RESEARCH ARTICLE

The Use of Customized Total Knee Arthroplasty Implants to Increase Efficiency in the Operating Room and Improve Patient Outcomes

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Abstract

Operating room efficiency during surgical procedures saves time and money, reduces waste of hospital resources and improves staff morale. Surgical efficiency in orthopaedic surgery can decrease medical complications, such as periprosthetic infection and venous thromboembolic disease, but also must be associated with equivalent or improved longer term patient reported outcomes. In total knee arthroplasty, the instruments used for bone preparation are excessive in number, are frequently redundant, and rely upon achieving average alignment and rotational parameters. As a result, approximately 15-25% of patients report dissatisfaction with their knee reconstructions. Patient specific customized instruments and patient specific implants improve intraoperative efficiency by reducing surgical steps and eliminating redundant steps. Further, because the customized instruments and implants provide anatomic reconstruction of each individual patient, patient reported outcomes have been higher. Additional demonstrated benefits include improved knee alignment and knee kinematics. This paper addresses the various sources of operating room inefficiency, provides suggestions to overcome them, and discusses the first decade of experience with the customized guides for customized implants as a method to improve efficiency.

Keywords: operating room; operating room efficiency; patient specific implants; patient specific instruments; total knee arthroplasty; patient outcomes

1. Introduction

The primary goal of increased efficiency during total knee arthroplasty (TKA) is reduced surgical time. After over five decades of experience in TKA, reduced operating room (OR) time has been shown to decrease: the risk of thromboembolic disease[1], the risk of infection[2], surgical blood loss[3], implant revision rates[4], and cost[5]. In addition, non-patient benefits included the ability to increase the number of surgical cases[5], and create more free time for surgeons[5]. The latter two can also be significantly affected by decreased turnover time between cases. A secondary goal of improved efficiency is reduced cost. This paper will discuss areas of inefficiency during the operative event, and how customized implants and patient specific instruments have been implemented to enhance efficiency of TKA and lower overall cost to the healthcare system.

2. Sources of Inefficiency during Tka

2.1. Perioperative

Prior to any operation, instrument preparation is required. For TKA, current implant systems require 5-7 trays of instruments such as resection guides and trial implants. However, only a small percentage of instruments are actually used. Nevertheless, every single instrument has to be repeatedly cleaned and sterilized in between every case. The cost to re-process a tray has been estimated to be between 75-120 dollars[6]. So for 7 trays, that equates to 525 to 840 dollars per case. Of course, this is a hidden cost that very few hospitals have the ability to measure accurately. Regardless, the instruments don't clean and sterilize themselves, and so this "hidden" cost is very real. Similarly, sterilized trays often become contaminated after processing and prior to use, thus requiring repeat processing, adding further hidden cost.

2.2. Intraoperative

Several sources of inefficiency exist during surgery. Even though most instruments in the trays will never be used, staff time is required to arrange the instruments anticipated to be needed so that they are handy (Figure 1). To find these tools, the scrub staff must sort through the unnecessary instruments. Usually, the implant trays are organized for weight efficiency, rather than for surgical expediency, thereby increasing the time and effort to organize the instruments. When an unexpected tool is needed, the scrub nurse must first locate the proper tray, and then isolate the proper instrument. This increases their work and leads to unnecessary delays and costs. For example, in one hospital in which the author works, 363 instruments are opened for every TKA case, when fewer than 50 are routinely used. To compound the ludicrousness of this approach, one retractor in the set has not been used in 28 years; yet it has been made available for every surgery, "just in case."

Figure 1. Photograph of the back table showing the limited number of instruments needed for a customized TKA.

Another source of inefficiency is surgeon and scrub staff unfamiliarity with a particular implant system, which can occur when surgeons use many different implant systems, or frequently change systems. Similarly, if scrub staff are expected to cover orthopaedic, general surgery, obstetric and neurosurgical procedures, they can never become truly proficient in any one area. The same is true when "orthopaedic" scrub staff are expected to cover hip, spine, shoulder and knee replacement cases, all of which have considerably different instrumentation and anatomy. It is amazing that health systems recognize that highly educated and trained physicians practice in only one surgical specialty, yet they expect scrub technicians and nurses, with less education and training, to be expert in multiple specialties.

Lastly, the surgeon is not free from scrutiny as it pertains to efficiency. When a surgeon shows up late for the start of a case, in addition to the unnecessary delay, the tone is set for the rest of the staff that a lackadaisical attitude is acceptable. Frequently, surgeons will use highly variable surgical approaches and techniques from case to case. This confuses the staff, making it difficult for them to predict which instruments will be needed. Another common mistake is for surgeons not to have a plan B, or if needed a plan C, in mind. Thus, when something unexpected happens, surgery must be halted; the surgeon determines a new course; and then the staff scramble to find new instrument sets to follow that course. All surgeons have experienced the situation where the needed instruments aren't sterile or are completely unavailable in the hospital. Detailed approaches to improve surgeon planning are beyond the scope of this paper. Nevertheless, the importance of preoperative planning and preparation, even for seemingly routine cases, should not be underestimated.

3. Strategies to Improve Efficiency

3.1. Streamline Instrument Sets

A simple approach to reduce the number of unutilized instruments in the OR is to streamline the sets.

i. Narrow usage down to one or two implant systems for the majority of cases.
ii. Write down in detail the steps of how to do a TKA. Eliminate redundant or repetitive steps. An example is depicted in Table 1.
iii. Determine which non-implant specific instruments will be used, e.g. retractors, power instruments, forceps, etc.
iv. Create a dedicated TKA set of instruments for TKA cases. This may require your hospital to purchase some new instruments, if not already in the hospital not being used.
v. Rearrange implant trays with the instruments arranged in sequence of use during the operation. One approach I used was to laminate this list so that it could be sterilized and placed on the back table for easy reference.

Table 1. Steps Utilized for Performance of Customized Total Knee Arthroplasty

SURGEON	1st Asst	2nd Asst
Exsanguinate	Hold leg	
Leg in Leg holder		
Flex to 30 degrees		
Incision	One rake distal	Two rakes proximal
Elevate medial skin flap		
Elevate lateral skin flap		
Bovie to incise capsule and VMO	Suction fluid	
Kocher to capsule flap	Suction smoke	Hold Kocher
Excise synovium		Remove Kocher
Extend knee	Hold one rake	Opposite rake
Forceps and bovie to elevate medial tibial soft tissue	Suction smoke	
½' curved osteotome & bovie		
Bovie to prepat fat pad		
Place Army Navy	Hold Army-Navy	
Excise fat pad		
Tilt patella to 90 degrees		
Place two towel clips	Hold towel clips	Rake to medial skin
Forceps and bovie to clean up fat		
Caliper to measure patella		
Saw to cut patella	Remove bone	

Remeasure with caliper		
Adjust with saw		
Measure Size		
Patellar drill guide and drill		
Patellar trial and measure		
Re-adjust if needed		
Fork to lateral femur	Suction	Hold rake to medial muscle
Forceps and bovie to excise fat pad		Rotate fork laterally
Flex knee to 60 degrees		Rake to medial skin
½" curved osteotome/mallet	Rongeur bone	
Kocher/Knife excise ACL/PCL		
Curette cartilage		
Apply F2-3 Guide	Place 3 pins	
Saw to cut femoral condyles	Kocher	
Remove pins	Remove distal cutter	Remove fork
Apply F4 guide		
Secure with 3 pins		
Drill Femoral lug holes		
Make anterior, posterior anterior Chamfer cuts	Kocher	
Remove pins	Remove F4 guide	
Apply F5 Guide	Hold F5 guide	
Make posterior cuts	Remove F5 guide	
Blunt Hohman	Medial retractor	Fork
Kocher/bovie to remove menisci	Suction smoke	
Apply T1 guide		
Place 3 pins		
Saw to make tibial cut		
Remove pins	Remove tibial cutter	
Finish cut with saw		
Kocher and bovie		
Adjust retractors		
Tibial block and rod		
Check extension gap		
Small rongeur		
Lamina spreader	Rake Spreader	Hold lamina
Kocher & bovie	Suction smoke	
½" curved osteotome		
Angled curette		
Kocher		
Flip lamina spreader	Flip rake	Hold Lamina spreader
Kocher & bovie		
½" curved osteotome		
Angled curette		
Kocher		

Injection	Remove rake	Remove lamina Spreader
Place femoral trial		
Place tibial trial		
Check ROM		
Adjust spacer thickness if needed		
Mark rotation		
Place retractors	Hold retractor	Hold retractors
Place T3 guide	Mallet	
Drill central hole		
Impact keel punch	Remove pins	
Prepare Mayo for cementing	Pulse evac	Suction
Flex knee		
Posterior blunt Hohmann		Hold hohmann
Fork laterally		Hold fork
Sharp hohmann medially	Hold sharp hohmann	
Remove debris		
Cement to tibia		
Place Tibial component		
Mallet & impactor		
Remove excess cement	Remove excess cement	Remove retractors
Fork laterally	Rake medially	Hold fork
Army Navy anterior		Hold army-navy
Cement blob		
Femoral component		
Mallet and impactor		
Remove excess cement	Remove excess cement	remove retractors
Sharp hohmann laterally	Hold sharp	hohmann
Blunt hohmann posterior		Hold blunt
	hohmann	
Place Tibial insert		
Reduce knee	Loosen IMP	Remove retractors
Leg in extension on bump	Hold tibia	
Clean patella		
Cement patellar button	Patella clamp	
Clean excess cement		
Patellar chamfer	Pulse evac	
Check for debris		
Suture	Suture scissors	Rakes proximally

3.2. Custom Cutting Blocks

A recent approach for instrumentation is to use computed tomography (CT) or magnetic resonance imaging (MRI) based measurements to pre-manufacture cutting blocks used to determine implant size, amount of bone to be resected, angle of the bone cuts and rotation of the cuts. These blocks can be customized to surgeon preferences, typically use anatomical standards for alignment and rotation, and fit onto the bone using its specificities in shape. However, and importantly, from a patient outcome standpoint, the implants used are still pre-made meaning they come in certain shapes and sizes, and the surgeon must make the implants fit to the individual patient. The so-called off the shelf implant in this approach remains the weak link, both from a PROM and OR efficiency standpoint. Nevertheless, several studies have validated the accuracy and efficiency provided by this approach. For example, Spender et al[7] showed that deviation from mechanical axis was on average only 1.4 degrees. Similarly, Nunley et al[8] reported that patient specific guides targeted at the mechanical axis were as accurate at traditional intramedullary instruments. Renson et al showed decrease OR time, reduced number of instrument trays, improved precision regarding surgical alignment targets, and accurate prediction of off the shelf implant sizes[27].

These guides are intended for single use, and are disposed of after the case, saving significant time and effort in turnover. However, there may be an additional cost to manufacture the guides, and so it is important to ensure that potential cost savings are not negated by the added cost[5]. Also, one must consider the added cost of the imaging scan, and the three week or so time lag to manufacture of the guide.

3.3 Custom Implants and Tools

A relatively recently introduced innovation, introduced by ConFORMis, Inc (Billerica, Massachusetts, USA), has been the use of customized cutting guides AND implants. A preoperative CT scan is used to create a three dimensional (3-D) model of the distal femur and proximal tibia, and to calculate the corrected mechanical axis. From these scans, customized cutting guides and patient-specific (shape, size, fit) implants and subsequently streamlined instrument trays are manufactured. The guides are similar to those discussed in section 3.2. The implants recreate individual patient anatomy, providing an anatomical reconstruction based upon the bone shape and orientation. With the implants provided, surgeons can further fine tune the ligament tension and soft tissue balance. The sagittal J curves of the femur are replicated in the femoral implant and in the articular surfaces. The size and shape of the femoral and tibial components are manufactured to match the predicted bone cuts. Trial implants, including multiple articular insert thicknesses, which match the actual implant are also provided. To aid in surgery planning, a detailed plan is provided for the surgeon, including the thickness of bone cuts and appearance of the implant on the bone (Figure 2). Bone models can also be provided. Thus, the surgeon has the benefit of detailed preoperative planning, patient specific cutting guides and streamlined, disposable instrumentation. Further, with patient specific implants, the surgeon is never forced to choose between sizes. Upon conclusion of the case, all guides and trials can be disposed. Cumulatively, this system saves significant time and effort in OR turnover.

Figure 2. Detailed surgical plan iView for a Customized TKA

There is now over a decade of experience with customized implants, including over 100,000 implantations worldwide. Previous peer-reviewed studies confirm that patient specific TKA implants provide improved fit and alignment[9,10,11,12], better kinematic function [13,14], reduced short-term complication rates [15, 16], higher patient satisfaction [17,18], and overall cost savings [15,16,19,20] when compared to standard off the shelf implants. Data from the UK National Joint Registry (UKNJR), recently released by Beyond Compliance, highlight a lower cumulative revision rate for the custom cruciate retaining implants than that of all other knee implants in the UKNJR [21]. The American Joint Replacement Registry (AJRR) has also now released survivorship data on these implants, showing similar lower revisions rates for customized TKA implants compared to off the shelf implants [22].

3.4 Comparative Approaches for OR Efficiency

Manufacturing principles such as Lean and Six Sigma have been introduced to the OR to improve efficiency. This approach is time consuming, requires deep process mapping, and frequent re-examination of each step[23]. Evenso, benefits can be multiplicative and can spill over into other perioperative arenas. Similarly, Farrokhi et al applied Toyota Production 5S methodology to track instrument availability in the OR for neurosurgery cases[24]. Using methodologies similar to those described in Section 3.1 above, they demonstrated a 70% reduction in the number of instruments and a 37% reduction in set-up time. Further, they suggested that the potential institutional savings could approach $2.8 million per year. In the orthopaedic OR, Lean methodology has demonstrated a 55% reduction in instruments from 792 to 433 in 11 of 102 instrument trays, with a weight reduction of over 574 pounds (22% lower)[25]. Another methodology for increasing surgeon efficiency during TKA is overlapping ORs[26]. Although personnel costs and surgical times were increased slightly ($80 and 8.3 minutes, respectively), the number of cases a surgeon could perform during an 8 hour period was increased by 1.2, which translated to an increased per case profit margin of $1215. Equally importantly, there was no increase in 90 day readmission. Another approach, similar to the ConFORMis system, is to use single use instruments (SUIs) with off-the-shelf implants. Mont et al compared navigated TKAs to TKAs performed with SUIs [28]. Only the navigated TKAs showed statistically significant reductions in combined instrument setup, cleanup times and surgical episode times. Attard et al reported a similar but slightly different experience[29]. They found that conventional instruments conferred higher, though not statistically significant, PROMs after TKA. Reusable patient specific instruments had lower OR times, fewer trays and less missing equipment. Single use patient specific instruments had higher blood loss and increased overall OR time, though were lighter and less expensive.

In the realm of customized, patient-specific implants, no other orthopaedic manufacturer currently provides such implants. Therefore, no direct comparison of the ConFORMis implant can be made to other customized, patient specific implants in terms of OR efficiency or patient outcomes. However, the ConFORMis approach marries streamlined instrumentation, single use instruments, preoperative navigation and surgical planning, and patient specific implants that eliminate the need for choosing between implants sizes in the OR.

4. Conclusions

The surgical episode of total knee replacement has been historically inefficient. Optimization efforts have focused upon waste reduction before, during and after the surgery. Besides the obvious benefit of cost and resource conservation, one added benefit may be improved accuracy and possibly outcomes. The use of customized, patient specific cutting guides and implants has been shown to improve patient outcomes as well as save the health system money and resources.

Literature Cited

1. Jaffer AK, Barsoum WK, Krebs V, Hurbanek JG, Morra N, Brotman DJ. Duration of anesthesia and venous thromboembolism after hip and knee arthroplasty. *Mayo Clin Proc*. 2005; 80(6):732-738.

2. Willis-Owen CA, Konyves A, Martin DK. Factors affecting the incidence of infection in hip and knee replacement: an analysis of 5277 cases. *J Bone Joint Surg Br*. 2010; 92(8):1128-1133.

3. Prasad N, Padmanabhan V, Mullaji A. Blood loss in total knee arthroplasty: an analysis of risk factors. *Int Orthop*. 2007;31(1):39-44.

4. Ong KL, Lau E, Manley M, Kurtz SM. Effect of procedure duration on total hip arthroplasty and total knee arthroplasty survivorship in the United States Medicare population. *J Arthroplasty*. 2008;23(6 Suppl 1):127-132.

5. Watters TS, Mather RC 3rd, Browne JA, Berend KR, Lombardi AV Jr, Bolognesi MP. Analysis of procedure-related costs and proposed benefits of using patient-specific approach in total knee arthroplasty. *J Surg Orthop Adv*. 2011;20(2):112-116.

6. JFK Memorial Hospital Working Group internal data.

7. Spencer BA, Mont MA, McGrath MS, Boyd B, Mitrick MF. Initial experience with custom-fit total knee replacement: intra-operative events and long-leg coronal alignment. *Int Orthop*. 2009;33(6):1571-1575

8. Nunley RM, Ellison BS, Zhu J, Ruh EL, Howell SM, Barrack RL. Do patient-specific guides improve coronal alignment in total knee arthroplasty? *Clin Orthop Relat Res*. 2012; 470(3):895-902.

9. Meier M, Zingde S, Steinert A, Kurtz W, Koeck F, and Beckmann J. What is the possible impact of high variability of distal femoral geometry on TKA? A CT data analysis of 24,042 knees. *Clin Orthop Rel. Res* 2019; 477(3): 561-570.

10. Schroeder L, Martin G. In vivo tibial fit and rotational analysis of a customized, patient-specific TKA versus off-the-shelf TKA. *J Knee Surgery* 2018; 25, https://doi.org10.1055/s-0038-1653966).

11. Arbab D, Reimann P, Brucker M, Bouillon B, Lüring C. Alignment in total knee arthroplasty – A comparison of patient-specific implants with the conventional technique. *The Knee* 2018; 25(5):882-887.

12. Ivie, C, Probst P, Bal A, Stannard J, Crist B, and Bal B. Improved radiographic outcomes with patient-specific total knee replacement. *J Arthroplasty* 2014; (29): 2100-2103.

13. Zeller I, Sharma A, Kurtz W, Anderle M, and Komistek R. Customized versus patient-sized cruciate retaining total knee arthroplasty: an in vivo kinematics study using mobile fluoroscopy. *J Arthroplasty* 2017;(32): 1344-1350.

14. Patil S, Bunn A, Bugbee W, Colwell C, and D'Lima D. Patient-specific implants with custom cutting blocks better approximate natural knee kinematics than standard TKA without custom cutting blocks." *The Knee* 2015; 22(6): 624–629.

15. Culler S, Martin G, and Swearingen A. Comparison of adverse events rates and hospital cost between customized individually made implants and standard off-the-shelf implants for total knee arthroplasty." *Arthroplasty Today* 2017; 3(4): 257–263.

16. O'Connor M and Blau B. The economic value of customized versus off-the-shelf knee implants in Medicare fee-for-service beneficiaries. *Am Health Drug Benefits* 2019; 12(2):66-73

17. Reimann P, Brucker M, Arbab D, and Lüring C. Patient satisfaction-A comparison between patient-specific implants and conventional total knee arthroplasty. *J Orthop* 2019; 16(3)273-277.

18. Schroeder L, Neginhal V, and Kurtz W. Patient Satisfaction, Functional Outcomes and Survivorship in Patients with a Customized Posterior-Stabilized Total Knee Arthroplasty. *Orthop Proc*, 2019; 101(4):46.

19. Buch R, Schroeder L, Buch R, and Eberle R. Does implant design affect hospital metrics and patient outcomes? TKA Utilizing a "Fast-Track" Protocol. *Recon Rev* 2019; 9(1): https://doi.org/10.15438/rr.9.1.203

20. Namin A, Jalali M, Vahdat V, Bedair H, O'Connor M, Kamarthi S, and Isaacs J. The adoption of new medical technologies: The case of customized individually made knee implants. *Value Health* 2019; 4:423-430.

21. Beyond Compliance. iTotal G2 and iTotal G2 XE.19/10/2020.14:18.2020 Northgate Public Services (UK) Limited

22. American Joint Replacement Registry Annual Report 2020: www.aaos.org

23. Rothstein D and Raval MV. Operating Room Efficiency. *Semin Pediatr Surg* 2018; 27(2):79-85.

24. Farrokhi FR, Gunther M, Williams B, Blackmore CC. Application of Lean Methodology for Improved Quality and Efficiency in Operating Room Instrument availability. *J Healthc Qual* 2015; 37(5):277-286.

25. Cichos KH, Hyde ZB, Mabry SE, Ghanem ES, Brabston EW, Hayes LW, McGwin G, Ponce BA. Optimization of Orthopedic Surgical Instrument Trays: Lean Principles to Reduce Fixed Operating Room Expenses. J. *Arthopl* 2019; 34(12):2834-2840.

26. Zachwieja E, Yayac M , Wills BW, Wilt Z , Austin MS , Courtney PM. Overlapping Surgery Increases Operating Room Efficiency Without Adversely Affecting Outcomes in Total Hip and Knee Arthroplasty. *J Arthropl* 2020;35(6):1529-1533.

27. Renson L, Poilvache P, Van den Wyngaert H. Improved alignment and operating room efficiency with patient-specific instrumentation for TKA. *Knee* 2014;21(6):1216-20.

28. Mont MM, McElroy MJ, Johnson AJ, Pivec R, and Single-Use Multicenter Trial Group Writing Group. *J Arthropl* 2013 28(7):1135-40.

29. Attard A, Fflur Tawy GF, Simons M, Riches P, Rowe P, Biant LC. Health costs and efficiencies of patient-specific and single-use instrumentation in total knee arthroplasty: a randomised controlled trial. *BMJ Open Qual* 2019 29;8(2)

