Customization of cutting blocks: Can this address the problem?

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Abstract Recent literature has challenged the notion that neutral coronal alignment is a requirement for long-term survivorship of TKAs. However a preponderance of classic and contemporary evidence supports increased failure rates with malalignment, especially varus. Patient-specific custom cutting guides are an attractive alternative to traditional instrumentation and computer navigation in achieving accurate alignment of total knee arthroplasties. The logistical benefits include possible decreased operating room time, decreased turnover time, less time spent sterilizing and preparing trays, less inventory, less strain on surgical technicians and nurses, and no capital cost associated with computer navigation. Patient benefits include potentially less tourniquet time, less surgical exposure, no requirement of intramedullary canal preparation, and improved mechanical alignment, which may translate to increased implant longevity. Surgeon benefits include potentially more accurate landmark registration than computer navigation, more efficient surgery, decreased intraoperative stress due to less required decision making, and the ability to perform more surgeries due to time saved.

Keywords Custom · Patient-specific · Knee arthroplasty · Instrumentation · Rapid prototyping · Imaging · Block · Guide · Preoperative planning

Introduction

Total knee arthroplasty remains one of the most successful surgical procedures in orthopedics today, and the demand

for primary and revision total knee arthroplasty is expected to increase dramatically over the next few decades [1]. In addition, there is expected to be a shortage of arthroplasty surgeons to address this increase in demand [2]. Surgeons and hospitals will need to improve their proficiency and volume to better accommodate the increased number of joint replacements. Improving proficiency will allow for increased surgeon volume, which has been shown to improve both immediate postoperative course as well as long-term survival of implants [3–6].

Recent literature has challenged the notion that neutral coronal alignment is a requirement for long-term survivorship of TKAs [7, 8]. However a preponderance of classic and contemporary evidence supports increased failure rates with malalignment, especially varus [9–14]. Computer navigation was developed to assist surgeons in achieving a neutral mechanical axis. Multiple studies have shown that navigation is superior to conventional techniques in restoring the mechanical axis within 3° [15–25]. Despite its accuracy, there are pitfalls including inability to accurately register landmarks into the computer, pin loosening, and fracture. Navigation also increases operating room time and cost [26].

Patient specific cutting blocks have been developed to address both the negative consequences of knee malalignment and the negative aspects of computer navigation while hopefully increasing efficiency and lowering cost. Are these customized blocks effective in achieving a neutral mechanical axis and decreasing the number of outliers while also increasing operating room efficiency?

Development

Computer navigation utilizes carefully arranged and positioned arrays mounted on pins placed in the femur and tibia. The surgeon manually registers bony landmarks to determine resections, implant sizes, and rotation. This process takes

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place completely during the intraoperative portion of the surgical process. In contrast patient-specific cutting guides shift bony landmark registration completely to the preoperative planning portion of the surgery. This process saves time during surgery; however additional preoperative time and planning by the surgeon are required.

Advanced imaging, either magnetic resonance imaging (MRI) or computed tomography (CT) scan, is obtained of the patient's knee along with either select slices of the hip and ankle or long leg alignment radiographs. Software programs utilize these images to determine overall alignment, develop a virtual three dimensional (3D) model of the femur and tibia to determine component sizes. Bony resections are mapped to obtain accurate postoperative alignment and rotation. A default surgical plan with images is sent to the surgeon, and upon approval custom disposable guides are fabricated to fit precisely to the patient's anatomy (Fig. 1). The surgeon has the ability to modify the plan to incorporate any patient-specific anatomic factors including flexion contractures or ligament contractures or deficiencies. Depending on the manufacturer, these guides can be used to determine accurate pin placement to be used with standard resection instrumentation or can also serve as slotted cutting guides.

Literature review

A potential benefit of patient-specific custom guides is increased accuracy and consistency of alignment. Lombardi et al conducted a study of 54 TKAs in 51 patients using custom MRI-based alignment guides [27]. Normal preoperative alignment was present in 22 % of knees, varus in 69 %, and valgus in 9 %. All surgeries were performed via a less invasive medial parapatellar arthrotomy and cruciate-retaining femoral components were used in all patients. Forty-four patients had 6 week follow up radiographs showing restoration of coronal alignment to 4–8° valgus without clinical instability, extensor lag, or reoperation.

Ng et al reviewed 569 TKAs performed with patient specific guides and 155 with manual instrumentation performed by 2 surgeons at 2 different institutions [28•]. Postoperative long leg radiographs were used to determine the relationship between the knee and the overall mechanical axis in all patients. One surgeon's cases (105 custom guide cases and 55 manual instrumentation cases) were evaluated for hip-knee-ankle angles, individual component angles compared with their respective mechanical axes, and the angle between the femoral anatomic axis (FAA), and femoral mechanical axis (FMA). The mechanical axis passed through the central third of the knee in 88 % of knees with custom guides compared with 78 % of knee with manual instrumentation ($P<0.001$). Hip-knee-ankle angles were similar between custom guides and manual instruments

Fig. 1 Custom disposable guides based on preoperative imaging studies are fabricated to fit precisely to the patient's anatomy. The surgeon is provided with models of the patient's distal femur (a) and proximal tibia (b) along with guides for precise placement of instrumentation. (Printed with permission of Joint Implant Surgeons, Inc., New Albany, Ohio.)

(180.6° vs 181.1°); however, there were fewer outliers $>\pm 3^\circ$ with custom guides (9 %) than manual instruments (22 %) ($P=0.018$). Component angles were closer to neutral with custom guides than manual instruments in the tibia (89.9° vs 90.4°, $P=0.005$) and femur (90.7 vs 91.3, $P<0.001$). However outliers $>\pm 2^\circ$ were similar in both groups in the tibia (10 % vs 7 %) and the femur (22 % vs 18 %). The angles between the FAA and FMA were similar in both the custom guide and manual instrument groups (5.6° vs 5.3°, $P=0.1$).

An additional proposed benefit of custom guides is accuracy of implant sizing. Bali et al prospectively studied 32 TKAs performed in 29 patients with MRI-based custom cutting guides [29]. Six-week postoperative radiographs were used to measure deviation from the mechanical axis as well as tibiofemoral angles. A tibial recut was required in 1 case and no femoral recuts were necessary. The planned femoral size was accurate in all knees, and 2 cases required

smaller tibial sizes than planned. Twenty-nine of 32 knees had a mechanical axis within 3° of neutral.

Patient specific guides can be an attractive alternative to standard instrumentation in patients with certain disease states and deformities. Mayer et al reported the benefits of custom guides in a patient with osteopetrosis [30]. This disease causes hard, sclerotic bone throughout the skeleton. Custom guides allowed avoidance of difficult intramedullary reaming of the femoral canal, and accurate alignment avoided the need for multiple difficult saw passes.

Noble et al randomized 29 patients to undergo primary TKA with either MRI-based custom guides or traditional instrumentation [31•]. All patients received cruciate-retaining femoral components via a medial parapatellar approach. No significant differences in preoperative alignment existed between the groups; however, postoperative mechanical axis was closer to neutral in the custom guide group compared with the standard instrumentation group (1.7° vs 2.8°, $P=0.03$). Average duration of hospital stay (59.2 hours vs 66.9 hours, $P=0.043$), operative time (121.4 minutes vs 128.1 minutes, $P=0.048$), and incision length (136 mm vs 151.8 mm, $P=0.014$) were improved in the surgeries utilizing patient-specific guides. The most significant difference between the groups was the lower average number of instrument trays required for the custom guides (4.3) vs standard instruments (7.5, $P<0.0001$).

Nunley et al. retrospectively reviewed 150 patients with osteoarthritis who received primary TKA with a cruciate-retaining prosthesis [32]. Fifty patients underwent TKA with standard instrumentation, 50 with MRI-based custom alignment guides designed to restore the mechanical axis, and 50 patients underwent TKA with custom MRI guides based on shape matching to restore the kinematic axis by restoring the pre-arthritis alignment of the limb. Surgeries in the first 2 groups were performed by one surgeon and surgeries in the kinematic group were performed by a second surgeon, both with experience in patient-specific guides who were past their initial learning curves. Postoperative CT scout images were performed at 6 weeks to determine femorotibial angles, hip-knee-ankle angles, and zones of the mechanical axis. The authors found that mean femorotibial angles were more varus in the standard instrument group than the custom mechanical axis group (-3.21° vs -4.75° , $P=0.03$), and the custom kinematic axis group had a more valgus mean femorotibial angle than the other groups (-6.30° , $P=0.043$). Mean hip-knee-ankle angles were similar between the standard and custom mechanical axis groups (0.08° vs -0.65° , $P=0.47$), and the custom kinematic axis group was again in more valgus (-2.76° , $P=0.0002$ and $P=0.0061$). The mechanical axis intersected the center zone of the knee in 60 % of standard instrumented knees, 68 % of custom mechanical axis knees, and 36 % of custom kinematic axis knees. No knees in any group had mechanic axes in moderate or severe

varus or severe valgus; however, 10 % of custom kinematic axis knees were found to be in moderate valgus. A similar percentage of outliers were found between the standard and custom mechanical axis groups, which had more varus outliers than the custom kinematic axis group that had a substantial amount of valgus outliers.

Slover et al performed a cost effectiveness analysis of custom guides in TKA [33]. A Markov decision model was employed to determine if custom guides are cost effective compared with traditional instrumentation. The authors concluded that custom guide technology was not cost effective unless it resulted in a significantly decreased revision rate. They did however note that the “new technology” perception of custom guides may be of marketing benefit, and when combined with the ability to do more cases will possibly increase revenue for an institution. They also advised consideration of the actual ability to do more cases and if additional resources including employee overtime would be required above the baseline costs of performing total knee arthroplasties.

Nunley et al also published a paper evaluating the cost effectiveness of custom cutting blocks by comparing 57 TKAs using MRI-based guides designed to restore the mechanical axis with 57 TKAs using standard instrumentation [34•]. All patients in both groups had preoperative deformity less than 10° varus or valgus. A postoperative CT scout film was obtained for measurements. The authors found no difference in surgical or tourniquet times between the groups; however, there was an average of 12.1 minutes less overall operating room time with the custom guides ($P=0.028$). No significant differences were found in femorotibial angles, hip-knee-ankle angles, zone of mechanical axis, or mechanical axis deviation in either group. They also found no difference in soft tissue balancing at the time of surgery or the immediate postoperative visit and no knee required revision. The authors concluded that having no significant improvement in radiographic outcome combined with the increased cost of the custom guides did not make this a cost-effective technology for high-volume arthroplasty surgeons.

Watters et al analyzed procedure-related costs and benefits of patient-specific total knee arthroplasty performed with standard instruments, computer navigation, and patient-specific custom guides [26•]. The authors found that compared with standard instrumentation, patient-specific guides decreased operative time by 13 minutes, and computer navigation increased operative time by 39 minutes. Using these figures and their institutional operational costs, the authors found minimal savings as a result of the 13 minutes of less operative time with the custom guides compared with traditional instrumentation (\$2122.89 vs \$2223.90 per TKA) but both were less per case than computer navigation (\$2526.93). Money was saved in the cost of processing operative trays. They found that one operative

tray was required at a cost of \$58.18 for patient-specific cases vs 6 trays at a cost of \$349.08 for both conventional and computer navigation cases. A survey of nursing staff at their institution revealed that turnover time was decreased by 15 minutes per case with patient-specific guides. Computer navigation costs \$500 per case and custom guides cost \$925 per case at the authors institution. Upon a per-case cost analysis, the authors found that cases utilizing patient specific guides cost \$3106.07 compared with conventional instrumentation (\$2572.98) and computer navigation (\$3376.01). They did note, however, that the 15 minutes saved in turnover combined with 13 less operative minutes would potentially allow for more cases to be performed, which would then affect the cost analysis.

Duffy described his experience with custom cutting guides and its improvement in operating efficiency and added benefit for a high volume arthroplasty surgeon [35]. He described the ability to improve overall operative time by estimating a reduction in 9 surgical steps and faster turnover time due to lower number of required trays. Improved implant sizing also allowed for less trialing during surgery. This time savings was predicted to allow for more cases to be done each day.

In contrast to the high-volume surgeon, Johnson describes the benefits of patient-specific guides to a low-volume surgeon [36]. He described his experience with 35 TKAs performed with patient-specific custom cutting blocks. A mechanical axis within 3° of neutral was achieved in 72 % of patients, femoral mechanical alignment was within 3° of neutral in 100 % of patients, and tibial mechanical alignment was within 3° of neutral in 83 % of patients. Femorotibial angles were between 2 and 8° of valgus in 78 % of patients with a mean of 3.7° of valgus. Accurate femoral component sizing was predicted in 78 % of patients and accurate tibial component sizing was predicted in 80 % of patients, and femoral and tibial component sizing was within 1 size in 100 % of cases. The custom guides along with accurate sizing allowed a decrease in pans from 8 vendor-specific pans to 1 single pan for all total knee cases. The authors also conducted a separate efficiency study comparing 6 cases performed with 8 standard instrumentation pans with 6 cases performed with a single efficiency pan for custom cases. They found a reduction in total processing and sterilization time by a mean of 116 minutes when using custom guides. In addition, time to open trays, as well as set up and break down of the back table was reduced by 31 minutes. Autoclave use and sterilization errors were decreased by 50 %. Cost-analysis showed a \$500 savings per case with the use of single efficiency pans.

Lionberger et al presented a study at the 2011 annual meeting the American Association of Hip and Knee Surgeons evaluating the efficiency of custom cutting guides compared with computer navigation in total knee arthroplasty [37]. The authors found less operating room time

(141.7 minutes vs 167.6 minutes, $P=0.0003$), and less turn-around time (29.1 minutes vs 42.9 minutes, $P<0.0001$) with custom guides compared with computer navigation. They were also able to increase their daily case load from 2 TKAs performed with computer navigation to 3 TKAs performed with custom guides.

Further study is required to determine if the lower operative times described above, in addition to not violating the intramedullary canal would translate into less morbidity and mortality associated with total knee replacement. One might hypothesize that custom guides may make minimally invasive total knee replacement more accurate than with traditional instrumentation with the added benefit of less morbidity and possibly faster recovery. Additional study would be needed to evaluate if increased efficiency would also translate to decreased infection rates.

The literature outlined above supports the notion that patient-specific cutting guides are at least as accurate if not better than traditional instrumentation, and equal to computer navigation in restoring the mechanical axis in total knee arthroplasty. Custom cutting blocks also eliminate the increased operating room time, increased exposure, and the potential complications with computer navigation. The pre-operative planning involved with patient-specific guides may also be more accurate in landmark registration than that of intraoperative registering with computer navigation.

Despite recent challenges, the literature overwhelmingly stresses the importance in the mechanical axis in assuring the longevity of knee replacements [9–14]. Malalignment has been found to be the factor responsible for 9.4 %–11.8 % of total knee revisions [38, 39]. The financial burden of revision knee arthroplasty could be greatly decreased with improved alignment of total knee implants. The literature supports the thought that patient-specific guides would be beneficial to the general orthopedist who does a low volume of total knee arthroplasties [36]. The low volume surgeon could expect to have more consistently accurate alignment of implants that may not be as reproducible with standard instrumentation.

With ever-decreasing reimbursement and the increasing demand for total knee arthroplasty, surgeons will be forced to increase their efficiency and volume to handle this burden. The literature is mixed with regards to the cost-effectiveness of patient-specific blocks for the high volume arthroplasty surgeon. The ability to increase the number of cases per day by the savings in operative time, tray processing, and turnover time may potentially offset the cost of patient-specific guides.

Conclusion

Patient-specific custom cutting guides are an attractive alternative to traditional instrumentation and computer navigation

in achieving accurate alignment of total knee arthroplasties. The logistical benefits include possible decreased operating room time, decreased turnover time, less time spent sterilizing and preparing trays, less inventory, less strain on surgical technicians and nurses, and no capital cost associated with computer navigation. Patient benefits include potentially less tourniquet time, less surgical exposure, no requirement of intramedullary canal preparation, and improved mechanical alignment, which may translate to increased implant longevity. Surgeon benefits include potentially more accurate landmark registration than computer navigation, more efficient surgery, decreased intraoperative stress due to less required decision making, and the ability to perform more surgeries due to time saved. We must stress that these proposed benefits are debated in the literature.

Some downsides to patient-specific guides include the time requirement of advanced imaging. This mostly falls on patients, as they must take extra time to obtain the imaging, and must be exposed to some radiation if CT-based guides are used. Some patients also have contraindications to obtaining MRIs. The time requirement to process the imaging and develop the blocks may delay the surgery, which is highly anticipated by some patients. Even though surgeons will potentially save time during surgery, they must be willing to put in more time during preoperative planning to view, change, and approve the custom plan. Surgeons too must be willing to delay surgeries in order to have the custom guides made. The surgeon may struggle with completely trusting the custom guides early in their experience with this technology. This may at first require more operative time if intraoperative checks with standard instruments are used to ensure accurate alignment. This may cause some frustration with the use of patient-specific technology.

Further study is necessary to compare custom cutting guides with traditional instruments and computer navigation with regards to long term implant survival and revision rates. This compared with evolving pricing will truly tell if patient-specific instrumentation will be a cost effective technology. In the meantime, orthopedic surgeons will need to weight the benefits and downsides of these guides and include patients in the decision making process.

Ethical standards All human studies discussed have been approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. All study subjects have given informed consent for inclusion in the study.

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