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Vascular impulse technology versus elevation for the reduction of swelling of lower extremity joint fractures: results of a prospective randomized controlled study

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Aims

Complex joint fractures of the lower extremity are often accompanied by soft-tissue swelling and are associated with prolonged hospitalization and soft-tissue complications. The aim of the study was to evaluate the effect of vascular impulse technology (VIT) on soft-tissue conditioning in comparison with conventional elevation.

Methods

A total of 100 patients were included in this prospective, randomized, controlled monocentre study allocated to the three subgroups of dislocated ankle fracture (n = 40), pilon fracture (n = 20), and intra-articular calcaneal fracture (n = 40). Patients were randomized to the two study groups in a 1:1 ratio. The effectiveness of VIT (intervention) compared with elevation (control) was analyzed separately for the whole study population and for the three subgroups. The primary endpoint was the time from admission until operability (in days).

Results

The mean length of time until operability was 8.2 days (SD 3.0) in the intervention group and 10.2 days (SD 3.7) in the control group across all three fractures groups combined (p = 0.004). An analysis of the subgroups revealed that a significant reduction in the time to operability was achieved in two of the three: with 8.6 days (SD 2.2) versus 10.6 days (SD 3.6) in ankle fractures (p = 0.043), 9.8 days (SD 4.1) versus 12.5 days (SD 5.1) in pilon fractures (p = 0.205), and 7.0 days (SD 2.6) versus 8.4 days (SD 1.5) in calcaneal fractures (p = 0.043). A lower length of stay (p = 0.007), a reduction in pain (p_{preop} = 0.05; $p_{discharge}$ < 0.001) and need for narcotics (p_{preop} = 0.064; p_{postop} = 0.072), an increased reduction in swelling (p < 0.001), and a lower revision rate (p = 0.044) could also be seen, and a trend towards fewer complications (p = 0.216) became apparent.

Conclusion

Compared with elevation, VIT results in a significant reduction in the time to achieve operability in complex joint fractures of the lower limb.

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Introduction

With an incidence of 174/100,000 per year, ankle joint fractures are the most common fracture of the lower limb.[1] Tibial pilon and intra-articular calcaneal fractures, each with an incidence of 10 to 15/100,000 per year, however, represent only a minor proportion.[2] But, because of the joint involvement with an usually serious damage to the articular surface, they are challenging injuries accompanied by many complications.[3-6] The basis for a good clinical outcome and high functionality in these joint fractures is surgical management with anatomical reposition.[4,7,8]

Definitive internal osteosynthesis cannot be undertaken until the swelling of the surrounding soft tissues has resolved.[9,10] This post-traumatic swelling is due to two main components: haemorrhage of the injured vessels and soft-tissue contusion. The subsequent soft-tissue oedema leads to a cycle of an ischaemia-related increase

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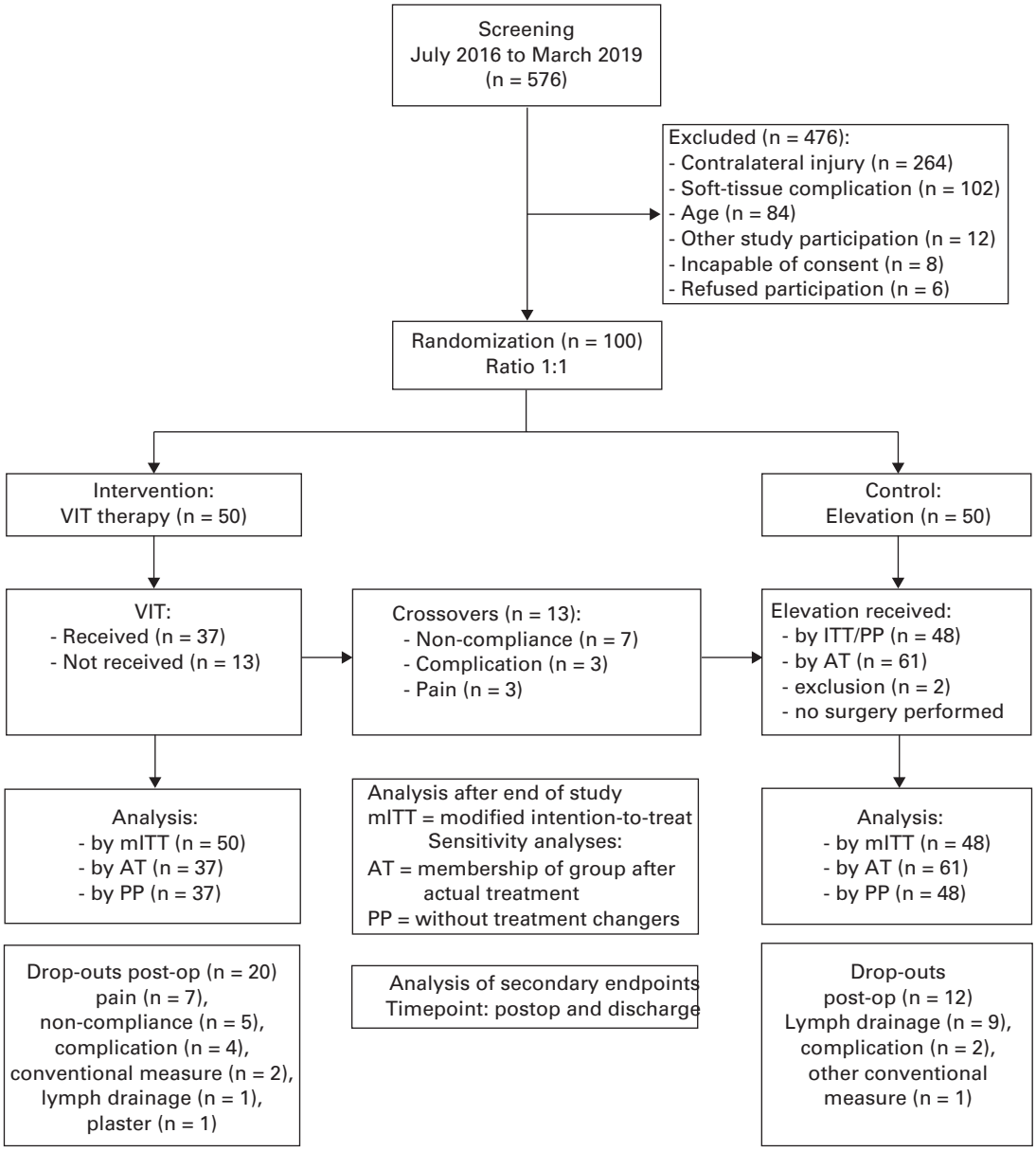

Fig 1

Flowchart of patients through the study. VIT, vascular impulse technology.

in vascular permeability followed by increased compartmental pressures, which in turn intensify the ischaemia by reducing the microcirculation.[11-17] This trauma-induced damage to the microcirculation starts around one to two hours after trauma, needs time to fully develop and usually reaches a peak after 24 to 72 hours.[18-22] This results in an increased risk of wound infections, wound healing disorders, and compartment syndromes.[9,23,24] In addition, because of pressure and hypoxaemia with the accumulation of toxic metabolites in the tissue, the swelling results in increased pain and an increased analgesia requirement.[24-27]

Conventional methods such as elevation and cooling produce a sufficient reduction in swelling, permitting internal osteosynthesis in about ten days.[28,29] Alternatively, vascular impulse technology (VIT) a form of intermittent pneumatic compression (IPC) may be used for soft-tissue conditioning. These pumps were originally developed for thrombosis prophylaxis in the 1980s by Gardner and Fox.[30] The authors were able for the first time to document the physiology of venous return via a venous foot pump by videophlebography. Based on these results, they developed the first pump for IPC with impulse technology, which induces a pulse-like venous return via the foot plexus.[31]

As a result of this enhanced venous return and assisted lymphatic removal, the resolution of swelling is accelerated, and the complication risk should be reduced.[32,33] Some studies have already described a stronger effect of this on swelling than conventional elevation in simple ankle joint fractures.[34,35] However, as systematic reviews have shown, the clinical benefit of VIT in joint fractures of the lower limb

Table I. Demographic data.

Variable	Intervention (n = 50)	Control (n = 48)	p-value
Age, mean (SD)	50.2 (15.4)	51.6 (14.6)	0.649*
Injury, n (%)			
Ankle	20 (40)	20 (41.7)	
Pilon	10 (20)	10 (20.8)	
Calcaneus	20 (40)	18 (37.5)	
AO ankle fracture type, n (%)			0.741†
B	6 (30)	8 (40)	
C	14 (70)	12 (60)	
AO pilon fracture type, n (%)			> 0.999†
B	3 (30)	3 (30)	
C	7 (70)	7 (70)	
Calcaneal fracture Sanders type, n (%)			0.529†
II	5 (25)	2 (11)	
III	10 (50)	10 (56)	
IV	5 (25)	6 (33)	
Injury Severity Score			0.908‡
Median (IQR)	4 (0)	4 (0)	
Mean (SD)	4.4 (1.2)	4.3 (1.0)	
Injury mechanism, n (%)			0.260†
Low-energy	39 (78)	32 (67)	
High-energy	11 (22)	16 (33)	
Sex, n (%)			0.567†
Male	36 (72)	32 (66.7)	
Female	14 (28)	16 (33.3)	
Academic degree, n (%)	**(n = 48)**	**(n = 41)**	0.040†
Yes	16 (33.3)	5 (12.2)	
No	32 (66.7)	36 (87.8)	
Disease requiring treatment, n (%)			0.230†
Yes	16 (32)	21 (43.8)	
No	34 (68)	27 (56.2)	
Smoker, n (%)			0.225†
Yes	14 (28)	19 (39.6)	
No	36 (72)	29 (60.4)	
Side, n (%)			0.213†
Right	25 (50)	30 (62.5)	
Left	25 (50)	18 (37.5)	

*Welch's *t*-test.
†Chi-squared test.
‡Mann-Whitney U Test.
IQR, interquartile range; SD, standard deviation.

with clinically relevant soft-tissue swelling has yet to be sufficiently investigated.[36-38]

The hypothesis of this study is that operability can be achieved more rapidly by means of VIT than by elevation in complex joint fractures of the lower limb.

Methods

This study was planned as a randomized, controlled, prospective, monocentre trial with a parallel group design to evaluate the efficacy of VIT compared with conventional elevation in complex joint fractures. Blinding could not be performed because of the apparent difference in how the attending staff were treated. Patients did not receive any form of payment for their participation.

The study was registered in the German Clinical Trials Registry (DRKS00010510), and approval was given by the Ethics Committee of the Rhineland-Palatinate State Medical Association (837.155.16/10474). The study protocol was published before subject recruitment began.[39]

After signing an informed consent form, patients aged 18 to 80 years with isolated ankle fracture dislocation, tibial pilon fracture type B/C according to AO,[40] or intra-articular calcaneal fracture were included, who required hospitalization and were unable to be definitively treated on the day of admission, i.e. by open reduction and internal fixation (ORIF).

Patients under 18 or over 80 years of age, who had not signed an informed consent form or who had additional limb injuries or local soft-tissue complications (infections, tension blisters, necrosis, compartment syndrome) were excluded. Further exclusion criteria included outpatient treatment, open fractures, decompensated heart failure, acute phlebitis, thrombosis or pulmonary artery embolism, drug or alcohol abuse, current imprisonment, pregnancy, or participation in another clinical trial.

Randomization. Randomization was performed in a 1:1 ratio for all three subgroups separated into permuted blocks of the same length by the web-based programme "Randoulette" (https://wwwapp.ibe.med.uni-muenchen.de/randoulette/index.jsp) on the day of enrolment, and the data were stored in pseudonymized form. Blinding of the subjects or study team was not feasible because of the acoustically and visually apparent intervention from the use of the VADOplex device.

Study procedure and data collection. The detailed description of the study procedure, data collection, and dropouts is outlined in Figure 1. Following randomization of the subjects, VIT therapy was administered in the intervention group by means of the VADOplex system (OPED, Oberlaindern, Germany). This involves a compressor inflating a connected air pad in less than half a second with a pressure of 130 mmHg and then deflating it again. This air pad stimulates the venous foot plexus in the sole of the foot at 20-second intervals and thus causes a pulse-like venous return which is triggered just as effectively as by full weight-bearing on walking.[34] As long as the VIT therapy was running, the study group discontinued elevation and rested the leg below heart level to achieve sufficient priming of the veins. The control group received only continuous elevation of the injured limb in an elevation pillow as a measure to reduce swelling. Both treatments were intended to be used for the whole day and the VIT therapy explicitly for at least six hours to eight hours daily. No further measures were used to reduce the swelling in either group.

Pending definitive internal osteosynthesis, all ankle and pilon fractures were initially stabilized and immobilized by an external fixator and every calcaneal fracture by a lower leg vacuum orthosis on the day of admission. The patients in both groups were immobilized preoperatively. Postoperatively, mobilization was performed by starting with partial weight-bearing for two weeks followed by a weekly increased weight-bearing of 10 kg to 20 kg until full weight-bearing was achieved. As long as full weight-bearing had not been achieved, both groups received DVT prophylaxis by administration of a low molecular weight heparin once daily.

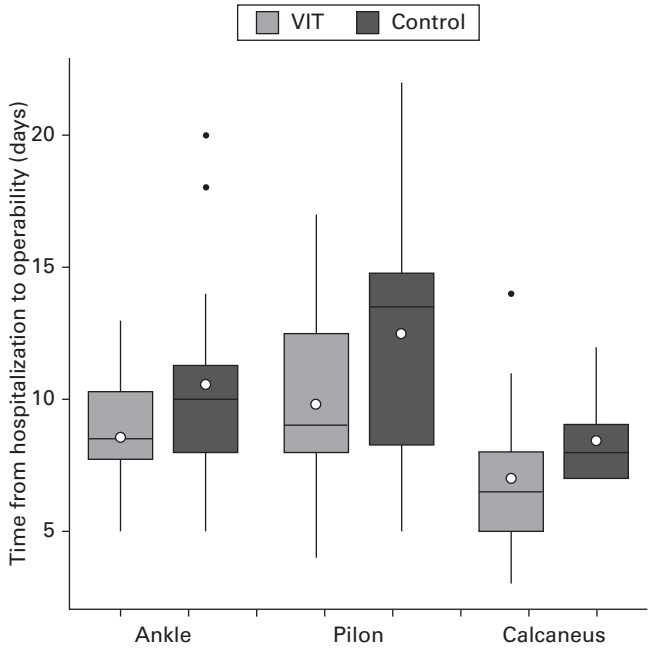

Fig. 2

Boxplot showing time from hospitalization to operability. VIT, vascular impulse technology.

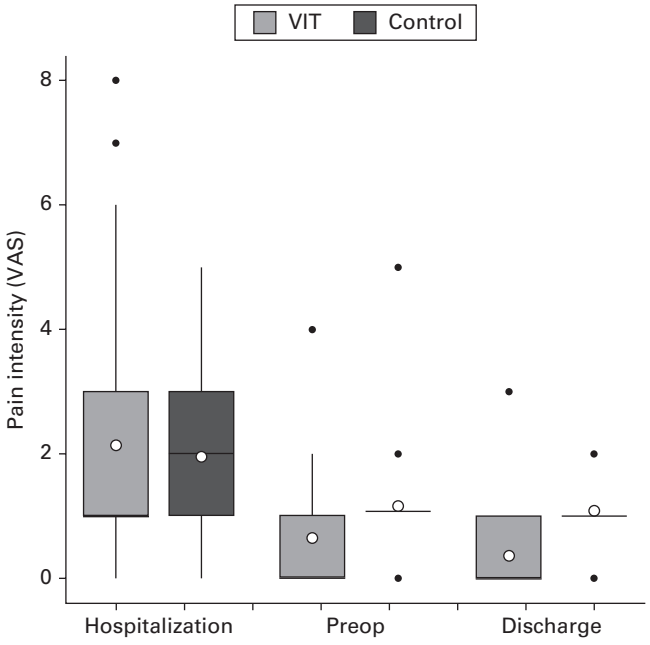

Fig. 3

Boxplot showing pain intensity. VAS, visual analogue scale; VIT, vascular impulse technology.

The primary endpoint of the study was the time from hospital admission until operability (in days), which was evaluated daily by an independent observer (one of two independent consultants). Similar to previous studies, limbs were deemed suitable for surgery as soon as the wrinkle sign turned positive.[9,41] This involved observing whether the physiological skin folds were visible again on eversion and dorsal extension of the foot. If this was the case, then the swelling had been sufficiently reduced to permit surgery. If not, the patient was not fit for surgery. A correlation analysis conducted as part of a preliminary study revealed almost complete consistency ($\kappa = 0.816$) between the two independent observers in terms of the assessment of operability.

Data on the secondary endpoints were also collected daily through a study visit. Secondary endpoints were: duration of hospitalization (days); pain on a visual analogue scale (VAS); as well as analgesia requirement (in accordance with the World Health Organization (WHO) step system[42]); and soft tissue swelling. The WHO step system consists of three steps, starting with the sole use of non-opioid analgesics in step 1. In step 2, low-potency opioids are added and in step 3 high-potency opioids. Soft-tissue swelling was calculated from the increase in circumference (in %) at the level of the smallest circumference of the lower leg and the level of the instep compared to the uninjured contralateral side. Since the aim was to analyze the effectiveness of swelling reduction, we presented the reduction in swelling per day in the VIT group in relation to the value in the control group (in %). In addition, complications and revision procedures during hospitalization were recorded. Complications were defined as any emerging condition requiring additional treatment, and revision procedure as any condition leading to a readmission to the operating theatre.

Statistical analysis. The primary problem statement concerned whether there was a difference in the time from hospitalization to operability between the treatment groups (VIT and conventional elevation). The target number of cases was 20 subjects per group (per fracture) to be able to demonstrate a reduction in the mean time from hospitalization to operability from seven days to five days (SD 2) with a significance level of 5%, a power of 80% and allowing for a dropout rate of 15%. The parameters are based on an earlier study of the effectiveness of IPC in simple ankle joint fractures.[34] This resulted in a total sample size of 40 subjects per fracture.

All data were described with suitable measurements of central tendency and dispersion. The analysis of the primary endpoint (difference in time from hospitalization to operability) was performed using a Welch's *t*-test (for unequal variances) based on the "intention-to-treat" (ITT) population. A modified ITT was used, since two patients were treated conservatively and therefore a value for the primary endpoint was non-existent. Sensitivity analyses were performed on the "as treated" (AT) and "per protocol" (PP) population. The secondary endpoints were analysed exploratorily by suitable statistical analysis:for continuous variables, differences were assessed using Welch's *t*-tests with adjustment for unequal variances, for ordinally scaled variables Mann-Whitney U tests were used, and for nominal scaled variables chi-squared tests were used). Multiple linear regression analyses were performed to investigate potential effects of five demographic characteristics (sex, age, smoking, educational level, previous disease treated by medication) on the primary endpoint.

Table II. Primary and secondary endpoints.

Primary endpoint	n_{VIT}/ n_{K}	VIT (n = 50)	Control (n = 48)	p-value
Time hospitalization to operability, mean (SD)				
Overall				
mITT	50/48	8.2 (3.0)	10.2 (3.7)	0.004*
AT	37/61	7.2 (2.2)	10.3 (3.5)	< 0.001*
Ankle				
mITT	20/20	8.6 (2.2)	10.6 (3.6)	0.043*
AT	15/25	8.3 (2.1)	10.3 (3.4)	0.024*
Pilon				
mITT	10/10	9.8 (4.1)	12.5 (5.1)	0.205*
AT	4/16	6.3 (2.1)	12.4 (4.3)	0.002*
Calcaneus				
mITT	20/18	7.0 (2.6)	8.4 (1.5)	0.043*
AT	18/20	6.5 (2.1)	8.8 (1.9)	0.001*
Secondary endpoints				
Mean pain intensity, VAS (SD)				
Admission	50/48	2.14 (1.86)	1.96 (1.05)	0.552*
Preop	41/48	0.66 (0.85)	1.17 (0.78)	0.005*
Postop	38/46	2.16 (1.91)	3.15 (1.59)	0.013*
Discharge	30/36	0.37 (0.67)	1.08 (0.55)	< 0.001*
Mean narcotics requirement, d (SD)				
Preop	41/47	8.2 (10.3)	12.2 (9.5)	0.064*
Postop	30/36	6.8 (7.7)	11.3 (11.9)	0.072*
Overall complications, n (%)†	50/48	5 (10)	9 (18.8)	0.216‡
Overall revisions, n (%)†	50/48	1 (2)	6 (12.5)	0.044‡
Median hospitalizations (IQR)	50/48	17.0 (14.3 to 21.0)	21.0 (16.8 to 24.0)	0.007§
		Preop	**Postop**	**p-value**
Mean swelling reduction/day, % (SD)		77.8 (55)	12.4 (0.1)	< 0.001*

*Welch's *t*-test.
†Percentages are derived from cases occurring in the corresponding group by ITT.
‡Chi-squared test.
§Mann-Whitney U test.
AT, as treated; IQR, interquartile range; ITT, intention to treat; mITT, modified intention-to-treat; SD, standard deviation; VAS, visual analogue scale; VIT, vascular impulse technology.

Statistical analyses were performed using R v. 3.6.0 (R Foundation for Statistical Computing, Vienna, Austria). Statistical significance was set at $p \leq 0.05$.

Results

Both groups were comparable in terms of demographic characteristics (such as age, sex, concurrent diseases, and smoking) and fracture severity (fracture classification, ISS, injury mechanism) except for educational level (whether or not a degree has been obtained from a university) (Table I). In the VIT group 16 patients required treatment for a pre-existing medical condition versus 21 in the control group (p = 0.230). Pre-existing conditions were comparable between both groups, mostly being high blood pressure (n = 22) or hypothyroidism (n = 11).

Primary study parameter. The primary study parameter was analyzed using Welch's *t*-test for unequal variances. By mITT, the mean time to achieve operability was two days shorter in the intervention group than in the control group (p = 0.004, Welch's *t*-test; Figure 2; Table II). The sensitivity analyses (as treated: group membership according to treatment; per protocol: without crossovers) revealed similar results with a difference of -3.2 days (SD 0.6; 95% confidence interval (CI) -4.3 to -2.0; p < 0.001, Welch's *t*-test). In Table II, the detailed results of the analysis by mITT is illustrated by individual fractures. In the AT population the difference increased to -2.1 days (SD 0.9) in the ankle, -6.1 days (SD 1.5) in the pilon and -2.3 days (SD 0.6) in the calcaneus group. Comparing the younger population with an age below 55 years to the older patients we found an increase in the primary endpoint of 0.7 days (SD 0.7; p = 0.683, Welch's *t*-test). The difference was higher in the control group with a difference of 1.4 days (SD 1.0) in favour of the older patients and 0.1 days (SD 0.9) in the VIT group ($p_c = 0.397$; $p_{VIT} = 1.000$, Welch's *t*-test).

Secondary study parameters. Analyzing the secondary endpoints, the median length of stay (LOS) of 17 days (14.5 to 21.0) in the intervention group was shown to be four days shorter than that in the control of 21 days (16.75 to 24.00; p = 0.007; Mann-Whitney U test). The subjects in the VIT group experienced reduced pain intensity (VA) from the beginning of treatment in comparison to the control (reduction by 0.51 preoperatively; (p = 0.050, Welch's *t*-test), 0.93 postoperatively (p = 0.013, Welch's *t*-test), and 0.71 on discharge; (p < 0.001, Welch's *t*-test) (Table II, Figure 3). During hospitalization, analgesia use in the two groups was comparable (Table III). On discharge, 70% (21/30) of patients in the VIT group were pain-free. By comparison, 11.1% (4/36) of the patients in the control group were pain-free on discharge (p < 0.001, Welch's *t*-test). Preoperatively, the study patients required narcotics in their

Table III. Secondary endpoints.

Secondary endpoints	n_{VIT}/ n_K	VIT group (n = 50)	Control group (n = 48)	p-value
Complications, n (%)*				
Ankle	20/20	2 (10)	5 (25)	0.212†
Pilon	10/10	2 (20)	3 (30)	0.606†
Calcaneus	20/18	1 (5)	1 (5.5)	0.939†
Revisions, n (%)*				
Ankle	20/20	1 (5)	3 (15)	0.292†
Pilon	10/10	0 (0)	3 (30)	0.060†
Calcaneus	20/18	0 (0)	0 (0)	
Median hospitalization (IQR)				
Ankle	20/20	17.0 (14.5 to 21.0)	18.0 (15.0 to 22.3)	0.166‡
Pilon	10/10	17.0 (15.3 to 24.0)	23.5 (21.0 to 26.8)	0.111‡
Calcaneus	20/18	17.0 (14.0 to 20.0)	21.5 (17.3 to 22.8)	0.081‡
$Analgesia_{preop}$ n (%)				
Ankle	17/20			
WHO Step 0		1 (5.9)	0 (0)	
WHO Step 1		12 (70.6)	16 (80)	
WHO Step 2		0 (0)	0 (0)	
WHO Step 3		4 (23.5)	4 (20)	
Pilon	5/10			
WHO Step 0		0 (0)	0 (0)	
WHO Step 1		4 (80)	5 (50)	
WHO Step 2		0 (0)	0 (0)	
WHO Step 3		1 (20)	5 (50)	
Calcaneus	19/17			
WHO Step 0		2 (10.5)	0 (0)	
WHO Step 1		14 (73.7)	14 (82.4)	
WHO Step 2		0 (0)	0 (0)	
WHO Step 3		3 (15.8)	3 (17.6)	
$Analgesia_{discharge}$ n (%)				
Ankle	11/17			
WHO Step 0		3 (27.3)	0 (0)	
WHO Step 1		8 (72.7)	16 (94.1)	
WHO Step 2		0 (0)	0 (0)	
WHO Step 3		0 (0)	1 (5.9)	
Pilon	4/6			
WHO Step 0		1 (25)	0 (0)	
WHO Step 1		3 (75)	6 (100)	
WHO Step 2		0 (0)	0 (0)	
WHO Step 3		0 (0)	0 (0)	
Calcaneus	15/13			
WHO Step 0		2 (13.3)	0 (0)	
WHO Step 1		13 (86.7)	13 (100)	
WHO Step 2		0 (0)	0 (0)	
WHO Step 3		0 (0)	0 (0)	

*Percentages are derived from cases occurring in the corresponding group by ITT.
†Chi-squared test.
‡Mann-Whitney U test.
IQR, interquartile range; ITT, intention to treat; VIT, vascular impulse technology; WHO, World Health Organization.

Table IV. Regression analyses.

Model variables	Estimator*	SE	p-value†
Group	-2.025	0.669	0.003
Age	-0.028	0.023	0.224
Group	-2.082	0.653	0.002
Sex (ref. men)	-1.792	0.709	0.013
Group	-1.823	0.737	0.015
Academic	-1.218‡	0.865	0.163
Group	-2.040	0.677	0.003
Disease requiring treatment	-0.457‡	0.698	0.514
Group	-1.996	0.679	0.004
Smoker	-0.078‡	0.718	0.914

*Interpretation of the estimator: For categorial variables, the estimator indicates the change in time from hospitalization to operability in the variable indicated compared with the reference category. Therefore in the Time ~ Group + Age model, for example, the time from hospitalization to operability in the VIT group is reduced by 2.025 days (because of a negative sign) compared with the control group. For continuous variables, theestimator describes the change in the time from hospitalization until operability with an increase in the continuous variables by 1.
†Welch's *t*-test.
‡The estimator relates to the intensity of the characteristic concerned.
SE, standard error.

pain medication for 4.0 days (SD 2.1) less (p = 0.064, Welch's *t*-test) and postoperatively for 4.5 days (SD 2.4) less (p = 0.072, Welch's *t*-test) than the patients in the control group (Table II).

Over all fracture groups combined, we saw a significant increase in swelling reduction in the VIT group by 77.8% (SD 55) preoperatively and by 12.4% (SD 0.1) postoperatively measured as mean of the swelling in % around the smallest girth of the calf and the instep ($p_{preop} < 0.001$ and $p_{postop} < 0.001$, Welch's *t*-test; Table II).

Complications and revisions. The complication rate of 10% (5/50) in the intervention group was lower than that in the control group of 18.8% (9/48), but without a significant difference (p = 0.216, chi-squared test). We saw five wound healing problems (VIT 1; control 4), three cases of challenging postoperative oedema (VIT 2, control 1), one bleeding from a pin site (VIT 1, control 0), one pressure ulcer (VIT 1, control 0), two subluxations in an external fixator (VIT 0, control 2), and two cases of deep infection (VIT 0, control 2). In the intervention group, a revision was performed in one patient (2%) (secondary suture following intraoperative VAC) while in the control group, six patients (12.5%) underwent revision (two compartment releases on the day after ORIF of a pilon fracture, two corrections of external fixator, one debridement and metal removal due to plate infection, one wound revision of tibial pin site and secondary suture laterally), representing a significant difference (p = 0.044, chi-squared test). Overall, the complication rate was slightly higher among the younger patients with 16% (10/62) compared to 11% (4/36) in the older patients (p = 0.564, chi-squared test).

Regression analyses. The regression analyses (duration~ group + demographic characteristics; Table IV) only showed a significant mean reduction for women by 1.8 days in the time to operability compared with men (p = 0.013; estimator factor group -2.08, p = 0.002). This reduction was only seen in the control group and not in the intervention group as well. No differences in duration were observed for the characteristics “age”,

"academic" (defined by a university degree), "disease requiring treatment" (i.e. anticoagulative drugs), or "smoker".

Discussion

Venous foot pumps were developed following the discovery of the venous foot plexus and its physiology in the prevention of deep vein thrombosis (DVT).[33] Several studies were conducted in this respect and demonstrated a prophylactic effect, particularly in major orthopaedic surgery, such as total hip arthroplasty, with a lower incidence of pulmonary embolisms.[32,33,43–47] Few studies to date have considered the benefit and effectiveness of VIT therapy on reducing swelling in fractures of the limbs.[34,48–53] Studies published so far relate mostly to small study populations or limited indications. Stranks et al[54] in 1992 demonstrated a swelling-reducing effect of IPC. With a treatment period of 15 hours daily, there was a reduction in swelling of up to 3 cm in the hip and 1.5 cm in the calf. In 2004, Caschman et al[34] conducted the only randomized controlled trial (RCT) of the present question to date. The authors specifically investigated the benefit of IPC for soft-tissue conditioning. In the case of simple, unimalleolar ankle joint fractures, a significantly more rapid reduction in swelling and a decrease in the soft-tissue complication risk was demonstrated with IPC compared with elevation. A further study by Dodds et al[48] from 2014 also demonstrated a positive effect of IPC. The authors reported that the patients in the intervention group were able to undergo surgery and be discharged one day earlier. The rate of wound infections decreased from 11% (8/73) in the control group to 3% (2/64) in the intervention group. However, more than half the cases involved unimalleolar ankle fractures, and a retrospective cohort was used as control. In a study by Arndt et al,[53] it was also examined whether IPC can help reduce the time to surgery in malleolar fractures. However, they used a device reaching from toe to the hip and performed treatment during elevation, both of which do not resemble the physiological function of the venous foot pump. With a mean time to surgery of around 22 hours in the study and the control group, their study design was inadequate to investigate prolonged preoperative hospitalization because of soft-tissue swelling. Alkner et al[51] used a protocol for distal radial fractures in which IPC was first used after four weeks of post-surgical immobilization and Yamazaki et al,[52] who also investigated the effect in distal radial fractures, used a non-physiological treatment protocol consisting of a continuous pressure of 20 mmHg.

All the discussed methodological weaknesses and potential sources of bias have also been covered in the systematic reviews of Winge et al[37] and Clarkson et al[36] that were published almost simultaneously in 2017. They also noted that despite this supporting evidence for the usage of IPC, surgeons still mostly use only passive methods for soft-tissue conditioning. These reviews and the medical guideline on IPC from 2018 came to the conclusion that, based on the available evidence, no valid conclusion can be drawn regarding the use of IPC on post-traumatic swelling and its effect in clinical outcomes. Further, well-designed studies are needed to assess their significance in perioperative fracture management.[45]

The literature results were confirmed in the present RCT study. The patients in the intervention group achieved operability significantly earlier. In the case of ankle fracture dislocation, operability was achieved two days faster, in intra-articular calcaneal fractures 1.4 days faster and in tibial pilon fractures almost 2.7 days faster. Intra-articular calcaneal fractures and pilon fractures, in particular, are associated with a high rate of soft-tissue complications, as the soft-tissue lining is very thin and the effect of force in these fractures is very marked.[3-5]

A significant effect of VIT therapy was also demonstrated in the present study in terms of the reduction in soft tissue swelling: preoperatively we achieved a faster oedema reduction by 77.8% and postoperatively by 12.4% in the study group. The lower difference postoperatively might be due to the lower swelling already achieved because of the better soft-tissue conditioning preoperatively, supported by the lower swelling in the VIT group with a median of 2.3 cm (1.5 to 3.6) versus 3.0 cm (1.5 to 4.0) in the control group. In this study, fewer complications (10% vs 18.8%) occurred in the intervention group. Revision surgery was performed in one patient in the intervention group (2.0%) and in four patients in the control (8.3%) for a soft-tissue-related complication. Furthermore, the patient in the intervention group reported significantly less pain with a relevant shorter dependence on narcotics in the medication, possibly as a result of improved microcirculation and increased venous return associated with lymphatic effects.[21] It may therefore be concluded that VIT therapy represents an effective tool for soft-tissue conditioning even in critical soft-tissue conditions. This is further confirmed by the comparison between the older and the younger study population. Among the older group no increase and even a slight decrease in preoperative hospitalization and complication rate could be found. Thus, it can be concluded that these groups are comparable and the VIT therapy seems to be an effective tool especially in older patients.

The small number of cases of tibial pilon fractures with only half the calculated sample size may be mentioned as a limitation of the study. This is because this patient population met too many exclusion criteria, primarily often presenting with bilateral injuries or serious soft-tissue complications such as compartment syndrome and tension blisters upon admission. To avoid protracting the course of this study further by an estimated three years until the planned number of cases may be achieved, we refrained from including a further 20 patients. A further limitation of the study is the number of patients who could not comply with the VIT therapy. A total of six patients discontinued the study intervention because of pain on use (n = 3) or complications (n = 3). The majority of protocol violators (n = 7% and 14% of all intervention patients) failed to use the device adequately. Frequently reported reasons for this were the noise associated with use or lack of interest. The treatment duration of VIT therapy recommended by the manufacturer and also in other studies is at least six to eight hours daily for sufficient benefit to be obtained. An effective benefit of VIT therapy can therefore only be achieved with sufficient patient compliance or monitoring, a conclusion also drawn by Braithwaite et al[55] in their feasibility study on the use of in-plaster VIT as thrombosis prophylaxis.[55]

The recording of the primary endpoint constitutes a further limitation of the study. The primary endpoint, operability,

was determined by two independent physicians based on the "wrinkle sign". The subjectivity of this parameter was offset to a certain extent by the fact that this parameter was recorded by two independent consultants at the hospital, between whom a very good correlation in such recording had been demonstrated in a previous study ($\kappa = 0.816$). In comparable earlier studies, operability was also used as a primary study parameter and "wrinkle sign" was given as a relevant criterion for this.[29,49,56–63] Furthermore, a significantly faster reduction in swelling was found in the VIT group. The validity of these data, however, is somewhat limited because of the error-prone measurement method using a tape measure and because of the large measurement error when measuring in 5 mm steps. To limit this error, circumference measurements were recorded daily and calculated from the reduction in swelling/day in % for the analysis of the mean. The previous studies mostly used volumetric measurements to determine the reduction in swelling. In the present study, unstable joint fractures were included for the most part, which in some cases were stabilized externally with a fixator. A volumetric measurement would therefore only have been possible to a limited extent, if at all.

In complex intra-articular fractures of the ankle, tibial pilon, and calcaneus, the use of IPC with vascular impulse technology (VIT) produces sufficient soft tissue conditioning and is superior to elevation alone. Operability is achieved on average at least two days earlier, reduction of swelling is accelerated, pain is decreased, and the usage of narcotics and rate of revision surgery tend to be reduced. VIT therapy therefore represents a helpful tool for soft-tissue conditioning in addition to other measures for reducing swelling, such as lymph drainage or elevation, and can be used as an adjunct to these in everyday clinical practice.

Take home message

- Vascular impulse technology therapy results in a faster operability compared to elevation, reduces pain, and tends to reduce the soft-tissue-related revision rate and swelling reduction compared to elevation.
- It is a low-complication, useful adjunct to soft-tissue conditioning of complex lower limb fractures, when used for at least six to eight hours per day.

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