ACCELEROMETER-BASED NAVIGATION VERSUS CONVENTIONAL TECHNIQUE IN TOTAL KNEE REPLACEMENT. A PROSPECTIVE STUDY IN A TERTIARY CARE MEDIUM VOLUME SETUP IN INDIA.

Orthopaedics

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ABSTRACT

The iASSIST system is a portable, accelerometer base with electronic navigation used for total knee arthroplasty (TKA) which guides the surgeon to align and validate bone resection during the surgical procedure. The purpose of this study was to compare the radiological outcome between accelerometer base iASSIST system and the conventional system.

Method: A prospective study between two group of 36 patients (50 TKA) of primary osteoarthritis of the knee who underwent TKA using iASSIST™ or conventional method (25 TKA in each group) from January 2018 to December 2019. A single surgeon performs all operations with the same instrumentation and same surgical approach. Pre-operative and postoperative management protocol are same for both groups. All patients had standardized scanogram (full leg radiogram) performed post operatively to determine mechanical axis of lower limb, femoral and tibial component alignment.

Result: There was no significant difference between the 2 groups for Age, Gender, Body mass index, Laterality and Preoperative mechanical axis ($p>0.05$). There was no difference in proportion of outliers for mechanical axis ($p=0.91$), Coronal femoral component alignment angle ($p=0.08$), Coronal tibial component alignment angle ($p=1.0$). The mean duration of surgery, postoperative drop in Hb, number of blood transfusion didn't show significant difference between 2 groups ($p>0.05$).

Conclusion: Our study concludes that despite being a useful guidance tool during TKA, iASSIST does not show any difference in limb alignment (mechanical axis), Tibial and femoral component alignment when compared with the conventional method.

KEYWORDS

Total knee arthroplasty, iASSIST, accelerometer-based navigation, TKA

INTRODUCTION

The success of the Total Knee Arthroplasty (TKA) depends on the restoration of knee alignment by achieving neutral mechanical axis that passes from centre of femoral head through the centre of knee and ankle joint⁽¹⁻³⁾. The proper mechanical alignment with proper placed artificial implants is imperative for desirable consequences. Thus, TKA is aimed at replacement of the eroded cartilage and bone with an artificial implant along with restoration of neutral mechanical alignment. Proper alignment enhances the durability of the implant⁽³⁾. The computer assisted knee Arthroplasty surgery has helped to seek balance between anatomical and kinematic alignment factors such as 1) Better alignment of components 2) soft tissue balance 3) Compatibility between articulation of femorotibial axis and quadriceps muscles balance are possibly better.

Use of computer assisted first intervention in knee is dated 1991. Dr. Stephen Lavallee from Grenoble University France in 1991 used navigation system for anterior cruciate ligament repairs. The further developments came with introduction of first kinematic navigation protocol to determine rotation centre of hip and knee by Prof. Dominique Saragaglia. In 1997, Dr. Saragaglia and Dr Picard performed the first navigated TKA⁽⁴⁾.

The various axes that plays the role are:- The motion of knee joint is based on coordinated rotation of 2 axis. Flexion extension axis (FEA) in posterior femoral condyle and longitudinal axis of tibia⁽⁵⁾. Mechanical axis of lower limbs is represented by line passing from centre of femoral head to centre of ankle crossing the centre of knee joints⁽⁶⁾. Mechanical axis has 2 components -1) Femoral components - line passing from femoral head centre to intercondylar notch on the knee joints. 2) Tibial components - represented by line passing from proximal tibial epiphysis to the centre of the ankle joint. Normally both components form a straight angle or the medial angle less than 180 degree^(7,8). The anatomical axis of femur and tibia are represented by a line traversing from centre of medullary cavity, perpendicular to a line drawn bisecting the shaft of these long bones at the centre or around 10cm above or below the knee joint respectively. The femoral anatomical axis in anteroposterior (AP) view is at 5°-7° valgus inclination with reference to the mechanical axis of femur whereas the

anatomical axis of the tibia coincides with its mechanical axis.

Hungerford and Krackow described technique for proper alignment of femoral and tibial components to make the joint line with alignment of 2-3-degree varus in relation to mechanical axis of lower limb. This alignment also helps to achieve a joint line that's parallel to the ground during normal gait⁽⁹⁾.

Mechanical alignment described by Insall et al. is one of the common methods used in TKA for high reproducibility. For proper mechanical alignment it requires femoral cut to be perpendicular to mechanical axis of femur and tibial cut perpendicular to tibial axis. Purpose of alignment is to achieve equal load distribution on new joint line. To balance flexion and extension gaps, femoral component positioning should be in 3 degree of external rotation⁽¹⁰⁾.

Fang et al. with study based on more than 6000 TKA for survivorship in well aligned knee compared with outlier that is more than 3 valgus / varus concluded goal of TKA should be to restore alignment within 2.4°-7.2° valgus⁽¹¹⁾. Jeffery et al. recommended prosthesis loosening rate (24%) higher with shifting of mechanical axis either medial or lateral compared to lesser (3%) loosening with mechanical axis crossing middle of prosthesis⁽¹²⁾. Ritter et al. reviewed more than 6000 knees for 2 years to conclude that failure occurs if tibial components orientation is less than 90 degree with respect tibial axis and femoral components more than 8° valgus. Failure was less in neutral orientation⁽¹³⁾. A significant number of patients (15-20%) were not completely satisfied with their replaced artificial knee even with a good alignment.

MATERIALS AND METHOD

In prospective, sequential TKA performed from Jan 2018 to Jan 2020, we investigated 36 patients (50 TKA) with primary osteoarthritis of knee operated by TKA in which 17 using iASSIST system (25 TKA) and 19 using conventional method (25 TKA). Each surgical procedure was performed by single surgeon. Our setup is multispecialty private clinic, we offer iASSIST method to every patient and the choice is patient dependant. The patients were offered the use of this modality however most of the patients in the conventional arm opted out of

iASSIST due to cost constraints. The iASSIST increases the cost of knee replacement by almost 25 percent in our hospital. Every patient is follow up after 6 weeks, 6 months, 12 months and then yearly for both the groups.

The study group included the conventional TKA (intramedullary jig for the femur, extramedullary jig for the tibia) and iASSIST navigation technique for the TKA. All patients were seen by the reviewer in the Patient Clinic at 6 weeks. Standard digital radiographs (AP, lateral) and digital scanogram were performed. All standard radiographs are taken using fluoroscopic control to obtain the correct orientation in the coronal plane. In patients who failed to achieve a full extension of 6 weeks, a full-leg standing radiograph was taken 3 months after surgery. The iASSIST is alignment system developed with inertial disposable electronic pods which exchanges information by a local wireless channel. After capturing data, alignment information displays on pods which directs the surgeon to take accurate bone resection cuts during surgery. The accuracy of bone cut can be validated after resection. Abduction, adduction, neutral position of leg creates angular relationship between the electric pods of digitizer and bony references as medial and lateral malleolus. Those movements activate inertial mechanism and create virtual coordinate system on which whole navigation system is based. Whole data is transferred to tibial cutting guide electronic pod which guides the surgeon to take bone resection cut of tibia as per the preference. Electronic pod with spike fixed to the trochlear groove. Thirteen thigh movements are carried out in a flexed knee in the form of star shape or in a circular pattern which detect the centre of hip. Electronic pod recorded multiple acquisitions to acquire mechanical axis. Second electronic pod attached to the resection guide of femur after transfer of navigational data to the second pod which guides surgeon for resection of distal femur considering mechanical axis and flexion. Visual indicators are displayed on pod as red light when out of alignment and green light when within desired alignment⁽¹⁴⁾. iASSIST has following advantages 1) No special surgical equipment 2) No special preoperative Imaging 3) No added incision or external pin fixation.

Outcome Measures

The primary outcome of this study was postoperative radiographic assessment of the lower limb alignment and component placement. Secondary outcomes measure surgical duration, perioperative drop in haemoglobin level and blood transfusion incidence. Complications of TKA have been documented including surgical site infection, significant cardiac events, pulmonary embolism, deep vein thrombosis and death within 45 days after surgery.

Figure: scanogram

Standard standing post-operative scanogram taken at full knee extension on 6 weeks after surgery. Both legs are spaced enough apart (intermalleolar distance-15 cm) with patella facing forward to serve as a guide for rotation. The radiograph was taken at a distance of 100 cm. Repeat radiograph was taken under guidance if malrotation was detected. Angle measurement is done on A4 size hard copy of radiographs. In the coronal plane, the 3 radiographic angle measurement- (1) Hip-knee-ankle (HKA) axis angle formed by the line joining the centre of the femoral head to the centre of the knee (mechanical axis of femur) and the line joining the centre of the

talus to the centre of the knee (mechanical axis of tibia) (2) Coronal femoral component angle (CFA), angle between the femoral component axis and the mechanical axis of the femur (3) Coronal tibia component angle (CTA), angle formed by the tibia baseplate and the mechanical axis of the tibia or anatomical axis of tibia (Figure-1). In the coronal plane, a negative value indicates a varus alignment and a positive value indicates a valgus alignment. Normal alignment is considered if 1) HKA axis is $180^\circ \pm 3^\circ$ varus / valgus⁽¹⁵⁾. (2) Coronal femoral component angle (CFA) is $6^\circ \pm 1^\circ$ valgus⁽¹⁶⁾. (3) coronal tibia component angle (CTA) is $90^\circ \pm 3^\circ$ ^(15,17,18). The analysis of the preoperative and postoperative radiographs was done by 2 independent reviewers who were blinded to the surgical technique on 2 separate occasions. In all patients, the measurement variability was less than 1° on 2 different occasions in between 2 reviewers. In two patients, measurements deviated by 1° .

Statistical Analysis

Statistical analysis was carried out using IBM® SPSS® 20.0. The Fisher test and Mann-Whitney U test was used to compare the two groups for categorical variables and continuous variables respectively which were deemed significant ($p < 0.05$).

RESULTS

There was no significant difference between the two groups for age, Body mass index (BMI), gender and side of operated knee ($p > 0.05$, Table 1). There was no significant difference in preoperative mechanical axis ($p=0.43$). No statistical significance was found between the navigated group and control group concerning the duration of surgery and blood transfusion incidence ($p > 0.05$) (Table 2). The median HKA, CFA, CTA, were comparable between the two groups on post-operative radiographic films ($p > 0.05$) (Table 2), (Figure-2). There was no difference in the proportion of outliers for mechanical axis ($p=0.917$), CFA ($p=0.083$), CTA ($p=1.0$) (Table 3). In spite of higher mean BMI in conventional method, results obtained were similar to iASSIST. None of the patients in the iASSIST and conventional group developed any major complications in the early post-operative period.

Table 1: Patients Demographics.

	iASSIST	Conventional	p value
Age (years)	64 (57,70)	64 (45,79)	0.96
BMI (kg/m ²)	28.61 (21.7,36)	30.10 (24.6,38.3)	0.33
Gender (Male: Female)	4:13	2:17	0.31
Side of surgery (Right: Left)	12:13	16:09	0.393

Table 2: Perioperative Outcome.

	iASSIST	Conventional	p value
Pre-operative Hb(g/dl)	11.92 (9.9,14.7)	11.85 (9.3,14.5)	0.9
Post-operative Hb(g/dl)	9.45 (7.4,12)	7.03 (6.6,11.5)	0.63
Drop in Hb (g/dl)	1.67 (1.4,1)	1.98 (1.1,4.2)	0.43
Number of Transfusion (mean)	0.71	1.1	0.1
Duration of surgery(min)	101.36 (70,145)	101.67 (58,130)	0.94
Pre-operative HKA (°)	169 (160,179)	167 (144,177)	0.43
Post-operative HKA (°)	177.24 (168,180)	176.96 (170,180)	0.544
CFA (°)	6.12 (5,8)	5.68 (4,7)	0.124
CTA (°)	90.08 (85,95)	90.52 (84,94)	0.289

Table 3: Number Of Outliers.

	iASSIST		Conventional		p value
HKA	$180 \pm 3^\circ$	Outliers	$180 \pm 3^\circ$	Outliers	0.917
No of patients	19	6	14	11	
CFA	$6 \pm 1^\circ$	Outliers	$6 \pm 1^\circ$	Outliers	0.083
No of patients	24	1	22	3	
CTA	$90 \pm 3^\circ$	Outliers	$90 \pm 3^\circ$	Outliers	1.0
No of patients	23	1	22	3

Figure 3: Scatter diagram

DISCUSSION

The iASSIST system is a navigation system which is a handheld accelerometer base, introduced as a method achieving a greater accuracy during surgical procedure. Our study showed no difference in accuracy of postoperative radiographic alignment of the implanted prosthesis and mechanical axis performed by using conventional method and iASSIST navigation system; as judged by number of outliers. Restoration of mechanical axis done by conventional method is as precise as done by iASSIST navigation method. Accelerometer base navigation is a portable tool used in TKA surgery to get accurate bone resection without using intramedullary jigs.

The factors such as sex, gender, height, femoral hip offset, rotation and physical anthropology of the person determines the femorotibial axis (FTA). Femorotibial axis is approximately 176°-178° and 175°-176° in men and women of Caucasian origin respectively whereas in Asian population these angles are slightly less⁽¹⁹⁾.

This result is congruous with result of Long How Moo et al⁽²⁰⁾ Bauwens et al⁽²¹⁾ who found that there was no significant difference in mechanical axis alignment between patients who underwent conventional and navigational total knee replacement. By contrast, our study shows contradictory result against many authors who shows that iASSIST gives significant better alignment of component and mechanical axis^(22,23).

Matziolis et al⁽²⁴⁾ reported no influence on clinical outcome in midterm follow up after TKA in mal-aligned varus knees, hence it's controversial, whether improved mechanical alignment result in good function. Huang et al⁽²⁵⁾ reported that the International Knee Society and SF 12 physical score at 6 weeks, 3 months, 6 months, 12 months postoperatively was superior when coronal alignment was within 3° of neutral. While Harvie et al⁽²⁶⁾ reported no difference in functional outcome (Knee society, SF 36, WOMAC scale and patient satisfaction score) with navigated and conventional TKA at five years follow up. similar result reported by Rajkumar Selvanagayam et al⁽²⁷⁾ by comparing functional outcome (knee society, WOMAC scale) at follow up of minimum 4 years, even though better accuracy was associated with navigation-assisted system. Kim YH et al⁽¹⁸⁾ showed that no differences in components alignment, clinical function and components survival between the computer navigational TKR knees and conventional TKR knees.

The advantages that we encountered during the course of the study are 1) Low learning curve 2) The iASSIST served as an excellent training tool where errors during surgical procedure checked and demonstrated to the trainees. 3) There was no added set up or initial capital 4) No lead time unlike what we had for 3D printed Patient specific instrumentation on jigs.

The strength of our study was that the 2 groups were compared demographically, operated by similar surgical approach, performed by single surgeon. The only difference was, bone resection in iASSIST is navigation guided. Our study focused only on radiological outcome in the form of mechanical axis, femoral and tibial component alignment; as there is lack of published data on post-operative radiological outcome of accelerometer based navigational TKA in Indian population despite being widely used in last 10 years. Standard radiograph is taken with patella facing forward at standard distance. Scanogram (long leg film) is used to access mechanical axis and component alignment.

Limitations of this study is that it is a non-randomized, sequential, observational, focuses only on coronal alignment which didn't evaluate sagittal and rotational alignment. Secondly, it has smaller sample size due to new nature of navigational method. Thirdly, there was a selection bias as all patients were self-funded.

CONCLUSION

iASSIST is a very useful tool to accurately achieve a predictable and a good outcome (radiologically) without violating the intramedullary canal. With increasing emphasis on faster rehabilitation, better pain management and accelerated discharge protocols, the added advantage of a minimally invasive surgery, is a step in the right direction, however with added costs.

Validation of this study by reviewing patients post operatively in an RCT is required. Technological advancement will needs to be done with biomedical engineering to drive the cost down and make it affordable for everyone.

Authors' Note:-

This Prospective comparative study was studied at Jupiter hospital, India.

Declaration Of Conflicting Interests:

Dr. Sanket Tanpure, Dr. Suyog Madje, Dr. Ajay Chavan, Dr. Rohit kumar Vaishya, Dr. Ashish Phadnis declared no potential conflicts of interest with respect to the research and publication of this article.

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Informed Consent:

Informed consent was obtained from all patients for being included in the study.

Ethical approval:

The procedures were performed in this study after ethical approval from institutional ethical committee.

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