

Computer assisted total knee arthroplasty: 2.5 years follow-up of 200 cases

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ARTICLE INFO

Article history:

Received 10 April 2020

Received in revised form

29 November 2020

Accepted 15 December 2020

Available online xxx

Keywords:

Total Knee Arthroplasty

Computer assisted navigation

CAS

Knee osteoarthritis

ABSTRACT

Introduction: Computer assisted surgery in total knee arthroplasty (TKA) should improve accuracy of both femoral and tibial components placement. This study evaluated the functional outcomes of computer navigated total knee arthroplasty through the Knee Society Score (KSS) and Tegner Lysholm Knee Scoring Scale (TLKSS).

Materials and methods: Between September 2007 and February 2013, 180 patients (200 knees; 109 females and 71 males; mean age: 64 years) undergoing computer-assisted TKA were recruited. Plain radiographs and CT scans were performed post-operatively to evaluate alignment. The clinical outcomes were measured using the KSS and TLKSS pre-operatively and after 6, 12 and 36 months.

Results: The mean follow-up duration was 2.5 years. The mean tourniquet time was 72 ± 13.4 min, and patients received an average of 0.6 ± 0.82 units of blood after surgery. The average preoperative KSS functional score of 44.6 ± 13.7 improved to 80.4 ± 16.4 after 2 years. The average preoperative TLKSS improved to 71.4 ± 13.5 after 2 years. The mechanical axis was within $\pm 3^\circ$ in all patients. No axial malalignments were observed on TC Scan. Three patients (1.6% of cases) required revision.

Conclusion: Computer assisted TKA allows reproducible alignment and kinematics, reducing outliers, provides ligament balancing and ensures good short term outcomes in terms of KSS functional score and TLKSS.

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Introduction

In Italy, about one third of older people present symptomatic osteoarthritis (OA), with a prevalence of 58.4% for women and 38.7% for men over 65 years in 2015.¹ The knee is the most commonly affected joint involved and, when conservative management fails, Total Knee Arthroplasty (TKA) should be

considered as a cost-effective solution to restore pain free mobility, enhancing quality of life and life expectancy. Accurate component placement is critical to reduce the risk of postoperative complications and ensure long term implant survival rates.² The restoration of correct alignment (frontal, sagittal and axial) and soft tissue balancing are most important objectives in TKA.³ Using conventional techniques, the

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<https://doi.org/10.1016/j.surge.2020.12.003>

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femoral component should be positioned with 3° of external rotation on axial plane, which would lead to a final alignment of the mechanical axis within $0^\circ \pm 3^\circ$ and impart adequate soft tissue balance, ensuring long term survival of the implant.² The various steps of the procedure are manually guided and controlled with the aid of extramedullary or intramedullary alignment guides, but significant errors in mechanical alignment occur in at least 10% of TKAs, even in experienced hands.³ Malalignment is considered the main cause of patient dissatisfaction, and 20% of patients who underwent TKA are not satisfied and continue to experience pain or other knee symptoms.⁴ To improve radiographical and clinical outcomes, computer navigation systems have been developed so that the mechanical axis restoration and components positioning are improved compared to conventional surgery.⁵ Furthermore, computer navigation systems do not necessitate to breach the medullary canal of the femur, mitigating blood loss and the dissipation of systemic marrow emboli associated with conventional TKA.⁶ Computer navigation uses infrared communication to track the spatial positioning of patient anatomy and surgical equipment. Computer-assisted surgery (CAS) was hypothesized to improve outcome and survivorship of TKA and reduce revisions and associated health care costs.⁷ Mechanical axis accuracy and component positioning improve with computer navigation, no superiority in functional outcomes has been shown yet. CAS technique provides higher functional scores in the short-term, but it is unclear whether it impacts on functional outcomes and survivorship of implant in the long-term.² This study evaluated the imaging and clinical outcomes of CAS for TKA. We hypothesized that CAS would give consistent alignment within 3° and good clinical outcomes in the short-term.

Materials and methods

Between September 2013 and February 2015, 180 patients (200 knees) undergoing computer-assisted TKA were recruited. Informed consent was obtained from all individuals participating in the study, which received IRB approval. The patient age, sex, body mass index (BMI), medical comorbidities, Knee Society Score (KSS) and Tegner Lysholm Knee Scoring Scale (TLKSS) were recorded at the pre-operative assessment.

Patient aged >50 years with knee pain and loss of function were included in the study. Exclusion criteria were previous knee surgery, revision surgery, several systemic disease, body mass index (BMI) $> 35 \text{ kg/m}^2$, previous fractures of the shaft of tibia or femur, active infection of the knee and severe valgus position of the knee ($>15^\circ$ from the mechanical axis of the knee).

All operations were performed by two surgeons (DN and AZ) who had each performed more than 500 conventional TKAs, and more than 50 CAS TKA before starting this study. An imageless navigation system (Mirò, BLU-IGS; Orthokey Italy Srl) was used according to the manufacturers' recommendations. All procedures were performed in a bloodless field obtained using an all-in-one exsanguination device (Hemaclear®, Grandville, MI, USA) or a tourniquet. All patients underwent standard antibiotic prophylaxis, injecting Cefazolin (2 g if $< 120 \text{ kg}$, 3 g if $\geq 120 \text{ kg}$) intravenously 10 min

before exsanguination of the leg, and receiving two other doses of intravenous Cefazolin within 24 h of the end of the procedure. The patient was under spinal anesthesia. The navigation kit includes a special mobile pointer designed for registration bones landmarks and two bone reference (for tibia and femur) points. The two bone reference points with the infrared reflecting diodes (LED) were positioned with a skin incision of $<1 \text{ cm}$: one diode should be positioned on the femur and one on the tibia 10 cm from joint line (Fig. 1).

The distal femur and proximal tibia articulating surfaces and the medial and lateral malleolus of the ankle were mapped and registered. The mechanical axis and hip joint center were determined moving the limb and using mathematical models by the navigator. The surgeon used a standard medial parapatellar approach to expose the interior of the knee, evaluated all the compartments and identified and marked, with a mobile pointer, the center of tibial plateau, both posterior femoral condyles, the superior femoral cortex, and medial and lateral epicondyles. With the data reported on the screen, the surgeon recalculated the deformity and the correction to be imparted (Figs. 2 and 3). The computer navigation system suggested implant size, amount of bone to be resected according to the deformity detected, and tridimensional implant alignment. The surgeon proceeded to release the ligaments and positioning the tibial cutting guide using a standard extramedullary guide. On the display, orientation (varus or valgus) and slope can be planned, and the tibial cut performed. The femoral cuts are already planned according joint space in flexion and extension, using spreaders. If flexion and extension gaps were not balanced, femoral cuts, rotation of the femoral component, size of prosthesis and polyethylene thickness were re-planned in order to equalize the gaps.

The distal femoral cut is then performed and checked on the screen. The tibial and femoral components are implanted using antibiotic-loaded cement fixation and, at the end, the polyethylene spacer was inserted. The rotation of the femoral component was referenced upon the epicondylar line, Whiteside line, and posterior condylar line. The Triathlon Total Knee System (Stryker®) was used in all 200 procedures, and the patella was not replaced. The mechanical axis and the ligament balance were checked in the whole range of motion, reading the values and the shape of the lower limb in motion



Fig. 1 – Bone references positioning.

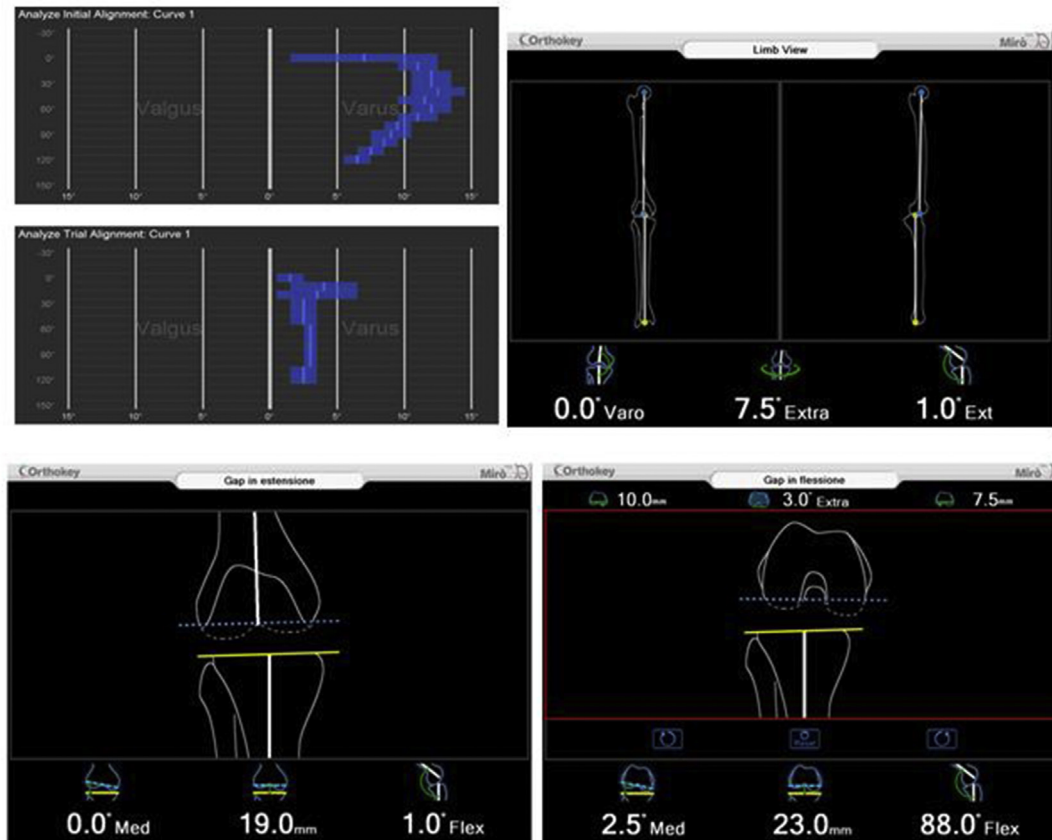


Fig. 2 – Data acquired by the computer navigation system.

on the computer screen. The Hemaclear ring was cut (or the tourniquet was released) after cement hardening. The skin incision was closed with staples after adequate haemostasis. No drains were used. Plain radiographs and CT scans were performed post-operatively.

Thromboprophylaxis was performed using Enoxaparin (4000 IU) subcutaneous injection: initial dose a night before surgery and once daily after surgery until restoration of a normal gait without crutches.

Tranexamic acid was injected intravenously 15 mg per kg body weight:

- Preoperatively: in bolus dose 20 min before incision
- Intraoperatively: prior to release of the tourniquet
- postoperatively: at 8 and 16 h from the end of surgery.

Operation and tourniquet time, use of antibiotic and thrombotic prophylaxis, tranexamic acid injections and blood transfusion were recorded. Each patient underwent the same post-operative rehabilitation, starting weight-bearing and exercises on the first post-operative day and continued during the in-hospital stay. Active ROM was encouraged and walking with two elbow crutches was allowed. Patients were discharged and physiotherapy undertaken two or three times per week for the first month.

The same surgeons performed the post-operative assessments of clinical and radiological outcomes. Standard anteroposterior and true lateral radiographs of the knee were

performed after 1, 6 month and annually thereafter. Bipodal weight-bearing long-leg radiographs were obtained preoperatively and after 1 month after surgery to assess the mechanical axis. A deviation within $\pm 3^\circ$ from the neutral axis was considered to be the optimal radiographic outcome. Computed tomography images were taken post-operatively to evaluate components rotational alignment.

The clinical outcomes were measured using the KSS and TLKSS pre-operatively, after 6, 12 and 36 months.

The Student t-test was used to compare the mean of KSS values before and after surgery and to compare the means of Tegner Lysholm Knee Scoring Scale. Statistical significance was set at $p < 0.05$.

Results

A total of 180 (200 knees) patients (females: 109; 60, 5%; males: 71; 39, 4%; mean age: 64 years) satisfied the inclusion criteria and underwent primary CAS TKA. The average body mass index (BMI) of these patients was 28 kg/m^2 . The mean follow-up duration was 2.5 years.

The mean tourniquet time for our patients was $72 \pm 13.4 \text{ min}$.

Blood transfusions were planned in patients with haemoglobin (Hb) below 7.8 g/dl : our patients received an average of 0.6 ± 0.82 units of blood post-operatively.

Knee Society Score (KSS) is divided in a knee and a functional score and is based on pain, range of movement

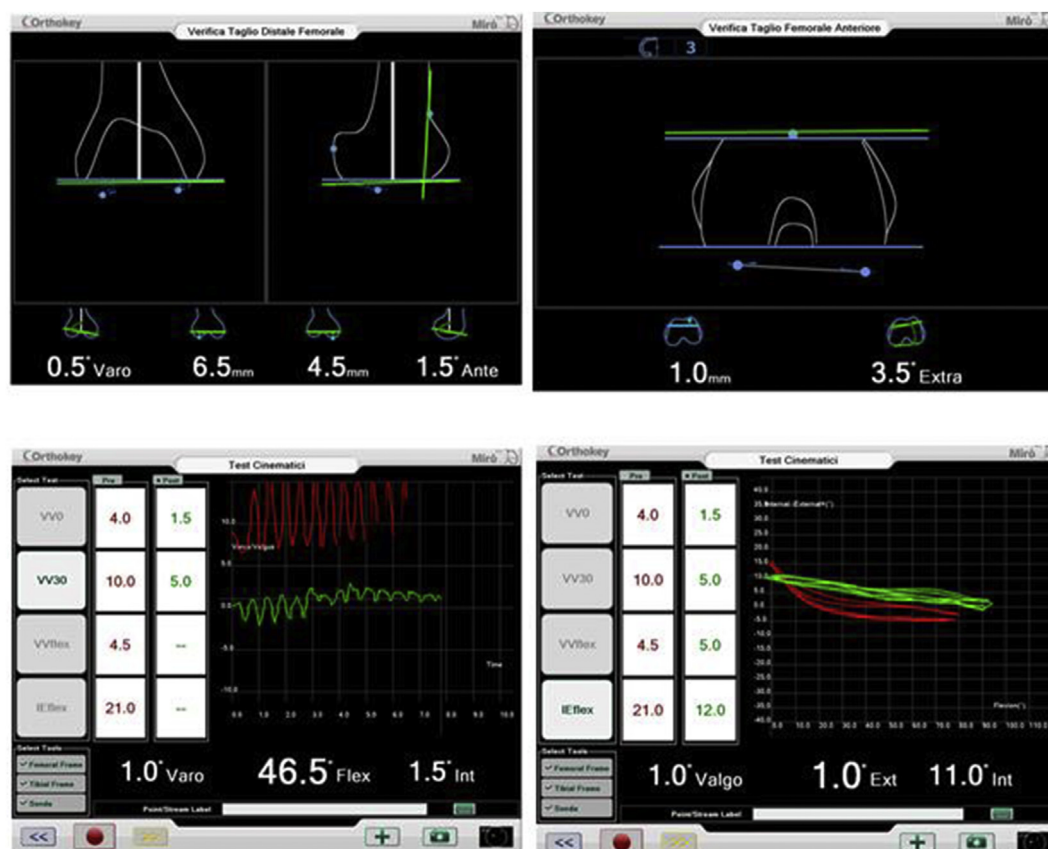


Fig. 3 – Data acquired by the computer navigation system.

(ROM) and activities of daily living. The total score possible is 200 points, 100 for each score. The average KSS functional scores assessed preoperatively was 44.6 ± 13.7 , after 6 months 75.4 ± 13.5 , after 1 year 83.4 ± 13.5 and after 2 years 80.4 ± 16.4 (Table 1). The Student's t-test showed statistically significant difference between the mean values of KSS before and at 6, 12 and 36 months after surgery ($p < 0.01$).

The Tegner Lysholm Knee Scoring Scale evaluates knee activity. The score is obtained adding points to eight question about: limp, need for support, pain, instability, locking, swelling, stair climbing and squatting. The sum of each response may range from 0 to 100, where scores lower than 65 indicate poor level of function while scores up to 90 indicate fewer symptoms and higher levels of function. The average Tegner Lysholm Knee Scoring Scale (TLKSS) preoperatively was 34.3 ± 6.9 , after 6 months 67.3 ± 12.6 , after 1 year 72.8 ± 9.2 and after 2 years 71.4 ± 13.5 (Table 1). The Student t-test showed statistically significant difference between the mean

values of Tegner Lysholm Knee Scoring Scale before and at 6, 12 and 36 months after surgery ($p < 0.01$).

Both KSS and TLKSS improved markedly, reaching good to excellent results in 90% of patients.

Clinical outcomes are shown graphically in Fig. 4.

At radiographic evaluation, no radiolucent lines, osteolysis or evidence for aseptic loosening were evident. The mechanical axis was within $\pm 3^\circ$ in all patients. No axial mis-alignment was observed on CT Scan (Fig. 5).

Three patients (1.6% of cases) required revision. Two patients developed *S. Aureus* MRSA infection, and one patient suffered from a traumatic tibial plateau fracture being involved in a road traffic crash.

Both patients with *S. Aureus* MRSA infection were treated with a 2 stage revision: a diagnosis of infection was made considering minor and major criteria for prosthetic joint infection (PJI). The first patient developed the infection after 3 months from surgery, and the second after 4 months. The Hoffman technique⁸ was performed as first stage: the original femoral stem was sterilized and re-implanted with antibiotic cement. The patients received in hospital systemic antibiotic therapy for 10 days, and then continued oral therapy until the follow-up at 6 weeks after the operation. White blood cell count (WBC), C reactive protein (CRP), and erythrocyte sedimentation rate (ESR) were examined at follow up; when these parameters were regularized, we proceeded with the second stage revision. The Triathlon TS Knee System (Stryker®) was used for both patients (Fig. 6).

Table 1 – The KSS and TLKSS before surgery and after 6, 12, and 36 months from surgery.

| | KSS | TLKSS |
|-----------------|-----------------|-----------------|
| Before surgery | 34.3 ± 6.9 | 34.3 ± 6.9 |
| After 6 months | 67.3 ± 12.6 | 67.3 ± 12.6 |
| After 12 months | 72.8 ± 9.2 | 72.8 ± 9.2 |
| After 36 months | 71.4 ± 13.5 | 71.4 ± 13.5 |

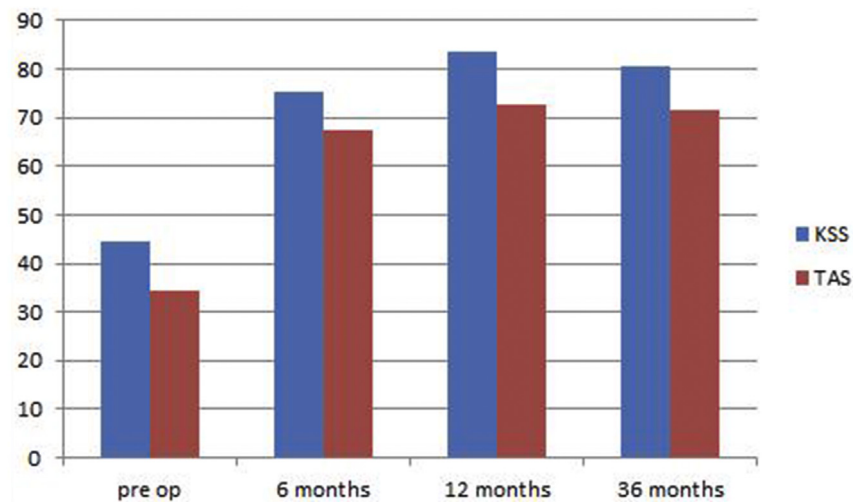


Figure 4 – Clinical outcomes of patient underwent to CAS before surgery and after 6, 12 and 36 months.

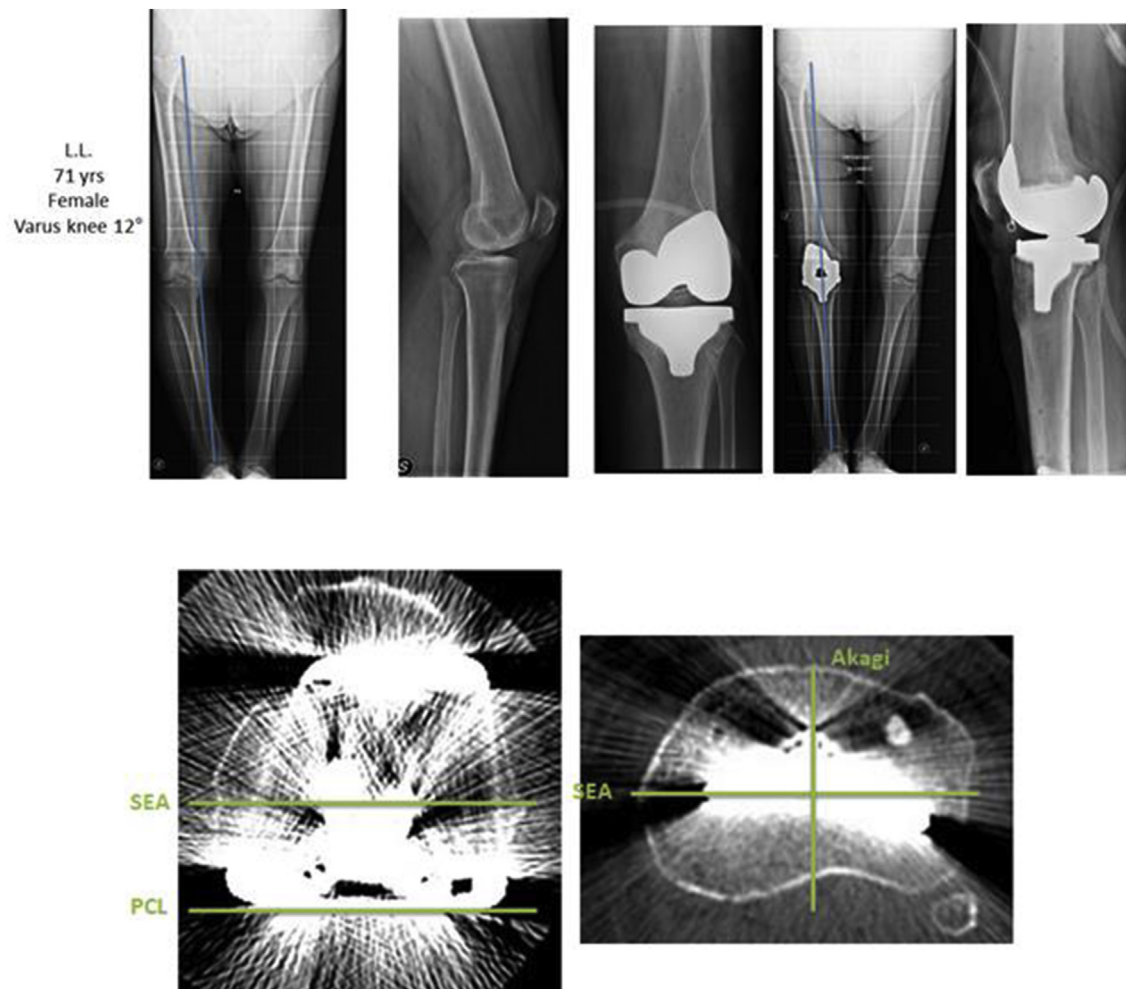


Fig. 5 – A: Radiographs of a female patient before and immediately after surgery, B: CT scan of the same patient 5 days after surgery.

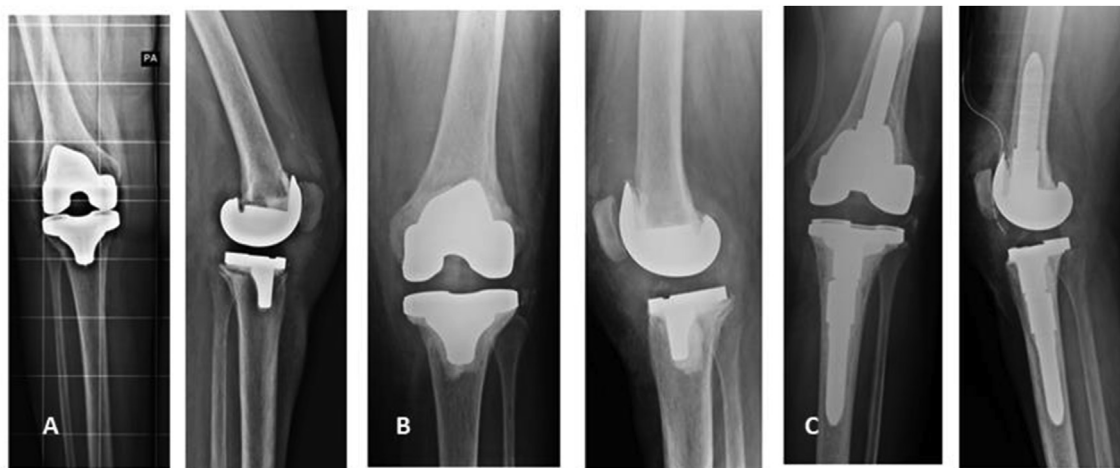


Fig. 6 – A: Plain radiographs of patient with *S. Aureus* MRSA infection before surgery, B: Plain radiographs after Hoffman Technique, C: Plain radiographs at second stage revision.

The third revision patient suffered from post-traumatic tibial plateau fracture with malalignment, loss of medial bone and radiolucent lines around components after 2 years from primary computer assisted TKA. Revision was performed using an S-ROM® NOILES™ Rotating Hinge Knee System (DePuy Synthes®). Loss of medial bone was not replaced but sleeves on tibial component fill the defect and enhance fixation (Fig. 7).

Discussion

The use of CAS in TKA has improved both the accuracy and reproducibility in the orientation of prosthetic components in frontal, sagittal and transverse planes.⁹ Frontal alignment is classically planned within $\pm 3^\circ$ of the mechanical axis, the sagittal alignment includes correction of abnormal tibial slope, and on the axial plane the torsional tibial and/or femoral deformities should be corrected.³ Conventional surgical technique with manual instruments may fail to restore neutral mechanical alignment in up to 30% of the patients despite surgeons' experience, and CAS has been proposed to improve the performance of TKA, detecting parameters such as the design trochlear groove of the prosthesis, patellar resurfacing, bone cuts, ligament balancing, antero-posterior femoral offset, medial-lateral positioning and rotation of the femoral component. Other advantages of CAS include improved restoration of the joint line, better results in patients with extra-articular deformities, and reduction in peri-operative blood loss.¹⁰ CAS TKA induces to lower level of inflammation markers and blood loss compared to conventional TKA.¹¹ In the present study, few units of blood were transfused post-operatively, a likely consequence of no intramedullary breaching and of tranexamic acid administration pre- and intra-operatively. CAS may present some disadvantages, including longer tourniquet and operative times, additional incisions (potentially risk of infection), fracture through tracker sites and increased cost.⁵ In this study, the short mean tourniquet time reflects the fact that the two surgeons were well beyond their learning curve both

in terms of traditional and CAS TKA. A beginner in CAS TKA can match reproduce the results of an expert TKA surgeon after a learning curve of 16 procedures.³ A mechanical axis mis-alignment greater than 3° in the coronal plane is associated with poor implant survival; nevertheless, it remains controversial whether improved alignment leads to better clinical results.¹² CAS technique could provide higher functional scores in the short-term, but it is debated whether functional outcomes and survivorship of implant in the long-term are influenced by CAS.¹³ In the present study, we hypothesized that CAS would result in high functional outcome and patient satisfaction. This has been indeed the case, and has been coupled with excellent limb alignment within 3° and ligament balancing, and an accurate axial orientation of the components. Positioning of the TKA components within 3° of the mechanical axis of the knee reduces the risks of abnormal wear, premature loosening and early implant failure, while a varus or valgus critical angle greater than 4° increases asymmetric tibial-femoral tracking, resulting in abnormal stresses at the weight bearing surface and, consequently, polyethylene wear abrasion.¹⁴ The use of CAS systems may also help in terms of ligaments and soft tissue balance.^{4,15} Navigation guided total knee arthroplasty is considered an effective tool in management large pre-operative coronal and sagittal deformities compared to conventional TKA¹⁶ and reduces the overall rate of TKA revision and the rate of revision for aseptic loosening/lysis, especially in patients young than 65 who exhibit high rates of revision from wear-related issues.¹⁷ The Australian Orthopaedic Association Joint Registry reported that the revision rate among younger patients was significantly lower after 9 years when managed with CAS (6.3%) than for those managed with traditional TKA (7.8%).¹⁸ In this study, only 3 patients (1.6%) underwent revision, but not for polyethylene wear. These results are encouraging but CAS continues to be cautiously included in orthopaedic practice across the world. In 2017, there was about 30% usage in Germany, 28.6% in Australia, and sporadic usage in Europe, North America, Brazil, South America and Asia.¹⁹ This is in part related to costs, and long-terms trial are required to evaluate the cost-effectiveness of CAS.⁷



Fig. 7 – Plain radiographs of patient with tibial plateau fracture before and after surgery.

The study has several limitations. When we started to use CAS, there was limited information about its use, and our goal was to evaluate how it impacted on functional outcomes. We did not assess the superiority of CAS TKA over conventional TKA. The size of our cohort of patients ($N = 180$) satisfied the inclusion criteria is a strength of this study, but to compare CAS to conventional TKA in surgical procedure (Operating time, Tourniquet time, blood loss, number of complications and learning curve), imaging and short/long clinical outcomes a control group of patients underwent to conventional TKA matched for age, sex and comorbidities is still needed. Another limit is that we only assess outcomes at 2.5 years

from the index procedure: longer follow-up is needed to establish whether these encouraging results are maintained over time. It is possible that the advantage in component survival using CAS will be reduced by the features of modern implant designs, which may show better wear rates and less loosening.²⁰

Conclusion

In conclusion, CAS TKA enables to obtain reproducible alignment and reduce kinematic outliers, providing optimal ligament balancing and reliably ensuring favorable clinical outcomes in the short term. More studies are needed to assess the superiority of CAS TKA over traditional TKA and to confirm the good outcomes of CAS TKA in long term.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declaration of Competing Interest

The authors declare that they have no conflict of interest that could inappropriately influence the work.

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