Implantable Shock Absorber Provides Superior Pain Relief, Functional Improvement, and Return to Weight-Bearing Compared to High Tibial Osteotomy in Patients with Medial Knee Osteoarthritis: Two-Year Results

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INTRODUCTION:

Many patients with moderate medial compartment knee osteoarthritis (OA) are not candidates for arthroplasty because of age, activity level, or patient preference. A surgically implantable shock absorber (ISA) has been developed to provide pain relief without violating the joint space. During an outpatient procedure, the device is implanted subcutaneously in the medial extra-capsular space with screw fixation to the femur and tibia that allows early range of motion and immediate weight-bearing as tolerated. Patients treated with the ISA were evaluated for pain relief, functional improvement, return to weight-bearing, and safety compared to a high tibial osteotomy (HTO).

METHODS:

An IDE pivotal, multicenter clinical trial based in the US and Europe evaluated the ISA: 81 patients were enrolled and followed prospectively for safety and efficacy of the device. This group was compared to 81 patients who underwent HTO. The two groups had similar baseline characteristics for KL grade, BMI, symptom duration, age, opioid usage, and patient sex. Improvements in WOMAC pain and function, time to recovery, and safety event rates were compared between the ISA and HTO groups through two-year follow-up visits.

RESULTS:

ISA treatment resulted in superior improvements in pain and function compared to HTO. At 24 months, the ISA group reported WOMAC pain reduction of 76.0% from baseline, compared to 64.7% improvement in the HTO group (p=0.014). Similarly, the ISA group reported 73.9% improvement in WOMAC function at 24 months, compared to 58.8% improvement in the HTO group (p=0.011). ISA patients achieved partial weight-bearing at 3.8 days compared to 28.2 days in the HTO group (p<0.001). The trend was repeated for return to full weight-bearing, with ISA patients reporting 13.4 days compared to HTO patients reporting 58.0 days (p<0.001). Per the core lab, one ISA patient had a screw partially back out, but the device remained in situ and the patient maintained clinically meaningful pain and function improvement at two years. All (100%) of the ISA devices remained intact, with zero disassemblies. One ISA patient underwent conversion (to UKA), and one HTO patient underwent joint modifying surgery that was deemed a study endpoint failure. There was no significant difference between groups in terms of safety and reported serious adverse events, with the exception of the HTO group having a significantly higher number of patients complaining of pain (35.8%) as compared to the ISA group (4.9%), (p<0.001).

DISCUSSION AND CONCLUSION:

These two-year results demonstrate the implantable shock absorber has superior pain relieving and function improving capability compared to HTO. Given the advantages of immediate weight-bearing and outpatient insertion in the subcutaneous joint space, the ISA has potential to offer patients an attractive alternative to HTO or arthroplasty in treatment of moderate medial knee osteoarthritis.