

High tibial osteotomy performed with PEEK implant demonstrated a failure rate of 28%

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ABSTRACT

Objectives Opening-wedge high tibia osteotomies (HTO) can be technically challenging. The HTO iBalance system was designed to reduce vascular complications and to avoid secondary plate removal. The purpose of the study was to evaluate the performance of the HTO iBalance system in patients with symptomatic medial osteoarthritis and varus malalignment.
Methods The study was performed as a retrospective cohort study investigating a consecutive series of patients who underwent HTO with the iBalance system performed by a single surgeon from August 2013 to March 2016 at Zealand University Hospital, Koge, and Aleris-Hamlet Hospital. The primary outcome was the degree of realignment. The secondary outcome was Knee injury and Osteoarthritis Outcome Score (KOOS). Follow-up was performed at mean (SD) 25 (9.7) months. Weight-bearing long-leg standing radiographs were taken before surgery and at follow-up. Failure was defined as collapse of the HTO defined as a correction <50% of the intended correction at time of follow-up. Logistic regression was used to identify risk factors for failure.

Results 44 patients and a total of 47 knees were included in this study. Preoperatively the mechanical axis was a mean (SD) 5.8° (2.9) varus and postoperatively 2.3° (3.7) varus. The HTO failed in 13 of 47 knees (28%). Patients with failure showed no statistically significant differences to non-failure in any KOOS subscore ($p>0.05$). American Society of Anesthesiologists (ASA) score ($p=0.01$) and body mass index (BMI) ($p=0.05$) were correlated with failure, whereas bone transplantation and smoking were not.

Conclusion In this study, the failure rate of HTO was 28%. High BMI and ASA-score were the only risk factors associated with failure while bone grafting and smoking were not.

Level of evidence Retrospective cohort study, level III.

INTRODUCTION

High tibial osteotomy (HTO) is a procedure recommended to younger and active individuals with symptomatic unicompartmental osteoarthritis (OA) with varus malalignment as an alternative to arthroplasty. HTO is a realignment procedure transferring the weight-bearing load from the affected medial compartment to the relatively intact lateral compartment of the knee. It relieves pain, improves function and slows the progression of OA.^{1–3} The procedure has been shown to delay the need for a total knee replacement when proper correction of the malalignment to approximately 3° of valgus is achieved.⁴ Ekland *et al*⁴ shows a 5-year osteotomy

What are the new findings

- ▶ The failure rate of high tibial osteotomy (HTO) using the iBalance system was found to be 28%.
- ▶ High body mass index and American Society of Anesthesiologists score were associated with a higher risk of failure.
- ▶ Bone grafting and smoking were not associated with a higher risk of HTO failure.

survival rate of 94% after HTO and a 10-year osteotomy survival rate of 83%.

Various different techniques have been developed and implemented over the years. Among them, the most widely used is the opening wedge HTO, and the closing wedge HTO with fibular osteotomy.⁵

Both the opening and the closing wedge HTO are usually fixated with a metal plate and screws to stabilise the osteotomy to allow for a quicker healing and reduce the risk of non-union.⁶ The two techniques are not without complications with peroneal nerve palsy and fracture through the lateral cortex being the most common.⁷ According to relevant literature, the rate of lateral cortex fractures is reported to be between 0% and 34%,^{8,9} and vascular complications ranged from 0% to 20%.¹⁰ The high risk of local irritation of the surrounding soft tissue can make it necessary to remove the plate eventually.^{11,12} In total, 7% of all opening and closing wedge HTOs were found to require secondary implant removal because of local irritation from the implant.¹³

To reduce the most common complications of the traditional osteotomy techniques, a system was introduced in 2009 using a non-absorbable wedge-shaped novel polyetheretherketone (PEEK) implant fixated in the bone with novel PEEK screws.^{7,14}

In addition to its less prominent design, the implant is designed to reduce neurovascular injury, avoid soft tissue irritation and thereby secondary device removal¹⁵ which is an important ability if later conversion to total knee arthroplasty (TKA) is deemed necessary.

Furthermore, the avoidance of metal makes the implant compatible with high-quality MR imaging postoperatively.

The implant guide system is developed with an 'envelope' shield to protect the neurovascular bundle and a hinge pinhole meant to maintain the lateral cortex acting as a stress reliever and thereby reducing the risk of intraoperative fracture of the lateral cortex.¹¹



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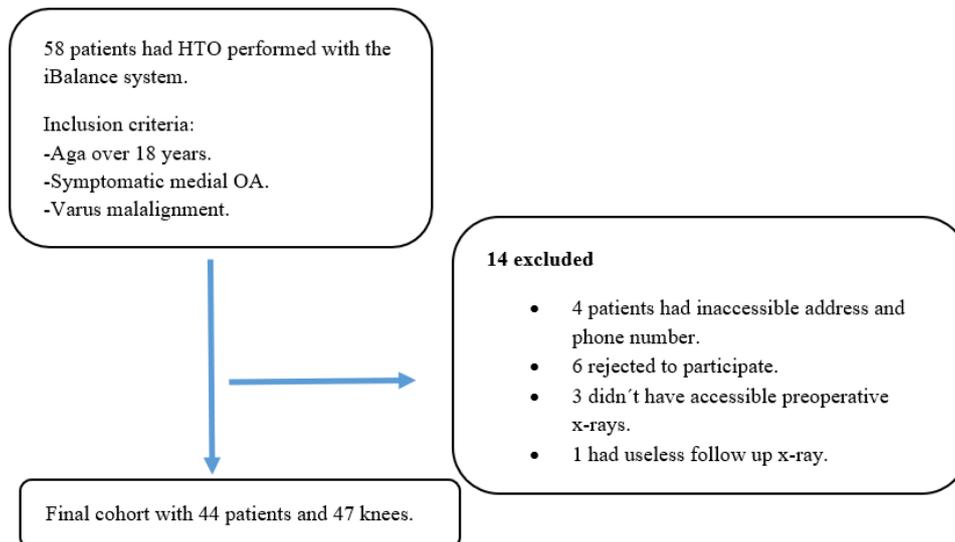


Figure 1 Inclusion/exclusion flowchart of the study population. HTO, high tibial osteotomy; OA, osteoarthritis.

Due to the lack of cortical fixation and potential subsidence in softer metaphyseal bone, some have expressed concern about loss of correction using this implant design.

The purpose of this study was to evaluate the performance of the HTO iBalance system, consisting of novel PEEK implant and anchors, in patients with symptomatic medial compartment OA and varus malalignment with regard to the stability of the HTO and patient-reported outcome. Based on the experience of the surgeon, it was hypothesised that less than 20% would have experienced failure at follow-up. Failure was defined as collapse of the osteotomy of 50% or more.

METHODS

The study was performed on a retrospective cohort of patients who were called in for follow-up investigation in the period from June to November 2017 at Zealand University Hospital. Informed written consent was obtained from all the participants.

Study population

A total of 58 patients underwent HTO with the use of the iBalance system from August 2013 to March 2016. They were all treated by a single surgeon either at the Zealand University Hospital Koege or Aleris-Hamlet Hospital. Both hospitals are located in Denmark.

The patients who underwent surgery at the Zealand University Hospital Koege were identified through the surgical register and patients who underwent surgery at Aleris-Hamlet Hospital were identified by the surgeons operating list. Inclusion criteria were age over 18 years and symptomatic medial OA and varus malalignment (figure 1). The patients were contacted by mail and phone and asked to participate in a follow-up investigation.

Measurement of alignment

Two independent investigators determined the mean of preoperative and postoperative mechanical axis and mechanical axis angle as described by Specogna *et al.*¹⁶ The mechanical axis was determined by a line drawn from the centre of the femoral head to the centre of the ankle. The centre of the knee was identified as a point halfway between the tibial spines on the intercondylar eminence and the centre of the ankle as a point in the middle of the width of the talar dome.¹⁶ The mechanical axis angle was defined as the angle between a line from the centre of

the femoral head to the centre of the knee and a line from the centre of the knee to the centre of the ankle. Normal alignment was defined as a mechanical axis crossing the centre of the knee. In a medial OA knee with varus malalignment, the mechanical axis would shift medially giving a positive mechanical axis angle. After a slight overcorrecting with the HTO iBalance, the mechanical axis would shift laterally and put the knee into slight valgus giving a negative mechanical axis angle (figure 2).

Surgical planning and technique

Preoperative planning was performed for every patient by measuring the mechanical axis angle on full-weight-bearing long-leg standing radiographs. The intended correction was



Figure 2 Preoperative and postoperative weight-bearing long-leg standing radiographs. The dashed line shows the mechanical axis and the solid line the measure of alignment. (A) Preoperative alignment was determined as 6° varus in the present case. (B) Follow-up radiographs show a slight overcorrection shifting the mechanical axis laterally to 1° valgus.

determined with the aim to overcorrect the mechanical axis into 2° valgus.

The novel PEEK implants were available in four sizes (small, medium, large and X-large) and each size was available in various angles from 5° to 15°. The implant size was chosen based on the width of the tibia in the coronal plane. The angle of the implant was chosen based on the intended correction.⁴

The procedure was performed according to the Arthrex surgical technique guidelines.¹⁷

By a medial incision distal to the joint line, the tissue was dissected to the level of the sartorius fascia. The periosteum was opened with an inverted L-shaped incision and the surrounding structures from the posterior medial tibia were released with a tissue elevator. Under fluoroscopy, the iBalance guide system was positioned, and the hinge pin was introduced to prevent fracture of the lateral cortex. A neurovascular shield was inserted posterior to the tibia to protect the neurovascular bundle. Through the guide system, the osteotomy cut was made with an oscillating saw before the osteotomy was opened with a distractor to the intended degree of correction (IDC). Finally, the novel PEEK implant was positioned in the osteotomy and fixed with screws.¹⁵ For the first 16 cases, no bone grafting was used. Between case 16 and 17, the surgeon changed surgical praxis from not filling the gap to always filling the gap and from then on all cases were filled with either autologous or allograft bone chips, or synthetic bone substitute (Quickset, Arthrex, Naples, USA).

Outcomes

The primary outcome was failure of the HTO at follow-up defined as a collapse of the osteotomy of 50% or more. Collapse was measured as the difference between the actual degree of correction (ADC) and the IDC. The ADC was defined as the change in alignment from the preoperative assessment to follow-up. The IDC was defined by the chosen angle of the PEEK implant. Collapse was measured in per cent as:

$$\text{Collapse} = (\text{IDC} - \text{ADC}) / \text{IDC} \times 100.$$

Postoperative full-weight-bearing long-leg standing radiograph after iBalance operations is not a standard procedure in the authors' practice. Therefore, it was not possible to assess the degree of correction immediately after the HTO procedure.

Secondary outcomes were the Knee injury and Osteoarthritis Outcome Score (KOOS)^{18,19} and the Numeric Rating Scales (NRS) for pain.²⁰ Participants were instructed to fill out the KOOS and NRS for pain at the time of follow-up. KOOS was not done preoperatively. The participants were asked to recall their preoperative NRS for pain at the time of follow-up. KOOS consists of five subscales: pain, other symptoms, function in daily living (ADL), function in sport and recreation, quality of life (QOL). KOOS ranges from 0 points representing extreme knee problems to 100 points representing no knee problems.^{18,19} NRS for pain is a subjective 11-point scale used for adults and children over 10 years of age where 0 is no pain and 10 severe pain.²⁰

Standing full-weight-bearing long-leg radiographs were taken for alignment measurements and weight-bearing knee radiographs for OA grading.

The demographic parameters age, gender, American Society of Anesthesiologists (ASA) score, smoking, diabetes mellitus (DM), cardiovascular disease, hypertension, prednisolone treatment, rheumatic disease and body mass index (BMI) of all included participants were registered.

Table 1 Demographic data of the cohort at time of follow-up

| | |
|----------------------------------|------------|
| Age at surgery (years) | 53.7 (8.8) |
| Gender | |
| Male | 28 |
| Female | 16 |
| Knee side | |
| Right | 20 |
| Left | 27 |
| BMI at surgery kg/m ² | 28 (5) |
| Kellgren-Lawrence preoperative | |
| Grade 1 | 11 |
| Grade 2 | 14 |
| Grade 3 | 14 |
| Grade 4 | 8 |
| ASA | |
| 1 | 32 |
| 2 | 7 |
| 3 | 5 |
| DM | 2/44 |
| Hypertension | 8/44 |
| Cardiovascular disease | 3/44 |
| Joint disease | 1/44 |
| Smoker | 10/44 |

Continuous variables are presented as 'mean (SD)'. Dichotomous variables are presented as 'affected/total'.

ASA, American Society of Anesthesiologists; BMI, body mass index; DM, diabetes mellitus.

Statistical analysis

Descriptive statistics of demographic data and outcome variables were performed using relevant statistics according to the characteristics of the variable. Normality of data was assessed visually by creation of histograms and density lines. Paired t-test was used to test the failure and non-failure group related to different descriptive variables. By using a linear regression model, the influence of the variables of interest on the risk of failure were tested. All analyses were performed using IBM SPSS Statistics V.22.0.0.0, and p values less than 0.05 were considered statistically significant.

RESULTS

A total of 58 patients were eligible for inclusion between 2013 and 2016. A total of 14 patients were excluded, giving a final cohort of 44 patients who underwent medial opening wedge HTO with the iBalance system. Follow-up was performed at mean 25 (SD 9.7) months. The demographic baseline characteristics are given in [table 1](#).

A total of 47 knees were included. Out of these, 13 were corrected into valgus and 34 were in varus at the time of follow-up. A total of 13 of the knees left in varus (28%) experienced failure. The last 21 left in varus did not meet our definition for failure.

Preoperative and postoperative measurement of alignment can be seen in [table 2](#).

In [figure 3](#), we see that 31 of the HTOs were filled with either bone graft or synthetic bone substitute. Ten of these (32%) developed failure. Of the 16 knees treated without bone fillers, three (19%) developed failure.

A 4-point improvement in NRS for pain was found between the preoperative NRS score, and the score at follow-up ([table 3](#)).

Table 2 Preoperative and postoperative measurement of alignment of the cohort, non-failure and failure groups

| | All patients (Mean (SD), (Range)) | Non-failure (Mean (SD), (Range)) | Failure (Mean (SD), (Range)) |
|--------------------|--|---|--|
| Preoperative axis | 5.8 varus (2.9), (1.1 varus–11.8 varus) | 3.1 varus (2.0), (1.1 varus–6.25 varus) | 6.8 varus (2.5), (3.4 varus–11.8 varus) |
| Postoperative axis | 2.3 varus (3.7), (4.3 valgus–12.5 varus) | 2.0 valgus (1.2), (0.9 valgus–4.3 valgus) | 2.9 varus (3.0), (0.2 varus–12.45 varus) |

A significantly greater improvement was found in the non-failure group compared with the failure group ($p=0.05$).

Linear regression analysis showed a statistically significant impact on ASA-score and BMI with regard to HTO failure ($p\leq 0.05$), indicating that higher BMI and/or ASA score lead to a higher risk of developing failure. The other investigated factors (steroids, cardiovascular disease, DM and smoking) were not individually associated with failure.

Postoperative KOOS score can be seen in figure 4. Interestingly, patients with failure showed no statistically significant differences to non-failure in any KOOS subscore ($p>0.05$). The failure and non-failure groups scored alike in KOOS except for the quality of life subscale where the failure group scored 10 points lower than the non-failure group.

DISCUSSION

Risk of failure

The most important finding was that out of 47 knees treated with the iBalance HTO system, 13 knees (28%) failed after a mean of 25 months, thereby rejecting our study hypothesis that less than 20% would experience failure. Additionally, two knees were converted to TKA because of pain and therefore excluded from the analysis. In one knee a superficial infection was found and intravenous antibiotics were sufficient. If these three were included, the failure rate would rise to 32%.

The high failure rate (between 28% and 32%) calls for an investigation of additional explanatory factors as other studies report better results. Morris *et al*²¹ investigated accelerated rehabilitation in 20 patients treated with HTO using novel PEEK implants and documenting a loss of correction of $>2^\circ$ in 4 out of 19 knees (21%) of which one required conversion to a TKA. They did not use a failure definition but described a postoperative target correction for all patients as 2° – 3° valgus. In traditional HTO procedures performed with plate fixation, El-Azab *et al*²² found an acceptable correction in 86% of his 56 patients with only 8% defined as undercorrected and 6% as overcorrected. A retrospective Norwegian study evaluated the number of failures in 49 patients treated with HTO. They defined failure as conversion to TKA and found that 13% of the osteotomies failed after a mean of 6.2 years.⁴ Roberson *et al*²³ reported a

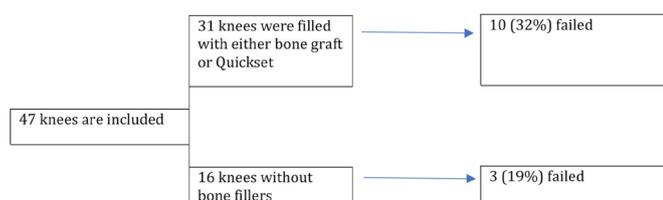


Figure 3 Overview of failure in knees with and without put fillers

Table 3 NRS for pain in all patients and in the failure and non-failure groups

| | Preoperative | Follow-up | Difference | SD | P value |
|--------------------------|--------------|-----------|------------|-----|---------|
| All patients | 7.7 | 3.7 | 4 | 3.1 | <0.01 |
| NRS in failure group | 7.4 | 4.7 | 2.7 | 2.4 | <0.01 |
| NRS in non-failure group | 7.8 | 3.3 | 4.5 | 3.2 | <0.01 |

NRS, Numeric Rating Scale.

lower failure rate with only 10% converted to a TKA with the same failure definition as the Norwegians.

The surgeon operating all cases in the present study describes a learning curve concerning placement of the novel PEEK wedge. Correct placement of the novel PEEK wedge is of utmost importance as it supports the HTO while healing. The novel PEEK wedge must be flush with the cortex to secure optimal cortical support. If the novel PEEK implant is displaced under the cortex while tightening the screws, it might lead to failure.

Undercorrection or overcorrection

Some authors consider the ideal degree of correction from neutral up to 7° valgus of the mechanical axis angle.^{4 24–27} As seen in table 2, the surgeon was careful not to overcorrect. The largest correction was 4.3° valgus. Therefore, no patients were considered overcorrected.

Generally, both undercorrection and overcorrection are related to poor outcomes.^{1 28} An undercorrection may lead to recurrence of the deformity whereas an overcorrection could cause increasing pain and OA in the lateral compartment.²² The postoperative mean axis in this study was 2.3° varus and 31 knees were left in varus malalignment. This is a source of concern that can speak to technical shortcomings of templating, surgical technique or the implant. Schuster *et al*¹ found a better 10-year survival of HTO in knees with 0–3 grades valgus compared with undercorrected knees or knees remaining in varus.

Bone grafting

We did not find association between filling of the osteotomy and development of failure. During the study period, the surgeon changed surgical praxis from not filling the gap to always filling the gap. Therefore, the size of the osteotomy gap was not a determining factor for filling of the osteotomy as it was included in this analysis. Slevin *et al*²⁹ investigated the role of bone filling in osteotomies with a mean opening gap of 9–10 mm. They found longer osteotomy healing time, higher risks of non-union and loss of correction in osteotomies without use of bone filling.^{30 31} Other authors recommended only to use bone graft when the osteotomy gap was >15 mm.³² Siboni *et al*³³ examined the correlation between obese patients and bone grafting and concluded that only corrections over 10° required grafting.

Demographic parameters and preoperative severity of OA

Age, gender, smoking and OA grade did not influence the risk of failure whereas elevated BMI and high ASA score were associated with an increased risk of failure. This was surprising as age previously has been shown to be a risk factor for developing failure of with an increasing failure risk of 7.6% per year.^{6 34} For patients over 65 years, the relative risk was found to be 1.5 times that of younger patients,³⁵ thus leading the authors to recommend not to perform HTO in patients older than 65 years.^{34 36} However, others have found good outcome in patients over 50 years of age with grade 3 and 4 OA and have recommended that nor age or OA grade should be a contraindication for HTO.¹

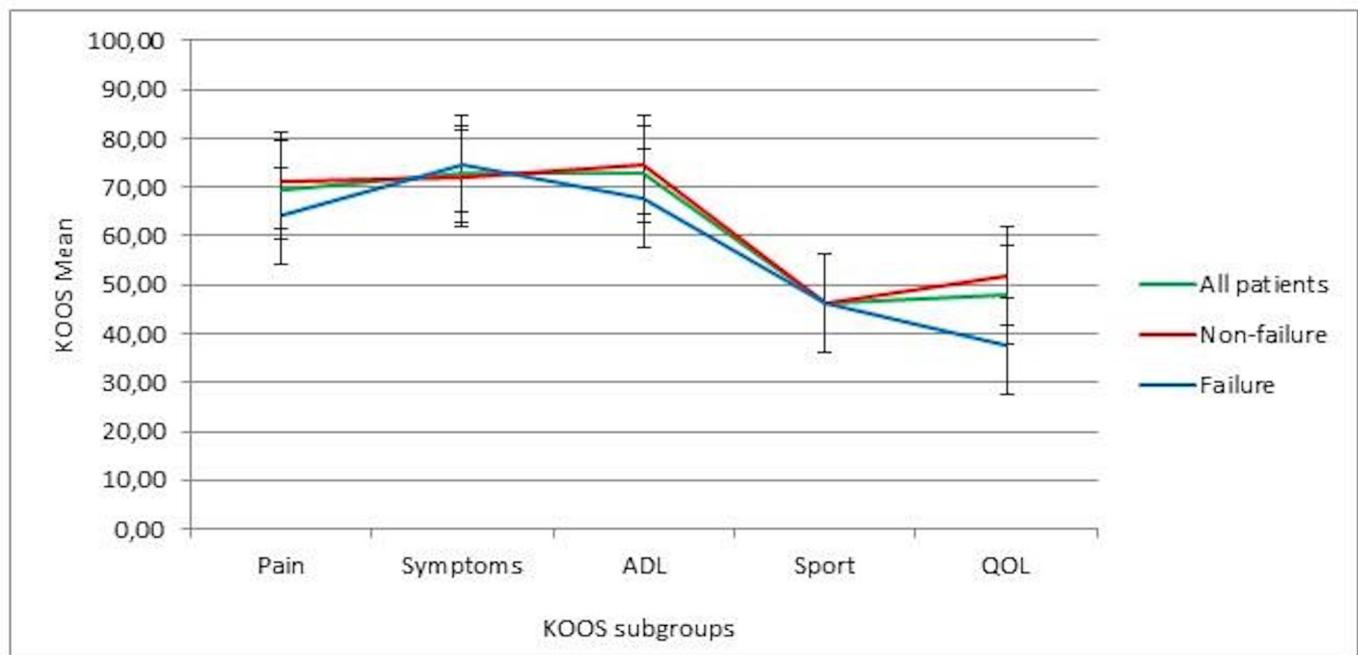


Figure 4 KOOS, mean subgroups score and SD for all patients, failure and non-failure groups. None of the subscores showed statistically significant differences between groups. KOOS, Knee injury and Osteoarthritis Outcome Score; ADL, activities in daily living; QOL, quality of life.

High BMI has been suggested to be associated with delayed healing of the osteotomy³³ and loss of correction,³⁷ but authors are divided with regard to BMI as El-Azab *et al*²² did not find correlation between BMI and the degree of correction.

Average pain measured with an NRS scale showed a significant reduction of pain at follow-up. The improvement was largest in the non-failure group but there was no statistically significant difference to the failure group. The same improvement has been found by Ghinelli *et al*²⁶ who described some important aspects that might have influenced their outcome such as a strong motivation in patients for a new kind of treatment and overall positive response from patients because of no major complication.

KOOS scores were slightly better in the non-failure group compared with the failure group but no statistically significant difference was found. Ekeland *et al*⁴ showed an improvement in KOOS score and later a plateauing in all subscores after 1 year postoperatively. QOL had influence on risk of later conversion to TKA in patients with a 2-year KOOS QOL < 44 compare with a KOOS QOL > 44.

Limitations

This study presents data from a single surgeon introducing HTO performed with the iBalance system as a new procedure. As such, the results cannot be generalised to experienced surgeons in a skilled setting with the iBalance procedure.

It should also be acknowledged that our failure definition was rather inclusive as both surgical and technical reasons for failure are included. The retrospective design yields limitations. Due to the lack of immediate postoperative X-rays, it is not possible to assess how many knees were left in varus postoperatively and whether the failure is caused by insufficient surgical correction or weakness of the iBalance implant. The preoperative NRS was collected at time of follow-up and as such prone to recall bias. No preoperative KOOS score was collected.

CONCLUSION

We found that 28% of patients experienced failure after HTO with the iBalance system. Increased BMI and ASA-score were the only risk factors associated with failure, bone grafting and smoking were not.

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Contributors MIH, LB and KWB conceived idea for the study. MIH, JS and NK acquired the data for the work. All authors contributed to the analysis and the interpretation of data. MIH wrote the manuscript in close cooperation with KWB. All authors have critically revised the manuscript and have agreed to the final version.

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Competing interests MIH, NK, JS and KWB declare to have no conflict of interest. LB is a paid consultant for Arthrex.

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