An Implantable Shock Absorber (ISA) for Treatment of Patients with Medial Meniscal Posterior Root Tears (MMRoot) and Medial Knee Cartilage Degeneration

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INTRODUCTION: Medial meniscal posterior root tears (MMRoot) are strongly associated with elevated joint reactive force, associated progression of osteoarthritis (OA) and increased rates of arthroplasty. A subcutaneous implantable shock absorber (ISA) provides functional unloading to the medial compartment and is specifically designed to alleviate pain and improve function, in the setting of failed meniscal function.

METHODS:

Subjects with symptomatic medial knee OA were treated with an ISA device in this prospective open-label study. Subjects rated their pain and functional outcomes at baseline and through 24 months on the Knee Injury and Osteoarthritis Outcome Score (KOOS)-derived Western Ontario and McMaster Universities Arthritis Index (WOMAC) scale. Pre-implant MRIs were graded by independent radiologists (multiple graders with tiebreaker methodology) for the presence or absence of concurrent MMRoot. No concomitant or subsequent treatment of the MMRoot was performed in the study. Analysis compared clinical, safety, and device performance for the MMRoot vs. non-MMRoot groups. RESULTS:

Outcomes for nine MMRoot subjects were compared with those of 71 non-MMRoot subjects. Pain improved by 41.1 points (69.9%) in the MMRoot group vs. 47.1 points (76.7%) for the non-MMRoot group (p=0.3996), and the proportion of subjects with clinically meaningful improvements in pain was 78% and 97%, respectively. Function improved by 38.3 points (70.6%) and 45.7 points (74.6%), respectively (p=0.3359), and the proportion of subjects with clinically meaningful improvements in function was 78% and 93%, respectively. There were no differences between groups in the rates of device- or procedure-related serious adverse events. At two years, none of the subjects in the MMRoot group underwent conversion to arthroplasty, compared with 1.4% of subjects in the non-MMRoot group.

DISCUSSION AND CONCLUSION: ISA treatment in patients with cartilage degeneration and medial meniscal root tears resulted in clinically meaningful improvements in pain and function. Outcomes were not statistically different to subjects who did not have medial meniscal root tears. Further research is needed to confirm these promising findings for ISA treatment in subjects with meniscal root tears.