Computer assisted total knee arthroplasty: a real navigation to better results?

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Summary. Background and aim of the work: Computer assisted surgery in knee replacement is still in discussion, but majority of papers affirm an increase of the accuracy in alignment. Aim of our study is to evaluate the accuracy of mechanical axis, the posterior tibial slope and the femoral component rotation with navigation, x-ray and CT data. Methods: We have analysed 145 patients who underwent total knee arthroplasty between January 2012 and December 2014. We have checked each patient at 6, 12 and 24 months of follow-up. During each visit, we did a clinical evaluation checking the ROM and a clinical score (KOOS). At 2 years, we did a CT evaluation and a plain x-ray evaluation. Results: 125 patients have completed the follow-up. Mean follow-up time was 2.6 years. Both ROM and KOOS values increased during follow-up. About the mechanical axis, both x-ray and CT data showed a mean deviation <2° from the target. About posterior tibial slope and femoral component rotation, CT data showed a mean deviation of <3° from the target. Mean difference between navigation and CT data was <1°. Conclusions: According to literature data, our data confirm that computer assisted surgery in knee replacement have a good accuracy of coronal alignment, rotational alignment and posterior tibial slope. (www.actabiomedica.it)

Key words: total knee arthroplasty, knee surgery, computer-assisted surgery, knee prosthesis, computer navigation, mechanical axis, posterior tibial slope, femoral component rotation

Introduction

Scientific progress comes through experimentation, failures, new attempts. Successes are never guaranteed. Innovations are often greeted with suspicion and, unfortunately, the economic interests sometimes have a role.

Navigation systems are not a recent innovation in prosthetic knee surgery; indeed, the first attempts were made over 20 years ago (1). This kind of surgery was born with the aim to obtaining a more accurate alignment of the implant (2) but additional benefit was found such reduction in blood loss (3) or such reduction of the revision rate for loosening or lysis (4).

From the very first experiences with CAS (Computer Assisted Surgery) (5), the opinion about it of orthopaedic community was discordant. Pros and cons are deeply debated: advantages seem to be accuracy of bony resection and decreasing of malposition of the implants, the ability for the surgeon to estimate the level of femoral and tibial joint line intra-operatively, a better soft tissue balancing and assessment of the gap and the stability. Disadvantage are increase of operating time, increase of cost and risk of intra-operative fractures (6). In literature there are numerous scientific articles that discuss about the navigated surgery: analysis of the latest long term follow-up works seems to bring out as the navigator assisted surgery is beneficial bringing the patient to better outcomes clinically and functionally (7).
Aim of this study is to evaluate the accuracy of intra-operatory navigation data, compared with x-ray and CT data.

**Material and methods**

We have analysed 145 patients who underwent total knee arthroplasty between January 2012 and December 2014. This study was approved by the Ethics Committee of the University Hospital of Udine and all the patient gave their written informed consent to the study. All surgery procedures have been guided by The Stryker eNact Precision Knee Navigation System (Stryker; Kalamazoo, Mitch) and have been done by the same senior surgeon. Exclusion criteria have been previous operations, dysplasia and severe laxity. We have checked each patient at 6, 12 and 24 months of follow-up. During each visit, we did a clinical evaluation checking the ROM and a clinical score (KOOS). At 2 years, we did a CT evaluation and a plain x-ray evaluation. With full-length standing radiographs of the lower extremities we checked the mechanical axis, studying the hip–knee–ankle angle (Fig. 1). According with Perth protocol (8, 9), at the CT evaluation we measured the mechanical axis, the posterior tibial slope and the femoral component rotation (Fig. 2-3-4). Following the target of 0° for the mechanical axis, 3° for posterior tibial slope and 0° for femoral component rotation (parallel to trans-epicondylar axis), we calculate the difference between navigation, x-ray and CT data.

**Surgical procedure**

Each surgery was performed using a tourniquet and a medial para-patellar approach. We registered all the navigation system data required. We use a CR type implant in all cases, preserving PCL (posterior cruciate ligament) The femoral rotational axis was set parallel to the surgical trans-epicondylar axis. The width of the flexion-extension gap and ligament balance were checked using a specific tool to avoid laxity, and the thickness of the polyethylene insert was determined. With navigation system we checked each osteotomy and, before cementation, we evaluate mechanical axis,

*Figure 1. Mechanical axis in full-length standing radiographs of the lower extremities*

*Figure 2. Femoral component rotation and trans-epicondylar axis in navigation system*
posterior tibial slope and femoral component rotation (Fig. 5). Then the components of femur and tibia were cemented. The patella was never resurfaced. After the completed cementation, we registered final data with navigation system. A single senior surgeon performed all the procedures.

Statistical analysis

For all values, mean and standard deviation were calculated. Shapiro-Wilk normality test was used for assess the distribution of each value and Kruskall Wallis test was used for statistical analysis. A p value <0.05 was considered statistically significant. All calculations were performed using the statistical software package SPSS (version 13, NC).

Results

Of 145 patients, 125 have completed the follow-up. Mean of age was 71.6 years, mean of BMI values was 30.3. Mean follow-up time was 2.6 years. Both ROM and KOOS values increased during follow-up, especially they showed an increased between 6 and 12 months and a stabilization of values between 1 and 2 years of follow-up (Table 1).

About the mechanical axis, x-ray data showed a mean deviation of 1.9°±1.2° from the target (±3°); CT data showed a mean deviation of 1.2°±0.8° and CAS a mean deviation of 1.7°±0.5. About posterior tibial
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slope, CT data showed a mean deviation of 2,1°±0,9 from the target (3°) versus the mean deviation of 2,7°±0,8 measured with CAS. About femoral component rotation mean deviation was 1,1°±0,8° from the target (0°) with CT scan and 1,3°±0,6 with navigation system (CAS) (Table 2).

Mean difference between navigation and CT data was 0,8°±0,5° for the mechanical axis, 0,5°±0,2° for tibial slope and 0,6°±0,3° for the femoral component rotation (Table 3).

No difference between the measurements was statistically significant (Kruskall- Wallis test: mechanical axis X-Ray vs CT vs CAS p=0.68).

### Discussion

There is a great discussion about use of CAS. Majority of works affirm that navigation technique improve accuracy of the coronal and rotational alignment and the ROM (7, 10-14); on the other hand, a lot of papers data didn't find any difference in accuracy and in complication between CAS and conventional technique (15-19). Han et al. has studied blood loss and his effect on transfusion between conventional technique and CAS: they found an effective reduction in blood loss without an effective effect on transfusion requirement (3). McClelland et al. shows a similar biomechanics of the knee between CAS and conventional technique (20). In most of case CAS has no complications like mechanical failures or fractures. Brown et al. in their works, studying 3100 patients, have an incidence of 0.065% fractures in navigated total knee arthroplasty, similar with the 0.16% rate of fractures published online (21). However, complications are rare and mostly related to pin tracks (22).

Today it’s in discussion if correct alignment brings to better results: Rienmuller et al. in 2012 and Pagnano at al. in 2010 had analyzed rotational alignment and coronal alignment; both showed the same results between group in range values and outlier group. These studies confirm that the outcome does not depend exclusively from the alignment; therefore, a perfect alignment does not guarantee a good outcome. The alignment correction should not be standard but must be adapted to the patient’s characteristics; for this reason, the pre-operative planning is paramount and we suggest it in every case.

According to literature, in this study our data confirm a good precision of navigation system. In mechanical axis, the difference in the measure between the x-ray and CT data may be explained by the influence of the weight bearing during the execution of full-length standing radiographs of the lower extremities; this may be the reason why x-ray data are 0,7° higher than CT data.

Limits of this paper are the absence of a control group with conventional surgery technique to asses a difference both in outcome and in alignments values, a short-term follow-up, a small sample of patients.

In conclusion, according to literature and to our data, CAS in knee replacement can give good results and accuracy in coronal alignment, rotational alignment and slope tibial value. It should be stressed that this is a technique not easy and not for beginners, so we suggest CAS only to expert surgeon. All recent papers about CAS encourage further studies with long-term follow-up and about intraoperative kinematic analysis using a navigation system in total knee replacement (10, 23). We need more research to analyse clinical results, failure rate and a cost-effectiveness analysis.

| Table 1. ROM and KOOS results |
|-----------------------------|
| 6 months | 12 months | 24 months |
| ROM | 100,3° | 115,7° | 117,2° |
| KOOS | 80,3 | 85,5 | 85,2 |

| Table 2. Difference in degrees from the target: 0° for mechanical axis (MA), 3° for posterior tibial slope (PTS) and 0° for femoral component rotation (FCR) |
|-----------------------------|
| MA | PTS | FCR |
| X-ray data | 1,9°±1,2° | - | - |
| CT data | 1,2°±0,8° | 2,1°±0,9 | 1,1°±0,8 |
| CAS data | 1,7°±0,5° | 2,7°±0,8 | 1,3°±0,6 |

| Table 3. Difference in degrees between navigation and TC data |
|-----------------------------|
| Δ CT/CAS data | MA | PTS | FCR |
| 0,8°±0,5° | 0,5°±0,2° | 0,6°±0,3° |
As seen in other surgeries like mosaicplasty (24) CAS promise better results in term of accuracy and reproducibility, but in a recent analysis of technology and accuracy in knee replacement, Authors conclude that navigation system and other actual technology like patient specific instrumentation or robotic surgery has an high cost and today it is not demonstrate that they are worth for this cost (25). We need long term study and, most of all, we agree with the idea that technology in knee replacement is not a way to have an easier job, but at least a safer way to do it, without forgetting the right surgical indication for surgery (26).

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