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Custom total knee arthroplasty combined with personalised alignment grants 94% patient satisfaction at minimum follow-up of 2 years

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Abstract

Purpose The purpose was to report detailed patient-reported outcome measures (PROMs) and satisfaction rates for computed tomography (CT)-based custom TKA at minimum follow-up of 2 years. The hypothesis was that custom TKA combined with 'personalised alignment' would yield equivalent or better PROMs compared to values reported in systematic reviews and meta-analyses on off-the-shelf (OTS) TKA.

Methods Of an initial cohort of 150 custom TKAs, four died (unrelated to surgery), one required a revision, and five refused participation, leaving 140 patients for analysis. Patients completed pre- and post-operative PROMs (Oxford Knee Score (OKS), Forgotten Joint Score (FJS), Knee injury and Osteoarthritis Outcome Score (KOOS), Western Ontario and McMaster osteoarthritis index (WOMAC)) as well as overall level of satisfaction. Proportions that attained a patient acceptable symptom state (PASS) were calculated for OKS and FJS. Clinical findings were compared to the average scores reported for PROMs in recent systematic reviews and/or meta-analyses on OTS TKA. Descriptive statistics were used to summarise the clinical findings as means, standard deviations (SD) and ranges, or numbers and percentages.

Results At mean follow-up 33.5 ± 4.5 months, 94% (135/143) were either satisfied or very satisfied. Proportions that achieved PASS were 89% for OKS (120/135), and 85% for FJS (118/139). Median OKS, WOMAC and KOOS Symptoms and Pain scores were all within the 4th quartile of medians reported in systematic reviews and/or meta-analyses.

Conclusions At a minimum follow-up of two years following custom TKA combined with 'personalised alignment', 94% of patients were either satisfied or very satisfied, and the PASS criteria were achieved in 89% for OKS and 85% for FJS, all of which compare favourably to published outcomes of OTS TKA. Direct comparisons to the literature may not be appropriate, however, considering the heterogeneity of patient demographics and alignment techniques. Randomised controlled trials with sufficient statistical power are needed to corroborate these findings and generalise them to unselected TKA patients.

Level of evidence IV, retrospective cohort study.

Keywords Total knee arthroplasty · Total knee replacement · Patient reported outcome measures · PROMs · Patient satisfaction · Satisfaction · Patient acceptable symptom state · Custom · Patient-specific

Introduction

Surgeons and manufacturers have introduced a number of modifications to total knee arthroplasty (TKA) over the past decades with the aim to improve outcomes and satisfaction. These include new alignment philosophies that aim to respect patient phenotypes, as well as patient-specific instrumentation and computer-assisted technologies that aim to improve implant positioning. Residual pain after TKA is reported by 8–27% of patients, and remains a major source of dissatisfaction [8, 25], potentially due

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to soft-tissue impingements in knees with prosthetic overhang or under-coverage [3, 4, 7], implant overstuffing [13] or over-voluming [31], as well as patellar maltracking [1, 9].

Oversized implants can generate residual pain after TKA due to impingement on the soft tissues surrounding the knee and overstuffing of the knee envelope [7]. Moreover, suboptimal TKA component size and/or positioning are also associated with aseptic loosening, instability and patellofemoral disorders [33]. Off-the-shelf (OTS) TKA can result in implant overhang, malalignment and/or abnormal kinematics [45]. This can be attributed to the inability of OTS TKA to cover the considerable morphologic variability observed in anthropometric studies [3, 4, 13]. Custom TKA based on computed tomography (CT) reconstructions has the potential to re-establish native tibial and femoral shapes, and reduce bone-implant mismatch, while restoring constitutional alignment (CA) within predetermined limits to maintain overall phenotype [18–20].

A recent systematic review and meta-analysis comparing custom versus OTS TKA revealed no significant differences in early clinical outcomes [34]; however, all studies that reported functional outcomes investigated the ConforMIS TKA system, which customises the tibiofemoral compartments and uses mechanical alignment, without customising the patellofemoral compartment or personalising alignment. A recent study reported the radiographic outcomes of a CT-based custom TKA system that customises all three knee compartments as well as a 'personalised alignment' strategy [5], after which two other studies reported early clinical outcomes of the same system at a minimum follow-up of 1 year [33, 39]. The purpose of the present study was therefore to report more detailed patient-reported outcome measures (PROMs) and satisfaction rate for this system at a minimum follow-up of two years. The hypothesis was that custom TKA combined with 'personalised alignment' would yield equivalent or better PROMs compared to values reported in recent systematic reviews and meta-analyses on OTS TKA.

Materials and methods

Cohort

From a consecutive series of 209 primary TKAs performed between January and December 2019 by one surgeon (MPB), 153 knees (150 patients, 73%) received CT-based posterior-stabilized cemented custom TKA (Origin® TKA, Symbios, Yverdon les bains, Switzerland) (Table 1, Fig. 1). All patients had provided written informed consent for the use of their data and images for research and publishing purposes and the institutional review board of Ramsay Santé pour l'Enseignement et la Recherche approved the study in advance (IRB reference number: COS-RGDS-2021-03-004-BONNIN-M).

During the inclusion period, the authors routinely used the same custom TKA system, unless patients needed to be operated within less than eight weeks (logistics for design and manufacturing processes), or if they met one or more of the following exclusion criteria: coronal deformities > 15°, stiff knees with extension deficit > 15°, flexion range < 90°, varus laxity > 10° and/or valgus laxity > 15°. The indications for surgery were medial osteoarthritis (OA) in 105, lateral OA in 32, global OA in nine, patellofemoral OA in four and rheumatoid arthritis (RA) in three knees. Thirty-nine of the 150 patients had prior surgeries: 18 had meniscectomies, nine had high tibial osteotomy (HTO), four had ligament reconstruction, three had tibial tubercle transfer, three had fixation of fractures, and two had distal femoral osteotomy.

Alignment strategy

The alignment technique facilitated realignment within predetermined limits defined as a 'target zone' with three criteria [5]. First, a ± 3° tolerance allowed a range from 87° to 93° for femoral mechanical angle (FMA) and tibial mechanical angle (TMA). Second, a ± 2° tolerance for implant obliquity extended the range to become 85° to 95° for FMA and TMA. Third, the hip knee ankle (HKA) angle was restricted within the range of 175° to 183°. In cases

Table 1 Initial and final cohort characteristics

	Initial cohort ($n = 153$ knees)			Final cohort ($n = 143$ knees)			p value
	Mean ± SD	|Median|	(Range)	Mean ± SD	|Median|	(Range)	
	n (%)			n (%)			
Age	72.1 ± 8.2	|72.1|	(48–90)	72.1 ± 8.1	|72.0|	(48–90)	n.s
BMI	27.4 ± 4.9	|26.6|	(18–44)	27.4 ± 4.9	|26.6|	(18–44)	n.s
Women	97 (63%)			92 (64%)			n.s
Right knees	79 (52%)			76 (53%)			n.s

BMI body mass index; *SD* standard deviation

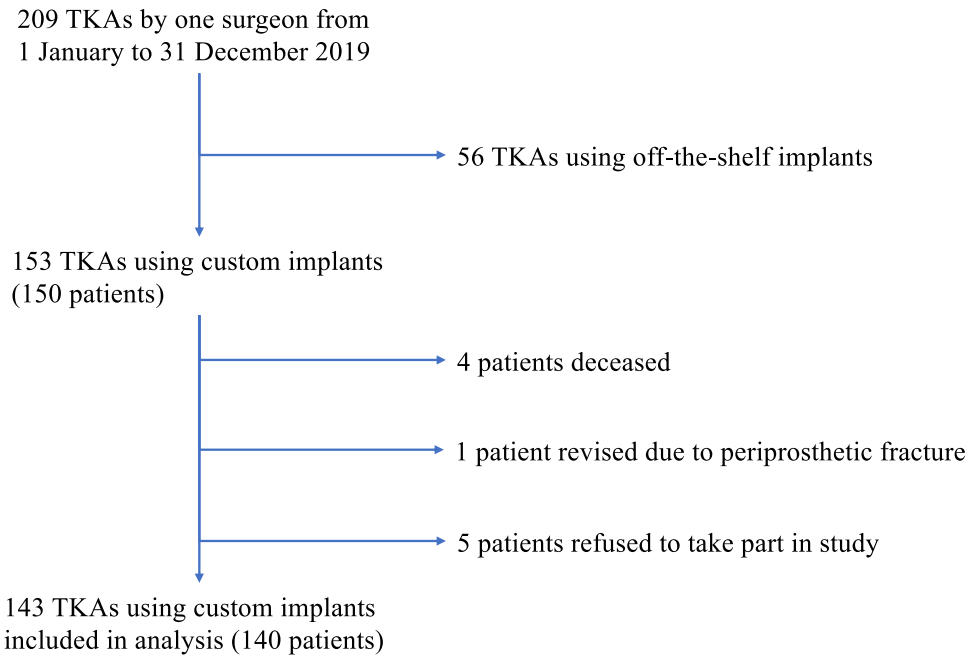

Fig. 1 Flowchart indicating numbers of patients (and knees) in the initial and final cohorts

where preoperative FMA and TMA were outside the 'target zone', the alignment was corrected to the closest configuration within the 'target zone'.

Surgical technique

The custom TKA prosthesis and its design process have been described previously [5]. Femoral and tibial resections were made using custom cutting guides by a 'femur-first' technique and medial parapatellar approach. Soft tissue balance was evaluated with a dynamic spacer, and if necessary, the level of tibial resection was adjusted by a 'recut' using a dedicated guide. Finally, the femoral component and tibial baseplate were cemented. Immediate full weight-bearing was authorised, and rehabilitation began on the same day of surgery.

Clinical evaluation

Patients completed preoperative PROMs which consisted of the Oxford Knee Score (OKS; worst, 0; best, 48), Forgotten Joint Score (FJS; worst, 0; best, 100), components of the Knee injury and Osteoarthritis Outcome Score (KOOS; worst, 0; best, 100), as well as the Western Ontario and McMaster osteoarthritis index (WOMAC; worst, 0; best, 96). At a minimum follow-up of two years, patients were contacted by an independent consultant (SD), without any direct contact between the patients and the clinician, to avoid any form of bias: The consultant assisted patients to complete the same PROMs as well as their overall level of satisfaction with the TKA on a Likert scale ('very dissatisfied', 'dissatisfied', 'neutral', 'satisfied' or 'very satisfied'). In addition, patients also reported their overall status and whether there were any adverse events. All post-operative PROMs were entered and analysed by the independent consultant. Finally, the number of knees that attained a patient acceptable symptom state (PASS) was calculated for OKS using a threshold of ≥ 30 points [21], and for FJS using a threshold of ≥ 38 points [17].

Statistical analysis

Descriptive statistics were used to summarise the clinical findings as means, standard deviations (SD) and ranges. The level of satisfaction and PASS for the different PROMs were reported as numbers and percentages. As the present study did not include a control group, clinical findings were compared to the average scores reported for PROMs in recent systematic reviews and/or meta-analyses on OTS TKA. Considering the findings of a recent large study that reported a satisfaction rate of 83.6% (3677/4402) at one year following TKA [2], and assuming that the satisfaction rate in the present study would be 93.6% (10% higher), an a priori analysis revealed that a minimum sample size of 120 would be required to determine whether the difference is statistically significant, with a power of 90%. Statistical analyses were performed using R version 4.1.0 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Of the final cohort, none had adverse events, and 94.4% (135/143) were either satisfied or very satisfied with their TKA. Two patients (2%) had comorbidities (Alzheimer

disease, one; Polytrauma with severe sequelae, one) that hindered their ability to complete PROMs but reported overall satisfaction. The net-improvement in OKS was 23.2 ± 9.1, in FJS was 52.6 ± 27.0, in WOMAC was 34.9 ± 18.4, and in KOOS was 29.5 ± 22.1 for Symptoms, 38.6 ± 21.8 for Pain, 35.8 ± 23.2 for ADL, 35.3 ± 30.2 for Function and, 52.9 ± 25.9 for QOL (Table 2). The proportion of patients that achieved PASS was 89% (120/135) for OKS, and 85% (118/139) for FJS.

The median values of OKS, WOMAC as well as KOOS Symptoms and Pain components of the present study were all within the 4th quartile (within the upper 75–100%) of mean values reported in recent systematic reviews and/or meta-analyses on TKA [10, 12, 14, 15, 23, 24, 26, 27, 29, 30, 38, 41–44]. The median values of FJS as well as the ADL, Function and QOL components for KOOS were all within the 3rd quartile (within the upper 50–75%) of mean values reported in recent systematic reviews and/or meta-analyses on TKA (Fig. 2).

Table 2 Satisfaction rate and PROMs of the final cohort ($n = 143$)

	Mean ± SD	|Median|	(Range)
	n(%)		
Follow-up (months)	33.5 ± 4.5	|34.9|	(24–41)
Overall satisfaction ($n = 143$)			
Very unsatisfied	0 (0%)		
Unsatisfied	5 (3%)		
Neutral	3 (2%)		
Satisfied	49 (34%)		
Very satisfied	86 (60%)		
OKS (worst, 0; best, 48)			
Preoperative ($n = 109$)	16.1 ± 6.5	|15.2|	(2–30)
Postoperative ($n = 135$)	39.6 ± 7.6	|42.0|	(17–48)
FJS (worst, 0; best, 100)			
Preoperative ($n = 109$)	16.2 ± 14.0	|12.5|	(0–77)
Postoperative ($n = 139$)	69.0 ± 27.7	|75.0|	(0–100)
WOMAC (worst, 0; best, 96)			
Preoperative ($n = 80$)	45.8 ± 16.0	|42.0|	(11–91)
Postoperative ($n = 100$)	82.0 ± 15.7	|87.0|	(24–96)
KOOS			
Symptoms (worst,0; best, 100)			
Preoperative ($n = 120$)	51.6 ± 19.3	|50.0|	(0–89)
Postoperative ($n = 140$)	82.1 ± 16.5	|85.7|	(14–100)
Pain (worst,0; best, 100)			
Preoperative ($n = 119$)	45.4 ± 16.1	|44.4|	(6–89)
Postoperative ($n = 140$)	84.9 ± 16.9	|91.1|	(19–100)
ADL (worst,0; best, 100)			
Preoperative ($n = 119$)	46.4 ± 17.0	|43.9|	(10–96)
Postoperative ($n = 139$)	82.9 ± 18.4	|88.3|	(25–100)
Function (worst,0; best, 100)			
Preoperative ($n = 105$)	16.5 ± 16.7	|15.0|	(0–75)
Postoperative ($n = 118$)	51.6 ± 27.5	|55.0|	(0–100)
QOL (worst,0; best, 100)			
Preoperative ($n = 120$)	21.3 ± 15.8	|18.8|	(0–75)
Postoperative ($n = 138$)	74.6 ± 25.2	|81.3|	(0–100)

OKS Oxford Knee Score; *FJS* Forgotten Joint Score; *KOOS* Knee injury and Osteoarthritis Outcome Score; *ADL* activities of daily living; *QOL* quality of life; *WOMAC* Western Ontario and McMaster osteoarthritis index

Discussion

The most important finding of the present study was that, at a minimum follow-up of two years following custom TKA combined with 'personalised alignment', 94% of patients were either satisfied or very satisfied, and the PASS criteria were achieved in 89% for OKS and 85% for FJS. Finally, median values of PROMs were all within the upper two quartiles of means reported in recent systematic reviews and meta-analyses, which supports the hypothesis that custom TKA combined with 'personalised alignment' could yield equivalent or better PROMs compared to values reported for OTS TKA.

In the present study, the proportion of patients that were satisfied or very satisfied (135/143, 94%) compares favourably to proportions reported for OTS TKA (81.3–92%) [16, 22, 28, 32, 35, 48] or other custom TKA systems (88–90%) [36, 45]. The proportion of dissatisfied patients in the present study (3%, 5/143) is also lower than the proportion (10%, 1388/13878) reported in a recent systematic review on eight studies with minimum follow-up of one to five years [11]. The PROMs of the present study compared favourably to those reported for OTS TKA in recent systematic reviews and meta-analyses, and were also similar to those reported for the ConforMIS TKA system (Table 3) [40, 45–47]. Differences in outcomes between the two custom TKA systems might be due to the level of component customisation and/or alignment strategy. The ConforMIS TKA system customises the tibiofemoral compartments and uses mechanical alignment, without customising the patellofemoral compartment or personalising alignment. The Symbios TKA system customises all three knee compartments and uses a 'personalised alignment' strategy.

The design process of the evaluated custom TKA system enables differentiation of constitutional versus arthritic bony deformities, in addition to estimation of the native femoral and tibial axes, while aiming to match the anatomical shape and size of a patient's knee. This potentially reduces the risk of bone-implant mismatch, while preserving or restoring a patient's constitutional alignment within predetermined limits, to maintain the native overall phenotype. Although patient-specific alignment strategies could yield

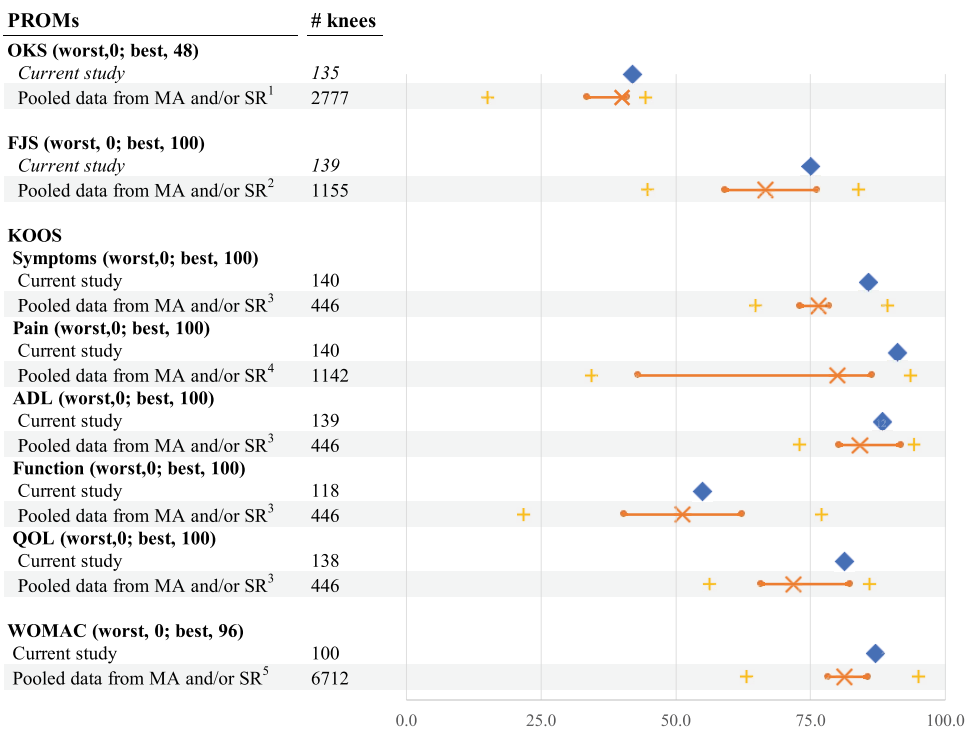

Fig. 2 Comparison of patient-reported outcome measures (PROMs) to pooled results in systematic reviews and/or meta-analyses on OTS TKA. Footnotes: [1]Rudran et al. [41] (5 studies); Elbardesy et al. [14] (4 studies); Li et al. [27] (2 studies); Qin et al. [38] (3 studies); Tso et al. [43]; Deng et al. [12] (3 studies); Gao et al. [15] (4 studies); Kim et al. [24] (2 studies); Luo et al. [29] (4 studies). [2]Tso et al. [43] (5 studies); Cacciola et al. [10] (2 studies); Luo et al. [29] (2 studies). [3]Rudran et al. [41] (2 studies); Gao et al. [15] (2 studies); Kim et al. [24] (2 studies). [4]Kim et al. [23] (3 studies), Rudran et al. [41] (2 studies); Gao et al. [15] (2 studies); Kim et al. [24] (2 studies). [5]Kim et al. [23]; Rudran et al. [41] (5 studies); Vishwanathan et al. [44] (2 studies); Sun et al. [42] (2 studies); Tso et al. [43] (5 studies); Cacciola et al. [10] (8 studies); Gao et al. [15] (4 studies); Lee et al. [26] (6 studies); Luo et al. [29] (4 studies)

better PROMs [15], there remains a risk for bone–implant mismatch and altered patellofemoral kinematics when implemented with OTS TKA implants [3, 4]. It is therefore encouraging that, when compared to literature, the median of the KOOS Pain component was within the top 75% to 100% of reported mean values for OTS TKA. Persistent pain and discomfort after TKA could, among other factors, be due to component malpositioning, over-voluming, and/or implant loosening [49]. The risk of persistent pain could increase due to prosthetic overhang that results in soft-tissue impingement on prosthesis edges [7, 37], or prosthetic under-coverage that results in soft-tissue impingement on bone resection edges [6].

In the present study PASS criteria were used to determine if patients reached a satisfactory or non-satisfactory state based on their OKS and FJS scores. It is noteworthy, that studies suggest different threshold values, which among other factors, depend on statistical methods, anchor questions, and the follow-up time-points [21]. Proportions of patients achieving PASS is therefore highly dependent on the chosen thresholds, which appear to be coherent considering the proportion of satisfied and very satisfied patients in the present study.

The findings of the present study should be interpreted with the following limitations in mind. First, there was no control group and therefore PROMs could only be compared to published reports for OTS TKA and/or other custom TKA systems. The results from the systematic reviews and/or meta-analyses are subject to high levels of heterogeneity due to different alignment strategies, implant types and/or surgical techniques of the pooled clinical studies. The authors have initiated a randomised controlled trial (NCT04460989) to compare 2-year outcomes of custom TKA with personalised alignment strategy versus OTS TKA. Second, it is unclear which alignment strategy was used in the studies analysed by the systematic reviews and meta-analyses, so it is difficult to determine the isolated effects of implant customisation and alignment personalisation. Third, patients could be biased when filling their PROMs as they were aware that they received custom implants. Fourth, the cohort had a high proportion of women which may influence the findings, as these patients may have had anatomical conditions that are more difficult to treat with OTS TKA. Fifth, the minimum follow-up period was only two years, and it is therefore inadequate to assess implant longevity and survival.

Table 3 Comparsion to PROMs of other custom TKA systems

	n	Follow-up (years)	Mean ± SD
FJS (worst, 0; best, 100)			
Present study	*139*	*2.8 ± 0.4*	*69.0 ± 27.7*
Wheatly et al.	16	1	56.0 ± 26.9
WOMAC (worst, 0; best, 96)			
Present study	*100*	*2.8 ± 0.4*	*82.0 ± 15.7*
White et al.	21	2.4 ± 0.4	80.6 ± 18.3
KOOS			
Symptoms (worst,0; best, 100)			
Present study	*140*	*2.8 ± 0.4*	*82.1 ± 16.5*
Reimann et al.	84	2.2	82.7 ± 17.4
Wendelspiess et al.	74	1	77.8 ± 16.0
Pain (worst,0; best, 100)			
Present study	*140*	*2.8 ± 0.4*	*84.9 ± 16.9*
Reimann et al.	84	2.2	89.5 ± 12.4
Wendelspiess et al.	74	1	84.5 ± 16.1
ADL (worst,0; best, 100)			
Present study	*139*	*2.8 ± 0.4*	*82.9 ± 18.4*
Reimann et al.	84	2.2	83.8 ± 16.1
Wendelspiess et al.	74	1	87.2 ± 13.8
Function (worst,0; best, 100)			
Present study	*118*	*2.8 ± 0.4*	*51.6 ± 27.5*
Reimann et al.	84	2.2	58.9 ± 21.8
Wendelspiess et al.	74	1	68.1 ± 21.8
QOL (worst,0; best, 100)			
Present study	*138*	*2.8 ± 0.4*	*74.6 ± 25.2*
Reimann et al.	84	2.2	69.3 ± 21.8
Wendelspiess et al.	74	1	71.9 ± 21.5

FJS Forgotten Joint Score; *KOOS* Knee injury and Osteoarthritis Outcome Score; *ADL* activities of daily living; *QOL* quality of life; *WOMAC* Western Ontario and McMaster osteoarthritis index

Conclusion

At a minimum follow-up of two years following custom TKA combined with 'personalised alignment', 94% of patients were either satisfied or very satisfied, and the PASS criteria were achieved in 89% for OKS and 85% for FJS, all of which compare favourably to published outcomes of OTS TKA. Direct comparisons to the literature may not be appropriate, however, considering the heterogeneity of patient demographics and alignment techniques. Randomised controlled trials with sufficient statistical power are needed to corroborate these findings and generalise them to unselected TKA patients.

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Data availability The authors can upon reasonable request provide access to the anonymised raw data.

Declarations

Conflict of interest LG, AD, SR, LB, JHM, SD, MS has nothing to disclose. COT reports personal fees from Symbios during the conduct of the study; personal fees from Smith & Nephew outside the submitted work. TASS reports personal fees from Symbios during the conduct of the study; reports personal fees from DePuy-Synthes outside the submitted work. MPB reports personal fees from Symbios during the conduct of the study; reports personal fees from Wright Medical, Integra, DePuy Synthesis outside the submitted work.

Ethical approval All patients had provided written informed consent for the use of their data and images for research and publishing purposes and the institutional review board of Ramsay Santé pour l'Enseignement et la Recherche approved the study in advance (IRB reference number: COS-RGDS-2021-03-004-BONNIN-M).

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