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Design of an Orthopaedic Instrument for Image Guided Anterior Cruciate Ligament Reconstruction

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Abstract

This is an interdisciplinary research project in which the methods of Industrial and Product Design Engineering are focused upon a problem in Orthopaedics.

One of the most controversial areas in Orthopaedics is the reconstruction of the anterior cruciate ligament (ACL). The current twin-instrument method for locating the ACL is difficult for surgeons with fewer than 500 surgical experiences. This was clearly demonstrated by Kohn, Busche and Cans (1995), and confirmed by Sommer, Friederich and Muller (2000), Sudhahar, Glasgow and Donell (2004), and Kuga, Yasuda, Hata et al. (2004). The above research indicates that the problem is not only one of anatomical location, but of how the operation takes place. The aim of the research was, therefore, to develop a new and improved surgical instrument and technique for locating the ACL anatomical landmarks.

The research described in this thesis employs a number of design methods that can be used separately or in combination (hybrid process). They form the theory base that guides the design process. This allows the designer to engage in a flexible process that is effective in finding design solutions to the problem. Within this process, iterative case studies were employed in order to design a new surgical device for ACL reconstruction.

The thesis describes a series of designed devices (case studies) that were iteratively developed and surgically tested, leading to a penultimate device. This latter device was tested via a number of surgical operations. The device provides a new method for externally locating the internal ACL attachment points.

The research has resulted in a commercial association with Smith and Nephew Surgical Australia and BrainLAB AG Germany for the commercialisation of this technique. At the time of writing, the next stage of research and development is under way. This is using a frameless computer-aided image guidance system in the place of X-ray.
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Statement of Authenticity

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or college of advanced education, and to the best of my knowledge and belief, contains no material published or written by another person, except where due reference has been made in the text of this thesis.

Signature

Dated – 5 August 2006
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CHAPTER 1

Introduction

1.1 Overview

This research was undertaken through collaboration between two professions, Industrial Design (candidate) and Orthopaedics. The research was conducted at the Industrial Research Institute Swinburne (IRIS) and the National Institute of Design (NID), Swinburne University of Technology, during the years 1998 to 2005. All orthopaedic trials were conducted at St Vincent’s, Bellbird Private, Epworth and Mercy Hospitals, in Melbourne, Australia, under the supervision of Orthopaedic Surgeon Mr Bruce R.T. Love, FRACS, the Associate Supervisor of the research.

1.2 Objectives of the Research

The purpose of the research was to design a novel device that simplifies the surgical requirements and technical demands placed on orthopaedic surgeons when performing
reconstructions of the anterior cruciate ligament (ACL). This simplification is to be achieved through an external image guided technique. The technique is explored via qualitative methods that validate iterative product design processes through a series of case studies.

ACL reconstruction of the knee has been undertaken using one particular style of handheld instrument and associated techniques since the mid 1980s. This operation has tolerable outcomes if the surgeon is both highly skilled and experienced. However, it has been shown to be technically demanding for most surgeons (Kohn, Busche et al. 1995). Sommer, Friederich and Muller (2000) recently demonstrated that the surgical technique remains extremely difficult. Sudhahar, Glasgow and Donell (2004) observed in their study that the ideal tibial tunnel position is still controversial, and they recommended that before surgeons operate on the tibial tunnel, image guided intraoperative confirmation of the device position would be helpful. It is assumed that one plane only needs to be referenced. This assumption is challenged in the research to be reported here. It is our aim to locate the ACL via the intersection of two planes.

To do this, an externally positioned device must be designed that will locate one of the two intraarticular ligaments of the knee joint – in this case the ACL. An image guided device is required to externally situate around the exterior of the knee joint and locate the complex three-dimensional attachment points of the damaged ACL at its femoral and tibial landmarks. Particular design methods were employed, involving a combination of design methods.

1.3 Structure of Thesis

The first three chapters provide a background to Orthopaedic knee ligament reconstruction and associated techniques.
The historical aspects of ACL reconstruction are described in Chapter 2. This frames the conception of ACL surgery from European and American perspectives, and the developments in twentieth century surgery through to current-day techniques including computer aided orthopaedic surgery. It points out the problems and also argues the need for a more effective approach to ACL surgery.

Chapter 3 examines the basic anatomy of the knee joint from an intra- and extraarticular perspective. The main intraarticular ‘cruciate ligament’ structures and associated ‘soft tissue and bony landmarks’ are discussed to gain an understanding of the knee joint’s complex geometry. Consider reading Sections 3.2.1 and 3.2.2 previous to Chapter 2 if possessing a lay understanding of anatomy.

Chapter 4 discusses the current surgical techniques for reconstructing the ACL, including their advantages and disadvantages. It is argued that a process is needed that is less reliant on specialists’ surgical interpretations, which are clearly subject to surgical errors.

Based on Chapters 2, 3 and 4, Chapter 5 utilises appropriate design research methods to design an external device for ACL reconstruction. This chapter describes the processes and methods used to design and test various ‘case studies’ developed by the author. These case studies led to a series of working prototypes. The subsequent Chapter 6 builds on this by developing a series of instruments (devices) for surgical trial with saw bones (foam bones) and human subjects.

Finally, the image guided instruments are evaluated in Chapter 7 through a series of actual surgical trials. Conclusions are drawn in Chapter 8.
CHAPTER 2

General Orthopaedic and Anterior Cruciate Ligament Surgery

2.1 Introduction

This chapter provides a brief overview of the history of orthopaedic surgery. The concept of orthopaedics is traced from conception through to present-day techniques. The focus is on the development of general orthopaedics, including the development of modern techniques used in anterior cruciate ligament reconstructive surgery.
Historical Review

2.2 Early Developments in Orthopaedics

Orthopaedics is the science of reconstructing abnormalities within the human skeleton. Abnormalities of the skeleton have been traced back to the earliest humans, circa Java man. A femur (the upper bone in the leg) from Java man has been dated at half a million years old. The femur displays a mass of bone within its femoral region, indicating that an injury was caused by local soft tissue damage. The first written references to surgery come from an Egyptian papyrus dated 1600 BC, and from the Greek Hippocratic books, dated between 400 BC and 100 AD. These references describe various types of fractures and the methods of treatment. They included traction and immobilisation of limbs by the use of splints and bandages. Examination of such human remains reveals how resourceful early humans were. For example, they provide evidence of crude braces that were used to strengthen fractured bones. Although man had learnt to use splints, bone stumps also showed evidence of the first forms of amputation.

The term orthopaedia is derived from the Greek words (orthos – straight; paidios or paidion – child), and was originally applied to the art of correcting child bone deformities. Andry, a French physician, published a book in 1741 entitled Orthopaedia, subtitled The art of Correcting and Preventing Deformities in Children: By such Means, as may easily be put in Practice by Parents themselves, and all such as are Employed in Educating Children. (Adams 1976; Bell and Jackson 1999).

Advancements in orthopaedic surgery seem to be minimal prior to the seventeenth century. It is said that orthopaedic surgery was developed by Galen (American Orthopaedic Association 1972; Larson 1993). He was described as the first of the neuromuscular physiologists who described the knee and its anatomy. His description
included the anterior cruciate ligament (ACL). The stabilising effects of the two main ligaments, anterior and posterior, were recognised as important structures within the knee. These ligaments support and restrict abnormal motion within the knee joint.

It was in the Renaissance that the designer and artist Leonardo da Vinci’s drawings of human dissections gave surgeons unbiased and accurate observations of the human form. During this period field armies required the services of medical surgeons. The improved knowledge of anatomy may well have benefited injured soldiers. One of the most famous military surgeons was Paré (Grana and Larson 1993), who performed one of the first surgical corrections of a dysfunctional knee. In 1558 he reported the removal of a loose body within the knee joint. Paré and other military surgeons attended field hospitals at the front line. The surgeons had armourers at their disposal who, under the surgeons’ guidance, designed the first functional prostheses (American Orthopaedic Association 1972).

The first person to carry out an arthrodesis for a deformity of the bone was Park in 1781. He attempted his operation on a knee marked for amputation. He sawed off two inches of femur and one inch of tibia and removed the patella. This allowed enough of the bone ends to lie in close contact, being held together with hamstrings. The patient needed crutches to walk because the wound took three months to heal. By the fifth month the union of the knee joint was strong enough to allow the leg to be elevated, and in another month the leg felt solid. The limb had been shortened by three inches. Subsequently the patient required a raised shoe with a protective upper support. Albert suggested, one hundred years later, that arthrodesis was an intelligent way of treating flail limbs.

Of all the formal orthopaedic reconstructive procedures, movable joints were one of the first suggested. Rang (1980) described how White proposed the excision of the head of the femur in 1770. This procedure was only carried out on cadavers.
Rang (1980) depicts the methods of similar operations performed in 1831, and how Syme published a book that summarised and introduced reasons for this procedure. He also notes how Hodge, in 1861, illustrated in a review that the mortality rate from excision of bone from the hip was 50 percent. This compared to a mortality rate of one hundred percent for amputation at the hip level. These results encouraged other orthopaedic surgeons to operate on joints in similar ways when possible.

By the eighteenth century orthopaedic surgery had became an established branch of medicine that specialised in the science of bone reconstruction. Hospitals were built enabling the treatment of skeletal abnormalities and disease, with the incorporation of general medical advancements such as anaesthesia. The design of supports and braces for the treatment of disorders reached new heights. Joint resection and tendon surgery were also introduced for the first time. The structures of the knee were described in 1836 (Grana and Larson 1993), including the interarticual relationship between the tibial plateau and the femoral condyles within the knee joint. Also, the internal dynamics of the knee were described, including the mechanical motion and functions of the knee.

Surgery was not a preferred option for the treatment of internal abnormalities. It had to be performed within a few minutes, as the patient’s consciousness could only be clouded by intoxication or by physically knocking them unconscious. Before the advent of anaesthesia, surgery was a lengthy process when trying to find a loose body (Adams 1976).

Advances in orthopaedic surgery were dependent on developments in science and medicine. Hence, it was not until the development of related disciplines like radiology and anaesthesia that a new era in joint surgery could commence.

Following these developments in medicine and surgery, Annandale popularised the use of antiseptic/anaesthetic precautions in knee joint surgery from 1870. This allowed for
the search for foreign bodies within the open and exposed knee joint, before the advent of arthroscopy, which is used in modern key hole surgery (Grana and Larson 1993).

Colombet (1999) described Georges K. Noulis as a brilliant Greek who had studied medicine in Greece and in 1875 moved to Paris to pursue his research. He wrote a thesis entitled *Knee Sprains* that described the role of the ACL and how to test for the ligament’s integrity with the knee in extension. Noulis test for ligament instability was almost identical to the one described by Lachman.

The first repair of a ‘crucial’ ligament (as it was then termed) repair was performed by Mayo Robson in 1895 (Colombet, Allard et al. 1999). This was performed on a 41-year-old miner who had suffered from instability of the right knee. Mayo Robson stitched the ligament in position at the femoral attachment point. Six years after the surgery, the patient described his knee as ‘perfectly strong’, and was able to work without illness. The case was not reported in the literature until 1903 (Mayo Robson 1903).

Radiological imaging of the body has given the orthopaedic surgeon the ability to view and diagnose bone fractures and deformities prior to surgery. In 1895 Röntgen, a professor of physics, found that when a high-voltage current was passed through a Crookes vacuum tube, a ray was produced. It was proposed that this ray be called ‘X-ray’ in a symposium in Würzburg. Within weeks of this discovery, X-rays were used in medical applications to discover metallic foreign bodies like lead bullets. X-ray has been used to locate foreign objects within the body i.e. spinal surgical techniques. The use of X-ray as a means of locating knee geometry would allow orthopaedic surgeons to accurately locate surgical instruments in their operations.
2.3 Developments in the Twentieth Century

In 1903 Lange performed the first ACL replacement. It used braided silk and was attached to the semitendinosus as a ligament substitute. Colombet, Allard, Bousquet et al. (1999) described how Lange’s compatriot Herz concluded that the use of silk was admirable, but the attempt to imitate nature had failed. *‘However, it was not, perhaps, quite such a misguided idea’* (Colombet, Allard et al. 1999).

Corner, in 1914, described one of the first true ACL reconstructions using a synthetic material. The material used was a silver wire in the configuration of a loop that was passed through the femur and attached to another loop in the tibias. In 1917 a new concept in reconstructing broken ACL was introduced by Groves. He used a graft of iliotibial tract transplant that was removed from its tibial point and directed through drilled tunnels in the femoral and tibial bones respectively. This allowed the graft to be approximately located through its original ACL attachment points within the knee (Figure 2.1) (Hay Groves 1920).

Colombet, Allard, Bousquet et al. (1999) described the importance of Hay Groves’ findings (Hay Groves 1920) that reported the anatomical and physiological findings of the cruciate ligaments, as well as the ruptures and repair. He also noted the presence of forward displacement of the tibia while the patient placed weight on their bent knee. This weight bearing test was also used to observe patients in clinical testing (Figure 2.2).
Figure 2.1. Hay Groves technique; graft passed through tibial and femoral tunnels.


Figure 2.2. Hay Groves test depicting anterior tibial shift.

The precise location of the femoral and, more importantly, the tibial tunnel’s location intraarticularly are most crucial. Anterior placement of the tibial tunnel in relation to the original ACL site is important, because the intercondylar notch can impinge on the ACL graft, resulting in graft failure. In 1936 Campbell introduced the method that is the basis of today’s ACL reconstruction (Figure 2.3). Campbell introduced the first use of a tibial graft of the medial one-third patellar tendon for reconstruction of the ACL (Grana and Larson 1993; Colombet, Allard et al. 1999).

Figure 2.3. Campbell’s procedure for tunnel and graft preparation.


This technique involved drilling two tunnels in the tibial and femoral bones respectively. The graft was passed through the tunnels and sutured into place at the periosteum, near the femoral tunnel exit. The knee was held in place with a posterior splint for a period of three weeks.
Campbell’s paper (1936) dealt with 17 anterior cruciate ligament reconstructions (Colombet, Allard et al. 1999). Most of these operations were performed on athletes, and nine patients were reported to have excellent outcomes playing sport in six to ten months. Campbell was conscious of the benefits that ACL surgery could have on non-athletic people, particularly if the procedure could be carried out rapidly and without undue intra- and extra-articular reaction.

Macy (1939) described the first ACL technique using the semitendinosus tendon (Figure 2.4). This was also a two tunnel technique like Campbell’s, differing in that the tendon was left attached to the tibia. The tendon was then passed through the tibial and femoral tunnels and was distally attached to the periosteum with the limb in full extension. A plaster of Paris cast was worn for four weeks, and full activity permitted at nine weeks.

Figure 2.4. Macy’s procedure.

The technique of the central one-third patellar tendon was revived by Jones in 1963 (Jones 1970) with patellar tendon–bone block. The technique was described by Colombet, Allard, Bousquet et al. (1999) as differing from today’s technique in the tendon being left attached to the tibial site. This negated the requirement to drill a tibial tunnel. Due to the shortness of the graft, the femoral tunnel was drilled from the anterior margin of the notch (Figure 2.5).

![Figure 2.5. Jones’s procedure 1963.](redrawn from Colombet, P., Allard, M., Bousquet, P. et al. (1999). The History of ACL Surgery. Merignac, France, Bordeaux–Merignac Centre of Orthopaedic and Sports Surgery: 5)

In the 1970s many techniques were devised that involved non-anatomical extra-articular reconstruction techniques. Some of these were pioneered by Galway, Beaupre and MacIntosh (1972), and Marshall, Warren and Wickiewicz (1979). They were open techniques that were quite aggressive.

### 2.3.1 Biocompatibility of Materials

The biocompatibility of a material is dependent on the chemical response of the medium within the living tissue of a host. If the material is totally reabsorbed with no
undesirable alterations to the host’s tissue, as in catgut sutures or some Ca$_3$(PO$_4$)$_2$ bone grafts (Driskell, O’Hara et al. 1972), the material can be considered compatible on an ultra-structural scale. This scale is the relationship of the chemical response of the anatomy to the surface depth between the absorbable material and that of the host. The result is a stable interface that is nearly indistinguishable from that which would be produced without the implant in place.

Functional compatibility must be considered from the outset when designing new biomaterial devices. Two reasons for this are: first, the biocompatibility of a material is linked with the use to which it is being put. For example, surgical stainless steel (316L) has adequate biocompatibility for the temporary fixation of devices, whereas the same material used in permanent orthopaedic implementation will fracture. Secondly, when materials are to be used in permanent fixation, sufficient functional strength must be maintained so as to withstand the mechanical stress applied to the material during the physiological demands of everyday life (Hench 1978).

2.3.2 Key Hole Surgery and Synthetic Ligaments

The techniques used up to the 1970s were aggressive to the soft tissue, and did not allow for repeatable and accurate results. Surgeons were now looking for alternate techniques. Historically, Lang (1903) was one of the first surgeons to use silk attached to the semitendinosus, without success. Corner (1914) used silver wire to augment the ACL. It was not until Rubin, Marshall and Wang (1975) developed a prosthetic ACL graft made of polyester that a true replacement was found. The 1980s brought a technological wave of development in ACL reconstruction, particularly in the area of synthetic ligaments.

The ideal type of synthetic ACL replacement graft should have a strength greater than or equal to the normal ACL. It should comply with the same standards as the original ACL, so that the synthetic graft can restore the normal kinematics and biomechanics of the knee joint. It should show no signs of wear or creep and be extremely durable.
Furthermore, the synthetic graft should be of a fibroblast nature, that allows the fibres to grow over it, therefore acting as a superstructure (Jackson, Heinrich et al. 1994).

As far back as 1958, Jenkins introduced carbon as a material to reconstruct the ACL. It was thought that the fibres of the carbon would act as a temporary scaffold, allowing the ligament to regrow by virtue of its fibroblast-simulating capabilities. Raw carbon fibre was used in ACL reconstruction, and was found to be inappropriate due to carbon fibre particles being randomly scattered throughout the knee (Rushton, Dandy et al. 1983). Clinical evaluation found that carbon had minimal fibroblast capabilities (Leyshon, Channon et al. 1984). Due to the lack of consistent evidence, the Federal Drug Administration (FDA) orthopaedic panel did not approve carbon fibre for this purpose in the United States of America: it did however continue in use in Europe and South Africa (Hunter).

As carbon fibre was disqualified in the United States, prosthetics and arthroscopy became the standard.

There were three classifications of synthetic ACLs: Prosthesis, Stent and Scaffold (Table 2.1).
### Table 2.1. Classifications of historical and contemporary ACL grafts.

(reproduced from Knee Surgery. F. Fu, C. Harner and K. Vince, Baltimore, Williams and Wilkins. 1: 812)

Permanent prosthetics are as strong when implanted as when manufactured, though they have limited potential for ingrowth. Such implants include the Gore-Tex ligament (McCarthy, Tolin et al. 1993) and the Stryker-Dacron ligament.

Scaffold prostheses are designed to encourage the ingrowth of tissue and allow the ingrowth of autogenous tissue – an example is the Leeds-Keio graft. This acts as a scaffold that collagen aligns to and grows on, forming a ligament for stable knee motion.

The stent prosthesis is used to transpose autogenous tissue and protect it as it matures. 3M™ make a ligament augmentation device, the ‘Kennedy LAD’ (Kennedy 1983). The use of these synthetic ligaments was rapidly taken up, as ACL surgery could be

<table>
<thead>
<tr>
<th>Classification</th>
<th>Historic</th>
<th>Contemporary</th>
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<tr>
<td>Prothesis</td>
<td>Silver</td>
<td>Gore-Tex</td>
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<tr>
<td></td>
<td>Silk</td>
<td>Dacron (Polyester)</td>
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<td></td>
<td>Polyflex (Polyethylene)</td>
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<tr>
<td></td>
<td>Proplast (Polyaramid/fluorinated ethylene propylene)</td>
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<td></td>
<td>Xenograft (Bovine collagen)</td>
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<tr>
<td>Scaffold</td>
<td>Carbon</td>
<td>Leeds-Keio (Polyester)</td>
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<tr>
<td></td>
<td>Dacron (Polyester)</td>
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</tr>
<tr>
<td>Stent</td>
<td>Carbon</td>
<td>LAD (Polypropylene)</td>
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performed with minimal trauma. However, towards the end of the ’80s there was a high rate of reported synovitis and subsequent rupture of the ligaments. The number of incidences of rupture increased to a level that required the synthetic technique to be abandoned (Johnson, Harner et al. 1994).

In 1918 Takagi developed the arthroendoscope (Kaplan and Fu 2002). In the 1970s instruments and techniques were developed and refined, but it was not until the 1980s that arthroscopic surgery became generally accepted. The orthopaedic community initially regarded arthroscopic surgery with some scepticism (Kaplan and Fu 2002), but its acceptance by patients, and the ability to document clinical results on video, led to widespread acceptance of the procedure. Since its acceptance, arthroscopy has become one of the most common procedures performed. In 2001 one million arthroscopies were performed in the United States alone (Kaplan and Fu 2002). In the 1980s metal interference screws were introduced for graft fixation. It was noted in a study by Kurosaka, Yoshiya and Adndrish (1987) that interference screws were the weak link for ACL graft fixation. The study showed that 9mm cancellous screws were superior at locating the ligament with regard to their alternative methods.

2.4 Modern Anterior Cruciate Ligament Surgery

Perhaps no other orthopaedic procedure has received more attention in the past 15 years than ACL reconstruction. Despite years of scientific, clinical research and millions of dollars from commercial industries, there is still no guaranteed solution to the reconstruction of an ACL injury. There have been improvements in surgical techniques, but there has been no complete solution to this problem (Harner 1996; Bell and Jackson 1999; Kaplan and Fu 2002).

During the 1990s one technique established itself as a leader in ACL reconstruction: this was the central one-third patellar tendon bone–tendon–bone graft.
Until this time, metal interference screws were the standard, but in 1990 bio-resorbable PGA (polyglycolic acid) and in 1992 PLA (polylactic acid) were introduced, due to their ability to be reabsorbed by the human body.

The competitive technique to one-third patellar tendon bone–tendon–bone grafts was the semitendinosus gracilis tendons graft. This was pioneered by Friedman (1988), who used a four-stranded hamstring autograft technique. This technique was adapted after a meeting of the American Academy of Orthopaedic Surgeons in Boston in 1993 (Howell 1993; Larson 1993; Pinczewski 1997). Pinczewski used either three or four strands of semitendinosus gracilis tendons with 8mm round-headed cannulated interference screws, called RCI screws (Smit+Nephew Donjoy).

2.4.1 Current Surgical Techniques

In 1994, 75,000 ACL reconstructions were carried out in the United States of America alone (Johnson, Harner et al. 1994). According to Harner (1996), 25 percent (18,750) of these operations had unsatisfactory results. These operations have stabilised to an approximate number of 50,000 ACL reconstructions in the United States annually (Kaplan and Fu 2002).

The successful location of the reconstructed ACL graft is dependent on many factors. This includes graft placement, tunnel location, tension and the nature of the tissue (allograft versus autograft) – see Chapter 3.

The rupture of an ACL occurs due to technical, mechanical or biological complications (Johnson, Harner et al. 1994), which should be taken into account when reconstructing the ruptured ligament. It has been shown that the replacement graft, either autograft or allograft, undergoes a sequence of biological remodelling in the areas of collagen, cellular, avascular and maturation (Arnoczky, Tarvin et al. 1982). This remodelling produces a loss in graft tensile strength. These changes cause the tendon to lose some of its characteristics and adopt those typically associated with ligaments. This change has
been termed ‘ligamentization’ (Amiel, Kleiner et al. 1986). Due to this change in graft structure, it is crucial that the ACL reconstruction be optimally positioned intraarticularly with regard to the original ACL sites.

The impingement caused by the intercondylar roof has been recognised as one of the common causes of ACL graft failure. Graft impingement is caused specifically by an anterior placement of the reconstructive tibial tunnel. Magnetic resonance imaging (MRI) examinations have shown grafts that are impinged actually became elongated. This suggests that roof impingement is one cause of progressive loosening of the ACL graft (Howell, Clark et al. 1991). This graft impingement has led surgeons to adopt the technique of roofplasty – ‘the physical removal of bone’. The removal of bone from the intercondylar notch prevents some of the impingement caused by the intercondylar notch on the ACL graft (Howell, Clark et al. 1991).

Nevertheless a roofplasty is not the single cure for graft impingement and accurate placement. A more appropriate and effective method is to ascertain the correct placement of the tibial tunnel and to avoid the necessity of a roofplasty. With this in mind, a more precise technique is to locate the geometry of the ACL so that it is in line with the anticipated tibial and femoral tunnel location.

2.4.2 Arthroscopic ACL Instruments

The primary role of ligament reconstruction operations including the ACL is to locate a replacement graft within the knee joint. This is achieved by creating two tunnels within the tibial and femoral bones.

Graft tunnels are required in order to locate the replacement ligament by means of a rigid construct.

The operations are performed with basically the same style/design of instrument. These instruments have a similar resemblance that has emerged from different manufacturers;
that is to say, the shape, structure and method of adjustment, as well as the technique of locating the tibial ACL origin including its graft tunnels, is the same. These instruments use a surgical technique called ‘Key Hole Surgery’ which involves an incision in the skin called a ‘portal’.

The instrument’s ACL location pin is inserted into the anteromedial portal and is visually positioned onto the sight of the ACL. Arthrex (1998) and Arthrotek (1998) are the exception to the rule, with their Transtibial ACL Reconstruction and One Step Tibial Guide systems respectively.

Arthrex (1998) locate the ACL origin with a pin that references the posterior cruciate ligament. This then places the tip of the pin in a close approximation, 7mm, with the isometric graft tunnel placement within the ACL site (Figure 2.6).

Arthrotek’s (1998) One Step Tibial Guide locates the distal aspect of the intercondylar notch. A modified hook design (Figure 2.7) is used to avoid graft impingement with the knee in full extension. This technique approximates the position of the tibial tunnel but does not stop an anterior tibial screw placement. This device also does not allow the surgeon to locate the 11 and 1 o’clock positions. This device is now known as the Howell 65° Tibial Guide (Arthrotek 2002).
Figure 2.6. Tibial tunnel length analysis.

All of these arthroscopic ACL reconstruction instruments rely on arthroscopic visualisation within the intraarticular joint and, more importantly, involve user-orientated decision processes that are oriented around repeatedly locating an angle with no visible anatomic reference points.

The technique of using an arthroscope to visualise the anatomy within the knee is a skill that relies totally on the expertise of the orthopaedic surgeon. A study by Kohn, Busche and Cans (1995) involved a group of 48 leading orthopaedic surgeons who were all proficient in ACL reconstructions (500+ operations). These surgeons were retrained in the technique of ACL reconstruction in lectures and then on knee simulators. After this advanced refresher course the surgeons were then required to reconstruct a cadaver knee. These cadaver knees were reviewed and examined for correct ACL graft placement. Out of the 48 surgeons, four reconstructed the ACL to the level required; the remaining surgeons made errors in some way or another. Sommer, Friederich and Muller (2000) reiterate the complex nature of ACL reconstruction. They state that ‘…it has not yet been possible exactly to replicate the normal ACL and its function because of its complex fibrous
architecture.’ They demonstrate that this surgical technique remains difficult due to femoral tunnel positioning, and advocate the use of radiographs (image guidance).

Sudhahar, Glasgow and Donell (2004) also discuss in their study that the ideal tibial tunnel position is still controversial, and they recommend that before surgeons operate on the tibial tunnel image guided intraoperative confirmation of the device position would be helpful.

From the above it is apparent that the current method of visualising or ‘eyeballing’ the geometry of the knee relying solely on arthroscopic means, is an inefficient way of reconstructing an ACL. A more effective method is required that can easily locate the anterior and posterior attachment zones of the native ACL.

### 2.5 Computer Aided Surgery

Like the rapid take-up in the ’80s of graft substitutes and technique, a natural sequence for ACL surgery has been, and remains through the use of computer technology.

There are two main types of computer aided orthopaedic surgery (CAOS) devices. The main difference is in the location method. These are Stereotactic (open system) or Magnetic Sensor (closed system) methods that allow the computer system to locate the instrumentation’s position. It should be noted that CAOS systems were not in general use for ACL surgery at the time of thesis write-up.

### 2.6 Conclusion

ACL reconstruction techniques have improved knee joint function, including the full range of motion in ACL deficient knees. The earlier a knee is rehabilitated, no matter what type of reconstructive technique is used, the quicker the knee will recover from the surgery.
The most elusive area in ACL reconstruction has been and still is the correct anatomic placement of the drill holes (tunnels). This occurs mainly in the tibia, but also in the femur due to incorrectly sited anatomical sites.

The method of surgically reconstructing the ACL intraarticularly through portals (key holes) has provided an improvement over open wound procedures, but it does not address the problem of accurately aligning the tibial and femoral graft tunnels, or the true placement of the graft under arthroscopic control.

The use of arthroscopic ACL equipment or devices involves a relatively steep learning curve. This is true in terms of locating critical geometry that is internal to the knee joint. As yet, the common technique of reconstructing the knee’s ACL through arthroscopic dependent means is limited. These limitations have not enabled the postoperative knee to reach the same structural properties and integrity as that of the original ACL. This is mainly due to the incorrect anatomical placement of the tibial and femoral tunnels within the knee joint.

With this in mind it is imperative that the surgeon has a good understanding of the knee’s anatomy with a particular focus in the area of the ACL’s points of attachment. This is emphasised by Kohn, Busche and Cans (1995), Sommer, Friederich and Muller (2000).and Sudhahar, Glasgow and Donell (2004).
CHAPTER 3

Anatomy of the Knee

3.1 Introduction

The knee joint (tibiofemoral joint) is one of the major weight bearing joints in the human body. The lower limbs in human bipeds have evolved entirely for the purpose of propulsion, in which the knee plays the crucial role. The knee, unlike the hip and ankle, has few, if any, bony references, i.e. socket joint, as in the hip, to stabilise the knee during its articular motion. The knee is totally dependent on the ligaments and the surrounding muscles to provide a stable and continuous articular motion while the limb is active.

The lower limbs are comprised of two main bones, tibial and femoral. These are the largest bones in the human body. Under load, these bones have intense forces acting upon the articular surfaces of the joint. These forces are restrained through the ligaments, in particular the anterior cruciate ligament (ACL). The forces that are applied
during load are immense, and can surpass the resistive forces of the knees entire anatomy. Therefore, it is not uncommon, within a wide range of ages, to rupture or tear a cruciate ligament, in particular the ACL. This is a particularly common sporting injury amongst elite athletes. However, ACL damage is as common amongst lay as non-sporting people.

In order to gain an understanding of the structures and functions of the ACL, it is important to understand the internal (intraarticular) anatomy of the knee joint. This is particularly important for correct placement and location of anterior and posterior cruciate ligaments. These structures and functions are references to Sagittal, Coronal and Transverse planes of the human body (Figure 3.1).

![Figure 3.1. Human body – sagittal, coronal and transverse planes.](image)

3.2 Articular Surface Morphology

The femur and tibia are rigid structures from which the body produces active motion. The joint between these bones articulates in such a way that it guides and lubricates this motion.

The knee is the primary articulation point between the femur proximally and the tibia distally. This includes the patella, which articulates with the femur only. The femur and the tibia have in the coronal plane a valgus alignment of 4.9° (± 0.7°). This is referred to as the anatomic axis (Hsu, Himeno et al. 1990).

The mechanical axis is positioned between the centre of the femoral head and the intercondylar notch for the femur; and for the tibia it is placed in between the centre of the plateau and the centre of the plafond. The angle of the mechanical axis is varus at 1.2° (± 2.2°), irrespective of age or gender (Kettlekamp and Chao 1972). The femur’s articular surface is at about 85° to its sagittal plane and is valgus to the coronal plane. The articular surface of the tibial plateau is angled varus to the coronal plane at 1° (± 1.5°) in men, and 0.1° (± 1.7°) in women (Figure 3.2) (Kettlekamp and Chao 1972; Morland, Bassett et al. 1987; Hsu, Himeno et al. 1990).
3.2.1 Femur

The femur is a long bone, approximately 430mm in length. The upper articular surface is called the head, and the lower articular surface is comprised of femoral condyles (Figure 3.3). An understanding of the mechanical characteristics of the proximal femur is crucial when explaining how the forces resulting from biped motion are directed through the mechanical axes of the knee.
The distal femur is comprised of two condyles, the lateral and the medial, that articulate with the tibia. The condyles contact anteriorly with the tibia, and also articulate with the patella, locating the patella throughout the knee’s full Range of Motion (Figure 3.4)
The distal femoral condyles are directed posteriorly when the body is standing upright. The void between these condyles is the intercondylar notch ‘A’. When viewed from its end, the height of the lateral condyle ‘B’ is larger in size than the medial condyle ‘C’, and the articulation surface of the lateral condyle is flatter overall ‘B’. In contrast, the medial condyle’s articulation surface is curved ‘C’ (Figure 3.4). This difference in the lateral and medial condyles allows the knee to twist on itself as it reaches full extension. The anterior portions of the condyles are flatter in their curvature, which allows for weight bearing in an upright position.
3.2.2 Tibia

The articular surfaces of the tibia are approximately perpendicular to the sagittal axis of the tibia (Hsu, Himeno et al. 1990). The distal end of the bone articulates with the talus (anklebone) and the fibula. Proximally, the tibia consists of the entire articular surfaces of the knee, tibial plateau. In the transverse plane, the articular surface of the medial plateau and the lateral plateau is relatively flat. In the sagittal plane the medial plateau is concave ‘A’, and the lateral plateau is convex ‘B’ (Figure 3.5). These two articular surfaces are separated by an intercondylar eminence (a rounded projection on the bone). The ACL is attached to the mid-portion of the tibial intercondylar eminence ‘A’ (Figure 3.6).

![Figure 3.5. Tibial articular surface, right tibia.](from Grana, W. and R. Larson (1993). Function and Surgical Anatomy. The Knee, Form Function, Pathology and Treatment. Philadelphia, Pennsylvania, W. B. Saunders Company: 16.)
Figure 3.6. Anterior view knee at 90°, right knee.

3.3 Other Structures

3.3.1 Menisci

The articular surface of the tibia does not conform to the surfaces of the femoral condyles. In order to maintain an even cartilage pressure, the load across the joint needs to be spread evenly over the widest possible area of articular cartilage. This is accomplished within the knee by using menisci. The menisci are a semicircular (C shaped) fibrocartilaginous medium occupying the space in between the tibia and the femur, allowing the transmission of the mechanical forces of the femur on the tibia.

3.3.2 Ligaments

Ligaments are bands of dense collagenous tissue that run from bone to bone. The function of a ligament is to restrain normal and abnormal motion caused during knee articulation. The ligaments are not only different in anatomical locations but also in genetic makeup and in their mode of attachment. Ligaments appear to be similar to tendons, as their structures seem to be bands of dense collagenous tissue that contain little cellular material, and even tend to bear and resist linear loads. However, in reality ligaments are not entirely parallel in their collagen arrangement and have more elastin (a form of protein). This allows for a change in length without a large internal stress. This is different to tendons, which must efficiently transfer forces from muscles to bones (Amiel, Frank et al. 1984).

Ligaments also differ from one another with respect to the difference in ratio of collagen to cellular material, and in the appearance of the nuclei of the fibroblasts. The medial collateral ligament has fibroblasts that are more similar to those of the patellar tendon, whereas the ACL and posterior cruciate ligament have rounder and more abundant cells similar to those of articular cartilage (Amiel and Kuiper 1990).
With respect to the above, the reconstruction of the ACL (graft) needs to be of a higher strength and similar make-up. For this reason, the grafts of choice are: central one-third patellar tendon bone–tendon–bone, and semitendinosus hamstring.

### 3.3.3 Isometricity

As an articulated joint, the knee has a 135° range of motion. Due to this large range of articulation, the importance of isometric stability is crucial in relation to graft ligament function (Brantigan 1941; Grana and Larson 1993). The sagittal movement of the knee is described by the four-bar linkage (Figure 3.7). Referencing (Figure 3.7) the vertical line ‘A’ represents the longitudinal axis of the femur. The roof of the intercondylar notch is at a 40° angle to this axis ‘A’. Point ‘B’ represents the femoral attachment of the ACL; the other attachment is that of the posterior cruciate ligament ‘C’.

![Figure 3.7. Four bar linkage.](image-url)

The bar that connects the ends of these ligaments represents the tibial plateau. If a line is drawn using the lower bar as a straight edge, a series of lines can be drawn (shown at 5° intervals). The curve produced closely corresponds to the shape of the posterior section of the femoral condyles, therefore showing an isometric representation obtained by the ACL and posterior cruciate ligament.

Grana and Larson (1993) state:

'Some authors have challenged the crossed four-bar linkage explanation as too simplistic because of the rotational aspects of the knee motion. This concept does, however, emphasize the contributions that the cruciate ligaments make to one another in their stabilizing action’

The four-bar linkage is cited in order to show the relationship between the cruciate ligaments.

### 3.3.4 Cruciate Ligaments

The cruciate ligaments play a crucial role towards the function of the knee in between the tibia and the femur. Their arrangement and location seem to have determined the shape and form of the articulation between the tibia and femur (tibiofemoral articulation). The ligaments are named *cruciate* as they cross over in the centre of the knee. The ACL is located in an anterior direction in relation to its attachment to the femur and tibia, preventing anterior displacement of the tibia on the femoral condyles. The posterior cruciate ligament runs in a posterior direction from the femur to the tibia and prevents posterior movement of the tibia (Dickhaut and DeLee 1982).

#### Anterior Cruciate

From femur to tibia, the ACL originates from the lateral femoral condyle on its medial surface. At its attachment the ACL resembles a semicircular shape, being longer in one
direction than the other (Figure 3.8). With the knee in its extended position, the outer surfaces of the ACL are parallel to each other (Dodds and Arnoczky 1994).

The tibial attachment of the ACL is wedge shaped, blunt anteriorly and pointed posteriorly, with a lateral twist (Figure 3.9). The ACL is comprised of two functional bands, anterior and posterior, with the anterior portion of the ACL being tighter in flexion, and the posterior portion of the ACL being taut in extension (Jackson and Grasser 1994). This is a gentle transition between the femur and tibia throughout the range of flexion and extension (Figure 3.10).
Figure 3.9. ACL attachment position – tibial plateau.

3.4 Overall Approach to Ligament Surgery

3.4.1 Selection of Graft

There are three different types of graft available to the surgeon: autograft, allograft and prosthesis. These grafts can be patellar tendon bone–tendon–bone (BTB) or hamstring (autograft), patellar tendon (BTB), and hamstring or achilles tendon (allograft), Gore-Tex™ and Kennedy LAD™. Prosthesis can be either a complete replacement of the ACL or a ligament augmentation device. Ligament augmentation devices protect the graft during early postoperative reconstruction.
A comparative study was undertaken by Engebretsen, Benum, Fasting et al. (1990), which compared primary ACL repair, with ligament augmentation device, and central one-third patellar tendon (BTB) autograft ACL reconstruction. It was found that the patellar tendon (BTB) reconstructions were far superior to the other reconstructions. When pre- and postoperative tests were conducted (Lachman’s, pivot shift and KT-1000 tests), they further demonstrated that the patellar tendon significantly increased the articulation range of movement.

Autographs and allografts are the two types of biological grafts. Biological grafts are used as they have a close resemblance to the characteristics of the ACL in stiffness, ultimate load and energy absorption up to their failure rate. The normal tensile strength of the ACL is 2500 N (Woo, Hollis et al. 1991). Central one-third patellar tendon (BTB) grafts are the strongest autograft structure, at 2900 N at a 14mm width (Noyes, Butler et al. 1984). The patellar tendon (BTB) graft is the most popular choice for ACL reconstruction, followed by the double looped hamstring tendon. This has changed over the years with hamstring tendon techniques being favoured, as demonstrated by the greater attention given to them in the research literature. The performance of these two types of ligament grafts have been readily compared. A sample of seventy-two patients were monitored over a two year period and, it was found that there was no difference in performance between the two grafts (Marder, Raskind et al. 1991).

3.4.2 Placement of Graft

One of the most difficult and complicated steps in ACL reconstruction is the placement of the tibial tunnel exiting on the tibial plateau intraarticularly.

The placement of the graft is of crucial importance to a successful outcome. The key factor in determining the intraoperative placement of an ACL graft is the duplication of the original anatomic placement of the ACL and its ability to maintain the forces present in the knee. The original ACL is not entirely isometric, as it undergoes a change in strain and load (Sapega, Moyer et al. 1990), though the anteromedial portion of the
ACL undergoes less change in length and strain. It is this portion of the ACL that a reconstruction attempts to mimic.

The position of the attachment site of the ACL graft in relation to the intercondylar notch is of considerable importance. Placing the femoral tunnel either anteriorly or posteriorly on the intercondylar roof has two effects. When the femoral tunnel is placed anteriorly it results in the graft tightening, increasing graft length during articular motion. A posterior placement of the femoral tunnel results in a lax graft tension. Hence, if an anterior position is attained the ACL graft will tighten during flexion, and if the femoral tunnel is placed posteriorly the graft will tighten in extension (Penner, Daniel et al. 1988).

The position of the ACL graft is critical for accurate and reproducible location of the femoral tunnel. This can be checked by the use of an isometer, which measures change in length. However, this instrument should not be used as an absolute means of locating the femoral tunnel (Johnson, Beynnon et al. 1992). It was found that by referencing the point on either lateral femoral condyle at its intersection with the intercondylar roof, 11 or 1 o’clock, a near isometric position could be obtained (Penner, Daniel et al. 1988). The approximate position of graft attachment should be at the junction of the lateral wall and the intercondylar roof, approximately 11 o’clock for the right knee and 1 o’clock for the left knee.

The tibial tunnel is located at the anatomic position of the ACL at the tibial plateau. The tunnel must be placed in such a position that it does not interfere with the posterior cruciate ligament and so that the intercondylar notch does not impinge the ACL graft when in full extension. Notchplasty can alleviate the problems of impingement on the intercondylar roof and the lateral condyle. The likelihood of impingement when drilling the guide pin through the tibia can be checked by bringing the knee into full extension. If the graft is going to impinge it would be evident through the use of an arthroscope or X-ray.
3.5 Conclusion

The ACL is a complex structure both mechanically and structurally. Cruciate ligaments are responsible for resisting the majority of the force placed and transferred through the knee joint. The tibial and femoral bones at their proximal and distal ends respectively, have bony landmarks where the ACL attaches. This attachment occurs at the tibial plateau (Figure 3.9) and crosses over the joint to the intercondylar notch (Figure 3.8). The ACL graft twists through 180° when the knee articulates through its range of motion (Figure 3.10). The anatomical placement of the ACL on its landmarks is crucial and only varies 0.5–1mm in anatomical placement (Howell, Clark et al. 1991).

When reconstructing the ACL it is extremely important to be able to visually recognise the anatomy under arthroscopic visualisation. It was shown by Kone, Busche and Cans (1995) that even experienced surgeons found it difficult in one aspect or another to locate the correct tibial and femoral anatomical landmarks.

There is a requirement to locate ACL geometry via arthroscopic means. However, there is a necessity to use another technique (X-ray) in conjunction with the arthroscope. The author proposes an extraarticular approach to locate the ACL attachment points. Currently, there are systems that locate the ACL via arthroscopic and X-ray means. However, this technique only images the grafts position in one plane, and is an intraarticular technique (Klos, Habets et al. 1998).

In order to understand the theory of ligament reconstruction from Chapters 2 and 3 an appreciation of surgical practice is required. Chapter 4 discusses the contemporary styles of autograft ligament reconstructive surgery.
CHAPTER 4

Anterior Cruciate Ligament Reconstruction: Surgical Diagnostics and Techniques

4.1 Introduction

This chapter discusses the methods used to determine in the knee the presence of a positive instability of the anterior cruciate ligament (ACL). The reconstructive techniques used in contemporary orthopaedic surgery include ligament choice and tunnel location within the knee joint. There are various techniques and associated devices available to the orthopaedic surgeon. In order to gain an overview of the current techniques, the Arthrex Transtibial single incision ACL technique (Arthrex 1998) is described. This focuses on tibial and femoral tunnel location intraarticularly and concludes with the advantages and disadvantages of this type of technique.
Revision ACL reconstruction is the most complicated form of ligament surgery. This chapter discusses the types of failure caused by surgical technique including graft impingement, inadequate graft fixation, and most importantly, non-anatomic tunnel placements – both the tibial plateau and intercondylar notch. Conclusions are then drawn around the complex nature of ACL surgery and revision surgery, with a primarily focus on graft tunnel placement.

4.2 Types of Anterior Cruciate Ligament Rupture

There are principally two types of ACL tears: partial and complete. Partial tears represent 10–43 percent of all ACL injuries (Noyes, Mooar et al. 1989). Complete isolated tears of the ACL are accompanied with a full anterior instability of the knee. These acute ACL injuries have an associated meniscal injury in 60 percent of cases, and associated chrondral lesions in 20 percent of cases (Noyes, Mooar et al. 1989). The treatment of ACL injured knees depends on a number of factors. However, due to the complex nature of ACL surgery, this research will focus on chronic ACL ruptures that only involve complete reconstruction.

4.2.1 Symptoms

Patients with a chronic ACL deficient knee will seek medical attention because their knee will have one or more of the following symptoms: instability, pain or locking. Pain and swelling are the predominant symptoms associated with acute tears, whereas instability is the prime symptom with most of the chronic knees (Kurzweil and Douglas 1994).

4.2.2 Physical Examination

The examination for chronic ACL deficient knees is quite different to that for acute ACL deficiencies. The method of diagnosing a chronic condition is made easier as the patient is often aware of the instability of their knee. However, if a patient presents a
knee with a relatively new rupture of the ACL, diagnosis may prove difficult. This is due to pain, swelling, muscle spasm and the inability to relax the hamstring muscles. These can hide the presence of a chronic ACL rupture (Noyes, Bassett et al. 1980). Unless the knee has recently been given a significant amount of pain, the muscle can retract due to discomfort. Chronic ligament deficient knees have the most dramatic lachman and pivot shift test results.

4.2.3 Clinical Evaluation Preoperatively

Generally a movement or giving way will be visualised at the knee joint if the patient has a deficient ACL. The following techniques describe the more common methods employed by the orthopaedic surgeon to determine ligament status preoperatively:

**Pivot Shift Phenomenon**

The pivot shift is a clinical phenomenon that gives rise to the subjective complaint of 'giving way', a physical sign that can be induced during examination of the injured knee. Arnoczky (1983) and DeHaven (1980) report that 95 percent of anaesthetised patients have a positive pivot shift test.

The pivot shift is detected by an anterior shift of the lateral tibial plateau on the femoral condyles as the knee approaches full extension. As this occurs the knee suddenly contracts during flexion. The pivot shift has been described as being pathognomonic for an injury such as a failure of the ACL. There are four different variations of test that demonstrate the pivot shift phenomenon: the pivot shift test, Losee's test, the anterolateral rotatory instability test and the jerk test. These tests allow the surgeon to demonstrate the amount of anterior shift and the posterior reduction. This also occurs in relation to lateral tibial plateau slide on the lateral femoral condyles.

The testing of an acutely damaged ACL is difficult when using the pivot shift test, as the patient can become apprehensive, causing the hamstrings to become taut and reducing knee movement. This primarily led Noyes (Noyes, Bassett et al. 1980) to develop the
flexion rotation draw test. This test differs from the standard pivot shift test. The subluxation, a dislocation of the knee joint with bone ends misalign while the joint is still in contact. This is then induced by the weight of the thigh as the leg is held in 20 to 30° of flexion; this allows for neutral tibial rotation around the sagittal plane. The femur is allowed to move freely while it is forced to sublux and reduce. During examination the knee is also extended and flexed while applying an anterior force to the tibia. This allows the surgeon to visually check for anterior movement of the knee joint. This test is more subtle for the patient compared to the pivot shift test.

**Anterior Drawer Test**

The anterior drawer test is positive in 24 to 52 percent of ACL cases when performed in an un-anaesthetised patient with a torn ACL. In an acute case it is more reliable to perform the test under anaesthesia to reduce patient anxiety. A firm, anteriorly direct force is applied in order to determine the amount of anterior draw between the tibia and the femur, while the tips of the examiner’s thumbs feel the amount of draw present. The bent knee should always be viewed from the patient’s side to determine the amount of movement within the knee.

**Lachman’s Manoeuvre**

Lachman’s test is positive in 68 to 100 percent of un-anaesthetised knees with an acute ACL injury, and is constantly 90 to 100 percent positive in anaesthetised knees. However the examiner must be careful not to twist the tibia, as this decreases the amount of anterior draw during this type of test. An indisputable result is displayed when a positive anterior tibial movement is visible at the knee in relation to the femur. This positive test is associated with a characteristic mushy or soft ending felt by the surgeon.
4.3 **Anterior Cruciate Ligament Reconstruction**

There are numerous reconstructive procedures to choose from for ACL graft reconstruction. The most common of these is the endoscopic or single incision technique. The popularity of the technique is due to advancements in arthroscopy. This technique is less invasive than an open technique; however it is technically demanding and therefore requires a steep learning curve on the part of the surgeon. The following points outline the steps taken to achieve a successful ACL reconstruction:

4.3.1 **Arthroscopic Evaluation under Anaesthesia**

The primary goal in reconstructing the ACL is to re-establish the same anatomical position and amount of graft tension. Therefore as a matter of routine the knee is examined for instability. Normally this is a pivot shift.

4.4 **Tibial Tunnel**

4.4.1 **Intraarticular Position**

In determining the intraarticular tunnel position, the surgeon’s ability to locate the correct landmark within the ACL remnant on the tibial plateau, is crucial. With chronic ACL deficiencies there may not be a remnant stump of the ACL remaining, and therefore other landmarks must be used. Howell (Howell 1998) developed one of the most common techniques. This relies on locating the anterior margin of the posterior cruciate ligament and then proceeding anteriorly seven millimetres in order to locate the approximate centre of the ACL. The graft location on the tibial plateau needs to be just posterior of the intercondylar notch when in full extension, otherwise the intercondylar notch will impinge on the ACL graft. This can cause a loss in limb extension and eventually lead to failure of the graft (Howell, Clark et al. 1991).
4.4.2 Extraarticular Position

The overall length of the ACL graft determines the total length of the tibial tunnel length. The average length of a patellar tendon (BTB) graft is 100mm, though this varies between knee anatomies. Because of the differences in graft length, the desired length of the tibial tunnel must be calculated. This is obtained by dividing the graft’s total length into sections, then adding the known variables together and subtracting the total length of the graft. The known variables are the femoral tunnel length and the intraarticular length. These lengths are normally 25 to 30mm, and 30mm, respectively. This leaves between 45 and 40mm of graft for the tibial tunnel. This allows the tibial drill guide to be adjusted to the required drilling length, plus 5mm clearance to obtain a required tibial tunnel length of 40 or 45mm.

4.4.3 Drilling the Tibial Tunnel

Tibial tunnel drilling is undertaken with the assistance of an arthroscope in the anterolateral portal. The ACL location pin of the drilling instrument is inserted in the anteromedial portal. The site of the previous ACL is located visually with the use of an arthroscope, and the drill guide pin is positioned. The lower portion of the incision is retracted and the drill sleeve is placed on the tibial cortex medially to the tibial tubercle.

When the tibial drill sleeve is located, a Kirschner wire (K-wire) is inserted in the drill sleeve; the K-wire is then drilled into the tibial bone and advanced through to the instrument’s guide pin. Once the K-wire penetrates the preselected intraarticular position, the tibial drill guide sleeve and tip can be removed from the knee. The tibial tunnel is then reamed with a cannulated reamer of an appropriate size. The reamer produces a core of bone that is used to plug the holes that are left in the tibia and patella as a result of the patellar tibial bone graft harvesting (reference appendix C and D). The tibial tunnel is debrided intraarticularly to provide a clear view of the tunnel so that the graft can be passed easily.
4.5  Femoral Tunnel

4.5.1  Tunnel Selection

Specially designed instruments, femoral tunnel placement guides, are used to locate the K-wire in the correct anatomical position for femoral tunnel drilling (reference appendix C and D). The size of the tunnel is normally 9, 10 or 12mm. In order to place the guide correctly on the femur, the knee must be moved into 120° of flexion. This allows the femoral drill guide to be introduced in through the anteromedial portal and positioned in the over-the-top position so that the tip of the guide is flush with the lateral wall of the intercondylar notch, 30° from the sagittal line. In order to correctly position the guide for femoral tunnel drilling, it may be necessary to flex the knee through 15° in either direction, anterior or posterior.

4.6  Anterior Cruciate Ligament Graft Selection

The original ACL is a complex arrangement of fibres that are difficult to replace. The ACL comprises three fibrous bundles, but for simplicity, two bundles will be referred to as anteromedial and posterolateral. The posterolateral bundle contributes to 47 percent of the ACL’s total strength in relation to anteroposterior stability (Aims and Dawkins 1991). The fibres that make up the ACL are not entirely isometric. The fibrous bundles tighten at different points throughout the knee’s full range of motion, with the anteromedial tightening in extension and the posterolateral bundle tightening in flexion (Aims and Dawkins 1991). The restraint in ACL reconstruction is that the graft is only one bundle of fibres. This calls for correct isometricity of the drilled ACL tunnels intraarticularly.

One of the most common grafts is the central one-third patellar tendon (BTB) which has longitudinal fibres. The semitendinosus hamstring is becoming more accepted in
ACL reconstruction. This graft has no bone blocks and requires special screws that are soft threaded to locate the graft in the tunnels.

4.6.1 Autograft Properties

**Central One-third Patellar Tendon (BTB)**

The central one-third patellar tendon (BTB) graft is common, as it can be harvested through the one incision that is also used to locate and drill the tunnels for isometric graft placement. When the patellar tendon is removed, bone blocks are harvested from the Patella and the Tibia. These bone blocks are used in conjunction with screws, thus creating a secure bone–screw–bone fixation method (Kurosaka, Yoshiya et al. 1987). However, problems with patellar tendon (BTB) graft procedures can arise. The patella can fracture and the patellar tendon can rupture, but this is an uncommon occurrence (McCarrell 1983). If a second revision is required due to ACL rupture, a new graft harvesting site is required, such as the opposite knee, or an allograft.

**Semitendinosus**

Semitendinosus grafts are convenient, and are therefore becoming more common in knee surgery. The same patellar tendon (BTB) incision technique is utilised during graft harvesting, resulting in fewer complications (Cross, Roger et al. 1992). The graft is on the medial side of the knee, and is easily visualised for harvesting with a tendon stripper. However, incidence of patellofemoral pain has become a more common complaint. This phenomenon suggests that patellofemoral pain is associated more with arthroscopic invasion and ligament replacement than with ‘bone–tendon–bone block harvesting’ (Sgaglione, Warren et al. 1990).
4.7 Anterior Cruciate Ligament Surgical Technique

There are many companies that make ACL reconstruction instrumentation. The instruments work in similar ways, but vary when it comes to incisions, tendon removal, drill tunnel location and bone harvesting (reference appendix C and D for descriptions of similar methods).

This section describes the surgical technique developed by Arthrex™, a Transtibial™ single incision ACL reconstruction technique (Arthrex 1998). This technique involves the use of autograft tissue from the central one-third patellar tendon bone–tendon–bone (BTB) graft during the ACL reconstruction.

4.7.1 Open Harvesting of the Central One-third Patellar Tendon

The patient lies on their back with their affected knee bent to 90º (Figure 4.1). A single incision is made above the central position of the patella down to the tibial pes-ansirinus. The tendon is then cut with one of a selection of 8, 9, 10 or 11mm wide retrograde cutters. This action separates the central one-third portion of the patellar tendon from its patella attachment, down to the tibial bone. After the patellar tendon is cut, a tendon stripper is placed around the proposed graft and drawn down to free the graft of fat pad and remaining soft tissue.
4.7.2 Patellar Tendon Bone–Tendon–Bone Block Harvesting

A bone cutting block is chosen appropriate to the size of the retrograde cutter being used. The cutting block guide is then placed on the patella and two holes at 2mm intervals are drilled into it. These holes are predrilled for the graft guide suture. Fixation pins are placed into the drill guide holes within the bone block guide and are secured to the patella. This prevents the saw from deviating from its cutting path (Figure 4.2).
Figure 4.2. Bone block harvesting.


Oscillating saw blades are used to cut the patella in a precise line that forms a trapezoidal shaped bone block. The bone block cutting guide can also be used with electrocautery to mark an exact-sized bone block. This resects the soft tissue that can interfere with the bone block resection.

With the exception of the bone block guide, the tibial bone block is harvested in a similar way. This guide is inverted to allow for a proper tibial bone block resection.
4.7.3 Tibial Tunnel Drilling Length

To determine the length of tibial tunnel that can accommodate the tibial end of the bone block with sufficient room for interference screw fixation, the following calculations must be applied (Table 4.1).

| Overall length of graft measured after harvesting: | 90mm |
| Graft length in femoral tunnel: | -25mm (a) |
| Minimum graft length between femoral and tibial tunnels: | -25mm (b) |
| Required tibial tunnel length to accommodate graft: | 40mm (c) |

Table 4.1. Graft length and femoral tunnel depth calculation.


To simplify the calculations, the length of the tibial tunnel can be estimated by subtracting 50mm from the total graft length. The resulting figure is the length of the tunnel.

4.7.4 Reproducible Tibial Tunnel Placement based on referencing the Anterior Margin of the Posterior Cruciate Ligament

The Arthrex Adapture Guide, with its appropriate posterior cruciate ligament Orientated Placement (POP) Marking Hook for left or right knees, is placed through a standard anteromedial portal to locate the guide pin’s position and pin angle, at 7mm distance from the anterior margin of the PCL. This reproduces a constant anatomical graft tunnel that is impingement free (Figure 4.3).
Figure 4.3. Determining tibial tunnel length.


The Adapture calibrated guide pin sleeve is advanced to the calculated tibial tunnel length and is lowered until it contacts the tibia, 10mm above the pes-ansirinus. This anatomical site places the guide at the correct drilling angle so that it obtains sufficient tibial tunnel length to accommodate the graft and interference screw for fixation.

The guide pin Kirschner wire (K-wire) is drilled to the end of the pin simulator hook. The calibrated guide pin sleeve is removed and the Adapture Guide separated from the marking hook and guide pin. The POP marking hook is removed from the joint through the anteromedial portal.
4.7.5 Preparation of the Tibial Tunnel for Bone Core Harvesting

A Coring Reamer allows for the harvesting of a cylindrical bone core that is extracted from the tibial tunnel. This is used to graft bone to the bone harvesting sites. An appropriate 8, 9, 10 or 11mm diameter coring reamer is used to harvest the bone graft (Figure 4.4).

![Figure 4.4. Tibial tunnel preparation.](reproduced from Arthrex (1998). Transtibial ACL Reconstruction: Surgical Technique. Naples, Florida, USA, Arthrex: 8.)

The guide pin is removed and the appropriate-sized collared pin is inserted by hand into the guide pinhole. The coring reamer is inserted by hand over the pin collar. A power
drill is then attached to the coring reamer. Drilling without excessive force is required to avoid potential deviation of the coring reamer (Figure 4.5).

Figure 4.5. Tibial tunnel coring and preparation.


Once the coring reamer is extracted from the tibial tunnel, it is clamped, and the pin tapped with a mallet to push the harvested bone core from the end of the coring reamer. The bone core is cut in two equal parts and tapped into the patellar tendon bone graft harvesting sites.
4.7.6  Femoral Tunnel Placement

The Transtibial Femoral Guide references the over-the-top position with a constant 2mm back wall that accurately reproduces femoral tunnel placement. The knee is flexed between 70 and 80° during femoral guide positioning and guide pin drilling. The guide pin is drilled through the Transtibial Femoral Guide and exits the lateral thigh (Figure 4.6). A cannulated reamer of a preferred diameter is then attached to the power drill and reamed into the femur to a depth of 35mm. This tunnel accommodates the graft bone block (Figure 4.7).

Figure 4.6. Femoral tunnel location.

Graft passing sutures are placed into the eye of the pin, and the proximal end of the pin is pulled to pass the sutures through the tibial and femoral tunnels. The guide pin is grasped with pliers that pull the pin, and guide the graft through the tibial tunnel and femoral tunnel. Care must be taken to ensure that the graft does not twist inside the tunnels (Figure 4.8).
4.7.7 Accurate Guide Pin Placement for Femoral Interference Screw.

The knee is flexed to 30° greater than its position during femoral tunnel drilling, so that the femoral tunnel is parallel to the anteromedial portal. A tunnel notcher is placed through the anteromedial portal and inserted in between the graft bone block and the femoral tunnel. The notcher cuts a keyway in between the bone block and the femoral tunnel. This allows for the accommodation of a 2mm Nitinol guide pin that has a 25mm depth marking. The Nitinol guide pin is inserted at the 25mm marking (Figure 4.9).
4.7.8 Graft Protection during Screw Insertion

An appropriate sheathed interference screw is used: 6, 7 or 8mm in diameter, at a length of either 20 or 25mm. A cannulated screwdriver is inserted into the sheath and a screw is engaged. The screwdriver and sheathed screw are inserted over the Nitinol guide pin. The sheath protects the graft from inadvertent damage during screw insertion. The Arthrex cannulated interference fit screw has a rounded back end. This avoids graft abrasion near the bone plug interface at the femoral tunnel. An interference screw, 2mm in diameter smaller than the original drill tunnel, and equal in length to the bone block, is used for femoral and tibial fixation (Figure 4.10).
4.8 Revision Anterior Cruciate Ligament Surgery

Reconstruction of the ACL is now accepted as the treatment of choice for young active patients. However, depending on different variables, long-term results for failed ACL reconstructions have ranged from 5 to 52 percent (Shino, Inque et al. 1990; Howe, Johnson et al. 1991; Harter, Ostering et al. 1998). The factors that influence the failure of an ACL reconstructive procedure include non-anatomic tunnel placement, improper rehabilitation, graft tensioning, impingement and graft fixation.
4.8.1 Failures Caused by Surgical Technique

Errors can occur in the operating theatre during an ACL reconstruction. Whether or not these errors occur relates to the attitude and expectation of the orthopaedic surgeon. Johnson, Harner, Maday et al. (1994) report that these errors result in graft failure after ACL reconstruction. While non-anatomic tunnel placement is a clearly demonstrable cause of knee failure, other causes can be identified (Howell, Clark et al. 1991; Khalfayan, Sharkey et al. 1996). For example, arthroscopic vision, graft impingement, inappropriate graft tension, inadequate graft fixation and inappropriate patient behaviour. However, the primary focus of the present research is upon the former.

The inappropriate placement of either the tibial or femoral tunnels will result in excessive change in length of the graft as the knee is articulated through its full ROM. As the graft can only accommodate small changes in length, the graft will either cause the knee to articulate in a smaller ROM, or cause a lengthening of the graft (Howell, Clark et al. 1991; Ramano, Graf et al. 1993).

The aim in locating the femoral tunnel is not to be too far anterior, yet not be so far posterior that a cortical breakout occurs, leaving a 2mm cortical wall posteriorly. A tunnel that is placed too far anteriorly causes an excessive extension in the graft. Conversely, a tunnel that is too posterior will cause graft length changes in extension (Khalfayan, Sharkey et al. 1996).

The ideal placement for the graft on the tibia is the anteromedial footprint of the original ACL. Tibial tunnels that are placed too far anterior will affect graft tension and result in roof impingement by the intercondylar roof (Fullerton and Andrews 1984; Tanzer and Lenezer 1990). Tibial tunnels that are too posteriorly placed will affect graft tension in extension. This will also breach the PCL. Grafts that are too lateral or medial can impinge on the femoral condyles (Shino, Inque et al. 1990). However, graft impingement can be alleviated by properly positioning the tunnels and performing an adequate notchplasty (Howell, Clark et al. 1991).
4.8.2 Revision Tunnel Placement

Placement of the new tibial and femoral tunnels has been found to be the most technically demanding operation for the orthopaedic surgeon, and can require innovative solutions to complex problems. During surgery the placement of new tunnels is a most technically demanding technique. The old graft is debrided and as both borders of the existing tunnels need to be evaluated, a notchplasty is performed so that the knee can be properly visualised. Radiographs need to be taken so that the tunnels can be evaluated, and if they are found to be in a suboptimal position, new tunnels need to be drilled.

4.9 Conclusion

The selection of a graft for ACL surgery is a complex issue. There are advantages and disadvantages for each type of graft. Autografts are the first call for ACL reconstruction, as the tissue is from the host’s body, and has a faster incidence of healing. There are two allografts to choose from, central one-third patellar tendon (BTB) graft and semitendinosus graft. These grafts have different forms of morbidity, knee stiffness, quadriceps muscle weakness, patellar tendinitis and, in the latter, hamstring muscle loss and weak soft tissue fixation. Each technique has its own merits. The choice of technique will depend upon such factors as the surgical procedure favoured and the physical activities the patient will engage in following surgery.

There are still many technically challenging areas within ACL reconstruction surgery. In particular, there are problems with the misalignment of the tibial and femoral tunnels. These tunnels can be either too posterior or too anterior, the latter causing graft impingement due to insufficient notchplasty (Kohn, Busche et al. 1995). Surgeons are not yet able to reliably locate the internal locations through which the ACL graft passes through the knee.
Chapter 5 introduces an iterative design process utilised to develop and prototype an external device for locating the internal attachment points of the ACL.
CHAPTER 4

Anterior Cruciate Ligament Reconstruction: Surgical Diagnostics and Techniques

4.1 Introduction

This chapter discusses the methods used to determine in the knee the presence of a positive instability of the anterior cruciate ligament (ACL). The reconstructive techniques used in contemporary orthopaedic surgery include ligament choice and tunnel location within the knee joint. There are various techniques and associated devices available to the orthopaedic surgeon. In order to gain an overview of the current techniques, the Arthrex Transtibial single incision ACL technique (Arthrex 1998) is described. This focuses on tibial and femoral tunnel location intraarticularly and concludes with the advantages and disadvantages of this type of technique.
Revision ACL reconstruction is the most complicated form of ligament surgery. This chapter discusses the types of failure caused by surgical technique including graft impingement, inadequate graft fixation, and most importantly, non-anatomic tunnel placements – both the tibial plateau and intercondylar notch. Conclusions are then drawn around the complex nature of ACL surgery and revision surgery, with a primarily focus on graft tunnel placement.

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knee with a relatively new rupture of the ACL, diagnosis may prove difficult. This is due to pain, swelling, muscle spasm and the inability to relax the hamstring muscles. These can hide the presence of a chronic ACL rupture (Noyes, Bassett et al. 1980). Unless the knee has recently been given a significant amount of pain, the muscle can retract due to discomfort. Chronic ligament deficient knees have the most dramatic lachman and pivot shift test results.

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There are numerous reconstructive procedures to choose from for ACL graft reconstruction. The most common of these is the endoscopic or single incision technique. The popularity of the technique is due to advancements in arthroscopy. This technique is less invasive than an open technique; however it is technically demanding and therefore requires a steep learning curve on the part of the surgeon. The following points outline the steps taken to achieve a successful ACL reconstruction:

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The primary goal in reconstructing the ACL is to re-establish the same anatomical position and amount of graft tension. Therefore as a matter of routine the knee is examined for instability. Normally this is a pivot shift.

4.4  Tibial Tunnel

4.4.1  Intraarticular Position

In determining the intraarticular tunnel position, the surgeon’s ability to locate the correct landmark within the ACL remnant on the tibial plateau, is crucial. With chronic ACL deficiencies there may not be a remnant stump of the ACL remaining, and therefore other landmarks must be used. Howell (Howell 1998) developed one of the most common techniques. This relies on locating the anterior margin of the posterior cruciate ligament and then proceeding anteriorly seven millimetres in order to locate the approximate centre of the ACL. The graft location on the tibial plateau needs to be just posterior of the intercondylar notch when in full extension, otherwise the intercondylar notch will impinge on the ACL graft. This can cause a loss in limb extension and eventually lead to failure of the graft (Howell, Clark et al. 1991).
4.4.2 Extraarticular Position

The overall length of the ACL graft determines the total length of the tibial tunnel length. The average length of a patellar tendon (BTB) graft is 100mm, though this varies between knee anatomies. Because of the differences in graft length, the desired length of the tibial tunnel must be calculated. This is obtained by dividing the graft’s total length into sections, then adding the known variables together and subtracting the total length of the graft. The known variables are the femoral tunnel length and the intraarticular length. These lengths are normally 25 to 30mm, and 30mm, respectively. This leaves between 45 and 40mm of graft for the tibial tunnel. This allows the tibial drill guide to be adjusted to the required drilling length, plus 5mm clearance to obtain a required tibial tunnel length of 40 or 45mm.

4.4.3 Drilling the Tibial Tunnel

Tibial tunnel drilling is undertaken with the assistance of an arthroscope in the anterolateral portal. The ACL location pin of the drilling instrument is inserted in the anteromedial portal. The site of the previous ACL is located visually with the use of an arthroscope, and the drill guide pin is positioned. The lower portion of the incision is retracted and the drill sleeve is placed on the tibial cortex medially to the tibial tubercle.

When the tibial drill sleeve is located, a Kirschner wire (K-wire) is inserted in the drill sleeve; the K-wire is then drilled into the tibial bone and advanced through to the instrument’s guide pin. Once the K-wire penetrates the preselected intraarticular position, the tibial drill guide sleeve and tip can be removed from the knee. The tibial tunnel is then reamed with a cannulated reamer of an appropriate size. The reamer produces a core of bone that is used to plug the holes that are left in the tibia and patella as a result of the patellar tibial bone graft harvesting (reference appendix C and D). The tibial tunnel is debrided intraarticularly to provide a clear view of the tunnel so that the graft can be passed easily.
4.5 Femoral Tunnel

4.5.1 Tunnel Selection

Specially designed instruments, femoral tunnel placement guides, are used to locate the K-wire in the correct anatomical position for femoral tunnel drilling (reference appendix C and D). The size of the tunnel is normally 9, 10 or 12mm. In order to place the guide correctly on the femur, the knee must be moved into 120° of flexion. This allows the femoral drill guide to be introduced in through the anteromedial portal and positioned in the over-the-top position so that the tip of the guide is flush with the lateral wall of the intercondylar notch, 30° from the sagittal line. In order to correctly position the guide for femoral tunnel drilling, it may be necessary to flex the knee through 15° in either direction, anterior or posterior.

4.6 Anterior Cruciate Ligament Graft Selection

The original ACL is a complex arrangement of fibres that are difficult to replace. The ACL comprises three fibrous bundles, but for simplicity, two bundles will be referred to as anteromedial and posterolateral. The posterolateral bundle contributes to 47 percent of the ACL’s total strength in relation to anteroposterior stability (Aims and Dawkins 1991). The fibres that make up the ACL are not entirely isometric. The fibrous bundles tighten at different points throughout the knee’s full range of motion, with the anteromedial tightening in extension and the posterolateral bundle tightening in flexion (Aims and Dawkins 1991). The restraint in ACL reconstruction is that the graft is only one bundle of fibres. This calls for correct isometricity of the drilled ACL tunnels intraarticularly.

One of the most common grafts is the central one-third patellar tendon (BTB) which has longitudinal fibres. The semitendinosus hamstring is becoming more accepted in
ACL reconstruction. This graft has no bone blocks and requires special screws that are soft threaded to locate the graft in the tunnels.

4.6.1 Autograft Properties

Central One-third Patellar Tendon (BTB)

The central one-third patellar tendon (BTB) graft is common, as it can be harvested through the one incision that is also used to locate and drill the tunnels for isometric graft placement. When the patellar tendon is removed, bone blocks are harvested from the Patella and the Tibia. These bone blocks are used in conjunction with screws, thus creating a secure bone–screw–bone fixation method (Kurosaka, Yoshiya et al. 1987). However, problems with patellar tendon (BTB) graft procedures can arise. The patella can fracture and the patellar tendon can rupture, but this is an uncommon occurrence (McCarrell 1983). If a second revision is required due to ACL rupture, a new graft harvesting site is required, such as the opposite knee, or an allograft.

Semitendinosus

Semitendinosus grafts are convenient, and are therefore becoming more common in knee surgery. The same patellar tendon (BTB) incision technique is utilised during graft harvesting, resulting in fewer complications (Cross, Roger et al. 1992). The graft is on the medial side of the knee, and is easily visualised for harvesting with a tendon stripper. However, incidence of patellofemoral pain has become a more common complaint. This phenomenon suggests that patellofemoral pain is associated more with arthroscopic invasion and ligament replacement than with ‘bone–tendon–bone block harvesting’ (Sgaglione, Warren et al. 1990).
4.7 Anterior Cruciate Ligament Surgical Technique

There are many companies that make ACL reconstruction instrumentation. The instruments work in similar ways, but vary when it comes to incisions, tendon removal, drill tunnel location and bone harvesting (reference appendix C and D for descriptions of similar methods).

This section describes the surgical technique developed by Arthrex™, a Transtibial™ single incision ACL reconstruction technique (Arthrex 1998). This technique involves the use of autograft tissue from the central one-third patellar tendon bone–tendon–bone (BTB) graft during the ACL reconstruction.

4.7.1 Open Harvesting of the Central One-third Patellar Tendon

The patient lies on their back with their affected knee bent to 90° (Figure 4.1). A single incision is made above the central position of the patella down to the tibial pesansirinus. The tendon is then cut with one of a selection of 8, 9, 10 or 11mm wide retrograde cutters. This action separates the central one-third portion of the patellar tendon from its patella attachment, down to the tibial bone. After the patellar tendon is cut, a tendon stripper is placed around the proposed graft and drawn down to free the graft of fat pad and remaining soft tissue.
4.7.2 Patellar Tendon Bone–Tendon–Bone Block Harvesting

A bone cutting block is chosen appropriate to the size of the retrograde cutter being used. The cutting block guide is then placed on the patella and two holes at 2mm intervals are drilled into it. These holes are predrilled for the graft guide suture. Fixation pins are placed into the drill guide holes within the bone block guide and are secured to the patella. This prevents the saw from deviating from its cutting path (Figure 4.2).
Oscillating saw blades are used to cut the patella in a precise line that forms a trapezoidal shaped bone block. The bone block cutting guide can also be used with electrocautery to mark an exact-sized bone block. This resects the soft tissue that can interfere with the bone block resection.

With the exception of the bone block guide, the tibial bone block is harvested in a similar way. This guide is inverted to allow for a proper tibial bone block resection.
4.7.3 Tibial Tunnel Drilling Length

To determine the length of tibial tunnel that can accommodate the tibial end of the bone block with sufficient room for interference screw fixation, the following calculations must be applied (Table 4.1).

| Overall length of graft measured after harvesting: | 90mm |
| Graft length in femoral tunnel: | -25mm (a) |
| Minimum graft length between femoral and tibial tunnels: | -25mm (b) |
| Required tibial tunnel length to accommodate graft: | 40mm (c) |

Table 4.1. Graft length and femoral tunnel depth calculation.


To simplify the calculations, the length of the tibial tunnel can be estimated by subtracting 50mm from the total graft length. The resulting figure is the length of the tunnel.

4.7.4 Reproducible Tibial Tunnel Placement based on referencing the Anterior Margin of the Posterior Cruciate Ligament

The Arthrex Adapture Guide, with its appropriate posterior cruciate ligament Orientated Placement (POP) Marking Hook for left or right knees, is placed through a standard anteromedial portal to locate the guide pin’s position and pin angle, at 7mm distance from the anterior margin of the PCL. This reproduces a constant anatomical graft tunnel that is impingement free (Figure 4.3).
Figure 4.3. Determining tibial tunnel length.


The Adapture calibrated guide pin sleeve is advanced to the calculated tibial tunnel length and is lowered until it contacts the tibia, 10mm above the pes-ansirinus. This anatomical site places the guide at the correct drilling angle so that it obtains sufficient tibial tunnel length to accommodate the graft and interference screw for fixation.

The guide pin Kirschner wire (K-wire) is drilled to the end of the pin simulator hook. The calibrated guide pin sleeve is removed and the Adapture Guide separated from the marking hook and guide pin. The POP marking hook is removed from the joint through the anteromedial portal.
4.7.5 Preparation of the Tibial Tunnel for Bone Core Harvesting

A Coring Reamer allows for the harvesting of a cylindrical bone core that is extracted from the tibial tunnel. This is used to graft bone to the bone harvesting sites. An appropriate 8, 9, 10 or 11mm diameter coring reamer is used to harvest the bone graft (Figure 4.4).

![Figure 4.4. Tibial tunnel preparation.](image)


The guide pin is removed and the appropriate-sized collared pin is inserted by hand into the guide pinhole. The coring reamer is inserted by hand over the pin collar. A power
drill is then attached to the coring reamer. Drilling without excessive force is required to avoid potential deviation of the coring reamer (Figure 4.5).

![Figure 4.5. Tibial tunnel coring and preparation.](reproduced from Arthrex (1998). Transtibial ACL Reconstruction: Surgical Technique. Naples, Florida, USA, Arthrex: 10.)

Once the coring reamer is extracted from the tibial tunnel, it is clamped, and the pin tapped with a mallet to push the harvested bone core from the end of the coring reamer. The bone core is cut in two equal parts and tapped into the patellar tendon bone graft harvesting sites.
4.7.6 Femoral Tunnel Placement

The Transtibial Femoral Guide references the over-the-top position with a constant 2mm back wall that accurately reproduces femoral tunnel placement. The knee is flexed between 70 and 80° during femoral guide positioning and guide pin drilling. The guide pin is drilled through the Transtibial Femoral Guide and exits the lateral thigh (Figure 4.6). A cannulated reamer of a preferred diameter is then attached to the power drill and reamed into the femur to a depth of 35mm. This tunnel accommodates the graft bone block (Figure 4.7).

Figure 4.6. Femoral tunnel location.

Graft passing sutures are placed into the eye of the pin, and the proximal end of the pin is pulled to pass the sutures through the tibial and femoral tunnels. The guide pin is grasped with pliers that pull the pin, and guide the graft through the tibial tunnel and femoral tunnel. Care must be taken to ensure that the graft does not twist inside the tunnels (Figure 4.8).
4.7.7 Accurate Guide Pin Placement for Femoral Interference Screw.

The knee is flexed to 30° greater than its position during femoral tunnel drilling, so that the femoral tunnel is parallel to the anteromedial portal. A tunnel notcher is placed through the anteromedial portal and inserted in between the graft bone block and the femoral tunnel. The notcher cuts a keyway in between the bone block and the femoral tunnel. This allows for the accommodation of a 2mm Nitinol guide pin that has a 25mm depth marking. The Nitinol guide pin is inserted at the 25mm marking (Figure 4.9).
4.7.8 Graft Protection during Screw Insertion

An appropriate sheathed interference screw is used: 6, 7 or 8mm in diameter, at a length of either 20 or 25mm. A cannulated screwdriver is inserted into the sheath and a screw is engaged. The screwdriver and sheathed screw are inserted over the Nitinol guide pin. The sheath protects the graft from inadvertent damage during screw insertion. The Arthrex cannulated interference fit screw has a rounded back end. This avoids graft abrasion near the bone plug interface at the femoral tunnel. An interference screw, 2mm in diameter smaller than the original drill tunnel, and equal in length to the bone block, is used for femoral and tibial fixation (Figure 4.10).
4.8 Revision Anterior Cruciate Ligament Surgery

Reconstruction of the ACL is now accepted as the treatment of choice for young active patients. However, depending on different variables, long-term results for failed ACL reconstructions have ranged from 5 to 52 percent (Shino, Inque et al. 1990; Howe, Johnson et al. 1991; Harter, Ostering et al. 1998). The factors that influence the failure of an ACL reconstructive procedure include non-anatomic tunnel placement, improper rehabilitation, graft tensioning, impingement and graft fixation.
4.8.1 Failures Caused by Surgical Technique

Errors can occur in the operating theatre during an ACL reconstruction. Whether or not these errors occur relates to the attitude and expectation of the orthopaedic surgeon. Johnson, Harner, Maday et al. (1994) report that these errors result in graft failure after ACL reconstruction. While non-anatomic tunnel placement is a clearly demonstrable cause of knee failure, other causes can be identified (Howell, Clark et al. 1991; Khalfayan, Sharkey et al. 1996). For example, arthroscopic vision, graft impingement, inappropriate graft tension, inadequate graft fixation and inappropriate patient behaviour. However, the primary focus of the present research is upon the former.

The inappropriate placement of either the tibial or femoral tunnels will result in excessive change in length of the graft as the knee is articulated through its full ROM. As the graft can only accommodate small changes in length, the graft will either cause the knee to articulate in a smaller ROM, or cause a lengthening of the graft (Howell, Clark et al. 1991; Ramano, Graf et al. 1993).

The aim in locating the femoral tunnel is not to be too far anterior, yet not be so far posterior that a cortical breakout occurs, leaving a 2mm cortical wall posteriorly. A tunnel that is placed too far anteriorly causes an excessive extension in the graft. Conversely, a tunnel that is too posterior will cause graft length changes in extension (Khalfayan, Sharkey et al. 1996).

The ideal placement for the graft on the tibia is the anteromedial footprint of the original ACL. Tibial tunnels that are placed too far anterior will affect graft tension and result in roof impingement by the intercondylar roof (Fullerton and Andrews 1984; Tanzer and Lenezer 1990). Tibial tunnels that are too posteriorly placed will affect graft tension in extension. This will also breach the PCL. Grafts that are too lateral or medial can impinge on the femoral condyles (Shino, Inque et al. 1990). However, graft impingement can be alleviated by properly positioning the tunnels and performing an adequate notchplasty (Howell, Clark et al. 1991).
4.8.2  Revision Tunnel Placement

Placement of the new tibial and femoral tunnels has been found to be the most technically demanding operation for the orthopaedic surgeon, and can require innovative solutions to complex problems. During surgery the placement of new tunnels is a most technically demanding technique. The old graft is debrided and as both borders of the existing tunnels need to be evaluated, a notchplasty is performed so that the knee can be properly visualised. Radiographs need to be taken so that the tunnels can be evaluated, and if they are found to be in a suboptimal position, new tunnels need to be drilled.

4.9  Conclusion

The selection of a graft for ACL surgery is a complex issue. There are advantages and disadvantages for each type of graft. Autografts are the first call for ACL reconstruction, as the tissue is from the host’s body, and has a faster incidence of healing. There are two allografts to choose from, central one-third patellar tendon (BTB) graft and semitendinosus graft. These grafts have different forms of morbidity, knee stiffness, quadriceps muscle weakness, patellar tendinitis and, in the latter, hamstring muscle loss and weak soft tissue fixation. Each technique has its own merits. The choice of technique will depend upon such factors as the surgical procedure favoured and the physical activities the patient will engage in following surgery.

There are still many technically challenging areas within ACL reconstruction surgery. In particular, there are problems with the misalignment of the tibial and femoral tunnels. These tunnels can be either too posterior or too anterior, the latter causing graft impingement due to insufficient notchplasty (Kohn, Busche et al. 1995). Surgeons are not yet able to reliably locate the internal locations through which the ACL graft passes through the knee.
Chapter 5 introduces an iterative design process utilised to develop and prototype an external device for locating the internal attachment points of the ACL.
CHAPTER 5

The Process of Designing a Surgical Instrument for Anterior Cruciate Ligament Reconstruction: Phase 1

5.1 Introduction

This chapter describes the design requirements of this project as an unfolding and non-linear process. The initial concept evolved through a series of developmental stages. These stages were complex, incorporating not only the technology of the mechanical device, but also human factors representing surgical performance and usability. In other words, the device needed to be suitable for application by a surgeon for a wide range of knee sizes and compatible with x-ray. Each stage represents an initial set of design requirements; some of these requirements were solved and others only partially solved. In seeking to meet the requirements, an additional set of problems frequently arose that
were not foreseeable. Therefore, additional design requirements were set in place that directed the subsequent stages.

An initial prototype is discussed that confirms the ability to externally locate the anterior cruciate ligament (ACL). Subsequent prototypes are developed that look at creating an external device (surgical instrument) and limb support to fix the limb in space during surgery.

5.2 The Design Process

Product and engineering design development has been described as complex in both method and process (Eisentraut 1999; Smith and Morrow 1999). This is due to the diverse nature of design methodologies and their applications to large-scale systems, in this case a surgical instrument and its surgical operating theatre environment.

According to Oxman (2004), it is important to introduce design knowledge acquisition methods that move beyond the idea that the more knowledge one gains the more skill one will acquire. The designer needs to move toward an understanding of where to obtain information and how to apply it in various situations. Designers need to be able to use their ‘thinking skills’ within the complex problems at hand.

Smith and Morrow (1999) discuss the complex nature of product development through an understanding of various product development processes. They argue that if designers can understand the common features of these various processes, they will better adapt a specific process for the task at hand. Eisentraut (1999) also describes the importance of designers being able to flexibly adopt different product development processes and apply the ones that best meet their task. This could be referred to as a hybrid approach to the design process (Sivaloganathan, Shahin et al. 2000).
A variant hybrid approach was utilised to design an orthopaedic device for ACL reconstruction. This hybrid approach allows alternate methods to be used as appropriate to the specific design problem.

Smith and Morrow’s (1999) extensive review focuses more on design management, and shows that various processes are concerned with the time that it takes to complete tasks. This thesis does not seek to use time constraints as a parameter, but rather focuses on the use of development processes themselves.

The particular processes of design can be framed within a number of main areas. These are: Creativity, Design Criteria, Analysis and Iteration. These processes become more intertwined as the complexity increases within the iterative process of product development.

5.2.1 Creativity

Most designers would say that the action of designing is a creative process. However, designers rarely appear to link between the distinct areas of thinking and sketching. Oxman (1999) stresses the importance of cognitive processes that link visual reasoning and conceptual processes. This link is essential if a clear direction is to be explored through design creativity. Designers must be able to clearly define sets of cognitive criteria to allow for clear reasoning. Conceptual visual reasoning is undertaken through sketching, and is one of the most important aspects of design communication (Purcell and Gero 1998; Rodgers, Green et al. 2000). Design sketches are used to visualise possible avenues for design criteria.

5.2.2 Design Methods: Theory Based Approach

The process of designing a device for ACL surgery required an understanding of unknown environments, surgical operating theatres and their procedures. In order to undertake this process, various design methods were discussed and utilised.
**User Centred Design**

In order to understand what happened in such environments, narrow samples of participants were interviewed, which allowed for an insight into their tasks within the operating theatre. This type of process is called User Centred Design. Sanders (2002) also describes this as Participatory Design: *‘It is a shift in attitude from designing for users towards one of designing with users.’* The social sciences also refer to this as qualitative participant observation (Adler and Adler 1994).

These processes occurred with orthopaedic surgeons (direct users) and theatre staff (indirect users), allowing an understanding to be gained of these types of environments.

**Scenario Based Design Process**

The initial stages of the design process are complex and require a clear strategy in order to identify design criteria. One approach is through the use of designed scenario tools. The process and application of the tools for scenario-based design have mainly been described within the field of human–computer interaction and software engineering (Carroll 1995). However, this is no longer the case with the integration of scenario-based design within the broader design community (Spreenberg, Salomon et al. 1995).

Carroll (1995) describes a scenario as being both meaningful and discussable by users: the scenario is an inherent part of people’s experience within their own understanding of their behaviour. Carroll argues that scenarios contrast with traditional functional analyses and their specifications: scenarios allow for the building of object-orientated models that allow users to create novel ideas.

*‘Scenario-based design is not a finished paradigm, a shrink-wrapped methodology, ready for passive consumption. It is, rather, a set of perspectives and approaches, linked by a radical vision of the use-orientated design. It is a set of case studies that will, and ought to, raise more questions than they settle.’* (Carroll 1995).
Design scenarios are increasingly referred to in participatory design as tools that make connections between people’s experience with products or services. Gage and Kolari (2002) discuss how new tools have emerged for defining participatory experience. These tools allow stakeholders to identify the correct ‘touch points’ or ‘key criteria’ through the use of scenarios. Gage and Kolari (2002) argue that these tools directly promote connections with the users in such a way that they inform participatory design teams (Connell, Jones et al. 1997).

Participatory design is an ethnographic tool allowing researchers to observe the actions of participants. These ethnographic tools allow the participants to play an active role in the development of systems through understandings of their tacit knowledge. The user centred tools were employed to determine how the operating theatre functioned at two different levels – surgical theatre nurses and theatre orderlies. The data were collected via discussions and observations. It was determined that only the role of the surgical nurse would be considered due to a direct working relationship. All other staff’s interaction was peripheral and would be called upon when required. Beyond the ACL Instrument Kit the surgeon or surgical nurse would request all devices and ancillary objects required. Therefore an understanding the implicit needs of the surgeon and the surgical nurse was critical.

**Universal Design Process**

Universal design focuses on users and how products can be used intuitively without the need for the user’s experience, knowledge or language skills (Connell, Jones et al. 1997). This process was pioneered by the Center for Universal Design, North Carolina State University (2001) in the mid to late 1990s.

Connell, Jones and Mace et al. (1997) describe the universal design process as a set of seven principles:
1. Equitable Use
2. Flexibility in Use
3. Simple and Intuitive
4. Perceptible Information
5. Tolerance for Error
6. Low Physical Effort
7. Size and Space for Approach and Use.

‘...Principles of Universal Design address only universally usable design, while the practice of design involves more than consideration for usability. Designers must also incorporate other considerations such as economic, engineering, cultural, gender, and environmental concerns in their design processes. These Principles offer designers guidance to better integrate features that meet the needs of as many users as possible.’

Universal design not only collectively focuses on the previous seven principles; it can be said that it is primarily concerned with including people who require specialised design. This is described by (Connell, Jones et al. 1997; Kahwaji 2002; Ringholz 2003). However Ringholz (2003) describes the important shift from ‘disability-centred’ design (design for one) including assistive, adaptive, barrier free and trans-generational towards a user-centred process (design for all). Well, almost everyone! Universal design is not a complete shrink-wrap methodology. It does try to cater for all. Ringholz (2003) gives the following example:

‘...a head phone jack may be required for a blind user to interface with an ATM. That feature allows other users to adjust auditory output to a suitable volume, block out background noise, and keep sensitive information confidential.’

The design professions and interdisciplinary teams now utilise the tools of universal design. Universal design processes were considered essential in determining the design criteria for the development of an orthopaedic instrument.
5.2.3 Design Processes: Analysis, Iteration and Application

Products are normally designed in two differing ways. One is concerned with advancing and reframing an existing product (Conventional and Systematic); the other is concerned with acquiring new knowledge and innovation (Hybrid). Both of these processes involve the application of emerging ideas, user requirements and emerging technologies, to name just a few.

**Conventional Process**

The conventional process is a concept of experience based learning. It relies on the skill of the designer/team and is a highly subjective process (Uluoglu 2000). This process of designing involves the interpretation of a design brief. This brief contains a basic set of criteria that the client requires the designer to address. Market research is accumulated to define a perception of the types of products available, to establish specifications and constraints. Initial design criteria are arrived at and the loose framework of designing occurs. This loose framework has been described in various ways, from a bubble analogy to a noodle soup respectively (Ashby and Johnson 2002; Whitfield 2004), due to its ad hoc nature. Ashby and Johnson (2002) describe a design/development/detail design model as an analogy of bubbles – the ‘bubble analogy’ (Figure 5.1).

‘…each bubble represents a step in the design process… There is no linear path from the initial “design brief” to the final “product specification” instead, many paths link the thousands of bubbles that lie between them. It is important to get into the initial bubble – to confront the problem. But there is no identified path from that bubble to the final bubble…’
Designers undertake such processes during product development within studio practice. The processes that occur through concept development are explored through the ‘testing of ideas’. An iterative process of design is undertaken to refine the designs and prototype models that are built. This is a conventional iterative process of design, and it occurs until the product addresses the final set of criteria. This outcome can be called ‘new design knowledge’, and as a rule is recognised at the final design and manufacturing stage (Figure 5.2).
Figure 5.2. Conventional design process.
The bubble analogy process is a valid representation of the conventional design process. However, like its metaphorical representation the ‘soap bubbles’, the act is somewhat random and difficult to chart. This is due to the fact that bubbles disappear over time as one transitions forward within the knowledge acquisition process, making it hard to retrace the process. Designers tend to have looser approaches to theory based approaches. A hybrid design approach seeks to overcome this limitation.

**Systematic Process**

The systematic approach to design is best applied when an existing product requires change. This is true when changes to form or function are required, as the systematic process breaks an existing product down into its essential elements or activities, creating a theory based approach to form design (Tjalve 1979).

Tjalve (1979) describes this form design as comprising two main methods:
(1) Structure Variation – the arrangement of elements, and (2) Form Variation – a set of four ‘variation parameters’: number, arrangement, form geometry and dimension. The variation parameters are defined in more detail through components and sub-assembly element arrangement. These groups then become unique specifications. Tjalve’s (1979) industrial design text is referenced in TuDelft and MIT design programs.

A function analysis can be performed that defines the apparent critical specifications for the design problem. From this analysis, the design is established and manufacturing methods are devised (Figure 5.3).
Figure 5.3. Systematic design process.
The systematic approach to design is scientific and engineering-like. Uluogiu (2000) describes it as inherently taking an objective approach to its outcome.

_Hybrid Process_

The hybrid design process is a subjective method that is continually in a state of flux. Within this approach to designing, sets of scenarios are devised that help define the product and its users (Rothenberg 1999). Market analysis or product placement is explored so that the product development is focused towards the consumer. The design team explores the scenarios with the users before the design process commences. Once the scenarios have been studied, the hybrid approach can be appropriately utilised. The combination of the conventional and systematic approaches that embody the hybrid approach is variable, and depends on the project. If the project has limited data, a conventional technique allows for a creative and experimental approach to be the principal tool to develop a knowledge base. Derived scenarios are then ordered from most to least important. This allows the designer to explore the individual avenues in order to un-code new and unforeseen data. This method allows the key data to form the foundation of the knowledge base.

The outcome of the hybrid approach is a specifically focused ‘knowledge base’. This knowledge base contains most of the centrally specific data obtained throughout the non-linear design process. The formation of ideas in this way is both conventional and systematic, and is structured within various subsets. These subsets are then approached in order of importance (Figure 5.4).
Figure 5.4. Hybrid design process.
5.3 Thesis Design Process

The process of design applied to an instrument for ACL reconstruction was a hybrid design process. This combines two approaches, one a conventional approach and the other systematic. These design approaches are applied where necessary to create a consistent knowledge base.

A hybrid approach was developed and utilised to design an orthopaedic device for ACL reconstruction. This hybrid approach allows alternate methods to be tested when contradictory data is present (Figure 5.5).
5.4 The Applied Design Process

In order to start the preliminary design, an initial idea or set of design requirements was required. This was informed by the literature review and formed the basic prerequisites for the surgical device. These prerequisites were supplemented by an understanding of operating theatre environments, participant observation and universal design principles. Through understanding the surgical environments and procedures, an initial set of design ideas was devised (Figure 5.6).

![Figure 5.6. Initial design research and UCD processes.](image)

5.4.1 Initial Design Requirements

The techniques used in ACL surgery have focused upon only one reference plane. An initial set of design requirements was as follows:

It was considered that two planes may better clarify positioning of the ACL. The location could occur with the use of two external wires that, under image intensification, locate the internal anatomical landmarks of the ACL.

The product must be sterilisable for each intended use over its functioning lifespan.

The sterile device must overcome problems of accessing the theatre table through sterile drapes (Steri-Drape).
Design requirement 1 was chosen as the first area of research. Requirement 2 was delayed, as the material, steel or plastic, would be determined at a later stage in the development process. At the early design stages, sheet steel would be the required material. Requirement 3 was initially delayed until further design development had occurred.

5.4.2 Initial Design

In order to establish if the method of two externally located wires could find the ACL visually using radiographic techniques (image intensification/ X-ray), a prototype device needed to be designed. A conventional approach to the design process was chosen, as no data were available to create design criteria. Figure 5.7 describes the process used.

To achieve this, mediolateral X-rays were cut in half and placed at various angles of flexion, varying from 60 to 100°. These angles were viewed by laying a straight wire across the two attachment points of the ACL. This wire was able to locate the two ACL attachment points through all angles of flexion and extension (0–120°) (refer to figure 3.7). It was observed that the ACL’s entrance and exit points within the tibial and
femoral bones were at their optimal location when the knee was at between 88 and 95°. The preferred angle of the knee was at $90^\circ \pm 2^\circ$ for the mediolateral view (Figure 5.8). In order to align the anteroposterior view, the knee was set at the preferred mediolateral angle, $90^\circ \pm 2^\circ$, and digital X-rays were imaged. These X-rays became the templates on which a thin wire was aligned between the two ACL attachment points (Figure 5.9). This wire aligned with the correct anatomical points, entering and exiting through the ACL’s intraarticular positions.

It was found that each individual wire was able to independently locate its respective ACL landmark on the tibia and femur. This established that independent mediolateral and anteroposterior X-rays could converge to form an intersecting plane, which could be centrally aligned within the intraarticular attachment points of the ACL.

The anatomy of the lower limb, soft tissue and bones, and their internal relationships, were studied (refer to chapter 3). The relationship between the upper portion of the tibia and the outer portion of the skin was of importance. It was found that the proximal portion of the tibia was placed so close to the surface of the skin that the bone profile is noted visually. This was confirmed with a transverse image from the Visible Human project (Center for Human Simulation 2000). The anterior portion of the tibia could also be felt through the skin by hand. It was postulated that perhaps a device could locate against this portion of the skin and tibial bone. This was reviewed and the following was found.
Figure 5.8. Sagittal section of Femur, showing ACL attachment and Tibial and Femoral bones at 90° of flexion.

A positive means of locating the device could be by fastening it against the tibia just below the tibial plateau. Cross-sectional views of the lower limb were analysed. The lower limb is relatively circular in shape, which lends itself to a C-shaped device that can be located against the tibia and clamped tightly, thereby containing the soft tissue (Figure 5.10).
A C-shaped device was subsequently designed that allowed for separate anteroposterior and mediolateral wire attachments (Figure 5.11). This device was prototyped in a ‘right leg only’ configuration and was X-ray tested with a human subject.

The mediolateral wire was angled at 60–63° to the horizontal (transverse) plane. This angle approximated the correct relationship between the mediolateral wire and the lateral margins of the ACL as found with X-ray testing (Figure 5.9).
Figure 5.11. Prototype No1, top & side projections.
Chapter 3 discussed the importance of the drill referencing an angle to the sagittal plane. This angle is described in the literature as being 30°. When referenced to the knee, this is identified as the 11 o’clock and 1 o’clock position for the right and left knees respectively. This angle sufficiently optimises the location of the ACL and creates an articular attachment point that is referred to as an optimised ‘isometric’ length throughout its articulation. Therefore, in order to locate the anteroposterior margins of the ACL, the wire must line up with the optimum attachment points at 30° for left and right knees.

In order to trial this idea, a rigid cardboard mock-up was profiled, which when bent in a circular fashion conformed to the required C shape (Figure 5.10). This mock-up was then placed around a limb and tested for its stability. The rigid cardboard mock-up was found to be unstable, as it tended to rotate around the calf muscle. Tabs were added to the ends of the mock-up, to give more reliable support and location within the soft tissue regions around the calf muscle. The device was fastened to the limb with Coban™. Coban allows the device to be strapped securely without the need for any secondary fasteners, as the Coban bonds to itself without leaving any residual glue. It was also found that the use of Transpore™ surgical tape was of more use to the surgeon if a wrap or tape was used as a device fastener to the limb. Transpore has a perforated surface that allows for an easy-to-tear action by tearing the tape at 90° to its length.

The C-shaped mock-up was prototyped in a steel material, which had rectangular profiled tabs added to its ends. These tabs were to resist soft tissue movement by increasing the contact area between the calf muscle and the tabs (Figure 5.12).
This prototype was informally tested in an operating theatre with a standard limb support. The limb was approximated to an angle of 90° in order to keep the limb at the required 90° ± 2°. With the limb support, the surgeon had to apply a force posteriorly at the ankle. The guide-wires were attached to the C-clip, and the assembly was then located to an approximate position under the tibial plateau. The C-clip was height-adjusted vertically under constant X-ray visualisation, and the appropriate position was located. This position was found to be approximately 55mm below the top of the tuberosity. X-rays were taken and the limb angle was adjusted according to the visual data presented on the X-ray screen. The X-rays were analysed and it was found that the anteroposterior wire needed to be adjustable so that the anatomical reference points of the ACL could be located correctly.

The C-arm was positioned laterally with the limb in 90° of flexion. The C-arm imaging head was placed at 0° to the transverse plane (refer to Figure 3.1), allowing for a clear lateral view of the knee with the wire in a relatively correct position (Figure 5.13). The Imaging Head of the C-arm was rotated through 90° parallel to the coronal plane and then swung anteriorly to approximately 45°. This allowed for a clear view of the intercondylar notch through an anteroposterior view. The anteroposterior guide-wire was out of alignment; an adjustment realigned this guide-wire to the marked line shown in (Figure 5.14), and allowed for an approximate view of the ACL.
Figure 5.13. Mediolateral X-ray, Prototype No1 with guide-wires.
5.4.3 Summary

Several prototypes underwent hybrid iteration during this developmental process (Figure 5.15).
Figure 5.15. Hybrid process and participant testing.

This process included the following product development changes:

- Profile variations.
- Tab slots for strap retention.
- An extension tab that adjusted one guide-wire assembly that included the mediolateral and anteroposterior wires.

The standard profile was inadequate as it allowed soft tissue movement to occur. The front profile of the C-clip was then revised so that it had a larger profile, and therefore more surface area. This solved most of the rocking movement on the anterior surface of the tibia, although the soft tissue could not be held sufficiently taut to eliminate soft tissue rotation around the tibia. To try and solve this problem, a fastening strap of some type was required with better structural properties than surgical tape. Various slots were profiled into the end tabs. This was trialled in six varying prototypes that resembled a style that mimicked a seat belt web retainer. These slots allow a rubber strap to be fed through and when fastened the C-clip would clamp tightly around the leg. This was more satisfactory, but the soft tissue still moved under the tightest fastening.

The C-clip demonstrated that two wires in a given external space could locate the attachment points of the ACL. The shape of the clip allowed for quick and easy access to locate the guide to the anterior region of the lower limb below the knee. Two wires were
easily attached to the C-clip, but were not easily adjusted to line up with the X-ray views, mediolateral and anteroposterior. If the anteroposterior wire had to be adjusted, the wire had to be unclipped. As this was performed the mediolateral wire would move out of alignment, due to the inability of the C-clip to immobilise soft tissue movement.

For these reasons a new design had to be envisaged that addressed the soft tissue problems and allowed for accurate positioning of the two wires.

5.5 Locating the Third Dimension

In order to accurately locate the ACL, its anatomical attachment points and its associated aspects, the structure and performance of the knee had to be carefully considered. After a thorough examination of the literature [covered in chapter 3 – Anatomy of the Knee], the anatomical position of the ACL was confirmed. It was found that the ACL does not lie parallel to the sagittal plane: it therefore does not align with a primary plane within the knee. The ACL is placed at an offset angle of $30^\circ$ to the sagittal plane (Figure 5.16).
From these observations the ACL was treated as a single three-dimensional entity that cannot be easily referenced to a primary plane or to a point in the knee, other than its attachment points at the tibial plateau and intercondylar notch.

Conventional instruments used for ACL reconstruction reference only one of the two ACL landmarks per hole drilled. These points of reference are at the device’s internal referencing tip, and locate the landmark required to drill one hole through the tibial plateau, the tuberosity and the approximated angle of the drill device. These two points are located as the instrument’s wire aligns these points, creating a straight path. This is a
relatively easy task to perform, as any two given points line up within a given space. The entry and exit points of the wire are predetermined when the two reference points are located.

When the two wires are observed from either the mediolateral or the anteroposterior view, the wires appeared to be parallel to one another. This was found to be true. Subsequent development occurred to prove this in relation to the converging planes.

In order to locate these points within a given space – ‘the knee joint’ – the relationships within this three-dimensional space had to be understood. It was found that the X- and Y-planes are at 90° to one other, like the edges of a half-open book. This confirmed the parallelism between the wires (Figure 5.17). The Z-axis ‘A’ is positioned at their intersection – the spine of this half-open book – with a projection that is perpendicular to the X- and Y-planes. Therefore, the Z-axis will be the line of the drill and ‘B’ and ‘C’ the wires, mediolateral and anteroposterior respectively (Figure 5.18). ‘A’ and ‘B’ live in the X-plane, and ‘A’ and ‘C’ lie in the Y-plane.

Figure 5.17. Parallel guide-wires.
5.5.1 Guide-wire Prototype No 1

A prototype was designed that consisted of a handle with two wires attached to it. The two wires were independent of each other, and corresponded to mediolateral and anteroposterior views. These wires were adjusted so that they conformed to an angle of 90° to one another on the X–Y planes. These wires are L-shaped, thereby allowing enough room for clearance around the knee. However two separate wires could not fit into the same space. To overcome this problem two options were considered, as follows:

Option 1:
The wires could be welded to one another at 90° and pivot around the same Z-axis hole.
This had advantages and disadvantages:

- Ease of adjustment, re-aligning the wires.
- Welding the wires would require a jig to correctly align the wires.
- The holes in the welding could cause undue stress due to steam sterilisation.
Option 2:
Two holes would be created and the wires would mount independently from each other. The advantages and disadvantages were as follows:

- Ease of adjustment, independent alignment of the wires.
- Two holes allow each wire to independently locate, giving strength.
- The mediolateral wire fits into the Z-axis hole. The anteroposterior wires hole sits directly above this and in alignment with the Z-axis.

Option 2 was the most practical. This was the easiest way to locate the wires for producing precise prototypes. The method of placing one hole above the other allowed the mediolateral wire to be in the same plane as the Z-axis. When viewed along the anteroposterior axis, the wire is in the same plane as the Z-axis (Figure 5.18; Figure 5.19).

Figure 5.19. Guidewire location at handle.
5.5.2 Summary

Two wires in a given space had been constrained in such a way that the planes crossing the wires intersected each other at 90°. These wires are parallel when viewed through their common plane. When the wires are viewed from their X-ray planes simultaneously, the intersection forms a Z-axis. X-ray testing confirmed that when two wires conform to the above rules, the Z-axis (drill axis) will be aligned.

These wires have been given a general name – Guide-wires – that includes the mediolateral and anteroposterior.

This initial design stage demonstrated that the project was viable; that is, two wires within a given space around the knee can locate the ACL and its intraarticular attachment points.

Additional Design Requirements

On the basis of the initial design stage, a new set of design parameters emerged that complement the original product design requirements outlined in section 5.4.1.

These additional requirements are as follows:

- The guide-wires must rotate around a fixed point to locate the mediolateral aspect of the ACL.
- The guide-wires are also required to adjust back and forth in a medial and lateral plane, providing left and right adjustment.
- The instrument needs to be height-adjustable so that the mediolateral guide-wire can adjust into position, thus allowing the ACL to be precisely located.
- An adjusting rail has to be fixed to the operating table so that the instrument is securely fastened.
5.6 Drill Guide Conceptualisation: Prototype No.1

The requirement that allows the guide-wires to assume accurate and predictable location of the ACL through the use of an Image Intensifier is paramount. The guide-wires must be able to rotate around a central axis so that when the mediolateral guide-wire is viewed under image intensification, the ACL attachment points are located. Once this is accomplished the anteroposterior guide-wire is positioned by sliding the guide-wire medially or laterally, depending on the guide-wire’s position. When this is completed, the guide-wire device is removed and the angle of drill should be sufficiently located. Once drilling commences, the drill path will cross the anterior and posterior landmarks of the ACL.

A solution that mechanically ties the guide-wire device and its locating fixture together is the next design requirement.

Sketches were commenced allowing the design to be verified. The major sections of these sketches were focused on side views ‘lateral’. These views of the lower limb allowed for, and approximated, the visualised area. The sketches included partial views of the operating table. This allowed revision of the geometry of the knee.

Having approximated the limb size and its coordinates that relate to the operating table, data were then input into a computer using AutoCAD™ as a 2D-drafting package. This allowed the data to be refined in relation to their environment, the OR theatre. The advantage of using the CAD system is that the data are represented at a one-to-one scale. This allows the user to construct a scale-virtual world, in this case a virtual surgical theatre. The coordinates of the OR table and a 95 percentile lower limb were entered into the CAD system, and from this a working drawing of the instrument was produced. Two views were referenced within the CAD system – the mediolateral and transverse planes.
The priority was to locate the mediolateral wire over the ACL so as to locate the anatomical attachment points. The wire was represented as a straight reference line. The design of the instrument was formed around the geometry of the limb, transverse section, and this reference line. A prescribed distance was chosen from the limb along this line. This marked a datum point from which the guide-wire handle would be positioned.

The major components of the device were represented in block form, allowing the size and shape of the product components to be easily visualised. The overall structure and relationships with each connecting component could then be taken into account. These components were then redefined in box form, allowing the product to be refined. Size approximations were made with regard to the product geometry. This was achieved by progressively altering the geometry of the CAD drawing, until a satisfactory solution was found.

The instrument now had to be determined from its anteroposterior view. Plan views of the product were the easiest way to start. Sketches commenced around a transverse view of a femur with the soft tissue shown at an approximated distance of 50mm in the sagittal plane from the tibial plateau (Center for Human Simulation 2000) (Figure 5.20). As the lower limb conforms to a circular shape, external reference points at the tuberosity would prove difficult to relocate. For this reason, a straight line was drawn across an approximated ACL attachment point. It was noted that this line should be at 30° to the sagittal plane.

The anteroposterior guide-wire would align the drill with the ACL. This will lie in-line with the anterior margin of the ACL, which was shown as a straight line. Three lines were then approximately placed, two of these lines being referenced from the sagittal plane and the other from the anteroposterior marking line. These three lines formed a skeletal structure, which directed the primitive shapes of the instrument. The lines in (Figure 5.20) represent the central path of each primitive shape.
Figure 5.20. ACL path transverse section, left leg.

The components were required to interact with one another. In order for this to occur, the mechanical aspects of the instrument needed to be rationalised. Two aspects of the instrument would need to adjust one component and its subassembly. This subassembly would be the main instrument to which the drill guide would attach.

The instrument was required to be height-adjustable so that the mediolateral edge of the ACL could be located. This requirement would be best achieved at the closest position near the OR table, i.e. the end termination rail or a device attached to it. The drill guide is required to rotate around a central plane, which is also the point from which the drill guide adjusts left to right from a predetermined position.

A rod-shaped form would allow the drill guide to rotate around its central axis, as well as adjust from side to side. An end profile of the rod was sketched, which allowed the drill guide's form to be explored. The width of the drill guide was 10mm. In order to make the guide stable while rotating and sliding, a 30mm sleeve was designed to press-fit into
the drill guide. The drill guide has a slot cut through to the sleeve, which allows the guide to be clamped when in its correct position (Figure 5.21).

A hole is situated at the top of the drill guide through which the drill is placed for tibial and femoral tunnel preparation. This hole has a 3mm slot which forms a keyway that opens the hole up to the top of the guide, allowing the guide-wire handle to locate centrally over the hole. This is one of the most critical aspects of the instrument (Figure 5.22). The drill guide hole must align with the mediolateral guide-wire, which allows the drill and the guide-wire to share the same plane (Figure 5.18).

The anteroposterior wire hole in the guide-wire handle is above the mediolateral hole. This can be achieved since the hole is located directly above the drill guide hole and the X-ray is taken directly overhead (Figure 5.18).
The main body of the instrument is angled at 15° to the coronal plane, which allows enough clearance for the X-ray to pass through all of the critical areas within the knee joint, without being clouded by the instrument. It has a rectangular hole in its end that allows the instrument to adjust up and down (Figure 5.23).
5.6.1 Problems and Solutions

When the instrument in section 5.6 was tested, various problems were found to exist, as follows:

- The instrument needed to be anteriorly length-adjustable.
- The instrument needed to be broken down into subcomponents forming subassemblies.
- When the current guide-wire assembly (section 5.5 and 5.6) was positioned to the correct mediolateral alignment, the anteroposterior adjustment could not occur because the guide-wire assembly was locked. If it was adjusted, the mediolateral position on the ACL would be incorrect.

A more efficient means of attaching the instrument to the theatre table was required. The limb support was constructed of aluminium, which clouded the X-rays. It was also flat in its contour, which allowed the limb to slide off the theatre table during surgery. A more sufficient supporting device was required that was also X-ray translucent.

The overall drill guide size was approximately 50 percent too small and required enlarging.

A drill guide sleeve was a crucial element that allowed a more direct and precise alignment of the drill. The guide-wires needed to be combined to create one wire to be bent into shape to form the guide-wire. Solutions were sought to these design problems. These solutions were divided into two sub-categories that would specifically address design parameters.

Two sub-categories were:

- The limb support design.
- The re-design of all the components that make up the ACL surgical device.
5.7 Summary of Functional Anatomy

In order to address the problems in 5.6.1, and to best appreciate how to determine and realise the geometries of a reconstructed ACL, a functional summary was required.

There are two key images that enable the ligament’s location geometries to be determined. These are the mediolateral and anteroposterior images respectively. The mediolateral image (Figure 5.24) clearly illustrates the anatomical points of the tibial plateau, the intercondylar notch, and their site of ligament attachment (Howell, Clark et al. 1991; Klos, Banks et al. 1999). This image also allows for the anterior and posterior positioning of the mediolateral guide-wire.

Figure 5.24. Mediolateral X-ray image.
However, to appropriately locate the ACL’s three-dimensional characteristics an anteroposterior image (Figure 5.25) is essential. This image allows the lateral and medial positioning of the anteroposterior guide-wire.

![Figure 5.25. Anteroposterior X-ray image.](image)

Having attained this, a more pragmatic approach to three-dimensional position can be achieved.

5.8 **Limb Support**

There are two main limb-holding techniques for reconstructing the ACL. These are with the patient lying flat on their back, with the leg bent to 45° and the knee at 90°, or with
the patient’s leg hanging over the end of the theatre table at 90°. The latter was chosen as the preferred option, due to greater stability of the limb.

The current limb supports that are in use in most Australian hospitals either support or clamp the lower limb in place (Figure 5.26).

![Figure 5.26. Limb support used in hospitals.](image)

Our instrument requires a surgical technique that holds the limb around the thigh so that the leg is at 90°. Current limb supports are made from steel, which cause ghosting in X-ray images. New materials were sought that were more translucent to X-ray. Materials that were more acceptable were epoxy fibreglass and plastics. These materials were more transparent to X-rays than aluminium and steel.

Surgical tables and their attachment rails are basically the same; it is only their design parameters that differentiate them. These tables have attachment rails that are fixed along their sides, to which various devices can be attached. The surgical tables do not have the rails at their ends. In order to attach a limb support to the end of the surgical table, an end termination rail is required. No Australian manufacturer could supply an off-the-shelf end termination rail for their surgical table. To design and manufacture one
was the last resort. An end termination rail is considered a critical component in terms of supporting the limb.

The existing rails on the surgical table have blocks that allow different devices to be attached. These blocks were used as a standard device for locating the end termination rail. These blocks have a clamping slot that is 10 x 8mm, and this was used as a standard for the end termination rail side plate post dimension. The side rails are L-shaped. For simplicity the end rail screws onto each end of the side plates, and the screws sit in a slot that allows the side plates to adjust to accommodate the difference between most surgical table side rails. In order to level the device, height adjustment markings are placed at 5mm intervals for a length of 40mm along the side plate posts (Figure 5.27).

![Figure 5.27. Theatre table end termination rail.](image)

During a guide-wire test the limb became unstable and moved, de-locating itself from the limb support during a subsequent ACL operation. It became apparent that a secure limb support was to be sourced so that a secure ‘over the top’ procedure could be
performed. A product study was commenced and it was found that no limb supports could be sourced within Australia that matched our needs.

5.8.1 Support Criteria

The lower limb has to be supported so that the knee joint is placed at an appropriate angle. The upper and lower sections of the limb need to be securely located. Autoclave sterilisation needs to occur, and the limb support needs to be simple and easy to adjust.

5.8.2 Limb Support Prototype No 1

Concepts of X-ray transparent limb supports were visualised on paper. Two simple C-shaped profiles were styled, one that fits the thigh, and the other that fits the ankle. These C-shaped forms were tied together with a central beam. The beam was U-shaped in profile and trimmed at its intersecting region with the C-shaped thigh and ankle supports.

5.8.3 Faults with Prototype No 1

This support prototype 1 seemed to accommodate the lower limb efficiently, except for the following problems:

- The thigh support needed to wrap around the thigh more to provide an efficient means of holding the limb.
- An interface between the end termination rail and the limb support needed to be integrated into the limb support.
- In order to fit a large range of limbs, from the 5th to 95th percentile, the limb support required adjustment throughout its length.

5.8.4 Limb Support Prototype No 2

A second prototype was conceived on paper that addressed the criteria listed above. This prototype was made of fibreglass cloth impregnated with epoxy resin, and was
manufactured using the plug technique. This technique uses a moulding plug. In this case, a foam plug was used for all components. The method of ‘once only’ moulds had an advantage, as each mould could be revised during the prototyping stages.

The shape of the upper thigh was studied, and foam plugs were roughly shaped and refined by placing limbs onto the plug until a satisfactory shape was found.

The support column was designed with a geometrically revised U-shape. This column adjusts through its central vertical path. To locate the limb support to the end termination rail, a polycarbonate block was attached to the upper region of the limb support. A rectangular block of laminated 12mm polycarbonate, 30 x 68 x 36mm, had the T-slot profile to match the end termination rail. The block of plastic had a thread cut into its end that allowed a locking screw to fasten the limb support to the end termination rail.

The support column was cut into two different sections which when assembled formed the adjustment section of the limb support. The components comprised upper and lower sections that were fastened together with three M5 socket head cap screws. Two screws were on the right side and the lock adjusting screw was on the left side. This allowed the components to interact when the lock screw was loosened.

5.8.5 Review of Prototype No.2

The connecting tabs in the upper component, prototype No 2, are 2.5mm thick. These were too thin and caused the lower component to flex. This problem had to be addressed, as component flex was not acceptable. The end termination rail interface connects separately to the limb support. This was to be an integrated feature. The ankle cup should integrate the lower support moulding.
5.8.6  Limb Support Prototype No 3

To securely locate a limb support on the OR table, the total limb support system required more substantial integration. The upper section of the support was prototyped with 24mm timber, which allowed the volume and size of the component to be easily visualised.

A suitable plastic was required to meet the requirements of medical sterilisation – steam or chemical, lifetime cycle and rigidity. There were two common plastics that met all requirements, and these were: (1) Lexan™, (Polycarbonate), is available as a sheet extrusion up to 12mm in thickness. Lexan is available in a medical grade – 144R in a 12mm sheet. (2) Acetal, (polyoxymethylene), available in a range of thicknesses including 24mm. The properties of Acetal match the requirement for medical devices. Several design variations were trialled during the material bonding tests. A strapping medium, eshmear bandage, was used in a trial to secure the thigh to the limb support. This proved successful and a hook shape was integrated into the top section of the limb support ‘A’ (Figure 5.28).

This hook had to allow the bandage to easily locate its required position without thought needing to be given to its placement. The thigh cup ‘B’ was separated from the upper-support ‘C’, which was screwed on to the plastic upper-support with a set of 5mm socket cap screws. The polycarbonate prototypes were laminated from two 12mm sheets. To fasten the thigh cup to the PC laminate, four screws were required; two in each laminate, one towards the front and one at the back. When assembled the screw-fastening pattern provided adequate location between the mating components under physical testing.
Figure 5.28. Limb support prototype 3.

The upper-support had a 50mm slot cut along the upper section parallel to the end termination rail. This slot allows the drill guide Prototype No 4 to height-adjust according to the size of the thigh muscle. The lower component ‘D’ of the limb support was re-designed to integrate the individual components in Prototype No 2 (section 5.8.4). The basic shape and function of the lower adjusting arm was kept, except for the method of attaching the ankle cup to the adjusting arm. The moulding of this
component was eventually more complicated, but the strength gained from integrating the components outweighed the cost of an intricate moulding process.

It was found in later trialling that there was an optimal region for placing the drill guide on the limb support.

5.8.7 Summary of Limb Support Design

The keyway that allowed the limb support to interface with the end termination rail required more width to increase strength, preventing the component from shearing. A wider footprint was required to isolate any movement that the limb support had under load while located on the end termination rail. Plastic material needed to be purchased in one thickness of 24–25mm, making the laminating process redundant.

The use of carbon-fibre as a major component material needed to be reduced due to cost. Only thigh cups and ankle cups were to be manufactured from this material, and fastened with screws.

Lower adjusting arms were to be made from the same plastic material as the upper support arm, with the two components integrated.

The Drill Guide Assembly needed to locate to the upper support arm, creating an interface to tie the two product assemblies together.

5.9 Drill Guide Prototype No 4

In the conceptual stages of forming the drill guide’s underlying and defining properties, only the external guide-wire and its method of defining the true anatomical position of the ACL were challenged. These external location problems were overcome by the first prototype. The challenge ahead was to design a totally integrated system that could easily attach to the surgical table and locate the ACL.
Drill guide prototype 4 and the process used to design it was reiterative, including its integration with limb support prototype 3. This occurred through various stages of ideation. These stages combined around these two products in relation to their intended geometric placement. This placement was achieved by simply viewing the two product sketches from a lateral view. The images were layered over each other, providing a general overview of the geometry.

Design sketches were commenced that focused on an overall approach to defining the parameters of the drill guide. All of the critical axes that required adjustment were reduced to sub-components. This allowed each independent axis to be adjusted autonomously. These independent adjustments overcame the problems that drill guide prototype 1 initiated through embracing a single action to adjust the two axes.

The drill guide was broken down into its major components:
- Main arms
  - Lateral
  - Sagittal (adjustment)
  - Mediolateral (adjustment)
- Drill guide
- Guide-wire handle

These components were then revised according to their specific function, i.e. sliding, rotating or interlocking. Plane views were sketched allowing the conceptual yet critical planes of component interaction to be visualised.

The design has two critical points that locate the drill guide. These points are the drill locator and the fixation point at the OR table. A drill angle was set at $30^\circ$ to the sagittal plane of the lower limb with a parallel plane of adjustment (Figure 5.29). This allows the drill to be positioned at the correct angle of $30^\circ$, i.e. the 11 or 1 o’clock positions.
The drill locator can then be pivoted around its rotation axis and aligned to the ACL in the mediolateral view. This rotation axis is the pivot point of the drill locator, as well as providing lateral adjustment of 55mm. A pawl and rack locking system ‘A’ control this. The rack consists of a set of V-shaped slots in which fits a compatible V-tooth: this is the pawl. This system allows the drill locator to be moved through 50mm of lateral adjustment. This lateral adjustment occurs at 60° to the sagittal plane.

Anterior and posterior adjustment is provided through the use of a sagittal arm, which allows the overall length adjustment of the drill guide device. This adjustment is applied through a 70mm interface between both sagittal and lateral arms. The sagittal arm has 85mm of lockable travel through the abovementioned pawl and rack locking system ‘B’.

The various two-dimensional designs for prototype 4 were revised and a three-dimensional computer model was digitally constructed. A rapid prototype ‘Fused Deposition Model’ (FDM) of prototype 4 was manufactured (Figure 5.30).
The lateral arm locates into the side of a limb support, which allows the arm to adjust its height, proximally or distally, to the knee joint. The lateral arm has a tab that is the joining interface between itself and the limb support (Figure 5.28). Various locking devices were devised; that is, ratchet locks, cam locks or thumb locks. These tightening devices would fix the lateral arm in place once the required height was acquired.

The guide-wire handle was re-designed where required. This was the handgrip and the wire attachment point (Figure 5.31). The handle retained the previously designed component mating system. This is a 4mm tab and slot system ‘A’. An elongated hole replaced the countersunkened thumb and four finger grip (Figure 5.21). This elongated hole allows fore and index fingers to fit inside, with the thumb pressing down to facilitate the removal of the handle. The two guide-wires were integrated to form a single guide-wire, which was placed into a 3mm slot and fastened with two countersunken screws ‘B’.

Figure 5.30. Fused deposition model (FDM) rapid prototype number 4.
The FDM model of prototype 4 was formally tested at Epworth Hospital, Melbourne. Non-invasive testing was performed in a standard operating theatre. Only the image intensifier was used to visualise the knee in both mediolateral and anteroposterior views.

The leg end of the theatre table was removed and the end termination rail was applied to this. The limb support was positioned for the left leg, as only one guide-wire was available, which was left in configuration. The subject was positioned supine on the theatre table with their left leg’s thigh in the limb support’s thigh cup. The leg subsequently hung at 90°. The right leg was placed into a limbthotity holder and bent at the hip joint to approximately 82°. This allowed the image intensifier to clear the field when in the mediolateral view (Figure 5.32). A standard Philips C-arm was used to obtain the image intensification.
The lateral arm was positioned into the limb support and the subsequent arms were placed into position, sagittal and medial arms respectively. Mediolateral X-rays were imaged. The sagittal arm was too anterior in this view. When adjusted posteriorly, the sagittal arm ran out of travel. To remedy this problem the subject had to be moved forward on the theatre table. This worked but the ankle was too far forward and the sagittal arm was still too close to the end of its travel. Anteroposterior views were imaged by rotating the image intensifier head through $90^\circ$ in the coronal plane, then tilted approximately $45^\circ$ anteriorly into the anteroposterior view.

To confirm that the mediolateral and anteroposterior views were properly aligning, the ACL’s isometric points were marked out on cadaver bones. A femur and tibia were taped together at $90^\circ$. The femur was placed into the limb support’s thigh cup and positioned with foam. An archery forceps’s tip was placed at the posterior portion of the ACL’s attachment point on the femur. When imaged, the guide-wire aligned with the
forceps’s tip in the mediolateral view. This was also true for the anteroposterior view, which proved that we were looking at a true view and not a hidden one (Figure 5.33).

![Mediolateral X-ray image with forceps's tip.](image)

Figure 5.33. Mediolateral X-ray image with forceps's tip.

Once the femoral attachment point of the ACL was correctly confirmed in both anteroposterior and mediolateral views, a method was devised that would locate the isometric points of the ACL.

The posterior margin of the ACL’s attachment point had been located. To locate the tibial landmark of the anterior attachment point of the ACL, constant image intensification was required. Constant mediolateral visualisation, via an image intensifier, allows the guide-wire handle to be rotated as the sagittal arm is moved either
anteriorly or posteriorly. While this is occurring, the surgeon is keeping the first point fixed while locating the second.

During the image intensification process it became apparent that the guide-wires were not properly aligned to their respective views. This was noticed on the anteroposterior view. The anteroposterior guide-wire was aligned with the drill hole, or Z-axis, in mediolateral view (Figure 5.34), and not aligned to the drill hole in the anteroposterior view (Figure 5.35). As a result, the radiographer had to position the image intensifier at 30° to the sagittal plane. The image intensifier is a heavy machine. It proved difficult to align the imaging head to the required angles. It was easier to align the image intensifier to a common reference plane, i.e. perpendicular to the theatre table. The anteroposterior and mediolateral guide-wires were then bent visually to align with their associated reference planes. X-rays were imaged and the isometric attachment points of the ACL were located accurately (Figure 5.36).
Figure 5.34. Guide-wire aligned in mediolateral view.

Figure 5.35. Guide-wire 30° out of alignment in anteroposterior view.
Figure 5.36. Cadaver bones with Guide-wires and archery forceps at posterior portion of the anterior cruciate ligament. Mediolateral view top and anteroposterior view bottom.
5.9.1 Summary

Problems with Drill Guide No 4

A summary of the problems found in prototype 4 were:

- The pawl and rack locking system was not sufficient in its construct to secure the anteroposterior and mediolateral components in place. New methods of fastening the adjustable components were required.
- The mediolateral arm was at 30° to the sagittal plane. This needed to be modified to 90°, with its tip at 30° for the drill guide.
- A stronger construct for attaching the guide-wires was required.
- In order to easily penetrate the Steri-Drape, the size of the lateral arm has to be reduced.
- The overall size of the sagittal arm has to be reduced, or the adjacent limb support has to be rearranged so that the full travel of the sagittal arm is obtained.

Solutions

The following design solutions were proposed:

- Changing the single movement multi-function idea from prototype 3 into a multi-movement, single-function action proved to be successful; that is, one operation for each adjustable component.
- Resizing the guide-wire handle allowed the user to acquire a firmer grip. This overcame the potential of dropping the handle and causing desterilisation.
5.10 Summary and Conclusions

5.10.1 Functional Anatomy

When designing and testing the new device, it was later understood that the location of the ligament was initially achieved at its femoral location, and not as anticipated at the tibial plateau. This led to a significant discovery that challenged the conventional method of locating the ligament’s reconstruction tunnels. Rather than independently locating the landmarks of tibial and femoral tunnels respectively, the ligament’s femoral location was initially established with the device. With this reference point oriented, the instrument was adjusted to locate the tibial landmark. With this method the two tunnels are located and the tibial tunnel’s entry point near the tibial cortex is predetermined (refer to Appendix A). This method endeavours to avoid guesswork – ‘eyeballing’ – by the surgeon when independently locating geometries, as in the conventional approach with hand held instruments (Appendix C and D). A detailed account of this technique is given in section 7.2.

5.10.2 Device Location

Conventional instruments used for ACL reconstructive surgery reference only one of the two ACL landmarks per hole drilled. Some of these instruments also use mediolateral imaging to view the knee joint. However, despite the development of these techniques, ACL reconstructive surgery is still a challenging operative technique.

A method was developed and tested to locate the landmarks of the ACL. This method occurs with two wires being externally placed over the knee, and visualised via a radiographic imaging technique. This geometric location technique was developed to position datum points at the landmarks of the ACL. The points are established intraarticularly at the intercondylar notch and tibial plateau. This technique aims to
locate the ligament in three dimensions, and was initially trialled with a combination of K-wires and X-ray imaging. It was able to locate the landmarks and subsequent ligament tunnels in both mediolateral and anteroposterior views, through a technique of locating the ACL instrument to a designed bed rail to provide a rigid surgical structure.

These imaging techniques were realised through design concepts and the testing of various prototype components, including drill guide (consisting of lateral arm, mediolateral arm, drill guide aimer and guide-wires), and limb support. These components underwent a series of tests and each component was refined through various design iterations (four prototypes were constructed).

Chapter 6 introduces the refined device from prototype to manufactured device. This manufacturing process underwent two levels of iteration. The manufactured ACL reconstruction device was then cleared for surgical trialling.
CHAPTER 6

Design Optimisation for Surgical Trials:
Phase 2

6.1 Introduction

This chapter describes the developments applied to the outcomes of chapter 5 (Phase 1): the creation of a prototype; and productivity improvements for a ligament reconstruction device. The prototype device examines the details of the mechanism and refines this to improve and simplify the surgical method. The device manufacturing was employed for the surgical trials (chapter 7).

6.2 Drill Guide Prototype 5

In order to complete various three-dimensional computer models, a new computer aided design package, was required. AutoCAD™ was a very powerful two-dimensional package
but in terms of three dimensions it was limited. If three-dimensional models were to be produced, they needed to be efficiently edited. Parametric modelling was chosen as it excels in this area. Various parametric tools were used, including DesignWave, SolidWorks and Catia.

Prototype 5 was designed according to each independent component and its location to a mating part. The main requirement was being able to interface between the limb support and the sterile side of the Steri-Drape.

A technique was devised for bypassing the problems of gaining access through a cloth sterile drape manufactured by 3M™ (Figure 6.1). This drape is a single use item made from plastic materials that allow incisions to be cut in the drape. This drape also uses a pouch through which the limb is inserted. By doing this, the knee is the only element exposed during the procedure.

Figure 6.1. 3M Steri-Drape with fluid pouch.

This new draping process allowed for the following technique. With the end termination rail in place, the limb support was located. Attached to this will be the lateral arm, and the Steri-Drape would be positioned around the leg, exposing the knee. The surgeon would then feel the lateral arm through the Steri-Drape and make a small
incision around this area, exposing the anterior portion of the lateral arm. Once the lateral arm was partially exposed, the rest of the device is positioned into place.

Various sketches were developed that analysed the best method for attaching the lateral arm to the limb support, and investigating the easiest method for accessing a minimal entry through the Steri-Drape. A way of aligning the anteroposterior and mediolateral guide-wires to their correct planes within the guide-wire handle was also needed.

6.2.1 Lateral Arm Re-design

The first component that required modification was the lateral arm. By extending the length of the lateral arm, the sagittal arm could be adjusted throughout its full range of adjustment without making contact with the end termination rail.

Prototype 4’s lateral arm was used as a template for the design of prototype 5. The distance from the limb support to the sagittal arm ‘A’ was maintained throughout this redesigning stage (Figure 6.2). The anterior edge of the lateral arm was extended approximately 55mm ‘B’. This allowed a greater range of access to the lateral arm and also kept the Steri-Drape removed from the end termination rail.

Any hole inserted into the Steri-Drape needs to be kept to a minimum, to limit the likelihood of cross-infection. To achieve insertion with the smallest possible hole in the drape, the anterior section of the lateral arm, which is the interfacing section of the sagittal arm, has to become a separate component (Figure 6.3).

The lateral arm then became a subassembly comprising two parts. These parts would be the lateral arm base and its connector block. These two parts would fit together through a tongue and groove style system, and lock in place with a sprung clip. The connector block contains a square hole (Figure 6.3) through which the sagittal arm fits. This is fastened in place with a thumb screw (not shown).
Figure 6.2. Lateral arm ‘X’ with inter-connecting block ‘Y’.

Figure 6.3. Lateral arm with connecting block before assembly.
6.2.2  Sagittal Arm Re-design

The sagittal arm is a long L-shaped arm. It has a square hole placed perpendicular to its length that allows the mediolateral arm to locate its position (Figure 6.4). Placing the hole at 90° to its sagittal plane allowed the mediolateral guide-wire to locate one point on the image-intensified screen when moved mediolaterally. This placement is in contrast to the previous prototype, which had its hole at 60° to the sagittal plane (reference Figure 5.28 and 5.29).

![Figure 6.4. Sagittal arm.](image)

6.2.3  Mediolateral Arm Re-design

The mediolateral arm is square in profile, with a 30° bend at one end. The bent profile has a cylindrical pivot attached (Figure 6.5) to which the drill aimer attaches. The drill aimer attaches to the mediolateral arm by locating to the cylindrical pivot. This pivot has an M8 thread that accepts a clamping device. A locking screw allows the drill aimer to be positioned via a tightening force between two surface areas ‘A’ (Figure 6.6), effectively clamping the three components together.
Figure 6.5. Mediolateral arm with pivot point.

Figure 6.6. Mediolateral arm assembled with drill guide angler and lock screw.
When the instrument is fully assembled (Figure 6.7), two different options can be applied. These options are locating the guide-wire handle or positioning the cannulated reamer.

Figure 6.7. ACL device assembled for left knee. Guide-wire and thumb screws not shown.
6.2.4 Guide-wire Handle and Drill Guide

These two components are used in a specific sequence: guide-wire handle and drill guide first, and cannulated reamer second.

Guide-wire Handle

The guide-wire handle is attached to the drill guide aimer. This attachment is facilitated through a female to male interface centrally located to a keyway (Figure 6.8). There are two guide-wire handles, left and right. The handles are mirror imaged. Only the left-hand guide-wire handle was prototyped and tested under image intensification.

In order to locate the correct alignment to the required views, the image intensifier has to be perpendicular to the theatre table. The L-shaped wire holder was rotated around the Z-axis ‘drill path’ to an angle $\alpha^\circ$, which aligned the correct views, mediolateral and anteroposterior, with the Z-axis (Figure 6.9).

This angle was optimised through parametric tools, which allow a user to view a virtual model with or without a natural perspective. By viewing the full assembly of the drill guide without perspective, the true alignment of the mating components could be explored (Figure 6.10). The mediolateral and anteroposterior views were shown on screen, as the image intensifier would display the instrument and knee on a monitor to the surgeon per-operatively.
Figure 6.8. Per-assembly of the Guide-wire handle to the Drill Guide aimer.

Figure 6.9. Parametric simulation to ascertain the correct guide-wire angle.
Figure 6.10. Parametric anteroposterior and mediolateral views.

When the guide-wire handle has been aligned to both the mediolateral and anteroposterior views respectively, the handle is separated from the drill aimer and placed aside.

A cannulated drill guide reamer ‘A’ is positioned through the drill guide aimer and up to the anterior cortex of the tibia. This reamer has an odd number of cutting teeth that ream the first 1.5 to 3mm of the pilot hole (Figure 6.11). The reaming allows the instrument to positively locate at the knee. The angle at which the drill approaches the knee is approximately 25–30° to the coronal plane of the tibial plateau, at 90° of flexion, and at 30° to the sagittal plane. The drill reamer is placed at a steep angle of 25-30°. This requires the drill reamer to be at least 200mm in length so that the anterior cortex of the tibia can be satisfactorily reamed.
6.2.5 Problems

The device, prototype 5, was too complicated at the Lateral Arm. The split component technique (Figure 6.2) was not a cost-effective manufacturing process. This is due to components with high-tolerance fits that may not meet Therapeutic Goods Administration (TGA) Document; ‘Reducing public health risks associated with reusable medical devices’ Part B: Factors that affect public health risks, B1. Instrument design (2004).
6.2.6  Review of Prototype No 5

Drill guide prototype 5 defined new design requirements, and solved previous problems that were addressed by the prototyping stages. These stages concluded by drawing on various design parameters that, when redesigned, formed the stricture for the previous design stages. The image intensification testing of prototype 5 confirmed that the various conclusions drawn on throughout the previous chapter 4 culminated to form prototype 5.

6.3  Regulatory Requirements

With a design ready for manufacture it is important to produce a device that meet both Australian and European Union (EU) Medical Device Standards. The device in sections 6.4 and 6.5 meet the following requirements:

- Under the classifications of the TGA the designed surgical device conforms to the following. Classified as a Class I device (TGA 2003) that complies to: Rule 3 Invasive Medical devices, section 3.1 invasive devices intended to be used to penetrate body orifices (TGA 2004).

- The EU classifies the surgical device as a transient device ‘normally intended for continuous use for less than 60 minutes’. Under Rule 6, ‘all surgically invasive devices that are intended for transient use are in Class I if they are reusable surgical instruments (NIST 2001).

The surgically invasive device also meets the design and safety requirements as outlined in the Australian and European guidelines (NIST 2001; Standards Australia 2003; TGA 2003; TGA 2004).
6.4 Anterior Cruciate Ligament Drill Guide Device No 1

Anterior cruciate ligament (ACL) drill guide device 1 was a direct copy of prototype 5 except for the modification of the lateral arm and the cannulated reamer. Prototype 5 separated the lateral arm into two components, allowing the Steri-Drape to be efficiently placed through an incision, then attaching the second component. The manufacturing method for this idea had to be revised, as costs were prohibitive. A cost-effective alternative was to combine the two components, investment-cast them and post-process their mating components. Minor amendments were made to the 3D parametric models. These changes were to the lateral arm and the drill guide aimer.

6.4.1 Manufacturing Methods

In order to utilise the investment casting technique, wax models were required. Wax models are normally injection-moulded in tools that require extensive machining and a minimum of two tools for each different component. To make several final prototypes, the process of manufacturing numerous tools was uneconomical. For this reason, rapid manufacturing techniques were employed. Fused deposition-modelling techniques were utilised as these machines can directly build casting wax prototypes. Two sets of wax models were made with a uniform increased size of 2.5 percent to compensate for end material shrinkage.

The investment casting ‘lost wax’ technique takes wax master models and coats them in various ceramic slurries. The slurry creates a 5mm uniform wall coating around the wax masters. Once dry, the ceramic wall is baked and the wax is fired away, leaving a ceramic shell. The end material, martensitic stainless steel 440A (Standards Australia 2003), is then founded and poured into the ceramic shell. When cool the ceramic is separated from the parts, which are then separated ready to be post-processed.
6.4.2 Device Changes

The location and fastening method for the lateral arm was made more reliable by machining an oval-shaped slot into the tongue. This oval slot ‘A’ allows a thumbscrew to locate and clamp the lateral arm into the limb support (Figure 6.12). The length measured parallel from the base of the lateral arm to the sagittal arm’s square hole was increased by 15mm. This increased the clearance around the calf muscle. The interface that accepts the sagittal arm ‘B’ was moved back 8mm. This is due to mounting the lateral arm further forward in the limb support.

Only a small alteration occurred to the sagittal arm (Figure 6.13) and mediolateral arm (Figure 6.14) by the addition of two chamfers at ‘A’. The guide-wire handles were increased in thickness ‘A’ (Figure 6.15). Thumbscrews were added to lock each component in place (Figure 6.13 and 6.14).
Figure 6.13. Sagittal arm with chamfer guides.

Figure 6.14. Mediolateral arm with chamfer guides.
Drilling a 3.5mm hole over a long distance, 200mm is a complicated task in stainless steel with conventional machine tools. There are many factors that complicate this process. Two that generally occur are the cutting tip’s balance and the pressure applied...
to the drill bit. Due to these factors, aluminium (7005 series) was used, as it is easier to machine. A hole of 3.5mm in diameter was drilled as far as could be obtained. This hole ended up being 173mm in length. Not all of this hole could be used, as the drill migrated to one side. This tendency was kept to a minimum by rotating the drill 180° every 8–10mm. A cannulated reamer of 115mm was obtained through the use of this technique (Figure 6.16). The reamer did not optimally realise the requirements. However, the component would work sufficiently for surgical trials (chapter 7).

Figure 6.16. Long Series Drill and prototype cannulated reamer. Note: No reaming flutes.

6.4.3 Product Solutions

In this stage of the product design process, the changes to the product were minimal. These changes were implemented as cost-saving measures. Also, by simplifying the drill aimer, three small components were replaced with a screw thread.

6.4.4 ACL Drill Guide Device No 1 – Completed Concept

A working ACL surgical instrument had been manufactured. It was now apparent that clinical trials could begin with the new device. Previous trials and experimentation had occurred with prototypes 1 to 5 as external non-surgical trials. In order to locate the attachment points of the ACL, a series of human trials was undertaken. Surgical testing of drill guide No 1 commenced when ethics approval had been granted via the St Vincent’s ethics approval board.
6.5 Device No 2

The preceding section 6.4 describes the device produced for surgical trials in chapter 7.

Per-surgical testing revealed several advantages:

- The image intensification method was achievable in the standard way, i.e. on top of the Operating Theatre table instead of the ‘over the end’ technique developed in chapter 6, sections 4.9 and 4.10.
- Weight issues were a concern so surgical grade aluminium was employed.
- To further meet TGA, EU and FDA standards, the device should be further simplified.
- The guide-wires can be easily thrown out of alignment and where possible should be shortened, or totally removed in the case of adopting CAOS. (Refer to sections 8.4.1 and 8.4.2)
- The drill guide pivot point is to be in line with the drill to enable a true anteroposterior image throughout its full range of motion.

6.5.1 Re-interpreting the Method

Previous design and testing methods in chapters 5 and 6 were performed via an analogue means vis-à-vis manual scrutiny via dissimilar tools. With the advent of more powerful parametric modelling, a holistic approach was implemented. A set of cadaver bones, tibial and femoral, were three-dimensionally scanned. This allowed for an accurate representation of the knee and associated data, so that a fully integrated device could now be designed parametrically. This device could be accurately tested at the ‘desktop’.

6.5.2 Per-surgical Device Modification

The revised device in section 6.4 could now undergo small revisions in relation to the intraarticular geometry in the parametric knee data set. This parametric knee was calibrated and positioned with reference to an MRI data set obtained in the field, allowing for a best fit regarding ACL attachment data (Figure 6.17). It should be noted
that the soft tissue at the thigh and calf overlaps the limb support. This overlap ‘A’ simulates the amount of soft tissue compression when the leg is strapped to the device (Figure 6.17).

Figure 6.17. MRI and standardised parametric tibial and femoral data calibration with ACL device.

With the standardisation of the anatomic knee data, a rigorous process of analysis could occur. The data analysis occurred at the mediolateral and anteroposterior X-ray axes respectively. Section views allowed for an inspection of the optimised tolerances (Figure 6.18; Figure 6.19). This analysis also verified that the device was positioned at the ligament landmarks: mediolateral (Figure 6.20) and anteroposterior (Figure 6.21).
Figure 6.18. Optimising cross-section with true anteroposterior view shown at left.

Figure 6.19. Optimising cross-section with true mediolateral view shown at left.
Figure 6.20. Mediolateral view from parametric data.

Figure 6.21. Anteroposterior view from parametric data.
In order to calibrate the mediolateral arm angle to the sagittal plane, a series of parameters were referenced within the CAD data. These were anatomical planes, intraarticular knee data and component construction planes. This reference data allowed a parametric formula to be optimised. A set of parameters 10 to 30° were referenced (Figure 6.22). An angle of 15° ‘A’ was determined to be most acceptable.

Figure 6.22. Mediolateral arm angle calibration.

**Simplified Device**

To simplify the device for manufacture and make pre-surgical sterilisation techniques easier, the geometry (form) of each component was revised to first principles. Universal design and element arrangement principles were applied (Tjalve 1979). The resulting components of the device were now rectilinear in form (Figure 6.23).
The data collected confirmed that the angle of the mediolateral component should be 15° to the sagittal plane of the device, as determined in section 6.4.

The device in section 6.5.2 was not manufactured. However, this device is the basis for discussions in chapter 8, section 8.4.

6.5.3 Summary

The amendments to the surgical device in sections 6.5 and 6.4 respectively confirmed the angle of 15° in the mediolateral component. Therefore, the device could be used for surgical trials (chapter 7).
6.6 Conclusion

Through the development of the final prototype, various parameters were further developed to best meet regulatory and practical surgical requirements. With a definitive manufactured design, section 6.4, the device was ready for surgical trialling. In order to initiate the testing guidelines, protocols are required. These will allow for a surgical framework that adheres to the operative protocol. The aim of implementing the protocol is to allow for surgical error due to complications that may arise. Chapter 7 discusses the protocol and the method used to undertake a series of eight surgical trials, employing seven patellar tendon bone–tendon–bone grafts, and one semitendinosus hamstring graft.
CHAPTER 7

Surgical Trials

7.1 Introduction

A suitable anterior cruciate ligament (ACL) reconstructive instrument was developed that had undergone a series of test trials. These trials were conducted in an operating theatre with the newly developed drill guide device. The instrument was non-invasively tested by the author and his co-supervisor (an orthopaedic surgeon). These trials achieved the instrument’s design requirements by visually locating the mediolateral and anteroposterior guide-wire handle at the isometric attachment positions of the ACL.

The apparent success of this trial confirmed the abilities of the instrument to externally locate a drill guide to the surgically determined intraarticular position of the ligament. Ethics approval was sought at St Vincent’s Public Hospital, Melbourne, and granted for a period of three years for human trials.
The following sections describe the methods and processes used to test the device in a surgical environment. Appendix A should be viewed in parallel to reading this chapter to understand the device, assembly process and surgical implementation.

7.2 Trial Failure Protocol

All existing trials of the ACL device have been conducted externally to the knee joint. The risks of human trials for the new intraoperative technique had to be considered.

Conventional reconstructive techniques require two independent tunnels to be drilled with hand-held instruments. Arthroscopic techniques are used to locate the damaged ligament’s intraarticular anatomy: tibial and femoral (section 3.1 and 3.2). The new technique for reconstruction varies from previous techniques by externally locating the position of the ligament and drilling one tunnel across the knee joint. This is achieved via an image intensifier, in a reverse order to conventional practice (section 4.7). The femoral tunnel position is found first ‘A’ and the tibial plateau second ‘B’, determining the entry point on the tibial cortex ‘C’ (Figure 7.1).

In the case of an unforeseen error in locating and/or drilling the tunnels, the procedure can be terminated midstream and conventional techniques applied. This protocol can be applied within the entire ACL operation and termination occurred in the first operation.
7.3 Materials and Methods

The study group so far consists of nine patients with ACL reconstructions performed by one orthopaedic surgeon during a one-year period. The first case study was excluded from the trial due to the extraordinary size of the operative limb.

Two different single incision graft techniques were employed: patellar tendon bone–patellar–bone (BTB) autograft with interference screw fixation in seven patients, and semitendinosus hamstring autograft with endo-button and twin staple fixation in one patient.

All eight patients underwent ACL reconstruction in the chronic phase (six months after injury). These patients had clinical evidence of ACL instability, with chronic rupture of the ACL in pivotal and side stepping sports. It was thought that the patients were at risk of functional instability and probable meniscal injury. All patients had failed results after
attending physical therapy and were suffering recurrent episodes of ‘giving way’. These patients had no medial or lateral ligament injury and only one patient had a meniscal injury. No patients had previous operative procedures on the affected knee.

7.4 Operative Technique: Device No 2

The patients are under a general anaesthetic and a tourniquet is applied high on the thigh ‘A’ (Figure 7.2). The patient is placed supine on the operating table, the non-operative leg is held in a lithotomy stirrup. First the leg is elevated and abducted, allowing the image intensifier beam to be positioned perpendicular to the leg to display a clear mediolateral view. By elevating the leg, the surgeon has improved access to the posteromedial edge of the knee for meniscal repair. The end section of the theatre table is removed. An end terminal rail ‘B’ (designed by the author) is fitted to the support rails on the middle section of the operating table with standard blocks. The operative leg is raised and prepared with Betadine antiseptic solution. The tourniquet is inflated once this has occurred.

Figure 7.2. Patient supine on theatre table. Note: end termination rail.
A sterilised limb-holder is positioned to the approximate sagittal plane of the operative leg (eight patients’ right knees were operated on) (Figure 7.3).

Figure 7.3. Sterilised limb-holder is approximated to the sagittal plane.
A custom designed arthroscopy sterile drape with fluid pouch (ProMedica) is applied to the leg. The first sterile component 'lateral arm' (reference Figure 6.12) is located to the limb-holder and fixed in place (Figure 7.4).

Figure 7.4. Introduction of lateral arm to limb holder through drape portal.
The leg is placed so that the limb-holder grips the proximal thigh and allows the leg to move freely to 90° of flexion (Figure 7.5). With the table end removed, a clear anteroposterior knee view can be obtained; also the knee can flex to 120°, allowing for ease of femoral interference screw fixation. With the knee at 90°, the intercondylar roof is almost parallel to the floor and provides a clear view.

**Figure 7.5. Arthroscopy drape with fluid pouch.**

Standard arthroscopy portals were made, anterolateral for the arthroscope and anteromedial for operative access. Further incisions were made to harvest the central one-third patellar tendon (BTB), and semitendinosus/gracilis grafts were used. The incision was placed at the distal aspect of the patella and directed to the proximal aspect of the tibial tubercle for the patellar tendon.
7.4.1 Graft Selection

**Central One-third Patellar Tendon (BTB) Graft**

A trapezoidal shaped bone block of approximately 25 x 9mm was removed from the patella and a further bone block of the same approximate size was taken from the tibia. The tendon was incised subcutaneously and removed. The graft was taken to the preparation area.

Standard grasping forceps locate the graft as the suture holes were drilled with a 2mm ball nose drill. Both bone blocks have holes drilled in the upper and lower halves, one hole drilled from the anterior to posterior face, and the other drilled from the lateral to the medial face; that is, the tunnels are perpendicular to one another. This allows for an even tension when passing graft through the tunnels. This practice differs to the conventional technique (section 4.7.2). Two 1mm Ti-Cron™ sutures were passed through the tunnels at both ends and clamped with artery forceps. The graft was wrapped in bandage and placed in saline solution (Figure 7.6).

![Figure 7.6. ACL BTB graft prepared with sutures for graft passing.](image)
Semitendinosus / Gracilis

The longitudinal incision for the semitendinosus/ gracilis autograft was placed medially to the tibial tubercle and was 20mm in length. The proximal end of the semitendinosus was located and blunt dissection occurred with the forefinger; then it was detached from the tibia with a Smillie knife. A 1mm Ti-Cron™ suture was secured to 10mm of the attached semitendinosus graft. This tensioned the semitendinosus to facilitate ease of graft removal. A tendon stripper (Acufex) was placed over the semitendinosus graft and slowly stripped distally until the tendon was removed from the femoral bone and taken to the preparation table. An Acufex Graft Master™ was used to prepare the graft. The semitendinosus graft was cleaned on the preparation block with an osteotome, and folded in half and sutured.

An endo-button with associated tape loop was inserted into its holding post, then the looped semitendinosus graft and the endo-button tape were tied. Two Ti-Cron™ sutures were fixed to the endo-button to facilitate button location (reference Appendix D). The semitendinosus graft was wrapped and placed in saline solution (Figure 7.7).

Figure 7.7. Semitendinosus hamstring graft harvesting.
After graft harvesting had occurred, the drill guide subassembly (consisting of sagittal arm, mediolateral arm and drill guide aimer (reference Figures 6.13 and 6.14)) was inserted and approximately adjusted. Either the left or right-hand guide-wire handle (reference Figure 6.15) was attached to the drill guide aimer, and rotated to an approximate angle of 60° to the horizontal plane (Figure 7.8).

Figure 7.8. ACL device in place with right guide-wire handle.
The image intensifier is positioned to show a mediolateral view. As this occurs, care must be taken when the distal imaging head of the image intensifier is being located because it could contaminate the outer edge of the Steri-Drape. A theatre technician adjusts the drape, if necessary, to avoid contact with the drape as the image intensifier is introduced within the field. The mediolateral view displays the tibial plateau with parallel medial and lateral condyles (Figure 7.9). While this is being viewed, the mediolateral guide-wire is positioned to match that of the original ACL. First, the wire is aligned five to six millimetres anteriorly to the posterior edge of the intercondylar notch (section 4.7.6) (Musahl, Plakseychuk et al. 2005), allowing for a two millimetre wall once the corresponding reamer is drilled. Second, the anteroposterior arm is moved proximally while the guide-wire handle is rotated to align the tibial insertion point. This is centrally located to the tibial plateau (Figure 7.10) (Litner, Dewitt et al. 1996). Once the ligament’s lateral attachment sites are located, the anteroposterior arm and drill guide aimer are locked in place.

Figure 7.9. Guide-wire imaging through mediolateral view to reference anatomy.
The image intensifier is swung into the vertical position and then aligned to the anteroposterior view at an angle of 35–40° to the horizontal plane (Figure 7.11). To position the anteroposterior guide-wire, the mediolateral arm is positioned either medially or laterally, locating the guide-wire centrally on the tibia and at the corresponding angle on the intercondylar notch (Figure 7.12). The mediolateral arm is fastened when the appropriate view is obtained.
Figure 7.11. Guide-wire imaging through anteroposterior view to reference anatomy.

Figure 7.12. Guide-wire at the femoral insertion point.

With the mediolateral and anteroposterior views aligned with the ACL, the tunnel preparation can occur. The guide-wire handle is removed and placed on a back table.
The 3.5mm cannulated reamer is inserted into the drill guide aimer toward the tibia. When the reamer makes contact with the tibia, a 2–3mm hole is reamed by hand. This allows the drill tip to locate against a flat face, resulting in zero degrees of drill deflection during proximal tibial tunnel preparation.

Tibial tunnel drilling commences when the image intensifier is repositioned to the mediolateral view. This provides the information required to locate the graft position (Litner, Dewitt et al. 1996). The drill is viewed under small constant bursts of X-ray when the surgeon requires a specific view – that is, tibial plateau exiting or intraarticular guidance to pass the PCL. This is also useful to check that the drill is touching 5–6mm anterior to the edge of the intercondylar roof (Figure 7.13). Note: the right image is passing the PCL, and the left has entered through the femoral intercondylar notch.

Figure 7.13. Tunnel drilling view via mediolateral image.

Having checked this, the femur is drilled through to the distal side. The 3.5mm drill remains in place ready to accept a 10–12mm cannulated reamer. With the cannulated reamer removed, the tibia is reamed through to the tibial plateau. The image intensifier is used in the mediolateral view to check that the reamer does not make contact with the
posterior cruciate ligament. Under direct image intensification the femoral tunnel is drilled for 30mm. This is also referenced via a notch on the reamer (Figure 7.14). This visual notch allows the surgeon to locate the exact tunnel depth at a glance, when compared to the arthroscopic reliance on locating a line and associated dimension.

![Figure 7.14. Reaming 10mm tibial tunnel.](image)
7.4.2 Application of Conventional Technique

With the tibial and femoral tunnels drilled in one process, the conventional surgical technique is reinstated to finish the ACL operation. Either an interference screw or endo-button technique is used to fixate the graft once it is positioned within the tibial and femoral tunnels. Patellar tendon BTB graft or semitendinosus hamstring is held in place with interference screws or endo-button techniques respectively. After fixation, the replacement graft can be shown to exhibit no pivot shift via a Lachman’s test. Refer to DVD – Surgical Case Study (Appendix A)

7.4.3 Summary of Results

Accurate placement of the reconstruction tunnels in ACL surgery is difficult under arthroscopic navigation. It is vital to position the tunnels correctly if roof impingement is to be avoided (Howell 1998). The ideal location of the tibial tunnel is at the 46 per cent mark of the total tibial plateau (Klos, Banks et al. 1999), with recommended variation from 44 to 48 per cent (Arnold, Kooloos et al. 2001; Takahashi, Doi et al.
The imaging device and technique described above proved effective in achieving this performance.

In the surgical study the results were derived from X-ray data collected at the conclusion of surgery. The eight operations reveal exceptional results for operations 1, 2, 5 & 6 at the tibial and femoral location points (Figure 7.16) and good results for operations 3, 4, 7 & 8 (Figure 7.17). At the tibial plateau seven of the eight trials were within the required landmark region, with the exception of trial eight. However, this was only 0.5mm outside of the landmark zone of area 3 x 5 millimetres (Figure 7.18). The grouping is compact and runs from the medial to lateral sides with a mean posterior placement at the 46 per cent. Such performance would successfully avoid femoral intercondylar roof impingement when standing.
Figure 7.17 Surgical trial location displaying the ACL representing the ‘within zone’ inside optimum reconstruction zones.

Figure 7.18 Surgical trial location of tibial insertion points referenced to optimal reconstruction zone ‘Y’.
The location of all eight operations at the lateral side of the femoral notch was within the acceptable anatomic zone (Arnoczky 1983; Mochizuki, Muneta et al. 2006; Takahashi, Doi et al. 2006). This optimal zone is shown in Figure 7.19 using Amis and Dawkins’ (1991) classification of high, low, shallow and deep.

Figure 7.19 Surgical trial location of femoral insertion points referenced to optimal reconstruction zone ‘X’.
7.4.4 Comparative X-ray Case Studies

Klos, Habets, Banks et al. (1998) describe one similar image guided technique to guide the location of the tibial and femoral tunnels. This visual technique works via a single viewpoint, is limited to a single plane, and does not take into account the true three-dimensional nature of the knee joint. The fluoro-arthroscopic technique also follows convention by locating the tibial tunnel first, and then the femoral tunnel.

This technique is in contrast to the author’s bi-planar method, viz., a two-plane technique for true three-dimensional visualisation; it only offers one part of the intraarticular story.

Kuga, Yasuda, Hata et al. (2004) also use a multi-plane, registration, technique for combining X-ray images with CT images. This varies to the author’s, as it combines three X-ray images to create three-dimensional bone data. It is not the author’s intent to create the three-dimensional bone data, but to reference bone anatomy and externally locate a guide device.

7.5 Conclusion

For the surgeon and support team, an ACL operation can be a long and exhausting operation. Many unforeseen complications can arise including incorrect alignment of the tibial and femoral tunnels, and vision loss due to fluids (Kohn, Busche et al. 1995; Sommer, Friederich et al. 2000; Kuga, Yasuda et al. 2004; Sudhahar, Glasgow et al. 2004). The ability to concentrate on advanced ACL techniques and not have to worry about rudimentary techniques is paramount.

This has been achieved via the use of a device that aids the surgeon to locate internal geometry by implementing the use of an external guidance system to find the precise
location of the ACL. The external guidance system allows the surgeon to avoid making errors in graft tunnel alignment due to an incorrect angle of drill. The angle $30^\circ$ is recommended in the literature as the preferred angle for accurate alignment of the ACL. Through the surgical trials it was found that this angle may not be correct and that an angle of between $15$ and $18^\circ$ was more suitable for locating the correct intraarticular position of the ACL graft tunnels. Thus it can be stated that surgeons need to be vigilant when referencing these angles in order to obtain the best location for the ACL graft. The relationship between the femoral and tibial attachment points and the association between the ACL and posterior cruciate ligament (PCL) is crucial.
Conclusions and Recommendations for Further Research

8.1 Introduction

The purpose of this study was to design a novel device that simplified the technical demands placed on orthopaedic surgeons when performing a reconstruction of the anterior cruciate ligament (ACL).

This simplification was achieved through the use of an external image guided technique via a series of design and surgical case studies. Over the period that this research was conducted, the initial and primary concern of repeatable location of the ACL has remained a common issue in the literature and continues to be controversial to this day.
8.2 Research Findings and Contributions

Design processes require strategies that allow for clear decisions. This thesis explores an approach that combines both conventional ‘design’ and systematic ‘engineering’ processes. This hybrid approach allows users to clearly break down a design process into experimental and scientific tasks. Hybrid approaches allow for the clear interpretation of interdisciplinary requirements of ‘orthopaedic and industrial design’, both speculative and known.

From this a ‘device’ was designed that comprised a support ‘limb-holder’ and an instrument for the ligament surgery. This device determines the ACL landmarks for correct drill position and angle. A series of adjustable parameters incorporated in the design caters for a full range of knee sizes and facilitates a full range of instrument adjustment.

In practice, a method was developed to externally locate the damaged ACL. This is a geometric method that combines bi-planar X-ray. The intersection of the X-ray images allows for the external position and orientation of a drill guide to the anatomical position of the ACL. Perhaps the most interesting finding related to this external location is the reference angle of the ACL to the sagittal plane. Importantly, the surgical literature refers to an approximated 25–30° valgus angle. The case studies found this to be incorrect. A valgus angle of 15–18° more accurately approximates the ACL attachment points of the tibia and femur.

There were considerations for ergonomic and universal design of the instrument and knee support for patient and surgeon. These include:

- Components with large surface areas to aid tactility with double gloves, and to reduce soft tissue damage.
- Lightweight materials that ease handling.
Less surgical intervention was a critical achievement in order to reduce possible pain and arthritis. This occurred through:

- A reduced amount of debride anatomy, i.e. rasping tunnels.
- Reduced requirement for notchplasty, due to controlled exit of the tibial tunnel at the plateau.
- Not relying on devices inside the knee to locate anatomy.

Other outcomes include an appropriate selection of materials for the instrument and other accessories, including a modified sterile drape to suit the surgical device and ACL surgical technique.

A procedure was developed in collaboration with the surgeon and theatre assisting medical staff to optimise the setting up and operation of the procedure.

### 8.3 Limitations of the Research

This study was limited in that only eight operations were performed with human subjects to trial device No 1, chapter 7. This was a slow and tedious process as patients were few and far between. However, this allowed for enough data collection, enabling Smith+Nephew Surgical Australia to further fund development of device No 2, chapter 7.

### 8.4 Recommendations for Further Research

At the conclusion of this thesis, considerable interest in the device and associated research has been shown by Smith+Nephew Surgical Australia, in collaboration with BrainLAB AG, Germany, who have engaged in this collaboration with their Image Guided System (IGS).
Capital investments and organisational time have been invested and the next stages of the device’s development are underway. This is described below, and effectively constitutes further research into the development and commercialisation of the device.

8.4.1 Computer Aided Orthopaedic Surgery

Computer Aided Orthopaedic Surgery (CAOS) has been in use in spinal, total hip and knee specialisations since the mid '90s (chapter 2). The addition of CAOS has allowed for a more accurate visualisation ‘image’ of the operative zone(s) involved. The CAOS systems have vastly improved visualisation; however, surgeons still rely on interpreting real time presentation data and keep the hand-held device in place while drilling both tibial and femoral tunnels.

There are distinct advantages for the adoption of (CAOS) to the image guided device. These are:

- No X-ray and associated image intensifier, so the wearing of lead aprons and the training of radiography staff are avoided.
- Instrument alignment window in both anteroposterior and mediolateral planes is automatically calibrated in the CAOS system.
- Physical guide-wires are not required, as the CAOS system maps them in the digital realm.
- Fewer requirements to hand-hold instrumentation while operating.

8.4.2 Applying Device to Computer Guided Surgery

The CAOS method has been adapted to the device No 2 (chapter 6). This has allowed for the following improvements in surgical technique and usability (universal design):

- With the Image Intensifier and X-ray no longer required, the CAOS system is now the image guiding tool – the guide-wire components are no longer required. The CAOS system is able to map this component via software and thus replace the external guide-wires with stereotactic devices ‘A’ (Figure 8.1).
The reliance on surgical placement of implants is still difficult and has not become an exact science, just a less demanding one. In order to create a system that maintains a rigid construct the limb positioner has been retained, which allows the system to maintain three points of stabilised fixation. This occurs at the femoral ‘A’ and ankle ‘B’ soft tissue sites and the device is rigidly fixed at the tibial cortex ‘C’ (Figure 8.2).
8.4.3 Surgical Trialling

The BrainLAB™ IGS works via stereotactic means; that is, two cameras are positioned to look into a predetermined space, and locate a set of reflective balls that reference the surgical instrument’s three-dimensional location. This allows the IGS to track the instrument with a real time frameless technique.

8.4.4 Summary

Commercial collaboration has allowed the device to be trialled with both low (X-ray) and high (CAOS) technologies, with some success. The advancement in CAOS is presently emerging in the area of ACL reconstructive surgery. This is occurring through the adaptation of current instruments (section 4.7 and appendix C and D), which should enable a more accurate graft location. However, the existing problems pertaining to the two-instrument technique of hand-held surgery could also be carried over into CAOS technologies. This depends on various factors such as surgical training and practical use. It should be noted that this is a highly subjective debate and opinions vary.
It has been our intention to objectively simplify the demands of this type of ACL reconstruction surgery. This has now occurred through the adaptation of CAOS techniques. However, it should be noted that hospitals outside of major cities do not have ready access to such equipment; thus the continuation of the image intensified device, which has the advantage of working in every hospital via the integration of low scatter image intensifiers. This technique and device could also aid less experienced orthopaedic surgeons to gain an understanding of the single tunnel approach (chapter 6 and 7). The image intensified technique also has relevance in veterinary science for the improved location of ACL reconstruction, primarily in dogs.

It is satisfying that the device has practical application in surgery, and that its commercial development in conjunction with related imagery techniques is in progress. Perhaps the most satisfying feature of the research, however, is the tentative discovery that the conventional surgical view of a 25–30° angle is incorrect. Instead, a 15–18° angle more accurately approximates the ACL attachment points. This is significant for ACL surgery.
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718.


References


Appendix A

Device Description and Surgical Trial DVD

This DVD explains, visually and verbally, the technique of the original Image Intensified device (refer to section 6.4), in an operating theatre setting. These are files:
ACLR – Device description.mvo
ACLR – Device non surgical example.mvo

A case study is also shown which explains the low-tech image guided technique. It describes the location techniques described in section 7.4. This is:
ACLR – Surgical case study.mvo
Appendix B

Glossary

A
Abduct vb. to move a limb or any other part away from the midline of the body. –abduction n.
ACL. anterior cruciate ligament see ligament.
Allograft n. see homograft.
Anterior adj. relating to the front part of the body or limb.
Arthroplasty n. surgical remodelling of a diseased joint.
Articulation n. (in anatomy) the point or type of contact between two bones.
Augment n.
Autograft n. a tissue taken from one part of the body and transferred to another part of the same individual.

B
BTB bone–tendon–bone.

C
CAOS. computer aided orthopaedic surgery.
Coronal plane adj. divides the body into dorsal and ventral sections.
Cortex n. the outer layer of an organ or other body structure, as distinguished from the internal substance.
Cortical adj. Of, relating to, derived from, or consisting of cortex.
Collagenous adj. relatively inelastic but with a high tensile strength.
Cruciate n.
Distal adj. (in anatomy) situated away from the origin or point of attachment or from the median line of the body.

Dorsal adj. relating to or situated at or close to the back of the body or to the posterior part of and organ.

E

Eminence n. a projection, often rounded, on the bone.
Effusion n. fluid that has escaped into a body cavity.
Extra- prefix denoting outside or beyond.

F

Forceps n. An instrument resembling a pair of pincers, used for grasping, manipulating, or extracting, especially in surgery.
Fibroblast n. A stellate or spindle-shaped cell with cytoplasmic processes present in connective tissue, capable of forming collagen fibers.

H

Homograft (allograft) n. a living tissue or organ graft between two members of the same species.

I

Industrial Design from IDSA Website

Industrial design is the professional service of creating and developing concepts and specifications that optimise the function, value and appearance of products and systems for the mutual benefit of both user and manufacturer.

Inter- prefix denoting between. Example: Intercondylar (in between the medial and lateral condyles).

Intra- prefix denoting inside; within. Example: Intraarticular (within the knee joint).
Lateral *adj.* 1. (in anatomy: relating to the region or parts of the body that are furthest from the median plane)  
2. (in radiology: in the sagittal plane)  

Ligament *n.* a tough band of white fibrous connective tissue that links two bones together at a joint. Ligaments are inelastic but flexible; they both strengthen the joint and limit its movements to certain directions.  

Medial *adj.* relating to or situated in the central region of an organ, tissue, or body.  

Median *adj.* (in anatomy) situated in or towards the plane that divides the body into right and left halves.  

Motion *n.* articulation cycles.  

P  

Peri- *prefix* near, around, or enclosing.  

Plafond *n.* An anatomical part or surface that is farthest from the midline of the body, especially the articular surface of the distal end of the tibia.  

Pre- *prefix* 1. (before: preceding)  
2. (in anatomy) in front of: anterior to.)  

Posterior *adj.* situated at or near the back of the body or an organ.  

Product Design see *Industrial Design*  

Proximal *adj.* (in anatomy) situated close to the origin or point of attachment or close to the median line of the body. *Compare* distal.  

S  

Sagittal plane *adj.* describing the dorsoventral plane that extends down the long axis of the body, dividing it into right and left halves.  

Saw Bones. bone forms cast in polyurethane foam.  

T
Transverse *adj.* (in anatomy) situated at right angles to the long axis of the body or an organ.

Tubercle *n.* An anatomical nodule. Also called *tuberculum.*

UCD user centred design.

Valgus *adj.* displaced away from the midline.

Varus *adj.* displaced toward the midline.
Appendix C

Arthrex – ACL Reconstruction for BTB Grafts
Recommended Transtibial ACL Reconstruction Instrumentation for BTB Grafts w/titanium interference screws:

<table>
<thead>
<tr>
<th>Item</th>
<th>Code</th>
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<tbody>
<tr>
<td>Adapteur Drill Guide C-Ring</td>
<td>AR-1875</td>
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<tr>
<td>Calibrated Guide Pin Sleeve for 2.4 mm Pins</td>
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<tr>
<td>Targe: POP Marking Hook, left</td>
<td>AR-1866</td>
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<tr>
<td>Targe: POP Marking Hook, right</td>
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<tr>
<td>Pin Simulator Tibial Marking Hook, 60°</td>
<td>AR-1878GP-60</td>
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<td>Transtibial Femoral ACL Drill Guide (TTG), 7 mm</td>
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<td>Parallel Guide Sleeve, 2.4 mm Pin</td>
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<tr>
<td>Cannulated Headed Reamer, 9 mm</td>
<td>AR-1409</td>
</tr>
<tr>
<td>Cannulated Headed Reamer, 10 mm</td>
<td>AR-1410</td>
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<tr>
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<td>AR-1411</td>
</tr>
<tr>
<td>Cannulated Drill, 9 mm</td>
<td>AR-1209L</td>
</tr>
<tr>
<td>Cannulated Drill, 10 mm</td>
<td>AR-1214L</td>
</tr>
<tr>
<td>Cannulated Drill, 11 mm</td>
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<td>Graft Harvesting Cutting Guide, 8.5 mm width</td>
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<td>Graft Harvesting Retractor</td>
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<td>Parallel Graft Knife Handle</td>
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<tr>
<td>Reusable Obturator for Tibial Tunnel Cannula</td>
<td>AR-1807</td>
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<tr>
<td>Tunnel/Notchplast Rasp</td>
<td>AR-1282</td>
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<tr>
<td>Notchplasty and Graft Harvesting Osteotome, 8 mm</td>
<td>AR-1830L</td>
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<tr>
<td>Tunnel Notcher</td>
<td>AR-1844</td>
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<tr>
<td>Jacob's Chuck Handle</td>
<td>AR-1415</td>
</tr>
<tr>
<td>PinLock II Cannulated Screwdriver, 3.5 mm hex</td>
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<tr>
<td>ACL Sterilization Case (with silicone nut base)</td>
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Recommended Transtibial ACL Reconstruction Instrumentation Accessories for BTB Grafts w/bioabsorbable PLLA interference screws:

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<tbody>
<tr>
<td>Racheting Screwdriver Handle</td>
<td>AR-1999</td>
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<tr>
<td>Cannulated Screwdriver Shaft for Bio-Interference Screw (femoral)</td>
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<tr>
<td>Cannulated Screwdriver Shaft for Bio-Interference Screw, Short (tibial)</td>
<td>AR-1997SH</td>
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<tr>
<td>Easy-In (stripped screw insertor)</td>
<td>AR-1992</td>
</tr>
<tr>
<td>Easy-Out (stripped screw extractor)</td>
<td>AR-1994</td>
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<tr>
<td>Tunnel Notcher for Bio-Interference Screw</td>
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Graft Prep Station for BTB Grafts:

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<td>Graft Prep Station Base</td>
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<td>Graft Workstation Posts for BTB Grafts</td>
<td>AR-1959</td>
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<tr>
<td>Graft Sizing Block, 6-12 mm diameters in 0.5 increments</td>
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Transtibial ACL Reconstruction Disposables:

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<td>ACL Disposables Kit, with Saw Blade, includes:</td>
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<tr>
<td>2 each Threaded Fixation Pins</td>
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<tr>
<td>1 each Hall Style Sagittal Saw Blade (other blade styles available)</td>
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<tr>
<td>Guide Pin w/ Suture Eye, 2.4 mm</td>
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<td>Drill Tip Guide Pin, 2.4 mm</td>
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<td>Guide Pin w/ 25 and 30 mm depth markings, 2.0 mm</td>
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<td>Nitinol Guide Pin for Bio Interference Screw, 1.1 mm</td>
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<td>Tibial Tunnel Cannula</td>
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<td>Backflow Cap</td>
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<td>Sterile marking pen, sterile packed, Qty. 5, single use</td>
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ACL Disposables Kit, without Saw Blade

(includes all the items in AR-18975 except a saw blade)

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<td>Parallel Graft Knife Blades, 8, 9, 10 &amp; 11 mm, Qty. 5 cs, sterile, single use</td>
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<tr>
<td>Guide Wire Introducer, 1.1 mm for Bio-Interference Screws</td>
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<tr>
<td>#2 FiberWire, braided polyblend suture, 38 inches w/tapered needle, box of 12 each</td>
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Tibial Tunnel Bone Graft Harvesting (optional):

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<td>Coring Reamer and Collared Pin, 10 mm, sterile, single use</td>
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<td>Coring Reamer and Collared Pin, 11 mm, sterile, single use</td>
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Femoral Tunnel Bone Graft Harvesting (optional):

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<tr>
<td>AIT Tube Harvester Set, 9 mm, unsterile, single use</td>
<td>AR-1855-09SU</td>
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<tr>
<td>AIT Tube Harvester Set, 10 mm, unsterile, single use</td>
<td>AR-1855-10SU</td>
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Refer to the Arthrex Product Catalog for specific screw types and sizes and additional ACL reconstruction instrumentation accessories.
Reference Anatomical Constants for Reliable, Reproducible ACL Reconstruction

The Arthrex Transtibial ACL Reconstruction System offers the orthopaedic surgeon instrumentation which provides reliable, reproducible ACL tunnels and socket placement by referencing anatomical constants.

The Aagemond™ Drill Guide C-Ring, used in conjunction with the Target™ POP Marking Hook, references a point 7 mm anterior to the leading edge of the PCL to reproduce the ACL/PCL relationship. This is the first step in creating an impingement-free reconstruction.

The Transtibial Femoral ACL Drill Guide allows precise guide pin placement by referencing the over-the-top position to reliably produce a femoral tunnel with a 1 to 2 mm cortical bevel, avoiding bevel downout.

Titanium or PEEK Interference Screws are specifically designed for the single-incision technique to protect the ACL graft during screw insertion. Endoscopic insertion of interference screws provides superior fixation of the graft against the posterior rim of the femoral tunnel and eliminates migration of the graft into the anterior rim of the tunnel in extension.

Special graft harvesting guides facilitate precise, reproducible patellar tendon harvesting. Saw blades with 7 mm depth markings provide precise depth control. Beveled, round bone plugs may be harvested from the tibial or femoral tunnel to graft patellar bone tendon harvest sites.

The Arthrex Transtibial ACL Reconstruction System... the Gold Standard in BTB ACL reconstruction.

The PCL is preferred as an anatomic constant for precise, reproducible tibial tunnel placement. An anterior or posterior Target POP Marking Hook attached to the Aagemond C-Ring is inserted through an anteromedial portal with the knee in 90° of flexion. The 7 mm tip extension of the marking hook is placed against the base of the PCL. A guide pin is introduced prior to cortical bone contact, maximizing pin accuracy. The guide pin exits through the marking hook 7 mm from the PCL. The guide sleeve, marking hook and guide are removed and correct pin position is confirmed.

If a standard tibial tunnel is desired, an appropriate diameter full-thickness Cannulated Drill (not shown) is used to create the tunnel. If a round-bone graft from the tibial tunnel is desired to graft patellar tendon harvest sites, a Cortig Reamer may be selected. The cortical bone is drilled to a depth of 1 cm with a Headed Reamer. A cannulated reamer is inserted to the desired length.
The appropriate diameter Coring Reamer is introduced over the Coloured Pin and gently drilled until the reamer exits the tibia. The Coring Reamer also eliminates bony debris in the joint while creating a smooth tibial tunnel. After the reamer is removed, the guide pin exiting the drill hole/s is tapped, extracting the round-bone graft. The graft may be split for grafting tibial and patellar harvest sites. The tunnel rim may be further smoothed with a Tunnel/Notchplasty Rasp.

The appropriate diameter Healed Reamer is inserted through the tunnel and past the PCL. A drilling depth of 30 mm is confirmed with the 5 mm calibrated depth markings to fully accommodate the 25 mm length bone block. If the guide pin is placed through the anteromedial portal, the Healed Reamer is inserted over the guide pin through the anteromedial portal with the knee in maximum flexion. If desired, an ATT Tube Harvester may be used to harvest a bone graft during femoral tunnel creation.

A notch is created in the femoral socket with the Tunnel Notcher, (for metal interference screws), or Tunnel Notcher for Bio-Interference Screws, to ease interference screw placement. The notch may be placed through the tibial tunnel or anteromedial portal. The notcher is tapped lightly with a mallet until the laser depth mark is flush with the femoral socket rim.
#2 FiberWire sutures are placed in the suture eye of the graft passing guide pin and the pin is pulled. The graft is pulled into the femoral socket through the tibial tunnel with the help of a probe. The methylene blue line should be flush with the femoral socket rim and the tibial fibers oriented posteriorly.

The knee is placed at least 120 degrees of flexion and the 2 mmintroductory pin for the titanium interference screw is inserted through the anteromedial portal up to the second laser line. The 1.1 mm diameter guide pin is inserted if a Bio-Interference Screw is used. A disposable Guide Wire Introducer facilitates accurate placement of 1.1 mm diameter guide pins.

A sheathed titanium or PLLA round head Bio-Interference Screw, 1 to 2 mm smaller than the tunnel diameter, is placed through the anteromedial portal with the sheath positioned to protect the PCL. The sheath window is positioned superiorly to provide clear visualization during screw insertion. The cannulated Ratchet Screwdriver Handle with appropriate shaft is inserted over the guide pin and into the sheath to engage the screw. The screw is inserted until the head of the screw is slightly countersunk into the femoral socket. The guide pin, screwdriver and excess FiberWire are removed.

Following femoral fixation, a titanium or PLLA Full Thread Bio-Interference Screw 1 to 2 mm smaller than the tibial tunnel diameter is selected. The knee should be cycled through a full range of motion to confirm graft position and to condition the graft prior to tibial fixation. The knee is placed in approximately 0-20° of flexion and the graft is fixed in this position. Following tibial fixation, a full range of motion and ligament stability tests should be carried out to confirm a successful reconstruction.
Appendix D

Smith+Nephew – Technique for ACL Reconstruction with Acufex Director, Drill Guide and EndoButton CL
TECHNIQUE FOR ACL RECONSTRUCTION USING THE ACUFEX DIRECTOR DRILL GUIDE AND ENDobutton® CL

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INTRODUCTION
Since Acufex® introduced endoscopic ACL reconstruction 10 years ago, the technique has steadily grown. Surgical exposure and precision have been facilitated. Reduction in surgical morbidity has been achieved and excellent stability following ACL reconstruction has become standard. The new Acufex Director System advances the simplicity and precision of endoscopic ACL reconstruction. New enhancements include:

- **Acufex Director Guide** achieves maximum rigidity, accuracy and simplicity with one hand operation.
- **Anti-Impingement Device** simplifies monitoring of the intrachondral notch prior to the creation of the tibial tunnel.
- **2 - 5 and 3 - 9 offset drill guides** facilitate precise guide pin placement.
- **Endoscopic Femoral Aimer with 3 or 4mm offset** optimizes femoral positioning for semitendinosus constructs.
- **Endobutton® CL** consistently provides the strongest and most versatile endoscopic femoral fixation utilizing soft tissue grafts.
- **NotchMaster™ Curette** facilitates removal of bone and soft tissue from the notch during notchplasty.
NOTCH PREPARATION

Perform appropriate notchplasty using the NotchMaster™ curette or NotchBlaster™ burr. Autografts typically require 2mm clearance. The proximal outlet of the notch should not be enlarged, rather it is carefully identified with the knee at 90° flexion.
TIBIAL TUNNEL LOCATION

The tibial guide is aimed from a point 3–4 cm distal to the joint line while hugging the tibial tubercle. The tip of the elbow aimer is placed in the posterior fibers of the ACL footprint as shown.

The technique can be performed with one hand.

Pin placement at a 45° angle to the tibial shaft is optimal for subsequent endoscopic positioning on the femur. The pin advances to a central position within the ACL footprint.
NOTCH ASSESSMENT

Notch assessment is correctly performed before drilling the tibial tunnel. The Drill Tip Guide wire is advanced into the joint and then assessed by:

a) placing the Anti-Impingement Device over the guide wire...

b) while viewing as the knee is extended.
If the guide wire is sub-optimally positioned, it is then repositioned using the 2 - 5mm Offset Drill Guide.

TIBIAL TUNNEL DRILLING

Drilling the tibial tunnel necessitates a standard cannulated drill bit which matches graft size.
FEMORAL TUNNEL LOCATION

With the knee at 90° flexion, an Endoscopic Femoral Aimer (3 - 4mm offset) is positioned over-the-top in direct contact with the bony cortex. A 2.7mm Passing Pin is inserted 3 - 4cm into the femur.

FEMORAL TUNNEL DRILLING

The Endoscopic Drill bit which matches the graft diameter is used to produce a socket. Depth is regulated according to the desired insertional length. Depth is 9–10mm greater than the desired graft insertion, to allow EndoButton® rotation.
The knee should now be flexed at least $90^\circ$. A 2.7mm Passing Pin and a 4.5mm Endoscopic Drill are used to produce the passing channel.

An EndoButton® Depth Gauge is used to measure the total length of the femoral channel.
GRAFT PREPARATION

Working on the GraftMaster®, the semitendinosus graft can be cut into 2 portions of equal length.

Each half can be doubled over to produce a quadrupled construct which is pre-sized as shown.
If desired, pretensioning may be standardized by placing the graft construct around the Tensioning Post, utilizing the Tensiometer.

(Usually 20 pounds for 10 minutes)
**ENDOBUTTON® CL SIZING**

The *EndoButton* CL length is determined by the difference between the total femoral channel length and the desired femoral graft insertion length. If this falls between two *EndoButton* CL sizes, "round off" to the closer size.

Note: The *EndoButton* CL is currently available in 5mm increments. If the required size falls outside the available range or if the *EndoButton* CL is not available, see Appendix A.

The grafts are passed through the continuous loop and the construct is loaded into the *EndoButton* Holder.

A line is placed on the graft 6mm distal to the total channel length. This will indicate the rotation point for the *EndoButton* CL.
GRAFT PASSAGE

A 2.7mm Passing Pin, which pierces the skin proximally, pulls the graft into position.
When the marking line reaches the internal femoral aperture, the trailing #2 suture is then pulled to deploy the *EndoButton*® CL on the external cortex.

As the graft is pulled distal, the marking line retreats 6mm and *EndoButton* CL deployment is confirmed.
GRAFT TENSIONING

Pretensioning can be performed by cycling the knee through a range of motion prior to tibial fixation.

TIBIAL FIXATION

The distally oriented “whip stitch” sutures are firmly tensioned and then tied around a suture post as shown or alternatively around a Suture Washer. Knotting is usually achieved at 20 - 30° of knee flexion.
APPENDIX A – ENDOBUTTON® TECHNIQUE
(WITH KNOTTED CONNECTOR)

Utilizing the EndoButton Holder the EndoButton Tape is attached. A doubled surgeon’s knot is used. The EndoButton Tape length plus the insertion length combine to equal the total channel length.
APPENDIX B – PATELLAR TENDON GRAFT PREPARATION AND TECHNIQUE WITH ENDOBUTTON®

Utilizing the GraftMaster® ACL Prep Board, the graft is attached through the two central holes of the EndoButton®.

#5 sutures, or 4mm–6mm wide polyester tape, can be used to connect the EndoButton to the bone block. The desired length of the graft insertion added to the span of the sutures must equal the total channel length.
A #5 suture is used to lead and pass the EndoButton®. A trailing #2 suture is later used to rotate the EndoButton as it exits the anterolateral femoral cortex.

The Drill Passing Pin (2.7mm x 15") is used for passage of the graft, piercing the quadriceps and skin proximally.
A patellar tendon graft may be seated more proximally than with other endoscopic techniques. Drilling perforation of the posterior cortex does not compromise the fixation.

An interference screw can be used for distal fixation.
TECHNICAL NOTES

- Drilling perforation of the posterior cortex does not compromise graft fixation and may optimize femoral graft placement.

- Patellar tendon grafts may be seated more proximally with EndoButton®, eliminating graft protrusion from the tibial tunnel.

- Bi-socket femoral tunnels may be used with soft tissue grafts to better reproduce the anatomy of the original ACL.

To adjust guide angle:
- Hold upright
- Set angle
- Tighten thumbscrew

To lock bullet, teeth must face down:

EndoButton® is covered by one or more of the following U.S. Patent numbers: 5,306,301; 5,643,588; other patents pending. Acufex®, EndoButton®, GraftMaster®, NotchMaster®, NotchBlaster®, are trademarks of Smith & Nephew, Inc.
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Book Section


Papers

Mayson, S (2000). Orthopaedics and Industrial Design: how interdisciplinary research creates innovation. Industrial Design Colloquium, Melbourne, RMIT University
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