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Custom Total Knee Arthroplasty offers high precision in the coronal plane and a short learning curve: a retrospective cohort

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Despite increased sizing possibilities for implants in total knee arthroplasty (TKA) complications such as mechanical loosening and unexplained pain still exist. Similarly, approximately 20% of patients remain dissatisfied postoperatively. This study aims to evaluate the effectiveness and precision of the custom ORIGIN® TKA and assess the learning curve for its implementation. This retrospective, single-institution cohort study was conducted from March 2023 to June 2024. Forty-one patients with end-stage primary osteoarthritis, treated with custom TKA, were included. Primary outcomes measured alignment precision comparing the preoperative plan and the postoperative result on weightbearing full leg radiographs; secondary outcomes assessed the learning curve for operation time and alignment using cumulative summation (CUSUM) analysis. No significant differences between the planned and postoperative coronal alignment parameters were found, with a difference in means of -0.30° [95% CI: -1.40; 0.70] for HKA ($P > 0.41$), 0.30° [95% CI: -0.40; 1.60] for mLDFA ($P > 0.43$) and 0,10° [95% CI: -0.80; 1.00] for mMPTA ($P > 0.75$) . However, significant deviations were observed in sagittal alignment, with a difference of -2.5° [95% CI: -5.10; -0.50] and -2.7° [95% CI: -4.00; -1.70] for PDFA ($P < 0.01$) and PPTA ($P < 0.000$) respectively. This indicates a loss of tibial slope and femoral flexion compared to the preoperative plan. CUSUM analysis indicated an inflexion point in operative time after twenty-six procedures. Linear regression did not show a significant correlation between the number of cases and operative time. No learning curve for alignment could be demonstrated. Custom TKA with patient-specific instruments provides high precision in coronal alignment but shows variability in sagittal alignment. The learning curve for operative time is short, indicating the practicality of integrating this technology into surgical practice.

Keywords: MCustom TKA, patient-specific instruments, alignment precision, learning curve, sagittal alignment.

INTRODUCTION

Origins of Custom TKA

Total knee arthroplasty (TKA) is a modern, commonly performed procedure, designed to alleviate pain and restore function in patients suffering from severe knee arthritis. Despite its widespread use, conventional TKA often faces challenges due to the limited range of prosthetic sizes and the lack of personalization, which can lead to suboptimal patient outcomes and complications. Improperly sized or positioned implants have been linked to multiple complications such as mechanical loosening resulting from undersized tibial components and the incidence of persistent postoperative pain as a result of oversized components[1,2]. Previous studies have demonstrated that ensuring precise sizing and implant position is essential for successful TKA outcomes[3]. TKA has evolved with advancements in technology and biomechanics. However, 20% of patients remain dissatisfied partially due to residual pain or unmet expectations, indicating the potential for further improvements[4]. This eventually led to the development of customized TKA.

A notable difference between conventional and custom TKA is the relationship between the tibiofemoral and patellofemoral joints. In conventional TKA, these joints are coupled, maintaining a consistent relationship between the components. However, custom TKA introduces a decoupling of the tibio-femoral and patellofemoral joints, allowing for a more individualized approach that can better accommodate the unique anatomical and kinematic characteristics of each patient's knee[5]. This decoupling may enhance joint alignment, stability, and overall function, potentially leading to improved patient outcomes[5,6].

The transition to custom TKA, however, is not without its challenges. The surgical technique for current custom implants requires the use of patient-specific instruments (PSIs), which are tailored based on detailed preoperative imaging and individualized surgical planning. Yet their practical application and accuracy in the operating theater require thorough evaluation[7]. As well, the introduction of new technology is often associated with a learning curve required to reach proficiency. With the implant's design process, the surgery is prepared preoperatively which might simplify the surgery and limit the learning curve. Based on current knowledge, there is no available information on the extent of the learning curve associated with the implementation of custom TKA.

This study aims to investigate the precision and application of PSIs in custom TKA by examining the radiological alignment parameters, as well as assessing the learning curve associated with its introduction into the operating theatre.

MATERIAL & METHODS

Study design

A retrospective, single-institution observational study was performed analyzing custom TKA performed by a fellowship-trained knee surgeon. This study was performed on procedures from March 2023 to June 2024. For this study, approval by the institutional ethical committee was obtained (ORT 20231207).

In- and exclusion criteria

All patients met the following inclusion criteria: End-stage primary knee osteoarthritis with treatment consisting out of custom TKA.

Exclusion criteria included conversion from unicompartmental knee arthroplasty to TKA, ligamentous insufficiency, infection, neurological dysfunction affecting knee mobility, and severe alignment anomalies or deformities (HKA coronal plane > 15°; HKA sagittal plane > 10°) due to prior trauma.

Patients meeting these criteria and deemed appropriate candidates by the surgeon's expertise received custom TKA (Origin®, Symbios, Switzerland).

In total 42 patients who underwent primary custom TKA met the inclusion criteria and exclusion criteria. One patient had perioperative complications necessitating the use of a different type of prosthesis. Eventually 41 patients were enrolled in this study.

From scheduling to procedure

Approximately eight weeks prior to surgery, Computed Tomography (CT) of the patients' lower limb is made. Using specific software (Knee-Plan®, Symbios, Yverdon-les-Bains, Switzerland) bony wear and lower limb alignment can be analyzed from the CT images to recreate the knee's pre-arthritic natural alignment[8], on which the design of the custom implant is based. The definitive implants are produced through automated quick milling of pre-formed shapes, ensuring high precision. The femoral implant is made from classic chromium-cobalt casting, and the tibial baseplate is fabricated from titanium. Additionally, all patient-specific instruments including custom cutting guides are made of polyamide. These patient specific guides enable the surgeon to make precise cuts and position the implants accurately[9]. The alignment strategy used aims to reproduce a natural alignment[10,11].

All custom instruments are single-use and are packaged in a single box, which is then sent directly to the hospital for the scheduled surgery.

Surgical technique

All procedures were performed using the medial parapatellar approach and the cruciate-retaining version of the custom implant. After full exposure, cartilage was removed from specific zones on the femur and tibia. Cutting guides were anchored to the exposed subchondral bone, which served as a lead for positioning these guides. The distal femur cut was done first, followed by the other femoral cuts, while ending with the proximal tibial cut. After removal of menisci and osteophytes, a satisfactory trial led to cementing both the tibial and the femoral component. The patella was selectively resurfaced.

Outcome measures

The primary outcome measurements consisted of differences between the preoperative, and postoperative coronal and sagittal alignment measurements. The preoperative planned alignment was made based on preoperative CT scan reconstructions (Symbios, Yverdon-les-Bains, Switzerland), while the postoperative alignment was evaluated on weightbearing full leg radiographs The measurements encompassed the Hip-Knee-Ankle (HKA) angle, the mechanical Lateral Distal Femoral articular surface Angle (mLDFA), the Posterior Distal Femoral angle (PDFA), the mechanical Medial Proximal Tibial articular surface Angle (mMPTA), and the Posterior Proximal Tibial Angle (PPTA). As a result, postoperative implant position could be compared to the planned implant position both in the coronal and sagittal plane.

The precision of component positioning was defined as the deviation between the postoperative component position on radiographs and the intraoperative plan.

Secondary, the surgeon's learning curve was evaluated based on operative time while using this specific implant by means of CUSUM (Cumulative Summation)[11]. CUSUM involves calculating a running total of deviations from a specified target. An inflexion point in a CUSUM chart marks the transition from the learning phase to the proficiency phase. The target for operative time was determined as the mean operative time of our cases. Operative time was defined as the interval from incision to end of suturing. These time stamps were retrieved retrospectively from the patient files.

Additionally, CUSUM analysis was applied to assess the learning curve to reach the intended postoperative coronal and sagittal alignment.

Statistical analysis

Results were analyzed using Microsoft Office Excel™ (Redmond, USA) and R Studio™ (Vienna, Austria. Previous sample size calculation proved a study cohort of minimum 24 patients is necessary in order to be able to detect a meaningful difference of 0.73° deviation in the coronal plane (alpha = 0.05; power = 0.80; assuming a normal distribution with σ2 of 1.5 degrees, corresponding to a detectable delta of 0.73 degree for coronal plane positional accuracy deviation)[13].

Negative coronal alignment is referred to as varus, whereas positive values correspond to valgus. Similarly, in the sagittal plane negative values indicate flexion, whereas positive values resemble extension. The Wilcoxon signed-rank or the paired samples T-test were used for comparing means of measures, dependent on normality of test data and the presence of equal variances between groups, assessed with Shapiro Wilk test and visually verified with boxplots. Homogeneity of variances was assessed using Levene's test. Learning curve analysis of the collected operative times was performed by means of CUSUM charts[14]. A p-value below 0.05 was considered statistically significant.

RESULTS

Population demographics

Of the 41 included patients, 22 were female (54%) and 19 (46%) were male. The mean age at time of surgery was 63 years (SD = 7.36). Operated sides concerned 20 right knees and 21 left knees. The mean Body Mass Index (BMI) for this population was 30.13 (SD = 4.21).

Component alignment

In Table I, the HKA, coronal and sagittal implant position were evaluated comparing the preoperative plan and the final postoperative result. No significant differences could be found between the planned and postoperative coronal alignment parameters.

In contrast, when comparing planned and postoperative sagittal measurements (PPTA & PDFA), significant differences in precision could be found. PPTA and PDFA show a significant deviation from planned measurements, exceeding the planned position with -2.70° [95% CI -3.70; -1.40] and -2.60° [95% CI -5.10; -0.50] respectively, indicating a loss of tibial slope and femoral flexion compared to the preoperative plan.

Secondary outcomes: CUSUM analysis

CUSUM Analysis of the learning curve as shown in figure 1 shows a clear evolution in operative time

Table I. — Pre-operative plannend and postoperative aligment measurements.

	Preop CT	Planned (based on CT) vs post-op RX			
	mean (range)	mean (range)	mean (range)	Difference between plan and postoperative measurements [95% CI]	P-value
HKA (°)	-1.54 (-15-8)	-0.02 (-5-3)	0.20 (-10-12)	-0.30 [-1.40; 0.70]	0.41
mLDFA (°)	86.8 (83-98)	88.8 (87-93)	88.6 (85-97)	0.30 [-0.40; 1.60]	0.43
mMPTA (°)	87.2 (83-92)	88.8 (87-91)	88.4 (82-92)	0.10 [-0.80; 1.00]	0.75
PPTA (°)	83.9 (77-93)	84.5 (82-87)	86.8 (80-92)	-2.70 [-4.00; -1.70]	0.000
PDFA (°)		85.3 (81-93)	88.4 (83-95)	-2.50 [-5.10; -0.50]	0.0103

HKA: Hip-Knee-Axis; mLDFA: mechanical Lateral Distal Femoral Angle; mMPTA: mechanical Medial Proximal Tibial Angle; PPTA Posterior Proximal Tibial Angle; PDFA: Proximal Distal Femoral Angle; CI: Confidence Interval.

throughout these cases. Noteworthy, after twenty-six procedures, a clear inflexion point in operative time duration can be identified as indicated in figure 1.

Nonetheless, linear regression could not show a significant correlation between the number of custom TKA cases performed and the operative time (figure 2).

CUSUM analysis of component alignment did not describe a clear inflexion point in the deviation from target of the postoperative alignment for either angle (fig. 3). However, for the HKA an inflexion "zone" can be visually assessed around case twenty-six, which is in accordance to the inflexion point identified for the operative time learning curve.

DISCUSSION

The current retrospective study demonstrates high precision to obtain the intended coronal implant position, while maintaining a short learning curve with custom TKA. As such, custom TKA has emerged as a promising approach to address the limitations associated with traditional TKA techniques, particularly in terms of implant fit, personalized alignment and decoupling of the tibiofemoral and patellofemoral joints.5,15 The use of customized implants aims to closely match the patient's unique anatomy, potentially leading to better surgical outcomes and improved patient satisfaction.

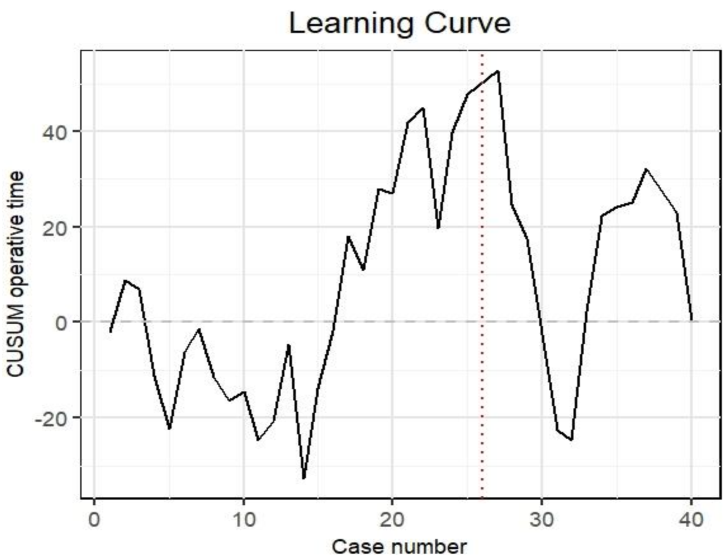

Fig. 1 — Cumulative Summation (CUSUM) analysis graph of custom TKA operative time. Inflexion point is identified at case 26 (marked by red line).

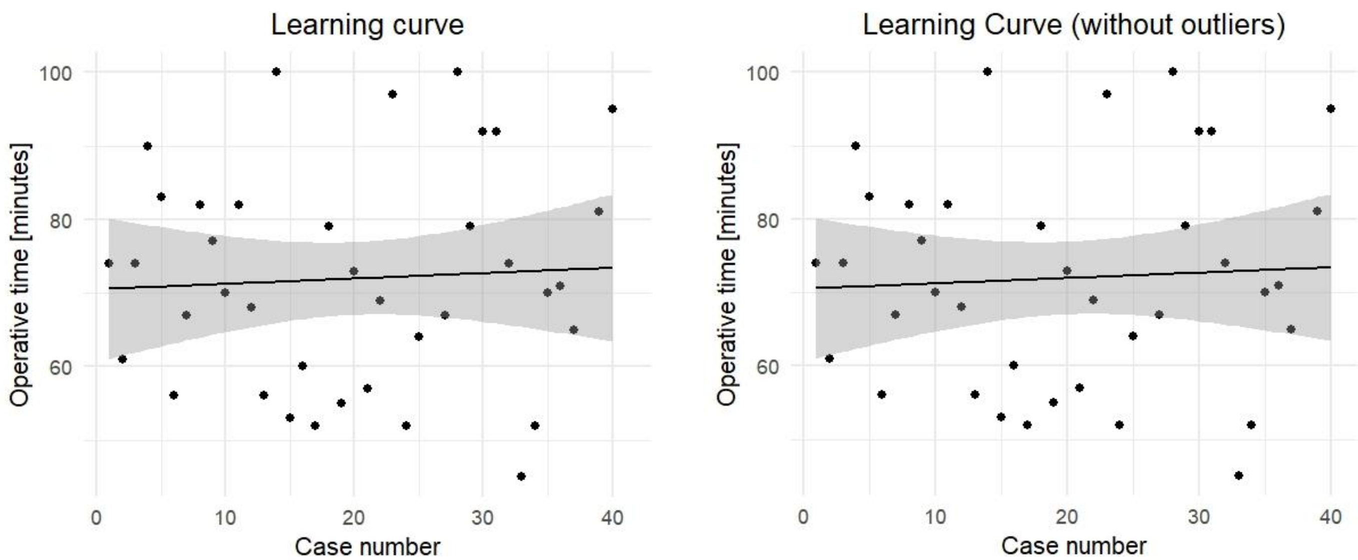

Fig. 2 — Learning curve on operative time scatter plot. Associated linear regression curve was not found to be significant. When assessing for outliers using 2 standard deviations or interquartile range, no significant linear regression could be found.

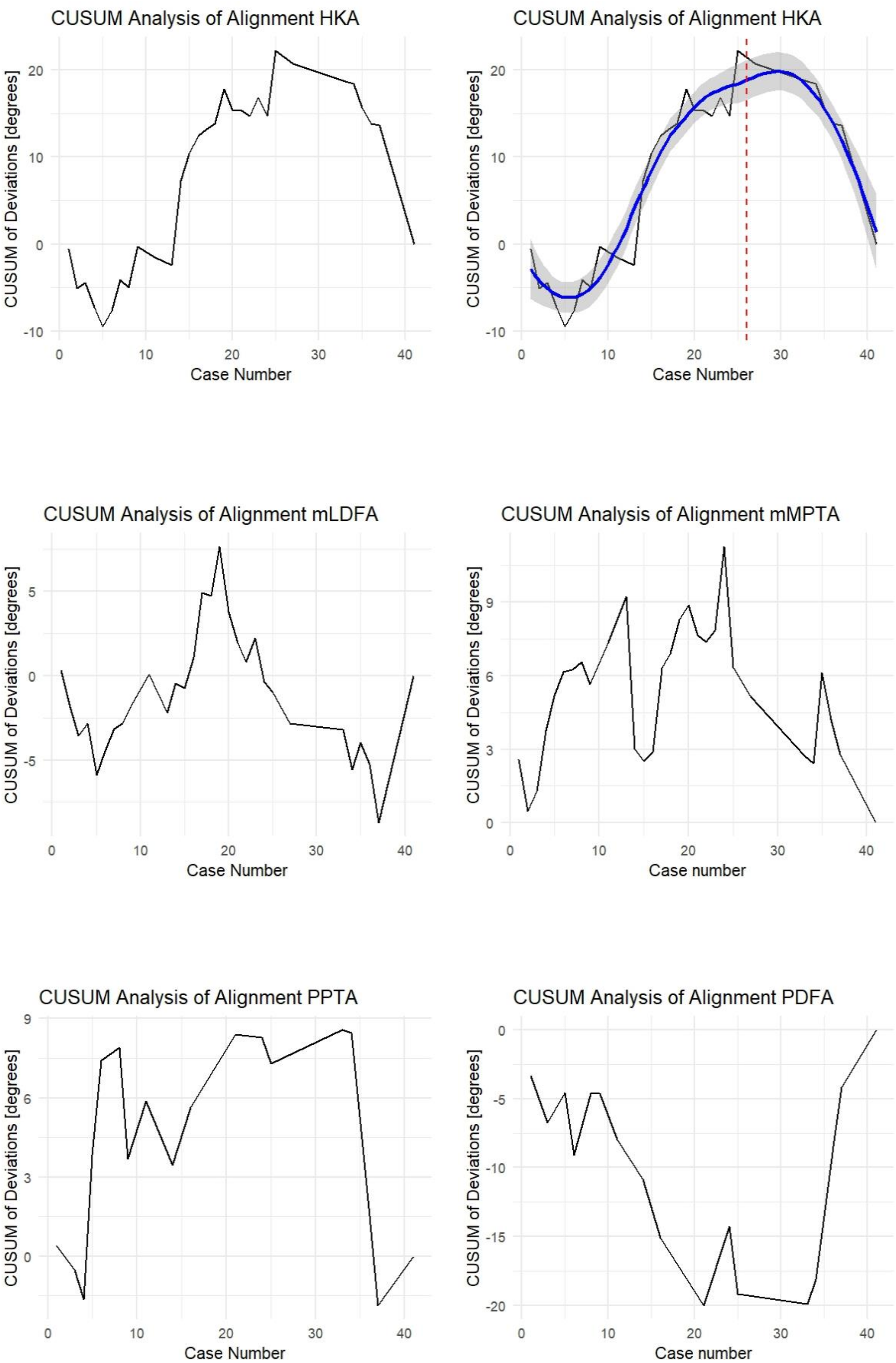

Fig. 3 — CUSUM-analysis charts for each corona and sagittal alignment. For HKA an inflexion 'zone' can be visually assessed around case 26, which is in accordance with the inflexion point for operative time. For mLDFA, mMPTA, PPTA and PDFA no clear inflexion points could be identified.

Although still a controversial topic, several studies have confirmed that custom total knee arthroplasty (TKA) can achieve equal or even improved fit and alignment compared to conventional TKA[8,9]. Our study reveals that custom TKA consistently achieves the planned alignment postoperatively, with minimal differences between both. Our findings confirm a high precision of coronal alignment parameters as HKA, mLDFA and mMPTA[16].

In contrast, the largest disparity observed was mainly in sagittal measures. Less is known about the sagittal alignment parameters PDFA and PPTA. These are less frequently assessed in studies and the possible related clinical outcomes are still unclear. Only a few studies have investigated the sagittal precision of custom TKA, they noted no difference in precision for coronal or sagittal alignment[16]. In the present study one case was converted intraoperatively to a more constrained implant due to flexion tightness. Possibly the decrease in posterior tibial slope compared to the preoperative plan could have had a significant influence on the flexion gap[17]. While the exact reason for the mismatch between the preoperative plan and intraoperative execution is still unknown, the unavailability of cruciate-stabilised inserts or impossibility to switch to a posterior stabilized implant would have allowed to maintain the custom implant. The authors advocate for a thorough analysis of the tibial cutting guide, suggesting that the working length between the bone and the guide may affect the accuracy of the tibial cut. Ensuring minimal distance between the tibia and the guide can limit the toggling of the guide relative to the tibia during the cut.

The learning curve of custom TKA is short and comparable to other new technologies in total knee surgery[12,14,18]. While this is the first study to analyze the learning curve with custom TKA, it stresses the ease of use of the cutting blocks during the surgical workflow. In addition, the satisfactory laxity assessment after the trial phase after each consecutive case was beneficial to build confidence in the system. The total operative time of the surgeon in this case series was 72 (SD 12) minutes, which lies well below the 82.0 (SD 18.7) minutes in a case series of the same surgeon using conventional TKA[14]. For surgeons starting with custom TKA it is crucial to understand that the measured resection technique may not accurately account for the soft tissue laxity in cases of bony wear. Therefore, for severe deformities, with difficulties assessing the extent of bony wear both on the femur and tibia, considering a more constrained TKA is advisable.Although not assessed in our study, custom TKA has been controversial when discussing patient's subjective and functional outcomes compared to standard TKA. Some studies on custom TKA have reported higher levels of physical function & mobility, as well as improvements in patient reported outcomes at four and twelve months postoperative[6].

Despite the benefits, custom TKA is not without challenges. The process of creating customized implants involves advanced imaging, sophisticated software for implant design, and specialized manufacturing processes, which can increase the overall cost of the procedure. Additionally, the reliance on preoperative imaging and planning requires a high level of precision and coordination between the surgical team and engineers. Although proven to be short in this study, there is also a learning curve associated with custom TKA, as surgeons must become familiar with the new techniques and tools involved. Furthermore, while custom TKA aims to improve outcomes, it may not be suitable for all patients. Factors such as severe deformities, previous knee surgeries, and certain comorbidities might affect the feasibility and success of custom TKA while offering a potential solution in certain cases at the same time[19]. It is essential for surgeons to thoroughly evaluate each patient's unique circumstances and weigh the potential benefits against the risks and costs.

The field of custom TKA is continually evolving, with ongoing research and technological advancements aimed at further improving outcomes. While currently most studies on custom TKA are performed to assess possible improvement in alignment and patient reported outcomes, less is known about the effect on patellofemoral kinematics, rehabilitation, and possible complications[8,9,15]. Additionally, long-term studies are needed to assess the durability and effectiveness of custom implants over time. As the body of evidence grows, it will become increasingly important to refine patient selection criteria and optimize surgical protocols to maximize the benefits of custom TKA.

The current study is not without limitations. A key limitation of our study is the small sample size, as well as the absence of a control group to be able to compare outcomes to conventional TKA, although the study was reasonably well powered for coronal alignment evaluation. While strongly correlated in a recent studies by Fontalis et al. and Corbett et al., lower limb alignment as measured on CT scans compared to weightbearing full leg radiographs might show discrepancies[20,21]. Bonnin et al. (2022) demonstrated a significant difference of 1.3° between weightbearing radiological and non-weightbearing

CT preoperative measurements, underscoring this challenge[8]. Some bias may exist as operative times were retrospectively reviewed from the patient files. However, at the moment of surgery, the nursing staff was well aware of the importance of these times, highlighted by a previous studies by our group[12,14].

CONCLUSION

In conclusion, custom TKA represents a significant advancement in knee arthroplasty, offering the potential for personalized alignment, improved implant fit, and superior patient-reported outcomes compared to conventional TKA. Our findings demonstrate high precision to obtain the intended coronal implant position while stressing a short learning curve with custom TKA. Further thorough evaluation of the implant position in larger studies will be necessary to confirm the precision of the sagittal implant position.

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