Use of smart trials for soft-tissue balancing in total knee replacement surgery

K. Gustke
From Florida Orthopaedic Institute, Florida, United States

Smart trials are total knee tibial trial liners with load bearing and alignment sensors that will graphically show quantitative compartment load-bearing forces and component track patterns. These values will demonstrate asymmetrical ligament balancing and misalignments with the medial retinaculum temporarily closed. Currently surgeons use feel and visual estimation of imbalance to assess soft-tissue balancing and tracking with the medial retinaculum open, which results in lower medial compartment loads and a wider anteroposterior tibial tracking pattern. The sensor trial will aid the total knee replacement surgeon in performing soft-tissue balancing by providing quantitative visual feedback of changes in forces while performing the releases incrementally. Initial experience using a smart tibial trial is presented.

Total knee replacement (TKR) provides excellent long-term results, with survival at 15 years reported between 85% and 97%. However, not all total knee patients are satisfied with their outcome. Noble et al reported that 14% of their patients were dissatisfied with their outcome. Problems with kneeling, squatting, gardening, lateral movements, and carrying loads were noted in 50% to 75% of the patients. Dickstein et al reported that one third of their patients were dissatisfied with their TKR, even though all their physicians rated their results as excellent. Bullens et al showed that the surgeon’s objective assessment of outcome is greater than the patient’s subjective assessment of outcome. So there is a disconnect between patient’s and surgeon’s assessments.

So why doesn’t TKR surgery consistently restore normal function and achieve high patient satisfaction? We have implant designs that have been highly developed with improved polyethylene with excellent wear characteristics over the last 20 years. We have instruments that with the aid of computer navigation or patient specific instrumentation that can make accurate bone alignment cuts. Radiological evaluation of most of these dissatisfied patients reveals normal component alignment and positioning. Physical examinations are also usually unremarkable. Perhaps part of the problem could be subtle soft-tissue imbalance and mal-tracking of the components that we have difficulty in assessing. Subtle or gross instability will accelerate polyethylene wear and can cause pain and stiffness. Fehring et al reported instability as the second highest reason for early revision surgery in their series.

Soft-tissue balancing is still an art. It relies on subjective feel and visual evaluation of gaps while relatively inconsistent varus and valgus stresses are applied to the knee. True component tracking cannot be assessed without the patella reduced and closure of the medial retinaculum. We do not have good instruments to assist with soft-tissue balancing. It is difficult to teach inexperienced surgeons how to assess and correct soft-tissue imbalance. Better tools are required to help with soft-tissue balancing and assessment of component tracking. Use of a smart tibial trial may be such a tool that may enable us to lessen some of the subtle instability.

Materials and Methods
The OrthoSensor Knee Balancer smart trial (Orthosensor Inc, Sunrise, Florida) was used in this series. It has miniaturised integrated circuits and microprocessors that are adapted from the cell phone industry (Fig. 1). These smart trials are connected to a computer via a wireless link (Fig. 2). They graphically show quantitative compartment load-bearing forces and component track patterns. The use of smart tibial trials is not a new concept. Wasieliewski, Galat and Komistek reported on the first smart tibial liner in 2004, a custom-made tibial trial with a modified Novel intra-operative pressure-sensing matrix array attached to the posterior surface. Subclinical soft-tissue imbalances were able to be
detected. Post-operative fluoroscopic studies showed femoral component lift-off in cases that demonstrated unequal compartment pressures. They did not use the device for soft-tissue balancing.

This particular smart tibial trial has the advantage of being technology that could easily be adapted to all total knee systems. It is fairly inexpensive because much of its technology was developed within the cell phone industry. The device is single-use and disposable. Use of this technology will be considered by many surgeons since the normal work flow is not changed. Bone cuts can be made in the usual order and familiar measured resection or gap balancing techniques can be used. Proper knee alignment is still necessary, since one does not want to produce a perfectly balanced misaligned knee.

A magnet is used to activate the smart tibial trial. After all the bone cuts are made, the smart trial is inserted just like a traditional tibial liner trial. Shims are placed under the smart trial insert to provide adequate initial soft-tissue tension. The medial retinaculum is temporarily closed with two or three towel clips. The hip is flexed and the posterior distal femur is supported with one hand. The knee is allowed to flex while lightly supporting the heel with the other hand. While ranging the knee, it is important to avoid applying varus or valgus stress to the knee. The computer screen will show the maximal femoral contact point in the medial and lateral compartment along with the force value at each paused position of flexion. In track mode, the contact path is drawn demonstrating if the knee is behaving properly in kinematic terms. In most total knee designs, the medial track will be fairly short and within the middle of the medial tibial plateau and the lateral side will move posteriorly with increased flexion.

Having the ability to close the medial retinaculum will provide a more normal knee kinematic tracking. Typically the deep medial collateral ligament is released past the midline on initial exposure. With the anteromedial soft-tissue sleeve open and the deep medial collateral ligament released, the medial femoral condyle can sit more anterior on the tibia and the medial load forces are lower (Fig. 3).

**Results**
The first six months use of the OrthoSensor Knee Balancer has shown that imbalance scenario patterns are readily graphically displayed. This includes knees with a tight medial collateral ligament, tight posterior cruciate ligament, tight iliobibial band, tight popliteus, and a non-functional posterior cruciate ligament. Bony malalignments such as tibial or femoral malrotation, tibial or femoral malalignment, and abnormal tibial slope can mimic the same imbalance scenarios so it is important to recheck bony alignment also. It is important if an imbalance scenario is present, that a thick enough shim is placed under the smart tibial trial to produce one compartment under significant load and the other under tension. As a soft-tissue release is performed the force numbers seen on the computer in the tight
compartment will drop. Incremental partial medial and lateral releases using a pie-crusting technique with a number eleven knife blade can be performed with the retinaculum closed while watching the force numbers equalize. While the releases are performed, it is helpful to provide a little varus or valgus stress or knee motion to allow the released soft-tissues to stretch.

A tight medial collateral ligament will produce higher force pressures medially in either flexion or extension, or both (Fig. 4). An incremental pie-crusting release of the anterior and mid medial soft-tissue sleeve is done if the forces are tight mainly in flexion. The posterior medial capsule is released if the forces are tight mainly in extension. A tight iliotibial band will show elevated lateral compartment pressures mainly in mid to full extension (Fig. 5). A similar pie-crust release is performed with the iliotibial band. A tight posterior cruciate ligament will demonstrate posteriorly positioned femoral condyles and high pressures (Fig. 6). One can do incremental releases of the posterior cruciate ligament or add more tibial slope. Proper rotation of the tibial component can also be facilitated by the smart tibial trial. The lateral side of the tibial tray can be pinned in place with the medial side allowed to float. If the medial femoral dwell point sits too posterior or anterior, the tibial tray can be rotated to bring the dwell point more mid tibia. Then the medial tray is pinned in place.

Discussion

A multicenter IRB monitored study is underway to evaluate the efficacy and ability to guide soft-tissue balance and positioning of the knee implant utilising the smart tibial trial. The ligament releases that are performed will be compared to its effect on knee balance. The sensor data will be correlated to patient outcome including knee scores, self-assessments, radiographs and survivorship.

A criticism of use of a sensor guided tibial trial is that it demonstrates forces in a static rather than a dynamic situation where the knee is not loaded by contracted muscles and weight bearing. However Wasielewski et al. showed that total knees with sensor determined uneven compartment pressures correlates with abnormal femoral condylar lift-off during post-operative fluoroscopic kinematic studies.

This technology has the potential to be further developed with computer recognition software so that abnormal force patterns can be recognised by the computer and formulated optional algorithms for correcting the scenario can be offered. This technology can also be extended into sensors permanently implanted into the implants to monitor for
abnormal inflammation, infection and wear. This will offer early warnings to facilitate earlier intervention.

The use of smart trials is a new approach to total knee replacement. The initial experience with this smart tibial trial has been very positive. It is a wonderful tool for educating surgeons in training, and should provide better results for experienced surgeons as well. Data on soft-tissue balancing for the first time can be quantified and entered into joint registries to obtain long-term outcome data to validate our soft-tissue balance techniques. It should produce better balanced total knees that hopefully will improve overall patient satisfaction and function for total knee patients.

The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article. This paper is based on a study which was presented at the Winter 2011 Current Concepts in Joint Replacement meeting in Orlando, Florida, 7th – 10th December.

This paper is based on a study which was presented at the Winter 2011 Current Concepts in Joint Replacement meeting in Orlando, Florida, 7th – 10th December.

References


