Computer Assisted Total Knee Arthroplasty

Using

Patient Specific Templates

By

Mahmoud Alm El-din Abdel Hafez

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ABSTRACT

Current techniques used for total knee arthroplasty (TKA) rely on conventional instrumentation (CI) systems that violate the intramedullary canals. The accuracy of these systems is questionable, and set up and assembly of their numerous pieces is time consuming. Navigation techniques are more accurate, but their broad application is limited by cost and complexity.

The aim of this study was to prove a new concept of computer assisted preoperative planning to provide patient-specific templates (PST) that can replace conventional instruments. Computed tomography based planning was used to design two virtual templates. Using rapid prototyping technology, virtual templates were transferred into physical templates (cutting blocks) with surfaces that matched the distal femur and proximal tibia. Forty five TKA procedures were performed on 16 cadaveric and 29 plastic knees using the PST technique. Six out of 29 TKA procedures were included in a comparative trial against 6 procedures performed using CI systems. Computer assisted analysis of 6 random postoperative CT scans was performed to evaluate the accuracy of this technique. A reliability test was performed, in which five observers positioned the templates on a plastic knee model and a navigation system was used to measure alignment and the level of bone cutting for the planned tibial and femoral cuts. Each observer repeated the test 5 times. Errors in placement of the templates as well as intraobserver and interobserver variations were measured.

The study showed that it was possible to perform all 45 TKA procedures without CI systems. There was no need for intramedullary perforation, tracking or registration. The mean time for bone cutting was 9 minutes (15 minutes for CI systems), when the surgeon had an assistant and 11 minutes (30 minutes for CI systems), when the surgeon was unassisted. Postoperative CT scans showed mean errors of 1.7° and 0.8 mm (maximum 2.3° and 1.2 mm) for alignment and bone resection respectively. The reliability test had a mean alignment error of 0.67° (maximum 2.5°). The mean error for bone resection was 0.32 mm (maximum 1 mm). The positioning of the templates was reliable, as there was no significant intraobserver and interobserver variation.

This study proved the concept of patient-specific templating for TKA. It also showed a satisfactory level of accuracy and reliability of this technique. In conclusion, the PST technique has several advantages over conventional instrumentation and it is a simple alternative to navigation and robotic techniques for TKA. Further clinical validation is required before recommending this technique for new users.

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Relative contributions of investigators

- The author (MAH): designed the study, interacted with KLC during preoperative planning and postoperative analysis of CT scans, performed surgical experiments, conducted the reliability test and collected and analysed data.
- Dr Kenneth L Chelule: was responsible for running Materialise software and designing the patient specific templates. He significantly contributed to the preparation of experiments and the interactive preoperative planning and postoperative analysis.
- Dr Bahaa Seedhom: Supervised all experimental work in this study, apart from the reliability test that was conducted at ICAOS, Pittsburgh, USA.
- Mr Kevin P Sherman: Supervised and conducted some surgical experiments

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DEDICATION

This thesis is dedicated to my wife Doaa, my daughter Noor and my son Yousef, who gave me the time to do this project.

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Abbreviations

AP = Anteroposterior

CAD = Computer Aided Diagnosis

CAS = Computer Assisted Surgery

CI = Conventional Instrumentation

CT = Computerised Tomography

ML = Mediolateral

MIS = Minimally Invasive Surgery

PST = Patient Specific Templating or Patient Specific Templates

RP = Rapid Prototyping

THA = Total hip arthroplasty

TKA = Total knee arthroplasty

UHMWPE = ultra high molecular weight polyethylene

vCJD = Variant Creutzfeldt-Jakob disease

1. INTRODUCTION

This chapter briefly outlines the importance of TKA and reviews the current surgical techniques of TKA in order to identify the limitations and deficiencies. It also describes the available solutions and their limitations. And then, it states the aim and objectives of this study.

1.1 Summary of the problem

Total knee arthroplasty (TKA) is one of the most common surgical procedures in orthopaedics. It is the treatment of choice for advanced arthritis of the knee in patients aged over 55. Currently, about 35,000 TKA procedures are performed each year in the UK and demographic changes are likely to increase the demand for TKA by 40% over the next 30 years (Birrell et al., 1999). The aim of TKA is to achieve long-term implant survival and successful functional outcome with minimal complications and cost effectiveness. For elderly patients, the long-term implant survival has been reported as 90–95% after 10–15 years (Hofmann et al., 2001, Khaw et al., 2001, Rand et al., 2003, Ritter et al., 2001). Many authors questioned the reported high success rates and highlighted the pitfalls in outcome measurement and the importance of functional assessment (Hafez et al., 2004, Insall, 1996, Moran and Horton, 2000, Murray et al., 1997, Murray and Frost, 1998). The outcome for TKA is worse for young, active patients, complicated cases, and revision surgery (Rand et al., 2003, Scuderi, 2001, Sierra et al., 2004). Rand et al reported a survival rate of 83% for patients younger than 50 years compared with 94% for patients older than 70 years at 10-year follow up. Sierra et al reviewed 3200 total knee revisions and reported a 26% cumulative rate of first re-operation after 10 years. Evaluation of the short-term outcome has not received much attention until the recent introduction of the minimally invasive techniques. Complications after TKA such as infection, bleeding, fat embolism, and thromboembolism still occur despite prophylactic measures.

The success of TKA is dependent on surgical techniques (Ecker et al., 1987, Fehring et al., 2001, Sharkey et al., 2002) that require a high degree of accuracy and reproducibility. Technical errors can have detrimental effects on function and survival of the implant. Component malpositioning may lead to wear and loosening, or patellar instability resulting in early failure and revision surgery (Jeffery et al., 1991, Jonsson and Astrom, 1988, Ritter et al., 1994, Werner et al., 2005) As little as 3° of varus/valgus angulation can significantly change the pressure distribution and total load in the medial and lateral compartments of the tibial component (Werner et al., 2005). Bone cutting and alignment has to be achieved in three mutually orthogonal planes. Accuracy can be difficult as surgeons differ in their abilities to correlate the preoperative two-dimensional (2-D) data from plain radiographs to the complex 3-D anatomy during surgery. Surgeons may not be able to recognize up to 10° of knee flexion secondary to flexed femoral and tibial components, and they tend to internally rotate the femoral implant (Stulberg, 2003).

Current surgical techniques rely on plain radiographs for preoperative planning and standardised conventional instrumentation (CI) for performing the procedure. Plain radiographs have limited accuracy (2002, Brouwer et al., 2003, Ilahi et al., 2001, Jazrawi et al., 2000, Kinzel et al., 2004, Koshino et al., 2002, Moreland et al., 1987, Lonner et al., 1996). Ten degrees of knee flexion and 20° of external to 25° of internal rotation can cause significant differences in knee alignment measurements (Lonner et al., 1996). CI systems have been reported to have limitations that affect the ultimate accuracy of surgery, especially bone cutting and implant alignment (Delp et al., 1998, Jenny and Boeri, 2004, Stulberg, 2003, Laskin, 2003). In addition, CI systems are based on average bone geometry, which may vary widely between patients. Nagamine, Miura et al (2000) reported several anatomical variations in 133 Japanese patients with knee osteoarthritis (OA). Other authors (Stulberg, 2003, Teter et al., 1995) reported that significant malalignment errors (> 3°) resulted from using extramedullary and intramedullary (IM) rods. The accuracy of using CI for sizing is also questionable (Section 2.5.2.1) (Incavo et al., 2004).

Conventional instrumentation systems are relatively complex tools with numerous jigs and fixtures. Their assembly is time consuming and may lead to errors. Their repeated use carries a theoretical risk of contamination. The use of alignment guides involves the violation of IM canals. This can lead to a higher risk of bleeding (Chauhan et al., 2004, Kalairajah Y, 2005), infection (McPherson et al., 2002, McPherson et al., 1997), fat embolism (Kim, 2001) and fractures (Dennis et al., 1993). Each TKA prosthesis has its own instrumentation. In the United Kingdom there are more than 30 TKA prostheses and it is common to have different prostheses used in the same hospital (Liow and Murray, 1997). This may overload hospital inventory, sterilization services, nurses' learning curves, and operating room time. Although conventional surgical instrumentation have been repeatedly modified, it appears that further refinements are unlikely to overcome their inherent drawbacks such as the multiplicity of instruments and the medullary canal perforation. Thus, an alternative to CI systems is required.

1.2 Alternative solutions

Computer assisted surgery (CAS) is an enabling technology that has the potential to improve accuracy and reproducibility and overcome drawbacks of conventional techniques of TKA such as intramedullary perforation. TKA, like many other orthopaedic procedures, is well suited for the application of CAS. It involves cutting and machining of bone, which is the most rigid structure in the body. Because of this inherent rigidity of bone, its location during surgery can be correlated repeatedly and consistently to a preoperative computer model (DiGioia-III et al., 1998). CAS systems are classified into active (robotic), semi-active (also, robotic) and passive (navigation). Navigation and robotic techniques have recently been introduced into clinical practice and they have proved to be more accurate than CI (Chauhan et al., 2004, Jakopec et al., 2001, Nabeyama et al., 2003, Perlick et al., 2004, Siebert et al., 2002, Stulberg, 2003). They have eliminated the use of alignment guides. However, navigation techniques still require the use of conventional instruments for making the various bone cuts and they even require additional instruments and insertion of pins onto which tracking instruments are attached. This doubling of instrumentation systems (navigational and conventional) would overload hospital inventory, sterilisation services and operating room time. They may also increase the number of decisions that have to be made by the surgeon. There is a growing need to introduce ergonomics in the surgical workplace (Stone and McCloy, 2004), which is more difficult to achieve with these bulky navigation devices that require continuous tracking.

Furthermore, navigation and robotics require registration (see section 5.4.2.1), which is an ambiguous process and subject to errors. Registration is defined as the process of determining the geometrical transformation between two sets of data. In simple terms, it means establishing a relationship (or matching) between imaging data and the patients' anatomy. The errors from registration can occur as a result of pin movement (in case of navigation) or movement of the limb (in case of robotics) and both may occur at any time during the operative procedure (Stulberg et al., 2002). The overwhelming intraoperative information from navigation systems may confuse the surgeon and complicate the decision-making process. These techniques can ultimately take senior surgeons away from their comfort zone and interrupt their learning curve. The rate of complications may increase during the early stages of learning the technique. All the above drawbacks have limited the broad clinical application of robotics and navigation techniques. There is a need for alternative approaches that are simple, less invasive, less expensive and accurate.

1.3 The aim of the study

The aim of this study was to explore the technology of computer assisted surgery to provide a solution that can improve the surgical techniques of TKA. This subsequently could improve the outcome of TKA in general and for complicated cases in particular. A new concept of computer assisted TKA using patient specific templating (PST) was proposed. This templating technique involved CT-based preoperative planning and designing of femoral and tibial patient-specific templates that could act as cutting blocks. For accurate execution of the preoperative plan, the templates required exact positioning over the distal femur and the proximal tibia guided by surface matching.

This laboratory study was designed to answer the following two primary research questions:

1. Can PST be an alternative to conventional instrumentation?
2. Is PST accurate and reliable?

It was intended to achieve this aim and to answer these questions through the following **objectives**:

a) A feasibility study to perform TKA on cadaveric and plastic knees using PST technique
b) A comparative trial between PST and conventional instrumentation for TKA
c) Accuracy and reliability testing by
    1) Evaluating postoperative CT scans
    2) Using a navigation system to measure errors as well as intraobserver and interobserver agreement in positioning the PST.

2. LITERATURE REVIEW

This chapter reviews the literature on the most important and relevant aspects of TKA that could help in understanding the deficiencies and limitations of the current techniques of TKA and the rationale behind the proposed approach. "Historical development" section is a useful reference as advanced technology may resurrect old principles that have previously failed. "Anatomy and biomechanics" outlines the basic facts relevant to TKA and reveals the complexity of the knee joint. "Current status of TKA" highlights the impacts of TKA on health care and the pitfalls in outcome measurements. "Current technique" reviews the standard conventional methods of TKA. "Deficiencies and limitations" analyses the current problems of TKA from the perspectives of surgeons, patients and health care providers and calls for a change.

2.1 Historical Development of TKA

2.1.1 Development of arthroplasty in general

The earliest attempts of arthroplasty procedures started in mid-nineteenth century with resection arthroplasty where only the diseased part of the joint was removed. This has progressed to interposition arthroplasty, initially with autogenous tissues such as capsule and fascia and later by artificial material such as glass and celluloid. However, none of these attempts produced good results until Smith-Petersen introduced the mould interposition arthroplasty of the hip in 1940 using Vitallium (cast cobalt-chrome-molybdenum alloy). The trial to transfer this success to the knee joint using metallic interposition arthroplasty failed. Although, at this time the introduction of hemiarthroplasty of the hip (particularly by Moore and Thompson) was only successful for short-term, it showed that metallic prostheses to be the implants of choice. Metal on metal joint arthroplasty was then developed for the hip and knee but they failed because of poor function, high excessive wear, infection and loosening. The success of joint arthroplasty did not materialise until 1960s when Sir John Charnley developed the total hip arthroplasty using metallic stem and head articulating against ultra high molecular weight polyethylene (UHMWPE) acetabular cup. The stem and cup were fixed to the bone using polymethylmethacrylate cement. Similar designs were developed for other joints starting with the knee and moving to the ankle, shoulder, elbow, and wrist. Only hip and knee arthroplasty continued to be performed in large numbers in comparison to other joints (Crockarell and Guyton, 2003).

2.1.2 Development of TKA

The current TKA is the replacement of damaged articular surfaces by metallic and plastic implants. The idea of restoring the knee function by modifying its damaged articular surface (arthroplasty) started as early as 1860s. At the time, Ferguson reported the first resection arthroplasty of knee and Verneuil suggested the interposition of soft tissues (Tooms, 1987). The results of these procedures were sufficiently poor to discourage anything more than occasional attempts in severe cases (Insall, 1993). On the other hand, hip arthroplasty progressed more satisfactorily into the metallic era. The relative success of hip metallic cup arthroplasty encouraged Boyd and Campbell to introduce metallic arthroplasty of the knee, using interposition femoral mould, in 1940 (Tooms, 1987). Similar ideas were introduced during that time but none was successful to withstand the test of time. In 1958 MacIntosh introduced the first hemiarthroplasty of the knee using acrylic, then metallic, tibial implant. It was not until 1960s that non-hinged knee arthroplasty was introduced as a prototype of modern TKA (Tooms, 1987). These types had cemented metallic femoral implants articulating against UHMWPE tibial trough. The modern TKA began about 1970; Insall (1993) has divided the history of design and technique of modern TKA into three decades:

a) The 1970s marked a period of experimentation and evolution. This progressed to surface replacement with a one-piece UHMWPE tibial component and patellar resurfacing.
b) The 1980s saw significant advances in surgical techniques and instrumentation that made TKA more reproducible. New concepts were introduced e.g. minimal bone resection.
c) The 1990s was the period of re-evaluation and return to earlier concepts e.g. increasing use of cement, more conforming surfaces.

According to Insall (1993), the failure rate of early modern TKA was high creating a bad reputation that persisted for several years. The advances in surgical techniques and instrumentation in 1980s made TKA more reproducible and successful than before. Since then there have been several attempts to improve implant designs and materials. Fixation methods have also improved and currently both cemented and uncemented fixations are equally successful (Hofmann et al., 2001, Khaw et al., 2001). An expert in designing TKA prostheses stated, "currently many of the principles of successful prosthesis designs have been established, nevertheless, performance and consistency are likely to be enhanced by advances in instrumentation"(Walker, 1999). However, attempts to refine surgical instrumentation have never stopped and have resulted in the increasing number of jigs and fixtures and in turn the complexity of the procedure.

Summary

Current TKA is now more successful than before due to the advanced technology in implant design, materials and fixation methods. At present further improvement in these areas seems to reach an end (apart from the attempts to improve bearing surfaces) and more focus is now directed to improve surgical techniques.

2.2 Anatomy and biomechanics of the knee

For better outcome of TKA it is of extreme importance for surgeons to understand the complex anatomy and biomechanics of the knee joint. The following section briefly outlines the anatomical and biomechanical facts that are relevant to TKA and within the scope of this study. The anatomy is focused on the osteology of the knee joint, which is important for preoperative planning, surface matching of the templates and bone cutting. There is a brief description of soft tissues that may interfere with the positioning of the templates. Little or no description has been given for menisci and other soft tissues, which are normally removed during TKA. The biomechanics is focused on kinematic and kinetic issues relevant to the surgical technique of TKA.

2.2.1 Anatomy of the knee

This section is derived with modification from "Surgery of the knee" (Clarke et al., 2006) and Grays Anatomy (Gray, 1995) textbooks. It only describes the anatomical structures that are relevant to this study. The knee is the largest and one of the most complex joints in the body. It is a weight bearing joint but unlike the hip it lacks the freedom of multiplane motion. The knee is diarthrodial, modified hinge joint. It consists of three bony structures (the distal femur, proximal tibia and patella) forming a tricompartmental joint with a gliding (patello-femoral) and two condylar (tibio-femoral) joints.

The distal femur (Figure 1) has a complex architecture with asymmetrical medial and lateral condyles. The medial condyle is larger and has a more prominent medial epicondyle. The lateral condyle as viewed from the side has a sharply increasing radius of curvature posteriorly. When viewed from the surface, articulating with the tibia, the lateral condyle is shorter. The intercondylar notch separates the condyles distally and posteriorly. The lateral epicondyle is a small but distinct prominence, to which attaches the lateral collateral ligament. The medial epicondyle is a C-shaped ridge with a central depression (sulcus) in the middle that gives the attachment of the medial collateral ligament. The epicondylar axis passes through the centre of the sulcus of the medial epicondyle and the lateral epicondylar eminence. The epicondylar axis is externally rotated about 3.5° in males and 1 degree in females in normal knees but it may rotate up to 10° in valgus knees in relation to the posterior condylar line. The width of the distal femur along the transepicondylar axis is narrower in females than males relative to anteroposterior dimensions.

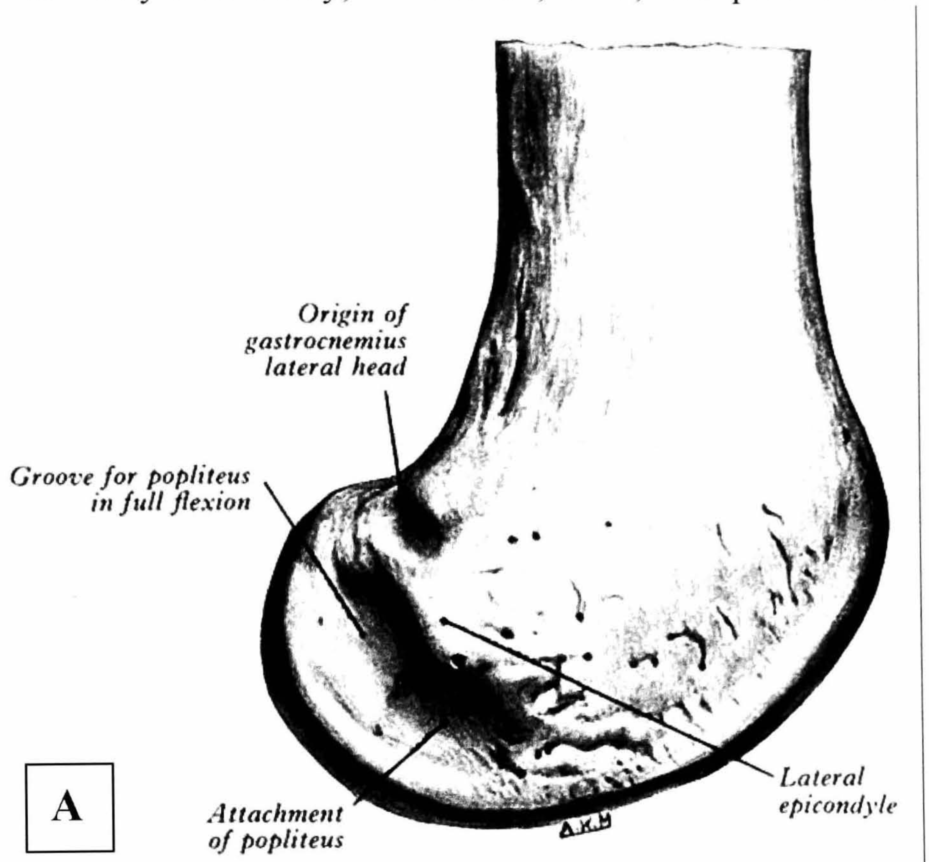
The proximal tibial (Figure 2) articular surface has a larger and concave medial plateau and a convex lateral plateau and both are separated by the intercondylar eminence. Both plateaux have a posterior inclination of 2 to 10° to the shaft of the tibia (Insall and Easley 2001). Intercondylar Area lies between the condylar articular surfaces. It is rough, narrowest centrally and forms an intercondylar eminence, the edges of which project slightly proximally as lateral and medial intercondylar tubercles. At the back and front of the eminence the intercondylar area widens as the articular surfaces diverge. In the anterior surface of the tibia the tuberosity is the most prominent feature and it is the attachment site of the patellar tendon.

The patella is asymmetrical oval in shape with the apex located distally. It articulates with the femoral trochlea. Patellar ligament is the central band of the tendon of quadriceps femoris, continued distally from the patella to the tibial tuberosity. It is strong, flat, about 8 cm in length. The patellar ligament is separated from the synovial membrane by a large infrapatellar fat pad and from the tibia by a bursa. The knee has unique intraarticular structures; the most important are menisci and cruciate ligaments. The medial and lateral menisci facilitate the rotation of the knee and act as cushions to

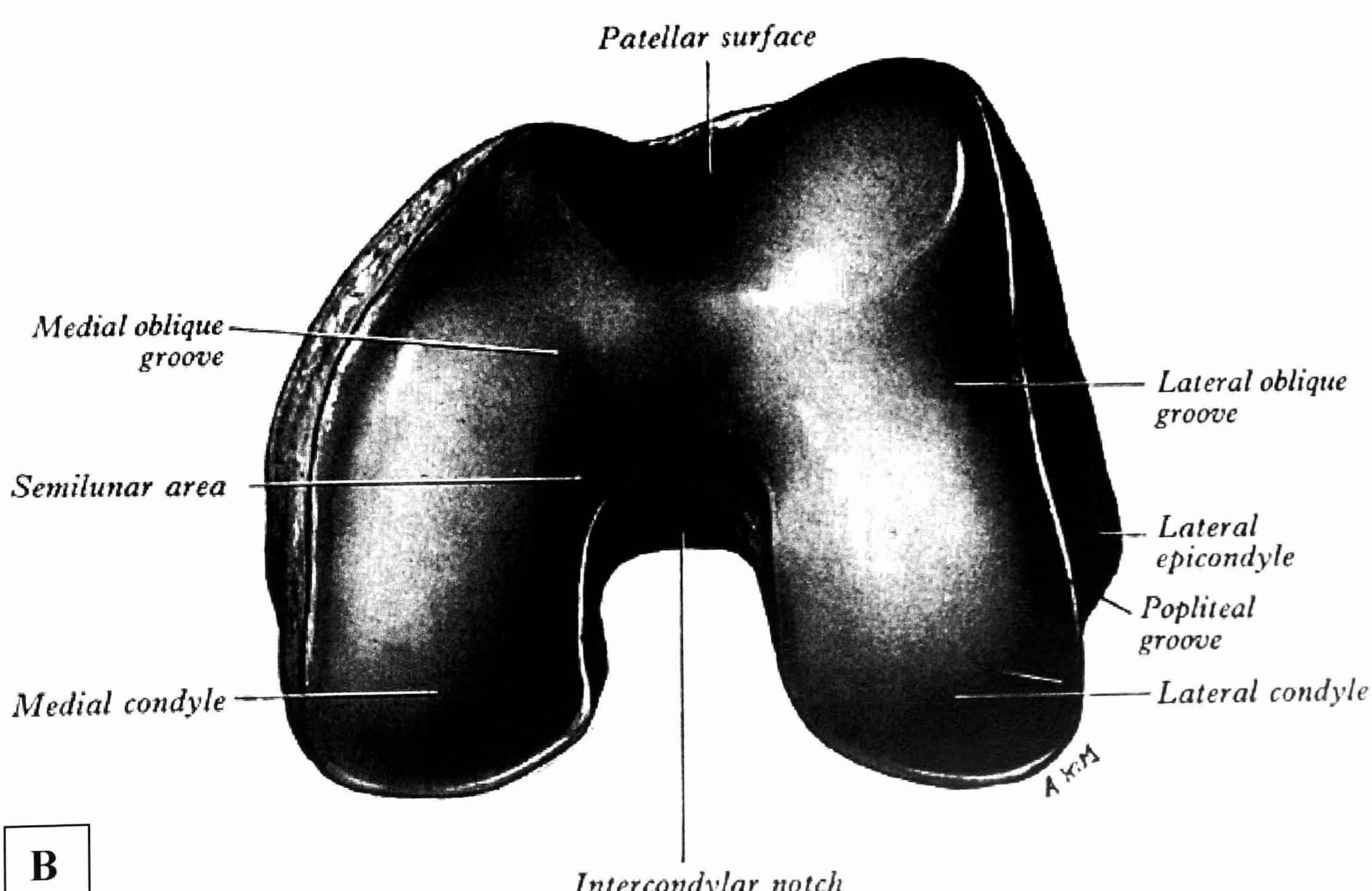
Figure 1

Anatomy of the distal femur

From Gray's Anatomy, 38th edition, 1995, with permission from Elsevier



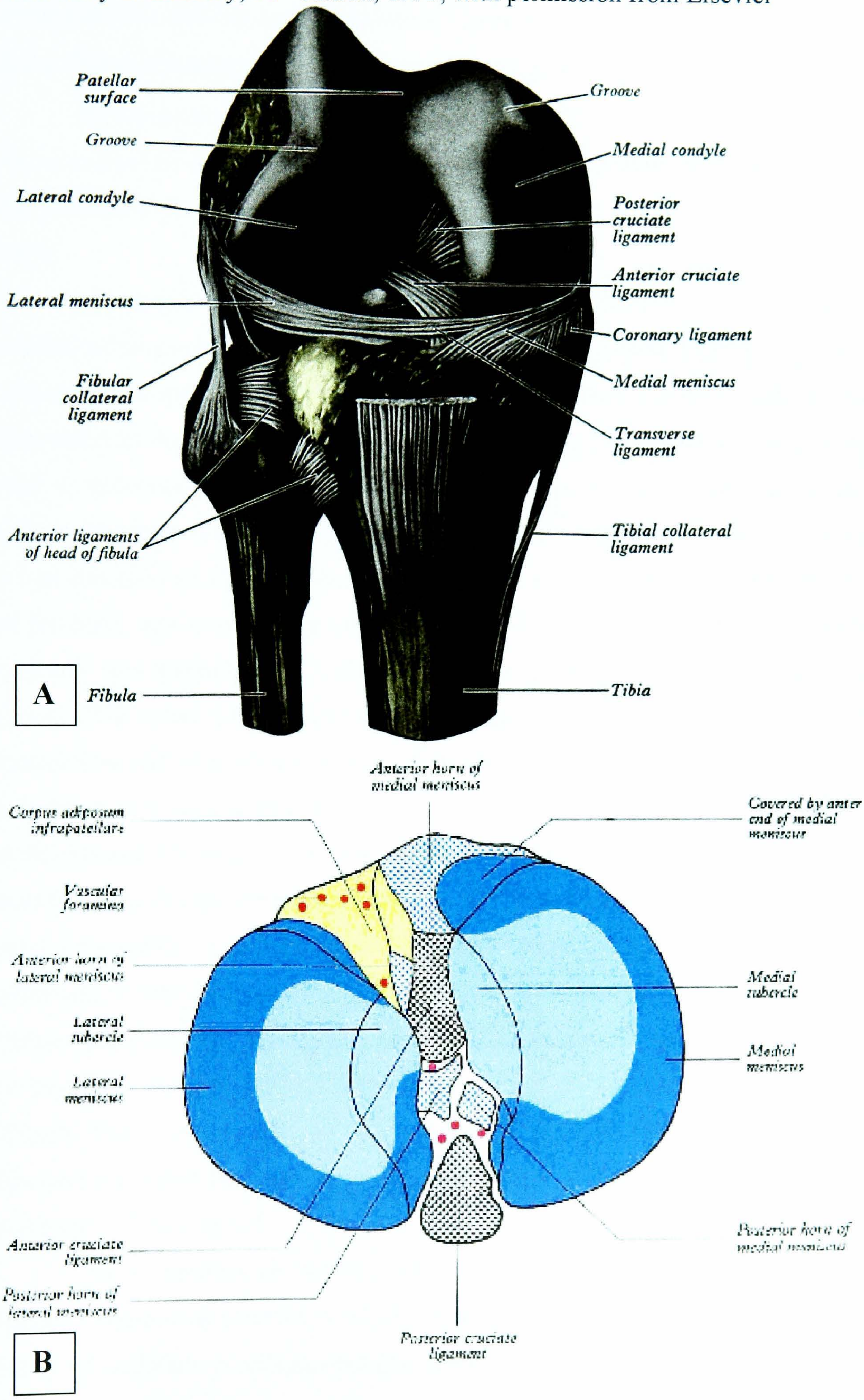
A



B

Figure 2
Anatomy of the proximal tibia

From Gray's Anatomy, 38th edition, 1995, with permission from Elsevier



protect the articular surface. They deepen the articular surface and improve the conformity between the tibia and the femur. The cruciate ligaments provide anteroposterior stability and the collateral ligaments provide mediolateral stability.

2.2.2 Biomechanical consideration for TKA

Biomechanics is the study of the mechanics of a living body, especially of the forces exerted by muscles and gravity on the skeletal structure. This section will outline the principles of knee kinematics and kinetics relevant to the surgical techniques of TKA.

Kinematics is the branch of mechanics that studies the motion of a body without consideration given to the forces acting on it. The review of detailed knee kinematics is outside the scope of this study. However, it is important here to briefly describe the kinematics of the normal knee and to highlight the fact that poor surgical technique will lead to abnormal kinematics of TKA and subsequently poor performance and early failure. The knee predominantly moves in one plane (sagittal flexion and extension) so it was classified as a hinge joint. In fact the knee -to a much lesser extent- has another 5° of freedom; movement in the coronal plane (valgus and varus), rotation (internal and external) and translation in 3 directions (anteroposterior, mediolateral and proximal-distal). This makes the knee a modified or atypical hinge joint. The motion of the knee ranges from 10° of extension to more than 145° of flexion but the functional movement is between 0° extension and 90° flexion. Movement in the coronal plane is only allowed in flexion and it is only few degrees of passive motion. Fluoroscopic analysis of normal human knees (Komistek et al., 2003) showed that during weight bearing there is an axial femorotibial rotation of about 16.5°-16.8° when the normal knee moves from full extension to 90° of flexion. The tibia rotates internally relative to the femur during flexion and externally during extension. Femoral rollback is another motion that occurs in the native knee so that the femur can clear off the posterior tibia and allows more flexion. The centre of rotation of the knee is located in the medial femoral condyle. Because the distal femur is polycentric the centre of rotation is changing and moves posteriorly during flexion.

The kinematics of the knee joint is somewhat complex and it is difficult to restore it completely after TKA. Fluoroscopic analysis (Banks et al., 2003, Dennis et al., 2004) of different prosthetic designs revealed different patterns from normal knee kinematics with abnormal rotation and femoral rollback. Reverse axial rotation (i.e. external rotation of the tibia during flexion) results in patellofemoral instability and reduction in femoral rollback leading to limited flexion. Abnormal femoral rollback may appear as paradoxical anterior femoral translation during flexion and this may lead to limited flexion and increased polyethylene wear (Banks et al., 2003, Blunn et al., 1991). Although the kinematics of TKA could be improved with appropriate implant design it is important for surgeons to avoid creating abnormal patterns of kinematics that result in abnormal wear and early failure. This target could be achieved through precise surgical techniques that result in normal alignment, joint line level and ligament balancing.

Kinetics is the branch of mechanics that is concerned with the effects of forces on the motion of a body, especially of forces that do not originate within the system itself. The knee is a weight bearing joint and the loading forces on the articular surfaces are 3 times body weight during walking and 4 times during stair climbing. Because the tibial anatomic axis has a 3° inclination relative to the transverse knee axis, a varus moment is created during normal gait. This explains why the distribution of contact forces across the knee joint is not symmetrical. Up to 60 to 75 % of these forces are carried by the medial compartment (Morrison, 1969). Racial variations may exist. Felson et al (1988) found that Beijing men have more valgus knees as compared to Caucasian, which may explain the higher prevalence of lateral osteoarthritis among Beijing men (more than twice the prevalence among Caucasian). Unlike the hip joint, the bony configuration of the knee lacks the conformity that can provide adequate bony stability. The collateral and cruciate ligaments and the muscles are the principal stabilizers of the knee joint. Normal distribution of load across the medial and lateral compartments is maintained by the normal action of ligamentous structures and the normal alignment of the knee.

The alignment of the knee is one of the most important and pertinent issues to the surgical techniques of TKA. Abnormal alignment results in varus or valgus moments with excessive loading on one side resulting in wear and early failure. The vertical axis of the body passes from the centre of gravity to the ground. The mechanical axis passes from the centre of the femoral head to the centre of the ankle and normally through a point just medial to the medial tibial spine. A line drawn through the long axis of the femur represents the femoral anatomical axis and a line drawn through the long axis of the tibia represents the tibial anatomical axis. The mechanical and anatomical axes of the tibia are the same, but there is an angle of about 6° between the mechanical and anatomical axes of the femur.

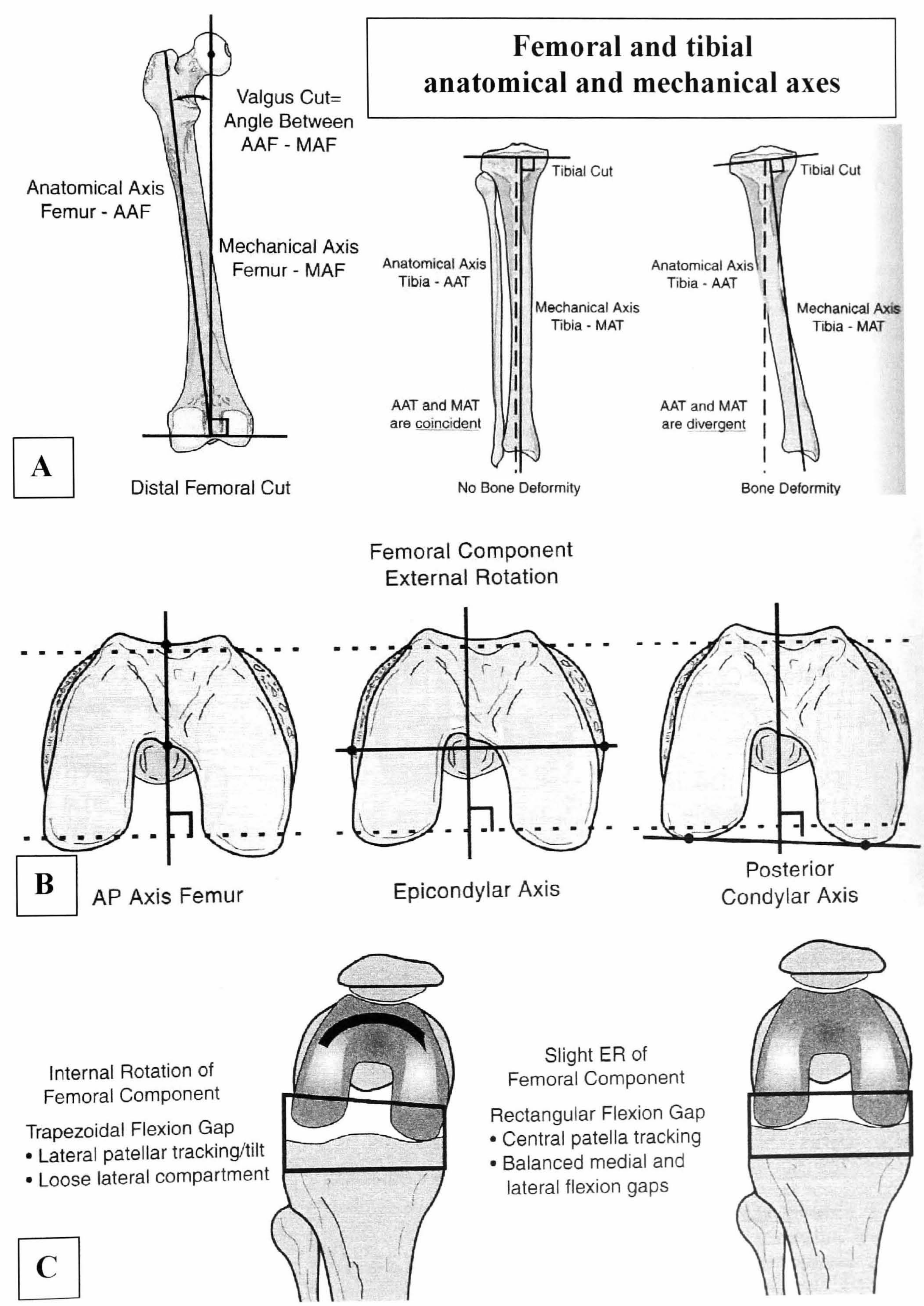
2.2.3 Restoring normal anatomy and biomechanics in TKA

The complex anatomy and biomechanics of the knee joint cannot be replicated by TKA. However there are some important anatomical and biomechanical parameters, which need to be maintained otherwise early failure of function and survival will occur. The technical goal of TKA, therefore, is to restore the normal alignment, preserve the joint line and maintain soft tissue balance. These three parameters will be discussed in more detail because they are very important and relevant to the surgical technique and the proposed approach. The proposed approach does not directly address soft tissue balance and this has been criticised by some surgeons. For this reason the standard techniques for soft tissue balancing with a comparison of different methods are detailed below. In the discussion chapter a plan will be proposed on how to deal with soft tissue while using the proposed technique.

1) *Restoring normal alignment:* Normal alignment (Figure 3) is required in TKA to allow normal distribution of load and so prevent early failure. To restore mechanical alignment the distal femoral TKA should be cut at 4° to 7° of valgus to the anatomical axis (Insall and Easley 2001), which is set by the IM guide. Due to the presence of soft tissues, extramedullary alignment guide is not reliable in the femur. However in case the IM guide could not be used due to a deformed femur it is recommended to use extramedullary guide. Tibial cuts are usually made

Figure 3
Restoring normal alignment and rotation in TKA

From Review of Orthopaedic (Miller), 3rd edition, 2000, with permission from Saunders, Elsevier



perpendicular to the anatomical or mechanical axes guided by an intramedullary or extramedullary rod respectively. In case of a deformed tibia extramedullary rod is recommended. With a perpendicular tibial cut there will be more bone removed from the lateral tibial side than the medial (about 3 mm). In extension this is compensated for by more bone resection medially than laterally from the femoral side. In flexion the posterior femoral cut must be externally rotated 3° to provide a symmetrical flexion gap. The posterior cut should form a 3°-angle to the posterior condylar line, be parallel to the epicondylar axis or perpendicular to the anteroposterior line axis (Whiteside, 2002). The rotational alignment of the tibia is guided by the tibial tubercle (along its medial third) and it should be accurately done as it affects patellofemoral tracking. The sagittal alignment of the femur is set with the IM guide and determined by the distal femoral cut which should be at neutral or 3 degree of flexion. The sagittal alignment of the tibia is determined by the anteroposterior inclination of the tibial cut, which slopes posteriorly with variable inclination ranging from 3° to 7°. This inclination should also vary with different implant designs as some tibial implants have a variable anteroposterior thickness. The normal alignment of the patellofemoral articulation (even if the patella is not replaced) will be restored when the femoral and tibial components are accurately implanted with normal alignment and rotation.

2) *Restoring joint line level:* This is required for normal function and normal kinematics of the knee. Restoring normal joint line level requires accurate sizing of the implant and precise bone cutting. Under-sizing of the femoral implant may result in a wide flexion gap forcing the surgeon to increase the thickness of the tibial insert and subsequently resecting more bone from distal femur. Excessive bone resection from distal femur results in elevation of the joint line level and subsequently patella baja (patella infera). The latter leads to limited knee flexion due to impingement of the patella on the tibia during flexion. Lowering the joint line results in patella alta that may affect the extensor mechanism of the knee (Insall and Easley 2001).

3) *Soft tissue balance:* Ligament balancing is an essential part of TKA. However overzealous soft tissue release can result in imbalance and instability. A rational approach needs to be adopted to avoid complications. First of all ligament balancing is dependent on correct alignment of TKA. Some authors (Whiteside,

2002) emphasized that perfect bone cutting can reduce the need for soft tissue release. The earlier teaching (Insall et al., 1976) was simply to release tight ligaments before bone cuts were made, and then resect distal and posterior femur to create equal flexion and extension gaps. This approach improved ligament balance but left little leeway for final precise ligament balancing and also provided no means for varus/valgus alignment in flexion. Another approach was to use tensioners to tension the ligaments in flexion, allowing the ligaments to dictate the rotation position of the flexed knee and subsequently the alignment of the patella. While this technique can result in equal tension in flexion, it can rotationally malalign the femoral component in flexion and maltrack the patella. The third approach (Whiteside, 2002) begins with correct alignment in flexion and extension by precise bone cutting of the tibia and femur separately and irrespective to ligament contracture or stretching. Once alignment, sizing and positioning of trial implants are correct, the ligaments can be assessed and released only if necessary. The aim in ligament balancing is to correct varus and valgus alignment in flexion and extension. Both lateral and medial ligamentous structures are complex and they consist of different bundles that behave differently in flexion and extension. The traditional approach of releasing the ligaments in extension may result in laxity in flexion. The contracture and stretching that occur due to deformity and osteophytes affect these ligamentous components unequally and after bone cutting it may cause different degrees of tightness or laxity in flexion and extension (Whiteside, 2002).

Therefore it is rational to do a precise bone cutting first which alone may correct any previous imbalance caused by deformity and osteophytes and then assess the ligaments and release accordingly. Incorrect bone cuts or sizing of the implant lead to soft tissue imbalance; e.g. abnormal sloping of the tibial cut leads to sagittal anteroposterior imbalance and under-sizing increases the flexion gap.

Summary

The anatomy and biomechanics of the knee joint is complex. The success of TKA depends on the restoration of normal alignment and kinematics of the knee joint. Accurate planning and precise implementation of the surgery are vital. The next section will discuss the importance of TKA and its impact on health care and will review the current outcome results of TKA.

2.3 The current status of TKA

2.3.1 Arthritis and the indications for TKA

The most common types of knee arthritis are osteoarthritis (OA), rheumatoid arthritis (RA) and post-traumatic arthritis. OA is the most common joint disease and the knee is more likely to be damaged by arthritis than any other joint (Felson, 1988). OA of the knee is even more prevalent in the Far East and Middle East due to the traditional and religious habits (Al-Arfaj et al., 2003, Yoshida et al., 2002, Zhang et al., 2001). Zhang et al (2001) found that prolonged squatting is a strong risk factor for knee OA in Chinese patients. Yoshida et al (2002) found a high prevalence of knee OA in Japanese women compared to Caucasian. In a survey of 5,894 adult Saudi populations, Al-Arfaj et al (2003) found that clinical OA of the knee was present in 13 % of adults above the age of 16 years. This prevalence increased with increasing age reaching 30.8% in those aged 46-55 years and 60.6% in the age group 66-75 years.

OA is a slowly progressive degenerative disease that usually affects middle aged and elderly people leading to gradual wear of their articular cartilage. Studies have shown that obesity or as yet unknown factors associated with obesity cause knee osteoarthritis. The association between weight and OA is stronger in women than in men (Felson et al., 1988). The primary radiographic signs of OA are joint space narrowing, articular sclerosis, subchondral cysts and osteophytes. The medial compartment is affected most often followed by the patellofemoral and the lateral. Severe OA of the medial compartment usually results in genu varus and that of lateral compartment results in genu valgus. RA is an inflammatory arthritis that is less common than OA. It affects the synovial membrane and subsequently destroys the cartilage. It can occur at any age, more common in females and usually affects both knees. In RA the radiographic appearances are somewhat different from those of the OA and may include periarticular osteoporosis, uniform narrowing of joint compartments, articular erosions and lack of sclerosis and osteophytes formation. Post-traumatic arthritis may develop very slowly following serious bony or soft tissue injuries. In a prospective study of 1321 students with a median follow up of 36 years it was found that the cumulative incidence of knee OA by 65 years of age was 13.9% in participants who had a knee injury during adolescence and young adulthood and 6.0% in those who did not (Gelber et al., 2000). The radiographic signs are similar to OA but signs of old fractures or deformities may be seen.

The main symptoms from arthritis are pain, stiffness and swelling. Patients with mild symptoms can manage their arthritis without treatment or with non-surgical measures (conservative treatment). However severe symptoms can limit the walking distance, disturb sleep and interfere with other activities of daily living. More than 40 percent of people with OA Knee rate their health as poor or fair and they report a higher degree of emotional distress (AAOS, 1998). The indications for TKA are severe pain and disability with accompanying radiological changes in patients where conservative treatment has failed but occasionally TKA may be offered for patients who have progressive deformity and/or instability when pain may not necessarily be the most significant factor (BOA-BASK, 2004).

2.3.2 Impact of TKA on health care

TKA is currently one of the most common surgical procedures. It is the treatment of choice for advanced arthritis of the knee in patients aged over 55. The majority of patients after recovery from TKA will experience dramatic relief of pain and would be able to perform activities of daily living. Other preoperative symptoms usually disappear and most patients can regain their normal independence and obtain a better quality of life. This improvement in function has been quantified by using specific knee scores (Callahan et al., 1994). Studies have also shown that TKA is a cost effective procedure (Lavernia et al., 1997). Because of demographic and economic differences between the developed and developing worlds the impact of TKA will be discussed separately.

Developed World: Statistics from USA (AAOS, 1998) showed that knee problems are the most common reason for visiting orthopaedic surgeons. In 1999, more than 5 million adults reported having knee joint pain, swelling and stiffness. People with OA Knee made more than 3.7 million visits to physicians' offices and more than 150,000 outpatient visits for a variety of reasons. Counting visits for all reasons, there were between 400,000 and 430,000 inpatient hospital stays for individuals with Knee

OA in 1999. 25 % of those adults with OA had surgery, most commonly TKA with an average charge of $18,000 per hospital stay.

Knee OA is common and it affects approximately 10 % of people aged 55 years or more (Felson, 1988). Knee arthritis is slightly more common than hip arthritis and 20 per 1000 individuals in the general population over 55 years would benefit from knee replacement. 4 per 1000 of these patients have extreme disability but many are not referred for surgery. In women aged 75 years and over, the incidence is 43 per 1000 (Tennant et al., 1995). The provision of TKA is variable in different countries and among different regions. In one report from the UK the ratio between TKA and THA was 1:2 (Tennant et al., 1995) while in USA this ratio is almost reversed TKA (267,000 per year) while THA (168,000). The possible causes for this low provision of TKA are; delayed referral until OA is advanced (Gidwani et al., 2003) reluctance to refer and barriers to treatment (Tennant et al., 1995) long waiting lists and the unmet need for joint arthroplasty.

Demographic changes are likely to increase the demand for knee replacement by 40% over the next 30 years (Birrell et al., 1999). Between 1991 and 2000 the incidence of primary TKA doubled to around 33, 000 and of revision TKA increased by 300% while that of primary and revision THA increased only by 18% and 100% respectively (Dixon et al., 2004). Projections estimate that primary TKA numbers would increase by 63% by the year 2010 with about 54, 000 TKA operations annually. TKA is also common in other western countries e.g. 267,000 TKA procedures are performed each year in the United States.

Developing world: Knee OA is more common in Middle and Far East compared to Caucasian (Al-Arfaj et al., 2003, Yoshida et al., 2002, Zhang et al., 2001). Considering that 85% of TKA in the developed world are performed for patients with OA, one would expect that in developing countries TKA would be a very common procedure. Unfortunately the high numbers of patients (many of them are young) who are suffering from OA with pain and disability are deprived of the privilege of having TKA. This is largely because of limited resources and training and the fear of infection and revision surgery. Infection is the most devastating complication in TKA and its incidence could be potentially high due to the absence of dedicated ultra clean air theatres.

2.3.3 Outcome results of TKA

Several reports in the literature showed successful long-term results of TKA in elderly patients with 15-year survival rate up to 95 % (Hofmann et al., 2001, Jacobs et al., 2004, Khaw et al., 2001, Ritter et al., 2001, Scuderi et al., 1989). These results are comparable for the different fixation methods, both cemented and cementless (Hofmann et al., 2001, Khaw et al., 2001), and for different designs of modern TKA. Both fixed-bearing and mobile-bearing designs have been reported to be successful (Price et al., 2003). Comparable results were also reported for PCL retaining, sacrificing or substituting (Misra et al., 2003, Straw et al., 2003).

On the other hand modifications to the design of TKA prostheses have never stopped, in UK alone there are more than 30 knee prostheses in current use (Liow and Murray, 1997). Given the high rate of survival, one would wonder why implant designers are striving to improve TKA design. Many authors (Murray et al., 1997, Murray and Frost, 1998, Hafez et al., 2004, Moran and Horton, 2000) questioned whether these impressive figures of success rate are reliable? It seems that the true failure rate is much higher than has been reported for the following reasons:

a) There is no agreed standardisation on outcome measures for TKA (BOA-BASK, 2004).
b) Using revision as an endpoint has resulted in not reporting other failed cases, which have not been revised due to insufficient symptoms for surgery, medical unfitness and other reasons. Murray and Frost 1998 reported a survival rate of 72% when pain was used as an endpoint compared with 97.5 % when revision was used as endpoint after 7 years follow up of 1429 TKAs. When patients' satisfaction was considered, the rate was reported as 80 % (Rand and Coventry, 1988, Robertsson et al., 2001). Another reason is loss of follow up, as patients with failed TKA may seek a second opinion and are referred to a subspecialist for revision surgery (Murray et al., 1997). Recent studies have introduced "worst case" analysis, where all patients lost to follow up are considered to have failed joints. This gives a more pessimistic, but possibly more realistic, view of joint survival.
c) Reporting small series of patients performed by one surgeon using a particular prosthesis in one centre may not be representative and may not reflect the overall results. Rand, Trousdale et al (2003) conducted a survivorship analysis of 11,606

TKA procedures and reported an overall survival of 91%, 84%, and 78% at ten, fifteen, and twenty years, respectively. The Swedish register in 1980s reported a survival rate 87% after 6 years for TKA (Knutson et al., 1986). Currently there is a trend in many countries to establish national registers similar to the Scandinavian arthroplasty registers.

d) Early outcome studies focused on the surgeon's view, where bias could not be eliminated. (Hafez et al., 2004) found that surgeon's assessment was high rated in comparison to patient's self-assessment. Most recent studies have considered patient's views and used generic health status questionnaires (such as the SF36) as well as knee scores to assess the outcome of TKA.

e) Most of the reported studies are done in specialised centres and by senior surgeons and their reported success rate may not be reproducible elsewhere. In USA, a significant number of TKA procedures are done by low volume surgeons who do less than 10 procedures per year. Literature is scarce in reporting results of junior surgeons or surgeons who have had no official training for TKA.

f) The success rate of TKA in developing countries is not known. In some places a high rate of complications and failures has been observed but not reported.

g) Literature is biased as most of our quotations come from English literature ignoring data reported in other languages and Medline contains only selected journals.

h) Most knee prostheses are repeatedly modified by manufactures so the reported results are for designs, which are no longer available. "There has been a failure to recognise that minor modifications to design, material, surface finish or fixation techniques can dramatically alter the performance of a knee replacement" (BOA-BASK, 2004).

i) The majority of outcome studies of TKA used short knee radiographs and few of them used long leg radiographs for assessment of alignment and loosening. The accuracy of plain radiographs is limited and may lead to clinically significant measurement errors that affect the overall outcome results (see chapter 2.5.1.1). Recent studies used CT scanning specially to assess computer-assisted TKA (Chauhan et al., 2004, Jazrawi et al., 2000, Lam and Shakespeare, 2003, Oberst et al., 2003). The high survival rate in the majority of these studies is related to elderly patients who, in most cases, place low demand on the implant by virtue of limited activities of daily living (ADLs). Therefore their TKA procedures are not subjected to the actual demands of ADLs as found in younger patients. These patients usually do well even in the presence of malalignment or other technical errors. They are usually satisfied because their main expectation is pain relief rather than function. Many of them die before the manifestations of technical failures of TKA.

j) Younger and active patients have lower survival rate. In one study (Rand et al., 2003) the 10-year survival rate for young patients less than 50 years was 83% while for patients older than 70 years it was 94%.

k) Results for complicated cases are poor as examples: deformities, haemophilia, following patellectomy, osteotomy, arthrodesed knees, etc

l) Revision TKA is more difficult, has more complications and the success rate is lower than of primary procedures. Diduch et al (1997) published the survivorship analysis of 108 revision TKA procedures for patients under the age of 55. The overall survival rate was 87 % at 18 years. Revision surgery is more difficult; results are unpredictable and can lead to a series of compromises (Scuderi et al., 1989).

Summary

Severe knee arthritis is a disabling condition that has socioeconomic consequences. TKA has a significant impact on health care systems and the society in general. Although TKA is successful the true success rate is much lower than has been reported. The next section will describe the requirements and the challenges of the current TKA techniques.

2.4 Current techniques for TKA: Requirements and challenges

2.4.1 Introduction

The term arthroplasty is used in this thesis although both terms replacement and arthroplasty are interchangeably used in the literature. TKA implies that all the three compartment of the knee including the patello femoral are replaced. Although the laboratory work in this thesis did not involve resurfacing of the patella we continued to use the term TKA in the entire thesis for two reasons. First, the proposed technique in principle could be applied to patellar resurfacing. Secondly, to avoid confusion as the majority of surgeons use the term TKA even when they do not replace the patella.

The replacement of the patella is controversial and there is no strong evidence to suggest routine replacement (Bourne et al., 1995, Keblish et al., 1994, Barrack, 2003). The practice is variable and depends on surgeons' preference and type of patients, as can be demonstrated by the results form two recent randomised trials. The first trial showed no difference in pain relief and function whether the patella was resurfaced or not (Mayman et al., 2003). While the second trial showed that patients with resurfaced patellae had better knee scores than those who had no patellar resurfacing but both groups had equal postoperative functional scores (Waters and Bentley, 2003).

Metal articulating with Polyethylene is the gold standard for TKA. The most commonly used metal implant for femoral component is cobalt chrome whereas the only material for tibial and patellar components is UHMWPE. Metal backing for UHMWPE of tibial and patellar components is optional. Wear of UHMWPE is a common cause for failure of TKA; nevertheless investigators have failed to find an alternative material. There are several causes for UHMWPE wear and early failure of TKA such as reduced thickness of UHMWPE, lack of conformity of the articulating surfaces and malalignment of the implants (Bartel et al., 1986, Edwards et al., 2002). To reduce failure between prosthetic components, a minimum thickness of between 6 and 12 mm UHMWPE is recommended (Bartel et al., 1986, Edwards et al., 2002, Wright TM, 1986). Therefore a thickness of tibial bone equivalent to the thickness of the UHMWPE plus the backing metal has to be removed. There are few variations in the currently available TKA prostheses but most modern designs are equally successful.

Each TKA prosthesis has its own surgical instrumentation that allows sizing and alignment of the prosthesis in addition to bone cutting. The Oscillating Saw is currently the standard instrument used for bone cutting. Implant fixation in TKA is not as crucial as in total hip arthroplasty (THA). Cemented TKA remains the gold standard although recently uncemented TKA has achieved as good results as cemented TKA (Hofmann et al., 2001, Khaw et al., 2001).

2.4.2 Requirements and criteria for successful TKA

The current technique of TKA is considered to be a major procedure and it requires certain hospital facilities and prophylactic measures. The BOA recommends the availability of ultra clean air theatre dedicated to clean elective orthopaedic surgery; trained assistant and scrub nurse; skilled anaesthetist and a full range of specialised implants (BOA-BASK, 2004). It is also necessary to have an adequate number of trained nurses and access to a high dependency or intensive care unit. When co-morbidities exist, risk benefit considerations may rule out the operation in an individual patient. In addition to an ultra clean air theatre, prophylactic antibiotic and antibiotic impregnated bone cement are routinely used to reduce the risk of infection. Prophylaxis against deep venous thrombosis and pulmonary embolism are also recommended. In appropriate cases it may be possible to do sequential or simultaneous bilateral TKA procedures under the same anaesthetic session. Although this practice is associated with more rapid rehabilitation (Stanley et al., 1990, Morrey et al., 1987), its broad application is still limited due to the possible morbidity (Wapner et al., 1984), the need for high surgical and anaesthetic skills and high dependency unit. Physiotherapy should start as early as possible after surgery and should be supervised by an experienced physiotherapist. Some of the above measures are just adjuncts to the current technique rather than essential requirements for TKA. They are troublesome and costly and they might be avoidable in the presence of a better alternative to the conventional technique (see adjuncts to TKA in section 2.5.1.2).

2.4.3 Challenges for TKA

The development of TKA was secondary to THA, as it was hindered by several factors. The anatomy of the knee is complex and its kinematics are not fully understood. The almost monoplanar motion of the knee subjects the prostheses to more stresses increasing the risk of loosening as the forces resulted from the motion in other planes (e.g. rotation) will be transmitted to the implant bone interfaces. The interfaces may be those of implant with cement in case of a cemented prosthesis, or, of implant with bone in case of a cementless prosthesis. The knee joint is superficial and although this makes the surgical approach easier it subjects the joint to higher risk of wound complications and infection. The large volume of TKA prostheses exacerbates this problem. Placement of the prosthesis is critical and must be accurate as a few millimetre of malalignment can lead to failure. Complication rates are higher than in THA (up to 26 % in primary TKA (Frosch et al., 2004) and salvage procedures are less successful. While excision arthroplasty can successfully salvage a failed THA it produces a very poor result in the case of TKA. Amputation is a recognised complication for TKA but not for THA.

Despite the above, knee arthroplasties are becoming more complicated over time with the introduction of new and more demanding techniques. Knee arthroplasties include TKA, unicompartmental (Murray et al., 1998) bicompartmental, Uni-spacer (Hallock and Fell, 2003) and patellofemoral arthroplasty (Amstutz et al., 2001). TKA could be a primary procedure (using unconstrained or hinged prostheses) or a revision procedure (using off-the-shelf or custom-made prostheses). The primary procedure has a number of choices including prostheses with any of the following features: fixed-bearing, mobile-bearing, cruciate substituting, cruciate retaining, non-modular tibial component, cemented and uncemented. Each of these implants has its own instrumentation system associated with a particular sequence of technical steps.

Minimally invasive surgical (MIS) approaches have recently received a lot of attention and have become a standard procedure for TKA and UKA in some specialised institutions. Few authors reported a unique and challenging technique of using arthroscopy to improve visualizing while performing minimally invasive UKA . In addition to the experience in arthroplasty, it requires mastering of arthroscopic techniques that involve the use of 2-D information to produce 3-D movements. Outpatient (day case) TKA and UKA have also been recently introduced and showed more rapid patient recovery and the advantages of reducing the duration of hospital stay to one day. All these require highly skilled surgeons, nurses, anaesthetist and other theatre staff.

Amongst the challenges is the widening of the indications for TKA to include difficult cases of arthrodesed knees, post patellectomy, bone deformities, HIV, haemophilia and others. These cases again require highly skilled and experienced surgeons and are usually done in specialised centres. Some of these cases require meticulous preoperative planning and very precise surgical performance.

Summary

Metal articulating with Polyethylene (PE) is the gold standard for TKA. The current techniques for TKA are considered to be major procedures that require skilled surgeon, nurse and anaesthetist. The challenges for TKA techniques are increasing with the introduction of new approaches such as minimally invasive, day case surgery and bicompartmental arthroplasty. The next section will analyse in depth the limitations and deficiencies of the current techniques of TKA.

2.5 Limitations of the current techniques for TKA

The previous section (2.3.3) has highlighted the pitfalls in the analyses of the outcome of TKA and revealed that the success rate is much lower than has been previously reported. The success of TKA is primarily dependent on surgical techniques (Ecker et al., 1987, Fehring et al., 2001, Sharkey et al., 2002). Other factors that can influence the outcome are, patient selection, implant design and effective perioperative care (Stulberg, 2003). There are several limitations of the current techniques, mainly the inadequacy of preoperative planning and the deficiencies of the CI systems. For the purpose of explanation, all limitations are classified according to their relationship to the surgeons, operative techniques, patients and health care providers (Flow Chart 1).

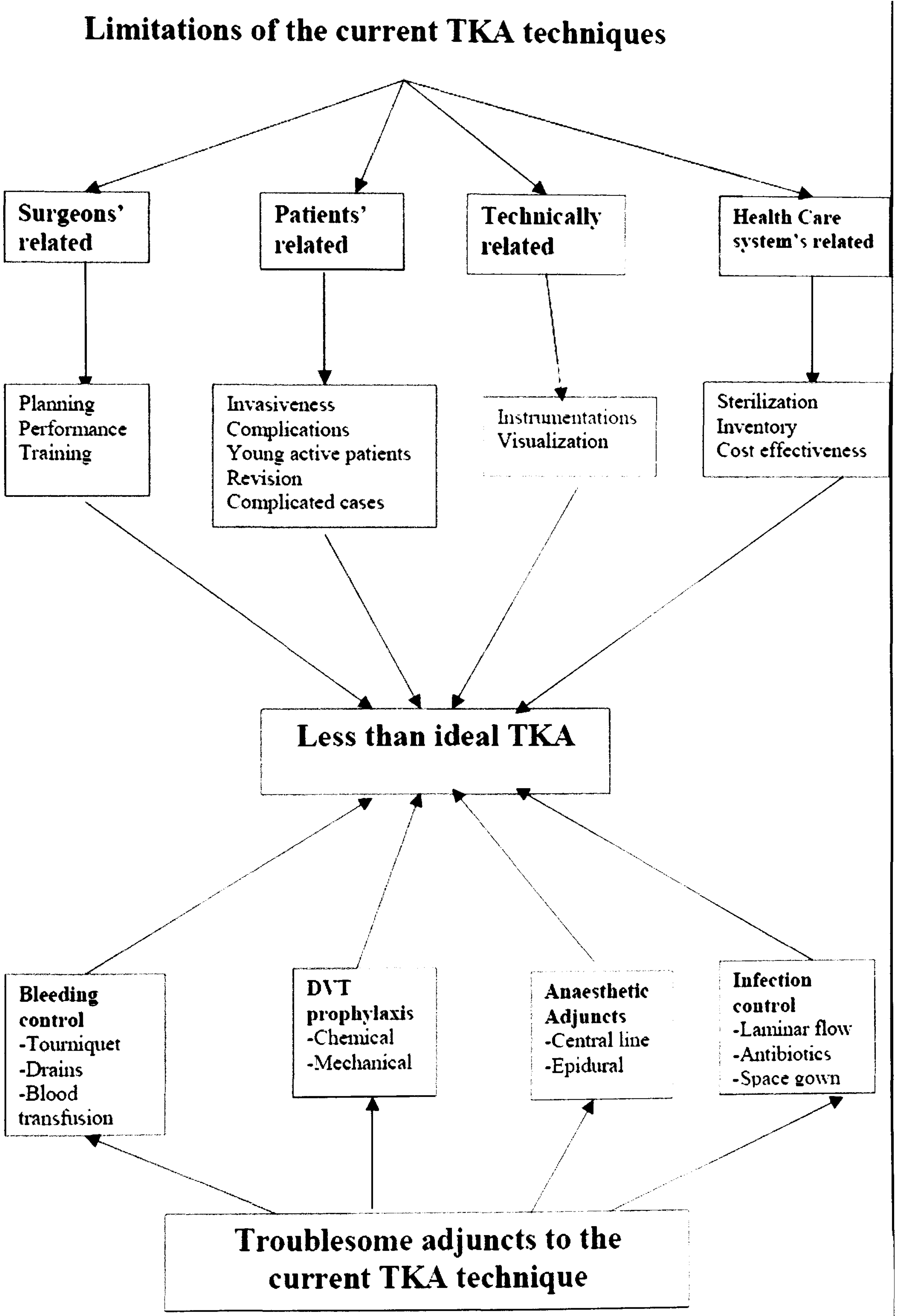
2.5.1 Limitations related to surgeons

2.5.1.1 Preoperative planning

Patient's selection

Selecting the right patient is one of the criteria for successful outcome of TKA. Patient selection for primary TKA depends on clinical assessment (history and examination) and plain radiography of the knee. The purpose of clinical assessment is to ensure that the indications for TKA have been met (see section 2.3.1), the patient is fit for anaesthesia and surgery and other considerations such as the patient's motivation and expectations. Plain radiography is needed to confirm the presence and the severity of arthritis although patient's symptoms are not always correlated to radiological signs (Gidwani et al., 2003). Some patients may have clinical indications for TKA that are not evident on plain radiography and occasionally those patients are denied surgery. This lack of correlation can be explained by the low sensitivity of plain radiographs in visualising the signs of arthritis (Mazzuca, 1997). Other imaging modalities such as CT are more sensitive and can identify abnormalities such as bone defects that may require planning and decision on the type of implant and the necessity and type of augmentation. The identification and quantification of complex bone deformity may

Flow chart 1


Limitations of the current TKA techniques
Surgeons' related
Patients' related
Technically related
Health Care system's related
Planning
Performance
Training
Invasiveness
Complications
Young active patients
Revision
Complicated cases
Instrumentations
Visualization
Sterilization
Inventory
Cost effectiveness
Less than ideal TKA
Bleeding control
-Tourniquet
-Drains
-Blood transfusion
DVT prophylaxis
-Chemical
-Mechanical
Anaesthetic Adjuncts
-Central line
-Epidural
Infection control
-Laminar flow
-Antibiotics
-Space gown
Troublesome adjuncts to the current TKA technique

contraindicate TKA and warrant other procedures such as corrective osteotomy.

Preoperative planning and plain radiographs:

Preoperative planning is an important prerequisite for successful TKA. It is dependent on clinical examination and plain radiographs. Although it is recommended to perform a standing full-length anteroposterior radiograph from hip to ankle, only short knee radiographs are routinely performed. The accuracy of preoperative planning is limited by the errors inherent in standard radiographs. Plain radiographs impose limitations on three important aspects that can affect the outcome of TKA. These are: accuracy of alignment measurement, accuracy of sizing of implants and visualisation.

1) The alignment measurement

Short knee radiograph cannot accurately define alignment axes. Measurement of mechanical axis requires a whole leg radiograph to measure the centres of the femoral head and tibial plafond or talus. Several studies showed about 1.5° of difference in measuring tibio-femoral alignment between short and long leg radiographs (Patel et al., 1991, Petersen and Engh, 1988). Even a complete series of plain radiographs including a whole leg are not without limitations. In addition to the drawbacks of cost, time and effect of radiation exposure on patients, the accuracy of plain radiographs has been questioned (Kinzel et al., 2004, Moreland et al., 1987); (Ilahi et al., 2001, Brouwer et al., 2003, Lonner et al., 1996); (Koshino et al., 2002). Plain radiographs are sensitive to changes of the leg positions and may lead to inaccurate interpretations or measurements due to the rotation of the leg or the inability to extend the knee fully. Ten degrees of knee flexion and 20° external to 25° internal rotation can cause statistically significant differences in measured knee alignment (Lonner et al., 1996). Varus angulation is usually underestimated with the flexion deformity of the knee (Koshino et al., 2002). Internal rotation of femur can be perceived as medial bowing and external rotation as lateral bowing. This effect is accentuated if the femur has excessive anterior bowing. The position of the patient has also an effect; Brouwer et al 2003 found 2° more varus angulation in standing whole leg radiograph compared with supine whole leg radiographs. In addition the physician interpretations have additional variations. Ilahi reported an interobserver error of 3.7° and intraobserver error of 3.1° compared to 5° for clinical measurement.

2) Selection of implants sizes

Using plain radiographs to determine the size of the implant is not accurate and is becoming less popular. In a retrospective study of 47 patients who underwent TKA, preoperative templating was found to be accurate for both tibial and femoral components in only 53.2% of cases as compared to the actual implant size that was used (Arora et al., 2005). Inter-observer and intra-observer mismatch between 2 observers was present in 46.8% and 43.6% of readings respectively. Authors concluded that preoperative templating is neither accurate nor reproducible. Heal et al (2002) compared the sizes of the actual components used in 49 Kinemax TKA procedures with the sizes predicted from the preoperative and postoperative radiographs. The preoperative radiograph was accurate in 57% of cases and the postoperative radiograph was accurate in only 41% of cases as compared to the sizes of the actual components used. The authors explained the possible reasons for this inaccuracy; first, the observer error in interpreting the radiograph. Second, rotation of the radiograph causes errors in measurement and difficulty with interpretation. Third, an intrinsic error in fixed flexion deformity of the knee could occur and as the degree of fixed flexion deformity increases, so does the distance from the X-ray plate, increasing the magnification of the knee appearing on the radiograph.

In a prospective study of 33 patients (53 knees) who underwent preoperative CT scanning before TKA, it was found that femoral sizing on a CT workstation had excellent or almost perfect correlation with intraoperative measurements (Lee IS et al., 2006). The CT was used to measure the transepicondylar distance, maximum anteroposterior dimension of medial and lateral femoral condyles, and trochlear width.

3) Visualisation

Short knee radiograph do not reveal bone and joint abnormalities away from the knee joint. Even with complete series and whole leg plain radiographs, the images are still 2-dimensional and they do not provide complete visualisation of the 3-D anatomical structures of the knee joint. There are variations in both the experience and ability of different surgeons to correlate preoperative 2-D radiographic data with intraoperative 3-D anatomy (DiGioia-III et al., 1998).

Accurate preoperative planning in revision surgery is more important and difficult than primary TKA (Scuderi, 2001). It should be performed with good quality imaging that allows the identification of bony defects and the preparation for their appropriate treatment; bone graft, cement or metal augmentation. It can assist the surgeon in selecting the type of the prosthesis to be used and deciding whether a custom-made prosthesis is required or not. In addition, it allows accurate planning for bone cutting and alignment.

2.5.1.2 Challenges of surgical performance

Technical considerations

TKA is a technically demanding procedure that requires a high degree of accuracy and reproducibility. Small degrees of errors can have adverse effects and may lead to early failure (Jeffery et al., 1991, Werner et al., 2005). The procedure involves several technical steps; measurement, bone cutting, soft tissue balancing and fixation. Bone cutting can affect the soft tissue tension and soft tissue release can affect bone cutting. Because the knee is a 3-D structure working in one plane or one parameter whether on bony or soft tissue structure can affect certain parameters in other planes (see limitations related to the operative technique, visibility). In complicated cases, it is difficult to obtain perfect sizing, normal alignment in three orthogonal planes and soft tissue balance while maintaining normal joint line level and minimal bone removal. All these tasks that are occasionally conflicting must be delivered in one sitting and within a time constraint. Currently surgeons rely on CI systems to carry out these steps in addition to a great deal of human assessment ("eyeballing"), decision-making and implementation of several technical steps. Working within so many constraints may lead to accomplishing some tasks at he expense of others (see examples in section 2.5.2.2).

Complexity of conventional instrumentation

CI systems are complex tools comprising numerous pieces of jigs and fixtures that need setting up before surgery, assembling and dismantling during the operative procedure. These have to be individually washed and sterilised afterwards for reuse in subsequent procedures. As an example, a demonstration kit for a standard size 3 primary TKA (DePuy PFC Sigma) has 84 different pieces. Most primary prostheses have various options; fixed-bearing, mobile-bearing, cruciate substituting, cruciate retaining, cemented and uncemented. There are different sizes (on average 6 sizes) of implants for each of these options. There are additional pieces of instruments to fit the different sizes and the different options. CI systems are frequently modified over time and it is not uncommon to have several instrumentation systems (old and new) for a single TKA prosthesis. The use of CI involves measuring different parameters such as sizes of implants, alignment, rotation and level of bone cutting. These measurements may not be exact and they usually require "eyeballing" and personal judgement that add to the complexity of CI. For example, the entry point of the intramedullary (IM) guide is based on "eyeballing" and inaccurate selection of the entry point may lead to inaccurate bone cutting and alignment of the prosthesis (Novotny et al., 2001).

There is a growing need to introduce ergonomics in the surgical workplace (Stone and McCloy, 2004), which is more difficult to achieve with the current technique. The CI set is packed in several trays (at least 4) that require one or two additional carrying table. Revision procedures or other options of primary (mobile-bearing, cruciate retaining, etc.) may require additional trays. These tables and trays need to be positioned as close to the surgeon and the nurse as possible but the environment is often not ergonomically efficient. The tables usually lie in the way of surgical assistant(s). There is usually a lack of space and these trays may cross the zone of the laminar flow, thus increasing the risk of infection (Ahl et al., 1995, Salvati EA, 1982). The numerous pieces of CI systems are metallic and some have sharp edges, spokes or pins. They may require drilling to attach them to bone at different steps of the procedure. These metallic edges and pins require careful handling and can potentially cause sharp injuries to the operator or the patient.

Surgeons' experience

Surgeons' abilities and experience vary. Although all the above difficulties may not apply to very experienced surgeons, there are many surgeons who are still at the early stages of their learning curve or are low volume surgeons (occasional operators). In one report, approximately 40% of surgeons who performed hip and knee replacements in New York, USA performed ten or more procedures per year and less than 31% of hip and knee arthroplasties were performed by such low volume surgeons (Matsen, 2002). In developing countries, TKA is not as common as in developed countries and many TKA surgeons are low volume surgeons (personal experience). On the other hand there is a false feeling of simplicity with regard to the relatively complex conventional techniques of TKA. In the absence of a simpler alternative for TKA techniques, surgeons usually get adapted to what is available and with experience the complex techniques become apparently simple. Experienced surgeons may perform several joint replacements in a single day in addition to other duties and this could be mentally and physically exhausting. Errors whether they are related to the operators or to the instrumentation are not uncommon. Intraoperative complications may occur due to technical errors, unforeseen circumstances or the complexity of cases. Intraoperative errors and complication may affect surgeons' performance leading to more mistakes.

Operative time

TKA has to be done within specific time limit guided by the constraint of the tourniquet time and anaesthetic considerations. The operative time is dependent on the experience and skill of the surgeon. However the surgeon is limited by the time required for the utilisation of CI as well as the setting time of the cement. Even with uncemented techniques and with the fastest surgeon TKA is unlikely to be done in less than 30-40 minutes. This time is required to assemble and attach the different pieces of jigs and fixtures, perforation of intramedullary canal and measurements for sizing, alignment, rotation and the level of bone resection. More time may be spent on "eyeballing", decision-making and assessment. However, operative time could be significantly shortened if there is an alternative to CI systems that can eliminate or minimise the time taken by setting up, assembling, dismantling or washing of numerous pieces of instruments.

<u>Drawbacks of longer operative time</u>

The longer the operative time the higher the risk of contamination as the wound is exposed to non-physiological atmosphere including the heat from theatre light, air and operators' hands and also longer time of disturbed normal anatomy due to dislocation of the patella and subluxation of the knee. Longer non-physiological and non-anatomical exposure may lead to longer rehabilitation time and longer hospital stay (Coon, 2005, Pierson et al., 2005). The longer the operative time the longer the tourniquet time and the higher the risk of infection and vascular complications. The longer the operative time the longer the anaesthetic time and the longer the recovery with more potential anaesthetic complications. A technically successful operation that exceeds the tourniquet time limit may predispose to complications (e.g. infection) and subsequent failure. In a retrospective review of 6489 total knee replacements, the rate of infection was higher when the operative time exceeded 2 ½ hours (Peersman et al., 2001). In a retrospective analysis of postoperative complications of 17,644 TKA procedures, it was found that extended surgery time increased the rate of haematoma and infection (Claus et al., 2005). With increased rate of complications, the rehabilitation time and hospital stay may increase.

Advantages of shorter operative time

Shortening of operative time can have significant impact on health care economics (see section 2.5.4.1). It can be very useful in avoiding the above-mentioned complications associated with longer operative times. Also, it may extend the indications of TKA and improve its outcome in more demanding conditions such as:

1. Bilateral simultaneous TKA (at the same time by 2 different surgeons) or sequential TKA (one after another by the same surgeon during the same anaesthetic). Bilateral symptomatic OA of the knee is a common clinical problem. (Alemparte et al., 2002) reported the results of bilateral sequential TKA in 604 patients (1208 knees) over 13 year and showed satisfactory outcome. Although there are some advantages to the performance of bilateral simultaneous or sequential TKA its application is only limited to certain centres with experienced surgeons and anaesthetists who are able to shorten the operative and anaesthetic time. Its broad application would be possible only if the technique of TKA has been significantly shortened in time and the blood loss has been reduced.
2. MIS & outpatient TKA has been reported by very experienced surgeons (Berger et al., 2005) the technique may not be reproducible else where.
3. Cases with bleeding disorders such as patients with haemophilia. These cases are difficult to operate on and have a high failure rate (Silva and Luck, 2005) due to the increased risk of bleeding, infection, arthrofibrosis and bone deficiency
4. Cases with high risk of infection such as patients with HIV or haemophilia (up to 30 % incidence of infection) (Rodriguez-Merchan, 2002).
5. Cases with high anaesthetic risk due to associated medical problems such as cardio-respiratory diseases.

Adjuncts to the current techniques of TKA:

There are several adjuncts to the current technique of TKA, such as tourniquet, drains, blood transfusion and DVT prophylaxis (Flow chart 1). These could potentially be dispensed with if there is an alternative technique of TKA to which these adjuncts are not essential. For example, an alternative that can eliminate the use of IM guides may reduce bleeding, fat embolism, contamination and infection (Chauhan et al., 2004, Kalairajah Y, 2005, McPherson et al., 2002). A technique that shortens operative time may reduce bleeding from the exposed bony and soft tissue surfaces. The shortening of operative time will also minimise the non-physiological exposure of tissues and the risk of contamination. Reduction in bleeding and operative time may reduce the need for using tourniquets. Thus, reducing the need for suction drains and blood transfusions. There is a possible link between DVT and the use of tourniquets in TKA (see DVT in section 2.5.3.1). Laminar flow is another adjuncts, which may not be available in every operating room especially in developing countries. Such an adjunct may theoretically become less essential in the presence of an alternative that can reduce the risk of infection in TKA (refer to infection in section 2.5.3.1).

2.5.1.3 Training

There has been an increased emphasis on teaching and evaluation of technical skills during surgical training (Kohls-Gatzoulis et al., 2004, Reznick, 1993). Knee arthroplasty procedures are increasingly becoming more complicated, especially for beginners due to the introduction of new and more demanding techniques such as unicondylar, bicondylar, patellofemoral and MIS for TKA. Developing expertise requires adequate training and practice and both involve a long learning curve. The word "learning curve" has now started to appear in surgical literature to differentiate poor results due to the procedure itself, from those due to the inexperience of the surgeon (Hutchison, Sept. 2004). Surgical skills require cognitive and motor skills and both require repetitive practice, with feedback. Cognitive skills also involve other steps such as error detection, forward planning and decision-making (Kohls-Gatzoulis et al., 2004).

Current methods of training are still very traditional and they are unlikely to keep pace with the speed of technology and the introduction of new techniques. Plastic or animal specimens that are used in workshops are not truly representative of human knee anatomy. Hands-on cadaveric courses are very useful but they are very expensive, scarce and are difficult to organise and conduct. Most of traditional workshops focus on teaching technical skills with less emphasis on cognitive skills (Kohls-Gatzoulis et al., 2004). The operating room is not the optimal environment for teaching either cognitive or technical skills, as it does not allow for repetitive actions or committing errors, analysing and correcting them. Chapter 6 will explain the potential of the proposed PST to be an easy to learn and perform technique and to act as a powerful, inexpensive training tool.

2.5.2 Limitations related to operative techniques

2.5.2.1 Conventional instrumentation systems

The failure rate of early modern TKA in the 1970s was high creating a bad reputation that persisted for several years. The advances in surgical instrumentation in the 1980s and the introduction of alignment guides and size-specific cutting blocks made TKA more reproducible and successful (Insall 1993). Implant designs and materials have been significantly improved and resulted in better performance and survival of TKA. However, the technology of instrumentation appears to be lagging behind the state of the art technology of implant material and design. CI systems have been reported to have limitations that affect the ultimate accuracy of surgery, especially bone cutting and alignment of the implant (Chauhan et al., 2004, Delp et al., 1998, Jenny and Boeri, 2004, Nabeyama et al., 2003, Stulberg, 2003). They are relatively complex tools with multiple pieces; each piece has a risk of error due to the degree of freedom of these instruments or the operator dependent errors during their applications. Their assembly is time consuming and may lead to accumulation of errors. Their repeated use carries the risk of contamination and transmission of diseases(DoH, 2001). The use of their alignment guides involves the violation of the IM canal leading to higher risk of bleeding, infection, fat embolism and fractures. Because of surgeons' preferences it is not unusual to have several different prostheses in the same department, which overloads the hospital inventory, sterilisation services, the nurses' learning curve and theatre time. The current trend to use MIS in TKA has resulted in the introduction of new arrays of reduced-size instruments, which are modified to fit the small incision. The accuracy of these mini instruments has not been validated and the reported errors from MIS could be due to the reduced accuracy of these new instruments. The drawbacks and limitations of CI are discussed in more details below:

1) Accuracy limitations

<u>The selection of implant sizes</u>

Selection of implant sizing is important as either over-sizing or under-sizing is not desirable. Over-sizing can result in over stuffing of the joint leading to patellofemoral problems. Under-sizing involves excessive bone removal and depletion of bone stock. The latter has a significant adverse effect on subsequent revision surgery, which is even more critical when it come to young patients who may require more than one revision procedure in their lifetime.

The selection of implant sizes at the preoperative stage has several advantages. It is part of the preoperative planning specially when under sizing is considered an option to correct imbalance in flexion and extension gaps. Identification of uncommon sizes (e.g. very small, very large) is also important, as some hospitals do not have a regular stock of these sizes. Since the preoperative selection of implant sizes is not accurate (see section 2.5.1.1) most surgeons rely on intraoperative sizing.

It has been reported that intraoperative sizing methods also have limited accuracy. Incavo et al (2004) compared the two currently used methods for sizing, namely; the size-matched-resection and the flexion-space-balancing during the performance of 50 consecutive TKAs. Neither of these methods showed superior results, they were not equivalent and could result in the selection of different sizes. The flexion-space-balancing method led to a smaller size selection in 56% of knees. On the other hand the size-matched method led to a larger size in 56 % of knees. The preoperative varus knees were more sensitive to the differences in measurement method. In a review of 268 consecutive patients underwent bilateral TKA, 18 (6.7%) femoral components varied in size between right and left knees but no statistical significant asymmetry for patellar or tibial component sizes (Brown et al., 2001). Component sizes were selected based on preoperative radiographic templating and intraoperative sizing measurements irrespective of the component sizes chosen for the other knee.

In many instrumentation systems, the size-matched resection is based on measuring the femoral anteroposterior (AP) dimension with no reference to the mediolateral (ML) dimension. Cadaveric studies have shown that females have smaller ML dimension in comparison to the AP dimensions of either medial or lateral condyles (Seedhom et al., 1972). The methods used to measure AP dimensions are variable among different systems, using either a stylus or a template either before or after the distal or posterior cuts. In cases where the sizing guide is rotationally aligned with the epicondylar axis there may be no contact with the posterolateral femur resulting in inadequate posterior bone removal (Incavo et al., 2004).

Intraoperative sizing may not be straightforward in some cases especially when there is deformity or bone loss. It is not unusual for the sizing template or stylus to fall between two sizes for the femoral components. Most of implant manufacturers recommend using the smaller size but the final decision is left to the surgeon. This adds to the number of intraoperative decisions required from the surgeon. Selecting a smaller size implant means cutting more bone and once the bone is cut it cannot be reattached. Bone cutting for a smaller size implant results in more bone cut posteriorly than distally creating a wider flexion gap. The correction of this imbalance may lead to a series of compromises; either more bone removed distally with elevation of the joint line or excessive soft tissue release, and both require a thicker tibial insert. Under-sizing may also result in notching of the anterior cortex of the femur that can potentially lead to a fracture.

Alignment and bone cutting

CI systems are used to perform several steps of alignment measurements and bone cuts. These steps are dependent on each other and this may lead to the accumulation of errors that can occasionally pass unnoticed. Most of these steps or actions (bone cuts) are irreversible. Correcting one error may come at the expense of something else thus a series of compromises may follow. The recent introduction of computer systems has allowed surgeons to evaluate objectively the accuracy of CI systems. There are several reports including randomized controlled trials that revealed the limited accuracy of bone cutting and alignment, when these are performed using CI systems (Chauhan et al., 2004, Delp et al., 1998, Jenny and Boeri, 2004, Nabeyama et al., 2003, Stulberg, 2003).

These jig systems are based on average bone geometry, which may widely vary between individual patients. Most of the jig systems are based on Caucasian populations. Nagamine, Miura et al 2000 (Nagamine et al., 2000) reported the anatomical variations in 133 Japanese patients with knee OA. They found proximal tibia vara, lateral offset of the tibial shaft with respect to the centre of the tibial plateau and external rotation of the femoral component more than 3° in 20% of the patients. (Tang et al., 2000) found that Chinese patients require 5° of external rotation of their femoral component in order to obtain a rectangular flexion gap as compared to the commonly reported 3° of external rotation. In revision surgery the situation is more challenging as the normal anatomy is disturbed and bony landmarks could be lost. The jigs are also difficult to position accurately in obese patients or in case of lower limb deformity. They have degrees of freedom and surgeons often rely on their own visual experience "eyeballing" in positioning these jigs, which may result in inconsistency and lack of reproducibility.

Stulberg (2003) used an image free navigation system to assess the accuracy of CI while performing 20 TKAs. Although the accuracy of frontal and sagittal limb alignment was within 3° there was a tendency to leave the knee in slight flexion with hyperextension of femoral component and posterior tilting of tibial implant. There was also a consistent tendency to internally rotate the femoral implant. Only 4 out of 20 TKA procedures had all the measured steps within 3° of the optimal positions. Other authors reported an alignment error of more than 3° in about 25 % of TKA and errors more than 10° in 6 % of TKA (Petersen and Engh, 1988, Mahaluxmivala et al., 2001).

Some authors recommended the use of intramedullary alignment guides whenever possible as they provide better alignment than extramedullary guides (Maestro et al., 1998). However, patients with significant extraarticular deformities, marked bowing, and those with prior surgery or fractures may not be suitable for intramedullary guides (Teter et al., 1995). reported that 8 % of tibial cuts were malaligned by more than 4° in the coronal plane when an extramedullary guide was used. Several other authors reported different sources of errors from using IM guides (Novotny et al., 2001, Reed and Gollish, 1997, Stulberg, 2003). Reed and Gollish 1997 stated, "substantial malalignment error resulted from minor malpositioning of the intramedullary rod". They found that the anatomic axis exits the distal femur at an average of 6.6 mm medial to the centre of the femoral notch while most implant manufacturers recommend making the entry point at the centre of the femoral notch.

Other sources of errors are using short rods that do not reach the isthmus of the femur or tibia, using thin rods in large IM canals and placing a straight rod in a deformed bone.

Malalignment was correlated with implant loosening and early failure (Ecker et al., 1987, Ritter et al., 1991, Ritter et al., 1994). Range of motion and function of TKA are influenced by anteroposterior displacement of the femoral component, posterior tilting of the tibial component and alteration of joint line (Fehring et al., 2001, Dorr and Boiardo, 1986). Anteroposterior displacement of 2.5 mm of the femoral component can affect knee range of motion by 20° (Garg and Walker, 1990). Posterior tilting of the tibial component can also affect knee range of motion and tibiofemoral kinematics (Dorr and Boiardo, 1986). Patellofemoral complications are among the most common complications following TKA. Although there are several factors contributing to such complications, the femoral and tibial components malpositioning are among the main factors.

The following limitations and drawbacks of CI systems are discussed under other sections in this chapter.

2) Complexity and lack of ergonomics (see section 2.5.1.2)

3) Invasiveness (see section 2.5.3.1)

4) Sterilization and the risk of disease transmission (see section 2.5.4.1)

5) Cost effectiveness (see section 2.5.4.2)

2.5.2.2 Limited visualization

The accuracy of visual inspection by surgeons is limited especially when using ill defined or inconsistent operative landmarks such as the centre of the femoral head, the centre of the ankle or epicondylar axis. The errors are even higher when dealing with obese patients or in the presence of bony abnormalities. Certain errors are difficult to appreciate visually in the operating room such as flexion deformity of the limb or of the components. Flexion deformity up to 5°-10° may not be appreciated by the surgeon, particularly in patients with large extremities in which the location and orientation of the bone may be difficult to appreciate (Stulberg, 2003).

The knee has a complex 3-D anatomy and biomechanics so bone cutting and soft tissue balancing have to be done in a 3-D fashion. The ability to understand the 3-D complexity of the knee is variable and depends on surgeons' experiences. Surgeons make intraoperative decisions based on what they visualise (eyeballing), which is usually focused on one plane. Unforeseen circumstances, errors in sizing or in bone cutting will require further measurements and decision making. This may increase the stress level of the surgeons and affects their ability to visualise and control the apparently conflicting targets in 3-D. The following are examples of certain targets or actions in one plane, which may affect certain targets in other planes (contradicting targets):

1. Femoral sizing: Femoral bone cuts are made through cutting blocks that are selected according to the sizing of distal femur (AP dimensions). Sizing of distal femur can have secondary effects on the mediolateral dimensions of the components (overhang or under cover), the flexion gap (wide or narrow), anterior cortex (notching) and patellofemoral articulation (overstuffing).
2. Bone cutting: The posterior sloping of the tibial cut can affect the flexion gap. The posterior femoral cut with external rotation can also affect the flexion gap. Tibial cut and distal femoral cut can affect the joint line level. Intraoperatively it is usually difficult to determine the normal level of the joint line accurately.
3. Soft tissue balancing: This is usually done in one plane (coronal varus-valgus) and also in one dimension (extension). Balancing the knee in the sagittal plane is as important as the coronal plane. The same apply to the balancing in flexion and in fact it should be throughout the arc of motion. Sagittal plane balance relies on femoral sizing and bone cutting (posterior sloping of tibial cut and the external rotation of the femoral posterior cut). Releasing collateral ligaments in extension can lead to imbalance in flexion. Overzealous soft tissue release on one side will lead to imbalance and the surgeon may then have to release the other side. This may lead to laxity and instability

Although conventional surgical exposure is relatively large it cannot reveal the full bony contour of the distal femur and proximal tibia. Bone abnormalities or osteophytes around the posterior aspects of the femur or the tibia are not visible. Posterior femoral condyles may be eroded or over grown and can affect bone cutting and rotation of femoral components. Large osteophytes can affect the soft tissue tension and normally require removal. The recent introduction of minimally invasive surgery (MIS) has made it more difficult to visualise the knee joint or even to fully visualise the bone during bone cutting. Errors in bone cutting and complication have been reported from using MIS (DiGioia-III et al., 2004). There is a trend to use computer-assisted surgical (CAS) techniques as a visualizing tool in MIS. Few clinical reports in the literature showed the advantages of using CAS in improving the visibility and accuracy in MIS(DiGioia-III et al., 2004). In another unique attempt to improve visibility, arthroscopy has recently been used as a visualizing tool to help the implementation of minimally invasive UKA (Randle, 2004). Arthroscopically assisted medial and lateral UKA were performed in 13 patients with no loosening at 18 months follow up.

2.5.3 Limitations related to patients

This type of limitations can be general and affect all patients undergoing TKA - such as invasiveness and complications- or specific and affect certain groups of patients such as young active patients, patients with bone deformities or those undergoing revision TKA.

2.5.3.1 Invasiveness

Intramedullary (IM) guides are relatively invasive and carry higher risk of bleeding, fat embolism, infection and fractures. Excessive bleeding is a known complication following the violation of IM canal (Chauhan et al., 2004, Ko et al., 2003) and may result in excessive use of suction drains, delayed recovery and higher risk of infection. Fat embolism has also been correlated to the placement of intramedullary alignment guides during TKA The medullary canals have also been found to be the most common site to yield a positive intraoperative culture following TKA . Fractures - intraoperatively and postoperatively- have also been related to the use of IM guides (Dennis et al., 1993).

2.5.3.2 Complications of TKA

The success of TKA has to be assessed in the light of the possible complications. Complications after TKA may occur at short-term or long-term. The traditional outcome assessment of TKA has focused on long-term implant survival. More recently short-term outcome has received more attention particularly following the introduction of MIS techniques. The reported incidence of complications following primary TKA is variable possibly because the documentation and reporting of complications is not standardised. Some authors (Frosch et al., 2004) who followed a comprehensive method in reporting found that complications could be as high as 23% and wound infection was the most common complication. While other authors (Scuderi,

2001) reported a nearly similar rate of complications (26%) for revision TKA! The following section will only discuss the complications that are related to the limitations of the conventional techniques and may be improved by alternative techniques. These are divided into long-term and short-term (Flow Chart 2).

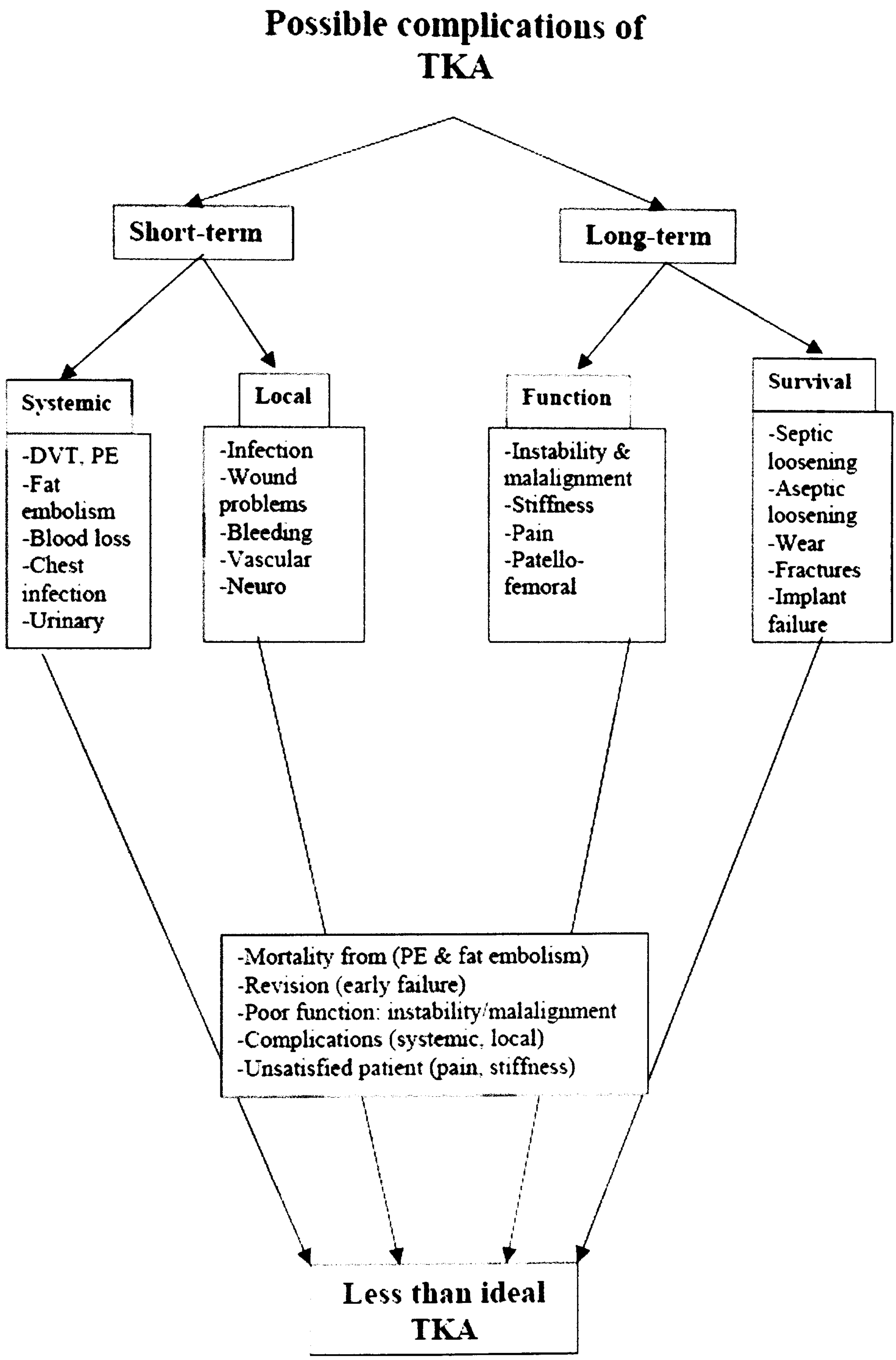
Long-term complications:

Successful TKA may last for more than 15 years. Late failure is not considered a complication because it is expected due to the limited survival of TKA. However, early failure within 5 years from the index surgery is considered a disastrous complication. The main causes of failure are infection, malalignment and instability. Malalignment and stability are discussed earlier (section 2.5.2.1).

Infection

Infection is one of the main causes of early failure in TKA (Fehring et al., 2001, Gioe et al., 2004, Sharkey et al., 2002). A review of 440 patients who had revision showed that 63% occurred early within 5 years of their primary surgery and infection was the most common cause of this early failure. Infection can occur at any time following TKA and is considered to be failure regardless of the timing. The risk of infection of primary TKA is 2.5%, nearly double that of THA and infection following revision TKA is more than double that of primary TKA. This rate may increase by up to 17% in certain conditions such as psoriasis (Hanssen and Rand, 1998). This rate could be even underestimated as it has been reported from specialist centres with strict aseptic techniques and where very experienced surgeons performed these procedures. There are cases of infection that could be missed either because they are low-grade infection with minimal symptoms, medically unfit patients or patients who have been lost to follow up. Literature from developing countries on the incidence of infection following TKA is scarce and infection rate is probably much higher than the reported figures from developed countries

Flow chart 2


Possible complications of TKA
Short-term
Long-term
Systemic
-DVT, PE
-Fat embolism
-Blood loss
-Chest infection
-Urinary
Local
-Infection
-Wound problems
-Bleeding
-Vascular
-Neuro
Function
-Instability & malalignment
-Stiffness
-Pain
-Patello-femoral
Survival
-Septic loosening
-Aseptic loosening
-Wear
-Fractures
-Implant failure
-Mortality from (PE & fat embolism)
-Revision (early failure)
-Poor function: instability/malalignment
-Complications (systemic, local)
-Unsatisfied patient (pain, stiffness)
Less than ideal TKA

Causes of infection could be related to the wound, operative technique, operating room environment and patient-related factors. The potential risk of contamination and infection from the current technique of TKA could be attributed to one or more of the followings:

1. Failed or imperfect sterilisation of the numerous reusable instruments that have multiple holes, canals and deep cavities.
2. Soft tissue trauma caused by the metallic sharp instruments
3. Intramedullary perforation: IM canals have been found to be the most common site to yield a positive intraoperative culture following TKA (McPherson et al., 2002, McPherson et al., 1997). Bacteria tend to gravitate towards the medullary canals due to restricted metabolic activity there.
4. Bleeding due to IM perforation or long operative time.
5. Intraoperative contamination of the numerous instruments, trays or tables that may come outside the zone of the laminar flow.
6. Long operative time with long non-physiological exposure of tissues and ischaemia from longer tourniquet time.

Infection following TKA has not been solved during the last 30 years and its rate has remained remarkably constant in spite of the improvement in antibiotic prophylaxis, operative techniques and operating room environment (Hanssen and Rand, 1998). CI systems could be a potential culprit or contributing factor since their drawbacks have not been overcome for the last 30 years. Although they have been repeatedly modified for the purpose of improving accuracy, they maintained the features that may still predispose to contamination such as IM guides and reusability of numerous metallic pieces with multiple holes and. It is of interest to note that the rate of infection for TKA is almost double that for THA and the instrumentation system for THA are not numerous.

Other long-term complications are fractures, neurovascular injuries and failure of extensor mechanism. The use of IM guides may predispose to fractures especially in presence of bone deformity or in case of inappropriate entry point or direction.

Short term complications

Short-term complications are important especially from patients' point of view. These complications can influence the functional recovery and patients' satisfaction.

They can lead to long-term complications as stiffness and infection and in the worst-case scenario they may lead to death following pulmonary or fat embolism. Compared with conventional techniques, MIS has the theoretical advantages of providing better short-term outcome with earlier recovery and shorter hospital stay. Any alternative technique that can shorten the operative time will have the theoretical advantages of MIS. Short-term complications are divided into local and systemic.

<u>Local complications</u>

1) Bleeding

Bleeding is a complication that can lead to other more serious complications as infection, stiffness and hypovolaemia. It is known that IM perforation cause significant bleeding during and after surgery. The recent introduction of navigation systems that does not require intramedullary guides has a potential to reduce bleeding. In 2 randomised control trials (Chauhan et al., 2004, Kalairajah Y, 2005), authors reported significant reduction in blood loss and the need for blood transfusion in navigated TKA as compared to conventional techniques. Many surgeons use IM plugs to seal the IM canal and reduce bleeding. Although this is a useful manoeuvre, it does not completely prevent postoperative bleeding due to the possible leak of blood through the plug. The plug also does not completely prevent intraoperative bleeding because it is only used towards the end of the procedure. Ko et al 2003 in a recent randomised control trial found that the use of IM plug did not reduce the postoperative bleeding through suction drains but it reduced the need for transfusion possibly by reducing intraoperative bleeding. Bleeding may lead to haematoma, which in turn can delay recovery and increase the risk of infection. In addition, excessive bleeding may necessitate blood transfusion. In a review of 17,644 TKA procedures, (Claus et al., 2005) found that allogeneic blood transfusion raised the risk of infection by a factor of 3.17 and increased the risk of cardiovascular complication risk by a factor of 3.9.

2) Joint stiffness and pain

Although revision has been used as main outcome measure to imply failure of TKA, recently functional assessment has received more attention as an outcome measure. The longer the operative time (with longer non-physiological and non-anatomical exposure of tissues) the more pain and stiffness and the longer recovery time. Several reports showed that MIS techniques resulted in better short-term outcome with reduced pain and stiffness as compared to conventional techniques where the patella is dislocated and the knee joint is subluxed (Laskin et al., 2004, Tria and Coon, 2003) Delayed recovery and longer hospital stay may lead to other complications such as chest and urinary tract infection.

Systemic complications

1) Fat embolism

Fat embolism can be mild and undiagnosed or fatal. There are several reports in the literature of diagnosed cases of fat embolism and some of these cases were fatal. It has been established that fat embolism is related to the insertion of IM guides (Kim, 2001). The incidence of fat embolism is higher in bilateral simultaneous TKA, 12 % compared with 4 % for unilateral TKA (Kim, 2001, Dorr et al., 1989). Chauhan 2004, in a randomised control trial, showed that the incidence of confusion was significantly reduced in navigated TKA as compared to conventional technique where IM guides are used. Confusion is one of the symptoms of minor fat embolism that might be caused by IM guides.

2) Deep venous thrombosis (DVT) and pulmonary embolism (PE)

DVT is very common after TKA and is more common than following THA. The incidence could be as high as up to 80-90 % without prophylaxis. Unlike THA, DVT following TKA is more refractory to treatment and it may drop to only 35-50 % (Sculco et al., 2002) even with DVT prophylaxis. DVT per se is not serious but the migration of the clot to the lung and the development of PE can be fatal. DVT prophylaxis is a routine practice and it reduces the incidence of DVT but not that of fatal PE.

The true cause of DVT in TKA is not very clear. (Sharrock et al., 1995) proved that the activation of clotting cascade occurs during IM instrumentation of THA. Sculco (2002) used this finding to logically suggest that the same could happen in TKA following instrumentation of the femoral IM canal. The blood stasis following the longer operative time with the use of the tourniquet and with the knee subluxed or dislocated (non-anatomical position) could be a contributing factor. Studies showed that the prevalence of DVT in the operated leg is 80 to 85% compared with the contra lateral leg (Pellegrini et al., 1994). Sculco (2002) also suggested that the use of tourniquets in TKA might explain this high prevalence due to the aggravation of the clotting cascade by venous stasis. It is a logical step to attribute the high incidence of DVT in TKA (compared with THA) to the use of tourniquet, which is only confined to TKA.

Others short term complications

The incidence of chest infection and urinary tract complications is higher in procedures that have longer anaesthetic and operative time with delayed recovery. Fat embolism is rare but occasionally it can be as serious as PE. It is usually attributed to the perforation of IM canal. Hypovolaemia due to bleeding may require blood transfusion and may lead to anaemia. Blood transfusion has its own complications and limitations, which are outside the scope of this study. It is worth mentioning here that Jehovah's Witness patients reject blood transfusion including auto-transfusion for religious reasons. Those patients are either denied surgery or have their surgery done by experienced anaesthetists and surgeons.

2.5.3.3 The unusual patients (young and active)

Younger and more active patients are more often deprived of the privilege of successful TKA procedures compared with elderly. Because of the limited life span of TKA, younger and more active patients with advanced arthritis have to suffer for years until they reach a suitable age for TKA. However, at a certain stage TKA becomes unavoidable for young patients who fail to respond to other supportive measures or who develop an end-stage knee from severe arthritis. Even when the procedure is perfectly performed and technically correct, there will still be a lack of sufficient durability to survive forever and one or more revisions are usually needed in their lifetime. Young age at the time of surgery has been shown to be a risk factor for revision (Robertsson et al., 2001, Rand et al., 2003). Rand et al (2003) reviewed 11,606 TKA procedures and found that the 10-year survival rate for patients younger than 55 was only 83% compared to 94% for patients older than 70 years. Moreover the level of their activity will be limited by the performance of TKA and high activity levels may result in a shorter survival time.

Bone preservation is very desirable for young patients, as they will most likely require more than one revision procedure in their lifetime. With every revision surgery, surgeons have to resect more bone. The conventional technique of primary TKA involves removal of significant amount of healthy bone. This is required to allow enough space for the measured thickness of the metal implant and to balance for the thickness of PE. A minimum of 8 mm of UHMWPE is recommended to avoid previous problems of failure due to UHMWPE wear (Insall, 1993). Unnecessary bone removal may result from incorrect sizing of the prosthesis (Delp et al., 1998). Bone loss may result from infection and failure due to bone resorption. Moreover, excessive bone loss may accidentally occur during removal of the old prosthesis (Scuderi, 2001).

2.5.3.4 The unusual knee (revision surgery)

Over 35,000 TKA revisions are performed worldwide annually, the cost and morbidity is substantial. In a review of 212 revision TKA procedures (Sharkey et al., 2002), authors found that more than 50% of revisions were performed to correct instability, malalignment and failure of fixation. They recommended that improvements in surgical techniques might diminish the incidence of knee revision significantly. The risk factors for revision are age (less than 55), obesity, OA, male gender and associated medical conditions (NIH, 2003). Revision surgery is more difficult and results are unpredictable. The overall complication rate for revision TKA is as high as 26%. Scuderi (2001) stated that revision TKA is a series of compromises, because reconstruction is often done with deficient bone and supporting soft tissues. Surgeons may resort to the use of bone graft, cement, metal or custom made prosthesis to compensate for the amount of bone loss. With every subsequent revision surgery, more bone will be removed and the infection and failure rate will also be increased. This renders arthrodesis more difficult due to a large dead space. If excision arthroplasty is considered, the joint becomes unstable with profound shortening of the limb. Unlike failed revision hip arthroplasty, which can be salvaged with a Girdlestone procedure, failed revision TKA may become unsalvageable and amputation can be the last resort. Accuracy of sizing and bone cutting is more critical in order to restore alignment and joint line. In one study 79% of patients who had revision had an elevated joint line of about 24 mm (Partington et al., 1999).

2.5.4 Limitations related to health care providers

2.5.4.1 Sterilization & the risk of disease transmission:

Variant Creutzfeldt-Jakob disease (vCJD) is a human Spongiform Encephalopathy that is similar to the cattle Bovine Spongiform Encephalopathy (BSE). It seems that human attracted the disease through the consumption of BSE-infected bovine tissues. To date, there have been over ninety cases in the UK and the disease has been untreatable and fatal in all these cases (DoH, 2001). The disease has a long incubation period and there may be many other people who are infective carriers.

The main concern here is whether vCJD could be transmitted through surgical instruments. Experiments showed that the infective agents of vCJD are highly resistant to ordinary measures of sterilisation. There are many uncertainties about this subject to the extent that experts in the field are unable to make straightforward pronouncements. The Department of Health, UK has issued a document on the risk of transmission of vCJD through the re-use of surgical instruments (DoH, 2001). It was emphasised that the risk of surgical transmission of vCJD cannot be ruled out and high quality decontamination and sterilisation of all surgical instruments is the key to reducing the risk and single-use instruments should be encouraged, where this is practicable.

The British Orthopaedic Association (BOA, 2001) stated that general orthopaedic procedures that do not entail contact with central nervous system tissues do not require precautions above standard infection control procedures. However this statement can be challenged by the limited knowledge on this subject and the possibility that infectivity may be widely distributed through the body. "Given the scarcity of direct data on vCJD in humans, many key inputs are based on research using scrapie as a model of the disease (implying that infectivity may be widely-distributed through the body. Ongoing research on vCJD itself lends support to this approach as a source of estimates for the development of infectivity in different tissues, and the relative efficiencies of different transmission routes" (DoH, 2001).

At present, it is understandable that the practicality and cost effectiveness of the wide introduction of single use surgical instruments is not feasible. The best example here is the CI systems for TKA, which are very expensive to be treated as single use instruments. However the alternative approach to single use instruments is to improve sterilisation services. The UK Government is investing £200 millions over two years period on a major programme of modernisation of decontamination facilities (BOA, 2001).

It seems reasonable to draw one conclusion from all the above that single use instruments are preferable to reusable ones especially if they are affordable and do not compromise the quality of surgical performance.

2.5.4.2 Cost-effectiveness

The cost of TKA is related to the cost of the implant and the surgical procedure. The latter depends on several factors including instrumentation, disposables, anaesthetic cost, theatre time and inventory.

The cost of instrumentation

This includes the cost of manufacturing, maintenance, storage, sterilisation, transportation and training. The manufacturing cost of a particular primary TKA prosthesis is 30,000 dollars, which has to be replaced after 5 years. The average use is 30 operations per year or 150 operations for their lifetime (DePuy, personal communication). This means that the cost of manufacturing alone for every operation is 200 dollars (more than 100 sterling). Occasionally some parts of these instruments are damaged before their expected lifetime and they will require replacement. The cost of the sterilisation of a primary prosthesis is around 100 sterling pounds; this does not include transportation. Technical training is usually costly and time consuming. During surgical training junior surgeons frequently encounter different types of prostheses while rotating to different hospitals and trainers. Although independent surgeons usually use one type of prosthesis they occasionally shift to a new version of instrumentation or prosthesis from the same or even from a different manufacturer. Nurses are unfortunate as they may assist different surgeons and they may have to become familiar with different types of prostheses. This again requires intensive and regular training. The total cost of instrumentation systems could be even higher due to the hidden costs. Developing countries cannot afford these costs and this is one of the reasons why TKA is not a common procedure in spite of the prevailing knee osteoarthritis.

Inventory

The standard set of CI systems for primary TKA is usually stored in 4 trays. A demonstration kit of one of the most common TKA implants in UK was counted to have 84 pieces. As mentioned above there are several types for primary prosthesis and revision instruments are different. There are new instruments, which have been recently introduced for MIS surgery. It is not uncommon for an orthopaedic department to have different prostheses from various manufacturers. Theatre spaces are usually limited and the complexity of this instrumentation is increasing with new instruments added every now and then. The option of storing these instruments away from the operating room is not convenient and prolongs the operative time.

Operating room time

Operating room time includes the actual operative time in addition to the time spent preoperatively on anaesthetic induction and set up of and postoperatively on patient's recovery and disposal of instrumentation. Operative time was discussed before (section 2.5.1.2) but it is worth mentioning here that longer operative time usually require longer time for anaesthetic induction and recovery. The time wasted preoperatively and postoperatively may exceed an hour in many hospitals. There is a recent trend to improve operating room efficiency especially for high volume surgeons who aim to perform 7 or more joint arthroplasty procedures per day. In one study, it was possible to reduce the surgeons' waiting time between cases from 75 minutes to 17 minutes (Coon, 2005). However, this highly efficient management system may not be reproducible in every hospital. Alternative techniques that may shift certain steps of the operative procedure to the preoperative stage such as sizing of implants, alignment measurements and planning may reduce operative time. An alternative to CI systems that does not have numerous pieces of jigs and fixtures may shorten the operating room time by saving the time spent on setting up, assembling, dismantling and disposal of instruments. Saving on operating room time will reduce the time pressure on surgeons, anaesthetist and nurses. It will also shorten the waiting list and will have economic impacts on health care providers that can make TKA more cost effective.

Length of hospital stay

It has been shown that MIS techniques have reduced hospital stay by 2.5 days due to the shorter recovery (Coon, 2005). Alternative techniques that avoid intramedullary perforation and reduce operative time and bleeding may have similar impact on hospital stay as MIS techniques.

Cost-effectiveness analysis

Health economists consider a surgical procedure that cost less than $ 30,000 per quality well year as a bargain to the society. Due to financial limitations certain procedures, which are less or not cost-effective will not be considered as treatment options by health care providers. Cost-effectiveness analysis is complicated but in simple terms it is the ratio of the cost of the procedure divided by the benefits received by the patients. Several studies have shown that TKA is a cost-effective procedure. Lavernia et al 1997 used a Quality of Well Being Index to calculate the cost per quality of well year in TKA. The difference in Quality of Well Being Index scores before and after the intervention was calculated and multiplied by the patient's life expectancy. The procedure cost was divided by this quantity resulting in the cost of a quality well year. The calculated costs per a quality well year were $11,560 at 1 year postoperatively. Cost effectiveness of knee arthroplasty surgery compares favourably with other surgical interventions such as coronary artery bypass surgery ($5000 per quality of well year) and extremely favourable with medical treatments such as renal dialysis ($50,000.00 for the quality well year).

The cost of the implant constitutes 24% of the whole procedure (Rissanen et al., 1997). THA was more cost-effective than TKA. Those over 60 years had a worse cost-effectiveness ratio of TKA compared with all other patient subgroups (Rissanen et al., 1997). In a literature review (Ethgen et al., 2004), 74 studies were selected on the outcome of both TKA and THA as evaluated by health-related quality-of-life instruments. Authors found that THA appeared to return patient to function to a greater extent than TKA. Primary TKA offers greater improvement compared with revision procedures.

Although TKA is cost effective, it appears that there is a need to make it more cost effective possibly by improving the outcome or by reducing the cost. Both targets could be achieved by finding an alternative to the current surgical technique that could improve the outcome and be less expensive.

Others issues related to health care providers

There are more issues discussed above in other sections such as training, outcome of TKA, complications, young patients and revision surgery.

Summary of limitations (section 2.5)

In view of the above, the deficiencies and limitations of the current TKA appear to be related to the surgical techniques and particularly CI systems. Several modifications of the modern CI systems have made it more complex and expensive without eliminating the drawbacks mentioned above such as medullary perforation, multiplicity of instruments and possible errors. Since the conventional techniques are more demanding and the training methods are inadequate, there remains a need to find better training tools, and/or a technique that is easier to learn and to perform. An alternative to conventional techniques is required to overcome these inherent limitations.

2.6 Alternative techniques

The literature review above showed that the current techniques for TKA and particularly the use of CI systems are less than ideal. For this reason, surgeons and scientists in the last decade have been focusing on improving surgical techniques. Minimally invasive and computer assisted surgery are two evolving techniques that have recently been introduced into clinical practice, as alternatives to conventional approaches.

2.6.1 Minimally invasive surgery

At present, there is a growing enthusiasm among patients, surgeons and health care providers in minimally invasive surgery (MIS) for joint arthroplasty. Adopting surgeons believe that the success of MIS techniques in trauma and spine surgery could be transferred to hip and knee arthroplasty. Although the terminology MIS is commonly used for arthroplasty, the accurate terminology should be less invasive surgery since these techniques allow arthroplasty to be performed from small incision approaches, as compared to the classic keyhole MIS approaches in laparoscopic and arthroscopic surgery. MIS for TKA involves not only a small skin incision but also more importantly, a minimal disruption of soft tissue. The skilful retraction using the mobile window principle markedly improves the access to the knee joint in MIS surgery. Quadriceps-sparing techniques preserve the extensor mechanism. The patella is shifted sideway, rather than everted or dislocated and excessive joint subluxation is avoided. Conventional instruments are modified and reduced in size to allow easy insertion and placement through small incisions. Compared with conventional techniques, MIS has the potential to provide a better short-term outcome, with earlier recovery and a shorter hospital stay. This may also involve modified anaesthesia and reduced short-term complications such as bleeding, stiffness and pain. Patients are usually satisfied with the better cosmoses and early return to work. Several authors are increasingly reporting good short-term results of such techniques (Laskin et al., 2004, Tria and Coon, 2003, Coon, 2005).

2.6.2 Computer assisted surgery

The application of computer technology in medicine has been progressing rapidly since the introduction of CT scanning. Computer assisted surgery has the ability to improve accuracy and reproducibly of surgical techniques, provide objective means to measure surgical performance and outcomes and supply powerful training tools. TKA, like many other orthopaedic procedures, is well suited for the application of CAS. It involves cutting and machining of bone, which is the most rigid structure in the body. Because of this inherent rigidity of bone, its location during surgery can be correlated repeatedly and consistently to a preoperative computer model (DiGioia-III et al., 1998). The applications of CAS in TKA have now moved from laboratory phase into clinical use. The technique is now routinely used in several centres in Europe, North America, Japan and Australia.

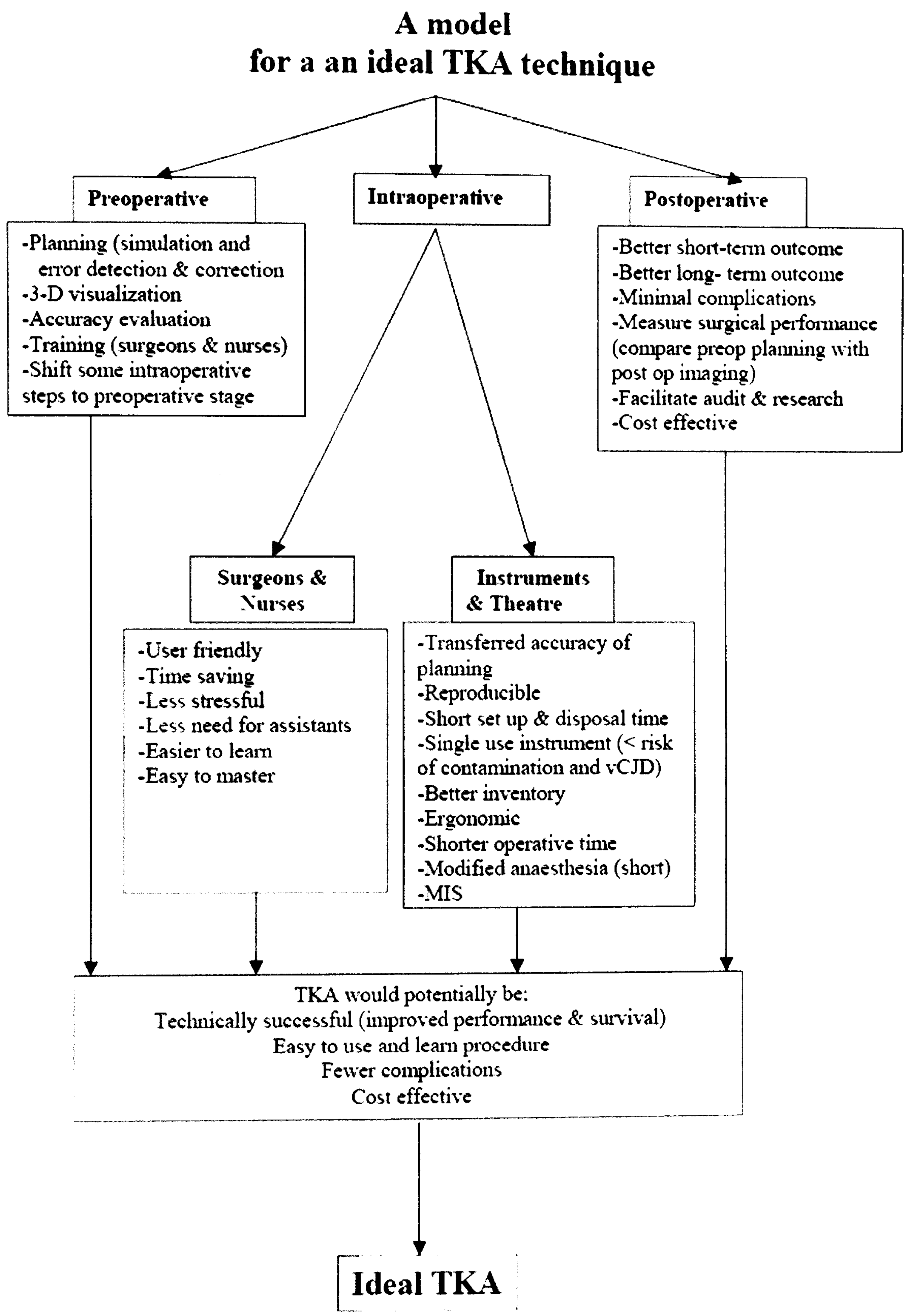
There are several classification systems for CAS techniques, but most recently, these systems were classified (Picard et al., 2004) into active robotic, semi-active robotic or passive, such as navigation. These are further classified according to the imaging requirements, which are either preoperative (CT-based), intraoperative (fluoroscopy-based) or image free. Robotic techniques can perform active steps of the surgical procedure such as bone cutting (milling) in TKA. The surgical actions are based on preoperative planning, which is typically CT-based. Robotic techniques require rigid fixation of the limb to the operating table during surgery. Few authors have reported their first experience with robotic TKA that showed higher levels of accuracy (Bauer, 2002, Jakopec et al., 2001, Siebert et al., 2002). However, robotic techniques face challenges to prove its safety and cost effectiveness.

Navigation techniques for TKA are now the most common clinically applied CAS procedure in all surgical specialities. This modality is passive and does not perform any steps of the surgical procedure. Rather, it provides the surgeon with intraoperative measurements and feedback. There are three different types of navigation systems (CT-based, fluoroscopy-based and image free), all of them have been employed in TKA but by far, image free systems are the most commonly used. Fluoroscopy-based navigation systems are the least commonly used, since TKA does not normally require intraoperative imaging. Fluoroscopy-based navigation is commonly used in trauma as it reduces the volume of intraoperative radiographic screening and the risk of radiation exposure, which is on the rise (Hafez et al., 2005). Literature is now abundant with reports comparing navigation against conventional techniques in TKA. Several randomised trials (Sparmann et al., 2003, Chauhan et al., 2004, Saragaglia et al., 2001, Chin et al., 2005, Decking et al., 2005, Victor and Hoste, 2004, Stockl et al., 2004) showed superior accuracy of navigation techniques over conventional instrumentation. Other comparative trials (Nabeyama et al., 2003, Perlick et al., 2004, Bolognesi and Hoffman, 2005, Anderson et al., 2005, Kim et al., 2005, Haaker et al., 2005) showed more precise placement of implants with navigation techniques. Also, a multicentre study on the outcome of navigation techniques in TKA showed better consistency and less outliers for alignment and rotation. Other benefits from navigation techniques are the potential reduction of blood loss and fat embolism, due to the elimination of IM rods. Two recent randomised trials (Chauhan et al., 2004, Kalairajah Y, 2005) showed a reduction in blood loss following navigated TKA. The first trial reported a lower incidence of postoperative confusion, possibly due to the reduced occurrence of fat embolism. Navigation techniques provide intraoperative measurements and can gauge the surgical performance. They can also provide a complete documentation of the surgical procedure and serve as training tools.

Summary of chapter 2

There are several limitations of the current techniques for TKA, especially the limited accuracy of planning and performance, and the drawbacks of conventional instruments. The available solutions (namely MIS and/or CAS) are not yet adequate, for the reasons outlined in the introduction and discussion chapters. A new alternative that can be user-friendly, inexpensive, minimally invasive and accurate is required. Such an alternative must allow surgeons to improve the outcome of TKA, provide a better training environment, and help surgeons to cope with the increasing challenges of new surgical techniques as MIS, and difficult cases of revision surgery. A model for the ideal TKA technique is displayed in Flow Chart 3.

Flow chart 3


A model
for a an ideal TKA technique
Preoperative
-Planning (simulation and error detection & correction
-3-D visualization
-Accuracy evaluation
-Training (surgeons & nurses)
-Shift some intraoperative steps to preoperative stage
Intraoperative
Postoperative
-Better short-term outcome
-Better long- term outcome
-Minimal complications
-Measure surgical performance (compare preop planning with post op imaging)
-Facilitate audit & research
-Cost effective
Surgeons & Nurses
-User friendly
-Time saving
-Less stressful
-Less need for assistants
-Easier to learn
-Easy to master
Instruments & Theatre
-Transferred accuracy of planning
-Reproducible
-Short set up & disposal time
-Single use instrument (< risk of contamination and vCJD)
-Better inventory
-Ergonomic
-Shorter operative time
-Modified anaesthesia (short)
-MIS
TKA would potentially be:
Technically successful (improved performance & survival)
Easy to use and learn procedure
Fewer complications
Cost effective
Ideal TKA

3. MATERIALS AND METHODS

This chapter outlines the design of the study and the outcome measures used for different experiments. It describes the materials used in this study, particularly cadaveric and plastic specimens and the methods used, to prove the proposed concept of patient specific templating (PST) and to evaluate its accuracy. The chapter explains in detail the technical steps of the PST technique that involved CT scanning, data reconstruction, planning for sizing and alignment, virtual verification of planning, designing and production of templates and finally the surgical experimentation. And then, it reports the surgical procedures, including the comparative trial. Lastly, this chapter describes the two experiments used for accuracy validation of PST by testing the accuracy of postoperative CT scans and the reliability of positioning the templates.

3.1 Introduction

This study was designed with two objectives in mind; the first was to test the hypothesis that the new approach of computer assisted preoperative planning and the production of PST is an alternative to CI systems of TKA (Figure 4). For this purpose, two sets of surgical experiments were conducted. In the first set, the PST technique was used to perform TKA on both cadaveric and plastic knee specimens. The second set was designed to compare the PST technique against CI systems, using only plastic knee specimens (comparative trial). The total number of experimental TKA procedures was 51 including 45 cases using PST and 6 cases using CI systems (Flow Chart 4). The primary outcome measures were: the complete performance of TKA without resorting to surgical jigs; ease of use and the operative time. A specific evaluation form (Appendix 1) was used during surgery, to record the following: (1) the ease of insertion of the femoral and tibial templates within the soft tissue and bony constraints; (2) successful positioning of the templates and the presence of a unique secure position of the templates over the distal femur and the proximal tibia; (3) the completion of all bone cuts using the templates; (4) the durability of the templates against bone cutting by saw blades; (5) the positioning of the prosthesis and the presence of overhanging of the implant on one side of the bone or notching of the

Flow chart 4

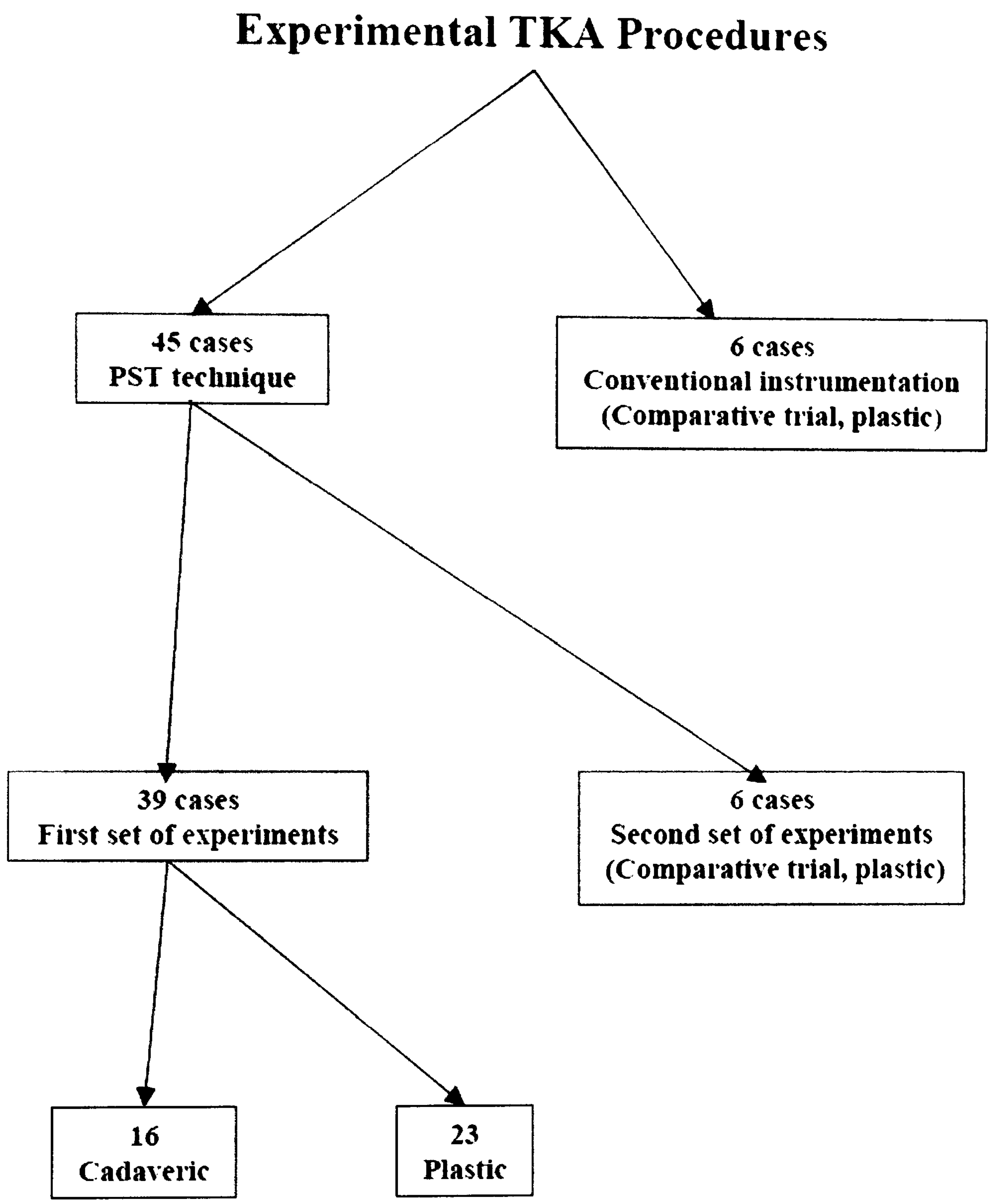
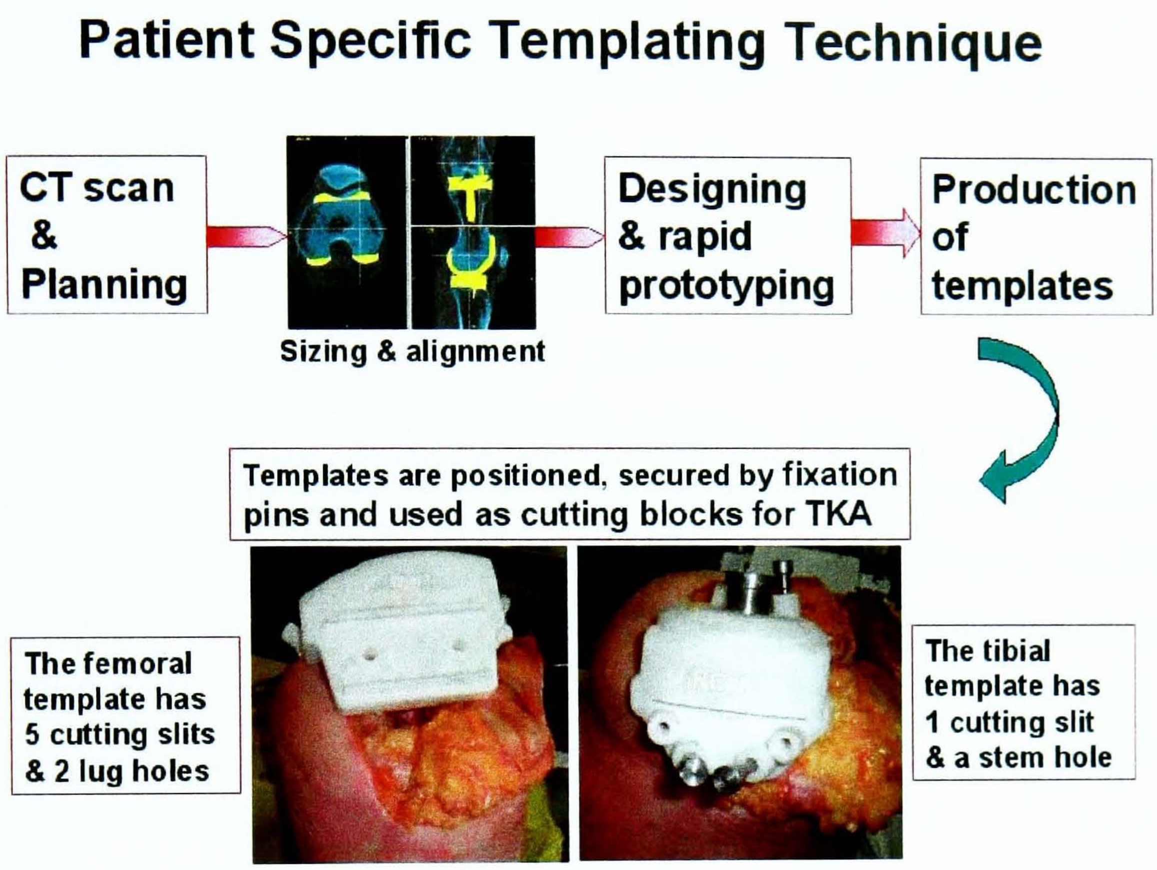

Experimental TKA Procedures
45 cases
PST technique
6 cases
Conventional instrumentation
(Comparative trial, plastic)
39 cases
First set of experiments
6 cases
Second set of experiments
(Comparative trial, plastic)
16
Cadaveric
23
Plastic

Figure 4
Patient specific templating technique



anterior femoral cortex; (6) the size of the gaps between the prosthesis and the surface of all bone cuts using steel shims; (7) the surgeon's opinion about the ease of use and the need for surgical assistance and (8) the operative time. For the comparative trial, the complexity of the CI system was compared to the PST technique, looking at the number of pieces, the need for setting up and assembling and the number of intraoperative technical steps such as sizing & alignment measurements).

The second objective of this study was to test the accuracy and reliability of the PST technique. Accuracy of sizing, alignment and bone cutting was evaluated by analysing postoperative CT scans of 6 random cadaveric knee specimens, with a comparison to preoperative planning. The reliability of positioning the templates was assessed through multiple users by measuring their interobserver and intraobserver variations. Five observers were asked to position the templates five times and a navigation system was used to measure the template position. The outcome measures used for the accuracy and reliability experiments were alignment and level of bone cutting in both femur and tibia. A specially structured form (Appendix 2) was designed to record the outcome measures; accuracy of sizing, alignment, rotation and the level of bone cutting. Evaluation of sizing was assessed in relation to the mismatch between the superimposed implants and bone and the presence of overhanging of implants, under-covering of bone and notching of anterior femoral cortex.

All experiments were conducted in the Bioengineering Division of the Academic Unit of Musculoskeletal Disease, Faculty of Medicine and Healthcare, The University of Leeds from (2001 to 2004), except for the reliability test that was performed during my fellowship (2004-2005) at the Institute for Computer Assisted Orthopaedic Surgery, The Western Pennsylvania Hospital, Pittsburgh, PA, USA. A post-doctoral engineer (KLC), experienced in computer aided designing was responsible for the computational work during the preoperative planning, designing of templates and postoperative analysis. The preoperative planning and postoperative analysis of the CT scans were conducted interactively between the surgeon and the engineer. A senior engineer (BBS) supervised all experimental work in this study, apart from the reliability test that was conducted at ICAOS, Pittsburgh, USA.

The new technique of PST was first developed using a generic CT scan of the knee joint. The reconstructed CT scan data allowed preoperative planning of TKA and designing of a virtual prototype for the femoral and tibial templates. The technique was then applied to cadaveric and plastic specimens. The experiments were performed one at a time in an iterative process, so that the intraoperative evaluation could be used to improve the planning and surgical performance for the next experiments.

3.2 Materials

Sixteen cadaveric legs were obtained from the Anatomy Lab, Faculty of Medicine and Healthcare, The University of Leeds. They were used consecutively, without selecting the quality of the specimens. All cadavers were from elderly donors whose knees were likely to have osteoarthritic changes. The demographic features are listed in Table 1. The mean age was 85 years (range, 61–102 years), the mean height was 162 cm (range, 150–183 cm), and the mean weight was 56 kg (range, 44.5–70 kg). Eleven cadaveric legs were from female donors, and five were from male donors. There were nine left legs and seven right legs. Cadaveric specimens were wrapped in plastic bags and kept frozen while not in use. Each specimen was labelled with the patient's initials and demographic details. They were thawed for several hours (depending on the weather conditions) before use for CT scanning or surgery. Cadaveric knees were more representative of clinical circumstances, since they have the soft tissue envelope, cartilage and human bone quality that plastic bones lack.

Thirty five plastic knee specimens were used in this study; 29 for the PST technique and 6 for the CI technique (comparative trial). They were obtained from Saw Bones (Malmö, Sweden), in the form of a complete femur and tibia, connected by rubber robes, representing posterior cruciate and both collateral ligaments. Initially, a trial was conducted to find the most suitable material of plastic bones for this study. The quality of CT images, the ease of bone cutting and the cost were the most important criteria for selecting the ideal material for this study. (this sentence was removed because it is already mentioned in the 1st page of results). Unlike cadaveric specimens, plastic models could be easily handled and kept as permanent records of the surgical procedures, allowing further evaluation when needed. Owing to the lack of soft tissue envelopes, the plastic bones allowed complete visualisation of the implant position during the intraoperative evaluation. They were readily available and less expensive. To simulate the variability of sizes of cadaveric knees, it was elected to use two sizes of plastic specimens (size 3 and 4) for the first set of experiments. For the comparative trial, identical knee specimens (in shape and size), were used to eliminate variables, since these models had none of the anatomical and pathological variables that exist in cadaveric joints.

Table 1: Demographic characteristics of cadaveric specimens

N°	**Age** [Years]	**Height** [cm]	**Weight** [Kg]	**Sex** Female [F] Male [M]	**Side** Right [R] Left [L]
1	83	165	57	F	L
2	66	180	64	M	R
3	66	180	64	M	L
4	89	183	70	M	L
5	91	160	63	F	R
6	91	160	63	F	L
7	61	154	44.5	M	R
8	61	154	44.5	M	L
9	85	158	64	F	L
10	85	158	64	F	R
11	99	167	57	F	R
12	99	167	57	F	L
13	90	150	44.5	F	R
14	90	150	44.5	F	L
15	102	155	51	F	L
16	102	155	51	F	R

The PFC prosthesis (DePuy/Johnson and Johnson, Leeds, UK) was used in this study. It has been the most commonly used prosthesis in the United Kingdom (Liow and Murray, 1997). The manufacturer provided computer aided design (CAD) files of different sizes for the femoral and tibial components, including the polyethylene tibial inserts. Patellar replacement was not considered in this study. The manufacturer also provided a set of conventional instrumentation, but with the restriction that they be used only for plastic and not cadaveric experiments. A personal computer (PC) was used as a workstation for all computational work during the preoperative planning and postoperative analysis. Computer aided design software (Materialise, Leuven, Belgium) (Materialize) was used with its two packages (Mimics and Magics) for 3-D planning, surgical simulation and designing of the patient-specific templates.

The rapid prototyping (RP) machine was a type of a vanguard selective laser sintering (SLS) (Sinterstation HIQ Series, 3D Systems, Valencia, CA) (3Dsystems). It was located at the Keyworth Institute, The University of Leeds and was hired per individual cases. The RP machine (Appendix 1) produced physical models identical to the designed templates acting as a 3-D printer. The templates were manufactured heat-fusible materials that are supplied in the form of powders. The templates were formed by tracing a laser beam across a container that holds the powder. The resulting heat leads to the formation of a thin slice of sintered (fused) powder. The next slice is then formed from the powder that covers the first one and so on, until the complete shape of the model is formed. These slices or layers fuse together as they form, leading to the production of a solid object. The template material was a Polyamide (Nylon) composite (DuraForm, 3D Systems, Valencia, CA, USA) (3Dsystems), which is a durable material for creating functional (tooling) prototypes. This material was licensed for in vivo exposure as an instrument, but not as an implant.

3.3 Methods

The experimental work in this study was conducted in two stages. The first stage was the surgical experimentation that involved preoperative planning and surgery for 45 TKA procedures. The second stage was the accuracy evaluation that involved analysis of postoperative CT scans and a reliability testing.

3.3.1 Surgical experimentation

3.3.1.1 Preoperative planning for PST

The preoperative planning (Figure 5) comprised the following steps: 3-D reconstruction of computed tomography (CT) scan data, sizing and alignment of the prosthetic components, surgical simulation, templates designing, and production of patient specific templates using the rapid prototyping technology. These steps were similar for both cadaveric and plastic experiments.

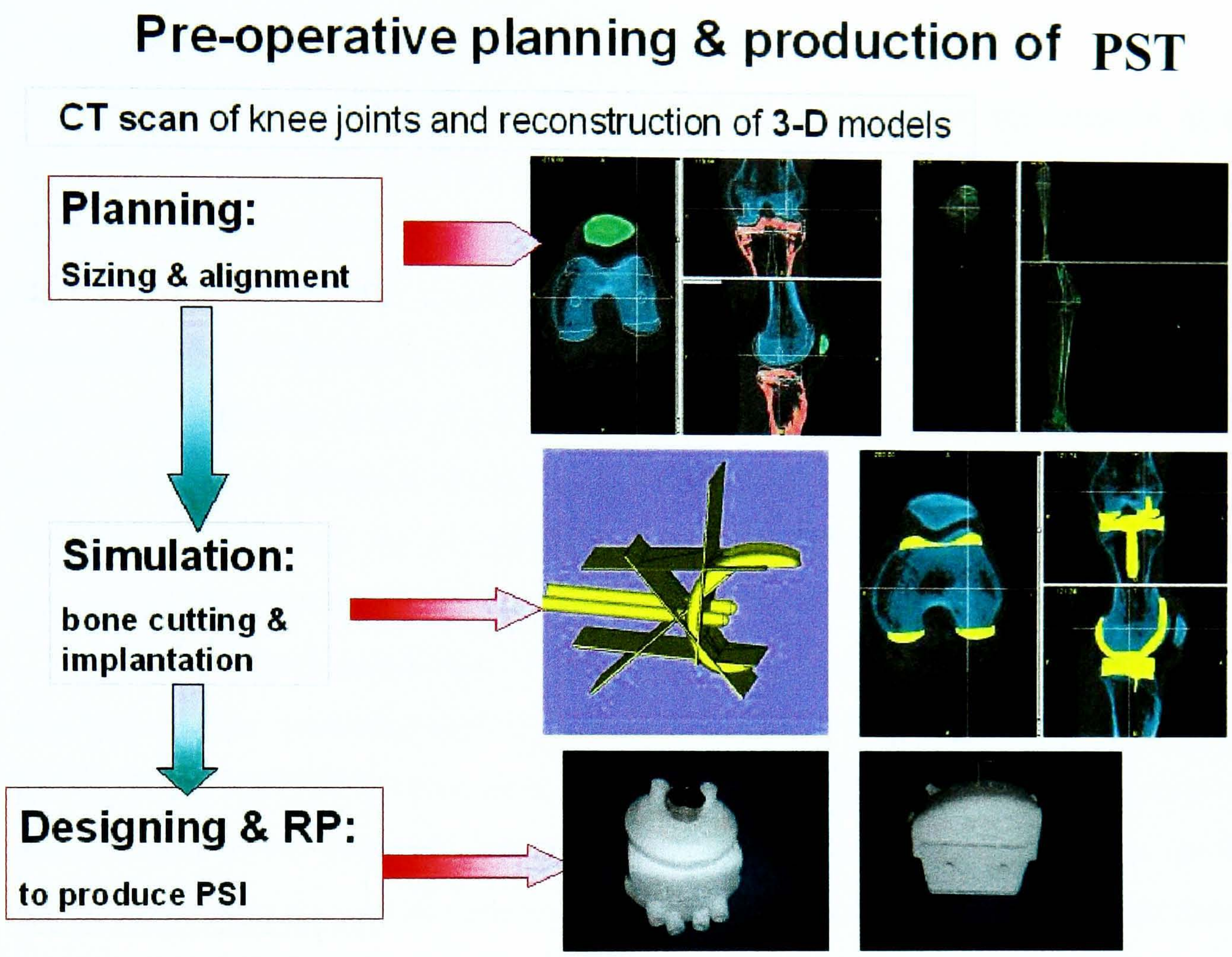
a. Data acquisition and segmentation

After adequate defrosting, the cadaveric legs were transferred to the CT scanner (high speed LX/I, GE). The cadaveric or plastic specimens were positioned in a leg holder that was specially designed for this purpose. The leg holder allowed adequate fixation of the leg in full extension during CT scanning. Computed tomography scanning was performed for the knee joint, distal tibia and proximal femur, with 1 mm thick slices and 1 mm spacing, which is the minimum requirement for accurate reconstruction of the joint. The femoral and tibial shafts were scanned with 5 mm thick slices and a scan space of 5 mm. This protocol optimised the image quality of the bone for areas of interest around the knee joint, as well as the proximal femur and distal tibia. CT scan images were imported to MIMICS software and were displayed in coronal, sagittal and transverse planes. The images were processed using a threshold value to differentiate the areas of interest in both femur and tibia, which could then be segmented from the soft tissue. Areas of interest were selected by defining sets of voxels, whose intensity was above the selected thresholds and the resolution of the undesirable structures such as soft tissues was reduced. The reconstructed images were displayed on the computer screen as a 3-D model.

b. Sizing of the implants

Similar to conventional techniques, component sizing was initially determined by measuring the anteroposterior (AP) dimension of the distal femur and the contour of the distal tibia. This allowed the selection of an exact or closely matched size of the femoral and tibial implants from the CAD files. Then, the selected component was superimposed over the bone and visualised in 3-D to confirm the accuracy of sizing and

Figure 5


Pre-operative planning & production of PST
CT scan of knee joints and reconstruction of 3-D models
Planning:
Sizing & alignment
Simulation:
bone cutting &
implantation
Designing & RP:
to produce PSI

exclude overhanging of the implant on one side of the bone or notching of the anterior femoral cortex.

c. Alignment of implants and bone cutting

The interactive 3-D manipulation of images allowed translation and rotation of the prosthetic components individually, until satisfactory prosthesis alignment was achieved. Standard anatomical landmarks and long axes of the femur and tibia were used as guides for proper alignment, rotation and placement of the prosthesis. The mechanical axis of the femur was defined as a line drawn from the centre of the femoral head to the midpoint of the distal femur in the coronal plane. A line drawn from the centre of the tibial plateau to the centre of the distal tibia defined the mechanical axis of the tibia. The landmark for the rotational alignment of the femur was the epicondylar axis and for the tibial component, it was the medial third of the tibial tubercle.

The standard parameters for aligning TKA components were used in this experiment. The recommended figures for aligning TKA components (Insall and Easley, 2001) were used in this experiment. In the coronal plane, the distal femoral cut was planned to be perpendicular to the mechanical axis (or 6° of valgus to the anatomical axis in the case of cadaveric specimens). The sagittal alignment of the femur was set to be in slight flexion (3°) to avoid notching. In flexion, the femoral cut was aligned at 3° of external rotation to the posterior condylar line or parallel to the epicondylar axis. The tibial cut was planned to be perpendicular to the mechanical axis in the coronal plane and to have a posterior slope of 5° in the sagittal plane.

The level of bone cutting was adjusted according to the recommended figures (Insall & Easley 2001) of 10 mm, as measured from the level of the healthy bone in both distal femur and proximal tibia. Since cartilage does not normally appear in CT scan images, its thickness (average 1 mm) (Shepherd and Seedhom, 1999) should be subtracted from these recommended figures. The thickness of the articular cartilage should be taken into consideration. The presence of articular cartilage and its effect on the level of bone cutting did not present as a practical problem because 1mm of over cutting or under cutting could be easily compensated by adjusting the thickness of UHMWPE. As an alternative, bone could be cut at 2mm from the diseased side of the joint. For example, in a varus knee the level of the tibial cut could be adjusted at 2mm distal to the lowest point in the diseased medial tibial plateau. Although the recommended figures for bone cutting level were used as guidelines, the final level of bone cutting was adjusted according to the virtual appearance of the implant position in 3-D. The software allowed this trial and error technique, where implants were superimposed over the bone and positioned at the level of bone cutting, then viewed in 3 planes. This allowed the operator to fine tune the level of bone cutting and to avoid compromising the attachment of important structures such as patellar tendon and collateral ligaments by placing bone cuts away from the relevant landmarks such as tibial tuberosity, fibular head and epicondylar eminences.

d. Virtual evaluation of the result

Virtual positioning of the implants over the bone was visualised in 3 planes (Figure 6) and allowed the identification of the volume of bone that needed to be removed. This step was similar to surgical simulation and it was used to evaluate implant placement and the intended bone cutting. Errors could be identified and corrected at this stage, until satisfactory planning was achieved.

e. Designing of templates

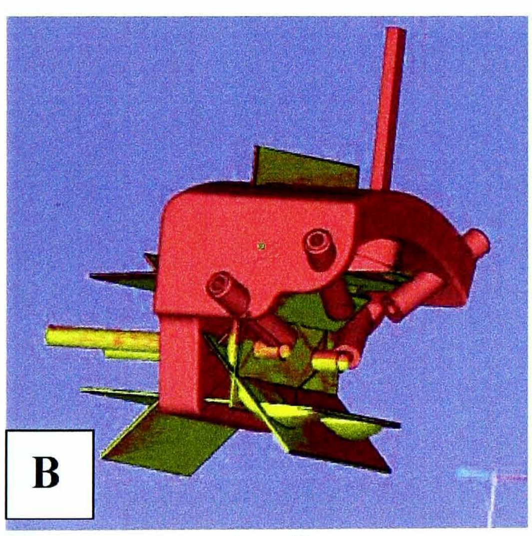
To design templates, the 3-D models of the femur and tibia, with aligned prosthetic components in situ (as described above), were imported to the CAD component of the Materialize software. One femoral and one tibial template (Figure 7) was designed, each in the form of cutting blocks to allow bone preparation based on preoperative planning. This was achieved by creating slits in the templates to allow five flat bone cuts in the distal femur and one cut in the proximal tibia. The size of the slits was 1mm to fit the size of the saw blades that was 0.9 mm. Lug holes and openings for the fixation stem and the keel were also created. The templates were designed to have five cylindrical locating probes (4 peripheral and one central) for the femur and four for the tibia (Figures 7 & 8). The diameter of the peripheral locating probes was 5 mm while that of the central probe was 12 mm. These probes protruded from the internal surfaces of the templates to match the surface geometry of the distal femur and proximal tibia. Because these probes were patient-specific, they could only allow the templates to be placed in a unique and secure position. The probes were cannulated to allow the passage of the fixation pins that provided additional stability to the templates over the bone. Figure 8 demonstrates some of the modifications to the template design. The code and number of the experiment was engraved on the body of the templates.

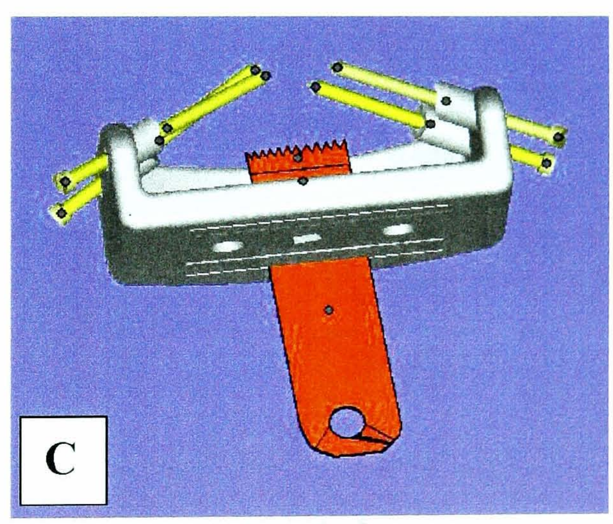
f. Production of templates

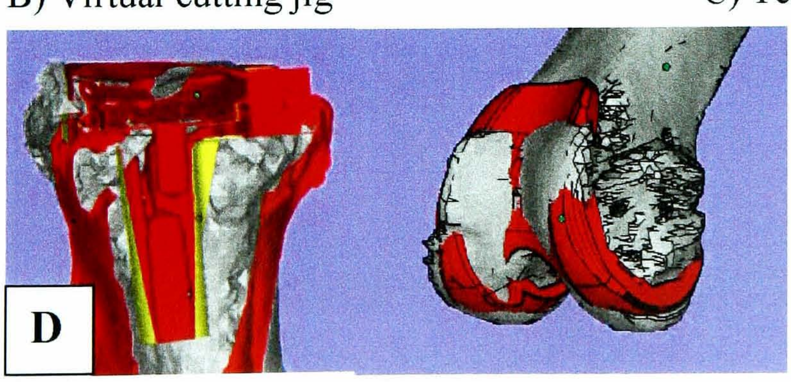
The final design of the patient-specific templates was transferred electronically to the rapid prototyping machine that produced the physical templates (Figure 9). Once manufactured, the templates were retrieved from the RP machine and cleared of the remaining powder. To simulate clinical circumstances; the templates were sterilised using an autoclave. These templates were designed for single use. The CAD files of the selected sizes of prosthetic components were also transferred to the RP machine to produce physical models of the components. These non-metallic duplicates were meant to prevent artefacts that metallic implants may cause during postoperative CT scanning.

Figure 6
Preoperative simulation of surgery

A) Sizing and alignment


B) Virtual cutting jig


C) Template design


D) Trial implantation

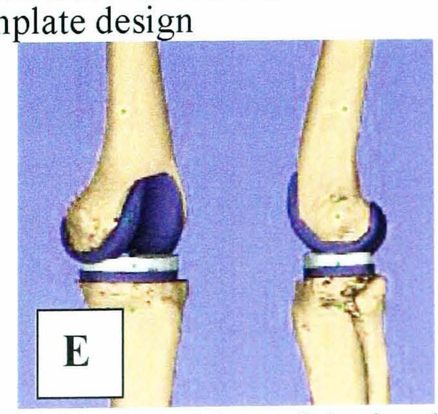
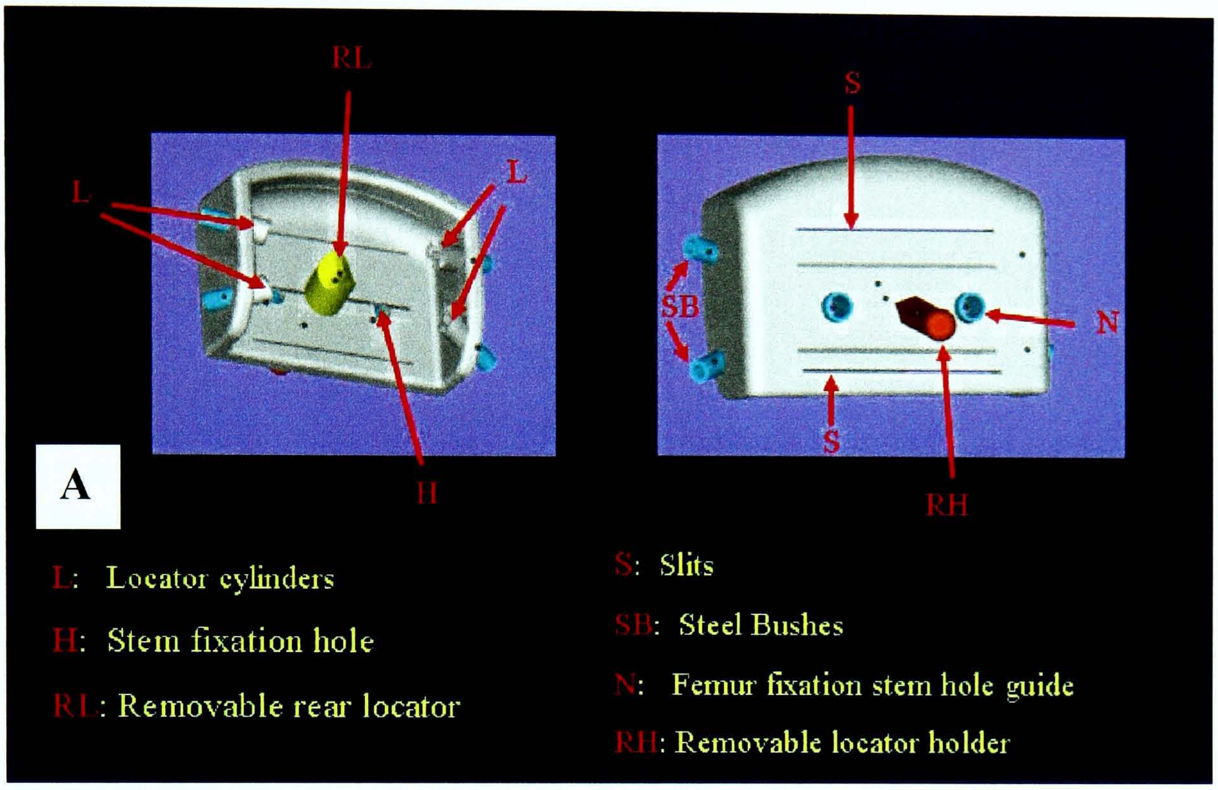
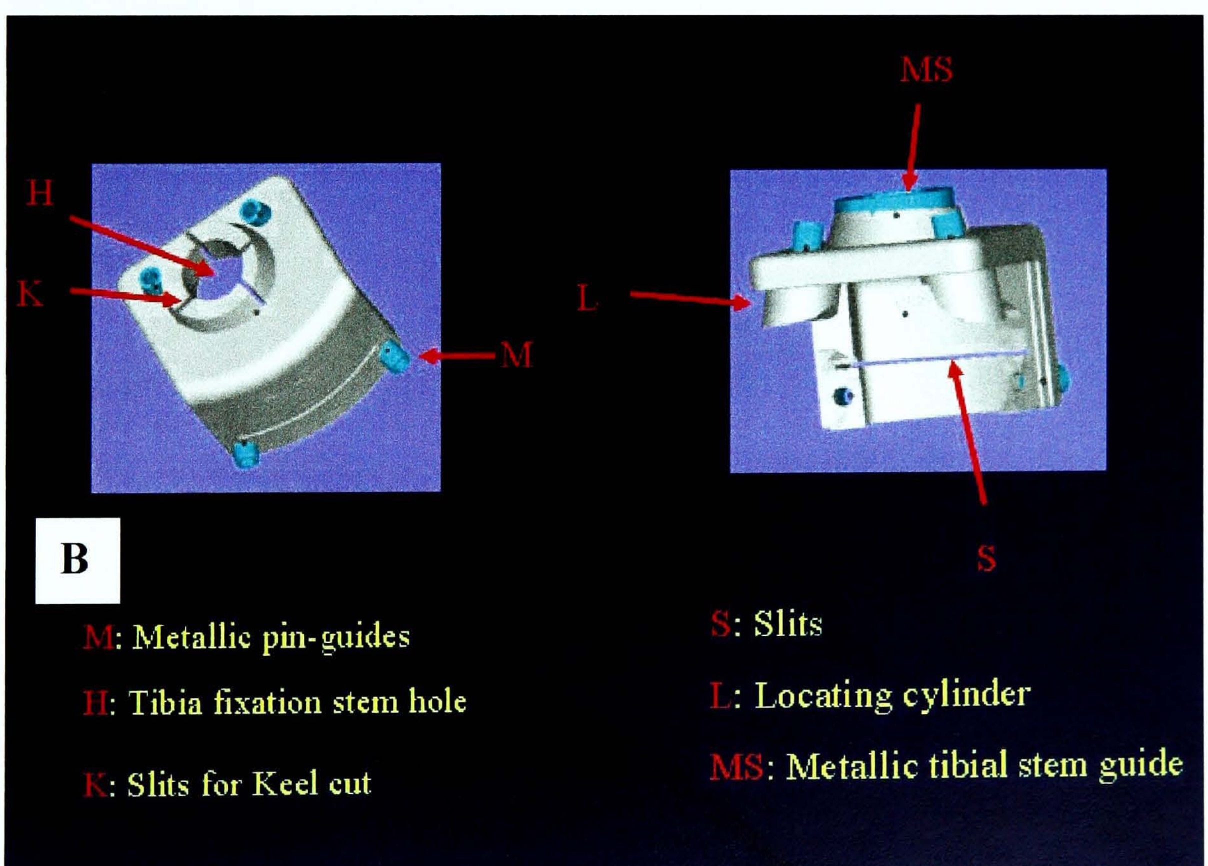

E) Final position of the implants

Figure 7
Designing of femoral and tibial templates

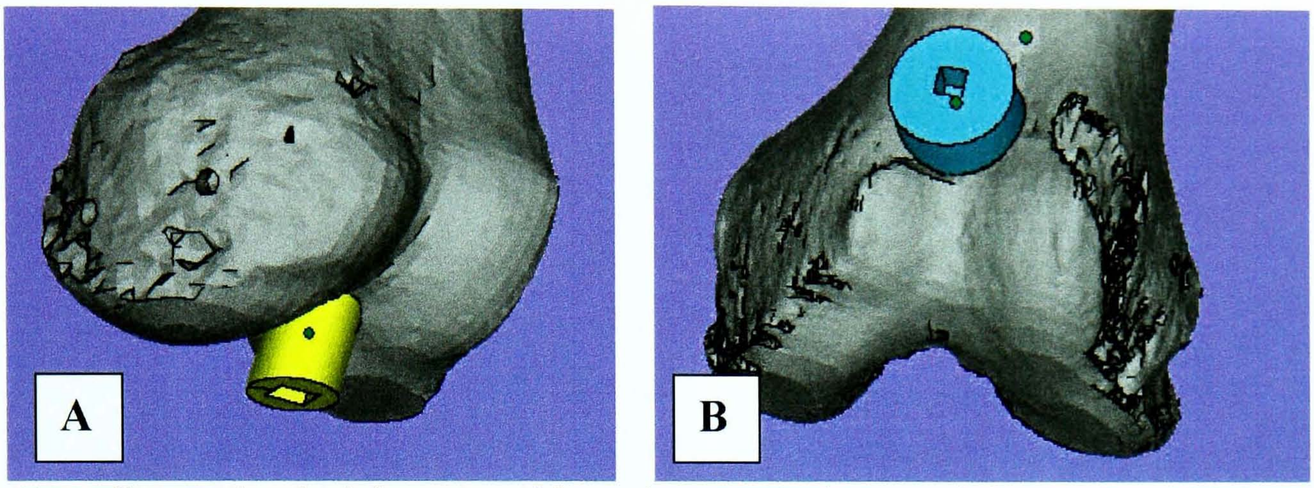


A) Femoral template

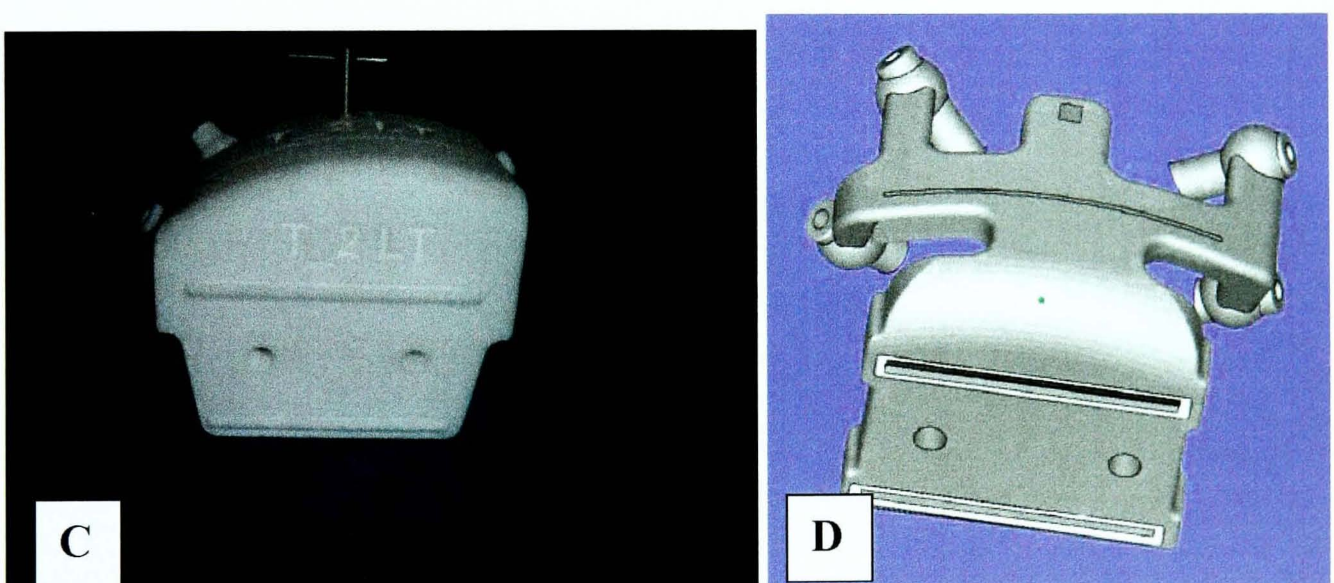


B) Tibial template

Figure 8
Developmental changes of the femoral template

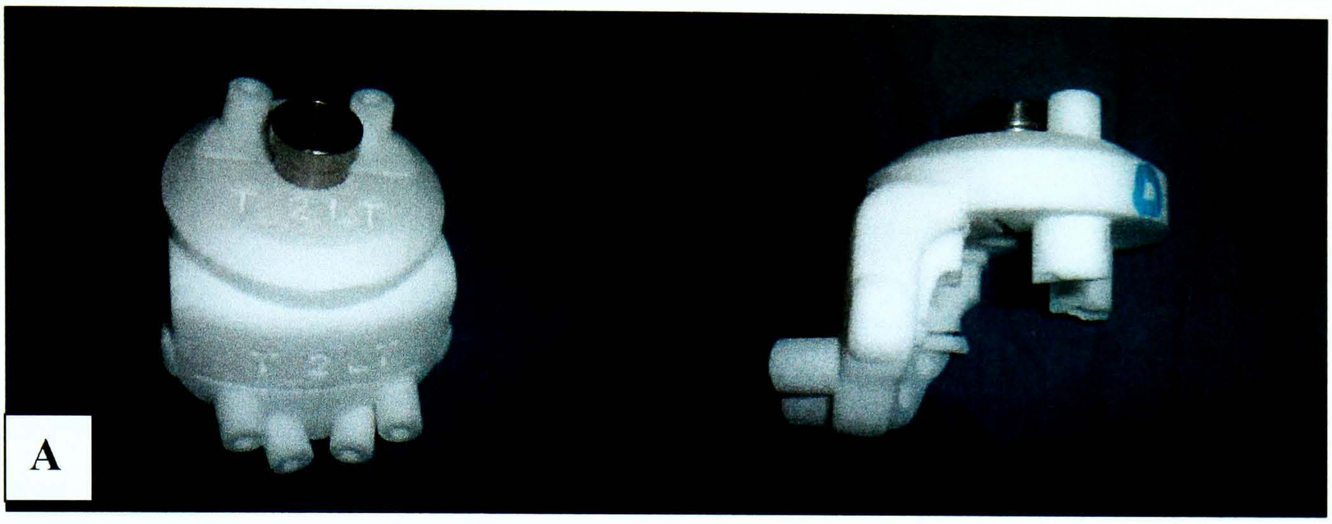


A) Earlier version had the removable probe over the intercondylar notch, which is a cartilage-covered area B) The standard version had the removable probe just proximal to the trochlea, which is a cartilage-free area

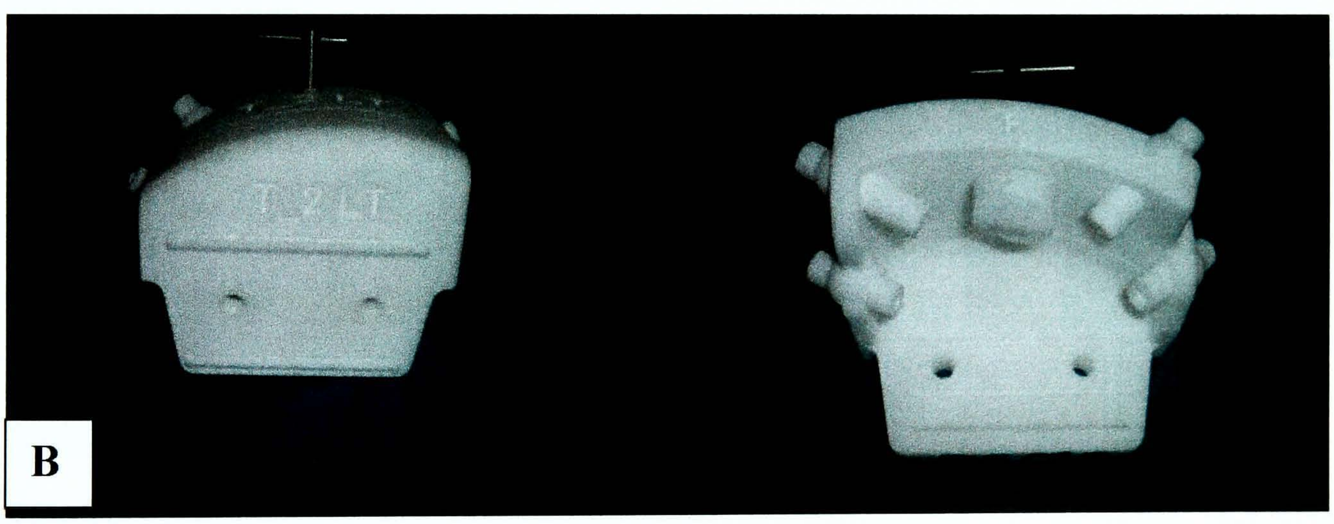


C) Standard femoral template. D) Latest version with the bulk of the body of the template being reduced in size while maintaining the feature for surface matching

Figure 9
Production of femoral and tibial templates



A) Tibial template: External surface of the front and the top (left) and internal surface as shown from a side view (right)



B) Femoral template: External surface of the front and the top (left) and internal surface of the front and the top (right)

3.3.1.2 Surgical procedures

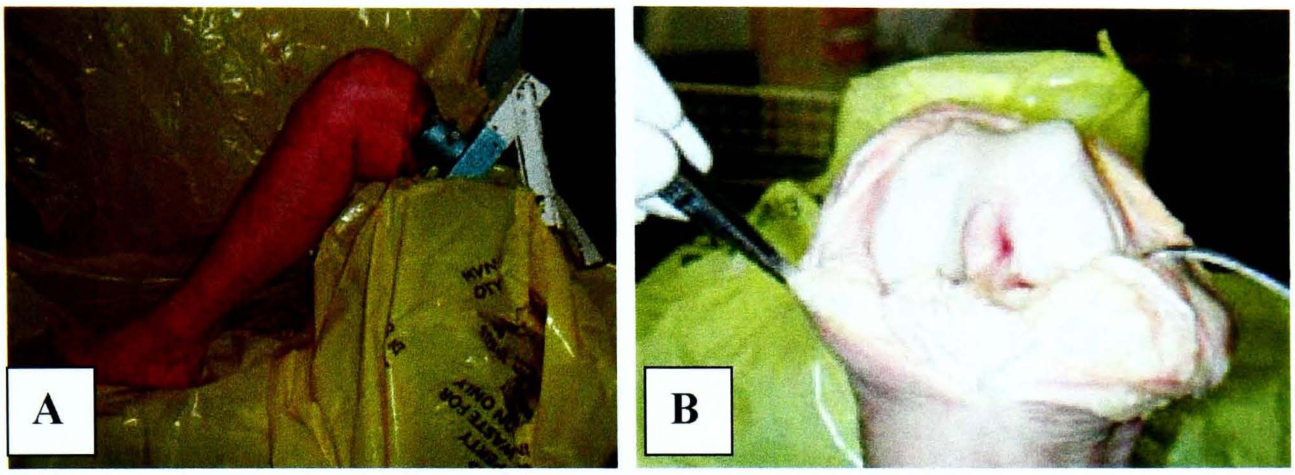
The rapid prototyped templates were used to perform TKA procedures on both cadaveric (Figure 10) and plastic specimens (Figure 11). The femur was rigidly held in a special leg holder that allowed the knee joint to move from full extension to more than 90° of flexion. For cadaveric experiments, a basic surgical set was used comprised of a knife with size 10 blade, heavy toothed forceps, Langenbeck's retractors, bone lever and bone nibbler. A powered (electric) oscillating saw (240V, AC 1.84 Amps) was used for bone cutting. It was a commercial off the shelf product (Model # 1621, Sawbones, Malmö, Sweden), incorporating a heavy-duty industrial high speed, high torque motor that designed for workshops on plastic bones. Compared to surgical saws, it was relatively heavier and produced excessive vibration and heat. The saw blade was 100 mm x .09 mm (Model # 1613-2 Sawbones, Malmö, Sweden). A surgical powered (electric) drill was used for drilling holes for the fixation pins of the templates, stem of the tibial implant and femoral lugholes. A leg holder mounted on a vice was used to hold the femur rigidly during surgery, but to allow free motion of the leg. The standard medial parapatellar approach was used for all of the cadaveric cases. As in conventional TKA, retractors were used to improve exposure, allow easy insertion of the templates and protect soft tissues during bone cutting.

The femoral and tibial templates, one at a time, were uniquely positioned over the respective bone, matching their unique geometry. All locating probes had to be in contact with the bone surface and the template had to fit in a single position. According to preoperative planning, the contact areas were cartilage free. Apart from locating probes, the body of the template did not have to be in contact with the joint surfaces, thus avoiding undue displacement by articular cartilage that did not appear on CT scan images during preoperative planning. For example, a gap was always present between the body of the template and the distal femur. Fixation pins were inserted into the bone through the cannulated locators to stabilise the templates during bone cutting. Traditional saw blades and drill bits of the appropriate diameter were used to make the various bone cuts and holes for lugs, stem, and keel. Resection of the posterior aspects of femoral condyles gave rise to a rectangular space in flexion normally called "flexion gap". The distal femoral resection created another rectangular space normally called "extension gap". There were 5 flat cuts for the distal femur: anterior, posterior, distal and 2 chamfering cuts and one transverse tibial cut. The author (MAH) performed all surgical procedures except 4 cadaveric TKA procedures that were done by the external supervisor (KPS). The reason for inviting KPS was to perform the PST technique by a different surgeon who has more surgical experience. The results of both surgeons are mentioned in results section 4.2.

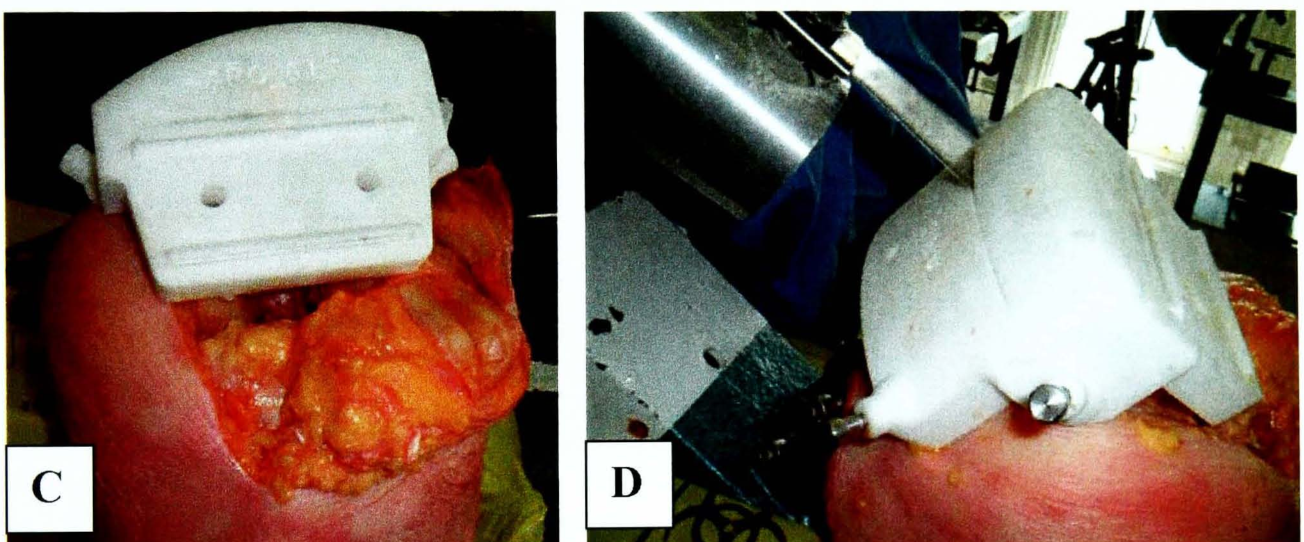
In the first set of experiments, the cadaveric specimens were used to optimise the shape of the templates, so they could be easily accommodated within the soft tissue and bony constraints. They also were used to identify the most reliable position for the locators and test the effect of articular cartilage for certain locators, such as the central femoral one. During this phase, the templates were modified and refined to improve the ease of use, particularly the insertion through soft tissue constraints and the positioning. The earlier experiments in this phase served to prove the concept of the PST rather than to optimise its accuracy.

In the second set of experiments, six pairs of plastic specimens were used to compare the PST technique against CI systems (Figure 12). Six identical plastic knee joints were used for each arm of the study, and all had features similar to those encountered in osteoarthritic knees. To avoid bias, the surgeon (MAH) had to acquire a nearly identical experience in knee prosthesis implantation, with PST and CI. Regardless of past experience, the surgeon in this test was required to perform three TKA procedures using CI systems on plastic bones. This exercise was performed outside the study and was conducted 2 days before the comparative trial. To test the ease of use of the PST and the CI techniques, the trial was designed to have the first three procedures for each arm performed with the support of a surgical assistant and the next three pairs without an assistant. For the purpose of cost comparison, information was gathered on the cost of the PST technique and conventional instrumentations.

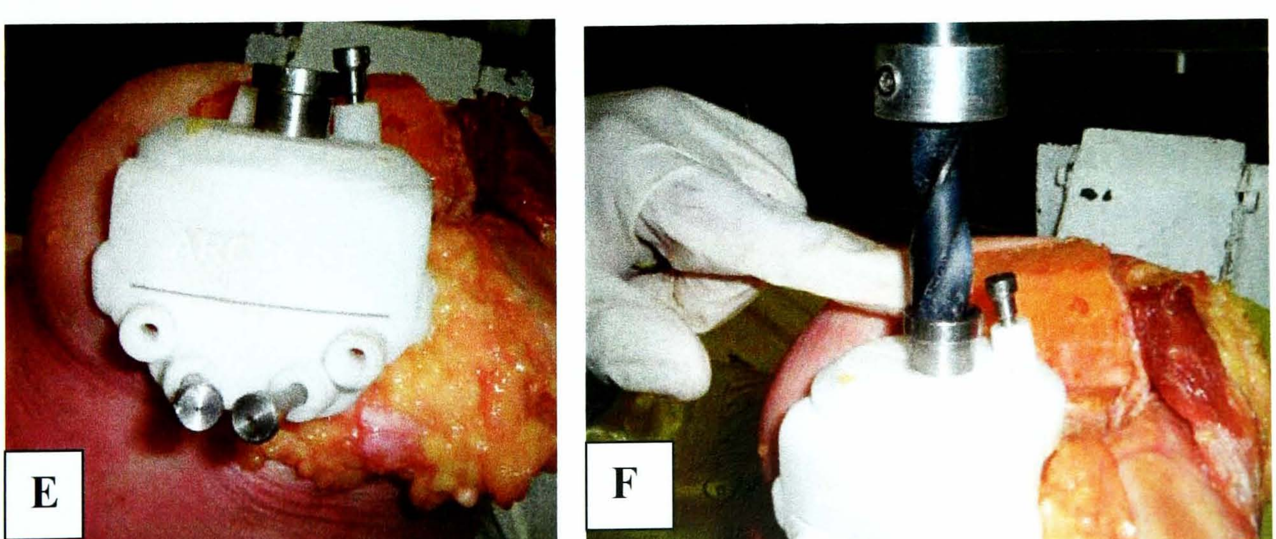
Figure 10
Photographs from cadaveric experiments



A) Left cadaveric specimen positioned in the leg holder
B) The knee was exposed through a standard parapatellar approach

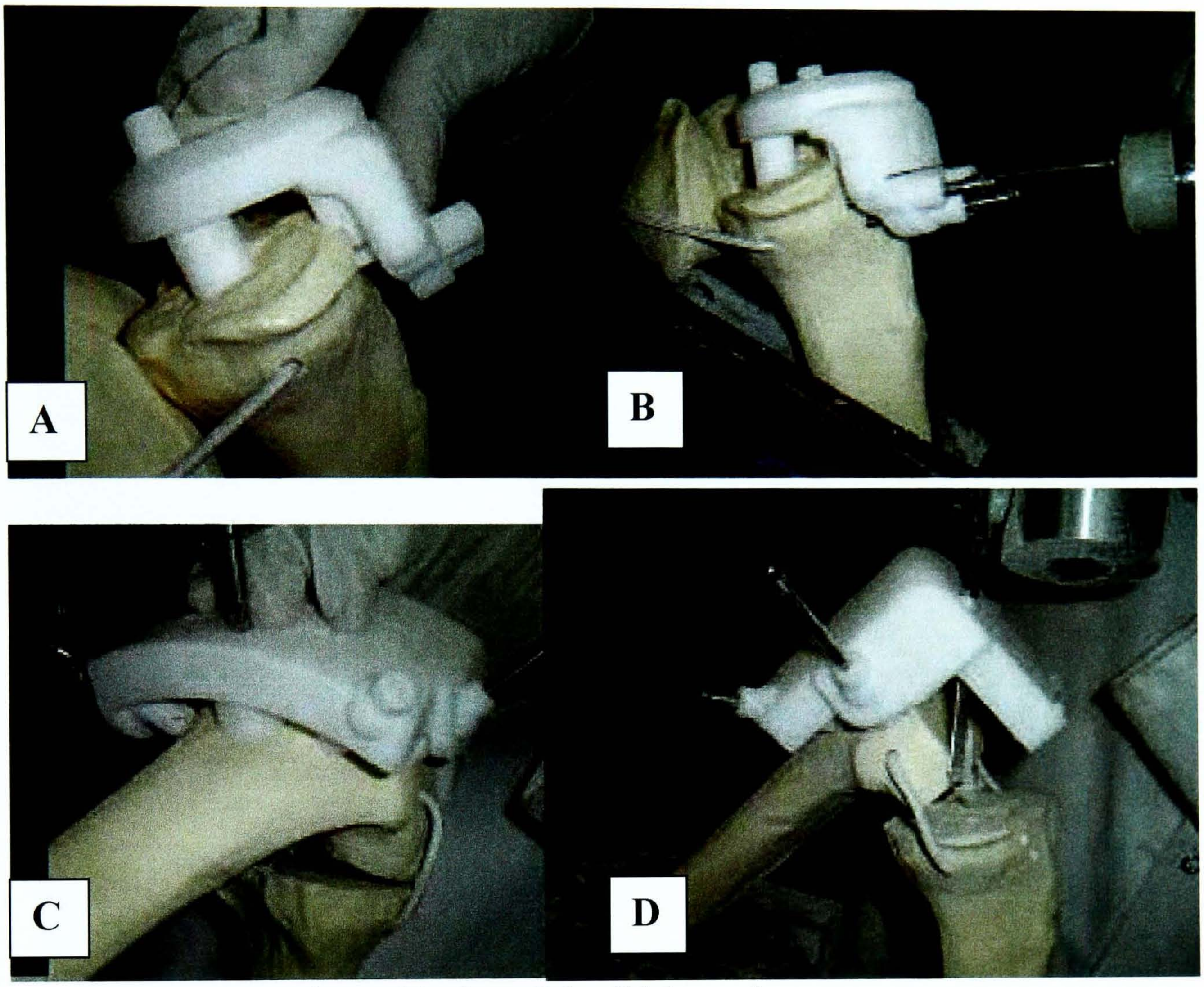


C) Front view shows the femoral template positioned over distal femur
D) Top view shows the template fixed by pins and the distal cut being performed



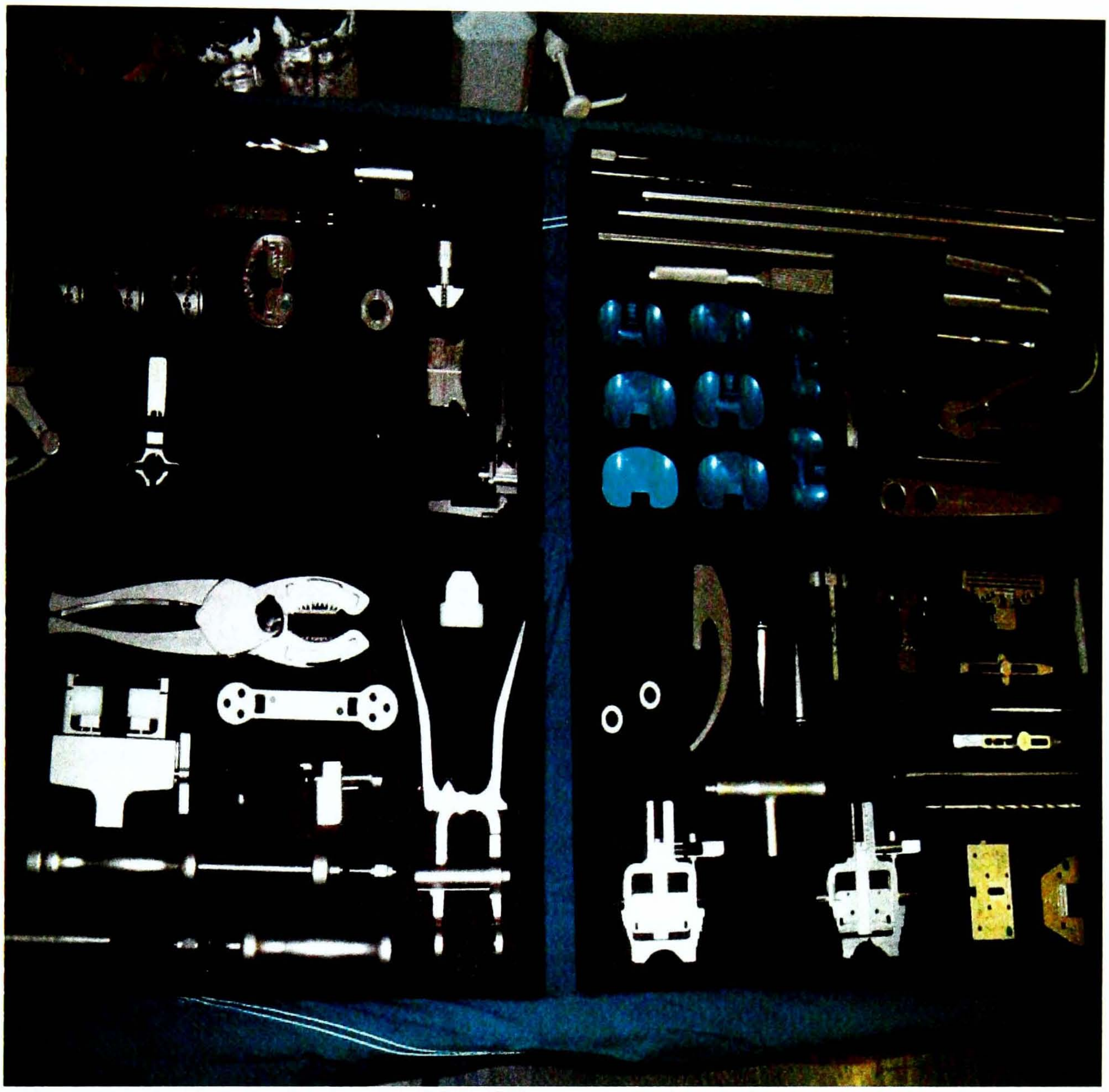
E) Front view shows the tibial template positioned and fixed by pins
F) Top view shows the preparation for the tibial stem

Figure 11
Photographs from an experiment on a plastic specimen



A) Side view shows the positioning of the tibial template
B) Side view shows the tibial template fixed and the tibial bone cutting in progress
C) Top view shows the femoral template positioned and fixed by pins
D) Side view shows the posterior chamfer cut

Figure 12
Conventional instrumentation



A photograph shows the Demo kit of the conventional instrumentation system (PFC, DePuy, Johnson & Johnson) that was used for the comparative trial. This kit was only for size 3 implant and it contained 84 pieces stored in 4 trays

3.3.2 Accuracy evaluation

3.3.2.1 Analysis of postoperative CT scan

The purpose of this experiment was to evaluate the accuracy of the PST technique by analysing the postoperative CT scans of 6 randomly selected cadaveric specimens. Non-metallic implants were in situ during CT scanning. The postoperative CT scanning was performed using the same protocol and the same CT scanner that was used for preoperative CT scanning. The techniques for segmentation and reconstruction of 3-D images were also similar to the ones used in preoperative planning. The planning software (MIMICS, Materialize) displayed the postoperative scans superimposed over the corresponding preoperative images in the coronal, sagittal, and transverse planes. The software allowed the engineer/surgeon to determine the amount of deviation of the resulting bone cuts from the preoperative plan and to measure errors in sizing, alignment and level of bone cutting.

A special form was used to record the measurements (Appendix 2) in degrees for alignment and in mm for the level of bone cutting. Sizing was recorded as "normal", "under-sizing" or "over-sizing". Accuracy of alignment and bone cutting of the femoral and tibial components was measured in the coronal and sagittal planes. Only reference cuts[1] were measured here to determine femoral coronal alignment (distal cut), femoral rotation (posterior cut) as well as the tibial coronal and sagittal (posterior sloping) alignment. Accuracy of the level of bone cutting was assessed at the distal femoral cut and the single tibial cut to determine the amount of deviation (undercut or over cut) as compared with preoperative planning. Under-cutting means cutting less bone than the preoperative plan and this may lead to lowering the joint line and limiting knee extension. Over-cutting means cutting more bone, compared with the preoperative plan and this may elevate the joint line and deplete bone stock.

3.3.2.2 Testing the reliability of positioning the templates

A reliability test was performed at the Institute for Computer Assisted Orthopaedic Surgery, The Western Pennsylvania Hospital, Pittsburgh, PA, USA. The

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[1] Reference cuts are the cuts that determine the alignment of the implant such as the single tibial cut and the anterior and distal femoral cuts as opposed to chamfer cuts that are just finishing cuts intended to provide matching surfaces for the internal geometry of implants.

purpose of this experiment was to test the reliability of positioning the templates by multiple new users. Five observers were involved in this experiment; a surgeon (MAH) who is familiar with the PST technique, and 4 engineers who were experienced in using computer assisted systems, but not familiar with the templating technique. These new users were sceptical about the accuracy of PST. The experiment was conducted using only one plastic knee specimen (Foam Cortical Shell, Model # 1151). The planning for TKA was based on the PFC prosthesis (DePuy/Johnson and Johnson, Leeds, UK). The typical steps for the PST technique (listed in pages 62, 64 & 67 and illustrated in Figure 4), were applied to this knee model. This includes CT scanning, reconstruction of 3-D images, sizing and alignment of prosthetic components, surgical simulation, template designing and finally production of patient specific templates using rapid prototyping technology. The knee specimen was held rigidly in a specific leg holder. The primary outcome measure was alignment and level of bone cutting, as determined by the position of the templates. A navigation system was used as a tool to measure alignment and level of bone cutting for reference cuts, while placing the femoral and then the tibial templates by each observer.

The navigation system used in this experiment was VectorVision (BrainLab, Heimstetten, Germany) (appendix 4). The navigation was just used as a measurement tool, without playing any role in guiding the observers, while placing the templates, since observers were not facing the navigation monitor. The routine steps (Stullberg et al., 2000) for using navigation systems in TKA were adopted by one of the observers who was familiar with such systems. Two tracking pins were inserted into the distal femur, about a handbreadth from the knee joint and another 2 pins were inserted into the proximal tibia about 2 handbreadths from the knee joint. The tracking pins were 2 mm each and they served as rigid bodies to which one femoral and one tibial tracker were inserted. Each tracker has at least 3 reflectors (spheres) to reflect the infrared light, which is emitted by an optical camera. This allowed the camera to track the position of the trackers in 3 planes. A continuous line of sight has to be maintained between the trackers and the camera. The optical camera was connected to the navigation system, where data were computed and relevant information was displayed in a computer monitor. Anatomical data of the plastic knee specimen were collected using a pointed probe that is attached to a tracker (Appendix 5). These data included a series of landmarks such as the centre of the hip, knee and ankle joints to allow the calculation of the mechanical axis by the navigation system. The centre of the hip (centre of the femoral head) was kinemtically calculated by the navigation system while the operator rotated the femur in a circular fashion (circumduction). The centre of the knee was determined by touching the midpoint of the distal femur by the tracking probe. The centre of the ankle was calculated by the navigation system after touching the medial and lateral malleoli. Epicondylar axis was used to determine the rotation of the femur. The operator collected data on the bone surfaces by sliding the pointed probe over the surfaces of the distal femur and proximal tibia. The navigation system used all data to create a model specific to the plastic specimen. This allowed the measurement of alignment, rotation and level of bone cutting in real time by tracking a tracking plate that was inserted one at a time into the slits of the templates that corresponded to the reference bone cuts. This step is typically performed during navigated TKA, where the tracking plate is inserted into the tibial, distal femoral and anterior femoral slits of the conventional cutting blocks to measure alignment and level of bone cutting, before actual bone cuts are performed.

Each observer was asked to position the tibial templates one at a time, with the tracking plate in-situ (Figure 13). The navigation system continuously tracked the position of the tracking plates and subsequently measured alignment (coronal and sagittal) and level of bone cutting, which were displayed on a computer monitor in real time. When the observer was satisfied with the template position, an independent assessor recorded the measurements that were displayed on the navigation monitor. These measurements were done before bone cutting, as is typically performed, when using navigation systems in TKA. The same process was repeated for the femoral template positioning, with 5 observers and 5 times each. However, in this case there were 2 reference cuts and the template was first positioned, with the tracking plate inserted into the distal femoral slit and then positioned again, with the tracking plate inserted into the anterior femoral slit. The distal femoral slit was meant to measure alignment (coronal and sagittal) and level of bone cutting and the anterior slit was for femoral rotation.

It was planned to collect 175 observations; 25 sets of observations (5 observers X 5 times) for each of these 7 measurements: tibial coronal alignment, tibial sagittal alignment, level of tibial resection, femoral coronal alignment, femoral sagittal alignment, femoral rotation and level of femoral resection. However, it was only possible to collect 163 observations, representing complete (25) sets of observations for all measured parameters, except for femoral rotation, which had only 13 sets of observations from 3 observers. Tibial rotation was not measured in this experiment, because it is difficult to accurately quantify the angle of rotation, based on ill-defined landmarks, such as the medial third of tibial tuberosity.

These recorded measurements were compared to the recommended figures[2] for alignment, rotation and level of bone cutting that have also been followed during preoperative planning of PST. These recommended figures were used as control measurements (ground truth) to determine the deviation of recorded measurement in degrees and mm. The difference between the recorded and the control measurements was considered as an error. When the recorded measurement was equal to the control measurement, the error was considered zero. These errors were analysed to calculate the mean, standard deviation and maximum (outliers). To assess the reliability of the PST technique, both qualitative and quantative data were used to measure interobserver and intraobserver agreement. Kappa statistics was used to analyse qualitative data and determine whether the recorded measurement was within 3° or 3 mm (agreement) or more than 3° or 3 mm (no agreement). The use of 3° as a limit was based on clinical studies that showed 3° to be the maximum error that could be clinically accepted (Jeffery et al., 1991, Jonsson and Astrom, 1988, Ritter et al., 1994, Werner et al., 2005).

Quantative analysis was performed using Fredman's repeated measure non-parametric analysis of variance (ANOVA) and Kruskal Wallis analysis of variance (ANOVA). The recorded measurements from all observers (would be 175) were compared to a control measurement of zero° or zero mm. This control represents the ideal measurement (i.e. no error). Interobserver and Intraobserver concordance was tested using Kundall coefficient of concordance. Correlation between the results of the study observers was done using Pearson moment correlation test (*r*). A probability value (*p* value) less than 0.05 was considered significant.

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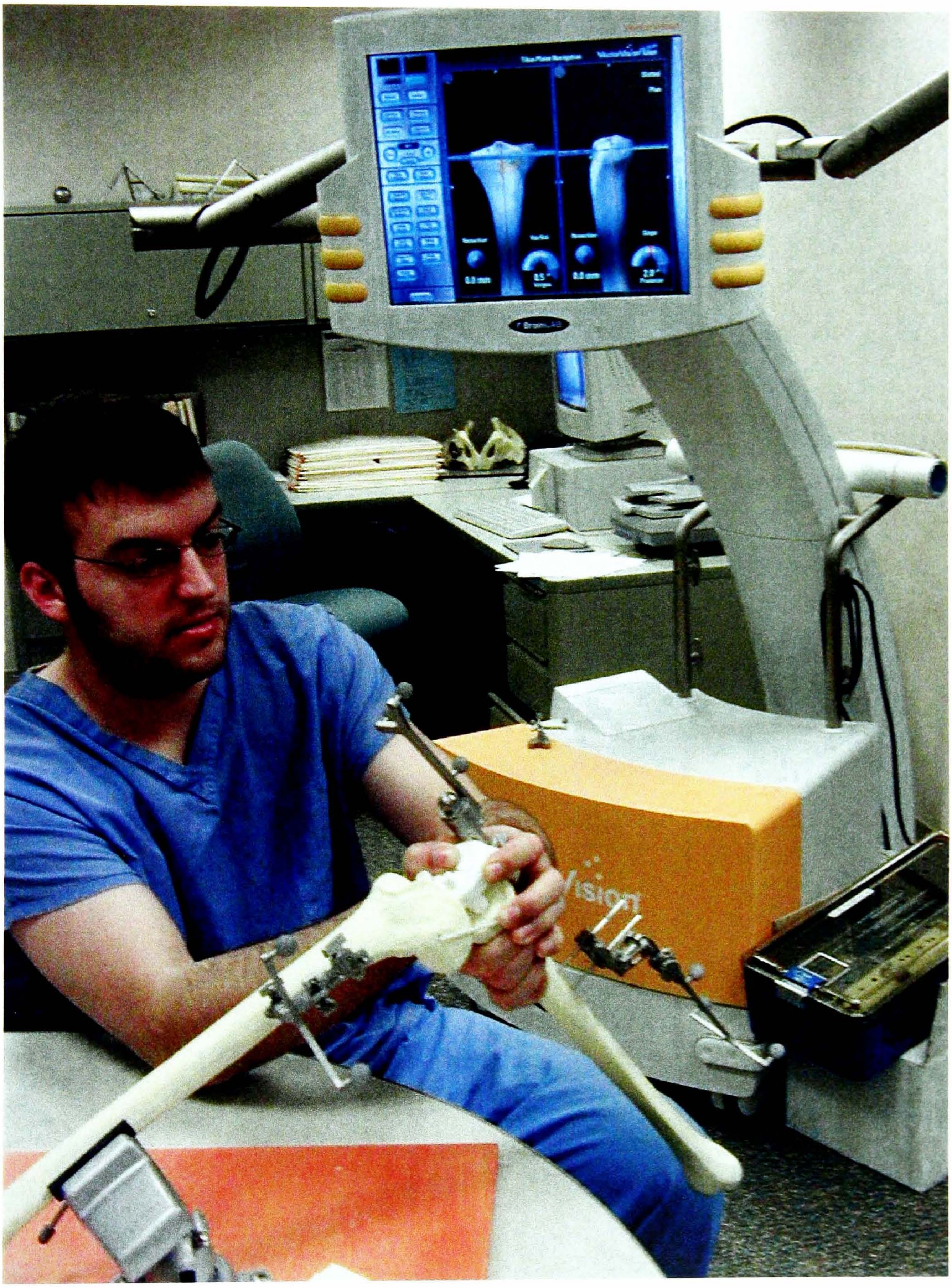
2 Femoral and tibial coronal are zero° to mechanical axis, femoral sagittal is 3° flexion, tibial sagittal is 5° posterior slope, level of bone cutting is 10 mm from the healthy component in both femur and tibia

Fig 13
The reliability testing



One of the observers was positioning the tibial template while a navigation system was measuring the alignment and level of bone cutting

All statistical calculations were done using computer programs Microsoft Excel version 7 (Microsoft Corporation, NY, USA) and SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) statistical program.

Summary

The experimental work was conducted in two stages. The first stage was the surgical experimentation, which included preoperative planning and surgical procedures. The preoperative planning comprised several steps, starting with data acquisitions and ending with the production of PST. The surgical procedures were performed in 2 sets of experiments; the first set was meant to prove the concept of PST and the second was to compare PST against CI systems. The second stage of experimentation was accuracy evaluation that involved an analysis of post operative CT scans and an experiment to test the reliability of positioning the templates by multiple observers.

4. RESULTS

This chapter reports the results of various experiments undertaken in this study, starting with a record of some observations on the preoperative planning of the PST technique. It describes the outcome of the surgical procedures including the comparative trial. And then it presents the data on the accuracy and reliability experiments.

4.1 Preoperative planning

The results of the trial for testing different types of plastic bones are listed in Table 2. The most suitable material was the Foam Cortical Shell, Model # 1151. This model was radiopaque, amenable to bone cutting by saw blades and had features of osteoarthritis. For this reasons, this model was used for all of the experiments except two, in which composite bones were used to represent young patients with very hard bones. An attempt was made to use the white plastic variety for surgical experimentation failed. A sample specimen was CT scanned and had the routine steps for the preoperative planning and production of templates. However, the surgical experiment was abandoned because it was not possible to perform bone cuts. The

Table 2: Details of various types of plastic knee specimens

	Composite bones	**White plastic**	**Foam cortical shell (FCS)**
CT scanning (image quality)*	Excellent quality	Good quality	Fair quality but required adjustment of the threshold**
Ease of cutting	Very hard (similar to young patients)	Extremely hard (much harder than human)	Easy to cut (similar to bones of elderly patients
Cost	Very expensive (£ 200)	Moderate cost (£ 70)	Least expensive (£ 30)
Availability of models with pathology	Required designing (8 weeks)	Required designing (4 weeks)	Off the shelf or required few days for designating
Common use (workshops)	Biomechanical testing	Internal fixation of fractures (nailing)	TKA

* Image quality was graded based on resolution and using a quantative score (fair, good or excellent)
**The threshold is the terminology used for adjusting the level of the image contrast, for example to differentiate between soft tissue and bone

cutting edges of 2 saw blades were damaged and became blunt before the cuts were completed. Thus this material was too hard to cut and was not suitable for this study.

Difficulties were encountered with the process of CT scanning, as the CT scan machine was relatively old and used to store the data in magnetic optical discs. Data had to be transferred to compact discs that could be read by the Lab computer. The use of plastic specimens saved the time and effort involved in the segmentation of bones that was routinely performed for cadaveric specimens. It was not possible to obtain from the manufacturer the full set of computer aided design (CAD) files for all of the different sizes of the PFC components particularly for the polyethylene inserts. Consequently, a near size polyethylene insert was used in some experiments. Measured prosthetic components were manufactured using RP machine and made of the same materials as templates (DuraForm). With repeated experimentations, different sizes of prosthetic components became available and reusable. It was possible to select femoral and tibial components of the appropriate size for a joint specimen, but not a tibial Polyethylene inset of the appropriate thickness. The sizing of polyethylene was therefore abandoned during preoperative planning, because it was difficult to estimate the gaps and soft tissue tension.

The design of the templates had several modifications aiming to optimise the surface matching and also the shape of the templates. The internal surface of the templates was designed to match the anatomical bony landmarks such as epicondylar eminences, intercondylar notch, trochlea, tibial tuberosity and tibial plateau. Following surface matching, templates had to be fixed to the bones with pins to allow steady position of the templates during bone cutting. An attempt was made to improve the stability of the femoral templates for the second cadaveric experiment by increasing the size and the prominence of the locators. However, this made it difficult for the template to be positioned on the femur because it required manoeuvring to press fit the template on the bone. This femoral template was redesigned using the usual size and prominence for the locators and was used for the same specimen which was completed successfully.

The femoral templates had more modifications than the tibial template possibly because the distal femur normally has an irregular surface and it requires 5 cuts compared to the proximal tibia. The four fixed side-locators of the femoral templates were successfully used from the first experiment onwards and they were subjected to fewer attempts of modifications compared with the position and shape of the central locator. The perpendicular orientation of the four fixed locators in relation to the bone surface allowed easier and steady positioning of the templates. The central locator was initially positioned to fit the intercondylar notch (Figure 8) and was fixed to the body of the template. This interfered, to some extent, with the path of the saw blades. Then, it was designed to be removable, but the positioning was not as secure as it should be, possibly because of the cartilage effect. Occasionally, the cartilage had to be scraped with a knife. The positioning was relatively better but there still was a minor rocking motion in flexion and extension. This locator was then moved to surface match a cartilage free area just proximal to the trochlea. This location was a constant anatomical landmark in the form of a small depression (dimple) that provided a steady position for the locator (Figure 8). This locator was also removable, but it required to be removed only during the anterior cut to allow complete cutting of the anterior cortex.

The external shape of the templates was also modified on several occasions to allow easy insertion of the templates within the soft tissue and bony constraints. The thickness of the templates was increased to provide a longer platform for the saw blades while inserted inside the slits. This was meant to reduce the deflection of the saw blades during bone cutting. It was thought that a template material that is durable and transparent would be useful in visualising the bone and the saw blade during bone cutting. However, such durable and transparent material was not available. Several sections were removed from the body of the templates to reduce its bulk and to allow the surgeon to visualise the bone and the saw blade during cutting. This modification along with the reduction in the size of the templates was meant to develop the templates for MIS techniques (Figure 8). However, at the time of developing these templates there were no more cadaveric specimens available and further testing for MIS surgery was not possible.

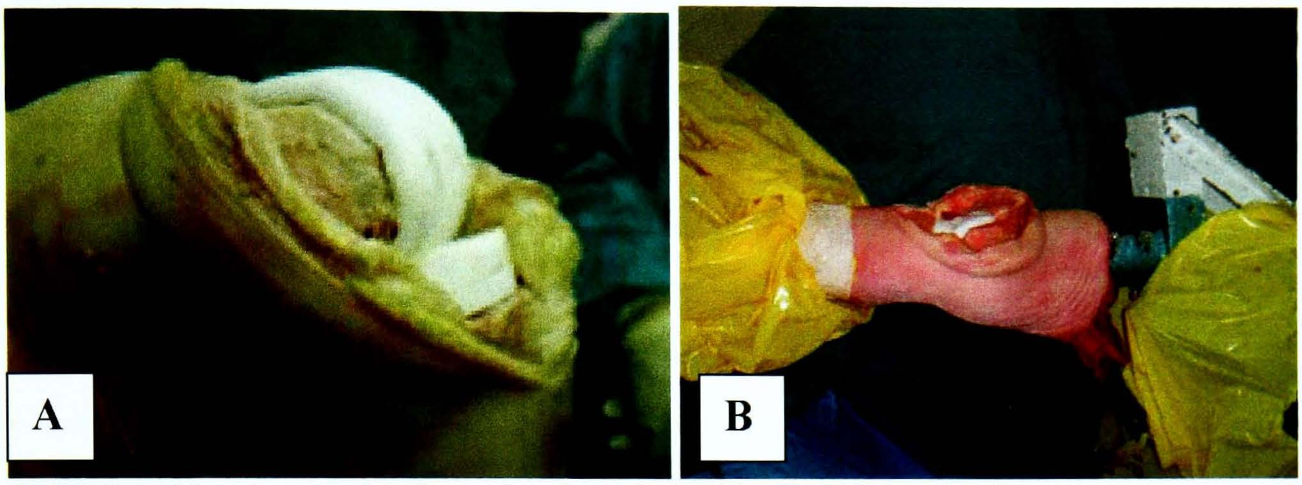
The labelling of the templates with the side of the knee and the number of the experiment was found to be useful in avoiding mixing up of different templates. This labelling was engraved on the body of the templates and remained as permanent records for further evaluation. The pinholes were standardised and it was possible to use standard drill bits that were readily available. The flat design of the pinholes facilitated the insertion of the drill bits and the fixation pins. The bone cutting slits were designed with fixed width, which allowed the use of saw blades with certain thickness (1.1mm) and reduced the risk of the deviation of the saw blades from the planned path for bone cutting. The modifications of different features of the templates came as a result of the experience gained from preoperative planning and the feedback from surgical implementation.

Although the RP machine (SLS) and the DuraForm material were used for all experiments, an attempt was made to use another variety of RP machines (SLA) that normally produce models (less robust materials) but not tools. The templates from these materials could not withstand the saw blades and it was shattered into small pieces when the cutting edge of the saw blades accidentally touched the template. This trial was done once and it was aimed at testing the suitability of SLA material for the PST technique. This again confirmed that SLA machine and materials are not suitable for TKA templates.

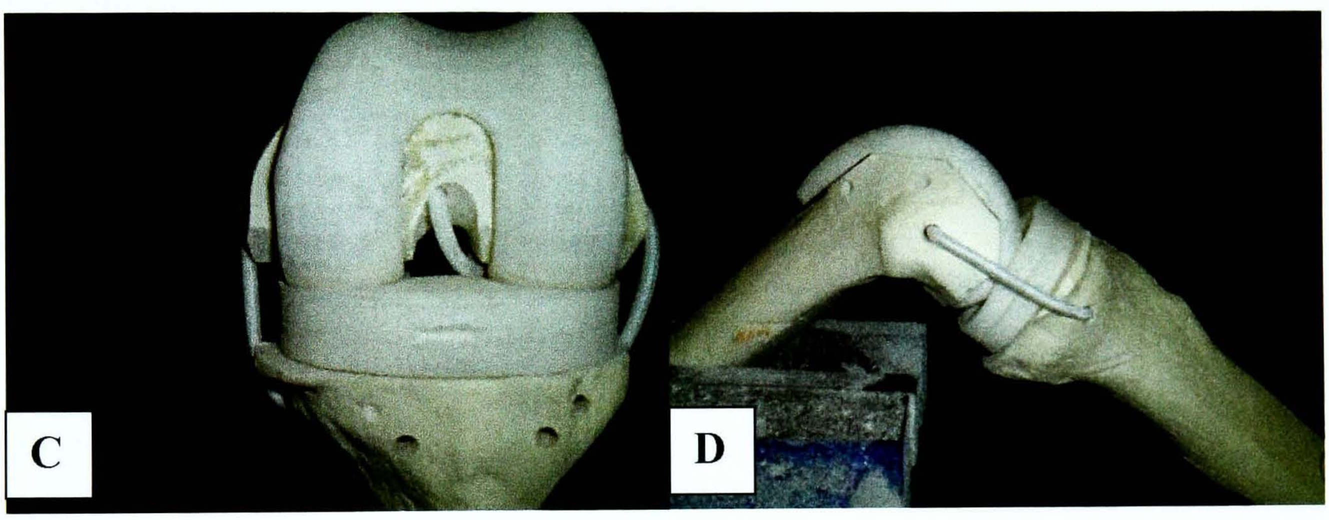
4.2 Surgical procedures

It was possible to completely perform the 45 TKA procedures using the PST technique, without resorting to conventional instrumentations. This result was based on: (1) the ability to insert the femoral and tibial templates within the soft tissue and bony constraints (for cadaveric experiments); (2) the successful positioning of the templates; (3) the complete preparation of the bone without resorting to conventional jigs; (4) the robustness of the template structures which enabled them to be used as cutting blocks, that could resist physical destruction from the saw blades and drill bits. Minor damage occurred to the slits of the templates due to excessive heat generation from saw blades, particularly while performing TKA on composite plastic specimens, which were very hard to cut. These damages were more likely to occur to the distal femoral and the tibial cuts that involved cutting relatively large pieces of bone. The damages typically occurred towards the end of the cut while the saw blade was still inside the bone. Therefore the damage did not affect the bone cutting. Based on the above criteria, there was no difference between the surgeons since both of them managed to complete the procedure without resorting to CI systems. Figure 14 shows cadaveric and plastic specimens after TKA procedures with the implants in-situ at different degrees of flexion and extension.

Fig 14
Intraoperative evaluation



A & B) Subjective evaluation of cadaveric TKA procedures by the surgeon to test the range of motion, and alignment



C & D) Evaluation of TKA on a plastic specimen that allowed complete visualisation of the implant and bone interface

Table 3 displays the data obtained during intraoperative evaluation of cadaveric TKA procedures. In addition to proving the concept of PST, the first set of experiments resulted in refining the templates to allow easier insertion within soft tissue constraints and easier positioning over the bone. For accurate positioning of templates, all locators had to remain in contact with the bone surface before inserting the fixation pins. Occasionally, surgeons had to remove osteophytes that interfered with the insertion and positioning of templates. It was difficult to insert and position the templates in obese cadaveric specimens due to the expected difficulty with surgical exposure and soft tissue retraction. In the earlier experiments, difficulties were also encountered while positioning the templates, as a result of designing the central femoral locators against the intercondylar notch. This area is normally covered by articular cartilage that does not appear in CT scan images. The positioning of the femoral template became easier after moving the central locator from the intercondylar notch to an area that was just proximal to the trochlea (cartilage-free area) (Figure 8).

It was found necessary to perform the femoral cuts first, since bone removal from the femur provided adequate space for the insertion and positioning of the tibial template. Similar to conventional techniques, reference cuts were performed first, then chamfer cuts and finally lugholes. The reference femoral cuts could be performed in any order. In the case of soft bone, it was found useful to perform the distal femoral cut before the anterior and posterior cuts. Following the distal femur cut, drill bits for the lugholes could be inserted and left in place while performing anterior and posterior cuts, thus providing additional stability for the templates. Before cutting the anterior femoral cortex, the central locator had to be removed, as it could interfere with the pathway of the cutting saw.

The comparative trial showed that operative time for the PST technique was reduced in comparison to the conventional technique (Table 4). This was more pronounced when surgery was performed without a surgical assistant, leading to a further increase of the operative time of the CI technique (more than double that of the PST technique). The PST technique was found to be less invasive, compared with CI systems, because of eliminating the IM rods that perforate the IM canals. The non-metallic material of the template was found to be lighter and easier to handle as compared with the numerous heavy and sharp metallic pieces of conventional instrumentations. During the comparative trial, the surgeon (MAH) had a minor injury while handling the conventional femoral cutting block that had two sharp spokes.

In addition to the surgeon's subjective assessment of user friendliness of PST, objective findings confirmed that PST was easier to use (Table 4). There were 84 pieces of jigs and fixtures in the CI set, compared with only two for the PST technique. Unlike the PST technique, the conventional technique required setting up, assembling and dismantling of numerous pieces of instruments. It also required spatial arrangements to provide an adequate space for the surgeon and the assistant and an easy access to the knee joint and instruments. The use of the CI system also involved several steps of sizing, alignment measurements, and bone cutting. Operative time was longer, and the requirement for surgical assistance was more important with the conventional technique. The PST technique was found to be relatively less demanding and more user friendly than the conventional technique. The measured gaps between implants and bone for the single tibial and the five femoral cuts were less in the PST technique as compared to the CI system (Table 4). Only two out of six cases in the PST arm of the study (four for CI system) had gaps of 1 mm or more as measured by steel shims.

Table 3: Intraoperative evaluation of cadaveric TKA

#	Joint status (bone & soft tissues)	PST positioning & soft tissue constraints	Bone cutting	Sizing	TKA Compl-eted by PST	Surgeon 's feeling	Problems identified & proposed solution
1	OA	Fine	Excessive Posterior cut	Size 2 for femur and tibia was fine	Yes	Good	Slits were wider than the thickness of the saw blades. They need to be narrowed to match the saw blades
2	Normal	Positioning was difficult for the press fit femoral template but was fine for the redesigned regular template	Fine	All, size 4, fine	Yes, with the regular design of the femoral templat e	Good	An attempt was made to provide a press fitting femoral template but it did not work, so the femoral template had to be re-designed
3	Normal	Fine	2 mm gap between prosthesis & bone at ant chamfer cut due to insecure pin fixation	All, size 4, fine	Yes	Good	Pin fixation not rigid and needs to be improved by lengthening the pins and make pre-drilling holes
4	OA	Fine, wide locating probes	2 mm gap between prosthesis & bone at post chamfer cut	All, size 5, fine	Yes	Good	None
5	OA, osteo-phytes	Fine, wide locating probes	2 mm gap between prosthesis & bone at post chamfer cut	All, size 3, fine	Yes	Good	Medial lug hole had to be re-drilled
6	OA	Fine	Missing data	All, size 3, fine	Yes	Missing data	Missing data
7	OA	Fine	Fine	All,	Yes	Good	None

				size 2, fine			
8	OA	Fine	2 mm gap between bone and prosthesis at ant chamfer & distal cuts	All, size 3, fine	Yes	Fair	None
9	OA, osteo-phytes	Fine	Fine	All, size 3, fine	Yes	Good	None
10	OA, osteo-phytes	Difficulty in positioning the posterolateral locating probe	Fine	2.5 femur & 3 tibia, fine	Yes	Good	posterolateral pin had to be removed to allow Proper fitting of femoral PST
11	OA, osteo-phytes	Fine, but Femoral template was difficult to position before removing osteophytes	Fine	All, size 4, fine	Yes	Good	KPS, distal cut was missed by the surgeon, template had to be repositioned to finish distal cut
12	OA, soft bone	Tight soft tissues, templates had to be held rigidly till pin insertion	Tibia had to be re-cut 3 mm distally because knee was tight in flexion and extension	All size 3, but during surgery, was between sizes 3 & 4	Yes	Fair	CT scan does not show tight ligaments, so tibial template should have 2 slits or 2 rows for pins
13	Tight medial Lig	Fine	Fine	2.5 femur, 3 tibia, fine	Yes	Good	Modify locating probes
14	Normal	Positioning improved because central was moved be close to the trochlea	Fine	2.5 femur 4 tibia	Yes	Good	Increase the length of fixation pins & reduce the width of the templates
15	Tight medial Lig	Fine	Fine	All, size 3, fine	Yes	Good	Damage to Post chamfer slits. Consider

							using plastic bones
16	Obese leg, soft bone, mal-united lower tibia	Fine but templates had to be held rigidly because bone was very slippery (fatty leg)	Fine	All, size 3, fine	Yes	Good	Appropriate size of PE insert (8mm) was not available

Table 4: Results of the comparative trail

Parameters	Patient-Specific Instrumentation	Conventional Instrumentation
Smoothness of cuts (gaps between implant and bone)	2 out of 6 cases had a gap ≥ 1 mm	4 out of 6 cases had a gap ≥ 1 mm
Storage & ergonomics	2 pieces (femoral and tibial templates) in a small tray	84 pieces stored in 4 large trays
Mean operative time (bone cutting) Without a surgical assistant With a surgical assistant	 11 minutes 9 minutes	 30 minutes 15 minutes
Ease of use Set up, assembling & dismantling Technical steps Need for surgical assistant(s)	 Not required Bone cutting Less important	 Required for the 84 pieces Several steps for sizing, alignment, and bone cutting More important, as operative time was doubled when the surgeon was unassisted

4.3 Accuracy evaluation

4.3.1 Evaluation of postoperative CT scanning

The planning software (MIMICS, Materialize) allowed accurate evaluation of sizing, alignment and level of bone cutting as measured from postoperative CT scans (Figure 15). The measurements for the femoral and tibial level of bone cutting and alignment form six postoperative CT scans are displayed in Table5. The measured errors represented the differences (deviation) in alignment and level of bone cutting between postoperative CT scans and preoperative planning. The mean errors for alignment and the level of bone cutting were within 1.7° and 0.8 mm, and maximum errors were 2.3° and 1.2 mm respectively. The computer assisted analysis also confirmed that the component sizing was accurate, as there was no evidence of under-cutting or over-cutting. The single case of femoral notching was among the 6 random specimens and the notching was easily identified on the CT scan images.

Table5: Measurements from postoperative CT scans

Errors	Femoral			Tibial		
	Level of bone cutting (distal cut)	Coronal alignment	Rotation	Level of bone cutting	Coronal alignment	Sagittal alignment
Mean errors	0.74 mm	1.02°	0.70°	0.35 mm	1.60°	1.22°
Range of errors	0–1.18 mm	0° –2.29°	0°–1.3°	0–0.90 mm	0°–1.60°	0°–2.0°

Figure 15

Computer Assisted Analysis of Postoperative CT Scans

A

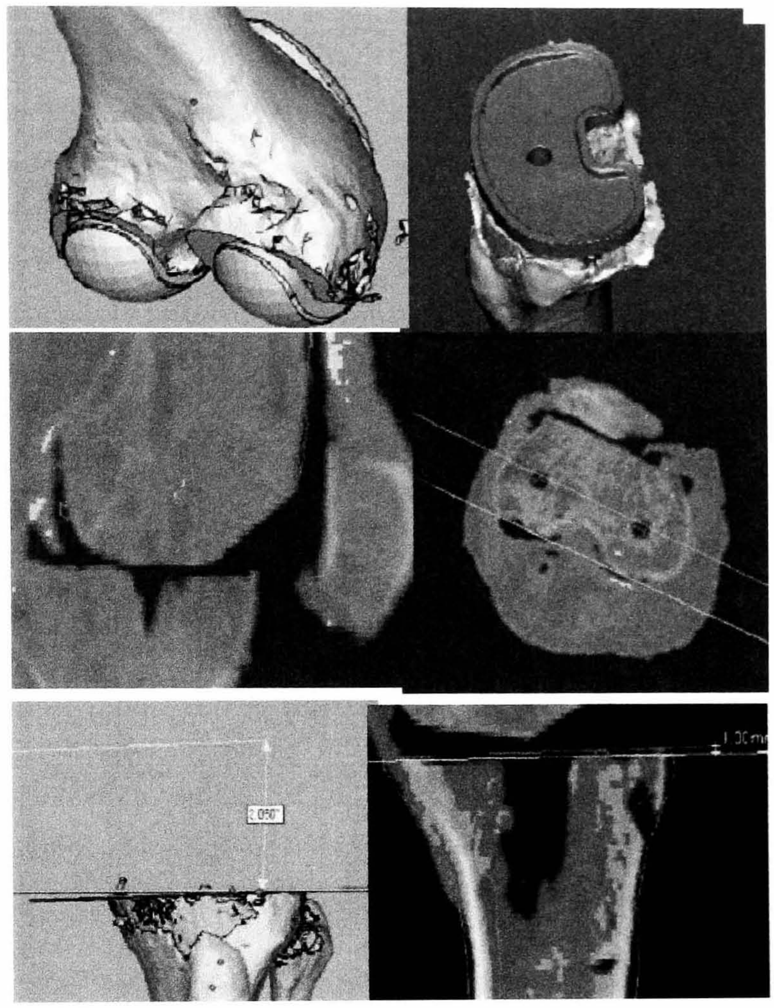
3-D Evaluation:
Implant sizing & position

B

3-D Evaluation:
Femoral cuts & alignment

C

3-D Evaluation:
Tibial cuts & alignment



4.3.2 Testing the reliability of positioning the templates

The reliability test showed that the positioning of the templates and the alignment of the subsequent femoral and tibial bone cuts had a mean error of 0.67°. The maximum error was 2.5°, which was recorded for the posterior sloping of one of the tibial cuts for one observer. The mean error in positioning the templates for the level of bone cutting was 0.32 mm (maximum 1 mm). The mean, standard deviation and maximum errors were calculated separately for each alignment measurements (tibial coronal, tibial post slope, femoral coronal, and femoral sagittal) and for each bone cutting measurements (femoral distal cut and tibial cut) (Table6).

For qualitative analysis, it was apparent (without even using Kappa statistics) that all measured values were within 3° indicating complete interobserver and intraobserver agreement. For quantative analysis using Friedman test and Kendall concordance coefficient, there was an overall significant agreement between the observers ($p < 0.05$). The concordance coefficient was high indicating a considerable interobserver agreement for all measured parameters except femoral cutting level that had a relatively low concordance coefficient (Table6). Comparison between different recorded measurements for the same observer (intraobserver variation test) showed significant agreement (p value < 0.003) and the concordance coefficient was very high. This means that there was no difference after repeating the same test by the same observer and there was a considerable intraobserver agreement (Table7).

Based on the 13 observations for femoral rotation measurements, the mean error of rotation was 1.86° (the standard deviation was 0.02° and the maximum error was 2.84° of excessive external rotation), as compared to the preoperative planning of 3° external rotation. No analysis was performed to determine interobserver or intraobserver variation for femoral rotation because of the incomplete data and the reduced number of observers (only 3 out of 5 observers).

The observers were able to do the experiment without surgical assistants. They found the templates to be user-friendly and could be uniquely positioned, and held with one or 2 hands. The raw data for this trial are displayed in Appendix 6.

Table 6: The reliability test: Errors & interobserver agreement

Alignment & bone cutting errors	Tibial coronal (in degrees)	Tibial post slope (in degrees)	Femoral coronal, (in degrees)	Femoral sagittal (in degrees)	Femoral distal cut (in mm)	Tibial cut (in mm)
Mean	0.36	1.24	0.90	0.18	0.38	0.26
St Dev	0.12	0.25	0.18	0.01	0.10	0.12
Range	0 to 0.50	0.5 to 2.50	0 to 1.50	0 to 0.40	0 to 1.00	0 to 0.50
Interobserver agreement (P value)	< 0.003	<0.014	<0.002	0.002	<0.039	<0.002
Interobserver agreement (concordance coefficient)	0.800	0.617	0.814	0.812	0.502	0.840

Table 7: The reliability test: Intraobserver agreement

Observers	A	B	C	D	E
Intraobserver agreement P value	<0.0002	<0.0003	<0.0002	<0.0002	<0.0032
Concordance coefficient	0.9497	0.9278	0.9638	0.9662	0.7118

Summary

The results of this study showed that it was possible to perform all 45 TKA procedures using the PST technique with no conventional instruments or intramedullary perforation. The comparative trial showed that the mean time for bone cutting was 9 minutes with a surgical assistant and 11 minutes without an assistant. Postoperative CT scans showed mean errors for alignment and bone cutting within 1.7° and 0.8 mm (maximum 2.3° and 1.2 mm) respectively. The reliability test showed a mean alignment error of 0.67° (maximum 2.5°) and a mean error for bone cutting of 0.32 mm (maximum 1 mm). The positioning of the templates was reliable, as there was no significant intraobserver and interobserver variation.

5. DISCUSSION

This chapter comments on the methodology and limitations of this study. It describes the observations and problems encountered during the study. Then it interprets the results and compares them to conventional techniques and available solutions such as minimally invasive and computer assisted surgery. Lastly, it outlines the limitations of the proposed technique.

5.1 Comments on methodology and limitations of the study

Traditionally, most of experimental trials in orthopaedics use the less expensive and readily available plastic models first and cadaveric specimens second. However, in this study the order was reversed. The initial plan was to use only cadaveric specimen, since they are more representative of the native knee joint and they have articular cartilage, soft tissue envelope and natural bone quality. However, the procurement of cadaveric knees was not always easy and for reasons out of our control, the supply of cadaveric knees suddenly stopped. This difficult situation was turned to the advantage of this study when plastic specimens were considered. The experiment on 3 different types of plastic bones made it clear that the Foam Cortical Shell (FCS) variety was the most suitable material for this study. It was amenable for bone cutting and CT scannable. Compared with cadaveric and other plastic specimens, FCS models were readily available, less expensive and could be supplied (off the shelf) in different pathological condition. The use of plastic specimens accelerated the performance of experiments and facilitated the conduction of the comparative trial.

The equipment used in the PST technique such as Materialize software, SLS rapid prototyping machine, and the template material (DuraForm) and the navigation system had previously been validated. The Materialize software had been used before in several surgical applications such as spine and trauma (Brown et al., 2003, Materialize). The rapid prototyping machine and materials had been used before in surgical applications and its technical accuracy is documented (Berry et al., 2005, 3Dsystems). Berry et al 2005 used DuraForm to produce patient specific templates for the spinal pedicle screws and found that the material was durable and stable against distortion from autoclaving. Navigation techniques were also used as measurement tools to test the accuracy of CI systems (Stulberg, 2003). The accuracy of navigation systems was reported by regulatory agencies (MDA, 2002) and in several clinical studies (Sparmann et al., 2003, Chauhan et al., 2004, Saragaglia et al., 2001, Chin et al., 2005, Decking et al., 2005, Victor and Hoste, 2004, Stockl et al., 2004). In laboratory setting (as for the reliability test), the accuracy of navigation systems for TKA was reported to be within 1° (Pitto et al., 2006).

Several limitations of this study were noted. The study was a laboratory rather than a clinical trial and it did not include all variables that may exist in real life circumstances. Plastic bones rather than cadaveric specimens were used for the comparative trial. The former do not have soft tissue envelopes and do not require image segmentation during planning. Plastic bones are not covered by synovial fluid and have higher friction than hyaline cartilage and therefore the reliability may not be as good as the experimental studies suggest. In other words, the unique positioning of the PST may not be so reliable when there is greater friction between the template and the joint surface. Owing to limited resources, time constraints, and availability of conventional instruments, the number of specimens for the comparative trial was small. The 6 pairs of plastic specimens for the comparative trial were identical. There was only one preoperative planning process for the 6 cases of the PST arm of the study. However, the main objective of the comparative trial was to evaluate the ease of use, ergonomics and operative time, rather than the accuracy of planning. Because of limited resources and time constraints, the analysis of postoperative CT scans was performed for only six random specimens and ideally, the evaluation of the postoperative CT scan should have been performed for all specimens. Nevertheless, the reliability testing resulted in the collection of 163 sets of observations for multiple new users, which allowed statistical analysis including the intraobserver and interobserver variability for 5 observers.

The reliability experiment had some limitations too. It was performed on a plastic knee model, rather than on a cadaveric specimen. This was justified earlier, based on reasons of practicality. The measurements for femoral rotation were only done for 3 observers, and were not complete. The experiment was accidentally stopped after the third trial of positioning, by the third observer. This occurred when the navigation monitor suddenly signed off, and it was not possible to operate the system further at the time of this experiment. This incident could be due to the prolonged operation of the system during experimentation. It was practically impossible to complete the measurements for femoral rotation or to repeat the whole experiment again, collecting 175 observations, while controlling all of the variables that could result from setting up the experiments, and repeating the registration and tracking processes. Measurements were also done before, rather than after bone cutting. This had the advantage of eliminating errors, which are surgeon- rather than template-dependent. Intraoperative measurements using the current navigation techniques are routinely performed before bone cutting, as the cutting process itself cannot be navigated due to the vibration of the saw blades. It was also pointless to waste resources and time, by allowing bone cutting to consume 25 specimens of plastic knee models.

Patellar replacement was not considered in this study. It was explained in Section 2.4.1 that patellar replacement is controversial and is not routinely replaced in TKA. Even when patella replacement is considered, patellar resection can be performed using freehand techniques, which has comparable accuracy to instrumented resection (Lombardi et al., 1998).

5.2 Observations & problems encountered during the study

5.2.1 Preparation for the experiments

At the preparation stage before starting this study, the initial proposal was aimed at optimising the techniques of TKA in young active patients. The plan was to conduct the experiments on 6 pairs of cadaveric knees with more emphasis on accurate selection of sizes of implants and perfect bone cutting to minimize bone removal. The conservation of bone was thought to be an important factor for the success of TKA in young patients who may require several revisions with subsequent depletion of bone stock. The focus was gradually modified when the results of the earlier experiments showed that the technique had the potential to achieve more important objectives than just minimising bone removal. As the technique evolved the aim has gradually expanded to provide an alternative solution that can overcome the major limitations of the conventional techniques of TKA in general. The initial plan of performing TKA on 6 pairs of cadaveric knees was extended to include 45 TKA experiments.

The time required to perform a single experiment was almost one week for earlier cadaveric specimens. It took nearly one day for each step of preoperative planning. This long time was due to the difficulty encountered in arranging and performing all the steps, which were dependent on each other. The involvement of several service providers at different location was another reason. Only preoperative planning and surgery were done in the Bioengineering Lab, University of Leeds. Other steps were done at different locations; CT scanning (St Luke's Hospital, Bradford), data conversion (DePuy Laboratories, Leeds), rapid prototyping (Keyworth Institute, University of Leeds). Cadaveric specimens involved more time and effort as they had to be preserved and then defrosted between the different steps of preoperative CT canning, surgical procedure and postoperative scanning. With experience gained from the arrangements of these steps and with the use of plastic specimens, it became possible to perform all of these steps in 2 days.

5.2.2 The comparative trial

The supplied set of the CI system was a demonstration kit that could be used only for size 3 knees. So, intraoperative steps for CI experiments did not include the process of sizing. This process normally takes a few minutes and this time was not included in the recorded operative time for CI experiments. For PST, sizing was performed during preoperative planning. Since the 6 plastic knees used for the PST technique were identical in size and shape, there was no reason to repeat the process of preoperative planning and designating of PST, which was performed only once for the first plastic knee specimen. This single design was then used to produce PST templates for the 6 experiments. This was justified in section 5.1 under comments on methodology and limitations. The production of all templates from a single design revealed the potential that the PST technique could be used for training workshops on plastic models. The production of metallic templates that could be employed as reusable cutting blocks for training purposes was considered. The RP machine (SLS) has the capability to produce metallic tools and models. However, time and resources did not provide the opportunity to produce these metallic templates.

5.2.3 Accuracy evaluation

The use of postoperative CT scans for accuracy evaluation of TKA is a current trend, advocated by many surgeons who employ computer assisted techniques (Jazrawi, Birdzell et al. 2000; Kinzel, Scaddan et al. 2004; Chauhan, Scott et al. 2004). The rationale was to provide more objective and accurate assessment methods as compared to traditional plain radiographs. Occasionally, it was difficult to measure the actual alignment and level of bone cutting due to minor erosion or crushing of the bone edges. For real patients, implants are fixed to the bone with cement or biological fixation. This fixation maintains the alignment and level of bone cuts that can be measured from postoperative radiographs or CT scans.

The reliability testing was performed during my fellowship training at The Institute for Computer Assisted Orthopaedic Surgery (ICAOS), The Western Pennsylvania Hospital, Pittsburgh, USA. The concern that the number of analysed postoperative CT scans was small (6 out of 45), the scepticism of ICAOS engineers about the accuracy of the templates, particularly for new users and the availability of navigation systems at ICAOS set the rationale and brought up the idea and for this experiment. The results of this experiment confirmed the accuracy and reliability of positioning the templates, particularly for new users and cleared the scepticism of the observers.

5.3 Comparison between PST and CI systems

In spite of the limitations and problems mentioned above, this study has achieved its objectives and proved the new concept of PST as an alternative to conventional techniques in TKA. PST provided a 3-D CT-based preoperative planning including sizing, alignment and bone cutting. The virtual planning was transferred to physical templates that could act as femoral and tibial cutting blocks, completely replacing conventional instrumentation. The results of using this technique in 45 experimental TKA procedures showed that this technique is relatively simple to use, less invasive and accurate. The PST technique allowed the shifting of several surgical steps to the preoperative stage, leading to significant reduction in the number of intraoperative steps. Several technical steps such as sizing and alignment measurement performed during the CI technique could result in a relatively higher incidence of mistakes and accumulation of errors. Unlike conventional instrumentation, which comprises up to 84 pieces, the PST technique required only 2 pieces of instruments (femoral and tibial templates). This 2-piece instrumentation system was associated with better ergonomics, as it required no extra carrying table. Templates were single use instruments eliminating the need for repeated sterilisation, transportation and storage. They required no setting up, assembling, dismantling or washing. The operative time for bone cutting was significantly reduced. The absence of the surgical assistant doubled the operative time for the conventional technique, but not for the PST technique (Table 3). The non-metallic material of the template was lighter and easier to handle while the heavy and sharp edges of metallic pieces of CI systems could lead to injuries of the surgeon and /or the patient (soft tissue or bone damage). The PST allowed the surgeons to see the virtual results of TKA before real surgery and it measured the surgical performance by comparing postoperative CT scans to the recorded preoperative planning.

The results of the analysis of the 6 random postoperative CT scans showed that the mean errors for alignment and bone cutting were within 1.7° and 0.8 mm, and maximum errors were 2.3° and 1.2 mm respectively. Although this level of accuracy is satisfactory, the number of CT scans was too small (6 out of 45) to prove the hypothesis that the PST technique is accurate and reproducible, particularly for new users. The reliability test showed that the positioning of the templates and subsequently the alignment of the bone cuts before cutting had a mean error of 0.67° (maximum 2.5°). The mean error in positioning the templates for the level of bone cutting was 0.32 mm (maximum 1 mm). The positioning of the templates was reproducible, since there was no significant intraobserver and interobserver variation for alignment, or levels of bone resection, in both the femur and the tibia. The level of accuracy and reliability is better than what was reported for conventional techniques that had errors > 3° (Ritter et al., 1994, Stulberg, 2003, Teter et al., 1995). Stulberg (2003) assessed the accuracy of CI using a navigation system as a measurement tool similar to the technique used in this study for the reliability testing. Only 4 out of 20 conventional TKA procedures had all the measured steps for alignment and rotation within 3° of the optimal positions.

Information from the manufacturer (DePuy/Johnson and Johnson) indicated that the actual cost of manufacturing a set of CI system is about $30,000. The instruments must be discarded after 5 years and the estimated average use is around 150 operations. Based on this information, the cost of manufacturing is around $200 for each operation. The cost of sterilisation of CI systems for each operation is around $180. This adds to the cost of maintenance, transportation, storage and training for CI systems. In this study, the cost of two templates was under $ 200, which was less than the estimated cost of using the CI system per one TKA procedure. The cost of a single CT scan in this study was under $ 100, which was less than the cost of sterilizing one set of CI systems ($ 180). Currently, there are hidden costs for the use of CI systems such as storage, transportation and training for nurses and surgeons and more importantly, the cost of the operating room time that is wasted during the setting up, assembling, dismantling, and washing of the numerous pieces of instruments. The use of PST does not have any of the above hidden costs but during the development of the PST technique, there was an additional cost due to the involvement of an engineer on full time basis. This cost can be reduced or eliminated by developing automated software that can plan straightforward cases of primary TKA (see Chapter 7 on future directions). On the other hand, the PST technique can save on the operating room time. Potential savings can be gained from shortening the hospital stay and reducing the complication rate, as a result of using a less invasive and more accurate technique such as the PST. The advantages of shorter operative time and hospital stay as well as lower complication rate were discussed in more detail at the end of Chapter 2 (section 2.5.4.2).

5.4 Comparison to current alternative solutions

5.4.1 Minimally invasive surgery

Although there several advantages for MIS that were detailed in section 2.6.1, MIS techniques are relatively difficult to perform and are usually done by experienced surgeons. They involve a long learning curve and are more difficult to teach. An experienced assistant is required and retraction may stretch or damage the skin and soft tissues. Bone cuts are done under skin cover with a higher risk of error. It is not easy to insert instruments and implants and the removal of excess cement is also difficult.

Although the small size of the instruments is more convenient, this may come at the expense of accuracy. The reduced exposure is also associated with reduced visibility and subsequently, higher risk of complications and inaccuracies (DiGioia-III et al., 2004). The main questions for MIS are: Can the short-term benefits from MIS be justified by the difficulty and limitations of these techniques? Is it possible to maintain a satisfactory long-term outcome that is comparable to conventional techniques? The answer to the second question will not be known for several years. Some surgeons are currently advocating the use of MIS in conjunction with computer-assisted techniques, to combine the benefits of both modalities. However, this is a highly demanding technique that is still experimental and may continue to have the current drawbacks of both navigation and MIS.

Although the PST technique in this study was performed through conventional rather than MIS approaches, the PST was relatively less invasive. First, it eliminated the use of IM rods and its aforementioned drawbacks. The short operative time is another feature of minimal invasiveness owing to the reduced non-anatomical (subluxation of patellofemoral and tibiofemoral joints) and non-physiological (open atmosphere and heat from the operating room light) exposure of bone and soft tissues. The feasibility of using PST through MIS approaches requires further investigation. The PST technique has the advantage of providing only 2 pieces of instruments (as compared to the numerous pieces in CI systems) that need to be inserted inside the knee joint. Also, the templates could be further reduced in size to allow easier insertion inside MIS incisions. However, surgeons need to visualise the surface matching of the templates, which may prove difficult in MIS approaches.

5.4.2 Computer assisted surgery (CAS)

The broad application of navigation and robotics is limited by cost, complexity, set-up time and a long learning curve. There are "problems with intraoperative man and machine interaction, and the spatially constrained arrangement of additional equipment within the operating room" (Radermacher et al., 1998). The technique may also involve the use of preoperative imaging (usually CT scan) or intraoperative fluoroscopy. Some techniques are imageless, but they require the intraoperative collection of kinematic or morphological data. The data collection depends on the surgeons' experience and familiarity with the technique. Erroneous collection of data will lead to inaccurate measurements and feedback from the system. The system cannot verify the accuracy of the inputted data. This has been described as "error in error out" (Hafez et al., 2006). Navigation and robotics require registration, which is the unfamiliar step to orthopaedic surgeons. An experienced surgeon in navigation techniques reported that it took up to 10 procedures to develop a reliable registration technique in TKA (Stulberg et al., 2002). The errors from registration can occur as a result of pin movement (in case of navigation) or movement of the limb (in case of robotics) and both may occur at any time during the procedure. Tracking is another step, which requires the insertion of pins into the tibia and the femur and a continuous line of sight between the tracking camera and the tracked objects. Data collection, registration and tracking add at least 15 minutes to the operative time (Stulberg et al., 2002).

Navigation techniques still rely on conventional instruments for making the various bone cuts and they also require additional instruments (tracking pointer and tracking plate) as well as the insertion of tracking pins. This double instrumentation system may overload hospital inventory, sterilisation services and operating room time. There is a growing need to introduce ergonomics in the surgical workplace (Stone McCloy 2004), which is more difficult to achieve with these bulky navigation devices that require continuous tracking. The overwhelming intraoperative information from navigation systems may result in conflicting decisions and the rate of complications may increase during the early stages of the learning curve. There are contraindications such as extreme obesity and fragile bones. Also, there are errors, pitfalls and precautions associated with navigation and robotic techniques (Hafez et al., 2006).

The cost of double instrumentation systems (conventional and navigation) is very high. The cost of CI is discussed in section 2.5.4.2. The cost of navigation is around $ 150,000 with a life span of roughly 5 years. So, if one assumes that the average number of TKA procedures per year for a medium volume hospital is 30, the total number of procedures over a 5-year period would be 150. Then, the estimated cost per one TKA procedure would be more than $ 1000. The volume of TKA procedures is variable and there are 2 known extremes; the high volume surgeons or group of surgeons who may perform more than 500 TKA procedures per year and the low volume surgeon who may perform less than 10 procedures per year. In developing countries, where TKA procedure is not common, most surgeons and hospitals have a low volume of arthroplasty procedures. Implant companies cannot permanently store their instrumentation systems in such hospitals; rather they provide the instruments on a case per case basis. A comparison between different categories of CAS systems including various types of navigation techniques is displayed in Table8.

Considering all the above drawbacks for navigation and robotic techniques, it appears that the proposed PST technique is relatively easier to use, less invasive, time saving and inexpensive. It confines the computer assisted work to the preoperative stage and provides the surgeon with 2-piece instrumentation system (femoral and tibial templates) but no bulky equipments. The PST technique requires no registration or tracking and can be used by surgeons who have no prior experience with CAS. PST shares some of the capabilities of CAS, particularly the high accuracy of CT-based planning (DiGioia-III et al., 1998, Jazrawi et al., 2000, Kinzel et al., 2004, Perlick et al., 2004, Siebert et al., 2002). The results of this study have demonstrated a level of accuracy (errors < 3°) that compares favourably with that of navigation techniques (Sparmann et al., 2003, Chauhan et al., 2004, Saragaglia et al., 2001, Chin et al., 2005, Decking et al., 2005, Victor and Hoste, 2004, Stockl et al., 2004), but less than that of robotic techniques (errors < 1° or 1mm) (Jakopec et al., 2001, Siebert et al., 2002).

5.4.3 Computer assisted templating techniques

The computer assisted templating is another example of passive CAS systems. It involves CT-based preoperative planning, followed by the production of templates that match the surface geometry of the individual bony structures. The templates are designed to transfer the preoperative planning to the intraoperative performance. The current templating techniques employ the technology of rapid prototyping (RP). The RP machine acts as a 3-D printer to produce physical objects from the 3-D computer-aided designs by joining together liquid, powder and sheet materials. The clinical applications of rapid prototyping in medicine are still in their infancy (McGurk et al., 1997). The majority of clinical reports come from dentistry and maxillo-facial (Harris and Rimell, 2002), where the terminology "rapid prototyping" is used to describe the mere production of anatomical models from CT scans, with no preoperative planning. Orthopaedic applications of RP are limited in number and confined to the production of customised anatomical models for tissue engineering, trauma surgery or allograft applications (Brown et al., 2003, Wang et al., 2004, Leukers et al.). Brown et al reported their clinical results using RP in the surgical planning of trauma surgery in 117 patients. Although the emergency nature of trauma surgery may not allow enough time for the production of anatomical models, the authors reported that they were able to do the preparation overnight, in as little as 3 hours. They found RP to be successful and cost effective and they depicted it as the future of trauma surgery. The main criticism to RP is the cost and time involved in producing the models and the use of CT scanning (cost and radiation); these drawbacks have to be justified.

A more sophisticated application of RP is the templating technique, which involves the production of guides that are based on planning and designing. Radermacher et al have pioneered the templating techniques in orthopaedics since the early 1990s and they used the terminology "individual templates" (Fortheine et al., 2004, Radermacher et al., 1998, Radermacher et al., 1994). Although they described several applications in spine, hip and knee surgery, most of their reports were based on laboratory, rather than clinical trials. Their work on TKA was to produce templates that can guide the conventional instruments (Appendix 7). They dispensed with the medullary alignment guides. However, the templates did not replace the CI system and templates were merely extra guides rather than instruments or tools. Therefore the drawbacks of CI system could not be eliminated. The cost and radiation from CT scans and the time and effort involved in preoperative planning have to be weighed against the benefits of these templates or guides. A comparison between the main features of different types of navigation, robotics and individual templating is displayed in Table8.

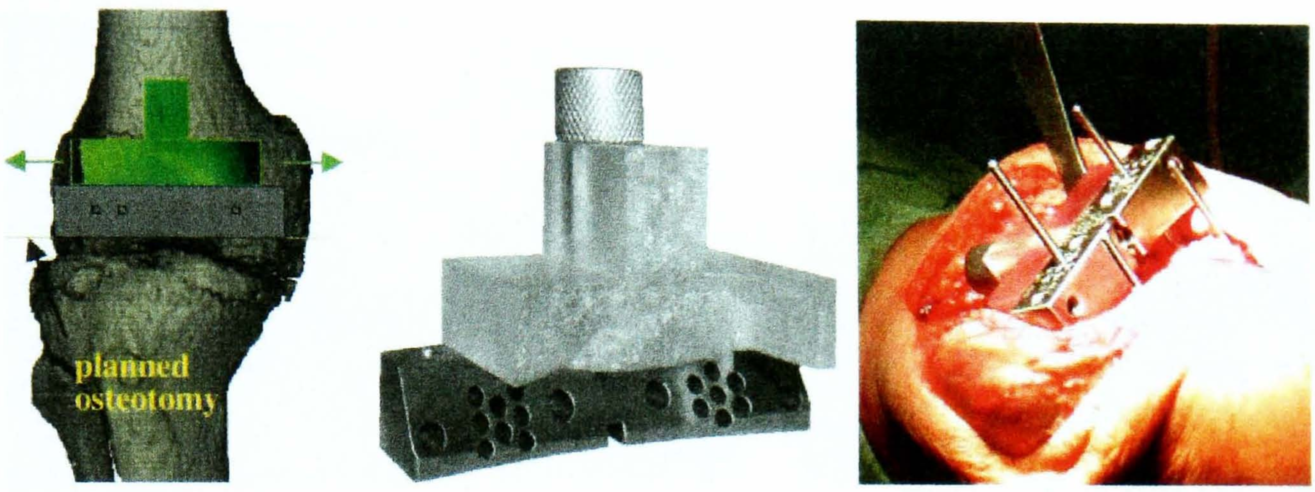
Literature review has not revealed any study that used patient-specific instruments (cutting blocks) based on preoperative planning of the entire surgical procedure, including the placement of the prosthetic components in 3-D , thus, completely replacing conventional instruments. In the proposed technique, the templates were designed to substitute for CI and this has been demonstrated by the results of this study. The use of CT scans here could be justified, because the templates eliminated the drawbacks of conventional instrumentations. The PST technique could be applied to any type of prosthesis, according to the surgeons' preference. The unique features of the PST technique in comparison to individual templates by Radermacher et al are displayed in Table9.

Table 8: Comparison between the currently available CAOS systems*

	Robotics	Navigation			Individual Templates (Radermacher et al)
		Imaged-based		Image-free	
		CT	Fluoroscopy		
Data source or imaging	Preop CT	Preop CT	Intraop X-ray	Intraop collection of kinematic & morphologic data	Preop CT
Planning	Preop 3-D	Preoperative 3-D	No preop planning but Intraop 2-D assessment		Preoperative 3-D
Spatial arrangement in OR	Robot, leg holder and clamps	Navigation cart, tracking devices			None
Registration and tracking	Registration ± tracking	Both required	Tracking + atypical registration		Not required
Intraop measurement & adjustment	No	Yes			No

* Hafez MA, Jaramaz B, DiGioia III AM. Computer Assisted Surgery of the Knee: An overview. In Surgery of the Knee (4th Ed.), Install JN, Scott N (Eds). Philadelphia, Churchill Livingston. 2006, 1655-1674

Figure 16
The individual templating technique for TKA as per Radermacher et al (with permission from professor Radermacher)



The virtual model (left), the physical template attached to a conventional femoral cutting block (middle) and an intraoperative image with the template and the cutting block attached to the bone (right).

Table 9: Unique features of PST in comparison to Radermacher's* individual templating technique

#	Features	The proposed PST technique	Individual templating by Radermacher et al
1	Preoperative planning	Involved a complete planning for TKA including sizing, alignment and bone cutting	Only alignment was considered
2	Simulation of surgery and prosthetic placement	Performed	Not performed, since the planning did not include the CAD files of TKA prostheses
3	Function of the templates	Serve as a complete instrumentation set for TKA with 20 machinery actions performed through the templates	Serve as extra guides for alignment
4	The use of conventional instrumentation	Not required	Still required, only medullary guides were dispensed with
5	Surface matching of templates	Based on protruding locating probes, fixed and removable	Based on total contact of the templates to the bony surfaces
6	Fixation of the templates	Locating probes are cannulated and have optional metallic sleeves to allow fixation pins to pass through and securely fix the templates to the bone	Not explained
7	Coupling with other surgical instruments	Not required	Required to connect the templates with the cutting blocks
8	Bone cutting, preparation for stem, keel and lug holes	Done through the templates	Done through conventional cutting blocks

*Radermacher K, Portheine F, Anton M, Zimolong A, Kaspers G, Rau G, Staudte HW. Computer assisted orthopaedic surgery with image-based individual templates. Clin Orthop Relat Res. 1998;354:28-38.

*Fortheine F, Ohnsorge JAK, Schkommodau E, Radermacher K. CT-Based Planning and Individual Template Navigation in TKA. In Stiehl JB, Konermann WH, Haaker RG (eds). Navigation and Robotics in Total Joint and Spine Surgery. Berlin, Springer 2004;336-342.

5.5 Limitations and drawbacks of PST

The PST technique has some drawbacks. The cost and radiation exposure from CT scans is a concern. Conventional techniques require preoperative plain radiographs not CT scans. The radiation dose from a knee radiograph is usually less than 0.01 mSv (Dewey et al., 2005). The radiation dose for a knee CT scan is around 1.2 mSv, which is higher than plan radiograph for the knee joint but relatively low as compared to the dose for a lumbar spine plain radiograph (1.3 mSv) and also lower than the average UK background (environmental) radiation, which is 2.2 mSv per year, range 1.5 to 7.5 mSv (National Radiation Protection Board, 1993). Attempts have been made to develop low cost, low radiation, CT scan devices (Rock et al., 2002). Even with conventional CT scanners, certain protocols for knee CT scans may result in reducing the dose to 0.1 mSv (Henckel et al., 2004). They stated that attempts to obtain an accurate X-ray might result in a higher radiation dose, without achieving the accuracy of CT. In our technique, the cost and radiation of CT can be justified by the benefits. Moreover, the PST technique has the potential to be used with MRI images, eliminating the risk of radiation exposure. The MRI scan was not used in this study because of cost, availability of MRI scanners and the long waiting list. However, the application of MRI for the PST technique will be considered in a future investigation.

With PST technique, the intraoperative measurement of alignment and adjustment of bone cutting is limited. However, surgeons traditionally rely on conventional cutting blocks that allow four or five femoral cuts at a time. Robotic techniques also have limited intraoperative adjustments and rely on the high accuracy of preoperative planning, similar to those of image based navigation and robotics. This level of accuracy should reassure the surgeon and minimise the need for intraoperative adjustment. The template design can be modified for complex conditions. In this study, there was a cadaveric specimen that had a fixed flexion deformity that required designing two femoral templates with different options for the level of bone cutting of the distal femur.

Another drawback is the lack of support for soft tissue balancing. In conventional techniques, surgeons use their own judgment to perform soft tissue balancing. In the PST technique, the accurate preoperative sizing and alignment should lead to precise bone cutting that will diminish the need for soft tissue release. Surgeons who routinely perform navigation techniques for TKA have observed that the need for soft tissue release has been diminished following the use of navigation (personal communication). The ease and speed of performing bone cuts using the PST technique, may allow surgeons to focus their efforts on soft tissue balancing if needed.

One of the criticisms for the PST technique is the change to the routine practice of TKA by shifting certain surgical steps from the intraoperative to the preoperative stage. Although this will reduce the operative time, some surgeons might not tolerate such a change. Surgeons used to make the necessary measurements and adjustments intraoperatively on a step-by-step basis. With the templating technique, the sizing and alignments have already been performed preoperatively and no further adjustments are required.

Summary

There is a need to improve the current techniques for TKA. The proposed PST technique has shown several advantages over the conventional techniques for TKA (Hafez MA et al., 2006). Alternative techniques such as MIS can provide a better short-term outcome, but there is a higher risk of complications and errors that may affect the long-term outcome. CAS has shown the capability to improve accuracy, but its broad application is limited by cost, complexity, set up time, spatial constraints and learning curve. The combination of MIS and CAS is promising, but it is only confined to a small group of surgeons who are able to combine and master two difficult new techniques. The PST shares the accuracy of image-based CAS techniques but is easier to use, less invasive, operating time saving and less expensive.

6. CONCLUSION

There are several limitations of the current techniques for TKA, especially the limited accuracy of planning and performance, and the drawbacks of CI systems such as the violation of IM canals and the multiplicity of instruments. The available solutions such as minimally invasive surgery, robotic and navigation techniques are not well developed and they have several drawbacks. A new alternative is required to achieve technical success as well as cost effectiveness with reduced rate of complications and minimal drawbacks.

This study investigated the new concept of using computer assisted preoperative planning to provide patient-specific templates (PST) that can replace conventional instruments. Computed tomography based planning was used to design two virtual templates. Using rapid prototyping technology, virtual templates were transferred into physical templates (cutting blocks) with surfaces that matched the distal femur and proximal tibia. The PST technique was applied to 45 TKA procedures using 16 cadaveric and 29 plastic knee specimens. Six out of the 29 PST procedures were included in a comparative trial against 6 cases of TKA using conventional instrumentations (CI).

All TKA procedures were successfully completed using the templates without resorting to CI systems. The PST technique was found to be less invasive, compared with CI, because of the elimination of intramedullary (IM) rods. The violation of IM canals by IM rods can theoretically lead to higher risk of bleeding, fat embolism, infection and fracture. There were 84 pieces of jigs and fixtures in the CI set, compared with only two for the PST technique. Unlike the PST technique, the conventional technique required setting up, assembling and dismantling of numerous pieces of instruments. It also required spatial arrangements to provide an adequate space for the surgeon and the assistant and an easy access to the knee joint and instruments. CI systems also involved several steps of sizing, alignment measurements, and bone cutting. The mean time for bone cutting was 9 minutes with a surgical assistant and 11 minutes without an assistant as compared to 15 and 30 minutes for conventional technique respectively. The smoothness of bone cutting, as measured by steel shims was better than that of CI as only two out of six cases (four for conventional technique) had gaps of 1 mm or more between bones and implants.

Unlike navigation and robotics, PST did not require computer equipments in the operating room nor did it require a registration process. Also, PST needed no tracking, pin insertion or continuous line of sight. The Computer assisted analysis of six random CT scans showed mean errors for alignment and bone resection within 1.7° and 0.8 mm (maximum 2.3° and 1.2 mm). The reliability test showed that the positioning of the templates and subsequently the alignment of the bone cuts before cutting had a mean error of 0.67°. There was an outlier of 2.5°, which was measured for the posterior sloping of one of the tibial cuts. The mean error in positioning the templates for the level of bone cutting was 0.32 mm (maximum 1 mm). No significant intraobserver and interobserver variation was found. The level of accuracy compares favourably with navigation techniques.

In this study, the cost of two templates ($ 200) was equal to the estimated cost of manufacturing the CI per one TKA procedure. The cost of a single CT scan in this study ($ 100) was less than the cost of sterilizing one set of CI ($ 180). Currently, there are hidden costs for the use of CI systems such as storage, transportation and training for nurses and surgeons and more importantly, the cost of the operating room time that is wasted during the setting up, assembling, dismantling, and washing of the numerous pieces of instruments. The use of PST does not have any of the above hidden costs but it may have the cost of employing an engineer unless automated designing software is established. On the other hand, current navigation systems still require CI and this double instrumentation system raise the cost of TKA procedure significantly. The cost of a navigation system is around $ 150,000 with a life span of roughly 5 years. Based on average use, the estimated cost per one TKA procedure would be more than $ 1000.

It appears that the PST technique has several advantages over CI. The PST technique is also an alternative to navigation and robotics. It confines the computational work to the preoperative stage and provides the surgeon with only two patient-specific instruments (cutting blocks) that are easy to use, less invasive, and time saving. The technique has the potential to be used as a training tool. Although this laboratory study proved the concept of PST and validated its accuracy, further clinical validation is required to confirm the results of this study.

7. FUTURE DIRECTIONS

This chapter deals with the potential applications and development of the PST technique and the challenges ahead. First, it addresses the issue of using the PST technique on patients and the need for a pilot clinical trial and solutions for the logistic barriers. Second, it looks at the potential development of PST technically and clinically, so that it could be used for difficult cases of TKA, other procedures and in training.

7.1 Clinical applications

Clinical validation of the PST technique is required before recommending its use. This can be conducted initially as a pilot study followed by a comparative clinical trial against conventional instrumentation. Following clinical validation, several logistic issues need to be addressed before recommending the PST technique for new users.

7.1.1 Pilot study

Ethical approval should be initially sought for a pilot study to use the PST technique on real patients. . The PST can be applied to any TKA prostheses, provided that manufacturers are willing to provide the CAD files of their prostheses for preoperative planning. The patient's initials, hospital number, and side of the knee should be engraved on the templates.

The clinical trial should adopt a graduated approach moving from initial testing to a randomised control trial. The staring step depends on the experience of the surgeon and whether he/she is a new user or one of the developers of the PST technique. The following steps are suggested and listed in order of complexity.

1. Testing PST on a patient specific plastic model

   During the early learning curve, the surgeon(s) can perform PST techniques on patient-specific plastic knee models that can be produced by a rapid prototyping machine based on patients' own CT scans. Thus, the surgeon can see the results of surgery before using the PST technique on real patients. The surgeon can also measure the size and shape of the removed pieces of bone from the RP model and compare them with the pieces of bone actually removed from the patient during TKA procedure with CI systems.

2. Positioning the PST on the knee of real patients with a comparison to CI systems
   The surgeon can position the templates over the bone to test the ease and accuracy of positioning and mark the level and inclination of bone cutting on the bone. And then, use conventional instruments for comparison and evaluation of the proposed PST cuts. If the surgeon is satisfied with the positioning of the PST, surgery can be completed using the PST technique. Otherwise, surgery will be done using CI systems.
3. Using a knee navigation system to evaluate the position of the PST
4. Navigation techniques (if available) can be used in a similar manner to what was performed for the reliability testing (Chapter 3) to measure the accuracy of the PST technique before and after bone cutting. Using PST on real patients without resorting to CI or navigation system
   Once the surgeon develops confidence with the PST technique, the latter can be used for bone cutting, without resorting to CI or navigation systems. Simple instruments such as angel wings (part of CI set) or similar devices can be used to mark the level of bone cutting for visual inspection and confirmation by the surgeon before real cuts.
5. Randomised control trial (RCT)
   With improved learning curve, possibly after performing 5-10 cases, the surgeon, may proceed to a randomised control trail with a comparison to conventional surgery. The methodology used in this study can be applied to evaluate the accuracy of TKA procedures; this should include the analysis of postoperative CT scans and the use of navigation systems as measurement tools.

7.1.2 Logistics for clinical use

7.1.2.1 Hospital-based model

In this model, a single surgeon or a hospital may apply the technique but without industrial exploitation. The clinical application in such cases requires only CT images and a personal computer with the specific software. The surgeon should be responsible for preoperative planning provided that the software is more user friendly and quicker to operate as most surgeons would not have the time or inclination to use time-consuming software. The template production by rapid prototyping machines can be performed off campus, obviating the need to purchase RP equipments and materials.

The design of the templates can be transferred to the rapid prototyping machine using electronic mails. The templates can be sent back to the hospital facility by post, where it will be autoclaved and used

7.1.2.2 Broad application model

This model is very optimistic and it can only be possible following successful clinical validation, licensing by regulatory body (e.g. CE or FDA), commercial exploitation and possibly, cost effectiveness analysis. In such cases, a central station will have a rapid prototyping machine(s) dedicated to the PST technique. CT scans will be electronically transferred to the central station using file transfer protocol (FTP) or similar methods. The templates will be produced and sterilised before being sent to the surgeon. The patient's initials and hospital number should be engraved in the body of the templates along with the side of the knee and the date. Preoperative planning software would be automated and based on the recommended parameters for TKA (Insall and Easley, 2001). For straightforward cases, a specialised technician will assess the planning before being e-mailed to the surgeon for verification. For complex cases, the planning should be performed by the surgeon and then e-mailed to the RP machine. The surgeon should have the planning software installed in his/her computer. Surgeons will require training for preoperative planning and intraoperative use of the templates.

7.2 Further development

7.2.1 Technical development

The PST technique can be developed further to accommodate alternative imaging modalities with no or lower risk of radiation, such as MRI and 3-D X-ray (Rock et al., 2002). MRI images have the advantage of visualizing the articular cartilage, a feature that CT scans lack. However, the segmentation of bone from MRI images is more difficult as compared with CT scans. From the technical point of view, the computer technologies are fast progressing and computer aided designing and manufacturing software systems are becoming increasingly more sophisticated and powerful. Rapid prototyping machines are frequently modified to add more features such as the ability to produce complex tools. There are new generations of compact RP machines that are as small as an office PC printer. These compact machines can be purchased by hospitals and stored inside the operating room, radiology department or outpatient clinic. This will allow imaging, planning and the template production to be done at one site, saving time and resources.

7.2.2 Clinical development

7.2.2.1 Applications for challenging cases of TKA

In addition to the promising results of this study and the demonstrated benefits of the PST technique, there are potential benefits that can be investigated and exploited in future such as:

1) **MIS techniques:** The PST is more amenable to minimally invasive techniques, as it provides only two-piece instruments and obviates the need for using IM guides. The current size and shape of the templates can be further reduced to fit into the minimally invasive approaches (Figure 7). The recent trend of combining MIS and CAS may prove to be more practical with the use of the PST technique. However, the problems of inserting the templates and observing the process of positioning and surface matching through small incisions have to be overcome.
2) **Complex TKA:** The PST technique would be useful for patients with complex deformed knees, in which the use of the conventional IM rods may not be recommended or possible. The restoration of multiplane deformities will benefit from the detailed 3-D CT-based preoperative planning of the PST technique. The same applies to revision surgery and for young active patients with the additional benefits of preserving bone stock by quantifying the volume of removed bone during planning and before actual surgery. In revision surgery, the cost of implants is much higher and the complexity of the surgery much greater, so the advantages of the PST technique with its pre-operative planning become more important and the costs become less significant.
3) **Patients susceptible for infection:** Theoretically, the PST can reduce the risk of contamination and infection by avoiding intramedullary perforation, shortening tourniquet time, and eliminating the reusable numerous instruments that have multiple holes and canals. The PST can further reduce the risk of infection by reducing bleeding and haematoma

formation. Unlike navigation techniques, the PST does not require tracking or the insertion of pins to the femur and tibial, which has a risk of pin track infection. The PST technique may prove useful for TKA in certain patients who are susceptible to infection such as HIV or those susceptible to infection and bleeding such as haemophilia. Reusable instruments also carry the theoretical risk of spreading serious diseases that require extraordinarily high levels of sterilisation such as variant Creutzfeldt-Jakob Disease (vCJD) (DoH, 2001). The PST has the advantage of being a single use instrument.

7.2.2.2 Applications for other surgical procedures

The PST technique has the potential to be used for other procedures, such as unicompartmental, bicondylar (a new procedure to replace the medial and lateral compartments only while preserving anterior and posterior cruciate ligaments) and patellofemoral arthroplasty that require a higher level of accuracy and less invasive approaches. The PST technique for these procedures might be easier to learn and perform and can provide a better environment for training in TKA.

7.2.2.3 The use of PST for training

The PST technique can serve as a powerful and inexpensive training tool. The preoperative planning software can be installed in desktop and laptop computers with modest cost. The software may provide the opportunity for surgeons in training to practice on the preoperative planning of TKA, including sizing, measuring alignment and rotation and performing virtual bone cutting. The surgical simulation allows the identification and analysis of errors in 3-D and in real time. It also provides training for both cognitive and motor skills, allowing repetitive practice and committing errors and correcting them. For workshops on plastic bones, RP machines can produce reusable metallic templates that are specific to the plastic knee model. Thus avoiding the need to keep producing new templates for each practice. The PST technique itself requires less training as compared with conventional instrumentation, since it is easier to use and it involves only a very few intraoperative steps. With further modification and refining of the PST technique and the combination with MIS approaches, it may prove possible to achieve the ideal TKA procedure, as displayed in Flow Chart 3.

Appendix 1
Rapid prototyping machine

Sinterstation® HiQ™ Series SLS® System (3Dsystems)

Technology: Selective Laser Sintering (SLS™) process
Material Classes: Powder - Thermoplastics, Thermoplastic Elastomers, Metals, Composites

Automatically build functional parts, casting patterns and tooling inserts from your 3-D CAD data. Representing the future of Instant Manufacturing technology, the Sinterstation HiQ system directly produces end-use plastic or metal parts, tooling inserts, or casting patterns from your 3-D CAD data files. Eliminate the need for machining, tooling, casting or other secondary processes and save time and money
The SLS system and materials enable you to create durable, metal, plastic, or rubber-like parts directly from any solid CAD model in as little as one day - and without dependence on costly tooling or skilled labor.
Large Range of Laser Sintering Materials for Multiple Solutions. SLS systems are optimized for use with the following laser sintering materials:
DuraForm PA polyamide nylon or DuraForm GF glass-filled nylon for complex plastic parts and prototypes

Appendix 2
Intraoperative evaluation

Preoperative set up

Experiment No.:
Date of surgery:
Surgeon: **Assistant:** **Observer/ assessor:**

Materials

Type of Knee specimen: Cadaveric
Plastic (foam cortical shell composite
others)
Side Right Left

Surgical instruments:
Basic surgical instruments:
Pins Drill Saw

Rapid prototyping (RP) materials:
PSTs: Plastic (Durafoam) Metallic
Size of femoral template: Size of tibial template:
Prosthesis: Type:
Size Femoral: Tibial:

PE thickness: PE size:

Positioning of the leg:
Is the leg rigidly fixed in the holder? Yes No
What is the range of motion of the knee in the leg holder? full limited

Surgical procedure

Surgical exposure: Medial Lateral
Anatomical examination: Normal joint Abnormal joint

	Femoral		Tibial		Comments
Bony abnormalities Osteophyte Bone loss (or cysts) Bone quality (soft/ hard) **Cartilage loss**	Medial	Lateral	Medial	Lateral	
Soft tissue abnormalities (Lax or absent collateral or cruciate ligaments)	MCL	LCL	ACL	PCL	

Comparison between physical anatomy and CT scan: Similar different

Comparison between physical anatomy RP anatomical models: Similar different

Surgical technique using the templates

Starting time:

Preparation of the femoral component

Positioning of the femoral PST

Coupling in a single secure position: yes no

If no reasons for difficulty in obtaining a single secure position:

One coupling position but not secure

More than one coupling position

Positioning is not possible because of:

Bony obstacles, osteophyte, soft tissue obstacles, shape of the template

Changes made to allow positioning:

Removal of osteophyte Soft tissue dissection

Manual modification of the template: e.g. removal of some prominent edges

Others:

Removable probe:

Removed easily removed with difficulty not removed

Pin Fixation:

Secure not secure

Reasons for lack of security: soft bone, very hard bone

Changes made to improve fixation

Template displacement as a result of the above

Bone cutting

The feed and the movement of the saw blade inside the slits of PSTs

Size of the slits: fine narrow slits wide slits

Were there any obstacles from the template? yes no

Comments:

Were all the cuts made by the template? yes no

If no, which cuts were done without the template:

	Medial	Lateral	Reasons for not using the template	Comments
Anterior				
Posterior				
Distal				
Ant Ch				
Post Ch				

Has the template been removed and repositioned again: yes no

Explain the reasons for this action:

Implanting the femoral component:

Easy difficult not possible

Reasons for difficulty or inability:

Problems with bone cutting: not enough not equal

Problems with lug holes: size direction place

Modification made to allow implantation:

Modifying lug holes: enlarging re-drilling

More bone cutting: Ant Post Distal Ant Ch Post Ch

Positioning of the tibial PST

Coupling in a single secure position: yes no

If no, what are the reasons?

- One coupling position but not secure
- More than one coupling position
- Positioning is not possible because of:
  - Bony obstacles, osteophyte, soft tissue obstacles, shape of the template

Changes made to allow positioning:

- Removal of osteophyte
- Soft tissue dissection
- Manual modification of the template:
  - e.g. removal of some prominent edges

Pin Fixation

Secure not secure

Reasons for lack of security: soft bone, very hard bone

Changes made to allow pin fixation

Template displacement as a result of the above

Tibia bone cutting

The feed and the movement of the saw blade inside the slits of PSTs

Size of the slits: Fine narrow slits wide slits

Were there any obstacles from the template? yes no

Comments:

Were all cuts made by the template? yes no

If no, which cuts were completed without the template:

Corners: anteromedial anterolateral posteromedial posterolateral Posterior

Stem hole Keel

Explain the reasons for not using the template:

Has the tibial cut been revised: yes no

If yes, explain

Has the template been removed and repositioned again: yes no

If yes, explain

Implanting the tibial component

Easy difficult not possible

Reasons for difficulty or inability to implant:

Obstacles:	bony (osteophyte)	soft tissues
Not enough space:	large PE	thin tibial cut
Keel space:	small	shifted
Stem hole:	small	shifted

Modification made to allow implantation:

Remove obstacles:		bony	soft tissues
Re-drilling:	keel	stem	

Finishing time of the procedure:

Condition of template at the end of the procedure:
Intact Damaged (which part?):

Intraoperative evaluation

Sizing of the prosthesis

	Fine	Under sizing	Over sizing	Comments
Femoral		Notching Larger flexion gap	Minimal anterior cut Smaller flexion gap Overhang on both sides	
Tibial		Uncovered bone all over	Overhang all over	
PE		Loose flexion and extension	tight flexion & extension	

Bone cutting & alignment

Accuracy of bone cutting:
Gaps at metal bone interface measured by shim gauge: record only gaps > 1 mm

	Lateral	Medial	Comments
Anterior cut			
Posterior cut			
Ant chamfer			
Post Chamfer			
Distal cut			

Overhanging:

Femoral:	No	Yes:	medial	lateral
Tibial:	No	Yes:	medial	lateral

Alignment

Coronal alignment:	Normal	Valgus (degree)	Varus (degree)
Sagittal alignment:	Normal	larger flex gap	larger ext gap

Rotational deformity	Normal	Internal	External
Patellar tracking	Normal	Not	N/A

Range of motion of the TKR

Extension:	full	minus........
Flexion:	full	up to.........

Completeness of the procedure

The whole procedure was completed using PSTs
The whole procedure had to be cancelled because of a problem with PSTs
Part of the procedure was done without PSTs:
Which part and how it was completed

Time recording

Total Periods of interruptions:

1) Duration: Reason:
2) Duration: Reason:
3) Duration: Reason:

Actual time for using the template:

Summary

Evaluation

Completeness of the procedure

Excellent Good Fair Deficient Poor

Sizing of the prosthesis:

Excellent Good Fair Deficient Poor

Bone cutting & alignment:

Excellent Good Fair Deficient Poor

Stability:

Excellent Good Fair Deficient Poor

ROM:

Excellent Good Fair Deficient Poor

Surgeons' feeling (user friendly):

Excellent Good Fair Deficient Poor

Overall:

Excellent Good Fair Deficient Poor

Comments

Problems identified

Proposed solutions

Appendix 3
Evaluation of postoperative CT

Experiment No: **Date of surgery:**

Evaluation of Femoral cuts:

1. **Accuracy of the level of bone cutting:**

Level of cuts	Difference from planned cuts in mm	
	Undercut	Over cut
Anterior		
Posterior		
Distal		
Anterior chamfer		
Posterior chamfer		

2. **Accuracy of alignment:**

Distal cut (coronal alignment)	Valgus (°)	Varus (°)	Comments
Sagittal alignment	Flexion (°)	Extension (°)	
Posterior cut (rotation)	Internal rotation (°)	External rotation (°)	

Evaluation of tibial cuts:

1. **Accuracy of the level of bone cutting:**

Under cut	mm	Over cut	mm	Comments

2. **Accuracy of alignment:**

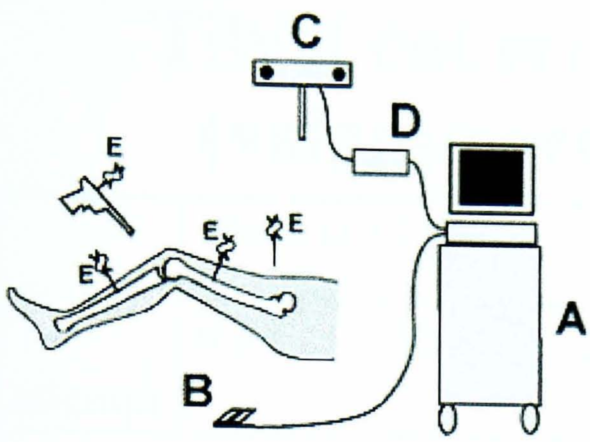
Medio-lateral cut (coronal alignment)	Valgus (°)	Varus (°)	Comments
Posterior sloping (sagittal alignment)	More posterior (°)	More anterior (°)	

Appendix 4
BrainLab Navigation system

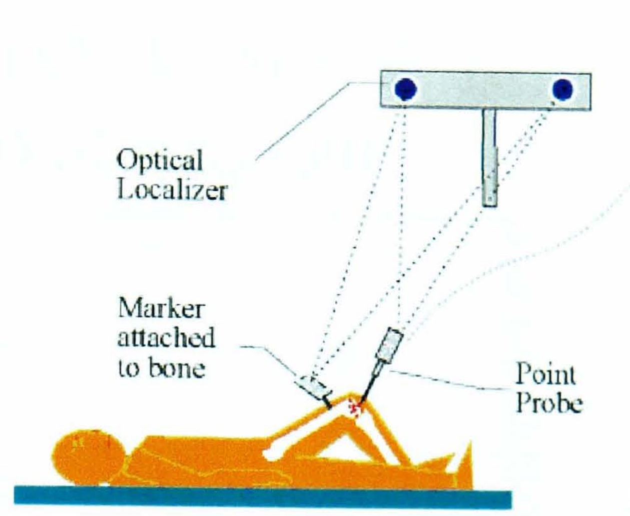
VectorVision® CAS Platforms
Touchscreen Monitor

Passive Marker Technology operates without wires and LED
- Versatile system for multiple medical specialties
- Fully upgradeable for newly developed software modules.
- The BrainLAB open platform design gives the flexibility of working with many implant vendors.

Appendix 5
Technical steps for using a navigation system*



A- System components: A) navigation station B) foot pedal (input device) C) optical camera (localizer) D) localizer interface unit E) tracking markers



B- Schematic for tracking and registration

1) **Data collection and planning:** For image-based navigation, CT or fluoroscopy is the source of data. For image free, data are collected intraoperatively using a kinematic method (e.g. rotating the hip joint to establish the centre of the femoral head) and a morphologic method (e.g. a point probe to localize certain bony landmarks). Planning is a typical feature for CT-based navigation and it is performed preoperatively.

2) **Registration:** Surface registration is used, where the surgeon collects a cloud of points by touching the bony surfaces with a pointed probe. The unique shape of the bone then matches the images (data) stored in the navigation system.

3) **Tracking:** It means real time updates about the position and movement of bone and instruments. The components of optical tracking are the tracking camera and tracking markers, which need to be attached to instruments and rigidly to the bone (through pins). Tracking requires a continuous line of sight between the camera and markers. The concept of tracking is similar to that of the global positioning system (GPS) that used in cars.

4) **Intraoperative measurement:** Continuous and real-time information about the position of instruments and implants is displayed in a computer monitor allowing accurate measurements of different parameters such as orientation of the implant and level of bone cutting.

* Hafez MA, Seel MJ, et al. Navigation in minimally invasive hip and knee arthroplasty. Operative Techniques in Orthopaedics. July 2006.

Appendix 6
Raw data for the reliability test

Tibial cut errors*: Coronal (valgus/varus) alignment

	Observer A	B	C	D	E
1st attempt	0.5	0.5	0.5	0	0.5
2	0.5	0	0.5	0	0.5
3	0.5	0.5	0.5	0	0.5
4	0.5	0.5	0.5	0	0.5
5	0.5	0	0.5	0	0.5

*Errors measured in degrees

Tibial cut errors*: Sagittal (posterior slope) alignment

	Observer A	B	C	D	E
1st attempt	1.5	1.5	1.5	1	1
2	1.5	1	1.5	1	1
3	1.5	2.5	1	0.5	1
4	1.5	1.5	1	1	1
5	1.5	1	1.5	1	1

*Errors measured in degrees

Femoral cut errors*: Coronal (valgus/varus) alignment

	Observer A	B	C	D	E
1st attempt	1.5	1	0.5	1	0.5
2	1.5	1	1	1	1
3	1.5	1	1	0.5	0
4	1.5	1	1	0.5	0
5	1.5	1	1	0.5	0.5

*Errors measured in degrees

Femoral cut errors*: Sagittal (Flex/Ext) alignment**

	Observer A	B	C	D	E
1st attempt	0.35	0.30	0.2	0.2	0.2
2	0.4	0.15	0.05	0.1	0.05
3	0.25	0.15	0.00	0.15	0.15
4	0.35	0.15	0.15	0.15	0.15
5	0.3	0.15	0.10	0.2	0.15

* Errors measured in degrees. ** These errors were calculated in relation to a sagittal alignment of 3° flexion similar to the preoperative planning.

Level of femoral cut: Errors in mm

	Observer A	B	C	D	E
1st attempt	0.5	1	0	1	0.5
2	0.5	0.5	0	0.5	0
3	1	0	0	0.5	0
4	0.5	0	1	0	0.5
5	0.5	0	0.5	0.5	0

Level of tibial cut: Errors in mm

	Observer A	B	C	D	E
1st attempt	0	0.5	0	0.5	0
2	0	0.5	0	0.5	0
3	0.5	0.5	0	0.5	0
4	0.5	0.5	0	0.5	0
5	0.5	0.5	0	0.5	0

Femoral cut errors*: rotation (posterior cut)

	Observer A	B	C	D	E
1st attempt	1.35	**	2.84	1.45	**
2	1.35	**	2.83	1.4	**
3	1.35	**	2.84	1.35	**
4	1.35	**	2.82	**	**
5	1.35	**	2.84	**	**

* Errors measured in degrees ** Missed data for observers B & E and also for the 4th and 5th attempts of observer D due to operational error of the navigation system

Presentation and publications related to this study

Presentations

1. Podium

Hafez MA, Chelule K, Seedhom BB, Sherman KP. Computer assisted total knee replacement: Could a two-piece custom template replace the complex conventional instrumentations? 4th Annual Meeting of International Society for Compute Assisted Orthopaedic Surgery, Chicago, 16-19 June 2004

2. Poster

Hafez MA, Chelule K, Seedhom BB, Sherman KP. Patient-specific instrumentation for total knee arthroplasty: A minimally invasive technique based on computer assisted planning. Symposium on Less and Minimally Invasive Surgery for Joint Arthroplasty: Fact and Fiction. Indianapolis, USA, 19-21 May 2005

Publications

1. Abstracts:

a. Hafez MA, Chelule K, Seedhom BB, Sherman KP. Computer assisted total knee replacement: Could a two-piece custom template replace the complex conventional instrumentations? Computer Aided Surgery. 2004;9(3):93-4

b. Chelule K, Seedhom BB, Hafez MA, Sherman KP. Computer-assisted total knee replacement. Osteoarthritis Cartilage. 2003;11 Suppl A:S11

2. Paper:

Hafez MA, Chelule K, Seedhom BB, Sherman KP. Computer-assisted total knee arthroplasty using patient-specific templating. Clinical Orthopaedic and Related Research. 2006;444:184-192

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