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U. Stöckle · B. König · A. Tempka · N. P. Südkamp · Trauma and Reconstructive Surgery,
Charité, Campus Virchow Klinikum, Humboldt University Berlin

Cast Immobilization or Vacuum Stabilizing System?

**Early Functional Results After Osteosynthesis
of Ankle Fractures**



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Early Functional Results After Osteosynthesis of Ankle Fractures

Abstract

In a prospective randomized trial the early functional results after immobilization in a cast were compared to those after using a vacuum stabilizing system. The vacuum stabilizing system Vacoped® offers equivalent stability compared to a plaster cast. In contrast to the cast the Vacoped can be removed for body care and physical therapy. Additionally the range of motion for dorsiflexion/-extension in the upper ankle joint can be adjusted. From 9/1996 to 7/1997 there were 40 patients included in the study with an operated ankle fracture as monotrauma. Six weeks postoperatively the patients with cast treatment showed significantly higher functional deficits for the upper ankle joint (20%), the lower ankle joint (40%) and muscle atrophy (2.1 cm side difference) than the group with the vacuum stabilizing system (upper ankle joint 15%, lower ankle joint 25%, 1.4 cm muscle atrophy). Five patients out of the group with the vacuum system were already at work three weeks postoperatively. Three months postoperatively the functional results for both groups were approximating. The vacuum stabilizing system Vacoped® offers better early functional results than conventional cast treatment after osteosynthesis of ankle fractures. Because of the increased patient comfort and the early ability for physical therapy the vacuum stabilizing system is preferable to cast treatment.

Keywords

Ankle fractures · Osteosynthesis · Functional results

Introduction

After osteosynthesis of ankle fractures, an early functional, postoperative treatment without cast is desired. However, soft tissue problems, concomitant ligament injuries and reduced patient compliance lead to the widespread practice of immobilization in a lower leg cast for 6 weeks. Atrophy of the lower leg muscles, an increase in the tendency to swell and a restriction of the mobility of the ankle joint (1) occur as a result of cast immobilization. During treatment with a plaster cast the patients are immobile to the point that they are unable to work, at least for this period of time.

The vacuum stabilizing system Vacoped® consists of a honeycomb-shaped plastic shell and a vacuum inlay that together offer stability equivalent to a plaster cast. The stabilizing system can be removed for body care. The cooperative patient can put on and remove the Vacoped® by himself. Physical therapy is also possible to preserve dorsiflexion/-extension in the upper ankle joint in the early postoperative phase. Various adapters enable restricted dorsiflexion/-extension while maintaining lateral stability.

Within the framework of a prospective, randomized trial the functional results after osteosynthesis of ankle fractures and immobilization in a lower leg cast are compared to those after immobilization in the vacuum stabilizing system (Vacoped®).

Materials & Methods

The inclusion criteria in this prospective, randomized trial were: surgically treated fractures of the upper ankle joint occurring as first time monotrauma. The age range was between 18 and 65 years and the patients had to submit declaration of consent. The assignment to one of the two treatment groups took place randomly after order of admittance to the emergency ward. Group I received postoperatively a lower leg cast for 6 weeks, the patients in Group II the vacuum stabilizing system Vacoped®. Both groups were mobilized for 6 weeks by partial weight bearing with the aid of forearm crutches. In both groups a thromboembolic prophylaxis with low molecular heparin was administered for the 6-week period.

The fractures were classified according to the Weber classification and the AO classification. In both of them the height of the fibula fracture defines the group of classification. In A-fractures the fracture of the fibula is below the syndesmosis, in B-fractures in height of and in C-fractures above the syndesmosis.

Address of correspondence:

Dr. Ulrich Stöckle
Trauma and Reconstructive Surgery
Charité, Campus Virchow Klinikum
Humboldt University Berlin
Augustenburger Platz 1, D-13353 Berlin, Germany
Tel.: 030 / 450 52012, Fax: 030 / 450 52905
E-mail: ulrich.stoeckle@charite.de

The vacuum stabilizing system (Fig. 1a, b) consists of 2 components, a plastic shell as stabilizing system and a moldable, solidly shaped vacuum boot. The inlay is isothermal; washable terry cloth socks provide for the outward flow of moisture so as to reduce the buildup of moisture and heat in the system. According to preclinical tests the static ability to withstand pressure is equivalent to a conventional plaster cast. Various adapters can be adjusted to provide restricted dorsiflexion/-extension. The system can be removed at any time to check the progression of wound healing and for body care. In case of sensation of pressure the system can be ventilated, the inlay filling redistributed manually and remolded to be free of compression through the vacuum system. The system is reusable. A change in material properties could not be observed in the technical endurance test¹.

The rental fee for 4 weeks' use is US\$ 230,-, for the length of time between 6 to 8 weeks US\$ 280,-. The purchasing price for the vacuum stabilizing system is US\$ 459,-. (Status as of 11/1999).

Calculating the costs for a 6 weeks cast treatment, a preoperative cast, a postoperative cast and a Scotch cast as walking cast, the material costs alone amount to US\$ 84,-. The working costs average US\$ 64,-, the cleaning and waste costs US\$ 20,-. Thus, the total expenditure for cast treatment amounts to US\$ 168,-.

Patient data

Between 9/1996 and 7/1997 40 patients with operated ankle joint fractures were included in the trial. The group of patients consisted of 19 women and 21 men aged from 20 to 65 years old, the average age being 45 years old. In 23 cases the fracture was on the left side and in 17 cases on the right side. In 27 cases the fracture was of a Weber B type and in 13 cases of a Weber C type. In 9 cases with Weber B fractures only the fibula was broken, and out of these there was a rupture of the anterior syndesmosis in 7 cases. In 12 cases bimalleolar fractures were registered, in 6 cases



Fig. 1a, b ▲ Vacoped®-boot

an additional fracture of Volkmann's triangle. On the whole, the anterior syndesmosis was ruptured in 23 of the 27 Weber B fractures. Regarding the 13 Weber C fractures, 9 bimalleolar and 4 trimalleolar fractures were recorded. The anterior syndesmosis was ruptured in 8 cases.

The surgical treatment was conducted according to the principals of AO[7]. In 9 cases a basic plate fixation osteosynthesis of the fibula, in some cases with a syndesmosis suture, was sufficient. The remaining 31 fractures required a combination of plate fixation osteosynthesis and screw fixation osteosynthesis with additional treatment of the medial malleolus and/or Volkmann's triangle. 12 Weber B and 8 Weber C fractures were assigned to Group I (cast treatment). Likewise, Group II (Vacoped®) consisted of 20 patients with 15 Weber B type fractures and 5 type C injuries.

The function in the upper and lower ankle joint as well as the extent of postoperative muscle atrophy in comparison to the opposite, healthy side was recorded 6 weeks and 3 months postoperatively using a standardized evaluation sheet. In addition to this, information regarding the patient's satisfaction and the length of his incapacity to work was obtained and evaluated.

Statistics

To compare two interdependent samplings, the Wilcoxon test was employed to determine the significance of the differences between the healthy and injured side with regard to the examination of function and measure-

ment of muscle atrophy. The statistical relevance of the differences in results between both patient groups I and II were checked with the Mann-Whitney Test for independent samplings. The level of significance was $p < 0.05$.

Results

All fractures consolidated during the examination period, i.e., during the 6-week check-up, all fractures showed signs of consolidation which was completed 3 months postoperatively at the latest. In both groups, one postoperative complication each occurred. In the cast group (Group I) one patient had to be reoperated for a postoperative hematoma, subsequent to which the healing of the wound proceeded without interruption and any complications. In the Vacoped® group (Group II) wound revision with secondary suture was necessary after 4 weeks for one patient who had been treated with steroid medication for many years due to Addison's disease. In neither of the groups could a clinically conspicuous phlebothrombosis of the leg be determined.

Dorsal-/plantarflexion in the upper ankle joint was significantly less restricted in the Vacoped® group than in the cast group. In Group I the difference to the opposite side for dorsiflexion was 17°, in Group II only 13°. Plantarflexion was reduced in the cast group by 23°, in the Vacoped® group by 18°. After 3 months the results were approximating with 8° or 7° respectively for dorsiflexion and 12° or 9° respectively for plantarflexion.

Even more significant were the results pertaining to the mobility of the lower ankle joint. Patients who had been treated postoperatively with Vacoped® achieved better functional results, as well. After 6 weeks Group I demonstrated a restriction of lower ankle joint mobility by 40%, Group II by only 20%. After 3 months the degree of mobility improved to the extent that patients with the cast treatment had a 30% restriction and the Vacoped®, group a 10% restriction.

The lower leg mid-calf circumference, taken as a measurement of muscle atrophy after 6 weeks was, on an average, 1.4 cm less than the opposite leg in the Vacoped® group, 2.1 cm in the cast group. After 3 months the difference

¹Technical Report Nr. 01.258.6.014.01 dated 11.2.1997, Safety Standards Authority Product Service

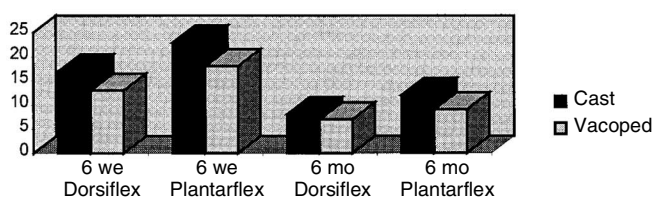


Fig. 2 ▲ Deficit of dorsiflexion and plantarflexion in the upper ankle joint in % after 6 weeks and 3 months in both therapy groups

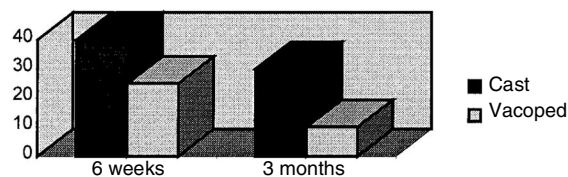


Fig. 3 ▲ Deficit of range of motion in the subtalar joint in % after 6 weeks and 3 months in both therapy groups

between the 2 groups was less significant with a difference in circumference of 1.9 cm in Group I as compared to 1.3 in Group II.

All 20 patients in the Vacoped® group were very satisfied with the treatment. In most cases the comfort provided by the system with the possibility of being able to remove the foot from the boot for body care and physical therapy purposes was clearly decisive. All of the patients were able to put on and remove the vacuum stabilizing system by themselves as well as manage the new installation of the vacuum for stabilization. 3 weeks after the operation 5 patients were already able to pursue their normal occupations. Likewise, the patients who were postoperatively treated with cast immobilization were essentially satisfied with the entire course of the treatment. In light of the easy handling of the vacuum stabilizing system and the obvious comfort it afforded, some patients were disappointed with the decision to be treated with a cast.

Discussion

After 6 weeks there were, on the average, significantly better functional results for the Vacoped® group. Mobility of the upper ankle joint and lower ankle

joint was better and atrophy of the calf muscles was significantly reduced. In this respect, the improved mobility for pro- and supination is astonishing, as this was not specially exercised. This can only be explained as part of the total mobility that periodically occurred in the course of hygienic measures and physiotherapy. After 3 months the results of both patient groups were approximate.

After stable osteosynthesis, cast immobilization follows primarily to provide protection for the soft tissue and promote the healing of the wound. Subsequently, a functional therapy, without cast, is recommended (6). Due to concomitant ligament injuries with Weber B and C fractures however, further immobilization and partial weight bearing up to and including the 6th postoperative week are for the most part necessary. In this connection, the Vacoped® boot, maintaining equivalent stability, allows a gradual increase in weight bearing, adapted to the symptoms and injury without a change in system. With respect to a cast treatment, after the healing of the wound there is a change from a lower leg bed cast to a walking cast which requires an increase in work, personnel duties and waste.

Because of the possibility of being

able to periodically remove the stabilizing system and put it on again without loss of stability, the prerequisite for regular wound examinations, care of the soft tissue and intermittent physical therapy is fulfilled. Due to the daily change of dressings and the necessity of removing the injured leg from the bed cast, the latter loses its shape in time, likewise caused by a reduction in swelling stemming from the fracture and by an increase in muscle atrophy due to immobilization. In this case, the vacuum stabilizing system is more flexible and a daily adjustable remodelling can take place without additional costs for ventilating and de-aerating the inlay. The positive effect of early physiotherapeutic exercise and early partial weight bearing on mobility and subjective pain sensation has already been proven in several trials (1-4, 7,8). The positive effect of early functional treatment with early weight bearing and/or exercise treatments was demonstrated in each study in the first 3 months and reached approximation afterwards. For this reason, only the results up to 3 postoperative months were recorded and evaluated within the framework of this trial.

A further relevant advantage is the almost complete X-ray permeability of Vacoped®, allowing for X-ray check-up examinations without removal of the stabilizing system and with equivalent picture quality.

Because of the high degree of comfort afforded by the vacuum stabilizing system the patients are less restricted in their mobility than with a plaster cast treatment, so that in the present trial 25% of the patients treated with Vacoped® were able to work 3 weeks postoperatively. In addition to this, in comparison to the plaster cast treatment, atrophy of the calf muscles is reduced due to the pressure of the calf flap on the muscles; i.e., calf muscle

Table 1
Average deficits in range of motion and circumference
Differences statistically significant by $p < 0.05$

Average deficit in comparison to opposite side	6 weeks			3 months		
	Cast	Vacoped	p	Cast	Vacoped	p
Dorsiflexion (degrees)	17	13	0.046	8	7	0.542
Plantarflexion (degrees)	23	18	0.014	12	9	0.059
Subtalar joint (total range of motion)	40%	25%	0.001	30%	10%	0.009
Midcalf circumference (in cm)	2,1	1,4	0.001	1,9	1,3	0.004

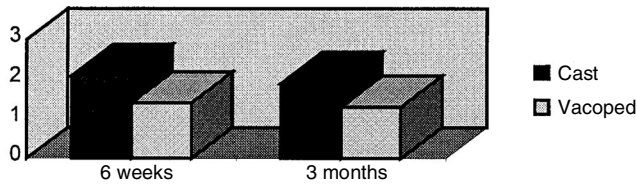


Fig. 4 ▲ Midcalf circumferential difference after 6 weeks and 3 months in both therapy groups

function is maintained. Apart from providing for a shorter and easier rehabilitation, this also has a thromboembolic prophylactic effect. To what extent, however, the medicinal thromboembolic prophylaxis with corresponding cost reduction can be dispensed with, also in the case of partial weight bearing, has to be determined in further trial studies.

A further advantage of the vacuum stabilizing system, particularly with respect to environmental compatibility, is its reusability.

One disadvantage of the vacuum stabilizing system consists in its relatively high price, which is almost twice as high as that of cast treatment, the costs of which not all medical insurances are prepared to assume at present. However, taking into consideration the patient's ability, depending on the occupation, to return to employment earlier as well as better functional results, the greater environmental compatibility due to the reusability of the system and waste avoidance, the concept proves to be an economically sound one that will replace the conventional cast treatment for many indications in future.

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