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Prospective evaluation of a new plate fixator for valgus-producing medial open-wedge high tibial osteotomy

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Abstract

Purpose The purpose of this study was to prospectively evaluate the clinical, radiographic, and sports-related outcome at 24 months after valgus-producing medial open-wedge high tibial osteotomy (owHTO) using a 2nd generation peek-carbon composite plate.

Methods Between 2010 and 2011, the 2nd generation PEEKPower HTO-Plate® was used for medial owHTO in 28 consecutive patients (19 men, 9 women; mean age ± SD: 45 ± 11 years; mean varus deviation ± SD: 4° ± 2°). All of the patients had an osteotomy gap height of ≤12 mm without bone grafting. Visual analog scale (VAS) for pain, WOMAC score, and Lysholm score were evaluated preoperatively and at 12 and 24 months postoperatively. Sports-related outcomes included the Tegner scale, and a self-designed questionnaire preoperatively and 24 months postoperatively. Fixation stability of the implant was evaluated radiographically in two planes by comparing the medial proximal tibial angle (MPTA) and tibial slope 2 days after medial owHTO (baseline measurements) and after implant removal (follow-up measurements). Complications were recorded during the whole study period.

Results Compared to preoperative conditions, VAS, WOMAC, and Lysholm scores improved significantly ($p < 0.05$) at the 12- and 24-month follow-up. No significant differences were found between the 12- and 24-month follow-up. After 24 months, the sports frequency increased significantly ($p < 0.05$). No significant differences between baseline and follow-up measurements for the MPTA and tibial slope were observed. Total complication rate was 4 %, with one patient developing non-union.

Conclusion In the clinical practice, the 2nd generation PEEKPower HTO-Plate® is a safe and efficient implant for medial owHTO without bone grafting in patients with an osteotomy gap of ≤12 mm.

Level of evidence III.

Keywords High tibial osteotomy · Open wedge · 2nd generation PEEKPower HTO-Plate · Plate fixator

Matthias Cotic and Stephan Vogt are contributed equally.

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Introduction

Valgus-producing medial open-wedge high tibial osteotomy (owHTO) is an established procedure for the treatment of medial compartment osteoarthritis in the varus knee [1, 29, 33, 39, 46, 47, 64, 75]. Secure fixation of the osteotomy is mandatory for owHTO in order to minimize the risk of correction loss and non-union [11, 54, 58]. Different fixation devices have been developed for owHTO, such as an inlay system [21], short spacer plates with or without locking screws [4, 6, 16, 32, 43, 48, 60], and locking screw plate fixators with [25] and without a spacer [13, 18, 19, 36, 40, 45, 49, 65].

In biomechanical and clinical studies, one of the most common used plate fixators, the TomoFix™ plate (Synthes Medical, Oberdorf, Switzerland), has shown to provide higher fixation stability compared to short spacer plates, even without bone grafting of the osteotomy gap [2, 53, 68]. However, disadvantages of this implant include its bulky design, which causes local discomfort in most patients until implant removal [49, 50]. Further non-variable predefined directions of the locking screws carry the risk for cross-threading and limit tunnel placement during concomitant anterior (ACL) or posterior (PCL) cruciate ligament reconstruction. To overcome these drawbacks, a new plate fixator made of CF PEEK (carbon fiber reinforced polyetheretherketone) was developed (1st generation PEEKPower HTO-Plate, Arthrex, Fl, USA). This device allows for multidirectional angle stable fixation and is markedly stiffer, smaller, and lighter compared to the TomoFix™ plate. However, because of its relatively high failure rate [15], the 1st generation was taken off the market and a 2nd generation PEEKPower HTO-Plate® was developed. To date, no data about this implant are available in the literature.

The purpose of this study was to evaluate the effectiveness and safety of the 2nd generation PEEKPower HTO-Plate® for valgus-producing owHTO without bone grafting by prospectively analyzing the clinical, radiographic, and sports-related outcomes, as well as complication rate during a follow-up period of 24 months.

It is hypothesized that the 2nd generation PEEKPower HTO-Plate® can be safely used in the clinical practice.

Materials and methods

Between 2010 and 2011, 28 consecutive patients were treated with valgus-producing owHTO without bone grafting using the 2nd generation PEEKPower HTO-Plate® at the senior authors institution. Indications for surgery were varus malalignment combined with medial compartment osteoarthritis, medial compartment overload, or localized chondral defects of the medial femoral condyle requiring cartilage repair. Respective additional ligamentous instabilities only elected injuries (isolated MCL grade 2 lesions, isolated LCL grade 2–3 lesions, isolated PCL and PLC lesions, isolated ACL lesions) were included. Contraindications were severe articular damage of the medial compartment with attritional bone loss, ICRS grades III and IV cartilage lesions of the lateral compartment, absence or extensive loss of the lateral meniscus, complex high-grade ligamentous instabilities (MCL lesions grade 3 and multiligamentous injuries), progressed patellofemoral osteoarthritis (ICRS grade IV) and markedly decreased range of motion (range of motion < 120°, flexion contracture >5°) [58].

Preoperative planning of the osteotomy was performed digitally using appropriate computer software (mediCAD®, Hectec GmbH, Germany) [61]. Patients who required an osteotomy gap larger than 12 mm were excluded from this study because in these cases, additional bone grafting was the treatment of choice. The detailed patient characteristics are provided in Table 1.

In the clinical practice, the implant is commonly removed when it has lost its benefit through complete osseus consolidation of the osteotomy gap and if patients complain about hardware irritations. Out of the 28 patients, removal of the plate was performed in 18 patients (64 %) at a mean of 17 ± 5 months after the index procedure (Table 1).

Characteristics of the 1st and 2nd generation PEEKPower HTO-Plate®

Both plates are consisting of carbon fiber reinforced polyetheretherketone (CF PEEK), are radiolucent, and threadless. They are locked angular stable without predefined

Table 1 Patient characteristics

Number of knees	28
Number of patients	
Total	28
Male	19
Female	9
Mean age (ys) ± SD	45 ± 11
Mean body mass index (kg/m^2) ± SD	25 ± 3
Smokers (*n*)	4
Mean preoperative mechanical axis (° of varus deviation)	4 ± 2
Planned postoperative valgus position (*n*)	
55 %	14
62 %	14
Mean osteotomy gap height (mm) ± SD (range)	7 ± 2 (4-12)
Concomitant procedures during HTO (*n*)	
Medial meniscectomy	5
Microfracturing	1
OAT	6
ACL reconstruction	1
Implant removal (*n*)	18
Mean time between HTO and implant removal (ms) ± SD	17 ± 5

SD, standard deviation; ys, years; n, number of patients; VAS, visual analog scale; °, degree; mm, millimeter; HTO, high tibial osteotomy; OAT, osteochondral autologues transfer; ACL, anterior cruciate ligament; ms, months screw placement to the bone via screwing of self-cutting threads and locking heads of harder titanium screws into the peek-carbon composite plate. The feature of this multi-directional locking provides a cone angle of 20° which is especially advantageous when combining HTO with ACL or PCL reconstruction procedures, because tunnel placement is not limited. Furthermore, no risk for cross-threading exists. Despite of plate abrasion, it is safe to use these plates for HTO because histological evaluations of CF PEEK wear consider good biocompatibility and do not show acute or chronic inflammations or tissue necrosis [37, 57, 62, 67]. Compared to the 1st generation PEEK-Power HTO-Plate®, the 2nd generation plate provides an improved anatomical shape, an improved geometry of the screw holes and a reduced flexural strength. Furthermore, the newer generation also provides utilization of a lag screw to obtain compression on the lateral cortex.

Surgical technique and postoperative rehabilitation

The procedure was started with arthroscopy to define the cartilage status in the patellofemoral and medial and lateral femorotibial compartments. Then, a biplanar osteotomy consisting of an osteotomy in the axial plane and an osteotomy in the frontal plane was performed in all patients [20, 26, 27, 39]. First, the frontal plane osteotomy, starting in the anterior one-third of the proximal tibia was performed using an oscillating saw. According to the status of the patellofemoral joint as follows, the osteotomy exited the bone either distal or proximal the tuberosity. To avoid altering patellofemoral kinematics [18, 31], the frontal plane osteotomy was aimed distally, leaving the tuberosity on the proximal fragment [26, 41]. That was done in 7 patients which had large correction angles (≥10°), preoperative patellofemoral complaints and mid to severe patellofemoral osteoarthritis (ICRS grade III). Preoperative complaints included, from the medical history, pain behind the patella during sports or activities of daily living (e.g., walking and climbing stairs) or, from the physical examination, pain behind the patella on pressure or mediolateral translation under pressure [26]. In the remaining patients, the osteotomy was exited proximally, leaving the tuberosity distal. The posterior two-thirds of the proximal tibia were sawed in the axial plane from the upper margin of the gracilis tendon to the tip of the fibular head, just proximal to the tibiofibular joint. During sawing, cooling was performed and when the osteotomy was opened gradually, it was to be ensured to leave the lateral cortex intact [27].

According to the preoperative planning, the weight-bearing line was placed at 62 % of the transverse diameter of the tibial plateau in patients with medial compartment OA, and at 55 % in patients with medial compartment overload or focal cartilage defects. The position of the weight-bearing line was controlled with a straight alignment rod under fluoroscopy [34, 35]. Special effort was made not to change the tibial slope using methods described in detail elsewhere [24, 26, 51].

The osteotomy was fixed with the 2nd generation PEEK-Power HTO-Plate®. If the frontal osteotomy was exited distally, the tuberosity was additionally fixed with one or two bicortical screws.

The postoperative rehabilitation program consisted of 20 kg partial weight-bearing until 6 weeks after surgery. After 6 weeks, full weight-bearing was allowed after radiographic control. In patients with concomitant microfracture or autologous osteochondral transplantation, weight-bearing was not allowed for 6 weeks. Active and passive free range of motion was allowed at the first postoperative day and was adapted to pain. In patients with concomitant microfracture or autologous osteochondral transplantation, active free range of motion was not allowed for 6 weeks.

Clinical evaluation

All patients were evaluated preoperatively and at 12 and 24 months postoperatively by an independent observer (M.C.). For clinical evaluation, knee pain, osteoarthritic symptoms, and function of the affected leg were assessed prospectively using the visual analog scale (VAS) [23] for pain, the WOMAC score [7], and the Lysholm score [71]. For the WOMAC score, standardized answer options were given as five Likert boxes and each question received a score from 0 to 4. A normalized percentage score (100 indicating no problems and 0 indicating extreme problems) was calculated (available at http://www.koos.nu/KOOSGuide2003.pdf). During the whole study period, postoperative complications were recorded.

The sports-related outcome was evaluated using the Tegner activity scale [71] and a sports questionnaire based on the literature [59] preoperatively and 24 months postoperatively. The sports questionnaire was slightly modified and assessed patients engagement in 34 different sports and recreational activities. In an open-ended section, patients could name disciplines which were not listed. Preoperative sports engagement was defined as regularly participated sports in the year before surgery within the onset of restricting symptoms. It was asked for sports frequency (defined as 0–7 sessions per week) and sports duration (defined as hours per week).

Radiographic evaluation

Radiographic analysis was performed by the same independent observer (M.C.) using the Picture Archiving and Communication System (PACS, Philips Medical Systems, Sectra Imtec AB, Sweden). True anterior–posterior

(AP) and lateral radiographs were obtained two days after owHTO (baseline measurements) and two days after implant removal (follow-up measurements). If the implant was not removed during the study period ($n = 10$), the last available follow-up radiographs were used (mean time between HTO and last follow-up radiograph: 12 ± 7 months).

Loss of correction in the frontal plane was assessed by comparing the medial proximal tibial angle (MPTA) on baseline and follow-up radiographs. According to the literature, the MPTA was defined as the angle between the proximal anatomical axis of the tibia and a tangent along the articular surface of the tibial plateau (Fig. 1a) [73]. Loss of correction in the sagittal plane was assessed by comparing the tibial slope (Fig. 1b) on baseline and follow-up lateral radiographs using the method described by Brazier et al. [10]. Both measurement methods are showing high accuracy in the literature [26, 56] and therefore are commonly used for studies about high tibial osteotomy [14, 17, 44].

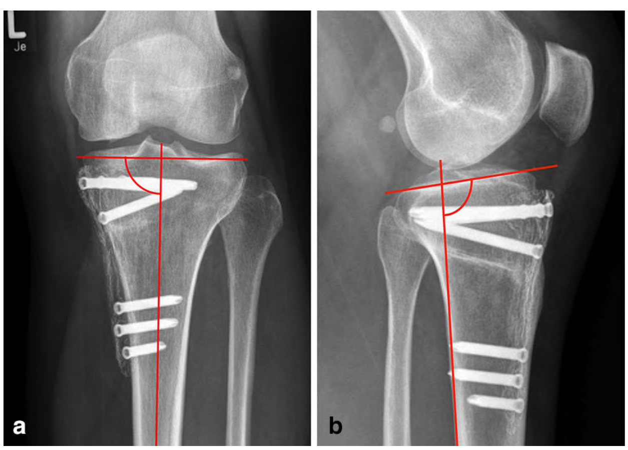

Fig. 1 Radiographic analysis. The medial proximal tibial angle was measured on anteroposterior radiographs (**a**) and the tibial slope was measured on lateral radiographs (**b**)

This study was approved by the Ethics Committee of the Faculty of Medicine of the Technische Universitaet Muenchen (Project-No.: 370/13). All enrolled patients provided informed consent to participate in this study.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows version 21.0 (IBM Inc., NY, USA). To compare the clinical scores between each follow-up examination, the nonparametric Friedman test for related samples was used. If the test showed significant differences over time, the nonparametric Wilcoxon test for two related samples was used to compare the values between two different time points. All statistical tests were performed two sided. Statistical significance was considered at $p < 0.05$. An a priori power analysis was calculated with a difference to detect 30 points and a standard deviation of 25 points in the Lysholm score. It established a sample size of 12 patients for a power of 80 %.

Results

Out of the 28 patients, one patient underwent revision surgery because of a non-union. To assure a homogeneous follow-up group, this case had to be excluded from the statistical analysis for the clinical and radiographic results. Therefore, 27 patients were available for the 12- (mean 12 ± 1) and 24- (mean 24 ± 2) month follow-up evaluation.

Clinical results

The detailed results of the clinical scores (VAS, WOMAC, and Lysholm) are shown in Table 2. Compared to preoperatively, statistically significant improvements ($p < 0.05$) of all three scores were observed at 12 and 24 months postoperatively. No significant differences were found between the 12- and 24-month follow-up.

Table 2 Clinical results

	Follow-up	Values	Significance compared to preoperatively
VAS ($n = 27$)	Preoperative	4 (3–7)	
	12 ms	2 (1–3)*	$p = 0.000$
	24 ms	1 (1–2)*#	$p = 0.000$
WOMAC ($n = 27$)	Preoperative	72 (58–85)	
	12 ms	96 (90–100)*	$p = 0.000$
	24 ms	98 (91–100)*#	$p = 0.000$
Lysholm ($n = 27$)	Preoperative	51 (40–62)	
	12 ms	82 (72–95)*	$p = 0.000$
	24 ms	83 (73–94)*#	$p = 0.000$

All values are given as median and interquartile range (25th–75th percentile)

VAS visual analog scale, *ms* months

* Statistically significant improvement compared to preoperatively

No statistically significant difference compared to 12-month follow-up ($p > 0.05$)

Sports-related results

Three patients (11 %) did not participate in any sports before surgery, whereas only one patient (4 %) did not participate in sports at 24 months postoperatively. Compared to preoperatively, a significant increase was found for sports frequency at the 24-month follow-up ($p = 0.021$). No significant change was observed for the Tegner scale, number of sports disciplines, and sports duration (Table 3). Figure 2 shows all sports disciplines in which patients participated in the year before and 24 months after surgery. Most patients participated in low- to moderate impact activities preoperatively as well as 24 months after surgery.

Radiographic results

The last radiographs of the 27 patients were available at a mean of 15 ± 6 months postoperatively. The median difference and interquartile range (25th–75th percentile) between baseline and follow-up measurements was 0.0 (−0.4–0.1)°

Table 3 Sports-related results

	Follow-up	Values	Significance compared to preoperatively
Tegner score ($n = 27$)	Preoperative	5 (3–6)	
	24 ms	4 (3–5)#	n.s.
Sports frequency (sessions per week) ($n = 27$)	Preoperative	2 (1–3)	
	24 ms	3 (1–4)*	$p = 0.021$
Sports duration (hours per week) ($n = 27$)	Preoperative	3 (1–6)	
	24 ms	4 (2–6)#	n.s.
Sports disciplines per week ($n = 27$)	Preoperative	3 (1–7)	
	24 ms	4 (2–7)#	n.s.

All values are given as median and interquartile range (25th–75th percentile)

ms months

* Statistically significant difference compared to preoperatively

No statistically significant difference compared to preoperatively

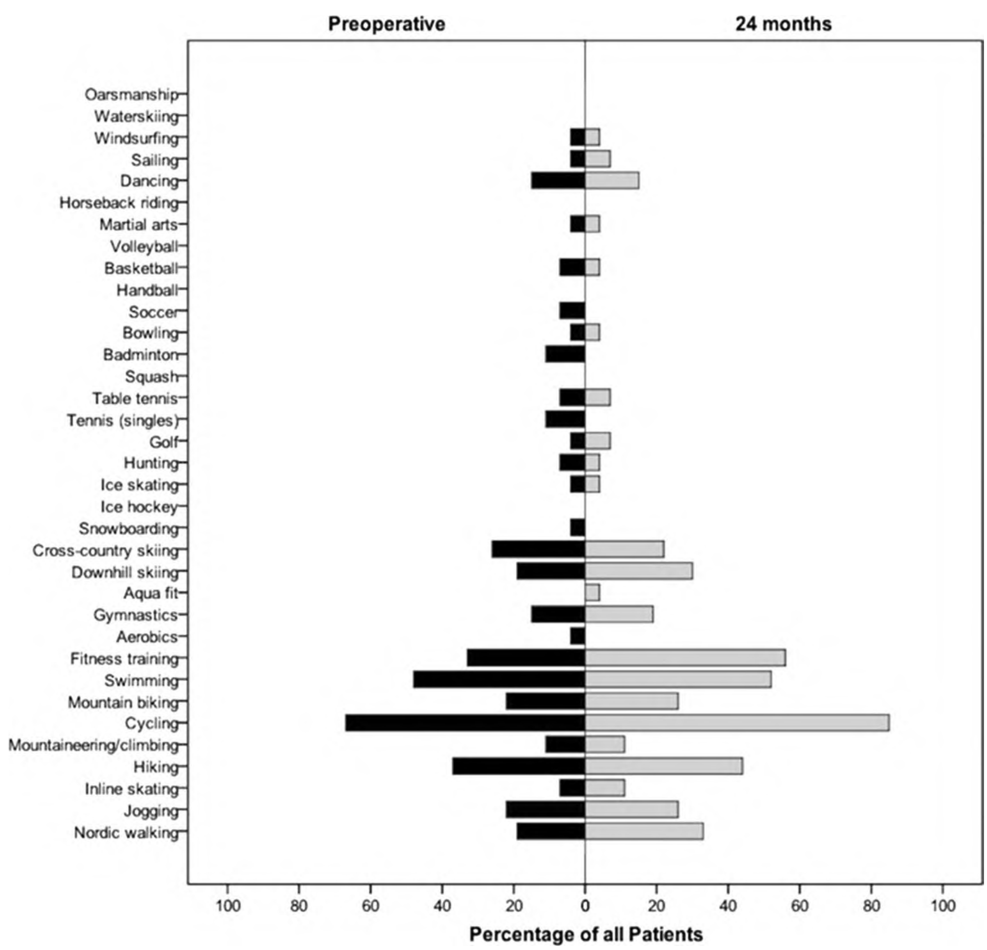

Fig. 2 Sports disciplines in which patients participated in the year before (*left*) and 24 month after the operation (*right*)

for MPTA, and 0.0 (0.0–0.1)° for tibial slope. No significant differences between baseline and follow-up measurements were observed for both values (see Table 4).

Complications

Out of the initial study group of 28 patients, one non-union of the osteotomy gap occurred in a 42-year-old male non-smoker with a body mass index of 23.4 kg/m^2. Failure analysis revealed a fracture of the lateral cortex with a lateral gap of 1.4 mm. At 9 months after the index procedure, the patient was successfully revised and treated by grafting of the osteotomy gap with autologous cancelous bone from the iliac crest. No further complications were observed during the study period. The overall complication rate was therefore 4 %.

Table 4 Radiographic results

	Values ($n = 27$)	Significance
MPTA (°) baseline	91.3 (90.5–93.1)	
MPTA (°) follow-up	91.3 (90.6–93.0)$^{\#}$	
Difference between MPTA (°) baseline and follow-up	0.0 (–0.4–0.1)	n.s.
TS (°) baseline	95.4 (92.7–98.5)	
TS (°) follow-up	95.5 (92.7–98.6)$^{\#}$	
Difference between TS (°) baseline and follow-up	0.0 (0.0–0.1)	n.s.

All values are given as median and interquartile range (25th-75th percentile)

MPTA, medial proximal tibial angle; TS, tibial slope; °, degree; n, number of patients; ns, not significant

$^{\#}$ No statistically significant difference (n.s.) compared to baseline measurements

Discussion

The most important finding of the present study was that valgus-producing owHTO without bone grafting of the osteotomy gap using the new 2nd generation PEEKPower HTO-Plate® showed significantly improved knee function and pain decrease as early as 12 months after surgery. After 24 months, this procedure allowed active patients to do sports with a higher frequency (compared to preoperatively). No significant loss of correction between baseline and follow-up radiographs was observed. With an overall complication rate of 4 %, this new implant can be considered as a safe fixation device for owHTO.

Several fixation devices for valgus-producing owHTO are currently available, including an inlay system (iBalance medial opening wedge HTO system, Arthrex, Naples, Fl, USA) which is even smaller than a short spacer plate [21]. However, it was concluded that an inlay system have no impact on clinical scoring compared to a short spacer plate 6 and 12 months after surgery [21]. One of the most popular short spacer plates is the Puddu plate (Arthrex, Naples, Fl, USA) which has a low profile design and which might avoid the need for implant removal [4, 43]. Using this plate, the functional Lysholm score and WOMAC scores reach mean values up to 90 and 75, 24 months after surgery, respectively [16, 43, 52, 55]. However, this plate without a bone graft shows implant failures from 6 to 16 %, osteotomies with broken screws in up to 21 % and a pseudarthrosis rate of up to 22 % [48, 63]. Secure fixation, low failures, and little non-unions of the osteotomy gap fixed with a short spacer locking Puddu plate were only found with the use of a bone graft [6, 16, 43]. Another short spacer, the Position HTO plate (Aesculap, Tuttlingen, Germany) also showed a high complication rate without a bone graft: Screw failures with non-union occurred in about 6 % and the loss of correction rate were about 3 % [32, 60]. Finally, it is proposed that short spacer plates should only be used for small osteotomy gaps (up to 8 mm) as well as with a bone graft regardless of the correction to prevent hardware-related complications [5, 43]. The reason is, that especially in cases of larger corrections, short spacer plates offer limited stability since they can not adequately eliminate the tremendous lever arm forces acting on the osteotomy gap [39, 48, 63].

One of the most common used plate fixators for owHTO is the TomoFix™ plate (Synthes Medical, Oberdorf, Switzerland) [40, 65]. Because of its high initial fixation stability, the risk of implant failure and correction loss is low, even with early weight-bearing [12] and without bone grafting of the osteotomy gap [2, 13, 30, 53, 66]. In general, owHTO with the TomoFix™ plate has shown to be a safe procedure with promising short- to midterm results [8, 19, 36, 42] However, with the increasing use of this implant, several drawbacks were observed. One disadvantage is the relative bulky design, which causes soft tissue irritation in most patients, leading to a protracted clinical course [49, 50]. A further disadvantage is the predefined and non-variable direction of the locking screws, which is dictated by threads inside the screw holes. Therefore, freedom in tunnel placement during concomitant ligament reconstruction is limited and screw insertion in a slightly different direction will lead to cross-threading with compromised fixation stability.

To overcome these drawbacks, the 1st generation PEEKPower HTO-Plate® was developed which is considerably smaller and lighter compared to the TomoFix™ plate. In a first series of 26 owHTOs using this implant, significant intraoperative handling benefits compared to the TomoFix™ plate were observed; however, early screw loosening and non-unions were observed in one (4 %) and three

(12 %) patients, respectively [15]. Implant-related factors were thought to be a (too) high flexural strength, too shallow plate holes and the lag of a temporary lag screw. For these reasons, a 2nd generation of the implant has been developed.

This study provides the first outcome data using the 2nd generation PEEKPower HTO-Plate®. At 24 months after surgery, VAS, WOMAC, and Lysholm scores had significantly improved to values comparable to those reported after owHTO using the TomoFix™ plate [18, 49, 50]. It is therefore concluded that both the TomoFix™ plate and the 2nd generation PEEKPower HTO-Plate® are viable implants for osteotomy fixation in valgus-producing owHTO in terms of clinical results at 24 months after surgery.

With regard to the time-dependent course of the clinical scores, no significant differences between the 12- and 24-month follow-up were found, despite of implant removal in 64 % of patients after a mean of 17 months. In other words, removal of the 2nd generation PEEKPower HTO-Plate® did not result in further clinical improvements and the clinical end-point of the patients was reached as early as 12 months postoperatively. In contrast, Niemeyer et al. [49, 50] found significant improvements of the clinical scores between 12 and 24 months after owHTO using the TomoFix™ plate. The authors attributed this finding to implant removal after 12 months. In their series, a high percentage of patients complained of local discomfort and pain associated with the implant, which disappeared after implant removal. Despite the patients of this study also might have had hardware irritations, this (64 % implant removal) had no impact on the clinical course. In the clinical experience with both implants, it feels that the smaller size and the lighter weight of the 2nd generation PEEKPower HTO-Plate® causes less local irritation and therefore provides an accelerated clinical course.

OwHTO is also used in young and active patients [3, 38] and the participation in sporting activities increased after this procedure [9, 22, 49, 59, 74]. In this study, 96 % of patients were engaged in sporting activities after 24 months, compared with 85 % before surgery (n.s.). Only the sports frequency (sessions per week) changed significantly ($p < 0.05$) from preoperative to postoperative (see Table 3). Regarding the ability for sporting activity after valgus-producing owHTO with the TomoFix™ plate, Salzmann et al. [59] found that 91 % of patients were engaged in sports and recreational activities postoperatively, compared with 88 % before surgery (n.s.). These results indicate that valgus-producing owHTO does not improve sporting activity 24 months after surgery compared to preoperatively.

No significant differences between baseline and follow-up measurements for MPTA and tibial slope were observed, indicating that loss of correction did not occur. However, only patients with an osteotomy gap of ≤12 mm were included in this study. Loss of correction after owHTO using the TomoFix™ plate was reported in 0–6 % of patients [13, 32, 65, 70] with mean osteotomy gap sizes of 13 mm. It is therefore concluded that the 2nd generation PEEKPower HTO-Plate® provides a safe fixation stability without bone grafting if the osteotomy gap height is ≤12 mm. The performance of this plate in larger osteotomy gaps has to be evaluated in further studies.

In the present study, the osteotomy exited the bone either distal or proximal the tuberosity, which has to be explained in more detail. El Azab et al. [17] showed that the incidence of patella infera increases after owHTO and therefore recommended to perform owHTO with the tuberosity left at the proximal tibia in cases of patellofemoral complaints. Hinterwimmer et al. [26] specified these complaints in patients with mid to severe patellofemoral arthritis as pain behind the patella during activities or under clinical examination. Moreover, it was shown that there was a significant increase in patellofemoral pressures after medial opening wedge proximal tibial osteotomies of only 10 mm (larger osteotomies resulted in a greater increases) [31]. To avoid these postoperative drawbacks (patella infera, high patellofemoral pressures) in these cases (preoperative patellofemoral arthritis and pain, great correction angles ≥10°), the frontal plane osteotomy was aimed distally, leaving the tuberosity on the proximal fragment. That this procedure is effective in these cases was already shown in the literature [26, 41].

With regard to complications, one non-union (4 %) occurred in a patient with a fracture of the lateral hinge. No further complications were observed. In a previous series with the more rigid 1st generation PEEKPower HTO-Plate®, a higher non-union rate was observed (12 %, 3 out of 26 patients) [15]. Reported implant-related complications after owHTO with the TomoFix™ plate vary between 2 and 6 %. [8, 13, 18, 19, 28, 32, 36, 45, 49, 50, 65, 69, 70, 72]. No complication such as screw loosening, screw breakage, or plate breakage was observed in our series. It is therefore concluded that the 2nd generation PEEKPower HTO-Plate® is a safe plate fixator for owHTO with an osteotomy gap height of ≤12 mm.

This study has some limitations which have to be considered when interpreting our results. No control group was evaluated and therefore this study does not provide the highest level of evidence. Nevertheless, the data were compared to the current results of the literature and to a previous study regarding the 1st generation PEEKPower HTO-Plate®.

Concerning our method to determine the amount of correction loss, serial long-leg weight-bearing AP radiographs or radiostereometric analysis might have been more precise, also for tibial slope measurements. Unfortunately, these methods were not allowed by the ethics committee due to the associated radiation exposure. However, by evaluating correction loss in two standard planes (frontal and sagittal) according to the literature, the accuracy of the radiological analysis increased.

Due to the lack of the postoperative serial long-leg weight-bearing AP radiographs, this study did not control if patients reached alignments exactly at 55 or 62 % postoperatively. However, the described valgus alignments were calculated preoperatively via the digitally computer software mediCAD®, Hectec GmbH, Germany which is validated in the clinical practice [61]. It gives appropriate intraoperative landmarks to reach the preoperative planned alignment postoperatively. This was done via a straight alignment rod, which was also validated in the literature [34, 35]. Moreover, the software also calculates the individual osteotomy gap height for each patient as an additional control for the surgeon. Therefore, the accuracy of owHTO surgery increased by these procedures.

Conclusion

In clinical practice, the 2nd generation PEEKPower HTO-Plate® is a safe and efficient implant for valgus-producing medial open-wedge high tibial osteotomy without bone grafting in osteotomy gaps ≤12 mm. 24 months after surgery with this implant, active patients do sports with a higher frequency (compared to preoperatively). The clinical end-point of the patients was reached as early as 12 months postoperatively. The performance of this implant in osteotomy gaps of >12 mm remains unknown.

Conflict of interest A. B. Imhoff and Stefan Hinterwimmer are consultants for Arthrex. The company had no influence on study design, data collection, and interpretation of the results or the final manuscript.

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