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Original Article

Total knee arthroplasty with computer-assisted navigation: an analysis of 200 cases^{☆,☆☆}

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ABSTRACT

Objective: to evaluate the results from surgery with computer-assisted navigation in cases of total knee arthroplasty.

Method: a total of 196 patients who underwent total knee arthroplasty with computer-assisted navigation were evaluated. The extension and flexion spaces (gaps) were evaluated during the operation and the alignment after the operation was assessed. The Knee Society Score (KSS) questionnaire for assessing patient's function was applied preoperatively and postoperatively after a mean follow-up of 22 months.

Results: in all, 86.7% of the patients presented good alignment of the mechanical axis (less than 3° of varus or valgus in relation to the mechanical axis) and 96.4% of the patients presented balanced flexion and extension gaps. Before the operation, 97% of the patients presented poor or insufficient KSS, but after the operation, 77.6% presented good or excellent KSS.

Conclusion: the navigation system made it possible to achieve aligned and balanced implants, with notable functional improvement among the patients. It was found to be useful in assessing, understanding and improving knowledge in relation to performing arthroplasty procedures.

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Artroplastia total do joelho auxiliada por navegação: análise de 200 casos

RESUMO

Objetivo: avaliar os resultados das cirurgias assistidas por navegação (CAN) nas artroplastias totais de joelho.

Palavras-chave:

Artroplastia de substituição

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Joelho
Cirurgia assistida por
computador

Método: foram avaliados 196 pacientes submetidos à artroplastia total de joelho com auxílio da navegação por computador. Avaliados no intraoperatório os espaços (*gaps*) de extensão e de flexão, o alinhamento pós-operatório e o questionário funcional da Knee Society Score (KSS) pré-operatório e pós-operatório com seguimento médio de 22 meses.

Resultados: dos pacientes, 86,7% apresentaram bom alinhamento do eixo mecânico (dentro de 3° de varo ou valgo em relação ao eixo mecânico) e 96,4% apresentaram ambos os *gaps* de flexão e extensão balanceados. No pré-operatório, 97% dos pacientes apresentavam KSS funcional ruim ou insuficiente, no pós-operatório 77,6% apresentavam KSS funcional bom ou excelente.

Conclusão: a navegação proporcionou a obtenção de implantes alinhados e balanceados com importante melhoria da função nos pacientes. Foram evidenciados sua utilidade no estudo, o entendimento e o aperfeiçoamento do conhecimento na execução das artroplastias.

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Introduction

Total knee arthroplasty (TKA) is a safe and effective treatment for restoring function and relieving pain in patients with gonarthrosis (knee osteoarthritis). With the aging of the population, there has been a tendency toward increasing numbers of patients with this pathological condition and greater demand for TKA. Within this scenario, searching for new options that might contribute toward improving the results and refining the procedure is very valuable.

Success in knee arthroplasty is influenced by factors relating to the patient, type of implant and surgical technique. In relation to the procedure, adequate positioning of the components and consequent good alignment of the limb are important prognostic factors. Incorrect positioning may affect implant functioning, increase the wear on the material and cause loosening of the prosthesis. Studies have demonstrated that aligning the components within 3° of the normal mechanical axis diminishes the risks of irregular wear and early loosening.¹

The development of instruments with intramedullary and extramedullary guides has increased the accuracy of implant alignment, but alignment errors still occur. Tibial component alignment errors exceeding 3° with the use of an extramedullary guide were described in 21.3% of the cases in one series.²

Navigation was developed as a tool to increase the precision of correct positioning of the implants in total knee arthroplasty. It is a reproducible and precise method for bone resection and ligament balancing, and is also accurate for evaluating limb alignment.³ A survey conducted among members of the European Society of Sports Traumatology, Knee Surgery and Arthroscopy and the Swiss Orthopedic Society showed that 33.1% of surgeons use navigation in at least 50% of TKA procedures and 25% use it in more than 75% of them.⁴

In this study, we discuss the short-term results from primary total knee prostheses that were implanted with the aid of computer-guided navigation, including evaluations of the postoperative mechanical axis and postoperative function over the short term.

Methods

Study design and sample characteristics

After approval by the Research Ethics Committee of Hospital São Paulo (Unifesp), 200 patients were selected consecutively to undergo TKA. All the patients presented indications for arthroplasty in conformity with the inclusion and exclusion criteria described below. This study was thus characterized as a prospective case series.

Patients with a radiographic diagnosis of primary osteoarthritis who had not presented improvement in their pain and functional conditions after a minimum of six months of conservative treatment were included. Revision arthroplasty patients and those with active infection or loss of extensor mechanism function were excluded.

Surgical technique

After a median longitudinal skin incision had been made, medial parapatellar arthrotomy was performed. After the joint had been exposed, pins with passive reflective sensors were implanted in the anteromedial region of the distal femur and proximal tibia, for the navigator to read. The reference points requested by the navigator were then gathered (femoral intercondylar center, center of hip rotation, internal and external rotation of the tibia, knee range of motion between 0° and 90°, center of ankle rotation, posterior limits of the femoral condyles, anterior femoral cortical bone, center of the medial and lateral plateaus, center of the proximal tibia, center of the ankle, centers of the lateral and medial malleoli and joint inclination of the femur). The information relating to the patient's anatomy and joint ranges of motion were then input to the software.

After data-gathering had been concluded, the patient's initial mechanical axis was informed by the system. Cuts were then made, firstly in the tibia, always orthogonal to its mechanical axis and without posterior inclination. Before femoral cuts were made, the ligaments were balanced in flexion and extension, by means of laminar tensioners under the control of the navigator on a millimeter scale. These data on the gap (space) in flexion and extension were filed by the system and registered as initial data. After this step, planning for

the femoral cut was done. At this time, using the data on limb alignment, balancing of flexion and extension gaps, femoral rotation and femoral joint inclination, the size of the prosthesis and its best positioning could be defined, always in relation to the mechanical axis.

After the femoral, tibial and patellar cuts had been made, the respective trial components were tested, and the quality of the limb alignment in relation to the mechanical axis in the coronal and sagittal planes and adequacy of the balancing for the planned implants were again investigated by means of the navigator. All these data were recorded and stored. All the components were then placed appropriately and cemented, including the patellar component (the patellae were replaced). The data were again gathered, confirmed and, at this time, recorded as final. This concluded the navigated stage of the procedure and the surgical site was then closed. The data were duly recorded and subsequently compared in order to produce this study.

All the operations were performed by the same surgeon. The implant used was the Columbus PS prosthesis and the navigator used was the Orthopilot 4 in all cases. No intramedullary guides were used. The bone cuts and all the other procedures were navigation assisted.

Extraction method for data and variables

To conduct the present study, the mechanical axis of the lower limb (initial and final) and the flexion and extension gaps (lateral and medial) were measured intraoperatively by means of navigation, as described above. All the data were obtained before and after performing the bone cuts and/or positioning the prosthesis, taking the first to be "initial" and the second, "final".

The alignment and balancing obtained intraoperatively were verified based on the mechanical axis of the lower limbs and the final flexion and extension gaps (in millimeters), respectively. Knees were considered to be well aligned if, after arthroplasty, they presented not more than 3° of deviation in the coronal plane.¹ In relation to the final flexion and extension gaps, knees that presented a difference between the medial and lateral gap of not more than 3 mm were considered to be balanced.

To evaluate the functional result, the Knee Society Score (KSS) was used. The questionnaire was applied before the operation and in the sixth month after the operation, to all the patients. The scoring scale was from 0 to 100, divided into four categories: excellent (more than 84 points), good (70–84), insufficient (60–69), and poor (less than 60 points).⁵⁻⁷

Statistical methods

The patients' flexion and extension gaps and the mechanical axis were described using absolute or relative frequencies.

The KSS was described using summary measurements (mean, standard deviation, minimum and maximum) before and after the treatment and comparisons were made using the paired Wilcoxon test.

Table 1 – Evaluation of balancing and alignment.

Variable	n	%
<i>Balancing of the flexion gap</i>		
No	5	2.6
Yes	191	97.4
<i>Balancing of the extension gap</i>		
No	2	1.0
Yes	194	99.0
<i>Alignment of the mechanical axis</i>		
No	26	13.3
Yes	170	86.7
<i>Balancing of the flexion/extension gap</i>		
No	7	3.6
Yes	189	96.4
<i>Balancing of the gap and alignment of the mechanical axis</i>		
No	33	16.8
Yes	163	83.2
Total	196	100

The pre- and postoperative KSS categories were also described and the changes in categories were compared using the paired Wilcoxon test.

Results

Of the 200 patients included in this study, 11.7% (23) were men, 88.3% (104) knees were right knees and the mean age was 68.7 years (25–88 years). Four patients were excluded from the study: one did not meet the inclusion criteria and three were excluded because of data-gathering mistakes.

In 96.4% of the patients, the relationship between the lateral and medial gaps was balanced both in flexion and in extension. Adequate alignment of the mechanical axis (not more than 3° of varus or valgus in relation to the mechanical axis) was attained in 86.7% of the patients. Ideal balancing of the gaps in association with adequate alignment of the mechanical axis was reached in 83.2% of the patients (Table 1).

In evaluating the sagittal axis, the ideal was considered to be not more than 5° of flexion or 10° of hyperextension. Thus, only 3% (six patients) presented flexion. In these patients, the mean was 7° and the maximum was 9°. None of the patients presented hyperextension above the limit considered.

The mean preoperative functional KSS was 44.13 (minimum of 15 and maximum of 70). Six months after the operation, the mean was 76.85 (minimum of 30 and maximum of 100) (Table 2). Before the operation, 97% of the patients presented poor or insufficient functional KSS; after the operation, 77.6% presented good or excellent KSS (Tables 3 and 4). Thus, there was a statistical difference between the two times ($p < 0.001$).

Discussion

Implant misalignment that results in early failure of total knee arthroplasty (TKA) is well known and documented in the medical literature.⁸ Thus, an implant deviation of as little as 3° in relation to the mechanical axis of the lower limb gives rise to increased risk of aseptic failure,¹ resulting from

Table 2 – Summary measurements of the pre- and postoperative functional KSS.

Variable	Mean	SD	Median	Minimum	Maximum	n	p
Pre-op KSS	44.13	11.58	45	15	70	196	<0.001
Post-op KSS	76.85	13.15	80	30	100	196	

Table 3 – Comparison of preoperative and postoperative KSS according to category.

KSS	Preoperative		Postoperative		p
	n	%	n	%	
Poor	173	88.3	19	9.7	<0.001
Insufficient	17	8.7	25	12.8	
Good	6	3.1	78	39.8	
Excellent	0	0.0	74	37.8	
Total	196	100	196	100	

the asymmetrical pressure exerted on the components when subjected to loads.

In this context, navigation-assisted surgery provides an addition to surgeons' experience: another very important factor in determining the quality of the result, with objective methods for measuring this alignment. On the other hand, despite the unequivocal benefit brought by this technology, which has been attested through a study of highest value in the literature, i.e. the meta-analysis conducted by Hetimish et al.⁹ on the radiographic alignment of components, the inherent clinical impact of this technique has yet to be proven.

Over a minimum follow-up of five years, Ishida et al.¹⁰ found better clinical and radiographic results through using navigation-assisted surgery than through using the traditional technique. This result was also found in the study by Longstaff et al.,¹¹ who were able to correlate correct alignment with better clinical results and early rehabilitation. On the other hand, there are also many reports in the literature that do not make any connection between better alignment and the clinical result,^{12,13} which shows that there is a need to design studies of better quality with longer follow-up, in order to evaluate the clinical results.

In a study on 80 TKA procedures, Bathis et al.¹⁴ achieved adequate alignment in 78% of the cases using the conventional technique. Martin et al.¹⁵ reached an ideal alignment in 76% of the 100 prostheses implanted using conventional instruments. In a study on 500 TKA procedures, Tingart et al.¹⁶ achieved adequate alignment in 74% using conventional

guides. Thus, in comparison with the literature, navigation in this study provided a higher percentage of aligned prostheses: 86.7%.

Other than the alignment, it is known that the ligament balance is a fundamental structure in constructing adequate results in TKA procedures. The kinematic ideal is for there to be a symmetrical balance between the spaces obtained in flexion and extension. Failure in this regard is shown by limitation of the range of motion, accelerated wear on the polyethylene and alterations to patellar excursions.¹⁷ Navigation is a useful instrument for suppressing subjective elements during the balancing, and this is its point of greatest benefit, according to various authors. Here, this instrument, with the use of objective measurements, makes it possible to replace "symmetrical laxity" with "symmetry measured in millimeters", thus bestowing precision on the classical approximation. In the study presented here, construction of the TKA followed the concepts preestablished through the gap technique. A balance was achieved in relation to both of the gaps in 96.4% of the cases operated.

In a similar manner, other authors have defended the hypothesis that through this method, greater coronal stability and alignment is attained.^{18,19} On the other hand, the fundamental point is the peculiar capacity of the technique to influence the alignment and balancing on a case-by-case basis, according to the surgeon's criteria. In the present study, despite the ideal ligament balancing seen with symmetrical gaps, this did not result directly in a neutral mechanical axis in all the cases. On the contrary, neutral alignment was only attained when the ligament balancing was symmetrical.

In some specific cases, sacrificing the alignment might be considered, i.e. a small deviation in relation to the neutral mechanical axis might be consciously allowed. This would be done to prioritize the ligament balance, especially in cases of great deformity in which reestablishment of a neutral axis would already be a debatable matter. Slight variation in the mechanical axis sometimes becomes the only way and, albeit undesirable, essential for obtaining symmetrical gaps. However, balanced ligament tensioning improves the dynamic alignment of TKA procedures, and navigation is a tool that aids in this objective.²⁰

Table 4 – Evaluation of the postoperative category in relation to the preoperative category.

Preoperative KSS	Postoperative KSS										p
	Poor		Insufficient		Good		Excellent		Total		
	n	%	n	%	n	%	n	%	n	%	
Poor	17	8.7	21	10.7	68	34.7	67	34.2	173	88.3	<0.001
Insufficient	1	0.5	3	1.5	7	3.6	6	3.1	17	8.7	
Good	1	0.5	1	0.5	3	1.5	1	0.5	6	3.1	
Excellent	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	
Total	19	9.7	25	12.8	78	39.8	74	37.8	196	100	

Ritter et al.²¹ demonstrated that patients with flexion contracture greater than 5° or hyperextension greater than 10° presented greater risk of pain and poor functional results assessed using the KSS. In the present study, only 3% (six patients) presented postoperative flexion contracture greater than 5°, and none of them presented hyperextension greater than 10°. We did not find any correlation between these data and the KSS.

The large population evaluated and the precision of the data gathered were insufficient to cover the methodological limitations of the study presented here. This was a cases series: it did not have a control group and the study subjects were not randomized. The minimum clinical observation was six months, which can be considered to be a short time within the evolution of arthroplasty results. Nonetheless, this study attained its objective with regard to demonstrating the contribution of navigation toward training and accumulation of knowledge on this topic.

Conclusion

Navigation made it possible to achieve aligned and balanced implants with significant functional improvement among the patients. It was found to be useful for evaluation, understanding and knowledge refinement regarding implementation of arthroplasty.

Conflicts of interest

The authors declare no conflicts of interest.

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