

Comparison of Hospital Metrics and Patient Reported Outcomes for Patients with Customized, Individually Made Vs. Conventional TKA

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INTRODUCTION

Traditionally, average patient morphology has been used as the basis for knee implant design. Recently, pre-operative CT scans have been used to design patient-specific posterior cruciate retaining total knee implants. These customized, individually made (CIM) implants have been shown to provide better alignment¹, implant fit² and in vivo kinematics^{3,4} than off-the-shelf (OTS), conventional TKA. The objective of this study was to compare intra-operative, post-operative and patient satisfaction parameters for patients implanted with CIM TKA (iTotal CR, ConforMIS, Inc., Bedford, MA) vs. OTS TKA (Triathlon, Stryker, Kalamazoo, MI).

METHODS

In this matched pair study, a consecutive series of the initial 35 CIM TKA performed at a single center by two surgeons between November 2012 and November 2013 were matched with 35 patients receiving an OTS TKA during the same interval based on age, gender and BMI. Intra-operative parameters including OR time, need for x-ray control (for sizing) and ligament releases were recorded. In-hospital parameters such as time to mobility and drop in hemoglobin were also collected for each patient. Patient reported outcomes (KOOS questionnaire) and patient satisfaction were collected from each patient at an average 1 year post-operatively.

RESULTS

Overall OR time was significantly lower by 16 mins ($p=0.028$) for the CIM TKA group when compared to the OTS TKA group. All CIM TKA surgeries were performed without x-ray control while the OTS TKA surgeries required x-ray control on every case, with 22.9% (8/35) of cases requiring implant adjustment during surgery ($p=0.005$). Ligament releases were required on 5.7% (2/35) of CIM TKA cases and 20% (7/35) of OTS TKA cases ($p=0.15$). Patients with CIM TKA were significantly quicker in return to activities of daily living by 1.7 days for walking (100m), 1.9 days for stair climbing and 2.4 days to achieve flexion to 90° ($p<0.001$ for each) (Figure 1). Drop in hemoglobin at 1 ($p<0.001$), 5 ($p=0.002$) and 10 ($p=0.03$) days post-op was significantly lower for patients with CIM TKA. Finally, when assessing patient outcomes at the 1 year post-op visit, patients with CIM TKA had a significantly higher ($p=0.037$) KOOS percentile (CIM 83.0 vs OTS 73.7) and patient satisfaction, with 94.3% of CIM patients satisfied vs. 74.2% in the OTS group ($p=0.04$) (Figure 2).

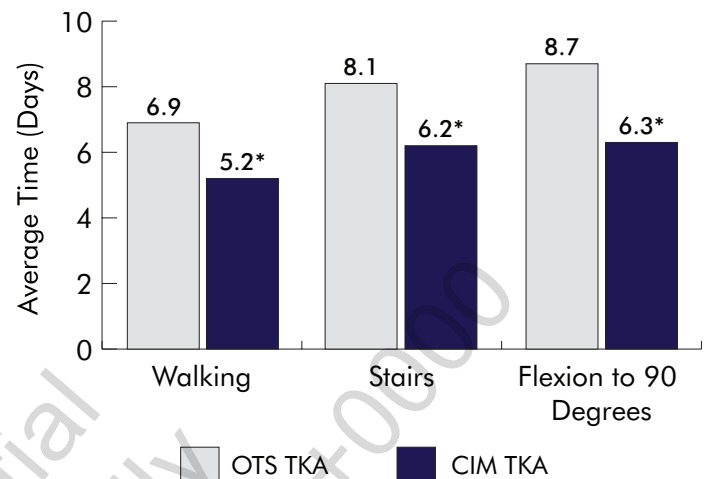


Figure 1: Comparison of post-operative functional outcomes between the OTS TKA and CIM TKA.

* indicates statistical significance.

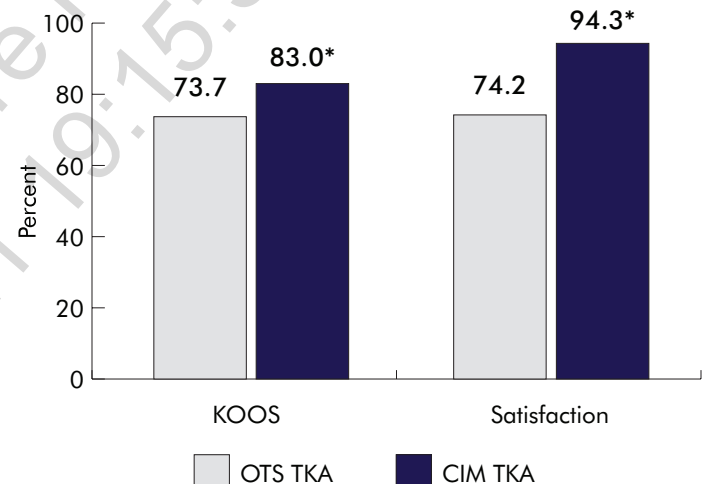


Figure 2: Comparison of key patient-reported outcomes between the OTS TKA and CIM TKA.

* indicates statistical significance.

DISCUSSION

This is the first study that prospectively compares intra-operative, post-operative and patient-reported outcomes between patients receiving CIM TKA or OTS TKA. Results indicate that the patient-specific nature of CIM TKA provides significant advantages during surgery by reducing OR time and by decreasing need for intra-operative re-adjustments. Since the CIM TKA is designed to cover all cut surfaces and removes less bone, CIM patients experienced a significantly reduced drop in hemoglobin levels when compared to their OTS counterparts. Furthermore, CIM TKA patients were able to return to ADLs faster than OTS TKA patients. KOOS scores and patient satisfaction at the 1-year follow-up visit were significantly higher in patients receiving a CIM TKA compared to patients receiving an OTS TKA.

1. Levensgood et al; Intraoperative Assessment of Mechanical Alignment Accuracy Using Computer Navigation in a Patient Specific TKA System; Proceedings of the 1st ICJR Pan Pacific Congress; July 2014; Kona, HI-USA
2. Martin et al; In-Vivo Tibial Fit Analysis of Patient-specific TKA System versus Off-the-shelf TKA; Proceedings of the 1st ICJR Pan Pacific Congress; July 2014; Kona, HI-USA
3. Kurtz et al; In Vivo Kinematics for Subjects Implanted With Either a Traditional or Personalized TKA; Proceedings of the 1st ICJR Pan Pacific Congress; July 2014; Kona, HI-USA
4. Cates et al; In Vivo Kinematics for Customized, Individually Made vs. Traditional TKA During a Deep Knee Bend and Rising From a Chair; Proceedings of the 1st ICJR Pan Pacific Congress; July 2014; Kona, HI-USA