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Basic Science

Second-Generation Electronic Ligament Balancing for Knee Arthroplasty: A Cadaver Study

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ABSTRACT

Background: Knee instability is emerging as a major complication after total knee arthroplasty (TKA), with ligament laxity and component alignment listed as important contributory factors. Knee balancing remains an art and is largely dependent on the surgeon's subjective “feel.” The objectives were to measure the accuracy of an electronic balancing device to document the magnitude of correction in knee balance after soft-tissue releases and measure change in knee laxity after medial release.

Methods: The accuracy of a second-generation electronic ligament-balancing device was compared with that of 2 mechanical balancing instruments. TKA was performed in 12 cadaver knees. Soft-tissue balance was measured sequentially before TKA, after mounting a trial femoral component, after medial release, and after resecting the posterior cruciate ligament. Coronal laxity of the knee under a 10 Nm valgus moment was measured before and after medial release.

Results: The electronic balancing instrument was more accurate than mechanical instruments in measuring distracted gap and distraction force. On average, before TKA, the flexion gap was wider than the extension gap, and the medial gap was tighter than the lateral gap. Medial release increased the medial gap in flexion and increased passive knee valgus laxity. Posterior cruciate ligament release increased the tibiofemoral gap in both flexion and extension with a greater increase in the lateral gap.

Conclusion: The second-generation electronic balancing device was significantly more accurate than mechanical instruments and could record knee balance over the entire range of flexion. More accurate soft-tissue balance may enhance outcomes after TKA.

Despite the excellent implant survival rates of total knee arthroplasty (TKA), patient-reported dissatisfaction rates are high [1–3], with overall satisfaction scores of only 59%, and with over 50% of patients reporting some degree of residual disability [4,5]. Dissatisfied patients have more pain and lower range of motion even when other clinical and radiographic findings are comparable with satisfied patients [6]. Improvement in implant design and durability of polyethylene have reduced revision rates because of implant loosening and polyethylene wear [7,8]. However, ligament imbalance is now emerging as one of the major causes of revision in the short term [9–11]. Knee instability is multifactorial, with ligament imbalance and component alignment listed as major contributory factors [12]. Although there are several sophisticated and reliable systems for component alignment, ligament balancing remains an art and is largely dependent on the surgeon's intuition and subjective “feel.”

The 2 major surgical techniques for making bone cuts and for balancing the knee are the measured resection approach and the balanced gap approach. In the measured resection technique, bone cuts are made relative to anatomic landmarks such as the posterior condyles, the transepicondylar line, and Whiteside's line. In the balanced gap approach, ligament releases are performed first, and the bone cuts are made such that the gap between the femoral and tibial bone cuts are rectangular and equal in flexion and extension. Although several instruments and surgical navigation systems are available for aligning bone cuts and components, there are fewer options for accurately measuring intraoperative balance. Mechanical

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Table 1
Study Design for Cadaver Testing With Electronic Balancer.

Intact Knee	After Tibial Cut	After TKA	After Medial Release	After PCL Release
Laxity measurement		Laxity measurement	Laxity Measurement	
	Electronic balance	Electronic balance	Electronic balance	Electronic balance

PCL, posterior cruciate ligament; TKA, total knee arthroplasty.

instruments typically used for ligament balancing can be classified as spacer blocks or joint distraction devices. With spacer blocks, the surgeon selects a block of appropriate size and manually checks the balance with the knee in full extension and 90° flexion. With distraction devices, the surgeon manually exerts force on the instrument to distract the joint and measures the gap between the bone cuts.

The so-called “first-generation” electronic balancing devices are equivalent in concept to spacer blocks instrumented with force sensors. We previously reported on a tibial tray trial instrumented with force sensors [13]; Wasielewski et al correlated intraoperative imbalance measured using pressure sensors with postoperative lift-off; while more recently trial tibial inserts with instrumented force sensors are now commercially available from OrthoSensor, Inc [14]. These devices measured forces in the medial and lateral compartments of the knee with the assumption that a balanced knee generated equal forces in flexion and extension and equal forces in the medial and lateral compartments. First-generation electronic balancing devices are more useful during the measured resection technique because they are typically used after making the femoral cuts (with trial femoral components).

“Second-generation” electronic balancing devices are equivalent in concept to mechanical distraction devices instrumented with pressure and displacement sensors [15]. Joint distraction is achieved by sensor-regulated pressure. Similar to mechanical distraction instruments, the electronic device measures the distracted gap in flexion and extension. The potential advantages of second-generation electronic balancing devices over mechanical instruments are more precise control of distraction force and greater accuracy in measured gaps. Second-generation electronic balancing devices only require that a tibial cut be made and can be used before making the femoral cuts, but are also compatible with trial components after all cuts have been made. These devices can therefore be used with either measured resection or balanced gap technique.

The objectives of this study were to measure the accuracy of a second-generation electronic ligament balancing device in comparison with that of 2 mechanical distraction devices, document the magnitude of correction in knee balance after soft-tissue releases, and measure the change in knee laxity after medial release.

Materials and Methods

Study Design

This study was conducted in 2 phases. In phase I, the accuracy of force and gap measurements was documented for 2 mechanical distraction instruments and 1 electronic balancing instrument. Phase 2 involved cadaver testing using only the electronic balancing instrument. Mechanical distraction instruments were not used in phase 2, as these instruments did not measure balance over the entire range of flexion and could not be used with trial components. Briefly, knee laxity in varus-valgus was measured sequentially in the intact knee, after making a measured resection TKA, and after conducting medial release (Table 1). Soft-tissue balance was measured electronically, after making the tibial cut (before TKA), and after conducting soft-tissue releases (Table 1).

Balancing Instruments

The accuracy of 2 mechanical distraction instruments (DePuy, Warsaw, IN, and Smith & Nephew, Memphis, TN) and 1 electronic balancing device (XpandOrtho Inc, La Jolla, CA) was measured. The XpandOrtho electronic balancing device (Fig. 1) consists of a trial insert connected to a pressure controller. During surgery, the controller is mounted on the thigh with the help of a strap. After making the tibial cut, the trial insert is introduced into the joint and the controller pressurized to the appropriate level with a syringe. The wireless controller communicates with a tablet for graphic display of pressure and knee balance. Joint distraction is achieved by means of a pneumatic pressure controller. Pneumatic pressure is initially generated using a syringe to pump air into the pressure controller, which maintains pressure in the trial insert. A pressure sensor monitors the pressure and computes tibiofemoral distraction force. Electromagnetic sensors measure the distance between the top and bottom plates of the trial insert and calculate the tibiofemoral gap (the gap between the femoral articular surface and tibial cut), the tilt between the femoral surface and tibial cut, and the height of the gap in the medial and lateral compartments, respectively. Inertial sensors in the controller and trial insert monitor knee flexion angle while measuring balance. The top plate of the trial insert is modular to facilitate flexion gap balancing before making the femoral cuts and to accommodate different knee designs in posterior cruciate-retaining and cruciate-substituting configurations.

The electronic balancing device only requires that the tibial cut is made, and can therefore be used during measured resection or gap balancing techniques. Surgeons using measured resection techniques typically cut the femur first, in which case the electronic balancing device is used after all cuts are made and with a femoral trial in place. Soft tissues are then released as necessary to balance the flexion-extension gap. Surgeons using gap balancing techniques typically cut the tibia first, in which case the electronic balancing device can be used to measure balance of the native femoral condyles (before the femoral cuts are made). This approach provides the surgeon with the appropriate angles to make the femoral cuts to balance the flexion-extension gap. In our cadaver study, we used both approaches. We cut the tibia first and measured the physiologic (pre-TKA) balance of the knee. Next, we cut the femur (using measured resection) and measured the post-TKA balance of the knee with a femoral trial. Finally, we measured the balance after a medial release and a posterior cruciate ligament (PCL) release (see Cadaver Testing subsection for details).

The DePuy mechanical distraction instrument (Fig. 2) consists of twin blades that are inserted into the knee, which are manually controlled using cylinders that apply a distraction force when rotated. Each cylinder has markings (A, B, and C), which correspond to 3 different forces of distraction, nominally 20, 40, and 60 N, respectively. Each cylinder also has markings to record the magnitude of distraction at a resolution of 2.5 mm.

The Smith & Nephew mechanical distraction instrument (Fig. 3) also consists of twin blades that are inserted into the knee, which are distracted by the use of spring-loaded levers [16]. The distraction force is measured from markings on the instrument at a resolution of 20 N and the distracted gap is measured from markings at a resolution of 1 mm.