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Original Research Article

Does patient-specific instrumentation in primary total knee arthroplasty improve long-term satisfaction or function? A randomized trial with a 9-year follow-up

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ABSTRACT

Background: Patient-specific instrumentation (PSI) aims to increase the accuracy of total knee arthroplasty (TKA). However, the long-term benefit compared to conventional instrumentation (CI), is still controversial. This randomized controlled trial compares the long-term outcomes between PSI and CI in TKA.
Methods: Patients submitted to PSI or CI TKA with a minimum follow-up of 8 years were evaluated. Satisfaction levels, forgotten joint score (FJS) and Western Ontario and McMaster university osteoarthritis index (WOMAC) scores were compared. Regarding descriptive statistics, mean, standard deviation and frequencies were obtained. For inferential statistics we used the t test for independent samples the Mann-Whitney test and the Wilcoxon Test.
Results: A total of 50 TKA were included (48% CI; 52% PSI) with an average follow-up time of 9.3 years. At the final follow-up the WOMAC score was similar between groups (p=0.846; CI:26.8±22.5; PSI:26.8±25.3). Similarly, no differences were seen for the FJS (p=0.785; CI:59.6±35.1; PSI:57.1±36.2) or satisfaction (p=0.486; CI:8.1±2.8; PSI:9.1±1.4). However, at the final follow-up, the total WOMAC score had worse results when compared to the previous evaluations (p=0.013 for CI group; p=0.009 for PSI group). No significant differences in the satisfaction levels were detected regarding the initial and final evaluations (p=0.581 for CI group; p=0.936 for PSI group).
Conclusions: Nine years after TKA, PSI and CI patients reported similar levels of satisfaction and functioning. Both groups achieved similar results concerning the WOMAC, FJS scores and satisfaction levels. This study suggests that long-term satisfaction and functioning levels are similar in both PSI and CI.

Keywords: TKA, CI, PSI, Patient satisfaction

INTRODUCTION

While standard TKA is a well-established and reproducible procedure, the average dissatisfaction rate is 10%, which demonstrates the need for improvement.[1] The factors that modulate patient satisfaction after TKA are not fully understood. However, individual variability in knee anatomy in size, coronal alignment and condylar offset have been suggested as predictor factors. These aspects can be adjusted with PSI, which utilizes patient-based

cutting blocks derived from pre-operative images, to approximate the native anatomy of the knee. Moreover, it is likely that customized approaches may lead to a reduction in soft tissue release, blood loss and surgical time. Nonetheless, it is still unclear whether PSI influences functional results or satisfaction levels after knee replacement surgery. Likewise, there is no evidence of long term PSI superiority, mainly due to the lack of prolonged studies. Therefore, the functional outcome and satisfaction levels between patients submitted to either PSI or standard CI were compared in order to understand the potential long term benefits of PSI.

METHODS

Study design

This randomized controlled trial was conducted at hospital particular do Algarve between January 2011 and May 2022 after ethical approval was obtained from the local ethical committee. Two randomized cohorts of 50 patients were initially created using the Rand formula from MS excel version 14.1.0 as previously published.[2] Inclusion criteria were following: adults with end-stage knee osteoarthritis who accepted TKA treatment and consented to enter study. Exclusion criteria were following: patients with previous fractures, ipsilateral limb surgeries, contraindication for MRI, inability to coordinate customized cutting block construction/procedure execution, patient refusal/unreachability, inability to respond, and death, 95 patients with end-stage knee osteoarthritis eligible for TKA were included: 48 were submitted to CI and 47 to PSI. Post-op alignment, surgical time, differences in intraoperative blood loss and length of stay of this cohort were already published.[2] Same cohort was included in this follow-up evaluation, 95 patients submitted to TKA, 50 eligible and agreed to continue in the study (24 submitted to CI and 26 to PSI) (Figure 1).

Surgical procedure

All surgeries were executed by same team of experienced surgeons. Same surgeons approved alignment settings provided by the manufacturer (Smith and Nephew Inc., Memphis, TN, USA) on PSI group, in which the visionaire cutting guidesTM were used. For both groups, mechanical alignment was used. In CI group, alignment was achieved using an intramedullary technique for femoral component, while an extramedullary technique was performed for tibial component. All procedures were performed using standard anteromedial para-patellar approach under spinal blockade and sedation. Legion System™ (Smith and Nephew Inc.) was used in both groups.

Outcomes

Functional scores were collected for all patients: Western Ontario and McMaster university osteoarthritis index (WOMAC) and forgotten joint score (FJS), respectively. These scores were compared between groups at the final follow-up and to results gathered at a shorter timepoint post-op when available. The FJS included 12 questions scored from 0 to 4. The final reported outcome was the score based on the percentage of questions answered. The best possible outcome is 100%, which would represent that the patient is not aware of their affected joint in their daily activities, and worst result is 0%. WOMAC questionnaire consisted of five questions for pain, two questions for stiffness, and seventeen questions for physical function. Each question was scored from 0 to 4. Therefore, the best result would be 0, and the worst result would be a score of 96. Similarly, a satisfaction score (min. 1-10 max.) was collected and compared with previous timepoints for same patients.

Statistical analysis

The Shapiro-Wilk test was performed to access the normal distribution for numerical variables. To compare groups, the t student test or the Mann-Whitney U test were used, according to the normal assumption. The Mann-Whitney U test was used to compare satisfaction, WOMAC and FJS scores between groups.

Related samples Wilcoxon Signed rank test was done to compare initial and final evaluations regarding satisfaction and WOMAC scores. Level of statistical significance considered $p<0.05$. All analyses were performed using SPSS (v. 28.0.11, Chicago, IL, USA) and graphs done utilizing GraphPad Prism (v.8.4.2 for Apple, GraphPad software, San Diego, CA, USA).

RESULTS

The 50 patients (n=24 CI; n=26 PSI) fulfilled the study length with a final follow-up average time of 111.6 (±5.5) months (9.3 years) (Figure 1).

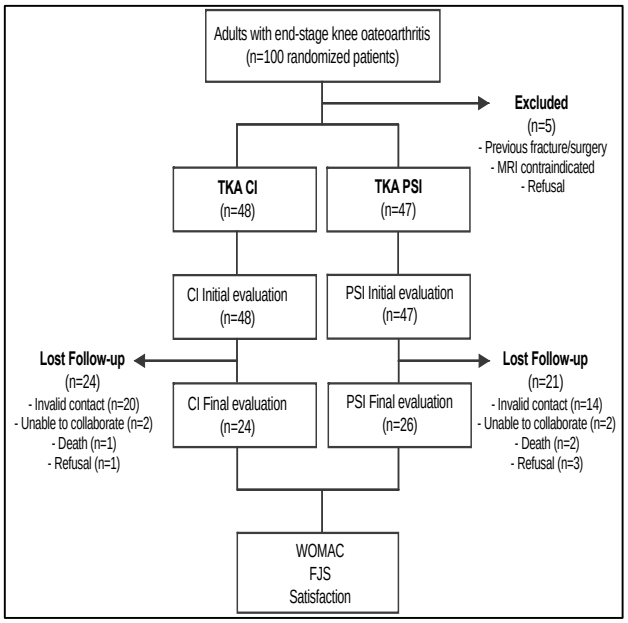

Figure 1: Study design.

A 100 patients with end-stage knee osteoarthritis randomized and proposed for TKA, 95 patients were eligible and underwent surgery (48 with CI and 47 with PSI). Initial evaluation of satisfaction was performed at 83.4 (±9.3) months post-op and at 32.1(±6.1) months for WOMAC. Forty-five patients lost during follow-up (24 CI and 21 PSI). Last evaluation was completed by 50 patients (24 CI and 26 PSI), and satisfaction levels, FJS and WOMAC were performed at 111.6 (±5.5) months post-op.

Demographic characteristics

Most of the patients included were females (CI: 79.2%; PSI:73.1%) and the average age at procedure was 66.9±5.0 years for the CI and 65.7±7.0 years for PSI group.

No statistical differences were found in demographic parameters between 2 groups evaluated (Table 1).

Functional scores

The WOMAC score was collected at the initial post-op [32.1(±6.1) months] and final evaluation [111.6 (±5.5) months post-op]. At the final follow-up, the WOMAC score was similar between groups (p=0.846): 26.8±22.5 for the CI patients and 26.7±25.3 for the patients submitted to PSI (Table 2).

When comparing initial and final scores, the total WOMAC score had worse results when compared to the previous evaluations of the same patient (p=0.013 for the CI group; p=0.009 for the PSI group).

Table 1: Demographic characteristics between the CI and PSI groups.

Variables	CI, n (%)	PSI, n (%)	P value
Gender			
Male	5 (20.8)	7 (26.9)	>0.999
Female	19 (79.2)	19 (73.1)	
Laterality			
Right	15 (62.5)	15 (57.7)	>0.999
Left	9 (37.5)	11 (42.3)	
Age (in years) (Mean ± SD)	66.9 (±5.0)	65.7 (±7.0)	>0.553
Follow-up time (Mean ± SD)	111.7 (±5.7)	111.6 (±5.5)	>0.996

Group characteristics (gender, laterality, age, and follow-up time) are represented for both CI and PSI groups. The t student test was used to compare ages, and the Mann-Whitney U Test was used for the rest of the variables. No statistical differences were obtained between groups regarding gender, laterality, age, and follow-up time.

Table 2: WOMAC and FJS scores between PSI and CI groups.

Variables	CI initial, (n=16)	PSI initial, (n=18)	P value	CI final, (n=24)	PSI final, (n=26)	P value
WOMAC						
Total	11.8 (±15.6)	5.6 (±8.2)	0.463	26.8 (±22.5)	26.7 (±25.3)	0.846
Pain	2.6 (±3.9)	1.4 (±2.7)	0.403	4.6 (±5.3)	5.6 (±6.3)	0.554
Stiffness	0.4 (±1.0)	0.3 (±0.9)	0.883	1.5 (±1.7)	1.2 (±1.9)	0.402
Function	8.8 (±11.2)	3.9 (±5.1)	0.384	20.8 (±17.3)	19.9 (±18.2)	0.712
FJS						
Total (%)	-	-	-	59.6 (±35.1)	57.1 (±36.2)	0.785

Initial and final WOMAC evaluations (total score and score divisions: pain, stiffness, and function) as well as the FJS final score are presented. The CI and PSI initial evaluations are represented on the left panel, and the final evaluation is on the right panel. The Mann-Whitney U test was used to compare FJS and WOMAC between groups. No significant differences were found in the WOMAC and FJS scores between groups at initial or final evaluations.

Table 3: Satisfaction levels between the CI and PSI groups.

Variables	CI initial, (n=24)	PSI initial, (n=26)	P value	CI final, (n=23)	PSI final, (n=25)	P value
Satisfaction	8.0 (±2.5)	9.1 (±1.6)	0.042	8.1 (±2.8)	9.1 (±1.4)	0.486

Satisfaction levels were collected from 24 CI patients and 26 PSI patients (one patient per group did not complete the final satisfaction evaluation: 23 CI; 25 PSI). Mann-Whitney U Test was used to compare FJS and WOMAC between groups. Satisfaction levels were significantly higher in the PSI group at the initial follow-up. No differences were detected at the final evaluation or when comparing the initial and final evaluations for the same patient.

Regarding the FJS score, no differences between groups were seen (p=0.785; CI: 59.6±35.1; PSI: 57.1±36.2) (Table 2).

Although consistent higher satisfaction scores were seen in PSI group, no statistically significant differences were detected between the groups at later time points (p=0.486; CI: 8.1±2.8; PSI: 9.1±1.4) (Table 3) concerning the initial and final evaluation for patients that completed both assessments (p=0.581 for CI group; p=0.936 for PSI).

DISCUSSION

The goal of mimicking the native knee anatomy with customized instrumentation is appealing, especially in optimizing implant positioning, size, and knee alignment, as well as decreasing complication rates, which in turn could lead to higher satisfaction levels.[3] However, the literature does not reach consensus on this topic. Some reports published promising results demonstrating that customized approaches can lead to better limb and implant alignment.[4-6] Furthermore, reduced surgical time was suggested, which was associated with a decreased rate of blood loss and infection.[2,7] Some studies also reported better functional outcomes.[8,9] Nonetheless, these findings have not been consistently reproduced.[10] Recent reviews have tried to consolidate the available data. A meta-analysis that included 13 high-quality randomized control trials concluded that PSI may reduce surgical time and benefit the tibial sagittal component but had no impact on the mechanical axis, femoral or tibial coronal alignment, post-operative function, or the need for blood transfusions.[7] A more recent meta-analysis has also failed to demonstrate functional benefits within the PSI group.[11] Similarly, no differences were found in terms of surgical complications or satisfaction.[10,12-14]

Although several comparative studies have been published, it is evident that most include a short follow-up time (up to 5 years).[7,10,15-20] Therefore, this study aims to fulfill the need for long-term data. To evaluate functional status, we used patient-reported outcome measurements (PROMS): WOMAC and the FJS score. The WOMAC score was developed to reflect the daily limitations of people with osteoarthritis based on the level of pain, stiffness, and function. Our results demonstrated satisfactory WOMAC scores, with no differences seen between groups either at initial or later follow-up, even when considering each of the three subgroups isolated. This result is in line with previous studies but also contradicts previous literature that evaluated shorter time points where WOMAC scores favored the PSI group.[8,11,21] While the observed difference may not be statistically significant, it is noteworthy to mention that the initial WOMAC scores for PSI were comparatively higher. This observation may suggest a potential bias towards utilizing the new approach (PSI) in cases that are considered to have a better prognosis. Consequently, this potential bias could possibly limit the ability to fully appreciate the advantages offered by a more precise technique like PSI. Theoretically, PSI could be more advantageous in complex scenarios.

The apparent individual degradation of WOMAC in our study might be explained by the patients' older age at the later evaluation, which can translate to decreased physical activity and independence in their daily activities. Nonetheless, this result should be further explored since comorbidities do not always correlate with aggravation of the WOMAC.[21] Although the WOMAC is a widely employed tool, it is important to consider its limitations. Examples are the difficulty in delineating a clear differentiation between the function scores and pain scores due to the questionnaire characteristics and the challenge in comparison to other studies due to variability in score implementation and analysis among publications.[22,23] The interpretation of these WOMAC scores is further conflicted by the fact that, based on previous publications, the minimum clinically important difference for WOMAC subgroups varies widely (from 13.3 to 36.0 for pain and 1.8 to 33.0 for function).[24,25] The FJS is another PROM created to access the patient's ability to "forget" their affected joint after surgery. In line with WOMAC score, the FJS scores were similar between PSI and CI groups, which reflects the good correlation between these scores.

Concerning satisfaction, high levels were reported in most patients for the duration of the study. It is noteworthy that at the initial evaluation, significantly higher scores were seen in the PSI group. To detail the reason for this difference, factors that were not included in this study should be considered, such as alignment, implant positioning, time of recovery, patient expectations, and family support. Surprisingly, this difference was no longer seen at later time points, which may suggest that the initial advantage seen in the PSI group could be linked to operative and/or acute post-op care. Another explanation is that, with time, other factors such as age and comorbidities diminished the differences between groups. Furthermore, it is important to consider that there are limitations in accessing satisfaction based on a 1-10 scale question since multiple factors can influence the end result. This can justify some of the discrepancies between functional results and satisfaction levels.[26]

Although more studies are required, our data suggests an initial higher satisfaction score in the PSI group. However, that difference declines over time, with similar long-term satisfaction levels being reported by patients submitted to PSI and CI. Satisfaction levels have been correlated with an increase in the WOMAC scores in the literature, though that data is difficult to access in our study since no pre-operative data were collected.[27] Besides the ones described above, the loss of follow-up for a significant portion of the patients is another study's limitation. This can be partially explained by the patients' age at enrollment, the possible need for additional care throughout the years that motivated relocation, a change of contact, or even the continuation of care at another institution. The inclusion of clinical and radiographic evaluation and its relationship

with functional and satisfaction scores long-term after surgery still needs to be further addressed. Moreover, we did not include complications and readmissions or determine if those had an impact on the outcomes. Nevertheless, our study demonstrates no significant long-term differences between groups.

Our study has the advantage of being a randomized trial where surgeries were performed by the same experienced surgical team, which reduces the potential impact of surgeons on the PROMs.[28] On the other hand, the fact that the team was composed of experienced surgeons may have faded the potential differences between the CI and PSI groups. Although increased total patient costs have been reported with PSI, in our experience, PSI reduces global operating room time, simplifies its logistics, and facilitates the surgical procedure, as reported by Dorling et al.[29] Therefore, in our hands, it has been a valuable tool that may be considered, especially in cases with severe deformities where alignment may be difficult. It is important to note that although there is a lack of long-term evaluation of PSI versus CI patients, the existing evidence is diverging, and thus stronger methodological studies are still needed to verify the long-term outcome and the potential benefit of PSI versus CI TKA.

CONCLUSION

In conclusion, this study comprises one of the longest follow-up series comparing patients submitted to CI and PSI. Even though no significant differences were found between the CI and PSI groups in a long-term evaluation, it is still interesting to see a tendency for higher satisfaction levels in the PSI group.

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