Multicenter Analysis of Patient Outcomes and Functional Tests for Patients with Customized, Individually Made or Off-the-Shelf TKR

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INTRODUCTION

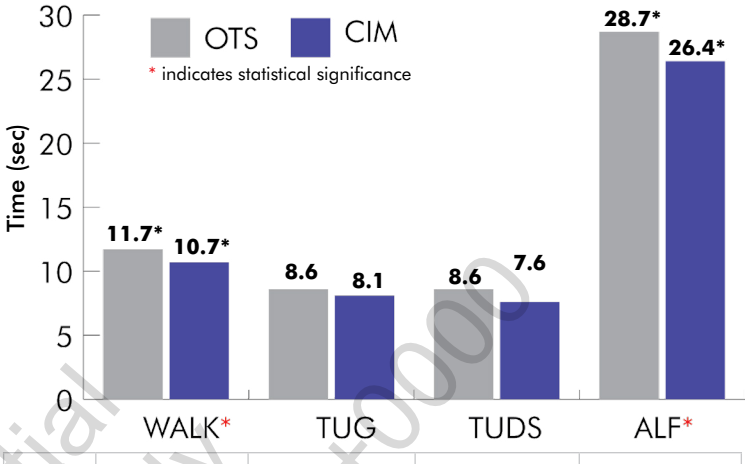
Knee implants have traditionally been designed using average patient morphology. However, customized total knee implants, which are designed based on individual patient anatomy using a preoperative CT scan, are now available. The objective of this study was to compare patient-reported outcomes and functional tests for patients implanted with these customized, individually-made (CIM) total knee replacement (TKR) implants to patients with the traditional, off-the-shelf (OTS) implants.

METHODS

This multicenter, prospective study consecutively enrolled 295 TKA patients at 7 centers. Each patient had previously undergone either a unilateral CIM-CR (iTotal CR, ConforMIS, Inc., Bedford, MA, 166 patients) or OTS-CR TKR (multiple brands, 129 patients). There were no significant differences between the two groups with regard to age, BMI, gender or side of implantation. Patients in the CIM TKR group were at a significantly earlier post-operative time-point compared to the OTS group (14 months vs 32 months; $p<0.001$). Testing was conducted by staff blinded to the type of TKR implanted in the patient. Each patient completed the 2011 New Knee Society Score (KSS) questionaire, performed a 8m Walk (WALK), Timed-Up-and-Go (TUG), and the Timed-Up-and-Down-Stairs (TUDS), normalized to 4 stairs.The Aggregated Locomotor Function (ALF) score was then calculated based on the addition of the average times of the three functional tests (ALF=WALK+TUG+TUDS). Comparisons were made between the CIM and OTS groups using a 2 sample t-test for the functional tests. Additionally, an odds ratio analytic was used to determine the unadjusted risk to have excellent/good or poor outcomes in the CIM and OTS TKR groups. This was calculated for the KSS objective domain and the discretionary activities in the KSS functional domain.

RESULTS

Analysis of the functional data showed that patients implanted with a CIM TKR exhibited faster times across all three functional activities analysed (Figure 1), with a significant difference in the WALK activity ($p=0.02$). Additionally, patients with CIM TKRs exhibited significantly faster ALF scores when compared patients implanted with OTS TKRs (26.4 seconds vs 28.7 seconds, $p=0.04$). Analysis of the objective KSS showed that patients with the CIM TKR were 1.7 times more likely to obtain an excellent or good outcome when compared to the OTS TKR patients. Also, OTS TKR patients were 2.6 times more likely to achieve a poor KSS objective score when compared to CIM TKR patients (Figure 2).



	WALK*	TUG	TUDS	ALF*
OTS st dev	4.64	3.00	5.25	11.26
CIM st dev	2.92	2.30	4.14	8.23

Figure 1: Comparison of functional tests.

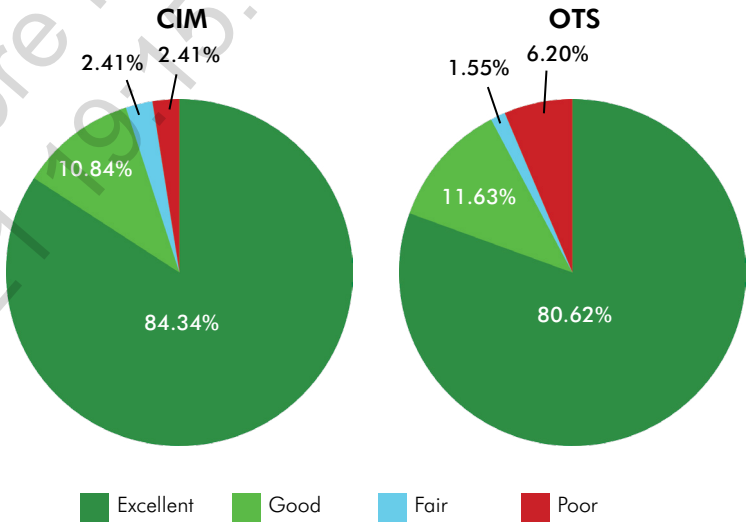


Figure 2: Comparison of Objective KSS between CIM and OTS

DISCUSSION

These results demonstrate several advantages to patients with CIM vs. OTS implants. CIM patients had a higher likelihood to perform high demand activities with no bother, though there were no differences between CIM and OTS patients for low demand activities. CIM patients were 1.7 times more likely to have an excellent or good objective KSS while OTS patients were 2.6 times more likely to have a poor objective KSS. Additionally, CIM patients performed ADLs significantly faster than OTS patients in blinded functional assessments. Especially considering the fact that patients in the CIM TKR group were significantly earlier post-op, we believe that the customized nature of the implant may provide better functional outcomes for patients implanted with a CIM TKR.

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