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Removal Rate of the Tomofix® System after High Tibial Osteotomy is Higher Than Reported*

A taxa de remoção do sistema Tomofix após a osteotomia tibial alta é superior à relatada

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Abstract

Objective Medial open wedge high tibial osteotomy (MOWHTO) significantly relieves pain in the medial joint line in medial compartment osteoarthritis of the knee. But some patients complain of pain over the pes anserinus even 1 year after the osteotomy, which may require implant removal for relief. This study aims to define the implant removal rate after MOWHTO due to pain over the pes anserinus.

Methods One hundred and three knees of 72 patients who underwent MOWHTO for medial compartment osteoarthritis between 2010 and 2018 were enrolled in the study. Knee injury and osteoarthritis outcome score (KOOS), Oxford knee score (OKS), and visual analogue score (VAS) were assessed for pain in the medial knee joint line (VAS-MJ) preoperatively, 12 months postoperatively, and yearly thereafter; adding VAS for pain over the pes anserinus (VAS-PA). Patients with VAS-PA ≥ 40 and adequate bony consolidation after 12 months were recommended implant removal.

Results Thirty-three (45.8%) of the patients were male and 39 (54.2%) were female. The mean age was 49.4 ± 8.0 and the mean body mass index was 27.0 ± 2.9. The Tomofix medial tibial plate-screw system (DePuy Synthes, Raynham, MA, USA) was used in all cases. Three (2.8%) cases with delayed union requiring revision were excluded. The KOOS, OKS, and VAS-MJ significantly improved 12 months after MOWHTO. The mean VAS-PA was 38.3 ± 23.9. Implant removal for pain relief was needed in 65 (63.1%) of the103 knees. The mean VAS-PA decreased to 4.5 ± 5.6 3 months after implant removal ($p < 0.0001$).

Keywords
- bone plates
- bone transplantation
- device removal
- osteotomy
- surgical wound infection
- tibia

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Conclusion Over 60% of the patients may need implant removal to relieve pain over the pes anserinus after MOWHTO. Candidates for MOWHTO should be informed about this complication and its solution.

Resumo

Objetivo A osteotomia tibial alta com cunha de abertura medial (MOWHTO, do inglês *medial open wedge high tibial osteotomy*) alivia de forma significativa a dor na linha articular medial em casos de osteoartrite do compartimento medial do joelho. Alguns pacientes, porém, se queixam de dor nos tendões dos músculos sartório, grácil e semitendinoso (pata de ganso) mesmo 1 ano após a osteotomia, o que pode exigir a remoção do implante. Este estudo define a taxa de remoção do implante após a MOWHTO devido à dor nos tendões dos músculos sartório, grácil e semitendinoso.

Métodos Cento e três joelhos de 72 pacientes submetidos à MOWHTO para tratamento da osteoartrite do compartimento medial entre 2010 e 2018 foram incluídos no estudo. A pontuação de desfecho de lesão no joelho e osteoartrite (KOOS, do inglês *Knee Injury and Osteoarthritis Outcome Score*), a pontuação de joelho de Oxford (OKS, do inglês *Oxford Knee Score*) e a escala visual analógica (EVA) de dor na linha articular medial do joelho (EVA-MJ) foram avaliados antes da cirurgia. A EVA nos tendões dos músculos sartório, grácil e semitendinoso (EVA-PA) foi adicionada a essas avaliações, também realizadas 12 meses após o procedimento e, a seguir, anualmente. A remoção do implante foi recomendada em pacientes com EVA-PA $\geq$ 40 e consolidação óssea adequada em 12 meses.

Resultados Trinta e três (45,8%) pacientes eram homens e 39 (54,2%), mulheres. A média de idade foi de 49,4 $\pm$ 8,0, e o índice de massa corpórea (IMC) médio foi de 27,0 $\pm$ 2,9. O sistema placa-parafuso tibial medial Tomofix (DePuy Synthes, Raynham, MA, EUA) foi utilizado em todos os casos. Três (2,8%) casos foram excluídos devido ao retardo de consolidação e à necessidade de revisão. Os resultados nas escalas KOOS, OKS e EVA-MJ melhoraram significativamente 12 meses após a MOWHTO. A EVA-PA média foi de 38,3 $\pm$ 23,9. A remoção do implante para alívio da dor foi necessária em 65 (63,1%) dos 103 joelhos. Três meses após a remoção do implante, a EVA-PA média diminuiu para 4,5 $\pm$ 5,6 ($p < 0{,}0001$).

Conclusão A remoção do implante pode ser necessária em mais de 60% dos pacientes para alívio da dor nos tendões dos músculos sartório, grácil e semitendinoso após a MOWHTO. Os candidatos à MOWHTO devem ser informados sobre esta complicação e sua resolução.

Palavras-chave
- placas ósseas
- transplante ósseo
- remoção de dispositivo
- osteotomia
- infecção da ferida cirúrgica
- tíbia

Introduction

Medial open wedge high tibial osteotomy (MOWHTO) has been accepted as an effective treatment option for medial compartment osteoarthritis of the knee in physically active patients with varus malalignment. Medial open wedge high tibial osteotomy involves the osteotomy of the proximal tibia, valgisation of the bone at the osteotomy site, and fixation of the osteotomy, which is usually done via a plate-screw system. The clinical results of MOWHTO are promising, with high rates of return to work and to sports.[1]

Despite reported promising results, MOWHTO is associated with some complications which may deteriorate the outcomes, such as lateral cortex fracture, neurovascular injuries, nonunion, delayed union, loss of correction, and implant irritation.[2] The plates used for MOWHTO can cause mechanical symptoms and pain by pressing on neighboring structures such as the pes anserinus and hamstring tendons, the medial collateral ligament, and the overlying fat and skin.[3]

Although pain in the medial joint line is significantly relieved after MOWHTO, some patients may complain of daily activity restricting pain and tenderness over the pes anserinus region or implants due to hardware irritation even after a MOWHTO procedure without any major complications. This may ultimately require implant removal after bony consolidation for pain relief in some of these patients. This study aimed to define the implant removal rate for Tomofix Osteotomy System (DePuy Synthes, Raynham, MA, USA).

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Table 1 Patient characteristics (*body mass index)

Sex	Male (n = 33) 45.8% Female (n = 39) 54.2%
Mean age (years)	49.4 ± 8.0
Mean BMI	27.0 ± 2.9
Mean correction angle	8.3° ± 1.8°

Abbreviation: BMI, body mass index.

Materials and Methods

Work approved by the institutional ethics committee on 22.10.2020 (No 140).

After obtaining institutional review board approval, a total of 106 knees of 72 patients who underwent MOWHTO by the senior surgeon for medial compartment osteoarthritis between May 2010 and February 2018 with a follow-up of at least 24 months were enrolled in the study. Fixation of the osteotomy site was achieved with the titanium medial high tibial locking compression plate and screw system of the Tomofix Osteotomy System in all knees. No grafts were used on the osteotomy site in any patients. All patients received the same physiotherapy protocol after MOWHTO. Patients were evaluated with the knee injury and osteoarthritis outcome score (KOOS), Oxford knee score (OKS), and visual analogue score for pain in the medial knee joint (VAS-MJ) before surgery. The VAS for pain over the pes anserinus (VAS-PA) was also evaluated with all clinical and functional tests at 12 months after surgery, and yearly thereafter. Patients with VAS-PA $\geq$ 40 after 12 months with adequate bony consolidation were recommended implant removal.

Implant removal surgery was undertaken at least 12 months after the index surgery for patients who had pain over the pes anserinus region or the implants that limited daily life and/or sports activity and had failed conservative treatment. Visual analogue scale for pain over the pes anserinus was also recorded at 3 months after implant removal.

Statistical Analysis

For the statistical analysis, the IBM SPSS Statistics for Windows, Version 22.0 software (IBM Corp., Armonk, NY, USA) was used. For quantitative variables between the two groups, the Student t-test was used. Data are expressed as mean +/− standard deviation (SD). The Chi-squared test and the Fisher exact test were used for the analysis of categorical variables when appropriate. A *p*-value lower than 0.05 was considered as statistically significant.

Results

Patient characteristics are given in ►**Table 1**. In 6 (5.8%) of the 103 knees, anterior cruciate ligament (ACL) reconstruction and 1 (0.9%) case ACL reconstruction revision were performed simultaneously with MOWHTO. No implant failure, non-union, lateral cortex fracture, neurovascular injury, loss of correction, or ACL failure were recorded. Three (2.9%) cases of delayed unions were observed and excluded. None of the patients needed conversion to total knee replacement. For 65 (63.1%) (with a mean VAS-PA of 53.5 ± 14.2) of the 103 knees, implant removal was needed for pain relief. There were no significant differences regarding KOOS ($p = 0.134$), OKS ($p = 0.287$) and VAS-MJ ($p = 0.416$) between cases for which implant removal was needed or not. For patients that had implant removal surgery, the VAS-PA value decreased to a mean of 4.5 ± 5.6 at 3 months after implant removal ($p < 0.001$) (►**Table 2**). The mean time of implant removal was 16.2 ± 3.7 (range 12-22) months after MOWHTO.

Discussion

The present study shows that implant removal was recommended in more than half (63%) of the knees due to pain after MOWHTO with titanium medial high tibial locking

Table 2 Pain and functional scores

	Preoperative (mean ± SD)	12 months after MOWHTO (mean ± SD)	3 months after implant removal (mean ± SD)	*P*-value
KOOS (all patients)	49.4 ± 8.2	77.5 ± 10.6	–	< **0.05**
OKS (all patients)	26.7 ± 5.2	43.1 ± 4.1	–	< **0.05**
VAS-MJ (all patients)	60.8 ± 12.2	8.8 ± 9.8	–	< **0.001**
VAS-PA (all patients)	–	38.3 ± 23.9	–	–
VAS-PA (patients with implant removal) (n = 65; 63.1%)	–	53.5 ± 14.2	4.5 ± 5.6	< **0.001**

Abbreviations: KOOS, knee injury and osteoarthritis outcome score; MOWHTO, medial open wedge high tibial osteotomy; OKS, Oxford knee score; SD, standard deviation; VAS-MJ, visual analogue score for pain in the medial knee joint; VAS-PA, visual analogue score for pain over pes anserinus.

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compression plate and Tomofix osteotomy system between 1 to 2 years postoperatively.

Medial open wedge high tibial osteotomy is an effective treatment for medial compartment osteoarthritis in young patients with low major complication rates, good outcomes, and high union rates;[4] however, relatively high minor complication rates have been reported (15.6–31%).[3] Pain due to soft-tissue irritation and the need for hardware removal are common complications[5] that have been associated with plate and screw fixation.[4] But the true rate of implant removal due to pain in the literature is vague and unclear. Although the Tomofix system is shown to be safe in MOWHTO,[6] a high incidence of pain due to soft-tissue irritation and consequent implant removal has been reported. In 2010, Niemeyer et al.[7] reported a patient complaint rate of 40.6% due to local irritation associated with the hardware after MOWHTO using the Tomofix system. But the rate of need for implant removal due to pain was unspecified because they removed the hardware of all patients but one (99%), who declined implant removal. Darees et al.[8] reported a hardware removal rate of 25% (12/48) due to discomfort over a 10-year follow-up. Nevertheless, many studies in the literature reported much less hardware-related irritation (0–23%) with a mean rate of implant removal need for pain relief of 7.2% for the Tomofix system.[3] Brouwer reported a rate of 60% for implant removal due to pain caused by the Puddu plate (Arthrex, Naples, FL, USA).[5] Two more studies compared the implant removal rate after MOWHTO using metal implants and all-polyetheretherketone (PEEK) systems. Hevesi et al.[4] reported the hardware removal-free survival for metal implants (Puddu, DynaFix [Biomet, Warsaw, IN, USA], and TomoFix,) as 80% for 2 years and 73% for 5 years, respectively. The removal-free survival for the all-PEEK implant (iBalance - Arthrex) was significantly higher, being 94% for both 2 and 5 years. Similarly, Roberson et al. compared the all-PEEK implant iBalance to traditional plate-and-screw systems (Contour-Lock HTO Plate [Arthrex] and VS Osteotomy Plate [EBI, Parsippany, NJ, USA]).[2] Their study showed no need for implant removal for the all-PEEK implant and a removal rate of 20% for the metal implants in a 2-years follow-up. Rates of complications, failure, and conversion to arthroplasty as well as clinical and radiological outcomes were similar for metal and all-PEEK groups were similar in those two studies. Recently, another study investigated the complication and implant removal rates of MOWHTO using Tomofix. They reported a low rate of complications (6.5%) but a high rate of implant removal due to soft-tissue irritation (52%).[9] In our study, we did not aim to report complication rates, but the implant removal rate due to hardware irritation. During a 2-year follow-up, we found an implant removal rate of 63.1% due to pain caused by hardware irritation after MOWHTO using the Tomofix osteotomy system. This rate of hardware irritation and consequent implant removal is higher than any study in the literature.

Although the Tomofix plate provides high stability at the osteotomy site and prevents lateral hinge fractures, it gives rise to local soft-tissue irritation in more than half of the cases. This may be due to the limited free space and the lack of abundant soft tissue between the bone and the skin on the anteromedial aspect of the proximal tibia to accept and cover the implant. Considering that more than 60% of the patients undergoing MOWHTO would need a second surgical intervention for the removal of the implants, we recommend and prefer to inform the patients about this most probable secondary surgery in our everyday practice routine.

The main limitations of our study are its retrospective nature, case series structure, and the lack of a control group. Moreover, with a 24-months follow-up, our study represents short-term outcomes and implant removal rates. Nevertheless, this study shows that hardware irritation and consequent implant removal rate after MOWHTO is more common than reported in the literature.

Conclusion

Over 60% of the patients may need implant removal to relieve pain over the pes anserinus after MOWHTO. Candidates for MOWHTO should be informed about this complication and its solution.

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Conflict of Interests
The authors have no conflict of interests to declare.

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