Original article

Fallacies of CT based component size prediction in total knee arthroplasty – Are patient specific instruments the answer?

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ABSTRACT

Background: The purpose of the study was to assess the accuracy of tibial and femoral component size prediction using computerised tomography (CT) based patient specific instruments in total knee arthroplasty.

Methods: Eighty-eight knees in 58 patients underwent total knee arthroplasty (TKA) using CT based patient specific instruments between March 2015 to April 2016. All patients were assessed for the pre operative femoral and tibial component sizes predicted by the CT-based pre-operative plan. These sizes were compared with the actually implanted sizes during surgery, and the results were assessed. The data were evaluated using Wilcoxon signed rank tests, and p value set at <0.05 for significance.

Results: Approximately 72% predicted tibia sizes matched the final implanted sizes whereas 66% femoral implants matched their pre-operative predicted sizes. The difference in the tibial implant size was not statistically significant (p-value > 0.05). However, the difference in the femoral size was statistically significant (p-value 0.009). The downsizing of the tibial component was needed in 14.8% knees whereas upsizing was required in 13.6% of the knees. At the femoral side, 22.7% components required downsizing at the time of implantation as compared to 11.4% components wherein a bigger component was used.

Conclusions: We conclude that size prediction using CT-based technology for patient specific instrumentation is not fool proof. The size prediction accuracy for femoral and tibial components at 66% and 72% are low and cannot be relied upon at present. The patient specific technology using CT scan based jigs holds promise for the future, needs refining and fine tuning.

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1. Introduction

Recently, the number of TKAs being performed worldwide is on the rise. These surgeries are conducted on a regular basis by the specialist arthroplasty surgeons. The customized jigs were introduced to mainly improve the mechanical alignment and hence the overall satisfaction rates post surgery. The customized jig technique works on the premise that the surgeon is able to plan the surgery virtually and is able to predict the outcomes of his proposed femoral and tibial cuts. Prior templating, as done in customized jigs, becomes more important as it also helps in determining the use of non-standard implant, and anticipation of intraoperative deviations from the usual steps.^{1,2} Customized jigs not only offer the advantage of the pre-operative planning for the surgery but also offer several other advantages over conventional

instrumentation like reduced surgical time, decreased blood loss, efficient operating room management.^{3–6} Another less known potential advantage of using customized jigs is the possibility of prediction of implant size to be used during the surgery.

Previously pre operative templating using digital and analog techniques were used for size determination in a conventional TKA.^{1–3,7} There are studies to determine the accuracy of templating, using analog and digital radiographs, in the primary hip and knee arthroplasty surgery. However, these studies show variations in the size predicted, and the sizes used and have used radiographs for templating.^{7,8} We undertook this study to assess the accuracy of prediction of implant sizes using customized jigs prepared using patient's preoperative CT scan. We hypothesized that the femoral, as well as tibial size prediction using the CT based customized blocks, was accurate.

2. Materials and methods

The study included 88 knees in 58 patients (39 females and 19 males) who had undergone TKA using Computed Tomography (CT)

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Fig. 1. Antero-posterior (AP) and medio-lateral (ML) pre-operative templating of the femur on 3D reconstructed model. Fig. 1a represents the AP templating of the femur and matching the size to avoid anterior notching and match the posterior proposed cut. Fig. 1b represents ML templating of the femur to avoid any medial overhang.

based customized jigs (Preplan™, Stryker) between March 2015 to April 2016. Out of a total of 58 patients, 30 patients underwent simultaneous bilateral TKA, and the remaining 28 cases underwent unilateral TKA. All the patients were explained regarding the procedure of CT scan, preoperative planning and the use of customized blocks. After a written informed consent, these patients were included in the survey. These patients were informed about the patient specific instruments, its possible advantages and disadvantages over the conventional method. Of these 88 cases, 21 cases had a history of replacement done on the opposite side using the conventional technique. None of the patients had any surgical intervention done on the knee which was included in the present study.

All the patients underwent cemented TKA using CT-based customized jigs (Scorpio Non-Restricted Geometry, NRG™, Stryker). The senior author performed all of the surgeries using the modified Insall exposure of the knee. Custom jigs were prepared in the research and development laboratory of a single company (Preplan™, Stryker). All the patients had undergone preoperative CT scans from the hip, knee to the ankle (HKA), which is according to the preoperative planning protocol. The CT scan was run on Toshiba CT Aquilion Prime 160 slice machine. The bone cuts were done at 3 mm at the hip and ankle. The CT scans were done at 1 mm increment at the knee and at 3 mm increase at the hip and ankle. The field of view at all the sites was kept as 30–35 cm. Particular care was taken while performing the CT scan to avoid any movement of the patient as any movement while the CT scan was being done would lead to the erroneous calculation of the mechanical axis. The studies of the CT scans of each patient were then sent to the jig manufacturing unit, where they used this information to construct a 3-D model of the arthritic knee. This was done using specially made software which analyses the anatomical landmarks and the surgeon's opinion regarding the rotation, alignment and the extra femoral resection that is needed, keeping in mind the preoperative flexion contracture if any. The design of the customized jigs was based on the mechanical axis and preoperative osteophytes so as to obtain a well-fitting jig. The software was also used to predict the sizes of femoral and tibial components based on the preoperative CT scan. Following this pre operative templating plan was forwarded to the operating surgeon.

The results of the postoperative limb alignment were also assessed, and the mean postoperative MFT angle measured on long-leg radiographs was 178.23° (SD = 2.67°, range: 176.9° to 182.5°).⁹

The CT scan images were also used to match the sizes of the component on the 3D reconstructed images of the femur and tibia, and the most likely size which would be implanted was also proposed (Figs. 1 and 2).

The ideal size of the components for the femur was decided after aligning along the trans-epicondylar axis and measuring the posterior femoral cut. As the thickness of the femoral component is 8 mm, the ideal component size was chosen which gave an 8 mm cut of the posterior condyles. This size was again counter-checked for notching and medial overhang (overhang should not be more than 2 mm). The ideal femoral size which gave 8 mm posterior cut, avoided anterior notching and gave minimum medial and lateral overhang was chosen. At the tibial side, the AP axis was defined from the posterior cruciate ligament footprint and the medial third of the tibial tuberosity. The ideal implant was calculated which minimized the component overhang while providing maximum bony coverage on the tibia. The tibial component was again counter checked for compatibility with the femoral component. After the decision for the bone cuts and the predicted sizes was made, the pre-operative plan was sent to the primary surgeon for approval.

Fig. 2. Sagittal pre-operative templating of the tibia on 3D reconstructed model and matching the tibial cut surface anatomy and adjusting the base plate based on the medial one-third of the tibial tuberosity and the PCL footprint.

Table 1

Component sizes predicted and used in the study. (Negative means component implanted was smaller than predicted, positive means component implanted was greater than predicted).

	-2	-1	0	1	2	3
Tibia	4 (4.55%)	8 (9.09%)	63 (71.59%)	3 (3.40%)	10 (11.36%)	0
Femur	5 (5.68%)	5 (5.68%)	58 (65.91%)	4 (4.55%)	12 (13.63%)	4 (4.55%)

The surgeon made changes, if any, in the proposed cuts as well in the predicted sizes and approved the plan for manufacturing the jigs. Whenever there was a difference between the predicted sizes of the technician and the surgeon, the surgeon predicted sizes were considered ideal.

The predicted size using the software was matched with the final implanted size and the data checked for statistical significance. The statistical significance was calculated on the basis of the total number of components which deviated from the actual sizes (irrespective of being under- or over-predicted). The data were analyzed, and results were listed in Microsoft Office Excel worksheet, and descriptive statistics were given as means or median. All categorical variables were expressed as frequencies and percentages.

Wilcoxon-signed ranks test was used to verify the significance of difference of predicted and observed value of tibia and femur. Statistical software SPSS version 22.0 and R-3.2.0 was used for all the statistical tests. For all statistical analysis, a p-value less than 0.05 were taken to indicate a significant difference.

3. Results

The average age of the patient population was 60.5 years. On matching the high flex knee system (Scorpio NRG), for the predicted size and the implanted size, it showed the more accurate prediction of the size for the tibia than for the femur. None of the preoperative plans were changed by the author as all the plans had fallen into neutral coronal mechanical axis. None of the femoral as well as tibial cuts needed to be re-taken, intra-operatively. Approximately 72% predicted tibia sizes matched the final inserted sizes whereas 66% femoral implants matched their pre-operative predicted sizes (Table 1). The difference in the tibial implant size was not statistically significant (p-value 0.825) (Fig. 3). However, the difference in the femoral size was statistically significant (p-value 0.009) (Fig. 4). The customized jig sizing was, therefore, more accurate for the tibial sizing (p value 0.825) as compared to the femoral sizing (p value 0.009). The downsizing of the tibial component was needed in 14.8% knees whereas upsizing was required in 13.6% of the knees. At the femoral side, 22.7%

components required downsizing at the time of implantation as compared to 11.4% components wherein a bigger component was used (Fig. 5).

4. Discussion

The usefulness of preoperative planning in a case of TKA has been widely accepted, but the choice of technology (either digital templating or custom jig based) for determination of femoral and tibial implant size has not been extensively studied.¹⁰ The custom jigs were introduced with the goal of improving postoperative mechanical alignment.¹¹ Apart from the possibility of achieving improved alignment, there are other potential advantages of custom jigs like decreased blood loss and decreased instrument requirement.⁹ There could be another potential advantage of custom jigs, to determine the implant sizes pre-operatively, has been largely unexplored. Hence, we undertook this study to determine the usefulness and the accuracy of the femoral and tibial component size prediction using a CT-based custom jig technique (Preplan™, Stryker).

Our results suggested that an approximately 72% of the predicted sizes were correct in the tibia, and 66% on the femoral side. There was no statistical difference (p-value 0.825) between the predicted and implanted tibial sizes whereas the femoral implant showed a statistically significant difference (p-value 0.009) in the predicted and final sizes. A downsizing of the tibial component was required in 14.8% (13 knees), whereas, in 13.6% (12 knees), the tibial size was upsized during surgery. The changes needed during the procedure from the predicted sizes were more in the femoral components as compared to the tibial components. 12.4% (10 cases) required upsizing of the femoral components and 22.7% (20 cases) the final implant component was downsized. The component size of the tibia is based purely on the anatomical fit of the plate on the cut surface of the tibia. In the femur, the sizes may vary on the basis of the antero-posterior as well as medio-lateral diameter of the distal femur. The increased number of variables on which the femoral sizing depends could explain the decreased accuracy of the CT scan based component size prediction of the femur as compared to the tibia.

Traditionally templating was used for size determination in TKA. Many studies have demonstrated the differences between the analog and digital templating technique for TKA.^{2,7} Some of the studies have shown that digital templating is better while the other studies indicate that there is no significant difference between the two or if digital was less accurate than routine templating.⁷ There are several benefits of preoperative templating of the femur and tibia for sizing in TKA. Preoperative templating

Fig. 3. Cross plot depicting the distribution of the correctly as well as the under- and over-predicted tibial sizes.

Fig. 4. Cross plot depicting the distribution of the femoral component sizes used in surgery.

Fig. 5. Frequency distribution (in percentage) for the correctly predicted as well as under- and over-predicted sizes on the femoral as well as tibial side.

can also contribute to decreasing the armamentarium of the tibial and femoral implants which are required in the operating room (OR) by determining the size which may be needed.^{12,13} This can assist in minimizing the OR traffic, which is one of the prime concerns of an arthroplasty set up. Also, this can have a bearing in small volume arthroplasty setups, where the whole gamut of the available tibial and femoral component sizes is not available. These centers can stack the necessary sizes of the components as decided by the pre-operative templating and hence reduce the added cost of transportation and storage of components which are highly unlikely to be used. Moreover, it can help the surgeon to define the need for any unique inventory to address the unusual sizes of femoral or tibial components. The correct size insertion is also of paramount importance for proper biomechanics of the knee. A change in the size of the femoral component affects the flexion gap. Moreover, an oversized implant can lead to soft tissue irritation whereas an undersized implant leads to increased stress at the cement-implant interface and implant loosening.¹⁴

Another advantage of pre-operative planning using CT-based custom jigs is that the pre-operative plan can be shared and discussed with the other members of the team and with the OR staff for better OR planning and efficiency. This can be of particular help in high-volume arthroplasty set up wherein such planning can improve surgical workflow.^{2,15}

Custom jigs and the preoperative planning can also assist in reducing the number of trays which are needed during the surgery. Since the prior determination of the implant size can help in reducing the number of trials required during the surgery, it may have an impact on reducing the cost of operation by reducing the number of trays which need autoclaving.¹⁶ This aspect of the size prediction would, however, need a cost analysis study and is an area open for future research.

The accuracy of customized jigs for prediction of TKA component sizes has not been validated well in the existing literature. We had evaluated the efficacy of CT-based customized jigs and NRG (Stryker™) knee system for performing surgeries in

Table 2
Accuracy of component size prediction in various studies.

Authors	Year	Scanning modality	Accuracy in femoral sizing	Accuracy in tibial sizing
Lustig et al.	2013	MRI based	52%	50%
Koch et al.	2013	CT based	98%	89.2%
Stronch et al.	2014	MRI based	23%	47%
Andrzej Kotelu et al.	2015	CT based	89.8%	75.5%
Our Study	2016	CT based	66%	72%

all TKAs. We found out that the component size prediction for the tibia was more accurate as compared to the femur.

There are only a few published studies of prediction of component sizing preoperatively, using either CT or MRI based technology (Table 2). Kotelu et al. found a high correlation between planned size of the prosthetic size of the prosthetic implants and those used, the difference being 10.2% and 24.5% for femoral and tibial component respectively.¹⁶ Koch et al. studied 301 TKAs that used CT-based Mcknee PSI, in which the pre-planned sizes were changed in only 10.8% of total 602 implanted components.¹⁷ The femoral component had to be downsized in 5 cases and upsized in 7 cases (12 cases in total). The tibial component was downsized in 27 cases and upsized in 26 cases (total of 53 cases). Stronch et al. had used an MRI-based technique and found that the correct component, sizes were seen in only 23% of the femur and 47% of the tibia.¹⁸ Similarly, Lustig et al. using MRI-based Visionaire PSI found matching in 52% of the femoral and 50% of tibial components.¹⁹ They reported downsizing in 28.3% and 23.3% of femur and tibia respectively. We have found mixed results using CT-based technology as our tibial size prediction was statistically correct, but the femoral matching was inferior. From the available published data, it seems that a pre-operative prediction of sizes is variable. It is further debatable whether the CT based patient specific technology is better to the MRI based technology in size prediction.

Recently, a study published by Schotanus et al. concluded that the accuracy of component size prediction improved when the preoperative sizes were determined by the operating surgeon.²⁰ The majority of the procedures done by the specialists in the study were done using MRI based patient specific jigs. Similarly, most of the studies which have investigated the component size prediction in TKA have used MRI based or 2-dimensional templating.^{1,12,15,18,20,21} The possible reason for the higher accuracy achieved by the authors as compared to the present study could be the difference in the technique used for jig manufacturing (MRI versus CT). It has been predicted that the CT based jigs may not be able to delineate the cartilage and also have a tendency to magnify the knee sizes predicted as compared to the MRI based jigs.²² Despite the potential disadvantages associated with the CT based jigs for size prediction, they are widely used for their decreased costs, minimal contraindications as compared to MRI. The final verdict on the accuracy of the MRI based as compared to CT based templating would require further research and better comparative studies.

This study has both its strengths and limitations. The strength is that the approval of pre operative analyzed data and the surgeries were done by a single surgeon, and thus there was no scope for interobserver variations. There are some limitations of this study, firstly it was a single center study with a limited number of cases. For further validation of the results, a larger sample size is needed. Moreover, the main quoted disadvantage of the PSI is an extra cost that the patient has to bear (\$1700 US), a waiting period for the planning and production of the jigs (up to six weeks) and the increased radiation exposure when compared to traditional X-rays. However, in our setup, we were able to get the jigs in an approximate period of 5 working days only, and the cost of manufacturing of the jigs had come down to \$400.¹³ It could be achieved due to the availability of the engineering and jig manufacturing facilities locally. We believe that the time of procurement of jigs, waiting period and the cost could be further brought down if the image analysis and production of the jigs are done locally at more centers.

The implant used in the present study (NRG™ Scorpio) had multiple options of implant sizes available to the surgeon. The choices of the implant sizes accessible to the surgeon vary with the system used, and this can have a bearing on the correlation of the

predicted and implanted sizes. This discrepancy can further upset the statistics of prediction of the component sizing.

5. Conclusion

This study reveals that at present the CT based technology of predicting sizes of prosthetic components used in TKA is not fool proof. The tibial component size prediction is better than that of the femoral side. Since the present technology is not still highly accurate, as far as component size prediction is concerned, and is associated with additional cost and utilization of manpower, it cannot be recommended or relied upon for routine use for component size prediction in TKA.

Conflict of interest

The authors declare that they have no conflict of interest.

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Ethical approval

Prior hospital ethical committee approval was taken before undertaking this study.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Author contributions

RV – helped in the conceptualization of the study and helped in the preparation and review of the manuscript.

MK – was one of the principal investigators. He helped in the collection of data, statistical analysis, preparation and review of the manuscript.

VV – was one of the principal investigators. He helped in the collection of data, statistical analysis, preparation and review of the manuscript.

AKA – helped in the preparation and review of the manuscript.

References

- Hsu AR, Kim JD, Bhatia S, Levine BR. Effect of training level on accuracy of digital templating in primary total knee arthroplasty. *Orthopedics*. 2012;35(2): e179–83. doi:10.3928/01477447-20120123-15.
- Specht LM, Levitz S, Iorio R, Healy WI, Tilzey JF. A comparison of acetate and digital templating for total knee arthroplasty. *Clin Orthop Relat Res*. 2007;464:179–183.
- Hafez MA, Chelule KL, Seedhom BB, et al. Computer-assisted total knee arthroplasty using patient-specific templating. *Clin Orthop Relat Res*. 2006;444:184–192. doi:10.1097/01.blo.0000201148.06454.ef.
- Harrysson OL, Hosni YA, Nayfeh JF. Custom-designed orthopedic implants evaluated using finite element analysis of patient-specific computed tomography data: femoral-component case study. *BMC Musculoskelet Disord*. 2007;8:9110.1186/1471-2474-8-91.
- Lombardi Jr. AV Jr., Berend KR, Adams JB. Patient-specific approach in total knee arthroplasty. *Orthopedics*. 2008;31(9):927–930.
- Spencer BA, Mont MA, McGrath MS, et al. Initial experience with custom-fit total knee replacement: intra-operative events and long-leg coronal alignment. *Int Orthop*. 2009;33(6):1571–1575. doi:10.1007/s00264-008-0693-x.
- The B, Dierckx RL, van Ooijen PMA, van Horn JR. Comparison of analog and digital preoperative planning in total hips and knee arthroplasties: a prospective study of 173 hips and 65 total knees. *Acta Orthop*. 2005;76(1):78–84. doi:10.1080/00016470510030364.
- Heel J, Blewett N. Kinemax total knee arthroplasty, trial by template. *J Arthroplasty*. 2002;17(1):90–94.
- Vaishya R, Vijay V, Birla V, Agarwal AK. Computerized tomography based patient specific blocks improve postoperative mechanical alignment in

- primary total knee arthroplasty. *World J Orthop.* 2015;7(7):426–433.10.5312/wjo.v7.i7.426.
10. Peek AC, Bloch B, Auld J. How useful is templating for total knee replacement component sizing? *Knee.* 2012;19(4):266–269.10.1016/j.knee.2011.03.010.
 11. Miller AG, Purtill JJ. Accuracy of digital templating in total knee arthroplasty. *Am J Orthop (Belle Mead NJ).* 2012;41(11):510–512.
 - [12]. Hernandez-Vaquero D, Abat F, Sarasquete J, Monllau JC. Reliability of preoperative measurement with standardized templating in total knee arthroplasty. *World J Orthop.* 2013;4(4):287–290.10.5312/wjo.v4.i4.287.
 13. Hitt K, Shurman JR, Greene K, et al. Anthropometric measurements of the human knee: correlation to the sizing of current knee arthroplasty systems. *J Bone Joint Surg Am.* 2003;85-A(Suppl. 4):115–122.
 14. Levine B, Fabi D, Deirmengian C. Digital templating in primary total hip and knee arthroplasty. *Orthopedics.* 2010;33(11):797.10.3928/01477447-20100924-04.
 15. Kotela A, Lorkowski J, et al. Patient specific CT-based instrumentation versus conventional instrumentation in total knee arthroplasty: a prospective randomized controlled study on clinical outcomes and in hospital data. *Biomed Res Int.* 2015;2015:165908.10.1155/2015/165908.
 - [16]. Koch PP, Müller D, Pisan M, Fucntese SF. Radiographic accuracy in TKA with a CT-based patient-specific cutting block technique. *Knee Surg Sports Traumatol Arthrosc.* 2013;21(10):2200–2205.10.1007/s00167-013-2625-6.
 17. Stronach BM, Pelt CE, Erickson JA, et al. Patient specific instrumentation in total knee arthroplasty provides no improvement in component alignment. *J Arthroplasty.* 2014;29(9):1705–1708.10.1016/j.arth.2014.04.025.
 18. Lustig S, Scholes CJ, Oussedik S, Coolican MR, Parker DA. Unsatisfactory accuracy as determined by computer navigation of VISIONAIRE patient specific instrumentation for total knee arthroplasty. *J Arthroplasty.* 2013;28(3):469–473.10.1016/j.arth.2012.07.012.
 19. Schotanus MG, Schoenmakers DA, Sollié R, Kort NP. Patient-specific instruments for total knee arthroplasty can accurately predict the component size as used peroperative. *Knee Surg Sports Traumatol Arthrosc.* 2016;10.1007/s00167-016-4345-1.
 20. Boonen B, Schrandt DE, Schotanus MGM, et al. Patient specific guides in total knee arthroplasty: a two year follow up of the first two hundred consecutive cases performed by a single surgeon. *JCRMM.* 2015;1:1–10.
 21. Rubin LE, Murgo KT. Brief report: total knee arthroplasty performed with patient-specific, pre-operative CT-guided navigation. *R I Med J.* 2013;96(3):34–37.