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The influence of a new plate fixator on valgus producing open wedge high tibial osteotomy and its outcome in sporting activity

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1 Introduction

1.1 Medial compartment osteoarthritis and varus malalignment of the knee

Medial compartment osteoarthritis indicate painful overload and attrition of the articular cartilage of the medial knee joint.[30, 59] Thereby the whole medial joint space is contracted (Figure 1B) and its grade of osteoarthrosis can be classified by Kellgren and Lawrence in the radiographic diagnosis.[40] Medial compartment osteoarthritis often occurs with varus malalignment in which a mechanical axis deviation [62] of the knee is recorded and is described in Figure 1.

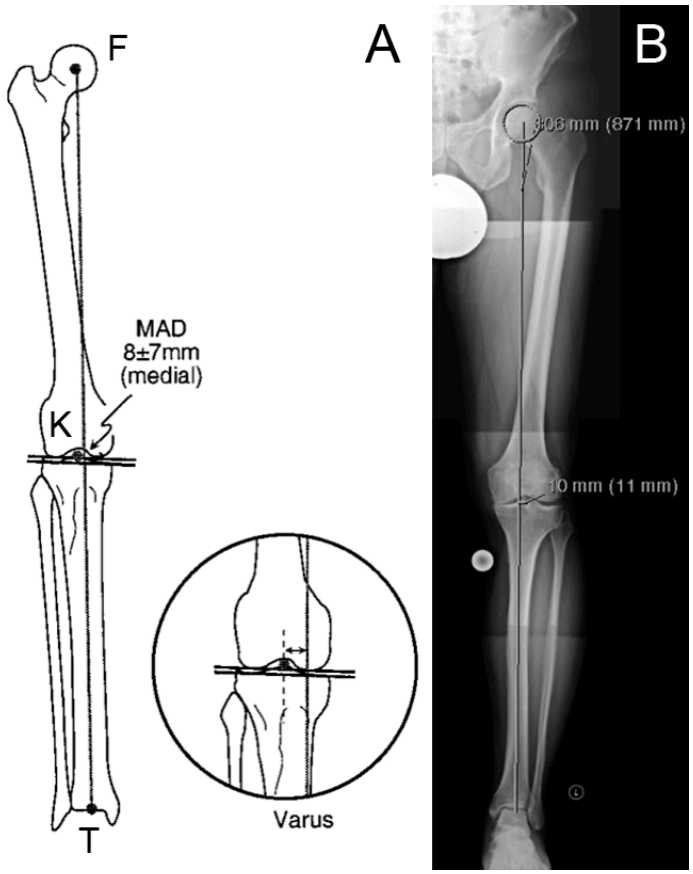

Figure 1: The mechanical axis of a right leg in the frontal plane (A)[60] connects the center of the femoral head (F) with the center of the talus (T). At physiological condtions, the medial deviation of the mechanical axis from the center of the knee (K) is up to 8±7 mm on the tibial tangent.[60] On the right side of this figure, long-leg weight bearing anteroposterior (AP) radiograph demonstrating painful overload in a left knee with medial compartment osteoarthritis and varus malalignment (B). The medial deviation of the mechanical axis from the center of the knee in this patient is 10 mm.

1.1.1 Sports related causes for medial compartment osteoarthritis and varus malalignment of the knee

In the athlete or the active patient, repetitive microtraumata of the knee are associated with the regular participation of high performance training and competition over years.[87] Sports that requires repetitive running, cutting and jumping like soccer, handball, volleyball, basketball and others can place significant loads across weight bearing joints. These stresses can exert microtraumata on the ligaments, the menisci and the articular cartilage which lead to further joint degeneration with secondary malalignment of the knee.[3, 36, 39, 55, 85]

Like the repetitive microtraumata, acute traumata are also responsible for medial knee joint degeneration and varus malalignment.[85] Traumatic ligamentous ruptures, meniscal tears or osteochondral lesions can lead to punctual osteochondral attrition and focal degeneration. If such an injury remains untreated, it leads to secondary malalignment with further additional degeneration. [3, 36, 39, 55]

Moreover, if such microtraumata and acute injuries occur together with congenital varus malalignemt, it exacerbates over time.[85]

Conservative treatment modalities for osteoarthritis in young and active patients are including anti-inflammatory pharmaceuticals, modification of the activity of daily living, custom orthotics and the use of hyaluronic acid or steroid injections.[10, 85] Within physical therapy and medical training therapy, proprioceptive training of the weight bearing line as well as the strengthening of the musculus quatriceps femoris via biofeedback are often used.[22] Shoe insoles rarely relieve the pain in the knee joint.[64]

However, young and active patients with heavy pain and failed conservative treatment as well as athletes with a threatened career often ask for surgical options.

1.2 Valgus-producing open wedge high tibial osteotomy (ow HTO)

Valgus-producing high tibial osteotomy (HTO) is an established intervention for young and active patients with painful medial compartment osteoarthritis and varus malalignment of the knee.[2, 34, 52, 73, 85] The principle of this procedure is to unload the diseased medial compartment by shifting the mechanical axis of the lower limb more laterally (Figure 2).[2, 5, 34, 52, 73]

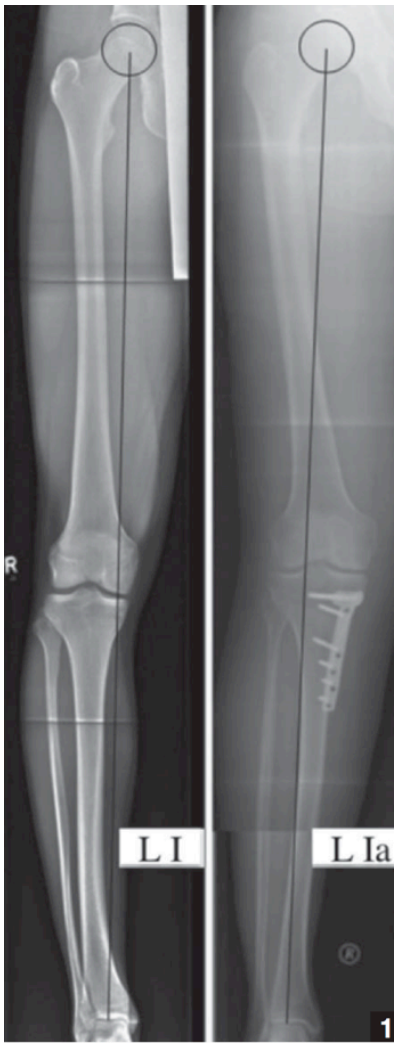

Figure 2 [23] Long-leg weight bearing AP radiographs preoperatively (left) and 6 months postoperatively (right) demonstrating the principle of ow HTO. Line I represents the preoperative mechanical axis. Line Ia represents the new mechanical axis which was shifted from medial to lateral.

How much the new mechanical axis must be shifted to lateral, depends on the concomitant pathology of the knee joint and is described in the literature.[32]

Unloading of the medial compartment not only reduces pain and improves knee function, but it is also a preventive intervention which delays the progression of medial degeneration and the need for unicompartimental or total knee arthroplasty. [13 2, 34, 52, 73]

Although different osteotomy techniques exist, the medial open wedge HTO (ow HTO) has replaced the lateral closed wedge HTO over the course of the last ten years. This is due to the fact that the lateral closed wedge technique is associated with a number of complications, including changes in tibial inclination, increase of tibial offset, patella baja, non-union, peroneal nerve palsy, loss of correction and bone stock. [38, 53, 86] Moreover, valgus-producing ow HTO for varus malalignment is indicated in a tibia with a decreased medial proximal angle (MPTA).[50, 60]

Valgus-producing ow HTO reduces the need for muscular detachment and risk of neurovascular complications, and precise intraoperative axial corrections can be made. [45]

The major concern in ow HTO is a completely secure fixation device (screw-plate construct) for stabilization of the proximal tibia while, at the same time, leaving the osteotomy gap open.

1.2.1 Fixation devices for valgus-producing ow HTO

Different fixation devices like short spacer plates with or without locking screws (e.g. Puddu plate, Arthrex, Naples, Fl, USA; Position HTO plate, Aesculap, Tuttlingen, Germany)[9, 69] and plate fixators without a spacer (e.g. TomoFix™ plate, Synthes Medical, Oberdorf, Switzerland)[46, 75] are existing. In biomechanical and clinical studies, the TomoFix™ plate, has shown to provide higher fixation stability compared to short spacer plates, even without bone grafting of the osteotomy gap. [4, 61, 77] Therefore, to achieve secure fixation at early weight bearing and low failure rates in great opening-wedges without a bone filler, angle stable plate fixators are favoured over short spacer plates. [17, 37, 69]

1.2.1.1 The “standard” plate fixator TomoFix™ plate

One of the most common used and described fixation devices for ow HTO with good short- to midterm results is the TomoFix™ plate (Synthes Medical, Oberdorf, Switzerland, Figure 3) [18, 23, 24, 42, 47, 51, 56, 57, 75, 78]. This T-shaped titanium plate is based on the Locking Compression Plate system (LCP) [26, 75, 76] and is currently used in the Department of Orthopaedic Sports Medicine, Technical University of Munich, Germany. It is a fixed-angle plate concept with non-variable and predefined directions of screw placement given by the thread or cone inside the screw hole of the plate. The TomoFix™ plate has a high initial fixation stability, therefore early weight bearing is allowed without the risk for screw- or plate- dislocation. [4, 16, 47, 61] Ow HTO without a bone graft is safe when the TomoFix™ plate is used.[24, 35]

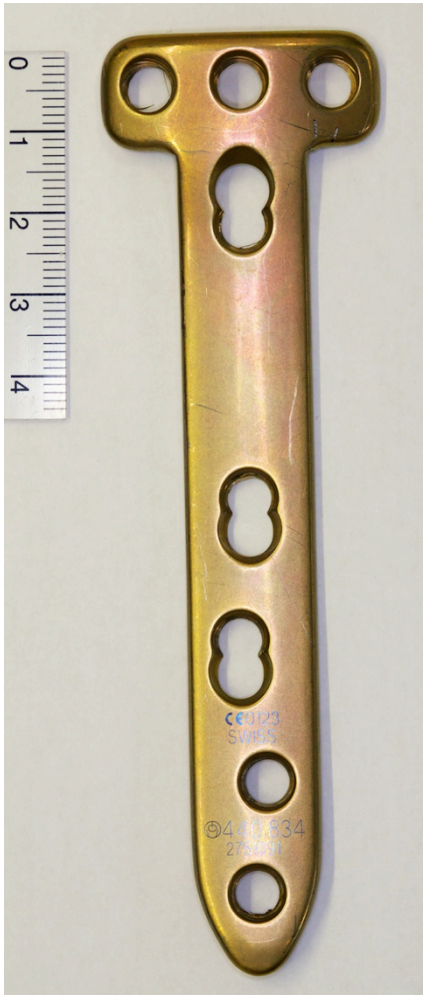

Figure 3: The TomoFix™ plate (Synthes Medical, Oberdorf, Switzerland).

Disadvantages of the TomoFix™ plate

One disadvantage is the fixed-angle plate concept with its non-variable and predefined directions of screw placement given by the thread or cone inside the screw hole of the plate. Thus, combined procedures like Crucriate Ligament reconstructions are associated with intraoperative limitations because the screws of the plate can not always be placed to allow a reconstruction tunnel.

Another record with the internal fixed-angle system is, that even with the optimal screw-in drill guide when these are removed from the plate there is a likelyhood to loose the drill holes directions. And at the time, when the identical axis of the plate hole and screw is not achieved, cross threading may accrue and secure fixation is compromised.

It is well-known that patients complain about hardware irritations until removal of the implant which was demonstrated in recent reports [56, 57]. The authors concluded, that direct local irritation of the hamstring tendons caused by the relative bulky implant are responsible for a protracted clinical course showing no significant improvement in function in the first 12 months after HTO, but instead from 12 to 24 months, starting after removal of the implant.

An alternative to the TomoFix™ plate is the PEEKPower HTO-Plate®.

1.2.1.2 The 1st generation PEEKPower HTO-Plate®

In 2008 a new plate fixator (1st generation PEEKPower HTO-Plate®, Arthrex, München, Germany) was released for CE by Notified Body. The plate consists of a carbon fiber reinforced polyetheretherketone (CF PEEK) or in short, a peek-carbon composition, which is considerably smaller and lighter compared to the TomoFix™ plate. It is a threadless plate which is locked angular stable without predefined screw placement to the bone. That works via screwing of self-cutting threads and locking heads of harder titanium screws into the peek-carbon composite plate. The multidirectional locking system provides a cone angle of 20°, which allows more variable screw placement. Therefore, this feature is especially advantageous when combining HTO with ligament reconstruction procedures, because tunnel placement is not limited. Furthermore no risk for cross threading exists and the material is radiolucent. (Figure 4)

Figure 4: The 1st generation PEEKPower HTO-Plate® (Arthrex, München, Germany)

1.2.1.3 The new 2nd generation PEEKPower HTO-Plate®

Like the 1st generation of the PEEKPower HTO-Plate®, the 2nd generation is markedly smaller and lighter compared to the TomoFix™ plate. Compared to the 1st generation PEEKPower HTO-Plate®, the most proximal part is reinforced and the geometry of the screw holes is improved. Moreover the 2nd generation PEEKPower HTO-Plate® provides a reduced flexural strength. The newer generation also provides the utilization of a temporary lag screw to obtain compression on the lateral cortex. (see Figure 5)

Figure 5: The 2nd generation PEEKPower HTO-Plate® (Arthrex, München, Germany)

1.3 Research Questions and Purposes

Part A:

Based on the only existing clinical data about the 1st generation PEEKPower HTO-Plate® (Cotic et. al., see Appendix) [19], there are currently no clinical reports regarding its safety and effectiveness compared to the commonly used and analog plate fixator TomoFix™ plate. Above all, there is less knowledge if a 1st generation PEEKPower HTO-Plate®, which is indeed lighter and smaller than an equal used TomoFix™ plate, also cause fewer subjective hardware irritations in the plate bed. Moreover, the advantage of its radiolucency have never been prooved yet.

Therefore, the first purpose of this study was **to compare the clinical and radiographic outcome of the TomoFix™ plate and the 1st generation PEEKPower HTO-Plate® in a matched-pair analysis** of patients undergoing valgus-producing ow HTO. The second purpose was **to objectively evaluate the consolidation of the osteotomy gap**, which is fixed by the 1st generation PEEKPower HTO-Plate®.

Part B:

Currently, it is not described why the 2nd generation PEEKPower HTO-Plate® has been introduced. The effectiveness and safety of this modified implant has not been investigated yet. Above all, sporting activity after valgus-producing ow HTO using the PEEKPower HTO-Plate® has never been studied before. However, since ow HTO became more popular in young and active patients [6, 44], the functional pretension, including sporting activities, has increased after this procedure [14, 28, 56, 68, 85].

Therefore the third purpose of this study was **to prospectively evaluate the clinical, radiographic and sports-related results at 24 months** after valgus-producing ow HTO without bone grafting **using the 2nd generation PEEKPower HTO-Plate®.**

Part A: A matched-pair comparison between a standardized titanium plate (TomoFix™ plate) and a new peek-carbon composite plate (1st generation PEEKPower HTO-Plate®).[20]

2 Materials and Methods of part A

2.1 Patient selection and study design

This study was approved by the Ethics Committee of the Faculty of Medicine of the Munich University of Technology (Project-No.: 5392/12, the ethics approval is attached to the Appendix). All enrolled patients provided informed consent to participate in this study (the patient informed consent is a part of the questionnaire which is attached to the Appendix). Between May 2008 and December 2011, 186 consecutive patients were treated with valgus-producing ow HTO at the Department of Orthopaedic Sports Medicine, Technical University of Munich, Germany.

The 1st generation PEEKPower HTO-Plate® was used in 26 consecutive patients, which were part of a prospective single group study. The TomoFix™ plate was used in the remaining 160 patients taken from the prospectively guided and institutional SAP- (System Analysis and Program Development, © SAP AG, 1993-2013) database. A matched-pair analysis was conducted in April 2012 via the SAS macro "match" software[12] (available at: http://mayoresearch.mayo.edu/mayo/re-search/biostat/sasmacros.cfm). Matching criteria were: gender, age (20-29, 30-39, 40-49, 50-59 years), body mass index (±5 kg/m²), preoperative knee pain (Visual Analog Scale ±2)[29], preoperative medial compartment osteoarthritis (Kellgren Score ±0)[40], preoperative mechanical axis (femorotibial varus angle, ±2°)[60] and the new valgus position of the transverse diameter of the tibial plateau (62 vs 55% coordinate). [41, 32] If the intraoperative noted valgus position was not listed in the surgery record, the preoperative planned valgus position was taken. A patient summary is listed in the Appendix and includes the anonymized patient numbers and matching values.

The 26 patients (26 knees) treated with the PEEKPower HTO-Plate® were assigned to group I. Of the 160 patients treated with the TomoFix™ plate, 26 patients (26 knees) were matched to the patients of group I and subsequently assigned to group II. The detailed patient characteristics of both groups are provided in Table 2.

2.1.1 Inclusion and Exclusion Criteria

The detailed In- and Exclusion Criteria are listed in Table 1.

Table 1: Inclusion and Exclusion Criteria. Abbreviations: °, degree.

Inclusion Criteria	Exclusion Criteria
painful varus malalignment combined with medial compartment osteoarthritis	severe articular damage of the medial compartment with attritional bone loss
medial compartment overload	ICRS grade III and IV cartilage lesions of the lateral compartment
localized chondral defects of the medial femoral condyle requiring cartilage repair	absence or extensive loss of the lateral meniscus
	complex high-grade ligamentous instabilities
	progressed patellofemoral arthrosis (ICRS grade IV) and markedly decreased range of motion (arc of motion <120°, flexion contracture >5°). [67]
	extreme corrections (valgus position >65% of the transverse diameter of the tibial plateau)

2.1.2 Baseline Demographics

The baseline characteristics, concomitant procedures as well as the matching criteria are listed in Table 2. None of these variables showed a statistically significant difference between both groups ($p > 0.05$).

Table 2: Baseline demographics of part A. Abbreviations: ys, years; n, number of patients; VAS, visual analogue scale; °, degree; mm, millimeter; HTO, high tibial osteotomy; OAT, osteochondral autologues transfer; MACI, matrix associated autologues chondrocyte implantation; ACL, anterior cruciate ligament; ms, months; IQR, Interquartilrange (25th-75th percentile); SD, standard deviation.

		Group I	Group II
number of patients			
total		26	26
male		20	20
female		6	6
Age (ys)	**Mean±SD**	41±11	41±10
	Median, IQR	44, 31-49	43, 35-49
Body mass index (kg/ m^2)	**Mean±SD**	27±4	28±3
	Median, IQR	27, 25-30	28, 25-30
Smokers (n)		5	5
Preoperative knee pain (VAS)	**Mean±SD**	6±3	6±2
	Median, IQR	6, 4-8	6, 4-7
Preoperative Kellgren Score	**Mean±SD**	3±1	3±1
	Median, IQR	3, 2-3	3, 2-3
Preoperative femoro-tibial angle (° of varus deviation)	**Mean±SD**	5±3	5±2
	Median, IQR	4, 4-7	4, 4-7
Noted valgus position (n)			
55%		8	10
62%		18	16
Osteotomy gap height (mm)	**Mean±SD**	9±4	9±3
	Median, IQR	9, 7-12	10, 7-11
Bone grafting of the osteotomy gap (n)		2	2
concomitant procedures during HTO (n)			
medial meniscectomy		6	6
microfracturing		2	1
OAT		3	3
MACI		1	2
ACL reconstruction		5	5
Implant removal (n)		22	22
Time between HTO and implant removal (ms)	**Mean±SD**	17±5	17±6
	Median, IQR	16, 14-22	16,13-22

2.2 Surgical technique of ow HTO for part A and part B

Preoperatively, the osteotomy was planned digitally using appropriate computer software (mediCAD®, Hectec GmbH, Germany). [70] All operations were performed or directly supervised by Univ.- Prof. Dr. med. Andreas B. Imhoff.

A biplanar osteotomy, consisting of an osteotomy in the axial plane and an osteotomy in the frontal plane was performed in all patients. [25, 31, 45] First, the frontal plane osteotomy, starting in the anterior one-third of the proximal tibia underneath the tibial tuberosity was performed using an oscillating saw. According to the status of the patellofemoral joint, the frontal osteotomy exited the bone either distal or proximal the tuberosity. To avoid decrease in patellar height in patients with preoperative patellofemoral pain[25, 31], the osteotomy in part A of this dissertation was exited distally in 7 patients of both groups, leaving the tibial tuberosity attached to the proximal fragment. The axial osteotomy was aimed from the upper margin of the gracilis tendon to the tip of the fibular head, just proximal to the tibiofibular joint (see Figure 6). The lateral 10 mm of the tibial head was left intact as a hinge for the osteotomy.

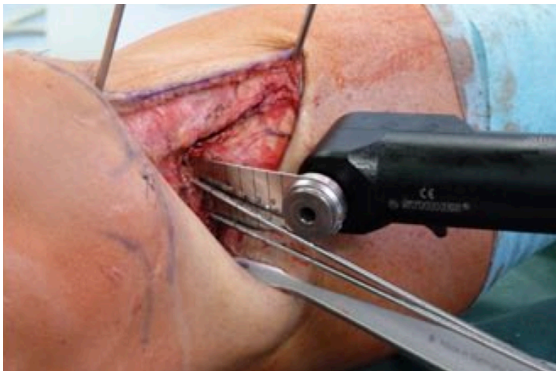

Figure 6: Osteotomy in the axial plane.[32] The saw cut was marked with two K-wires under fluoroscopic control. The K-wires were directed from the upper margin of the gracilis tendon to the tip of the fibular head, just proximal to the tibiofibular joint. The posterior two thirds of the proximal tibia was osteotomized distal to the K-wires with an oscillating saw.

Thereafter, the axial osteotomy was opened gradually by stepwise insertion of chisels. The chisels were replaced by an osteotomy spreader, which opened the axial osteotomy until the preoperatively planned gap size was reached (see Figure 7). The gap size was measured intraoperatively via a graduated milimeter disc.

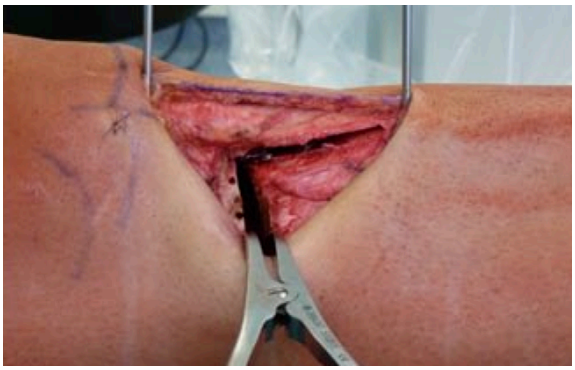

Figure 7: The axial osteotomy was opened with an osteotomy spreader which was inserted as posteromedial as possible.[32]

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 osteoarthritis, and at 55% in patients with medial compartment overload or focal cartilage defects.[32] The position of the weight bearing axis was controlled intraoperatively with a straight alignment rod under fluoroscopy.[41] The matching in part A of this dissertation produced two groups with equal valgus positions (Gr. I: median 62, interquartilrange 55-62, mean 60, standard deviation 3, range 55-62%; Gr. II: median 62, interquartilrange 58-63, mean 60, standard deviation 4, range 50-65%; no significant difference between both groups ($p = 0.24$)). Overall, the osteotomy was fixed with either the 1st generation PEEKPower HTO-Plate®, the 2nd generation PEEKPower HTO-Plate® (see Figure 8), or a TomoFix™ plate.

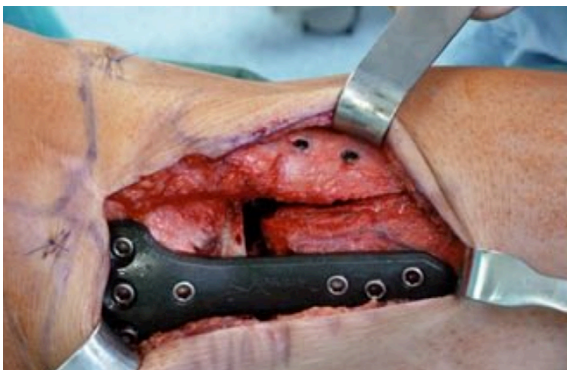

Figure 8 [32]: This ow HTO belong to part B of this dissertation and was fixed with the 2nd generation PEEKPower HTO-Plate®. The tuberosity was additionally fixed with two bicortical screws.

Before distal fixation of the 2nd generation PEEKPower HTO-Plate® and the TomoFix™ plate, a temporary lag screw was inserted distal to the osteotomy. This maneuver pre-tensioned the plate and induced compression on the lateral cortical hinge[76]. This technical feature was not supported by the 1st generation PEEKPower HTO-Plate®.

If the frontal osteotomy was exited distally, the tuberosity was additionally fixed with one or two bicortical screws (see Figure 8). In part A of this dissertation, bone grafting of the osteotomy gap was performed in 4 patients (8%), whereas the osteotomy gap was left open in 48 patients (92%). For details, please see Table 2.

2.3 Postoperative rehabilitation program

The postoperative rehabilitation program for isolated HTO, HTO combined with partial meniscectomy and HTO combined with ACL reconstruction involved limited weight bearing with 20 kg for the first 6 weeks. After 6 weeks full weight bearing was allowed after radiographic controll. In patients with concomitant cartilage repair weight bearing was not allowed for 6 weeks.

2.4 Clinical evaluation

All patients were followed prospectively. Clinical outcomes were assessed preoperatively and at a minimum follow-up of 24 months postoperatively using the WOMAC Score [11], Lysholm Score [48], and the visual analogue scale (VAS Score) for pain [29]. The WOMAC Score was assessed according to the KOOS User´s Guide (available at http://www.koos.nu/KOOSGuide2003.pdf). Standardized answer options were given as 5 Likert boxes and each question got a score from 0-4. A normalized percentage score (100 indicating no problems and 0 indicating extreme problems) was calculated. At the last follow-up, pain of the plate bed was also asked via VAS Score for the timepoint 2 days before implant removal. Postoperative complications were noted during the whole study period. The whole patient questionnaire is attached to the Appendix.

2.5 Radiographic evaluation

2.5.1 Loss of correction

For the radiographic analysis of correction loss, the Picture Archiving and Communication System (PACS, Philips Medical Systems, Sectra Imtec AB, Sweden) was used. Anteriorposterior (AP) and lateral radiographs were obtained two days after HTO (baseline measurements) and two days after removal of the implant (follow-up measurements). If the implant was not removed during the study period (n = 8), the last available follow-up radiographs were used (mean time between HTO and last follow-up radiographs 10±5 months).

Loss of correction in the frontal plane was assessed by comparing the medial proximal tibial angle (MPTA) on baseline and follow-up radiographs. 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 (see Figure 9). [50, 84] Loss of correction in the sagittal plane was assessed by comparing the tibial slope on baseline and follow-up radiographs using the method described by Brazier et al. [15] (see Figure 9).

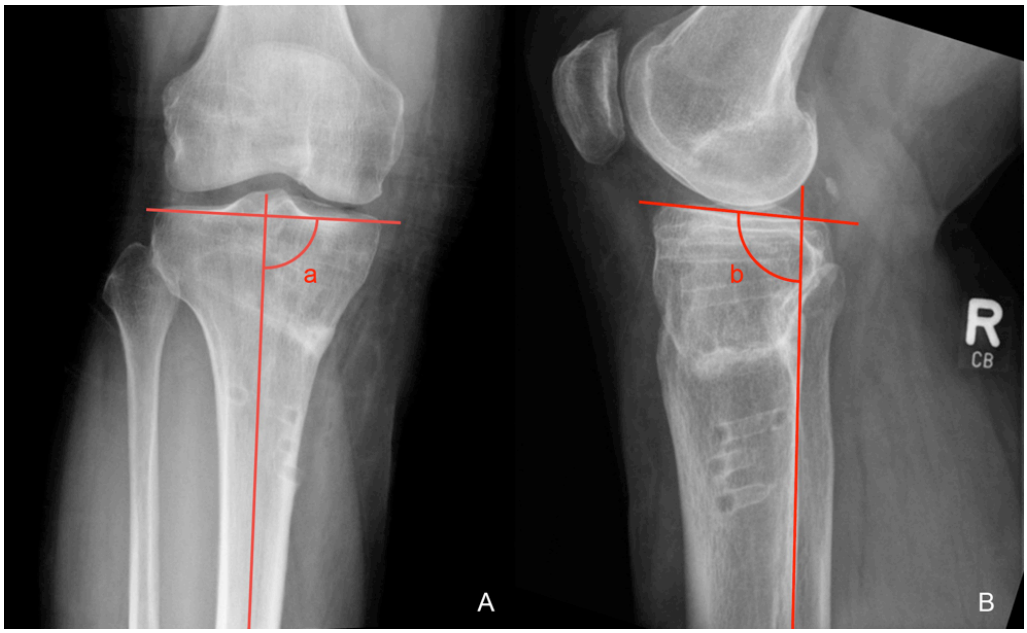

Figure 9: On the left side (A) AP radiograph two days after removal of the implant showing the method for measurements of the medial proximal tibial angle (angle a, MPTA). On the right side (B) lateral radiograph two days after removal of the implant demonstrating the method for measurements of the tibial slope (angle b).

2.5.2 Consolidation of the osteotomy gap

The percentage of consolidation of the osteotomy gap was objectively determined in group I. For this purpose, an in-house developed threshold segmentation plug-in for ImageJ [1] was used on the available AP radiographs (DICOM files). First, a region-of-interest (ROI) was selected, which was the osteotomy gap. Additionally, a second ROI proximal to the gap in a healthy region of the bone was selected. In this second ROI, the mean and standard deviation of pixelation were determined. These measurements were used to define the threshold for the segmentation. For segmenting bone and air in the gap, a threshold criterion was applied: the pixels (voxel) having intensities above the threshold were considered to be bone, and those below the threshold as air. Image quality and x-ray exposure was also verified. Finally, the pixels (voxel) segmented as bone or air were reported and then used to determine the percentage of bone in the gap (representative ImageJ reconstruction is shown in Figure 10).

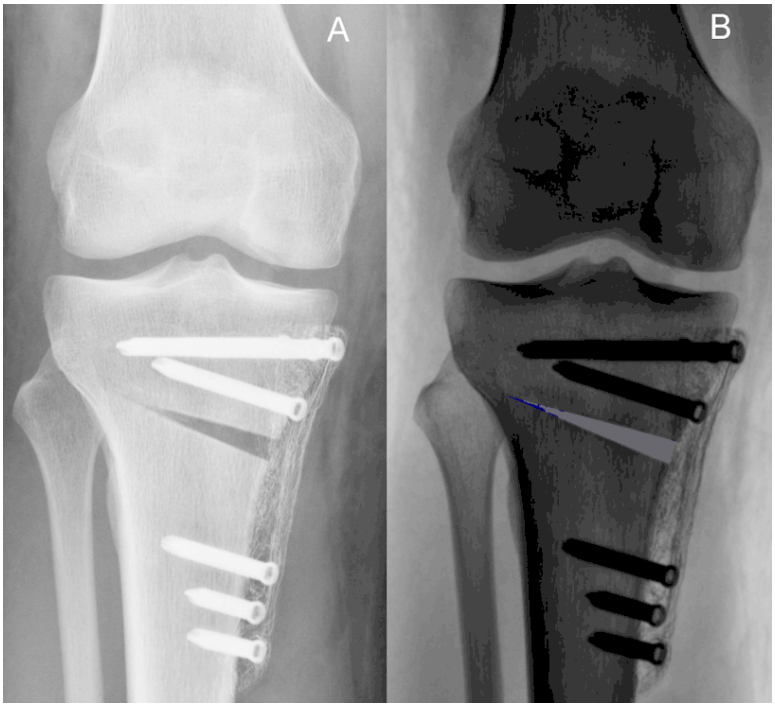

Figure 10: Postoperative AP radiograph (A) at the inpatient stay after ow HTO with the radiolucent PEEKPower HTO-Plate®. ImageJ reconstruction (B) showing the voxel (blue color) for bone in the osteotomy gap.

2.6 Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows version 19.0 (IBM-SPSS, New York, USA) and SAS software version 9.2 (SAS Institute Inc., Cary, NC, USA.). The nonparametric Wilcoxon-test for two related samples was used to compare the pre- and postoperative values within each group. The nonparametric Mann-Whitney-U-test for independent samples was used to compare patient characteristics, follow-up, clinical scores, and radiographic data between the two groups. All statistical tests were performed two sided. Statistical significance was considered at $p < 0.05$.

3 Results of part A

Three patients of group I underwent revision surgery with implantation of the TomoFix™ plate and were excluded from the statistical analysis of the clinical and radiographic results (see complications). One patient in group II was lost to follow-up because of the development of a psychiatric disorder. Therefore, 23 patients (23 knees) of group I and 25 patients (25 knees) of group II were available for final follow-up.
The preoperative questionnaires of the patients were evaluated during their admission. The postoperative questionnaires of all patients were evaluated between June 2010 and June 2013 via postal shipment. Out of them 15 patients were asked by phone call because they did not answer the questionnaires via postal shipment or it was not possible for them to come to the outpatient department.
All questions were responded by the patients. Only two patients of group II did not answer the question about the pain in the plate bed.

3.1 Clinical results

The final follow-up (Gr. I: median 25, interquartilrange 24-30, mean 29, standard deviation 6, range 24-43 months; Gr. II: median 25, interquartilrange 24-32, mean 29, standard deviation 6, range 24-43 months) did not differ significantly between both groups ($p = 0.80$). The detailed results of the clinical scores (VAS Score, WOMAC Score, Lysholm Score) are shown in Table 3. In both groups, statistically significant improvements of all three scores (VAS Score, $p = 0.00$; WOMAC Score, $p = 0.00$; Lysholm Score, $p = 0.00$) compared to preoperatively were observed at final follow-up. No statistically significant difference between both groups ($p > 0.05$) was found preoperatively as well as at final follow-up. See Figure 11 for the detailed time-dependet course in graphical description.
Pain in the plate bed (VAS Score) 2 days before implant removal was lower in group I (n = 23, median 2, interquartilrange 1-5, mean 3, standard deviation 3, range: 0-8) than in group II (n = 23, median 3, interquartilrange 1-6, mean 4, standard deviation 3, range: 0-9) but was not significantly different ($p = 0.53$).

Table 3: Clinical results of part A. All values are given as median, interquartilrange (25th-75th percentile) as well as mean, standard deviation and range. Abbreviations: *, statistically significant improvement compared to preoperatively ($p < 0.05$); VAS, visual analog scale; IQR, interquartilrange (25th-75th percentile); SD, standard deviation.

		Group I	**Group II**	**Significance**
VAS	Mean±SD, range	5±3, 0-10	6±2, 1-10	
preoperative	Median, IQR	5 (4-8)	6 (4-7)	p = 0.44
VAS	Mean±SD, range	2±2, 0-7*	2±2, 0-6*	
follow-up	Median, IQR	1 (0-4)*	2 (1-3)*	p = 0.71
WOMAC	Mean±SD, range	75±16, 44-100	78±14, 51-99	
preoperative	Median, IQR	74 (68-90)	80 (67-91)	p = 0.71
WOMAC	Mean±SD, range	91±11,67-100*	90±12,58-100*	
follow-up	Median, IQR	95 (89-99)*	91 (84-99)*	p = 0.76
Lysholm	Mean±SD, range	46±20, 9-79	49±16, 20-78	
preoperative	Median, IQR	44 (31-60)	50 (40-60)	p = 0.62
Lysholm	Mean±SD, range	83±19, 33-100*	75±18,46-100*	
follow-up	Median, IQR	90 (80-97)*	80 (54-93)*	p = 0.10

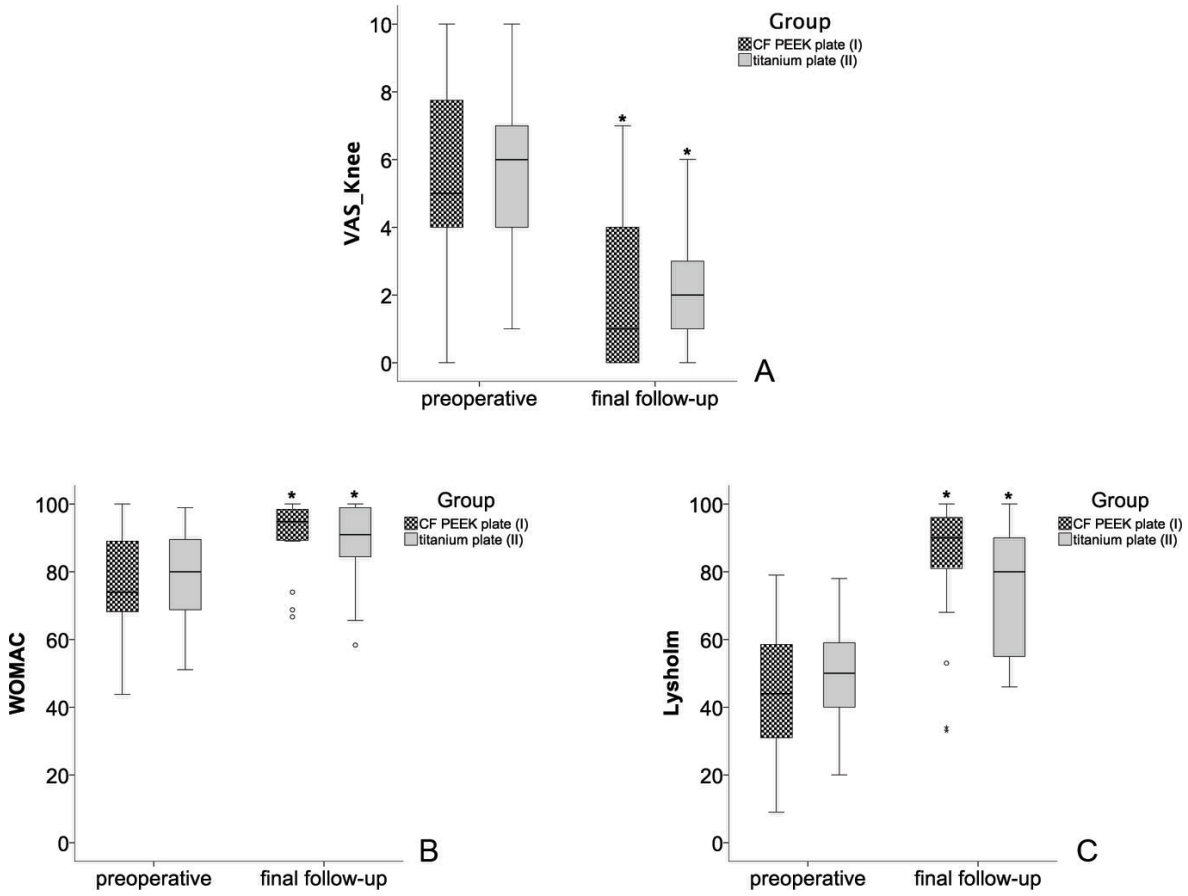

Figure 11: Time-dependent course as boxplots of the part A. VAS Score (A), WOMAC Score (B) and Lysholm Score (C) between both groups I and II. The bar in the boxplot illustrades the median. The box of the boxplots shows the interquartilrange (25th-75th percentile). The whiskers pose the area without outliers. The circles are mild outliers and the small stars are extreme outliers. Abbreviation: *, statistically significant difference compared to preoperatively ($p < 0.05$); VAS, visual analog scale.

3.2 Radiographic results

3.2.1 Loss of correction

The final follow-up (Gr. I: median 14, interquartilrange 12-18, mean 15, standard deviation 6, range 6-28 months; Gr. II: median 16, interquartilrange 13-21, mean 17, standard deviation 7, range 6-37 months) did not differ significantly between both groups (p = 0.35). The detailed radiographic results are shown in Table 4. Differences of MPTA (Gr I: p = 0.92, Gr II: p = 0.74) and tibial slope (Gr I: p = 0.36, Gr II: p = 0.12) between baseline and follow-up measurements did not differ significantly between both groups (p > 0.05).

Table 4: Radiological results of part A. All values are given as median, interquartilrange (25th-75th percentile) as well as mean, standard deviation and range. Abbreviations: #, no statistically significant difference (p > 0.05) compared to baseline measurements; MPTA, medial proximal tibial angle; TS, tibial slope; °, degree; IQR, interquartilrange (25th-75th percentile); SD, standard deviation.

		Group I	**Group II**	**Significance**
MPTA (°) baseline	Mean±SD, range Median, IQR	90±2, 86-95 91 (89-91)	91±2, 86-96 91 (89-93)	p = 0.18
MPTA (°) follow-up	Mean±SD, range Median, IQR	90±2, 86-95 # 91 (89-91) #	91±2, 87-95 # 91 (89-93) #	p = 0.25
Difference between MPTA (°) baseline and follow-up	Mean±SD, range Median, IQR	0±0, -1-0 0 (0-0)	0±1, -1-1 0 (0-0)	p = 0.39
TS (°) baseline	Mean±SD, range Median, IQR	96±4, 90-105 95 (93-100)	96±4, 86-106 95 (94-100)	p = 0.70
TS (°) follow-up	Mean±SD, range Median, IQR	96±4, 90-106 # 95 (93-100) #	96±5, 87-106 # 96 (94-100) #	p = 0.54
Difference between TS (°) baseline and follow-up	Mean±SD, range Median, IQR	0±0, 0-1 0 (0-0)	0±1, -1-2 0 (0-1)	p = 0.25

3.2.2 Consolidation of the osteotomy gap

Prior to implant removal, AP radiographs were analyzed to evaluate the percentage of consolidation relative to the osteotomy gap at various intervals postoperatively: at the inpatient stay (n = 23), at a mean of 6±2 months (n = 19), at a mean of 12±1 months (n = 17) and at a mean of 17±2 months (n = 11). Image J analysis showed a mean of 14±11%, a mean of 52±26%, a mean of 78±22% and a mean of 85±9% respectively of bone relative to the osteotomy gap. The mean pixels (voxel) segmented as bone or air as well as the mean threshold of group I for every timepoint is shown in Table 5. An illustrated result is shown in Figure 10.

Table 5: Consolidation of the osteotomy gap. Total voxel and evaluated voxel of bone, air and threshold are given as mean and standard deviation (SD, ±) at each timepoint.

	Voxel Bone	**Voxel Air**	**Threshold**	**Total Voxel**
Inpatient stay	3007±3224	16794±7773	1331±350	19800±9248
6 months	8806±6344	8685±8715	1833±813	17491±10571
12 months	14459±9068	4414±4450	2400±564	18874±10348
17 months	18682±8800	3047±2382	2454±700	21730±9641

3.3 Complications

The complications of both groups are listed in Table 6.

Table 6: Complications of part A (group I, group II and the remaining TomoFix™ plate fixations). Abbreviations: n.r., not reported; %, percentage; n, number of patients.

	Group I (n = 26)	**Group II (n = 26)**	**The remaining TomoFix™ fixations (n = 134)**
Overall complication rate	5 (19%)	3 (12%)	n.r.
Screw loosening/ breakage	1 (4%)	0	1 (1%)
Non-unions	3 (12%)	0	6 (5%)
Superficial or deep wound infections	1 (4%)	3 (12%)	n.r.

In group I, screw loosening of one of the most proximal screws with subsequent loss of correction was obeserved in one 52 year old patient (height: 181 cm, weight: 87 kg, BMI: 27 (kg/ m^2)) after a fall with twisting of the lower limb at 4 weeks postoperatively. (see Figure 12) The patient was successfully revised using the TomoFix™ plate.

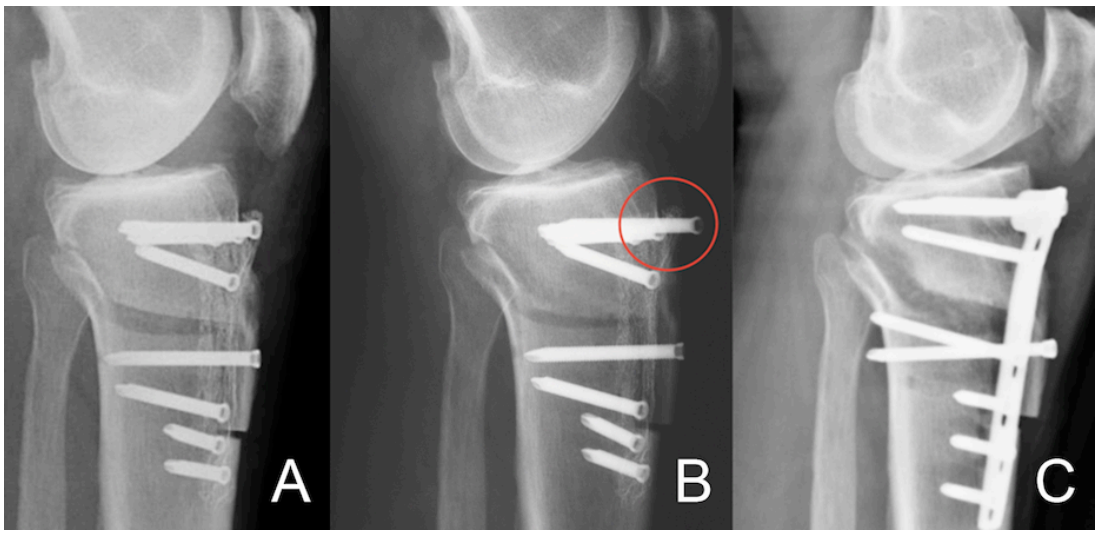

Figure 12: Postoperative lateral radiograph at the inpatient stay show a regular fixation of ow HTO with the 1st generation PEEKPower HTO-Plate® in a 52 year old patient (A). Postoperative lateral view 4 weeks after surgery show screw loosening (red circle) of one of the most proximal screws with subsequent loss of correction after a fall with twisting of the lower limb (B). Postoperative lateral radiograph at the inpatient stay show successfully revised ow HTO with the TomoFix™ plate (C). In this patient, removal of the TomoFix™ plate within complete consolidation of the osteotomy gap was done 14 months after initial ow HTO.

A non-union of the osteotomy gap was found in a 58 year old male smoker (BMI: 29 (kg/ m^2)) which is decribed in Figure 13.

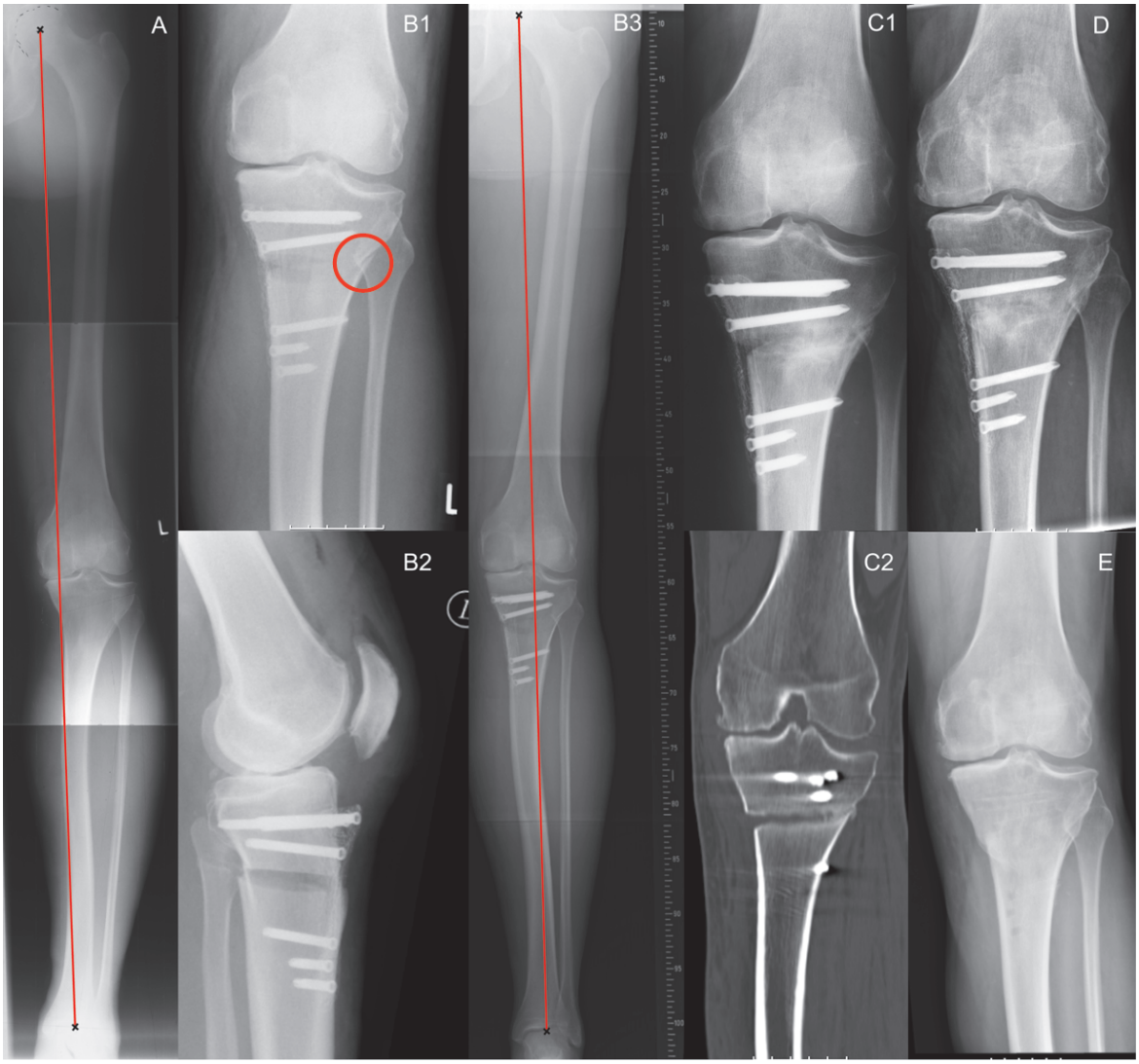

Figure 13: Although varus deformity (A, preoperative AP long-leg weight bearing radiograph) has been corrected sufficiently (B1 and B2, postoperative AP and lateral views; B3, postoperative AP long-leg weight bearing radiograph), the patient presented with persistent pain. Postoperatively, a fracture of the lateral cortex was observed (red circle, B1). 6 months after surgery a pseudarthrosis of the osteotomy gap was found on radiographs (C1, AP view; C2, computed tomography) and was treated with autogenous cancellous bone graft from the iliac crest. Five months after revision surgery, consolidation of the osteotomy gap was evident (D, AP view) and implant was removed 21 months after initial ow HTO. Complete consolidation (E, AP view).

Failure analyzis of the remaining 2 non-unions is described in Figure 14 and in Figure 15.

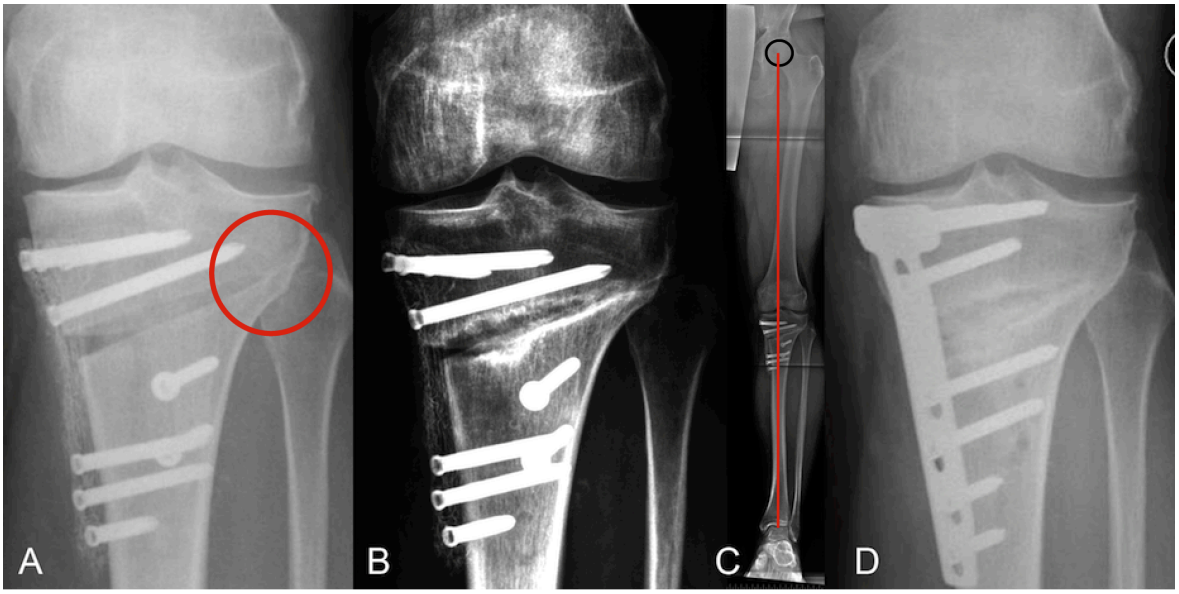

Figure 14: Postoperative AP radiograph at the inpatient stay might show a minimal sawed lateral cortex but not a remaining lateral gap (red circle) in a 48 year old male smoker (BMI: 33 (kg/ m^2) (A). A non-union with persistent pain was diagnosed six months after ow HTO (B). On the postoperative AP long-leg weight bearing radiograph a medial deviation of the mechanical axis (red line) from the center of the knee with a femoro-tibial angle of 2° varus was observed (C). This disagreed the preoperative planning. The PEEKPower HTO-Plate® was replaced by the TomoFix™ plate and the mechanical axis was corrected. Thereby it was possible to obtain compression on the lateral hinge by using a temporary lag screw (D). The osteotomy gap was successfully filled with autologous cancelous bone from the iliac crest. In this patient, removal of the TomoFix™ plate within complete consolidation of the osteotomy gap was done 23 months after initial ow HTO.

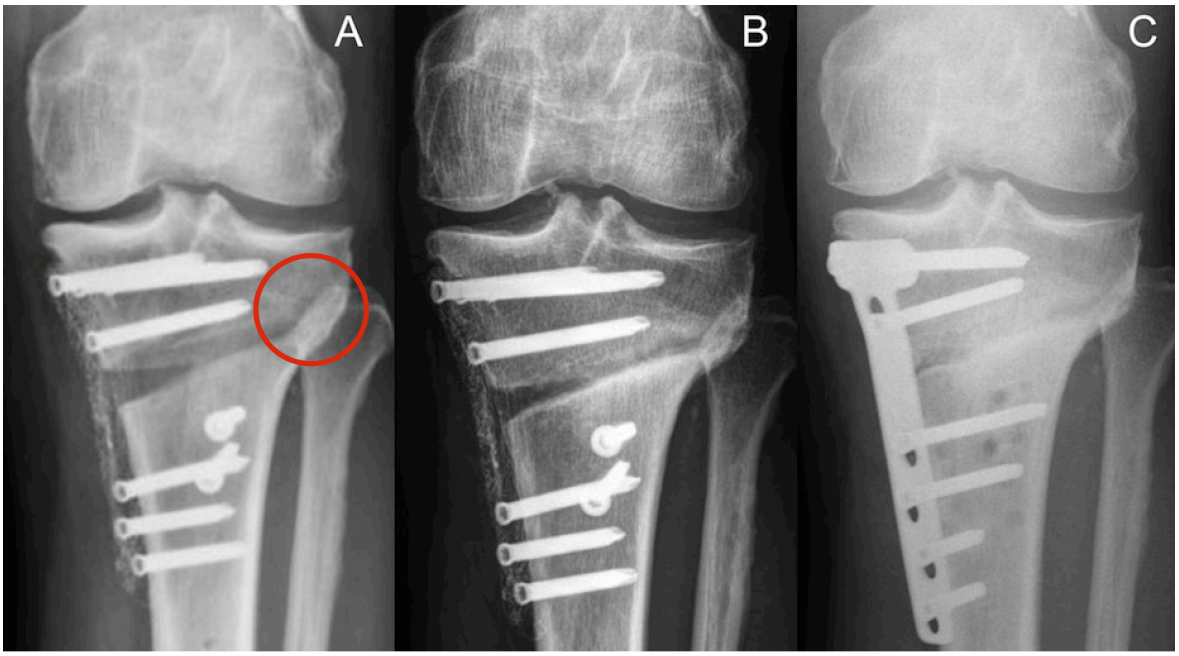

Figure 15: Postoperative AP radiograph at the inpatient stay might show a minimal fracture of the lateral cortex (red circle) in a 57 year old male smoker (BMI: 28 (kg/ m^2)) (A). After a diagnosed non-union with persistent pain (B), this patient was successfully treated by filling of the osteotomy gap with autologous cancelous bone from the iliac crest at nine months after ow HTO. The surgeon decided to replace the PEEKPower HTO-Plate® by the TomoFix™ plate. Thereby it was possible to obtain compression on the lateral hinge by using a temporary lag screw (C). In this patient, removal of the TomoFix™ plate within complete consolidation of the osteotomy gap was done 27 months after initial ow HTO.

All patients with wound infections were succesfully treated with repeated wound lavage and debridement combined with systemic antibiotics. No neuro-vascular complications were obeserved.

4 Discussion of part A

Summary:

In the present study, for osteotomy fixation in valgus-producing ow HTO, twenty-six 1st generation PEEKPower HTO-Plates® were compared with twenty-six TomoFix™ plates. The main finding was that the 1st generation PEEKPower HTO-Plate® provided the same clinical and radiographic results as the TomoFix™ plate at a minimum follow-up of 24 and 12 months respectively. However, more implant related complications occured with the 1st generation PEEKPower HTO-Plate®.

Clinical evaluation

The literature provides, that valgus-producing ow HTO using the TomoFix™ plate is a safe procedure with promising short- to midterm results [18, 23, 24, 42, 57, 75, 78]. However several drawbacks regarding implant design and surgical technique have been recognized with the TomoFix™ plate because it has a relative bulky design. Niemeyer et al. [56, 57] found a high percentage of patients complained of local irritation associated with this implant and which disappeared after the removal. In contrast, the 1st generation PEEKPower HTO-Plate® is considerably smaller, lighter and has another material compared to the TomoFix™ plate. Aside from the first published clinical results of the 1st generation PEEKPower HTO-Plate® (Cotic et. al., see Appendix) [19], there are currently no clinical reports regarding its outcome and safety compared to a commonly used and standard plate fixator in literature. Therefore this study presents the first results of a matched-pair comparison between this new implant and the standardized TomoFix™ plate.

Although the 1st generation PEEKPower HTO-Plate® has a smaller design and another material, differences regarding clinical scores between both groups in the present study were not observed. Respective the pain in the plate bed, also no significant differences between both groups were found. If the smaller implant design of the PEEKPower HTO-Plate® may provide more patient comfort and may avoid the need for implant removal must be proved by further comparative studies. It can be concluded that, the TomoFix™ plate and the 1st generation PEEKPower HTO-Plate® are viable implants for osteotomy fixation in valgus-producing ow HTO in terms of the clinical results 24 months after surgery.

Removal of the Implant

In this prospective study, decision of complete consolidation and indication for implant removal was made by the surgeon who performed the HTO. In group II the surgeon indicated all implant removals because of patient complaints about soft tissue irritation around the plate. In contrast, implant removal in group I was primarily recommended to the patients by the surgeon because of unknown biologic behaviour of CF PEEK.

Observation of the consolidation of the osteotomy gap

Cross-sectional consolidation of the osteotomy gap was analyzed objectively with the use of ImageJ. This observation showed consolidation of 52%, 78% and 85% at 6, 12, and 17 months after sugery, respectively and was not shown in the literature before. Analyses with a titanium implant were not possible because of its radiological artifacts. Therefore, in this observation it was not possible to evaluate the influence of any implant on bone healing after ow HTO. It is concluded that for the objective bony-evaluation after ow HTO, a radiolucent PEEKPower HTO-Plate® is superior to a TomoFix™ plate on standardized AP radiographs.

Biomechanical observation

In a preclinical biomechanical evaluation, a TomoFix™ plate as well as the 1st generation PEEKPower HTO-Plate® were tested in a comparable worst-case compression bending test (white paper, published by Arthrex, available at: http://www.arthrex.com; attached to the Appendix). For both specimen groups lifetime decreased with increasing loads. Compared to the peek-carbon composite results the titanium results reveal decreased lifetimes at lower loads, but show a tendency to compensate this mismatch at higher load levels. Therefore, the PEEKPower HTO-Plate® shows increased flexural strength compared to a TomoFix™ plate with increased flexural deformation. That could be attributed to the different degree of rigidity between both plate-materials. Titanium has got the characteristic that it is more flexible than PEEK and carbon and therefore has got the tendency to be more elastic and to compensate loadings with increased flexural deformation. In contrast, the PEEKPower HTO-Plate® showed its characteristical increased flexural strength through a higher accepted alternation of load on the plate.

Loss of correction

In the present study, no statistically significant differences between baseline and follow-up measurements were observed for MPTA and tibial slope in both groups. Furthermore, there were no significant differences between both groups in the timepoints of complete consolidation, in the median delta of MPTA as well as in the median delta of slope. It is concluded that both plates are stable enough to maintain the amount of correction until complete ossification without significant differences between each other.

Complications

Non-Unions:

In the clinical comparison analysis were no incidences of any nonspecific complications, such as nerve injury, vessel injury or necrosis of the tibial plateau. There were 3 incidences (12%) of delayed consolidation of the osteotomy gap occurred in patients with a 1st generation PEEKPower HTO-Plate®. Patients with a TomoFix™ plate showed not any non-union (0%).

Compared to the literature, smokers and patients with a fracture of the lateral cortex after HTO [56, 75, 83] are showing inferior consolidation. These findings are concordant to the present study, because it was about three smokers who developed the non-union of the osteotomy gap and were treated with autogenous cancellous bone graft from the iliac crest after initial therapy. Additionally, a fracture of the lateral cortex was also found.

Nevertheless, also implant related factors might have negatively influenced bone healing. Compared to the TomoFix™ plate, the 1st generation PEEKPower HTO-Plate® does not provide the use of a temporary lag screw. By inserting this screw through the first distal hole below the osteotomy, interfragmentary compression of the lateral cortex is induced. Studies about instable osteotomies due to fractures of the lateral cortex resulting in non-union showed, that a lag screw was not used [56]. Furthermore, it is fact that well-controlled micromotion at the interface of a screw-shaped implant stimulates bone healing [82] and therefore flexural deformation of the hardware is needed. However, the 1st generation PEEKPower HTO-Plate® has a higher flexural strength compared to the TomoFix™ plate (data provided by Arthrex and attached to the Appendix). Therefore, insufficient flexural deformation of the PEEKPower HTO-Plate® might also be a reason for the higher non-union rate in group I. The non-union rate of the remaining 134 patients treated with the TomoFix™ plate during the study period was 5% (Table 6).

Other authors found non-union rates of 0-7% after ow HTO fixed with the TomoFix™ plate. [18, 24, 51, 81] Therefore, the risk for non-union seems to be higher with the 1st generation PEEKPower HTO-Plate®.

Screw-loosening:

In one patient of group I (4%), loosening of one of the most proximal screws with accompanying loss of the corrected MPTA was observed. Whereas no screw backouts were found in group II (0%). The literature described screw breakages during extraction but no screw looesenings with the TomoFix™ plate. [81] Therefore, the following implant related failures might also be responsible for the screw loosening of the 1st generation PEEKPower HTO-Plate®. According to the biomechanical evaluation mentioned above (data provided by Arthrex, see Appendix), the increased flexural strength of the peek-carbon composite plate did not allow as much flexural deformation as a titanium plate. Therefore this new plate accepted a higher alternation of load on the plate without fracturing compared to the titanium plate. Accordingly that could be the reason for increased loads not on the peek-carbon plate but in the bone anchoring with ejection of the screws. These findings suggest that the 1st generation PEEKPower HTO-Plate® has a too thin and weak hole-bed for a save screw fixation via the self-cutting threads and locking heads of the screws into the plate and a too less flexural deformation at the same time.

Interestingly, in the remaining 134 patients treated with the TomoFix™ plate, a screw breakage due to a fall onto the lower limb was found (Table 6). Though the hole-bed of the TomoFix™ plate is save, it does not prevent from screw breakages needing revision surgery through unphysiological high impacts.

Histological Evaluation

The novel implant investigated in this study is made of CF PEEK, which is increasingly used for trauma, orthopedic, and spinal implants. [43] This non-metallic biomaterial provides the high strength of metals combined with good biocompatibility and imaging compatibility of polymers. [43] Because of the locking concept of the PEEKPower HTO-Plate®, abrasion of the plate material commonly occurs during osteotomy fixation. In this study, histological evaluation of CF PEEK wear was performed in 15 cases by a pathologist of the Institute of Pathology, Technical University of Munich, Germany. The observation did not show acute or chronic inflammation or tissue necrosis.[19, 20] This fin-

ding is in line with other studies, which found good biocompatibility of CF PEEK.[66, 71] Furthermore, it has been shown that carbon-carbon composites have low wear rates and no osteolytic or cytotoxic potential in cell cultures[33]; It has to be concluded that material abrasion seen in this technique has no influence on the postoperative outcome and has to be accepted when stabilizing HTO with a peek-carbon composite plate. Therefore, from a biological point, the PEEKPower HTO-Plate® can be safely used for HTO and plate removal would not be mandatory.

Limitations of the Study

The patients were not randomized preoperatively. Nevertheless, a matched-pair design was chosen to achieve adequate comparability by minimizing confounding factors.

ImageJ analysis was limited by user interpretation, image quality, and by the fact that 2D projections were used and not 3D data. However, compared to simple subjective and visual inspection, as used in the literature [74], this is a robust method to objectively analyze the consolidation on standardized AP radiographs.

Concerning the method to determine the amount of correction loss, serial long-leg weight bearing AP radiographs or radiostereometric analysis might have been more accurate in every patient. Unfortunately, these methods were not allowed by the ethics commitee due to the associated radiation exposure. However, by evaluating correction loss in two standard planes (frontal and sagittal), the accuracy of the radiological analysis increased.

Conclusion

Considering the drawbacks of the 1st generation PEEKPower HTO-Plate® discussed above, it is recommended to adapt this 1st generation peek-carbon composite plate and to create a new plate allowing as much micromotion as is necessary to achieve no implant failure and screw loosening at the same time. A 2nd generation has been introduced by the manufacturer in the meanwhile. The new plate provides an improved geometry of the screw holes and a reduced flexural strength. The newer generation also provides the utilization of a temporary lag screw to obtain compression on the lateral cortex. Further studies must prove whether these modifications result in less implant related complications.

Part B: Clinical, radiographic, and sports-related results after valgus-producing open wedge high tibial osteotomy fixed with a new plate fixator (2nd generation PEEKPower HTO-Plate®)

5 Materials and Methods of Part B

5.1 Patient selection and study design

Between March 2010 and July 2011, 25 consecutive patients were treated with valgus-producing ow HTO without bone grafting using the 2nd generation PEEKPower HTO-Plate® at the Department of Orthopaedic Sports Medicine, Technical University of Munich, Germany. All enrolled patients provided informed consent to participate in this study.

5.1.1 Inclusion- and Exclusion Criteria

The Inclusion- and Exclusion criteria are listed under 2.1.1. Only patients without bone grafting were included in the present study.

5.1.2 Baseline Demographics

The baseline characteristics and concomitant procedures are listed in Table 7.

Table 7: Baseline demographics of the patients treated with the 2nd generation PEEKPower HTO-Plate®. Abbreviations: SD, standard deviation; ys, years; n, number of patients; VAS, visual analogue scale; °, degree; mm, millimeter; HTO, high tibial osteotomy; OAT, osteochondral autologues transfer; ACL, anterior cruciate ligament; %, percentage.

Number of knees	25
number of patients	
total	25
male	17
female	8
Mean age (ys) ± SD, range	45±10, (19-58)
Mean body mass index (kg/ m^2) ± SD, range	25±3, (20-31)
Smokers (n)	3
Mean preoperative femoro-tibial angle (° of varus deviation) ± SD, range	5±3, (1-16)
Intraoperative valgus position (n)	
55%	11
62%	14
Mean osteotomy gap height (mm) ± SD, range	8±3, (4-15)
Concomitant procedures during HTO (n)	
medial meniscectomy	4 (17%)
microfracturing	1 (4%)
OAT	4 (17%)
ACL reconstruction	1 (4%)

5.2 Surgical technique

The detailed surgical technique is described under 2.2. In 7 cases, out of this patient cohort with the 2nd generation PEEKPower HTO-Plate®, the osteotomy was exited distally, leaving the tibial tuberosity attached to the proximal fragment. In these cases, the tuberosity was additionally fixed with one or two bicortical screws. In the remaining patients, the osteotomy was exited proximally, leaving the tuberosity attached to the distal fragment. As mentioned above, bone grafting of the osteotomy gap was not performed.

5.3 Postoperative rehabilitation program

The postoperative rehabilitation program is listed under 2.3.

5.4 Clinical evaluation

All patients were evaluated preoperatively and at 12 and 24 months postoperatively. For clinical evaluation, knee pain, osteoarthritic symptoms and function of the affected leg were assessed prospectively using the visual analogue scale (VAS Score) [29] for pain, the WOMAC Score [11] and the Lysholm Score [48]. For the WOMAC Score, standardized answer options were given as 5 Likert boxes and each question got a score from 0-4. A normalized percentage score (100 indicating no problems and 0 indicating extreme problems) was calculated (for details, see: http://www.koos.nu/KOOSGuide2003.pdf). During the whole study period, postoperative complications were also noted.
The sports-related outcome was evaluated using the Tegner activity scale[80] and a self designed questionnaire, which assessed the number of sport disciplines, sports frequency (defined as sessions per week) and sports duration (defined as hours per week) one year before surgery and 24 months postoperatively. The whole questionnaire is attached to the Appendix.

5.5 Radiographic evaluation

Radiographic analysis was performed by using the Picture Archiving and Communication System (PACS, Philips Medical Systems, Sectra Imtec AB, Sweden). AP and lateral

radiographs were obtained two days after ow HTO (baseline measurements) and two days after implant removal (follow-up measurements). If the implant was not removed during the study period (n = 9), the last available follow-up radiographs were used (mean time between HTO and last follow-up radiograph: 10±6 months). Lateral radiographs were taken with the knee in 30° of flexion.
The assessment for the loss of correction in the frontal plane as well as in the sagittal plane is described in detail under 2.5.1.

5.6 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 $p < 0.05$.

6 Results of part B

Three patients underwent revision surgery with implantation of another implant and were excluded from the statistical analysis of the clinical and radiographic results (see complications). Therefore, 22 patients were available for the 12 (mean 12±1) and 24 (mean 24±2) months clinical follow-up evaluation.
The preoperative questionnaires of the patients were evaluated during their admission. The postoperative questionnaires of all patients were evaluated between February 2011 and July 2013 via postal shipment. Out of them 13 patients were asked by phone call for the 24 months scores. This was due to the fact that these patients did not answer the questionnaires or it was not possible for them to come to the outpatient department. Out of them, 1 patient did not sign the consent form of the questionnaire but still participated in the telephone survey.

6.1 Clinical results

The detailed results of the clinical scores (VAS Score, WOMAC Score, Lysholm Score) are shown in Table 8. Compared to preoperatively, statistically significant improvements ($p < 0.05$) of all three scores were observed at the 12 and 24 months follow-up. The time-dependent course of the clinical scores is shown in Figure 16. No significant differences were found between the 12 and 24 months follow-up (VAS, $p = 0.29$; WOMAC, $p = 0.22$; Lysholm, $p = 0.11$). Out of the 22 patients implant removal was done in 14 patients. The mean time between HTO and implant removal was 17±5 months.

Table 8: Clinical results of the 2nd generation PEEKPower HTO-Plate®. All values are given as median, interquartilrange (25th-75th percentile) as well as mean, standard deviation and range. Abbreviations: *, statistically significant improvement compared to preoperatively ($p < 0.05$); #, no statistically significant difference compared to 12 months follow-up ($p > 0.05$); VAS, visual analog scale; ms, months; IQR, interquartilrange (25th-75th percentile); SD, standard deviation.

		Values	**Significance compared to preoperatively**
VAS preoperative	**Mean±SD, range** **Median, IQR**	5±3, 1-10 4 (3-7)	
VAS 12 ms	**Mean±SD, range** **Median, IQR**	2±1, 0-4* 2 (1-3)*	p = 0.00
VAS 24 ms	**Mean±SD, range** **Median, IQR**	2±1, 0-6*# 1 (0-2)*#	p = 0.00
WOMAC preoperative	**Mean±SD, range** **Median, IQR**	70±20, 27-97 72 (55-85)	
WOMAC 12 ms	**Mean±SD, range** **Median, IQR**	92±10, 69-100* 97 (89-100)*	p = 0.00
WOMAC 24 ms	**Mean±SD, range** **Median, IQR**	94±8, 75-100*# 98 (91-100)*#	p = 0.00
Lysholm preoperative	**Mean±SD, range** **Median, IQR**	50±17, 15-80 51 (39-63)	
Lysholm 12 ms	**Mean±SD, range** **Median, IQR**	80±14, 56-100* 80 (69-95)*	p = 0.00
Lysholm 24 ms	**Mean±SD, range** **Median, IQR**	84±14, 51-100*# 84 (76-96)*#	p = 0.00

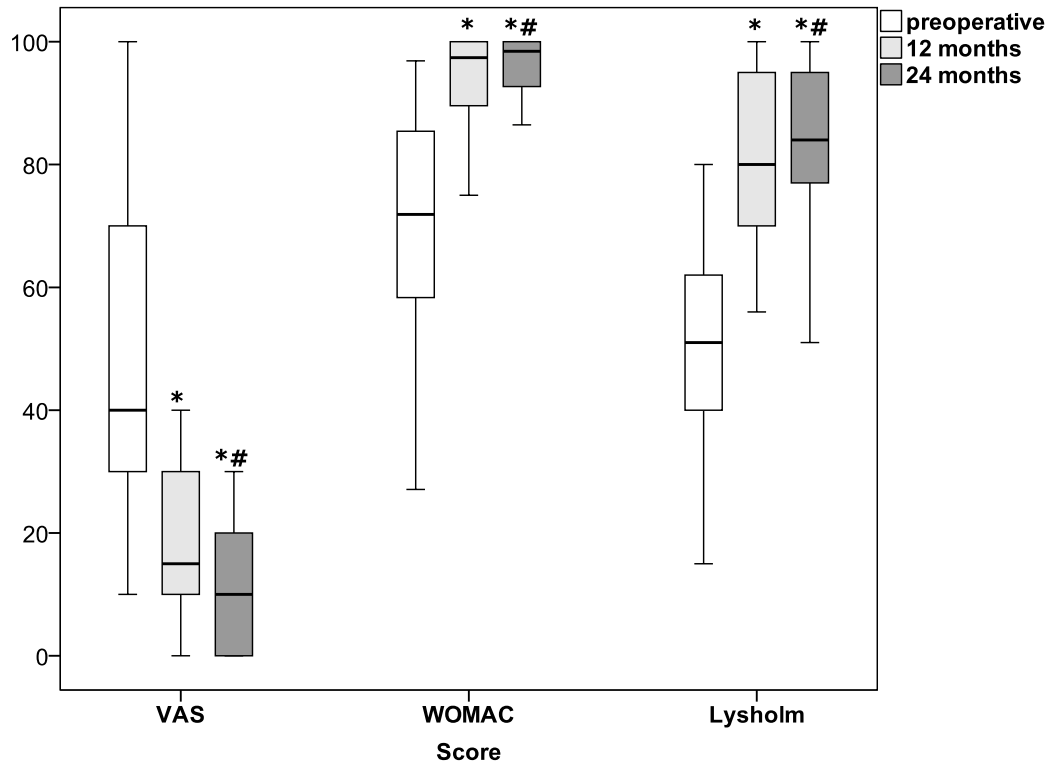

Figure 16: Time-dependent course as boxplots of the part B: VAS Score, WOMAC Score and Lysholm Score. For descripitve purpose, VAS scores were multiplied by 10 (100 indicating an extreme amount of pain and 0 indicating no pain). Abbreviations: *, statistically significant difference compared to preoperatively ($p < 0.05$); #, no statistically significant difference was found between the 12 and 24 months follow-up ($p > 0.05$); VAS, visual analog scale.

6.2 Sports-related results

Three patients (14%) did not participate in any sports one year before surgery, whereas only one patient (5%), who sustained from a coronary thrombosis, 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 ($p < 0.05$). No significant change was observed for the Tegner scale, number of sports disciplines and sports duration ($p > 0.05$, Table 9). Figure 17 shows all sports disciplines in which patients participated one year before and 24 months after surgery. Most patients participated in low- to moderate impact activities preoperatively as well as 24 months after surgery.

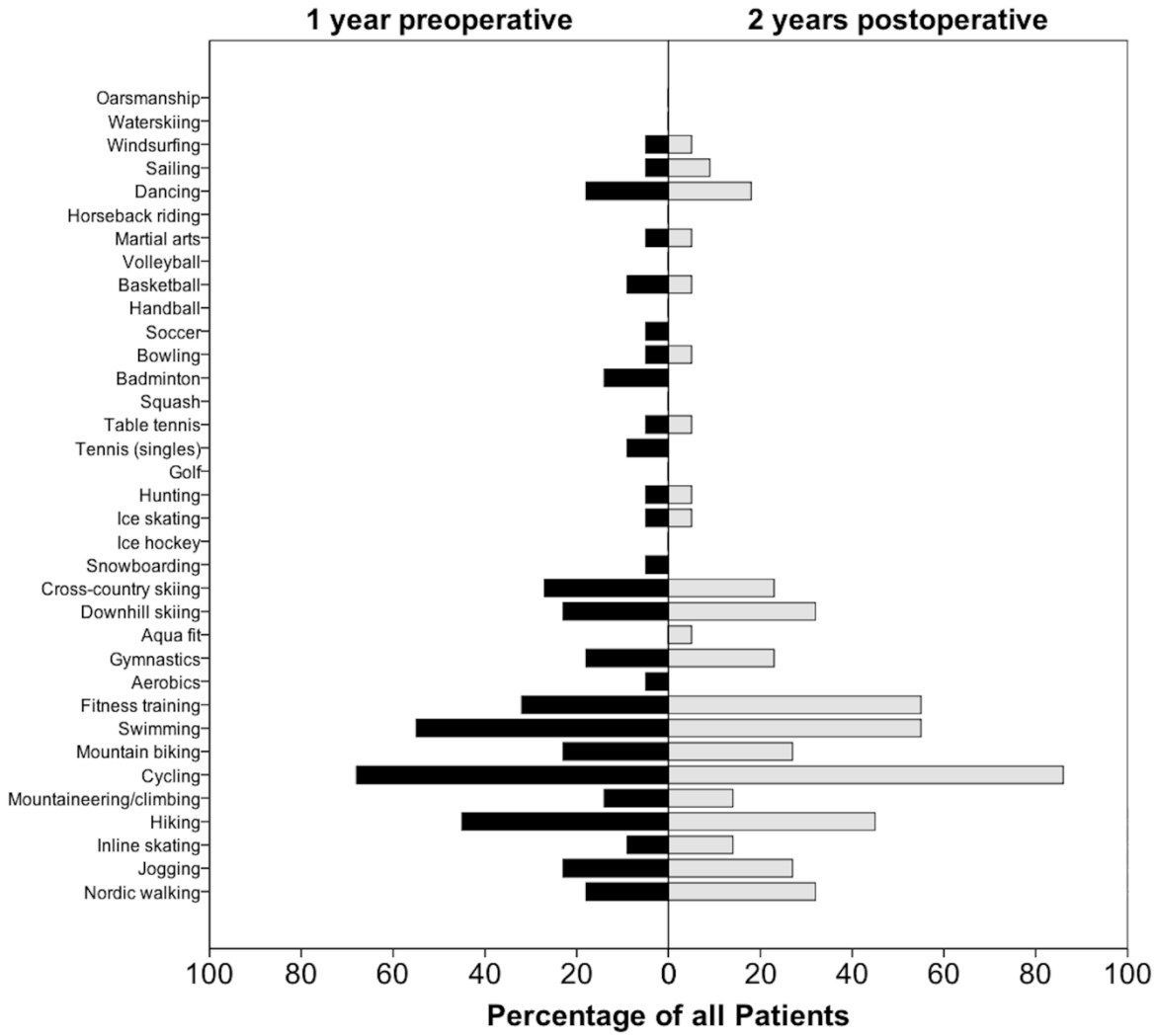

Figure 17: Sports disciplines which were asked in the questionnaire. Out of them, the sports disciplines in which patients participated one year before (left in black) and 24 months after surgery (right in grey).

Table 9: Sports related results of the 2nd generation PEEKPower HTO-Plate®. Sports frequency (sessions), sports duration (hours) and the number of sports disciplines are given as median, interquartilrange (25th-75th percentile) as well as mean, standard deviation and range. Abbreviations: *, statistically significant improvement compared to preoperatively ($p < 0.05$); #, no statistically significant difference compared to preoperatively ($p > 0.05$); ms, months; IQR, interquartilrange (25th-75th percentile); SD, standard deviation.

		Values	**Significance compared to preoperatively**
Tegner preoperative	**Mean±SD, range** **Median, IQR**	5±2, 1-9 5 (3-6)	
Tegner 24 ms	**Mean±SD, range** **Median, IQR**	4±1, 2-8# 4 (3-5)#	p = 0.37
Sessions per week preoperative	**Mean±SD, range** **Median, IQR**	2±1, 0-5 2 (1-3)	
Sessions per week 24 ms	**Mean±SD, range** **Median, IQR**	3±2, 0-9* 3 (1-4)*	p = 0.04
Hours per week preoperative	**Mean±SD, range** **Median, IQR**	4±3, 0-10 3 (1-6)	
Hours per week 24 ms	**Mean±SD, range** **Median, IQR**	5±4, 0-12# 4 (1-7)#	p = 0.19
Disciplines per week preoperative	**Mean±SD, range** **Median, IQR**	5±4, 0-14 3 (2-7)	
Disciplines per week 24 ms	**Mean±SD, range** **Median, IQR**	5±3, 0-13# 4 (3-7)#	p = 0.66

6.3 Radiographic results

The last radiographs of the 22 patients were available at a mean follow-up of 15±6 months. The median difference and interquartil range (25th-75th percentile) between baseline and follow-up measurements was 0 (-1-0) for MPTA, and 0 (0-0) for tibial slope. No significant differences between baseline and follow-up measurements were observed (MPTA, p = 0.13; tibial slope, p = 0.07). See Table 10.

Table 10: Radiographic results of the 2nd generation PEEKPower HTO-Plate®. All values are given as median, interquartilrange (25th-75th percentile) as well as mean, standard deviation and range. Abbreviations: #, no statistically significant difference (p > 0.05) compared to baseline measurements; MPTA, medial proximal tibial angle; TS, tibial slope; °, degree; IQR, interquartilrange (25th-75th percentile); SD, standard deviation.

		Values	Significance
MPTA (°) baseline	**Mean±SD, range** **Median, IQR**	92±2, 90-95 92 (91-93)	
MPTA (°) follow-up	**Mean±SD, range** **Median, IQR**	92±1, 90-95 # 92 (91-93) #	p = 0.13
Difference between MPTA (°) baseline and follow-up	**Mean±SD, range** **Median, IQR**	0±1, -2-1 0 (-1-0)	
TS (°) baseline	**Mean±SD, range** **Median, IQR**	96±3, 91-102 95 (93-99)	
TS (°) follow-up	**Mean±SD, range** **Median, IQR**	96±3, 91-102 # 95 (93-99) #	p = 0.07
Difference between TS (°) baseline and follow-up	**Mean±SD, range** **Median, IQR**	0±0, 0-0 0 (0-0)	

6.4 Complications

The complications are listed in Table 11.

Table 11: The Number of complications of the 2nd generation PEEKPower HTO-Plate®. Abbreviations: %, percentage.

Overall complication rate	3 (12%)
Screw loosening	2 (8%)
Non-unions	1 (4%)
Superficial or deep wound infections	0 (0%)

A Non-union of the osteotomy gap occured in one patient (4 %) and a screw loosening occured in 2 patients (8%) with a detailed failure analysis in Figure 18, in Figure 19 and in Figure 20.

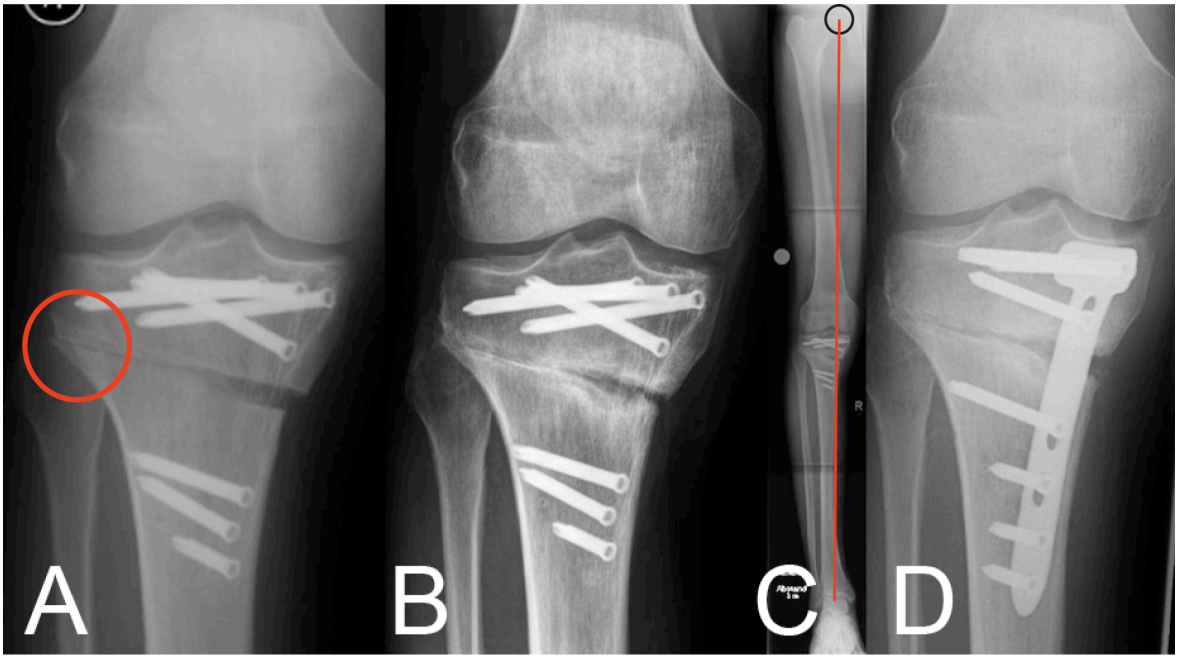

Figure 18: Postoperative AP radiograph at the inpatient stay show a completely sawed lateral cortex with a remaining lateral gap (red circle) in a 42 year old male non-smoker (BMI: 23 (kg/ m^2)) (A). A non-union with persistent pain was diagnosed nine months after ow HTO with the 2nd generation PEEKPower HTO-Plate® (B). On the postoperative AP long-leg weight bearing radiograph a medial deviation of the mechanical axis (red line) from the center of the knee was observed (C). This disagreed the preoperative planning. The PEEKPower HTO-Plate® was replaced by the TomoFix™ plate and the mechanical axis was corrected (D). The osteotomy gap in this patient was successfully filled with autologous cancelous bone from the iliac crest. In this patient removal of the TomoFix™ plate within complete consolidation of the osteotomy gap was not done until today.

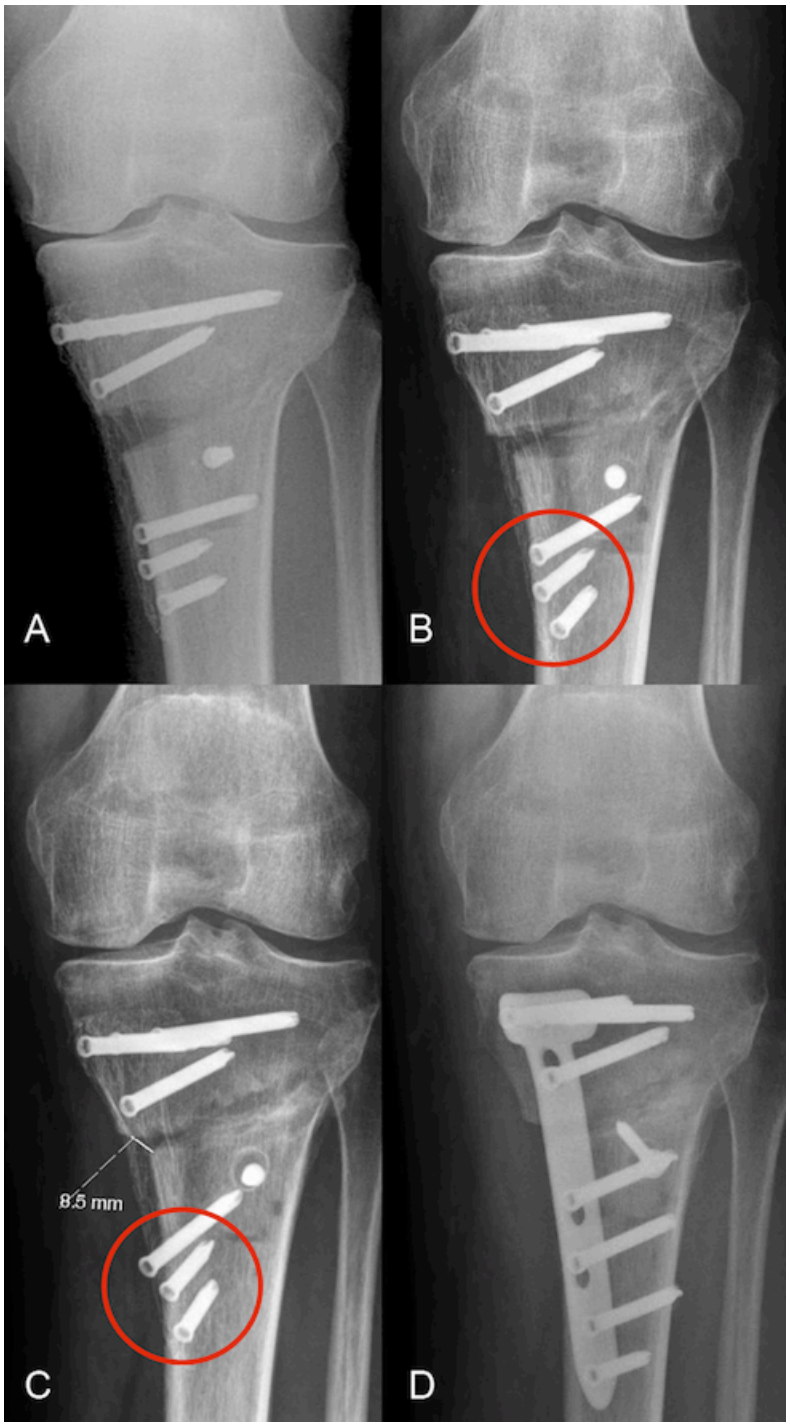

Figure 19: Postoperative AP radiograph at the inpatient stay (A) after ow HTO with the 2nd generation PEEKPower HTO-Plate® in an overweight 48 year old patient (height: 196 cm, weight: 119 kg, BMI: 31). The initial osteotomy gap in this case was 13 mm. Minimal dislocation of the distal screws (red circle) was observed after he increased partial weight bearing 6 weeks postoperatively up to 40 kg (B). Afterwards, screw loosening of one of the most distal screws (red circle) with a subsequent loss of the osteotomy gap was observed 4 months postoperatively (C). The patient was successfully revised with the TomoFix™ plate, the osteotomy gap was filled with autologous cancelous bone from the iliac crest and the mechanical axis was corrected (D). Removal of the TomoFix™ plate within complete consolidation of the osteotomy gap was done 20 months after initial ow HTO.

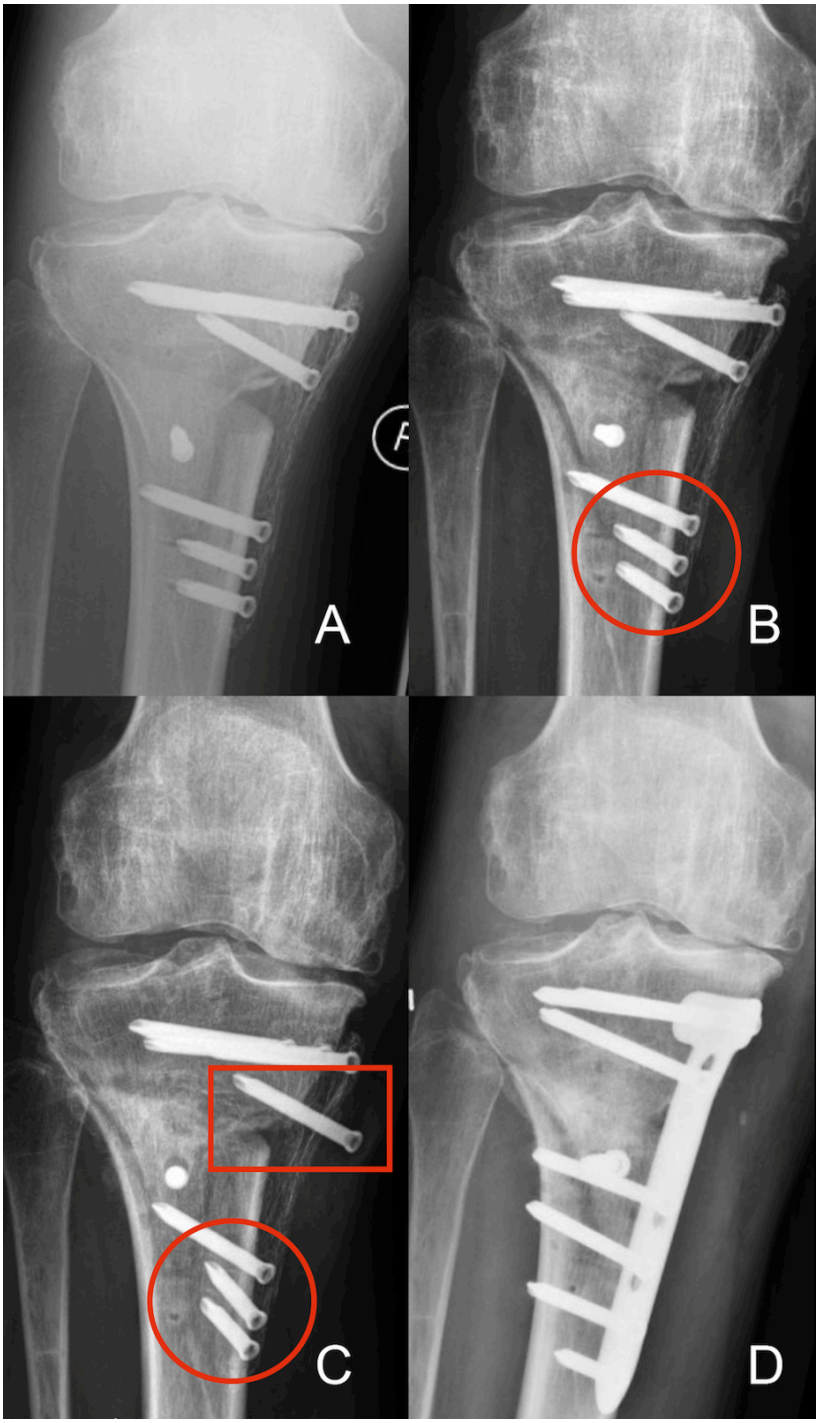

Figure 20: Postoperative AP radiograph at the inpatient stay (A) after ow HTO with the 2nd generation PEEKPower HTO-Plate® in in a 49 year old sportsperson (height: 175 cm, weight: 76 kg, BMI: 25). The initial osteotomy gap in this case was 15 mm. Also minimal dislocation of the distal screws (red circle) was observed after he started bicycle training on the ergometer with 200 watts 6 weeks postoperatively (B). Afterwards, additional screw loosening of one of the most proximal screws (C, red oblong) with subsequent loss of the osteotomy gap was observed 3 months postoperatively. The patient was also successfully revised using the TomoFix™ plate, the osteotomy gap was additionally filled with autologous cancelous bone from the iliac crest and the mechanical axis was corrected. Removal of the TomoFix™ plate within complete consolidation of the osteotomy gap was done 18 months after initial ow HTO.

7 Discussion of part B

Summary:

The most important finding of part B of this dissertation was that valgus-producing ow HTO without bone grafting in osteotomy gaps of up to 12 mm using the 2nd generation PEEKPower HTO-Plate® showed significantly improved knee function and pain situation as early as 12 months after surgery. Moreover, ow HTO with the use of this new plate allowed active patients to return to their sports-status 1 year before surgery with a higher frequency. No significant loss of correction between baseline and follow-up radiographs was observed in osteotomy gaps of up to 12 mm. With an overall complication rate of only 4% in osteotomy gaps of up to 12 mm, this new implant can be considered as a safe fixation device for ow HTO. However, because of two plate failures in osteotomy gaps of more than 12 mm without bone grafting, valgus-producing ow HTO does not work with the 2nd generation PEEKPower HTO-Plate® in these cases.

Existing Implants described in the literature

Several fixation devices for valgus-producing ow HTO are currently available, including an inlay system (iBalance medial opening wedge HTO system, Arthrex, Naples, Fl, USA)[27], short spacer plates with or without locking screws (e.g. Puddu plate, Arthrex, Naples, Fl, USA; Position HTO plate, Aesculap, Tuttlingen, Germany) and plate fixators without a spacer (e.g. TomoFix™ plate, Synthes Medical, Oberdorf, Switzerland; PEEKPower HTO-Plate®, Arthrex, Fl, USA).[4, 37, 69, 77 19]

iBalance medial opening wedge HTO system

Short spacer plates for ow HTO provide the advantage of a small design and therefore might provide low pain with fast improvements in clinical scoring. Moreover, a new inlay system (iBalance medial opening wedge HTO system) for valgus-producing ow HTO was introduced which is even smaller than a short spacer plate and therefore might provide better clinical results. It was shown that the clinical KOOS Score of a short spacer plate and the new inlay system improved significantly as early as 6 months after surgery without significant differences between each other.[27] Therefore 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.[27]

Puddu plate

The main advantage of the Puddu plate is its low profile design, which might avoid the need for implant removal.[7, 49] By using this plate, the functional Lysholm Score and WOMAC Score reach mean values up to 90 and 75 twenty-four months after surgery, respectively.[21, 58, 63 49] However, this plate shows high failure rates for ow HTO without a bone graft for augmentation of the osteotomy gap: In mean opening-wedges up to 11 mm, implant failures vary from 6% to 16%, osteotomies with broken screws were found in up to 21% and the pseudarthrosis rate rise up to 22%.[54 72] Secure fixation, low failures and little non-unions of the osteotomy gap fixed with a short spacer locking plate was only found with the use of a bone graft.[49 9, 21]

Position HTO plate

Another short spacer, the Position HTO plate (Aesculap, Tuttlingen, Germany) showed in a clinical study a significantly ($p > 0.05$) improved functional mean Lysholm Score twelve months after surgery (73) compared to preoperatively (56). The mean Tegner activity scale improved from 3 to 4 at the same timepoints.[69] However, high complication rates in a mean gap size of about 8 mm without a bone graft was also found: Screw failures with non-union occured in about 6% and the loss of correction rate was about 3%.[37, 69]

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.[8, 49] 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.[45, 54, 72]

TomoFix™ plate

Therefore, it is suggested, that angle stable plate fixators are favoured over short spacer plates to achieve a secure fixation after ow HTO without a bone graft. [4, 37, 61, 77] In biomechanical and in clinical studies, it was shown that short spacer plates with or without locking screws provide inferior axial and torsional stability and a loss of correction compared to the plate fixator TomoFix™ plate.[4, 37, 61, 65, 77] Pape et al.[61] compared the TomoFix™ plate and the 2nd generation Puddu plate over a 2 year period using radiostereometric analysis. Compared to patients treated with the TomoFix™ plate, a signifi-

cant higher lateral translation of the distal tibia and a significantly increased subsidence, varus and internal rotation of the tibial head was observed in patients treated with the 2nd generation Puddu plate. In clinical studies, valgus-producing ow HTO using the TomoFix™ plate has shown that the postoperative mean Lysholm Scores can improve significantly compared to preoperatively and can reach up to about 90 points out of 100.[23, 56, 57]

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. [56, 57] A further disadvantage is the predefined and non-variable direction of the locking screws, which is dictated by threads inside the screw holes.

1st generation PEEKPower HTO-Plate®

The 1st generation PEEKPower HTO-Plate® was introduced to overcome these drawbacks. The plate consists of a CF PEEK composition and is considerably smaller and lighter compared to a TomoFix™ plate. Furthermore this system provides multidirectional locking by threading the harder titanium screw heads into the none-threaded plate holes. Based on the first clinical data about the 1st generation PEEKPower HTO-Plate® (Cotic et. al., see Appendix) [19], significant improvements of the VAS Score, WOMAC Score, IKDC Score and Lyshom Score after ow HTO were recognized. According to part A of this work, the 1st generation PEEKPower HTO-Plate® provided the same clinical and radiographic results compared to the TomoFix™ plate. However, more implant related complications occured with the 1st generation PEEKPower HTO-Plate® (see part A). It was about 1 (4%) early screw loosening and 3 (12%) non-unions out of 26 patients. Implant related factors were thought to be a (too) high flexural strength, too shallow plate holes and the lag of a temporary lag screw.

The clinical results of the 2nd generation PEEKPower HTO-Plate®

For these reasons, a 2nd generation of the implant has been developed. The new 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.

In clinical studies, valgus-producing ow HTO using the TomoFix™ plate has shown that preoperative mean Lysholm Scores started at 50 and improved significantly up to about 90, twenty-four months postoperatively ($p < 0.05$). [23, 56, 57] In the present work, mean VAS Score, WOMAC Score and Lysholm Score after 2nd generation PEEKPower HTO-Plate® fixation were 2, 94 and 84 respectively and improved significantly compared to preoperatively (5, 70, 50 respectively; $p < 0.05$; see Table 8). Therefore, it is concluded that both, the TomoFix™ plate and the 2nd generation PEEKPower HTO-Plate® are viable implants for osteotomy fixation in valgus-producing ow HTO without bone grafting in osteotomy gaps up to 12 mm in terms of clinical results at 24 months after surgery. Although the implant was removed in 61% of the patients after a mean of 17 months, no significant differences in clinical scoring between the 12 and 24 months follow-up were found. 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. [56, 57] found significant improvements of the clinical scores between 12 and 24 months after ow HTO 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. It might be possible that the smaller size and the different material of the 2nd generation PEEK-Power HTO-Plate® causes less local irritation and does not provide a protracted clinical course. Therefore, implant removal could be nonessential with the 2nd generation PEEKPower HTO-Plate®.

Sporting Activity after ow HTO with the 2nd generation PEEKPower HTO-Plate®

In this study, 95% of patients were engaged in sporting activities, compared with 86% before surgery ($p = 0.32$). The number of different sport disciplines, the activity duration per week as well as the sporting intensity according to the Tegner scale did not change significantly from the year before surgery to 24 months after HTO (Table 9, $p > 0.05$). Only the sports frequency (sessions per week) changed significantly ($p < 0.05$) from

preoperative to postoperative (see Table 9). Regarding the ability for sporting activity after valgus-producing ow HTO with the TomoFix™ plate, Salzmann et. al.[68] found that 91% of patients were engaged in sports and recreational activities, compared with 88% before surgery ($p = 0.18$). The number of different sporting activities declined from one year preoperatively to thirty-six months after surgery (from 4 to 3 respectively) without significant differences ($p > 0.05$). Also, there were no significant differences in the sports frequency per week (2 session) and the activity duration per week (4 hours) preoperatively compared to postoperatively (2, $p = 0.21$; and 4 hours, $p = 0.71$, respectively). Declines were also noted in the Tegner scale (5±2 to 4±2, $p < 0.05$). These results indicate that valgus-producing ow HTO with the plate fixators 2nd generation PEEKPower HTO-Plate® and the TomoFix™ plate allow active patients to return to sports similar to their preoperative level. Moreover, if patients are motivated enough, they can held their sporting intensity and can also improve their sports frequency (sessions per week) without increasing pain in low- to moderate impact activities (only showed with the PEEKPower HTO-Plate®, see Table 9 and Figure 17). However, according to Bonnin et. al.[14], patients which are highly motivated to increase their preoperative sporting intensity must be informed, that strenuous activities after ow HTO will lead to pain and not to a recovery of the pre-pathology. In the Department of Orthopaedic Sports Medicine, Technical University of Munich, Germany, this information is generally given to a patient receiving ow HTO. Therefore, most patients in this study participated in low- to moderate impact activities 24 months after surgery (see Figure 17). Despite the fact that the patients were not allocated to do sports more often, their sports frequency improved significantly (see Table 9). In contrast, that was not shown in the patients with the TomoFix™ plate indicating even less sports frequency (sessions per week) and a decline of the sporting intensity (Tegner scale).[68] Whether the shorter and lighter PEEKPower HTO-Plate® is responsible for these better sports-related results was not observed. This situation must be proved by further comparative studies.

Loss of correction

Significant differences between baseline and follow-up measurements for MPTA and tibial slope were not recorded, indicating that loss of correction did not occure. However, only patients with an osteotomy gap of ≤ 12 mm were included in this evaluation. Loss of correction after ow HTO using the TomoFix™ plate was reported in 0-6% of patients [18, 37, 75, 78, 79] with osteotomy gap sizes up to 20 mm. It is therefore concluded that the 2nd generation PEEKPower HTO-Plate® provides at least equal fixation stability without bone grafting if the osteotomy gap height is ≤12 mm. However, the performance of this plate in osteotomy gaps of >12 mm is poor (see complications).

Complications

Non-union

One non-union (4%) occured in a patient with an iatrogenic fracture of the lateral hinge. The surgeon decided to replace the 2nd generation PEEKPower HTO-Plate® by the TomoFix™ plate. Because a 2nd generation PEEKPower HTO-Plate® was not used again, it might be reasonable, that the surgeon in this case had less than full confidence in this system at this timepoint.

No further non-unions were observed. In part A of this dissertation, a non-union rate of 12% was observed in the previous series with the 1st generation PEEKPower HTO-Plate®. These findings suggest that in terms of bone healing, the 2nd generation performed better than the 1st generation, possibly due to the reduced flexural strength of the plate. Compared to the non-union rate of the TomoFix™ plate, the literature reports incidences of 0-7%. [18, 23, 24, 37, 42, 51, 56, 57, 75, 78, 79, 81] It is therefore concluded that a 2nd generation PEEKPower HTO-Plate® and a TomoFix™ plate demonstrate nearly the same rate of non-unions after ow HTO.

Screw-loosening:

In two patients (8%), loosenings of one of the screws with accompanying loss of the corrected MPTA were observed. In both cases the osteotomy gaps of >12 mm experienced higher forces than designated for the early postoperative rehabilitation period of this procedure. According to part A of this dissertation, the 2nd generation PEEKPower HTO-Plate® has been introduced to avoid screw loosenings. That was done by improving the geometry of the screw holes as well as by reducing the flexural strength of the plate. Moreover, the literature described screw breakages during extraction but no

screw looesenings of the TomoFix™ plate after ow HTOs with osteotomy gap sizes up to 20 mm. [81] With critical analysis, the modified screw hole geometry and the changed flexural strength of the 2nd generation PEEKPower HTO-Plate® do not endure increased loads in the bone anchoring after ow HTO with osteotomy gaps of >12 mm. Therefore it is concluded that the safety of the 2nd generation PEEKPower HTO-Plate® is at least equal to the TomoFix™ plate, as long as the osteotomy gap is not larger than 12 mm.

Study limitations

There is no control group existing. Nevertheless, the data of part B of this dissertation were compared to the current results of the literature for valgus-producing ow HTO. Because the patients were only followed for 24 months, no conclusion about the further clinical course of the patients can be drawn. However, a follow-up of 24 months was adequate because significant improvements of the clinical scores after ow HTO are within the first 24 months and afterwards they are unchanged. [2, 34, 52, 57, 73] Concerning the method to determine the amount of correction loss, serial long-leg weight bearing AP radiographs or radiostereometric analysis might have been more accurate in every patient. Unfortunately, these methods were not allowed by the ethics commitee. However, by evaluating the correction loss in two standard planes (frontal and sagittal), the accuracy of the radiological analysis increased.

Conclusion

The 2nd generation PEEKPower HTO-Plate® is a safe and efficient implant for valgus-producing open wedge high tibial osteotomy without bone grafting and in osteotomy gaps of up to 12 mm. Valgus-producing ow HTO with this implant demonstrates favorable clinical results as early as 12 months after surgery and allows active patients to return to their preoperative sports-status with a higher frequency. Compared to a standardized TomoFix™ plate, it might be possible that the 2nd generation PEEKPower HTO-Plate® causes less local irritation and therefore implant removal could be nonessential. For ow HTO with osteotomy gaps of >12 mm, it is recommended to use a bone graft or to use the standardized TomoFix™ plate for fixation.

8 Summary and Perspective

In the first part (part A) of this dissertation, for osteotomy fixation in valgus-producing ow HTO, twenty-six 1st generation PEEKPower HTO-Plates® were compared with twenty-six TomoFix™ plates. The main finding was that the 1st generation PEEKPower HTO-Plate® provided the same clinical and radiographic results as the TomoFix™ plate at a minimum follow-up of 24 and 12 months respectively. However, more implant related complications occured with the 1st generation PEEKPower HTO-Plate®. Considering the drawbacks of the 1st generation PEEKPower HTO-Plate®, a 2nd generation PEEK-Power HTO-Plate® was introduced to achieve no implant failure.

Therefore, the purpose of the second part of this work (part B) was to prospectively evaluate if valgus-producing ow HTO without bone grafting using the 2nd generation PEEKPower HTO-Plate® is safe. The most important finding was that ow HTO without bone grafting in osteotomy gaps of up to 12 mm showed significantly improved knee function and pain situation as early as 12 months after surgery. Ow HTO allowed active patients to return to their sports-status 1 year before surgery with a higher frequency. Compared to the TomoFix™ plate in the literature, there is a tendency that the 2nd generation PEEKPower HTO-Plate® causes less local irritation and therefore implant removal could be nonessential. With an overall complication rate of 4% in osteotomy gaps of up to 12 mm, this new implant can be considered as a safe fixation device for ow HTO. Because of two plate failures in osteotomy gaps >12 mm without bone grafting, valgus-producing ow HTO does not work with the 2nd generation PEEKPower HTO-Plate® in these cases. For ow HTO with osteotomy gaps >12 mm, it is recommended to use a bone graft or to use the standardized TomoFix™ plate for fixation.

9 List of Abbreviations

ACL	anterior cruciate ligament
AP	anteroposterior
BMI	body mass index
CF PEEK	carbon fiber reinforced polyetheretherketone
e.g.	for example
et al.	abbreviation from Latin et alii (and others)
Gr	Group
HTO	high tibial osteotomy
IQR	interquartilrange (25th-75th percentile)
ys	years
kg/ m^2	kilogram/ square meter
MACI	matrix associated autologues chondrocyte implantation
mm	millimeter
MPTA	anatomical medial proximal tibial angle
ms	months
n	number of patients
n.r.	not reported
OAT	osteochondral autologues transfer
ow	open wedge
SD	standard deviation
TS	tibial slope
VAS	visual analogue scale
*	statistical significant difference ($p < 0.05$)
#	no statistical significant difference ($p > 0.05$)
°	degree
%	percentage

10 List of Tables

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12 References

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13 Appendix

Publications:

Cotic M, Slotta-Huspenina J, Noël PB, Imhoff AB. Paper # 69: Two-Year Result of Open-Wedge Tibial Osteotomy with Fixation by the PEEKPower HTO-Plate for Varus Malalignment with Unicompartimental Osteoarthritis of the Knee. *Arthroscopy : the journal of arthroscopic & related surgery : official publication of the Arthroscopy Association of North America and the International Arthroscopy Association.* 2011;27:e111-e112.

Ethics approval

Patient summary of part A

Patient questionnaire of part A

White paper about the biomechanical observation provided by Arthrex

Patient questionnaire of part B

osteotomy (OWHTO), we shall investigate two variables: implant stability and integrity of the opposite cortex.
Methods: Experimental models of polyurethane fibers simulating the proximal segment of the tibia were fixed with DCP ®, T-LCP ® and Tomofix ® plates. Conventional and locking head screws were used to stabilize the medial side. Opening wedges were made to simulate the distraction of high tibial osteotomy in the medial side. Tests were also performed on models in the lateral side with normal(NL) and broken cortex (GAP) within space between the cortices to simulate fractures. The lateral cortices in the GAP groups were fixed with 2 different types of screws to check the stability of the system in cases where it unintentionaly breaks. Torsion and axial compression tests were assessed by simulating a level walk. Compression load was measured at a point at 62% of the medial margin corresponding to an overcorrection of the mechanical axis. According to the assemblies 10 different groups were formed. The mechanical tests reported the relative stiffness and deformation percentage.
Results: The lateral compression or position stabilization screw was as rigid as normal cortical (NL) ($p < 0.001$) in torsion tests. Measures of compression obtained in the group with non damage cortical (NL) were similar between the models with conventional fixation and fixed-angle ($p > 0.05$). The lateral compression or position stabilization screw with broken cortex were statistically lower when compared with the group of normal lateral cortex implants ($p < 0.001$).

The Tomofix® plate showed superior torsion stability ($p < 0.001$) with normal lateral (NL) and broken cortex (GAP). In axial compression tests, the implants showed similar mechanical outcomes between the groups.
Conclusion: In an experimental model, using different methods of fixation in OWHTO, DCP ®, T-LCP ® and Tomofix ® plates proved to be a stable option for mechanical forces to simulate a level walk. The lateral cortex is relevant to the stability of the system in OWHTO.

Paper # 68: Effect of High Tibial Osteotomy on Medial Meniscus Degenerative Root Tear and Varus
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Summary:
Open high tibial osteotomy should be combined with meniscectomy to improve functional outcomes

Abstract:
Purpose: We compared the clinical and radiological results of meniscectomy with HTO or without HTO for medial meniscus degenerative root tear with varus deformity.
Methods: Fifty-four patients who had medial meniscus degenerative root tear with varus deformity more than 3 degrees were included for this study. Among them, 30 patients were performed meniscectomy combined with open wedge HTO and 24 patients were performed meniscectomy without HTO. The mean follow-up period was 52.5 months (36-76.6). The clinical results were evaluated based on symptom improvement, patient's satisfaction and HSS score. Mechanical femorotibial angle and osteoarthritic progression were evaluated on preoperative and at last follow-up radiograph.
Results: Symptom improvement was achieved in 83.3%(25 cases) with HTO group and 66.7% (16 cases) without HTO group and it showed statistically significant difference($p=0.04$). Patient's satisfaction was achieved in 83.3% (25 cases) with HTO group and 58.3% (14 cases) without HTO group, which showed significant difference ($p=0.03$). The HSS score was improved from 56.9 preoperatively to 90.8 at last follow up with HTO group and 67.9 preoperatively to 89 at last follow up without HTO group with no significant difference ($p=0.95$). Mechanical femorotibial angle was corrected from mean 6.5°(3.1~12.4) varus preoperatively to 2.6°(0.3~6.4) valgus with HTO group and from mean 5.6°(3.6~9.9) varus preoperatively to 6.6°(4.6~10.6) varus without HTO group. Osteoarthritis progression with HTO group was 7 cases (23%) and 4 cases (33%) without HTO group ($p=0.07$).
Conclusions: Meniscectomy with HTO group showed significantly better results in symptom improvement and satisfaction. However, HSS score and OA progression showed no significant difference between two groups.
Summary: For degenerative posterior root tear of medial meniscus with varus deformity, open high tibial osteotomy should be combined with meniscectomy to improve functional outcomes.

Paper # 69: Two-Year Results of Open-Wedge Tibial Osteotomy with Fixation by the PEEKPower HTO-Plate for Varus Malalignment with Unicompartimental Osteoarthritis of the Knee *Matthias Cotic, MSc, GERMANY*
Julia Slotta-Huspenina, MD, GERMANY
Peter Benjamin Noël, PhD, GERMANY
Andreas B. Imhoff, MD, Prof., GERMANY · Department of Orthopaedic Sports Medicine
Munich, Bavaria, GERMANY

Summary:

In this prospective study it was the challenging subject to stabilize open-wedge tibial osteotomy with a new internal fixation system which does not predefine the placement of the screws in a multimodal concept of joint preservation.

Abstract:

Objectives: According to varus malalignment with unicompartimental osteoarthritis of the knee, open-wedge high tibial osteotomy (HTO) is an established intervention to treat young and active patients. To stabilize the osteotomy cleft, current internal fixation devices offer improvements but do still show aspects of weakness. The new PEEKPower HTO-Plate (Arthrex, Karlsfeld, Germany) was developed and authorized to improve intraoperative handling and postoperative outcome by combining the advantages of a multi directional system and eliminating the disadvantages of cross threading.

Methods: We present a prospective study of open-wedge HTO with fixation by the first clinical proven and available PEEKPower HTO-Plate. Thereby we accept varus malalignment with mild to severe unicompartimental osteoarthritis of the knee. After predrilling with a 4.3 mm drill, the anatomically shaped, nonbendable and threadless peek plate (length: 95 mm; thickness: 3.2 mm) is fixed to the bone with seven 5.0 mm titanium locking head screws with threaded conical heads. Therefore we create a locked and angular stable screw-plate construct while the plate only has contact with its rim to the periosteum.

Results: From May until October 2008 a total of 25 patients (5 female, 20 male) with a mean age at surgery of 40.4±11.4 years underwent open-wedge osteotomy (gap: 9.5±3.5mm) stabilized with the PEEKPower HTO-Plate. According to the underlying pathology, twenty-five cases were combined with 5 cruciate ligament reconstructions, 10 medial chondral resurfacings and 6 medial meniscectomies.

Analysis of the clinical program after HTO revealed that all patients showed significant improvement ($p<0.05$) 2 years after surgery based on the following scores: Visual Analog Scale (pre-op 5.3±2.6, post-op 2.2±2.3), Lysholm (pre-op 46.0±18.8, post-op 80.9±20.2), IKDC (pre-op 50.2±16.3, post-op 70.4±15.7) and WOMAC (pre-op 23.5±14.7, post-op 9.5±10.2).

Conclusions: The number of subjects evaluated in this study is small. However, all patients (100%) stabilized with the PEEKPower HTO-Plate had improved scores in this multimodal concept of joint preservation. Additionally the artifact free radiological data show a safe fixator until complete ossification. Within the histological tissue analysis no negative findings such as a severe or specific inflammation were found.

Paper # 70: Ibalance High Tibial Osteotomy with Concomitant Meniscal Scaffold Implantation ***Konrad Slynarski, MD, PhD, POLAND***

Emilia Kurowska, PT, POLAND

Tadeusz Tomasz Scinski, MD, PhD, POLAND · CMS Sports Medicine Center
Warszawa, POLAND

Summary:

High tibial osteotomy with concomitant medial meniscus scaffold repair results in higher level of knee function comparing to group treated with osteotomy and debridement alone.

Abstract:

Purpose: Medial open wedge high tibial osteotomy (MOWHTO) is common procedure of treatment option for patients with symptomatic medial compartment knee arthritis associated with varus osseous deformity.

MOWHTO correct only knee alignment, but does not correct intraarticular pathologies of medial compartment.Our hypothesis was that patients with malalignment and medial meniscus loss would benefit with concomitant MOWHTO and meniscus repair with bioresorbable meniscus implants.

Material and Methods: In this study, we evaluated 30 patients aged between 39 to 65 years, treated for symptomatic early medial compartment knee arthritis. All of them underwent medial open wedge high tibial osteotomy with innovative Ibalance system using PEEK wedge implant and anchors. Patients were subdivided into three groups, each consisting of ten patients, in respect to type of treatment for medial meniscus loss. First group of patients underwent medial opening wedge osteotomy with concomitant arthroscopic medial meniscus repair with collagen implants. Second group underwent the same procedure using polyurethane meniscus implants . Each of the patients was case-matched to a control patient from third group who had undergone MOWHTO using the same system with concomitant debridement arthroscopy. Weight-bearing status, range of motion restrictions, muscle strengthening, proprioceptive retraining and soft tissue care (dealing with swelling and the avoidance of fat pad contraction) are the main goals of rehabilitation. Patients were evaluated with specific quality of life (KOOS), SF 36 and radiographic assessments of union and maintenance of correction. Clinical union was measured by the patient's ability to full weight bear and walk without the use of crutches.

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(English Version August3th 2012)
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Im Hause

25.05.2012
Project-No.: **5392/12**

Dear Mr Cotic,
dear Dr. Vogt,

the project **„Auswertung und Publikation von Patientenfragebögen"** (aus einer matched-pair Analyse zweier unterschiedlicher CE-Implantate Tomofix Platte, PEEKPower HTO-Platte) zur Stabilisierung der Hohen Tibialen Umstellungsosteotomie)" has been reviewed today by the *Ethikkommission der Fakultät für Medizin der Technischen Universität München* (Ethics Committee of the Faculty of Medicine of the Munich University of Technology).

The proposal is approved from an ethical and legal point of view.

Yours sincerely

Prof. Dr. G. Schmidt
Member of Ethics Committee

Die Ethikkommission der Fakultät für Medizin der Technischen Universität München arbeitet gemäß den nationalen gesetzlichen Bestimmungen und den ICH-GCP-Richtlinien.
Mitteilungen über schwerwiegende oder unerwartete unerwünschte Ereignisse sind mit einer Stellungnahme des Prüfarztes zum Nutzen/Risiko-Verhältnis des Vorhabens einzureichen (§ 40, Abs. 1, Satz 4 AMG)
Bei Vorlage von Amendments sind Änderungen oder Ergänzungen deutlich zu kennzeichnen.
Der Prüfarzt sollte die Protokolländerungen (aufgeteilt nach „wesentlichen" und „nicht wesentlichen" Änderungen) einzeln auflisten und mitteilen, ob die Änderungen nach seiner Ansicht ethisch relevant sind. Falls erforderlich, ist eine revidierte Patienteninformation/ Einverständniserklärung einzureichen.
Nach Publikation der Studie bittet die Ethikkommission um Zusendung eines Sonderdruckes.

Patient-Nr.	Man(1), Woman(0)	Age (years)	BMI (kg/m²)	Varus (°)	valgus position (%)	VAS-Score	Kellgren-Score
1	1	58	29	7	55	8	4
2	0	47	29	11	55	6	4
3	0	49	30	5	62	7	3
4	1	38	26	6	62	5	3
5	1	20	25	4	55	2	1
6	1	47	27	6	62	5	2
7	1	50	27	10	55	6	4
8	0	38	26	2	62	8	2
9	1	54	35	5	62	5	3
10	1	25	26	4	55	0	1
11	1	57	28	10	62	6	3
12	1	24	23	4	55	4	1
13	1	48	33	4	55	7	3
14	1	45	29	3	55	4	4
15	1	43	37	4	55	9	2
16	0	31	27	2	62	8	2
17	1	36	30	3	62	4	3
18	1	44	26	6	62	2	2
19	1	20	21	10	55	4	2
20	0	43	32	4	62	10	4
21	1	30	25	7	62	8	3
22	1	25	23	2	62	5	2
23	1	48	23	9	62	2	3
24	1	40	26	4	62	8	2
25	0	49	25	2	62	4	3
26	1	51	27	5	62	8	3

Patient-Nr.	Man(1), Woman(0)	Age (years)	BMI (kg/m²)	Varus (°)	valgus position (%)	VAS-Score	Kellgren-Score
27	1	42	12	4	55	8	3
28	1	58	30	4	70	2	3
29	0	48	25	3	62	9	3
30	1	44	25	1	67	7	2
31	1	39	29	6	62	6	4
32	1	43	38	5	55	4	3
33	1	32	26	4	55	2	3
34	1	44	23	1	62	8	3
35	1	26	24	7	55	4	2
36	1	58	29	6	62	4	3
37	1	52	28	1	55	4	3
38	1	57	29	9	62	7	4
39	1	38	28	6	62	6	3
40	1	46	29	4	62	3	4
41	1	44	26	2	67	2	3
42	0	43	23	1	55	0	3
43	1	62	31	6	55	5	3
44	1	44	26	6	62	6	2
45	1	43	25	10	62	3	3
46	1	33	26	4	62	0	3
47	0	26	21	1	62	3	3
48	0	62	24	5	55	7	3
49	1	31	21	10	62	3	3
50	1	35	29	6	62	3	3
51	1	48	28	8	62	5	3
52	1	35	25	2	62	6	3

all values are in round figures
The PEEKPower HTO-Plate was used in Patient-Nr. 1 - 26, the TomoFix plate was used in the rest
For convenience the valgus position was classified in the 62% or 55% coordinate as follows:
A 62% intraoperative valgus position included all patients with a coordinate from 60% to 65%
A 55% intraoperative valgus position included all patients with a coordinate from 50% to 59%

Patient-Nr.	Man(1), Woman(0)	Age (years)	BMI (kg/m²)	Varus (°)	valgus position (%)	VAS-Score	Kellgren-Score
53	1	56	30	5	62	7	3
54	1	30	28	4	55	3	3
55	0	46	23	4	62	4	4
56	1	33	27	3	62	6	2
57	1	48	28	4	62	3	4
58	1	42	27	4	55	4	3
59	1	53	28	7	55	5	3
60	0	43	25	5	62	2	3
61	0	45	21	9	62	3	4
62	1	45	22	5	55	5	2
63	1	52	26	2	62	9	3
64	1	57	26	6	62	5	4
65	1	42	21	5	55	2	3
66	1	46	32	9	55	8	3
67	0	48	29	2	62	5	3
68	1	43	28	10	62	8	4
69	1	46	28	3	55	4	3
70	1	38	30	6	62	7	3
71	1	33	30	5	62	8	3
72	1	48	35	4	55	9	2
73	0	46	22	5	62	6	3
74	1	50	30	9	62	7	3
75	0	28	32	0	55	7	4
76	1	38	24	6	62	8	3
77	1	58	30	4	68	8	2
78	1	60	28	5	62	8	4

Patient-Nr.	Man(1), Woman(0)	Age (years)	BMI (kg/m²)	Varus (°)	valgus position (%)	VAS-Score	Kellgren-Score
79	1	39	28	2	62	8	4
80	0	42	21	2	62	5	3
81	0	47	30	10	55	6	4
82	1	50	32	6	55	9	3
83	0	52	21	3	62	6	3
84	1	23	21	4	55	4	1
85	0	43	23	5	62	9	2
86	1	47	27	4	55	5	2
87	1	25	24	3	62	4	2
88	1	39	32	5	55	3	2
89	1	32	26	4	55	2	2
90	1	43	30	7	62	6	2
91	1	42	25	4	55	4	2
92	1	50	27	3	62	3	4
93	0	24	25	1	55	5	2
94	1	51	24	9	55	7	3
95	0	30	25	4	55	7	2
96	0	57	29	7	55	8	4
97	0	26	27	6	55	6	3
98	0	52	22	11	62	9	3
99	1	30	43	4	55	6	3
100	1	57	26	8	55	10	3
101	1	36	27	4	62	4	2
102	1	46	28	1	55	6	3
103	1	51	28	6	62	7	3
104	1	43	28	4	55	3	2

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A 55% intraoperative valgus position included all patients with a coordinate from 50% to 59%

Patient-Nr.	Man(1), Woman(0)	Age (years)	BMI (kg/m²)	Varus (°)	valgus position (%)	VAS-Score	Kellgren-Score
105	1	47	25	9	62	3	3
106	0	39	25	2	62	7	2
107	0	45	27	3	62	0	2
108	1	37	26	1	62	6	2
109	0	22	22	4	55	4	3
110	0	41	27	0	55	5	3
111	0	53	28	2	55	8	2
112	1	44	29	2	62	5	3
113	1	51	28	4	62	5	4
114	1	52	28	5	55	0	2
115	1	27	30	4	55	2	1
116	1	31	27	13	55	8	3
117	1	43	29	4	62	5	2
118	1	46	29	4	55	5	3
119	1	53	32	4	55	8	3
120	0	44	22	0	62	7	4
121	1	25	28	4	55	1	1
122	1	61	27	10	62	7	3
123	1	35	25	3	55	2	2
124	0	50	26	5	62	3	2
125	0	47	28	5	62	6	3
126	1	55	25	4	55	7	4
127	1	56	25	9	55	8	4
128	0	51	23	4	55	3	3
129	1	50	23	9	55	8	3
130	1	57	24	12	62	3	4

Patient-Nr.	Man(1), Woman(0)	Age (years)	BMI (kg/m²)	Varus (°)	valgus position (%)	VAS-Score	Kellgren-Score
131	1	42	24	6	62	5	4
132	1	50	26	9	62	8	4
133	1	55	27	7	55	7	3
134	1	53	28	4	62	2	3
135	1	53	32	5	55	3	2
136	0	40	27	4	55	7	2
137	1	41	22	6	55	4	2
138	1	58	23	9	55	3	2
139	1	51	25	7	55	7	4
140	1	50	30	6	62	2	2
141	0	56	22	7	62	2	4
142	1	43	32	1	55	4	2
143	1	52	26	7	62	7	4
144	1	44	33	8	55	6	3
145	1	43	27	6	55	3	2
146	1	43	35	2	62	6	2
147	1	68	24	8	55	6	2
148	0	43	22	4	55	7	2
149	1	48	30	5	62	6	2
150	1	51	25	3	62	3	3
151	0	47	24	4	55	8	2
152	0	31	24	5	55	2	3
153	1	47	22	5	55	5	3
154	1	42	28	3	55	5	3
155	1	24	28	3	55	8	3
156	1	52	26	3	55	6	3

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Patient-Nr.	Man(1), Woman(0)	Age (years)	BMI (kg/m²)	Varus (°)	valgus position (%)	VAS-Score	Kellgren-Score
157	1	46	24,44	2	55	4	3
158	0	50	34,66	5	62	10	4
159	0	28	22,21	2	55	8	3
160	1	53	24,69	3	62	7	3
161	1	34	26,12	4	62	5	3
162	0	15	22,49	5	55	2	0
163	0	46	26,37	4	62	3	3
164	1	45	26,30	3	55	5	4
165	1	46	27,10	8	55	4	2
166	1	43	28,41	3	62	8	3
167	1	40	23,92	2	55	7	2
168	1	49	28,34	6	62	2	4
169	1	60	28,38	9	55	6	4
170	0	41	27,22	4	55	6	3
171	1	48	26,88	4	55	3	2
172	1	40	27,77	3	55	2	3
173	1	54	29,41	4	55	7	3
174	1	47	28,04	9	55	0	4
175	0	45	25,34	6	55	6	3
176	1	33	28,08	6	55	6	3
177	0	60	34,49	5	62	7	4
178	1	63	27,77	7	55	2	3
179	1	43	28,72	4	55	2	3
180	1	41	28,31	5	55	7	3
181	0	41	22,49	8	55	2	3
182	1	45	24,14	2	55	4	3
183	0	41	19,03	4	55	8	3
184	1	34	24,15	2	55	7	2
185	1	62	29,94	9	62	8	4
186	1	46	32,14	6	55	7	4

all values are in round figures
The PEEKPower HTO-Plate was used in Patient-Nr. 1 - 26, the TomoFix plate was used in the rest
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des Klinikum rechts der Isar
der Technischen Universität München
Anstalt des öffentlichen Rechts

Vorstand: Univ.-Prof. Dr. A. B. Imhoff

Fragebogen zu Ihrer Umstellungsoperation am Kniegelenk

Sehr geehrte Patientin, sehr geehrter Patient,

ihr freundliches Einverständnis vorausgesetzt, würden wir Sie bzw. Ihr Kniegelenk gerne mit Hilfe der folgenden Fragebögen (s.u.) beurteilen. Falls Sie andere Beschwerden, z.B. an anderen Gelenken haben, so blenden Sie diese für die Beantwortung des Fragebogens bitte aus.
Die Teilnahme an dieser Befragung ist völlig freiwillig und hat keinerlei Auswirkung auf Art und Qualität ihrer Behandlung. Selbstverständlich können Sie Ihre erteilte Zustimmung ohne Angabe von Gründen jederzeit widerrufen.
Die Befragung und die daraus resultierenden Ergebnisse sind Inhalt einer klinischen Studie, die später von uns veröffentlicht wird. Die Veröffentlichung der Daten geschieht völlig anonym. Wenn Sie sich etwa fünfzehn Minuten Zeit nehmen, um die folgenden Fragebögen auszufüllen, würden Sie der universitären Wissenschaft einen großen Schritt weiterhelfen.
Die Befragungstermine finden an den regulären Kontrollterminen in unserer Ambulanz statt oder es werden Ihnen die Fragebögen incl. frankiertem Rückumschlag per Post zugesandt. Dies alles soll für Sie keine Mehrbelastung bedeuten.

Wenn Sie mit der anonymen Befragung einverstanden sind, bitten wir Sie, mit Ort, Datum und Unterschrift Ihr Einverständnis schriftlich niederzulegen.

Vielen Dank für Ihre Kooperation.

Ort, Datum, Unterschrift

1. Allgemeine Daten

Name _____

Vorname _____

Telefon _____

Email _____

Adresse _____

Geb. Datum _____

_____ _____ _____

Alter Größe Gewicht

---

2. Allgemeine Fragen

Nehmen Sie derzeit Schmerzmedikamente wegen des Knies?

Ja, regelmässig ☐ Ja, bei Bedarf ☐ Nein ☐

Wenn Sie Sport treiben/ Rehabilitationstraining machen, müssen Sie dann zur Durchführung Schmerzmedikamente nehmen?

Ja, regelmässig ☐ Ja, bei Bedarf ☐ Nein ☐

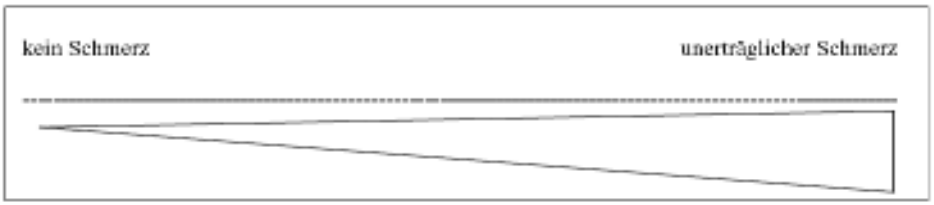
---

3. VAS

Visuelle Analogskala = subjektive Einschätzung Ihrer Schmerzen

Wie beurteilen Sie den Schmerz in Ihrem Knie?

Bitte ankreuzen:



4. LYSHOLM- Kniescore

Bitte kreisen Sie den entsprechenden Punktwert ein.

	Punkte
1. Hinken oder humpeln Sie ?	
a) nie	5
b) wenig oder nur zeitweise	3
c) schwer und ständig	0
2. Benötigen Sie eine Gehilfe?	
a) nein	5
b) Stock oder Krücke	3
c) gehunfähig	0
3. Treppensteigen?	
a) problemlos	10
b) etwas erschwert	6
c) langsam, Stufe um Stufe	2
d) unmöglich	0
4. In die Hocke gehen?	
a) problemlos	5
b) etwas erschwert	4
c) schwer möglich (nicht über 90°)	2
d) unmöglich	0
5. Unsicherheitsgefühl im Kniegelenk?	
a) nie	30
b) selten beim Sport oder schweren Anstrengungen	25
c) häufig beim Sport oder schweren Anstrengungen	20
d) gelegentlich bei Alltagsarbeiten	10
e) oft bei Alltagsarbeiten	5
f) bei jeder Bewegung bzw. jedem Schritt	0
6. Schmerzen?	
a) keine	30
b) ab und zu ein wenig bei schwerer Anstrengung	25
c) Auftreten bei Knieunsicherheit	20
d) Auftreten bei schweren Anstrengungen	15
e) Auftreten während oder nach einem Spaziergang von mehr als 2 km Länge	10
f) Auftreten während oder nach einem Spaziergang von weniger als 2 km Länge	5
g) ständig und stark	0
7. Schwellung des Kniegelenkes ?	
a) keine	10
b) bei Knieunsicherheit	7
c) bei schwerer Anstrengung	5
d) bei leichter Anstrengung	2
e) ständig	0
8.Muskelschwäche des/ der Beine(s) ?	
a) keine	5
b) gering (Oberschenkelumfang 1-2 cm verringert)	3
c) ausgeprägt (Oberschenkelumfang mehr als 2 cm verringert)	0

5. WOMAC-Score

Bitte kreuzen Sie das entsprechende Feld an.

Teil A

Wie schwer sind Ihre Schmerzen?

	keine	**leichte**	**mittelschwer**	**schwer**	**sehr schwer**
1.Gehen auf flacher Ebene					
2.Treppensteigen					
3.Während der Nachtruhe					
4.Sitzend oder liegend					
5.Aufrecht stehend					

Teil B

1. Wie schwer ist die Gelenksteifheit nach dem morgendlichen Aufstehen?
keine leicht mittelschwer schwer sehr schwer

2. Wie schwer ist die Gelenksteifheit nach dem Sitzen, Liegen oder Ruhen während des Tages?
keine leicht mittelschwer schwer sehr schwer

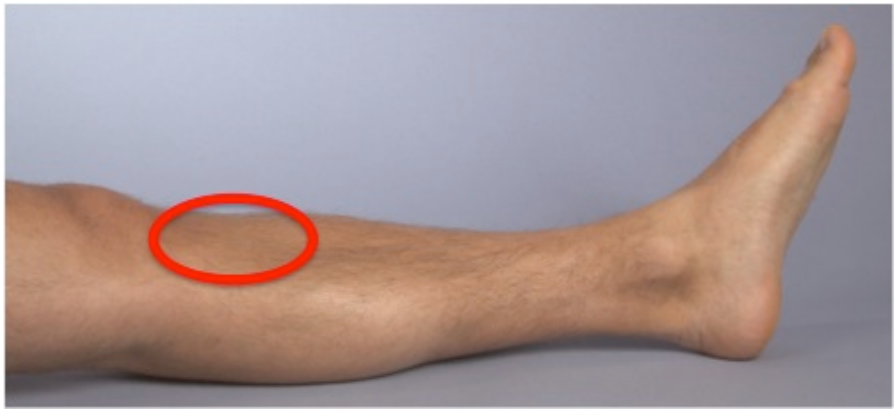
Teil C

Wie schwierig ist für Sie ?

	einfach	**eingeschränkt**	**mittel**	**schwer**	**sehr schwer**
1. Treppen hinabsteigen					
2. Treppen hinaufsteigen					
3. Aufstehen aus dem Sitzen					
4. Stehen					
5. Zum Boden bücken					
6. Gehen auf flachen Boden					
7. In/Aus dem Auto steigen					
8. Einkaufen gehen					
9. Strümpfe anziehen					
10. Aufstehen aus dem Bett					
11. Strümpfe ausziehen					
12. Im Bett liegen					
13. In/Aus der Badewanne steigen					
14. Sitzen					
15. Auf die Toilette Setzen/ wieder Aufstehen					
16. Schwere Hausarbeit					
17. Leichte Hausarbeit					

6. Fragen zu Ihrer Schmerzhaftigkeit des Plattenlagers

Bitte geben Sie auf einer Skala von 0 bis 10 an, wie hoch Ihre Schmerzhaftigkeit des Plattenlagers auf Ihrem Unterschenkel (siehe Kreis im Bild) nach Ihrer Umstellungsosteotomie (HTO) ist. 0 bedeutet gar keine Schmerzhaftigkeit und 10 die höchste Schmerzhaftigkeit.



Zeitpunkt:	**2 Tage vor der Plattenentfernung**
Bitte geben Sie jetzt eine Zahl **zwischen 0 und 10** an:	

7. OP-Zufriedenheit

Sehr zufrieden ☐ Zufrieden ☐ Bedingt zufrieden ☐ Unzufrieden ☐

Herzlichen Dank für Ihre Mithilfe. Sie unterstützen uns in unserem steten Bemühen, den Wünschen und Ansprüchen von Patienten besser zu genügen

PEEKPower High Tibial Osteotomy Plate

Introduction

The medial opening wedge technique for high tibial osteotomies (HTO) is now a well-established method for the treatment of medial unicompartimental osteoarthritis of the knee (1). Compared to the traditional lateral closed-wedge technique, which is accompanied with a removing bone wedge procedure at the proximal tibia, the popularity of the HTO can be ascribed to advantages of maintaining bone stock and no necessity to perform a fibular osteotomy. The success of the HTO outcome relies on the preservation of the appropriate correction angle and bony consolidation postoperatively. Thus a stable osteotomy fixation is mandatory during the time frame of bone healing in order to minimize the risk of non-union and loss of correction. In recent studies the biomechanical behavior of different implant designs for HTO fixation has been assessed within distinct study designs (2; 3; 4; 5; 6). Due to varying load application, specimen preparation and the large range of dissimilar used osteosynthesis systems a directly biomechanical comparison with regard to fixation stability is difficult.

Within a preclinical experimental study the peek-carbon composite PEEKPower High Tibial Osteotomy Plate (Arthrex, München, Germany) was tested using a composite tibia sawbone model under static as well as dynamic loading and compared to a titan plate (TomoFix™, Synthes Medical., Bettlach, Switzerland). The purpose of this study was to evaluate the biomechanical behavior of these two plate systems in a comparable worst case compression bending test design.

Material & Methods

Two different HTO plates were tested in preclinical static and dynamic (each n=5) compression bending tests. Therefore a peek-carbon composite system (PEEKPower HTO-Plate®) as well as titanium plates (TomoFix Plate™) were used (Fig. 1b). All tests were performed at EndoLab® Mechanical Engineering GmbH (Rosenheim, Germany). The plate was mounted onto an artificial bone (large left tibia, Sawbone) 15 mm below the medial rim of the tibia plateau (Fig. 1a). A gap of 10 mm was applied between 40 and 50 mm below the medial rim of the tibial plateau. The plate was hand-tight fixed with four proximal and three distal bicortical screws, each with a diameter of 4 mm. Maximum loads for the endurance tests ranged overall from 80 to 220 N and were applied in the centre of the tibia plateau along the shaft axis (Fig 1c). The minimum dynamic load was set to 10 % of the maximum load. The tests were performed dry in ambient air at room temperature with a test frequency of 5 Hz for dynamic tests. The static load was applied with a loading rate of 5 mm/min. Dynamic tests have been stopped after attainment of 3 million load cycles or functional implant failure.

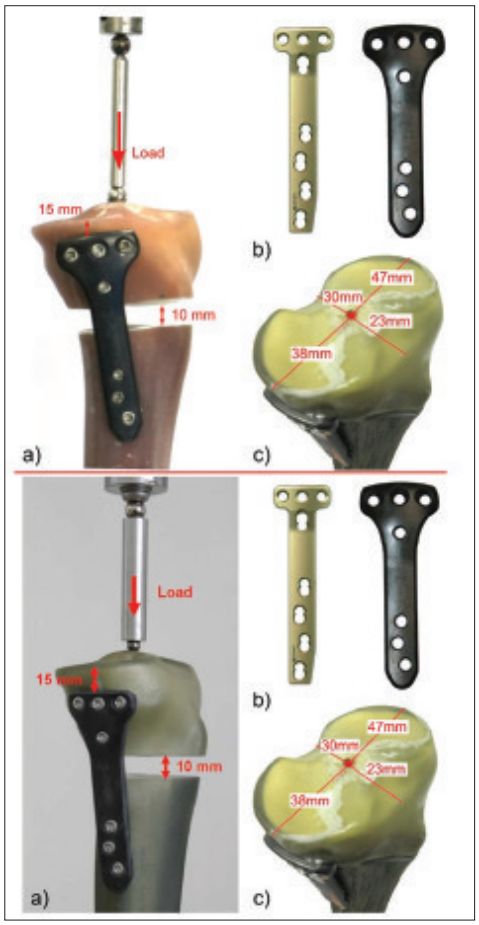


Fig. 1 Experimental set-up with load application and bone gap definition (a, c) for both HTO plates (b)

Results

The static compression bending tests revealed a distinct elastic-plastic deformation behavior between both plate constructs. Thereby higher construct stiffness, with decreased ultimate load as well as decreased ultimate displacement was assessed for the peek-carbon composite plates (Tab.1). While the titan plate test was terminated before tibial bone contact, failed the peek plate due to distal screw backout.

Specimen	Ultimate load [N]	Ultimate displacement [mm]	Stiffness [N/mm]	Plate material
1	230	7.53	77.0	Titanium
2	200	6.54	87.3	PEEK-carbon

Tab. 1:Results for the static compression bending tests

A relationship between applied dynamic loads and reached cycles until test stop were obtained in a lifetime diagram (Fig. 2). The lifetime curves are functional derived with power laws, which are shown in a semi-logarithmic manner. For both specimen groups lifetimes decrease with increasing loads. Compared to the peek carbon composite test results the titanium results reveal decreased lifetimes at lower load levels, but show a tendency to compensate this mismatch at higher load levels. Within the same test set up the titanium plate reached run out level at a maximum applied dynamic load of 80 N, while the peek-carbon composite system revealed a higher load with 160 N. All titanium plate specimens, with an early functional failure exhibit fracturing of the plate at the superior screw hole close to the resection line, whereas the peek-carbon composite plate specimens failed due to distal screw backouts.

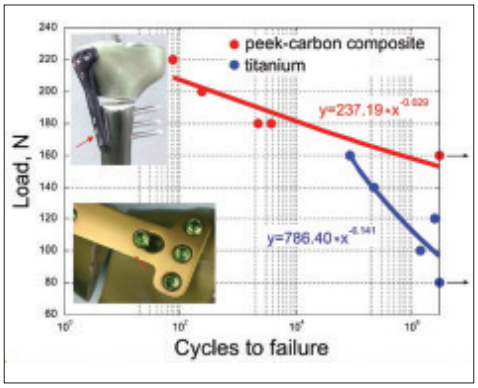


Fig. 2: Endurace curves for peek-carbon composite and titanium plates with mode of failure. Black arrows represent run out level specimen without failure (n=1).

Discussion

In this biomechanical comparative experiment the mechanical behavior of two different HTO plates was studied in a static and dynamic compression bending test. Bone substitute material was used to eliminate the effects of the variability of native bone. In order to simulate worst case conditions and avoid composite bone influences on the lateral side a fully bone gap was created, thus a direct comparison of the mechanical bending strength of the plate systems was guaranteed. The distinct static as well as long time stabilities of the two plate systems can be ascribed to design and material specific differences. While the peek-carbon composite plates resist higher dynamic loadings and showed a higher static flexural rigidity, the titanium plates evidenced a more elastic construct behavior with increased deformations.

The increased flexural strength of the peek-carbon plate is liable for the observed screw backouts at the distal plate side, where tensile forces arises due to an induced bending moment with the upper distal bone edge as pivot. Due to the fact that only functional plate failure determines early stop in this study and no additional failure parameter regarding loss of angle correction or flexural deviation was established, especially the dynamic test results of the higher loaded titanium plates approximate to the results of the peek-carbon plates. Also material specific differences in the damage mechanisms of both implant types may contribute to both distinct observed mechanical failures. The carbon fiber reinforced peek material exhibits a brittle material characteristic with deformations predominantly in the elastic regime of its stress-strain cure, whereas titan possess a more elastic material behavior with material weakening effects during cyclic loading. These effects evoke fracture initiation, propagation and final global implant failure as seen within all dynamic tests.

Within this comparable worst case compression bending test design the peek-carbon composite plate exhibit an increased static flexural strength compared to a titanium plate and an increased lifetime curve at higher load levels. Increased plate deformation may lead to the possibility of non-union and failure of fracture fixation. An appropriate ratio between rigidity and load bearing over a defined number of cycles are required for a successful long term function of the implant.

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LA2-0118-EN_A

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Die Befragung und die daraus resultierenden Ergebnisse sind Inhalt einer klinischen Studie, die später von uns veröffentlicht wird. Die Veröffentlichung der Daten geschieht völlig anonym. Wenn Sie sich etwa fünfzehn Minuten Zeit nehmen, um die folgenden Fragebögen auszufüllen, würden Sie der universitären Wissenschaft einen großen Schritt weiterhelfen.
Die Befragungstermine finden an den regulären Kontrollterminen in unserer Ambulanz statt oder es werden Ihnen die Fragebögen incl. frankiertem Rückumschlag per Post zugesandt. Dies alles soll für Sie keine Mehrbelastung bedeuten.

Wenn Sie mit der anonymen Befragung einverstanden sind, bitten wir Sie, mit Ort, Datum und Unterschrift Ihr Einverständnis schriftlich niederzulegen.

Vielen Dank für Ihre Kooperation.

Ort, Datum, Unterschrift

1. Allgemeine Daten

Name _____

Vorname _____

Telefon _____

Email _____

Adresse _____

Geb. Datum _____

_____ _____ _____

Alter Größe Gewicht

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2. Allgemeine Fragen

Nehmen Sie derzeit Schmerzmedikamente wegen des Knies?

Ja, regelmässig ☐ Ja, bei Bedarf ☐ Nein ☐

Wenn Sie Sport treiben/ Rehabilitationstraining machen, müssen Sie dann zur Durchführung Schmerzmedikamente nehmen?

Ja, regelmässig ☐ Ja, bei Bedarf ☐ Nein ☐

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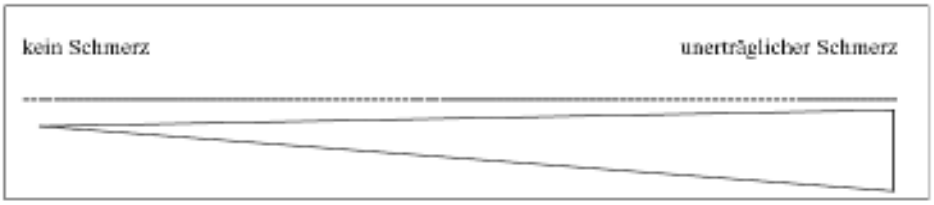
3. VAS

Visuelle Analogskala = subjektive Einschätzung Ihrer Schmerzen

Wie beurteilen Sie den Schmerz in Ihrem Knie?

Bitte ankreuzen:



4. LYSHOLM- Kniescore

Bitte kreisen Sie den entsprechenden Punktwert ein.

	Punkte
1. Hinken oder humpeln Sie ?	
a) nie	5
b) wenig oder nur zeitweise	3
c) schwer und ständig	0
2. Benötigen Sie eine Gehilfe?	
a) nein	5
b) Stock oder Krücke	3
c) gehunfähig	0
3. Treppensteigen?	
a) problemlos	10
b) etwas erschwert	6
c) langsam, Stufe um Stufe	2
d) unmöglich	0
4. In die Hocke gehen?	
a) problemlos	5
b) etwas erschwert	4
c) schwer möglich (nicht über 90°)	2
d) unmöglich	0
5. Unsicherheitsgefühl im Kniegelenk?	
a) nie	30
b) selten beim Sport oder schweren Anstrengungen	25
c) häufig beim Sport oder schweren Anstrengungen	20
d) gelegentlich bei Alltagsarbeiten	10
e) oft bei Alltagsarbeiten	5
f) bei jeder Bewegung bzw. jedem Schritt	0
6. Schmerzen?	
a) keine	30
b) ab und zu ein wenig bei schwerer Anstrengung	25
c) Auftreten bei Knieunsicherheit	20
d) Auftreten bei schweren Anstrengungen	15
e) Auftreten während oder nach einem Spaziergang von mehr als 2 km Länge	10
f) Auftreten während oder nach einem Spaziergang von weniger als 2 km Länge	5
g) ständig und stark	0
7. Schwellung des Kniegelenkes ?	
a) keine	10
b) bei Knieunsicherheit	7
c) bei schwerer Anstrengung	5
d) bei leichter Anstrengung	2
e) ständig	0
8.Muskelschwäche des/ der Beine(s) ?	
a) keine	5
b) gering (Oberschenkelumfang 1-2 cm verringert)	3
c) ausgeprägt (Oberschenkelumfang mehr als 2 cm verringert)	0

5. WOMAC-Score

Bitte kreuzen Sie das entsprechende Feld an.

Teil A

Wie schwer sind Ihre Schmerzen?

	keine	**leichte**	**mittelschwer**	**schwer**	**sehr schwer**
1.Gehen auf flacher Ebene					
2.Treppensteigen					
3.Während der Nachtruhe					
4.Sitzend oder liegend					
5.Aufrecht stehend					

Teil B

1. Wie schwer ist die Gelenksteifheit nach dem morgendlichen Aufstehen?
keine leicht mittelschwer schwer sehr schwer

2. Wie schwer ist die Gelenksteifheit nach dem Sitzen, Liegen oder Ruhen während des Tages?
keine leicht mittelschwer schwer sehr schwer

Teil C

Wie schwierig ist für Sie ?

	einfach	**eingeschränkt**	**mittel**	**schwer**	**sehr schwer**
1. Treppen hinabsteigen					
2. Treppen hinaufsteigen					
3. Aufstehen aus dem Sitzen					
4. Stehen					
5. Zum Boden bücken					
6. Gehen auf flachen Boden					
7. In/Aus dem Auto steigen					
8. Einkaufen gehen					
9. Strümpfe anziehen					
10. Aufstehen aus dem Bett					
11. Strümpfe ausziehen					
12. Im Bett liegen					
13. In/Aus der Badewanne steigen					
14. Sitzen					
15. Auf die Toilette Setzen/ wieder Aufstehen					
16. Schwere Hausarbeit					
17. Leichte Hausarbeit					

6. Tegner Aktivitäts-Index

Bitte kreuzen Sie in der untenstehenden Liste die *höchste* Stufe (nur ein Stufe) an, in die Sie sich einordnen können.

10. Wettkampfsport ☐
Fussball, nationale und internationale Elite

9. Wettkampfsport ☐
Fussball, niedrigere Ligen
Eishockey
Ringen oder Kampfsport
Gymnastik

8. Wettkampfsport ☐
Squash oder Badminton
Leichtathletik (Sprungdisziplinen)
Alpin Ski

7. Wettkampfsport ☐
Tennis
Leichtathletik (Laufdisziplinen)
Motorcross
Handball
Basketball

Freizeitsport ☐
Fussball
Eishockey
Squash
Leichtathletik (Sprungdisziplinen)

6. Freizeitsport ☐
Tennis
Badminton
Leichtathletik (Laufdisziplinen)
Motorcross
Handball
Basketball
Alpin Ski
Jogging (mindestens 5 Mal pro Woche)

5. Arbeit/Beruf ☐
Schwere körperliche Arbeit (z. B. Bauarbeiten, Waldarbeiten, usw.)

Wettkampfsport ☐
Velo oder Mountainbike
Langlauf

Freizeitsport ☐
Jogging auf unebenem Untergrund (mindestens 2 Mal pro Woche)

4. Arbeit/Beruf ☐
Mässig schwere körperliche Arbeit (z. B. Chauffeur, schwere Hausarbeiten, Lagerarbeit, usw.)

Freizeitsport ☐
Rad oder Mountainbike
Langlauf
Jogging auf ebenem Untergrund (mindestens 2 Mal pro Woche)

3. Arbeit/Beruf ☐
Leichte körperliche Arbeit (z. B. Gastronomie, Pflegeberufe, usw.)
Wettkampf- oder Freizeitsport ☐
Schwimmen
Waldspaziergänge (auf unebenem Untergrund) möglich ☐

2. Arbeit/Beruf ☐
Leichte Arbeit (wechselnd Sitzen, Stehen, Laufen und Treppensteigen)
Gehen auf unebenem Untergrund möglich, aber keine Waldspaziergänge ☐

1. Arbeit/Beruf ☐
Sitzende Tätigkeit (z. B. Büro, Callcenter, usw.)
Gehen auf ebenem Untergrund möglich ☐

0. Krankschreibung oder IV-Rente wegen Kniebeschwerden ☐

7. Sportaktivitäts-Fragebogen

1. Bitte kreuzen Sie die Sportarten bzw. Aktivitäten an, die Sie regelmässig vor der Umstellungsosteotomie (HTO) ausgeübt haben bzw. derzeit ausüben. Beachten Sie bitte Folgendes:

Jahr vor OP bedeutet: Kreuzen Sie bitte die Sportarten an, die Sie im letzten Jahr vor der Umstellungsosteotomie regelmässig ausgeübt haben. Sie müssen nichts ankreuzen, wenn Sie keine Sportart regelmässig ausgeübt haben**.**

24 Monate nach HTO bzw. Aktuell bedeutet: Kreuzen Sie bitte die Sportarten an, die Sie zu diesen Zeitpunkten regelmässig ausgeübt haben bzw. ausüben. Sie müssen nichts ankreuzen, wenn Sie keine Sportart regelmässig ausgeübt haben bzw. ausüben.

Saisonsportarten (z. B. Langlauf, Skifahren, Golf, usw.) sind auf die jeweilige Saison (z. B. Winter) zu beziehen. Bitte kreuzen Sie jetzt das entsprechende Kästchen an:

	Jahr vor HTO	**24 Monate nach HTO**
Radfahren		
Bergwandern		
Nordic Walking		
Gymnastik/Turnen		
Fitness-/Krafttraining		
Tanzen		
Schwimmen		
Golf		
Aqua Fit		
Aerobic		
Segeln		
Rudern		
Badminton		
Inline Skating		
Tennis (Einzel)		
Alpin Ski		
Langlauf		
Reiten		
Kampfsport		
Bowling		
Bergsteigen/Klettern		
Mountainbiking		
Eislauf		
Tischtennis		
Wasserski		
Jogging		
Handball		
Volleyball		
Basketball		
Fussball		
Squash		
Snowboard		
Eishockey		
Andere:_____		

2. Wie oft in der Woche sind bzw. waren Sie sportlich aktiv?

	Jahr vor HTO	**24 Monate nach HTO**
Bitte geben Sie je **0x, 1x, 2x, 3x, 4x, 5x, 6x** oder **7x** an:		

3. Wie viele Stunden pro Woche sind Sie bzw. waren Sie sportlich aktiv?

	Jahr vor HTO	**24 Monate nach HTO**
Bitte geben Sie je **die Stundenzahl (h)** an:		

Herzlichen Dank für Ihre Mithilfe. Sie unterstützen uns in unserem steten Bemühen, den Wünschen und Ansprüchen von Patienten besser zu genügen