AO Clinical Investigation

Kantonsspital Luzern

Shortened rehabilitation of ankle fractures using a vacuum orthosis

A randomized controlled trial

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Introduction: The aim of this study was to investigate whether early full weight bearing with an orthosis (Figure 1) in contrast to a functional treatment and partial weight bearing would lead to improvements in functional results, subjective walking confidence, patients comfort and earlier return to work. In addition to this we were interested to explore clinical aspects such as duration of hospitalisation, range of motion (ROM), swelling, haematoma under different treatment settings.

Figure 1: Vacoped®

Methods: Patients between 16 and 65 years (BMI < 35) with an operatively-treated (one third tubular plate with compression screw) malleolar fracture (AO 44 A1-B2) were preoperatively randomized in two groups regarding rehabilitation:

- functional / Orthosis postoperatively
- begin mobilization after reduced swelling
- training of partial weight bearing (Kistler plate®)
- 9 stairs-test → discharge

Control group	Orthosis group
- partial weight bearing 15 kg using crutches for *6 weeks* - full weight bearing afterwards	- partial weight bearing 15 kg using crutches for *2 weeks* - full weight bearing afterwards

Figure 2: Postoperative regimen for patients in the control- & orthosis group

Outcome parameters:

- early full weight bearing possible?
- better functional outcome (Olerud & Molander Score)
- duration of hospitalisation
- return to work
- swelling around the ankle
- range of motion (ROM)
- patient satisfaction (VAS, SF12)

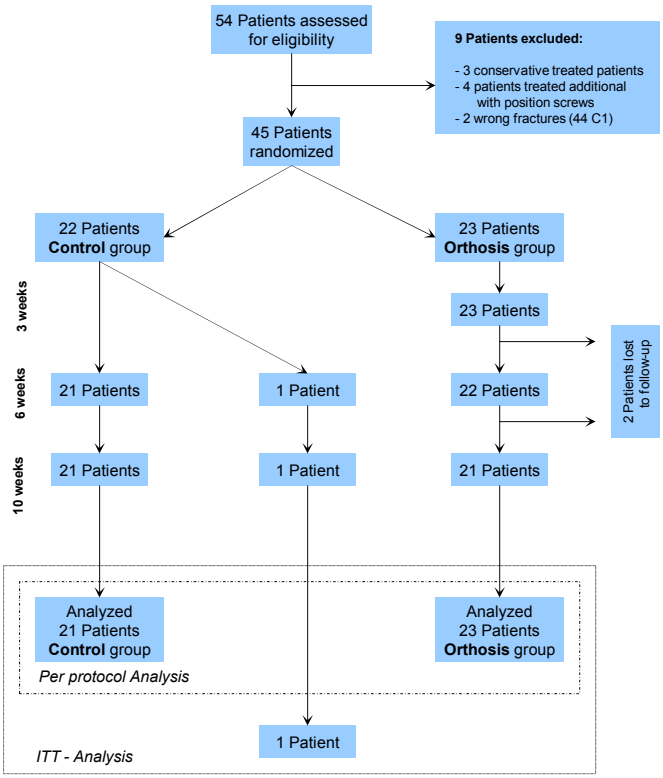

Figure 3: Flow diagram of patient recruitment, treatment, allocation and follow-up

Results: 45 patients fulfilled the inclusion criteria and were randomized to either the control- (n=22) or the orthosis group (n=23) (Figure 3). The hospitalisation time was significantly reduced from 4 to 3 days (p = 0.03) with the use of the Vacoped®. There was no significant difference in the functional outcome, patient satisfaction and circumference of the lower leg and ankle neither after 6 nor after 10 weeks. Patients in the Vacoped®-group returned to work 12 days earlier than in the control group (p = 0.13)(Figure 4).

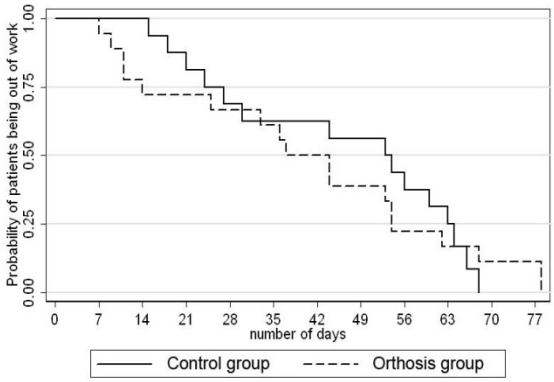

Figure 4: Kaplan-Meier curves for the time to return to work for the two groups

Conclusions: The postoperative treatment of malleolar fractures with the Vacoped® leads to earlier discharge from the hospital. Earlier return to work seems to be possible with the Vacoped® but could not be statistically proven because of the small group size.

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