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Computer-assisted versus intramedullary and extramedullary alignment system in total knee replacement: Long term follow-up

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ABSTRACT

Introduction: The aim of this work is to compare in a retrospective study, the radiological results of three series of different total knee replacements performed using Orthopilot computer-based alignment system (Group A, 31 patients), a totally intramedullary alignment system (Group B, 34 patients) and a totally extramedullary alignment system (Group C, 32 patients).

Materials and methods: At a medium follow-up of 15 years, all patients underwent call interview for clinical update. Of the 115 patients initially enrolled in the study, only 97 were available for radiological assessment. Both standing long-leg antero-posterior radiographs and lateral radiographs of the knee had been taken for every patient at 1 year-follow-up and at the last follow-up.

Results: At the last follow-up, the mean hip-knee-ankle angle (HKA) was 179.1° (range: 176°–184°) for group A, 178.6° (range: 173°–186°) for group B and 177.8° (range: 172°–186°) for group C with no statistically significant difference among the 3 groups. The mean frontal femoral component angle (FFC) was 90.5° (range: 87°–94°) for group A, 91.05° (range: 85°–95°) for group B and 91.19° (range: 85°–96°) for group C and there was no statistically significant difference among the three groups. The mean frontal tibial component angle (FTC) was 89.9° (range: 83°–97°) for group A, 90.6° (range: 87°–95°) for group B and 90.8° (range: 86°–95°) for group C and there was no statistically significant difference among the three groups. The mean tibial component inclination in the sagittal plane was 1° (range: 3°–0°) for group A, 3.6° (range: 7°–0°) for group B and 3.1° (range: 6°–0°) for group C.

Discussion and conclusion: Our results demonstrated statistically significant differences between computer-assisted and extramedullary group, in favour of navigated group in terms of implant position and mechanical alignment. Computer-assisted group showed superior but not statistically significant differences compared to intramedullary alignment system in terms of implant position and mechanical alignment. We advocate the use of computer-assisted system routinely in total knee replacement. As an alternative, we suggest the use of intramedullary system.

1. Introduction

The survival rate of total knee replacement (TKR) is influenced by several factors, such as patient selection, implant characteristics, surgical technique and finally mechanical alignment. It has long been suggested that restoration of a neutral mechanical axis improves durability following TKR.[1–3] On the other hand, other studies have reported no significant difference in survivorship when a traditionally safe zone of 0-3° was used to define aligned versus malaligned knees.[4–6]

Nowadays, neutral mechanical alignment is considered the “gold standard” and the primary aim in every TKR. This can be achieved through different surgical techniques, such as extramedullary and intramedullary guides, patient-specific instrumentation (PSI) and computer-assisted surgery (CAS), each one with advantages and disadvantages. Regarding the intramedullary guide, there is an increased risk of fatty embolism,[7] there are great limitations on its use, or even impossibility, in cases of bone deformity, sequelae of trauma or presence of osteosynthesis material that obliterates the medullary canal. Regarding the extramedullary guide, it becomes more difficult to use it in cases of great obesity or increased soft-tissue volume around the tibia. PSI for TKR

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has been introduced to improve alignment, reduce outliers, operation time and the risk of fatty embolism by avoidance of intramedullary canal violation. Recent randomised controlled trails and meta-analysis proved no advantage of PSI in improving mechanical axis and implant survivorship.[8,9]

CAS has provided a useful tool in assisting the surgeon to achieve more accurate post-operative mechanical axis through precise and reproducible bone resection and ligament balancing.[10] CAS for TKR has been reported to provide more precise component placement in coronal, sagittal and rotational alignment; more accurate bone cuts and better restoration of coronal limb alignment.[11–13] In a meta-analysis of 29 studies comparing CAS with conventional technique, Mason et al.[14] demonstrated 90.4% of patients with a femoral varus/valgus alignment within 2° of the femoral mechanical axis (versus 65.9% in the conventional group) and 95.2% of patients with a tibial varus/valgus alignment within 2° of the tibial mechanical axis (versus 79.7% of the conventional group). While has been proved that CAS improves mechanical alignment and consequently implant survivorship, improved patient outcomes have been harder to demonstrate.

The aim of this work is to compare in a retrospective study, the radiological results of three series of different TKRs performed using Orthopilot computer-based alignment system (Group A), a totally intramedullary alignment system (Group B) and a totally extramedullary alignment system (Group C) at a medium follow-up of 15 years.

2. Materials and Methods

Between December 1998 and March 2003, the Authors performed 389 TKRs using 3 different alignment systems, of which 126 were enrolled into the study. The inclusion criteria were: a diagnosis of primary osteoarthritis, a body mass index ≤35 kg/m square, a pre-operative hip-knee-ankle angle (HKA) in the frontal plane ranging from 165° to 195° and a pre-operative knee flexion deformity not exceeding 10° both calculated on pre-operative radiographs.

Both standing long-leg antero-posterior radiographs and lateral radiographs of the knee had been taken for every patient at 1 year-follow-up and at the last follow-up. 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 radiographs quality was assessed by an independent radiologist not involved in the study.

At medium follow-up of 15 years, all patients underwent call interview for clinical update. Of the 115 patients enrolled in the study, only 97 were available for radiological assessment. The Authors compare the radiological results of the 3 series of TKRs using a computer-based alignment system (Group A, 31 cases), a totally intramedullary alignment system (Group B, 34 cases) and a totally extramedullary alignment system (Group C, 32 cases). In all cases the preoperative end-point was to achieve an ideal alignment of mechanical axis of 180°.

Group A includes 31 knees operated on by computer navigator assisted alignment Orthopilot (version 3.0) using Search Total Knee Prosthesis (Aesculap, Tuttlingen, Germany) retaining the Posterior Cruciate Ligament (PCL).

Group B includes 34 knees operated on by totally intramedullary alignment system for both tibia and femur cut using the prosthesis Genius Tri-ccc (Astromedical, Vimercate, Milan, Italy) sacrificing the PCL.

Group C includes 32 knees operated on by totally extramedullary alignment system for both tibia and femur cut using Scan (Mitab, Sjoborg, Sweden) prosthesis retaining the PCL.

All the TKRs were performed by one of the Authors (N.C.). An anterior mid-patella approach and a medial arthrotomy were used in all the cases. All the 3 alignment instruments were set to achieve an ideal HKA of 180° in the frontal plane and a tibial slope according to the implant design in the sagittal plane (0° for Search, 5° for Scan and Genius Tri-ccc).

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

The same post-operative rehabilitation protocol was adopted for all the patients with a full weight-bearing as soon as tolerated by the patients.

At the first follow-up (1 year) and at the final follow-up, an independent radiologist not involved in the study assessed the frontal femoral component angle (FFC), the frontal tibial component angle (FTC), the HKA and the sagittal orientation (slope) of the tibial component. The FFC angle is designed by the mechanical axis of the femur and the transverse axis of the femoral component, while the FTC angle is designed by the mechanical axis of the tibia and the transverse axis of the tibial component. Before starting the study, we had considered ideal alignment prosthesis with a FFC angle of 90°, a FTC angle of 90°, a HKA angle of 180° and an ideal slope of the tibial component just as the value suggested by the implant design.

Furthermore, we calculated for each group the proportion of femoral and tibial components not aligned within 2° of 90°, the proportion of prostheses aligned within 2 and 4° of an ideal HKA (180°) and the proportion of tibial components aligned within 2° of ideal slope suggested by the 3 prostheses design.

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

3. Results

At medium follow-up of 15 years, all patients underwent call interview for clinical update. Of the 115 patients enrolled in the study, only 97 were available for radiological assessment. The demographic data of the patients are shown in Table 1. There were no statistical differences in the pre-operative HKA and flexion deformity.

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

According to the surgical charts the mean operative time was 109.2 min (range: 89–133) in group A (CAS), 91.2 min (range: 74–112) for group B (intramedullary system) and 82.2 min (range: 65–106) for group C (extramedullary system). The operative time was statistically longer in group A than both group B and group C ($p = 0.0000$). However even in group B the operative time was statistically longer than group C ($p = 0.0002$).

At the last follow-up, the mean HKA was 179.1° (range: 176°–184°) for group A, 178.6° (range: 173°–186°) for group B and 177.8° (range: 172°–186°) for the group C with no statistically significant difference among the 3 groups.

The mean frontal femoral component angle (FFC) was 90.5° (range: 87°–94°) for group A, 91.05° (range: 85°–95°) for group B and 91.19° (range: 85°–96°) for the group C and there was no statistically significant difference among the three groups.

The mean frontal tibial component angle (FTC) was 89.9° (range: 83°–97°) for group A, 90.6° (range: 87°–95°) for group B and 90.8° (range: 86°–95°) for the group C and there was no statistically

Table 1
Demographic and clinical data of all patients.

	Group A n = 31 (CAS)	Group B n = 34 (intramedullary)	Group C n = 32 (extramedullary)
Mean age	70 (range: 56–84)	68 (range: 47–81)	71 (range: 39–86)
Gender	17 male 14 female	19 male 15 female	16 male 16 female
Mean pre-op HKA	175.8° (S.D.:6.7)	174.1° (S.D.: 7.6)	176.1° (S.D.:6.3)
Mean flexion deformity	2.3° (S.D.: 2.6)	2.1° (S.D.: 2.1)	2.2° (S.D.: 2.2)

significant difference among the three groups.

The mean tibial component inclination in the sagittal plane was 1° (range: 3°–0°) for the group A, 3.6° (range: 7°–0°) for the group B and 3.1° (range: 6°–0°) for the group C (Table 2).

In terms of the proportion of femoral components aligned within 2° of 90°, in group A there were 26 (83.8%) femoral components aligned within 2° of 90°, in group B there were 27 (79.4%) femoral components aligned within 2° of 90° and in group C there were 19 (59.3%) femoral components aligned within 2° of 90°; with a statistically significant difference ($p = 0.03$) between group A and C (A > C).

In terms of the proportion of tibial components aligned within 2° of 90°, in group A there were 27 (87%) tibial components aligned within 2° of 90°, in group B there were 29 (85.2%) tibial components aligned within 2° of 90° and in group C there were 22 (68.7%) tibial components aligned within 2° of 90° and there was no statistically significant difference among the three groups.

In terms of the proportion of prostheses aligned within 2° of an ideal HKA (180°), in group A there were 27 (87%) prostheses aligned within 2° of 180°, in group B there were 28 (82.3%) prostheses aligned within 2° of 180° and in group C there were 20 (62.5%) prostheses aligned within 2° of 180° with a with a statistically significant difference ($p = 0.02$) between group A and C (A > C).

In terms of the proportion of prostheses aligned within 4° of an ideal HKA (180°), in group A all the implants were aligned within 4° of 180°, in group B there were 30 (88.2%) prostheses aligned within 4° of 180° and in group C there were 24 (75%) prostheses aligned within 4° of 180° with a with a statistically significant difference ($p = 0.002$) between group A and C (A > C).

Furthermore, in terms of the proportion of tibial component with a sagittal inclination aligned within 4° of an ideal slope suggested by the design prostheses (0° for Search, 5° for Scan and Tri-ccc), in group A all the implants were aligned within 4° of 0°, in group B there were 33 (97%) prostheses aligned within 4° of 5° and in group C there were 28 (87%) prostheses aligned within 4° of 5° without any statistically significant difference among the 3 groups.

4. Discussion

Restoring the mechanical axis in TKR is a key factor to optimize the load sharing and prevent the eccentric loading through the prosthesis, which could avoid implant loosening, instability or early failure.[15,16] The concept of mechanical axis was introduced by Insall et al.[17] in 1985: it requires that both femoral and tibial cuts must be perpendicular to the mechanical axis of the femur and tibia. The purpose is to create equal load distribution on the new joint line.

Several studies have reported significant difference in implant survivorship when a traditionally safe zone of 0–3° was used to define aligned versus malaligned knees respect to a neutral mechanical axis. For example, Berend et al.[1] reported a statistically increased rate of failure of tibial components positioned in >3.9° of varus. Ritter et al.[3] found an increased rate of failure in knees with a femoral component in > 8° of anatomical valgus and in those with a varus tibial component relative to the tibial axis. Collier et al.[5] reported a significantly greater loss of thickness of polyethylene in the medial compartment when the limb was aligned in > 5° of varus.

On the other hand, some authors have found no statistically significant differences in survivorship between aligned versus malaligned knees respect to a neutral mechanical axis. One of the most influential studies is reported by Parratte et al.,[2] who retrospectively reviewed the clinical and radiological data of 398 TKRs. They found that a post-operative mechanical axis of 0° did not improve the rate of survival 15 years post-operatively and stated that the description of alignment as a dichotomous variable (aligned versus malaligned) provided little value in regards to durability. Nevertheless, they concluded that “until additional data can be generated to more accurately determine the ideal post-operative limb alignment in individual patients, a neutral mechanical axis remains a reasonable target and should be considered as the standard for comparison if other alignment targets are introduced”. Similar to Parratte et al.,[2] also other authors found that the relationship between coronal alignment and survivorship was weak.[4,18,19]

Table 2
Radiological results at the last follow-up.

	Group A n = 31 (CAS)	Group B n = 34 (intramedullary)	Group C n = 32 (extramedullary)
Mean surgical time	109 min (range: 82–133)	92 min (range:67–112)	81 min (range: 57–106)
Mean post-op FFC angle	90.5° (S.D.: 1.6)	91.05° (S.D.: 2.17)	91.19° (S.D.:2.68)
Mean post-op FTC angle	89.97° (S.D.: 1.5)	90.6° (S.D.: 2.1)	90.8° (S.D.: 2.5)
Mean post-op HKA	179.18° (S.D.: 1.8)	178.6° (S.D.: 2.6)	177.8° (S.D.: 3.3)
Mean tibial slope	1.2° (S.D.: 1.03)	3.6° (S.D.: 1.31)	3.1° (S.D.: 1.35)

While the emphasis of this paper is not the clinical and functional outcomes related to alignment, it is important to mention that two studies, performed by Choong et al.[20] and Longstaff et al.,[21] noted improvements in the 1 year functional outcomes for patients with coronal alignment within 3° of neutral. Conversely, Magnussen et al.[18] found no difference in International Knee Society scores between TKRs which were in neutral versus varus mechanical alignment.

Several studies reported that with conventional technique the percentage of malaligned knees is between 20% and 30%.[22–26] It has been shown that only 70–80% cases would obtain the ideal positioning of the prosthesis when using the intramedullary system.[19] CAS in TKR has been introduced in order to improve limb axis correction and component alignment. CAS in TKR provides more accurate bone cuts, more precise component placement in the coronal, sagittal and rotational planes, better restoration of coronal limb alignment and lower gap asymmetry.[27–32] Three recent meta-analyses definitively proved that CAS technique improves mechanical axis and implant survivorship, but nowadays there is no clinical evidence of functional outcome improvement.[33–35] So, the question is: does CAS improve clinical outcomes in TKR? Up to now we don't know, but we are strongly convinced that the improvement in implant position and coronal and sagittal limb alignment is decisive for final outcome and could justify its application in TKR.

Our results for intramedullary and extramedullary groups are consistent with those reported in other studies. Oswald et al. reported a malalignment exceeding 4° in the sagittal plane in 8% of his series using an extramedullary alignment system.[36] Recently Reed et al.[37] 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 and 35% not aligned within 2° of 90° in the extramedullary group which are very similar to our findings. In 2003 Sparmann et al.[38] in a randomised study reported statistically better alignment in both the frontal and sagittal plan for computer assisted alignment implant than without navigation support, emphasizing the immediate benefits of applying computer assisted techniques to TKR.

Our study owns some limitations and bias: retrospective and not randomised, radiological evaluation in one plane only and different prostheses design with different tibial slopes (PCL sparing or sacrificing). Besides, the type of knee alignment was not performed randomly but according surgeon's desire and this could have biased the results. We identified very strict inclusion criteria (diagnosis, pre-operative deformity, body-mass index, excellent x-ray quality) and very 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, in our inclusion criteria we had intentionally excluded difficult cases with major deformity where according to our experience the computer assisted alignment guide has obvious advantages compared to implant without navigation support.

5. Conclusion

Our results demonstrated statistically significant differences between CAS and extramedullary group, in favour of CAS group in terms of implant position and mechanical alignment. CAS technique showed superior but not statistically significant differences compared to intramedullary alignment system in terms of implant position and mechanical alignment.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jcot.2018.07.005.

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