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ORIGINAL STUDY

Reliability of patient specific instrumentation in total knee arthroplasty

Harold JENNART, Marie-Ange NGO YAMBEN, Theofylaktos KYRIAKIDIS, David ZORMAN

Department of Orthopaedic and Traumatology, CHU Tivoli, Belgium

The aim of this study was to compare the precision between Patient Specific Instrumentation (PSI) and Conventional Instrumentation (CI) as determined intra-operatively by a pinless navigation system. Eighty patients were included in this prospective comparative study and they were divided into two homogeneous groups. We defined an original score from 6 to 30 points to evaluate the accuracy of the position of the cutting guides. This score is based on 6 objective criteria. The analysis indicated that PSI was not superior to conventional instrumentation in the overall score (p = 0.949). Moreover, no statistically significant difference was observed for any individual criteria of our score.
Level of evidence II.

Keywords : PSI ; TKA ; navigation ; HKA.

INTRODUCTION

One of the aims of total knee arthroplasty (TKA) is to restore the mechanical axis and the alignment of the leg. Many studies showed that a Hip-Knee-Angle (HKA) deviation higher than +/-3° is associated with a higher risk of implants failure (*9,14,20*). Conventional instrumentation depending on extramedullary (tibia) and intramedullary (femur) alignment guides achieves a HKA between 0 and 3° in more than 78% of cases (*1*). In addition, the use of navigation increases this incidence in more than 96% of cases (*1,12,26*). Some studies showed a significant advantage of PSI TKA over conventional TKA for alignment of the femoral component in the coronal plane, but not in the sagittal plane (*18,22,24*). Nevertheless, controversy still exists about the accuracy of these two techniques (*18,19,21,24*). The hypothesis of this study was that the accuracy of patient specific instrumentation is higher than that of conventional instrumentation as controlled during surgery with a navigation system.

MATERIALS AND METHODS

In our series we included eighty consecutive patients who had undergone a TKA for primary osteoarthritis between May 2012 and October 2013. Exclusion criteria were previous osteotomy, posttraumatic deformities and rheumatoid arthritis. The institutional ethics committee approved the study. All surgeries were performed by two senior surgeons (H.J. and D.Z.). The study population was divided in two equal groups of forty patients in each group (PSI and CI). The demographic characteristics are shown in Table I.

■ Harold Jennart.
■ Marie-Ange Ngo Yamben.
■ Theofylaktos Kyriakidis.
■ David Zorman.
Department of Orthopaedic and Traumatology, CHU Tivoli, Belgium.
Correspondence : D. Zorman, Avenue Max Buset 34, 7100 La Louvière, Belgium. E-mail : dzorman@gmail.com

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Table I. — Demographic characteristics of study population

	PSI	CI	P Value
Number of Patients	40	40	
Age (Years) Median (IQR)	70 (66-71)	68 (66-72)	0.949
Sex Male/Female (%)	9/31 (22.5%/77.5%)	11/29 (27.5%/72.5%)	0.874
Side Right/Left (%)	23/17 (57.5%/42.5%)	22/18 (55%/45%)	0.748
BMI (Kg/m^2) Median (IQR)	28.9 (28.4-29.6)	28.4 (27.9-29.1)	0.262

The surgical plan was based on standing full length and standard radiographs of the knee. The patients that were included in the PSI group had also a specific MRI. The data were analysed by Materialize® for the production of three-dimensional images of the knee and for the position of the guides. The final result was available with the use of specific software and was sent to the surgeon who accepted or modified the angles and the height of the cuts. The mean fabrication time for PSI was 5 weeks. The medial parapatellar approach without tourniquet was used in general or regional anaesthesia.

In both groups, the evaluation of the accuracy of the cutting guides was done intraoperatively by a non-invasive navigation system (BrainLAB® express, software VectorVision CT-free knee 2.5).

The Vanguard® Knee System (Biomet, Warsaw, US) was used for the conventional instrumentation for the first study group and the Signature® Personalized Patient Care System of Materialize® for the second group.

For each patient, 6 intra-operative parameters were registered : the tibial and femoral axis, the thickness of the tibial and femoral cut, the tibial slope and the femoral flexion.

For the CI group, tibial cutting guide was placed by extramedullary device and intramedullary for the femoral guide. For the PSI group, PSI guides were placed on the bone surface and the pins were placed accordingly. Then, the PSI guides were removed and the conventional cutting guides were placed over the already present pins. The control was performed for both groups with the pinless navigation and the values were recorded. From this point the surgical procedure continued as usual.

An original score was defined (Tivoli Score, Table II) that allows evaluating the difference between the values that were planned and those found with the use of the 6 parameters. In agreement with the Vanguard design, our values of reference were 0° for the tibial axis, 0° for the femoral axis, 10 mm for the tibial cut thickness, 9 mm for the femoral cut height, 3° for the tibial slope and 3° for the femoral flexion. The total maximum score was 30, and each individual parameter was evaluated from 1 to 5. Any deviation of one unit (degree or mm) affects adversely the total score.

A power analysis was performed by the StatMate version 2 software (GraphPad Software, Inc. La Jolla, CA, USA) on two groups of 40 patients. A power of 0.80 and alpha of 0.05 will detect a deviation of 1.27 on the total score. Statistical analysis was performed by the InStat version 3.10 (GraphPad Software, Inc. La Jolla, CA, USA) and p value < 0.05 was considered statistically significant. Normality was checked with Kolmogorov-Smirnov test and Mann-Whitney U test was used to make comparisons between the medians of the groups.

RESULTS

The median total score for the PSI group was 27.70 compared to a total median score of 27.75 for the CI group. No statistically significant difference was found between the two groups ($p = 0.949$). Moreover, the individual median scores for the PSI and the CI groups regarding the three tibial parameters were respectively, 4.82 and 4.72 ($p = 0.388$) for the axis, 4.57 and 4.45 ($p = 0.236$) for the slope and 4.80 and 4.60 ($p = 0.328$) for the thickness of the cut. There was not a statistically significant difference in these values. Referring to the three femoral parameters, we found the following scores correspondingly for the PSI and for the CI groups, 4.25 and 4,75 ($p = 0.059$) for the axis, 4.60 and 4.85

Table II. — Tivoli Score

	Deviation value	Score
Tibial axis Varus(-) / Valgus (+)	0° ± 1°	5
	0° ± 2°	4
	0° ± 3°	3
	0° ± 4°	2
	0° ± > 4°	1
Femoral axis Varus(-) / Valgus (+)	0° ± 1°	5
	0° ± 2°	4
	0° ± 3°	3
	0° ± 4°	2
	0° ± > 4°	1
Tibial slope Post (+)	3° ± 1°	5
	3° ± 2°	4
	3° ± 3°	3
	3° ± 4°	2
	3° ± > 4°	1
Femoral flexion Post (+)	3° ± 1°	5
	3° ± 2°	4
	3° ± 3°	3
	3° ± 4°	2
	3° ± > 4°	1
Thickness of tibial cut	10 mm ± 1 mm	5
	10 mm ± 2 mm	4
	10 mm ± 3 mm	3
	10 mm ± 4 mm	2
	10 mm ± > 4 mm	1
Thickness of femoral cut	9 mm ± 1 mm	5
	9 mm ± 2 mm	4
	9 mm ± 3 mm	3
	9 mm ± 4 mm	2
	9 mm ± > 4 mm	1
TOTAL	Between	6-30

(p = 0.053) for the thickness of the cuts and 4.35 and 4.37 for the flexion (p = 0.581). All values were found without significant difference (Table III). We considered as outlier a score inferior than 3 in one parameter of our score. In our study we found 5 outliers with a score of 2. Out of them, one was in the PSI group and four were in the CI group also without significant difference (p = 0.248) (Table IV).

DISCUSSION

This study consists in an intra-operative comparison of the cutting guides precision between the PSI and the CI with the use of a non-invasive navigation system. The most important finding was that the accuracy of PSI was not higher than that of CI.

Our study has also some limitations such as the lack of randomisation. In addition we used a navigation system to measure the cutting guides position, even if there is still a controversy in the literature about its precision. Furthermore, it should be noted that our score has not yet been validated.

One of the strengths of our study is that all surgeries were performed by two senior surgeons, with more than 10 years of experience, with the Vanguard prosthesis and the navigation. Additionally another strong point of this study is the comparative cohorts, as well as the use of our original score.

More precisely, we established a six criteria score for an objective comparison of the precision of the cutting guides position. Our score not only evaluates the restoration of the mechanical axis, but also the entire precision of the cutting guides. Requiring a high level of precision, we used for our score narrow limits of deviation by degree or millimeter. Moreover this score permits to quantify the results and to make it an objective and reproducible method of comparison independently of the prosthesis design and the surgical technique. To our knowledge it is the first time in the literature that a study uses a score to evaluate the precision of the cutting guides. The other studies were limited to a postoperative radiological evaluation of the mechanical axis restoration. In addition, we used a non-invasive navigation system during the surgical procedure that gives the opportunity for immediate results and permits to correct the cutting guides position if this was necessary. Recent studies demonstrate that navigation systems improve implants position (*5,6, 14,16*) as well as the restoration of the mechanical axis (*1,12*) and also that they decrease the outliers (*2, 5,7,13,16,19*). Many authors (*1,5,6,12,16,25,26*) used the VectorVision CT-free knee 2.5. software for their navigation system and reported more than 96% of precision (*1, 12,25*).

Table III. — Median Tivoli Score Values

Average score	Tibial Axis	Femoral Axis	Tibial Slope	Femoral flexion	Tibial thickness	Femoral thickness	Total
PSI (n = 40)	4.82	4.25	4.57	4.35	4.80	4.60	27.70
CI (n = 40)	4.72	4.75	4.45	4.37	4.60	4.85	27.75
P value	0.388	0.059	0.236	0.581	0.328	0.053	0.949

Table IV. — Outliers

Outliers	Tibial Axis	Femoral Axis	Tibial Slope	Femoral flexion	Tibial thickness	Femoral thickness	Total
PSI (n = 40)	0	0	1	0	0	0	1
CI (n = 40)	1	0	0	2	1	0	4
P value							0.248

In our study, we used the MRI scan to fabricate the 3D guides of PSI, similarly to most of the other studies. Mannan *et al* (*13*) in their review of 26 studies found that only in 3 of them the guides were fabricated based on CT imaging. However, there is no consensus in the literature for the superiority of one of these two fabrication methods.

Our data have shown a total median score of 27.70 for the PSI group and 27.75 for the CI ($p = 0.949$) without statistically significant difference. Relating to these values we concluded that there is no difference in the precision between PSI and CI methods. This finding is in accordance with many other studies. For example, Chareancholvanich *et al* (*4*) in their series of eighty patients did not find significant difference between the groups in terms of alignment. Similarly, Victor *et al* (*23*) in their randomized controlled trial of 128 patients, who underwent TKA, compared the component alignment between PSI and CI. They concluded that PSI does not improve accuracy in TKA. Our finding has also been confirmed by the meta-analysis of Cavaignac *et al* (*3*).

In contrast, Noble *et al* (*15*) in their randomized series of 29 patients found a higher accuracy for the PSI group. Correspondingly, Voleti *et al* (*24*) in their systematic review concluded that PSI improved accuracy in femorotibial angle compared to CI.

With regard to the criteria of our score, we found better results in every separate parameter for the tibia in the PSI group. On the other hand, the reliability of the femoral cuts was inferior in the PSI group compared to the CI. Nevertheless, these differences were not statistically significant. Furthermore, the CI group presented more outliers compared to the PSI group also without significant difference ($p = 0.248$). Many authors reported the same results. For example, Victor *et al* (*23*) found a similar number of outliers in both cohorts. Equally, Voleti *et al* (*24*) reported no significant differences in the ability of either technique to avoid outliers. On the other hand, Ng *et al* (*16*) reported fewer outliers in the overall HKA angle, but with similar numbers of outlier independently for tibia and femur.

It should be noted that even if our results are comparable to other studies, we used a different evaluation method. In fact, we measured the guides position before performing the cuts, with an intraoperative navigation system. Contrarily other authors measured the precision after the final bone cuts based on the implants position in post-operative radiographs. We believe that the two methods give important but different information.

CONCLUSION

We concluded that the accuracy of the PSI is not superior to the conventional instrumentation as measured during surgery with a pinless navigation system. Furthermore, we established a six criteria score that allows an objective comparison of the

precision of the cutting guides position as well as to quantify our results. Nevertheless, we believe that more studies are recommended in order to validate our results and our original score.

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