EMS MEDICAL

Study Results

Study of the effectiveness of ballistically generated shockwaves on tennis elbow and heel spur with the Swiss DolorClast®

12 months results of a multicentric, prospective, placebo-controlled, randomized, single-blind study

Introduction

In September 1997 a multi-centric, randomized, single-blind and placebo-controlled clinical study was carried out to investigate the effects of Radial Shockwave Therapy® with the EMS Swiss DolorClast® for the treatment of the indications tennis elbow and calcaneal spur. This study was lead by Prof. Dr. G. Haupt of the University of Cologne, Germany.
The doctors involved in the study were:

- Dr. Diesch, orthopaedic surgeon, Friedrichshafen, Germany
- Dr. Frölich, orthopaedic surgeon, Böblingen, Germany
- Drs. Lohrer and Schöll, Institute of Sports Medicine, University Frankfurt, Germany
- Drs. Straub and Penninger, orthopaedic surgeon, Dingolfing, Germany

Except for the Institute of Sports Medicine in Frankfurt, the treatment centers chosen were doctor's offices, as they are visited by a greater number of patients with the relevant indications. In this way it was possible to recruit the **219 patients** needed to take part in this study in a relatively short space of time. All the orthopedic surgeons involved in the study had comprehensive experience with therapies for heel spur and tennis elbow using conventional, focussed shockwave devices.

Criteria for Participation

The admission criteria for patients for the participation in the study were:

- complaints lasting more than 6 months
- at least two unsuccessfully completed conventional therapies
- age between 18 and 75 years
- indication for surgery

The exclusion criteria were:

- Karnofsky-Index < 70 (standard for general well-being)
- specific therapy over the past 14 days
- pregnancy
- coagulation disorders
- tumors in the region of treatment
- systemic illnesses as cause of pain (rheuma, collagenosis)

The Radial Shockwave Therapy®

The patients of this study were treated with the **Radial Shockwave Therapy®** using the Swiss DolorClast®. The Swiss DolorClast® was developed by EMS S.A. in Nyon (Switzerland). The device consists of a control unit and a handpiece with two applicators of different diameters. A pressurized air source and a power source are required to operate the device.

The **indications for the pain therapy** are close to the skin. There is no need for elaborate focussing.

The source of the shockwave of the Swiss DolorClast® emits a shockwave from the tip of the applicator that disperses radially in the body. Clinical studies have demonstrated that the **therapeutically effective penetration depth** of radial shockwaves in humans is up to 35 mm.

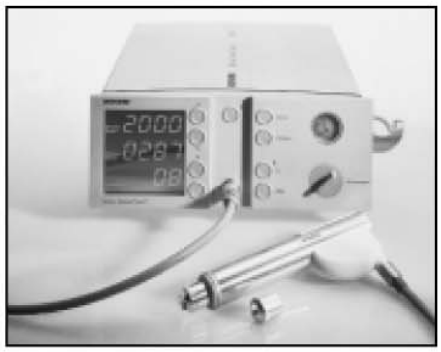

Figure 1: The Swiss DolorClast® Unit

The **radial shockwave** is **pneumatically generated**. A projectile in the handpiece is propelled at high speed by a precision-controlled pressurized air pulse. When the projectile hits the applicator installed in the handpiece, its kinetic energy is converted into acoustic energy. This energy is transmitted from the projectile to the applicator, which does not move.
The pneumatically generated shockwaves are transmitted into the affected regions over the wide area through the freely moveable handpiece. To minimize transmission losses in the layer of air between the applicator and the skin, a coupling gel is used.

General effects of the Radial Shockwave Therapy® on the tissue:

- Increased metabolism in the area of treatment
- Resorption of irritative calcium deposits in the tendons
- Reduction in tenderness

Treatment and Follow-up

The protocol of the study prescribed an intensive **preliminary examination** of the patients and a **uniform treatment** by the doctor.

- The treatment maximum for all patients was three sessions.
- 2,000 impulses per session were applied.
- The energy flow density during treatment was equal to a operating pressure of 2 bar with a treatment frequency of 3 Hz in continuous pulse mode.
- Placebo patients were treated with a absorber between skin and applicator. In this way the energy of the shockwave was absorbed almost entirely.
- Follow-up examinations took place 1, 4, 12, and 52 weeks after the final treatment.
- Patients of the placebo group, who were dissatisfied with the treatment, were allowed to receive a verum treatment four weeks after their last treatment. The data of these "**changers**" were collected and assessed in a separate group.

Treatment for both indications took place according to the same pattern: The doctor localized the site of pain by palpation and marked the skin over the corresponding area. If local anaesthesia was necessary, this was carried out subcutaneously, but injecting in the treatment area was avoided. After that, a coupling gel was applied to the treatment area.

The applicator was moved over the marked area with circular movements in continuous pulse mode. When treating tennis elbow, only light pressure was applied. Although the pressure had to be increased for heel spur, the patients still considered the treatment to be bearable.

Figure 2: Localization by palpation

Figure 3: Marking of the pain zone

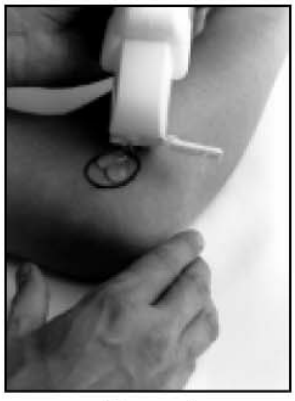

Figure 4: Application of the coupling gel

Figure 4: Treatment with circular movements

Results

At the end of 1998 the admission of patients to this study was concluded.

103 patients (55 verum / 48 placebo) with heel spur and 116 patients (55 / 61) with tennis elbow participated in the study. The evaluation of the study after 1, 4, 12 and 52 weeks for the indications heel spur and tennis elbow in the verum, placebo and **changer group** was carried out separately. Subsequently, the results of the different groups were compared.

Local Anaesthesia

Due to the non-invasive coupling qualities of the shockwave with the Swiss DolorClast® and the radial expansion of the wave, only 11 % of the patients with heel spur and 26 % with tennis elbow needed local anaesthesia.

In case of patients with a very low pain threshold, the application pressure may be reduced slightly and a local anaesthesia may be given. Injections into the treatment area should be avoided. Anaesthesia is carried out with 5 ml local anaesthetic. In case of heel spur, the region of the insertion of the plantar aponeurosis is injected from medial position. In case of tennis elbow, injections should be into the region of the epicondylus radialis.

Side Effects

The following side effects of the pain therapy with the Swiss DolorClast® have been observed: irritation, petechiae, hematoma, swelling and pain. The table below shows the frequency of the side effects according to indication.

Side Effect	Heel Spur	Tennis Elbow
Irritation	76 %	82 %
Petechia	18 %	35 %
Hematoma	6 %	6 %
Swelling	35 %	54 %
Pain	33 %	62 %

Table 1: Side effects of the treatment

All side effects were tolerated by the patients and disappeared within one week after the treatment.

Randomization

The number of patients chosen in the verum and placebo groups was statistically balanced for all characteristics.

Heel Spur

The significant symptoms of heel spur were limitations of the patients' different activities (sporting activities, work, daily life, walking time). Patients treated with the Swiss DolorClast® showed a considerable improvement in their ailments. As shown in the following figures, a continuously rising number of patients in the verum group improved in walking time.

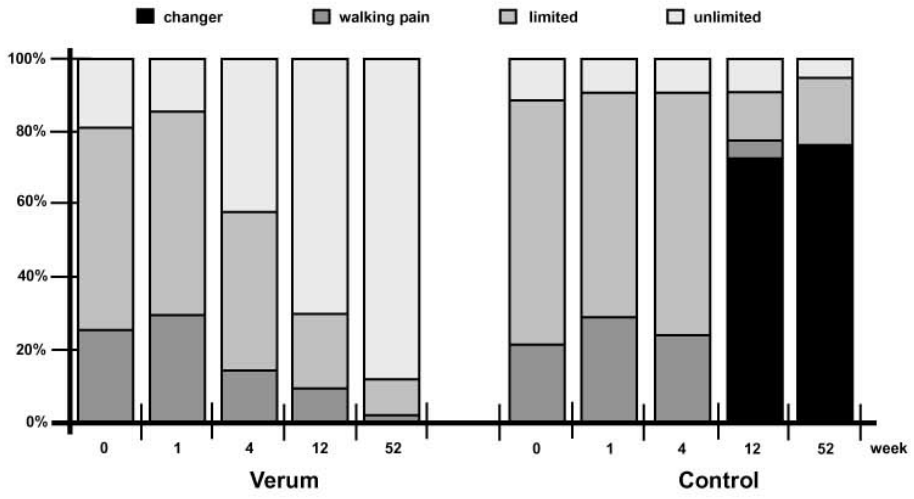

Figure 6: *Heel spur limitations in walking time*

Similarly, symptoms of night pain and walking pain showed considerable improvement four weeks after final treatment with the Swiss DolorClast®, despite initial persistence. Pain improvement 52 weeks after treatment was on patients' average at approx. 77 %.

The results of the 12-month follow-up in figures:

- **88 %** of the patients with **night pain** were completely free of pain after 12 months (94 % free of pain after three months).
- **73 %** of the patients who were **limited in their sporting activities** before the treatment had no limitation 12 months after the final treatment (48 % free of pain after three months).

- Healing success with patients with **limitations in daily life** was **81 %** (66 % free of pain after three months).
- **80 %** of the patients who suffered **limitation in their work** were completely free of pain after 12 months (50 % free of pain after three months).

Tennis Elbow

For patients with the indication of tennis elbow the Radial Shockwave Therapy® with the Swiss DolorClast® also proved highly successful. The healing process after treatment is similar to the healing of heel spur. First, the complaints improved rather slowly only to give way to considerable improvement four weeks after the final treatment (see figure 7). The diagram shows a significant pain improvement of approx. **80 %** after 52 weeks compared to the preliminary examination.

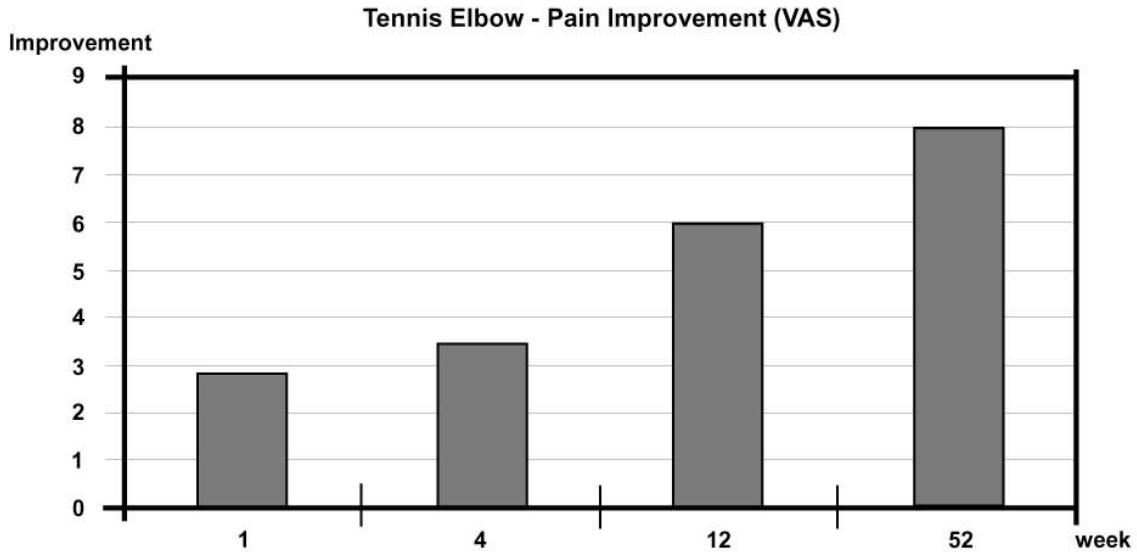

Figure 7: Subjective pain improvement in tennis elbow, measured with a visual analogue scale (VAS)

The results of the 52-weeks follow-up in figures:

- **Night pain**: **95 %** free of pain (100 % after three months)
- Limitations in **sporting activities**: **56 %** free of pain (37 % after three months)
- Limitations in **daily life**: **93 %** free of pain (73 % after three months)
- Limitations in **work**: **92 %** free of pain (65 % after three months)

Acceptance

A measure for the acceptance of the Radial Shockwave Therapy® with the Swiss DolorClast® is the wish of many patients to repeat the therapy, if it is required.

91 % of the heel spur patients and 94 % of the patients with tennis elbow gave an affirmative answer to the question "Would you repeat this treatment?" (see figure 8 and figure 9). This result confirms the high acceptance of the Radial Shockwave Therapy®. The main reasons for this acceptance are

a) the non-invasive coupling of the shockwave and its radial expansion in the body and
b) considerable improvement (free of pain) after a short time.

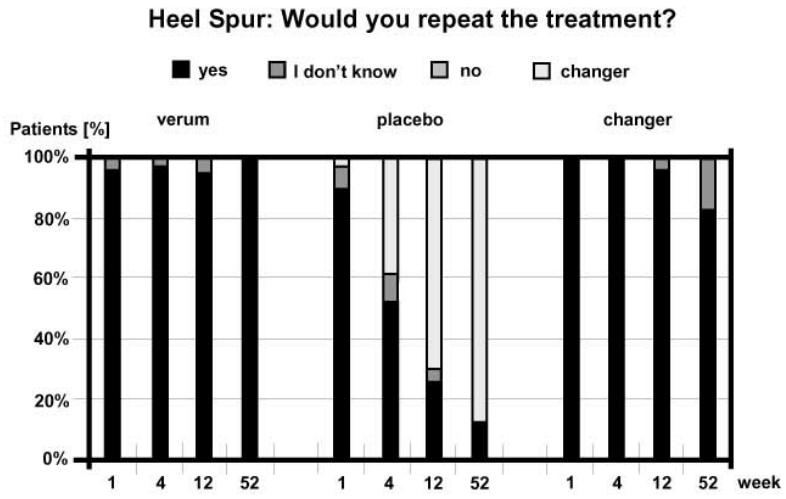

Figure 8: Heel spur patients' wish to repeat the treatment

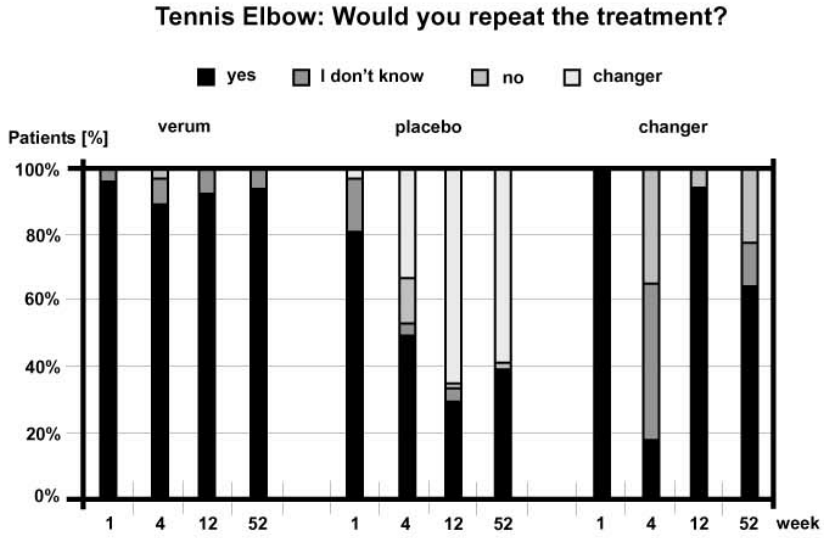

Figure 9: Tennis elbow patients' wish to repeat the treatment

Patient Satisfaction

The diagram below illustrates the patients' answers to the question: "Are you satisfied with the treatment?"

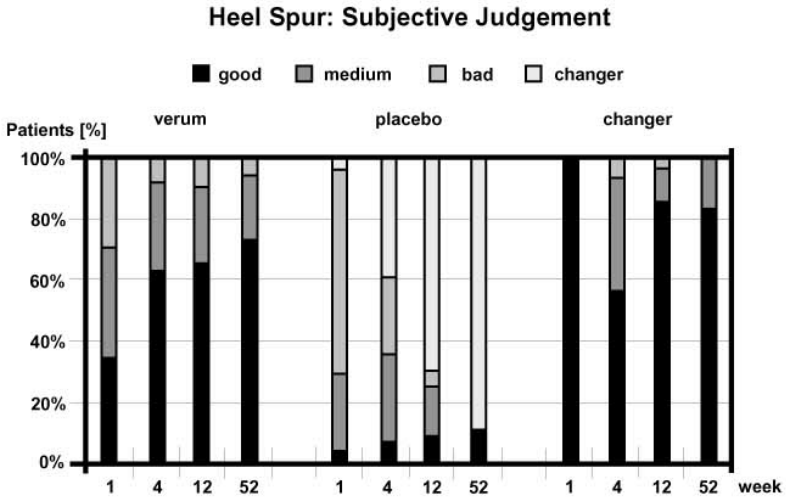

Figure 10: Heel spur patients' subjective judgement

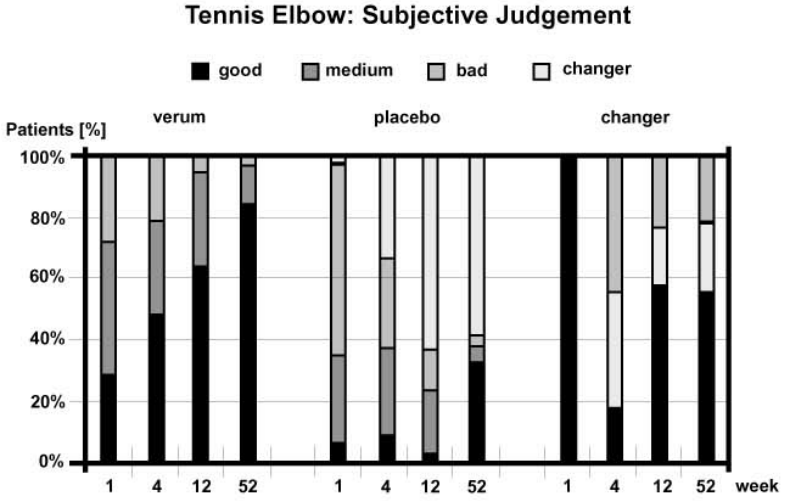

Figure 11: Tennis elbow patients' subjective judgement

52 weeks after the last treatment, 94 % of the (verum-) treated patients with heel spur judged the therapy as good (83 %) or moderate (11 %). For tennis elbow the quota was 95 % (good 85 %, moderate 10 %).

Summary

The study proved that treating the indications heel spur and tennis elbow with the Swiss DolorClast® leads not only to a considerable reduction in chronic pain, but also in the limitations caused by this chronic pain regarding to work, sporting activities and daily life.
There is a high acceptance of the Radial Shockwave Therapy®. This is essentially due to the good tolerance of the therapy (only a few patients needed local anaesthesia) and the small side effects. Although a placebo effect could be observed, the control group showed clearly different and smaller results compared to the verum-group.

Therefore, the Radial Shockwave Therapy® with the Swiss DolorClast® is a highly effective and considerably less expensive alternative, not only to the conventional shockwave therapy but also to the operative treatment of the indications heel spur and tennis elbow.

Figure 12: Radial Shockwave Therapy®
with the Swiss DolorClast®