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14. ABSTRACT

The major reportable outcome of this study is the development of an operational Bioskills Training facility at The Methodist hospital in Houston for the development of surgical skills in trainees within the medical school and residency training programs, and in practicing surgeons within the community who may wish to further refine their technical skills or learn new procedures. Discussions are underway with the administration of Methodist- Cornell Medical School, Baylor College of medicine, and The University of Texas to incorporate this facility into the training of Residents and fellows in orthopedic Surgery and other specialties.

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FINAL REPORT

Computer-Based Training Methods for Surgical Training

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The Methodist Hospital Research Institute

Houston, Texas, USA

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RESEARCH ACTIVITY REPORT

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Introduction

It is generally accepted that successful joint arthroplasty surgical operations require skill in terms of both technique and judgment. While the traditional apprenticeship model of surgical training adequately addresses the judgment aspect, it puts patients at unnecessary risk as the learning curve is arduous to hone technical skills. Even so, few satisfactory alternatives exist to the apprenticeship model of surgical training. Additionally, it is well established that the outcome of an arthroplasty procedure such as total knee replacement is critically determined by technical factors, such as the positioning of the prosthetic components with respect to the skeleton, and the recreation of the natural ligamentous restraints of the joint that accompany joint motion (Coventry 1979, Stulberg 2002, Berend 2004, Stulberg 2006). However, there is no validated, objective method for quantifying technical skill. Consequently, there is limited information available in terms of precise, quantitative measures about the extent to which technical goals are achieved. Previously, we developed and validated a computer-based prototype system for evaluating errors in instrument alignment for total knee arthroplasty (TKA) (Conditt 2007). This system is designed to measure the technical success of a surgical procedure in terms of quantifiable geometric, spatial, kinematic or kinetic parameters. This allows for surgeons to train outside the operating room to develop and refine skills specific to a particular surgical procedure while objectively quantifying their technical skill. Another goal of this project was to test the hypothesis that the use of computerized training significantly enhances the speed and efficiency of acquisition of surgical skills within the context of orthopedic procedures.

The purpose of the current project was to implement this previously validated methodology into a turn-key, computerized Bioskills training facility based on commercial motion analysis hardware and customized software.

The technical specific objectives of this project entailed:

1.0 To develop an operational computer-based Bioskills System to quantify the extent to which surgeons achieve technical goals defining the outcome of each step of a surgical procedure.

2.0 To incorporate the Bioskills System into a surgical training facility which allows for simultaneous training of four surgeons using cadavers or surrogate anatomic models.

3.0 Assess the effectiveness and efficiency of the computer-based facility in training surgeons to perform at least one operative procedure.

Technical Objective 1.0. Development of Computerized Bioskills System

OVERVIEW

The goal of Technical Objective 1.0 was to deliver an integrated, turn-key, computerized bioskills system based on commercial motion analysis hardware and software developed for installation into a surgical training facility. All tasks were successfully completed and implemented for Technical Objective 1.0.

METHODS AND RESULTS

Software

A software development contract was awarded by Motion Analysis Corporation (MAC) to Innovative Sports Training (IST) to fulfill the requisite subtasks outlined by Technical Objective 1.0. This partnership was necessary to interface software that generated coordinate data acquired from motion analysis cameras ("Cortex" distributed by MAC) with software developed to describe the kinematics of bodies ("The Motion Monitor" (TMM) distributed by IST). The TMM platform was utilized for all data collection, specimen specific coordinate system extraction algorithms, measurement processing, and error computations. The software was developed and validated as a joint effort with Innovative Sports Training and Motion Analysis Corporation. Individual templates were created in Cortex to automatically identify each tool and bone based on its unique marker configuration. All identified marker data was collected real-time in Cortex and streamed to TMM software for data capture, computations, and data export.

Specimen specific models were generated from computer tomography (CT) scans after attachment of arrays to each of the bones being tracked. Details of model preparation are discussed in a previous publication (Conditt et al., 2007) (Appendix A). CT scans were then obtained of each specimen using a helical scanner. Contiguous CT slices of .8 mm in thickness were taken through the knee. Three-dimensional reconstructions of the tibia and femur were prepared using specialized image processing software (Materialise, Belgium) resulting in solid models of each bone with a dimensional accuracy of approximately 0.2mm (Figure 1.1).

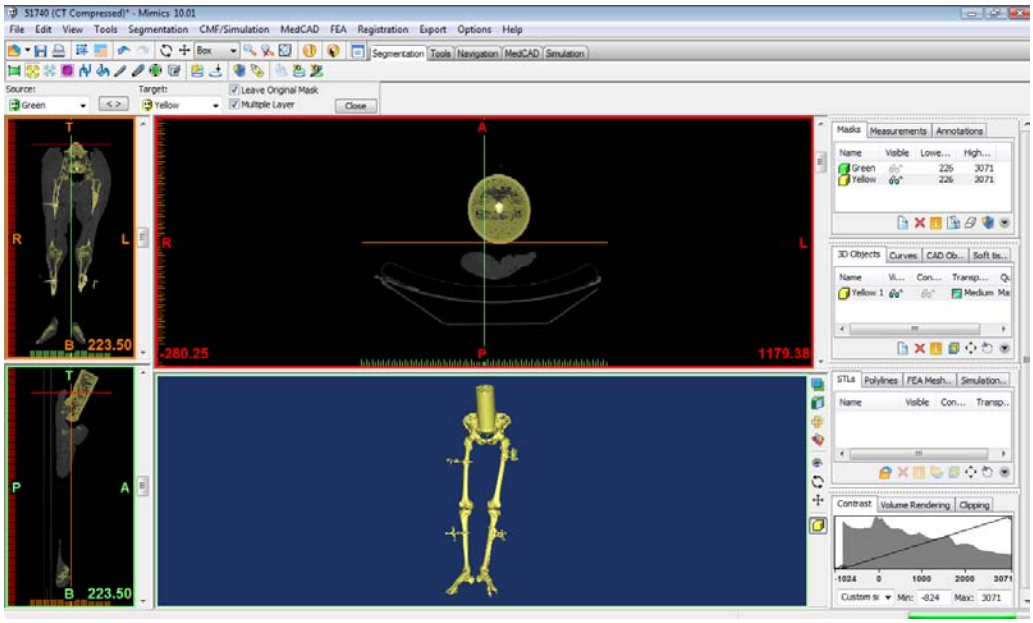


Figure 1.1. Reconstructed CT image and corresponding solid model

The TMM software was developed to automatically extract assign coordinate systems to the femur and tibia within each specimen-specific model, based on the recommended conventions of the ISB (Wu et al., 2002) (Figure 1.2). Additionally, other specimen-specific geometries used for calculating deviations from the target values of each computed parameter were generated by TMM software algorithms.

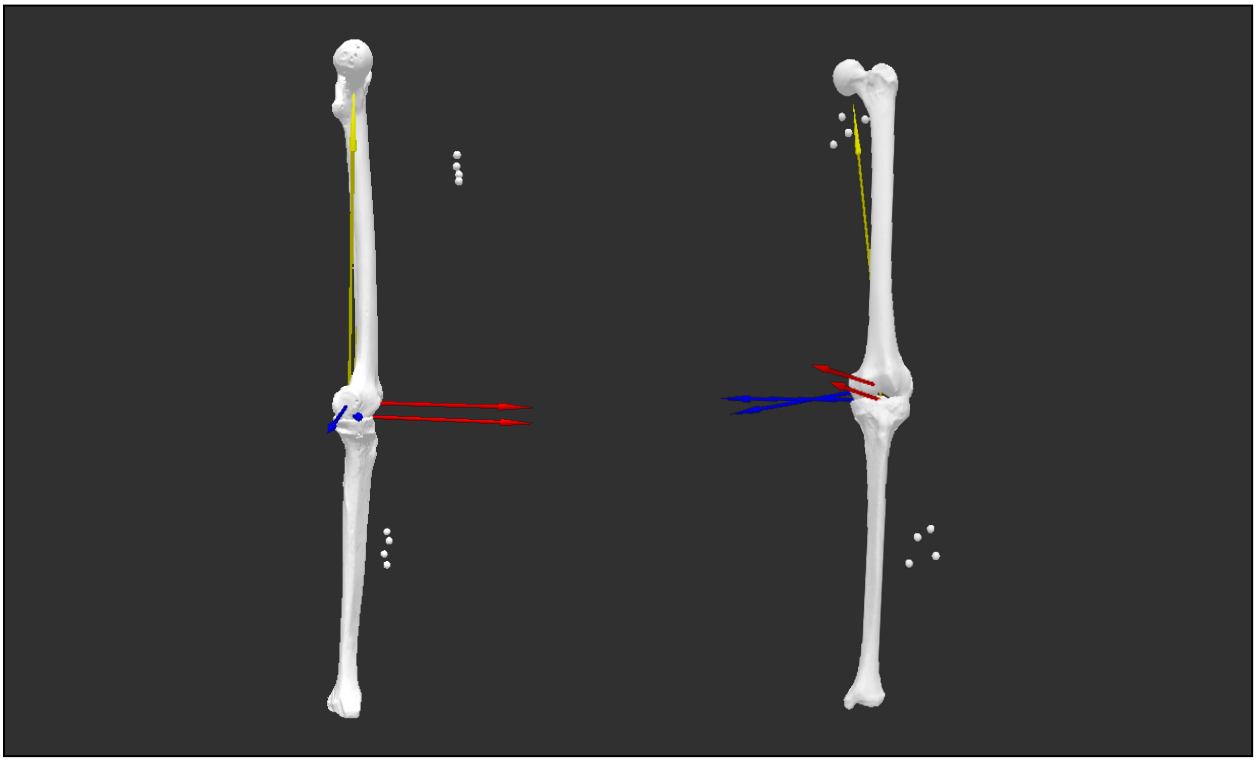


Figure 1.2. Example of a specimen-specific coordinate system automatically generated by the software

The Bioskills analysis software developed for this project is comprised of a series of files that collect and export the appropriate data for each step of the surgery. A script automates the process and can be controlled by the command center operator or a surgical assistant via an analog hand held event trigger. Appendix B lists the individual files with a description of the functional purpose of each.

Measurement data, error data and figures from the preference files are imported into Microsoft Excel via macros. IST created a 'report generator' in MS Excel which incorporates all of the data for a specific user into a report format. The requirement for report generation is a full set of appropriate files exported from the individual preference files. Report generation takes less than one minute; therefore the final report is immediately available at the conclusion of the session or may be generated at another time in the future. See Appendix C for an example of the report.

The trainee communicates the target orientations and alignments of the components, which are recorded in the report for comparison to actual component placement. Targets include femoral component flexion/extension (Figure 1.3 (a)), varus/valgus (Figure 1.3 (b)), internal/external rotation (Figure 1.3 (c)), medial/lateral placement (Figure 1.3 (d)), tibial component varus/valgus (Figure 1.4 (a)), internal/external rotation (Figure 1.4 (b), and tibial slope (Figure 1.4 (c)).

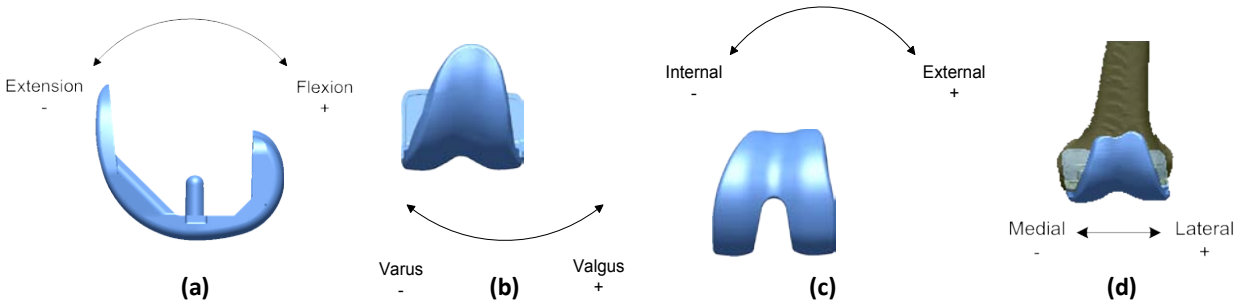


Figure 1.3. Trainee specified femoral component targets: (a) flexion/extension, (b) varus/valgus, (c) internal/external rotation and (d) medial/lateral alignment.

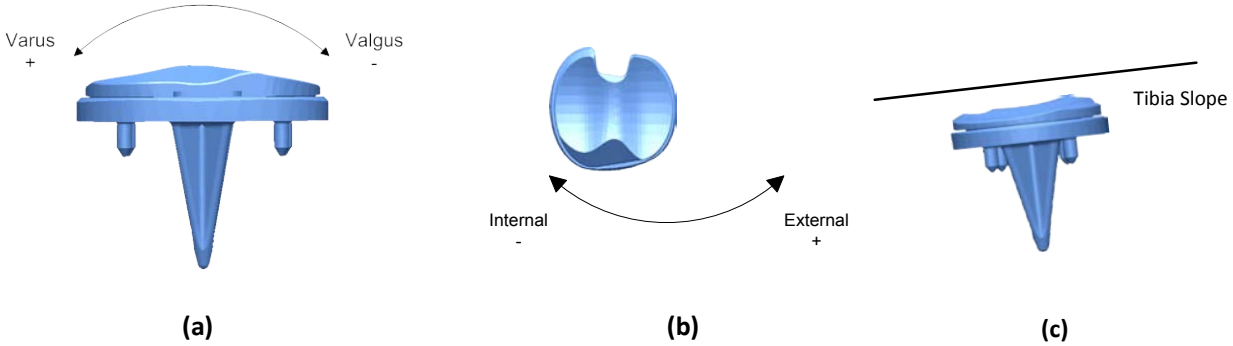


Figure 1.4. Trainee specified tibial component targets: (a) varus/valgus, (b) internal/external rotation and (c) tibial slope

Parameter	Target Value
Femoral component position/alignment	
(+)medial/(-)lateral (mm)	0
(+) varus/(-)valgus (deg)	-5
(+)flexion/(-)extension (deg)	0
Tibial component alignment	
(+) varus/(-)valgus (deg)	0
(+)anterior/(-)posterior slope (deg)	-7
(+)internal/(-)external rotation (deg)	6

Table 1. Typical target values for parameters defining the position and alignment of the femoral and tibial components

Hardware

The motion capture system operates on the principle that the spatial location of all tools and bones within the bioskills laboratory can be tracked by measuring the position , in space, of arrays of 3-4 spherical retro-reflective markers attached to each tool , bone, or implant. In practice, this necessitates that the geometric relationship between the markers within each array is precisely known throughout the preparation and eventual tracking of each specimen in surgery. This is realized by attaching each marker to a metal post which is inserted into a threaded hole in the base of an aluminum mounting plate (Figure 1.5). By varying the spacing of the hoes utilized for marker attachment, unique geometric configurations of markers are created, enabling each array to be identified from a set of spatial coordinates of all bones, instruments and implants in use at any one instant. The array of holes for attachment of markers to each plate was designed to provide at least 19 unique combinations of marker positions with sufficient variation in marker separation to be recognized as unique by the camera system. Further information relating to the design of the mounting plates is presented in Appendix D. Figure 1.6 illustrates the original CAD model of the mounting plate, and a photo image of one such late after fabrication in a CNC milling machine.

Previous experience has shown us that preparation of cadaveric specimens for use in bioskills experiments is time-consuming and often necessitates freezing and storage of each specimen after CT scanning, prior to its use in a training session. This creates a potential problem because the performance of reflective markers deteriorates dramatically with exposure to sub-zero conditions. However, removal and reattachment of markers from bones or mounting plates results in errors in tracking of each specimen and any instrumentation. To overcome these challenges, we devised a novel design of modular bone plate and mounting plate assembly to allow the mounting plate to be detached from the bone after imaging and then reattached prior to a training session without loss of accuracy in tracking.

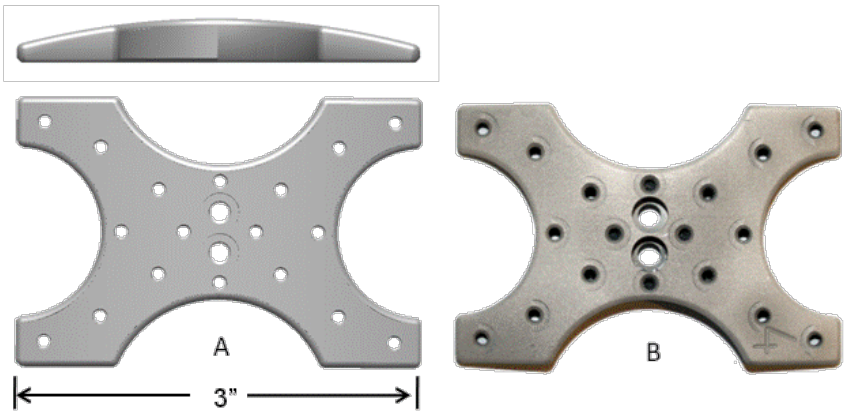


Figure 1.5. Interchangeable flag system (A) CAD model (B) physical model

The assembly consists of a bone plate rigidly attached to the bone or surrogate anatomic model with screws (Figure 1.6 (A)). The universal flag mates to a post that mates to the bone plate (Figure 1.6 (B) and (C)). The bone plates were fabricated with a CNC milling machine.

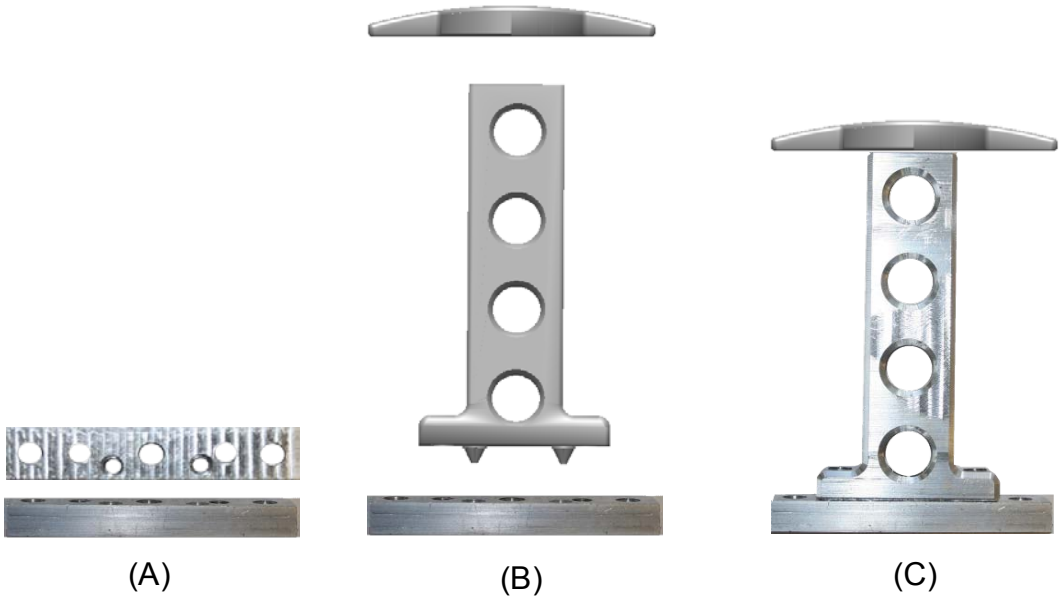


Figure 1.6. Detachable mounting system: (A) bone plate with holes to allow attachment to the femur of tibia using bone screws, (B) Assembly (bone plate, post and universal flag) shown in exploded view, and (C) Assembly in final orientation used for attachment to the bone via a skin incision.

The position and/or orientation of the surgical cuts, the surgical instruments, and the prosthetic components were all measured with an instrumented plane jig and an intramedullary (IM) rod which we designed in-house and fabricated on the CNC milling machine.

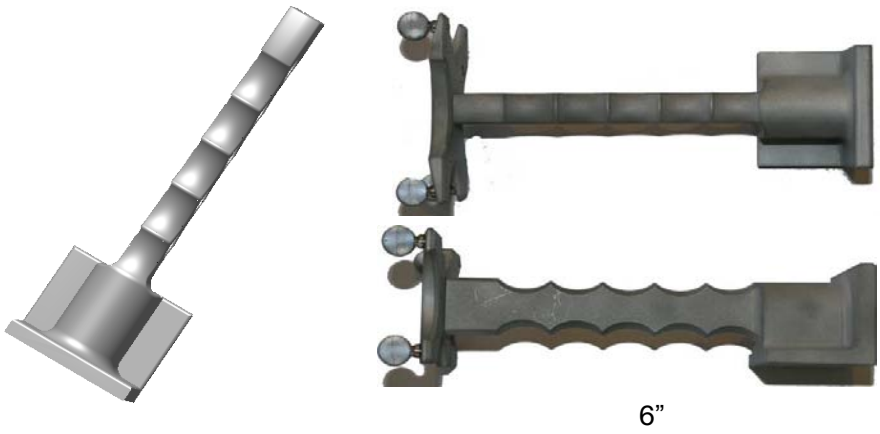


Figure 1.7. Plane jig positional measurement tool: (A) CAD model and (B) physical model.

The plane jig (Figure 1.7) was designed with two faces (planes) for measuring the orientation of cut bony surfaces with respect to the anatomical axes defined by the software. The IM rod (Figure 1.8) was developed to enable measurement of the location and alignment of the femoral distal cutting guide with respect to the femoral origin and axis system.

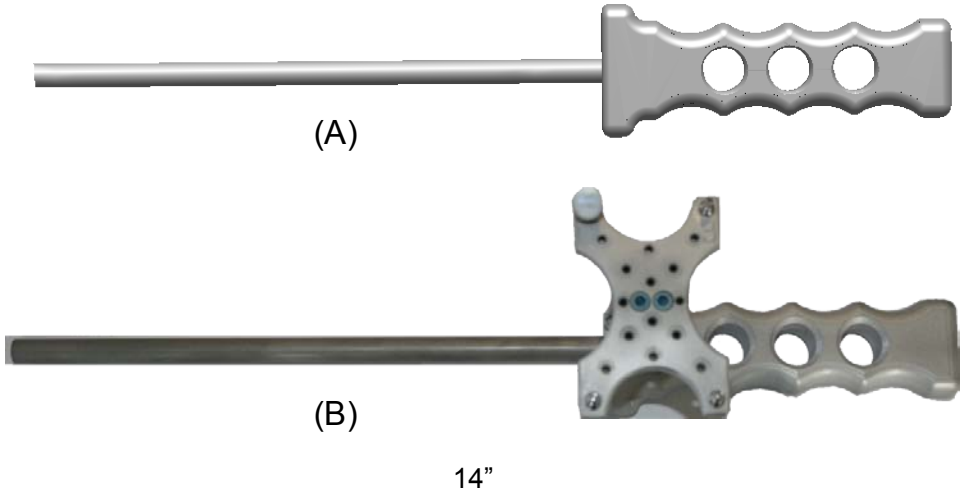


Figure 1.8. IM rod positional measurement tool: (A) CAD model and (B) physical model.

Data Collection Sequence and Report Generation

At the commencement of each surgical training session, pre-operative values of a number of parameters are measured to define the native alignment, range of motion and inherent laxity of the knee joint. These data include:

1. Pre-operative alignment
2. Pre-operative laxity in the frontal (varus/valgus) and transverse (internal/external rotation) planes at full extension, 30°, 60° and 90° (Shultz et al., 2007).

3. Passive pre-operative range of motion (ROM) in the sagittal (flexion/extension) plane was measured by moving the knee through its extension to flexion arc.
   (c) tibial slope.

At the conclusion of each surgical step the position and orientation of the appropriate bones and tools were measured with the motion analysis system. TMM software computed the following geometric parameters:

1. The medial/lateral and anterior/posterior entry point of the femoral intramedullary (IM) rod (Figure 1.8) and its inclination with respect to the anatomic axis of the femur in the sagittal (flexion/extension) and frontal (varus/valgus) planes (Figure 1.9).

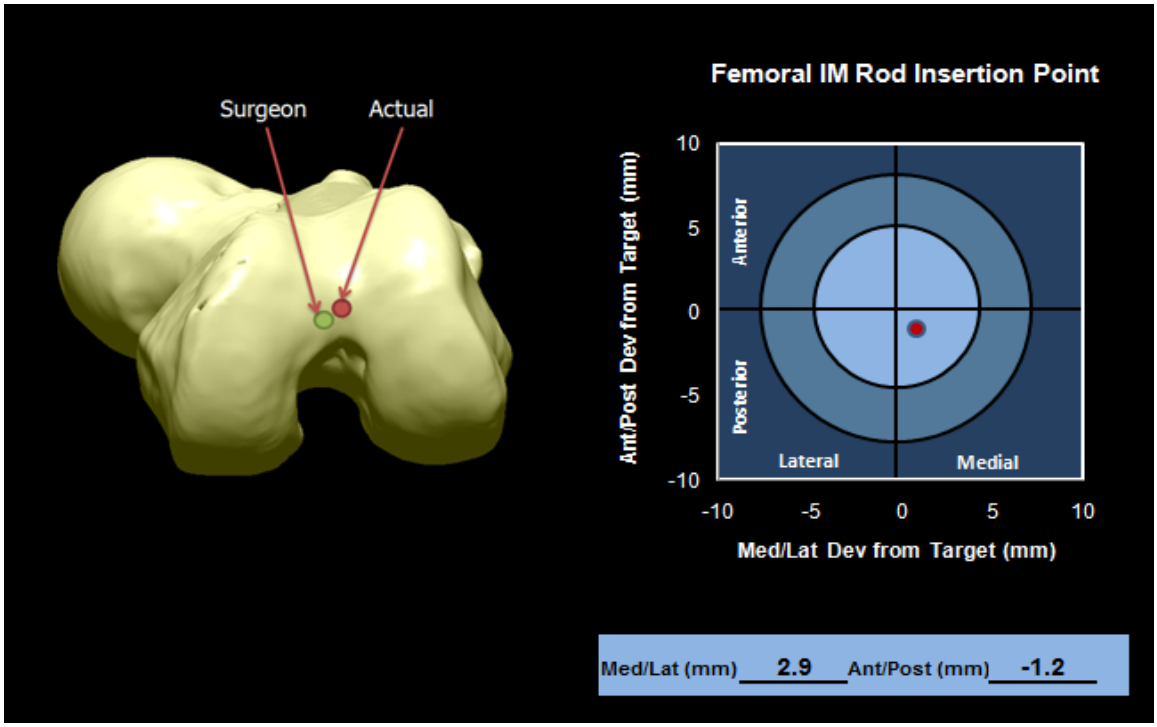


Figure 1.8. Example of reported medial/lateral and anterior/posterior insertion point error (mm) of intramedullary rod.

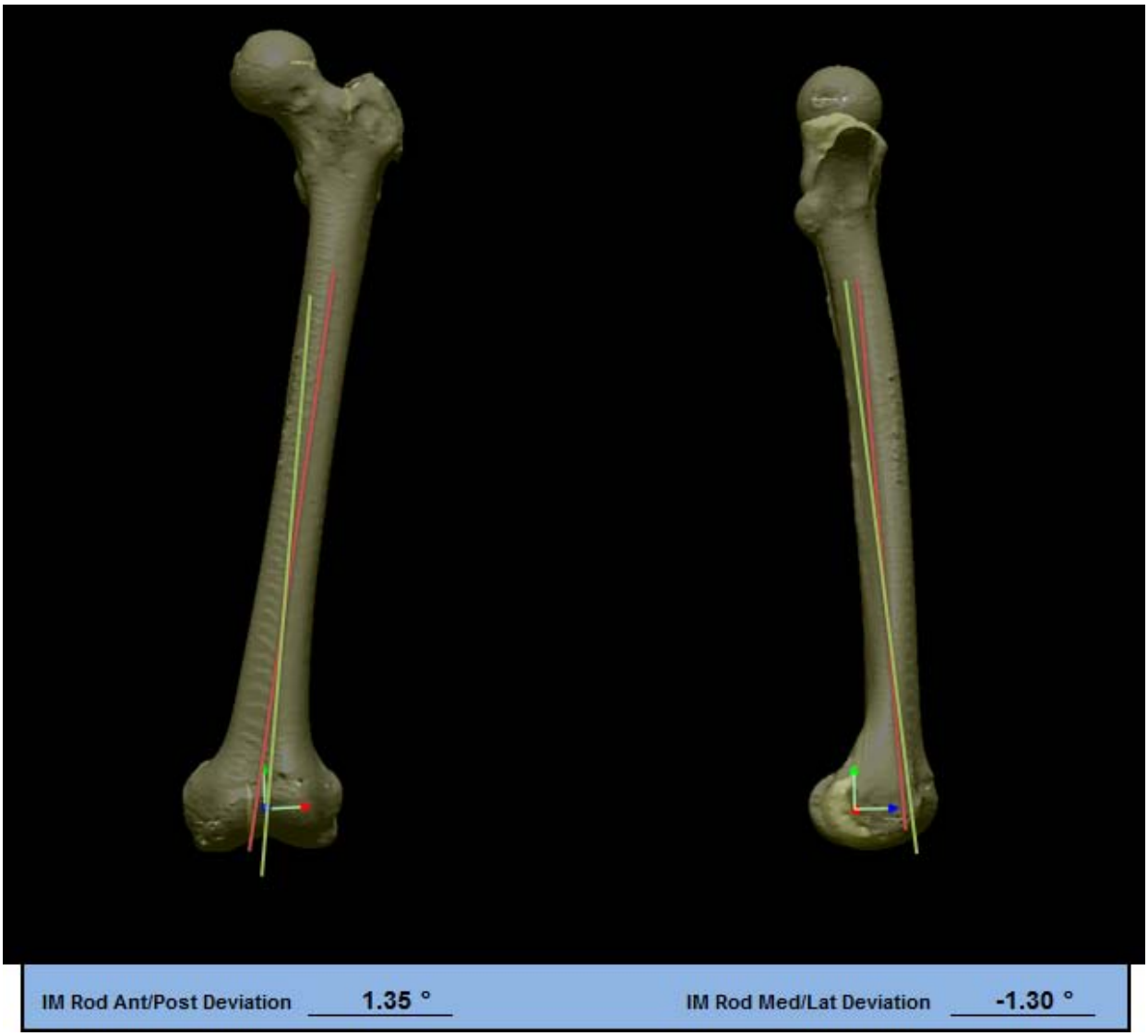


Figure 1.9. Example of reported medial/lateral and anterior/posterior insertion angle error (degrees) of intramedullary rod.

2. The alignment of the distal femoral cutting guide and cut with respect to the anatomical axis of the femur in the sagittal (flexion/extension) and frontal (varus/valgus) planes (Figure 1.10).

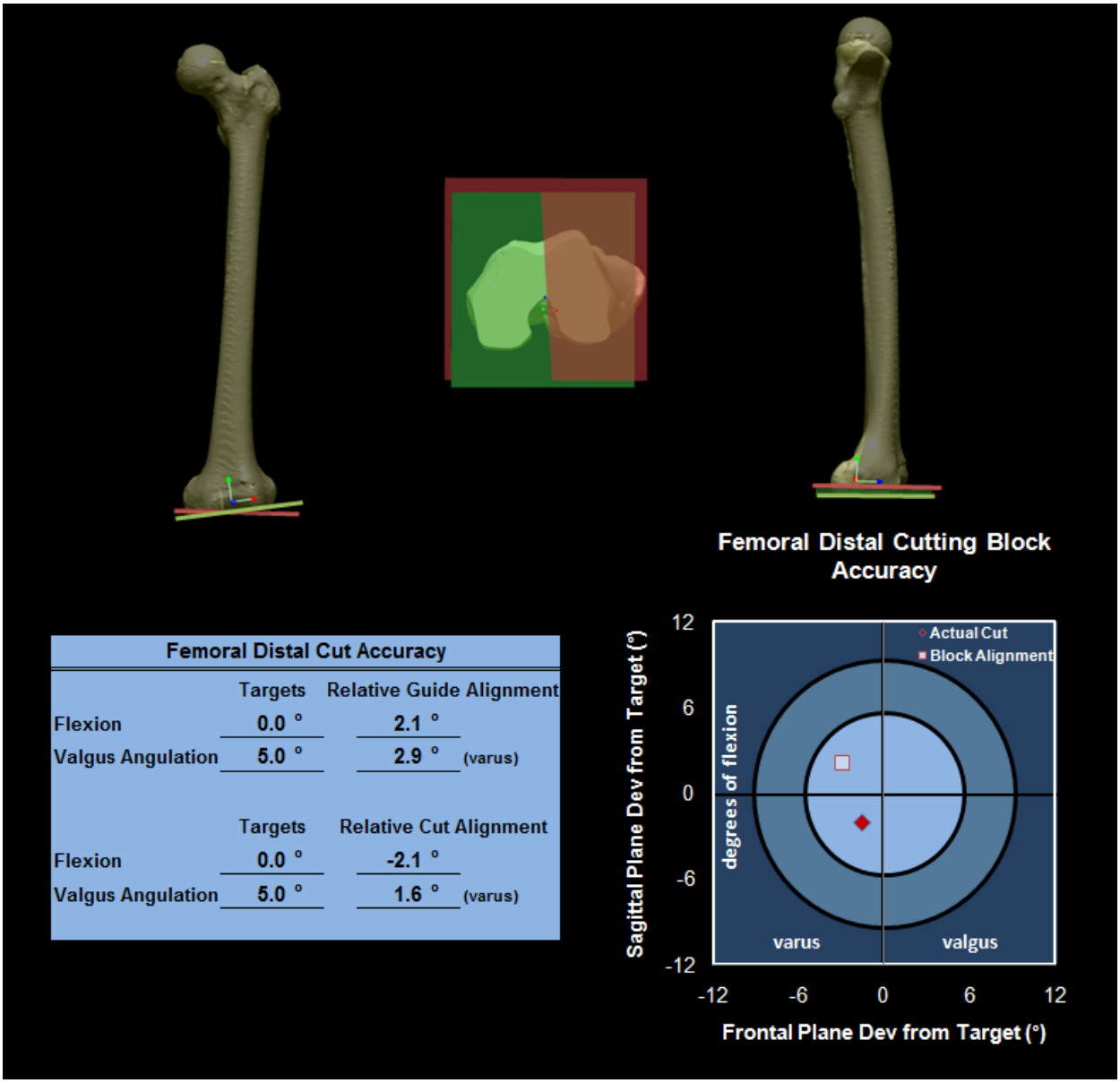


Figure 1.10. Example of plane jig orientation on cut surface (left) and reported deviations for femoral distal cutting guide alignment and femoral distal cut alignment (right).

3. The alignment of the posterior (4-in-1) femoral cutting guide and cut with respect to the anatomical axis of the femur in the sagittal (flexion/extension) and transverse (internal/external rotation) planes (Figure 1.11).

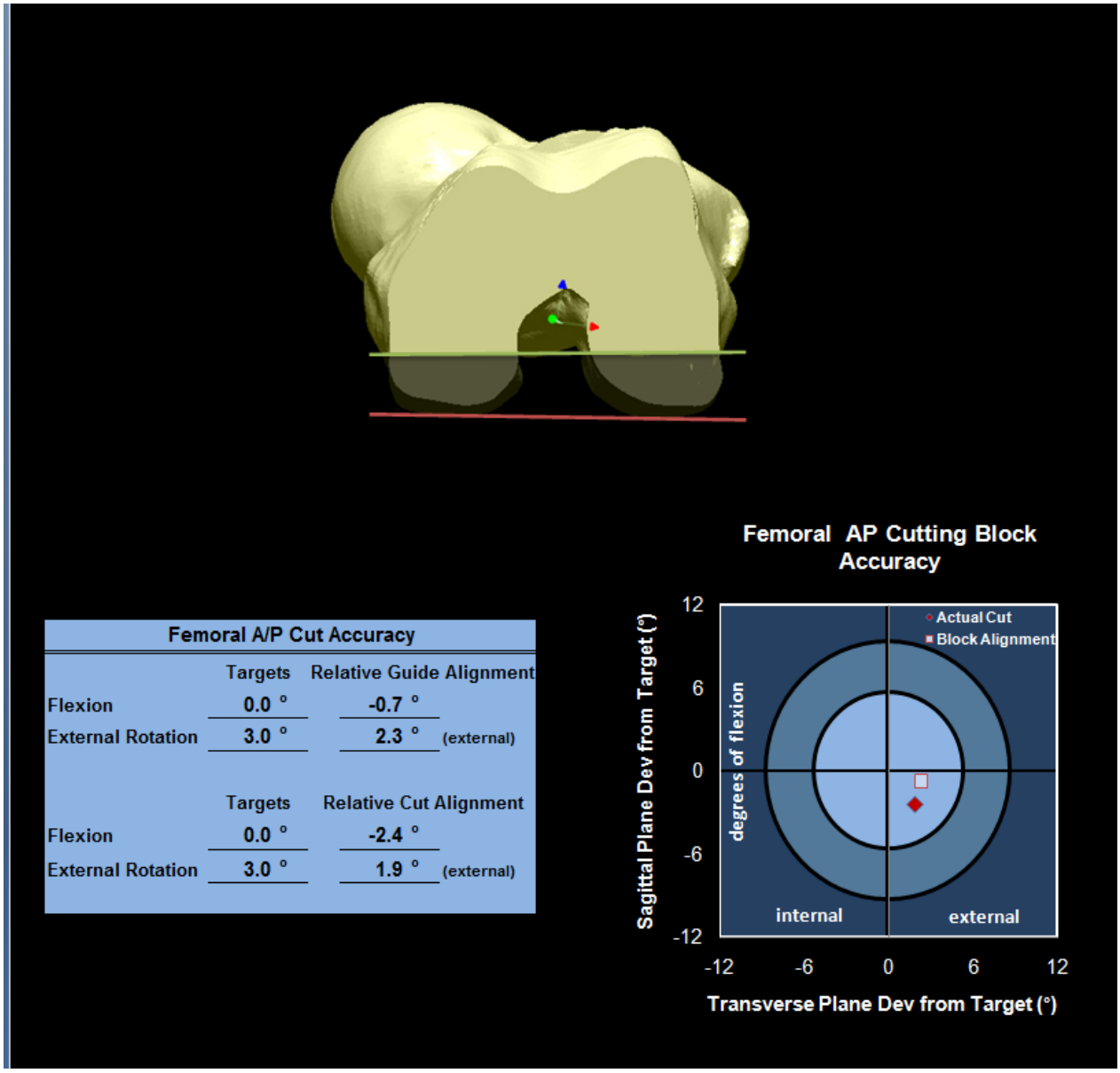


Figure 1.11. Example of plane jig orientation on cut surface (left) and reported deviations for femoral posterior cutting guide alignment and femoral posterior cut alignment (right).

4. The resection depth of both the posterior and distal cuts. (Figure 1.12).

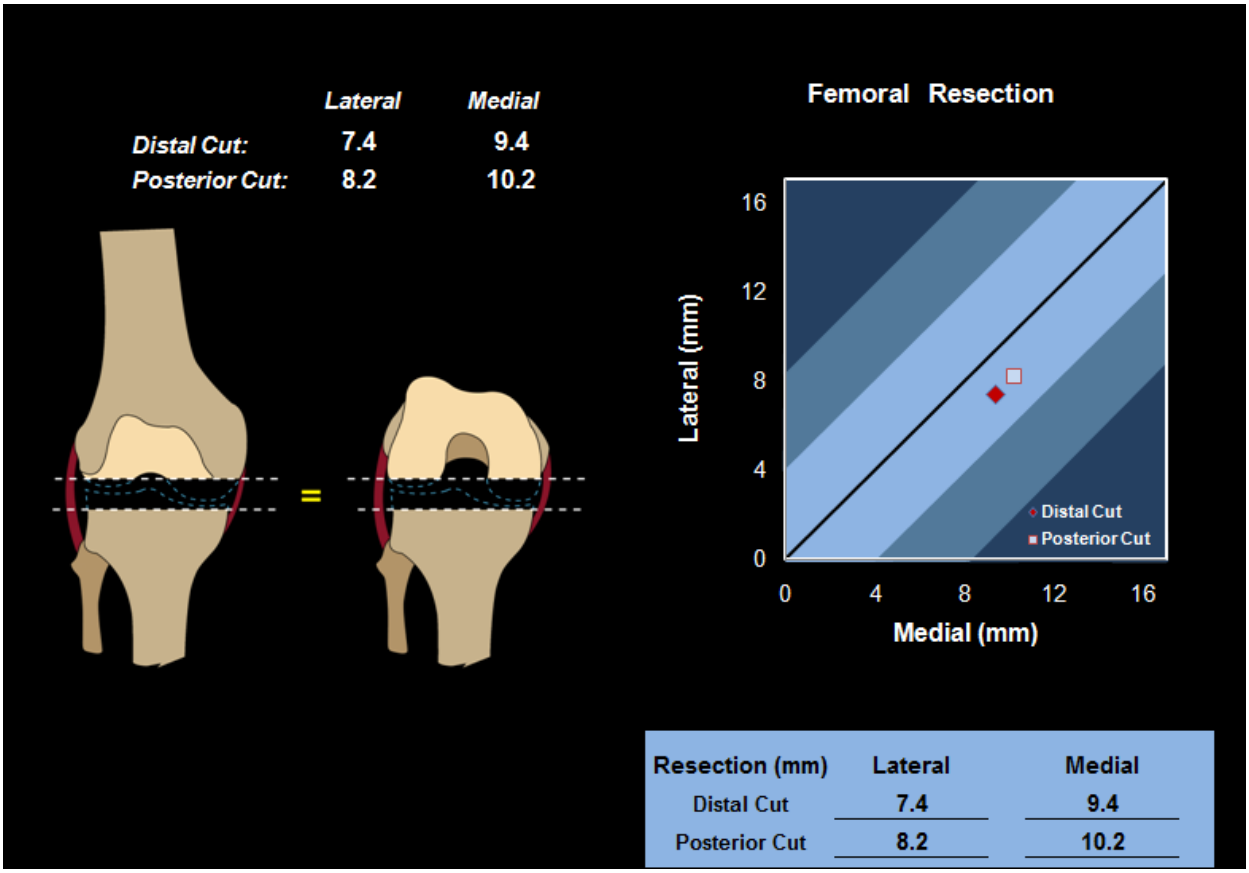


Figure 1.12. Example of reported medial and lateral femoral condyle resections (distal and posterior cuts).

5. The alignment of the tibial cutting guide and cut with respect to the anatomical axis of the tibia in the sagittal (tibial slope) and the frontal (varus/valgus) planes. (Figure X)
6. The depth of tibial resection for the lateral and medial condyles. (Figure X)
7. The alignment of the tibial component in the transverse (internal/external rotation) plane (Figure 1.13).

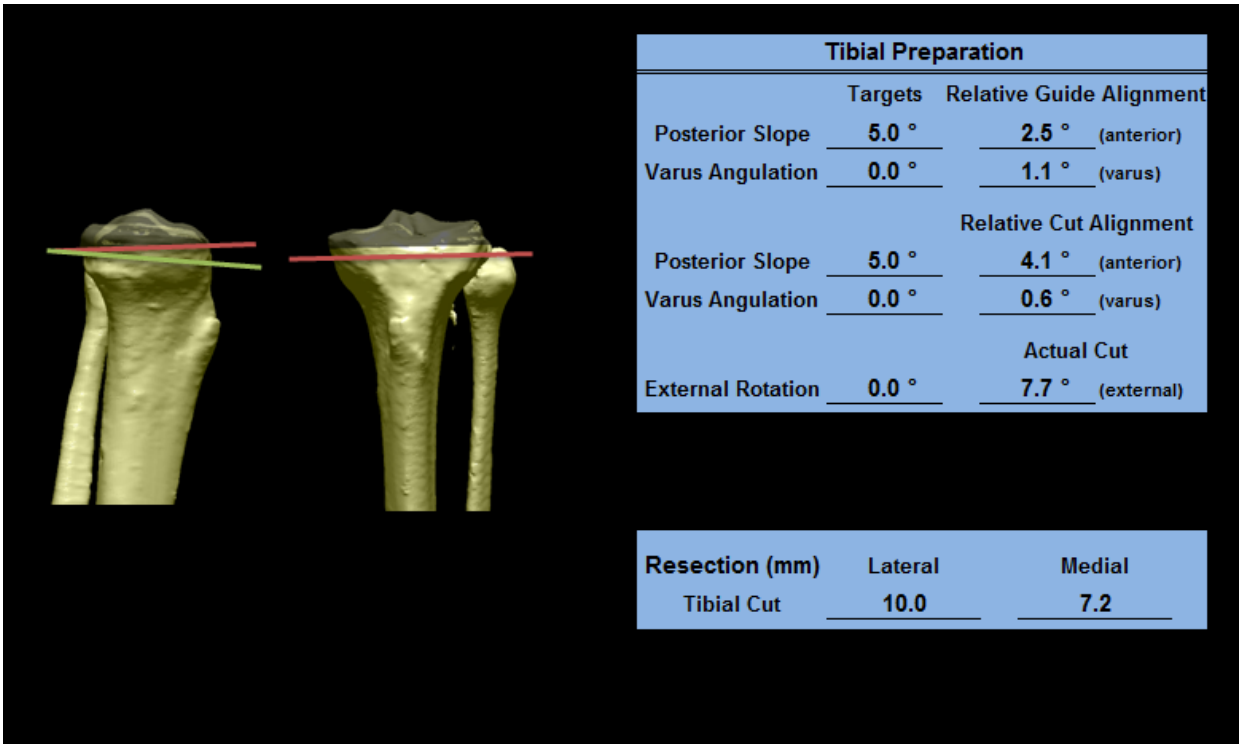


Figure 1.13. Example of tibial measurements.

8. The net alignment of the knee joint was calculated in full extension post-operatively (Figure 1.14):
    a) changes in the relative position of the tibia with respect to the femur were calculated based on the displacement of the tibial coordinate system relative to the femoral coordinate system.
    b) the tibiofemoral alignment of the knee in the frontal plane (varus/valgus) was defined by the angle between the tibial and femoral anatomical axes.
    c) the tibiofemoral alignment of the knee in the transverse plane (internal/external rotation) was defined by the angle between the medial/lateral femoral and tibial axes.

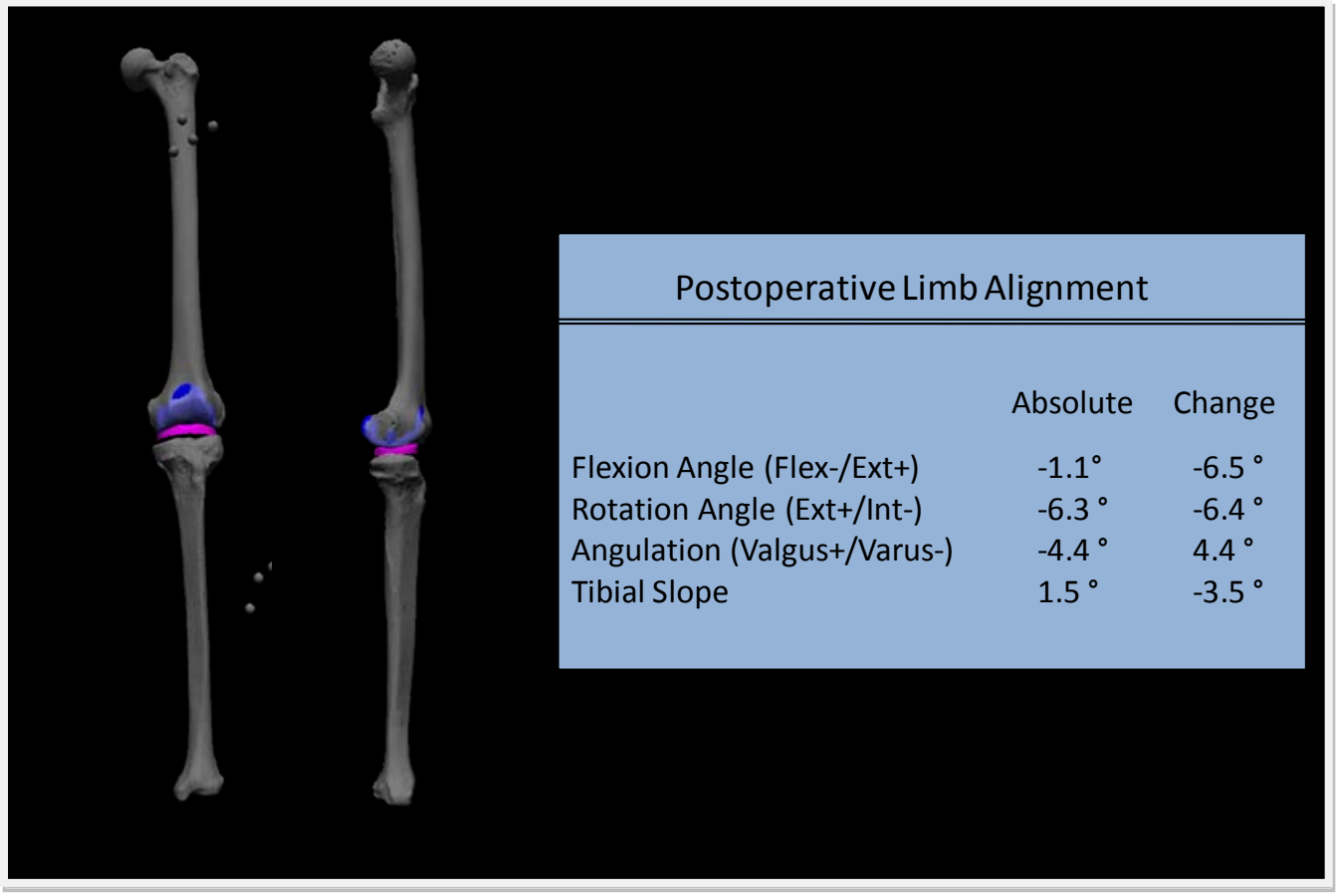


Figure 1.14. Example of frontal plane and sagittal plane alignment with components (left) and reported postoperative limb alignment measures (right).

9. Post-operative laxity in the frontal (varus/valgus) and transverse (internal/external rotation) planes at full extension, 30°, 60° and 90°.
10. Passive post-operative range of motion (ROM) in the sagittal (flexion/extension) plane was measured by moving the knee through its extension to flexion arc.
11. Post-operative laxity in the frontal (varus/valgus) and transverse (internal/external rotation) planes at full extension, 30°, 60° and 90°.
12. Passive post-operative range of motion (ROM) in the sagittal (flexion/extension) plane was measured by moving the knee through its extension to flexion arc.

Technical Objective 2.0. Development of a Surgical Skills Training Facility

OVERVIEW

The goal of Technical Objective 2.0 was to develop a facility for training surgeons in musculoskeletal procedures using the computerized surgical skills system. This objective was successfully completed. A fully operational training facility integrating the computerized bioskills trainer with all supporting instrumentation was developed and implemented with the ability to conduct up to four surgical training surgery sessions simultaneously.

METHODS AND RESULTS

We successfully developed a surgical training facility (Figure 2.1) consisting of the hardware necessary to support up to four independent, simultaneous surgical training sessions in orthopedic procedures. This facility is located within the Methodist Institute for Training, Research and Innovation at The Methodist Hospital in Houston, and occupies a decommissioned operating room which was actively utilized for surgical procedures until 2006. This location of this facility is ideal for demonstrating the capabilities of any surgical training system because of the authenticity of the operative environment and the existence of extensive infrastructure, including refrigerated storage rooms for human and animal cadavers.

As previously stated, the backbone of the surgical skills system is a 12-camera, infra-red digital camera system (Motion Analysis Corporation, Santa Rosa, CA). The cameras identify the positions of reflective markers attached to the bones and measurement instruments, with unique marker array combinations representing each individual object. These marker position data are to TMM software for data collection and analysis. The cameras are mounted to a custom frame designed to isolate the cameras from external vibrations while maximizing the field of view of each camera.

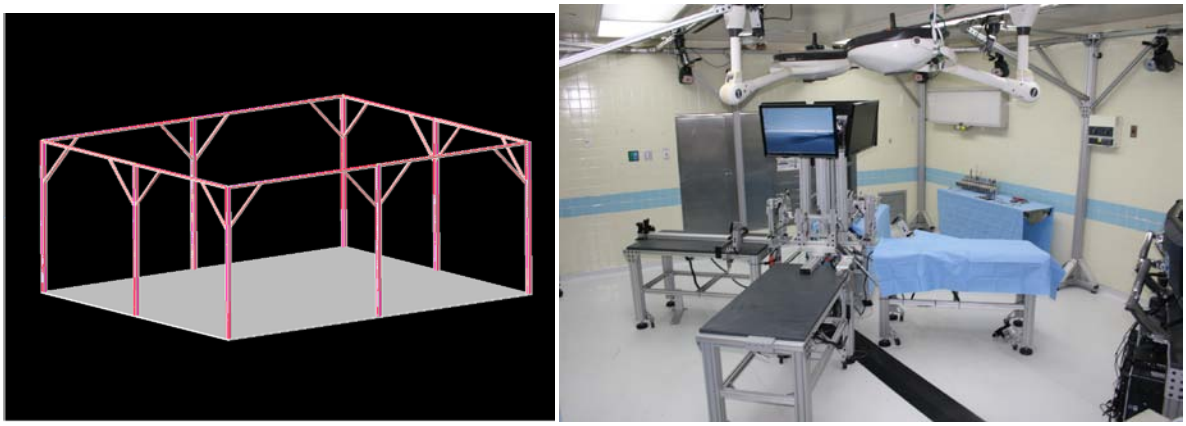


Figure 2.1. Bioskills surgical training facility.

Design and development of supporting instrumentation was a significant aspect of implementing a fully functional training facility. Off-the-shelf surgical tools such as saw sets and retractor sets were purchased, however the majority of hardware was developed and fabricated in-house. Customized

tools and supporting instrumentation included: an interchangeable flag system, detachable mounting plates for cadaver flags, plane jig and intramedullary (IM) rod tracking tools, surgical tables with incorporated laxity test apparatus, and command center. Appendix D contains a description, computer aided design (CAD) model and illustration of the finished product for each customized tool or piece of hardware. Key components of the facility are the specialized operating tables and the command center.

The surgical tables (Figure 2.2) were designed and constructed to meet surgical, specimen fixation and joint laxity test requirements. The table secures a cadaver specimen (L5 spinal segment to feet) prepared for surgical procedures or a surrogate model. The foot of the specimen is secured on a rail that accommodates a surgeon's preference for knee flexion positioning as well as passive range of motion during the procedure. Joint laxity testing is accomplished by applying both axial and perpendicular torques to the tibia in a controlled manner via the laxity test apparatus (Figure 2.2). A torque wrench with an intergraded torque sensing load cell (*FUTEK* Advanced Sensor Tech, Irvine Ca) was used to apply the torques (5 Nm internal/external rotation, 10 Nm Varus/Valgus) to each specimen. Each surgical station had its own dedicated data acquisition system (Measurement Computing, Norton, MA) used to measure the output signal of each torque wrench during laxity test. This raw torque data was synced with TMM software and joint laxity was calculated.

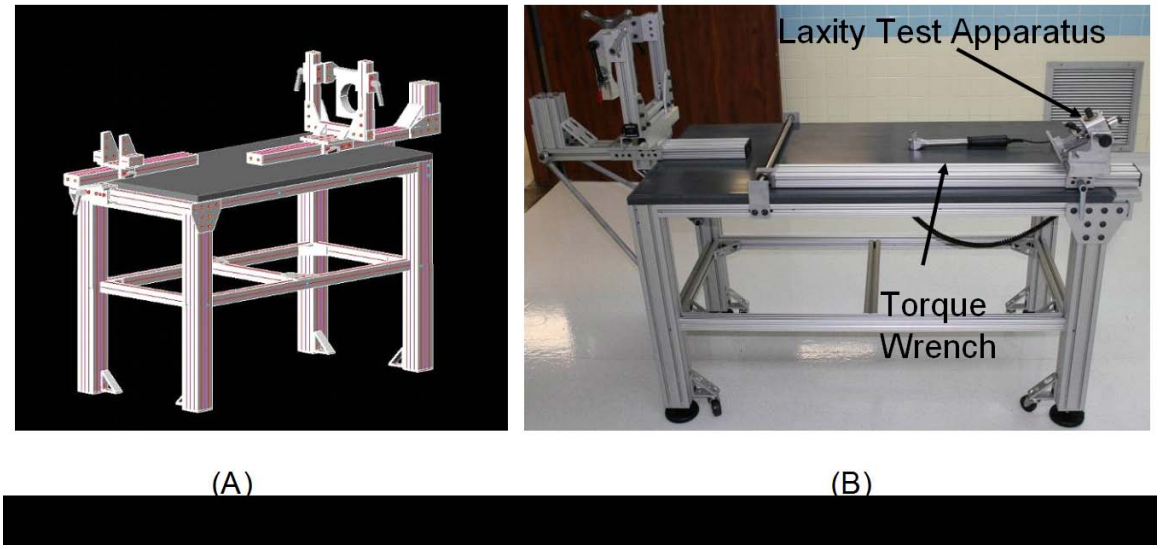
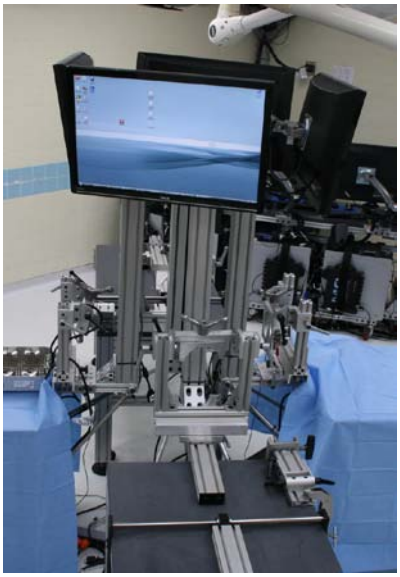


Figure 2.2. Customized surgical table with laxity test apparatus: (A) CAD model and (B) physical model.



Each surgical station has its own dedicated video monitor allowing the trainee to receive live feedback from the training software (Figure 2.3).

A central command center (Figure 2.4) was designed such that one person could monitor all surgical stations and the motion capture system (Cortex) simultaneously. The command center accommodates a dedicated computer and monitor for each surgical station, a separate computer for Cortex and four data acquisition boards for all analog data.

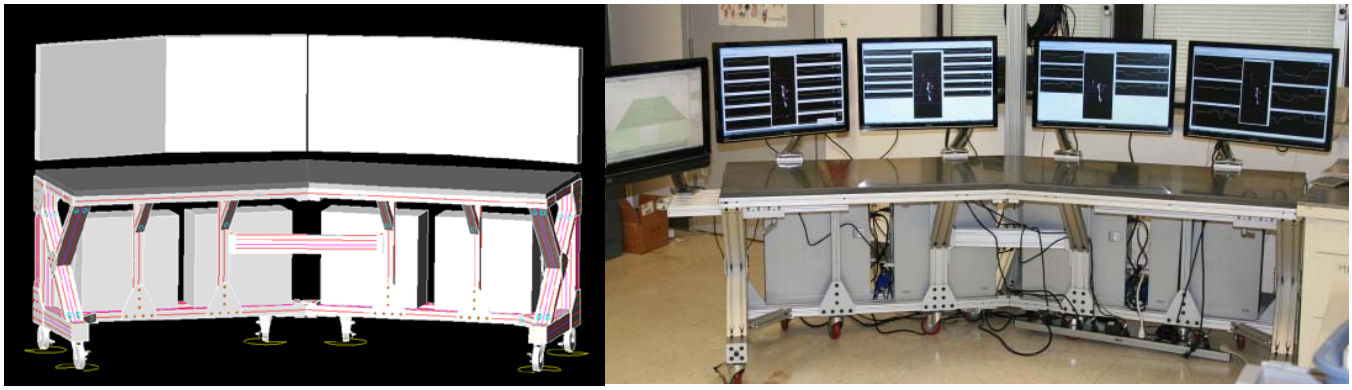


Figure 2.4. Central command center.

Technical Objective 3.0. Validation of Integrated Bioskills Surgical Training System

OVERVIEW

The goal of Technical Objective 3.0 was to test the hypothesis that the Bioskills Training System enhances the speed and efficiency of acquisition of surgical skills. The objective was successfully completed.

METHODS

Eleven trainees were recruited to participate in the study. Trainees consisted of surgical students, residents and fellows enrolled in programs at The University of Texas, Baylor College of Medicine, or Methodist Hospital in Houston, Texas. Each trainee filled out a standard form describing their previous surgical experience, including the total number of knee replacement procedures they have previously observed, assisted or performed. Each trainee was given surgical procedure documentation for the NexGen (Zimmer, Warsaw, Indiana) total knee replacement system (see Appendix E for the NexGen surgical documentation). Trainees were graded based on their average of six different measures on their initial sawbone surgery. Based on their initial assessment, trainees were divided into two groups of average equal skill. Group 1 (n=6) performed the knee replacement first on a polymeric model then a cadaver with conventional training. An instructor was available to supervise each trainee, providing feedback and suggestions for the conventional (apprentice style) sessions. Group 2 (n=5) performed the knee replacement procedure on a polymeric model with performance assessed by the Computerized Bioskills system. Results of each surgical step as well as the final alignment as determined by the Bioskills system were communicated to the trainee. The trainee then performed the procedure on a cadaver under surveillance of the Bioskills system. Finally, the trainees exchanged group assignments and the protocols were repeated.

RESULTS

Final Limb Alignment

All Cadaver Trials

The primary outcome of this surgical procedure is the post-operative alignment of the knee in full extension. Final limb alignment measures included:

1. axial rotation of the tibia with respect to the femur (i.e. relative internal or external rotation),

2. axial alignment of the tibia with respect to the femur in the frontal (i.e. coronal) plane, commonly referred to as the varus/valgus alignment of the knee, , and

3. the posterior slope of the tibial component with respect to the longitudinal axis of the tibia.

When analyzed as one group, tibiofemoral rotation changed from 4.9°±1.1° of external rotation pre-operatively to 2.4°±1.7° of internal rotation after knee replacement (Figure 3.1). Pre-operative alignment of the knee in the frontal plane averaged 0.06 °±0.64° of varus and changed by less than one degree to 0.74°±0.57° of varus after surgery (Figure 3.2). The trainees reduced the posterior slope of the tibia from average of 6.0°±0.2° pre-operatively to 3.9°±0.6° after knee replacement (Figure 3.3).

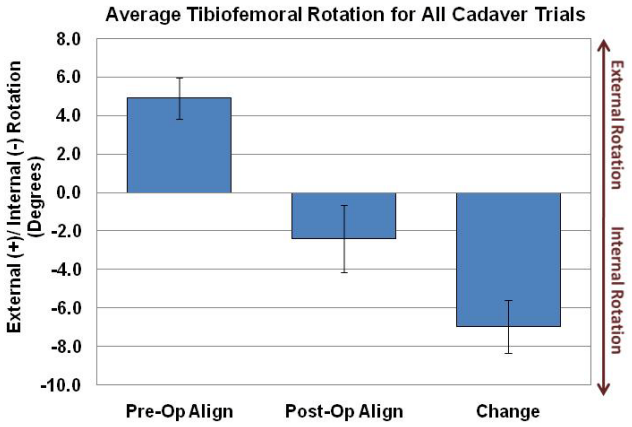


Figure 3.1. Average tibiofemoral rotation for all cadaveric trials expressed in terms of the pre-operative and post-operative alignment, and the change in alignment due to the surgical procedure.

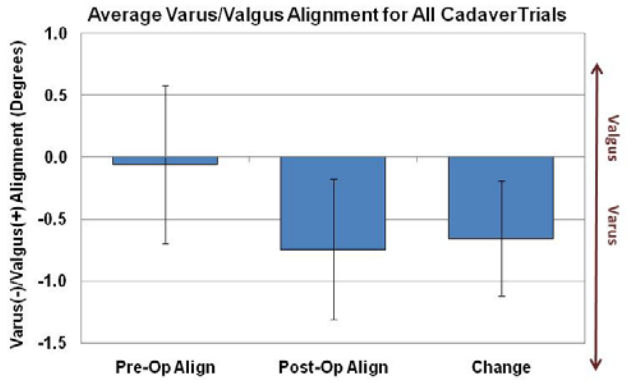


Figure 3.2. Average varus/valgus alignment for all cadaver trials compared pre-operatively, post-operatively and in terms of the change in alignment due to the surgical procedure.

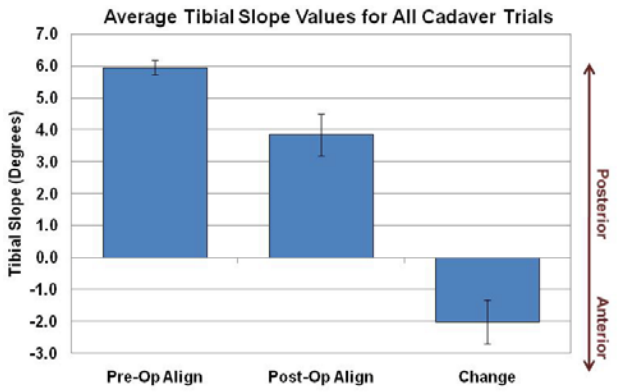


Figure 3.3. Average tibial slope for all cadaver trials compared pre-operatively, post-operatively and for the change in alignment due to the surgical procedure.

Group Analysis

When analyzed by assigned groups, tibiofemoral rotation went from 4.68°±1.73° external rotation to 4.03°±2.16° internal rotation in Group 1 (Figure 3.4). Group 2 averaged 5.21°±1.22° of pre-operative external rotation and 0.22°±2.85°of post-operative internal rotation. Pre-operatively Group 1 averaged 0.28 °±0.93° of varus and post-operatively averaged 0.29°±0.87° of varus (Figure 3.5). Group 2 averaged 0.23 °±0.88° of valgus pre-operatively and post-operatively averaged 1.34°±0.63° of varus. Tibial slope averaged 6.33°±0.28° for Group 1 and 5.44°±0.29° for Group 2 pre-operatively. Tibial slope post-operative measures were 2.33°±0.80° and 5.88°±0.57°, respectively (Figure3.6).

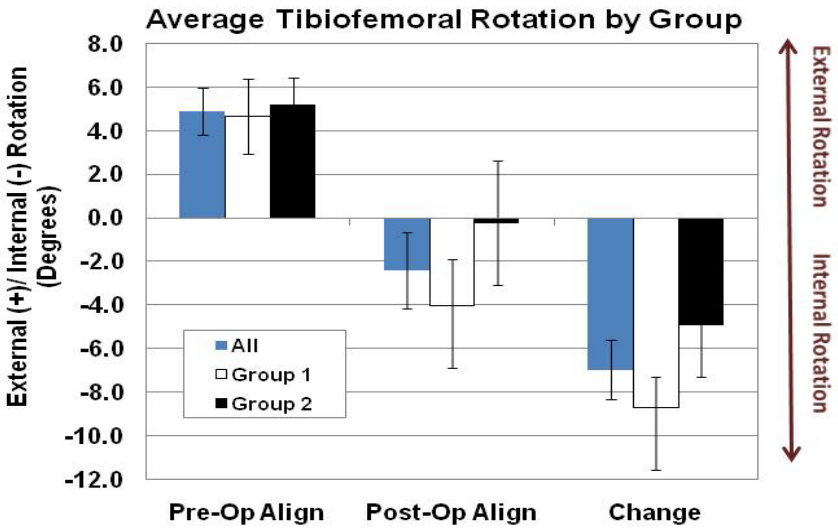


Figure 3.4. Average tibiofemoral rotation by group compared pre-operatively, post-operatively and for the change in alignment due to the surgical procedure.

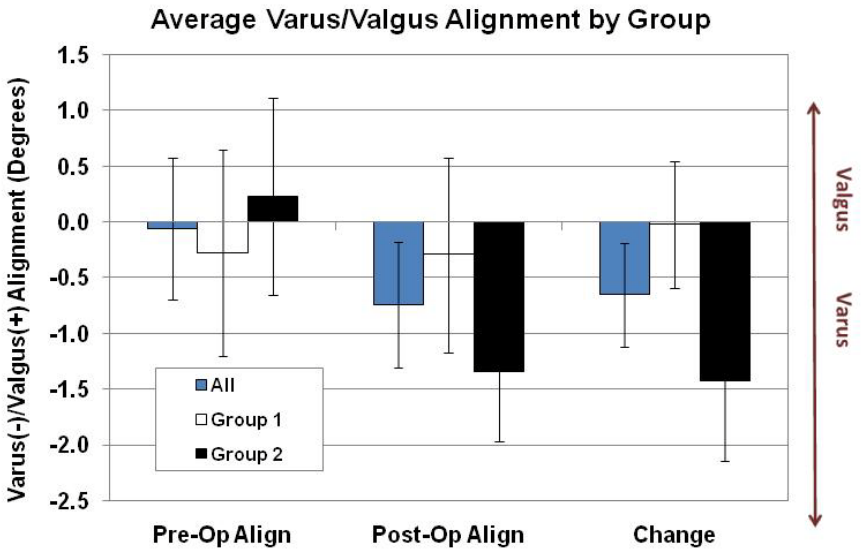


Figure 3.5. Average varus/valgus alignment by group compared pre-operatively, post-operatively and for the change in alignment due to the surgical procedure.

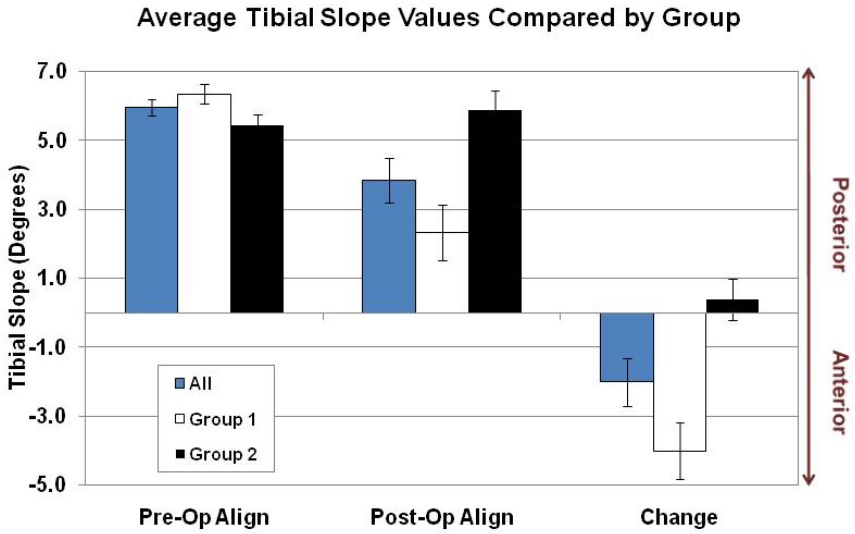


Figure 3.6. Average tibial slope by group compared pre-operatively, post-operatively and for the change in alignment due to the surgical procedure.

Analysis by Trial Type

When analyzed by the type of trial performed (first cadaver trial or 'Cadaver 1' versus second cadaver trial or 'Cadaver 2'), tibiofemoral rotation measures pre-operatively were 5.42°±1.86° external rotation for Cadaver 1 trials and 4.34°±1.14° external rotation for Cadaver 2 trials (Figure 3.7). Post-operative measures were 0.11°±2.58° external rotation for Cadaver 1 trials and 5.15°±2.1° internal rotation for Cadaver 2 trials (Figure 3.8). Pre-operatively Cadaver 1 trials averaged 0.01°±0.92° of varus and post-

operatively averaged 1.13°±0.832° of varus (Figure 3.8). Cadaver 2 trials averaged 0.11°±0.95° of varus pre-operatively and post-operatively averaged 0.32°±0.78° of varus. Tibial slope averaged 6.09°±0.32° for Cadaver 1 trials and 5.8°±0.33° for Cadaver 2 trials pre-operatively. Post-operative measures were 3.48°±0.88° and 4.25°±0.98°, respectively (Figure 3.9).

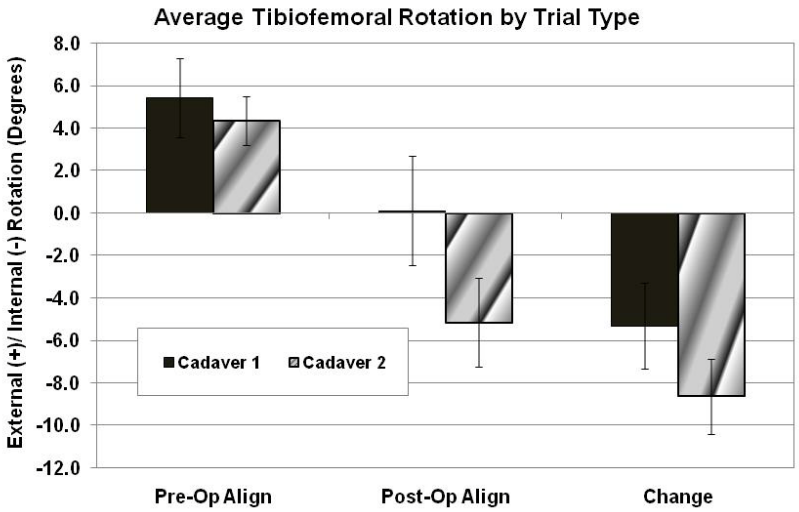


Figure 3.7. Average tibiofemoral rotation by trial type compared pre-operatively, post-operatively and for the change in alignment due to the surgical procedure.

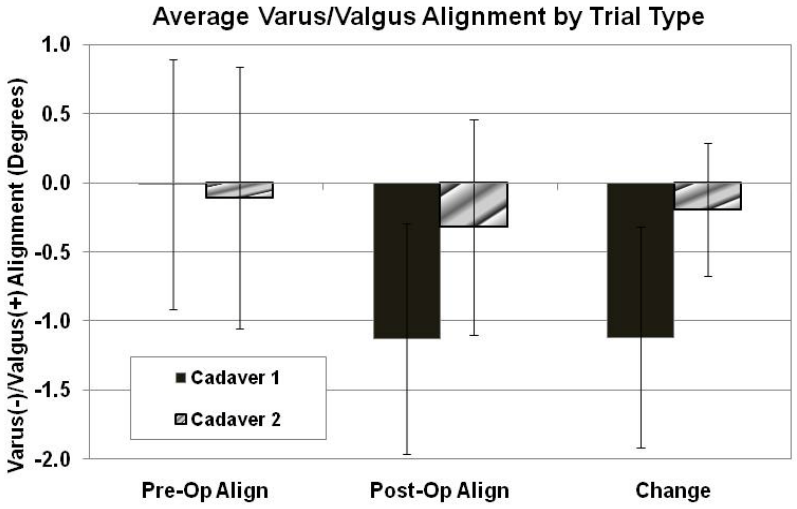


Figure3.8. Average varus/valgus alignment by trial type compared pre-operatively, post-operatively and for the change in alignment due to the surgical procedure.

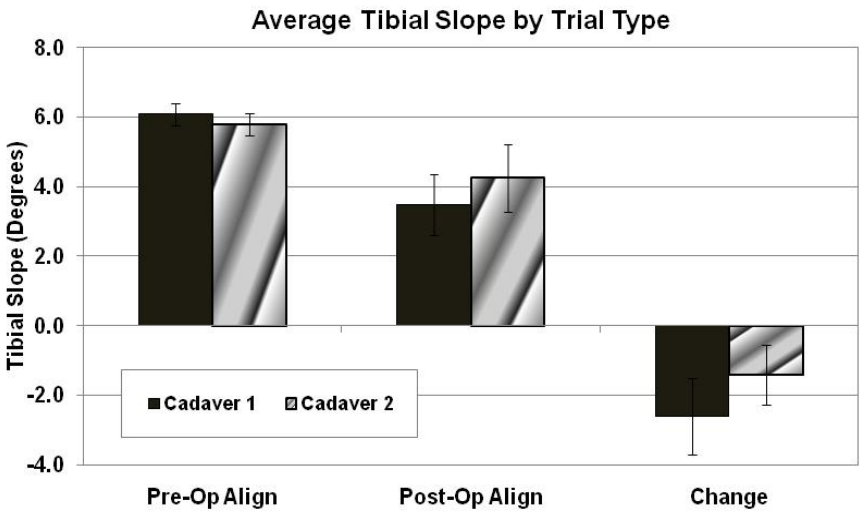


Figure 3.9. Average tibial slope by trial type compared pre-operatively, post-operatively and for the change in alignment due to the surgical procedure.

Conclusions

- These results demonstrate that that surgical trainees generally have difficulty in achieving correct alignment total knee replacement in terms of the axial rotation of the tibia with respect to the femur . Additional difficulty is observed in achieving adequate posterior slope of the tibial component. Interestingly, although the knees were generally left in more varus than planned, the average error was less than one degree.

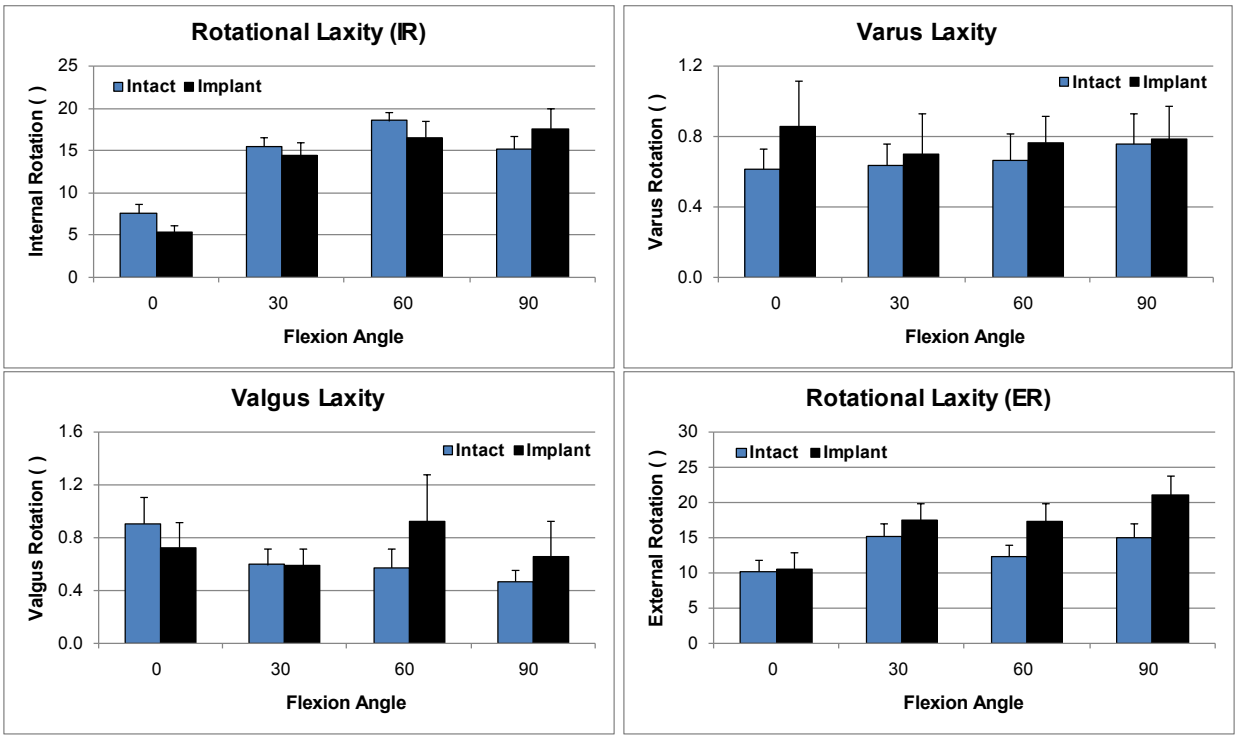
- In terms of the method of training, trainees instructed with traditional didactic methods were further from target values of rotational alignment and tibial slope than those trained with data derived from the Bioskills training system. However, varus/valgus alignment was superior in the traditionally trained group.

- When these errors are broken down by the number of repetitions of the training exercise., varus/valgus alignment and tibial slope improved with the second cadaver session, compared to the first, however tibio-femoral rotation deteriorated.

Soft Tissue Balancing

Pre-operative and post-operative frontal and transverse laxities were determined for each of the twenty cadaver knees. For all pre-operative specimens, when subjected to 5 N/m varus torque, varus angulation of the tibia relative to the femur generally increased across all flexion angles (full extension: 0.61° ± 0.12°, 30°: 0.64° ± 0.12°, 60°: 0.67° ± 0.15°, 90°: 0.76° ± 0.17°). Post-operative varus angulation did not differ significantly from pre-operative angulation in flexion (30°: 0.70° ± 0.23°, 60°: 0.77° ± 0.23°, 90°: 0.78° ± 0.19°), although post-operative full extension was slightly increased (full extension: 0.86° ± 0.26°; p=0.39). When 5 N/m valgus torque was applied, valgus angulation in pre-operative knees generally decreased as flexion increased (full extension: 0.90° ± 0.20°, 30°: 0.60° ± 0.12°, 60°: 0.57° ±

0.14°, 90°: 0.47° ± 0.08°). At full extension and at 30° of flexion, post-operative valgus angulation was similar to pre-operative angulation (full extension: 0.72° ± 0.19°, 30°: 0.59° ± 0.13°) and slightly increased at higher flexion angles (60°: 0.93° ± 0.35°, 90°: 0.65° ± 0.27°), although no differences were statistically significant. Application of 10 N/m internal and external torque revealed more transverse rotational laxities than frontal varus and valgus laxities both pre- and post-operatively. Internal torque resulted in corresponding internal rotation of the tibia relative the femur that increased with any flexion pre-operatively (0°: 7.62° ± 1.03°, 30°: 15.54° ± 1.04°, 60°: 18.54° ± 0.99°, 90°: 15.16° ± 1.47°) and post-operatively (0°: 5.42° ± 0.64°, 30°: 14.51° ± 1.51°, 60°: 16.57° ± 1.91°, 90°: 17.52° ± 2.42°). Similarly, although pre- and post-operative full extension external rotation was greater than internal, external rotation increased with any flexion as external torque was applied pre-operatively (0°: 10.18° ± 1.65°, 30°: 15.26° ± 1.77°, 60°: 12.38° ± 1.59°, 90°: 15.07° ± 1.83°) and post-operatively (0°: 10.52° ± 2.37°, 30°: 17.54° ± 2.25°, 60°: 17.25° ± 2.54°, 90°: 20.99° ± 2.83°).



Figures 3.10 - 3.13. Pre-operative and post-operative frontal and transverse laxity measurements for all surgeons.

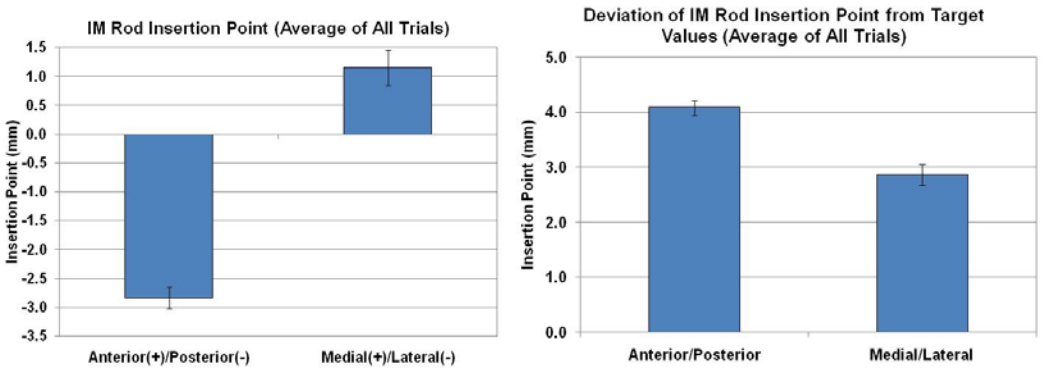
The pre-operative and post-operative frontal and transverse laxity measurements were categorized into subgroups based on Group 1 versus 2 and phase cadaver 1 versus cadaver 2 (Figure A1 and A2, respectively). Group 2 post-operative frontal laxity measurements tended to approach those of the intact specimen with less deviation as compared to group 1's post operative measurements, whereas both groups had similar trends with regards to post-operative transverse laxity measurements matching up with pre-op measurements. However, no significantly different trends were noticed between groups. The only significant differences noted between the two groups were the pre-operative frontal laxity,

varus measurement at 60 degrees of flexion (p=0.04) and in the pre-operative transverse laxity, external rotation measurements at 90 degrees of flexion (p=0.04).

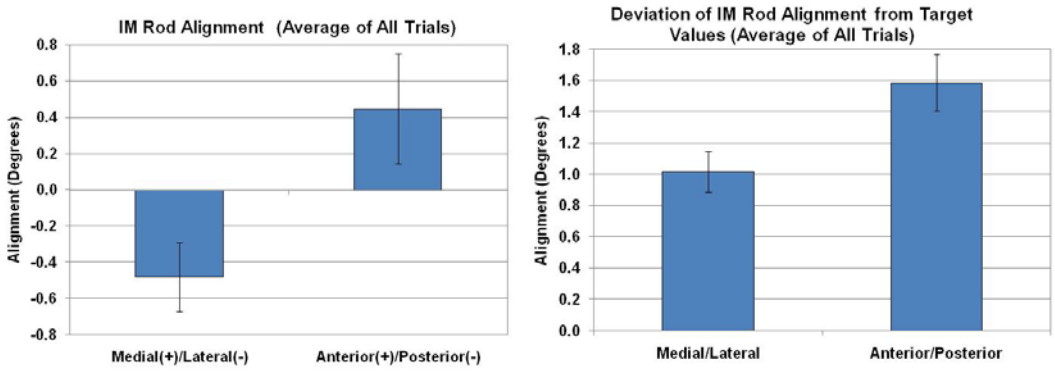
Femoral Preparation

All Trials

The alignments of the surgical instruments were measured after each step of the surgical procedure. As a group, the average error in the IM rod insertion placement caused it to be positioned 1.15±0.56 mm medial and -2.83±0.65 mm posterior to the projection of the actual intramedullary axis (Figure 3.14). The IM rod was angled 0.48°±0.19° lateral (varus) and 0.45°±0.31° anterior (flexion) to the anatomical axis (Figure 3.16). This corresponded to group average deviations from the target insertion point of 4.09±0.48 mm anterior/posterior and 2.87±0.40 mm medial/lateral (Figure 3.15). Group average deviations from target alignment were 1.02°±0.13° medial/lateral and 1.59°±0.18° anterior/posterior (Figure 3.16).



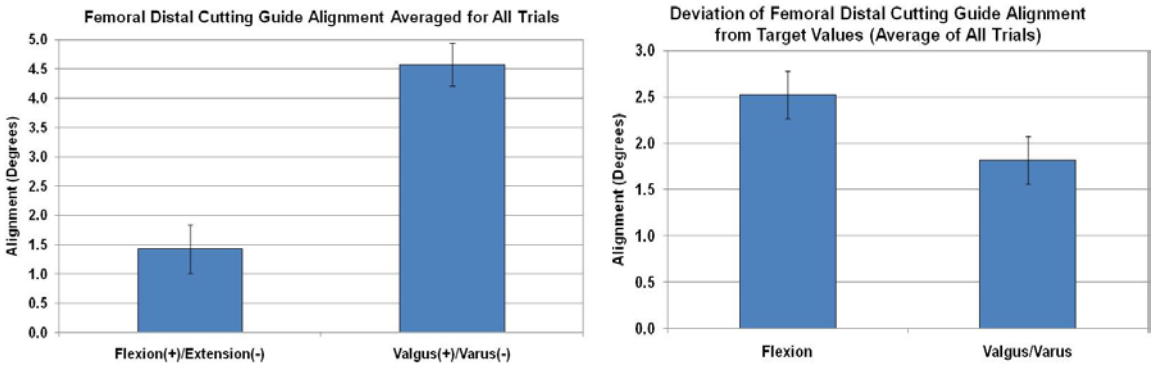
Figures 3.14 and3.15. Average IM rod insertion point relative to the ideal insertion point (the projection of the actual intramedullary axis on the distal femur) for all trials (left) and deviation of the IM rod insertion point from target values averaged for all trials (right).



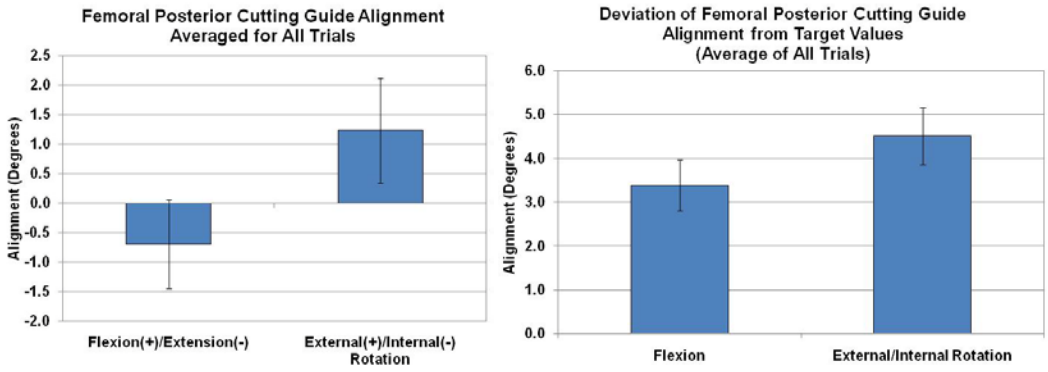
Figures 3.16 and 3.17. Average IM rod alignment for all trials (left) and deviation of IM Rod alignment from target values averaged for all trials (right).

The distal cutting guide was positioned in 1.43°±0.42° of flexion and 4.58°±0.37° valgus with respect to the femoral anatomical axis (Figure 3.18) for the entire group. This corresponded to deviations from

target values of 2.52°±0.26° flexion/extension and 1.82°±0.26° varus/valgus (Figure 3.19). On average, the posterior cutting guide (4-in-1 cutting guide) was placed in 0.70±0.75° of extension and 1.23°±0.89° of external rotation with respect to the anatomical axis (Figure 3.20). The average deviation from target in flexion/extension was 3.38°±0.57° and 4.51°±0.68° in external/internal rotation (Figure 3.21).

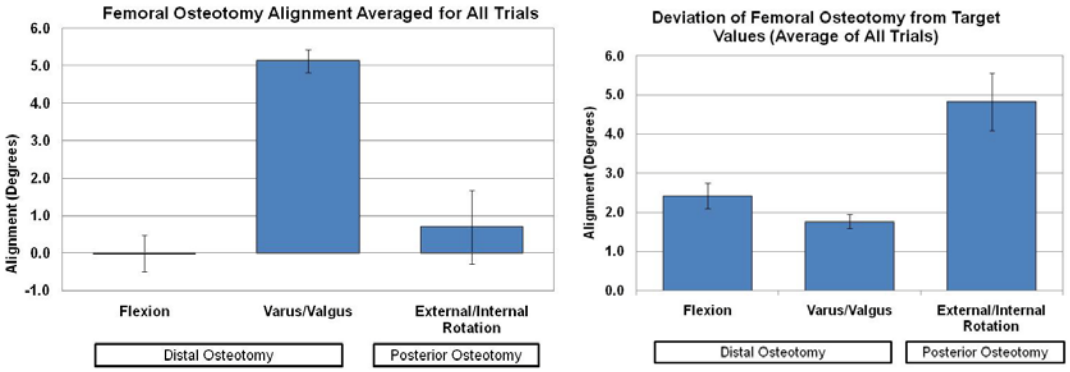


Figures 3.18 and 3.19. Average alignment of the femoral distal cutting guide for all trials (left) and deviation of alignment from target values averaged for all trials (right).



Figures 3.20 and 3.21. Average alignment of the femoral posterior (4-in-1) cutting guide for all trials (left) and deviation of alignment from target values averaged for all trials (right).

The femoral distal osteotomy alignments averaged 0.01°±0.49° in extension and 5.14°±0.31° in valgus for all trials (Figure 3.22). The posterior osteotomy averaged 0.70°±0.98° in external rotation (Figure 3.22). Corresponding deviations from the intended targets were 2.42°±0.32° in flexion/extension, 1.76°±0.18° in varus/valgus and 4.83°±0.73° in external/internal rotation (Figure 3.23).



Figures 3.22 and 3.23. Average alignment of the femoral osteotomies for all trials (left) and deviation of alignment from target values averaged for all trials (right).

Conclusions

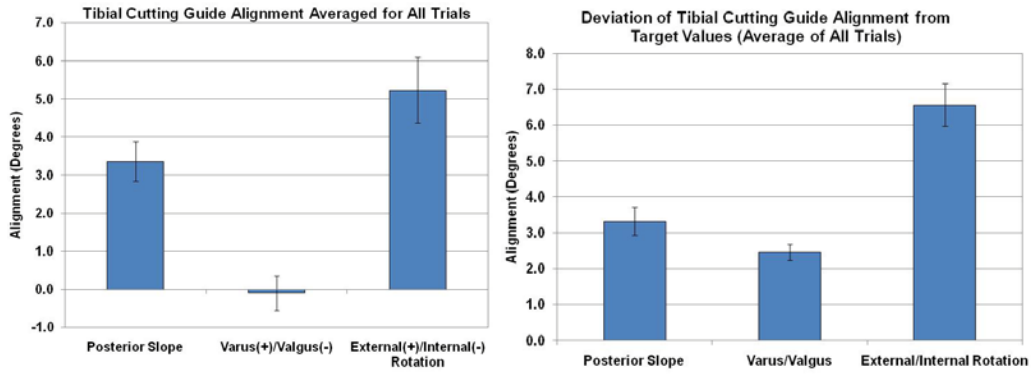
- These results demonstrate that surgical trainees tend to place the intramedullary guide rod at a significant displacement away from the target position corresponding to the longitudinal axis of the intramedullary canal. These errors are much larger in the anterior/posterior direction than medial/laterally. In contrast, errors in the axial alignment of the rod are relatively small.
- Errors in placement of the distal cutting guide lead to 2-3 degree misalignment of the femoral resections, both in flexion/extension and varus/valgus alignment. The varus/valgus component is of particular concern, because deviations were typically in a varus direction.

Tibial Preparation

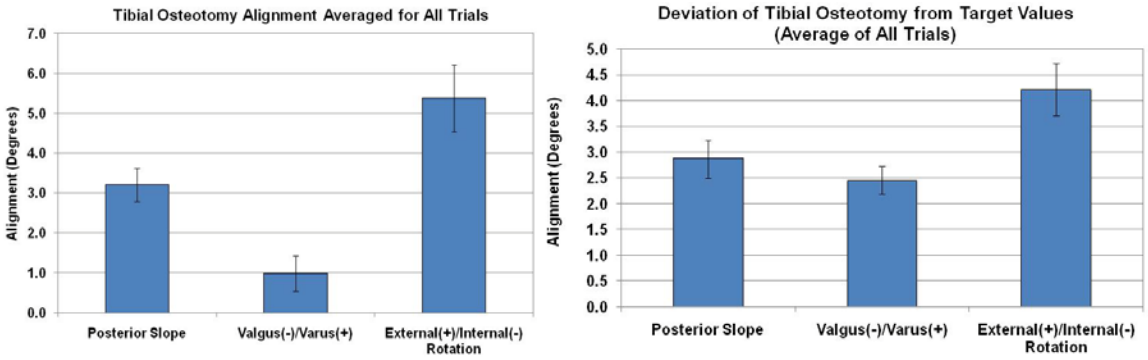
The alignments of the tibial cutting guide and tibial osteotomy were measured relative to the anatomic and medial/lateral axes of the tibia.

Post-operatively, the average alignment of the **tibial cutting guide** was 3.36°±0.52° in posterior slope, 0.10°±0.45° in valgus and 5.23°±0.86° in external rotation for all trainees combined (Figure 3.24). This corresponds to average deviations from target values of 3.33°±0.39° in posterior slope, 2.46°±0.22° in varus/valgus alignment , and 6.56°±0.60° in external/internal rotation (Figure 3.25).

Similar values were measured for the actual orientation of the **tibial osteotomies**. These were aligned at an average of 3.22°±0.41° in posterior slope, 0.98°±0.44° in varus and 5.38°±0.84° in external rotation (Figure 3.26). This corresponds to deviations of 2.87°±0.36° posterior slope, 2.45°±0.27° varus/valgus and 4.22°±0.51° external/internal rotation compared to target values (Figure 3.27).



Figures 3.24 and 3.25. Average alignment of the tibial cutting guide for all trials (left) and deviation of alignment from target values averaged for all trials (right).



Figures 3.26 and 3.27. Average alignment of the tibial osteotomies for all trials (left) and deviation of alignment from target values averaged for all trials (right).

Conclusions

- These results support the conclusion that the surgical trainees had significant difuculty in preparation of the tibia, with an average increase of deviations of 2-3 degrees in varus alignment, with a 3-4 degree shortfall in posterior slope.
- A source of major concern is the difficulty experienced by trainees in achieving the correct axial rotation of the tibial component with respect to the femur, which could have serious clinical consequences if reproduced in treatment of patients.

Table 3.1. Group instrument and osteotomy alignment errors

	Mean	Standard Error	Deviation from Target	Standard Error
Femoral intramedullary rod				
(+)medial/(-)lateral (mm)	1.15	0.56	2.87	0.40
(+)anterior/(-)posterior (mm)	-2.83	0.65	4.09	0.48
(+)med/(-)lat (deg)	-0.48	0.19	1.02	0.13
(+)posterior/(-)anterior (deg)	0.45	0.31	1.59	0.18
Distal femoral cutting guide				
(-)varus/(+)valgus (deg)	4.58	0.37	1.82	0.26
(+)flexion/(-)extension (deg)	1.43	0.42	2.52	0.26
Posterior femoral cutting guide				
(+)internal/(-)external rotation (deg)	1.23	0.89	4.51	0.65
(+)flexion/(-)extension (deg)	-0.70	0.75	3.38	0.57
Tibial cutting guide				
(+)varus/(-)valgus (deg)	-0.10	0.45	2.46	0.22
(-)anterior/(+)posterior slope (deg)	3.36	0.52	3.33	0.39
(+)external/(-)internal rotation (deg)	5.20	0.86	6.56	0.60
Femoral Osteotomy				
(+)flexion/(-)extension (deg)	-0.01	0.49	2.42	0.32
(+)varus/(-)valgus (deg)	5.14	0.31	1.76	0.18
(+)internal/(-)external rotation (deg)	0.70	0.98	4.83	0.73
Tibial Osteotomy				
(-)anterior/(+)posterior slope (deg)	3.22	0.41	2.87	0.36
(+)varus/(-)valgus (deg)	0.98	0.44	2.45	0.27
(-)internal/(+)external rotation (deg)	5.38	0.84	4.22	0.51

Surgical Procedure Metrics

Results from the analyses of specific surgical procedures are given in Appedix F. All major surgical steps of the knee arthroplasty procedure were analyzed in terms of quantifying: (1) alignment of the cutting guides and alignment of the resulting osteotomies. Group analyses (Group 1 assignment versus Group 2 assignment) and trial specific (sawbone versus cadaver) analyses are presented for alignment of the guides/osteotomies and deviations from the intended targets.

Analyses by Group Assignment

Analyses by group demonstrated that significant differences did not exist between the skill levels of the two groups when individual steps were analyzed. Therefore, the average skill level represented by each group was representative of the overall skill level of study participants.

With respect to femoral preparation surgical steps, anterior/posterior placement of the IM rod, both in terms of insertion point and alignment, demonstrated higher deviation from the intended target than

medial/lateral measures (Figures F.1-F.4). There was also greater variability in alignment (i.e. angle) measures compared to insertion point measures. Femoral cutting guide measures also showed consistent similar alignment measures as well as deviations from intended targets when the two groups were compared (Figures F.5-F.8). Similar trends were seen for tibial cutting guide alignment and tibial osteotomy metrics (Figures F.21-F.25)

Analyses by Trial Type

Analyses by trial type involved grouping metrics based on the specific surgical trial for all surgeons who performed that trial (i.e. Sawbone Trial 1, Cadaver Trial 1, Sawbone Trial 2, and Cadaver Trial 2).

With respect to femoral preparation surgical steps, there was great variability between sawbone trial outcomes and cadaver trial outcomes. For example, in flexion/extension measures of IM rod alignment the sawbone trials averaged IM rod alignmenst in flexion while the cadaver trials averaged IM rod alignments in extension (Figure F.11). The same trend is seen in IM rod insertion point measures (Figure F.13) and femoral cutting guide alignment (sawbone trials averaged net external rotational alignment while cadaveric trials averaged net internal rotational alignment). These results might indicate that sawbone polymeric models are not adequate surrogate models for knee arthroplasty procedures.

Tibial preparation steps demonstrated a learning curve trend, in terms of both sawbone trials and cadaveric trials. Tibial guide placement improved with each subsequent trial of the same type (Sawbone 1 → Sawbone 2 and Cadaver 1 → Cadaver 2). For example, measurements of posterior slope increased from 3.82°±0.91° to 5.30°±1.21°, where 5.5° was the average target value of posterior slope (Figure F.26). Varus/valgus measures also demonstrated a learning curve (Figure F.28 and F.30) as the magnitude of the deviation from target values decreased with subsequent surgeries of the same type. Interestingly, external/internal rotation measures were highly variable and did not necessarily show a learning curve effect, however tibial osteotomy alignment values in external/internal rotation closely follow tibial cutting guide alignment values. This suggests that the design of the guide and associated surgical tools to perform the osteotomy lends themselves to low error propagation (Figure F.27 and F.29) for this particular alignment metric.

Key Research Accomplishments

1. We have developed a reliable and accurate turnkey system for measurement of technical performance parameters in orthopedic procedures, primarily total knee replacement.

2. Successful development of a robust software for automated measurement of bony landmarks, computation of anatomic axes , and real time monitoring of the position and alignment of surgical implants and instruments.

3. We have successfully developed a reproducible methodology for measuring the laxity of the knee joint win all positions of normal function before and after joint replacement.

4. We have succeeded in generating automated reports documenting the technical performance of each individual surgeon with case-specific illustrations and data with virtually no delay. This enables surgeons to receive personalized reports immediately upon completion of each training exercise.

5. We have determined that bioskills training has variable impact on the technical skills of trainees and that more structured use of the system is required to optimize its impact on skill acquisition and the spectrum of technical tasks successfully acquired.

6. Our results have demonstrated that current surrogate models of the knee ("Sawbones"), used worldwide for surgical training, do not emulate the acquisition of transferrable technical skills. We have determined that more realistic anatomic models are needed for use in surgical training to replace completely or at least to a significant degree the need for human cadavers.

Reportable Outcomes and Conclusions

The major reportable outcome of this study is the development of an operational Bioskills Training facility at The Methodist hospital in Houston for the development of surgical skills in trainees within the medical school and residency training programs, and in practicing surgeons within the community who may wish to further refine their technical skills or learn new procedures. Discussions are underway with the administration of Methodist- Cornell Medical School, Baylor College of medicine, and The University of Texas to incorporate this facility into the training of Residents and fellows in orthopedic Surgery and other specialties.

Experts at other training centers (D Chit Ranawat, Hospital for Special Surgery, New York and Dr Ron Lehman, Walter Reed Hospital, Washington DC) have expressed an interest in developing satellite versions of the Bioskill Systems to use in their own facilities. awe are interested in obtaining funding to test and develop the outcome of training using this system, both in the sense of acute improvement of technical skill, but, more importantly, in terms of outcomes and prevention of complications in clinical practice. We are in the process of exploring funding sources to make this possible.

Manuscripts of our findings will be prepared once we have completed enrollment of experienced surgeons to serve as a reference datum. Nonetheless, the bioskills system has been presented to surgeons and manufacturers in a variety of conference venues, including the American Academy of orthopedic Surgery and the Australian Orthopedic Association.

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Appendices

Appendix A.1. Previously published journal article detailing methodology

Conditt M, Noble P, Thompson M, Ismaily S, Moy G, and Mathis K. A computerized bioskills system for surgical skills training in total knee replacement. Proc Inst Mech Eng H. 2007; 221(1): 61-9.

A computerized bioskills system for surgical skills training in total knee replacement

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Abstract: Although all agree that the results of total knee replacement (TKR) are primarily determined by surgical skill, there are few satisfactory alternatives to the 'apprenticeship' model of surgical training. A system capable of evaluating errors of instrument alignment in TKR has been developed and demonstrated. This system also makes it possible quantitatively to assess the source of errors in final component position and limb alignment. This study demonstrates the use of a computer-based system to analyse the surgical skills in TKR through detailed quantitative analysis of the technical accuracy of each step of the procedure. Twelve surgeons implanted a posterior-stabilized TKR in 12 fresh cadavers using the same set of surgical instruments. During each procedure, the position and orientation of the femur, tibia, each surgical instrument, and the trial components were measured with an infrared coordinate measurement system. Through analysis of these data, the sources and relative magnitudes of errors in position and alignment of each instrument were determined, as well as its contribution to the final limb alignment, component positioning and ligament balance. Perfect balancing of the flexion and extension gaps was uncommon (0/15). Under standardized loading, the opening of the joint laterally exceeded the opening medially by an average of approximately 4 mm in both extension (4.1 ± 2.1 mm) and flexion (3.8 ± 3.4 mm). In addition, the overall separation of the femur and the tibia was greater in flexion than extension by an average of 4.6 mm. The most significant errors occurred in locating the anterior/posterior position of the entry point in the distal femur (SD = 8.4 mm) and the correct rotational alignment of the tibial tray (SD = 13.2°). On a case-by-case basis, the relative contributions of errors in individual instrument alignments to the final limb alignment and soft tissue balancing were identified. The results indicate that discrete steps in the surgical procedure make the largest contributions to the ultimate alignment and laxity of the prosthetic knee. Utilization of this method of analysis and feedback in orthopaedic training is expected rapidly to enhance surgical skills without the risks of patient exposure.

Keywords: total knee replacement, computer model, limb alignment

1 INTRODUCTION

It is well established that the outcome of total knee replacement, whether gauged by the short-term function of the artificial joint or its ultimate durability, is critically determined by technical factors [**1**, **2**]. These include the position and alignment of the prosthetic components with respect to the skeleton, and the soft-tissue balance achieved intraoperatively [**3**–**6**]. It is generally agreed that in the frontal plane the desired alignment of the reconstructed knee is such that the mechanical axis of the limb passes through the middle of the knee joint [**7**, **8**] or through the middle third of the prosthesis [**9**]. In the sagittal plane the goal is to restore normal patellofemoral tracking and stability while simultaneously providing

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sufficient knee flexion for everyday activities. It is also important to recreate the preoperative orientation of the femur and tibia in internal/external rotation with the knee in full extension, although opinions differ concerning optimal rotational alignment with respect to the bony tibia. In addition to the final limb alignment, another surgical goal of TKR is to create symmetric and balanced flexion and extension gaps [**10**].

Over the past 30 years of knee arthroplasty, there have been numerous suggestions of the most effective procedures for achieving acceptable balance and alignment of the artificial knee on a routine, reproducible basis [**7**, **11**–**16**]. Traditionally, the location of each prosthetic component has been referenced to anatomic landmarks on either the femur or the tibia, often without reference to the other bones in the joint. For example, the internal/external rotation of the femoral component is traditionally aligned with the posterior edges of the femoral condyles or the epicondylar axis, while the rotational position of the tibial component on the tibia is based on the location of the tibial tubercle, the shape of the tibial plateau, or the alignment of the malleoli. These techniques have been shown to be unreliable in the osteoarthritic knee [**17**]. More recently, the accuracy of preparation of the tibia and femur has been increased through adoption of a coupled-component technique in which the relative orientation of the articulating components is referenced intraoperatively [**18**]. In addition, cutting guides for both the femur and the tibia are commonly referenced to extramedullary and/or intramedullary landmarks to overcome the difficulty of visualizing the mechanical axis of the extremity via the surgical incision. Although these guides increase the reliability of implant placement, errors still occur owing to the variability of bony anatomy, and the difficulty of achieving rigid fixation of the guide to the underlying bone, especially in osteoporotic cases.

It is even more difficult to restore the normal stability of the knee joint throughout the arc of motion as the forces developed in the ligaments controlling joint motion are sensitive to precise placement of the prosthetic components. Moreover, the placement of the new articulating surfaces must compensate for the effects of the pathologic process, in addition to the effects of differences in the geometry of the prosthetic and native joints [**19**]. In order to address bony deformities, joint contractures, or instability, it may be necessary to perform a series of soft tissue releases in addition to the bony cuts to create symmetric and balanced flexion and extension gaps. These soft-tissue balancing procedures are typically performed without the aid of any instrumentation, and consequently it is not surprising that, even when specific techniques are employed to create equal flexion and extension gaps, perfect soft-tissue balancing is achieved in only approximately 50 per cent of cases [**20**].

Clearly, successful completion of the operation requires skill, in both technique and judgement. However, there is limited information demonstrating in precise, quantitative terms the extent to which these technical goals are achieved on a case-by-case basis. Moreover, it is not possible to establish which specific errors/variations in surgical technique account for deviations of alignment and balance from the idealized preoperative plan. As there are multiple sources of error, a quantitative method is needed to measure the contribution of each potential factor to the surgeon's success in achieving the technical goals of the procedure. In this study, such a method is presented, and its effectiveness in discerning causes of malalignment of prosthetic components and imbalance of the knee following TKR is demonstrated.

2 MATERIALS AND METHODS

2.1 Preparation of computer knee models

Twelve normal lower extremities without evidence of pre-existing contractures or deformities were harvested from cadaveric donors (eight males, four females; average age 76 years). Anteroposterior and lateral radiographs were prepared of each specimen to exclude cases with evidence of previous trauma, or significant skeletal pathology. Computer tomography (CT) scans were obtained of each specimen using a helical scanner (GE Medical Systems) and contiguous slices of 2.5 mm through the shafts of the tibia and femur with slices at a thickness of 1.25 mm through the joint. Three-dimensional reconstructions of the tibia and femur were prepared (Materialize, Belgium), resulting in solid models of each bone with a dimensional accuracy of approximately 0.2 mm.

Utilizing computer aided design (CAD) software routines (Unigraphics Inc., Cypress, California), a set of anatomically based coordinate systems was developed to define the location and orientation of the tibia and the femur from the three-dimensional solid models. For the femur, the true flexion/extension axis was found by fitting spheres to the posterior condylar surfaces of the intact femur [**21**]. The longitudinal anatomic axis was defined by the line of best fit through the centroids of cross-sections from the

distal third of the femur (Fig. 1). The anterior/posterior axis was defined by a line mutually orthogonal to the other two axes. The origin of the femoral coordinate system was the point on the longitudinal axis closest to the flexion/extension axis. The mechanical axis of the femur was defined as the axis lying in the plane of the femoral anatomic axis and perpendicular to the flexion/extension axis. The longitudinal tibial axis was defined by the line of best fit through the centroids of cross-sections from the proximal third of the tibia, as shown in Fig. 1. For the medial/lateral axis of the tibia, circles were fitted to the cortical edges of the medial and lateral sides at slices 2, 4.5, and 7 mm distal to the tibial plateau. The medial/lateral axis was then calculated by averaging the centres of these circles (Fig. 1). The anterior/posterior axis was defined by a line mutually orthogonal to the other two axes. The origin of the tibial coordinate system was the point on the medial/lateral axis closest to the longitudinal axis.

2.2 Surgical preparation of each specimen

Following radiographic evaluation, the twelve cadaveric knees were prepared for implantation of a posterior cruciate ligament (PCL) sacrificing posterior stabilized total knee replacement using one standard set of instruments [Insall-Burstein II (IBII), Zimmer]. This particular instrument set was selected for use in these experiments because it incorporates most of the design features common to many other instrument systems without the specialized features or accessories characteristic of more contemporary instrumentation. The first step of the procedure involved resection of the proximal tibia using a cutting guide mounted on an extramedullary alignment jig. An intramedullary alignment rod was then inserted through a drilled hole within the intercondylar notch of the distal femur. The anterior cutting guide was then indexed off the anterior femoral cortex, guiding the resection of a preliminary anterior cut to avoid notching of the femur. The distal femoral cutting guide was then mounted on the cut anterior femur to determine the level of the distal femoral resection. The femur was then sized and the posterior condylar and the final anterior cuts were made. The flexion and extension gaps were checked and, if necessary, the distal femur was recut. The appropriate femoral notch/chamfer guide was then pinned to the cut distal femur and controlled the chamfer cuts and removal of the intercondylar notch. The rotational position of the tibia was determined by pinning the tibial stem template on the cut tibial surface in rotational alignment with the tibial tubercle. The tibial stem punch was then driven into the cancellous bone, creating the cavity for the stem of the tibial tray. Twelve individuals performed the tibial and femoral cuts on the cadaveric knees: four experienced surgeons (orthopaedic faculty), one total joint fellow, five orthopaedic residents, one physician's assistant, and one orthopaedic assistant.

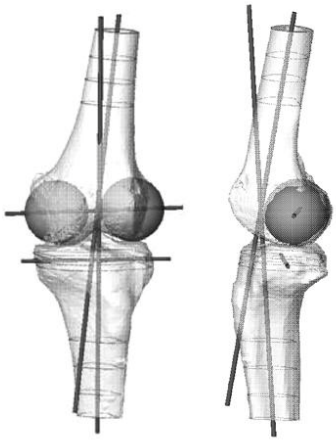


Fig. 1 Example of CT reconstruction and definition of anatomic and mechanical axes

2.3 Quantitative assessment of instrument alignment

During surgical preparation of each knee, the position and orientation of the femur and tibia, each surgical instrument, and the trial components were measured with a three-dimensional coordinate measurement system (NDI, Waterloo, Ontario, Canada). Specifically, the instruments tracked were the extramedullary tibial cutting guide, the femoral intramedullary rod, the anterior femoral cutting guide, the distal femoral cutting guide, and the tibial stem punch. Based upon these spatial measurements, the following geometric parameters were calculated.

1. The medial/lateral placement of the extramedullary rod within the tibia and its inclination with respect to the longitudinal anatomic axis of the tibia in both the frontal (varus/valgus) and sagittal planes (tibial slope) (Fig. 2).
2. The medial/lateral and anterior/posterior entry point of the femoral intramedullary rod and its inclination with respect to the mechanical and anatomic axes of the femur in both the frontal

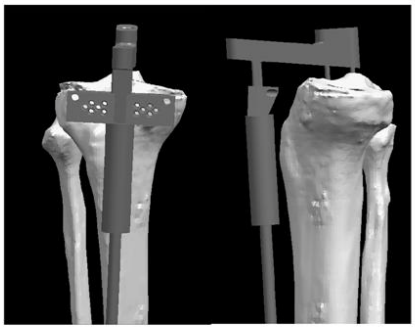


Fig. 2 Computer reconstruction of the tibia with a cutting block mounted on an extramedullary alignment guide prior to pinning to the proximal tibia. The height of the guide is determined by a threaded sleeve; its inclination is determined by the position of the rod with respect to the distal tibia in both the frontal and sagittal planes

(varus/valgus) and sagittal planes (flexion/extension).

3. The alignment of the anterior femoral cutting guide with respect to the mechanical axis of the femur in both the sagittal (flexion/extension) and transverse planes (internal/external rotation).
4. The alignment of the distal femoral cutting guide:
   (a) with respect to the mechanical axis of the femur, in both the sagittal plane (flexion/extension) and the frontal plane (varus/valgus);
   (b) with respect to the flexion/extension axis of the femur in the transverse plane (internal/external rotation).
5. The alignment of the tibial stem punch, relative to the medial/lateral axis of the tibia in the transverse plane (internal/external rotation).
6. The inclination of the femoral component with respect to the mechanical axis of the femur in both the sagittal (flexion/extension) and frontal planes (varus/valgus).
7. The internal/external rotation of the femoral component with respect to the flexion/extension axis of the femur in the transverse plane.
8. The alignment of the tibial component in the sagittal plane (tibial slope) and in the frontal plane (varus/valgus), both with respect to the longitudinal axis of the tibia and in the transverse plane (internal/external rotation) with respect to the medial/lateral axis of the tibia.
9. The net alignment of the lower extremity, both before and after implantation, was calculated in full extension (Fig. 3) and 90° of flexion:
   (a) changes in the relative position of the tibia with respect to the femur were calculated from the displacement of the centre of the tibial coordinate system with respect to the femoral coordinate system;
   (b) the tibiofemoral alignment of the knee (varus/valgus) was defined by the angle between the tibial and the femoral anatomic longitudinal axes in the frontal plane of the femur;
   (c) the internal/external rotation of the femur with respect to the tibia was defined by the angle between the medial/lateral femoral and tibial axes in the transverse plane of the femur.

The ligamentous balance of each knee was measured in extension and 90° of flexion after completion of the bony cuts. An instrumented distraction instrument was placed between the cut surfaces of the femur and the tibia, and a fixed force of 44 N (10 lbf) was applied to distract the joint (Fig. 4). During distraction, the pivoting design of the tensometer allowed differential opening of the medial and lateral edges of the joint. During distraction, the medial and lateral separation of the tibia and femur were measured with the coordinate measuring system. Based on these measurements, the 'flexion gap' was defined as the mean separation of the joint surfaces under the distraction load with the knee fixed in 90° of flexion. The 'extension gap' was defined as the same measurements performed with the knee in full extension. The imbalance of each gap was assessed by measuring the angle between the cut tibial and femoral surfaces within the frontal plane.

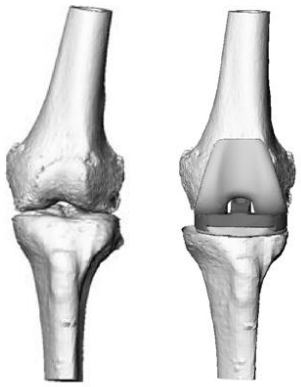


Fig. 3 Computer reconstructions of the knee joint before and after total knee replacement

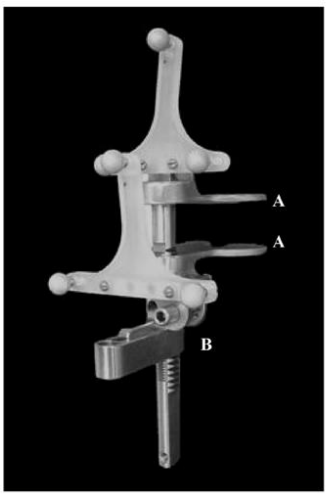


Fig. 4 Photograph of a navigated joint distraction device. The metal plates (A) are placed within the joint space and are separated by turning the rack and pinion mechanism (B) with a torque wrench until a total distraction resistance of 44 N is developed between the femur and the tibia. The distraction plates are free to angulate to allow for unequal opening of the medial and lateral compartments

3 RESULTS

3.1 Final limb alignment

One primary outcome variable defining the technical goals of this procedure is the final limb alignment in full extension. Post-arthroplasty, tibiofemoral alignment increased by an average of $2.1 \pm 5.8^\circ$ of varus with a range of 10.8° of valgus to 8.2° of varus with respect to the initial, preoperative alignment. In every specimen, the tibia was placed in more external rotation than in the intact knee, with postoperative external rotation ranging from 0.7 to 12.8° (average value $5.6 \pm 4.3^\circ$). In addition, the postoperative tibia was shifted 3.1 ± 4.9 mm medially and 13.9 ± 9.7 mm posteriorly in relation to the femur, and the tibiofemoral joint space was increased 4.7 ± 3.1 mm relative to the intact knee.

3.2 Soft tissue balancing

Another primary outcome variable is the balance of the flexion and extension gaps. Gap measurements were taken with 44 N (10 lbf) of force spreading the joint open. The average extension gap was 13.9 ± 5.9 mm and the average flexion gap was 18.6 ± 6.8 mm. Within each surgery, the average difference between the flexion and extension gap distance was 4.6 mm more flexion gap, with a range of 0.3 mm tight in flexion to 8.0 mm tight in extension. Only 1 out of 12 surgeries is within a 1 mm acceptability range in difference in the flexion/extension laxities, with all others more lax in flexion. If 2 mm of difference in the medial and lateral gaps is considered acceptable varus/valgus laxity, two out of 12 knees were satisfactory in extension and two out of 12 knees were satisfactory in flexion. It should be noted that these were not the same two knees. On average, the extension gap was lax laterally 4.1 ± 2.1 mm and the flexion gap was lax laterally 3.8 ± 3.4 mm. In 58 per cent of the knees, there was greater asymmetry in medial–lateral joint space opening in extension than in flexion.

3.3 Femoral preparation

The alignments of the femoral intramedullary rod, the anterior cutting block, the distal cutting block, and the final component were measured relative to the femur. The knees in this study had an average of $7.5 \pm 1.5^\circ$ anatomic valgus prior to surgical preparation. Post-operatively, the femoral component was positioned in $2.2 \pm 5.2^\circ$ of flexion, $1.0 \pm 4.4^\circ$ valgus, and $0.2 \pm 2.4^\circ$ of external rotation with respect to the mechanical and medial/lateral axes of the femur.

The alignments of the femoral instruments were measured during the surgical procedure. On average, errors in the insertion point of the intramedullary rod caused it to be positioned 1.2 ± 3.2 mm lateral and 2.6 ± 8.4 mm posterior to the projection of the actual intramedullary axis on the distal femur. In alignment, the intramedullary rod was angled $0.7 \pm 3.6^\circ$ anterior (flexion) and $6.2 \pm 2.1^\circ$ lateral (varus) to the anatomic axis. In the sagittal plane, the anterior cutting guide was positioned in $2.4 \pm 6.2^\circ$ of flexion and the distal cutting was positioned in $3.7 \pm 6.1^\circ$ of flexion. In the transverse plane, both the anterior cutting guide and the posterior cutting guide were externally rotated $2.7 \pm 12.1^\circ$ and $2.2 \pm 12.4^\circ$ respectively. The distal femoral cutting guide was positioned in $1.1 \pm 2.0^\circ$ varus. While the mean values for these alignments are not far from the intended configuration, the extreme variability should be noted (Table 1).

3.4 Tibial preparation

The alignments of the tibial extramedullary rod, the tibial stem punch, and the final component were

Table 1 Instrument and component alignment errors

	Goal	Mean	Standard deviation	Minimum	Maximum
Tibial EM rod					
(+)varus/(−)valgus (deg)	0	−0.1	3.1	−5.8	3.9
(+)anterior/(−)posterior slope (deg)	−3	−4.4	3.8	−13.0	1.2
(+)medial/(−)lateral position (mm)	0	1.4	13.9	−21.5	27.2
Tibial punch					
(+)internal/(−)external rotation (deg)	0	−8.1	14.5	−39.4	16.3
Distal femoral cutting guide					
(+)varus/(−)valgus (deg)	0	1.1	2.0	−1.8	3.2
(+)internal/(−)external rotation (deg)	0	−2.2	12.4	−22.5	27.7
(+)flexion/(−)extension (deg)	0	3.7	6.1	−5.6	12.2
Anterior femoral cutting guide					
(+)internal/(−)external rotation (deg)	0	−2.7	12.1	−22.5	26.1
(+)flexion/(−)extension (deg)	0	2.4	6.2	−6.9	11.9
Femoral intramedullary rod					
(+)medial/(−)lateral position (mm)	0	−1.2	3.2	−9.1	2.8
(+)anterior/(−)posterior position (mm)	0	−2.6	8.4	−19.9	12.4
(+)varus/(−)valgus (deg)	0	6.1	2.1	2.1	8.6
(+)flexion/(−)extension (deg)	0	0.7	3.6	−5.5	6.8
Femoral component					
(+)flexion/(−)extension (deg)	0	2.2	5.2	−8.5	9.3
(+)varus/(−)valgus (deg)	0	1.0	4.4	−6.5	8.9
(+)internal/(−)external rotation (deg)	0	−0.2	2.4	−3.0	3.2
Tibial component					
(+)anterior/(−)posterior slope (deg)	−3	−1.2	3.2	−5.9	5.8
(+)varus/(−)valgus (deg)	0	2.2	2.0	−1.6	6.5
(+)internal/(−)external rotation (deg)	0	−7.4	13.2	−32.6	13.6

measured relative to the anatomic and medial/lateral axes of the tibia. Post-operatively, the tibial component was aligned in $1.2 \pm 3.2^\circ$ of posterior slope, $2.2 \pm 2.0^\circ$ varus, and $7.4 \pm 13.2^\circ$ of external rotation relative to the tibia. The intraoperative measurement of the extramedullary cutting guide showed it positioned in $0.1 \pm 3.1^\circ$ of valgus and $4.4 \pm 3.8^\circ$ of posterior slope. In addition, the cutting guide was positioned 1.4 ± 13.9 mm medially to the centre of the tibia plateau. The tibial stem punch was inserted externally rotated $8.1 \pm 14.5^\circ$ (Table 1).

3.5 Performance evaluation

A system that quantitatively assesses all alignment aspects of TKR allows objective performance evaluations of the most critical aspects of the procedure. For example, Fig. 4 shows a performance plot for two variables critical to successful total knee replacement. Because healthy knees were used for this study, a desired alignment outcome was the restoration of the preoperative varus/valgus alignment. The post-operative change is plotted versus the amount of imbalance in the extension gap. Quantitative criteria can then be applied to assess performance. For example, one standard might be that the varus/valgus angle should not be more than 3° in either direction from normal healthy alignment and that the difference in the medial and lateral measurement of the extension gap should not be more than 3 mm. Only three out of 12 surgeries met these criteria, as shown in Fig. 5.

Similarly, the accuracy of instrument alignment can be quantified. Figure 6 shows a performance plot of the posterior slope of the extramedullary tibial cutting guide versus the flexion of the intramedullary

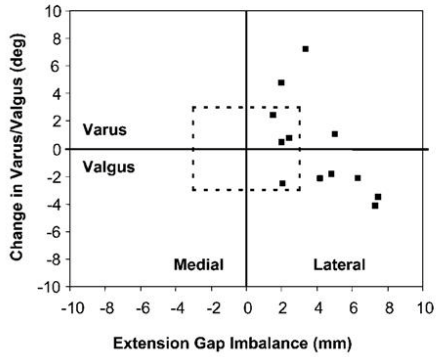


Fig. 5 Data points recorded from the 12 surgeons participating in this study, superimposed on a performance plot of the change in the tibiofemoral varus/valgus alignment versus the extension gap imbalance during application of a fixed distraction force. The outlined area represents the zone of acceptable performance for these performance metrics

Appendix B – Preference Files

SetupVerificationFemur: Welcome message and trial that can be used to verify the correctness of the initial Administration|EditBoneData and Administration|EditToolData through real time display of bones and instrumentation. Trials are 15 seconds long and are autosaved as STrainerSetupVerificationxxxx.

PreOpAlignment: This preference file displays a message that a neutral alignment recording will be performed. After the recording the bones are displayed with their software generated mechanical axis (femur) and anatomical axis (femur and tibia). Also, the derived coordinate systems for the bones are displayed (Figure X.X).

PreOpROM: This preference file displays a biofeedback window with flexion angle and rotation angle graphs. Trial will terminate after maximum flexion is reached and the knee joint is returned to less than 15 degrees of flexion. Playback is automatic with flexion/extension and varus/valgus graphs together with rollback information. The surgeon is prompted to specify targets that must be recorded in the report.

IntactLaxity00, 30, 60, 90: The purpose of these files is to collect displacement information about the joint when a specified toque is applied. Displacement indicates how tight or lax the joint is prior to surgical intervention. This preference file will take the surgeon through a series of trials in which the shank is flexed to specific angles (full extension, 30°, 60° and 90°). First internal and external rotation tests are performed with a 5 Nm applied torque, then varus and valugus tests at 10 Nm of applied torque. The user is provided a visual and auditory signal indicating when the proper combination of flexion and torque is achieved and the trial ends automatically when the appropriate conditions are met. Rotational displacement at target torque is the output.

IMInsertionAxis: Records trial with no feedback to compute deviation between the 'ideal' (software computed) femoral IM rod insertion point and the actual insertion point. Output data includes AP and ML insertion errors and AP and ML angle errors. The IM rod tool is used to take this measurement.

DistalCuttingGuide: determines the orientation of the femoral distal cutting guide relative to the femoral anatomical axis. Orientation of the guide is reported in terms of flexion/extension and varus/valgus. The plane jig tool is used to take this measurement.

FemurDistalCut: determines the orientation of the femoral distal cut relative to the femoral anatomical axis. Orientation of the cut is reported in terms of flexion/extension and varus/valgus. In addition, the distance from the plane of the tool to the most distal point of the medial and lateral condyles is computed and reported as a measure of depth of resection. The plane jig tool is used to take this measurement.

PosteriorCuttingGuide: determines the orientation of the femoral 4-in-one cutting guide (used to make the posterior cut of the condyles) relative to the femoral anatomical axis. Orientation of the guide is reported in terms of flexion/extension and internal/external rotation. The plane jig tool is used to take this measurement.

PosteriorCut: determines the orientation of the posterior condylar cut relative to the femoral anatomical axis. Orientation of the cut is reported in terms of flexion/extension and internal/external rotation. Additionally, the distance from the plane of the tool to the most posterior point of the medial and lateral condyles is computed and reported as a measure of the depth of resection. The plane jig tool is used to take this measurement.

TibiaCuttingGuide: determines the orientation of the tibial cutting guide relative to the tibial anatomical axis. Orientation of the guide is reported in terms of flexion/extension and varus/valgus. The plane jig tool is used to take this measurement.

TibiaCut: determines the orientation of the tibial cut relative to the tibial anatomical axis. Orientation of the cut is reported in terms of flexion/extension and varus/valgus. Additionally, the distance from the plane of the tool to the tibial plateau is computed and reported as the depth of resection. The plane jig tool is used to take this measurement.

TibialComponentPlacement: determines the internal/external rotational orientation of the tibial component. The plane jig is used to take this measurement.

PostOpAlignment: This preference file displays a message that a neutral alignment recording will be performed. After the recording the bones are displayed with the femoral and tibial components.

PostOpROM: This preference file displays a biofeedback window with flexion angle and rotation angle graphs. Trial will terminate after maximum flexion is reached and the knee joint is returned to less than 15 degrees of flexion. Playback is automatic with flexion/extension and varus/valgus graphs together with rollback information.

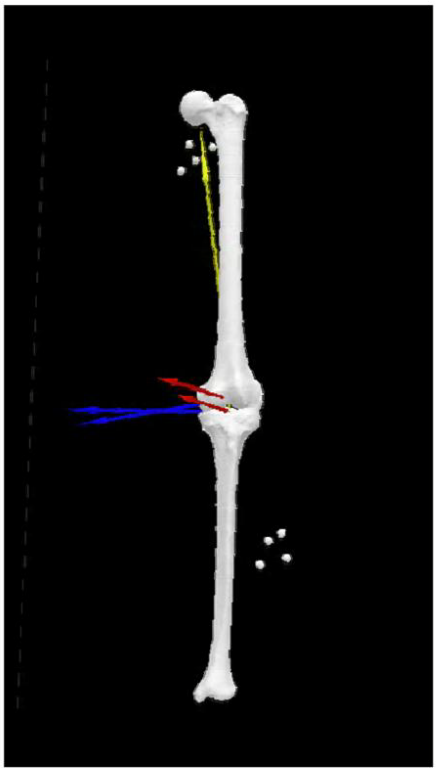
ImplantLaxity00, 30, 60, 90: The purpose of these files is to collect displacement information about the joint when a specified toque is applied. Displacement indicates how tight or lax the joint is prior to surgical intervention. This preference file will take the surgeon through a series of trials in which the shank is flexed to specific angles (full extension, 30°, 60° and 90°). First internal and external rotation tests are performed with a 5 Nm applied torque, then varus and valugus tests at 10 Nm of applied torque. The user is provided a visual and auditory signal indicating when the proper combination of flexion and torque is achieved and the trial ends automatically when the appropriate conditions are met. Rotational displacement at target torque is the output.

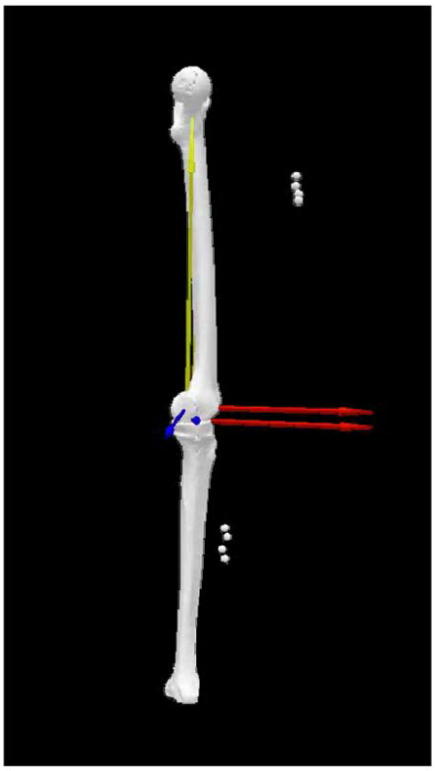
Appendix C – Sample Report

Surgeon	Charles
SAB	Sawbone2
Surgical Station	4
Date	10/2/2009

PreOperative Limb Alignment

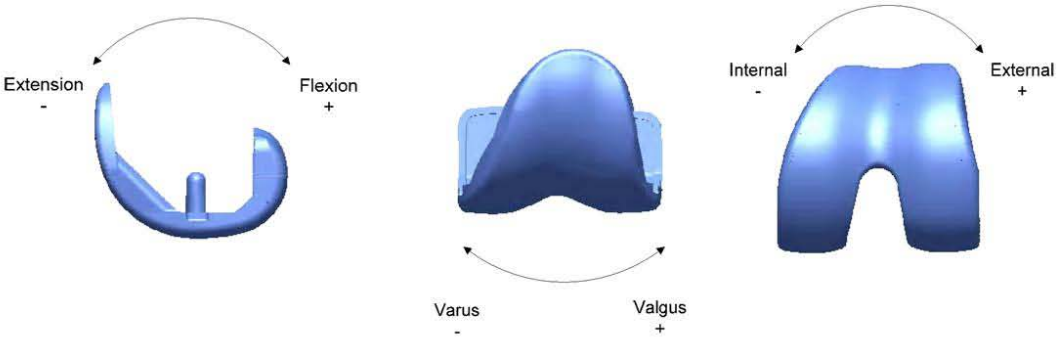
Flexion Angle (°)	**0.7 °**	**Angulation (Valgus+/Varus-)**	**-8.9 °**
Rotation (Ext+/Int-)	**6.7 °**	**Posterior Tibial Slope**	**5.0 °**



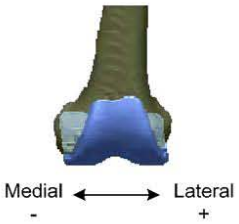


Alignment Accuracy

Femoral Component:

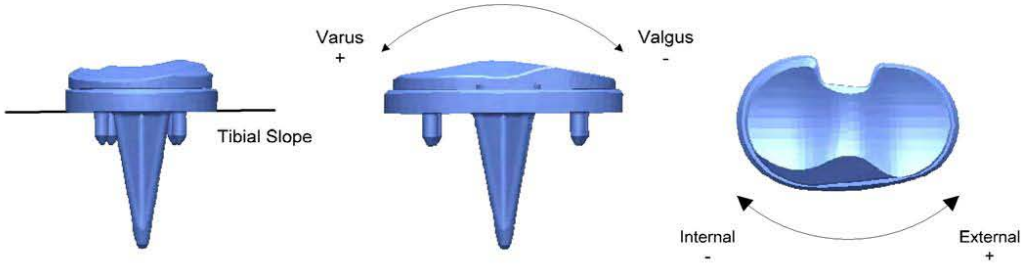


Flexion (°)		Valgus Angulation (°)		External Rotation (°)	
Target	0	Target	5	Target	3
Actual	-2.1	Actual	3.4	Actual	4.9



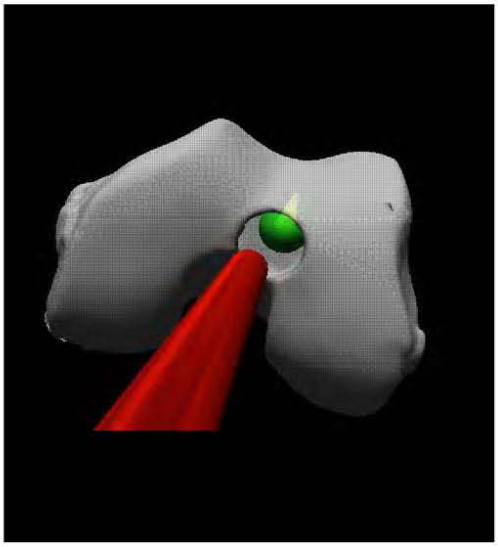
Lateral Displacement (mm)
-2.1

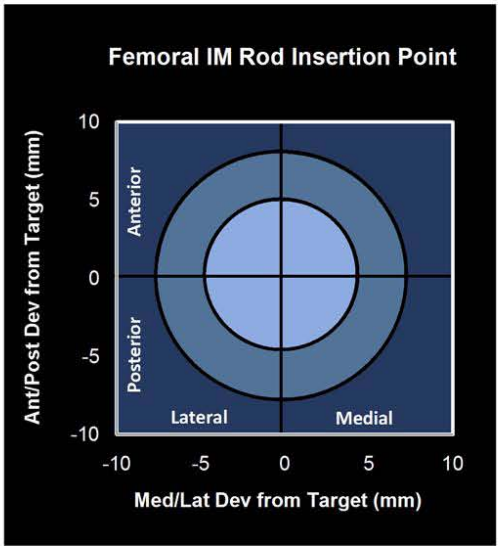
Tibial Component:



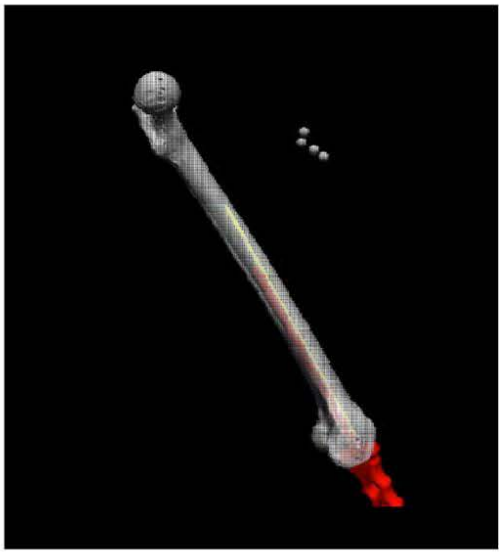
Posterior Tibial Slope (°)		Varus Angulation (°)		External Rotation (°)	
Target	5	Target	0	Target	0
Actual	0.9	Actual	0.6	Actual	7.7

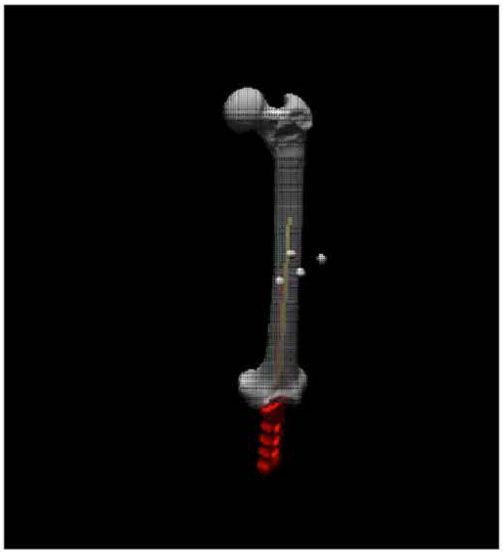
Deviations From Planned



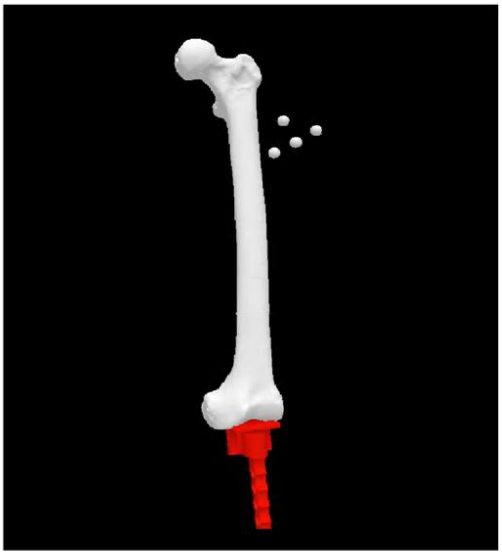


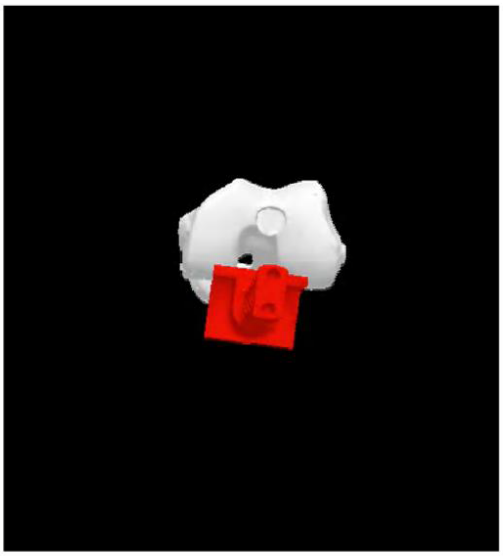
Med/Lat (mm)	5.9	Ant/Post (mm)	-11.9

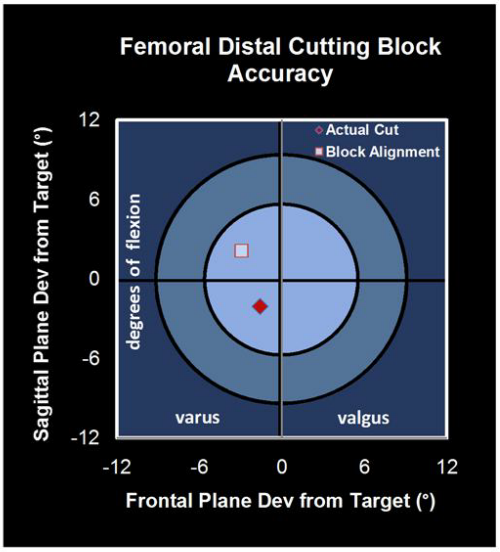


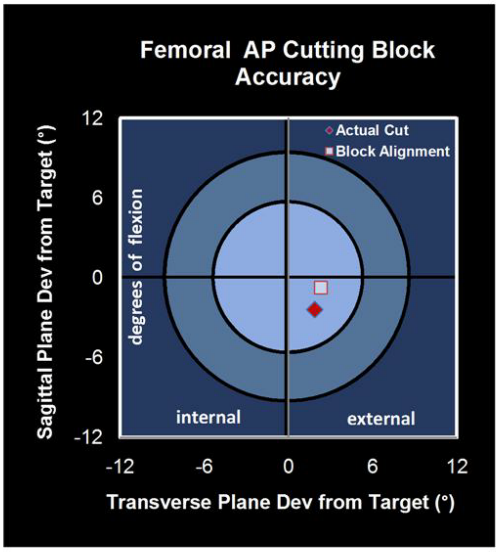


IM Rod Ant/Post Deviation	0.35 °	IM Rod Med/Lat Deviation	-1.30 °



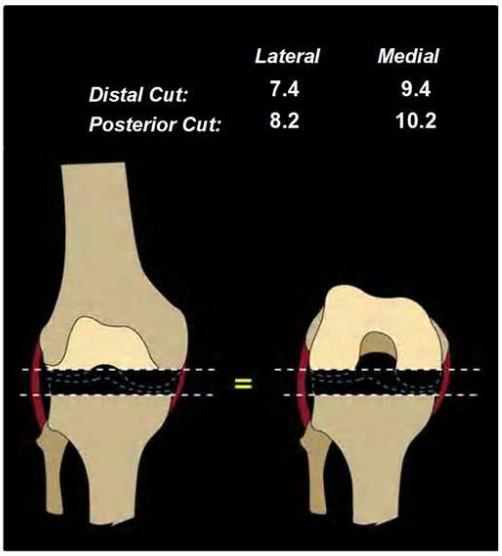


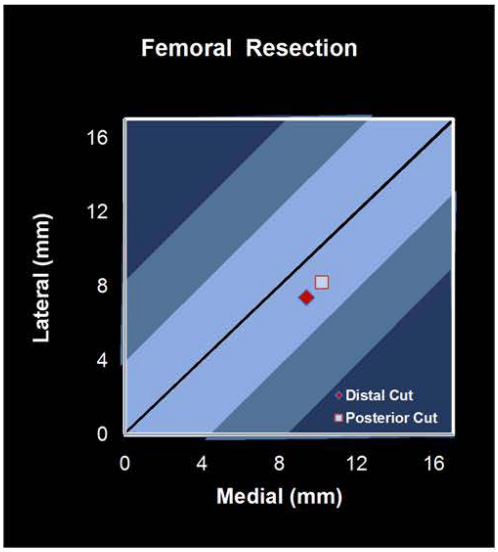




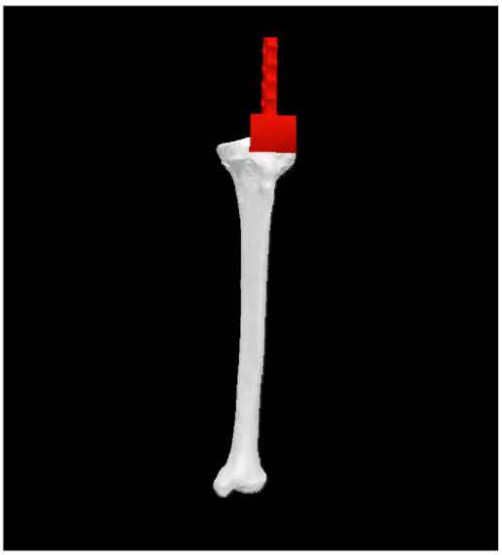
Femoral Distal Cut Accuracy		
	Targets	Relative Guide Alignment
Flexion	0.0 °	2.1 °
Valgus Angulation	5.0 °	2.9 ° (varus)
	Targets	Relative Cut Alignment
Flexion	0.0 °	-2.1 °
Valgus Angulation	5.0 °	1.6 ° (varus)

Femoral A/P Cut Accuracy		
	Targets	Relative Guide Alignment
Flexion	0.0 °	-0.7 °
External Rotation	3.0 °	2.3 ° (external)
	Targets	Relative Cut Alignment
Flexion	0.0 °	-2.4 °
External Rotation	3.0 °	1.9 ° (external)



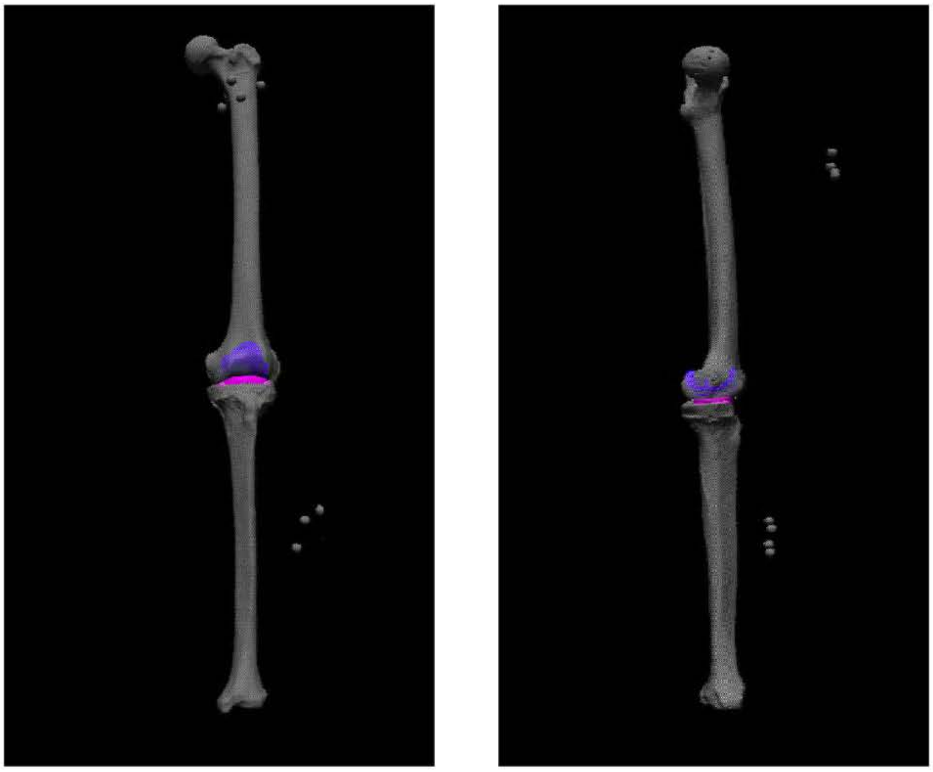


Resection (mm)	Lateral	Medial
Distal Cut	7.4	9.4
Posterior Cut	8.2	10.2



Tibial Preparation		
	Targets	Relative Guide Alignment
Posterior Slope	5.0 °	2.5 ° (anterior)
Varus Angulation	0.0 °	1.1 ° (varus)
		Relative Cut Alignment
Posterior Slope	5.0 °	4.1 ° (anterior)
Varus Angulation	0.0 °	0.6 ° (varus)
		Actual Cut
External Rotation	0.0 °	7.7 ° (external)

Resection (mm)	Lateral	Medial
Tibial Cut	10.0	7.2



PostOperative Limb Alignment		
	Absolute	Change
Flexion Angle (°)	-3.0 °	-3.7 °
Rotation (Ext+/Int-)	-0.4 °	-7.1 °
Angulation (Valgus+/Varus-)	-5.1 °	3.8 °
Tibial Slope	0.9 °	-4.1 °

Appendix D – Supporting Instrumentation Developed and Fabricated In-House

Interchangeable Flag System

A flag system (base to attach reflective markers) was needed to track the three dimensional positioning of measurement tools, bones and prosthetic implants during surgical training sessions. Several criteria needed to be met in terms of marker array flags used for tracking: (a) that marker arrays be rigidly attached, (b) there needed to exist at least 19 unique flag array combinations with sufficient variability so as to be recognized as unique by the camera system, (c) a marker array needed to consist of no less than 3 markers with no camera system limitation for the maximum, (d) the marker array needed to be sufficiently small as to not interfere with the surgery and (e) the marker array base needed to have dimension (i.e. not be a flat surface). Markers attach to rigid posts which interface with the threaded holes in the base. Figure D.1 illustrates the CAD and physical models of the interchangeable flag system. The flag was fabricated with a CNC vertical machining center (HAAS, Oxnard, CA).

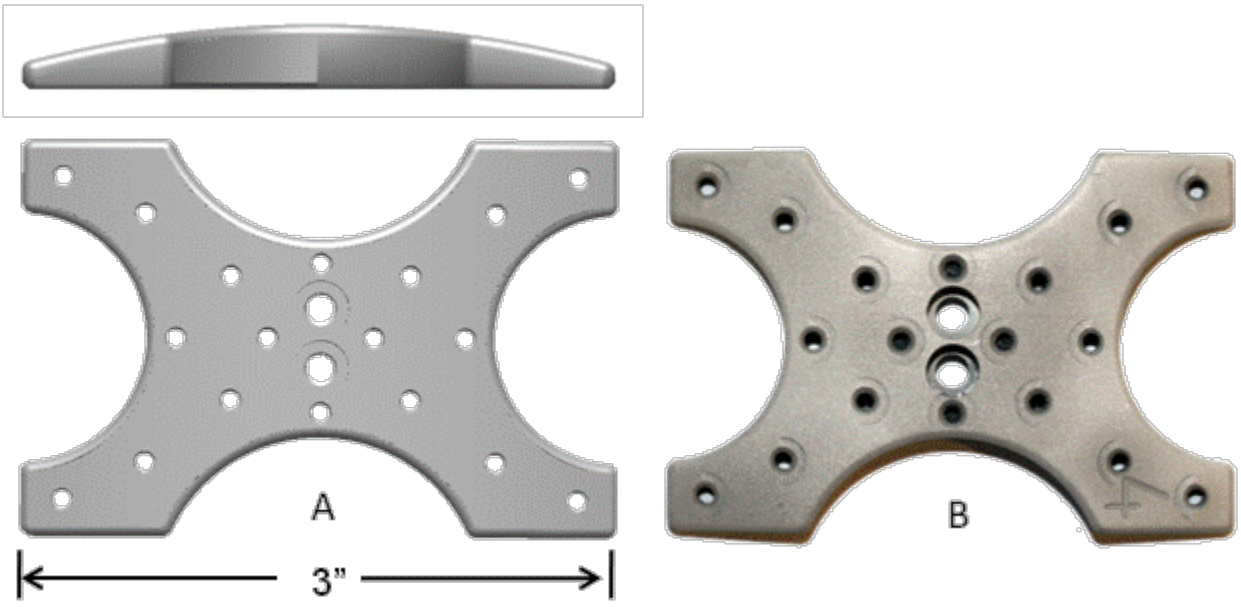


Figure D.1. Interchangeable flag system (A) CAD model (B) physical model

Detachable Mounting Plates for Cadaveric Flags and Sawbone Models

The detachable mounting plates were designed to meet the challenge of storing and performing CT scans of the specimens prior to the training sessions. To ensure accuracy, there could exist no deviation in the position of the marker flag array between the time of specimen CT and the surgical training session. Additionally, the markers themselves had to be removed prior to freezing the specimen after the CT was performed. A system was created to allow the marker array flag to detach from the bone with the ability to reattach the flag in the same position for the surgical trial. The system consists of a bone plate which is rigidly attached to the bone or sawbone (Figure D.2 (A)). The universal flag mates to

a post that mates to the bone plate (Figure D.2 (B) and (C)). The bone plates were fabricated with a CNC milling machine.

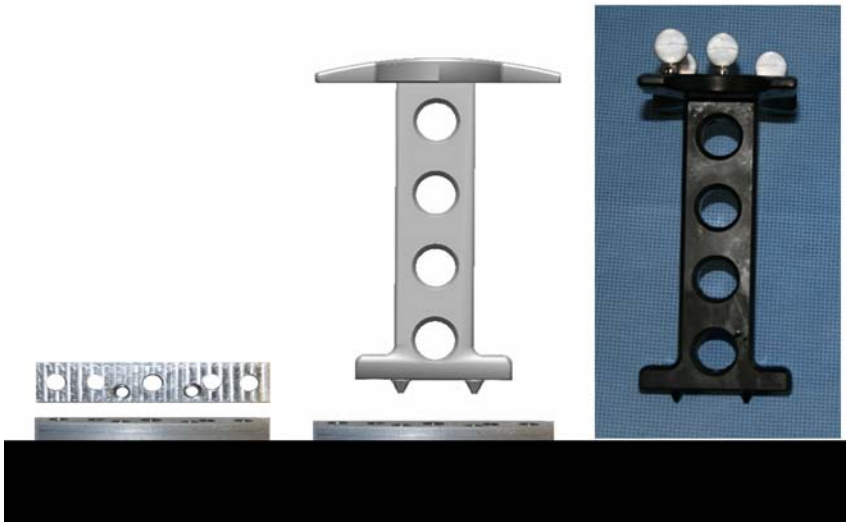


Figure D.2. Detachable mounting system: (A) bone plate, (B) bone plate, post and universal flag CAD model and (C) physical model with reflective markers attached.

Positional Tracking Tools

Two positional tools, the plane jig and intramedullary (IM) rod, were designed and fabricated on the CNC vertical machining center (HAAS, Oxnard, CA) to track and determine the position/orientation of the surgical cuts, surgical instrument placement and implant component placement. The plane jig (Figure 2.3) has two faces (planes) available for measurement. Either plane can be used to take any measurement. The plane jig has an assigned coordinate system in the software so the appropriate measurement is computed by determining the plane jig position with respect to anatomical landmarks defined by the software. The IM rod (Figure 2.4) is the positional tool used to locate the position of the drilled canal on the femur to allow the insertion of the surgical IM Rod (Figure 2.5). The IM rod, like the plane jig, has an assigned coordinate system in the software so that the appropriate measurement is computed by determining the IM rod orientation relative to femoral landmarks defined by the software.

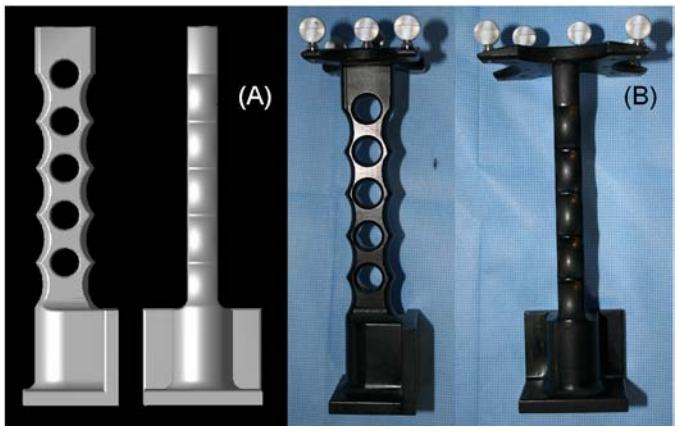


Figure 2.3. Plane jig positional measurement tool: (A) CAD model and (B) physical model with marker flag attached.

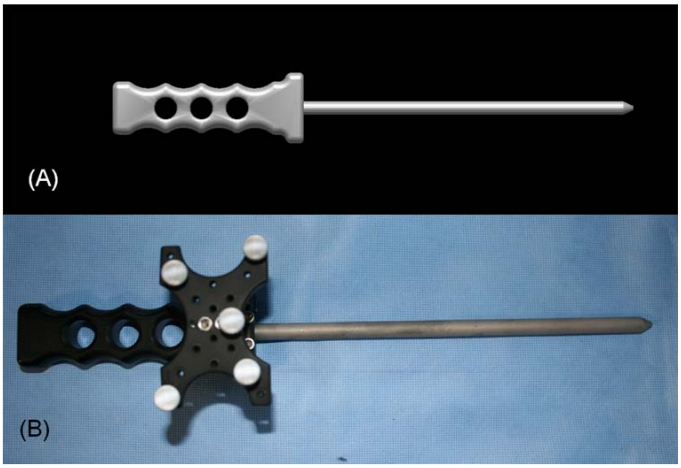
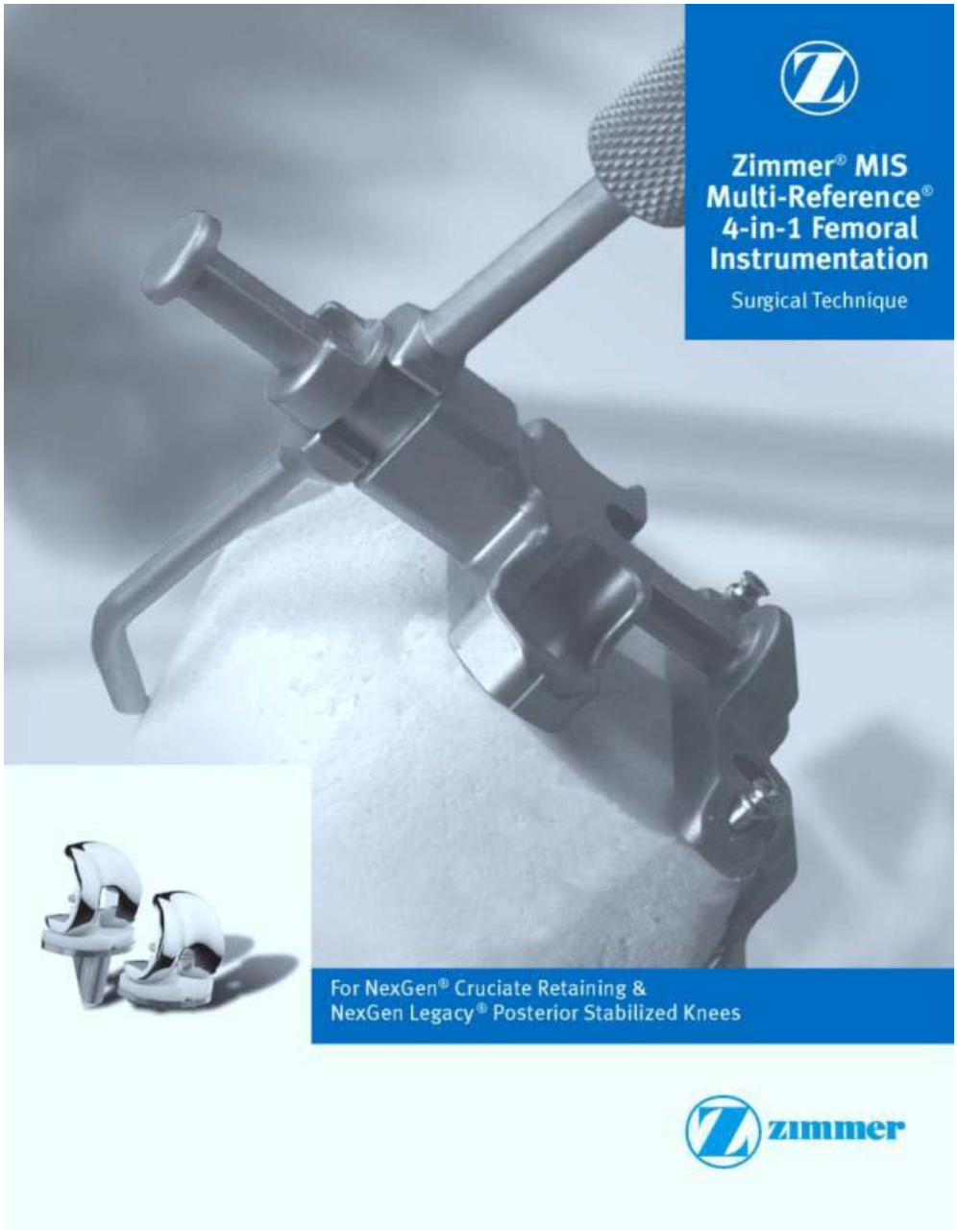


Figure 2.4. IM rod positional measurement tool: (A) CAD model and (B) physical model with marker flag attached.

Figure 2.5 Surgical IM Rod.

Appendix E – Zimmer Nex-Gen Surgical Technique

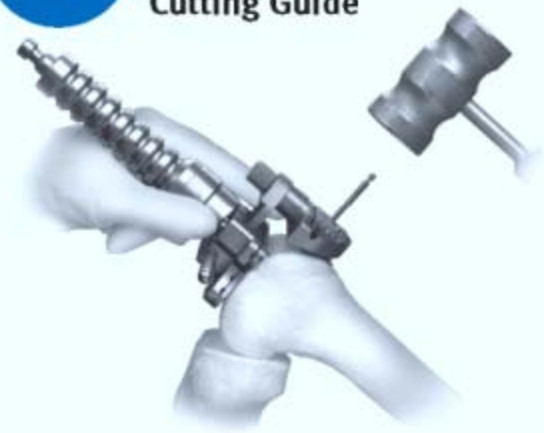


Surgical Technique For MIS Multi-Reference 4-in-1 Femoral Instrumentation

Table of Contents

1 Drill 8mm Pilot Hole

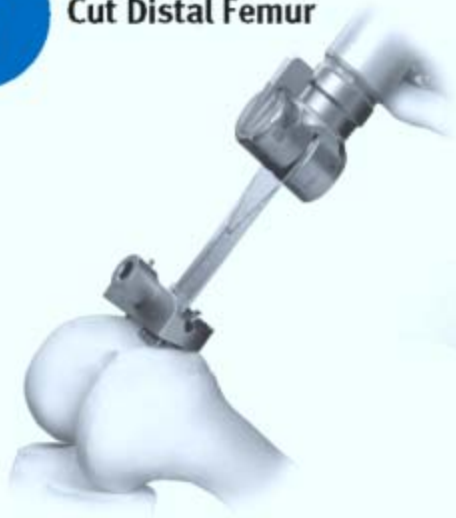
2 Insert and Secure Mini Distal Femoral Cutting Guide



5a Set External Rotation (Anterior Referencing)

5b Set External Rotation (Posterior Referencing)

3 Cut Distal Femur

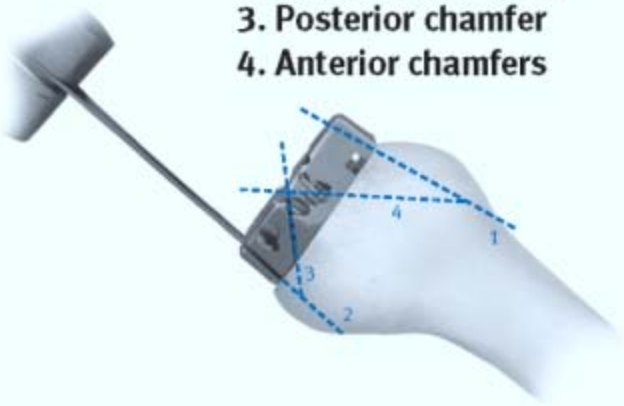


4 Size the Femur

6 Place Femoral Finishing Guide; Adjust M/L & Pin (Anterior Referencing)

7 Finish the Femur

1. Anterior condyles
2. Posterior condyles
3. Posterior chamfer
4. Anterior chamfers



Introduction

Successful total knee arthroplasty depends in part on re-establishment of normal lower extremity alignment, proper implant design and orientation, secure implant fixation, and adequate soft tissue balancing and stability. The *NexGen* Complete Knee Solution and *Multi-Reference* 4-in-1 Instruments are designed to help the surgeon accomplish these goals by combining optimal alignment accuracy with a simple, straight-forward technique.

The instruments and technique assist the surgeon in restoring the center of the hip, knee, and ankle to lie on a straight line, establishing a neutral mechanical axis. The femoral and tibial components are oriented perpendicular to this axis. Femoral rotation is determined using the posterior condyles or epicondylar axis as a reference. The instruments promote accurate cuts to help ensure secure component fixation. Ample component sizes allow soft tissue balancing with appropriate soft tissue release.

The femur, tibia, and patella are prepared independently, and can be cut in any sequence using the principle of measured resection (removing enough bone to allow replacement by the prosthesis). Adjustment cuts may be needed later.

The *Multi-Reference* 4-in-1 instruments provide a choice of either anterior or posterior referencing techniques for making the femoral finishing cuts. The anterior referencing technique uses the anterior cortex to set the A/P position of the femoral component. The posterior condyle cut is variable. The posterior referencing technique uses the posterior condyles to set the A/P position of the femoral component. The variable cut is made anteriorly.

The Mini-Incision TKA technique has been developed to combine the alignment goals of total knee arthroplasty with less disruption of soft tissue. To accommodate this technique, some of the original *Multi-Reference* 4-in-1 Instruments have been modified. However, if preferred, a standard incision can be used with the instruments. Prior to using a smaller incision, the surgeon should be familiar with implanting *NexGen* components through a standard incision.

Total knee arthroplasty using a less invasive technique is suggested for nonobese patients with preoperative flexion greater than 90°. Patients with varus deformities greater than 17° or valgus deformities greater than 13° are typically not candidates for an MIS technique.

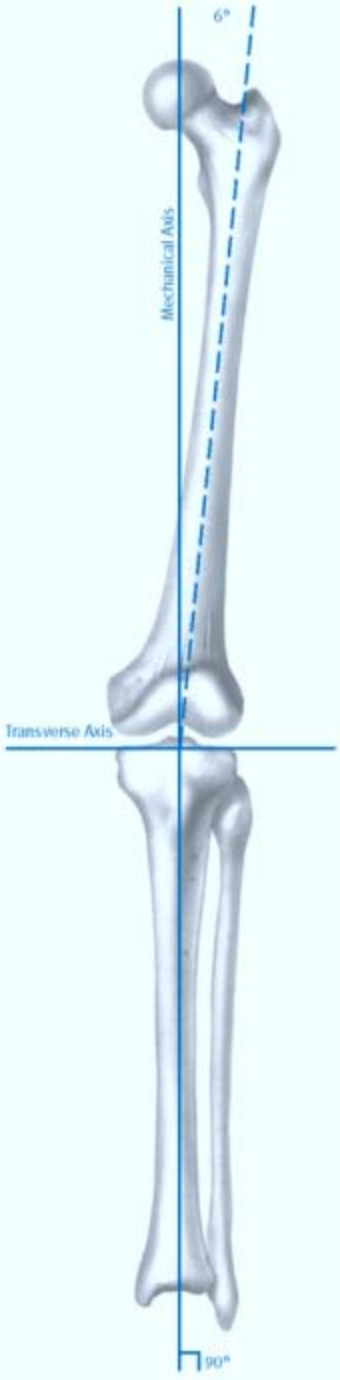
Please refer to the package inserts for complete product information, including contraindications, warnings, precautions, and adverse effects.

Preoperative Planning

Use the template overlay (available through your Zimmer Representative) to determine the angle between the anatomic axis and the mechanical axis. This angle will be reproduced intraoperatively. This surgical technique helps the surgeon ensure that the distal femur will be cut perpendicular to the mechanical axis and, after soft tissue balancing, will be parallel to the resected surface of the proximal tibia.

Surgical Approach

The femur, tibia, and patella are prepared independently, and can be cut in any sequence using the principle of measured resection (removing enough bone to allow replacement by the prosthesis). Adjustment cuts may be needed later.



Patient Preparation

To prepare the limb for MIS total knee arthroplasty, adequate muscle relaxation is required. This may be accomplished with a short-acting, nondepolarizing muscle relaxant. The anesthesiologist should adjust the medication based on the patient's habitus and weight, and administer to induce adequate muscle paralysis for a minimum of 30-40 minutes. It is imperative that the muscle relaxant be injected prior to inflation of the tourniquet. Alternatively, spinal or epidural anesthesia should produce adequate muscle relaxation.

If desired, apply a proximal thigh tourniquet and inflate it with the knee in hyperflexion to maximize that portion of the quadriceps that is below the level of the tourniquet.

Once the patient is draped and prepped on the operating table, determine the landmarks for the surgical incision with the leg in extension.

Incision and Exposure

The incision may be made with the leg in extension or flexion depending on surgeon preference. The surgeon can choose a midvastus approach, a subvastus approach, or a parapatellar medial arthrotomy. Also, depending on surgeon preference, the patella can be either everted or subluxed.

The length of the incision is dependent on the size of the femoral component needed. Although the goal of a MIS technique is to complete the surgery with an approximately 10cm-14cm incision, it may be necessary to extend the incision if visualization is inadequate or if eversion of the patella is not possible without risk of avulsion at the tibial tubercle. If the incision must be extended, it is advisable to extend it gradually and only to the degree necessary. The advantage of a MIS technique is dependent on maintaining the extensor mechanism insertion.

Make a slightly oblique parapatellar skin incision, beginning approximately 2cm proximal and medial to the superior pole of the patella, and extend it approximately 10cm to the level of the superior patellar tendon insertion at the center of the tibial tubercle (Fig. 1). Be careful to avoid disruption of the tendon insertion. This will facilitate access to the vastus medialis obliquis, and allow a minimal split of the muscle. It will also improve visualization of the lateral aspect of the joint obliquely with the patella everted. The length of the incision should be about 50% above and 50% below the joint line. If the length of the incision is not distributed evenly relative to the joint line, it is preferable that the greater portion be distal.

Divide the subcutaneous tissue to the level of the retinaculum.

NOTE: Using electrocautery to complete the exposure will help minimize bleeding after deflation of the tourniquet, as well as late muscle bleeding.

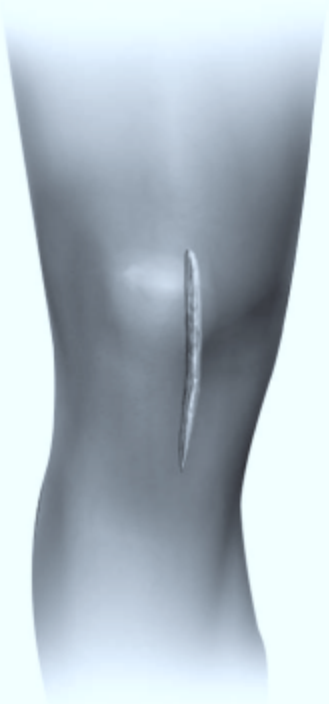


Fig. 1

MIS Midvastus Approach

Make a medial parapatellar incision into the capsule, preserving approximately 1cm of peritenon and capsule medial to the patellar tendon. This is important to facilitate complete capsular closure.

Split the superficial enveloping fascia of the quadriceps muscle percutaneously in a proximal direction over a length of approximately 6cm. This will mobilize the quadriceps and allow for significantly greater lateral translation of the muscle while minimizing tension on the patellar tendon insertion.

Split the vastus medialis obliquis approximately 1.5cm-2cm (Fig. 2).

Use blunt dissection to undermine the skin incision approximately 1cm-2cm around the patella.

Slightly flex the knee and remove the deep third of the fat pad.

The patella can be either everted or subluxed. If everting the patella, release the lateral patellofemoral ligament to facilitate full eversion and lateral translation of the patella. Then use hand-held three-pronged or two-pronged hooks to begin to gently evert the patella. Be careful to avoid disrupting the extensor insertion. To help evert the patella, slowly flex the joint and externally rotate the tibia while applying gentle pressure. Once the patella is everted, use a standard-size Hohmann retractor or two small Hohmann retractors along the lateral flare of the tibial metaphysis to maintain the eversion of the patella and the extensor mechanism.

NOTE: It is imperative to maintain close observation of the patellar tendon throughout the procedure to ensure that tension on the tendon is minimized, especially during eversion of the patella and positioning of the patient.

Remove any large patellar osteophytes.

Release the anterior cruciate ligament, if present. Perform a subperiosteal dissection along the proximal medial and lateral tibia to the level of the tibial tendon insertion. Then perform a limited release of the lateral capsule (less than 5mm) to help minimize tension on the extensor mechanism.

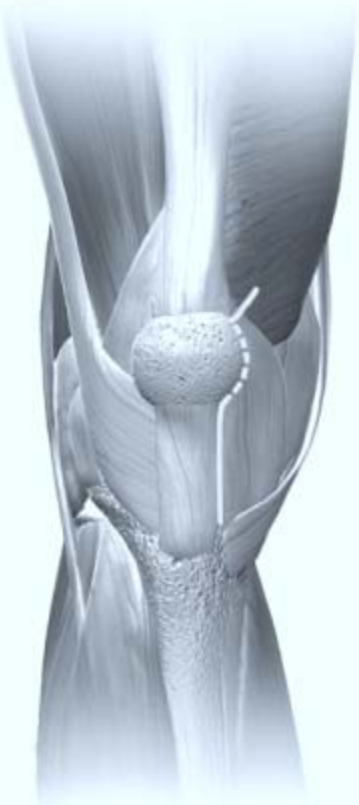


Fig. 2

MIS Subvastus Approach

The subvastus medial arthrotomy has been slightly modified to optimize minimally invasive surgery. It provides excellent exposure for TKA while preserving all four attachments of the quadriceps to the patella. This approach does not require patellar eversion, minimizes disruption of the suprapatellar pouch, and facilitates rapid and reliable closure of the knee joint.

Dissect the subcutaneous tissue down to but not through the fascia that overlies the vastus medialis muscle.

Identify the inferior border of the vastus medialis muscle, and incise the fascia at approximately 5cm to 8cm medial to the patellar border (Fig. 3) to allow a finger to slide under the muscle belly but on top of the underlying synovial lining of the knee joint. Use the finger to pull the vastus medialis obliquis muscle superiorly and maintain slight tension on the muscle.

Use electrocautery to free the vastus medialis from its confluence with the medial retinaculum, leaving a small cuff of myofascial tissue attached to the inferior border of the vastus medialis.

The tendonous portion of the vastus medialis extends distally to insert at the midpole of the medial border of the patella. Be careful to preserve that portion of the tendon to protect the vastus medialis muscle during subsequent steps. An incision along the inferior border of the vastus medialis to the superior pole of the patella will result in a tear, split, or maceration of the muscle by retractors. Incise the underlying synovium in a slightly more proximal position than is typical with a standard subvastus approach. This will allow a two-layer closure of the joint. The deep layer will be the synovium, while the superficial layer will be the medial retinaculum and the myofascial sleeve of tissue that has been left attached to the inferior border of the vastus medialis.

Carry the synovial incision to the medial border of the patella. Then turn directly inferiorly to follow the medial border of the patellar tendon to the proximal portion of the tibia. Elevate the medial soft tissue sleeve along the proximal tibia in a standard fashion.

Place a bent-Hohmann retractor in the lateral gutter and lever it against the robust edge of the tendon that has been preserved just medial and superior to the patella. Retract the patella and extensor mechanism into the lateral gutter. If necessary, mobilize the vastus medialis either from its underlying attachment to the synovium and adductor canal, or at its superior surface when there are firm attachments of the overlying fascia to the subcutaneous tissues and skin. Depending on surgeon preference, the fat pad can be excised or preserved.

Flex the knee. The patella will stay retracted in the lateral gutter behind the bent-Hohmann retractor, and the quadriceps tendon and vastus medialis will lie over the distal anterior portion of the femur. To improve visualization of the distal anterior portion of the femur, place a thin knee retractor along the anterior femur and gently lift the extensor mechanism during critical steps of the procedure. Alternatively, bring the knee into varying degrees of extension to improve visualization by decreasing the tension on the extensor mechanism.

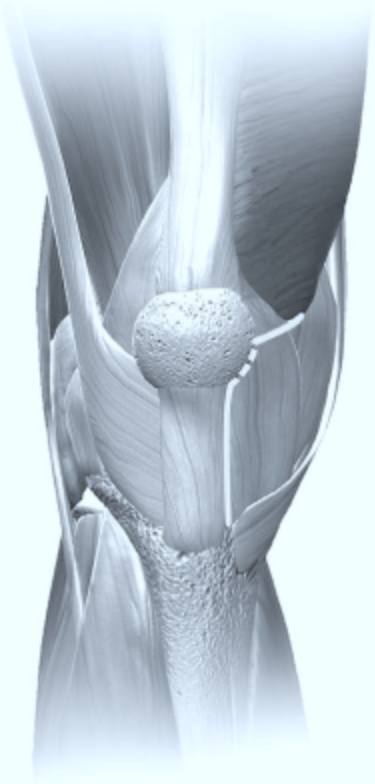


Fig. 3

MIS Medial Parapatellar Arthrotomy

Minimally invasive total knee arthroplasty can be performed with a limited medial parapatellar arthrotomy. Begin by making a 10cm-14cm midline skin incision from the superior aspect of the tibial tubercle to the superior border of the patella. Following subcutaneous dissection, develop medial and lateral flaps, and dissect proximally and distally to expose the extensor mechanism. This permits mobilization of the skin and subcutaneous tissue as needed during the procedure. In addition, with the knee in flexion, the incision will stretch 2cm-4cm due to the elasticity of the skin, allowing broader exposure.

The goal of minimally invasive surgery is to limit the surgical dissection without compromising the procedure. The medial parapatellar arthrotomy is used to expose the joint, but the proximal division of the quadriceps tendon should be limited to a length that permits only lateral subluxation of the patella without eversion (Fig. 4). Incise the quadriceps tendon for a length of 2cm-4cm initially. If there is difficulty displacing the patella laterally or if the patellar tendon is at risk of tearing, extend the arthrotomy proximally along the quadriceps tendon until adequate exposure is achieved.

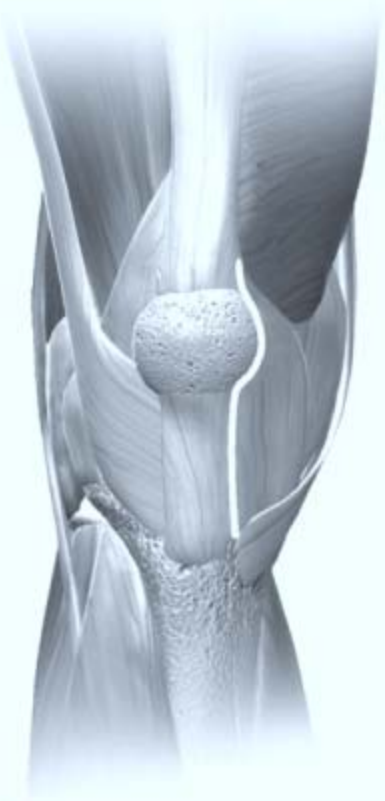


Fig. 4

Step One
Establish Femoral Alignment

Use the 8mm IM Drill w/Step to drill a hole in the center of the patellar sulcus of the distal femur (Fig. 1a), making sure that the drill is parallel to the shaft of the femur in both the anteroposterior and lateral projections. The hole should be approximately one-half to one centimeter anterior to the origin of the posterior cruciate ligament. Medial or lateral displacement of the hole may be needed according to preoperative templating of the A/P radiograph.

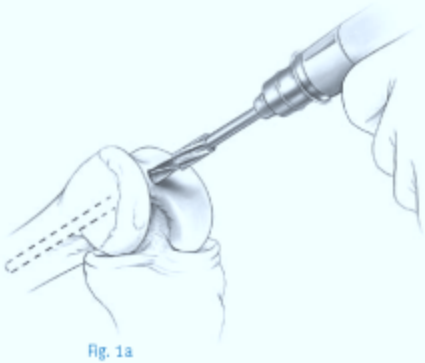


Fig. 1a

The step on the drill will enlarge the entrance hole on the femur to 12mm. This will reduce intramedullary pressure during placement of subsequent IM guides. Suction the canal to remove medullary contents.

The Mini Adjustable IM Alignment Guide is available with two intramedullary rod lengths. The rod on the standard instrument is 229mm (9 inches) long and the rod on the short instrument is 165mm (6.5 inches). Choose the length best suited to the length of the patient's leg, which will provide the most accurate reproduction of the anatomic axis. If the femoral anatomy has been altered, as in a femur with a long-stemmed hip prosthesis or with a femoral fracture malunion, use the Adjustable IM Alignment Guide, Short and use the optional extramedullary alignment technique.

NOTE: The Mini Adjustable IM Alignment Guide, Short (Fig. 1b) is a shortened version of the Mini Adjustable IM Alignment Guide, Long. When the Mini Standard Cut Plate is attached to the Mini Adjustable IM Alignment Guide, Short, the same amount of bone is removed as when it is attached to the Mini Adjustable IM Alignment Guide, Long. This is different than the original Multi-Reference 4-in-1, Micro IM Alignment Guide 165mm (6.5 inch) which was intended for use with Micro implants. When the Standard Cut Plate was attached, the Micro IM Alignment Guide removed one millimeter less distal bone than the standard Adjustable IM Alignment Guide with the Standard Cut Plate attached. The new Mini IM Alignment Guides accommodate the resection for the Micro implants with the Mini Micro Cut Plate.

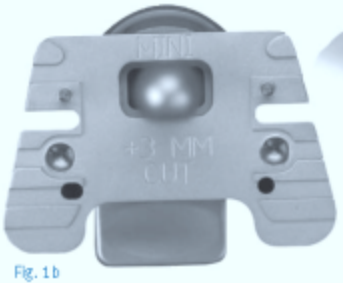


Fig. 1b

NOTE: It is preferable to use the longest intramedullary rod to help ensure the most accurate replication of the anatomic axis.

Set the Mini Adjustable IM Alignment Guide to the proper valgus angle as determined by preoperative radiographs. Check to ensure that the proper "Right" or "Left" indication (Fig. 1c) is used and engage the lock mechanism (Fig. 1d).

Fig. 1c

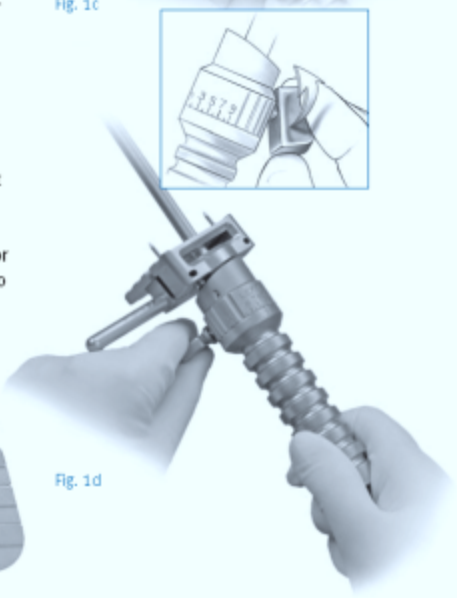


Fig. 1d

The Standard Cut Plate must be attached to the Adjustable IM Alignment Guide for a standard distal femoral resection. Use a hex-head screwdriver to tighten the plate on the guide prior to use (Figs. 1e & 1f), but the screws should be loosened for sterilization. If preferred, remove the Standard Cut Plate if a significant flexion contracture exists. This will allow for an additional 3mm of distal femoral bone resection.

NOTE: The Mini Micro Cut Plate can be used when templating has indicated that a Micro implant is likely. When the Mini Micro Cut Plate is attached to the MIS Adjustable IM Alignment Guide, Short, one millimeter (1mm) less bone is removed. However, if a significant flexion contracture exists and no plate is attached, an additional 4mm will be removed compared to the distal femoral cut when the Mini Micro Cut Plate is attached. For less bone resection, adjustments can be made using the +2mm/-2mm holes on the Mini Distal Cut Guide.

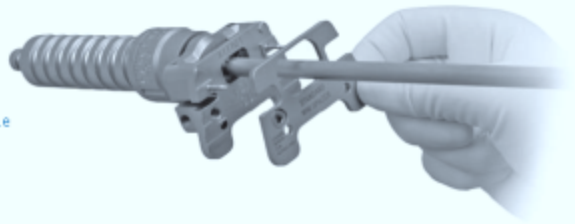


Fig. 1e

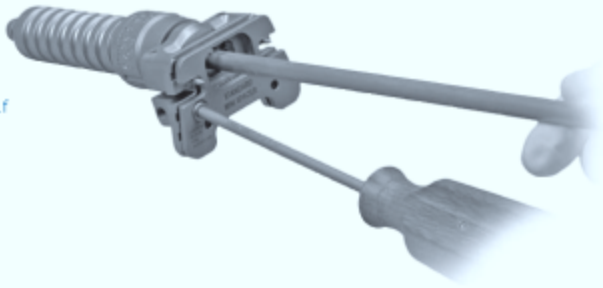


Fig. 1f

Insert the IM guide into the hole in the distal femur. If the epicondyles are visible, the epicondylar axis may be used as a guide in setting the orientation of the Adjustable IM Alignment Guide. If desired, add the Threaded Handles to the guide and position the handles relative to the epicondyles. This does not set rotation of the femoral component, but keeps the distal cut oriented to the final component rotation.

Once the proper orientation is achieved, impact the IM guide until it seats on the most prominent condyle. After impacting, check to ensure that the valgus setting has not changed. Ensure that the guide is contacting at least one distal condyle. This will set the proper distal femoral resection.

Optional Technique: An Extramedullary Alignment Arch and Alignment Rod can be used to confirm the alignment. If this is anticipated, identify the center of the femoral head before draping. If extramedullary alignment will be the only mode of alignment, use a palpable radiopaque marker in combination with an A/P x-ray film to help ensure proper location of the femoral head.

Step Two
Cut the Distal Femur

While the Adjustable IM Alignment Guide is being inserted by the surgeon, the scrub nurse should attach the Mini Distal Femoral Cutting Guide to the 0° Distal Placement Guide (Fig. 2a).

Fig. 2a

Ensure that the attachment screw is tight. Insert the Distal Placement Guide with the cutting guide into the Adjustable IM Alignment Guide until the cutting guide rests on the anterior femoral cortex (Fig. 2b). The Mini Distal Femoral Cutting Guide is designed to help avoid soft tissue impingement.

Fig. 2b

Optional Technique: The 3° Distal Placement Guide can be used to place the Mini Distal Femoral Cutting Guide in 3° of flexion to protect the anterior cortex from notching.

Using the 3.2mm drill bit, drill holes through the two standard pin holes marked "0" in the anterior surface of the Mini Distal Femoral Cutting Guide, and place Headless Holding Pins through the holes (Fig. 2c).

Fig. 2c

Additional 2mm adjustments may be made by using the sets of holes marked -4, -2, +2, and +4. The markings on the cutting guide indicate, in millimeters, the amount of bone resection each will yield relative to the standard distal resection set by the Adjustable IM Alignment Guide and Standard Cut Plate.

If more fixation is needed, use two 3.2mm Headed Screws or predrill and insert two Hex-head Holding Pins in the small oblique holes on the Mini Distal Femoral Cutting Guide, or Silver Spring Pins may be used in the large oblique holes (Fig. 2d).

Fig. 2d

The IM guide can be left in place during resection of the distal condyle, taking care to avoid hitting the IM rod when using the oscillating saw.

Completely loosen the attachment screw (Fig. 2e) in the Distal Placement Guide. Then use the Slaphammer Extractor to remove the IM guide and the Distal Placement Guide (Fig. 2f).

Fig. 2e

Fig. 2f

Cut the distal femur through the cutting slot in the cutting guide using a 1.27mm (0.050-in.) oscillating saw blade (Fig. 2g). Then remove the cutting guide.

Check the flatness of the distal femoral cut with a flat surface. If necessary, modify the distal femoral surface so that it is completely flat. This is extremely important for the placement of subsequent guides and for proper fit of the implant.

Fig. 2g

If you prefer to complete tibial cuts prior to completing the femur, refer to page 22.

Step Three
Size Femur and Establish External Rotation

Flex the knee to 90°. Attach the MIS Threaded Handle to the Mini A/P Sizing Guide, and place the guide flat onto the smoothly cut distal femur (Fig. 3a). Apply the guide so that the flat surface of the Mini A/P Sizing Guide is flush against the resected surface of the distal femur and the feet of the Mini A/P Sizing Guide are flush against the posterior condyles.

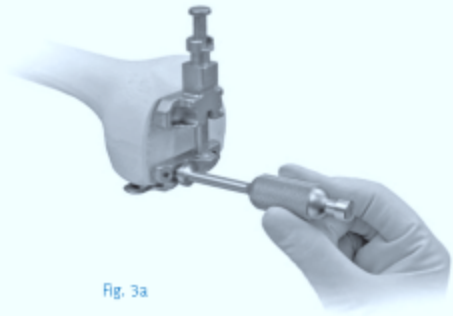


Fig. 3a

Slide the body of the Mini A/P Sizing Guide along the shaft to the level of the medullary canal. Position the guide mediolaterally, and check the position by looking through both windows of the guide to ensure that the medullary canal is not visible through either.

NOTE: Remove any osteophytes that interfere with instrument positioning.

While holding the Mini A/P Sizing Guide in place, secure the guide to the resected distal femur using short 3.2mm (1/8 inch) Headed Screws or predrill and insert short head Holding Pins into one or both of the holes in the lower portion of the guide. Do not overtighten or the anterior portion will not slide on the distal femur.

MIS Screws are available in 3 lengths (27mm, 33mm, 48mm). The length needed will vary depending on the patient's bone dimensions.

NOTE: Remove the Threaded Handle before using the Screw Inserter/Extractor.

Slightly extend the knee and retract soft tissues to expose the anterior femoral cortex. Clear any soft tissue from the anterior cortex. Ensure that the leg is in less than 90° of flexion (70°-80°). This will decrease the tension of the patellar tendon to facilitate placement of the guide.

Attach the MIS Locking Boom to the Mini A/P Sizing Guide. Ensure that the skin does not put pressure on the top of the boom and potentially change its position. The position of the boom dictates the exit point of the anterior bone cut and the ultimate position of the femoral component. When the boom is appropriately positioned, lock it by turning the knurled knob (Fig. 3b).

Fig. 3b

See Appendix 1 for alternative MIS Telescoping Locking Boom technique.

Read the femoral size directly from the guide between the engraved lines on the sizing tower (Fig. 3c). There are eight sizes labeled "A" through "H". If the indicator is between two sizes, the closest size is typically chosen. If using a posterior referencing technique, and the indicator is between two sizes, the larger size is typically chosen to help prevent notching of the anterior femoral cortex.

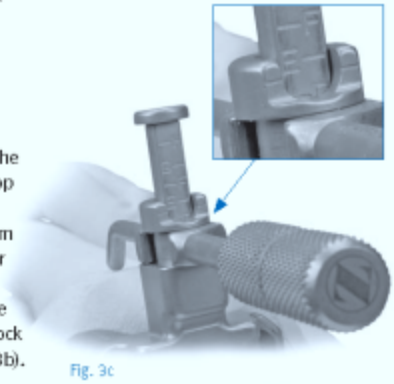


Fig. 3c

If using a posterior referencing technique, remove the Mini A/P Sizing Guide and go to page 19, "Step Four – Finish the Femur, Posterior Referencing Technique."

There are four External Rotation Plates: 0°/3° Left, 0°/3° Right, 5°/7° Left, and 5°/7° Right. Choose the External Rotation Plate that provides the desired external rotation for the appropriate knee. The 0° option can be used when positioning will be determined by the A/P axis or the epicondylar axis. Use the 3° option for varus knees. Use the 5° option for knees with a valgus deformity from 10° to 13°. The 7° option requires a standard exposure, and is for knees with patellofemoral disease accompanied by bone loss and valgus deformity greater than 20°. In this case, use the A/P axis to double check rotation.

Attach the selected plate to the Mini A/P Sizing Guide (Fig. 3d). Place two Headless Holding Pins in the plate through the two holes that correspond to the desired external rotation, and impact them (Fig. 3e). Leave the pins proud of the guide.

NOTE: Do not impact the Headless Holding Pins flush with the External Rotation Plate.

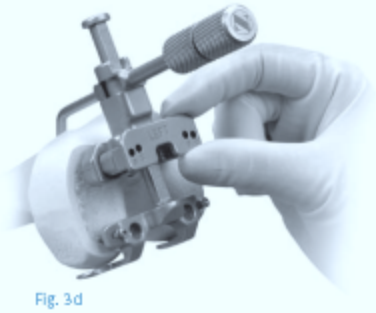


Fig. 3d

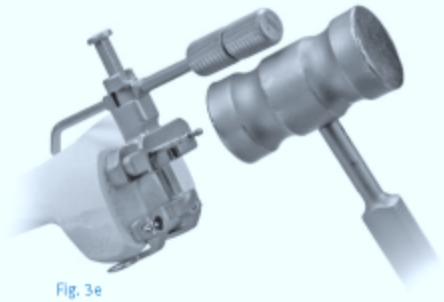


Fig. 3e

Careful attention should be taken when placing the headless pins into the appropriate External Rotation Plate as these pins also set the A/P placement for the MIS Femoral Finishing Guide in the next step of the procedure. It is important to monitor the location of the anterior boom on the anterior cortex of the femur to help ensure the anterior cut will not notch the femur. Positioning the anterior boom on the "high" part of the femur by lateralizing the location of the boom can often lessen the likelihood of notching the femur.

Unlock and rotate the boom of the guide medially until it clears the medial condyle. Then remove the guide, but leave the two headless pins. These pins will establish the A/P position and rotational alignment of the Femoral Finishing Guide.

Step Four
Finish the Femur

Anterior Referencing Technique

Select the correct size MIS Femoral Finishing Guide (silver colored) or MIS Flex Femoral Finishing Guide (gold colored) as determined by the measurement from the A/P Sizing Guide. An additional 2mm (approximately) of bone is removed from the posterior condyles when using the Flex Finishing Guide.

Place the finishing guide onto the distal femur, over the headless pins (Fig. 4a). This determines the A/P position and rotation of the guide. Remove any lateral osteophytes that may interfere with guide placement. Position the finishing guide mediolaterally by sliding it on the headless pins. The width of the finishing guide replicates the width of the *NexGen* CR Femoral Component. The width of the flex finishing guide replicates the width of the *NexGen* LPS, LPS-Flex, and CR-Flex Femoral Components.

Fig. 4a

When the M/L position of the Femoral Finishing Guide is set, use the Screw Inserter/Extractor to insert a 3.2mm Headed Screw or predrill and insert a Hex-head Holding Pin through the superior pinhole on the beveled medial side of the guide (Fig. 4b). Then secure the lateral side in the same manner. If needed, predrill and insert two Short-head Holding Pins through the inferior holes on one or both sides of the guide. For additional stability, use 6.5mm screws in the peg holes.

Fig. 4b

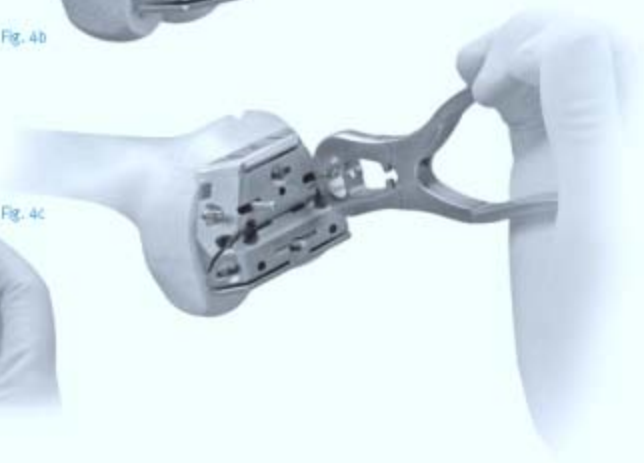


Fig. 4c

Remove the headless pins from the Femoral Finishing Guide (Fig. 4c) with the Headless Pin Puller.

Use the Resection Guide through the anterior cutting slot of the finishing guide, and check the medial and lateral sides to be sure the cut will not notch the anterior femoral cortex (Fig. 4d).

Fig. 4d

Optional Technique

To check the location of the anterior cut and determine if notching will occur, securely tighten the Locking Boom Attachment to the face of the finishing guide. Make certain that the attachment sits flush with the Femoral Finishing Guide (Fig. 4e). Connect the MIS Locking Boom to the attachment (Fig. 4f). The boom indicates the depth at which the anterior femoral cut will exit the femur.

Fig. 4e

Fig. 4f

Use a 1.27mm (0.050-in.) narrow, oscillating saw blade to cut the femoral profile in the following sequence for optimal stability of the finishing guide (Fig. 4g):

1 Anterior condyles

2 Posterior condyles

3 Posterior chamfer

4 Anterior chamfers

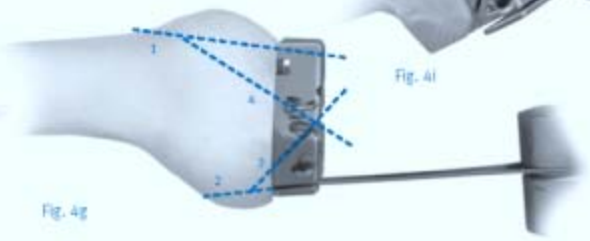


Fig. 4g

Use the Patellar/Femoral Drill Bit to drill the post holes (Fig. 4h).

Fig. 4h

Use the 1.27mm (0.050-in.) narrow, reciprocating saw blade to cut the base of the trochlear recess (Fig. 4i) and score the edges (Fig. 4j). Remove the finishing guide to complete the trochlear recess cuts.

Fig. 4i

Fig. 4j

Posterior Referencing Technique

Select the correct size MIS Femoral Finishing Guide (silver colored) or MIS Flex Femoral Finishing Guide (gold colored) as determined by the measurement from the A/P Sizing Guide. An additional 2mm (approximately) of bone is removed from the posterior condyles when using the flex finishing guide.

Attach the Posterior Reference/ Rotation Guide to the selected femoral finishing guide (Fig. 4k). Lock the femoral position locator on the rotation guide to the zero position (Fig. 4l). This zero setting helps to ensure that, when the feet are flush with the posterior condyles, the amount of posterior bone resection will average 9mm when using the standard MIS Femoral Finishing Guides, and approximately 11mm when using the MIS Flex Femoral Finishing Guides.

Fig. 4k

Fig. 4l

Place the finishing guide on the distal femur, bringing the feet of the rotation guide flush against the posterior condyles of the femur (Fig. 4m).

Fig. 4m

Set the rotation of the finishing guide parallel to the epicondylar axis. Check the rotation of the guide by reading the angle indicated by the Posterior Reference/Rotation Guide. The epicondylar line is rotated externally 0° to 8°, (4±4°), relative to the posterior condyles. The external rotation angle can also be set relative to the posterior condyles, lining up the degrees desired.

If desired, attach the MIS Locking Boom to the face of the finishing guide to check the location of the anterior cut and determine if notching will occur (Fig. 4n). The boom tip indicates where the anterior femoral cut will exit the bone.

Remove any lateral osteophytes that may interfere with guide placement. Position the finishing guide mediolaterally. The width of the finishing guide replicates the width of the *NexGen* CR Femoral Component. The width of the flex finishing guide replicates the width of the *NexGen* LPS, LPS-Flex, and CR-Flex Femoral Components.

Fig. 4n

When the proper rotation and the mediolateral and anteroposterior position are achieved, secure the finishing guide to the distal femur. Use the Screw Inserter/Extractor to insert a 3.2mm Headed Screw or predrill and insert a Hex-head Holding Pin through the superior pinhole on the beveled medial side of the Femoral Finishing Guide (Fig. 4o). Then secure the lateral side in the same manner. For additional stability, predrill and insert two Short-head Holding Pins through the inferior holes on one or both sides of the guide.

Fig. 4o

Use a 1.27mm (0.050-in.) narrow, oscillating saw blade to cut the femoral profile in the following sequence for optimal stability of the finishing guide (Fig. 4p):

1 Anterior condyles

2 Posterior condyles

3 Posterior chamfer

4 Anterior chamfers

Fig. 4p

Use the Patellar/Femoral Drill Bit to drill the post holes (Fig. 4q).

Fig. 4q

Use the 1.27mm (0.050-in.) narrow, reciprocating saw blade to cut the base of the trochlear recess (Fig. 4r) and score the edges (Fig. 4s). Remove the finishing guide to complete the trochlear recess cuts.

Fig. 4r

Fig. 4s

Option 1
MIS Notch/Chamfer Trochlear Guide

The MIS Notch/Chamfer Trochlear Guide consists of 2 pieces for each size, the MIS Notch/Chamfer Guide and the MIS Trochlear Guide. Matching sizes must be used.

The MIS Notch/Chamfer Trochlear Guide may be used to complete the chamfer cuts, the trochlear groove, the intercondylar box and to drill the peg holes after the anterior and posterior cuts have been made with the MIS Femoral Finishing Guide.

After the anterior and posterior cuts have been made, check the flexion gap and the extension gap using the MIS Spacer Block. Make the necessary adjustments.

Knee in slight flexion

Position the appropriate size MIS Notch/Chamfer Guide onto the femur so it is flush against the resected surfaces both distally and anteriorly. Ensure that no soft tissue or osteophytes interfere with instrument positioning. Position the guide mediolaterally (Fig. 4t).

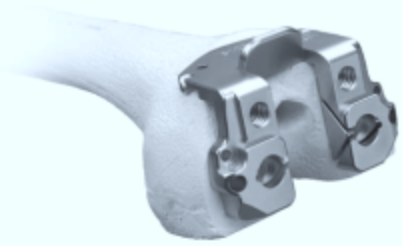


Fig. 4t Position the MIS Notch/Chamfer Guide flush against the femur

Note: The distal mediolateral profile of the MIS Notch/Chamfer Guides, anterior to the tabs, can be used to position the guide referencing the lateral condyle.

Insert two short headed pins or short screws through the anterior flange of the guide to secure the guide in position (Fig. 4u).

Fig. 4u Insert two short headed pins or short screws through the anterior flange

Knee in 90° flexion

Secure the MIS Notch/Chamfer Guide to the femur distally with two Short Spring Screws or 3.2mm (1/8-inch) headed screws. Alternatively, insert two headed pins (Fig. 4v).

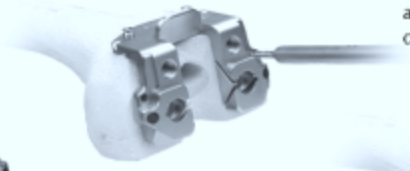


Fig. 4v Secure the MIS Notch/Chamfer Guide to the femur

Use a reciprocating saw to cut the sides and base of the intercondylar box (Fig. 4w). Protect the tibia with a wide osteotome.

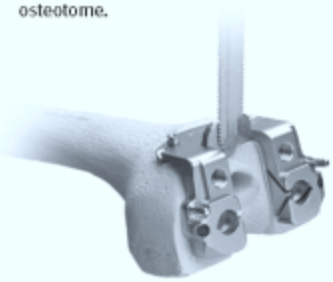


Fig. 4w Cut the sides and base of the intercondylar box

Use the Patellar/Femoral Drill to drill the femoral post holes.

Note: Do not use the LPS-Flex Femur Peg Drill, size A, B with the MIS Notch/Chamfer Guide as there is no stop on the guide for this smaller drill. If using a micro size (A, B) LPS-Flex Femoral Component, the femoral post holes must be drilled when the anterior and posterior condyle cuts are made using the appropriate size MIS Flex Femoral Finishing Guide and the LPS-Flex Femur Peg Drill.

Then use an oscillating saw to cut the anterior chamfer and the posterior chamfer (Fig. 4x).

Fig. 4x Cut the anterior and posterior chamfers

Apply the matching size MIS Trochlear Guide to the MIS Notch/Chamfer Guide with the holes in the Trochlear Guide aligned with the threaded holes in the Notch/Chamfer Guide (Fig. 4y). Thread the MIS Threaded Handle through one of the threaded holes to secure the Trochlear Guide to the MIS Notch/Chamfer Guide (Fig. 4z).

Fig. 4y Apply the matching size MIS Trochlear Guide with the holes aligned

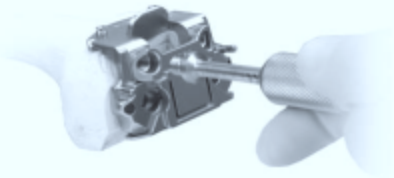


Fig. 4z MIS Trochlear Guide secured to MIS Notch/Chamfer Guide

Protect the tibia. Use a reciprocating saw through the slots in the Trochlear Guide to cut the sides and base of the trochlear groove (Fig. 4aa). Remove the Trochlear Guide, and insert an osteotome over the resected tibial surface below the trochlear groove. Then use the reciprocating saw to finish the trochlear cuts.

Remove the MIS Notch/Chamfer Guide.

Fig. 4aa Cut the sides and base of the trochlear groove

Using the MIS Notch/Chamfer Guide to downsize the femur

If there is a need to downsize the femur, the MIS Notch/Chamfer and Trochlear Guide can be used for sizes C-G Standard implants and the Notch/Chamfer Guide can be used for all flex sizes.

NOTE: Size A, B and H MIS Trochlear Guides cannot be used for downsizing.

Select the preferred size Notch/Chamfer Guide and pin to the distal femur with two Short Spring Screws or 3.2mm (1/8-inch) headed screws (48mm length). Alternatively, insert two Hex Headed pins. Ensure that the guide is seated on the anterior and distal femur. Use a reciprocating saw to recut the sides of the intercondylar box. Use an oscillating saw to recut the anterior and posterior chamfers.

If downsizing for a CR-Flex or LPS-Flex implant, use the posterior surface of the MIS Notch/Chamfer Guide for the posterior cut. If downsizing for a CR or LPS implant, use the MIS Threaded Handle to attach the matching size MIS Trochlear Guide to the Notch/Chamfer Guide, and use the posterior surface of the MIS Trochlear Guide for the posterior cut.

Remove the MIS Trochlear and Notch/Chamfer Guides.

Surgeon Notes & Tips

- Although a sequence of femoral cuts has been provided, the cuts may be made in any sequence. It is recommended for the surgeon to complete the cuts in a consistent sequence to help ensure that all cuts are performed. However, the peg holes should be drilled prior to assembling the MIS Trochlear Guide.
- If the MIS Femoral Finishing Guide is used, the flexion gap should equal the extension gap.
- If the MIS Flex Femoral Finishing Guide is used, then the flexion gap will be approximately 2mm greater. For a Flex implant, use an MIS Spacer Block with the MIS Spacer Block Flex Adapter to check flexion gap.
- An oscillating saw with a narrow blade may also be used, or a reciprocating blade may be used to cut the sides and a chisel or osteotome used to cut the base of the notch.
- Remember that the incision can be moved both medial-to-lateral and superior-to-inferior as needed to gain optimal exposure.
- To facilitate the use of the mobile window, when resecting on the medial side, use retraction on the medial side while relaxing the lateral side. Likewise, when resecting on the lateral side, use retraction on the lateral side while relaxing the medial side.

Option 2
MIS QS Notch Guide

Position the appropriate size MIS QS Notch Guide onto the femur so it is flush against the resected surfaces both distally and anteriorly. The MIS QS Notch Guide will not contact the anterior chamfer. Use the previously prepared trochlear recess and/or the femoral post holes to position the MIS QS Notch Guide mediolaterally.

Secure the MIS QS Notch Guide to the femur with two 3.2mm (1/8-inch) Headed Screws or predrill and insert two 3.2mm (1/8-inch) Holding Pins (Fig. 4bb). Use a reciprocating saw to cut the sides and the base of the intercondylar notch (Fig. 4cc). Then remove the MIS QS Notch Guide (Fig. 4dd).

Fig. 4bb

Fig. 4cc

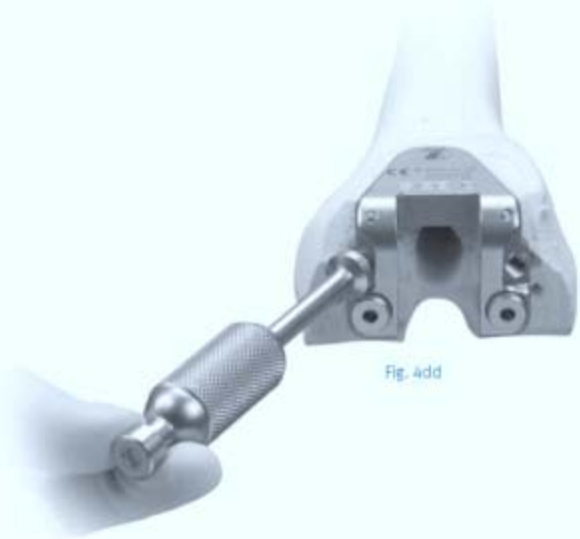


Fig. 4dd

Step Five
Resect Proximal Tibia

This step explains the alignment of the tibial cut to help ensure proper posterior slope and rotation, and the resection of the tibia perpendicular to the mechanical axis. The MIS Tibial Cut Guide Assembly is designed to facilitate tibial preparation through a shorter incision and without everting the patella.

Instruments Used

MIS Tibial Cut Guide Assembly

- MIS Tibial Cut Guide (Right or Left)
- MIS Tubercle Anchor (Right or Left)
- MIS Tibial Adjustable Rod
- MIS Distal Telescoping Rod
- Ankle Clamp or Spring
- Ankle Bar

Resection Guide

MIS Tibial Depth Resection Stylus

Osteotome

Various retractors

Kocher clamp

Hex-head Screwdriver

Drill/Reamer

MIS Screw Inserter/Extractor

MIS Screws

Assemble the Guide

The MIS Tibial Cut Guide Assembly consists of instruments for right or left (Fig. 5a).

- Tibial Cut Guide
- Tubercle Anchor
- MIS Tibial Adjustable Rod
- MIS Distal Telescoping Rod
- Ankle Clamp or Spring
- Ankle Bar

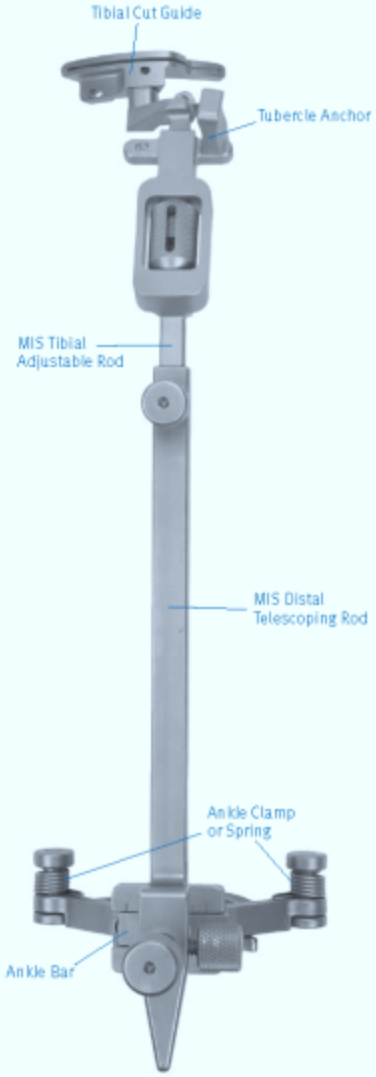


Fig. 5a MIS Tibial Cut Guide Assembly

Attach the Ankle Clamp or optional Spring to the Ankle Bar. Then slide the Ankle Bar onto the dovetail at the bottom of the MIS Distal Telescoping Rod. Turn the knob opposite the dovetail to temporarily hold the bar in place.

Arrows are etched onto both the MIS Tibial Adjustable Rod and the MIS Distal Telescoping Rod to indicate the correct orientation during assembly. With the arrows aligned, insert the MIS Tibial Adjustable Rod into the Distal Telescoping Rod (Fig. 5b). Adjust the length to approximate the length of the patient's tibia and temporarily tighten the thumb screw at the proximal end of the distal rod.

Fig. 5b Arrows showing correct alignment

Attach the correct right or left Tubercle Anchor onto the corresponding side of the MIS Tibial Adjustable Rod. For a left knee, the left anchor is inserted into the right hole (Fig. 5c).

Fig. 5c

For a right knee, the right anchor is inserted into the left hole (Fig. 5d).

Fig. 5d

Be sure that the etched line on the side of the Tubercle Anchor aligns with the corresponding etched line on the anterosuperior face of the Adjustable Rod (Fig. 5e).

Fig. 5e

NOTE: The Tibial Cut Guide and Tubercle Anchor are available in left and right configurations. If the incorrect Tubercle Anchor is used, the Cut Guide will not fully retract into the Adjustable Rod and the varus/valgus angle of the tibial cut may be affected.

Insert the correct right or left Tibial Cut Guide into the Adjustable Rod and rotate the thumb wheel counterclockwise until the threads engage (Fig. 5f).

Fig. 5f

Continue to rotate the thumb wheel until the guide is approximately midway through its range of travel. This will allow the depth of the tibial resection to be adjusted after the assembly is secured to the bone via the Tubercle Anchor.

Position the Guide

Place the spring arms of the Ankle Clamp around the ankle proximal to the malleoli and loosen the anterior knob that provides mediolateral adjustment at the ankle. If preferred, the Ankle Spring may be used instead of the Ankle Clamp.

Loosen the knob on the proximal end of the Distal Telescoping Rod and adjust the length of the guide until the Tibial Cut Guide is positioned at the approximate depth of cut. With the Tibial Cut Guide and Tubercle Anchor contacting the bone, move the Tibial Cut Guide mediolaterally to align the rod with the medial third of the tibial tubercle (Fig. 5g). This will usually place the proximal end of the Adjustable Rod so it is centered below the intercondylar eminence. The Tibial Cut Guide will contact the tibia at an oblique angle and the low-profile portion of the cutting head will fit under the patellar tendon. The Tubercle Anchor is shaped to fit between the patellar tendon and the base of the cutting head.

Fig. 5g

NOTE: Be sure that only the low-profile portion of the cutting head extends beneath the patellar tendon (Fig. 5h).

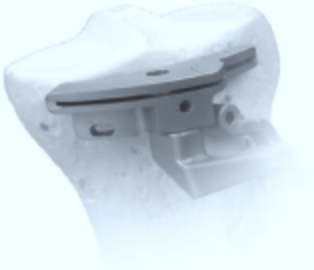


Fig. 5h

When correctly aligned, the Distal Telescoping Rod and Adjustable Rod should be parallel to the tibia in the coronal and sagittal planes. To help avoid rotational malalignment of the rod, check its position from a direct anterior view, ie, stand at the foot of the operating table.

Adjust the distal end of the MIS Distal Telescoping Rod by moving the slide at the foot of the rod medially or laterally until the guide is aligned with the mechanical axis of the tibia. The end of the MIS Distal Telescoping Rod should be positioned about 5mm-10mm medial to the midpoint between the palpable medial and lateral malleoli. The tip should point to the second toe (Fig. 5i). When the proper M/L position is achieved, tighten the anterior knob to secure the MIS Distal Telescoping Rod to the Ankle Bar.

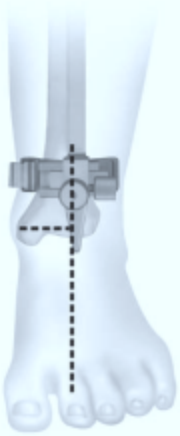


Fig. 5i

Loosen the knob on the side of the distal end of the MIS Distal Telescoping Rod. Then use the slide adjustment to align the rod in the sagittal plane so it is parallel to the anterior tibial shaft. This will create a 7° posterior tibial slope. If more or less slope is desired, use the slide adjustment to obtain the desired slope. Then tighten the knob. If there is a bulky bandage around the ankle, adjust the rod to accommodate the bandage. This will help ensure that the tibia will be cut with the proper slope.

Insert an MIS Screw near the tibial tubercle through the hole in the Tubercle Anchor (Fig. 5j).

Fig. 5j

NOTE: The Tubercle Anchor position does not determine the varus/valgus of the tibial cut.

Then use the Resection Guide through the cutting slot to assess the slope of the cut (Fig. 5k).

Fig. 5k

Set the Final Resection Level

With the Tibial Cut Guide flush against the anteromedial edge of the tibia, insert the MIS Tibial Depth Resection Stylus into the hole on the top of the Tibial Cut Guide. For a minimal cut, swing the 2mm arm of the stylus over the defective tibial condyle. Adjust the Tibial Cut Guide up or down by rotating the thumb wheel until the tip of the 2mm stylus rests on the surface of the condyle (Fig. 5l). This will position the Tibial Cut Guide to remove 2mm of bone below the tip of the stylus.

Fig. 5l

Alternatively, swing the 10mm arm of the MIS Tibial Depth Resection Stylus over the least involved tibial condyle. Adjust the Tibial Cut Guide until the tip of the 10mm arm rests on the surface of the condyle (Fig. 5m). This will position the Tibial Cut Guide to remove 10mm of bone below the tip of the stylus.

Fig. 5m

These two points of resection will usually not coincide. The surgeon must determine the appropriate level of resection based on patient age, bone quality, and the type of prosthetic fixation planned.

NOTE: The grooves on the stem of the Tibial Cut Guide represent 2mm increments (Fig. 5n).

Fig. 5n

Use the Hex-head Screwdriver to tighten all of the screws on the tibial assembly to maintain position.

Insert an MIS Screw through the medial oblong hole on the cutting head (Fig. 5o). This hole is angled to facilitate screw insertion.

Fig. 5o

Place another MIS Screw through the central anterior hole on the cutting head (Fig. 5p).

Fig. 5p

Resect the Proximal Tibia

Use a 1.27mm (0.050-in) oscillating saw blade through the slot on the Tibial Cut Guide to cut the proximal surface of the tibia flat (Fig 5q). After cutting through the medial side and as far as possible into the lateral side, remove the cut guide assembly. Extend the knee and retract soft tissue on the lateral side.

Fig. 5q

NOTE: Take care to protect the patellar tendon when cutting the lateral side.

Use a Kocher clamp to remove the tibial bone fragment. Then trim any remaining bone spikes and meniscus on the posterior and lateral aspects of the resected tibial surface.

Step Six

Check Flexion/Extension Gaps

Use the Spacer/Alignment Guides to check the flexion and extension gaps. With the knee in extension, insert the thinnest appropriate Spacer/Alignment Guide between the resected surfaces of the femur and tibia (Fig. 6a). Insert the Alignment Rod into the guide and check the alignment of the tibial resection (Fig. 6b). If necessary insert progressively thicker Spacer/Alignment Guides until the proper soft tissue tension is obtained.

Then flex the knee and check ligament balance and joint alignment in flexion. When using the MIS Flex Femoral Finishing Guide, the flexion gap will be approximately 2mm greater than the extension gap. For example, if the extension gap is 10mm, the flexion gap will be 12mm. To account for this difference, the appropriate MIS CR-Flex Spacer Adapter or MIS LPS-Flex Spacer Adapter (Fig. 6c) should be placed on top of the Spacer/Alignment Guide that was used in extension to accurately check ligament balance in flexion. The combined construct will equal the total posterior condylar thickness of the final implant.

If the tension is significantly greater in extension than in flexion, re-cut the distal femur using the appropriate instrumentation. This will enlarge the extension space.

If the tension is significantly less in extension than in flexion, either downsize the femur or perform additional ligament releases.

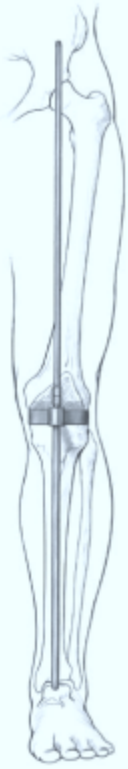


Fig. 6a

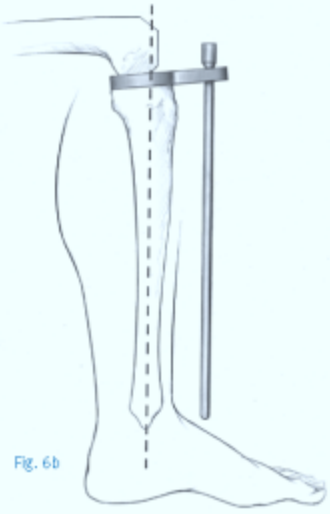


Fig. 6b

Fig. 6c

Step Seven
Prepare the Patella

Sharply dissect through the prepatellar bursa to expose the anterior surface of the patella. This will provide exposure for affixing the anterior surface into the Patellar Clamp.

Remove all osteophytes and synovial insertions from around the patella. Be careful not to damage tendon insertions on the bone. Use the Patellar Caliper to measure the thickness of the patella (Fig. 7a). Subtract the implant thickness from the patella thickness to determine the amount of bone that should remain after resection.

Patella Thickness
– Implant Thickness
= Bone Remaining

Implant Thickness Guide

Patella Thicknesses	Micro Implant	Standard Implant
26mm	7.5mm	–
29mm	7.5mm	8.0mm
32mm	8.0mm	8.5mm
35mm	8.0mm	9.0mm
38mm	–	9.5mm
41mm	–	10.0mm

NOTE: At least 11mm of total bone will remain to allow for implant pegs if the Patella Reamer is used.

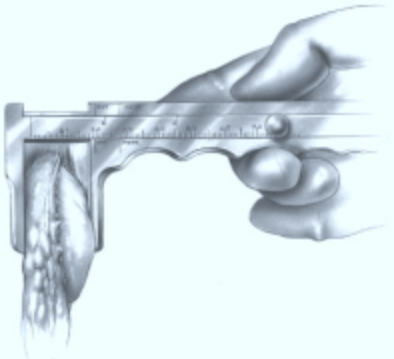


Fig. 7a

Resect the Patella

Universal Saw Guide Technique

Apply the Universal Patellar Saw Guide in line with the patellar tendon. Push the patella up between the jaws of the saw guide. Level the patella within the saw guide jaws and use the thumbscrew to tighten the guide.

The amount to be resected across the top of the saw guide jaws should be approximately the same on all sides. Check to be sure that the 10mm gauge does not rotate beneath the anterior surface of the patella. If the gauge hits the anterior surface of the patella as it is rotated, this indicates that at least 10mm of bone stock will remain after the cut (Fig. 7b).

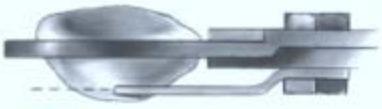


Fig. 7b

Cut the patella flat so that a smooth surface remains (Fig. 7c).

Fig. 7c

Patellar Reamer Technique Total Surfacing Procedure

Use the Patellar Reamer Surfacing Guides as templates to determine the appropriate size guide and reamer. Choose the guide which fits snugly around the patella, using the smallest guide possible (Fig. 7d). If the patella is only slightly larger than the surfacing guide in the mediolateral dimension, use a rongeur to remove the medial or lateral edge until the bone fits the guide.

Fig. 7d

Insert the appropriate size Patellar Reamer Surfacing Guide into the Patella Reamer Clamp (Fig. 7e). Turn the locking screw until tight.

Fig. 7e

Apply the Patellar Reamer Clamp at a 90° angle to the longitudinal axis with the Patellar Reamer Surfacing Guide encompassing the articular surface of the patella. Squeeze the clamp until the anterior surface of the patella is fully seated against the fixation plate (Fig. 7f). Turn the clamp screw to hold the instrument in place. The anterior surface must fully seat upon the pins and contact the fixation plate.

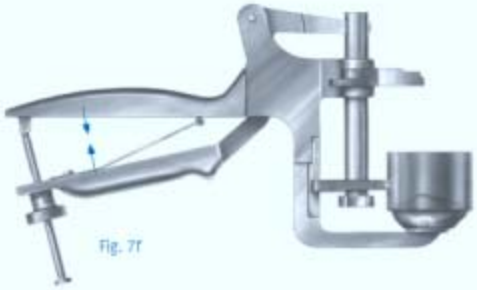


Fig. 7f

Turn the depth gauge wing on the Patellar Reamer Clamp to the proper indication for the correct amount of bone that is to remain after reaming (Fig. 7g).

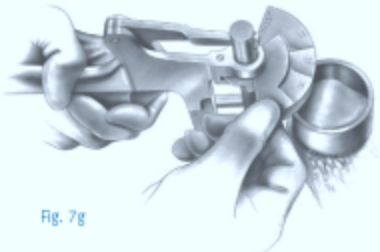


Fig. 7g

Attach the appropriate size Patellar Reamer Blade to the appropriate size Patellar Reamer Shaft (Fig. 7h). Use only moderate hand pressure to tighten the blade.

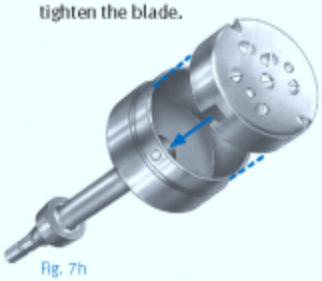


Fig. 7h

Do not overtighten the blade. Insert the Patellar Reamer Shaft into a drill/reamer. Insert the reamer assembly into the Patellar Reamer Surfacing Guide. Raise the reamer slightly off the bone and bring it up to full speed. Advance it slowly until the prominent high points are reamed off the bone. Continue reaming with moderate pressure until the step on the reamer shaft bottoms out on the depth gauge wing of the Patellar Reamer Clamp. Remove the reamer clamp assembly.

Proceed to "Finish the Patella" on page 31.

Insetting Technique

Use the Patellar Reamer Insetting Guides as templates to determine the appropriate size guide and reamer. Choose the guide which will allow approximately 2mm between the superior edge of the patella and the outer diameter of the guide (Fig. 7i).

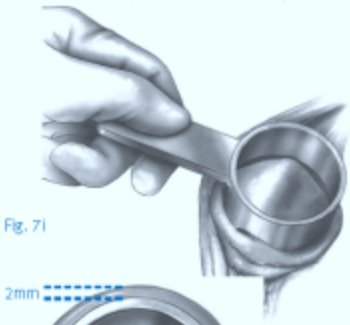
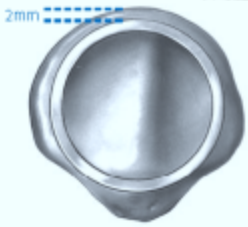


Fig. 7i



Insert the appropriate size Patellar Reamer Insetting Guide into the Patellar Reamer Clamp. Turn the locking screw until tight. Apply the Patellar Reamer Clamp at a 90° angle to the longitudinal axis with the Patellar Reamer Insetting Guide on the articular surface. Squeeze the clamp until the anterior surface of the patella is fully seated against the fixation plate. Turn the clamp screw to hold the instrument in place. The anterior surface must fully seat on the pins and contact the fixation plate.

Turn the clamp wing to the "inset" position.

Attach the appropriate size Patellar Reamer Blade to the appropriate size Patellar Reamer Shaft (Fig. 7j). Use only moderate hand pressure to tighten the blade. **Do not overtighten the blade.** Insert the Patellar Reamer Shaft into a drill/reamer.

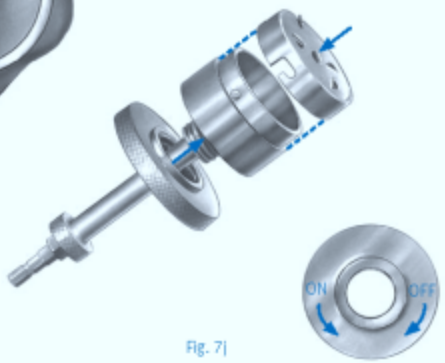


Fig. 7j

Use the Patellar Reamer Depth Stops to control the amount of bone to be removed based on the thickness of the implant chosen.

NOTE: If using a Primary Porous Patella with *Trabecular Metal*™ Material, all implants are 10mm thick.

The depth gauge wing on the Patellar Reamer Clamp can be used instead of the stops to control the amount of bone remaining, rather than the amount of bone removed.

Insert the reamer assembly into the Patellar Reamer Insetting Guide. Raise the reamer slightly off the bone and bring it up to full speed. Advance it slowly until the prominent high points are reamed off the bone. Continue reaming with moderate pressure. Remove the reamer clamp assembly.

Finish the Patella

For the NexGen Primary Porous Patella With Trabecular Metal Material

Center the appropriate Patellar Drill Guide over the resected patella surface with the handle on the medial side of the patella and perpendicular to the tendon. Press the drill guide firmly in place so that the teeth fully engage and the drill guide sits flat on the bone surface (Fig. 7k). Drill the peg hole making sure the drill stop collar contacts the top of the drill guide (Fig. 7l).

Fig. 7k

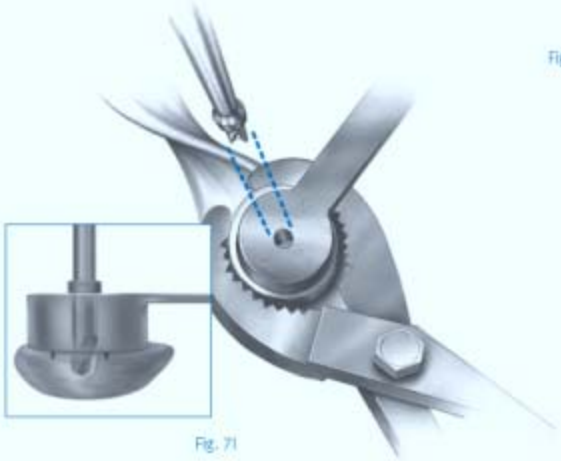


Fig. 7l

NOTE: The Primary Porous Patellar Clamp may be used to fully seat the drill guide on hard sclerotic bone surfaces.

For the NexGen All-Polyethylene Patella

Center the appropriate Patellar Drill Guide over the patella with the handle on the medial side of the patella and perpendicular to the tendon. Holding the drill guide firmly in place, drill the three peg holes using the Patellar/ Femoral Drill Bit (Fig. 7m).

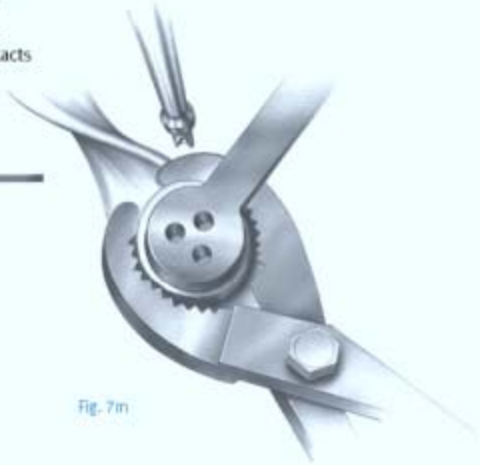


Fig. 7m

Option 1
Patella Protectors

NOTE: If the patella will not be resurfaced, be careful to avoid injury to the patella during surgery.

NOTE: The Patella Protectors are not recommended for use in an insetting technique.

There are 3 sizes of Patella Protectors available to cover the patella while completing the remaining bone resections. Choose the size that best covers the patella – 26mm, 32mm, or 38mm. Handle with care; the spikes may be sharp.

A suture needs to be placed through the hole in the Patella Protector (Fig. 7n). Loosely tie a suture through the hole on the Patella Protector. Attach a hemostat to the end of the suture material. Leave an adequate amount of suture material to position the hemostat away from the incision.

After the initial patella cut is completed, use thumb pressure to press the Patella Protector against the bone. If the bone is particularly hard, apply the Patellar Clamp against the Patella Protector. Squeeze the clamp until the Patella Protector is fully seated against the bone.

The Patella Protector should be part of the instrument count before closing the wound. It is not intended for implantation. Completely remove the suture material at the end of the operation and before sending the instrument for cleaning.

Surgeon Notes & Tips

- The suture placed through the hole in the Patella Protector provides a tether for finding and removing the Patella Protector.

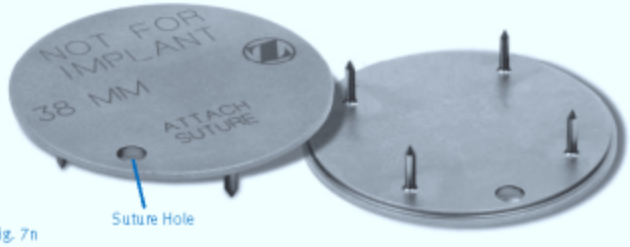


Fig. 7n

Step Eight
Perform a Trial Reduction

After preparing the tibia, select the appropriate Pegged or Stemmed Tibial Sizing Plate/Provisional that provides the desired tibial coverage. Check the size matching chart (for the style of *NexGen* Knee implant) for component matching instructions.

Insert the Femoral Provisional, Patellar Provisional, Tibial Sizing Plate/ Provisional, and Articular Surface Provisional.

Flex and extend the knee with the provisionals in place. Check the range of motion and ligament stability. Perform any necessary soft tissue releases. With proper soft tissue balancing complete the tibial component tends to seat itself in the position where it best articulates with the femur (Fig. 8a)

NOTE: During the trial reduction, observe the relative position of the Femoral Provisional on the tibial Articular Surface Provisional by using the lines on both provisionals. The lines can be used to determine if posterior rollback is occurring, whether the PCL is functional, and if the femoral component will contact the tibial articular surface in the proper location. If the PCL is properly balanced, the Femoral Provisional should sit near the anterior or center lines on the tibial Articular Surface Provisional in extension and near the posterior line in flexion.

If the Femoral Provisional sits posterior to the lines, the PCL may be too tight or the articular surface may be too thick. If the Femoral Provisional sits anterior to the lines, the PCL may be too loose.

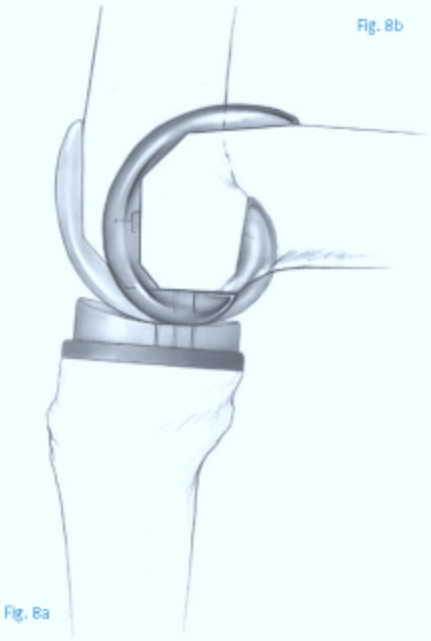


Fig. 8a

After this self-centering process has occurred, mark the position of the component with methylene blue or electrocautery (Fig. 8b). Then remove the provisional components. The Femoral Extractor can be used to remove the Femoral Provisional.

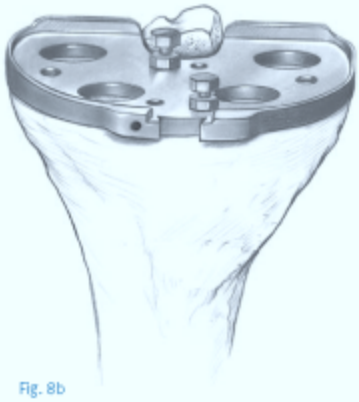
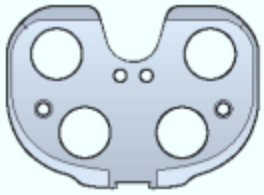


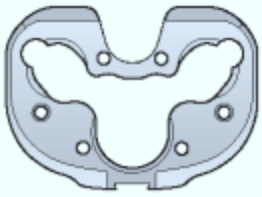
Fig. 8b

Option 1
Tibial Position based on Anatomic Landmarks

The position of the tibial component can also be determined based on anatomic landmarks prior to trial reduction. Select the appropriate Pegged or Stemmed Tibial Sizing Plate/Provisional that provides the desired tibial coverage (Fig. 8c). Please refer to the *Zimmer® NexGen® MIS Tibial Component Cemented Surgical Technique* (97-5950-002-00) for complete product information and instructions for the MIS Tibial Stemmed component.



Pegged Tibial Sizing Plate



Stemmed Tibial Sizing Plate

Fig. 8c

Attach the Universal Handle to the selected Tibial Sizing Plate/Provisional by depressing the button on the handle and engaging the dovetail on the handle with the dovetail on the sizing plate/provisional and secure it by tightening the thumbscrew (Fig. 8d).

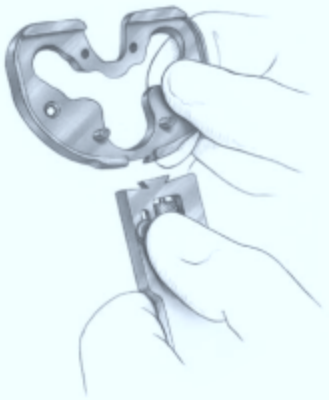


Fig. 8d

Generally, the handle aligns with the anterior aspect of the tibia. Rotate the sizing plate/provisional so the handle points at, or slightly medial to, the tibial tubercle (Fig. 8e). The Alignment Rod can be used to aid in double checking varus/valgus alignment.

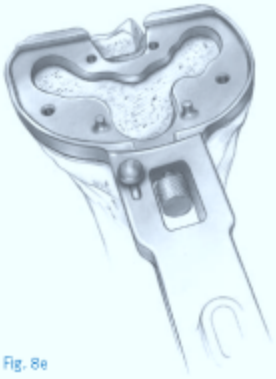


Fig. 8e

Pin the plate in place with two Short Head Holding Pins.

Step Nine
Perform Trial Reduction

In this step, a trial reduction is performed to check component position, patellar tracking, ROM, and joint stability.

The Tibial Sizing Plate is in place.

Knee in 70°-90° flexion
Place the Collateral Retractor laterally, an Army-Navy retractor anteriorly, and a rake retractor on the meniscal bed medially.

Insertion of Femoral Provisional using Optional MIS Femoral Inserter/Extractor

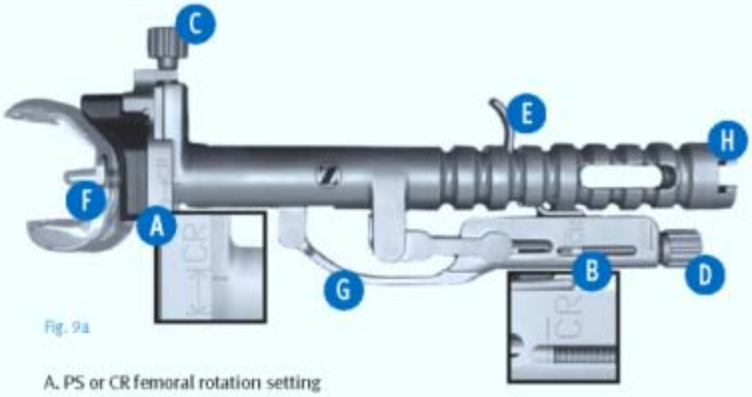


Fig. 9a

A. PS or CR femoral rotation setting
B. PS or CR tension setting
C. Femoral rotation adjustment knob
D. Tension adjustment knob
E. Trigger
F. Instrument hook
G. Locking handle
H. Slaphammer slot

Determine type of *NexGen* implant or provisional being used – Posterior Stabilized (PS) or Cruciate Retaining (CR). Refer to the side of the instrument, labeled PS or CR (see (A) & (B)) which corresponds with the implant or provisional type (Fig. 9a).

Initially adjust femoral rotation setting and tension setting. For the femoral rotation setting, a good starting point is between the lines of the implant type (A). For the tension setting, start with the two lines aligned (B).

Open locking handle (G) to attach implant or provisional. Attach implant or provisional by positioning the instrument hook (Fig. 9b).

Fig. 9b

If needed, turn adjustment knob (C) to achieve desired rotation of the femoral component (Fig. 9c).

Fig. 9c

Turn tension adjustment knob (D) to increase (tighten) or decrease (loosen) the clamping force (Fig. 9d).

Fig. 9d

Close locking handle to secure instrument to implant or provisional (Fig. 9e).

Fig. 9e

Align implant or provisional onto prepared bone, impact end (H).

Open locking handle by pressing trigger (E) to release instrument from implant or provisional.

If preferred, the Femoral Provisional may be positioned by hand.

Translate the Femoral Provisional laterally until the lateral peg of the provisional aligns with the drill hole in the lateral femoral condyle. Push the provisional in place beginning laterally, then medially. Be sure that soft tissue is not trapped beneath the provisional component.

Knee in extension

Check to ensure that the Femoral Provisional is flush against the resected surface on the medial condyle. Then retract the lateral side and check to make sure it is flush on the lateral side. The Femoral Provisional should be centered mediolaterally on the distal femur.

Attach the appropriate Tibial Articular Surface Provisional and perform a trial reduction. Check ligament stability in extension and in 30°, 60°, and 90° flexion. Attempt to distract the joint in flexion to ensure that it will not distract. If a posterior stabilized component is used, hyperflex the knee and check to make sure that the spine still engages the cam.

Insert the Patellar Provisional onto the resected patellar surface. Perform a ROM to check patellar tracking.

When component position, ROM, and joint stability have been confirmed, remove all provisional components.

Removal of Femoral Provisional using Optional MIS Femoral Inserter/Extractor

Ensure (A) and (B) are still set properly for provisional type being used (PS or CR).

Position instrument hook under provisional (F) (Fig. 9f).

Fig. 9f

Turn tension adjustment knob (D) to tighten or loosen as needed.

Close locking handle (G).

Attach slaphammer (H), extract.

Surgeon Notes & Tips

- In performing the trial reduction and during implantation of the Femoral Provisional or prosthesis, make certain that no portion of the quadriceps or soft tissue is pinned beneath the component.

Step Ten
Implant Components

In this step, the final components are implanted, and the tibial articular surface is secured to the implanted tibial base plate. When using cemented components, it is recommended to use two batches of cement.

After the implants have been chosen, make a final check to ensure that the femoral, tibial base plate, and tibial articular surface components match. If using a cemented component, mix the first batch of cement. The cement should have a doughy consistency when ready for use.

Tibial Base Plate

If a stemmed tibial base plate will be used with a stem extension, attach the desired stem extension to the stem and strike it once with a mallet. If a 10mm-14mm thick tibial articular surface will be used, insert the locking screw for the stem extension.

If a stemmed tibial base plate will be used without a stem extension, consider the need for a taper plug. If a 17mm or 20mm articular surface will be used, a stem extension or taper plug is required. A taper plug also can be used with the 10mm-14mm tibial articular surface. If it is planned to use a 14mm articular surface or if the flexion and extension gaps are not balanced, consider using the taper plug in case the final reduction reveals that it is necessary to switch to a 17mm or 20mm articular surface. Furthermore, if the articular surface should ever require revision with a 17mm or 20mm thick component, the taper plug is already in place and revision of the tibial base plate may not be necessary. Assemble the taper plug onto the tibial plate by striking it several times with a mallet to allow the ring on the taper to deform.

Position the PCL Retractor posteriorly, the Collateral Soft Tissue Protector laterally, and the Collateral Retractor medially. Sublux the tibia anteriorly. Place a layer of cement on the underside of the tibial base plate, around the keel, on the resected tibial surface and in the tibial IM canal. Position the tibial base plate onto the tibia and use the Tibial Impactor to impact it until fully seated (Fig. 10a). Thoroughly remove any excess cement in a consistent manner.

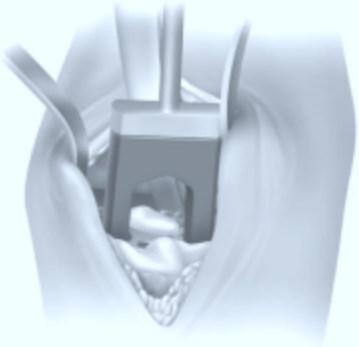


Fig. 10a Use the Tibial Impactor to impact the tibial base plate.

Femoral Component

Attach the femoral component to the Femoral Impactor/Extractor.

Knee in 70°-90° flexion

Place the Collateral Retractor laterally, an Army-Navy retractor anteriorly, and a rake retractor on the meniscal bed medially.

Place a layer of cement on the underside of the prosthesis and in the holes drilled in the femur.

Attach the Femoral/Impactor/Extractor to the femoral component. Insert the femoral component onto the distal femur by translating the component laterally until the lateral peg aligns with the drill hole in the lateral femoral condyle. Take care to avoid scratching the implant component surfaces. Disposable, plastic Tibial Plate Protectors may be temporarily inserted onto the Tibial Base Plate to protect the implant surfaces during insertion of the femoral component. Remove the Tibial Plate Protector after the femur is seated. Be sure that soft tissue is not trapped beneath the implant. Use a mallet to impact the component until fully seated.

Remove the Femoral Impactor/Extractor, and the retractors. Check the medial and lateral sides to make sure the femoral component is fully impacted. Remove any excess cement in a thorough and consistent manner.

Alternatively, push the component in place by hand beginning laterally, then medially.

Component Implantation

After the implants have been chosen, make one last check to ensure that the femoral, tibial, and articular surface components match.

Articular Surface Insertion

The Articular Surface Inserter applies both downward and rearward forces to aid in the insertion of the articular surface onto the tibial base plate. Push the lever on the inserter fully to either side. Place the articular surface onto the tibial base plate, engaging the dovetails (Fig. 10b). Steady the surface on the base plate with one hand by applying downward pressure near the posterior cruciate cutout. Engage the hook on the inserter with the mating slot in the front of the base plate and close the lever with your index finger. This should lock the inserter to the base plate. Squeeze the handles of the inserter to seat the articular surface (Fig. 10c). Open the lever and remove the inserter. **Insert an articular surface only once. Never reinsert the same articular surface onto a tibial base plate.**

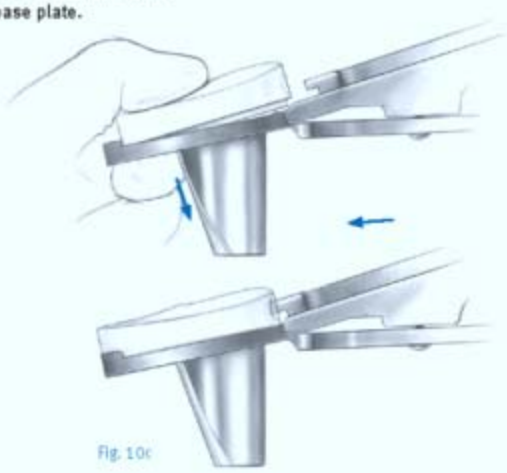


Fig. 10c

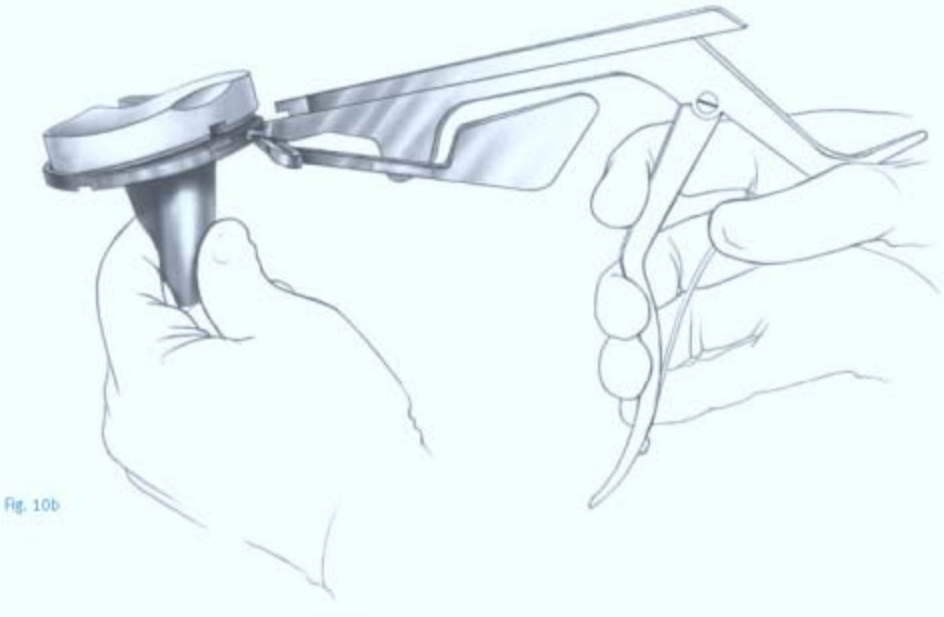


Fig. 10b

Patellar Component
NexGen Primary Porous Patella with Trabecular Metal Material
Knee in 70°-90° flexion

NOTE: If the implant post begins to engage at an angle, the implant should be removed and repositioned perpendicular to the resected surface. Insert the patella again and reclamp, applying an even distribution of pressure on the patellar surface.

NexGen All-polyethylene Patella
Knee in 70°-90° flexion

Apply cement to the anterior surface and pegs of the patellar component while in a doughy consistency. Locate the drilled peg holes and use the Patellar Clamp to insert and secure the patella in place. Fully open the jaws of the clamp and align the teeth to the anterior surface of the patella and the plastic ring to the posterior surface of the implant. Use the clamp to apply a significant amount of pressure to the implant to fully seat the implant on the patellar surface. Then remove excess cement.

Tibial Articular Surface
Knee in 70°-90° flexion

Use the Articular Surface Insertion Instrument to attach the appropriate tibial articular surface onto the tibial base plate (Fig. 10d).

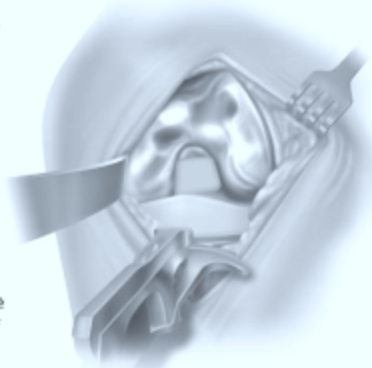
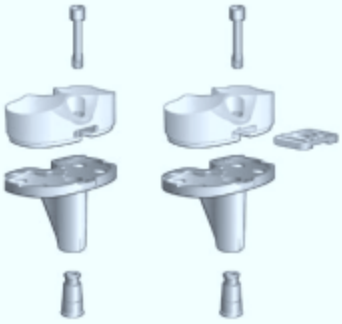


Fig. 10d Insert the tibial articular surface onto the tibial base plate.

Technique for 17mm and Thicker Tibial Articular Surface Assemblies

A secondary locking screw is required for the 17mm and thicker tibial articular surface components if using a Flex Femoral Component. Therefore, stemmed tibial base plates with either a stem extension or taper plug must be used with these thicker components (Fig. 10e). This assists in lift off resistance at higher flexion positions.



Net-Shape Molded *Prolong* Polyethylene

Fig. 10e

NOTE: The pegged plate cannot be used with the 17mm or thicker Net-Shape molded or *Prolong*® Highly Crosslinked Polyethylene articular surface.

With the *Prolong* Highly Crosslinked Polyethylene Articular Surface Component (17mm and thicker only), the metal locking clip and screw are packaged separately from the tibial articular surface container, but in the same box. Before inserting the tibial articular surface, insert the metal locking clip into the anterior slot of the compartment. The rail should be aligned with the space in the slot. There is an arrow on the superior side of the locking clip that indicates the correct direction for insertion. The purpose of the rail is to prevent the clip from being assembled incorrectly. The metal locking clip should glide easily into the slot. The clip is properly seated when a click is heard. For the molded tibial articular surface, the metal locking clip is preassembled into the component.

A taper plug also can be used with the 10mm to 14mm articular surface components. If you plan to use a 14mm component or the flexion and extension

gaps are not balanced, consider using the taper plug in case, during final reduction, it would be necessary to use a 17mm or thicker component. Then, if the articular surface should ever require revision with a 17mm or thicker component, the taper plug is already in place and revision of the tibial plate component may not be necessary.

For Back Table Assembly:

1. Assemble the stem extension or the taper plug onto the tibial plate by striking it with a mallet once for the stem extension or several times for the taper plug to allow the ring on the taper plug to deform.
2. Place the tibial plate onto the holding fixture, which is an integral part of the instrument case.
3. Use the articular surface Inserter to insert the articular surface onto the tibial plate.
4. With the articular surface in place, insert the secondary locking screw (packaged with the anticular surface).
5. Use the LCCK Deflection Beam Torque Wrench with the 4.5mm Hex Driver Bit attached to torque the screw to 95 in.-lbs. Alternatively, if using a stem extension, use the Tibial Plate Wrench to assist when torquing the screw. Do not over or under torque.

For in vivo Assembly:

If preferred, 17mm or thicker articular surface can be inserted after the tibial plate has been implanted.

1. Assemble the stem extension or the taper plug onto the tibial plate by striking it with a mallet once for the stem extension or several times for the taper plug to allow the ring on the taper plug to deform.

   It is recommended to secure the taper plug/stem extension using a Replacement Stem Extension Locking Screw: 00-5980-090-00 (available as a separate sterile item) before implanting the tibial component. This screw will hold the taper plug/stem extension in place when the tibial plate is impacted.
2. Implant the tibial plate*. Remove the Replacement Stem Extention Locking Screw and discard. If bone cement is being used, wait for the cement to completely cure before inserting the articular surface. An articular surface provisional may be inserted to use as space while the cement cures.
3. Remove the articular surface provisional and insert the articular surface onto the plate using the Articular Surface Inserter.
4. Select the Tibial Plate Wrench that matches the size of the implant to be assembled. Place the end of the wrench over the tibial plate. Ensure that the wrench is in line with the base of the tibial plate.
5. Place the locking screw (packaged with the articular surface) through the hole in the articular surface.
6. Use the LCCK Deflection Beam Torque Wrench attached to the 4.5mm Hex Driver Bit to torque the screw to 95 in.-lbs.

*For cemented applications, apply a layer of bone cement to the underside of the tibial plate, around the keel, on the resected tibial surface and in the tibial IM canal. Remove the excess cement.

Recheck the ROM and stability of the knee.

Surgeon Notes & Tips

- Take care that the retractors do not inadvertantly dislodge the tibial base plate, particularly on the posterolateral corner.
- Verify that the femoral component is fully seated before closing the wound.
- Confirm that no portion of the quadriceps mechanism has been pinned beneath the femoral component.

Surgical Support Team Tips

- The cement may need to be prepared in two separate batches to implant the components.
  - Place cement onto the tibial bone, position the implant, and impact into place. Remove excess cement.
  - Place cement onto the femoral component, then position the implant and impact into place. Remove all excess cement in a consistent manner.
- After the tibial base plate component has been implanted, ensure that the tibial base plate component has not been dislodged when the femur is subluxed anteriorly to implant the femoral component.

Apply cement to the *Trabecular Metal* surface and post while in a doughy consistency. Locate the drilled post hole and use the Primary Porous Patellar Clamp to insert and secure the patella in place. Fully open the jaws of the clamp and align the teeth to the anterior surface of the patella and the plastic ring to the posterior surface of the implant. Use the clamp to apply a significant amount of pressure to the implant to fully seat the implant on the patellar surface (Fig. 10f). Remove excess cement.

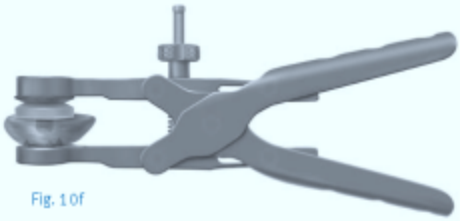


Fig. 10f

NOTE: If the implant post begins to engage at an angle, the implant should be removed and repositioned perpendicular to the resected surface. Insert the patella again and reclamp, applying an even distribution of pressure on the patellar surface.

Apply cement to the anterior surface and pegs of the patellar component while in a doughy consistency. Locate the drilled peg holes and use the Patellar Clamp to insert and secure the patella in place. Fully open the jaws of the clamp and align the teeth to the anterior surface of the patella and the plastic ring to the posterior surface of the implant. Use the clamp to apply a significant amount of pressure to the implant to fully seat the implant on the patellar surface. Remove excess cement.

Step Eleven
Close Incision

Freely irrigate the wound with the solution of choice. A drain may be placed intracapsularly. Then close the wound with sutures, and apply a bandage.

Appendix 1

This appendix should be used as a supplement to the MIS *Quad-Sparing*™ and MIS *Multi-Reference* 4-in-1 surgical technique when the optional MIS Telescoping Locking Boom (Fig. A) is used. Follow the instructions for the MIS Locking Boom (00-5983-028-00) within the MIS *Quad-Sparing* and MIS *Multi-Reference* 4-in-1 surgical techniques with the following additional instructions.

Surgical Technique

Attach the MIS Telescoping Locking Boom to the yoke on the appropriate MIS *Quad-Sparing* A/P Sizing Tower or MIS *Multi-Reference* 4-in-1 A/P Sizing Guide. The position of the boom dictates the exit point of the saw blade for anterior bone cut and the desired anterior position of the femoral component.

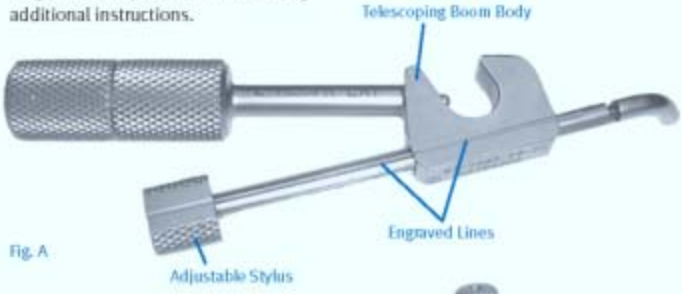


Fig. A

Adjustable stylus: The Telescoping Boom is attached to the yoke of the A/P Sizing instrument (Fig. B). The Stylus Tip is extended to the ideal point on the anterior femoral cortex which is located slightly lateral of patellar femoral groove, proximal of the lateral condyle where the slope begins to flatten (i.e. valley).

The Telescoping Boom can easily be adapted for use on either left medial/right lateral or right medial/left lateral cases. For left medial/right lateral use, the etching - L MED/R LAT must be facing up with the stylus tip pointing down. If the stylus tip is pointing up, slide the stylus fully distally using the knob and rotate the knob 180 degrees counterclockwise.

NOTE: The Stylus is designed to be rotated at only one position.

The engraved lines on the stylus and the Body of the Telescoping Locking Boom must be in alignment during sizing.

NOTE: Clear any soft tissue or bony fragments that interfere with the Telescoping Boom Body prior to sizing.

Fig. B

Please refer to package insert for complete product information, including contraindications, warnings, precautions, and adverse effects.

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Appendix F – Results

Femoral Preparation

Group Analysis

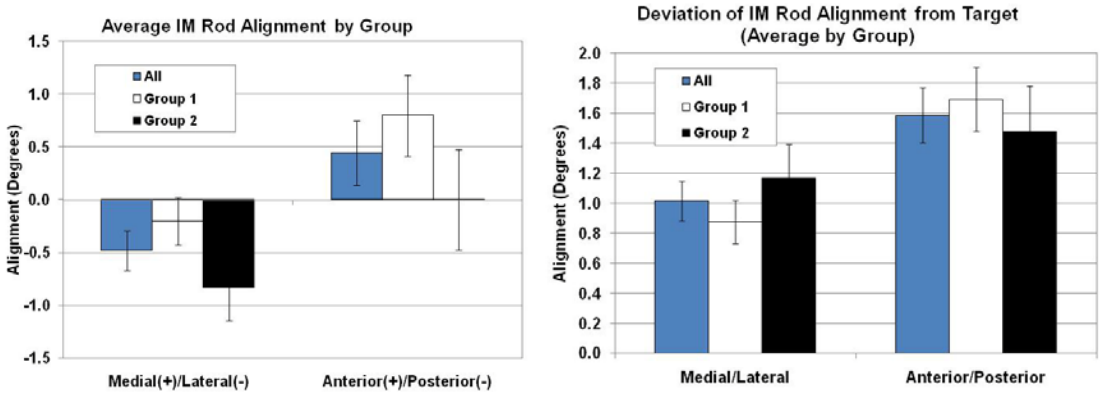


Figure F.1. and F.2. Average IM rod alignment (left) and deviation from target (right) (Degrees) by group in the cadaveric trials.

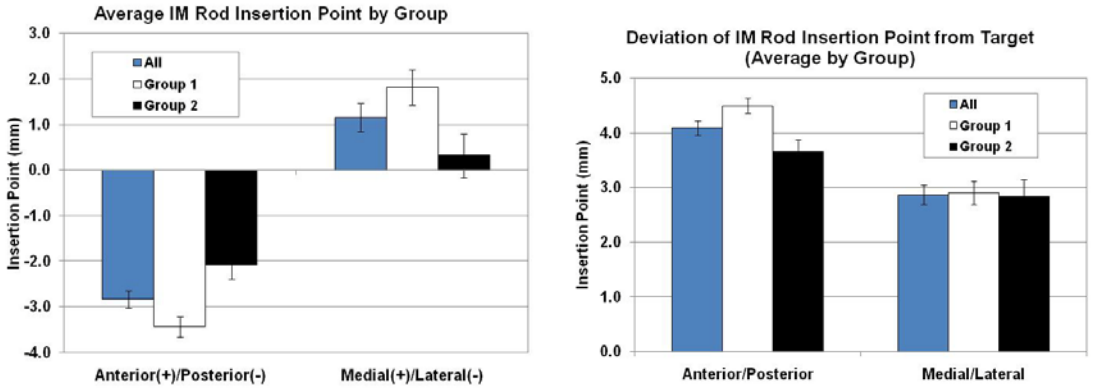
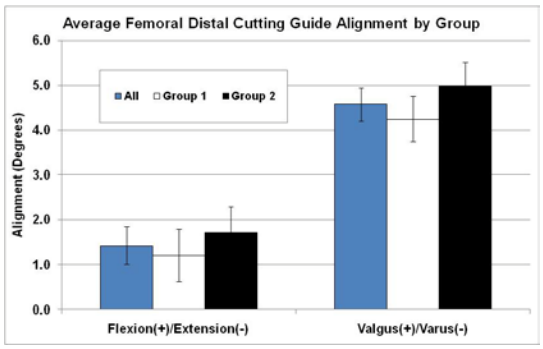


Figure F.3 and F.4. Average IM rod insertion point (left) and deviation from target (right) (mm) by group in the cadaveric Trials.



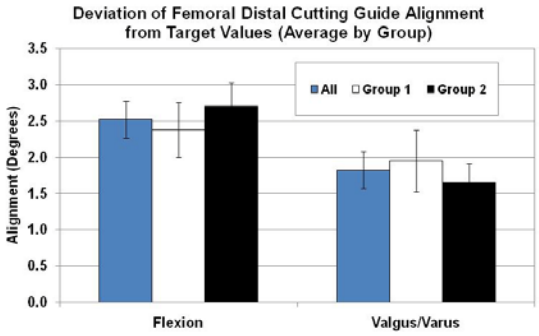
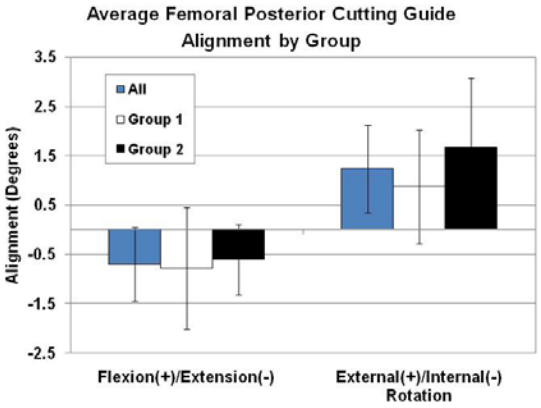


Figure F.5 and F.6. Average femoral distal cutting guide alignment (left) and deviation from target (right) (Degrees) by group in the cadaveric Trials.



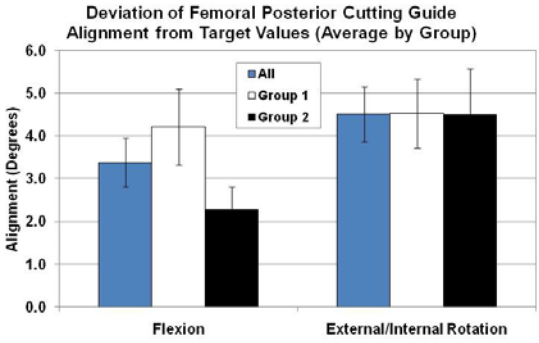
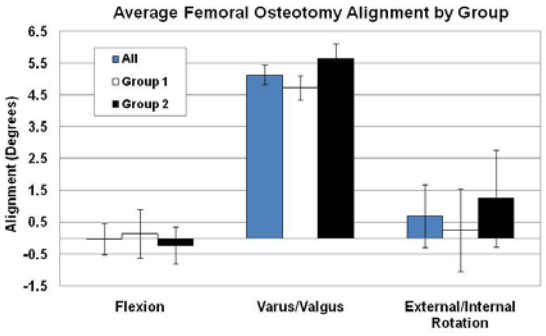


Figure F.7 and F.8. Average femoral posterior cutting guide alignment (left) and deviation from target (right) (Degrees) by group with regards to flexion/extension and external/internal rotation iin the cadaveric trials.



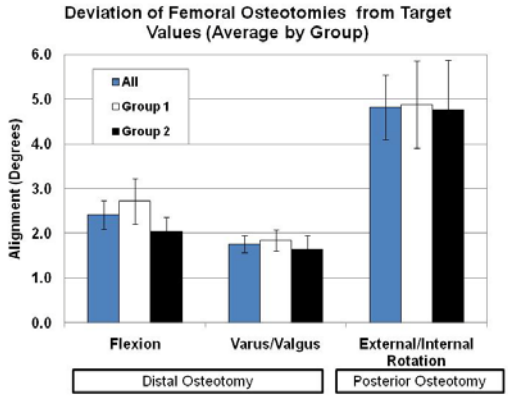


Figure F.9 and F.10. Average femoral osteotomy alignment (left) and deviation from target (right) by group with regards to flexion, varus/valgus and external/internal rotation in the cadaveric trials.

Analysis by Trial Type

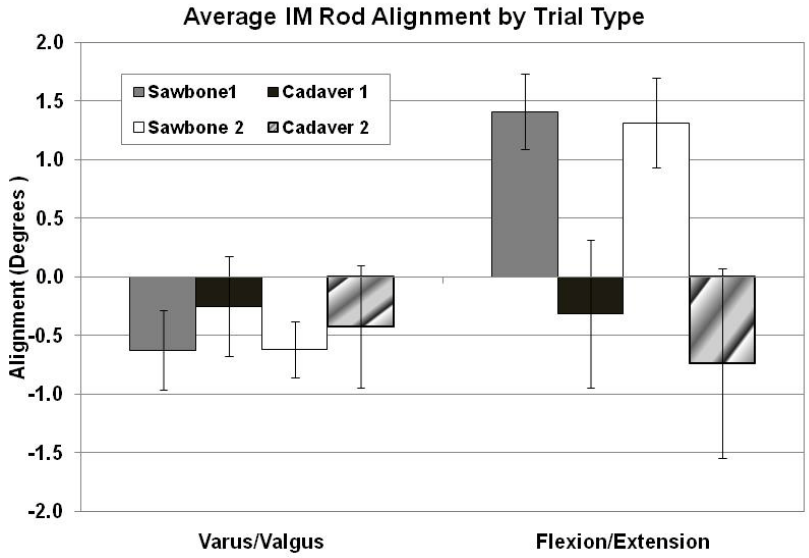


Figure F.11. Average IM rod alignment for each trial with respect to the varus/valugus and flexion/extension angle (Degrees).

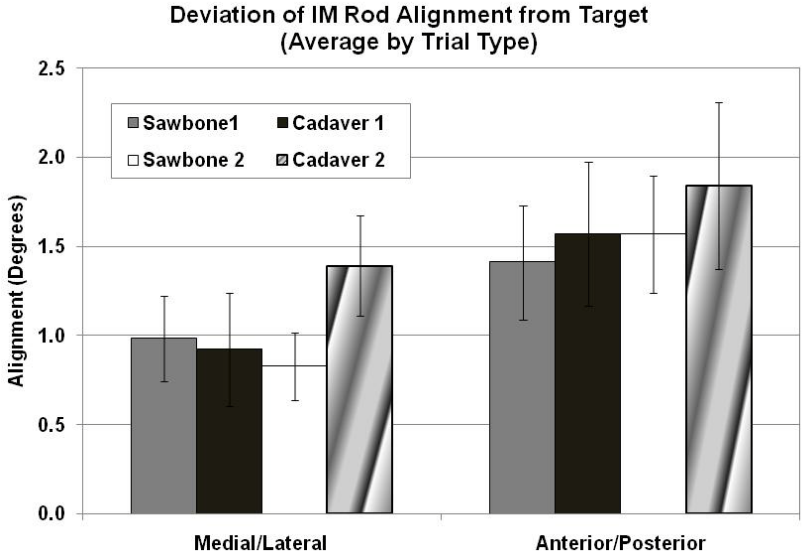


Figure F.12. Average deviation of IM Rod alignment from target for each trial with respect to the medial/lateral and anterior/posterior angle (Degrees).

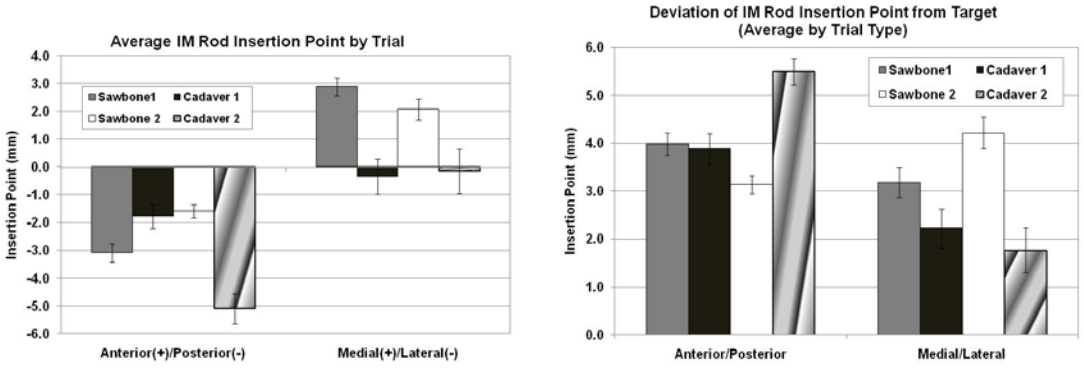


Figure F.13 and F.14. Average IM rod insertion point (left) and deviation from target (right) (mm) for each trial with respect to the anterior/posterior and medial/lateral distance.

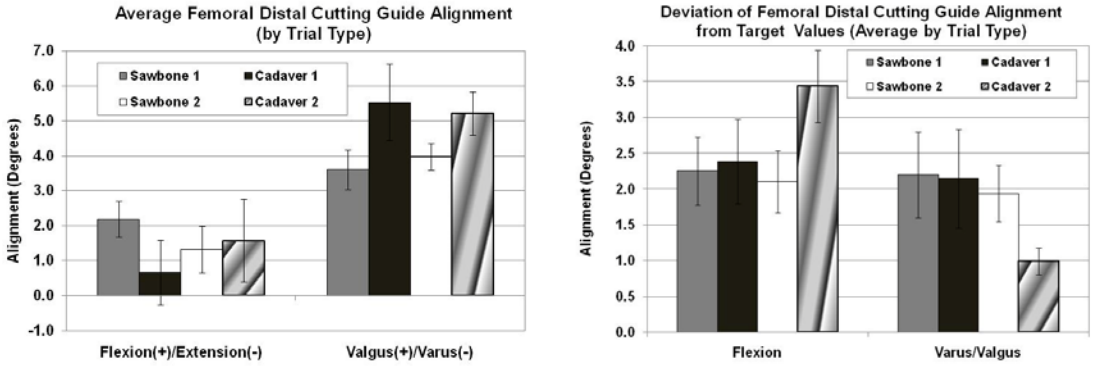


Figure F.15 and F.16. Average femoral distal cutting guide alignment (left) and deviation from target (right) (Degrees) for each trial with respect to the flexion/extension and varus/valgus angles.

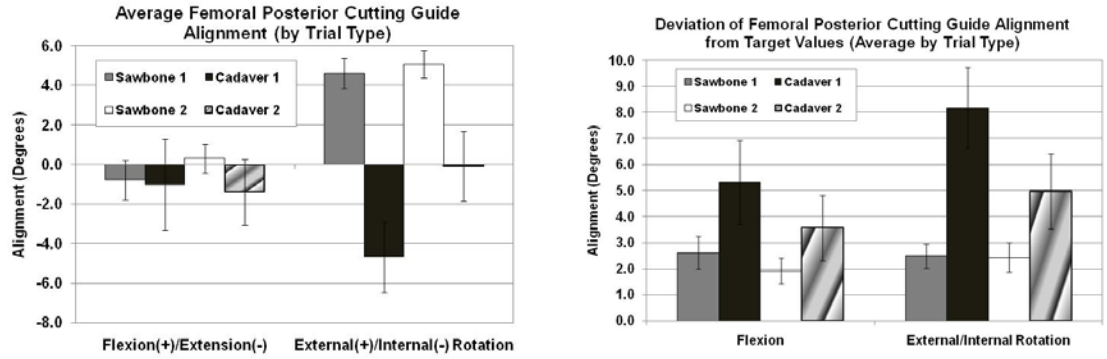


Figure F.17 and F.18. Average femoral posterior cutting guide alignment (left)and deviation from target (right) (Degrees) with respect to the flexion/extension and external/internal rotation angles.

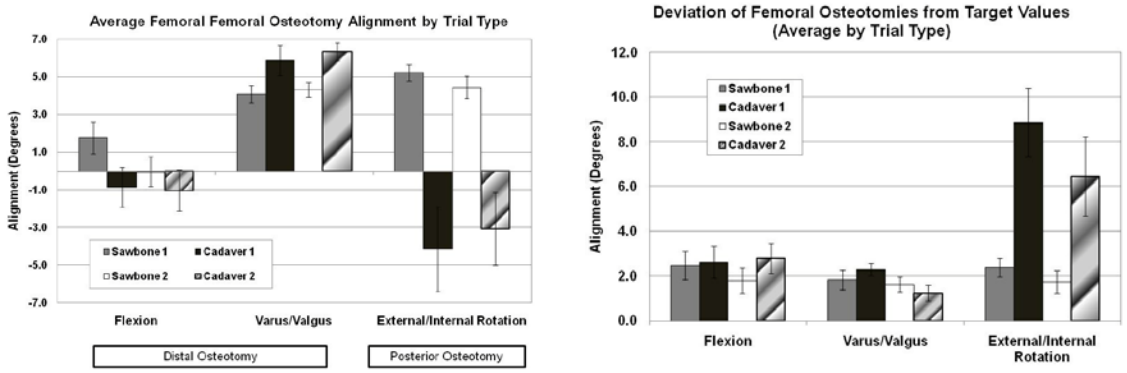


Figure F.19 and F.20. Average femoral osteotomy alignment (left) and deviation from target values (right) (Degrees) for all trials with respect to the flexion, varus/valgus and external/internal rotation angles.

Tibial Preparation

Group Analysis

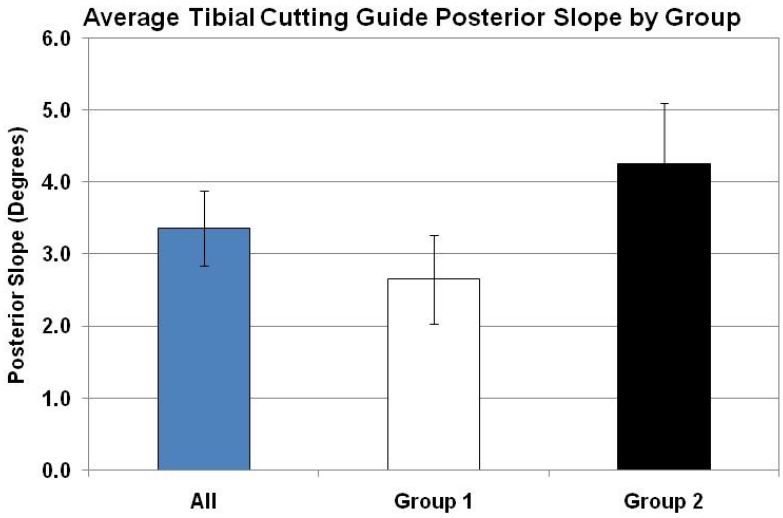


Figure F.21. Average posterior slope (Degrees) of the tibial cutting guide by group.

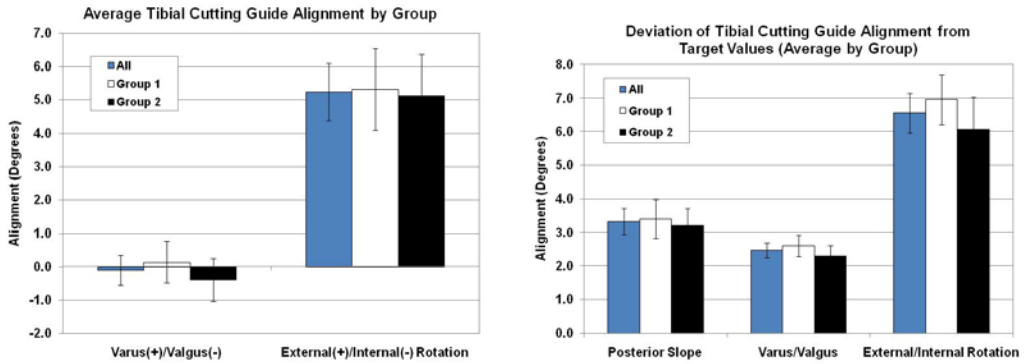


Figure F.22 and F.23. Average tibial cutting guide alignment (left) and deviation from target (right) (Degrees) by group with respect to the varus/valgus, external/internal rotation and posterior slope angles.

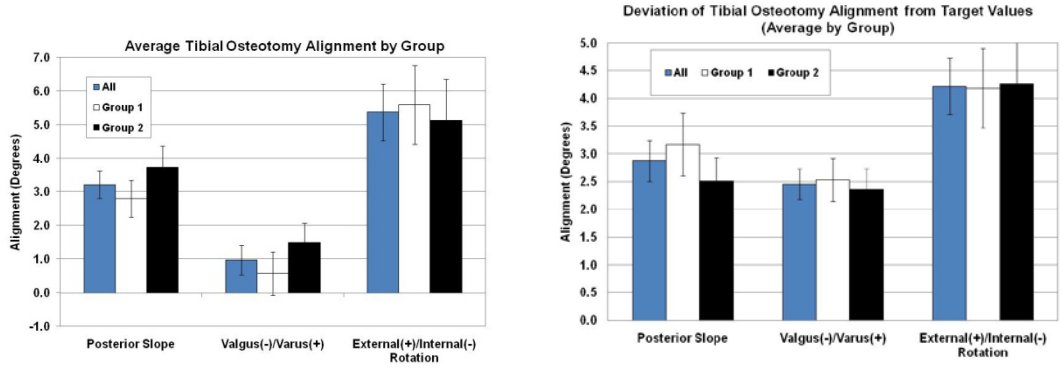


Figure F.24 and F.25. Average tibial osteotomy alignment (left) and deviation from target (right) (Degrees) by group with respect to the varus/valgus, external/internal rotation and posterior slope angles.

Analysis by Trial Type

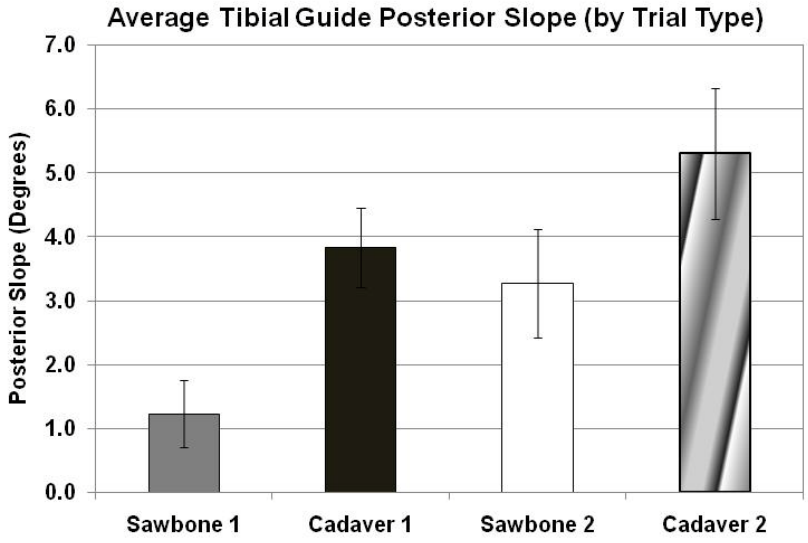
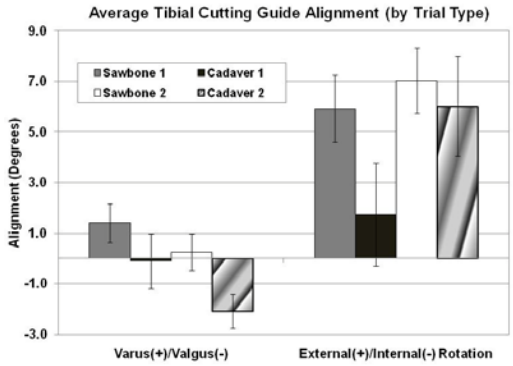


Figure F.26. Average posterior slope of the tibial guide (Degrees) for each trial type.



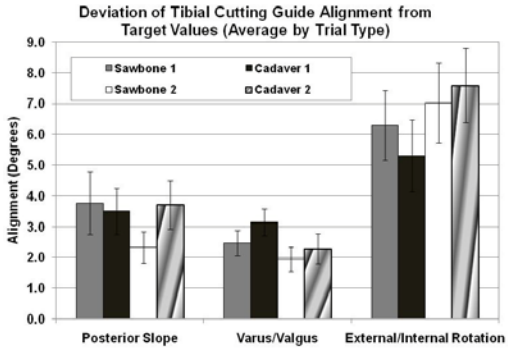


Figure F.27 and F.28. Average tibial guide alignment (left) and deviation from target values (right) (Degrees) for each trial type with respect to the varus/valgus, external/internal rotation and posterior slope angles.

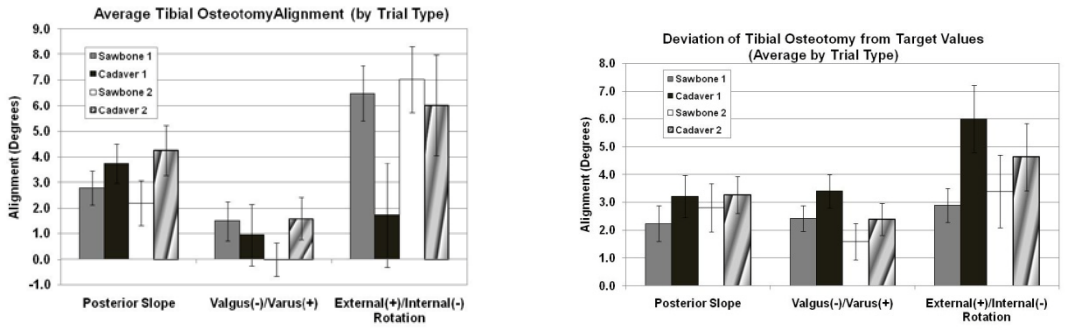
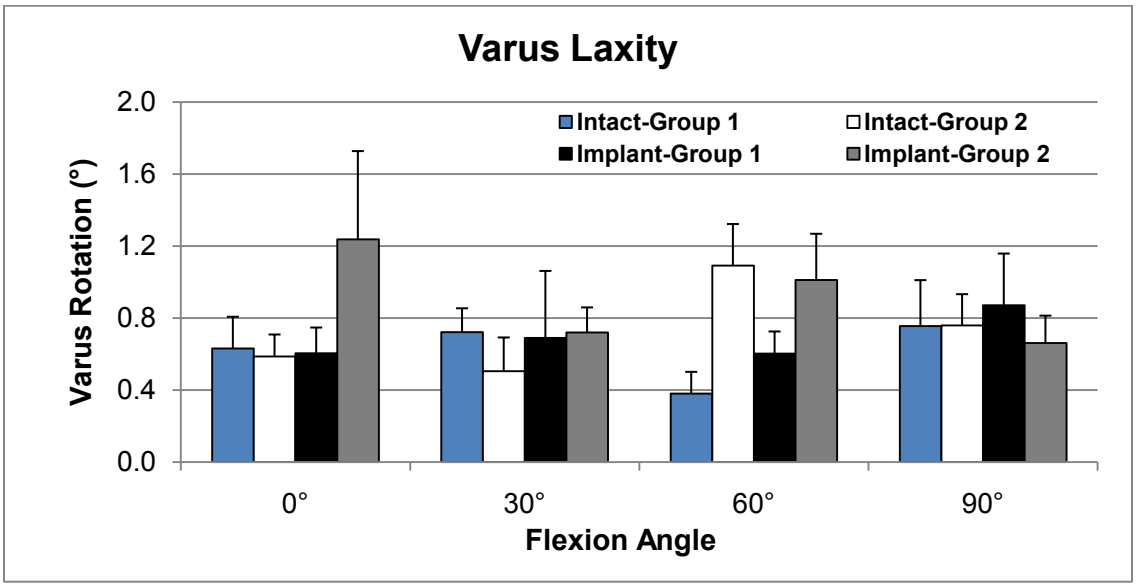
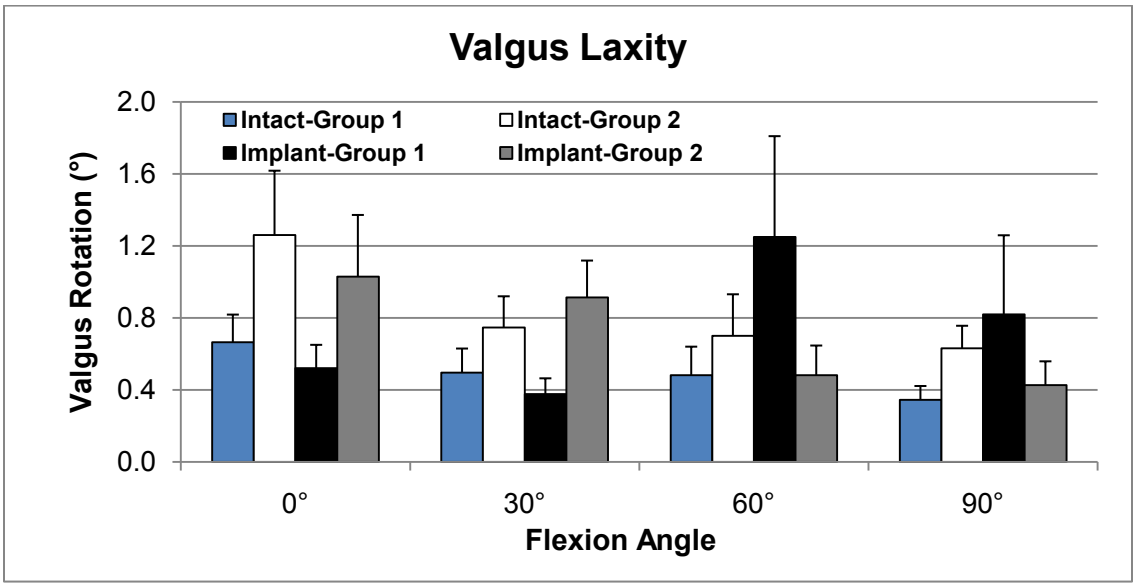
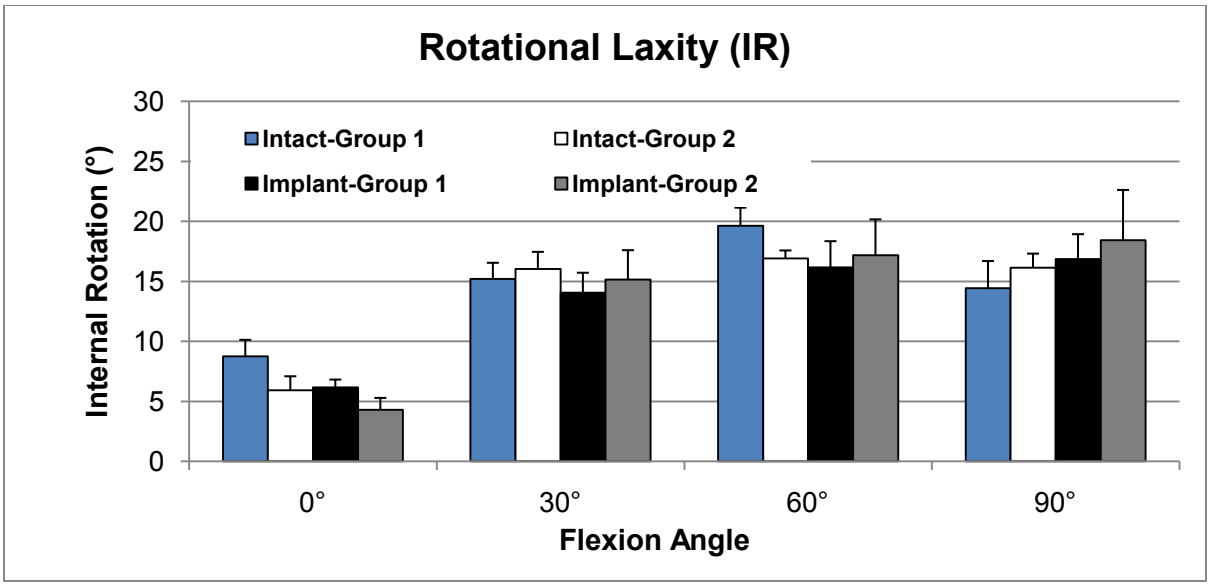


Figure F.29 and F.30. Average tibial osteotomy alignment (left) and deviation from target (right) (Degrees) for each trial type with respect to the varus/valgus, external/internal rotation and posterior slope angles.

Appendix G – Soft Tissue Balancing







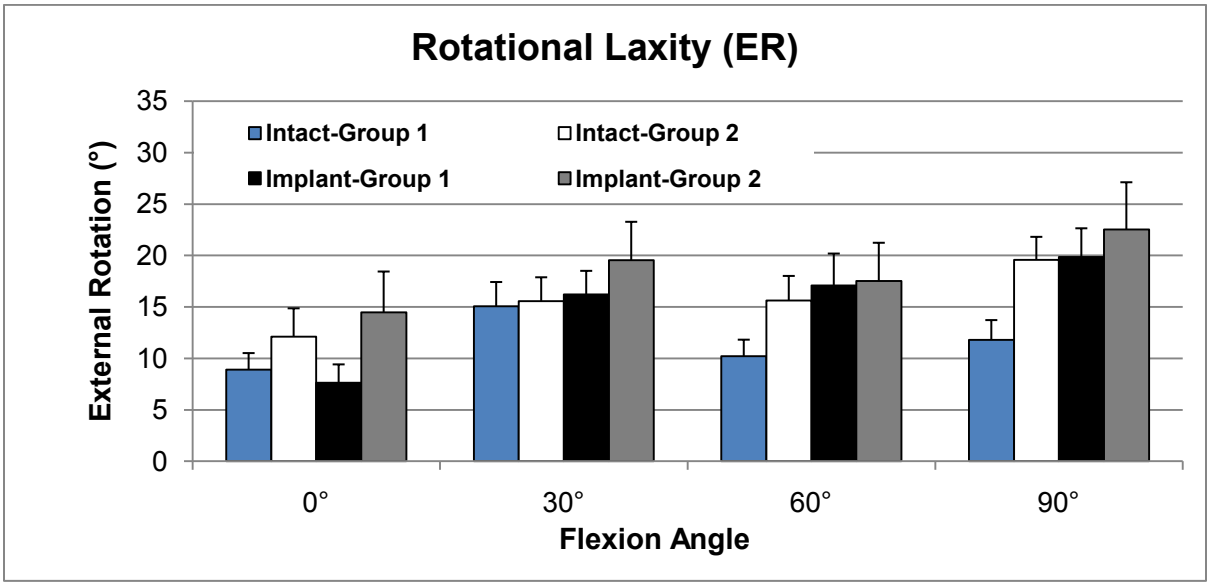
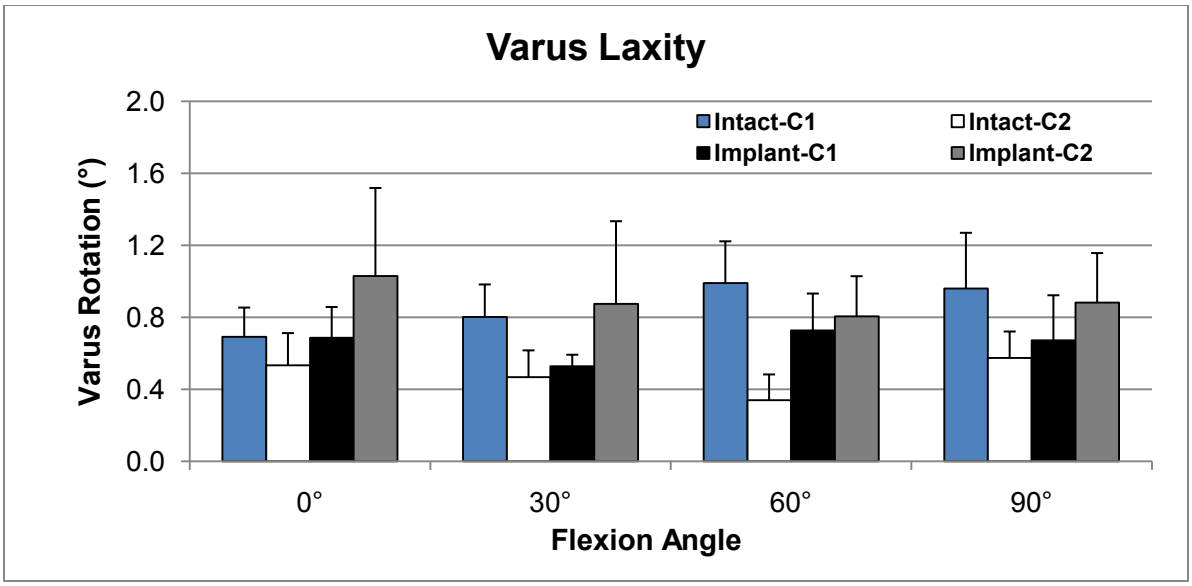
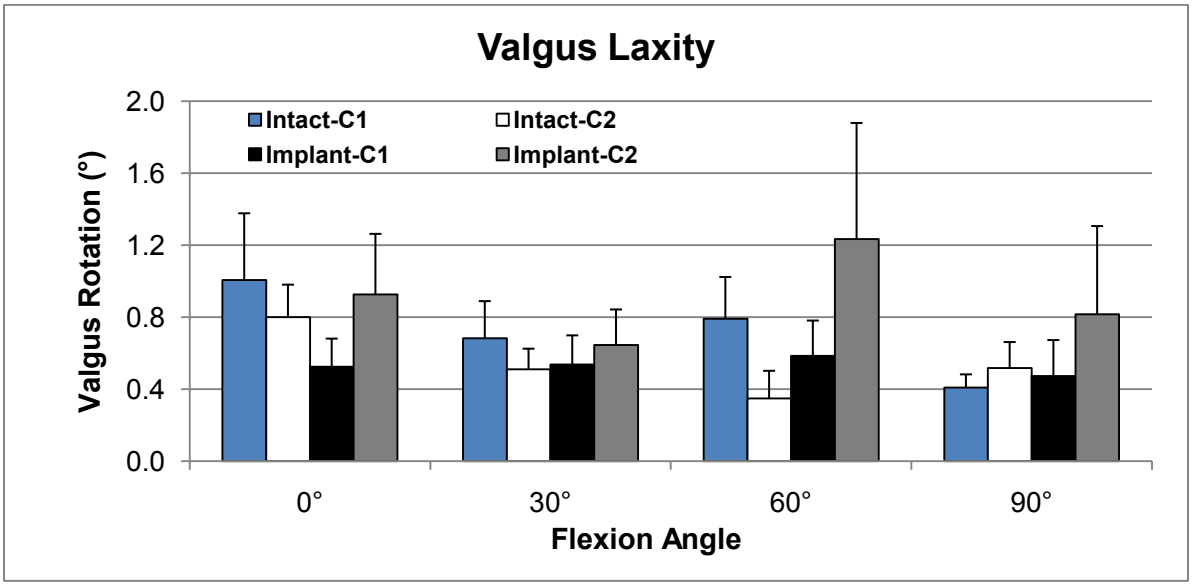
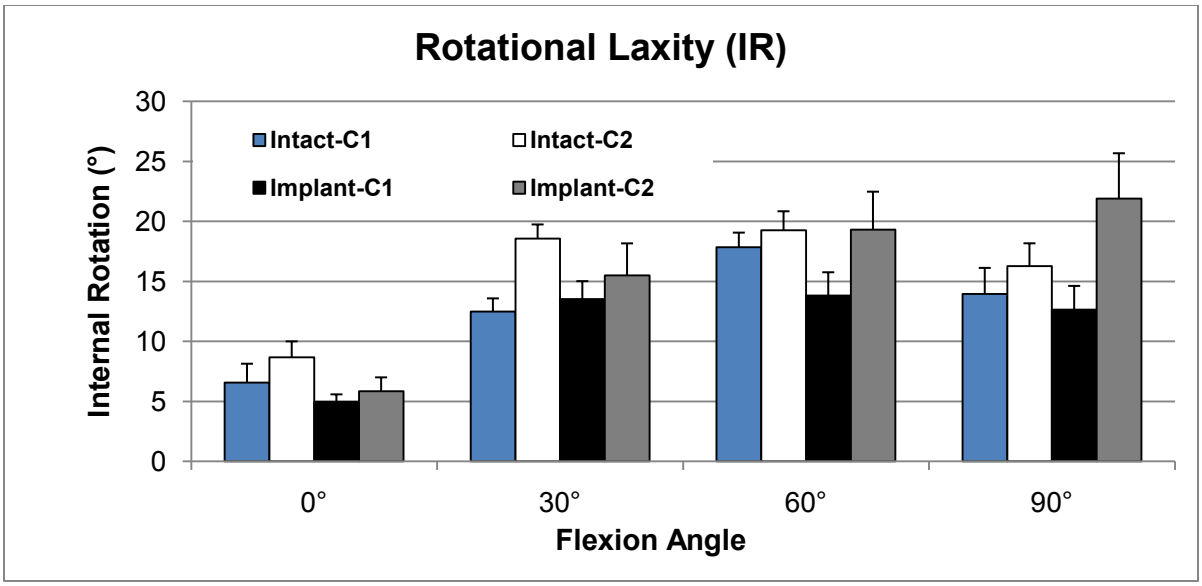


Figure A1. Pre-operative and post-operative frontal and transverse laxity measurements comparing surgeons in Group 1 and Group 2


Varus Laxity
Intact-C1
Intact-C2
Implant-C1
Implant-C2
Varus Rotation (°)
2.0
1.6
1.2
0.8
0.4
0.0
0°
30°
60°
90°
Flexion Angle


Valgus Laxity
Intact-C1
Intact-C2
Implant-C1
Implant-C2
Valgus Rotation (°)
2.0
1.6
1.2
0.8
0.4
0.0
0°
30°
60°
90°
Flexion Angle



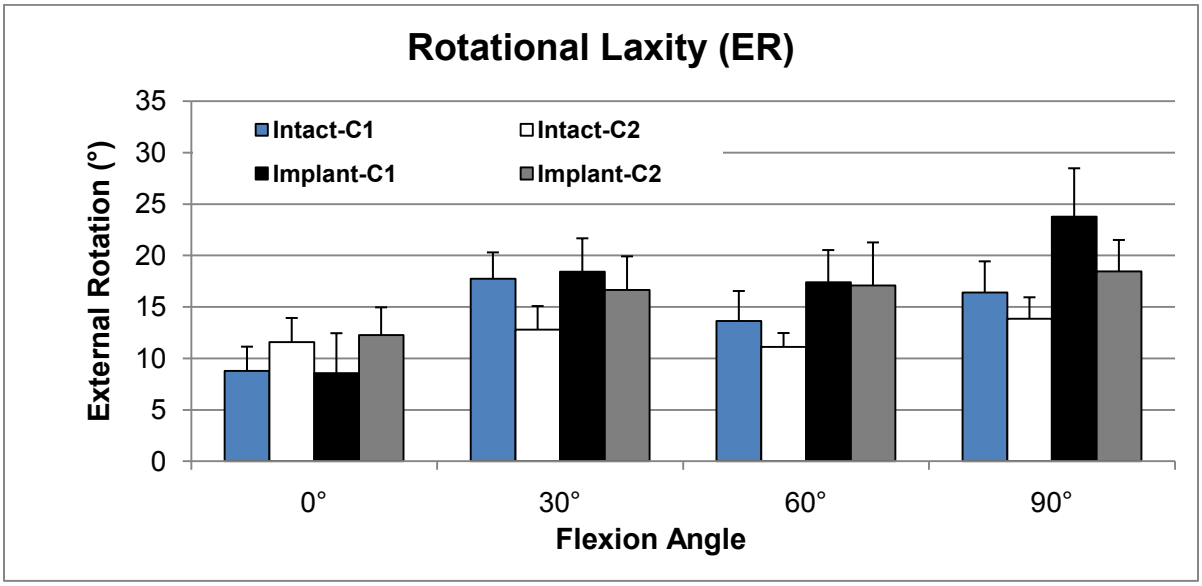


Figure A2. Pre-operative and post-operative frontal and transverse laxity measurements comparing all measurements obtained in surgery performed on cadaver 1 and cadaver 2

Appendix H– Bioskills Patent

(12) **United States Patent**
Noble et al.

(10) **Patent No.: US 7,427,200 B2**
(45) **Date of Patent: Sep. 23, 2008**

(54) **COMPUTER-BASED TRAINING METHODS FOR SURGICAL PROCEDURES**

(76) Inventors: **Philip C. Noble**, 3620 Albans Rd., Houston, TX (US) 77005; **Michael Conditt**, 1110 Anofover, Pearland, TX (US) 77504

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 908 days.

(21) Appl. No.: **10/417,403**

(22) Filed: **Apr. 16, 2003**

(65) **Prior Publication Data**

US 2004/0030245 A1 Feb. 12, 2004

Related U.S. Application Data

(60) Provisional application No. 60/372,873, filed on Apr. 16, 2002.

(51) **Int. Cl.**
G09B 23/28 (2006.01)
A61B 5/00 (2006.01)

(52) **U.S. Cl.** **434/274**; 600/416; 703/11; 378/20; 345/581; 345/619

(58) **Field of Classification Search** 434/274; 703/11; 600/416; 378/20
See application file for complete search history.

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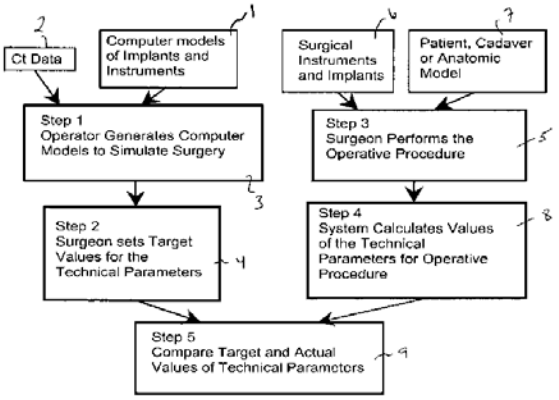
(Continued)

Primary Examiner—Brian L. Casler
Assistant Examiner Parikha S Mehta
(74) *Attorney, Agent, or Firm* Conley Rose, P.C.

(57) **ABSTRACT**

A method is disclosed for analyzing surgical techniques using a computer system for gathering and analyzing surgical data acquired during a surgical procedure on a body portion and comparing that data to pre-selected target values for the particular surgical procedure. The inventive method allows the surgeon, for example, to measure the technical success of a surgical procedure in terms of quantifiable geometric, spatial, kinematic or kinetic parameters. The method comprises calculation of these parameters from data collected during a surgical procedure and then comparing these results with values of the same parameters derived from target values defined by the surgeon, surgical convention, or computer simulation of the same procedure prior to the operation itself.

36 Claims, 21 Drawing Sheets



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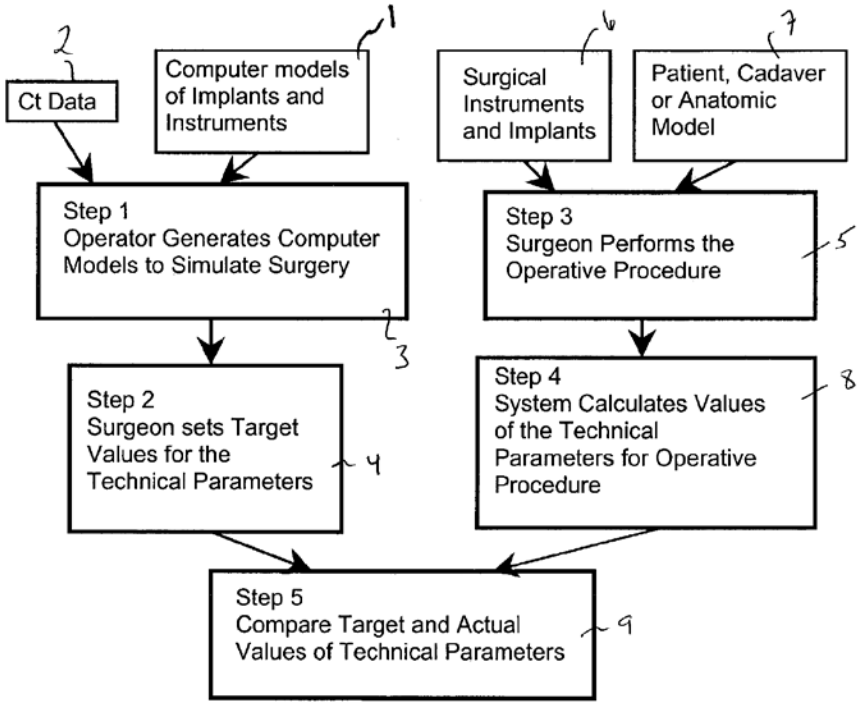
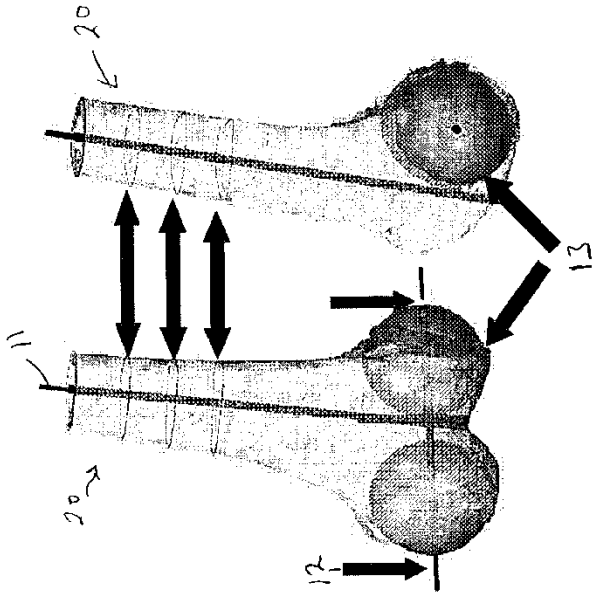

2
Ct Data
1
Computer models of Implants and Instruments
6
Surgical Instruments and Implants
7
Patient, Cadaver or Anatomic Model
Step 1
Operator Generates Computer Models to Simulate Surgery
3
Step 3
Surgeon Performs the Operative Procedure
5
Step 2
Surgeon sets Target Values for the Technical Parameters
4
Step 4
System Calculates Values of the Technical Parameters for Operative Procedure
8
Step 5
Compare Target and Actual Values of Technical Parameters
9

FIG. 1

FIG. 2



Femoral Axes

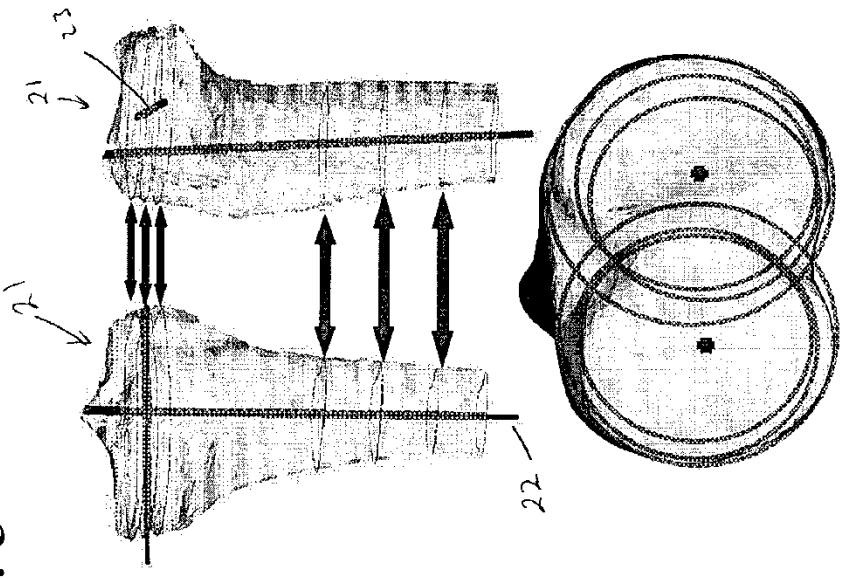
F/E Axis – centers of spheres fit to the condylar surfaces of the intact femur

Longitudinal Axis – line of best fit through the centroids of femoral cross sections

Mechanical Axis – in the plane of the longitudinal axis and perpendicular to the F/E axis

AP Axis – mutually orthogonal to the longitudinal and F/E axes

FIG. 3



Tibial Axes

Longitudinal Axis – best line fit through the centroids of tibial cross sections

M/L Axis – average of centers of circles fit to the cortical edges of surfaces of the intact tibia at slices 2, 4, and 7 mm distal to the tibial plateau

AP Axis – mutually orthogonal to the above axes

FIG. 4

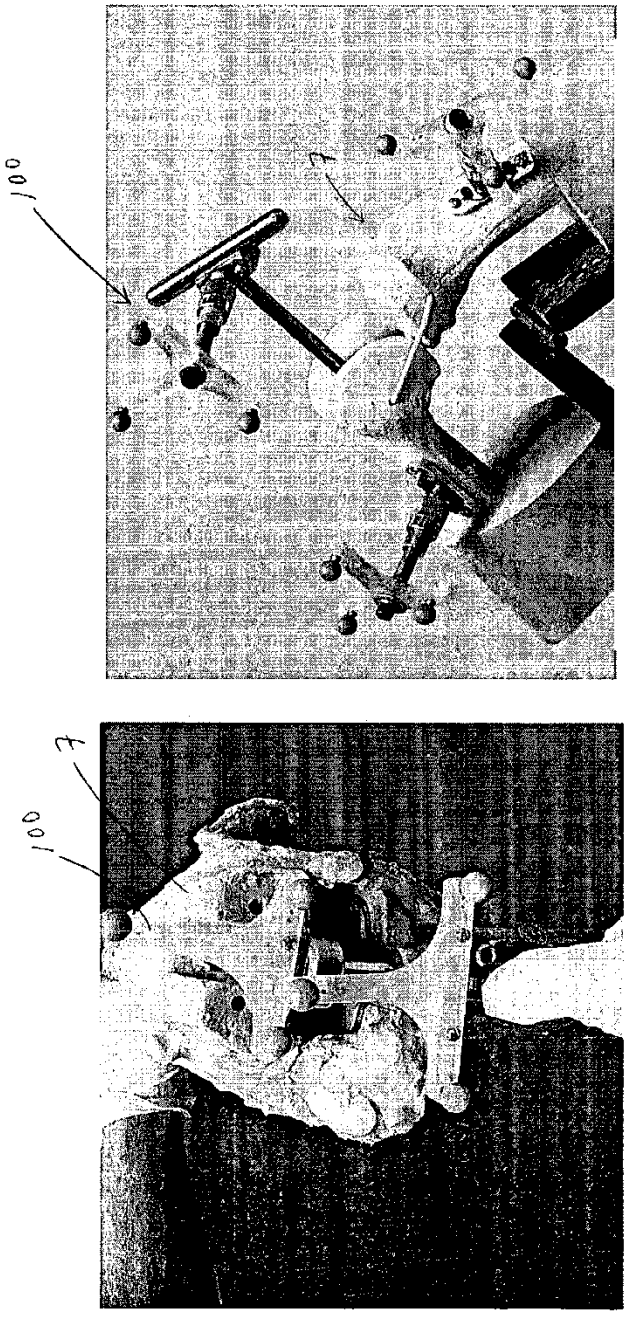
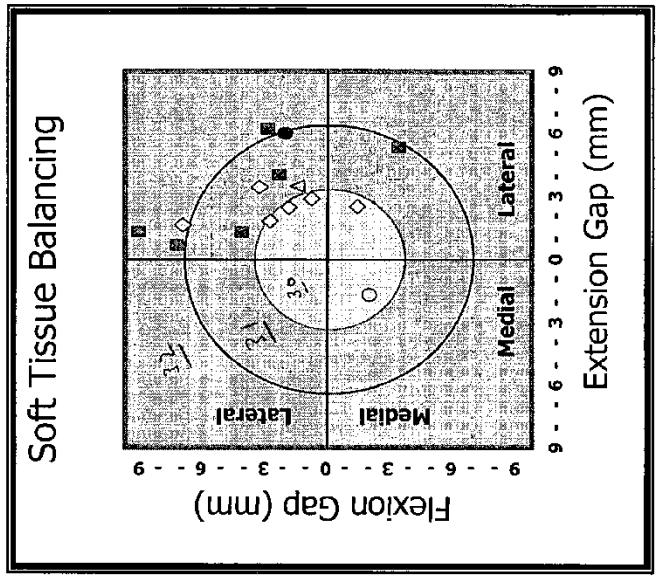


FIG. 5


Soft Tissue Balancing
Flexion Gap (mm)
9 - - 6 - - 3 - - 0 - - 3 - - 6 - - 9
Lateral
Medial
Medial
Lateral
9 - - 6 - - 3 - - 0 - - 3 - - 6 - - 9
Extension Gap (mm)
2°
3°
0°

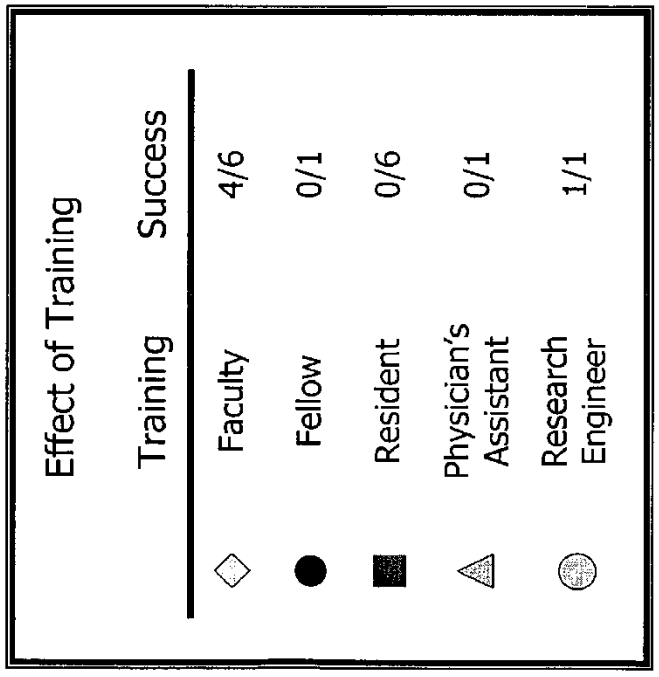

Effect of Training
Training
Success
Faculty
4/6
Fellow
0/1
Resident
0/6
Physician's Assistant
0/1
Research Engineer
1/1

FIG. 6

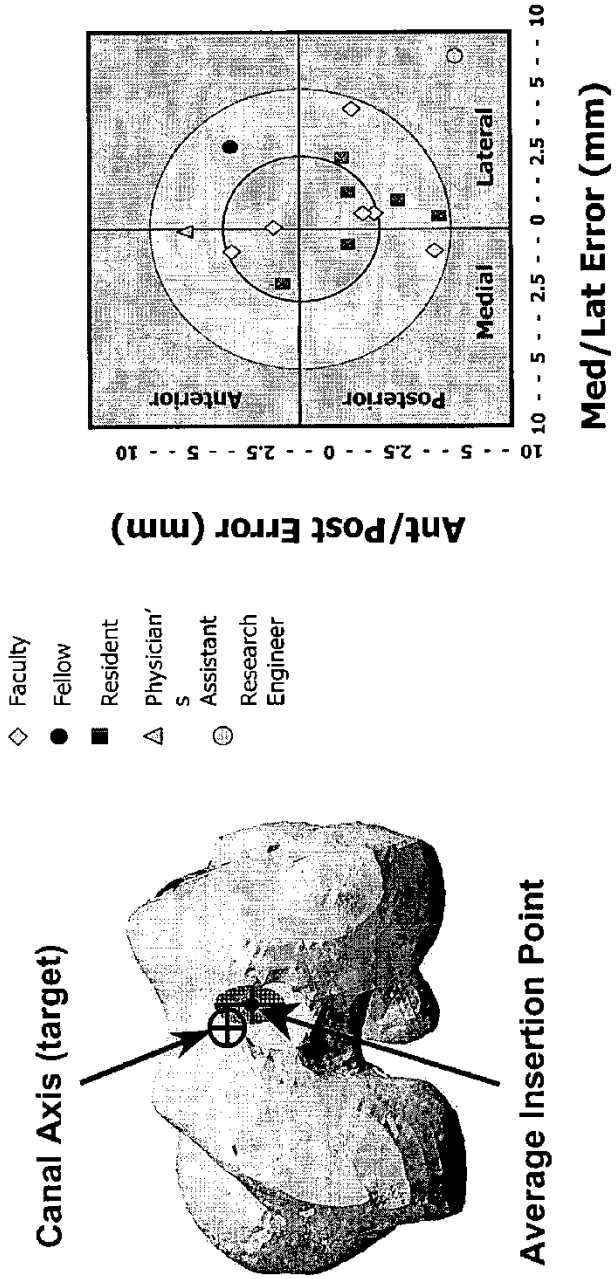

Med/Lat Error (mm)
10 - - 5 - - 2.5 - - 0 - - 2.5 - - 5 - - 10
Lateral
Medial
Posterior
Anterior
Ant/Post Error (mm)
10 - - 5 - - 2.5 - - 0 - - 2.5 - - 5 - - 10
Faculty
Fellow
Resident
Physician's Assistant
Research Engineer
Canal Axis (target)
Average Insertion Point

FIG. 7

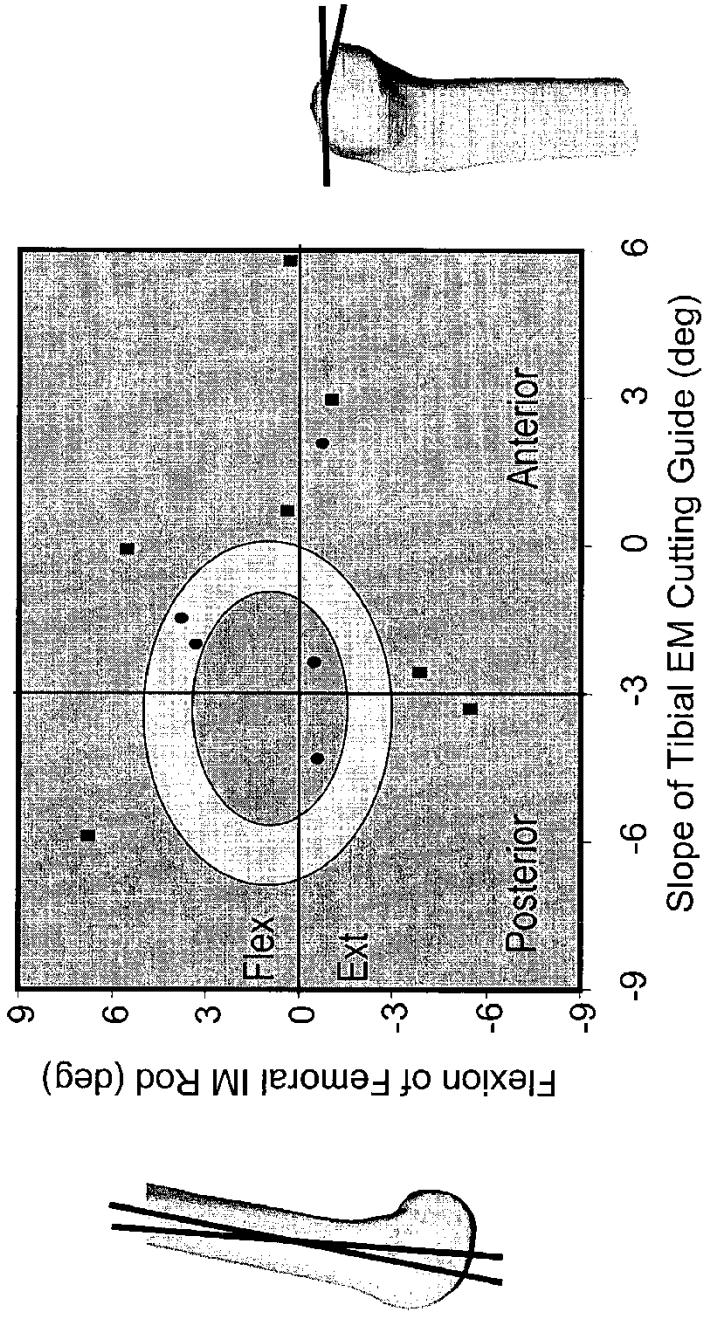

Flexion of Femoral IM Rod (deg)
9
6
3
0
-3
-6
-9
Flex
Ext
Anterior
Posterior
-9
-6
-3
0
3
6
Slope of Tibial EM Cutting Guide (deg)

Fig. 8

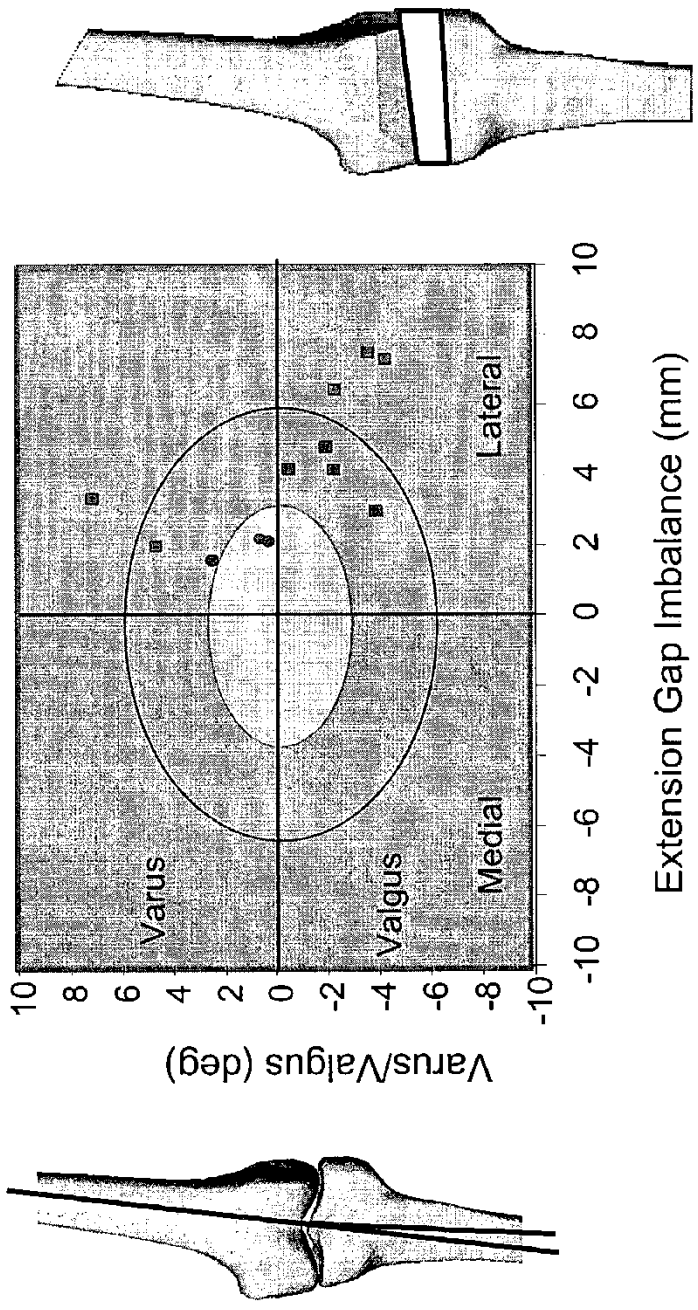

Varus
Valgus
Medial
Lateral
10
8
6
4
2
0
-2
-4
-6
-8
-10
Varus/Valgus (deg)
-10
-8
-6
-4
-2
0
2
4
6
8
10
Extension Gap Imbalance (mm)

FIG. 9

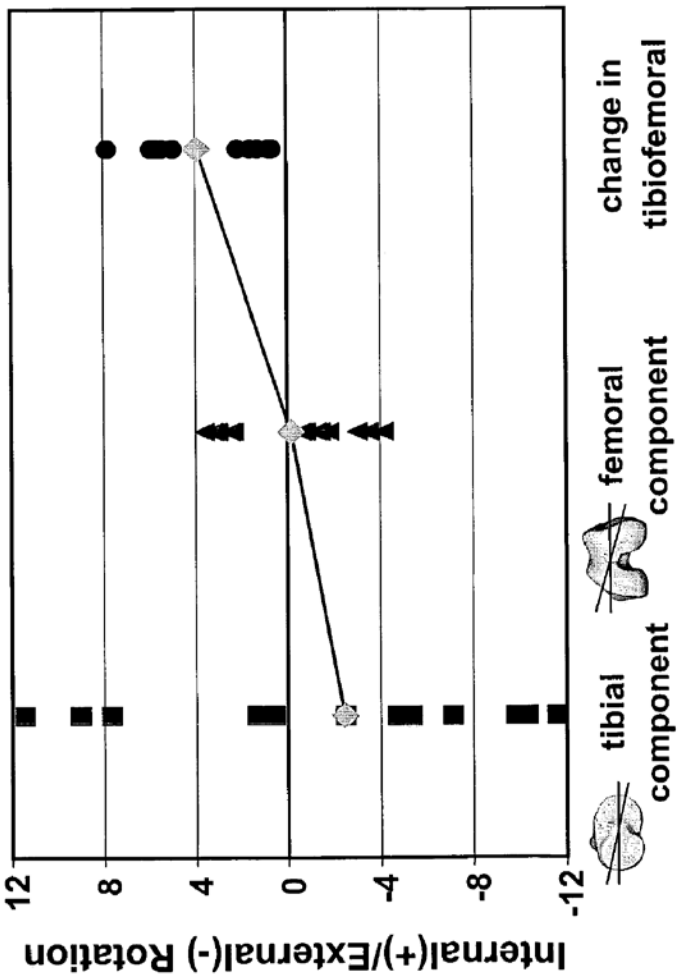

change in tibiofemoral
femoral component
tibial component
12
8
4
0
-4
-8
-12
Internal(+)/External(-) Rotation

FIG. 10

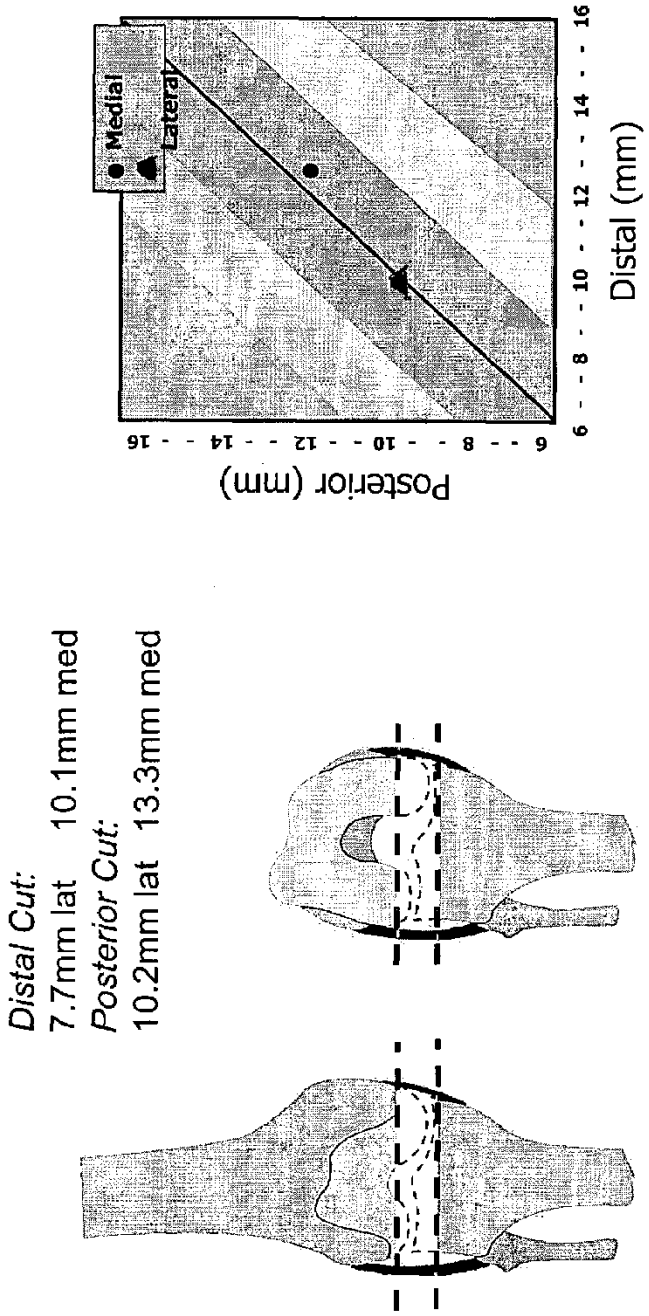

Medial
Lateral
6 - - 8 - - 10 - - 12 - - 14 - - 16
Distal (mm)
6 - - 8 - - 10 - - 12 - - 14 - - 16
Posterior (mm)
Distal Cut:
7.7mm lat 10.1mm med
Posterior Cut:
10.2mm lat 13.3mm med

FIG. 11

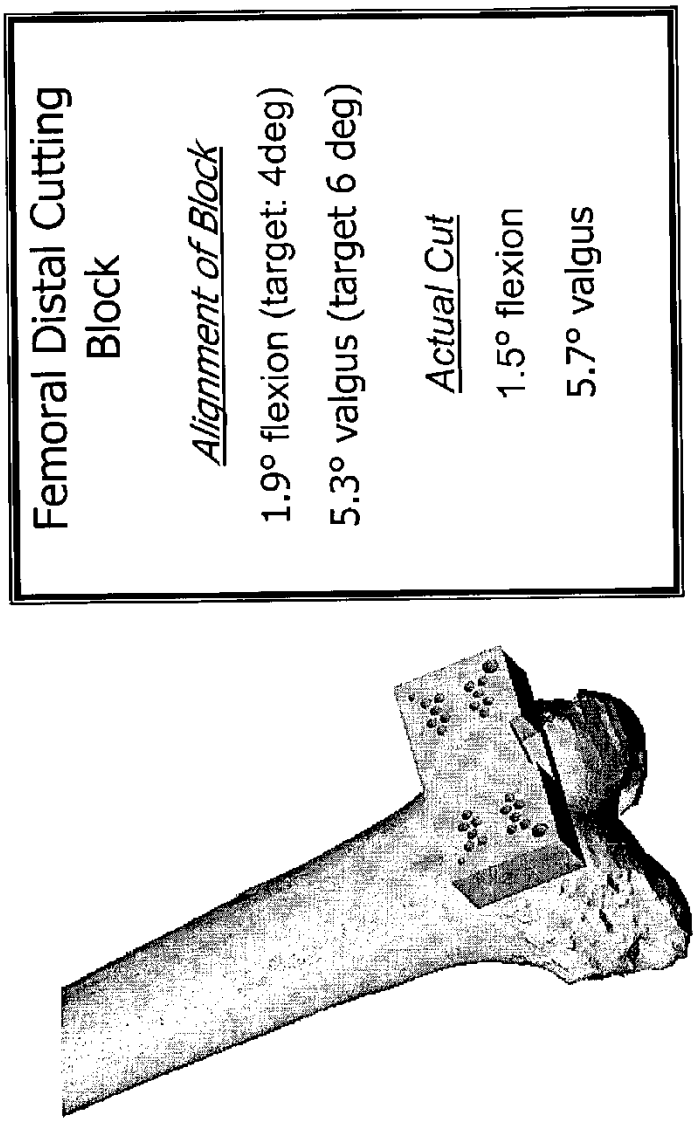
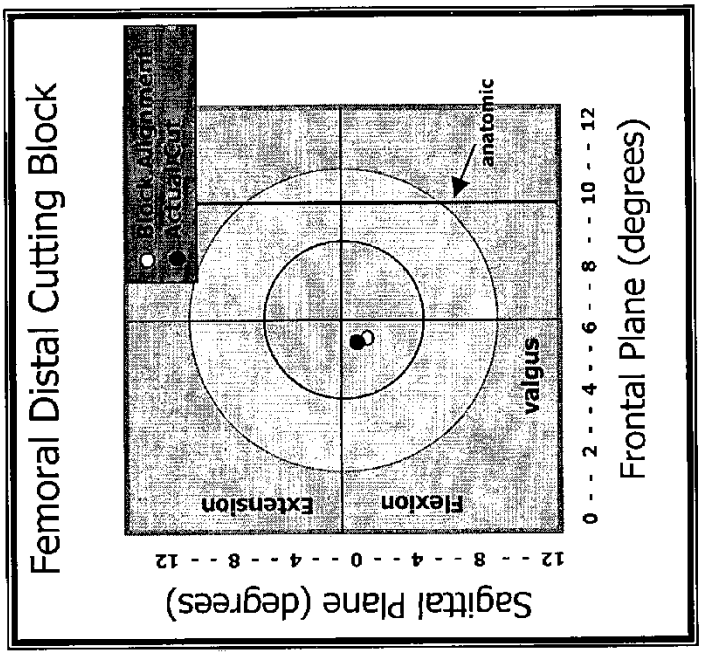

Femoral Distal Cutting Block
Alignment of Block
1.9° flexion (target: 4deg)
5.3° valgus (target 6 deg)
Actual Cut
1.5° flexion
5.7° valgus

FIG. 12


Femoral Distal Cutting Block
Block Alignment
Actual Cut
anatomic
Flexion
Extension
valgus
Sagittal Plane (degrees)
12 - - 8 - - 4 - - 0 - - 4 - - 8 - - 12
0 - - 2 - - 4 - - 6 - - 8 - - 10 - - 12
Frontal Plane (degrees)

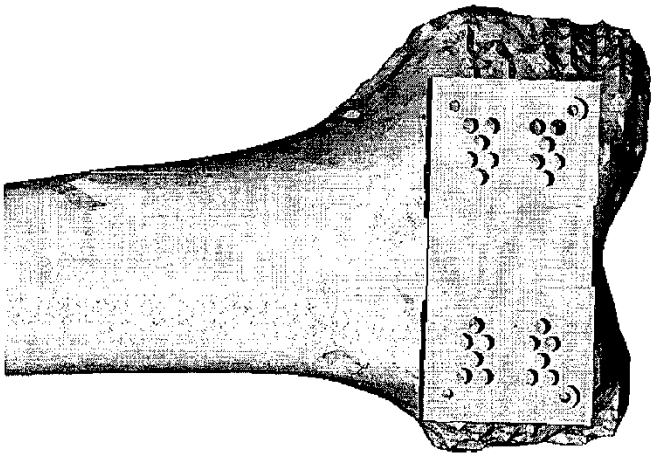
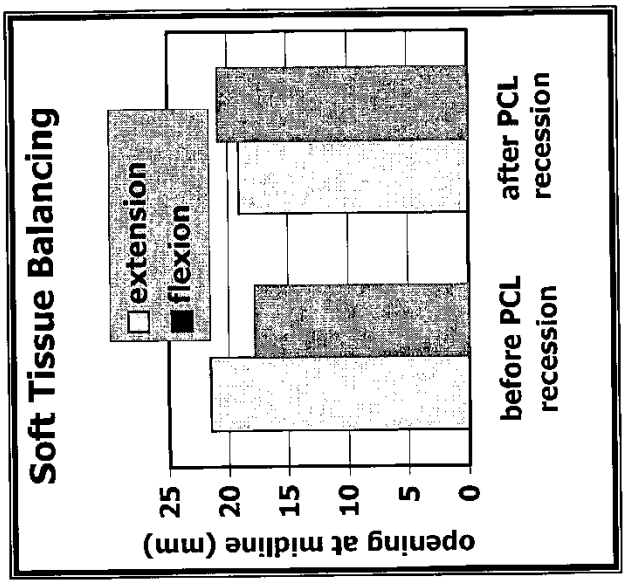


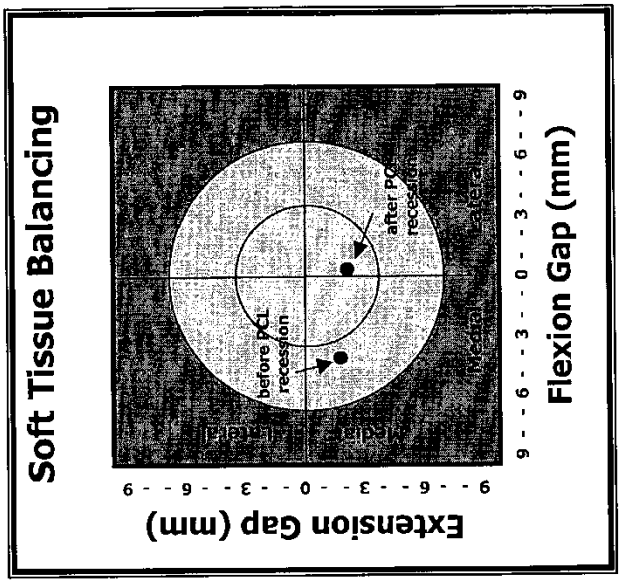
FIG. 13



Changes in Gap Opening with Soft Tissue Release

	Before PCL recession	After PCL recession
Extension Gap	21.5mm	19.1mm
Flexion Gap	17.8mm	20.8mm

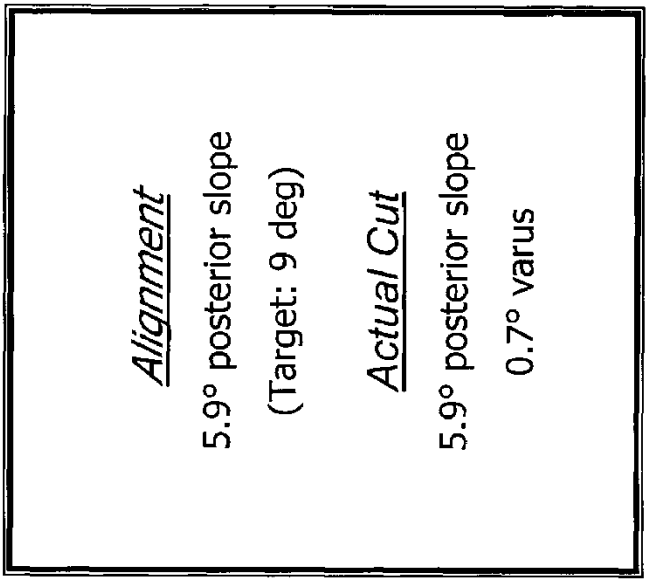
FIG. 14



Changes in Gap Balancing with Soft Tissue Release

	before PCL recession	after PCL recession
Extension Gap	1.8mm medial opening	2.0mm medial opening
Flexion Gap	4.3mm medial opening	0.8mm lateral opening

FIG. 15


Alignment
5.9° posterior slope
(Target: 9 deg)
Actual Cut
5.9° posterior slope
0.7° varus

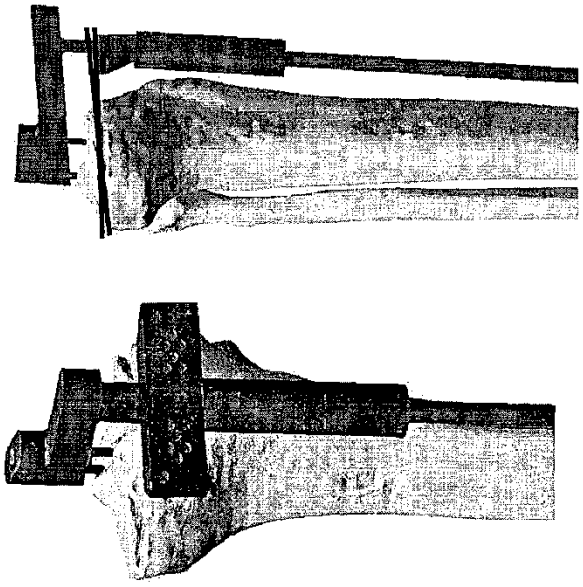
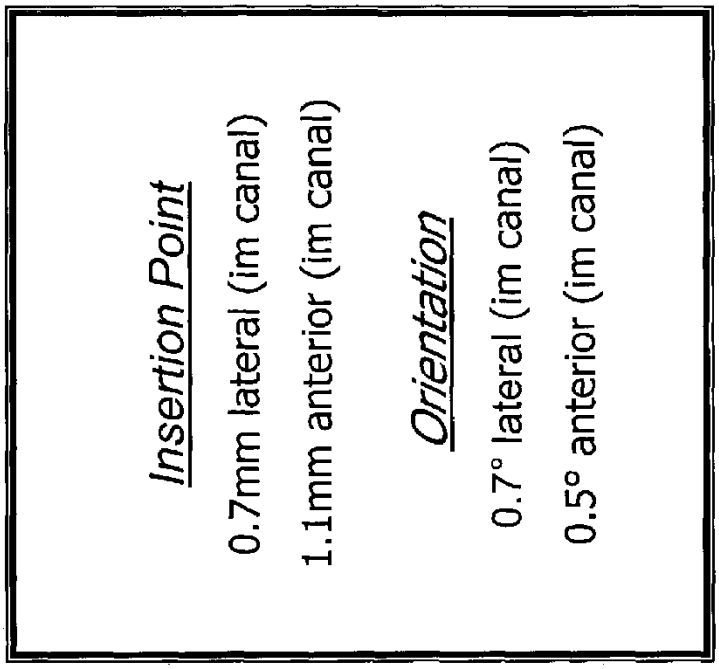


FIG. 16


Insertion Point
0.7mm lateral (im canal)
1.1mm anterior (im canal)
Orientation
0.7° lateral (im canal)
0.5° anterior (im canal)

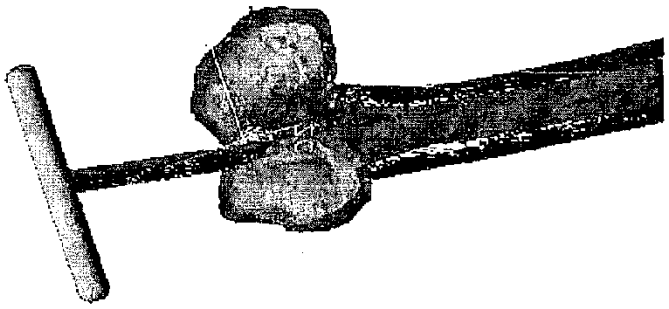


FIG. 17

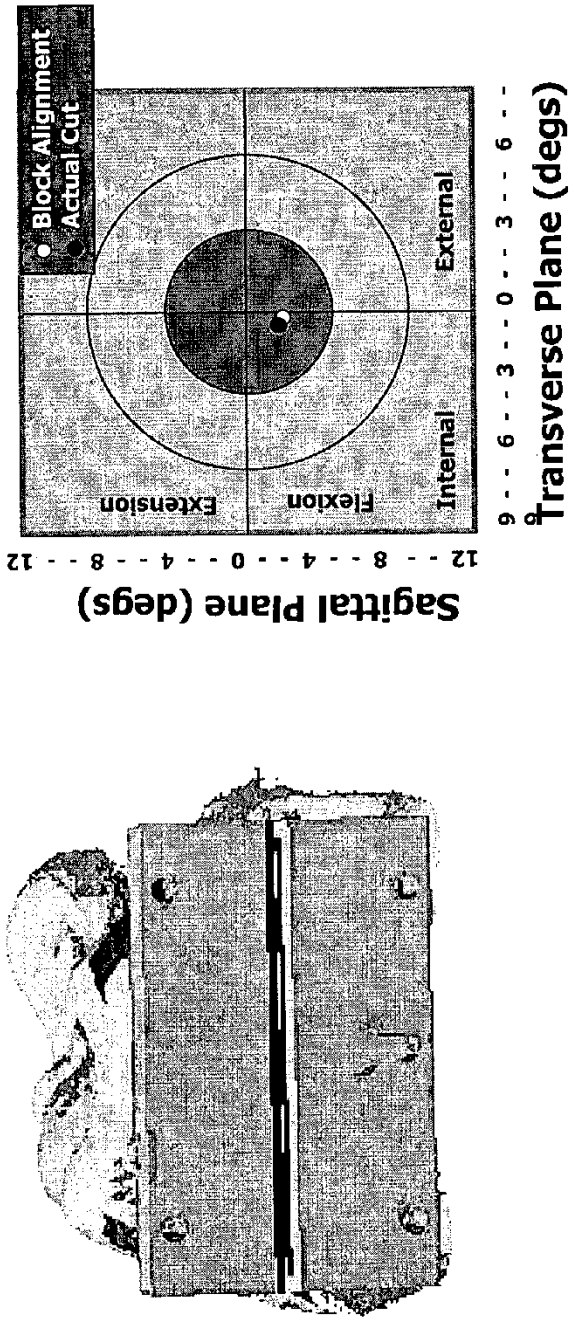
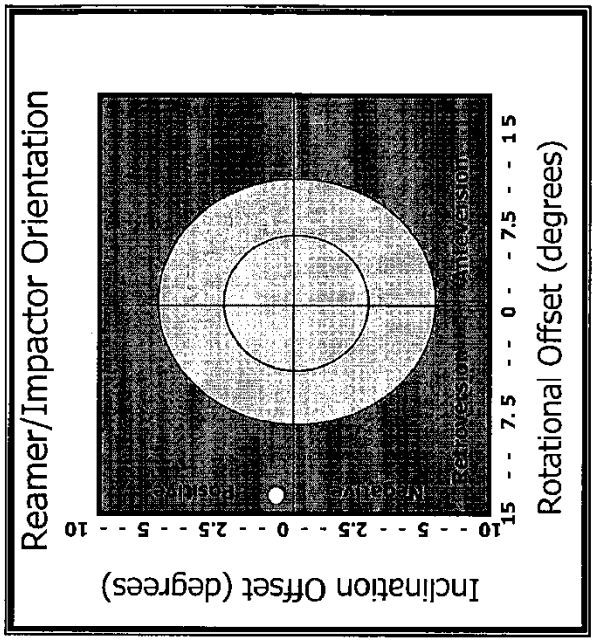

Block Alignment
Actual Cut
External
Internal
Flexion
Extension
12 - - 8 - - 4 - - 0 - - 4 - - 8 - - 12
Sagittal Plane (degs)
9 - - 6 - - 3 - - 0 - - 3 - - 6 - - 9
Transverse Plane (degs)

FIG. 18


Reamer/Impactor Orientation
Inclination Offset (degrees)
10 -- 5 -- 2.5 -- 0 -- 2.5 -- 5 -- 10
Rotational Offset (degrees)
15 -- 7.5 -- 0 -- 7.5 -- 15

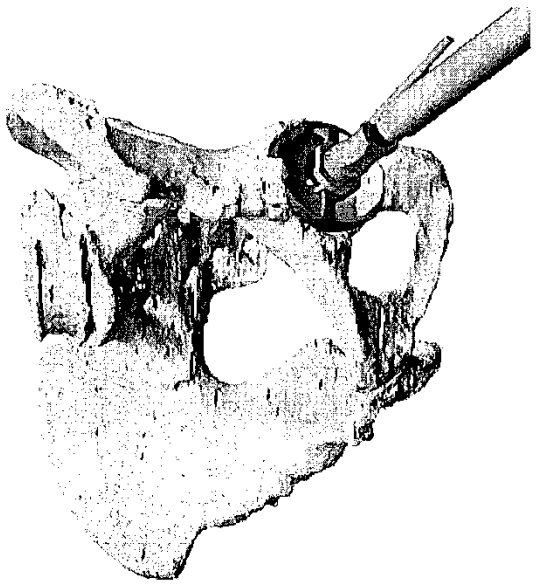
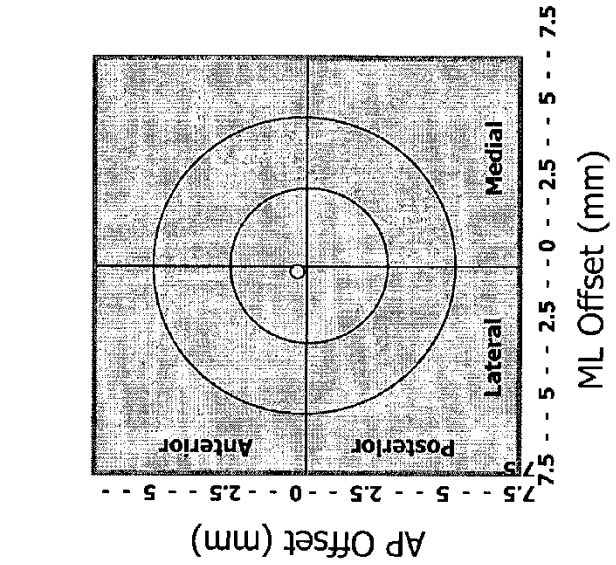


FIG. 19


Anterior
Posterior
Lateral
Medial
AP Offset (mm)
ML Offset (mm)
7.5 -- 5 -- 2.5 -- 0 -- -2.5 -- -5 -- -7.5
7.5 -- 5 -- 2.5 -- 0 -- -2.5 -- -5 -- -7.5

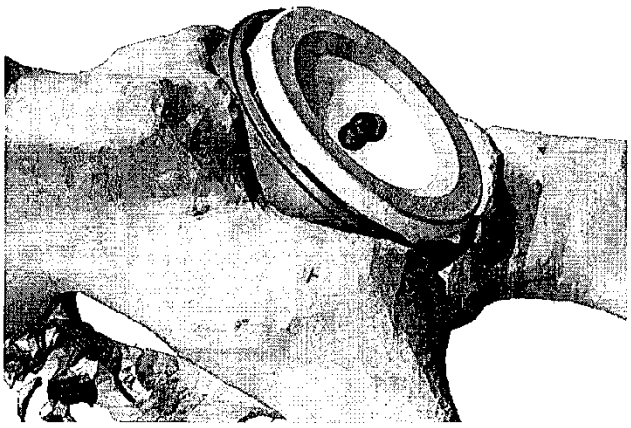
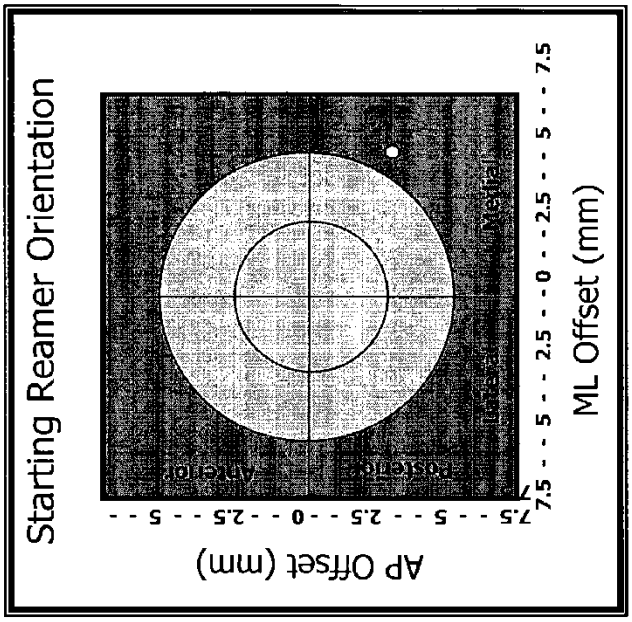


FIG. 20


Starting Reamer Orientation
AP Offset (mm)
7.5 - - 5 - - 2.5 - - 0 - - 2.5 - - 5 - - 7.5
ML Offset (mm)
7.5 - - 5 - - 2.5 - - 0 - - 2.5 - - 5 - - 7.5

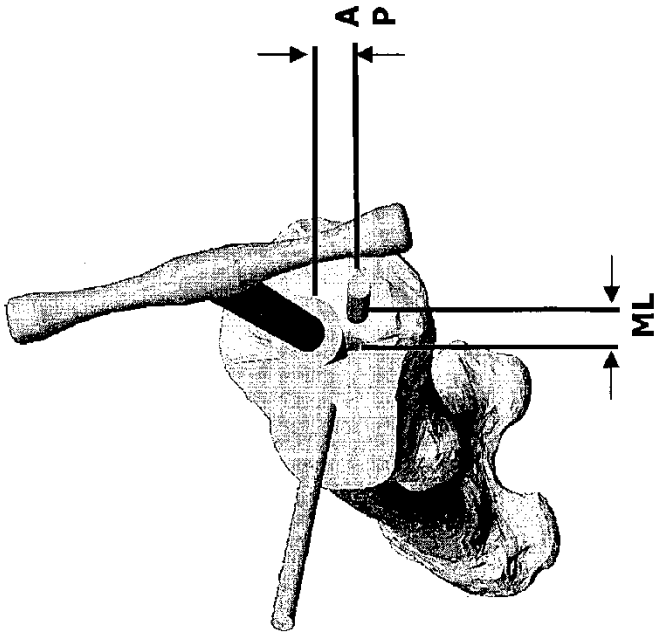
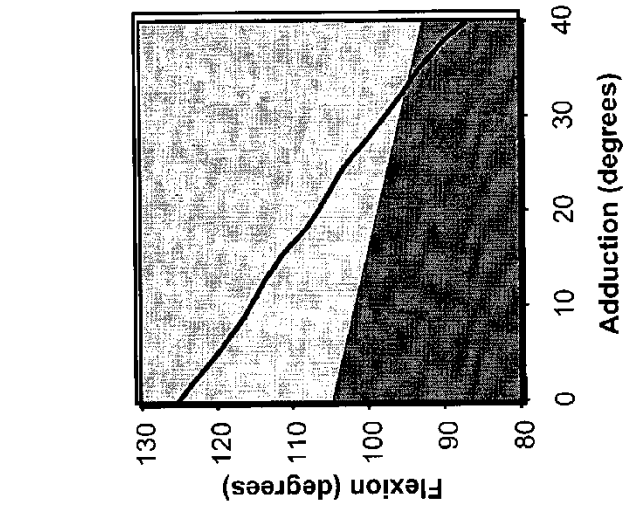
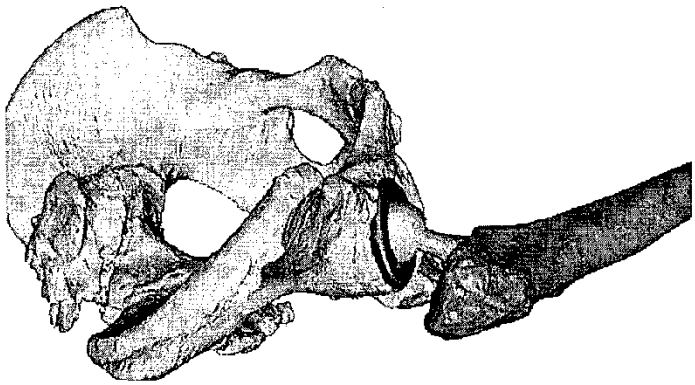

A
P
ML

FIG. 21


Flexion (degrees)
130
120
110
100
90
80
Adduction (degrees)
0
10
20
30
40



COMPUTER-BASED TRAINING METHODS FOR SURGICAL PROCEDURES

This application claims the benefit of the filing of co-pending U.S. Provisional application No. 60/372,873, filed Apr. 16, 2002, and which is incorporated by reference herein in its entirety.

BACKGROUND OF THE INVENTION

Many different surgical procedures are performed to restore normal function of the musculoskeletal system after acute injury (eg fracture of a bone), or to treat long standing deformities or chronic diseases (eg. arthroplasty to replace arthritic joints). Certain mechanical and spatial parameters define the technical success of these procedures. These parameters typically describe quantities such as:

1. The alignment of bones on each side of a joint or bony fragments fixed in position after a fracture;
2. The shift in the original position of musculoskeletal tissues (e.g. bones or bony fragments, tendons, muscles, and ligaments) with respect to their relative position in the healthy skeleton;
3. The laxity of joints under external distracting or shearing loads; and
4. The relative position of bones during joint motion, including the limits of motion imposed by the joints or body tissues.

Based on extensive experience in reviewing the results of each operative procedure, and the function of the musculoskeletal system in health and disease, orthopedic surgeons have developed quantitative guidelines for target values of each of these parameters. Through reference to these target values, surgeons are able to gauge their success in achieving the "technical goals" of each procedure. Although many surgeons agree on the values of each of the parameters defining the technical success of each operative procedure, few tools are available, during the surgical procedure, to tell the surgeon the extent to which the technical goals of the procedure have been achieved. Numerous disclosures within the patent literature teach methods for guiding surgeons during surgery using computer-based systems within the operating room. These systems have been introduced into many operating rooms in Europe and are generally termed "Surgical Navigation Systems." These systems generally consist of a computer connected to opto-electrical devices that are utilized to measure the relative position of musculoskeletal structures, typically bones, during the operation. Typically, optical devices are rigidly connected to bony structures and to instruments that are aligned with bony surfaces cut or machined by the surgeon. The system collects information from the measurement devices and is able to calculate the alignment and relative spatial position of each bone and any other feature of interest through reference to the known geometry of each instrument, bone and machined bony surface. Typically, information is displayed in graphical form on a computer monitor to provide information that is useful as a guide to the surgeon. In many systems, the surgeon sees a three-dimensional rendering of the bones of relevance to the procedure and the relative position and alignment of his instruments and reference axes.

Although Surgical Navigation Systems can be useful to the surgeon in providing immediate spatial information during surgery, this approach has several practical shortcomings:

1. To generate accurate, patient-specific models of bony anatomy, computer tomographic (CT) scans are required of each patient. In many parts of the world, this adds significant expense to the use of the System, because of the cost of the CT scan and the time required to prepare a three-dimensional computer model from the CT data. Although this issue may be addressed through use of generic computer models, or through collection of data intraoperatively, both of these solutions involve either a reduction of accuracy or additional expense through time and equipment.
2. Surgical Navigation Systems require additional time and personnel in the operating room to set-up and operate the equipment, to attach optical markers to the skeleton, to register computer models to the optical markers, and to collect and interpret data. This leads to longer operations and a significant reduction in productivity for the operating room. As operating room time is extremely expensive and reimbursement for operative procedures is often fixed, independent of the equipment utilized to perform the procedure, utilization of Surgical Navigation Systems is often commercially unattractive.
3. The computer routines developed for use with these systems are specific to each surgical procedure performed by orthopedic surgeons. This means that surgeons who are not specialized, in that they perform procedures involving different parts of the body (eg. knee replacement, ligamentous reconstruction, and fracture reduction), can only gain access to this technology if they operate at large medical centers with the resources to afford the cost of the Surgical Navigation System and each of the specialized computer programs. As most surgery in the United States, as well as many other countries, is performed at many small facilities, most patients will not be able to receive the benefit of the existing Surgical Navigation Technology.
4. Some of the present Surgical Navigation Systems are cumbersome to use and necessitate increased surgical exposure. This is only possible through larger surgical incisions which increases the length of the patient's recovery and the risk of an intraoperative infection. Some systems also utilize optical marker arrays which are connected to the computer with wires which can complicate the surgical procedure.

SUMMARY OF THE INVENTION

To overcome these obstacles, the present invention takes a different approach to Surgical Navigation utilizing similar technology. Specifically, the present invention comprises, in certain aspects, a computer-based system that allows the surgeon to train outside the operating room to develop and refine skills specific to a particular surgical procedure. Once these skills have been developed using the inventive training method, the surgeon is able to operate freely in the operating room without the expense or the impediments associated with conventional Surgical Navigation Systems.

Specifically, the present invention, in certain aspects, is a method that comprises (a) generating three-dimensional (3D) computer models of orthopedic devices (i.e. orthopedic instruments and implants), wherein the data corresponding to the 3D models is stored in a memory system of a computer, the computer being operatively interfaced with a visual display monitor; (b) generating 3D models of a targeted surgical site on a body portion based upon tomographic data stored in the memory system for the surgical site; and (c) inputting into the memory system select target values corresponding to one or more measurable technical parameters associated with the surgical procedure. These technical parameters include three-dimensional positioning and dimensions of bones, three-dimensional positioning and dimensions of soft tissue struc-

tures, three-dimensional positioning and dimensions of orthopedic devices for surgery, and values corresponding to range and loading forces associated with physiologic joint motion, and joint laxity. One or more tracking devices, such as optical tracking devices, for example, which are operatively in communication with the computer system, are attached to the body portion. The surgical procedure is then performed on the surgical site, during which time data generated during the surgical procedure is recorded by the tracking devices and stored in the computer memory system. This tracking data corresponds to positioning of the orthopedic devices, bones, and soft tissue structures. Next, actual values based upon the tracking data are calculated, the actual values corresponding to the technical parameters set for the surgical procedure.

Once the actual values are calculated, the actual values are compared to the target values set for the technical parameters selected. In certain aspects of the present invention, this is achieved by generating (on a computer monitor or via a computer paper print-out, for example) a final three-dimensional model corresponding to the 3D models of the orthopedic devices and body portion post-surgery. The final 3D model shows actual positions compared to targeted positions of the orthopedic devices with respect to selected anatomical features (i.e. bones and soft tissue structures) within the targeted surgical site of the body portion. The actual positions correspond to the actual values calculated while the targeted positions correspond to the target values inputted previously. In certain embodiments, the final 3D model shows differences between (a) actual positions of the orthopedic devices with respect to the anatomical features and (b) target positions of the orthopedic device with respect to the anatomical features. Here, the target positions may be defined by one or more of the following: i) fixed anatomic landmarks, ii) derived mechanical axes, iii) derived anatomic axes, iv) positions selected by a surgeon, and v) positions pre-determined by consensus or convention within a surgical community.

The comparison between actual and target values set for the technical parameters selected may also be achieved, in certain aspects of the present invention, by generating and displaying on the monitor a final 3D model corresponding to the 3D models of the orthopedic devices and body portion post-surgery. Here the final model may show actual responses of anatomical features to loading forces based upon the actual values calculated as compared to predicted responses of the anatomical features (i.e. bones and soft tissue structures) to loading forces based upon the target values inputted. In certain aspects, the actual and predicted responses to the loading forces displayed on said final three-dimensional model include displaying (a) geometry of space between resected bony surfaces, (b) overall position of a bone or extremity, (c) changes in length of a bone or extremity, (d) magnitude or distribution of mechanical axes, (e) magnitude or distribution of anatomic axes, (f) positions selected by a surgeon, and (g) positions pre-determined by consensus or convention within a surgical community.

In certain aspects of the present invention, once the actual values are calculated based upon the tracking data recorded, one or more actual values may be compared to the target values via a graph displayed on the monitor and/or printed out directly on paper via a computer printer. The graph may, in certain embodiments, comprise X- and Y-axes, each of which corresponding to a range of technical parameters. The graph may further include one or more visual target zones corresponding to an acceptable range of target values, wherein the actual values are plotted on the graph, either outside or within one or more of the target zones.

The method, in certain aspects, may include performing a surgical procedure having two or more procedural steps and then evaluating one or more of the steps per the inventive method. Here, the comparison of actual and target values may be achieved by generating and displaying on the monitor a final 3D model corresponding to the 3D models of the orthopedic devices and body post-surgery for at least one of the procedural steps, the final model showing actual positions of the orthopedic devices with respect to the body portion compared to targeted positions of the devices with respect to the body portion for at least one of the procedural steps. The actual positions correspond to the actual values calculated, and the targeted positions correspond to the target values inputted. Thus, comparisons can be made for each step of the surgical procedure.

In all of the foregoing aspects of the inventive method, the final three-dimensional model may be used as a surgical training tool for understanding the errors and reasons for those errors that occurred during the surgical procedure, for evaluating different surgical techniques, for evaluating the abilities of different surgeons, and for evaluating the performance characteristics of one or more orthopedic devices used during the surgical procedure.

The inventive method, in certain aspects, also includes (a) generating three-dimensional (3D) computer models of orthopedic devices (i.e. orthopedic instruments and implants), wherein the data corresponding to the 3D models is stored in a memory system of a computer, the computer being operatively interfaced with a visual display monitor; (b) generating 3D models of a targeted surgical site on a body portion based upon tomographic data stored in the memory system for the surgical site; and (c) inputting into the memory system select target values corresponding to one or more measurable technical parameters associated with the surgical procedure. These technical parameters include three-dimensional positioning and dimensions of bones, three-dimensional positioning and dimensions of soft tissue structures, three-dimensional positioning and dimensions of orthopedic devices for surgery, and values corresponding to range and loading forces associated with physiologic joint motion and joint laxity. Once the 3D models are generated, data generated from two or more surgical procedures is inputted into the memory system. This data, which was recorded previously via tracking devices used in those surgical procedures, corresponds to the positioning of the orthopedic devices, bones, and soft tissue structures. Actual values based upon the tracking data for all of the surgical procedures is then calculated. These actual values are then compared to the target values via the display of one or more graphs on the computer monitor. In certain aspects of the invention, two or more of the surgical procedures are performed by different surgeons, such that a graph may be generated comparing the surgical results of the different surgeons. As for the other aspects of the present invention, this embodiment of the invention (i.e. comparing results of different surgeons) may also be used as a surgical training tool for understanding the errors and reasons for those errors that occurred during the surgical procedure, for evaluating different surgical techniques, and for evaluating the performance characteristics of one or more orthopedic devices used during the surgical procedure, the performance or efficacy of different surgical techniques used for certain surgical procedures, in addition to evaluating the skills of the different surgeons. In other aspects of the present invention, the method may be used as an aid in developing preoperative plans for future surgical procedures, wherein, for example, actual data collected over time via multiple operations of the inventive method may be compared and analyzed to deter-

mine optimal positioning of surgical instruments and/or implants for a particular procedure. Similarly, actual data collected via multiple operations of the inventive method may be compared and analyzed to predict "variability envelopes" and final alignment of implants for use in the development of future preoperative plans.

BRIEF DESCRIPTION OF THE FIGURES

FIG. **1** is a flow chart of describing broadly the inventive method.

FIGS. **2** and **3** illustrate femoral and tibial axes defining the absolute coordinate system used in generating 3D models of these anatomical features in knee arthroscopy.

FIG. **4** illustrates an exemplary tracking system attached to the femur and tibia of a knee model.

FIGS. **5-9** are various graphs and drawings used to illustrate the use of the inventive method in a knee arthroscopy experiment described in Example 1.

FIGS. **10-17** are various graphs and drawings used to illustrate the use of the inventive method in a second knee arthroscopy experiment described in Example 2.

FIGS. **18-21** are various graphs and drawings used to illustrate the use of the inventive method in a hip replacement, as described in Example 3.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is directed to a method suitable for analyzing surgical techniques using a computer system for gathering and analyzing surgical data acquired during a surgical procedure on a body portion and comparing that data to pre-selected target values for the particular surgical procedure. The present invention allows the surgeon, for example, to measure the technical success of a surgical procedure in terms of quantifiable geometric, spatial, kinematic or kinetic parameters. This process entails calculation of these parameters from data collected during a surgical procedure and then comparing these results with values of the same parameters derived from target values defined by the surgeon, surgical convention, or computer simulation of the same procedure prior to the operation itself.

For purposes of illustration only, much of the following description of the present invention is made with specific reference to its utilization in total knee and total hip arthroplasty. It will be readily recognized by those of ordinary skill in the art, however, that the present invention may be utilized in almost all orthopedic surgical procedures, including, but not limited to, joint reconstruction, fracture reduction, surgical excision and ablation of tumors, and the like.

A. Generation of Computer Models:

FIG. **1** is a flow chart illustrating broadly the inventive method. As shown therein, the method first comprises, in certain aspects, the generation of three-dimensional computer models of the surgical devices **1** to be used during a surgical procedure using available software programs commonly known and used by those of ordinary skill in the art. Exemplary software programs include computer-aided design (CAD) software such as UNIGRAPHICS (vended by EDS in Plano, Tex.), PROENGINEER (vended by PTC, in Needham, Mass.), and AUTOCAD (vended by Autodesk, in San Rafael, Calif.). Data associated with the generation of these three-dimensional models is stored in a memory system of a computer system, the computer system being operatively interfaced with a visual display monitor. A preferred computer system includes a Windows-based x86 class machine. As used herein, "surgical devices" include, but are not limited to, orthopedic surgical instruments, such as cutting guides, spreaders, various cutting and drilling tools, intramedullary rods, stabilizing pins, reamers, awls, extramedullary alignment guides, distal femoral components, custom devices to measure the planarity of cut surfaces, and the like. "Surgical devices" also include, but are not limited to orthopedic implants, such as femoral stems, acetabular cups, distal femoral components, tibial trays, stem extensions, tibial inserts, patellar components, and the like.

The inventive method further comprises gathering tomographic data for a target surgical site on a body portion of a human or animal **2**. In orthopedic applications, the body portion will generally be any of the major joints, such as the hip, knee, shoulder, wrist, elbow, ankle, and joints associated with the fingers and toes, as well as the soft tissue structures (i.e. ligaments, tendons, cartilage, muscle) associated with these bony areas. The body portion may also include the spine and skull. It will be recognized by those of ordinary skill in the art that the present inventive method may be suitable for non-orthopedic procedures, and thus, the body portion associated with the targeted surgical site may be elsewhere. Moreover, "body portion," as used herein, may be of a live patient (human or animal), a whole cadaver, partial cadaver, or an inanimate anatomical models. While computed tomography (CT) is preferred, other suitable tomographic techniques may be employed, including, but not limited to, magnetic resonance imaging (MRI), positron emission tomography (PET), or ultrasound scanning, as discussed in U.S. Pat. No. 6,205,411 to DiGioia, III et al. (hereinafter "DiGioia III, et al"), and incorporated by reference herein in its entirety.

The tomographic data of the body portion is transmitted to a computer memory system. Based upon this tomographic data, the computer system uses software loaded therein and programmed to create three-dimensional models of the body portion, namely the bony and soft-tissue structures affected during the surgical procedures **3**. Exemplary software programs include, but are not limited to, MATERIALIZE and ANALYZE 3D.

B. Setting of Target Values for Technical Parameters:

Once the computer models are generated, select target values corresponding to one or more measurable technical parameters associated with the surgical procedure are inputted into the memory system **4**. These parameters form the basis for evaluating the surgeon's technical performance in performing the surgical procedure. Typically, these parameters will define the three-dimensional position and dimensions of bones, bony fragments, and soft tissue structures during the surgical procedure. [Note: as used herein, the term "bones" includes whole bones, bone portions, or bony fragments. Moreover, the terms "position" and "positioning" are intended to include the ordinary meaning of the terms "alignment" and "orientation," as well.]. Technical parameters may also define the three-dimensional positioning and dimensions of devices used (or implanted) during the surgical procedure. In knee arthroplasty, for example, technical parameters are defined with respect to the femoral axes (i.e. flexion/extension: longitudinal, mechanical, and anterior/posterior) and tibial axes (i.e. longitudinal, medial/lateral, and anterior/posterior) (FIGS. **2-3**). The technical parameters selected may also describe the range and loading forces associated with physiologic joint motion, including, but not limited to, joint laxity, soft-tissue balance, range-of motion. In some instances, the surgeon may simply elect to accept default values for each parameter that have been adopted from pub-

lished guidelines. In other cases, the surgeon may choose to simulate the surgical procedure within the computer using computer-generated models of bony and soft-tissue structures and the surgical instruments and implants. On the basis of this simulation and, quite possibly, computer routines that predict some parameters describing expected joint function, the surgeon may elect to modify the default parameters or may accept their applicability.

C. The Surgical Procedure:

Once the surgeon has set the target values for each technical parameter, he or she performs the same surgical procedure **5** on the body portion (i.e. an inanimate model, cadaver or cadaveric portion, or live patient) **7**. During this procedure, the three-dimensional position and orientation of the surgeon's instruments **6** and/or surgical implants and the bones and/or soft tissues **7** are recorded using an tracking system **100**, such as an optical tracking system, vending by Northern Digital, Inc. (Waterloo, Canada), or similar devices, including but not limited to infrared optical, DC magnetic, AC magnetic, laser optical and inertial tracking technologies, as also described in DiGioia, III et al. (see FIG. **4**, for example). This tracking data, in orthopedic applications, corresponds to one or more of the technical parameters discussed above (e.g. positioning of the surgical devices, bones, and soft tissue structures as well as the range and forces of physiologic joint motion. The tracking device is operatively connected to the computer, and thus the tracking data recorded is stored within the computer memory system, It should be noted that during the data collection process the surgeon receives no information regarding his technical performance or any differences between the intended position or orientation of each instrument or implant, and the actual position or orientation achieved during the surgical procedure.

D. Calculation of Technical Parameters (i.e. Actual Values:

The actual data collected during the surgical procedure is processed to obtain calculated actual values that may be depicted visually on the computer monitor, for example (and/or printed out on paper via a computer printer), either via generation of a graph or three-dimensional models **8**. These actual values correspond to the technical parameters set for the surgical procedure, as discussed in more detail below.

E. Evaluation of Technical Performance:

The actual values derived from the surgical procedure are compared with the original target values **9**. In the case of many operations, this entails comparing the three-dimensional position of implanted components after surgery with the intended or target values. Specifically, in this regard, the inventive method comprises generating and displaying on the computer monitor a final three-dimensional model corresponding to the three-dimensional models of the surgical devices and body portion post-surgery. This final three-dimensional model shows the actual positions and target positions of the surgical devices with respect to selected anatomic features (i.e. bone and soft tissue structures). These actual positions correspond to the actual values calculated, and the targeted positions correspond to the target values selected and inputted into the computer memory system.

F. Data Representation:

Several different report formats are available to display the results of the inventive method in a way that is most meaningful for the surgeon. One form is a graph in which at least two variables are displayed (e.g. measures of bony alignment and joint laxity). As used herein, "graph" includes, but is not limited to, two-axis graphs (i.e. X-axis vs. Y-axis), pie charts, bar charts, three-axis graphs (i.e. X-, Y-, and Z-axes), and other types of diagram suitable for depicting the desired results (see FIGS. **5-10** and **13**, for example). For example, the graph may have an X-axis and a Y-axis corresponding to a range of two separate technical parameters, as shown in FIG. **7**, for example. The graph may further comprise one or more visual target zones corresponding to an acceptable range of target values. The actual values calculated for the technical parameters are labeled on the axes and may be visually plotted on the graph, either within or outside one or more target zones.

It is also possible to depict the performance of one individual surgeons in comparison with a group of surgeons who have performed the same procedure (see FIGS. **5-6**, for example). Alternatively, parameters or information summarizing the distribution of those values on the graph may be displayed. The figures shown herein illustrate various ways to represent the actual data versus target data values described herein.

G. Diagnostic Routines:

The results of the procedure may be displayed on a computer monitor using visualization routines that allow the surgeon to view the following:

a. each step of the surgical procedure,

b. the placement of each instrument with respect to each bone and/or soft tissue structures, and

c. the consequences of each surgical decision in terms of the final placement of the orthopedic implants.

When differences between the intended (i.e. target) and achieved (i.e. actual) results are detected, the inventive method displays the cause of the deviation in terms of each surgical step and variations in the placement and/or alignment of the relevant instruments. The inventive system allows the surgeon to determine the specific errors in surgical technique that have led to the observed deviation of outcome from the original pre-operative goal. For example, following a total knee replacement procedure, the system may reveal that the knee has inadequate range of motion in flexion and that this is associated with an osteotomy of the proximal surface of the tibia that has too little posterior slope. The diagnostic routines might then show the surgeon that this error was due to malalignment of the tibial cutting guide in the sagittal plane, and that correct placement required that the distal foot of the guide be elevated by an additional 10 mm above the anterior surface of the tibia.

H. Prognostic Routines:

The inventive method also enables the surgeon to predict the functional result achieved by the original plan and the actual placement of the components at surgery. Computer routines "exercise" models of the prosthetic components, simulating motion and laxity, as viewed on the computer monitor. These routines allow the surgeon to decide whether a hip replacement will allow adequate range of motion in performing prescribed procedures, or whether a knee replacement can be performed without soft-tissue releases to achieve acceptable gap kinematics.

The inventive method has numerous applications, as summarized below and described in the examples to follow, these applications including, but not being limited to, the following:

1. To demonstrate the outcome of the surgical procedure in terms of the position or alignment of any instrument or implant.

2. To determine the optimal position or orientation of a surgical instrument with respect to the musculo-skeletal system.

3. Through use of the ability of the system to predict the functional performance of an implant, it is possible to assess the performance or function of new designs of implants, or compare the relative performance or function of alternate designs of devices.
4. To assess the performance or function of any surgical instrument or to compare the relative performance or function of alternate instruments.
5. To demonstrate the difference between the alignment or position of each instrument and/or implant with respect to the bones and/or soft-tissues and a target alignment or position defined by:
   a. fixed anatomic landmarks, and/or
   b. derived mechanical and/or anatomic axes, and/or
   c. positions and/or orientations nominated by the surgeon, and/or
   d. positions and/or orientations pre-determined by consensus or convention.
6. To demonstrate the outcome of the surgical procedure in terms of the predicted response of the bones, joints and soft-tissues to loading, including, but not limited to:
   a. the geometry of the space between resected bony surfaces;
   b. overall alignment and position of a bone or extremity;
   c. changes in the length of a bone or extremity;
   d. the magnitude or distribution derived mechanical and/or anatomic axes, and/or
   e. positions and/or orientations nominated by the surgeon; and/or
   f. positions and/or orientations pre-determined by consensus or convention.
7. To demonstrate the position and alignment of the surgeon's hands and/or the surgical instruments during a surgical procedure.
8. To predict or demonstrate the magnitude, direction or distribution of forces imposed on body tissues, surgical instruments or implanted devices during a surgical procedure.

As described above, the present invention is an application of surgical navigation technologies that allows the quantitative assessment of surgical procedures with reference to a preoperative plan. This preoperative plan defines the target positions and orientations of the instruments and the components relative to the bones. During the operative procedure, the three-dimensional motions of the bones, the instruments, and the final implant components are tracked as the surgeon performs, without providing any feedback or guidance to the surgeon during the procedure. The entire procedure is then reconstructed in virtual space to compare the actual outcome with the ideal outcome. Moreover, by knowing the orientation of each and every surgical instrument, the causes of malalignment of prosthetic components or soft tissue imbalance can be diagnosed in terms of the errors in the orientations of specific instruments. In other words, the exact step at which errors are introduced into the procedure can be determined, and how they propagate and manifest themselves in the final alignment and soft tissue balance can be tracked.

The following examples illustrate specific applications of the inventive method described herein. The examples are not intended to limit the scope of the invention, but are intended to illustrate the various aspects of the invention.

EXAMPLE 1

The following experiment was conducted to assess a number of surgeons with varying skill levels, performing the same procedure with the same instrumentation. Here, fifteen lower extremities were harvested from cadaveric donors (ten males, five females; average age: 76 years). Anteroposterior and lateral radiographs were prepared of each specimen to exclude cases with evidence of previous trauma, or significant skeletal pathology. Scans were obtained of each specimen using a helical scanner (GE Medical Systems) and contiguous slices of 2.5 mm through the shafts of the tibia and femur with slices at a thickness of 1.25 mm through the joint. Three-dimensional computer models (solid models) of the tibia and femur, with a dimensional accuracy of approximately 0.2 mm, were prepared by reconstruction of the data derived from the CT slices. This procedure was performed using commercially available computer programs (MATERIALIZE, vended in Belgium).

Using CAD software routines (Unigraphics Inc, Cypress, Calif.), axis systems were developed to define the location and orientation of the tibia and femur from the three-dimensional solid models. As shown in FIG. **2**, for the femur **20**, the true flexion/extension axis was found by fitting spheres **13** to the posterior condylar surfaces of the intact femur. The line of best fit through the centroids of cross-sections from the distal third of the femur defined the longitudinal anatomic axis **11**. A line mutually orthogonal to the other two axes defined the anterior-posterior axis. The origin of the femoral coordinate system was the point on the longitudinal axis closest to the flexion/extension axis. The mechanical axis of the femur was defined as the axis lying in the plane of the femoral anatomic axis and perpendicular to the flexion/extension axis. As shown in FIG. **3**, the line of best fit through the centroids of cross-sections from the proximal third of the tibia **21** defined the longitudinal tibial axis **22**. For the medial/lateral axis **23** of the tibia, circles were fit to the cortical edges of the medial and lateral sides at slices 2, 4.5, and 7 mm distal to the tibial plateau. The medial/lateral axis was then calculated by averaging the centers of these circles (FIG. **3**). A line mutually orthogonal to the other two axes defined the anterior/posterior axis. The origin of the tibial coordinate system was the point on the medial/lateral axis closest to the longitudinal axis. These axes were utilized to develop a pre-operative plan for ideal placement of the knee replacement components and post-operative alignment and balance of the extremity.

Following radiographic evaluation, the fifteen cadaveric knees were prepared for implantation of a PCL-sacrificing posterior stabilized total knee replacement using one standard set of instruments (Insall-Burstein II, Zimmer). The first step of the procedure involved resection of the proximal tibia using a cutting guide mounted on an extramedullary alignment jig. An intramedullary alignment rod was then inserted through a drilled hole within the intercondylar notch of the distal femur. The anterior cutting guide was indexed off of the anterior femoral cortex, guiding the resection of a preliminary anterior cut to avoid notching of the femur. The distal femoral cutting guide was mounted on the cut anterior femur and determined the distal femoral resection. The femur was sized and the posterior condylar and final anterior cuts were made. The flexion and extension gaps were checked to determine the need to recut the distal femur. The appropriate femoral notch/chamfer guide was then pinned to the cut distal femur and controlled the chamfer cuts and removal of the intercondylar notch. The rotational position of the tibia was determined by pinning the tibial stem template on the cut tibial surface. The tibial stem punch was then pounded into the cancellous bone, creating the cavity for the stem of the tibial tray. Fifteen individuals performed the tibial and femoral cuts on the cadaveric knees: 6 faculty members, 1 total joint fellow, 6 orthopedic residents, 1 physician's assistant, and 1 research engineer. During implantation, the motion analysis system

tracked the three-dimensional motions of the bones, all of the instruments, and the final components.

Some interesting results from this example were related to the ability to equally balance the flexion and extension gaps. A well balanced-knee is often considered a primary objective in total knee replacement as soft tissue releases and/or re-cutting bony surfaces are often performed to achieve equal balancing. In this experiment, gap measurements were taken with a custom spreader applying 10 lbs. of opening force at the midline of the joint while measuring the gap opening and the rectangularity. Typically, the knee joint opened more on the lateral edge of the resected surface compared to the medial edge, this difference in (the medial-lateral (ML) gap opening) averaging 2.9±0.5 mm with the knee extended, and 2.4±0.9 mm with the knee flexed. However, the average distance between the femur and the tibia was significantly larger ($p<0.05$) in flexion (19.3±1.8 mm) than extension (14.2±1.4 mm). FIG. **5** shows the individual surgeon performance results for soft tissue balancing of each procedure. The graph In FIG. **5** shows general consensus target zones where the centermost zone **30** is the true goal, the next concentric zone **31** is acceptable but suspect laxity, and the outermost zone **32** represents gap imbalances greater than 6 mm. Analyzing surgical technique in this manner exemplified the effect of experience as 67% of the faculty surgeons were within the pre-operative target zone. As shown in FIG. **5**, for example, errors and variability generally increased with decreased training.

Similarly, the accuracy of individual instrument alignment was quantified in this experiment. On average, errors in the insertion point of the intramedullary rod caused it to be positioned 1.6±3.2 mm lateral and 1.9±4.0 mm posterior to the projection of the actual intramedullary axis on the distal femur, as shown in FIG. **6**. In alignment, the intramedullary rod was angled 0.3±4.0° anterior (flexion) and 1.0±2.2° medial (varus) to the anatomic axis. FIG. **6** also shows the individual surgeon performance plot for the identification of the correct insertion point for the femoral intramedullary guide. This particular metric depends solely on the judgment of the surgeon, and does not rely on instrumentation, which may explain the significant variability, particularly in the anterior/posterior direction across all skill levels.

FIG. **7** shows a performance plot of the posterior slope of the extramedullary tibial cutting guide versus the flexion of the intramedullary femoral rod in this experiment. The criteria applied stipulate that the zone of acceptance of the posterior slope is ±2° from the objective of 3° posterior slope be built into the instrumentation. The criterion for femoral flexion of the intramedullary rod was from 1° of extension to 5° of flexion. Forty-two percent of the surgeons met these criteria.

A system that quantitatively assesses all alignment aspects of TKA allows objective performance evaluations of the most critical aspects of the procedure, as shown in this experiment. For example, FIG. **8** shows a performance plot for two variables critical to successful total knee replacement. Because healthy knees were used for this study, a desired alignment outcome was the restoration of the pre-operative varus/valgus alignment. The post-operative change was plotted versus the amount of imbalance in the extension gap. Quantitative criteria can then be applied to assess performance. For example, one standard might be that the varus/valgus angle should not be more than 3 degrees in either direction from normal healthy alignment, and that the difference in the medial and lateral measurement of the extension gap should not be more than 3 millimeters. Only 25% of the surgeries surgeries met these criteria in this experiment.

The present method also quantifies the propagation of variability throughout the surgical procedure, as demonstrated in this experiment. The variability in the axial alignment of the components is dominated by the rotational variability of the tibial tray, which in this instrument set is aligned with the tibial tubercle, explaining its average external rotation (FIG. **9**). The graph in FIG. **9** also shows how, on average, external rotation of the tibial articular surface coupled with neutral rotation of the femoral component causes a net internal rotation of the limb when reduced in extension.

EXAMPLE 2

On a case by case basis, measuring the alignment of many of the instruments during the surgical procedure allows the identification and tracking of errors throughout the surgery. The following describes the results of one particular surgery using PCL retaining components and instrumentation. The philosophy of this surgical procedure was a "balanced resection" technique (FIG. **10**). Unlike other techniques, balanced resection requires equality in the distal and posterior cuts independently on the lateral and medial side. The difference in resection medial to lateral was insignificant. The amount of resection medially and laterally was determined by a fixed valgus cut of the femur distally (dependent on the design of the femoral cutting guide and femoral component). Once this level was determined in full extension, the amount of resection of the posterior condyles in flexion is matched. FIGS. **11-12** quantitatively show the implementation of this plan, while FIG. **10** shows the how accurate this technique was followed with the 45 degree line indicating perfect balanced resection.

After the cuts were made intraoperatively and the trial components were positioned, it was found that this particular knee was extremely tight in extension and gapping open excessively medially in flexion. While the actual cause could not be determined by the surgeon intraoperatively, the course of action was a partial PCL release. FIGS. **13-14** show that this corrective technique shifted the gap imbalance to acceptable if not ideal levels. The present method was able to quantitatively diagnosis the error that caused this instability. It was determined that this particular specimen had an excessive natural posterior tibial slope of 11 degrees. The preoperative plan was to slightly undercut the natural slope resulting in 9 degrees of posterior slope in the tibial insert. However, due to the cumbersome technique of adjusting the ankle clamp of extramedullary tibial guides, the actual cut was 6 degrees (FIG. **15**). This error was the cause of the inability to fully extend the knee with the trial inserts. While the partial PCL release was successful, a second option was to recut the tibia as diagnosed by the quantitative bioskills system. FIGS. **16** and **17** display the accuracy of location and orientation of the femoral intramedullary rod and the femoral anteroposterior cutting block, respectively.

EXAMPLE 3

The present method was also applied to total hip replacement. FIG. **18** shows the rotational orientation of the acetabular reamer. This particular surgery fell outside acceptable range in terms of rotational offset resulting in significant retroversion of the prepared acetabular surface. FIG. **19** shows that when seated, the cup did reach the intended position. On the femoral side, FIG. **21** shows the positional malalignment of the entry point for the start awl. Finally, FIG. **20** shows the combined effect of the positional and rotational placement of the implanted components in terms of the pre-

dicted range of motion of the reconstructed joint. The graph in FIG. **21** shows the combinations of hip flexion and hip adduction that may have a higher propensity for impingement.

We claim:

1. A method suitable for analyzing surgical techniques, said method comprising:

a. generating three-dimensional computer models of orthopedic devices, said devices selected from the group of orthopedic instruments and implants, wherein data corresponding to said models is stored in a memory system of a computer;

b. generating three-dimensional models of a targeted surgical site on a body portion based upon tomographic data stored in the memory system for the surgical site;

c. inputting into said memory select target values corresponding to one or more measurable technical parameters associated with said surgical procedure, said parameters selected from the group consisting of three-dimensional positioning and dimensions of bones, three-dimensional positioning and dimensions of soft tissue structures, three-dimensional positioning and dimensions of said orthopedic devices for surgery, and predicted values corresponding to range and forces associated with physiologic joint motion and joint laxity;

d. attaching one or more tracking devices to said body near said target surgical site, said tracking devices operatively in communication with said computer system;

e. performing a surgical procedure on said target surgical site;

f. communicating tracking data generated during said surgical procedure to said computer system;

g. calculating actual values based upon said tracking data, said actual values corresponding to said technical parameters set for the surgical procedure; and

h. comparing said target values and said actual values of said technical parameters after performing said surgical procedure.

2. The method of claim **1** further comprising recording data generated during said surgical procedure via said tracking devices for storage of said data onto said computer memory system, said data selected from the group consisting of positioning of said orthopedic devices, bones, and soft tissue structures.

3. The method of claim **1** further comprising utilizing said comparison of said target values and said actual values as a training tool.

4. The method of claim **3** further comprising generating a final three-dimensional model corresponding to said three-dimensional models of said orthopedic devices and body portion post-surgery, said final model showing actual responses of anatomical features to loading forces based upon said actual values calculated as compared to predicted responses of said anatomical features to loading forces based upon said target values inputted, said anatomical features selected from the group consisting of bones and soft tissue structures.

5. The method of claim **4**, wherein said actual and predicted responses to said loading forces displayed on said final three-dimensional model are selected from the group consisting of a) geometry of space between resected bony surfaces, b) overall position of a bone or extremity, c) changes in length of a bone or extremity, d) magnitude or distribution of mechanical axes, e) magnitude or distribution of anatomic axes, f) positions selected by a surgeon, and e) positions pre-determined by consensus or convention within a surgical community.

6. The method of claim **5**, wherein said final three-dimensional model is used to evaluate performance characteristics of one or more of said orthopedic devices during said surgical procedure.

7. The method of claim **5**, where said final three-dimensional model is used as a surgical training tool for understanding errors and reasons for said errors that occurred during said surgical procedure.

8. The method of claim **5**, wherein said final three-dimensional model is used to evaluate performance characteristics of one or more of surgical techniques used during said surgical procedure.

9. A method suitable for analyzing surgical techniques, said method comprising:

a. generating three-dimensional computer models of orthopedic devices, said devices selected from the group of orthopedic instruments and implants, wherein data corresponding to said models is stored in a memory system of a computer;

b. generating three-dimensional models of a targeted surgical site on a body portion based upon tomographic data stored in the memory system for the surgical site;

c. inputting into said memory select target values corresponding to one or more measurable technical parameters associated with said surgical procedure, said parameters selected from the group consisting of three-dimensional positioning and dimensions of bones, three-dimensional positioning and dimensions of soft tissue structures, three-dimensional positioning and dimensions of said orthopedic devices for surgery, and values corresponding to range and loading forces associated with physiologic joint motion and joint laxity;

d. attaching one or more tracking devices to said body portion, said tracking devices operatively in communication with said computer system;

e. performing a surgical procedure on said target surgical site;

f. communicating tracking data generated during said surgical procedure to said computer system;

g. calculating actual values based upon said tracking data, said actual values corresponding to said technical parameters set for the surgical procedure;

h. training a surgeon after the surgery by reviewing the calculated actual values and the target values corresponding to said technical parameters.

10. The method of claim **9** wherein training the surgeon further comprises comparing said target values and said actual values of said technical parameters after performing said surgical procedure.

11. The method of claim **9** further comprising recording data generated during said surgical procedure via said tracking devices for storage of said data onto said computer memory system, said data selected from the group consisting of positioning of said orthopedic devices, bones, and soft tissue structures.

12. The method of claim **11** further comprising generating a graph for comparing one or more of said actual values to said target values.

13. The method of claim **12**, wherein said graph comprises an X-axis and a Y-axis, each of said axes corresponding to a range of technical parameters, said graph further including one or more visual target zones corresponding to an acceptable range of said target values, and wherein said actual values calculated for said technical parameters labeled on said axes are visually plotted on said graph either within or outside said one or more target zones.

14. The method of claim 13, where said final three-dimensional model is used as a surgical training tool for understanding errors and reasons for said errors that occurred during said surgical procedure.

15. The method of claim 13, wherein said final three-dimensional model is used to evaluate performance characteristics of one or more of said orthopedic devices during said surgical procedure.

16. The method of claim 13, wherein said final three-dimensional model is used to evaluate performance characteristics of one or more of surgical techniques used during said surgical procedure.

17. A method suitable for analyzing surgical techniques, said method comprising:

a. generating three-dimensional computer models of orthopedic devices, said devices selected from the group of orthopedic instruments and implants, wherein data corresponding to said models is stored in a memory system of a computer;

b. generating three-dimensional models of a targeted surgical site on a body portion based upon tomographic data stored in the memory system for the surgical site; p1

c. inputting into said memory select target values corresponding to one or more measurable technical parameters associated with said surgical procedure, said parameters selected from the group consisting of three-dimensional positioning and dimensions of bones, three-dimensional positioning and dimensions of soft tissue structures, three-dimensional positioning and dimensions of said orthopedic devices for surgery, and values corresponding to range and loading forces associated with physiologic joint motion and joint laxity;

d. attaching one or more tracking devices to said body portion, said tracking devices operatively in communication with said computer system;

e. performing a surgical procedure on said target surgical site;

f. recording data during said surgical procedure via said tracking devices for storage of said data onto said computer memory system, said data selected from the group consisting of positioning of said orthopedic devices, bones, and soft tissue structures;

g. calculating actual values based upon said tracking data, said actual values corresponding to said technical parameters set for the surgical procedure; and

h. comparing said target values and said actual values of said technical parameters after performing said surgical procedure.

18. The method of claim 17, wherein said body portion is an inanimate anatomical model.

19. The method of claim 17, wherein said body portion is from a cadaver.

20. The method of claim 17, wherein said body portion is a live patient.

21. The method of claim 17 further comprising utilizing said comparison of said target values and said actual values as a training tool.

22. The method of claim 21 further comprising:

comparing said actual values from two or more surgical procedures to said target values to determine optimal positioning of said surgical instruments with respect to said bones and soft tissue structures of future target surgical sites in order to creating a preoperative surgical plan based upon said determination of optimal positioning.

23. The method of claim 21 further compromising:

generating a final model corresponding to said models of said surgical devices and body portion post-surgery, said final model showing actual positions compared to targeted positions of said devices with respect to selected anatomical features within said targeted surgical site of said body, wherein said actual positions correspond to said actual values calculated and said targeted positions correspond to said target values inputted.

24. The method of claim 21 further comprising generating a final three-dimensional model corresponding to said three-dimensional models of said orthopedic devices and body portion post-surgery, said final model showing actual positions compared to targeted positions of said orthopedic devices with respect to selected anatomical features within said targeted surgical site of said body portion, said anatomical features selected from the group consisting of bones and soft tissue structures, and wherein said actual positions correspond to said actual values calculated and said targeted positions correspond to said target values inputted.

25. The method of claim 24, wherein said final three-dimensional model shows differences between a) actual positions of said orthopedic devices with respect to said anatomical features and b) target positions of said orthopedic device with respect to said anatomical features, said target positions defined by one or more of the group consisting of i) fixed anatomic landmarks, ii) derived mechanical axes, iii) derived anatomic axes, iv) positions selected by a surgeon, and v) positions pre-determined by consensus or convention within a surgical community.

26. The method of claim 25, where said final three-dimensional model is used as a surgical training tool for understanding errors and reasons for said errors that occurred during said surgical procedure.

27. The method of claim 25, wherein said final three-dimensional model is used to evaluate performance characteristics of one or more of said orthopedic devices during said surgical procedure.

28. The method of claim 25, wherein said final three-dimensional model is used to evaluate performance characteristics of one or more of surgical techniques used during said surgical procedure.

29. The method of claim 21 further comprising:

comparing said target values and said actual values of said technical parameters for at least one of said procedural steps by generating a final three-dimensional model corresponding to said three-dimensional models of said orthopedic devices and body portion post-surgery, said final model showing actual positions of said orthopedic devices with respect to said body to targeted positions of said devices with respect to said body for at least one of said procedural steps, said actual positions corresponding to said actual values calculated, and said targeted positions corresponding to said target values inputted.

30. The method of claim 29, wherein said final three-dimensional model shows differences between a) actual positions of said orthopedic devices with respect to said anatomical features and b) target positions of said orthopedic device with respect to anatomical features, said target positions defined by one or more of the group consisting of i) fixed anatomic landmarks, ii) derived mechanical axes, iii) derived anatomic axes, iv) positions selected by a surgeon, and v) positions pre-determined by consensus or convention within a surgical community.

31. The method of claim 30, where said final three-dimensional model is used as a surgical training tool for understanding errors and reasons for said errors that occurred during said surgical procedure.

32. The method of claim 30, wherein said final three-dimensional model is used to evaluate performance characteristics of one or more of said orthopedic devices during said surgical procedure.

33. The method of claim 21 further comprising generating one or more graphs for comparing one or more actual values to said target values.

34. The method of claim 33, wherein said graph comprises an X-axis and a Y-axis, each of said axes corresponding to a range of technical parameters, said graph further including one or more visual target zones corresponding to an acceptable range of said target values, and wherein said actual values calculated for said technical parameters labeled on said axes are visually plotted on said graph either within or outside said one or more target zones.

35. The method of claim 34, wherein said each of said two or more surgical procedures are identical, each performed by different individuals, such that upon further analysis of said graph, individual surgical performances of each of said individuals may be compared.

36. The method of claim 33, wherein said each of said two or more surgical procedures are identical, each performed by different individuals, such that upon further analysis of said graph, individual surgical performances of each of said individuals may be compared.

* * * * *

Appendix I – Dr. Mathis Curriculum Vitae

CURRICULUM VITAE

Kenneth B. Mathis, M.D.

A. **GENERAL INFORMATION**

Office Address:	6550 Fannin, #2500 Houston, TX 77030
Office Telephone:	713-441-3740
Office Fax:	713-790-2141
Home Address:	6443 Vanderbilt Houston, TX 77005
Home Telephone:	713-666-9447
Cell Phone:	713-702-0078
Beeper:	713-268-0846
Email:	kbmathis@aol.com
Citizenship:	USA

Optional Information:

Birth Date:	February 3, 1960
Birthplace:	Houston, Texas
Marital status:	Married
Spouse's Name:	Kimberly
Children's names and ages:	Scott 7/1/94 Bradford 2/1/92
Race/Ethnicity:	Caucasian

B. **EDUCATIONAL BACKGROUND**

Degree Awarded	*Institution name, city and state*	*Dates Attended*	*Year*
B.S.	Baylor University Waco, TX	1978-1981	1996
M.D.	The University of Texas Health Science Center Southwestern Medical School Dallas, TX	1981-1985	1985

C. **PROFESSIONAL POSITIONS AND EMPLOYMENT**

Post-doctoral training including residency/fellowship

Title	*Institution Name, city and state*	*Dates*
General Surgery Internship	University of Missouri Columbia, Missouri	1985-1986
Orthopedic Surgery Residency	Louisiana State University Shreveport, Louisiana	1986-1990
Adult Reconstruction & Total Joint Arthroplasty Fellowship, Orthopedic Surgery	Baylor College of Medicine Houston, TX	1990-1991

Academic positions (teaching and research)

Title	*Institution Name, city and state*	*Dates*
Assistant Professor Department of Orthopedic Surgery	Baylor College of Medicine Houston, TX	1991-2005
Section Chief Department of Orthopedic Surgery Joint Replacement	Baylor College of Medicine Houston, TX	2000-2005
Director of Adult Reconstruction Fellowship Program	Baylor College of Medicine Houston, TX	2000-2005

Hospital positions (attending physician, if applicable)

Title	*Institution Name, city and state*	*Date*
Chairman Department of Orthopedics	The Methodist Hospital Houston, TX	2005-present
Active Staff Orthopedic Joint Replacement	The Methodist Hospital Houston, TX	1991-present
Chief of Orthopedic Surgery	V.A. Medical Center	1996-2001
Attending Surgeon	V.A. Medical Center Houston, TX	2001-present

Employment (other than positions listed above)

Title	*Institution Name, city and state*	*Dates*
M.D.	Hopestar Orthopedic Group, LLP Houston, TX	1/97-3/02

D. **LICENSURE, BOARD CERTIFICATION, MALPRACTICE (if applicable)**

Licensure

State	*Number*	*Date of Issue*	*Date of last registration*
Texas	H0610	1986	2-05
Louisiana	MD.07317R	1986	2-05
Arizona	27891	1999	2-05

DEA Number: BM0505555

Board Certification

Name of specialty	*Board Certificate Number*	*Date of Certification*
American Board of Orthopedic Surgery	Written 1990	Oral 1993
American Board of Orthopedic Surgery	Recertification	1/2004

Malpractice Insurance

Do you have Malpractice insurance? YES

Name of Provider: The Methodist Hospital Corporate Risk & Insurance Department

Premiums paid by: The Methodist Hospital

E. **PROFESSIONAL MEMBERSHIPS *(medical and scientific societies)***

Member/officer	*Name of Organization*	*Dates held*
Member	American Medical Association	1985-present
Member	American Academy of Orthopedic Surgeons	1990-present
Member	Texas Orthopedic Association	1991-present
Member	Harris County Medical Society	1991-present
Member	Houston Orthopedic Society	1993-present
Diplomat	American Board of Professional Disability Consultants	1995
Member	Southern Orthopedic Association	2003-present

F. **HONORS AND AWARDS**

Name of award	*Date awarded*
M.D. Anderson Hospital Summer Research Program	1978
Baylor University, Waco, TX Alpha Chi Honor Society	1979-1981
Baylor University, Waco, TX Student Congress Representative	1980-1981
Baylor University, Waco, TX Dean's Distinguished Academic Honor Roll	1981
Student Delegate Texas Medical Association	1984-1985
Baylor University, Honors Program: Summa Cum Laude	1996
Listed in "Best Doctors in America"	2001-2002 2003-2004 2004-2005
11th Annual Insall Award Title: "Factors Affecting Patient Satisfaction with Total Knee Arthroplasty"	2006
Knee Society Educational Committee John Callaghan, MD – Program Chair	

G. **INSTITUTIONAL/HOSPITAL AFFILIATION**

Primary Hospital Affiliation: The Methodist Hospital

Other Hospital Affiliations: Veteran's Affair Medical Center Hospital,
St. Luke's Episcopal Hospital
Memorial Southeast Hospital
Clear Lake Regional Hospital

Other Institutional Affiliations: Baylor College of Medicine

H. **EMPLOYMENT STATUS**

Name of Employer(s): The Methodist Hospital Physician Organization

Employment Status: Full time salaried at Cornell-affiliated hospital

CURRENT AND PAST INSTITUTIONAL RESPONSIBILITIES AND PERCENT EFFORT

Teaching (*list courses and your role*)	**Dates**
Baylor College of Medicine Department of Orthopedic Surgery Total Joint Conference	2003-2004

Department of Orthopedic Surgery Baylor College of Medicine Orthopedic Grand Rounds	2002-2005
Arthritis Surgery Core Lecture Series Department of Orthopedic Surgery Baylor College of Medicine Ongoing Lectures to Medical Students	2002-2005
Director of Adult Reconstruction Fellowship Program Baylor College of Medicine	2000-2005

Clinical Care	**Dates**
Orthopedic Surgeon/The Methodist Hospital	2005-present
Office Consultations Surgery Hospital Consultations/Post-operative care On-Call Coverage	
Orthopedic Surgeon/Baylor College of Medicine	2002-2005
Office Consultations Surgery Hospital Consultations/Post-operative care On-Call Coverage	
Orthopedic Surgeon/Hopestar Orthopedics Group, LLP	1997-2002
Office Consultations Surgery Hospital Consultations/Post-operative care On-Call Coverage	

Administrative duties ***(including committees)***	**Dates**
Orthopedic Surgery Service Meeting Chair	2004-present
Physician Advisory Group Committee	2004-present
Executive Committee Meeting	2004-present
Academic Council Committee	2004-present
2nd Annual Discovery Forum Committee	2004-present
1st Annual Discovery Forum Committee	2003-2004
Baylor College of Medicine Advisory Committee	2003-2004
West Pavilion OR Subcommittee	2003-present
Orthopedic Care Management Performance Improvement Subcommittee Chair	2003-present
The Leading Medicine Advisory Board	2003-present

Residency Review Committee	2002-present
Resident Research Committee	2002-present
Records Committee	2001-2003
Section Chief, Department of Orthopedic, BCM	2000-2005
Baylor College of Medicine Journal Club	1998-2003
Dunn OR Subcommittee	1997-2001
Pharmacy & Therapeutics Committee	1997-present

Research **Dates**

Current percent effort %

Teaching	10
Clinical Care	40
Administration	35
Research	15
Total:	100%

I. **RESEARCH SUPPORT (past and present)**

Source	*Amount*	*Date*	*Name of Principal Investigator*
"METASUL System in Cementless Total Hip Arthroplasty Study" IOI #0111	$5,000	August 1995	Kenneth B. Mathis, M.D.

Principle investigator, recruited patients, performed surgeries as well as follow up. 100% effort.

Source	*Amount*	*Date*	*Name of Principal Investigator*
"Amulticenter, randomized, parallel, assessor-blind, dose ranging study of subcutaneous SR 90107A/ORG 31540 with a comparative control group of subcutaneous LMWH in the prevention of deep vein thrombosis after elective total hip replacement" Protocol DRI 2642	$5,000	June 1996	Kenneth B. Mathis, M.D.

Principle investigator, recruited patients, performed surgeries as well as follow up. 100% effort.

Source	*Amount*	*Date*	*Name of Principal Investigator*
Howmedica Inc.	$360,000	1996 – 1999	Co-Investigator
Development and Implementation of Computer-Based System for Measurement and Documentation of Patient Outcomes after Total Joint			

Source	*Amount*	*Date*	*Name of Principal Investigator*
"H#5534-A Retrospective Review of Constrained Total Hip Arthroplasty To Evaluate Long Term Outcomes"	$0	December 1996-December 1997	Kenneth B. Mathis, M.D.

Principle investigator, recruited patients, performed surgeries as well as follow up. 100% efffort.

Source	*Amount*	*Date*	*Name of Principal Investigator*
"An Open-Label, Randomized, Parallel-Group Study Comparing the Pre-operative Administration on Procrit (Epoetin Alfa) to the Standard of Care in Blood Conservation in Primary Total Hip "Reconstruction"	$3,000	August 1997	Kenneth B. Mathis, M.D.

Principle investigator, recruited patients, performed surgeries as well as follow up. 100% effort.

Source	*Amount*	*Date*	*Name of Principal Investigator*
"A MultiCenter, Multinational Randomized Double Blinded Comparison of Subcutaneous SR90107A with Enoxaparin in the Prevention of Deep Vein Thrombosis and Symptomatic Pulmonary Embolism After Elective Hip Replacement or Revision Total Hip Replacement: (phase 3 clinical trials)	$10,000	December 1998	Kenneth B. Mathis, M.D.

Principle investigator, recruited patients, performed surgeries as well as follow up. 100% effort.

Source	*Amount*	*Date*	*Name of Principal Investigator*
"Kinematic and Kinetic Analysis of Total Knee Arthroplasty Under Dynamic Conditions"	$150,000	December 1998	Kenneth B. Mathis, M.D.

Performed procedures on cadavers, recruited patients with implants and assisted in analyzing data.

Source	*Amount*	*Date*	*Name of Principal Investigator*
Sulzer Medica Inc.	$150,000	2000	Co-Investigator
Kinematic Benchmarking of TKA Performance (LCS vs. NKII vs. NexGen PS)			

Source	*Amount*	*Date*	*Name of Principal Investigator*
Zimmer Inc.	$750,000	2003-07	Co-Investigator
The Biomechanics and Functional Performance of Total Knee Replacements.			

Source	*Amount*	*Date*	*Name of Principal Investigator*
The Methodist Hospital	$125,000	2004	Co-Investigator
The Biomechanics of Minimally Invasive Total Hip Replacement.			

K. EXTRAMURAL PROFESSIONAL RESPONSIBILITIES

Co-chairman for the 1st Annual Discovery Forum, Minimally Invasive Surgery Conference held in Houston, Texas September 2004. The conference was attended by physicians form around the world and broadcasted live in Mexico City to a panel of distinguished orthopedic surgeons. The event was jointly sponsored by the Institute of Orthopedic Research and Education and The Methodist Hospital.

Co-chairman for the 2nd Annual Discovery Forum, Tissue Sparing Treatment of Degenerative Joint Disease, held in October 2005. The discovery forum included live surgeries and surgical bioskills demonstrations that were broadcast to five international sites, Mexico, Spain, Turkey, Chile, and Saudi Arabia.

L. BIBLIOGRAPHY

Published in Referred Journals

1. "Limitations of Qualitative Angiographic Grading in Aortic & Mitral Regurgitation" Croft, C. H.; Libscomb, **K.; Mathis**, K.B.; Firth, B.G.; Nicod, P.; Titton, G; Winifred, M.D.; and Hillis, L.D.The American Journal of Cardiology 53: 1593-1598, 1984

2. "What Functional Activities are Important to Patient's with Knee Replacements?" Weiss, J.M., Noble, P.C., Conditt, M.A., Kohl, H.W., Roberts, S., Cook, K.F., Gordon, M.J., **Mathis, K.B.** Clinical Orthopedics 2002 Nov ;(404): 172-88

3. "What Functional Activities Are Important to Patients With Knee Replacements?" Weiss, J.M., Noble, P.C., Conditt, M.A, Kohl, H.W., Roberts, S., Cook, K.F., Gordon, M.J. **Mathis, K.B**. Clinical Orthopedics 2003 Nov; (416): 120-8

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5. "Computer Simulation: How can it help the Surgeon Optimize Implant Position?" Noble, P.C., Sugano, N., Johnston, J.D., Thompson, M.T. Conditt, M.A., Engh, C.A., Sr., **Mathis, K.B.** Clinical Orthopedics 2003 Dec; (417): 242-52.Review

6. "Wear Damage of Patellar Components in TKA"
   Conditt, M.A., Noble, P.C., Allen, B., Shen, M., Parsley, B.S., **Mathis, K.B**.
   Journal of Bone and Joint Surgery 2004

7. Does Total Knee Replacement restore Normal Knee Function?
   Noble, PC, Gordon MJ, Weiss JM, Reddix RN, Conditt MA, **Mathis, KB** Clin Orthop Relat Res. 2005 Feb; (431): 157-65.

8. Cracking and impingement in ultra-high-molecular-weight polyethylene acetabular liners.
   Birman MV, Noble, PC, Conditt MA, Li S, **Mathis KB** J Arthroplasty. 2005 Oct; 20(6 Suppl 3):87-92.

Books, Book Chapters and Reviews

1. **"An Orthopedic Perspective of Osteoporosis"** Heggeness, M.D. and **Mathis, K.B**.,Osteoporosis, 1097-1111,1996, Academic Press

2. **"Pre-operative Templating in Revision THR" Mathis, K.B.;** Noble, P.C.; Tullos, H.S.
   Revision Total Hip Arthroplasty Bierbaum BE, Bono JV, McCarthey JC, Thornhill TS, Turner MD (editors. Springer, New York Inc., 1999

3. **"An Orthopedic Perspective of Osteoporosis"** Heggeness, M.D. and **Mathis, K.B**.,Osteoporosis, Second Edition, Academic Press,2001

New Publication to be published early 2006 – Journal of Engineering In Medicine

1. **"A Computerized Bioskills for Surgical Skills Training in Total Knee Replacement"** Michael Conditt, PhD; Philip C. Noble, PhD, Matthew T. Thompson, MD, Sabir K. Ismaily, BS, Gregory L. Moy, BS, Kenneth B. Mathis, MD

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3. **Physical Activity After Total Knee Replacement (TKR): What is important to the patient?**, **Noble PC**, Weiss JM, Kohl HW, Mathis KB, Roberts S, Parsley BS International Society for Technology in Arthroplasty, 13th Annual Symposium, Berlin, Germany, September 20-23, 2000.
4. **The Reliability of Distal Fixation in Total Hip Replacement, Noble PC**, Alexander JW, Atchison SM, Paravic VP, Kamaric E, Mathis KB, International Society for Technology in Arthroplasty, 13th Annual Symposium, Berlin, Germany, September 20-23, 2000.
5. **Pilot Study: Application of Visualization Technology to Quantify Bioskills in TKR**, **Noble PC**, Conditt MA, Thompson MT, Ismaily SK, Moy GJ, Mathis KB. Dorr LL Orthopedic Research Society, San Francisco, California, February 25-28, 2001
6. **Kinematic Benchmarking of TKA Performance (LCS vs NKII vs NexGen PS), Noble PC, Conditt MA, Thompson MT, Mathis KB, Parsley BS** American Academy of Orthopedic Surgeons, San Francisco, California, February 28-March 4, 2001.

7. **The Reliability of Distal Fixation in Total Hip Replacement**, **Noble PC,** Alexander JW, Atchison SM, Paravic VP, Kamaric E, Mathis KB, 68th Annual Meeting**,** American Academy of Orthopedic Surgeons, San Francisco, California, February 28-March 4, 2001.
8. **Functional Outcomes of TKA: What is Important to the Patient? Noble PC,** Conditt MA, Weiss JM, Mathis KB, Olson S, Cook K,11th Annual Meeting**,** American Association of Hip and Knee Surgeons, Dallas, Texas, November 9-11, 200
9. **Pilot Study: Application of Visualization Technology to Quantify Bioskills in TKR**, **Noble PC**, Conditt MA, Thompson MT, Ismaily SK, Moy GJ, Mathis KB. Dorr L, 69th Annual Meeting, American Academy of Orthopedic Surgeons, Dallas, Texas, February 13-17, 2002.
10. **Computer Assisted Surgery (CAS): New Tools for Minimally Invasive Approaches: CAS Tools for Training and Research, Noble PC,** Conditt MA, Thompson MT, Paravic V, Ismaily SK, Moy GJ, Mathis KB Orthopedic Research Society/American Academy of Orthopedic Surgeons Combined Day Symposium, New Orleans, Louisiana, February 5, 2003
11. **A Quantitative Comparison of Two Alternative Incisions for MIS Hip Replacement, Noble PC,** Thompson MTT, Mathis KB, Heinrich M, Alexander JW, Ismaily SK, Johnston JD, International Society for Technology in Arthoplasty, San Francisco, California, September 22 – 27, 2003
12. **To What Extent Does Total Knee Replacement (TKR) Restore the Normal Function of the Knee, Noble PC,** Gordon MJ, Weiss J, Mathis KB, Condit MA**,** International Society for Technology in Arthoplasty, San Francisco, California, September 22 – 27, 2003
13. **Which Physical Activities Should We Recommend After TKA, Noble PC,** Weiss J, Kohl W, Mathis KB, Dorr L, 13th, Annual Meeting, American Association of Hip and Knee Surgeons, Dallas, Texas, October 31 – November 2, 2003.
14. **The Mechanics of Minimally Invasive Hip Replacement,** Thompson MT**, Noble PC**, Mathis KB, Heinrich M, Ismaily SK 71st, Annual Meeting American Academy of Orthopedic Surgeons, San Francisco, California, March 10-14, 2004 Paper #209.
15. **The Mechanics of Minimally Invasive Hip Replacement Surgery (Modified with The Mobility of Single Incision in MIS)**, Heinrich M, **Noble PC,** Thompson MT, Mathis KB, Alexander JW, Ismaily SK, Johnston JD, The 77th Annual Congress, Japanese Orthopedic Association, Kobe, Japan, May 20-23, 2004.
16. **Anterior Impingement After THR; The Role of Implant Placement and The Level of The Femoral Neck Osteotomy**, Thompson MT, **Noble PC,** Johnston JD, Okawa T, Mathis KB, The 77th Annual Congress, Japanese Orthopedic Association, Kobe, Japan, May 20-23, 2004.
17. **Cracking and Impingement in UHMWPE Acetabular Liners, Noble PC**; Birman MV; Johnston JD; Alexander JW; Li S; Mathis KB 14th Annual Meeting American Association of Hip and Knee Surgeons, Dallas, Texas, November 5-7, 2004.
18. **A Computerized Bioskills System for Surgical Skills Training in Total Knee Replacement**, Conditt MA; **Noble PC**; Thompson MT; Ismaily SK; Mathis KB; 72nd Annual Meeting, American Academy of Orthopedics Surgeons, Washington, DC - February 23-27, 2005, Paper No: 068
19. **Cracking and Impingement in UHMWPE Acetabular Liners**, Birman MV; **Noble PC**; Johnston JD; Alexander JW; Li S; Mathis KB; Orthopedic Transactions, 30:09,2005
20. **Factors Affecting Satisfaction with Knee Function After TKR**, Noble PC, Conditt MA, Mathis KB, Orthopedic Transactions,30:168 ,2005

Invited lectures, presentations, research seminars:

Experience with Interlocking Intramedullary Nailing of Femoral Shaft Fractures
At LSUMC Shreveport, LA 1983-1986

Louisiana Orthopedic Association Annual Meeting
Shreveport, Louisiana 1987

Fractures of the Femur Treated with Interlocking Nails at LSMU- Shreveport
Annual LSU Orthopedic Alumni Weekend
Shreveport, Louisiana 1987

A Comparison of Distal Fixation Methods in Intramedullary Tibial Nails
Annual LSU Orthopedic Alumni Weekend
Shreveport, Louisiana 1988

Seventeen Year Survivorship Analysis of Effects of Heterotopic Bone Formation on Total Hip Arthroplasty
Annual LSU Orthopedic Alumni Weekend
Shreveport, Louisiana 1989

Use of the Stanisavljevic Procedure in Congenital and Developmental Dislocations of the Patella
Annual LSU Orthopedic Alumni Weekend
Shreveport, Louisiana 1990

"Use of Constrained Acetabular Components in Total Hip Replacement"
Joint Medical Products
San Antonio, Texas
October 1994

"Lower Extremity Amputations"
Basic Science Course in Vascular Surgery
Houston, Texas
April 1995

American Academy of Orthopedic Surgeons, 63rd Annual Meeting
Atlanta, Georgia
February 1996

Hip Society - Specialty Day
San Francisco, California
February 1997
American Academy of Orthopedic Surgeons, 64th Annual Meeting
San Francisco, California
February 1997

XIV National Congress of Orthopedics and Traumatology
Merida, Yucatan, Mexico
October 1997

Arthritic Hip, Knee and Shoulder Course 1998
The University of South Florida College of Medicine
Park City, Utah

American Academy of Orthopedic Surgeons, 65th Meeting
New Orleans, Louisiana
March 1998

13th Annual Combined Orthopedic Symposium
Honolulu, Hawaii
April 1998

Harris Hip Course
Harvard University September 1998

American Academy of Orthopedic Surgeons, 66th Annual Meeting
Anaheim, California
February 1999

Hip, Knee, and Shoulder Symposium
Park City, Utah
March 1999

Total Knee, Hip and Shoulder Arthroplasty Workshop
Pinehurst, North Carolina
April 1999

Techniques in Arthritis Surgery, 6th Annual Masters Series
Pasadena, California
April 1999

The Hip, Knee & Shoulder Symposium
"Revision Total Hip Replacement"
Park City, Utah
July 1999

Chandeleur Island Meeting
Knee and Hip Arthroplasty Workshop
"Use of Grit Blast Titanium in Revision Total Hip Arthroplasty"
Venice, Louisiana
October 1999

Total Joint Arthroplasty
"Primary and Revision Surgical Techniques"
Phoenix, Arizona
October 1999

Metasul Hip Presentation
Dallas, Texas
November 1999

"New Advances in Medical and Surgical Treatments of Arthritis"
Houston, Texas
January 2000

"Total Joint Arthroplasty: Revision Surgical Techniques"
Tampa, Florida
February 2000

"Contemporary Treatment of Revision Hip Arthroplasty"
New York, NY
December 2000

Hip, Knee, Shoulder Symposium
"Cementless Revision: Long Stems"
Park City, Utah
March 2001

LSU Health Science Center
"Why Do Hips Still Dislocate?"

"Approaching Revision Hip Replacement from Stability"
Shreveport, Louisiana
May 2001

Current Techniques in Arthroplasty
"Prevention and Treatment of the Over Lengthened Leg"
"Management of Fractures about Total Hip Implants
Key Largo, Florida
June 2001

11th Annual Total Knee, Hip and Shoulder Arthroplasty Seminar
"Patella Femoral Complications. Keep it on Track"
"Why Do Hips Still Dislocate?"
Beaver Creek, Colorado
August 2001

31st Annual Fall Hip Course
"Precedent Revision Stems"
Boston, Massachusetts
October 2001

Excellence in TJR Outcomes: Focus on Design and Techniques
"Approaching Revision Hip Arthroplasty from Stability"
Newport Beach, California
November 2001

Excellence in Revision: Contemporary Treatment of Revision Knee Arthroplasty
"Mechanisms of Failure in TKA"
"Management of Collateral Ligament Insufficiency"
New York City, New York
December 2001

American Academy of Orthopedic Surgeons, 69th Annual Meeting
Dallas, Texas
February 2002

The 2002 Hip, Knee & Shoulder Symposium
Park City, Utah
March 2002

The 75th Annual Meeting of the Japanese Orthopaedic Association
Asia-Pacific Orthopaedic Meeting
Okayama, Japan
May 2002

12th Annual Total Knee, Hip and Shoulder Arthroplasty Seminar
"Blood Serum Levels with Metal-on-Metal"
"Less is Better: MIS Straight from the Hip"
"Mastering the Revision Hip"
Raleigh, North Carolina
June 2002

Excellence in TJR Outcomes: MIS Techniques Meeting
"Adapting Minimally Invasive Total Hip Replacement"
Dana Point, California
November 2002

Scientific Seminar/Live Surgery
Queensland Medical Board
Queensland, Australia
January 2003

American Academy of Orthopedic Surgeons, 70th Annual Meeting
New Orleans, Louisiana
February 2003

The 33rd Annual Meeting of the Japanese Society for Replacement Arthroplasty
"The Effect of Implant Design on the Kinematic Performance of Total Knee Replacements"
"Ion Release in Metal-On-Metal Couplings in THR"
Oita, Japan
February 2003

The 2003 Hip, Knee & Shoulder Symposium
"MIS Primary Knee"
"Metal on Metal THA"
"Distal Fixation"
Park City, Utah
March 2003

Tenth Annual Masters Series – Techniques in Arthritis Surgery
MIS/Computer – Assisted THR Live Surgery
Moderator – MIS TKR
Pasadena, California
April 2003

Current Techniques in Arthroplasty
"Prevention and Treatment of the Over-lengthened Leg"
"Management of Fractures about Total Hip Implants"
Key Largo, Florida
May 2003

The 16th Annual Symposium for the International Society for Technology In Arthroplasty
"A Quantitative Comparison of Two Alternative Incisions for MIS Hip Replacement"
"To What Extent Does Total Knee Replacement (TKR) Restore Normal Function of the Knee"
San Francisco, California
September 2003

Natural-Knee MIS Instrument Evaluation
"Converge Acetabular Cup"
Park City, Utah
November 2003

North American Hip & Knee Symposium
"Dislocations – Prevention, New Options for Treatment
Beaver Creek, Colorado
January 2004
Scientific Seminar/Live Surgery
Queensland Medical Board
Queensland, Australia
February 2004

20th Annual Hip, Knee & Shoulder Symposium
"Avoiding Dislocation with Soft Tissue Repair"
Park City, Utah
February 2004

American Academy of Orthopedic Surgeons, 71st Annual Meeting
San Francisco, California
March 2004

Hawaiian Orthopedic Association
"Advances in Total Hip Arthroplasty: Minimally Invasive Approaches & Alternate Bearing Studies"
The Queen's Medical Center
Honolulu, Hawaii
April 2004

Exhibits

Preoperative Templating in Cementless Hip Replacement: How Wrong Can You Be?
Noble, P.C.; Tullos, H.C.; Eckrich, S.G.J.; **Mathis, KB**; Dooley, L.
Scientific Exhibit: 59th Annual Meeting, American Academy of Orthopedic Surgeons
Washington, D.C., February 1992.

Migration of the Femoral Head to the Polyethylene Insert of Initial Radiographs
Sugano N, **Mathis KB**, Kamaric E, Inkofer H, Kadakia N, Noble PC
Paper Exhibition: 65th Annual Meeting, American Academy of Orthopedic Surgeons
New Orleans, LA, February 1998

Is an Initial Postoperative Radiograph Necessary for Radiographic Measurement of Acetabular Wear in Total Hip Replacement?
Sugano N, **Mathis KB**, Kamaric E, Noble PC, Inkofer H, Kadakia N
Scientific Exhibit: 65th Annual Meeting, American Academy of Orthopedic Surgeons
New Orleans, LA, February 1998

Institutional Analysis of Patients with Constrained Acetabular Liners
Mathis KB, Inkofer HE, Sugano N, Femeau R
Paper Exhibition: 65th Annual Meeting, American Academy of Orthopedic Surgeons
New Orleans, LA, February 1998

Stem/Bone Contact and Rotational Stability of Cementless Prostheses in Revision THA
Atchison SM, Noble PC, Alexander JW, Kamaric E, **Mathis, KB**
Poster Exhibition: Orthopedic Research Society
Anaheim, CA, February 1999

Total Hip Replacements Done with a Femoral Stem Design which has an Integral Performed Proximal Centralizer Made of PMMA
Atchison SM, Huo MH, Davidson JP, **Mathis KB**
Paper Exhibition: 66th Annual Meeting, American Academy of Orthopedic Surgeons
Anaheim, CA, February 1999

Cemented Total Hip Replacements Performed Using A Femoral Stem With Proximal & Distal Centralizers.
Huo MH, Atchison SM, Davidson JP, **Mathis KB**
Poster Exhibition: 66th Annual Meeting, American Academy of Orthopedic Surgeons
Anaheim, CA, February 1999

Cementless Total Hip Replacements Done With an Extensively Coated Femoral Stem Design. A 6-8 Year Follow-up Study
Atchison SM, Huo MH, Davidson JP, **Mathis KB**, Tullos HS
Poster Exhibition: 66th Annual Meeting, American Academy of Orthopedic Surgeons

Anaheim, CA, February 1999

A New Method for Tibial Cement Pressurization in Total Knee Arthroplasty
Paravic V, Conditt MA, Stampel BA, Noble PC, **Mathis KB**
American Association of Hip and Knee Surgeons
Anaheim, CA 1999

Physical Activity After Total Knee Replacement (TKR) What is Important to the Patient?
Weiss JM, Kohl HW, Noble PC, **Mathis KB**, Roberts S, Parsley BS
American Association of Hip and Knee Surgeons
Anaheim, CA 1999

Surgeon's Recommendations Regarding Activity After Total Knee Replacement: Is There a Consensus?
Weiss JM, Noble PC, Kohl HW, **Mathis KB**
American Association of Hip and Knee Surgeons
Anaheim, CA 1999

High Demand Activities After Total Knee Replacement (TKR)
Weiss JM, Noble PC, Kohl HW, **Mathis KB**, Robert S
American Association of Hip and Knee Surgeons
Anaheim, CA, February 1999

The Total Knee Replacement (TKR) Patient in 1999
Weiss JM, Noble PC, Kohl HW, **Mathis KB**, Robert S
American Association of Hip and Knee Surgeons
Anaheim, CA, February 1999

The Total Knee Replacement (TKR) Patient in 1999
Weiss JM, Noble PC, Kohl HW, **Mathis KB**, Robert S
International Society of Technology in Arthroplasty
Chicago 1999

Choice of Ingrowth Coating Dramatically Affects the Torsional Stability of Cementless Stems
Alexander JW, Noble PC, Atchison SM, Kamaric E, **Mathis KB**
Paper Exhibition: 67th Annual Meeting, American Academy of Orthopedic Surgeons
Orlando FL, February 2000

High Demand Activities After Total Knee Replacement (TKR)
Weiss JM, Noble PC, Kohl HW, **Mathis KB**, Roberts S
Orthopedic Research Society
Orlando, FL, February 2000

Physical Activity After Total Knee Replacement (TKR) What is Important to the Patient?
Weiss JM, Roberts S, Kohl HW, Noble PC, **Mathis KB**
Orthopedic Research Society
Orlando, FL 2000

Surgeons' Recommendations Regarding Activity after Total Knee Replacement: Is There a Consesus?
Weiss JM, Noble PC, Kohl HW, **Mathis KB**
Orthopedic Research Society
Orlando, FL 2000

The Reliability of Distal Fixation in Cementless Hip Replacement
Noble PC, Alexander JW, Atchison SM. Paravic VP, Kamaric E, **Mathis KB**
Orthopedic Research Society

Orlando, FL 2000

Kinematic Benchmarking of TKA – Performance (LCS vs NKII NexGen PS)
Noble PC, Conditt MA, Thompson MT, **Mathis KB**, Parsley BS
Orthopedic Research Society
Orlando, FL 2000

Functional Outcomes of TKA: What is Important to the Patient?
Noble PC, Conditt MA, Weiss JM, **Mathis KB**, Conditt MA
Paper Exhibition: 67th Annual Meeting, American Academy of Orthopedic Surgeons, Orlando, FL, February 2000

The Total Knee Replacement (TKR) Patient in 2000
Weiss JM, Noble PC, Kohl HW, **Mathis KB**, Robert S
Paper Exhibition: 67th Annual Meeting, American Academy of Orthopedic Surgeons
Orlando, FL, February 2000

Kinematic Benchmarking of TKA Performance (LCS vs NKII vs NexGen PS)
Noble PC, Conditt MA, Thompson MT, **Mathis KB**, Parsley BS
International Society for Technology in Arthroplasty
Chicago 2000

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Kenneth B. Mathis, M.D.

_____
Date

Appendix J. Dr. Phillip C. Noble Curriculum Vitae

CURRICULUM VITAE

Date of preparation: March 2, 2009

A. GENERAL INFORMATION

Office Address: 6550 Fannin, Suite # 2512
Houston, Texas 77030

Office Telephone: 713-441-3010

Office Fax: 713-790-2214

Home Address: 3620 Albans
Houston, Texas 77005

Cell Phone: 713-261-0137

E-mail: pnoble@bcm.edu

Citizenship: Australia, immigrant visa

Date of Birth: September 22, 1952

Birthplace: Australia

Spouse's Name: Kathy

Children's Name: David and Katherine

B. EDUCATION BACKGROUND

Degree	*Institution name and location*	*Dates attended*	*Year Awarded*
Doctor of Philosophy	Strathyclyde University- Glasgow, United Kingdom Dissertation "The Biomechanics of the Acetabulum and Acetabular Replacement" Advisor: Professor J. P. Paul Examiners: Professor S. A. V. Swanson, Dr. A. C. Nicol	1988-1995	1995
Master of Engineering Science	University of Melbourne, Melbourne, Australia Thesis title "The Development of a Method for the Measurement of Fracture Compression Forces in-vivo"	1974-1975	1975
Bachelor of Engineering (Metallurgical)	University of Melbourne Melbourne, Australia	1970-1973	1973

C. PROFESSIONAL POSITIONS AND EMPLOYMENT

ACADEMIC APPOINTMENTS:

John S. Dunn Professor of Orthopedic Surgery (Research)

The Methodist Hospital, Houston, Texas

1994-Present

Professor (Non-Tenured)

Joseph Barnhart Department of Orthopedic Surgery

Baylor College of Medicine, Houston, Texas

1999-Present

Director of Orthopedic Research

Joseph Barnhart Department of Orthopedic Surgery

Baylor College of Medicine, Houston, Texas

1984-Present

Director of Research

Institute of Orthopedic Research and Education, Houston, Texas

1994 – Present

OTHER POSITIONS:

Chair/Program Chair

Computer Modeling Special Interest Group, Society for Biomaterials, 2002

Associate Professor

Joseph Barnhart Department of Orthopedic Surgery, Baylor College of Medicine, Houston, Texas

1995- 1999

Research Associate Professor

Department of Orthopedic Surgery, Baylor College of Medicine, Houston, Texas,

1989-1995

Director, Orthopedic Research Laboratory

The Methodist Hospital, Houston, Texas, 1983-1993

Technical Director

Texas Rehabilitation Engineering Center, Texas Institute of Rehabilitation and Research

Houston, Texas, 1982-1983

Research Associate

Fondren Orthopedic Group, Houston, Texas, 1983-1989

Project Bioengineer

Department of Medical Physics, Royal Perth Hospital, Western Australia, 1976-1981

Tutor and Examiner in Engineering Materials

University of Melbourne, Melbourne, Australia, 1975

Demonstrator in Metallurgy and Engineering

University of Melbourne, Melbourne, Australia, 1974

Research in Bioengineering

Department of Surgery

Monash University and Department of Engineering

University of Melbourne, Melbourne, Australia, 1974-1975

D. PROFESSIONAL MEMBERSHIPS

JOURNAL EDITORIAL BOARDS*:*

The Editorial Committee-The Journal of Arthroplasty-Present

Arthroplasty Editorial Committee- Sports Medicine News, 1991-1993

Advisory Board - Hip International

REVIEW PANELS:

Reviewer of Manuscripts:

The Journal of Arthroplasty

The Journal of Bone and Joint Surgery

Clinical Orthopedics and Related Research

Orthopedics and Related Sciences

Orthopedic Special Edition

Journal of Shoulder and Elbow Surgery

Journal of Applied Biomaterials

Journal of Orthopedic Research

Hip International

PROFESSIONAL SOCIETIES:

American Academy of Orthopedic Surgeons

The Hip Society

The Knee Society

Texas Orthopedic Association

American Association of Hip and Knee Surgeons

International Society for Technology in Arthoplasty

Orthopedic Research Society

Chartered Engineer, Australia and United Kingdom 1976-1982

Australian Orthopedic Association, Affiliate Member 1982 - 1992

Australian Institution of Engineers, Member 1976 - 1982

E. HONORS:

1. Exhibition of Metallurgical Engineering, University of Melbourne, Melbourne, Australia, 1973
2. Neill Greenwood Medal - Outstanding Exhibitioners in Mining and Metallurgy, University of Melbourne, Melbourne, Australia, 1973
3. Sir Winston Churchill Traveling Fellowship, 1979
4. Frank Stinchfield Award - Outstanding Research Related to the Hip. "The Anatomic Basis of Femoral Component Design," The Hip Society, 1988
5. Visiting Professor - Department of Orthopaedic Surgery, University of Aiche, Nagoya, Japan, 1990
6. Guest Lecturer, Central Japan Association of Orthopaedic Surgery and Traumatology, Biwa, Japan, 1995
7. Houston Orthopedic Society Research Award, Houston Orthopedic Society, 1999
8. The Herodicus Society, Best Paper Award: "Incongruity of Osteochondral Grafts" presented during the Annual Meeting of the American Orthopedic Society for Sports Medicine, 1999
9. The Otto Aufranc Award for Outstanding Research Related to the Clinical Treatment of Hip Disease: "The Role of Labral Lesions in the Development of Early Degenerative Hip Disease," The Hip Society, 2001
10. The Otto AuFranc Award for Outstanding Research Related topic: "The Dysplastic Femur: 3D Morphology and Implications for Total Hip Replacement," The Hip Society, 2002
11. The John Insall Award for Outstanding Clinical Research Related to Total Knee Arthroplasty for the study: "Patient Satisfaction After Total Knee Replacement", The Knee Society, 2006
12. Frank Stinchfield Award for Outstanding research related to the hip: "The Biomechanics of the Hip Labrum and the Stability of the Hip Joint". The Hip Society, 2007
13. Elected Member of the Knee Society, 2008

F. INSTITUTIONAL/HOSPITAL AFFILIATION

Baylor College of Medicine

The Methodist Hospital

G. EMPLOYMENT STATUS

Name of Employer: John S. Dunn Foundation

Employment Status: Endowed Professor

Name of Employer: Cognoscenti Inc

Employment Status: President

Name of Employer: Advanced Technology in Orthopedics LP

Employment Status: Managing Partner

Name of Employer: Orthopedic Discovery LLC

Employment Status: President

H. CURRENT AND PAST INSTITUTIONAL RESPONSIBILITIES AND PERCENT EFFORT

TEACHING DUTIES

Lectures to Residents

Subject Areas: Orthopedic Research, Biomechanics, Biomaterials, Statistics, Joint Replacement.

Barnhart Department of Orthopedic Surgery, Baylor College of Medicine

Supervision of Research Activities of Faculty, Fellows, Residents and Students

Department of Orthopedic Surgery, Methodist/Cornell College of Medicine

Barnhart Department of Orthopedic Surgery, Baylor College of Medicine

ADMINISTRATIVE DUTIES

1. Member, Institutional Review Board, The Methodist Hospital, Houston, Texas, 1991-1994
2. Chairman, Residency Research Committee, Joseph Barnhart Department of Orthopedic Surgery, Baylor College of Medicine, Houston, Texas
3. Member, Residency Review Committee, Joseph Barnhart Department of Orthopedic Surgery, Baylor College of Medicine, Houston, Texas
4. Chairman, Search Committee, Alexander and Ruth Brodsky Professorship of Surgery of the Spine, Department of Orthopedic Surgery, Baylor College of Medicine, 1990-1991
5. Member, Graduate Medical Education Committee, Joseph Barnhart Department of Orthopedic Surgery, Baylor College of Medicine, Houston, Texas, 1999-Present
6. Member, Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals, Baylor College of Medicine, Houston, Texas, 1999-2003
7. Vice Chair, Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals, Baylor College of Medicine, Houston, Texas, 2003-Present

CURRENT PERCENT EFFORT

Students/Researchers

Teaching 10%

Administration 50%

Research 40%

Total 100%

I. RESEARCH SUPPORT

1998-2003: TOTAL FUNDING: $2,029,477

1. **Institutional Supporting Grants for Research**
Funding Source: Communities Foundation of Texas

Date: 1998 Amount: $20,000

2. **Institutional Supporting Grants for Research**
Funding Source: Communities Foundation of Texas/The Methodist Hospital Foundation

Date: 1999 Amount: $100,000

3. **Regional Variations in the Morphology of CDH in the Japanese Population**
Co-Investigator Funding Source: Howmedica- Osteonics

Date: 1999 Amount: $188,000

4. **Development of a Virtual Biomechanics System for Design & Analysis of Total Knee Replacements**

Primary Investigator Source: Sulzer, Inc

Date: 1999 Amount: $375,000

5. **The Scientific Validity of the Intra-operative Torques Test**
Primary Investigator Source: Howmedica Inc.

Date: 1998 Amount: $12,500

6. **Institutional Supporting Grants for Research**
Source: Communities Foundation of Texas/ The Methodist Hospital Foundation

Date: 1997 Amount: $20,000

7. **Patello-Femoral Kinematics of the LCS Knee Prosthesis**
Co-Investigator Source: Depuy, Inc.

Date: 1998 Amount: $20,886

8. **Pilot Study: Automated Integration of Biomechanical and Clinical Data to Expedite Patient Management**

Co-Investigator Source: Searle Pharmaceutical Inc

Date: 1998 Amount: $9,500

9. **Cement Pressures and Cancellous Penetration Achieved with the Stamper**
Co-Investigator Source: Sulzer Medica

Date: 1998 Amount: $29,736

10. **The Biomechanics of ACL Reconstruction with Hamstring Tendon Autografts**
Co-Investigator Source: Institute of Orthopedic Research and Education Date: 1998-1999 Amount: $27, 719

11. **Cadaveric Evaluation of the Ankle Mortise with Anatomical**
Primary Investigator Source: Institute of Orthopedic Research and Education Date: 1998 Amount: $15,800

12. **Glenohumeral Joint Translation and Range of Motion after Selective Arthroscopic Thermal Capsulorrhaphy with a Radiofrequency Probe**

Co-Investigator Source: Institute of Orthopedic Research and Education Date: 1999 Amount: $18,649

13. **Intra-operative Measures of Enhance Cement Fixation of Tibial Components in TKR**
Co-Investigator Source: Sulzer Medica Inc

Date: 1998-1999 Amount: $30,000

14. **Backside Polyethylene Wear in Modular Tibial Components**
Co-Investigator Source: Institute of Orthopedic Research and Education

Date: 1999 Amount: $11,008

15. **Polyethylene Insert Micromotion in Modular TKR**
Co-Investigator Source: Institute of Orthopedic Research and Education Date: 1999 Amount: $20,360

16. **Tekscan Thin-Film K-Scan Pressure Measurement System**
Co-Investigator Funding Source: Institute of Orthopedic Research and Education Date: 1999 Amount: $17,550

17. **Effect of Rotational Alignment on Kinematics following TKR**
Co-Investigator Source: Institute of Orthopedic Research and Education

Date: 1999 Amount: $27,017

18. **Development of Mechanical Fixation Testing System**
Co-Investigator Source: Institute of Orthopedic Research and Education

Date: 1999 Amount: $65,739

19. **Institutional Supporting Grants for Research**
Primary Investigator Funding Source: Communities Foundation of Texas/ The Methodist Hospital Foundation

Date: 2000 Amount: $250,000

20. **Grant: Stem Length and Fill Design Features for Revision TKR**
Co-Investigator Funding Source: Depuy

Date: 2000 Amount: $36,418

21. **Grant: Tibial Tray and Stem Design Features for Primary TKR**
Co-Investigator Funding Source: Depuy

Date: 2000 Amount: $39,488

22. **Grant: The Effect of Notchplasty on Contact Area and Contact Pressures in the Knee**
Co-Investigator Funding Source: Institute of Orthopedic Research and Education

Date: 2000 Amount: $15,957

23. **Effect of Posterior Tibial Slope on the Kinematics Following TKR(Natural Knee II)**
Co-Investigator Funding Source: Institute of Orthopedic Research and Education Date: 2000 Amount: $27,017

24. **Grant: Pilot Study: Application of Visualization Technology to Quantify Bioskills in TKR**
Primary Investigator Funding Source: Institute of Orthopedic Research and Education

Date: 2000 Amount: $100,000

25. **Grant: Quantitative Analysis of Wear and Cold Flow of Tibial Bearing Inserts**
Primary Investigator Funding Source: Institute of Orthopedic Research and Education Date: 2000 Amount: $26,133

26. **Grant: Kinematics Benchmarking of TKA Performance (LCS vs. NKII vs. NexGen PS)**
Primary Investigator Funding Source: Sulzer Medica

Date: 2000 Amount: $150,000

27. **Institutional Supporting Grants for Research**
Primary Investigator Funding Source: Communities Foundation of Texas/ The Methodist Hospital Foundation

Date: 2001 Amount: $75,000

28. **Institutional Supporting Grants for Research**
Primary Investigator Funding Source: Communities Foundation of Texas/ The Methodist Hospital Foundation

Date: 2002 Amount: $300,000

2003-2007 TOTAL FUNDING: $2,850,662

29. **Institutional Supporting Grants for Research**
Primary Investigator Funding Source: Communities Foundation of Texas/ The Methodist Hospital Foundation

Date: 2003

30. **Contract: Validation of an Automated, Fluoroscopically-Based Method for Measuring Anterior Displacement of the Tibia**

Primary Investigator Source: Medical Metrics Inc

Date: 2003 Amount: $18,000

31. **Contract: The Biomechanics of Tibial Fixation of Revision Knee Prostheses**
Co-Investigator Source: DePuy/ J&J

Date: 2003 Amount: $115,000

32. **Grant: Experimental Biomechanics of Cemented Hip Replacement**
Co-Investigator Source: Zimmer Inc

Date 2003-4 Amount: $150,000

33. **Contract: Development of a New Design of Cemented Hip Replacement**
Co-Investigator Source: ATO/ Zimmer Inc

Date 2003-4 Amount: $150,000

34. **Grant: Institutional Supporting Grants for Research**
Source: Communities Foundation of Texas/ The Methodist Hospital Foundation

Date: 2003 Amount: $100,000

35. **Research Grant: The Biomechanics and Functional Performance of Total Knee Replacements**

Co-Investigator Source: Zimmer Inc

Date: 2003-7 Budget: $750,000

36. **Grant: IORE Minimally Invasive Joint Replacement Course**
Primary Investigator Source: The Dannemiller Foundation

Date: 2004 Amount: $45,000

37. **Research Contract: Research and Development of Total Knee Prostheses**
Co-Investigator Source: Zimmer Inc

Date: 2003-7 Budget: $750,000

38. **Grant: Computer Simulation of Motion of the Dysplastic Hip after Modular Joint Replacement**

Primary Investigator Source: Stryker-Japan Inc

Date: 2004 Budget: $9,350

39. **Grant: Salary Support for Preparation of Manuscripts and Conference Abstracts**
Co-Investigator Source: The Methodist Hospital

Date: 2004 Amount: $109,764

40. **Grant: Salary Support for Resident and Fellows Research Projects**
Co-Investigator Source: The Methodist Hospital

Date: 2004 Amount: $77,880

41. **Grant: The Biomechanics of Minimally Invasive Total Hip Replacement**
Co-Investigator Source: The Methodist Hospital

Date: 2004 Amount: $125,668

42. **Grant**: **The Biomechanics of Cementless Fixation in Total Hip Replacement**
Co-Investigator Source: Plus Orthopedics AG

Date: 2005-7 Budget: $450,000

43. **Research Grant: Stability of Single vs Double Bundle BPTB Reconstructions of the ACL**
Co-Investigator Source: Paulos Research Foundation

Date: 2007-2008 Amount: $25,000

44. **Does Single Bundle ACL Reconstruction with an Anatomic Tibial Tunnel Recreate Normal Knee Kinematics?**

Co-Investigator Source: Baylor College of Medicine, Department of Orthopedic Surgery

Date: 2007-8 Amount:$

2008-2009 TOTAL FUNDING: $1,286,916

45. **Grant: Computer-Based Methods for Surgical Training and Skills Assessment**
Co-Investigator Source: Department of Defense (USA MRMC)/ TMHRI

Date: 2008-2009 Amount: $840,0000.

46. **Grant: ACL Deficiency and Repair in UKA**
Co-Investigator Source: Stryker

Date: 2008-2009 Amount**:** $60,000

47. **Research Grant: Hip Range of Motion: What is Impingement and How is it Minimized in THR Surgery?**
Co-Investigator Source: The Methodist Hospital

Date: 2008-2009 Amount: $45,600

48. **Research Grant: Can the Transcondylar Femoral Axis be used for TKA Implant Positioning Sizing?**
Co-Investigator Source: The Methodist Hospital

Date: 2008-2009 Amount: $30,000

49. **Research Grant: SynFix- Micromotion Study**
Co-Investigator Source: The Methodist Hospital

Date: 2008-2009 Amount: $30,000

50. **BioNanoScaffolds (BNS) for Post-Traumatic Osteoregeneration**
Co-Investigator Source: DARPA Fracture Putty Project (DARPA-BAA-08-50)

Date: 2008-2012 Amount: $341,316

J. EXTRAMURAL PROFESSIONAL RESPONSIBILITIES

- Co-chairman for the 1st Annual Discovery Forum, Minimally Invasive Surgery Conference held in Houston, Texas September 2004. The conference was attended by physicians form around the world and broadcasted live in Mexico City to a panel of distinguished orthopedic surgeons. The event was jointly sponsored by the Institute of Orthopedic Research and Education and The Methodist Hospital.

- Co-chairman for the 2nd Annual Discovery Forum, Tissue Sparing Treatment of Degenerative Joint Disease, held in October 2005. The discovery forum included live surgeries and surgical bioskills demonstrations that were broadcast to five international sites, Mexico, Spain, Turkey, Chile, and Saudi Arabia.

- Co-chairman (With Prof. R. Ganz) of the Scientific Symposium on Reconstruction of the Diseased Hip, Bern, Switzerland, May 06, 2006.

- Member, Outcomes Task Force developing a new Knee Society Score, The Knee Society, 2007-8

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Signature: _____

Date: _____