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Navigation in total knee arthroplasty. A multicenter study

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Abstract We carried out a multicentre study to compare the postoperative femorotibial radiographic axis in two total knee replacement groups; one using manual instrumentation and the other using navigation. In the latter group, three navigation systems were used: Stryker, Orthopilot and Navitrack. The prior circumstances of patients in terms of age, weight, aetiology, epicondylar perimeter, patellar tendon length and knee deformity was similar in both groups. The duration of the operation was longer in the group with navigation (16.7 min). A normal femorotibial axis was more frequently obtained in the group with a navigator compared to the manual group (48.1% and 30%, respectively). A varus axis was most common in the manual group (42.2 and 26.9%, respectively). When we analysed the final postoperative radio-

graphic axis, taking 180° to be a normal result, we noted that cases where manual instrumentation was used deviated by 1.19° more than those carried out with navigation, with this difference being statistically significant ($P < 0.001$). No significant differences were found in the final angle of the extremity with the different navigation systems. The navigation systems used in this study improve the frontal angle of the arthroplasty.

Résumé Nous avons réalisé une étude multicentrique pour comparer l'axe fémoro-tibial post-opératoire dans deux groupes de prothèses totales du genou, réalisée soit avec détermination instrumentale manuelle de l'axe ou avec navigation. Dans le deuxième groupe, trois systèmes de navigation ont été réalisés : le système de Stryker, l'Orthopilot et le Navitrack. Les paramètres concernant l'âge, le poids, l'étiologie, la déformation du genou, la longueur du tendon rotulien, l'axe épicondylien sont similaires dans les deux groupes. Le temps opératoire est plus long dans le groupe avec navigation (16,7 min). Un axe fémoro-tibial normal est plus couramment rencontré dans le groupe navigation comparé au groupe avec détermination manuelle de l'axe (48,1% contre 30%). Cependant, la présence d'un axe en varus est plus fréquente dans le groupe avec détermination manuelle de l'axe (42,2% contre 26,9%). Lorsque nous analysons la radiographie finale post-opératoire, en prenant 180° comme axe normal, nous devons noter que pour le groupe utilisant la détermination manuelle instrumentale la déviation axiale est de 1,19° de plus que ceux traités avec navigation. Il s'agit d'une différence statistiquement significative ($p < 0.01$). Nous considérons que le système de navigation améliore la détermination de l'angle frontal en post-opératoire.

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Introduction

The excellent results obtained today with total knee replacements (TKR) are due to design improvements, new materials and the use of better instrumentation. The

Fig. 1 Hospital patient distribution

correct alignment of the components, the reproducibility of the extremity's mechanical axis and the solution to defective ligament balance are factors arising from the surgical technique, the ideal objective of which should be to obtain a long-lasting, painless new joint that works well.

Imprecise positioning of the implant changes the axis of the extremity and has been mentioned as a cause of medium- and long-term failure, leading to wear and tear in the polyethylene, patellar complications and loosening with asymmetrical subsidence of the components. Previous studies have insisted on these determining factors [1, 16, 19], and exact alignment has been constantly sought when introducing proposed new techniques. Today's instruments have obvious advantages in terms of the safety and reproducibility of bone cuts, and the position of the implant as regards femoral and tibial rotation. However, it is acknowledged that some types of standard instrumentation are subject to frequent errors that affect the positioning of the arthroplasty [12]. Attention has been drawn to the errors made when introducing the intramedullary femoral alignment guide, to inaccurate cuts due to the flexibility of the saws, to the difficulty of the reproducibility of the extramedullary tibial alignment guide and especially to errors in finding the ideal rotation of the components [15, 18]. Standard instrumentation, even when used by experts, does not achieve the right arthroplasty alignment in 25% of cases, and the error amounts to 10° in over 6% of cases [13]. Finally, conventional intramedullary alignments cannot be used in patients with femoral or tibial osteosynthesis, hip arthroplasties with long stems, post-traumatic deformities, etc., meaning that extramedullary alignments must be used instead, with the subjectivity that this entails. In the last

Table 2 Knee data description

	Navigation group	Standard group	P value
Mean EP (cts) (SD)	43 (4.31)	43.2 (5.38)	0.83
Mean PT (cts) (SD)	37.8 (5.48)	37.8 (5.18)	0.97
EP/PT relation (SD)	1.15 (0.10)	1.15 (0.06)	0.889
Limb axis alignment			
Normal (%)	3.0	3.4	0.975
Valgus (%)	12.0	12.6	
Varus (°%)	85.0	84	

decades of the last century, following advances made in computing, experimental aid systems were designed, and these were called computer-assisted orthopaedic surgery (CAOS) [5]. There are various CAOS systems on the market for knee arthroplasties, but no multicentre studies have been carried out with different systems and different surgeons. In this study, our aim is to show the experience of a group of surgeons using different navigation systems in the implantation of primary knee arthroplasty. Our objective was to compare the final value of the frontal femorotibial axis in patients operated on using the navigator and patients operated on with mechanical instrumentation (the conventional technique).

Materials and methods

A random prospective and multicentre clinical trial was carried out in 2004 in which five Spanish hospitals participated under the auspices of the Spanish Society of Knee Surgery (*).

The variables of age, body mass index (BMI), surgical time, epicondylar perimeter (EP), patellar tendon (PT) length and radiological data for the femorotibial axis (measurement of femoral and tibial varus or valgus and mechanical femorotibial axis) were collected. All patients underwent a preoperative standing X-ray, including the hip, knee and ankle, which was repeated in the first few days after the operation. One group of patients was operated on using the conventional technique, following the specific recommendations for each implant model. Another group was operated on with the help of navigation, following the steps recommended in the different systems used. The pre- and postoperative studies were similar in all patients. Hospitals 1,

Table 1 Age and BMI description

	Navigation group	Standard group	Total	P value
Mean age (range)	71.6 (69.5–73.8)	72.3 (70.9–73.8)	71.9 (70.6–73.3)	0.593
Mean BMI (range)	30.4 (29.5–31.3)	31.4 (30.4–32.4)	30.9 (30.2–31.5)	0.138
Distribution of BMI				
BMI <5 (normal)	12	7	19	0.710
BMI 25–30 (overweight)	33	30	63	
BMI <30 (obese)	57	47	104	
Missing	7	9	16	

Table 3 Postoperative limb axis alignment

Limb axis alignment	Navigation group (%)	Standard group (%)	P value
Normal	48.1	30.0	0.024
Valgus	25.0	27.8	
Varus	26.9	42.2	

2 and 3 used the Stryker system, hospital 4 used the Navitrack system and hospital 5 used the Orthopilot system.

In order to detect a difference equal to or greater than 20% of deviation from the normal postoperative femorotibial axis between both groups of patients, a minimum sample size of 93 subjects per group was evaluated. An alpha risk of 0.05 and a power level of 0.80 in a bilateral contrast were accepted. Treatment was assigned using tables of random numbers and the statistical analysis was by treatment intention. The distribution of frequencies by percentages was used for the description of qualitative variables, and for the description of quantitative variables, central trend measures and the confidence interval at 95% for the average was used. The χ^2 test was used in the bivariate analysis of qualitative variables, while single-factor ANOVA and Student's t-test were used for the quantitative variables or their equivalent non-parametric tests if the conditions for application of the former were not met. Version 11.0 of the SPSS programme for Windows was used for the statistical analysis of data. An alpha level of significance of 0.05 was established for all the comparisons.

Results

Two hundred and two cases of primary knee arthroplasty were included in the study, of which 109 were assigned to surgery using a navigator and 93 to surgery using the standard technique (manual instrumentation). Postopera-

tive radiographic measurement was not possible in 16 cases, 7 of which were in the navigation group and 9 in the standard technique group. The results are therefore for 102 patients with navigation and 84 with the manual technique. Figure 1 shows the distribution of patients in each participating hospital. The Stryker system was used for the navigation in 66 cases, the Navitrack system in 20 and Orthopilot in 16.

The average age of the patients was 71.9 years (SD: 9.1) and the average BMI was 30.9 (SD: 4.6). Fifty-six percent of the patients were obese and 34.9% were overweight. No statistically significant differences were observed for these variables between the two groups (Table 1). The average EP was 43 mm and the average PT length was 38 mm in both groups. When the relationship between EP and PT was calculated, an average value of 1.15 was obtained, and this value was also the same in patients operated on using the navigator and in those operated on using the manual technique (Table 2).

The average duration of the operation in the entire series was 86 min. Significant differences were detected in the surgical time between the two procedures ($P < 0.001$), with an average duration of 76.9 min in the manual group and 93.6 min in the navigator group.

No differences were noted in the distribution of patients with a normal, varus and valgus preoperative axis between both groups, with the axis varus the most frequent in both (85% in the group with the navigator and 83.9% in the manual group). However, significant differences were observed in the distribution of the postoperative axis. The normal axis ($180^\circ \pm 3^\circ$) was more common in the group with the navigator than in the manual group (48.1 and 30%, respectively). However, a varus axis was more frequent in the manual group (42.2 and 26.9%, respectively) (Table 3).

When analysing the final postoperative radiographic axis, we found that cases of surgery using manual instrumentation deviated 1.19° more from the normal axis than those carried out with navigation, with this

Fig. 2 Postoperative axis deviation in both groups

difference being statistically significant ($P < 0.001$) (Fig. 2). No significant differences were found in the final angle of the extremity with the different navigation systems.

Discussion

CAOS, and surgical navigation in particular, is defined as a system able to carry out a task better than the machine or human working separately [6]. The aim of the synergy of action between the computer and surgeon is to increase the quality of the technique and to quantify, to characterise and to validate the surgery. Since 2001, there have been articles showing comparative radiographic results of implants placed manually or with navigation. Various studies [2–4, 9, 10, 14, 17, 20, 23] have shown that navigation contributes to better positioning of the arthroplasty with regard to the axis of the extremity. Other articles have focused on partial aspects of the surgical technique, especially in terms of rotation of components, stressing the advantages of these systems in an area that is so difficult to reproduce with normal instrumentation systems [8, 24].

Our study has some aspects that make it original. It is a multicentre study with a prospective randomised design, which evaluates the results obtained in two statistically comparable groups, using different navigation systems and carried out by different surgeons with no specialisation in surgical navigation in TKR. These characteristics of our work distinguish it from the studies published to date on CAOS in knee arthroplasties. It may therefore contribute a wider and more realistic perspective than other studies that only show the experience of surgeons who have developed their own navigation system or who are specialists in surgical navigation and who always use the same method.

The results we have obtained for the operating time and the femorotibial angle are similar to those published by other authors who use a single navigation system. In our series, the implant was positioned in an average time of 76.9 min using manual instrumentation, while with navigation the duration of the surgical operation was 93.6 min - a difference of 16.7 min, which was statistically significant ($P < 0.001$). We found that the ideal axis of the extremity is achieved most often with the CAO, and in fact this doubles when navigation is used. Our study also showed that the manual instrumentation system generally tends to place the implants in varus, an error which is improved when the navigation is used. We did not find any differences when studying the postoperative angle obtained with navigation when comparing the three systems used. This means that any of the navigation systems that we analysed meets the objective of obtaining an improved alignment compared to the manual technique.

Despite the well-known advantages that CAOS offers to knee arthroplasty, there are some concerns as to the safety of the technique. The navigation guides the surgeon depending on the information supplied to the computer in terms of bone references and the position of ligaments.

Attention has been drawn to possible errors that may arise from the manual location of femoral epicondyles [11]. There is also no experience in navigation in major deformities, and there is still very little in revision surgery [22]. Furthermore, even in experienced hands, and as our results show, the length of the surgery is at least 15 min longer than in conventional surgery.

It is not yet possible to predict whether the introduction of CAOS will have an impact on our practice similar to that of the fluoroscope or the arthroscope, as some authors assure us [21]. New suggestions for navigation are appearing in the literature [7], and it is possible that in the coming years a work station with a computer will be a normal feature in our operating theatres. In any event, the responsibility for the procedure will remain with the surgeon, and navigation will only help in the best technical positioning of the arthroplasty.

(*) The Navigation Group of the Spanish Society of Knee Surgery consists of the University Hospital Clinic in Barcelona, Juan XXIII Hospital in Tarragona, the IMAS Hospitals in Barcelona, the University Hospital Clinic in Zaragoza and the University General Hospital in Valencia.

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