© J ORTHOP TRAUMA SURG REL RES
16(9) 2021
Research Article

Prospective study to evaluate the functional and radiological outcome of robotic-assisted total knee arthroplasty

SHEIKH KHALID NISAR, AVTAR SINGH, RAJEEV VOHRA, THORAT BABAJI, RAVI MAVANI, SHARAD SALOKHE

Department of Orthopaedics, Amandeep Hospital, Amritsar, Punjab, India

Address for correspondence:
Dr. Sheikh Khalid Nisar, Department of Orthopaedics, Amandeep Hospital, Amritsar, Punjab, India
nisarkhalid18@gmail.com

Statistics

Figures	03
Tables	03
References	21

Received: 01.09.2021

Accepted: 24.09.2021

Published: 05.10.2021

Abstract

Background: Osteoarthritis of the knee is rising problem along with sedentary lifestyle and increased longevity of life. Most patients are able to manage conservatively but a large number of patients with debilitating disease are referred to specialist surgeon for further management. Long-term survival of total knee arthroplasties (TKAs) depends on patient selection, implant design, surgical technique, soft-tissue balancing, and peri-operative care. Robotic TKA is newer technique and present study proposed to find functional and radiological outcome of robotic TKA.

Methods: This is a Prospective observational study conducted at our institute after obtaining the ethical clearance from institutional ethical committee. A total 100 adult patients between 18-90 years undergoing Primary TKA for osteoarthritis, rheumatoid arthritis and other degenerative diseases, having a mechanical axis of the lower limb between 20 degrees varus and 10 degrees valgus were included as a study participant. Data was collected by verbal communication, physical examination and radiographic features. Final assessment was done at 5 years follow-up period as per Radiological and functional evaluation criteria.

Results: The majority of the patients (n=74) were in age range of 51-70 yrs with mean age of 61.37+7.8 yrs (range-45-82yrs). Female : Male ratio was 2.7:1. Osteoarthritis (99%) was the most common reason for TKA. On Post-operative follow up it was observed that all coronal and sagittal alignment were within normal range. There was statistically significant difference in mean value of HKA, KSS, WOMAC score and ROM in pre- and post-operative follow up ($p<0.05$).

Conclusion: Robotic-assisted TKA was associated with improved postoperative limb alignment and clinical function at final follow-up suggesting that potential radiographic improvements are mirrored into functional outcomes.

Keywords: Robotic-assisted; Total Knee Arthroplasty; Knee Osteoarthritis; Functional Outcome

INTRODUCTION

Osteoarthritis of the knee is the most common; affecting almost a tenth of the population aged over 55years [1]. This number would certainly increase among population with extended longevity. Apart from osteoarthritis, conditions like rheumatoid arthritis, seronegative arthritis, post-traumatic arthritis and malignant tumors of the knee joint do cause significant morbidity.

Most patients with osteoarthritis of the knee are able to manage their symptoms with medical treatment and conservative methods, but a large number of patients referred to the specialist surgeon for further management have debilitating disease. Reconstructive knee surgeries such as Uni-compartmental Knee Arthroplasty (UKA), Multi-Compartmental Knee Arthroplasty (MCKA), or Total Knee Arthroplasty (TKA), are commonly performed on patients with end-stage disease. The demand for Total Knee Arthroplasty (TKA) is increasing mainly because of longer life expectancies and rising public expectations for quality of life and mobility in later years. Currently, approximately 2% of the population of 55 years age and above are so disabled that they need Total Knee Arthroplasties (TKAs), and this rate increases with age [2].

Long-term survival of Total Knee Arthroplasties (TKAs) depends on patient selection, implant design, surgical technique, soft-tissue balancing, and peri-operative care. Mal-positioning/orientation of the prosthesis may result in premature mechanical loosening of components and patellofemoral problems [3-6]. Malalignment of >3º of the mechanical axis is associated with accelerated implant wear and poor function [6,7].

The accuracy of alignment in conventional TKAs depends on the skill of the surgeon and the anatomy of the femur and tibia. Correct location of crucial alignment landmarks (centers of the femoral head and ankle joint) for determination of the mechanical axis can be difficult to achieve [8]. Recently computer-assisted TKA has been developed to improve alignment and implant positioning, to increase accuracy and reproducibility of the operative technique, to enable real-time kinematic analysis and soft-tissue balancing, and to reduce the risk of fat embolism and blood loss by not entering the intramedullary space [9,10]. It is especially advantageous in obese patients or those with severe preoperative mal-alignment, in whom identification of anatomic landmarks and soft-tissue balancing can be particularly difficult.

Navio PFS (Smith and Nephew, Memphis, TN), is a handheld and imageless device that uses an open platform and provides freehand sculpting for unicondylar, patella-femoral, and total knee arthroplasty. Navio utilizes optical-based navigation with an imageless system to provide 3D morphed images and views of the procedure, thus creating a virtual model of the osseous knee. The system continuously tracks the position of the patients' lower limb and the handheld burr, so that the limb position and degree of knee flexion can be changed constantly during the surgical procedure to gain exposure to different parts of the knee during registration and bone preparation.

Among advantages of robotic TKR includes small incision and scar, dynamic assessment of deformity at any angle of flexion with patella in situ. Calculation of soft tissue tension gives a perfectly balanced knee, accurate restoration of mechanical limb axis, reduced blood loss. Decrease in incidence of fat embolism due to extra-medullary instrumentation Accuracy of data on soft tissue tensions even in 1 mm and 1°. Surgeon is given control, feedback, ability to correct errors and documentation needed by Robot-assisted surgery, quicker recovery and shorter hospital stay.

Few disadvantages of robotic TKR include prolonged operative time, certain learning curves and significant cost implication for purchase and maintenance of the system.

Currently there is paucity of literature especially in study geographical area on independent assessment of robotic TKR in terms of functional outcome and complication of robotic TKR so present study was carried out to evaluate the outcome of robotic primary total knee arthoplasty in terms of Alignment of the mechanical axis of the limb with the help of scanogram, positioning of the prosthetic components with the help of antero-posterior and lateral radiographs of the knee at six months follow-up visit, Functional rehabilitation on the basis of Knee Society Score (KSS) and Western Ontario and McMaster (WOMAC) Score, range of motion (ROM) and to foresees any complication.

METHODOLOGY

A Prospective observational study was conducted at our institute after obtaining the ethical clearance from institutional ethical committee. A total 100 adult patients between 18-90 years undergoing Primary Total Knee replacement for osteoarthritis of knee, rheumatoid arthritis of knee and other degenerative diseases, Patients with mechanical axis of the lower limb between 20 degrees varus and 10 degrees valgus were included as a study participants between January 2016-June 2016. Patients not willing to be part of the study, extensor mechanism dysfunction, vascular disease of lower limbs, recurvatum deformity of knee, remote source of infection, medical contraindications for surgery, flexion contracture more than 10 degrees were excluded.

Preoperative investigations and preparations were done in all patients. Preoperatively the coronal alignment was recorded by using computer assisted scanogram (weight bearing) and flexion deformity of the knee was assessed radiographically using plain Lateral radiographs. Preoperatively functional outcome of the knee was evaluated by using Knee Society Score (KSS) and Western Ontario and McMaster University (WOMAC) score and Range of Motion (ROM).

The Robotic system used in this study is the NAVIO (Smith & Nephew, Inc., Memphis, TN, United States) which is a semiautonomous handheld robotic tool that is held and moved by the surgeon, restricting the bone cutting to within the planned resection area by providing robotic control of the speed or exposure of the tool. All knee replacements were done by same surgeon without tourniquet and surgical time was taken from incision to wound closure. Postoperative drain was used to calculate blood loss.

Postoperatively radiological outcome was assessed using scanogram of lower limbs to evaluate alignment of the mechanical axis of the limb and antero-posterior and lateral radiograph were obtained at six months follow up to evaluate positioning of the prosthetic components in term of coronal femoral inclination angle (α, optimum, 90°), coronal tibial inclination angle (β, optimum, 90°), sagittal femoral inclination angle (γ, optimum, 0°), sagittal tibial inclination angle (δ, optimum, 83°). Functional outcome of the knee was evaluated by using Knee Society Score (KSS) and Western Ontario and McMaster University (WOMAC) score, ROM and any complications postoperatively were assessed during 6 months follow up visits and functional outcome at 5 years follow-up.Data was collected by verbal communication, examination and radiographic features. Final assessment was done at 5 years postoperative period as per Radiological and functional evaluation criteria.

Data analysis: Data was entered into Microsoft Excel and analysed using SPSS (Statistical Package for Social Sciences) Software 20. Categorical variable were expressed in terms of frequency and percentage and continuous were expressed in terms of mean and SD. Paired t test was applied to see any significant difference in continuous variables (HKA, KSS,WOMAC and ROM) among study group in pre and post-operative follow up with $p<0.05$ as significant value

RESULTS

Out of 100 subjects' maximum (74) were in age range of 51-70 yrs. Overall age range was 45-82 yrs with mean age of 61.37+7.8 yrs. F:M was

2.7:1. Among study subjects most of (99%) were having osteoarthritis as a reason for TKA. More than half (54%) had operated on left side joint. Mean operation time among study subjects was 115.23+13.66 minutes and range of 90-136minutes and mean blood loss was 238.65+61.66ml (100 ml-400 ml) (Table 1).

On Post-operative follow up it was observed that all coronal and sagittal alignment most of the angles are within normal range. Maximum 3 outliers were observed for sigma angle and least one outlier for beta angle (Table 2).

It was found that there was statistically significant difference in mean value of HKA,KSS, WOMAC score and ROM in pre and post-operative follow up ($p<0.05$) (Table 3) (Figures 1, 2 and 3).

Table 1. Procedural details of study subjects

Indication	Frequency	Percent
OA	99	99
RA	1	1
Operated joint		
Left	54	54
Right	46	46
Blood lost amount		
101-200ml	36	36
201-300ml	55	55
301-400ml	9	9
Operation time		
90-110 minutes	31	31
111-130 minutes	58	58
>130 minutes	11	11

Table 2. Knee Angle assessment

Angles (Normal angel)	Within Normal Range	Outliers	Total
Alpha (96◦+3◦)	98	2	100
Beta (90◦+3◦)	99	1	100
Gamma (6◦±3◦)	98	2	100
Sigma (86◦+3◦)	97	3	100

Table 3. outcome measure comparison in pre -op and 5 years post op follow up

Outcome Measures	Pre-op	Post op 5 years follow up	p value
HKA	172.08+2.88	178.57+0.63	0.0001
WOMAC	65.77+9.47	1.75+0.98	0.0001
Knee Society Score (KSS)	20.85+8.11	87.73+2.85	0.0001
ROM	96.85+10.67	123.4+4.48	0.0001

Fig. 1. Pre OP X-RAY (right knee) and Pre OP scanogram

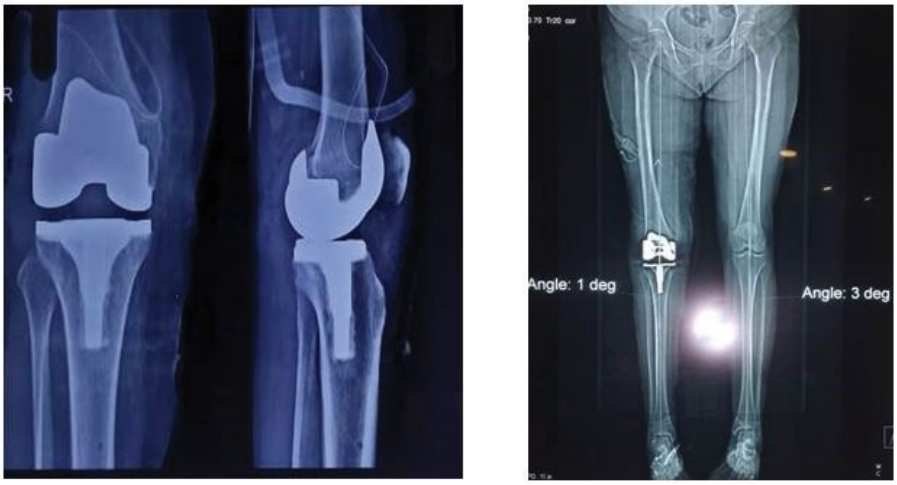

Fig.2. Post OP X-RAY and post OP scanogram

Fig 3. Stages of the patient's femoral and tibial anatomy, soft tissue ligament tension, and joint balance

DISCUSSION

Total Knee Arthroplasty (TKA) is a surgical procedure in which an artificial joint or prosthesis replaces a damaged knee joint. The primary indication for Total Knee Arthroplasty (TKA) is pain, followed by functional ability. Usually, a person's daily activities must be significantly affected by pain and functional limitations for him or her to be considered a candidate for TKA. TKA is a successful procedure when looking at pain relief and restoration of patient mobility with 10-15 years implant survival rates of greater than 90%. Accurate alignment of the components and soft tissue balancing have been cited as two of the most important factors in successful knee arthroplasty [11,12].

Advances in operative technology have led to the use of robotic-assisted devices in several medical fields. Recently, robotics has been adopted in many reconstructive surgeries. The development of Robotic Arm-Assisted Total Knee Arthroplasty (RATKA) potentially provides orthopaedic surgeons an additional tool to achieve successful outcomes.

NAVIO is a handheld and imageless device that uses an open platform and provides freehand sculpting for Uni-condylar, patella-femoral and total knee arthroplasty. The interactive, surgeon-controlled, handheld cutting tool has an end-cutting burr that extends and retracts so that only the planned bone is removed. As a semiautonomous system, it monitors the surgeon's movements of the burring tool, with safeguards in place to optimize both accuracy and safety via the retraction of the burr tip when the edge of the desired bone removal volume is approached.

The primary indication for Total Knee Arthroplasty (TKA; also referred to as total knee replacement [TKR]) is relief of significant, disabling pain caused by severe arthritis. In present study among study subjects most of (99%) were having osteoarthritis as an indication for TKR and more than half (54%) had operated on left side joint.

In our study Maximum (58%) subjects were operated in 111-130 minutes and very few (11%) required >130 minutes. Mean operation time among study subjects was 115.23+13.66 minutes and range of 90-136 minutes. Mean intra-operative blood loss was 238.65+61.66 ml and range was 100 ml-400 ml. Study by Ameer M, et al. [13] found that mean age was 68 ± 7 years, and gender breakdown was 75% female and 25% male. Intraoperative, average Estimated Blood Loss (EBL) was 292 mL ± 85 mL, and surgical time was 130 ± 43 min. Present study results are somehow similar with their findings.

Incorrect alignment can lead to abnormal wear [14] early mechanical loosening of the components [6,15] and patella-femoral problems [16]. Deviations of greater than 3º varus/valgus will increase the rate of loosening in the coronal plane [3], and the posterior tilting of the tibial component will affect the femoral rollback on the tibia, the tension of the posterior cruciate ligament, and the range of motion in the sagittal plane. [17,18] In present study postoperatively very few (1%-3%) of the patient had alignment >3º in any of the plane. Similarly study by Ameer M et al [13] found postoperative alignment was within ± 3° for all cases.

We didn't find intra or postoperative complications, no reoperation or revision surgeries required for the observed follow up duration. Success rate (outcome) of surgery was 100%. A recent systematic review by

Khlopas, et al. [19] evaluating a total of 40 studies reported that robotic-assisted TKA may improve patient satisfaction and outcomes with an anticipated learning curve of roughly 15 cases.

In present study subjective satisfaction was carried out using KSS and WOMAC score it was found that there was statistically significant improvement in mean value of KSS and WOMAC Score in pre and post-operative follow up ($p<0.05$). Kim, et al. [20] performed a study on 32 patients who underwent RATKA and found Knee Society scores significantly improved postoperatively (27-82.8, $p<0.001$). Song, et al. [21] performed study with 30 patients who underwent bilateral sequential total knee replacement with one knee operated on using the robotic device and the other using the manual technique. The group found the robotic cohort to have none significantly better last follow-up HSS scores (95.2 *vs*. 94.7) and WOMAC scores (11 *vs*. 13) than the manual cohort. Although these studies report non-significant differences in patient satisfaction, both studies still report greater overall clinical satisfaction in patients who underwent RATKA.

CONCLUSION

Study found that NAVIO RATKA technology has shown significantly improved mechanical axis alignment and reduced alignment outliers-an important factor which can influence the survivorship and functionality of an implant for long term period. Also, study findings found excellent patients' satisfaction in terms of clinical and radiological outcome without any complication on short term follow up. The results from this study showed a distinct advantage to patients in terms of operative procedure and length of hospital stay with better overall patient satisfaction scores.

However, since this technology is relatively new, further comparative studies with large sample size, multiple sites and long-term clinical outcomes are required to find patient satisfaction and functional outcome which will help us to decide usefulness and benefits of RATKR over manual procedure.

ACKNOWLEDGEMENTS

Patients and hospital staff.

CONFLICT OF INTEREST

No

References:

1. *Felson DT.: Epidemiology of hip and knee osteoarthritis. Epidemiol Rev. 1988;10:1-28.*
2. *Tennant A., Fear J., Pickering A., et al.: Prevalence of knee problems in the population aged 55 years and over: identifying the need for knee arthroplasty. BMJ. 1995;310:1291-1293.*
3. *Ritter MA., Faris PM., Keating EM., et al.: Postoperative alignment of total knee replacement. Its effect on survival. Clin Orthop Relat Res. 1994:153-156.*
4. *Wasielewski RC., Galante JO., Leighty RM., et al.: Wear patterns on retrieved polyethylene tibial inserts and their relationship to technical considerations during total knee arthroplasty. Clin Orthop Relat Res. 1994:31-43.*
5. *Moreland JR.: Mechanisms of failure in total knee arthroplasty. Clin Orthop Relat Res. 1988:49-64.*
6. *Jeffery RS., Morris RW., Denham RA.: Coronal alignment after total knee replacement. J Bone Jt Surg Br Vol. 1991;73:709-714.*
7. *Taylor M., Barrett DS.: Explicit finite element simulation of eccentric loading in total knee replacement. Clin Orthop Relat Res. 2003;414:162-171.*
8. *Stulberg SD.: How accurate is current TKR instrumentation?. Clin Orthop Relat Res. 2003;416:177-184.*
9. *Kalairajah Y., Simpson D., Cossey AJ., et al.: Blood loss after total knee replacement: effects of computer-assisted surgery. J Bone Jt Surg. Br Vol. 2005;87:1480-1482.*
10. *Kalairajah Y., Cossey AJ., Verrall GM., et al.: Are systemic emboli reduced in computer-assisted knee surgery? a prospective, randomised, clinical trial. J Bone Jt Surg. Br Vol. 2006;88:198-202.*
11. *Insall J., Scott WN., Ranawat CS.: The total condylar knee prosthesis. A report of two hundred and twenty cases. J Bone Jt Surg. 1979;61:173-180.*
12. *Freeman MA., Todd RC., Bamert P., et al.: ICLH arthroplasty of the knee: 1968-1977. J Bone Jt Surg. 1978;60:339-344.*
13. *Lonner JH.: Robotics in Knee and Hip Arthroplasty. Current Concepts, Techniquesand Emerging Uses.156-157.*
14. *Laskin RS. The classic: Total condylar knee replacement in patients who have rheumatoid arthritis. A ten-year follow-up study. Clin Ortho Relat Res 2008;466:2589–2596.*
15. *Tew M., Waugh W.: Tibiofemoral alignment and the results of knee replacement. J Bone Jt Surg. 1985;67:551-556.*
16. *Figgie 3rd HE., Goldberg VM., Heiple KG., et al.: The influence of tibial-patellofemoral location on function of the knee in patients with the posterior stabilized condylar knee prosthesis. J Bone Jt Surg. 1986;68:1035-1040.*
17. *Piazza SJ., Delp SL., Stulberg SD., et al.: Posterior tilting of the tibial component decreases femoral rollback in posterior-substituting knee replacement: A computer simulation study. J Orthop Res. 1998;16:264-270.*
18. *Singerman R., Dean JC., Pagan HD., et al.: Decreased posterior tibial slope increases strain in the posterior cruciate ligament following total knee arthroplasty. J Arthroplasty. 1996;11:99-103.*
19. *Khlopas A., Sodhi N., Sultan AA., et al.: Robotic arm–assisted total knee arthroplasty. J Arthroplasty. 2018;33:2002-2006*
20. *Kim KI, Kim DK, Juh HS, Khurana S, Rhyu KH. Robot-assisted total knee arthroplasty in haemophilic arthropathy. Haemophilia 2016;22(03):446-452*
21. *Song EK., Seon JK., Park SJ., et al.: Simultaneous bilateral total knee arthroplasty with robotic and conventional techniques: a prospective, randomized study. Knee Surg Sports Traumatol Arthrosc. 2011;19:1069-1076*