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Does Implant Design Affect Hospital Metrics and Patient Outcomes? TKA Utilizing a "Fast-Track" Protocol

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Abstract

Background: "Fast-Track" protocols have been introduced in TKA with the intention to increase health care savings while maintaining or improving patient outcomes. The influence of the implant design in a "Fast-Track" setting has not been described yet. The primary goal of this study was to compare a customized implant with standard off-the-shelf (OTS) devices when utilizing a "Fast-Track" protocol

Methods: Sixty-two (62) patients were prospectively enrolled at a single center and implanted with either a customized or a standard off-the-shelf implant resulting in thirty (30) patients being treated with an OTS design and thirty-two (32) with the customized design. The same institutional fast-track protocol was utilized on all patients and included pre-, intra-, and postoperative medical treatment. We assessed total length of stay (LOS), discharge destination and range of motion at 6-8 weeks post-op and at an average of 16 months post-op follow-up to compare the OTS implant with the customized device. Implant survivorship was assessed at a minimum of 25 months post-op.

Results: Using the fast track protocol we were able to decrease overall LOS to 2.1 days versus 3.6 days prior to introduction of the protocol. The use of the customized implant further reduced LOS significantly to 1.6 days. Significantly higher number of patients who got implanted with the customized device (66%) were discharged within 24 hours than in the OTS group (30%). Patients treated with the customized implant were found to be discharged home more often than patients treated with the OTS implants (97% vs. 80%) and achieved higher range of motion both at 6-8 weeks (114° vs. 101°) and at an average of 16 months (122° vs. 114°) than patients who got treated with the OTS device. At an average follow-up of 28 months, there was 1 implant revision in the customized group (due to tibial fracture resulting from patient fall). For the OTS group there was 1 implant revision (late infection) and 1 poly swap (due to instability).

Discussion: Based on our analysis we observed a positive influence of the customized device on patient outcomes and hospital metrics and we therefore conclude that the implant choice is an important factor for TKA in a "fast-track" setting.

Background

In the current health care environment there is an increased focus on health care savings while maintaining or improving patient outcomes. This has become an important factor for patients undergoing total knee arthroplasty (TKA) with practicing physicians constantly aiming to increase the efficiency and cost effectiveness of the proce-

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dure. One methodology to decrease patient's length of stay (LOS) is to incorporate a fast track protocol and thereby reducing per patient burden on the hospital. "Fast-track" has been defined as a hospitalization which provides best possible evidence-based treatment, using fewer clinical resources within a hospital stay while maintaining high patient satisfaction and few complications [1]. Success criteria have been described as reduction of perioperative morbidity, optimized pain management, shorter convalescence, a reduction in postoperative length of stay and a rapid functional recovery due to early mobilization [1-3].

Previous studies examining clinical outcomes following a fast track protocol have shown that changing patient care has its benefits and drawbacks. They have investigated various factors such as the type of anesthesia, postoperative rehabilitation and optimized pain relief that can influence faster discharge while maintaining optimum patient care [4-6]. Preoperative anemia in fast-track TKA however has been seen to be associated with an increased risk of patients receiving transfusion during admission, increased risk of readmission within 90 days from the procedure and increased risk of LOS of more than 5 days [7].

To our knowledge, the effect of an implant design on overcoming these challenges has not been examined. Customized implants, designed to provide optimal fit by replicating patient individual knee geometry, and particularly, restoration of the patient's femoral condylar anatomy, have been introduced to the market with the goal to achieve better patient outcome, faster recovery and mobilization post-surgery and therefore reducing the time of hospitalization.

Hence the purpose of our study was to compare standard off-the-shelf implants with a customized TKA design in a well-defined "Fast-Track" setting to determine, if implant design has any significant influence on hospital metrics or patient outcomes.

Methods

In this single-center case series sixty-two (62) patients were prospectively enrolled and were implanted with one of two implant systems. All surgeries were performed by the same surgeon. All patients consented for their data to be used for research purposes. Patients were given the option to choose between the customized and a standard off-the-shelf (OTS) implant based on the preference for timing of the surgery. Patients who preferred their procedure to be on the next possible date were treated with the OTS implant and patients who were willing to wait 6 weeks, the timespan needed for the implant manufacturing process, with the customized design.

This resulted in thirty (30) patients being treated with an OTS (53% female) (Columbus® Total Knee System, B Braun Melsungen AG, Hessen, Germany; Vanguard® Knee System, Zimmer Biomet, Warsaw, Indiana) and thirty-two (32) with the customized implant (41% female) (iTotal®G2, Cruciate Retaining TKA, ConforMIS, Inc., Billerica, MA). Regardless of component brand, all patients in both groups received a cruciate retaining TKA level of constraint. Patient demographics in terms of age at the time of surgery (57.2yrs OTS and 57.3yrs Customized; p=0.969), BMI (31.0 OTS and 33.4 Customized; p=0.116) and 17 tracked comorbid conditions (e.g. Diabetes, coronary artery disease, hypertension etc.) were collected preoperatively to ensure patients of both groups were comparable. No statically significant difference could be seen in the observation (Tables 1 and 2). During hospitalization the same institutional fast track protocol was utilized on all patients included in this study. As such it involved preoperative medical treatment with Hibiclens® (Mölnlycke, Norcross, Georgia, USA) daily for three days and Bactro-

Table 1. Patient demographics

	OTS	Customized	p-value
Number of Patients	30	32	
Gender (% Female)	53%	41%	0.45
Body Mass Index (BMI)	31.0 (22-38)	33.4 (24-53)	0.116
Age at Surgery (Years)	57.2 (34-67)	57.3 (42-72)	0.969

Table 2. Patients comorbidities. Seventeen comorbidities were tracked pre-operatively but no significant differences were seen between the two groups

	OTS	Customized	p-value
Diabetic	5	6	>0.05
CAD	0	2	>0.05
HTN	13	16	>0.05
RA	2	2	>0.05
Smoker	5	6	>0.05
Contracture	2 < 100	3 < 100	>0.05

Table 3. Medication flow chart of the fast-track protocol

One Week Before Surgery	At Surgery	Hospital / Home
Celebrex 200Mg	Marcaine	
5 Minutes Before	Celebrex 200Mg	
Cymbalta 60Mg	Exparel 20Cc W/ 100CC of Saline	Norco 10/325 Prn
Norco T Prn	Spinal	Morphine/Dilaudid
	Lovenox	Cymbalta 60Mg
		Aspirin 325

ban® nasal ointment (GlaxoSmithKlein, Brentford, London, UK) starting 48 hours prior surgery to remove potentially pathogenic bacteria from the nasopharyngeal region as well as patients ceasing all anticoagulants 5 days prior to the procedure. All study participants underwent an educational review consisting of a preparation course, a CD and a pamphlet to inform about the operational flow, possible complications and evaluating and setting patient's expectations. A standard set of medications (Table 3) was given to all subjects participating in this study pre-, at and post-surgery. Post-operatively all patients were mobilized within 3 hours and were treated with CPM or Active Ice® 3.0 (Polar Products, Inc., Stow, OH, USA) if needed. As for criteria of discharge, patients had to be able to walk over 100 feet, get out of bed independently and needed to have at least 60° of flexion. Both, discharge criteria and the time of discharge was determined by physical therapist and hospitalist, independent of the surgeon.

During the data collection we assessed patient's time of discharge, the total length of stay in the hospital (LOS) as well as their discharge destination. Patient's range of motion (ROM) and the need for walking aids were examined at their 6-8 week post-op visit and at an average of 16 months post-op. All adverse events including manipulation under anesthesia (MUA) and revisions were followed up to a minimum of 25 months post-op (average 28 months).

Statistical analysis was performed in Minitab 17.1 (MiniTab Inc, PA-USA). All data was included for the analysis. Continuous variables were tested for normality prior to statistical comparisons. Variables with a normal distribution were compared using 2 tailed t-test assuming unequal variances. Non-normal variables were tested using Mann-Whitney test. Categorical variables were compared between the customized and OTS outcomes using frequency counts. Significance was determined using a Fisher Exact Test. A p value of 0.05 was used to determine a significant difference between the customized group and OTS group outcomes.

Results

Overall, when utilizing the "Fast Track" protocol, LOS was decreased to 2.1 days versus 3.6 days, which was the average LOS after TKA for patients in our institution that did not undergo the fast track protocol.

The data analysis revealed that the average length of stay using standard OTS implant designs was found to be 2.7 days (range, 1-6 days) and 1.6 days (range, 1-6 days) when the customized TKA got implanted. This difference was found to be of statistical significance (p=0.004). Although the LOS range was seen to be the same, there was one patient in the customized group who was hospitalized for 6 days compared to 6 patients who received the OTS TKA.

We observed that significantly more patients treated with the customized implant were discharged from the

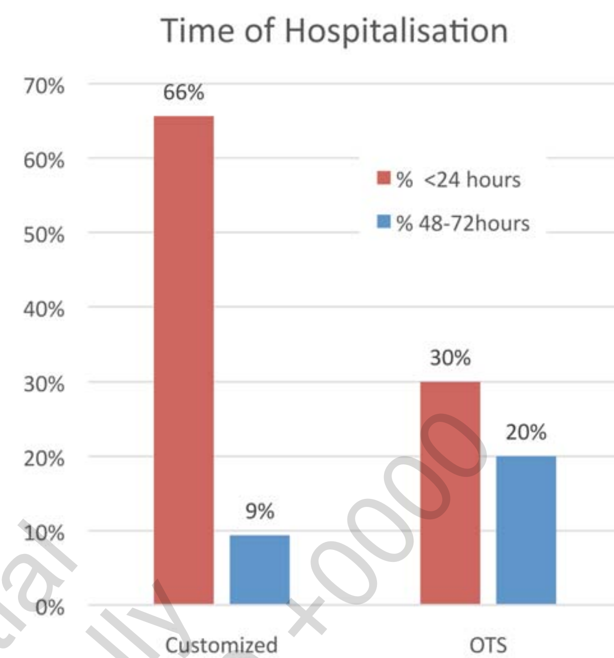

Figure 1. Comparison of patient's time of hospitalisation between the customized and the OTS implants

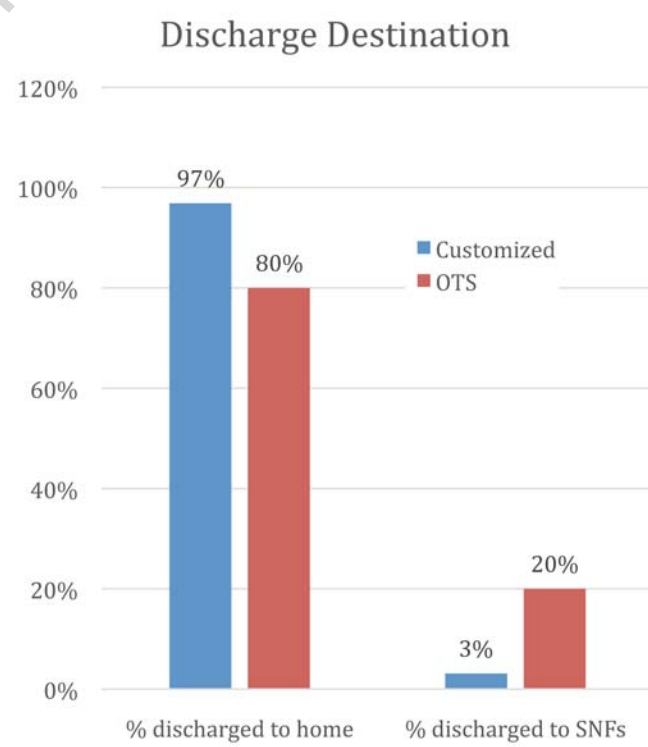

Figure 2. Destination of discharge after the time of hospitalisation

hospital within 24 hours post-surgery (66%) compared to patients from the OTS TKA group (30%) (Figure 1) (p=0.006). When assessing patients discharge destination a significantly higher proportion of patients discharged home was seen in the customized group (97%) compared to the OTS group (80%) (Figure 2) (p=0.05).

At the 6-8 week follow-up time point significantly less patients with a customized implant needed a walking aid (13%) compared to patients with an off-the-shelf implant (60%)(p=0.02). During that time period we found a difference in range of motion between both groups with patients who got an OTS TKA implanted (101°) experiencing 13% less ROM on average than patients with the patient specific implant (114°)(Figure 3).

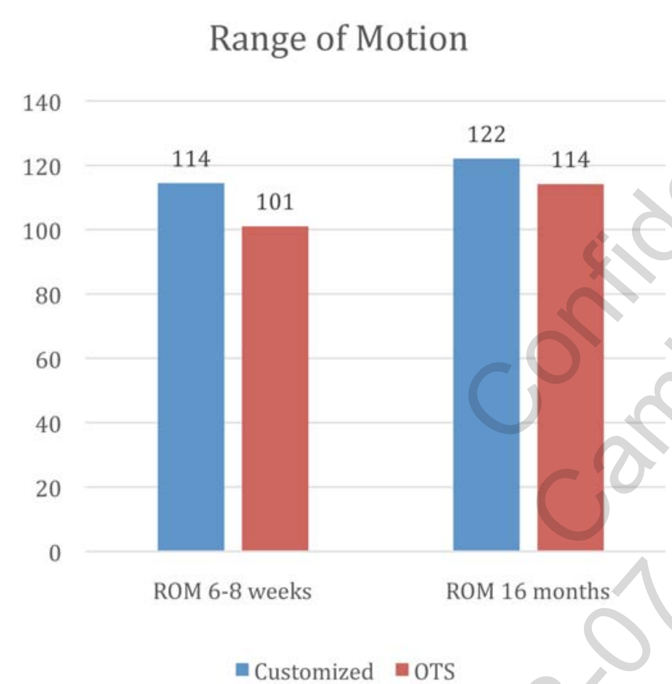

Figure 3. Patient's range of motion post-surgery

Range of motion at an average of 16-month follow-up continued to be significantly higher among patients with the customized TKA (122° vs. 114° p<0.001). Additionally, a significantly higher proportion of patients with the customized TKA than patients with the standard TKA were found to have a ROM of ≥120° at the final time of follow-up (84% vs. 45%; p=0.003). None of the patient with the customized implant showed a ROM of <100° compared to 13% of patients with the OTS implant at the time of the final follow-up (Table 4). This was shown to be of statistical significance (p=0.046).

Table 4. Patient's ROM at an average of 16 months.

	OTS	Customized	P-value
ROM ≥ 120 degrees (%)	45%	84%	0.003
ROM < 100 degrees (%)	14%	0%	0.046

For adverse event reporting the average follow-up of the cohort was 28 months. Post-operatively there were two manipulations under anesthesia in the customized group and one among the OTS patients (p=0.99). There were no returns or re-admissions to hospital in a 60-day period. One patient in the customized group underwent a revision procedure at 30 months post op due to a fractured tibia resulting from a fall that loosened the tibial baseplate. In the OTS group there was 1 patient who developed a late infection at 2.5 years and had to be revised. In addition, one patient in the OTS group underwent a poly swap procedure to correct instability.

Discussion

Fast-track surgery has been implemented to improve surgical management by improving perioperative care and decreasing postoperative complications and therefore shorten the time of full recovery and reduce the need for hospitalization and convalescence. The "Fast-Track"-program has been introduced by Kehlet et al and been developed and applied to clinical practice over the last 15 years [8,9]. With the purpose of enhancing the cost-effectiveness and general efficiency of health care, multiple factors during patient's time of hospitalization and their impact on patient's recovery have been analyzed. Optimized pain management, transfusion strategy, rehabilitation and physiotherapy, patient's information, fluid management and anaesthetic technique has led to a LOS of 1-2 days after TKA and better patient post-operative outcomes [4,6,10,11]

To our knowledge the potential influence of the implant design on peri- and post-operative outcomes after TKA in a fast-track setting has not yet been described. We believe this is the first study to compare the effect of the knee implant design on length of stay and hospital metrics in a defined fast-track program. Our study was not without limitations which have to be taken into consideration when interpreting the results. This study was carried out prospectively with patients selecting the implant design. Including blind randomization of the patient / component matching may have eliminated potential selection bias between the two study groups. Therefore we had little influence on the composition of the study cohorts which might have led to inequalities between the study groups. However, since patient demographics and comorbid conditions were similar and no statistically significant difference was detected between the two groups we consider our result to be valid. With a total of 62 patients participated in this study our patient cohort was relatively small. Nevertheless, the differences seen between the groups were large enough to be of significance and we believe they would be similar for a larger study population. We suggest that further research with a larger study population should be undertaken in the future. For this study all TKAs were performed by a single surgeon who is experienced with all devices used. Experience and a high expertise in performing TKA has been shown to result in better outcomes and additional studies at different sites should be conducted to verify if the implant design does have an impact on a faster discharge. Lastly, fast track surgery can be implemented in multiple ways with the same guidelines but different protocols. Our results only reflect the fast-track protocol we utilized in this study. As there is no single definition of the "fast track protocol" in literature we propound that our protocol should be used in future research in order to validate our findings.

Overall, we observed a reduction in length of stay of 0.4 days after implementing the fast track protocol (3.1 days to 2.7 days). However, when using the customized implant, the average length of stay was reduced by a further 1.1 days. Culler et al compared LOS after TKA of patients treated with a customized implant and patients treated with an OTS design and noticed a tendency of reduced LOS in the customized group. Additionally, they found that a significantly greater proportion of patients in the customized study arm were being discharged from their TKA hospitalization in <3 days (<72 hours from admission to discharge) than in the OTS arm [12]. We can therefore agree with and support their findings that patients treated with the customized implant experience shorter LOS than patients with the OTS design.

In a study to evaluate whether there is a significant difference in surgical time, intraoperative blood loss, postoperative range of motion and length of stay between customized and OTS TKA Schwarzkopf et al observed a decreased range of motion with customized compared to off-the-shelf implants [13]. When assessing postoperative ROM, we had different findings. Patients with the customized implant design showed significantly better results both, at 6-8 weeks after surgery and at an average of 16 months post-op, than patients treated with the OTS implant. As having more than 60° of flexion was a discharge criterion in our study we believe that providing better results in ROM early after surgery could be one reason for higher ROM of customized patients.

The number of patients being discharged to a rehab facility (SNFs) was significantly higher in the OTS study group than among the customized patients. Additionally, more patients in the customized group went home after their time of hospitalization than patients in the OTS group. Reasons for a discharge to rehab care facilities have been examined in previous research and found to be correlated to patient's demographics and characteristics e.g. comorbid conditions [14-16]. As we observed no significant difference in those metrics between our study arms, we assume that the difference in the implant plays a crucial role in patient's post-surgical recovery and therefore in their discharge destination.

In the light of the Comprehensive Care for Joint Replacement (CJR) program, bundled payments will be paid for TKA procedures based on multiple variables in order to improve healthcare costs and treatment efficiency. Previously published studies have revealed great cost variations for different discharge settings and potential savings due to shortened length of stay [17-19]. Utilizing discharge costs analysis as published by Ramos et al we observed a potential average cost reduction when using the customized implant for less patients being discharge to inpatient rehab facilities of $1,100 per patient. Furthermore, our results would potentially save hospitals $1,100 per patients on average from a shortened average length of stay of 1.1 days (LOS of 2.7 days in OTS group and 1.6 days in the customized group). In summary, based on our findings healthcare costs could be potentially cut by approximately $2200 by using the customized compared to OTS implants.

We believe that the customized implant has a positive influence on patient outcomes in a "Fast Track" setting and surgeons and hospitals should consider implant choice as an important factor in fast-track TKA surgery.

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AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.