■ MANAGEMENT FACTORIALS IN TKA

Patient specific cutting blocks are currently of no proven value

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Patient specific cutting guides generated by preoperative Magnetic Resonance Imaging (MRI) of the patient's extremity have been proposed as a method of improving the consistency of Total Knee Arthroplasty (TKA) alignment and adding efficiency to the operative procedure. The cost of this option was evaluated by quantifying the savings from decreased operative time and instrument processing costs compared to the additional cost of the MRI and the guide. Coronal plane alignment was measured in an unselected consecutive series of 200 TKAs, 100 with standard instrumentation and 100 with custom cutting guides. While the cutting guides had significantly lower total operative time and instrument processing time, the estimated $322 savings was overwhelmed by the $1,500 additional cost of the MRI and the cutting guide. All measures of coronal plane alignment were equivalent between the two groups. The data does not currently support the proposition that patient specific guides add value to TKA.

Variability in component alignment continues to be a major issue in total knee arthoroplasty (TKA). In the short term, this may be a factor in persistent pain, stiffness, and dissatisfaction.[1,2] In the longer term, coronal plane malalignment has been associated with an increased risk of loosening, instability, and wear.[3] After more than a decade of clinical use, computer navigation has not had a consistent, positive impact on this issue.[4,5] A possible new approach is the use of patient specific guides in which MRI or Computed Tomography (CT) scan is used to generate a model of each patient's lower limb and an associated cutting guide is generated based on the model. The goals of patient specific instrumentation are to improve the accuracy of post-operative alignment and eliminate outlier cases that are more prone to complications and early failure, as well as to increase the efficiency of the procedure by potentially decreasing the operative time. The latter can be achieved by decreasing the time and cost associated with managing and sterilising fewer instruments associated with cases utilising patient specific guides. To test these hypotheses, a study was undertaken to evaluate the cost of performing a case with standard instrumentation versus a patient specific guide as well as quantifying the coronal plane alignment between a group of patients who underwent TKA using custom guides *versus* standard instrumentation.

Patients and methods

An unselected consecutive series of 200 patients undergoing primary TKA using the same cruciate retaining cemented total knee system (Vanguard™, Biomet, Inc, Warsaw, Indiana) between January 2009 and December 2011 were studied. The alignment goals were a neutral mechanical axis defined as a Hip-Knee-Ankle (HKA) angle of 0° with the femoral and tibial components aligned perpendicular to the mechanical axis. All currently FDA approved alignment systems in the U.S. are based on such a mechanical axis model. Patients were included only if they were deemed to be candidates for a cruciate retaining TKA. Patients were excluded if they had prior open surgery including hardware in the lower extremity, a flexion contracture greater than 20°, or severe valgus or varus deformity. Patients with other contraindications to an MRI, including those with a pacemaker or prior metal clips associated with brain or eye surgery, were also excluded. All patients were offered the option of undergoing a pre-operative MRI and TKA with a patient specific guide. Patients self-selected for one group or the other based on their willingness to have an MRI and a six week delay in their surgery for processing of the imaging, production and delivery of the guide. The first 100 patients that elected patient specific instrumentation were compared with the first 100 that were performed with the standard instrumentation.

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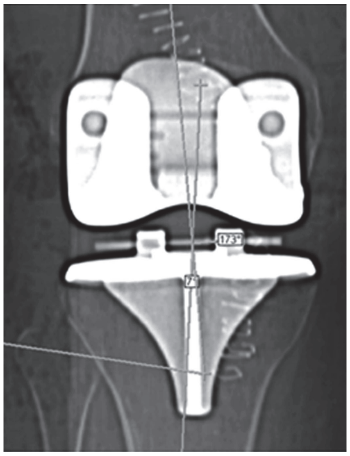

Fig. 1

Scout CT scan showing two holes on either side of the femoral component for placement of a posterior augment.

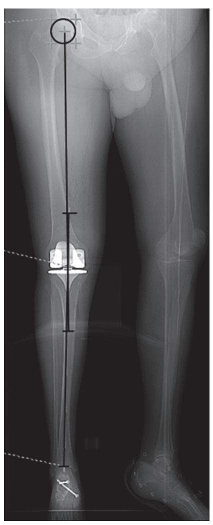

Fig. 2

The hip-knee-ankle angle (HKA), formed between the mechanical axis of the femur and the mechanical axis of the tibia.

Fig. 3

The femorotibial angle (FTA), formed between lines bisecting the distal fourth of the femur and the proximal fourth of the tibia.

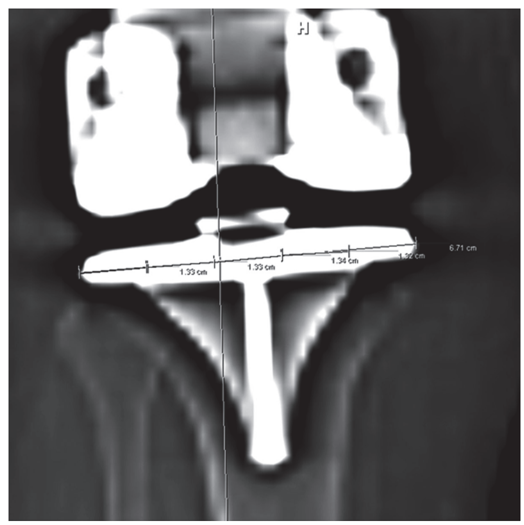

Fig. 4

The zone of mechanical axis (ZMA), where the line connecting the center of the femoral head to the center of the ankle passes when the tibial base plate is divided into five equal zones.

All patients had a post-operative coronal scout CT scan of the hip, knee, and ankle with extremities rotated into a neutral position in order to standardise the measurements as previously described by Nunley et al.[6] The femoral component of this system has two oval holes to allow the potential for placement of a posterior augment (Fig. 1). The limb was rotated until the posterior augment holes were centered relative to the anterior flange of the femoral component so that the extremities were in a similar degree of rotation in order to minimise the impact of variable rotation on measurements of alignment. The three coronal plane alignment measures were 1) the HKA angle, which is an angle formed between the mechanical axis of the femur and the mechanical axis of the tibia (the mechanical axis of the femur is defined as the line connecting the center of the femoral head with the center of the knee, and the mechanical axis of the tibia is the line connecting the center of the ankle mortise to the center of the knee) (Fig. 2); 2) the femorotibial angle (FTA), which is an angle formed between lines bisecting the distal fourth of the femur and the proximal fourth of the tibia (Fig. 3); 3) the zone of the mechanical axis (ZMA) is the zone through which the line connecting the center of the femoral head to the center of the ankle passes when the tibial base plate is divided into five equal zones, as described by Kennedy and White[7] (Fig. 4).

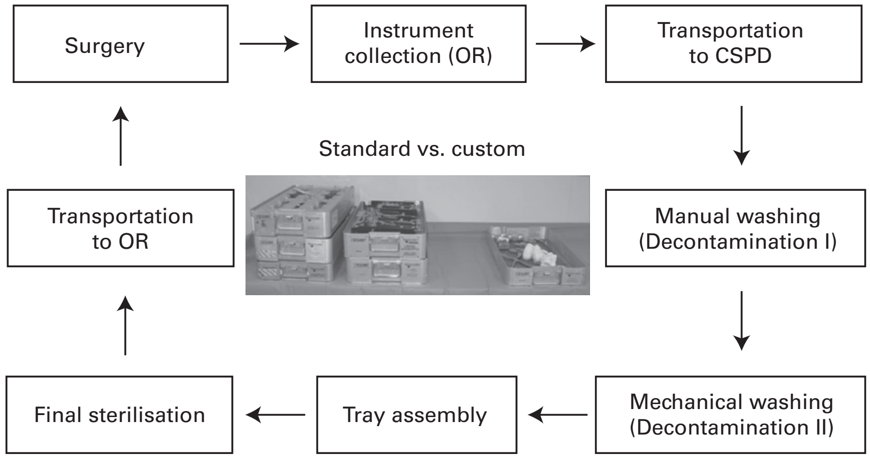

Fig. 5

Flowchart depicting the steps of the sterile processing cycle.

Table I. Demographics comparing standard instrumentation group to custom cutting block group.

Demographics	**Standard (n = 100)**	**Custom (n = 100)**	**p value**
Age at Surgery; years (Range)	65.6 (42.8 to 91.0)	64.8 (31.6 to 90.1)	0.583
Gender; Male / Female	43 / 57	40 / 60	0.667
Operative Side; Left / Right	48 / 52	52 / 48	0.572
Average Postoperative FTA (+ SD)	3.7 (± 2.5)	5.5 (± 2.9)	<0.001
Average Postoperative HKA (+ SD)	-0.5 (± 2.3)*	-1.7 (± 2.5)*	<0.001

* Negative indicates valgus.

Time and cost data were quantified utilising an operating room database. The total tourniquet time and the total time in the room between TKAs performed with standard instrumentation and those performed with patient specific guides was compared for the first 50 cases in each group. In addition, all steps in the instrument processing cycle were timed utilising industrial deficiency methodology. A single observer established all steps in the instrument processing cycle and utilised a stop watch to time each step of the cycle, starting with instrument collection and transportation to central supply and ending with transportation back to the operating room (Fig. 5). Five consecutive unselected cases for each group were studied for this portion of the analysis. The times were converted into costs utilising the fixed hospital overhead, which included the labor associated with assembling and decontaminating the trays as well as the material costs for the sterilisation process and the equipment utilised. The operating room time was also converted to costs utilising the fixed overhead estimates provided by the hospital administration. The other costs considered included the cost of the MRI; this consisted of the professional component, which is the charge for the radiologist reading, and the technical component, which is the facility fee for performing the imaging study. Total fees collected for the MRI from Medicare and privately insured patients were added to the hospital cost for the custom cutting guide to determine the total additional cost of performing a TKA with custom guides. The savings from decreased operative and instrument processing time were subtracted to determine the average net cost to the operating room budget, exclusive of costs to insurers for imaging.

Statistical analysis. Simple *t*-tests were used to assess group differences in continuous variables and χ^2 tests were used to assess categorical variables. A p-value of 0.05 was considered statistically significant. All statistical analyses were performed using SPSS for Windows, version 20 (SPSS, Inc, Chicago, IL).

Results

The two groups were similar in demographics (age, gender, and operative side; Table I). The two methods of component alignment did align the limbs differently. The FTA in the custom cutting guide group was closer to the target of 5° (5.5° *versus* 3.7°, $p < 0.001$), while the standard instrumentation was more successful in restoring the HKA angle closer to zero (0.5° *versus* 1.7°, $p < 0.01$), which was the alignment target. Analysis of the ability of either technique to avoid outliers, which is probably more important than the group averages, showed no difference in any of the measurements of component angle. The number of outliers for FTA was virtually identical between the two groups. For the HKA angle and the central ZMA, there were actually more outliers in the custom cutting guide group than the standard instrumentation group, although this did not achieve statistical significance (Table II).

Table II. Comparison of outliers by group for the three coronal alignment measurements.

Measurements	Standard (n = 100)	Custom (n = 100)	p value
FTA 2° - 8° valgus / Outliers	73 / 27	71 / 29	0.753
HKA 0 ± 3° / Outliers	77 / 23	69 / 31	0.203
ZMA Central Zone / Outliers	63 / 37	57 / 43	0.386

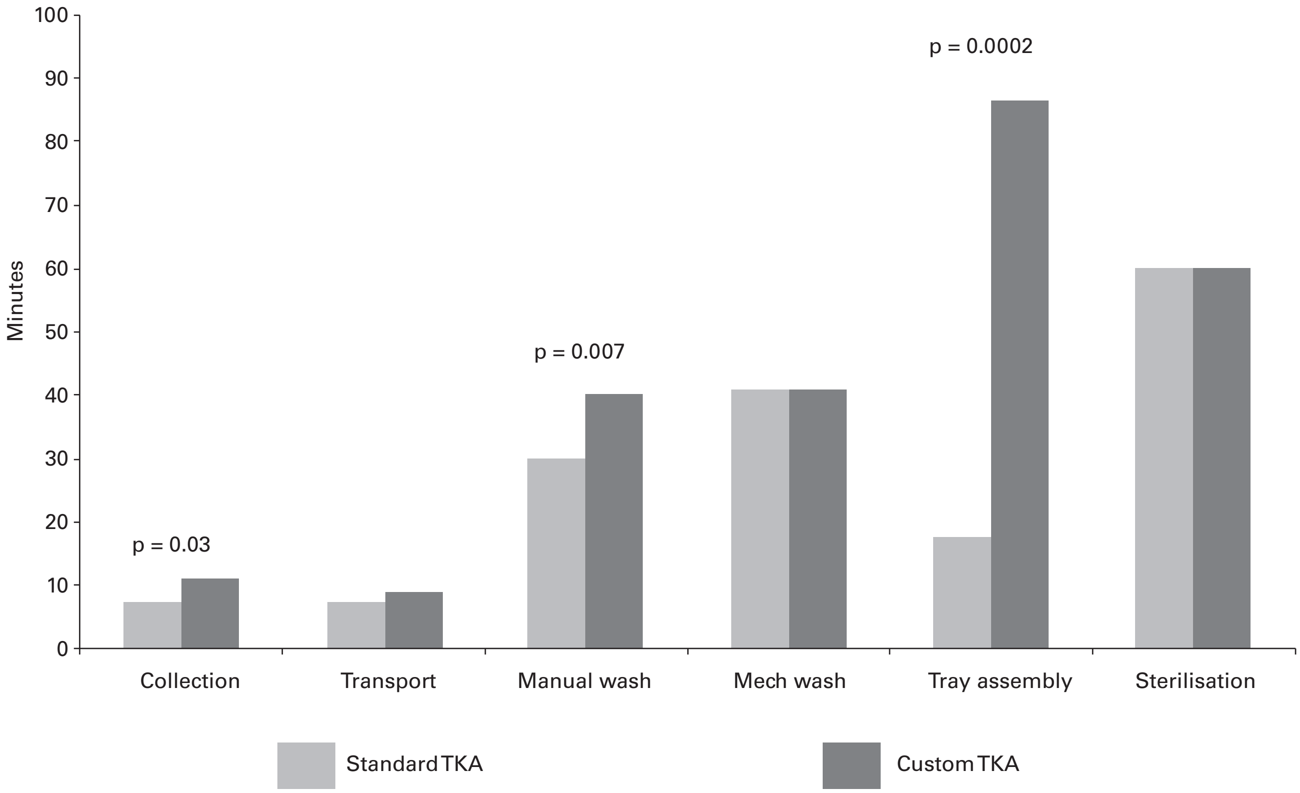

Fig. 6

Bar graph depicting the time difference between the standard instrumentation group and the custom cutting guide group for each step of the sterile processing cycle.

Managing the instrumentation for the custom cutting guide cases involved substantially less time for the sterile processing cycle for three of the six steps (Fig. 6). The total time savings of sterile processing was 90 minutes. Labor costs for assembling four trays and decontaminating seven trays per hour achieves a savings of $6.72 per tray. The materials and equipment costs include filters, locks, indicators, and the cost of the utilities, which is another $1.02 per tray for a total processing cost of $7.74 per tray. Due to the low cost of wages and materials, even with four fewer trays per case, this translates into a cost savings of only $30.96 per tray.

The savings associated with the 11 minutes of decreased total operative time translated into a cost savings of $201.37 per case, for a total savings of $322.23 per case in personnel, materials, and fixed hospital overhead costs. When this is subtracted from the cost of the cutting guide, the results is a net cost to the operating room of $627.77.

The cost associated with performing the MRI varied dramatically depending on whether the patient was on Medicare or privately insured. The average cost of the professional and technical component for Medicare was approximately $400 whereas that for private pay insured patients was approximately $1250, and approximately half of our patients were on Medicare. The cost of the custom cutting guide was approximately $950 per case. When the cost of the guide plus the cost of the scan were added, the total net cost per case was $1475.

Discussion

The ability of patient specific guides to increase accuracy of TKA has been variable with inconsistent results reported. In the hands of some developers and early adopters, improved alignment has been achieved with patient specific guides compared with standard instrumentation. Bugbee et al[8] did achieve a higher degree of accuracy with patient specific guides, but the absolute differences were only approximately 1°, which is a questionable clinical significance. Ng et al[9] substantially improved their percentage of outliers from 22% to 9%, which is similar to the improvement in avoiding outliers that they achieved with computer navigation. Conversely, Stronach et al[10] reported no improvement in overall alignment and frequently made corrections at the surgeon's judgment overwriting the guides. They made an average of 2.4 modifications per case (161 in 66 cases).

Cost analysis of patient specific instrumentation has also yielded variable results. A study by Watters et al[11] compared the cost of TKA utilising standard instrumentation *versus* computer navigation *versus* patient specific instrumentation. They analysed fixed, variable, direct, and indirect costs for 12 consecutive cases of each and also considered operating room time, tray processing cycle cost, and preparation and turnover time. Their savings in operative time with the patient specific instrumentation was 13 minutes, which was very similar to our report. Their estimated costs savings per tray, however, was $58.18, which is substantially higher than reported in our series. The difference may reflect the fact that at a large academic center, central supply processes a much higher number of instruments and trays and runs around the clock. Smaller centers are able to close down their operations at the end of a day and may be able to realise greater savings by finishing their cases earlier. In addition, at our center we converted to hard cases for instrument sterilisation which obviated the need to utilise a sterile wrap, saving personnel time and equipment costs per case by avoiding the need for wrapping trays.

There are limitations to this study. Scout CT methodology has not been standard methodology historically and while it has theoretical advantages, it could bias measurements in the coronal plane. The rotational alignment of the components cannot be determined and it is possible that improved rotational position of the femoral and/or tibial component may well be more important than the coronal plane alignment.[1] In addition, the lateral radiographs and sunrise view were not assessed. Also, clinical assessment of the patients' results was not objectively quantified utilising any outcome measures including patient satisfaction or range of motion.

The use of patient specific instrumentation did achieve modest savings through decreased costs of processing instruments and shorter total operative time. However, these savings were overwhelmed by the cost of the imaging and the guides themselves, which were approximately $1775 more per case than the savings achieved in operative time and instrument processing. Of greater concern was that we could demonstrate no improvement in coronal alignment in any of the three measures utilising standard scout CT methodology, which corrects for rotation.

In conclusion, we were unable to demonstrate an improvement in coronal plane alignment and there was a definite increase in total cost per case associated with utilising this technology. In the absence of a proven clinical or radiological advantage, while this technology may hold promise for the future, the current data shows that the value of this technology is yet to be proven, at least for the mechanical axis cutting block that was the subject of this investigation.

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One author (RMN) is a paid consultant for Smith & Nephew Orthopaedics, Wright Medical Technology Inc., Salient Surgical, and CardioMEMS.

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The authors have full control of all primary data and agree to allow the journal to review data if requested.Each author certifies that his or her institution has approval for this investigation and that all investigations were conducted in conformity with ethical principles of research. This work was performed at Washington University in St. Louis, Missouri.

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