INTRAOPERATIVELY MEASURING LIGAMENTOUS CONSTRAINT AND DETERMINING OPTIMAL COMPONENT PLACEMENT DURING COMPUTER-ASSISTED TOTAL KNEE REPLACEMENT

By

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B.A.Sc., The University of New Brunswick, 1999

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF APPLIED SCIENCE

in

THE FACULTY OF GRADUATE STUDIES
(Department Of Mechanical Engineering)

We accept this thesis as conforming
To the required standard:

The University of British Columbia

February 2002

Abstract

The biomechanical goals of total knee replacement surgery are to restore neutral alignment to the lower limb and balance the soft tissues of the knee. Currently, this soft tissue balancing is considered an art; there are few ways to quantify the appropriateness of the soft tissue balancing that a surgeon does. Furthermore, the few existing techniques for quantifying balance are applied after the bone cut is complete, so the state of the soft tissue cannot enter into the surgical planning process. Since problems with soft tissue balancing represent one of the major unsolved problems in knee surgery, there is considerable interest in developing tools to assist with this process

In this thesis, I report on the development and preliminary testing of two specific algorithms. The first is an intraoperative method to precisely identify ligament anatomy for use in a kinematic knee model using a computer assisted surgical system. The second is a method to determine the component placement that minimizes ligament strain and laxity throughout the entire range of motion of the knee. Both methods are requirements for a comprehensive surgical advisory system.

The ligament identification method proved sufficiently repeatable on porcine specimens to warrant further testing on cadaver specimens. The component placement algorithm was able to determine optimal placement locations accounting for imbalances introduced on a simulated knee model, and was robust to errors introduced when using the ligament measurement routine to obtain model inputs. Further testing on physical knee models is required for validation of the method's ability to determine optimal component placement and predict passive kinematics. I conclude that the two methods presented have the potential to provide the surgeon with accurate quantitative intraoperative information for use in soft-tissue balancing and surgical planning procedures and warrant further investigation.

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Acknowledgements

I would like to thank Dr. Antony Hodgson for his valuable guidance and patience in the supervision of this project. Thanks also go to Dr. Robert McGraw and Dr. Bassam Masri for their clinical input and support. Thanks to Kevin Inkpen for providing inspiration for this project and encouragement throughout its duration.

Dr. Tom Oxland, Simon Sjovold and all of the students at the UBC Department of Orthopaedic Engineering Research went out of their way to provide me with valuable assistance and use of their lab facilities. Thanks also to Paul McBeth and Cameron Shute for their assistance with experiments, input and support during the project. Special thanks to Christopher Plaskos for enduring exceptionally long hours of experimental collection and specimen preparation.

Chapter 1 – Importance of Soft-tissue Balance in Total Knee Arthroplasty

"The challenge to duplicate with manufactured parts the relationship between articular geometry and ligamentous stability that is programmed genetically and that is structurally evident at seven weeks' gestation is prodigious. To duplicate in less than two hours of surgery the relationship between parts that evolves in utero and through childhood and adolescence is daunting. Resolving fixation, kinematics and wear is not simple. Nor is it completely biologic or mechanical."

- Kelly G. Vince, M.D. 1994 (Vince, 1994)

1.1 Overview

In total knee arthroplasty (TKA), the surgeon aims to restore limb alignment and relieve patient pain by removing the damaged surfaces of the knee joint and replacing them with metal and plastic (or sometimes ceramic) components. These components must be precisely aligned to maximize the implant's lifespan. The procedure can best be described as a total re-surfacing of the deformed articular surfaces of the knee. The distal surface of the femur is replaced with a metallic femoral component. The tibial surface is typically replaced with a metallic tray upon which sits a polyethylene insert referred to as the tibial insert. In most instances the deep surface of the patella is also replaced with polyethylene, sometimes referred to as the patellar button. These components thus create metal-on-plastic bearing surfaces in each of the three compartments of the knee (medial and lateral tibiofemoral compartments and the patellofemoral compartment, Figure 1.1). The components are held together by soft-tissue structures surrounding the knee, primarily the ligaments: posterior cruciate (PCL) and lateral (LCL) and medial (MCL) collateral ligaments (the anterior cruciate ligament (ACL) is resected). These ligaments must be properly balanced to match the bone cuts – they cannot be too long or the knee will separate (a problem known as instability) and they cannot be too short or they may rupture or limit the motion of the knee when strained. Currently, this soft-tissue balancing is considered an art; there are few ways to quantify the

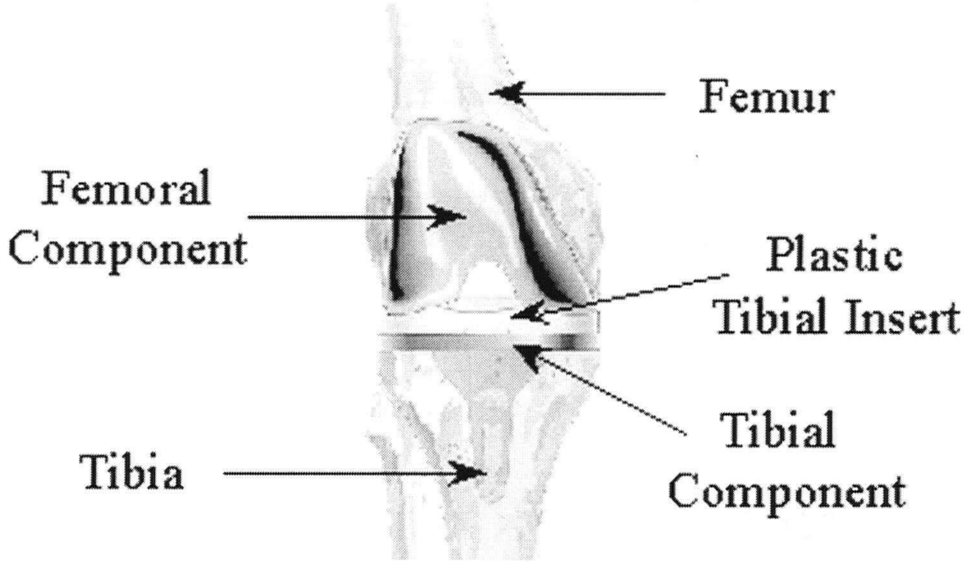


Figure 1.1 - Total knee replacement components (Image adapted from Johnson & Johnson Orthopaedics)

appropriateness of the soft-tissue balancing that a surgeon does. Furthermore, the few existing techniques for quantifying balance are applied after the bone cuts are complete, so the state of the soft-tissue cannot enter into the surgical planning process. Since problems with soft-tissue balancing represent one of the major unsolved problems in knee surgery (Attfield, 1995; Cooke, 1998; Sambatakakis, 1991), there is considerable interest in developing tools to assist with this process. I have developed a technique to quantitatively assess the degree of soft-tissue constraint and to present the surgeon with this information prior to making the final bone cuts so that they can incorporate these considerations into their surgical planning. In this chapter I present evidence of soft-tissue problems in TKA, attempts to address these problems, and describe our approach.

1.2 Objectives of Total Knee Arthroplasty

The objectives of TKA are to relieve the patient's pain and to restore appropriate knee function (Cooke, 1998). Appropriate knee function is restored by lower limb re-alignment and balance of the surrounding ligaments to match the newly implanted components. Proper alignment occurs when the knee is centred on the mechanical axis of the leg, which passes through the centre of the femoral head and the centre of the ankle (Jeffery, 1991; Moreland, 1988; Cooke, 1998,

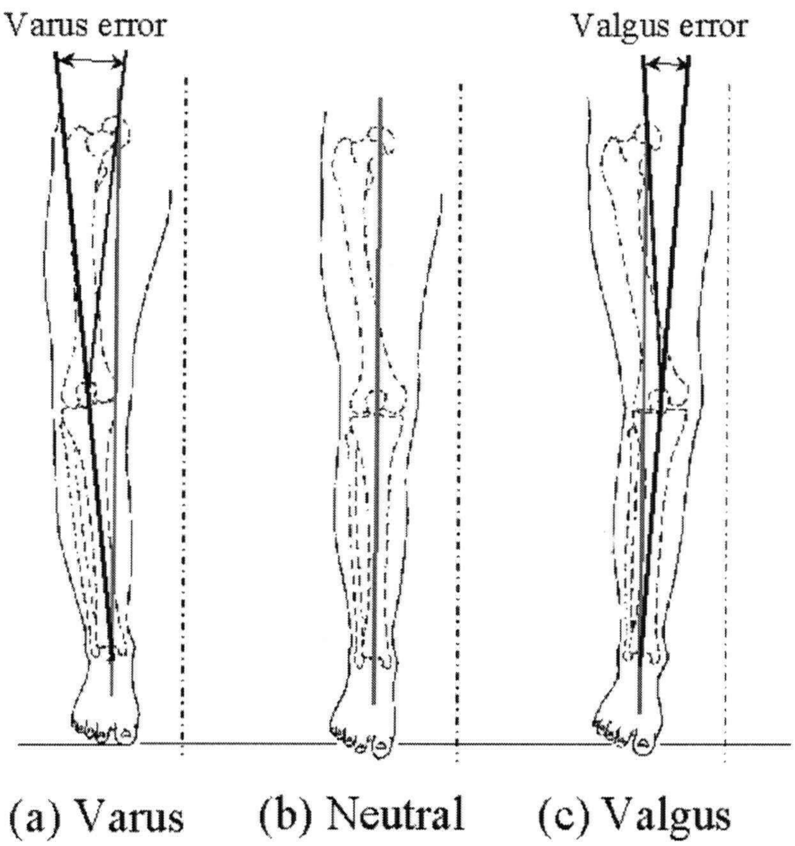


Figure 1.2 - Lower limb alignment (Image: Inkpen 1999)

Figure 1.2b). If the knee centre lies lateral to the mechanical axis, the limb is in varus ('bow-legged', Figure 1.2a), and if the knee lies medial to the mechanical axis the limb is in valgus ('knock-kneed', Figure 1.2c). In addition to alignment through bone cuts, soft-tissue management is of equal importance (Insall, 1985). The soft-tissues of the joint can deform during theyears of the arthritic disease process, contracting with bone loss to fix the joint in its deformed position (Attfield, 1995). The soft tissues form a capsular sleeve that surrounds the knee. In many patients who require TKA, in addition to bone and cartilage deficiency, there is a contracture of this sleeve medially, laterally or posteriorly, resulting in fixed varus, valgus or flexion deformities, respectively. Correction of these deformities is an essential part of the procedure to bring the knee into proper alignment. If this is not performed, asymmetric loading will result leading to excessive loading on one compartment of the implant and eventual loosening (Laskin, 1989).

The correction of the soft-tissue deformations is commonly known as soft-tissue balancing. Strictly speaking, this implies the restoration of ligaments and other surrounding structures to the appropriate state such that acceptable passive knee kinematics (i.e. with no muscle forces involved) and knee stability are obtained when the new components are implanted; although in practice this is not always easily achieved. Ideally proper soft-tissue balancing will allow correct alignment of the limb and lead to appropriate loading across the knee.

1.3 Current Success of TKA Procedures

Total knee replacement surgery has increased in popularity in the last 10-15 years with 280,000 operations in the United States and 35,000 operations in the United Kingdom being performed each year (Inkpen, 1999; Moran, 2000). The move towards less constrained prostheses, which rely on surrounding soft-tissue for stability, has resulted in fewer mechanical failures and has made TKA one of the most common major surgical procedures. Despite the wide use of the procedure, implant failure and knee complications still occur. About 2% of TKAs require revision (replacement) within two years (Heck, 1998), half of which are due to aseptic problems such as poor alignment or poor ligament tension. Approximately 2.7% of TKAs have required revision for aseptic reasons at four to five years (Callahan, 1994). At 10 years, revision rates for aseptic problems have been reported at 4% (Ansari, 1998) and 5% (Robertsson, 1997). Revision costs in the United States are US$15,000 to $20,000; a 2.7% revision rate due to aseptic problems at four years represents an annual cost of US$100 million in the United States alone. This number is expected to rise due to the current aging population and the increase in the required lifespan of implants as increases in patient expectations regarding TKA continue to advance faster and further than implant advances and technical abilities (Winemaker, 2002).

1.3.1 Failure of Total Knee Arthroplasty

Failure of total knee replacement procedures fall under two categories: septic and aseptic. Infection represents a significant percentage of knee failures. Rodriguez (Rodriguez, 2001) reported 29% of knees revised for infection and Miyasaka (Miyasaka, 1997) reported 33% for revisions related to sepsis. Despite these high occurrences, sepsis is generally not seen as an area for improvement in TKA as it is typically related to factors out of the surgeon's control, such as the operating room environment and the health of the patient. On the contrary, aseptic failures are generally attributed to factors under the surgeon's control such as component alignment, component placement and soft-tissue balance. Aseptic failures can take on many forms including component loosening, component wear, instability and poor range of motion.

Malalignment of the lower limb has long been thought to be associated with component failure (Coventry, 1979; Lotke, 1977). Poor alignment in the coronal plane leads to excessive loading in one compartment of the knee. This may result in excessive wear of the polyethylene insert of the tibial component, loosening and even fracture of the components. Wear of the polyethylene has also been shown to cause resorption of the bone surrounding the components, a condition known as osteolysis (Kilgus, 1991) leading to component loosening.

However, poor component placement and sizing may also lead to aseptic failure or complications (Rhoads, 1993). Oversizing of the femoral component may lead to poor range of motion, also known as overstuffing the joint. This also redirects the line of action of the quadriceps tendon and patellar ligament leading to anterior knee pain (Wasielewski, 1994). Undersizing of the femoral component or posterior placement can lead to notching of the anterior femoral cortex, which creates a high stress concentration and may also lead to quadriceps complications (Moreland, 1988). Full bone coverage by the tibial component is important so that the cortical bone of the tibia fully supports the component. Failure to achieve this condition leads to component subsidence and/or migration, which can cause malalignment or instability. The rotation of the femoral component with respect to the neutral position of the femur, known as rotational alignment, is also an important placement consideration. This rotation translates the patellar groove of the component to a more lateral position that allows for better tracking of the patella on the femur (or more precisely the patellar insert on the femoral component), Figure 1.3. Rotational alignment is recognized by many authors to be a vital factor in a successful TKA (Anouchi, 1993; Berger, 1998; Berger, 1993; Whiteside, 1995).

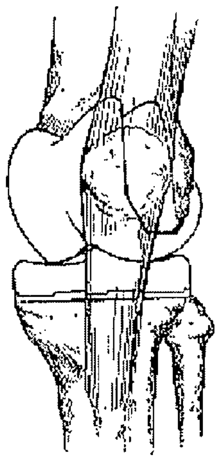


Figure 1.3 - Maltracking of the patella due to internal rotation of the femoral component (Image: Arima, 1995)

Obtaining appropriate balance of the soft-tissue is important to ensure proper limb alignment of unconstrained components as discussed in the next section, however other complications aside from malalignment also arise as a result of poor ligament balance. Complications arising from incorrect ligament tensioning can vary from a limited range of motion in the case of excessive tension, to subluxation or dislocation of the knee due to inadequate tension (requiring surgical correction.) If the ligaments surrounding the knee are not sufficiently lengthened to accept the new components, then the range of motion of the prosthesis may be compromised. This can be an inability to obtain full extension, full flexion or a combination of the two. If the ligaments are overlengthened this can lead to instability of the knee, evidenced by patient pain and/or a "giving way" sensation. Instability has also been shown to increase component wear as excessive motion results in unconventional contact occurring between the components (Wasielewski, 1994).

1.3.2 Alignment versus Balance as a Cause of Failure

The relative importance of bone cuts and soft-tissue alignment is still controversial (Sambatakakis, 1991; Moreland, 1988). Many authors believe that alignment obtained by the bony resection planes is the most important aspect of the surgery in terms of failure (Jeffery, 1991; Moreland, 1988; Ritter, 1994). However, other authors (Cooke, 1998; Insall, 1985; Wallace, 1998) claim that soft-tissue balance is of equal importance to alignment. This is not surprising considering the function of unconstrained component designs. They rely heavily on the ligaments and surrounding soft-tissues of the knee for proper kinematic constraint, thus the importance of appropriate soft-tissue integrity and component interaction for these prostheses cannot be understated. It has also been noted that with these prostheses alignment results from the soft-tissues, as the bone cuts are always performed in the same manner, regardless of the deformity (Moreland, 1988).

Many authors have reported on the occurrence of soft-tissue complications in TKA. Wasielewski (Wasielewski, 1994) reported on the wear patterns of 55 tibial inserts retrieved at the time of revision surgery. He found that 14 of 16 knees that had a preoperative varus deformity showed predominant wear patterns in the medial compartment of the knee despite correction of the deformity to a normal anatomic axis by appropriate bone cuts. Twelve of these 14 knees were noted to have not undergone a medial release at the time of surgery, suggesting the MCL was in postoperative tension. Wasielewski concluded that unconstrained tibial component wear patterns and severity may be associated with clinical and mechanical factors under the surgeon's control, including component size and position, knee alignment and ligament balance.

Sambatakakis (Sambatakakis, 1991) reported on radiological findings in a

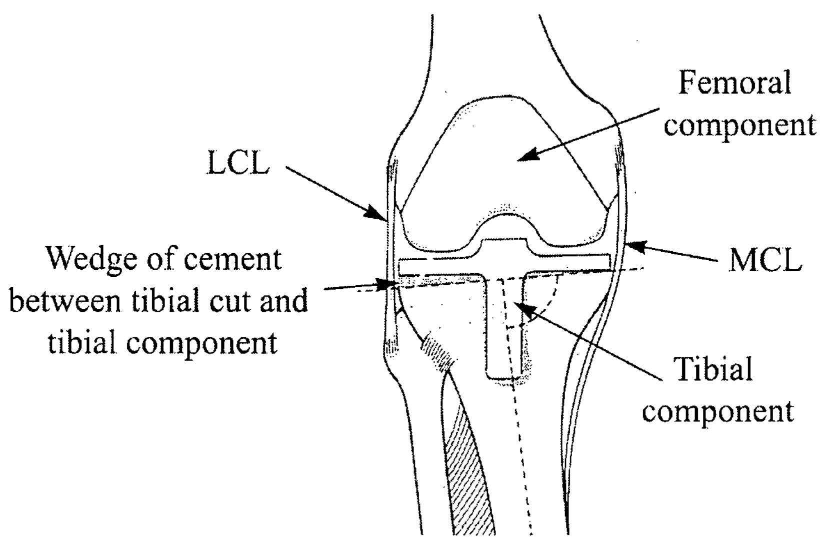


Figure 1.4 - Cement wedge sign noted by Samabatakakis, 1991

series of 871 consecutive primary condylar knee replacements, followed up for an average of four years. He identified a radiological sign consisting of a smoothly tapering wedge of cement visible beneath the horizontal portion of the tibial component on the anteroposterior radiograph (Figure 1.4). The wedge sign was found in 25.4% of the cases studied. Sambatakakis claimed that this indicated persistent soft-tissue imbalance following surgery. He stated the cause of this phenomenon was a disparity between the alignment of the limb as determined by the bony cuts, and the soft-tissue 'alignment' at the time of cementing. If the components are cemented simultaneously with the leg lying freely on the table with no varus or valgus force applied by the surgeon, the unequal tension in the collateral ligaments will force more cement out of one side of the knee than the other. The final tibiofemoral alignment in the case of an improperly balanced varus knee would then be slightly more varus than that intended by the bony cuts.

Several authors have identified soft-tissue balance as a factor leading to failure when reviewing knees at the time of revision. Fehring (Fehring, 1994) looked at 126 knee revisions from 1986 to 1994. He reported that 25 (20%) of the knees were revised for instability of the tibiofemoral joint. Reasons for instability were ligamentous imbalance and incompetence, malalignment and late ligament incompetence, a deficient extensor mechanism, inadequate prosthetic design and surgical error. He stated that accurate ligamentous balancing is one of the key determinants of postoperative stability. Friedman (Friedman, 1990) reported on 137 revision TKAs. Ten percent were revised for instability. Three patients in the series had disabling instability after revision. Rand (Rand, 1982) reporting on 142 revision TKAs, noted that 42 (30%) were revised for instability. He noted that the most frequent reasons for revision were failure to obtain stability and failure to restore proper axial alignment at the time of the initial operation.

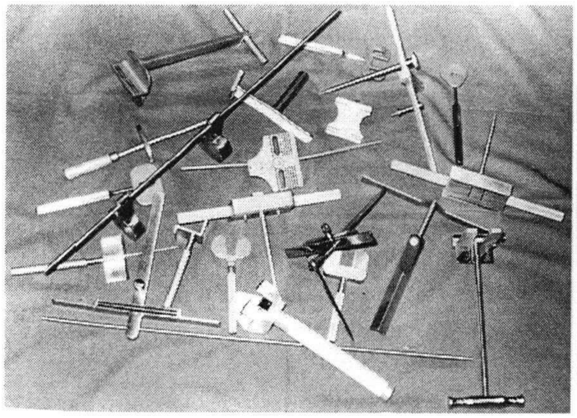
Tew (Tew, 1985) examined the relationship between stable tibiofemoral alignment and outcome in 428 TKAs. He found that the highest success rate was in those knees with neutral alignment at time of operation and such knees were most likely to remain stable. However, half of the failures occurred in knees correctly aligned at the operation and two-fifths in knees that had remained stable in this alignment. He concluded that malalignment was not the only, and possibly not the most important, cause of failure in the knees studied, as a high failure rate was found in cases in which malalignment could not have been the primary cause of deterioration. He indicated that inadequate soft-tissue balancing is most likely a significant factor.

Schneider (Schneider, 1984) reviewed 55 failed total condylar knee replacements with 32 of those due to aseptic loosening. Of the 32, he attributed 10 (31%) to instability. Schneider states in his discussion that instability (varus/valgus) is prevented by the medial and lateral collateral ligaments; if they are not balanced during surgery, instability will result.

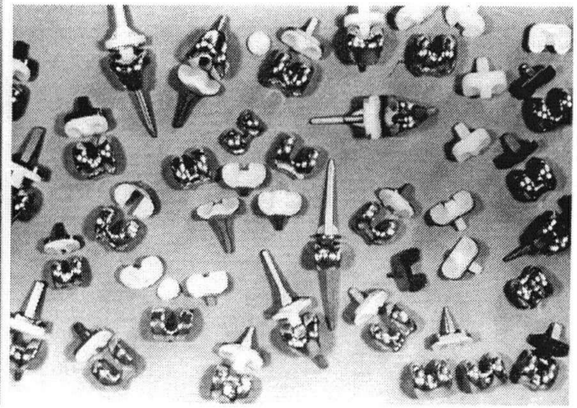
Soft-tissue imbalance can also cause complications that lead to poor outcomes in TKAs aside from direct failure. It likely represents a larger problem than is currently thought as many studies use only failure as a measure of poor outcome. Soft-tissue balance is often the factor in TKA that separates a good result from an excellent result in terms of both function and patient pain.

1.4 Current Soft-tissue Balancing in TKA Procedures

Many different total knee systems are commercially available with slightly



A



B

Figure 1.5 - A wide array of A. instrumentation and B. component systems available in the 70's and 80's (Image adapted from Scott, 1987)

different concepts behind the component designs and instrumentation (Figure 1.5). However, modern minimally constrained systems all share common implantation strategies. For primary procedures after pre-operative templating, the first step is incision and exposure. The patella is reflected and relevant structures are dissected. At this time, the surgeon assesses the alignment and soft-tissue balance of the knee, and any preliminary releases are performed. Usually these are done in knees with rather marked varus or valgus deformities. The bone cuts are then performed using intra and/or extramedullary instrumentation. The order of the cuts, and to some extent the way they are determined, differ depending on the system being used and the surgeon's preference. However, with all systems the surgeon performs a tibial plateau cut, an anterior femoral cut, a posterior femoral cut, a distal femoral cut and chamfer finishing cuts on the femur using a combination of intra and extramedullary instrumentation (Figure 1.6). These cuts, along with the soft-tissues surrounding the knee, create gaps between the cut surface of the tibia, and the cut surfaces of the femur when the knee is in full extension or 90 degrees of flexion. These two gaps are known as the extension and flexion gaps respectively (Figure 1.7). During the course of the procedure, soft-tissue

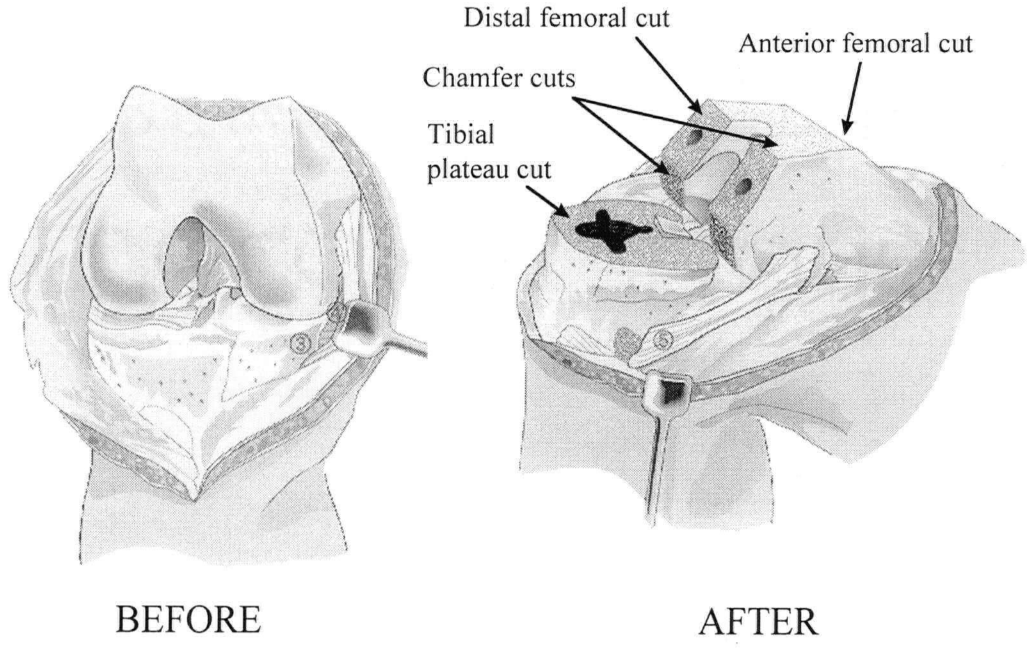


Figure 1.6 - Typical bone cuts perfomed during TKR (Image adapted from Johnson & Johnson Orthopaedics)

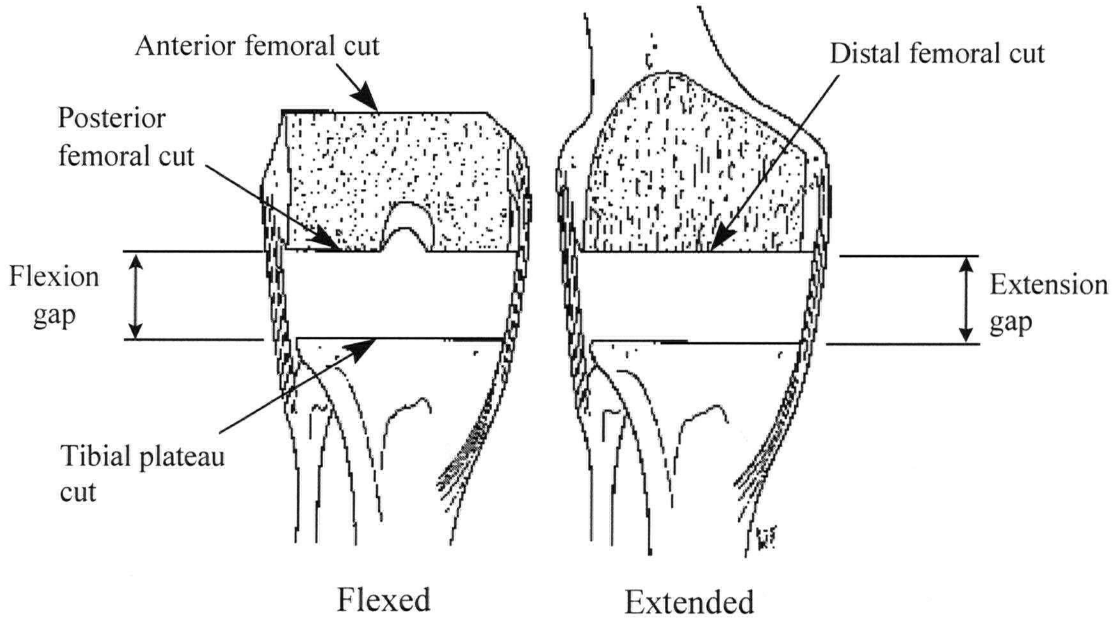


Figure 1.7 - Rectangular flexion and extension gaps formed by the bone cuts and collateral ligaments (Image adapted from Krackow, 1991)

balance is most commonly judged by assessing the flexion and extension gaps. The surgeon performs soft-tissue releases to correct imbalances until the flexion and extension gaps appear rectangular and of equal height. If the gaps are trapezoidal, uneven loading will occur at the tibiofemoral joint leading either to

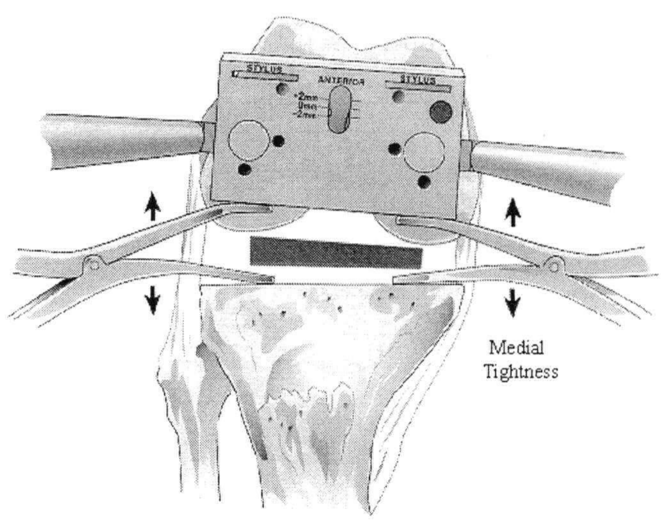


Figure 1.8 - Assessment of balance using a tensioning device (Image adapted from Johnson & Johnson Orthopaedics)

high loading in one compartment or instability. Unequal height of the flexion and extension gaps will lead either to a limited range of motion or joint instability depending on the size of the tibial spacer chosen. Tensioning devices are sometimes used to distract the bones for more accurate assessment of the imbalance (Figure 1.8). More releases may be appropriate once the trial or final prostheses have been placed to correct excessive ligament tension or poor passive range of motion. The trial prostheses are mock implants inserted temporarily by the surgeon to assess the fit of the intended components. At this time the surgeon may test different sizes of components (most commonly tibial inserts of varying thickness) to evaluate the overall function of the modified knee.

The posterior cut on the femur is an important variable in determining the shape of the flexion gap as it makes up the uppermost surface. This cut is determined in one of two ways; it is referenced from bony landmarks on the femur (example: parallel to the transepicondylar axis or perpendicular to the anteroposterior axis, etc. Figure 1.9) or it is cut to be parallel to the cut surface of the tibial plateau. This is also an important cut as it determines the rotational alignment of the femoral component. Thus it affects the flexion gap balance and patellar tracking (Figure 1.3).

The different types of contracture require different techniques for their correction. A fixed varus contraction is the most common contraction seen in patients undergoing TKA (Laskin, R. S., 1989) and is most often due to osteoarthritis. Laskin (Laskin, R.S., 1987) reported 870 of 1,382 (63%) knees in

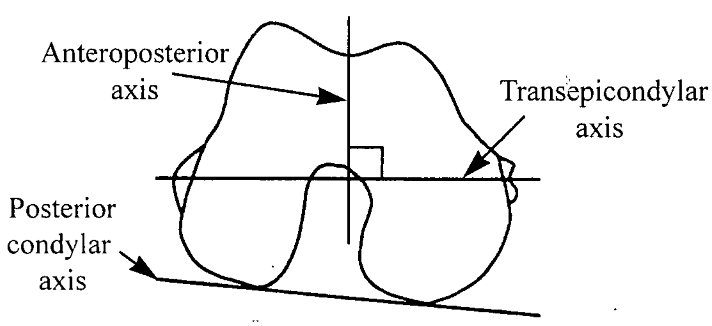


Figure 1.9 - Axes used to reference rotational alignment of femoral component (Image adapted from Berger, 1993)

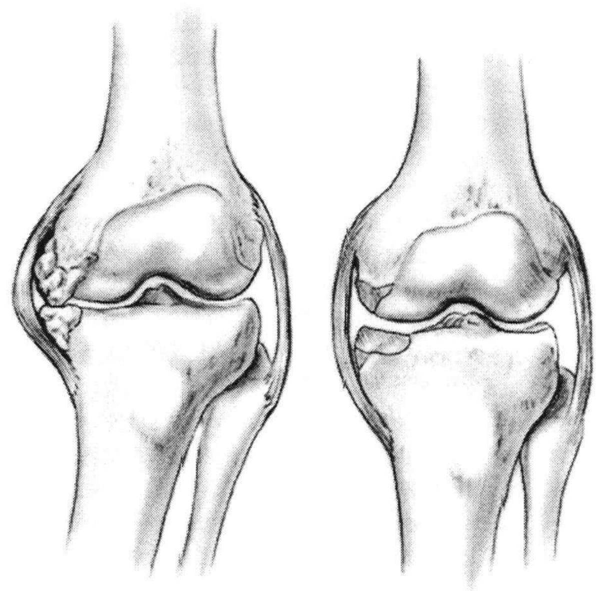


Figure 1.10 - Osteophytes tend to "tent" and effectively shorten the collateral ligaments. Osteophyte removal effectively relengthens the ligaments and is the first step to restoring ligament balance. (Image adapted from Scott, 1994)

varus before operation. This condition is characterized by a contracture of the medial soft-tissue structures, including the deep and superficial medial collateral ligaments, capsule, pes anserinus tendons, and posterior cruciate ligament with a concurrent laxity in the lateral soft-tissue. The specific releases used to balance the soft-tissues vary somewhat between surgeon and institution and a certain amount of freedom is available in terms of the selection of release. A varus deformity is easier to correct than a valgus deformity because most of the soft-tissue balancing is done during the usual surgical approach to the knee. The surgical approach for a valgus knee does not significantly assist in balancing the knee. In an attempt to redistribute the forces across a larger surface area in response to the destructive effect of the osteoarthritis, the body forms osteophytes (reparative bone and cartilage) at the joint surface. These osteophytes interfere with the motion of the knee and any osteophytes from the tibia and femur are removed (D'Ambrosio, 1994; Insall, 1985; Laskin, R. S. and Rieger, 1989). In relatively small contractures this is sometimes all that is required to obtain neutral alignment (Figure 1.10). The medial varus release includes a tibial subperiosteal elevation of the superficial

MCL and pes anserinus tendon. Distally the periosteum can be elevated on the anteromedial surface.

The correction of valgus deformities, like varus deformities progresses in stages. Valgus contracture is less common and more often seen in patients with rheumatoid arthritis. Krackow(Krackow, 1991) found only 301 of 981 knees (31%) in valgus pre-operatively. The lateral capsular contracture characteristically proceeds to include the iliotibial band (ITB). This is a more challenging correction than a varus deformity due to the presence of the peroneal nerve near the proximal tibia which limits the extent of the releases that may be performed. Releases that may be performed for this deformity include: release of the ITB band by transection of tight fibres in extension, release of the popliteus tendon, partial or complete release of the LCL from its origin and release of the biceps tendon (Figure 1.11).

In combination with a fixed varus or valgus deformity, a fixed flexion

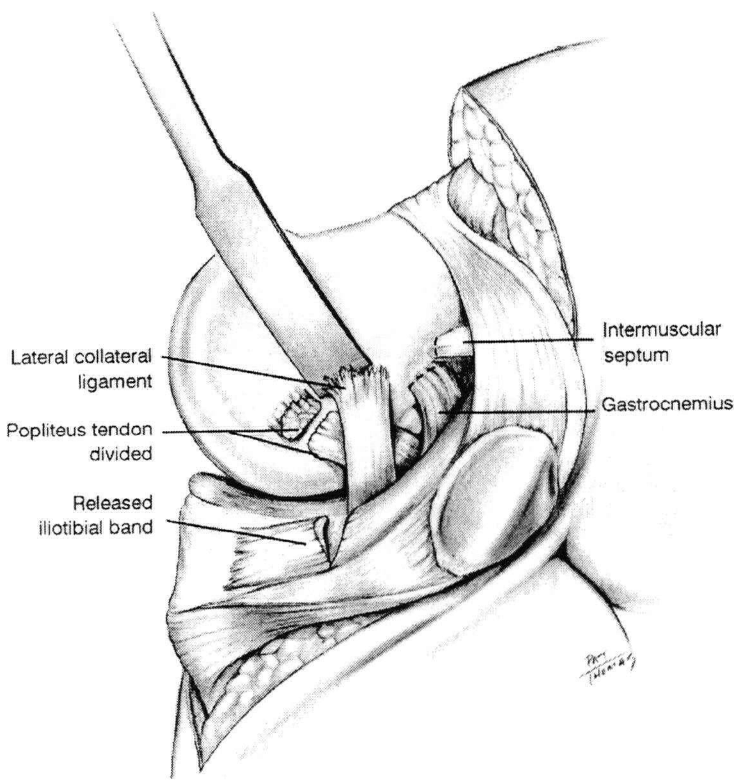


Figure 1.11 - Lateral release for a valgus knee (Image adapted from Scott, 1994)

contracture may also be present. Again the first step in the correction of this deformity is the removal of any osteophytes that may be present. In flexion contractures less than 10 to 15 degrees, the presence of an anterior tibial osteophyte may be the only cause of the contracture. (Laskin, 1989; Scott, 1994). For severe flexion contractures, it may be necessary to resect more bone from the distal femur to obtain full extension. This is viewed by some as the only situation where soft-tissue balance should be corrected using non-standard bone resections instead of relying solely on soft-tissue release. For flexion contractures greater than 15 degrees, resection of the PCL is normally recommended. The selection of the type of release, as well as the degree of release is left to the expertise and experience of the surgeon. Additional measures may be required to balance the flexion and extension gaps. Residual tightness may exist in flexion but not in extension or vise versa. To correct these types of imbalances, additional bone resection may be required or selection of different components.

1.5 Survey to Assess Concerns with Soft-tissue Balance in TKA

We conducted a nation-wide survey of Canadian orthopaedic knee surgeons to assess the current view of the importance of soft-tissue balance in TKA. We wanted to determine if soft-tissue balance is perceived as an important area for improvement in TKA and if more advanced soft-tissue balance instrumentation should be developed. We also wanted to learn how a device to assist in soft-tissue balance would be used in TKA and what capabilities it should have.

A list of Canadian knee specialists was obtained from the Canadian Orthopaedic Association. The survey was issued by e-mail and post, with 80 TKA specialists responding. This number represents approximately 50% of all surgeons who perform TKA procedures in Canada. The survey was issued as follows:

Soft-tissue Balance in TKA; A Survey (5 minutes)

Researchers

Dr. Robert W. McGraw, Division of Orthopaedics, VGH
Dr. Antony Hodgson, Department of Mechanical Engineering, UBC
Scott Illsley, Department of Mechanical Engineering, UBC

We propose to develop an assistive device to be used intraoperatively that would address issues in the area of soft-tissue balance in TKA. One of the main applications of this device would be to quantify some of the more subjective parameters in TKA such as the degree of passive medial/lateral tension across the components, the degree of tightness/looseness of the overall replacement, or the range of motion during trial reduction.

To ensure our research focuses on issues relevant to a broad cross-section of surgeons, we invite you to spend 5 minutes to complete the survey below. Your responses, along with those of other TKA surgeons in Canada, will be used to direct our research efforts.

To complete the survey, simply reply to this email, including the original text in your response, and fill in the required information wherever there is a blank. If you currently do not perform TKA surgery, we apologize for the inconvenience, and simply ask that you reply to this message indicating that you do not perform TKA surgeries in the subject header.

We greatly appreciate your co-operation.
Yours,

Scott Illsley, M.A.Sc. Candidate

In this survey, please consider only primary procedures.
Prevalence and Severity of Soft-tissue Balance Issues

1. To what extent do the following represent unsolved problems with current surgical techniques? Please consider both the severity and frequency of complications.

Please rank on a scale of 1-3 with:
3 = Major concern
2 = Of some concern
1 = Not a concern

Sepsis - rank: __
Implant malalignment - rank: __
Debris from wear sites - rank: __
Patellofemoral tracking- rank: __
Soft-tissue imbalance - rank: __

2. What percentage of procedures do you feel result in complications due to soft-tissue imbalance? - ______ %

3. In what percentage of procedures do you feel fully satisfied with the soft-tissue balance in a TKA? - ______ %

Difficulty in Balancing Soft-tissues

4. Please complete the following for the three types of pre-operative patient condition:

Preoperative patient condition:

A. Articular damage, no gross deformities:
i) percentage of patients you see with this condition - __ %
ii) Typical time required for trial reduction - __ mins
iii) Typical number of iterations in trial reduction - __ iterations

B. Mild deformities (< 15 degrees varus/valgus)
i) percentage of patients you see with this condition - __ %
ii) Typical time required for trial reduction - __ mins
iii) Typical number of iterations in trial reduction - __ iterations

C. Severe varus/valgus and/or flexion contracture deformities(s) (> 15 degrees)
i) percentage of patients you see with this condition - __ %
ii) Typical time required for trial reduction - __ mins
iii) Typical number of iterations in trial reduction - __ iterations

5. In what percentage of procedures does an imbalance problem or less than optimum range of motion become apparent post-operatively that was not apparent during intra-operative assessments? - ______ %

Potential Utility of Measuring Device

6. How beneficial do you feel quantitative measures of the following parameters will be in improving consistency and quality of soft-tissue balance?

Please rank on a scale of 1-3 with:
3 = Definitely beneficial
2 = Potentially beneficial
1 = Not beneficial
0 = Unsure

Range of motion (flexion and extension) - rank: __
Ligament tensions - rank: __
Contact pressure across joint - rank: __
Tightness/looseness of joint - rank: __
Degree of component yawning during flexion tests - rank: __
Ability to monitor grade of release - rank: __
Ability to check overall balance prior to closing - rank: __

7. In what percentage of procedures would you use a quantitative measurement device to:

A. Assist in the grading (optimizing) of soft-tissue releases through quantitative feedback. - ______ %

B. Provide a final check of soft-tissue balance against pre-determined criteria. - ______ %

8. What do you feel would be a reasonable cost for such a device? - $__________

9. How useful do you feel such a device would be in training Orthopaedic surgeons?

Please rank on a scale of 1-3 with:
3 = Very useful
2 = Of some use
1 = Of no use

rank: __

Surgical Experience

10. How many years have you been a practicing Orthopaedic surgeon? - _____

11. On average, how many TKA procedures do you perform a year? - ______ knees

If you have time, we would appreciate you thoughts on the following issues:

12. Are there any specific areas of concern surrounding soft-tissue balance that you would like to see addressed, or where an assistive device may be beneficial?

13. Do you find valgus correction more difficult than varus correction? Please Explain.

14. Do you feel that you have adequate control over the extent of soft-tissue releases that you perform?

15. Do you feel that the value of this device would be different in revision surgery?

16. Any other questions or concerns.

Thank you very much for your co-operation; your help is greatly appreciated.

The first question concerning representation of unsolved problems in current practice which are under the surgeon's control was asked to get an understanding of how soft-tissue balance compares with other problems in TKA. The results are summarized in Figure 1.12. Of the problems listed, only three are immediately apparent at the time of operation: implant malalignment,

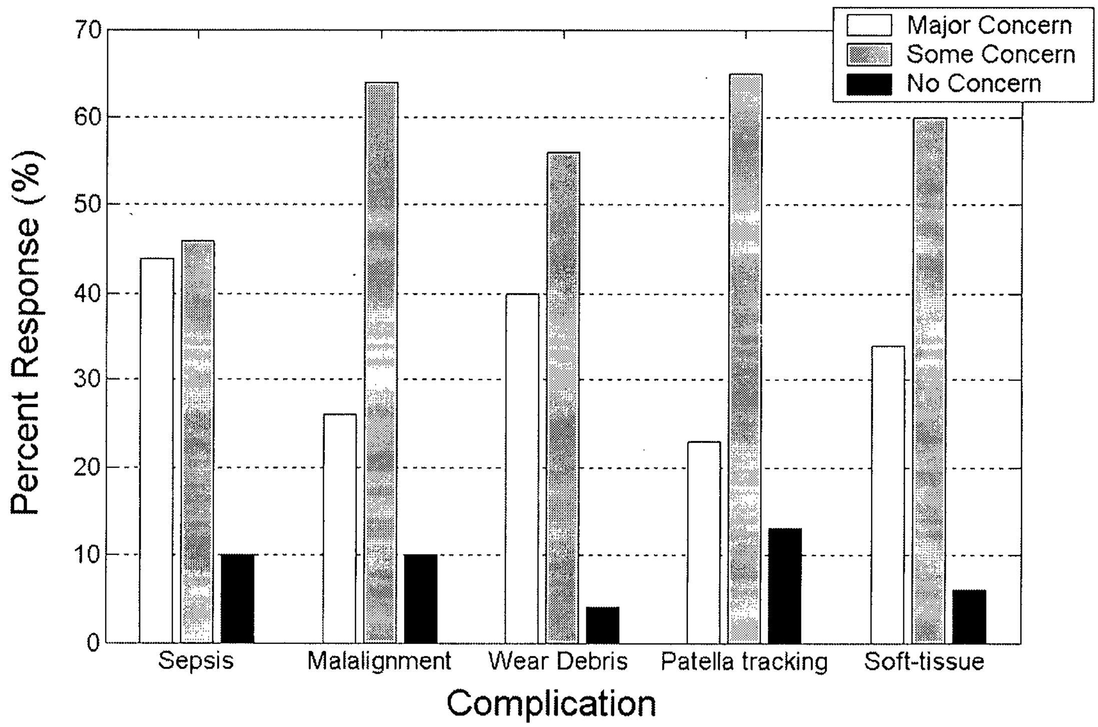


Figure 1.12 - Survey response for question one. Representation of unsolved problems in current practice

patellofemoral tracking and soft-tissue imbalance. Debris from wear sites emerges over the longer term and is generally caused by malalignment or ligament imbalance. Sepsis is generally related to patient factors and/or the operating environment. The respondents to this survey indicated that soft-tissue balance is in fact more of a concern than implant malalignment or patellofemoral tracking.

Questions two and three were asked to assess the perceived frequency of soft-tissue balance problems in TKA. The average response was 11% (range 1%-50%) of procedures result in complications due to soft-tissue imbalance. The average response for what percentage of procedures surgeons felt fully satisfied with soft-tissue balance was 82% (range 11%-100%). These numbers do not differ largely from the failure and survivorship rates of primary TKAs reported in literature. Questions four and five on the survey were asked to better understand the technical challenge soft-tissue balance represents. The results from question four are summarized in Figure 1.13. The average response for question five was that in 9% of procedures an imbalance problem or less than

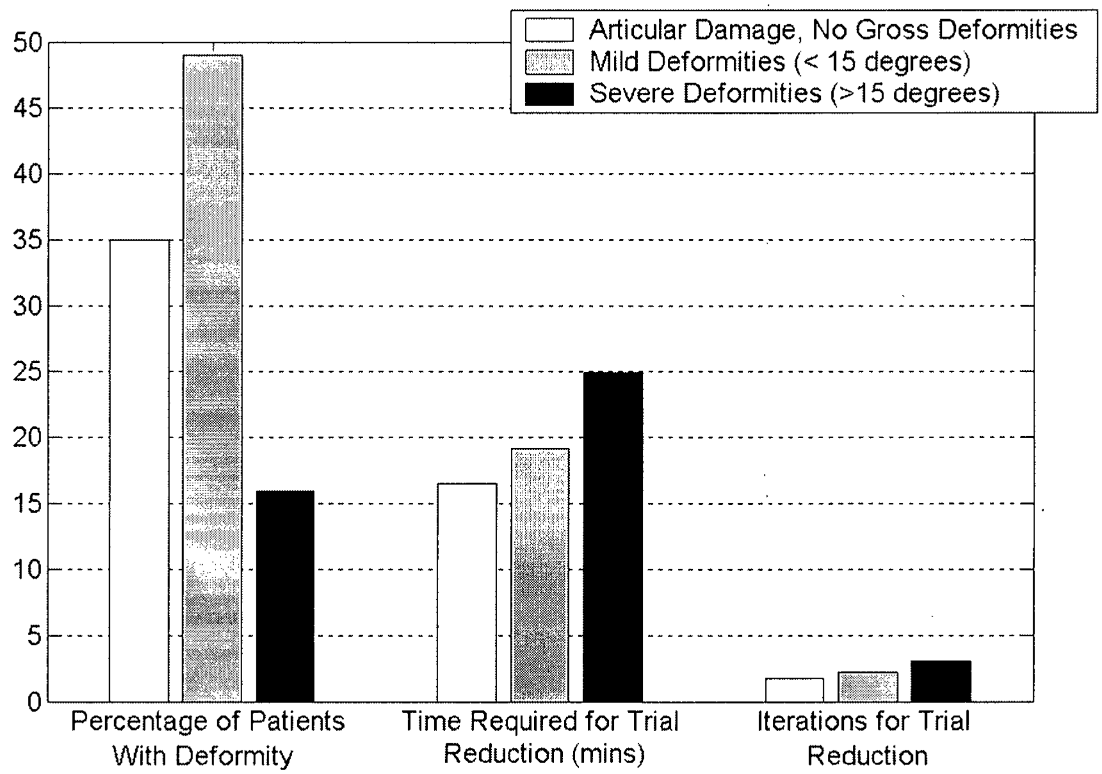


Figure 1.13 - Survey response for question four. Technical challenge of soft-tissue balance.

optimal range of motion becomes apparent post-operatively that was not apparent during intraoperative assessment (range of responses 0%-40%). These results indicate that soft-tissue balance is a challenging part of the surgery with more time and effort spent on knees with higher degrees of deformity.

Questions six through nine address the potential utility of a measuring device for use in soft-tissue balance. Question six looked at the utility of a measuring device for use in specific aspects of the surgery and the results are summarized in Figure 1.14. Areas where a measuring device would provide the most benefit included: ligament tensioning, assessing the tightness or looseness of the joint, correction of ligament contracture, correction of alignment and for use as an overall check of balance prior to closure. Surgeons indicated that they would use quantitative feedback of a measuring device to assist in the grading of releases in 42% (range 0%-100%) of procedures on average, and as an overall check of balance prior to closure in 53% (range 0%-100%). Forty-five percent of

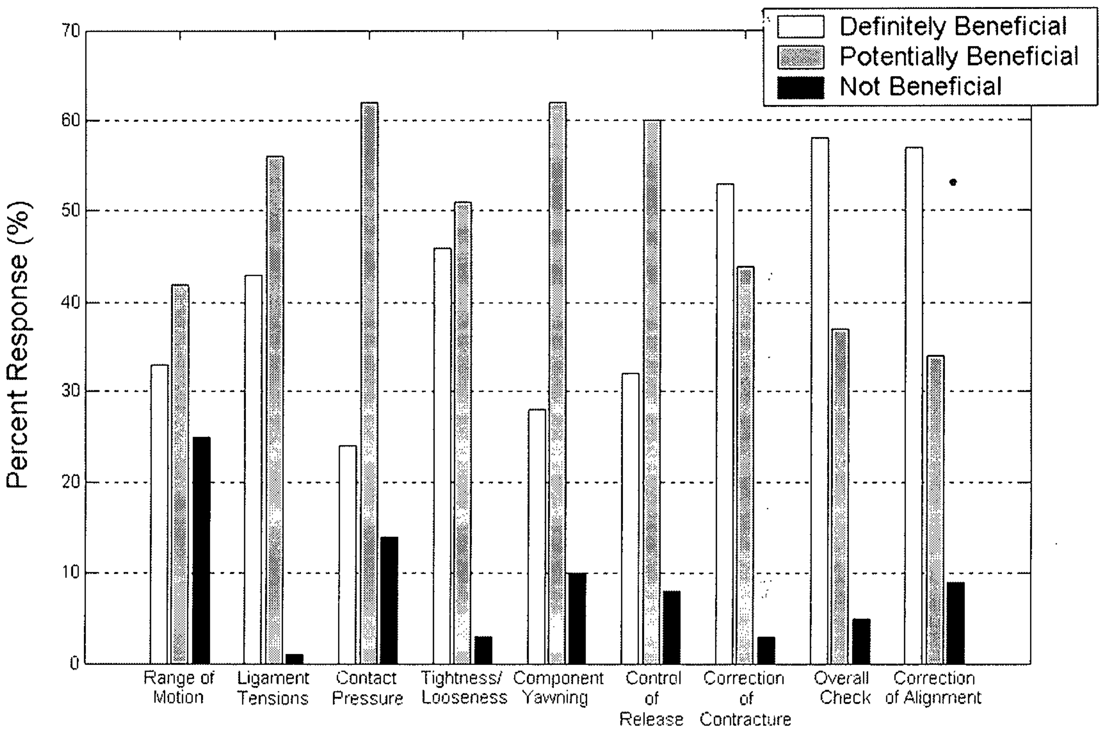


Figure 1.14 - Survey response for question six. Utility of a measuring device for use in specific aspects of the surgery.

surgeons felt that a measuring device would be very useful in training new surgeons and the average price they felt such a device would be worth was \$1000.00 Cdn.

The average experience of the respondents was 16 years (range 3-30 years) and 59 procedures per year (range 5-175 procedures/year). Comments from the surgeons included:

- Most surgeons indicated that valgus correction is more difficult than varus correction. This is due to the fact that it is performed less frequently, potential injury to the peroneal nerve limits the extent of the releases, more complex anatomy is involved, patellar problems are more common, and more severe bone deformity is typically present.

- Surgeon opinion varied as to whether they felt they had adequate control over ligament releases. Most of those who felt they did attributed this to experience and great care in performing the releases.

- Many surgeons felt that quantitative measurement of soft-tissues would prove more valuable in revision surgery due to the absence of landmarks, the uncertainty of constraint integrity and importance of proper joint line restoration.

- Surgeons expressed interest in the ability to determine optimal posterior tilting of the tibial component, optimal rotational alignment of the femoral component and optimal sequence of releases.

- Surgeons felt the cost of the device would depend on its success in terms of its reliability, ease of use and the value of information it could provide.

- "The ability to assess balance throughout the complete range of motion rather than just the flexion and extension gaps would be helpful. Also the ability to assess balance with the patella reduced would be helpful."

The survey indicated that practicing surgeons in Canada feel soft-tissue balance is an area well worth addressing in TKA. The survey also indicated that the ability to measure the state of the soft-tissues intraoperatively would prove very beneficial for guidance during balancing, for checking balance prior to closure and for training of new surgeons.

1.6 Quantification of Soft-Tissue Constraint

Ligament balance problems continue to be a leading cause of poor outcomes in TKR, and their prevention is the most technically demanding yet least controlled and understood aspect of current surgical technique. Surgeon skill and experience are crucial and success depends on making good qualitative judgments under less than ideal conditions during the operation. Soft-tissue balance is difficult to perform for several reasons. It is not always clear which structures should be released and in which order to perform such releases. It is difficult to control the grade of releases and their effect is not always easy to predict or assess. It is often difficult to characterize the state of the ligaments and other soft-tissues due to the fact that they may be deformed from the arthritic process and they must be evaluated in a surgical environment.

Despite the consequences of failing to achieve proper balance, there are no commonly used techniques for objective intra-operative assessment of soft-tissue restraint. This is clearly an area in need of technical development (Cooke, 1998; Sambatakakis, 1991). This type of measurement would prove beneficial in several aspects of the surgery. With intraoperative quantitative measures of imbalance, surgeons would be able to more accurately alter the state of the soft-tissues to approach predefined conditions of balance. This would be particularly useful for training new surgeons, as well as for assisting those surgeons who perform the procedure comparatively infrequently. Perhaps most importantly, as stated by Sambatakakis (Sambatakakis, 1992), the allowable limits for imbalance can only be established by the long-term follow-up of balanced and imbalanced arthroplasties. To discuss the problem quantitatively, a clear definition of balance and how to measure it needs to be developed.

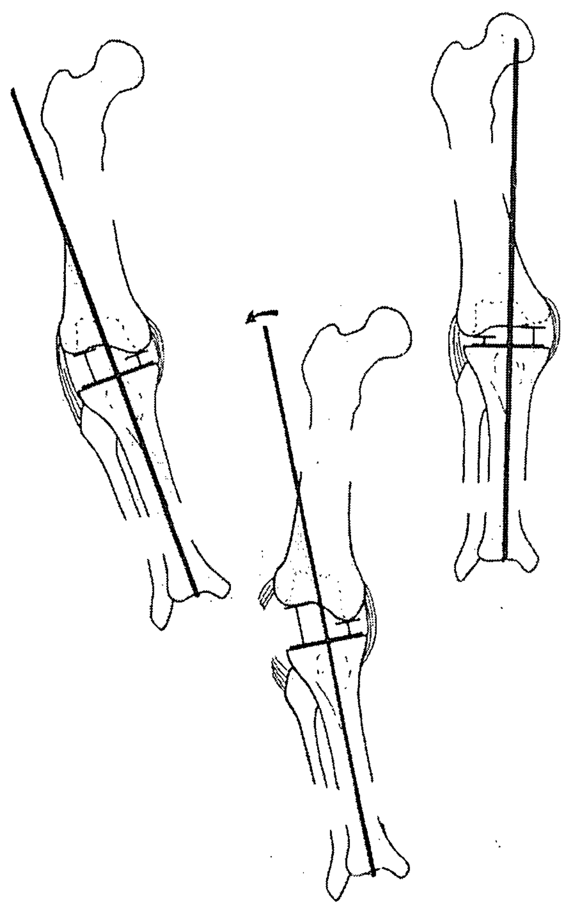


Figure 1.15 - The Tenser (after Freeman, 1978)

1.6.1 Attempts to Quantify Soft-Tissue Constraint

Numerous approaches have been proposed to address the need to quantify ligament balance intraoperatively (Attfield, 1994; Sambatakakis, 1992; Stulberg, 2001; Takahashi, 1997; Wallace, 1998). The two main categories are: (1) tensioning devices which apply loads to the collateral ligaments and indicate imbalance by means of an angle measurement, and (2) pressure sensors which assess contact pressures in the medial and lateral knee compartments.

Freeman (Freeman, 1978) introduced an instrument, the Tenser, which applied a distracting force to the extension gap, and related the soft-tissue changes to the mechanical axis of the femur (alignment, Figure 1.15). Since then

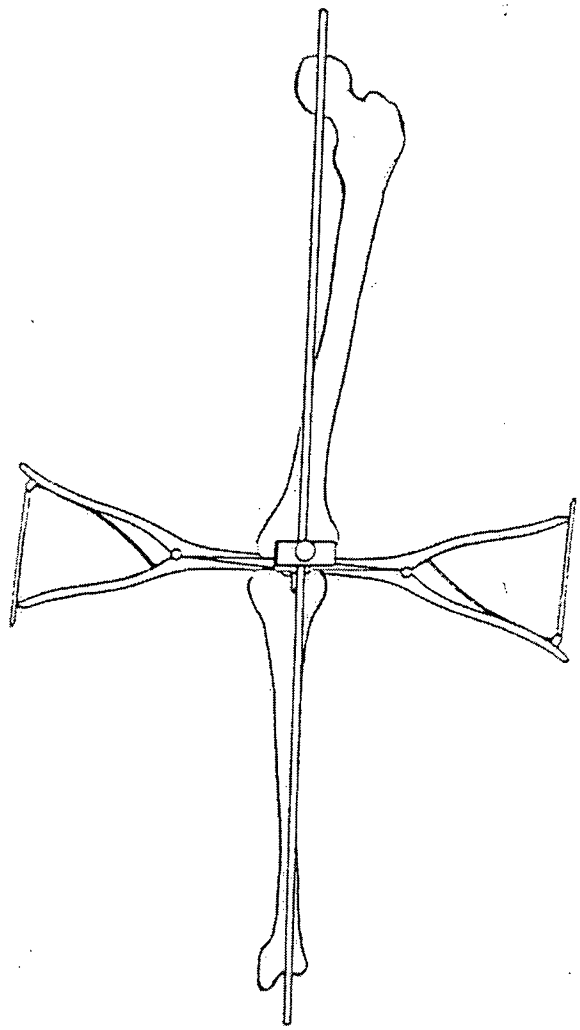


Figure 1.16 - Laminar spreaders used as tensers (after Laskin 1989)

numerous modifications to the basic concept of the Tenser have been described and used (Insall, 1985; Krackow, 1991). Laskin (Laskin, 1989) described the use of two laminar spreaders, one in each compartment of the knee, to diagnose imbalance during the operation in a similar fashion (Figure 1.16).Sambatakakis (Sambatakakis, 1992) developed a surgical instrument consisting of two plates separated by four compression springs at each corner. The plates were compressed before being inserted into either the flexion or extension gap using a specially designed applicator and then allowed to come to rest once released in the gap. Soft-tissue releases were then performed to bring the plates into a parallel configuration where balance was said to occur, as equal force would be applied by all four springs (Figure 1.17). Attfield (Attfield, 1994) developed an instrumented joint distraction device that is inserted into the flexion or extension gap and gradually separated. The instrument consists of two plates

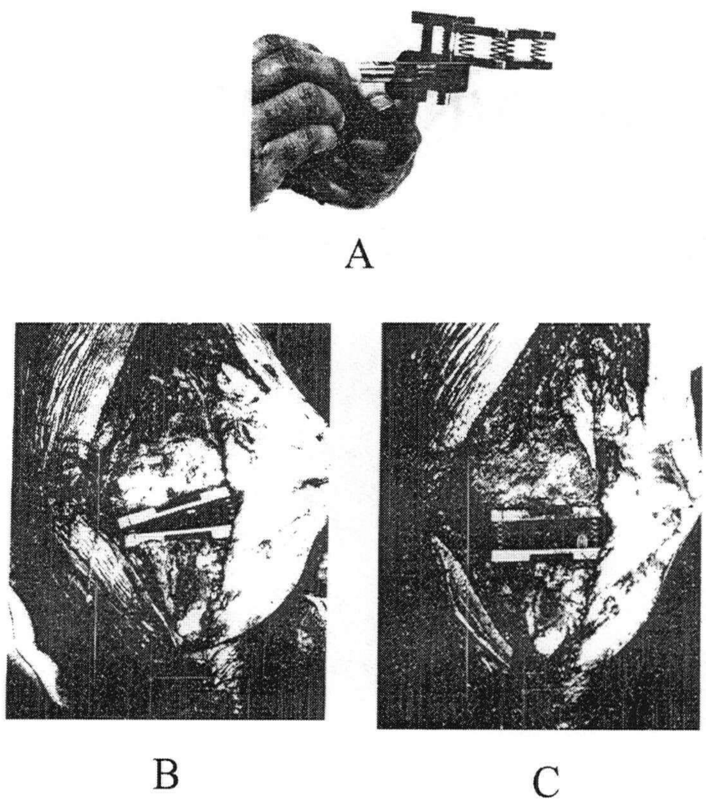


Figure 1.17 - Spring loader spacer used by Sambatakakis (Samabatakakis, 1992). A. Custom designed applicator. B. Instrument showing trapezoidal shape of soft tissue imbalance. C. Instrument showing parallel shape of balance after soft tissue release.

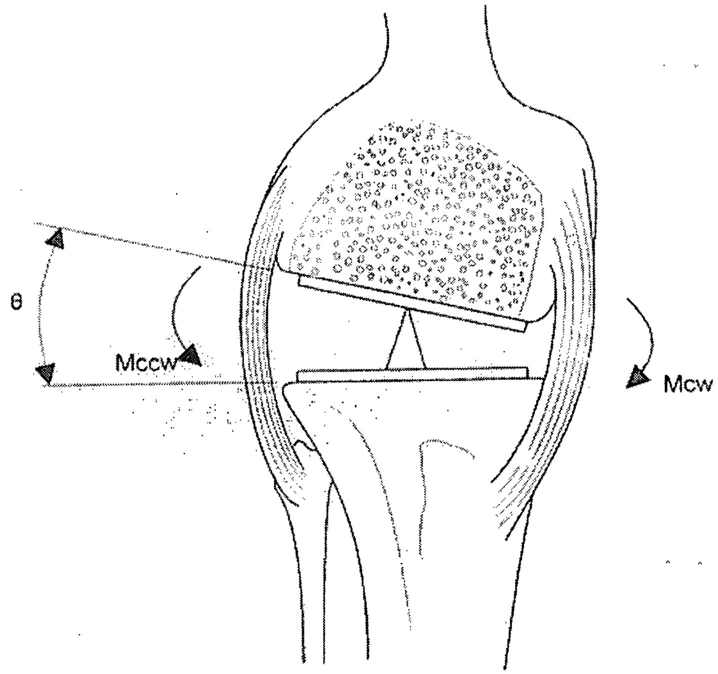


Figure 1.18 - Concept behind Attfield's device (Attfield, 1994). Imbalance is quantified by angular deviation between the upper and lower plates as distraction is applied through the centre of the knee.

that are separated using a ratchet mechanism. The top plate is able to pivot at the knee centre with respect to the lower plate. A ligament imbalance is defined as the change in angle between the two plates. They examined the degree of imbalance versus controlled 0.25 mm increments of distraction. The surgical goal was to release the ligaments to obtain a rectangular joint space under a controlled amount of distraction, indicating equal load in the medial and lateral collaterals for the given bone resectiongeometry. Several similar designs have been developed by other authors (Ashby, 1999; Nuelle, 2000; Rohr, 1986).

Takahashi (Takahashi, 1997) used pressure-sensitive film (Fugi Photo Film Co.,Tokyo, Japan) in 63 knees in an attempt to minimize collateral and lateral retinacular releases. The film was placed between the femoral and tibial trial components and the contact pressure imposed by the surrounding soft-tissues measured. Wallace (Wallace, 1998) used an electronic pressure transducer interfaced to K-scan™ software (Tekscan Inc., Boston, MA) on one patient tomeasure tibiofemoral contact stresses after various releases had been performed.

The tensioning methods in general are limited in that they only assess the flexion and extension gaps. The degree to which they provide quantitative measures of balance may also be debated. Another consideration is that the flexion-extension gap balancing technique does not imply ligament balancing, per se (Krackow, 1991). One can have taut posterior soft-tissues that give the sensation of ligament balance in extension, and collateral tissues that give ligament balance in 90 degrees of flexion; but in midrange there is, in fact, ligamentous collateral laxity as the posterior soft-tissues are loosened. Even for correctly balanced flexion and extension gaps, mid-flexion over-tightening or instability may be present which would go undetected. This is due to the choice of femoral component radii with respect to the corrected anatomy. Figure 1.19 illustrates how a midflexion instability may occur despite having properly sized flexion and extension gaps if the femoral component is improperly placed or oversized (Jiang, 1993). In contrast, the methods that measure contact

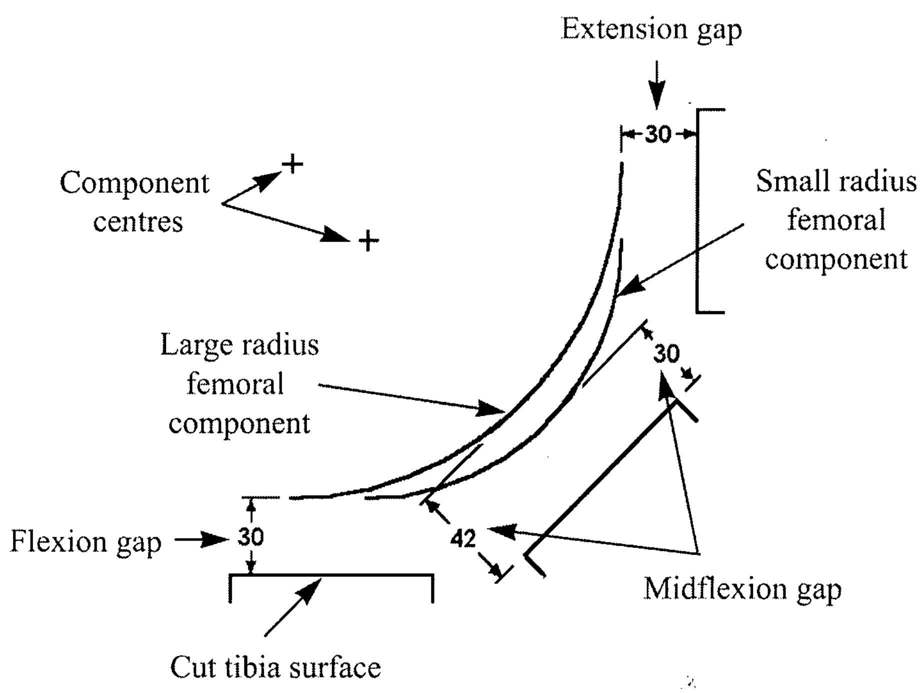


Figure 1.19 - Despite having equally sized flexion and extension gaps, selection of the large radius femoral component will lead to midflexion instability.

pressures between the trial and final components do have the potential to measure mid-flexion instability or excessive tension. These methods do not measure tension or imbalance directly, but infer it from the distribution of contact pressure. These methods have technical limitations such as temperature dependence, limited range and resolution, poor flexibility and frequent calibration.

Recently, computer-assisted surgical (CAS) systems have been introduced for TKA and commercial systems (e.g., Aesculap's Orthopilot™) are now available. The primary intent of these systems is to reduce the malalignment of the tibia and femur by measuring the locations of the hip, knee and ankle centres, and guiding the relevant bone cuts to ensure that the mechanical axis of the reconstructed limb passes from the hip centre to the ankle centre through the knee centre. Much of this research has focused on determining the proper component alignment while relying on conventional techniques for soft-tissue balance. Soft-tissue balance is not explicitly supported by current systems, although some authors have used the motion measurement capabilities of the systems to check, the degree of slackness of the collateral ligaments when varus/valgus torques are applied to the knee (Kunz, 2001; Stulberg, 2001).

All the systems described above are designed for use after the surgeon has made the transverse cuts on both bones and the posterior cut on the femur and, in the case of the pressure sensors, after the surgeon has inserted the trial components. Many factors are involved in successful knee replacement including component selection, component placement (bone cuts) and soft-tissue constraint. The surgeon's component selection and placement may change after soft-tissue releases have been performed and balance re-assessed. At this time, in order to alter the component placement or size, additional bone cuts must be made, increasing surgical time and the amount of bone resected. There is also the possibility that the surgeon has overcut the bones requiring shims or less than ideally sized components to be implanted. The ability to assess and perform soft-tissue balancing prior to performing bone cuts would eliminate this problem and allow surgeons to include soft tissue considerations in the planning process of the TKA.

1.7 Kinematic Knee Models

Proper knee function is dependent on interactions between the articulating surfaces of the prosthetic components and the surrounding ligaments of the knee, which is determined by the surgical placement of the components and state of the ligamentous structures (Wilson, 1998). In TKA procedures the shape and size of the articular surfaces and their locations relative to the ligaments are changed. Through the process of soft tissue balancing, the ligaments are also modified in an attempt to match the newly implanted components. These factors affect knee function in a complex manner such that changing a single factor often results in a global change of knee function. General guidelines exist as to what strategies to use to correct specific mechanical problems, but often the decision is not clear due to the complex interdependencies of the parameters involved in the procedure. To determine the optimal interaction of these structures, a method to predict clinically relevant performance measures must be available intraoperatively. Knee models show great potential for simulating and analyzing these interactions. The ability to simulate a surgical strategy and evaluate its effect on knee function intraoperatively would be a tool of great value, especially in difficult cases where the decisions are not clear.

The introduction of CAS systems in TKA has allowed for the real-time intra-operative application of computer knee models in the surgical procedure. Incorporation of kinematic knee models into a more comprehensive surgical planning and guidance system has great potential for improvements in long-term outcome (Chen, 2001).

Many passive kinematic knee models have been described and validated in literature. Although, passive kinematics does not reflect how the knee will behave under full weight bearing and muscle loads, the passive behaviour is still of interest as this is how the surgeon evaluates function in the operating room when the patient is anesthetized. These models range in application but have typically been used to understand the mechanical role of anatomical structures in passive motion of the knee.

Wismans (Wismans, 1980) described a three-dimensional mathematical model of the intact knee. He approximated the articular surfaces as rigid polynomials in space and the surrounding ligaments and capsule by non-linear springs. For given three-dimensional loading at various flexion angles, the location of contact points, magnitude and direction of contact forces, magnitude of ligament elongation and ligament forces can be calculated. For this model, material properties were found from literature, and Wismans concluded that the predictions of the model agreed well with experiments described in the literature. Blankevoort's group has described a three-dimensional model (Blankevoort, 1991; Blankevoort, 1996; Mommersteeg, 1996) that is one of the most complex models in current literature. It requires as input the geometry of the articular surfaces and the ligament insertions (including individual fibre bundles), along with the mechanical properties of the ligaments and articular cartilage (for natural knees) or polyethylene tibial insert (for prosthetic knees). Quasi-static knee kinematics are found by equilibrating the forces and moments on and about the soft-tissues and deformable surfaces. The study revealed that including deformable contact did not substantially alter the motion characteristics from that predicted by non-deformable contact. The model was validated by obtaining input data from a single cadaver knee specimen and comparing model predictions to experimental loading on the same specimen.

Blankevoort (Blankevoort, 1991) also described a three-dimensional knee model that took into account the wrapping of the MCL around the bony edge of the tibia. He compared the effect of the bony interaction on varus/valgus and internal-external rotation laxities. It was found that, in comparison with a model without bony interactions, the bony edge redirected the ligament force of the MCL in such a way that it counterbalanced valgus moments on the tibia more effectively. The effect of the bony interaction with the MCL on the internal-external rotation laxity, however, was negligible.

Wilson (Wilson, 1998) investigated the hypothesis that passive knee flexion is guided by articular contact and by isometric fascicles of the ACL, PCL and MCL. In his model the medial and lateral articular surfaces and the isometric fascicles in the ACL, PCL and MCL are represented as five constraints in a one degree-of-freedom parallel spatial mechanism. This model is simpler than those presented by Blankevoort's group as it models ligaments as a single inextensible fascicle, has non-deformable articular surfaces and is restricted to passive motion. The model was validated using a cadaver specimen with reasonable results as the kinematic predictions corresponded well with the measurements of the cadaver specimen's motion.

Models have also been developed specifically for understanding the passive and active kinematics of TKA. Essinger (Essinger, 1989) developed a three-dimensional model to evaluate the mechanical behaviour during flexion of a condylar-type knee prosthesis. The model is based on the minimization of total strain energy in all deformable components and takes into account the articular surfaces (with a deformable tibial insert), body weight, and strain in all four primary ligaments and the patellofemoral joint. The model generates the kinematics of the joint, the motion of the centre of contact, the quadriceps force, the pressure distribution on the tibial plateau, and the ligament lengths and forces between 0° and 120° of flexion. The model predictions were reported to be consistent with those reported in literature.

Martelli (Martelli, 1998) described a simplified version of Essinger's model in which the passive kinematics in a two-dimensional knee model are determined from the minimization of the strain energy in the LCL, MCL and PCL. In her model she assumed all articular surfaces to be rigid. Chen (Chen, 2001) furthered Martelli's model by extending it to three dimensions and representing the ligaments as multi-fibred bundles. This model was used for predicting both instability and the range of knee motion based on intraoperative measurements of ligament anatomy and component positions. Good correlation was found between predicted and measured outcomes in 10 procedures, through subjective evaluation by the participating surgeon, although it is often difficult to locate the ligament origins and insertions accurately in the operating room and the repeatability of this procedure has not yet been reported.

For intraoperative use of a knee model it is essential that inputs can be accurately and rapidly obtained. It is also important that the model be computationally efficient so that results can be obtained in a timely fashion to limit the impact on surgical completion time. These requirements necessitate the use of a simple yet sufficiently accurate model in terms of its ability to predict clinically relevant parameters. The model developed by Martelli and Chen meets these requirements as it is limited to passive kinematics, assumes rigid contact of articular surfaces (which was shown by Blankevoort's group and Wilson to be a reasonable assumption) and has a small number of simple inputs that may be quickly obtained intraoperatively.

1.8 Inspiration for Proposed System

We are currently developing a CAS system at the University of British Columbia that incorporates an optoelectronic localizer (Flashpoint 5000™, Image Guided Technologies, Boulder Colorado) to improve the accuracy of the registration and performance of the bone cuts while also reducing the invasiveness of the procedure. This system is non-CT or MRI based (no image acquisition) and determines the patient anatomy through biomechanical manipulations and direct digitization. As is typical of most TKA CAS research, we have focused to date on registration of landmarks and accuracy of bone cuts to obtain proper alignment. We wish to enhance the capabilities to the system to meet the current need for quantitative soft-tissue assessment, without introducing significant changes in the hardware or any dependence on image data. We have outlined the following objectives for further development of the system:

1. Incorporate quantitative intraoperative soft-tissue guidance.

2. Allow for soft-tissue considerations to enter into surgical planning.

3. Allow for intraoperative simulation of alternative component placements.

Through the use of a kinematic knee model, we feel that we can meet these objectives and provide the surgeon with a comprehensive surgical planning and guidance system that incorporates both bony alignment and soft-tissue balance considerations. The proposed system is meant to play an advisory role only and does not substitute for the surgeon's diagnostic, planning, implant selection, and final implant installation skills.

In this thesis, I outline two specific algorithms that are required for these objectives to be realized. The first is an intraoperative method to precisely identify ligament anatomy for use in a kinematic knee model using the CAS system. The second is a method to determine the component placement that minimizes ligament strain and laxity throughout the entire range of motion of the knee. Both methods are requirements for a comprehensive surgical advisory system.

1.8.1 Identifying Ligament Anatomy

The passive kinematic knee model developed by Martelli and furthered by Chen shows great potential for use in TKA procedures as it allows the surgeon to predict the consequences of a proposed component placement. By going through this process before making the cuts, the surgeon has an opportunity to make intraoperative surgical adjustments. For this model, the inputs include the knee joint geometry, the attachment sites and neutral lengths of individual ligaments, the surgeon's choice of implant placement and the degree of flexion of the knee. The outputs of the model are the location of the contact point between the components' bearing surfaces and the resulting state of the ligaments. By evaluating the model at successive degrees of knee flexion, a quasi-static representation of the kinematics of the knee joint and the resulting strain in each ligament throughout the range of motion is found. The model is sensitive to the accuracy of the inputs. Although the component geometries are well known and their placement can be accurately specified, it is difficult to obtain accurate information regarding the ligament lengths and attachments due to the limitations present in the intraoperative environment. During surgery, access to the ligament origin and insertion sites is limited and overlying soft tissue and bodily fluids hamper clear visualization. The attachment sites of the ligaments cover a small area of bone, making it difficult to identify a unique attachment. Martelli performed relatively crude measurements using engineering calipers and claimed ligament measurement to be the most critical step in building an individual model of the knee.

In chapter two I introduce a method to intraoperatively determine the functional attachment sites and lengths of the ligaments surrounding the knee. This information may then be incorporated into a model similar to those cited, to assess ligament balance throughout the functional range of knee motion. The method may be incorporated into our CAS system and requires no additional hardware. The measurements can be made prior to any femoral bone cuts and after a preliminary tibial cut. Motion data is captured while manually distracting and manipulating the knee to determine the effective ligament attachment sites and lengths. For the method to prove successful, it must be possible to repeatably identify the functional attachment sites and lengths of the ligaments surrounding the knee joint across different users and knees. Chapter two describes the formulation and validation of this method.

1.8.2 Optimal Component Placement

It is known that the geometry of the articular surfaces can affect the location of the contact point during knee motion and ultimately affect the trajectory of the leg (Essinger, 1989). The position and orientation of the implant can also significantly affect the pattern of knee motion (Martelli, 1998). Surgical implantation strategies, such as placement and sloping of the components, can affect the postoperative range of motion achieved. As a result, surgeons may choose to implant prosthetic components at different positions or orientations than those suggested by the manufacturer. However, the component geometries, component positions and orientations and the state of the ligamentous constraint all affect the knee kinematics in a complex manner such that changing a single factor often changes several key outcome measures. This makes it difficult for surgeons to decide what placement to adopt for a particular patient.

The literature supporting soft-tissue balance as an important factor in function and outcome has led some authors to consider soft-tissue balance as being as important, if not more important, than component alignment. Booth (Booth, 1999) stated that when given the choice, most successful knee surgeons would prefer the arthroplasty to be perfectly balanced even at the expense of slight malalignment. A total knee replacement with symmetrical soft-tissue balancing and 4 degrees of malalignment is more likely to have a longer life than a total knee with well-aligned components but 4 mm of laxity (Booth, 1999).

Given the existence of models that can predict various outcome measures as a function of component placement, I introduce an optimization algorithm to find the component placements that result in the best behaviour of the surrounding ligaments throughout the range of motion. As a first approach to the problem, I defined the optimal component placement to be the one which minimizes the strain and laxity in each ligament over the entire range of motion, although this criteria may be modified should some strain or laxity be desired as part of the ligament behaviour. The algorithm requires parameters describing the patient's ligament attachment locations and neutral lengths (as determined from my ligament identification method), as well as the geometries of the prosthetic components.

This method will provide valuable information to the surgeon, as it will present an alternative to the manufacturer's recommended placement. At this point the surgeon would have several alternatives. (1) They may wish to retain the manufacturer's recommended placement and analyze the resulting strain in the ligaments and passive kinematics. If acceptable they may proceed. Otherwise, (2) they may choose to modify the proposed placement of the component to match that recommended by the optimization algorithm. (3) They may choose re-run the optimization routine after customizing its parameters to determine a placement that is a compromise between perfect alignment and perfect soft-tissue balance. (4) They may choose to modify the soft tissues by performing additional releases such that the optimal placement would approach the manufacturer's placement. (5) They may simulate implanting different components (size or shape).

1.9 Thesis Overview

The thesis organization is as follows:

Chapter 1: Introduction, justification and literature review: Includes results from nationwide survey of orthopaedic surgeons to assess the current view of the importance of soft-tissue balance in TKA

Chapter 2: Formulation and validation of intraoperative ligament measurement technique. Results from testing on porcine specimen. This chapter is presented in journal submission format.

Chapter 3: Formulation and validation of component placement algorithm. Results from simulations and input data gathered from porcine specimens. This chapter is presented in journal submission format.

Chapter 4: Summary and conclusions, description of clinical use of the methods and indications of future work.

Appendix A: Intraoperative measurement of ligamentous constraint during computer-assisted total knee replacement. A pilot study presented at the Computer Methods in Biomechanics and Bio-medical Engineering Conference, Rome 2001.

Appendix B: Provisional patent application: Intraoperative measurement of ligamentous constraint during computer-assisted TKR.

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Chapter 2 - Quantifying Soft Tissue Constraint With Applications to Computer-Assisted Total Knee Replacement

2.1 Abstract

Current computer-assisted surgical (CAS) systems for total knee replacement focus on achieving correct bone alignment but do not assist in balancing the soft tissues to prevent instability or limited range of motion of the joint. Some devices exist to address this issue, but they require additional hardware and are typically used only after the bone cuts are made. We propose a manual manipulation technique performed in conjunction with a standard CAS system and show in a porcine model that we are able to obtain parameters of a ligament model with excellent intra- and interoperator repeatability (standard deviations on the order of 1 mm). This repeatability, if confirmed in human studies, would be sufficiently good to support using this technique to incorporate soft tissue balancing issues at the planning stage of computer-assisted total knee replacement procedures.

2.2 Introduction

One of the major goals of total knee arthroplasty (TKA) is to restore normal knee kinematics. To succeed, the surgeon must both restore the correct mechanical alignment of the leg through properly selecting and placing the implant components and achieve a matching balance of the ligaments through performing one or more releases (e.g., of a contracted ligament on the most affected compartment of an osteoarthritic knee) (Andriacchi, 1986; Chao, 1994; Faris, 1994). Ligament balance is important because the ligaments control relative movement of the femur and tibia when the joint surfaces are in contact and resist distraction of the joint when a tensile load is applied. If the ligaments are too loose at any point in the joint's range of motion, the knee is said to be unstable and could give way under the patient. If they are too tight, they could either limit the range of motion of the joint or tear under load, necessitating a repair procedure.

Despite the severe consequences of failing to achieve proper balance, surgeons rarely use objective methods to assess the results of their ligament releases, and soft tissue imbalance remains an important clinical problem. According to several studies, 10%-30% of revision procedures are performed because of instability, which is primarily attributable to incorrect ligament balancing (Fehring, 1994; Friedman, 1990; Rand, 1982; Tew, 1985). Sambatakakis (Sambatakakis, 1991) reported that 25.4% of 871 knees were imbalanced following a TKA procedure. In 2000, we performed a survey of orthopaedic surgeons across Canada (80 responses; ~50% response rate) and found that 95% ranked soft tissue balancing as a concern in terns of an unsolved problem in TKA. There would therefore appear to be a strong need for a practical technique to evaluate soft tissue balance intraoperatively; this would be particularly useful for training new surgeons, as well as for assisting those surgeons who perform the procedure comparatively infrequently.

Numerous approaches have been proposed to address this need to quantify ligament balance intraoperatively (Attfield, 1994; Sambatakakis, 1992; Stulberg, 2001; Takahashi, 1997; Wallace, 1998). The two main categories are: (1) tensioning devices which apply loads to the collateral ligaments and indicate imbalance by means of an angle measurement, and (2) pressure sensors which assess contact pressures in the medial and lateral knee compartments. The tensioning devices and certain pressure sensors (e.g., the Fuji pressure film) are typically used in full extension (and occasionally in flexion), whereas real-time pressure monitoring systems such as the K-Scan system can be used throughout the range of motion. With the tensioning systems, the knee is considered to be balanced when rectangular gaps have been obtained (and equally spaced when measured in both extension and flexion). All existing systems are designed to be used only after the surgeon has made the transverse cuts on both bones and the posterior cut on the femur and, in the case of the pressure sensors, after the surgeon has inserted the trial components. While each of the systems has its proponents, none have been widely adopted, possibly because of the additional hardware involved.

Recently, computer-assisted surgical (CAS) systems have been introduced for total knee arthroplasties (Leitner, 1997) and commercial systems (e.g., Aesculap's Orthopilot™) are now available. The primary intent of these systems is to reduce the malalignment of the tibia and femur by measuring the locations of the hip, knee and ankle centres and guiding the relevant bone cuts to ensure that the mechanical axis of the reconstructed limb passes from the hip centre to the ankle centre through the knee centre. There is some evidence that the accuracy of some components of the procedure is enhanced by these systems (Inkpen, 1999; Inkpen, 1998), although whole-system performance is still comparable to the manual procedure (Saragaglia, 2001) and the bone cutting process itself contributes significant variability (Plaskos, 2002). Soft tissue balance is not explicitly supported by current systems, although some authors have used the motion measurement capabilities of the systems to check, for example, the degree of slackness of the collateral ligaments when varus/valgus torques are applied to the knee (Kunz, 2001). Martelli (Martelli, 1998) and Chen (Chen, 2001) have developed a technique for predicting both instability and the range of motion of the knee joint based on intraoperative measurements of the origins, insertions and lengths of the various ligaments crossing the knee joint. Based on subjective evaluations by the participating surgeon, they have shown good correlations between predicted and measured outcomes (e.g., range of motion or slackness) in 10 procedures, although they did not report the repeatability of their procedure. In addition, it is often difficult to locate the ligament origins and insertions accurately in the operating room because the relevant landmarks are obscured by overlying tissue.

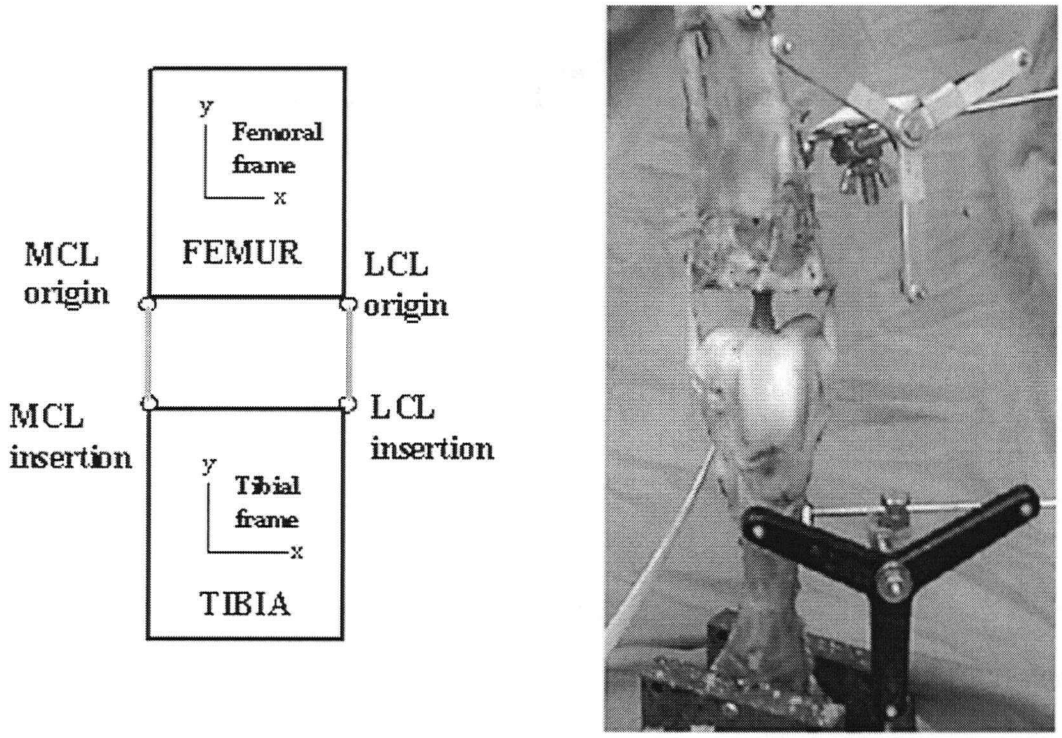
In this paper, we propose an alternative technique for intraoperatively identifying the effective ligament attachment sites and ligament lengths based on a manual manipulation process rather than digitization. We assume that the ligaments can be modeled as inextensible strings and we find the set of ligament parameters (origin and insertion coordinates and length) which best fit the data obtained during manipulation. This information may then be incorporated into models similar to those developed by Martelli and Chen to assess ligament balance throughout the functional range of knee motion. We expect that the attachment sites we identify will correlate well with anatomic attachment sites, most probably the portion of the site closest to the joint line. These anatomic attachment locations were used by Martelli, Chen and Wilson (Wilson, 1998) as inputs to their passive kinematic knee models. The method is intended to be used in conjunction with an existing CAS system for knee arthroplasty and requires no additional hardware. In contrast to most existing soft tissue assessment devices, the measurements could be made after a preliminary tibial cut, but prior to any femoral bone cuts. We hypothesize that the intra- and interoperator repeatability of this technique will be sufficient to support its inclusion in computer-assisted surgical systems for total knee arthroplasties. In this study, therefore, we assess intra- and interoperator repeatability as well as cross-specimen repeatability and the relation of the effective attachment sites to the corresponding anatomic locations. We also consider the significance of assuming that the ligaments behave as inextensible strings.

2.3 Materials and Methods

2.3.1 Modeling Ligamentous Constraint

As described above, we used a simple knee model in conjunction with a manual manipulation technique (in which we attempted to keep all the ligaments taut at all times) to determine the ligament attachment sites and lengths. We tested two models as part of this study: a two-ligament model consisting of only the collateral ligaments (medial and lateral – MCL and LCL, respectively), and a three-ligament model consisting of the two collateral ligaments and the posterior cruciate ligament (PCL). These two models represent the most common TKA procedures: a PCL sacrificing (or *substituting*) procedure, in which the PCL is resected, and a PCL retaining procedure.

We modeled the tibia and femur as blocks and the two or three remaining ligaments as inextensible strings attached to each bone at a single point (Figure 2.1). We did not model several other soft tissue structures surrounding the knee such as the joint capsule, iliotibial band and muscle attachments. The posterior capsule of the joint is taut only near full extension (O'Connor, 1990) and muscle attachments do not play a significant role in passive kinematics.



A B

Figure 2.1 - Conceptual and experimental models: A. Knee joint modeled as blocks and inextensible strings. B. Porcine specimen with marker arrays rigidly mounted.

As a first approach, the iliotibial band was not included as it is part of the insertion of the tensor fascia latta muscle and we therefore assumed it did not contribute significantly to the passive knee kinematics. We also considered that the ligaments passed directly from origin to insertion without wrapping around or otherwise interacting with the blocks. During the manipulation process, each of the bones had a marker array attached to it, which defined a local reference frame; as described in the next section, we used an optical metrology system to measure the spatial locations of the two marker arrays throughout the manipulations and at the end of the manipulation process we performed a fitting procedure to determine the optimal model parameters to describe the effect of the ligamentous constraint. These model parameters consisted of the origin and insertion coordinates of each ligament expressed in the appropriate local coordinate frame, from which the lengths of each ligament were found. We used knowledge of typical anatomy to make reasonable estimates for the model parameters prior to performing the optimization computations.

According to our model, the distance between the origin and insertion sites of each ligament should be invariant throughout the manipulations if the ligament remains taut and inextensible. The cost function which we minimized was therefore the sum of variances of all ligaments about their corresponding mean lengths:

$$C(p)=\sum_{i=1}^{N_l}\frac{1}{N_s}\sum_{j=1}^{N_s}(L_i(t_j,p)-\overline{L}_i(p))^2 \tag{1}$$

where N_l is the number of ligaments in the model, N_s is the number of measurements taken, t_j is sample time j, p is the parameter vector, and L_i is the Euclidean distance between the origin and insertion of ligament i at time t_j (found by computing the transform between the tibial and femoral reference frames, transforming the femoral insertion site into the tibial frame, and taking the difference between the origin and insertion locations, both expressed in the tibial frame). We used a non-linear least squares optimization algorithm (Trust-region reflective Newton method) to determine the parameter vector that minimized $C(p)$ over the entire dataset of measured positions.

This method assumes that the ligaments remain taut throughout the motion – a condition which may be difficult to guarantee in practice. To make the analysis more robust to occasional lapses in keeping one or more ligaments taut during manipulation, we implemented an algorithm in which we removed data points where one or more of the ligaments was found to be slack. The data is originally processed as described above, and the length of each ligament at each sampling instant is found. We assume that the set of estimated lengths for each ligament comes from a strongly asymmetrical distribution in which the upper limit represents tautness, and lower values represent slackness. We removed all data points where the estimated ligament length was 2 mm less than the median value (which represented outliers) and repeated the optimization.

2.3.2 Hardware

We used an optoelectronic metrology system to collect data during the experiment (Flashpoint 5000, Image Guided Technologies, Boulder Co.). Marker arrays consisting of three infrared light emitting diodes arranged in an equilateral triangle 120 mm on a side were rigidly attached to both the femur and tibia using custom-made bone pins (see Figure 2.1); these defined the femoral and tibial reference frames. The operator used a foot pedal to activate the data collection system during manipulation of the limb, and the system captured the marker positions every time one of the markers moved more than 2.5 mm from its previous location.

2.3.3 Model Validation

One of the sources of variability in estimating the model parameters is measurement noise in the metrology system. Image Guided Technologies reports that the Flashpoint 5000 system has a one-dimensional accuracy of 0.35 mm (RMS) when tracking infrared emitting diodes (IREDs) within a 1 m diameter volume. To assess the effect of this noise on the estimates of the model parameters, we performed a simulation using Working Model 3D© v3.0 (Working Model Inc. 1996) in which we created a model of similar geometry to the test specimens and moved it through a range of motion representative of that used in the experiment described in the following sections (the flexion range is typically ~90°). In addition, to test whether or not our simplified model could be used when more limited data is available, we performed a simulation in which the flexion range was limited to 0-30°. To simulate the Flashpoint's measurement noise, we added white noise with zero mean and 0.2 mm standard deviation in each principal direction (~0.35 mm RMS) and computed the resulting parameter vector. To assess the variability in the results, we repeated the process of adding noise and performing the optimization a total of 30 times for each combination of range of motion (30° & 90°) and model type (2 ligament & 3 ligament).

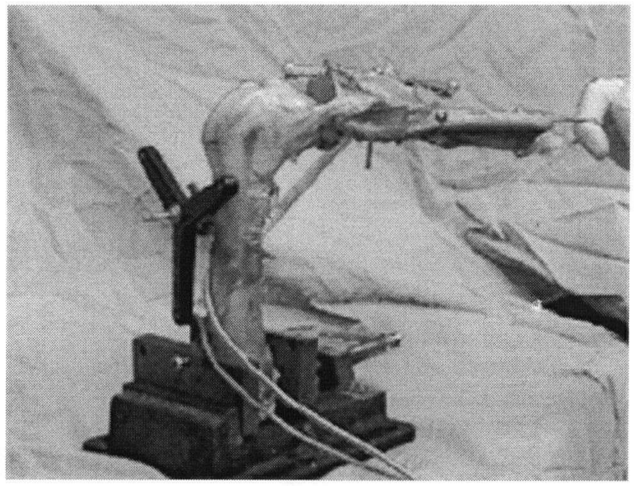


Figure 2.2 - Experimental setup showing porcine specimen under manual distraction.

2.3.4 Specimen Preparation and Limb Manipulations

We obtained six fresh frozen intact porcine hind limbs in accordance with the University of British Columbia animal testing regulations. The animals were six months old and had a mean weight of 150 ± 15 kg. Prior to testing, we allowed the limbs to thaw for a period of 10-12 hours. Each limb was dissected, leaving only the tibia, femur and relevant ligaments (MCL, LCL and PCL) intact. In addition, we removed the PCL from three specimens to create the two-ligament preparations. Using a surgical cutting guide and oscillating saw, we cut the proximal end of the tibia according to the manufacturer's recommendations (P.F.C. Sigma Knee System, DePuy Orthopaedics, Inc.). The proximal end of the femur was then rigidly mounted to a tabletop and the optoelectronic marker arrays attached to both the tibia and femur. A small cord was attached to the distal end of the tibia to allow the user to effectively grasp the limb and apply a distracting force (Figure 2.2). Care was taken to maintain distraction at a level greater than 90 N while capturing data. The user then manipulated the limb in seven distinct motions to explore all the potential degrees of freedom of the two bones and observe the constraint provided by the ligaments. These motions are illustrated in Figure 2.3 and represent anterior/posterior, medial/lateral and distal translations, as well as varus/valgus and internal/external rotations and flexion/extension motions around transverse axes at approximately the levels of the collateral ligament origins and insertions. For all the motions, care was

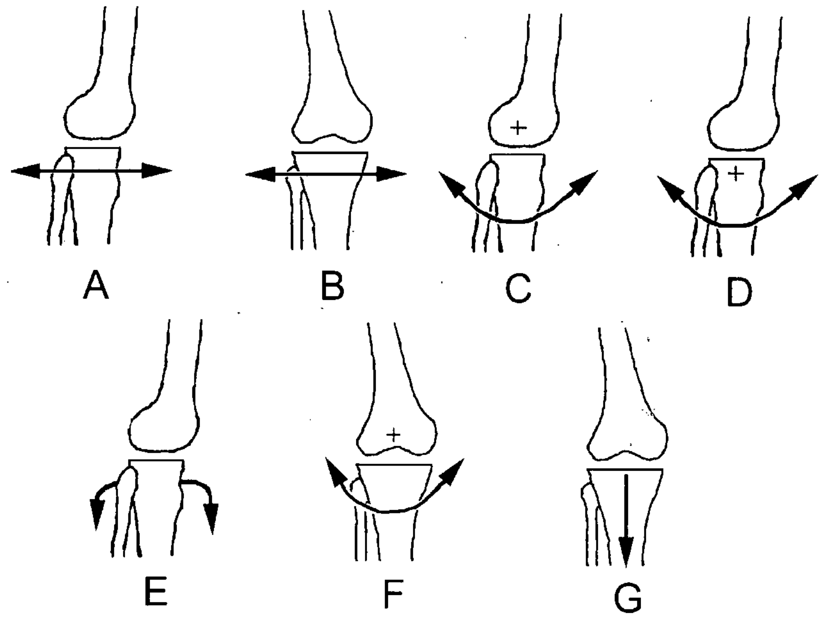


Figure 2.3 - Manipulations of the tibia with respect to the femur. A. **anterior/posterior translation,** B. **medial/lateral translation,** C. **flexion/extension about the origins of the collateral ligaments,** D. **flexion/extension about the insertions of the collateral ligaments,** E. **internal/external rotation,** F. **varus/valgus rotation,** G. **distal distraction.**

taken to ensure that all ligaments were taut throughout. Certain directions of force application produced negligible motion due to the ligamentous constraints. For example, the collateral ligaments essentially prevented varus/valgus rotation.

Our simplified model ignores wrapping effects (i.e., where the effective origin or insertion site shifts during manipulation) and changes due to different ligament fibres coming under tension at different flexion angles. To determine whether or not the apparent constraint changes with flexion angle, we asked the operators to perform the set of seven manipulations described above at three different flexion angles (0°, 45° & 90°); at each position, the range of flexion/extension was limited to about 30°. We analyzed the data for each position both separately and after combining all the data into a single larger dataset. A set of seven manipulations at each of the three flexion angles is considered one trial.

2.3.5 Experimental Protocol

We recruited three operators for this study with no previous surgical experience (male, aged 24-26). We randomly chose one porcine specimen from each of the two-ligament and three-ligament groups and had each operator perform 30 trials on both specimens so that we could assess intraoperator repeatability. All operators used the same two specimens so that we could assess interoperator repeatability. One operator additionally performed 30 trials on each of the remaining four specimens to determine interspecimen repeatability.

We used a stylus to digitize estimates for the origins and insertions of each ligament once per specimen. After all trials were performed on a specimen, we dissected the ligaments from the bones and digitized the perimeter of their anatomical attachment sites. We also estimated the locations of the hip and ankle centres. We used these digitized anatomical locations to construct anatomically meaningful reference frames at the centre of the distal femur and proximal tibia to clarify the presentation of our results, although the accuracy of our results does not depend on the accuracy or repeatability of defining these reference frames.

2.3.6 Data analysis

The output of the optimization resulted in 21 parameters for the three-ligament model (18 coordinates and 3 ligament lengths) for a single set of data and 14 parameters for the two-ligament model (12 coordinates and 2 ligament lengths). Each trial produced three primary datasets, one from each of the three nominal flexion angles. We constructed a fourth dataset by combining the three datasets from a single trial. To assess intraoperator repeatability, we use the χ^2 distribution to compute 95% CI's for the population standard deviations for each of the 21 variables over the 30 trials. To assess interspecimen repeatability, we compute 95% CI's for the population standard deviations of each of the parameters. Finally, to assess interoperator repeatability, we report 95% CI's for the difference in means of the parameters from each individual and the corresponding group mean.

2.3.7 *Fixed Point Constraint Identification*

The main application for an accurate assessment of the constraints imposed by the ligaments is computer-assisted surgery. For this application, we are not primarily interested in knowing the attachment site locations *per se*, but when the ligament will become taut; variation in the location of the attachment sites along the line of action of the ligament is almost irrelevant. To provide a more useful measure of the repeatability with which we can determine when the ligaments become taut, we select a fixed point on each bone for each ligament (here taken to be the mean origin and insertion sites found in the 30 trials) and compute the mean distance between these points for each trial. From the resulting distribution of 30 mean distances, we compute the standard deviation (which we will call the fixed point variability), along with the associated 95% confidence intervals (CIs). We hypothesize that the fixed point variability will be less than the variance in the attachment site locations and optimized ligament lengths themselves.

2.4 Results

2.4.1 *Model Validation*

Our simulations demonstrate that measurement errors do have a noticeable effect on the repeatability of the parameter estimates. Each panel in Figure 2.4 compares the 95% CI for the population standard deviation in the model parameters (averaged over all ligaments) as a function of the range of flexion motion through which the simulated joint was moved; the two panels show results for the two- and three-ligament models (left and right, respectively). The average repeatability for the two-ligament model exercised through the 90° range of flexion motion was 0.1 mm SD for locating the attachment sites. When the flexion motion was reduced to 30°, the repeatability for the attachment sites worsened by an order of magnitude to 1.3 mm SD. For the three-ligament model exercised through 90°, the attachment site repeatability was 0.4 mm SD. Again, attachment site repeatability increased to 2.5 mm SD with a reduced flexion range. (Note: all SD's reported are population SD's based on the χ^2 distribution, used to predict population variance based on sample estimate.) In

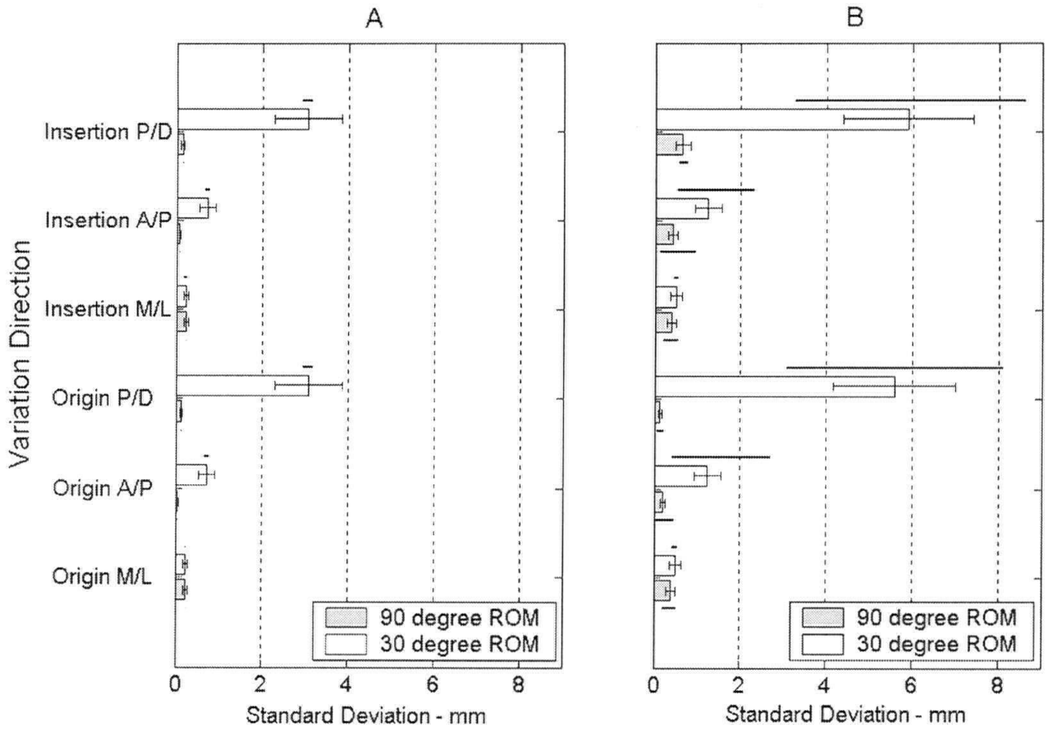


Figure 2.4 - 95% CI for the population SD in ligament attachment locations from model simulations for 30° and 90° ranges of motion. The variance is averaged over all ligaments. A. **Two-ligament model.** B. **Three-ligament model. (The solid line indicates ranges in SD for each parameter.)**

general, repeatability for the three-ligament model is ~2-3X greater than the two-ligament model for all cases. For both models the differences in ligament length repeatability between the 30° range of motion and the 90° range of motion were not significant. Although the variability associated with measurement errors alone is comparatively small for the full range of flexion, when the flexion range is decreased the variability increases to such a level that it may compromise clinical utility. Indeed, when we analyzed the portions of the experimental datasets corresponding to 30° flexion motions rather than the aggregated data, we observed unusably high variances in the parameter estimates (on the order of 3-7 mm). For this reason, in the balance of this paper we present results only for the aggregated datasets in which the total range of flexion motion is 90°.

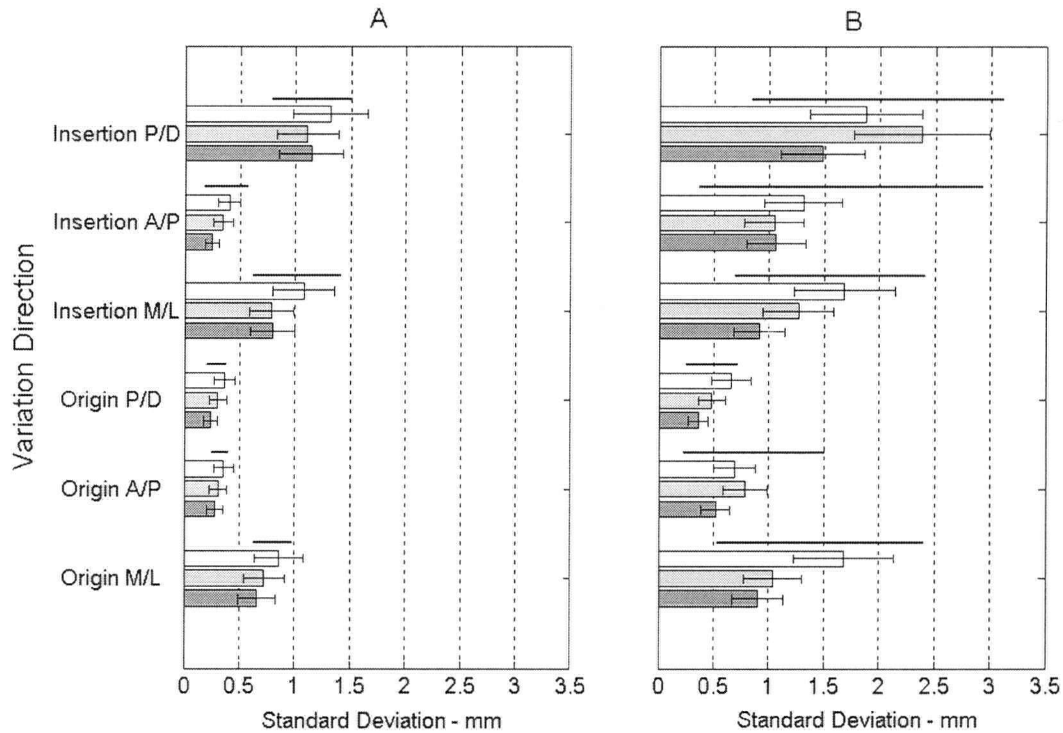


Figure 2.5 - Intraoperator variability: 95% CI for the population SD in ligament attachment locations performed on the same specimen. The three bands represent each of the three operators. The variance is averaged over all ligaments for more concise presentation. A. **Two-ligament model.** B. **Three-ligament model. (The solid line indicates ranges in SD for each parameter over all operators.)**

2.4.2 Intraoperator Repeatability

Figure 2.5 shows repeatability results from the experiment corresponding to the full range of motion simulation presented in Figure 2.4; each row contains three bars, one for each operator. As with Figure 2.4, Figure 2.5 shows the parameter 95% CI for the population SD averaged over all ligaments. For the two-ligament model, the standard deviations were on the order of 0.6 mm for ligament attachment locations and 1.3 mm for ligament lengths [ranges across the three operators: 0.2-1.3 and 0.8-1.7 mm]. Corresponding results for the three-ligament model were 50-80% higher at 1.1 mm and 1.9 mm, respectively [ranges: 0.4-2.4 and 0.6-2.8 mm]. (Note: all SD's reported are population SD's based on the χ^2 distribution.) Insertion locations showed the greatest variance for both models, with the largest variances in the proximal/distal direction.

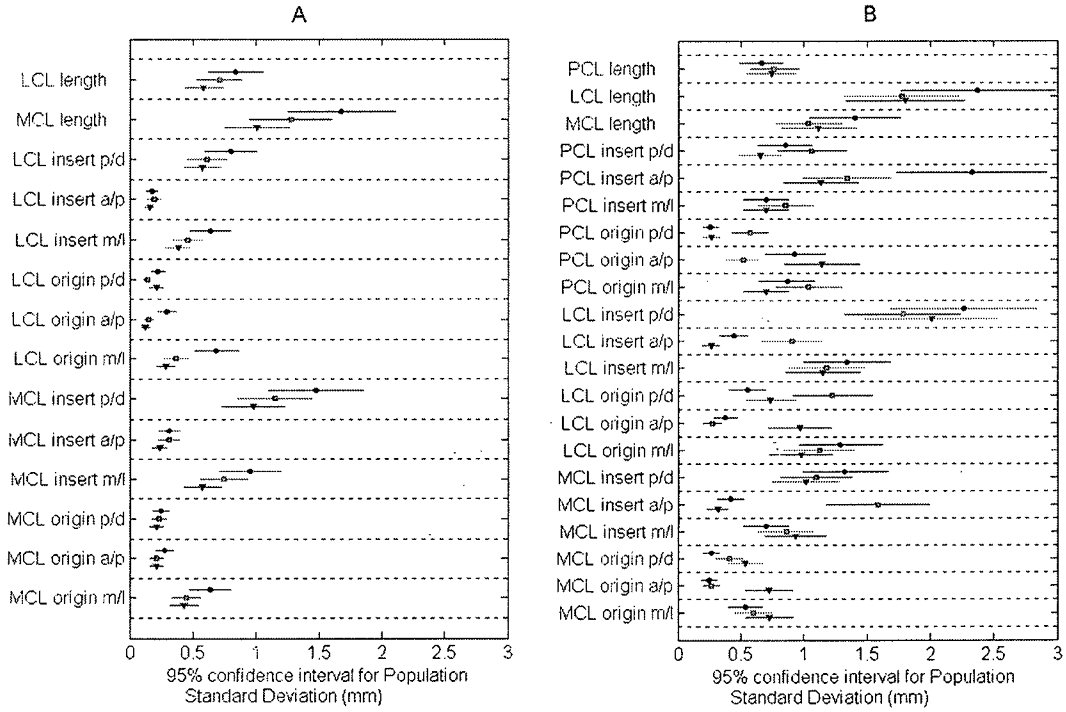


Figure 2.6 - Interspecimen repeatability; 95% confidence intervals of the population standard deviations for each output parameter based on a χ^2 distribution for three specimens. Manipulations on all three specimens performed by the same operator and represented by the three different symbols. A. **Two-ligament model.** B. **Three-ligament model.**

The variance in the ligament lengths throughout a manipulation using the optimized attachment locations for that trial gives an indication of the fitting error of the model. We computed these variances for each ligament in each trial. These values ranged from 0.5 mm to 0.7 mm, and the averages over all ligaments, trials and experimental conditions were 0.6 mm for both the two-ligament model (300 measures) and three-ligament model (450 measures).

2.4.3 Interspecimen Repeatability

Figure 2.6 presents 95% CI's for the standard deviations for each model parameter across the three specimens assessed by Operator A. Each specimen had similar deviations for all parameters. Larger differences were seen for the three-ligament model; although, only 4 of 21 parameters showed noticeable differences and all differed by less than 1.2 mm.

2.4.4 *Interoperator Repeatability*

Figure 2.7 depicts the difference of each of the three operators from the group mean, along with corresponding 95% CI's. For the two-ligament model, absolute differences were typically less than 1 mm with all parameters differing by less than 2 mm. The mean absolute difference was only 0.3 mm. The differences for the three-ligament model were substantially higher, with a mean absolute difference of 1.5 mm and a maximum absolute difference of 5.8 mm.

2.4.5 *Fixed Point Constraint Identification*

Figure 2.8 compares the variability in the "fixed point" estimate of ligament length (see §2.3.7) with the variability in the ligament length reported in §2.4.2 above. We computed the averaged fixed point variability estimate by first computing the fixed point variabilities and associated 95% CI's for each of the five experimental conditions (three operators on one specimen plus one operator on two additional specimens) and then averaging the CI's across the

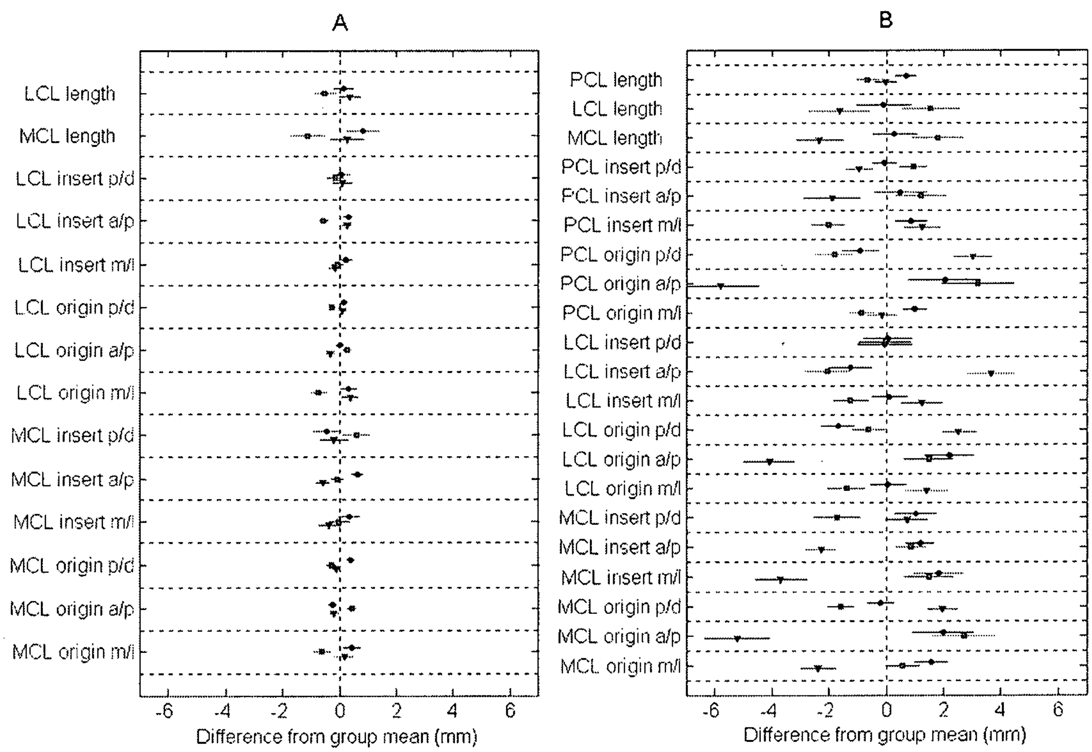


Figure 2.7 - Interoperator repeatability; 95% confidence intervals for the difference in means of each operator from the group mean for each output parameter. A. **Two-ligament model.** B. **Three-ligament model.**

five experimental conditions. For both the two- and three-ligament models, the fixed point method yields average standard deviations under 0.2 mm for all ligaments (average values of 0.1 mm and 0.2 mm for the two- and three-ligament models, respectively). These values are markedly lower than the values of 1.3 and 1.9 mm reported in §2.4.2 and the intratrial values of 0.6 mm computed using the optimized ligament lengths for each trial (also reported in §2.4.2). The average fixed point variability across all ligaments assessed by the three different operators on a single specimen ranged from 0.07 mm to 0.13 mm for the two-ligament model and from 0.1 to 0.4 mm for the three-ligament model.

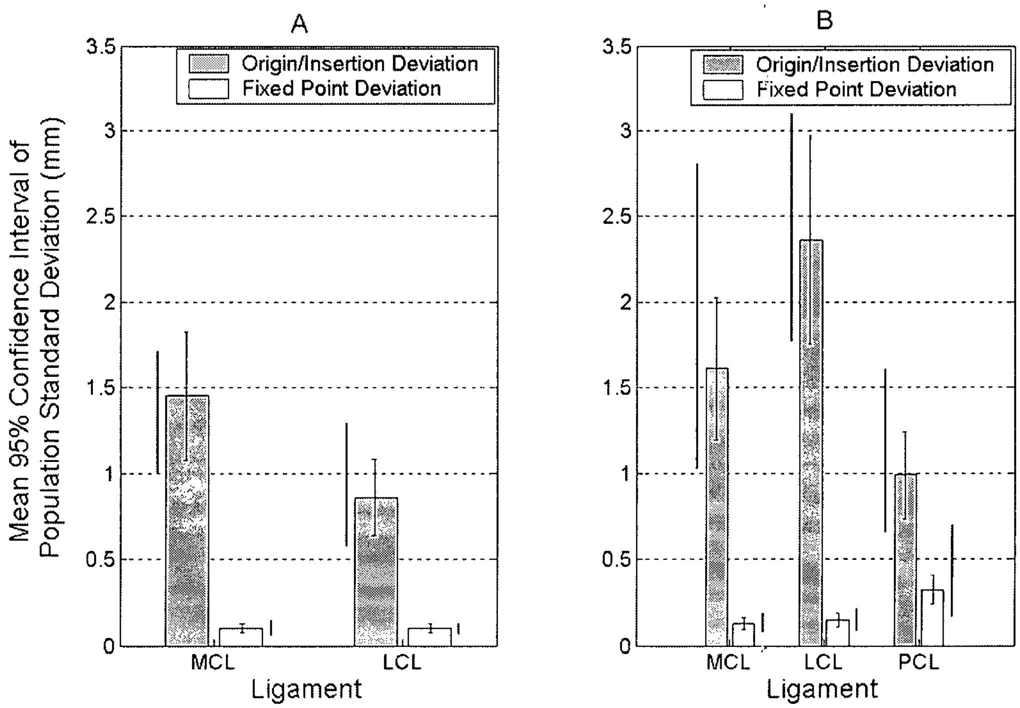


Figure 2.8 - 95% CI for the population SD in ligament lengths from output parameters (see §2.4.2) and from fixed point constraint identification (see §2.4.5), both averaged across all users and specimens. A. **Two-ligament model.** B. **Three-ligament model. (The solid line indicates ranges in SD for each ligament over all operators and specimens.)**

2.4.6 Comparison to Anatomy

In Figure 2.9, we overlay the estimated ligament attachment points from one set of 30 trials on the digitized anatomy of the corresponding specimen (the figure shows digitized outlines of the femoral condylar surface, the resected tibial surface and the attachment sites of the various ligaments). In all cases, we see that the estimated ligament locations are close to the digitized locations, although not coincident; the estimated locations tend to lie closer to the joint line than the digitized locations. Figure 2.10 shows the mean absolute distance between the centroid of each digitized ligament attachment site and the corresponding set of 30 attachment site estimates. We see that the discrepancy between these ranges from roughly 5-7 mm for the collateral ligament origins to upwards of 15-25 mm for their insertions.

2.5 Discussion

The primary purpose of this study was to determine if a manual manipulation technique performed in conjunction with an optical metrology system could

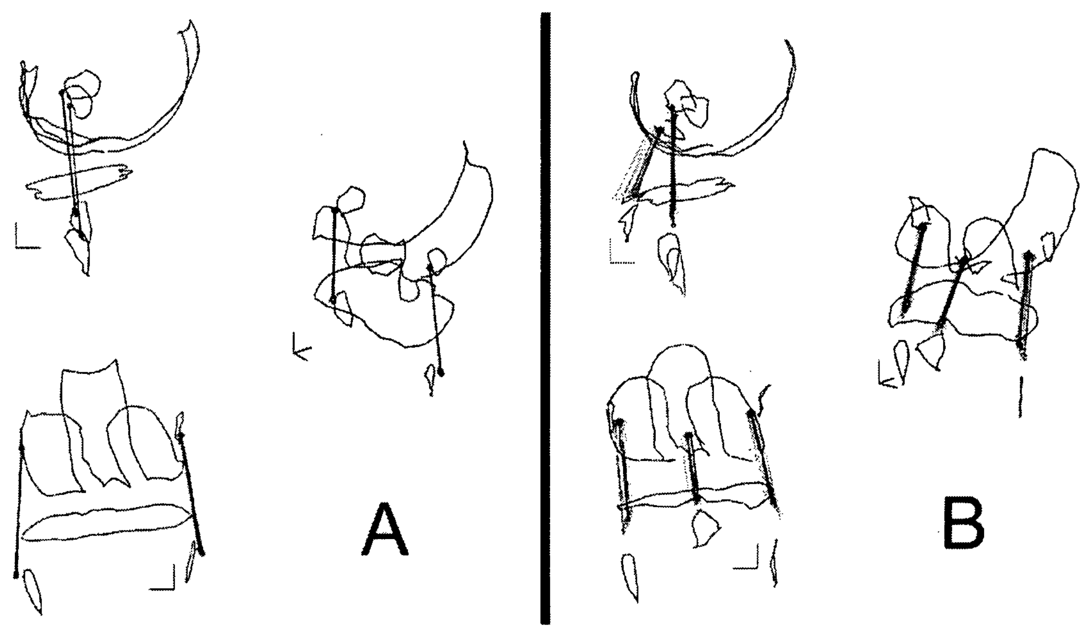


Figure 2.9 - Overlay of the estimated ligament attachment points from one set of 30 trials on the digitized anatomy of the corresponding specimen. A. **Two-ligament model.** B. **Three-ligament model.**

characterize the state of soft tissue constraint with sufficient repeatability to allow a computer-assisted surgical system to support quantitative soft tissue balancing at the planning stage of the procedure, prior to making the femoral bone cuts. Our results show that this conclusion is reasonable.

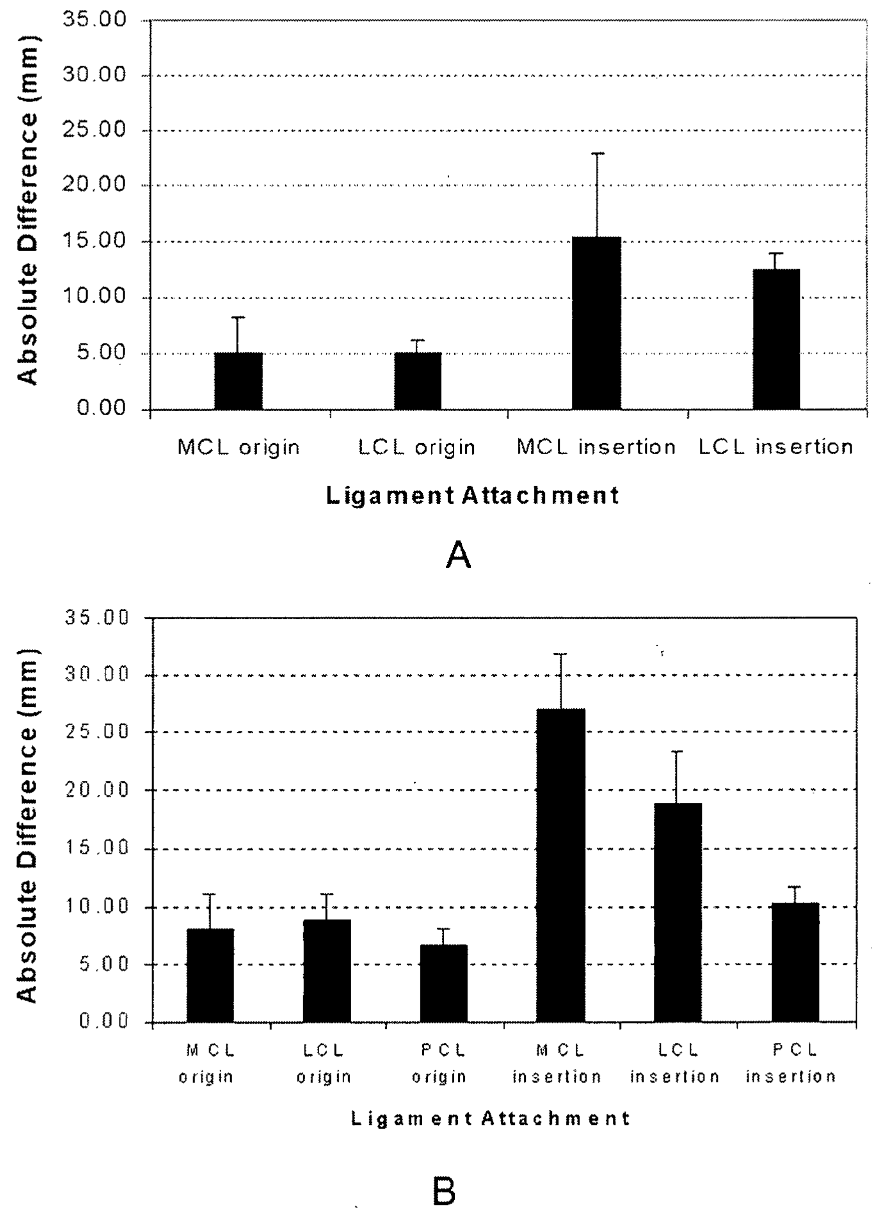


Figure 2.10 - Mean absolute distance between the centroid of each digitized ligament attachment site and the corresponding set of 30 attachment site estimates. Averaged over all users and specimens. A. **Two-ligament model.** B. **Three-ligament model.**

In our experiments, all the trials converged to plausible solutions with respect to the digitized porcine anatomy, as shown in Figure 2.9. Intraoperator repeatability was excellent for the two-ligament model and good for the three-ligament model (SDs of the model parameter estimates were on the order of 0.6 and 1.1 mm, respectively – see Figure 2.5). The simulations suggest a major source of variability in the three-ligament model: the combination of reduced range of motion, an increased number of parameters in the model and measurement noise increased the parameter variability by a factor of 2-3X; a comparable increase was found in our experiments. We also saw no significantdifference in the variance of the parameters across the specimens when a common operator performed the manipulations (Figure 2.6).

Interoperator repeatability was also excellent for the two-ligament model (Figure 2.7). The ease of manipulation and large range of motion of the two-ligament model resulted in very similar motions for the three operators on the single specimen. For the three-ligament model, however, the interoperator differences were much larger – differences in individual parameters could range up to almost 10 mm. The reduced range of motion of the manipulations, the reduced number of free motions and the more challenging technique resulted in different approaches being adopted by the different operators. We saw the largest differences in the proximal/distal and anteroposterior directions. It is possible that as operators gain experience with the technique, they will develop a more consistent approach to performing the manipulations and that this standard approach will produce lower interoperator variability. The current technique was performed manually to avoid increasing the amount of instrumentation required for a computer-assisted procedure and to minimize setup time. If better repeatability is desired, it may be possible to design or adapt a tool to apply controlled tension to the ligaments during the manipulation to improve the consistency of the estimates.

The results from the fixed point constraint identification investigation show, however, that such a tool is almost certainly not necessary. As we mentioned in §2.3.7, we are primarily interested in assessing when the ligaments become taut, rather than in obtaining repeatable estimates for the parameters of a model. The model parameters with the greatest uncertainty were the proximal/distal locations of the attachment sites, but since these are substantially along the line of action of the ligaments, errors in locating these points will have little effect on identifying when the ligaments become taut. The fixed point estimates of ligament length are a better measure of the transition to tautness, and we found that they varied by an extremely low amount, on the order of 0.1 mm SD and 0.2 mm SD for the two- and three-ligament models respectively. This indicates that the ligaments go taut in a highly repeatable manner and, in consequence, the variability in the model parameters is irrelevant to our ability to measure the effective constraint.

How then can we decide if the accuracy of the manual manipulation technique is sufficient for practical use? The goal of the constraint assessment process is to provide accurate inputs for a kinematic model of the knee. This model is then used to predict strains in the ligaments and knee kinematics for a proposed implant. The surgeon is concerned not to overstrain a ligament or to allow it to go slack. Since the ultimate strain limit of a typical knee ligament is approximately 17%, (Quapp, 1998) we must be able to identify the point where the ligament goes taut with an accuracy comparable to roughly one quarter of this value (i.e., ~4% strain). To estimate the amount of strain which could be caused by errors in estimating the ligament length, we divided the standard deviations of our ligament length estimates by the mean effective lengths of the corresponding ligaments. These errors were 2.3% ± 0.9% and 4.4% ± 1.8% for the two- and three-ligament models, respectively, which are close to the maximum limit for being useful. However, these values overestimate the effect of parameter variability. Using the fixed point variability estimates in conjunction with the effective ligament lengths, we find that the uncertainties in strain for the two-ligament and three-ligament models are markedly smaller (0.2 ± 0.1% and 0.7 ± 0.7%, respectively) and are almost certainly within acceptable limits. Furthermore, in §2.4.6 it was shown that the estimated locations for the ligament attachments tend to lie closer to the joint line than the digitized locations of the anatomical attachments. This results in the effective neutral ligament lengths being shorter than the anatomical lengths, with the reduction being much greater in the three-ligament model (effective lengths are as short as half the length in the two-ligament model). As a result, the strains we report here overestimate the physiological strains and, because the fixed point variability is comparable between two- and three-ligament models, the strain in a three-ligament specimen would be comparable to that in a two-ligament one (i.e., in both cases the variability in the true strains due to measurement error could be approximated by dividing the largest fixed point variability by the digitized length of the ligament; the resulting variability in true strain is generally less than about 0.4% SD).

There has been no strong evidence to support the use of a PCL-retaining over a PCL-sacrificing/substituting prosthesis in terms of function or long-term outcome. As a result, PCL-sacrificing/substituting prostheses have become a popular choice for surgeons as they avoid the additional complications of soft-tissue balancing associated with retaining the PCL. Pereira (Pereira, 1998) reported the frequency of PCL resection by one surgeon at their institution to be 65% from 1988-1992. Thus, we can say that, given current practice, the more repeatable two-ligament model presented here will be appropriate for the majority of procedures.

Having established that the manipulation and optimization process produces acceptably repeatable estimates, we also need to ask whether or not the simple model we have proposed is sufficiently accurate for its intended purpose. That is, does it adequately represent the true relative motions of the tibia and femur, or do we require a more complex model which incorporates effects such as ligaments wrapping around bony structures, load sharing between different fibre bundles, viscoelasticity of the ligaments, or the constraint introduced by other surrounding soft tissue structures (Attfield, 1995; Blankevoort, 1991; Mommersteeg, 1997; Mommersteeg, 1996)? If these latter effects are significant, we may consider either using a more general constraint model characterized by more parameters or using a series of simple models fitted to portions of the data. We attempted the latter approach in this paper, but found that limiting the data used to that obtained over roughly 30° of flexion produced unacceptably large variances in the resulting parameter estimates. It may be possible to develop a repeatable constraint model which is more general than our simple model, but the fact that the fitting errors are so low with the simple model (intratrial fitting errors on the order of 0.6 mm) suggests that there will be little to gain. The simple model presented here may also be appropriate in that the functional attachment site and neutral lengths may account for the combined constraint of the surrounding structures of the knee. This is a reasonable expectation because although one of the collateral ligaments in often released during surgery, the remaining adjacent soft tissue structures often have a similar orientation and will function in much the same manner.

The ligament identification method was validated on healthy young porcine specimens which may not adequately represent the diseased knees involved in TKA surgery. Although the porcine model is a reasonable representation of the human knee, there exist significant differences in geometry, load bearing and knee kinematics. Also, the effect of the arthritic disease and the surgical releases on the function of the ligaments may be significant in this model. Thus, experimental validation on cadaver specimens and arthritic knees is required.

Even if it is found that surrounding soft tissue structures do not play a significant role in determining the passive kinematics of the knee, they may affect the manipulations required for the measurement technique. The joint capsule and/or other structures may in fact limit the range of internal/external rotation and/or translations that can be obtained, thereby potentially increasing the variability of the method. (For example in §2.4.1 we found that a reduced range of flexion resulted in an increase in the proximal/distal variability with little increase in the other directions.) This has to be investigated further by testing on more complete physical specimens.

We also found significant discrepancies between the origins and insertions found by manipulation and by direct digitization of the anatomical sites, ranging from 5-25 mm depending on the ligament and the number of ligaments retained in the preparation. These discrepancies may appear to call into question the appropriateness of the simple model. In all cases, the functional sites lie significantly closer to the joint line than the actual sites. This is to be expected based on the anatomy. The anatomical ligament attachments for the porcine specimens covered an area approximately 1.5 cm^2 for the origin sites and 2 cm^2 for the insertion sites. The attachments in general were elliptical in shape, with the long axis oriented in the proximal/distal direction. During the manipulations, the ligament fibres that most constrained the motions appeared to be those that attached closest to the joint centre. Also, the wrapping of ligaments around bone during the manipulations had the effect of shortening the ligament by moving the effective constraint position even closer to the joint centre. Thus, if the effective origin were located at the point on the anatomical attachment closest to the joint line, the ligament would be effectively 5-10 mm shorter, and ligament wrapping would increase this discrepancy. In the three-ligament model, the PCL significantly limited relative bone movement, which resulted in greater discrepancies between the effective and digitized attachment sites. However, although the discrepancies are comparatively large, their existence does not negate the value of the manipulation method because the solution represents the functional attachment sites of the ligaments and so represents the constraints imposed by the ligaments better than the anatomical attachment sites. The functional attachment locations and neutral ligament lengths found using this method it most likely more appropriate for use in kinematic knee models as it the function of the constraint that dictates the motions of the knee as opposed the anatomy.

Once we have an adequate representation of the constraints produced by the ligaments, we can consider using these measurements to assess and plan total knee replacement surgeries. A small number of authors have reported on the use of commercially available computer-assisted surgical (CAS) systems to perform soft-tissue balancing during TKR procedures, although these uses have so far been restricted to measuring mechanical axis alignment at full extension or full flexion after bone cuts have been made and/or trial components have been placed (Kunz, 2001; Stulberg and Sarin, 2001). In contrast, we propose to use the method presented here as the basis for a more comprehensive approach to soft-tissue balance which would include full range of motion assessment, ligament strain prediction and intraoperative simulation, all done prior to any femoral bone cuts. Our approach would require no additional hardware beyond that already included in a typical CAS system. A system of the type we envision would require three primary components: (1) a typical CAS hardware setup (optoelectronic localizer, marker arrays for the tibia and femur, and a computer to process and guide the procedure), (2) a constraint measurement system or method, and (3) a kinematic model of the knee, the implant and the ligaments.

Several useful kinematic knee models have been presented in the literature (Blankevoort, 1991; Blankevoort, 1991; Chen, 2001; Essinger, 1989; Martelli, 1998; Mommersteeg, 1997; Mommersteeg, 1996; Wilson, 1998). Martelli (Martelli, 1998) developed a model to analyze the passive kinematics by quasistatically minimizing strain energy in the ligaments; their approach is similar to earlier work by Essinger (Essinger, 1989). The inputs to Martelli's model include the knee joint geometry, the origins, insertions and lengths of the various ligaments, the surgeon's choice of implant placement and the flexion angle of the knee. The outputs of the model are the location of the contact point between the components' bearing surfaces and the resulting state of the ligaments, which allows them to predict the kinematics of the knee joint and the resulting strain in each ligament throughout the range of motion. This model was later extended from 2D to 3D by Chen (Chen, 2001), who also modeled each ligament as a set of fibre bundles to simulate the ligaments' varying activity at different flexion angles. This interaction of ligament fibres may alter the functional attachment location of the ligament, as the effective point of ligamentous constraint depends on which fibre bundles are active. However, it has also been suggested by experimental studies (Fuss, 1989; Sidles, 1988) that a single fibre bundle remains isometric throughout the range of motion and it is this bundle that governs the function of the ligament. As mentioned above, the low variance in length we found between the fixed points supports these latter studies.

In the studies by Martelli and Chen, the authors use digitized estimates for the origins, insertions and lengths of the ligaments, and they recognize that accurate estimates are crucial in building an accurate knee model. They do not, however, report the repeatability of obtaining these estimates. During surgery, access to the ligament origin and insertion sites is often limited and overlying soft tissue and bodily fluids hamper clear visualization. The attachment sites of the ligaments are also distributed over an area of ~2 cm^2, making it difficult to identify a unique effective attachment point. Furthermore, our study suggests that the effective attachment sites are often a significant distance from the digitized sites, so the method presented here to obtain quantitative constraint information for input into a kinematic knee model may be both more practical and more accurate in the live operating room setting.

2.6 Conclusions

Using a manual manipulation technique in combination with a simple kinematic model, we identified the origins, insertions and lengths of the ligaments with very good intraoperator repeatability in a porcine preparation. The two- and three-ligament models had repeatabilities on the order of 0.6 and 1.1 mm (SD), respectively, for the parameter estimates. Interspecimen repeatability was consistent, and interoperator repeatability was excellent for the two-ligament model (2 mm or less from the mean), but larger for the three-ligament model (8 mm or less from the mean). The fixed point estimate of ligament length, which is more appropriate for assessing when the ligaments reach tautness, had markedly smaller variability (0.1 – 0.2 mm SD). This degree of repeatability, if confirmed in a human study, would be sufficiently good to support incorporating quantitative constraint measurements into the assessment and planning of soft tissue balance in computer-assisted total knee replacement procedures.

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Chapter 3 - Determining Component Placement to Optimize Soft Tissue Balance

3.1 Abstract

Given the existence of models that can predict various outcome measures as a function of component placement, we introduce an optimization algorithm to find the component placements that result in desired strain behaviour of the surrounding ligaments throughout the range of motion. As a first approach to the problem, we define the optimal component placement to be that which minimizes the strain and laxity in each ligament over the entire range of motion, although this criteria may be modified should some strain or laxity be desired. The algorithm requires parameters describing the patient's ligament attachment locations and neutral lengths (as determined from the ligament identification method, see chapter two), as well as the geometries of the prosthetic components. The placement algorithm was successful at determining a placement that results in the prediction of near isometric behaviour of the ligaments throughout the range of motion by a passive kinematic model when various ligament imbalances are introduced in a simulated knee. The algorithm also proved robust to variance in the ligament input parameters that were obtained from the ligament identification method.

3.2 Introduction

The objectives of total knee arthroplasty (TKA) are to relieve the patient's pain and to restore appropriate knee function (Cooke, 1998). Although TKA is generally a successful procedure, failures still occur due to sepsis, component loosening, instability, dislocation or fracture in 5% to 8% of cases (Stern, 1992; Vince, 1989).

The success of total knee replacement depends on interactions between the articulating surfaces of the prosthetic components and the surrounding ligaments of the knee which are determined by the surgical placement of the components and the state of the ligamentous structures (Wilson, 1998). Current instrumentation systems have focused on achieving accurate bone cuts, which leads to proper limb alignment, and leaves it to the surgeon to determine if the soft tissues are correctly balanced. While techniques for alignment and bone cutting continue to advance, soft tissue balancing still largely relies for its precision on the skill and experience of the surgeon (Cooke, 1998). Since the state of the surrounding soft tissues of the knee has a direct effect on the performance and life of the replacement (Fehring, 1994; Sambatakakis, 1991; Tew, 1985; Wasielewski, 1994), there is clearly a need for technological development in this area.

Approaches have been made to develop intraoperative tooling to provide quantitative assistance in balancing soft tissue (Attfield, 1994; Sambatakakis, 1992; Takahashi, 1997; Wallace, 1998). These developments generally fall into two categories: (1) tensioning devices which apply loads to the collateral ligaments and indicate balance by means of an angle measurement, and (2) pressure sensors which assess contact pressures in the medial and lateral compartments. All existing systems are designed for use after the surgeon has made the transverse cuts on both bones and the posterior cut on the femur, and, in the case of pressure sensors, after the surgeon has inserted the trial components. While these methods do provide quantitative measures of balance, they do not allow the state of the soft tissues to enter into the planning process as the bone cuts have already been made. These approaches assume that appropriate component placement may be determined exclusively from the bony anatomy using conventional instrumentation. However, when using most mechanical alignment systems and following standard guidelines for placement, there still exists some amount of freedom, such as rotation of the femoral and tibial components, posterior sloping of the tibial tray and sizing of the components, which is often modified by the surgeon to match the anatomy and corrected deformity of the patient.

As proper performance of unconstrained knee components is highly dependent upon the surgical placement of the components and state of the ligaments (Wilson, 1998), component placement and soft tissue balance should be considered simultaneously when deciding upon a surgical strategy. For a given patient there exist two approaches to proper placement of the knee components: (1) optimal alignment would satisfy all necessary requirements for proper alignment with the mechanical axis and any other component specific requirements (these may vary with the manufacturer), whereas (2) optimal balance would minimize the strain and laxity of the ligaments throughout the range of motion without regard for proper mechanical alignment. The current approach in TKR surgery is to focus on optimal alignment and is the basis for most currently used instrumentation. If it were possible to determine the optimal balance, it could then be compared to the optimal alignment, the difference giving an indication of the state of soft tissue balance. The surgeon could then decide whether to select one of the two optimal placements or a compromise between the two extremes; alternatively, the surgeon could attempt to modify the soft tissue balance to better satisfy both criteria. Given current practice, it is likely that the majority of surgeons would select optimal alignment and adjust the soft tissues to reduce the difference between the two. However, given results as reported by Tew (Tew and Waugh, 1985) and others (Fehring and Valadie, 1994; Goldberg, 1988; Sambatakakis, 1991), there may be a trend towards optimal balance as this may prove an important condition for long-term success. Booth (Booth, 1999) stated that when given the choice, most successful knee surgeons would prefer the arthroplasty to be perfectly balanced even at the expense of slight malalignment.

In TKA procedures the shape and size of the articular surfaces and their locations relative to the ligaments are changed. Through the process of soft tissue balancing, the ligaments are also modified in an attempt to match the newly implanted components. These factors affect knee function in a complex manner such that changing a single factor often results in a global change of knee function. To determine the optimal interaction of these structures, a method to predict clinically relevant performance measures must be available intraoperatively. The use of knee models for simulating and analyzing this interaction show great potential in this role.

Many investigators have reported on the passive kinematics of the knee (Godest, 2000; Mommersteeg, 1997; Wilson, 2000) as dictated by the relevant structures. Martelli and Chen (Martelli, 1998; Chen, 2000) have described a 3D mathematical model of the knee to determine the passive kinematics of a knee replacement. The model relies on knowledge of the prosthetic bearing surface and intraoperative measurements of ligament anatomy. Based on the principle of ligament-strain minimization, the model determines the quasi-static knee kinematics by finding successive contact points on the femoral and tibial bearing surfaces over a range of flexion angles. With this model they were able to predict the trajectories of the points of contact between the femoral and tibial components as well as the state of strain in the ligaments over the course of flexion. These clinical parameters are valuable in assessing the performance of the knee for a given component placement. The continuous behaviour of the ligaments throughout the entire range of motion as determined by an anatomical model allows the effect of ligament release or component placement to be better understood, as opposed to assessing the balance at only 0 and 90 degrees of flexion.

Intraoperative use of computer models has not been feasible until recently. Computer assisted total knee surgery systems have been developed to obtain accurate registration of bone cut planes. These systems have arguably shown early success and are expected by some to have an impact on long term outcomes (Delp, 1998). Recent efforts have been made to add soft tissue balancing capabilities to existing non-CT based computer assisted knee surgery systems. Stulberg (Stulberg, 2001) used information from a CAS system (Orthopilot, Aesculap Ag & Co. KG, Tuttlingen, Germany) to assess ligament laxity before and after the insertion of the implants in the fully extended position. He concluded that the CAS system is useful in guiding the surgeon in the need for ligament releases and it makes it possible to correlate the intra-operative stability and flexion with the post-operative function. Kunz (Kunz, 2001) used a CAS system to determine the component selection and placement and ligament releases that result in balanced flexion and extension gaps. Although these methods provide quantitative assessment of soft tissue balance, they are limited in that they assess balance and/or component selection at only 0 and 90 degrees of flexion.

Existing models perform well at predicting passive knee kinematics given component placement and anatomical descriptions. However, these models have not yet been used as an integrated component of the surgical planning process. These models do have the potential to allow the surgeon to simulate alternative component placements intraoperatively, although this is a trial and error process and even when performed interactively with a computer, can be cumbersome. A more efficient alternative would be to use a computer model to determine what placement would result in the best pre-determined clinical function directly. For this to be realized, our approach is to wrap a passive kinematic knee model within an optimization process that modifies component placement parameters to determine the ideal component placement for a given component geometry and soft tissue state. The models discussed do not currently predict contact positions of maximal slackness at a given knee flexion. Martelli did look at instability of the knee at a given flexion angle by modifying the contact position about the ideal point contact point and observing the rise in the strain energy. She indicated that instability occurs if the contact position could be modified > 5 mm from the ideal position with less than a 2.5% rise in the strain energy. The determination of the position of maximal slackness is important as at this position we can calculate the degree of ligament slack that results at this flexion angle and component placement. This component placement would then be appropriately penalized in the optimization process. Thus, the goals of this method are to incorporate a model that adequately predicts passive knee kinematics, determines the component position (not placement) of maximal slackness at a given flexion angle, and prospectively finds the component placement for optimal balance.

Incidentally, it is not trivial to achieve an adequate trade-off between tension and slackness in a ligament throughout the range of motion. Despite studies such as that of Wilson (Wilson, 1998) which show that the kinematics of an intact knee can be well-modeled by a parallel spatial mechanism with five constraints (two contact points and three isometric ligaments: MCL, PCL and ACL) and one degree of freedom (flexion), we typically cannot assume ligament isometry when installing artificial components. If we were justified in treating the ligaments as isometric, then a model with five constraints and one degree of freedom would have a unique solution for the position of the femur relative to the tibia at each flexion angle, regardless of the component placement (within limits). In reality, however, ligaments cannot sustain compression, so the isometric model is inappropriate whenever the femur can be moved relative to the tibia to produce slackness. While this slackness can be reduced at a particular point by changing the component placement (e.g., by changing the varus angle of the tibial plateau cut to take up slack in a collateral ligament), this tends to align the ligament with the normal constraint due to contact between the femoral and tibial components. If flexing the knee to a new angle forces the ligament origin further away from its insertion, the ligament will become tensed, which is to be avoided. Since no unique component placement solution exists, the optimal placement cannot be computed using a parallel spatial mechanism model but must be found by properly formulating a cost function which represents tradeoffs between tension and slackness and minimizing this function by altering the component placement parameters.

The passive kinematic models described above are crucial in that they allow surgical strategies to be simulated and analyzed in terms of clinical performance prior to performing any irreversible actions on the patient. Provided ligament measurements are obtained prior to performing any bone cuts, the ligament-strain minimization model may be used to evaluate proposed component placements or ligament modifications. This would be beneficial for guidance when performing balancing procedures or determining the best surgical strategy. Surgeons who perform TKR procedures infrequently would also benefit, as they would be less experienced with difficult cases. This approach, while effective, is a trial and error process, as the surgeon must systematically evaluate different alternatives. As mentioned previously, a more efficient alternative would be to use a computer model to determine what placement or soft tissue modification would result in the best pre-determined clinical function.

This paper presents an optimization algorithm to determine the component placement for optimal soft tissue balance. The algorithm requires intraoperative measures of the patient's ligament attachment locations and neutral lengths, as well as the geometries of the prosthetic components. We have devised an intraoperative method of identifying the ligament attachment sites and lengths (described earlier – see chapter two). This method has a mean variance of 1.0 mm for the absolute position of the attachment locations and 1.8 mm for the neutral ligament lengths for a three-ligament model (MCL, LCL and PCL) averaged over three operators and three porcine specimens. We test the hypothesis that the algorithm will be successful in determining optimal placement for soft tissue balance and report the degree to which the algorithm is affected by variance in the input parameters found using the intraoperative measurement technique.

3.3 Materials and Methods

Passive knee kinematics are well predicted by solving a series of instantaneous quasi-static energy minimization problems (Essinger, 1989). In our model, we use a quasi-static kinematic model to determine the tension or slack in ligaments as a function of flexion angle for a given component placement. The placement that results in ligaments approaching isometric behaviour (which is defined as optimal ligament behaviour) over the range of flexion angles is then determined.

In our model, we assume simplified component geometries. Actual component geometries were not readily available and in principle are not required to successfully demonstrate the method. The femoral component is represented by a cylinder and the tibial component by a flat plate. Current prostheses designs have bearing surfaces that are not geometrically congruent which introduce additional degrees of freedom in knee motion that are captured by the represented geometries. Line contact between the cylinder and flat plate is assumed to occur at all times.[1]

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[1] Alternatively, the femoral component could be represented by a pair of spheres rigidly attached to one another. The two spherical surfaces would contact the tibial plate in two locations. This is the same contact condition satisfied by modern unconstrained TKR components (eg, P.F.C. Knee System, Johnson and Johnson Orthopaedics).

3.3.1 Reference systems

The coordinate system used in this model was selected to fit with the CAS system under development at our institute (Inkpen) and similar to those of Grood and Suntay (Grood, 1983) and Martelli (Martelli, 1998) (Figure 3.1). Two Cartesian coordinate systems were assigned to the major bones of the lower limb. The z-axes were directed along the mechanical axis of the bone in the proximal direction. The x-axes were perpendicular to the z-axis directed to the right in the coronal plane. The y-axes were found from $y = z \times x$ and directed anteriorly. The origin of the femoral frame (F_F) was located at the midpoint of the origins of the two collateral ligaments (lying on the transepicondylar axis, (Grood, 1983)). The origin of the tibial frame (F_T) was located at the midpoint of the insertions of the collateral ligaments. Both reference frames were fixed to the corresponding bones. The coronal plane for each bone was separately defined as a plane passing through two ligament attachment points, and the hip (centre of the femoral head) or the ankle centre (midpoint between the medial and lateral malleoli).

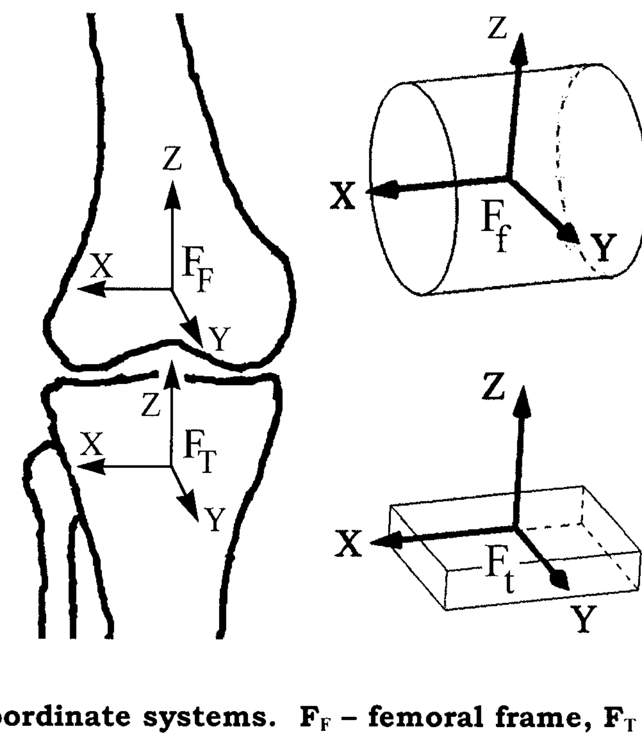

Figure 3.1 - Coordinate systems. F_F – femoral frame, F_T – tibial frame, F_f – femoral component frame, F_t – tibial component frame

Two additional Cartesian coordinate systems were assigned to the prosthetic components. The femoral component frame (F_f) was positioned at the centre of mass of the cylinder, with the x-axis directed along the major axis of the cylinder. The z-axis was perpendicular to the x-axis with the y-axis defined as y = z × x. The tibial component frame (F_t) was positioned on the proximal surface of the flat plate. The z-axis was coincident with the normal to the surface of the flat plate. The x and y axis were located in the plane of the flat plate forming a right hand coordinate system with the z-axis.

3.3.2 Coordinate system transformations

For the calculation of ligament lengths, is it necessary to know the orientation of the femur with respect to the tibia. Thus, a homogeneous rigid-body transform (Sciavicco, 1996) from the femoral frame to the tibial frame (T_{TF}) was found by multiplying successive transforms moving from the femur to the tibia:

$$T_{TF} = T_{Tt} * T_{tf} * T_{fF} \tag{3.1}$$

where: T_{Tt} = transform from F_t to F_T

T_{tf} = transform from F_f to F_t

T_{fF} = transform from F_F to F_f

The pose of each component with respect to each bone was represented by the homogeneous transform between the two associated frames. The homogeneous transform is made up of basic fixed frame rotations and displacements as found in Sciavicco (Sciavicco, 1996) (Refer to appendix for a more detailed description of the homogeneous transforms used in this method). The transform T_{fF} represents the position of the femoral frame in the femoral component frame and was defined by four parameters:

1) Femoral varus/valgus alignment (VV_F)= rotation about y-axis of F_f

2) Femoral internal/external alignment (IE_F) = rotation about z-axis of F_f

3) Femoral anterior/posterior position (AP_F) = translation along y-axis of F_f

4) Femoral proximal/distal position (PD_F) = translation along z-axis of F_f

The transform T_{Tt} represents the position of the tibial component in the tibial frame and was defined by three additional parameters:

5) Tibial varus/valgus alignment (VV_T)= rotation about y-axis of F_T

6) Tibial component tilt ($Tilt_T$)= rotation about x-axis of F_T

7) Tibial proximal/distal position (PD_T) = translation along z- axis of F_T

These seven parameters are the only component placement parameters that were modified to affect knee kinematics in the model. They represent the placement parameters most likely to be modified by the surgeon intraoperatively. The two transforms are calculated using fixed frame transformations with the actual transformations occurring in the reverse order in which they are multiplied:

$$T_{fF} = Rot_y(VV_F) * Rot_z(IE_F) * Trans_{x,y,z}(0, AP_F, PD_F) \tag{3.2}$$

$$T_{Tt} = Trans_{x,y,z}(0,0,PD_T) * Rot_x(Tilt_T) * Rot_y(VV_T) \tag{3.3}$$

The orientation of the femoral component with respect to the tibial component can be described by a homogeneous transformation derived from five parameters:

1) Anterior/posterior displacement (AP_{comp}) = translation along y-axis of F_t

2) Medial/lateral displacement (ML_{comp}) = translation along x-axis of F_t

3) Proxial/distal displacement (PD_{comp}) = translation along z-axis of F_t

4) Internal/external rotation (IE_{comp}) = rotation about z-axis of F_t

5) Flexion/extension rotation (FE_{comp}) = rotation about x-axis of F_t

Thus the transform T_{tf} is calculated as follows:

$$T_{tf} = Trans_{x,y,z}(ML_{comp}, AP_{comp}, PD_{comp}) * Rot_z(IE_{comp}) * Rot_X(FE_{comp}) \tag{3.4}$$

Assuming that the components are always in contact, and that the simplified femoral component is used, PD_{comp} is a constant equal to the femoral component radius. This only applies for the simplified cylindrical femoral component described in this paper, for a more complex geometry, PD_{comp} would vary with flexion angle. The flexion angle is set to a distinct value for each evaluation of the model, to form a quasi-static solution.

3.3.3 Passive knee kinematics

The main ligaments of the knee are the anterior cruciate ligament (ACL), the posterior cruciate ligament (PCL), the medial collateral ligament (MCL) and the lateral collateral ligament (LCL). During implantation of most total knee prostheses, the ACL is resected, so it was not used in this model. The origins of the three ligaments were represented as x,y,z cartesian coordinates in F_F, with the insertion locations represented in F_T. A fixed component placement was assumed for the femoral and tibial components (T_{fF} and T_{Tt}).

For a distinct flexion angle (FE_{comp}) and an initial guess for AP_{comp}, ML_{comp} and IE_{comp}, the transformation T_{TF} was found. Using this transformation the locations of the ligament origins were transformed to F_T. The length of each ligament was defined as the difference between the origin and insertion locations. Ligaments were modeled as tension-only linear springs, with the strain energy increasing quadratically with extension and being zero in compression. The total energy of the system was the sum of the strain energies of the individual ligaments. Let L_i be the instantaneous length of the i^{th} ligament, $\overline{L_i}$ be its neutral length and K_i be its spring constant. The strain energy of each ligament is defined as (Martelli, 1998):

$$E_i = \begin{Bmatrix} \dfrac{K_i\left(L_i - \overline{L_i}\right)^2}{\overline{L_i}^2} & if\ L_i \geq \overline{L_i} \\ 0 & if\ \ L_i < \overline{L_i} \end{Bmatrix} \quad where\ \ i = MCL,\ LCL,\ PCL \tag{3.5}$$

The total strain energy is defined as:

$$E_{Total} = \sum_i E_i \quad where \ i = MCL, LCL, PCL \tag{3.6}$$

The parameters AP_{comp}, ML_{comp} and IE_{comp} were found such that this strain energy was at a minimum using a non-linear unconstrained optimization algorithm (Quasi-Newton) at distinct flexion angles in the range of 0° – 135° at 5° increments. Thus the input variable to the passive kinematics algorithm was the flexion angle and the outputs were three orientation parameters, from which the strain in each ligament was found.

3.3.4 *Component placement algorithm*

The objective of the component placement algorithm was to determine the seven placement parameters that result in the ligament lengths remaining as close as possible to their neutral lengths (isometric) throughout the range of 0°–135° of flexion (at 5° increments). This criterion may be easily modified should different ligament behaviour be desired. The passive kinematic model described above was used to observe the stretch in ligaments throughout the range of motion for a given component placement. However, this model is unable to quantify the amount of slack resulting from a poor component placement due to the fact that it is possible for one or more ligaments to be slack at the energy minimum, resulting in multiple solutions for this optimization. To quantify the degree of instability in a component placement such as this, it is necessary to solve a secondary problem – computing the component position (not the component placement) that maximizes the slack in the ligaments while maintaining the strain energy in the ligaments at a level less than or equal to the previously determined energy minimum. This is found by minimizing the sum of the lengths of each ligament, subject to the energy being less than or equal to that found by the passive kinematic routine:

$$C(p) = \sum_{i=1}^{N_l} \left(L_i(p) - \overline{L}_i \right) \quad \text{subject to} \quad E_{Total}(p) \le E_{Total}(p_{op}) \tag{3.7}$$

where N_l is the number of ligaments in the model, p is the parameter vector defining the component position (determined by ML_{compL}, AP_{comp} and IE_{comp}), p_{op} is the component position determined from the passive kinematic knee model, $\overline{L_i}$ is the neutral length of ligament i, and L_i is the Euclidean distance between the origin and insertion of ligament i at position p. Thus a placement was to be found which minimized not only the stretch in the ligaments, but also the slack in the ligaments.

The deviation of each ligament from its neutral length was then compared to the deviation found using the passive kinematic model at that flexion angle. The larger of the two deviations was used in the global formulation of the placement cost for that angle (equation 3.8).

The steps of the placement algorithm are summarized as follows:

1. A guess is made for the seven component placement parameters (We used pure mechanical alignment placement for an initial guess).

2. For a distinct flexion angle, the component position (AP_{comp}, ML_{comp}, IE_{comp}) that minimizes the strain energy in the ligaments is found using the passive knee kinematic model. (Note: if one or more ligaments is slack at this position, then the solution is not unique; see step 5.)

3. The transform T_{TF} is calculated and the ligament origins are transformed into F_T.

4. Each ligament is tested to see if it is in a slack condition. ($L_i < L_{Ni}$)

5. If one or more of the ligaments is found to be slack, the position that results in the most slack in the ligaments is found, subject to having less than or equal the strain energy found in step 2.

6. If the ligament deviation ($\sum\left|L_i - L_{Ni}\right|$) at the most slack position is larger than the deviation found using the passive knee kinematic model, this deviation is recorded for that flexion angle (to be used in equation 3.8).

7. Steps 2 – 6 are repeated for the entire range of flexion angles.

8. Using a non-linear unconstrained optimization procedure (Nelder-Mead Simplex Method), the seven placement parameters are found that minimize the total ligament deviation:

$$C(p) = \sum_{i=1}^{N_l} \sqrt{\sum_{j=1}^{N_\theta} (L_{i,C}(\theta_j, p) - \overline{L}_i)^2} \tag{3.8}$$

where N_l is the number of ligaments in the model, N_θ is the number flexion angle intervals, θ_j is flexion angle at interval j, p is the parameter vector, $\overline{L_i}$ is the neutral length of ligament i, and L_i is the Euclidean distance between the origin and insertion of ligament i at time θ_j (found from the passive kinematic knee model in tension or in the most slack position). We used a non-linear least squares optimization algorithm (trust region reflective Newton method) to determine the parameter vector that minimized $C(p)$ over the entire dataset of measured positions.

3.3.5 Validation

An idealized knee model was used to investigate the performance of the component placement algorithm. In the model we used a cylinder with a 25 mm radius to represent the femoral component and a flat plate to represent the tibial component (Figure 3.2). The coordinates used for the ligament attachment sites are shown in Table 3.1, and the ligament neutral lengths and their relative stiffness are shown in Table 3.2. In this model the stiffness of the PCL is four times that of the collateral ligaments and was implemented to represent the relative cross sectional area of the ligaments, consistent with the model used by Martelli et al. (Martelli, 1998). For simplicity in interpreting the results, we defined the MCL and LCL as mirror images of each other across the saggital plane running through the centre of the knee. Since the number and type of these constraints is unaltered by this modification, there will be no effect on the generalizability of using the optimization algorithm with more realistic ligament attachment sites. The attachment sites of the PCL were chosen to simulate the action of the PCL in the normal knee.

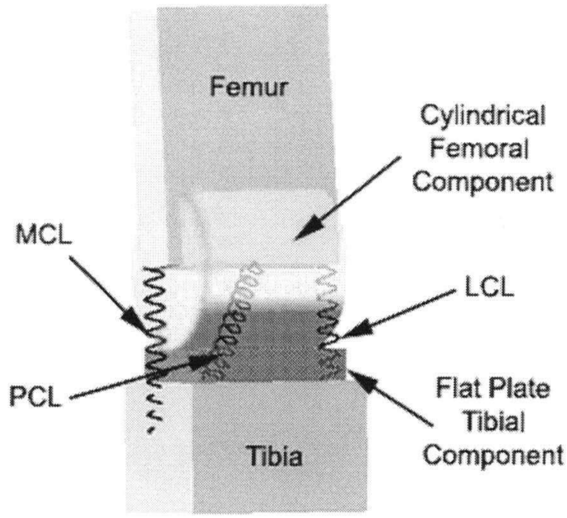

Figure 3.2 - Idealized knee model used in simulations

Table 3.1 – Ligament Attachment Site Coordinates for Validation Model

Ligament Attachment	Frame	X coordinate	Y coordinate	Z coordinate
MCL origin	F_F	30 mm	0 mm	0 mm
LCL origin	F_F	-30 mm	0 mm	0 mm
PCL origin	F_F	0 mm	5 mm	-5 mm
MCL insertion	F_T	30 mm	0 mm	5 mm
LCL insertion	F_T	-30 mm	0 mm	5 mm
PCL insertion	F_T	0 mm	-25 mm	25 mm

Table 3.2 – Ligament Data for Validation Model

Ligament	MCL	LCL	PCL
Neutral Length	45 mm	45 mm	33 mm
Relative Stiffness	1	1	4

Optimal alignment for this model was defined as the placement where the component frames are coincident with the frames of the respective bones. The balanced idealized model did not result in isometric ligament behaviour over the range of motion at optimal alignment component placement. Thus, the first run of the placement algorithm was to determine an optimal placement for the balanced idealized model.

The neutral lengths of the ligaments were then altered to simulate various ligament imbalances. In the first simulation, the MCL was shortened by 5 mm to represent a varus imbalance. In the second simulation, the PCL was shortened by 5 mm to represent a flexion contracture. The MCL and PCL were then both simultaneously shortened to represent a more complex imbalance. A simulation was also performed with the MCL lengthened by 5 mm to investigate the ability of the model to manage a slack ligament. For all simulations the kinematics and ligament behaviour both before and after the placement optimization were calculated.

The degree to which the algorithm is affected by variance in the input parameters was investigated by running the placement optimization on a set of 30 ligament attachment and neutral length solutions found using a porcine specimen for the three ligament model (solutions were obtained from experiment described in chapter 2). The solutions were taken from a previous experiment and had an average standard deviation of 0.9 mm for ligament locations and 1.1 mm for ligament neutral lengths (see chapter two). The variance of the seven component placement parameters and the resulting predicted kinematic behaviour was determined over the 30 trials.

3.4 Results

Table 3.3 presents the component parameters resulting in optimal placement for soft tissues as found by the placement algorithm for all simulations. For the initial, near-balanced model, we expected the modification in placement parameters to compensate mainly for the location of the PCL as the collaterals were of equal length and mirrored about the saggital plane. This simulation recommended a modification of the posterior tilt of the tibial component (which affects mainly the PCL behaviour), slight modifications in the translation of the femoral and tibial components and little modification of the varus/valgus and rotational alignment of the components.

When the MCL was shortened for the second simulation to emulate a varus imbalance, we saw the placement of the components shift to accommodate the imbalance. A large varus/valgus modification is needed to reduce the tension in the MCL and this is seen in the tibial component placement. The tibial component was also translated in the distal direction, thereby reducing the distance between the origin and insertion of the ligaments when the components are in contact. The posterior tilt of the tibial component was changed to an anterior tilt as indicated by the negative value, which was not expected considering the solution to the first model which produced a posterior tilt for the same PCL condition. However, the anterior tilting of the tibial component was appropriate when combined with the other placement parameters as the evidenced by an overall improvement in ligament isometry. Even in this simple model the complexities that arise from imbalance in the ligaments when the whole range of motion is considered can be appreciated.

The remaining simulations resulted in appropriate modifications to the component placements to adapt to the imbalances introduced. Of particular interest were the results of the elongation of the MCL by 5 mm. We see that although the varus/valgus angles of the components were, as expected, significantly modified, the modifications were not simply the negative of those seen in the MCL-shortened case. Here we see more of the imbalance accounted for by the femoral component and an increase in the internal/external rotation of the femoral component. Again, without an explicit optimization process, it would be difficult to predict the appropriate changes in component placement using rules of thumb alone.

Table 3.3 – Component Parameters from Placement Simulations

Simulation	Femoral Component Varus/Valgus Angle (degrees)	Femoral Component Internal/External Rotation (degrees)	Femoral Component Anterior/Posterior Displacement (millimeters)	Femoral Component Proximal/Distal Displacement (millimeters)	Tibial Component Varus/Valgus Angle (degrees)	Tibial Component Posterior Tilt (degrees)	Tibial Component Proximal/Distal Displacement (millimeters)
Initial Guess	0	0	0	0	0	0	25
Balanced initial model	-0.2	0.1	-0.5	0.6	0.2	2.7	24.3
MCL 5 mm shorter	0.7	-0.4	-1.0	0.2	4.2	-2.6	22.2
PCL 5 mm shorter	-1.0	1.0	-0.7	1.4	1.3	3.1	22.6
MCL and PCL 5 mm shorter	0.5	-0.7	-1.7	0.6	4.2	2.6	21.7
MCL 5 mm longer	-1.4	1.5	-0.1	1.5	-3.1	1.9	25.5

Figure 3.3 shows the deviation in ligament length from neutral for all ligaments in each of the four imbalanced simulations. The deviations are shown (A) before and (B) after the placement algorithm was implemented to demonstrate the success of the algorithm. Also shown is the total absolute deviation of all ligaments to give an indication of the degree to which the cost is minimized by the optimization routine. For each simulation the deviations in ligament lengths are significantly reduced, approaching near isometric behaviour throughout the range of motion. After the placement algorithm, no ligament exceeded 0.8 mm of deviation from neutral length for any flexion angle. The mean absolute ligament deviation across all ligaments and flexion angles was 0.1 mm, 0.1 mm, 0.1 mm and 0.2 mm for the MCL shortened, PCL shortened, MCL and PCL shortened and MCL lengthened simulations respectively. Figure 3.4 shows the passive kinematics of the femoral component with respect to the tibial component before and after the placement algorithm for all four imbalanced simulations. Each plot shows the anterior/posterior translation, medial/lateral translation and internal/external rotations as a function of flexion angle. For all four simulations, the final kinematics are very similar and reasonably approximate the kinematics of true knees. For example, the femoral component exhibits gradual rollback on the tibial component. However,

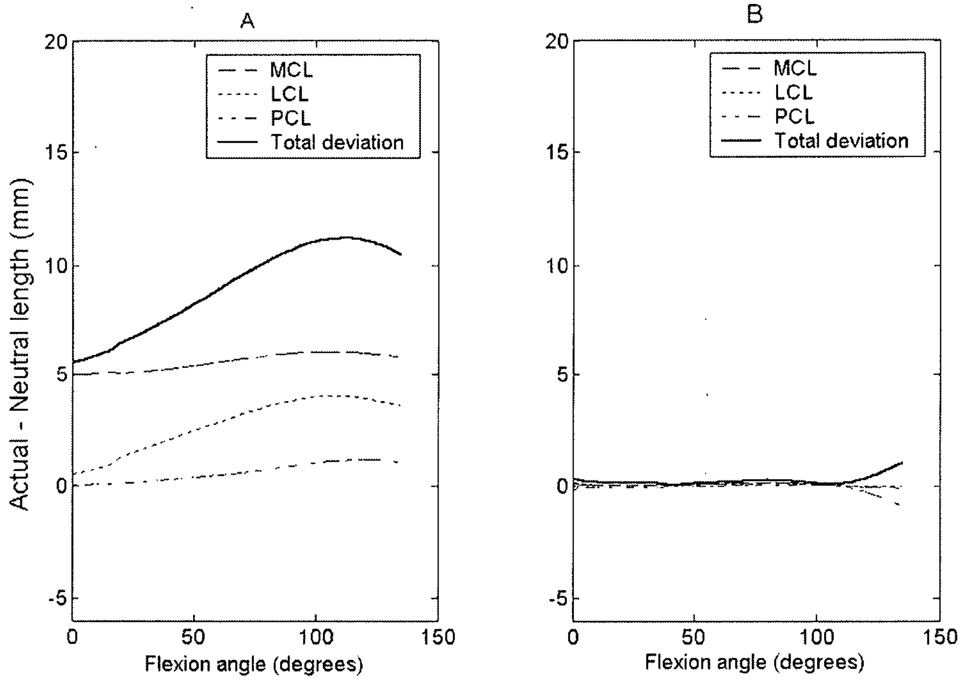

Figure 3.3 – i

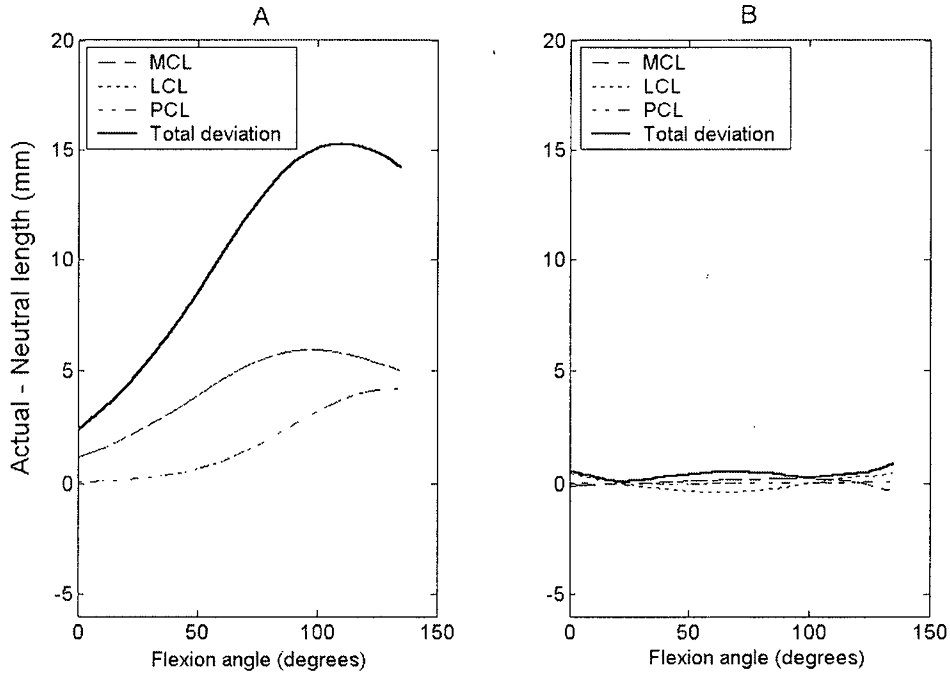

Figure 3.3 - ii

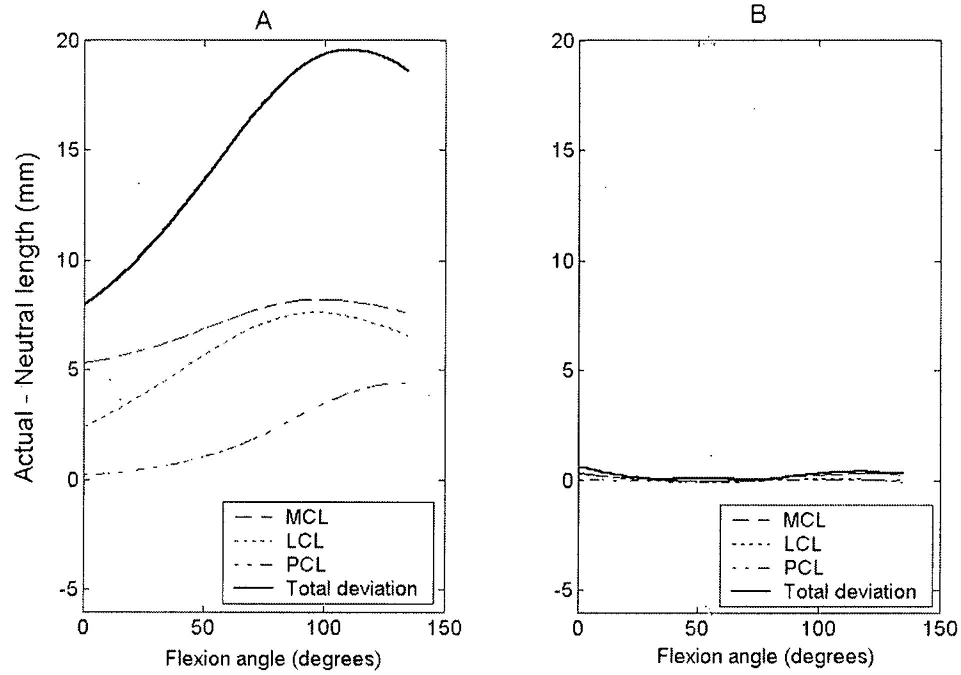

Figure 3.3 – iii

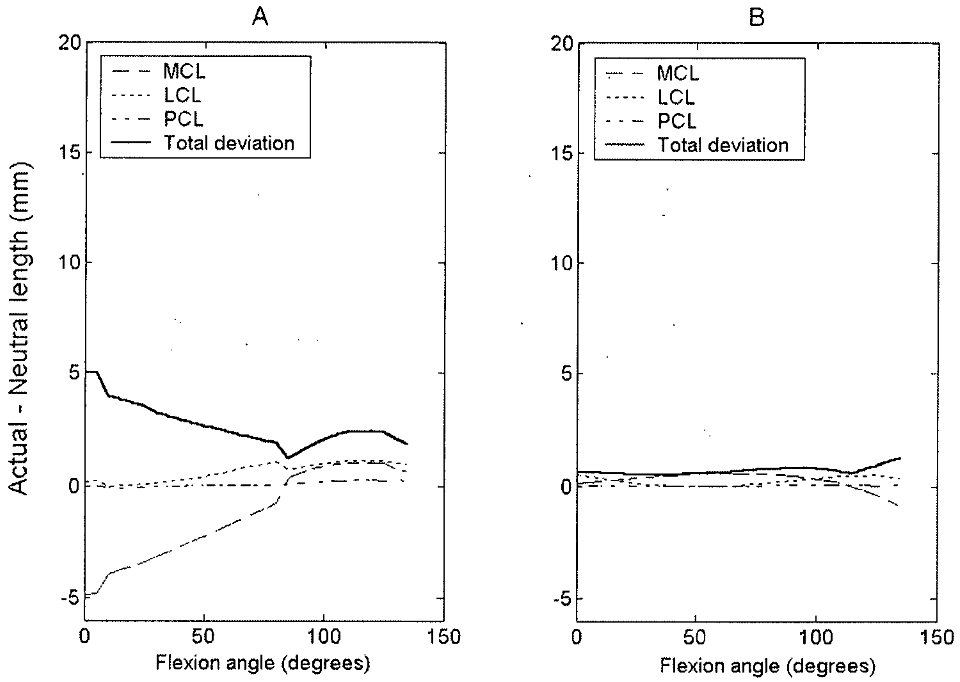

Figure 3.3 - iv

Figure 3.3 - Predicted ligament length changes for simulated imbalances from kinematic model at a given component placement. A. Standard placement B. Placement determined by optimization i. MCL shortened by 5 mm (varus deformity) ii. PCL shortened by 5 mm (flexion contracture) iii. MCL and PCL shortened by 5 mm (complex contracture) iv. MCL lengthened by 5 mm (valgus instability)

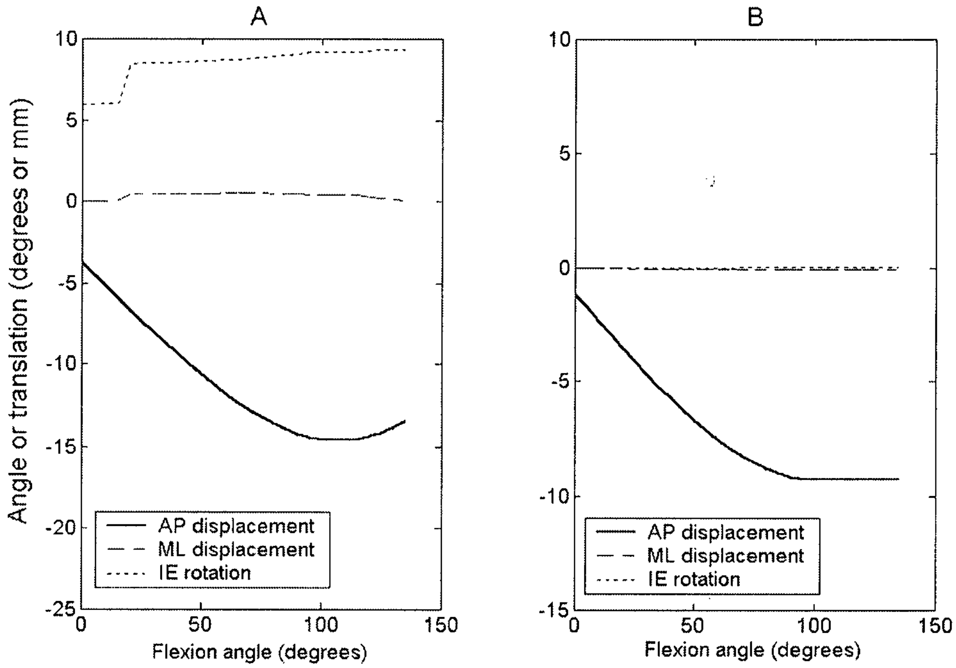

Figure 3.4 – i

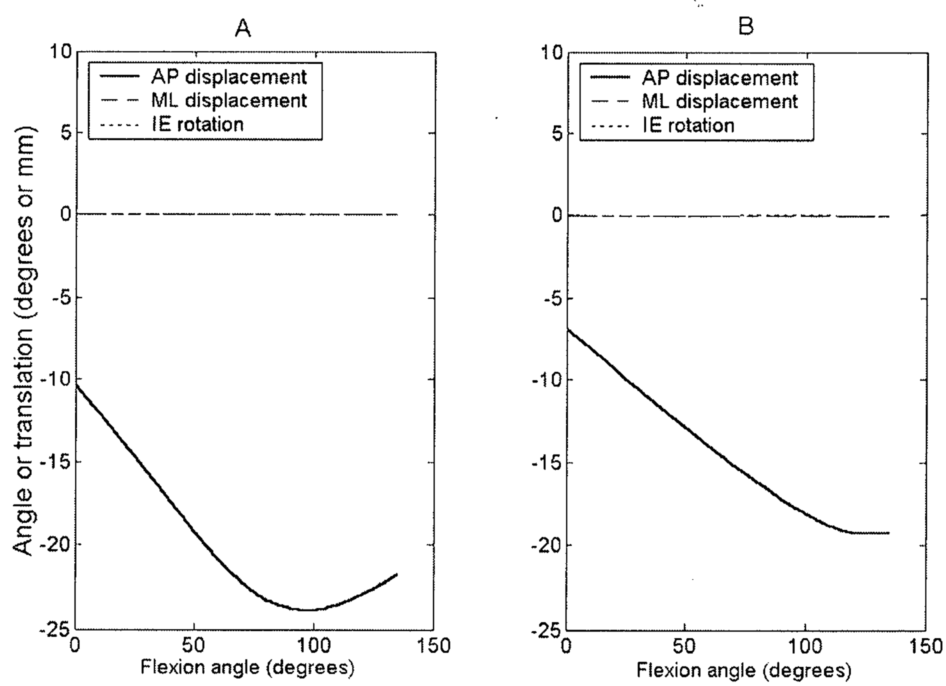

Figure 3.4 - ii

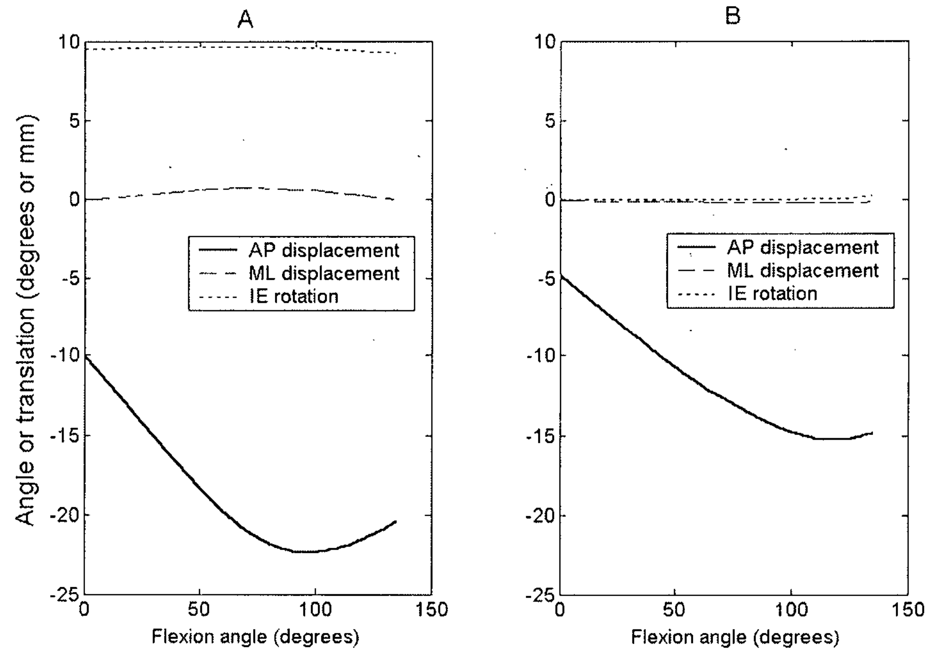

Figure 3.4 – iii

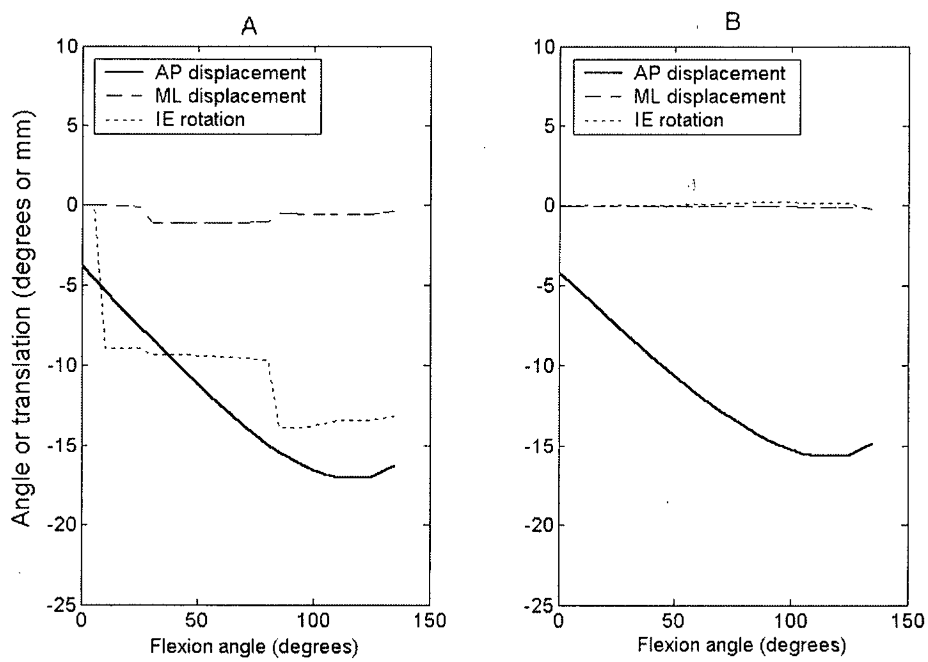

Figure 3.4 – iv

Figure 3.4 - Predicted kinematics for simulated imbalances from kinematic model at a given component placement. A. Standard placement B. Placement determined by optimization i. MCL shortened by 5 mm (varus deformity) ii. PCL shortened by 5 mm (flexion contracture) iii. MCL and PCL shortened by 5 mm (complex contracture) iv. MCL lengthened by 5 mm (valgus instability)

because of various simplifications in the models of the components (e.g., the symmetric locations of the collateral ligaments), other normal features such as internal/external rotation (i.e., the screw-home effect) are absent. The kinematics prior to the placement algorithm are not monotonic and exhibit occasional discontinuities and somewhat erratic trends. This is most likely due to the inability of the passive kinematic model to account for slack in knee ligaments, and represents an unstable knee. We see that after the placement algorithm has been implemented, all discontinuities are virtually eliminated and the kinematics are consistent with a stable configuration.

The variances in placement parameters determined from the thirty trials on the porcine specimen are shown in figure 3.5. The average standard deviation for all parameters was 0.8 mm/°. The variance in deviation from neutral length of each ligament over the 30 placements is shown in figure 3.6a. For all three ligaments the standard deviation in ligament length was generally less than 0.4 mm for all flexion angles. Figure 3.6b shows the variance in kinematics predicted by the passive kinematic model over all 30 placements. The

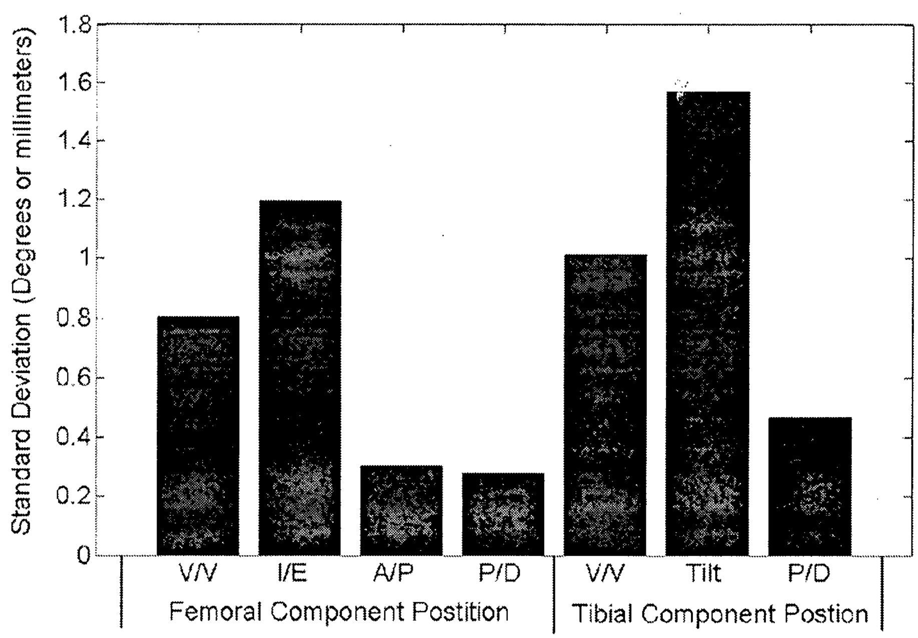

Figure 3.3 - Variances in placement parameters resulting from input data determined from intraoperative measurement technique on thirty porcine specimen trials.

kinematics had a standard deviation of 2 mm/° or less for all three of the parameters presented for all flexion angles and the trends were consistent across all trials. These results show that the placement algorithm is robust as it converges to repeatable placements and the predicted kinematics are not substantially altered by the variance of the ligament measurement technique.

3.5 Discussion

The component placement algorithm proved successful at determining a component placement that produced near isometric ligament behaviour throughout the range of motion for all simulations. Despite starting from markedly different states of ligament imbalance, the algorithm produced both

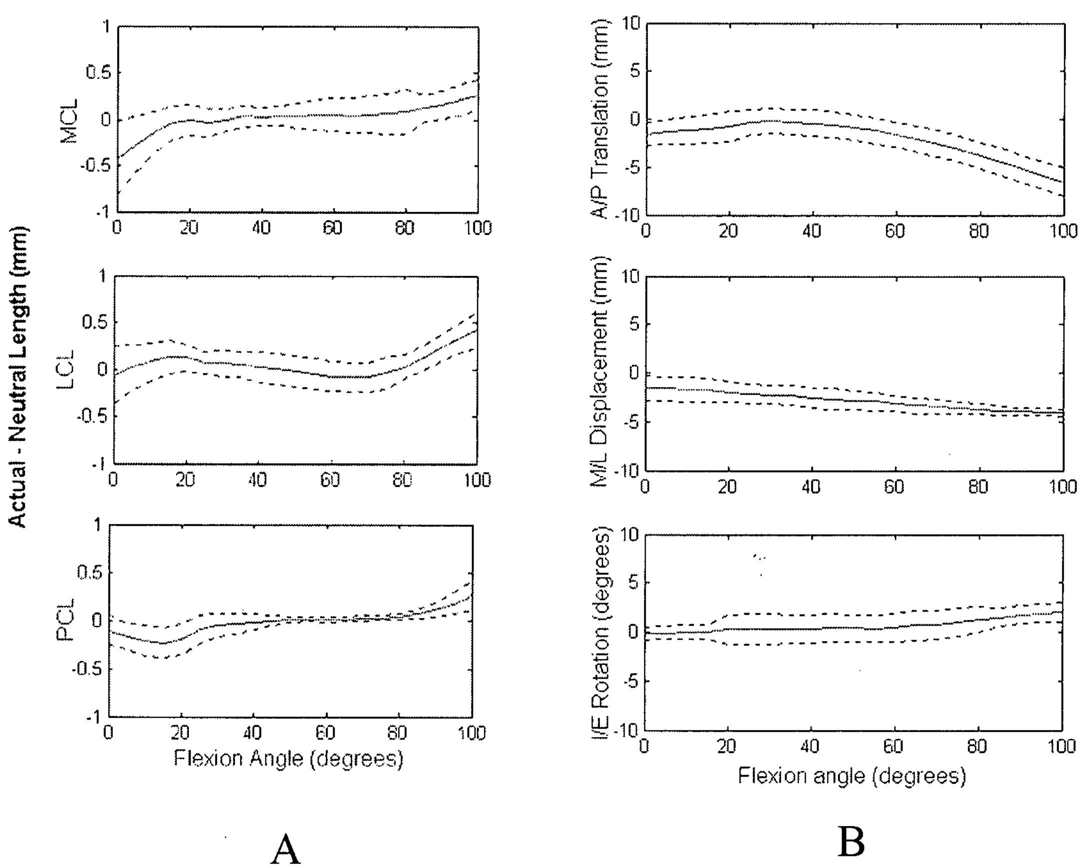

Figure 3.4 - Variances in predicted parameters from kinematic model resulting from input data determined from intraoperative measurement technique on thirty porcine specimen trials. A. Change in ligament lengths B. Kinematics

greatly reduced deviations from neutral length of each ligament, and similar kinematics. The algorithm proved robust to the variance in input resulting from our ligament measurement routine. The largest standard deviation in component placement parameters was 1.5° for the posterior tilting of the tibial component. Due to the flat geometry of the tibial component in our model, this parameters. The variation of the placement parameters due to variation of the input parameters resulted in repeatable ligament behaviour (less than 0.4 mm standard deviation in ligament deviation for all flexion angles, Figure 3.6a) and passive kinematics, (less than 2 mm/° standard deviation in passive kinematics for all flexion angles, Figure 3.6b).

The model used for the simulations in this paper is greatly simplified; it uses simple ligament models, simplified component geometries and non-deformable surfaces, and does not model wrapping of ligaments around bone. However, the model is in all respects topologically identical to the unconstrained prostheses currently being used and so captures the essential geometric relations which are necessary to model the behaviour of the knee complex and test the effectiveness of the placement algorithm. The attachment locations of the ligaments simulate the constraint found in the natural knee and result in similar kinematics when properly balanced. Our approach may be easily adjusted to accommodate more realistic geometric representations of implant components.

For example, Chen (Chen, 2001) described a bicompartmental knee model with the components having two condylar surfaces and non-congruent interaction. Our model was simpler as it did not account for the concavity of the tibial component or the geometries of the two condyles. However the goal of this study was to see if the placement algorithm could converge to an optimal solution for soft tissue placement and the incorporation of more complex component geometries should simply act to refine the result and can be easily implemented. Indeed, congruency of the components would likely increase the robustness of the placement algorithm, as it would result in larger strains in the soft tissues as the placement deviates from the optimal (i.e. the cost function would increase more rapidly away from the minimum).

We implemented the passive kinematic knee model used by Martelli and our analysis is thus subject to the same limitations. In particular, the model does not account for the non-linear toe region in the stress-strain curve of knee ligaments that is reported by many authors (Butler, 1986; Noyes, 1984; Quapp, 1998; Woo, 1991). In our ligament measurement routine, we manually distracted the knee joint using a force of 90-120 N. Quapp (Quapp, 1998) investigated the stress-strain behaviour of the human MCL. In his measurements the effect of the initial non-linear toe region is negligible after approximately 3 MPa of stress. If we assume the cross-sectional area of the MCL to be 20 mm^2, this corresponds to a load of 60 N. In our intraoperative measurement technique, we calculate the neutral lengths of the ligaments under the distraction load; thus, this length represents a pre-loaded ligament. Any strain occurs in the linear stress-strain region and contributes significantly to the overall strain energy. Quapp stated that the material properties of the MCL specimens were comparable to those reported by Bulter (Butler, 1986) for the ACL, PCL and LCL. It is therefore reasonable to assume that all the knee ligaments share similarly-shaped stress-strain curves and to use a linear approximation for the preloaded behaviour. At this stage, we have modelled the ligaments as single bundle elements. Multiple ligament bundles may be added to the model at a later stage, although it is not directly evident that this would increase the accuracy of the model (see chapter two) and care should be taken to limit the number of bundles, as more bundles decreases computational efficiency. Our model also does not account for deformations of the articular surfaces, which would be present due to the polyethylene tibial component being more compliant than the cobalt-chrome material of the femoral component. However, since passive knee kinematics are assessed in an unloaded state which produces low compressive forces across the knee, it is reasonable to assume rigid surface contacts. Blankevoort (Blankevoort, 1991) described a more complex model that determined knee kinematics by equilibrating the forces and moments on and about soft tissues and deformable surfaces. He revealed that inclusion of deformable contact did not substantially alter the motion characteristics for that predicted by non-deformable contact.

The three ligaments addressed here are not the only soft tissues involved when balancing a knee during TKA. Other structures such as the illio-tibial track, capsule and tendon attachments are modified when obtaining proper balance of the knee (Faris, 1994; Insall, 1985; Laskin, 1989), but although our model neglects these structures, the ligaments alone have been shown to substantially control the behaviour of the entire knee complex (Wilson, 1998), so it is a reasonable first approximation. More detailed modeling of other relevant structures will be required to examine their role in passive knee kinematics and soft-tissue balance.

Despite the simplifications in the model and anatomy, we were able to obtain reasonable kinematics in comparison to other authors. The model implemented by Martelli (Martelli, 1998) was a 2D model in the sagittal plane. She tracked the point of contact on both the femoral and tibial components. If both points of contact moved simultaneously in the posterior direction, she concluded that the femoral component was rolling back upon the tibial component, resulting in posterior displacement of the femoral component with respect to the tibial component. However, if posterior displacement of the femoral component occurs with a stationary point of contact on the tibial component, she concluded that the femoral component was in fact spinning in place on the tibial component with little anterior/posterior translation. For our model, we reported only on the anterior/posterior translation of the femoral component with respect to the tibial component as a function of flexion angle. Thus, an increasing translation in the posterior direction with increasing flexion angle indicates femoral rollback, and an increase in flexion angle with no change in translation indicates spinning (as can be seen in Figure 3.2 etc.). When comparing our kinematics as shown in Figure 3.2 with those presented by Martelli, we see very similar trends in femoral spin and rollback as a function of flexion angle. Chen extended Martelli's model to three dimensions and included multiple fibre filaments, and reported similar rolling/spinning kinematics. Minor differences between our model and those developed by Martelli and Chen are expected due to the differences in component geometries and fibre bundles; however, the results still indicate similar trends. Wilson (Wilson, 1998) developed a model of the intact knee in which the articular surfaces in the medial and lateral compartment and the isometric fascicles in the ACL, PCL and MCL were represented as five constraints in a one degree-of-freedom parallel spatial mechanism. This model was different in that it modeled the intact knee with an ACL and did not include the LCL. Wilson argued that although the LCL is taut in full extension, evidence suggests that is goes slack in flexion, rendering the ligament unable to constrain knee flexion. In his model he found that the ACL, PCL and MCL combination best represented the passive kinematics of the natural knee. With the resection of the ACL in TKA, the LCL may play a more important role in passive kinematics and it is reasonable to include it in our model. His model also exhibited similar kinematic features including femoral rollback and tibial rotation coupled to flexion angle. Tibial rotation was not present in our model due to the simplified component geometries and symmetric collateral ligaments, although modifying the modeling parameters could potentially produce this motion. Our model was able to capture the essential kinematics of the implanted knee and predict essential functional parameters such as ligament strain behaviour that allowed us to validate the placement algorithm. The model may be easily modified to accommodate more realistic geometries.

3.5.1 Clinical Use

The component placement algorithm provides the surgeon with an intra-operative surgical planning and guidance tool that incorporates bone cuts, ligamentous constraint and component geometries. The system may prove especially useful in difficult clinical cases where the proper surgical strategy is not obvious. The system allows the surgeon to perform intraoperative measurements and simulations to evaluate different surgical options prior to making any irreversible cuts or releases. Evaluation of the resulting kinematics and ligament strain behaviour over the entire range of motion through simulation will identify any potential problems such as ligament rupture, limited range of motion or instabilities.

The optimal placement routine will increase the efficiency of the planning process, as it is able to identify a single optimal placement, as opposed to simply evaluating simulations of placements provided by the surgeon. In this paper, the placement goal was to obtain isometry in all ligaments throughout the full range of motion of the knee, which is a good approximation of normal function (Arms, 1983). This goal may be easily modified to better match the individual surgeon's preference should they wish to implement a different surgical goal. A simple example would be to weight strain deviations higher than laxity deviations should some degree of laxity be desired. In this manner, the system can assist the surgeon in satisfying their functional goals.

The typical goal of TKA is to obtain perfect implant alignment with respect to the mechanical axis of the leg in the coronal plane. In obtaining this goal, the surgeon still has a significant amount of freedom to choose some of the other variables involved in the procedure including component size, femoral component rotation, level of resection, anterior/posterior placements etc. These variables may be adjusted within certain bounds (ex. posterior placement of the femoral component is limited by notching of the femoral condyle when performing the anterior femoral cut) to obtain a more optimal placement, although it is not always apparent what the best combination of these variables should be for a specific patient. The routine developed in this paper may be used in conjunction with pre-specified limits on or setting of selected placement parameters to find the optimal placement within these constraints. This gives the surgeon a predictive method in which to evaluate surgical strategies as opposed to the iterative "adjust and evaluate" method currently used.

Comparison of the optimal placement for soft tissue with the optimal placement for alignment gives an indication of the expected degree of imbalance of the knee after the procedure. If there is a significant conflict, the surgeon must either accept some malalignment or modify the soft tissues. There is research that supports the notion that soft tissue balance plays a significant role in the long-term success of an implant and, as a result, the surgeon may wish to obtain a compromise between the alignment placement and soft tissue placement (Booth, 1999). Since it is easier to control placement of components than it is to control the grade of a release, it is often challenging to match soft tissues to a specific placement. Matching the bone cuts to the state of the ligaments is one solution to this problem and this type of approach is seen in some implantation systems (Surgical Navigation System, Medivision/Stratec Medical, Oberdorf, Switzerland). Once the optimal placement for soft tissue has been determined, a compromise between the two placements may be found, for example, by augmenting the cost function to penalize placements that deviate from the mechanical axis alignment.

3.6 *Appendix*

A basic translation along the current axes a distance ***a*** in the x direction, ***b*** in the y direction and **c** in the z direction is represented by:

$$Trans(a,b,c)=\begin{bmatrix}1&0&0&a\\0&1&0&b\\0&0&1&c\\0&0&0&1\end{bmatrix} \tag{3.9}$$

Rotation about the current x-axis, an amount α:

$$Rot_X(\alpha)=\begin{bmatrix}1&0&0&0\\0&\cos\alpha&-\sin\alpha&0\\0&\sin\alpha&\cos\alpha&0\\0&0&0&1\end{bmatrix} \tag{3.10}$$

Rotation about the current y-axis, an amount ϕ:

$$Rot_Y(\phi)=\begin{bmatrix}\cos\phi&0&\sin\phi&0\\0&1&0&0\\-\sin\phi&0&\cos\phi&0\\0&0&0&1\end{bmatrix} \tag{3.11}$$

Rotation about the current z-axis, an amount γ:

$$Rot_Z(\gamma)=\begin{bmatrix}\cos\gamma&-\sin\gamma&0&0\\\sin\gamma&\cos\gamma&0&0\\0&0&1&0\\0&0&0&1\end{bmatrix} \tag{3.12}$$

3.7 References

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Chapter 4 – Summary of Results and Future Work

4.1 Introduction

Total knee arthroplasty is a very successful procedure by most surgical standards. Great advances have been made over past few decades to improve the long-term outcome of these procedures. Despite the current success, significant failure rates are still being reported that result in substantial costs in terms of revision surgery and patient dissatisfaction. Recent computer-assisted knee surgery systems have the potential to address many of the reported causes of failure by providing the surgeon with a more comprehensive approach to the procedure with predictive measures of outcome based on intraoperative courses of action.

Although a CAS system is not a substitute for good surgical judgment and a thorough understanding of knee biomechanics and the limitations posed by an individual patient's anatomy, a CAS-based surgical advisory system may well be useful as a tool to provide the surgeon with relevant clinical information to assist with surgical decisions. The system proposed in this thesis does not substitute for the surgeon's diagnostic, planning, implant selection, and final implant installation skills.

The objectives we set out for this research included incorporating quantitative intraoperative soft-tissue guidance in a CAS system and performing these measures reliably enough that soft-tissue considerations may be used in surgical planning and intraoperative simulations. In this thesis I investigated two methods that were required to meet these objectives: the first was a method of measuring the ligament anatomy of a patient before extensive bone cuts are made, while the second was a method to determine the component placement that best satisfies ligament strain behaviour throughout the full range of motion.

4.2 Results

The ligament identification method proved very repeatable at finding the attachment locations and ligament lengths of the porcine specimens. The two-and three-ligament models had repeatabilities on the order of 0.6 and 1.1 mm (SD), respectively, for the parameter estimates. Interspecimen repeatability was consistent, and interoperator repeatability was excellent for the two-ligament model (2 mm or less from the mean) and somewhat larger for the three-ligament model (8 mm or less from the mean). The fixed point measure, which is more appropriate for assessing when the ligaments reach tautness, had significantly smaller variability (0.1-0.2 mm SD). The attachment locations determined using this method represent the functional attachment locations of the ligaments in terms of their constraint on the knee joint. They differed significantly from the anatomical attachment locations and may be more appropriate to use in kinematic knee models. This degree of repeatability is sufficiently precise to support incorporating quantitative constraint measurements into the assessment and planning of soft tissue balance in computer-assisted total knee replacement procedures.

The component placement algorithm was successful at determining a placement that results the prediction of near isometric behaviour of the ligaments throughout the range of motion by a passive kinematic model when various ligament imbalances were introduced in a simulated knee. In all simulations, after the placement algorithm, no ligament exceeded 0.8 mm of deviation from neutral length for any flexion angle. The algorithm also proved robust to variance in the ligament input parameters that were obtained from the porcine specimen using the ligament identification method. The average standard deviation for the placement parameters determined from the thirty trials on the porcine specimen was 0.8 mm or degrees. The standard deviation in deviation from neutral length of each ligament over the 30 placements was generally less than 0.4 mm for all flexion angles. The standard deviation in kinematic parameters predicted by the passive kinematic model over all 30 placements was 2 mm or degrees or less for all three of the parameters (anteroposterior translation, mediolateral translation and internal/external rotation), for all flexion angles and the trends were consistent across all trials.

4.3 *Clinical Use of the Overall System*

The two methods presented in this thesis are the first steps in the development of a surgical advisory system. Used in conjunction with the proven capability of the non-CT based CAS system in determining the mechanical axis (under development at the Neuromotor Control Lab, Department of Mechanical Engineering, University of British Columbia), they have the ability to provide the surgeon with extensive clinical information upon which to base surgical decisions. The following is a brief overview of how a surgical advisory system would be used in a typical TKA procedure.

1. Patient has a non-invasive hip tracker installed by pre-operative staff, which tracks the motion of the pelvis using an optoelectronic system. (Refer to Inkpen(Inkpen, 1999)).

2. The knee is exposed and the patella reflected. Bone pin markers are rigidly attached to the distal femur and proximal tibia.

3. The centres of the hip joint, knee joint and ankle joint are found through limb manipulation and digitization of relevant anatomy (Inkpen, 1999; Leitner, 1997). Through digitization of anatomical features, bounds can be set on component placement to avoid problems such as anterior notching, under/over sizing of components, distortion of joint line and/or inadequate bone coverage.

4. Any preliminary soft tissue releases are performed and may be verified by checking alignment with the CAS system.

5. The proximal tibial cut is performed with the use of instrumented cutting guides.

6. The ligament attachment locations and neutral lengths are found by manually distracting and manipulating the tibia with respect to the femur (as described in Chapter 2). For this manipulation it may be necessary to return the patella to its anatomic position.

7. At this time the surgeon has several options available.

a. Option A – The ligament data is input into a kinematic knee model (as described in Chapters 2 and 3) with simulated standard component placement and sizes. The model predicts the resulting knee kinematics and strain in each ligament over the entire range of motion. The surgeon then uses this information to evaluate the current state of ligamentous balance and to decide upon further release.

b. Option B – The ligament data is input into a kinematic knee model and the surgeon simulates an alternative placement, component size and/or release to evaluate resulting function.

c. Option C – The ligament data is input into the optimal placement algorithm (as describe in Chapter 3) and the component placement that results in the best ligament behaviour over the range of motion is determined. The surgeon may use this placement to evaluate the current state of soft tissue release and guide further release. Alternatively the surgeon may elect to modify the standard component placement to better approximate the placement determined by the optimization routine.

d. Option D – The ligament data is input into the optimal placement algorithm along with custom limits on component placement, a customized cost function that targets a compromise between optimal alignment and optimal balance and/or modified ligament behaviour and an optimal placement is found. The surgeon may use this placement as a guide to evaluate surgical strategies and resulting kinematics.

8. Once an appropriate surgical strategy has been determined and all soft tissues addressed, the cuts on the femur are completed with the use of instrumented cutting guides.

9. The procedure is completed in the standard fashion through trial reduction and final soft tissue adjustment if required.

4.4 Surgical Advisory System Concept

Computer assisted surgery systems have the potential to greatly affect the outcome of TKA procedures as they are able to register surgical parameters and take advantage of computational power and accurate tracking of surgical tools. The advantages offered by CAS systems that rely on imaging technologies have been demonstrated (Delp, 1998; Saragaglia, 2001) and appreciated by the surgical community. The drawback to these image-based systems is the added cost of each procedure; TKA is a very successful procedure and institutions may find it difficult to justify a significant increase in procedure cost for relatively small gain in terms of survivorship.

I have demonstrated how it is possible to add more features to the CAS system without relying on image acquisition. I have shown that it is still possible to assess soft-tissues and plan surgical strategies with a low cost non-CT based system. In chapter three of this thesis, I demonstrated how an optimal component placement could be found to obtain desired ligament behaviour. This is only one demonstration of the potential used of a surgical advisor system. As I discussed in chapter one, there is debate over the importance of whether bony alignment versus soft-tissue balance in replacement outcomes. The most likely solution is a trade-off between the two extremes. With the system proposed in this procedure, it is possible to incorporate a weighting scheme into the optimization algorithm between optimal alignment and optimal balance to establish this trade-off. The surgeon could also modify this weighting scheme to meet their preference.

4.5 General Representation of Constraint

Aside from patient selection, the interaction of the articular surfaces (determined by component geometry and placement) with the constraint imposed on them by the surrounding tissues, determines the success of an implantation. During the procedure the surgeon is able to modify both of these aspects. The passive soft tissue constraint on the knee is imposed by many structures including the ligaments, the joint capsule and the muscle attachments. The most appropriate component placement must account for all of the contributions to constraint. In this thesis, I choose to represent the constraint by fitting a model to the motion data collected in an attempt to explore the spatial degrees of freedom allowed by the constraint. However, a more general representation of the soft-tissue constraint of the 6 degrees-of-freedom between the femur and tibia may be more robust than fitting the simplified model described in chapter two. The variance found by calculating the separation of two fixed points representing the origins and insertions of the ligaments on the femur and tibia across all data points in the fixed point measurements, was less than the variance found from the outputs of the optimization routine. This indicates that the onset of ligamentous constraint was indeed more repeatable than the fit of parameters to the model. Thus, a more general representation of constraint, that is less dependant on model parameters may be a more suitable approach (Roweis, 2000; Tenenbaum, 2000). The challenge of this approach will be relating this representation to clinical parameters.

4.6 Future Work

4.6.1 Validation

The investigation of the ligament identification method can be considered a pilot study and more specimens and operators are required to verify the robustness of the method. To our knowledge, this is the first time a manual manipulation method has been used to identify ligament anatomy and the manipulation technique should be further refined. The operators recruited in this study had no previous experience in performing these manipulations and showed a noticeable improvement as the experiment progressed. With more practice and instruction, the intraoperator repeatability should improve and the interoperator differences should decrease.

The component placement algorithm was validated only through simulation. The ligament measurement method resulted in functional attachment locations and neutral ligament lengths that differed significantly from the anatomical values. I argued in chapter two that these functional values most likely better represent the ligamentous constraint imposed on the knee than anatomical values. Results found from the simulation using functional values must be compared to those from a physical model. Thus, experimental validation of the model and its inputs is required.

4.6.2 More Sophisticated Model

More realistic component geometries should be used in the placement algorithm for more accurate clinical validation and comparison with other models in the literature. Other authors have talked of the need to model the ligaments as multi-fibred structures to capture the non-linear constraint introduced by varying bundle function with flexion angle. In this thesis I have shown that for the porcine model, the single fibre model proved adequate as the model fitting errors reported in chapter two were very low, less that 0.6 mm. Thus the need for multi-fibre ligament modeling is questionable for the porcine model, although this will need to be assessed again when applied to the human knee.

4.6.3 Cadaver testing

The ligament measurement method presented in chapter two was tested and validated using porcine specimens. The next step is validation using cadaver specimens. Although the porcine model is a reasonable representation of the human knee, there exist significant differences in geometry, load bearing, and knee kinematics. The porcine knee is in general much smaller than the human knee, with more acute condyles. Also, the porcine knee does not go into full extension and has a much smaller functional range of motion. To investigate cadaver models, we did perform a small number of trials on an embalmed cadaver specimen with reasonable success. However, due to the low number of trials, repeatability could not be appropriately assessed. It is also unclear how the embalming procedure affects the integrity of the soft tissues, thus fresh cadaver specimens should be used.

4.6.4 Clinical Feasibility

This method has shown potential for use in clinical settings, although assumptions have been made that must be verified.

- It has been assumed that the extensor mechanism will not interfere with the ability to perform the manual manipulations required in the ligament identification procedure. It is believed that due to the relaxed state of the muscles as the patient is under anesthetic, the patella will be not add constraint to the motions and may be left in the reflected position or at worst return to the anatomic position.

- As a first step, it has been assumed that the primary ligaments of the knee are the only structures that provide significant constraint to dictate passive knee kinematics. It has also been assumed that the spatial degrees of freedom exploited by the manipulation technique will be constrained solely by the two or three ligaments being modeled, and that other structures such as the joint capsule, illio-tibial band, muscle attachments and soft-tissue mass will have no significant effect. It may prove necessary to model more structures or develop a more general model-independent representation of constraint.

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Appendix A – Computer Methods in Biomechanics and Biomedical Engineering Proceeding, Rome 2001

INTRAOPERATIVE MEASUREMENT OF LIGAMENTOUS CONSTRAINT DURING COMPUTER-ASSISTED TOTAL KNEE REPLACEMENT

Scott Illsley and Antony J. Hodgson

1. ABSTRACT

A new motion-based procedure for identifying effective ligament lengths and attachment sites surrounding the knee during computer-assisted total knee replacement surgery is introduced. A non-linear least squares optimization algorithm was used to identify effective attachment locations and ligament lengths based on motion data captured using an optoelectronic metrology instrument (Flashpoint 5000, Image Guided Technologies). The data was applied to a two-ligament model of the knee consisting of the collateral ligaments only, and a three-ligament model consisting of the collateral ligaments and the posterior cruciate ligament. The models were validated using a porcine specimen with all structures dissected except the modeled tissues. Repeated measures were performed by two operators on a single specimen for both ligament models. For the two-ligament model, the standard deviation of identifying effective ligament locations was 0.8 mm and 0.6 mm for the two operators. For the three-ligament model the standard deviations were 1.1 mm and 2.4 mm. The average standard deviation of identifying effective ligament lengths was 1.6 mm for the two-ligament model and 2.4 mm for the three-ligament model.

2. INTRODUCTION

One of the major goals of total knee arthroplasty (TKA) is the restoration of normal knee kinematics. This is dependent on the geometry of the components, the placement of the components and ligament balance.(1-3) During passive knee kinematics, as observed by a surgeon in the operating room, the components are kept in contact by the tensile forces exerted by the surrounding ligaments. Thus for given component placements and geometries the passive kinematics are governed by the interaction of the contacting surfaces of the femoral and tibial components under the influence of the surrounding ligaments. Obtaining appropriate ligament balance during the procedure is a requirement for a successful implantation.

Attempts have been made by many researchers to quantify the degree of ligamentous balance intraoperatively.(4-7). These methods generally involve static measures of contact pressure and/or relative tension in the ligaments and focus mainly on imbalance in the frontal plane (varus/valgus). They generally measure the imbalance apparent in the flexion and extension gaps formed after the femoral and tibial bone cuts have been completed. The knee is "balanced" when equally spaced, rectangular gaps have been obtained. Assessment of the overall kinematics of the knee throughout the range of motion is not performed.

Computer models can be beneficial in exploring the knee kinematics throughout the range of motion. Martelli et al.(8) have developed a model to analyze the passive kinematics as the instantaneous quasi-static solution to ligament strain energy minimization. For this model the inputs include the knee joint geometry, the state of individual ligaments, the surgeon's choice of implant placement and the degree of flexion of the knee. The outputs of the model are the location of the contact point between the components' bearing surfaces and the resultant state of the ligaments. This provided the kinematics of the knee joint and the resulting strain in each ligament throughout the specified range of motion..

The strain energy model is sensitive to the accuracy of the inputs. The component geometries are well known and their placement can be accurately specified, however obtaining accurate information regarding the ligament lengths and attachments is difficult due to the limitations introduced due to the intraoperative environment. During the surgery access to the ligament origin and insertion sites is limited and overlying soft tissue and bodily fluids hampers clear visualization. The attachment sites of the ligaments cover a small area of bone making it difficult to identify a specific functional attachment. Martelli et al. performed measurements using engineering calipers and claimed this to be the most critical step in building an individual model of the knee.

This paper introduces a method to intraoperatively determine the functional attachment sites and lengths of the ligaments surrounding the knee. This information may then be incorporated into a model similar to that developed by Martelli et al. to assess ligament balance throughout the functional range of knee motion. The method is to be used in conjunction with an existing CAS system for knee arthroplasty and requires no additional hardware. The measurements can be made prior to any femoral bone cuts, having first made the tibial cut. Motion data is captured while manually distracting and manipulating the knee to determine the effective ligament attachment sites and lengths. Our hypothesis is that the method will repeatedly identify the functional attachment sites and lengths of the ligaments surrounding the knee joint across different users.

3. MATERIALS AND METHODS

Through mechanical manipulation of the tibia with respect to the femur, the effective constraints introduced by the soft tissue may be quantified, provided adequate manipulations are performed. We propose a model-based simplification of this general approach and propose to determine the effect of ligamentous constraint.

3.1 Optimization Routine

An optimization algorithm based on a simple knee model was used to determine the ligament attachment sites and lengths. Two models were tested as part of this study, a two-ligament model consisting of only the collateral ligaments, and a three-ligament model consisting of the two collateral ligaments and the PCL. These two models represent the most common occurrences in TKA, that of a

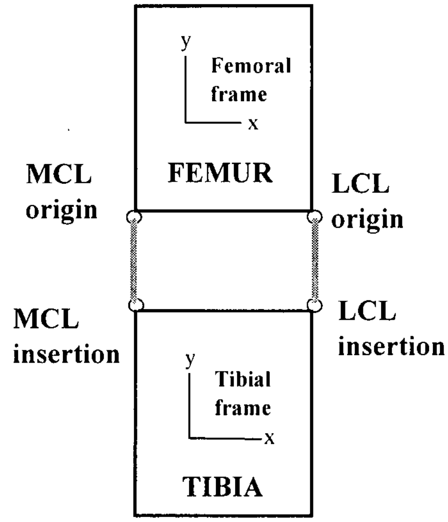


Figure 1 - Ligament Model

PCL sacrificing or substituting implant (where the PCL is resected) and a PCL retaining implant.

The two bones and remaining ligaments were modeled as two blocks and inextensible strings (Figure 1). Each of the bones had a unique reference frame defined arbitrarily by the marker array attached to it. An initial guess was made for the ligament attachment sites, the origins represented in the femoral frame and the insertions represented in the tibial frame. The position and orientation of the tibial frame in femoral frame co-ordinates was measured with the ligaments assumed under tension. A homogeneous transform relating the femoral frame to the tibial frame was then determined. The coordinates of the ligament origin guesses were then transformed into the tibial frame, and the lengths of the ligaments found by simple subtraction (origin-insertion; Euclidian distance). The position of the tibial frame in the femoral frame was then varied over a large series of different positions in space while maintaining full tension in the ligaments. At each position the ligament lengths were calculated. A non-linear least squares optimization algorithm (trust region) was used to determine the insertion and origin locations that minimized the variance of the ligament lengths over the entire dataset. The input to the optimization was a guess for the ligament attachment sites and the position of the tibial frame at each data point. The output was the x, y, z coordinates of the ligament attachment sites (in the femoral and tibial frames) that minimized the change in ligament lengths. The optimized attachment sites were then used to calculate the ligament lengths at each data point and the mean lengths reported.

3.2 Experimental Protocol

A fresh frozen intact porcine hind limb was obtained in accordance to the University of British Columbia animal testing regulations. The animal was six months old at time of death and had a mass of 150 kg. Prior to testing the limb was allowed to thaw for 12 hours. The limb was then dissected leaving only the tibia, femur and relevant ligaments (MCL, LCL and PCL) intact. Using a surgical cutting guide and oscillating saw, the proximal end of the tibia was cut in accordance to the manufacturers recommendations (J&J).

The proximal end of the femur was then rigidly mounted to a tabletop to represent an intact hip joint. A small cord was attached to the distal end of the tibia to allow the user to effectively grasp the limb. The limb was distracted manually by applying tension to the tibia in the distal direction. Care was taking to maintain distraction at a level greater than 20 lbs throughout the data capture. An optoelectronic metrology system was used to collect data during the experiment (Flashpoint 5000, Image Guided Technologies, Boulder Co.). Marker arrays consisting of three infrared light emitting diodes were rigidly attached to both the femur and tibia using custom made bone pins, thus defining the femoral and tibial reference frames (Figure 2). The limb was then manipulated in seven distinct motions to explore all the potential degrees of freedom of the two bones and observe the constraint provided by the ligaments. For all the motions, care was taken to ensure that all ligaments were taut throughout the motion. Two operators performed 20 trials each on the porcine specimen. Each operator digitized a guess for the origins and insertions of each ligament using a stylus once per specimen. The PCL was then resected creating a two-ligament model and the trials repeated. After all trials were performed, the ligaments were dissected from the bones and the perimeter of their anatomical attachment sites digitized. Approximations of the hip and ankle centres were also digitized. The digitized anatomy was used to construct

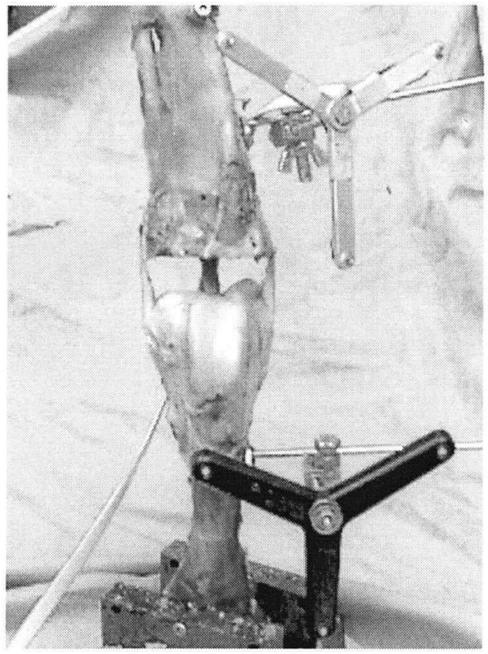


Figure 2 - Experimental Setup

reference frames at the centre of the distal femur and proximal tibia. These frames were used to convert the optimization parameters to value more relevant to the anatomy.

4. RESULTS

4.1 Intra-operator Repeatability

Figure 3a shows the standard deviation of each of the 12 two-ligament model output parameters averaged for each principle direction over the 20 trials for each operator. Figure 4 shows the standard deviation of each of the 18 three-ligament model output parameters averaged for each principle direction. Each operator showed an increase in variance for the three-ligament model. Insertion locations showed the greatest variance in general for both models with the largest of these variances being seen typically in the proximal/distal directions. The average standard deviations of identifying effective ligament lengths for the two-ligament model were 2.1 mm and 1.1 mm for the two operators respectively. For the three-ligament model the standard deviations were 1.9 mm and 2.9 mm respectively.

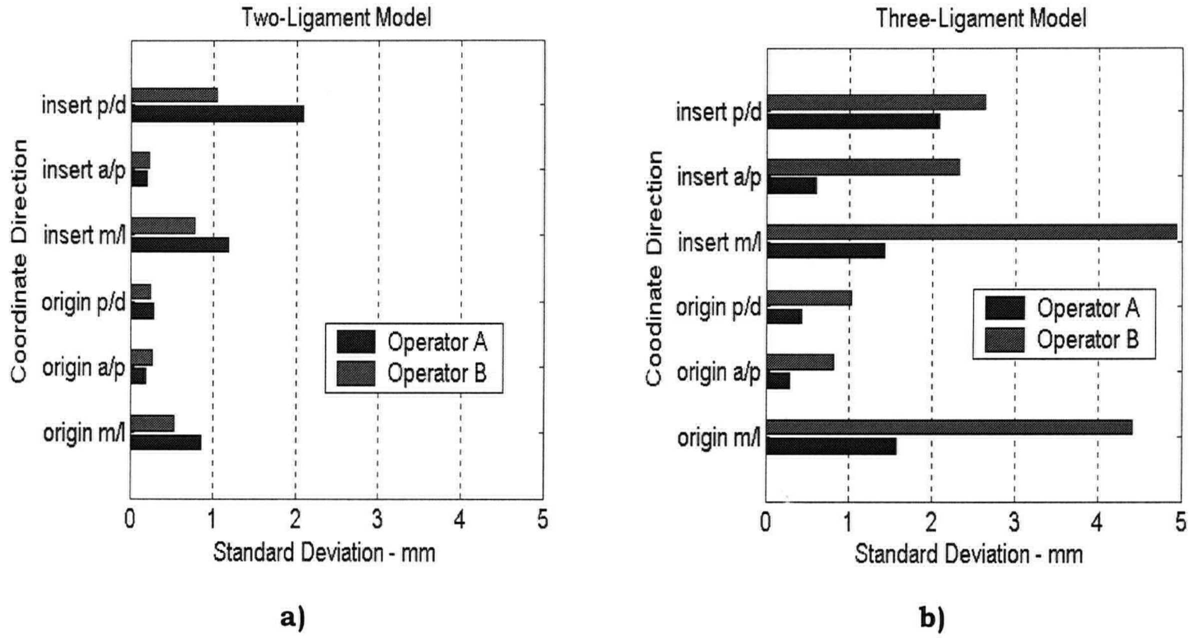


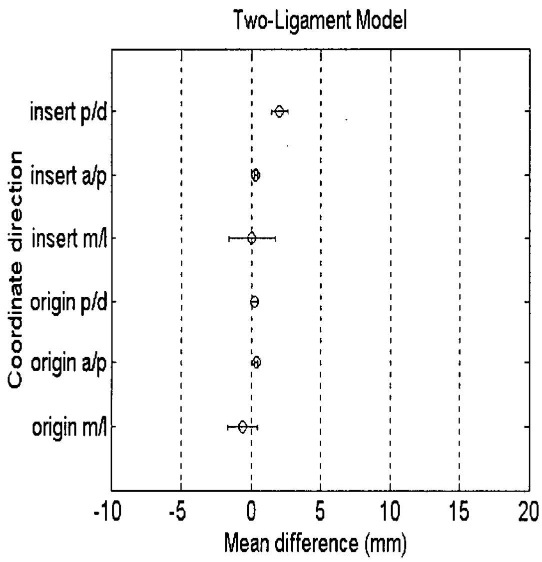
Figure 3 - Inter-operator Repeatability

4.2 Inter-operator Repeatability

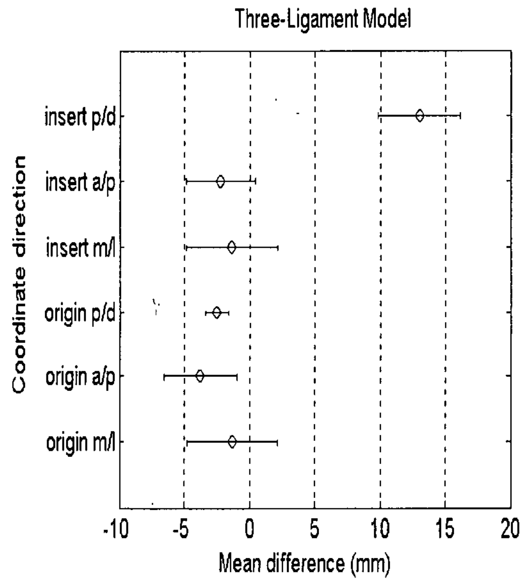
Figure 4 shows the differences between the operators for the two-ligament and three ligament-models. The 95 % confidence intervals for the difference in the mean of each output parameter are presented.

5. DISCUSSION

The results from this experiment show that the motion-based method is able to repeatedly identify effective ligament attachment sites and lengths. For the two-ligament model both operators had high repeatability over the 20 trials with typical standard deviations of less than 1 mm. For the three-ligament model, one operator show good repeatability with an average standard deviation of 1.1 mm, while the second operator showed poorer repeatability with and average standard deviation of 2.7mm. Retention of the PCL in the three-ligament model results in higher variance in the model. The PCL reduces the amount of motions that are possible to perform and also makes the motions more difficult to perform in a manner where by all ligaments remain taut.



a)



b)

Figure 4 - Intra-operator Repeatability

The differences between the operators were small for the two-ligament model but quite large for the three-ligament model. This may be due again to the fact that the manipulations were more difficult to perform in the three-ligament case. With more experience with the manipulations and a more strict approach, inter-operator differences may be significantly reduced.

This experiment is limited in sample size (2 operators, 1 specimen) and further testing is required to fully validate the method. Success of the method must be verified through the incorporation of the present results in a passive kinematic model.

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Appendix B – Provisional Patent Application

Intraoperative Measurement of Ligamentous Constraint During Computer-Assisted Total Knee Replacement

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Introduction

In total knee replacement surgery, the surgeon aims to restore limb alignment by removing the damaged surfaces of the knee joint and replacing them with metal and plastic (or sometimes ceramic) components. These components must be precisely aligned to maximize the implant's lifespan. The components are held together by soft tissue structures surrounding the knee, primarily the ligaments: posterior cruciate and lateral and medial collateral ligaments. These ligaments must be properly balanced to match the bone cuts – they cannot be too long or the knee will separate (a problem known as instability) and they cannot be too short or they may rupture when strained. Currently, this soft tissue balancing is considered an art; there are few ways to quantify the appropriateness of the soft tissue balancing that a surgeon does. Furthermore, the few existing techniques for quantifying balance are applied after the bone cut is complete, so the state of the soft tissue cannot enter into the surgical planning process. Since problems with soft tissue balancing represent one of the major unsolved problems in knee surgery, there is considerable interest in developing tools to assist with this process. We have developed a technique to quantitatively assess the degree of soft tissue constraint and to present the surgeon with this information prior to making the final bone cuts so that they can incorporate these considerations into their surgical planning.

Existing Post-Cut Assessments

Prior art includes devices for measuring the deviation from rectangularity of the space created by the distal femoral and tibial plateau rections when the limb is placed in extension or by the posterior femoral and tibial plateau rections when the limb is placed in flexion [1-3]. Others have also used pressure films or sensors after a trial component is placed to detect evidence of overly tight ligaments [4-5]. Martelli *et al.* present a technique for predicting the extent of overtensioning of the ligaments based on intraoperative digitization of the ligament origins and insertions [6]. While this could in principle be applied at the planning stage of the procedure, it has not been to date. Sarin *et al.* recently used the position measurement system integrated into a computer-assisted surgical system to measure the extent of varus or valgus looseness after the components had been placed [7].

Inadequacy of Anatomically-Based Technique

We take a fundamentally different approach. It is currently unclear how accurately a digitized centre for the ligament origins or insertions represents the actual constraint because ligaments consist of a large number of fibres; the load borne by the fibres may well shift throughout the range of motion of the knee and the fibres themselves typically wrap around bony portions of the knee, so the anatomical centres of the ligament origins and insertions may not be particularly good approximations of the effective positions of the constraints they provide. We have therefore developed a technique for measuring the effective constraints directly through analysis of the constrained motion of one limb segment relative to the other.

Our Motion-Based Method

In our approach, the surgeon first makes the standard tibial plateau cut (if so desired, this cut can be conservative, leaving enough bone stock for a further trim cut to adjust the final location of the cut). Once the proximal tibial segment is removed, the surgeon distracts the tibia until all ligaments are tensed and then attempts to manipulate the tibia in all possible directions and orientations, some of which will be resisted by the tensed ligaments. By modelling the ligaments as inextensible strings, we can perform an optimization computation to identify the effective origins, insertions and lengths of the ligaments. Our study of the effectiveness of this procedure shows that it is repeatable with a standard deviation on the order of 0.5-1.5 mm for one operator (2 & 3 ligament models, respectively) and exhibits interoperator repeatability of approximately 1-4 mm (2 & 3 ligament models, respectively).

Use of Motion-Based Technique in Surgical Advisory System

Once the constraint measurements have been made, we can compute the consequences of specified bone cuts on both the mechanical alignment of the limb and the soft tissue-related issues such as stability, ligament strain, joint range of motion, patellar tracking, risk of anterior notching, etc. Furthermore, because we can predict all these outcome variables, we can also estimate the optimal implant alignment if the surgeon provides us with target values and weightings for the outcome variables. The result of this computation could be provided to the surgeon in near real time so that the surgeon can decide whether to go ahead with the recommended bone cuts or to spend more time adjusting the soft tissue balance to further optimize the predicted outcome.

Contributions

We therefore claim as novel contributions to knee surgery:

1. A manipulation-based technique for quantifying soft tissue constraint.

2. A surgical technique in which the soft tissue constraint can be considered and adjusted prior to making the determinative bone cuts.

3. A surgical advisory system which facilitates this technique.

There is no special instrumentation required to implement our process beyond that which is routinely used in computer-assisted knee replacement procedures. In particular, there is no device related to this work which we consider patentable.

Documents Attached

In this submission, we have included the following documents; the first two are preliminary drafts of papers we intend to submit:

1. Quantifying Soft Tissue Constraint
2. Surgical Advisory System
3. PowerPoint Presentation prepared for BioRome Conference (Oct 31-Nov 3, 2001)

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