Outcomes after Customized Individually Made Total Knee Arthroplasty

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INTRODUCTION

Customized Individually Made (CIM) TKA implants with patient customized femoral components, customized tibial trays, and customized inserts are available as an alternative to traditional, off-the-shelf implants. Preliminary data obtained with this implant are encouraging.[1,2] Hence, the objective of this multicenter study was to prospectively analyze adverse events and outcomes scores on a larger series of patients implanted with a CIM TKA.

METHODS

At 9 centers across the United States a cohort of 252 patients have been prospectively recruited and implanted with a CIM TKA (iTotal CR, ConforMIS, Inc., Bedford, MA) to date. Institutional Review Board approval was obtained at all sites and all patients were consented prior to participating in the study. Consistent with the indications for cruciate retaining TKA, patients with compromised posterior cruciate or collateral ligaments or having a varus/valgus deformity >15° were excluded from the study. Patients were assessed for Range of Motion, the 2011 Knee Society Scoring (KSS), the Knee Injury and Osteoarthritis Outcome Score (KOOS) pre-operatively, at 2-weeks, 6-weeks, 6-months, and 1-year post-operatively. In addition, post-operative adverse events such as manipulations under anesthesia (MUA), transfusions and revision rates were tracked.

RESULTS

Average age of the patient population was 65 yrs (range: 40-84), while the average BMI was 30 (range: 19-41). 50% of the enrolled patients were female. Range of motion was improved from an average of 114° pre-operatively to 120° at 1 year post-op (110° at 6 wks, and 119° at 6 months). By the 6 week time-point, patients demonstrated significant changes from baseline scores across all 5 domains of the KOOS ($p<0.05$) and all 4 domains of the KSS ($p<0.05$), with continued improvement at the one year follow up visit (Figure 1 and 2). Post-operative analysis revealed 9 (3.57%) reported MUAs for stiffness or reduced range of motion. Four (1.58%) patients received transfusions post-surgery. There was 1 (0.4%) poly swap revision due to Reflex Sympathetic Dystrophy (RSD) Syndrome and 1 (0.4%) revision to PS TKA due to patient fall resulting in tibial fracture.

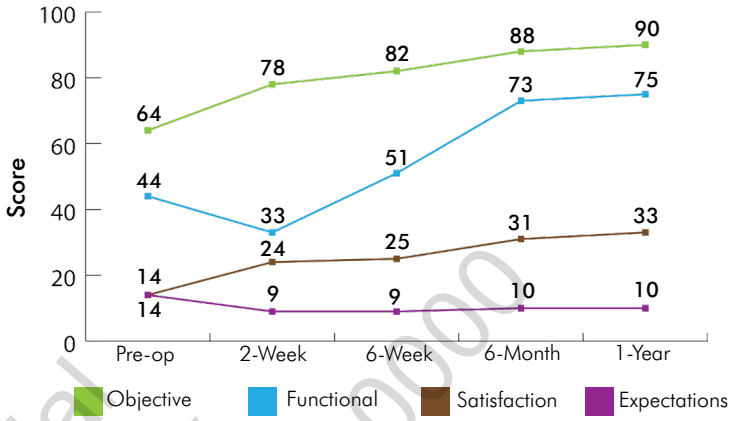

Figure 1: Results of KSS from pre-op through 1-year follow-up

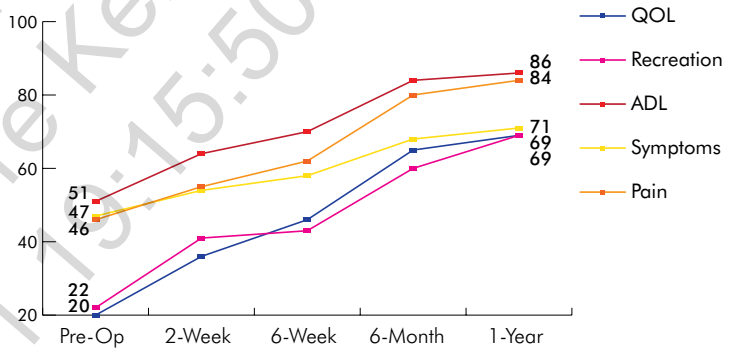

Figure 2: Results of KOOS from pre-op through 1-year follow-up

DISCUSSION

The 1-year follow up data collected on CIM TKA compares favorably to adverse event rates, as well as patient outcome scores, when compared to multicenter studies published on off-the-shelf implants. Manipulation rates are consistent with published studies of 4.6%[3]. Results from this study support previous findings that patients implanted with the CIM TKA experience significant improvements in outcome scores for the KSS, KOOS, and higher range of motion from baseline post-surgery. The CIM TKA also demonstrated an excellent safety profile, with a low transfusion rate (1.58%), low manipulation rate (3.57%) and a low mechanical revision rate (0.4%) observed.

References:

1. Kurtz, W; Sinha, R; Martin, G; Kimball, K; Early Outcomes Utilizing a First-Generation Patient-Specific TKA Implant: A Retrospective Review; British Association for Surgery of the Knee Annual Meeting; 2014
2. Katthagen, BD; Chatziandreou, I; Comparison of Hospital Metrics and Patient Reported Outcomes for Patients with Customized, Individually Made Vs. Conventional TKA; International Congress for Joint Replacement World Arthroplasty Congress; 2015
3. Rubinstein, RA; DeHaan, A; The Incidence and Results of Manipulation After Primary Total Knee Arthroplasty. The Knee; vol 17(1)pp29-31; 2010