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Limited Femoral Navigation Versus Conventional Intramedullary Femoral Jig Based Instrumentation for Achieving Optimal Restoration of Mechanical Axis Post Total Knee Arthroplasty: A Prospective Comparative Study of 200 Knees

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ABSTRACT

A prospective comparative study was conducted to compare the mechanical axis post total knee arthroplasty (TKA) between two groups: In the first group of 100 knees (ASM group) Articular Surface Mounted navigation system was used to guide the distal femoral cut. In the second group of 100 knees (JIG group) conventional intramedullary femoral jig was used. The postoperative mechanical axis of the leg was within 3° of neutral alignment in 90% of the TKA in the ASM group (mean 178.12°) as compared to 74% in the JIG group (mean 177.02°). This difference was statistically significant ($P < 0.05$). The data presented show that the use of limited femoral navigation leads to more accurate restoration of mechanical axis alignment when compared to conventional intramedullary femoral jigs.

Total knee arthroplasty (TKA) represents one of the most significant advances in orthopedic surgery as it achieves an immediate and exceptional restoration in the quality of life that is comparable only to a few other procedures [1,2]. Restoration of the mechanical axis post TKA is considered to be of paramount importance to allow optimum load sharing and prevent eccentric loading through the prosthesis which may lead to loosening, instability and early implant failure [3,4]. Computer navigation is recognized as a valuable tool in restoring the mechanical axis post TKA and thereby increases long-term survivorship and function of the prosthesis [5,6]. However, the disadvantages associated with the use of computer navigation are its cost [7], increased surgical time [8] and risk of an iatrogenic fracture through the pin sites [9–12].

With the use of conventional intramedullary femoral jig for distal femoral cut, an error up to 8° can occur in restoration of neutral mechanical femoral axis depending on the size and length of the intramedullary guide [13]. Femoral bowing in the coronal plane makes accurate placement of intramedullary jig even more challenging. Incidence of femoral bowing is high in the Asian population especially females [14,15] which constitute the majority of patients who need a TKA. We decided to use navigation for the distal femoral cut with a specialized navigation unit called Articular Surface Mounted (ASM) navigation system (Stryker). Navigation was not used for the rest of the bony cuts as all other bony landmarks i.e. femoral epicondyle, tibial malleoli and tibial tuberosity are all subcutaneous and palpable which make accurate placement of jig possible [16].

Materials and Method

A prospective comparative study was set up to compare the alignment achieved post TKA with limited femoral navigation using the ASM navigation system and with the intramedullary femoral jig based technique after ethical committee approval. Between July 2008 and December 2010, the senior author performed TKAs at 2 different tertiary centers, one of which was equipped with ASM navigation. 188 patients (200 knees) were divided geographically by place into two groups based on their preference for the hospital according to the proximity of the hospital from their residence. The patients were excluded if they had prior knee surgery, were not willing for the study after counseling and were not willing for follow-up. In the first group (ASM group) ASM navigation system was used to guide the distal femoral cut during TKA. In the second group (JIG group) the angle between mechanical and anatomical femoral axes was measured on long leg standing x rays and intramedullary femoral jig was set at this angle to guide the distal femoral cut (generally 6°).

All surgeries were performed by the senior author using the subvastus approach. In the ASM group, after adequate exposure, a dedicated mini jig was mounted on femoral articular surface to which

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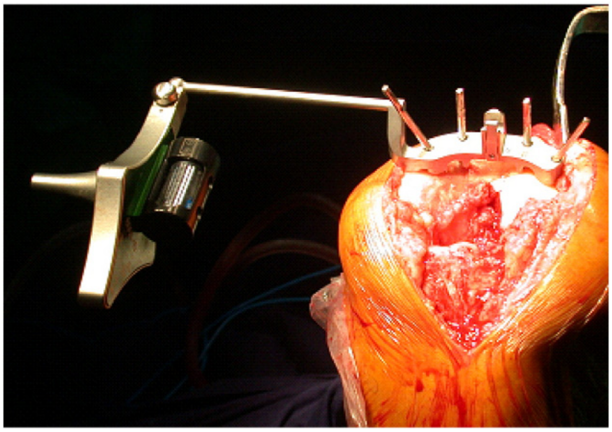

Fig. 1. Dedicated mini jig for distal femur.

the tracker was attached (Fig. 1). The center of the hip was located by circumducting the hip. The rest of the distal femur was then digitized viz: the knee center, the femoral AP axis and the medial and the lateral condyles of the femur. The dedicated distal femoral cutting block was then positioned on the anterior surface of the femur (Fig. 2) and the intended bone cut was adjusted according to the navigation unit screen for the desired depth (typically 9 mm off the intact condyle), flexion 3° and varus–valgus angle 0°. The mini jig from articular surface with the tracker was removed and the distal femur was sawed. The cut distal femoral surface was checked for accuracy by applying the verification jig with tracker on the cut femoral surface. The cut was modified if required. The rest of the procedure was performed without the use of navigation as per conventional technique.

In the JIG group the distal femoral cut was made with the help of intramedullary femoral jig set at the required valgus angle (angle between mechanical axis and anatomical axis of femur, generally 6°) and the rest of the procedure was carried out as per the conventional technique. Post-operative management for both the groups was identical.

The post operative follow up was at 6 weeks, 3 months, 6 months and 2 years. At 6 weeks we took scanogram, antero-posterior, lateral and skyline views of the operated knees. These radiographs were measured by 2 observers (Dr BK and Dr AD) who were blinded. We measured angle alpha, beta, gamma and sigma (Fig. 3) and mechanical axis by software called "Image J". Image J is digital software which can measure the angle to 1/100th of a degree. All data variables were analyzed by an independent external statistician. Student *t* test and analysis of variance was used to evaluate significance of difference in values. *P* value of less than 0.05 was taken as significant. For the 2 observer's radiographic

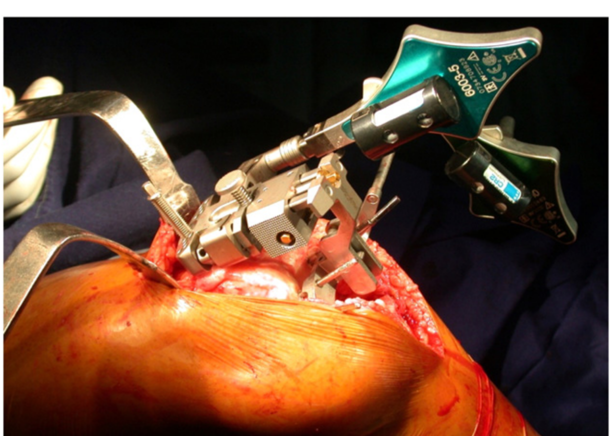

Fig. 2. Dedicated distal femoral cutting block.

measurements in the present study, the *P* value was more than 0.05 so there was no significant difference in the findings of both observers.

Observation and Results

The two groups were similar in their preoperative demographic profile and amount of deformity (P value >0.5) (Table 1). In the ASM group there were 94 patients (100 knees), 73 women and 21 men with a mean age of 64 (range 49–80). The average BMI was 38.4 (range 28–41). In the JIG group there were 94 patients (100 knees), 76 women and 18 men with mean age of 62 years (range 48–82). The average BMI was 40.12 (range 28–43). The average preoperative knee society score (KSS) was 41 (range 28–48) in the ASM group and 44 (range 28–50) in the JIG group.

Post TKA the mechanical axis of the leg was within 3° of neutral alignment in 90% of the knees in the ASM group (mean 178.12°) and 74% of the knees in the JIG group (mean of 177.02°). This difference was statistically significant ($P < 0.05$) (Table 2). Compared to the JIG group the ASM group had lower variance in the mechanical axis alignment. The femoral component in the frontal plane (angle alpha) was within 3° of neutral alignment in the 93% of cases in the ASM group and 71% of the JIG group. Though there were no differences between means in both groups for frontal femoral alignment, the JIG group had more variance than the ASM group. There was no significant difference in the mean and the standard deviation of the tibial alignment (angle beta) in the ASM and the JIG group. At the end of two years the average KSS score was 88 (range 76–94) in the ASM group and 84 (range 74–94) in the JIG group.

The mean surgical time (skin to skin) for the ASM group was 82.06 min (range 65–106) and for the JIG group was 72 min (range 61–94). We did not encounter any complication related to the use of ASM navigation and in no case was the procedure abandoned. We had one case of MCL disruption in the JIG group and one case of partial patellar tendon avulsion in the ASM group.

Discussion

Restoring proper alignment and correction of the deformity remain the primary goals of the TKA. It is well established that malalignment of either the tibial or femoral components is associated with loosening, instability and early implant failure [17]. Many studies have shown that placement of components within 3° variation of the mechanical axis reduces the risk of early loosening [17,18] while other studies have shown this threshold to be higher [19–21]. However, it may reasonably be assumed that a poorly aligned TKA would function less satisfactorily than a well aligned one and hence our aim should be to achieve alignment as close to neutral as possible after a TKA.

Computer assisted orthopedic surgery (CAOS) was first introduced in 1999 by Krackow et al [22]. Its objective was to improve the accuracy of implant positioning and extremity alignment. Proponents of computer assisted orthopedic surgery believe that computer navigation reduces the risk of malalignment in TKA [3,4,23]. Computer assisted navigation systems for joint arthroplasties are of two categories: image based and image-free navigation systems. In image based navigation systems, pre-operative morphological data are acquired using imaging devices either CT scan, MRI or peri-operative fluoroscopy. CT-scan imaging modality allows 3D reconstruction of bone morphology and bony landmarks. MRI can also be used but definition of bony landmarks is inferior to that of a CT-scan. However, MRI avoids the radiation associated with the CT scan. Peri-operative fluoroscopy requires maneuvering of the specialized fluoroscopy unit in the Operating room to gather the data which adds to the surgical time and requires additional resources. In these image based navigation systems, the registration and identification of bony landmarks during surgery are needed to match it with the pre-operative image saved on the computer screen. The advantage of image based systems is that they can be used in cases with extreme

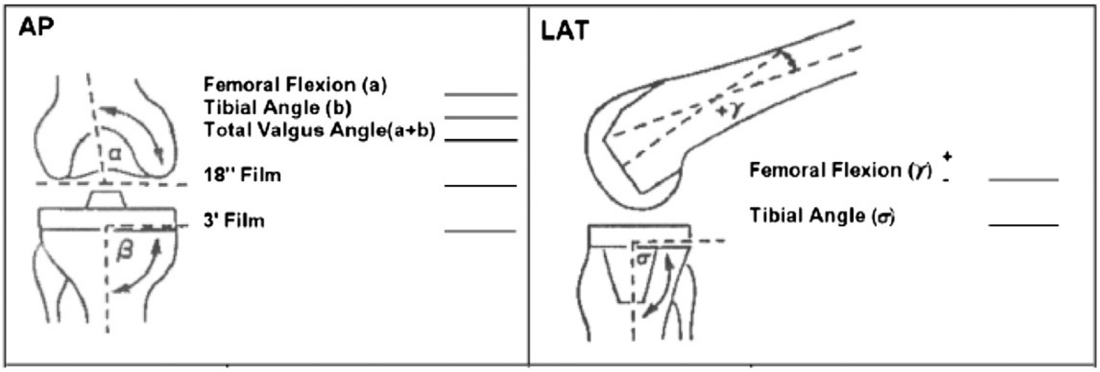

Fig. 3. Radiographic measurements. Alpha: inclination angle of femoral component formed with the anatomical axis of femur. Beta: inclination angle of tibial component formed with mechanical axis of tibia on antero-posterior view. Gamma: angle of femoral component formed between anatomical axis of the femur and perpendicular line to prosthesis. Sigma: angle of tibial component formed with the mechanical axis of tibia.

deformities, patients with ipsilateral hip disease and also in cases of revision knee arthroplasty.

Image free navigation systems using infrared light are currently more widely employed. These systems utilizes either optical (infra-red light), or electromagnetic devices that detect the position of active or passive markers implanted on the leg through rigid bodies or special instruments, which must remain within the line of sight. The most important characteristic of this system is its ability to provide instant information regarding in vivo kinematics of the joint thus allowing the surgeon to quantify data and to have dynamic intra-operative feedback.

Image free navigation system is available in two forms; full navigation system and ASM navigation system. Full navigation system uses an infra-red camera array to track 2 fixed infrared trackers that are fixed to the distal femur and proximal tibia by bicortical screws. The camera can also track the position of a pointer or attachment and relate their positions to the mapped anatomy. The relationship of the pointer to the patient's anatomy is shown intra-operatively in real time and allows the accurate planning of all bone cuts in 3 dimensions (varus/valgus, flexion/extension, and external/internal rotation). Component sizing and the effect of bony cuts on flexion–extension balancing and its effect on alignment can be determined prior to making these cuts. Knee kinematics both with trial components and after definitive prosthesis implantation can also be reviewed in real time.

The ASM navigation system is also an image free system and avoids the use of bicortical femoral and tibial screws by using mini jigs attached directly to the respective femoral/tibial articular surfaces. Infrared trackers are attached directly to the ASM mini jigs. By using an active pointer, the articular geometry of the femur and the tibia can be digitized. By circumducting the hip and movement of the ankle the hip or the ankle center can be located. The cutting block can be positioned at the desired inclination, angle and depth on the femur or the tibia and the desired cut can be made. The cut can also be verified for accuracy. The ASM system does not allow for intra-operative planning of component rotation but does allow for confirmation of the desired bone cuts. In addition, it does not provide kinematic assessment. Despite this, it is regarded as being less invasive (with no risk of fracture associated with bicortical tracker pin placement) and a faster system to use than the fully navigated system.

Harvie et al in a prospective randomized study compared full tibiofemoral navigation and ASM navigation [24]. Forty patients participated (20 fully navigated and 20 ASM-navigated TKAs). They found no statistically significant difference with respect to 3-dimensional component alignment or function at one year between two groups. Operative time for the ASM group was significantly less than the fully navigated cohort ($P = 0.001$). They concluded that both systems appear to perform equally well, and the ultimate choice of system should therefore be determined according to the specific requirements of the operating surgeon.

Zumstein et al in 2006, evaluated the results of TKAs performed with restricted femoral navigation without navigating the tibia [16]. They studied 90 knees in 88 patients. There were three groups: conventional TKAs, image-based computer navigated TKAs and TKAs with image-free navigation. In their study the mechanical axis of the leg was within 3° of neutral alignment in 89% of the patients in the image based navigation group, 83% in image free navigation group and 73% in conventional

Table 1
Patient Demographics.

		ASM Group	JIG Group
Total no. of patients		94	94
Total no. knees		100	100
Gender	Male	21	18
	Female	73	76
Mean age (years)		64 (range 49–80)	62 (range 48–84)
Average Height (cm)		154 (148–171)	152.69 (146–171)
Average Weight (kg)		86 (63–125)	87.32 (60–120)
Average BMI		38.4 (28–41)	40.12 (28–43)
Cases with Deformity <15°		81	78
Cases with Deformity >15°		13	16
Average Pre-op Knee Score		41 (28–48)	44 (28–50)

Table 2
Radiographic Measurements.

Mechanical Axes in Leg	ASM Group	JIG Group	*P* Value
Mean	178.12	177.02	
SD	2.165	3.23	
Variance	4.11	7.93	
Component between −3° and + 3° malalignment	89%	74%	<0.05 (significant)
Femur in Frontal Plane (Alpha)			
Mean	90.96	90.92	
SD	1.47	3.082	
Variance	3.65	9.49	
Component between −3° and + 3° malalignment	93%	71%	<0.05
Tibia In Frontal Plane (Beta)			
Mean	90.72	90.55	
SD	2.20	2.21	
Variance	4.85	4.88	
Component between −3° and + 3° malalignment	88%	89%	>0.05
Femur in Sagittal plane (Gamma)			
Mean	4.21	3.82	
SD	1.21	1.20	
Tibia in Sagittal plane (Sigma)			
Mean	87.53	87.57	
SD	2.25	2.13	

group. Both navigated groups showed less outliers of the mechanical axis than the conventional group. In the conventional group, there was strong correlation ($r = 0.66$) between femoral component malalignment and total mechanical axis than between tibial component malalignment and mechanical axis ($r = 0.46$). Their study showed that navigating only the femur gives as good results as full tibio-femoral navigation and both techniques of restricted femoral navigation i.e. image based navigation and image free navigation give better results than conventional TKA. Zumstein in his technique of restricted femoral navigation used 2.5 mm bicortical pins for the femur so the risk of pin-related complications persists.

Hence we believed that there is a role for a comparison between limited femoral navigation with the ASM technique with the standard femoral jig based technique. Intramedullary femoral jig relies on placement of the intramedullary rod along the anatomic axis of the femur at an angle equal to the difference between the mechanical and the anatomical axis of the femur (generally 6°). With the use of traditional intramedullary femoral alignment system for distal femoral cut, deviation up to 8° can occur in femoral axis depending on the size and the length of the intramedullary rod [13,25]. Varied reasons have been proposed for this inaccuracy in the distal femoral cut such as femoral bowing [14,15], wide medullary canal and incorrect entry point [26,27]. Hence, a system which helps in making reproducible and consistent distal femoral cut perpendicular to the mechanical axis of the femur (computer navigation) can be useful.

Despite the improvements in alignment, the role of computer navigation in improving outcomes of TKA has been the subject of controversy [7]. Justification for using computer navigation and its cost effectiveness is based on the implication that accurate alignment improves implant survival, thereby reducing the rate of costly revision [28]. But the evidence supporting this is scarce. In addition, there is a concern about additional surgical time [7], fracture related to pin placements [9–12] and prolonged drainage from pin sites [29] when computer navigation is utilized.

There is no consensus as to whether the femoral component rotation can be improved by navigation. Though there are studies showing that navigation improves femoral component rotational alignment [30,31], some investigators found that rotational alignment of the femoral component was not improved by navigation [32,8]. We did not use navigation to aid our femoral component rotational alignment. It is widely accepted that the transepicondylar axis represents the functional flexion extension axis of the knee [33–37]. We aimed to align the femoral component parallel to the transepicondylar axis in both study groups.

The bony landmarks for the tibial cut i.e. tibial malleoli and tibial tuberosity are palpable hence with the help of extramedullary guide the tibial cut can be taken with reasonable accuracy. Matsuda et al reported that the tibial axis can be determined precisely at the time of surgery according to bony landmarks by showing satisfactory postoperative mechanical tibial alignment [38]. Verifying the accuracy of the tibial cut is also easier by placing tibial tray or spacer block over cut surface of tibia and dropping a rod trough it. Most people would align the rod to the 2nd metatarsal.

The patient specific instrumentation (PSI) has been recently developed to aid in making precise cuts perpendicular to the mechanical axes of the femur and the tibia without the use of computer navigation [39,40]. These blocks require a pre-operative CT or an MRI of the knee which is then sent to the manufacturer of the knee implant and after a few days or weeks PSI is delivered. Recent reports have shown that PSI is not infallible and has in fact produced results inferior to conventional jigs [41,42].

In the current study, we found that limited femoral navigation using the ASM navigation system was more accurate than the conventional intramedullary femoral jig based technique for achieving optimal mechanical axis alignment post TKA. Restoration of mechanical axis within 3° neutral alignment was possible in 90% of cases using the ASM navigation system compared to 74% cases in which the intramedullary femoral jig was used (P values < 0.05). The reason for deviation of mechanical axis more than 3° of neutral alignment in 10% of cases when ASM navigation system is used is not known. It is interesting that most authors who have used computer navigation have shown such outliers [1–4,43–48]. This may be due to errors in the registration process or in actual use of the oscillating saw or during final implantation of the components with cement. It is also interesting to note that these outliers have not been reduced by full tibio-femoral navigation despite the dynamic intra-operative feedback.

Table 3
Percentage of Knees with Well Aligned Implants i.e. Optimal Mechanical Tibio Femoral Angle (177° to 183°).

	No of Patients	Navigated	Non Navigated
Cip J et al 2014 [43]	100/100	90	81
Gothesen O et al 2014 [44]	192	82.1	62.1
Blakeney WG et al 2011 [4]	36/34	80.55	61.76
Dutton et al 2009 [13]	59/59	92	68
Ek ET et al 2008 [45]	50/50	78	62
Tingart M et al 2008 [3]	500/500	95	74
Ensini et al 2007 [46]	60/60	98.3	80
Martin A et al 2007 [47]	100/100	92	76
Bolognesi et al 2005 [48]	50/50	98	90
Sparmann et al 2003 [2]	120/120	100	86.7
Jenny et al 2001 [1]	30/30	83.3	70
Current Study	100/100	(ASM navigation) 90	74

Our results with limited femoral navigation with ASM technique were comparable to those studies using full tibio-femoral navigation in literature (Table 3). Additionally, the ASM group showed less outliers of the mechanical axis than the JIG group. We did not find any downside or complication which could be ascribed to the use of the ASM Navigation.

This study is admittedly limited in that it is not a multicentric study and all the cases were performed by a single experienced surgeon. The patients do not undergo any randomization process, their treatment of choice being dictated by their geographical location. Also, besides coronal alignment rotational alignment of femoral and tibial component has a critical role to play in the success or failure of TKA. Measuring rotational alignment would require a post-operative CT scan. We have not measured rotational alignment of the components in this study. We consider this as a weakness of our study design and recommend that it should be measured in future studies of this nature to support the role of limited femoral navigation in TKA. However, the strength of our study is that we have shown a definite statistically significant advantage of limited femoral navigation in aiding the mechanical axis post TKA without any disadvantages.

Conclusion

The limited femoral navigation by the ASM navigation system offers an effective option for reducing the outliers for optimal mechanical axis alignment post TKA. It obviates pin site complications of computer navigation. It is particularly valuable in knees that have pronounced femoral bowing and wide medullary canal. Further multicentric randomized studies will be needed the future to establish its role in TKA.

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