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Comparison of Polyethylene Thickness between Patient-Specific Templating and Conventional Techniques in Total Knee Arthroplasty

Nader Sherin El Khorazati [1], Ahmed Tamer [1], Mohamed Soliman Kotb [1], Ahmed Toreih[2], Mahmoud A Hafez [1]*

[1] Orthopedic Department, Faculty of Medicine, October 6 University, Giza, Egypt
[2] Orthopedic Department, Faculty of Medicine, Suez Canal University, Ismailia, Egypt
* **Corresponding author:** Mahmoud A. Hafez, **Email:** mhafez@msn.com:, **Phone**: +2 0 100 756 6299

ABSTRACT

Background: Polyethylene thickness in total knee arthroplasty (TKA) can affect outcomes and the need for revision surgery. The thickness of polyethylene is dependent on the level of the proximal tibial cut. Computer-assisted techniques can accurately determine the level of tibial cut and help in bone preservation.

Objective: The aim was to compare the thickness of the polyethylene inserts in patients who have undergone TKA using patient-specific templating (PST) versus conventional instrumentation.

Patients and Methods: We prospectively collected TKA data from the Egyptian Community Arthroplasty Register (ECAR), with controlled age, sex, BMI, deformities, and preoperative knee society score (KSS). The total number included was 315 knees (150 conventional TKA knees and 165 PST knees). All TKAs were done by one surgeon. Statistical analysis was done using Microsoft Excel and R programming language.

Results: The average polyethylene thickness in the conventional and PST groups were 11.6 (SD=2.9) and 11.1 (SD=2.1) mm, respectively, which was not statistically significant. However, there was a significant difference in outliers in favor of PST (maximum thickness was 14 and 20 mm in the PST and conventional groups, respectively). The PST group had more improvement in the KSS (p=0.023).

Conclusion: This study showed that PST reduced the outliers in polyethylene thickness, which helps in the preservation of bone stock and subsequently may improve implant survival. This study may not be representative as the operations were done by one surgeon. Therefore, further studies are required.

Keywords: Total knee arthroplasty; Total knee replacement; Patient-specific instrumentation; Conventional instruments; Polyethylene thickness.

INTRODUCTION

Total knee arthroplasty (TKA), commonly referred to as total knee replacement, is a highly effective surgical procedure designed to reconstruct the knee joint, offering long-lasting pain relief and enhanced functional capacity [1,2].

It is particularly beneficial for individuals suffering from symptomatic osteoarthritis affecting at least two of the three knee compartments who have not responded to conservative treatment. The evolution of TKA dates back to the 1800s, initially involving the use of ivory implants, which were later replaced by metal implants in the 1930s. In the 1950s, the development of a hinged prosthesis emerged, though it was associated with a high failure rate. Since the 1970s, significant advancements have been made in prosthesis design to better mimic the natural anatomy and function of the knee joint, alongside improvements in fixation techniques and bearing surface wear characteristics to enhance longevity [3,4].

Patient-specific instrumentation (PSI) represents a modern approach in TKA, aimed at streamlining the prosthesis implantation process. Customized cutting blocks are created based on a preoperative 3D model generated from CT scans. Achieving a precise surgical plan is vital for successful implantation, as proper knee alignment, gap kinematics, and soft tissue balancing are all contingent on accurate component placement. The PSI guide is tailored to accommodate any deformities or osteophytes and applies preoperative planning for bone resection, considering the predetermined implant size, position, and rotation. This technology provides consistent neutral postoperative alignment, reduces surgical time, and enhances efficiency and cost-effectiveness [5].

Despite significant investment by manufacturers in PSI technology, the literature lacks consensus on its accuracy and reliability, largely due to the limited number of studies conducted on this technique. Further complicating these findings, the thickness of the polyethylene inserts has been assessed for its impact on the long-term survival of joint prostheses [6-8]. However, no definitive evidence currently exists to demonstrate how the PSI technique influences this aspect.

In light of this, our study aimed to compare the thickness of polyethylene inserts in TKA patients using conventional instrumentation versus PST.

PATIENTS AND METHODS

Study design

Data for this study was gathered prospectively from the Egyptian Community Arthroplasty Register (ECAR) over the period from 2007 to 2022 [9,10]. To ensure the quality of reporting, this cross-sectional study was evaluated in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist [11], specifically the version tailored for cross-sectional studies.

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Participants

The study had 315 knees in total, distributed between the two groups (150 conventional instrumentation TKA knees and 165 PST knees). To be included, patients must have had varus knee osteoarthritis, tri-compartmental disease (medial, lateral, and patellofemoral), and been considered for TKA as their final treatment option. Participants were excluded if they had anteromedial knee arthritis, no bone contact in standing weight-bearing scanogram, previous arthroplasty surgery on the same knee, extra-articular deformity, bone defects requiring grafts or blocks, valgus knee osteoarthritis, or severe varus deformity that exceeds twenty degrees.

To alleviate some risk of bias, all surgeries were done by one surgeon, **Hafez, M**. Moreover, all patients had the same preoperative, postoperative, and follow-up protocol.

Outcome measures

The basic characteristics including the age, sex, body mass index (BMI), and preoperative joint deformity of the sample were first summarized. The primary outcome was to compare the polyethylene thickness in cm between the two groups. As for the secondary outcomes, they included comparing the preoperative and postoperative knee society score (KSS) and range of motion (ROM) as well as assessing the complications.

Ethical considerations

Participants were fully informed about the purpose, procedures, potential risks, and benefits of the study before giving their consent to participate. They were also made aware of their right to withdraw from the study at any time without facing any negative consequences. Moreover, researchers ensured that participants' personal information remains confidential and is not disclosed to unauthorized individuals. Data collected during the study were de-identified to protect participants' privacy. Further, researchers took all necessary precautions to minimize potential harm or discomfort to participants during the study. This included using appropriate surgical techniques, monitoring for adverse events, and providing adequate postoperative care. Lastly, this study was conducted per the Declaration of Helsinki, and ethical approval was obtained from the ethical committee of the October 6 University Hospital.

Statistical Analysis

Statistical analysis was conducted using Microsoft Excel and R software. Continuous variables are reported as mean (standard deviation), as well as median and range. Categorical variables are presented as frequencies and percentages. The percentages for sex and sides are calculated based on the total number of patients in each group. Given the normal distribution of the data, Student’s t-test was employed to compare continuous outcomes between the two groups. For categorical variables, the Chi-squared test was used. P values less than 0.05 were considered significant.

RESULTS

The finally included patients were a total of 315 patients, 150 in the conventional group and 165 in the PST group.

The PST group was slightly older by about two years. Both groups had a nearly equal distribution of males and females, with females comprising 74% of the total sample. No statistically significant differences were also found between the two groups regarding the BMI, varus deformity, valgus deformity, preoperative KSS, and preoperative ROM of included patients. However, the PST group had worse preoperative fixed flexion deformity. All the other details about basic characteristics are summarized in **Table 1**.

Table 1. The basic characteristics of the whole sample and both groups.

	Total (N=315)	Conventional (N=150)	PST (N=165)	P-value
Age				
Mean (SD)	61.0 (8.2)	59.9 (6.72)	62.0 (9.32)	0.024*
Median [Min, Max]	60.0 [36.0, 95.0]	60.0 [43.0, 79.0]	60.0 [36.0, 95.0]	
Sex				
Female	234 (74.3%)	119 (78.8%)	115 (70.1%)	0.102
Male	81 (25.7%)	32 (21.2%)	49 (29.9%)	
BMI				
Mean (SD)	36.2 (5.4)	36.1 (5.34)	36.2 (5.45)	0.832
Median [Min, Max]	36.1 [20.3, 53.3]	36.1 [21.5, 53.3]	36.2 [20.3, 52.1]	
Varus deformity				
Mean (SD)	14.1 (6.4)	13.4 (5.62)	14.7 (6.96)	0.078
Median [Min, Max]	10.0 [5.00, 40.0]	10.0 [5.00, 40.0]	15.0 [5.00, 40.0]	
No deformity	12 (3.8%)	7 (4.6%)	5 (3.0%)	
Valgus deformity				
Mean (SD)	20.4 (8.9)	18.6 (6.27)	23.0 (12.0)	0.482
Median [Min, Max]	20.0 [10.0, 40.0]	20.0 [10.0, 30.0]	20.0 [10.0, 40.0]	
No deformity	303 (96.2%)	144 (95.4%)	159 (97.0%)	
Fixed flexion deformity				
Mean (SD)	15.3 (10.8)	16.6 (11.0)	14.2 (10.6)	0.046*
Median [Min, Max]	10.0 [0, 60.0]	15.0 [0, 50.0]	10.0 [0, 60.0]	
Preoperative KSS				
Mean (SD)	31.7 (10.7)	32.9 (10.7)	30.7 (10.5)	0.069
Median [Min, Max]	35.0 [1.00, 49.0]	38.0 [13.0, 49.0]	28.0 [1.00, 49.0]	
Preoperative ROM				
Mean (SD)	77.0 (18.7)	77.2 (18.7)	76.7 (18.7)	0.818
Median [Min, Max]	80.0 [30.0, 125]	75.0 [35.0, 125]	80.0 [30.0, 125]	

SD: standard deviation, ROM: range of motion, KSS: knee society score, *: Statistically significant.

As for the primary outcome, there were no statistically significant differences between the two groups in the polyethylene insert thickness **(Table 2)**. However, the PSI group experienced a better improvement in the KSS. No differences between the two groups were found regarding the improvement in ROM and postoperative complications. However, the conventional group had overall more complications (7.9% vs 3.7%). All specific details about the outcomes are presented in **Tables 3-4**. Lastly, a significant piece of data pertains to the outliers in conventional TKA, which reached a maximum polyethylene length of 20 mm, which is much larger than in PST, which reached a maximum of 14 mm only.

Table 2. The primary outcome of polyethylene thickness in mm.

	Total (N=315)	Conventional (N=150)	PST (N=165)	P-value
Polyethylene size in mm				
Mean (SD)	11.3 (2.5)	11.6 (2.91)	11.1 (2.13)	0.091
Median [Min, Max]	11.0 [6.00, 20.0]	11.0 [6.00, 20.0]	11.0 [6.00, 14.0]	

SD: standard deviation.

Table 3. Postoperative differences in outcomes between the two groups.

	Total (N=315)	**Conventional (N=150)**	**PST (N=165)**	**P-value**
Length of hospital stay				
Mean (SD)	5.5 (2.4)	6.86 (2.86)	4.32 (0.574)	<0.001*
Median [Min, Max]	5.00 [3.00, 17.0]	6.00 [4.00, 17.0]	4.00 [3.00, 7.00]	
Postoperative KSS				
Mean (SD)	97.1 (2.5)	96.9 (2.46)	97.3 (2.53)	0.161
Median [Min, Max]	97.0 [87.0, 100]	97.0 [87.0, 100]	97.5 [89.0, 100]	
Improvement in KSS				
Mean (SD)	65.4 (10.1)	64.1 (10.1)	66.6 (10.0)	0.023*
Median [Min, Max]	62.0 [45.0, 95.0]	59.0 [45.0, 82.0]	69.0 [49.0, 95.0]	
Postoperative ROM				
Mean (SD)	111 (13.3)	111 (13.4)	112 (13.2)	0.251
Median [Min, Max]	110 [60.0, 135]	110 [60.0, 135]	113 [70.0, 130]	
Improvement in ROM				
Mean (SD)	34.9 (16.0)	33.8 (15.0)	36.0 (16.8)	0.213
Median [Min, Max]	35.0 [0, 80.0]	35.0 [0, 70.0]	40.0 [0, 80.0]	

*: Statistically significant.

Table 4. Complications reported in the whole sample and the two groups.

	Total (N=315)	**Conventional (N=150)**	**PST (N=165)**	**P-value**
Complications				
None reported	297 (94.3%)	139 (92.1%)	158 (96.3%)	0.491
Aseptic loosening	1 (0.3%)	1 (0.7%)	0 (0%)	
Drop foot that improved in 6 months	1 (0.3%)	1 (0.7%)	0 (0%)	
DVT	1 (0.3%)	2 (1.3%)	0 (0%)	
Infection	1 (0.3%)	1 (0.7%)	1 (0.6%)	
Instability	2 (0.6%)	1 (0.7%)	0 (0%)	
Mortality	2 (0.6%)	2 (1.3%)	1 (0.6%)	
Periprosthetic fracture and septic loosening	1 (0.3%)	2 (1.3%)	1 (0.6%)	
Periprosthetic fracture of the femur	1 (0.3%)	1 (0.7%)	0 (0%)	
Periprosthetic fracture of the tibia	3 (1.0%)	1 (0.7%)	0 (0%)	
Septic loosening	3 (1.0%)	0 (0%)	1 (0.6%)	
Stiffness, MUA 2 months after surgery, improved completely afterward	1 (0.3%)	0 (0%)	1 (0.6%)	

DVT: deep venous thrombosis, MUA: Manipulation under anesthesia

DISCUSSION

In this paper, we aimed to compare the polyethylene thickness used in conventional versus PST TKA to determine whether either technique can provide more bone stock following TKA. Although we found only a weak statistically significant difference between the two groups for this outcome, we believe that by increasing the sample size, statistical significance in favor of thinner polyethylene insert in the PST technique will be reached. Also, the PST technique had more consistent measurements of the polyethylene thickness, where the range of thickness ranged from 6 to 14 mm for the PST versus 6 to 20 mm for conventional instrumentation. Moreover, the PST group in our study had more improvement in the KSS.

The literature lacks a similar study that compared the polyethylene thickness in different TKA techniques. The focus was always on the overall best thickness of the polyethylene insert, where it is declared that the safest size ranges between 8 and 12 cm [8]. Therefore, the scientific community requires further research about the potential differences in the polyethylene insert size in different TKA techniques and whether this can alter the outcomes.

Although the difference in polyethylene thickness between conventional and PST techniques may not till now prove clinically significant, the preoperative planning feature of the PST technique may provide some benefits for the surgeon. For example, according to the results of a 2022 study, PSI is a helpful method for enhancing the repeatability of the intended tibial rotational orientation in TKA [12]. The researchers of a different study conducted by the Center for Joint Preservation and Replacement, Rubin Institute for Advanced Orthopedics, Baltimore, Maryland, perceive that the excellent intraoperative concordance of the preoperative plan at the default settings with minimal changes was achieved by the design and manufacture of PSI in conjunction with a thorough templating [13].

Contrastingly, regarding clinical and patient-reported outcomes at various postoperative time points (3 months, 6 months, 12 months, and 24 months), a recent systematic review and meta-analysis found no clinical difference between PSI and conventional instrumentation, except for KSS at 24 months, when the PSI was marginally better (MD=2.37, 95%-CI: 0.42-4.31). Nevertheless, the meta-analysis's included studies had small cohort sizes, and prospective research was prone to methodological bias [14]. However, further randomized controlled trials and longitudinal research are needed to validate these findings. Further, there is till now no clear-cut evidence of cost-saving when using the conventional or PSI technique as the implementation can differ from one setting to another [15,16].

This study suffers from some limitations. Firstly, we were not able to investigate the effect of simultaneous versus staged TKA due to sample size constraints. This comparison can be useful to compare various other outcomes like leg length discrepancy. Therefore, researchers may need to focus on this aspect in future studies. Another main issue faced in this study is the lack of literature about polyethylene size differences between conventional instrumentation and PST. This highlights the need for more research about the subject and the importance of this study in shedding some light on the effect of PST on polyethylene insert size and possible clinical correlations.

CONCLUSION

This study, comparing polyethylene size between conventional instrumentation and PST, has shown that PST may not provide bigger bone stock when performing TKA. However, we believe that by increasing the sample size, a clearer picture may be drawn, where PST can provide more consistently perfect-size polyethylene inserts that are no slimmer than 6 mm or thicker than 14 mm. An important piece of data concerns the outliers in conventional TKA, which had a maximum polyethylene length of 20 mm, significantly larger than the maximum of 14 mm observed in PST. Moreover, in our sample, we found that PST may offer better clinical outcomes in terms of better improvement in the KSS. It is, however, recommended that other authors verify the results of this study in the context of implant survivability and more studies with more than one surgeon should be performed to exclude the issue of surgeon experience variance.

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