RESEARCH ARTICLE

Promising Results of Total Knee Arthroplasty in Patients with Severe Varus Deformity with High Constrained Prosthesis: A Prospective Study

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Abstract

Objectives: The existing literature does not provide a clear definition of the outcomes of total knee arthroplasty (TKA) and prosthesis constraint in patients with severe varus deformity. In this study, for the first time, we evaluated the outcomes of TKA and the relationship between prosthesis constraint and these outcomes in patients with severe varus deformity (>30 degrees).

Methods: This prospective cohort study was conducted on 41 patients (54 knees) with varus deformity greater than 30 degrees who underwent TKA between April 2013 and April 2019. The patients were divided into two groups based on the type of prosthesis (high constraint and low constraint). Surgical outcomes were evaluated using the Knee Society Score (KSS), Oxford Knee Score (OKS), range of motion (ROM), and postoperative complications.

Results: High-constrained prostheses (HCP) and low-constrained prostheses (LCP) were used in 44 and 10 knees, respectively. The mean follow-up duration was 77.11 ± 6.55 months. The mean KSS, KSS function, OKS, and ROM significantly improved after surgery compared to preoperative values (P<0.05). The mean improvement in the KSS function score after surgery was significantly higher in patients with HCP compared to those with LCP (p = 0.021). No significant differences were observed for the other variables. No cases required revision.

Conclusion: This prospective non-randomized study, conducted on 41 patients (54 knees) with severe varus deformity (>30º) who underwent total knee arthroplasty (TKA), demonstrated that the mean improvement in the Knee Society Score (KSS) function score after surgery was greater for high-constrained prostheses (HCP, N = 44) compared to low-constrained prostheses (LCP, N = 10). The HCP group included 40 Legacy Constrained Condylar Knees (LCCK) and four hinged knee prostheses, while the LCP group included posterior-stabilizing (PS) prostheses. The mean follow-up duration was 6.5 years. Given the small sample size, randomized clinical trials are needed to validate our preliminary findings.

Level of evidence: III

Keywords: Constrained prosthesis, Functional score, Knee osteoarthritis, Severe varus, Total knee arthroplasty

Introduction

Osteoarthritis (OA) is the most common progressive disease of the human musculoskeletal system.[1,2] According to study findings, the prevalence and incidence of OA are increasing worldwide, with an estimated 250 million people affected by the condition globally.[1,3] Research has shown that the knee is the joint most commonly affected by OA, with its prevalence in individuals over 60 years of age estimated at 13% in women and 10% in men.[1,2,4] Total knee arthroplasty (TKA) has been established as the gold-standard treatment for patients with knee OA.[5-7] Knee varus deformity is the most prevalent deformity in patients eligible for TKA.[8,9] The severity of varus deformity is a critical factor in determining the success of TKA and its outcomes.[10,11]

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Studies have shown that the success rate of total knee arthroplasty (TKA) and its outcomes vary in patients with varus deformities before surgery.[6,10,12-15] Several methods have been employed for TKA in cases of severe varus deformity; however, there is still no consensus on the optimal prosthesis type or the preferred method of ligament balancing for orthopedic surgeons in these patients.[6,16-19] Sorrells et al. have demonstrated that selecting the appropriate prosthesis can reduce the impact of varus deformity severity on postoperative outcomes.[20] However, there are very few studies focusing on the correction of varus deformity in TKA based on the severity of the deformity. Therefore, given the importance of this issue, the present study was designed to evaluate the outcomes of TKA in patients with severe varus deformity (varus angle >30 degrees) and to investigate the association between prosthesis constraint and postoperative outcomes in these patients.

Materials and Methods

This study was approved by the Ethics Committee of Iran University of Medical Sciences under the code IR.IUMS.FMD.REC.1399.719. In this prospective cohort study, 49 patients who were candidates for total knee arthroplasty (TKA) with severe varus deformity, and who were referred to Shafa Yahyaian Hospital, affiliated with Iran University of Medical Sciences, between April 2013 and April 2019, were included after meeting the inclusion criteria. A varus angle greater than 30 degrees was defined as severe varus according to Muylder et al.[21] The inclusion criteria were patients with severe varus deformity (>30 degrees), at least 36 months of follow-up, Kellgren and Lawrence OA grade III or IV, and willingness to cooperate in the study. Exclusion criteria included: patients with traumatic knee injuries, varus deformities less than 30 degrees, body mass index (BMI) >40 kg/m^2, previous surgeries (revision), and non-cooperative patients for follow-up. During follow-up, six patients did not return for follow-up visits, and two patients died due to causes unrelated to TKA. A total of 41 patients (54 knees) with severe varus deformity were included in this study. Informed consent was obtained from all patients before surgery. Preoperative radiographs and physical assessments were performed and recorded for all patients. All surgeries were performed by a senior knee orthopedic surgeon with over 30 years of experience (J. Mah).

All surgeries were performed using an anterior midline incision and medial parapatellar arthrotomy, following the mechanical alignment concept. Based on the type of prosthesis constraint used in total knee arthroplasty (TKA), patients were divided into two groups: high-constrained prosthesis (HCP) and low-constrained prosthesis (LCP). The HCP group included Legacy Constrained Condylar Knees (LCCK) and hinged knee prostheses, while the LCP group included posterior-stabilizing prostheses. Decision-making regarding the level of constraint was primarily based on ligament balancing. If ligament balancing was achieved during surgery (with a maximum difference of 2-3 mm between the medio-lateral gap in extension and flexion, and a medial gap no greater than 1 mm, with equal flexion and extension gaps) using trial components, then a low-constrained prosthesis (LCP) was used. Otherwise, or in knees with ligamentous insufficiency, particularly in the medial collateral ligament, a high-constrained prosthesis (HCP) was used. In such cases, a Legacy Constrained Condylar Knee (LCCK) or hinged knee prosthesis was chosen based on the severity of ligamentous imbalance. All surgeries employed the Zimmer Biomet (Warsaw, IN) Nexgen system knee prosthesis. Patients were followed up postoperatively to assess outcomes and adverse effects. Follow-up visits occurred at 1 week, 1 month, 3 months, 6 months, and 1 year after surgery, followed by annual visits thereafter, with assessments conducted by an orthopedic specialist in terms of surgical outcomes. The individual who collected postoperative data and scores was unaware of the type of prosthesis used during surgery (A.A).

Patient information was collected using a checklist in two parts: demographic characteristics (age, gender, BMI, duration of follow-up, and underlying diseases) and clinical information before and during surgery (severity of varus, range of motion (ROM), and stage of release).[22] The lateral distal femoral angle (LDFA), congruence angle, medial proximal tibial angle (MPTA), and type of prosthesis used (HCP and LCP) were also recorded.

The outcomes of the surgery were evaluated using functional questionnaires, including the Knee Society Score (KSS) and Oxford Knee Score (OKS). Additionally, the range of motion (ROM), flexion contracture, and postoperative complications of all patients were assessed.

Knee Society Score (KSS): This questionnaire consists of two subsets: the knee score (assessing the knee joint) and the KSS function score (evaluating the patient's ability to walk and climb). The total score is 200 points: 100 points for the knee score, including 50 points for pain, 25 points for range of motion, and 25 points for stability. The remaining 100 points are for the patient's performance, including 50 points for climbing stairs and 50 points for walking distance. A lower score indicates worse knee function. The Oxford Knee Score (OKS) questionnaire was also used to evaluate outcomes. The scoring system for OKS ranges from 12 to 60, with a higher score indicating worse outcomes and a lower score indicating better results. The validity and reliability of these questionnaires have been confirmed for the Iranian population.[23,24]

The success rate of the operation was evaluated by comparing the mean scores before and after surgery for the Knee Society Score (KSS), KSS function, Oxford Knee Score, range of motion (ROM), flexion contracture or recurvatum, and varus angle. All outcome scores and measures mentioned above were evaluated in two groups (HCP and LCP) and compared with each other.

Statistical analyses

All data were analyzed using SPSS version 22 statistical software. Descriptive statistics, including mean and standard deviation, were used for quantitative and qualitative variables. The normality of the distribution of quantitative variables was assessed using the Kolmogorov-Smirnov test. To compare quantitative variables between two groups, the t-test was used for normally distributed variables, and the Mann-Whitney test was applied for non-normally distributed variables. A paired t-test was used to compare the mean scores of the questionnaires before and after surgery. The Chi-square test was used to compare qualitative variables. One-way ANOVA was used to analyze the association between variables across more than two

groups. A p-value of less than 0.05 was considered statistically significant.

Results

Overall, 41 patients (54 knees) were included in the study. Of these, 38 (92.7%) were female. The mean age of the patients was 66.22 ± 7.55 years, ranging from 31 to 81 years. The mean follow-up duration was 77.11 ± 6.55 months, with a range from 36 to 101 months. Twenty-one patients (51.2%) had a history of at least one underlying disease, with hypertension being the most common chronic condition among surgical candidates. The mean body mass index (BMI) was 28.8 ± 3.22 kg/m^2. The mean varus angle before surgery was 32.8 ± 2.1º. The overall mean preoperative lateral distal femoral angle (LDFA) was 96.2º. The mean preoperative range of motion (ROM) was 88.7 ± 7.12º. Recurvatum was observed in 12 knees, with angles ranging from 5 to 10º. The degree of flexion contracture in 12 knees was less than 10º. Five patients required stage 2 release, and 24 knees (44.4%) required stage 4 release. In addition to tissue release, Pie Crusting was performed during surgery in 7 knees. Reduction osteotomy was used in all surgeries to some degree. High-constrained prosthesis (HCP) was used in 44 knees, and low-constrained prosthesis (LCP) was used in 10 knees [Table 1]. No significant difference was observed in demographic characteristics and preoperative scores between the two prosthesis groups [Table 2].

Table 1. Demographic and clinical characteristics of patients before surgery

Patients number	41 (54 knee)
Mean Age (Year)	66.22±7.55
Mean follow-up (month)	77.11±6.55
Sex • Male • Female	 3(7.3%) 38(92.7%)
PMH • Spine disorders • Hypertension • Diabetes • Thyroid disorders • Others	 19(46.3%) 21(51.2%) 6(14.6%) 5(12.2%) 1(2.4%)
Varus Angle º	32.8±2.1
LDFAº (Lateral distal femur angle)	96.2±3.1
MPTAº (Medial proximal tibia angle)	76.2±5.1
CAº (Congruence angle)	12.4±4.8
ROMº	88.7±7.12
Stage of Release (54 Knee) • II • III • IV	 5/54(9.3%) 25/54(46.3%) 24/54(44.4%)
Prosthesis Constrain • HCP LCCK Hinge knee • LCP PS	 44/54 (81.48%) 40/54(74.1%) 4/54(7.4%) 10/54(18.51%)

LCCK: Legacy constrained condylar knee, Nexgen, Zimmer Biomet, PS: Posterior Stabilized, LDFA: Lateral Distal Femur Angle, MPTA: Medial proximal Tibia Angle, CA: Congruence Angle, ROM: Range Of Motion, HCP: High constrained prosthesis, LCP: low constrained prosthesis

Table 2. Comparison of demographic and clinical characteristics of patients in two prosthesis groups

Variable	Prosthesis Type		P-value
	HCP (N:44 Knee)	LCP (N:10 Knee)	
Age (Year)	66.56±7.3	64.1±9.8	0.36
Mean follow-up (month)	78.44±16.44	77.2±15.66	0.53
BMI(Kg/m^2)	28.1±3.11	28.9±3.15	0.86

Table 2. Continued			
Sex			
• Male	2(4.5%)	1(10%)	0.33
• Female	42(95.5%)	9(90%)	
Past Medical History			
• Spine disorders	16(36.4%)	4(40%)	0.51
• Hypertension	18(40.9%)	4(40%)	
• Diabetes	5(11.4%)	1(10%)	
• Thyroid disorders	4(9.1%)	1(10%)	
• Others	1(2.1%)	0(0%)	
Varus º	32.93±2.54	32.5±1.89	0.23
KSS	6.52±4.25	8.3 ±5.2	0.12
KSS Function	22.98±10.5	27.4±14.12	0.15
Oxford Knee Score	51.61±3.2	51.3±4.42	0.83
ROM º	89.61±22.3	92.1±14.93	0.44

HCP: High-constrained prosthesis, LCP: low-constrained prosthesis, ROM: Range of Motion, KSS: Knee Society Score

The mean Knee Society Score (KSS) after surgery (92.1 ± 13.2) showed a significant improvement compared to before surgery (6.1 ± 4.3) ($p < 0.001$). Additionally, both the KSS function and the Oxford Knee Score improved significantly after total knee arthroplasty (TKA) [Table 3].

The mean range of motion (ROM) improved from 88.7 ± 7.12 before surgery to 113.3 ± 6.4 after surgery, which was statistically significant ($P = 0.001$). Additionally, the mean flexion contracture improved significantly after surgery compared to before surgery ($P = 0.001$) [Table 3]. After surgery, recurvatum was not observed in any of the patients. Follow-up radiographs showed that, despite the severe deformities before surgery, limb alignment was well restored in all patients (Varus angle 2.53 ± 2.2) [Table 3].

Table 3. Comparison of functional outcomes of patients before and after Total Knee Arthroplasty			
Variable	**Pre-operation (Mean ±SD)**	**Post-Operation (Mean ±SD)**	**P-value**
KSS	6.1±4.3	92.1±13.2	0.001
KSS Function	20.12±12.8	83.1±14.2	0.001
Oxford Knee Score	51.8±3.66	22.3±5.8	0.001
ROM º	88.7±7.12	113.3±6.4	0.001
Flexion Contracture º	15.3±13.1	0.51±2.1	0.001
Varus º	32.8±2.1	2.53±2.2	0.001

ROM: Range of Motion, KSS: Knee Society Score

No significant difference was observed in any functional measures before surgery. The mean improvement in KSS function score after surgery was significantly higher in patients who received high-constrained prosthesis (HCP) (65.23 ± 15.31) compared to those who received low-constrained prosthesis (LCP) (49.13 ± 13.88) ($P = 0.021$) [Table 4].

No statistically significant difference was observed for KSS, OKS, and ROM between the two types of prostheses ($P > 0.05$) [Table 4]. The mean functional scores for all indices improved significantly after surgery compared to before surgery in both types of prostheses ($P < 0.05$).

The rate of postoperative complications in this study was very low. The most significant complication was one case of infection in the LCP group. No other serious complications, including deep vein thrombosis, prosthesis loosening, or fractures around the prosthesis, were reported. None of the patients required revision surgery.

Table 4. Comparison of the functional outcomes of patients after surgery based on the type of prosthesis

Variable	Prosthesis Type		P-value
	HCP (N:44 Knee)	LCP (N:10 Knee)	
KSS difference before and after surgery	88.11±8.25	85.4±4.22	0.26
KSS Function difference before and after surgery	65.23±15.31	49.13±13.88	0.021
Oxford Knee Score difference before and after surgery	30.11±5.35	26.77±4.35	0.12
Rom º (Mean ±SD) after surgery	112.3±7.11	115.2±4.31	0.51

HCP: High-constrained prosthesis, LCP: low-constrained prosthesis, ROM: Range of Motion, KSS: Knee Society Score

Discussion

Very few studies have investigated the outcomes of total knee arthroplasty (TKA) in patients with varus deformity greater than 30 degrees. Given the characteristics and severity of the deformity in these patients, several factors may influence the outcomes of TKA. One such factor is the type of prosthesis constraint used during surgery. To the best of our knowledge, no study has compared the results of TKA with different prostheses. Given the significance of this issue, this study not only evaluates the effect of TKA in patients with severe varus deformity but also assesses the relationship between the type of prosthesis constraint and TKA outcomes.

Our study showed that the majority of patients were women, with a mean age of 66.22 ± 7.55 years. Almost half of the patients had a history of at least one underlying disease, with hypertension being the most common condition. The mean scores for KSS, KSS function, Oxford Knee Score (OKS), and range of motion (ROM) improved significantly after surgery, consistent with the findings of other studies in this field. AB Mullaji et al., in examining the outcomes of surgery after total knee arthroplasty (TKA) in 173 patients with varus deformity greater than 20 degrees, found that the mean scores for KSS and KSS function improved significantly compared to preoperative values, which is similar to the results of our study.[25] L. Vanlommel et al., in a cohort study examining 132 patients with severe varus deformity before surgery, showed that the functional status of patients improved significantly based on the Knee Society Score (KSS) compared to preoperative levels. They reported no need for revision in their study. In a prospective cohort study, B.S. Lee et al., by examining 168 knees with varying degrees of varus deformity, demonstrated that, like other patients, total knee arthroplasty (TKA) can significantly improve the quality of life and functional status of patients with severe varus deformity.[26]

Our study showed that, in follow-up radiographs performed after surgery, the alignment of the patient's limbs was well restored in all patients, despite the severe deformities present before surgery. Very few studies have investigated the relationship between prosthesis type and postoperative outcomes and functional measures in patients with severe varus deformity. Our study found that the kind of prosthesis was only associated with the Knee Society Score (KSS) function score. Specifically, in surgeries where a high-constrained prosthesis (HCP) was used, the mean KSS function score after surgery was significantly higher compared to surgeries where a low-constrained prosthesis (LCP) was used. No significant association was observed between the type of prosthesis and functional scores for KSS, Oxford Knee Score (OKS), and range of motion (ROM) after surgery ($P > 0.05$). Only one patient developed an infection one year after surgery. No other serious complications were observed, and none of the patients required revision surgery, consistent with the findings of different studies.[13,21,27]

J. De Muylder et al., in a retrospective study examining functional criteria, including KSS, ROM, KSS function, and stability after total knee arthroplasty (TKA) in 51 knees with severe varus and valgus deformity, showed that surgery was successful in all patients who received a low-constrained prosthesis (LCP). Their study demonstrated that LCP can establish joint stability, restore limb alignment, and improve clinical outcomes in patients with severe deformities. However, none of the patients in their study had a varus deformity greater than 30 degrees.[21] In our study, only 10 of the 54 operated knees were treated with a low-constrained prosthesis (LCP). At the same time, 81.5% required a high-constrained prosthesis (HCP), particularly the Legacy Constrained Condylar Knee (LCCK) prosthesis (74.1%). In a study by P. Cholewinski et al. (2015), the outcomes of knee surgeries using the LCCK prosthesis were examined. Over an 11-year follow-up period, they reported a 97.7% rate of no need for revision, which was not significantly different from the revision rates required for other prostheses.[28] Although the follow-up period in our study was much shorter than that in the study mentioned above, the results did not indicate any need for revision in either prosthesis group, which aligns with the findings of that study. Given that very few studies have been conducted in this field, we are unable to further discuss or compare the results of our study with those of others. However, based on the findings from both this study and previous research, which show no loosening of high-constrained prostheses (HCP) in long- and mid-term follow-ups, it seems logical and perhaps inevitable that the trend toward not using high-constrained prostheses may become more common in patients with severe varus deformities.

Our study had both strengths and limitations that should be acknowledged. The most significant limitation was the small sample size in the LCP group, which was a result of the study design and the short-term follow-up period after surgery.

This limitation could potentially impact the study results. Additionally, due to the study design, the severity of the deformities, and unpredictable ligamentous balancing issues, we were unable to randomly assign patients to the HCP and LCP groups. A randomized clinical trial design would allow for more accurate estimation of the results. The primary strength of this study was its prospective cohort design, which enabled us to evaluate surgical and functional outcomes after total knee arthroplasty (TKA) in patients with varus deformity greater than 30 degrees based on the prosthesis constraint.

Conclusion

This study demonstrated that total knee arthroplasty (TKA) is effective in patients with severe varus deformity greater than 30 degrees. Despite the severe deformity before surgery, limb alignment was successfully restored in all patients. Most patients required a high-constrained prosthesis (HCP), and the mean KSS function score improved after surgery, with better results observed in patients who received HCP. No significant association was found between the type of prosthesis and other outcomes, nor was there any need for postoperative revision. High-constrained prosthesis (HCP), particularly with varus-valgus constraint, can be used effectively in TKA for patients with severe varus deformity, yielding promising midterm results without significant complications.

Availability of data and materials

The datasets generated or analyzed during the current study are available from the corresponding author on reasonable request.

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