# Clinical outcomes of patient-specific (MyKnee™) cutting blocks in total knee arthroplasty: preliminary prospective study results

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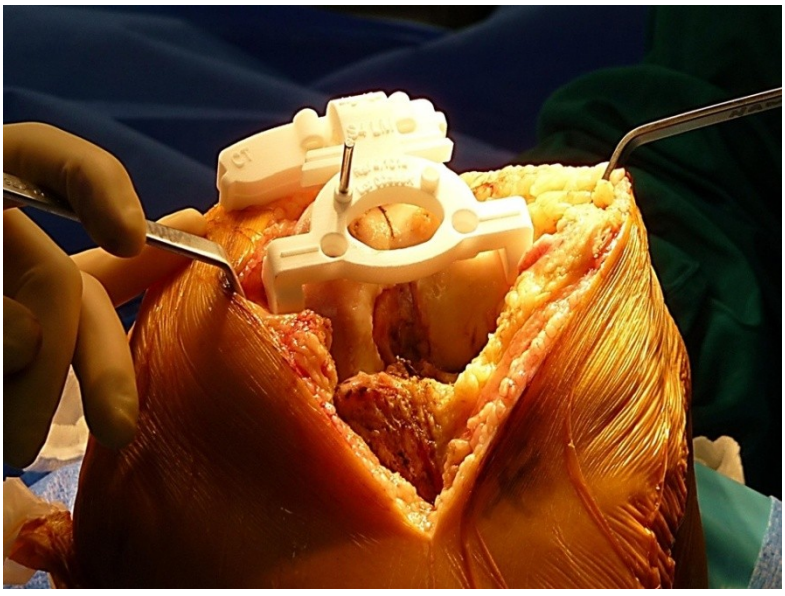
**Introduction:** There is a paucity of published data available to support patient specific technology in performance of total knee arthroplasty (TKA). A prospective study is currently underway, designed to evaluate clinical outcomes resulting from this technique. This technique uses a pre-operative CT scan of the lower extremity to plan the surgery. Cutting blocks are built, based on the positive topography of the bones, to achieve a neutral mechanical axis after the surgery. The surgeon has oversight throughout the process, with the ability to evaluate the CT data and make changes to the plan prior to construction of the cutting blocks. The blocks are designed to achieve pre-planned bony resection depths, and thus appropriate intraoperative implant placement. The theoretical benefits are that speed of surgery should increase and intraoperative complexities should be reduced. IRB approval for prospective research was obtained prior to study conduct.

**Methods:** One hundred (100) patients of the senior author will be consented into the research study, and undergo TKA using the MyKnee technique. Pre-operative assessments, including patient pain and quality of life scores, long-standing radiographs, CT scans, and relevant clinical data are considered. Intraoperative data includes tourniquet time, patient in-out time, estimated blood loss, complications, and actual vs. intended bone resections of the femur and tibia. Femoral resections captured include distal medial cut, distal lateral, posterior medial and posterior lateral. Medial tibia, and lateral tibia cuts are likewise compared. Post-operative follow-up for this report includes data captured up to 3 months following the subject date of surgery, for the first 50 research subjects.

**Results:** 50 femoral and 49 tibial resections, from 50 knees of 49 study subjects, were available for review using the MyKnee technique. For patients with varus pre-operative deformities, the mechanical alignment was 6.5° (range 1°-12.5°). For patients with valgus deformities, the average was 6.5° (range 1°-13.5°). Post-operative alignment for all patients (n=50) was 1.75° (range 0°-3.5°). The actual vs. planned resections for the distal medial femoral resection was 7.5 vs. 7.7mm respectively. Further actual vs. planned femoral resections include distal lateral femoral 6.7 vs. 6.3mm; posterior medial femoral 8.9 vs. 9mm; and posterior lateral femoral 7.4 vs. 7.0mm. The actual vs. planned tibial resections recorded include medial 6.2 vs. 6.4mm and lateral 8.4 vs. 8.1. All patients had cartilage "scraped" by the surgeon, to remove cartilage that may cause erroneous measurements, as CT scans don't account for cartilage. Tourniquet time averaged 29.7 minutes (range 21-53). No



intraoperative complications occurred that compromised the surgeries. Also, one tibia cutting block wasn't used by the surgeon because he wasn't comfortable with the fit, and standard instrumentation was used seamlessly and successfully.

**Discussion:** Many techniques exist for performance of TKA. Patient-specific cutting blocks allow the surgeon to pre-operatively determine resection depths, rotations, alignment, and sizing prior to the operative procedure itself. The present study shows definitively that intraoperative resections and post-operative alignments can be accurately achieved with pre-operative CT planning and using patient-specific instrumentation. Intraoperative speed of surgery is important to all participants in TKA: surgeon, hospital, and patient. Obviously accuracy should not be sacrificed for speed so it is important for any new technology introduced to the market to accelerate surgery not compromise results. In the current study, the average tourniquet time was less than 30 minutes. In a retrospective study of the MyKnee cutting blocks, the surgeon achieved 37.03 minutes in his first 30 MyKnee cases. This difference of over 7 minutes is statistically significant ($p=.11$), and documents the surgeon's rapid progression through the shallow learning curve of this technique. Furthermore, the goals of surgery were maintained radiographically. Regardless of the deformity, the patient's post-operative mechanical axes averaged 1.1°. These results were obtained via long-standing X-rays, which are well known to have error in alignment secondary to potential flexion and rotation of the extremity. Ten (10) post-operative CT scans will be conducted to a random sample of study subjects for comparison, and will be available upon completion of the study.

In conclusion, using patient-specific instrumentation (MyKnee) is safe, quick, and accurate in performance of TKA.