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Original Research

Time is Money! Influence on Operating Theater and Sterilization Times of Patient-specific Cutting Guides and Single-use Instrumentation for Total Knee Arthroplasty: A Full Factorial Design of 136 Patients

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ABSTRACT

Background: Patient-specific cutting guides (PSGs) and single-use disposable instrumentation (SUI) have emerged as potential beneficial innovations for total knee arthroplasty. The aim of this study was to evaluate the impact of PSG and SUI for total knee arthroplasty on operating room (OR) and sterilization times.

Methods: A monocentric, prospective, interventional, full factorial design study, including 136 patients, compared patient-specific (PSG, n = 68) to conventional cutting guides (n = 68) and SUI (n = 68) to conventional instrumentation (CVI, n = 68). In the OR, we recorded the number of instrument trays, operating time, and room occupancy time. In the central sterile services department, the total sterilization duration was assessed. The primary outcome was operating time and sterilization duration. Secondary outcomes were difference in the number of trays, Oxford Knee Score, and postoperative mechanical axis.

Results: The median operating time was 80 minutes (Q1-Q3: 73-90) and was significantly increased for SUI compared to that for CVI (+5 minutes, $P = .0072$). The median sterilization duration was 1261 minutes (Q1-Q3: 934-1603). It was significantly in favor of SUI (936 minutes) over CVI (1565 minutes) (+629 minutes, $P < .0001$). The total number of instrument trays was 404 for 136 patients: 252 for CVI and 152 for SUI ($P < .0001$) and 189 for PSG and 215 for conventional cutting guides ($P = .0006$). There was no significant difference in OKS ($P = .86$) nor in the postoperative alignment which was between 177° and 183° (75% patients, $P = .24$).

Conclusions: SUI lowers the number of instrument trays and sterilization duration. PSG is not associated with significant OR or sterilization time reduction. The use of SUI could reduce the risk of noncompliance of instrument trays.

Introduction

Total knee arthroplasty (TKA) has revolutionized the care of patients with end-stage arthritis of the knee. As it results in good outcomes in terms of function [1] and survival rates greater than 90% at 15 years of follow-up [2], it is considered to be a safe procedure, and it is used extensively worldwide [3]. By 2030, the demand for primary TKA is estimated to grow by 673% to 3.48 million procedures in the United States alone [4].

The successful clinical outcomes and the longevity of TKA are thought to be related to adequate patient selection, three-dimensional (3D) alignment of the components, ligament tension, and rehabilitation [5]. The increasing demands for orthopedic procedures, along with the budgetary constraints on health-care facilities, have led to several important technological advances

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(eg, computer-assisted surgery, accelerometer-based navigation, patient-specific cutting guides [PSGs]). The use of computer-assisted surgery over conventional surgery results in better frontal alignment [6]. However, this technique has not been broadly adopted due to the marginal functional improvement, high initial capital costs [7,8], long learning curve, increased surgical time [9], and occurrence of specific complications [10].

PSGs and single-use instrumentation (SUI) have emerged as potential beneficial innovations in light of their advantages in terms of cost, operating room (OR) efficiency, and comparable patient outcomes [11,12]. Patient-specific instrumentation (PSI) is a modern technique in TKA aimed at facilitation of prosthesis implantation using PSGs generated from preoperative 3D models based on computed tomography or magnetic resonance imaging. Most of the data in the literature, including systematic reviews and meta-analyses, suggest that PSI is comparable to conventional instrumentation in terms of clinical, radiological, and cost outcomes. SUI has been developed to lower the rate of surgical site infection and the overall OR occupancy time [12–14]. Operating theater efficiency could be improved by using SUI as a result of not having to undertake multiple sterilizations and packaging of instrumentation sets. Recent data suggest that the use of single-use fully disposable PSGs provides similar clinical and radiological results as using PSI-metal or full-metal conventional instrumentation [12], but there is a lack of evidence regarding the economic outcomes.

The aim of this study was to evaluate the impact of PSGs and SUI for primary TKA on OR and sterilization times.

Materials and methods

The study was approved by the relevant research ethics committee and was registered with the ClinicalTrials.gov database, which is operated by the US National Library of Medicine (ID NCT02966613). All the patients provided their informed consent.

Eligible patients included those aged between 18 and 90 years with symptomatic osteoarthritis of the knee who the treating surgeon thought would benefit from TKA. Patients were excluded if they had an extraarticular deformity requiring an associated osteotomy, an active or suspected infection, a previous knee surgery, or a bone tumor in the vicinity of the knee or if they were unable to comply with the trial procedures.

Enrollment started in September 2015 and ended in January 2017. The final follow-up assessment was completed in March 2017. Surgeries were performed by 2 senior surgeons (P.A., M.H.) in a teaching hospital.

This was a monocentric, prospective, interventional study that included 136 patients who underwent TKA at the study center. A 2 × 2 full factorial design was used to determine the influence of 2

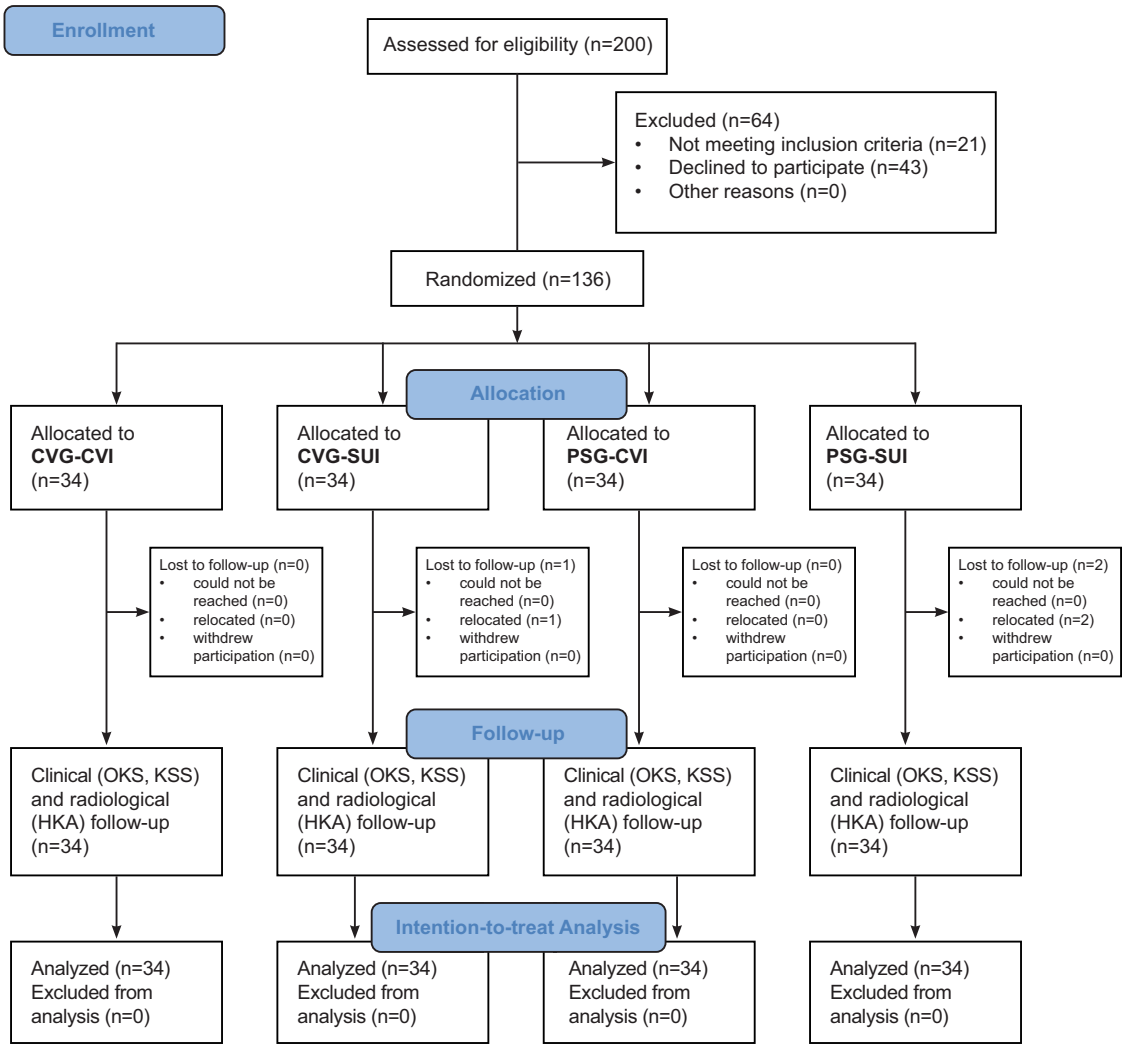

Figure 1. The Consolidated Standards of Reporting Trials (CONSORT) diagram of the flow of patients through the trial.

factors: the type of instrumentation and the type of cutting guides and interactions between them.

The number of patients to include was calculated assuming a difference of 300 minutes in sterilization duration (standard deviation 600) between variables (type of instrumentation and type of cutting guides). With a type 1 risk of 5% and a type 2 risk of 80%, measured with a bilateral test, we estimated that 59 patients per group would be required for this study. With an estimated 15% dropout rate or unexploitable data, we included 68 patients per group, making 136 patients in total.

We compared patient-specific (PSG, n = 68) to conventional cutting guides (CVG, n = 68) and SUI (n = 68) to conventional instrumentation (CVI, n = 68) (Figs. 1 and 2). Hence, 4 groups were analyzed, providing reliable data for each factor (instrumentation and cutting guides). Per-group analysis of the 4 possible combinations (CVG-CVI, PSG-CVI, CVG-SUI, and PSG-SUI) was also performed. The groups were operated on at different times to ensure stock availability and to minimize contamination between the groups. To regulate the period effect, 2 separate evaluation phases were carried out per group (Fig. 3).

The following data were recorded in the OR (Fig. 4): the number and type of instrument trays, the operating time, the scrub nurse time, the room occupancy time, and the manual scrubbing time of the instrument trays (tn1). In the central sterile services department (CSSD) (transport to CSSD: tn2), the following times were recorded to assess the time for total sterilization: decontamination (tn3, tn4), assembly and packaging (tn5, tn6), sterilization processes (tn7), and quality assurance (tn8, tn9). The sterilization time was calculated by adding up the duration of each step per patient.

As there is no human intervention or monitoring between midnight and 8:00 AM, incidences of trays being held up in the CSSD were recorded and corrected by deduction of the mean overall hold-up duration from the holdup period in question. The total sterilization time was defined as the duration after data imputation and hold-up period adjustment.

The clinical assessment included the Knee Society knee function and global score (KSS; 0-100 representing worst to best) [15] and the Oxford Knee Score (OKS; 0-48 representing worst to best) [16] reported at baseline and 2 months postoperatively. The mechanical axis of the lower limb was measured by 2 independent observers at baseline and after 2 months using digitized bipedal standing leg-length radiographs. Lower extremity examinations were performed using EOS 2D/3D (EOS imaging system; Biospace, Paris, France). Three-dimensional computer reconstructions were created using anteroposterior and lateral EOS images with the sterEOS 3D workstation software (EOS imaging system; Biospace, Paris, France) [17].

The primary outcome was operating and sterilization duration assessment.

The secondary outcomes were the difference in the number of instrument trays, the KSS, the OKS, and the mechanical axis using the hip-knee-ankle angle.

There was no significant difference in the preoperative evaluation between the groups except for the median KSS ($P = .0088$) (Table 1). The preoperative alignment revealed 58% varus and 23% valgus knees. Two patients in the PSG-SUI group required conversion to CVG-CVI: one on the femoral side because the femoral guide was a poor fit at the time of the operation and the other on the tibial side because the SUI trial implant was too small. One patient in the CVG-SUI group required conversion to CVG-CVI because tibial intramedullary alignment could not be achieved with the SUI guides. These 3 patients were analyzed in their allocated groups.

The continuous data were described as medians (interquartile range), and the categorical data as numbers (%). For the continuous data, statistical comparisons between 2 groups were performed using Student's *t*-test, and comparisons between 4 groups were

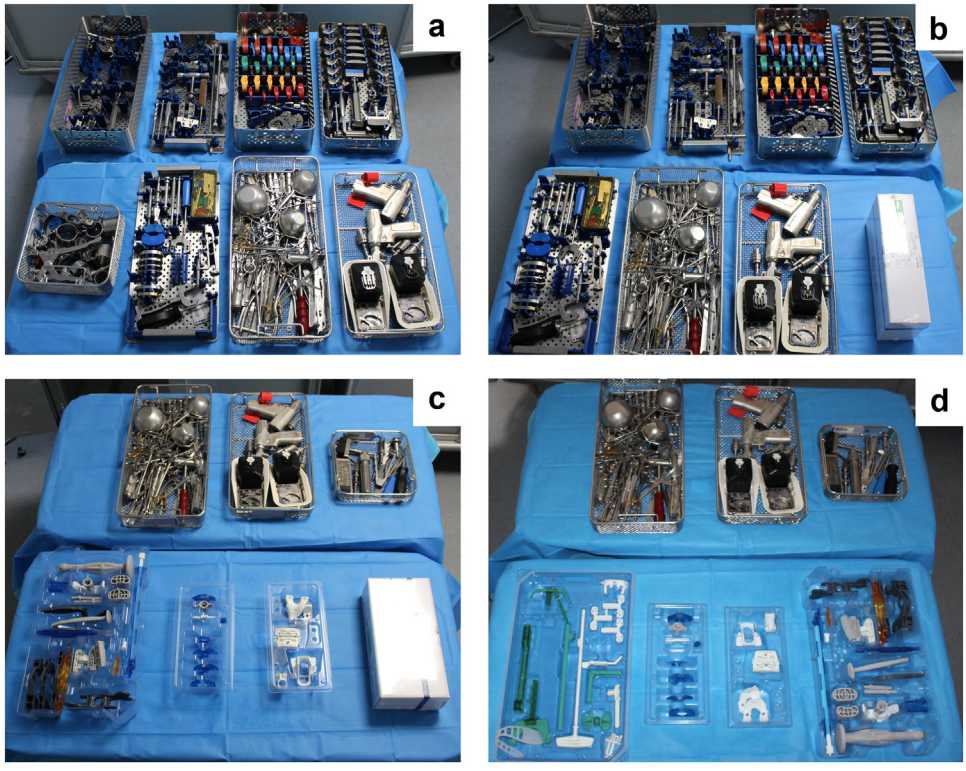

Figure 2. Cutting guides and instrument sets by groups. (a) CVG-CVI; (b) PSG-CVI; (c) PSG-SUI; (d) CVG-SUI.

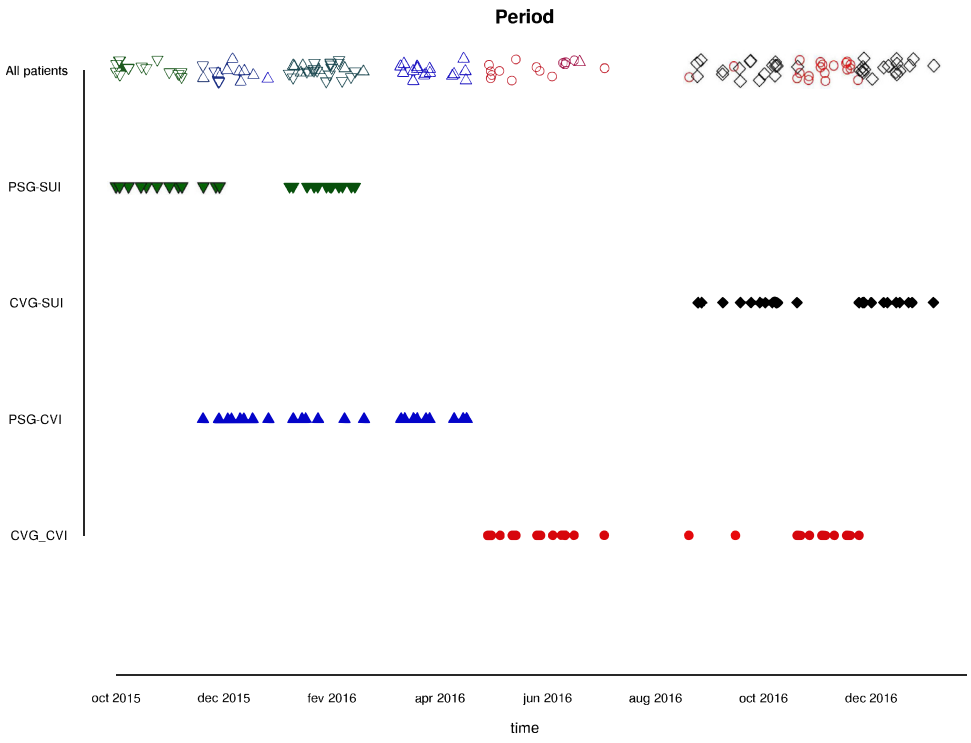

Figure 3. Evaluation phases per group.

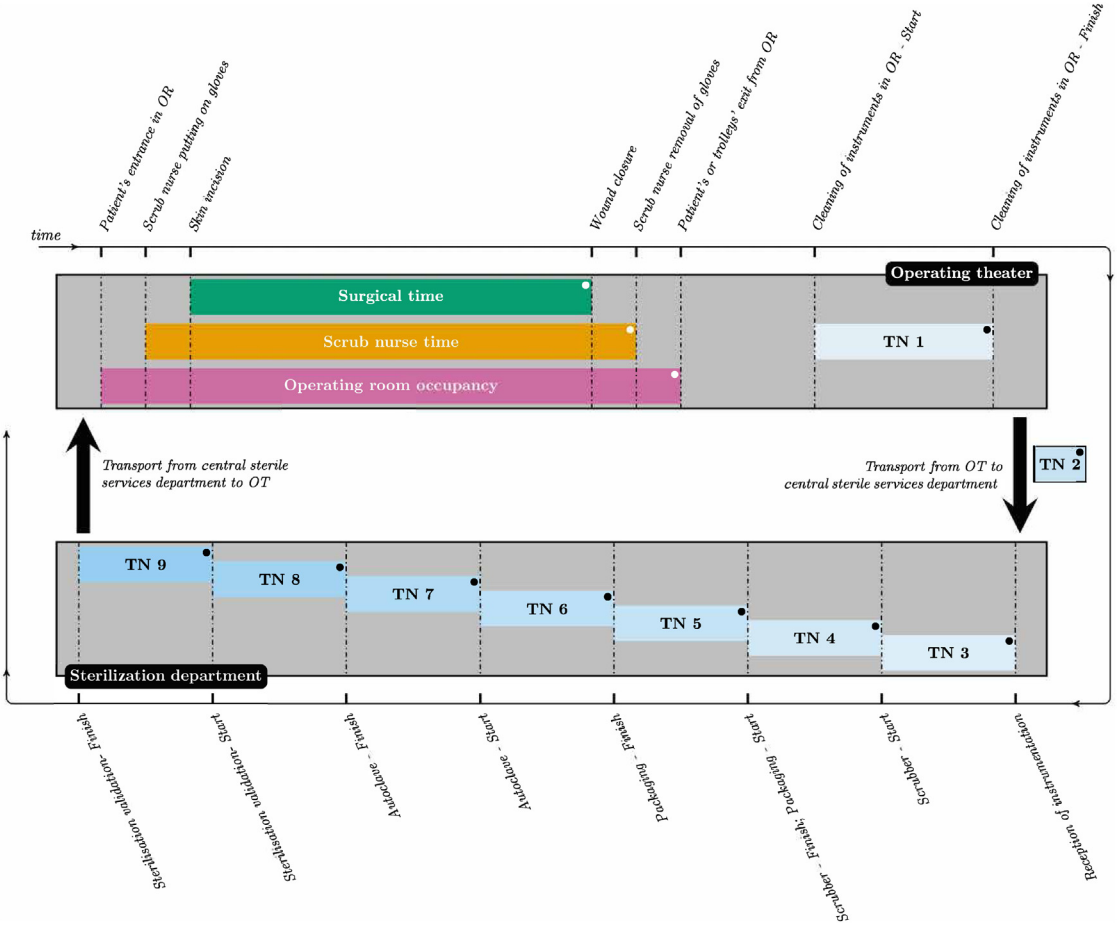

Figure 4. Follow-up times of instrument trays in operating theater and CSSD. Measurements are made by patient (white dot) and by box (black dot).

Table 1
Preoperative data of patients by groups.

Characteristics	PSG-SUI (n = 34)	PSG-CVI (n = 34)	CVG-CVI (n = 34)	CVG-SUI (n = 34)	*P*	All patients (n = 136)
Age, median (Q1-Q3)	68 (64-73)	74 (65-80)	74 (64-77)	75 (70-81)	.088	73 (65-78)
Sex					.98	
Woman	23 (67.6)	23 (67.6)	24 (70.6)	25 (73.5)		95 (69.9)
Man	11 (32.4)	11 (32.4)	10 (29.4)	9 (26.5)		41 (30.1)
BMI, median (Q1-Q3)	28 (25-31)	27 (24-32)	26 (24-31)	26 (23-29)	.47	27 (24-31)
Side					.5	
Right	17 (50%)	16 (47.1%)	15 (44.1%)	21 (61.8%)		69 (50.7%)
Left	17 (50%)	18 (52.9%)	19 (55.9%)	13 (38.2%)		67 (49.3%)
HKA, median (Q1-Q3)	174 (170-179)	174 (170-182)	177 (173-184)	175 (170-184)	.28	175 (170-183)
Deformation						
Varus	22 (64.7%)	20 (58.8%)	14 (48.3%)	19 (59.4%)		75 (58.1%)
Aligned	7 (20.6%)	6 (17.6%)	7 (24.1%)	4 (12.5%)		24 (18.6%)
Valgus	5 (14.7%)	8 (23.5%)	8 (27.6%)	9 (28.1%)		30 (23.3%)
Oxford, median (Q1-Q3)	17 (14-20)	16 (13-19)	15 (13-17)	16 (14-18)	.13	16 (14-18)
KSS, median (Q1-Q3)	60 (52-68)	52 (46-59)	53 (51-56)	54 (48-57)	.0088*	54 (48-59)

BMI, body mass index; CVG-CVI, conventional cutting guides–conventional instrumentation; CVG-SUI, conventional cutting guides–single-use instrumentation; HKA, hip-knee-ankle angle; PSG-CVI, patient-specific cutting guides–conventional instrumentation; PSG-SUI, patient-specific cutting guides–single-use instrumentation.
Varus: HKA <177°.
Aligned: 177° ≤ HKA ≤ 183°.
Valgus: HKA >183%.
Data are presented as median (interquartile range) or numbers (percentage).
* Statistical significance with $P < .05$.

performed with linear regression models. The categorical variables were compared using the nonparametric Fisher's exact probability test or the Chi-squared test. Paired tests were used to compare the preoperative and postoperative data. As it was a full factorial design, an interaction between the type of instrumentation and the type of cutting guides was sought. An intention-to-treat analysis was carried out. Multiple imputation procedures by predictive mean matching were used to replace missing or outlier data (20

Table 2
Recorded and calculated times in OR and CSSD by groups (sum per patient).

Recorded and calculated times (min)	PSG-SUI (n = 34)	PSG-CVI (n = 34)	CVG-CVI (n = 34)	CVG-SUI (n = 34)	*P*	All patients (n = 136)
Operating time	83 (75-103)	78 (70-85)	78 (72-85)	82 (73-95)	.047*	80 (73-90)
Scrub nurse time	114 (101-138)	103 (93-112)	108 (100-123)	106 (97-130)	.094	106 (98-119)
Room occupancy time	116 (105-138)	115 (100-121)	112 (104-121)	113 (106-130)	.29	114 (104-126)
tn1	9 (7-10)	18 (16-21)	25 (20-29)	9 (6-12)	<.0001*	14 (9-21)
tn2	257 (184-366)	401 (296-464)	453 (341-615)	267 (186-369)	<.0001*	348 (222-451)
tn3	45 (32-62)	85 (53-129)	92 (76-121)	41 (24-70)	<.0001*	62 (36-98)
tn4	157 (136-188)	237 (196-261)	279 (249-312)	128 (120-145)	<.0001*	196 (140-261)
tn5	243 (150-413)	304 (189-441)	369 (200-563)	111 (69-175)	<.0001*	238 (141-402)
tn6	208 (133-268)	242 (165-327)	353 (204-432)	173 (119-306)	.0011*	232 (149-350)
tn7	280 (246-326)	405 (368-449)	457 (427-508)	217 (204-229)	<.0001*	369 (235-439)
tn8	62 (37-90)	92 (41-128)	92 (61-144)	54 (38-67)	.00012*	69 (40-111)
tn9	7 (5-13)	12 (8-28)	12 (8-23)	8 (4-15)	.003*	10 (5-19)
Total sterilization including blockage period and excluding missing data	1146 (841-2303)	1600 (1351-2159)	1728 (1375-2550)	735 (668-1045)	<.0001*	1435 (962-2173)
Total sterilization including blockage period and after imputation for missing data	1146 (840-2259)	1653 (1375-2199)	1767 (1414-2946)	791 (679-1262)	<.0001*	1480 (989-2173)
Total sterilization excluding blockage period and missing data	1063 (889-1325)	1481 (1317-1675)	1705 (1418-1865)	712 (655-953)	<.0001*	1261 (934-1603)
Total sterilization excluding blockage period and after imputation for missing data = final analysis	1039 (852-1262)	1481 (1331-1686)	1710 (1444-1961)	775 (679-982)	<.0001*	1263 (933-1606)

CVG-CVI, conventional cutting guides–conventional instrumentation; CVG-SUI, conventional cutting guides–single-use instrumentation; PSG-CVI, patient-specific cutting guides–conventional instrumentation; PSG-SUI, patient-specific cutting guides–single-use instrumentation.
Operating time: from incision or tourniquet inflation to wound closure.
Scrub nurse time: from scrub nurse gloving to degloving.
Room occupancy time: from patient entering the operating room to the last instrument tray going out.
tn1: Manual scrubbing time of the instrument trays in the operating theater.
tn2: Transport to the sterilization department.
tn3: Receipt of instrument trays in the sterilization department.
tn4: Decontamination.
tn5: Assembly and packaging.
tn6: From tn5 to autoclave cleaning.
tn7: Autoclave cleaning.
tn8: From tn7 to quality insurance.
tn9: Quality assurance.
Data are presented as median (interquartile range).
* Statistical significance with $P < .05$.

Table 3
Number and type of instrument trays by groups.

Instrument trays	PSG-SUI (n = 78)	PSG-CVI (n = 111)	CVG-CVI (n = 141)	CVG-SUI (n = 74)	*P*	All trays (n = 404)
Base	0	6 (5.4)	34 (24.1)	1 (1.4)	<.0001*	41 (10.1)
Femur	2 (2.6)	33 (29.7)	33 (23.4)	2 (2.7)		70 (17.3)
Patella	38 (48.7)	34 (30.6)	39 (27.7)	36 (48.6)		147 (36.4)
Tibia	3 (3.8)	34 (30.6)	34 (24.1)	1 (1.4)		72 (17.8)
Efficiency	33 (42.3)	1 (0.9)	1 (0.7)	33 (44.6)		68 (16.8)
Other	2 (2.6)	3 (2.7)	0	1 (1.4)		6 (1.5)

Base: generic instruments.
Femur: femoral ancillary, cutting guides, trial implants.
Patella: patella ancillary, patella cutting guide or reamer, trial implants.
Tibia: tibial ancillary, ancillary, cutting guides, trial implants.
Efficiency: generic instruments selected specifically for TKA using SUI.
Other: other tray used for the surgical intervention.
Data are presented as numbers (percentage).
* Statistical significance with $P < .05$.

imputations, maximum number of iterations: 30). The data were recorded anonymously in Excel 2016 (Microsoft, Richmond, WA). All the data were analyzed and graphs were created with R version 3.3.3 (2017-03-06) software from the R Foundation for Statistical Computing (Platform: x86 64-pc-linux-gnu; 64-bit) (http://www.R-project.org/), with significance defined as a P value < .05. Additional packages used were mice, Visualization and Imputation of Missing Value, ggplot2, xtable, chron, gmodels, and plyr.

Results

The median operating time was 80 minutes (Q1-Q3: 73-90) (Table 2). The operating time was significantly increased for the SUI group compared to that of the CVI group (median SUI: 83 minutes vs median CVI: 78 minutes, +5 minutes, $P = .0072$). There was no significant difference between the PSG and the CVG in terms of the operating time (median: 80 minutes for both groups, $P = .83$). Per-group analysis revealed a significant difference in favor of the CVG-CVI and PSG-CVI groups (median: 78 minutes) over the CVG-SUI (median: 82 minutes) and the PSG-SUI groups (median: 83 minutes) ($P = .047$).

The median scrub nurse time was 106 minutes (Q1-Q3: 98-119) and comparable for all groups ($P = .11$).

The median room occupancy time was also comparable for all groups (114 minutes, Q1-Q3: 104-126) ($P = .078$).

The median sterilization time was 1261 minutes (Q1-Q3: 934-1603). It was significantly in favor of SUI (median: 936 minutes) compared with CVI (median: 1565 minutes) (+629 minutes, $P < .0001$). The sterilization times were comparable between the PSG (median total sterilization time per patient: 1343 minutes) and the CVG (median: 1188 minutes) ($P = .28$). The median time for surgical instrument cleaning was 14 minutes. It was significantly in favor of SUI (median: 9 minutes) compared with CVI (median: 21 minutes) ($P < .0001$). No significant difference was found between the PSG (median: 13) and the CVG (median: 14) ($P = .89$).

Per-group analysis also showed a significant difference in the median sterilization time among the types of knee replacement, with procedures performed with conventional cutting guides and SUI (CVG-SUI) being the least time-consuming ones ($P < .0001$).

The total number of instrument trays used and sterilized was 404 for 136 patients (Table 3): 252 in the CVI group and 152 in the SUI group ($P < .0001$) and 215 in the CVG group and 189 in the PSG group ($P = .0006$). Per procedure type, the mean number of instrument trays used was 2.3 for the PSG-SUI group, 3.2 for the PSG-CVI group, 2.2 for the CVG-SUI group, and 4.1 for the CVG-CVI group.

After 2 months, no significant difference was observed among the CVG-CVI, CVG-SUI, PSG-CVI, and PSG-SUI groups in terms of the alignment, the OKS, and the KSS ($P = .24$, .39, and .079, respectively) (Table 4).

Discussion

It is now widely accepted that PSGs are comparable to conventional cutting guides in terms of alignment and clinical outcomes [11,12,18–22], and our results are consistent with the literature in this regard. Although there was a significant difference in the postoperative alignment and the KSS functional score between the CVG group and the PSG group, there was no clinically relevant difference (median 180° vs 179° and median 93 vs 92, respectively). However, the use of PSI is of great interest when conventional intramedullary guides cannot be used, for instance, when the femoral anatomy has been altered, such as with a femur with a long-stemmed hip prosthesis or with a femoral fracture malunion.

A recent study based on Bayesian statistics to estimate the likelihood that a new trial would demonstrate the efficacy of PSG over CVG concluded that only an overly-optimistic effect size associated with unrealistic trial design parameters could conceivably change the evidence obtained to date [23]. However, to the best of our knowledge, only a few studies to date have focused on associated SUI [12–14], and none of them evaluated the OR or the CSSD efficiency.

The sterilization time was significantly reduced when SUI was used compared to CVI, which is a novel finding. This can be explained by the fact that the number of instrument trays used was significantly reduced. These data are of considerable interest to health facilities in which sterilization is carried out separately from the OR. SUI allows the instrumentation set to be immediately available, without being encumbered by CSSD delays. Moreover, since the median duration of the cleaning of surgical instruments is reduced when SUI is used, the nurse time and availability are, therefore, increased. The impact on safety is hard to evaluate, but SUI could be associated with a reduced risk of infection as the instruments are disposed of after the surgical procedure [13].

In addition to the fact that the sterilization process is time-consuming, it is an important aspect of being able to safely perform a surgery, as substandard equipment or technology can lead to surgical errors and adverse events. Previous studies have reported that equipment-related errors accounted for a median of 23.5% of all errors [24] in the OR and that the unavailability of surgical instruments represented approximately 40% of all equipment-related errors [25]. An independent audit in our CSSD

Table 4
Postoperative data of patients by groups at month 2.

Characteristics	PSG-SUI (n = 34)	PSG-CVI (n = 34)	CVG-CVI (n = 34)	CVG-SUI (n = 34)	P^*	All patients (n = 136)
HKA, median (Q1-Q3)	179 (178-181)	179 (178-181)	180 (178-182)	180 (178-182)	.24	180 (178-182)
Deformation					.46	
Varus	6 (18.2)	5 (16.1)	2 (6.7)	4 (13.8)		17 (13.8)
Aligned	25 (75.8)	24 (77.4)	24 (80.0)	19 (65.5)		92 (74.8)
Valgus	2 (6.1)	2 (6.5)	4 (13.3)	6 (20.7)		14 (11.4)
Oxford, median (Q1-Q3)	41 (38-44)	43 (38-45)	43 (39-45)	42 (37-45)	.39	42 (38-45)
KSS, median (Q1-Q3)	91 (87-95)	94 (90-96)	93 (90-95)	93 (90-96)	.079	93 (89-96)

HKA, hip-knee-ankle angle.
Varus: HKA <177°.
Aligned: 177° ≤ HKA ≤ 183°.
Valgus: HKA >183%.
Data are presented as median (interquartile range) or numbers (percentage).
* Statistical significance with $P < .05$.

reported a noncompliance rate of up to 25% after sterilization. In most of the cases, this was an instrument of minor importance although it also sometimes involved a key instrument for the procedure. As SUI sets are fully equipped with all the necessary ancillary items, this issue can readily be resolved as all key instruments for the procedure are provided with the SUI kit.

A recent study has shown that SUI may provide a benefit to the patient by potentially decreasing the risk of infection and by reducing the overall hospital costs [13]. The infection rate can be reduced in the OR by several factors associated with SUI. The preoperative tomodensitometry for PSG manufacturing also provides reliable sizing information that allowed to determine the definitive implant size in advance. In the study facility, definitive implants were stored outside the OR. Hence, definitive implants could be brought into the operating theater before the surgery started, based on the preoperative planning. This reduces the number of times someone enters or exits, thereby helping maintain the positive pressure of the environment [26].

It is of interest to evaluate whether the time savings in CSSD observed with PSG and SUI are associated with cost savings. Siegel et al. [13] reported cost savings of $480-$600 with single-use vs conventional instrumentation for TKAs, based on measurements of the resource requirements and costs associated with OR turnover and tray sterilization. They also reported significantly fewer infections with SUI. In a multisite simulation study (200 sites, 500 cases per site), Goldberg et al. used a cost-modeling study to evaluate potential logistic and economic benefits of single-use instruments [27]. They analyzed variables related to TKA costs and logistics (OR turnover time, tray sterilization, tray management time, and 90-day infection rates). They reported an estimated cost savings of $994 per case. The largest driver for cost savings was tray sterilization, and sites with higher staff wages and sterilization costs would benefit from a greater probability of achieving cost savings. This finding is consistent with our results regarding sterilization times and volumes. Accordingly, for a high-volume department, the cost of SUI and/or a PSG ancillary could easily be offset by the cost savings associated with their use.

This study has several limitations. First, the study design and instrumentation availability did not allow a randomized controlled trial to be carried out. Nevertheless, the groups were comparable preoperatively, and they were operated on at different times with 2 separate evaluation phases per group. Furthermore, the primary study endpoint was an objective assessment, recorded by an independent examiner. Second, although it has been used for several years before this study, the SUI set was still under minor development while the study was being carried out, and it could be argued that all the patients in the SUI groups did not undergo the exact same surgery. Indeed, the engineers adjusted the instrumentation sets by incorporating feedback from the surgeons. However, these technical improvements of the disposable ancillary were minor, and the participating surgeons always had the opportunity to switch to CVG in case this was required intraoperatively. Third, the postoperative alignment only focused on coronal alignment. As shown in other studies, even though there can be differences in the tibial slope and femoral flexion in the lateral view, there is no associated clinically significant effect [27], and this is why we did not perform this analysis.

Conclusions

PSI and SUI are comparable to CVI in terms of clinical and radiological outcomes. SUI lowers the number of instrumentation trays and the sterilization time in primary TKAs, and it allows the instrumentation set to be immediately availability, without being encumbered by potential delays with CSSD. The increase in surgical time was not considered clinically significant as it would not allow another surgery to be performed (+5 minutes), and the need to switch from patient-specific to single instrumentation, based on the surgeon's assessment, can arise in any surgery. It would be desirable, however, if the manufacturers of SUI would find ways to reduce their cost or to assess by further analysis if savings could be made in the health-care facilities, especially in CSSDs.

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Conflicts of interest

Pr. P. Anract receives personal fees from Medacta during the conduct of the study and personal fees from Grunenthal and Mathys outside the present work. Pr. D. Biau receives personal fees from Medacta during the conduct of the study and personal fees from Stryker outside the present work. Pr. M. Hamadouche receives personal fees from Medacta SA outside the submitted work. The other 2 authors declare no potential conflicts of interest.

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References

[1] Ethgen O, Bruyère O, Richy F, Dardennes C, Reginster J-Y. Health-related quality of life in total hip and total knee arthroplasty. A qualitative and systematic review of the literature. J Bone Joint Surg Am 2004;86-A:963–74.
[2] AOA Australian Orthopaedic Association. National joint replacement registry. Hip, Knee and Shoulder Arthroplasty; 2017. https://aoanjrr.sahmri.com/.

[3] Cram P, Lu X, Kates SL, Singh JA, Li Y, Wolf BR. Total knee arthroplasty volume, utilization, and outcomes among Medicare beneficiaries, 1991–2010. JAMA 2012;308:1227–36. https://doi.org/10.1001/2012.jama.11153.
[4] Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am 2007;89:780–5. https://doi.org/10.2106/JBJS.F.00222.
[5] Victor J, Dujardin J, Vandenneucker H, Arnout N, Bellemans J. Patient-specific guides do not improve accuracy in total knee arthroplasty: a prospective randomized controlled trial. Clin Orthop Relat Res 2014;472:263–71. https://doi.org/10.1007/s11999-013-2997-4.
[6] Gøthesen O, Espehaug B, Havelin LI, Petursson G, Hallan G, Strøm E, 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:609–18. https://doi.org/10.1302/0301-620X.96B5.32516.
[7] Novak EJ, Silverstein MD, Bozic KJ. The cost-effectiveness of computer-assisted navigation in total knee arthroplasty. J Bone Joint Surg Am 2007;89:2389–97. https://doi.org/10.2106/JBJS.F.01109.
[8] Nunley RM, Ellison BS, Ruh EL, Williams BM, Foreman K, Ford AD, et al. Are patient-specific cutting blocks cost-effective for total knee arthroplasty? Clin Orthop Relat Res 2012;470:889–94. https://doi.org/10.1007/s11999-011-2221-3.
[9] Jenny J-Y, Miehlke RK, Giurea A. Learning curve in navigated total knee replacement. A multi-centre study comparing experienced and beginner centres. Knee 2008;15:80–4. https://doi.org/10.1016/j.knee.2007.12.004.
[10] Burnett RSJ, Barrack RL. Computer-assisted total knee arthroplasty is currently of no proven clinical benefit: a systematic review. Clin Orthop Relat Res 2013;471:264–76. https://doi.org/10.1007/s11999-012-2528-8.
[11] Abane L, Anract P, Boisgard S, Descamps S, Courpied JP, Hamadouche M. A comparison of patient-specific and conventional instrumentation for total knee arthroplasty: a multicentre randomised controlled trial. Bone Joint J 2015;97-B:56–63. https://doi.org/10.1302/0301-620X.97B1.34440.
[12] Abane L, Zaoui A, Anract P, Lefevre N, Herman S, Hamadouche M. Can a single-use and patient-specific instrumentation be reliably used in primary total knee arthroplasty? A multicenter controlled study. J Arthroplasty 2018;33:2111–8. https://doi.org/10.1016/j.arth.2018.02.038.
[13] Siegel GW, Patel NN, Milshteyn MA, Buzas D, Lombardo DJ, Morawa LG. Cost analysis and surgical site infection rates in total knee arthroplasty comparing traditional vs. single-use instrumentation. J Arthroplasty 2015;30:2271–4. https://doi.org/10.1016/j.arth.2015.05.037.
[14] Mont MA, Johnson AJ, Issa K, Pivec R, Blasser KE, McQueen D, et al. Single-use instrumentation, cutting blocks, and trials decrease contamination during total knee arthroplasty: a prospective comparison of navigated and non-navigated cases. J Knee Surg 2013;26:285–90. https://doi.org/10.1055/s-0033-1333664.
[15] Scuderi GR, Bourne RB, Noble PC, Benjamin JB, Lonner JH, Scott WN. The new knee society knee scoring system. Clin Orthop Relat Res 2012;470:3–19. https://doi.org/10.1007/s11999-011-2135-0.
[16] Murray DW, Fitzpatrick R, Rogers K, Pandit H, Beard DJ, Carr AJ, et al. The use of the Oxford hip and knee scores. J Bone Joint Surg Br 2007;89:1010–4. https://doi.org/10.1302/0301-620X.89B8.19424.
[17] Than P, Szuper K, Somoskeöy S, Warta V, Illés T. Geometrical values of the normal and arthritic hip and knee detected with the EOS imaging system. Int Orthop 2012;36:1291–7. https://doi.org/10.1007/s00264-011-1403-7.
[18] Chareancholvanich K, Narkbunnam R, Pornrattanamaneewong C. A prospective randomised controlled study of patient-specific cutting guides compared with conventional instrumentation in total knee replacement. Bone Joint J 2013;95-B:354–9. https://doi.org/10.1302/0301-620X.95B3.29903.
[19] Voleti PB, Hamula MJ, Baldwin KD, Lee G-C. Current data do not support routine use of patient-specific instrumentation in total knee arthroplasty. J Arthroplasty 2014;29:1709–12. https://doi.org/10.1016/j.arth.2014.01.039.
[20] Roh YW, Kim TW, Lee S, Seong SC, Lee MC. Is TKA using patient-specific instruments comparable to conventional TKA? A randomized controlled study of one system. Clin Orthop Relat Res 2013;471:3988–95. https://doi.org/10.1007/s11999-013-3206-1.
[21] Abdel MP, Parratte S, Blanc G, Ollivier M, Pomero V, Viehweger E, et al. No benefit of patient-specific instrumentation in TKA on functional and gait outcomes: a randomized clinical trial. Clin Orthop Relat Res 2014;472:2468–76. https://doi.org/10.1007/s11999-014-3544-7.
[22] Kotela A, Lorkowski J, Kucharzewski M, Wilk-Frańczuk M, Śliwiński Z, Frańczuk B, et al. Patient-specific CT-based instrumentation versus conventional instrumentation in total knee arthroplasty: a prospective randomized controlled study on clinical outcomes and in-hospital data. Biomed Res Int 2015:165908. https://doi.org/10.1155/2015/165908.
[23] Biau DJ, Boulezaz S, Casabianca L, Hamadouche M, Anract P, Chevret S. Using Bayesian statistics to estimate the likelihood a new trial will demonstrate the efficacy of a new treatment. BMC Med Res Methodol 2017;17:128. https://doi.org/10.1186/s12874-017-0401-x.
[24] Weerakkody RA, Cheshire NJ, Riga C, Lear R, Hamady MS, Moorthy K, et al. Surgical technology and operating-room safety failures: a systematic review of quantitative studies. BMJ Qual Saf 2013;22:710–8. https://doi.org/10.1136/bmjqs-2012-001778.
[25] Wubben I, van Manen JG, van den Akker BJ, Vaartjes SR, van Harten WH. Equipment-related incidents in the operating room: an analysis of occurrence, underlying causes and consequences for the clinical process. Qual Saf Health Care 2010;19:e64. https://doi.org/10.1136/qshc.2009.037515.
[26] Bullock MW, Brown ML, Bracey DN, Langfitt MK, Shields JS, Lang JE. A bundle protocol to reduce the incidence of periprosthetic joint infections after total joint arthroplasty: a single-center experience. J Arthroplasty 2017;32:1067–73. https://doi.org/10.1016/j.arth.2016.11.028.
[27] Goldberg TD, Maltry JA, Ahuja M, Inzana JA. Logistical and economic advantages of sterile-packed, single-use instruments for total knee arthroplasty. J Arthroplasty 2019;34:1876–83. https://doi.org/10.1016/j.arth.2019.03.011.