RESEARCH ARTICLE

RETRACTED: Enhanced conventional method is as precise as navigation for distal femur resection during total knee replacement: a randomized controlled trial [version 1; peer review: 1 approved with reservations]

Rohan Bhimani<sup>1,2</sup>, Fardeen Bhimani<sup>3</sup>, Rohan Bir Singh<sup>4</sup>, Preeti Singh<sup>1,5</sup>

<sup>1</sup>Department of Medicine, Beth Israel Deaconess Medical Center, Boston, MA, 02115, USA
<sup>2</sup>Department of Orthopedics, Hinduja Healthcare Surgicals, Mumbai, Maharashtra, 400052, India
<sup>3</sup>Department of Orthopedics, Bharati Hospital, Pune, Maharashtra, 411043, India
<sup>4</sup>Government Medical College and Hospital, Chandigarh, Chandigarh, 160036, India
<sup>5</sup>Department of Orthopedics, Osmania General Hospital, Hyderabad, Telangana, 500012, India

Retraction

At the request of authors Rohan Bhimani, Fardeen Bhimani, Rohan Bir Singh, and Preeti Singh, the article titled “Enhanced conventional method is as precise as navigation for distal femur resection during total knee replacement: a randomized controlled trial [version 1; peer review: 1 approved with reservations]” (doi: https://doi.org/10.12688/f1000research.18154.1) has been retracted from F1000Research.

Since publication, it has come to the attention of the authors that the data collected for the two trial groups were combined; therefore, the study findings and conclusions cannot be relied upon. The authors apologise for this honest error.

F1000Research also became aware that the clinical trial registration data were obscured due to this error. Please note that this is not standard practice. The editorial office have appealed to both the authors and the UMIN Clinical Trials Registry to restore these data in order to maintain the integrity of the scientific record.

7th June 2019: The retraction notice has been updated to accurately reflect the status of the associated clinical trial registry.

Abstract

Introduction: The purpose of this prospective study was to determine the accuracy of distal femoral cut and femoral component placement in the coronal plane with the enhanced conventional technique when compared to computer navigation during total knee replacement (TKR).
Methods: In total, 475 total knee arthroplasties (TKA) were analyzed (200 optimized conventional TKAs and 275 navigated TKAs) for postoperative mechanical alignment or hip-knee-ankle angle and femoral component coronal alignment and compared between the two groups.

Results: Mean femoral component coronal alignment was not significantly different (p=0.35) when navigation and enhanced conventional groups were compared. There was no significant difference in the mean femoral component coronal alignment between knees with a valgus correction angle (VCA) <5° (p=0.28), knees with VCA 5°-7° (p=0.48) and knees with >7° (p=0.09). No significant difference was noted in the mean femoral component coronal alignment between knees with varus deformity <10° (p=0.19), varus deformity 10°-20° (p=0.72) and valgus deformity (p=0.35).

Conclusions: Using the enhanced conventional technique in each patient to perform distal femoral cut during total knee arthroplasty can help achieve the coronal alignment of the femoral component comparable to navigation technique.

Registration: UMIN-CTR ID UMIN000036204.

Keywords
distal femur, total knee arthroplasty, valgus cut, computer navigated arthroplasty, alignment, conventional knee arthroplasty
Introduction

The survival of implants used during total knee replacement (TKR) is influenced by many factors, such as precision of bone cuts, accurate positioning of the component, and soft tissue balancing during surgery\textsuperscript{3,4}. Malpositioning of the component during the surgery can result in early failure of TKR due to early polyethylene wear and aseptic loosening\textsuperscript{5-7}. Throughout TKR, the goal is to align within ±3° of neutral with regard to their mechanical axis, both femoral and tibial components, to aid equal dispersal of forces across the implant post-operatively. As the anatomical and mechanical axes of the femur are not coincident, a distal femoral cut is accomplished by resecting the distal femur perpendicular to the coronal femoral mechanical axis using the valgus correction angle (VCA) which is equivalent to the angle formed between the mechanical and anatomical axis of the femur\textsuperscript{8,9}. The different techniques of performing the distal femoral cut using the VCA include taking a 5°–7° fixed VCA for all cases, measuring VCA on preoperative scanogram (i.e. measuring angle between the mechanical and anatomical axis on a full-length, standing, hip-to-ankle radiograph), and with a computeraided navigation system. Regular practice for the surgeon is to reference the distal femoral cut using an extramedullary rod for the anatomical axis using a fixed VCA range of 5°–7°. Nevertheless, numerous studies have shown a wide variation in VCA in patients undergoing TKR, where it can range between 2°–13° and use of a fixed VCA range can result in miscalculation in distal femur cut and malalignment of the femoral component\textsuperscript{9,11}. Thus, it is suggested that VCA should be modified in each patient by measuring it on scanogram. Computer navigation aids the surgeon in femoral component alignment perpendicular to the mechanical axis in the coronal plane without depending on the VCA and to overcome any disparity between the anatomical and mechanical axis of femur. Previous studies found that modified VCA results in more precise positioning of the femoral component in the coronal plane in comparison to utilizing a fixed distal VCA\textsuperscript{9,13}. However, these past studies are unclear on the precision of femoral component placement using the VCA technique modified in respect to each patient when compared to computer navigation during TKR.

To our knowledge, no study has been undertaken which aimed to determine the precision of cut for distal femur and femoral component placement in the coronal plane with the enhanced conventional technique when compared to computer navigation during TKR. We hypothesised that the enhanced conventional technique will be as precise as computer navigation in carrying out the distal cut for femur during TKR.

Methods

Recruitment, eligibility and allocation

We prospectively included 475 consecutive, primary TKRs from August 2016 to July 2017. The inclusion criteria included patients who underwent primary TKR for tricompartmental knee arthritis and provided their informed consent for participation in this study. The exclusion criteria included patients with inappropriate quality of pre- or post-operative radiographs, patients whose radiographs were unavailable for evaluation and patients who were lost in follow-up. All surgeries were performed by a single surgeon. We randomized 475 patients into enhanced conventional or navigated TKR group. The randomization was performed on the day of the surgery from a set of two envelopes with computer navigation and conventional techniques mentioned in each of them. The envelope was placed randomly by a junior resident on the day of the surgery and it was conveyed to the surgeon on the type of technique (enhanced conventional vs. computer navigation) selected for the patient. There were no changes in methods after commencement of the trial. Out of 475 TKRs, 200 patients underwent total knee arthroplasties in the enhanced conventional group and 275 patients underwent total knee arthroplasties in the computer navigation group. There were 455 varus knees and 20 valgus knees in the study. The sample size was calculated to give a 95% confidence interval and 4.5% margin of error. This gave us a sample size of 464. We decided to include 475 patients to allow for any dropouts. However, there were no dropouts.

Ethical considerations

The study was approved by the Ethics Committee of Hinduja Healthcare Surgicals (Approval Number: HHS/16-17/EC/091) and conducted according to the guidelines of the Declaration of Helsinki. Written informed consent was obtained from all patients.

Imaging

Weight-bearing, full-length, hip-to-ankle radiographs (scanogram) were obtained before and within 4 weeks after surgery. The postoperative scanograms were all acquired using standard radiographic techniques with both patellae facing forward, knees in complete extension, and both feet pointing forwards to avoid malrotation of the limb during scanogram. All scanograms were screened by one of the authors for any malrotation in the coronal plane, which made it inappropriate for the study. Excessive rotation in the coronal plane was measured on radiographs not only by the position of the lesser trochanter and head of the fibula, but also the position of the patella in terms of central, medial or lateral positioning. Digital pictures of the scanogram were utilized for measurement of several radiographic

Editorial note:

Since publication the authors have alerted the F1000Research editorial office to disagreements regarding author contributions to the study and the interpretation of results. All editorial activity has been suspended pending further investigation. Further action will be dependent on the outcome of these discussions.
factors using ImageJ image processing and analysis software (version 1.41, U.S. National Institute of Health). Scanogram factors measured included pre- and post-operative coronal limb alignment also known as hip-knee-ankle (HKA) angle described as the angle between the femoral mechanical axis (i.e. line joining the center of the femoral head and center of the knee joint) and the tibial mechanical axis (i.e. line joining the center of the knee joint and center of the ankle joint), the distal femoral valgus correction angle (VCA), defined as the angle between the femoral anatomical and mechanical axis (i.e. the mid-medullary axis of the distal diaphysis of the femur), and the post-operative femoral component coronal alignment (described as the medial angle between the femoral mechanical axis and the line tangential to the prosthetic femoral condyles). All measurements on scanogram were performed independently by two authors who were unaware of the technique used by the operating surgeon.

Surgical procedures

All surgeries were carried out with a tourniquet and after the cementing of the implant, the tourniquet was deflated and haemostasis was achieved by electrocautery. A polyethylene liner then was inserted followed by layered closure of the wound. There was an interval of approximately 40 to 50 minutes between tourniquet deflation and conclusion of surgery. The tourniquet was deflated when the cement hardened. A standard medial parapatellar arthroscopy approach was used in all cases. A cemented, posterior-stabilized, fixed-bearing implant, PFC®Sigma series of total knee prostheses (DePuy Ortho-paedics Inc, Warsaw, IN, USA) with patellar resurfacing was performed in all patients. The cutting blocks used for carrying out all bony resection in both the groups were identical. The purpose was to achieve a coronal mechanical axis of the limb in the range of 180° ±3° and place the femoral component perpendicular to the femoral mechanical axis ±1°. The amount of soft tissue release was based on the amount of soft tissue tightness assessed using spacer and an appropriate amount of soft tissue release was allowed.

In the computer navigation-assisted total knee group, registration of the anatomic landmarks was performed in standard fashion using the Ci Navigation System with accompanying software (Brain Lab, Munich, Germany). The coronal mechanical axis of the lower limb in the coronal plane was derived by navigation using the center of femoral head, the center of the intercondylar notch, centre of the tibial plateau and the center of the ankle palpion. The navigation system arrays also aided in positioning the cutting blocks and verified and quantified the distal femoral cut.

In the enhanced conventional TKR group, preoperative scanograms were used to measure VCA in each knee which in turn assisted to customize the coronal plane of distal femoral resection in each patient. Therefore, if the VCA on the scanogram was measured, for example as 7°, the distal femoral resection guide was set at 7° valgus, so as to accomplish a distal femoral cut perpendicular to the femoral mechanical axis. After the patient was under anaesthesia, an image intensifier was used to recognize the centre of the head of femur and an adhesive radio-opaque marker was placed in the groin over the approximate center of the head of femur. Intra-operatively, an extra-medullary rod was attached to the cutting block to determine the accuracy of the distal femoral resection with reference to the previously placed femoral head centre served by the radio-opaque marker.

Statistical analysis

Statistical analysis was performed using Stata® 8.2 software. Data from the two groups of patients were compared using Student’s t-test and Fisher exact test. The significance level used for all tests was p ≤ 0.05.

Results

There was no significant difference between demographic parameters in the conventional and navigation groups (Table 1). The mean femoral component coronal alignment was not significantly different (p=0.35) when navigation and optimized conventional groups were compared (Table 2). No harms were observed during this study. Raw data are available on Harvard Dataverse.

Table 1. Comparison of demographic parameters between the enhanced conventional and navigation groups. All values presented as mean ± standard deviation.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Conventional</th>
<th>Navigation</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>200</td>
<td>275</td>
<td>-</td>
</tr>
<tr>
<td>Male/Female ratio</td>
<td>47/153</td>
<td>65/210</td>
<td>0.79</td>
</tr>
<tr>
<td>Age (years)</td>
<td>64.9±8.2</td>
<td>64.7±9.1</td>
<td>0.68</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>29.1±4.1</td>
<td>29.3±5.2</td>
<td>0.51</td>
</tr>
<tr>
<td>Varus/Valgus knees</td>
<td>190/10</td>
<td>265/10</td>
<td>0.07</td>
</tr>
<tr>
<td>Mean preoperative deformity</td>
<td>167.1±10.4</td>
<td>166.9±8.7</td>
<td>0.31</td>
</tr>
</tbody>
</table>

BMI, body mass index; n, number of knees.
Table 2. Radiographic measurements in the enhanced conventional and navigation groups. All values presented as mean ± standard deviation.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Conventional</th>
<th>Navigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>200</td>
<td>275</td>
</tr>
<tr>
<td>VCA (degrees)</td>
<td>7.2±1.6 (3-13)</td>
<td>6.9±1.9 (2-13)</td>
</tr>
<tr>
<td>Mean Preoperative HKA angle (degrees)</td>
<td>167.1±10.4 (125.8-212)</td>
<td>166.9±8.7 (138.4-205.9)</td>
</tr>
<tr>
<td>Mean Postoperative HKA angle (degrees)</td>
<td>178.6±2.4 (162-185.6)</td>
<td>179.4±1.4 (175-183.9)</td>
</tr>
<tr>
<td>Mean Femoral component coronal alignment (degrees)</td>
<td>89.4±1.7 (82.4-94.1)</td>
<td>89.5±2.0 (80.1-96.1)</td>
</tr>
</tbody>
</table>

VCA, distal femur valgus correction angle; HKA, hip-knee-ankle.

Table 3. Femoral component coronal alignment in conventional and navigation groups based on valgus correction angle (VCA). All values presented as mean ± standard deviation.

<table>
<thead>
<tr>
<th>VCA sub-groups</th>
<th>Conventional</th>
<th>Navigation</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>Mean femoral component coronal alignment (degrees)</td>
<td>Mean femoral component coronal alignment (degrees)</td>
<td></td>
</tr>
<tr>
<td>&lt;5°</td>
<td>18</td>
<td>89.4±1.2</td>
<td>25</td>
</tr>
<tr>
<td>5°–7°</td>
<td>111</td>
<td>89.7±2.3</td>
<td>186</td>
</tr>
<tr>
<td>&gt;7°</td>
<td>71</td>
<td>89.2±1.9</td>
<td>64</td>
</tr>
</tbody>
</table>

Table 4. Femoral component coronal alignment in conventional and navigation groups based on preoperative hip-knee-ankle (HKA) angle. All values presented as mean ± standard deviation.

<table>
<thead>
<tr>
<th>Preoperative HKA sub-groups</th>
<th>Conventional</th>
<th>Navigation</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>Mean femoral component coronal alignment (degrees)</td>
<td>Mean femoral component coronal alignment (degrees)</td>
<td></td>
</tr>
<tr>
<td>&lt;10° Varus</td>
<td>51</td>
<td>88.9±2.4</td>
<td>85</td>
</tr>
<tr>
<td>10°–20° Varus</td>
<td>103</td>
<td>89.5±1.8</td>
<td>151</td>
</tr>
<tr>
<td>&gt;20° Varus</td>
<td>36</td>
<td>90.3±1.5</td>
<td>29</td>
</tr>
<tr>
<td>Valgus</td>
<td>10</td>
<td>90.1±2.2</td>
<td>10</td>
</tr>
</tbody>
</table>

deformity <10° (p=0.19), varus deformity 10°–20° (p=0.72) and valgus deformity (p=0.35). However, knees with varus deformity >20° showed significant (p=0.003) differences in the mean femoral component coronal alignment between the two groups.

The restoration of the coronal mechanical alignment was significantly more accurate (p <0.0001) in terms of mean postoperative HKA angle in the navigation group than the optimized conventional group.

Discussion

The key outcome of this study was that the mean femoral component coronal alignment was not significantly different when enhanced conventional and navigation groups were compared. Thus, our study found an enhanced conventional technique using modified VCA in each patient and the extramedullary guide rod is as accurate as computer navigation in performing distal cut for the femur during TKR.

In a meta-analysis of 29 studies comparing computer-assisted TKR to conventional TKR, Mason et al.15 found that 90.4% of computer-assisted TKRs had femoral component positioning within 2° of perpendicular to the mechanical axis, as opposed to 65.9% in the conventional total knee arthroplasty group. However, the majority of such studies in the literature8–10 comparing conventional and navigated TKRs used a fixed VCA range of 5°–7° and have not modified VCA in each patient.
during total knee arthroplasty, which may be the reason for accurateness of conventional technique in distal femoral resection being inferior to computer navigation method. Palanisami et al. in a prospective study described substantial enhancement in both femoral component placement and postoperative alignment when VCA was modified in each patient when matched to taking a fixed VCA of 5° in patients with moderate and severe varus deformity. Shi et al., in a randomized prospective study, stated that 83.6% of knees with femoral component alignment within ±3° of the mechanical axis of femur were in the customized VCA group compared to 39.4% in the knees with fixed VCA group.

The VCA demonstrates extensive deviation among knees, especially those accompanied with extra- articular deformities such as excessive coronal bowing of the femur or significant varus deformities. Using a fixed VCA range of 5°–7° in these patients can cause major inaccuracies in distal femoral resection and final femoral implant coronal alignment. In a study on Chinese patients, Yau et al. stated that result if a routine VCA of 5°, 6°, or 7° was chosen then it would result in a planning error of greater than 2° in at least 31%, 31%, and 34% of the limbs with femoral bowing, respectively. Even though the enhanced conventional technique by customized VCA in each patient can help attain precise distal femoral cuts during the knee arthroplasty, the use of an extra-medullary guide rod instead of an intramedullary rod is essential. An intramedullary rod may be deceptive in patients with significant femoral bowing or an extra-articular abnormality; for instance, a fracture malunion in the distal femur may lead to malalignment of the intramedullary guide rod over distal femoral cutting block. The precision of the extramedullary guide is improved by determining the center of the femoral head in advance using image intensifier. However, one downside of the enhanced conventional technique is an slight increase in the overall surgical time due to the use of an image intensifier to locate the center of the femoral head over the patient has been anesthetized. On the other hand, computer navigation can avoid any extra-articular deformity in the distal femur and aids in directly aligning the distal femur cutting block perpendicular to the coronal mechanical axis of the femur, thus decreasing the chances of an erroneous cut. Furthermore, the majority of conventional distal femur cutting guides have a maximum VCA setting of 9°, beyond which the surgeon may have to lateralisate the entry point, increasing the chances of cutting error. In such cases, using computer navigation or the described enhanced conventional method can help improve precision of femoral component placement.

There are some limitations to our study. As the objective of this study was to compare the accuracy of locating the femoral component in the coronal plane on scanogram, there is no clinical follow-up data regarding functional scores or revision rates. Future studies based on clinical outcome and implant survival between the two follow-up groups may be needed. This study involved measuring various parameters on a scanogram, which is predisposed to errors in measurement. Nonetheless, the measurements of limb and component alignment on full length hip-to-ankle radiographs (scanogram) have been reported to be reliable and reproducible with good intra- and inter-observer correlation.

**Conclusion**
Using the enhanced conventional technique in each patient to perform distal femoral cuts during total knee arthroplasty can help achieve the coronal alignment of the femoral component comparable to navigation technique.

**Data availability**

Underlying data
Harvard Dataverse: Enhanced conventional method is as precise as navigation for distal femur resection during total knee replacement. https://doi.org/10.7910/DVN/DKOK6714.

This project contains de-identified raw data on pre- and post-operative knee angles, age and body mass index.

**Reporting guidelines**

Harvard Dataverse: CONSORT checklist for article “Enhanced conventional method is as precise as navigation for distal femur resection during total knee replacement: a randomized controlled trial”. https://doi.org/10.7910/DVN/DKOK6714.

Data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CC0 1.0 Public domain dedication).

**Grant information**
The author(s) declared that no grants were involved in supporting this work.

**References**

Open Peer Review

Current Peer Review Status: RETRACTED

Version 1

Reviewer Report 17 April 2019

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Robert Wen-Wei Hsu
Department of Orthopaedic Surgery, Chang Gung Memorial Hospital, Chiayi, Taiwan

This is a concise draft with clear, specific aims and somewhat reasonable conclusions. The authors conducted an RCT to study the specific radiographic outcomes between the “enhanced conventional” and “computer assisted” TKAs. However, some points related to the article can be raised for discussion. These were described in the following:

1. Two terminologies, “optimized conventional” and “enhanced conventional” methods, were stated inside the article. What was the difference?

2. The “enhanced conventional method” was not clearly defined, please address it.

3. The “Radio-opaque marker” method was used before and abandoned later. During the TKA procedures, the lower limb was frequently moved. The accuracy of femoral head center is uncertain, especially in the obese patients. The stability of marker locations were in question. That is why this method is not popular in current TKA practice. Was there any modification in current method comparing previous recants?

4. “BMI” might have some influence on this “enhanced conventional method outcome, please discuss it.

5. The use of fluoroscopy with potential radiation is another disadvantage with this method.

6. The overall alignment of lower limbs. Including MA and FVA in the coronal plane are not the only factors which might affect the final “functional outcomes”. The impact of this “enhanced conventional method” on future outcome is still unknown.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

**Are sufficient details of methods and analysis provided to allow replication by others?**
Partly

**If applicable, is the statistical analysis and its interpretation appropriate?**
Partly

**Are all the source data underlying the results available to ensure full reproducibility?**
Partly

**Are the conclusions drawn adequately supported by the results?**
Partly

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** TKA.THR. Arthroscopy

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

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