A Double-blinded, Randomized, Controlled Trial of Total Knee Replacement Surgery Using Custom Cutting Block Instrumentation versus Regular Instrumentation

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Introduction & Background

Total knee replacement (TKR) is a common operation used for the treatment of knee arthritis. Its effectiveness relieving pain and improving function has been well documented[1, 2]. While the majority of knee replacements last 10-15 years {Lidgren, 2004 #334}, some do not [3] leading to early revision and poorer function [1];Lidgren, 2004 #334}. One of the main determinants of knee implant survivorship and function is adequate correction of limb alignment and proper component placement at time of surgery [4-7]. Traditional surgical instrumentation for knee replacement surgery has relied on the intramedullary canal of the femur and tibia, or on external landmarks such as the ankle, tibial tubercle, symphysis pubis and anterior iliac crest for positioning of the bone cutting guides. The bony cuts made with these guides ultimately determine the amount of correction of leg alignment and the position of the knee replacement components. Unfortunately, these instruments are imperfect, and malalignment of the leg and components can occur in the hands of even the most skilled surgeon [8, 9].

In an effort to address this problem, a variety of technologies have been developed to assist with positioning of the cutting blocks and balancing of knee ligaments. One of the newest technologies uses magnetic resonance imaging to create a three-dimentional computer model of the cartilage and bone of a disease knee. A 3-foot standing radiograph determines the mechanical alignment of the limb. The data from these two imaging modalities is combined to determine the ideal position for cutting both the tibia and the femur. The computer model and proposed cut locations are then forwarded in electronic file format for adjustment and approval by the treating surgeon. Because of the varying anatomy of each patient coupled with the unique nature of each patient's osteophyte pattern, patient-specific cutting blocks can then be rapidly manufactured. These cutting blocks sit on the patient's unique anatomical landmarks and position the bone cuts in the optimal locations based on the pre-operative imaging. The cutting blocks are held in place with traditional pins. In the case of an intra-operative discrepancy, the pins can be left in place with the cutting blocks removed and traditional instruments can be used to complete the procedure.

Custom-cutting blocks are touted to have several advantages over traditional instrumentation. With bone cuts being determined by pre-operative imaging, the alignment can be customized to the individual patients. Also, errors in alignment stemming from the intra- and extra-medullary alignment rods are removed. The preservation of the femoral and tibial canals may reduce blood loss in the perioperative period and reduce post-operative hemarthrosis and pain, thereby improving mobility and potentially leading to earlier discharge from hospital. One of the limitations of this new technology is additional cost. The cutting blocks themselves cost $500 per patient. This is in addition to the cost of the MRI for pre-operative planning. While these costs are significant, if clinical outcome can be improved by either reduced length of stay or avoidance of mal-alignment by 3 degrees, then the cost would be mitigated immediately (in the case of length of stay) or in the long-term (based on reduced need for revision). While several companies currently are under taking similar studies with competitive products, each technique differs from the others and need to be assessed independently.

The purpose of this study is to compare the outcomes between traditional and patients-specific custom cutting blocks using the Smith and Nephew Visionaire system.

Study Objective

Primary objective: To determine if the use of patient-specific custom cutting blocks for implantation of total knee components results in improved limb alignment and component positioning compared to regular instrumentation.

Secondary objectives: To determine if the use of patient-specific custom cutting blocks for implantation of total knee components results in improved knee function as measured by the EuroQol questionnaire, Oxford 12 Knee questionnaire, Pain Catastrophizing Scale, Knee Replacement Expectations Survey, visual analogue scales (VAS) for pain and satisfaction, and the UCLA Activity Level Scale.

Methods

Study design

This is a randomized controlled trial. Patients will be randomized to have their knee implanted using either the patient-specific custom cutting blocks or the regular instrumentation system. Functional and radiographic outcomes will be assessed in a blinded fashion. The Smith and Nephew Legion Primary® total knee system will be used in both groups; this is an implant with a good long term track record based on the GII design {Lidgren, 2004 #334}. The four surgeons participating in this study are Drs Turgeon, Hedden, Burnell and Bohm; together they form the Concordia Joint Replacement Group. All surgeons have used and are familiar with the regular instrumentation. They will be instructed in the use of the patient-specific custom cutting blocks prior to study initiation. Outcome measures include post operative limb and component alignment, as well as knee functional scores.

Subjects

Inclusion Criteria:

1) All patients from the Concordia Joint Replacement Group (CJRG) booked for primary total knee replacement surgery who had agreed to be contacted regarding participation in research. Subjects will be contacted approximately 3-5 months prior to their surgical date to invite them to participate. This will provide adequate time for MRI imaging and production of the custom cutting blocks.

Exclusion Criteria:

1) Deformity of the femur preventing use of the intra-medullary guide utilized in the regular instrumentation set.

2) Necessity for the use of constrained implants. These types of implants have intra-medullary stems, therefore all bone cuts need to be referenced off intramedullary guides, making image guided bone cuts inappropriate.
3) Patients undergoing knee replacement revision surgery. Theses types of implants also have stems, making the use of image guided bone cuts inappropriate for the same reasons.
4) Patients scheduled for bilateral knee surgery (simultaneous or staged)

Procedure

Recruitment:

Potential participants will be identified by our group's research staff from the surgical booking list kept by the Concordia Replacement Group. Permission to review their medical chart for purposes of research and to contact them regarding participation in research will have been obtained using the group's database consent form (HREB approval H2003:004).

Research staff will contact potential participants by telephone approximately 3-5 months before their surgical date to explain the study and ask if they would like to participate. If they agree, they will be sent a cover letter, two copies of the study consent form, and copies of the clinical outcome scores to complete. They will be asked to sign the consent form (if no questions) and complete the questionnaires before meeting with study staff at the pre-anesthetic clinic, who will collate the forms and answer any further questions.

Randomization:

Randomization will occur after enrolment and subjects will be blinded to assignment group. All subjects will be scheduled for and receive the same MRI experience. It is not possible to blind the surgeon to the surgical technique. The block randomization process will be stratified by surgeon to ensure equal distribution between the two surgical techniques.

Surgery:

Anesthetic and surgical technique will be identical for both groups, and will only differ in type of instrumentation used. Patients are normally given an spinal anaesthetic for intra-operative anesthesia. Patients are placed supine with a 5L saline bag beneath the buttock on the operated side and a tourniquet around the thigh. After appropriate prepping and draping, the tourniquet is inflated and a midline skin incision is used, followed by a medial para-patellar arthrotomy. This allows access to the joint for bone cuts using the appropriate instrumentation, soft tissue balancing, and component implantation. To reduce the incidence of infection, all patients are given 1 pre-op and 3 post-op doses of cephazolin or vancomycin (if penicillin allergic), and body exhaust suits are used by all surgical staff in the operating room. As per our group's normal routine, AP and lateral x-rays of the knee are performed in the recovery room to assess for any undetected intra-operative complications (fracture or gross component malposition). These are not the x-rays used for formal assessment of component position – these are done at the 6 month office follow up visit.

Hospital care:

Patient in-hospital care and rehabilitation is standardized using our group's total knee replacement care map. Deep venous prophylaxis consists of sequential compression devices for 24 hours with elastic stockings while in hospital and rivaroxaban for a minimum of 2 weeks post-surgery. Analgesia is obtained oral narcotics and acetaminophen with patient-controlled intravenous analgesia used when necessary.

Follow up:

All patients will follow our group's pre-existing routine follow-up schedule: a fracture clinic visit 2 weeks post-op for surgical staple removal and wound check, a 8 week office visit for clinical, radiological examination and completion of the clinical outcome questionnaires, a 6 month post-op office visit for clinical & radiographic examination and completion of the clinical outcome questionnaires, followed by yearly visits for clinical & radiographic examination and completion outcome questionnaires. For the purposes of this study, data will be gathered until subjects reach two years from surgery.

The only change from our normal clinical follow-up will be at the 8 weeks follow-up radiological examination. A 3 foot standing AP x-ray of the leg will be substituted for the routine AP x-ray of the knee, and a 3 foot lateral x-ray of the leg will be substituted for the lateral knee x-ray. These modified views increase x-rays exposure minimally, while providing proper standardized films for assessment of limb alignment and component alignment {Hewitt, 2001 #206;Jeffery, 1991 #210}.

Special Sub-group follow up:

15 patients from each arm of the study (30 patients in total) will be asked to participate in a CT scan sub-group to assess component rotation. While standardized plain x-rays are good for assessing component alignment in the coronal and saggital planes, CT scans are required to assess component rotation relative to the long axes of the femur and tibia {Jazrawi, 2000 #209;Berger, 1998 #196}. To minimize time commitment from patients, a single CT scan will be undertaken during the hospital stay using a standardized technique {Berger, 1998 #196}. This CT scan is in addition to the plain x-rays as previously described. This sample size of 30 patients was chosen based upon previously published work {Berger, 1998 #196}.

Data storage

Data for this study will be stored in the Concordia Joint Replacement Group's PHIA compliant database (HREB approval H2003:004). Data will be exported to SAS statistical analysis software in a de-identified fashion for statistical analysis.

Outcome Measures

Primary outcome measures:

1. Leg alignment
    a. Frontal limb alignment as measured on the 3 foot standing film (fig.1-A).

    b. Sagittal limb alignment as measured on the 3 foot lateral film (fig.1-D & E).
2. Femoral component position
    a. Varus/valgus alignment relative to mechanical axis of femur as measured on the 3 foot AP film (fig.1-A).
    b. Flexion/extension alignment relative to mechanical axis of femur as measured on the 3 foot lateral film (fig.1-D).
    c. Rotation relative to epicondylar axis as measured by CT scan
3. Tibial component position
    a. Varus/valgus alignment relative to mechanical axis of tibia as measured on the 3 foot AP film (fig.1-C).
    b. Amount of posterior slope as measured on the 3 foot lateral film (fig.1-E).
    c. Rotation relative to tibial tubercle as measured by CT scan

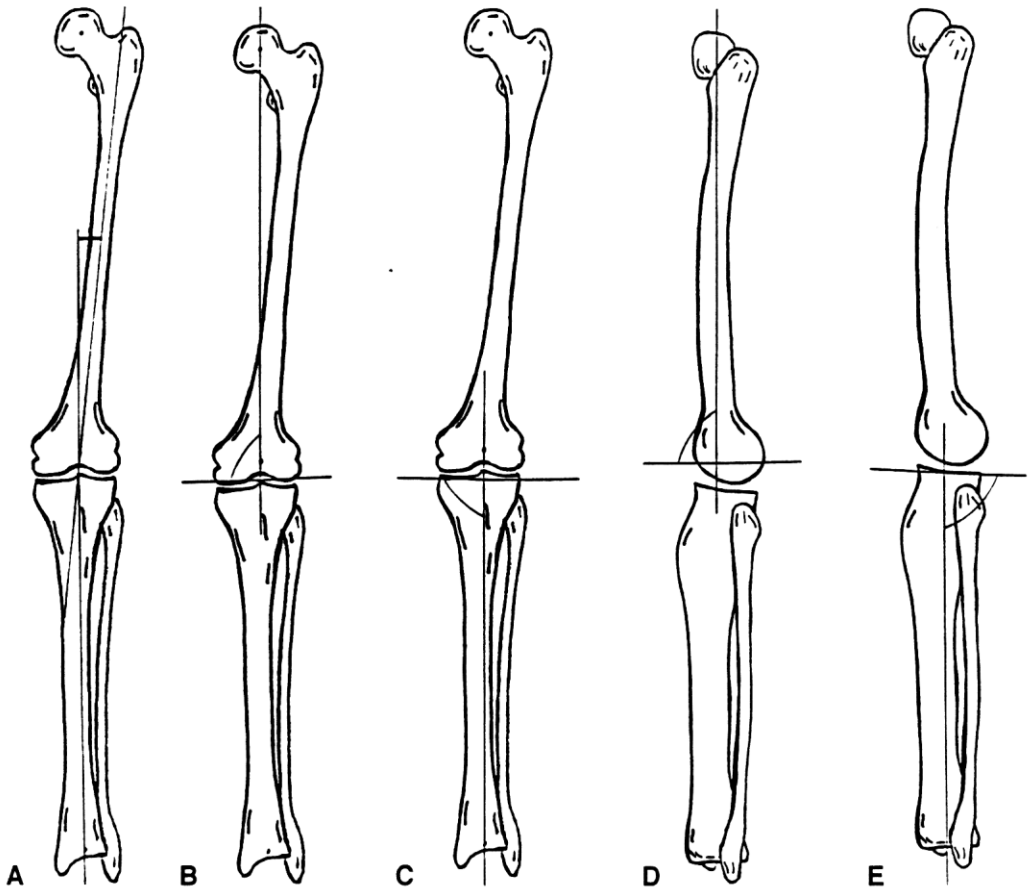

Figure 1 - Limb Alignment

Secondary outcome measures:

1. EuroQol score at 1 and 2 years
2. Oxford 12 score at 1 and 2 years
3. Pain Catastrophizing Scale score at 1 and 2 years
4. Knee Replacement Expectations score at 1 and 2 years
5. Visual analogue scales (VAS) for pain and satisfaction at 1 and 2 years
6. UCLA Activity Level score at 1 and 2 years.

Miscellaneous measures:

1. Surgical and tourniquet time
2. Number of instrument pans used
3. Length of hospital stay
4. Peri-operative complications such as deep venous thrombosis, pulmonary emboli, wound complications and cardiac events.

Sample Size

This trial is powered to detect a difference in post-operative frontal limb alignment between the two groups. The CJRG have recently had a computer navigation study accepted for publication assessing alignment with the same protocol as outlined in the study. The standard deviation for frontal plane alignment in the traditional instrumentation group was 3.1 degrees. Previous studies have indicated increased risk of early revision with alignment more than 3 degrees from the mechanical axis{Ritter, 1994 #334}. Assuming p=0.05 and power of 95%, a sample size of 29 per arm is required. Allowing for 20% drop-out requires 35 subjects per arm total.

Study End Points

The study will end when all enrolled patients are followed out clinically and radiographically to two years. No interim analysis is planned, as this would adversely affect significance testing. The surgeons involved in this study follow their patients closely in the post-operative period; any unforeseen significant complications arising from using the patient-specific custom cutting blocks that cannot be resolved would prompt cessation of the trial. This process is facilitated by the Concordia Joint Replacement Group's weekly planning & post-operative x-ray review rounds.

Analysis

Data for this study will be stored in the Concordia Joint Replacement Group's PHIA compliant database (HREB approval H2003:004). Data will be exported to SAS statistical analysis software in a de-identified fashion for statistical analysis. The two groups will be compared to assess the adequacy of randomization, relevant data will be assessed for normalcy, and the appropriate parametric and non-parametric tests will be used for comparing means and proportions between the two groups. Multiple regression analysis will be used to look for other factors that may affect post operative limb alignment and component position.

Dissemination

The results of this study will be submitted to peer reviewed journals and presented at orthopedic conferences.

Budget

There is no set budget for this study. The 35 patient-specific custom cutting blocks required for this study will be provided free-of-charge by Smith and Nephew Canada. The MRI imaging required for this study will be provided by Dr. Michael Davidson at the Pam Am clinic. Clinical research will be performed using existing funding from the research accounts of the Concordia Joint Replacement Group.

Table 1. Data Collection Summary

	Preop	Intra-operative	8 weeks (±1week)	6 months (±2weeks)	12 months (±1month)	24 months (±2months)
Leg Alignment	√		√			
Questionnaires & Functional Assessment	√		√	√	√	√
Surgical variables		√				
CT Scan		√*				
Complication/Adverse Event	√		√	√	√	√

* CT Scan will be completed during hospital stay.

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