Summary

In an application study with 57 patients, skin tolerance, the functional result as well as patients and users satisfaction with the thermoplastic cast bandage Rhena® therm were investigated. Patients with fractures and conditions in periarticular structures were treated. In 75% of the cases Rhena therm was used for the stabilisation of an upper extremity and in 25% of the cases for the stabilisation of a lower extremity. The patients wore the cast bandage for 30 days on average.

The physicians and cast technicians were very satisfied with the use and the treatment outcome of Rhena therm. In 45% of the patients the functional result was much better or better than expected; and in another 50% the treatment result met their expectations. A decisive factor for the positive assessment of the use of Rhena therm was the excellent skin tolerance which was assessed as very good or good in 95% of the treated patients. Skin reactions, pressure or chafing spots occurred rarely even during longer wearing times.

The application study shows that with Rhena therm a thermoplastic cast bandage with excellent skin tolerance and easy use is available for the treatment of fractures as well as ligament, capsule and tendon injuries with a high acceptance in users and patients alike.

When extremities have to be immobilised after an injury or condition, stabilising bandages are used in surgery, orthopedics and trauma. In addition to the treatment of fractures, stabilising bandages are indicated for ligament, muscle and joint injuries. The most frequent indications include:

- Conservative fracture treatment (to keep the setting result or the fracture in an anatomically functional position)
- Post-operative care (for immobilisation of an unstable osteosynthesis)
- Ligament, capsule or tendon injury or during settlement of ligament reconstructions (syndesmoplasty)
- Dislocations

Early functional treatment improves the result of treatment

Irrespective of the indication, the immobilised body part must be mobilised in the range of motion without pain as early as possible. This can reduce complications such as atrophy of muscles or of the tendon and capsule system which inevitably occur due to long immobilisation. The preferred method in this case is early functional treatment which leads to distinctly better treatment outcomes. The implementation of synthetic cast bandages of varying strength simplified early functional treatment decisively. immobilisation of injuries not only improved the patients comfort but also reduced complications and subsequent problems that might occur with rigid immobilisation.

Skin tolerance of Rhena therm

The occlusion and the moist environment resulting when plaster casts and cast bandages are used, may cause skin maceration and damage to the barrier function of the skin may occur. In case of longer wearing times, patients complain frequently about an unbearable itching underneath the bandage. Moreover, the damaged barrier function of the skin may facilitate the development of allergic reactions.

For this reason, the present study concentrates primarily on the skin tolerance as well as potential allergic reactions when Rhena therm is applied. As Rhena therm does not contain any harmful and allergenic components, no allergic reactions were diagnosed in the patients during the application study.

Overall, the skin tolerance was very good so that itching or skin macerations occurred rarely.

In orthopaedic and surgical practice, particularly thermoplastic casts like Rhena therm are suited for this due to their versatile use. These casts enable the attending physician to treat the patients not only with classic treatment but also with flexible and removable fixations (bandages, self-made braces etc.). The alternation of unencumbered motion and interim immobilisation brings about motor-sensory stimulation of the injured body part. This supports the healing process in a stabilising manner.

Rhena® therm

The thermoplastic cast bandage Rhena therm is used for indications corresponding to conventional support plaster casts or reactive resin cast bandages and enables a light, moderate through to strong stabilisation. It can be applied without gloves and does not stick to the patient's skin. Its flexible knitted polyester fabric combined with thermoplastic polyester material does not contain any isocyanate-based polyurethane resin. Prior to application, Rhena therm is activated by moist heat (e.g. in a water bath at 60-70°C). Its excellent transverse extensibility, allows the cast bandage to be applied and moulded without any creases (open time approx. 3 minutes). Rhena therm adheres only to itself, thus guaranteeing excellent bondage of layers. After a setting time of approx. 5 minutes, a solid, hard support bandage is formed that is load-bearing after 15 minutes. The setting time can be accelerated with cold water or ice spray if required.

Application of thermoplastic cast bandages without gloves

Compared to conventional synthetic casts, Rhena therm has even more benefits - for users as well as patients. Synthetic cast bandages contain an isocyanate-based polyure-thane resin. Therefore the user has to wear gloves during application and the patient has to be protected appropriately. In addition to harmful emissions, synthetic cast bandages can stick to the skin. With Rhena therm, however, no special precautions need to be taken during application. Because this cast is physically activated it does not contain any resin compounds. Users and patients are not exposed to any harmful emissions, gloves or skin protection are not necessary.
In addition Rhena therm can be remodelled by heating at any time. Thus sharp edges no longer cause any problems because the user can easily round them off.

Otherwise Rhena therm offers all the other benefits that conventional synthetic casts have compared to white plaster. Despite their greater stability, they are more pleasant to wear for the patients because they are very light. This is a great benefit particularly in older patients and enables faster mobilisation. In addition, Rhena therm is much more transparent during radiography compared to white plaster. As a result it is much easier to check the healing status.
Clinical studies that investigated the benefits of thermoplastic cast bandages for users and patients have not been conducted until now. This application study with Rhena therm closes this gap. In addition to the functional result of treatment with Rhena therm, special attention was paid to satisfaction and skin tolerance.

57 patients with fractures and ligament, capsule or tendon injuries were treated with Rhena therm

The application study was conducted at the Accident, Hand and Plastic Surgery Clinic of the St. Antonius Clinics in Wuppertal (Germany). Altogether 57 patients (average age of 36 years) with fractures or conditions in periarticular structures were included in the study. Patient data as well as treatment-relevant data (etiology, diagnosis, treatments before application of Rhena therm, type of treatment (conservative/surgical), type and duration of stabilisation with Rhena therm) were collected with the aid of a standardised questionnaire. After removal of the bandage, the attending physicians assessed the functional results of the use of Rhena therm as well as skin tolerance.
Patients with fractures as well as patients with ligament, capsule or tendon injuries were included. Except for a few exceptions, trauma was the cause of the injury (93%). The upper extremities were affected in 75% of the cases (Fig. 1). Radial fractures (34%) were the most frequent indications for treatment with Rhena therm, followed by hand (24%) and elbow (14%) injuries. The cast bandage was used for the immobilisation of a lower extremity in about 25% of the patients.

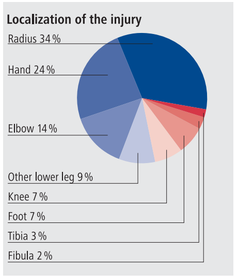

Fig. 1 Localisation of the injuries treated with Rhena therm. 75% of the patients had an injury of the upper extremity and 25% of the lower extremity.

Initial treatment with Rhena therm in more than 50% of the patients

Approximately one third of the patients underwent surgery due to their injury prior to the application of Rhena therm (e. g. fixation with 2-K wires, osteosynthesis etc). Another third was first provided with a white plaster or immobilised with a plaster splint. More than 50% of the patients (55.1%) were treated with the thermoplastic cast bandage during initial care.
While lower extremity injuries were solely treated with a circular bandage, longuets as well as circular bandages were used for the treatment of upper extremity injuries. Altogether 60% of the patients were treated with circular bandages and 34.5% with slabs. 68% of the circular bandages were split after application to prevent pressure spots in case of swelling or to enable special braces and bandages to be made. In over 80% of the cases, treatment with Rhena therm aimed at a moderate stabilisation of the injury, in 17% a strong stabilisation was required (Table. 1).

Table. 1: Type of the desired stabilisation with Rhena therm

Localisation	Light	Moderate	Strong
Radius	0	18	2
Elbow	0	6	2
Hand	0	11	3
Lower extremity (tibia, knee, fibula, other lower leg, foot)	0	13	3

Rhena therm was worn for one month on average

The fractures and injuries in periarticular structures were stabilised with Rhena therm for 30 days on average. Very long wearing periods of 37 days on average were required for the radial fractures, while very short ones were required for the elbow injuries (21 days). An overview of the wearing duration is shown in Table 2.

Because Rhena therm was applied as a splint or orthosis in most of the patients, special tools were used to remove the cast bandage in only 28% of the patients: 17.5% of the applied immobilisation bandages were removed with scissors, another 10.5% with the aid of an oscillating saw.

Physicians were very satisfied with the use of Rhena therm

The physicians were very satisfied with the use as well as the treatment outcome of Rhena therm. According to their information, the functional result of the treated fractures and periarticular injuries was either much better or better than expected in almost 45% of the patients. Treatment progressed as expected in 50% of the patients. Only in one patient was the final result worse or distinctly worse than expected after the use of the cast bandage (Fig. 2).
Altogether more than 90% of the physicians rated the expectations that they had for Rhena therm before its use as fulfiled (84%) or even exceeded. Their expectations were not fulfiled in two patients in whom the final result was worse than expected.
(Fig. 3).

Table. 2: Wearing duration on average of Rhena therm depending on the indication

Localisation	Days
Radius	37
Elbow	21
Hand	30
Lower extremity (tibia, knee, fibula, other lower leg, foot)	26

Skin tolerance in 95% of the patients very good or good

The positive assessment of the course of treatment was supported not only by the favourable functional result but also by Rhena therm's excellent skin tolerance. Skin reactions, pressure or chafing spots occurred rarely even during longer wearing times.
The attending physicians assessed the skin tolerance in 54 patients (95%) as very good or good. In two cases they were marked satisfactory (Fig. 4).

Example case 1
Radial head fracture in the left elbow, treatment with an upper arm plaster splint for one month

A fracture of the radial head was diagnosed in a 52-year-old man after he fell on his left elbow (Fig. 5). The radial fracture without dislocation was treated with an upper arm plaster cast. Rhena therm was applied as a slab starting from the hand and first roughly fitted to the upper arm. After hardening, the thermoplastic cast bandage was submerged again in the water bath, exactly fitted to the arm, cut to size and firmly wrapped on with an elastic bandage (Fig. 6-7). Prominent spots were padded with the padding bandage Rolta soft. According to the attending physician, the upper arm splint was supposed to provide moderate stabilisation of the radial head fracture. In addition to immobilisation by Rhena therm, the patient also performed physiotherapy exercises.

No complications during the follow-up calls

During the following three weeks the patient was summoned for a check-up three times and the healing process was checked radiologically. At all follow-up calls, peripheral blood circulation, motor response and sensory function were intact in the injured extremity and the cast splint was on correctly. No skin changes or complaints occurred. The healing process progressed without any complications.

The plaster cast was removed after 4 weeks (Fig. 8). As the attending physician reported, the functional final result was as expected. The cast splint did not cause any undesired side effects such as pressure spots or skin reactions on the arm or at the cast edges during the course of treatment.
The skin tolerance was assessed as good. Based on the good treatment outcome and the good skin tolerance, the attending

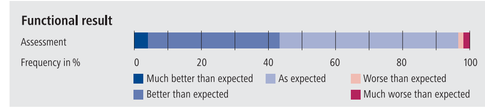

Fig. 2 Functional result after completion of the treatment with Rhena therm

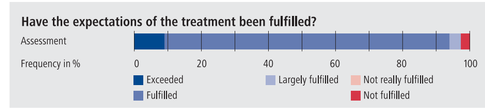

Fig. 3 Fulfillment of expectations of treatment with Rhena therm

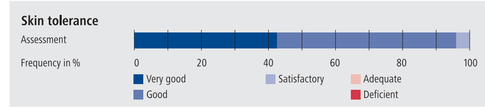

Fig. 4 Assessment of the skin tolerance of Rhena therm

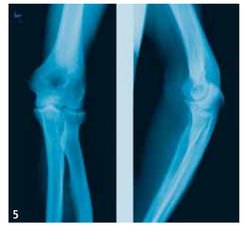

Fig. 5 Radiograph of the radial head fracture at the first examination.
Fig. 6 Application of the upper arm plaster splint. The slab was applied starting at the hand and prominent spots were padded.
Fig. 7 Completely applied lower arm plaster splint. The cast splint was wrapped on with an elastic bandage.
Fig. 8 Function of the upper arm after removal of the splint.

physician would use Rhena therm again for this indication.

Example case 2
Distal radial fracture in the left hand, treatment with a lower arm brace for six weeks

In a car accident a 62-year-old woman sustained a distal radial fracture in her left hand (Fig. 9). A circular bandage with Rhena therm was applied on the patient, split and a lower arm brace was made with a velcro strip (Fig. 10/11). The cast edges were taped, no other padding was attached. The radial fracture was to be stabilised moderately.

Further treatment was carried out by her family doctor. The healing process progressed without any complications. The brace cast was removed at six weeks (Fig. 12). According to the attending physician, the functional result of the use of Rhena therm was much better than he had expected. No pressure spots or skin reactions occurred under the cast bandage during the six week wearing duration, nor any pressure or chafing spots or skin reactions at the cast edges. Physiotherapy and massages were prescribed for the patient as secondary therapeutic measures after removal of the bandage.
The patient was also very enthusiastic about the treatment with Rhena therm. She particularly stressed that she was able to remove the brace for showering and washing and apply it again without any problems. In addition she stated that the wearing comfort was very high. Although the treatment with Rhena therm took place during a period of warm weather, she rarely suffered from itching or similar problems. Because Rhena therm can be used without any additional padding, it is particularly user and patient friendly.

9

10

11

12

Fig. 9 Radiograph of the distal radial fracture
Fig. 10/11 Lower arm brace with velcro strip

Fig. 12 Removal of the lower arm brace after six week wearing duration

Summary and final assessment
The application study as well as two selected example cases show that with Rhena therm a thermoplastic cast bandage, with a high acceptance in users and patients alike, is suitable for the treatment of fractures as well as ligament, capsule and tendon injuries. This applied for the application to the lower as well as upper extremities and for all types of techniques, be it as slabs or circular and split bandages. It was possible to prove the excellent skin tolerance in the study. Because Rhena therm is activated physically (and not chemically) prior to application, no harmful polyurethane resins are released. In addition it does not stick to the skin. Therefore the thermocast can be directly applied to the patient's skin without any further protection. Moreover, users do not need any gloves during application.

As the study also showed, Rhena therm is easy to use. According to the attending physicians and cast technicians, it was also possible to reactivate the material again even after hardening and to modify edges and cuffs. Moreover it was possible to make orthopedic splints and orthosis from Rhena therm for functional treatment with ease.

Holger Kapp
Clinical Research Department
PAUL HARTMANN AG
D- 89522 Heidenheim

HARTMANN

www.hartmann.com.au

HARTMANN

Hartmann Immobilisation Clinical Series No.1

Application study confirms good skin tolerance of the thermoplastic cast bandage Rhena® therm

Holger Kapp
Clinical Research Department.
Paul Hartmann AG, Heidenheim.

Summary

In an application study with 57 patients, skin tolerance, the functional result as well as patient and user satisfaction with the thermoplastic cast bandage Rhena® therm were investigated. Patients with fractures and conditions in periarticular structures were treated.

- In 75% of the cases Rhena therm was used for the stabilisation of an upper extremity and in 25% of the cases for the stabilisation of a lower extremity.
- The physicians and cast technicians were very satisfied with the use and the treatment outcome of Rhena therm.
- A decisive factor for the positive assessment of the use of Rhena therm was the excellent skin tolerance which was assessed as very good or good in 95% of the treated patients.
- Users and patients are not exposed to any harmful emissions, gloves or skin protection are not necessary. In addition Rhena therm can be remodelled by heating at any time. Thus sharp edges no longer cause any problems because the user can round them off easily.