 1979	Late 1990's	2007
<b>Incision Length</b>	100 mm to 150 mm	Two incisions of 20 mm each	60 mm
<b>List of Components</b>	a) Lag screw, b) angled side plate, and c) optional compression screw.	a) Side plate with angled slots, and b) 2 × telescoping screws	a) Side plate with angled slots, and b) 4 × telescoping screws
<b>Material of construction</b>	Stainless Steel	NA	Titanium alloy Ti6Al4V
<b>Type of fixation screw</b>	Cylindrical lag screw with flattened sides to avoid rotation	Cylindrical telescoping screws	Cylindrical telescoping screws with maximum slide of 20 mm
		<i>Note: Rotation controlled with multiple screws</i>	
<b>Range of fixation screw lengths</b>	55 mm to 140 mm in increments of 5 mm	90 mm to 140 mm in increments of 10 mm	70 mm to 110 mm in increments of 10 mm
<b>Type of side plate</b>	Fixed angle side plate with barrel and 2-14 distal slots for shaft screws	Side plate with two angled slots for telescoping screws and three distal screw holes for shaft screws	Side plate with four angled screw holes for telescoping screws and two distal screw holes for shaft screws
<b>Range of side plate angles</b>	120 degrees to 150 degrees in increments of 5 degrees	Only 135 degrees	Only 130 degrees

	<b>Generic DHS implant</b>	<b>Gotfried PC.C.P.</b>	<b>Targon FN</b>
<b>Advantages</b>	<p>Simple surgical technique</p> <p>Consistent positive results over the last four decades of use</p> <p>Reduced inventory cost (associated instruments) to the hospitals</p>	<p>Minimally invasive procedure</p> <p>Provides additional rotational stability</p> <p>No lateral protrusion due to telescoping nature of the fixation screw</p>	<p>Minimally invasive procedure</p> <p>Provides additional rotational stability</p> <p>Limited sliding of 20 mm prevents lateral protrusion of the fixation screw</p>
<b>Disadvantages</b>	<p>Large incision causing relatively more blood loss and soft tissue damage</p> <p>Lateral protrusion of the fixation screw is possible - may lead to complications and failure of fracture treatment</p>	<p>Technically demanding surgical procedure</p> <p>Additional expense to the hospitals due to the need of procuring new associated instruments including extensive assembling jigs</p> <p>No variability in the neck/shaft angle</p>	<p>Technically demanding surgical procedure</p> <p>Additional expense to the hospitals due to the need of procuring new associated instruments including extensive assembling jigs</p> <p>No variability in the neck/shaft angle</p>

### **3.9. Identified medical devices for MIS of DHS**

#### **3.9.1. Overview**

The standard fixation device for the treatment of proximal femur fractures is considered to be the DHS, as discussed in this chapter. It was also realised that proximal femur fractures are very common injuries and represent a significant financial burden to the society.

With the rise of MIS as a surgical option, the new devices and instruments are increasingly permitting the smallest incision possible. The new implants and techniques discussed in section 3.8 allow for incision lengths in the range of 20 mm to 60 mm as compared to the incision length of 100 mm to 150 mm required by the conventional surgical technique of implanting the generic design of DHS. However, it was also noted in section 3.5.3 and 3.6.1 that the popularity of DHS is also due to the simplicity of the surgical procedure. The implants introduced in section 3.8 to reduce the incision size require new instruments and a new surgical procedure. The change does not only require an increase in hospital inventory but also challenges the surgical technique that has been established for over four decades, thus requiring a steep learning curve for the surgeons. Although the techniques shown in similar surgical approaches (section 3.8.3) did exercise an incision length of only 20 mm, the use of an angle guide was compromised to achieve the small incision. It is also assumed by the author of this thesis that the



surgeon would have to be thoroughly experienced to practice the similar surgical approaches discussed in section 3.8.3.

### **3. 9. 2. Design Brief**

The points discussed above were taken into consideration to define the objectives to ensure that the newly developed medical devices from this research would be accepted by the market and also successfully aid in treating the fractures of the proximal femur. The design objectives of each medical device to be developed will be discussed at the beginning of the respective design process. The general guidelines set for the new medical devices are stated below.

- i. The medical device(s) should aid in conducting a MIS approach to treat fractures of the proximal femur with an incision of not more than 30 mm in length.
- ii. The devices should facilitate the use of a surgical approach, which would be similar to the conventional method used to implant the DHS.

Based on the guidelines and on the surgical technique used to implant the DHS, the medical devices that were identified to allow MIS of DHS were – i) the angle guide, ii) the T-handle, and iii) the implant comprising of the DHS lag screw and the angled side plate.

The angle guide was chosen as it was discovered to be the only device due to which the incision in the conventional procedure could not be reduced to less than 40 mm. The T-handle would be redesigned to be ergonomic and comfortable for the surgeon to use. The new implant would utilise the same principle as the DHS and a similar surgical approach. However, it would allow easier insertion through an incision length of 30 mm or less without the requirement of a steep learning curve for the surgeons.

The goal of the design process was to allow the use of the new angle guide and the new T-handle with the existing set of instruments to insert the existing generic DHS implant using the conventional surgical procedure; also to be able to use the new angle guide and the new T-handle with the existing set of instruments to insert the new implant using a similar approach.

### **3. 9. 3. Product Design Specifications of the Identified Medical Devices**

Product design specification (PDS) was developed for the three identified medical devices – (i) angle guide, (ii) T-handle and (iii) implant. The PDS, along with relevant generic aspects of a PDS – performance, ergonomics, competition, etc. (Childs, 2004), also considered the general requirements of surgical implants and associated instruments specified in standards BS EN ISO 12011 (1998), BS EN ISO 14630 (2009), BS EN ISO 14602 (2010) and BS 3531-15 (1992). The specifications were generated following literature research and expert opinion from Prof. N.

Maffulli. The justification and rationale behind the specifications is discussed in the respective “design requirements” section of each of the new medical devices – section 4.5 for the new angle guide, section 7.5 for the ergonomic T-handle and section 8.4 for the new implant.

### 3. 9. 3. 1. PDS for a New Angle Guide

#### a. Function and Performance

- The device should be able to accurately guide a pin (diameter of 2.5 mm) into the femoral head and neck at an angle of 120, 125, 130, 135, 140, 145 or 150 degrees (corresponding to the side plate to be used during the surgery).
- The angle guide should grip the femur surface and provide a steady structure to the surgeon to allow accurate insertion of pin.
- The angle guide should sit parallel to the long axis of the femoral shaft on the curved surface.
- The angle guide should aid the surgeon in locating the point of insertion of the pin, which is approximately 20 mm below the *vastus lateralis* ridge for a 135 degrees angled side plate. The entry point is to be moved 5 mm distally or proximally for each 5 degrees increase or decrease in the angle of the side plate respectively.

- The angle guide should not require an incision length of more than 30 mm to perform the function.
- The angle guide should be able to withstand a compressive force of 222 N due to the surgeon pushing the device against the femoral shaft surface; compressive force of 4 N due to the weight of the muscles and soft tissues.
- The device should be designed for both single-use and re-use markets.

#### b. Environment

- The angle guide will be used in a sterile environment. The device should not retain appreciable residue such as blood or bone fragments in gaps during operation.
- During surgery, the angle guide will be placed on the curved femoral shaft surface. The angle guide should not cause injuries to the muscles or soft tissues surrounding the device when it is being inserted.

#### c. Material

- The angle guide should be made of material which is biocompatible, and is able to withstand sterilisation through steam or irradiation.
- The material should have more than required ultimate tensile strength to withstand the loading the angle guide will endure while in use.
- The base material interfacing with the femoral shaft surface will have to provide a steady grip without causing damage (scratching or digging into) the bone.

d. Sterilisation

- The instrument should be sterilised prior to use, with steam in a single-use, and using irradiation in a re-use market.

e. Packaging

- The packaging will be sealed air-tight in a double pack to prevent any contamination during transportation. It should clearly state the environmental conditions necessary during transportation to avoid damage.
- It should be possible to open the packaging without use of instruments such as knife or scissors.
- The packaging will be clearly labelled with the instrument description and material. The labels will also state the manufacturer's name and contact details, along with the necessary testing and approval mark. The packaging should specify whether the device is for single-use or re-use.

f. Shape and Dimensions

- The shape and dimensions of the design of the new angle guide should not require an incision length of more than 30 mm for insertion and use.
- The angle guide should allow a pin of 2.5 mm to pass through its tube for insertion into the femoral head and neck.

- The base plate will be in contact with a curved surface with a radius of curvature in the range of 13 mm to 18 mm. The base plate should grip and form a steady construct on top of the curved surface.

#### g. Ergonomics

- The design of the new angle guide should allow comfortable use by a surgeon with one hand of either handedness.
- The front end of the base plate should be tapered to slide through soft tissues and muscles layer during insertion.
- The surgeon should not “sense” any bending of the angle guide while pushing it against the bone surface during use.
- If the new design consists of an assembly, the individual components should form a sturdy construct.
- The product should not have any sharp edges to injure the patient, surgeon or the surgical staff.

#### h. Customers

- The customer will be orthopaedic surgeons, who will be utilising the angle guide during surgical implantation of the DHS. The angle guide will also be handled by the assisting surgical staff for a short period.

i. Manufacturing

- The most suitable manufacturing process should be chosen according to the finalised concept.
- The angle guide should be manufactured to the tolerances mentioned in the final engineering drawings of the design.

j. Documentation

- A detailed technique for using the instrument during the surgery should be documented in a manual supplied along with the product.
- If the final design has detachable parts, documentation should also include assembly and disassembly instructions.
- Procedure for sterilisation and re-sterilisation (re-use market) should be included in the information supplied by the manufacturer.

k. Disposal

- If the final design has detachable parts, it should be easy to disassemble by any member of the surgical staff.
- If any, it should be possible to separate the recyclable and non-recyclable parts of the instrument during disposal.
- The manufacturer will have to document the appropriate disposal technique for the instrument.

## l. Competition

There are two prominent designs in the market.

- A very common design of the angle guide produced by most manufacturers of DHS instrument set including Synthes GmbH (Solothurn, Switzerland) and Smith & Nephew plc. (London, UK).
- A variable angle guide offering all required angles (120 degrees to 150 degrees) through a single device is manufactured by Depuy Orthopaedics (Warsaw, USA).

## m. Testing

- The design of the new angle guide should be verified using risk analysis and finite element analysis.
- Prototypes of the final design should be manufactured for testing by orthopaedic surgeons in operating conditions for final verification.

## n. Standards

- Angle guide is classified as a class I device according to medical device directive, 1993. The device should conform to the requirements of a class I device to obtain the necessary marking and certification.
- Other standards include
  - ISO 12011 for general requirements for surgical instruments,
  - ISO 14971 for application of risk management,



- ISO 15223-1 for requirements of symbols to be used with medical device labels,
- ISO 17664 for information to be provided by the manufacturer for the processing of resterilisable medical devices,
- ISO 17665-1 for sterilisation process using steam, and
- ISO 11137-1, ISO 11137-2 and ISO 11137-2 for sterilisation process using irradiation

### ***3. 9. 3. 2. PDS for an Ergonomic T-handle***

The new T-handle will be attached to instruments such as the angle guide and insertion wrench. Therefore, certain aspects such as standards, environment, packaging and documentation would not apply specifically to the handle but to the whole instrument. Hence, they were not considered in the PDS of the new T-handle.

#### **a. Function and Performance**

- The T-handle will be used to
  - push and hold the angle guide against the femoral shaft surface, and
  - advance the lag screw into the femoral head and neck using torque.
- The new T-handle should be comfortable to hold and not cause tiredness to the user due to inappropriate dimensions or shape.

- The T-handle should predominantly provide a power grip. However, precision grip is also necessary due to the minimally invasive surgical application.
- The handle should provide sufficient grip to the surgeon to use the instruments efficiently.

#### b. Material

- Layers of different materials will be used to manufacture the ergonomic T-handle. The skeleton should be stainless steel 316L, which will be the same as the surgical instruments. The skeleton should be overmolded with soft polymer.
- The material should be able to withstand multiple cycles of steam sterilisation for a re-use market. It should also be able to withstand sterilisation using irradiation in markets where the device is to be supplied sterile.

#### c. Shape and Dimensions

- The T-handle should be a minimum of 125 mm long, and have a diameter in the range of 30 mm to 50 mm.
- The cross section of the T-handle will be cylindrical. The diameter of the handle should be largest at the centre and reduce as it moves towards the ends.

- The surfaces which will engage with the user's hand should have a radius of curvature of about 25 mm.

#### d. Ergonomics

- It should be possible for surgeons of both sex and handedness to grip the handle comfortably.
- The exterior surface of the handle should be soft to touch and not consist of any sharp edges.
- It should be possible to manufacture the T-handle in different colours.

#### e. Customers

- The customer will be the orthopaedic surgeon performing the DHS implantation procedure. The handle may also be used by the assisting surgical staff during the procedure. The handle should be safe and comfortable to use by the surgeon, and not cause any injuries to the patient or the users.

#### f. Manufacture

- The manufacturing process should allow the T-handle to be produced along with the associated instrument as a joint assembly.

#### g. Competition

- A detachable stainless steel T-handle used with generic DHS surgical instrument set is commonly supplied by manufacturers.

- Ergonomic T-handles are supplied by certain reputed manufacturers like Stryker (Kalamazoo, Michigan, USA) and B. Braun Melsungen AG (Melsungen, Germany).

#### h. Testing

- A manufactured prototype of the ergonomic T-handle should be assessed subjectively by practicing orthopaedic surgeons in a simulation of the DHS surgery for its comfort and efficiency.

### 3. 9. 3. 3. *PDS for a New Implant*

#### a. Function and Performance

- The new implant will be a non-active implantable device to be totally introduced into the human body by means of surgical intervention. The device should promote minimally invasive surgery and require an incision length of less than 30 mm.
- The device is intended to provide support to the femur for at least a period of 90 days after the surgical procedure.
- The implant is designed for treatment of fractures of the proximal femur in adults. The device should stabilise and reduce the fracture of the proximal

femur. It is designed to prevent rotation of the fracture fragments at the site.

- The new implant assembly should comprise of a fixation screw and an angled side plate, and it should retain the basic principle of present generic DHS implant, which is to allow the fixation screw to slide down the angled side plate.
- The implant will be designed to allow for removal from the human body if required.
- The implant will be designed for single use only.
- The surgical procedure of the new implant should be identical to the conventional surgical technique for DHS available in the market. However, the procedure should allow for angled side plate to be fixed on the femur before advancing the fixation screw through the plate. This would permit a shorter incision length.
- Activity level of patients undergoing this treatment will be low, and the device should help the patient in returning to functional weight bearing some 6 to 12 weeks after implantation.
- The new implant should be able to withstand static and cyclic (fatigue) loading equivalent to or better than the generic DHS implant.

**b. Environment**

- The new implant should be kept in a sterile environment before use. The device will be designed for use in live patients, with an otherwise intact soft tissue envelope around the proximal femur.
- After surgery, the implant will be secured in the femur, and should aid in the healing process of the proximal femur fracture. The device should not interfere with homeostatic conditions.

**c. Material**

- Stainless steel 316L will be used for the manufacture of the new implant. The characteristics of the stainless steel to be used should comply with standard BS 5832-1.
- If different materials are used in the implant, their compatibility should be checked to avoid any reactions.

**d. Design attributes**

- The shape and dimensions of the new implant should require an incision length for insertion and assembly of less than 30 mm.
- The fixation screw would be of telescoping screw assembly consisting of the lag screw telescoping out of the barrel
- The design should allow for a collapse of 20 mm of the fixation screw. There should be a clearance of 1 mm between the outside surface of the sliding nail and the inside surface of the barrel.

- The range of effective lengths of the fixation screw should be from 50 mm to 150 mm, with preferred increment of 5 mm.
- The angled side plate would have three distal screw holes to secure the plate to the femoral shaft.
- The angled side plate will be designed so that the fixation screw-angled side plate will have an angle of 120 degrees to 150 degrees in increments of 5 degrees.
- The region of the angled side plate that interfaces with the femoral shaft surface will have a curved profile with a radius of curvature of more than 18 mm.
- The sliding mechanism should not allow for rotation of the fixation screw.

e. Ergonomics

- The steps in the surgical procedure should be colour coded for easy classification for the surgical room staff and surgeon.
- It should be possible to visualise the position and orientation of the implant once in the human body through means of imaging equipment.
- The angled side plate will have a tapered bottom edge to slide down the lateral femoral shaft.

f. Customers

- The customers will be the orthopaedic surgeon and the assisting surgical staff that will use the new implant during surgery to treat proximal femur fracture.
- The patient will be the consumer, who should be able to avail the benefits of this treatment by using the new implant without complications. The doctors must make sure the patient is a suitable candidate for treatment with the new implant and advice must be given on proper care during post-surgical recovery.

g. Sterilisation

- The new implant will be supplied sterile. The sterilisation process shall be validated and routinely controlled.
- The implant will be sterilised using irradiation.

h. Packaging

- The implant shall be supplied in double blister packaging.
- The packaging shall be labelled “STERILE” and should state the name and address of the manufacturer.

i. Documentation

- A detailed surgical procedure along with description of the implant should be provided along with the device by the manufacturer.



- The manufacturer should also supply information on the points mentioned in clause 11 of standard BS EN ISO 14630 (2008)

#### j. Manufacture

- The implants shall be manufactured such that the specified design attributes are achieved and the manufactured samples are within the tolerances mentioned in the engineering drawing of the final detail design.

#### k. Disposal

- It should be possible to remove the implant from the patient's femur.
- The manufacturer should specify the method of disposal of the device following removal from the patient.

#### l. Competition

- The generic DHS implant is produced and marketed by numerous large and small manufacturers. Other notable and similar devices by reputed manufacturers, which also promote minimally invasive surgery, are listed below.
  - Gotfried PC.C.P (Orthofix srl, Italy)
  - Targon® FN (B. Braun Melsungen AG, Melsungen, Germany)

#### m. Testing

- The device should undergo pre-clinical evaluation, which involves
  - risk analysis of the implant,

- finite element analysis of the design, and
- *in vitro* testing of manufactured prototypes according to methods described in ASTM F 384 (2006) to assess static and cyclic (fatigue) loading of the implant.
- It is necessary that the device undergoes a clinical evaluation in accordance with requirements of ISO 14155-1 and ISO 14155-2.

#### n. Standards

- The standards that the new implant should comply with are
  - ASTM F384 for testing methods,
  - BS 3531-15 for specifications for devices for the fixation of the ends of the femur in adults,
  - BS EN ISO 14602 for particular requirements of implants for osteosynthesis,
  - BS EN ISO 14630 for general requirements of non-active surgical implants,
  - BS 7254-2 for general requirements for materials and finish in orthopaedic implants,
  - BS ISO 5832-1 for requirements of wrought stainless steel in implants for surgery,
  - BS EN ISO 11607-1 for requirements of packaging for sterilised medical devices,

- BS EN ISO 14155 for clinical investigation of medical devices for human subjects
- BS EN ISO 11137-1 and 2 for sterilisation process using irradiation, and
- BS EN 1041 for information to be supplied by the manufacturer of the medical devices

### 3. 10. Summary

The summarising points of this chapter are listed below.

- i. Hip fractures are the most common form of injuries in the elderly and with the increase in life expectancy, there is a likelihood of an increase in the number of incidences.
- ii. Amongst the surgical treatments available to treat fractures of the proximal femur, dynamic hip screw (DHS) is considered to be the standard fixation device.
- iii. The advantages of minimally invasive surgical (MIS) approach are significant and new devices designed to treat fractures of the proximal femur attempt to exercise this approach.
- iv. The devices that were identified to allow for MIS of DHS and will be redesigned are a) the angle guide, b) T-handle, and c) the DHS implant. The new devices should require an incision length of less than 30 mm, and should utilise a surgical approach similar to the conventional procedure used to implant the generic DHS. Product design specifications were developed for the three new medical devices to be designed in this research.

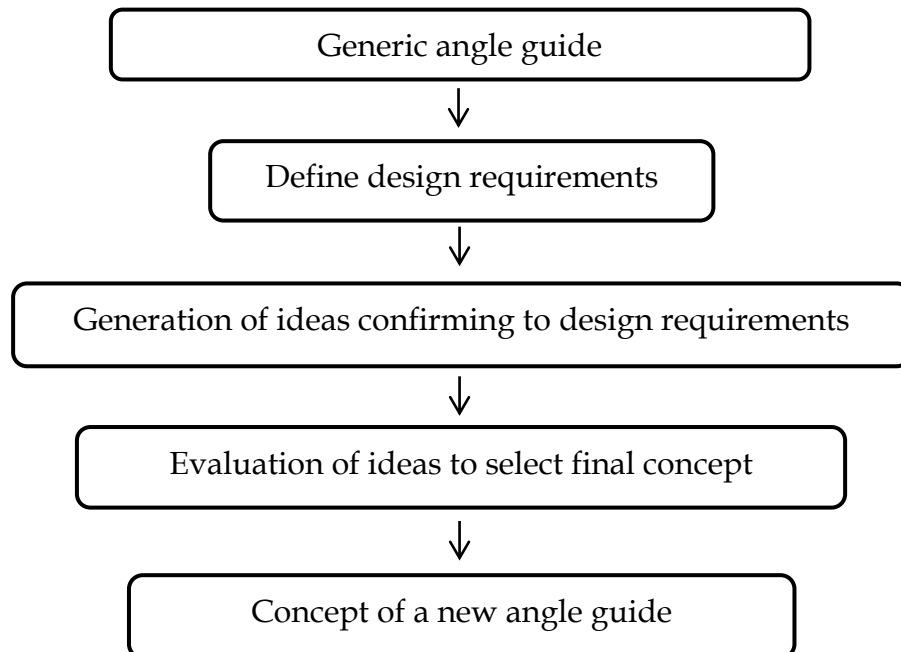
# CHAPTER 4

## CONCEPT OF A NEW ANGLE GUIDE

### 4.1 Chapter at a glance

#### 4.1.1. Chapter overview

Figure 4.1 shows the chapter overview in the form of a flowchart.



**Figure 4.1: Flowchart of the chapter structure**

#### 4.1.2. Keywords

BS EN 12011 (1998); DHS angle guide; concept design generation; product design specification

## 4. 2. Introduction

The angle guide, shown in Figure 3.9, is the first device to be used from the surgical instrument set for the implantation of a dynamic hip screw (DHS) as discussed in section 3.6.3. It is used to insert the guide pin at the anatomically required angle, usually between 125 and 150 degrees, into the femoral neck and head (Canale, 2002). The accurate positioning of the guide pin is important as it is the basis of lag screw insertion. A lag screw cut-out, which accounts for up to 16.8% of complications associated with the DHS, and other complications such as non-union of the fracture, could follow an incorrect placement of the guide pin (Kumar *et al.*, 2007). Guide pin insertion using the angle guide is, therefore, an important step of the surgery.

The advent of minimally invasive surgery (MIS) requires a revaluation of the current surgical procedure, implant and instruments of their respective surgery to enable their use through a smaller incision. It was discussed in section 3.8.3 that the base plate of the angle guide requires a minimum incision of 40 mm to be inserted and used during the surgery. It was also concluded during the description of the surgical procedure in section 3.6.3 and 3.8.3 that all the instruments with the exception of the angle guide are capable of operating within an incision length of less than 30 mm. The angle guide is hence the incision-controlling device, which was clearly demonstrated in a few techniques (section 3.8.3(ii)) that have avoided the use of an angle guide and conducted MIS with an

incision of only 20 mm. MIS techniques that have engaged the angle guide (section 3.8.3(i)) needed a minimum incision of 40 mm. Although MIS has been successfully conducted without the use of an angle guide to implant a DHS, the importance of correct placement of the guide pin and subsequently the lag screw to avoid implant failures urges the use of an angle guide for safer treatment. Guide pin placement is described by the application and technique manual for TK2 compression hip screw system (DePuy Orthopaedics, Warsaw, Indiana, USA) as the most important step of the surgery.

The redesigned angle guide would allow its use in a MIS to implant a DHS with an incision length of less than 30 mm. The following sections in this chapter describe the process of introducing a new concept of an angle guide for use in MIS to implant a DHS.

### **4. 3. Existing angle guides**

The shape and dimensions of a current angle guide were taken from the DHS angle guide shown in Figure 3.9, which was manufactured by Sushrut Surgicals Pvt. Ltd. (Pune, Maharashtra, India). It should be noted that the design is similar to the angle guide supplied by other leading manufacturers in the medical device industry such as Synthes GmbH (Solothurn, Switzerland) and Smith & Nephew plc. (London, UK), amongst others. The generic design of a fixed angle guide is a

long solid rod connected perpendicularly to a base plate which has three or four prongs at the bottom. The upright rod is connected to the base plate with a fixed angle strut like member fixed at different angles (between 120 degrees to 150 degrees). The strut is not a supporting component for the structure, but a pipe (henceforth pipe refers to the path for the guide pin) through which the guide pin is advanced. The design was constructed of stainless steel, and could be sterilised. Surgeons use a detachable T-handle, which fixes to the top of the angle guide to hold the instrument. During surgery, the angle guide grips the bone using the prongs at the bottom. A guide pin with a maximum diameter of 2.5 mm is advanced through the fixed angle pipe into the femoral neck and head.

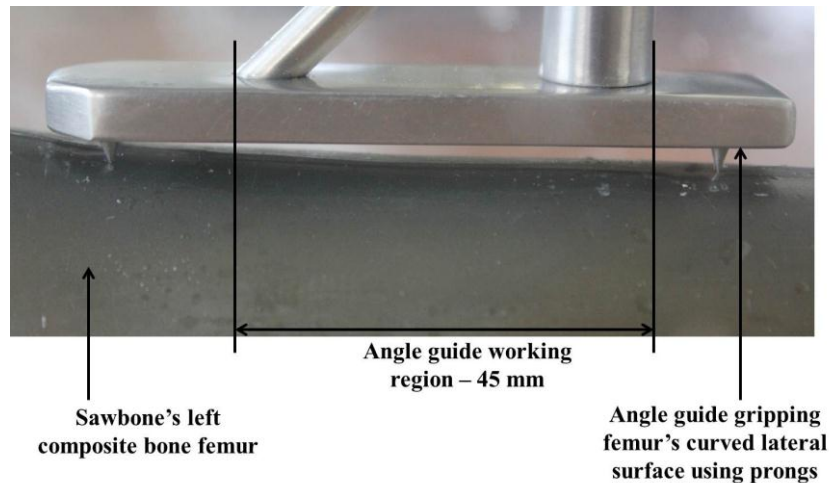
A design analysis of the generic fixed angle guide was conducted by a consultant surgeon - Prof. N. Maffulli, and by engineers - Prof. D. W. L. Hukins, Dr. D. E. T. Shepherd and the author. The concerns of the design are listed below. The concerns were either raised by Prof. N. Maffulli from his professional experience or by emulating the use of an angle guide in surgery by placing the device on a medium left composite bone femur (item #3403) supplied by Sawbone Europe AB (Malmo, Sweden), as shown in Figure 4.2. The engineering drawing of the generic angle guide (without the prongs) is shown in Figure 4.3

- i. The dimensions of the base plate were unjustifiably large, which prevented smaller incisions. The purpose of the base plate was to – a) support the perpendicular rod from the handle, b) provide an exit hole for the guide pin to



advance through, and c) to grip the bone (prongs at the bottom in the current design). The working area of the base plate for all these functions was approximately 45 mm x 15 mm, however the dimensions were larger, 63 mm x 15 mm, as shown in Figure 4.2.

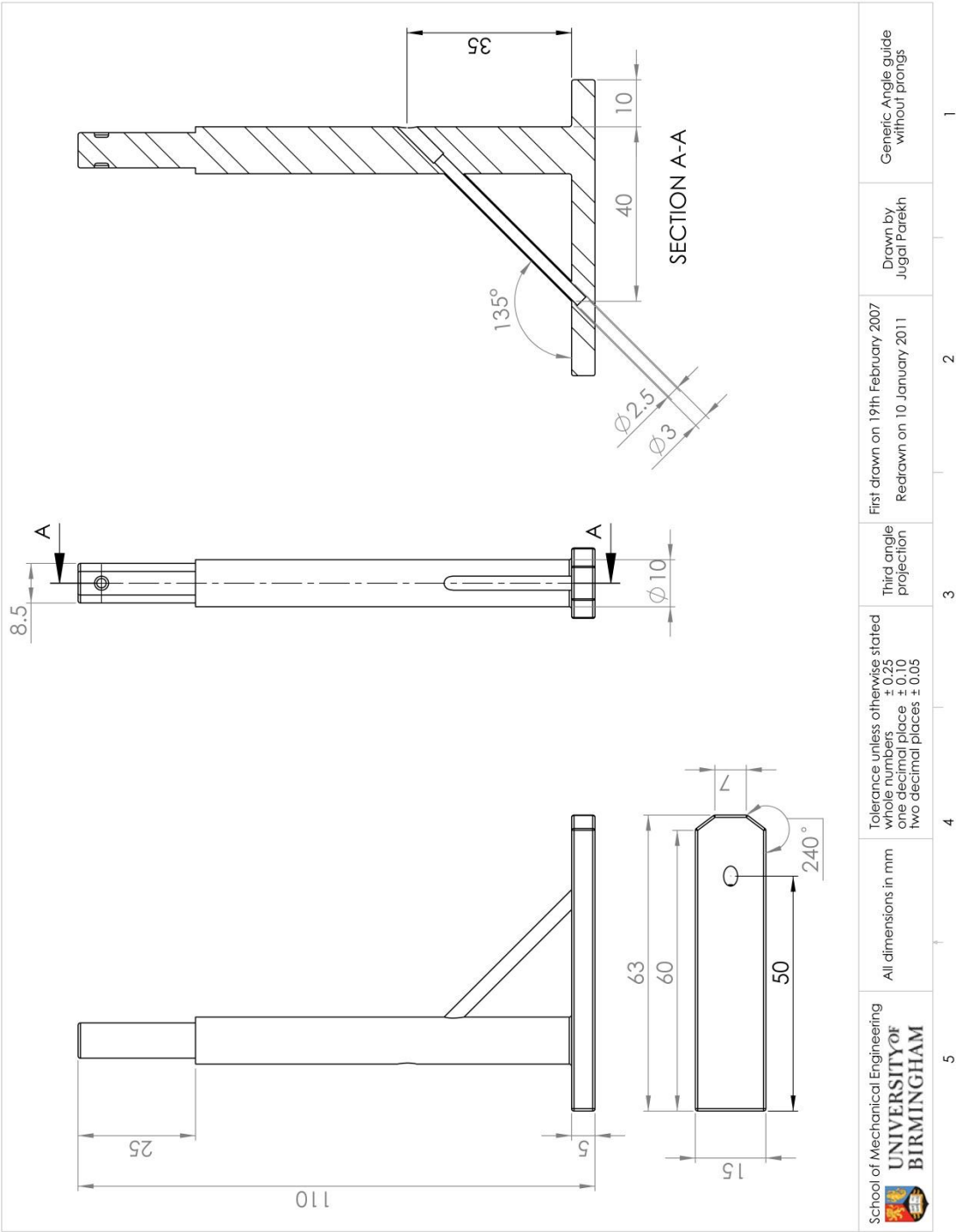
ii. The base of the guide was flat, whereas the surface of the femur where it is placed was curved and slippery. Although the prongs achieved reasonable grip by digging into the bone (Figure 4.2), it was not able to achieve stability because of the uneven and curved femur surface. There was also a concern of misjudgement with the alignment of prongs on the bone surface. This could affect accuracy as the instrument might not be parallel to the femoral shaft when in contact.



**Figure 4.2: Angle guide gripping the curved lateral surface of a left composite bone femur (Sawbone Europe AB, Malmo, Sweden) with sharp prongs**

- iii. The guide was connected to the T-handle using a locking mechanism. Even following locking, the handle moved relative to the guide, which might affect the surgeon's judgement of correct placement on the bone. The handle itself was too small to hold in the hand, and was taken up for redesign (Chapter 7).
- iv. The guide was unable to provide any level of intimation to the surgeon on correct placement on the bone without the aid of fluoroscopy. This would be a drawback especially during a MIS, as direct visual assistance will be limited.
- v. The prongs achieved grip by digging in and scratching the bone. This may be harmful to the bone especially in patients with weak bones, where the prongs could cause considerable damage. The sharp prongs may also pose as a hazard to the surgical staff as they might cause tearing of surgical gloves or injury to the staff due to contact.

The design analysis of the generic angle guide was compared to the PDS developed in section 3.9.3.1, and the resulting successes and failures of the design's conformity to the PDS are tabulated in Table 4.1.



**Figure 4.3: Engineering drawing of the 135 degrees angle guide (without prongs) manufactured by Sushrut Surgicals Pvt. Ltd. (Pune, Maharashtra, India)**

The angle, at which the guide pin is to be inserted into the femoral head, ranges from 125 degrees to 150 degrees. As an alternative solution to requiring different fixed angle guides for each angle, a variable angle guide is used. However, the design of a variable angle guide requires a much bigger base to accommodate the different angled pipes; thus requiring a bigger incision. Hence, these devices would not be viable for MIS.

**Table 4.1: Summary of the existing generic angle guide's compliance to the PDS (section 3.9.3.1)**

<u><i>Success</i></u>	<u><i>Failure</i></u>
Accurately guides the pin at the required angles	Requires a minimum incision of 45 mm
Grips the femoral shaft surface	Sharp prongs as base may cause damage to patient and the surgical staff handling the instrument
Structure successfully withstands loading with no feel of bending	
Stainless steel 316L withstands sterilisation using steam or irradiation	The levelled prongs are unable to accurately place the angle guide parallel to the curved femur surface
	Does not guide the surgeon to the pin's entry point on the femoral shaft
	The assembly of T-handle and angle guide results in an unstable structure

#### **4. 4. Design objectives of a new angle guide**

The assessment of the existing angle guide summarised in Table 4.1 identified the short-comings of the current design. The goals of the process, listed below, would attempt to eliminate these weaknesses and design a comprehensive new angle guide for minimally invasive surgery.

- i. The device should be able to accurately target and advance the guide pin at the anatomically appropriate angle into the femoral head.
- ii. It should be possible to insert and utilise the angle guide within an incision length of 30 mm.
- iii. An alternative base should be designed to replace the existing prongs to grip the bone and guide the surgeon to the pin entrance point on the femoral surface.

#### **4. 5. Design requirements of a new angle guide**

##### **4. 5. 1. Overview**

This section discusses the general requirements of the new angle guide and justifies the specifications listed in the PDS in section 3.9.3.1. The points discussed in this section are in accordance with the standard BS EN 12011 (1998), which

states the general requirements for instruments used in association with non-active surgical implants. The standard was subsequently replaced by BS EN 16061 (2008) on 31<sup>st</sup> May 2009; and eventually by BS EN 16061 (2009) on 31<sup>st</sup> December 2009.

#### **4. 5. 2. Function**

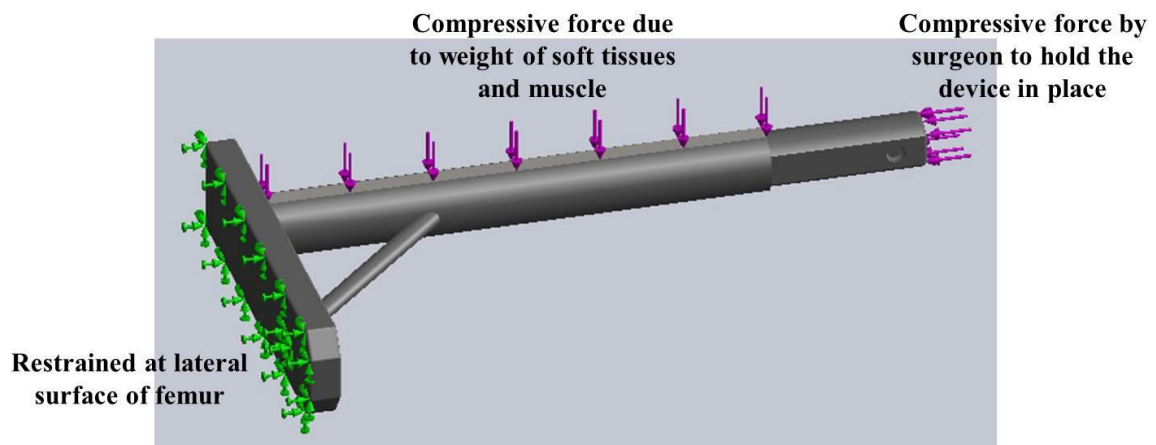
The intended function of an angle guide is to be temporarily placed on the lateral surface of the proximal femur to accurately provide both horizontal and vertical reference required by the surgeon to insert a guide pin of a maximum diameter of 2.5 mm into the femoral head. This would aid in the correct placement of the lag screw of the DHS implant and prevent complications during fracture treatment. Owing to the differing femoral anatomy in patients, the angle of insertion of the guide pin could range from 120 degrees to 150 degrees (at increments of 5 degrees), and thus the angle guide should cater to the required angle of insertion. To achieve accuracy during the targeting of the guide pin, the device needs to provide a stable grip on a curved and slippery bone surface.

#### **4. 5. 3. Forces**

The device will have to withstand two sets of forces – both compressive whilst in use. They are - i) the surgeon's force to hold the device in place, and ii) the force due to the weight of soft tissues and muscle acting on top of the angled device.

The forces acting on the generic angle guide are illustrated in Figure 4.4. The determinations of values of the forces are discussed in detail below.

i. *Surgeon's arm push force*: The surgeon will be applying force through the handle onto the device to hold it in place on the femur surface while inserting the guide pin. The average available arm force has been stated to be 26.5 N (Hill, 1998). The same was checked and verified by the author by pushing against a weighing scale placed on a wall, and the result was  $27 \pm 4$  N after 5 trials. Additionally, the maximum force that a fifth percentile American male, which includes ninety percent of the US male population, is able to transmit is 222 N (Tilley, 2002). This force was assumed as the maximum compressive load that the device will have to endure.



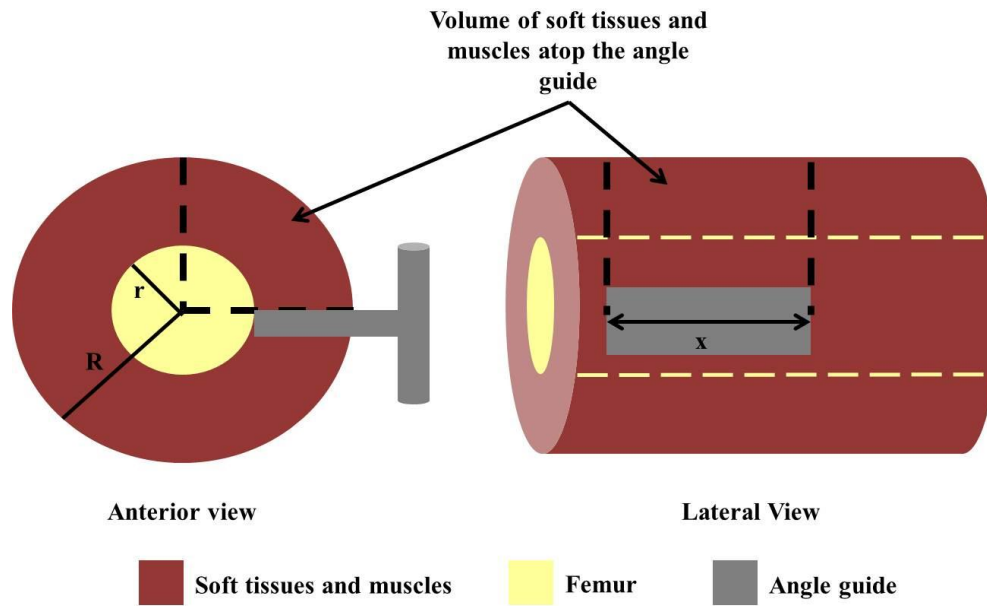
**Figure 4.4: Forces acting on a generic angle guide whilst in use**

ii. *Weight of soft tissues and muscles* – The weight of soft tissues and muscles acting on the angle guide was estimated to be only 4 N, on the basis of the calculations described below. The calculations assume that the thigh and femur are perfect cylinders, where  $x$  is the length of base plate of the angle guide (0.063 m as shown in Figure 4.2),  $R$  is the radius of thigh (radius of 0.0985 m or less includes ninety eight percent of the US male population – Tilley, 2002), and  $r$  is the radius of femur (0.014 m is the average radius of the femoral shaft at the concerned region – Stephenson and Seedhom, 1999). The formula to calculate the volume,  $V$ , of soft tissues and muscles in a single thigh (volume of a cylinder) within the region of the angle guide as shown in Figure 4.5 is given by:

$$V = \pi x(R^2 - r^2) \quad (4.1)$$

The total volume of soft tissues and muscles in a single thigh was calculated to be 0.0015 m<sup>3</sup>. Assuming that the volume of soft tissues and muscles on top of the angle guide is a quarter of the total (Figure 4.5), the value was calculated to be 0.00038 m<sup>3</sup>. The density of muscle is reported to be 1060 kg/ m<sup>3</sup> (Urbanchek *et al.*, 2001). Therefore, the resulting mass of muscles and soft tissues on top of the angle guide would equal 0.40 kg, or approximately 4 N.





**Figure 4.5: Anterior and lateral schematic view of the thigh region. It is assumed that the thigh and the femur are perfect cylinders**

#### 4. 5. 4. Material

The main requirement of a material in a medical device is that it should be biocompatible and it should be able to resist sterilisation. The device was to be designed for single-use and re-usable markets, and hence is required to withstand sterilisation through irradiation prior to packaging in single-use markets and through autoclave using steam in re-usable markets. Gamma radiation sterilisation is an effective, economical and proven method used prior to packaging of medical devices (Hill, 1998). The material should also be strong enough to withstand the compressive forces of the surgeon and the weight of the soft tissues and muscles that were mentioned in the section 4.5.3. The material at the bottom of the base plate should provide sufficient grip with the bone to avoid any slipping of the guide.

#### **4. 5. 5. Shape and Dimensions**

The shape or dimensions of the angle guide should not require an incision length of more than 30 mm. According to the design of the generic guide in use currently, the distance from the front end of the pipe to the back end of the cylindrical bar should not be more than 30 mm. The length of the perpendicular shaft connecting the base to the handle should be long enough for the handle to stay out of the patient's body (outside of soft tissues, muscle and skin) when the base is in contact with the femur. The measured length of the generic angle guide and T-handle assembly manufactured by Sushrut Surgicals Pvt. Ltd. (Pune, Maharashtra, India; angle guide shown in Figure 3.9) was 165 mm. The distance from the bottom of the base plate to the centre of the guide pin inserting hole on the angle guide was 40 mm.

#### **4. 5. 6. Ergonomics and design attributes**

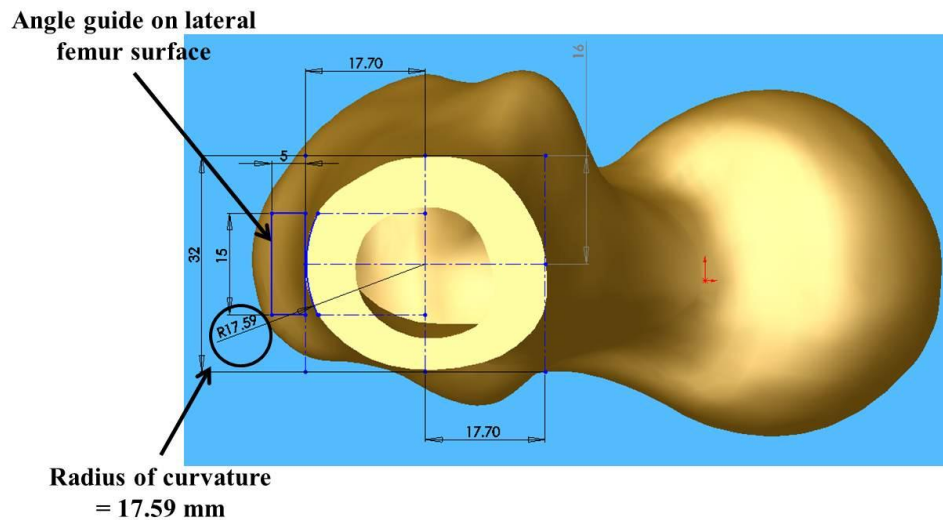
The guide was to be designed for use by surgeons of either handedness. It was noted by Prof. N. Maffulli that the guide should feel sturdy and that the surgeon should not experience a 'feeling' of bending during the use of the device, especially when pushing the guide against the femur. The design of the new angle guide was to be kept simple to avoid a steep learning curve for the surgeons.

#### 4. 5. 7. Base plate and surface of femur

One of the important objectives of the design process was to replace the steel prongs in the generic angle guide used to grip the bone surface. It was important to understand the surface anatomy of the bone in the region that will interface with the angle guide to understand the requirements of a design that would conform to the bone surface.

The base of the angle guide would be in contact with a curved cortical bone, which might be slippery due to the presence of blood. Using a standardised three dimensional model of the femur on SolidWorks (Dassault Systèmes SolidWorks Corp, Concord, Massachusetts, USA), and using values stated in past literature work on the structure of the femur, it was possible to derive a range for the value of the radius of curvature of that particular region of femur. Figure 4.6 shows a three dimensional model of the third generation composite femur (#3306, Sawbone Europe AB, Malmo, Sweden) created by Rob Day, Subajan Sivandran and Shandip Abeywickrema; it is available on the Internet (<http://bit.ly/gjpt4k>) through the BEL Repository managed by the Istituti Ortopedici Rizzoli, Bologna, Italy. An angle guide was placed at the location where it is supposed to be during the surgery, and using SolidWorks tools, the radius of curvature was measured to be 17.59 mm. Stephenson and Seedhom (1999) have stated the cross-sectional area of human femoral shafts (including medullary canal) to be in the range of 550 mm<sup>2</sup> to 675 mm<sup>2</sup>. Assuming the shaft is cylindrical, the radii would hence range from

13.2 mm to 14.7 mm. After taking into consideration these two findings, the range of radius of curvature for the lateral femoral surface was deduced to be between 13 mm and 18 mm. However, the cross-sectional area might differ with race and sex. No further studies were found stating the cross-sectional area of femur at the concerned region. Therefore, the value of radius of curvature selected for the design specification of the new angle guide was higher at 20 mm to consider the variability.



**Figure 4.6: Three dimensional model of composite bone femur was used on SolidWorks to calculate the radius of curvature of the lateral surface**

#### 4. 5. 8. Single-use or re-use market

The new angle guide, along with forming a part of the new implant's instrument set, was also designed to replace the existing angle guide from the generic DHS instrument set in use presently to promote minimally invasive surgery and the relating benefits. Considering the world-wide popularity of the existing DHS, it is

important for the design specifications of the new angle guide to comply with requirements of both re-use and single-use markets. Apart from the material specifications to allow sterilisation using both methods, as mentioned in section 4.5.4, it is also important to package the device differently in the two markets. It is required by standard BS EN ISO 12011 (1998) to clearly mention on the packaging whether the instrument would be re-usable. It will also be required to supply the sterilisation and disposal instructions according to the different market. In case of a re-usable instrument, it would be important for the manufacturer to specify the maximum cycles of use that the instrument can endure before disposal. The new angle guide should be able to perform the intended functions efficiently and safely in either market.

It could be argued that substituting the material which can withstand both types of sterilisation with a suitably cheaper one, which can withstand the sterilisation as required by the type of market, may lower the cost of the manufactured product. However, the economies of scale due to mass production of a single design, the possibility of recycling the material from used instruments from both markets, and the ability to supply according to demands from the markets would be highly beneficial. Hence, a single design of the new angle guide was to be made to comply with requirements of both markets. This would allow the product to be supplied in either market with appropriate changes to be made only to the packaging and information to be supplied by the manufacturer.

## 4. 6. Evolution of a concept

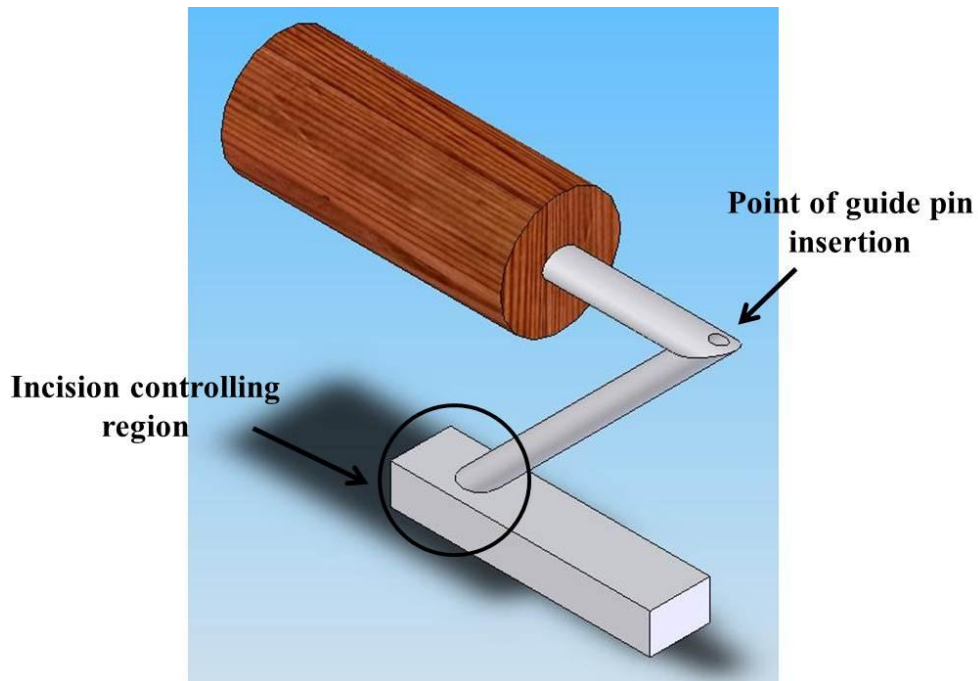
### 4. 6. 1. Overview

Various concept ideas were generated for the new angle guide based on the design objectives and requirements discussed in the previous sections. The ideas are discussed in detail in this section. The section concludes with the final concept that was selected to be taken forward for detail design.

After consultation with Prof. N. Maffulli, it was decided to design the handle and the angle guide as one structure. Elimination of the locking mechanism would reduce the probability of manufacturing defects and an unstable jig. However, it was also decided to inspect the handle individually at a later stage of the research (Chapter 7). Hence, the ideas and the final concept of a new angle guide were connected to a cylindrical handle with a diameter of 30 mm. Also for the convenience of the design process, angle of 135 degrees was considered for all specifications and discussions as the fractured femur's neck/shaft angle. The final design specification of the new angle guide (section 6.3.1) discusses the possibilities of the other angles.

#### 4. 6. 2. Idea 1

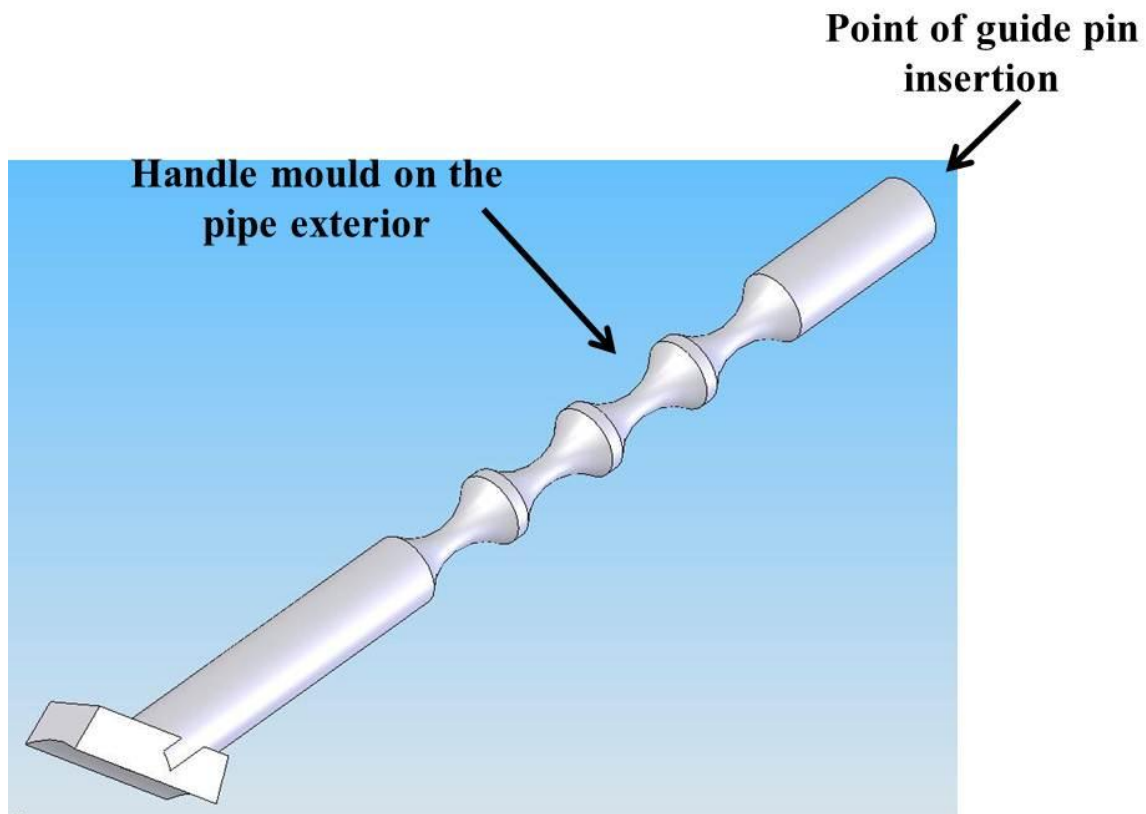
The first idea for a new angle guide, shown in Figure 4.7, was a 'Z' shaped structure. The angle between the pipe and the base plate corresponded to the angle required for the surgery (135 degrees). The pipe connected to a shaft with an ergonomic handle superiorly. The base could be inserted through an incision length of 20 mm and then slid down distally on the lateral femoral shaft until it sat parallel to the shaft on the bone. The guide pin would be advanced through the angled pipe into the femoral neck and head.



**Figure 4.7: Idea 1 for a new angle guide – 'Z' shaped structure**

#### 4. 6. 3. Idea 2

Idea 2 consisted of an angled pipe connected to a base plate. The exterior of the angled pipe was moulded to resemble a handle for holding the device, as shown in Figure 4.8. The objective of this concept was to design a simple device to satisfy the function of an angle guide. An incision of only 25 mm would allow the insertion of the device, as the diameter of the shaft was the largest of the dimensions that controlled the length of incision required for this design.



**Figure 4.8: Idea 2 for a new angle guide**

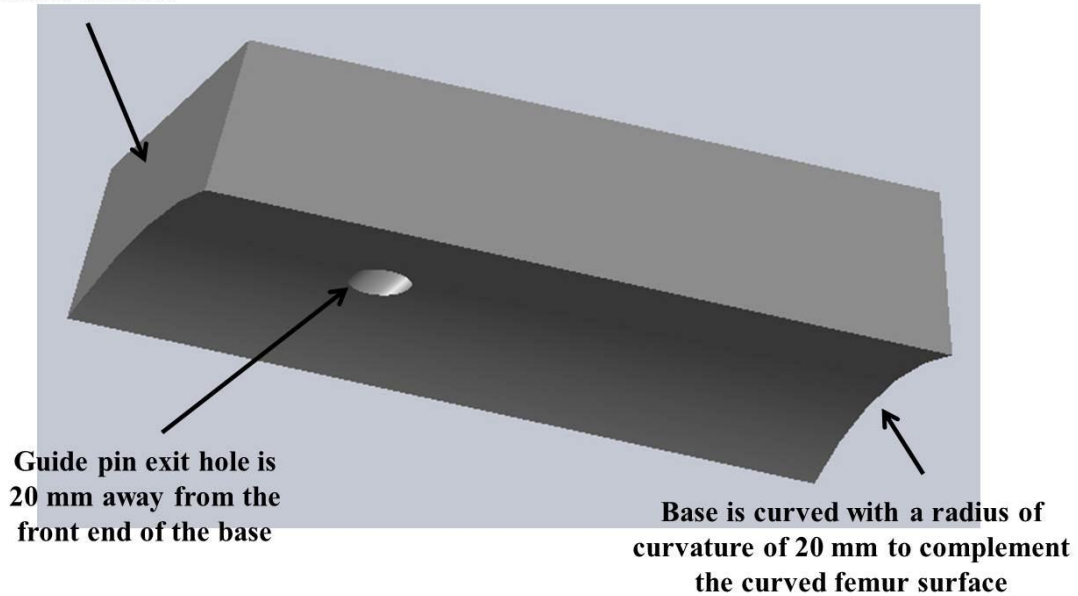


The idea applied two new innovations to the base plate which would assist the device to attain - i) the stability and avoid slippage on the bone; and ii) provide feedback to the surgeon when it is in position on the femur for insertion of the guide pin. The innovations are shown in Figure 4.9, and are described in detail below.

i. ***Stability and Grip:*** The bottom of the base plate was curved to complement a curved femur. The radius of curvature of the femur was found to be in the range of 13 mm to 18 mm. However, to accommodate any irregularities in the radius of curvature of the femur, the radius of curvature of the base plate was determined to be 20 mm. The curvature on the base plate would restrict lateral motion of the device once it is placed on the bone.

The grip of the device on the bone would be enhanced by eliminating the sharp prongs from the design by attaching a layer of either silicone elastomer or using stainless steel with a rough texture, or a combination of both. This proposition is discussed in more detail in Chapter 5, which describes a test conducted to find the values of the static coefficient of friction of the different materials. The results assisted in finalising the material that would provide the best grip on a slippery bone surface.

Front end is chamfered  
to easily slide over  
femur surface



**Figure 4.9: Innovations applied to the base of the new angle guide**

ii. **Feedback:** The guide pin entry point for a 135 degrees femoral neck is approximately 20 mm below the *vastus lateralis* ridge as discussed in the surgical technique in section 3.6.3. The distance from the hole for the guide pin exit at the bottom of the base plate to the front end of the base plate in Idea 2 was 20 mm. The surgeon would hence be able to estimate the correct placement of the angle guide on the femur, which later may be confirmed with fluoroscopy images. This may reduce the time and effort required to correctly place the angle guide.

#### 4. 6. 4. Idea 3a/ 3b

Idea 3a was a 'C' shaped structure, and differs from Idea 1 in the positioning of the base plate with relation to the angled pipe. The reason for the change was to include the feedback feature as discussed in Idea 2 and to align the handle (the line of force) parallel to the base plate (the line of restraint). The new alignment would make the design stable. The guide would slide proximally on the femur after insertion through an incision of 20 mm. The base plate would have the stability and grip features discussed in Idea 2 (section 4.6.3).

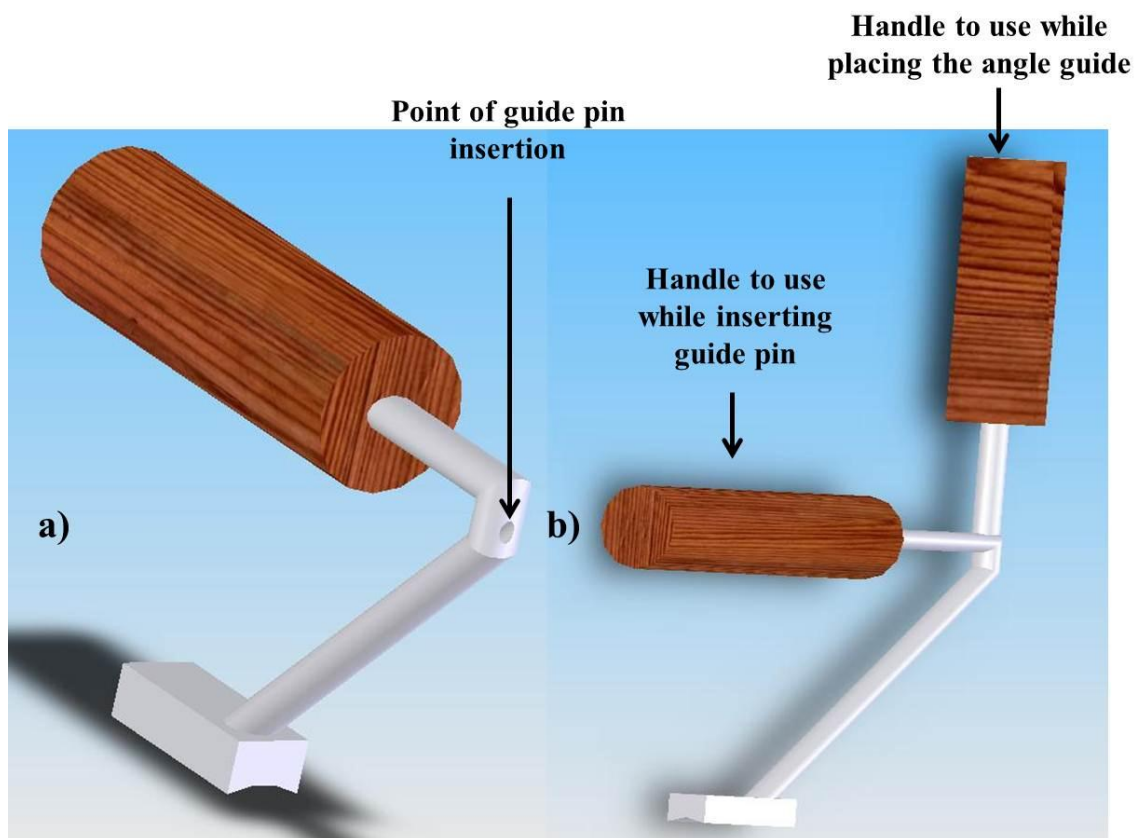


Figure 4.10: a) Idea 3a, and b) Idea 3b for a new angle guide

Idea 3b added a vertical handle to Idea 3a. The vertical handle would make it easier for the surgeon to insert the guide through the smaller incision, and holding the horizontal handle would keep the guide stable while inserting the guide pin. Idea 3a and 3b are shown in Figure 4.10a and 4.10b.

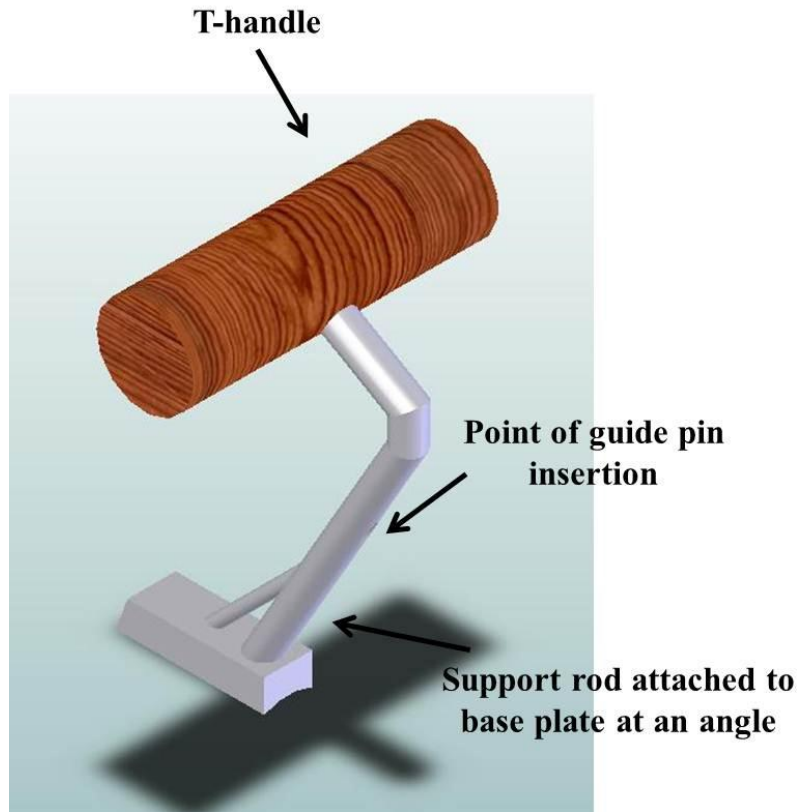
#### **4. 6. 5. Idea 4**

Idea 4 was a union of the existing market design of the angle guide to the requirements stated earlier to reduce the surgical incision length to less than 30 mm. The cylindrical support shaft of the generic design was connected to the base plate at an angle of 120 degrees for a 135 degrees angle guide, as shown in Figure 4.11. This reduced the distance between the support shaft and the pipe for the guide wire from 45 mm to 23 mm, and hence the incision required to insert the guide was reduced. The stability and grip, and the feedback features were the same as in Idea 2. The concept also included a T-handle instead of a normal cylindrical handle. The T-handle is used in the existing set of generic DHS instruments.

#### **4. 6. 6. Concept Evaluation**

The ideas underwent a thorough inspection by a team of engineers – Prof. D. W. L. Hukins, Dr. D. E. T. Shepherd, the author and by a consultant surgeon – Prof. N.

Maffulli. They were evaluated subjectively based on their strengths, feasibility and disadvantages.



**Figure 4.11: Idea 4 for a new angle guide**

Idea 1 was the breakthrough concept of a device which could be used within a 30 mm incision. The device would only require an incision of 20 mm to be inserted. However, the design lacked the features of the proceeding ideas. The design also posed a problem with the structure as the pushing down of the handle could result in the lifting of the base plate. Another problem of the design was that it could cause trauma to the soft tissues and muscles distal to the incision. It could be noted that if the base plate of Idea 2 was added to Idea 1, it would effectively turn into Idea 3.

Idea 2 gave a simple solution to the design objectives. The idea was accompanied by two novel approaches to address the issues of gripping and feedback to the surgeon. However, the solution was not feasible from an engineer's point of view as excessive or accidental application of force by the surgeon could result in the guide slipping forward, which could cause injury to the patient and the user. From the surgeon's perspective, the design lacked the character of being a surgeon's instrument. This was an important point considering the new angle guide was attempting to replace an instrument that has been in use for over two decades.

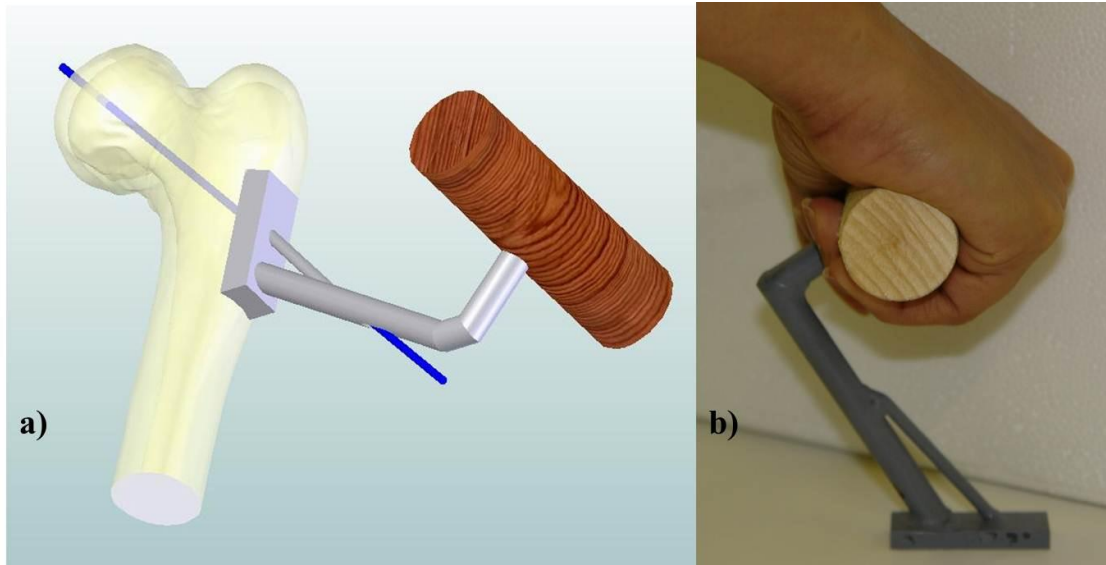
Idea 3a was a stable design which included all the features and objectives that were required of a new concept. Idea 3b was a practical solution but it got too bulky for the intended function, and thus Idea 3b was eliminated from being selected as the final concept.

Idea 4 was able to achieve all the objectives in a design which was very similar to the existing generic design of an angle guide. Idea 3a and 4 did not pose any problems from an engineer's perspective. However, Idea 4 was preferred not only due to the familiarity that would add to the confidence of surgeons whilst using the new instrument, but also due to the existence of a T-handle, which was described by the surgeon as more comfortable to use than a normal cylindrical handle.

#### **4. 6. 7. Concept of a new angle guide**

The objective of a new angle guide design was to utilise it through an incision less than 30 mm. The new concept should not compromise on its primary function of accurately inserting a guide pin into the femoral head. It should also provide a good stable grip on the bone and intimate the surgeon on correct placement to insert the guide pin.

Idea 4 was selected as the final concept for a new angle guide and is simulated in use in Figure 4.12a. The new concept was able to combine the familiarity of the existing angle guide design with the objectives of this design process. A prototype of the concept was manufactured for visual evaluation and is shown in Figure 4.12b. The prototype was manufactured at the automotive workshop at the School of Mechanical Engineering in the University of Birmingham using materials available from within the workshop. The device was manufactured by the author and Mr. Lee Gauntlett from the automotive workshop. The angle guide was made using mild steel, and the handle was made of beech wood. Following the concept evaluation, it was decided to bring the position of the handle in line with the front end of the base plate to add more stability to the design.



**Figure 4.12: a) Final concept of the new angle guide shown with a guide pin passing through it, and b) A manufactured prototype of the final concept**

The concept was taken forward through a detail design process and verification, discussed in Chapter 6. Prior to that, a new base material was selected (Chapter 5) for the new angle guide to provide grip on slippery bone surfaces.

A survey was conducted by the author and Dr. D.E.T. Shepherd, and organised by Prof. N. Maffulli on 7<sup>th</sup> December 2007 at the City General Hospital (Stoke-on-Trent, UK). The purpose of the survey was to determine an appropriate material (silicone elastomer or stainless steel) that would be most comfortable to use for the interface of the instrument's base with the bone. The details of the survey are described in Appendix A. Although the survey was not conclusive, as mentioned in section A.5, the author was able to get the surgeon's perspective on handling of a bone-interfacing instrument. A useful observation was that eight out of ten surgeons faced difficulty in placing an instrument on to the bone surface; seven



reasoned that slippage of the instrument was the factor; stability of the instrument was a factor for two respondents; poor design, insufficient access to bone site and learning curve were considered to be factors by one respondent (each respondent gave more than one factor). Two surgeons also suggested that better grip and curved base would enhance the bone-instrument interface. Due to the inconclusive results and the small sample size, the findings were not considered in the design process of the new angle guide.

#### **4. 7. Summary**

The summarising points of the chapter are listed below.

- i. A new angle guide, which would be capable of being inserted through a maximum incision length of 30 mm for use during minimally invasive surgery, was taken up for design.
- ii. A PDS for the new angle guide was prepared in accordance with clauses stated in standard BS EN 12011 (1998), which states the general requirements for instrumentations for use in association with non-active surgical implants.
- iii. A total of five concepts, based on the requirements laid in the PDS, were discussed in this chapter. Idea 4, a design similar to the generic DHS angle guide was selected to be taken through to the detail design stage.

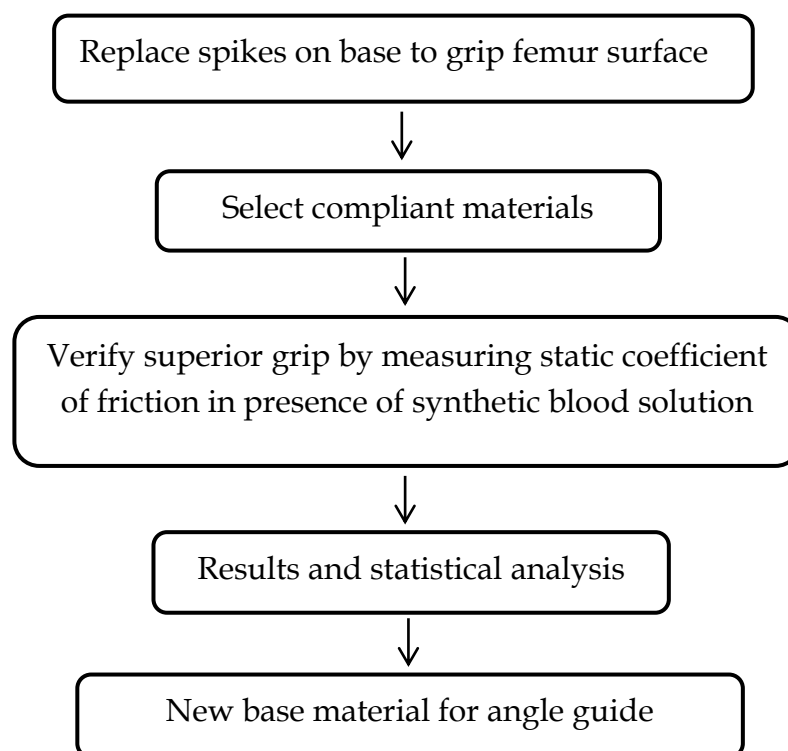
# CHAPTER 5

## A NEW BASE MATERIAL FOR THE NEW ANGLE GUIDE

### 5. 1. Chapter at a glance

#### 5. 1. 1. Chapter overview

Figure 5.1 shows the chapter overview in the form of a flowchart.



**Figure 5.1: Flowchart of the chapter structure**

#### 5. 1. 2. Keywords

Bone – instrument interface material; silicone elastomer; static coefficient of friction; synthetic blood solution; textured stainless steel

## 5. 2. Introduction

It was decided in section 4.4 that the new design of the angle guide would not have spikes as a feature to grip the bone. The spikes are unstable as they do not follow the curvature of the bone and could also cause trauma during use. These problems might be overcome by having a roughened steel surface. The only publication discovered by the author on the frictional forces between distinctive metal surfaces and polyurethane or bone was by Dammak *et al.* (1997). They concluded that a surface with a cast meshed texture provided the highest friction coefficient on the bone. In this work the surfaces were specially designed and manufactured to be considered for joint arthroplasty implants intended for long term fixation. On the contrary, the angle guide would be used for a much shorter period and the purpose of the instrument would not justify the manufacturing costs of a meshed surface. Furthermore, the surfaces used during the tests by Dammak *et al.* (1997) were dry. However, in practice, the interface between instrument and the bone surface would be covered by blood, leading to a reduced coefficient of friction.

An alternate approach to the use of stainless steel was to use a compliant material that conforms to the bone surface without plastic deformation when the surgeon pushes down on the instrument. Silicone elastomers were chosen as examples of compliant, biocompatible materials (Colas and Curtis, 2004) in this study. The elasticity of a silicone insert would also be beneficial as it would conform to the

bone surface on application of force. Furthermore, this material is also able to withstand sterilisation with irradiation and steam, which was considered as an important specification for the new angle guide (section 4.5.4)

### **5. 3. Investigation objective**

The purpose of this study was to determine whether textured stainless steel manufactured with conventional metal finishing processes or silicone elastomer would provide superior grip on the bone. Standard textured stainless steel surfaces were used that had been roughened by surface grinding, sand blasting and spark erosion. Three different grades of silicone elastomers were used that were intended for fabrication of medical devices.

The superior grip was evaluated by measuring the coefficient of static friction,  $\mu$ , at the bone - material interfaces in the presence of a synthetic solution that had a comparable viscosity to blood. The determination of the coefficients would aid in selecting the material to provide grip and stability to the angle guide on a slippery bone.

## 5. 4. Materials and Methods

### 5. 4. 1. Variables affecting the measurement of coefficient of friction

The various factors that would influence the value of coefficient of static friction measured in a system are – a) interfacing materials and their surface texture (Surface roughness and method of surface preparation), b) normal force, c) lubricant, d) displacement and velocity, and e) environmental factors - temperature and humidity (ASTM G115, 2004).

This experiment measured the coefficient of static friction by changing the interfacing materials, the surface textures of the materials and the normal axial force acting on the interface. The purpose of this experiment was to determine a material that would provide better grip on bone *in vivo*. There was no rationality in measuring the coefficient of static friction due to variability in the other factors since the lubricant (blood) and environmental factor would remain the same in actual conditions. The angle guide is supposed to grip the bone and not shift from its position. Hence, the effect of displacement and velocity on the coefficient would also not affect the selection of material.

In this experiment, bone would be coupled with six different kinds of materials (three types of stainless steel surfaces and three types of silicone elastomers). It was necessary that the bone samples had flat external surfaces for a steady slide of

the coupling material. Although it would be beneficial for the final test results to have high number of bone samples, it was difficult to find and extract them with flat external surfaces. However, a minimum of three samples were procured, and were put through five test runs with each of the coupling material to ensure valid statistical comparison.

The surface roughness of the materials used in this experiment were characterised using  $R_a$  (centre line average). Other descriptors of surface roughness include  $R_t$  (distance between highest peak and the lowest valley),  $R_p$  (distance between highest peak and the mean line),  $R_v$  (distance between mean line and lowest valley), and  $R_z$  (distance between the averages of five highest peaks and five lowest valleys) (Bhushan, 2001). The average value denoted by  $R_a$  was selected over the extreme values of the other descriptors to minimise the error caused due to an unrepresented peak or valley. The purpose of measuring the surface roughness in this experiment is to reproduce it during manufacturing of the new angle guide using conventional methods, which would be possible with an average roughness value. Manufacturing of a surface profile with accurate surface roughness measurements denoted by the extreme descriptors would result in an expensive process, usually applied for highly-polished items.

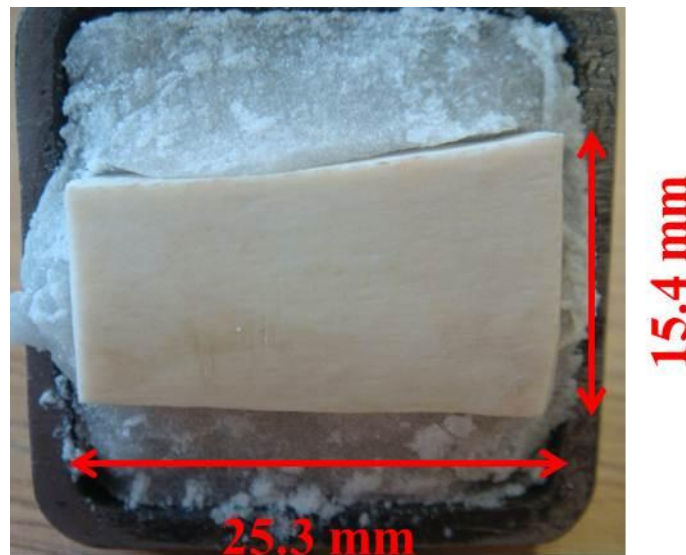
Low friction can be achieved with presence of a layer of lubrication between the coupling materials. The ability of the fluid to lubricate will depend on the ease with which it will flow into the bearing surface to form a lubricating film, which is

influenced by the viscosity of the fluid. The presence of blood as a lubricant in between the stationary instrument and the bone *in vivo* would reduce the coefficient of static friction at the interface. On the contrary, lubricity is defined as the ability of a lubricant to reduce wear and friction, other than by its purely viscous properties (Hamrock *et. al.*, 2004; Bhushan, 2001). The lubricity of the lubricant would have been useful in a study to measure friction at the ball-socket joint in total hip replacement implants, where multiple cycles of loading are expected, and a lubricant with good lubricity would elongate the life of the implant. Therefore, a blood analogue solution that has comparable viscosity to blood to act as a lubricant between the coupling materials will be selected for this experiment.

#### **5. 4. 2. Bone specimen**

Three cortical specimens (approximate dimensions of 25 mm × 15 mm × 5 mm) were cut from the flattest region of the femoral shaft of a frozen bovine femur obtained from Fresh Tissue Supplies (East Sussex, UK). The flattest region was discovered at the lateral-proximal end of the bone. The bone was initially cut in a safety cabinet, with a saw to achieve a roughly rectangular-shaped block. Subsequently a file was used on the inner sides of the cortical bone to file it down to the desired dimensions. The outer surface of the bone was not cut or filed. The soft tissues were removed with a surgical scalpel. The specimen was then rinsed with distilled water to clean the blood and remaining soft tissues off the surface of

the bone. The bone was then dried with a lint-free wipe. Each sample was secured in an open steel box (internal dimensions being 31 mm × 26 mm × 5 mm) using acrylic cement (WHW Plastics, Hull, UK). The bone surface was levelled using a spirit level and protruded above the top of the box by about 3 mm as shown in Figure 5.2. The three samples were stored in a vacuum-sealed plastic bag, wrapped in tissue soaked in Ringer's solution, in the freezer at -40°C, when not in use. The samples were defrosted for 12 hours, rinsed with distilled water and dried with a lint-free wipe prior to the experiment.



**Figure 5.2: Bone specimen (average dimension of 25.3 mm × 15.4 mm) secured in an open steel box with acrylic cement**

#### **5. 4. 3. Stainless steel samples**

Standard samples of finishes on stainless steel surfaces obtained by surface grinding (SG), sand blasting (SB) and spark erosion (SE) (surface dimension being



30 mm × 30 mm, manufactured by Rubert & Co. Ltd. Cheadle, Cheshire, England) were used. The three surfaces are shown in Figure 5.3. Surface roughness ( $R_a$ ) values were measured using a contact method (Form Talysurf-120L, Taylor-Hobson Ltd., Leicester, UK) using a diamond tipped stylus (radius 2  $\mu\text{m}$ ) over a surface area of 1 mm<sup>2</sup>. The machine was calibrated to 0.1443  $\mu\text{m}$ . The readings were taken 6 times on different regions of the samples' surface and the values are tabulated in Table 5.1.



**Figure 5.3: Surface finishes providing roughened texture on stainless steel samples**

#### 5. 4. 4. Silicone elastomer samples

Three different grades of silicone were used: Silastic Q7-4720, Silastic Q7-4750 and Silastic Q7-4780 (all from Dow Corning Ltd, Coventry, UK). All three were biomedical grades intended for fabricating medical devices, including those intended for implantation in humans for less than 30 days (as per manufacturer's data sheet). The angle guide in contrast would not be in use for more than a few

minutes and therefore these materials were considered suitable as a candidate material.

According to the supplier's data sheet, the softest silicone was Q7-4720 (Shore A hardness 23) followed by Q7-4750 (Shore A hardness 50) and Q7-4780 (Shore A hardness 77). The materials were supplied in two parts that were mixed in a Schwabenthan Berlin two-roll mill (Engelmann & Buckham Ltd, Alton, UK). Sheets of silicone (2 mm thick) were prepared in a Moor E1127 hot press (George E Moore & Sons Ltd, Birmingham, UK) under a 50 kN load (applied to an area of 175 mm × 150 mm) at a temperature of 116°C for 12 minutes, as recommended by the supplier. Circular samples of 70 mm diameter were cut from these sheets using a template. Surface roughness values were measured for each grade of silicone sheet as described for stainless steel in section 4. 4. 2., and are shown in Table 4.1.

#### **5. 4. 5. Blood analogue solution**

The synthetic blood solution (1000 g) was made by dissolving xanthan gum (0.4 g; CAS - 11138-66-2, Sigma Aldrich, Town, Dorset, UK) and sodium chloride (5 g; table salt, J Sainsbury, London, UK) in glycerol (400 g; Fisher Scientific, Loughborough, Leicestershire, UK) and distilled water (594.6 g) (Brookshier and Tarbell, 1993). The solution has been used in various studies, including in a test by Banerjee *et al.* (2008) in their study to assess the severity of epicardial coronary stenosis and by Pohl *et. al.* (1996) for *in vitro* testing of artificial heart valves.

#### **5. 4. 6. Measurement of coefficient of friction**

ASTM G115 (2004) was used as a guide for the setup and execution of this experiment. The setup of the experiment is shown in Figure 5.4. The force to overcome the friction between the bone and the silicone or textured steel was provided by a Bose ELF 3200 materials testing machine, operated under the control of WinTest software (Bose Corporation, ElectroForce Systems Group, Minnesota, USA). The machine was equipped with a load cell of full scale of 225 N and a displacement transducer with a full scale of 13 mm. The force required to overcome friction and move the box containing the bone (Figure 5.5) was applied by a nylon monofilament fishing line (Sunset line and twine, Kansas, USA; diameter 0.50 mm and capacity of 13.6 kg). As the purpose of the study was to calculate the coefficient of static friction, an elastic force measuring system was very important (ASTM G115, 2004). Due to its compliance, a nylon monofilament line had substantial elastic strain prior to initiation of motion of the box. This allowed the force measuring transducer to record the gradual accumulation of the force, and finally the “breakaway force” at which the box was able to overcome static friction and commence sliding. The breakaway force was used to calculate the coefficient of static friction.

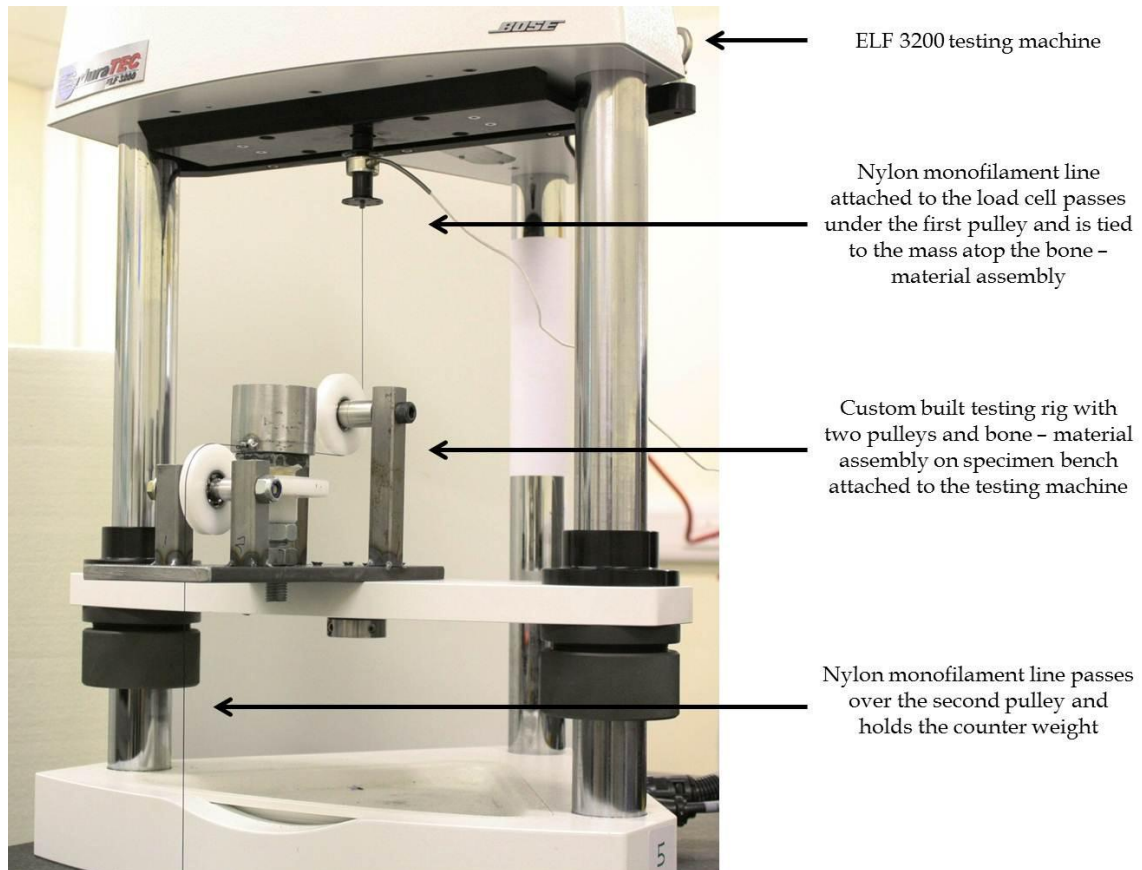
The line to the testing machine from the box was passed under a pulley. The pulley was made of nylon (60 mm diameter, thickness of 9 mm, 0.50 mm wide and 0.25 mm deep groove for nylon line) with a single row radial ball bearing (inner

diameter 10 mm, outer race diameter 26 mm, sourced from RS Stock # 286-7568, RS Components Ltd., Northamptonshire, UK) in the centre to facilitate negligible friction. Nylon was chosen as the material for fabrication as it provided negligible friction with the nylon monofilament line (nylon-on-nylon static coefficient of friction is 0.15 to 0.25, Avallone *et al.*, 2007), was readily available at the time of testing and because of its ease of processing.

From the other side of the bone box, the line passed over a second pulley and was tied to a counter weight of 7.03 N (a weight block of 5.01 N on a 2.02 N holder). The reason for the counter weight were two-fold – a) the downward force due to the counterweight would balance the upward force from the first pulley towards the machine; and b) to stabilise the box containing the bone and weight assembly by providing tension through the fishing line. To attain a flat piece of bone, the size of the sample had to be very small. Thus, the assembly of the bone with the box and weight on top would not be steady due to the shape of the structure and would be unstable during sliding causing errors in force measurements. The height of the bench on which the material-bone assembly rested was adjusted to ensure that the nylon filament lines were straight between the set of pulleys.

The resistance provided by the pulleys was negligible when compared to the force measured. To verify the presence of negligible resistance, a weight was hung off the monofilament line over the pulleys and the force measured by the transducer was recorded. For a weight of 20.05 N (measured using an Ohaus GA200D

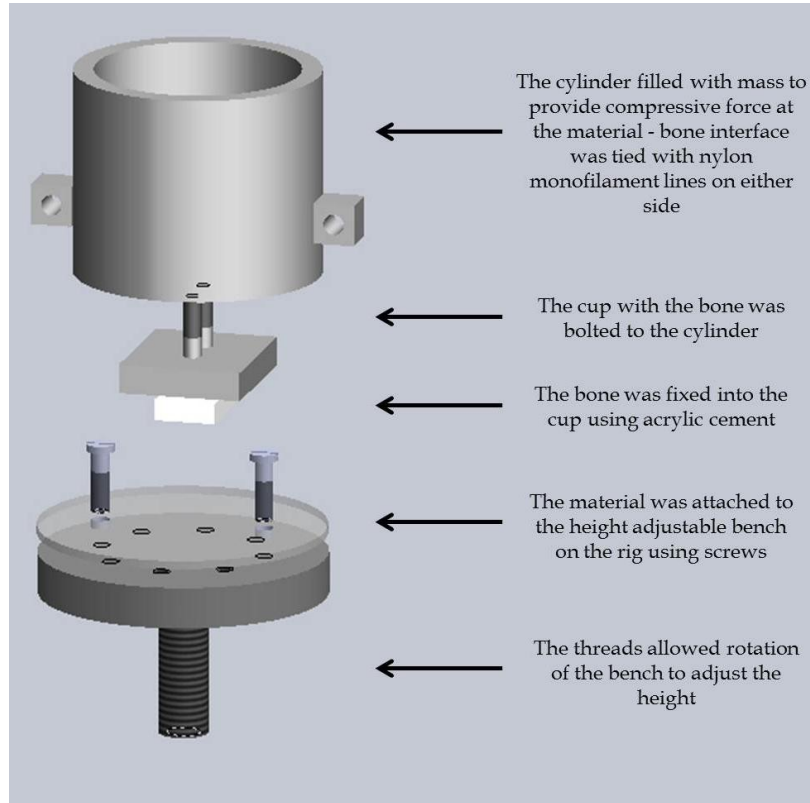
balance, Ohaus, New Jersey, US) that hung off the line, the transducer recorded a value of 20.01 N; 5.00 N for a weight of 5.01 N.



**Figure 5.4: Test rig setup on ELF 3200 testing machine to measure the static coefficient of friction**

Two test runs with dry steel on steel interface were conducted on the test apparatus to measure their static coefficient of friction. The literature value for grease-free steel on steel interface is 0.78 (Avallone *et al.*, 2007). The test runs yielded coefficient values of 0.60 (normal force of 2.36 N; force required to initiate slide was 1.41 N) and 0.66 (normal force of 2.97; force required to initiate slide was 1.96 N). Although the test results were not the same as the literature value, the aim of the experiment was to compare the different material combinations, and not

provide bench-mark values for the different interfaces. It should also be noted that the coefficient values would also depend on the surface roughness and other factors discussed in section 5.4.1.



**Figure 5.5: Exploded view of bone-material assembly setup on the testing rig**

Figure 5.5 shows how the samples and equipment were assembled onto a custom made testing rig to measure the coefficient of static friction. The cup holding the bone specimen (Figure 5.2) was screwed to a mass at the top (gross mass of assembly was 0.47 kg and masses were added in the range of 0.1 kg to 0.4 kg). This assembly was placed on top of the material (stainless steel or silicone elastomer) sample. Silicone elastomer was screwed on top of a height-adjustable specimen bench, whereas stainless steel samples were attached to the bench using double-

sided adhesive-tape. The samples were verified for absence of any undesirable movement due to application of shear force by pushing against them. The mass on top of the bone sample created a compressive force at the interface between the bone and the material.

Before measuring the coefficient of friction, the bone surface was coated with the blood analogue solution, described in section 5.4.4, to mimic the lubrication of blood. A pipette was used to pour 5 mL of the solution on the surfaces of the material and the bone; a paintbrush (diameter 10 mm) was then used to evenly distribute the analogue. Measurements were made at room temperature (20°C). The testing machine was operated in displacement control (0.1 mm/s for a total displacement of 7 mm) and the force was recorded (200 data points per second). The procedure measured the horizontal load-displacement response of the interface in the presence of a constant normal force. Five measurements were made between each pair of surfaces; each pair was loaded with five different weights. CAD drawings of the testing rig and the pulley can be found in Figures 5.6 to 5.8.

#### **5. 4. 7. Data analysis**

A plot of recorded force to slide the bone against displacement was generated for each test run. The graphs were plotted using SigmaPlot 11 (Systat Software Inc., Chicago, Illinois, USA). The breakaway force,  $F'$ , defined as the force required for

overcoming static friction and initiating slide, was considered to be the first maximum force in the plot. The breakaway force could be lower, higher, or even equal to the force needed to maintain the surface sliding in the subsequent relative motion (Bhushan, 2001). If static friction is much larger than kinetic friction, it is possible for a system to exhibit stick-slip (ASTM G 115, 2004). The interface was considered to be stick-slip when the bone block assembly would repeatedly stick to the interfacing material, followed by a slide of certain distance (slip) due to accumulation of a certain force. During such an occurrence,  $F'$ , was determined as the highest force recorded before the bone slipped on the material.  $F'$  was then plotted against the respective compressive load and a regression line was fitted to the data for every bone-material pair. The value of the slope of the regression line was the coefficient of static friction,  $\mu$ , for that particular interface.

#### **5. 4. 8. Statistics analysis**

Statistical calculations were performed using MINITAB Release 16 Statistical Software (Minitab Inc., Pennsylvania, USA). Normality of the distributions was assessed using the Anderson-Darling test (Bland, 2000). Data was compared using the one-way ANOVA for the normally distributed data with the significance level set at 0.05 for all tests.



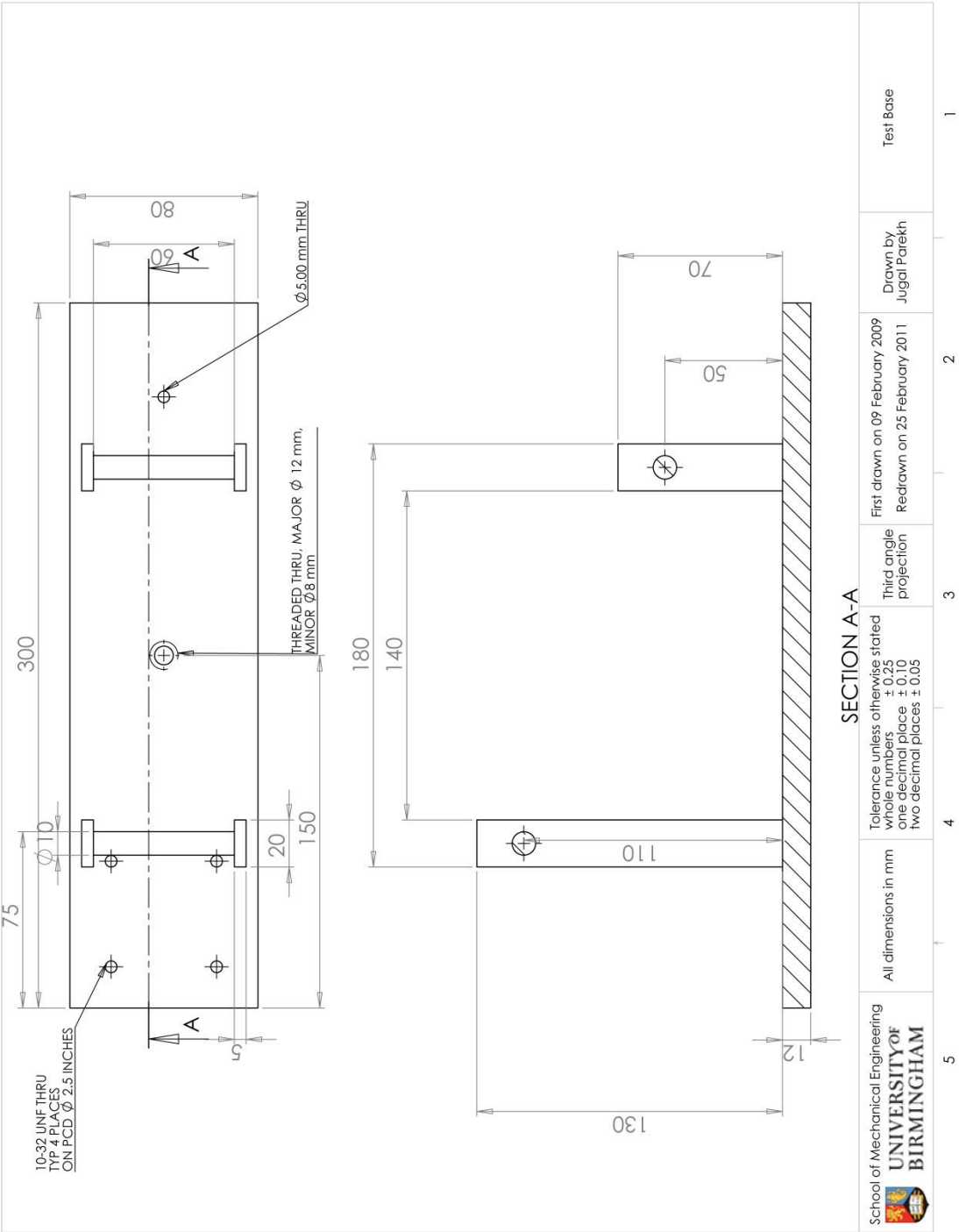


Figure 5.6: Engineering drawing of the custom made test rig base used to measure the static coefficient of friction

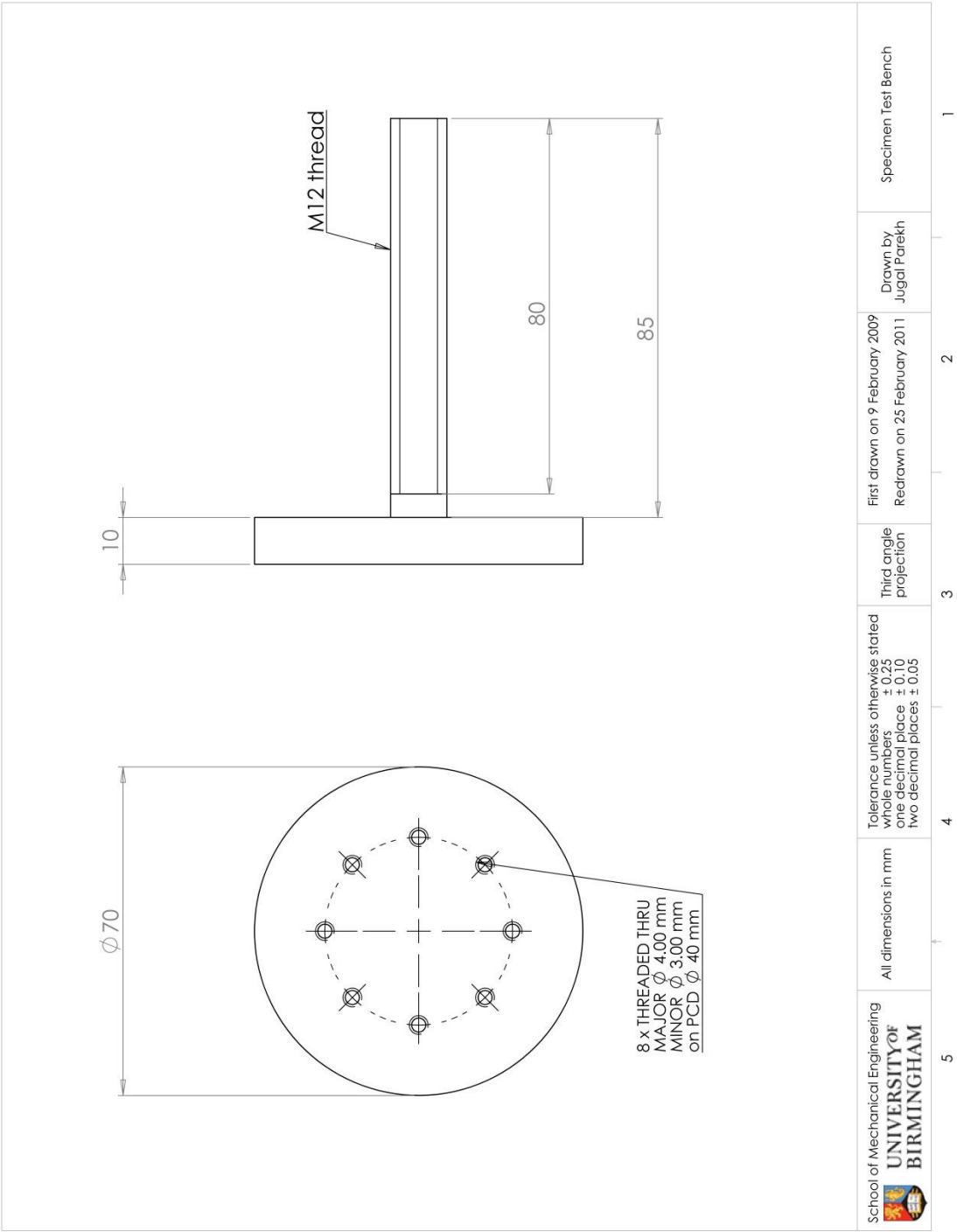
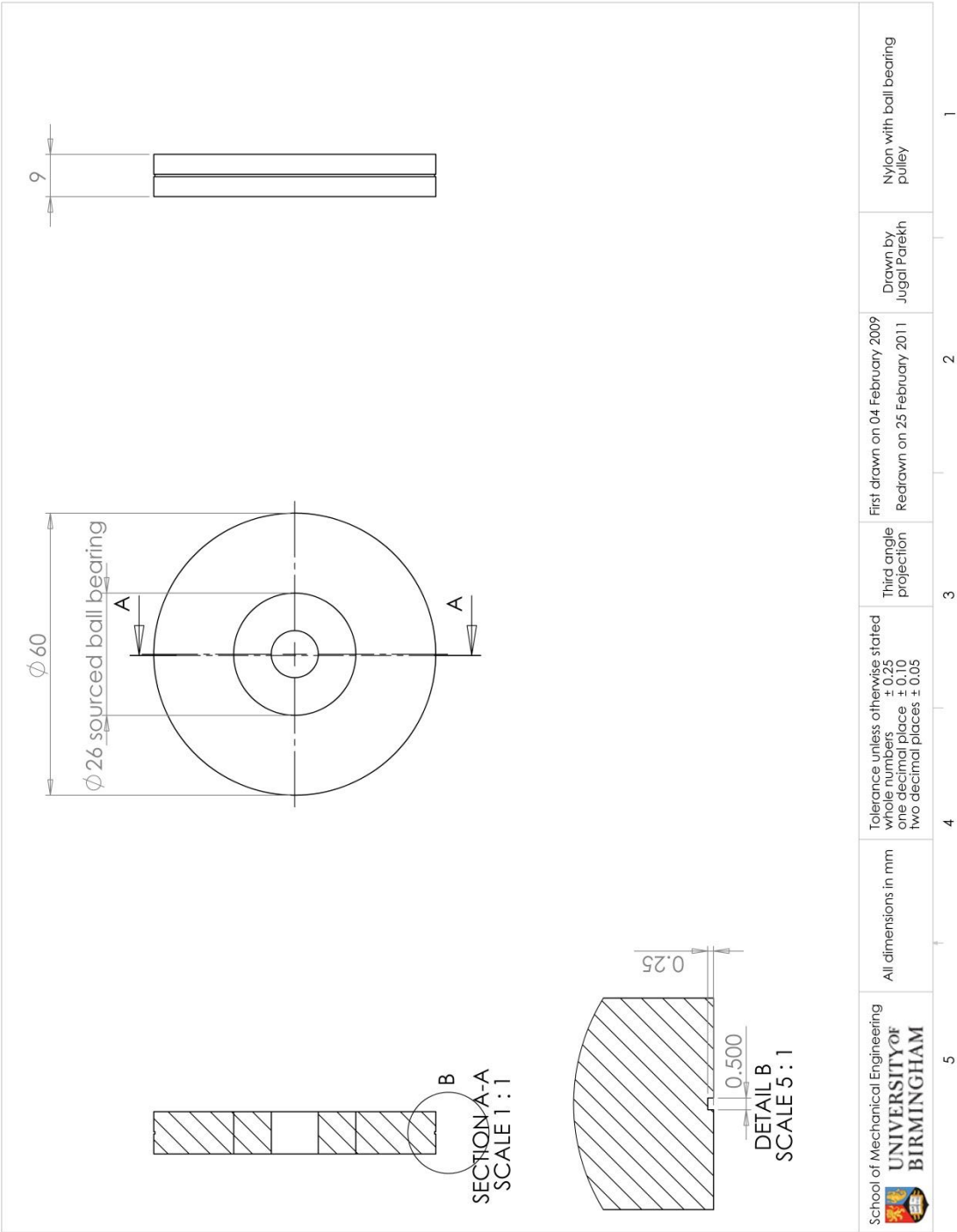


Figure 5.7: Engineering drawing of the height-adjustable specimen bench, which was screwed on to the testing rig



**Figure 5.8: Engineering drawing of the nylon pulley manufactured for use on the testing rig. The pulley was fixed with a sourced ball bearing in the centre.**

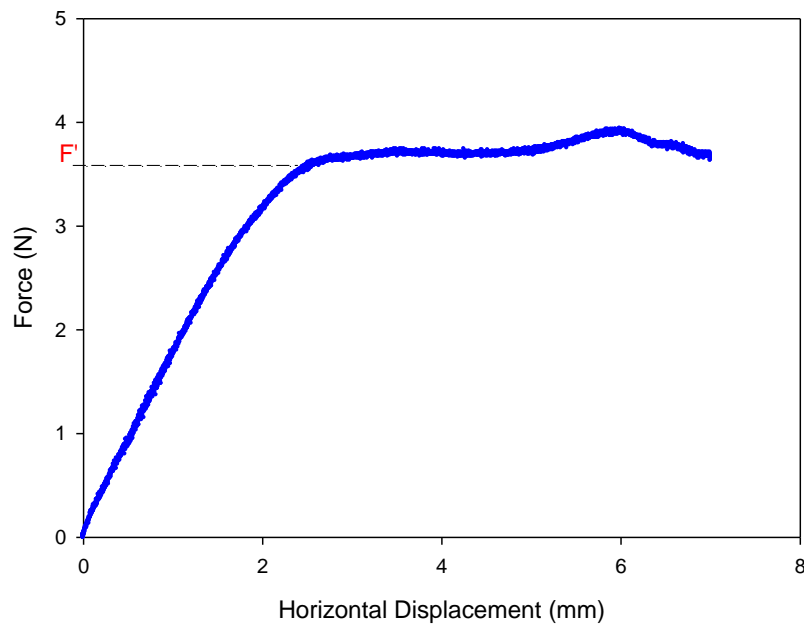
## 5. 5. Results

Table 5.1 gives the surface roughness of the bone, silicone elastomers and steel surfaces used in these experiments.

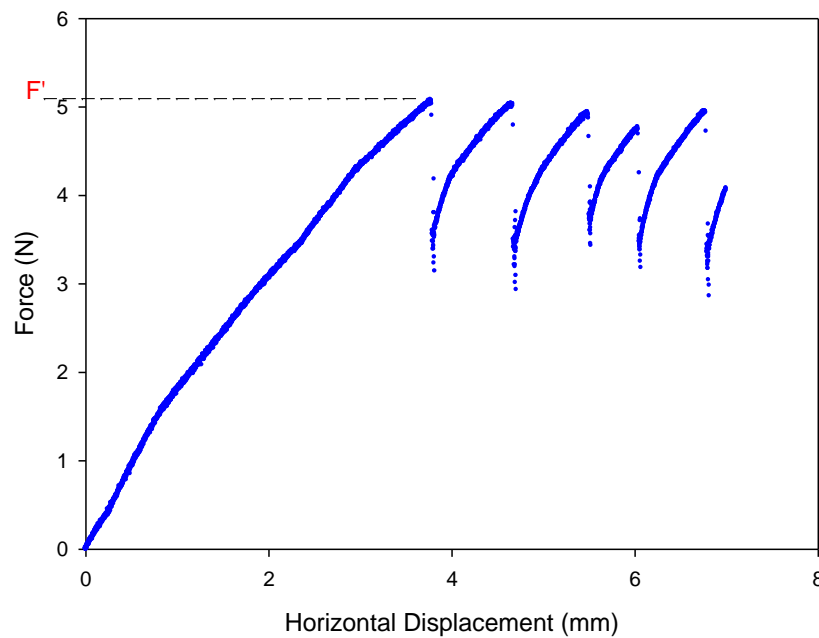
**Table 5.1: Mean surface roughness (mm) measured using a contact method along with their standard deviations**

Material	Surface Roughness ( $R_a$ - $\mu\text{m}$ )
Silastic Q7 - 4720	$1.08 \pm 0.30$
Silastic Q7 - 4750	$1.45 \pm 0.08$
Silastic Q7 - 4780	$1.73 \pm 0.28$
Surface Grind	$0.13 \pm 0.04$
Sand Blast	$2.19 \pm 0.14$
Spark Erode	$8.94 \pm 1.56$

A typical plot of force against displacement for a silicone surface in contact with bone is given in Figure 5.9. The interface did not exhibit a high breakaway force compared to the force required to sustain slide. Figure 5.10 shows a typical plot of force against displacement for a textured stainless steel surface in contact with bone. The system exhibited stick-slip behaviour as the static friction was much larger than kinetic friction.

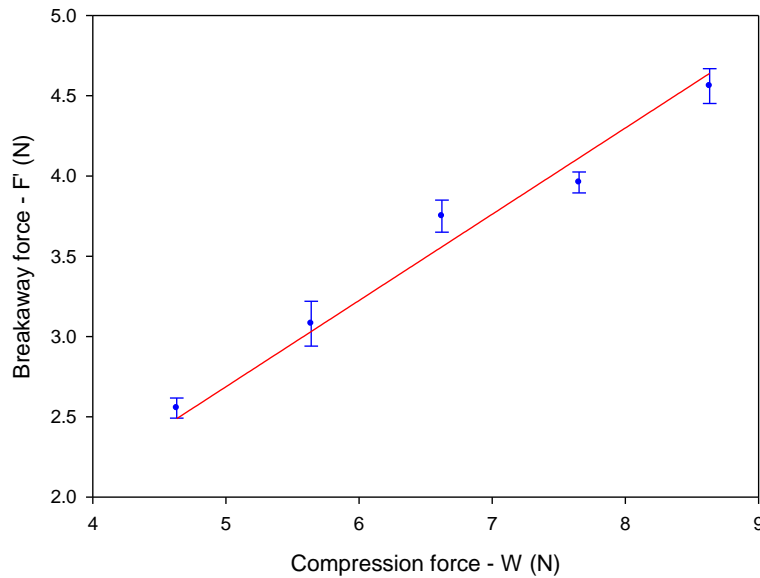


**Figure 5.9:** Horizontal displacement of bone on silastic Q7-4780 was plotted against force required to initiate and sustain slide at a compressive load of 4.63 N.  $F'$  was defined by the first maximum force

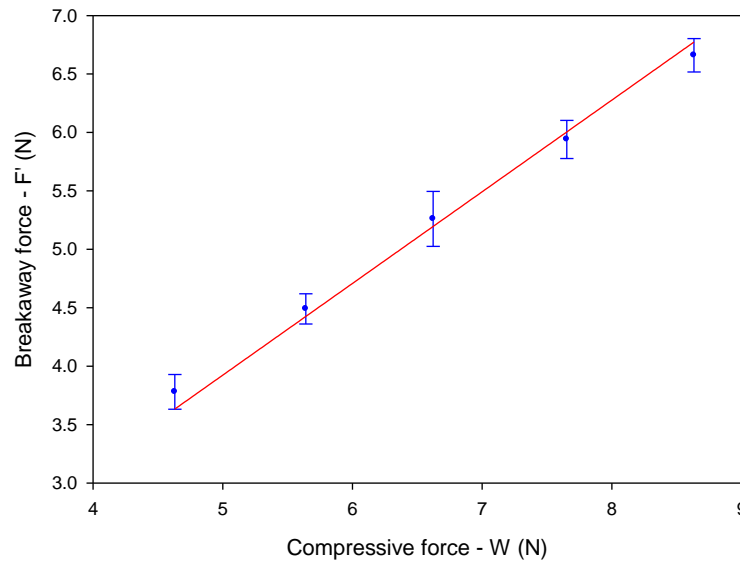


**Figure 5.10:** Horizontal displacement of bone on spark eroded stainless steel was plotted against force required to initiate and sustain slide at a compressive force of 4.63 N. The interface exhibits stick-slip behaviour.  $F'$  was indicated by the highest force prior to slip

Figures 5.11 and 5.12 shows examples of typical plots of breakaway force,  $F'$  against the compressive force,  $W$ , between a bone specimen and silicone surface – silastic Q7-4780 (Figure 5.11) and a textured steel surface – spark erode (Figure 5.12). In both cases there was a linear relationship between  $F$  and  $W$ ; values of the squared linear correlation coefficient ranged from 0.9139 to 0.9910 and there was no systematic displacement of data points from the line which was constrained to pass through the origin. The slope of this line is the coefficient of static friction,  $\mu$ . Table 5.2 shows values of  $\mu$ , with standard deviations, obtained by fitting a regression line to the experimental data for all interfaces.



**Figure 5.11: Breakaway force for bone to initiate slide on silastic Q7 – 4780 calculated at different compressive force were plotted, and the value of coefficient of static friction was taken as the slope of the regression line ( $R^2$  value: 0.9701, p value: 0.8610)**



**Figure 5.12: Breakaway force for bone to initiate slide on spark eroded stainless steel surface calculated at different compressive force were plotted, and the value of coefficient of static friction was taken as the slope of the regression line ( $R^2$  value: 0.9910, p value: 0.5810)**

All data were normally distributed. There was no significant difference between the results from the three bones. Silicone 4780 was an exception from the silicone elastomers, as no significant differences were detected in  $\mu$  for silicone 4780 and the stainless steel samples. All three stainless steel samples were significantly different to silicone 4720 and silicone 4750 ( $p < 0.05$ ). Amongst the silicone elastomer samples, there was no significant difference in  $\mu$  between silicone 4720 and silicone 4750. However, both had significantly less values than silicone 4780 ( $p < 0.05$ ). Amongst the textured stainless steel samples, there was significant difference in  $\mu$  ( $p < 0.05$ ) between sample obtained by surface grind and the sample obtained by spark erode. The sample obtained by sand blast was not significantly different in  $\mu$  to either of the two.

**Table 5.2: Values of coefficient of static friction,  $\mu$ , for different interfaces obtained by fitting a regression line to the experimental data along with mean ( $\pm$  standard deviation) coefficients of static friction**

<b>Silicone elastomer samples</b>			
	<b>Silastic Q7 – 4720</b>	<b>Silastic Q7 – 4750</b>	<b>Silastic Q7 - 4780</b>
Bone 'A'	0.254	0.257	0.537
Bone 'B'	0.240	0.266	0.442
Bone 'C'	0.261	0.279	0.562
<b>Static Coefficient</b>	<b><math>0.252 \pm 0.011</math></b>	<b><math>0.267 \pm 0.011</math></b>	<b><math>0.514 \pm 0.063</math></b>
<b>Textured Stainless steel samples</b>			
	<b>Surface Grind</b>	<b>Sand Blast</b>	<b>Spark Erode</b>
Bone 'A'	0.599	0.654	0.785
Bone 'B'	0.578	0.620	0.713
Bone 'C'	0.607	0.684	0.728
<b>Static Coefficient</b>	<b><math>0.595 \pm 0.015</math></b>	<b><math>0.652 \pm 0.031</math></b>	<b><math>0.742 \pm 0.038</math></b>

## 5. 6. Implications of result on material selection

The results of this study showed that in general textured steel surfaces finished with sand blast or spark erode provide a significantly better grip to bone that is coated with a blood analogue than silicone surfaces that conform to the bone, with the exception of Silastic Q7 - 4780. A stainless steel surface textured by spark erosion (surface roughness  $R_a = 8.94 \pm 1.56$  mm) gave the best grip in the



experiments reported here. Its value of  $0.742 \pm 0.038$  was within the range of values of friction coefficient measured by Dammack *et. al.* (1997) for their metal – bone interfaces (range of  $0.68 \pm 0.10$  to  $0.94 \pm 0.12$ ). It has to be noted that the meshed surfaces in that experiment were specially prepared and barring the value of one specimen from that study ( $0.94 \pm 0.12$ ), spark erode and sand blasted samples from this study ( $0.742 \pm 0.038$ ;  $0.652 \pm 0.031$ ) had comparable values of coefficient of friction to the other specimens ( $0.68 \pm 0.10$ ;  $0.75 \pm 0.12$ ;  $0.66 \pm 0.09$ ).

It was mentioned in section 4.5.3 that an average arm push force available is 26.5 N (Hill, 1998). However, due to the limitations presented by the test setup owing to the small bone size, the maximum compressive force applied in the test was 8.55 N. Nevertheless, the results from the experiment exhibited a linear relationship between the compressive force and the breakaway force. This finding concurs with results shown by Dammack *et. al.* (1997), which concluded that the friction coefficient was not affected by the magnitude of normal stress. Thus, it would be safe to assume and use these results in the situation of a surgeon pushing down the angle guide onto the femur surface with a force of 26.5 N or even higher.

Silastic Q7 – 4780 provided high coefficient of static friction, which was not significantly different to those provided by the stainless steel textured surfaces. The high coefficient combined with the ability of moulding without plastic deformation would give the surgeon the flexibility to adjust the angle guide

according to his/ her convenience without compromising on the grip provided on a bone covered with blood. Korvick *et. al.* (1989) attached silicone elastomer to a stainless steel compression plate at the interface between the plate and the bone. The plate was secured on to the bone using screws. The study concluded that the modified plate with viscoelastic materials resulted in less bone loss. This would prove beneficial for a fracture of the proximal femur, which as mentioned before in section 2.3, are predominantly a result of weakening bone due to increasing age. Although the damage due to the angle guide would be different to that due to an implant, the scratching and digging of bones by the current prongs could be avoided by removing them.

The results identified the material with the most superior grip and one with reasonable grip which could mould without plastic deformation. Therefore a combination of the two materials would be devised for use as a base for the new angle guide. Stainless steel surface finished by spark erosion would provide high static friction to grip the bone and resist sliding. The silicone elastomer silastic Q7-4780 would allow minor adjustments to the surgeon, and will conform to the exact shape of the bone surface on force application to give good stability.

Other than the angle guide, bone plates used to fix various fractures of pelvis, tibia and humerus particularly in osteopenic (bones with low bone mineral density) are medical devices which interface with the bone surface. Korvick *et.al.* (1989) modified bone plates by inserting silicone elastomer sheets in between the plate

and the bone. The study concluded that *in vitro* plate-bone contact was greater and interface pressure was lower as compared with the standard plate. This could be particularly useful as bone plates are used on weaker bones. An elaborate version of the experiment discussed in this chapter with inclusion of wear testing and more coupling materials could aid in designing a new bone-plate interface.

### 5. 7. Summary

The concluding points of this chapter are listed below.

- i. In general, textured surfaces of stainless steel provided better grip than silicone elastomers.
- ii. Stainless steel surface prepared by spark erosion exhibited the highest value of coefficient of friction of  $0.742 \pm 0.038$ .
- iii. A combination of Silastic Q7 – 4780 grade of silicone elastomer and stainless steel surface prepared by spark erosion would be used for the base of the new angle guide. This would ensure conformity to the bone surface providing stability, and superior grip to prevent slippage on a bone covered with blood.

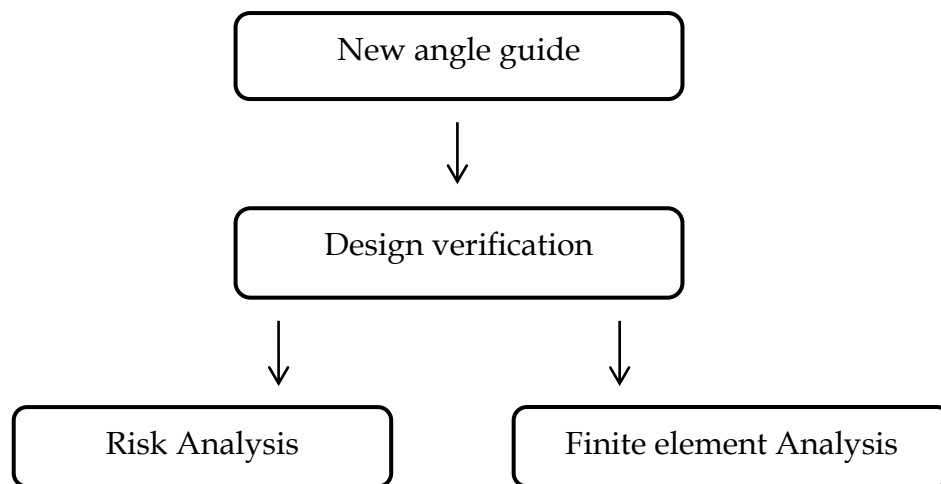
# CHAPTER 6

## THE NEW ANGLE GUIDE

### 6.1 Chapter at a glance

#### 6.1.1. Chapter overview

Figure 6.1 shows the chapter overview in the form of a flowchart.



**Figure 6.1: Flowchart of the chapter structure**

#### 6.1.2. Keywords

Angle guide; finite element analysis; risk analysis.

## 6. 2. Introduction

A new concept for the angle guide was selected in Chapter 4. The new design most notably included a new base, the material of which was confirmed after a test described in Chapter 5. With all the parameters of the concept selected, an overall detail design of the new angle guide is presented in the following sections.

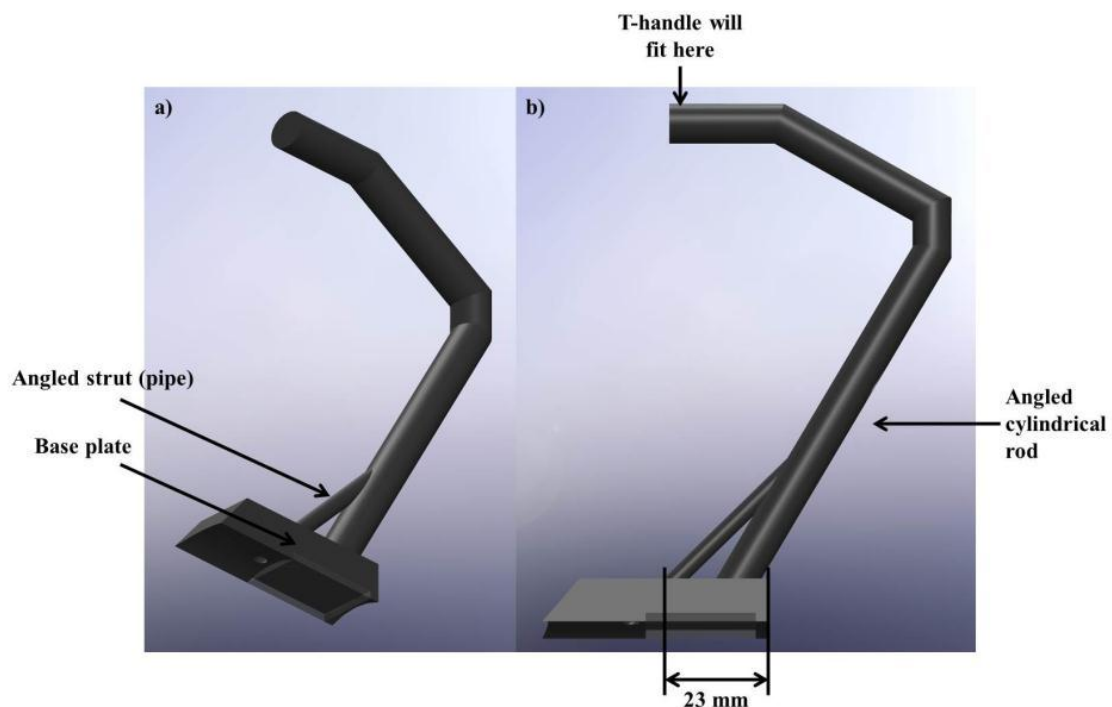
It is important to verify the authenticity of the conceptualized design to the intended function of the device, and also to ensure that the design offers safety, efficiency and effectiveness in the operating environment. The methods for design verification of a medical device include risk analysis and finite element analysis (FEA) (Aitchison *et al.*, 2009). This chapter discusses the results of design verification methods conducted on the new angle guide.

## 6. 3. The new angle guide in detail

### 6. 3. 1. Design Overview

The new angle guide, shown in Figure 6.2a-b, was intended to be a re-usable medical device for use in a minimally invasive approach for surgical implantation of the generic dynamic hip screw (DHS). The new angle guide was designed to replace the generic angle guide used currently in the DHS surgical procedure

(section 3.6.3). The new device required an incision of 23 mm for insertion and utilisation, compared to 40 mm required by the generic angle guide (section 4.3). This device was also proposed to be used during the surgical procedure for the insertion of the new implant designed in this research (Chapter 10) for treatment of proximal femur fractures. The primary function of the new angle guide was to provide the surgeon with a reference to insert a guide pin, at an angle determined by the femoral neck/shaft angle of the patient's femur, into the femoral head. Although the new angle guide was primarily designed to be a re-usable medical device, it would also be possible to supply it sterile for single-use if required by the market.

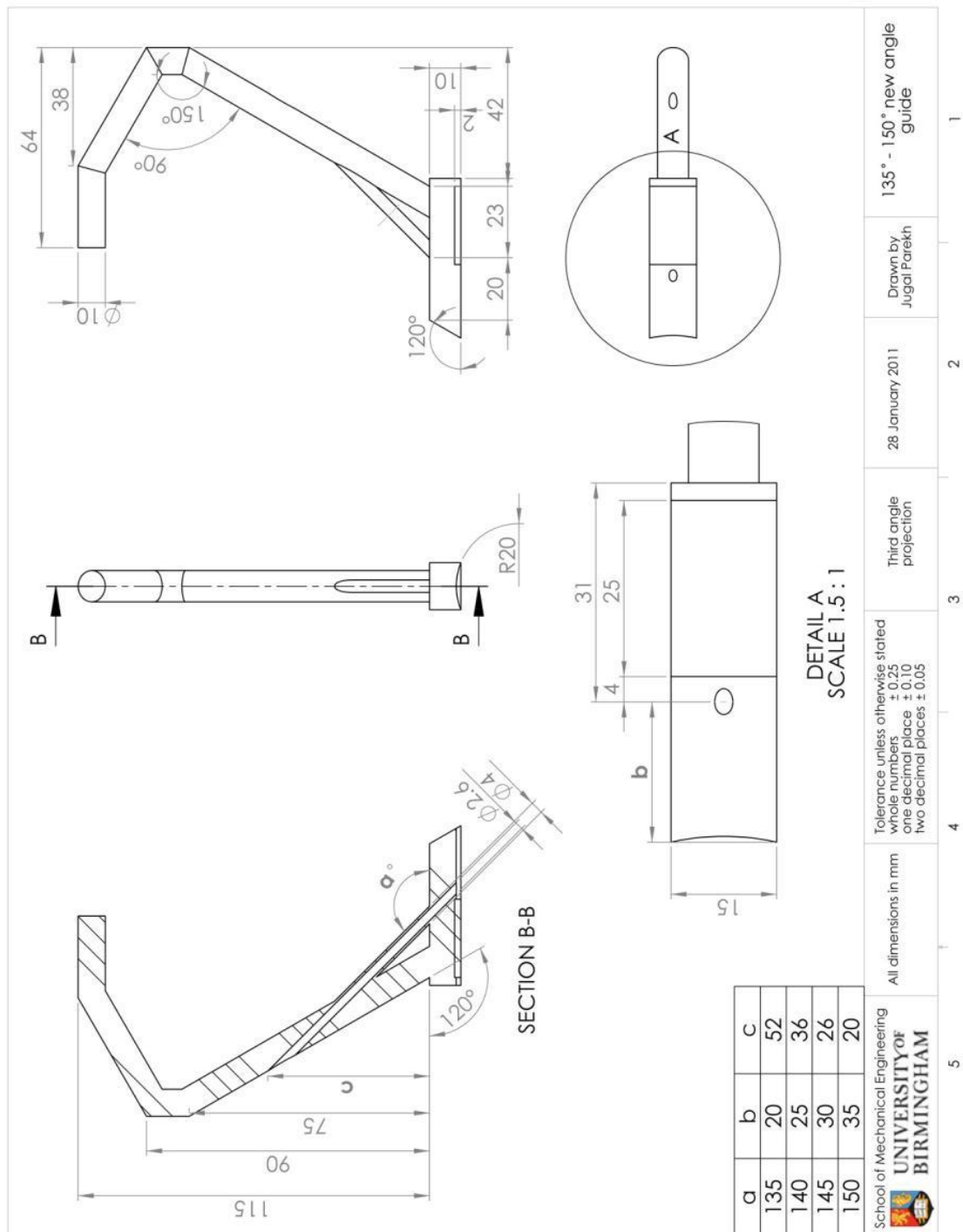


**Figure 6.2a-b: The new angle guide – a) view of the base plate, and b) view from the side plane**

The new angle guide would be able to insert a guide pin of maximum diameter of 2.5 mm into femurs with neck/shaft angles in the range of 120 degrees to 150 degrees at 5 degree increments. A neck/shaft angle of 135 degrees is most common (Canale, 2002). Hence, the corresponding 135° new angle guide is used for discussion and analysis for the remainder of this chapter. The guide pin would be advanced through a strut like structure (pipe with outer diameter of 4 mm and inner diameter of 2.6 mm) connecting a cylindrical angled rod and the base plate. The cylindrical rod of diameter of 10 mm was connected to the base at an angle of 110 degrees for 120° to 130° angle guides (engineering drawing shown in Figure 6.3); and 120 degrees for 135° to 150° angle guides (engineering drawing shown in Figure 6.4). The reason for the difference in angle was to maintain the incision length of 23 mm, which was controlled by the distance between the further ends of the cylindrical rod and the pipe, as shown in Figure 6.2b. The device would be held using a new ergonomic T-handle (not shown here - discussed in Chapter 7 of this thesis) and grip the curved surface of lateral femur using a new base, which is discussed in more detail in section 6.3.2.



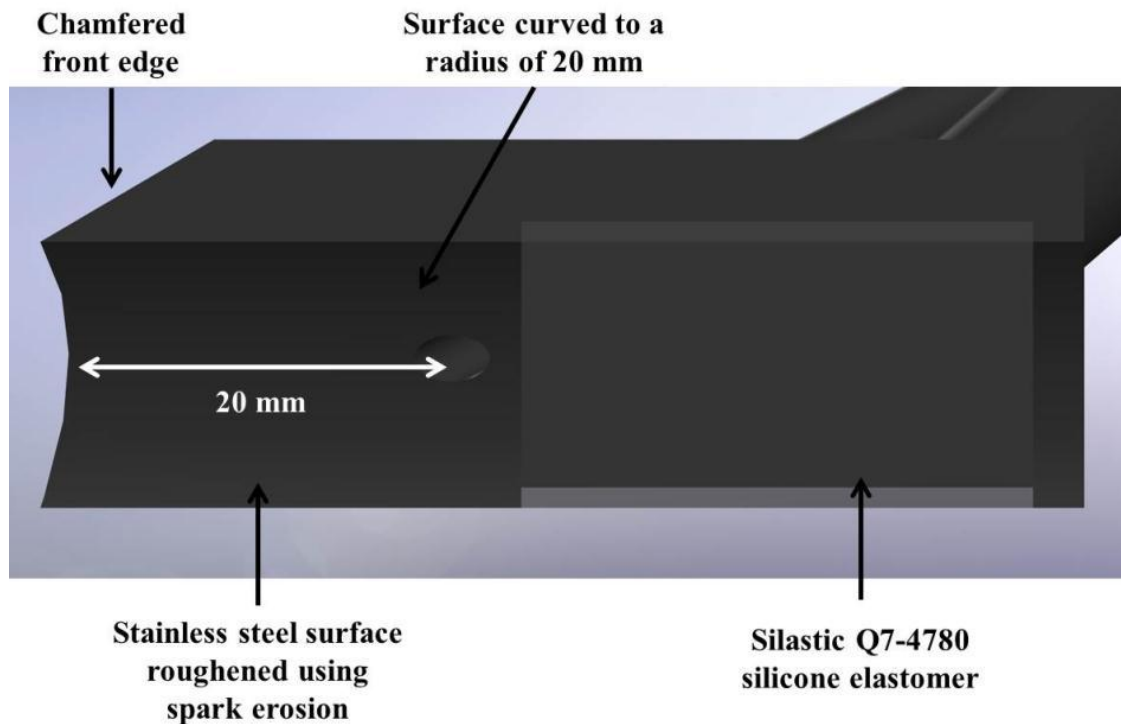




**Figure 6.4: Engineering drawing of the 135 to 150 degrees new angle guides**

### 6. 3. 2. New base

It was concluded in Chapter 5 that a stainless steel surface roughened using spark erosion offers the best grip on slippery bone surface. Also, silicone elastomer would be able to deform to the curved shape of the bone surface and withstand compression between the guide and bone, which would prevent lateral movement of the device on the bone surface. Hence, the base of the new angle guide, shown in Figure 6.5, utilised a combination of attributes provided by the selected materials to provide good stability and avoid slippage, whilst not harming the bone.



**Figure 6.5: Features of the new base on the 135 degrees new angle guide**

The base of the new angle guide also incorporated the “feedback” feature discussed in section 4.6.3. This feature proposed to aid the surgeon on the insertion point for the guide pin by placing the guide pin exit-hole 20 mm from the front edge of the base. The front end of the base plate was chamfered to slide easily over the femur surface. The roughened stainless steel surface was also curved with a radius of 20 mm to complement the radius of curvature of the femur surface.

### 6. 3. 3. Material

The new angle guide was designed for both single-use and re-use. Hence, the material of manufacture should be able to withstand sterilisation by either steam or irradiation. The angle guide would be made of stainless steel 316L (ASTM F138, Young’s modulus – 690 MPa, tensile strength – 860-1100 MPa, Poisson’s ratio – 0.33, values sourced from BS 5832-1, 2007 and Ratner *et al.*, 2004) which is the most commonly used stainless steel for the manufacture of medical devices (Ratner *et al.*, 2004 and Harper, 2001). A rectangular sheet (25 mm × 15 mm × 2 mm) of Silastic Q7-4780 (Shore A hardness of 77 from Dow Corning Ltd, Coventry, UK) would be attached to the base of the guide with Type A Silastic medical adhesive silicone (Dow Corning Ltd, Coventry, UK). This is a one part silicone adhesive, often termed as room temperature vulcanising (RTV), and is viable for bonding stainless steel to silicone elastomer. These adhesives are biocompatible, can withstand sterilisation and offer good shear, tensile, impact and peel strength

(Hill, 1998). The adhesive offers easy curing and causes no reaction in the body even after 90 days of implantation (product data sheet for Silastic medical adhesive). It was successfully used by Kovick *et al.* (1989) to bond Silastic sheets of 1.5 mm thickness to 316L stainless steel compression plates in a study to investigate the effect of modifying the plate-bone interface with Silastic silicone elastomer sheets on stress shielding. The stainless steel surface at the bottom of the base plate would be prepared by using spark erosion method to roughen the surface to a  $R_a$  (surface roughness) value of  $8.9 \pm 1.50 \mu\text{m}$  (as measured in Chapter 5). The materials selected for the new angle guide would be able to withstand sterilisation by either steam or irradiation (Ratner *et al.*, 2004; Hill, 1998; product data sheet for Type A Silastic medical adhesive silicone).

#### 6. 4. Risk Analysis

Risk analysis, discussed in section 2.3.5.3, aimed to identify the hazards associated with the new angle guide and determine the control measures to prevent the hazards. The methodology is described in section 2.3.5.3, and the results are shown in Table 6.1. The analysis should not be considered exhaustive and was conducted by the author following consultation with Prof. Maffulli. The analysis only included the angle guide and did not take into consideration the handle or the packaging and manufacture of the product.

Table 6.1: Risk analysis of the new angle guide

Possible hazard or failure mode	Effect of hazard or failure	Cause of hazard or failure	O	S	D	RPN	Control measure
Wrong insertion of guide pin	DHS implant will not be placed correctly as per the femur's anatomy; may lead to non-union or lag screw cut-out	Incorrect placement of angle guide on femur	5	6	6	180	Verify with fluoroscopic images
		Wrong angled - angle guide	1	6	6	36	Pre operation planning is required to verify the angle as per patient's anatomy
Damage	Device does not function as intended	'Feel of bending' on the handle when device is pushed onto the femur by the surgeon	1	5	2	10	Appropriate material selected and FEA was conducted to verify the design.
		Failure of bonding of silicone elastomer to stainless steel	1	7	5	35	The selected adhesive can withstand sterilisation and is apt for the device's materials, loading, service life and environment
Fracture/ Breakage of device	Delay to surgery	Excessive application of force	1	10	2	20	FEA was conducted on the design to check for maximum stresses
Reaction due to adhesive	Harmful to patients	Reaction due to materials selected	1	7	10	70	The selected materials (stainless steel, silicone elastomer and adhesive) are biocompatible

The hazard which scored relatively high was the wrong insertion of guide pin due to incorrect placement of angle guide on femur. The hazard could be prevented by the surgeon verifying the guide pin position using an image intensifier. This procedure would be included in the surgical technique to avoid this particular risk. Finite element analysis was conducted on the angle guide to verify an absence of noticeable bending of the device when pushed down by the surgeon.

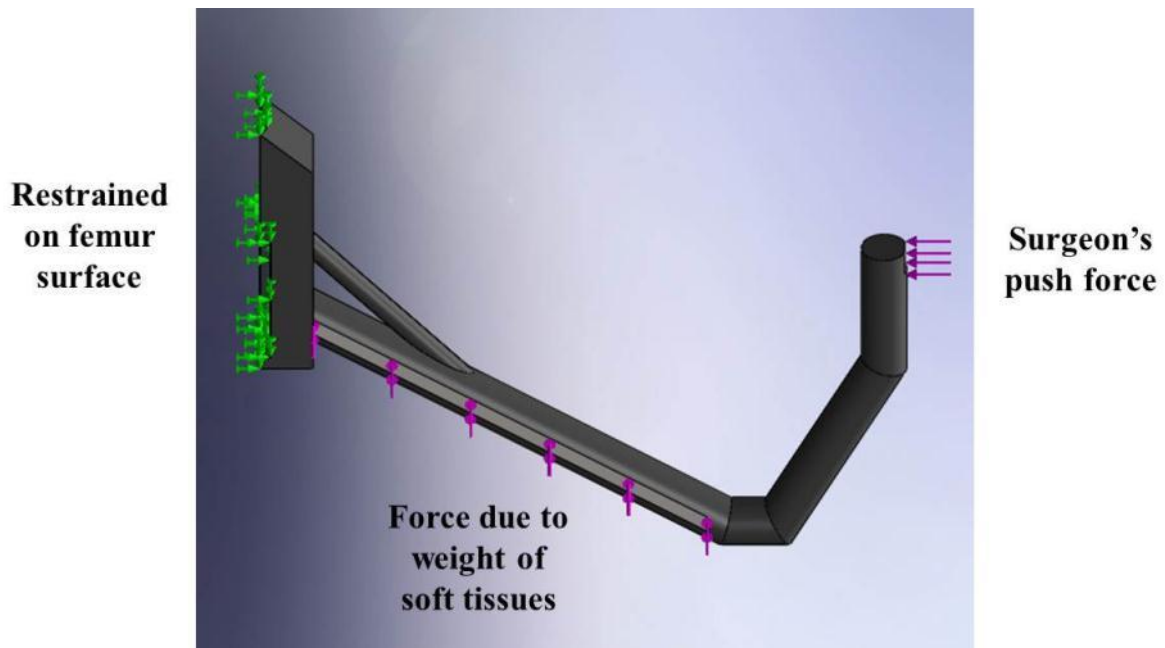
## **6. 5. Finite Element Analysis (FEA)**

### **6. 5. 1. Overview**

FEA, discussed in detail in section 2.3.5.3, was conducted on the new angle guide to inspect for any undesirable deflection of the design and regions of high stress whilst in use. The three dimensional model of the new angle guide was created using SolidWorks CAD software (3DS Daussalt Systemes, Version 2006-2010, Lowell, MA, USA); and the static analysis on the model was conducted using the integrated FEA tool called SolidWorks Simulation (COSMOS in versions 2008 and earlier). The 135 degrees new angle guide was used for the analysis and the engineering drawing was shown in Figure 6.4.

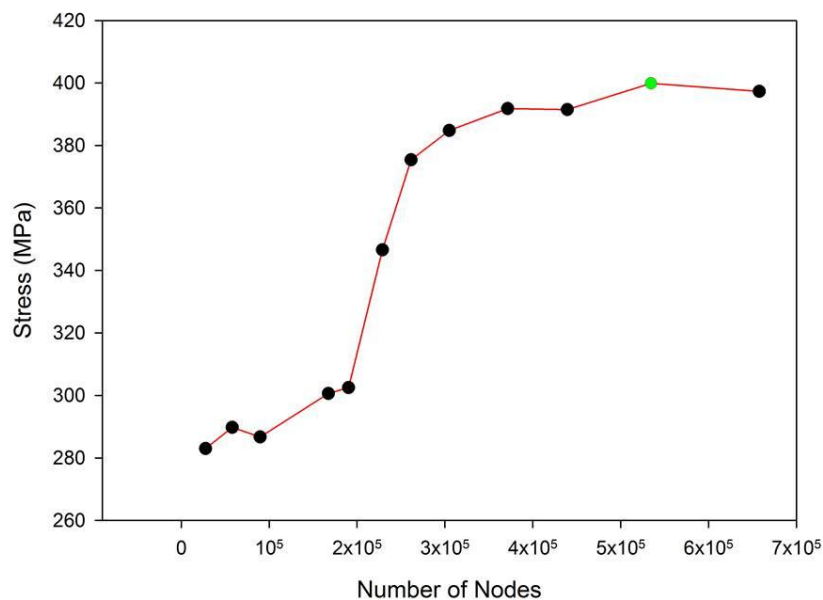
### 6. 5. 2. Pre-processing

Material properties of stainless steel 316L were assigned to the model of the new angle guide. A 222 N downward compressive force was applied to the handle to emulate the maximum pushing force generated by the arm of a fifth percentile man, and 4 N representing the weight of muscles and soft tissues on the angle guide's structure when inserted were applied on the model (values of these forces were derived in section 4.5.3). The device was restrained in all directions at the bottom of the base plate, as it would be sitting on the bone surface. The model loaded with forces and restrained at the bottom is illustrated in Figure 6.6.



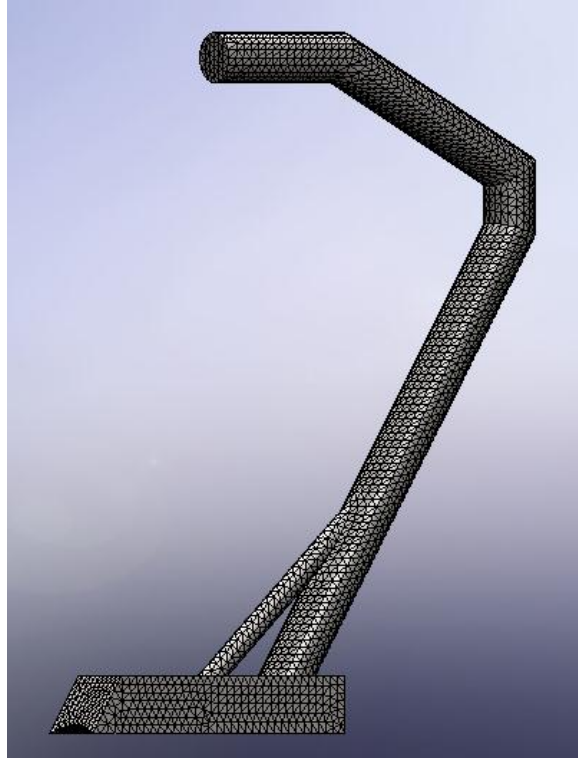
**Figure 6.6: Three dimensional model of the 135 degrees new angle guide loaded (pink arrows) and restrained (green arrows)**

The mesh size to be used for FEA analysis was determined by plotting a convergence graph (stress vs. number of nodes). As the mesh size is reduced, the number of elements (and nodes) are increased, which usually results in an increase in accuracy of the solution. This step is repeated until the solution is reached (signified by similar results); and a convergence graph is plotted for the mesh size to be selected (Avallone et al., 2007). The mesh size selected for the analysis was 0.65 mm (tolerance of 0.0325 mm, number of nodes - 802755, number of elements - 554833). It was not possible to conduct the analysis with a mesh size smaller than 0.60 mm due to limitation of processing power of the computer. The convergence plot is shown in Figure 6.7, and the meshed model of the new angle guide is shown in Figure 6.8.



**Figure 6.7: Convergence plot to select mesh size for 135 degrees new angle guide. Green point signify the values of von Mises stress and the number of nodes for the selected mesh size (0.60 mm)**





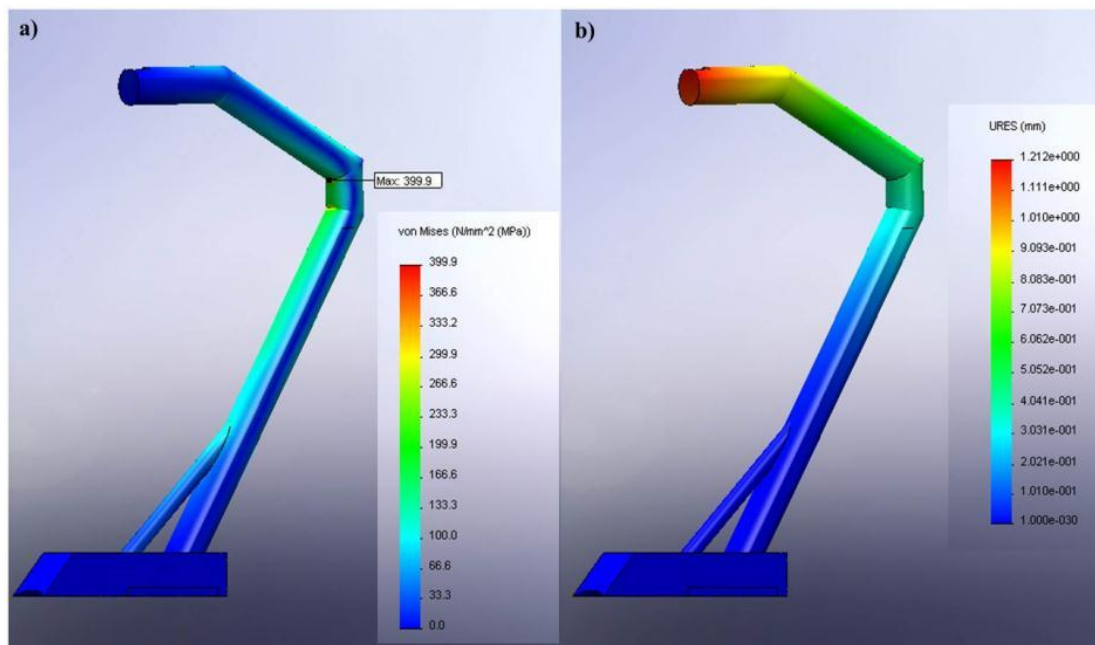
**Figure 6.8: Meshed model of the new angle guide using mesh size of 1.50 mm**

### 6. 5. 3. Post-processing

Graphical representations of the deformed model, along with the values of the solutions were displayed. The displacement of the model in units of mm, and stresses on the model in units of MPa, were presented at the end of the analysis as results.

The maximum von Mises stress was calculated at the bend in the cylindrical rod as shown in Figure 6.9a with a value of 400 MPa. The maximum displacement in the downward direction was 1.2 mm, at the point where the handle would be attached to the angle guide (Figure 6.9b). The presence of a displacement of 1.2 mm was

significant as it corresponded to the degree of bending the surgeon would experience while using the guide. However, it should be noted that a force of 222 N is the maximum pushing force, and would not be expected to be applied normally. The purpose of the surgeon's compressive force is to only hold the guide in position by pushing it against the femur. However, even with these loading conditions, the stresses were acceptable and below the tensile strength (1100 MPa) of the material, and hence the material and the design would be able to withstand the loading conditions while in use.



**Figure 6.9: Graphical representation of FEA results on the 135 degrees new angle guide depicting a) stress in MPa, and b) displacement in mm**

The normal arm push force is 26.5 N (Hill, 1998). The FEA study was conducted to verify the absence of any excessive bending of the angle guide on application of such force. The point of maximum stress of 48 MPa was noted at the bend on the cylindrical rod. The value of displacement was 0.15 mm, which can be considered

trivial and would go unnoticed. Hence, the design of the new angle guide was able to meet the requirement of “no feel” of bending by the surgeon when in use.

## **6. 6. The new angle guide**

The design of the new angle guide was verified using risk analysis and finite element analysis, and did not pose any severe concerns or hazards. The design was able to cover the PDS stated in section 3.9.3.1, and is described in detail in section 6.3. The new angle guide was proposed to replace the generic angle guide in the DHS surgical procedure (section 3.6.3.) to permit a minimally invasive approach using surgical techniques described in section 3.8.3., and would also be used to insert the new implant, presented in Chapters 8 and 9, to treat proximal femur fractures. The surgical technique for the new implant is described in Chapter 10.

## 6. 7. Summary

The summarising points of the chapter are listed below.

- i. The new angle guide, made of stainless steel 316L, would be able to insert a guide pin of maximum diameter of 2.5 mm into femurs with neck/shaft angles in the range of 120 degrees to 150 degrees at 5 degrees increment. The most prominent features of the new design were: a) that it would require a maximum incision length of only 23 mm, and b) a new base made of silicone elastomer and stainless steel surface roughened by spark erosion method.
- ii. Risk analysis of the design of the new angle guide did not present any major hazards.
- iii. FEA was conducted on a three dimensional model of the new angle guide. The maximum stress recorded was 400 MPa with a bending of 1.2 mm at application of 222 N surgeon push force and 4 N force due to weight of soft tissues on top of the device. The maximum stress reduced to 48 MPa with bending of only 0.15 mm on application of the normal arm push force of 26.5 N. The results suggested that the design was strong enough and would be able to withstand the forces while in use without noticeable bending.

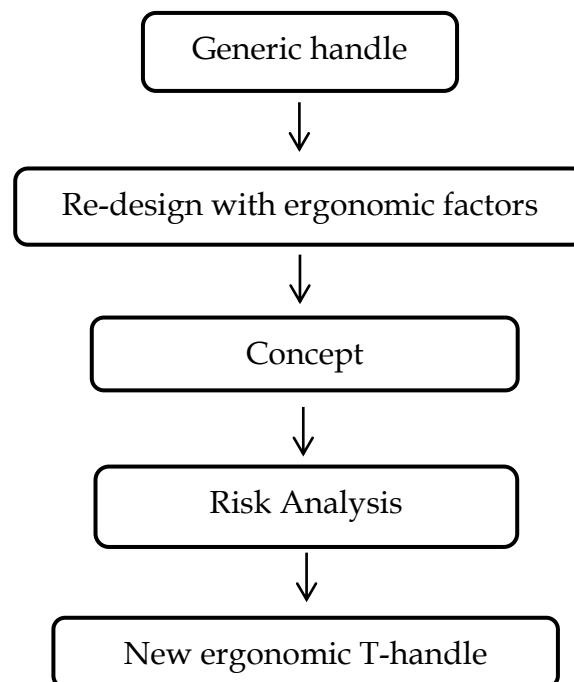
# CHAPTER 7

## THE NEW ERGONOMIC T-HANDLE

### 7.1 Chapter at a glance

#### 7.1.1. Chapter Overview

Figure 7.1 shows the chapter overview in the form of a flowchart.



**Figure 7.1: Flow chart of the chapter structure**

#### 7.1.2. Keywords

Ergonomics in surgical environment; human factors; handgrips; T-handle

## 7. 2. Introduction

Handles of surgical instruments are the first point of contact for the surgeon and they aid in control of the instrument. A well designed handle would consider the comfort of the surgeon and aim to reduce the fatigue caused to the surgeon's hand. The aim of this research was to introduce an easy and comfortable minimally invasive surgery (MIS) approach to the implantation of the dynamic hip screw (DHS). However, MIS results in a decrease in incision size and working space, which may prove rather disadvantageous to the surgeon and the surgical staff as it would restrict the movements of the hand and the instruments. This has led to the designing of new and ergonomic laparoscopic instruments and operating tables (Berguer, 1999) to make them safer, more effective and comfortable to use. Although new handles for laparoscopic instruments have also been designed (Matern *et al.*, 1999; Buchel *et al.*, 2010; Matern *et al.*, 1999), the conventional T-handle (Figure 3.15) used extensively in the DHS surgical procedure has not been reevaluated and redesigned considering ergonomic factors. The handle connects with various instruments like the angle guide and the impactor during the course of the surgery (Baumgaertner, 1998).

T-handles are supplied by every manufacturer in their DHS instrument set. The design analysed in this research is of the generic T-handle supplied by most manufacturers including Synthes GmbH (Solothurn, Switzerland) and Smith & Nephew plc (London, UK). Certain manufacturers like Stryker (Kalamazoo,

Michigan, USA) and B. Braun Melsungen AG (Melsungen, Germany) do manufacture T-handles with ergonomic features. However, there is no data available either through academic or corporate publications regarding their dimensions, material or ergonomic factors, which would assist in analysing their design and compare them to the points stated in the PDS (section 3.9.3.2). However, it was considered important to include an ergonomic T-handle with the new angle guide, and also as part of the instrument set for the new implant.

The novelty of this redesign process was that it reviewed the literature for ergonomic principles of a handle from other industries and skilled professions such as material handling (Karwowski and Marras, 2003), anthropometry (Pheasant 2002) and manufacturing (Das *et al.*, 2005). These findings were then integrated with the requirements as stated in BS EN 12011 (1998), especially the material requirements of a medical device, to be used in a sterile surgical environment. This was to ensure that the T-handle classified as a class I medical device (Medical Device Directive, 1993) on its own right. The resulting T-handle concept design could also be used for instruments in other surgical procedures.

### **7. 3. Design objectives of a new T-handle**

The general design objectives of the new T-handle are listed below.

- i. The T-handle should be designed to be used with instruments required to implant a DHS.
- ii. The handle should integrate ergonomic principles to make it comfortable to use by surgeons and surgical staff in MIS.
- iii. The handle would be designed for use in a single-use and a re-use market and hence the material of construction should be able to withstand sterilisation as per standards BS EN 554 (1994), BS EN 556-1 (2001) and BS EN 556-2 (2003).
- iv. The design specifications for the new T-handle should be in accordance with the standards and regulations for surgical instruments, i.e. BS EN 12011 (1998).

### **7. 4. Existing T-handles**

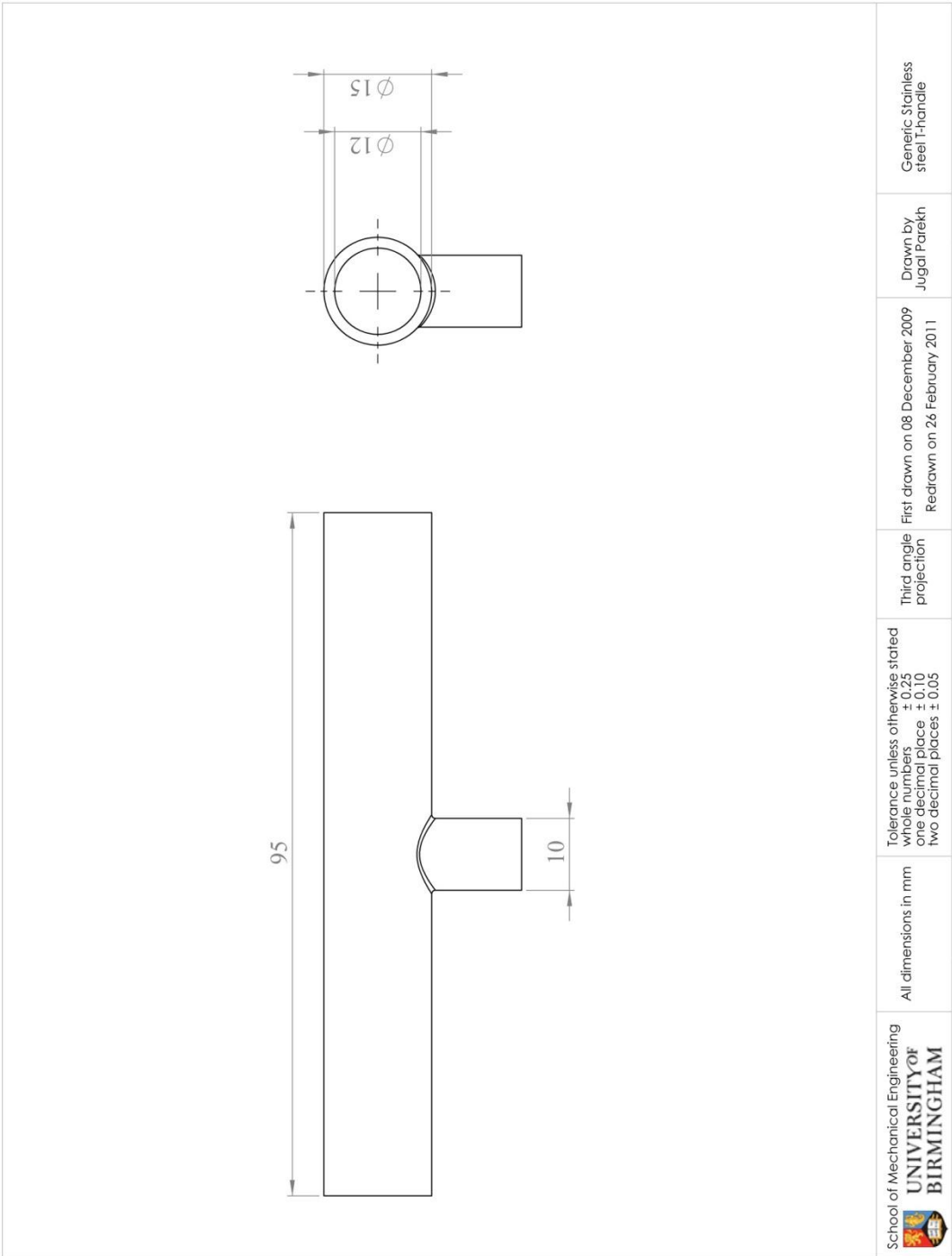
The shape and dimensions of a current T-handle were taken from the detachable T-handle (Figure 3.15) used with the DHS surgical instruments, and manufactured by Sushrut Surgicals Pvt. Ltd. (Pune, Maharashtra, India). The engineering drawing of the generic T-handle (without locking mechanism) is shown in Figure



7.2. This design was similar to the T-handle supplied by other orthopaedic medical device manufacturers such as Synthes GmbH (Solothurn, Switzerland). The dimensions were measured using a digital vernier caliper (resolution of 0.01 mm and accuracy of  $\pm 0.03$  mm, Fisher Scientific UK Ltd., Loughborough, Leicestershire, UK). The handle was made of stainless steel, and was a plain hollow cylinder with an outer diameter of 15 mm and inner diameter of 12 mm. The shaft of the instrument was connected exactly at the centre, and the length of the handle was 95 mm.

The design of the generic T-handle was compared to the PDS mentioned in section 3.9.3.2. Although the T-handle performs the function of a handle for the instruments and is able to be sterilised, the main reasons because of which the handle was not considered ergonomic are listed below.

1. The length of the handle is shorter than 120 mm causing the ends to dig into the palm of the hand and not allowing adequate control due to the lack of space for all the fingers and thumb to fit on it.
2. The diameter of the handle is smaller than 30 mm causing the fingers to overlap and not offer a comprehensive grip to the user.
3. Stainless steel surface was too hard to touch, and hence not comfortable to hold. The presence of sharp edges at the ends of the handle could be injurious to the user or the patient.



**Figure 7.2: Engineering drawing of the generic T-handle (without locking mechanism) manufactured by Sushrut Surgicals Pvt. Ltd. (Pune, Maharashtra, India)**

Additionally, a survey was conducted by the author and Dr. D.E.T. Shepherd, and organised by Prof. N. Maffulli on 7<sup>th</sup> December 2007 at the City General Hospital (Stoke-on-Trent, UK). The purpose of the survey was to determine an appropriate material that would be most comfortable to use for the interface of the instrument's base with the bone. This survey was first mentioned in section 4.6.7, and further details could be found in Appendix A. Within the survey, surgeons were also asked to compare two lengths (95 mm and 115 mm), and two diameters (25 mm and 30 mm) of a handle, and rate them based on the comfort fit it provided in their hands. Although the results of the survey were inconclusive, there was a definite inclination towards a longer (115 mm) and thicker (30 mm) handle. Two out of the ten respondents also asked for a better handle than the one they use in surgery at present. The findings of the survey were not used in the design process due to the inconclusive results and the small sample size.

## **7. 5. Design requirements for the new DHS T-handle**

### **7. 5. 1. Overview**

The designing of the new T-handle integrated ergonomic factors into the medical design device process. The integration of ergonomic stages in the design process of a hand tool comprises of understanding the requirements and the collaboration of the user, the product and the task/ environment (Karwowski, 2001). Hence, it

was important to specify ergonomic factors and the type of task along with the intended function of the device, and state the specifications of the device accordingly. This section also provides the justification of the statements in the PDS (section 3.9.3.2).

### **7. 5. 2. Function**

During the surgical procedure of the DHS implant (section 3.6.3.1), the T-handle is used with a variety of instruments. The purpose of the handle can be broadly classified into two actions – i) push and hold while using the angle guide, and ii) torque application while using the insertion wrench and the lag screw tap. The handle should be effective and comfortable during its execution with the instruments mentioned for the respective applications.

### **7. 5. 3. Grip**

Handles could be used for a variety of functions. The handle should be designed after understanding the hand grips while performing the various functions. It is suggested that the prehensile movements of the hand, which includes the grasping or gripping of objects can be divided into two categories of gripping action (Napier, 1956) – 1) power grip or cylinder grip (Figure 7.3a), where the object is held with the fingers and thumb against the plane of the palm; 2) precision grip or ball grip (Figure 7.3b), where the object is pinched between the

fingers and the thumb. The T-handle in the DHS surgery would be required to be used during push and hold after manoeuvring and torque applications, which is a combination of both precision and power grip tasks respectively. It should hence be possible for the handle to be held with either of the grips.



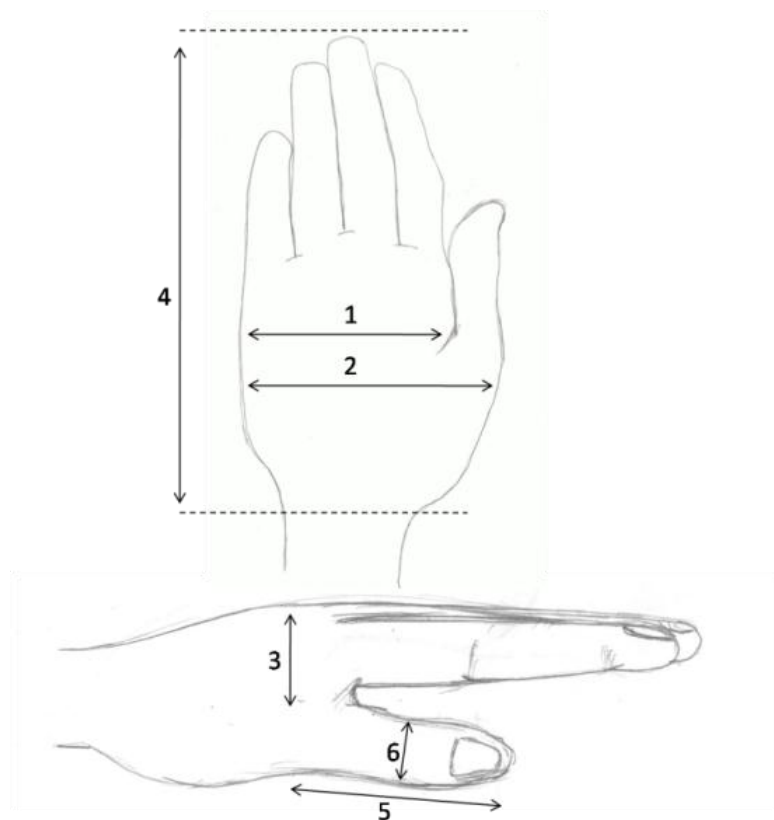
**Figure 7.3: Different grips of the hand – a) power grip with the object placed in the palm of the hand and the fingers and thumb curl around to hold it, b) precision grip with the object held by pinching it between the finger(s) and thumb**

#### 7.5.4. Size

It is important for the handle to fit the hand of a variety of surgeons with different hand sizes. The relevant dimensions of 5<sup>th</sup>, 50<sup>th</sup> and 95<sup>th</sup> percentile British adult men and women are listed in Table 7.1 (Pheasant, 2002), along with the dimension notation in Figure 7.4. It is important that these dimensions are considered, especially if one handle is designed to suit all the different hand sizes. The hand

breadth will determine the length of the handle, and the hand length and thickness could be used to determine the diameter of the handle.

The length of the handle would depend on the anthropometric data provided. It is recommended to design a longer handle to prevent the digging of the handle into the palm of the user. A minimum handle length of 100 mm, with 125 mm being more comfortable is suggested for handles held axially for power grip, where all four fingers would make contact. A length of 125 mm, with an additional length of 12.5 mm for users with gloves is recommended for a precision grip handle (Das *et al.*, 2005).



**Figure 7.4:** Sketch of a hand depicting the anthropometric data tabulated in Table 7.1

**Table 7.1: Anthropometric measurements of hand for design of hand tool handles.**  
**Dimensions are in mm**

No	Dimensions	Men			Women		
		5th %ile	50th %ile	95th %ile	5th %ile	50th %ile	95th %ile
1	Hand breadth (metacarpal)	78	87	95	69	76	83
2	Hand breadth (across thumb)	97	105	114	84	92	99
3	Hand thickness (metacarpal)	27	33	38	24	28	33
4	Hand length	173	189	205	159	174	189
5	Thumb Length	44	51	58	40	47	53
6	Thumb Breadth	20	23	26	17	19	21

#### 7. 5. 5. Cross section

The cross section of the handle depends on the use of the instrument. A rectangular handle provides more purchase, however cylindrical handles are more comfortable to hold (Cochran *et al.*, 1986). The diameter of the handle should not be too large, as the requirement of substantial force for grip leads to muscle fatigue in a relatively short time. In contrast, a handle with a small diameter, will not allow much force to be generated leading to local tissue pressures due to the shortening of the finger muscles (Das *et al.*, 2005). The literature recommends a handle diameter in the range of 30 to 50 mm (Pheasant, 2002; Cochran *et al.*, 1986).

The lower end of the range would be best for flexibility and dexterity, whereas the upper end of the range would provide the maximum torque (Karwowski and Marras, 2003). It was the aim of this process to design a comfortable handle and thus the surgical T-handle should be circular with a diameter in the lower range of 30 to 50 mm.

#### **7. 5. 6. Material**

The material should withstand multiple cycles of steam sterilisation (autoclave) to allow the handle to be re-used; irradiation sterilisation that would be used prior to packaging of the handle if it is to be supplied in a single-use market. The outer material should be soft to touch for comfort, but at the same time the inside should offer structural integrity to not get damaged during falls, and to provide a firm grip. The design would need to use layers of different materials to achieve the requirements. The material at the surface of the handle should neither be too rough, nor too smooth. A compromise of the two would ensure that the handle provides enough friction to avoid slipping, and at the same time avoid abrasion of the user's hand.

#### **7. 5. 7. Shape**

The main principle in an ergonomic design of hand tools is to fit the tool to the hand (Berguer and Hreljac, 2004). The shape of the handle should conform to the

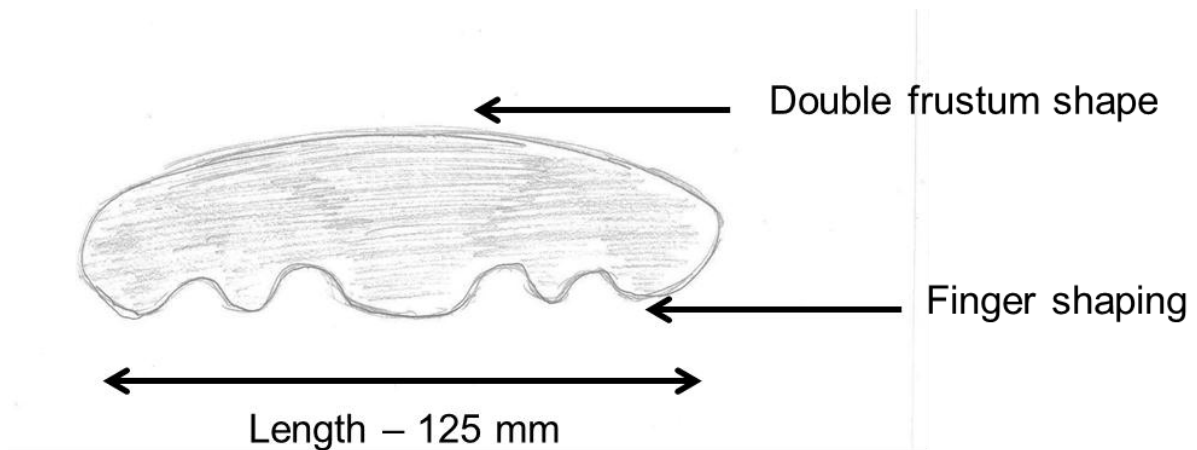


curvature of the palm engaging with the handle surface. Pheasant (2002) suggests a minimum radius of curvature of about 25 mm for the surface area which engages with the hand. A double frustum handle with a reducing diameter along both the axis from the centre would provide more comfort as this would allow each finger to grip at a different handle circumference. This was demonstrated in an experiment where double frustum handles scored higher than handles with oval cross section for comfort (Kong *et al.*, 2004). Maximising the grip surface area would enable the pressure to be distributed over a much larger area, hence not creating any high pressure at the palm-handle interface. This would also reduce shear stress on the skin, thereby reducing abrasion (Pheasant and O'Neill, 1975).

## **7. 6. Evolution of a new concept**

### **7. 6. 1. Concept 1**

Concept 1, shown in Figure 7.5, consisted of a double frustum cylindrical handle with the diameter reducing from 40 mm at the centre to 30 mm towards the two ends. The bottom part was finger shaped for a better grasp of the handle. The length of the handle was 125 mm, and was sufficiently long even for a 95<sup>th</sup> percentile man's hand (114 mm) to not dig into his palm. The design gave preference to a power grip, and the circular cross section to provide comfort.



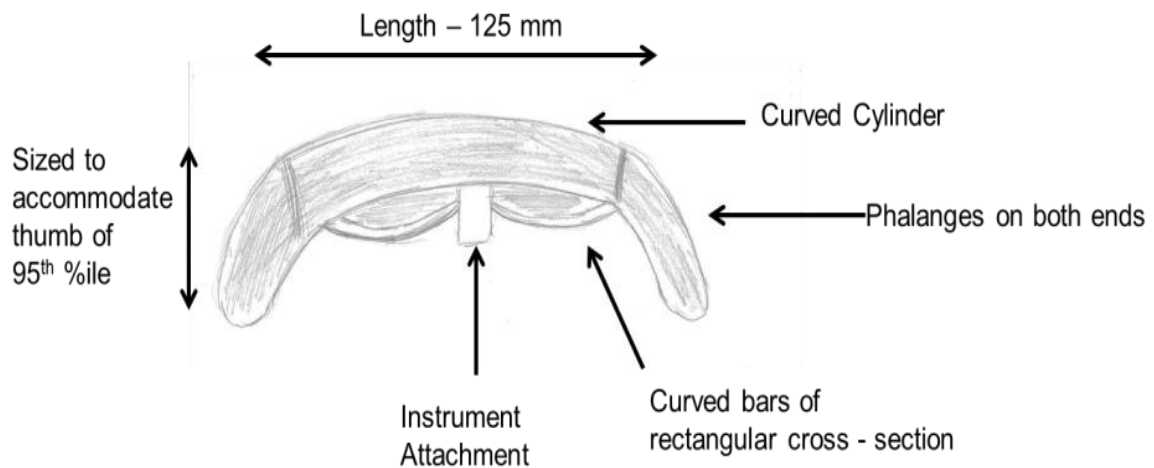
**Figure 7.5: Concept 1 of a new ergonomic T-handle**

The skeleton of the handle would be made of stainless steel 316L, which is the same as the material of the instruments with which it would be used. The metal would be overmolded with a soft polymer, which can withstand both irradiation and autoclave, for a comfortable grip.

However, the concept seemed unable to provide comfort to different hand sizes and grip for different tasks. These limitations were mainly due to the double frustum shape and the finger shaping of the handle. A surgeon with a smaller hand would find it difficult to grasp the large diameter at the centre. The thumb would be wrapped around the handle, which would restrict the grip to a power grip. These were important factors as the T-handle was to be designed for use by a variety of surgeons of different built and with instruments of different applications.

### 7. 6. 2. Concept 2

Concept 2 evolved from Concept 1 with an attempt to overcome the limitations discussed in the previous section. The new concept, shown in Figure 7.6, was a curved cylinder of constant diameter with a length of 125 mm. The curved bottom of Concept 1 was replaced with curved rectangular cross-sectioned bars. This addressed the issue of grasping with fingers of different length, and also reduced the inconvenience caused to small hands due to the large diameter towards the centre. The rectangular cross sections also provided more purchase, as was discussed in 7.5.5. The handle curved beyond the cylinder on both ends to provide support to the users' thumbs (the curved extensions on both ends will henceforth be termed as phalanges). This increased the gripping area without increasing the length of the handle. It is pointed out by Phesant (2002) that although the basic power grip requires the thumb to wrap around the back of the finger for stability and gripping force, extra control, which is provided by precision grip, could be attained by moving the thumb along the shaft of the tool handle. Hence, with the new design, the thumb could rest along the cylinder onto a phalange to provide extra control over the handle. It can also be noted that finger shaping was avoided as the target users could have a wide range of different finger sizes. Concept 2 would utilise the same material combination as concept 1. The concept fulfilled all the design requirements laid out, and hence was taken forward to the detail design stage of the medical device design process.



**Figure 7.6: Concept 2 of a new ergonomic T-handle**

## 7.7. The new ergonomic T-handle in detail

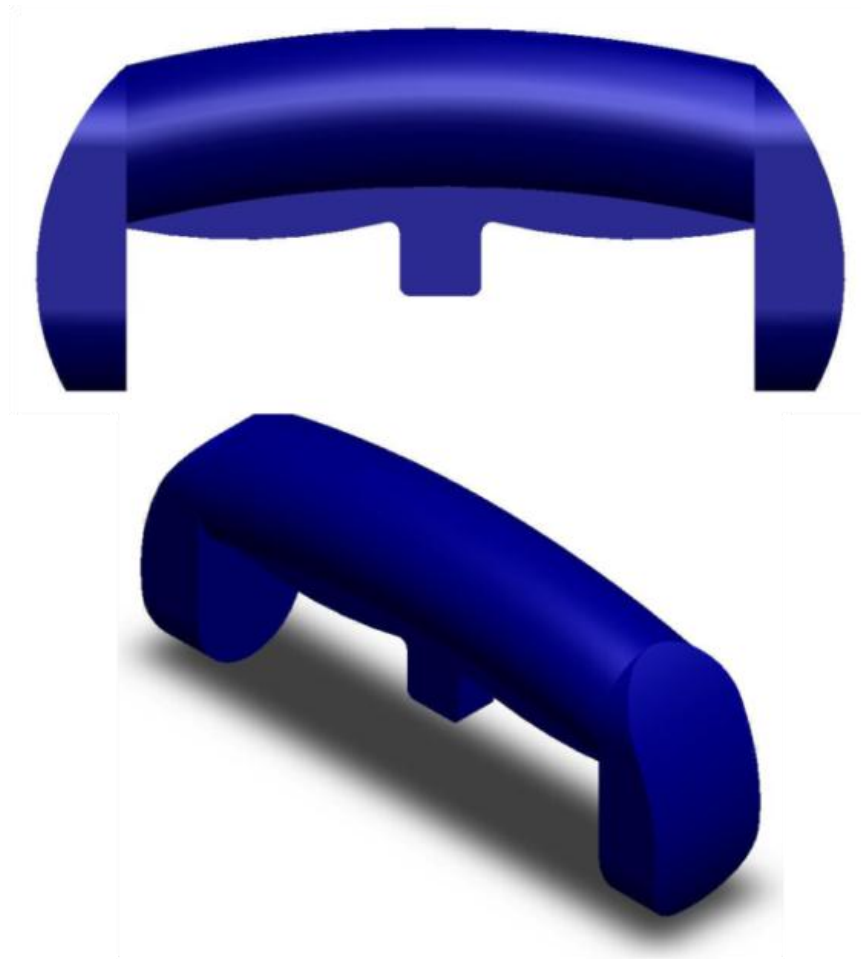
### 7.7.1. Overview of the design

The new T-handle was intended to function as a comfortable interface for the user to hold, grip and use appropriate surgical instruments without causing any injury and at the same time result in minimum tiredness to the user

In a surgical environment, the T-handle predominantly would require a power grip with some allowance for control and flexibility to rotate the tool attached to the handle. Taking this into consideration, the length of the ergonomic T-handle was 125 mm. This allowed the handle to extend beyond the palm of the 95 percentile man (114 mm), along with all the diversities. The additional length allowed for the thumb to be placed along the shaft to enhance the dexterity of the

surgeon, while using the surgical instrument in a tight working space. The handle included phalanges on both ends. This accommodated for either handedness, and also for larger hand sizes. The provision of phalanges would encase the fingers, and prevent the dropping of the tool even with a loose grip. The phalanges were designed to be wide and long enough (30 mm × 60 mm) to accommodate 95 percentile man's thumb with a width of 26 mm. A rendered three dimensional image of the new T-handle, drawn on SolidWorks CAD software (3DS Daussalt Systemes, Version 2010, Lowell, MA, USA) is shown in Figure 7.7.

The handle was cylindrical with constant diameter of 30 mm and a radius of curvature of 250 mm. The rectangle section with width of 10 mm extruded 50 mm towards the centre and was curved with a radius of curvature of 110 mm, from the phalanges on both sides. The provision of the rectangular sections was to accommodate the varying lengths of different fingers of a hand and also different hand sizes of surgeons. The combination of circular and rectangular cross section would provide comfort and grasping purchase to the surgeon. A provision for the shaft of the instrument to be inserted was provided at the centre. Figure 7.8 shows an engineering drawing of the handle.



**Figure 7.7: A three-dimensional rendered image of a new ergonomic T-handle for use with instruments during MIS of DHS**

The handle was only meant for use by a skilled user, and was to be sterilised using autoclave if re-used.

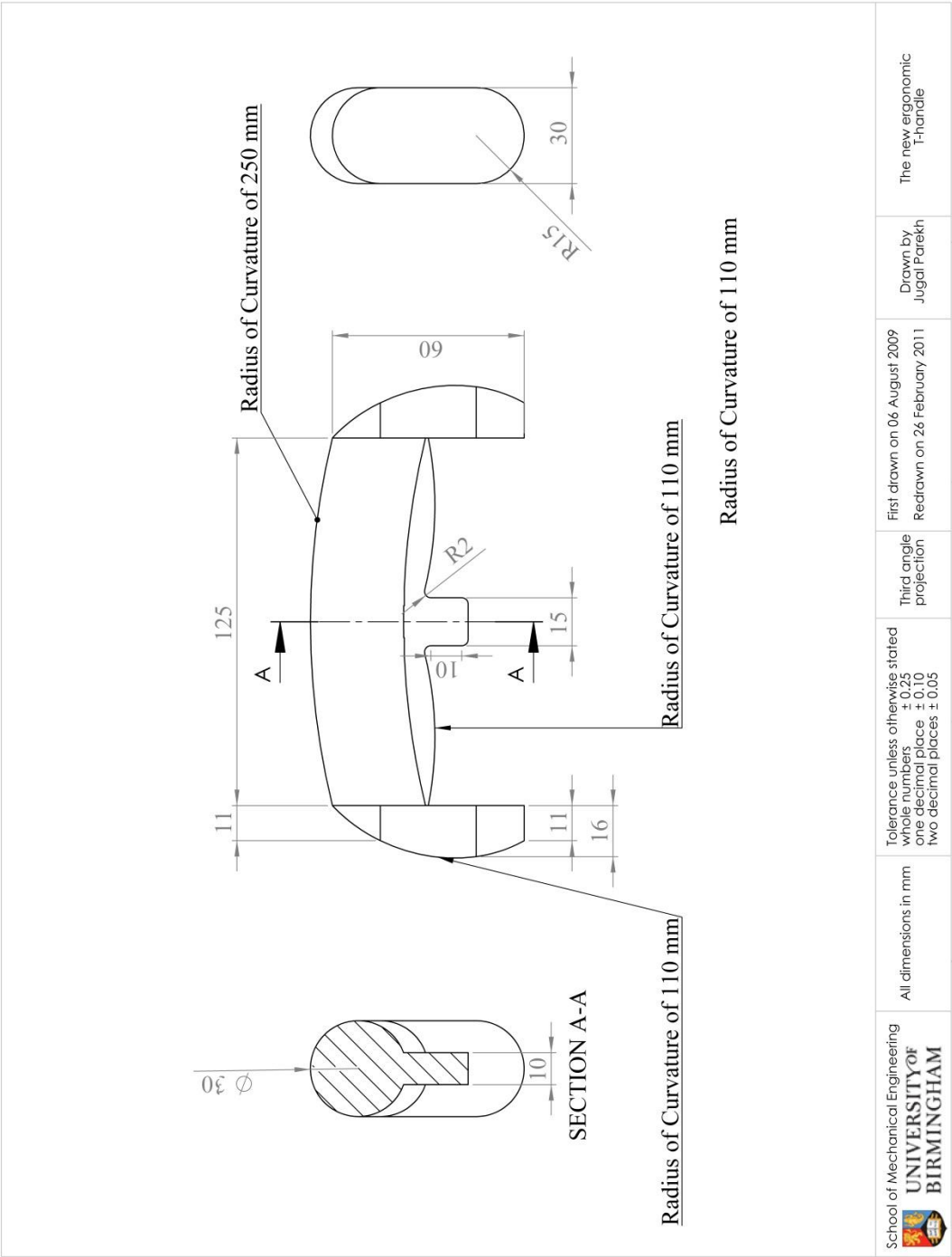
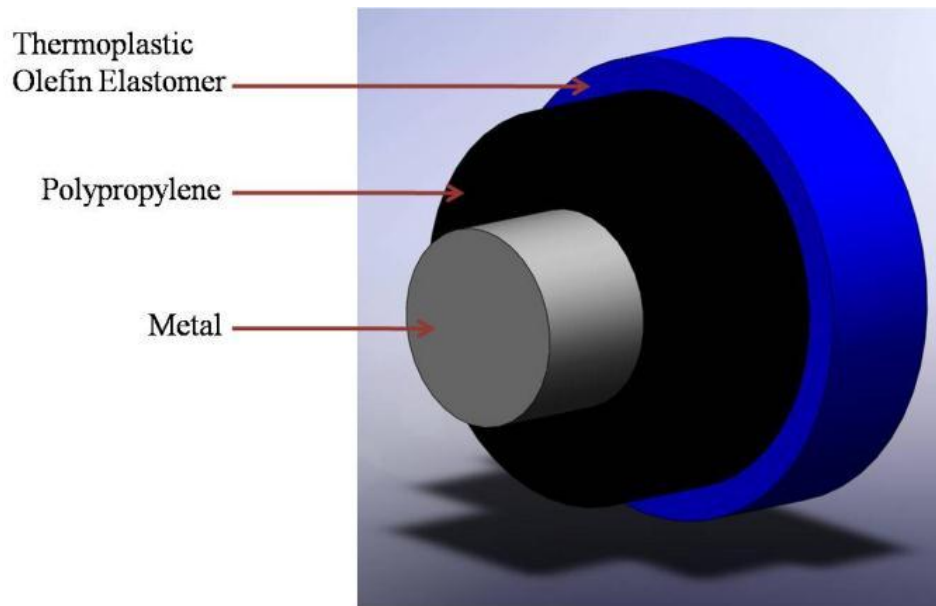


Figure 7.8: Engineering drawing of the new ergonomic T-handle

### **7.7.2. Material of the new T-handle**

The handle was designed for single-use and re-use markets, and hence, it would have to withstand sterilisation through irradiation and through steam. This was an important criterion to consider while selecting the materials to match the requirements of an ergonomic T-handle. It was also important to consider the compatibility of the different materials and cost of manufacturing a complicated shape when choosing the material. A curved metal rod would be overmolded with polypropylene (PP) to give the desired shape, and then would be overmolded again with thermoplastic polyolefin (TPO) elastomer to give a soft and comfortable touch. Figure 7.9 shows a cross-section of the handle with the different materials. The metal underlay would be the same as the one used to fabricate the instrument (Stainless Steel 316L). PP is a cheap material, can be easily processed (Hill, 1998) and is able to withstand both steam and irradiation sterilisation (Massey, 2005). PP would be used to give the handle the ergonomic shape over the metal cylinder. Finally TPO, which is resistant to radiation and autoclaving as well (Massey, 2005), would provide the soft touch while reducing slippage, possibility of colour coding the instrument and an option of brand embossing. The colour coding and brand embossing option with the TPO could be customised for easy indication of surgical step and the type of instrument (discussed in section 10.4.2).





**Figure 7.9: The three layers of materials to be used in the new t-handle to combine ergonomic interface with the handle and rigidity of the structure**

## 7. 8. Design verification

The design of the new ergonomic T-handle was verified using a risk analysis. The FMEA method, described in section 2.3.5.3, was conducted by the author. The results of the analysis are shown in Table 7.2. The analysis should not be considered exhaustive, and did not include the packaging, labelling and manufacture of the handle.

Although none of the risks scored high in the analysis, all the identified hazards described in table 7.2 were addressed with effective control measures.

**Table 7.2: Risk analysis conducted with the FMEA method on the new T-handle**

Possible hazard or failure mode	Effect of hazard or failure	Cause of hazard or failure	O	S	D	RPN	Control measure
Damaged	Device does not function as intended	Sterilisation	3	7	1	21	Materials selected which can withstand sterilisation procedures
		Bending of handle	1	7	1	7	Stainless steel will form the skeleton of the design
		Break at shaft/handle junction	1	7	1	7	Stainless steel (material of instrument shaft) used
Unsafe to user	Injury to surgeon	Sharp edges	2	7	3	42	Sharp edges were avoided in the design. Soft touch layer for handle - hand interface
		Slip out of hand	1	2	10	20	Appropriate material selected
Uncomfortable to user	Fatigue	Handle size not appropriate	3	5	5	75	Designed as per available anthropometric data
Handle contaminated with blood	Harmful to patients	Not sterilized before re-use	1	7	10	70	Supply information on sterilisation procedures
Breaking of handle	Delay to surgery	Materials not strong enough	1	10	2	20	Designed with appropriate materials

## **7. 9. The new ergonomic T-handle**

The design of the new T-handle is described in detail in section 7.7, and successfully underwent the risk analysis in section 7.8. The T-handle was designed to replace the existing generic design being used in the DHS surgery described in section 3.6.3. It would also be used with the instruments in the minimally invasive surgical technique for the new implant developed in Chapters 8 and 9. The surgical technique of the new implant is shown in Chapter 10.

## **7. 10. Summary of the design process**

The summarising points of this chapter are listed below.

- i. Ergonomic factors including size, shape, function, etc. were considered in the medical device design process for a new T-handle.
- ii. The new T-handle would be able to provide a comfortable interface to surgeons with varied hand sizes for using instruments of the DHS surgery.
- iii. The material of the T-handle combined the stiffness of stainless steel with the malleability of PP with the soft touch of TPO – all materials able to withstand sterilisation procedures to manufacture a comfortable yet firm surgeon's T-handle.

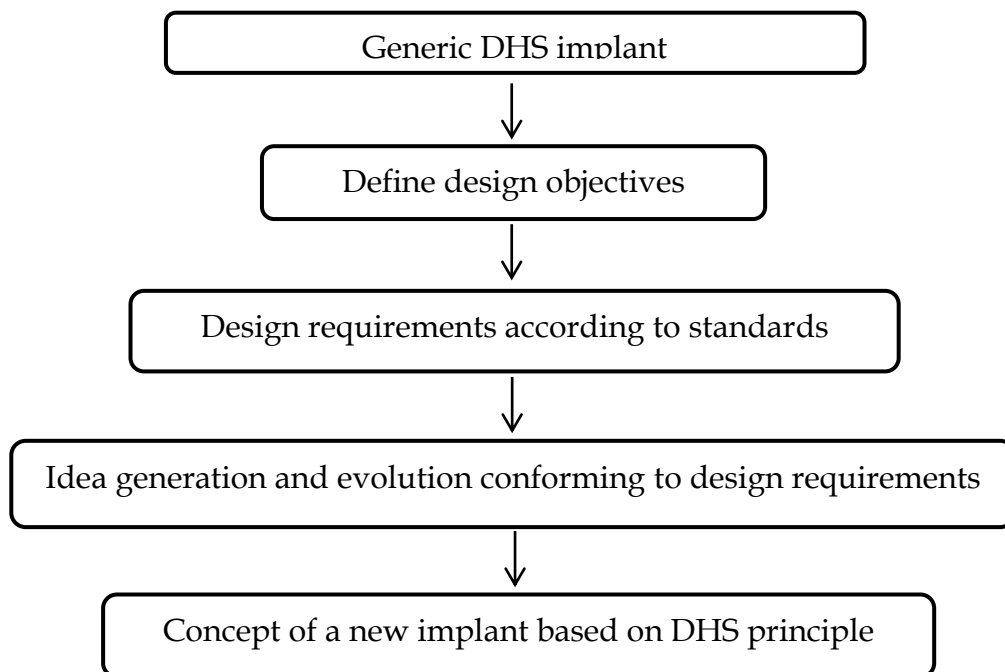
# CHAPTER 8

## CONCEPT OF A NEW IMPLANT

### 8.1 Chapter at a glance

#### 8.1.1. Chapter overview

Figure 8.1 shows the chapter overview in the form of a flowchart.



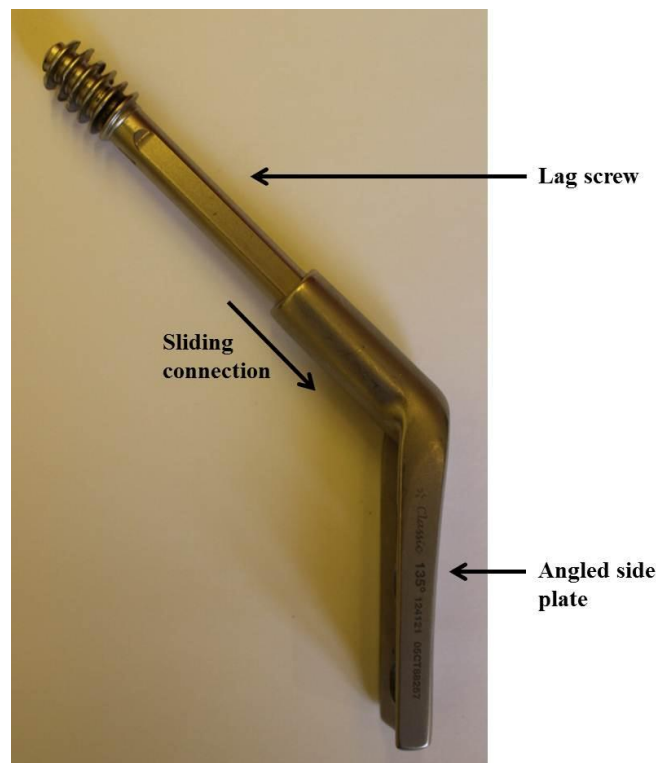
**Figure 8.1: Flowchart of the chapter structure**

#### 8.1.2. Keywords

BS 3531-15 (1992); BS EN ISO 14630 (2009); BS EN ISO 14602 (2010); dynamic hip screw

## 8. 2. Introduction

The Dynamic Hip Screw (DHS), discussed in Chapter 3, is the standard implant used to treat proximal femur fractures (Chirodian *et al.*, 2005; Harrington *et al.*, 2002; Esser *et al.*, 1986). In brief, the DHS assembly consists of a collapsible lag screw inserted into the femoral neck and head that slides within an angled side plate attached to the lateral side of the femur. The compression at the fracture site promotes bone-on-bone contact and results in fracture healing while decreasing loading on implant. The implant is discussed in more detail in section 3.6 and is shown in Figure 8.2.



**Figure 8.2: Generic dynamic hip screw (DHS) manufactured by Smith & Nephew plc. (London, UK)**

A new angle guide (Chapter 4 to 6) and a new handle (Chapter 7) were designed in this research, which would facilitate easy implantation of the existing DHS implant through an incision of 30 mm. The DHS implant was also identified in section 3.9 for redesign to allow for easier implantation in minimally invasive surgery (MIS). Since the introduction of AO DHS implant in 1979, the design of the generic implant has not been modified greatly. Owing to its success and decades of use, the surgical techniques and the implant's use has established itself as the "gold standard" for the treatment of proximal femur fractures (Parker and Handoll, 2009). New implants, most prominently the Gotfried PC.C.P., are based on the principles of the DHS and also combine the benefits of MIS (discussed in section 3.7). However, they have yet not replaced the DHS as the preferred device. The reasons may include a steep learning curve for the new surgical technique (Scuderi and Tria, 2010), need to increase the hospital inventory as the implants require new sets of tools for implantation (Ho *et al.*, 2008), and the existence of similar surgical approaches (section 3.8.3) that allow smaller incisions with minimum modification to the generic DHS surgery (instruments and technique).

The research presented in Chapters 8, 9 and 10 describes a detailed design process of a new implant to treat proximal femur fractures. The new implant was based on the sliding screw principle of DHS, and allowed for implantation through an incision length of less than 30 mm. It was attempted to build on surgeon's experience with the generic DHS instruments and surgical technique by keeping them as similar as possible for the new implant.

### 8. 3. Design objectives

The objectives of the design process were to -

- a) redesign the established and popular DHS implant to allow easy insertion and implantation through an incision length of less than 30 mm;
- b) retain the principle of sliding of the lag screw into the side plate to promote bone on bone impact for faster healing and weight bearing; and
- c) retrieve the experience of surgeons with the surgical technique of implanting a DHS by utilizing similar instruments and surgical procedure steps for the new implant to avoid a steep learning curve.

### 8. 4. Design specifications

#### 8. 4. 1. Overview

The design specifications of a new implant, stated in section 3.9.3.3, were prepared in accordance with clauses stated in the general requirements of surgical implants (BS EN ISO 14630, 2009), particular requirements of implants for osteosynthesis (BS EN ISO 14602, 2010), and requirements of devices for the fixation of adult femur ends (BS 3531-15, 1992). Information for the topics was collected from published literature on existing DHS implants and through discussion with Prof N. Maffulli (Consultant Surgeon). Certain topics such as sliding mechanism (8.4.3)

are not mentioned in any of the standards. However, they were added to enable a comprehensive requirement discussion before designing a concept. The specifications for devices supplied by competitors, shown in Table 3.1, were used as benchmarks.

#### **8. 4. 2. Functional characteristics**

The new implant would be a non-active (does not depend on electrical energy or any sorts of power apart from that directly generated by the human body or gravity - BS 3531-15, 1992) implantable device to be totally introduced into the human body by means of surgical intervention. The existing DHS implant consists of two main parts - (A) the fixation screw - type C fixation (clause 4 of BS 3531-15, 1992) and (B) the fixed angled plate with a barrel. The concept is for the screw to slide down the barrel, which allows for compression of the fracture site, and also bone-on-bone contact. The new implant should retain the basic principle of the fixation screw sliding down the angled plate. The implant should be designed to allow for removal from the human body if required, and would be designed for single-use only.

#### **8. 4. 3. Fracture treatment**

The design and purpose of the new implant was based on the existing generic DHS and angled side plate implant. Like the DHS, the new implant was intended



for implantation for treatment of fractures of the proximal femur in adults. The implant would not be designed for paediatric use because of the requirement for different plate and lag screw dimensions. The implant would not allow for rotation of the fracture fragments at the site, and it would promote faster healing of the fracture and early weight bearing due to the sliding connection between the lag screw and the angled side plate.

As suggested by Prof. N. Maffulli, following the surgical treatment, the device would be designed to allow immediate weight bearing as able by the patient. The patient is expected to maintain a low activity level and would return to functional weight bearing some 6 to 12 weeks after implantation of the device.

#### **8. 4. 4. Sliding mechanism**

Implant cut-out is a major complication after repair of proximal femoral fractures (Canale, 2002). The rate of cut-out was significantly reduced as the implants shifted from mostly rigid fixation principles to sliding devices such as the DHS (Linden *et al.*, 2006). The sliding of lag screw in a DHS offers biomechanical advantages as the hip gets more stable by impaction of bones and medial displacement of the femoral shaft. The shortening of the lever arm also reduces the stresses applied to the implant and bone (Flores *et al.*, 1990).

Complications and fixation failure is also attributed to excessive or insufficient sliding of the lag screw (Kim *et al.*, 2001; Gundle *et al.*, 1995). Kim *et al.* (2001)

reported that excessive sliding may also result in extrusion of the lag screw from the lateral wall; other complications may include displacement of fracture, shortening of the affected limb and hip pain with sliding of more than 20 mm. In a study of 100 patients with unstable intertrochanteric fractures by Gundle *et al.* (1995), a slide of 20.5 mm was required during the healing process in patients treated with the DHS. It was also shown that slides of less than 10 mm were a significant predictor of fixation. Success in fracture fixation was always achieved in the study when the range of available slide was 10 mm to 29 mm. The Targon FN implant (B. Braun Melsungen AG, Melsungen, Germany), which allows for minimally invasive surgery (discussed in section 3.8.2) permits a maximum lag screw slide of 20 mm.

The design of the new implant should incorporate a sliding connection of 20 mm between the lag screw and the angled plate to allow bone impaction for faster healing and early weight bearing. The design should also accommodate a clearance of 1 mm between the outside surface of the lag screw and the inside surface of the barrel, as mentioned by BS 3531-15 (1992).

#### **8. 4. 5. Material**

Although the implant would be designed for single-use, the device should be supplied sterile for immediate use in the operating theatre during trauma surgery, and hence should be able to withstand sterilisation through irradiation. Gamma

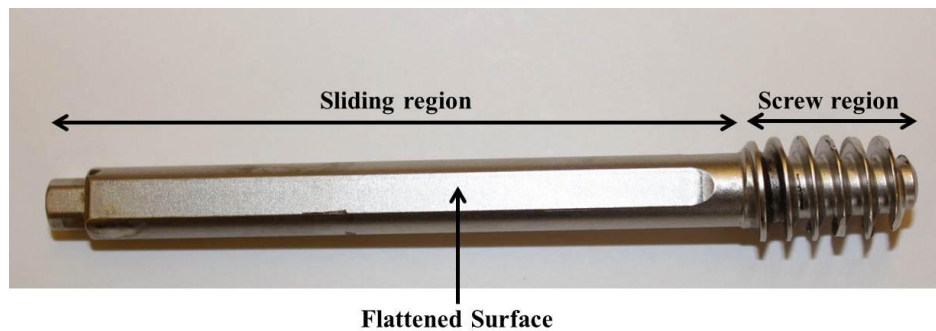
radiation sterilisation is an effective, economical and proven sterilisation process for package of medical devices (Hill, 1998). The material should also be biocompatible for implantation into the human body for a long period of time (minimum period of 90 days as mentioned by Prof. N. Maffulli). The material should also be strong enough to withstand the loading that shall be subjected on to the implant during the course of healing of the fracture.

#### **8. 4. 6. Lag screw**

The generic DHS lag screw is a Type C fixation screw (clause 4 of BS 3531-15, 1992), which is designed to be inserted only after preparation of the femoral neck and head (drilling and tapping as described in the surgical technique in section 3.6.3.2). The fixation screw could be divided into two regions – a) screw region and b) sliding region, as shown in Figure 8.3. The screw region grips onto the femoral head through purchase of the cancellous bone in the head of the femur. This hold is essential for a successful fracture fixation. The sliding region is a cylinder with two opposite sides flattened. The outer shape of the sliding region on the lag screw corresponds to the inner flattened surface of the barrel, restricting rotation of the lag screw.

The length of lag screw to be used in a particular surgery is dependent on the patient's femoral anatomy. The length is measured during the course of surgery as described in section 3.6.3.2. According to the standard BS 3531-15 (1992), the range

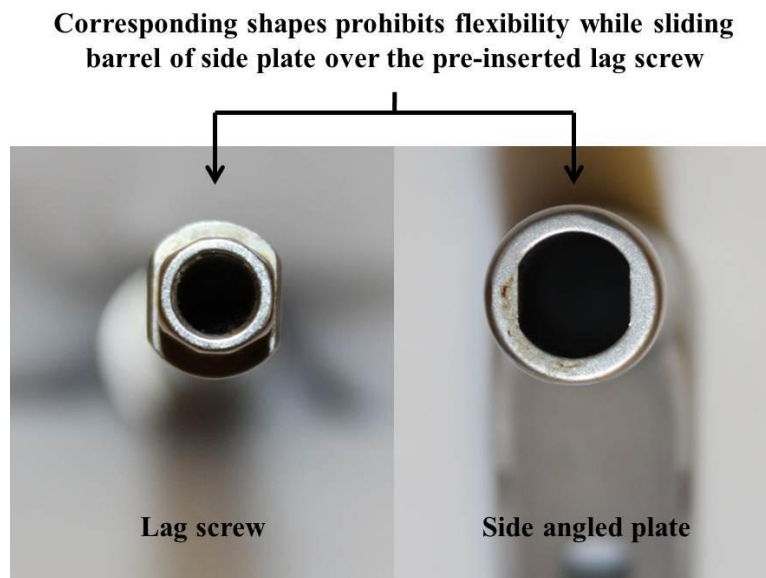
of effective lengths of fixation screws should be from 50 mm to 150 mm with preferred increments between lengths of 5 mm. However, the range of lag screw lengths offered by the orthopaedic manufacturers with their products differs. Smith & Nephew plc. (London, UK) offers lag screws in length ranging from 55 mm to 140 mm in increments of 5 mm with their compression hip screw plate; whereas the length of telescoping screws (assembly of lag screw in a close ended barrel) available with P.C.C.P. Gotfried and Targon FN implants range from 90 mm to 140 mm in increments of 10 mm, and 70 mm to 110 mm in increments of 10 mm respectively.



**Figure 8.3: Regions of a DHS lag screw**

Although, in the generic implant, the lag screw is separate to the barrel (the barrel is fixed to the angled side plate), new devices based on the DHS principle such as Targon FN (B. Braun Melsungen AG, Melsungen, Germany) and Gotfried PC.C.P. (Orthofix srl, Italy) have telescoping screws where the barrel is connected to the lag screw. In the generic implant, as stated earlier, two opposite sides of the cylindrical lag screw and the corresponding inner surfaces of the barrel are

flattened to prevent rotation of the screw inside the barrel, which provides rotational stability to the fracture. However, the non-circular cross sections of the lag screw and the inner surface of the barrel demands that the side plate be inserted vertically-straight so that the barrel is able to slide over the pre-inserted lag screw (Figure 8.4). This problem could be resolved with a telescoping screw where the barrel and lag screw are inserted together as one part. Additionally, the latest implants offer multiple lag screws to assist in rotational stability of the fracture.



**Figure 8.4: Requirement of inserting the side plate vertically straight to slide over the pre-inserted lag screw**

It was important for the lag screw in the new implant to provide rotational stability to the fracture, adequate purchase of bone at the femoral head for a strong hold, simple insertion with a minimally invasive approach, and availability of different lengths to cater to patients with differing femoral anatomy.

#### 8. 4. 7. Side plate

The generic DHS implant side plate consists of a fixed angled plate with a barrel and multiple distal screw holes as seen in Figure 8.5. The side plate is inserted vertically-straight during the conventional surgery of the generic DHS. The barrel slides over the lag screw, and then the plate is secured on to the femur with distal screws.



**Figure 8.5: A generic DHS angled side plate**

The side plates manufactured by Smith & Nephew plc. (London, UK) are supplied as fixed angled plates at angles of 130, 135, 140, 145 and 150 degrees. Prof. N. Maffulli had suggested an inclusion of 120 degree angled side plate as well. It was also discussed in section 3.6.1 that it is important to include an angle range of 120 degree to 150 degrees in increments of 5 degrees to cater to the global population. The side plate of the new design should be designed to serve to all the mentioned

neck/shaft angles. The inner surface of the generic side plate, which interfaces with the lateral femur surface, is curved to correspond to the curvature of the surface of the bone. As discussed in Chapter 4, the radius of curvature of the femoral surface is in the range of 13 to 18 mm, and hence the radius of curvature of the inner surface of the new side plate should be 20 mm to accommodate variability due to difference in population.

The length of incision made during a DHS surgery depends on the length of the side plate used (surgical technique by Michael R. Baumgaertner, Smith & Nephew plc., London, UK) because of the vertically straight insertion of side plate as discussed in section 8. 4. 7. A four-hole side plate DHS is a commonly used side plate for the treatment of intertrochanteric hip fractures (Laohapoonrungsee *et al.*, 2005). A rare occurrence of side plate pull-out or breakage has resulted in a few studies to evaluate the implications of reducing the length of the side plate by decreasing the number of distal screw holes (Laohapoonrungsee *et al.*, 2005; Yian *et al.*, 1997; McLoughlin *et al.*, 2000 and Bolhofner *et al.*, 1999). In their biomechanical studies, Yian *et al.* (1997) found no advantage in inserting more than three distal screws to achieve adequate side plate fixation; McLoughlin *et al.* (2000) did not establish any significant difference in the stability of two and four holes DHS implants. Bolhofner *et al.* (1999) did not report any failure in two holes side plate DHS fixation in 69 patients; and it was also concluded by Laohapoonrungsee *et al.* (2005) after their trial on 112 intertrochanteric fractures that two holes side plate DHS is adequate for fixation of such fractures. The length

of a standard barrel side plate manufactured by Smith and Nephew plc. (London, UK) with 2 screw holes is 60 mm, with a 20 mm increase in length for every additional slot. These findings were important as a shorter side plate in the new design would aid in reducing the length of incision required. It should also be noted that a minimum of two distal screw holes would be required in the side plate of the new implant.

A study by Jewell *et al.* (2008) showed that a side plate of a DHS with fixed angle locking screws would reduce the risk of DHS failure. The experimental results showed a statistically significant increase in the number of cycles to failure for locking plates compared to standard plates. The same research also argued that a locking plate would have biological advantages over standard plates as they do not compress the bone. This is because a standard plate would grip the bone by friction, which is created by compression of the plate against the bone by the screws. This phenomenon would be absent in case of locking screws and hence would prevent a decrease in cortical thickness and cancellous transformation of the bone. The idea of locking plate is applied by Synthes Holding AG (Solothurn, Switzerland) in the form of “combi-hole” design in their side plates. The “combi-hole” allows for insertion of both conventional and locking screws for fixation. The distal holes for either locking or conventional screws in the new implant would have to conform to the dimensions and tolerances stated in standards on specifications for holes and slots for use with screws in bone plates (BS 3531-23.2, 1993).



#### 8. 4. 8. Surgical Technique

The conventional surgical technique of implanting a DHS and side plate for the treatment of proximal femur fractures was described extensively in 3.6.3.2. The surgical procedure for the new implant should try and retain the surgical steps and instruments used in the conventional surgery. This would enable faster acceptance by the surgeons due to a gentler learning curve and less burden on the hospital inventory and costs.

However, the most important objective of the new implant was to require an incision length not larger than 30 mm. The existing generic DHS requires the lag screw to be advanced first and set in a position such that the angled plate is able to fix on to it. The Percutaneous Compression Plate (P.C.P., Orthofix srl, Italy) is an existing implant, which has evolved from the DHS, and was discussed in detail in section 3.8.2. The PCCP allows for minimally invasive surgery and the surgical technique involves securing the plate before advancing the lag screw (Peyser, *et al.*, 2005). This method makes it easier to assemble the implant through a smaller incision because of the new locking method between the lag screw and side plate. Unlike the conventional surgical method, the side plate is first inserted through a small incision, slid down the lateral femur into position and secured. This method now permits the lag screw to advance into the femoral head through the angled plate through the same small incision without any requirements of a particular insertion method.

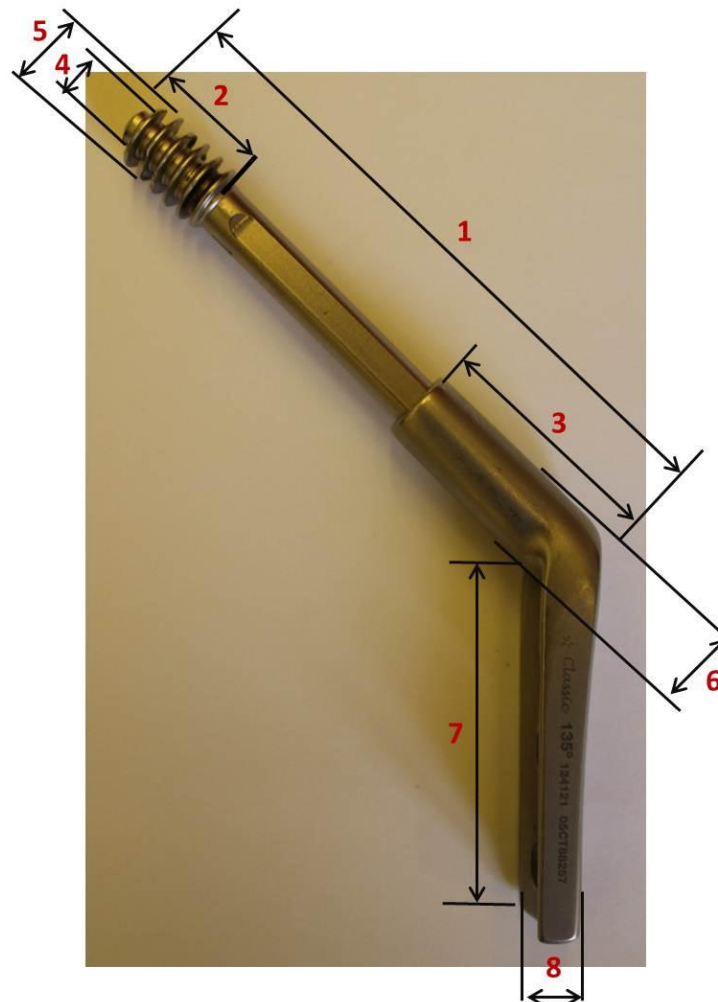
The surgical technique for the new implant should build on the existing conventional surgical procedure for the DHS implant, and not require a steep learning curve. However, it should also include steps that would result in reducing the incision length to less than 30 mm, and aid in easy and comfortable insertion.

#### **8. 4. 9. Dimensions**

The dimensions of the existing DHS and side plate implant assembly are shown in Figure 8.6 and tabulated in Table 8.1. The nomenclature of dimensions as shown in Figure 8.6 is in accordance with clause 5.1 of standard BS 3531-15 (1992). The standard barrel two holes side plate of 60 mm angled at 135 degrees (catalogue no. 12-4121) and lag screw with an effective length of 105 mm (catalogue no. 12-1110) are part of the DHS implant set manufactured by Smith & Nephew plc. (London, UK). The mentioned dimensions were used as reference for the design of the new implant. The dimensions were measured using digital vernier callipers (resolution of 0.01 mm and accuracy of  $\pm 0.03$  mm, Fisher Scientific UK Ltd., Loughborough, Leicestershire, UK)

**Table 8.1: Dimensions of a generic 135 degrees DHS implant shown in Figure 8.6**

No	Dimension	mm
1	Effective screw length	105
2	Thread length	21
3	Barrel length	38.1
4	Shaft diameter	9
5	Thread diameter	12.7
6	Barrel diameter	13
7	Effective plate length	60
8	Plate thickness	Ranges from 6 at bottom to 10.5 at the top end

**Figure 8.6: Nomenclature of dimensions of a generic 135 degrees DHS implant in accordance to standard BS 3531-15 (1992)**

#### **8. 4. 10. Mechanical testing**

The fixation device should be subjected to the testing method ASTM F 384 (2006), which describes the static loading and fatigue testing methods for metallic angled orthopaedic fracture fixation devices. The mechanical testing conducted on the device is discussed in more detail in Chapter 9.

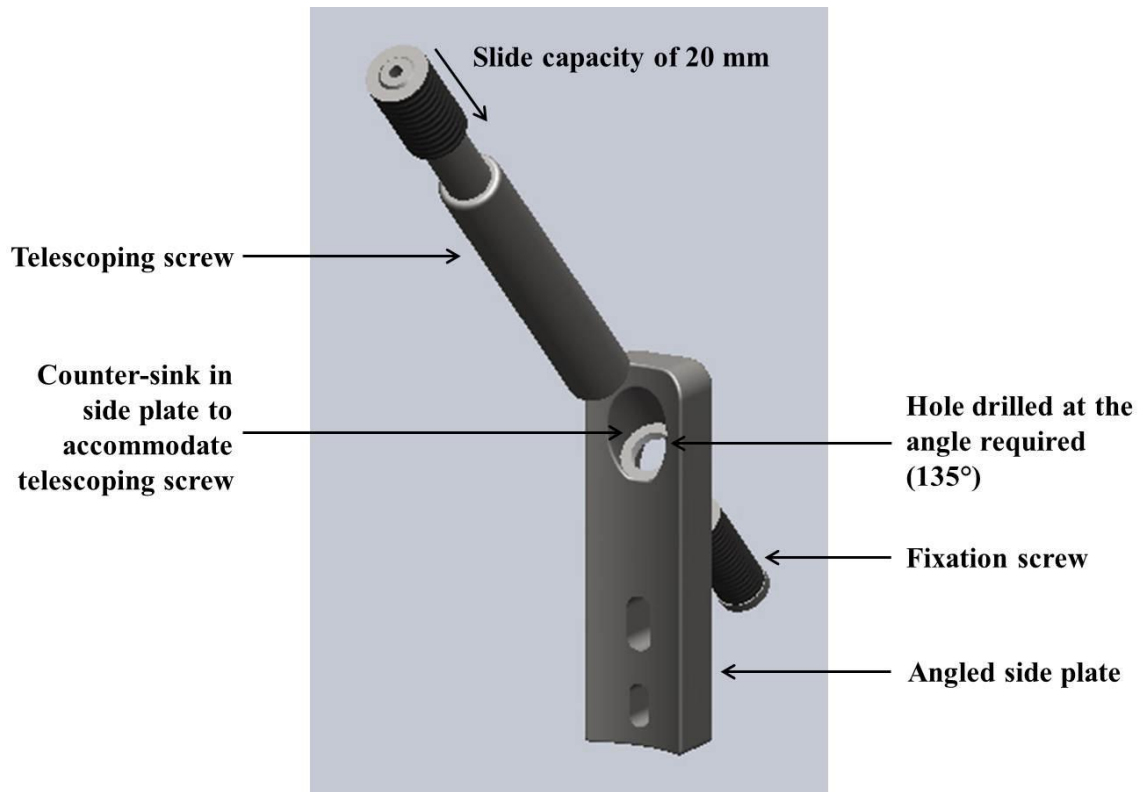
### **8. 5. Evolution of a concept**

#### **8. 5. 1. Overview**

The information discussed in section 8.4 was used to conceptualise a new implant that would utilise the sliding principle of the DHS implant, and allow for an implantation through an incision length of less than 30 mm using a simple surgical technique. It was realised that the length of incision could be majorly reduced by changing the way the lag screw was to be attached to the side plate during the surgery. The concepts although different, evolved from the first (8.5.2) to the second (8.5.3).

### 8. 5. 2. Concept 1

The first concept was a three part implant as shown in Figure 8.7. The three part assembly comprised of a telescoping screw, a three holes side plate and a fixation screw. The telescoping screw had a lag screw with large threads at one end, which would be inserted into the femoral head for purchase and hold. The other end of the lag screw was placed inside a barrel, which had female screw threads at the bottom end. The telescoping screw would have a maximum slide of 20 mm as discussed in section 8.4.4. The two opposing sides of the outer surface of the lag screw, and the corresponding inner surface of the barrel would be flattened. This would provide the rotational stability at the fracture. The side plate shown in Figure 8.7 was designed to be a flat plate with two distal holes without an external barrel. The proximal hole in the plate for the lag screw would be supplied drilled and threaded at a fixed angle required by the patient's femoral anatomy. The angle shown in the figure is 135 degrees. The counter sink of the fixed angle hole on the side plate was dimensioned to ensure a fit with the bottom end of the telescoping screw. This would prevent the telescoping screw to slide beyond the plate while in compression during the healing process of the fracture. The final part of the assembly is a fixation screw which would connect and fix the side plate to the barrel of the telescoping screw. The dimensions of the concept would be kept similar to the existing generic DHS implant.



**Figure 8.7: Concept 1 of the new implant**

Two incisions would be required to insert this concept into the femur. The first incision should be 25 mm to accommodate the new angle guide (Chapter 4 to 6) and the diameter of the barrel of the new implant (diameter of the barrel on the generic DHS implant is 13 mm). The next step would be to insert a guide pin at the pre-operative determined angle into the femoral head using the new angle guide. The femoral neck and head would then be reamed through using a triple reamer, following which the telescoping screw would have to be inserted with the lag screw completely extended to its full sliding capacity of 20 mm. As a result of the new locking method between the telescoping screw and the side plate, the side plate in this surgical procedure could be inserted through the same minimal incision that was required to insert the telescoping screw, and then slid down the

lateral femur surface. A second incision would then be made to secure the side plate with distal screws. The final surgical step would be to insert the fixation screw to secure the telescoping screw to the side plate. The incision required for the surgical procedure of this concept was less than 30 mm.

However, this concept had a problem because of the thin angled thread that was drilled through the side plate for the telescoping screw. Although this was an alternate solution for attaching the side plate to the lag screw, there was a very high risk that stress concentration at the thread could lead to implant failure. At the same time, although the system was not exactly the same, there are patents published which use a fixation screw to attach the lag screw to the side plate (Frigg, 1994; Shaw, 2007). Therefore, this idea was not taken forward to be selected as the final concept for a new implant.

### **8. 5. 3. Concept 2**

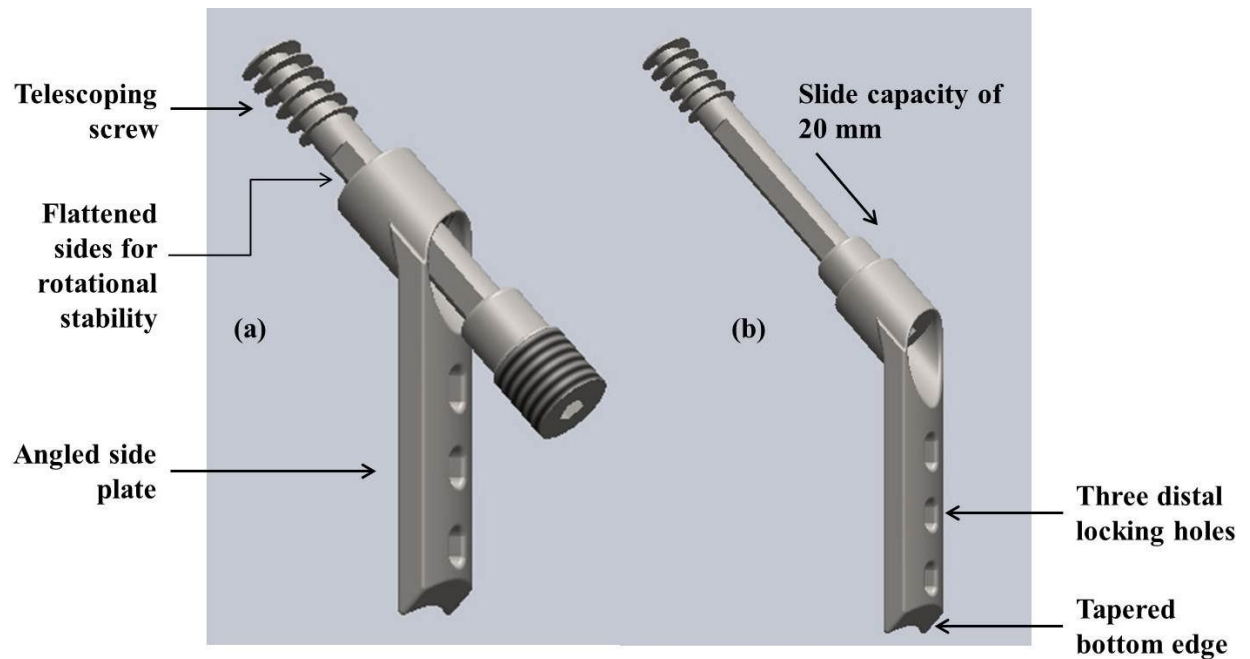
The second concept was a two part implant consisting of a telescoping screw and a fixed angled side plate as seen in Figure 8.8. The telescoping screw was adapted from concept 1, discussed in section 8.5.2. However, the bottom end of the barrel has the screw threads on the outside. The telescoping screw allowed for a maximum slide of 20 mm and the dimensions would be adapted from the generic DHS lag screw and barrel. The side plate on the other hand was different to the one discussed in concept 1. The side plate had an extrusion in the shape of a barrel

through which the telescoping screw would pass. The barrel had threads on the inner surface, on which the telescoping screw would secure itself when it was advanced through it into the femoral neck and head. Other distinctive features included in the side plate were three distal locking screw holes and a tapered bottom of the side plate. The advantages of the locking side plate were discussed in section 8.4.7. The tapered bottom would make it easier for the side plate to slide over the lateral femoral surface.

The implant would require a two incision approach for incision. The first incision should be large enough to accommodate the angle guide and the diameter of the barrel of the new implant (i.e. 25 mm). The second incision would be made to insert the distal screws. This should be followed by inserting the guide pin into the femoral neck and head using the new angle guide designed during this research (Chapter 4 to 6). The next step would be to use a triple reamer and a tap (optional) to create a tunnel for the telescoping screw and side plate. The side plate would then be inserted through the incision, slid down the lateral femur surface and secured in position using locking screws. The telescoping screw would be advanced through the proximal incision into the femoral neck and head with its sliding capacity fully extended till the threads of the telescoping screw and side plate meet. The telescoping screw would then be turned until it would be secured in position with the side plate. The concept would require two additional instruments – i) a side plate inserter to assist in implanting the side plate on to the



femur and ii) a hexagonal screw driver to advance the telescoping screw fully extended into the femoral neck and head.



**Figure 8.8: (a) telescoping screw being advanced through a secured angled side plate; (b) an assembled concept 2 of the new implant**

Concept 2 did not present any immediate concerns and was able to fulfil all the design specifications stated at the beginning of the Chapter. The concept was taken forward for design verification, and is discussed further in Chapter 9.

## 8. 6. Summary

The summarising points of this chapter are listed below.

- i. A new implant based on the principle of DHS implant, which would be capable of being inserted through a maximum incision length of 30 mm using a surgical technique similar to the one used for inserting the generic DHS, was taken up for design.
- ii. A PDS for the new implant was prepared in accordance with clauses stated in the general requirements of surgical implants (BS EN ISO 14630, 2009), particular requirements of implants for osteosynthesis (BS EN ISO 14602, 2010), and requirements of devices for the fixation of adult femur ends (BS 3531-15, 1992).
- iii. Two concept ideas were generated based on the requirements laid in the PDS. Concept 2, a two part implant, was selected to be taken through the detail design stage, which is discussed in Chapter 9. The concept consisted of a telescoping lag screw and an angled side plate.

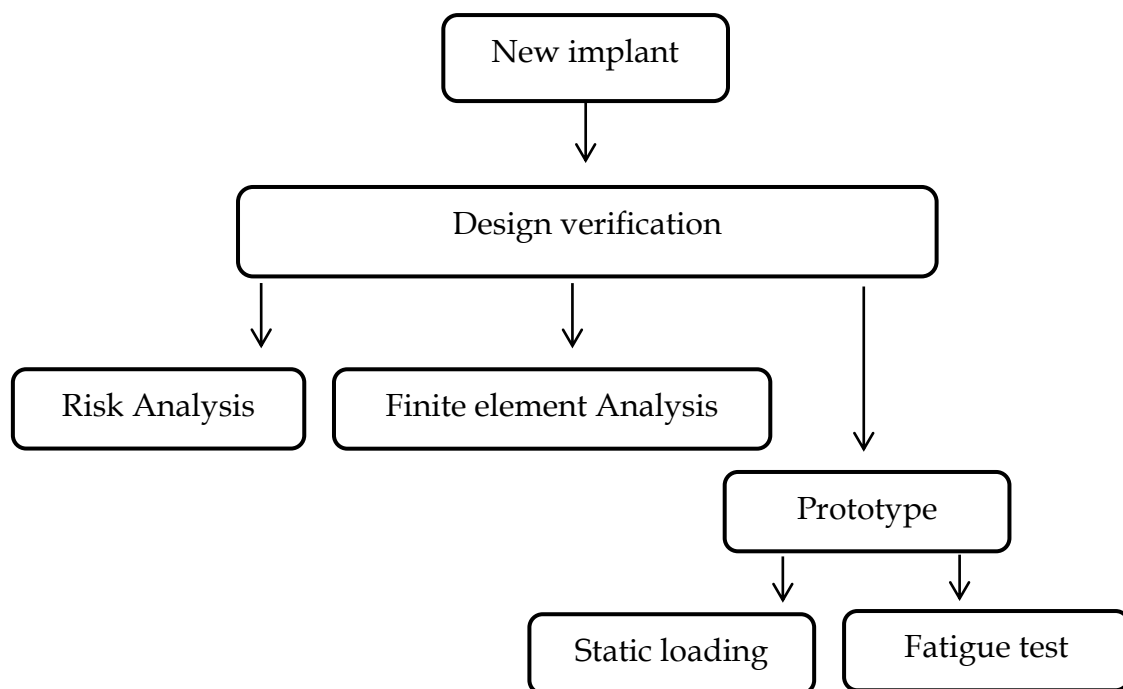
# CHAPTER 9

## THE NEW IMPLANT

### 9.1 Chapter at a glance

#### 9.1.1. Chapter overview

Figure 9.1 shows the chapter overview in the form of a flowchart.



**Figure 9.1: Flowchart of the chapter structure**

#### 9.1.2. Keywords

Fatigue test; finite element analysis; new implant; risk analysis; static loading

## 9. 2. Introduction

The concept for a new implant to treat fractures of the proximal femur was selected in Chapter 8. The concept, based on the dynamic hip screw (DHS) implant, incorporated the sliding mechanism. Furthermore, it would be possible to implant this concept using a minimally invasive approach (surgical technique described in Chapter 10). This chapter describes the new implant and its components in detail.

The design of the new implant was verified using risk analysis, finite element analysis and through mechanical tests conducted on manufactured prototype samples to check for safety and effectiveness of the concept. The results of these verifications are discussed in this chapter.

The dimensions used at first for the concept of the new implant (denoted as model 1) meant it was unable to withstand the loading conditions during the mechanical tests as there was excessive bending of the angled side plate and fracture of telescoping screw's barrel (testing method described in section 9.7.2.3.). The engineering drawings for model 1 are in Appendix B, along with pictures of the ruptured barrel and the bent side plate. The dimensions (thickness of angled side plate; and thickness of barrel) were reassessed, and the newer concept (model 2) was used for detailed description and verification.

### 9. 3. New implant in detail

#### 9. 3. 1. Implant overview

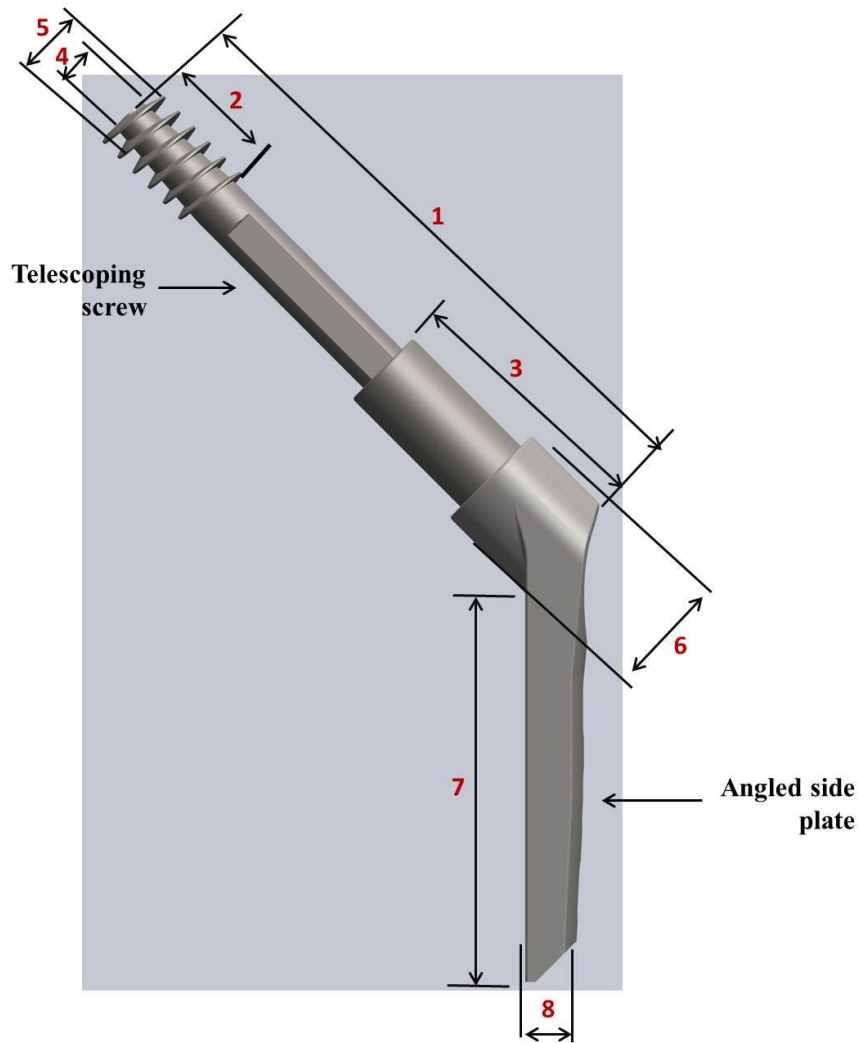
The new implant, a two component assembly consisting of an angled side plate and a fixation screw as shown in Figure 9.2, was designed to treat fractures of the proximal femur in adults. Unlike the lag screw in the generic DHS (section 8.4.6), the fixation screw in the new implant is called a telescoping screw which included a lag screw enclosed in a barrel with a closed end. The purpose of the telescoping screw was to provide rotational stability to the fracture, and allow a restricted slide (telescoping pipe mechanism) of the lag screw inside the barrel to enable compression at the fracture site and promote bone-on-bone contact for faster healing of the fracture. As determined in section 8.4.4., the maximum available slide for the lag screw would be 20 mm; clearance of 1 mm between the lag screw and inner surface of the barrel.

The implant would be manufactured using stainless steel 316L (ASTM F138, Young's modulus - 690 MPa, tensile strength - 860-1100 MPa, Poisson's ratio - 0.33, values sourced from BS 5832-1, 2007; Ratner *et al.*, 2004), which would also be used to manufacture the new angle guide (discussed in Chapter 6). This material is the most commonly used stainless steel for the manufacture of medical devices, provides excellent resistance to corrosion, and is able to withstand sterilisation using gamma radiation (Ratner *et al.*, 2004; Harper, 2001). The new implant would

be able to fix fractures of femurs with neck/shaft angles in the range of 120 degrees to 150 degrees at 5 degree increments. A neck/shaft angle of 135 degrees is most common (Canale, 2002); hence the corresponding 135° angled side plate is used for description and analysis for the remainder of this chapter. The dimensions of the new implant assembly as required by clause 5.1 of standard BS 3531-15 (1992) is shown in Figure 9.2, with values tabulated in Table 9.1. The dimensions of the new implant were based on the existing DHS implant (section 8.4.9). The engineering drawings for the individual components of the assembly, along with further details are discussed in their respective sections. The surgical technique for the new implant is discussed in detail in Chapter 10.

**Table 9.1: Dimensions of the new implant shown in Figure 9.2**

<b>No</b>	<b>Dimension</b>	<b>mm</b>
1	Effective screw length	105
2	Thread length	21
3	Barrel length	40
4	Shaft diameter	9
5	Thread diameter	12.7
6	Barrel diameter	19
7	Effective plate length	65
8	Plate thickness	Ranges from 6 at bottom to 10.5 at the top end



**Figure 9.2: Nomenclature of dimensions of the new implant in accordance to standard BS 3531-15 (1992)**

### 9. 3. 2. Angled side plate

The new angled side plate, like the generic side plate in the DHS implant, was a fixed angled plate with a large superior hole for the fixation screw (telescoping screw for the new implant, and lag screw in the DHS implant), and distal holes to secure the plate to the femoral shaft using screws. The engineering drawing of the

new angled side plate is shown in Figure 9.3. However, unlike the generic side plate, the superior and the distal holes of the new angled plate were threaded. The angled extrusion at the head of the side plate was a short cylinder with fine threads (5/8-18 UNF 3B) on its inner surface to lock with the fine threads on the surface of the barrel of the telescoping screw during implantation. The threaded distal holes would allow locking screws to secure the plate onto the femoral surface. The advantages of locking screws over conventional screws were discussed in section 8.4.7.

The angle of the side plate was fixed between 120 degrees and 150 degrees at 5 degree increments to cater to the varying neck/ shaft angles of fractured femurs. The inner surface of the plate, which interfaces with the femoral shaft surface, was curved with a radius of 20 mm as the radius of curvature of the femur surface in that region was determined to be between 13 to 18 mm in section 4.5.7. The effective length of the angled side plate was fixed at 65 mm, and, like the PC.C.P. implant (Orthofix srl, Italy – discussed in section 3.8.2.), it would only be available with three distal holes as this number is considered to be adequate for fixation of proximal femur fractures (section 8.4.4). The side plate exhibited an increasing thickness ranging from 6 mm at the bottom end to 10.5 mm at the top, as shown in Figure 9.3.



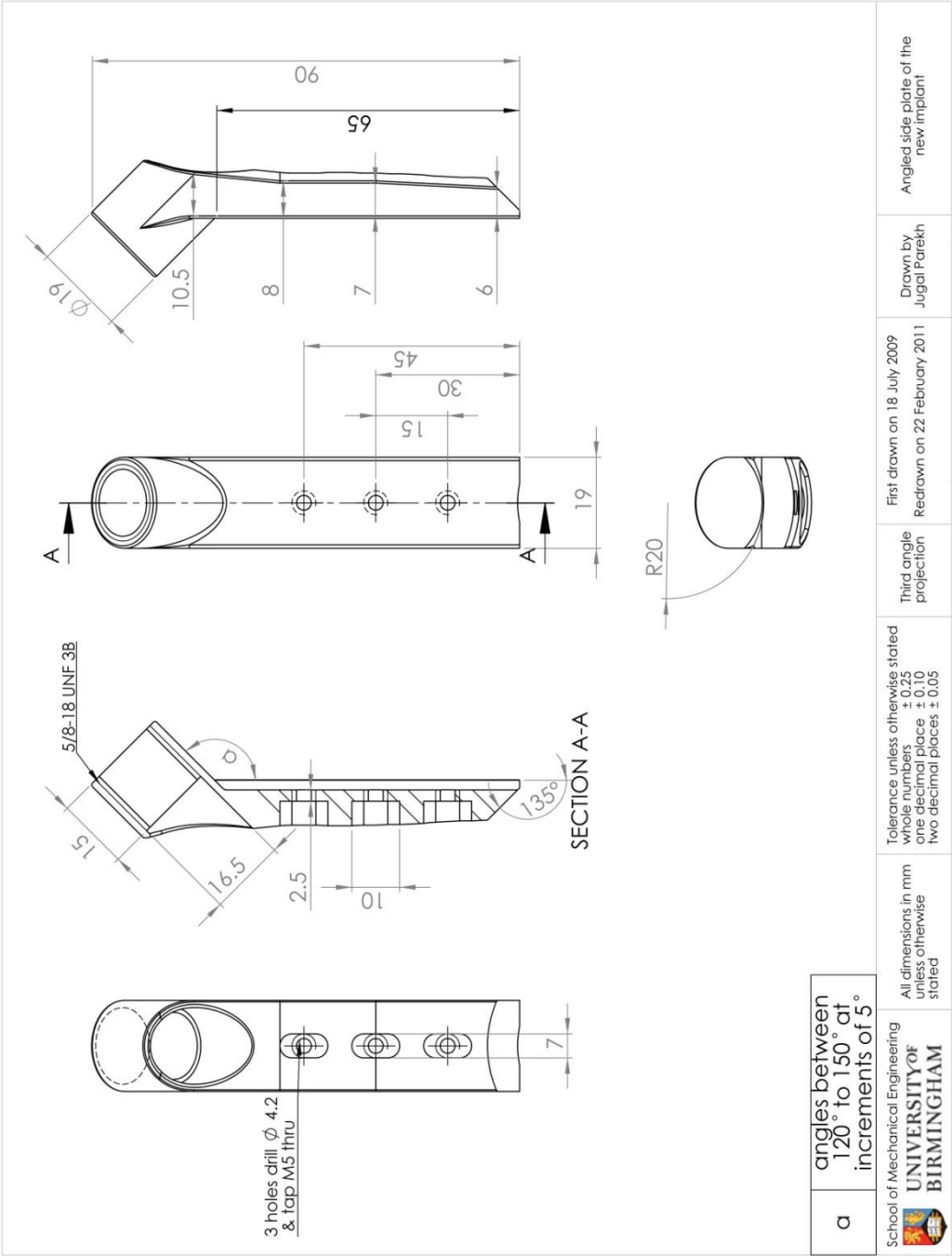
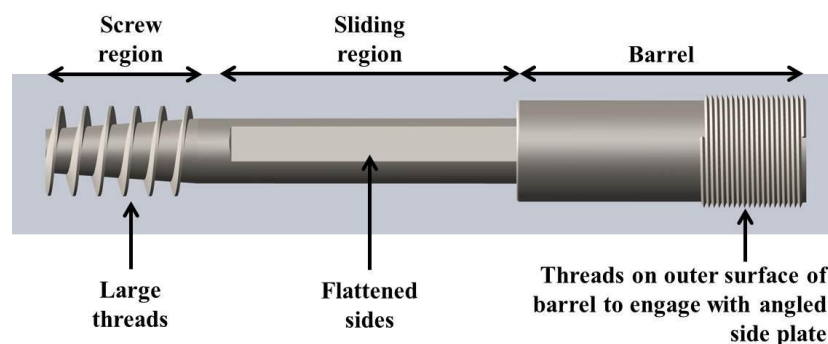


Figure 9.3: Engineering drawing of the angled side plate of the new implant

### 9.3.3. Telescoping screw

The telescoping screw of the new implant, a type C fixation screw (designed to be inserted only after preparation of femoral neck and head – BS 3531-15, 1992), was an assembly comprising of a lag screw of differing lengths enclosed in a barrel with a closed end. The lag screw could be divided into a screw region and a sliding region as shown in Figure 9.4. The screw region (length of 21 mm) would be inserted into the femoral head for grip, and the sliding region would be able to displace within the barrel to a maximum distance of 20 mm. The effective lengths of telescoping screw available would range from 90 mm to 150 mm in increments of 5 mm. Telescoping screws of lengths less than 90 mm were not possible as the sliding region on the lag screw was too short to permit the 20 mm slide. Although the PDS (section 3.9.3.3) stated lengths from 50 mm to 150 mm, successful implants including the Gotfried PC.C.P. (section 3.8.2) only provide lengths from 90 mm to 110 mm. There have been no published concerns regarding the low variability in lengths offered. A 105 mm telescoping screw was used for design verification stages of this research (the engineering drawing shown in Figure 9.5.).



**Figure 9.4: Regions of the telescoping screw of the new implant**

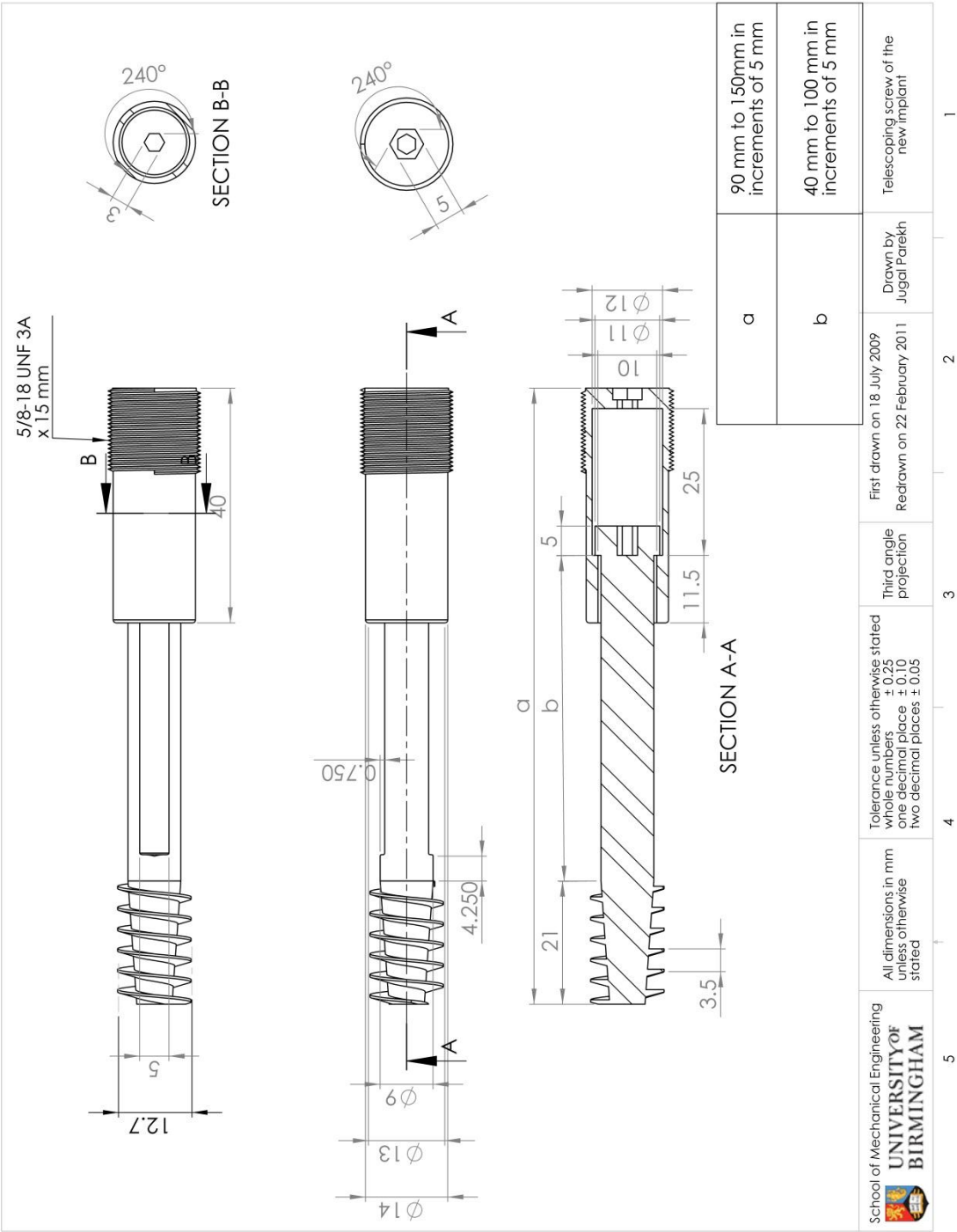


Figure 9.5: Engineering drawing of the telescoping screw of the new implant

Two opposing sides of the sliding region of the lag screw and the corresponding inner surfaces of the barrel were flattened to provide rotational stability at the fracture site. Hexagonal recesses were provided at the bottom of the lag screw and the barrel to allow for insertion of the telescoping screw into the femur using a telescoping screw inserter (section 10.4.5).

#### **9. 4. Risk Analysis**

Risk analysis, discussed in section 2.3.5.3 and conducted on the angle guide in section 6.4., aimed to identify the hazards associated with the new implant and to discuss control measures to eliminate or reduce the hazards. The methodology is described in section 2.3.5.3 and the results are shown in Table 9.2. The analysis should not be considered exhaustive and was conducted by the author following literature review on the existing DHS implant failure presented in section 3.6.1, and consultation with Prof. Maffulli (Consultant surgeon). The analysis only included the telescoping screw and the angled side plate, and did not take into consideration the packaging and manufacturing process of the product.

The hazards identified during the risk analysis of the new implant in Table 9.2 were addressed by effective control measures ensuring that the design is safe to use. No major hazards were discovered during the analysis.

Table 9.2: Risk analysis of the new implant

Component	Possible hazard or failure mode	Effect of hazard or failure	Cause of hazard or failure	O	S	D	RPN	Control measure
Telescoping screw	Cut-out of the femoral head		Incorrect placement due to wrong guide pin insertion	5	6	6	180	To be used by skilled surgeon & image intensifiers to be used to verify correct placement of guide pin
			Insufficient slide due to jamming of lag screw in barrel	1	7	5	35	Clearance of 1 mm between lag screw and barrel was provided
	Fractured fragments displace	Unsuccessful treatment/ injury to patient	Wrong length of telescoping screw selected	1	3	7	21	Surgical procedure provided to select correct screw length
			Excessive slide of the lag screw	3	6	6	108	Maximum slide of lag screw inside barrel is restricted to 20 mm
	Fracture/ Breakage		Excessive bending of screw	1	10	5	50	Static bending tests were conducted to check stiffness of design
			Failure at Barrel	1	10	5	50	
Angled side plate	Excessive bending/ failure	Non-union of fracture/ injury to patient	Design is not strong enough	2	5	7	70	Static bending tests were conducted

Component	Possible hazard or failure mode	Effect of hazard or failure	Cause of hazard or failure	O	S	D	RPN	Control measure
	Protrusion through skin	Injury to patient	Failure of distal screws	2	10	2	40	Locking screws were provided to enhance side plate fixation
			Breakage of side plate	1	10	5	50	Static bending tests were conducted
	Injury to soft tissue during insertion	Minor delay to surgery/ patient experiences post-operative pain	Tapered bottom edge of the side plate	1	7	8	56	Sufficient incision and cleaning of operating site
Angled side plate	Telescoping screw does not fit into the superior hole	Major delay to surgery	Wear of screw threads on telescoping screw or side plate	1	10	1	10	Should be manufactured well.
								Threads should be checked prior to surgery for any defects

## 9. 5. Finite Element Analysis (FEA)

### 9. 5. 1. Overview

The principles of FEA were described in section 2.3.5.3., and the methodology was discussed while conducting the analysis on the new angle guide in section 6.5. The following sections discuss the FEA conducted on a three dimensional model of the new implant, which was created using SolidWorks CAD software (3DS Daussalt Systemes, Version 2008-2010, Lowell, MA, USA). The engineering drawings of the individual components (telescoping screw and angled side plate) of the implant assembly are shown in Figure 9.3 and 9.5. However, due to meshing errors (models would not mesh successfully), three features of the models were removed – namely the large threads at the head of the telescoping screw, the flattened sides on the surfaces of the lag screw and the barrel, and the various fillets on the model. Furthermore, the distal holes were replaced with a thin flat layer (thickness of 0.5 mm) on the inner curved surface of the angled side plate. The layer was used to restrict the model in all directions during the analysis as the plate will be fixed against the femur with distal screws in that region. The details are further discussed in section 9.5.2, and the FEA model is shown in Figure 9.6a. The static analysis on the model was conducted using the integrated FEA tool called SolidWorks Simulation (COSMOS in version 2008).

The FEA was also conducted on a three-dimensional model of the generic DHS implant. The dimensions of the model were taken from the 135 degrees DHS implant with three holes side plate (catalogue no. 12-4126) and 105 mm lag screw (catalogue no. 12-1110) manufactured by Smith & Nephew plc. (London, UK), and their engineering drawings are shown in Figures 9.6 and 9.7. The results of FEA studies on the new implant and the DHS implant were compared to verify the feasibility of the new design.

### **9. 5. 2. Pre-processing**

The three dimensional models of the generic DHS and the new implant were assigned with material properties of stainless steel 316L. ASTM F 384 (2006), a standard discussing the test methods for metallic angled orthopaedic fracture fixation device, was used as a guide for specification of loading conditions on the models. According to the standard, the side plate of the implant has to be rigidly attached to a fully constrained body with the distal screws, and the load has to be applied at a point which equals to 80 % of the length of the fixation screw (84 mm for a 105 mm long fixation screw). However, the direction of load applied was not parallel to the long axis of the side plate as suggested by the standard, but was applied perpendicular to the long axis of the fixation screw. The modification to the configuration was made as this setup would prevent damage to the load cell of the testing machine due to reaction forces generated in other axis due to probable slide of the telescoping screw during mechanical tests conducted on the prototype



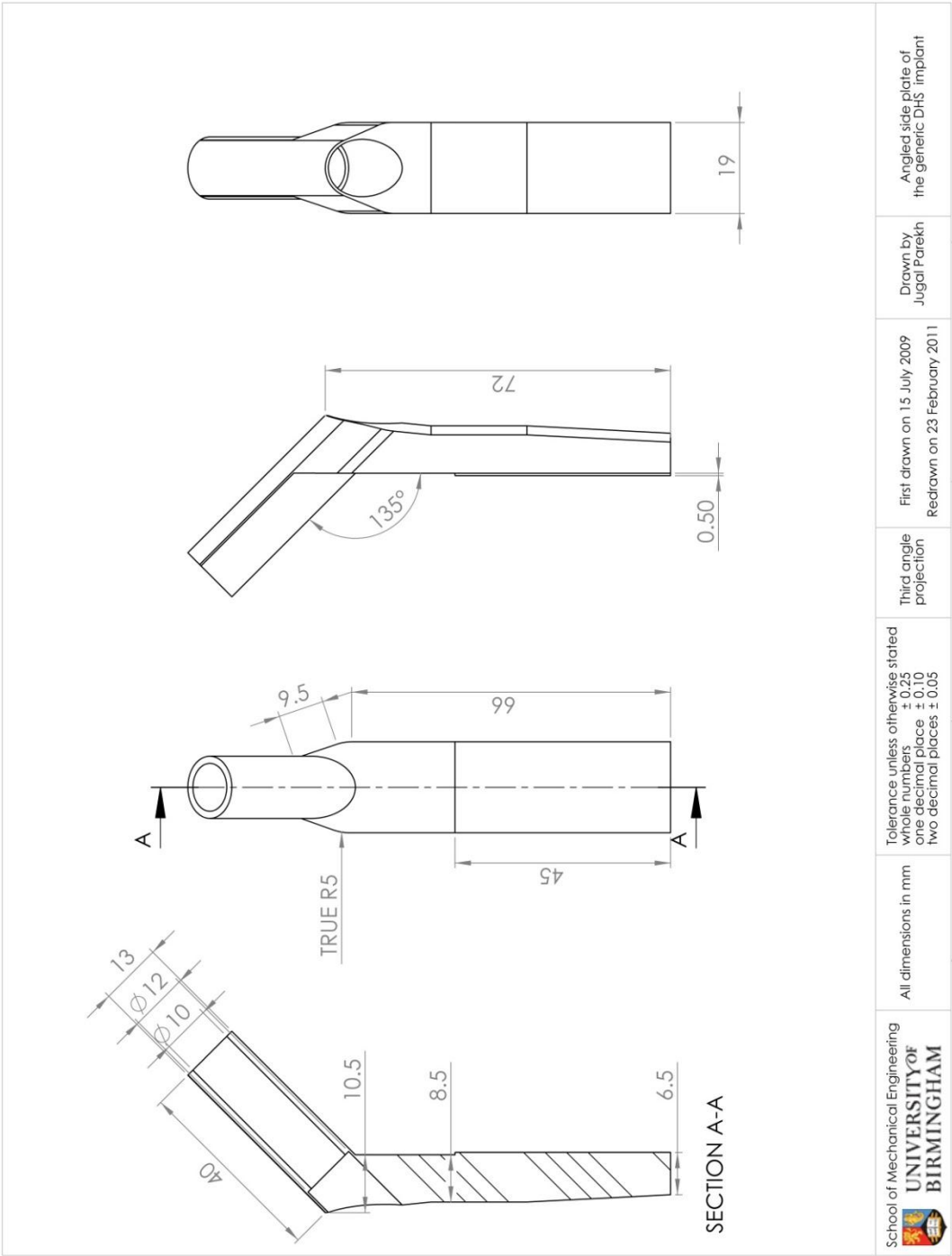


Figure 9.6: Engineering drawing of the angled side plate of the generic DHS implant

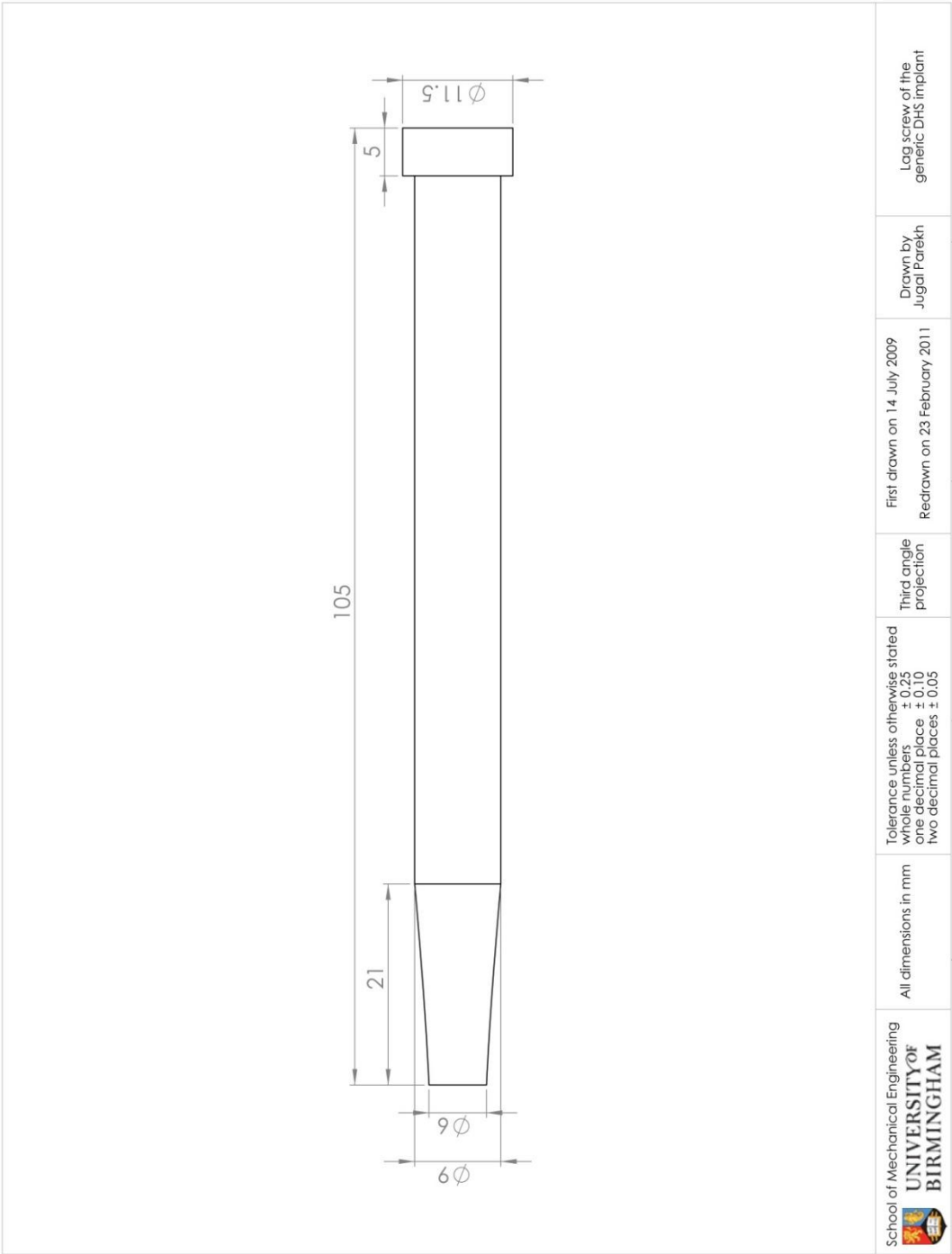
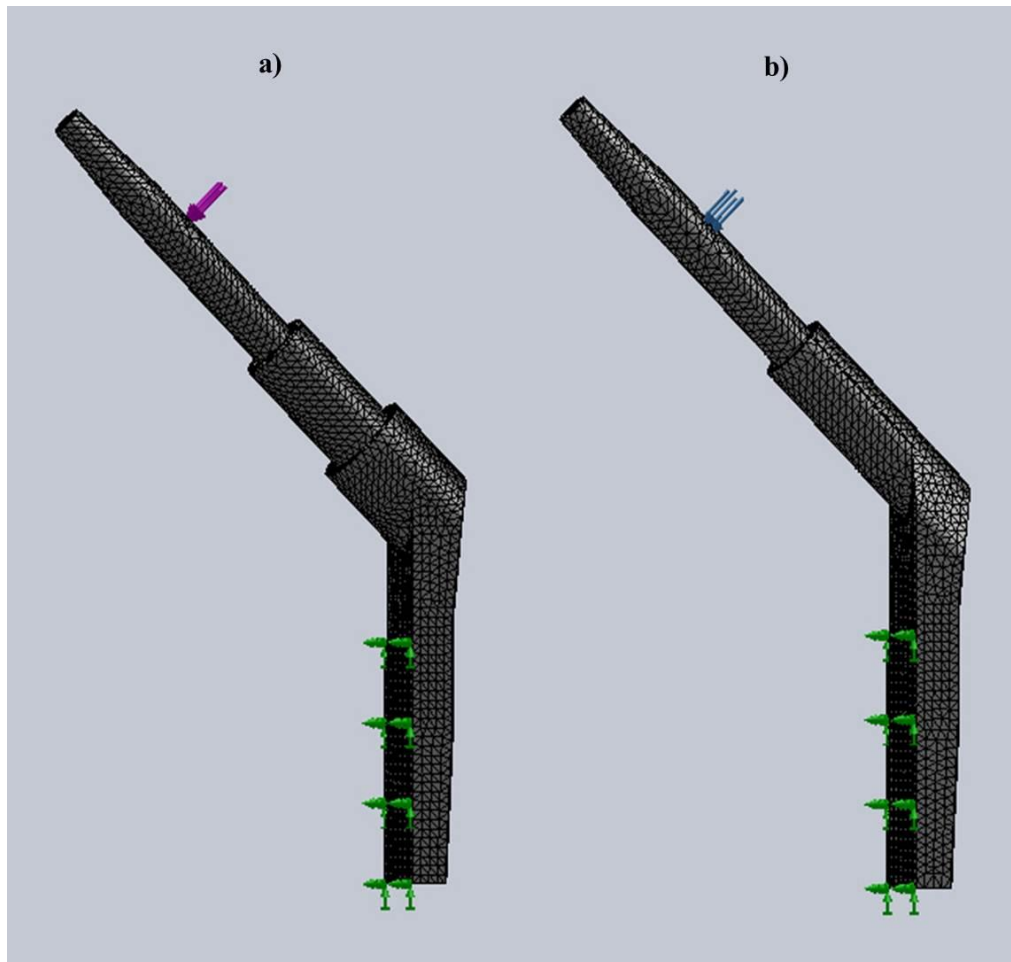
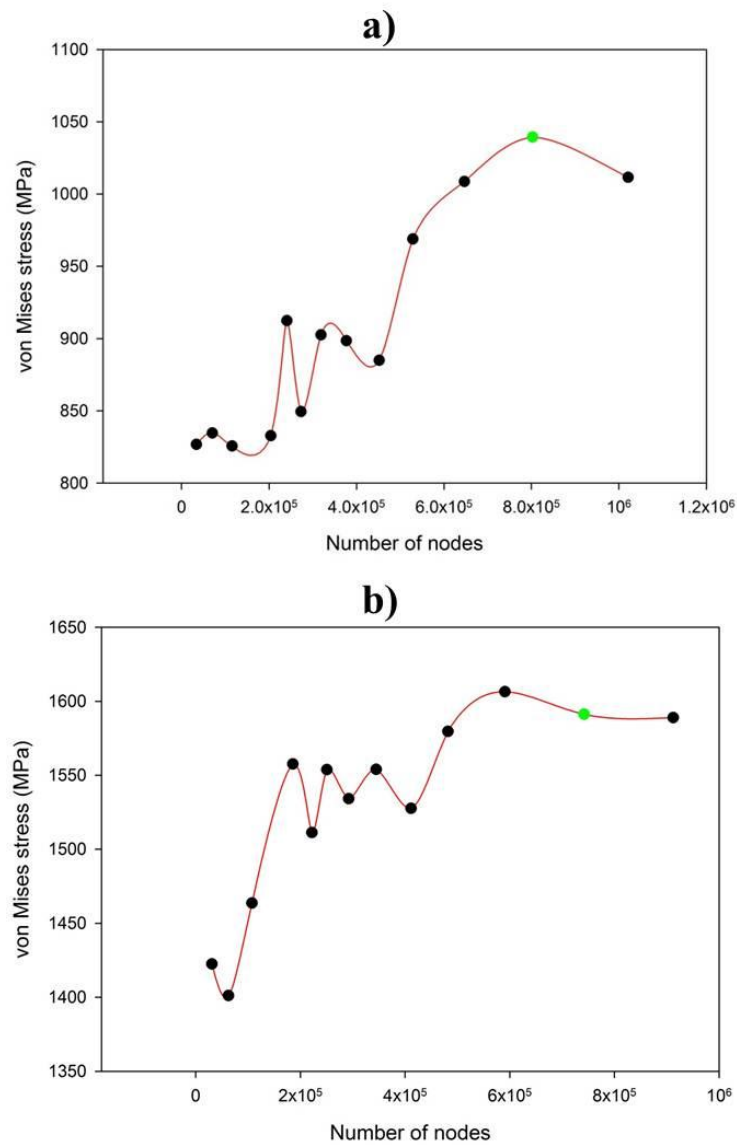


Figure 9.7: Engineering drawing of the lag screw of the generic DHS implant

(section 9.7). Secondly, the configuration was also used by Zirn (2008) to analyse the load capacity of their newly designed hip compression screw device. This was the only study discovered which had published the results of static load and fatigue testing conducted on a DHS and a similar implant. Hence, it allowed for comparison of results during the mechanical tests (section 9.7). The loading conditions during the FEA were kept similar to maintain consistency of testing method and configuration during this research.



**Figure 9.8: Three dimensional models of a) the new implant, and b) the generic DHS implant, meshed at size of 1.75 mm. The loading and fixtures of the models were specified as discussed in section 9.5.2.**



**Figure 9.9: Convergence plots to select mesh size for a) the new implant, and b) the generic DHS implant. The green points signify the values of von Mises stress and the number of nodes for the selected mesh size (0.60 mm for both models)**

A load of 800 N (as applied by Zirn (2008)) was applied perpendicular to the top edge of the fixation screw at 21 mm from the front edge in models of the generic DHS and the new implant. The angled side plate was fixed in the region of the distal screws in all directions. The loading and fixture of the models are illustrated in Figure 9.8a and 9.8b. Following the plotting of convergence graphs (stress vs.

number of nodes), shown in Figure 9.9a-b, for the respective implant models, the mesh size selected were: 0.60 mm (number of elements - 554833; number of nodes - 802755) for the model of the new implant and 0.60 mm (number of elements - 515412; number of nodes - 742004) for the model of the generic DHS.

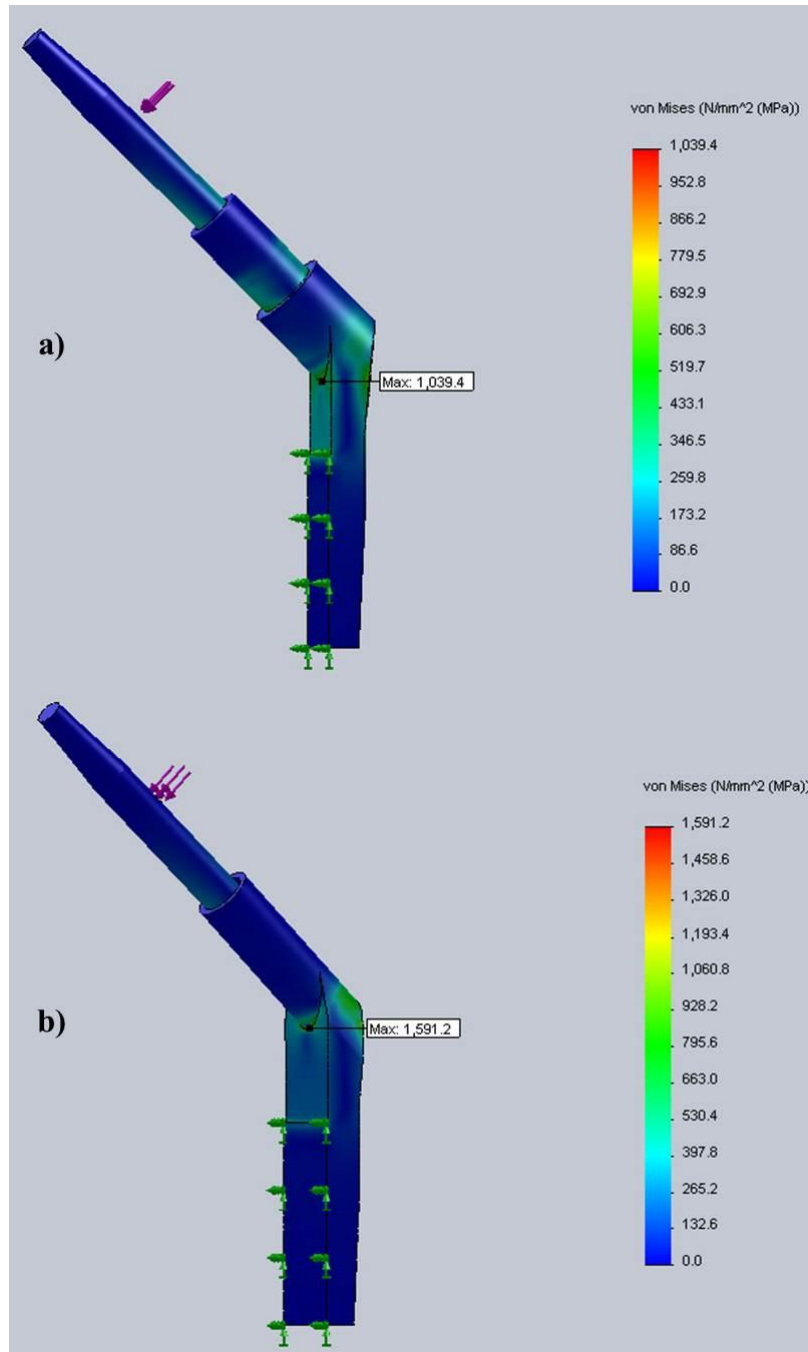
### **9. 5. 3. Post-processing**

Graphical representations of the deformed model, along with the values of the solutions were generated, and are shown in Figure 9.10. The displacement of the model in units of mm, and von Mises stresses on the model in units of MPa, were presented at the end of the analysis as results.

The maximum stress in the new implant model was found on the angled side plate at the angled bend as shown in Figure 9.10a to have a value of 1039 MPa. The maximum displacement was 2.4 mm, at the front of the fixation screw. Similarly, on the generic DHS implant, the highest stress of 1591 MPa (Figure 9.10b) was on the angled bend on the angled side plate; with the maximum displacement of 3.6 mm at the front of the fixation screw.

The values of stresses and displacement on the new implant were less than in the generic DHS implant, which is already being used in the market as a successful device for proximal femur fracture treatment. The value of the maximum stress in the new implant was also less compared to the maximum tensile strength of the

material (1100 MPa). Therefore, this design was concluded to pass the verification using FEA.



**Figure 9.10: Graphical representation of von Mises stress generated on a) the new implant, and b) the generic DHS implant, due to a load of 800 N during the FEA**

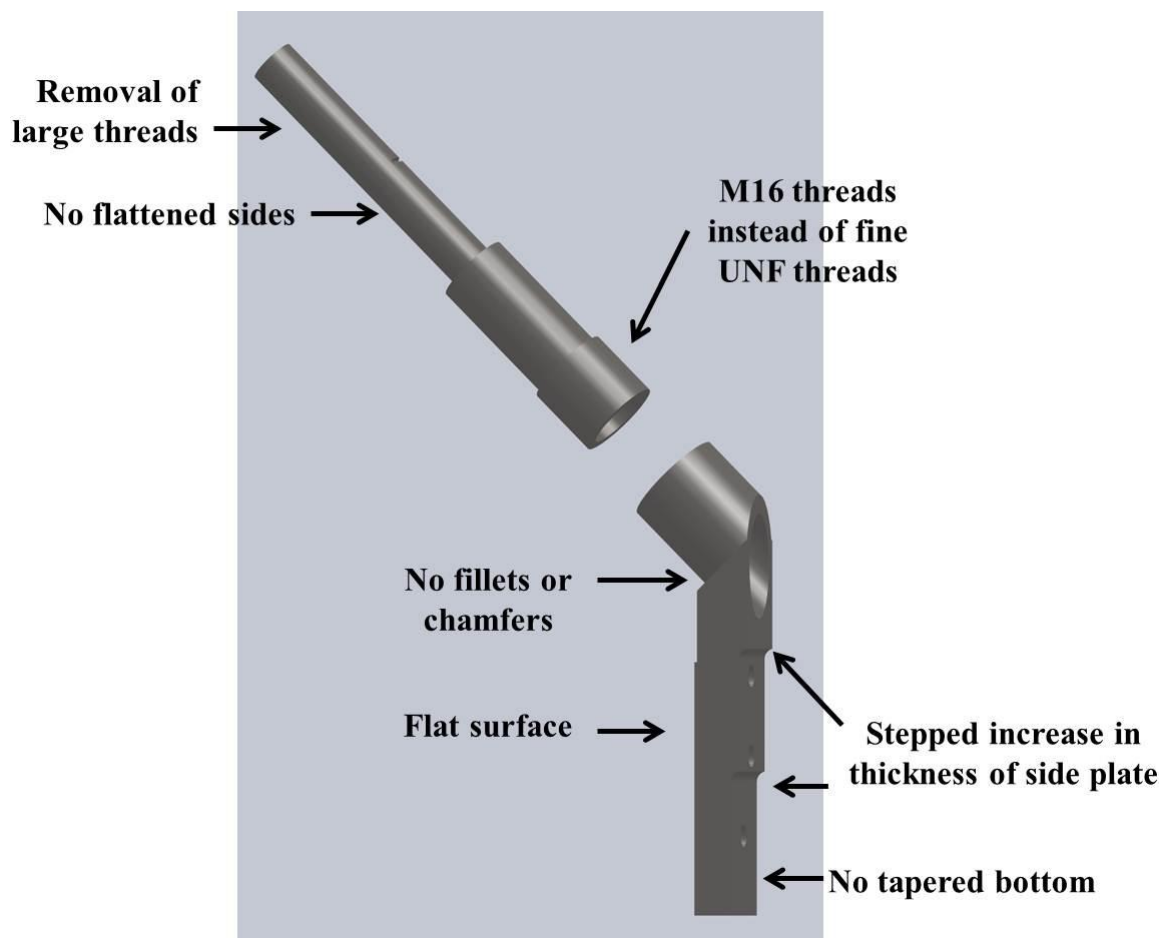
## 9. 6 Prototype manufacture

### 9. 6. 1. Overview

Prototypes of the new implant were prepared to conduct mechanical testing to analyse the effect of static and fatigue (cyclic) loading on the design. However, a perfect physical reproduction of the computer generated design would require an expensive mould to be manufactured, and therefore minor modifications were made to the actual design for ease of manufacture in a basic machining workshop. Care was taken to minimise the effect of changes on performance and strength of the design, and it was verified by conducting FEA to compare the values of stresses and displacement in the modified and the actual design of the new implant.

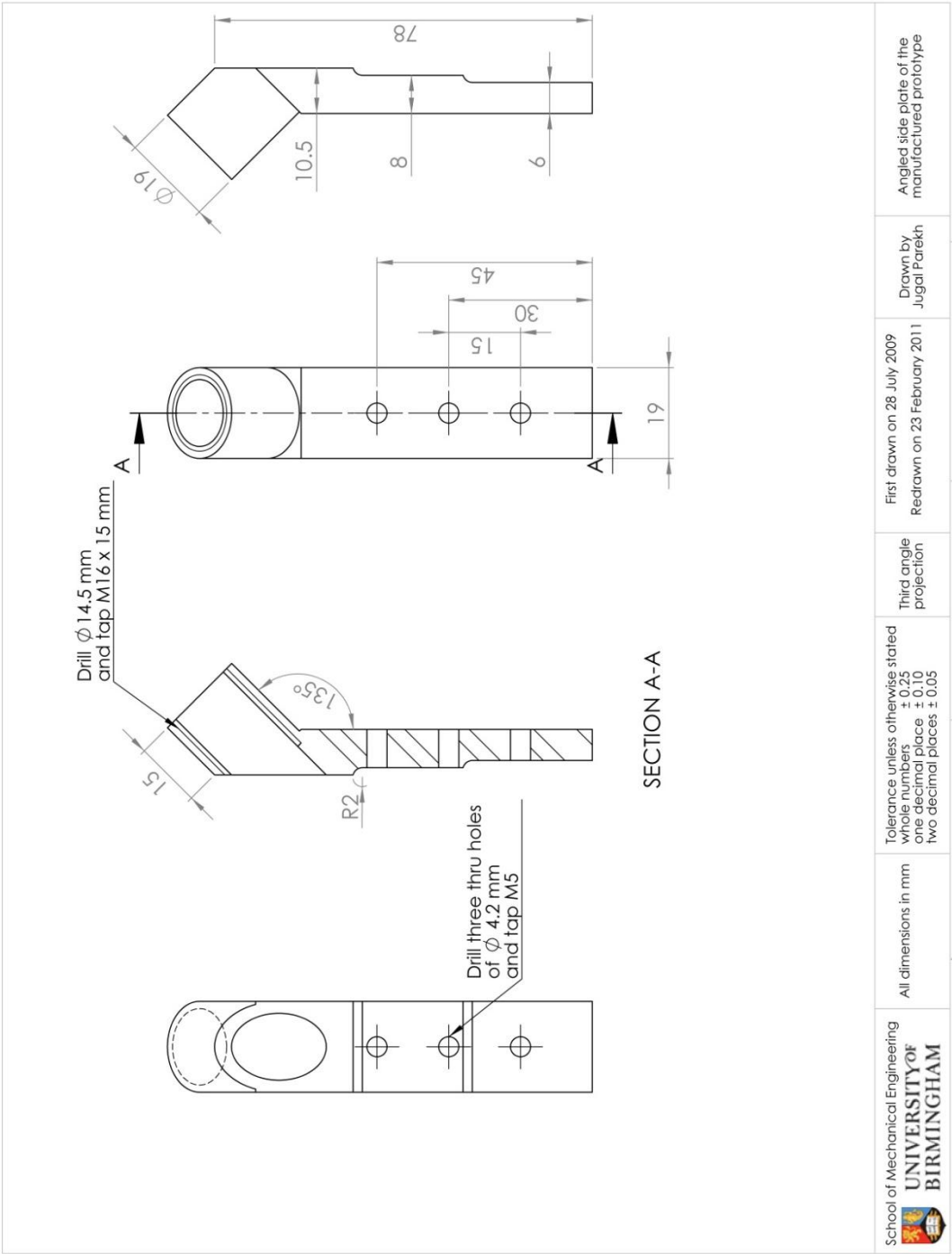
The changes in the manufactured model, as shown in Figure 9.11, included the removal of large threads at the head of telescoping screw, removal of flattened sides on the surfaces of lag screw and barrel, replacement of curved thickness increase of the angled side plate with stepped increase, replacement of curved inner surface of angled side plate with a flat surface, the angled circular extrusion at the top of the angled side plate was not chamfered or filleted, the angled circular extrusion on the angled side plate was not threaded through due to which the telescoping screw was to be screwed on from the front end, removal of tapered bottom of the angled side plate, and finally the fine threads on outer surface of the

barrel of the telescoping screw and on the inner surface of angled circular extrusion on the angled side plate were replaced with standard M16 threads. Engineering drawings of the modified telescoping screw and the angled side plate, which were manufactured, are shown in Figures 9.12 and 9.13 respectively.

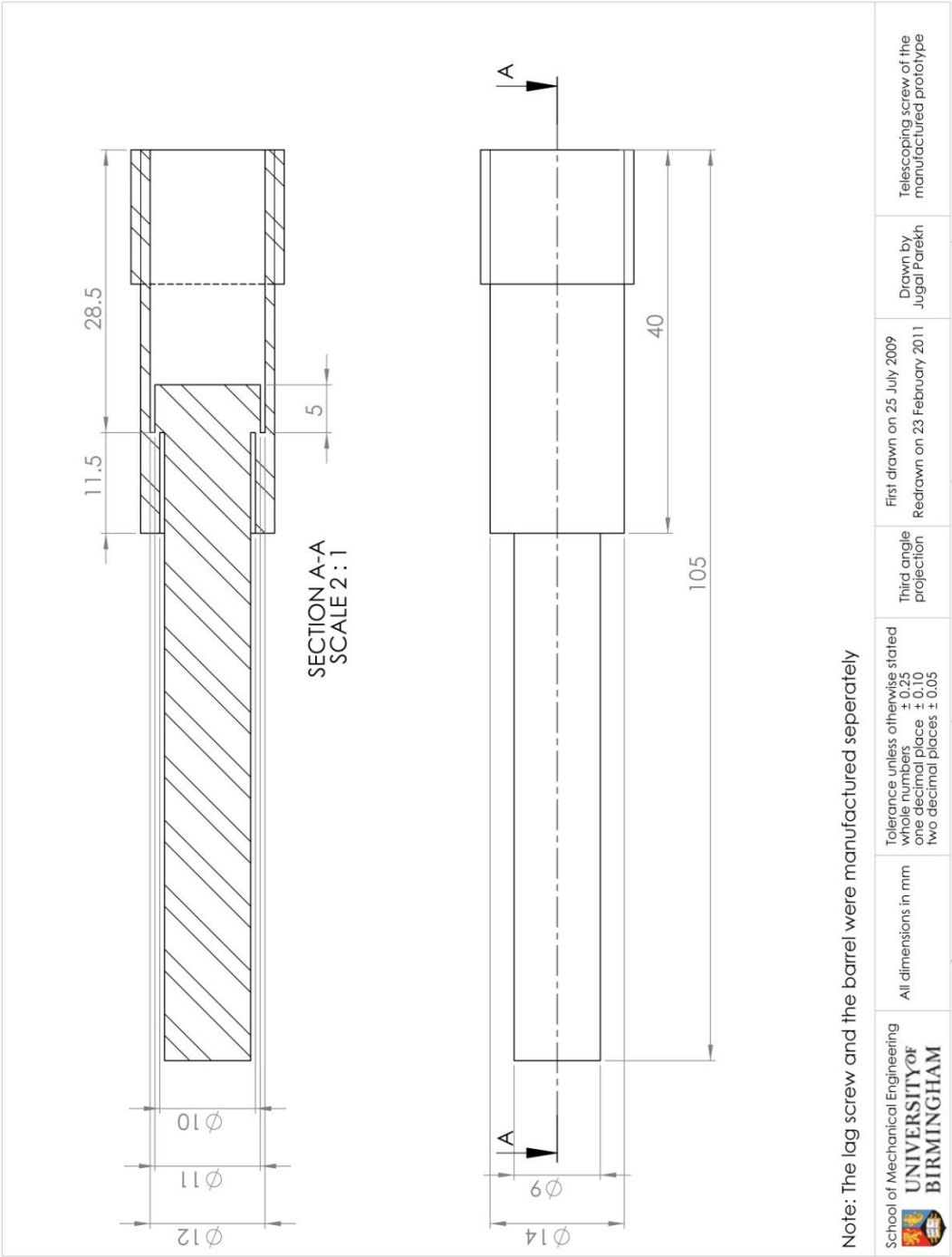


**Figure 9.11: Changes made in the design of the new implant to ease the manufacturing process**





**Figure 9.12: Engineering drawing of the modified angled side plate of the new implant for manufacture**



**Figure 9.13: Engineering drawing of the modified telescoping screw of the new implant for manufacture**

### **9. 6. 2. FEA of prototype**

The three dimensional stainless steel 316L model of the prototype was loaded with 800 N of downward axial force acting on the top edge at 21 mm from the front edge of the telescoping screw. Similar to the FEA conducted on the actual design of the new implant in section 9.5, the prototype model was restrained at the angled side plate. The mesh size selected for the model after plotting of a convergence graph was 0.60 mm (number of elements - 513629; number of nodes - 748641). The maximum value of von Mises stress on the model was 1018 MPa, and was recorded at the angled bend on the angled side plate. The maximum displacement calculated was 2.31 mm at the front of the telescoping screw. These values were very close to the results of FEA on the new implant three dimensional model that is discussed in section 9.5.4.

### **9. 6. 3 The manufactured prototype**

Four prototypes of the new implant made of stainless steel 316L were manufactured by Mr Bryan Jarvis of Truturn Precision Engineering Ltd. (Stroud, Gloucestershire, UK). The assembly was supplied in three parts – the angled side plate, the barrel and the lag screw. The angled side plate was manufactured out of a single block of stainless steel. The dimensions of the delivered samples were verified for consistency to the supplied engineering drawings.

## **9. 7. Mechanical testing**

### **9. 7. 1. Investigation objective**

As previously stated, the new implant would be used to treat fractures of the proximal femur. Therefore, the design would have to withstand multiple cycles of compression loading at the site for the duration of the healing process until the bone is able to provide mechanical support to reduce the stresses in the implant.

The purpose of this study was to analyse the load capacity of the new implant subjected to a) single cycle compression bending load to measure the displacement response of the design, and b) constant frequency sinusoidal cyclic bending moment waveform load to determine the cycles to failure of the new implant (fatigue test). ASTM F-384 (2006), which describes the specifications and test methods for metallic angled orthopaedic fracture fixation devices, was used as a guide for the setup of the testing configuration.

The Dynamic Martin Screw (DMS) was first implanted in 1992, and has since been used to treat more than 50000 patients (Dittel and Rapp, 2008). The implant utilises the sliding lag screw principle with an adjustable angle side plate. The tests conducted on the DMS by Zirn (2008) were the only published material found by the author that measured and recorded the loading capacity values from static and cyclic bending load test, as directed by ASTM F-384. The study conducted by Zirn

concluded that the DMS out-performed the 135 degrees DHS-plate implant in the static bending load test, and the results for the cyclic tests were within the range of values measured on the DHS-plate implant. The results of mechanical tests conducted on the new implant were compared to those of the DMS to verify the loading capacity of the new design.

### **9. 7. 2. Materials and method**

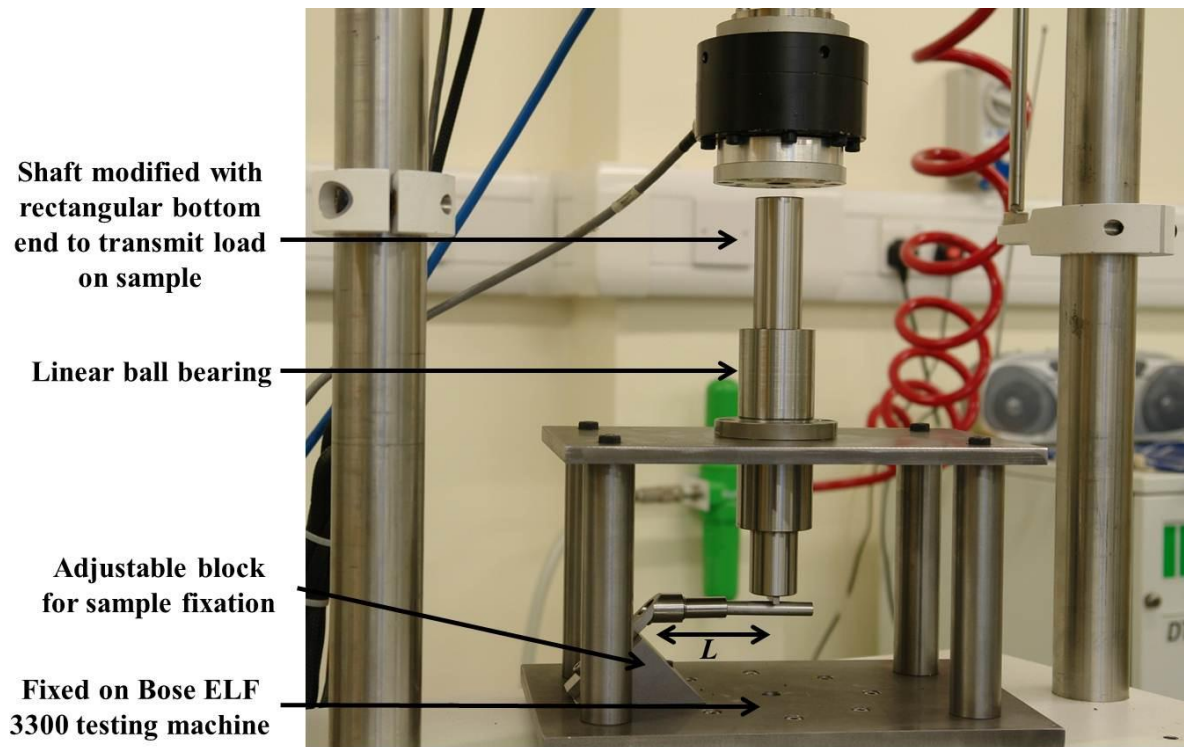
#### **9. 7. 2. 1. *New implant samples***

Four samples of the modified version of the new implant were manufactured for the mechanical tests. The details of the manufactured design were discussed in section 9.6. Three samples were used for the static loading tests, and one for the fatigue test. The new implant assembly was put together by first inserting the lag screw into the barrel to complete the telescoping screw assembly, followed by screwing the telescoping screw into the angled side plate.

#### **9. 7. 2. 2. *Test rig***

A custom rig (Figure 9.14), manufactured with stainless steel 316, was designed for fixation to a Bose ELF 3300 testing machine (Bose Corporation, ElectroForce Systems Group, Minnesota, USA) to conduct both the mechanical tests on the prototypes discussed in this section. The rig was manufactured by Mr Bryan Jarvis

of Truturn Precision Engineering Ltd. (Stroud, Gloucestershire, UK), and the engineering drawing of the rig is shown in Figure 9.15.



**Figure 9.14: Custom built test rig configured for the loading tests on the Bose ELF 3300 testing machine**

The rig, along with its other fixtures, consisted of a triangular block and a linear ball bearing. The position of the triangular block, which was attached with samples of the new implant, was adjustable horizontally for correct placement of the sample as directed by the protocol during the mechanical tests. The block was also removable, enabling replacement by other fixtures that could be attached for similar tests of other devices on ELF 3300 testing machine in the future. The linear ball bearing (inner diameter 30 mm, outer diameter 47 mm, length 123 mm, sourced from catalogue no. L1730.030, Automotion (Int'l) Limited, Cranleigh,

Surrey, UK) and the accompanying cylindrical shaft (hardened stainless steel 316, diameter 30 mm, length 350 mm, sourced from catalogue no. SSS-30M-350, Automotion (Int'l) Limited, Cranleigh, Surrey, UK) were attached at the top of the rig to allow only axial transmission of the compressive load from the ELF 3300 testing machine onto the samples. This linear bearing was used to prevent damage to the testing machine's load cell due to forces generated in other directions during the bending tests. The bottom surface of the shaft was modified to form a rectangular surface (5 mm × 25 mm) at the centre, which would be placed on top of the lag screw during the bending tests.

### ***9. 7. 2. 3. Static loading test***

#### ***9. 7. 2. 3. 1. Test setup***

The configuration used during the static loading test is illustrated in Figure 9.14. The Bose ELF 3300 testing machine, operated under the control of WinTest software was used to supply the compressive bending load during the test. The machine is equipped with a load cell of full scale of 4500 N, and displacement transducer with a full scale of 25 mm. The test rig discussed in section 9.7.2.2 was fixed onto the testing machine. The compressive force from the machine was transmitted to the sample through the cylindrical shaft placed inside the linear bearing on the test rig. The new implant sample was secured onto the triangular block on the testing rig using three M5 screws. The block was adjusted

horizontally to ensure that the cylindrical shaft atop the lag screw was placed to allow for a lever arm,  $L$  (distance from top point of triangular block to the point of loading on the new implant), of 80 % of the length of the telescoping screw (84 mm for 105 mm long telescoping screw, as directed by ASTM F-384). The load was applied perpendicularly to the long axis of the lag screw rather than parallel to the long axis of the angled side plate, as suggested by ASTM F-384, due to the reasons discussed in section 9.5.2.

The testing machine was operated in displacement control (0.17 mm/s for a total displacement of 16 mm – displacement restricted due to test rig setup and machine's limited stroke of 25 mm) and the force was recorded at a rate of 200 data points per second. The procedure was to measure the compressive load required to bend the implant, which was used to generate a load versus displacement diagram. The test was deemed to have ended on reaching a maximum displacement of 16 mm or due to failure of the sample. The test was repeated three times with a fresh sample of the new implant for every run.

#### 9. 7. 2. 3. 2. Data Analysis

A graph of load against displacement was plotted for all the three samples. The corresponding displacement,  $M$ , at a load of 784.8 N (80.0 kg) was recorded.



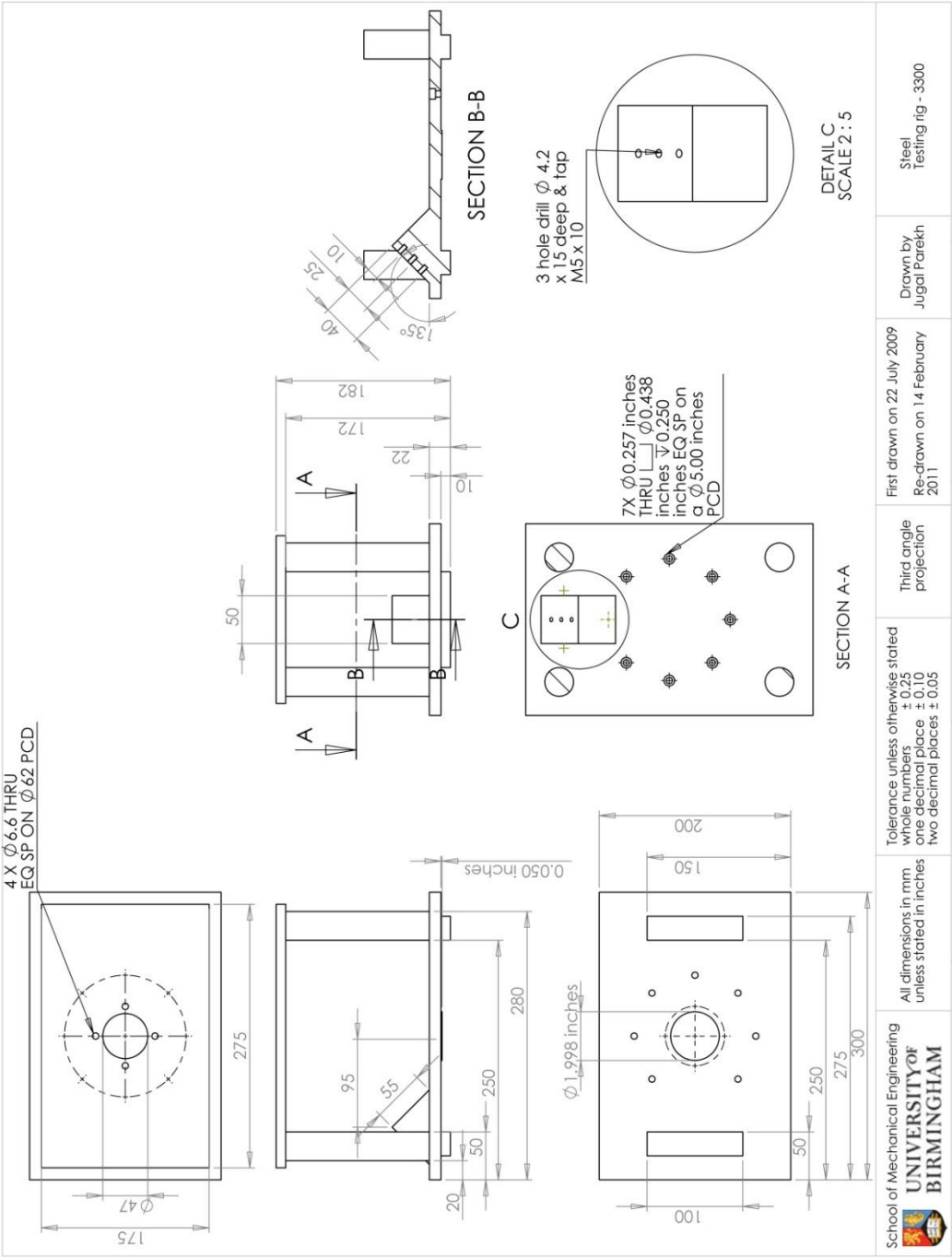


Figure 9.15: Engineering of the test rig used for the mechanical tests discussed in this section

#### 9. 7. 2. 4. Fatigue test

The test configuration for the fatigue test was the same as the setup described for the static loading test in section 9.7.2.3.1 and shown in Figure 9.14. A sinusoidal load was applied with frequency of 5 Hz up till failure under load control. The maximum loads experienced were determined by a load ratio,  $R$ , of upper load to lower load of 0.01 (ASTM F-384), with upper load of 800 N (Zirn, 2008). The test was considered to have ended either on failure of implant or on reaching one million cycles (ASTM F-384).

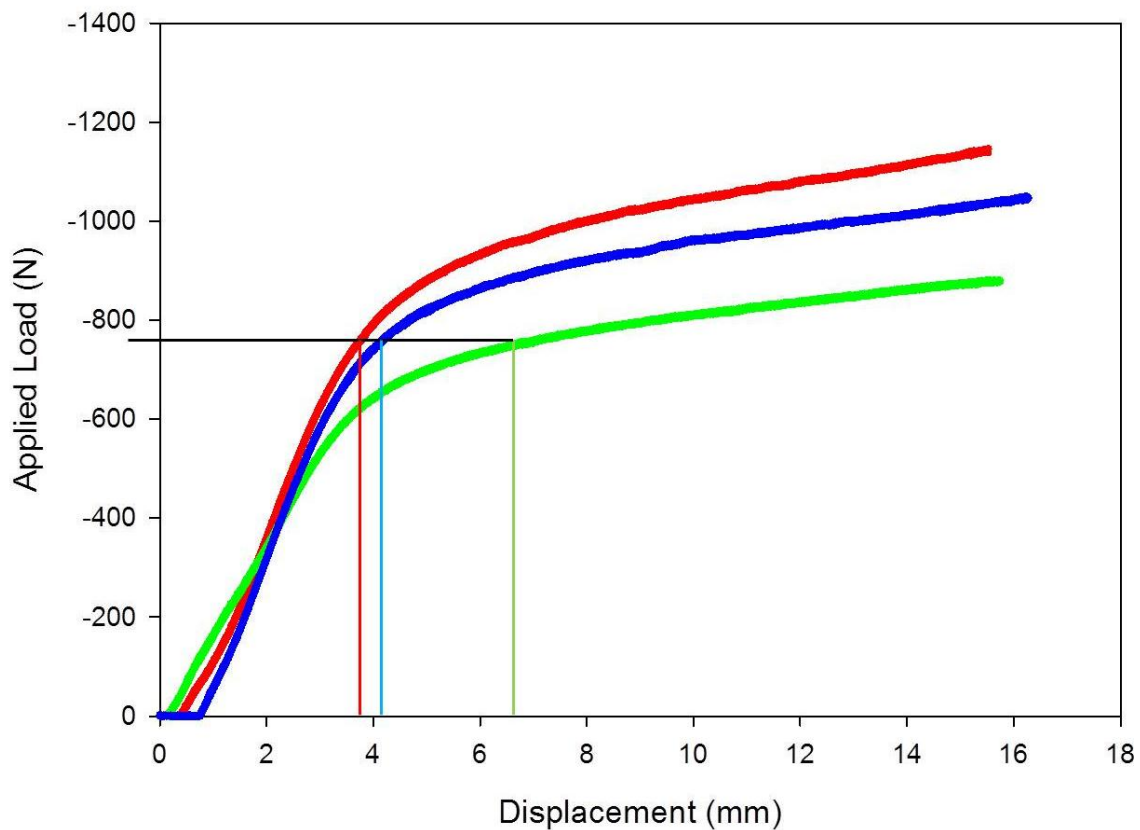
### 9. 7. 3. Results

#### 9. 7. 3. 1. Static loading test

All the three samples completed the displacement of 16 mm without failures. A graph of applied load was plotted against displacement, as shown in Figure 9.16. The average displacement recorded at the application of 784.8 N of load in the three samples was  $4.7 \pm 1.5$  mm. The values are tabulated in Table 9.3.

**Table 9.3: Values of displacement, in mm, of samples of the new implant at loading of 784.8 N**

	Sample 1	Sample 2	Sample 3
<b>Displacement (mm)</b>	6.5	4.1	3.7

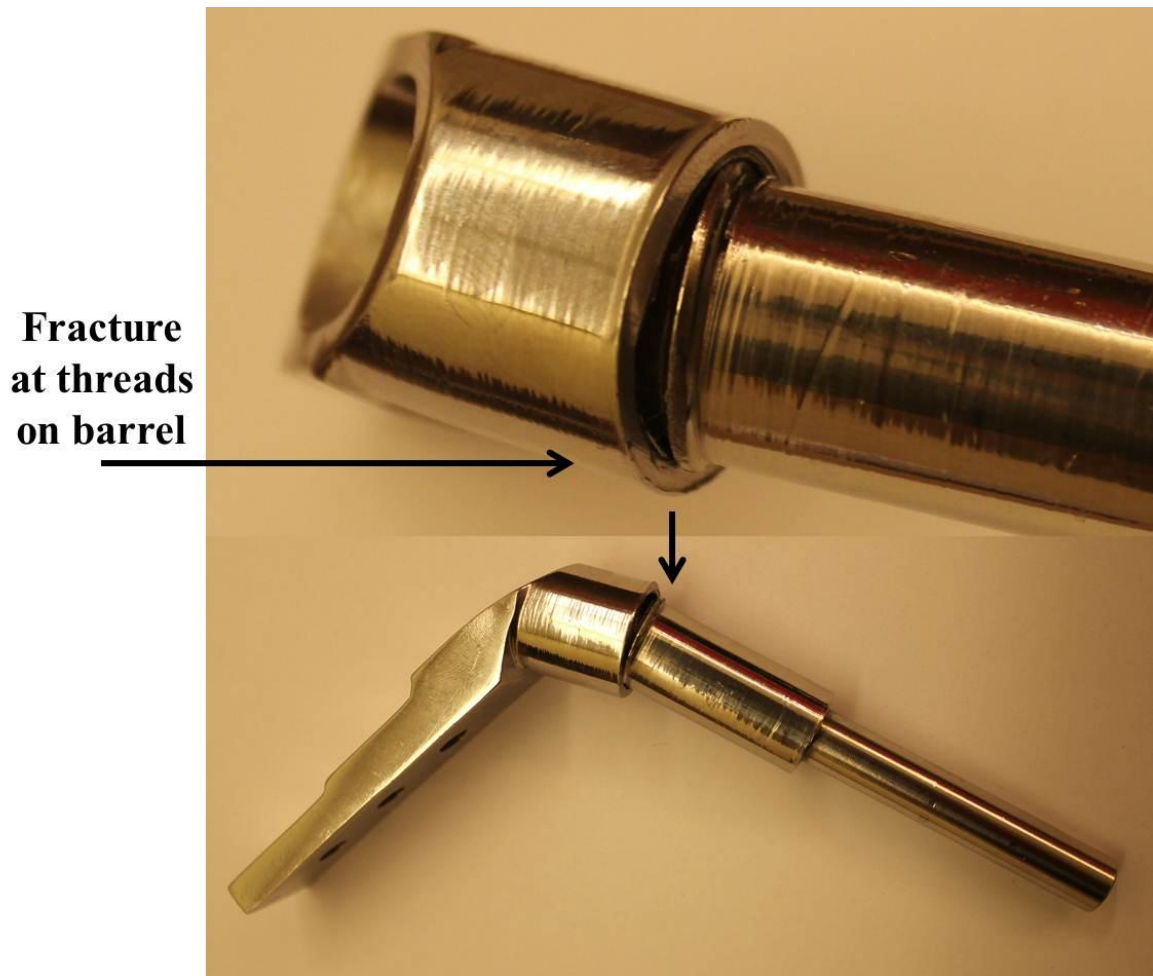


**Figure 9.16: Graph of applied load, in N, versus displacement, in mm, realised in the new implant during the static loading test of sample 1 (green), 2 (blue), and 3 (red).**

The vertical lines from x-axis represent the bending in mm of the respective new implant sample when applied with a load of 784.8 N (80 kg). The bending values are tabulated in Table 9.3

#### 9. 7. 3. 2. Fatigue test

The new implant failed after 86267 cycles of loading between 80 N and 800 N at a frequency of 5 Hz. The cause of the failure was a fracture at the threads on the outer surface of the barrel of the telescoping screw. The fractured prototype is shown in Figure 9.17.



**Figure 9.17: Location of fracture on the prototype after it underwent 86267 cycles of loading between 80 N and 800 N at a frequency of 5 Hz**

#### 9. 7. 4. Implications of results

The recorded deflection of the DMS at a load of 80 kg during the static bending load test was 4.6 mm (Zirn, 2008) as compared to  $4.7 \pm 1.5$  mm for the new implant. For the fatigue test, the DMS was reported to fail after 64000 cycles, whereas the new implant was able to survive 86267 when loaded between 80 N and 800 N. The results suggested that the design of the new implant is able to

withstand static and cyclic bending loading condition required of an implant for treatment of proximal femur fractures. The samples of the implant were manufactured using tools available in a normal workshop, and hence were not produced to the standard of a medical implant. This caused variability in the static loading results. However, considering the results were still within the values mentioned in the literature, prototypes manufactured with the appropriate machinery to the exact specification should produce better results.

## **9. 8. The new implant**

The design of the new implant, described in section 9.3, successfully underwent thorough verification procedures in the form of risk analysis, finite element analysis and mechanical testing of manufactured prototype. The new implant, along with its associated instruments is presented in Chapter 10 for the description of surgical technique. The new implant fulfilled all the requirements that were stated in the product design specification stage in Chapter 8.

## 9. 9. Summary

The summarising points of the chapter are listed below.

- i. The new implant, made of stainless steel 316L, was designed for treatment of proximal femur fractures. The assembly comprised of a telescoping screw and an angled side plate. A minimally invasive approach would be utilised to surgically implant the new device. The design was verified using risk analysis, FEA and mechanical testing.
- ii. The hazards identified during the risk analysis of the new implant were addressed with suitable control measures to minimise/ avoid the risk.
- iii. The results of the new implant during FEA showed that the design would undergo smaller displacement and would generate less stress than the generic DHS implant when subjected with a compressive load of 800 N. The mechanical tests conducted on the new implant also concluded that the deflection of  $4.7 \pm 1.5$  mm during application of compressive bending load of 80 kg (784.8 N), and 86267 cycles to failure during fatigue tests was better and within range of the values generated by the generic 135° DHS-plate implant respectively.

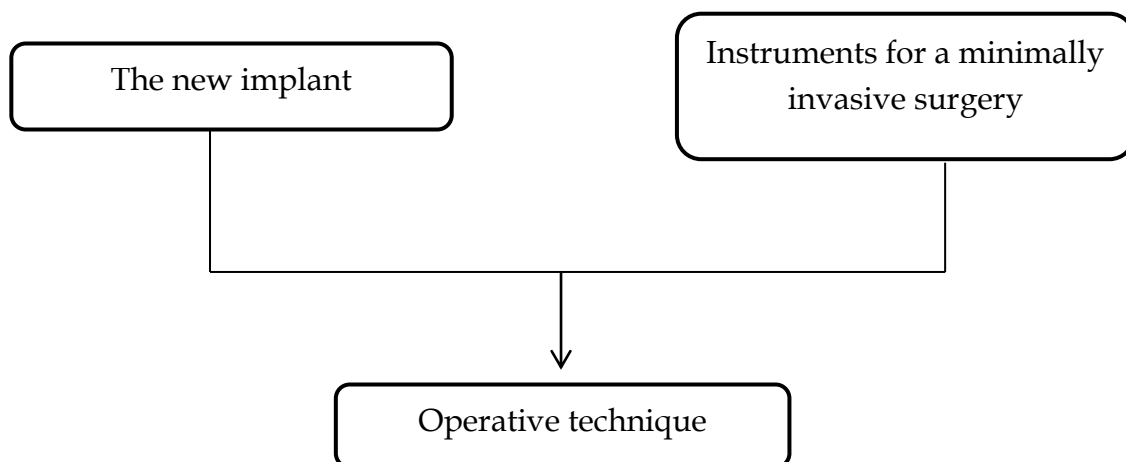
# CHAPTER 10

## OPERATIVE TECHNIQUE FOR THE NEW IMPLANT

### 10.1 Chapter at a glance

#### 10.1.1. Chapter overview

Figure 10.1 shows the chapter overview in the form of a flowchart.



**Figure 10.1: Flowchart of the chapter structure**

#### 10.1.2. Keywords

Minimally invasive surgery; operative technique

## **10. 2. Introduction**

Operative technique manuals are published by all leading orthopaedic device manufacturers to let the surgeon know the method of implantation and also to promote their products. Some examples include the application and technique information for the TK2 compression hip screw system by DePuy Orthopaedics (Warsaw, Indiana, USA) and the surgical technique for compression hip screw plates and nails by Smith & Nephew plc. (London, UK). The purpose of this chapter is to present the new medical devices designed during the course of this research, and highlight their features and attributes. Although the new instruments developed (new angle guide and ergonomic T-handle) in the research could be used for the dynamic hip screw (DHS) implant surgery by simply replacing the conventional instruments, they also form an integral part of the surgical procedure for the new implant. This chapter describes the surgical procedure to be used for fixing the new implant on a fractured femur using a minimally invasive approach. The layout of sections 10.3. to 10.5. in this chapter attempts to present the information required for a corporate brochure for an orthopaedic implant in the format required of a PhD thesis. Hence, instead of using conventional referencing system, statements are cross-referenced to the appropriate part of the thesis where justification is provided. The operative technique for the generic DHS was discussed in section 3.8.3. The three dimensional models of medical devices shown in this chapter were drawn using SolidWorks CAD software (2010, 3DS Daussalt Systemes, MA, USA).



### **10. 3. The new implant**

#### **10. 3. 1. Overview**

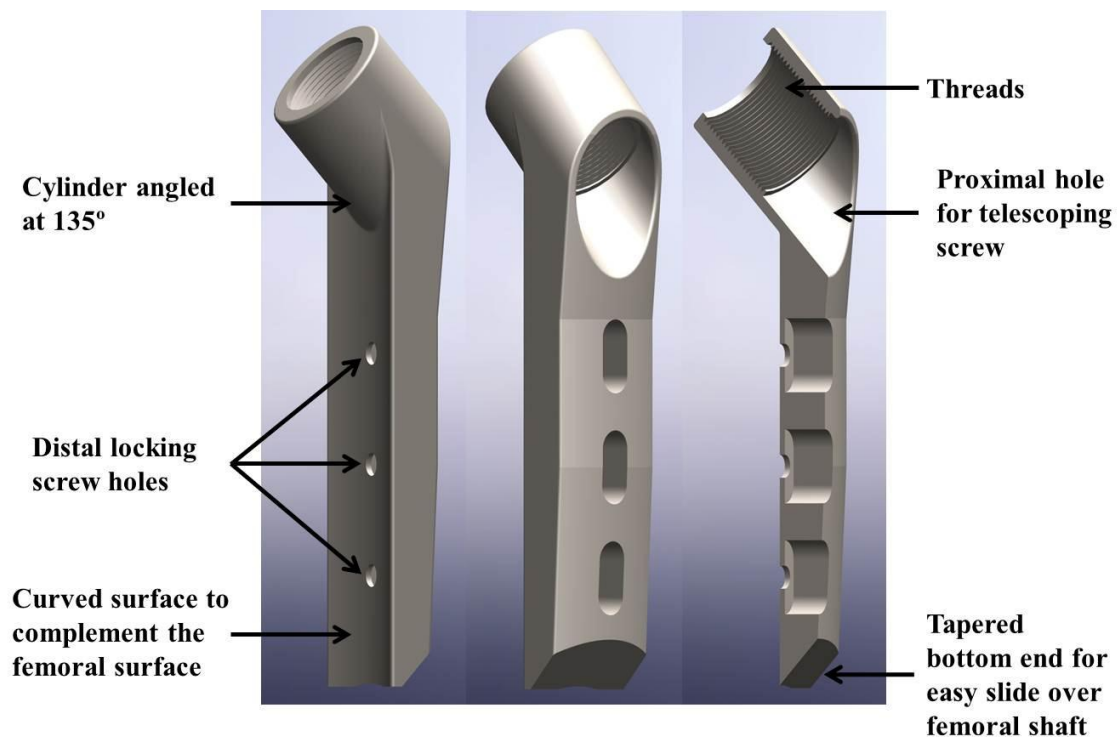
The new implant was a two part assembly consisting of an angled side plate and a telescoping screw; both made of stainless steel 316L (section 9.3.1). The implant was designed to treat fractures of the proximal femur. The three fundamental principles of the new implant were to –

- a. evolve the established and popular dynamic hip screw (DHS) implant to allow easy insertion and implantation through an incision of less than 30 mm;
- b. utilise the principle of sliding the lag screw into the side plate to promote bone-on-bone contact for faster healing and weight bearing;
- c. provide a comfortable and confident experience to the surgeons by applying similar instruments and surgical procedure steps, as the generic DHS, to insert the new implant.

#### **10. 3. 2. Angled side plate**

The angled side plate of the new implant, as shown in Figure 10.2, consisted of a plate with three distal locking screw holes; and was proximally attached to a short angled, threaded cylinder. The cylinder/ plate angle was fixed at 120, 130, 135, 140, 145 or 150 degrees; the angle required would be selected by the surgeon based

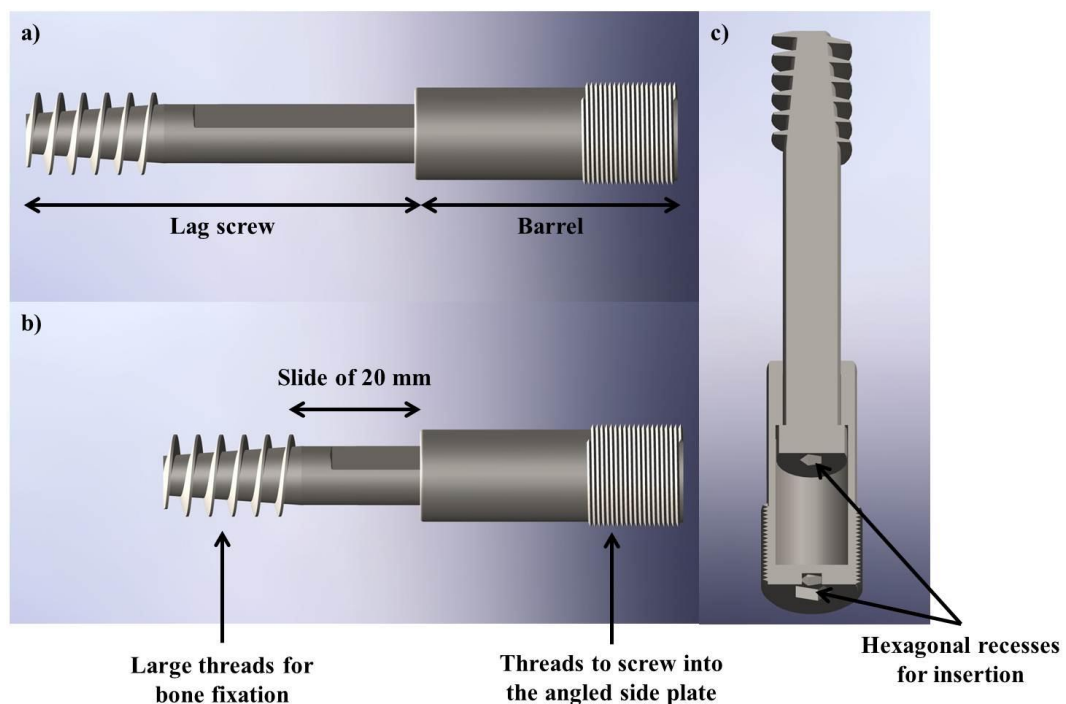
on the neck/shaft angle of the patients' fractured femur before surgery. While inserting the plate, the angled cylinder would be connected to a side plate introducer (section 10 .4. 4), and the bottom end would slide down the lateral femur surface. The inner surface of the side plate was curved with a radius of 20 mm to complement the lateral femur surface and the tapered bottom edge would aid in sliding through the tissues on the femoral surface (section 9.3.2). The three distal holes would secure the plate to the femur with 5.00 mm diameter locking screws to enhance stability and fixation of the implant on the fractured bone.



**Figure 10.2: The new angled side plate**

### 10. 3. 3. Telescoping screw

The telescoping screw was a two-part system consisting of a lag screw, enclosed in a barrel, with a closed end and a maximum slide capacity of 20 mm (section 9.3.3). The different features of the device are illustrated in Figure 10.3a-c. The available lengths of the telescoping screw would range from 90 mm to 140 mm in 10 mm increments. The threads at the bottom end of the barrel screw into the angled side plate, and the large threads at the head of the lag screw would be advanced through the femoral neck into the head for fixation. The hexagonal recesses in the lag screw and the barrel would allow the lag screw inserter to advance the telescoping screw, fully extended (with the 20 mm slide), into the femur.



**Figure 10.3: Telescoping screw – a) fully extended, b) after maximum slide of 20 mm, and c) cross section view**

#### **10. 3. 4. Potential features and benefits**

The foremost advantage of the new implant would be that it was designed for minimally invasive surgery (MIS), and at the same time included the features of the popular DHS implant. The advantages of MIS were discussed in detail in section 3.7. The inclusion of the locking side plate for enhanced implant stability (section 8.4.7), and telescoping screws which avoid excessive slide of the lag screw (section 8.4.6) were incorporated in the new implant to overcome the causes of implant failures that were reported in the generic DHS (3.6.1). The surgeons would encounter a gentler learning curve due to a similarity of the new surgical technique to the conventional DHS operative technique. The new instruments also added ergonomic features to their design to ensure a comfortable experience for the surgeon. The surgical procedure for this implant would require only two additional instruments to those already in use for the generic DHS implant and hence would not provide an additional burden on the hospital inventory.

## **10. 4. Instruments for a minimally invasive surgery**

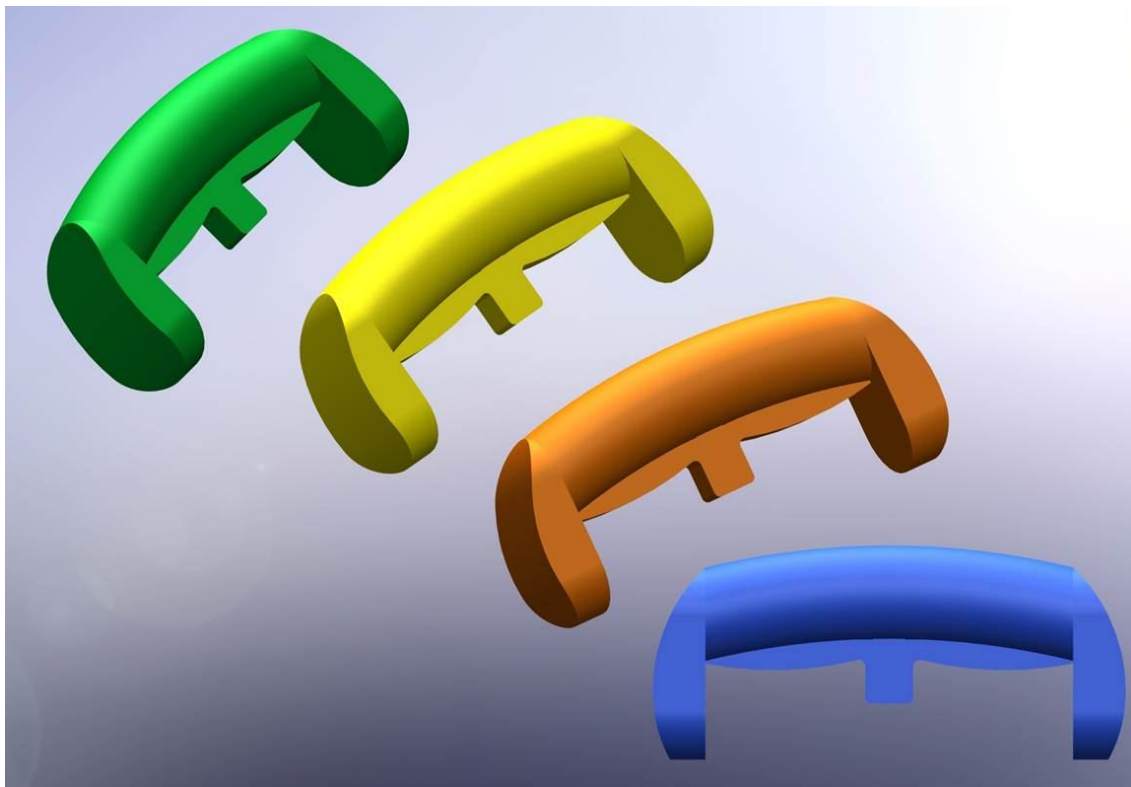
### **10. 4. 1. Overview**

This section discusses the instruments that will be required for the surgical procedure for the new implant. The instrument set for the new implant would include two additional instruments – a side plate inserter (section 10.4.4), and a telescoping screw inserter (section 10.4.5), in addition to the generic DHS implant's instrument set. A new angle guide (Chapter 4-6) and an ergonomic T-handle (Chapter 7) were designed to aid in the minimally invasive approach. The instruments were designed to withstand steam sterilisation or sterilisation with irradiation to cater to the differing needs of a re-use and single-use market respectively.

### **10. 4. 2. An ergonomic T-handle**

The ergonomic T-handle, shown in Figure 10.4 and discussed in detail in Chapter 7, was designed to provide a comfortable interface to the surgeon to hold, grip and use the various instruments whilst bringing about minimum tiredness during a minimally invasive surgery. The shape and dimensions of the handle would allow surgeons of differing hand sizes and either handedness to use it comfortably. The combination of circular and rectangular cross section of the handle would provide comfort and grasping purchase to the surgeon. The design of the T-handle was

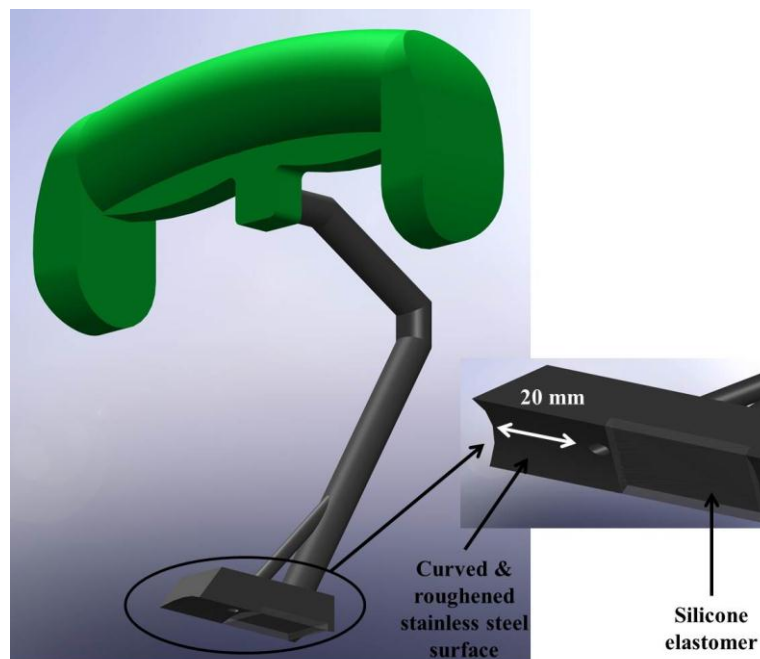
optimised to provide the surgeon with a grip enabling him/ her to transfer required torque at the same time as exhibiting control and flexibility of the instrument. The stainless steel 316L skeleton would be molded with polypropylene to give the desired shape, and overmolded with thermoplastic polyolefin (TPO) elastomer to provide the surgeon with a soft and comfortable touch (section 7.8.2). The soft touch TPO elastomer would be colour coded to correspond to different stages of the surgical procedure to allow for easy identification of instruments during the surgery. The colour coding is stated in section 10.5.



**Figure 10.4: Colour coded ergonomic T-handles**

### 10. 4. 3. New angle guide

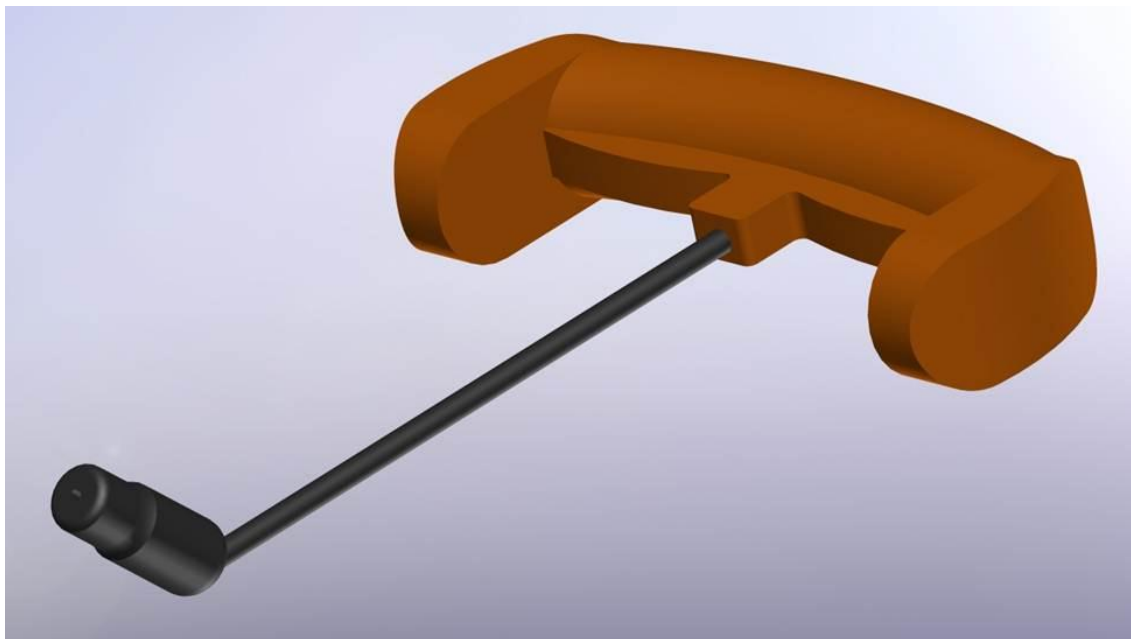
The new angle guide (Figure 10.5) combined the familiarity of the generic angle guide, used in the “gold standard” DHS surgery, with ergonomic features for use in minimally invasive surgery. The new base replaced the sharp prongs with a curved profile made of biocompatible and mouldable silicone elastomer (Silastic Q7-4780, Dow Corning Ltd, Coventry, UK) for improved stability on the uneven and curved lateral femur surface; and stainless steel surface roughened using spark erosion for enhanced grip (Chapter 5; section 6.3.3). The guide pin exit-hole at the bottom of the base plate was placed 20 mm from the front edge of the base to guide the surgeon to correctly place the angle guide on the femur, as the guide pin insertion point is 20 mm below the *vastus lateralis* ridge (shown in Figure 10.9a; details in section 6.3.2).



**Figure 10.5: The new angle guide**

#### 10. 4. 4. Side plate inserter

The side plate inserter, shown in Figure 10.6, would consist of a stainless steel 316L rod (diameter of 10 mm, length 150 mm) connected at an angle to a cylinder of two different diameters at one end, and to the T-handle (section 10.4.2) at the other end. The rod/ cylinder angle would correspond to the angle of the side plate to be used during surgery. The head of the introducer, which would have two diameters to correspond to the threaded (diameter of 13.75 mm, length 15 mm) and unthreaded parts (diameter of 15.75 mm, length 20 mm) of the proximal hole of the side plate, would fit inside the side plate hole. The side plate would then be manoeuvred into position on the patient's femur for fixation. The engineering drawing of this instrument is shown in Appendix C.

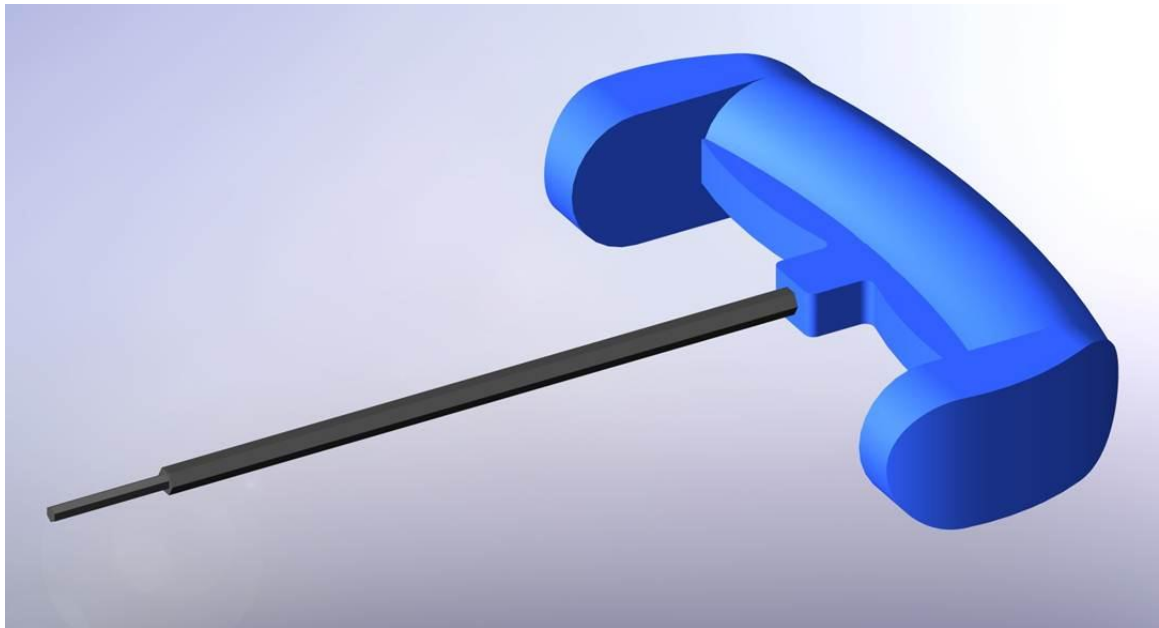


**Figure 10.6: Side plate inserter**



#### 10. 4. 5. Telescoping screw inserter

The telescoping screw inserter would consist of a stainless steel 316L hexagonal rod (length 176.5 mm), of two diameters, connected to an ergonomic T-handle (Figure 10.7). The hexagonal rod with the smaller diameter (3 mm) would correspond to the hexagonal recess in the lag screw; the larger diameter rod (5 mm) would correspond to the recess in the barrel of the telescoping screw. The purpose of this instrument was to advance a fully extended (20 mm) telescoping screw into the femoral head, and screw it into the secured side plate. The engineering drawing for this instrument is shown in Appendix C.



**Figure 10.7: Telescoping screw inserter**

#### 10. 4. 6. Other instruments

The other instruments, shown in Figure 10.8a-d, would include (a) a 2.5 mm diameter guide pin, (b) a depth gauge, (c) a triple reamer, (d) a tap, and a soft-tissue retractor (not shown). The instruments and their design would remain the same as the ones used during the current DHS implant surgery (section 3.6.3.1). However, the dimensions on the triple reamer and the tap would be modified to suit the new implant if the new implant were to be manufactured. Also, the generic T-handles of these instruments would be replaced with colour coded ergonomic T-handles discussed in section 10. 4. 2.



**Figure 10.8: The other instruments to be used during the surgical procedure include: a) 2.5 mm guide pin, b) depth gauge, c) triple reamer, and d) tap. The instruments shown are manufactured by Sushrut Surgical Pvt. Ltd. (Pune, Maharashtra, India) for the generic DHS implant surgery.**

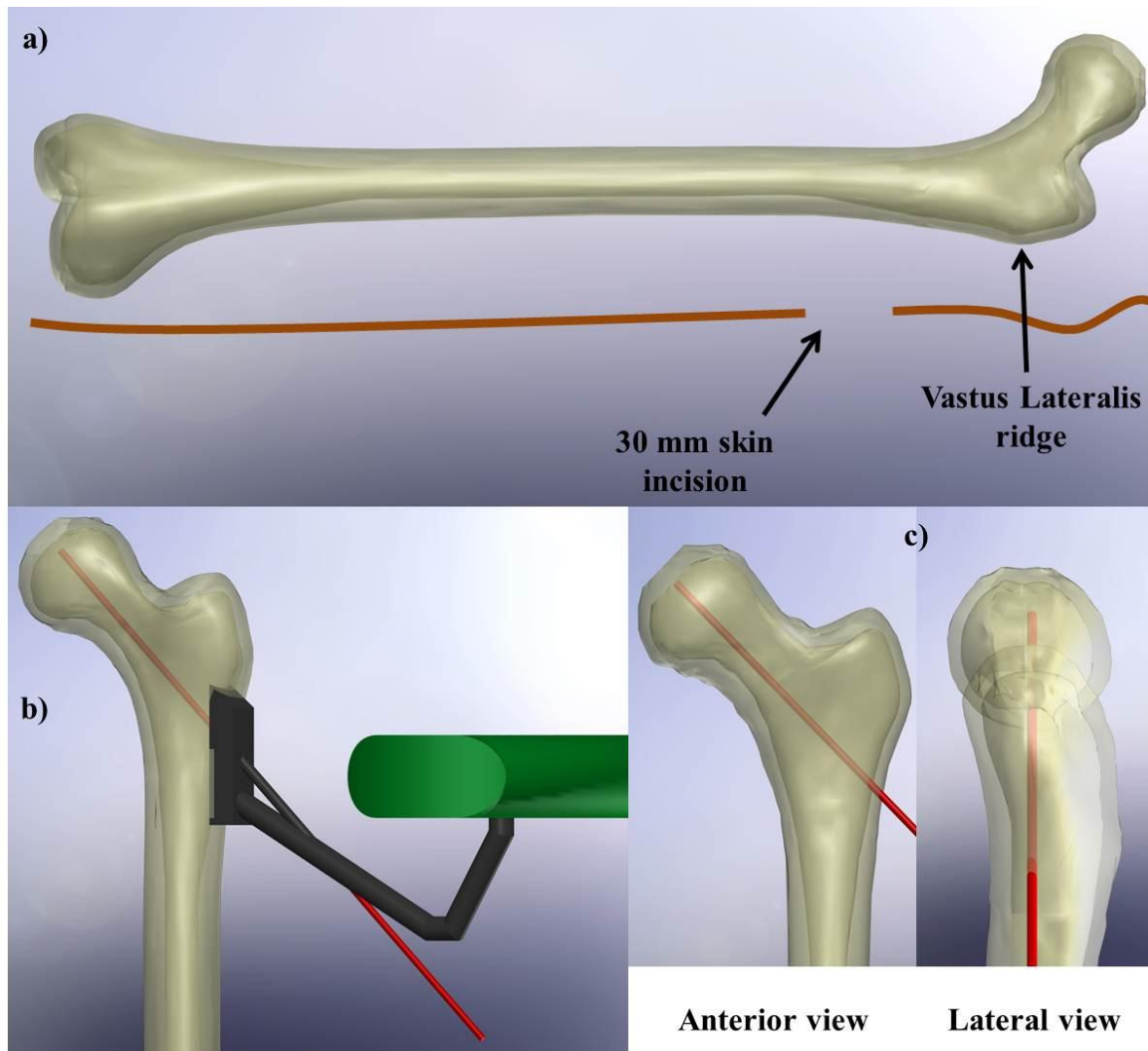
## 10. 5. Operative technique

### 10. 5. 1. Overview

This section discusses the surgical procedure required to insert and secure the new implant on to the femur. The procedure is divided into four colour coded stages. The unique colour for each stage is mentioned in the headings below. The chosen fractured femoral neck/shaft angle was 135 degrees, and hence a 135 degrees angled side plate and corresponding angle guide shall be used in the technique described. The surgical procedure was reviewed by Prof. Maffulli; it should be noted that the operative technique does not include pre-operative planning and post-operative care details. The technique assumed that the patient is already placed in a supine position on the operating table and is prepared for implantation following anatomical reduction of the fracture.

### 10. 5. 2. Guide pin placement (Green)

The *vastus lateralis* ridge is regarded as an important landmark throughout this surgical approach. The incision start point would be located approximately 30 mm below this landmark. An approach to the lateral side of the proximal femur would be made with a straight incision of 30 mm extending distally as shown in Figure 10.9a. The guide pin in the figures is red for illustration purposes only.



**Figure 10.9:** Steps for guide pin placement includes a) incision of 30 mm, b) insertion of guide pin, and c) correct guide pin placement verification.

Guide pin insertion would be considered to be the most critical step in the surgical procedure as the subsequent placement of the telescoping screw is dependent on correct guide pin positioning. An approximate guide pin insertion point would be 20 mm below the *vastus lateralis* for an angle of 135 degrees. (Note: The guide pin exit hole at the base of the new 135 degrees angle guide is 20 mm from the front edge to help correct positioning of the angle guide and the guide pin under image intensifier) For each 5 degrees change in side plate angle, the guide pin insertion

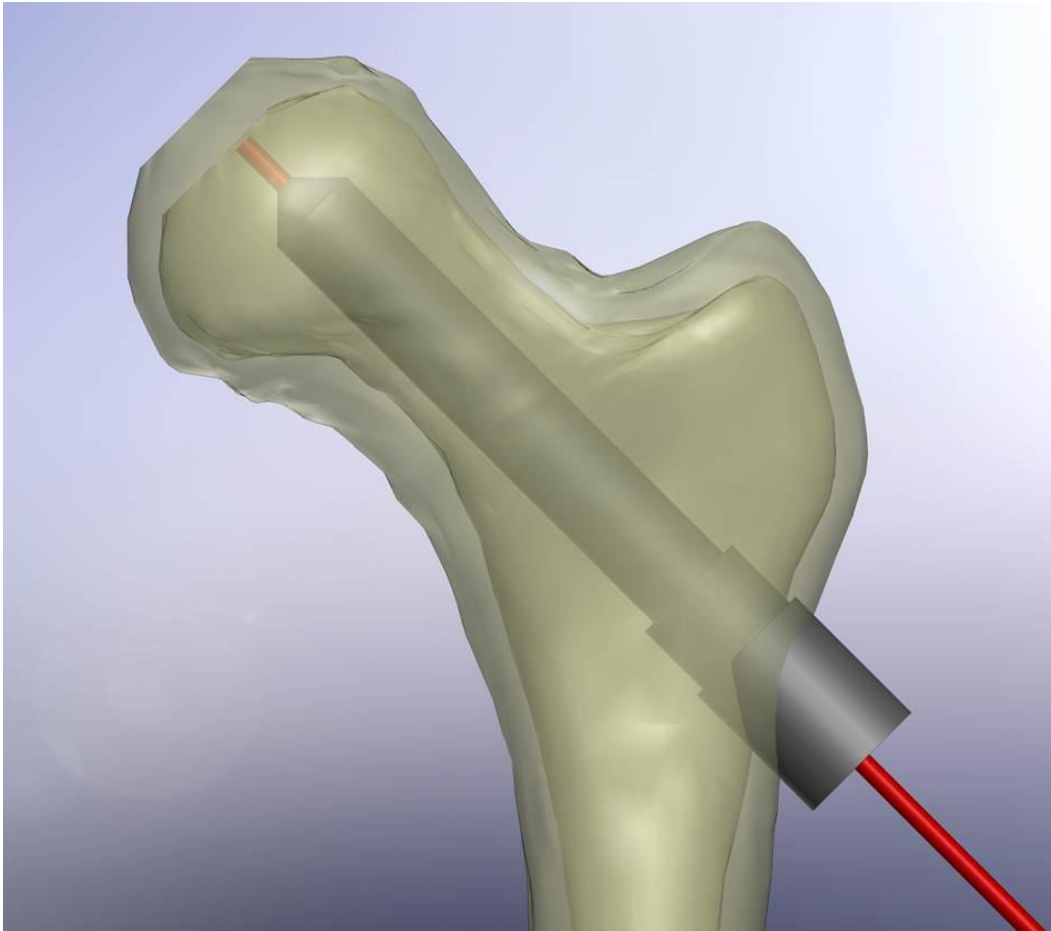
point would shift approximately 5 mm distally or proximally for increased or decreased angle, respectively.

The new angle guide would be held firmly on the lateral femoral shaft, and the 2.5 mm guide pin would be advanced through the hole in the angle guide into the femoral head (Figure 10.9b) until it reaches the centre of the femoral head, as shown in both anterior and lateral view in Figure 10.9c.

### **10. 5. 3. Reaming and tapping (Yellow)**

After the guide pin is placed in a satisfactory position, the depth gauge would slide over the guide pin to measure the length of pin in bone. The reaming depth and the telescoping screw length selected would be 10 mm shorter than the depth gauge reading. (For example, if depth gauge reading = 110 mm; reaming depth = lag screw length = 100 mm)

A tunnel of three diameters corresponding to the three different diameters of the lag screw (diameter of 9 mm), barrel (diameter of 14 mm) and side plate cylinder (diameter of 19 mm) would have to be made using the triple reamer over the guide pin, as shown in Figure 10.10. Following the reaming, the femoral head and neck would be tapped (outside thread diameter – 12.7 mm). This would be an optional step, particularly important only in dense bone. The tapping depth would be the same as the reaming depth.

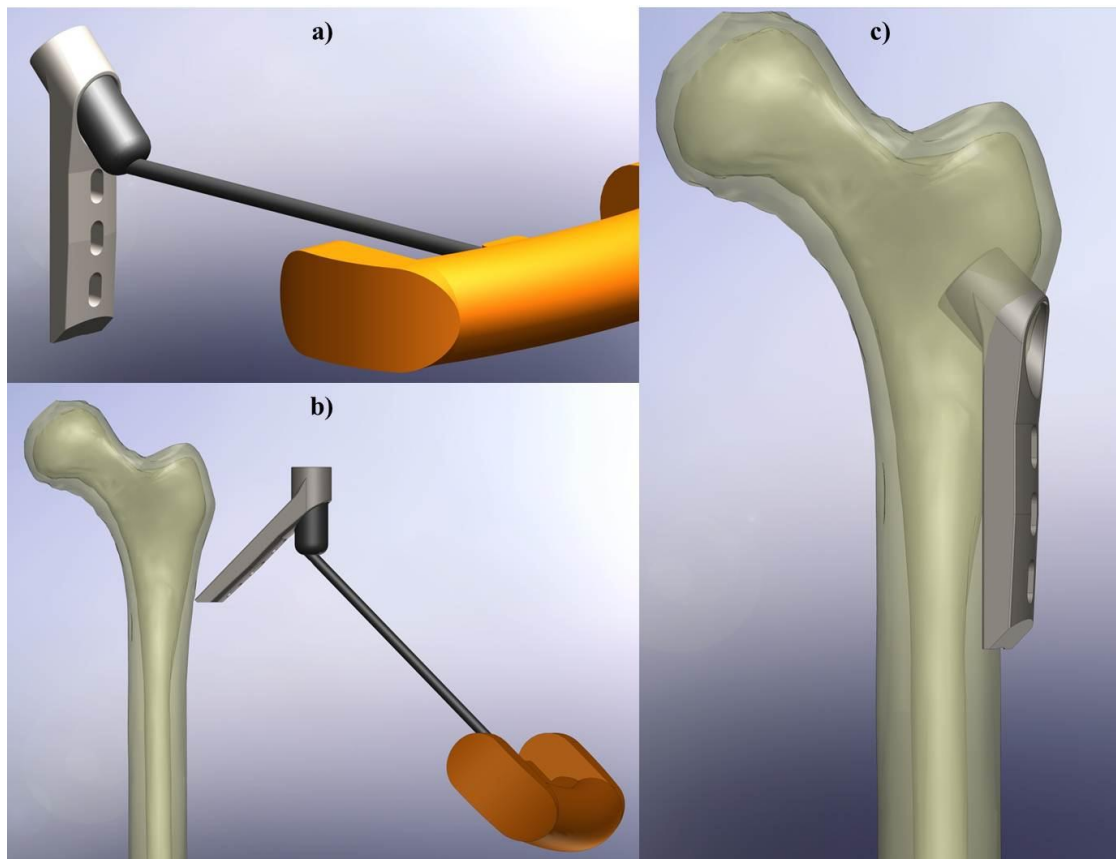


**Figure 10.10: Reaming of the femur using a triple reamer over the guide pin.**

#### **10. 5. 4. Side plate fixation (Orange)**

The guide wire would have to be removed and then reinserted at the end of this stage. The steps in this stage are illustrated in Figure 10.11a-c. The side plate inserter would be placed inside the proximal hole of the angled side plate (a), which would then be introduced into the patient's body with the bottom end of the side plate advanced first through the incision, following which it would slide down the femoral shaft into position (b). The skin and soft tissues would then be pulled back with the aid of a soft-tissue retractor, following which the side plate

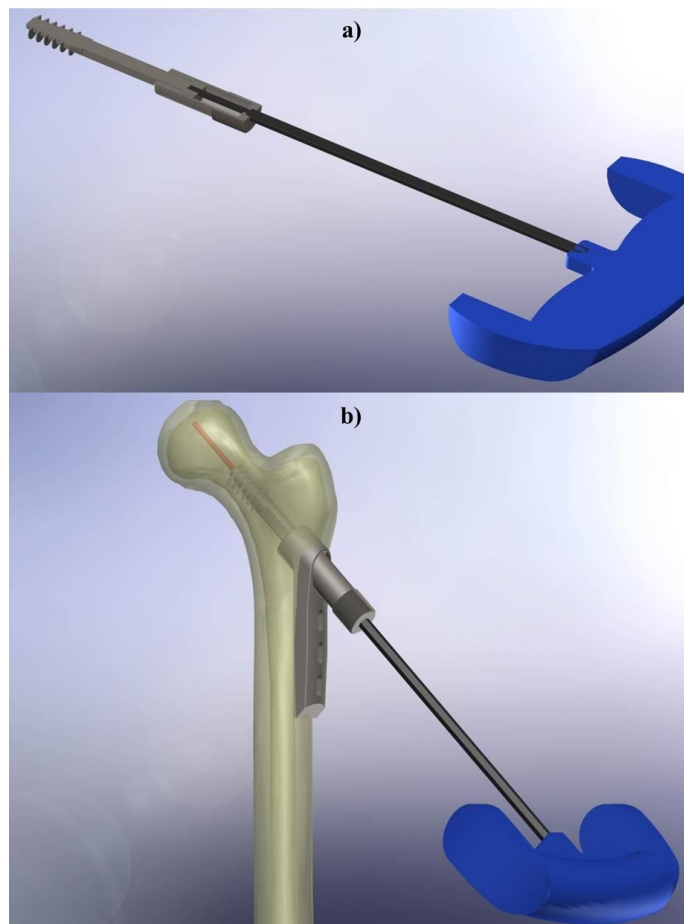
would be secured onto the femoral shaft with the insertion of distal locking screws. The side plate inserter would be pulled out of the side plate proximal hole after the distal holes are locked onto the femoral shaft with screws (c).



**Figure 10.11: Steps for side plate fixation include – a) placing the side plate inserter inside the angled side plate, b) sliding the side plate bottom end first on the femur, and c) securing the side plate on the femur with distal locking screws (screws not shown).**

### 10. 5. 5. Telescoping screw insertion (Blue)

The steps in this stage are illustrated in Figure 10.12a-b. The telescopic screw would be assembled on the telescopic screw inserter with the lag screw fully extended out of the barrel (a). The assembly would then be advanced into the femoral head through the incision and over the guide pin (b), until completely screwed into the secure angled side plate. The side plate inserter and the guide pin would then be removed from the femur.

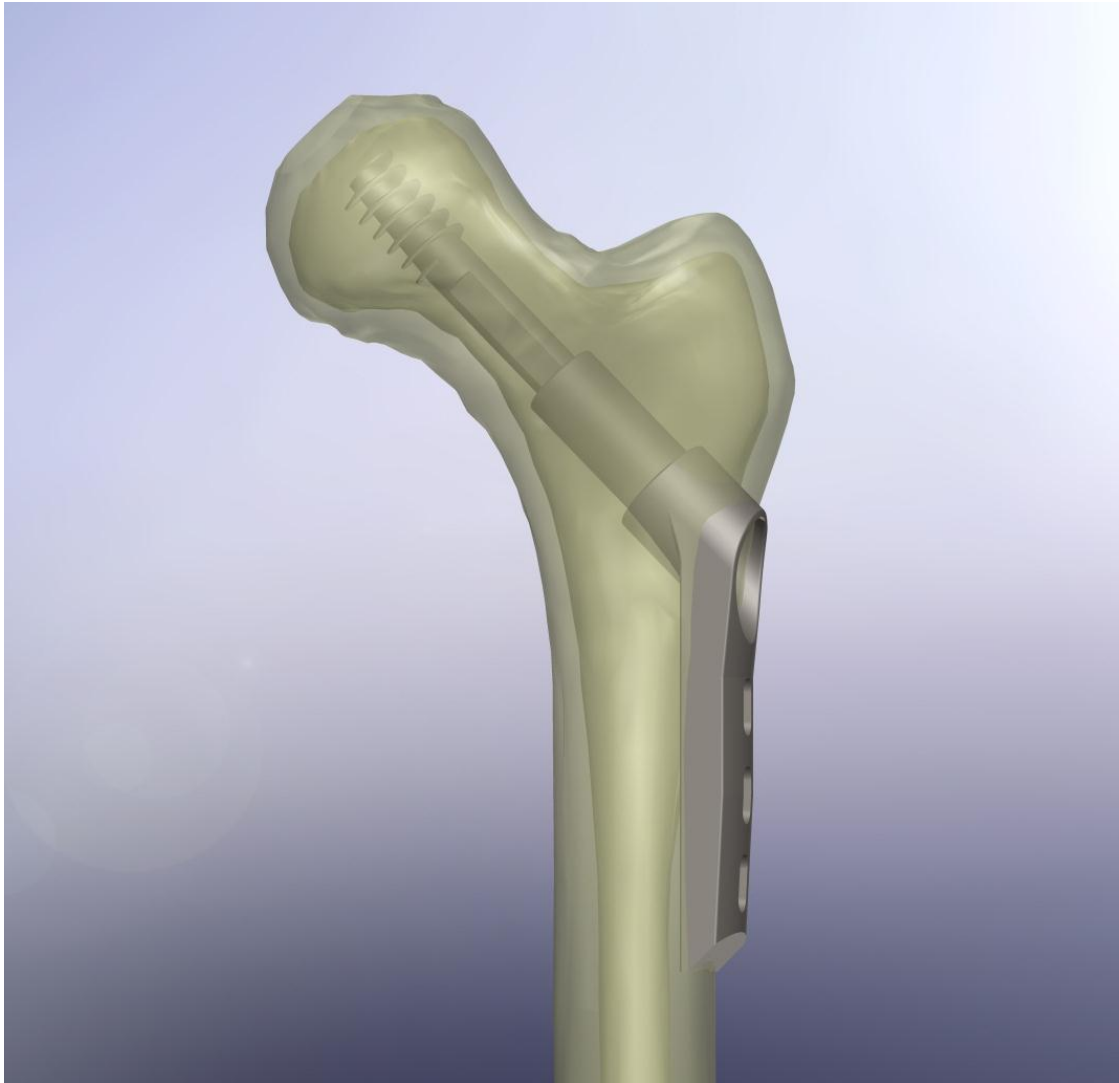


**Figure 10.12: Steps for telescoping screw insertion includes: a) extending the telescopic screw by 20 mm using the telescopic screw inserter (cross section view), and b) advancing the screw into the femur through the secure angled side plate.**



**10. 5. 6. Completion**

The 30 mm incision would be closed with stitches. The completely inserted and secured new implant on the femur is shown in Figure 10.13.



**Figure 10.13: The new implant assembled and secured on to the femur.**

## **10. 6. Summary**

The summarising points of this chapter are listed below.

- i. The chapter highlighted the features and design attributes of the new implant and associated instruments. The new instruments could either directly replace their counterparts in the existing generic DHS surgery, or be a part of the instrument set to be used in the surgical procedure of the new implant.
- ii. The surgery described in this chapter used a minimally invasive approach with a maximum required incision of 30 mm to insert the new implant.
- iii. The surgical procedure of the new implant was divided into four stages, each denoted by a unique colour – guide pin placement (green), reaming and tapping (yellow), side plate fixation (orange) and finally telescoping screw insertion (blue). The T-handles on instruments would be colour-coded corresponding to its stage of use.

# CHAPTER 11

## CONCLUSIONS

The research presented in this thesis was initiated on Prof. N. Maffulli's observation for a need of minimally invasive approach for the surgical treatment of fractures of the proximal femur. The research concluded with the development of three new medical devices taken through a thorough medical device design process to facilitate minimally invasive surgery (MIS) for these fractures.

In Chapter 3, a feasibility study was conducted to investigate the fractures of the proximal femur, and identify the medical devices currently used in the market for their treatment. The results showed that surgical treatment of these fractures was possible either with Intra-Medullary fixation devices or Dynamic hip screw (DHS); of which DHS was considered the standard implant for proximal femur fracture fixation. A further assessment of the DHS implant, associated instruments and surgical technique, identified the angle guide, the T-handle and the DHS implant as key medical devices to allow for MIS of DHS. A review of commercially

available implants which utilise MIS for the treatment of these fractures also revealed the superiority of the DHS because of the simple surgical procedure and decades of use. Therefore, the objective of this research was to redevelop the three identified medical devices to reduce the incision length for the implantation to less than 30 mm (from the existing 100 – 150 mm), whilst attempting to maintain the surgical technique utilised to implant the DHS.

The angle guide was the first to be redesigned, as it was discovered to be the only instrument during the feasibility study that prevented a viable (safe) MIS with less than 30 mm incision using the existing set of instruments and implant with a modified operative technique. Hence, the new angle guide would not only replace the existing device to aid in MIS, but also be a part of the operative technique for the new implant that was to be developed at a later stage of the research. In Chapter 4, the concept of the new angle guide was generated following an in depth analysis of the current device, and compilation of detailed design specifications which conformed to the standard for surgical instruments – BS EN 12011 (1998). Additional to the functional requirement and the need to reduce the incision length for utilising the device, it was also considered necessary to design an alternative base for the new angle guide to replace the existing prongs to grip the bone and provide improved stability. The new angle guide was described in detail in Chapter 6 and it successfully passed design verification methods such as finite element analysis (FEA) and risk analysis.

Chapter 5 described an *in vitro* experiment that was conducted to measure the static coefficient of friction between bone and candidate materials for the new base of the new angle guide in presence of a blood analogue solution. The inclusion of blood analogue solution in the testing methods mimicked the slippery surface of bone due to presence of blood and hence increased the authenticity of the experiment. Apart from the standard stainless steel surface, silicone elastomers were selected due to their properties of biocompatibility, resistance to sterilisation methods and ability to mould on application of force without plastic deformation. The determination of values of static coefficient of friction between bone and these materials aided in selecting a new base material which would provide the best grip on the slippery bone surface. In general, textured surfaces of stainless steel provided better grip than silicone elastomers and the highest value of coefficient of friction was demonstrated when bone interfaced with stainless steel surface prepared by spark erosion. However, it was also necessary for the new base to provide stability on the curved bone surface, and hence Silastic Q7-4780 (silicone elastomer grade with the highest static friction coefficient) was also selected. The base of the new angle guide was a combination of these two materials. The results generated from this test could also be used in design processes of other medical devices in the future as no publications were found which provided these values. The custom built testing rig was designed such that it can also be used for experiments to determine static coefficient of friction values of other materials.

The redesigning of the DHS instruments' T-handle involved a design process which emphasized on ergonomics. The specifications for a comfortable and effective T-handle were derived from published literature relating to other industries, and were combined with the requirements of a surgical instrument as stated in BS EN 12011 (1998). Although comfortable T-handles are manufactured and supplied by reputable orthopaedic implant manufacturers such as Stryker (Kalamazoo, Michigan, USA) and B. Braun Melsungen AG (Melsungen, Germany), no publications were found on design specifications of a T-handle based on ergonomic principles. The resulting new ergonomic T-handle design, like the new angle guide, was proposed for use with the existing DHS surgical instruments, and in the surgical technique for the new implant.

The final leg of this research involved designing a new implant (presented in Chapters 8 to 10) that utilised the sliding principle of the DHS implant, avoided the complications caused due to the existing DHS, maintained the surgical technique of the DHS and required an incision length of less than 30 mm for insertion to treat the fractures of the proximal femur. These objectives were used to produce a product design specification for the new implant that conformed to the requirements stated in the standards for general surgical implants, implants for osteosynthesis and for devices for the fixation of adult femur ends. The new implant assembly consisted of a telescoping screw which combined the lag screw of the DHS with a close ended barrel to avoid lag screw cut-outs (regarded as the

highest complication linked to the DHS), and a locking angled side plate that would enhance the fixation and stability of the implant on the femur. A prototype of the new implant was manufactured and successfully underwent mechanical testing as required by ASTM F-384 (2006). The design was also verified using risk analysis and FEA. Chapter 10 exhibited the surgical technique for the new implant using a minimally invasive approach. The operative technique utilised the new angle guide along with the new ergonomic T-handle and other existing DHS instruments for the implantation.

Although the design process used to develop the three medical devices were comprehensive, the selected designs of the three new medical devices need further work before they could be passed on for manufacturing and eventual regulatory approval. The new devices need further testing with prototypes manufactured to exact specifications. Also, packaging and manufacturing aspect of the total design approach were ignored during the design process mentioned in the research, although their requirements were stated in the respective device's PDS. However, the aim of this research was to develop new medical devices to enable MIS for treatment of fractures of proximal femur. The designs of the medical devices presented in this research are viable, conform to the regulatory standards, and would be competitive due to their own unique advantages in the global market.

The future work required on the new medical devices is listed below.

- Prototypes of the three new medical devices designed in this research should be manufactured to exact specifications. Manufactured samples of the new implant are required for an elaborate and accurate mechanical testing (static and cyclic). The samples should also be assessed by surgeons and the appropriate surgical staff for practicality and performance. It would also be beneficial to survey surgeon's reactions and suggestions through a practical session, specifically for the usability of the new angle guide, comfort provided by the ergonomic T-handle, and surgical procedure of the new implant.
- Appropriate packaging design, manufacturing techniques, engineering drawings according to the final materials selected and a bill of materials need to be prepared for the new medical devices and the other instruments that would form a part of the new instrument set for MIS of DHS.
- Clinical investigation of the new medical devices on live human subjects and the proceeding analysis of the design is very important before the design is forwarded to the manufacturer for regulatory approval and sale in the market.



# APPENDIX A

## SURGEON'S PERSPECTIVE ON A NEW BASE MATERIAL

### A. 1. Introduction

A new base material was to be selected for the design of the new angle guide to replace the existing prongs (section 4.4). Apart from conducting an *in vitro* test to measure the static coefficient of friction of the selected materials (three grades of silicone elastomer; three different surface preparations of the stainless steel surface) described in Chapter 5, it was also decided to evaluate the surgeon's perspective of the selected materials as the new base material for an instrument-bone surface interface in an angle guide. The survey was conducted at the City General Hospital (Stoke-on-Trent, UK) on the 7<sup>th</sup> of December, 2007 by the author and Dr. D.E.T. Shepherd (PhD supervisor), and was organised by Prof. N. Maffulli. The experiment was attended by ten orthopaedic surgeons. It was portrayed to the surgeons that the experiment would aid in designing any orthopaedic instrument where base material and bone surface interaction would be involved. Along with the base material, the thickness and length of a T-handle

was also assessed to aid in the design process of the new ergonomic T-handle (Chapter 7). Unfortunately, the survey proved inconclusive in selecting a new base material because of the reasons mentioned in section A.4; hence the results were not included in the design process of the medical devices. The following sections describe the experiment in detail, and the questionnaire used during the experiment is included towards the end of this appendix in section A.6.

## **A. 2. Materials and Methods**

### **A. 2. 1. Instruments**

Five instruments, named A - E were used for this experiment. All the instruments were manufactured by welding a mild steel cylindrical rod, 10 mm in diameter and 110 mm long to the centre of a mild steel base, with dimension of 60 mm × 15 mm × 2 mm. Instruments C, D and E were fitted with a beech wood handle of 25 mm in diameter and 115 mm long. The handle on instruments A and B had a diameter of 30 mm and was 95 mm long.

The bases of all the five instruments were different from each other. A base was cut off from a generic design of DHS 135 degrees angle guide, and then welded on to the cylindrical rod at the centre to make instrument A. The base of instrument C was machined to have a radius of curvature of 20 mm, and then, as with the base

of instrument B, it was also attached to a sheet of Silastic Q7-4720 silicone of the same dimension as the base using Araldite (Huntsman, Switzerland). Instrument D had a sheet of Silastic Q7-4780 silicone attached to the base. The base of instrument E was roughened to a non-specific Ra value using a wire mesh.

### **A. 2. 2. Setup of Apparatus**

A SawBone femur (Sawbones Europe AB, Sweden) was cut just above the vastus lateralis ridge, and approximately 100 mm below the ridge, as this is the area of concern for an angle guide. The femur was also cut off medially. All the sides which were cut off were smoothened using a sanding machine. The cut femur was then attached with Araldite to the base of a 5-sided clear box (150 mm × 150 mm × 150 mm) made of PolyMethyl MethAcrylate (PMMA) clear acrylic sheets.. The bone was then submerged in a blood analogue solution (section 5.4.4). Enough solution was poured into the box to cover the bone-instrument interface during the experiment.

### **A. 2. 3. Questionnaire and respondents**

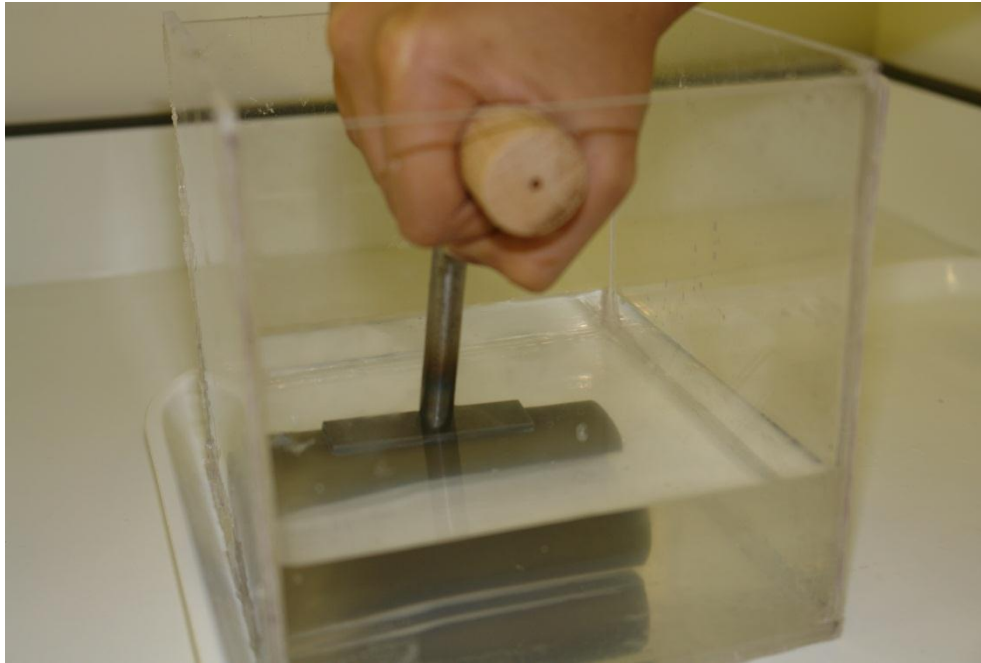
The questionnaire was designed specifically to assess the comfort levels, and the confidence in the surgeon while using the instruments. These parameters were measured on the basis of the base material and the handle size. Each instrument would be given a score out of 8 (2 questions – diameter and thickness) for the

different handles experience and out of 16 (4 questions – stability, grip, complement fit and comfort) for the different base materials. These were followed by subjective questions on their experience with instruments which interface with/ are placed on the bone surface. The questionnaire used for the survey is included at the end of this appendix.

The respondents included two orthopaedic consultants, six orthopaedic specialist registrars, one senior house officer and one staff grade surgeon.

#### **A. 2. 4. Evaluating the surgeon's perspective**

Each assessor was called to the setup area, and asked to pick up one of the five pieces of paper with the instrument code on it. The instrument was used by the surgeon (Figure A.1.). At the same time, the six questions relating to the handle and the base material were asked. This step was repeated until all the 5 different instruments were tested. The assessor was then asked to complete the rest of the questionnaire.



**Figure A.1: Setup used to assess the surgeon's perspective of an instrument's handle and the base material**

### **A. 3. Results**

#### **A. 3. 1. The handle**

Table A.1. shows the points given to the different handles by the 10 assessors. The points were added up to give a total. The thicker handle diameter of instrument B was liked by the surgeons, but the length was not highly ranked. However, the longer length of instrument D was preferred, but the smaller handle diameter was marked as less comfortable.

**A. 3. 2. The base material**

Table A.2. summarises the answers to the questions based on the base materials of the five different instruments. Each base material of an instrument was to be assessed out of 16 points – 4 per question. The results were added to give an overall standing of the instrument out of 160 points.

Instrument A, the current base with prongs, was selected as the best by the surgeons. Softer silicone elastomer, i.e. instruments B and C were preferred over harder silicone elastomer – instrument D. The silicone elastomer did not make as much of an impact (difference between instruments B and E), as the curved base did, which is seen in the results for instrument C.

Instrument A provided the best stability, grip, complement fit and comfort to the surgeons. On the other hand, instrument D was consistently rated the worst for all the above factors. Instrument B provided a better stability, and E was better for grip and comfort, and both were similar for complement fit. Instrument C was the second best for all the factors.

**A. 3. 3. General questions**

These questions were optional, and the assessors were asked to fill in the boxes at their own convenience. Many answers were left blank, and some assessors

provided more than one answer to a question. Hence, the results do not actually display the percentage of the assessor that chose one answer, but they show the percentage of the recorded answers. 80% (8 of 10) of the answers acknowledged the difficulty in placing an instrument on the bone surface. The main reason (59% - 7 of 12) was slippage of the instrument on the bone surface. Another major factor was the stability of the instrument (17% - 2 of 12) on the bone surface. Poorly designed instrument, insufficient access to the operating region, and the learning curve of using the instrument were equally contributing factors (8% - 1 of 12). The answers to “how to improve the instrument – question 10” included a new concave base (29% - 2 of 7), a better handle (29% - 2 of 7), better grip (29% 2 of 7) and by designing the instrument to experience less strain on hand (14% - 1 of 7).

**Table A.1. Handle design ratings summary**

Instrument	Question	Assesor										
		1	2	3	4	5	6	7	8	9	10	
<b>B</b>	Handle Diameter	3	3	3	4	3	3	2	3	3	2	<b>29</b>
	Handle Length	3	2	4	2	1	3	2	3	2	2	<b>24</b>
		6	5	7	6	4	6	4	6	5	4	<b>53</b>
<b>D</b>	Handle Diameter	4	2	2	3	1	3	3	1	2	1	<b>22</b>
	Handle Length	4	3	4	4	2	3	3	3	3	3	<b>32</b>
		8	5	6	7	3	6	6	4	5	4	<b>54</b>

**Table A.2. Base materials ratings summary**

<b>Assessor</b>	<b>Instruments</b>				
	<i><b>A</b></i>	<i><b>B</b></i>	<i><b>C</b></i>	<i><b>D</b></i>	<i><b>E</b></i>
<i><b>1</b></i>	14	8	14	7	9
<i><b>2</b></i>	13	6	11	6	11
<i><b>3</b></i>	15	12	10	8	9
<i><b>4</b></i>	16	6	8	6	9
<i><b>5</b></i>	14	8	10	11	9
<i><b>6</b></i>	15	6	9	5	7
<i><b>7</b></i>	15	8	10	6	9
<i><b>8</b></i>	6	9	14	8	8
<i><b>9</b></i>	11	7	13	9	7
<i><b>10</b></i>	12	12	8	5	5
<b>Total / 160</b>	131	82	107	71	83
<b>Percentage</b>	<b>82%</b>	<b>51%</b>	<b>67%</b>	<b>44%</b>	<b>52%</b>

## A. 4. Discussion

The results of the handle questions leaned towards a longer and a thicker handle. All the surgeons that took part in the experiment were male, which could have biased the results.

Regarding the base material, 80% of the answers suggested a problem with the current design of a bone resting instrument, and 59% suggested the problem to be slippage. However, the surgeons marked the current base material with the prongs as the best, and gave it almost full marks for every question, even though they were not asked to mark the base material relative to each other. One of the explanations for this result could be the familiarity with the base material. This instrument has been in use for decades, and it is therefore possible that the



assessors gave a higher mark to the instrument they were more familiar with. The test was conducted towards the end of the working day on a Friday, and the assessors had a long day at work. This could have affected the results, and actually caused the higher marking of the familiar instrument. Instrument C, which was an intended success for a new base material was marked higher than Instrument A, the generic design, by a Consultant and a Senior House Officer. All the registrars except one marked Instrument A higher than C.

In the present investigation, the current design was marked the highest, followed by a softer silicone elastomer lining over a curved base. The softer silicone elastomer (Q7-4720) was preferred over the harder one (Q7-4780). Another observation was that the curved base surface was preferred to a flat one. In fact, it was even suggested by two assessors that a concave base surface would enhance the grip and stability achieved by the instrument on the bone.

## **A. 5. Conclusions**

The test was unable to give conclusive answers towards choosing a better base material for the instruments, but it did provide a very useful insight into the way surgeons' perceive and use the instrument, and also on the different factors that are important to improve the surgeons' comfort while using the instrument.

## **A. 6. Questionnaire**

7<sup>th</sup> December 2007

### **Bone – instrument interface experiment**

Respected Sir/ Madam,

I am currently a PhD student in the Biomedical Engineering Research Group at The University of Birmingham, working under the supervision of Dr. Duncan Shepherd and Prof. David Hukins. My research includes studying the factors that affect the level of comfort experienced by surgeons while using orthopaedic instruments.

The aim of this experiment is to determine an appropriate material that would be most comfortable to use for the interface of the instrument's base with the bone.

The setup includes 5 instruments (A – E) of identical dimensions with different base materials. The handle size has also been changed in one of the instruments. You would be required to place each instrument at the specified position on the bone, and answer the series of questions by rating each instrument from 1 to 4; with 1 being the worst to 4 being the best.

The questionnaire includes some general questions which would aid in designing a better base for numerous orthopaedic instruments that interact with the bone surface.

All responses will be treated with the utmost confidence and the results will only be presented in aggregated format.

I would like to thank you for participating in this experiment. Any feedback or extra comments would be highly appreciated.

Kindly contact me regarding any queries about the experiment.

Yours sincerely,

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[jugalparekh@gmail.com](mailto:jugalparekh@gmail.com)

Kindly state your profession

--

Please specify your current position

--

This questionnaire consists of **11 questions**, with 6 related to your experience while using the instruments (A – E) during the experiment.

Kindly answer all the questions.

Rate the following questions from 1 to 4; 1 being the worst and 4 being the best. The same rating could be applied to more than one instrument.

The following two questions are based on the handle of the instrument:

1. Please rate on the **diameter of the handle** and the comfort fit it provided in your hand

	1	2	3	4
B				
D				

2. Please rate on the **length of the handle** and the comfort fit it provided in your hand

	1	2	3	4
B				
D				

The following three questions relate to the base of the instrument and its fit with the bone:

3. Please rate the **stability** of the instrument on the bone based on the base material of the respective instrument

	1	2	3	4
A				
B				
C				
D				
E				

4. Please rate the amount of **grip** provided by the instrument on the bone due to the base material, i.e. the prevention of slipping because of the base material

	1	2	3	4
A				
B				
C				
D				
E				

5. Kindly rate the **fit** of the instrument on the curvature of the surface of the bone, i.e. how well did the instrument sit on the bone?

	1	2	3	4
A				
B				
C				
D				
E				

The following question is based on the overall experience of the instrument

6. Please rate the **comfort** while using the instrument

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>A</b>				
<b>B</b>				
<b>C</b>				
<b>D</b>				
<b>E</b>				

The following questions are based on your experience with orthopaedic instruments. You could refer and discuss with your colleagues for answering the following questions.

7. Have you experienced **any difficulties** while placing an instrument onto a bone surface?

Yes ☐ No ☐

8. If you answered yes to question 7, please **state any such experiences** and the reason (stability, slipping issues)

9. What bone surface **instruments** do you regularly use? (e.g. Angle guide)

10. Kindly state **any other factors** that you consider important in improving the bone – instrument interface

11. Any **additional comments**

**Thank you for your time!**

# **APPENDIX B**

## **THE NEW IMPLANT – MODEL 1**

### **B.1. Introduction**

It was stated in section 9.2 that model 1 failed during the mechanical testing discussed in Chapter 9. Hence, the dimensions were reassessed and model 2 was used for the detailed design process. Model 2 was regarded as the new implant.

This appendix shows model 1 of the new implant in Figure B.1, followed by the engineering drawings in Figures B.2 and B.3, and finally the modified manufactured prototype along with the fracture and excessive bending it endured during the static loading test in Figure B.4.



**Figure B.1: Model 1 of the new implant**



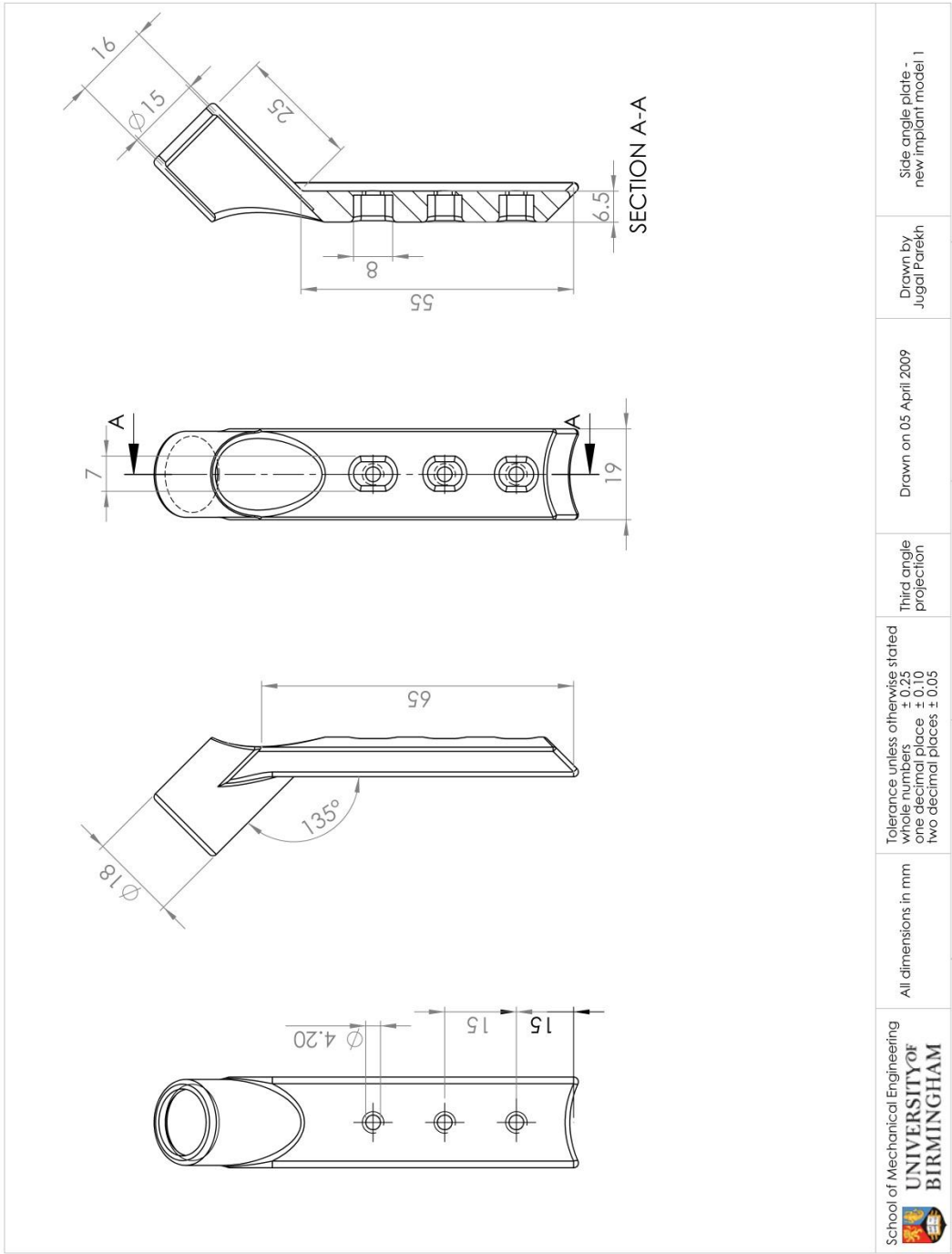


Figure B.2: Engineering drawing of the angled side plate of model 1 of the new implant

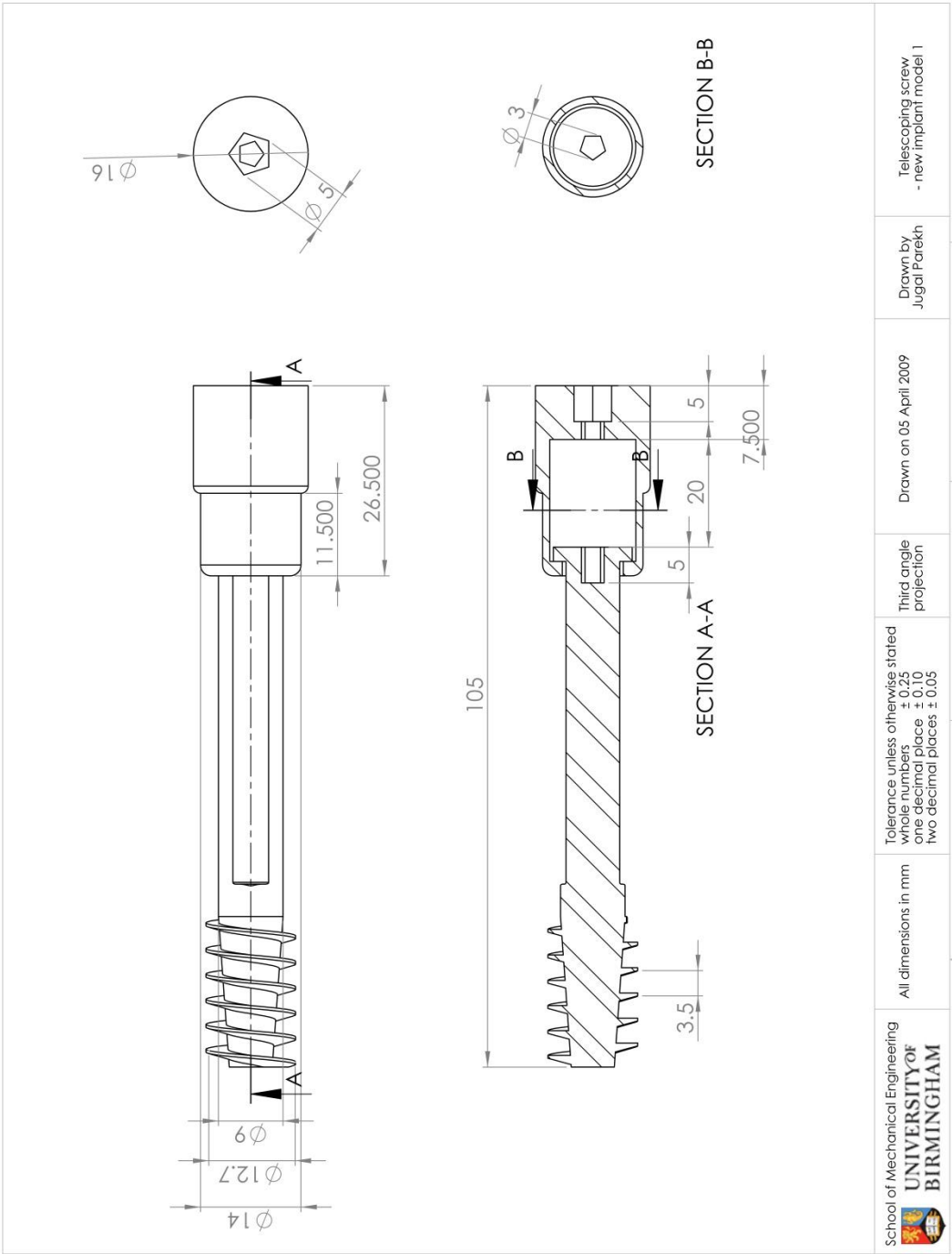
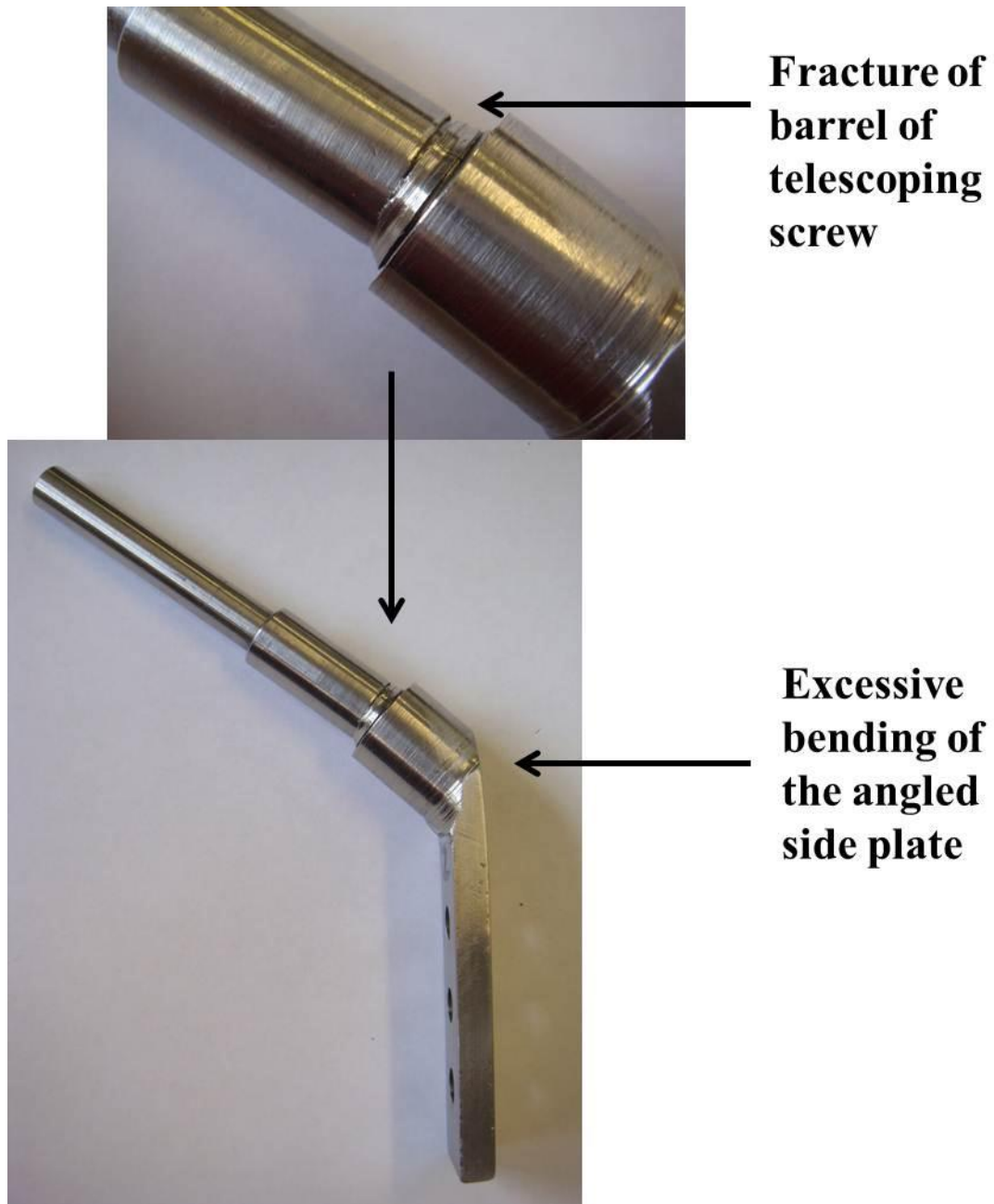


Figure B.3: Engineering drawing of the telescoping screw of model 1 of the new implant



**Figure B.4: Static loading test on the modified manufactured prototype of model 1 resulted in excessive bending of the angled side plate and fracture of barrel of the telescoping screw**

# **APPENDIX C**

## **NEW INSTRUMENTS FOR THE NEW IMPLANT**

### **C.1. Introduction**

The surgical technique (Chapter 10) required two additional new instruments for insertion of the new implant into the proximal femur. They were – a) side plate inserter (section 10.4.4), and b) telescoping screw inserter (section 10.4.5). This appendix shows the engineering drawings of the new instruments in Figure C.1 and C.2. The engineering drawings do not include the new ergonomic T-handle (Chapter 7).

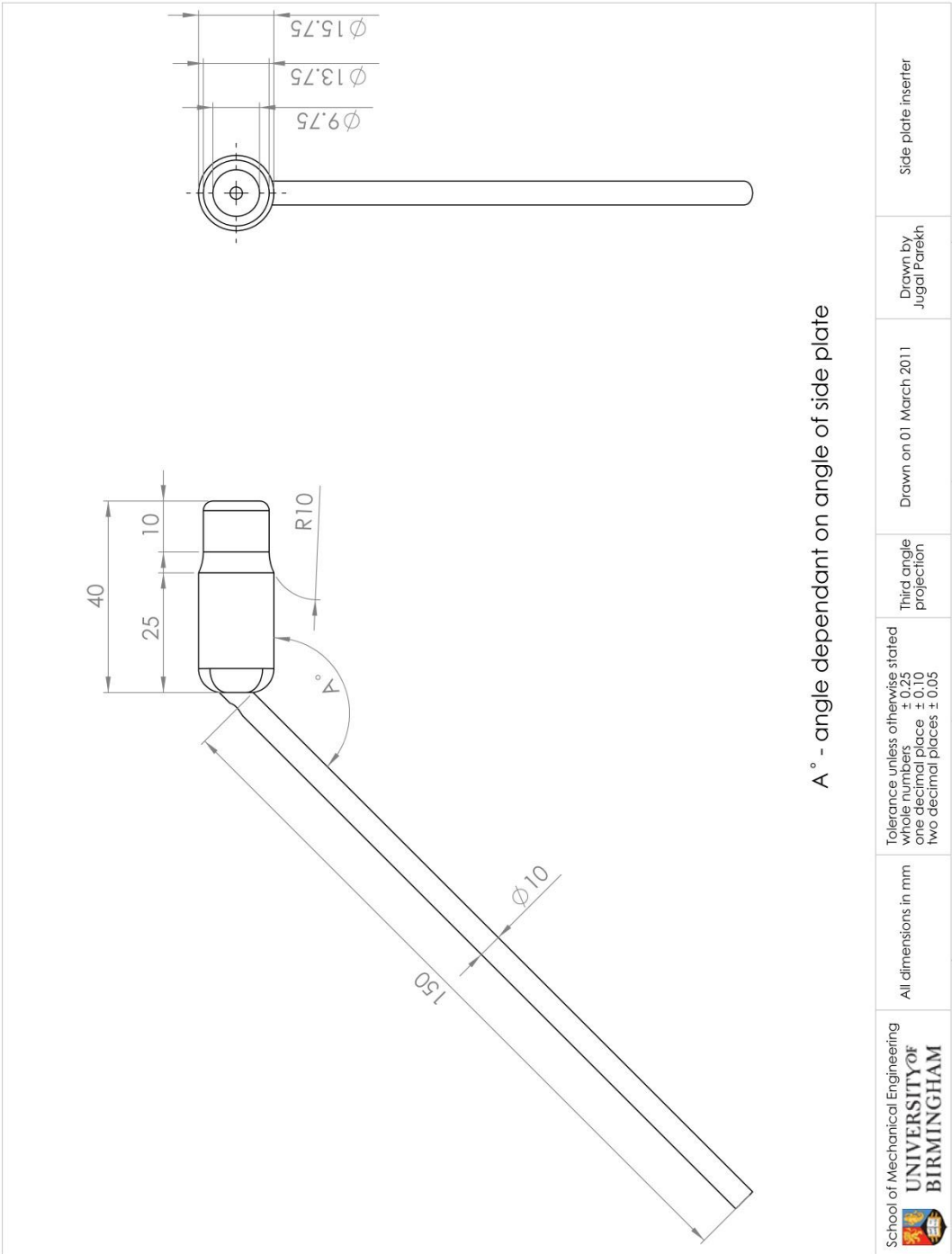


Figure C.1: Engineering drawing of the side plate inserter

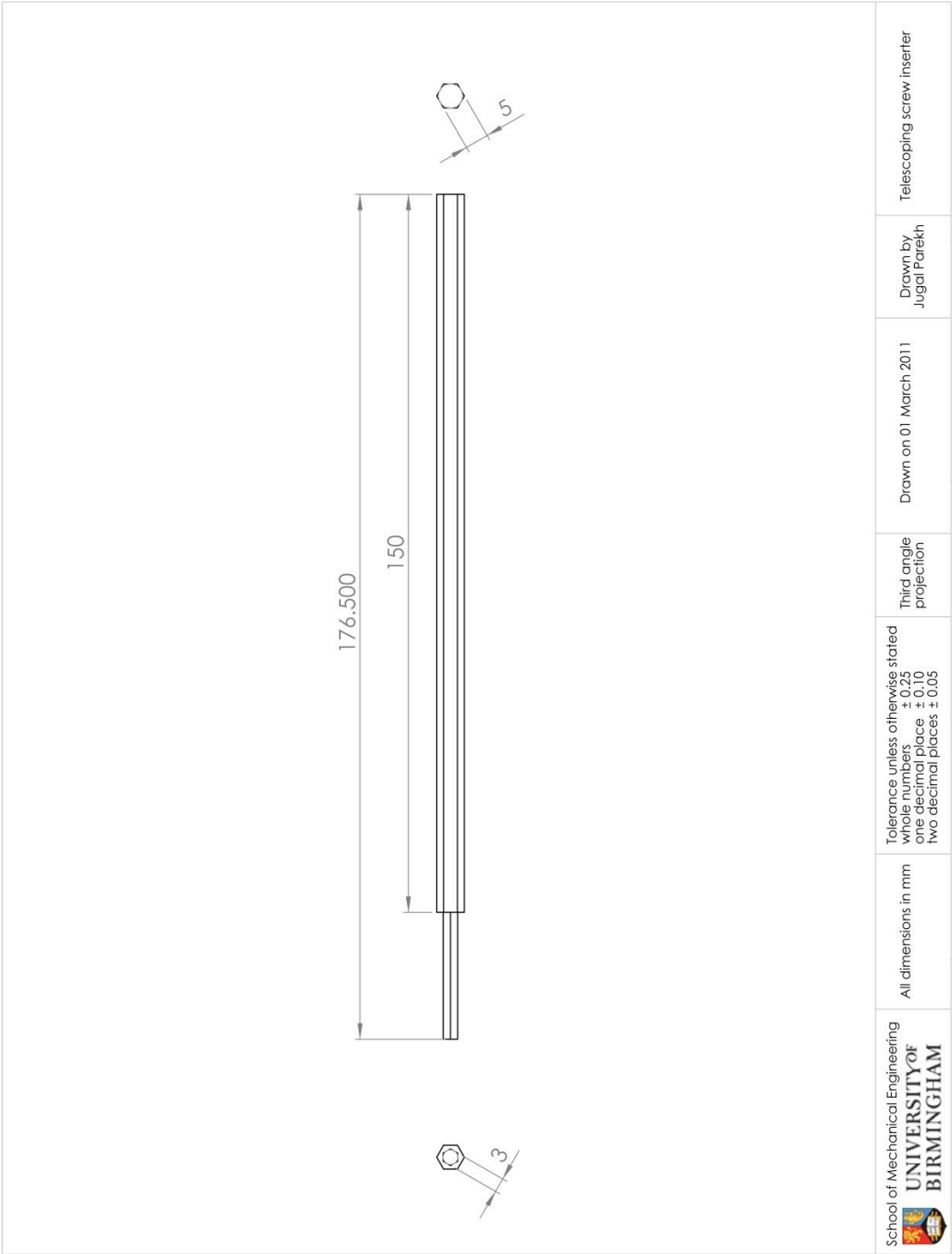


Figure C.2: Engineering drawing of the telescoping screw inserter

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