Curr Rev Musculoskelet Med (2012) 5:296–302
DOI 10.1007/s12178-012-9140-0

The use of customized TKA implants for increased efficiency in the OR

Raj K. Sinha

Published online: 19 October 2012

Abstract Efficiency in surgical procedures saves time and money and can decrease medical complications. Several sources of inefficiency exist in the operating room, including preoperative and intraoperative. The instruments used during TKA are frequently redundant. Customized instruments and implants can improve efficiency by reducing steps. Additional benefits may include improved alignment and kinematics. This chapter addresses the various sources of inefficiency, provides suggestions to overcome them, and introduces the concept of customized guides and implants as a method to improve efficiency.

Keywords Knee replacement · Efficiency · Customized instruments · Patient specific implants

Introduction

The primary goal of increased efficiency during TKA is reduced surgical time. Many benefits have been shown from reduced OR time, including deceased risk of thromboembolic disease [1], decreased risk of infection [2], decreased blood loss [3], lower revision rates [4], decreased cost [5••], increased number of surgical cases [5••], and more free time for surgeons [5••]. The latter 2 can also be significantly affected by decreased turnover time between cases. A secondary goal of improved efficiency is reduced cost. This article will discuss areas of inefficiency during the operative event, and how customized implants and patient specific instruments can be implemented to enhance efficiency of TKA.

R. K. Sinha (✉)
STAR Orthopaedics, Inc.,
47110 Washington Street, Suite 201,
La Quinta, CA 92253, USA
e-mail: drsinha@starortho.com

Sources of inefficiency during TKA

Perioperative

Prior to the start of any operation, instrument preparation is required. For TKA, current implant systems from most manufacturers require 5–7 trays of instruments such as resection guides and trial implants. In any given case, however, only a small percentage of instruments are actually used. Nevertheless, every single instrument has to be cleaned and sterilized prior to the surgery and then re-cleaned and re-sterilized after the surgery. It has been estimated that the cost to re-process a tray is between 75–120 US dollars [6]. So for 7 trays, that translates to 525–840 US dollars per case. Of course, this is a hidden cost which very few hospitals have the ability to measure accurately. Regardless, the instruments do not clean and sterilize themselves, and the cost associated with this step is therefore very real. Similarly, sterilized trays often become contaminated after processing and prior to use. This necessitates repeat processing, adding another hidden cost to the operative episode.

Intraoperative

During the surgery, there are several sources of inefficiency. As mentioned above, many instruments that will never be used are opened and placed on the back tables. Scrub staffs have to arrange the instruments that they anticipate will be needed so that they are handy (Fig. 1). To find these tools, the scrub staff must sort through the unnecessary

Fig. 1 Photograph of the back table showing all the customized instruments needed for customized TKA

instruments. Frequently the implant trays are not organized in the manner in which the instruments will be used, 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. To avoid these delays, the scrub staff will often hedge their bets and add occasionally used instruments to the sets, further compounding the problem of extraneous instrument setup and reprocessing. 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 actually used in 24 years; yet it has been made available for every surgery, “just in case.”

Another source of inefficiency is surgeon and scrub staff unfamiliarity with a particular implant system. This occurs when surgeons use many different implant systems, or frequently change systems. Similarly, if scrub staffs are expected to be “jacks of all trades,” covering orthopedic, general surgery, obstetric, and neurosurgical procedures, they will never have the opportunity to be proficient in any one area. It is interesting that hospital administrators accept that highly educated and trained physicians practice in 1 surgical specialty, yet they expect scrub techs and nurses, with less education and training, to be experts in multiple specialties.

Lastly, some blame for inefficiency must be placed at the feet of the surgeon. If a surgeon shows up late for the start of a case, not only is there an unnecessary delay, but it also sets the tone for the rest of the staff that a lackadaisical attitude is acceptable. Frequently, surgeons will not have a set approach to the procedure, changing technique as often as from case to case. This confuses the staff and makes it difficult for them to predict which instruments will be needed and when. Another common mistake is for the surgeon not having a plan B, or if needed a plan C, in mind. Thus, when something unexpected happens, the surgery must be halted while the surgeon first determines the new course, and then second while staff scrambles to find new instrument sets to follow that course. We have all been in the situation where the needed instruments are not sterile or are completely unavailable in the hospital. Although detailed approaches to improve surgeon planning are beyond the scope of this paper, it is nevertheless worthwhile to underscore the importance of preoperative planning and preparation, even for seemingly routine cases.

Methods to improve efficiency

Streamline instrument sets

A simple approach to reduce the number of unutilized instruments in your OR is to streamline your sets. First, decide on 1 or 2 implant systems that you will use for the majority of your cases. Then actually write down in detail the steps of how you prefer to do a TKA. Eliminate redundant or repetitive steps. An example is depicted in Table 1. From there, determine which non-implant specific instruments you use (eg, retractors, power instruments, forceps, etc.) Create a dedicated TKA set of instruments for your TKA cases. This may require your hospital to purchase some new instruments, but quite likely those instruments are just lying around not being used. Regardless, the time saved in turnover and re-processing will easily make up for the effort of being streamlined. Then, go through your implant trays and rearrange them in the way you actually do the operation. If that is not possible because many different surgeons use the same sets, at least you have a written list of what you will need and when to which the scrub staff can easily refer. One approach I used was to laminate this list so that it could be sterilized and placed on the back table for easy reference.

Some companies have started to streamline instrument sets for the surgeon. For example, Stryker has a Precision set that requires staff to only open limited trials once all the measurements are done and cuts have been made. This approach eliminates the need to open and reprocess 2–3 trays of trial components.

Custom cutting blocks

Another approach is to use CT or MRI based measurements to premanufacture cutting blocks that determine

Table 1 Steps utilized for performance of total knee arthroplasty

SURGEON	First Assistant	Second Assistant
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	
1/2-inch curved osteotome and bovie		
Bovie to prepat fat pad		
Place Army Navy	Hold Army-Navy	
Excise fat pad		
Tilt patella to 90 degrees		
Place 2 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		
Readjust 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
1/2 in. curved osteotome/mallet	Rongeur bone	
Kocher/knife excise ACL/PCL		
IM femoral drill		
IM guide and mallet	Place one headed pin	Rotate fork
Mallet		
Distal cutter	Two pins	
Mallet	Screwdriver	
Flex Knee		
Slap hammer to remove sword		
Smiley around MFC		Hold smiley
Saw to cut MFC	Kocher	
Move smiley laterally		Hold smiley
Saw to cut LFC	Kocher	Remove smiley
Slap hammer	Remove distal cutter	Remove fork
Blunt Hohmann to post tib	Rake medially	Hold Hohman
Fork to lat tibia		Hold fork
Kocher/bovie to remove menisci	Suction smoke	
Adjust tibial cutter height		
Place first pin		
Adjust tibial cutter alignment		

Table 1 (continued)

SURGEON	First Assistant	Second Assistant
Angel wing to check	Screwdriver	
Place second pin		
Sharp Hohmann medially	Hold sharp Hohmann	
Saw		
Remove pins	Remove tibial cutter	
Finish cut with saw		
Kocher and bovie		
Adjust retractors		
Mark rotation		
Tibial plate and rod		
Adjust cut if needed		
Small pin on Kocher	Mallet	
Second pin on Kocher	Mallet	
Drill bushing		
Drill		
Keel punch and mallet	Remove small pins	
1/8 in. drill bit		
10 mm block	Loosen IMP	remove all retractors
Alignment rods		
Check extension gap and balance		
Fresh cuts if needed		
Remove block		Rake to medial skin
Place fork laterally		Hold fork
Flex knee to >60 degrees		Rotate fork distally
Place femoral sizer		
1/8 in. drill		Large headed pins
Mallet		
Extend knee		Rotate fork proximal
Place anterior stylus	Place rotation guide	
Two threaded pins		
Check rotation/flexion gap		
Adjust if needed		
Remove stylus/rotation guide	Slaphammer	Rotate fork distally
Flex knee		
Place 4 in 1 block	Large headed pins/mallet	
Trilogy screws		
Double check rotation		Rotate fork proximal
Saw to anterior cut		
Saw to anterior chamfer	Place jack and smiley medial	
Saw to post MFC		
Saw to post med chamfer	Move smiley laterally	remove fork
Saw to post LFC		
Saw to post lat chamfer	Remove smiley & jack	
Recip saw		
Power screwdriver	Slaphammer	Remove gold block
3/4 in. osteotome/mallet	Kocher	Rakes anterior
Small rongeur		
Lamina spreader	Rake	Hold lamina spreader
Kocher & bovie		

Table 1 (continued)

SURGEON	First Assistant	Second Assistant
1/2 in. curved osteotome		
Angled curette		
Kocher		
Flip lamina spreader	Flip rake	Hold Lamina spreader
Kocher & bovie		
1/2 in. curved osteotome		
Angled curette		
Kocher		
Injection	Remove rake	Hold lamina spreader
Spreader		
Tensor at 90 degrees		
Torque wrench		
12 mm block		
Remove Tensor	Loosen IMP	
Place 12 mm block		
Check flexion stability		
Tensor at full extension		
Torque wrench		
10 mm block		
Remove tensor		
Place 10 mm block		
Check stability		
Adjust bone/ligaments if needed		
Fork laterally	Rake medially	Hold rake and fork
Flex knee		Rotate fork distally
Femoral finisher & mallet	2-Headed pins	
Drive in pins	Place jack	
Reciprocating saw	Slaphammer	
Kocher		
Femoral trial		
Mallet and impactor		Remove retractors
Blunt Hohmann posterior		Hold Hohmann
Tibial trial and insert	Loosen IMP	Remove Hohmann
Reduce knee into extension		
Check stability/ROM		
Place in IMP and flex to 90 degrees		
Sharp Hohmann to remove insert		Rake and fork
Femoral slaphammer	Leg in extension	
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 and impactor		
Remove excess cement	Remove excess cement	Remove retractors
Fork laterally	Rake medially	Hold fork

Table 1 (continued)

SURGEON	First Assistant	Second Assistant
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	
Hot saline		
Check for debris		
Drain		Rakes proximally
No. 2 quill suture	Suture scissors	

implant size, amount of bone to be resected, angle of the cuts, and rotation of the cuts. These can be customized to surgeon preferences, use anatomical standards for alignment and rotation, and attach to the bone using the shape of the patient's own bone. Several studies have validated the accuracy and efficiency provided by this approach. For example, Spencer et al. [7] showed that deviation from mechanical axis was on average only 1.4 degrees. Nunley et al. [8•] showed that patient specific guides targeted at the mechanical axis were at least as accurate at traditional instruments.

These guides are intended for single use, and so they can be disposed of after case completion, saving significant time and effort in turnover.

However, there often is an additional cost for manufacture of the guides, and so it is important to determine whether the cost savings from the ease of reprocessing is not negated by the added cost [5••] of the custom cutting guides. Also, there is the added cost of the imaging scan, and the 3 week or so time lag from scan to manufacture of the guide.

One word of caution: customized guides cannot solely correct alignment if ligament releases are needed. Similarly, they cannot balance flexion and extension gaps in all cases. Because this approach relies on anatomical landmarks to set rotation, the knee can be imbalanced, necessitating further ligament balancing or repeat bone cutting. Also, if the imaging scan is inaccurate, the guides may not fit properly or the recommended components may be incorrectly sized. So, this approach does not absolve the surgeon of the responsibility of being a surgeon. Lastly, trial implants are still required for final assessment of the reconstruction prior to implantation. Nevertheless, for most surgeons in the majority of cases, this approach has the potential to speed up surgery.

Custom implants and tools

A recently introduced innovation, introduced by a new company called ConforMIS, Inc, (Burlington, MA, USA) has been the use of customized cutting guides and implants. In this approach, a preoperative CT scan is used to create a three dimensional model of the distal femur and proximal tibia, while also calculating the corrected mechanical axis. From these scans, customized cutting guides are prepared, as are patient-specific implants. The guides are similar to those discussed in the section above, although they do require gap balancing prior to making the final bone cuts. The implants are manufactured to recreate the individual patient anatomy, providing an anatomical reconstruction based upon the bone shape and orientation, with the added benefit of fine tuning the ligament tension and balance. The sagittal J curves of the femur are reproduced in the femoral implant and in the articular surfaces. The shape and size of the femoral and tibial components are matched to the predicted bone cuts. Trial implants, which replicate the actual implant are also provided, including multiple poly articular insert thicknesses. Upon conclusion of the case, all guides and trials can be disposed. Again, this can save significant time and effort in turnover. Currently, the cost of the disposable guides and trials are factored into the cost of the implant. In my hospital, both off the shelf and customized implants are competitively priced. Also, there is the added cost of the imaging scan, which may range from $400–$800, but can be an added revenue source for the hospital.

Early data are not yet available, although studies are underway assessing the biomechanics of custom implants, clinical outcomes and CT alignment. The primary pitfalls of using customized implants, besides added cost, are the time to manufacture the implants and the risk of wasted implants. Time to manufacture is typically about 6 weeks or so from the time the imaging scan is completed. This time frame can dissuade patients, who are in pain, and otherwise might be able to receive their surgery within a few weeks, depending upon surgeon availability. Similarly, surgeons may fear losing patients who are compelled to wait 6 weeks or more. Another theoretical concern is that at the time of surgery, if the reconstruction cannot be successfully completed, the custom implants will be necessarily wasted in favor of off the shelf implants.

Conclusions

Optimization of the surgical episode of total knee replacement has been historically inefficient. Recent 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. Further research will be necessary to confirm these possibilities.

Disclosure RK Sinha: board membership with ConforMIS, Inc, consultant to Zimmer and Robodoc, has grants from ConforMIS, Inc, Zimmer, and Superstat, receives royalties from ConforMIS and Zimmer, develops educational presentations for Angiotech, and has stock options with ConforMIS, Inc.

References

Papers of particular interest, published recently, have been highlighted as:

- • Of importance
- •• Of major importance

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;80:732–8.
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;92:1128–33.
3. Prasad N, Padmanabhan V, Mullaji A. Blood loss in total knee arthroplasty: an analysis of risk factors. Int Orthop. 2007;31:39–44.
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):127–32.
5. •• Watters TS, Mather III RC, Browne JA, Berend KR, Lombardi Jr AV, 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(6):112–6. *This study compares custom guide based, navigation based, and standard TKA. Costs were similar between standard and custom guide TKA, but surgical time of the latter was, on average, 28 minutes shorter.*
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;33:1571–5.
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;470:895–902. *This study compared conventional instruments, patient specific guides targeting the mechanical axis, and patient specific guides targeting the kinematic axis. Overall percentages of outliers vis-à-vis the mechanical axis were similar between the first 2, although conventional guides tended to produce more overall varus. Kinematic axis guides produced more valgus outliers.*