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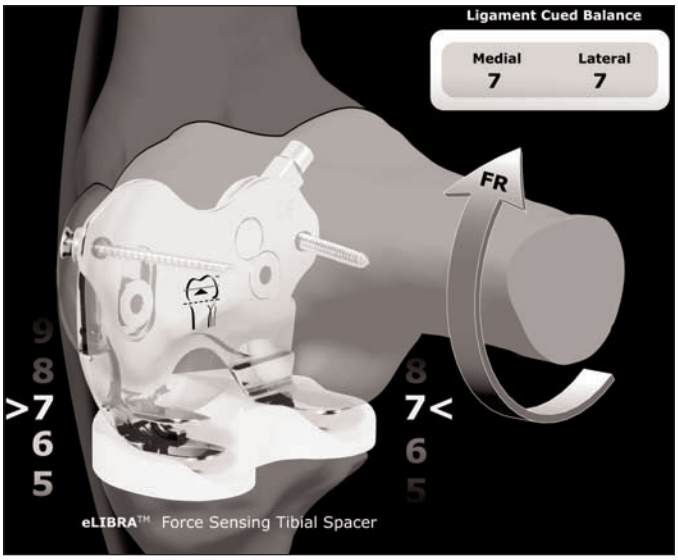
THE LIBRA™ DYNAMIC KNEE BALANCER BY SYNVASIVE TECHNOLOGY, INC.

Anticipation over the eLIBRA™ Force Sensing Tibial Spacer is transforming the discussion among surgeons on how to balance deformed knees.

Well-balanced TKR's share a common factor for success: flexion gap symmetry developed by femoral implant rotation relative to the proximal tibia. While one of the most important aspects in reconstructing deformed knees, proper rotation of the femoral component continues to be one of the most illusive outcomes for conventional instrumentation to achieve in all procedures. Current techniques rely on empirical landmarks documented to produce variability in developing symmetry within 3 degrees to avoid potential instability and indifferent results. Olcott, MD and Scott, MD found that the transepicondylar axis did not accomplish this symmetric flexion gap in 10 percent of varus knees and 14 percent of valgus knees and showed greater variability using the AP axis (Whiteside line) and the posterior condylar axis (*1*). Unlike conventional instruments, the **LIBRA™ Dynamic Knee Balancer** by **Synvasive Technology, Inc.** (El Dorado Hills, CA), establishes flexion gap symmetry by determining the femoral implant rotation needed to develop stable articulation across the joint prior to resecting the posterior femoral condyles with the patella positioned in situ.



Clinical Adoption Continues to Expand

Empirical landmarks continue to produce inconsistencies, particularly in patients with anatomic variations, hypoplastic deformities, or imbalance of the collateral ligaments. Deformities and the condition of laxity in an arthritic knee also challenge current balancing techniques. In many cases the deformity of a particular knee can act or present itself surgically as a different deformity. Many surgeons experience varus knees that surgically present the challenges of a valgus deformity. Tight or lax soft tissue conditions can challenge current balancing techniques as well. According to Martin W. Roche, MD, Chief of Orthopedics, Holy Cross Hospital in Ft. Lauderdale, Florida, "current techniques promote femoral-first preparation using bony landmarks to develop femoral rotation. The problem is that once the femur is cut, rotation is fixed. If this technique challenges balancing a deformed knee, especially in flexion, there are really no good options to correct residual imbalance. With respect to knee kinematics, ligament releases affect the extension and flexion gaps in different ways. The object is to reestablish alignment and balance while satisfying patellar tracking."

Steven L. Barnett, MD, of St. Joseph's Hospital in Orange, California, sees the main advantage of the LIBRA device to be its independence of variable, bony anatomy to create flexion and extension spaces. "By using the LIBRA device to balance the knee under collateral tension, you automatically ensure that your flexion and ex-tension gaps are not only symmetrical, but also rectangular. While traditional landmarks can result in a rectangular flexion space, it is not achieved routinely or reliably, especially in difficult cases like valgus deformities or deformities involving condylar dysplasia or hypoplasia." Dr. Barnett describes a patient with a history of hip dysplasia and leg length inequality that had a distal femoral epiphysiodesis as a child and, as a result, had

condylar deformity, leaving no palpable epicondylar landmarks. "There was no way that I could use the anatomy of the femur to set femoral rotation and the knee was in approximately 10 degrees of valgus. That's a perfect example of where using the LIBRA device made sense."

Dr. Roche described a situation with a 70 year old male patient with a 12-degree valgus alignment as well as a 10-degree flexion contracture. "We knew we would have to create the desired long limb alignment and we knew that the normal anatomic reference points would not be present due to the deformity. The benefit of using the LIBRA device in this procedure allowed me to perform the required soft tissue releases while understanding how these releases affected the gaps and soft tissue tone to develop a balanced reconstruction for that patient."

Force Sensing Technology Resolves Subjectivity

Given the clinical benefits the LIBRA device is providing surgeons in balancing challenging knees, resolving the issue of subjectivity offered the next advance. Interfacing force sensing technology with advanced electronics created the **eLIBRA™ Force Sensing Tibial Spacer*** to provide direct feedback to the surgeon regarding femoral rotation prior to completing the bone cuts to accept the femoral implant. Premarket testing and evaluation of this force sensing technology has received generous praise from surgeons interested in developing a more reliable solution to develop well-balanced TKR's, regardless of the pre-operative deformity or soft tissue condition.

The initial challenge in implementing force sensing technology is to determine the clinical definition of a "balanced knee." The surgical concept adopted parallels the reconstructive philosophy that the medial structures provide primary stability in a TKR and that load sharing supports reconstructive longevity in the knee. The display supporting the eLIBRA spacer is designed to present the surgeon with relative force values in the medial and lateral compartments during surgery, not absolute values. This technique assures dynamic balance is constant knee to knee, only reflecting a difference in magnitude in reconstructions requiring A/P translation of the femoral resection guide (4-in-1 block) or selection of a thicker/thinner tibial spacer to satisfy a reconstructive objective.

The result is a new technique facilitated by the eLIBRA spacer, used in conjunction with the LIBRA device, enabling the surgeon to simply adjust the femoral rotation to register equal relative force values on the display, removing the subjective nature of "balancing by feel."

Dr. Roche notes that, "in certain patients, it's difficult to stabilize the hip and test flexion balance because the hip naturally rotates about the socket. By adding sensors to the tibial insert, we can get true quantitative readings of the medial to lateral compartment pressures. Externally rotating the LIBRA device, I can dial in the exact pressure that equalizes both compartments." S. David Stulberg, MD, Professor of Clinical Orthopedic Surgery Northwestern University Feinberg School of Medicine in Chicago, Illinois, agrees with Dr. Roche that the eLIBRA Force Sensors will give surgeons a more objective measurement of whether the knee is actually balanced for any given rotational position replicating the femoral implant, while simultaneously being able to assess whether or not the patellar tracks well. "To me, that is a significant advantage over any ligament balancing technique that maintains the patellar in a translocated or everted position."

Adaptable Technology

To accomplish greater accuracy in alignment, surgeons continue to investigate the value computer-assisted surgical techniques offer in reducing clinical outliers associated with malalignment. Dr. Stulberg finds that the use of computer navigation in TKR has resulted in the ability to make accurate cuts with regard to the mechanical axis of the extremity, but that balancing the reconstructed knee remains a challenge even in this surgical environment. "I think emerging data indicates that the most accurate resection is carried out using navigation. Using the LIBRA and eLIBRA devices in conjunction with these accurate resections to develop proper rotation of the femoral component to dynamically balance the knee is a marriage of two complementary technologies being developed to advance total knee reconstruction."

The LIBRA Dynamic Knee Balancer and eLIBRA Force Sensing Tibial Spacer will enhance your primary TKR technique.

* The eLIBRA Force Sensing Tibial Spacer is not currently available for sale in the U.S. Please check our web site for updates on availability.

For more information concerning these products, and to discover how our STABLECUT® resection technology can change the way you think about saw blades visit www.synvasive.com.

References:

1. Christopher W. Olcott, MD and Richard Scott, MD, "A Comparison of 4 Intraoperative Methods to Determine Femoral Component Rotation During Total Knee Arthroplasty," Journal of Arthroplasty, Vol. 15 [1], 2000: pgs 22-26.