

The dynamic vacuum orthosis: a functional and economical benefit

a randomized controlled trial

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Introduction: Rehabilitation of ankle fractures decisively influences functional results and patient contentment as well as the total costs of treatment. The purpose of this study was therefore to investigate whether functional rehabilitation of surgically treated ankle fractures in a dynamic vacuum orthosis (Fig. 1) 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.

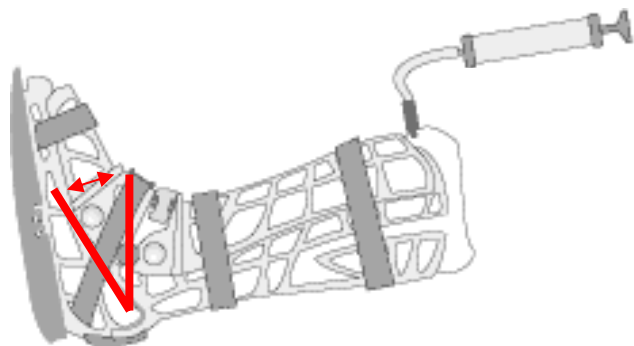


Fig. 1: Vacoped®

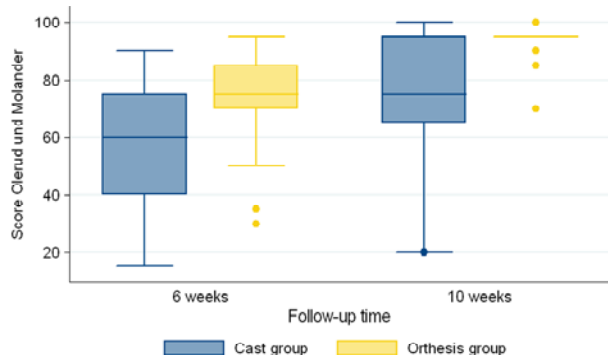
Methods: 27 patients with operated ankle fractures (AO 44 B1-2) were treated by application of either a dynamic vacuum orthosis with permitted mobilization to 10-0-10° at the ankle joint or a synthetic cast. Full weight-bearing was prescribed in both groups after two weeks. The patients of the control group attended physiotherapy three times a week for four weeks, following their six weeks of immobilization. Medication for thrombosis prophylaxis was administered in the control group for the duration of immobilization and in the experimental group until full weight-bearing had been achieved.

The **primary study outcome** was the functional score of Olerud and Molander. As a secondary outcomes the range of motion at the upper ankle joint, the patient satisfaction measured with the Visual Analogue Scale (VAS) and the SF 12, and the time to return-to-work were recorded.

In order to evaluate the 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.

Results: After 10 weeks the Olerud and Molander score showed a significant difference ($p=0.02$) in favor of the orthosis (Fig. 2).

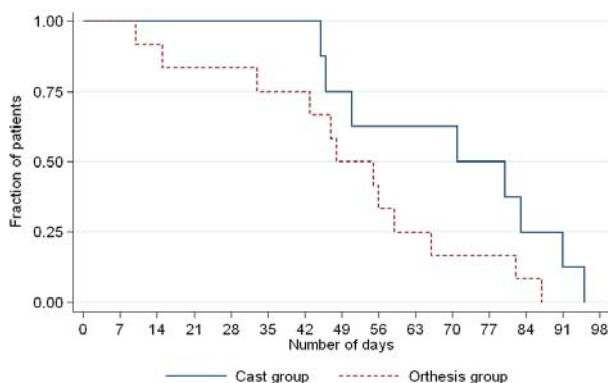
Fig. 2: Olerud and Molander score. Boxes represent median and range; extreme values (outliers) are presented as symbols.



Patient satisfaction as measured on the visual analog scale was significantly higher at the 10-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 10 weeks.

The patients in the orthosis group who were in formal employment returned to work 24 days earlier than those in the control group. The rate of **return-to-work** was 4.7 times higher on average than in the control group at any given time after treatment ($p = 0.02$) (Fig. 3).

Fig. 3: Kaplan-Meier curve for return-to-work in both groups



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 **SF12 composite “mental health score”** after 10 weeks was significantly 7.9 points higher ($p=0.008$) in the orthosis group (median = 59.9) compared with the cast group (median = 52).

The average **time for treatment** with an orthosis was 25 minutes (min 19; max 30), and 105 minutes (min 97; max 116) in the control group. Thus, treatment with the orthosis appears to take up approx.

3-4 times less working time for the medical personnel than for treatment with a cast.

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

Conclusions: The 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.