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Primary total knee arthroplasty in advanced osteoarthritis knee with sever varus deformity which level of constraint?

Mohammed A. Mousa
Orthopedic Surgery Department, Faculty of Medicine - Cairo University
Corresponding author email: dr.Mohamedaliortho@gmail.com

Ahmed A. Ahmed
Orthopedic Surgery Department, Faculty of Medicine - Cairo University

Ahmed M. Gad
Orthopedic Surgery Department, Faculty of Medicine - Cairo University

Mahmoud A. Abdel-Aziz
Orthopedic Surgery Department, Faculty of Medicine - Cairo University

Ahmed M Lymona
Orthopedic Surgery Department, Faculty of Medicine - Cairo University

***Abstract*---**Background: Varus deformity is predominantly the most common deformity seen in candidates for Total Knee Arthroplasty (TKA). Adjusting a stable knee prosthesis and restoring both the limb and the joint line position to fit the normal mechanical axes have been shown to have an important bearing on the outcome of TKA. Objective: To choose an appropriate level of the constraint of knee prosthesis intraoperatively after a proper gap and soft tissue balancing in primary TKA in the advanced osteoarthritic knee with sever varus deformity. Methods: Our study was a prospective case series study including 45 knees with primary advanced osteoarthritis (OA) in varus deformity ≥ 15° totally intraarticular conducted for primary TKA. Results: The range of movement (ROM) increased from a mean of 85.15° to a mean of 100.75°.The mean flexion deformity enhancement was 1.7 postoperative in comparison with 9.088 preoperative. Clinical scores were significantly improved postoperatively. The average Knee Society Scoring (KSS) was 86.8 compared with the average pre-operative KSS of 23.089. The average Knee Function Score (KFSS) was 80.67 compared with the average pre-operative KFSS of 37.44. The average Knee injury and Osteoarthritis Outcome Score (KOOS) was 84.73 in comparison with

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the mean preoperative KOOS of 25.37 showing a significant P-value of (< 0.05) upon statistical calculations. Conclusion: A proper choice of prosthesis type depends on many factors, pre-operative as the level of OA, TFA, ROM, flexion deformity and ligament contracture, and intraoperative like proper gap balancing soft tissue release, and ML laxity.

***Keywords*---**Osteoarthritis, Total Knee Arthroplasty, Varus deformity.

1. Introduction

Knee joint Osteoarthritis (OA) is a chronic disease that is accompanied by pain and also functional limitations. Total Knee Arthroplasty (TKA) is a method that can help pain relief and successful function restoration among patients who are suffering from advanced OA. Long-term success in TKA can be achieved through maintaining steady fixation and stable establishment of the components with the underlying bone (Touzopoulos et al., 2015). The most common angular deformity, especially among patients suffering from primary TKA, is the Varus deformity which is represented on the X-rays and indicated when a mechanical femorotibial axis of less than 180° on full leg standing and the medial joint line is detected (Mancino et al., 2021).

The proper alignment of the knee to reach the angular anatomical normal adjustment of about 5° valgus can be challenging and may involve intraoperative procedure for ligament releases and/or even ligament tensioning as well for restoring proper balance (Ritter et al., 2004). Ligamentous contracture and laxity are usually present and accordingly, the degree of deformity is either a fixed one with contracture of the soft tissue structures or in the form of instability reflecting stretching of the soft tissue without contracture of the structures (Mullaji and Shetty, 2009).

Numerous surgical techniques have been stated to correct the deformity of the varus knee depending on adjusting the soft tissues' balance during TKA to achieve a tibial cut perpendicular to the shaft of the bone and the femoral cut until being perpendicularly adjusted upon the femur mechanical axis. Bone graft augmentation or metal may be added to worn sides for severe types of intra-articular deformity with bone loss (Hamai et al., 2015, Zhang et al., 2019).

After all, techniques to correct varus knee deformity must not compromise the Total knee replacement (TKR) main principles, which involve correct limb alignment, correct implant position, the balance of flexion and extension gaps, joint line proper restoration, central tracking of the patella, and adequate range of motion (Apostolopoulos et al., 2010). Achieving a properly positioned and steady stable prosthetic construct along with adjusting the limb and the joint line until restoring the normally fixed axis have proved their significance on the outcome consequences that are seen after the replacement operation of the knee (Chua and Wang, 2013).

The aim of this work is to choose an appropriate level of the constraint of knee prosthesis intraoperatively after a proper gap and soft tissue balancing in primary TKA in the advanced osteoarthritic knee with varus deformity ≥15 degrees to achieve a properly positioned and steady placed prosthetic construct with the adjustment of the limb to restore its normal axis and functional range of motion.

2. Patients and Methods

Over 20 months, a prospective case series study including 34 patients with 45 knees was conducted by a Senior Author at the University of Cairo, Faculty of Medicine, within the time from March 2016 till November 2017, who underwent primary TKA. All included patients were diagnosed as primary advanced OA with varus deformity ≥ 15° totally intraarticular. We excluded knees with any deformity due to inflammatory arthritis (e.g. Rheumatoid arthritis), post-traumatic O.A, extra-articular deformity, previous high tibial osteotomy, and previous unicondylar arthroplasty. Also, any patients with other general contraindications of arthroplasty were excluded.

Ethical consideration:

The Institutional Review Board and Ethical Committee approval was taken. The patient's informed consent was gathered from all of them after a thoughtful explanation of the nature of the study and the surgical procedure. According to regulation of the faculty of medicine Research Ethics Committee – Cairo University.

Pre-operative

A full-length standing X-ray long film AP radiographs that include hip, knee, and ankle were obtained in order to fix the mechanical pre-operative axes, tibiofemoral angles, and bone deformities along with standard weight-bearing AP and lateral x-rays to assess the degree of osteoarthritis, knee alignment, patellar height, tibial slope, and posterior osteophytes for all patients.

Pre-operative routine laboratory and clinical assessments of the patients were done. Knee Society Scoring (KSS) system (Odum et al. 2017) and Knee Injury And Osteoarthritis Outcome Score (KOOS) (Collins et al., 2016) were both registered for each patient preoperatively.

Surgical Technique

All patients were given first-generation cephalosporin antibiotic as a prophylactic antibiotic and spinal anesthesia plus ultrasound-guided insertion of adductor canal catheter for continuous infusion of local anesthetics for postoperative pain control. Supine position and knee hold flexed at 70-90 ° by a sandbag for foot, lateral hip post is placed to avoid leg rotation externally, especially at the hip, and a tourniquet was applied high in the thigh. The main approach performed was the medial para-patellar approach Midline skin incision with avoidance of skin undermining then medial parapatellar arthrotomy is performed. Both menisci

were eliminated from the menisco-capsular junction. Also, the cruciate ligaments including the anteriorly situated and the exterior ones were both excised.
The preparation of the bone started with distal femur cutting at 6° of valgus regarding the femur anatomical axis using intramedullary instrumentation. The external rotation of the femur was determined by the aid of the following axis the trans-epicondylar, posterior condylar, and also the white side line. Then the anterior, posterior, and chamfer femur cuts were formed using a properly sized saw.

With the aid of extramedullary guidance, a proximal cut in the tibia was performed aligned with the tibia sharp anterior crest of the tibia and the second metatarsal bone perpendicularly positioned to the tibia mechanical axis with a posterior inclination o about 7° in the sagittal bearing based on the height of the intact lateral bone surface. A normal lateral tibial plateau of approximately 8-10 mm bone thickness was resected from the proximal tibia which may leave a bony defect on the medial side of the tibia.

Varus and valgus stress were applied on both the extension and the flexion, using spacer blocks, for gap balancing. Our goal was to make a balanced rectangular space between distal femur cuts in extension (extension gap) and cuts, which are proximally situated in the tibia and posteriorly located in the femur, in flexion (flexion gap). Lateral knee opening on applying a varus force was often more than the side opening that is medially formed upon applying a valgus force because of the tightness of medial structures.

Intraoperative assessment of knee prosthesis type (constraint level) has been done post balancing, continuing with the knee trial femoral, tibial, and polyethylene components insertion. A trial range of motion detecting patellar tracking, full extension, full flexion, and joint opening in both the lateral and medial compartments with varus and valgus forces respectively.

Normal mediolateral (ML) laxity was about 2-4 mm joint opening approximately that proceed with PS Prothesis done in 26 knees (57.8 %) and if ML laxity was approximately 5-8 mm, we used CCK Prothesis to control laxity and no more cut to preserve a level of the joint line was done in 16 knees (35.6 %). We used RHK prosthesis in 3 knees (6.7 %) when ML laxity opened more than 10 mm in both the laterally located and medially situated compartments. Through adopting a valgus force, the knee is investigated for any residual medial tightness during flexion and extension.

All patients underwent Patelloplasty without any patella resurfacing. All implants were fixed using bone cement (Polymethyl-Meth-Acrylate PMMA) with an antibiotic. A long stem tibial component was used to unload the deficient metaphyseal bone in all patients. Proximal tibial bone defects were managed by bone cement filling obtained for the majority of cases (93.33%) with minute defect of < 5mm, cementing using reinforcing 3.5 screws were performed in one case (2.22%) for defect of about 5 to 10mm, and in case of large defect of >10mm metal block augmentation with stem was done and used in two cases (4.44%). Finally, closures of parapatellar arthrotomy and subcutaneous tissue were done.

Postoperative Protocol

The average hospital stay was average of three days. Postoperative measures for all patients included continuous ice packing and removal second layer of the bandage after 2 hours postoperative. Hemoglobin and hematocrit levels were done first day postoperatively. Medications, including analgesic, anticoagulant, broad-spectrum IV antibiotic, and anti-oedematous were prescribed. Postoperative x-rays were done for all patients.

The day after surgery, patients were encouraged to start assisted full weight-bearing using a walker. Continuous passive motion (CPM) machine used in full extension and 70°flexion 30 min every 4 hours with an increased degree of flexion as tolerated. Physical therapists started work with the patients on the second day after surgery.

Patients visited the outpatient clinic at time intervals of 1, 2, 4, 6, and 8 weeks and also 3 and 6 months, all that for pain, edema, wound healing, and uprising complications identification and management. Radiological evaluation was done at 6 weeks and 3 months including by standing AP, and lateral radiographs and for evaluating the successful extent of the TKA alignment results, a full-length hip-to-ankle radiograph may also be done.

The functional evaluation consisted of a range of movement (ROM), maximum flexion, and clinical scoring by KOOS and KSS which consists 2 parts:1st Part - Knee Score KSS (pain, alignment, flexion total range, stability, contracture of the flexion, and the extension lag), and 2nd Part Function Score KFSS (walking, stairs and walking aids are used).

Statistical analysis

Data coding and entering have been done by using the statistical package SPSS (Statistical Package for the Social Sciences) version 25. Summarization of data is done to express its mean, standard deviation, minimum and maximum values for quantitative data and calculate the frequency (count) and relative frequency (percentage) for the categorical type of data. The non-parametric Kruskal-Wallis and Mann-Whitney tests are performed for comparing the quantitative data type. While categorical data are compared by performing the Chi-square (x 2) test for them. Instead, in case the expected frequency is found less than 5. P-values less than 0.05 were considered statistically significant by using an Exact test.

3. Results

Our study's mean age was 61.9 years (ranged from 48 to 78 years). Out of the 34 patients (45 Knees), 5 were males (15%) and 29 were females (85%). Twenty-three knees were left-sided (51%) and 22 were right-side (49%). All were Unilateral TKA except one male did bilateral TKA and ten females did bilateral TKA in separate operations.

The average postoperative ROM was 100.75° (ranged from 70-135°). There were three knees (7%) with a maximum range of above 110°, forty-one knees (91%)

ranged between 80 and 110 °, and one knee (2%) with a range below 80 °. Improved in comparison to the pre-operative ROM the average was 85.15 ° (ranged from 50-100º). The average post-operative range of maximum flexion was 100.7º (ranged from 75-130º). There was one knee (2%) with maximum flexion of above 110 °, forty-one knees (91%) ranged between 80 and 110° and three knees (7%) with a range below 80 °. In comparison to the pre-operative maximum flexion, the average was 94.1º (ranged from 65º -100º). The average postoperative flexion deformity was 0.73º (ranged from 0-5º). In comparison to the pre-operative flexion deformity was 9.08º (ranged from 5-20º). (Table 1)

Table (1): Pre and Post-operative ROM, max knee flexion, and flexion deformity

	Max	Min	Mean	SD	P-value
ROM					
Preoperative	55 º	100 º	85.15 º	10.5 º	0.235
Postoperative	70 º	135 º	100.75 º	14.7 º	0.946
P value (> 0.05) Statistically insignificant					
Maximum Knee Flexion					
Preoperative	65 º	100 º	94.1	8.67	0.561
Postoperative	75 º	135 º	100.7	15	0.971
P value (> 0.05) Statistically insignificant					
Flexion Deformity					
Preoperative	5 º	20 º	9.08	3.6	0.037
Postoperative	0 º	5º	0.73	1.6	0.076
P value (> 0.05) Statistically insignificant					

ROM: range of movement

At the last follow-up, the average KSS of those within the range of 60 up to 97 was about 86.8, in comparison to the pre-operative average KSS which was 23.08 (within the range of 0 up to 35), there was a significant improvement. The calculated total scores were within the range from 5 to 100 points, knowing that high scores indicated a much better function. If the involved total score is within the range between 85 and 100 points, it can be admitted to be excellent; if it lies between 70 and 84 points, good; within 60 and 74 points, fair; if lower than 60 points, poor. Thirty-eight (85%) knees displayed excellent score results from 85 to 100 points, five (15%) knees showed good score results within the range of 70 to 84 points, and two knees only displayed fair results that range from 60 to 69 points.

At the last follow-up, the average KFS was 80.67 (lying within the range of 65 to 95 points) in comparison to the preoperative average KFS which was about 37.44 (within the range of 0 to 55). At the last follow-up, the average KOOS was 84.73 (range from 59.5 to 92.1) in comparison to the mean preoperative KOOS which was about 25.37 (within the range between 3.6 and 32.9), with significant improvement postoperatively.

In this study,4 knees had complications (9%). Superficial skin infection occurred in three cases, repeated postoperative dressing and follow-up with an appropriate course of antibiotics were done. Intra-operative partial patellar tendon rupture (of

less than 50% of tendon width) with maintained continuity of the tendon occurred in one case. It occurred due to the nature (osteoporotic bone and weak ligaments) and rigid retractors. This condition was managed by direct repair by a non-absorbable suture (Ethibond No. 5) and a postoperative knee immobilizer for two weeks.

Table (2): Pre and Post-operative KSS, KFSS, and KOOS

	Max	Min	Mean	SD	P-value
KSS					
Preoperative	0	35	23.08	7.06	0.057
Postoperative	60	97	86.8	8.02	0.014
P value (< 0.05) Significant improvement of KSS postoperatively					
KFSS					
Preoperative	0	55	37.4	14.1	0.041
Postoperative	65	95	80.67	10.5	0.017
P value (< 0.05) Significant improvement of KOOS postoperatively					
KOOS					
Preoperative	3.6	32.9	25.37	9.26	0.635
Postoperative	59.5	92.1	84.73	6.63	0.023
P value (< 0.05) Significant improvement of KOOS postoperatively.					

KSS: Knee Society Score**,** **KFSS:** Knee Function Score**,** **KOOS:** Knee injury and Osteoarthritis Outcome Score

4. Discussion

The technical goals of TKA include the normal alignment restoration for the limb, the contracted and also stretched soft tissue structures balancing around the joint, and accurate orientation and placement of the appropriate constraint prothesis level. In the current study, there was a correlation between pre-operative tibio-femoral angle (TFA) and the level of constraint (prosthesis type) used intraoperatively to have a stable and aligned knee with ML laxity within 2 mm opening after osteophyte removal and gap balancing. That was with a statistically calculated p-value of about 0.012 which was significant. There was marked improvement of deformity either in a coronal plane or in the sagittal plane. The mean post-operative TFA was 3.6 ° (ranged from 0° to 6°), in comparison to the pre-operative mechanical TFA mean of 17.11° (ranged from 15° to 26° varus). The ROM increased from a mean of 85.15° (ranged from 55° to 100°) to a mean of 100.75° (ranged from 70° to 135°). The mean flexion deformity post-operative improvement mean was 1.7 in comparison with the preoperative mean that was 9.088. Clinical scores were significantly improved postoperatively. The average KSS was 86.8 (ranged from 60 to 97) compared with the average pre-operative KSS of 23.089 (ranged from 0 to 35). The average KFSS was 80.67 (ranged from 65 to 95) compared with average pre-operative KFSS of 37.44 (range from 0 to 55). The average KOOS was 84.73 (ranged from 59.5 to 92.1) compared with the average pre-operative KOOS of 25.37 (ranged from 3.6 to 32.9) with a statistically calculated P-value (< 0.05) that was significant.

Yaratapalli et al. (2015) had prospectively 20 knee series in 15 patients with varus deformity exceeding 15 ° using CR and PS prosthesis. There was an improvement in the mean preoperative KSS and KFS were 29.45 (ranged from 15 to 52) and 26.50 (ranged from 10 to 40) respectively to 84 (ranged from 60 to 92) and 79.5 (ranged 70 to 90) respectively. Their obtained results were coressponding with this present existing result of the study.

Lee et al. (2011) expressed their obvious average KSS series of enhancement from 21 at preoperative to 96 postoperative, and the KFS improvement in the mild varus group from 39 to 77 at 2 years follow-up and average KSS improvement being 14 at preoperative away from being 97 postoperatively and KFS displayed enhancement in severe varus group from 33 to 79 at 2 consequent years follow up. The calculated postoperative average mean of TFA of the final follow-up displayed a result of 7.10 among the mild varus group and 6.40 among the severe varus group. Their results have coincided with our study results.

In Mullaji (2005) series, 117 patients (172 knees) with severe varus deformities had TKA, with improvements in the mean KSS from 22.8 preoperatively to 99.1 postoperatively and KFS from 22.8 to 72.1. Postoperative TFA was restored to 5.3° valgus with a range of 2 ° valgus to 9 ° varus. Their obtained results correspond to the existing results of this study.

Dixon et al.(2004 worked on 12 knees with severe OA with PFA >15° using CR and PS prosthesis and reported that the mean KSS increased from 24 (lying within the range from 0 to 43) to 94 (within a range from 78 to 100). Mean FKS improved from being just 34 (range, 0 to 70) to 85 (range, 45 to 100). Moreover, mean TFA was 4° of valgus (being within the range of 2° to 7°). The tibial component mean anatomic alignment was 90° (lying within the range from 90° to 92°). Their stated results were highly coincident with the existing results of the present study.

On 39 cases that had severe varus deformity, Ritter et al. (2004) reported a significant flexion and alignment postoperatively, and a residual contracture of flexion applying the PS prosthesis when compared to the CR prosthesis. It was also a significant improvement in the preoperative KSS for severe deformity from 44.5 to 87.8.

Teeny et al. (1991) stated in their 27 study case series, that the mean postoperative angle among both the femur and tibial mechanical axes was 3° of varus (ranged from 9° valgus–11° varus) and the mean postoperative KSS was 89. Moreover, they displayed that among the varus deformity group sixteen knees (59%) were reported excellent and 11 knees (41%) rated good. No reported fair or poor results. Their results were also going hand in hand with the results of the current study.

The **strength** of our study includes being the first in our hospital to determine the adequate level of constraint needed for OA knees with varus deformity >15° which can help us to establish guidelines for appropriate choosing prosthesis types for TKA in our hospitals. A single-center study of all operations using the same

operative theatres, inpatient wards, and infection control measures, helped us to assess our measures and scores.

Limitations

However, the limitations rely on the small sample size; extensive statistical analysis could not be performed to correlate different types of prosthesis with different tibiofemoral varus angles. We **suggest** that further studies with a larger number of patients to correlate different deformities to different levels of constraint and longer follow-up to exclude any loosening or other complications occurrence.

Conclusion

We concluded that the proper choice of prosthesis type depends on many factors, pre-operative as the level of OA, TFA, ROM, flexion deformity and ligament contracture, and intraoperative like proper gap balancing, soft tissue release, and ML laxity. Having balanced extension and flexion gaps, an intra-operative assessment of which level of constraint is needed to have a stable knee by a trial ROM with trial knee prothesis detecting patellar tracking, full extension, full flexion, and an opening in both the lateral and medial compartments of the joint applying both varus and valgus forces respectively in extension and flexion.

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