



## Computer-assisted total knee arthroplasty : comparative results in a preliminary series of 72 cases

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The aim of this study was to assess the value of navigation in achieving correct positioning of the implants and soft-tissue balance in total knee arthroplasty. We compared the axis alignment achieved in 72 LCS TKA's performed with navigation assistance to a historical cohort of 62 LCS TKA's implanted with the conventional instrumentation. The position of the tibial and femoral implants and the post-operative mechanical axes of the lower limbs were compared in the two series : there was a highly significant improvement in the alignment accuracy in the navigated series ( $p < 0.0001$ ). There were no outliers in the computer-assisted series whereas 47% of the cases in the conventional series showed deviations of the mechanical axis of the lower limb of more than  $2^\circ$  from neutral alignment. However, the position of the femoral implants in rotation was not improved, suggesting that there may be a need for a more refined technique for rotational alignment of the femur, which was based essentially in the present series on ligament balance in flexion. The height of the joint line was preserved in 89% of the cases, validating the empirical use of the spreader tool prototype used during the study.

Navigation eases optimal ligament balancing, by providing information that is used for appropriate release of soft tissue to achieve the proper mechanical axis. No major complication related to the use of navigation was observed. Operation time was lengthened on average by 30 minutes. Long-term studies are necessary to show whether better accuracy in ligament balancing and higher precision in restoration of mechanical axes will improve the functional results and the survival rate of knee arthroplasty.

**Key words :** total knee arthroplasty ; computer-assistance.

### INTRODUCTION

Total knee arthroplasty is currently a procedure which is frequently performed in Belgium (11,515 primary cases in 2004). The functional results reported in the literature are generally good ( $\pm 90\%$ ) ; aseptic loosening amount to approximately 1% per year. The instrumentation with extra- or intramedullary guides facilitates correct positioning of the implants. The objective is to decrease mechanical stresses, as well as to minimise the risk of biological loosening due to tissue reaction to particulate wear debris, and of mechanical loosening associated with shear stresses.

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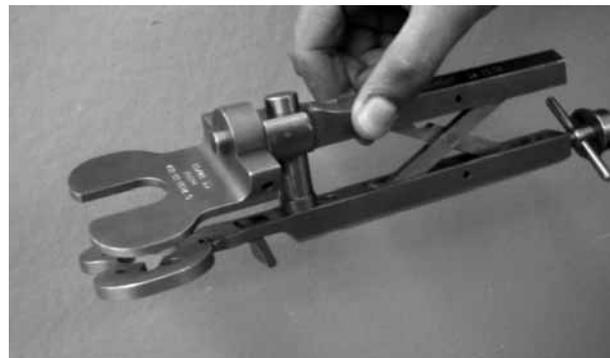
We have used the LCS knee prosthesis (rotating platform mobile-bearing knee, DePuy, Warsaw, IN, USA) in our department since 1993. This prosthesis designed in 1977 by Buechel and Pappas (2) was approved by the FDA in 1985. Its tribology is traditional (CoCr/polyethylene); its design was original at that time, as it was the first total knee prosthesis with full congruence from 0° to 45° flexion (gait congruence), thanks to its mobile-bearing design. Studies carried out *in vitro* as well as *in vivo* showed a marked reduction in contact stresses, due to the increased femorotibial contact areas achieved without a corresponding increase in shear stresses, thanks to the mobility of the polyethylene tibial bearing (10). The stability of the mobile bearing depends on the achievement of a perfect soft-tissue balance throughout the whole range of motion.

Our non-navigated series was reviewed and reported by Devos in 2001 (3). The functional results were good and excellent in 90.3% of cases with a minimum follow-up of one year.

Navigation (Brainlab VectorVision CT-free) (7) was introduced in our department in November 2003; it has been used systematically for primary knee arthroplasty since January 2004. We prospectively evaluated the contribution of navigation to correct positioning of the implants and ligament balancing.

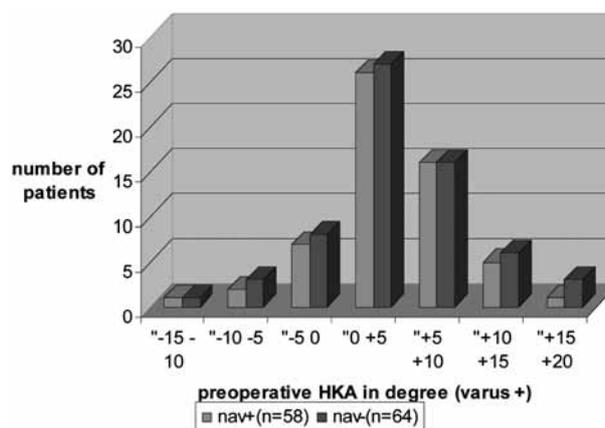
## MATERIALS AND METHODS

We carried out a prospective study of primary TKA assisted by navigation, by comparing the implant positioning and the alignment achieved in our first 72 cases to a historical cohort made up of 62 patients included in the study by Devos (3). We also tried to develop a method to quantify ligament balancing based on the use of a spreader tool prototype (fig. 1), an angle measurement provided by the computer and the anatomical study carried out by Whiteside (19). The historical series used as control was evaluated based on analysis of radiographs, of which the limits of precision have been largely discussed in the literature (18), namely a human misreading of 1° (max), and a 2° error (max) due to inconsistency in rotatory positioning.



**Fig. 1.** — Spreader tool prototype – the lower plate rests on the tibial cut, the upper plate swivels and lifts the femoral condyles, as the soft tissues are put under tension by turning the screw.

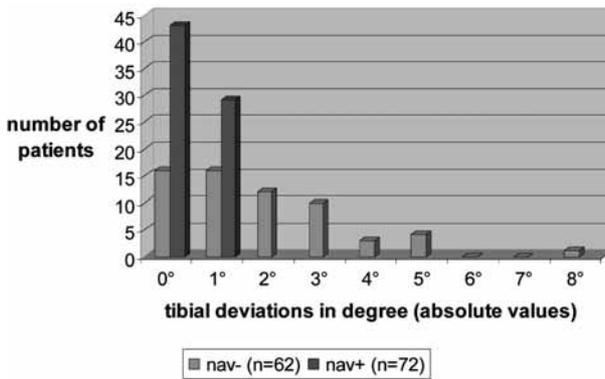
The precision of the navigation system, as stated by the manufacturer, is 1°. In order to assess the precision of the system before clinical use, we carried out goniometric tests using radioopaque markers placed on an articulated axis simulating the lower limb. We then compared the angles measured by the computer with those measured with a goniometer. This preliminary study confirmed the precision (1°) and reliability of the system. The measurements were thus performed differently in the two cohorts of patients, with a higher degree of accuracy for the navigated series. However, we found no statistically significant differences between the val-



**Fig. 2.** — Comparison of the preoperative limb axes (HKA angle) in the series without and with navigation

N	$\mu$ (°)	SD	Range	
Nav-	64	3.9	6.5	(-14 ; 17)
Nav+	58	4	5	(-12 ; 15)

p = 0.97 (Welch's corrected t test)



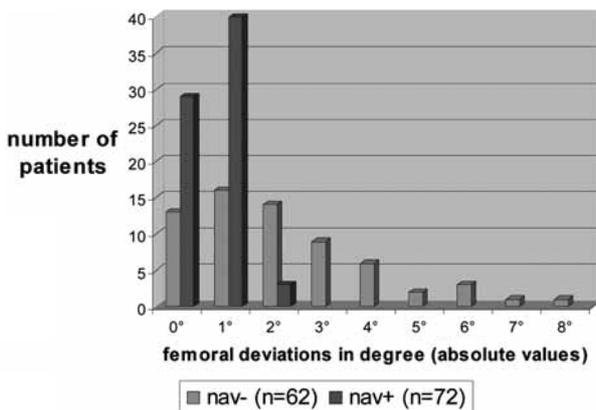
**Fig. 3.** — Comparison of the deviations into varus and valgus (in absolute values) of the tibial implants without and with navigation

N	$\mu$ (°)	SD	Range
Nav- 62	1.8	1.7	(0 ; 8)
Nav+ 72	0.4	0.3	(0 ; 1.4)

p < 0.0001 (Mann-Whitney test)

ues obtained in the two cohorts in preoperative measurement of the axes, which suggests that using different measuring tools in the two cohorts did not introduce a bias (fig 2).

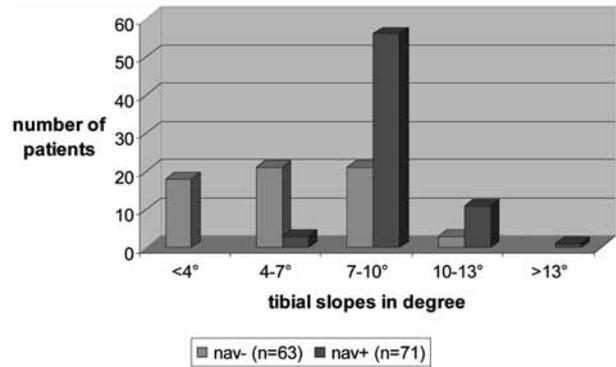
Restoration of the physiological alignment and ligament balance requires in some cases sequential ligament release. When the ligaments are put under tension by the spreader, the navigation system measures the mechanical axis of the limb, which helps



**Fig. 5.** — Comparison of the deviations into varus and valgus (in absolute values) of the femoral implants without and with navigation

N	$\mu$ (°)	SD	Range
Nav- 64	2.2	1.9	(0 ; 8)
Nav+ 72	0.6	0.4	(0 ; 1.8)

p < 0.0001 (Mann-Whitney test)



**Fig. 4.** — Comparison of the slopes of the tibial implants without and with navigation

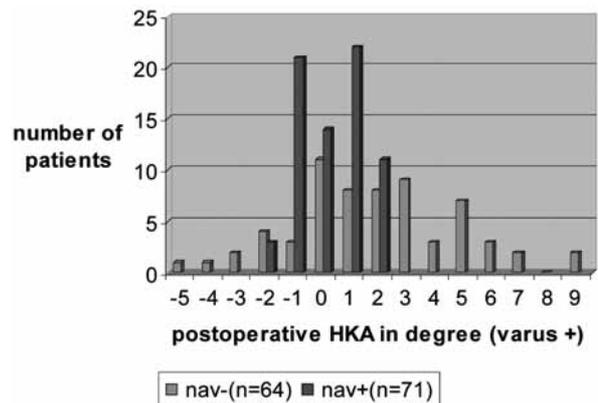
N	$\mu$ (°)	SD	Range
Nav- 63	5.2	3.5	(-4 ; 11)
Nav+ 71	8.8	1.8	(6 ; 14.8)

p < 0.0001 (Mann-Whitney test)

in avoiding a possible ligament imbalance. We record that information to guide the surgical release.

## RESULTS

The following parameters were compared statistically in the two series : varus or valgus positioning of the tibial implant (fig 3), tibial slope (fig 4),



**Fig. 6.** — Comparison of the postoperative mechanical axial deviations of the lower limb (HKA angle) without and with navigation

N	$\mu$ (°)	SD	Range
Nav - 64	2.7	2.2	(0 ; 9)
Nav + 71	1	0.6	(0 ; 2)

p < 0.0001 (Mann-Whitney test) deviation in absolute value

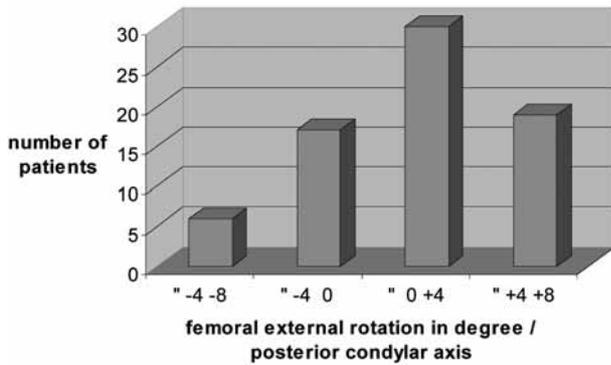


Fig. 7. — External rotation of the femoral component (+) with respect to the posterior condylar axis for the navigated prostheses.

N	$\mu$ (°)	SD	Range
72	15	35	(-6.6 ; 7.8)

varus or valgus positioning of the femoral implant (fig. 5), and postoperative mechanical alignment of the limb (fig. 6). In all these comparisons the results in the navigated series were more precise than in the conventional series. These differences were shown to be highly significant ( $p < 0.0001$ ), and there were no outliers in the navigated series, contrary to the conventional series.

In the technique of implantation of the LCS prosthesis, we first performed ligament balancing in extension using the spreader tool resting on the tibial cut. We then tried to achieve an identical soft-tissue tension in flexion using the spreader, which allows free rotation of the femur, and the posterior

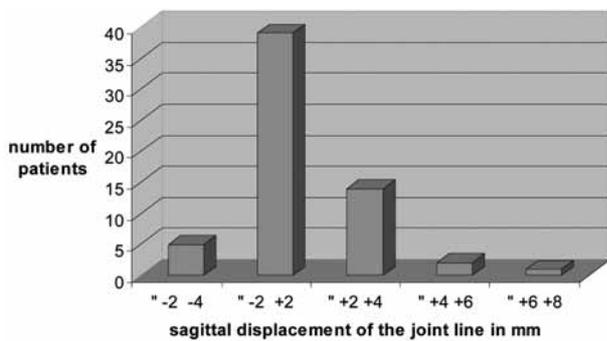


Fig. 9. — Displacement of the joint line in the sagittal plane for the navigated prostheses (+ = anterior displacement ; - = posterior displacement)

N	$\mu$ (mm)	DS	extremes
6	0.8	2.2	(-4 ; 8.5)

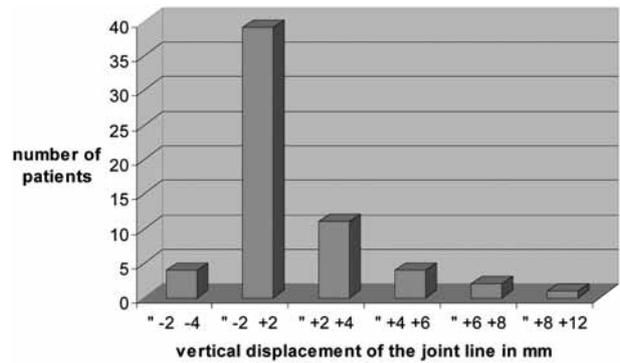


Fig. 8. — Vertical displacement of the joint line for the navigated prostheses (+ = proximal displacement ; - = distal displacement).

N	$\mu$ (mm)	SD	Range
61	1.1	2.8	(-3 ; 12)

femoral cut was made parallel to the tibial cut once the ligaments had been put under symmetrical tension. On this basis, the computer calculates identical gaps in extension and in flexion and determines the height of the distal femoral cut. We also measured the external rotation of the femoral component (fig 7).

Usually, the height of the joint line is measured compared to a distal reference mark such as the tip of the fibular head, which makes it possible to record a proximal or distal displacement of the joint line (fig 8). Navigation also evaluates the height of the joint line compared to a femoral reference mark and takes account of an antero-posterior displacement of the joint line, which is of importance in flexion (fig 9). Preservation of the height of the joint line in extension and in flexion is directly related to the accuracy of the ligament balancing. The axis measurements with the spreader in place

Table I. — Actions for capsule and ligament releases

	Extension	Flexion
MCL Ant portion	-	+
Post portion	+	-
LCL Ant. portion	-	+
Post. portion	+	-
Medial Post Capsule	++	+/-
Lateral Post Capsule	++	+/-
Post Capsule	+	-
Muscles	+	-

enabled us to specify the various surgical actions to be carried out in cases with severe deformity (table I).

No major complication related to the technique of navigation occurred. Operation time was lengthened 30 minutes on average for the recording of the anatomical reference marks by the computer (morphing). Partial loss of data occurred in 8 cases, owing to displacement of the beacons of location, which suggests that positioning of the tibial beacon should be done by a short independent incision.

## DISCUSSION

As in other series published (1, 5, 15, 16), the navigation system was found to provide very efficient assistance to achieve correct positioning of the implants in the frontal plane. The axis deviation can easily be limited to  $1^\circ$  for each implant and  $2^\circ$  for the postoperative mechanical axis (HKA angle). In the series carried out using the traditional Milestone<sup>R</sup> instrumentation, significant deviations were noted in some cases, reflecting insufficient precision of the mechanical guides and cutting instruments. With the conventional instrumentation, the precision is estimated to be  $3^\circ$  for each implant (8, 9, 11, 17). The unfortunate coincidence of two variations going in the same direction may result in a marked axis deviation. According to Pappas (12), the LCS prosthesis can tolerate variations in varus - valgus positioning up to a certain point owing to its congruence, without undergoing severe stress concentration on the mobile bearing. However, marked deviations are worrying for the future because several authors have shown a correlation between deviations greater than  $3^\circ$  and reduction in survival rate (4, 13, 14).

In the sagittal plane, the tibial slope recommended by the designers is between  $7^\circ$  and  $10^\circ$ . Without navigation this slope was often found to be insufficient, although this did not translate into a limitation in the range of flexion or into hyperextension. From a biomechanical point of view, positioning of the femoral component in rotation must ideally be tuned by reference to the epicondylar axis; otherwise, it will result into a varus or valgus deviation when going from extension to flexion. One may

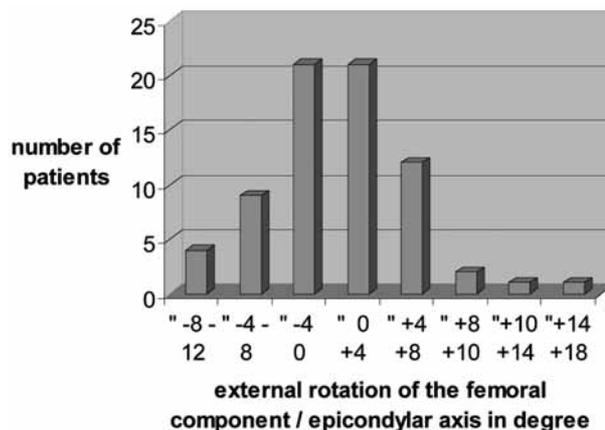


Fig. 10. — External rotation of the femoral component (+) with respect to the epicondylar axis for the navigated prostheses (+ : external rotation ; - : internal rotation)

N	$\mu$ ( $^\circ$ )	SD	Range
71	0,55	5,2	(-11 ; 15)

indeed question the biomechanical value of a mechanical axis which would be neutral in extension but would go into varus or valgus while walking. Nevertheless, the technique of implantation of the LCS privileges rotation of the femoral implant based on ligament balancing instead of referring to the epicondylar axis. The rotation of the femoral implant is chosen after ligament balancing has been achieved in extension. In our series, 32 % of the femoral implants were placed in internal rotation with reference to the posterior condylar line (fig 7). However, knees presenting with major laxity of the medial capsule were considered to be contraindications to the use of a mobile bearing TKA. In our opinion, these malrotations are related to undue release of the medial structures located anteriorly to the epicondylar axis during ligament balancing in extension. For this reason, it seems important to be more selective in our releases, as described in table I. On this point, navigation assistance only offers subsequent control and the release should therefore be progressive and targeted. The distribu-

Table II. — Correlation according to Pearson of the rotation of the femoral implant compared to the posterior condylar line (fig 7) and compared to the epicondylar line (fig 10)

N	r	CI 95 %	p	r <sup>2</sup>
71	0.19	-0.04 to 0.4	0.11	0.04%

tion of the individual values for rotation of the femoral implants for the navigated prostheses show a relatively and perhaps alarming dispersion, although none of the patients presented any problem in the short term, particularly regarding the femoro-patellar joint.

The epicondylar axis is usually in 3° external rotation with respect to the posterior condylar axis. However, we could find no significant correlation between the rotation of the femoral implant measured with reference to the posterior condylar line and that measured with reference to the epicondylar axis (fig 10 and table II). This shows in our opinion as well as for other authors (6), the intrinsic lack of precision involved in the determination of the epicondylar axis, which is nevertheless used as a reference in certain surgical techniques.

Displacements of the height of the joint lines in extension and in flexion are usually minimal, which tends to prove that the spreader tool functions correctly on an empirical basis. It suffers however from the absence of a precise system to measure the tension applied to the soft tissue, which could be recorded by the computer. This currently appears difficult to achieve, taking into account the viscoelastic behaviour of the ligaments and muscles, the variability in the weight of the limbs of the patients and the individual characteristics.

From a more general point of view, the surgical technique was not modified by the introduction of navigation. In the event of a technical failure of the system, the surgeon should be able to proceed with the operation on a traditional basis. This is why we prefer to use a conventional instrumentation which has been adapted to navigation. The responsibility of the surgeon and his initiative must be preserved to allow for possible corrections of intraoperative errors due to incomplete information of the system. The accuracy of the information transmitted to the navigation system during the intervention is of course essential.

The parameter settings of the computer must remain open and the stages of the procedure must correspond to the philosophy of implantation specific to the implant and to the surgeon. Finally the precision and the reliability of the system must be

evaluated on site. No published data is available to date with respect to the possible improvement of the clinical outcome of navigated total knee prostheses. In order to achieve the necessary power, a study should include a cohort of 1000 patients followed during more than one year. Other studies are thus necessary to show that improvement in soft-tissue balancing and in restoration of axis alignment are elements that may improve the functional results and the survival rate of mobile-bearing knees.

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