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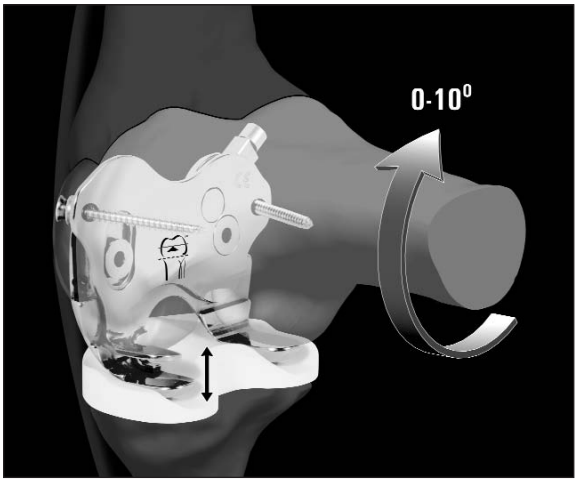
THE LIBRA DYNAMIC KNEE BALANCER™ BY SYNVASIVE TECHNOLOGY, INC.

Enabling dynamic balance during TKR to assure gait stability in demanding patients

Synvasive Technology, Inc. (El Dorado Hills, CA), introduces the **Libra Dynamic Knee Balancer**™ to surgeons performing primary Total Knee Replacement (TKR). This device is the first "dynamic" balancing instrument to aid surgeons in reproducibly establishing rotation of the femoral implant to improve stability in total knee patients. Libra is specifically designed to adjust femoral component rotation *in situ* while evaluating range of motion to verify *dynamic balance* between resection planes and the supporting envelop of soft tissues in the knee. Unlike existing "static" balancers or spacer blocks, the Libra device achieves dynamic balance through femoral rotation cued to the surgeon by patient specific ligamentous tone throughout this range of motion, not static tension at zero and ninety degrees of flexion. This technology introduces the first "active trial" for total knee arthroplasty.



Since its inception, total knee arthroplasty has enjoyed tremendous growth as an elective procedure by effectively mitigating activity-limiting pain resulting from arthritis, growth driven by patient satisfaction, awareness and expanding patient demographics. The designs of knee prostheses have been revolutionized by breakthroughs in biomaterials, biomechanics and the evolution of surgical exposures to enable the potential for more rapid recovery following TKR. Despite these breakthroughs, revision surgery is a reality for many patients and the problems are often the result of poor alignment and balancing during implantation. "I just had my knee replaced, but I'm having trouble walking down stairs" is an all too common complaint heard when patients return to a surgeon after under-going an otherwise successful total knee replacement. According to Anthony Hedley, MD, Chairman of Orthopaedic Surgery, St. Luke's Hospital, Phoenix, AZ, and co-inventor of the Libra device, "The commonest cause of failure in total knee replacement is instability."

Traditionally, anatomic landmarks such as the transepicondylar axis, Whiteside's line and the posterior condylar axis are used in total knee surgery to establish rotational alignment of the femoral implant onto the distal femur. These empirical landmarks provide reference points, but are known to produce inconsistencies among patients with anatomic variations, hypoplastic deformities or laxity of the collateral ligaments. The transepicondylar axis has attempted to address skeletal variations, but still introduces error when attempting to create a symmetric flexion gap (*1*). Traditional surgical techniques generally externally rotate the femoral implant 3 degrees to develop a symmetric flexion gap without paying much attention to the interplay between resection planes and soft tissue structures during gait. There are several balancers integrated into knee systems today designed to establish symmetric flexion and extension gaps, but these instruments do not provide any indication of stability in the knee throughout the entire range of motion until all resections are complete and the trial implants are positioned in the joint. Dynamically balancing a reconstructed knee is

important because normal gait produces a varus thrust or adduction moment as the majority of a patient's body weight is transferred to the medial compartment due to anatomic limb alignment. Traditional prosthetic alignment, used to ensure implant longevity, reduces the ability of the lateral soft tissue structures to resist this thrust, especially in mid-flexion, unless dynamic balance is achieved.

Surgically, the Libra instrument is introduced into the extension space after the distal femoral and proximal tibial resections have been made and prior to making the posterior condylar resection. The Libra femoral component is secured to the distal femur and its posterior skids are positioned flush against the posterior condyles. Following insertion of the appropriately sized tibial spacer, the knee is reduced and long limb alignment is assessed and adjusted if soft tissue releases are needed to bring the leg into the targeted alignment. The knee is then brought into flexion and the lateral femoral condyle is elevated to establish the required femoral rotation to achieve functional tone in the lateral soft tissue sleeve without the need to reference any bony landmarks. The knee is then run through a range of motion to verify the established tone and stability prior to positioning the femoral finishing block to complete the distal femoral resections. This technique *dynamically balances* the femoral and tibial implants with the supporting soft tissue structures to eliminate any guesswork during surgery and assure stability during post-operative gait.* According to Dr. Hedley, "since I have been using the Libra Dynamic Knee Balancer™ the guesswork in attaining accurate and, more importantly, consistent flexion balance has been eliminated. This is particularly so with valgus deformities, which in the past have required arbitrary additional external rotation of the femoral component. I am now able to do this accurately and specific to each case. The Libra has contributed greatly to my reproducibility."

Synvasive is currently selling the Libra Dynamic Knee Balancer for use with most primary knee systems. It is available in two models, one for true posterior referencing implant systems with a fixed lug location and another for use with implants where the lug position moves as the implant size grows. Future plans include expanding the function of the device to display relative pressure readings between compartments in addition to integrating the concept into a device to facilitate dynamic balance in revision knee arthroplasty.

Since its founding in 1990, Synvasive Technology, Inc. continues to develop a strong reputation of innovation with orthopaedic surgeons by providing operative solutions to enhance reconstructive surgery in the global orthopaedic marketplace. As a small medical device business, Synvasive is committed to providing lasting value to every surgeon, hospital and patient around the globe. In addition to the new Libra Dynamic Knee Balancer (patents pending), Synvasive currently supplies its patented ***STABLECUT***® large bone resection technology, in the form of oscillating saw blades, to orthopaedic surgeons and hospitals around the world. For information on *STABLECUT*® blades go to our new interactive web based environment at www.synvasive.com/eBladeShop.

** The Libra device should not be used if a complete soft tissue release has been performed to align a severely deformed knee. The ability to "tone" soft tissue structures in flexion will be adversely affected. In these procedures excessive opening will occur on the released side which could lead to excessive rotation of the femoral component by the Libra device. In these cases, the transepicondylar axis is the best reference for determining rotation of the femoral implant.*

Investigate the advantages the Libra Dynamic Knee Balancer™ and *STABLECUT*® can offer you in your next primary TKR at www.synvasive.com. For a first hand look, please visit the Synvasive booth, #3618 (Hall A), at the AAOS in Washington, D.C., February 23-25, 2005.

Reference:

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