Original Article

Does Tibial Axis Alignment Correlate with Mechanical Axis Alignment and Clinical Outcome?

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Background: Total knee arthroplasty (TKA) is the surgical treatment for osteoarthritis knee. Results of treatment are measured by clinical outcome and by longevity of the implant. The coronal plane axis of the tibial implant and the mechanical axis alignment of the leg are factors affecting outcome of the surgery. Mechanical axis malalignment results in early loosening, limited function, and reduced survivorship.

Objective: To determine if good tibial alignment correlates with mechanical axis alignment and clinical outcome.

Materials and Methods: This was a retrospective cohort study of 62 TKA patients. All TKAs were done by a single surgeon. The surgical protocol included the use of computer-assisted surgery and antibiotic cementing of the posterior cruciate-retaining knee without resurfacing of the patella. Preoperative, postoperative clinical outcome, WOMAC score, and KSS was record. One year postoperative x-rays (tibia implant alignment, mechanical axis alignment) and clinical outcomes (WOMAC score, KSS) were record. The patients were classified as good tibial alignment (Group A) if the tibia implant alignment was $\pm$2° of the tibia axis (neutral) and outlier tibial alignment (group B) if the tibia implant alignment was more than 92° or less than 88°. Clinical outcomes and the mechanical axis of good tibial alignment and outlier tibial alignment patients were compared. The good tibial alignment group was subdivided into neutral mechanical alignment (Group A1) if the mechanical axis alignment was $\pm$3° and outlier mechanical alignment (group A2) if the mechanical axis was less than 177° or more than 183°. WOMAC score and KSS were compared between the good tibial alignment and neutral mechanical alignment group (Group A1) and the good tibial alignment and outlier mechanical alignment group (Group A2).

Results: The good tibial alignment group had significantly better postoperative mechanical alignment than the outlier tibial alignment group (p = 0.003). There was no statistically significant difference in WOMAC score (p = 0.18) between the groups, but the good tibial alignment group had significantly higher (better) KSS scores (p = 0.04). Between the good tibial alignment with neutral mechanical alignment group and the good tibial alignment with outlier mechanical alignment group, there was no statistically significant difference in clinical outcome with either WOMAC score or KSS.

Conclusion: Tibia implant alignment in the coronal plane is one factor that affects postoperative mechanical axis alignment. If the tibial implant alignment is within $\pm$2° of neutral (90°), then the mechanical axis will be better aligned, although clinical outcome may not be improved. Clinical outcome was not correlated with tibial implant alignment within $\pm$2° of neutral with mechanical axis alignment deviation of less than 3° and tibial implant alignment within $\pm$2° of neutral but with alignment deviation greater than 3°.

Keywords: Total knee arthroplasty, Coronal tibial alignment, Mechanical axis alignment, Clinical outcome, Osteoarthritis knee

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Total knee arthroplasty [TKA] is a surgical treatment for osteoarthritis of the knee (OA knee). The outcome of this surgery is measured by patient satisfaction, absence of pain, and the functionality, stability and longevity of the implant. Clinical results are measured by the alignment axis of the implant, the position of the implant, and the soft tissue balance. The mechanical axis of alignment is a line along the center of the hip through the center of knee down to

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the center of the ankle. The medial angle formed by the mechanical axis of the femur and the mechanical axis of the tibia is usually slightly less than 180° in normal knees[1,2].

Mechanical alignment[3]. The tibial cut is made perpendicular to the tibial anatomical axis, then soft tissue balance is achieved after which the femoral cut is made. Coronal plane alignment of the implant has been described as an important factor in survivorship and in clinical outcomes. Malalignment is associated with early loosening, patellofemoral joint disorder, and limited function. If the malalignment of the mechanical axis is more than 3°, it can result in early failure. A number of studies have reported a correlation between mechanical axis alignment outliers of more than 3° and early failure, although the relationship of the mechanical axis alignment and clinical outcome is still a topic of discussion: some studies have reported no correlation between alignment and clinical outcomes. The presented study focused on the coronal plane alignment of the tibia for three reasons. First, there have been few published reports of the relationship of clinical results and tibial implant alignment[4]. Second, there has been debate over the relationship of clinical results and both mechanical and kinematic alignment in TKA. Third, with a cruciate retaining TKA implant such as that described in this study, the tibial cut has to be made first, followed by gap balancing, and then the femoral cut or femoral rotation which are done to conform to the tibial cut. In this system, tibial alignment is the key factor. The aim of this study was to determine the relationship between tibial implant alignment, mechanical axis alignment, and clinical outcome.

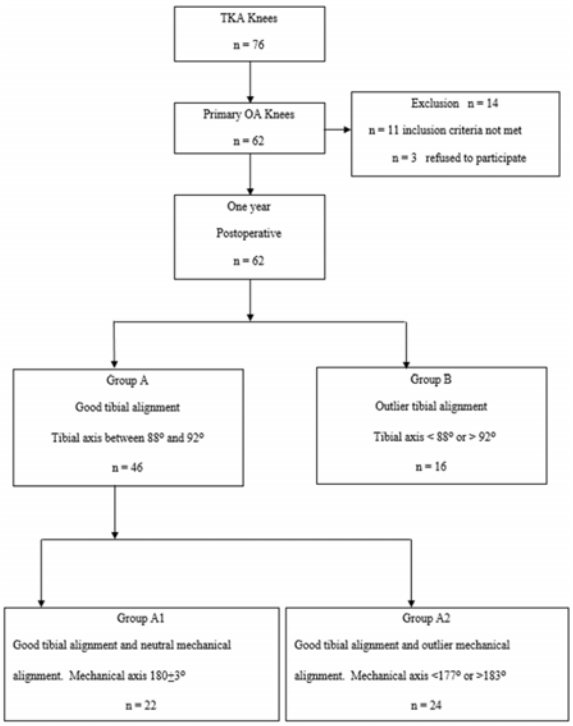

Figure 1. Flow chart of the study.

Materials and Methods

This retrospective cohort study included all OA knee patients from January through December 2015 who received a total knee arthroplasty performed by a single surgeon (SN) who had previously done more than 500 TKA operations. Inclusion criteria was osteoarthritis of the knee. Patients were excluded if they had infection of the knee, if they had had previous knee surgery or revision surgery, or if patient records were not complete. Prior to, and again one year post operation, the patients completed the modified Western Ontario and McMaster Universities Osteoarthritis Index score [WOMAC] and Knee society knee score [KSS] surveys which were conducted by two interobserver nurses (NC and CS). The WOMAC and KSS were completed as individual interviews. One year after the TKA, standing x-rays of the knee, a long standing film of the hip, knee, and ankle (mechanical alignment), and the medial angle formed by the mechanical axis of the femur and the mechanical axis of the tibia were done. The tibial plateau-ankle angle, i.e., the tibial implant axis (tibial alignment), was record. All measurements were performed by one radiologist (ST). A total of 76 TKAs were reviewed. Four patients were lost to follow-up, four patients were excluded because of incomplete data, and three patients who refused to participate in the study were excluded. Three additional patients who needed revision surgery were excluded: one required revision because of patellar complications, one had an osteoporosis fracture of the tibial plateau, and one had a periprosthetic fracture of the femur. Based on the work of Sikorski[6], tibial alignment within $\pm$2° of the tibia axis was defined as good tibial alignment (Group A). Outlier tibial alignment was defined as a tibial axis <88° or >92° (Group B). WOMAC scores, KSS scores, and mechanical axis alignment of Group A and Group B were compared. Group A was further divided into subgroups based on mechanical alignment: patients with neutral mechanical alignment (axis $\pm$3°) were designated as Group A1, and patients with outlier mechanical alignment (mechanical axis <177° or >183°) were designated as Group A2. Groups A1 and A2 were

Table 1. Patient demographic data

Demographic data	Good tibial alignment (Group A) (n = 46) n (percent)	Outlier tibial alignment (Group B) (n = 16) n (percent)
Sex		
Male	1 (2.17)	4 (25.00)
Female	45 (97.83)	12 (75.00)
Age (years)		
51 to 60	19 (41.30)	1 (6.25)
61 to 70	16 (34.78)	8 (50.00)
71 to 80	11 (23.91)	7 (43.75)
Mean ± SD	64.04±6.91	68.38±6.21
Median (min; max)	63.50 (53.00; 76.00)	68.00 (57.00; 75.00)
Mechanical axis angle		
Mean ± SD	176.76°±3.11°	174.75°±1.77°
Median (min; max)	176.50° (171.00°; 192.00°)	175.00° (170.00°; 178.00°)
Preoperative WOMAC score		
Mean ± SD	120.78±33.73	112.50±36.81
Median (min; max)	124.00 (50.00; 84.00)	122.50 (49.00; 167.00)
Preoperative KSS		
Mean ± SD	103.96±20.14	113.88±25.45
Median (min; max)	109.00 (65.00; 152.00)	111.00 (65.00; 154.00)

Table 2. Preoperative WOMAC scores of groups A and B

WOMAC score	n	X	SD	t	*p*-value	95% CI
Good tibial alignment (group A)	46	120.78	33.73	0.83	0.41	-11.76 to 28.33
Outlier tibial alignment (group B)	16	112.50	36.81			

There was no statistically significant difference between the groups (*p*-value = 0.41, Independent t-test)

Table 3. Preoperative KSS of groups A and B

Preoperative KSS	n	X	SD	t	*p*-value	95% CI
Good tibial alignment (group A)	46	103.96	20.15	-1.58	0.12	-22.46 to 2.62
Outlier tibial alignment (group B)	16	113.88	25.45			

There was no statistically significant difference between the groups (*p*-value = 0.12; Independent t-test)

investigated to determine the differences in clinical outcomes as measured by WOMAC and KSS.

Surgical technique

A navigate cemented posterior cruciate-retaining TKA without a resurfaced patella, e.motion® Total Knee System (B. Braun Melsungen AG) tourniquet was used. The midvastus approach with an imageless navigator system, Aesculap OrthoPilot® Navigation System (Aesculap, Tuttlingen, Germany) was used to asses the anatomical landmarks and the position of the cutting points. The tibia was cut first, perpendicular to the mechanical axis and with a posterior slope of 3°. All cutting guides were extra medullary, including the femoral cutting guide. The distal and posterior condyles were record by 4-point contact. This data was used to determine femur component size, flexion gap, extension gap, cutting height for the distal and posterior femoral resection, and the rotation of the femur component. Measurement of the flexion and extension gap was checked using a distractor device. Femoral planning included calculation of the distal femoral cutting height

for the extension gap and mechanical axis alignment. The mechanical axis alignment was set at 180°. The posterior femoral cutting height was for flexion gap and external femoral rotation. External rotation was set at 3° to balance the medial and lateral gap. After distal femur resection, the rotational alignment cut was done as planned by navigation. Then finishing cuts for the femur and tibia implantation were done and the e.motion® Total Knee System was inserted with antibiotic cement. Periarticular injection was given for local pain control and a Redivac drain was placed.

Clinical and radiographic evaluation

Clinical evaluation was done by two independent observers (NC and CS). WOMAC has a maximum score of 220 points. Higher scores indicate a worse condition, e.g., pain, stiffness, and physical functioning of the joints; scores near zero indicate good clinical results. KSS[7] scores include objective, symptoms, level of satisfaction, expectations, and function, e.g., walking and standing, standard activities, advanced activities, and discretionary activities. Scores near 230 mean the patient is doing well; scores near zero indicate poor clinical results. Patients' WOMAC and KSS scores were recorded prior to the operation and again one year post operation. One year after the operation, coronal alignment of the limb was evaluated using a postoperative long standing x-ray with full weight bearing done by one radiologist (SN). The mechanical axis of the leg and the tibial axis were recorded. The mechanical axis is the hip, knee, and ankle axis, the medial angle formed between the mechanical axis of the femur and the mechanical axis of the tibia. The tibial axis is the tibial plateau-ankle angle.

Statistical analysis

Quantitative values are expressed as mean and standard deviation (SD). Demographic information is reported as frequency and percentage. Sample size was calculated using STATA/SE 12.1 (StataCorp LP, TX, USA) with significance level (alpha) = 0.05 and power of the test = 0.8 (two-sided test). Sample size needed to achieve statistical significance for the mechanical axis angle was 37 patients in the good tibial alignment group and 13 patients in the outlier tibial alignment group. Comparison between the good tibial alignment group and the outlier tibial alignment group was done using the independent t-test. Comparison between postoperative WOMAC scores and KSS was done using the Mann-Whitney U test and the independent t-test. Differences were considered statistically significant when $p<0.05$.

Results

Fifty-eight patients (62 TKAs) were included in the study (89.06% female). The mean age of the patients was 66.21 years. Forty-six of the TKA patients had a tibial axis angle of between 88° and 92° (Good tibial alignment-Group A): 16 TKA patients had a tibial axis angle of less than 88° or more than 92° (outlier tibial alignment-Group B). The mean ages of group A and group B were 64.04 years and 68.38 years, respectively. There was no statistically significant difference in preoperative WOMAC scores or KSS scores between groups A and B. There was also no significant difference in severity of disease between the two groups. The mean mechanical axis of group A was 176.76° SD = 3.11°, and group B was 174.75° SD = 1.77°. That difference was statistically significant (p = 0.003) (Table 4).

There was no difference in postoperative WOMAC scores between Groups A and B (Table 5), but there was a significant difference in postoperative KSS scores (p = 0.04) (Table 6). There was no statistically significant difference in clinical outcome of WOMAC and KSS between the good tibial alignment group with neutral mechanical alignment group (group A1) and the good tibial alignment with outlier mechanical alignment (group A2) (Table 7 and 8).

Discussion

TKA is the standard treatment for osteoarthritis of the knee. This was a retrospective cohort prognostic factor study. A coronal plane

Table 4. Comparison of post-operative mechanical axis of groups A and B

Mechanical axis	n	X	SD	t	*p*-value	95% CI
Good tibial alignment (group A)	46	176.76	3.11	3.16	0.003*	0.73 to 3.29
Outlier tibial alignment (group B)	16	174.75	1.77			

The difference between the groups was statistically significant (p-value = 0.003, independent t-test)

Table 5. Postoperative WOMAC scores of groups A and B

Postoperative WOMAC score	n	X	Median	z	*p*-value	95% CI
Good tibial alignment (group A)	46	14.78	10.00	1.35	0.18	-1.00 to 11.00
Outlier tibial alignment (group B)	16	9.06	6.00			

There was no statistically significant difference between the groups (*p*-value = 0.18 Mann-Whitney U test)

Table 6. Postoperative KSS of groups A and B

Postoperative KSS	n	X	SD	t	*p*-value	95% CI
Good tibial alignment (group A)	46	190.13	22.03	2.01	0.04*	0.09 to 27.79
Outlier tibial alignment (group B)	16	176.19	28.65			

* The difference in tibial alignment between the groups was statistically significant (*p*-value = 0.04, Independent t-test)

Table 7. Postoperative WOMAC scores of Groups A1 and A2

Postoperative WOMAC score	n	X	Median	z	*p*-value	95%CI
Good tibial alignment and neutral mechanical alignment (177° to 183°) (group A1)	22	13.86	9.50	-0.30	0.77	-10.00 to 7.00
Good tibial alignment and outlier mechanical alignment (<177° or >183°) (group A2)	24	15.63	12.00			

Postoperative WOMAC scores of groups A1 and A2 showed no statistically significant correlation (*p*-value = 0.77 Mann- Whitney U test)

Table 8. Postoperative KSS of groups A1 and A2

Postoperative KSS	n	X	SD	t	*p*-value	95% CI
Good tibial alignment and neutral mechanical alignment (177° to 183°) (Group A1)	22	193.55°	21.86°	1.01	0.32	-6.56 to 19.65
Good tibial alignment and outlier mechanical alignment (<177° or >183°) (Group A2)	24	187.00°	22.18°			

Postoperative KSS of groups A1 and A2 showed no statistically significant correlation (*p*-value = 0.32 Independent t-test)

mechanical axis beyond 3° may affect both the longevity of an implant and the clinical results. Several studies have reported on the relationship between mechanical axis and clinical results. Computer navigation-assisted surgery [CAS] has resulted in increased precision in axis alignment[8-11] and has significantly reduced the incidence of mechanical alignment outliers[12]. For example, a study by Leelasestaporn C reported the mean mechanical axis deviation was less with CAS than with conventional TKA[15]. The operations in this study were done using CAS to achieve a more precise tibial alignment. With the mechanical surgery technique, the

tibial cut is perpendicular to the tibial axis. Several studies have shown that wear and premature failure of components can occur if total knee replacements are mechanically misaligned. Fang et al[21] retrospectively evaluated whether well-aligned total knee arthroplasty resulted in better survivorship compared with outliers (>3° valgus or varus). Multiple studies have reported that improved coronal limb alignment is not necessarily accompanied by improved functional outcomes[17-19], but some studies have shown that postoperative lower extremity alignment (measured on anteroposterior radiographs) is an important determinant of long-term outcomes following TKA[20,21]. However, whether improved implant alignment, including both tibial and mechanical alignment, results in better functional outcomes remains controversial, i.e., whether is the good alignment of the tibia is the factor that generates good clinical outcomes.

The aim of this study was to identify relationships between good tibial alignment with the mechanical axis and clinical outcomes. Good tibial alignment was defined as a tibia axis within 2° of neutral (90°) as described by Sikorski and Longstaff[5,6]. An outlier tibial axis has an angle of more than 92° or less than 88°. This study showed that the tibial axis of the implant had an effect on the mechanical axis. If the tibial axis was aligned within $\pm$2° of 90°, the mechanical axis was closer to 180° than in the outlier tibial alignment group. WOMAC scores of the good tibial alignment group showed no statistically significant difference postoperatively compared to the outlier tibial alignment group, but there was a significant difference in KSS results. Considering the mechanical axis, clinical outcomes in the good tibial alignment with neutral mechanical alignment group and the good tibial alignment with outlier mechanical alignment group showed no statistically significant difference in either WOMAC scores or KSS. This study showed that clinical outcome was not correlated with whether or not the mechanical axis deviated by more than 3°; several studies have reported similar results. A study by Khan et al[13] showed that patients who had an alignment deviation greater than 3° had significantly increased difficulty with activities of daily living, but that study found no correlation between alignment and WOMAC scores. Similarly, Mugnai[14], using multivariate analysis of clinical outcomes, reported that leg alignment had no impact on clinical outcome. Studies comparing conventional and computer navigation-assisted TKAs have found that navigation assistance, despite providing improvements in limb alignment, did not result in better functional outcomes than conventional TKAs[18,22]. Chowdhry M[23] found that functional outcomes of TKA were determined by multiple factors, not just coronal limb alignment, and that improvement in coronal limb alignment alone did not improve functional outcomes. Several previous studies have reported that improved coronal limb alignment was not necessarily accompanied by improved functional outcomes[17,18,19,24].

This study showed that good alignment of the tibial axis of the implant may affect clinical outcome as measured by KSS, although there have been a few studies which have found a relationship between good tibial alignment of the implant and clinical outcome. Longstaff[5] reported good coronal tibia alignment resulted in better function at one year but no significance. He suggested that good alignment can also lead to better function with quicker rehabilitation and earlier hospital discharge. The cause of the study cannot showed statistical difference between good alignment and outlier tibia alignment on WOMAC score was multiple factor. The number of patients in this study may have been insufficient. Also, the study only reported on early outcomes (one year); long term follow-up is needed as well. Another reason for lack of statistical significance is that clinical outcomes of TKA are multifactorial. Other factors include soft tissue balance and gap balance. Factors affecting component alignment include not only the coronal plane of the tibia but also the femur. The surgeon has to consider the sagittal and transverse plane of the tibia as well as femoral rotation.

Clinical outcomes, rather than using the sum of scores, should evaluate each score category individually, e.g., pain, functional, and activity score.

Conclusion

Tibial implant alignment in the coronal plane is one factor that can affect the postoperative mechanical axis. If the tibial implant alignment is within $\pm$2° of neutral (90°), then the mechanical axis will be better aligned; however, that may not affect clinical outcome. Clinical outcome was not correlated with tibia implant alignment being within $\pm$2° of neutral and mechanical axis deviation of less than 3°. Clinical outcomes and tibial alignment may require further investigation.

What is already known on this topic?

Mechanical axis alignment of greater than 3° from neutral can affect the longevity of an implant, but

may not be correlated with functional outcome. The coronal plane of the tibial implant is one factor affecting functional outcome. Computer-assisted surgery can produce more precise results and help prevent outlier axis alignment. There is some indication that tibial implant alignment within ±2° of neutral results in better functional outcomes.

What this study adds?

Tibial implant alignment in the coronal plane of the cruciate retaining TKA within ±2° of neutral provides improved mechanical axis alignment. Tibial alignment within ±2° of neutral results in better KSS than in the outlier group. However, tibial alignment within ±2° of neutral and mechanical axis deviation of less than 3° does not result in better clinical outcomes than outlier axis alignment.

Potential conflicts of interest

The authors declare no conflict of interest.

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