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Alignment in total knee arthroplasty — A comparison of patient-specific implants with the conventional technique

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A B S T R A C T

Background: Incorrect positioning and malalignment of total knee arthroplasty (TKA) components can result in implant loosening. Restoration of neutral alignment of the leg is an important factor affecting the long-term results of TKA. The aim of our retrospective study was to compare mechanical axis in patients with conventional and patient-specific TKAs.

Methods: 232 patients who underwent TKA between January 2013 and December 2014 were included to compare postoperative mechanical axis. 125 patients received a patient-specific TKA (iTotal CR®, Conformis) and 107 a conventional TKA (Triathlon®, Stryker). Standardized pre- and postoperative long-leg standing radiographs were retrospectively evaluated to compare the two patient cohorts.

Results: 113 (90%) radiographs of patient-specific TKA and 88 (82%) of conventional TKA were available for comparison. The preoperative deviation from neutral limb axis was 9.0° (0.1–27.3°) in the patient-specific TKA cohort and 8.2° (0.2–18.2°) in the conventional TKA group. Postoperatively the patient-specific TKA group showed 3.2° (0.1–8.4°) and the conventional TKA cohort 2.3° (0.1–12.5°) deviation. However, the rate of ±3° outliers from neutral limb axis was 16% in the patient-specific TKA cohort and 26% in the conventional TKA group.

Conclusions: Patient-specific TKA demonstrated fewer outliers from neutral leg alignment compared to conventional technique. Potential benefits in the long-term outcome and functional improvement require further investigation.

1. Introduction

Total knee arthroplasty (TKA) is a reliable and highly successful treatment for osteoarthritis of the knee [1, 2]. Correct positioning of the TKA components with axial alignment of the limb and restoration of the mechanical axis are associated with a better outcome [3, 4]. Incorrect positioning and malalignment of the TKA components can result in implant loosening, loss of thickness of polyethylene tibial bearings, eccentric loading, and eventual early revision [5–9]. Previous studies could show that postoperative alignment within the range of 0° ± 3° of the mechanical axis is recommended [3, 4]. Despite various attempts to improve accuracy of conventional TKA positioning errors may occur due to variations in the bony anatomy, visual misjudgement by the surgeon or limitations of technique [10]. Computer-assisted surgery (CAS) can improve mechanical alignment over conventional

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instrumentation but did not result in better outcomes [11]. Customized cutting guides (CCGs) are a further modification of surgical technique in TKA. These are individually manufactured cutting blocks depending on preoperative three-dimensional imaging.

Patient-specific implants (PSI) aim to improve postoperative alignment and positioning using anatomical data obtained primarily from preoperative axial computed tomography (CT) or magnetic resonance imaging (MRI). Disposable cutting jigs and implants specific to a patient's unique anatomy are created. One such PSI system is the iTotal CR® (ConforMIS, Burlington, Massachusetts, USA) which was designed to restore a neutral postoperative mechanical axis, reducing bone resection and optimize component fit using a CT scan to obtain anatomical data to create individual cutting jigs and individual implant components.

The aim of our retrospective study was to compare the mechanical axis in patients with conventional and patient-specific TKAs.

2. Methods

We retrospectively compared 232 patients who underwent TKA in our hospital between January 2013 and December 2014. 125 patients received a patient-specific TKA (iTotal CR, Conformis) and 107 a conventional cruciate retaining TKA (conventional TKA) (Triathlon, Stryker) using a standard instrumentation. Indication for TKA was primary or posttraumatic osteoarthritis, no signs of a mediolateral instability or a massive varus/valgus deformity. All patients underwent a full-leg radiograph standing on both legs and lateral knee radiograph and patella tangential pre- and postoperatively. TKAs were performed by different surgeons. Axial alignment of the limb was evaluated on pre- and postoperative full-length weightbearing radiographs by an independent orthopedic surgeon (DA). For the mechanical axis of the leg and frontal alignment the following angles were measured: the hip–knee–ankle (HKA) angle defined as the angle between the mechanical axis of the femur and the mechanical axis of the

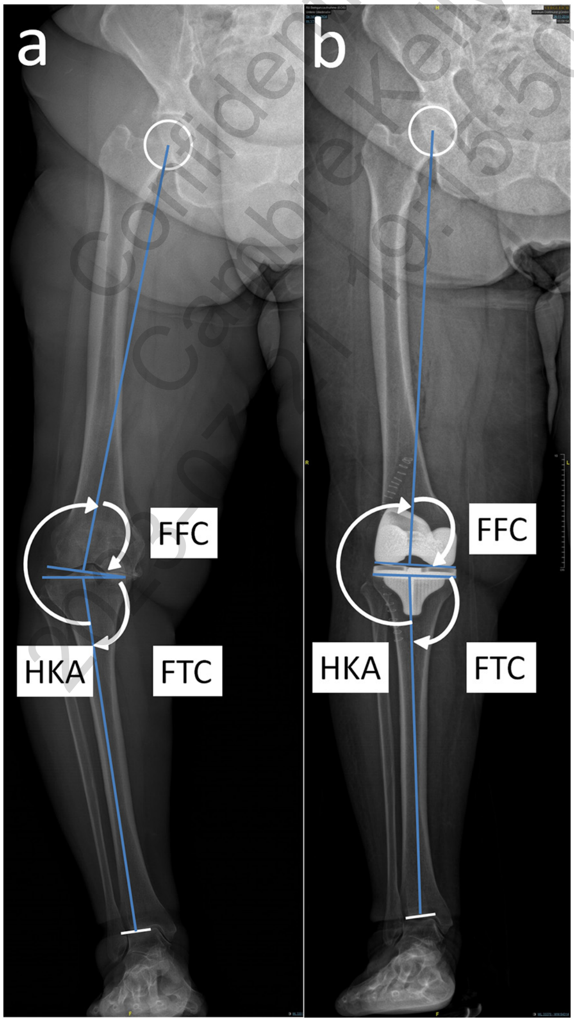

Figure 1. Radiological measurement showing the HKA mechanical axis of the leg, the FFC angles and FTC angles on a a) preoperative and b) postoperative long leg radiographs.

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tibia, with both lines crossing at the center of the knee (mechanical axis of the leg), the frontal femoral component (FFC) angle and the frontal tibial component (FTC) angle (Figure 1). Descriptive analysis mean ± standard deviation was done using Microsoft Excel (Microsoft Corporation, Seattle, USA). The Kolmogorov–Smirnov test was used to evaluate axial alignment. For comparing post-operative alignment of the leg between the two groups, box-and-whisker plots were used and deviations compared using the Mann–Whitney U-test. The box limits represent the lower quartile (25th percentile) and upper quartile (75th percentile) and the box height is the interquartile range (IQR). For continuous variables and differences between two means, 95% confidence intervals (CI) were calculated. Two-tailed values of $p < 0.05$ were considered to be statistically significant. Analysis of the data was performed using SPSS v24 (SPSS Inc. Chicago, Illinois).

3. Results

In the patient-specific TKA cohort 113 (90%) patients were included for limb alignment measurement. 12 patients (10%) have been excluded due to missing pre- or postoperative pictures, radiographs of minor quality or missing femoral head. In the conventional TKA cohort 88 (82%) patients could be included for measurement, 19 (18%) were excluded due to above-mentioned reasons. The preoperative deviation from neutral limb axis was 9.0° (0.1–27.3°, median 5.7°) in the patient-specific TKA cohort and 8.2° (0.2–18.2°, median 5.6°) in the conventional TKA group. Postoperatively the patient-specific TKA group showed 3.2° (0.1–8.4°, median 0.7) and the conventional TKA cohort 2.3° (0.1–12.5°, median 1.7°) deviation. A ±3° deviation from neutral limb axis could be demonstrated for 16% in the patient-specific TKA cohort and 26% of the conventional TKA group. The preoperative FFC showed a mean deviation of 3.3° (0.1–14.3°, median 1.3°) in the patient-specific TKA cohort and 2.6° (0.1–9.2°, median 0.5°) in the conventional TKA. Postoperatively the patient-specific TKA group demonstrated mean deviation of 2.3° (0.1–9.3°, median 0.9°) and the conventional TKA of 2.2° (0.1–6.4°, median 1.0°). Preoperative FTC angle was 3.8° (0.1–12°, median 4.0°) in the patient-specific TKA and 4.2° (0.1–12.7°, median 2.5°) in the conventional TKA cohort. Postoperative FTC angle was 1.6° (0.1–9.1°, median 0.2°) in the patient-specific TKA group and 1.6° (0.1–9.1°, median 0.3°) in the conventional TKA cohort indicating no significant change (Table 1).

4. Discussion

Axial alignment of the limb and correct positioning of components are of paramount interest in TKA. Postoperative malalignment of the mechanical axis of the leg showed to increase incidence of aseptic loosening. Rand and Coventry demonstrated that deviation of the neutral leg axis less than four degrees is associated with a survival rate of 90% at ten years [12]. They showed that survival rates decreased to 71% in valgus and 73% in varus deviation exceeding four degrees from the neutral leg axis. CAS was developed to improve surgical accuracy and decrease the number of outliers. Even so CAS proved to restore postoperative axis of the limb better than conventional intra- or extramedullary guides [10, 13], better outcomes could not be demonstrated [11, 14]. CCGs are a further modification of surgical technique in TKA. These are individually manufactured cutting blocks depending on preoperative three-dimensional imaging. Their potential benefits besides improvement of postoperative leg alignment are ease of use, decrease of operative times and instrument trays [15]. A systematic review of Level I and II studies concluded that CCGs did not improve coronal alignment in TKA [16]. Furthermore a decrease of blood loss and lowering the risk of fat embolism not using intramedullary femoral or tibial rods have been stated. Femoral or tibial malrotation due to inaccurate visual referencing of bony landmarks may be decreased. Patient-specific TKA is of emerging interest promising to improve postoperative alignment and positioning, reducing bone resection and optimizing component fit by using anatomical data obtained from preoperative MRI or CT scans. The iTotal CR® is a patient-specific TKA system designed to meet above-mentioned demands by using a CT scan to obtain anatomical data to create individual cutting jigs and individual implant components.

To our knowledge, the current study is the first to present radiological results of a patient-specific TKA system. In the patient-specific TKA group mean deviation from neutral leg axis changed from 9.0° (0.1–27.3°) preoperatively to 3.2° (0.1–8.4°) postoperatively. In the conventional TKA cohort preoperative mean deviation was 8.2° (0.2–18.2°) and postoperative 2.3° (0.1–12.5°). A ±3° deviation from neutral limb axis could be demonstrated for 16% in the patient-specific TKA cohort and 26% of the conventional TKA group (Figure 2). However the results of patient-specific TKA for outliers and pre- and postoperative leg axis change are better compared to conventional

Table 1
Hip–knee–ankle (HKA) angles, the frontal femoral component (FFC) angles and the frontal tibial component (FTC) angles in the conventional TKA and patient-specific TKA groups pre- and postoperatively.

	Patient-specific TKA				Conventional TKA			
	Mean	Median	Varus max	Valgus max	Mean	Median	Varus max	Valgus max
HKA preop	9.0	5.7	27.3	18.9	8.2	5.6	18.2	15.7
HKA postop	3.2	0.7	7.6	8.4	2.3	1.7	10.1	12.5
FFC preop	3.3	1.3	14.3	11.9	2.6	0.5	6.0	9.2
FFC postop	2.3	0.9	9.3	5	2.2	1.0	6.9	7.4
FTC preop	3.8	4.0	12.0	6.7	4.2	2.5	12.7	7.0
FTC postop	1.6	0.2	4.8	9.1	1.6	0.3	4.8	9.1

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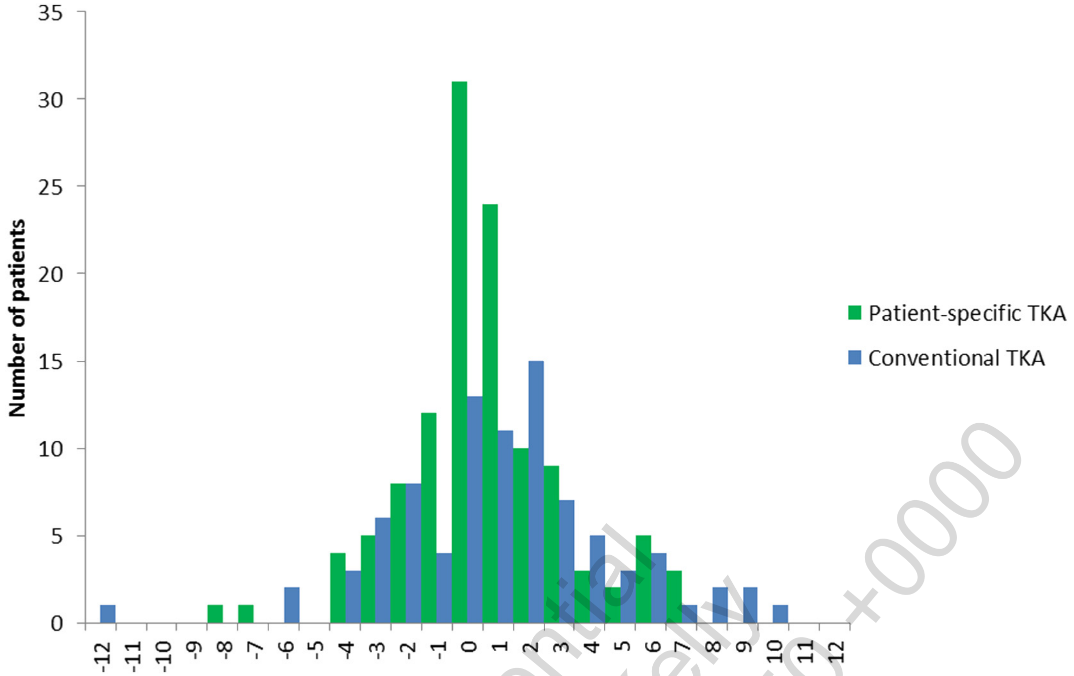

Figure 2. Histogram showing the distribution of the post-operative mechanical axis of the leg between the patient-specific and conventional groups.

TKA, they are showing no significant difference (Figure 3). The rate of outliers for the conventional TKA group is in line with other studies, where postoperative axial alignment of the limb outside ±3° is pending between 2 and 52% (Table 2). So far there are no studies to compare our results with other patient-specific TKA cohorts.

Certain limitations of this study should be discussed. A limitation is that it is a retrospective comparative analysis and hence selection bias cannot be excluded. We assessed only one PSI design and our findings might not be applicable to other patient-specific implants that currently are commercially available. We did not perform a power analysis before starting this study. Furthermore the results from this study are limited to the coronal plane and do not take into account lateral or rotational component positioning which may play a role in long-term survivorship of total knee implants. Yet we do not report on clinical outcomes such as pain, stiffness, range of motion, patient satisfaction, or outcome scoring systems, which may limit the clinical relevance of the findings in our study.

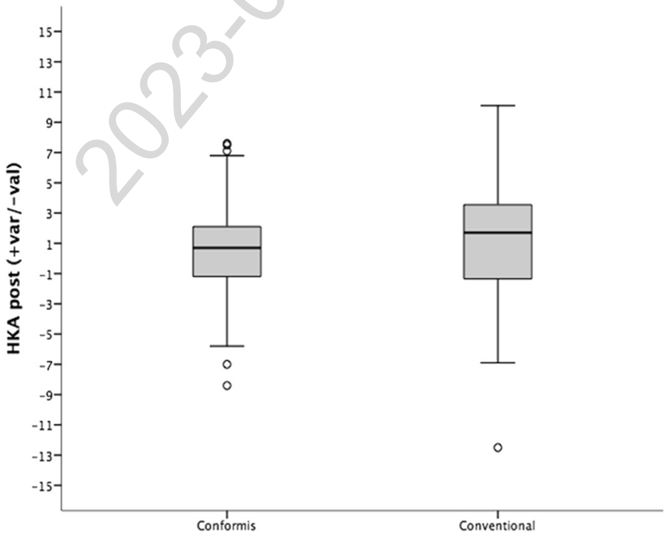

Figure 3. Distribution of the post-operative mechanical axis of the leg comparing patient-specific and conventional groups. HKA: hip–knee–ankle angle, var: varus, val: valgus.

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Table 2
Percent of coronal alignment outliers in conventional (manual) instrumentation in prior studies.

Author	Year	N	Percentage of postoperative outliers exceeding ±3° from neutral axis
Tilett et al. [17]	1988	50	14
Hart et al. [18]	2003	60	30
Sparmann et al. [19]	2003	120	13
Stockl et al. [20]	2004	32	6
Matsumoto et al. [21]	2004	30	33
Chauhan et al. [22]	2004	36	28
Bäthis et al. [10]	2004	80	22
Haaker et al. [23]	2005	100	28
Matziolis et al. [24]	2007	28	25
Kim et al. [25]	2007	100	18
Yau et al. [26]	2008	52	25
Bonutti et al. [27]	2008	50	2
Hernandez et al. [28]	2010	40	52
Ng et al. [29]	2011	155	28
Daniilidis et al. [9]	2014	156	21
Marimuthu et al. [30]	2014	185	17

In conclusion our data suggest that patient-specific TKA may offer an advantage over conventional TKA in terms of restoration of the mechanical axis. Further studies are needed to confirm our results and to assess clinical outcome. Controlled trials are needed to critically evaluate if potential benefits of patient-specific TKA will finally result in better survivorship and support this more expensive technology for use in routine TKAs.

Conflicts of interest and source of funding

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Ethical approval

This article does not contain any studies with human participants or animals performed by any of the authors.

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