Customized, Individually Made Bi-compartmental Knee Replacement: A Prospective, Multicenter Study of Clinical Outcomes

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Summary from the BASK 2016 Presentation

Introduction
The purpose of this study was to assess the clinical and patient-reported outcomes of a customized, individually made (CIM) bi-compartmental knee replacement (BKR) prostheses.

Methods
A prospectively recruited cohort of 79 patients was implanted with a CIM-BKR at 8 centers. Patients were diagnosed with bi-compartmental osteoarthritis of the patello-femoral joint in addition to the medial or lateral compartment. Patients with compromised cruciate or collateral ligaments or having a varus/valgus deformity >15° were excluded. Patients were assessed for the 2011 KSS, KOOS & ROM pre-operatively (79 patients), at 2 weeks (77), 6 weeks (77), 12 weeks (76) and 1-year (58) post-operatively.

Results
Average patient age was 58 yrs (range: 45-76), average BMI was 31 (range: 18.8-44.7) and 61% of the enrolled patients were female. Post-operative analysis revealed that range of motion significantly improved to 130° at the 1 year post-operative time point from the 2 week postoperative time point (p<0.05) (figure 1). The objective KSS score significantly improved from 67 at the pre-operative visit to 93 at the 1 year post-operative time point (p<0.05) (figure 2). Similar improvements were observed for the KSS function and satisfaction domains. Beginning at the 6 week time-point, significant improvements from pre-operative levels were observed in the KOOS (figure 3). None of the patients included in the study required a blood transfusion.

Discussion
Previous studies on off-the-shelf (OTS) monolithic bi-compartmental knee replacements have reported higher than average revision rates and lower outcome scores. This has led to the withdrawal of monolithic OTS-BKR devices from the market. The data collected on the CIM-BKR compares favorably to published scores. CIM-BKR implants offer better function with higher ROM compared to previously published data on OTS total knee replacements. CIM BKR implants provide surgeons performing Uni+PFJ surgeries for bi-compartmental disease with a viable and patient-specific monolithic implant solution.