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A comparison of conventional and patient-specific instruments in total knee arthroplasty

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Abstract

Purpose Several authors have observed that standard instrumentation (SI) may be insufficient for addressing component malalignment. Patient-matched cutting blocks (PMCB) technology was introduced to improve surgeons' ability to achieve a neutral postoperative mechanical axis following total knee arthroplasty (TKA). The current retrospective study was designed to compare the ability of SI and PMCB to achieve a hip-knee-ankle angle (HKA) within $\pm 3^{\circ}$ of the ideal alignment of 180°.

Methods Between October 2009 and December 2012, 170 TKAs in 166 patients (four bilateral) using VISIONAIRE (Smith & Nephew) PMCB technology were performed. Additionally, 160 TKAs in 160 consecutive patients that had received a total knee arthroplasty using SI during the same time period were used as a control group, All surgeries were performed by the same surgeon. Standardized pre- and postoperative long-leg standing x-rays were retrospectively evaluated to compare the two patient cohorts.

Results X-rays were available for analysis for 156 knees in the SI group and 150 in the PMCB group. The average postsurgical HKA was 178.7 ± 2.5 in the SI group and 178.4 ± 1.5 in the PMCB group. However, the rate of $\pm 3^{\circ}$ outliers was 21.2 % in the SI group and 9.3 % in the PMCB group. There were no intraoperative complications with the use of PMCB technology or SI.

Conclusions PMCB technology proved superior to conventional instrumentation in achieving a neutral mechanical axis

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following TKA. Further follow-up will be needed to ascertain the long-term impact of these findings.

Keywords Total knee replacement \cdot Total knee arthroplasty \cdot Patient matched cutting blocks . Standard knee instrumentation . Component malalignment . Neutral mechanical axis . Hip-knee-ankle angle

Introduction

Total knee arthroplasty (TKA) has a high success rate for addressing pain and improving function [\[4\]](#page-4-0). However, in instances where incorrect positioning and malignment of the TKA components are observed, patients can experience a range of negative postoperative outcomes such as loss of thickness of polyethylene tibial bearings, eccentric loading, implant loosening, and eventual early revision [\[10,](#page-5-0) [35,](#page-5-0) [36](#page-5-0), [39,](#page-5-0) [43\]](#page-5-0). To avoid these complications, achieving a postoperative alignment within the range of $0^{\circ} \pm 3^{\circ}$ of the mechanical axis is recommended [\[20,](#page-5-0) [33\]](#page-5-0). Manual intramedullary/extramedullary guides are not thought to be capable of consistently achieving axes in this range [\[30,](#page-5-0) [41](#page-5-0)], and though computer-assisted navigation has shown superior results in comparison with conventional instrumentation [\[30\]](#page-5-0), it is also limited by increased surgical times and no clear superiority in improving short-term clinical outcomes [\[8](#page-4-0)].

Thus, there has been in a push in the orthopaedic community to create more precise technologies to aid in the reconstruction of the knee's mechanical axis. Patient-specific instrumentation (PSI), which uses anatomical data obtained primarily from pre-operative axial computed tomography (CT) or magnetic resonance imaging (MRI) to create disposable cutting jigs individualized to the patient's unique anatomy, was created with this goal [\[16\]](#page-5-0).

The aim of the current comparative analysis was to analyze post-surgical alignment in a cohort of patients

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undergoing TKA with a PSI system (VISIONAIRE; Smith & Nephew, Memphis, TN, USA) and a cohort undergoing TKA with conventional instrumentation. The study is based to our previous clinical results with a single analysis of the clinical outcome of PSI technology [\[12](#page-5-0)].

It was hypothesized PSI would lead to a neutral mechanical axis on average more frequently than conventional instrumentation.

Methods

This study was conducted between October 2009 and December 2012. During that period, the senior author (C.O.T.) performed 170 TKAs in 166 patients (four bilateral) using VISIONAIRE patient-matched cutting blocks technology (PMCB group). A group of 160 TKAs in 160 consecutive patients using standard instrumentation (SI group) from the same time period served as control group. These two groups were obtained from different hospitals. In the one hospital, the VISIONAIRE technology is used for all TKAs, whereas in the other hospital standard instrumentation is employed. This study follows the Declaration of Helsinki. In Germany, where this study was conducted, retrospective epidemiological studies without personally identifiable data do not need to be sent to the ethical committee for approval.

Patients had a diagnosis of either primary or posttraumatic osteoarthritis, no signs of a mediolateral instability or a varus/ valgus deformity with a deviation of $>15^\circ$, and to be able to undergo preoperative MRI, with no metallic hardware in close proximity to the operated knee. Additionally, those in the PMCB group needed to be willing to wait the four to six weeks typically required for this specialized instrumentation to be prepared.

In the SI group, there was no calculation of the rate of patients who were lost to follow-up, as they were chosen based on the availability of x-rays. However, in four cases (2.5 %) the x-rays could not be evaluated due to the following reasons: rotation on the whole leg x-ray was incorrect (three patients) and flexion contracture >10° (one patient). This left a cohort of 156 evaluable knees. In the PMCB group, there were 159 x-rays available. Eleven x-rays (6.4 %) were not available as they were either incomplete or not available due to patient refusal or lack of attendance of follow-up visits. Additionally, nine x-rays (5.3 %) could not be evaluated due to the following reasons: rotation on the whole leg x-ray was incorrect (two), femoral head not on the leg length x-ray (one), flexion contracture $>10^{\circ}$ (three), extra-articular malalignment, whereas the pre-operative planning was not done for a neutral axis (two bowed femur, one posttraumatic malalignment after a fracture). This left a cohort of 150 evaluable knees. Demographic data for both groups can be found in Table 1.

Table 1 Baseline demographics for SI group (156 knees) and PMCB group (150 knees)

Variables	SI Group	PMCB Group
Mean age, years (range; SD)	$65.0(41-93; 9.2)$	$66.1(26-88; 8.8)$
Mean weight, kg (range; SD)	$85.9(51-134;$ 17.9)	$92.6(69 - 116)$ 13.7)
Mean height, cm (range; SD)	168 (148–194; 9.3)	171 (149–186; 8.8)
Mean BMI (range; SD)	$30.3(20.2-42.1;$ 5.3)	31.7 (25.6-44.2; 4.6
Gender $(n, \frac{9}{6})$		
Male	79 (50.6 %)	$95(63.3\%)$
Female	$77(49.4\%)$	55 (36.7 %)
Operated side (n, %)		
Left	83 (53.8 %)	68 (43 %)
Right	73 (46.2 %)	$91(57\%)$
Diagnosis $(n, \%)$		
Varus OA	$127(81.4\%)$	114 (71.7 %)
Valgus OA	$16(10.3\%)$	$20(12.6\%)$
Posttraumatic OA	$9(5.8\%)$	$15(9.4\%)$
Patellofemoral OA	$4(2.6\%)$	10 $(6.3\%$
Operative time, minutes (range; 51.1 (38–76; 7.2) SD)		$50.9(35-90;$ 10.0)

All patients received a cemented Genesis $IITM$ (Smith and Nephew, Memphis, TN) posterior-stabilized high-flexion prosthesis and were operated upon using a conventional medial parapatellar approach. In the PMCB group, patients received femoral components fabricated from an oxidized zirconium alloy (Oxinium™, Smith and Nephew, Memphis, TN), whereas those in the SI group had cobalt-chrome components. The knees of the patients in the PMCB group underwent a full-leg radiograph and MRI preoperatively.

The process by which the VISIONAIRE instrumentation is produced has been described in detail in other studies [\[11,](#page-5-0) [18](#page-5-0), [31\]](#page-5-0). The surgeon's preferences called for a 9-mm proximal resection, a posterior slope alignment of 3°, a varus/ valgus alignment of 4–7° if there was no rotation in the xrays or, if there was rotation due to malalignment or degenerative joint, 5° for varus knees and 7° for valgus knees.

Standing long-leg x-rays were performed pre- and postoperatively to ascertain all radiographic endpoints, which is part of the senior author's routine care. An independent orthopaedic surgeon (K.D.) then performed radiographic measurements for the following endpoint: hip-knee-ankle angle (HKA), defined as the angle between the mechanical axis of the femur and the mechanical axis of the tibia, with both lines crossing at the center of the knee (Fig. [1a-b](#page-2-0)) The following were considered the ideal (i.e., normal or in-range) values for these radiographic measurements: 0°±3° varus/valgus for HKA. HKA was calculated as a mean for the entire patient cohort, and additionally patients outside the $\pm 3^{\circ}$ range were noted.

Fig. 1 a-b: The hip-knee-ankle angle (HKA) was determined as the angle between the mechanical axis of the femur and the mechanical axis of the tibia. Both lines cross the center of the knee (red marked circle). In this preoperative image HKA value is 168.72° (a). The postoperative HKA value is 179.42° (b)

We used a non-parametric Fisher's exact test in the analysis of contingency tables. Descriptive analysis (mean±standard deviation was done using Microsoft Excel (Microsoft Corporation, Seattle, USA) and IBM SPSS Statistics 18 (PASW 18, SPSS Inc., Chicago, IL, USA).

Results

Postoperative x-ray analysis occurred at a mean interval of 3.5 months (range, 2.5-3.5) in the SI group and 3.5 months (range, 2.5–3.5) for the PMCB group.

Patients in the PMCB group experienced a post-TKA neutral mechanical alignment outside $\pm 3^{\circ}$ of the ideal alignment of 180° HKA at a significantly lower rate than those in the SI group (p=0.0031; Table 2; Fig. [2](#page-3-0)).

There were no intraoperative complications encountered in either group, and the specialized instrumentation used in the PMCB group was optimally fitted to all the patients' individual anatomy and did not require any additional modifications.

Discussion

VISIONAIRE technology was designed to restore a neutral postoperative mechanical axis. By using pre-operative MRI data and full-length anterior/posterior radiographs to ascertain the current and planned mechanical axis, engineers are able to produce tibial and femoral resection guides fitted to the patient's specific anatomy. This is the latest study to support the accuracy of this technology [\[12](#page-5-0), [18](#page-5-0), [31\]](#page-5-0). It also represents an update of an earlier analysis in which results for a smaller cohort (100 knees) operated with this technology were presented without a comparison cohort [[12\]](#page-5-0). With the addition of 50 knees to the PMCB cohort, alignment outcomes continued to be highly positive, and the number of knees $\pm 3^{\circ}$ beyond the ideal alignment of 180 $^{\circ}$ actually fell slightly from 11 % to the 9.3 % noted in the current analysis.

Although these results attest to the viability of PMCB technology, it was equally important for us to include a cohort of patients operated with standard instrumentation in order to more fully understand how these two different techniques impact frontal alignment. Indeed, as hypothesized there was a substantial difference in the number of knees $\pm 3^{\circ}$ beyond the ideal alignment (21.2 % for the SI group, 9.3 % for the PMCB group). Our rates with PMCB compare favorably to the average 10.2 % rate resulting from computer-assisted navigation in prior studies, and substan-

Table 2 Mean hip-knee-ankle angle (HKA) findings for SI group (156 knees) and PMCB group (150 knees), including outliers beyond the ideal alignment of 180°

		Range of Alignment						
	Mean \pm SD (Range)		$<177^{\circ}$		$>183^\circ$		Outlier $\pm 3^{\circ}$	
	SI	PCMB	SI	PCMB	SI	PCMB	SI	PCMB
HKA preop HKA postop	175.2 ± 6.3 (163-198) 178.7 ± 2.5 (173.2-188)	173.7 ± 3.9 (163.5–186.5) $178.4 \pm 1.5(172.5 - 182.1)$	110 22	116 14	16 11	2 θ	80.8% 21.2%	78.7 % 9.3%

Fig. 2 Range of knees falling $\pm 3^{\circ}$ outside of the ideal hip-knee-ankle angle (HKA) alignment of 180°, pre- and post-operatively

tially improves on the 28.2 % rate encountered with conventional instrumentation [\[30](#page-5-0)].

An overview of studies reporting frontal plane alignment within this range for both conventional instrumentation and PMCB are provided in Tables 3 and [4](#page-4-0). With 90.7 % of knees in the current analysis within the ideal range, our results can be considered amongst the best yet noted. They are in line with other studies of PSI which reported improved alignment [\[16](#page-5-0), [30,](#page-5-0) [38](#page-5-0)]. Although it should be noted that other studies have failed to show a clear advantage for PSI technology [[24,](#page-5-0) [32](#page-5-0)], and that one study with the technology employed in the current analysis observed only a fair rate of accuracy, with higher risk of error $>3^\circ$ in the sagittal plane [\[11](#page-5-0)], there does appear to be an overall trend for the superiority of these new technologies over earlier instrumentation methods.

As highlighted in Table [4](#page-4-0), there are several different evaluation methods employed in the assessment of frontal knee alignment in studies of custom jigs, including postoperative x-rays and intraoperative navigation. Studies of the VISIONAIRE that evaluated this endpoint with postoperative x-rays, including the current analysis, routinely reported approximately 90 % of knees within the ideal range of alignment [\[16](#page-5-0), [41](#page-5-0)]. Conversely, the study that evaluated this endpoint with intraoperative navigation reported only 79 % of knees within this range [[45\]](#page-5-0). It is possible that utilizing intraoperative navigation to measure front alignment may account for a 10 % increase in the number of knees reported with malalignment; however, this is outside the scope of the current analysis and should be addressed in a future study. Establishing the best method for measuring this endpoint will be essential for gauging the true value of this technology going forward.

There were no relevant intraoperative issues arising from the use of PMCB in the 150 patients treated in this group throughout the study. This is in line with earlier studies with

Table 3 An overview of published data using conventional instrumentation that reported total frontal knee alignment within $\pm 3^{\circ}$ of ideal

Author, year	Method	Evaluation method	N	Percentage of knees within $\pm 3^{\circ}$ of ideal
Yau et al. 2008 [45]	Manual	postop x- ray	52	75
Stockl et al. 2004 [40]	Manual	postop x- ray	32	94
Hart et al. 2003 $[17]$	Manual	postop x- ray	60	70
Hart et al. 2003 $[17]$	Manual	postop x- ray	60	93
Matsumoto et al. 2004 $\left[27\right]$	Manual	postop x- ray	30	67
Tillett et al. 1988 [42]	Manual (IM)	postop x- ray	25	92
Tillett et al. 1988 [42]	Manual (IM)	postop x- ray	25	92
Tillett et al. 1988 [42]	Manual (EM)	postop x- ray	25	80
Tillett et al. 1988 [42]	Manual (EM)	postop x- ray	25	80
Decking et al., 2005 [13]	Manual	postop x- ray	25	36
Decking et al. 2005 [13]	Manual	postop x- ray	25	68
Kim et al. 2005 [23]	Manual	postop x- ray	78	73
Haaker et al. 2005 [15]	Manual	postop x- ray	100	72
Matziolis et al. 2007 [28]	Manual	CT scanner	28	75
Kim et al. 2007 $\lceil 23 \rceil$	Manual	postop x- ray	100	82
Chauhan et al. 2004 [7]	Manual	postop x- ray	36	72
Chin et al. 2005 [9]	Manual (IM)	postop x- ray	30	63
Chin et al. 2005 [9]	Manual (EM)	postop x- ray	30	63
Bathis et al. 2004 [3]	Manual	postop x- ray	80	78
Sparmann et al. 2003 [37]	Manual	postop x- ray	120	87
current study	Manual	postop x- ray	156	-79

this technology, which also reported no intraoperative complications to date [[11,](#page-5-0) [18,](#page-5-0) [31\]](#page-5-0).

There are several limitations to the current analysis that must be taken into account when analyzing these results. Firstly, although a control arm was offered as means of a comparison, there were notable differences in the demographics between the two groups (e.g., more male patients in the PMCB group). It is possible that these factors influenced the overall results. Secondly, this study exclusively deals with radiographic outcomes. Expanding the outcomes to other important aspects of TKA such as pain, stiffness, and range of motion would have provided important further data with

Table 4 An overview of published data using custom jigs that reported total frontal knee alignment within $\pm 3^{\circ}$ of ideal

which to compare these two separate strategies. PSI has also been shown to shorten surgical steps and operative times, reduce the burden for surgical instrumentation, and lessen adverse outcomes such as blood loss, infection, and systematic fat emboli [[16](#page-5-0), [19,](#page-5-0) [24](#page-5-0), [31,](#page-5-0) [38](#page-5-0)]. Therefore, the proposed utility of this technology should not be limited to radiographic aspects. Thirdly, it must be noted that the operating surgeon undertakes approximately 550 knee replacements annually and it is possible that this high level of experience positively influenced the results. The learning curve for beginner surgeons has been shown to be acceptably low with computerassisted navigation systems, with the exception of a general increase in operative and tourniquet times during initial cases [\[14,](#page-5-0) [21](#page-5-0), [34\]](#page-5-0). Another limitation of the present study is that we did not perform a power-analysis. Additional research is

required, however, to ascertain whether less-experienced surgeons would encounter a similar learning curve with this particular PSI technology. Furthermore, it should be noted that the costs for using the PMCB technology are higher than with conventional methods.

In conclusion, PMCB technology proved superior to conventional instrumentation in achieving a neutral mechanical axis following TKA. As this is an update of an earlier study [\[12](#page-5-0)], in which data from 50 additional patients were available, these results also reconfirm the earlier conclusion that this specific technology is effective in addressing the issue of malalignment. Further follow-up will be needed to ascertain the long-term impact of these findings.

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Conflict of interest No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. C.O.T is a paid teaching consultant to Smith $\&$ Nephew. The authors declare that there are no other potential conflicts of interest in connection with this paper.

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