PRECISION AND ACCURACY IN
COMPUTER-ASSISTED TOTAL KNEE REPLACEMENT

by

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Abstract

In this study, I report on the development and preliminary testing of a computer-assisted technique for total knee replacement (TKR) surgery. In TKR, poor limb alignment increases the chances of early implant failure or complications requiring revision surgery. Errors of 3° to 5° in varus/valgus have been shown to cause poor outcomes. Based on 7 published studies (753 knees), I estimate the standard deviation (SD) of varus/valgus errors resulting from the current technique to be 2.6°. My long term hypothesis is that affordable and clinically practical computer assisted techniques can substantially reduce alignment errors and thereby improve outcomes enough to justify the additional cost, and my specific aim in this study is to estimate what alignment precision can be reasonably expected using such techniques.

I propose a system which would use optoelectronic tracking of the patient and the cutting guides to potentially allow adjustment of the guides to the desired orientation with greater precision than current techniques. The system would be completely passive and the surgeon would perform all cutting and other interventions by conventional means. It would also eliminate the use of intramedullary rods (potentially reducing the risk of fat emboli), would not require any additional preoperative procedures or imaging (such as CT scans) other than conventional TKR planning, and would not require any invasive procedures (such as insertion of bone pins) remote from the normal operating field. The goal of the system would be to help surgeons, particularly those less experienced in TKR, to consistently achieve their intended alignment with little or no increase in invasiveness, operating time, or recurring costs. The capital cost of the additional equipment and software is projected to be about C$75,000.

With the proposed system, the mechanical axis is located intraoperatively by tracking motions of the femur to compute the hip centre, selecting the desired knee centre at the distal femur with an optoelectronic probe, and either tracking motion of the foot or digitizing the ankle malleoli with a similar probe. I designed and built a prototype non-invasive hip tracker to eliminate the need for a bone pin or immobilization of the pelvis during this procedure. For the ankle centre, I tested a similar non-invasive foot tracker to allow tracking of foot motion without bone pins. As an alternative to tracking foot motion, I designed and built an ankle digitizing probe to robustly locate the midpoint between the malleoli. To start a cadaver testing program, I wrote MATLAB operating functions for the optoelectronic localizer system as well as routines to test and simulate the TKR procedure on cadavers. To estimate the improvement in alignment we
can expect from the system, I did three studies: First, I tested precision and accuracy of locating the hip and ankle centres by doing repeated measurements on 2 embalmed cadavers and one fresh cadaver. Secondly, I tested the precision and robustness of the new ankle digitizing probe with 6 different operators and 8 cadavers. Finally, to estimate the orientation difference between the cutting guide plane and the cut bone plane, I measured 20 simulated TKR cuts made by 2 surgeons and 3 untrained operators in cadaver bone using conventional cutting techniques.

At the 95% confidence limit of the results from these studies, standard deviation (SD) of overall varus/valgus alignment for the limited cadaver population studied is 1.1°. This is approximately twice as precise as the current technique as reported in the literature. Flexion/extension SD of the distal femoral cut and the posterior slope of the tibial plateau cut are each 1.2°, two to three times better than published estimates of current technique. Cutting errors (the orientation difference between the guide setting and the cut bone) account for 90 to 95% of this variance. Proximal/distal SD of the hip and ankle centres is about 2 mm, limiting the precision of specifying femoral and tibial lengths; alternately depth of resection can be set by conventional means. Rotational alignment has not been addressed at this stage, although repeated measures on one specimen show SD of 1.1° (at 95% confidence limit) of internal/external rotation when digitizing the transepicondylar axis. The system can be used in its current state to test the TKR procedure on cadavers, although a clinically acceptable hip tracker, optically tracked adjustable cutting guides, and a more complete user interface to the software should be developed to make future testing more representative of the complete clinical procedure.

These first results must be considered as a pilot study until more cadavers are tested. Robustness of the hip tracker on different individuals has not been shown, and results could be considerably worse on individuals with indistinct iliac crests (primarily due to obesity). Although precision of the new ankle probe has been shown (318 measurements), accuracy of the resulting ankle centre with respect to the centre of area of the talocrural joint could only be measured on one specimen, and the relationship to a true kinematic centre has not been investigated. More surgeons must be included in the bone cutting test to fairly represent average TKR technique. Considering these limitations, I conclude that the proposed system has the potential to allow TKR alignment with SD of about 1° and that further development and testing is warranted.
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Chapter 1:

Importance of component alignment in Total Knee Replacement and review of current techniques

1.0 Chapter Summary

Knee implant position and orientation and the resulting lower limb alignment have long been recognized as important factors in total knee replacement (TKR) outcomes. Poor alignment can cause short term failure or significantly reduce the life of the implant, requiring revision surgery. About 2% of TKRs fail requiring revision within 2 years (Heck, 1998), about half of which are due to aseptic problems such as poor alignment or ligament tension. At 4 to 5 years, approximately 2.7% have required revision for aseptic reasons (Callahan, 1994). With 280 000 TKRs per year in the United States alone and a revision cost of US$15 000 to $20 000, aseptic revisions at about 4 years represent a US$100 million annual cost which could be reduced by better alignment techniques. At up to 10 years follow up, typical revision rates are 4% (Ansari, 1998) to 5% (Robertsson, 1997). Coronal plane alignment errors of 3° to 5° have been shown to cause early failure (Jeffery, 1991; Schneider, 1984). In a meta-analysis involving 10 reports of the accuracy and precision of TKR alignment in the coronal plane, I estimate the standard deviation (SD) of current technique to be 2.6° for overall alignment, 1.9° each for the distal femoral and tibial plateau cuts. This shows that if the average TKR surgeon can align implants as well as the surgeons who measure and report their results, 5% of TKRs will be misaligned by more than 5°. Rotational alignment errors are related to patellar tracking problems, another major source of poor outcomes (Lewonowski, 1997; D'Antonio, 1996) and although it is generally agreed that internal rotation of the femoral component should be avoided, there is no precise definition of ‘ideal’ rotational alignment. Variation in the relative positions of rotational alignment landmarks is 2° to 4°. There are several techniques of setting the tibial tray rotation, with SDs from 2° to 4°, and a 20° range of positions between methods was found in one study (Eckhoff, 1995). Alignment precision in the sagittal plane has not been as widely reported, but 2 studies (Hofmann, 1991; Maestro, 1998) found SD of 3° to 4° for posterior slope and flexion of the femoral component.
1.1 Objectives

The goal of total knee replacement (TKR) surgery is to increase the patient’s mobility and give long lasting relief of pain with adequate range of motion. Many studies state that alignment is one of the most important factors in the success of TKR (Lotke, 1977; Moreland, 1988; Jeffery, 1991; Ritter, 1994). These studies have shown that poor alignment increases the chance of complications and/or early failure of the prosthesis, leading to revision surgery.

![Image of Total Knee Replacement Components](image from orthoweb.com)

**Figure 1.1: Total knee replacement components (Image from orthoweb.com)**

The long term objective of this project is to develop and test a system for improving alignment accuracy in TKR surgery. To achieve good alignment, the surgeon must be able to:

1. Plan correct limb alignment.
2. Register the plan to the patient intraoperatively
3. Accurately cut bone and achieve final implant positions as planned.

In this study, my specific aim is to improve requirement 2 above by developing and testing a passive computer-assisted alignment system that simply helps the surgeon locate the mechanical axis and then position conventional cutting guides at the desired orientation. To
address requirement 3, I measure the accuracy of conventional cutting techniques to see if
development of better cutting tools (such as robotically guided bone saws) is justified.

A good alignment system is no substitute for good surgical judgement and a thorough
understanding of knee biomechanics, the implant, and the limitations posed by the individual
patient’s anatomy. Accordingly a ‘cookbook’ alignment approach should be avoided, but careful
design of a system that improves accuracy, precision, and eliminates potential sources of error
will improve outcomes particularly when the surgeon is less experienced in TKR. Accurate
alignment will also improve future study of TKR outcomes by reducing the confounding
variables associated with component positioning. The proposed system does not, however, offer
any substitute for the surgeon’s diagnostic, planning, implant selection, and final implant
installation skills.

Obtaining the proper ligament tension (‘soft tissue balancing’) is also one of the most
difficult and important aspects of TKR and is not addressed directly in this study, although the
ability to put the components where intended is an essential step towards further development of
tools to optimize ligament tensions (Martelli, 1998). In addition to knowing the alignment
correction possible within ligament balancing limits, the surgeon must also make the proper
implant selection and control the overall position to give full bone coverage without creating
stress concentrations (such as notching of the anterior femoral cortex). As an implant may
migrate (‘subside’) from its original position as the patient returns to weight bearing (particularly
if full bone coverage is not achieved), changing alignment by several degrees over time, it is
important to note that an alignment system can only improve the initial bone cuts.

Moreland (Moreland, 1991) stated that “The bony preparation for knee replacement
consists of the creation of a series of flat bony planes. Each flat plane requires three factors to
describe the plane’s relationship to the bone. Two angles are needed along with the depth of the
cut into the bone. The two angles and the depth of the bone resection must take their orientation
from bony landmarks. There is currently debate as to which bony landmarks are the optimal ones
for determining the position of the bony resections.” He also points out that preoperative
deformities may make use of these landmarks difficult. An improved system would minimize
the number of bony landmarks required and, for those still necessary, provide a robust way of
using the landmark.
The most biomechanically relevant and well defined reference for TKR alignment is the line between the centres of the hip and ankle joints (Jeffery, 1991; Jessup, 1997), the ‘mechanical axis’ of the lower limb. TKR tooling must accurately define both the mechanical axis and a point off the axis (usually in the coronal plane) to define a reference frame for positioning and orienting the components. It is generally agreed (Moreland, 1988; Jeffery, 1991; Elloy, 1992) that the centre of the knee joint should lie on the mechanical axis (Figure 1.3a), often referred to as ‘neutral alignment’. If the knee centre lies lateral to the mechanical axis, the limb is in varus (‘bow-legged’, Figure 1.3b), and if the knee lies medial to the mechanical axis the limb is in valgus (‘knock-kneed’, Figure 1.3c). Many studies refer to the angle between the shaft of the tibia and the shaft of the femur (the ‘tibiofemoral angle’), stating that ‘normal’ alignment is 5° to 9° valgus. This method, sometimes referred to as ‘anatomic alignment’, is not as well defined as referring directly to the hip joint centre due to individual differences and worse measurement accuracy (Jessup, 1997). The tibiofemoral angle that gives neutral alignment varies substantially among individuals and error is introduced in finding the shaft axis, particularly if the femur or tibia is bowed. In contrast, the mechanical axis refers directly to the function of the lower limb as a whole, regardless of the shape of the individual femur and tibia, and is well defined by the joint centres.
1.2 Justification

To justify the use of a better TKR alignment system, it must be shown that:

1. Better outcomes will result from a certain improvement in accuracy.
2. The proposed system offers this improvement in accuracy over current techniques.
3. Costs of the new system are offset by improvement in outcomes.
4. The system poses equal or fewer risks to the patient.

1.2.1 Importance of alignment to outcomes

The objective of this section is to estimate the proportion of poor outcomes of TKR that can be attributed to poor alignment. For example, can we say that on average, a certain percentage of revisions are a direct result of inaccurate component placement? If so, that percentage of revisions could be prevented by use of a better alignment system and a breakeven analysis could be done to justify investment in the new system. Moreland (Moreland, 1988) reviewed mechanisms of TKR failure and concluded that “Prosthetic alignment is the most
important factor influencing postoperative loosening and instability”. The three distinct aspects of component orientation are as follows:

- About the anteroposterior axis, ‘coronal plane alignment’ (or ‘frontal plane alignment’)
- About the mechanical axis, or ‘rotational alignment’
- About the mediolateral axis, ‘posterior slope’ at the tibial plateau, ‘flexion-extension’ at the femur

The position of the components is defined by the bone stock available and the depth of resection required.

1.2.1.1 Coronal plane alignment

Coronal plane alignment has long been said to be a significant factor in the longevity of TKR (Lotke, 1977; Coventry, 1979). It is generally accepted that error leaving the limb in varus leads to substantially worse outcomes: Varus alignment increases compressive loading on the medial compartment and increases tensile loading on the lateral collateral ligament, increasing wear and chance of instability (Andriacchi, 1994; Hilding, 1995). Ritter (Ritter, 1994) found better survivorship among normal and valgus postoperative alignment knees as compared to varus, concluding that the surgeon should aim for neutral or slightly valgus alignment. Jeffery (Jeffery, 1991) studied 115 TKRs done between 1976 and 1981 and at median 8 year (range 0-12) follow up they found a highly significant correlation between poor alignment and component loosening. When the postoperative mechanical axis did not pass through the middle 1/3 (±11 mm) of the knee, corresponding to a varus or valgus misalignment of 3° or more, the incidence of loosening was 24% compared to 3% for knees aligned within ± 3°.

1.2.1.2 Rotational alignment

The rotational position of the femoral component about the mechanical axis defines the mediolateral (ML) position of the patellar groove and the anteroposterior (AP) positions of the posterior condyles, affecting patellar tracking and the distances of the posterior condyles to the tibial plateau in flexion (the flexion gap). If the patellar groove location of the component does not line up with the patient’s leg extensor apparatus (quadriceps muscle group, quadriceps tendon, patella, patellar ligament, and tibial tubercle) discomfort, excessive component wear, or dislocation of the patella may result (Figure 1.4). If the flexion gap is not the right size or shape and soft tissue balancing cannot be done to compensate, the knee may have limited range of
flexion (flexion contracture) or instability. Some clinicians and researchers claim that patellar tracking problems are currently the leading cause of TKR problems (Lewonowski, 1997; D'Antonio, 1996). Berger (Berger, 1998) compared a group of 30 patients with patellar tracking problems ranging from lateral tracking and tilt to patellar dislocation and implant failure to a control group of 20 well functioning TKRs. All 50 patients had coronal plane alignment within 1° varus to 2° valgus. Based on a CT analysis referring to the surgical epicondylar axis and the tibial tubercle, they found that internal rotation (relative to typical anatomy found in previous studies) of the femoral and tibial components of 1° to 17° was correlated to the severity of the patellar problems, while the control group with no patellar problems had external rotation of 0° to 10°.

At the tibia, the rotational position of the tibial component is found after the femoral component is in place. Most modern prostheses have some degree of congruency between the femoral and tibial articular surfaces, requiring the tibial component rotational position to match the femoral component. Once the tibial component is fixed to the tibia, the tibia is constrained in internal/external rotation (except in mobile bearing prostheses) by the congruency with the femoral component, the alignment of the extensor apparatus attaching to the tibial tubercle, and to a lesser degree by the remaining soft tissues around the joint. Mismatch between these constraints may lead to premature wear of the bearing surfaces, poor patellar tracking, or instability.

1.2.1.3 Posterior slope

Orientation of the tibial plateau about the ML axis, commonly referred to as the ‘posterior slope’, is a posterior-distal tilt of the tibial plateau. Posterior slope is increased to as much as 7° from the transverse plane to loosen the PCL in the flexed position and increase the flexion gap relative to the extension gap (Krackow, 1990). Quality of the resected tibial plateau bone may be an equally important consideration, and cutting the tibial plateau parallel to the natural posterior slope has been shown to increase load carrying capacity by 40% and stiffness by 70% compared to a cut normal to the mechanical axis (Hofmann, 1991).
1.2.1.4 Flexion/extension

The femoral component is normally designed with the distal cut plane normal to the mechanical axis. Improper size, AP position, or extension error in the distal femoral cut could create a notch on the anterior aspect of the femur, causing a stress concentration and increasing the chance of femoral fracture.

1.2.2 Accuracy of current techniques

To set accuracy and precision goals and to see if a new system is justified, we must estimate what alignment the typical patient is likely to have after TKR at the typical clinic.

1.2.2.1 Coronal Plane Alignment

Many surgeons currently use a femoral intramedullary (IM) rod (86% in the U.K., for example (Phillips, 1996)). IM femoral alignment is generally seen as an improvement over the original extramedullary femoral alignment techniques, which required estimation of the femoral head by palpation or preoperative application of a marker based on radiographs (Cates, 1993). However, there are several drawbacks in using IM alignment. Preoperative measurement of the
angle from the mechanical axis to the anatomic axis of the femur must be accurate and, intraoperatively, the IM rod must accurately represent the femoral anatomic axis used in planning. This means that the rod must engage the isthmus of the femur and the insertion hole must be located on the anatomic axis exactly as estimated on the preoperative radiographs. IM rods cannot be used in some cases, such as patients with bowed femora, long stem hip implants, or other conditions resulting in a blocked or abnormal medullary canal. For example Teter (Teter, 1995b) found 3.5% of 201 femurs to be unsuitable for IM alignment. Finally, IM rods potentially increase the risk of injury or death due to fat emboli (discussed further in Section 1.2.4). A typical femoral IM rod is shown in Figure 1.5.

Many surgeons currently use an extramedullary (EM) guide to make the tibial plateau cut (for example 76% in the U.K. (Phillips, 1996)). Most EM tibial guides use a clamp at the ankle to define the midpoint of a line between the malleoli. Some ML adjustment is usually provided so the surgeon can ‘fine tune’ the guide according to their estimate of the true ankle centre. Orientation about the ML axis (affecting the posterior slope) is set by visually aligning the guide with the anterior crest of the tibia. Depth of resection is usually referenced from features on the tibial plateau. A typical tibial EM guide is shown in Figure 1.5.

![Drilling of distal femur for IM rod](image1)

![IM rod inserted in femur](image2)

![EM guide on tibia](image3)

**Figure 1.5:** Typical alignment tooling used in current TKR practice (Images from Johnson & Johnson Orthopaedics)
Ritter (Ritter, 1994) stated that “Even when using sophisticated intramedullary alignment systems, surgeons find it difficult to achieve knee replacement within 2° to 3° in either varus or valgus alignment”. Many groups have analysed and reported their alignment results and compared alignment techniques by measuring postoperative radiographs of their patients. The radiographs must be long films of weight bearing stance, with the hip and the ankle included. An observer draws lines from the hip centre to the knee centre and the knee centre to the ankle centre. Neutral alignment is defined as 180° between these two lines, and error is expressed as the difference from 180° towards varus or valgus (Figure 1.3).

To estimate the coronal plane alignment error that the typical patient could expect after TKR, I did a meta-analysis of published studies which report mean error and standard deviation of final alignment with respect to the mechanical axis or some other well defined cutting goal. I searched MEDLINE for papers in English with “alignment” and “knee replacement” or “knee arthroplasty” in the title or abstract. Studies with less than 30 knees and those limited to atypical cases such as large deformity corrections were excluded. This search resulted in 7 eligible studies for overall alignment, one reporting femoral component results only, and 2 reporting tibial component results only. All are retrospective analyses of patients treated and assessed at the reporting clinic. I weighted results of different series reported within a study by sample size, and where the investigators found a significant difference between techniques I only used results from their best method. These selection criteria limit the generalizability of the meta-analysis results: Clinics that report their alignment performance may not represent the ‘average’ clinic, and not all clinics will test for and use the best of several alignment methods. These limitations are conservative, however, in that they should produce a lower estimate of error than the true ‘average’ clinic error.

**Overall alignment:** The data extracted from the studies are shown in Table 1.1 and the individual studies are summarized below:

- Brys (Brys, 1991) found no significant difference in overall alignment between 52 EM femur/IM tibia and 62 EM femur/EM tibia TKRs. I weighted the results by number of knees to give mean error of 3.0° varus (SD 4.1°) for all 114 knees.
- Elloy (Elloy, 1992) assessed 100 TKRs performed using IM alignment on both the femur and the tibia and found a mean error of 0.67° valgus with SD of 2.47° from the desired neutral alignment.

- Campbell (Campbell, 1993) found a mean difference of 1° varus with SD 5.6° between alignment correction desired and correction obtained in 30 consecutive TKRs performed by two surgeons using an “ASAP” (Richards Medical Co., Memphis, TN, USA) tooling system.

- Cates (Cates, 1993) found 41.5% of 200 TKRs to be more than ±2° from neutral alignment using both IM and EM tools, corresponding to a SD of 2.45°. Mean error was 0°.

- Ishii (Ishii, 1995) found no significant difference in overall alignment between 50 IM femur/IM tibia and 50 IM femur/EM tibia TKRs, with a mean error of 0.45° varus (SD 3.1°) for all 100 knees.

- Jessup (Jessup, 1997) obtained best results using IM femoral and EM tibial instruments, with a mean error of 1.3° (SD 2.7°) from neutral alignment in a series of 93 TKRs.

- Maestro (Maestro, 1998) found no significant difference in tibiofemoral angle in 61 IM femoral/IM tibia TKRs vs. 55 IM femur/EM tibia TKRs. I weighted the results by number of knees in each group, giving a mean error of 2.3° varus (SD 3.7°) for all 116 knees.

**Femoral cuts:** Four of these studies (Campbell, 1993; Ishii, 1995; Jessup, 1997; Maestro, 1998), along with one additional study that does not show overall alignment (Teter, 1995b), report errors in the distal femoral cut, and I apply the same analysis to estimate distal femoral cut precision. The studies are summarized below and results are in Table 1.2:

- Campbell (Campbell, 1993) found a mean error of 0.9° varus (SD 3.4°) between the desired and actual femoral cut angles in the coronal plane.

- Ishii (Ishii, 1995) found mean error of 1.30° valgus (SD 2.1°) for 100 IM distal femoral cuts.

- Teter (Teter, 1995b) found mean error of 0.1° valgus (SD 2°) from the intended femoral component to femoral anatomic axis in 201 TKRs.

- Jessup (Jessup, 1997) found a 0.2° mean varus error (SD 2.1°) in 93 distal femoral cuts with IM alignment.

- Maestro (Maestro, 1998) also found mean error of 0.2° varus (SD 2.2°) for 116 distal femoral cuts with IM alignment.

**Tibial cuts:** Similarly, 6 of the overall alignment studies also report tibial errors (Brys, 1991; Campbell, 1993; Cates, 1993; Ishii, 1995; Jessup, 1997; Maestro, 1998), and I have
included 2 additional studies of tibial errors only (Teter, 1995a; Yang, 1998). The data extraction is summarized below and results are in Table 1.3:

- Brys (Brys, 1991) found 52 IM tibial cuts (1° valgus, SD 1.6°) to be significantly better than 62 EM cuts (0° mean error, SD 2.5°). As overall alignment in the two groups was not significantly different, I weighted the results to include all 114 knees, giving error of 0.5° valgus (SD 2.1°) for the tibial cut.
- Campbell (Campbell, 1993) found a 0.9° mean valgus error (SD 2.8°) for 30 tibial plateau cuts.
- Cates (Cates, 1993) found 27.5% of 200 tibial cuts to be worse than ± 2° using EM tools, with a mean error of zero. This represents an SD of 1.8°.
- Ishii (Ishii, 1995) found 50 EM tibial cuts (mean 1.5° varus, SD 2.5°) to be not significantly different from 50 IM cuts (mean 2.0° varus, SD 2.2°), giving mean error of 1.75° (SD 2.35°) for all 100 cuts.
- Teter (Teter, 1995a) also found no significant difference between EM and IM tibial cuts, with weighted mean error of 1.5° varus. 92% of 140 EM cuts and 94% of 179 IM cuts were within ± 4°, representing a weighted SD of 2.2° for all 319 cuts.
- Jessup (Jessup, 1997) obtained their best results EM tibial instruments, with a mean error of 1.1° varus (SD 1.75°) in 93 cuts.
- Yang (Yang, 1998) compared 50 IM tibial cuts to 50 EM and found no significant difference, with overall mean error of 1.3° varus in the tibial component. 83% were within ±2°, corresponding to SD of 2.9°.
- Maestro (Maestro, 1998) found 61 IM tibial cuts (1° varus, SD 2.9°) to be significantly better than 55 EM cuts (2.7° varus, SD 3.5°). As overall alignment was not significantly different, I weighted the results to include all 116 knees, giving error of 1.8° and SD of 3.2° for the tibial cuts alone.

Most papers do not discuss their accuracy and/or precision of measurement alone, so it is difficult to tell how much of the reported alignment error is due to the surgeon and how much is due to the observer. However, some reports of observer accuracy and precision show that observation errors are not negligible compared to the errors reported. In a study of 50 surgeons measuring the same radiograph, Laskin (Laskin, 1984) found an interobserver standard deviation
of +/- 2.1° in measuring the tibiofemoral angle. When the surgeons measured the same radiograph 2 weeks later, the intraobserver S.D. was +/- 2.5° with a difference greater than 4° from 14% of the surgeons. Jeffery (Jeffery, 1991) stated that tibiofemoral angles could only be measured to “within 2°” and found SD of 0.8° in measurement of different films of the same patient, while Hilding (Hilding, 1995) reports an “interobserver SD of 0.5° in 2 series of repeated measurements by 2 independent observers (maximum 1.4° difference with 95% probability)” and “reproducibility in 7 double exposures on the same day of 1° difference in 4 and no difference in 3 knees”. Since the observed variance in alignment is a sum of the actual and measurement variances and the alignment errors we are interested in are only about five times the measurement variance, I assume that each clinic used a single observer with mean error of zero and measurement SD of 0.80° (Jeffery, 1991) and calculate the net alignment error SD attributable to the surgeon as shown in Equation 1 (Glantz, 1997).

$$SD_{surgeon} = \sqrt{SD_{reported}^2 - 0.8^2}$$

**Equation 1: Removing observer SD from overall reported alignment errors**

To estimate the overall mean error across the eligible studies, I weight each study mean error by its sample size divided by its sample variance (Equation 2). The variance of the error in each study is weighted by its sample size over the square of its variance (Equation 3). This weighting scheme was recommended for this particular case by the UBC Statistics department. The effect in both cases is to underweight studies with small sample sizes and large variances which have correspondingly large confidence intervals around their results. The final meta-analysis is shown in Tables 1.1, 1.2 and 1.3.

\[
\bar{X} = \frac{\sum n_i \bar{x}_i}{\sum n_i} \\
\bar{s}^2 = \frac{\sum \frac{n_i - 1}{s_i^4}}{\sum n_i - 1}
\]

Equation 2: Overall mean alignment error

\[
SD^2 = \frac{\sum \frac{n_i - 1}{s_i^2}}{\sum n_i - 1}
\]

Equation 3: Overall alignment error variance
Table 1.1: Meta-analysis of overall alignment errors

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample (knees)</th>
<th>Obser. SD</th>
<th>Mean error (degrees)</th>
<th>Std. error of mean</th>
<th>Reported S.D.</th>
<th>Net S.D. of surgeon</th>
<th>95% CI of net SD:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brys 91</td>
<td>114</td>
<td>0.8</td>
<td>3.00</td>
<td>0.38</td>
<td>4.10</td>
<td>4.02</td>
<td>3.56 4.62</td>
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<tr>
<td>Elloy 92</td>
<td>100</td>
<td>0.8</td>
<td>-0.67</td>
<td>0.23</td>
<td>2.47</td>
<td>2.34</td>
<td>2.05 2.71</td>
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<tr>
<td>Campbell 93</td>
<td>30</td>
<td>0.8</td>
<td>1.00</td>
<td>1.01</td>
<td>5.60</td>
<td>5.54</td>
<td>4.41 7.45</td>
</tr>
<tr>
<td>Cates 93</td>
<td>200</td>
<td>0.8</td>
<td>0.00</td>
<td>0.16</td>
<td>2.45</td>
<td>2.32</td>
<td>2.11 2.57</td>
</tr>
<tr>
<td>Ishii 95</td>
<td>100</td>
<td>0.8</td>
<td>0.45</td>
<td>0.30</td>
<td>3.10</td>
<td>2.99</td>
<td>2.63 3.48</td>
</tr>
<tr>
<td>Jessup 97</td>
<td>93</td>
<td>0.8</td>
<td>1.27</td>
<td>0.27</td>
<td>2.73</td>
<td>2.61</td>
<td>2.28 3.05</td>
</tr>
<tr>
<td>Maestro 98</td>
<td>116</td>
<td>0.8</td>
<td>2.27</td>
<td>0.33</td>
<td>3.65</td>
<td>3.56</td>
<td>3.15 4.09</td>
</tr>
</tbody>
</table>

Table 1.2: Meta-analysis of distal femoral cut errors

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample (knees)</th>
<th>Obser. SD</th>
<th>Mean error (degrees)</th>
<th>Std. error of mean</th>
<th>Reported S.D.</th>
<th>Net S.D. of surgeon</th>
<th>95% CI of net SD:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campbell 93</td>
<td>30</td>
<td>0.8</td>
<td>0.90</td>
<td>0.62</td>
<td>3.40</td>
<td>3.30</td>
<td>2.63 4.44</td>
</tr>
<tr>
<td>Ishii 95</td>
<td>100</td>
<td>0.8</td>
<td>-1.30</td>
<td>0.21</td>
<td>2.10</td>
<td>1.94</td>
<td>1.70 2.26</td>
</tr>
<tr>
<td>Teter 95</td>
<td>201</td>
<td>0.8</td>
<td>-0.10</td>
<td>0.14</td>
<td>2.00</td>
<td>1.83</td>
<td>1.67 2.03</td>
</tr>
<tr>
<td>Jessup 97</td>
<td>93</td>
<td>0.8</td>
<td>0.20</td>
<td>0.22</td>
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<td>1.98</td>
<td>1.73 2.32</td>
</tr>
<tr>
<td>Maestro 98</td>
<td>116</td>
<td>0.8</td>
<td>0.21</td>
<td>0.20</td>
<td>2.19</td>
<td>2.04</td>
<td>1.81 2.34</td>
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</table>

Table 1.3: Meta-analysis of tibial plateau cut errors

<table>
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<tr>
<th>Study</th>
<th>Sample (knees)</th>
<th>Obser. SD</th>
<th>Mean error (degrees)</th>
<th>Std. error of mean</th>
<th>Reported S.D.</th>
<th>Net S.D. of surgeon</th>
<th>95% CI of net SD:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brys 91</td>
<td>114</td>
<td>0.8</td>
<td>-0.46</td>
<td>0.18</td>
<td>2.07</td>
<td>1.91</td>
<td>1.69 2.20</td>
</tr>
<tr>
<td>Campbell 93</td>
<td>30</td>
<td>0.8</td>
<td>-0.90</td>
<td>0.51</td>
<td>2.80</td>
<td>2.68</td>
<td>2.14 3.61</td>
</tr>
<tr>
<td>Cates 93</td>
<td>200</td>
<td>0.8</td>
<td>0.00</td>
<td>0.13</td>
<td>1.83</td>
<td>1.65</td>
<td>1.50 1.83</td>
</tr>
<tr>
<td>Ishii 95</td>
<td>100</td>
<td>0.8</td>
<td>1.75</td>
<td>0.24</td>
<td>2.35</td>
<td>2.21</td>
<td>1.94 2.57</td>
</tr>
<tr>
<td>Teter 95</td>
<td>319</td>
<td>0.8</td>
<td>1.54</td>
<td>0.12</td>
<td>2.20</td>
<td>2.05</td>
<td>1.90 2.22</td>
</tr>
<tr>
<td>Jessup 97</td>
<td>93</td>
<td>0.8</td>
<td>1.10</td>
<td>0.16</td>
<td>1.75</td>
<td>1.56</td>
<td>1.36 1.82</td>
</tr>
<tr>
<td>Yang 98</td>
<td>100</td>
<td>0.8</td>
<td>1.30</td>
<td>0.29</td>
<td>2.92</td>
<td>2.81</td>
<td>2.47 3.26</td>
</tr>
<tr>
<td>Maestro 98</td>
<td>116</td>
<td>0.8</td>
<td>1.81</td>
<td>0.29</td>
<td>3.18</td>
<td>3.08</td>
<td>2.73 3.53</td>
</tr>
</tbody>
</table>
Table 1.1 shows that clinicians who measure and report their overall alignment precision have an average SD of 2.6°. Although 7 studies is a small sample of the population of TKR clinics, there is not much reason to believe that the clinics that do not measure and report are significantly better. The indicated bias of 0.5° varus is not conclusive, as the standard error of this mean are ±1.0°. Variability is evenly shared by femoral and tibial cuts at SD 1.9° each (see Tables 1.2 and 1.3). Assuming these studies fairly represent all TKRs, the result suggests that about 5% of TKRs overall alignment error will be greater than 5° (n = 753 knees).

1.2.2.2 Rotational Alignment

The posterior condylar line (tangent line across the posterior limits of the posterior femoral condyles), the surgical epicondylar axis (line between the medial sulcus and lateral prominence of the femoral epicondyles, (Berger, 1993)), the clinical epicondylar axis (line between the medial and lateral prominences of the femoral epicondyles (Berger, 1993)), and the AP axis (line between the deepest point of the patellar groove and the centre of the intercondylar notch (Whiteside, 1995)) have all been suggested as references for setting the rotational position of the femoral component (Figure 1.6). The best choice of reference may depend on the condition of the existing femur. For example, the posterior condylar line in arthritic knees may be difficult to locate due to missing cartilage or deformity and is absent altogether in revision surgery. Some researchers have proposed that the transepicondylar axis is the most reliable landmark. Berger (Berger, 1993) measured 75 cadaveric knees and found that the surgical epicondylar axis was externally rotated from the posterior condylar line by 3.5° (SD 1.2°) in males and 0.3° (SD 1.2°) in females, and precision was much worse (SD 3.5° male, 4.1° female) using the clinical epicondylar axis. Poilvache (Poilvache, 1996) measured 100 knees during TKR and found typical standard deviations of 2.0° to 2.5° in the angles between the posterior condylar line, the clinical transepicondylar axis, and the AP axis. They had difficulty locating the medial sulcus, therefore could not use the more precise surgical transepicondylar axis as suggested by Berger. Feinstein (Feinstein, 1996) found the patellar groove position to be highly variable relative to the distal anatomic, mechanical, transcondylar, and transepicondylar axes of the femur, with ranges of 11° to 16° about the mean in a series of 15 cadaveric specimens. Nagamine (Nagamine, 1998) used CT scans to study 84 knees in Japanese women and found SD of 1.9° to 2.7° between the clinical epicondylar axis and posterior condylar line. The AP axis
was internally rotated from the clinical epicondylar axis by 90.3° (SD 3.3°) in knees with femorotibial arthritis, 91.3° (SD 3.3°) in knees with patellofemoral arthritis, and 92.3° (SD 3.1°) in normal knees. These studies show that rotational alignment variability is at least of SD 2° due to choice of landmark alone and that the orientation of the patellar groove, which has the most direct functional importance for patellar tracking, cannot be precisely defined using the transepicondylar axis or posterior condylar line.

![Figure 1.6: Rotational alignment landmarks (Image adapted from Berger, 1993)](image)

In current technique, the posterior condylar line or the epicondylar axis is usually used to set the rotational position of the femoral component. The goal is to create a rectangular flexion gap (Figure 1.7) with the ligaments at the correct tension in the flexed position, and the amount of rotation from the reference will depend on the ligament balance and whether the prosthetic joint line is to be normal to the mechanical axis (‘classical’ alignment) or parallel to the ground (‘anatomic’ alignment) (Krackow, 1991). Patellar tracking is usually checked after installation of the components and corrected by lateral retinacular release to medialize the patella or by a medializing osteotomy of the tibial tubercle to medialize the extensor apparatus. According to Hofmann (Hofmann, 1997), however, lateral release should be avoided due to the possibility of increased postoperative pain, wound healing complications, and reduced in vascularity of the patella. Also, Miller (Miller, 1996) and Farahmand (Farahmand, 1996) independently found in
cadaveric studies that while lateral release may appear to improve patellar tracking in
intraoperative passive motion, actual patellar contact pressures and dislocating forces with
muscle forces applied are not substantially changed.

Figure 1.7: Rectangular flexion and extension gaps at even ligament tension
(Image adapted from Krackow, 1991)

One common tooling system ("Specialist 2", Johnson & Johnson Orthopaedics,
Raynham, MA, USA) provides for several finite steps of rotation of the femoral component
relative to the posterior condylar line. Another approach is to cut the tibial plateau normal to the
mechanical axis, insert a tensor device to distract the knee joint in the flexed position, and to set
the posterior femoral cutting guide parallel to the tibial plateau, creating a rectangular flexion
space (Scuderi, 1989). In a series of consecutive TKRs, Stiehl (Stiehl, 1996) set the rotation of
the femoral component parallel to the posterior condylar line in 54 knees and perpendicular to the
tibial mechanical axis with the knee flexed in 46 knees. Using the tibial mechanical axis
significantly reduced the need for lateral release (74% vs. 28%). Based on previous anatomic
studies (Stiehl, 1995; Yoshioka, 1987), this method was considered equivalent to aligning the
femoral component with the transepicondylar axis and required the joint line to be normal to the
mechanical axis. All of these methods effectively externally rotate the femoral component about
3° relative to the posterior condylar line while maintaining a rectangular flexion space by rotating
the joint line in the coronal plane from the natural 3° varus (parallel to the ground) orientation to
90° to the mechanical axis. In all cases, however, the location of the patellar groove is still defined by the implant design and, considering the high variability between individuals, will not necessarily match the patient’s extensor apparatus.

For the tibial component, a common way to set rotational alignment (in non-mobile bearing prostheses) is to move the knee through a normal range of flexion/extension with a freely rotating dummy tibial component in place, allowing the dummy component to rotate about the mechanical axis to its ideal position (‘ROM technique’). The tibia is then marked for future installation of the final, non-rotating component. This technique allows the remaining soft tissues to define the rotation of the tibia itself while the femoral component defines the most congruent position of the tibial component. To compare techniques, Eckhoff (Eckhoff, 1995) installed femoral components in 7 cadaveric knees and had two surgeons each set the rotational alignment of the tibial component 6 different ways in each specimen for a total of 84 simulated tibial component placements. There was no significant difference between the two surgeons. The mean result for the ROM technique was external rotation of 14° (SD 4°) relative to the femoral component. Reference to the tibial tubercle resulted in 19° (SD 3°), the most externally rotated mean position. Tensing the soft tissues with the knee in extension and installing the tibial component correctly relative to the femoral component had SD of 2°. This study showed a surprising 21° range of mean rotational position relative to the femoral component across the 6 methods, indicating that the question of what method reliably matches the tibial and femoral articular surfaces needs further investigation. Precision we could expect from current practice is SD 2° to 4°.

The size and rotational position of the component must also be adjusted to give complete coverage of the tibial plateau, such that the component is supported by cortical bone around its perimeter without overhanging the bone and interfering with the soft tissues crossing the joint. If a significant segment of the component perimeter rests on cancellous bone, there is a high risk of subsidence, or sinking of the component distally into the tibia after the patient returns to weight bearing activity. Lemaire (Lemaire, 1997) compared the rotational position of the tibial tray giving best bone coverage to the position giving best alignment of the tray AP centreline with the tibial tubercle and found a mean difference of 9.8° (SD 4.1°, range 1° to 16°), indicating that rotational alignment to the extensor apparatus could be compromised approximately 10° to obtain good bone coverage.
1.2.2.3 Posterior slope

Typical extramedullary instruments are adjusted by ‘eye’ to parallel the mechanical axis in the sagittal plane, from which the cutting guide is set in finite steps of posterior slope. For example one common EM tibial guide (Specialist 2’ series, Johnson & Johnson Orthopaedics, Raynham, MA, USA) provides AP adjustment (marked in cm) at the ankle and interchangeable tibial plateau cutting guides of 0°, 3°, and 5° posterior slope. Sometimes an intramedullary rod is used in the tibia to approximate the mechanical axis before applying the cutting block of the appropriate angle. Hofmann (Hofmann, 1991) reviewed 33 knees intended to but cut at 0° posterior slope, and found a mean result of 3° (SD 3°, range 0° to 10°) as measured on postoperative lateral radiographs. Maestro (Maestro, 1998) found mean error of 0.6° flexion (SD 3.6°) in posterior slope in 116 TKRs using either EM or IM tibial guides.

1.2.2.4 Flexion/extension

Maestro (Maestro, 1998) found mean error of 0.8° flexion (SD 3.5°) of the femoral component in 116 TKRs using IM femoral alignment.

1.2.2.5 Summary

All aspects of alignment show intratechnique precision of 2° to 4° using current methods, and in the case of rotational alignment the different methods and landmarks are widely variable.

1.2.2.6 Recently introduced techniques

Howmedica-Osteonics (www.osteonics.com) offer an alignment system which locates the femoral mechanical axis by distracting the femur from a point at the desired knee centre (see US Patents 5 520 694, 5 601 566, 5 690 638), but the system does not address the tibial mechanical axis. I could not find any published results, nor did Osteonics or their local representative provide any information.

Computer assistance is currently being introduced for TKR but reported results are limited at this time. Krackow (Krackow, 1999) has tested a prototype computer assisted TKR system for setting varus/valgus angle of the distal femoral cut. In 100 measurements on 8 cadaveric limbs by 3 investigators, mean error of locating the hip centre was 2.0 mm (SD 1.5) in ML and 3.3 mm (SD 1.8) in AP. For the shortest expected patient (375 mm hip - knee length), at 2 SD from the mean, ML error will be about 0.75° and AP error will be about 1°, to which cutting error would be added.
MusculoGraphics (Evanston, Ill., USA: www.musculographics.com) advertise a computer assisted knee replacement system (‘KRS-1’) which uses CT scans of the patient for preoperative planning. The resulting 3D computer model of the lower limb and the proposed implant placement are registered to the patient intraoperatively and used to guide the surgeon. MusculoGraphics claims that implants can be “aligned within one degree of planned placement” but report average registration (matching of the computer model to the actual patient intraoperatively) accuracy from 0.4° to 2.7°.

Medivision, a division of Synthes-Stratec (www.stratec.com) is currently selling computer assistance systems for TKR and other orthopaedic procedures in Europe. This system is also based on full 3D models of the patient. PRAXIM (www.praxim.fr) is a new company in France working towards commercialization of work done by Stephane Lavallee and his co-investigators on a variety of computer assisted surgical systems, including the TKR alignment system reported by Francois Leitner (Leitner, 1997).

1.2.3 Costs of system vs. improvement in outcomes

The objective of this section is to estimate the probability of TKR failure due to poor alignment, where failure is defined as revision surgery or recommended revision. Direct cost savings due to improved alignment could then be estimated in terms of reduced incidence of revision and if a proposed system offers a certain reduction in percentage of knees that will require revision, a breakeven point (in terms of number of TKRs) can be predicted. Obviously, we should strive for the best quality procedure possible as revision surgery imposes additional risk and trauma on the patient which cannot be assigned a dollar value. However, some measure of cost vs. benefit must be made to justify expenditures and guide efforts to improve quality. To the health care provider, revision of a TKR due to problems arising from poor alignment is a direct additional cost that could be avoided through use of the proposed system. In addition to having similar (Lavernia, 1995) or higher (Ritter, 1996) costs than primary TKR, revision TKR has been shown to have less satisfactory results and worse survivorship (Rand, 1991), so the additional costs of a poor primary procedure may compound beyond the first revision. From the patient’s point of view, a painful knee may be considered a failure even if revision is not deemed necessary. Although pain or low knee rating scores are less precise endpoints for outcomes and survivorship analysis, they certainly should be considered in assessing the success of current
practice. A summary of reported revision rates from large scale, multi clinic studies (Heck, 1998; Robertsson, 1997; Ansari, 1998; Murray, 1998) considering both revision or recommended revision and pain as endpoints, is shown in Figure 1.8.

![Revision rates graph]

**Heck, 1998**  
$n = 200,000$ knees

**Robertsson, 1997**

**Ansari, 1998**

**Murray, 1998**

10 others  
$n = 10,973$ knees

**Figure 1.8: Revision rates, considering both revision and pain as endpoints**

In the U.S., 1993 “HCUP-3” data for Medicare patients shows a mean TKR cost of US$18384. Stern (Stern, 1995) found the cost of a primary TKR in a U.S. teaching hospital doing frequent (600/year) joint arthroplasty to be US$15200 to US$17415 (1994 inflation controlled US$). In 1996 a US hospital (Virginia Medical Center, Charlottesville) offered primary TKR for US$15000 total cost to the patient (Johnston, 1996). Although Ritter (Ritter, 1996) found a series of 25 revision TKRs to have significantly longer anesthesia time (mean 41%, range +3% to +78%), implying higher costs, Lavernia (Lavernia, 1995) found no statistical difference in total cost between primary (US$19230) and revision (US$21833) TKR in a sample of 25 cases. Although each health care provider will have their own cost estimates for TKR, for this feasibility cost analysis I will assume a revision cost of C$25 000 (approximately US$17 500). Actual costs in Canada are lower, but at this stage I will use the published US costs expressed in Canadian dollars for comparison to the estimated C$75000 capital cost of the system.

In this cost analysis I am primarily interested in short term (< 5 years) failures due to alignment errors in the initial TKR procedure. Longer term failures that would have been postponed by better alignment are also important but are more difficult to include in the analysis.
Looking at the short term, Heck (Heck, 1998) reported an overall revision rate of 2.2% within 2 year follow up for over 200,000 U.S. Medicare TKRs between 1985 and 1990. Although reason for revision is not reported, early failures are typically caused by infection in less than 1% of cases (Ritter, 1997) or problems such as pain, instability, misalignment, and limited range of motion. We can make an estimate of the proportion directly caused by poor alignment from Schneider (Schneider, 1984), who reviewed 55 revisions with mean interval between installation and revision of 20 months and specifically attributed 4 revisions to alignment errors of greater than 5° (mean interval from insertion to revision of 10.5 months). Making the conservative assumption that none of the additional 18 loosened (mean interval 31 mos.) and 10 unstable (mean interval 20 months) knees in this series were caused by misalignment within ± 5°, the proportion of revisions due to misalignment is 7.3% and, assuming that this series represents typical incidence of alignment errors, the chance of short term revision due to misalignment is 0.16% (7.3% x 2.2%). Although this is a very rough estimate based on the experience in one clinic, it is useful to find an 'order of magnitude' for a reasonable capital cost assuming the proposed new alignment system will eliminate these short term failures (Figure 1.9).

Looking at the longer term, Ansari (Ansari, 1998) found a 4% revision or recommended revision at 10 years in a series of 445 TKRs. Robertsson (Robertsson, 1997) found a 10 year cumulative revision rate of 5% for 4381 primary TKR operations performed between 1985 and 1995. Callahan (Callahan, 1994) reviewed 130 studies of TKR outcomes (12,506 knees) and found an overall revision rate of 3.8% at mean follow up of 4.1 years, 71% of which were due to mechanical (aseptic) loosening or failure. It is generally agreed that poor alignment will reduce the lifespan of the knee, causing conditions that lead to subsidence of the underlying bone, accelerated wear of the components, loosening, and instability. Although it is impossible to predict exactly what degree of misalignment will reduce the lifespan a given amount, we can reasonably estimate from Callahan’s results that 2.7% of TKRs could realize benefits of better alignment at 4 years follow up. Based on these longer term results, a less conservative analysis is to assume that of the 5% of knees that will be poorly aligned (based on reports of current technique, Section 1.2.2), 2.7% will have a poor enough outcome to require revision and that the proposed new system reduces this amount by 50% by doubling alignment precision for the average surgeon (Figure 1.10).
Capital Recovery, 6% MARR, 0.15% short term (0 to 2 years) revisions prevented, C$25K rev. cost, C$75K system cost

Figure 1.9: Breakeven analysis for elimination of short term revision in 0.15% of knees

Capital Recovery, 6% MARR, 1.35% revisions prevented at ~4 years, C$25K rev. cost, C$75K system cost

Figure 1.10: Breakeven analysis for prevention of revision in 1.35% of knees
On a per knee basis, using a capital recovery over 5 years at 6% cost of capital and no salvage value at the end of the period, the extra cost ranges from C$200/knee for a clinic doing 100 knees per year on average, down to C$50/knee when the system is used for 400 knees per year (Figure 1.11).

![Bar chart showing cost per knee](chart.png)

**Figure 1.11: Per-knee cost of C$75 000 capital cost at 6%, zero salvage at 5 years**

Note that the system I propose in this study does not require a CT scan (approximately C$700 per patient) and I predict that after the initial learning process, there will be no substantial increase in operating time and recurring costs. There is no increased risk of infection or other complications (see the following section) that could create new reasons for revision. I also assume that the system will have no salvage value and I do not account for the fact that most of the equipment could also be used for other computer assisted procedures, a potential benefit to lower volume clinics.
1.2.4 Risk posed to the patient and operators

1.2.4.1 Fat emboli

As with many orthopaedic procedures, there is a risk of death during or shortly after TKR due to fat emboli. Less catastrophic effects are neurologic changes (such as prolonged confusion) and hypoxemia. Dorr (Dorr, 1989) reports that the incidence of fat emboli syndrome is “about 3%, with the majority of these in bilateral TKR, especially with stemmed components” and that the mortality rate of this syndrome is 10% to 20%, a bilateral TKR mortality rate of 0.30% to 0.60%. In his own series of 65 bilateral TKRs with intramedullary alignment, Dorr experienced fat embolism syndrome in 8 cases (12%) leading to neurologic changes in 7 cases and one death. Ansari (Ansari, 1997) reviewed 1390 TKRs including 1, 2 and 3 compartmental unilateral procedures and 1 stage bilaterals, and concluded that the maximum incidence of fatal pulmonary embolism is 0.4% (95% CI 0.1% to 1.1%). The risks of fat embolism due to insertion of intramedullary rods has been reduced in modern technique by use of fluted rods, careful insertion, and the common practice of using an oversize insertion hole (Ries, 1998). In addition, many surgeons use an IM alignment rod in the femur only (see Section 1.2.2), eliminating the tibial insertion. There are many risk factors other than IM rods, for example pressurization of the medullary canal of the tibia as the keel or stem of the tibial tray is inserted, or if a stemmed femoral component is used. Lane (Lane, 1997) reported one death in a series of 100 one stage bilateral TKRs with EM alignment only. Even if it has not been conclusively shown that modern IM rods significantly increase risk of fat emboli syndrome, most clinicians would eliminate the uncertainty and choose a non-invasive alternative if similar accuracy could be achieved. Considering that the precision of IM rods is limited (see Section 1.2.2) and that further variability is introduced when an oversize insertion hole is used, it is clear that a new alignment system should eliminate IM rods altogether.

1.2.4.2 Radiation exposure

Although radiographs, fluoroscopy, and CT scans are routine and radiation exposure from a once or twice in a lifetime procedure such as TKR may not be of great concern to the patient, a new system would ideally not require any more preoperative radiographs than those required in current diagnosis and planning. To protect patient and operators, as well as reduce the amount of equipment used in the procedure, intraoperative fluoroscopy should also be avoided.
1.2.4.3 Invasiveness

Some recently proposed computer assisted surgery techniques require additional invasive procedures such as installing bone pins intraoperatively at the hip and foot (Leitner, 1997) or preoperative installation of small metal balls or pins in the patient’s bones (Bargar, 1998). This increases pain and risk of infection, and may require additional clinical visits. I have limited the use of bone pin type markers to two locations within the normal operating field: one in the anterior cortex of the distal femur, and one (near the distal limit of the incision) in the anterior cortex of the tibia. As an alternative to Steinmann type pins, I have designed a base that attaches to the bone with a small unicortical screw and a matching marker array that can be removed from the base and reinstalled (via a quick release collar) in precisely the same location (see Appendix C). In the femur, it may be possible to install the screw within the area of cortex removed in the anterior femoral cut if measurement of the final pose of the femoral implant is not required.

1.3 Thesis Overview

The organization of this thesis is as follows:

**Chapter 1:** Objectives, justification, and literature review: Includes review of current techniques, outcomes, costs, and a meta-analysis of current technique precision.

**Chapter 2:** Description of the proposed computer assisted surgical procedure.

**Chapter 3:** Joint centre location: Study of joint centre and mechanical axis definition precision and accuracy using the proposed intraoperative motion tracking techniques. Description and testing of novel non-invasive hip and foot trackers, designed and built for this study to eliminate the need for bone pin markers at the hip and foot.

**Chapter 4:** Ankle digitizing precision: Description of a novel ankle digitizing probe, designed and built for this study, to be used as an alternative to motion tracking techniques to find the ankle centre. Results of cadaveric testing with multiple specimens and operators.

**Chapter 5:** Bone cutting accuracy: Reports the errors between cutting guide orientation and the orientation of a dummy implant placed on the cut bone, using cadaver bone and conventional cutting techniques.

**Chapter 6:** Summary of overall accuracy and precision: Estimation of the alignment accuracy we could reasonably expect from the proposed system, based on the tests described in this thesis.
Appendix A: Description of the joint centre location testing procedure (Chapter 3) and processing of the data.

Appendix B: Probe design to robustly locate anatomical features: A related study describing sphere fitting methods (used in joint centre location) and digitizing probe design (basis of ankle probe design).

Appendix C: Detail drawings of equipment designed for this study.

Appendix D: Provisional patent filed for the non-invasive hip and foot trackers used in Chapter 3.
Chapter 2:

Proposed computer assisted TKR procedure

2.0 Chapter Summary

In this Chapter I describe the intraoperative procedure for TKR using the proposed new computer assisted methods. This is intended as a working document and describes the setup of the current prototype software at this stage only: This procedure and software has not yet been tested in a full simulated TKR and some of the required tools have not been made. I also describe the corresponding steps in terms of the tool setup, software functions, and coordinate frames used.

2.1 Proposed surgical procedure

1. Patient has hip tracker (see Chapter 3 and Appendix D) installed by pre-op staff, with marker array protruding through drapes.

2. Expose knee, reflect the patella, and install femoral and tibial bone pin markers (Fig. 2.1).

![Femoral and Tibial Marker Array Installation](Image adapted from Johnson & Johnson Orthopaedics)
3. Put the limb in approximate stance position and press the optoelectronic localizer footswitch. Move femur through range of motion, minimum of one flexion/extension, ab/adduction, and circumduction motion. The system calculates the hip centre relative to the femoral marker array and the hip tracker allows pelvic motion during this procedure to be compensated for in the calculations. The hip tracker is no longer required after this step but the femoral marker base must not be disrupted. The marker array itself can be removed from the base and reinstalled as required.

4. Select the desired centrepoint for the femoral component at the distal femur. Currently the midpoint of the transepicondylar axis is used, but special purpose tooling will be developed for this step (Fig. 2.2).

5. With the tibial marker array in place, locate the ankle centre by digitizing the malleoli (Fig. 2.3, see also Chapter 4).

6. **OPTIONAL TRIAL ALIGNMENT STEP:**
At this stage the existing alignment can be checked by extending the limb and pressing the footswitch. Preliminary ligament release and re-checking of alignment can be done if required.

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**Figure 2.2: Selecting the knee centre** (Images adapted from Berger, 1993 and Johnson & Johnson Orthopaedics)

- Transepicondylar midpoint (current method)
- Instrumented AP cut/sizing tool (proposed future method)
7. Select the desired overall varus/valgus alignment desired, flexion/extension of the femoral component, joint line orientation (0° for joint line perpendicular to mech. axis, 2° or 3° valgus rotation for joint line parallel to the ground), rotational alignment, and posterior slope. Specify the extension and flexion gaps corresponding to the chosen implant (using previously stored implant dimensions). Currently the rotational alignment is referred to the transepicondylar axis, but other references can be used in future versions of the system.

8. Position the distal femoral cut guide roughly at the desired resection depth and pin to femur (Fig. 2.4). The system displays the difference between the guide setting and the calculated cut plane. Adjust the guide orientation and make the distal femoral cut. At this stage the intersection of the mechanical axis and the distal cut plane can be marked on the femur for future reference.

9. **TIBIAL PLATEAU PREPARATION**

   **OPTION A:** Select a point on the tibial plateau through which the mechanical axis should pass that optimizes bone coverage, and a ML line through this point defining the desired tibial tray rotation (A preliminary resection of the tibial plateau may be required for this step). A special purpose tool may be used, for example a dummy tibial tray with a marker array attached (Fig. 2.5). Mark the tibia at this position. The system calculates the ideal tibial resection plane and the ideal relationship between the femur and the tibia.
Figure 2.4: Adjustable guide for distal femoral cut

Figure 2.5: Selecting the tibial tray position (Image adapted from Johnson & Johnson Orthopaedics)
**OPTION B:** Distract the extended knee using a tensing device and check alignment as described in Step 6 above. Balance ligaments until acceptable alignment is reached and record the final tibial position. The system calculates the ideal tibial resection plane based on this tibial position. This option uses the previously defined femoral component centre and rotational alignment to define the tibial mechanical axis and tibial rotation, assuming that at this tibial pose the axis passes through the middle of the tibial bone stock and that the corresponding rotation of the tibial tray will give adequate bone coverage.

10. Position the tibial guide at roughly the correct alignment and resection depth (Fig. 2.6). The system displays the difference between the guide setting and the calculated cut plane. Adjust the guide orientation and make the final tibial plateau cut.

![Figure 2.6: Adjustable guide for tibial plateau cut](image)

11. **POSTERIOR FEMORAL CUT**

This stage is subject to future development on rotational alignment.
OPTION A: With the appropriate flexed tibial position set (for example by tensing ligaments), the posterior femoral cut can be set relative to the prepared tibial plateau. This can be done manually using conventional tools, and the ML position of the femoral component can be matched to the previously marked point. Alternately the posterior femoral cut can be calculated by the system and a tracked AP/chamfer femoral cutting guide adjusted to suit. With either method, the corresponding anterior cut can then be checked against the femoral anterior surface using conventional methods and the femoral component moved in AP if required (this will affect the sagittal plane alignment slightly).

OPTION B: If the rotational alignment has been previously defined (i.e. the desired joint line has been specified as described in the preceding steps) the posterior femoral cut is defined by the implant dimensions and a tracked AP/chamfer femoral cutting guide can be adjusted to the ideal position. The corresponding anterior cut can then be checked and adjusted as described above. With the ligaments tensed in the flexed position, the flexion gap can be calculated by the system or checked manually.

12. Use a tibial tray installation guide with a marker array attached to locate the tibial component at the previously selected or calculated location and complete the procedure as usual.

2.2 Tool and software setup

This section is a guide through the proposed TKR procedure describing the tools and ports to plug them in to, reference frames, coordinate transformations, and the MATLAB functions used at each step. The script ‘do_TKR.m’ runs this procedure, makes all the function calls, and provides some minimal prompting. The variable ‘com’ must be set to the name of the serial port of the host computer (usually com = ‘COM1’ or com = ‘COM2’). The variable ‘samples’ is the number of repeated measures for each procedure, e.g. samples = 1 prompts for only one measurement of the hip centre, one digitized point at each end of the transepicondylar axis, and one point at each of the ankle malleoli. Transforms are all 4 x 4 homogeneous, subscripted from the ‘old’ frame to the ‘new’, e.g. ‘T_{on}’ is made up of the direction cosines of the ‘new’ frame and the translation from the ‘old’ origin to the ‘new’ origin, all in ‘old’ coordinates. ‘*’ indicates a constant transform, usually recorded from the static (anatomic) position approximating normal stance.
2.3 Coordinate system subscripts

'\text{o}' body coordinates

The body coordinate frame is aligned for each specimen with the femoral mechanical axis found from the mean of the digitized femoral head results and the mean of the transepicondylar axis midpoints (digitized knee centres). The transepicondylar axis defines the frontal plane.

'h' Hip tracker

'f' Femoral bone pin

't' Tibial bone pin

For each local reference frame, the first three emitters define the frame as follows:

Emitter #1 Local origin
Emitter #2 Defines local x axis direction.
Emitter #3 Defines local xy plane.

Tool names such as AUXDRF, DRF1, etc. correspond to particular tools, and matching tool files have been written and stored on the Flashpoint operating system. Changing these tools or the ports they are plugged in to requires changes in the Flashpoint output formatting specified in the MATLAB function or script reading the data.

2.4 System procedure

1. Plug in hip tracker (AUXDRF, Port B3), femoral array (DRF1, Port B1), and tibial array (DRF2, Port B2) (Hip tracker strapped in place, knee exposed, and marker arrays installed rigidly to the distal femur and the proximal tibia at this point).

2. \[
[\text{hip}_f, \text{Tft}, \text{Ttf}, \text{staticdata}] = \text{find\_hip}\,(\text{com})
\]

records a static position of the femoral marker array in hip tracker coordinates and finds hip centre in hip tracker coordinates by prompting for femoral movement and fitting a sphere. Transforms the result from hip tracker coords back to femoral coords. The hip tracker is no longer required after this step.

3. \[
[\text{TE\_f\_lateral}, \text{TE\_f\_medial}, \text{knee}_f] = \text{find\_TE\_axis}\,(\text{com}, \text{samples})
\]

prompts for digitizing of the transepicondylar (TE) axis in femoral coords, using the MED135 point probe. \(K_f\) is the midpoint of the TE axis, for now assumed to be the desired centrepoint of the implant (roughly the middle of bone stock at the distal femur). Future versions will use a special purpose tool for this step.
4. \([\text{ankle}_t] = \text{find_ankle}(\text{com}, \text{samples})\] Finds ankle centre \(A_t\) in tibial coords by prompting for the ankle probe data and calculating the midpoint between the malleoli using the probe contact points.

5. Define ‘body’ coords with origin at hip centre:
\[z_0\] axis = \text{cross}(\text{TE}_f(\text{lateral}) \text{TE}_f(\text{medial}), \text{K}_f\text{H}_f)\]
(i.e. \(z_0\) axis points anteriorly, normal to plane defined by the TE axis and the hip centre)
\[y_0\] axis along \(\text{K}_f\text{H}_f\) (i.e. \(y_0\) axis positive pointing proximally, along femoral mechanical axis)
\[x_0 = \text{cross}(y_0, z_0)\] (i.e. \(x_0\) axis points from patient R to L)
Gives transform \(T_{f0} = [x_0 \ y_0 \ z_0 \ H_f; 0 \ 0 \ 0 \ 1]\]
Transform knee centre to body coordinates: \(K_0 = T_{of} \ast K_f\)
By definition, \(K_0 = [0 -(\text{segment length}) \ 0]\) and \(H_0 = [0 \ 0 \ 0]\) where segment length is the magnitude of \(K_fH_f\). Also transform the ankle centre to body coordinates at the current alignment: \(A_0 = T_{of} \ast T_{ft} \ast A_t\) and plot the limb using ‘plot_TKR.m’.

6. **OPTIONAL TRIAL ALIGNMENT STEP:**

Gives the surgeon the option to propose an alignment correction by releasing ligaments and manipulating the leg to the correct alignment and ligament tension:

\([\text{flexion}, \text{varus}_\text{valgus}, T_t, T_{tf}, \text{ankle}_o] = \text{check_alignment}(\text{side}, \text{knee}_o, \text{ankle}_t, T_{of})\]
records the proposed femoral-tibial pose \(T_t\), transforms the ankle centre to body coords, and reports the alignment (angle of \(K_0A_0\) in frontal \((x_0,y_0)\) and sagittal \((y_0,z_0)\) planes). Prompts for iterations as required. The varus and flexion angles reported at the maximum amount of alignment correction possible give ‘\text{varus}\_\text{req’d}’ and ‘\text{flexion}\_\text{req’d}’ for the following step.

7. Prompt for the desired overall alignment, joint line orientation, and posterior slope, giving constants \([ (\text{varus}\_\text{req’d} + \text{joint}\_\text{line}\_\text{angle}) \ \text{flexion}\_\text{req’d} \ \text{femoral}\_\text{length}\_\text{req’d} ]\) and corresponding distal femoral cut plane (DFC\(_o\)) using current frame rotations about \(z_0\), then \(x_0\).

‘\text{Joint}\_\text{line}\_\text{angle}’ is the rotation about \(z_0\) putting \(+x_0\) parallel to the desired joint line, \(0^\circ\) for ‘classical’ alignment (joint line perpendicular to mech. axis), \(2^\circ\) to \(3^\circ\) valgus rotation for ‘anatomic’ alignment (joint line parallel to the ground). Note that for the RH limb a +ve angle is varus, opposite for the LH limb (flexion is +ve for both limbs), so it is necessary to prompt in terms of ‘\text{varus/valgus}’ and convert the value accordingly knowing the affected side (prompt for variable ‘\text{side}’ = ‘r’ or ‘l’). The mechanical axis \((y_0)\) intercept is the
femoral_length_required (found from desired femoral length - implant distal thickness or from resection desired from existing bone). For example, typical input values for a RH limb with a neutral, anatomic alignment goal with the mechanical axis adducted 2° in normal stance would be:

side = 'r'
varus_req’d = 0
joint_line_angle = 2°
flexion_req’d = 0
femoral_length_req’d = 400

Joint line direction ‘joint_line_dir_o’ = [ cos(joint_line_angle) -sin(joint_line_angle) 0 ].

The joint line may be drawn along this direction from a point on the mechanical (y₀) axis defined by the implant design (usually the y₀ intercept of a plane offset proximally from DFC₀ by implant curvature radius - implant thickness). Until rotational alignment is investigated, the joint line is always in the plane of the TE axis and the hip centre.

8. Prompt for adjustment of the distal femoral guide to set final orientation, then resection depth. ‘Length_error’ may be ignored if resection depth is used:

[flexion_error, varus_valgus_error, segment_length_error, plane_o]=
check_guide(com, bytes_per_sample, first_port, emitters_per_sample, samples, calibrated_plane_p, Tol, required_plane_o)

Using the returned guide position of the final distal femoral cut (plane_o), move the joint line along the y₀ axis to match the actual femoral cut made and the implant dimensions.

9. **OPTION 9A**: Record a point on the tibial plateau through which the mechanical axis should pass and a ML line through this point defining the desired frontal plane for the tibia (use a dummy tibial tray with alignment handle and marker array attached, calibrated such that the centre point, ML axis, and plane are known). Calculate the Tᵀ₉ that makes the femoral and tibial frontal planes and mechanical axes coincident and the posterior slope (90° - angle between trial implant plane and tibial frontal plane). Provide option to tense ligaments and manipulate the tibia to this position to confirm feasibility using the routine check_alignment.m.

**OPTION 9B**: Use check_alignment.m to record the final extended femoral-tibial transform Tᵀ₉ with the tibia positioned appropriately by the surgeon (This option uses the
knee centre as defined in the femoral frame to define the tibial mechanical axis at an acceptable tibial pose, assuming that the resulting axis passes close enough to the middle of the tibial bone stock and the tibial rotation relative to the femur leads to adequate bone coverage).

10. Define the proximal tibial cut plane (PTC₀) by rotating DFC₀ by [posterior_slope_required] about the joint line and setting the \( y₀ \) intercept = (femoral_length_required + extension gap). Prompt for adjustment of the tibial guide to set final orientation, then resection depth and record the guide plane at which the cut is made using:

\[
[\text{flexion_error}, \text{varus_valgus_error}, \text{segment_length_error}, \text{plane_o}] = \text{check_guide}(\text{com}, \text{bytes_per_sample}; \text{first_port}, \text{emitters_per_sample}, \text{samples}, \text{calibrated_plane_p}, \text{Tot}, \text{PTC₀})
\]

11. **OPTION 11A:** Use a combination tenser/AP cutting block (to be designed) to tense the ligaments and define a posterior femoral cutting plane normal to the distal femoral cut, offset parallel from the prepared tibial plateau by the required flexion gap (this tool would force the tibia into flexion of 90° + posterior slope). Posterior drawer would be applied for PCL retaining, and some method of fixing the tibial AP position to correspond to the tibial post for the chosen implant would be required for PCL sacrificing.

**OPTION 11B:** If the joint line has been previously defined, calculate PCP₀ from the implant dimensions and the recorded distal femoral cut DFC₀. Position AP cutting guide (with marker array) and adjust to final position using:

\[
[\text{in_external_error}, \text{ML_error}, \text{AP_error}, \text{PFC₀_final}] = \text{check_posterior_guide}(\text{com}, \text{bytes_per_sample}; \text{first_port}, \text{emitters_per_sample}, \text{samples}, \text{Tpm_calibrated}, \text{joint_line_to_post_cut}, \text{Tof}, \text{PCP₀});
\]
Chapter 3:

Accuracy and Repeatability of Joint Centre Location

3.0 Chapter summary

To properly align knee prostheses, we must accurately define the mechanical axis which joins the hip and ankle centres. In this chapter I test a method (also used by other researchers) of measuring motion of the femur and the foot intraoperatively using an optoelectronic tracking system and fitting a sphere to the data to calculate the kinematic hip and ankle centres. Some current techniques (Leitner, 1997) rely on markers pinned not only to the distal femur and proximal tibia, but also to the pelvis and calcaneus, thereby increasing pain and the risk of infection. Others have tried immobilizing the pelvis manually (Krackow, 1999) and using conventional skin mounted marker arrays (Leardini, 1999). To eliminate bone pins remote from the knee while maintaining accuracy and precision good enough for sub-degree alignment, I have designed and tested prototype non-invasive “trackers” that are strapped to the patient’s pelvis and foot and are insensitive to skin motion. I tested the trackers on 1 fresh and 2 embalmed cadavers by mounting them alongside conventional bone pin markers in the pelvis and calcaneus and locating the hip and ankle centres 30 times. To measure accuracy, I dissected out and digitized the femoral head (under the assumption that the centre closely matches the kinematic joint centre). I also digitized the perimeter of the talocrural articular surface on one specimen.

The hip tracker worked very well on the fresh specimen, the mean result being within 0.4 mm (ML) and 0.8 mm (AP) of the physical centre of the femoral head at the 95% confidence limit. Compared to the digitized centre, the hip tracker introduces femoral mechanical axis error of less than 0.14° (frontal plane) and 0.42° (sagittal plane) 95% of the time, compared to 0.11° (frontal) and 0.24° (sagittal) for the pelvic bone pin. On one embalmed specimen, the means of the two methods differed by 2 mm (ML) and 5 mm (AP), although precisions were less than 0.8 mm SD. On the second embalmed cadaver, however, the hip centre results were poor due to insufficient range of motion of the femur and poorly distributed data points.

At the ankle, precision was similar for the calcaneus pin and the foot tracker at SD approximately 1.0 mm in both directions (P > 0.3) on the first embalmed specimen. Both methods were medially (0.5 to 2 mm) and anteriorly (14 mm) biased compared to the mean digitized midpoint between the malleoli. On the fresh cadaver, both methods also had a medial
(4-7 mm) and anterior (1 to 7 mm) bias, leading to overall error within 0.9° (frontal) and 1.8° (sagittal) 95% of the time using the bone pin and 1.7° (frontal) and 1.6° (sagittal) using the foot tracker. On the second embalmed cadaver, I used a special purpose digitizing probe (see Chapter 4) instead of foot motion tracking, and axis errors are within 0.65° (frontal) and 1.44° (sagittal) 95% of the time compared to the talocrural joint centroid.

At the knee, the one set of 30 repeated measures suggests that the midpoint of the transepicondylar axis can be found repeatably using a conventional point probe (SD 0.3 mm (ML) and 0.9 mm (AP)). Variability in the transverse plane orientation (rotational alignment), however, is within a ±2.1° range 95% of the time and special purpose tooling will be required to improve rotational alignment precision substantially.

Although more specimens must be tested to show robustness, the results from the single fresh specimen suggest that bone pins at the hip are unnecessary for sub-degree alignment. At the ankle, both the calcaneus bone pin and the foot tracker results are biased from the midpoint between the malleoli. The purpose-built ankle digitizing probe has similar precision to the calcaneus pin and is a viable alternative to current foot motion tracking/sphere fitting methods.

3.1 Introduction

Current non-computer assisted technique in total knee replacement surgery (TKR) has overall limb alignment standard deviations (SD) of approximately 2.6° (see Chapter 1). Since alignment errors of as little as 3° have been shown to cause poor outcomes (Jeffery, 1991), my goal is to achieve a SD of 1°. This improvement will be large enough to potentially improve outcomes and will enable future assessment of the effects of alignment on implant longevity. Prosthesis alignment begins with an accurate definition of the mechanical axis (the line between the hip and ankle centres) since this axis is the datum to which bone cuts and the resulting alignment are referenced. Additional errors are introduced when positioning the knee centre and joint line relative to the mechanical axis and when making the bone cuts, so an improved alignment system must define the mechanical axis to a SD well within 1°.

The computer assisted TKR technique developed by Leitner (Leitner, 1997) defines the mechanical axis intraoperatively using a 3D optoelectronic localizer. They find the hip centre by tracking a point at the distal femur in a reference frame rigidly pinned to the pelvis as they move the femur through its range of motion. Similarly, they find the ankle centre by tracking a marker
pinned to the calcaneus in a coordinate frame rigidly pinned to the tibia. This technique requires two incisions and bone pin holes remote from the operating site which increases the patient’s pain and risk of infection.

Leardini (Leardini, 1999) compared hip joint centre locations measured on live subjects using landmarks and published regression equations, roentgen stereophotogrammetry (RSA) based on marker balls stuck to the skin, and femoral motion tracking/sphere fitting using marker arrays attached to “the pelvic component of a Milwaukee orthosis” and to the thigh using elastic straps. The motion tracking method had intrasubject SD of 2 to 4 mm (11 subjects, 6 repeated measures on each subject). Compared to the RSA result, mean errors for the motion method were approximately 2 mm (SD 4) in the mediolateral direction (ML), 4 mm (SD 6) in the anteroposterior direction (AP), and 3 mm (SD 6) in the proximal-distal direction (PD). Regression equation mean errors were at least 2 times greater than those of the motion method, and SDs were also two times greater in all but one case.

Krackow (Krackow, 1999) has tested a similar technique to find the hip centre only, but simply had an assistant hold the pelvis steady while motion of the femur was tracked in a reference frame fixed to the OR table. In 100 trials with 8 cadaveric limbs and 3 investigators, the reported centre was biased from the true centre 2 to 3 mm, with SDs of 1.5 mm (ML) and 1.8 mm (AP) and errors ranging up to 6.2 mm (ML) and 7.6 mm (AP).

I propose a similar approach of tracking motion of the femur and foot to locate the hip and ankle joint centres. In an effort to eliminate bone pins remote from the operating site, yet avoid the potentially large errors possible due to pelvic or tibial motion during the procedure, I have designed and tested devices that are strapped to the patient intraoperatively and used to track the motion of the pelvis and the foot without requiring incisions or immobilization.

At the knee, Leitner used motion of the existing knee joint to find a centre, but I propose that a point should be defined at the distal femur where the surgeon wants the centre of the femoral component to lie, ensuring that the component will cover the bone stock available without notching the anterior femoral cortex. This method avoids the problem of referring to existing knee motion or the femoral condyles, which are often distorted in the TKR patient.

In this chapter I compare the accuracy and repeatability of mechanical axis definition using the prototype non-invasive hip and foot trackers to results using bone pins and I compare both methods to the mechanical axis defined by digitizing the femoral head and ankle centre. I
also measure the precision of digitizing the transepicondylar axis midpoint for use as a knee reference point.

3.2 Methods

3.2.1 Hip and Foot Tracker Design

In order to minimize artifacts due to relative motion caused by skin sliding over bone, I designed the trackers to constrain all six degrees of freedom by applying six reaction forces oriented normal to the underlying bone (Figure 3.2; note that proximal-distal components of forces are not shown). The trackers are fully adjustable to accommodate different patients and seating forces are applied by straps. Each tracker has an optical marker array rigidly attached. See Appendix D for the provisional patent filed for the tracker concept.
Figure 3.2: Hip tracker (a) and foot tracker (b) schemes

(a) Transverse section (looking proximally) through pelvis  (b) View looking distally on right foot.

Figure 3.3: Hip tracker in position on skeleton mock-up and view on underside
3.2.2 Measurement system description and validation

I used a Flashpoint 5000 optoelectronic localizer (Image Guided Technologies, Boulder, CO, USA) for all measurements. This system has a typical accuracy of approximately 0.5 mm (Chassat, 1998) to track infrared emitting diodes (IREDs) within a 1 m diameter volume. In preliminary testing I found a noise level (SD of reported IRED marker position under static conditions) of about 0.12 mm at the typical poses used in this study. To find the precision of the measurement equipment and the sphere fitting algorithms alone, I tested a mockup with a
spherical bearing representing the hip joint, a 400 mm long rod representing the femur, and IRED marker positions approximately equal to a typical TKR setup. Range of motion for the femur was approximately 0 to 60° flexion, 30° abduction, and 20° adduction. The Flashpoint records a point after 10 mm of motion from the previous position, and I recorded 50 points randomly spread out through the ROM for each measurement. The standard deviations (SD) and ranges across 30 repeated measurements of each joint are shown in Table 3.1 (ML = medial/lateral, AP = anterior/posterior, PD = proximal/distal).

### Table 3.1: Measurement system precision for hip centre location

<table>
<thead>
<tr>
<th>Hip Simulation</th>
<th>ML (mm)</th>
<th>PD (mm)</th>
<th>AP (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Deviation</td>
<td>0.23</td>
<td>0.90</td>
<td>0.85</td>
</tr>
<tr>
<td>Range</td>
<td>1.07</td>
<td>3.38</td>
<td>3.09</td>
</tr>
</tbody>
</table>

For digitizing, I used the 135 mm two-emitter point probe supplied with the localizer. Each local coordinate frame is defined by an array of 3 IREDs arranged in an equilateral triangle, 120 mm on a side for the pelvis bone pin and hip tracker and 60 mm on a side at the femur, tibia, calcaneus, and foot tracker.

#### 3.2.3 Setup and Procedure

At the beginning of each test, I record the pose of all the local coordinate frames at anatomic position. To find the hip centre on each specimen, I recorded 50 points from a single IRED on the distal femur array as I moved the femur slowly through the maximum range of motion possible, creating a ‘cloud’ of data points in the pelvic bone pin coordinate frame. At each of the 50 sampling points, I also recorded the pose of the hip tracker marker array. I found the hip centre in pelvic bone pin coordinates by fitting a sphere (by least squares) to the data and also found the corresponding centre in hip tracker coordinates by expressing each data point in hip tracker coordinates using the transform recorded at that point, fitting a sphere, and transforming the resulting centre back to pelvic pin coordinates using the anatomic position transform. I repeated this procedure 30 times, producing 30 pairs of hip centres. Similarly, I calculated 30 ankle centres in the tibial coordinates by recording the foot tracker and calcaneus pin arrays while moving the foot. To find the ankle centres according to the calcaneus pin to the
foot tracker, I transform the data to the desired frame and treat the tibial array origin as the tracked marker, find the centre by least squares, and transform the result back to overall body coordinates using the anatomic position transform.

I tested the hip and foot trackers on one embalmed cadaver (E1) and one fresh cadaver (F1), and the hip tracker only on one additional embalmed cadaver (E2). For each test I adjusted the hip and foot trackers, strapped them in place, and drove bone pins (4 mm dia) into the ilium, distal femur, proximal tibia, and calcaneus on the right side. One array of three IREDs was rigidly attached to each bone pin. See Table 3.2 for specimen information.

<table>
<thead>
<tr>
<th>Specimen #</th>
<th>Sex</th>
<th>Height (m)</th>
<th>Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1</td>
<td>M</td>
<td>1.7</td>
<td>RH side, lightweight</td>
</tr>
<tr>
<td>F1</td>
<td>F</td>
<td>1.5</td>
<td>RH side, lightweight</td>
</tr>
<tr>
<td>E2</td>
<td>M</td>
<td>1.7</td>
<td>RH side, midweight, limited ROM</td>
</tr>
</tbody>
</table>

3.2.3.1 Specimen E1

In addition to finding the hip and ankle centres using pins and trackers as described above, I also digitized the malleoli 30 times using the conventional point probe supplied with the localizer. I cut tendons as required to get a reasonable range of motion at the ankle, but other than the insertion of bone pins, the ligaments crossing the ankle joint remained intact. Although I did not record the anatomic position on this specimen, all results are roughly in the standard AP, ML, and PD directions: All reference frames were visually aligned with anatomic position, with the xy plane of the hip tracker array defining the frontal plane. Results were transformed to an overall coordinate frame with the origin at the mean hip centre (from the bone pin results) and the y axis pointing proximally along the line through the mean digitized ankle centre.

3.2.3.2 Specimen F1

On the fresh specimen I digitized the the midpoint between the malleoli once only in anatomic position and took this as the true ankle centre. After the 30th trial I dissected out the femur (with the femoral IRED array still attached) and digitized 50 points on the head of the femur, taking the best fit sphere as the true hip centre. All results are transformed to a common
coordinate frame with the vertical (y) axis along the line from the digitized transmalleolar midpoint and the digitized femoral head, with the frontal plane defined by the hip tracker marker array.

3.2.3.3 Specimen E2

On specimen E2 two different operators (both engineering graduate students using the equipment for the first time) found the hip centres as described above and also found the ankle centre 30 times using a special purpose ankle digitizing probe (see Chapter 4). I exposed the knee per typical TKR practice and digitized the transepicondylar (TE) axis 30 times using the point probe. I did not gather any motion data from the foot on this specimen. In addition to dissecting out and digitizing the femoral head, I exposed the distal tibial and digitized the perimeter of the articular surface. The ‘true’ ankle centre in this case is the centroid of the transverse plane projection of the articular surface. All results are transformed to a common coordinate frame with the vertical (y) axis along the line from the mean TE axis midpoint to the digitized femoral head and the frontal plane defined by the mean TE axis. This is the common coordinate system I currently use in the prototype TKR system.

3.2.4 Data Analysis

Although there are differences in the recording of anatomic position between the specimens, all results are expressed in coordinates nominally aligned with the body axes and directional precisions and biases (versus the ‘true’ values for each specimen) are directly comparable as presented. On each specimen, I separately compare the two motion-based results (trackers and bone pins) to the digitized joint centres to find maximum expected errors. To compare the bone pins to the trackers, I analyze the differences between them in each direction under the null hypothesis that the mean difference is zero. Note that analysing the paired differences reduces the degrees of freedom of the test; this is appropriate as the pin and tracker result of each of the 30 repeated measures are indeed paired, not independent, due to other variables such as range of motion and operator technique. All groups of 30 centres and differences were normally distributed (checked using normal scores plots), so I used standard parametric methods ($F$ test to compare variances, $t$ statistic for confidence limits of the mean and power estimates). To find the 95% population limits at 95% confidence (ie. to say “95% of the time the result will be within …”), I add 1.64 times the upper 95% confidence limit of the
standard deviation (SD) to the 95% confidence limit of the mean, where the 1.64 factor is the one-sided cumulative standard (SD = 1) normal distribution at 95% (Lewis, 1966; Glantz, 1997).

Note that this 'population limit' refers to the population of all possible measurements on the particular specimen and there is a 5% chance that a single measurement on that specimen will be outside the stated limits. No conclusions can be made about the population of all TKR patients until a number of different specimens are tested.

For a given amount of joint centre location error, angular error in defining the mechanical axis is magnified with shorter limb segments. To be conservative I use the femoral and tibial segment lengths (375 mm each) for a 5th percentile female (mean of Japanese and Swedish populations; about 1.5 m tall) for computing all angular errors.

To portray the motion of the trackers relative to the bone pin frames, I compute changes in the vector between the nominal joint centre and the origin of the tracker coordinate frame as the limb is moved and plot these changes on a 5° grid representing the limb motions (e.g., flexion & abduction). Each motion vector represents the average motion in the surrounding 5° x 5° neighbourhood. The magnitude of these motion vectors depends on the distance between the joint centre and the tracker coordinate frame, which is approximately equal in all tests.

3.3 Results

3.3.1 Specimen E1

On this first embalmed specimen, I did not digitize the femoral head so the results show the precision and bias between the ilium bone pin and the hip tracker only. At the ankle, the results show the precision of digitizing with a conventional point probe along with the bone pin and foot tracker results. Figures 3.5 and 3.6 show the results along with average of the range of motion (ROM) extremes across the 30 trials. Motion of the trackers is shown in Figs. 3.7, 3.8, 3.9 and 3.10 for this specimen.

3.3.2 Specimen F1

Figures 3.11 and 3.12 show the results along with the average of the (ROM) limits across all 30 trials. Motion of the trackers is shown in Figs. 3.13, 3.14, 3.15 and 3.16.
Figure 3.5: Frontal plane results, Specimen E1 (embalmed)
Specimen E1

Tracker motion in sagittal (zy) plane (mm) vs. position: Mean of 30 trials.

Figure 3.8: Hip tracker motion in sagittal plane vs. femur position, specimen E1
Specimen E1

Tracker motion in frontal plane (mm) vs. position: Mean of 30 trials.

Figure 3.9: Foot tracker motion in frontal plane vs. foot position, specimen E1
Specimen E1

Tracker motion in sagittal plane (mm) vs. position: Mean of 30 trials.

Figure 3.10: Foot tracker motion in sagittal plane vs. foot position, specimen E1
Figure 3.11: Frontal plane results, Specimen F1 (fresh)
Figure 3.12: Sagittal plane results, Specimen F1 (fresh)
Specimen F1

Tracker motion in sagittal (zy) plane (mm) vs. position: Mean of 30 trials.

Figure 3.14: Hip tracker motion in sagittal plane vs. femur position, specimen F1
Figure 3.15: Foot tracker motion in frontal plane vs. foot position, specimen F1
Figure 3.16: Foot tracker motion in sagittal plane vs. foot position, specimen F1
3.3.3 Specimen E2

Figures 3.17 and 3.18 show the results. The digitized transepicondylar axis in the transverse plane is shown in Figure 3.19. Hip tracker motion plots for this specimen are shown in Figure 3.20 Figure 3.21.

Figures 3.17: Frontal plane results, Specimen E2 (embalmed)
**Figure 3.18:** Sagittal plane results, Specimen E2 (embalmed), n = 30 trials

**Specimen E2**

Transverse plane through R knee: *= midpoint of TE axis

Digitized TE axis internal/external rotation:
SD $0.8^\circ$
Range $4.0^\circ$

**Figure 3.19:** Transverse plane result, specimen E2, transepicondylar axis, n = 30 trials
Figure 3.20: Hip tracker motion in frontal plane vs. femur position, specimen E2

Figure 3.21: Hip tracker motion in sagittal plane vs. femur position, specimen E2
3.4 Discussion

3.4.1 Specimen E1

With embalmed specimens, the stiffened skin develops pronounced dimples at the tracker contact points and although the straps were released and the tracker reset between repeated measures, the position was well defined by the dimples. I expect this reduces tracker motions, making the results appear better than what we should expect on a real patient. On the other hand, it is difficult to get a full range of motion on an embalmed specimen, and the forces exerted near the limits of the range may disrupt the trackers more than in real use. Due to these uncertainties, I consider the embalmed specimens as pilot studies to show the basic feasibility of the methods.

This first embalmed specimen shows very little difference in precision between the bone pins and the trackers (Figures 3.5 and 3.6). The hip centre found using the hip tracker was significantly (P < 0.001) biased laterally 2.4 mm and anteriorly 5.1 mm, but not significantly less precise (F test, ML P = 0.07, AP P = 0.25) than the results from the bone pin. Based on the variance of the centre locations, this test can detect differences between the bone pin and the hip tracker of 0.4 mm (ML) and 0.6 mm (AP) (95% power). There is no way to check accuracy at the hip because I was not able to dissect out and digitize the femoral head on this specimen.

The ankle centre found using the foot tracker was significantly (P < 0.001) biased medially 1.7 mm and posteriorly 0.3 mm (P = 0.013) compared to the calcaneus pin (Figures 3.5 and 3.6). Precision was similar for both methods in both ML and AP directions (P = 0.33, 0.35). The 95% power of this test is 0.6 mm (ML) and 0.4 mm (AP). There is a significant 14 mm anterior bias for both motion based methods compared to the midpoint between the malleoli, and a less pronounced medial bias of 0.5 mm (bone pin, P = 0.005) and 2.2 mm (foot tracker, P < 0.001). I found a similar precision and direction of bias in a pilot study on a live subject (Emrich, 1998), where under passive motion using a simple plate strapped to the sole of the subject’s shoe we found the ankle centre with reasonable precision (SD 1.0 mm in ML, 2.4 mm in AP) but 58 mm anterior, 18 mm distal, and 2.1 mm medial to the midpoint between the malleoli.

The digitizing precision using the conventional point probe is comparable to that of the new ankle probe used on specimen E2, however E1 was done by a single operator (the author) and I consider the precision to be artificially high due to the divots created by the point. For
specimen E2, two different operators used the new probe and marking of the skin after several trials was less severe. Digitizing results are described in more detail in Chapter 4.

Relative to the ilium pin coordinate frame, the average maximum movement of the hip tracker coordinate origin (Figures 3.7 and 3.8) across the 30 trials was 4 mm (range 3 to 5). Relative to the calcaneus pin coordinate frame, the mean magnitude of movement of the foot tracker coordinate origin (Figures 3.9 and 3.10) was 8 mm (range 5 mm to 11 mm).

3.4.2 Specimen F1

On the fresh specimen, the mean hip centre found using the hip tracker is very accurate at 0.3 mm lateral (95% CI 0.2 to 0.4), 0.5 mm posterior (95% CI 0.1 to 0.8), and 0.2 mm proximal (95% CI -0.3 to 0.7, P = 0.43) to the digitized femoral head centre (Figures 3.11 and 3.12). The upper 95% confidence limits of the hip tracker SD represent femoral mechanical axis precision of 0.05° (varus/valgus) and 0.18° (flexion/extension) based on a 375 mm long femur (For example in varus/valgus for the hip tracker (Fig. 3.11), arctan{(0.25 SD + 0.07 CL/375)} = 0.05°). Compared to the digitized centre, there is a 95% chance that the hip tracker introduces femoral mechanical axis error less than 0.14° (frontal plane) and 0.42° (sagittal plane) on this specimen, compared to 0.11° (frontal) and 0.24° (sagittal) for the pelvic bone pin (for example in varus/valgus for the hip tracker, arctan{((0.30 bias + 0.09 CI) + 1.64 * (0.25 SD + 0.07 CI))/375} = 0.14° (Lewis, 1966; Glantz 1997)). The mean results of the two methods are essentially the same with the tracker 0.2 mm medial (95% CI 0.1 to 0.3) and 0.4 mm anterior (95% CI 0.0 to 0.7, P = 0.05). In PD, which has little effect on the mechanical axis definition, the tracker mean was 0.4 mm distal (95% CI -0.9 to 0.2, P = 0.20). This test can detect differences between the bone pins and the trackers of 0.2 mm (ML) and 0.7 mm (AP) at the hip 95% of the time.

The average maximum movement of the hip tracker relative to the ilium pin (Figures 3.13 and 3.14) across the 30 trials was 3 mm (range 2 mm to 4 mm). This is comparable to motion found by Lea (Lea, 1994) for a pelvis immobilizer. The directions of motion are as expected, with a medial shift particularly in flexion and adduction due to the thigh contacting the rod passing through the crotch. This particular specimen was very lean with prominent iliac crests and results using the hip tracker may be worse for obese patients.

At the ankle, the calcaneus pin method was biased medially and anteriorly from the digitized midpoint between the malleoli, tilting the tibial mechanical axis into varus by 0.6° and
into extension by 1.1° (Figures 3.11 and 3.12). Precision was similar to that of the ankle digitizing probe (see Chapter 4) and including the bias, the tibial mechanical axis error will be within 0.9° (frontal) and 1.8° (sagittal) 95% of the time. The foot tracker was also biased and was about 2 times more variable than the pin, leading to errors within 1.7° (frontal) and 1.6° (sagittal) 95% of the time. Compared to the pin, the tracker mean result was 2.8 mm medial and 6.3 mm posterior. Due to the high variance, 95% power to detect differences between the foot tracker and the calcaneus pin is only 4.3 mm (ML) and 4.8 mm (AP). This particular specimen was very small and the foot tracker could not be adjusted to give the ideal fit and seating forces, so I don't consider the foot tracker results to be valid in this case. The average maximum movement across the 30 trials was 22 mm (range 17 mm to 26 mm) with irregular directions (Figures 3.15 and 3.16).

I would expect a difference between digitized and motion tracking results at the ankle because they are really two different measurements. Most notable is the anterior bias of the motion result. The digitized ankle centre lies roughly on the same PD line as the centre of the talus, making the mechanical axis pass approximately through the centre of area of the talocrural articular surface and the body of the talus. Lundberg (Lundberg, 1989) found that the instantaneous rotation axes of the talocrural joint all crossed near the midpoint between the malleoli in weight bearing ankle motion on live subjects, suggesting that this is an effective centre for talus motion only (In preliminary testing I found tracking the talus and fitting a sphere to be the most imprecise method, particularly in the frontal plane. This is as expected due to limited inversion/eversion of the talus). On the other hand, the weight bearing ankle involves motions at additional joints, the most important being the subtalar joint with its externally rotated and inverted axis of rotation. Therefore using calcaneus motion and sphere fitting models a multi-joint complex as a spherical joint. I could not find any studies that show this approach is biomechanically valid, despite being used by Leitner (Leitner 1997) for TKR. Leardini (Leardini, 1999A) studied unloaded motion of the calcaneus relative to the tibia and found it to be 1 degree of freedom governed by the calcaneofibular and tibiocalcaneal ligaments with little motion at the subtalar joint, further suggesting that sphere fitting to unloaded motion is not valid. The current results suggest that a more appropriate model of the AJC must be used if a true kinematic centre is to be found.
One possibility is to apply a biaxial model to the ankle motion (as done at the knee by Churchill (Churchill, 1998), where we would expect the two axes to lie along the nominal talocrural and subtalar joint axes. Then the intersection of these axes projected into a plane normal to the expected ground reaction force line is the ankle ‘centre’ point about which moments are minimal. To do this properly, however, simulated weight bearing would have to be applied during the ankle motion measurement, and the measurement itself would have to be precise enough to allow repeatable location of the axes.

Although using a true kinematic centre would be the most correct approach biomechanically, all existing studies and techniques of lower limb alignment refer to the midpoint between the malleoli (sometimes with a correction towards medial to compensate for the more prominent lateral malleolus) so for the time being I consider this to be the ‘gold standard’. As a practical alternative to motion tracking methods, I suggest developing a robust method of digitizing the malleoli quickly and precisely for computer-assisted TKR (see Chapter 4).

3.4.3 Specimen E2

I tested an additional embalmed specimen to measure precision of digitizing the transepicondylar axis with the typical exposure used in TKR and to try the hip tracker on a different individual with less distinct iliac crests. Unfortunately, this specimen was very stiff and muscular, requiring a lot of force to flex the hip joint resulting in low range of motion and very poor hip centre results from both the bone pin and the tracker (Figures 3.17 and 3.18). Note that precision is not significantly different between the tracker and the pin (ML P = 0.24, AP P = 0.10). Both have significant medial and anterior bias (P < 0.001) compared to the digitized femoral head and the tracker mean is 1.0 mm lateral and 4.2 mm anterior to the bone pin mean (P < 0.001). There is a 95% chance that the maximum femoral axis errors on this particular specimen are within 2.0° (frontal) and 2.6° (sagittal) using the bone pin and 1.9° (frontal) and 3.7° (sagittal) using the hip tracker (see 3.4.2 for examples of this calculation). This test can detect differences between the ilium bone pin and the hip tracker of 0.4 mm (ML) and 3.2 mm (AP) 95% of the time. Relative to the pin, the average maximum movement of the hip tracker (Figures 3.20 and 3.21) across the 30 trials was 8 mm (range 5 mm to 10 mm).
Precision of sphere fitting using non-linear least squares is affected by radius, measurement noise, and the angle subtended by the patch of data. The range of hip flexion was about 50% and the ab/adduction range was about 65% of that on specimen F1. As expected, the hip centres are spread out along the radial line roughly through the middle of the range because, along with variations in the sphere radius, the sphere centre is free to move along this line with very little change in the fit to the data. This is also shown by the cost function for least squares circle fitting to an arc, which has a long flat 'valley' along the arc bisector. The range of motion is only slightly less than that of specimen E1, however, and I attribute the worse results on E2 to the lack of data in the middle of the range (Figure 3.17); it appears the femur was moved mainly in circumduction. This also gives the best fit sphere more ‘freedom’ to shift along the bisector with corresponding radius changes (up to the point where if the data describes a circle, the sphere radius is undefined). I suggest preventing this kind of error by adding a check of the range of motion and the distribution of the data in the software before calculation of the hip centre. If the data is inadequate, the surgeon will be notified and the femoral motion procedure can be repeated.

The ankle centre results using the ankle digitizing probe are fully described in Chapter 4. Compared to the centre of area of the talocrural articular surface, the mean digitized ankle centre was 2.4 mm lateral (95% CI 2.1 to 2.7, SD 0.75) and 3.8 mm posterior (95% CI 2.9 to 4.6, SD 2.3). Total tibial axis error relative to the centroid will be within 0.7° (frontal) and 1.4° (sagittal) 95% of the time. The 95% power of this test to detect differences between the digitized result and the centroid is 0.5 mm (ML) and 1.55 mm (AP). Note that the precision is similar to that of the conventional point probe used on specimen E1 (Figures 3.5 and 3.6), although two different operators made the measurements on E2.

The variability of locating the transepicondylar (TE) axis midpoint does not directly contribute to femoral mechanical axis error, as the axis is defined by this chosen point. Error will arise, however, if the final femoral component centre position varies from this point. Also, the TE axis midpoint may not lie exactly at the desired centre of the femoral component. At this stage, however, I will use this result as an estimate of femoral component ML and AP positioning precision, assuming a special purpose tool (for example a femoral sizing tool modified to include a marker array) is eventually developed. The SD of the midpoint of the TE axis (Figures 3.17 and 3.18) corresponds to SD of 0.05° varus/valgus and SD 0.14°
flexion/extension to the femoral mechanical axis definition and error should be within 0.1° and 0.3° 95% of the time. There is no way to define the ‘true’ TE axis midpoint, so I cannot quote accuracy in this case.

Internal/external rotation of the TE axis (SD 0.84°) will vary within a ±2.1° range 95% of the time (Figure 3.19). There is no way to define the ‘true’ TE axis orientation, so again there is no way to estimate accuracy. The TE axis landmarks are difficult to locate repeatably (Poilvache, 1996) and this axis varies with SD 2° to 4° in relation to the posterior condylar line and the patellar groove (Berger, 1993; Nagamine, 1998), so digitizing the TE axis does not really offer any improvement over a conventional instrument that picks up the same landmarks. As rotational alignment and patellar tracking issues are incorporated in the system, however, we will have to develop special purpose tools to locate the optimal rotation by referring to functional features as the true value; the precision of these tools about this ‘true’ value will likely be at least as good as digitizing. In the current system I do use the TE axis to define the frontal plane of the overall coordinate system and small variations in its orientation do not affect the results.

3.5 Conclusions
The results of fresh specimen F1 suggest that for sub-degree alignment accuracy in computer assisted knee surgery, bone pins at the hip can be eliminated provided the hip tracker can be shown to be robust across different individuals. It is important to note that larger errors were encountered on the embalmed specimens and more testing is required to conclude that errors will be sub-degree. Although digitizing the transepicondylar axis midpoint on one specimen had sub-millimetre SD in ML and AP directions, tooling to relate a digitized reference point at the knee to the desired centre of the femoral component must be developed, and errors in final placement of the femoral component relative to this point must be measured to find the contribution of the knee centre to alignment errors. At the ankle, motion tracking/sphere fitting methods using both the calcaneus bone pin and the foot tracker are biased anteriorly and distally from the traditional ankle centre estimate. Digitizing the joint centre appears to have similar precision to the calcaneus pin method and is an adequate solution until a sufficiently precise non-invasive method of finding the true kinematic ankle centre is developed.
4.0 Chapter Summary

In total knee replacement (TKR), an estimate of the ankle joint centre is required for proper alignment of the implants. In this chapter I report the precision and accuracy of finding this point using an optoelectronic digitizing probe designed to centre itself on each malleolus. The probe data recorded from a single ankle digitization can be used in two ways: to approximate the malleoli as spheres, where the midpoint between the spheres is used as the ankle centre, and to find the most medial and lateral points on the surfaces of the malleoli, again taking the midpoint as the ankle centre. To compare precision and mean result between probe operators, four operators each made 20 to 30 repeated measurements on a single embalmed cadaver. To estimate precision across different patients, one of these 4 operators made 30 repeated measurements on each of 6 additional cadavers. To estimate accuracy two different operators made 20 repeated measures each on an 8th cadaver, after which I dissected out the talus and digitized the talocrural articular surface. None of the operators tested in this study were surgeons, and all were using the probe for the first time. In all of the 12 sets repeated measures, the contact point method was more precise (by factors up to 5) than the spherical approximation method in the mediolateral direction (ML), so the spherical approximation method results are not included in this report. Standard deviations (SD) for the contact point method ranged from 0.3 mm to 1.7 mm in ML, with an average SD of 0.8 mm (95% CI 0.61 to 0.98). In the anteroposterior direction (AP), precision ranged from SD 0.6 to 2.7 mm, with an average of 1.1 mm (95% CI 0.91 to 1.46). Differences in the means between three operators on the same cadaver were significant in all but one comparison (max. P = 0.035), but all means were within 0.8 mm in both directions. The mean ankle centres from two different operators were both within 3 mm (ML) and 5 mm (AP) of the digitized centroid of the talo-crural articular surface (as projected onto the transverse plane). From this total of 318 ankle centre measurements, I conclude that the SD of the tibial mechanical axis registration due to ankle centre location will be within 0.25° and should average about 0.15° using the new ankle probe (based on the shortest expected ankle to knee length of 375 mm). There is no direct comparison between the new probe and a conventional point probe in this study. Additional measurements on different individuals...
are required to see if a reliable relation between the probe result and a physical or kinematic centre of the ankle joint complex can be found.

### 4.1 Introduction

In total knee replacement (TKR), the line between the ankle and knee centres is required to set the proper implant alignment. My objective is to design and test a non-invasive tool that can precisely locate a characteristic point of the ankle which can then be correlated to the physical 'centre' of the ankle joint complex (AJC) or some other point through which the mechanical axis should pass. The tool must be robust to both variations in individuals and, within reason, to user technique.

Current practice estimates the ankle centre as the midpoint between the malleoli, usually found using an external clamp-type guide and often adjusted by eye to line up with the tibial crest or the second ray of the foot (Fig. 4.1). While this point may not represent a true kinematic centre of rotation of the tibia about the ground in normal weight bearing stance and gait (as the subtalar joint is not considered), it is roughly on the centroid of the transverse plane projection of the talocural articular surface and therefore is a reasonable estimate of the talocural joint centre. Also, the fact that this point is the only ankle centre currently referred to in TKR practice and associated studies suggests that we should first develop a way to precisely locate it during TKR, then make a correlation to further knowledge of ankle kinematics. Even if an adequate non-invasive method of finding a true kinematic centre intraoperatively could be developed (see Chapter 3), a robust and precise digitizing method would likely be simpler, faster, and require less equipment.

I could not find any published studies on the precision of locating a characteristic point of the ankle from surface anatomy. In a separate study, colleagues and I found that a digitizing probe minimally constrained to some reasonable approximation of a feature shape can improve precision compared to conventional digitizing of individual points (Inkpen, 1998) (see Appendix B for a complete copy of this study). Although this work was not directly applied to the ankle joint, the probe design approach was used to develop the ankle probe for this study.
4.1.1 Motivation for a new digitizing probe design

Using a conventional point probe, a user who is asked to digitize an ankle malleolus could select any point within an area up to 20 mm x 20 mm and still consider the point to be 'on' the malleolus. Although a careful operator may be very precise using this method, I would not expect it to be robust across different operators and patients, and precision would decrease further on patients with indistinct malleoli. In preliminary testing on an embalmed cadaver, digitizing one point on each of the malleoli and taking the midpoint resulted in a SD of 1 mm (ML) and 2.2 mm (AP) over 30 trials (see Chapter 3, specimen E1), although after this many repetitions on an embalmed specimen there were depressions in the skin which tended to guide subsequent probe placements, thereby artificially increasing precision. In a separate test, a
different operator digitized 10 points on each malleolus of a different specimen using a piece of latex stretched over the malleoli to mask any divots left from the previous trial. SD of the resulting 10 midpoints was 1.4 mm (ML) and 0.8 mm (AP), while taking all 55 different combinations of medial-lateral point pairs gave similar SD of 1.5 mm (ML) and 0.8 mm (AP). The ranges of the selected points were 5 mm (lateral) and 3 mm (medial) in PD, 4 mm (lateral) and 1 mm (medial) in AP. In this particular case the medial side AP range was very narrow, giving the surprisingly low AP variance. There is no obvious explanation for this other than operator technique. These results suggest that carefully digitizing a medial and lateral point pair with a conventional point probe has adequate precision, but robustness to poor technique is still in question. Provided it is not substantially more expensive or time consuming to use than the point probe, a more robust technique and/or probe is preferable.

Some improvement could be gained by mapping out the malleoli with a group of points, although it would increase the time and work involved. To estimate the precision of mapping 10 points on each malleolus, four different operators digitized a total of 270 points on each malleolus of an embalmed cadaver. I took 30 random groups of 10 points from each side, simulating 30 repeated measures, and found the midpoint of the longest line between the point groups. SD was 1.8 mm (ML) and 1.1 mm (AP), reducing to 1.4 mm and 0.71 mm using 20 points per side, although I don’t consider this much digitizing to be practical for normal TKR practice.

Precision and robustness could be improved if the digitizing probe only fit onto the malleolus in a certain way, forcing the user to place the probe in a smaller range of positions and in effect ‘mapping’ the malleolus with a single reading. As the malleoli are roughly spherical in shape (even indistinct malleoli can often be palpated well enough to find some amount of spherical protrusion), I propose a probe with four contact points, three arranged symmetrically around the probe centreline and a fourth contact on this centreline, allowing a spherical approximation of each malleolus to be made at a single probe position (Fig. 4.2). This design also forces the probe onto a radial line through the centre of the approximate sphere and, unless used in a completely careless way, limits the area that the fourth contact point will fall to the extreme medial and lateral surfaces of the malleoli.
The purpose of this study is to test such a probe by measuring its precision in finding transmalleolar midpoints across various operators and specimens, and to compare the probe results to the centre of area of the talocrural joint surface.

4.2 Method and Equipment

4.2.1 Probe design and calibration

The ankle probe (Fig. 4.2) contacts the anatomical feature with three 7.8 mm diameter balls spaced evenly on a common 12.8 mm radius about the probe centreline, with all 3 contact ball centres lying in a plane normal to the centreline. A plunger is free to move along the probe centreline and contacts the feature with a normal planar face. When the probe is pressed against a sphere, the three contact balls force the centreline of the probe to pass through the sphere centre, and the position of the plunger face relative to the 3 contact balls determines the sphere diameter. A non-spherical feature is approximated by a sphere which depends on the four contact points: The less spherical the feature, the more the approximation varies with different contact points (probe positions). A 2 dimensional representation of the probe function is shown in Figure 4.3 and Figure 4.5. To record the pose of the centreline, 3 optoelectronic emitters are rigidly attached to the plunger. A 4th emitter is attached to the outer sleeve and contact ball assembly to report the plunger displacement along the centreline. Detail drawings of the probe are in Appendix C.

The probe can be used to digitize the ankle centre in two ways (see Figure 4.3):

- Contact point method: Recording the contact point of the plunger on each malleolus and using the midpoint between these as the characteristic point

- Sphere centre method: Approximation of each malleolus as a sphere, using the midpoint between the sphere centres as the characteristic point.
Outer sleeve assembly, free to rotate and slide axially about plunger

3 contact balls, spaced evenly about probe centreline

Plunger, with calibrated contact point on centreline

Fourth emitter on outer sleeve (fixed w.r.t. contact balls)

3 emitter reference frame fixed to the plunger and the probe centreline

Figure 4.2: Prototype ankle probe

Figure 4.3: View showing the two probe measurement positions
Note that the contact point method using the current probe differs from using a conventional point probe (as supplied with most optoelectronic localizers) in that the 3 contact balls force the probe centreline, and therefore the recorded contact point, to lie on a radial line through the centre of the approximately spherical malleolus. When the probe is roughly aligned with the transmalleolar axis (ML direction), as it must be to get the 3 contact balls to seat on the malleolus, the contact points approximate the extreme ML points of the malleolar surfaces.

4.2.1.1 Probe calibration

For all calibration and testing, I used a Flashpoint 5000 optoelectronic localizing system (Image Guided Technologies, Boulder, Colorado, USA) with accuracy around 0.50 mm for measurement tasks similar to those in this study (Chassat, 1998). In preliminary testing, I found a typical noise level of 0.12 mm for reading a static emitter location.

To calibrate the probe, I placed the plunger face on a granite machinist's reference plane. With the plunger at its fully extended position, I adjusted the three contact balls so they all touched the reference plane. Working in the probe coordinate system (PCS, subscript ‘p’) fully defined by the 3 emitters rigidly attached to the plunger, I first found the probe centreline direction by rotating the outer sleeve and finding the least-squares best fit plane to the arc swept out by the 4th emitter. The normal distance from the PCS origin to this plane is the zero position for the plunger displacement. Using a 19 mm radius ball bearing fixed relative to a three emitter array, I found the fixed vector from the probe coordinate origin to the centre of the reference sphere (see Figure 4.4) by pivoting the probe about the sphere, taking at least 50 readings of all three emitters on the fixed array in the PCS, and finding the least squares best fit sphere to the points swept out by each emitter. The mean of these three spheres is ‘sphere_p’. The fixed vector ‘Xtip_p’ from the PCS origin to the plunger contact point is ‘sphere_p’ plus a vector along the probe centreline direction of magnitude equal to the reference sphere radius. See the MATLAB code ‘calibrate_ankle_probe.m’ for details of the probe data processing.

By repeating the calibration 20 times using a variety of probe emitter poses relative to the Flashpoint sensor array and the local reference frame, I found the mean and standard deviation (SD) of each of the calibration parameters (Table 4.1). Assuming that the calibration errors are normally distributed about the true value (ie. assuming that using a variety of positions in the Flashpoint operating area eliminates any overall measurement bias), there is a 95% chance that the mean of the 20 calibrations will lie within the confidence intervals shown. Note that a true
accuracy measurement, which I did not consider necessary at this time, would require known ‘gold standard’ geometry in a local coordinate system and would ideally be done to metrology standards.

![Probe Coord. System origin](image)

**Figure 4.4: Probe calibration**

**Table 4.1: Standard Deviation and Standard Error of the Mean of ankle probe calibration**

<table>
<thead>
<tr>
<th></th>
<th>X_{tip_p} x (mm)</th>
<th>X_{tip_p} y (mm)</th>
<th>X_{tip_p} z (mm)</th>
<th>Centreline orientation (degrees)</th>
<th>Plunger zero (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SD</td>
<td>0.07</td>
<td>0.39</td>
<td>0.11</td>
<td>0.18</td>
<td>0.28</td>
</tr>
<tr>
<td>95% confidence limits of mean</td>
<td>± 0.03</td>
<td>± 0.18</td>
<td>± 0.05</td>
<td>± 0.09</td>
<td>± 0.13</td>
</tr>
</tbody>
</table>
4.2.1.2 Using the probe

As the probe dimensions can be measured after manufacture and symmetry about the probe centreline was maintained by careful machining, I made no attempt to incorporate asymmetry or non-normality of the contact ball positions into the calibration or measurement routines. Therefore, knowing the radius of the contact balls ‘r’, the pitch circle radius ‘a’ on which they are evenly spaced, and the plunger displacement ‘d’ from the 4th emitter data the spherical feature radius ‘R’ can be found as follows (refer to Figure 4.5):

\[ R = a \left( \tan^{-1} \left( \frac{a}{d} \right) - \tan^{-1} \left( \frac{d}{a} \right) \right) + d - r \]

Using identity:

\[ \tan(x - y) = \frac{\tan x - \tan y}{1 + \tan x \tan y} \]
the radius can be found from the probe dimensions and data by:

\[ R = \left( \frac{a^2 - d^2}{2d} \right) + d - r \]

With the probe centreline direction and the plunger contact point known from probe calibration, the centre of the spherical feature can be easily found in the PCS by adding \( R \) * the centreline direction unit vector to \( 'X_{tip_p}' \) and then transforming to the required local reference frame. See the MATLAB code 'use_ankle_probe.m' for details of the probe data processing.

4.2.1.3 Accuracy and precision when using the probe

The SD of 30 repeated measures of the reference sphere at various probe positions relative to the Flashpoint sensor array and the local reference frame is shown in Table 4.2. For 30 samples at 95% confidence a single reading will fall within 2.5 standard deviations of the population mean 95% of the time (taking into account the confidence limits of both the sample mean and the sample SD (Glantz, 1997)). Adding this variability to the confidence limits of the calibration accuracy gives the single expected reading accuracy limits shown in Table 4.2.

| Table 4.2: Results of repeated measures on a true sphere using ankle probe |
|-----------------|-----|----|---|------|
| Radius          | x   | y  | Z  |      |
| SD (mm)         | 0.22| 0.31| 0.24| 0.22 |
| 95% of single readings accurate within: (mm) | 0.58 | 0.94 | 0.65 | 0.68 |

To confirm the probe accuracy in relation to the standard digitizing probe supplied with the Flashpoint system (MED135 2 emitter probe), I digitized 30 points well distributed around the reference sphere surface and found the best fit sphere by least squares. The mean of the 30 repeated measures taken with the ankle probe is well within 1 mm in all dimensions (Table 4.3).

| Table 4.3: Comparison of ankle probe to point probe in sphere measurement |
|-----------------|-----|----|---|------|
| Radius          | X   | y  | Z  |      |
| Ankle probe (mean of 30 trials, mm) | -209.61 | 130.31 | 9.64 | 19.40 |
| MED135 point probe (30 points, mm) | -209.40 | 129.64 | 10.44 | 19.49 |
| Difference (mm) | -0.21 | 0.67 | -0.80 | -0.09 |
4.2.2 Cadaver Testing

To simulate conditions in a computer assisted TKR, trial measurements of the ankle centre using the ankle probe were made by 6 different operators on 8 different embalmed cadavers (Table 4.4 and 4.5). One operator made repeated measures on 7 different specimens (#2 through #21), three additional operators measured specimen #21, and two additional operators measured specimen #27 for a total of 12 sets of 20 to 30 repeated measures (318 measurements). All measurements were recorded relative to a 3 emitter triangular local reference frame (120 mm on a side) pinned rigidly to the proximal tibia and nominally aligned with the body planes. I removed indentations in the skin between measurements to prevent the probe contact balls from repeatedly falling into the same position. Since proximal-distal (PD) variation in ankle centre location has comparatively little effect on TKR alignment, I only report mediolateral (ML) and anteroposterior (AP) direction results.

Table 4.4: Embalmed cadaver specimen information, ankle probe study

<table>
<thead>
<tr>
<th>Specimen #</th>
<th>Sex</th>
<th>Height (m)</th>
<th>Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>F</td>
<td>1.6</td>
<td>RH side, midweight</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>1.7</td>
<td>RH side, midweight</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>1.5</td>
<td>LH side, midweight</td>
</tr>
<tr>
<td>13</td>
<td>F</td>
<td>1.5</td>
<td>LH, overweight, indistinct malleoli</td>
</tr>
<tr>
<td>18</td>
<td>M</td>
<td>1.7</td>
<td>RH side, overweight</td>
</tr>
<tr>
<td>20</td>
<td>F</td>
<td>1.6</td>
<td>RH side, midweight</td>
</tr>
<tr>
<td>21</td>
<td>M</td>
<td>1.7</td>
<td>LH side, lightweight</td>
</tr>
<tr>
<td>27</td>
<td>M</td>
<td>1.7</td>
<td>RH side, midweight</td>
</tr>
</tbody>
</table>

Table 4.5: Operators participating in ankle probe study

<table>
<thead>
<tr>
<th>Operator</th>
<th>Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Engineering professor with medical experience</td>
</tr>
<tr>
<td>B</td>
<td>Engineering professor with medical experience</td>
</tr>
<tr>
<td>C</td>
<td>Graduate engineering student, no experience</td>
</tr>
<tr>
<td>D</td>
<td>Graduate engineering student (author)</td>
</tr>
<tr>
<td>E</td>
<td>Graduate engineering student, no experience</td>
</tr>
<tr>
<td>F</td>
<td>Graduate engineering student, no experience</td>
</tr>
</tbody>
</table>
4.2.2.1 Contact point vs. spherical approximation methods

Each probe measurement can be analyzed by both methods, so I compare the standard deviations of the two methods for all 12 tests.

4.2.2.2 Comparing precision across patients

To estimate intra-observer precision on a variety of patients, I report the standard deviation (SD) of 30 ankle centre measurements by a single operator (operator D) on 7 different embalmed cadavers (#’s 2, 5, 8, 13, 18, 20, 21).

4.2.2.3 Comparing operators

To show the probe’s robustness when used by different operators, operators A through D each made 21 to 30 repeated measurements on specimen #21. I compare the mean ankle centre locations and the precision of each operator. Unfortunately, I moved the local reference frame before testing with operator ‘D’, so this mean cannot be included in the comparison but the SD is valid and is included in the precision comparison.

4.2.2.4 Probe result vs. centre of articular surface area

To show the relation between the characteristic ankle ‘centre’ point found with the probe and the centre of area for the articular surface, operators E and F each made 20 repeated measures of specimen #27, after which I dissected out the talo-crural joint and digitized about 100 points around the perimeter of the articular surface using the conventional point probe. To approximate the centre of load bearing area in normal stance and walking, I project the perimeter into the transverse plane, find the centroid, and compare it to the projection of the probe results.

4.2.2.5 Data analysis

As the results of these tests are normally distributed (checked on normal scores plots) and the sample sizes are 21 to 30, I use a ‘t’ test ($\alpha = 0.05$, Bonferroni correction for multiple comparisons) to test the null hypothesis that there is no difference between observers measuring the same specimen. To compare precision, I compare the standard deviations (with 95% confidence limits based on chi-squared) from each set of repeated measurements.
4.2.3 Results

4.2.3.1 Contact point vs. spherical approximation methods

To view all the data from all tests on one plot, I normalized the orientation of each test to place the mean transmalleolar axis on the horizontal and normalized the scale of each test to the mean transmalleolar axis length across all tests. The transmalleolar axis for each test was taken as the line from the mean lateral contact point to the mean medial contact point. Left side ankles were reflected about the ML plane after normalization so that all tests are shown as right ankles. Results from the contact point method are shown in Fig. 4.6 and the corresponding sphere method results are shown in Fig. 4.7.

Looking at the data from each test in the local reference frame on the tibia, which is aligned with anatomical position on each specimen, the contact point method is consistently more precise (up to 5 times) in the ML direction (Fig. 4.8) and there is no clear difference between the methods in the AP direction (Fig. 4.9). Because ML precision is most important in TKR, I report only the contact point method for the remainder of the study.

Figure 4.6: Ankle centres and contact points, contact point method, normalized, all 12 tests
Figure 4.7: Ankle and sphere centres, spherical approx. method, normalized, all 12 tests

Figure 4.8: Contact point vs. spherical approximation methods in ML direction
4.2.3.2 Comparing precision across specimens

Figure 4.9: Contact point vs. spherical approximation methods in AP direction

Figure 4.10: Comparing precision on 7 specimens, one operator
4.2.3.3 Comparing operators

Figure 4.11: Mean ankle centre locations from three operators

Figure 4.12: Standard deviations of 4 operators, one specimen
4.2.3.4 Probe result vs. centre of articular surface

Transverse plane through ankle: o = operator E, * = operator F, . = digitized surface

![Graph showing probe results](image)

Figure 4.13: Transverse plane projection of tibial plafond perimeter

4.2.4 Discussion

4.2.4.1 Contact point vs. spherical approximation methods

The variability of the spherical approximation method indicates that the malleoli are not particularly well approximated by spheres, making the results sensitive to operator dependent factors such as the position of the 3 contact balls on the skin surface and the pressure applied (Figs. 4.8 and 4.9). These factors would be difficult to control in actual use.

With the current design, the plunger contact point is restricted to a small area at the medial and lateral limits of the malleoli by the 3 contact balls. This is the distinguishing feature over a conventional point probe. All operators maintained a consistent enough alignment of the probe centreline with the transmalleolar line to give reasonable precision with no gross errors or outliers.

4.2.4.2 Comparing precision across patients

Ideally, the SD of repeated measures would be near zero on all specimens. Some individuals, however, may have indistinct or non-spherical malleoli which I would expect to decrease precision. In this test (Fig. 4.10), 3 of the 4 female specimens (#'s 2, 8, and 13) and one
of the 4 male specimens (#18) had indistinct malleoli, but it was possible to palpate the malleoli reasonably well in all cases. Surprisingly there is no clear relation between poor precision and indistinct malleoli. The outlying precision on specimen #5, particularly in the AP direction, may be due to the fact that this was the first test done by operator D. There is no obvious explanation for the poor ML precision on specimen #8.

4.2.4.3 Comparing Operators

A truly robust method would have no significant differences between the operator means. Making all possible comparisons between operators A, B, and C measuring the same cadaver, differences in the means are significant (P = 0.0001 to 0.035) in all but one comparison (B vs. C in ML direction, P = 0.62). All means are within 0.8 mm in both AP and ML directions (Fig. 4.11) and the range of the 95% confidence limits of the means is 1.6 mm (ML) and 1.3 mm (AP). These comparisons can detect differences between the three operator means of 1.4 (ML) and 0.9 mm (AP) with 95% confidence. At 95% confidence, maximum tibial mechanical axis registration bias between these three operators is 0.24° based on a 375 mm long tibia. Figure 4.12 shows that there is no clear difference in the precisions of operators A through D.

4.2.4.4 Probe result vs. centroid of articular surface

Clearly, with only one specimen I cannot make any correlation between the probe results and the physical centroid of the talocrural articular surface and cannot even estimate the number of specimens required to do so. Several more specimens must be tested in a pilot study to estimate the variance of this relation before an estimate of sample size for a complete study can be made. The current result does, however, show that for at least one specimen the characteristic point found by using the probe is reasonably close to the talocrural joint centroid (Fig. 4.13).

4.2.5 Conclusions

I have shown that the prototype ankle probe described in this study is a robust way of digitizing a characteristic point of the ankle in computer assisted TKR. Based on the average precision found in this study and the mean number of repeated measures (n = 26), results from the new probe will be within ±1.9 mm (ML) and ±2.9 mm (AP) of the population mean characteristic point 95% of the time. This is a 0.3° varus/valgus error and a 0.4° flexion/extension error when registering a 375 mm long tibial mechanical axis.
The average SD over all 12 sets of 20 to 30 repeated measures by 6 different operators on 8 different specimens is 0.75 mm (ML) and 1.12 mm (AP). The upper 95% confidence limit of the maximum SD observed was 2.15 mm (ML) and 3.0 mm (AP). The maximum range is 6.5 mm (ML) and 10 mm (AP), giving a maximum tibial axis range of 1.0° varus/valgus and 1.5° flexion/extension from a sample of 318 measurements. On the one specimen available for dissection, 2 operators both obtained mean results within 2 to 3 mm (ML) and 2 to 5 mm (AP) of the talocrural articular surface centroid. None of the operators tested in this study were surgeons, and all were using the probe for the first time. This study does not show that the new probe is better or worse than a conventional point probe for this task: A similar study of the point probe would be required to make this comparison.
Chapter 5:

Accuracy and precision of bone cuts in total knee replacement.

5.0 Chapter Summary

In this study I measure the accuracy and precision of bone cuts made with an oscillating bone saw and open cutting guides as typically used in Total Knee Replacement (TKR). I thawed and mounted 2 fresh frozen human femora and 3 tibiae rigidly in positions simulating a typical TKR and pinned a cutting guide in place to simulate a typical cut. Cuts were made by one experienced TKR surgeon, one orthopaedic surgeon with no TKR experience (trained overseas, not currently practicing), and 3 graduate students with no surgical training. After measuring the orientation of the guide, the bone was cut and I measured the orientations of the guide, the cut bone surface, and a dummy implant placed on the cut bone surface. All measurements were made in a local reference frame pinned to the bone using a custom optoelectronic digitizing probe, and rotated to a common coordinate frame aligned with the guide. To confirm the measurement system precision, I made 30 repeated sets of measurements on one cut and found standard deviation (SD) for the difference between the initial guide orientation and the implant orientation within 0.09° for varus/valgus errors and 0.17° for flexion/extension (all results at 95% confidence limits). Precision of measuring the cut bone surface directly was poor at SD 0.3° to 0.4° and these measurement are not used. 5 distal femoral, 3 anterior femoral, and 12 tibial plateau cuts were made. Looking at all 20 cuts, there was no significant bias of the implant orientation in the frontal plane of guide (varus/valgus for distal femoral and proximal tibial cuts) and SD was within 0.75°. In the sagittal plane (flexion/extension of the implant) there was a significant bias within 1.16° towards bending of the blade upwards from the guide surface and SD was within 1.12° (all results at 95% confidence limits). Based on these results, implant position on the cut bone surface will be within ±1.5° in the frontal plane of guide and maximum sagittal plane error will be within 3.0° 95% of the time. More testing is required to make comparisons between different conditions such as open vs. slotted guides, cut types, and surgeons. Since cuts made by untrained operators are included in the results, this should be considered a pilot study and the results are a conservative estimate of the cutting errors we can expect in TKR.
5.1 Introduction

If conventional cutting guides for total knee replacement (TKR) can be positioned accurately by some means such as computer assistance, how precise and accurate will the final implant orientation be using conventional cutting techniques? Are more sophisticated cutting methods such as robotic guidance of the bone saw required to make a substantial improvement in TKR outcomes? My objective in this study is to answer these questions by comparing the precision and accuracy of final implant position relative to guide placement using conventional cutting techniques.

Many researchers have proposed using computer assistance and optoelectronic tracking to allow accurate and precise placement of conventional cutting guides for a variety of procedures (Leitner, 1997; Moody, 1998; Tonetti, 1998). In these systems, the actual cutting is done by the surgeon in a more or less conventional manner after the tool alignment or position has been reported by the computer. In early experience with computer assisted acetabular cup installation, for example, up to 10° error was found after driving the cup into place even though the tool was initially aligned accurately (Moody, 1998).

Others have proposed robotic cutting tools to improve the accuracy and quality of the intervention. Much of the effort in robotic bone cutting for orthopaedics is aimed at cementless implants (Toksvig-Larsen, 1991; Bargar, 1998; Van Ham, 1998), where close contact between the cut bone and the implant surface is essential for bone ingrowth and fixation. For cemented implants, however, the surface roughness and flatless is not as critical because the bone cement fills the small gaps (up to reasonable limits) between implant and bone. The final orientation of the implant is, of course, just as important for both techniques. As cemented TKR remains predominant and it is unlikely that robotic cutting will be practical and cost effective for most clinics in the near future, it is important to find what improvement in TKR alignment can be expected from a practical, low cost approach such as passive guidance of conventional cutting guides.
Figure 5.1: Typical tibial plateau cut (Image adapted from Johnson & Johnson Orthopaedics)

Figure 5.2: Typical distal femoral cut (Image adapted from Johnson & Johnson Orthopaedics)
Cooke (Cooke, 1985) developed a jig (pinned to the femur and using sliders to passively guide a conventional bone saw) and found implants could be ‘regularly implanted, aligned $\pm 1^\circ$’, but this result is not described in the paper. Such a device could, however, be accurately located by passive computer guidance and is potentially a practical alternative to robotic cutter guidance. Otani (Otani, 1993) studied cuts in balsa wood blocks using conventional tools and a various blade thicknesses and found a maximum mean error of $1^\circ$ (SD 0.25°) in the sagittal plane, with the blade flexing up and away from the guide surface. Otani did not report errors in the frontal plane. Toksvig-Larsen (Toksvig-Larsen, 1991) investigated the surface flatness of tibial plateau cuts in cadaveric specimens to find the amount of bone directly contacting the implant, but was mainly concerned with cementless implants and does not report the overall orientation of the implant relative to the original placement of the cutting guide.

5.2 Method and Equipment

One experienced TKR surgeon made femoral cuts simulating typical TKR practice on 2 fresh frozen human femora and one orthopaedic surgeon with no TKR experience made tibial plateau cuts on two fresh frozen tibia. Three engineering graduate students with no surgical training also made tibial plateau cuts (see Table 5.1 for operator information). The inexperienced operators each made at least one practice cut that was not included in the results. All operators were right-handed. The specimens had no obvious abnormalities in bone quality and all five were from different individuals (see Table 5.2 for donor information). Several cuts were made on each specimen, approximating primary, revision, and subsequent revision bone resections. We used open guides (Johnson & Johnson, Raynham, Mass. USA) for all but one cut. All cuts were made with a conventional pneumatic oscillating bone saw (CPS #1535) supplied with 90 psi. For the femoral cuts, surgeon A used a 0.8 mm thick, 75 mm long blade (Synvasive ‘Stablecut’ #11-0470). For the remaining cuts, we used a 1 mm thick, 90 mm long blade (Johnson & Johnson #26-6050). Cut type, resection depth, guide type, operator, and blade are listed in the results (see Table 5.3) for each cut.
Table 5.1: Surgeons/students participating in bone cutting study

<table>
<thead>
<tr>
<th>Operator</th>
<th>Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Orthopaedic surgeon, TKR experience</td>
</tr>
<tr>
<td>B</td>
<td>Orthopaedic surgeon, no TKR experience</td>
</tr>
<tr>
<td>C</td>
<td>Graduate engineering student, no experience (author)</td>
</tr>
<tr>
<td>D</td>
<td>Graduate engineering student, no experience</td>
</tr>
<tr>
<td>E</td>
<td>Graduate engineering student, no experience</td>
</tr>
</tbody>
</table>

Table 5.2: Specimen information, bone cutting study

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Sex</th>
<th>Age</th>
<th>Weight</th>
<th>Height</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1022R</td>
<td>F</td>
<td>70</td>
<td>53 kg</td>
<td>160 cm</td>
<td>Caucasian, right femur</td>
</tr>
<tr>
<td>1019L</td>
<td>M</td>
<td>85</td>
<td>74 kg</td>
<td>170 cm</td>
<td>Caucasian, left femur</td>
</tr>
<tr>
<td>1030R</td>
<td>M</td>
<td>73</td>
<td>45 kg</td>
<td>145 cm</td>
<td>Caucasian, right tibia</td>
</tr>
<tr>
<td>1031L</td>
<td>M</td>
<td>72</td>
<td>59 kg</td>
<td>188 cm</td>
<td>Caucasian, left tibia</td>
</tr>
<tr>
<td>1033R</td>
<td>M</td>
<td>99</td>
<td>65 kg</td>
<td>175 cm</td>
<td>Right tibia</td>
</tr>
</tbody>
</table>

To simulate orientation of the components after placement on the cut bone, I made dummy components from flat aluminum plate by copying the profile of the of tibial trays and the distal footprints of the femoral components in a Johnson & Johnson PFC implant series. Note that the dummy components are flat plates only with no keels or pegs.

For each test cut, the surgeon pinned the guide to the specimen in the typical manner and I measured the front face and cutting plane orientations. The surgeon then made the cut, including any trimming and checking as would normally be done in TKR. When the surgeon was satisfied with the cut, I re-measured the guide, measured the plane of the cut bone, placed a dummy implant on the cut surface to simulate placement of an implant with proper bone coverage, and measured the plane of the dummy implant.

5.2.1 Measurement procedure

I attached a 3 emitter triangular reference frame (120 mm on a side) rigidly to each specimen using a 4 mm bone pin driven through both cortices. Each pin has a tab through which an additional unicortical screw is installed to prevent rotation. The origin of this local reference plane is within 300 mm of the cutting site, and all data is recorded in this frame. For a consistent
definition of rotational errors across all tests, I define the front face of the cutting guide as the xy plane and cutting surface of the guide as the xz plane (see Figs. 5.1 and 5.2). The intersection of these planes defines the x axis direction, nominally mediolateral (ML), and the z axis is normal to the front face of the guide pointing towards the operator. Rotations about the x axis are always flexion-extension errors, and I orient the local frame for each type of cut such that positive flexion/extension error (positive rotation about the x axis) corresponds with the saw blade flexing up and away from the guide surface. Conversely a negative error is the blade skiving deeper into the bone. Rotations about the z axis are varus-valgus for distal femoral and tibial plateau cuts, internal/external rotation for anterior femoral cuts, and a positive error is always a counterclockwise rotation of the implant relative to the guide, as viewed by the operator. Note that the z axis always lies in the cutting plane, so errors about the z axis are apparent as one looks along the cut. Thus before each cut, I record the front face and cutting plane of the guide and define the rotation matrix from the local reference frame to a new ‘body’ frame aligned with the guide. Using this rotation, I transform all measurements to the body frame.

The reported errors are the fixed frame rotations that make the original guide plane parallel to the measured plane. For example, if the quoted error of the distal femoral cut is +5°
varus/valgus +10° flexion/extension, the cut has been first tilted upwards 10° from the guide surface about the body ‘x’ axis (indicating that more bone must be resected from the far edge of the cut) and then rotated counterclockwise 5° about the body ‘z’ axis. Note that these are ‘fixed frame’ or ‘RPY’ rotations commonly used in robotics, where the rotation axes remain fixed relative to the patient. In these cuts with no features in the plane, rotation about the ‘y’ axis (in the cutting plane) is undefined. Details of the procedure and error calculation can be found in the accompanying MATLAB routines ‘cut_test_planes.m’ and ‘find_plane_orientation.m’.

5.2.2 Measurement probe design and calibration

For all calibration and testing, I used the Flashpoint 5000 optoelectronic localizing system (Image Guided Technologies, Boulder, Colorado, USA) described in the preceding chapters.

To measure planar surfaces, I made a planar plobe with a rigidly mounted 3 emitter triangular array, 120 mm on a side (Figure 5.4). The planar face is 38 mm in diameter and has 3 radial grooves for installation of an optional adapter with three spherical contact points (not used in this study). Detail drawings of the probe and adapter are in Appendix C. To find the constant vector normal to the planar face of the probe, I placed the probe on a 300 mm x 460 mm granite reference surface (flat within 0.005 mm), digitized 10 points widely spaced on the reference surface using the 135 mm 2 emitter point probe supplied with the Flashpoint system, and fit a plane to the 10 points by least squares. Repeating this calibration 30 times using a variety of positions on the reference surface and a variety of planar probe emitter poses relative to the Flashpoint sensor array, I found a standard deviation (SD) of 0.046°, giving standard error of the mean (SEM) of 0.008°. The mean result of the 30 calibrations is therefore accurate within ±0.017° with 95% confidence. Similarly, the calibrated normal distance from the probe coordinate system origin to the plane is accurate within ±0.051mm at 95% confidence. See the MATLAB routine ‘calibrate_plane_probe.m’ for details of this procedure. Note that this calibration can also be used for any planar surface on a tool by digitizing points directly on the tool surface; using a granite reference plane simply expands the plane to increase precision.
5.2.3 Measurement Precision

To confirm that the plane probe and the Flashpoint system could measure planes with enough precision to detect differences of 0.25°, I made 30 repeated sets of measurements on specimen 1019 L (a revision anterior femoral cut). The mean guide movement should be zero and SD should be the measurement system precision alone, since this is just a repeated measure of a flat machined plane. Since even a high quality cut plane in cancellous bone will have local high and low areas and the probe face can be placed in a variety of places on the bone, I expect poor precision from the cut bone measurement. The dummy implant orientation is defined by the three high points of the cut surface, which should not change significantly if the implant is placed to simulate full bone coverage each time. Results are shown in Figure 5.6.
As expected, the mean of repeated measurements on the guide is indistinguishable from zero (Mean = -0.01°, 95% CI ± 0.02°, P = 0.15). For varus/valgus errors, the dummy implant placement does decrease precision but SD is still < 0.10°. System precision is worse in measuring flexion/extension errors and in this case the dummy implant does not significantly add to the variability. With the Flashpoint system, SD of a static emitter position reading is two times greater in the depth direction (normal to the sensor array face) than in the plane of the sensor face, and in the test setup the depth direction corresponds roughly to flexion/extension variability. Due to the local roughness, measuring directly on the cut bone surface is not precise enough to detect sub-degree errors (SD approximately 0.35°) and this measurement is not included in the results.

5.2.4 Data analysis

For this test, the null hypothesis is that there is no difference between the guide setting and the resulting implant orientation (ie. implant error = 0). At the 20% confidence level (α = 0.20) and an estimated error SD = 0.25° from Otani (Otani, 1993), a sample size of 10 cuts gives the test 95% power to detect a 0.25° error. The large α in this case means that there is a 20% chance of falsely reporting a difference between the guide and the implant when they are really the same, but there is only a 5% chance of missing a true error of 0.25°. A minimum of 10 cuts should therefore allow adequate detection of error when analysed together as one sample, but additional specimens will be required to detect differences between guides, surgeons, and cut
types. I have included 11 cuts of various types by surgeons and 9 additional cuts done by students.

5.3 Results

Mean errors and variances of all cuts are summarized in Figure 5.9. In two cases, the local reference frame marker array was disturbed during the cut, so the implant orientation is compared to the guide position after the cut and the guide movement is not available.

Table 5.3: Cut description and errors for all cuts

<table>
<thead>
<tr>
<th>DIFFERENCE FROM INITIAL GUIDE PLACEMENT (degrees):</th>
<th>VARUS - VALGUS</th>
<th>FLEXION - EXTENSION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surg/Oper</td>
<td>Blade (mm)</td>
<td>Guide moved</td>
</tr>
<tr>
<td>1022 R, Femur, 1st rev. distal</td>
<td>A</td>
<td>0.8</td>
</tr>
<tr>
<td>1022 R, Femur, 2nd rev. distal</td>
<td>A</td>
<td>0.8</td>
</tr>
<tr>
<td>1022 R, Femur, Prim. anterior</td>
<td>A</td>
<td>0.8</td>
</tr>
<tr>
<td>1019 L, Femur, Prim. distal</td>
<td>A</td>
<td>0.8</td>
</tr>
<tr>
<td>1019 L, Femur, 1st rev. distal</td>
<td>A</td>
<td>0.8</td>
</tr>
<tr>
<td>1019 L, Femur, 2nd rev. distal</td>
<td>A</td>
<td>0.8</td>
</tr>
<tr>
<td>1019 L, Femur, Prim. anterior</td>
<td>A</td>
<td>0.8</td>
</tr>
<tr>
<td>1019 L, Femur, Rev. ant., slot</td>
<td>A</td>
<td>0.8</td>
</tr>
<tr>
<td>1030 R, Tibia, 1st rev.</td>
<td>B</td>
<td>1.0</td>
</tr>
<tr>
<td>1030 R, Tibia, 2nd rev.</td>
<td>B</td>
<td>1.0</td>
</tr>
<tr>
<td>1033 R, Tibia, Primary</td>
<td>B</td>
<td>1.0</td>
</tr>
<tr>
<td>1033 R, Tibia, 1st rev.</td>
<td>C</td>
<td>1.0</td>
</tr>
<tr>
<td>1033 R, Tibia, 2nd rev.</td>
<td>C</td>
<td>1.0</td>
</tr>
<tr>
<td>1033 R, Tibia, 3rd rev.</td>
<td>C</td>
<td>1.0</td>
</tr>
<tr>
<td>1031 L, Tibia, Primary</td>
<td>D</td>
<td>1.0</td>
</tr>
<tr>
<td>1031 L, Tibia, 1st rev.</td>
<td>E</td>
<td>1.0</td>
</tr>
<tr>
<td>1031 L, Tibia, 2nd rev.</td>
<td>D</td>
<td>1.0</td>
</tr>
<tr>
<td>1031 L, Tibia, 3rd rev.</td>
<td>E</td>
<td>1.0</td>
</tr>
<tr>
<td>1031 L, Tibia, 4th rev.</td>
<td>D</td>
<td>1.0</td>
</tr>
<tr>
<td>1031 L, Tibia, 5th rev.</td>
<td>E</td>
<td>1.0</td>
</tr>
</tbody>
</table>
Figure 5.7: Mean guide movement and implant position error, all cuts

Figure 5.8: Standard deviation of guide movement and implant error, all cuts
Mean error 0.0° (95% CI -0.2 to 0.2)  
SD 0.64 (95% CI 0.57 to 0.75)  
Range 2.34

Mean error 0.87° (95% CI 0.6 to 1.2)  
SD 0.95 (95% CI 0.85 to 1.12)  
Range 3.21

Frontal plane, all cuts
Sagittal plane, all cuts

Figure 5.9: Summary results of all cuts (Image from Johnson & Johnson)

5.4 Discussion

Both the guide movement and implant errors follow a normal distribution (checked using normal scores plots). Based on the actual variances, the test has 95% power to detect implant error of 0.4° in varus/valgus and 0.7° in flexion/extension.

Figure 5.7 shows that both the mean guide movement and mean implant error in varus/valgus are indistinguishable from zero (P = 0.8 for both), meaning that there is no clear directional bias in rotation about the saw centreline. Precision of the implant orientation in varus/valgus is within SD 0.75° (Figure 5.8), where guide movement accounts for about 25% of this variance (50% of the SD). Note that the measurement variance in varus/valgus (SD within 0.10°, see Figure 5.6) accounts for less than 3% of the observed variance (20% of the SD).

In flexion/extension (Figure 7), there is a clear bias towards flexing of the saw blade up and away from the guide surface of about 1° (P = 0.0006). This sagittal plane bias agrees well with Otani’s (Otani, 1993) largest mean error of 1°, but our precision is 4x worse (Otani’s SD = 0.25). This is probably due to the variety of operators and the use of cadaver bone from different donors in the current study as opposed to Otani’s use of balsa wood blocks. The greatest flexion/extension errors in the current study occurred on large specimens where the saw blade did not reach the end of the cut before the saw body hit the guide, requiring the cut to be finished off ‘freehand’ at the far cortex. Also, the guide often started sliding (towards the surgeon) on the fixation pins during the cut, creating a gap between the bone and the guide and increasing the
unsupported length of the blade. Precision of the implant orientation in flexion/extension is within SD 1.12° (Figure 5.8), where guide movement accounts for about 19% of this variance (44% of the SD). The measurement variance in flexion/extension (SD within 0.17°, see Figure 5.6) accounts for about 2% of the observed variance (15% of the SD).

Although comparisons between operators cannot be made until more testing is done, it is worth noting that the experienced TKR surgeon (A) was substantially more precise in varus/valgus compared to the overall results (SD 0.25°, 95% CI 0.21 to 0.34) and that the two cuts with large (about 1.4°) varus/valgus errors were done by inexperienced operators.

I was only able to measure one slotted guide cut at this time, and although error in this particular cut was negligible the lack of more slotted cuts makes it impossible to make any comparison between guides. When slotted guides and more specimens are available, the effect of the various factors can be measured in a two-way ANOVA. I suggest cutting additional specimens with several more surgeons of different experience levels in a randomized block design, assume the population of surgeons and patients is fairly represented, and take type of cut (distal femoral vs. tibial plateau) and type of guide (open vs. slotted) as two different treatments. The remaining femoral cuts (anterior, posterior, and chamfer) could be similarly compared.

5.5 Conclusions

Based on 20 bone cuts made under a variety of simulated TKR conditions in cadaver bone, the implant position on the cut bone surface will be within 1.5° in the frontal plane of guide (varus/valgus for distal femoral and proximal tibial cuts) and 3.0° in the sagittal plane (flexion/extension) 95% of the time. This study included cuts by untrained operators and the results suggest that precision in varus/valgus among TKR surgeons will be substantially better. There is a significant bias of 0.9° towards flexing of the blade upwards from the guide surface. These results represent the orientation accuracy and precision of the bone cuts relative to the initial guide placement, and errors introduced during cementing and final seating of the component are not included.
Chapter 6:

Summary of results and future work

6.0 Chapter summary

The final accuracy and precision possible in TKR arises from the sum of the errors and variances of finding the mechanical axis and making the cuts. The current results, which should be considered as a pilot study (mechanical axis location errors are based on one specimen only), suggest that the standard deviation of overall alignment will be within 1.1° varus/valgus while femoral component flexion/extension and the posterior slope of the tibial component both have SD within 1.2°. All results are at the 95% confidence limits and include cutting errors estimated from testing of expert as well as untrained operators. If the observed biases are included, there is a 95% chance that the maximum errors on the particular specimen tested would be within 2.8° overall varus, 3.2° extension of the femoral component, and 3.8° less posterior slope than planned. Additional errors of several degrees may still occur if the implants are not seated properly on the cut bone or if the implants subside after the patient returns to weight bearing. It is important to note that while the uncertainty of sampling is accounted for by looking at the upper 95% confidence limits of the results, more specimens and operators must be tested (particularly for the hip and knee location procedures) to show that these estimates fairly represent the whole population of TKR surgeons and patients. Within these limitations, however, the results suggest that using the proposed computer assisted method will be approximately twice as precise as current techniques (as reported in the literature) in overall varus/valgus alignment. In the sagittal plane, precision of femoral component flexion/extension and tibial component posterior slope will be 2 to 3 times more precise than estimates of current technique. Proximal/distal precision in joint centre location is about 2 mm at the hip and ankle, so segment length precision is limited and conventional methods of setting the depth of resection from the existing bone can be used. Cutting errors account for over 90% of the variance and cutting error bias of approximately 1° in the sagittal plane accounts for 30 to 40% of the maximum expected flexion/extension & posterior slope errors.
6.1 Introduction

In Chapter 1, I estimated that typical current TKR technique has standard deviation (SD) of 2.6° varus/valgus and about 3° flexion/extension based on published studies and estimates. Based on testing of the proposed computer assisted alignment system, I hoped to show that a 2 to 3 times improvement in precision was feasible. In Chapters 3, 4 and 5, I describe cadaveric trials of joint centre finding and bone cutting that give estimates of the precision at each of these steps. As the final orientation of the bone cuts results from the sum of these variances, they are added and the square root of the sum is an estimate of the overall precision (Glantz, 1997). In the cases where the true value could be measured directly from the specimen, these first tests also show bias of the mean result from the true value. Although a general trend in the biases cannot be found without more testing, we can get an estimate of what the maximum errors would be by including them in an overall error estimate.

6.2 Alignment precision

To estimate the potential alignment precision of TKR possible with computer assistance, I use the upper 95% confidence limit of the SD found at each step from the tests as follows: Hip centre location using the hip tracker on specimen F1 (Figs. 3.11 and 3.12), transepicondylar axis midpoint digitized on specimen E2 (Figs. 3.17 and 3.18), and the average of the +95% SDs from all ankle probe tests (contact point method, Figs. 4.8 and 4.9). All angular errors are based on 375 mm hip-knee and knee-ankle distances, so I convert each of these SDs (in mm) to degrees by taking arctan(SD/375). I use the angular SD of the implant position error from all bone cuts tested (Fig. 5.9) which includes cuts by untrained operators. Finally, the angular precision of locating the cutting guides will be similar to that of the reading the planar probe (Chapter 5), so to be conservative I use the upper 95% confidence limit of the repeated plane measurements found under test conditions (greater of the two ‘System’ precisions in Fig. 5.6). Actual precision of checking the guides will be better as the marker arrays will be built in to the guide. As overall alignment is the sum of all these errors, I add these variances and take the square root to find the overall alignment SD (Glantz 1997). The precisions only are listed in Table 6.1 and overall results are shown in Figure 6.1.

Note that knee centre precision is based on our ability to select an appropriate point at the distal femur and at the proximal tibia where the centre of the implant should lie, and then
accurately put the component there. For example, cutting the distal femur based on the selected knee centre then placing the component 1 mm medial results in a 0.15° valgus error. This procedure has not been fully investigated and special purpose tools still need to be designed (see Chapter 2), but precision should be similar to that of digitizing the transepicondylar axis with a conventional point probe, as tested on specimen E2. Note also that the uncertainty of sampling is accounted for by taking the 95% confidence limits of each test, but this applies to the particular specimen/operator only and more specimens and operators must be tested (particularly for the hip and knee location procedures) to show that these precision estimates fairly represent the whole population of surgeons and patients.

Table 6.1: Summary of estimated TKR precision

<table>
<thead>
<tr>
<th></th>
<th>Frontal plane</th>
<th>Sagittal plane</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ML distance SD (mm)</td>
<td>Angle SD (°)</td>
</tr>
<tr>
<td>Hip</td>
<td>0.32</td>
<td>0.05</td>
</tr>
<tr>
<td>Knee</td>
<td>0.38</td>
<td>0.06</td>
</tr>
<tr>
<td>Cut + Implant</td>
<td>0.75</td>
<td></td>
</tr>
<tr>
<td>Set guide</td>
<td>0.17</td>
<td></td>
</tr>
<tr>
<td>FEMORAL SUBTOTAL:</td>
<td></td>
<td>0.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Frontal plane</th>
<th>Sagittal plane</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ML distance SD (mm)</td>
<td>Angle SD (°)</td>
</tr>
<tr>
<td>Knee</td>
<td>0.38</td>
<td>0.06</td>
</tr>
<tr>
<td>Ankle</td>
<td>0.98</td>
<td>0.15</td>
</tr>
<tr>
<td>Cut + Implant</td>
<td>0.75</td>
<td></td>
</tr>
<tr>
<td>Set guide</td>
<td>0.17</td>
<td></td>
</tr>
<tr>
<td>TIBIAL SUBTOTAL:</td>
<td></td>
<td>0.8</td>
</tr>
<tr>
<td>OVERALL SD (°):</td>
<td></td>
<td>Varus/valgus:</td>
</tr>
</tbody>
</table>

6.3 Alignment accuracy and maximum expected error

Total error arises from any difference the average of each measurement has from the true value (bias), and the variance of that measurement about its own mean. At the hip and ankle, I assume the digitized femoral head and the centroid of the talocrural joint surface define the ends of the ‘true’ femoral and tibial mechanical axes. Note that the final implant positions relative to the selected points at the distal femur and proximal tibia define the ‘true’ knee centre, and until this procedure can be tested I will assume that there is no bias at the knee.
### Table 6.2: Estimated biases and 95% population limits of total TKR errors

<table>
<thead>
<tr>
<th>Bias</th>
<th>Frontal plane</th>
<th>Sagittal plane</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ML distance</td>
<td>Angle (°)</td>
</tr>
<tr>
<td><strong>Hip bias</strong></td>
<td>0.39 mm lateral</td>
<td>-0.12</td>
</tr>
<tr>
<td><strong>Femoral cut bias</strong></td>
<td>-0.22</td>
<td></td>
</tr>
<tr>
<td><strong>Femoral SD (Table 6.1)</strong></td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td><strong>FEMORAL SUBTOTAL:</strong></td>
<td>-1.6</td>
<td>-3.2</td>
</tr>
<tr>
<td><strong>Ankle bias</strong></td>
<td>2.7 mm lateral</td>
<td>-0.41</td>
</tr>
<tr>
<td><strong>Tibial cut bias</strong></td>
<td>-0.22</td>
<td></td>
</tr>
<tr>
<td><strong>Tibial SD (Table 6.1)</strong></td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td><strong>TIBIAL SUBTOTAL:</strong></td>
<td>-1.9</td>
<td>-3.8</td>
</tr>
<tr>
<td><strong>MAX. ERROR 95% OF THE TIME WITHIN.</strong></td>
<td>-2.8</td>
<td>-5.8</td>
</tr>
</tbody>
</table>

**Overall alignment**

- **Varus/Valgus:**
  - **Femoral component**
    - Varus/Valgus: +95% SD 0.8°
    - Max. error 1.6° (varus)
  - **Tibial component**
    - Varus/Valgus: +95% SD 0.8°
    - Max. error 1.9° (varus)

- **Flexion/Extension:**
  - **Femoral component**
    - Flexion/Extension: +95% SD 1.2°
    - Max. error 3.2° (extension)
  - **Posterior slope:**
    - +95% SD 1.2°
    - Max. error 3.8° (extension)

---

**Figure 6.1: Component orientation precision and errors**

If a bias is known it can be compensated for, but we would need to do accuracy testing with many different specimens to be confident the bias exists in all cases before applying a general correction (for example medializing the ankle centre by 2 or 3 mm). However, it is...
useful at this stage to estimate the maximum error we would expect to see (with no bias correction) on the specimens tested. To do this I take the hip and ankle centre biases at the 95% confidence limit (using the hip tracker on specimen F1, Figs. 3.11 and 3.12, and the ankle probe on specimen E2, Figs. 3.17 and 3.18), add the 95% confidence limit mean cutting errors (Fig. 5.9), and add 1.64 standard deviations using the upper 95% confidence limit of the femoral and tibial subtotal SDs from Table 6.1 (Lewis, 1966; Glantz, 1997). The biases are listed in Table 6.2 and the resulting maximum errors are shown along with the precision in Figure 6.1.

6.4 Rotational alignment
As discussed in Chapter 3, there is currently no improvement in rotational alignment precision in the system as the same landmarks are still used as in conventional technique. Results from one specimen suggest that the transepicondylar axis can be digitized within SD 1.1° internal/external rotation or within 2.1° 95% of the time.

6.5 Segment length
As shown in the Chapter 3 results, the proximal/distal precision of hip and ankle centre location is approximately 2 mm. Although this variability has little effect on alignment, it limits the precision of specifying the femoral or tibial length (ie. the desired intercept of the cutting plane with the mechanical axis). Conventional methods of setting the resection depth from the existing joint surfaces can be used instead at this stage.

6.6 Simulation
To find the range of cutting planes the system would propose in a simulation of 30 repeated TKRs, I applied the hip tracker results from specimen F1 to the knee and ankle results from specimen E2 (see Chapter 3), normalized to 375 mm hip-knee and knee-ankle distances, and calculated 30 sets of cutting planes for neutral alignment with the joint line normal to the mechanical axis and in the plane of the transepicondylar (TE) axis. All 30 sets of distal femoral, posterior femoral, and tibial plateau cuts are shown in Figures 6.2 and 6.3. Approximate implant dimensions (joint line to distal cut plane and the total implant buildup of thickness between the distal femoral and proximal tibial cuts) were assumed for the simulation. This simulation shows the system precision to which the cutting errors would add.
Figure 6.2: Simulation of 30 repeated procedures, cutting variance not included
Figure 6.3: Simulation of 30 repeated procedures, rotational alignment

6.7 Conclusion

The testing completed so far suggests that the proposed computer assisted TKR system has the potential to improve alignment precision by about 2 times over conventional techniques without using bone pins remote from the operating site, intramedullary rods, extra imaging such as CT scans, or unconventional cutting techniques such as robotic saw guidance. The current results suggest that initial bone cuts can each be made within standard deviation of 0.8° varus/valgus and 1.2° flexion/extension, and an overall varus/valgus alignment SD of 1.1°. Cutting errors (variance in angle between the guide setting and a dummy implant placed on the cut bone) account for 90 to 95% of this variance. Robustness of the new technique across different patients and operators has not yet been shown: For example results may be substantially worse with obese patients on where the hip tracker is not as effective. In all cases, substantial errors may still occur due to improper final implant installation and postoperative subsidence.

6.8 Future work

- Clearly, this is early work and more specimens are required to show robustness of the hip tracker across different individuals, particularly those with indistinct iliac crests.
- A kinematic centre of the weight bearing ankle should still be investigated, even if finding it during TKR turns out to be impractical. The relationship between the digitized ankle centre and the kinematic centre (or some other biomechanically relevant physical measure such as centre of joint area) should then be found by testing on different specimens.
- As large errors were experienced in hip centre location on one specimen, software checks of the femoral motion data must be added to allow repetition of the procedure if the data is inadequate.
- Development and testing of tools to locate the desired femoral component centre and tibial tray location given the bone stock available must be done to avoid making preliminary cuts, checking the location of a trial component, and then recutting to the precise alignment. I suggest adapting a conventional femoral sizing guide and trial tibial tibial tray by adding marker arrays and calibrating.
- To show whether the ankle probe really offers greater robustness, a series of tests similar to those in Chapter 4 could be done using a conventional point probe.
- Bone cutting tests should be continued with a variety of different surgeons and residents as additional specimens and tool sets become available.
- When tracked, adjustable guides are completed, the computer assisted TKR procedure can be tested on cadavers and compared to a conventional technique on the contralateral side.
Bibliography


Emrich RJ, & Inkpen K.B. Locating the Ankle Joint Centre: A Pilot Study of Motion Tracking Techniques. (un pub)


Appendix A:  
Joint centre location test procedure

Put all the .m files from the accompanying CD in your host computer MATLAB path and set the current directory set to where you want the files to be written (like named files will be overwritten without warning). Assuming you have set up the Flashpoint system and the TKR tools, follow these steps to do repeated measurements of the joint centres on a cadaver. Refer to the well documented .m files for more detail if required.

1. Install hip tracker with AUXDRF in Port B3 & MEDDRF on bone pin in ilium, Port A.
2. Install DRF1 in distal femur, Port B1 & DRF2 in proximal tibia, Port B2.
3. » runtest ... enter 'static', 'X', 1 at prompts. Runs 'statictest.m', recording the stance position and writing the variable 'static_data_p' to file 'staticdataX.mat'. Only one sample is required since this is an arbitrary reference position and repeated trials will just be overwritten.
4. » runtest ... enter 'hip', 'X', 30 at prompts. Runs 'hiptest.m', finding hip centre in MEDDRF and recording DRF1, AUXDRF. Saves the 30 hip centres and radii as trials x 4 matrix 'hipX' to 'hipX.mat' and data from each trial as 'hipdataXNN.mat' in current directory.
5. » save hipdata hipdataX** when finished all 30 trials to get all trials in one .mat file for this specimen.
6. » runtest ... enter 'knee', 'X', 30 at prompts. Runs 'kneetest.m', prompting you to digitize the transepicondylar axis in femoral coordinates (DRF1). Saves a trials x 6 matrix of axis endpoints 'kneedata_f' to file 'kneedataX.mat'.
7. If doing ankle motion, follow steps 8 - 16. If digitizing the ankle only, go to step 17.
8. Install DRF3 in calcaneus, to Port B, slot 1 = DRF3 (calcaneus).
10. Install DRF5 in foot tracker, to Port B, slot 3 = DRF5 (foot tracker).
11. Remove MEDDRF, plug A123 into breakout box.
13. Port A2 = DRF2 (tibia).
15. » runtest ... enter 'move_ankle', 'X', 30 at prompts. Runs 'move_ankletest.m', finding
centre in DRF2 (tibia) and recording DRF3 & DRF4, DRF5. Saves 30 ankle centres
'move_ankleX' and data from each trial as 'move_ankledataXNN.mat'.

16. » save ankledata ankledataX** when finished all trials to consolidate the raw data in one file.

17. » runtest ... enter 'digitize_ankle', 'X', 30 at prompts. Runs 'digitize_ankletest.m', finding
centre in DRF2 (tibia) and recording the ankle probe data. Saves 30 ankle centres
'digitize_ankleX' and all ankle probe data, including contact point and spherical
approximation results, to 'digitize_ankledataXNN.mat'.

18. Dissect out ankle without disturbing DRF2 in tibia.

19. » [tibial_plafond_t] = digitize_tibial_plafond('COM1',50,'tibial_plafondX') prompts you to
digitize the talocrural articular surface using the MED135 point probe in breakout box port C
with about 50 points in DRF2 (tibial) coords. If 'COM1' doesn't work, try 'COM2' or
whatever your host computer calls the serial port going to Flashpoint. Writes the resulting
~50 x 3 matrix 'tibial_plafond_t' to 'tibial_plafondX.mat'.

20. Dissect out femoral head without disturbing DRF1 in distal femur.

21. » [digitized_hip_f,probe_data_f,pts_digitized_hip_f,pts_f] =
digitize_femoral_head('COM1',50,'femheadX') stores results and data from digitizing the
exposed femoral head in femoral coordinates (DRF1) using both the ankle probe and the
MED135 point probe as a backup. The variable 'digitized_hip_f' from the ankle probe is the
one used in the post processing.

Coordinate system subscripts:

'o' body coordinates

The body coordinate frame is aligned for each specimen with the femoral mechanical axis found
from the mean of the digitized femoral head results and the mean of the transepicondylar axis
midpoints (digitized knee centres). The transepicondylar axis defines the frontal plane.

'p' Ilium bone pin

'h' Hip tracker

'f' Femoral bone pin

't' Tibial bone pin

For each local reference frame, the first three emitters define the frame as follows:
Emitter #1  Local origin
Emitter #2  Defines local x axis direction.
Emitter #3  Defines local xy plane.

Data files:

For registration precision testing, each specimen ‘X’ has the following raw data files:

**hipdataX.mat:**

Raw data from hip centre finding in ilium pin coordinates.
Contains variables ‘hipdataXNN’ where NN = 1 to N trials (usually N = 30)
Each variable is an array of emitter coordinates, with depth dimension of 1 to k sampling points:
Usually k ~ 50 samples positions during the sweep of the femur. Each row contains \([xp\ yp\ zp]\)
of an emitter as follows:

<table>
<thead>
<tr>
<th>Row #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Femur 1 (‘f’ origin)</td>
</tr>
<tr>
<td>2</td>
<td>Femur 2 (‘f’ x axis direction)</td>
</tr>
<tr>
<td>3</td>
<td>Femur 3 (lies in ‘f’ xy plane)</td>
</tr>
<tr>
<td>4</td>
<td>Tibia 1 (‘t’ origin)</td>
</tr>
<tr>
<td>5</td>
<td>Tibia 2</td>
</tr>
<tr>
<td>6</td>
<td>Tibia 3</td>
</tr>
<tr>
<td>7</td>
<td>Hip tracker 1 (‘h’ origin)</td>
</tr>
<tr>
<td>8</td>
<td>Hip tracker 2</td>
</tr>
<tr>
<td>9</td>
<td>Hip tracker 3</td>
</tr>
</tbody>
</table>

Note that the tibial markers are not really required in this test.

**kneedataX.mat**

Raw data from digitizing the transepicondylar (TE) axis in femoral coordinates.
Contains variable ‘kneedata_f’, a ‘trials’ x 6 matrix of transepicondylar axis endpoints arranged
as follows for each row:
Similarly to hipdataX.mat, this is the raw data from ankle centre finding in tibial pin coordinates. Contains variables ‘ankledataXNN’ where NN = 1 to N trials (usually N = 30) Each variable is an array of emitter coordinates, with depth dimension of 1 to k sampling points: Usually k ~ 50 samples positions during the sweep of the foot. Each row contains [xt yt zt] of an emitter as follows:

<table>
<thead>
<tr>
<th>Row #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Calcaneus pin 1</td>
</tr>
<tr>
<td>2</td>
<td>Calcaneus pin 2</td>
</tr>
<tr>
<td>3</td>
<td>Calcaneus pin 3</td>
</tr>
<tr>
<td>4</td>
<td>Talus pin 1</td>
</tr>
<tr>
<td>5</td>
<td>Talus pin 2</td>
</tr>
<tr>
<td>6</td>
<td>Talus pin 3</td>
</tr>
<tr>
<td>7</td>
<td>Foot tracker 1</td>
</tr>
<tr>
<td>8</td>
<td>Foot tracker 2</td>
</tr>
<tr>
<td>9</td>
<td>Foot tracker 3</td>
</tr>
</tbody>
</table>

Also contains the following variables from the ankle digitizing probe:

lateral_ankledata_t: 4 x 3 x trials raw data from the ankle probe on the lateral malleolus.
medial_ankledata_t: 4 x 3 x trials raw data from the ankle probe on the medial malleolus.

Where row numbers are the four emitters on the ankle probe. See files calibrate_ankle_probe.m and use_ankle_probe.m for details on how a sphere centre and radius as well as the plunger contact point are derived from this emitter data.

<table>
<thead>
<tr>
<th>Row #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ankle probe coordinate origin</td>
</tr>
<tr>
<td>2</td>
<td>Probe coordinate x axis direction</td>
</tr>
<tr>
<td>3</td>
<td>Probe coordinate xy plane definition</td>
</tr>
<tr>
<td>4</td>
<td>Probe plunger emitter</td>
</tr>
</tbody>
</table>
lateral_points_t: n rows [xt yt zt] of the probe contact point to the lateral malleolus.

medial_points_t: n rows [xt yt zt] of the probe contact point to the medial malleolus.

lateral_spheres_t: n rows [xt yt zt radius] of the lateral malleolus spherical approximation.

medial_spheres_t: n rows [xt yt zt radius] of the medial malleolus spherical approximation.

mid_sphere_centres_t: n rows [xt yt zt] of midpoint between the spherical approximations.

mid_points_t: n rows [xt yt zt] of midpoint between the contact points.

**femheadX.mat**

Results and raw data from digitizing the femoral head in femoral pin coordinates using the ankle probe (sphere approximating probe). Contains the variable ‘digitized_hip_f’, an n x 3 matrix where n = # of repetitions of the measure and ‘probe_data_f’ raw data from the 4 emitter probe. If the femoral head was also digitized with the point probe, contains the raw digitized data ‘pts_f’, a 50 x 3 x n array of points touched on the femoral head [x_f y_f z_f] and the centre ‘pts_digitized_hip_f’.

**tibial_plafond_X.mat**

Digitized points the distal tibia articular surface in tibial coordinates. Contains the variable ‘tibial_plafond_t’, an n x 3 matrix where n = # of points gathered, usually about 30.

**staticdataX.mat**

Data in ilium pin coordinates recorded at a static, extended position approximating normal stance with the hip tracker, femoral, and tibial pin marker arrays installed. Contains variable ‘static_data_p’, a 9 x 3 matrix of the static points. Each row contains [xp yp zp] of an emitter as follows:
After processing the results using 'process_TKR_registration.m', 'staticdataX' is rewritten with the all static position transforms between the reference frames, as calculated with 'calculate_static_transforms.m'.

**Data processing:**

With the data .mat files described above in the current MATLAB directory, calculation of joint centres, storage of the results and writing of .dat files for import into spreadsheets, and plotting of the joint centres can be done by running the following scripts.
Process_TKR_registration.m

- Loads the data
- Calculates the body coordinate system for this specimen, along with all the static position transforms between the various reference frames. Overwrites 'staticX.mat' with the calculated results as well as the original 'static_data.p'.
- Calculates two sets of hip centres, using the ilium pin as the local reference frame for the first set and the hip tracker for the second, allowing direct comparison of the pin to the tracker for each trial.
- Calculates four sets of ankle centres, using two different tracked marker sets and two different characterizations of the malleoli from the ankle digitizing probe:
  1. Calcaneus pin
  2. Foot tracker
  3. Ankle probe spherical approximations
  4. Ankle probe contact points.

Writes the file 'resultsX.mat' (see below) to the current directory.

resultsX.mat

Contains the processed variables all in the common body coordinate frame:
- side
- hipcentres_o = trials x [x y z] x 2 centres based on (1) ilium pin and (2) hip tracker.
- hip_tracked_pts_o = (trials * min. # of samples) x [x y z] of first tracked marker.
- hip_position = (trials * min. # of samples) x [adduction flexion] in degrees.
- hip_ROM = trials x [abduction adduction extension flexion] x 2 ROM limits.
- kneecentres_o = trials x [x y z] transepicondylar (TE) axis midpoints.
- kneedata_o = trials x [x_lat y_lat z_lat x_med y_med z_med] TE axis endpoints.
- tibial_plafond_o = perimeter of talocrural joint surface.
- ankle_centroid_o = centroid of transverse plane projection of 'tibial_plafond_o'
- anklecentres_o = trials x [x y z] x 4 centres.
- ankle_tracked_pts_o (if motion data was taken)
• ankle_position (if motion data was taken)
• ankle_ROM (if motion data was taken)

Note that by definition, digitized_hip_o = [0 0 0].

**plot_TKR_registration.m**

When ‘resultsX.m’ is in the path, run this script to plot all the views of the joint centres.

**plot_tracker_motion.m**

When ‘resultsX.m’ is in the path, run this script to see the range of motion and the tracker motion plots for either a hip or ankle.
Appendix B:

Probe Design to Robustly Locate Anatomical Features

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Abstract. Computer-assisted surgical techniques which seek to avoid relying on CT or MRI scans often require intraoperative location of anatomical features. The conventional optoelectronic probe measures a cloud of points on the feature surface, but the resulting location estimate is subject to bias and variation due both to local deformations in the surface and to measurement noise. We compare three probe designs – the conventional point probe, a flat probe and a V-probe – and show that all exhibit strong directional variability when estimating the centre of a quarter arc. We also show that the V-probe design is superior in tests on a 2D image, reducing the variability in localizing a femoral condyle by 50%.

1 Introduction

We are currently developing a technique for computer-assisted total knee replacement (TKR) surgery which does not require preoperative CT scans (similar to [1]). Certain variations of our approach require approximating centres of the posterior portions of the femoral condyles, which have been shown to closely fit spherical surfaces [2]. We propose to pass an optoelectronic digitizing probe over the condylar surfaces and fit a sphere to them, taking the centre of the fitted sphere as the condylar centre. This paper concentrates on the reliability of this latter process. In particular, we wish to characterize the repeatability with which we can define these centres.

Commercially available probes usually have a point or small (about 2 mm diameter) spherical end that touches the subject (see Figure 1). Such probes are versatile in that they can be used define points on surfaces with detailed concave and convex features. In our application, however, the subject surface is generally convex with local flaws that do not represent the ideal sliding surface that we are trying to locate. We suggest alternative probe designs that may be less sensitive to local deformations in the articular surface and may lead to more reliable estimates of the condylar centres. For general registration applications as discussed in [3], the effect of probe design should be considered when the goal is to quickly gather data that accurately constrain a convex feature.

In this paper we investigate using a probe with a flat contact surface to provide data as a series of tangent lines (rather than points) as the probe is swept along a surface. We also investigate the use of a V shaped probe that returns a series of local curvature bisector lines from a similar scan. A best fit 'centre' point of the contour can be found by minimizing an appropriate cost function. At this stage, we are interested in the repeatability of an estimated centre point location found from a single scan of a surface.
We simulate 1000 scans each over two different 2D test curves using each probe design and compare the standard deviations from the mean of the resulting estimated centres. We show that the V-probe exhibits significantly less standard deviation, thus better repeatability, than the other two designs.

2 Methodology

We simulated tests of a point probe, a flat probe, and V-probes with a variety of \( \beta \) angles (10° increments from 120° to 170°) on two reference curves:
(1) the circumference of a true quarter arc with a 13 mm radius.
(2) the posterior-distal quadrant of a 2D contour of the lateral condyle of a human femur (~13 mm radius) obtained from a sagittal MRI of a 31 year old female with no significant knee pathology.

For both curves, we simulated sweeping the probes across a 90° range, added measurement noise, and found the best-fit centre point by minimizing an appropriate cost function (see Sections 2.1 - 2.3) using MATLAB’s Nelder-Mead simplex method.

For each probe type and each reference curve, we ran 1000 simulated scans which resulted in 1000 estimated centres. We then computed the standard deviation of centre point location as a measure of the repeatability of the probe type.

We simulated the intraoperative process of acquiring points along the curve as a rotation of the probe about the origin (roughly the centre of the curve) with the radius being determined by the requirement that the probe maintain contact with the curve. In practice the surgeon would tend to start with the probe at one end of the curve with zero velocity, sweep through approximately 90°, and come to rest at the end of the curve. We therefore calculated the sampling position vector \( \theta \) as:

\[
\theta = \theta_s + (\theta_f - \theta_s)(1 + \sin(\pi ((t / t_s) - 0.5))) / 2
\]

where \( t \) is a vector of time steps from \( t = 0 \) to total scanning time (\( t_s \)) with a step size of (sampling frequency)\(^{-1}\). \( \theta_s \) and \( \theta_f \) are the start and finish angles of the scanned range. In this study \( t_s = 1 \) s, sampling freq. = 60 Hz, \( \theta_s = 90° \), and \( \theta_f = 180° \) for all simulations and all angles are measured positively CCW from the x axis. For the V-probes, the range of \( \theta \) was reduced to \([\theta_f - (\pi - \beta)/2]\) - \([\theta_s + (\pi - \beta)/2]\) to ensure that there was no contact outside of the sampled range used for the other probes.
During each simulation, we added white noise with $\sigma = 0.02$ radians to each sampling position $\theta$ to ensure that we were not always sampling at the same points. We also added white noise with $\sigma = 0.2$ mm to all $(x, y)$ coordinate data to simulate the measurement errors of a typical optoelectronic localizer. Assuming a distance of 120 mm from the probe surface to the probe markers, a corresponding white noise with $\sigma = 0.20/120 = 0.0017$ radians was added to all angular data.

### 2.1 Point Probe

To estimate the centre of the best-fit circle, we computed the contact point of the probe to the surface at each sampling position $\theta$ and added noise as described above, producing a set of noisy data points $(x_p, y_p)$. With candidate circles defined by their centre coordinates and radius $(x_c, y_c, r_c)$, the point probe cost function ‘PPCF’ is the sum of squared normal distances from the points to the candidate circle:

$$PPCF = \sum (r_c - ((x_p - x_c)^2 + (y_p - y_c)^2)^{1/2})^2$$  \hspace{1cm} (2)

### 2.2 Flat Probe

For the flat probe, we calculated the contact point between the probe and the surface contour, $(x_f, y_f)$, and the angle of the probe face, $\alpha$, at each sampling position $\theta$ and added noise. The flat probe cost function ‘FPCF’ is the sum of squared distances along the lines coperpendicular to both the candidate circle and the flat probe:

$$FPCF = \sum ((x_f - x_t) \sin \alpha + (y_f - y_t) \cos \alpha)^2$$  \hspace{1cm} (3)

where $(x_t, y_t)$ are the co-ordinates of the point on the candidate circle whose tangent is parallel to the probe face.

### 2.3 V-Probe

At each sampling position $\theta$, the V-shaped probe contacts the surface contour in two places and the centre of any ‘local’ best-fit circle at this sampling position must lie somewhere along the bisector of the V. As the probe is swept along the surface contour over the scanned range, these bisectors form a set of lines intersecting near the centre of an overall best-fit circle. The angle of each bisector, $\gamma$, and a point on the bisector at the apex of the V, $(x_v, y_v)$, form the data set and have noise applied. The cost function ‘VPCF’ expresses the sum of the squared normal distances between the candidate centre point, $(x_c, y_c)$, and the bisectors:

$$VPCF = \sum ((x_v - x_c) \sin \gamma - (y_v - y_c) \cos \gamma)^2$$  \hspace{1cm} (4)

Note that in this case, we cannot explicitly estimate the radius of the arc.
3 Results

3.1 True Arc

Figures 2 and 3 show the 1000 estimated arc centres for the point probe and 140° V-probes respectively. The results for the flat probe are comparable to the point probe and so are not shown here. Note the extended distribution of these estimates along the axis of symmetry of the arc.

To evaluate the repeatability of each probe design, standard deviations in centre point location were found for two different measures: ‘Sym. Axis’ is the standard deviation measured parallel to the bisector of the scanned range. ‘Perp. Axis’ is the standard deviation measured perpendicular to the bisector of the range.

Table 1. Standard deviations of centre point location from true arc

<table>
<thead>
<tr>
<th></th>
<th>Sym. Axis (mm)</th>
<th>Perp. Axis (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Point</td>
<td>0.134</td>
<td>0.043</td>
</tr>
<tr>
<td>Flat</td>
<td>0.116</td>
<td>0.041</td>
</tr>
<tr>
<td>V120</td>
<td>0.137</td>
<td>0.025</td>
</tr>
<tr>
<td>V130</td>
<td>0.112</td>
<td>0.027</td>
</tr>
<tr>
<td>V140</td>
<td>0.080</td>
<td>0.027</td>
</tr>
<tr>
<td>V150</td>
<td>0.070</td>
<td>0.028</td>
</tr>
<tr>
<td>V160</td>
<td>0.062</td>
<td>0.030</td>
</tr>
<tr>
<td>V170</td>
<td>0.056</td>
<td>0.028</td>
</tr>
</tbody>
</table>

3.2 Posterior-Distal Condyle Image

As in the first test, 1000 scans were simulated with each probe design on the same set of points representing the contour of a sagittal section through the distal femur. All three probe designs proposed a different mean centre point location (See Fig. 4).
Fig. 2. Point probe: Estimated centre point locations for true arc.

Fig. 3. V140 Probe (β = 140°): Estimated centre point locations for true arc.
Fig. 4. Average centre point estimation for each probe design on condyle image.

Fig. 5. Distribution of centre point estimates for point and V140 probes on condyle image.

Repeatability of each probe design was calculated again and is shown in Fig. 6.
Fig. 6. Standard deviation of centre point location on condyle image, all probe designs.

4.0 Discussion

The extent of the cloud of centre point estimates derived from the true arc indicates sensitivity to measurement noise. All three probes exhibited 2-5X more deviation along the arc’s axis of symmetry than perpendicular to it. This can be explained by looking at the cost functions: For the point and flat probes, the circle descriptors involve three parameters (x, y, and r), where negative displacements of (x,y) along the arc’s axis of symmetry coupled with increases in radius (r) will cause the least change in cost. For the V-probe, (x,y) are found to minimize the summed distances to the radial data lines (set of bisectors), so displacements in the direction ‘most parallel’ to the average data line (i.e. along the arc’s axis of symmetry) will cause the least change in cost. The SD of the flat probe’s centre estimate distribution is ~15% lower than that of the point probe, but the V-probe’s distributions showed further reductions of 35-50% in SD, showing that it is markedly less sensitive to measurement noise. Increased V-probe angles (β) produced significantly lower standard deviations of the point location along the axis of symmetry but had no significant effect perpendicular to the axis of symmetry.

On the condyle image, all three probes again showed maximum SD along the axis of symmetry of the best fit arc. There is a small difference in SD between the point and flat probes, although this time the point probe has the smallest value. As on the true arc, the V-probes with β in the range of 130° to 160° showed SD’s up to 50% lower than the point and flat probes along both axes and showed less pronounced variation along the axis of symmetry, creating a more circular cloud of points.
The mean centre point estimated by the point probe was located about 3 mm from those estimated by the flat and V-probes (Figs. 4 & 5). It appears that this difference is caused by the near flat region over the first half of the scanned range in this particular contour. The point probe will record many points on this flat region, forcing the best fit circle downwards and to a greater radius. In contrast, contact points for the flat and V-probes will move counterclockwise onto the downward slope of the contour earlier in the scanned range (assuming the probe surfaces are large enough), reducing the influence of the flat region.

5.0 Conclusions

The V-shaped probe design enables us to locate a characteristic feature of condylar geometry (i.e., the centre of a best fit arc) with up to half the variability of a flat probe or conventional point probe. The variability of this localization is greatest along the arc’s axis of symmetry. We are planning to extend this study to three dimensions, where the V-probe will be replaced by a three-faced pyramidal probe. Such a probe is also likely to have benefits in other registration applications.

Acknowledgements

We thank Dr. Boris Flak of the UBC Department of Radiology for help in obtaining the MRI scan of the knee, Roger Tam of the UBC MAGIC Lab for assistance in converting the image for use in this project, and Robert W. McGraw of the UBC Department of Orthopaedics for discussions on TKR procedure.

References

Appendix C: Drawings

Figure C.1: Hip tracker details

PLATE, HIP TRACKER
NOT TO SCALE
MATERIAL: CONV. ALUM. PLATE 0.25" THICK
ALL DIMS IN INCHES
TOLERANCE +/- 0.003 UNLESS NOTED
Figure C.1: Hip tracker details, continued

PUBIC TUBERCLE CONTACT, HIP TRACKER
NOT TO SCALE
MATL: ALUMINUM
ALL DIMS IN INCHES
TOLERANCE +/- 0.030 UNLESS NOTED

ILIAC CREST CONTACT
NOT TO SCALE
MATL: ALUMINUM
ALL DIMS IN INCHES
TOLERANCE +/- 0.030 UNLESS NOTED
Figure C.1: Hip tracker details, continued

ROD, PUBIS CONTACT
NOT TO SCALE
MAT'L: STAINLESS STEEL
ALL DIM'NS IN INCHES
TOLERANCE +/- 0.030 UNLESS NOTED

SECTION VIEW 'A--A'
Figure C.2: Foot tracker details, continued

1. ALL DIMENSIONS IN INCHES.
2. TOLERANCE ± 0.03 UNLESS OTHERWISE NOTED.
3. MATERIAL: COMMERCIAL ALUMINUM
FOREFOOT CONTACT, FOOT TRACKER

1. ALL DIMENSIONS IN INCHES.
2. TOLERANCE +/- 0.03 UNLESS OTHERWISE NOTED.
3. MATERIAL: COMMERCIAL ALUMINUM 0.50 THICK

5TH METATARSAL CONTACT, FOOT TRACKER

1. ALL DIMENSIONS IN INCHES.
2. TOLERANCE +/- 0.03 UNLESS OTHERWISE NOTED.
3. MATERIAL: COMMERCIAL ALUMINUM 0.50 THICK
Figure C.2: Foot tracker details, continued

FOREFOOT CONTACT CARRIER, FOOT TRACKER

1. All dimensions in inches.
2. Tolerance +/- 0.03 unless otherwise noted.
3. Material: Commercial aluminum 0.50 thick
Figure C.3: Foot tracker assembly
Figure C.4: Ankle probe details
Figure C.5: Ankle probe details, continued

END PLATE, ANKLE PROBE
NOT TO SCALE
MATL: STAINLESS STEEL
ALL DIMMS IN INCHES
3 DEC. PLACE TOLERANCE +/- 0.005
2 DEC. PLACE TOLERANCE +/- 0.030

CONTACT BALL ASSY., ANKLE PROBE
NOT TO SCALE
MATL: STAINLESS STEEL
ALL DIMMS IN INCHES
3 DEC. PLACE TOLERANCE +/- 0.005
2 DEC. PLACE TOLERANCE +/- 0.030

TAB, ANKLE PROBE
NOT TO SCALE
MATL: STAINLESS STEEL
ALL DIMMS IN INCHES
3 DEC. PLACE TOLERANCE +/- 0.005
2 DEC. PLACE TOLERANCE +/- 0.030
Figure C.5: Ankle probe assembly

ANKLE PROBE ASSY.
SHOWN FULL SCALE
Figure C.6: Plane probe details

PLANE PROBE END, 1 REQ'D
MATL: STAINLESS STEEL
ALTERNATE MATL: MILD STEEL (NICKEL PLATE REQ'D AFTER ASSY.)
ALL DIM'S IN INCHES, TOL. +/- 0.030 UNLESS OTHERWISE NOTED.

HANDLE, 1 REQ'D
MATL: STAINLESS STEEL
ALTERNATE MATL: MILD STEEL (NICKEL PLATE REQ'D AFTER ASSY.)
ALL DIM'S IN INCHES, TOL. +/- 0.030 UNLESS OTHERWISE NOTED.
Figure C.6: Plane probe details, continued

PROBE ADAPTER, 1 REQ'D
MATL: STAINLESS STEEL
ALTERNATE MATL: MILD STEEL (NICKEL PLATE REQ'D AFTER ASSEMBLY)
ALL DIM'NS IN INCHES, TOL. +/- 0.003 UNLESS OTHERWISE NOTED.
Figure C.7: Plane probe assembly

Emitter Array, 1 Req’d

Finish: if stainless steel, sandblast
If mild steel, nickel plate after assy.

Plane Probe Assembly, 1 Req’d

Material: stainless steel, 0.19 thick
Alternate material: mild steel (nickel plate before assy.)
All dimensions in inches. Tol. +/- 0.005 unless otherwise noted
Optional: anneal from one piece or fabricate.
Figure C.8: Quick release bone pin details

QUICK RELEASE PIN
NOT TO SCALE
MAT'L: STAINLESS STEEL
ALL DIM'NS IN INCHES
3 DEC. PLACE TOLERANCE +/- 0.005
2 DEC. PLACE TOLERANCE +/- 0.030
Figure C.8: Quick release bone pin details, continued

STUD, BONE PIN BASE
NOT TO SCALE
MAT'L: STAINLESS STEEL
ALL DIM'NS IN INCHES
3 DEC. PLACE TOLERANCE +/- 0.005
2 DEC. PLACE TOLERANCE +/- 0.030

BONE PIN BASE
NOT TO SCALE
MAT'L: STAINLESS STEEL
ALL DIM'NS IN INCHES
3 DEC. PLACE TOLERANCE +/- 0.005
2 DEC. PLACE TOLERANCE +/- 0.030
Figure C.8: Quick release bone pin details, continued

QUICK RELEASE COLLAR
NOT TO SCALE
MAT'L: STAINLESS STEEL
ALL DIM'NS IN INCHES
3 DEC. PLACE TOLERANCE +/- 0.006
2 DEC. PLACE TOLERANCE +/- 0.030

SLIDING FIT ON PIN (0.38 DIA. REF.)

SECTION VIEW C-C

KNURL

NOTE OPPOSITE CUTOUT DIRECTIONS

25'

'C'

'C'

10' CHAMFER

0.03 RAD.
2 PLC'S

0.063
0.030

0.75 DIA.

0.75

0.190

0.10

DRILL 0.125
DIA. 3 PLC'S

0.063

0.125 TRUE

0.047
Figure C.9: Quick release bone pin assembly

0.18 nominal: set distance to clear spring pin 0.010 with spring bottomed.

CIRCLIP, 1 REQ'D
PIN, 1 REQ'D
SPRING, 1 REQ'D (ADD SPACERS AS REQ'D)
COLLAR, 1 REQ'D

STUD, SPHERICAL END NEAR SIDE
3 REQ'D
0.094 dia. x 0.38 spring pin
or solid pin soldered
in place, 2 REQ'D

QUICK RELEASE PIN ASSY.
USED TO SET STUD HEIGHTS
0.030 GAP
BASE DETAIL
1 REQ'D

PUSH EACH STUD UP TO CONTACT BOTH FACES
OF GROOVE IN PIN WHILE MAINTAINING GAP
AND BRAZE OR SOLDER AS REQUIRED.

QUICK RELEASE PIN ASSY.
SHOWN FULL SCALE
PIN, COLLAR, SPRING, CIRCLIP: 1 EACH REQ'D
MATCH TO ONE BASE ASSY.
ALL DIM'NS IN INCHES

BONE PIN BASE ASSY.
SHOWN FULL SCALE
3 STUDS, 2 SPRING PINS, AND ONE BASE REQUIRED
BASE ASSY. MATCHED TO PIN USED TO SET STUD HEIGHTS
ALL DIM'NS IN INCHES
Appendix D:

Provisional Patent Application for a Device Constrained Against an Apposed Body Through Normal Forces

Antony J. Hodgson and Kevin B. Inkpen  
September 15, 1999

Motivation:

There are a variety of situations in surgery, biomechanical research, gait analysis and ergonomic analysis in which one would like to know the position of a bony structure during motion or manipulation. Approaches to measuring body motion can be classified are either invasive (typically using bone pins or screws placed through a skin incision) or non-invasive (attaching external markers to the skin or simply making a video record of the motion).

Non-invasive markers are clearly attractive from the patient’s or subject’s perspective, but they suffer from comparatively low accuracy since they are not mounted directly to the bony structure of interest. In particular, skin typically moves easily over bone during motion, which results in discrepancies between the marker position and the position of the bony structure which is presumed to be moving together with the marker. In some cases, these discrepancies can be on the order of centimetres.

Invasive markers are rigidly attached to the underlying bone and so can yield more accurate measurements at the cost of increased pain to the subject and the need for wound care.

There is, therefore, clearly a need for a non-invasive marker that can sustain a fixed relation to the underlying bone while being insensitive to skin motion artifacts. We have developed such markers for the pelvis and ankle, but the underlying principles could be used to design markers for scapular tracking, mounting stereotactic frames to the skull, designing remountable clamps for the distal femur, and a variety of other applications.

Design Concept

Our approach relies on the recognition that one object has six degrees of freedom relative to another when free to move, and zero degrees of freedom when locked together. The difficulties with conventional non-invasive markers arise because they are comparatively free to move in the plane tangent to the skin surface. In contrast, skin which overlies bone is relatively incompressible in the direction normal to the bone, so motion in this normal direction is essentially zero. By creating a larger structure (the “tracker”) which contacts the skin overlying a rigid bony object in six locations across interfaces which consist of substantially point contacts (by substantially point contacts, we mean that any individual contact patch is insufficiently large...
to resist moments which might reasonably be applied to the two bodies in contact and must therefore be paired with another contact patch at some distance from the first), and by applying one or more seating forces (forces which are comparatively insensitive to small motions of the body upon which they act; e.g., gravity, electromagnetic or spring forces) oriented to ensure compressive forces at each contact point, we can constrain the tracker to follow the underlying bony structure. Furthermore, if we do not adjust the relative positions of the tracker's contact surfaces, we should be able to release the seating forces, remove the tracker, and replace it again with high repeatability. This capability would be particularly useful when the tracker is required on two different occasions, as is often the case in stereotactic procedures where the halo is mounted for a computed tomographic scan and left in place until the surgery for fear of replacing it in a different orientation.

Typical means of achieving point contact depend on the local radius of curvature and orientation of surface features of the object to which the tracker is to be mounted. If the object has low curvature radii, it is often beneficial to design the tracker interfaces with planar or high curvature radius surfaces (see example below). Conversely, if the object is substantially flat in the region of a desired contact point, the tracker should be designed with a small radius of curvature. Finally, if the object has different radii of curvature in different directions (e.g., a cylinder has a small radius perpendicular to its axis and an infinite radius along its axis), we can achieve a substantially point contact by creating a cylinder-like feature on the tracker and orienting its axis so that it is substantially perpendicular to that of the object (again, see hip tracker example below).

**Hip and Foot Tracker Design**

The following section is an extract from a paper we have recently written describing the implementation of this design concept in the form of trackers for the pelvis and foot for use in computer-assisted knee surgery:

In order to minimize artifacts due to relative motion caused by skin sliding over bone, we designed our hip and foot trackers to constrain all six degrees of freedom by applying six reaction forces only normal to the bone (see Figure 1; note that proximal-distal components of forces are not shown). The trackers are fully adjustable to accommodate different patients and seating forces are applied by straps. Each tracker has an optical marker array rigidly attached.

![Fig. 1. (a) Hip tracker and (b) foot tracker devices](image-url)
Photographs of Hip Tracker Design

Figure 1. Detail of hip tracker. The central blue block is a planar surface which rests on the pubic tubercle at a single contact patch. The extension rod crosses the pubic ramus at an angle and so also creates a single contact patch. Each of the remaining two blue blocks have two planar surfaces which rest on the pelvic iliac spines and so create two contact patches each.
Figure 2. A photograph of the device in use on a skeletal model. Note that the distribution of normal forces is designed to resist any force or torque applied to the tracker up to a finite limit determined by the preload on the straps.
Claims:

1. A device which consists of six rounded or planar surfaces (“interface elements”) which can be placed tangent to six corresponding surfaces on a second body, and one or more force-generating means (such as springs, weights or electromagnetic fields) aligned so as to ensure positive contact at all six interface elements. The interface elements should be oriented such that the resulting normal forces substantially constrain the device relative to the second body (by having, for example, sufficient relative moment arms to resist applied torques about arbitrary axes). Each interface element should generate a contact patch that is essentially point-like in nature; by point-like, we mean that the contact patch alone is insufficiently large to prevent relative movement when typical moments are applied to the two bodies in contact.

2. A device as described in (1) which allows for adjustability in the position and orientation of one or more of the interface elements, so as to allow for optimal fitting to different second bodies.

3. A device as described in (1) or (2) to which is mounted some means for detecting its position in space (e.g., an optoelectronic or magnetic tracker) for the purpose of inferring the position of the apposed second body.

4. A device as described in (1), (2) or (3) in which the second body consists of a rigid structure overlaid with a comparatively thin layer of a deformable substance which is comparatively free to move in directions tangent to the rigid structure (e.g., a bony structure overlaid with a comparatively thin layer of soft tissue and skin).

5. A device as described in (4), customized for the pelvis (as outlined in our paper).

6. A device as described in (4), customized for the foot (as outlined in our paper).

7. A device as described in (1), (2), (3) or (4) with fewer than six interface elements so as to constrain selected degrees of freedom between the device and the second body.