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The dynamic vacuum orthosis: a functional and economical benefit?

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Abstract In a prospective, randomised study, 27 patients with internally fixed ankle fractures were treated post-operatively for a period of six weeks by application of either a new dynamic vacuum orthosis with permitted mobilisation to 10°–0°–10° at the ankle joint or a synthetic cast. Full weight bearing was allowed in both groups after two weeks. The cast group was prescribed four weeks of physiotherapy following six weeks of immobilisation. After ten weeks, the Olerud and Molander score showed a significant difference in favour of the orthosis. Early functional outcomes were significantly better for this group after six weeks and ten weeks. Patients in the orthosis group who were in formal employment returned to work 24 days earlier than those in the control group. Treatment of the orthosis patients took up three to four times less working time for the medical personnel. A saving of 38 euros on directly ascertainable costs could be evaluated. Rehabilitation of ankle fractures with a dynamic vacuum orthosis leads to better early functional results and greater patient satisfaction. The orthosis fulfils the conditions for early return to work. Treatment with an orthosis not only reduces working time for medical personnel but economises on expenditure for treatment and rehabilitation.

Résumé Une étude randomisée a été réalisée chez 27 patients présentant une fracture de la cheville et traités sur une période de six semaines soit par une orthèse dynamique permettant une mobilisation de 10° dans chaque secteur soit par une immobilisation plâtrée. Une marche avec appui complet a été autorisée dans les deux groupes, après 15 jours. Le groupe des patients plâtrés a bénéficié de 4 semaines de rééducation après six semaines d'immobilisation. Après 10 semaines, le score d'Olerud et de Molander montre une différence significative dans les résultats en faveur de l'orthèse. En effet, le devenir fonctionnel de ces patients a été de façon significative bien meilleur pour ce groupe après six semaines et après dix semaines. Ces patients sont retournés au travail 24 jours plus tôt que dans le groupe contrôle. Le traitement par orthèse permet d'économiser 38 euros et du temps médical. La rééducation de la fracture des chevilles grâce à l'orthèse dynamique permet un résultat fonctionnel excellent et relativement rapide. Cette orthèse met les patients dans de bonnes conditions pour un retour précoce à l'emploi, ce traitement permet également d'économiser le travail des médecins et permet également de faire des économies sur le temps de rééducation.

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Introduction

There are important areas in the surgical treatment of ankle fractures that are of specific interest to surgeon and patient alike. One deserving special mention is the functional outcome that, influenced by pain and oedema, makes a fundamental contribution to the restoration of the patient's level of activity before the accident and, thus, to quality of life. In addition to other factors such as fracture pattern, soft tissue injury and surgical procedure, the methods of rehabilitation are also important with regard to patient satisfaction and functional outcome [7, 24]. Early mobilisation can prevent the negative consequences of joint immobilisation [4] such as muscle atrophy [12], thrombosis [11] and cartilaginous damage [21].

Several studies have shown that immobilisation in a cast leads to distinct atrophy of the calf musculature, especially in the first two weeks [25]. There are also metabolic, neurological and functional adaptive manifestations that may lead to a reduction of muscular strength by almost half after four to six weeks' immobilisation in a cast [18]. Numerous studies have addressed the issue of preventing the above-mentioned negative manifestations of cast immobilisation and have compared aftercare by application of a cast with functional rehabilitation with or without an orthosis/brace. The results are not entirely uniform. Some researchers have found no difference [24]; others report a better functional outcome for functional rehabilitation as seen predominantly in the early postoperative phase (up to ten weeks), which then equates over time with outcomes for cast immobilisation [8, 22]. However, early functional rehabilitation will generally not include an early increase in weight bearing, even though this might result in more rapid consolidation of the fracture [3, 15]. A pre-condition is adequate stabilisation of the fracture, otherwise there is a risk of delayed bone union [5] or even secondary dislocation [13], which should be avoided for joint fractures requiring congruous reduction [14, 20]. There are also reports of a greatly increased rate of impaired post-operative wound healing after functional rehabilitation in a brace [13].

One possible solution to the problem might be the application of a dynamic vacuum orthosis that offers not only the stability of a circular cast [1], including the possibility of early weight bearing at low risk [2], but that also facilitates limited movement at the upper ankle joint. Furthermore, patient comfort is enhanced by the fact that an orthosis is not as heavy as a cast, the patients can apply the orthosis themselves after adequate instruction, and regular personal hygiene is possible. In addition, the opportunity for limited movement helps to achieve a physiological gait pattern. A further aspect is that the favourable progress of the post-operative phase may lead to earlier return to work for those patients in formal employment [8, 17].

The purpose of this randomised study was therefore to investigate whether functional rehabilitation of surgically treated ankle fractures in a dynamic vacuum orthosis that permits early full weight bearing and early continuous limited movement can lead to an improved functional clinical outcome at lower cost compared with aftercare in a cast.

Materials and methods

Study participants

All patients in the study were recruited at the Berufsgenossenschaftliche Unfallklinik (Liability Insurance Traumatology Clinic), Ludwigshafen; all data were recorded by one investigator, who also performed all follow-up assessments. The study was supervised externally by the Association for Osteosynthesis Clinical Investigation and Documentation (AOCID), including analysis of the statistical data. Those included in the study were monotraumatised patients with surgically treated ankle fractures classified as Weber type B; that means the typical displaced oblique fracture of the distal fibula passing upwards and backwards from the tibial plafond. The fractures to be included were simple and bi-malleolar, providing Volkmann's triangle did not require treatment. The age limit was set at eighteen to sixty five years. Exclusion criteria were open fractures, multi-fragmentary fractures and fractures requiring a positioning screw, as well as patients with any other disorders involving restriction of mobility, limited ambulation on forearm crutches, or situations affecting the healing process (e.g. joint disease, neurological disorder, amputation).

The randomised controlled study was commenced after completion of a small pilot study aimed at testing recording procedures whereby patients were allocated to the two different groups by opening an opaque envelope after post-operative evaluation of the inclusion and exclusion criteria. Treatment allocation was decided by a computer-generated block-randomisation sequence with blocks of two, four and six patients. Every patient signed an informed consent form and agreed to participate in the study before surgery.

Treatment protocol

In the experimental group, a dynamic vacuum orthosis (Vacoped) was applied for six weeks. The orthosis consisted, on the one hand, of a rigid plastic lattice frame divided into a dorsal and a ventral cover, and on the other hand, of a vacuum cushion that conformed to the patient's individual anatomy and provided additional stability. A joint in the frame allows limited movement of 10°–0°–10° in the upper ankle joint. With this orthosis, not only 20-kg partial weight bearing was permitted from the second post-operative day, but also mobilisation of the ankle joint. Full weight bearing was allowed from day 15 onwards.

In the control group, a circular cast was applied to the lower leg postoperatively, and after removal of the drains, a window was cut into the cast on the second post-operative day to permit dorsal extension of the talocrural joint. Patients were initially mobilised without loading of the affected leg. After replacement of the synthetic cast by a plastic supportive bandage (Baycast), partial weight bearing of 20 kg was prescribed from the time of wound healing to the 14th postoperative day. Full weight bearing was permitted thereafter. Patients of the control group attended physiotherapy three times a week for four weeks following their six weeks of immobilisation. The decision for cast

immobilisation was made according to the standard treatment protocol for our and other hospitals.

Medication for thrombosis prophylaxis (1× daily low-weight heparin, Clexane 20) was administered in the control group for the duration of immobilisation and in the experimental group during the period of limited mobility until full weight bearing had been achieved.

Outcome

The primary study outcome was the functional score of Olerud and Molander [16]. As a secondary outcome, the range of motion, patient satisfaction measured with the visual analogue scale (VAS) and the SF-12 and time to return to work were recorded. The investigator had no influence on the period of disability. The time of return to work was appointed by the family practitioner. Regular follow-up examinations were performed six and ten weeks after the operation.

In order to evaluate economic parameters, the time spent treating the patient was recorded for a sample of patients from both groups, and details of overall costs were recorded for all patients. Time parameters included the following information: working time for doctor/care personnel to apply the orthosis/cast, change the cast, create a window in it, remove it and likewise to change the orthosis and to remove it. Cost parameters included costs for the cast itself and for dressings and the cost of the orthosis, thrombosis prophylaxis and physiotherapy. Expenditure for the synthetic cast, bandaging materials and thrombosis prophylaxis were calculated on the basis of the amounts used and in-house costing per item.

Statistical methods

All randomised patients were included in the analysis. Basic demographic and important prognostic factors were investigated by treatment groups by standard descriptive statistics. Because of the randomised allocation, no statistical tests were used to compare treatment groups with regard to baseline factors. Group differences regarding these factors therefore were assessed by clinical judgement, and factor imbalances that could potentially have an influence on the outcomes were considered for statistical adjustment.

Differences between treatment groups regarding continuous (e.g. the Olerud and Molander score) and categorical outcomes (e.g. range of motion categories) were tested using the Wilcoxon rank sum test and Fisher's exact test, respectively. Multivariable regression analyses were used to adjust for differences in baseline characteristics and prognostic factors between the groups. The "time to return to work" parameter was tested by the Kaplan–Meier method and Cox regression analysis.

Time parameters were recorded for a sample of patients. A Monte Carlo simulation model was created in Microsoft Excel and run on Add-in Software @ Risk Version 4 (Palisade Corporation, USA) for better interpretation of the results. On the basis of the available data, probability distributions around an estimated mean for each group were plotted for each time parameter. In such a modelling approach, probability distributions are used to account for the observed variability of a parameter in the study groups as well as for our uncertainty about the group means. Latin hypercube sampling with 1,000 replications was applied to derive most likely time distributions for both treatment options.

Table 1 Basic data for both patient groups

		Orthosis group			Control group		
		Number	Median	Min–Max	Number	Median	Min–Max
No. of patients		14			13		
Age (years)		14	44.3	20.3–59.4	13	40.8	25–64.1
Gender	Male	7			8		
	Female	7			5		
Formal employment	Yes	13			10		
	No	1			3		
Fracture side	Right	6			5		
	Left	8			8		
Body mass Index (kg/m^2)		14	27.8	20.8–34.3	13	26.8	17.9–34.6
AO classification (44–)	B 1.1	13			13		
	B 1.2	1			0		
Danis & Weber	B simple	13			13		
	B bi-malleolar	1			0		
Time from accident to hospital admission (days)		14	4	0–11	13	5	0–20
Time from accident to operation (days)		14	5	0–13	13	7	0–21

Min minimum, *Max* maximum, AO Association for Osteosynthesis

Results

Unless stated otherwise, the data given are median values. Twenty-seven patients were randomised and included in the study, and one patient from the orthosis group and two patients from the control dropped out within the first two weeks for personal reasons. Consequently, 24 patients were available for statistical analysis of outcome parameters. There was a slight imbalance for patient age, with 44.3 years in the orthosis group and 40.8 years in the control group, as well as for the time between accident and operation, with five days in the orthosis group versus seven days in the cast group. The reasons for this delay were either a distinctive swelling or the delayed admission later than six hours after injury. There was homogenous distribution of the other basic patient data in both groups (Table 1). All injuries were caused by torsion. No tourniquet was used.

Primary outcome

An Olerud and Molander score of 75 points for the orthosis group did not differ significantly from that of 60 points for the control group at the six-week follow-up (p=0.33). At the ten-week follow-up, there was a significant difference of 20 points (p=0.02) in favour of the orthosis group with 95 points (Fig. 1).

Secondary outcomes

Evaluation of range of motion at the six-week follow-up revealed a highly significant difference of plantar flexion (p=0.005) in favour of the orthosis group (Table 2).

No significant differences were found for the other range of motion values or at other follow-ups. Patient satisfaction as measured on the VAS was significantly higher at the ten-week follow-up (p=0.03) and at discharge (p=0.01) for the parameter "comfort" in the orthosis group. Patient satisfaction for the parameter "pain" was significantly better (p=0.004) in the orthosis group after ten weeks.

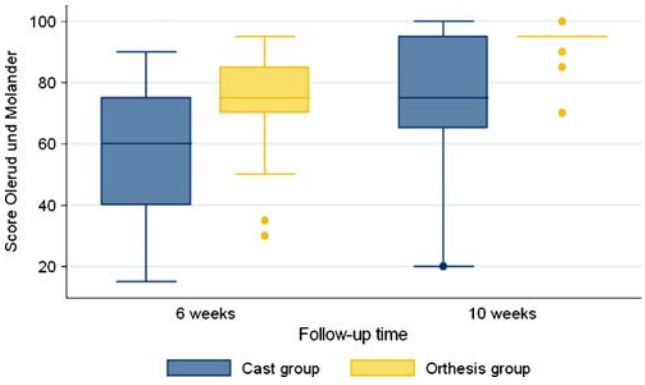

Fig. 1 Olerud and Molander score. *Boxes* represent median and range; extreme values (outliers) are presented as *symbols*

Table 2 Range of motion (ROM) at the six- and ten-week-follow-up (Fisher's exact test)

	6 weeks			10 weeks		
	Cast	Orthosis	p value	Cast	Orthosis	p value
Plantar flexion (°)			0.005			0.77
20	3	0		0	0	
30	8	5		1	0	
35	0	1		1	0	
40	0	6		7	10	
45	0	0		0	1	
50	0	1		2	2	
Dorsal extension (°)			0.40			0.22
0	1	0				
5	1	0				
10	7	11		6	4	
15	2	1		3	2	
20	0	1		2	7	
Lower ankle joint			0.06			0.10
Percent of healthy side						
33	1	0				
50	2	0				
66	8	8		6	3	
75	0	1		1	0	
100	0	4		4	10	

Complications in the orthosis group included two cases of impaired wound healing, of which one required surgical revision. In the control group, one case of impaired wound healing was managed conservatively. Loss of reduction did not occur. Thrombosis prophylaxis was administered in the control group for 42 days and in the orthosis group for 16 days, whereby thromboembolic complications were not observed.

The SF-12 composite "mental health score" after ten weeks was significantly 7.9 points higher (p=0.008) in the orthosis group (median=59.9) compared with the cast group (median=52). Patients from the orthosis group who were in formal employment returned to work 52 days after the operation (10–87 days) and those in the control group 76 days after the operation (45–95 days). If the factors age and time to operation were taken into account, the rate of return to work was 4.7 times higher on average in the orthosis group than in the control group at any given time after treatment (p=0.02) (Fig. 2).

The average time for treatment with an orthosis was 25 min (minimum 19; maximum 30), and 105 min (minimum 97; maximum 116) in the control group. Thus,

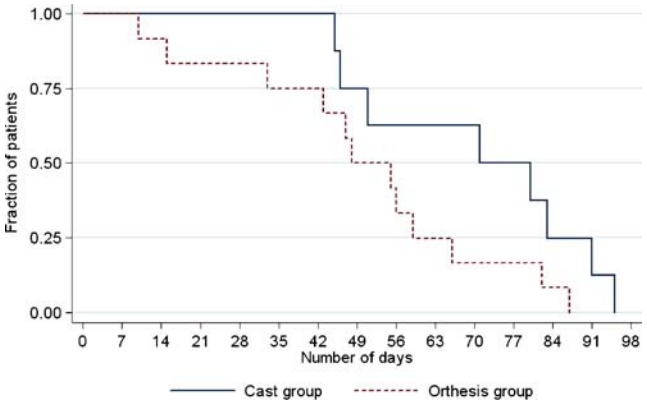

Fig. 2 Kaplan–Meier curve for return to work in both groups (adjusting for age and time to operation; p value=0.02)

treatment with the orthosis appears to take up approximately three to four times less working time for medical personnel than does treatment with a cast (Fig. 3).

The directly ascertainable costs in the orthosis group came to 381 euros compared with 419 euros in the control group. Overall, expenditure for treatment with the orthosis amounted to 38 euros less than cast treatment.

Discussion

This study was designed to investigate whether functional rehabilitation with a dynamic vacuum orthosis after surgical treatment of ankle fractures leads to an improved clinical outcome and makes better economic sense than aftercare in a cast. Because of the rigourous inclusion and exclusion criteria, the results presented here were obtained for only 27 patients. Thus, the most important limiting factor was the low number of patients. This also restricts the validity of statements made on the basis of statistical analysis with regard to the study hypothesis. It does not devalue the statistically significant results, but no definite conclusions can be drawn about the statistically non-significant outcomes.

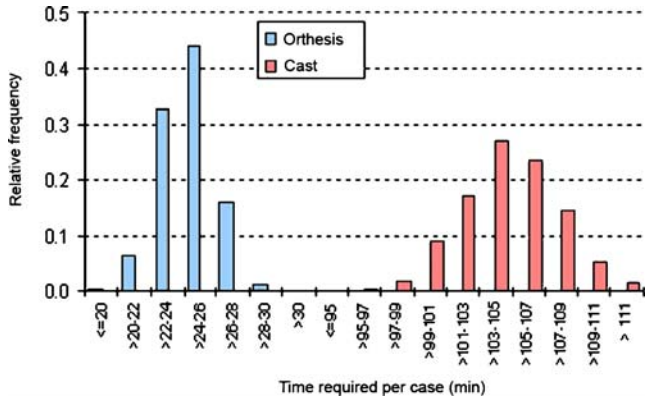

Fig. 3 Probability distribution of the simulated overall working time (1,000 repetitions)

The mechanical properties of the circular cast applied post-operatively in the control group were not sufficient to permit partial loading from the second post-operative day in contrast to the orthosis. Therefore, it cannot be determined with absolute certainty whether the differences observed were exclusively the result of the different splinting methods with their different mobilisation options or whether the results were also influenced by early loading.

Part of the costs arising from physiotherapy of the cast group is related to the treatment protocol. It has to be considered, because physiotherapy is an essential part of the conservative post-fracture care. Costs of the thrombosis prophylaxis are also related to the treatment protocol. With respect to our observations, there is no need for pharmacological prophylaxis in patients once fully weight bearing and able to move the ankle. Therefore, the thrombosis prophylaxis was terminated in an average of 16 days.

Our study differed from comparable studies reported in the literature [8, 23] in that mobility in the orthosis was prescribed, but also, early full weight bearing after two weeks was permitted in both groups. This was well tolerated by all patients. All ankle fractures healed well with comparably good radiological and clinical outcomes by the time of the ten-week follow-up. Advantages of early full weight bearing for ankle mobility are a topics of controversial debate [6, 24]. Isolated reports of negative consequences for fracture healing following early full weight bearing [5] conflict with studies that show that a certain amount of mechanical stimulation promotes fracture healing [9, 10].

Patient satisfaction with regard to pain and comfort was significantly better in the orthosis group at the ten-week follow-up. The difference in the VAS comfort score at discharge showed that patients found the orthosis more comfortable, even at discharge. The significantly better value for mental health on the SF-12 at ten-weeks of follow-up also indicated that the overall feeling of satisfaction with the orthosis was greater. This reinforces the results on the VAS and correlates with the findings of other authors who have reported a good correlation of “mental health” parameters recorded by VAS and SF-36 [19].

Patients in formal employment in the orthosis group were able to return to work 24 days earlier than those in the control group. Egol was also able to show in a randomised study that patients with ankle fractures that had been treated with an orthosis were able to return to work sooner than patients with a cast [8]. Possibly, this can be attributed to greater comfort and less restriction as well as to an improved functional outcome due to the orthosis.

Functional rehabilitation of ankle fractures with a dynamic vacuum orthosis leads to functionally better outcomes and greater patient satisfaction compared with

conventional cast application. The orthosis is the prerequisite for early return to work. Its application not only reduces the working time required by the medical personnel but is also likely to save on expenditure for treatment, aftercare and rehabilitation.

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