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Validation of an Imageless Computer-assisted Navigation System for Total Knee Arthroplasty

William Xiang[1], Eric N. Windsor[1], Sheila Wang[2], Allan Inglis[1], and Peter K. Sculco[1]
[1] Hospital for Special Surgery, 535 E 70th St, New York NY 10021, USA
[2] Intellijoint Surgical, 809 Wellington St N Unit 2, Kitchener ON N2H 5L6
William.xiang@yahoo.com, enwindsor22@gmail.com, s.wang@intellijointsurgical.com, ainglisjr@gmail.com, sculcop@hss.edu

Abstract

Background: Restoration of the hip-knee-ankle (HKA) angle to within ±3° of the neutral mechanical axis is considered a well-aligned total knee arthroplasty (TKA), with outliers associated with higher failure rates. Thus, efforts to improve intraoperative surgical accuracy are of strong clinical interest. This study evaluated the accuracy and safety of a novel, imageless, computer-assisted navigation system (CAS) for TKA.

Methods: 112 consecutive patients who underwent primary TKA between January-December 2020 with 2 board-certified, high-volume orthopedic surgeons using the same imageless CAS were retrospectively reviewed. Patient age, BMI, sex, postoperative complications, and reoperations were collected. Two trained reviewers independently assessed tibial and femoral component mechanical alignment measurements in a standardized manner on postoperative full-leg AP and lateral radiographs. The primary outcome was mean absolute degrees of difference for each measurement compared to intraoperative CAS measurements. Outcomes were reported as means ± standard deviation.

Results*:* 38%(N=43/112) of patients were male. Mean age was 69±8 years and mean BMI was 31.1±5.9. 71%(N=79/112) of patients had a well-aligned TKA (HKA within ±3°).

The mean absolute difference was 1.5°±1.2° for femoral coronal alignment, 1.0°±0.8° for tibial coronal alignment, 2.2°±1.5° for femoral flexion, and 1.8°±1.6° for tibial slope.

Two patients(1.8%) underwent reoperation; specifically, 1 patient received a 1-stage revision for periprosthetic joint infection 5 months postoperatively and the other underwent lysis of adhesions 9 months postoperatively for arthrofibrosis.

Conclusions*:* This novel imageless CAS provides accurate readings within 2° for tibial and femoral coronal and sagittal alignment, and patients have low complication rates at early follow-up.

1 Introduction

The styles Total knee arthroplasty (TKA) is recognized as an effective procedure to treat a variety of knee disease and disability, including osteoarthritis, post-traumatic arthritis, and deformity [1-3]. Operative success is defined as restoration of the mechanical axis of the lower limb to within ±3° of neutral, accomplished by accurately positioning the femoral and tibial implants [4]. However, optimal cutting angles and resulting implant positioning are not always achieved even amongst experienced surgeons. Post-operative issues arising from suboptimal placement include aseptic loosening, decreased implant survivorship, reduced function, and complications that lead to readmission and revision [5,6]. With the number of TKA procedures anticipated to rise, it is of interest to limit post-operative complications and optimize alignment accuracy. [7,8]. To remedy this, attention has been given to technological advancements that aim to consistently achieve neutral alignment [9].

Various computer-assisted surgical navigation systems (CAS) have been developed to improve component placement accuracy. Such systems can be image-based or imageless, using imaging techniques or key anatomical landmarks, respectively, to register the patient. CAS devices have enabled surgeons to place TKA components with significantly increased accuracy and precision compared to procedures performed via conventional methods [10-13]. Successful restoration of the mechanical axis has in turn been associated with improved outcomes [8,13-16]. Despite the improved radiographic and clinical results, CAS systems are not without disadvantages. There are several reports of systems significantly increasing operating time [17,18], thus increasing opportunities for complications. In addition, high capital investments can make such systems prohibitory from a cost perspective for low volume centers [19]. As such, adoption rates for computer-assisted navigation in TKA have remained low [20].

The purpose of this study was to assess the accuracy of a novel, imageless navigation device for TKA. Previous cadaver testing has demonstrated coronal and sagittal plane measurements to be highly correlated with those obtained from computer tomography (CT) images [21]. This pilot study will compare angular measurements from the two modalities with patients undergoing primary TKA.

2 Methodology

Patients who underwent a primary TKA utilizing a novel imageless CAS navigation system (Intellijoint KNEE™, Intellijoint Surgical Inc., Kitchener, Ontario, Canada) from January-December 2020 were retrospectively reviewed. All procedures were performed by two board-certified, high-volume orthopedic surgeons who employ mechanical alignment targets during TKA. Patients who had significant joint deformity (>15 degrees), underwent a previous contralateral TKA, or were required to have a femur or tibia cut greater than 3° relative to their mechanical axis were not eligible for inclusion in the study. Plain-film or 3D stereoradiographic imaging (EOS Imaging System, EOS Imaging Inc., Paris, France) was obtained pre-operatively and 6-weeks post-operatively for each patient.

Intellijoint KNEE is an imageless, pin-less navigation device that uses infrared optical technology and integrated microelectronics to provide real-time positioning of femoral and tibial cutting guides during TKA (Fig. 1). The system includes an optical probe tracker that identifies landmarks for patient registration and monitors cutting guide position, and an optical bone tracker that is attached to the distal femur or proximal tibia via a bone screw. The bone screw can be inserted onto the intra-articular or extra-articular surface, with the latter allowing for cut verification. The camera is placed where it can detect the position and orientation of both trackers and communicates with a computer workstation situated outside the sterile field, where real-time coronal (varus/valgus) and sagittal plane (flexion/extension, anterior/posterior slope) angles for the femoral and tibial cuts are displayed. All measurements are made relative to the mechanical axis. The navigation device accommodates either a femur or tibia-first workflow and has been cleared by the Food and Drug Administration and Health Canada for use in the United States and Canada, respectively.

Demographic data (age, sex, operative side, body mass index (BMI)) was collected for all eligible patients. Adverse events, if any, were documented at routine follow-up appointments with minimum 1-year follow-up.

Intraoperative measurements for the femoral and tibial cuts were saved and stored by the navigation device, including: varus/valgus angle, flexion/extension, and anterior/posterior slope. Post-operative measurements were obtained from plain-film radiographs and stereoradiographs using independently validated 3D sterEOS® software protocols (EOS Imaging System; EOS Imaging Inc., Paris, France) and included measurements of the hip-knee-ankle angle (HKA), mechanical lateral distal femoral angle (mLDFA), mechanical medial proximal tibial angle (mMPTA), and femoral and tibial slope angles. Radiographic measurements were performed by two trained independent observers.

The primary outcome was navigation accuracy, defined as the mean absolute difference (ABS) between intraoperative measurements and post-operative radiographic measurements for femoral and tibial varus/valgus and slope angles. All summative data is expressed as mean ± standard deviation (SD).

Radiographic measurements from a subset of 20 randomly selected cases were used to calculate intra-class correlation coefficients (ICC) for assessment of intra-rater reliability. ICC values under 0.5 were classified as poor reliability, between 0.5-0.75 as moderate reliability, between 0.75-0.9 as good reliability, and over 0.9 as excellent reliability [22].

The rate of restoration of the mechanical axis and frequency of adverse events were reported as proportions/percentages of the entire cohort. All statistical analyses and calculations were performed using Microsoft Excel, version 16.16.27 (Microsoft Corporation, Redmond, WA).

3 Results

A total of 112 patients were included in this study, with 38% of the cohort being male (n= 43/112). The mean BMI was 31.1 ± 5.9, and the mean age at the time of surgery was 69.0 ± 8.0 years.

In the coronal plane, the mean absolute difference between intraoperative navigation-recorded measurements and those made on post-operative radiographs was 1.5° ± 1.2° for femoral alignment and 1.0° ± 0.8° for tibial alignment. In the sagittal plane, the mean difference was 2.2° ± 1.5° for femoral flexion and 1.8° ± 1.6° for tibial slope. Radiograph assessment showed that 71% (N= 79/112) of patients had an HKA ± 3° .

ICC was rated as excellent for HKA (ICC = 0.96), good for femoral coronal measurements (ICC = 0.82) and femoral flexion (ICC = 0.78), moderate for tibial coronal measurements (ICC = 0.60), and poor for tibial slope (ICC = 0.30).

There were no instances of perioperative complications. Two patients (1.8%) were required to undergo reoperations. One patient received a one-stage revision for periprosthetic joint infection (PJI) that occurred 5 months postoperatively, while the other patient underwent lysis of adhesions for arthrofibrosis at 9 months postoperatively.

4 Discussion

Accurate implant placement is essential to the success of achieving a well-balanced and well-aligned TKA. Historically, proponents of mechanically aligned TKA argue that creating a “biomechanically friendly prosthetic knee" is paramount to achieving long-term prosthesis survivorship and preventing complications such as patellar instability and early aseptic loosening [23,24]. This principle has received abundant support in the literature, with excellent all-cause TKA survivorship rates of over 80% at 20 to 25-year follow-up [25,26]. At the same time, the importance of defining a successful neutral mechanical axis has also seen ample attention, with most surgeons relying on a margin of ± 3.0°. Exceeding this threshold, especially in varus deformity, has been correlated with both decreased survivorship and worse patient-reported outcome measures in previous studies [6,27,28].

To provide surgeons with increased fidelity when making tibial and femoral bone resections, CAS devices have been introduced in recent years as an advancement from traditional manual instrumentation. Previously, the novel imageless CAS navigation system studied here was assessed in a cadaveric study of 10 knees to compare the accuracy of measurements between CAS and CT scans [21]. The result from that study demonstrated that the mean absolute difference for both the femoral and tibial cuts were roughly 1.0° in the coronal plane and 2.0°-3.0° in the sagittal plane. In this clinical retrospective study using radiographs as the comparative standard, the CAS system again demonstrated accuracy within 3.0° of absolute difference in both the coronal and sagittal planes. This result notably reinforces the efficacy of this system to assist surgeons with meeting target benchmarks for implant placement during TKA.

In addition to performance, safety is also naturally of tantamount importance for navigation systems. Although a non-navigation control group of patients was unavailable for comparison, this cohort of 112 patients did not experience any perioperative complications, such as acute blood loss anemia requiring transfusion. Additionally, while there were two reoperations that occurred at 1-year follow-up, it is unlikely that they are attributable to the use of navigation as the pin sites are intra-articular and within the incision. For the case of arthrofibrosis, there was no evidence that component malpositioning in the coronal or sagittal plane contributed to the development of postoperative stiffness.

This study has several limitations. First, postoperative radiographs were used as they are routinely obtained for all patients at the institution, while other imaging modalities that provide more rigorous implant measurements, such as CT, are not. Thus, this may introduce some degree of error during comparisons with navigation-recorded measurements, particularly for gauging the tibial component, as evidenced by greater inter-observer disagreement for those measurements. However, the fact that the differences from navigation-recorded measurements are still very similar to those previously found when using CT as a comparative standard, as discussed above [21], likely indicates that the magnitude of error was limited. Finally, both surgeons in this study are high-volume arthroplasty surgeons with established familiarity with this navigation system. Thus, it is possible results may be less optimal for less-experienced surgeons. However, a previous study of a navigation tool for total hip arthroplasty, utilizing similar technology and developed by the same manufacturer, demonstrated that just 3-5 cases were sufficient to significantly improve proficiency [29].

5 Conclusion

This novel imageless, pin-less navigation device for TKA provides accurate tibial and femoral measurements within roughly 2.0° in both the coronal and sagittal planes when using postoperative radiographs as a comparative standard. There were no instances of perioperative complications and patients had a low reoperation rate at early follow-up. Together, these results support this imageless optical computer navigation device as a promising and safe alternative to traditional navigation for TKA.

References

1. Kornah, BA, Safwat, HM, Abdel-Hameed, SK, et al. Managing of post-traumatic knee arthritis by total knee arthroplasty: case series of 15 patients and literature review. J Orthop Surg Res. 2019;14(1):168.
2. Rai, S, Liu, X, Feng, X, et al. Primary total knee arthroplasty using constrained condylar knee design for severe deformity and stiffness of knee secondary to post-traumatic arthritis. J Orthop Surg Res. 2018;13(1):67.
3. Mora, JC, Przkora, R, Cruz-Almeida, Y. Knee osteoarthritis: pathophysiology and current treatment modalities. J Pain Res. 2018;11:2189-96.
4. Jeffery, RS, Morris, RW, Denham, RA. Coronal alignment after total knee replacement. J Bone Joint Surg Br. 1991;73(5):709-14.
5. Sparmann, M, Wolke, B, Czupalla, H, Banzer, D, Zink, A. Positioning of total knee arthroplasty with and without navigation support. A prospective, randomised study. J Bone Joint Surg Br. 2003;85(6):830-5.
6. Berend, ME, Ritter, MA, Meding, JB, et al. Tibial component failure mechanisms in total knee arthroplasty. Clin Orthop Relat Res. 2004(428):26-34.
7. Jenny, JY, Boeri, C. Low reproducibility of the intra-operative measurement of the transepicondylar axis during total knee replacement. Acta Orthop Scand. 2004;75(1):74-7.
8. 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(8):1097-106.
9. Delp, SL, Stulberg, SD, Davies, B, Picard, F, Leitner, F. Computer assisted knee replacement. Clin Orthop Relat Res. 1998(354):49-56.
10. Choong, PF, Dowsey, MM, Stoney, JD. Does accurate anatomical alignment result in better function and quality of life? Comparing conventional and computer-assisted total knee arthroplasty. J Arthroplasty. 2009;24(4):560-9.
11. 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 Am. 2011;93(15):1377-84.
12. Chin, PL, Yang, KY, Yeo, SJ, Lo, NN. Randomized control trial comparing radiographic total knee arthroplasty implant placement using computer navigation versus conventional technique. J Arthroplasty. 2005;20(5):618-26.
13. Rebal, BA, Babatunde, OM, Lee, JH, et al. Imageless computer navigation in total knee arthroplasty provides superior short term functional outcomes: a meta-analysis. J Arthroplasty. 2014;29(5):938-44.
14. Petursson, G, Fenstad, AM, Gøthesen, Ø, et al. Computer-Assisted Compared with Conventional Total Knee Replacement: A Multicenter Parallel-Group Randomized Controlled Trial. J Bone Joint Surg Am. 2018;100(15):1265-74.
15. Gøthesen, O, Espehaug, B, Havelin, LI, et al. Functional outcome and alignment in computer-assisted and conventionally operated total knee replacements: a multicentre parallel-group randomised controlled trial. Bone Joint J. 2014;96-b(5):609-18.
16. Blakeney, WG, Khan, RJ, Palmer, JL. Functional outcomes following total knee arthroplasty: a randomised trial comparing computer-assisted surgery with conventional techniques. Knee. 2014;21(2):364-8.
17. Bauwens, K, Matthes, G, Wich, M, et al. Navigated total knee replacement. A meta-analysis. J Bone Joint Surg Am. 2007;89(2):261-9.
18. Cheung, KW, Chiu, KH. Imageless computer navigation in total knee arthroplasty. Hong Kong Med J. 2009;15(5):353-8.

19. Slover, JD, Tosteson, AN, Bozic, KJ, Rubash, HE, Malchau, H. Impact of hospital volume on the economic value of computer navigation for total knee replacement. J Bone Joint Surg Am. 2008;90(7):1492-500.
20. Boylan, M, Suchman, K, Vigdorchik, J, Slover, J, Bosco, J. Technology-Assisted Hip and Knee Arthroplasties: An Analysis of Utilization Trends. J Arthroplasty. 2018;33(4):1019-23.
21. Foley, K, Muir, JM. Improving accuracy in total knee arthroplasty: A cadaveric comparison of a new surgical navigation tool, Intellijoint KNEE, with computed tomography imaging. Intellijoint Surgical, Inc Waterloo, ON. 2019.
22. Koo, TK, Li, MY. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. J Chiropr Med. 2016;15(2):155-63.
23. Rivière, C, Iranpour, F, Auvinet, E, et al. Alignment options for total knee arthroplasty: A systematic review. Orthop Traumatol Surg Res. 2017;103(7):1047-56.
24. Whiteside, A. Principles of ligament balancing and alignment in total knee arthroplasty. Javad Parvizi MFRCS, editor The knee construction, replacement, and revision. 2013;1-2:2349-444.
25. Evans, JT, Walker, RW, Evans, JP, et al. How long does a knee replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up. Lancet. 2019;393(10172):655-63.
26. Patil, S, McCauley, JC, Pulido, P, Colwell, CW, Jr. How do knee implants perform past the second decade? Nineteen- to 25-year followup of the Press-fit Condylar design TKA. Clin Orthop Relat Res. 2015;473(1):135-40.
27. Zhang, Z, Chai, W, Zhao, G, et al. Association of HSS score and mechanical alignment after primary TKA of patients suffering from constitutional varus knee that caused by combined deformities: a retrospective study. Sci Rep. 2021;11(1):3130.
28. Liu, HX, Shang, P, Ying, XZ, Zhang, Y. Shorter survival rate in varus-aligned knees after t otal knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2016;24(8):2663-71.
29. Muir, JM. The learning curve for a new surgical mini-navigation system for total hip arthroplasty: A review of cases using Intellijoint HIP. 2016.