ORIGINAL ARTICLE

Mechanical Alignment and Functional Outcome of Orthoalign Navigation System vs Conventional Total Knee Arthroplasty

Ahamed Sherif alias Irfan Sherif[1], Thennavan AS[2]

Abstract

Introduction and purpose: Total knee replacement (TKR) is a common surgical procedure done for severe knee joint degeneration and arthritis. The deviations of mechanical axis (MA) greater than 3× from the normal neutral alignment have been correlated with worsening of clinical outcomes, abnormal wear, premature loosening, and early implant failure. The failure of conventional total knee replacement (CTKR) to achieve within 3° of the MA accounts for 30% of the TKR being unable to produce the desirable results. This study intended to compare the alignment outcome of accelerometer-based portable navigation system (orthoalign) with CTKR.

Materials and methods: This is a prospective study with 68 cases divided into two groups of 34 each in conventional and navigation. Study period is from July 2019 to July 2021 where patients underwent TKR procedure in Kovai Medical Center and Hospital, Coimbatore. Preoperative evaluation data include age, sex, BMI, diagnosis, side of pathology, and knee range of motion (ROM). Radiological evaluation was done by X-rays includes full-length standing scanogram, anteroposterior (AP) and lateral view. Functional outcome was assessed by Knee Society Score (KSS) interval of 1 month, 6 months, 1 year, and 2 years.

Results and discussion: Navigation (orthoalign system) based TKR group showed improved mechanical alignment outcome compared to CTKR group but functional outcome was almost similar in both the groups which needs longer study duration and follow-up. Main objective of this study is to show improving mechanical alignment through navigation so that we can prevent abnormal wear, premature implant loosening, and failure.

Keywords: Conventional total knee replacement, Improved mechanical alignment, Navigation total knee replacement, Orthoalign navigation system, Prevents wear and implant loosening.

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Introduction

Total knee replacement is done in the case of advanced osteoarthritis (OA) to reduce pain and restore normal alignment and improve functional outcomes. Ideal alignment is the most important factor for the long-term success of TKR. While malalignment is associated with increased rates of revision and reduced survival. An ideal MA of ±3° is considered to be an ideal alignment.[1] According to Ritter et al., if the femoral component alignment was greater than 8°, the likelihood of aseptic loosening of implants after TKR increased.[2] Achieving the ideal alignment using conventional instruments in cases of severe deformities, high body mass index (BMI), malunited femur/tibia fracture, and ankle bowing would be challenging. Newer advanced techniques have been developed and combined with conventional instruments to improve the MA and component alignment. One such innovation is computer-assisted TKR.[1]

Mason et al. compared computer-assisted TKR with CTKR and showed that the percentage of femoral varus/valgus alignment and tibial varus/valgus alignment in the computer assisted surgery (CAS) group was better than in the conventional group.

However, Kim et al. suggested that CAS had certain unavoidable drawbacks, including high costs, extra pin-sites, pin-site fractures, a steep learning curve, and large consoles.

So, to avoid complications, accelerometer-based navigation (ABN) has been introduced recently. It does not necessitate the use of a huge computer console, additional pin-sites, navigation arrays, or mechanical intramedullary devices. In comparison to CAS, the surgical procedure of ABN is similar to conventional operations with a shorter learning curve.

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The purpose of the study is to compare the postoperative mechanical alignment and functional outcome of ABN vs CTKR in a tertiary care referral hospital. We hypothesized that using an ABN system during TKR would improve postoperative mechanical alignment significantly more than the conventional group.[1]

Materials and Methods

This study is a prospective study with patients who underwent TKR surgery with either a conventional or orthoalign navigation system from the Department of Orthopedics. Patients were selected based on inclusion and exclusion criteria. The inclusion criteria were as follows: patients who underwent TKR for OA and rheumatoid arthritis with the same approach, same cemented implants, and a minimum of 2-year follow-up. The exclusion criteria were as follows: patients with gross osteoporosis, bone defects requiring grafting, no preoperative MA, revision surgery due to infection,

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simultaneous hip and knee replacement, or morbid obesity (BMI > 40 mg/m^2).

A total of 68 patients were selected according to inclusion and exclusion criteria from July 2019 to July 2021. Patients were categorized into two groups who underwent CTKR and navigation (orthoalign) assisted total knee replacement (NATKR), with 34 members in each group. Preoperative evaluation data included age, sex, BMI, diagnosis, side of pathology, and knee ROM. All the surgeries were performed by a single experienced surgeon who was familiar with the navigation system incorporating the implants from the same manufacturer. Details were collected from hospital records and from the patients through phone calls and follow-up visits after obtaining informed consent. Ethical committee approval was obtained from the hospital's ethical committee board.

The radiological evaluation was done by X-rays, which included a full-length standing scanogram, anteroposterior (AP), and lateral views of the knee. Both groups' functional outcomes were assessed independently with the KSS.

Preoperative Evaluation

A complete and detailed history of all patients were documented. The preoperative medical evaluations of all patients were done to prevent potential complications that could be life threatening. No limb length discrepancies were noted. The extensor mechanism was assessed for any quadriceps contractures. In all patients thorough examination of spine and hip was done and power of all muscle groups were documented separately. All the patients' limb vascular status were evaluated. If necessary, Doppler was done to rule out any vascular insufficiency.

Routine blood investigations included CBC, ESR, CRP, urea, creatinine, sodium, potassium, RBS, HbA1c, HIV I & II, HbsAg, anti-HCV, and urine routine were done. All patients underwent a complete cardiac workout (ECG, echocardiography) before surgery. A preanesthetic evaluation was done. Blood grouping and cross matching were done, and two packed cell units were reserved preoperatively. All patients were thoroughly screened for any septic foci in their bodies. In all patients, we routinely advocated for a dental opinion to rule out any dental sepsis. Routine instructions given preoperatively in the ward included no shaving in the ward, chlorhexidine mouth wash, bactroban nasal ointment, sterile preparation of the operative limb with chlorhexidine twice a day before surgery, and cutting toenails.

Preoperative radiographic assessment was done with full leg, weight-bearing radiographs (scanograms). The femorotibial angle was measured on the radiograph and the deformity was quantified. The Kellgren–Lawrence classification was used to grade the OA.

Operative Procedure

In all patients, surgical intervention was planned after obtaining written informed consent. All surgeries were done under spinal anesthesia combined with epidural anesthesia with the patient in a supine position. All patients were operated on by the senior author only. An IV cefuroxime 1.5 gm injection was given half an hour before inflating the tourniquet in the operating room. Cases were done under tourniquet control with the knee in 90° flexion with the help of leg support. All the cases were performed through a midline skin incision with a medial parapatellar approach. With the knee in flexion, an anterior longitudinal midline skin incision is made. Lateral skin flaps developed. Arthrotomy was done, leaving a 3–4 mm cuff of tendon over the patella. The medial side of the knee was exposed by elevating the anteromedial capsule and deep medial collateral ligament off the tibia. Osteophytes were removed. Soft tissue release was done according to the type of deformity. Patellar osteophytes were removed and circumcauterization of the patella was done.

Conventional Method

The femoral entry point is formed by the intersection of the Whiteside and trans-epicondylar lines. It was drilled with a 9 mm diameter drill bit. A distal femoral cut was taken at 5° valgus and 3° external rotation. Typically, a 9 mm cut was made with the assistance of pins. Four in one resection block was fixed over the distal femur. The four cuts taken were anterior, anterior chamfer, posterior chamfer, and posterior.

The extramedullary jig was attached to the tibia with a cross headpin, a resection guide, and an ankle yoke with 3–5° of posterior slope. The jig was parallel to the tibia, with the tibial tray matched at the center of the tibial tuberosity and was checked with the help of an alignment rod. With the help of the stylus, the amount of tibial cut was measured. Typically, 9 mm was cut from the less affected size. The resection guide was then fixed to the tibia using two straight and one cross pin. Measured bone cuts were taken with reference to the medial tibial condyle. The final tibial cut was completed with an osteotome.

Flexion and extension gaps were assessed. Knee stability was checked with trial implants. After satisfactory reduction, the cut ends were thoroughly washed with saline solution until blood clots were removed and dried up with mops. Bone cement mixing was done and time noted. Bone cement was applied over implants and bone surfaces. Definitive implant placement was done. Extra bone cement was removed to avoid third degree wear. An appropriate tibial insert was locked into place. A thorough wash was given. Drain was left in place, and the closure was completed with 1 and 2–0 vicryl. Skin was closed with 3–0 monocryl or staples. Sterile dressing was done.

Navigation Method (Orthoalign System)

The orthoalign is a compact, ABN device that does not require a large computer console to use. A disposable display console and a reference sensor are included (Figs 1 and 2).

On a nutshell, this technology uses femoral head navigation during hip movement to provide real-time input to the surgeon on distal femoral and tibial resection in a compact display

Fig. 1: Orthoalign navigation system

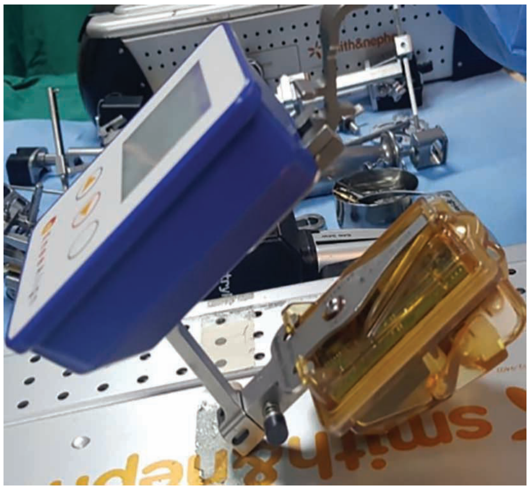

Fig. 2: Orthoalign navigation system

Fig. 3: Femoral cut with orthoalign navigation

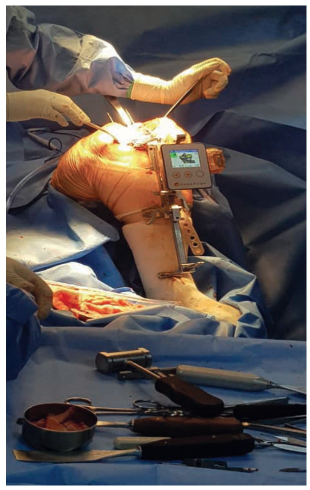

Fig. 4: Tibial cut with orthoalign navigation

console, eliminating the need to consult a monitor outside the operating area.[3]

Femoral Navigation

The microblock and sensor must be secured to the distal femur once the knee joint has been exposed. In analogue, the center pin is positioned at the same location as the intramedullary (IM) guide rod (Fig. 3). The guides follow the AP offset guideline. The next step is to determine the femur center of rotation, which is done by moving the leg from medial to lateral and flexion and extension of the hip. The navigation unit determines the resection plane. The surgeon determines the appropriate resection depth. The distal femur resection is completed in the same way as a CTKR.

Tibia Navigation

Place the stylus over the ACL footprint and align the proximal guide with the medial 1/3 of the tibial tubercle. A cutting guide is linked to the orthoalign navigation device (Fig. 4). The positions of the medial and lateral malleolus, as well as their offsets, are recorded. The resection plane is determined by the angles of varus, valgus, and posterior slope. The surgeon specifies the resection depth. The remaining steps of the proximal tibial cut are identical to those used in traditional TKR.

Postop Protocol

Patients are usually given a femoral nerve block or epidural analgesia for postoperative pain. The patients were continued on IV antibiotics for 2 days postop routinely, and deep venous thrombosis (DVT) prophylaxis in the form of subcutaneous enoxaparin was started on postop day 1. The patient was assessed for quadriceps power and made to walk full weight-bearing on the operated limb. Dynamic quadriceps exercises and active ROM knees were taught to the patients.

Antibiotics were stopped after 2 days. Subcutaneous enoxaparin was continued until the date of discharge. After discharge, usually we switch over to an oral tablet form of aspirin 75 mg once daily. If the patients were not able to achieve a ROM of at least 90°, we routinely used the continuous passive motion (CPM) machine to achieve a 90° ROM. Usually, patients were discharged on the 4th or 5th postoperative day (POD). And they were asked to come back on the 14th POD for stapler removal. Then, the patients were assessed 6 weeks postoperatively (1 month from the date of suture removal).

Then the patient was assessed clinically and functionally using the KSS at an interval of 6 months, 1 year, and 2 years. All the patients were radiologically and clinically assessed for deformity progression, signs of infection, signs of instability, and loosening. The KSS was documented at each follow-up. The minimum follow-up period was 2 years.

Statistical Analysis

A total of 68 patients who met inclusion and exclusion criteria and underwent primary TKR at our hospital were included in the study, divided into navigation (group A) and conventional groups (group B), with 34 members each in the group.

The median age group of the study participants was 66 and 65.50 among group A and group B, respectively, with a mean year of follow-up of 2 years.

The majority of study participants were female among both the groups, with 53% in group A and 68% in group B. The left was the majority involved in group B, whereas both sides were equally involved in group A. The median BMI of the study participants was 23.5 and 24 among groups A and B, respectively.

The majority of the study participants had OA in both groups. Osteoarthritis of 82.4% in group A and 85.3% in group B compared to rheumatoid arthritis (RA) of 17.6% and 14.7% in groups A and B, respectively. The mean range of movements was slightly higher among group A (90.88) and group B (87.06).

Most of the study participants had varus deformity of 82.4% in group A and 85.3% in group B, with flexion deformity almost equal between the groups.

The mean difference between the pre and postop operative mechanical alignment was 8.5 ± 1.796 in group A and 6.6 ± 2.198 in group B, with a p-value of 0.001, which remains significant (Table 1). The mean difference between the pre and postoperative KSS remains clinically significant with a p-value of 0.001 (Fig. 5). There was no statistical difference between the mean knee score and the knee functional score except at 6 months.

Discussion

In our study, we found that the MA was more accurately restored in patients undergoing NATKR as compared to CTKR. However, clinical parameters like the knee score and functional score in both groups were similar at the final follow-up. Total knee replacement is done in cases of severe knee joint degeneration, which helps with the correction of deformity, increased mobility, good relief of pain, and improvement in quality of life. Despite the benefits, some patients may experience a wide range of complications like infection, aseptic loosening, pain, stiffness, fracture, and global dissatisfaction.[4,5] For the above-mentioned complications, differences in implant design, type of fixation, indication for TKR, surgical technique, and patient factor are all recognized causes.[6]

In surgical techniques, the one aspect which significantly affects patient satisfaction and implant survival is the correct positioning and alignment of components. Among the alignments, mechanical alignment remains an important factor. Mason et al.[7] and Hetaimish et al.[8] reported that navigated TKR significantly improved prosthesis alignment. Blakeney et al. reported that Oxford Knee Score was better for navigated knee arthroplasty in which MA was within 3° of neutral.[9]

Jeffery et al. reported a reduction in implant loosening in a properly aligned knee when compared to a poorly aligned knee.[10] More than 3° of varus or valgus misalignment results in eccentric loading and significantly increased polyethylene wear.[11,12] Sogabe et al. reported that varus and valgus alignment have poor muscle function compared to the normally aligned knee by calculating different cross-sectional areas in the quadriceps muscles.[13] Longstaf et al. reported that better functional outcome was seen in good coronal alignment during a 1-year follow-up period.[14] Kim et al. could not find differences in functional outcomes between the CTKR and the NATKR groups.[15] Hoffart et al. demonstrated improved KSSs for navigated TKRs.[16] There was no significant difference in satisfaction, pain, or quality of life outcomes in many studies. This conclusion, however, has been published in a variety of ways.[17,18] de Steiger et al. compared the long-term survival of TKR following navigation-assisted vs conventional instrumentation, demonstrating that the navigation group had a lower total revision rate.[19] Neutral MA plays a very crucial role in the success and longevity of an implant prosthesis and validates postsurgical clinical and functional outcomes.

Despite the fact that the requirements for appropriate implant location and neutral axis have been questioned, inadequate implant position and alignment remain one of the leading causes of TKR failure.[2,12,20–22] The Australian Orthopaedic Association National Joint Registry discovered that navigated TKRs for loosening/lysis had a decreased revision rate in patients aged 65 and older.[23] A number of studies have indicated that CAS is more accurate than CTKR.[24] Large initial start-up expenses, a steep learning curve, femoral notching, large consoles, optical tracking, and line-of-sight issues are all CAS drawbacks. Furthermore, the additional pin-site may cause pain, infection, and pin-site fracture.[25] Total knee replacement surgery is a challenging invasive surgery, and these complications will adversely affect the outcomes. Early functional rehabilitation and patient satisfaction are both influenced by pain and stiffness. Postoperative pain following TKR is a crucial factor in long-term recovery.[26] The ABN system can help patients recover faster after surgery by reducing intraoperative damage (no need for an intramedullary placement and reduced blood loss), as well as enhancing patient compliance during early rehabilitation. This could be one of the reasons for the better stiffness score in the ABN group.

Although the navigation system has been found to lower the chance of malalignment, it is unclear whether the navigation system can improve the prosthesis' long-term survival rate and clinical outcomes. Several studies have shown that a navigated group had a higher 10-year survival rate than a conventional group.[27,28] In certain investigations, however, no significant differences in long-term survival or clinical outcomes were found between NATKR and CTKR.[20,29,30] These inconsistencies may raise concerns about whether improving component and total limb alignment accuracy over time

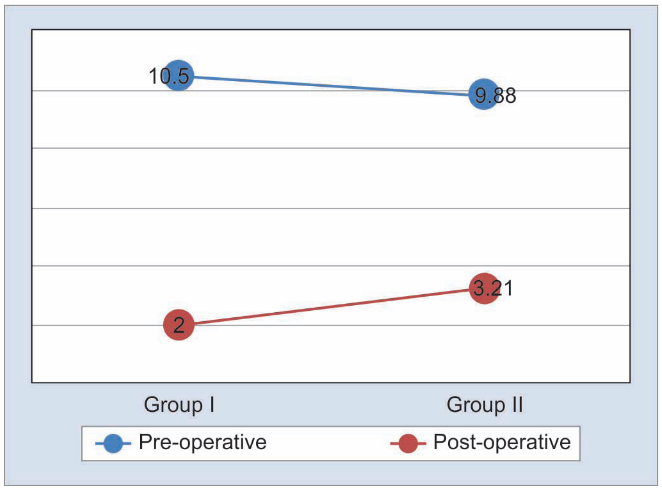

Fig. 5: Pre and postop mechanical outcome graphical representation

Table 1: Mechanical alignment among the study participants

		Group A		*Group B*		
Sl. no.	*MA*	*Mean*	*SD*	*Mean*	*SD*	*p-value*
1	Preoperative	10.50	2.573	9.88	2.143	0.283
2	Postoperative	2.00	1.326	3.21	1.366	0.001

leads to better outcomes. According to Jones and Jerabek, the improved alignment accuracy acquired with the navigation system may eventually transfer to lower revision rates over time.[31] Based on clinical experience, precise mechanical alignment and implant location may considerably contribute to long-term surgical success. Ritter et al. compared the failure rate of TKR in patients with a BMI of 23–26 kg/m^2 with the failure rate in patients with a BMI ≥ 41 kg/m^2 and showed increased failure rates with high BMI.[2] Another study indicated that the ABN method is accurate in attaining neutral mechanical alignment and optimal implant position following TKR in patients with extra-articular deformity during the preparation of our study.[32] In our study, we compared the mechanical alignment outcome between the NATKR and CTKR groups along with the functional outcome by using the KSS.

Conclusion

The study's findings show that patients who had (orthoalign) ABN had better mechanical alignment outcomes than those who had CTKR. Except for the 6-month follow-up, both groups' functional outcomes were similar. The degree to which the alignment of bone resection and components affects the function and longevity of TKR is unknown. The potential benefits of computer navigation are becoming more accessible and user-friendly for surgeons with the introduction of hand-held systems that use accelerometers and inertial sensors. The navigation system is a one-time use device that works with all platforms. It is used to make accurate cuts on the distal femur and proximal tibia. accelerometer based system (ABS), we feel, offers the advantages of computer navigation and CTKR without the cost, time commitment, or disruption to productivity that large console navigation requires. We conclude that ABN improves mechanical alignment, but the functional outcome is comparable to the conventional group, for which a longer study period is required.

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