NAVIGATION IN TOTAL KNEE ARTHROPLASTY: IS THERE ANY ADVANTAGE?

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ABSTRACT

Objective: Aiming to evaluate whether navigation aided surgery? offers any advantages over the conventional technique, a randomized, prospective, comparative study was carried out, analyzing the placement of components, alignment of the limb, surgical time, blood loss and functional rehabilitation. Material and methods: We studied 39 patients submitted to 42 Total Knee Arthroplasties. In group 1 (n = 21) the surgery was navigated and in group 2 (n = 21) it was conventional. The patients were evaluated on panoramic radiographs of the lower limbs, CT scan and the Knee Society Score (KSS) preoperatively and three months postoperatively. Surgery time and postoperative blood loss were also evaluated. Results: Surgery time was longer in group 1. There was no significant difference in blood loss and the KSS. There was a greater proximity of the three degrees of external rotation and the five degrees of tilt in the coronal in group 2. The mechanical axis was closer to zero degree in group 1. Conclusions: Navigation promotes individualizing of the positioning of the components of the prosthesis, and offered advantages in limb realignment, compared with traditional methods. The surgerytime has a tendency to be higher in group 2, but this difference is not statistically significant. There were no differences between the groups in relation to blood loss and improvement in KSS. Level of Evidence: Level I, therapeutic studies.

Keywords: Arthroplasty, Knee. Surgery, computer-assisted/methods. Knee prosthesis.

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INTRODUCTION

Total knee arthroplasty (TKA) is firmly established as one of the orthopedic procedures of greatest success and best cost-benefit ratio in the field of orthopedics, with significant improvement of quality of life and over 95% of survival of the implant after 15 years.[1,2]

Total knee arthroplasty is a highly complex surgical procedure that has been evolving constantly since its creation. The longevity of the human population has made this surgery more and more commonplace. The implants present more modern designs, closely resembling normal knee anatomy, associated with the more precise instruments that cause less aggression in the soft parts. Thus, the surgical technique becomes more reproducible causing surgical indications to become more comprehensive.[3,4]

Modern computer-assisted (navigated) surgical techniques arose at the beginning of the 80s with applications in neurosurgery, and soon after, this technology was transferred to orthopedics, initially in spinal surgery than gradually, in hip and knee surgery.[5] Navigation can be applied in the pre-, intra and postoperative period, for planning, simulation, guidance and training, with the main goal of overcoming the limitations of the conventional technique.[6]

Aiming to evaluate whether navigated TKA offers any advantages over the conventional technique (non-navigated), a randomized, prospective and comparative study was developed with the following parameters evaluated: limb alignment, positioning of the prosthetic components, surgical time, postoperative blood loss and postoperative functional rehabilitation.

MATERIALS AND METHODS

We assessed 39 patients submitted to 42 total knee arthroplasties in the period between March 1, 2009 and January 31, 2010. The patients were randomized and divided into two equal groups: those from group 1 (n=21) were submitted to the navigated procedure and those from group 2 (n=21) were submitted to the conventional technique. The randomization was based on simple random sampling (lottery draw).

The inclusion criteria in this study were presence of advanced degenerative knee joint disease, Ahlbäck IV or V, patients over 55 years

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of age and without previous TKA. Individuals that presented severe instability with indication of constrained prosthesis were excluded. All the operations were performed by the same surgeon, a specialist in knee joint replacements and experienced in the navigated technique. The preparation of the patients followed the same routine, and consisted of a chlorhexidine bath two hours before the procedure (in the infirmary), blood collection before the induction of anesthetic, in order to determine the preoperative hemoglobin (Hb) and hematocrit (Ht) values, and administration of two grams of cefazolin. No patient received venous hydration and/or blood transfusion after surgery. The pneumatic sleeve for limb ischemia was used in all the cases, with the creation of a medial parapatellar approach and introduction of cemented and non-constrained prosthesis (Search Evolution®, Aesculap Orthopaedics Navigation, Tuttlingen, Germany).

The information on the group to which the patient belonged was transmitted to the surgeon after the creation of the surgical approach. The decision on the use of the posterior stabilized femoral component without preservation of the posterior cruciate ligament occurred intraoperatively. In the cases where it was necessary to make a wider tibial cut, compromising the posterior cruciate ligament origin, we opted for the posterior stabilized femoral component. The patella was not replaced in any patient, and was approached with removal of the osteophytes and circumferential parapatellar denervation. A continuous suction drain (Haemovac®) was used in all the cases. The surgery was timed from the start of the incision until the complete closure of the skin.

The postoperative protocol followed the same routine, with emptying of the drain tube every 500 milliliters, and reestablishment of aspiration, recording the total volume drained in the first 24 hours postoperatively. A new laboratory test was performed 24h postoperatively to determine the postoperative Hb and Ht. Full load bearing was allowed on the operated knee according to the patient's pain tolerance, and physiotherapeutic rehabilitation was started on the 1st postoperative day. The first dressing was changed about two days after the procedure (in the infirmary), during which period the patients were discharged from hospital. All the subsequent dressings were changed in the outpatient clinic every other day and the stitches were removed 21 days postoperatively. Outpatient follow-up was continued after this, with one appointment per month until the 3rd postoperative month when a functional evaluation was applied through the (*KSS*).

The *TKA* 4.0 software of the Orthopilot® navigation system (Aesculap Orthopaedics, Tuttlingen, Germany) was used in the computer-assisted surgery. Bicortical Schanz pins used to support the spherical reflective sensors were positioned through separate skin incisions, approximately 10cm proximal to the distal articular surface of the femur and 10cm distal from the anterior aspect of the tibial tuberosity. The anatomical references were recorded by the surgeon and the bone cross-sections, the soft tissue balance, the size and positioning of the implants were guided fully by navigation. The femoral cut was made in conformity with the navigation guidelines to obtain the best soft tissue balance, and the tibial cut was aligned at 90º with mechanical axis of the tibia on the frontal plane, both with 0º of posterior slope. The pre- and postoperative data were recorded by the system.

Intra- and extramedullary guides were used to position the femoral and tibial components, respectively, in the conventional technique. The planning of the positioning of the femoral component on the frontal plane was determined by the angle between the mechanical and anatomical axes of the femur in the preoperative tomography, and on the sagittal plane it was parallel to the anterior femoral cortical line and the rotational positioning was established at 3º of external rotation in relation to the posterior region of the femoral condyles. The tibial alignment was based on the same references used in the computer-assisted surgery.

The radiographic evaluation included a panoramic radiograph and a computed tomography of the lower limbs performed seven days before the surgery and three months postoperatively. The scanned images were evaluated using the eFilmLite® program (Merge eMed).

The panoramic radiographs of the lower limbs were taken in the anteroposterior projection, in orthostatic position, with the feet together in cases of varus deformity or with the knees together in cases in valgus, in maximum extension of the knees and maintaining neutral rotation of the lower limbs through forward positioning of the patella in the direction of the X-raytube.[7]

Computed tomography images were taken on the frontal plane with scanning of the image from hip to ankle constituting the overview scan of the upper limbs. The patients were positioned supine, with their heels on a wedge allowing maximum extension of the knees, maintaining neutral rotation of the lower limbs through the positioning of the patella at the zenith and with the feet together in cases of varus deformity or with the knees together in cases in valgus. The tomographic study also included the axial cross sections of 2mm of the knees[8].

The inclination of the mechanical axis (MA) was established by the angle formed between a line from the center of rotation of the femoral head to the center of rotation of the knee (mechanical axis of the femur) and another from the center of rotation of the knee to the center of rotation of the ankle (mechanical axis of the tibia). (Figure 1) The coronal tilt of the femoral component was established by the angle between the anatomical axis of the femur and the line of the articular surface of the femur. (Figure 2) These measurements were evaluated both in the panoramic radiograph of the lower limbs and in the computed tomography (overview scan).

The rotational alignment was studied in the two-millimeter axial cross-sections of the computed tomography. In the preoperative period, the first step was to draw a line through the posterior region of the femoral condyles. After this another line was drawn through the medial and lateral epicondyles (transepicondylar axis). The angle formed between these lines determined the rotation of the transepicondylar axis in relation to the posterior region of the femoral condyles. (Figure 3) In the postoperative period, the rotation of the prosthesis was evaluated by the inclination of the axis of the intraosseus fixation pins in relation to the transepicondylar axis. (Figure 4) This allowed us to determine the actual final positioning of the femoral component in relation to the posterior region of the condyles established in the axial cross-section of the preoperative computed tomography.

For the evaluation of results it was considered satisfactory: mechanical axis of 0º, accepting variation of up to 3º of varus or valgus; coronal tilt of the femoral component of 5º of valgus, accepting variation of 3º; rotational alignment of 3º of external rotation of the femoral component in relation to the posterior region of the condyles, established in the preoperative tomography, accepting variation of 3º.

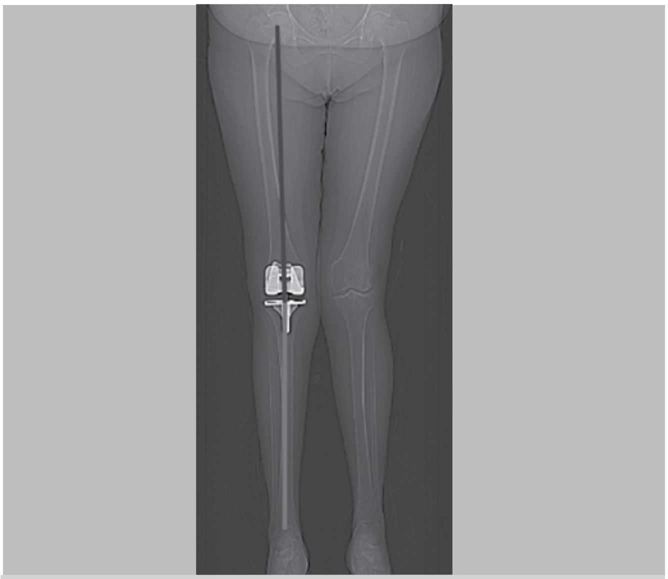

Figure 1. *Mechanical axis in the overview scan.*

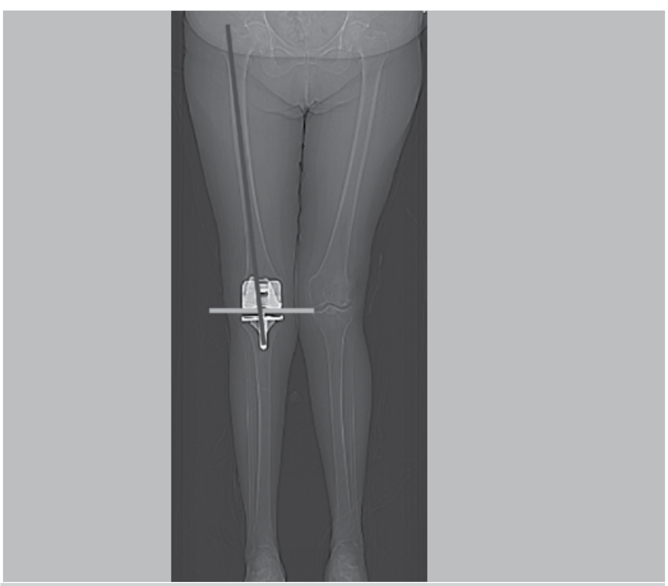

Figure 2. *Inclination of the prosthesis on the coronal axis.*

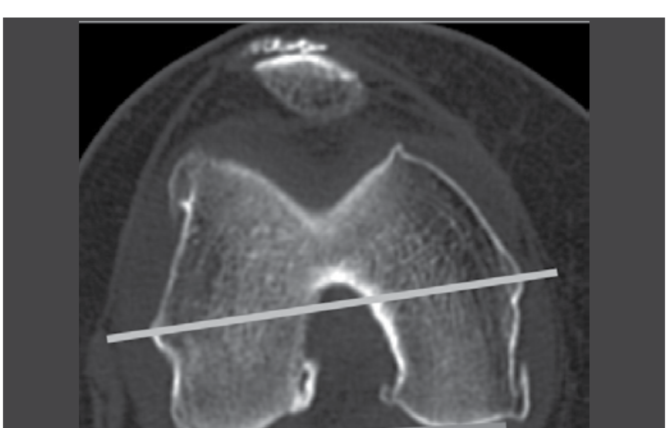

Figure 3. *Rotation of the transepicondylar axis in the preoperative period.*

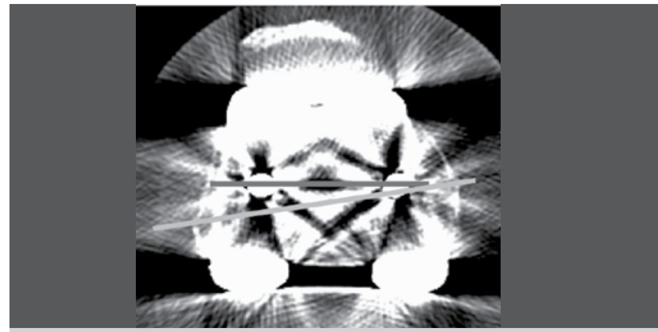

Figure 4. *Rotation of the prosthesis in the postoperative period.*

Wilcoxon's signed-rank test was used in the statistical methodology to verify whether there was significant variation in the KSS and in blood loss. To verify whether there was significant difference between the treatment groups (navigated and conventional) in the numeric variables and in the deltas (absolute and relative) we applied the Student's t-test or the Mann-Whitney test for independent samples, and in the categorical variables we applied the chi-square test (X^2)or Fisher's exact test. Non-parametric methods were used as the variables did not present normal distribution (Gaussian distribution). The significance determination criterion adopted was the level of 5%. The statistical analysis was processed by the SAS® System statistical software.

RESULTS

There was no significant difference in the preoperative basal numeric variables (age, preoperative KSS, preoperative Hb and Ht) and categorical variables (side and type: varus or valgus) between the two treatment groups, at the level of 5%.Therefore, the groups were similar from the point of view of these variables in the preoperative period.

The absolute variation of the KSS from the pre- to the postoperative period was obtained by the formula: Delta KSS = (KSS in the postoperative period - KSS in the preoperative period). The relative variation (%) of the KSS from the pre- to the postoperative period was obtained by the formula: relative delta KSS (%) = (KSS in the postoperative period - KSS in the preoperative period) / KSS in the preoperative period x 100. The same formula was used for the variable hemoglobin and hematocrit.

Aiming to verify whether the two groups evolve in a similar manner in the KSS, Hb and Ht from the pre- to the postoperative period, it was observed that there is no significant difference in the absolute delta ($p = 0.35$) and in the relative delta ($p = 0.32$) of the KSS between the treatment groups. The same occurred with Hb ($p=0.79$ and $p=0.92$) and Ht ($p=0.52$ and $p=0.78$).

Verifying whether there is any significant difference in the postoperative variables between the two treatment groups, it was observed that there is no significant difference in the surgical time ($p = 0.060$) and in the drain volume ($p = 0.35$) between the two treatment groups, at the level of 5%. We can say that there is a tendency for the navigated group to present a longer surgical time (median equal to 99 minutes) than the conventional group (median equal to 88 minutes).

The conventional group presented satisfactory MA (33.3%) that was significantly smaller than the navigated group (76.2%), with p

= 0.005. (Figure 5) The conventional group also presented satisfactory external rotation (80.9%) that was significantly higher than the navigated group (38.1%), with p = 0.005. (Figure 6) Moreover, it was observed that there is no significant difference in coronal tilt (*p* = 0.34) between the two groups, at the level of 5%. (Figure 7)

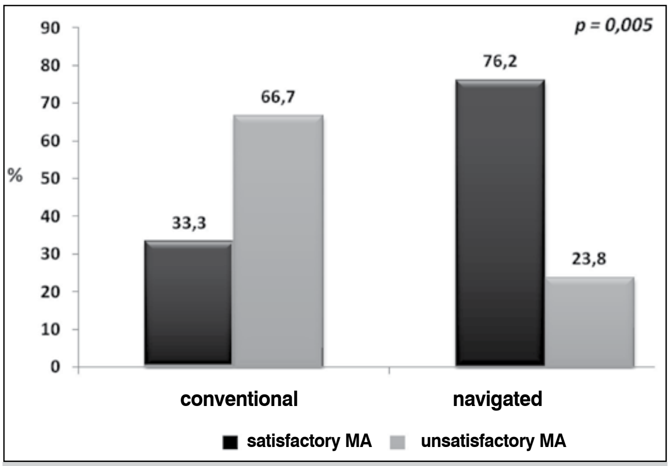

Figure 5. *Mechanical axis (MA) according to the treatment group.*

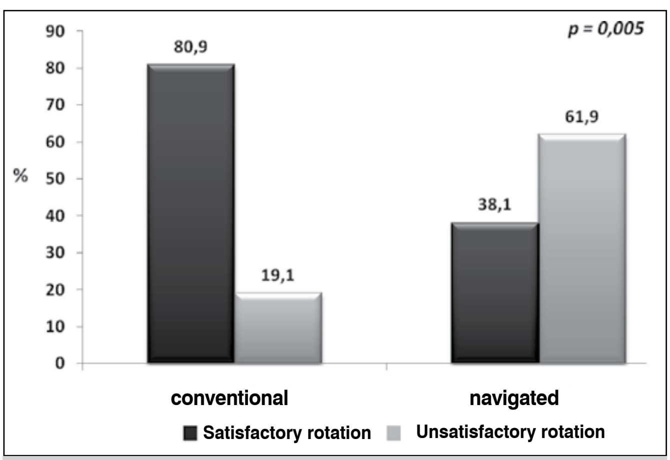

Figure 6. *External rotation according to the treatment group.*

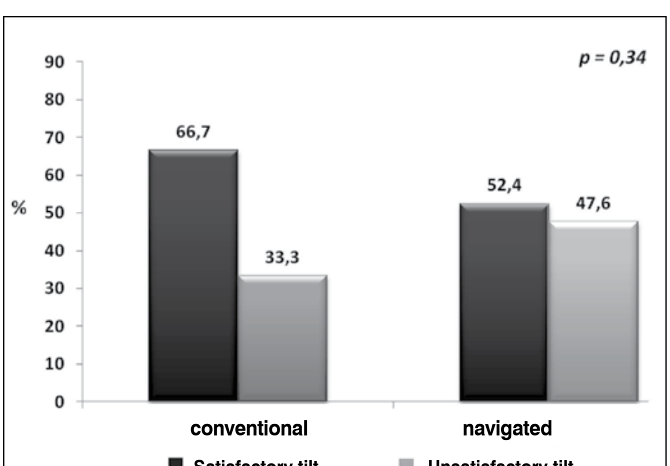

Figure 7. *Coronal tilt according to the treatment group.*

DISCUSSION

The success or failure of TKA depend on the accuracy and on the precision of the surgical technique[7,9] and are directly related to mechanical axis alignment and the positioning of the prosthetic components.[10,11] In an evaluation of 3,152 TKAs, survival of 90% was observed when the mechanical axis was between 0º and 4º of varus or valgus, and of less than 73% when the mechanical axis was above 4º of varus or valgus apud Ensini *et al*[4]. We believe that navigation serves to correct minor axis deviations axis that occur due to human error and can compromise the survival of the implant.

The high rates of success of the conventional technique presented in literature are questionable, since most studies do not include an adequate radiographic evaluation with panoramic radiograph and computed tomography[12,13] and do not present a standardized follow-up.[14]

Inadequate positioning of the components, besides increasing the risk of mechanical failure and loss of the implant, is detrimental to functional rehabilitation, reducing the arc of movement and stability of the knee.[15,16] This occurs due to the insufficient soft tissue balance generated by poor positioning of the components and asymmetric bone cross-sections, a line of reasoning that we corroborate and defend.

Degenerative joint disease provokes structural alterations in the knee. Cartilage and bone wear causes progressive rotational and angular deviations of the articular surfaces and, consequently, of the axis of the lower limbs. In addition, modifications occur in the adjacent soft tissues - ligaments, tendons and muscles - that adapt to the new structural conformation of the knee. Accordingly, at the time of surgery, patients present anatomical alterations that diverge from the expected physiologic pattern and that should be weighed individually to enable the surgeon to achieve the final objective: a mechanical axis of 0º and adequate soft tissue balance.

In the conventional technique, the aim is to position the femoral component with 3º of external rotation in relation to the posterior condyles so that it is aligned with the transepicondylar axis. Moreover, the surgeon aims to position the femoral component with coronal tilt based on the angle between the mechanical and anatomical axes of the femur. This positioning would lead to final alignment of the mechanical axis close to 0º and to adequate soft tissue balance, allowing long survival of the prosthesis.[17]

This study showed that in the group of patients submitted to TKA by the conventional technique the axial rotation and the coronal tilt of the femoral component were satisfactory in, respectively, 80% and 70% of the cases. However, in spite of the occurrence of higher rates of adequate prosthesis positioning, the mechanical axis was satisfactory in only 30% of the patients. Thus, it is observed that the positioning of the prosthetic component according to the patterns defined as ideal does not guarantee good results of the final axis of the limb.

In the group of patients submitted to computer-assisted TKA, axial rotation and coronal tilt of the femoral component were satisfactory in, respectively, 30 and 40% of the cases. Even with this result that is not consistent with the set patterns, the mechanical axis was satisfactory in 70% of the patients.

Therefore it is concluded that positioning the prosthesis while perceiving the value of anatomical characteristics of each patient, without sticking to the conventional pattern, does not prevent the surgeon from achieving an adequate final result.

In navigated surgery, soft tissue balance occupies a prominent place. After the tibial cross-section, the computer measures the difference between the medial and lateral tensions for the surgeon to perform adequate balancing. Once this has been done, the computer indicates the ideal positioning of the femoral component to maintain the soft tissue balance. Most of the time, this positioning does not follow the conventional pattern as observed in this study. This is explained by the fact that the computer uses the individual anatomical marks made at the start of the operation as a basis. Therefore, it is observed that navigation offers an advantage over the conventional technique to obtain a satisfactory final mechanical axis.

The variation of the positioning of the femoral component demonstrates that navigation allows the individualized treatment of patients. However, this was not correlated with the improvement of early postoperative function. Using the KSS, there was no significant difference between the groups studied. Therefore it is necessary to perform prolonged follow-up with these patients to evaluate whether, besides reestablishment of function, the survival of the prosthesis is really better in navigated surgery.

Kalairajah et al[18] observed less blood loss in navigated TKA due to the theoretical advantage of the navigated technique in not violating the spinal channel to determine the coronal tilt of the femoral component as is the case in the conventional technique providing less intra- and postoperative bleeding. However, this study did not demonstrate a significant difference in the volume drained in the first 24h and in the variation of the pre- and postoperative laboratory tests. Accordingly, computer-assisted surgery did not offer any advantage over the conventional technique as regards blood loss.

Albuquerque *et al*[19] concluded that navigation in TKA is a precise procedure affording accurate alignment and not causing morbidity when compared to conventional surgery. Our survey reaffirms the benefits of navigated surgery. The negative factor that is allegedly longer surgical time, on average 11 minutes in this series, due to the positioning of the Schanz pins for the transducers, is counterbalanced by a better positioned implant, respecting the patient's knee anatomy and theoretically leading to greater durability of the prosthesis, without clinical repercussions that increase the risk to life. Moreover, additional surgical time close to 10 minutes in the navigated procedure is acceptable, without any negative impacts on the patient.[20]

CONCLUSIONS

Navigation offers advantages in limb realignment over the conventional technique.

Navigation has the advantage of producing the individualized positioning of the prosthetic components.

There is a tendency for the surgical time to be longer in navigated surgery, without statistical significance.

Navigated surgery does not improve functional rehabilitation in the recent postoperative period in comparison to the conventional technique.

There are no significant differences in relation to blood loss between the two techniques.

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