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Proof of Functionality of the Heel Relief Orthosis according to Dr. Settner/Münch

The treatment of calcaneus fractures was discussed controversially in the past. Until the development of the Heel Relief Orthosis an early loadability of the concerned leg was not reached by either a conservative or an operative treatment. In this article the proof of functionality of the Heel Relief Orthosis is furnished. Because of different measurements on patients who had been fitted with the orthosis as well as interosseous measurements on dissected specimen from dead bodies the effects could be proved. Besides this, human specimen were produced, which make the functionality and effects of the Heel Relief Orthosis clearly visible.

Introduction

The Heel Relief Orthosis developed by us and Dr. Settner occurred in-house in close collaboration with Employer's Liability Insurance Association Trauma Hospital in Duisburg-Buchholz, and has been used to treat calcaneus fractures since 1994.

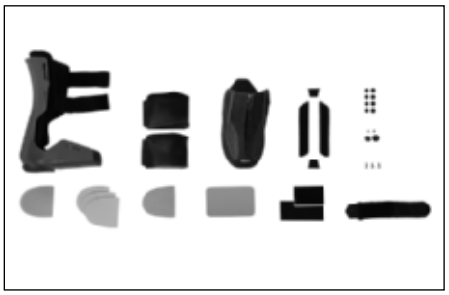

Abb. 1 *Semi-finished product in modular design.*

Since 1998, the Heel Relief Orthosis has been available as semi-finished product in modular design. The finishing techniques are taught in workshops. Deviations from our treatment concept have led to negative results. A total of 671 Heel Relief Orthosis have been manufactured by the author's company through December 1, 2001. The fitting and treatment concept remained unchanged over the years. Both partial and full loading of the heel fracture side is possible and desired. The thrombosis prophylaxis has been reduced as required. The calcareous salt remains preserved in the bone. The orthosis has no influence on the primary treatment. Therefore, the Heel Relief Orthosis can be used for any type of fracture whether it receives surgical or conservative treatment.

The initial lack of acceptance, both in medical and technical circles, prompted us to demonstrate the technical and scientific functionality and effectiveness of the Heel Relief Orthosis.

Our position concerning the contribution of this treatment is supported by the statistics of insurance companies showing that the number of workdays lost due to heel bone fracture treatment was reduced from 212 days in 1995 to 109 days in 1998.

Abb. 2 *Special orthosis made for testing.*

The total costs of treatment were reduced from 28,415 EUR to 12,226 EUR, that is, by more than half.

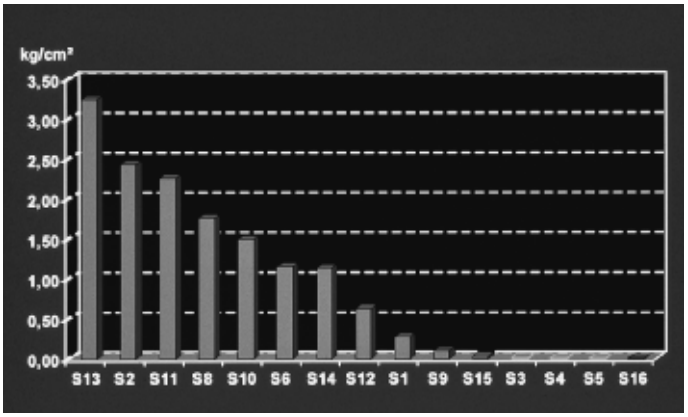

Abb. 3 Heel Relief Orthosis 1 without contour foam.

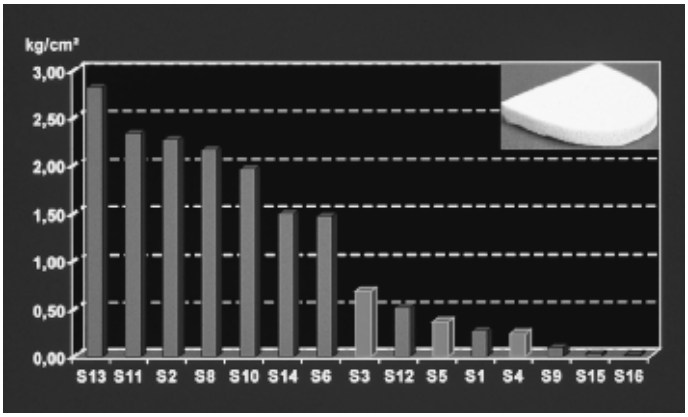

Abb. 4 Heel Relief Orthosis 2 with contour foam.

This statistical data proves that the effectiveness of Heel Relief Orthosis treatment really exists, which was assumed to be subjective until then.

In spite of all the documentation, however, the authors fear that the impressive results might still be doubted or looked upon with mistrust.

Test procedures

Therefore, pressure tests were performed to identify the pressure loads occurring in the Heel Relief Orthosis under the heel.

A special orthosis was made which was equipped with take-offs in the loaded spots. In collaboration with Basis-TÜV Munich, 16 electrodes were attached to these spots to yield actual data during the various step cycles, to be evaluated later.

The heel loading pads were inserted successively and the spot load values measured under the heel.

Eight test runs were documented, each consisting of 6000 measurements.

To document the load further, measurements were continued through the application of the third compression pad, but various materials were integrated into the orthosis to achieve a significant heel load, which is also reflected in the pressure curves.

Pressure testing in detail

Heel Relief Orthosis 1

Testing without contour foam insert. The heel is fully free. The pressure range is located below the measuring points 3, 4 and 5. These measuring points are situated in the orthosis directly below the heel. The statistics show that the pressure of the significant heel area located below the heel amounts to about 0.

Heel Relief Orthosis 2

Testing with contour foam. This picture shows still negligible pressure occurring below S3-S4 and S5, but the heel is in contact with material here and thus achieves a proprioceptive effect.

Heel Relief Orthosis 3

The introduction of one compression pad will obviously result in a minimal pressure increase.

Heel Relief Orthosis 4

Testing with two compression pads. The use of the second compression pad provides a continuous excessive load.

Heel Relief Orthosis 5

Testing with three compression pads. A peak pressure value of about 30 kg over an area of about 25 cm_ is achieved with the third compression pad.

To summarize: A peak value of up to seven kg can be developed using contour foam. A maximum pressure peak of about 45 kg can be achieved using three compression pads. This data is to be taken as peak values and also includes further test results.

In order to show to what extent the heel can be unloaded, the gap between the Heel Relief Orthosis bottom and heel was cast with Alginate. This Alginate impression was

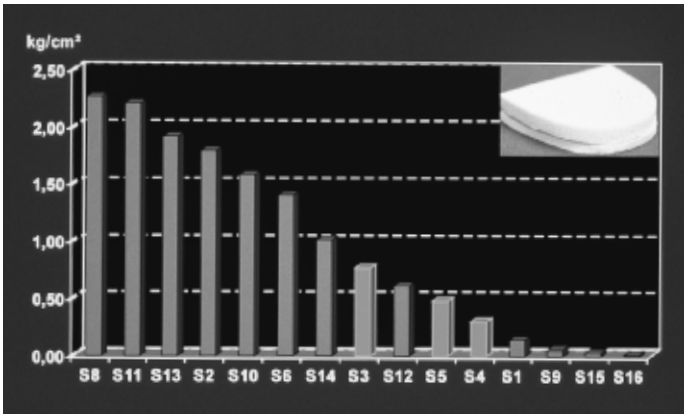

Abb. 5 Heel Relief Orthosis 3 with contour foam and one compression pad.

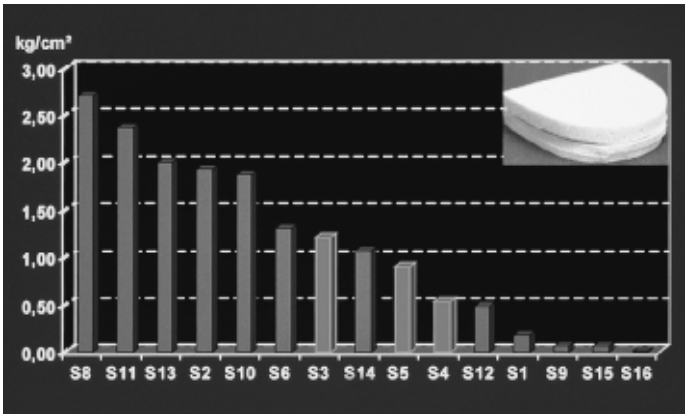

Abb. 6 Heel Relief Orthosis 4 with contour foam and two compression pads.

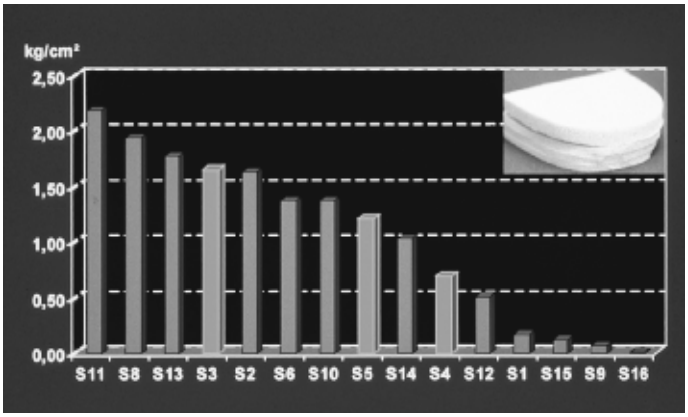

Abb. 7 *Heel Relief Orthosis 5 with contour foam and three compression pads.*

cut open to measure and document the open space. An open space of about 1.3 cm was created under the heel.

Additionally, about 50 patients were examined with Laser Posture. During the examination it was determined that the average load on the Heel Relief Orthosis in the center was about 38.9 kg with an average body weight of 82.7 kg. This is the load on the fracture side without being able to prove substantial load on the fracture spot under the heel.

Since we did not have unlimited access to measuring sensors, we switched to Fuji printing foils and inserted two of them into the heel area. The patient can walk on these contact foils.

The heel pressure was to be determined using a special color indication device based on foil coloration. These statistical test data are included in the above diagrams.

The question remained whether the Heel Relief Orthosis works within the calcaneum proper. To answer this question, two cadaver feet were fitted with Heel Relief Orthosis.

One fitting was used to obtain intraosseous measurements. When the specimen without contour foam was subjected to a pressure of 100 N, a pressure value of 33.9 kg/cm_ was reached below the heel.

At a pressure value of 200 N without contour foam, the peak load reached 38.23 kg/cm^2.

The test was extended by osteotomizing the calcaneum and inserting a measuring foil. At a load value of 200 N, a pressure of 34.88 kg/cm^2 was registered.

Both values were determined using pressure foils at the Institute for Anatomy at the University of Cologne under the supervision of Prof. Dr. med. Köppke, using the existing pressure load values.

The question concerning how we are to understand and verify the way the Heel Relief Orthosis brings about pressure relief still remains, however.

As we already published in our report in OT 3/99, a thin wire was attached on the longitudinal vault in the first months to prove through X-ray images whether and to what extent the longitudinal vault transfers the proper load to the os naviculare. To define the function with anatomical accuracy, a human specimen with Heel Relief Orthosis was prepared using the second cadaver specimen. The specimen was plastinized and clearly shows what the Heel Relief Orthosis looks like and which anatomical structures are loaded or unloaded.

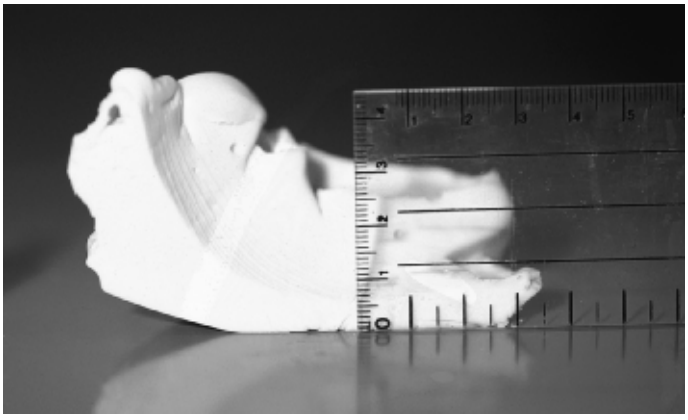

Abb. 8 *Alginate impression with intermediate space.*

Abb. 9 *Osteotomized cadaver foot with contact measuring foils.*

Abb. 10 *Plastinized human specimen with Heel Relief Orthosis*

Treatment concept

As a rule, patients initially use crutches, which they should stop using as soon as they can, depending on their individual perception of pain and pressure. In weeks four, eight and twelve X-ray checks of the heel bone are made with standard as well as digitoplantodorsal X-rays, and by using the Halgrimsson techniques.

The first heel loading pad is inserted in week six, the second one in week eight and the third one in week ten. It should be noted that the loading pads are always placed under the contour foam. The contour foam is always in contact with the heel, from the first to the last day.

The orthopedic inserts or, if necessary, orthopedic shoes are fitted in week twelve. As a rule, the heel is subjected to normal load without the use of crutches at this time.

Summary

Based on the test results, the conclusion can be drawn that fitting the patient with our Heel Relief Orthosis results in accelerated recovery and enables the fracture side to be fully loaded right away. The ongoing testing of the patients will be used to provide scientific proof.

The physiological gait picture is not significantly affected. The cost saving in comparison to previous treatment plans amounts to about 50 percent.

This clear and sound treatment concept for healing bone fractures has been documented and proven.

It should be also noted that for trauma patients suffering from excessive fracture edema, the additional prescription of compression stockings Class II A-D is necessary.

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