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Original Research Article

Functional evolution in total knee arthroplasty: first and second-generation patient-specific instrumentation compared with conventional instrumentation

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ABSTRACT

Background: This study compares the functional evolution between the first- and second-generation patient-specific instrumentation and conventional instrumentation pre-surgery and the third month post-surgery after TKA. We analyzed the functional outcomes achieved and the absolute gains of each study variable. In addition, we aimed to elucidate the results of the three surgical techniques regarding the surgery length of time, length of hospital stay, percentage drop in hemoglobin (Hg) at 24 h, and hip-knee-ankle angle post-surgery.
Methods: We reported our experience in TKA using PSI Visionaire System® and CI technique in 688 procedures. The patients were divided into first (N=272) and second-generation (N=151) PSI designs. The control group (N=265) underwent TKA with the CI. The instruments for assessing the functioning were: visual analog scale, goniometry, 6-minute walk test (6MWT), and domains of the WOMAC Index.
Results: The functioning achieved three months after surgery was lower in the CI than the first-generation PSI. The respective differences at absolute gains were found in the 6MWT and pain and function WOMAC scores ($p=0.023$, $p=0.049$, and $p=0.018$, respectively). The mean surgical time was higher in the CI compared to PSI designs (both $p<0.001$), and the mean hospital length of stay was higher in the CI compared to second-generation PSI ($p=0.002$). The percentual drop in Hg was higher in the first-generation PSI than with the CI ($p=0.006$).
Conclusions: Three months after TKA, the functioning achieved with the first-generation PSI was greater than the CI. However, the functional results between second-generation PSI and CI were similar.

Keywords: Functioning, Functional outcomes, Patient-specific instrument, Total knee arthroplasty, Knee replacement

INTRODUCTION

Total knee arthroplasty (TKA) is a highly effective procedure with good functional results. During the last decade, the number of TKAs increased significantly because of population aging, the increasing prevalence of obesity, and the effects of leisure activities.[1,2] Conventional instrumentation (CI), the standard option for TKA, uses intramedullary and/or extramedullary alignment systems that rely heavily on visual references, which may even lead experienced surgeons to produce undesired postoperative complications.[3] These devices not only complicate the workflow and prolong surgery time, but they can also increase blood loss and the risk of fat embolism given they are highly invasive.[3]Patient-specific instrumentation (PSI) was developed in recent years and is an alternative for TKA; PSI consists of custom-made blocks for the distal femur and proximal tibia and is designed from pre-operative three-dimensional (3D) computed tomography (CT) or magnetic resonance imaging (MRI) based reconstructions of the knee to improve accuracy, cost-effectiveness in daily use, reduce operating times, and blood loss of TKA.[3] Due to the use of pre-operative 3D imaging, patient-specific cutting blocks must improve rotational component alignment, namely the accurate assessment of landmarks such as the epicondylar axis, trochlear sulcus, tibial tubercle, and tibial crest, which can be used to determine component rotation and is incorporated into the cutting blocks. This preparation can reduce the surgical procedure by as many as 21 steps, which not only increases intraoperative efficiency but improves turnover and setup time because fewer trays need to be processed or opened before surgery.[4] This way, the theoretical advantages of PSI over CI are improved accuracy, reduced proportion of outliers, shorter operating time, and lower costs through improved resource management such as less blood loss (because it avoids violation of the intramedullary canal), reduced hospital length of stay, and faster rehabilitation.[5,6] Nevertheless, the second generation of PSI was developed to improve the fit between the bone and the cut guides. In the first generation, the fit of the cutting blocks was not always perfect, resulting in “floating blocks,” which sometimes forced the PSI technique to be discontinued, leading the surgeon to finish the surgery by the conventional method or cutting with the cutting block positioned incorrectly. This problem is even more frequent on the tibial side. Hence, the second generation was created to reduce or eliminate this issue by increasing the contact area and creating expansions, improving the visibility of the bone surface and joint stability. Additionally, the new PSI system has a new alignment test system, which is easier to use and more reliable. Despite these promising factors, the superiority of PSI remains to be proven, particularly in terms of functioning. Systematic reviews have shown different results and data in the literature is scarce. We found studies where no differences in the results between PSI and CI TKA were found, while other authors have reported better results using PSI[9] or even where the results are worse regarding the use of the same technique.[5-8] In addition to knowing that the results between the first-generation PSI and CI are unclear, we can also say that, to our knowledge, there is no known study comparing the second-generation PSI and CI. Given this scenario, this comparative and longitudinal study sought to analyze and compare the functional evolution between first- and second-generation PSI designs and the CI technique at pre-surgical times and the third-month post-surgery. For this, we analyzed the functional outcomes achieved and absolute gains of each study variable to hypothesize whether the results of PSI systems are more favorable in relation to CI.

METHODS

This observational and retrospective study (level of evidence III) was implemented using data collected from the hospital Particular do Algarve (Faro, Portugal) regarding all patients that underwent TKA between 2011 and 2020. We report our experience in TKA using the PSI and CI techniques in 688 procedures. The PSI system used was the Visionaire® (Smith & Nephew, Memphis, USA). The patients were divided into first- (N=272) and second-generation (N=151) PSI designs. The control group (N=265) underwent TKA with the CI technique. This study was approved by the medical ethical committee of the hospital; patients and medical personnel gave permission to use their data for this study. The dependent variables of this study were knee pain intensity (visual analog scale, VAS), range of motion (knee flexion, goniometry), gait distance (6-minute walk test, 6MWT), and the WOMAC Index; the independent variable is the surgical instrumentation. All patients were evaluated 7-15 days before surgery and after 3 months of follow-up. The sample size consisted of all the patients who had symptomatic arthrosis resistant to conservative treatment (convenience sampling) and underwent TKA at Hospital Particular do Algarve between 2011 and 2020, which amounted to 688 TKA procedures. Exclusion criteria were: previous history of arterial or venous occlusion, preoperative platelet value <150,000/mm^3 and failure to complete the WOMAC Index. All patients were assigned by default to the PSI group. However, whenever technical (inability to perform MRI or poor fitting of the cutting blocks) or logistical (lack of time to do the cutting blocks or delays) constraints occurred, the individual was automatically assigned to the CI group. Since January 2018, we only used the second-generation technique because the first design was discontinued and we were part of the limited market release. The HKA angle was measured by first finding the femoral head center using the oval tool (maximum difference to place an acceptable circle between length and height was 0.1 mm). We placed the center of the circle on the center of the femoral head (point H). Then, at the tibial plateau level, we measured half the length of the tibial plateau and placed the second point of the angle there (point K). Lastly, we placed the last point of the angle on the lowest point of the tibiotarsal joint at the ankle level (point A). Positive angles were valgus and negative ones were varus.

The femoral and tibial angles were measured between the real anatomical line (which corresponds to the HKA angle) and the expected anatomical line (calculated using the perpendicular lines). For this, we placed a line on the tibial plateau level (directly on the line we used to calculate the second point of the HKA angle) and then a perpendicular line to this one. The angle between this perpendicular line and the HKA line corresponded to the femoral angle (above the tibial plateau level) and the tibial angle (below the tibial plateau). Surgeries were performed with a tourniquet inflated at the beginning of the surgery and removed after dressing the sutured wound. All operations were done by the conventional medial parapatellar approach. Patients received a cemented implant without patella replacement and preserving the posterior cruciate ligament. If preserving the posterior cruciate ligament was not possible, an ultracongruent implant was used. The capsule was closed with continuous suture without the use of a drain. We performed peri- and intra-articular instillation of ropivacaine, and the knee was in flexion for 15 min after tourniquet release. Chemical thromboprophylaxis with enoxaparin (40 mg), once a day for the first 30 postoperative days, was used for each patient. Transfusion triggers were Hb <7 g/dl and Hb <8 g/dl in patients with symptomatic anemia or cardiovascular disease. To analyze the drop in Hg, we only considered patients who received tranexamic acid (TXA) as its use refers to intravenously administering a bolus dose (1 g) 15 min before opening the tourniquet. The same team operated on all patients with the continuous presence of the senior surgeon, and the rehabilitation team included two physical therapists.

The rehabilitation protocol included; 7-15 Days before the surgery: evaluation of all measures of functioning; teaching of isometric contractions of the large muscle groups of the lower limb; sitting and standing training; gait training with crutches on regular ground and stairs; active mobilization of the lower limb joints. On the first post-surgery day: the program begins with teaching and mobilizing exercises in the bed according to hospital protocol for operated lower limbs; continuous passive motion for 30-45 min per day until hospital discharge; sitting and standing training; walking gait training inside the room. Regarding the days until discharge: the same up and down stairs training; walking gait training out of the room; independent exercises in the standing position. When the surgery took place in the morning, the first day's training took place on that day in the afternoon. The discharge criteria for the home were no clinical complications, perform transfers independently, walking with crutches (at least 60 m), and going up and down 10 steps. The database was anonymized before performing descriptive and inferential statistical analysis using the SPSS® 26 software (IBM Inc., Armonk, NY). As for the descriptive statistics, the mean, standard deviation, and frequencies (absolute and relative) were obtained depending on the variable studied. The t-test for independent samples was applied in the continuous numeric variables and chi-square tests in the dichotomic nominal variables. Statistical significance was set at p<0.05.

RESULTS

Regarding the type of instrumentation, the sample (n=688) was divided into 265 (38.5%) for the CI group, 272 (39.5%) for the first-generation PSI, and 151 (21.9%) for the second-generation PSI. The prevalence of the female sex was higher in the CI group compared to the first-generation PSI (p=0.037). The individuals operated by CI had a higher body mass index (BMI) than those operated by first-generation PSI (p=0.038).We found significant differences in the surgery length of time (p<0.001) and in the length of stay (p=0.002), whereas in both variables, the results were more favorable for PSI designs. The drop of Hg was higher in first-generation PSI compared to the CI group (p=0.006). None of the mechanical alignment angles revealed differences between groups. All results are presented in (Table 1). In the pre-operative evaluation, the CI group revealed a greater disability in pain than the results of the second-generation PSI group (p=0.046), although this difference disappeared in the assessment 3 months after surgery. In the functioning evolution at the third month, we found significant differences in the 6MWT and the pain and function domains of the WOMAC Index, both with unfavorable results for the CI group compared to the first PSI design (p=0.009, p=0.027, and p=0.049, respectively) (Table 2).The absolute values achieved in functioning three months after surgery were also lower for CI. In the gait distance and domains of the WOMAC, the results were also better for the first-generation PSI (p=0.023, p=0.049, and p=0.018, respectively) (Table 3).

DISCUSSION

The best results found in the PSI designs regarding the surgery length of time, hospital length of stay, and drop of Hg corroborate several systematic reviews and meta-analyses.[9,10] Our results are favorable for the surgery length of time, with an almost 25% of reduction (49 vs. 61.2 min) for PSI designs. We found other authors with equally favorable results, of which the major differences were found by DeHaan et al (86.8 vs. 107.2 min; p<0.01), Myers et al(89.6 vs. 116.1 min; p<0.01), and Vide et al(54.4 vs. 72.4 min; p<0.001).[10-13] This finding is related to the technique itself: the number of instrument trays used, the pre-planning, and the design processes.[3,4]Our team analyzed the factors associated with the surgical time and noted that the CI requires 25 steps compared to the 13 of the PSI techniques, and for the decision steps, the values were 9 versus 3. In this study, we considered the technique as an important factor, the vast experience of the team of surgeons, and the stability of the nursing and anesthesia teams. Indeed, the operative time can be extremely variable based on surgeon training and the number of cases the surgeon has done with the technique due to the learning curve associated with any procedure.[11] The second-generation PSI design resulted in a mean hospital length of stay of 2.8 days compared to 3.2 days for the CI group, and similar results have been reported elsewhere.[12,13] The longer hospital length of stay observed in the CI group may be related to surgical aggression, femoral canal invasion, and surgical and tourniquet time. The drop in Hg was more favorable in the CI group regarding the first-generation PSI design, and this can be attributed to the characteristics of the sample in the presence of TXA and the femoral medullar perforation. Moreover, sex and BMI influence the effects of this drug, as TXA administration appears to be more protective in women and overweight and obese individuals.[14,15] The blood-sparing effect of TXA could be explained the increased levels of plasminogen activator inhibitor-1 (PAI-1), which is an inhibitor of fibrinolysis.[14] The TXA and PAI-1 are important fibrinolysis inhibitors, and their synergism can significantly improve antifibrinolytic effects.[16]Nevertheless, TXA is more favorable in the presence of perforation of the canal; the invasive surgery promotes a hypercoagulable state, which results in lower blood loss and PAI-1 production at the site of tissue injury resulting from inflammation associated with the surgical incision.[17-19]

Table 1: Characteristics of the sample (n=688).

Parameters	CI group N=265	First-generation PSI N=272	Second-generation PSI N=151	P value (first-generation PSI: CI group)	P value (second generation PSI: CI group)
Age (years); mean±SD	70.2±8.0 (50-92)	70.2±7.6 (48-87)	69.9±8.0 (49-86)	0.942	0.681
Sex (women; men) N (%)	189 (71.3%); 76 (28.7%)	171 (62.9%); 101 (37.1%)	111 (73.5%); 40 (26.5)	0.037	0.632
BMI; mean±SD	30.1±4.9 (14.2-43.0)	29.0±4.4 (19.1-42.5)	29.5±5.0 (17.6-44.4)	0.038	0.340
Surgery length of time; mean±SD	61.2±15.3 (29-125)	50.0±11.0 (31-95)	48.0±11.3 (32-125)	<0.001	<0.001
Length of stay; mean±SD	3.2±1.0 (2-7)	3.4±0.8 (2-7)	2.8±1.1 (2-10)	0.078	0.002
Pre Hb; mean±SD	13.6±1.5 (8.9-17.8)	14.0±1.5 (10.5-17.3)	13.8±1.5 (9.4-17.9)	0.036	0.374
Hb 24H; mean±SD	11.6±1.4 (7.5-15.1)	11.6±1.4 (8.5-15.9)	11.7±1.4 (7.1-15.4)	0.855	0.652
Difference Hb pre-24H; mean±SD	2.1±0.9 (-0.2-4.6)	2.5±1.1 (-0.4-7.6)	2.1±0.9 (0.1-4.5)	0.003	0.665
% Hb Drop 24H; mean±SD	15.0±6.0 (-1.6-31.5)	17.3±7.2 (-2.6-46.1)	15.2±5.9 (0.7-30.1)	0.006	0.758
Mechanical femoral angle; mean±SD	1.530±1.296 (0.056-5.503)	1.598±1.168 (0.000-4.819)	1.815±1.643 (0.069-8.160)	0.644	0.199
Mechanical tibia angle; mean±SD	1.521±1.131 (0.028-4.898)	1.651±1.366 (0.048-9.121)	1.438±1.247 0.011-4.944	0.403	0.633
Hip-knee-ankle (HKA) angle post-surgery; mean±SD	2.488±1.869 (0.000-8.921)	2.197±1.742 (0.000-7.581)	2.330±1.982 (0.000-8.462)	0.190	0.577

Despite not having any significant differences, the HKA angle of the PSI designs revealed a more aligned value. The meta-analysis by Lin et al concluded that PSI does not improve the alignment of the mechanical axis compared with CI, although MRI-based PSI and Visionaire® specific PSI significantly decrease the risk of malalignment.[9] Our study does not agree with that conclusion due to the particular aspects of its development. Until 2018, we had always performed the imaging exams with the same team, but from that year on, we started recruiting other radiology centers, which may have influenced the results. We believe that the stability of technical imaging teams can be decisive for collecting data at the level of mechanical axis alignment. The functioning achieved at the end of the third month after TKA seems more favorable for the first-generation PSI technique in relation to CI due to align mental though there are no significant differences - and personal factors, namely sex and BMI. The HKA angle was better for the first-generation PSI; the second-generation PSI effectively overcame the tibial fit problems (1.651 vs. 1.438), albeit with worse results on the femoral side (1.598 vs. 1.815), leading to a worse HKA angle (2.330 higher than the 2.197 of the first generation), but still better than the CI group (2.488). In our opinion, the quality of the HKA angle is an objective by itself, albeit it is also an index of the reproducibility of the PSI concept. Having in mind that the frontal alignment is likely one of the most accessible goals to achieve in CI, having more objective references than implant rotation or tibial slope, we believe that this slight advantage is also true in all the other aspects of the implant positioning and sizing, being consequently responsible for the better function at 3 months. In spite of not being perfectly linear, some studies have reported worse functional results for women and individuals with higher BMI after TKA.[20-22] Pua et al had a large sample (1025 patients) and reported that sex and BMI influenced the time course of post-TKA quadriceps strength: women and patients with higher BMI gained strength more slowly than men or patients with lower BMI.[21] Likewise, the same authors showed that post-TKA gait speed was consistently lower in women than in men, while BMI was negatively and nonlinearly related to gait speed.

Table 2: Pre and post-surgery functioning and respective differences.

Parameters	CI group N=265 Mean±SD (range)	First-generation PSI N=272 Mean±SD (range)	Second-generation PSI N=151 Mean±SD (range)	P value (first-generation PSI: CI group)	P value (second-generation PSI: CI group)
Pre-surgery functioning					
Pain (VAS)	5.9±2.4 (0-10)	6.0±2.3 (0-10)	5.1±2.5 (0-10)	0.954	0.046
Knee flexion	103.5±22.9 (10-136)	100.6±21.2 (33-140)	103.1±19.9 (45-140)	0.409	0.900
6MWT	237.8±99.6 (0-488)	231.6±101.1 (15-501)	260.9±97.4 (0-522)	0.689	0.136
WOMAC pain	11.0±3.0 (3-19)	11.3±3.8 (0-19)	10.2±3.8 (5-20)	0.578	0.117
WOMAC function	35.1±12.0 (0-57)	37.6±12.7 (8-61)	33.2±13.2 (9-68)	0.203	0.336
Post-surgery functioning in the third month					
Pain (VAS)	1.6±1.9 (0-8)	1.5±1.8 (0-8)	1.3±2.0 (0-8)	0.599	0.362
Knee flexion	105.1±12.3 (75-134)	102.5±13.1 (70-127)	104.8±13.0 (78-153)	0.212	0.899
6MWT	276.5±76.2 (80-420)	312.6±87.8 (120-560)	294.9±88.4 (132-528)	0.009	0.198
WOMAC pain	3.2±2.5 (0-10)	2.3±2.3 (0-11)	2.8±2.8 (0-12)	0.027	0.498
WOMAC function	12.3±8.4 (0-33)	9.7±7.5 (0-36)	11.3±9.0 (0-44)	0.049	0.529

Table 3: Absolute gains of each functioning variable and respective differences at the third month of follow-up.

Parameters	CI group N=265 Mean±SD (range)	First-generation PSI N=272 Mean±SD (range)	Second-generation PSI N=151 M±SD (range)	P value (first-generation PSI: CI group)	P value (second-generation PSI: CI group)
Pain (VAS)	4.4±2.9 (-4-10)	4.4±3.0 (-6-10)	3.7±3.0 (-3-10)	0.944	0.204
Knee flexion	1.6±23.7 (-38-85)	2.0±24.8 (-45-92)	1.7±20.9 (-42-54)	0.904	0.757
6MWT	45.2±83.0 (-127-287)	80.5±107.4 (-108-371)	30.4±83.1 (-174-220)	0.023	0.308
WOMAC pain	7.8±3.5 (-3-15)	9.0±4.1 (-1-18)	7.5±4.1 (-3-18)	0.049	0.677
WOMAC function	22.9±13.4 (-7-51)	28.2±13.9 (-2-55)	22.1±13.9 (-13-57)	0.018	0.733

These findings seem complex and multifactorial, and our study does not allow us to draw any conclusions about these differences. However, the authors mentioned that there may be physiological and epidemiological reasons: women showed a lower hypertrophic response after resistance training than men there are sex differences in anabolic hormonal levels and/or muscle protein synthesis rates; the incidence and severity of osteoarthritis are usually higher in women, and from a psychosocial perspective, women with osteoarthritis have a greater perceived disability compared to men; women take longer to decide to be operated.[20-29] In relation to BMI, we cannot give any conclusions that explain the differences in functioning, although we can mention some explanations cited by other authors. The association between higher BMI and slower strength recovery may be related to intermuscular adipose tissues that have previously been shown to impair muscle force production and blunt the adaptive response to resistance training.[30-33] This group of physiological differences will influence the gait performance and activities of daily living. There were no significant differences in increased flexion, and this is perhaps because the mean baseline value was already functional for all groups (>100). We acknowledge that, to date, minimal clinically important differences (MCID) have not been defined for the 6MWT with a reference equation in the TKA population, limiting our ability to definitively state the clinical significance of the absolute gains we found. However, Naylor defined an improvement threshold for the 6 MWT for TKA by triangulating methods using patient-perceived anchor-based improvement thresholds and distribution-based improvement thresholds that define values between 26 to 55 m at 26 weeks post-surgery.[34] Despite being 3 months post-surgery, our results can be compared with these authors and consequently be considered positive and with significant gains. Nonetheless, we also found higher values, as in the study by Kennedy et al who reported 61.3 m or more as a set of good values, and evidence of a true change occurred in the first 12 weeks after TKA. If we accept this value, we only observed this gain in the first-generation PSI.[35] The differences observed in absolute gains in the WOMAC domains were similar to the differences observed in their scores: the first-generation PSI achieved greater absolute gains in pain and function domains compared to the CI. Between the CI and second-generation PSI, the absolute gains obtained were identical. Different terminologies, methods, and values are referred to in the most recent studies about MCID in WOMAC.[36-38] In addition to the MCID, we found other definitions and interpretations, such as the minimum important change or minimum detectable change with 95% confidence. Given that the statistical methods and results are so different and because we used the 96-point scale, as a precaution, we interpreted our results as percentages. For the pain domain, the absolute gains in percentage were 70.9% (CI), 79.7% (first generation), and 73.5% (second generation); the function domains were 65.2% (CI), 75% (first generation), and 66.6% (second generation). These data show that the gains were important. The percentage values that we found corroborate other authors, such as Escobar et al who considered that the MCI% was high if all domains were above 59% or when the MDC% was higher than 65% in pain and function domains.[39] We did not find in the literature any study that independently analyzed the second-generation PSI, and therefore, we cannot compare the results of this study. The determinants of functional outcomes are multifactorial and include the surgical intervention itself, particularly at the early follow-up.[40,41] However, patient-reported outcomes are the best subjective measurements of functional outcome after joint arthroplasty and, thus, they must always be evaluated together with other clinical and mechanical criteria.[42]We recognize some strengths of our findings: it seems to be the first study, to our knowledge, that independently analyzed the functioning of second-generation PSI; the sample size of the PSI designs is larger than the ones found in most studies; the team of surgeons has nine years of experience with PSI techniques. Finally, our findings can help teams plan their rehabilitation programs. Given that female patients and patients with higher BMI can have poorer functional outcomes, they may be targeted for specific interventions to prevent post-TKA disability, such as a pre-surgical rehabilitation program or preoperative weight management.

Limitations

Nevertheless, this study had some limitations. Firstly, we do not know the continuity or absence of the rehabilitation after discharge from the hospital and how this may have influenced the functional outcomes. Secondly, three months may be a short period to know the actual results of the functioning achieved, despite numerous studies showing that most improvements occur in the first three months after knee surgery. Thirdly, we did not study the effects of sex and BMI in a stratified way.

CONCLUSION

The lack of research reporting better functional results for the PSI design leads us to conclude that this is because of the better alignment of the technique, although this was not the explanation for this study. Significant improvements in surgical time and hospital length of stay were observed in the PSI designs compared with the CI technique. The drop in Hg that was more favorable in the CI group seems to be linked to the characteristics of the sample (sex and BMI) and explained by the synergistic antifibrotic effect of TXA with adipokines found in the surgical technique implies femoral medullar perforation. The functioning achieved at the end of three months after TKA seems to be more favorable for the first-generation PSI technique, namely in walking distance and the dimensions of the WOMAC Index, and this is apparently due to personal factors such as sex and BMI. Nonetheless, despite the promising findings presented herein, further research must be conducted with larger cohorts and more extended follow-up periods.

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