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ORIGINAL STUDY

Computer-assisted technique versus intramedullary and extramedullary alignment systems in total knee replacement : A radiological comparison

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Malalignment in total knee replacement (TKR) is frequently associated with earlier failure and poor functional results. The authors compare the radiological results achieved in three consecutive series of TKRs using a computer-based alignment system (38 cases), a totally intramedullary alignment system (40 cases) and a totally extramedullary alignment system (37 cases). The frontal-femoral-component angle (FFC), the frontal-tibial-component angle (FTC), the hip-knee-ankle angle (HKA) and the sagittal orientation of the tibial component (slope) were evaluated 12 months after operation.

The results did not show any statistically significant differences between the mean values of FFC, FTC, HKA angles and tibial slope among the three groups. However in the extramedullary alignment group there was a statistically higher percentage of TKRs with abnormal FFC and HKA angles. Furthermore all the implants in the computer aligned group were aligned within 4 degrees both of an ideal HKA and tibial slope.

Key words : total knee arthroplasty ; computer assistance.

INTRODUCTION

Optimal surgical technique is one of the most important factors influencing the outcome of total knee replacement *(1, 8)*. Early wear and loosening of the implant or a poor performance can indeed be caused by incorrect positioning or orientation of the implant as well as faulty limb alignment *(10, 20)*.

Although mechanical alignment guides have improved and are still progressing in the accuracy with which implants can be inserted, errors in implant and limb alignment continue to occur. It has been suggested that errors in tibial and femoral alignment of > 3° occur in at least 10% of TKRs, even with the most skilful orthopaedic surgeon and with the most modern mechanical alignment guides *(6, 13, 15)*.

Furthermore even the most sophisticated mechanical system to assist the surgeon in the positioning of the prosthesis relies on visual inspection to confirm the correct limb alignment and stability. The accuracy of the pre-operative planning is limited by the lack of precision of standard radiographs ; during the surgery, it is very difficult to maintain a continuous and correct monitoring of the alignment landmarks, and a standardised bone geometry is not found in every patient.

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For this purpose computer-based alignment systems (CT-based or CT-less) have been developed to address the limitations in mechanical axis alignment, and more recently a totally robot assisted TKR system to achieve both mechanical and rotational alignment *(12, 16)*. Despite a lower accuracy, CT-less systems are able to find the mechanical axis of the leg intra-operatively without any pre-operative imaging or planning.

Since 1999 we have been using a computer-based CT-less alignment system in TKR (Orthopilot, Aesculap, Tuttlingen, Germany) widely described in literature by different authors *(4, 11, 18, 19)*. This system, intraoperatively using specific probes, identifies and acquires joint centers, tracks surgical tools and aligns prosthetic components in a correct mechanical axis, assisting the surgeon during the surgical procedure.

The aim of this study was to compare retrospectively the radiological results achieved in three series of different total knee replacements (TKRs) performed using the Orthopilot computer-based alignment system (group A), a totally intramedullary alignment system (group B) and a totally extramedullary alignment system (group C).

MATERIALS AND METHODS

Among 389 TKRs performed in our department between December 1998 and March 2003 using three different prostheses with different alignment systems, 126 TKRs were enrolled in the study. The inclusion criteria were a diagnosis of primary osteoarthritis, a body mass index $\leq$ 35 kg/m^2, a pre-operative hip-knee-ankle angle (HKA) in the frontal plane within a range from 165° to 195°, and a pre-operative knee flexion deformity not exceeding 10°. These two values were measured on pre-operative radiographs. Furthermore, in order to avoid a surgeon-related bias related to learning curves, the first 10 cases of each of the three different implants have been excluded from this study.

Twelve months post-operatively, standing long-leg anterior-posterior radiographs and lateral radiographs of the knee were taken for every patient. For the long standing radiographs the patient had to maintain the knee in maximum extension, the patella pointing forward and with both hips and ankles visible on the film.

The quality of the radiographs was assessed by an independent radiologist not involved in the study.

Of the 126 knees included in this study, acceptable both pre-operative and post-operative film were available for 115, with 38 knees in Group A, 40 knees in group B and 37 knees in group C.

Group A includes 38 knees operated on with the computer navigator assisted alignment Orthopilot (version 3.0) using the Search[R] knee prosthesis (Aesculap, Tuttlingen, Germany) retaining the posterior cruciate ligament (PCL) with a fixed tibial bearing.

Group B includes 40 knees operated on using a totally intramedullary alignment system for both tibia and femur cuts using the Genius TriCCC[R] prosthesis (Dedienne Santé, Maguio, France) sacrificing the PCL with a mobile tibial bearing.

Group C includes 37 knees operated on using totally extramedullary alignment guides for both tibial and

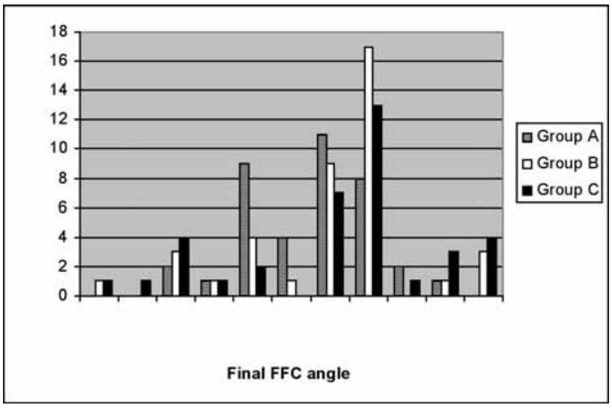

Fig. 1. — Histogram showing the distribution of the individual values of the final Frontal Femoral Component Angle (FFC) for the Computer-Assisted group (Group A), the Intramedullary group (Group B) and the Extramedullary group (Group C).

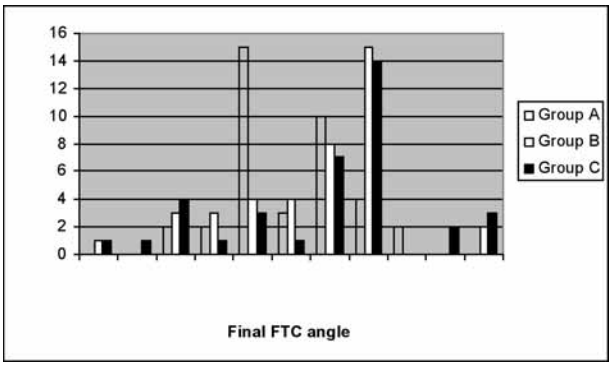

Fig. 2. — Histogram showing the distribution of the individual values of the final Frontal Tibial Component Angle (FTC) for the Computer-Assisted group (Group A), the Intramedullary group (Group B) and the Extramedullary group (Group C).

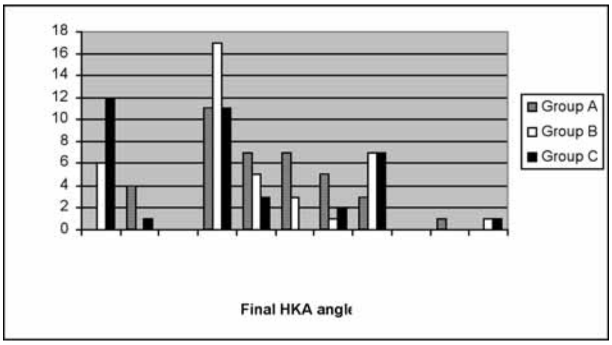

Fig. 3. — Histogram showing the distribution of the individual values of the final HKA angle for the Computer-Assisted group (Group A), the Intramedullary group (Group B) and the Extramedullary group (Group C).

femoral cuts, to implant a Scan[R] PCL-retaining prosthesis (Mitab, Sjoborg, Sweden) with a fixed tibial bearing. The femoral alignment is achieved using an extramedullary alignment rod over the femoral head and is checked by an intraoperative radiograph of the hip.

All TKRs were performed by one of the authors (NC). An anterior mid-patella approach and a medial arthrotomy were used in all the cases. All three alignment instruments were set to achieve an ideal hip-knee-ankle angle (HKA) of 180° in the frontal plane and a tibial slope in the sagittal plane according to the implant design (0° for Search, 5° for Scan and TriCCC).

The same cementing technique was used in all cases for both tibial and femoral components and in no case was the patella replaced.

The same postoperative rehabilitation regimen was adopted for all patients, with full weigh-bearing as soon as tolerated.

On the 12-month radiographs, an independent radiologist not involved in the study assessed the frontal femoral component angle (FFC), the frontal tibial component angle (FTC), the hip-knee-ankle angle (HKA) and the sagittal orientation (slope) of the tibial component. The FFC angle is determined by the mechanical axis of the femur and the transverse axis of the femoral component, while the FTC angle is determined by the mechanical axis of the tibia and the transverse axis of the tibial component. Before starting the study we had considered as an ideal alignment a prosthesis with an FFC angle of 90°, a FTC angle of 90°, an HKA angle of 180°and an ideal slope of the tibial component according to the implant design.

We calculated in each group the proportion of femoral and tibial components not aligned within 2 degrees of 90°, the proportion of prostheses aligned within 2 and 4 degrees of an ideal HKA (180°) and the proportion of tibial components aligned within 2 degrees of ideal slope suggested by the design of the prostheses.

Statistical analysis was performed using both parametric (Anova) and non parametric (Kruskal-Wallis) tests. Comparisons between groups were made using Chi-square test, Bonferroni test for the operative time ; Kruskal-Wallis test for the post operative values of HKA, FFC and FTC. Tukey's test was used to study the different proportions of HKA, FFC, FTC angles and tibial component slopes. All differences noted were considered statistically significant when $p < 0.05$.

RESULTS

The demographic data of the patients are shown in table I. There were no significant differences between groups with respect to the pre-operative Hip-Knee-Ankle angle (HKA) and flexion deformity.

Table I. — Demographic data

	Group A n = 38 (computer assisted)	**Group B n = 40 (intramedullary)**	**Group C n = 37 (extramedullary)**
Mean age	72 (range : 56 to 84)	67 (range : 47 to 81)	70 (range : 39 to 86)
Gender	20 male 18 female	22 male 18 female	18 male 19 female
Mean pre-op HKA	175.8° (SD : 6.7)	174.1° (SD : 7.6)	176.1° (SD : 6.3)
Mean flexion deformity	2.3° (SD : 2.6)	2.1° (SD : 2.1)	2.2° (SD : 2.2)

SD = standard deviation

No intra-operative complication is reported in the surgical charts.

The mean operative time was 109.2 minutes (range : 89 to 133) in the navigated group (group A), 91.2 minutes (range : 74 to 112) in the group using intramedullary alignment guides (group B) and 82.2 minutes (range : 65 to 106) in the group using extramedullary alignment guides (group C).

The operative time was statistically longer in group A than in group B and group C (p = 0.0001).

However even in group B the operative time was statistically longer than in group C (p = 0.0002).

At the 6-month follow-up the mean Hip-Knee-Ankle angle (HKA) was 179.1° (range : 176° to 184°) in group A, 178.6° (range : 173° to 186°) in group B and 177.8° (range : 172° to 186°) in group C, with no statistically significant differences beween the three groups.

The mean frontal femoral component angle (FFC) was 90.5° (range : 87° to 94°) in group A, 91.05° (range : 85° to 95°) in group B and 91.19° (range : 85° to 96°) in group C, and there were no statistically significant differences between the three groups.

The mean frontal tibial component angle (FTC) was 89.9° (range : 83° to 97°) in group A, 90.6° (range : 87° to 95°) in group B and 90.8° (range : 86° to 95°) in group C ,and there were no statistically significant differences between the three groups.

The mean tibial component slope in the sagittal plane was 1° (range : 3° to 0°) in group A, 3.6° (range : 7° to 0°) in group B and 3.1° (range : 6° to 0°) in group C (table II).

Thirty three (86.8%) femoral components in group A were aligned within 2 degrees of 90°in the coronal plane, versus 32 (80%) in group B and 23 (62.1%) in group C, with a statistically significant difference (p = 0.03) between groups A and C (A > C).

Thirty four (89.4%) tibial components in group A were aligned within 2 degrees of 90° in the coronal plane, versus 34 (85%) in group B and 26 (70.2%) in group C ; there was no statistically significant difference between the three groups.

Thirty three (86.8%) prostheses in group A were aligned within 2 degrees of 180° in the coronal plane, versus 33 (82.5%) in group B and 23 (62.1%) in group C, with a with a statistically significant difference (p = 0.02) between groups A and C (A > C).

All implants in group A were aligned within 4 degrees of an ideal HKA (180°), versus 35 (89.5%) in group B and 28 (75.7%) in group C , with a with a statistically significant difference (p = 0.002) between groups A and C (A > C) (table III).

In the sagittal plane, all implants in group A were aligned with a slope within 4 degrees of the targeted value (0°) ; in group B there were 39 (97.5%) prostheses aligned within 4 degrees of the

Table II. — Final results : mean values for various parameters studied

	Group A n = 38 (computer assisted)	**Group B n = 40 (intramedullary)**	**Group C n = 37 (extramedullary)**
Mean surgical time	109 min (range : 82 to 133)	92 min (range : 67 to 112)	81 min (range : 57 to 106)
Mean post-op FFC angle	90.5° (SD : 1.6)	91.05° (SD : 2.17)	91.19° (SD : 2.68)
Mean post-op FTC angle	89.97° (SD : 1.5)	90.6°	90.8° (SD : 2.1) (SD : 2.5)
Mean post-op HKA angle	179.18°	178.6° (SD : 1.8)	177.8° (SD : 2.6) (SD : 3.3)
Mean tibial slope	1.2° (SD : 1.03)	3.6° (SD : 1.31)	3.1° (SD : 1.35)

SD = standard deviation

Table III. — Final results : proportions of optimal values for the various angles measured in the three groups

	Group A n = 38 (computer assisted) Number of cases	**Group B n = 40 (intramedullary) Number of cases**	**Group C n = 37 (extramedullary) Number of cases**
FFC angle between 88° and 92°	33 (86.8%)	32 (80%)	23 (62.1%)
FTCA between 88° and 92°	34 (89.4%)	34 (85%)	26 (70.2%)
HKA angle between 177° and 183°	33 (86.8%)	33 (82.5%)	23 (62.1%)
HKA <176° or >184°	0 (10.5%)	5 (24.3%)	9

	Group A n = 38 (computer assisted) Number of cases	**Group B n = 40 (intramedullary) Number of cases**	**Group C n = 37 (extramedullary) Number of cases**
Tibial Slope within 4° of ideal alignment	38 (100%)	39 (97.5%)	33 (89.1%)

targeted value (5°) and in group C there were 33 (89.1%) prostheses aligned within 4 degrees of 5° without any statistically significant difference among the 3 groups (table III).

DISCUSSION

In total knee replacement, proper axial alignment is of primary importance for the longevity of the implant. Malpositioning in any anatomical plane can cause significant complications : varus or valgus malalignment is the commonest cause of early loosening, and alterations in the position of the joint line lead to limited movement *(7, 13, 20)*. Ritter *et al (15)* reported that malalignment in TKR occurred in more than 10% of the cases.

The introduction of extramedullary and intramedullary alignment systems has definitely improved the accuracy of the alignment of the implants. Nowadays intramedullary guides are identified as the gold standard for the positioning of the femoral components but opinions are divided as to which alignment guide is really superior in positioning the tibial component *(2, 11)*. One study was in favour of a totally intramedullary technique even if this could increase the risk of fatty embolism *(14)*.

Computer-assisted systems have been developed in order to improve the alignment of components, even though not all studies have demonstrated this issue. Despite initial scepticism among most orthopaedic surgeons, recent trials have demonstrated that the use of a navigation system can improve the alignment of the implants, it permits to implant components with greater accuracy and to reduce individual defects and their cumulating effects *(3-5, 9, 18)*.

In our trial we have compared the sixth month follow-up radiological results of three different guiding systems : totally intramedullary, totally extramedullary and computer-assisted.

Our study has some limitations : it was retrospective and not randomised, radiological evaluation was in one plane only and different prostheses designs (PCL sparing or sacrificing) were used in the three groups studied. However we have excluded the first 10 cases for each implant, to avoid a possible bias related with the learning curve . We defined strict inclusion criteria (diagnosis, preoperative deformity, body-mass index, excellent radiograph quality) and we chose a selective definition of the results (alignments and their proportions within 2° of 90° and within 2° and 5° of 180°) to compare three alignment instrumentations in TKR in the frontal plane.

Furthermore our inclusion criteria intentionally excluded difficult cases with major deformity where, according to our experience, the computer assisted alignment guide has obvious advantages compared to implantation without navigation support.

Although the mean values of the postoperative Hip-Knee-Ankle angle were similar in the three groups, there was no implant with an alignment diverging from the targeted 180° by more than 4 degrees in the computer assisted group, and this was not the case in the other two groups.

There was a higher proportion of prostheses aligned within 2 and 5 degrees of an ideal HKA angle (180°) in the computer-assisted group than in the other two groups, and the difference with the extramedullary group reached statistical significance.

Likewise, in terms of the proportion of implants aligned within 2 degrees of an ideal FFC (90°), we registered a higher percentage of correct alignments in the computer-assisted group than in the other two groups, with a statistically significant difference compared to the extramedullary group.

The surgical time was statistically longer in the computer assisted group than in the other two groups. It was also significantly longer in the intramedullary group than in the extramedullary group. On the other hand, in the computer-assisted group there were no additional costs incurred by intra-operative imaging procedures or preoperative trial measurements for the implant.

Our results for the intramedullary and extramedullary groups are consistent with those reported in other studies. Oswald *et al* *(13)* reported a malalignment exceeding 4° in the sagittal plane in only 8% of his series using an extramedullary alignment system. Recently, Reed *et al* *(14)* in a randomised prospective comparison of extramedullary and intramedullary tibial alignment guides in the frontal plane reported 15% tibial components not aligned within 2° of 90° in the intramedullary group, versus 35% in the extramedullary group ; these findings are very similar to ours.

In 2003, Sparmann *et al* *(17)* in a randomised study reported statistically better alignment in both the frontal and sagittal plan for computer assisted alignment of implant than without navigation support, emphasising the immediate benefits of computer assisted techniques in TKR.

Furthermore, stressing the knee in varus/valgus during all the phases of the registration process for the navigated implant demonstrates how much of the deformity is correctable, which may guide the soft-tissue release *(3)*.

Our results demonstrate significant improvement in the accuracy of implant alignment using a computer assisted system, compared to an extramedullary guide. In the computer assisted group we did not report any cases of malalignment exceeding 3 degrees from an ideal implant position in both the frontal and sagittal plane.

REFERENCES

1. **Aglietti P, Buzzi R.** Posteriorly stabilized total condylar knee replacement : three to eight years follow-up of knees. *J Bone Joint Surg* 1988 ; 70-B : 211- 216.
2. **Brys DA, Lombardi AV Jr, Mallory Th, Vaughan BK.** A comparison of intramedullary and extramedullary alignment systems for tibial component placement in total knee arthroplasty. *Clin Orthop* 1991 ; 263 : 175-181.
3. **Chauban SK, Scott RG, Breidahl W, Beaver RJ.** Computer assisted knee arthroplasty versus conventional jig-based technique : a randomised, prospective trial. *J Bone Joint Surg* 2004 ; 86-B : 372-376.
4. **Confalonieri N, Saragaglia D, Picard F *et al.*** Computerised OrthoPilot system in arthroprosthesis surgery of the knee. *J Orthop Traumatol* 2000 ; 2 : 91-98. Springer-Verlag Italy srl, Milan.
5. **Confalonieri N, Saragaglia D, Picard F *et al.*** Il sistema computerizzato Orthopilot negli interventi di artroprotesi di ginocchio. *Giorn Ital Ortop Traumat* 2000 ; 26 (suppl. 1) : 5415-5422.
6. **Ecker Ml, Lotke PA, Windor RE, Cello JP.** Long term results after total condylar knee arthroplasty. *Clin Orthop* 1997 ; 216 : 151-157.
7. **Garg A, Walker PS.** Prediction of total knee motion using a three-dimensional computer graphics model. *J Biomech* 1990 ; 23 : 45-50.
8. **Insall JN, Scott W, Ranawat CS.** The total condylar knee prosthesis. A report of two hundred and twenty cases. *J Bone Joint Surg* 1979 ; 61-A : 173-177.
9. **Jenny JY, Boeri C.** Computer-assisted implantation of total knee prostheses : a case control comparative study with classical instrumentation. *Comput Aided Surg* 2001 ; 6 : 217-223.
10. **Lotke PA, Ecker ML.** Influence of positioning of prosthesis in total knee replacement. *J Bone Joint Surg* 1977 ; 59-A : 77-82.
11. **Maestro A, Harwin S, Sandoval MG *et al.*** Influence of intramedullary versus extramedullary alignment guides on final total knee arthroplasty component position : a radiographic analysis. *J Arthroplasty* 1998 ; 13 : 552-556.

12. **Nabeyama R, Matsuda S, Miura H *et al.*** The accuracy of image-guided knee replacement based on computed tomography. *J Bone Joint Surg* 2004 ; 86-B : 366-372.
13. **Oswald MH, Jakob RP, Schneider E, Hoogewoud HM.** Radiological analysis of normal axial alignment of femur and tibia in view of total knee arthroplasty. *J Arthroplasty* 1993 ; 8 : 419-423.
14. **Reed MR, Bliss W, Sher L *et al.*** Extramedullary or intramedullary tibial alignment guides : a randomised prospective trial of radiological alignment. *J Bone Joint Surg* 2002 ; 84-B : 858-862.
15. **Ritter MA, Faris PM, Keating EM, Meding JB.** Postoperative alignment of total knee replacement : its effect on survival. *Clin Orthop* 1994 ; 299 : 153-158.
16. **Saragaglia D, Picard F, Chaussard R.** Computer assisted knee arthroplasty : comparison with a conventional procedure. Results of 50 cases in a prospective randomised study. *Rev Chir Orthop* 2001 ; 87 : 18-23.
17. **Sparmann M., Wolke B, Czupalla H *et al.*** Positioning of total knee arthroplasty with and without navigation support. A prospective randomised study. *J Bone Joint Surg* 2003 ; 85-B : 830-834.
18. **Stulberg SD, Loan P, Sarin V.** Computer-assisted navigation in total knee replacement : results of an initial experience in thirty-five patients. *J Bone Joint Surg* 2002 ; 84-A (suppl. 2) : 90-94.
19. **Stulberg SD.** How accurate is current TKR instrumentation? *Clin Orthop* 2003 ; 416 : 177-183.
20. **Wasielewski RC, Galante JO, Leighty R *et al.*** Wear patterns on retrieved polyethylene tibial inserts and their relationship to technical considerations during total knee arthroplasty. *Clin Orthop* 1994 ; 299 : 31-36.