International Orthopaedics (SICOT) (2014) 38:55–60
DOI 10.1007/s00264-013-2082-3

ORIGINAL PAPER

Does obesity and nicotine abuse influence the outcome and complication rate after open-wedge high tibial osteotomy? A retrospective evaluation of five hundred and thirty three patients

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Received: 7 July 2013 / Accepted: 11 August 2013 / Published online: 11 September 2013

Abstract
Purpose Nicotine abuse and obesity are well-known factors leading to common post-operative complications. However, their influence on the outcome after high tibial osteotomy is controversial. Thus, the aim of this study was to evaluate their effect on the clinical outcome with particular regard to bone non-union and local complications.
Methods The functional outcome after open-wedge high tibial osteotomy using the TomoFix® plate was assessed by means of the 12-item Oxford knee score in a multicentre study. In addition the intra- and post-operative complications were determined.
Results Of 533 eligible patients, 386 were interviewed after a mean follow-up of 3.6 years. The median Oxford knee score was 43 points (max. 48 points). Six per cent of these patients experienced at least one local post-operative complication. Patients with a body mass index (BMI) of up to 25 and between 25 and 30 had a higher mean score by 3.5 and 1.8 points, respectively, compared with those having a BMI of more than 30 showing a score of 37.5. No correlation was observed between smoking and the functional outcome. Smoking habits, BMI, the absolute patient weight and the interaction term between smoking and BMI were not significant with reference to the complication rate.
Conclusions This study reveals favourable mid-term results after high tibial osteotomy in varus osteoarthritis even in patients who smoked and obese patients. The indication in patients with a BMI above 30 should be handled with care due to the slightly inferior outcome, although the complication rate was not increased in these patients.

Keywords High tibial osteotomy · Medial osteoarthritis · Oxford knee score · TomoFix · Smoking · Obesity

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Introduction

An increasing number of patients suffer from knee osteoarthritis (OA) which is the most frequent joint disorder worldwide [10]. The medial compartment is most frequently affected in knee OA due to its association with a metaphyseal varus malalignment leading to a fourfold increased risk of progression of medial OA [18]. The open-wedge high tibial osteotomy (HTO) represents a common technique which leads to a medial decompression. This allows pain relief and decelerates the progression of the medial OA [1].

However, it is still discussed controversially whether nicotine abuse and obesity should be exclusion criteria for HTO

Table 1 Characteristics of the 533 open-wedge HTO patients

Characteristic	
Weight (kg), $n=504$[a]	
Mean (SD)	82.2 (13.4)
Height (cm), $n=506$[a]	
Mean (SD)	173.7 (9.4)
BMI (kg/m^2), $n=504$[a]	
Mean (SD)	27.2 (4.0)
Smoking, no. (%), $n=533$	
No	435 (81.6)
Yes	98 (18.4)
Number of cigarettes per day	
< 10	31 (31.6)
10–19	40 (40.8)
> 20	27 (27.6)

[a] $n \neq 533$ due to missing data

due to the supposed increased risk of delayed bone and wound healing. Their negative influence on bone and soft tissue and thus on the clinical outcome after surgical interventions is well known. For instance, Sikorski and Sikorska described a 7.8-fold increased risk of infection for morbidly obese patients receiving a total knee arthroplasty (TKA) and an increased overall risk by 17 % in smokers [19].

Thus, the aim of this study was to evaluate the mid-term effect of smoking habits and obesity on the outcome after open-wedge valgus HTO up to five years post-operatively in order to give advice for possible limitations.

Materials and methods

Patient recruitment: This multicentre study involved retrospective capture of baseline data and prospective outcome assessment of patients with medial knee OA who underwent an open-wedge HTO using the TomoFix® plate (Synthes, USA). Three European clinics (Hanover, Tübingen and Lucerne) were involved and ethics approval was obtained for all centres.

The study included 533 patients who underwent an open-wedge HTO between April 2004 and April 2006 using the TomoFix® plate. Inclusion criteria were an age of at least 18 years, an intact lateral joint compartment prior to surgery and an informed consent to participate in the study. A telephone interview was conducted to assess functional outcome with the Oxford knee score (OKS) questionnaire. Of these patients, 97 were unavailable and another 50 were unwilling to provide their informed consent. A final number of 386 (72 %) patients who gave their informed consent were interviewed after an average follow-up period of 3.6 years (2.4–4.7).

Retrospective analysis of patient demographics: Baseline characteristics as well as treatment information were collected for all 533 patients. Intra- and post-operative complication data were assessed from medical records. According to the WHO international classification of adult weight the following groups were defined [8]: group A consisting of patients with a normal weight [body mass index (BMI)<25 kg/m^2], group B consisting of pre-obese patients (BMI 25–30 kg/m^2) and group C consisting of obese patients (BMI >30 kg/m^2). With reference to nicotine abuse patients were divided into non-smokers and smokers with the subgroups of less than ten, ten to 19 and greater than 20 cigarettes per day.

Follow-up evaluation: The German version of the OKS was used as a reliable and valid tool to assess the outcome of surgical treatment for knee OA [16]. The OKS consists of 12 questions regarding pain and function, each with five categories of response. The standard scoring system, in which each question is scored between zero and four, was used [15]. The final score obtained ranges from 0 to 48 points where 48 represents the best outcome.

Statistical analysis: Data management and analyses were conducted using Intercooled Stata version 11 (StataCorp LP, College Station, TX, USA). Baseline variables and the OKS were assessed using standard descriptive statistics. Continuous variables were described with use of mean value, standard deviation and ranges, whereas categorical variables were tabulated as absolute and relative frequencies. Multivariable regression analyses were used to explore and quantify the influence of BMI, absolute weight and smoking habits on the

Table 2 Post-operative complications reported within the 2- to 5-year follow-up period

Complication type	*n*	%[a]
Implant/surgery		
Implant breakage	1	0.2
Bone		
Pseudarthrosis[b]	8	1.5
Soft tissue/wound		
Haematoma	11	2.1
Infection	11	2.1
Infected haematoma	3	0.6
Impaired wound healing	2	0.4
Other soft tissue	3	0.6
General		
Thromboembolic complication	1	0.2

[a] Risk (%) is reported as the number of reported events during the follow-up period divided by the number of patients at baseline (i.e. $n=533$)

[b] This complication was defined as healing insufficiency (with a high risk of pseudarthrosis) diagnosed within the first three months after surgery, which led to a reoperation in order to circumvent pseudarthrosis at a later stage

Table 3 Distribution of the 386 interviewed patients according to the two to five year OKS outcome

Factors	Categories	*n*	%	OKS		*p* value
				Mean	SD	
BMI (kg/m^2)[a]	≤ 25	111	29	41.5	7.2	0.0034
	> 25–30	191	50	40.1	8.6	
	> 30	79	21	37.5	9.1	
Smoking	No	314	81	40.2	8.0	0.7896
	Yes	72	19	39.1	9.9	

SD standard deviation

[a] $n \neq 386$ due to missing data

outcome and complications. Direct associations were initially tested using univariate statistics. All factors showing a significant association with OKS at $p \leq 0.10$ (or considered sufficiently clinically important) were entered into a full model and a stepwise backwards elimination procedure was used to sequentially remove factors showing a lack of statistical significance with the Wald test (i.e. $p \leq 0.05$). After removing the non-significant factors from the initial regression model, each of these factors were re-entered into the model to examine if their lack of association was due to other factors that were also removed later in the model building process. Individual factor categories were significantly associated with the outcome when $p < 0.05$ based on the Wald test.

The risks of complications with their binominal exact 95 % confidence intervals were estimated by the cumulative number of reported events during the follow-up period (up to the time of the telephone interview) divided by the number of patients at baseline.

Results

A total of 386 patients were interviewed for follow-up after an average of 3.6 years (range 2.4–4.7 years) (Table 1). The median OKS was 43 (range 8–4 8) points. The mean patient age was 49 years (18–84). Regarding obesity the mean BMI was 27.2 kg/m^2 (range 18.4–43.9). Eighteen per cent ($n = 98$) were smokers with 27 patients smoking more than 20 cigarettes per day. Medical records showed one intra-operative complication which was documented for four patients and included one case of overcorrection (classified as an adverse event definitely related to the surgical intervention), two cases involving technical problems associated with the positioning of the screws and substantial bleeding for the last case.

Post-operatively 32 (6 %) of the 533 patients experienced at least one local post-operative complication within the two to five year follow-up period (Table 2). The majority of adverse events affected soft tissue and were found among the eight cases of delayed bone healing (Table 3). There was only one case of an implant failure. This patient underwent a secondary intervention to replace the broken implant with a TKA. In addition one pulmonary embolism occurred.

The factor experiencing at least one local post-operative complication ($p = 0.35$) was forced into the multivariable model due to clinical relevance. Smoking status, BMI, the absolute patient weight and the interaction term between smoking and BMI were not significant with respect to the complication rate. Based on univariate linear regression analyses, smoking ($p = 0.79$) was not significantly associated with a decreased post-operative OKS (Fig. 1 and Table 4). The factor BMI was significantly associated with the two to five year functional outcome. Having a BMI<25 as well as a BMI>25 and<30 was identified as a positive predictor of the OKS up to five years post-operatively (Table 4).

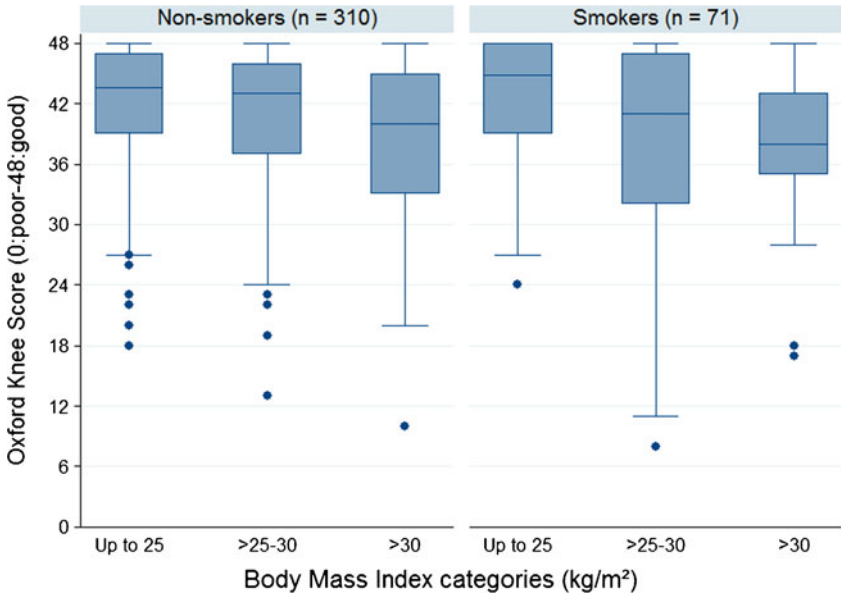

Fig. 1 Influence of smoking habits and BMI on the OKS

Table 4 Features of the eight cases of pseudarthrosis

Patient	BMI	Height (cm)	Weight (kg)	Smoking	
				Yes	No
HAH-007	23.3	191	85		X
HAH-046	25.6	178	81		X
HAH-051	33.1	178	105		X
HAH-106	26.9	181	88		X
HAH-143	33.1	178	105		X
HAH-155	28.7	179	92		X
HAH-219	27.7	190	100	X	
TUB-004	32.5	184	110	X	

A BMI above 30 led to a significant decrease of the OKS (Fig. 2). The presence of obesity and nicotine abuse in the same patient was not significant for OKS.

Discussion

The aim of this retrospective multicentre study was to determine the influence of obesity, absolute weight and nicotine abuse on the clinical outcome and complication rate in patients with medial OA treated with an open-wedge HTO. The data of this study revealed a significant inferior clinical outcome for patients with a BMI above 30. The absolute weight, nicotine abuse and the combination of obesity and nicotine abuse did not influence the outcome and complication rate after HTO.

The local vasoconstrictive properties of nicotine abuse are well known. Hence, a lower blood supply in the region of surgery represents a negative prognostic factor [7]. Moreover, carbon monoxide, produced by cigarette combustion, has a great affinity for haemoglobin, consequently decreasing the total amount of oxygen carried in the healing site [20]. This may result in local complications after surgery such as non-union or delayed wound healing. In the literature the rate of delayed bone union and common complications after open-wedge HTO differs widely. Authors report about a non-union rate ranging between 2.4 and 35 % and a common complication rate ranging between 6.3 and 36.9 % when analysing various types of fixators [2, 4, 14, 17].

The TomoFix® plate is a well-established implant for HTO, and earlier studies showed promising short- and mid-term results [5, 6, 9, 12]. Studies evaluating the outcome after HTO using TomoFix® revealed a pseudarthrosis rate ranging between 0 % and 7 % and a common complication rate between 0 % and 10 % [5, 6, 9, 11, 13, 22, 23]. However, factors influencing the appearance of these complications were hardly analysed. Kolb et al. found 1 case of pseudarthrosis in a study group of 51 open-wedge HTO and mentioned that this patient was a smoker [9]. Birmingham et al. evaluated 126 patients two years after HTO with a median BMI of 29.5 [4]. Despite obesity the rate of non-union was 2.4 % and the common complication rate was 6.3 % in that study. No further data can be found regarding a correlation between weight and clinical outcome or complication rate. Our data support earlier results with a complication rate of 6 % and an incidence of non-union requiring a revision surgery of 1.5 %. The clinical outcome according to the OKS was comparable to non-smokers. According to our data the incidence of a complication was independent from smoking habits of the patients. Thus, the proposed negative influence does not seem to

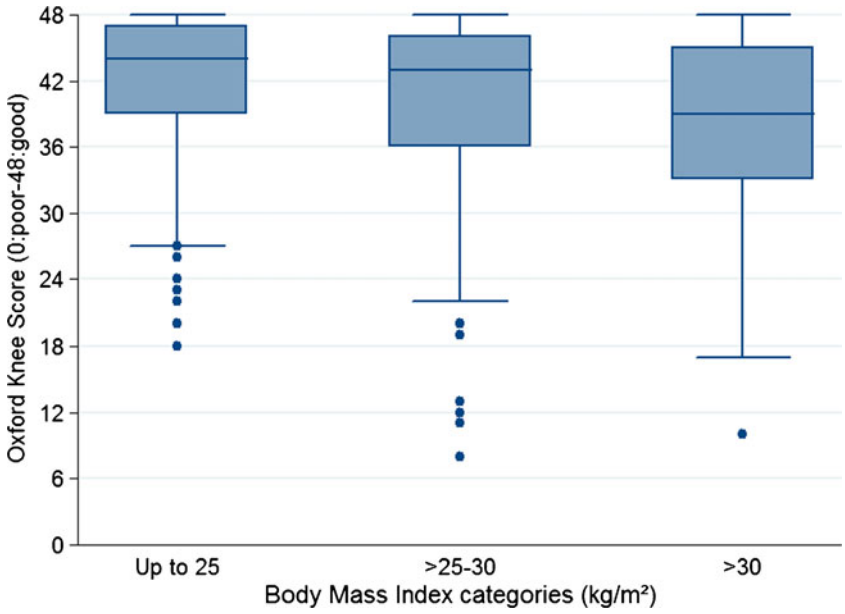

Fig. 2 Influence of BMI on the OKS

affect the local healing conditions in the proximal tibia after open-wedge HTO in a clinically relevant way. Only two patients who smoked were found among the eight cases of delayed bone healing (Table 4).

These positive results might be affected by the design of the TomoFix® plate, which is a locking compression plate system and enables angular stable connections between screw and plate [11]. Thus, a stable fixation after open-wedge HTO is ensured allowing appropriate tissue healing. The clinical outcome after open-wedge HTO using other fixators (e.g. spacer plate, C-plate, position plate, staples) was promising even in long-term results with a good improvement of the knee function [3]. Nevertheless, high complication rates of up to 43.6 % were often associated with these fixator types [21].

Considering the rising tendency of BMI in the population [25] the question about the influence of obesity on the outcome after HTO is even more interesting than ever. The data of our study showed a negative influence of a BMI above 30 on the clinical outcome. A BMI above 30 was correlated with a significantly lower OKS but did not increase the complication rate. In contrast to our small rate of impaired wound healing of 0.4 % ($n=2$), Wagner et al. stated based on an animal study that a BMI above 30 impairs the bone marrow-derived vasculogenic progenitor cell's response to peripheral injury and this, in turn, impairs wound closure [24]. Facing the lower success rates of knee arthroplasty in heavier patients, these patients seem to be even more suitable for HTO [2].

Furthermore, we tried to distinguish between the effect of a high BMI and a high absolute weight on the clinical outcome and determined that a high absolute weight might cause more complications like implant failure or pseudarthrosis due to increased forces within the osteotomy gap. However, this presumption could not be confirmed by our results. Neither a high BMI nor a high absolute weight was significantly correlated with post-operative complications. Only three patients among the eight cases of pseudarthrosis had a BMI above 30 and four individuals had an absolute weight of 100 kg and more (Table 4). This fact underlines again the importance of a sufficient osteosynthesis during the HTO procedure.

With respect to the observed decrease of the OKS in patients with a BMI>30 it must be kept in mind that in obese patients possibly the increased stress on the degenerative, medial part of the knee is associated with pain and a more distinctive limited function compared to normal-weight patients.

This study has some shortcomings like the missing determination of the preoperative OKS. The complication data were collected from the medical records of the clinics and from the patient comments during the telephone interview. Thus, we have no information about possible complications of those patients who were not contactable.

Conclusion

This study reveals favourable medium-term results after HTO in varus OA even in smokers and moderately obese patients. No correlation between obesity or smoking habits and the complication rate including non-union could be determined. Thus, open-wedge HTO can be performed even in smokers. The indication should be handled with care in patients with a BMI greater 30 since a negative tendency for the functional outcome according to the OKS was determined.

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