International Journal of Research in Orthopaedics
Vanniar SR et al. Int J Res Orthop. 2018 May;4(3):350-356
http://www.ijoro.org

DOI: http://dx.doi.org/10.18203/issn.2455-4510.IntJResOrthop20181793

Original Research Article

iAssist versus conventional total knee arthroplasty in patients with varus and valgus deformities

Senthur Rajendren Vanniar[1]*, Li Ming Wang[1], Qing Qiang Yao[1], Taraka Venkata Pavan Maddali[2]

[1]Department of Orthopedics, Nanjing Medical University, Nanjing, China
[2]Department of Orthopaedics and Traumatology, Malla Reddy Medical College for Women, Hyderabad, Telangana, India

Received: 07 February 2018
Accepted: 09 March 2018

***Correspondence:**
Dr. Senthur Rajendren Vanniar,
E-mail: senthur.r89@outlook.com

ABSTRACT

Background: Accelerometer and gyroscope based iAssist system's accuracy in restoring the hip knee angle (HKA) in valgus and varus deformity patients is compared to that of conventional system.
Methods: In this retrospective study we compared the HKA of 26 patients in iAssist group with that of 26 patients in conventional group. The knee joints were evaluated with full leg length radiographs.
Results: The iAssist group patients' post-operative hip knee angle was much near to our target angle when compared to that of patients in conventional technique group.
Conclusions: iAssist brings the high accuracy associated with large console CAS systems with lower costs and helps surgeons in low volume hospitals achieve specific intra operative goals with the familiarity of conventional guides.

Keywords: iAssist, Navigated TKA, Varus and valgus deformity, Conventional TKA

INTRODUCTION

The frequency in which knee replacements are performed is truly staggering. This reality increases the burden on joint replacement surgeons to get it right on the first time as the demand for total knee arthroplasty (TKA) is expected to increase significantly over the next 20 years.[1]

TKA is effective in improving quality of life of those suffering from osteoarthritis. The success of TKA depends on various factors like the restoration of mechanical axis, component positioning, joint line restoration, flexion and extension gaps and soft tissue balance. This is particularly true in cases of valgus and varus knees.[2]

Many studies confirm that achieving accurate component implantation and mechanical axis of ±3° to neutral mechanical axis leads to long term prosthesis survival and decreased component loosening.[2-6] Ritter et al noted significant risk of aseptic failures with tibial component orientation of less than 90° relative to tibial axis and femoral component orientation greater than 8° of valgus relative to femoral axis.[7] Berend et al in a review of 3152 TKA's confirmed the chance of implant failure escalated by roughly 17 times due to a tibial varus alignment of greater than 3°.[8] Jeffry et al analyzed the outcome of TKA in 115 patients and found cases of implant loosening at 24% when the Valgus and or Varus exceeded ±3° whereas it was only 3% in other cases.[3]

In every TKA performed, the surgeon aims to achieve a neutral mechanical axis and a number of technologies are available to aid and guide the surgeon intra operatively like intra- medullary (IM) and extra medullary (EM) jigs, patient specific instrumentation (PSI) large console CAS,

[5] and recently hand held navigation systems.[6] The conventional method of using IM and EM jigs to achieve distal femoral and proximal tibial cuts has limited degree of accuracy in achieving overall component placement and restoration of mechanical axis.[10] Several studies have shown that despite the surgeons' experience, conventional guides can still be unreliable and it has a limited degree of accuracy.[11-13] Errors can happen as this technique is dependent on surgeons' judgment, fixation of instruments, knowledge of knee kinematics and hand eye coordination.[13,14] Mahaluxmivala et al analyzed 673 TKA's and found that 25% of cases had Varus and/or Valgus of ±3° regardless of the surgeons' experience.[15]

CAS was developed as an alternative to conventional technique to help surgeon reduce errors in bone preparation and improve alignment of the components.[2] Most studies have shown significant improvement in knee alignment in favor of CAS when compared to Conventional techniques.[16,17] Mason et al showed 65.9% to achieve perpendicular femoral varus and/or valgus alignment within 2° of femoral mechanical axis and 79.7% to achieve tibial varus and/or valgus alignment within 2° of perpendicular to tibial mechanical axis in conventional group vs. 90.4% and 95.2% achieved respectively in CAS group.[13]

However despite positive results seen with CAS techniques, the penetration rate has failed to exceed 5%. It's probably due to large console positioning, difficulty with optical instruments, sensitivity, increased capital costs, perceived complexity of use, longer operative time, learning curve required and fractures from pin insertion sites.[12,18]

Recently navigation systems have been developed using accelerometer and gyroscopes in attempt to combine the accuracy associated with CAS and convenience of conventional systems which does not require the use of large computer systems for registration and alignment results to provide the surgeon intra operatively.[5,6,9,11,19] The iAssist (Zimmer Inc, Warsaw, IN) system uses four pods which are attached to the surgical instruments and intraoperatively using accelerometer and gyroscope provides the precise alignment and position in relation to anatomic landmarks. Within these pods are inertial gyroscopes that exchange information using a secure local wireless channel, and information is displayed to the surgeon intraoperatively.[2]

The purpose of the study was to find out if iAssist accelerometer based navigation system results in better postoperative alignment in patients with varus and valgus deformities. When compared to conventional techniques. Our hypothesis is that iAssist will result in a better knee alignment even for patients with severe varus and valgus deformities.

METHODS

Patient selection

We obtained the approval of institutional review board and retrospectively analyzed the varus and/or valgus outcome data of patients with primary osteoarthritis who underwent TKA using either iAssist accelerometer based navigation technique or the conventional technique. 26 patients underwent TKA using iAssist systems at our academic hospital performed by a senior surgeon from August to October 2016.

In this non randomized study patients who underwent iAssist surgery and who had a valgus and/or varus deformity were selected and patients of similar varus and/or valgus deformity from the conventional group were selected to get an accurate comparison. All the TKAs in iAssist group and conventional group were performed using posterior-cruciate substitute (PS) implants. No exclusions were made on the basis of age, sex, body mass index (BMI) and there was no significant difference in both groups. All the surgeries were performed using spinal anesthesia. High thigh tourniquet was used for the entire duration of the surgery. All the TKA were performed with a mid-patellar incision. Femur was first resected followed by tibial resection and all the implants were fixed with bone cement.

iAssist surgical technique

The iAssist (Zimmer Inc., Warsaw, IN) is an accelerometer-based navigation device that does not require large console computer devices for the registration and alignment feedback processes.[2,20] As there is no need for additional pin placements used for optical trackers with large console CAS, no additional incisions are made. All the data and feedback is available during the operation via a screen which receives information from the accelerometer and gyroscopes from the pods which transmit the information over a secure Wi-Fi network.[2,5] To establish the mechanical axis, the femur is first prepared with a intramedullary guide. A 7.9mm spike is impacted in the Whiteside's line Figure 1.[21] After aligning the femoral reference guide in a neutral position and fixing it, 13 stable positions are acquired by accelerating and stopping the leg creating a star shaped pattern. Audio feedback confirms the acquiring of each stable position. After acquiring the positions, the resection guide is fixed to the reference guide the femoral Valgus and/or Varus is set at 0° and flexion and/or extension is set at 3° which can be set by turning the two knobs and the degrees are confirmed in the screen and by the green lights on the pods Figure 2. The green light indicates the resection guide is in acceptable alignment. The distal femur is resected after the femoral adjustment mechanism is secured with screws when it's fully seated in the most distal condyle and the spike assembly removed. Following the bone resection, the cut is confirmed using a validation tool secured with captive spikes and the values are displayed in the screen. Adjustments can be made if necessary and further cuts are made using the chosen implant.

Figure 1: Inserting the 7.9 mm spike on white sides line.

Figure 2: Validating femoral positioning before resection.

Figure 3: Tibial component positioning before resection.

The tibia is prepared by an extra medullary guide Figure 3. 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. The longer mechanical axis digitizer spike is partially inserted on the highest point of the tibial plateau and after orienting the guide with the medial third of the tubercle, the guide spike is further impacted while gripping the distal clamps and now the tibia guide is aligned to the patients' mechanical axis. The tibia resection guide is placed to the tibia tuberosity and fixed 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 is set at 0° and posterior slope is set at 7° indicated by the green lights in the pods with the help of two knobs similar to femoral resection guide. The depth of cut is determined using a stylus.

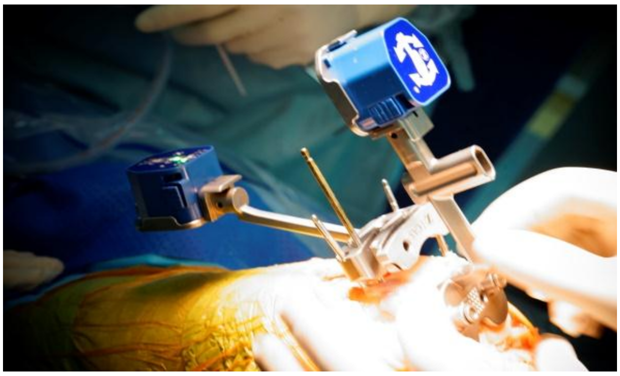

Figure 4: Validating the femoral cut.

Figure 5: Validating tibial cut.

After the resection of tibia, the cuts are validated with a validation tool Figure 4 and 5 and further resection can be done if required. Now the tibia is ready to proceed with the next step.

Conventional surgical technique

All surgeries were performed under tourniquet with medial patellar approach and femur first technique using the intra medullary guide. After finishing the femoral cuts, extramedullary guide was used to perform tibia cuts. All the cuts were targeted to achieve neutral mechanical axis based on manufacturers' guidelines. Gap balancing, stability and patellar tracking was checked first with trial components and them the final components were implanted.

Statistical analysis

All date were collected and recorded in Microsoft Excel (Microsoft Corp. Redmond, WA). Statistical analyses were all carried out using GraphPad prism software version 5 (GraphPad Software, Inc. La Jolla, CA.) Mean, standard Deviation, and T test were all carried out and p<0.05 was considered statically significant.

Radiographic analysis

Axial alignment and orientation of components were computed with standard pre and postoperative non weight bearing full leg length radiographs in coronal and sagittal planes. The following data was recorded: Hip knee Angle (HKA) also Known as the mechanical axis is the angle measurement between the center of femoral head to the center of the ankle joint, and passes through knee joint just medial to the tibial spine with 180° set as target angle.

RESULTS

Our study has 26 patients in both iAssist and Conventional groups with no patients lost to follow up. 15 patients in iAssist group had varus deformity (164°-177°) and 11 patients had valgus deformity (182°-190°) when measured from the medial side. Similar to iAssist group, is patients with varus deformity (165°-177°) and 11 patients with valgus deformity (183°-193°) were chosen in conventional group.

Table 1: Distribution of cases.

Category	Number of patients			Mean age	Mean BMI kg/m^2	Mean HKA	KSS score
	Total	Male	Female				
iAssist	26	12	14	65.2±7.6 (57-78)	23.34±4.29 (20.8-30.2)	175.8 ± 7.5 (164-190)	69.1±8.89 (57-78)
Conventional	26	13	13	64.9±7.9 (58-79)	22.27±4.48 (19.89-29.8)	175.2±7.8 (165-193)	65.9±10.3 (59-75)
P value				0.27	0.88	0.49	1.20

Table 2: Length of hospital stay.

Category	iAssist-TKA (n=26)	Conventional-TKA (n=26)	P value
Operating time (min)	82.1±7.9 (81.0-93.3)	59.8±8.1 (50.4-73.8)	0.001
Length of hospital stay	6.26 (5-9)	7.5 (6-10)	0.004
VAS pain score	7.9±1.5	7.9±1.6	>0.05

Table 3: Pain score based on visual analog score.

VAS pain score	iAssist group	Conventional group
1 week	7.9±0.8	9.1±0.8
1 month	4.4±0.9	3.4±0.9
3 months	2.9±1.9	2.6±1.6
6 months	1.9±1.9	2.1±0.9
12 months	1.3±1.8	1.5±1.2

Table 4: Hip knee angle in both categories.

Category	iAssist	Conventional	P value
HKA within 3°	180.0±0.2079 (n=26)	179.9±0.3480 (n=26)	0.9639
HKA within 2°	179.8±0.1826 (n=24)	179.6±0.3197 (n=16)	0.5925

Table 5: Postoperative varus deformity in patients.

Post operative varus deformity patients			
	iAssist	**Conventional**	**P value**
Within 2°	178.78-180.88 (n=15)	178.22-181.45 (n=10)	0.049
Within 3°	178.78-180.88 (n=15)	177.35-182.9 (n=15)	0.002

Table 6: Postoperative valgus deformity in patients.

Postoperative valgus deformity patients			
	iAssist	Conventional	P value
Within 2°	179.82-181.32 (n=9)	178.45–181.99 (n=6)	0.0115
Within 3°	179.82-182.09 (n=11)	177.98–182.25 (n=6)	0.008

There was no significant difference in age 65.2±7.6 (57-78 years) in iAssist group vs. 64.9±7.9 (58-79 years) in conventional group, (p=0.27). BMI 23.34±4.29 (20.8-30.2) in iAssist vs. 22.27±4.48 (19.89-29.8) in conventional, (p=0.88). Similarly mean HKA and KSS score for iAssist vs. conventional was 175.8°±7.5° (164°-190°) vs. 175.2°±7.8° (168°-193), (p=0.49) and 69.1±8.89 (57-78) VS. 65.9±10.3 (59-75) (p=1.20) respectively.

There was a significant difference in length of hospital stay, which was 6.26 days (5-9 days) for iAssist group and 7.5 days (6-10 days) for Conventional TKA (p=0.004). The duration of surgery was however longer in iAssist group, 82.1±7.9 minutes compared to 59.8±8.1 in conventional group p=0.001.

Both the groups experienced significant improvements in KSS and VAS pain score from preoperative to six months postoperatively. In each group 11 patients had valgus deformity and is patients had varies deformity. Postoperatively the HKA of all the 52 patients were within 3 degrees of the target angle of 180.

Even though both the groups had similar results the iAssist group had more accurate outcome. The test revealed out of 15 only 10 of varus deformity patients in conventional group were within 2° of target angle. The difference of degrees to target angle was statically significant in iAssist group where it was p=0.002 in less than 3° to target angle patients and p=0.049 in those patients where the difference to target angle was less than 2°. Similarly for those who had valgus deformity p=0.008 in those patients whose postoperative HKA was within 3° to target angle and p=0.0115 in those HKA was within 2° to target angle.

DISCUSSION

The primary aim of this study was to evaluate the accuracy of iAssist surgical technique to achieve neutral mechanical axis of the limb and compare its accuracy to Conventional techniques. The mechanical axis of the leg was determined by comparing the preoperative and post-operative radiographs of iAssist and Conventional group patients.

Though the need to achieve neutral mechanical axis is challenged, imperfect implant positioning has been the most important reason for implant failure. Due to excess wear of the implant, loosening of implants leads to periprosthetic fractures.[4,7,22] Several literatures have been published in the past which focuses on long term results of TKA and concludes that exceeding the neutral mechanical axis by 3° in varus or valgus is responsible for the worst functional outcomes in TKA.[3,8,15,23] Parratte et al concluded that achieving a neutral mechanical axis should be considered a gold standard until more data is collected and accurate postoperative limb alignment for individual patients is determined.[24]

In this study our results confirms the initial hypothesis. The postoperative results of patients indicate that iAssist group patients have an alignment much closer to our target angle compared to conventional group. Our results coincide with previously published data that iAssist results are comparable to other navigation systems.[25] Bathis et al compared a Vector Vision CT free knee, Brain Lab, Munich, Germany) with Conventional technique and achieved mechanical axis of ±3° of valgus and/orvarus in 96% of navigational group compared to 78% in conventional group.[14]

For a TKA performed in osteoarthritic knees with valgus and/or varus deformity, there are several specific procedures performed by the surgeon to achieve well-balanced knee and a neutral mechanical axis by achieving slightly oblique bone resection in frontal and sagittal plane; releasing the soft tissues for a well-balanced stable knee and equal flexion and extension gaps.[5] iAssist like other CAS systems need accurate data input to determine the mechanical axis, it does not take into account for variations in anatomy, like a very bowed femur or tibia in the sagittal plane.[26] Also the soft tissue balancing and implant sizing information is not provided to the surgeon so the size of the implants are determined by sizing jigs as used in conventional systems.[5]

Tourniquet time for patients in iAssist group was comparatively higher than conventional group. This was associated with errors acquiring the femoral registration points and the 13 stable positions. 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. It is mostly associated with the learning curve that accompanies with any new technique. One of our results is contradictory to that of Nam et al in which they reported less tourniquet time in the navigational group than conventional group.[27]

Compared to large console CAS systems, iAssist has several advantages like no additional initial costs to set up consoles, avoidance of using additional tracking pins for surface registration found no pin placement related complications in on study for any patient in iAssist group and it also eliminates line of site issues associated with large console systems, as reported by Hoke et al and Owens et al.[18,28] Goh et al mentioned that the surgical time in iAssist is significantly lower when compared to large console CAS systems.[5] This may be associated with degree of familiarity that iAssist provides to surgeons who have used conventional systems as the pods are clipped into the guides that are similar to conventional guides.

The most important feature about iAssist system is its ability to validate the femoral and tibial cuts, as we know the bone saw can be flexible and can drift during resection even with a well fixed cutting jig, it adds to the confidence of the surgeons to check the plane of resection and confirm the alignment and adjustments can be made to the cuts if necessary. As reported by Scuderi et al iAssist systems was reliable within 1° compared to optical navigation systems.[2]

Several limitations to this study have to be acknowledged. All the patients were treated by an experienced joint replacement surgeon, so even though there was a longer operating time associated with iAssist group, the mechanical axis was restored within 3° of neutral mechanical axis and there were no outliers in iassist group whereas there was only one outlier in the conventional group. Absence of significant difference in both groups may reflect a type II error.

During a surgery in iAssist group, while following the procedures of tibial registration for tibial resection after the femoral resection is completed, the pods suddenly lost the signal with the systems and all attempts to reconnect and recalibrate the pods by the hospital support staff failed and the surgeon had to finish the tibial cut using conventional guides. Although Confalonieri et al have shown that a novice surgeon trained with CAS techniques, after a finite number of cases can replicate the results of an experienced surgeon still experience plays a huge role in recovering and achieving the desired result when occasionally the components fail.[29]

CONCLUSION

iAssist brings the high accuracy associated with large console CAS systems with lower costs and it help the surgeons in low volume hospitals achieve their specific intra operative goals along with the familiarity of conventional guides even in severe varus and/or valgus knees.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

REFERENCES

1. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplastyin the United States from 2005 to 2030. J Bone Joint Surg Am. 2007;89:780.
2. Scuderi GR. Total knee arthroplasty performed with inertial navigation within the surgical field. Seminars Arthroplasty. 2014;25:179-86.
3. Jeffery RS, Morris RW, Denham RA. Coronal alignment aftertotal knee replacement. J Bone Joint Surgery Br. 1991;73:709–14.
4. Iorio R, Mazza D, Drogo P, Bolle G, Conteduca F, Redler A, et al. Clinical and radiographic outcomes of an accelerometer-based system for the tibial resection in total knee arthroplasty. Int Orthop (SICOT). 2015;39:461–6.
5. Goh GSH, Liow MH, Lim WSR, Tay, DKJ, Yeo SJ, Tan MH. Accelerometer-Based Navigation Is as Accurate as Optical Computer Navigation in Restoring the Joint Line and Mechanical Axis After Total Knee Arthroplasty. J Arthroplasty, 2016;31:92–7.
6. Thiengwittayaporn S, Fusakul Y, Kangkano N, Jarupongprapa C, Charoenphandhu N. Hand-held navigation may improve accuracy in minimally invasive total knee arthroplasty: a prospective randomized controlled trial. Int Orthop. 2016;40:51–57.
7. Ritter MA, Davis KE, Meding JB. The effect of alignment and BMI on failure of total knee replacement. J Bone Joint Surg Am. 2001;93(17):1588–96.
8. Berend ME, Ritter MA, Meding JB. Tibial component failure mechanisms in total knee arthroplasty. Clinical Orthop Rel Res. 2004;498:26–34.
9. Nam D, Cody EA, Nguyen JT, Figgie MP, Mayman DJ. Extramedullary Guides Versus Portable, Accelerometer-Based Navigation for Tibial Alignment in Total Knee Arthroplasty: A Randomized, Controlled Trial: Winner of the 2013 HAP PAUL Award. J Arthroplasty. 2014;29:288–94.
10. Anderson KC, Buehler KC, Markel DC. Computer assisted navigation in total knee arthroplasty: comparison with conventional methods. J Arthroplasty. 2005;20(7):132.
11. Gharaibeh MA, Solayar GN, Harris IA, Chen DB, Samuel J. MacDessi SJ. Accerelator-based, portable navigation (KneeAlign) Vs conventional instrumentation for total knee arthroplasty: A prospective randomized comparative trial. J Arthroplasty. 2017;32(3):777-82.
12. Anderson KC, Buehler KC, Markel DC. Computer assisted navigation in total knee arthroplasty: comparison with conventional methods. J Arthroplasty. 2005;20:132–8.
13. Mason JB, Fehring TK, Estok R, Banel D, Fahrbach K. Meta-analysis of alignment outcomes in

computer-assisted total knee arthroplasty surgery. J Arthroplasty. 2007;22:1097–106.
14. Bathis H, Perlick L, Tingart M. Alignment in total knee arthroplasty. A comparison of computer assisted surgery with conventional technique. J Bone Joint Surg Br. 2004;86B:682–7.
15. Mahaluxmivala J, Bankes MJ, Nicolai P. The effect surgeon experience on component positioning in 673 press fit condylar posterior cruciate-sacrificing total knee arthroplasties. J Arthroplasty. 2001;16:635.
16. Blakeney WG, Khan RJ, Wall SJ. Computer-assisted techniques versus conventional guides for component alignment in total knee arthroplasty: a randomized controlled trial. J Bone Joint Surg Br. 2011;93:1377–84.
17. Barrett WP, Mason JB, Moskal JT, Dalury DF, Oliashirazi A, Fisher DA. Comparison of radiographic alignment of imageless computer-assisted surgery vs conventional instrumentation in primary total knee arthroplasty. J Arthroplasty. 2011;26:1273–84.
18. Hoke D, Jefari M, OrozcoF, Ong A. Tibial shaft stress fractures resulting from placement of navigation tracker pins. J Arthroplasty. 2011;26(3):504.
19. Fujimoto E, Sasashige Y, Nakata K, Yokota G, Omoto T, Ochi M. Technical Considerations and Accuracy Improvement of Accelerometer-Based Portable Computer Navigation for Performing Distal Femoral Resection in Total Knee Arthroplasty. J Arthroplasty. 2017;32:53-60.
20. Scuderi GR, Fallaha M, Masse V. Total knee arthroplasty with a novel navigation system within the surgical field. Orthop Clin North Am. 2014;45(2):167.
21. Available at: https://www.wheelessonline.com/ ortho/rotational alignment of femoral app cutting guide. Accessed on 3 October 2017.
22. Abdel MP, Oussedik S, Parratte S, Lustig S, Haddad FS. Coronal alignment in total knee replacement: historical review, contemporary analysis, and future direction. J Bone Joint Surg. 2014;96:857-62.
23. Rand JA, Coventry MB. Ten-year evaluation of geometric total knee arthroplasty. Clin Orthop Related Res. 1988;232:168.
24. Parratte S, Pagnano MW, Trousdale RT. Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements. J Bone Joint Surg Am. 2010;92:2143.
25. Desseaux A, Graf P, Dubrana F, Marino R, Clave A. Radiographic outcomes in the coronal plane with iASSITTM versus optical navigation for total knee arthroplasty: A preliminary case-control study. Orthop Traumatol Surg Res. 2016;102:363-8.
26. Pickering S, Armstrong D. Focus On Alignment in Total Knee Replacement. J Bone Joint Surg. 2012;1:3.
27. Nam D, Cody EA, Nguyen JT, Figgie MP, Mayman DJ. Extramedullary guides versus portable, accelerometer-based navigation for tibial alignment in total knee arthroplasty: a randomized, controlled trial. J Arthroplasty. 2014;29:288-94.
28. Owens Jr RF, Swank ML. Low incidence of postoperative complications due to pin placement in computer-navigated total knee arthroplasty. J Arthroplasty. 2010;25(7):1096-8.
29. Confalonieri N, Chemello C, Cerveri P. Is computer assisted total knee replacement for beginners or experts? Prospective study among three groups of patients treated by surgeons with different levels of experience. J Orthop Traumatol. 2012;13:203-10.

Cite this article as: Vanniar SR, Wang LM, Yao QQ, Maddali TVP. iAssist versus conventional total knee arthroplasty in patients with varus and valgus deformities. Int J Res Orthop 2018;4:350-6.