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TRAUMA SURGERY

Aftertreatment of malleolar fractures following ORIF—functional compared to protected functional in a vacuum-stabilized orthesis: a randomized controlled trial

Philipp Honigmann · Sabine Goldhahn · Jan Rosenkranz · Laurent Audigé · Daniel Geissmann · Reto Babst

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Abstract In a monocenter randomized controlled trial, 45 patients with isolated malleolar fracture type OTA/AO 44 A1–B2 undergoing ORIF were allocated randomly to a postoperative treatment either with a vacuum-stabilized orthesis with prescribed full weight bearing after the second week (23 patients) (orthesis group—OG) or with functional aftertreatment with partial weight bearing of 15 kg for 6 weeks (22 patients) (control group—CG). Outcomes were compared at 6- and 10-week follow-up examinations. The Olerud and Molander ankle (OMA) score, ankle swelling, usage of crutches, range of motion, Short Form 12, patient-reported visual analogue scales (VAS) (pain, comfort, walking confidence) and time to return to work were evaluated. All patients of OG showed reduced swelling at discharge. The median OMA scores after 6 weeks were 42 and 42.5 ($p = 0.46$) and after 10 weeks 69 and 72 ($p = 0.55$) in the OG and CG, respectively. The time to achieve secure walking capacity was reduced by 1 day ($p = 0.03$) in the OG. After ORIF of simple malleolar fractures, patients with a vacuum-stabilized orthesis can bear full weight 2 weeks postoperatively. This group experienced no adverse events. Postoperative swelling was significantly reduced and of the ability to walk on stairs confidently was shorter as compared to a functional aftertreatment without any external stabilization of the ankle.

Keywords Ankle fractures · Osteosynthesis · Functional aftertreatment · Orthesis

Introduction

The adequate postoperative aftertreatment of ankle fractures is still a topic of debate [1–8] and it may influence not just functional outcome but also the time needed for adequate walking capacity using crutches. Functional results did not show a significant difference in long-term outcome between ankles treated functionally without external stabilization compared to plaster immobilization for 6 weeks after ORIF of malleolar fractures [7]. However, early mobilization has shown to prevent late complications of joint immobilization like muscle atrophy, [8–11] thrombosis, damage of cartilage and seems to enhance fracture healing [12–15]. Patient compliance and other factors request plaster immobilization in many clinical settings. Functional aftertreatment often requires partial weight bearing for a period of 6 weeks, whereas immobilization in a plaster cast permits earlier weight bearing when simple malleolar fractures after ORIF are considered. Postoperative treatment in a removable vacuum orthesis with limited

The authors Philipp Honigmann and Sabine Goldhahn have contributed equally to this work.

P. Honigmann (✉) · J. Rosenkranz · R. Babst
Department of Surgery, Trauma Unit,
Kantonsspital Luzern, Postfach,
Lucerne 6006, Switzerland
e-mail: philipp.honigmann@ksl.ch

S. Goldhahn · L. Audigé
AO Clinical Investigation and Documentation,
AO Foundation, Clavadelerstrasse,
Davos Platz, 7270, Switzerland

D. Geissmann
Regionalspital Emmental AG,
Burgdorf 3400, Switzerland

range of motion (ROM) improved functional outcome and allowed to withdraw crutches earlier, similar to the regimen with the use of plaster immobilization [16].

The aim of this randomized controlled trial was to investigate whether an early full weight bearing in an orthesis (Fig. 1) in contrast to a functional treatment and partial weight bearing would lead to improvements in functional results, subjective walking confidence, patient comfort and earlier return to work. In addition to this we were interested to explore clinical aspects such as duration of hospitalization, ROM, swelling, haematoma under different treatment settings.

Materials and methods

Patients between 16 and 65 years, with a body mass index (BMI) <35, who had sustained a displaced malleolar fracture type Weber A or B (AO 44 A1, 2, 3 and AO 44 B1, 2) because of a single trauma, were eligible. Operation was performed in accordance with the AO principles of fracture management [17] using a one-third tubular plate with or without a plate-independent compression screw (Fig. 2). Patients fulfilling the eligibility criteria were included after an informed consent. The study was approved by the local Ethical Committee of the Kanton Lucerne, Switzerland (approval number 345).

After obtaining the informed consent patients were randomized to either functional postoperative treatment without external stabilization (control group—CG) or postoperative stabilization in a vacuum orthesis (Vacoped®; orthesis group—OG) using opaque envelopes provided by an external independent investigator.

The initial postoperative procedure for all patients was the removal of drainage after 24–48 h. The operated leg was either placed in a plaster of Paris splint for the CG or in the orthesis for the OG on a 45° Hess-splint followed by 2–4 days bed rest depending on postoperative soft tissue swelling. Actively assisted mobilization of the upper ankle joint was started on the first postoperative day under the supervision of a physiotherapist. No additional physical therapy was applied postoperatively.

Fig. 1 The vacuum orthesis (Vacoped®) with the possible ROM (plantarflexion/dorsalextension) of 10°/0°/10°

Fig. 2 Example of anterior–posterior and lateral postoperative radiograph of an ankle fracture 10 weeks after osteosynthesis

Orthesis group

Depending on postoperative swelling, the orthesis was applied between the second and the fourth day postoperatively. Partial weight bearing of 15 kg and free ankle movements (plantarflexion, dorsalextension, inversion and eversion) were then established. Full weight bearing depending on the pain level was allowed after 14 days postoperatively. Walking without crutches was allowed after follow-up at 3 weeks. If the latter was possible, thrombosis prophylaxis was stopped in patients without additional risk factors. Patients were allowed to take the orthesis off for the actively assisted physiotherapy (pain depending free movement of the ankle) and during night rest.

Control group

A bandage was applied around the ankle postoperatively. Mobilization with partial weight bearing of 15 kg on crutches with free movement of the ankle joint started between the third and fifth postoperative day. It was continued until the end of the sixth postoperative week. Full weight bearing was allowed after the 6-week follow-up with X-ray control.

The determining factor for discharge was the ability to climb nine defined steps on stairs safely. Patients were allowed only to exercise their walking ability on stairs after a safe partial weight bearing walking on even ground was confirmed by a standardized protocol. This protocol consisted of testing the amount of partial weight bearing on a force plate applying 15 ± 5 kg three times at a 1-min interval [18].

Outcome

Functional outcome (primary investigation goal) was assessed according to the Olerud and Molander ankle (OMA) score [19], the Short Form (SF12) physical and mental health score and the duration of working incapacity, which was determined either during follow-up or by the patients' general practitioner. Working capacity was defined as the ability of the patient to return to the work prior to the accident. Subjective perception of walking security and satisfaction with the treatment regimen was measured by visual analogue scales (VAS). Additionally the ROM, pre- and postoperative swelling (ankle circumference), atrophy of calf muscles 15 cm below knee joint were measured, and the presence of pre- and postoperative haematoma was determined. The duration of hospitalization was recorded (secondary investigation goals).

All patients were examined using a standard protocol at 6 and 10 weeks postoperatively.

Following a pre-study pilot phase, we hypothesized that the median point score of OMA would be at least ten points higher at 6 and 10 weeks follow-up for patients in the OG and that this difference was clinically relevant.

All personal and examination data were collected and documented on the examination form and manage with MS Access.

The imbalance of the treatment groups with regard to baseline characteristics was checked by descriptive statistics. The Wilcoxon rank-sum test and the Fisher exact test were applied to compare outcomes between groups. An intention-to-treat analysis (ITT) [20] was performed. The effect on outcomes of an obvious imbalance of baseline characteristics between the groups was assessed using uni- and multivariable regression analysis.

Results

Forty-five of 54 patients examined were eligible and enrolled into the study (Fig. 3). Data of 45 patients were available for the final statistical analysis. One patient randomized to the CG was treated with a circular plaster cast. Due to an ITT analysis the patient was not excluded and was treated like a patient from the CG. Two patients from the OG were lost to follow-up, one after 3 weeks and the other after 6 weeks. The available data were included in the final analysis.

Twenty-two patients (13 women) were in the control and 23 patients (9 women) in the OG, with a median age of 38.1 and 42.5 years, respectively (Table 1). The median BMI was 24.4 kg/m^2 in both groups. Ten patients in the control and 11 patients in the OG fell or slipped and 8 patients in both groups injured themselves in a supination trauma. The main fracture type was AO 44 B1 in both groups. Two patients of the OG had a fracture type AO 44 A1 and eight patients of the CG sustained a fracture type AO 44 B2. In both groups no additional ligamentous lesions were clinically observed. Two patients in the OG had co-morbidities that might affect the rehabilitation programme i.e. one had a depression and another sciatica. The median time between the accident and the operation was 4 days in the OG and 2 days in the CG. In both groups no complications occurred during surgery. The median operation times were 63 and 80 min in the OG and CG, respectively. Taking into account the fact that groups were imbalanced with regard to gender, fracture type, time to and duration of surgery; multivariable analyses were used to control these factors.

The times to follow-up were scheduled, as in the protocol, except at the 10-week follow-up; patients in the CG were examined 3 days later on average ($p = 0.05$) (Table 2). At discharge and at the 6-week follow-up, no significant difference in the ability to partial weight bearing was observed between the groups as assessed using the force plate [18].

Median OMA scores were 70 (range 35–95) at 6 weeks and 80 (range 40–100) at 10 weeks; they showed no significant differences between treatment groups. By multivariable regression analysis correction for the imbalance of baseline characteristics, and the mean difference between groups were non-significant and estimated at 1.9 (95% CI: −14.2 to 10.4; $p = 0.81$) and 5 points (95% CI: −18.4 to 8.6; $p = 0.53$) in favour of the CG.

For the subjective assessment of walking confidence the patients' satisfaction VAS was similar for pain and comfort in both groups (Fig. 4). A significant difference of one point ($p = 0.02$) in favour of the CG was measured at the 10-week follow-up. A difference of six points ($p = 0.01$) in favour of the CG was observed in the SF12 mental health score after 6 weeks (Fig. 5). The SF12 physical health score after 6 and 10 weeks and the SF12 mental health score after 10 weeks did not significantly differ between groups.

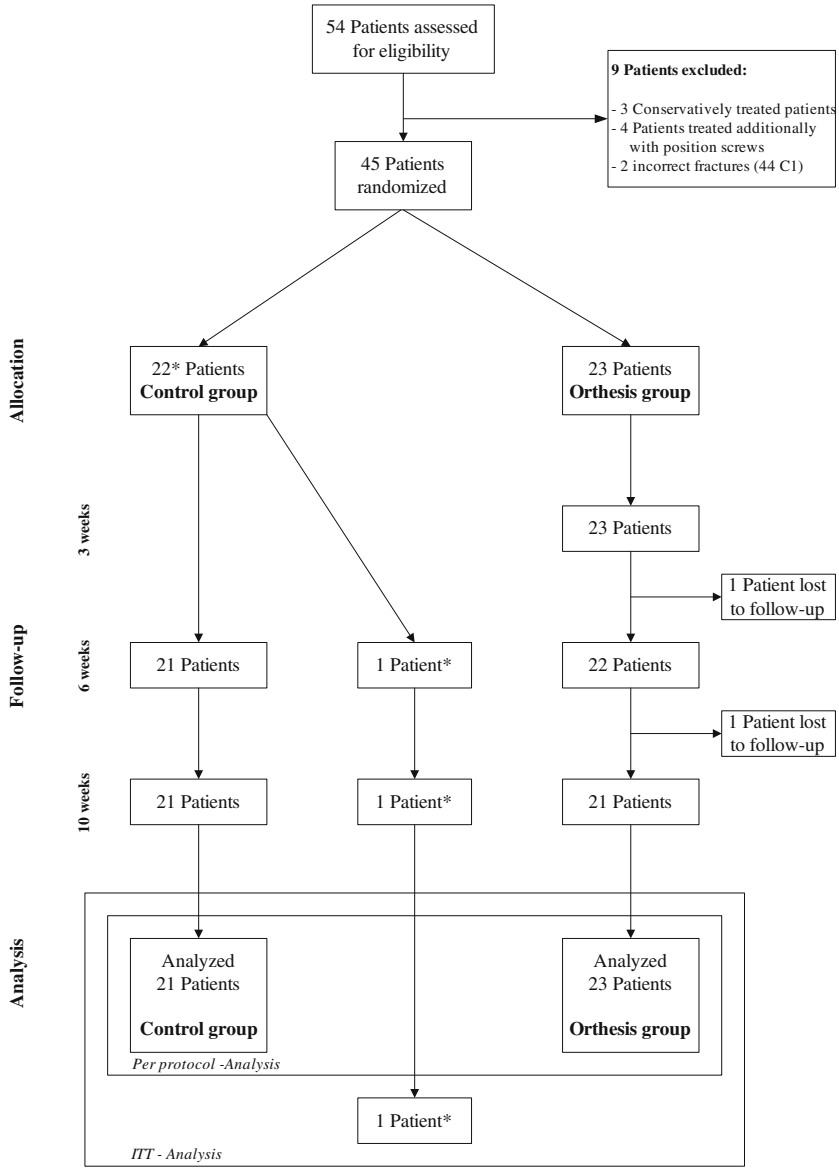

Fig. 3 Flow diagram of patient recruitment, treatment allocation and follow-up. Patient flow chart adapted from the CONSORT statement [26] (*1 Patient treated with below knee plaster cast and not excluded by ITT—principles)

The difference in perimalleolar circumference decreased significantly from 2 cm at baseline to about 1 cm the 6 and 10 week follow-ups ($p < 0.008$) (Fig. 6). In the OG, it was significantly reduced by 1.5 cm ($p = 0.02$) at discharge.

At the discharge and at the follow-up visits no signs of atrophy were observed (Fig. 7). Postoperative haematoma and local swelling subsided in all patients during the follow-up period without a significant difference between the treatment groups.

Four patients of the OG were able to bear full weight after 3 weeks and 21 after 6 weeks postoperatively. Nine of the CG patients were fully weight bearing after 6 weeks. Full weight bearing was possible for all patients after 10 weeks.

A median difference of plantar flexion of 2.5° ($p = 0.05$) and inversion of 10° ($p = 0.02$) occurred in favour of the CG after the 6-week follow-up (Fig. 8). No further significances were observed for the ROM.

The overall hospitalisation time was equal in both groups with 6 days (range for CG 3–15 and 2–10 for OG). The postoperative hospitalization time was significantly reduced by 1 day in the OG (1–7 days) ($p = 0.04$). Crutches were used for 12.5 days ($p = 0.007$) less in the OG (median 32 days; range 16–68) than in the CG (median 44.5 days; range 26–91). One patient in each group had not returned to work at the time of the last follow-up. For the other patients, the median time until their return to work was 37 days (18 patients; range 7–78) for the OG and 53 days (16 patients; range 15–68) for the CG ($p = 0.79$). Patients in the OG tended to return to their previous work earlier than the CG patients (Kaplan–Meier curves in Fig. 9).

Table 1 Baseline and operation-related parameters

		Orthesis group			Control group		
		n	Median	Range	*n*	Median	Range
Number of randomized patients		23			22		
Age (years)		23	42.5	(17.3–61.9)	22	38.1	(18.5–65.7)
Gender	Male	15			9		
	Female	9			13		
Employed	Yes	20			16		
	No	3			6		
Body mass index (kg/m^2)		23	24.4	(15.6–32.4)	22	24.4	(20.7–33.8)
Injury mechanism	Fall, slip	11			10		
	Direct trauma	1			1		
	Supination	8			8		
	Pronation	1			0		
	Not specified	2			3		
AO-classification (44)	A1	2			0		
	A2	0			0		
	A3	1			0		
	B1	20			14		
	B2	0			8		
Danis and Weber	A	1			0		
	B	22			21		
Time between accident and admission to hospital (days)		23	1	(0–9)	22	0	(0–4)
Earlier injuries to the injured leg		3			1		
Circumference perimalleolar preoperative[a] (cm)		23	2.5	(0.5–6)	22	2.25	(0–4)
Haematoma	Yes	17			14		
	No	6			8		
Time of surgery (days)	Primary	5			8		
	Postprimary	18			14		
Waiting period for surgery (days)		23	4	(0–9)	22	2	(0–7)
Duration of surgery (minutes)		23	63	(42–114)	22	80	(37–125)
Haemostasis	Yes	14			12		
	No	9			10		

[a] Absolute difference

Table 2 Time to follow-up examination, partial weight bearing and primary functional score

		Orthesis group			Control group			
		n	Median	Range	*n*	Median	Range	*P*[a]
Time to follow-up (days)	Discharge	23	3	(1–7)	22	4	(2–14)	0.04
	6 weeks	23	42	(35–47)	22	42.5	(35–51)	0.54
	10 weeks	21	69	(62–80)	21	72	(57–131)	0.05
Kistler force plate (kg)	Discharge	21	14.3	(7.6–19.9)	21	12.9	(7.2–27.5)	0.97
	6 weeks	16	25.3	(10.8–58.3)	17	18.8	(5.6–43.8)	0.26
Score Olerud and Molander	6 weeks	22	72	(35–95)	21	70	(45–90)	0.46
	10 weeks	21	80	(40–100)	22	85	(40–100)	0.55

[a] Wilcoxon rank-sum (Mann–Whitney) test

Discussion

This randomized controlled trial was conducted to test whether early mobilization of operatively treated ankle fractures supplemented by the use of a vacuum-stabilized orthesis with a limited ROM could lead to a better functional outcome than a functional aftertreatment. Comparing the same orthesis that was used in this study with complete immobilization in a plaster cast, Stöckle et al. [21] found better functional outcome parameters. In our study, the OMA score was established as our primary investigation goal to assess the functional outcome of the injured ankle. Although we planned to randomize 64 patients, recruitment was stopped after 45 patients. The immediate consequence was a reduction of the power of the study to detect an expected ten-point difference in favour of the OG. The lack of significant differences between our groups might be related to small sample size, but considering the small differences in scores between the groups (and

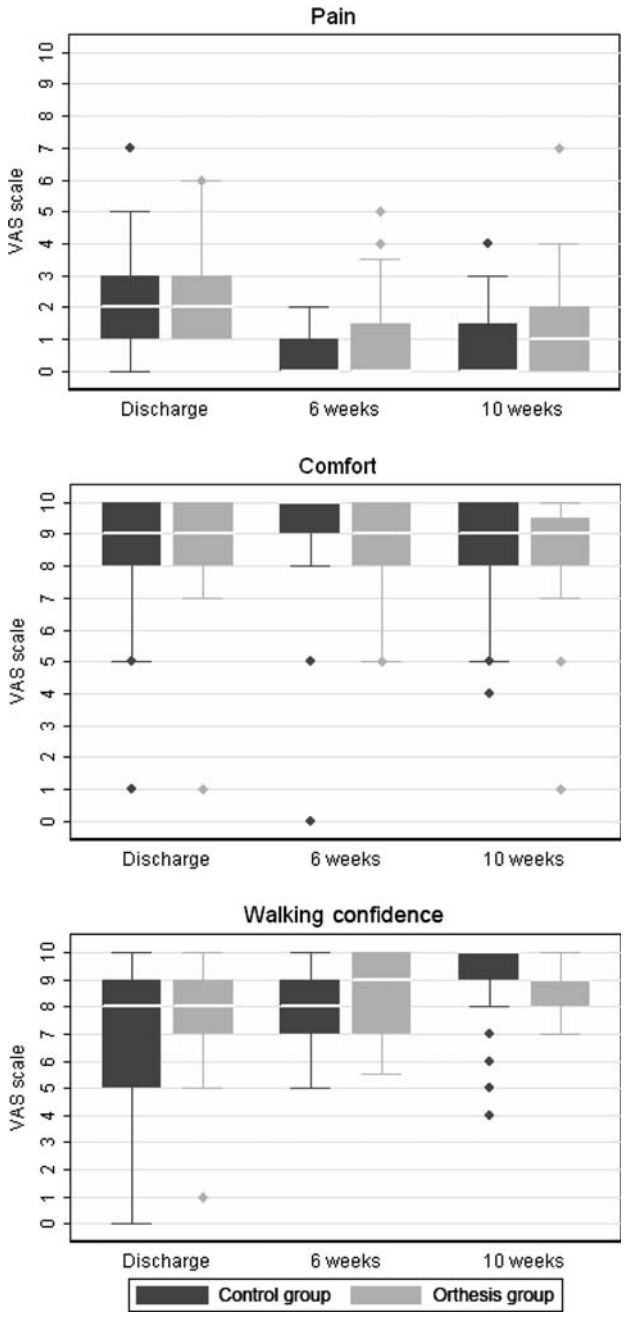

Fig. 4 Comparison of patient-reported VAS—scores for the OG and CG

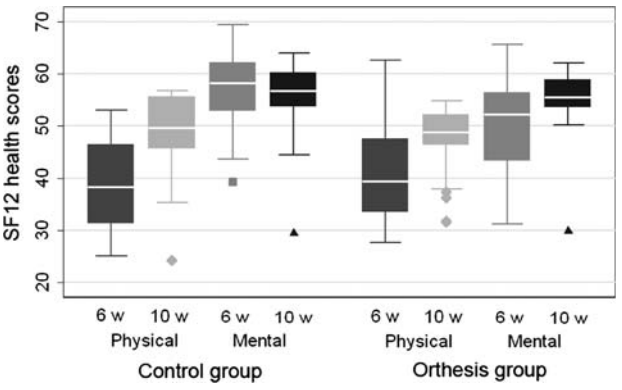

Fig. 5 Comparison of the SF12 physical and mental health score

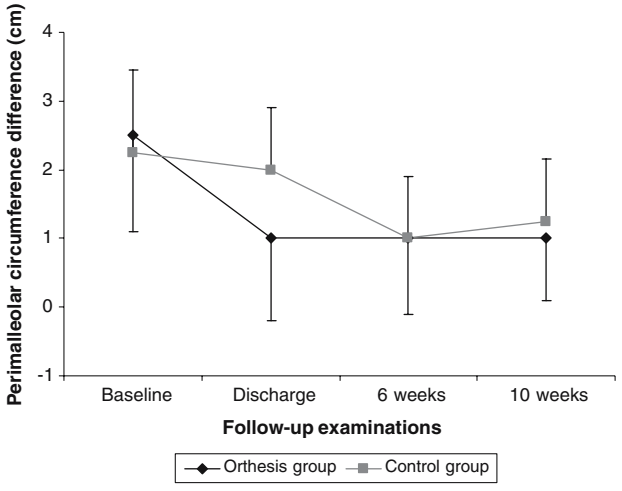

Fig. 6 Median perimalleolar circumference difference at baseline and follow-up examinations

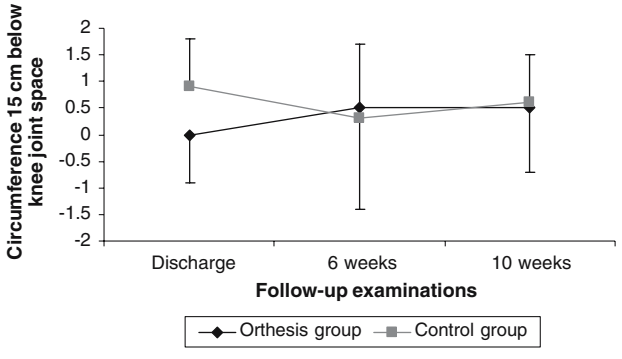

Fig. 7 Median and circumference difference 15 cm below the knee joint space at follow-up examinations as a sign of muscle atrophy

their confidence intervals), we believe that a primary goal of 12-point difference in the OMA score with our number of patients would have led to significant differences between the groups. For a significant difference in our result of the OMA score, we needed to have at least 1,000 patients in each group.

One eligible patient randomized to the CG received a below-knee circular plaster cast. According to the ITT principles, the patient remained in the study. ITT means that all patients need to be analysed in the treatment group they have been randomized to, even if the treatment changes [20, 22]. This patient was primarily analysed as a member of the CG. We did, however, reanalyze the data excluding this patient by performing a per-protocol (PP) analysis but the results remained unchanged.

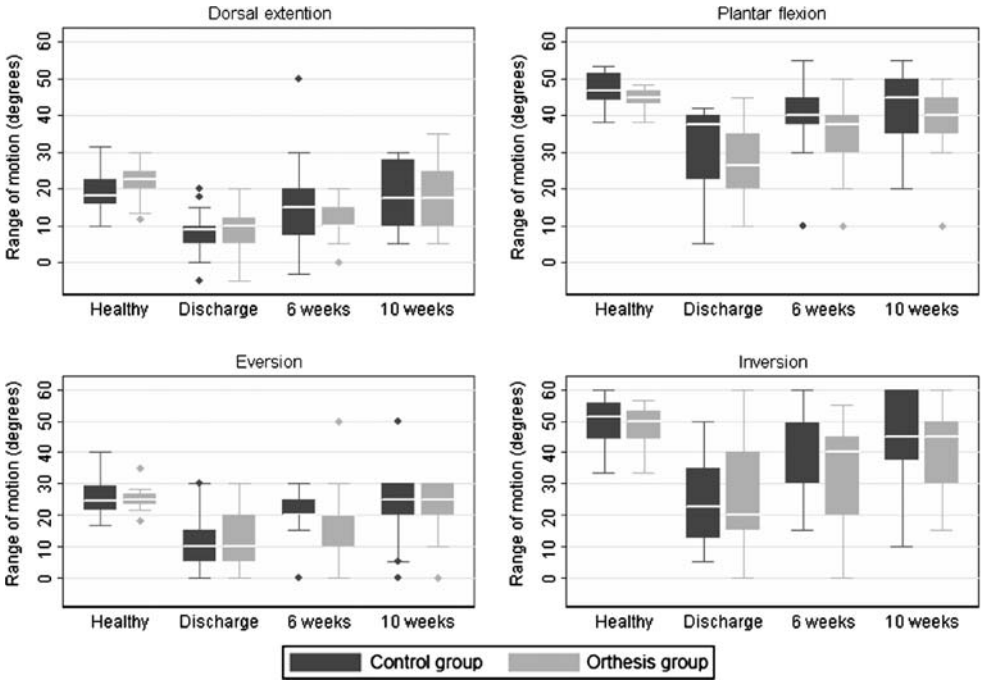

Fig. 8 Range of motion measurements of injuries and contralateral side in both the OG and the CG

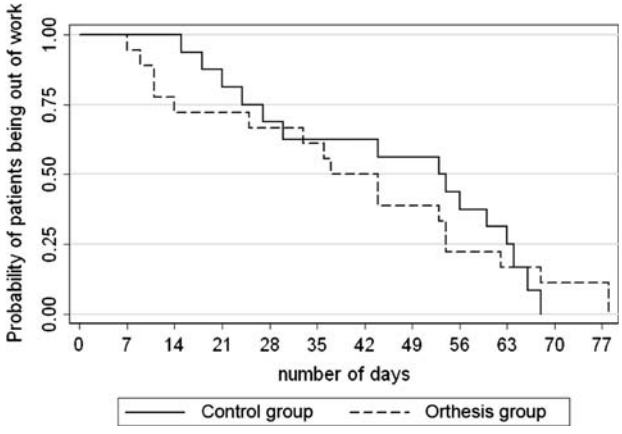

Fig. 9 Kaplan–meier curves for the time to return to work between for the OG and CG

We used a force plate for validation and quality control of the ability to potentially bear 15 ± 5 kg bodyweight as prescribed and as the discriminating factor to proceed with the postoperative protocol of climbing the stairs [18]. This protocol was intended to clarify whether mobilization with an orthesis had the potential to speed up rehabilitation due to greater self-confidence when wearing an orthesis as compared to a functional aftertreatment. Using this protocol we were able to shorten the rehabilitation phase, i.e. the period from the start of the first postoperative mobilization using crutches until discharge, by 1 day. During follow-up patients in both groups showed similar non-significant differences in compliance with regard to performing the prescribed partial weight bearing. Interestingly, patients appeared to bear more weight at the 6-week follow-up, in particular, in the OG-group, which may either reflect increased walking security or a neglect of partial weight bearing since the last examination.

The observed non-significant differences of two and five points in the score of OMA (in favour of the CG) at 6 and 10 weeks, respectively, do not support our hypothesis**.** Patients in both groups gained high values on the OMA score reflecting a good [19] overall functional outcome for all patients in our study and showing no functional disadvantage due to partial immobilization in an orthesis.

All ankle fractures had consolidated by the last follow-up with comparable radiological and clinical results in both groups. The operations were performed in the OG 2 days later, which may favour the occurrence of complications such as wound closure problems, blistering, necrosis of the wound margins and infection following internal fixation [23]. However, we did not observe any of these complications. In addition, no re-operations were necessary and the radiological findings in the follow-up were in an acceptable range and not particularly obvious at the 6 and 10 week follow-ups.

The postoperative swelling of the ankle could be significantly reduced in the OG by the time of discharge and reached equal values at the follow-up visits. We believe that the vacuum cushion of the orthesis fits tighter with increased compression and may act as a kind of lymph drainage.

Twelve of the 23 OG patients still used their crutches at 3 weeks of follow-up, whereas 11 did not need to use their crutches any longer.

This early full weight bearing is consistent with the findings of Ahl et al. [1, 9] who reported in two studies on the possibility of bearing full weight early after the surgical treatment of malleolar fractures.

Although the patients in the treatment group started the full weight bearing and full use of muscles earlier, no signs of atrophy were observed in the CG either.

A significantly reduced plantar flexion and an inversion of about 10° after 6 weeks in favour of the CG were observed. This is probably related to the restricted mobility in the orthesis, which may lead to lower ROM in the upper and lower ankle joints at the 6-week follow-up [24].

However, control patients appeared more secure in walking at 10 weeks and achieved higher values in the SF12 mental health score after 6 weeks (Figs. 4, 5). Using a postoperative protocol with clear criteria for climbing stairs and discharge from hospital, we observed a significant reduction of the postoperative stay in the hospital in the OG. This and the reduced swelling as well as the shorter time until the start of full weight bearing indicate that the vacuum orthesis is beneficial in the immediate postoperative period.

Though patients in the OG tend to go back to their previous work sooner, this was not significant. This contrasts with previous findings [25] that reported an earlier return to work in the group of plaster cast patients compared with patients using a brace for postoperative treatment of malleolar fractures. A larger study needs to be conducted to further verify the likelihood of earlier recovery of working capacity using an orthesis.

Taking into account the factors of shorter rehabilitation time in the postoperative period, earlier termination of the thrombosis prophylaxis, the possibility to allow the patients an earlier return to work when using an orthesis suggests some cost effectiveness compared to a functional treatment using crutches for 6 weeks—without negative effects on functional outcome parameters. According to Lehtonen and Järvinen who divided the overall costs of the treatment of any injury into direct and indirect costs, we believe that using the orthesis can reduce the indirect costs [25].

The strength of the study is the randomized protocol. Limitations are the different starting points of the physiotherapy protocol after the operation because of the individual postoperative local swelling. This time point was at the discretion of the operating surgeon not to risk dehiscence by mobilizing the patient to early.

To our knowledge, this is the first randomized study that compares conventional functional aftertreatment with a functional aftertreatment in a vacuum-stabilized orthesis with limited ROM. We observed that patients receiving surgical treatment for malleolar fractures of the types Weber A and B experienced no adverse events when being treated with a functional orthesis. Full weight bearing after 3 weeks was supported without complications and with an equally good functional result. Patients benefited from the reduction in postoperative swelling and from a shorter period with crutches. Additionally, the hospitalization time was reduced by 1 day since secure walking capacity on stairs was regained more rapidly.

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