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Original Research Article

Comparing conventional and patient specific instrumentation in total knee arthroplasty: an early analysis of function and satisfaction

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ABSTRACT

Background: Patient specific instrumentation (PSI) in TKA is a surgical technique created to improve the accuracy of implantation, surgical time, blood loss and workflow that has been a growing trend over the past decade. Our work aims to determine if there are improvements in patient satisfaction and functional results using PSI in comparison with conventional instrumentation (CI) in TKA.
Methods: The authors evaluated 716 patients from the past 10 years that underwent TKA, either by PSI (n=456) or by CI (n=260). The authors recorded the WOMAC index, articular range of motion, and the six-minute walking test at pre-op and day 90 post-op. T-student and Mann-Whitney tests were used considering $p<0.05$.
Results: The functional scores achieved 90 days after surgery were better for PSI compared to CI. The respective differences are found in the extension ($p=0.022$), gait distance ($p=0.010$) and in the pain and function WOMAC index (respectively $p=0.018$ and $p=0.020$). No statistical differences were found in satisfaction.
Conclusions: 90 days after TKA, the functional scores achieved with PSI were better compared to CI. However, better results in this area did not translate to significantly higher satisfaction in the patients. There seems to be a tendency in favor of better functional results in patients that underwent TKA by PSI in comparison to those submitted to CI. These results seem to follow the tendencies demonstrated in available literature.

Keywords: PSI, Total knee arthroplasty, Satisfaction, Function

INTRODUCTION

With an ever-aging active population, it comes as no surprise that the demand for total knee arthroplasties (TKA) has increased in recent years.[1-3] With increased demand comes an increased level of expectation, which in turn leads to innovation and a search for more perfect solutions. This search has led to the introduction of new types of instrumentation, one of which we know as PSI. This is a surgical technique using disposable cutting block guides tailored to fit each patient's three-dimensional knee anatomy. Created to improve the accuracy of implantation, surgical time, blood loss and workflow, PSI in TKA has been a growing trend over the past decade.[4] This is of paramount importance when dealing with TKA because we know that restoring the mechanical axis and correctly implanting the components are closely tied to better outcomes.[5-7] On the other hand, we know that imperfect implantation and malalignment in TKA leads to precocious loosening and higher revision rates.[5]

Our work aims to determine if there are improvements in functional results and patient satisfaction using PSI in comparison with CI in TKA.

METHODS

Study design

Our database was used to retrieve information about all patients that underwent TKA between 2011 and 2022 in hospital particular do Algarve-Gambelas, in Faro, Portugal. A non-randomized retrospective study (evidence level III) was designed, where both patients and clinicians gave their consent for the use of collected data. The study was approved by the hospital ethics committee. The authors retrospectively evaluated 716 patients that underwent TKA from February 2010 to August 2022, either by PSI or by CI. 456 (63,7%) received PSI and 260 (36,3%) received CI. Patients included were those with primary osteoarthritis resistant to conservative treatment. Patients excluded were those with previous same-limb fractures or osteotomies; those unable to undergo pre-operative imaging studies (MRI or CT scan) or inability participate in the PSI cutting blocks production process. No patients were excluded based on pre-operative coronal plane limb alignment.

Procedures

All arthroplasties were performed using the Visionaire system (Smith and Nephew). Between 2011 and 2013, the TC plus primary prosthesis was used, and later replaced with the LEGION prosthesis until the end of the study period. In our opinion this had no impact on outcomes, since the design and rationale of implants are extremely similar, like conclusions by Fontes et al.[8] All patients were operated by the same surgical team.

A tourniquet was used on all patients-inflated at the beginning of surgery and deflated after dressing of the wound. Traditional medial parapatellar approach was used and patients received a cemented, cruciate-retaining (CR) implant, without patella replacement. When CR was not possible, a posterior-stabilized (PS) implant with ultra-congruent tibial polyethylene was implanted. Capsule continuous sutures were used to close the wound, and no drains were left, 1 gm of IV tranexamic acid was given to all patients 15 minutes before tourniquet release and intraarticular instillation of ropivacaine was performed at closure. Subcutaneous enoxaparin (40 mg/day) was recommended during 30 days post-operatively. Authors evaluated the WOMAC index (pain, function, stiffness), articular range of motion, pain according to the visual analog scale (VAS) and the six-minute walking test at pre-op and day 90 post-operatively.

Statistical analysis

The database was anonymized before performing descriptive and inferential statistics analysis using the SPSS 26 software (IBM Inc., Armonk, NY). Regarding descriptive statistics, mean, standard deviation and frequencies (absolute and relative) 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 $p<0.05$.

RESULTS

There were no statistical differences between the groups in terms of sex (p=0,191), age (p=0,855), body-mass index (BMI)(p=0,089) and length of hospital stay (p=0,310). The pre-operative evaluation in both groups was very similar: Flexion (p=0,491), extension (p=0,243), gait distance (p=0,451), WOMAC pain (p=0,754), WOMAC stiffness (p=0,591) WOMAC function (p=0,934) and also pre-operative VAS score (p=0,381) were homogenous. All results are presented in Tables 1 and 2.

Table 1: Demographic data.

Variables	CI, (n=280)	PSI, (n=456)	P value
Age (mean, in year)	70.22	70.22	0.855
Gender (%)			
Female	199 (71.1)	303 (66.4)	0.191
Male	81(28.9)	153 (33.6)	
BMI (mean)	30.029	29.277	0.089
Length of hospital stay (mean, days)	3.18	3.07	0.310

Table 2: Pre-operative evaluation of patients undergoing TKA.

Pre-op evaluation	CI, (n=72)	PSI, (n=202)	P value, (T-student)
Pain (VAS)	2.9±1.9 (0-8)	3.1±2.2 (1-10)	0.654
Flexion (º)	97.4±13.1 (45-125)	94.3±13.7 (42-127)	0.092
Extension (º)	4,9±6.5 (0-30)	3.7±5 (-10-24)	0.139
6 minute walking test (m)	216.4±85 (20-414)	234.2±79.3 (36-436)	0.115
WOMAC pain	5.3±3 (0-12)	5.5±3.1 (0-14)	0.596
WOMAC stiffness	2.9±1.5 (0-6)	2.2±1.6 (0-7)	0.783
WOMAC function	22.5±9.6 (5-53)	20.5±10.1 (0-48)	0.155

Functional scores

The functional scores achieved ninety days after surgery revealed greater functioning with Patient specific

instrumentation: extension (1.70±2.9 vs. 3.01±4.3, p=0.022), gait distance (308.6±87.5 m vs. 276.6±83.6 m, p=0.010), WOMAC (Western Ontario and McMaster universities arthritis index) pain (2.5±2.6 vs. 3.4±2.6, p=0.018) and in WOMAC function (10.1±8.2 vs. 13±9.6, p=0.020) (Table 3).

Satisfaction

Mean satisfaction of patients who underwent CI was 8.5 (±2) and those who underwent PSI 8.7 (±1.8). Although higher in the PSI group, no statistical difference was found in regards to satisfaction (p=0.195) (Table 4).

Table 3: Day 90 post-operative evaluation of patients that underwent TKA.

Day 90 evaluation	CI, (n=68)	PSI, (n=178)	P value (T-student)
Pain (VAS)	1.7±1.9 (0-8)	1.4±1.8 (0-8)	0.199
Flexion (º)	105.3±12.5 (75-134)	104.2±13.2 (70-153)	0.558
Extension (º)	3±4.3 (-4-15)	1.7±2.9 (-5-12)	0.022
6 minute walking test (m)	276.6±83.6 (40-460)	308.6±87.5 (120-560)	0.010
WOMAC pain	3.4±2.6 (0-10)	2.5±2.6 (0-12)	0.018
WOMAC stiffness	1.4±1.4 (0-8)	1.2±1.2 (0-5)	0.288
WOMAC function	13±9.6 (0-49)	10.1±8.2 (0-44)	0.020

Table 4: Post-operative satisfaction of patients that underwent TKA.

	Group	N	Minimum	Maximum	Mean	SD	P value
Satisfaction (0-0)	CI, (n=224)	224	1	10	8.6	2	0.195
	PSI, (n=390)	390	1	10	8.7	1.8	

DISCUSSION

There seems to be a tendency in favor of better functional results in patients that underwent TKA by PSI in comparison to those submitted to CI. Satisfaction was also slightly higher in this group, although without statistical relevance. These results seem to row against some tendencies demonstrated in available literature. Most published literature does not clearly support any improvement of postoperative pain, activity, function, or ROM when PSI is compared with traditional instrumentation. As reported by Kizaki et al. TKA-PSI does not improve patient-reported outcome measures, surgery time, and complication rates as compared to standard TKA.[9] Likewise, Boonen et al. found no difference in either clinical outcomes or complications associated with PSI, and hence questioned the cost effectiveness of the new technique.[10]

Very few studies evaluated patient satisfaction, rather clinical scores or limb alignment. In one study we found that PSI in TKA might increase patients' satisfaction, and although unclear as to why, the authors suggested it be because of prosthetic design or the expectation of receiving an individualized implant.[12] Most published studies that include patient reported outcome measurements (PROMs) showed no statistical difference in these evaluations. Kizaki et al. showed that among patients followed for 1-year or more post operatively, no clinically important differences between TKA-PSI and standard TKA groups.[9]

The main strength of this work lies in the number of patients. Other strengths, such as the fact that we analyzed the patients operated by one experienced surgeon alone, could be a factor in reporting these favorable results. In the hands of less experienced surgeons, the data collected might be more difficult to interpret and only a weaker conclusion could be reached.

On the other hand, this study also presents limitations that should be discussed. By design, a retrospective comparative analysis cannot exclude selection bias. Likewise, only one design of PSI was studied and so generalizing the conclusions for other PSI implants may be farfetched.

In the future patients should be cohorted by age, BMI and sex to study any differences within these specific subgroups, allowing for a more tailored and patient-based approach to TKA to achieve higher patient satisfaction rates.

CONCLUSION

The 90 days after TKA, the functional scores achieved with PSI were greater compared to CI. However, better results in this area did not translate to significantly higher satisfaction in the patients. Longer follow up times are necessary for a more complete overview of their behavior, which will allow us a more tailored approach to the patients' needs in the future.

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