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An Experimental Study of iAssist Total Knee Arthroplasty Technique

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Abstract

Zimmer® iAssist is an accelerometer and gyroscope-based system, which is as accurate as computer-assisted systems and other optical navigation systems in achieving a neutral mechanical axis. It has better functional outcomes when compared with conventional systems. In this paper, we experimented on a 3D printed model to determine the accuracy of the iAssist system and also checked how the system responded in determining the mechanical axis when the guides were not positioned properly. In our experiment, the iAssist system produced acceptable and consistent results when its guides were positioned properly and when it was improperly positioned, the results were more skewed, which would result in valgus or varus deformity depending on the position of the guide. The iAssist system depends on the surgeon to input accurate data and proper positioning of the guides to acquire the correct mechanical axis of the knee. Even though it's not perfect, it is definitely a step in the correct direction to achieve higher accuracy associated with computer-assisted systems with the familiarity associated with conventional systems.



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Note

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Introduction

Total knee arthroplasty is being performed in large numbers every year and the number of replacements done keeps on increasing year by year. This puts the pressure on the joint replacement surgeons to get the desired results in the first attempt [1]. Arthritis, especially osteoarthritis is the most important cause of joint pain and in spite of various treatments available, total knee replacements remain the best and effective treatment for treating and improving the quality of life for those suffering from osteoarthritis. The success of every total knee arthroplasty depends on various factors like component positioning, component alignment, flexion and extension gaps and the balance of soft tissue achieved [2-6]. As proved by many previous studies that an accurate implanted component and the mechanical axis of $\pm 3^\circ$ to the neutral mechanical axis leads to long-term prosthesis survival and decreased component loosening [2, 7-13].

Berend et al. [14] in a review of 3152 total knee arthroplasties proved that the chance of implant failure was greater by about 17 times just because of tibial varus alignment of greater than 3° . Jeffry et al. [9] in an analysis of 115 people found implant loosening in 24% of cases when valgus and/or varus deformity exceeded 3° to the neutral mechanical axis, but it was only 3% in other cases. Richard et al. [15] in their study of people under 65 years of age and underwent total knee arthroplasty got a significant difference in the revision rate in favor of those who underwent navigated total knee arthroplasty versus those who underwent conventional knee arthroplasties. While performing total knee arthroplasty, the operating surgeon aims to achieve a position close to the neutral mechanical axis [16]. The more conventional method of using intramedullary and extramedullary jigs to achieve the cuts have a limited degree of accuracy to achieve correct component placement and mechanical axis restoration to be as close to the neutral mechanical axis as possible. Several studies have confirmed this irrespective of the surgeon's experience [17-23]. Errors can happen as this technique is dependent on the surgeon's judgment, fixation of instruments, knowledge of knee kinematics and hand-eye coordination [23-25]. Mahaluxmivala et al. [26] in an analysis of 673 total knee arthroplasties found varus and/or valgus alignment of more than 3 degrees with the neutral

mechanical axis irrespective of the surgeon's experience.

Many published papers show computer-assisted surgery to be superior in achieving the desired results when compared to conventional systems [27-30]. Mason et al. [23] in their study showed that 65.9% achieved perpendicular femoral varus and/or valgus alignment within 2° and 79.7% achieved tibial varus and/or valgus alignment 2° perpendicular to the tibial mechanical axis in the conventional group while in the computer-assisted surgery group those were achieved by 90.4% and 95.2%, respectively. In a recent study, it was shown that iAssist system had fewer outliers in low limb alignment [31]. Matthew et al. [32] in their study got a malalignment of $\geq 3^\circ$ in 4% of cases who underwent iAssist surgery compared to 36% in the conventional group. They also showed iAssist had significant improvement in the variances of both femoral and tibial mechanical axis. However, despite promising results, computer-assisted surgery still failed to penetrate more than 5%. It may be due to the sensitivity of the instruments, increased capital costs, the complexity of use, longer operation time and an obvious learning curve associated with any new technique. Some studies have reported cases of fractures arising due to the additional placement of pins [20, 33-40].

Recently, navigation systems have been developed using accelerometer and gyroscopes like iAssist systems in an attempt to combine the accuracy associated with large console computer-assisted systems and convenience of conventional systems without the need for large computers to assist in recording and provide the alignment results to the surgeon intra-operatively [18, 41]. In a study, Dessaux et al. [42] showed iAssist system had similar results in the restoration of hip knee angle, component positioning, and optimal success compared to other optical navigation systems. In addition, they showed that iAssist achieved 95% cases with a neutral mechanical axis and optimal component positioning. The iAssist (Zimmer Inc, Warsaw, IN) system uses four pods, which house gyroscopes and accelerometers that are attached to the surgical instruments, and intra-operatively, it provides the precise alignment and position in relation to anatomic landmarks. All the information from the pods is sent to a screen placed near the operating table in the line of sight of the surgeon using a secure Wi-Fi network. The data displayed on the screen is also verified by the flashing green

and red lights on the pods themselves. Green lights indicate the jigs are positioned within an acceptable range, whereas red light signals the alignment is not according to the accepted values and have to reposition the jigs accordingly [2].

All surgeries are to be performed under tourniquet with medial patellar approach and femur first technique using the intramedullary 7.9 mm spike guide. Ideally, the starting point is slightly medial and posterior to the center of the notch between both epicondyles [2, 12]. To establish the mechanical axis, the femur is first prepared with an intramedullary guide. A 7.9 mm spike is impacted in the Whiteside's line (Fig 1A) [43]. After aligning the femoral reference guide on the spike and leg placed in a neutral position, 13 stable positions are acquired by accelerating and stopping the leg creating a star-shaped pattern. Audio feedback from the system confirms the acquiring of each stable position. After completing the step of acquiring positions, the resection guide is fixed to the reference guide the femoral valgus and/or varus and flexion and/or extension are set as per preoperative goals. Led lights on the pods indicate the exact degree and it can be set by turning the two knobs which change the alignment of the resection guide accordingly and the degrees are confirmed on the screen as well. After securing, the femoral adjustment mechanism with screws the distal femur is resected. Following the bone resection, the cuts made are confirmed using a validation tool secured with captive spikes and the values of valgus/varus and flexion /extension are displayed on the screen. Adjustments can be made if necessary and further cuts are made using the chosen implant.

The tibia is prepared by an extramedullary guide. After positioning the tibial alignment guide to left on right leg accordingly, the guide is installed on the ankle by gripping the distal clamps around the malleoli similar to conventional guides. The longer mechanical axis digitizer spike is partially inserted in the highest point of the center of the tibial plateau and after orienting the guide with the medial third of the tubercle, the guide spike is further impacted to align it to the patient mechanical axis. The tibial resection guide is placed to the tibial tuberosity after fixing it with three screws, the bone reference is attained by positioning the leg in abduction, adduction and neutral position. After removal of the digitizer, the tibial varus and/or valgus and posterior slope are set according to preoperative goals. The degrees can be changed with the help of two knobs similar

to femoral resection guide. The depth of tibial cut is determined using the tibial stylus. The cuts are validated with a validation tool and further resection can be done if required. After checking the joint space and range of motion using trial components and spacers, the tibial component is inserted followed by femoral component insertion and then finally inserting the polyethylene component similar to the conventional technique. Care is taken to avoid femoral component flexion during the insertion.

Materials and methods

We conducted a simple experiment in our hospital lab with the help of 3D printed model of the knee. We followed the iAssist protocol to achieve the normal neutral mechanical axis in our 3D printed model (Fig. 1A-1F). For the femoral resection guide, we set the valgus and varus at 0 degrees and flexion and extension at 3 degrees. For the tibial resection guide, we set the varus and valgus at 0 degrees and the posterior slope at 7 degrees. After achieving the results, we recorded the site of impaction of the bone saw on the surface of the femur and tibia respectively, and later we changed the orientation of the 7.9 mm spike directed towards the lateral position of the femur, instead of normal axis and we carried out the 13-step process for acquiring the mechanical axis of the femur. We recorded the various angles of offset while getting the femoral cuts. Similarly, for the tibial alignment guide, we impacted the digitizer spike on the lateral condyle of tibial plateau rather than the highest point on the center of the tibial plateau and recorded the angles where we would get the cut of the bone saw (Fig 2).

Results

In our experiment, when 7.9 mm spike was spiked orienting towards the lateral part of the femur, the angle of resection was skewed, which would result in more resection of the medial surface compared to the lateral surface of the femur and it would result in a varus knee postoperatively (Fig 3). Similarly, when the orientation of the spike would change to the medial side, it would have similar results, but on the opposite side resecting more of the lateral surface than the medial resulting in varus alignment. When we impacted the digitizer spike on the lateral surface of the tibial plateau instead of the highest point of the center of the tibial plateau, we got the angle skewed with resecting more part of the lateral condyle than the medial part (Fig 4). This would

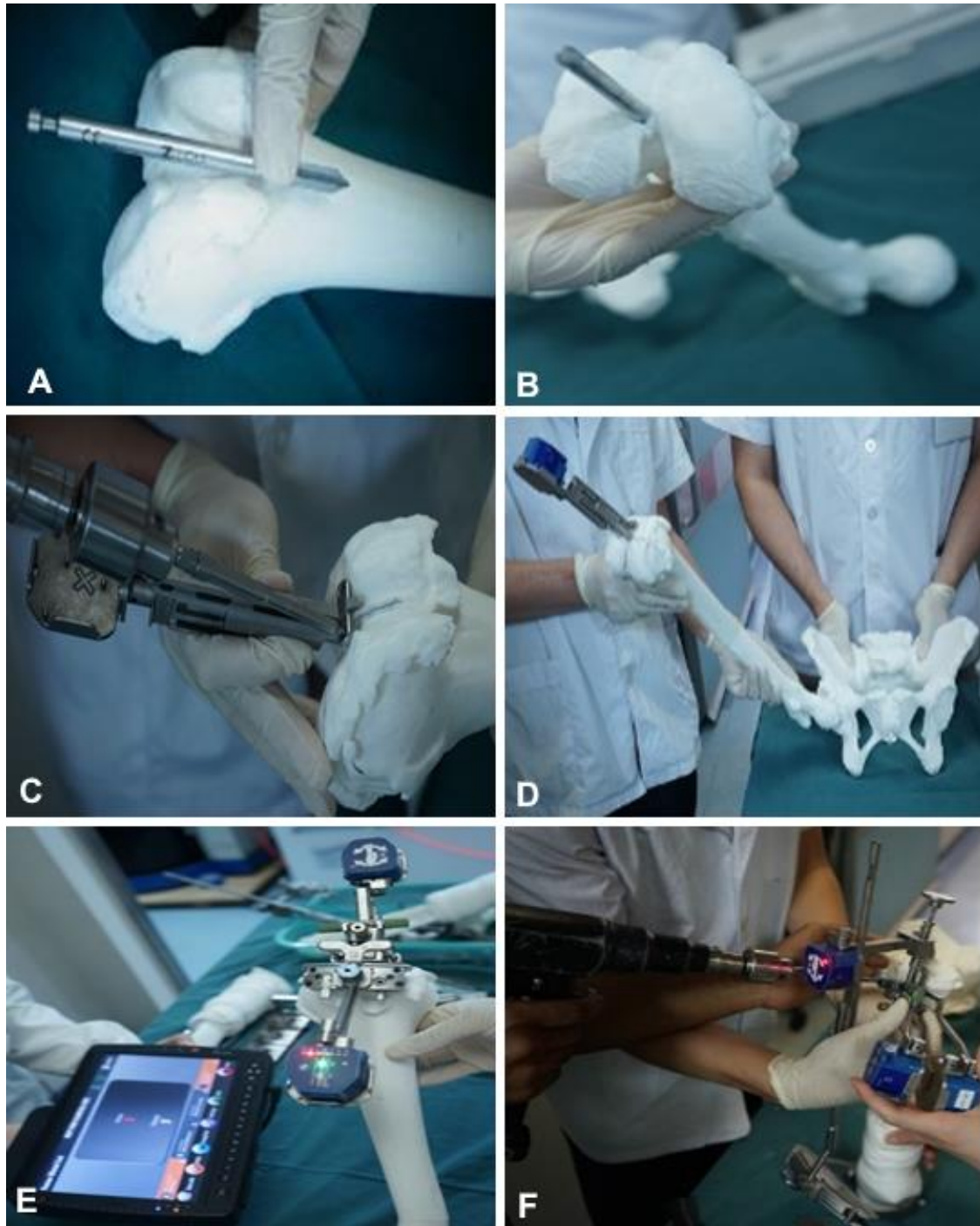


Fig. 1 The orientation and depth of impaction of the 7.9 mm spike impaction on the femoral section of the 3D printed model (A), correct positioning after impaction of the 7.9 mm spike on the Whiteside's line (B), fixation of femoral resection guide with screws (C), acquiring of 13 stable positions via accelerating and stopping the knee creating a star-shaped pattern after fixing the iAssist pod to the femur resection guide (D), setting of degrees of valgus or varus and flexion or extension gaps on the femoral resection guide according to our pre-operative goals (E) and fixation of tibial resection guide (F).

result in more of a varus alignment and similarly if we would have impacted the digitizer on the medial surface, it would result in varus knee as more of the lateral surface would be resected. This is seen due

to the alignment error, we feed, the system does not take human error into account and it recognizes the knee to be very bowed. It compensates for the error even when we set the varus and valgus to 0° by



Fig. 2 Placement of the tibial resection guide lateral to the highest point in the center of the tibia.



Fig. 3 The offset of angles of bone cut when 7.9 mm spike is spiked in an angle facing the lateral condyle versus the correct alignment angle. When it 7.9 mm spike is impacted by incorrect orientation, the cuts made are straight and when the spike is oriented laterally then the bone saw cuts more on the medial surface of the femoral condyle.



Fig. 4 The offset in the alignment of the bone cut when the tibial spike was impacted on the lateral surface of the tibial plateau as shown in Fig. 3, versus the correct position of spiking it on the highest point of the tibial plateau. The oblique line is the angle which the bone saw cuts when its spike is impacted laterally and the straight line is the cut, which the bone saw makes when digitizer spike is placed correctly.

achieving an oblique cut.

Discussion

Though the necessity to achieve neutral mechanical axis is challenging, the most common reason for implant failure is imperfect implant positioning, which results in excessive wear of the implant on a particular side if it is not aligned properly as per the design of the implant [43]. In addition, loosening of implants can lead to periprosthetic fractures [11, 14, 45, 46]. Several papers have been published in the past, which mainly focus on long-term results of implant survival of total knee arthroplasty. All concluded that the worst functional outcome was achieved when the implant is maligned by more than 3 degrees in varus or varus axis to the neutral mechanical axis [47-50]. Parratte et al. [51] concluded that achieving a neutral mechanical axis has to be considered a gold standard until more data is collected and accurate postoperative limb alignment is determined for each individual patient. In this experiment conducted, we found that iAssist system is a very good system in determining the neutral mechanical axis provided that the spikes are aligned properly and the proper input is given to the system. In every knee arthroplasty performed, the surgeon achieves a well-balanced knee by achieving a slightly oblique cut in the frontal and sagittal plane, by releasing the soft tissues and equal flexion and extension gaps to get the desired result [12].

In a study conducted by Vanniar et al. [52] showed that tourniquet time for patients in the iAssist group was comparatively higher than conventional group. This was associated with the learning curve associated with learning a new technique to acquiring the 13 stable positions for the femoral registration guide. Sometimes the system is not able to register the points successfully and the procedure has to be repeated until the system registers the points accurately, it is similar for tibial registration as well. But their result was contradictory to that of Nam et al. [53] and Mathey et al. [54] in which they reported less or equal tourniquet time in the navigational group to that of conventional group. Confaloneri et al. [55] in their study proved that superior results were achieved by those surgeons who had experience in computer-assisted surgeries compared to novice surgeons and they had less operative time initially but found no significant difference after 9 surgeries. They set the learning curve in 16 cases, which seems to be acceptable and in spite of all the advantages, there

were no significant results in the number of outliers and just after 11 surgeries, there was no significant difference in the number of recuts made. Compared to large console computer-assisted surgery (CAS) systems, iAssist has several advantages like no additional initial costs to set up consoles, avoidance of using additional tracking pins for surface registration, so no additional incisions for the placement of additional pins and hence no complications related to placement of pins. It also eliminates the issue of line of site as reported by Goh et al. [12]. The surgical time in iAssist is significantly lower when compared to large console computer-assisted surgical systems. This can be associated with the degree of familiarity which Zimmer iAssist system pods connect to the instruments similar to those used in conventional systems. The iAssist system uses a 7.9 mm spike impacted into the femur and as there is no need to remove the fat from femur using a cannulated rod like the ones used in conventional systems, it lessens the probability of fat embolism [12, 40, 58]. The most important feature about iAssist which adds to the confidence of the surgeon is its ability to validate the femoral and tibial cuts to the precise degree of accuracy as planned preoperatively and the cuts can be adjusted if necessary. As the bone saw can be flexible and can drift during resection even when the cutting jigs are secured well. Scuderi et al. [2] found that iAssist systems were reliable within 1° to optical navigation systems.

Several limitations about iAssist have to be acknowledged. The system should not be used in cases of hip pathology, which severely limits the range of motion (e.g., arthrodesis, severe contractures, and chronic severe dislocation) or in cases of hip joint pathology or knee pathology with significant bone loss (e.g., avascular necrosis of the femoral head with collapse, severe dysplasia of the femoral head or the acetabulum and femoral condyle collapse) and for total knee arthroplasty using the Quad-Sparing technique. iAssist systems heavily depend on the surgeon to position and input accurate data to determine the mechanical axis as proved in our experiment. If the positioning or the orientation of the femoral or tibial spikes are varied the iAssist system doesn't take it into account as there are no associated imaging techniques like some computer-assisted systems, it does not take into account for variations in anatomy, like a very bowed femur or tibia in the sagittal plane [53]. Also the soft tissue balancing and implant size information is not provided to the surgeon so the

size of the implants is determined by sizing jigs as used in conventional systems, thus the surgeon needs to have experience in using the conventional system to correctly determine the size of implant to be used and achieve proper soft tissue balancing for a well-balanced knee [12]. In a study, it was shown that during tibial registration, a pod suddenly got disconnected and attempts to reconnect and recalibrate by the staff was futile and the surgeon had to complete the tibial resection by himself, as in that case, he was an experienced surgeon, so he had no problem in determining the required level and the orientation of the cut required [56]. Confalonieri et al. [57] also proved that a novice surgeon trained in computer-assisted techniques, after a finite number of cases can replicate the results of an experienced surgeon, although experience plays a huge role in recovering and achieving the desired result when occasionally the components fail.

Conclusions

iAssist system depends on the surgeon to input accurate data and proper positioning of the guides to acquire the correct mechanical axis of the knee and even though it's not perfect. It is definitely a step in the correct direction to achieve higher accuracy associated with computer-assisted systems with the familiarity associated with conventional systems.

Conflict of Interest

The authors declare that we have no conflict of interest to declare.

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