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Original Research

Accuracy of a New Augmented Reality Assisted Technique for Total Knee Arthroplasty: An In Vivo Study

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ABSTRACT

Background: Total knee arthroplasty (TKA) remains the standard of care for treating end-stage osteoarthritis of the knee. Approximately 15%-20% of the patients are dissatisfied following surgery. To improve accuracy and outcomes of TKA, various assistive technologies have been introduced. For this study, an augmented reality (AR) system was explored and tested.

Methods: The Knee + system (Pixee Medical, Besancon, France) was used to guide TKA. It uses a combination of quick response-code labeled instruments and AR glasses to guide tibial and femoral cuts. The primary research goal was to evaluate its accuracy by direct comparing the planned angular values for lateral distal femoral angle, medial proximal tibial angle, hip-knee-ankle axis, and tibial slope to the intraoperative obtained values and the measured angles on postoperative full leg radiographs. The secondary research goal was to assess its feasibility.

Results: This retrospective study evaluated 124 patients, with a follow-up of at least 1 year. The average absolute difference between planned and measured postop values were 1.39° for lateral distal femoral angle, 1.03° for medial proximal tibial angle, 2.16° for tibial slope, and 1.51° for hip-knee-ankle axis. Within the follow-up period, 8 complications were observed. The average surgical time was 83 minutes.

Conclusions: This study has demonstrated a high accuracy, comparable to robotic-assisted total knee arthroplasty, of the Knee + AR system. It has shown to be a safe, cheap and time-efficient assistive technology for patients undergoing medial pivot TKA.

Introduction

Assistive technologies have emerged in the realm of total knee arthroplasty (TKA) with the primary goal of enhancing both the accuracy and consistency of implant positioning. In early 2000s, computer-assisted surgery began to attract attention as a potential solution to challenges posed by conventional instrumentation [1]. Although numerous studies have indicated that navigation systems can indeed optimize the precision of component placement, their clinical efficacy remains a topic of debate [2]. This is primarily because they have not shown a marked improvement in patient function, quality of life, or implant longevity [3]. Approximately a decade later, in an effort to circumvent substantial capital expenditures, accelerometer-based navigation and patient-specific instrumentation were integrated into surgical practices. While these technologies demonstrated enhanced accuracy in component positioning, they unfortunately did not yield significant short or medium-term clinical benefits for patients [4,5].

In recent times, the adoption of robotic-assisted techniques, especially robotic-assisted total knee arthroplasty (RA-TKA), has surged. While RA-TKA has proven its capability to heighten surgical precision and minimize anomalies, no randomized controlled trial has yet established any noteworthy clinical advantage [6]. A significant concern is the increased financial burden of a robotic system accompanied by longer surgical times, which could potentially lead to elevated infection risks or other complications [7].

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Table 1
Patient characteristics.

Variable	AR-TKA
Number of patients	124
Mean age, y (SD)	68.6 (10.1)
Women, n (%)	77 (63.7)
Mean body mass index, kg/m^2 (SD)	29.4 (4.7)
Mean preoperative HKA (SD)	178.3 (6.7)
Left knee, n (%)	58 (46.8)
Average surgical time (min)	
Overall	83
Surgeon 1 (excl. learning curve)	75
Surgeon 2 (excl. learning curve)	89

In pursuit of a solution that is both cost-effective and efficient in time, augmented reality (AR) has been presented as a potential aid in TKA surgeries. AR is a groundbreaking technology that superimposes digital information onto our physical surroundings. By using smart glasses, surgeons can augment their operational viewpoint with real-time metrics and valuable insights. These systems hold the promise of enhancing precision and potentially improving patient results at a lower cost than RA-TKA. Within this context, we hypothesized that an AR-based navigation system would exhibit accuracy in frontal and sagittal component placements during TKA. Our study thus sought to assess:

1. the accuracy, determined by comparing intraoperative angular values provided by the system with postoperative angular values from anteroposterior full leg and lateral radiographs.
2. the system's safety, as gauged by complication rates.
3. the duration of the surgery.

Material and methods

In a single-center retrospective analysis, which relied on data that was prospectively gathered as standard of care follow-up, we evaluated 164 consecutive patients who underwent AR-TKA for end-stage osteoarthritis symptoms between April 2021 and March 2022. We did not intersperse the AR-TKA cases with conventional cases. All surgeries were performed by 2 experienced surgeons at a high volume orthopedic clinic (Hip & Knee Unit at AZ Maria Middelares Hospital, Ghent, Belgium). We considered patients eligible for this study if they:

- were undergoing primary TKA due to knee osteoarthritis.
- were aged between 18 and 80 years.

Conversely, we excluded patients who:

- underwent arthroplasty following a fracture.
- transitioned from unicompartmental to total knee replacement.
- lacked full-leg postoperative radiographs or had radiographs of subpar quality.

Routine data collection included patients' age, gender, body mass index, operated side (left/right), and surgical time. These details were tabulated (Table 1). All participants were monitored for at least 1 year postsurgery. No patients were lost to follow-up. We specifically reviewed medical records for any complications, especially those directly attributed to the AR system.

In this study group the Knee + system was used (Pixee Medical, Besancon, France). The system offers orthopedic surgeons a real-time guidance for implant positioning through AR glasses. These smart glasses, integrated with an onboard camera, identify and interpret quick response-code markers on instruments, calculating their three-dimensional (3D) coordinates. The device enriches the surgeon's view with real-time navigational data, allowing interactions with the system's software through the glasses' accelerometers. This method eliminates the necessity for intramedullary rods or the drilling of percutaneous pins, permitting direct visual guidance of proximal tibial and distal femoral bone cuts. Several physical landmarks are acquired to perform the surgery:

1. Hip center of rotation
2. Medial and lateral femoral condyle (3 points each, as distal as possible)
3. Medial and lateral tibial plateau (3 points each, as central as possible)
4. Medial and lateral malleolus
5. A static reference point mount on the operating table

In every procedure, a cemented medial pivot total knee prosthesis (Evolution, MicroPort Orthopedics, Shanghai, China) was implanted via a standard medial parapatellar incision. All patients had patellar resurfacing and no tourniquet was used during surgery. A series of precise steps, reliant on the AR system, were followed for both the distal femoral and proximal tibial cuts, as shown in Figure 1. After these AR-guided and AR-checked cuts, conventional methods were used to achieve appropriate ligament balance and to determine the final tibial and femoral component size and rotation before implanting the final components.

Surgeons predetermined target values for several angles, including the medial proximal tibial angle (MPTA), lateral distal femoral angle (LDFA), and the tibial slope. The target values were based on preoperative full leg and lateral radiographs aiming for a personalized alignment philosophy. Both surgeons assessed the preoperative radiographs of their own patients. When a patient was scheduled for TKA surgery, the surgeon wrote down the targeted angular values on a blank form. During the surgery, the form was displayed on a monitor in the operating room. In case of preoperative varus or neutral alignment, both surgeons aimed to reconstruct the MPTA (restricted to maximum 5° of tibial varus), whereas in case of preoperative valgus, an overall neutral

Table 2
Average values of the angles in degrees (±SD).

Radiographic parameter	Average planned angle ± SD (Q1-Q3)	Average measured postop angle ± SD (Q1-Q3)	Outliers (%)
LDFA	88.7 ± 1.0 (88-90)	89.2 ± 1.9 (88.3-90.5)	8.48
MPTA	88.2 ± 1.3 (87-89)	87.9 ± 1.7 (86.8-89)	2.54
Tibial slope	4.9 ± 1.4 (4-5)	3.1 ± 1.9 (1.9-4.3)	20.2
HKA	179.5 ± 0.9 (179-180)	179.0 ± 2.1 (177.8-180.5)	10.2

Average values of planned LDFA, MPTA, tibial slope, and HKA along with standard deviation and first and third quartiles. Average values of measured LDFA, MPTA, tibial slope, and HKA along with standard deviation and first and third quartiles. Percentage of outliers (defined as 3° deviation from targeted angle).

Table 3
Average difference (mean of the differences between the 2 measurements for each patient) between planned and measured postop angles.

Radiographic parameter	P-MP	*P*
LDFA	1.39	.018
MPTA	1.03	.036
Tibial slope	2.16	<.01[a]
HKA	1.51	.018

MP, measured postop; P, planned.
[a] Statistical significant difference based on unpaired *t*-testing (threshold $P < .05$).

mechanical alignment was aimed for. Reconstruction of the original tibial slope was attempted in every patient, with an exception for these with preoperative upslope. Two independent reviewers analyzed both preoperative and postoperative radiographs, and a third author resolved any discrepancies. Specific angles, like the hip-knee-ankle axis (HKA), LDFA, MPTA, and tibial slope were measured. Malalignment was statistically analyzed by considering up to 3° deviation from the target angle as acceptable, whereas values outside of this range were considered outliers. The preop planned and postop obtained angles were compared.

Data analysis was carried out using R statistics, 4.3.0 (R foundation for Statistical Computing, Vienna, Austria), with a significance threshold of $P < .05$. We applied analysis of variance multivariate analysis with Tukey's honestly significant difference correction. The sample size was dictated by a power calculation, assuming an effect size of 0.25, a power of 0.9, and an alpha error probability of 0.05, resulting in n = 130. The learning curve of the AR-TKA time consumption was evaluated using cumulative summation analysis, similar to Kayani et al. and Vermue et al. [8,9].

Results

From the initial set of 164 patients, 19 patients were excluded due to incomplete imaging and another 21 were excluded because of inferior radiographic quality. Thus, 124 AR-TKA procedures were left for final analysis.

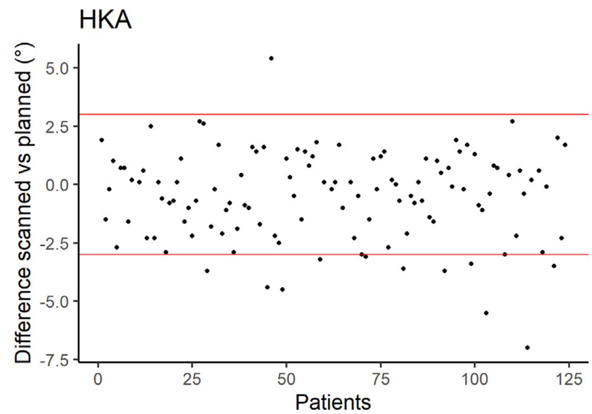

Figure 2. Deviation from HKA target. Visual representation of the deviation from target HKA (preoperative planned vs postoperative measured angles).

Table 2 showcases average results, with standard deviations (SDs), for the planned and measured angle values. For LDFA, the following values were measured: average planned 88.7 (SD 1) and average postop 89.2 (SD 1.9). Following are the measured values for MPTA: average planned 88.2 (SD 1.3) and average postop 87.9 (SD 1.7). Tibial slope measurements were average planned 4.9 (SD 1.4) and average postop 3.1 (SD 1.9). Finally, HKA values were average planned 179.5 (SD: 0.9) and average postop 179.0 (SD 2.1). Comparisons between the planned and postoperative measured angles are shown in Table 3.

Overall, the differences between the planned angles and the measured angles followed a normal distribution of sufficient sample size. With the tibial slope as an exception, the mean differences in all cases remained under 2°.

Figure 2 details the distribution of deviation from targeted postoperative HKA alignment. The mean postop HKA was 179° (SD 2.1). An average absolute difference of 1.51° was noticed between planned and measured HKA. Similarly, differences between planned and measured LDFA, MPTA, and tibial slope were 1.39°, 1.03°, and 2.16°, respectively.

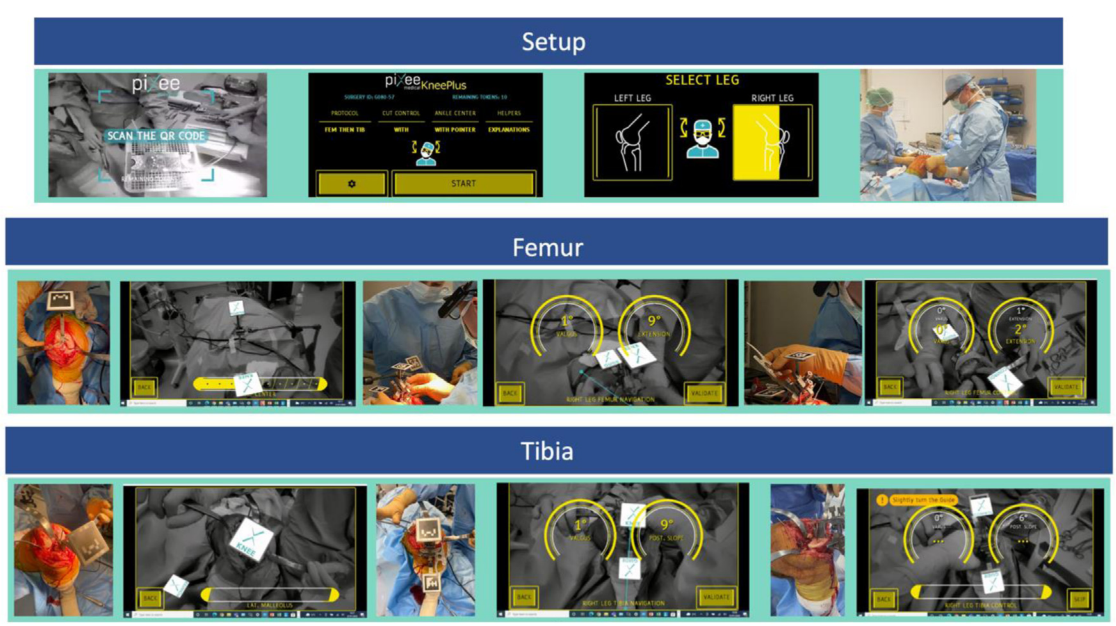

Figure 1. Knee + intraoperative workflow.

Table 4
Complications.

Complications	AR-TKA
Stiffness, MUA	3
Deep venous thrombosis	2
Gastrointestinal bleeding	1
Periprosthetic joint infection	1
Superficial wound infection	1

MUA, mobilization under anesthesia.

Within a year of follow-up for all patients, 8 complications were observed, as detailed in Table 4. There were 3 cases that necessitated a mobilization under anesthesia, 2 deep venous thromboses that resolved after adequate treatment, 1 gastrointestinal bleeding, 1 periprosthetic joint infection that was treated and resolved with a debridement, antibiotics, and implant retention-procedure, and 1 superficial wound infection that resolved with antibiotics and proper wound management. Notably, none of these complications can be directly related to the AR systems usage.

The average skin-to-skin surgical time was 83 minutes, as shown in Figure 3. Cumulative summation analysis indicates an inflexion point post 28 and 10 cases for surgeons 1 and 2, respectively. For the initial 10 AR-TKA cases vs the latter 10, there was a mean shift in operating room times of minus 18.25 min (SD 5.45). Excluding the learning curve, the average skin-to-skin time was 79 minutes (surgeon 1: 75 minutes, and surgeon 2: 89 minutes). Compared to manually conducted TKAs in the same hospital by identical surgeons, AR-guided implantation extended the skin-to-skin duration by 14 minutes for surgeon 1 and 10 minutes for surgeon 2, as shown in Figure 4.

Discussion

Over the last few years, the use of assistive technologies in TKA has significantly grown. Literature has shown that it can improve accuracy in component placement compared to conventional instruments [6-8].

To our knowledge, this is one of the first large case series evaluating the accuracy of AR technology in TKA. A recent study by Bennett et al. demonstrated acceptable accuracy of the Knee + technology in a series of 18 patients [10]. They compared the intraoperative validated bone cuts with the component position measured on postoperative computed tomography scans and observed a mean absolute difference of 1.3°, 1.1°, 1.6°, and 2.0° for respective LDFA, MPTA, tibial slope, and femoral flexion [10]. Similar results were found by Sakellariou et al. in a series of 30 patients [11]. Waitzman et al. described a case series of 17 patients operated with the Knee + system and reported a mean absolute difference of 0.44°, 1.23°, 1.67°, and 1.21° for respective LDFA, MPTA, HKA, and tibial slope [12]. Castellarin et al. utilized the Knee + system to guide the tibial cut in a series of 76 patients and compared the preoperative planned angles to the intraoperative obtained angles. They reported a mean difference of 0.59° for the MPTA and 0.70° for the tibial slope [13]. In 2021, Fucentese et al. stated that AR has the potential to improve accuracy in TKA [14]. Even though the authors did not report statistical data, they assumed that it might be a more efficient and cost-effective solution compared to robotics.

Several studies evaluating the accuracy of robotic systems have been published comparing preoperative targeted MPTA, LDFA, HKA, and tibial slope with the same values as measured on postoperative full leg radiographs. Li et al. reviewed 36 TKAs and found a mean absolute difference of 0.92° for the HKA [15]. Deckey et al. analyzed 91 robot-assisted cases and reported an absolute difference of 1° for the final coronal limb alignment [16]. Kayani et al. observed a difference of 1.5° between the planned HKA and the measured HKA in 60 patients [8]. Vermue et al. analyzed a subgroup of 108 RA-TKAs. On average, they measured a 1.2° deviation toward valgus as compared to the preoperative plan [9]. Shin et al. reported a mean difference of 0.88° for the LDFA, 1.24° for the MPTA, and 2.04° for the tibial slope in 37 RA-TKAs [17]. Rossi et al. presented slightly better results with a mean difference of 0.3° for the LDFA, 0.6° for the MPTA, 0.03° for the slope, and 1.2° for the HKA [18]. Vanlommel et al. identified a mean absolute difference of 0.46° for the LDFA, 0.32° for the MPTA, and 0.89° for the slope in 58 patients [19]. Savov et al. reported a difference of 1.6° for the LDFA, 1.0° for the MPTA, 1.4° for the slope, and 2.0° for the HKA in 70 RA-TKA cases [20]. These values are presented in Table 5.

In our case series, the average difference between the planned HKA, LDFA, and MPTA vs the measurements of these angles on postoperative standing full leg radiographs was 1.51, 1.39, and 1.03°, respectively. Recreating the desired tibial slope in the sagittal plane turned out to be slightly more difficult with an undercorrection of the slope of 2.16° on average.

Assistive technologies come with an extra cost, increased surgical time, and potential risks. Different complications have been described in literature. Many commonly used navigation and robotical systems necessitate the placement of 1 or 2 pins in either the femoral or tibial shaft. Due to weakening of the cortical bone,

Table 5
Literature Comparison of studies reporting on accuracy of assistive technology.

Author (robot/N)	HKA	MPTA	LDFA	Slope
Li (MAKO/ 36) [15]	0.92 (SD: 0.65)	0.48 (SD: 0.16)	0.57 (SD: 0,65)	0.54 (SD: 0.25)
Deckey (MAKO/ 91) [16]	1.0 (SD: 1.7)	0.3 (SD: 0.9)	0.9 (SD: 1.2)	0.3 (SD: 1.3)
Kayani (MAKO/ 60) [8]	1.5 (SD: 0.9)	1.0 (SD: 0.5)	1.0 (SD: 0.4)	1.4 (SD: 0.6)
Shin (ROSA/ 37) [17]	N.R.	1.24 (SD: 1.06)	0.88 (SD: 0.71)	2.04 (SD: 1.55)
Rossi (ROSA/ 75) [18]	1.2 (SD: 1.1)	0.3 (SD: 0.25)	0.6 (SD: 0.5)	0.03 (SD: 1.9)
Vanlommel (ROSA/ 75) [19]	N.R.	0.46 (SD: 0.32)	0.32 (SD: 0.25)	0.89 (SD: 0.74)
Savov (CORI/ 70) [20]	2.0 (SD: 1.2)	1.0 (SD: 0.8)	1.6 (SD: 1.3)	1.4 (SD: 1.3)
Bennett (Knee+ / 18) [10]	N.R.	1.1 (SD: N.R.)	1.3 (SD: N.R.)	1.6 (SD: N.R.)
Waitzman (Knee+ / 17) [12]	1.67 (SD: 1.32)	1.23 (SD: 0.81)	0.44 (SD: 1.08)	1.21 (SD: 1.8)
Present study (Knee+ /124)	1.51 (SD: 1.25)	1.03 (SD: 0.8)	1.39 (SD: 1.07)	2.16 (SD: 1.46)

N.R., not reported.
Mean absolute difference of HKA, MPTA, LDFA, and tibial slope along with SD. The data points included in this table were explicitly reported in each study.

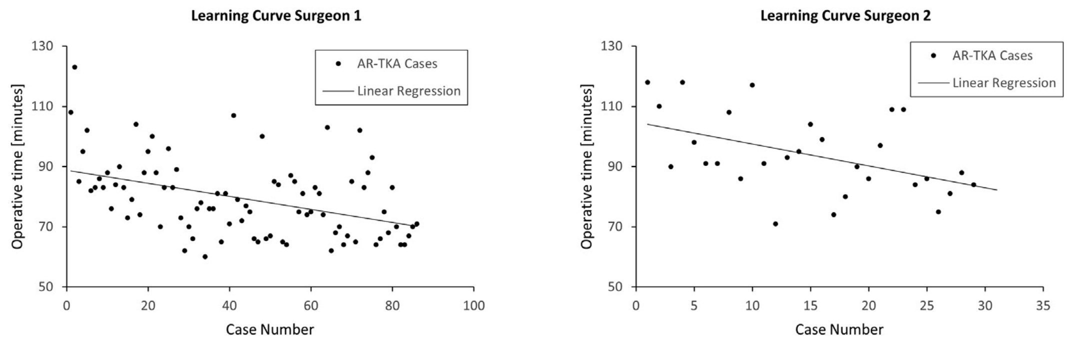

Figure 3. Visualization of skin-to-skin time of the augmented reality total knee arthroplasty cases for every surgeon.

this might result in patients developing diaphyseal fractures in the postoperative period with little or no preceding trauma [21]. Another concern is the fact that techniques requiring pin placement are also prone to pin-site infections. According to the literature, it might occur in 0.47% −2.70% of TKA patients [22]. Two recent studies have even described an increased incidence of deep prosthetic joint infection in RA-TKA [23,24].

The AR system used in our institution alleviates the need of diaphyseal pin placement, which is a major benefit. We observed one superficial wound infection and one deep prosthetic joint infection in our case series, which is definitely within the normal boundaries found in literature and could not be attributed to the use of the AR system [25].

In general, the use of assistive technology is associated with prolonged surgical duration. This is an undeniable drawback because the risk of infection rises drastically as operating time increases [26]. The average skin-to-skin time of 83 minutes in our series is quite fast when we compare it with the available literature on assistive technologies in TKA. Bennett et al. performed 18 AR-TKAs with a mean operative time of 98.5 minutes [10]. In the RA-TKA series described by Vermue et al., the average operating time per surgeon ranged from 76.3 minutes to 124.2 minutes in the proficiency phase [9]. Even though some authors declare to work time-neutral with a robot, literature shows that the use of robotics is associated with longer operative times compared to conventional TKA [27].

So far no studies have been published on the learning curve associated with AR-TKA. We observed a time-based learning curve of 10-28 cases, similar to what has been reported in literature on the learning curve of RA-TKA [8,9,20,28].

Several limitations of this study should be outlined; first, the absence of any functional results. The core aim was to check the system's accuracy and feasibility in real-world conditions, rather than comparing results to any clinical evaluations. Clinical results will be described in a future manuscript. Second, due to missing postoperative full legs or radiographs of poor quality, we were unable to include all 164 patients in the data analysis. The final analysis was performed on a subset of 124 patients. As a result, we did not meet the targeted sample size of 130 patients. Nonetheless, we think 124 patients is a respectable number, given the fact that we chose a power of 0.9 for the sample size calculation. Computed tomography scans instead of plain radiographs would have offered more precision in determining component position and limb alignment. Specifically, measuring the tibial slope on short lateral standing radiographs proved to be challenging.

The lack of data on femoral and tibial component rotation in this study is a third limitation. Future versions of the Knee + system will be able to assist in axial component alignment, which was not the case at the moment of study initiation.

A final limitation was the retrospective nature of this study. A prospective randomized trial comparing AR-TKA and RA-TKA will be initiated in the near future in our institution.

Conclusions

This study has demonstrated a high accuracy, comparable to RA-TKA, in reproducing the planned angular values for LDFA, MPTA, and HKA using the Knee + system. It has shown to be a safe, cheap, and rather time-efficient assistive technology for patients undergoing TKA.

Conflicts of interest

P. Vansintjan is a Microport consultant and receives research support from Microport. P. V. Overschelde receives royalties and research support from Microport and is a Microport consultant. All other authors declare no potential conflicts of interest.

For full disclosure statements refer to https://doi.org/10.1016/j.artd.2024.101565.

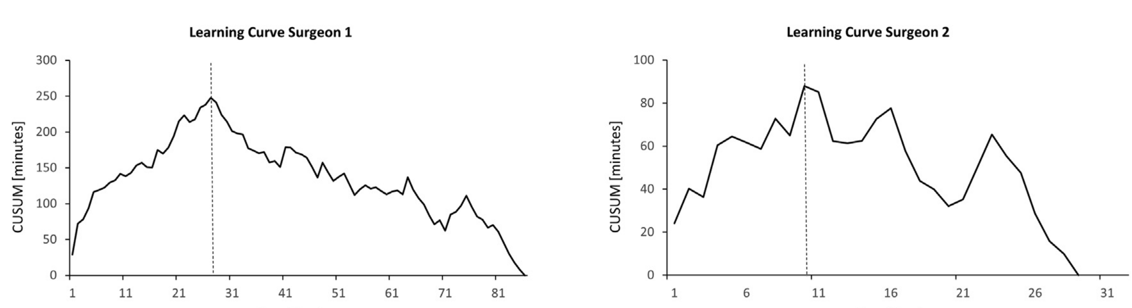

Figure 4. Cumulative summation analysis of the initial augmented reality total knee arthroplasty cases of 2 surgeons. Inflexion points can be seen at 28 and 10 cases for surgeons 1 and 2, respectively. CUSUM, cumulative summation.

CRediT authorship contribution statement

Jasper Lambrechts: Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Data curation, Conceptualization. **Pieter Vansintjan:** Writing – review & editing, Validation, Supervision, Resources, Methodology, Conceptualization. **Cynthia Lapierre:** Resources, Project administration, Data curation. **Farah Sinnaeve:** Resources, Project administration, Data curation. **Wouter Van Lysebettens:** Software, Data curation. **Philippe Van Overschelde:** Writing – review & editing, Validation, Supervision, Methodology, Investigation, Conceptualization.

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