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Different targets of mechanical alignment do not improve knee outcomes after TKA☆,☆☆

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ABSTRACT

Background: Accurate alignment is a basic principle of TKA surgery, but achieving alignment within this target may not translate into superior outcomes after surgery.
Purpose: To assess if neutral TKA mechanical alignment was associated with superior knee outcomes and to examine the effect of various aspects of pre-operative and post-operative alignment on knee function.
Methods: Analysis of a database of 444 TKA patients between June 2009 and October 2016. Knee outcomes (WOMAC, AKSS and knee range of motion) were collected before surgery and during follow-up at a minimum of six months.
Results: Analysis included 444 TKA patients (62% female, mean age 66 years, mean follow-up 23 months). Deformity varied from 21° varus (mean = 7.9, SD = 2.8) to 17° valgus deformity (mean = 7.7, SD = 2.8). Pre-operatively, 101 (23%) knees were in native neutral mechanical alignment, while 278 (63%) were in varus and 65 (15%) were in valgus. Post-operatively, a group of 365 (82%) TKA were found to be in neutral mechanical alignment and a group of 79 (18%) TKA were noted to be 'Outliers' (17 [4%] TKA > 3° varus and 62 [14%] TKA > 3° valgus alignment). Restoration of the target of alignment of 0 ± 3° or 0 ± 1°, did not have better functional outcomes scores, range of motion or prosthesis longevity than those in the outlier range.
Conclusion: Neutral TKA alignment did not appear to be a significant contributing factor to the improvement in knee function in short-medium term follow-up.

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☆☆ Each author certifies that his or her institution has approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research, and that informed consent was obtained

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1. Introduction

Patient satisfaction with total knee arthroplasty (TKA) has lagged behind that for hip arthroplasty despite the two procedures being performed on demographically similar patient populations [1–3]. Up to 20% of patients after TKA are not satisfied with the outcome of surgery [4]. Conventional thinking is that improvements in component design [5] and accuracy of component alignment [6–8] could improve knee function and quality of life after TKA [9,10] and consequently improve patient satisfaction. Thus, numerous technical advances such as computer navigation, patient specific instrumentation and robot assisted surgery have been introduced to improve the accuracy of TKA alignment. However, clinical outcomes and the proportion of dissatisfied patients after TKA surgery have not improved substantially with the use of these innovations [7,11–18], while adding significant costs to the procedure.

The Hip-Knee-Ankle (HKA) angle is the angle between the mechanical axis of the femur and the mechanical axis of the tibia. The convention is to achieve so-called neutral alignment which is a target HKA of 0 ± 3°. Achieving this target of mechanical alignment has been a long-held tenet of arthroplasty with proposed benefits in balance of forces on bone [19,20] and knee soft-tissue envelope [21–24] allowing appropriate knee function and long-term prosthesis survival [11,21].

The aim of achieving neutral alignment has been challenged with the knowledge that a large proportion of the healthy non-arthritic population are not normally in neutral alignment [25,26], therefore achieving neutral alignment after TKA could be considered abnormal for this group. Some propose maintaining constitutional alignment [17,27,28], whereby the knee is maintained closer to the original knee alignment rather than correcting it to mechanical neutral alignment, as a way of improving TKA function as the ligamentous structures around the knee are not placed in a relatively abnormal position [22–24,29]. Even the traditional methods of measured resection or ligamentous balance have been challenged more recently by the concept of kinematic alignment [28,30,31] in which the femoral and tibial components are aligned with the natural axis of flexion and rotation of the knee of each particular individual. Thus, the traditional dichotomy of aligned or mal-aligned knees may be an artificial concept as reports show comparable function and survival between these two groups [32,33]. Satisfactory results after TKA may be more related to other factors affecting pain and physical function rather than accuracy of restoration of neutral mechanical alignment.

Given this uncertainty the primary aim of this study was to assess if restoration of neutral mechanical alignment post-TKA (defined as HKA 0 ± 3°) was associated with improved early knee function, knee range of motion (ROM) or TKA survival compared to alignment outliers. Secondary aims were: to assess if more accurate component alignment (HKA 0 ± 1°) confers a greater improvement over outliers compared to using the conventional cut off (HKA 0 ± 3°). We also aimed to assess if pre-operative alignment, post-operative alignment and any changes in alignment affect outcomes after TKA.

2. Material and methods

2.1. Study design

After approval for the study was obtained from the Health Research and Ethics Committee (Reference: PID 00089), retrospective analysis was performed of a database of prospectively collected data from a cohort of patients who underwent TKA. The inclusion criteria were all adult patients undergoing unilateral TKA for any pathology, performed between June 2009 and October 2016 by a single fellowship trained arthroplasty surgeon (RMS) with over 15 years of experience in arthroplasty surgery, using either magnetic resonance imaging (MRI) or computer tomography (CT) based patient specific instrumentation (PSI). The patients had to have a complete data set of patient related outcome measure (PROM) questionnaires before surgery and at least six months afterward, and patients had to have undergone a post-operative CT scan to assess TKA alignment and component orientation. We excluded patients who did not have complete PROM data or who did not have a post-operative CT scan. Cases of bilateral TKA were excluded, as both knees were assessed with one set of knee scores before and after surgery, which would potentially mask the results of patient dissatisfaction with one of the TKA.

2.2. Participants

The database included 600 TKA procedures, we excluded 14 patients (28 TKA) with bilateral TKA; 106 patients did not complete the pre-operative PROM questionnaires, and 22 patients did not have a post-operative CT available.

2.3. Pre and post-operative radiological assessment

From 2009, the surgeon began to use patient specific instrumentation, as part of the preoperative planning, all patients were assessed with either a CT or MRI for the purposes of manufacturing patient specific cutting blocks. All TKA surgeries were performed using Biomet Vanguard TKA (Zimmer Biomet, Warsaw, Indiana, USA) with the assistance of Signature™ patient specific instrumentation (Zimmer Biomet, Warsaw, Indiana, USA) [34]. The CT protocol was used in 31 TKA (7%) when the patient was unable to have an MRI because of claustrophobia, implanted metallic devices or scan metal artefact. The pre-operative scan allowed measurement of pre-operative mechanical axis in the supine non-weight bearing position, which was used instead of conventional measurement using standing films.

Postoperatively, all patients were assessed routinely with a low radiation dose CT scan (1–1.5 mSv) according to the Perth protocol [35] as part of routine surgical follow-up within six months from surgery. The CT scan provided measurement of the post-operative mechanical alignment in supine position, according to the protocol described by Chauhan et al. [35]. This method of assessment of the mechanical axis post-TKA in the supine position was similar to the method for pre-operative measurement of mechanical axis also measured in supine position using either MRI or CT. Thus, both the pre-operative and post-operative HKA measurement do not account for any ligament instability that could be present before or after TKA. An adjustment to compare supine to weight bearing measurements was not performed. The relationship between the change in the direction of alignment before and after surgery was recorded as a categorical variable.

2.4. Clinical assessment

All outcomes were collected during the pre-operative consultation and during routine assessment six months after surgery and in a subset of patients at a later time. At the time of most recent follow-up, an independent investigator (AX) invited patients to attend a clinical assessment of the operated knee ROM and to complete a follow-up American Knee Society Score (AKSS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score. The date of this assessment was considered the most recent patient follow-up, and time from surgery was calculated. Knee ROM was measured as the maximum arc of active knee flexion using a goniometer with reference lines in the direction of the greater trochanter and the lateral malleolus. This was measured as part of routine clinical examination before and after TKA.

2.5. Surgical approach

A cruciate retaining (CR) or a posterior stabilised (PS) prosthesis was used depending on patient pathology, the need for intraoperative releases, TKA balance, ligament deficiency or required bone resection. The patella was not routinely resurfaced unless there was inflammatory arthritis, severe chondral wear or if resurfacing was intended to balance the patellofemoral joint. Patella osteophytes were debrided routinely. Release of the lateral patellar retinaculum was recorded when required for balance of the patellofemoral joint.

2.6. Analysis

At the time of data analysis, a report was requested from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) regarding TKA revisions in our patient cohort from the time of surgery until the beginning of 2018. The information was divided into two groups: TKA in neutral mechanical alignment (HKA $0 \pm 3°$) and a second group of alignment outliers. The two groups were compared for number, reason and type of revision, the observed years of TKA survival and the yearly cumulative percent revisions of the primary TKA.

Continuous variables were described using means and standard deviations and comparisons of continuous variables were performed using independent sample *t*-test. Dichotomised variables were compared using the Chi-square test. We considered a *p*-value <0.05 to show a statistically significant relationship, and when this occurred, we examined the magnitude of the effect

Table 1
Demographic data of patients included in the study.

	Mean (n = 444)	Percentage or range (SD)	Missing data n (%)
Gender			
Female	276	62	
Male	168	38	
Age	66.4 years	42–91 (8.5)	
Surgical time	70 min	46–130 (13.1)	134 (30)
Time of latest follow-up	23 months	6–85	
Follow-up >6 months	237	53	
Type of TKA			
CR	291	83	93 (21)
PS	60	17	
Patella resurfaced?			
No	243	70	95 (21)
Yes	106	30	
Lateral release			
No	298	85	93 (21)
Yes	53	15	
Preop WOMAC	78	31–138 (14.8)	
Preop AKSS	87	9–171 (28.2)	
Preop knee flexion	103	50–130 (13.8)	
Postop WOMAC	42	20–119 (15.8)	
Postop AKSS	158	58–213 (31.8)	
Postop knee flexion	117	75–150 (10.8)	

CR: cruciate retaining, PS: posterior stabilised, WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index, AKSS: American knee society score.

to determine if it represented a clinically relevant change in outcome. Statistical analysis was performed using SPSS v25 (IBM SPSS Statistics for Windows, Version 25.0, 2017, Armonk, NY: IBM Corp).

We conducted a retrospective power analysis; our study had 90% power to detect a difference of 6.5 points, and a power of >99% to detect the minimum clinically important difference (15 points) in the WOMAC score used for the primary analysis [36,37].

3. Results

The group of patients who were excluded from the study were similar in age and gender to the included group of patients. The demographics of the patient population are recorded in Table 1. The pre-operative degree of deformity varied from 21° varus (mean = 7.9, SD = 2.8) to 17° valgus deformity (mean = 7.7, SD = 2.8). A cementless cruciate retaining femoral component was used in 291 TKA (83%) and patella resurfacing was performed in 106 TKA (30%).

Follow-up beyond routine six-month assessment was available in 237 (53%) TKA. The follow-up period in this group ranged from 12 to 85 months after surgery (mean = 38 months). A sensitivity analysis was conducted comparing these two groups and showed no significant differences in age, gender distribution, prosthesis type, patella management, pre-operative or post-operative knee scores or ROM (Table 2).

A group of 365 (82%) TKA were found to be in neutral mechanical alignment (HKA 0 ± 3°) post-operatively and a group of 79 (18%) TKA to be outside of these parameters 'Outliers' (17 [4%] TKA > 3° varus and 62 [14%] TKA > 3° valgus alignment). The two groups were similar in age (mean 66 years in both groups) and time of follow-up (mean = 22 months vs 26 months, $p = 0.12$). There were no differences between the two groups (Figure 1) in the latest post-operative follow-up in WOMAC score, AKSS or knee flexion ROM (Table 3).

A similar relationship was observed when considering a narrower target for neutral TKA alignment (HKA 0 ± 1°). Using this parameter, the neutral alignment group included only 191 (43%) TKA, with the remaining 253 (57%) TKA in the outlier group (65 [15%] TKA varus >1° and 188 [42%] TKA in valgus >1°). The two groups were similar in age (mean = 67 years [SD 8.8] vs 66 years [SD 8.3], $p = 0.61$) and time of follow-up after surgery (mean = 22 months [SD 20.5] vs 24 months [SD 21.5], $p = 0.57$). There were no differences between the two groups in post-operative WOMAC score, AKSS or knee flexion at the latest follow-up (Table 3). Therefore, there was no clinical benefit to achieving neutral alignment using either HKA 0 ± 3° or HKA 0 ± 1° as target alignment (Figure 1).

The AOANJRR reported data available on 440 matched TKA from the cohort. The overall revision/100 observed years of prosthesis function was 0.39 (95% CI 0.17, 0.77). Short-medium term survival data were available up to six years after TKA surgery. There were seven revisions in the neutral alignment group and one in the outlier group. The two groups were similar in the primary diagnosis for TKA, but the cumulative percent revision was higher in the first group (Table 4).

We examined the relationship between the nature of knee alignment (direction) before and after TKA on knee outcomes after surgery. *Pre-operatively*, we found 101 (23%) knees to be in native neutral mechanical alignment (HKA 0 ± 3°), while 278 (63%) were in varus alignment, and 65 (15%) were in valgus alignment. Comparison between the groups revealed no significant differences in the mean post-operative scores of WOMAC, AKSS or flexion ROM. A similar relationship existed between the nature of *post-TKA* alignment and knee outcome measures (Table 3). Hence, neither the preoperative knee deformity nor the post-TKA nature of alignment affected outcomes after TKA (Figure 2).

Comparison of the effect of change in direction of post-operative alignment compared to pre-operative knee alignment (Table 3) showed that patients who achieved neutral alignment (n = 365) did not show significantly different results compared

Table 2
A comparison of demographics, surgical factors and knee outcomes before and after surgery in the group of patients with short-term follow-up of six months only and the group of patients with follow-up beyond 12 months.

		Six-month follow-up Mean or n = 207 (47%)	Follow-up ≥12 months Mean or n = 237 (53%)	*p*
Age		66	67	0.38
Gender	Female	128 (62)	148 (62)	0.90
Prosthesis type	CR	124 (82)	167 (84)	0.57
Patella resurfacing		44 (29)	62 (31)	0.71
Lateral release		25 (16)	28 (14)	0.54
	Varus	137 (66)	141 (60)	
Pre-TKA alignment	Neutral	43 (21)	58 (25)	0.35
	Valgus	27 (13)	38 (16)	
	Varus	9 (4)	8 (3)	
Post-TKA alignment	Neutral	174 (84)	191 (81)	0.37
	Valgus	24 (12)	38 (16)	
Pre-TKA WOMAC		78	77	0.28
Post-TKA WOMAC		42	41	0.21
Pre-TKA AKSS		85	89	0.88
Post-TKA AKSS		155	161	0.05
Pre-TKA flexion		103	103	0.84
Post-TKA flexion		116	117	0.17

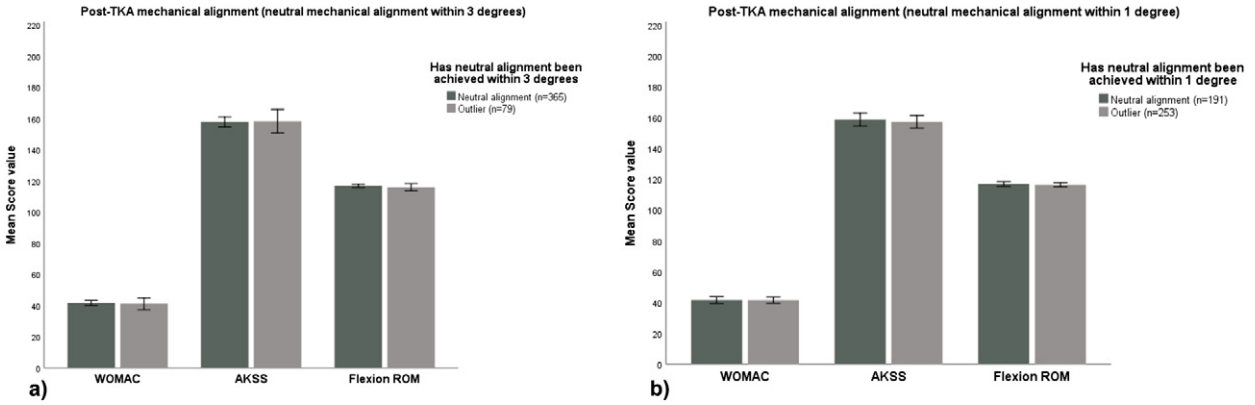

Figure 1. Comparison of outcomes in patients with TKA in Neutral alignment and Outliers using (a) conventional alignment parameters of (HKA 0 ± 3°) or (b) a narrower range of alignment (HKA 0 ± 1°).

to patients who remained outside this range, closer to their original pre-operative deformity (i.e., constitutional alignment) (n = 20). More importantly, the group of patients who had a change to their post-TKA mechanical alignment in the opposite direction compared to their pre-operative alignment (n = 59), i.e., varus-to-valgus alignment or vice versa, did not report significantly worse WOMAC score, AKSS or flexion ROM (Figure 3).

4. Discussion

The main findings of this study are that the achievement of mechanical alignment of TKA within the conventional range (HKA 0 ± 3°) did not significantly improve knee function, knee ROM or prosthesis survival; furthermore, a tighter target alignment range (HKA 0 ± 1°), did not confer any advantage. Neither the preoperative nature of knee alignment, nor the nature of postoperative deformity affected these outcomes either.

While Berend and Ritter [20] showed that an important mode of component failure requiring revision TKA was medial bone collapse in TKA which were outside of target alignment of HKA 0 ± 3°, Bonner et al [38] did not show significant improved implant survival or better knee function if mechanical alignment within this target was achieved. Similarly, Paratte et al [39] and Howell et al [40] have found TKA that are outliers in alignment did not show increased revision rates with more than ten-year follow-up. In this study, we have shown similar knee function in the group of TKA which were in target alignment and those that were outliers irrespective of the range of this measurement. The prosthesis survival data in this study available from the AOANJRR showed the reported revision rate in the outlier group was very low and was lower compared to the neutrally aligned group up to six years after TKA.

The main limitations of this study are that limb alignment was assessed using different methods before and after surgery. Preoperative coronal alignment was assessed using MRI or CT scans for the purposes of PSI manufacturing, performed with the

Table 3
The relationship between various parameters of knee alignment and knee function measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, the American Knee Society Score (AKSS) and knee flexion range of motion (ROM).

Nature of alignment		N (%)	WOMAC	*p*-Value	AKSS	*p*-Value	ROM	*p*-Value
			Mean (SD)		Mean (SD)		Mean (SD)	
Target alignment post TKA (HKA 0 ± 3)	Neutral	365 (82)	42 (15.6)	0.81	158 (31.4)	0.93	117° (10.9)	0.50
	Outlier	79 (18)	41 (16.6)		158 (33.6)		116° (10.5)	
Target alignment post TKA (HKA 0 ± 1°)	Neutral	191 (43)	41 (15.1)	0.98	159 (30.2)	0.62	117° (10.5)	0.63
	Outlier	253 (57)	41 (16.3)		157 (32.9)		116° (11.1)	
Preoperative knee alignment (HKA 0 ± 3)	Neutral	101 (23)	43 (14.8)		157 (29.4)		117° (9.2)	
	Varus	278 (63)	42 (16.6)	0.32	158 (32.7)	0.95	116° (11.6)	0.87
	Valgus	65 (15)	39 (13.4)		157 (31.7)		117° (10.0)	
Postoperative TKA alignment (HKA 0 ± 3)	Neutral	365 (82)	42 (15.6)		158 (31.4)		117° (10.9)	
	Varus	17 (4)	39 (16.9)	0.87	159 (34.6)	0.99	112° (10.1)	0.17
	Valgus	62 (14)	41 (16.6)		158 (33.6)		117° (10.3)	
Change in direction of knee alignment after TKA	Neutral	365 (82)	42 (15.6)		158 (31.4)	0.99	117° (10.9)	
	A degree of preoperative deformity remains	20 (5)	39 (17.5)	0.68	159 (41.0)		115° (11.9)	0.69
	Swing in alignment after TKA in the opposite direction	59 (13)	42 (16.3)		158 (31.1)		116° (10.0)	

Table 4
Comparison of primary TKA in whom neutral mechanical alignment was achieved and a group of TKA considered alignment outliers (HKA > ±3°). The two groups were compared for number, reason and type of revision, the observed years of TKA survival and the yearly cumulative percent revisions of the primary TKA. Data provided by the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). The revisions/100 observed years of all joints reported in AONJRR is 0.63.

		TKA in neutral mechanical alignment n = 361 (%)	TKA alignment outliers n = 79 (%)
Primary diagnosis for TKA (%)	Osteoarthritis	355 (98.3)	78 (98.7)
	Rheumatoid arthritis	5 (1.4)	1 (1.3)
	Other	1 (0.3)	0
Revision number		7	1
Observed years		1661	373
Revisions/100 Obs. Yrs (95% CI)		0.42 (0.17, 0.87)	0.27 (0.01, 1.49)
Yearly cumulative percent revision of primary TKA (95% CI)	1 Year	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	2 Year	0.9 (0.3, 2.6)	0.0 (0.0, 0.0)
	3 Year	1.8 (0.8, 4.1)	1.4 (0.2, 9.2)
	4 Year	1.8 (0.8, 4.1)	1.4 (0.2, 9.2)
	5 Year	1.8 (0.8, 4.1)	1.4 (0.2, 9.2)
	6 Year	2.7 (1.2, 5.9)	1.4 (0.2, 9.2)
Revision diagnosis (%)	Pain	2 (0.6)	
	Patella erosion	2 (0.6)	1 (1.3)
	Infection	1 (0.3)	
	Instability	1 (0.3)	
	Loosening	1 (0.3)	
	TKA (Tibial/Femoral)	3 (0.8)	
Revision type (%)	Patella only	2 (0.6)	1 (1.3)
	Cement spacer	1 (0.3)	
	Insert/Patella	1 (0.3)	

patients in supine position. Post-operative coronal alignment was assessed using a CT scan in the supine position. Neither the pre-operative nor the post-operative limb alignment were assessed with the conventional method using long leg standing radiographs which take into account the weight bearing effect on the knee and any dynamic deformity due to laxity, ligament instability or knee imbalance; thus, the supine measurement would underestimate the degree of deformity. We did not evaluate the differences between the group of patients with CT based PSI and the group with MRI PSI for any differences in the accuracy of establishing TKA mechanical alignment or for differences in knee outcome measures. There is limited evidence to compare the two methods for the establishment of post-TKA mechanical alignment but recent systematic reviews showed that MRI based PSI results in a lower proportion of outliers in overall coronal alignment compared to CT based PSI protocol [41–43]. Furthermore, the scans were assessed by multiple reporting radiologists with no assessment of inter-observer or intra-observer reliability, and the margin of error for these measurements is not known which is especially an issue when considering a narrower target of HKA 0 ± 1°.

While this study focused on the effect of restoration of neutral mechanical alignment, we concede that mechanical alignment alone may not dictate TKA outcome. Even in cases of neutral mechanical TKA alignment, other factors such as sagittal alignment and individual component orientation may be of similar importance. While in this study only coronal alignment was assessed, other parameters of component alignment such as femoral component orientation and tibial slope were collected from the post-operative CT scan, and the results have been reported in a previous publication [44] that showed achievement of desired femoral component rotation in 96.2% of cases and desired posterior tibial slope 76.6% of cases. Similarly, we did not assess the potential contribution of other important variables like body mass index and medical comorbidities on patient reported outcomes.

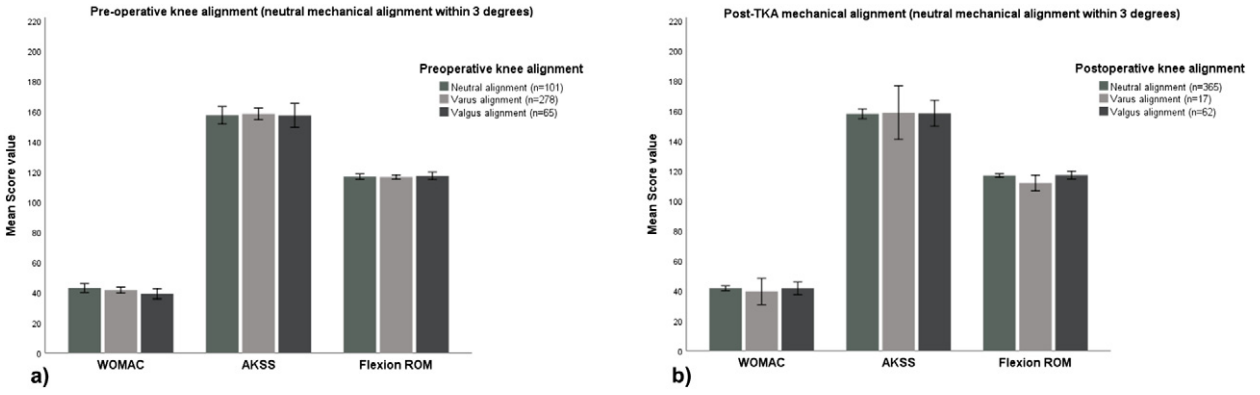

Figure 2. Comparison of outcomes in patients with respect to knee alignment (a) before and (b) after TKA.

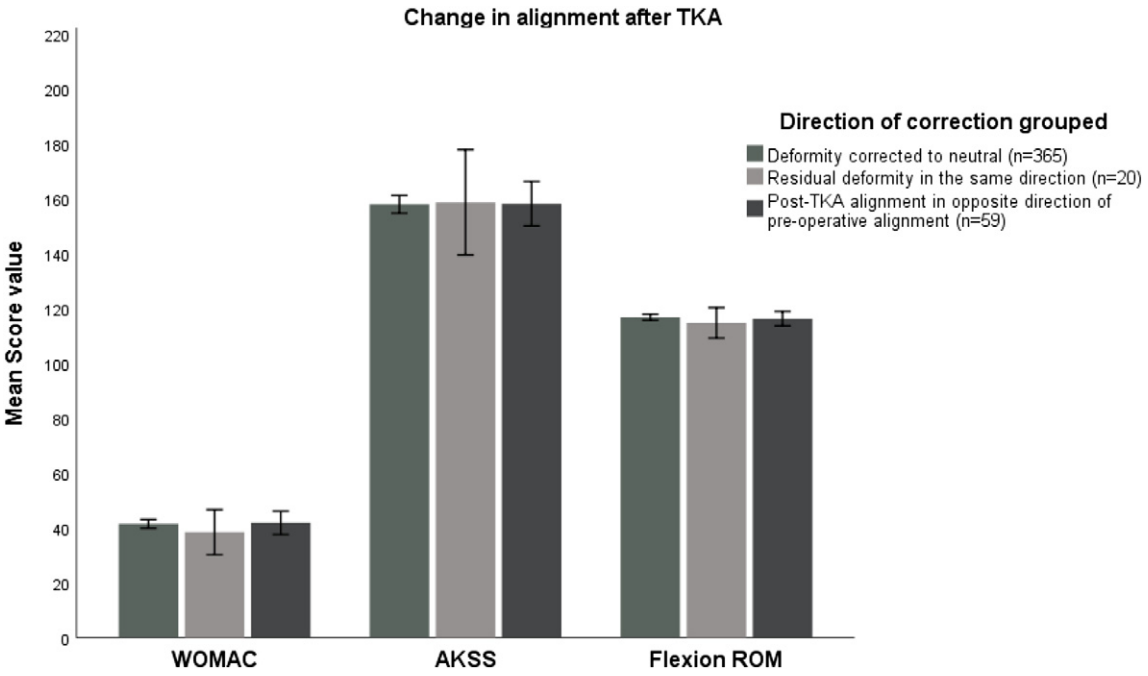

Figure 3. Comparison of the effect of change in direction of post-operative alignment compared to pre-operative knee alignment on knee outcomes.

The heterogeneity in follow-up is a limitation of many observational studies like ours in which 47% of our cohort had only short term follow-up at routine six-month assessment. Despite this limitation we showed that the outcomes in this group were not significantly different from the group with medium term follow-up who were on average 3 years after surgery. Furthermore, prosthesis survival up to six-year survival was not affected in cases that were outliers in mechanical alignment.

5. Conclusion

In this study of TKA alignment, achieving neutral mechanical alignment in the coronal plane measured in the supine position was not associated with improved knee function, knee ROM or prosthesis survival in short-to-medium term follow-up regardless of prosthesis type. The pre-operative nature of knee deformity and the change in alignment after TKA did not influence outcomes. The effect of other parameters of TKA alignment and component orientation in the coronal, sagittal and axial planes and how these impact on patient reported outcomes was not assessed and should be the focus of future research efforts.

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