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Total knee arthroplasty with patient-specific instruments improves function and restores limb alignment in patients with extra-articular deformity

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ABSTRACT

Background: Restoring function and alignment when treating knee arthritis with a total knee arthroplasty (TKA) in patients who have an extra-articular deformity (EAD) from a malunion or with retained femoral hardware is a challenge. The normal anatomical landmarks are hard to find and difficult to use to obtain correct alignment. The procedure will be further challenged by angular deformity of the femur or tibia. A retrospective study was performed on a case series of patients with EAD or obliteration of the canal treated with patient-specific instruments (PSI).

Methods: A multicenter retrospective review of 10 patients with multiplanar deformities in which the knee components were aligned with patient-specific instruments was performed. Outcome and alignment were studied.

Results: At a mean follow-up of 3.4 years, function improved from preoperative as evidenced by a mean increase in the KS pain score of 53 points, KS function score of 48 points and Oxford Score of 28 points ($P < 0.05$). Flexion improved from 94° +/− 11° to 112° +/− 15° ($P < 0.05$). Limb alignment was restored with a mean Hip-Knee-Ankle angle of 179.3° +/− 1.3° ($P < 0.05$). Maximum outliers were 177° to 181°. An average tourniquet time of 75 +/− 9 minutes (range, 62–83 min) was observed.

Conclusions: The use of patient-specific instrumentation systems to perform TKA in patients without access to the intramedullary canal because of EAD or fixation devices, improved function and restored limb alignment. Mechanical alignment can easily be obtained with this technique by intra-articular correction of deformities under 20°.

Level of Evidence: Level IV.

1. Introduction

Alignment is crucial in total knee arthroplasty (TKA) for implant survival and clinical outcome [1–3]. Both conventional instruments and computer-assisted navigation (CAS) have been used to obtain these objectives [4–6]. Intra-medullary (IM) instruments recreate the mechanical axis by using the anatomical axis and landmarks [1–7]. CAS is based on finding the center of the femoral head, the knee and the ankle allowing surgeons to find the mechanical alignment without using the anatomical axes [3,4]. The use of these navigation systems has resulted in improved alignment [2] but has not completely eliminated outliers or improved clinical outcomes [9,10].

The area where the advantages of CAS is clear, is in the presence of posttraumatic extra-articular deformities (EAD), retained hardware, ipsilateral long stem total hip arthroplasty or any situation where traditional instrumentation is not feasible [3,4,11–13].

Recently a new instrument for aligning the limb in all three planes, patient-specific instruments (PSI) using MRI or CT-scan, has been developed. Patient-specific positioning guides or cutting blocks are designed from radiological images and are supposed to allow surgeons to improve accuracy in the three planes or the six degrees of freedom of a knee implant [10,14]. As with navigation, these instruments are based on direct mechanical alignment without using the anatomical axes [3,4].

Extra-articular deformities have always been a challenge to obtain alignment either by corrective osteotomy or by intra-articular correction of the axis [4,11,15,16]. For these special cases, navigation has proven to be of added value [1,3,4,12,17]. However, EAD cases can be even more challenging than standard TKA. These complex angular

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deformity cases ask for experience of the surgeon with the navigation system, especially with the finding of the anatomical landmarks and the technical aspects of correcting EAD via intra-articular resections [13,17].

In a retrospective multicenter case series, the authors analyzed nine cases of extra-articular deformity and one case of femoral canal obliteration with an internal fixation device, operated with patient-specific instruments (PSI) and intra-articular correction of the alignment using primary implants.

The hypothesis of this study was [1] that PSI restores mechanical limb alignment in total knee arthroplasty with EAD and [2] that PSI assisted TKA for EAD restores function.

2. Materials and Methods

Between 2008 and 2010, ten patients (6 men and 4 women) with posttraumatic knee arthritis and femoral or tibial canal obliteration or deformity were operated for total knee arthroplasty by 3 of the authors (ET 6; MP 3; MH 1 case). All patients presenting during that consecutive period of time were selected for patient-specific instrumented TKA. At the time of surgery, the mean age of the patients was 58.5 +/− 8.5 years. The average BMI was 33.2 +/− 3.5 kg/m^2. Obliterations of the canal were caused either by malunions, presence of osteosynthesis material or sclerosis (see Fig.1). One patient had a long femoral nail. Eight other patients had femoral malunion that precluded the use of intramedullary alignment guides and one other patient had tibial malunion. As for the site of EAD at the femoral level 6 deformities were at the distal one third, two were midshaft and finally 1 was proximal. At the tibia level, one was located at the proximal level. There were 4 uniplanar and 6 multiplanar deformities. Time between fracture and total knee arthroplasty was on average 16 years (range, 6 to 32 years). Many patients had a history of additional operations following their fracture, prior to arthroplasty, with a mean of 3 interventions (range, 1–8). These included removal of hardware, wound debridement, open meniscectomy and arthroscopy. One patient was ASA I, six patients were ASA II and finally three patients were ASA III. Five implants were Vanguard (Biomet, Warsaw, US), three Nex Gen (Zimmer, Warsaw, US), one GMK (Medacta, Switzerland), and one SLK-Evo (Implants Int, UK). In five cases Signature (Biomet via Materialise, Belgium), in three PSI (Zimmer via Materialise, Belgium), in one case My Knee (Medacta, Switzerland) and finally in one case a Hafez guide was used (Table 1). The Hafez guide is a generic cutting guide designed and produced by Dr Hafez who contributed his case. All patients underwent preoperative MRI scan except the patient with a femoral nail (My Knee, Medacta) and the patient of Dr Hafez who underwent a CT scan. Mechanical alignment was priority in all patients and an HKA-angle of 180° +/− 3° was the alignment aim. After validating the preoperative planning, patient specific instruments were designed. Eight guides had a cartilage fit and two a bone and osteophyte contact.

In all patients a minimally invasive medial parapatellar approach was used. The patella was displaced laterally but never everted. After

Fig. 1. Frontal radiograph of the femur showing EAD and obliteration of the femoral canal by sclerosis.

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Table 1
Data on femoral/tibial deformity and treatment.

Case N	Preop diagnosis	Age (years)	Sex (M/F)	Preop deformity in degree	Site of deformity	PSI type	Implant	Postop mech alignment
1	fracture malunion	59	M	15 of varus, 18° exorotation	distal 1/3 femur	signature	Vanguard PS	177°
2	fracture malunion	60	F	9 of varus, 12 antecurvatum	distal 1/3 femur	signature	Vanguard PS	181°
3	IM nail	62	M	4 of varus	prox femur	my knee	GMK -Sphere	177°
4	fracture malunion	69	F	12 of varus, 6 of recurvatum	prox tibia	signature	Vanguard PS	180°
5	fracture malunion	54	F	7 of varus, 9 antecurvatum	distal 1/3 femur	signature	Vanguard PS	180°
6	fracture malunion	59	M	9 of varus	distal 1/3 femur	signature	Vanguard PS	179°
7	fracture malunion	68	M	5 of varus	mid femur	PSI	Nex Gen PS	180°
8	fracture malunion	56	M	4 of varus, 3 antecurvatum	mid femur	PSI	Nex Gen PS	180°
9	fracture malunion	68	F	4 of varus	distal 1/3 femur	PSI	Nex Gen PS	180°
10	fracture malunion	43	F	14 of varus, 8 antecurvatum	distal 1/3 femur	Hafez guide	SLK-Evo	179°

Shows preop diagnosis of posttraumatic arthritis, the demographics of the patient, site and degree of deformity, type of PSI guide and type of implant used and finally the site of correction of the deformity.

clearing the medial soft tissues and for the CT-based guides the cartilage contact surface, good contact was obtained for all guides. Except for the My Knee guide and the Hafez guide, who were cutting block guides, these were all pin locator guides. Conventional cutting blocks were used and gaps were checked with spacer blocks. Extramedullary alignment rods were used to control alignment after the cuts. In all cases except one, the planned cuts were performed as planned with the patients-specific instruments. In this one patient with an important femoral rotational deformity, a balancer (eLIBRA, Synvasive, Zimmer, US) was used to balance the flexion gap and adjust rotation according to the soft tissues. The planned epicondylar axis was in internal rotation compared to the rotation decided by the soft tissues. With this soft tissues guided rotation the knee was balanced in flexion and correct patellofemoral tracking was obtained. Primary cemented implants were used in all cases and all patellae were resurfaced. No lateral retinacular releases were necessary. In six knees partial release of the medial collateral ligament was necessary. No drains were used. Full weight bearing was allowed the day after surgery as were active range of motion exercises. The tourniquet time was on average 62 minutes (range, 36–83 min). There were no transfusions in this study group. Mean hospital stay was 7 +/− 2 days (range, 2–12 days). No major complications or re-operations were observed or reported.

Full leg standing weight-bearing radiographs were taken preoperatively and at one year post-operatively and the axis deviation was analyzed as described by Moreland et al. [18]. The mechanical axis of the lower limb was measured using digital radiographs and special software (Carestream Health, Rochester, US). The femoral mechanical axis connected the center of the femoral head determined by a Mose circle and the center of the femoral condyles. The tibial mechanical axis was determined by the center of the knee and the center of the talus (45–55% ratio of malleoli). Varus or valgus deformity was measured in between these two axes as the tibiofemoral angle. The mechanical axis was found to run according to the Kennedy score [19] through zone 0 in 3 knees, zone 1 in 4 knees, zone 2 in 2 other knees, zone C in 1 knee preoperatively.

Standard radiographs were measured at one year with Merchant views for patellofemoral alignment and potential tilt. The alignment of the femoral and tibial component was assessed according to the Knee Society radiographic evaluation system [20]. The femoral anatomical axis was measured using AP radiographs by drawing a line from the greater trochanter to the middle of the distal femur. A second line was drawn tangent to the articular surface of the distal femoral condyles. The angle at intersection of these two lines was measured. The tibial anatomical axis was measured using a line drawn within the shaft of the tibia and another line drawn along the tibial baseplate. The angle at intersection of both lines was measured. On the lateral radiograph, femoral flexion or extension and tibial slope were measured.

The overall mean pre-operative hip-knee-ankle angle was 172.6° +/− 4.5° varus alignment (range, 165° to 187°). The mean femoral extra-articular deformity in the coronal plane was 9° varus (range, 8° varus to 20° varus). The mean tibial extra-articular deformity in the coronal plane was 11° varus (range, 23° varus to 2° valgus). The mean femoral extra-articular deformity in the sagittal plane was flexion of 5° (range, 7° flexion to 9° extension). The mean tibial extra-articular deformity in the sagittal plane was 6° flexion (range, 12° flexion to 15° extension).

The Knee Society knee scoring system, range of motion and stability of the knee evaluated function. Transfusion rate and hospital stay were observed. The average follow-up was 3.4 years (range, 2–5 years) after surgery. There were no reported complications in this group of patients.

2.1. Statistical analysis

Preoperative and postoperative clinical data like arc of flexion, Knee and Oxford Scores and alignment were compared as mean and standard deviation (SD) using the Students *t* test. $P < 0.05$ was considered significant. All the analyses were performed using the SPSS version 16 software (SPSS Inc, Chicago, US).

3. Results

At a mean follow-up of 3.4 years (range, 2–5 years), the mean Knee Society function score increased from 44 +/− 11 points pre-operatively to 92 +/− 7 points postoperatively ($P < 0.05$). The mean Knee Society pain score improved from 38 +/− 6 points pre-operatively to 91 +/− 9 points postoperatively ($P < 0.05$). The Oxford Score improved from a mean 15.6 +/− 5 to 43.5 +/− 4 points ($P < 0.05$) (Fig. 1).

For all patients, the extension improved from – 7° +/− 3° (range, +5° to - 11°) to 0° (range, +2° to −3°) ($P < 0.05$) and the flexion improved from 94° +/− 11° (range, 70°-126°) to 112° +/− 15° (range, 90°-138°) ($P < 0.05$) (Table 2). Frontal and sagittal stability was within 5 mm for all patients at clinical examination.

At one year follow-up the mechanical alignment was corrected to 179.3° +/− 1.3° varus (range, 177° to 181°) ($P < 0.05$) (Table 3). The coronal alignment of the femoral component was 89° +/− 3° and the coronal alignment of the tibial component 89.4° +/− 1.8°.

According to the Knee Society Radiological analysis [20] on the anteroposterior radiograph the femoral angle averaged 5° valgus (range, 4°-7° valgus). The tibial angle averaged 1.2° varus (range, 3° varus-1° valgus). On the lateral radiographs the femoral

Table 2
Preoperative and postoperative function.

Data (Mean +/− SD)	Preop value (points)	Postop value (points)
Knee society pain	38 +/− 6	91 +/− 9
Knee society function	44 +/− 11	92 +/− 7
Oxford score	15.6 +/− 5	43.5 +/− 4
Flexion	94° +/− 11°	112° +/− 15°

Shows preoperative and postoperative function and arc of flexion.

flexion averaged 3° (range, 4° extension- 9° flexion). The tibial slope averaged 2° posterior (range 2° anterior-7° posterior) (Table 3). Postoperatively the axis runs through zone 2 in 2 knees, zone C in 7 knees and finally zone 3 in 1 TKA.

No patient had radiographic loosening and in only one patient, radiolucent lines (zone 1–2) were observed. Patellar tracking was esteemed optimal in 9 patients with one patient showing lateral tilt without subluxation.

4. Discussion

The most important findings of this study were a statistical improvement in function from preoperative observed for all patients as evidenced by a significant increase in both Knee Society and Oxford Scores and a restoration of the mechanical alignment with PSI in EAD total knee arthroplasty.

Secondary findings of this study were that posttraumatic arthritis patients have reduced pre-operative flexion but that a significant amelioration in flexion can be obtained after TKA. However their postoperative flexion remains relatively low compared to normal primary TKA [7,22]. And that none of our 10 patients needed transfusion, despite that these were all complex cases. A published advantage of navigation is the reduction of blood loss and a decreased risk of fat embolism by avoiding IM guides and violation of the canal [1,4,23,24]. In theory, the same advantage should be found when using PSI since there is no violation of the canal but this still remains to be proven.

Recently, PSI was successfully used in a case of osteopetrosis, to avoid the sclerotic and obliterated canal [25]. PSI is based on the same principles of mechanical alignment as a navigation system, but without the trackers and the surgical mapping asking the surgeon to identify the necessary anatomical landmarks. Adequate restoration of the mechanical axis was observed using these different PSI devices.

Navigation has a learning curve and finding the anatomical landmarks can be especially difficult in this altered anatomy. The potential time impact on the surgery can change the clinical outcome [9,13,26–28]. PSI has a very limited learning curve only related to the haptic feeling of the guides. Since anatomical landmarks are determined during the preoperative planning on MRI or CT, the outsourcing of the planning reduces the surgical time in these difficult EAD cases. Tourniquet times observed in this series are very similar to primary cases in the contrast to navigation related tourniquet times published in previous series [7,13,21].

Extra-articular deformity can be addressed by a modification of the resurfacing cut, a corrective osteotomy or by staged TKA with potential complications [2,7,12,13].

Wang et al. concluded that an EA femoral coronal deformity of less than 20° and a tibial coronal deformity of 30° or less may be corrected without an EA osteotomy [11]. If the deformity is too large, dealing with it by intra-articular bone resection and extensive soft tissue release may cause imbalance of the collateral ligaments and may ask for more constraint [4,22]. Corrective osteotomy may be indicated when bone resections would compromise the collateral attachments or create large asymmetric soft tissue gaps [4,11,16].

In this case series, intra-articular correction of the EAD was possible in all cases and only primary implants were used. An advantage of PSI planning is that pre-operatively the alignment can be analyzed as well as the postoperative correction. The bone resection levels of femur and tibia, both in flexion and extension, can be observed on the planning. This is a clear advantage compared to computer-navigation that only allows accurate alignment and gap measurements during surgery [7].

Sagittal alignment corrections are difficult in TKA. Navigation systems have the intrinsic risk of notching because of the sagittal axis determination. In patients with posttraumatic sagittal malalignment this risk is even higher. This potential complication can be avoided with PSI, because notching will be seen during the preoperative planning [6,29]. Wang et al. showed that intra-articular correction of sagittal deformities up to 15° of recurvatum and 16° of antecurvatum of the femur is feasible [15,30].

Another limitation of navigation is the accuracy of femoral rotation [26,27,31]. In cases were the anatomical landmarks are difficult to find, inaccuracy of rotational axes can be important [26,27]. In the published navigation assisted EAD cases several authors used gap balancing to determine the correct femoral rotation [1,8]. In PSI these landmarks are determined on MRI or CT and can be checked in the pre-operative planning [31]. In only 1/1O cases with a combined proximal and distal femoral deformity, gap balancing was necessary for rotational alignment.

A major drawback of this study is the limited number of patients treated by several surgeons with different PSI systems. EAD is relatively rare since we collected only 10 cases among 3 surgeons that were pioneers in the use of patient-specific instruments during a three-year period. PSI is a new technology and we have a minimal two years follow-up on our cases (mean 3.4 years). Earlier published series on the use of navigation for the correction of extra-articular deformity were also mostly case series [3,8,17]. The biggest series on TKA after EAD is published by Mullaji et al. on 34 cases treated with computer-navigation [4].

Another limitation is that we were not able to compare PSI for EAD with computer navigation prospectively and analyze alignment, tourniquet times and clinical outcomes [9,28]. Based on literature reports on the use of navigation for EAD, we noticed significant lower tourniquet times in our series but similar amelioration of function and correction of mechanical alignment [7,13,21]. Because of the limited number of EAD cases it will be difficult to set up a prospective randomized study comparing navigation with PSI.

Table 3
Alignment of components.

Data	Mean	Range
Preop mechanical alignment	172.6°	165°–187°
Postop mechanical alignment	179.3°	177°–181°
Femoral anatomical alignment	+ 5°	+4° to +7° valgus
Femoral flexion angle	+ 3°	−4° extension to +9° flexion
Tibial anatomical alignment	- 1.2°	−3° varus to +1° valgus
Tibial slope angle	- 2°	+2° ant to −7° post

Shows preop and postop mechanical alignment and anatomical alignment of components measured according to Knee Society Radiographic evaluation system.

5. Conclusions

Patient-Specific Instruments are an alternative for conventional instruments and computer-assisted navigation for osteoarthritic knees with extra-articular deformities or retained hardware. Improvement in function and mechanical alignment were obtained at a minimal two years follow-up.

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