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Case Series

Pixee knee+ augmented reality assisted navigation for total knee arthroplasty in an ambulatory surgical center

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ABSTRACT

Total knee arthroplasty (TKA) requires precise alignment for optimal post-operative outcomes and prosthesis longevity. Recently, augmented reality (AR) has emerged as a promising technology in surgical procedures, including TKA. This case series evaluates the feasibility and accuracy of the knee+ augmented reality-assisted navigation (ARAN) system by Pixee Medical in an ambulatory surgical center (ASC) setting. Our study involved 17 consecutive TKA patients performed with the knee+ ARAN system at an ASC from August 2022 to October 2022. Demographic data, including sex, age, ASA score, height, weight, and BMI, were recorded. Postoperative measurements of the mechanical distal femoral angle (MDFA), mechanical distal tibial angle (MDTA), posterior tibial slope (PTS), femoral-tibial angle (FTA), and posterior femoral flexion (PFF) were compared to the ideal intraoperative angles. Outliers were defined as deviations greater than 3° from the planned angles. In this study, 15 out of 17 TKAs utilizing the Pixee knee+ ARAN system were analyzed. All mean post-operative radiographic measurements were within clinically acceptable ranges. The study also found that surgeries using the knee+ system had a slightly longer incision-to-closing time relative to the control group of patients undergoing normal TKA. Our results indicate clinically acceptable accuracy and precision in alignment with the knee+ ARAN system, albeit with a slight increase in surgery duration. This is the first study evaluating the knee+ ARAN system in an ASC setting indicates its suitability for outpatient centers, highlighting its precision, portability, and cost-effectiveness. Larger studies utilizing outcome measures can further assess the system's advantages and disadvantages.

Keywords: Ambulatory surgical center, Total knee arthroplasty, Augmented reality-assisted navigation

INTRODUCTION

In total knee arthroplasty (TKA), accurate alignment is essential to favorable post-operative outcomes as well as longevity of the prosthesis.[1] Over the past several decades technology has been increasingly used in the operating room to achieve this goal. Specifically, technology in the form of computer assisted surgery, navigation and robotics has been used to improve precision and accuracy. Research shows that using technological assistance in TKAs is generally associated with superior alignment, however there is still uncertainty regarding whether this will improve outcomes or longevity of the implants.[2] Robotic systems can pose a challenge to smaller centers and ambulatory surgical centers (ASC) because of space constraints and costs. In recent years, innovations in the augmented reality (AR) sector have made it increasingly feasible to utilize AR tools in various surgical procedures.

The knee+ system by the Pixee Medical Company is an AR system that provides visual aids to the surgeon for accurate alignment during a TKA procedure.[1] By providing these visual aids, the knee+ system should theoretically improve the accuracy of prosthesis placement. Additionally, this system has a minimal footprint and can be used with any implant system since it

is implant agnostic. Along with the low cost per use, this system may be an ideal choice for ASCs.

The system consists of a single tray with reusable markers and a pair of smart glasses. The surgeon wears a pair of smart glasses that allows them to view mechanical axes and positioning of the femur and tibia in real-time throughout the procedure. The smart glasses are calibrated using markers that are placed in specific positions by the surgeon. In addition to arguably providing superior alignment and positioning relative to normal TKA, the utilization of an AR navigation system such as knee+ allows for a less invasive approach without the need for intramedullary alignment rods. It has been found that minimally invasive TKA approaches are particularly useful in regards to obese patients; a study by Millar et al found that TKAs assisted by computer navigation resulted in significantly reduced blood loss in obese patients.[3]

Although the use of modern technology with TKA can improve accuracy of implant placement, there is usually a tradeoff of increased surgical time and cost associated with the use of the technology. Surgical robots tend to be large, expensive and time intensive.[4] Patient-specific instrumentation tools paired with computer navigation produce excellent patient outcomes however they also require extensive lead up time.[4] The knee+ augmented reality-assisted navigation (ARAN) system is both cost-effective and does not substantially lengthen the time course of TKA. The purpose of this study is to evaluate the feasibility and effectiveness of the knee+ ARAN system for TKA in an ASC setting.

CASE SERIES

The Pixee knee+ ARAN system (Pixee medical company, Besancon, France) was utilized intraoperatively by the same surgeon for 17 consecutive patients undergoing TKA from August 2022 to October 2022 at an ASC. These cases were the first cases performed by this surgeon utilizing the Knee+ ARAN technology. These were some of the first cases to use the knee+ ARAN system exclusively at an ASC. All patients had Biomet (Warsaw Indiana) Vanguard femoral and tibial components. There were no preoperative exclusion criteria for the patients in this study. Two patients were excluded from our data set. The first due to postoperative trauma that resulted in ineligibility and the other due to intra-operative calibration error. All patients were made aware of the use of this technology in the procedure and provided informed consent to the technology being used as well as the subsequent data collection and analysis. IRB approval was obtained. All surgeries were performed by the same surgeon who has extensive experience in performing TKA procedures at an ASC. Technique involved medial parapatellar arthrotomy without tourniquet use. The goal was to obtain mechanical alignment using the knee+ system.

Demographic information such as sex, age, ASA score, height, weight, and body mass index (BMI) were collected (Table 1). Postoperative measurements were collected of the mechanical distal femoral angle (MDFA), mechanical distal tibial angle (MDTA), posterior tibial slope (PTS), femoral-tibial angle (FTA), and posterior femoral flexion (PFF).[5] These measurements were compared to the planned intraoperative angles. The differences were analyzed and outliers were defined as any measurement greater than 3° from the ideal intra-operative angle.

Table 1: Demographic data of sample.

Characteristics (n=15)	Mean±standard deviation or n (%)
Age	66.60±6.40
Body mass index (BMI)	28.70±6.30
Male: female	1:14
ASA rates	
1	5 (33)
2	10 (67)

*Located after the second paragraph of the case series section, where collection of demographic data is discussed

Additionally, surgical times were collected to aid in determining whether these surgeries were time-neutral in relation to TKAs performed by this surgeon without the knee+ ARAN system whilst using the same implants. Surgical time was determined from time of skin incision to placement of dressing. These times were compared to a cohort of patients who had conventional TKA during the same time period at another institution by the same surgeon.

The knee+ AR system utilizes smart glasses and specific markers which are placed within the incision. This technique involves obtaining the hip and ankle centers to provide the femoral and tibial mechanical axes, respectively, which are superimposed onto the surgical field in the smart glasses.[1] The femoral guide allows for control of the distal varus-valgus and flexion-extension angles. The hip center is obtained by taking the hip through range of motion and collecting data points. This allows the cutting block to be pinned into place with extreme accuracy with regards to the patient's mechanical axis.[1]

The Pixee knee+ ARAN technology was utilized for a total of 17 TKAs in this study. As mentioned previously, two cases were excluded from statistical analysis: one due to an intraprocedural calibration error with the ARAN and the other being due to post-op trauma unrelated to the initial surgery. Thus, we included a total of 15 cases in our statistical analysis.

Accuracy was assessed by collecting MDFA, MDTA, PTS, PFF, and FTA for all patients in the knee+ cohort and subsequently performing comparative analysis for each measurement.[5]

Table 2: Postoperative alignment measurements.

Measurements	Mean	Range	Standard deviation	Ideal targeted value
MDFA	94.56°	92.60-96.00°	1.08°	95.00°
MDTA	88.77°	87.00-90.00°	0.81°	90.00°
FTA	183.33°	181.50-186.00°	1.32°	185.00°
PTS	6.21°	3.10-8.70°	1.80°	5.00°
PFF	2.20°	0.40-3.40°	0.87°	2.00°

*Located at the end of the case series section

Figure 1: The Pixee knee+ system being used in real-time.

*The axis of the tibia is obtained by registering the medial and lateral malleoli. The mechanical axis of the tibia is then projected onto the field in the smart glasses. The tibial guide allows for control of varus-valgus and posterior slope

Figure 2: Real-time projection of smart glasses image to an or monitor.

*By placing the markers within the operative field and having a display built into the glasses the surgeon can maintain visualization of the operative field at all times without having to deviate from their normal workflow

The mean MDFA was 94.56° (range: 93.00-96.00°) with a standard deviation of 1.08°. The mean deviation from the ideal targeted value of 95.00° was -0.44° (range: -2.40–1.00°).

The mean MDTA was 88.77° (95% CI: 88.33°, 89.22°) with a standard deviation of 0.81°. The mean deviation from the ideal targeted value of 90.00° was -1.23° (range: -3.00–0.00°), indicating that clinically acceptable accuracy and precision were achieved for MDTA. Both mean MDFA and MDTA were within 3° of the targeted ideal measurements.

Mean FTA was 183.33° (range: 181.50–186.00°) with a standard deviation of 1.32°. The mean deviation from the ideal targeted value of 185.00° was -1.67° (range: -3.50–1.00°). This shows that clinical acceptable accuracy and precision was achieved in regards to FTA in these patients.[5]

The mean PTS was 6.21° (range: 3.10-8.70°) with a standard deviation of 1.80°. The mean deviation from the targeted ideal value of 5.00° was +1.21° (range: -1.90–3.70°). The mean PFF was 2.20° (range: 0.40–3.40°) with a standard deviation of 0.87°. The absolute mean deviation from the ideal targeted value of 2.00° was 0.62° (range: -1.60–1.40°).

The knee+ group was found to have a significantly longer mean incision-to-closing duration relative to the control group ($p<0.05$) with mean durations of 48.33 minutes and 40.90 minutes respectively. The knee+ group had a higher standard error of mean time relative to the control group, 2.40 versus 1.80 minutes respectively. The range for incision-to-closing times was 35.00–69.00 minutes.

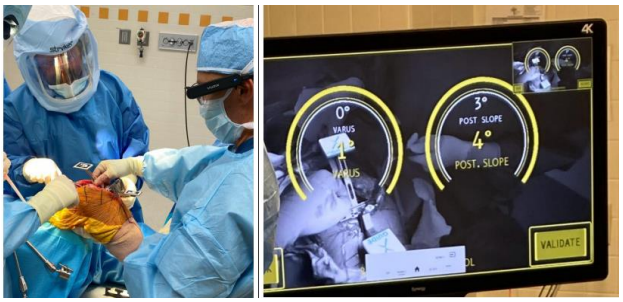

Figure 3: An intraprocedural view through the Pixee smart glasses.

*Intraprocedural real-time depiction of mechanical axes and alignment are visible to the surgeon through the glasses

DISCUSSION

Technology is becoming pervasive in the operating room. Many centers are using robotic assisted total knee arthroplasty (RA-TKA) to improve implant placement and limb alignment. Ultimately the goal is to improve patient outcomes and increase implant longevity. Eason et al noted that although RA-TKA can be safely and effectively

done at a ASC, the robotic platforms pose challenges in the free standing ASC setting since they require extra space, are expensive and may initially increase surgical time.[6] They also pointed out that there is usually a cost of advanced imaging prior to surgery for some of the systems. The knee+ system overcomes many of these challenges while providing accuracy, efficiency, and not requiring any advanced imaging preoperatively. The findings of this study demonstrate that the Pixee knee+ system can be utilized to feasibly achieve accurate alignment in TKA procedures.

We had no outliers, defined as greater than a 3.00° deviation in regards to our femoral or tibial coronal alignment. The FTA was within 1.70° of expected with a standard deviation of 1.32°. These findings are consistent with other studies that demonstrate accuracy with navigation.[7] Furthermore, our findings are consistent with Iacono et al who found that the knee+ system could provide accuracy to within 1-2°.[8] The sagittal alignment demonstrated less variability in regards to PFF and PTS. The PFF and PTS were within 2.00° of the targeted values. When compared to other studies utilizing the Knee+ system our results demonstrate improved sagittal plane alignment accuracy.[1]

Our results demonstrated significantly increased time for the knee+ group. This could be a result of the small sample size observed and the learning curve for this novel technology. The fact that the knee+ group had a higher standard error of mean relative to the control group suggests that further studies with larger cohorts could yield more generalizable time results as the learning curve aspect of utilizing the Knee+ system becomes a less pertinent factor.

The knee+ system has a very compact footprint and does not require external cameras and dedicated operators. Additionally, the ARAN system allows implant placement without any significant deviation from the normal workflow of the conventional TKA. Although there was a statistically significant increase in operative time when using this system relative to a matched cohort, the actual added time was minimal at 8 minutes. This is consistent with findings by Bennett et al who also showed a significantly increased time with this system but a shallow learning curve and reproducible accuracy.[1]

CONCLUSION

To our knowledge, this is the first series to look at the utilization of the knee+ ARAN system in an ASC setting. We found that this system to be ideally suited for the outpatient surgical center when compared to other advanced technology offerings. The system requires no major capital expenditures or fixed equipment costs. Additionally, this system has a minimal footprint, is portable and can be used with any implant system since it is implant agnostic. Along with the low cost per use, this system may be an ideal choice for ASCs. This series demonstrates that the knee+ system can be safely and effectively used in an ASC setting. Larger studies with outcome measures can further delineate the advantages and shortcomings of this system.

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