

# Complication rate following high tibial open-wedge osteotomy with spacer plates for incipient osteoarthritis of the knee with varus malalignment

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## Abstract

**Purpose** Medial open-wedge high tibial osteotomy (HTO) with spacer plates is recommended to correct varus malalignment of the knee with symptomatic overload of the medial compartment.

**Methods** Fifty-five knees in 50 patients were assessed. Intra- and post-operative complications were recorded, and Tegner, Lysholm and IKDC scores were used to evaluate functional results. Radiological parameters consisted of medial proximal tibial angle (aMPTA), femorotibial angle (aFTA), posterior proximal tibial angle, lateral distal femur angle, mechanical axis deviation (MAD) and osteoarthritis score (Jäger and Wirth).

**Results** Duration of follow-up was  $5.0 \pm 1.4$  years. Overall and implant-related complication rates were 27.3 and 10.9 %, respectively. No statistical association could be detected between overall and implant-related complication rates and age, gender, wedge size, angle of correction or body mass index. Mean improvement in Lysholm score was 26.8. Overall IKDC scores at follow-up were A25, B26, C2 and D2. Post-operative correction of MPTA and FTA averaged to  $89.6^\circ$  and  $173^\circ$  and to  $89^\circ$  and  $173.5^\circ$  at follow-up, respectively. Initial MAD of 21.8 mm was corrected to 11.8 mm at follow-up. Osteoarthritis score increased from  $1.4 \pm 0.9$  to  $1.9 \pm 0.9$  points.

**Conclusions** HTO with spacer plates improves knee function and is an effective procedure in selected patients. Overall and implant-related complication rates should be considered and seem to be lower with a smaller angle of

correction corresponding to incipient osteoarthritis and less varus deformity.

**Level of evidence** Retrospective case series, Level IV.

**Keywords** High tibial osteotomy · Open wedge · Spacer plate · Complication rate · Results

## Introduction

Medial open-wedge high tibial osteotomy (HTO) has been established as an effective surgical procedure in selected patients with symptomatic unicompartmental medial overload and osteoarthritis of the knee [3–11, 25]. To avoid the complications associated with closing-wedge osteotomies (infection, thromboembolic event, opposite cortex and intra-articular fractures, neurovascular complications, under-correction and recurrence of deformity, non-union and delayed union have been reported), HTO has become widely accepted as the treatment of choice in young and active patients to prevent progression to partial or total joint replacement and allow for unrestricted activity levels [9]. The decompressive effect on the cartilage of the medial compartment following correction of alignment decreases the risk of progression of osteoarthritic changes and improves knee function [3–11, 13, 17, 24]. Several studies have demonstrated the importance of adequate surgical correction of malalignment for a successful outcome [9, 20]. Loss of correction and functional outcome correlate with the type of fixation, the degree of correction [9, 25] and the period to osseous union. Numerous implants and techniques have been described for open-wedge HTO, but spacer plates and plate fixators seem to be prevalent. Plate fixators yield increased stability in clinical and experimental studies [19, 21] and decrease the necessity of

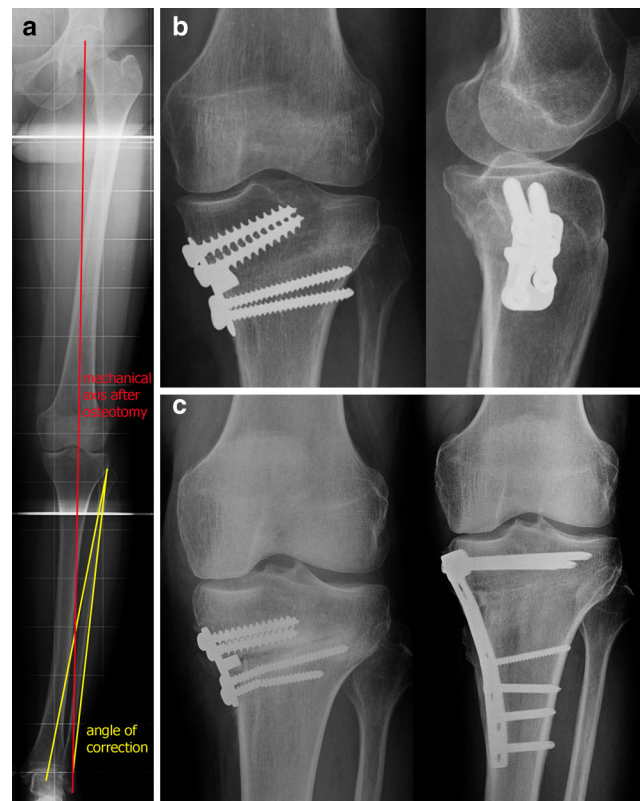
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autologous or artificial bone grafting. Depending on the implant utilized for the medial opening HTO procedure, several authors have reported variable complication rates [1, 15, 17, 18, 22–24].

This study reports the complication rate as well as clinical and radiological results following HTO with spacer plates in patients with varus malalignment of the knee and symptomatic incipient medial osteoarthritis. The hypothesis was that HTO using spacer plates is associated with similar complications and subjective and objective outcome measures comparable to other open-wedge techniques and implants.

## Materials and methods

Fifty-five knees in 50 patients who had undergone HTO with a non-locking spacer plate (Puddu I, Arthrex Inc., Naples, FL, USA) for incipient medial unicompartmental osteoarthritis of the knee and concomitant varus malalignment between 2001 and 2005 were evaluated. Out of 110 osteotomies performed at the Department of Trauma Surgery and Sports Traumatology, Academic Hospital Feldkirch, Austria, a total of 33 male (66 %, mean age  $53.8 \pm 13.6$ , range 19.8–79.9 years) and 17 female (34 %, mean age  $57.3 \pm 9.3$ , range 41.7–71.6 years) patients were included. Osteotomies performed for post-traumatic deformities and in combination with ligament reconstruction surgeries as well as patients with a history of other diseases or severe trauma involving the knee were excluded. Post-operative rehabilitation included partial weight bearing for 4–6 weeks and physiotherapeutic exercises with unlimited range of motion. Twenty-four patients (48 %) were operated for the right, 21 (42 %) for the left and five (10 %) for both knees. The mean age of the patients at the time of osteotomy was  $54.7 \pm 12.6$  years (range 19.8–79.9 years). Mean body mass index (BMI) was  $26.8 \pm 3.6$  (range 21.4–34.8). All patients initially presented with symptoms of unicompartmental medial overload originating from varus malalignment of the leg with incipient medial femorotibial osteoarthritis. Preoperative and follow-up assessment of clinical parameters was performed using Tegner score, Lysholm score and IKDC score. For radiological evaluation, anteroposterior, lateral and tangential standard knee radiographs and standing long-cassette radiographs of the lower limbs were obtained preoperatively, post-operatively, at the time of implant removal and at follow-up. Radiological measurements included anatomical medial proximal tibia angle (aMPTA, angle between tibial anatomical axis and the articular surface of the proximal tibia and anteroposterior images), anatomical femorotibial angle (aFTA, angle between the anatomical axis of femur and tibia), anatomical posterior



**Fig. 1** **a** Preoperative standing long-cassette radiograph demonstrating the plotted mechanical axis after osteotomy and the resulting angle of correction. **b** Uneventful osseous consolidation of the osteotomy gap after fixation with spacer plate. **c** Loss of correction after delayed union with implant failure requiring revision surgery (*left*). Conversion to a plate fixator (Tomofix) resulted in stable osseous union (*right*)

proximal tibia angle (aPPTA, angle between the tibial anatomical axis and the articular surface of the proximal tibia on lateral images), anatomical lateral distal femur angle (aLDFA, angle between anatomical axis of femur and the articular surface of the distal femur), mechanical axis deviation (MAD, distance between the centre of the knee joint and the mechanical femorotibial angle) and the classification of osteoarthritic changes according to the system described by Jäger and Wirth [12]. Complications occurring intra- or post-operatively or in the course of follow-up examination were recorded. For a retrospective analysis of patient data and images, IRB approval was not required.

## Statistical analysis

Paired *t* test for matched variables was used to compare continuous data before and after intervention. To analyse contingency tables, two-tailed Fisher's exact test and to compare continuous and categorical data of subgroups one-way analysis of variance (ANOVA) were applied. To

compare ordinal scale values, the nonparametric Wilcoxon signed-rank test was used. Statistical significance was defined as  $p < 0.05$ .

## Results

The mean follow-up period was  $5.0 \pm 1.4$  years (range 2.6–7.8 years). The overall complication rate was 27.3 %. Four implant failures (two plate breakages and two patients with screw loosening) and two delayed unions resulted in an implant-related complication rate of 10.9 %, which required revision surgery with conversion to a different fixation system. All other osteotomies healed uneventfully (Fig. 1). Specific complications and accordant treatment are demonstrated in Table 1. Infection occurred in four cases (7.3 %). Three were treated with debridement and antibiotics, and one required septic implant removal and restabilization with an external fixator. The non-implant-related complication rate was 16.4 %.

No statistical association was detected between BMI and overall or implant-related complication. Wedge sizes according to the spacer bar of the osteotomy plate averaged  $5.9 \pm 2$  mm (range 3–12 mm) and yielded no statistically significant correlation either with overall or with implant-related complications. The majority of patients ( $n = 42$ , 76.4 %) received implant size 5 and 7.5 mm. Subgroup

comparison between wedge sizes equal to or below 5 mm and equal to or above 7.5 mm and overall and implant-related complication rate showed no statistically significant association. The mean angle of correction between pre- and post-operative measurements in this series was  $3.8^\circ \pm 3.3^\circ$ . Analysis of correction angle and overall or implant-related complication rate revealed no statistically significant correlation. Subgroup analysis of correction angles equal to or below  $4^\circ$  and above  $4^\circ$  yielded no statistically significant association with overall or implant-related complication rate. Age and gender did not correlate with overall complications. Implant-related complications and age or gender yielded no statistical association. One knee (1.8 %) was converted to a total knee arthroplasty after 3.2 years.

Implant removal was performed in 30 patients (54.5 %) on average  $1.2 \pm 0.7$  years (range 0.5–3.6 years) after the initial operation. All of them felt uncomfortable with the implant causing pseudo-bursitis on the medial tibial head. The classification of osteoarthritis according to the system described by Jäger and Wirth is presented in Table 2. Additional arthroscopic surgery was necessary in 36 patients (65.5 %) and is displayed in Fig. 2. To fill the osteotomy gap, 48 patients underwent cancellous bone autografting from the anterior iliac crest, two had a bovine hydroxylapatite graft, and five did not have any graft (the latter were cases with a low correction angle).

The results of preoperative and follow-up clinical evaluation utilizing Tegner, Lysholm and IKDC scores are demonstrated in Table 3. Post-operative MAD and FTA were concordant with the preoperatively planned angle of correction and mechanical axis (Fig. 1). Preoperative radiological findings, post-operative angle of correction and corresponding values at the time of implant removal and follow-up examination are displayed in Fig. 3. Pre-operative MAD of on average  $21.8 \pm 15.3$  mm (range –10–50 mm) was corrected to a follow-up value of  $11.8 \pm 15.9$  mm (range –30–50 mm).

## Discussion

The most important finding of the present study was that medial open-wedge HTO with spacer plates yields a lower

**Table 1** Complications and treatment after HTO

Persistent pain after HTO	2/55 (3.6 %)	
Infection	4/55 (7.3 %)	Debridement, implant removal, external fixator
Palsy of superficial branch of the peroneal nerve	1/55 (1.8 %)	No adverse effect on outcome
Deep vein thrombosis	1/55 (1.8 %)	Medicamentous and conservative therapy
Tibial head fracture	1/55 (1.8 %)	Stabilization with proximal tibia plate
Implant failure	4/55 (7.3 %)	Refixation with TomoFix-System
Delayed union	2/55 (3.6 %)	Refixation with TomoFix-System
Non-implant-related	16.4 % (9/55)	Implant-related 10.9 % (6/55)

**Table 2** Results of preoperative and follow-up osteoarthritis score according to Jäger and Wirth

	Grade 0	Grade I	Grade II	Grade III	Mean
Preoperative	8 (14.5 %)	29 (52.7 %)	10 (18.2 %)	8 (14.5 %)	$1.4 \pm 0.9$ n.s.
Follow-up	2 (3.6 %)	21 (38.2 %)	12 (21.8 %)	20 (36.4 %)	$1.9 \pm 0.9$ n.s.

Absolute and relative values with mean  $\pm$  SD

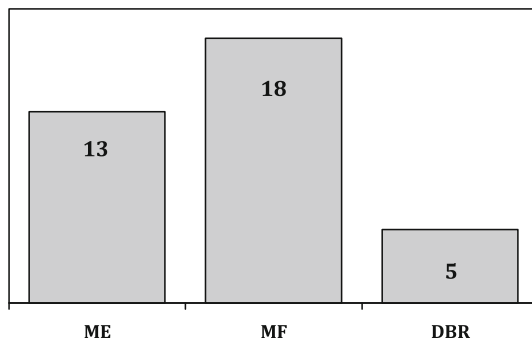
n.s. not significant

complication rate compared to previous reports and can be considered a safe and effective procedure in selected and active patients with slight varus malalignment and incipient osteoarthritis of the medial compartment requiring only minor correction of the leg axis.

Complication rates after HTO range between 2 and 50 % in literature [1, 4, 15–17, 22–24, 27]. A variety of implant types have been investigated in a comparable population to that of our study with the exception of our tendency towards smaller correction values. This series included patients with slight varus deformities and incipient symptoms of medial knee compartment overload. Most previous reports in literature analysing functional and radiological results and complication rates after HTO with spacer plates used consistently larger angles of correction [15, 17, 23] and found a significant correlation between wedge size and complication rate. An adverse effect on subjective and objective outcome measures is not always notable, however. The comparably smaller osteotomy gap size of 5.84 mm in our patients is likely to account for the lower complication rate. Most authors define the threshold osteotomy wedge size at 10 mm. In an analysis of 85 patients, Spahn reported the failure rate of spacer plates at 14.4 % compared to 0 % with the use of a C-plate [23]. Miller et al. [15] reviewed 46 patients after HTO with spacer plates and noted a statistical association between fixation device and loss of correction. The authors concluded that second-generation implants of spacer plates will probably improve the mechanical stability of

osteotomy fixation and, moreover, that the aetiology of complications is likely multifactorial and should not be attributed to the device alone. Regarding a selected group of patients, we agree with this statement. Non-locking spacer plates allow for a stable fixation if additional bone graft is performed and osteotomy gap sizes are small. As a matter of course, the use of locking implants with increased stability must be recommended. Existing literature reports a correlation between age, gender, BMI, wedge size or angle of correction and complication rates [15, 17]. We could only indirectly confirm this observation with our investigation. With smaller angles of correction, the complication rates are likely to decrease. In early and accurately timed corrective surgery, smaller osteotomy gap sizes seem to be sufficient. A positive influence on functional and radiological outcome as well as on complication rates is conceivable. In a retrospective analysis of 45 patients, Nelissen et al. [17] report an overall complication rate of 45 % following HTO with spacer plates. The authors conclude that the spacer plate they surveyed provides inadequate stability. In contrast to our investigation, the mean osteotomy wedge size was 10.7 mm and the defect was filled with artificial bone substitutes. In addition to a lower correction gap, the autologous bone graft might be a reason for a significantly reduced complication rate in this series. Bone grafting seems to be essential in osteotomy gaps with larger wedge sizes and especially if conventional non-locking implants are used. The subsequent generation of spacer plates (Puddu II, Open wedge plate, Arthrex Inc., Naples, FL, USA) was not applied in this series. Successful osseous consolidation without bone grafts regardless of the wedge size and with an early weight-bearing rehabilitation protocol is reported in association with locking plate fixators [18].

In a recent report, Pape et al. [19] utilized radiostereometric analysis to investigate the fixation stability of spacer plates and plate fixators in vivo and found both significantly increased subsidence of the tibial head and increased micromotion in the osteotomy gap for the spacer plate. The authors concluded that a weight-bearing rehabilitation protocol after 6 weeks might alter the stability of the bone-implant construct following this modality of fixation. This confirms the results of biomechanical studies [21], certifying an improved stability for plate fixators and might also



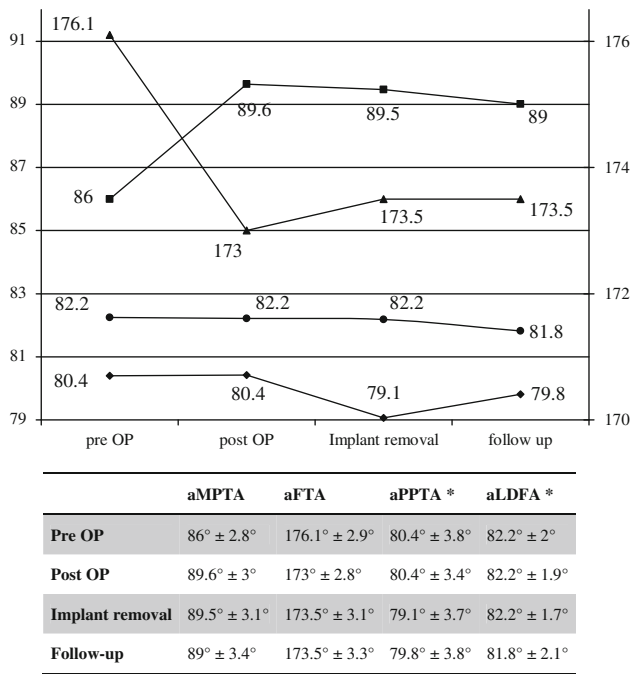
**Fig. 2** Frequency of additional surgery (ME partial medial meniscectomy, MF microfracturing or smoothing of flaps and fibrillations, DBR combined joint debridement)

**Table 3** Results of preoperative and follow-up Tegner (median with range) and Lysholm scores

	Tegner	Lysholm*	IKDC A	IKDC B	IKDC C	IKDC D
Preoperative	3.0 (range 1–4)	55.7 ± 15.3	–	–	–	–
Follow-up	3.0 (range 1–7)	82.5 ± 17.9	25	26	2	2

Mean ± SD and follow-up IKDC score

\*  $p < 0.05$  between preoperative and follow-up values



**Fig. 3** Pre-, post-operative, implant removal and follow-up values for aMPTA (filled square), aFTA (filled triangle), aPPTA (filled diamond) and aLDFA (filled circle) (mean ± SD, \* not significant)

explain implant failure and delayed union following early weight-bearing rehabilitation in our series. In addition, utilizing a plate fixator resulted in uneventful osseous consolidation in all patients requiring revision surgery. A report about a different biomechanical implant design that reduces the necessity of additional bone graft and further reduces complication rate by Niemeyer et al. [18] found a significant number of patients with local irritation caused by the implant. Miller et al. [15] found only two cases in a series of 46 patients following HTO with spacer plates, which complained about painful hardware and required implant removal. The advantage of a smaller implant design regarding local irritation was not visible from our data. In our series the majority of patients underwent implant removal. The additional adverse effect on local irritation of a longer and bulkier implant remains unknown. The infection rate of 7.3 % in our series is in accordance with literature. Even though Anagnostakos et al. [1] found oblique skin incision and one-day hospitalization to be risk factors for infection emergence, we did not notice an immoderate infection rate utilizing the same surgical approach.

Stability of the implant and bone–implant anchorage seems to be an important factor for successful outcome [9, 17]. The relative risk of HTO compared to total knee arthroplasty and medial unicompartmental replacement has been outlined by Sikorski et al. [22]. The authors found

HTO to be the most likely to produce local technical problems. Nevertheless, HTO is a potent treatment option to prevent progress of degeneration of the joint and avoid or delay partial or total knee replacement [11, 26].

The target value for correction is controversially discussed [3–11, 20]. Since this series consisted of athletic and demanding patients in terms of sportive activity who did not present with extensive varus deformities, we specified a corrected leg axis between neutral and slightly valgus as appropriate to release the medial compartment. An average follow-up MAD of  $11.8 \pm 15.9$  mm reflects this target value. Overcorrection to a valgus position might negatively influence the patients’ ability to proceed in their sport-specific and demanding leisure activity levels. The preoperative classification of degenerative changes according to Jäger and Wirth [12] revealed an average osteoarthritis score of  $1.4 \pm 0.9$ , also indicating an early onset of therapeutic intervention in this series.

The functional and radiological results of this investigation are comparable to literature with significant improvement in the Tegner and Lysholm scores and a normal and almost normal knee function in 92.3 % according to IKDC score. aPPTA and aLDFA yielded only marginal alteration following HTO, excluding a negative influence on functional outcome and knee kinematics [2, 13, 14]. aMPTA and aFTA measurements suggest only a slight and statistically no significant sintering of the osteotomy gap. This indicates sufficient stability of the fixation device in our investigation. Tegner score of  $3.7 \pm 1.2$  at follow-up reflects a high maximum age (79.9 years) in this sample. However, corresponding to their lower biological age, these patients are reported to benefit from HTO [4].

In fact, there are several limitations to this investigation: the retrospective approach to a small study population, the use of a non-locking implant and the almost routinely performed bone grafting. Angular stability might further reduce the necessity of bone grafting. Stable fixation of the osteotomy gap and low complication rates without additional bone graft are well documented for larger plate fixators, but not for spacer plates, yet.

### Conclusion

In consistency with existing literature, the functional and radiological medium-term results after HTO with spacer plates are predictable. Complication rates seem to be lower in patients with early symptoms of medial femorotibial overload due to varus malalignment of the knee requiring an osteotomy gap size equal to or less than 7 mm. Additional bone graft and a non-weight-bearing rehabilitation protocol seem to be necessary, however.

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