

Patient-Specific Knee Replacement Implants Preserve Bone and Decrease Blood Loss & Swelling

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INTRODUCTION

Total knee arthroplasty has been a very successful procedure with a strong clinical track record. The success rate for a revision knee procedure is, however, substantially lower than that of a primary knee replacement procedure. When the revision procedure takes place, the failed implant components are removed and some portion of the underlying bone is also removed to establish a new flat surface for the revision implant. The additional bone removal in the revision procedure means that the secondary implant installed needs to be thicker than the original implant in order to preserve the joint line, which is important for functional requirements.

Patient-specific cutting guides coupled with individualized femoral and tibial implants maximize bony coverage and have articulating surfaces that more closely approximate the subjects' natural anatomy. Individualized cuts using a 6 cut design also allows the implants to be thinner while distributing stresses.¹

We hypothesized that a patient-specific total knee implant system made to reproduce a patient's native articular geometry would preserve more native bone during a primary knee procedure as compared to a standard total knee and result in lower intraoperative trauma.

METHODS

This study compares two groups of total knee replacement (TKR) patients performed by a single surgeon: traditional total knees using off-the-shelf implants (Zimmer® NexGen®) and a commercially available customized total knee system with patient-specific instruments (ConforMIS® iTotal®). This IRB approved prospective cohort study enrolled 66 traditional TKR (60 patients) and 66 custom TKR (54 patients). Intra-operatively, the thickness of the femoral (distal and posterior medial/lateral), and tibial (medial/lateral) resections, were measured using the methods described by Hodge². The thickness of the femoral and tibial implants were measured via direct measurement.

Additionally, the frequency of soft tissue releases, transfusions, changes in hematocrit (HCT) levels, length of hospital stay, and knee girth on postop day 2 were noted to assess the impact of the procedure on clinical metrics typically associated with recovery. Finally, the patient's outcomes were evaluated postoperatively using the New Knee Society Score (KSS)³ and coronal alignment on long leg radiographs.

RESULTS

The results of the bone resection measurements are tabulated in **Table 1**. In this study, the average total of all bone resection measurements for patient-specific knees was 27% (14mm) less than for traditional, off-the-shelf total knees (p<0.001). In particular, resections on the medial posterior femur (32.8%) and lateral posterior femur (31.3%) and on the medial tibia (53.8%) showed the greatest differences between the two groups. Additionally, the total thickness of the patient-specific implants was 25% (15.7mm) thinner on average than the traditional total knee replacements (p<0.001).

The patient-specific TKRs also required fewer soft tissue releases (p = 0.046) than a standard, off-the-shelf knee. Patient-specific knee replacement patients also had less swelling on postoperative day 2 (p = 0.2) and a smaller average change in HCT (6.8 for customized TKR and 9.6 for traditional, p<0.001). While none of the customized TKR patients required blood transfusions, 4 (6%) of the off-the-shelf TKR patients required transfusions (5 units). (See **Table 2**).

The Functional Knee Society Score was 72 for the customized TKR and 64 for the off-the-shelf TKR (p = 0.16). Functional KSS and swelling were improved with the patient-specific TKR, but did not meet clinical significance at this interim study point. Length of stay was on average shorter for customized knee patients (2.66 days) versus off-the-shelf knee patients (3.04 days, p = 0.064).

Coronal alignment, as measured on post-operative hip knee ankle films, was similar for both knee replacement groups.

Table 1: Bone Resection Measurements

	Femoral Thickness				Tibial Thickness		Total Thickness
	Distal Thickness		Posterior Thickness		Medial Tibia	Lateral Tibia	Total of All Measurements
	Medial Femur	Lateral Femur	Medial Femur	Lateral Femur			
Patient-Specific	6.04mm	6.45mm	7.21mm	5.93mm	2.95mm	7.72mm	36.30
Off-the-Shelf	7.71mm	7.52mm	10.73mm	8.62mm	6.39mm	9.20mm	50.17
% Difference	21.6%	14.2%	32.8%	31.3%	53.8%	16.1%	27.6%
p-value	<0.001	0.013	<0.001	<0.001	<0.001	0.069	<0.001

Table 2: Blood Loss

	Off-the-Shelf	Patient-Specific	p-value
Preoperative HCT	40.1	40.5	0.43
Post-op Day 2 HCT	30.43	33.84	0.0001
Change in HCT			
All Knees	9.64	6.78	<0.001
Unilateral Knees	8.54	6.25	<0.001
Bilateral Knees	13.95	9.12	0.009
# of transfusions	4 (5 units)	0	

CONCLUSION

New technology has made it possible to produce patient-specific TKR implants that approximate the native geometry of an individual patient. The customization process enables femoral components that are thinner, implants that fit each anatomy, and better replicate the native condylar shape and joint line of the patient.

In this study, patient-specific TKRs preserve more bone, require fewer soft tissue releases and cause less blood loss than traditional TKRs. Achieving similar coronal alignment with fewer soft tissue releases also suggests that an implant that reproduces the condylar geometry is more easily balanced than a standardized, off-the-shelf knee.

Patient-specific knee replacement patients also had less swelling on postoperative day 2 (p = 0.2) and a smaller decrease in the POD#2 HCT. The differences in blood loss and swelling may be explained by the lack of femoral canal penetration and the ability to completely cover all cut bone surfaces in the customized TKR group.

In this study, patient-specific TKR patients maintained more bone stock and had post-operative clinical metrics consistent with lower intraoperative trauma than patients with off-the-shelf TKRs.

References

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