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Intraoperative Comparison of Measured Resection and Gap Balancing Using a Force Sensor: A Prospective, Randomized Controlled Trial

Krishna R. Cidambi, MD [a, b], Nicholas Robertson, MD [a], Camille Borges, BA [a], Nader A. Nassif, MD [a], Steven L. Barnett, MD [a, *]

[a] Department of Orthopedic Surgery, Hoag Orthopedic Institute, Irvine, CA
[b] Department of Orthopaedic Surgery, University of California, San Diego, San Diego, CA

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ABSTRACT

Background: For establishing femoral component position, gap-balancing (GB) and measured resection (MR) techniques were compared using a force sensor.
Methods: Ninety-one patients were randomized to undergo primary total knee arthroplasty using either MR (n = 43) or GB (n = 48) technique using a single total knee arthroplasty design. GB was performed with an instrumented tensioner. Force sensor data were obtained before the final implantation.
Results: GB resulted in greater range of femoral component rotation vs MR (1.5° ± 2.9° vs 3.1° ± 0.5°, $P < .05$) and posterior condylar cut thickness medially (10.2 ± 2.0 mm vs 9.0 ± 1.3 mm) and laterally (8.5 ± 1.9 mm vs 6.4 ± 1.0 mm). Force sensor data showed a decreased intercompartmental force difference at full flexion in GB (.8 ± 2.3 vs 2.0 ± 3.3u, 1u ≈ 15 N, $P < .05$).
Conclusion: GB resulted in a greater range of femoral component rotation and thicker posterior condylar cuts resulting in an increased flexion space relative to MR. Intercompartmental force difference trended toward a more uniform distribution between full extension and full flexion in the GB vs MR group.

Femoral component position is critical to total knee arthroplasty (TKA) as it affects patellofemoral and tibiofemoral kinematics and ligamentous balance. Correcting alignment with bone resection, balancing of the surrounding soft-tissue envelope, and placing components accurately are essential surgical steps in a successful procedure.

Although proper bone cuts result in restoration of alignment as well as providing proper fit of the prosthesis, ligamentous stability remains a key component for the success and longevity of TKA. Instability and problems with ligament balance have been shown to lead to early failure secondary to condylar lift-off, flexion instability, accelerated bearing surface wear, loosening, pain, patellar maltracking, and material failure [1–8].

Positioning of the femoral component in all 3 planes (coronal, sagittal, and transverse) directly affects the kinematics of TKA with respect to both the tibiofemoral and patellofemoral articulations. Intraoperative techniques for femoral preparation can be classified as either measured resection (MR) or gap-balancing (GB), and most surgeons will use one or a combination of these 2 options when aligning the femoral component.

In MR, anatomic landmarks on the distal femur are used to position the femoral cutting block in both the sagittal and transverse plane followed by performing condylar and chamfer resections. In this scenario, the soft tissues are "balanced" after femoral positioning has been set to ensure proper kinematics with respect to flexion-extension and patellafemoral motion. Anatomical landmarks associated with the use of this technique include the transepicondylar axis (TEA), posterior femoral condyles (PCs), and the anteroposterior (AP) axis (Whiteside's line).

Accuracy of identifying any of these landmarks can be variable. Whiteside defined the AP axis and showed improved patellar tracking as well as stability in patients with valgus knees who underwent TKA using this landmark to set femoral rotation compared to the posterior condyles [9]. Others have shown more variability when using this landmark [10,11]. Yau et al [11] demonstrated a 32° range of error using the AP axis (15° of internal rotation to 17° of external rotation). In varus knees with medial compartment degenerative disease,

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* Reprint requests: Steven L. Barnett, MD, Orthopaedic Specialty Institute, 16300 Sand Canyon Avenue #511, Irvine, CA 92618.

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Nagamine et al [10] found significant external rotation errors using the AP axis.

The TEA is another well-recognized landmark to assist in setting femoral rotation and has been shown to be perpendicular to the tibial mechanical axis in 90° of flexion [12,13]. Condylar lift-off has been shown to be minimized when using this technique to create a rectangular flexion space [14]. Olcott and Scott [15] analyzed the ability of creating a rectangular flexion space utilizing the TEA compared to the AP axis and posterior condyles. The TEA was most accurate and resulted in a rectangular flexion space within ±3° 90% of the time. However, accurate identification of the TEA has more recently been questioned. Kinzel et al [16] demonstrated that the TEA is correctly identified within ±3° only 75% of the time using postoperative computed tomography scans to check accuracy. In the previous study by Yau et al [11], errors in identifying the TEA ranged from 11° of external rotation to 17° of internal rotation.

Previous studies have documented that the posterior condylar axis is rotated an average of 3° relative to the TEA [17,18]. Deficiencies exist, however, with the use of the PC axis that arise from a high degree of anatomic variability within patient populations. For example, knees with valgus deformities often have hypoplasia of the lateral femoral condyle, which will result in internal rotation of the femoral component when strictly relying on this landmark as a reference point.

GB is another technique supported by many authors as a means to achieve a symmetric, rectangular flexion space [1,11,13,19–23]. As an alternative to MR, this technique relies on soft-tissue tension to set femoral rotation in flexion. Typically, the distal femoral and proximal tibia cuts are performed first followed by releasing tight structures in extension to achieve a rectangular extension space. Once this is completed, the knee is flexed to 90°, and the flexion space is "tensioned" with some kind of distraction device. Once tension of the flexion space is achieved, the femoral cutting block is positioned such that the condylar cuts are parallel to the resected tibia surface to insure a rectangular flexion space. As an additional step, most tensioning devices provide the surgeon with the ability to translate the femoral block anteriorly or posteriorly to achieve equal flexion and extension gap thickness.

Fehring [20] performed 100 TKAs using a balanced technique. He calculated that the use of fixed external rotation relative to the posterior condylar axis to set femoral rotation would result in a trapezoidal flexion space 45% of the time. Dennis analyzed 212 TKA patients with the use of computer navigation. The TEA, PC axis, and AP axis were registered before resection and then GB was performed. He showed a higher variability with femoral component position using the TEA and only 43% of cases matched the balanced alignment within ±3° [19]. Similar discrepancies were identified using the PC axis (58% accuracy) and AP axis (39% accuracy).

Camarata [24] integrated an intraoperative force sensor with a tensioning device in his GB work flow. The eLIBRA Dynamic Knee Balancing System provides the surgeon with real-time compressive force data and assists in balancing flexion and extension gaps. Our study provides an intraoperative comparison of the GB and MR techniques for establishing femoral component position using this force sensor.

Methods

The institutional review board approval was obtained before patient enrollment. Patients were enrolled by 2 high-volume fellowship-trained arthroplasty surgeons. Surgery was performed at a single institution. Inclusion criteria for the study included diagnosis of degenerative, noninflammatory arthritis of the knee, and demonstrated failure of nonarthroplasty management. Ninety-one patients were enrolled, 43 in the MR arm and 48 in the gap balanced arm. There were 41 (45.1%) females and 50 (54.9%) males. The average age in this study was 62.3 (range 47.9-73.9) years.

Surgical Protocol

Each subject was randomized to undergo primary TKA using either an MR technique or a GB technique. Randomization was performed utilizing a third party at the time of enrollment. The surgeon was not blinded to the enrollment status. Variability was minimized by using a single implant company and design. Posterior-stabilized implants (Zimmer Persona; Warsaw, IN) were used in all patients. Anesthesia was standardized as per the protocol of the institution including general and spinal anesthesia with an adductor canal block catheter. Preoperative antibiotics were administered per protocol. Standardized rehabilitation and pain management protocols were used for both patient groups in the postoperative period.

Surgical Technique

The surgery was performed using a standard anterior, midline longitudinal incision followed by a medial parapatellar arthrotomy. The patella was retracted laterally and not everted in all cases during exposure or instrumentation steps of the procedure. An extramedullary guide was used to cut the tibia with 3° of slope.

For the MR cohort, after the distal femur resection, a posterior condylar referencing jig was applied, which allowed for femoral sizing and 4-in-1 cutting block localization. Drill holes were made based on an approximation to the TEA, using 3° of external rotation to the posterior condylar axis in 93% of the patients and 5° in the remaining patients. The tibia was then cut perpendicular to its mechanical axis. Trial tibial and femoral implants were then applied, and the femoral box resection was completed. Ligament balancing was then performed until soft-tissue tension was appropriate based on the surgeon's discretion in both medial and lateral components throughout flexion and extension.

For the GB cohort, the knee was brought to extension after proximal tibia and distal femoral cuts were completed. Any large, posterior osteophytes were removed before extension space balancing. Medial and lateral releases were completed until the extension space was rectangular. If full extension was not achieved, additional tibial resection was performed in an effort to accommodate the thinnest insert without elevating the joint line. A spacer block was placed into the extension gap to confirm it was large enough to at least accommodate the thinnest insert. The Zimmer FuZion jig was then inserted in extension (Fig. 1) and tensioned with a torque hex driver. The gap thickness was achieved, and the applied torque measurements were recorded. The FuZion flexion space jig was applied between the resected proximal tibia and native posterior condyles with the knee in 90° of flexion and thigh supported. A torque, matching the measurement noted in extension, was applied to tension the flexion space. The femur rotated freely based on lateral and medial soft-tissue tension. Holes were then drilled matching the extension gap thickness and parallel to the resected tibia to ensure a rectangular, symmetric gap (Fig. 2). At this stage, the angle between posterior condylar axis and cut tibial surface reported by the balancer was recorded. This angle, by the geometric theorem of congruent alternate interior angles, is equivalent to the angle between the posterior condyles and the drilled holes. Even if the tibial cut was not perfectly perpendicular to the mechanical axis, that is, in varus or valgus, while the orientation of the drilled holes would change based on how the collateral ligaments are tensioned, the reading on the balancer still defines the angle between the drilled holes and the posterior condylar axis,