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What's new in the Visionaire system® in second-generation for TKA? a comparative study of accuracy, efficiency and functional results

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ABSTRACT

Background: The aim of the study was to analyze and compare the accuracy, efficiency and functional evolution between the first- and second-generation Patient-specific instrumentation (PSI).
Methods: We report our experience in TKA using PSI Visionaire System® (Smith and Nephew®) in 456 procedures. The patients were divided into first- (N=272) and second-generation PSI design (N=184). For the accuracy was analyzed the mechanical results, namely Hip-knee-ankle (HKA) alignment post-TKA and outliers' frequency; for the efficiency was analyzed the length time surgery, the length of stay and satisfaction, for the functional outcomes was compared the evolution at pain, range of motion, gait perimeter and the domains of the Western ontario and mcmaster osteoarthritis index (WOMAC). The t-test for independent samples was applied in the continuous numeric variables and Qui square tests in the dichotomic nominal variables. Statistical significance was p value<0.05.
Results: The alignment of the femur worsened significantly in the second-generation (p=0.002), but the alignment of the tibia was improved (p=0.010). However, not enough to improve significantly the HKA. No significant differences were observed in the frequency of outliers. The length of stay decreased in the second-generation (<0.001). The functioning achieved at first and third months after surgery was lower in second-generation PSI; at first month in the pain and stiffness WOMAC (p=0.030; p>0.001) and in the third in WOMAC stiffness (p<0.001).
Conclusions: The second-generation PSI of Visionaire system® improved the alignment of the tibia, but not the alignment of the femur. This change did not produce any improvements in functioning.

Keywords: Patient-specific instrumentation, Total knee arthroplasty, Total knee replacement, Functional outcomes, Navigation system, Visionaire system®

INTRODUCTION

The first Patient-Specific Instrumentation (PSI) design have been developed in 2011 and is an alternative for Total knee arthroplasty (TKA). These are custom-made blocks for the distal femur and proximal tibia and are designed from pre-operative three-dimensional (3D), Computed tomography (CT) or Magnetic resonance imaging (MRI) based reconstructions of the knee. Nam et al, 2012 summarize their advantages in the following manner: (i) the surgeon can formulate a preoperative plan before the surgery (in this series the aim was to achieve mechanical alignment 0º) and this allows him to start the surgery with knowledge regarding the size, location of the bony resections, implant sizing as well as rotation information; (ii) improved alignment should be obtained with the use of patient-specific cutting blocks; (iii) third, due to the use of 3D imaging preoperatively, patient-specific cutting blocks should be able to 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 for determining component

rotation and is incorporated in the cutting blocks; (iv) fourth, the use of PSI technology should lead to a more efficient surgery, as operative times should be shorter since the number of steps is decreased.[1] 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, also because fewer trays must be processed or opened before surgery.[2]

On the other hand, PSI system is more surgeon friendly as there are lesser number of instruments required, surgery has already been planned in the preoperative templates, and there is no need to register fixed bony landmarks into the computer as in navigated surgery, leaving lesser room for intraoperative errors.[3]

However, in the first-generation, the fit of the cutting blocks was not always perfect, resulting in 'floating blocks', which sometimes forced the abandonment of the PSI technique, leading the surgeon to finish the surgery by the conventional method or to cut with the wrongly positioned cutting block. This problem was more frequent in the tibia. This was the reason for the creation of the second-generation of PSI in 2018, to improve the fit between the bone and the cut guides. The contact area was increased and were created expansions to increase contact. These two changes improved the visibility of the bone surface and joint stability. The new PSI system also has a new alignment test system, easier and more reliable.

The aim of the study was to analyze and compare the accuracy, efficiency and functional evolution between the first- and second-generation PSI designs at the first- and third-month post-surgery.

METHODS

Study design

This observational and retrospective study (level of evidence III) was implemented using data collected from the Hospital Particular do Algarve (Faro, Portugal) database, regarding all patients undergoing PSI TKA between 2011 and 2020. Our experience with first PSI started in March 2011 and since then we have been using this technique systematically. In January 2018, with the discontinuation of the first-generation PSI, we started our experience with the second-generation PSI, which we maintain today.

We reported our experience in 456 procedures with the PSI Visionaire® system (Smith and Nephew, Memphis, USA). The patients were divided into first- (N=272; 59,6%) and second-generation PSI design (N=184; 40,4%). The study was approved by the medical ethical committee at the hospital. Patients and professionals allowed the usage of their data for this study.

The dependent variables of this study were the following: for the accuracy dimension was analyzed the mechanical results, namely femur, tibia, HKA alignment pre and post-TKA and outliers frequency; for the efficiency variables was analyzed the length time surgery, length of stay and satisfaction; the functional outcomes was compared in the knee pain intensity (visual analogue scale- VAS), range of motion (flexion and extension knee- goniometry), gait distance (6-minute walk test- 6MW test) and the WOMAC index. The independent variable was the surgical instrumentation, and all patients were evaluated 7-15 days before surgery and after 1 and 3 months of follow-up.

Inclusion and exclusion criteria

Sample size consisted in all the patients who had symptomatic arthrosis resistant to conservative treatment (convenience sampling).

Procedures

To measure the HKA angle, we firstly found 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 here (point K). At last, at the ankle level, we placed the last point of the angle on the lowest point of the tibio-tarsal joint (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 tool). To do this, we placed a line on the tibial plateau level (directly on the line we used to calculate 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 released after dressing the sutured wound. All cases were done by conventional medial parapatellar approach. Patients received a cemented implant without replacement of patella and with preservation of the posterior cruciate ligament. If preservation of the posterior cruciate ligament was not possible, an ultra-congruent implant was used. The capsule was closed with continuous suture without use of drain. We performed peri and intra-articular instillation of ropivacaine, and the knee was in flexion for 15 minutes after tourniquet release. Chemical thromboprophylaxis with enoxaparin 40 mg once daily for the first 30 post-operative 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.

For the analysis of the drop in hemoglobin we only considered patients who take Tranexamic acid (ATX),

whose use refers to the administration of a bolus of 1 g intravenously 15 minutes before opening the tourniquet.

All patients were operated by the same team with constant presence of the senior surgeon and the rehabilitation team included two physical therapists.

Statistical analysis

The database was anonymized before performing descriptive and inferential statistics analysis using the software SPSS® 26 (IBM Inc., Armonk, NY). Regarding descriptive statistics, mean, standard deviation and frequencies (absolute and relative) were obtained depending on what variable was being studied. The t-test for independent samples was applied in the continuous numeric variables and Qui square tests in the dichotomic nominal variables. Statistical significance was set at p value<0.05.

RESULTS

Regarding the type of instrumentation, the sample (N=456) was divided into 272 (59.7%) for first-generation PSI and 184 (40.3%) for second-generation PSI.

The prevalence of female gender was higher in the second-generation group (p=0.049). The age and the BMI were similar between the subsamples. These results are in Table 1.

We found significant differences in the femur and tibia angles (respectively p=0.002 p=0.010). The femur angle worsened in the second- generation (1.214±1.950 vs 0.484±1.775), contrary to the tibia angle which improved in this group (0.083±1.649 vs -0.517±1.997). None of the mechanical alignment HKA angles revealed differences between groups and the frequencies of the different outliers was also similar. All results are presented in Table 2.

The second-generation PSI revealed significant improvements in the efficiency dimension, namely in the length of stay (2.8±1.1 vs 3,4±0,8 days; p<0,001); These, the length time of surgery and satisfaction results are presented in Table 3.

In the pre-operative evaluation, the second-generation revealed greater functioning on pain (5.2±2.4 vs 6.0±2.4; p=0.025), in the 6 MW test (270.9±96.9 vs 231.6±101,1 m; p=0.04), in the WOMAC pain (10.2±3.8 vs 11.3±3.8; p=0.029) and in the WOMAC function (32.6±12.8 vs 37.6±12.7; p=0.004). In the assessment 1 and 3 months after surgery this difference not only disappeared, as it was observed higher levels of disability in the second-generation. At first month the pain and stiffness scores of the WOMAC index were worse (respectively 6.0±3.4 vs 5.0±2.7; p=0.030 and 2.7±1.7 vs 1.7±1.4; p<0.001) and in the third were observed similar results in stiffness domain (1.6±1.3 vs 0.8±1.0; p<0.001). All results are presented in Table 4.

Table 1: Characteristics of the sample.

Characteristics	First-generation PSI N=272	Second-generation PSI N=184	P value
Age*	70.2±7.6 (48-87)	70.0±7.7 (49-86)	0.786
Gender (women, men)**	171 (62, 9%); 101 (37, 1%)	132 (71, 7%); 52 (28, 3%)	0.049
BMI*	29.0±4.4 (19.1-42.5)	29.5±4.9 (17.6-44.4)	0.287

Note: Values are mean±SD (range); values are N (%).

Table 2: Accuracy dimension.

Mechanical results	First-generation PSI N=272	Second-generation PSI N=184	P value
HKA pre-surgery*	-5.589±9.272 (-24.30-21.70)	-4.201±9.532 (-25.70-24.80)	0.128
HKA post-surgery*	2.197±1.742 (0.000-7.581)	2.265±1.987 (-0.902-8.462)	0.775
Femur*	0,484±1.775 (-5.155-4.581)	1.214±1.950 (-5.808-8,160)	0.002
Tibia*	-0.517±1.997 (-5.502-5.179)	0.083±1.649 (-4.579-3.589)	0.010
Outliers fémur (≥3º; <3º)**	23 (13.4%); 149 (86.6%)	14 (15.4%); 77 (84.6%)	0.656
Outliers tíbia (≥3º; <3º)**	23 (13.4%); 149 (86.6%)	7 (7.7%); 84 (92.3%)	0.169
Outliers HKA (≥3º; <3º)**	52 (30.2%); 120 (69.8%)	29 (31.9%); 62 (68.1%)	0.785

Note: Values are mean±SD (range); values are N (%).

Table 3: Efficiency dimension.

Clinical results	First-generation PSI N=272	Second-generation PSI N=184	P value
Length time surgery	50.0±11.0 (31-95)	48.8±12.4 (30-125)	0.279
Length of stay	3.4±0.8 (2-7)	2.8±1.1 (2-10)	<0.001
Satisfaction	8.7±1.9 (1-10)	8.8±1.6 (1-10)	0.554

Table 4: Functional dimension.

Pre-surgery functioning	First-generation PSI N=272	Second-generation PSI N=184	P value
Pain (VAS)	6.0±2.4 (0-10)	5.2±2.4 (0-10)	0.025
Knee flexion	100.6±21.2 (33-140)	105.2±19.7 (45-140)	0.109
Knee extension	3.0±3.9 (0-22)	3.9±6.0 (-10-25)	0.181
6 MW test	231.6±101.1 (15-501)	270.9±96.9 (0-522)	0.004

DISCUSSION

We did not found in the literature any study that independently analyzed the second-generation PSI using the Visionaire system® and therefore we cannot compare the results of this study. In this way, the discussion will be reflected based on our experience of more than 10 years and the fact that we are an international center for experimentation and training in the PSI technique.

The best mechanical results that were expected to occur in second-generation were not observed in the study. Although the alignment of the tibia has improved, the results have not been significant enough that the alignment of the HKA has proved to be better, as the femur has worsened its results. Likewise, the frequency of outliers was also not significantly different between the two instrumentations. The tibia showed in the second-generation a lower frequency of outliers, but again without significant differences.

Regarding the values observed in the alignments, we admit a weakness that may have influenced the results. Until 2018**,** we had always performed the imaging exams with the same team, but from that year forward, we started recruiting other radiology centers and we believe this fact may have influenced the results. We believe that the stability of technical imaging teams can be decisive for the collection of data at the level of mechanical axis alignment.

The significant difference found in the length of stay will not be related to the surgical technique, but to the criteria adopted for discharge.

In fact, as of May 2016, the discharge criteria for the home are (in the absence of clinical complications): carry out transfers independently, walk with crutches for at least 60 meters and go up and down 10 steps. Also, the rehabilitation program started from that date to have an earlier start; when the surgery takes place in the morning, the first session was established on the same day, in the afternoon.

In this way, we believe that the best results found in the length of stay in the second-generation PSI are based on the adoption of these 'fast track', since all its participants had this procedure from the beginning (2018).

Satisfaction was slightly higher in second-generation, but without significant differences.

Despite having started with an advantage in the functional evaluation, the second-generation was not able to maintain these results. On the contrary, it presented greater disability in pain and stiffness.

An average value higher than 4º was observed in the two follow-up evaluations to second- generation, which were not significant or had an impact on the performance of activities.

As suggested by Török et al, the evaluation of the effectiveness of PSI techniques (with each other and with the conventional instrumentation) still has many pitfalls that need to be addressed, namely: long-term follow up data is missing regarding the patient-reported outcome measures and when assessing surgery time, the authors suggest focusing on operating room turnover instead of procedure time.[4]

We admit some limitations in this study: we don't knew the continuity or absence of the rehabilitation after discharge from the hospital and to what extent this may have influenced the functional outcomes; three months may be a short time to know the true results of the functioning achieved, despite of many studies showing that most improvement occurred during the first 3 months following knee surgery; we did not study the effect of gender in a stratified way and the study is conducted in a single-centre.[5]

CONCLUSION

In the present study the second-generation PSI has no advantages over the first-generation. Despite the second-generation showing better alignment of the tibia, this result did not reveal improvements in HKA or in functional outcomes. Perhaps increasing the samples and their follow-up following may bring different results.

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