Outcomes after Customized Individually Made Total Knee Arthroplasty

Tait, R[1]; Huber, B[2]; Kurtz, W[3]; Burkhardt, J[4]; Swanson, T[5]; Clyburn, T[6]

[1]Orthopedic Institute of Henderson, Nevada, USA; [2]Copley Hospital, Vermont, USA; [3]Tennessee Orthopaedic Alliance, Tennessee, USA; ; [4]Southern Michigan Orthopaedics, Michigan, USA; [5]Desert Orthopaedic Center, Nevada, USA; [6]Memorial Hermann Texas Medical Center, Texas, USA

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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. Data obtained in studies with this implant are encouraging.[1,2] Hence, the objective of this multicenter study was to prospectively analyze patient reported outcomes scores and adverse events on a larger series of patients implanted with a CIM TKA.

METHODS

At 9 centers across the United States a cohort of 360 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 Score (KSS), the Knee Injury and Osteoarthritis Outcome Score (KOOS) pre-operatively, at 6-weeks (348 patients), 6-months (296), 1-year (224), and 2 years (81) 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 66 yrs (range: 40-96), while the average BMI was 30 (range: 18.5-42). 56% of the enrolled patients were female. Range of motion was improved from an average of 115° pre-operatively to 123° at 2 years post-op (109° at 6 weeks, 120° at 6 months, and 122° at 1 year)(Figure 1). Patients demonstrated significant improvement from baseline scores across all 5 domains of the KOOS ($p<0.05$) and 3 out of 4 domains of the KSS (objective, function and satisfaction) ($p<0.05$) at 2 years. By analyzing the KSS satisfaction domain we determined that overall patient satisfaction with CIM implants at 1 year is high, at 92% (Figure 2) and 90% at 2 years. Post-operative analysis revealed 11 (3.1%) reported MUAs for stiffness or reduced range of motion. Five patients (1.45%) received transfusions post-surgery. There have been four (1.1%) poly-swap reoperations in patients who continue to be enrolled in the study, in addition to two (0.6%) complete revisions to OTS TKA to date (one due to traumatic fracture after patient fall, one due to nickel allergy).

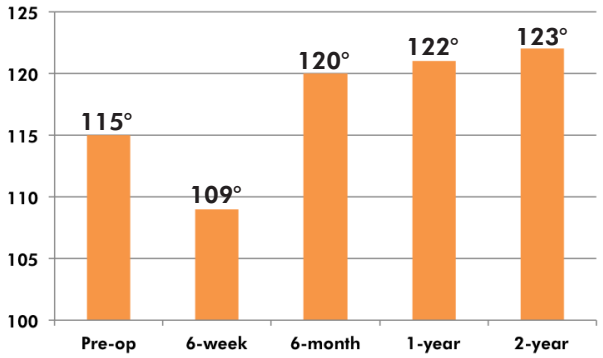

Figure 1: Average Range of Motion for patients at pre-operative and different post-operative time points.

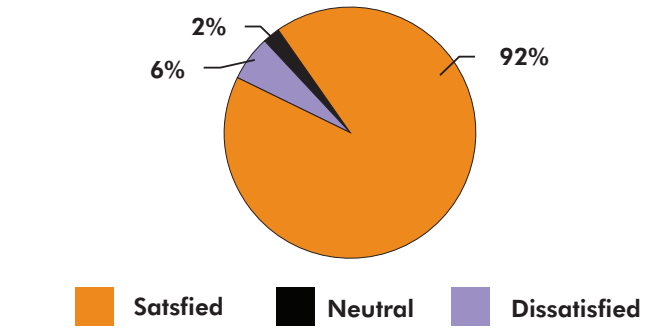

Figure 2: Overall patient satisfaction at 1 year

DISCUSSION

The 2-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. Patient satisfaction at one year is high, at 92% satisfied. 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. Manipulation rate of 3.1% for the CIM TKA are consistent with published studies that report MUA rates on total knee arthroplasty[3]. Patients in this study also demonstrated a low transfusion rate, complete revision rates and poly-swap rates.

References:

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