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CASE REPORT

Single-Use and Reusable Instruments for Total Knee Replacement: A Comparison of Clinical Performances

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Abstract

Introduction: The rise in life expectancy has led to an increasing number of medical interventions, with total knee arthroplasty (TKA) being a prime example. In response to this growing demand, single-use instrumentation (SUI) has been market to address the need for readily available surgical tools, thus expanding their adoption across care units. While these instruments have the potential to mitigate procedural costs, minimize cross-contamination risks and streamline surgical workflow, their clinical efficacy compared to conventional reusable instruments (RI) remains understudied.

Purpose: This study presents a prospective comparative case series evaluating the clinical and radiographic outcomes associated with SUI versus RI in primary TKA, with a focus on alignment, early functional recovery, and perioperative parameters.

Methods: We conducted a prospective case series including 20 consecutive patients undergoing primary TKA. Participants were stratified into two groups: one receiving surgery with RI and the other with SUI. All procedures were performed using the same prosthetic model and surgical technique, with the sole difference being the type of surgical instrumentation. Clinical outcomes were assessed at 3 and 12 months post-operatively, including hip-knee angle (HKA) as well as functional scores (Knee Society Score, Knee Injury and Osteoarthritis Outcome Score, and Short-Form 12). Additional data included intraoperative time and length of hospital stay. The analysis was primarily descriptive, given the limited sample size.

Results: Both groups demonstrated comparable radiographic and clinical outcomes. At one-year, mean HKA was 177.8° ± 3.4° in the RI group and 175.8° ± 4.4° in the SUI group ($p = 0.270$). Operative durations were also similar, with the RI group averaging 58.5 ± 8.8 minutes and the SUI group averaging 65.0 ± 10.8 minutes ($p = 0.158$). Both groups had similar hospital stays. At 3 months, the RI group showed significantly higher KSS; however, this difference was not observed at one year, where functional outcomes converged across all measured scores. No intraoperative or postoperative complications were reported in either group

Conclusion: The clinical and functional outcomes evaluated in this study show that both SUI and RI achieved equivalent performances. These findings support the feasibility and safety of SUI as an alternative to conventional instruments for TKA. Larger, randomized studies are warranted to confirm these observations and better define the role of SUI in TKA.

Keywords

Total knee arthroplasty, Reusable instruments, Single-use instruments, HKA angle

Introduction

Total knee arthroplasty (TKA) is a well-established and effective treatment for advanced osteoarthritis, providing significant pain relief and restoring joint function. With an aging global population and rising obesity rates, the incidence of osteoarthritis is expected to escalate, thereby driving a surge in TKA procedures [1,2]. Concurrently, advancements in both surgical techniques and implant technologies-particularly those designed for greater longevity-have broadened the indications for TKA to younger, more active patients with

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higher physical demands [1,3]. This growing demand for TKA procedure, along with the rising use of premium-bearing implants designed for greater longevity, has placed additional financial pressure on healthcare systems [3] and imposed the need to optimize operative efficiency, including reduction in surgical time and equipment inventory while maintaining high-quality care [4,5].

Patient-specific instrumentation (PSI) and single-used instruments (SUI) are both recent polymer-based solutions that can be used in combination to address these needs. PSI, such as customized 3D-printed cutting guides, are preoperatively designed from computed tomography or magnetic resonance imaging data to precisely fit the patient's anatomy [4,6,7], thereby improving the accuracy of the bone resection [8]. This solution is frequently being used in conjunction with SUI sets which require fewer instruments as the procedure is tailored for a specific implant size and are delivered sterile.

While conventional TKA relies on multiple reusable, metallic instruments that require meticulous sterilization and maintenance between procedures, polymer-based SUI offer immediate readiness obviating the need for reprocessing or upkeep [9-11]. These instruments have gained attention for their potential to eliminate sterilization-related costs, reduce setup and packaging time [12] and streamline surgical workflows [13]. Additionally, SUI are praised for minimizing the risk of cross-contamination [12,14,15].

Although the economic and logistical advantages of SUI are well-documented [8,12,13,16-18], their clinical performance remains insufficiently explored. Published studies investigating disposable systems have focused on PSI whereas fewer data are available on standard SUI sets used for routine bone preparation and implant positioning [18-22]. This comparative case series assesses whether the use of SUI is associated with comparable clinical and functional outcomes to those obtained with conventional reusable instruments.

Materials and Methods

Study design

We conducted a prospective, observational, single-center, non-randomized, comparative case series. The primary aim was to compare the clinical outcomes of patients undergoing TKA using RI vs SUI. The second objective was to evaluate the operative time with both surgical sets. Twenty patients were enrolled in this study between March 2016 and March 2018, divided equally into two consecutive groups: RI and SUI. The follow-up visits were scheduled at 3 and 12 months post-operation. Ethical approval was obtained from the local institutional review board (IRB00008526). The inclusion criteria were: patients aged between 45 to 90 years old, requiring a primary TKA, coronal plane deformity <15° and health insurance coverage. The exclusion criteria were a history of surgical site infection and knee tumor.

Description of implants, ancillaries and surgical technique

The GM efficiency set is delivered pre-packaged and terminally sterile. The set contains the essential instruments for tibial and distal femoral resections, as well as implant site preparation. This includes alignment guides, cutting block fixation systems, resection verification tools, and spacer components for accurate gap assessment. The operations were performed by a senior surgeon, familiar with the knee implant and both types of surgical sets. Each patient received the same implant-Global Medacta Knee Sphere®, (Medacta International SA, Castel San Pietro, Switzerland)-a posterior-stabilized, fixed-bearing, all-cemented total knee prosthesis with patellar resurfacing. The objective was to achieve coronal plane alignment of the lower limb, with the femoral and tibial components oriented perpendicular to their respective mechanical axes. All bone resections were performed with conventional GMK-Sphere tools, utilizing an intramedullary rod for femoral guidance and an extramedullary rod for tibial guidance. The only difference between the groups was the instrument set: SUI used GMK® Efficiency, while RI used GMK® Sphere; both manufactured by Medacta.

Data collection

Clinical and functional outcomes were recorded preoperatively, then at 3 and 12 months post-intervention. The hip-knee-ankle (HKA) angle was measured from a digitized full-length, weight-bearing anteroposterior radiographs, using a radiological measurement software. The HKA angle was defined as the angle formed between the mechanical axis of the femur (center of femoral head to knee center) and the mechanical axis of the tibia (knee center to center of the talus) [23]. An HKA angle > 180° indicated valgus alignment, while an angle < 180° indicated varus. Mechanical axis alignment (MAA) was calculated based on the HKA angle as follows: MAA = HKA-180° [22,23]. Lateral distal femoral angle (LDFA) was measured as the angle formed between the distal femur joint line of the femur and the anatomic axis of the femur, in the frontal plane, and the medial proximal tibial angle (MPTA) was considered as the angle formed between the mechanical axis of the tibia and the tibial knee joint line in the frontal plane. Functional scores were evaluated using knee Society Score (KSS) [24], Knee Injury and Osteoarthritis Outcome Score (KOOS) [25], and Short-Form-12-health survey (SF-12 survey) [26]. Postoperative complications, operative time and length of hospital stay were also recorded. The operative time was measured by a dedicated nurse, but the instrument setup time was not included.

Statistics

Statistical analysis was performed using XLSTAT 2025 (Addinsoft, Paris, France). Continuous variables were expressed as mean ± SD and range. To assess the functional score difference between baseline and last follow-up, given the non-normal distribution of this variable, we applied the Wilcoxon signed-rank test for paired variables. Between-group comparisons were performed using the Mann-Whitney test for continuous variables and Fisher's exact test for categorical variables. Statistical significance was set at $p < 0.05$.

Results

Ten patients were included in each group. Demographic, preoperative clinical, and functional characteristics are summarized in (Table 1). The two groups were comparable at baseline, with no significant differences except for gender distribution ($p < 0.05$; Table 1) and the pre-intervention SF-12 Physical Component Score (PCS) ($p = 0.012$; Figure 1). All patients underwent surgery for gonarthrosis, except one in the SUI group who was treated for a post-traumatic condition. Only one patient in the RI group had a history of prior surgery on the operated knee.

Regarding postoperative radiographic outcomes, LDFA values were significantly higher in the SUI group than in the RI group at both 3 and 12 months (3M: 84.6° ± 1.9° vs. 88.2° ± 3.8°; 12M: 84.1° ± 2.5° vs. 87.7° ± 3.9°; Table 2). Flexion angles also differed between groups (Figure 2 and Figure 3): they were significantly lower in the SUI group at 3 months (104° ± 15.8° vs. 116° ± 8.5° in the RI group), with a trend toward significance at 12 months ($p = 0.054$; Table 2). At 12M, no significant differences were observed for HKA, MPTA, or knee extension.

Functional outcomes analysis revealed a significantly higher KSS in the RI group at 3 months ($p < 0.05$; Figure 1) although by 12 months both groups demonstrated comparable results. KOOS scores at 3 months followed a similar pattern, with higher scores in the RI group, but the difference did not reach statistical significance ($p = 0.067$; Table 2).

The operative time was comparable in both groups, averaging 58.5 ± 8.8 min in the RI group and 65.0 ± 10.8 min the SUI group ($p = 0.158$; Table 1). The mean length of hospital stay was also comparable (RI: 6.9 ± 3.1 days; SUI: 6.8 ± 2.0 days; $p = 0.934$), indicating equivalent recovery durations. No complications were reported in either group during the entire follow-up period.

Discussion

With the advent of 3D printing, patient-specific and disposable instruments have gained considerable attention in orthopedic surgeries. While the economic advantages and improvements in surgical workflow associated with these techniques in TKA are well documented [8,12,13,16,17], clinical outcomes have been more extensively evaluated for PSI [18-22]. Some studies report that PSI have no significant impact on alignment outliers [20] while others observed improved precision [27,28]. On the other hand, evidence on

Table 1: Comparison of preoperative data, expressed as mean ± SD (ranges).

Variable	RI group (n = 10)	SUI group (n = 10)	p-value
Age at surgery	68.5 ± 6.5; (53.2-78.1)	65.4 ± 8.4; (51.7-80.5)	0.374
Gender:			<0.05
Male	6	3	
Female	4	7	
BMI (kg/m²)	29.9 ± 5.0; (20.8-38.7)	35.1 ± 6.1; (29.3-50.3)	0.053
HKA (°)	173.1 ± 6.2; (164.0 -184.0)	173 ± 8.2; (158.0-187.0)	0.976
LDFA (°)	88.6 ± 7.3 (83-102)	87.9 ± 5.9 (81-98)	0.816
MPTA (°)	88.5 ± 2.6 (84.0 – 92)	88.7 ± 4.2 (84.0-97.0)	0.900
Flexion (°)	104.0 ± 9.7; (90.0-120.0)	101.1 ± 18.3 (70-130)	0.668
Extension (°)	1.0 ± 7.0 (-5.0-20.0)	2.2 ± 8.7 (-10-20)	0.739
Operative time (min)	58.5 ± 8.8; (50.0-70.0)	65.0 ± 10.8; (50.0-90.0)	0.158
Hospital stay (days)	6.9 ± 3.1; (4.0-12.0)	6.8 ± 2.0; (4.0-10.0)	0.934

HKA: Hip-Knee-Ankle; LDFA: Lateral Distal Femoral Angle; MPTA: Medial Proximal Tibial Angle

Table 2: Comparison of the postoperative clinical and functional outcomes for reusable instruments (RI) and single use instruments (SUI). Data are expressed as mean ± SD; median (ranges).

	At 3 months			At 12 months		
Variable	RI	SUI	P-value	RI	SUI	P-value
HKA (°)	NA	NA		177.8 ± 3.4; (172.0-183.0)	175.8 ± 4.4; (168.0-181.0)	0.270
LDFA (°)	84.6 ± 1.9; (83-88)	88.2 ± 3.8; (85-97)	0.020	84.1 ± 2.5; (81-88)	87.7 ± 3.9; (83-97)	0.034
MPTA (°)	87.4 ± 0.9; (86-89)	87.7 ± 2.4; (84 -92)	0.801	87.6 ± 1.6; (85.0-90.0)	87.4 ± 2.1; (85.0 -92.0)	0.902
Flexion (°)	116.5 ± 8.5; (100-130)	104.0 ± 15.8 (80-120)	0.041	118.3 ± 5.6 (110.0-125.0)	108.9 ± 12.4 (90-120)	0.054
Extension (°)	-5.0 ± 6.7; (-15-0)	-6.0 ± 9.4; (-20-10)	0.786	-3.3 ± 5.6 (-15.0-0.0)	-1.7 ± 3.5 (-10.0-0)	0.461

NA: Not Available

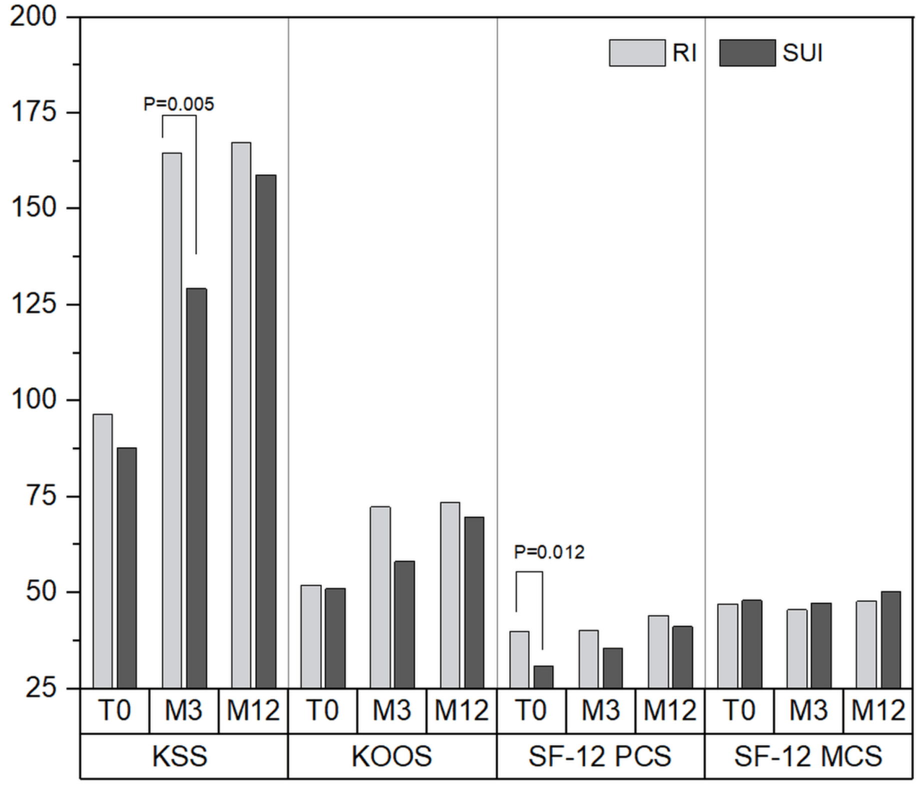

Figure 1: Knee functional scores for reusable instruments (RI) and single-use instruments (SUI) groups at different time points. PCS: Physical Component Score; MCS: Mental Component Score.

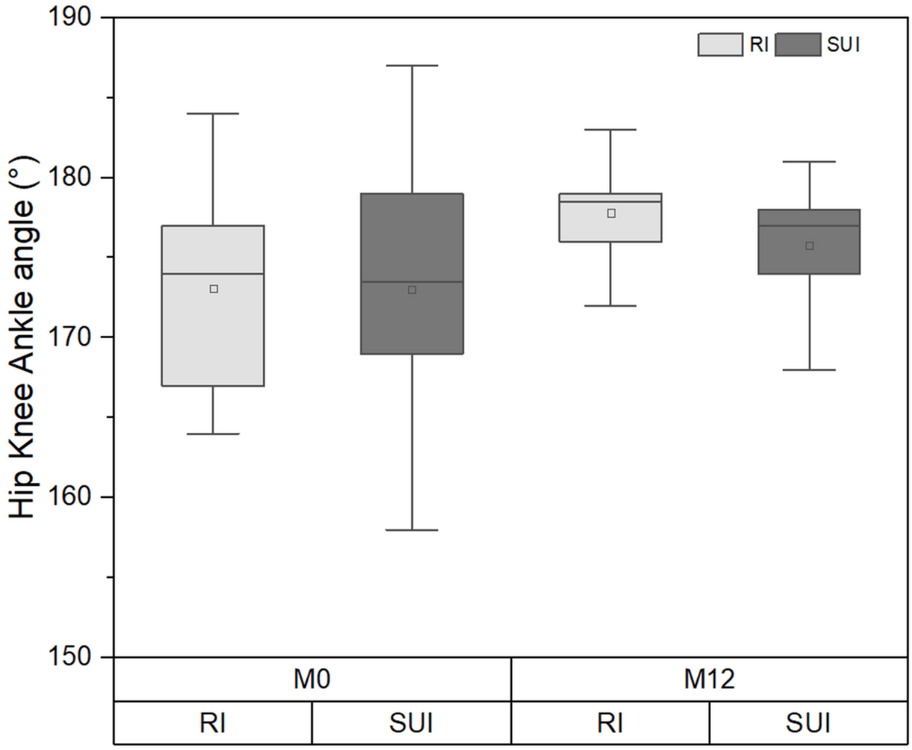

Figure 2: Hip knee ankle (HKA) angles of the reusable instruments (RI) group and the single use instrument (SUI) group; preoperatively and at 12 months of follow-up.

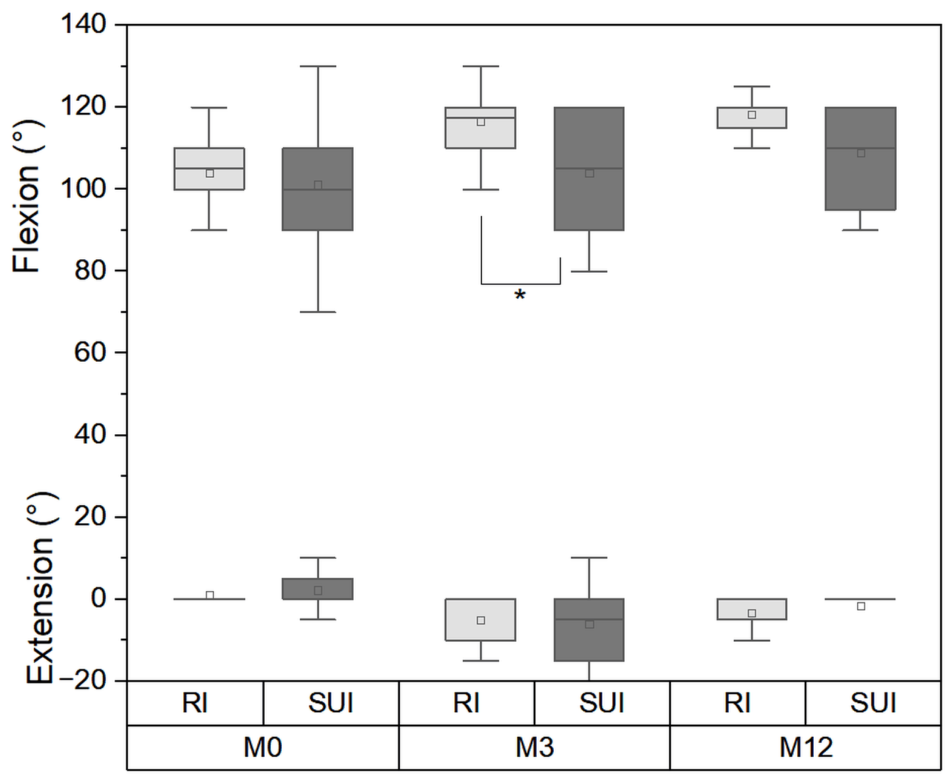

Figure 3: Flexion and extension angles at different time points; (*p = 0.041).

the performance of SUI alone remains limited, as most studies assessing SUI have included PSI in their comparisons. The main objective of this study was to evaluate the efficacy of SUI in comparison to RI, by assessing clinical outcomes in patients undergoing TKA.

Achieving a stable knee with appropriate component alignment is supposed to be warrant of successful clinical outcomes and implant survivorship [29,30]. In fact, alignment errors greater than 3° are associated with more rapid failure and poorer functional outcomes [30,31]. Therefore, assessment of lower limb alignment represents a key parameter for evaluating the performance of different surgical instrumentation systems. In the present study, although the LDFA was higher in the SUI group at both 3 and 12 months, no significant difference was observed in the overall mechanical alignment (HKA angle) between the groups. This suggests that the variation in distal femoral alignment did not substantially impact the mechanical axis of the limb.

Abane, et al. [22] have also evaluated the component alignment of conventional TKA instruments and SUI but with a follow-up of 3 months. Similar to our study, patients in the SUI group were assigned consecutively without randomization. At 3 months post-operation, the authors found an HKA angle of 179.8 ± 3.1° for the conventional group and 178.3 ± 2.5° for the SUI group, at 3 months post-operation. In contrast to our findings, the SUI group in their study had a lower HKA angle compared to the RI group, suggesting a tendency toward varus alignment. However, although this difference reached statistical significance, it was considered clinically negligible. The authors suggested that this observation might be related to the inherent elasticity of the SUI polymer.

Similarly, Gaukel, et al. [19], in a retrospective study, compared conventional instrumentation with PSI, including CT-based cutting guides. They reported that patient-specific cutting blocks enabled accurate postoperative alignment and mechanical axes with few outliers (>3°), and that SUI were not inferior to standard instrumentation.

Regarding range of motion, patients in the RI group achieved greater postoperative knee flexion than those in the SUI group, despite no preoperative difference. Knee flexion ≥110° is generally considered necessary for activities of daily living such as deep knee bending [32]. However, this result should be interpreted with caution, as postoperative flexion is influenced by multiple factors, including rehabilitation protocols and patient adherence to physical therapy [33].

In terms of functional outcomes, our results showed significant differences in KSS at 3 months, with the RI group demonstrating superior functional performances. However, by the end of the follow-up period, both groups achieved comparable results, suggesting that recovery trajectories ultimately converged and that reusable and disposable instrumentation yield equivalent long-term functional results. In the existing literature, data on the efficacy of fully disposable TKA instrumentation remains limited. Contrary to our findings, Abane, et al. [22] reported no significant difference in KSS between the SUI and RI groups at 3 months. However, these authors had a larger cohort than this study. Similarly, Attard, et al. [18] observed no significant differences in functional scores at one year of follow-up when evaluating functional outcomes in patients who underwent bone resection using either PSI or conventional equipment using the OKS questionnaire [34]. The authors also highlighted a disparity in group sizes, with 6 patients in the SUI subgroup compared to 23 in the RI group, despite the randomized study design.

No complications or extended hospital stays were observed in either group in our study. This contrasts with findings from a previous study [18] which reported the need for tibial recutting due to inaccuracies associated with the SUI equipment.

Another objective of this study was to assess the duration of the surgical procedure using RI and SUI systems. In our findings, the mean operating time ranged from 58.5 to 65.0 minutes, with no significant difference observed between the two groups. These results are consistent with previous studies, which also reported no substantial variation in surgical duration between SUI and conventional instrument trays; in general time savings associated with disposable equipment are primarily attributed to set-up, clean-up, and instrument counting phases of the procedure [11,12,18].

This study had several limitations that should be acknowledged. The non-randomized design and relatively small sample size may limit the generalizability of the findings. Patients were included consecutively; however the lack of randomization may result in residual confounding. In addition, all procedures were performed using instrumentation from a single manufacturer, which limits the applicability of our findings to other systems and limits broader extrapolation. Radiological evaluation was based on standing full-length anteroposterior radiographs, which may be less precise than computed tomography in assessing component alignment. Despite these limitations, the study offers meaningful preliminary insights. As an exploratory investigation, this study can help clinical decisions and be useful for future, larger-scale randomized studies.

Conclusion

This study provided insights into the reliability of disposable orthopedic instruments in TKA. In our experience, SUI were not inferior to RI in terms of performance as both sets achieved equivalent clinical outcomes, functional recovery, and operative time. The absence of complications further supports the feasibility of SUI as a safe and effective alternative option to conventional instruments for TKA.

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