

Primary orthotic treatment of ruptured ankle ligaments: a recommended procedure

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Abstract

The results of a study after 1 and 2 years of a prospective randomised trial of operative versus conservative treatment of ankle ligament rupture, demonstrate that purely functional orthotic therapy is the method of choice. This relates both to patient need and economical considerations. The trial demonstrated that without an operation it was possible to achieve a high degree of mechanical stability, a reduction of work disability time down to 3 weeks and full sports capability within 3 months. Consequently, and as a result of the trial, the only remaining surgical indications would seem to be dislocations of the foot and ankle, ankle ligament rupture with additional intra-articular pathology, and second-stage injuries or re-ruptures.

The joint-stabilising function of the prototype splint developed in this study was improved on the basis of experimental investigations, using a Y-shaped leather band (designated CALIGAMED), which is available in 6 sizes for right and left ankle.

Introduction

Since the early eighties there has been considerable controversy in Europe regarding the treatment of severe ankle sprains with ruptured lateral ligaments. This is the most common injury of the recreational and school athlete and most patients are between 15 and 25 years old. There are important socio-economic implications to this injury in respect of medical

expenses as well as time off work and also disability payments through the workman's compensation system. The 1985 rehabilitation study of the workman's compensation system in Germany (REHA, 1985) demonstrated, that during the twelve month period 13,554 patients were hospitalised for an average of 12.6 days for the treatment of ruptured ankle ligaments as an isolated injury. In the light of these important economic implications and with the instruments of modern medical research currently available, it was felt that treatment strategies should no longer be based on personal judgement, general trends or retrospective studies. Experimental studies and prospective randomised trials are necessary to make these important decisions.

A number of clinical trials which compared conservative immobilisation with operative treatment could not show any difference in the results between these two treatment modalities (Brooks *et al.*, 1981; Evans *et al.*, 1984; Klein *et al.*, 1988; Niedermann *et al.*, 1981; Zwipp, 1986). Other authors have published excellent results with early functional treatment with tapes, orthoses and special shoes (Brooks *et al.*, 1981; Hoogenband *et al.*, 1982; Hoogenband and Moppes, 1987; Jakob *et al.*, 1986; Klein *et al.*, 1988; Korkala *et al.*, 1987; Neumann, 1987; Stover, 1980; Stover 1986; Wetz *et al.*, 1987; Zwipp *et al.*, 1986).

Study design

A prospective randomised trial on the treatment of ruptured ankle ligaments was carried out at the Trauma Department of Hannover Medical School between 15th April,

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Group	Treatment	N	excellent	good	sat.
A		52	76%	21%	3%
B		50	89%	11%	0%
C		48	76%	21%	3%
D		50	79%	21%	0%

Fig. 1. Treatment groups and ankle performance score results averaged over all 3 follow-up periods.

1985 and 31st July, 1986. Two hundred patients were randomly assigned into 4 groups in respect of treatment method.

Fifty patients in each group were evaluated on a 100 point scoring system based on clinical, radiographic and dynamometric results. They were evaluated 3, 12 and 24 months after the injury (Fig. 1).

The groups were classified as follows:

Group A: Surgery and cast immobilisation.

Group B: Surgery and early functional orthotic treatment.

Group C: Conservative treatment and cast immobilisation.

Group D: Conservative and early functional orthotic treatment.

The study was evaluated and accepted by the Institution's ethical commission.

Group A

Within 60 hours after the injury surgery was performed under general, or regional, anaesthesia. A lateral malleolar approach to the ankle was used, as previously described (Zwipp *et al.*, 1986). The patients were hospitalised for one or two days and the involved extremity was immobilised in a short leg plaster cast and elevated on a foam splint. Oral non-steroidal anti-inflammatory agents and mini DHE dose Heparin were administered while the patients were in hospital. Active range of motion exercises to 10° of plantarflexion and 20° of dorsiflexion were initiated on the first postoperative day. Between the 5th and 8th postoperative days, a lower leg walking cast was applied in a neutral ankle position and used until 5 weeks after the operation.

Group B

Surgery and medical management were the same as for Group A. However, 8–10 days after the operation this group was fitted with a newly designed small splint which provides protection against supination and also incorporates a pronation wedge. This splint can be worn in a sports shoe and patients were instructed to wear the orthosis continuously day and night. Co-operative patients were allowed to remove the orthosis to shower. Patients were allowed to drive a motor vehicle as soon as pain free full weight-bearing was possible. Light work was allowed after 3 weeks.

Group C

These patients were initially immobilised in a short leg plaster cast. This was removed at about 3–5 days post-injury when the haematoma around the malleolar aspect had subsided with the aid of oral non-steroidal anti-inflammatory agents and elevation of the affected limb. A walking cast was then reapplied moulded in a position of pronation and eversion of the foot as recommended by Schatzker (1984). This was retained for a total of 5 weeks post-injury.

Group D

This group was initially immobilised in a short leg plaster cast for 3–5 days. They were then fitted with the functional orthosis used on Group B. The total period of functional treatment was again 5 weeks. The patients were allowed to drive some days after injury, when full weight-bearing was pain free. Most patients returned to work within 3 weeks after the injury.

For all patients, after removal of the cast or discontinuation of the use of the ankle splint, a series of 6 sessions of physical therapy was prescribed with special emphasis on proprioception and pronator muscle training.

The development of the functional orthosis and its use

The intention was to create a technical aid which would provide stabilising functions of conventional plaster cast therapy (short-leg cast) while utilising the pathological and kinetic knowledge behind modern therapeutic

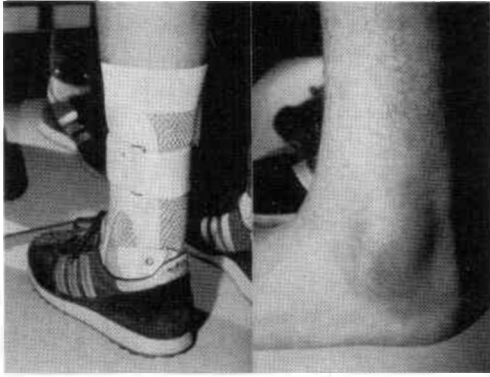


Fig. 2. The MHH splint.

concepts, especially in the case of injuries to the outer ligaments. The result of this work is the MHH (Medizinischen Hochschule Hannover) ankle splint (Fig. 2).

The functional principles of the therapeutic concept were to protect against supinatory sprain through stabilisation of the ankle and talocalcaneal joints while allowing the wound and swollen areas in the outer ankle area to remain accessible.

The design was developed through a number of successive prototypes before a practical solution was achieved. This involved application trials which benefitted, in particular, from trial fittings on the initial patients.

The large number of plaster impressions made to provide patient data gradually revealed certain consistent features, since the patients, for the most part, had no major anatomical abnormalities. There was also the urgent demand for a technical aid that could be applied immediately.

For these reasons, the authors' workshop constantly produced new, improved, versions

prepared in the form of raw thermoplastic blanks requiring only customised fitting to the individual patient. Since the splints did not generally constitute a fixed element in therapeutic plans for longer than 4–6 weeks, costly and complicated cushioning and leather reinforcement were deemed unnecessary.

The best structural method of achieving relief of motion of the outer ankle ligaments is by the use of a moulded thermoplastic orthosis incorporating a pronatory wedge and in combination with strong elastic adhesive bands. This fulfilled the basic requirement of limiting undesirable tilt in the entire foot and especially in the outer ankle area.

The device described here can be compared to a shoe inlay. During the day it is worn inside a normal shoe of a size sufficient to provide room for non-attached insoles. The shoe should have a flat heel profile. Used additionally and simultaneously as an overnight and bedding aid, this special splint form can be worn practically "round-the-clock".

Three closure tapes wrapped around in opposite directions to provide reaction forces give the MHH ankle splint an adaptive but solid fit on the foot. A modification of this orthosis, described as the CALIGAMED ankle splint, was developed with anti-supinatory stabilising components to resist tilt and displacement of the talus under extreme varus stress load. An important element is the Y-shaped leather cuff, which encloses the ankle area tightly from the inner side, while leaving the wound surface accessible (Figs. 3 and 4).

Therapeutic success depends, amongst other things, on total patient co-operation. When technical aids are prescribed, careful instructions for their use must be provided. It is also important to make regular physical checks



Fig. 3. The MHH splint (right side) and the CALIGAMED splint (left side).

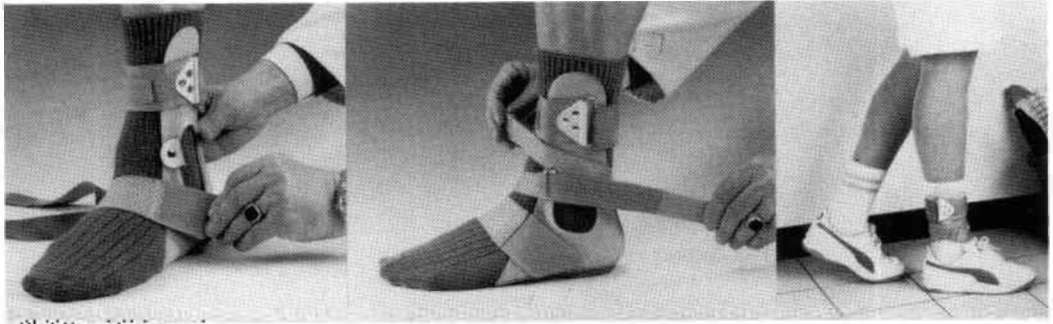


Fig. 4. Application of the CALIGAMED splint.

on the use of the device during the course of therapy. A special patient brochure was written in conjunction with the development of this ankle splint, which conveys important information on the condition, the orthosis and the likely progress of treatment.

The splint may be removed 5 weeks after the accident. This is followed by physical therapy. This consists of at least 6 repetitions of muscle-strengthening exercises (dorsiflexion of foot) and reflex training (balancing exercises, jump-rope, etc.). This follow-up treatment is important and extremely necessary in order to regain control over the foot for walking on uneven surfaces.

Results

In the operative Groups A and B there were no cases of wound infection or neuroma and only 6 cases of dysaesthesia in the vicinity of the wound. A small wound dehiscence developed in 2 patients. These wounds eventually healed with conservative management without any residual problems. No manifestation of thrombosis or pulmonary embolism were observed.

The extent of the injury – single ligament (34%), versus double ligament (66%) – was evenly distributed in the treatment groups and each treatment group had approximately 50 patients. All other characteristics, i.e. age, sex, laterality, were also evenly distributed in the study populations.

At 3 months follow-up it was possible to evaluate 185 of the 200 randomised patients (93%). Statistically significantly better active range of motion was found for the patients in the primary functional group. The subjective feeling of stability was, however, better in the operative groups with a tendency towards less

favourable impressions in the cast group. There were no significant differences in all other subjective criteria, such as fear of the ankle giving way, gait stability, and limitations in sports or work. The results of radiographic stress testing did not confirm the subjective impression and showed no statistically significant differences when all patients in all groups were compared. It was, however, observed that there was a higher percentage of absolutely stable ankle joints as determined by stress views in the operative groups. This difference did not reach statistical significance. No patient developed radiographic signs of degenerative joint disease.

As summarised in Figure 5, the evaluation score in relation to excellent performance was somewhat lower in the group which was operated and cast. When compared with all other groups there was, however, no statistically significant difference when analysis of variance was used.

At 12 months follow-up 168 patients (84%) were available for review. At this interval no significant differences were found between the 4 treatment groups with regard to clinical joint stability, range of motion, incidence of re-injury, subjective limitation, or joint instability graded by stress X-rays. Additionally, the ankle performance score was not significantly different between the treatment groups. After 24 months 159 patients (80%) were available for follow-up. After the one and two years follow-up it was observed that there was a more even distribution of joint stability patterns in the different treatment groups. The type of after-treatment did not seem to have an influence on joint stability. Subjective results, however, did not reflect these findings. Neither the rate of recurrent "giving way", nor the

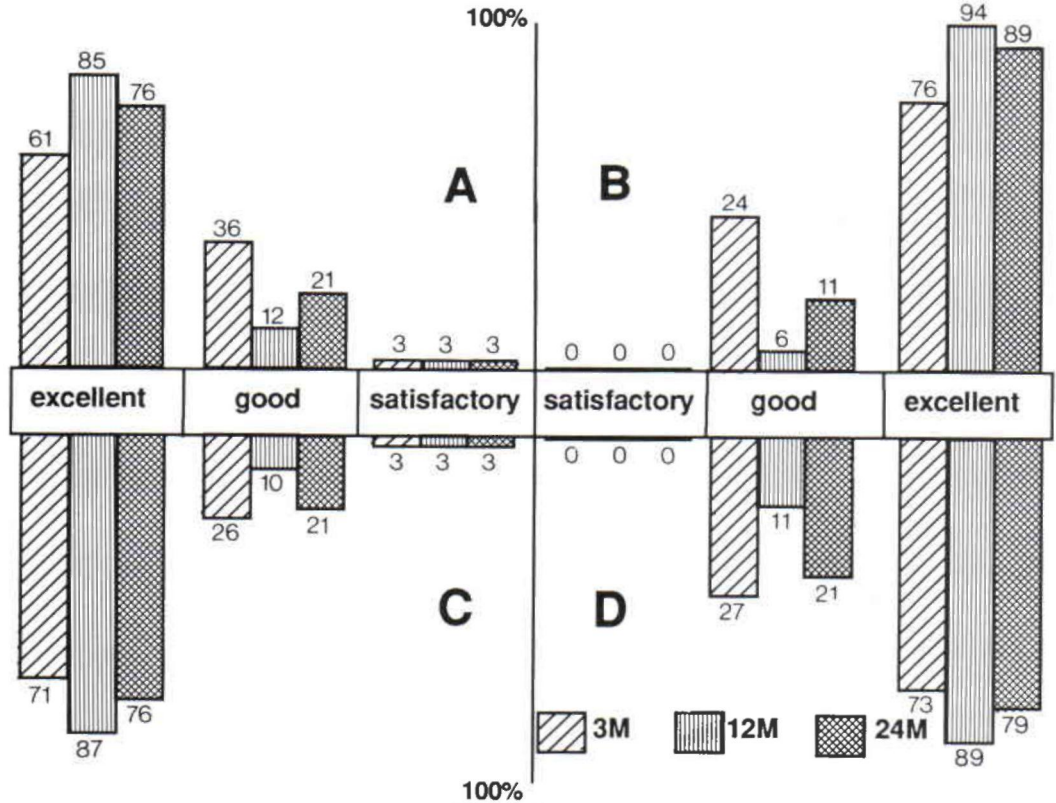


Fig. 5. Detailed description of ankle performance score results.

subjective grading of joint stability was significantly different within the treatment groups. No radiological signs of progressive degenerative joint disease were observed. The functional score again did not reveal a difference between the treatment groups as determined by analysis of variance.

When the results of the stress radiographs taken at follow-up were analysed separately for those patients with single versus double ligament tear, it was not possible to demonstrate different results for each period of follow-up with regard to clinical or radiological instability (Fig. 6).

Therapeutic results

Further experience with the use of the MHH ankle splints makes it clear that at least the following patient groups can be treated successfully:

1. Persons suffering from a lateral ligament rupture at the ankle joint:
 - a) where the lateral ligaments require

follow-up treatment after surgery (5 weeks);

- b) where, mostly without surgery, they are to be treated for purely functional reasons (5 weeks);

- c) where there is chronic instability and muscular decompensation and there is a requirement for external anti-supinatory foot support until the ankle joint is restabilised by specific pronator strengthening and proprioceptive training and/or surgery.

2. Persons who require a temporary foot support to treat a purely functional instability, post-traumatic sinus-tarsi syndrome, isolated instability of the calcaneal joint or other foot instability syndromes.

3. Persons requiring long-term external stabilisation of the ankle joint, in whom the ankle and/or calcaneal joints are unstable and for whom surgical

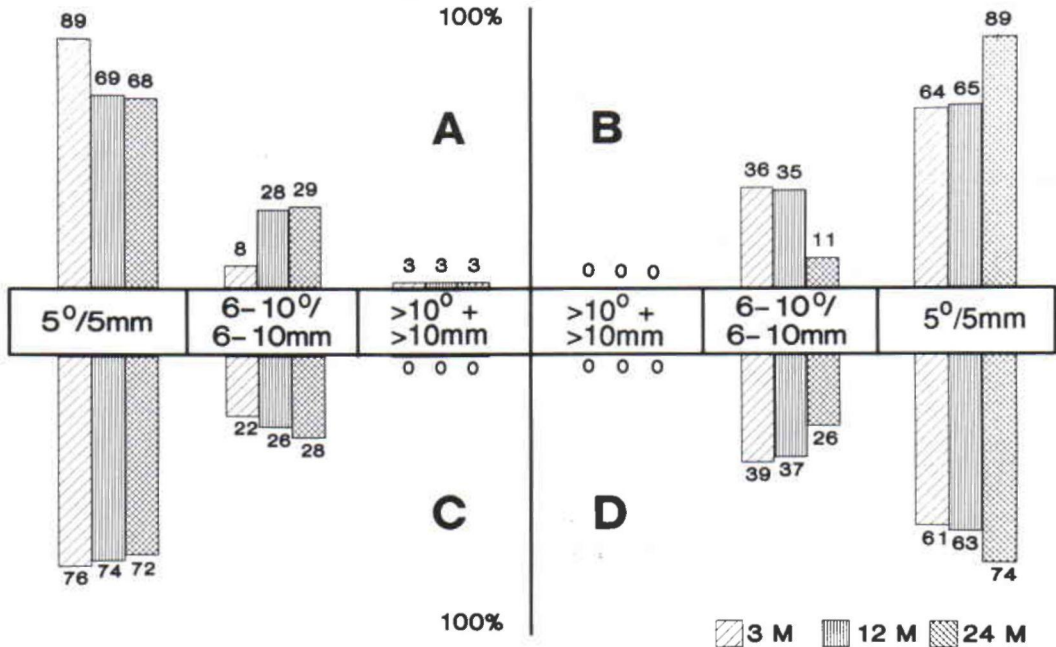


Fig. 6. Joint stability determined by stress X-rays.

stabilisation is contra-indicated when other conservative measures have failed.

Application of the splint concept has revealed several apparent advantages which must be subject to objective measurement and subjective evaluation:

1. Protection against rotation:
 - a) external rotation through stabilisation of the ankle joint;
 - b) supinatory: as a result of the force actions provided by the guidance bands.
2. Relief of the lateral malleolar ankle ligaments – through the heel effect of the pronation wedge.
3. Relief of pressure on the wound or haematoma in the lateral malleolar region – as a result of the large, pear-shaped window.
4. Protection of damaged ligamentous structures when putting on, or taking off, shoes through protection provided by orthotic device inside shoe.
5. Usable 24 hours a day, as night or positioning aide without shoes and as support splint in ordinary shoes.
6. Facilitation of patient co-operation: for hygiene splint may be removed for cleaning of foot and as a part of functional

therapy during post-operative wound healing.

Discussion

A change in scientific knowledge and clinical practice formed the background of the development of this improved form of splint. The development, however, was only possible as a result of the closest collaboration between the medical specialist and the orthopaedic industry.

The indications for these ankle supports are, as a result of this trial, well defined and the clear finding that surgery is no longer a necessity for the majority of cases meant that a cost effective solution is available.

Orthopaedic manufacturers can, using modern practice, often make use of prefabricated construction elements to provide quick and dependable service to the clinic team. As a result of the development described above, there are now available:

- Splint blanks and prepared strapping in construction kit form (to be customised by the orthopaedic master craftsman and delivered to fill the clinical prescription).
- Completely prepared splint blanks (for rapid availability).

- Splint blanks (to be used by the physician in combination with tape bandages and self-adhesive wrapped bandages).

These product forms are available to satisfy individual requirements. Physician and manufacturer must both ensure that they are communicating properly in regards to the therapeutic requirements, as well as technical feasibility. Medical practitioners and the manufacturing industry both share an interest in making a real contribution to lowering medical costs while ensuring and protecting improvement in patient therapy. The technical development of the MHH/CALIGAMED ankle splints described here, as supported by a controlled scientific study, contributed to these efforts.

Splints are now available in 6 sizes (each for left and right) for use ranging from child's size 27 to adult size 50 (measured in French "stitches"). This corresponds to English sizes from 9 for children up to 14 for adults.

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