

Piezo-generated extracorporeal shockwave therapy in the treatment of the DIGEST standard indications

– Medium-term results –

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Introduction

Extracorporeal shockwave therapy (ESWT) has been used successfully since the mid-1990s in treating the locomotion system at the Department of Orthopedics and Accident Surgery in the Eilbek General Hospital (formerly the Barmbek General Hospital) in Hamburg. These treatments are carried out solely with devices utilizing piezoelectric principles and the results have been scientifically evaluated. In the report which follows we would like to present a retrospective, non-randomized, non-controlled study to provide an overview of the medium-term results of ESWT at the locomotion system to treat standard indications.

Among the standard indications listed by the German and International Society for Extracorporeal Shockwave Therapy (DIGEST) are

fasciitis plantaris (heel spur),

epicondylopathia humeri radialis and ulnaris (tennis elbow),

tendinosis calcarea (frozen shoulder) and

pseudarthrosis.

Fasciitis plantaris is an insertion endopathy in the area of the origin of the plantar fascia at the calcaneus. Prevalence of fasciitis plantaris is estimated at up to 21%. This ailment is manifested clinically in localized tenderness in the area of the tuberculum calcanei, somewhat toward the medial. The patients usually complain of pains in the ankle, proportional to the amount of loading or stress applied. The success rate for conservative therapies including physiotherapy, orthopedic insoles and non-systemic antiphlogistic therapy is not satisfactory.

Alternatives to ESWT in treating fasciitis plantaris are found in infiltration therapy, neurolysis, heel spur resection and fasciotomy. An elevated complication rate is, however, associated with surgical procedures. Moreover, the success rate for surgical procedures, at 50 to 95%, is only comparable in its range to the success of conservative therapy. The positive therapeutic effect of ESWT in the treatment of the fasciitis plantaris has been demonstrated.

Epicondylitis of the humeri radialis and ulnaris represents tendinosis at the origin of the long extensors and flexors for the hand and fingers. This manifests itself in stress pain and tenderness at the tendonous origin of the musculature. Treatment is primarily in the form of physiotherapeutic exercises intended to stretch the musculature, Cyriax (transverse) massage and percussion massage with slender rods. Over and above this, infiltration therapy under local anesthesia and the use of cortisone are described. It has been possible in current, controlled studies to demonstrate the efficacy of ESWT in treating the fasciitis plantaris and **epicondylitis of the humeri radialis**.

Pseudarthrosis is the failure of bone to knit. Depending on the location, it may appear in from 10 to 50% of all cases following a fracture or osteotomy. The state of the art in dealing with pseudoarthrosis is osteosynthesis, including the application of spongiosa, where indicated. Non-controlled studies describe a positive therapeutic effect for ESWT.

A further standard indication is **tendinosis calcarea** at the shoulder. A monocular calcific deposit, Type I or II after GÄRTNER, is an indication for ESWT. Patients report subjective pain in the shoulder under stress and in some cases at rest, as well. Moreover, the patients experience localized tenderness in the area of the tuberculum majus humeri and frequently exhibit a positive “zero-degree” abduction test and positive signs for impingement. The alternatives available for therapy include physiotherapeutic exercises, massage, needling and infiltration therapy as well as surgical removal of the calcific deposit.

Materials and methods

Therapy techniques

Therapy for all the patients presented below was undertaken three times each, at intervals of one week. The extracorporeal shockwave therapy was administered with a PIEZOLITH 100 unit, manufactured by the RICHARD WOLF company in Knittlingen; this device utilizes the piezoelectric principle. Sonographic exploration of the pathology was undertaken prior to each treatment session, accompanied by localization of the problem to enable proper focusing. Treatment was regularly carried out without local anesthesia, at 4 Hz and 3600 pulses per session.

No infiltration treatments were to have been undertaken within the period six weeks prior to the first ESWT. Also defined as an exclusionary criterion for ESWT was any prior surgery. The contraindications for ESWT as specified by DIGEST were applied in full.

In treating the fasciitis plantaris and in treatment for tendinosis calcarea and pseudarthrosis we utilized high-energy ESWT with energy density of > 0.6 mJ/mm². When treating epicondylitis, medium-energy ESWT was employed (0.2 to 0.4 mJ/mm²).

Patient population

In the follow-up examination period, from 2000 to 2003, **92 patients suffering from fasciitis plantaris** were treated with ESWT in the Orthopedic Department at the Barmbek General Hospital (today the Department of Orthopedics and Accident Surgery at the Eilbek General Hospital), a facility under the auspices of the Hamburg State Hospital Operation Agency. Of those patients, we were able to include 81 in our retrospective, non-randomized, non-controlled study. In addition, ESWT was carried out for 63 patients suffering epicondylopathia humeri radialis (EHR) and for four patients suffering epicondylopathia humeri ulnaris (EHU). Of this total patient population we were able to conduct retrospective examinations on **56 patients exhibiting EHR**. The patients with EHU could not be examined at this time because they had either moved away or were not willing to participate in this study.

A total of **39 patients suffering tendinosis calcarea** were treated with ESWT and **35** of them could be included in the study.

Additionally, it was possible to investigate the medium-term results of the treatment for **15** of 16 patients suffering from **pseudoarthrosis**. This was a heterogeneous population of 15 patients where pseudoarthrosis had appeared postoperatively following an osteotomy, or posttraumatically, at the ilium (1), fibula (3), first metatarsal (4), tibia (2), femur (4) and cuboid calcaneus, in some cases following arthrodesis (1). The patients had been treated osteosynthetically either as primary treatment or in the course of a revision. Only one WEBER B fracture was treated, solely with conservative therapies, prior to ESWT. Following therapy the patients continued to receive partial relief of the affected extremity.

Objectives

We examined each of the patients six weeks after therapy and, on average, one year afterward. We are presenting below the medium-term results, which were determined on average 17 months following extracorporeal shockwave therapy.

In all the follow-up examinations the current degrees of tenderness, stress pain and pain at rest were determined for the patients suffering **fasciitis plantaris** and **epicondylopathia radialis and ulnaris** ("EHR" and "EHU"). Following the treatment for **tendinosis calcarea**, pain at rest and under stress was established using the "Visual Analog Scale" (VAS) with an evaluation range of from 0 to 10.

The objective in the treatment of **pseudarthrosis** was bone knitting, demonstrated radiologically at the fracture line, which was viewed in the unmodified X-ray image or in a tomograph or computer tomograph which may have been prepared optionally.

The pain-free walking distances for patients suffering **fasciitis plantaris** were subdivided into the categories "none," "less than 200 m" and "more than 200 m." In addition, each patient was asked for a subjective estimate of satisfaction with the therapy. The responses were grouped into three categories: "very satisfied," "satisfactory" and "unsatisfactory." The patients were also questioned at each follow-up examination about any further therapies which might have been

undertaken subsequent to ESWT (such as physiotherapy, surgery). The patients were also asked to compare their current athletic activity capacities with the status prior to therapy. The categories used here were “better,” “the same” and “worse.”

We documented complications following each treatment and patients were queried once again at each follow-up examination.

Results

Fasciitis plantaris

The follow-up examination, a year after high-energy ESWT was carried out, found a significant reduction of tenderness and stress-induced pain among the fasciitis plantaris patients; in regard to pain at rest, there was pain relief, measured on the Visual Analog Scale (VAS), from 2.7 prior to therapy to 1.1 following therapy. As regards tenderness and stress-induced pain, there was in both cases a significant decrease on the VAS with its 0 to 10 scale.

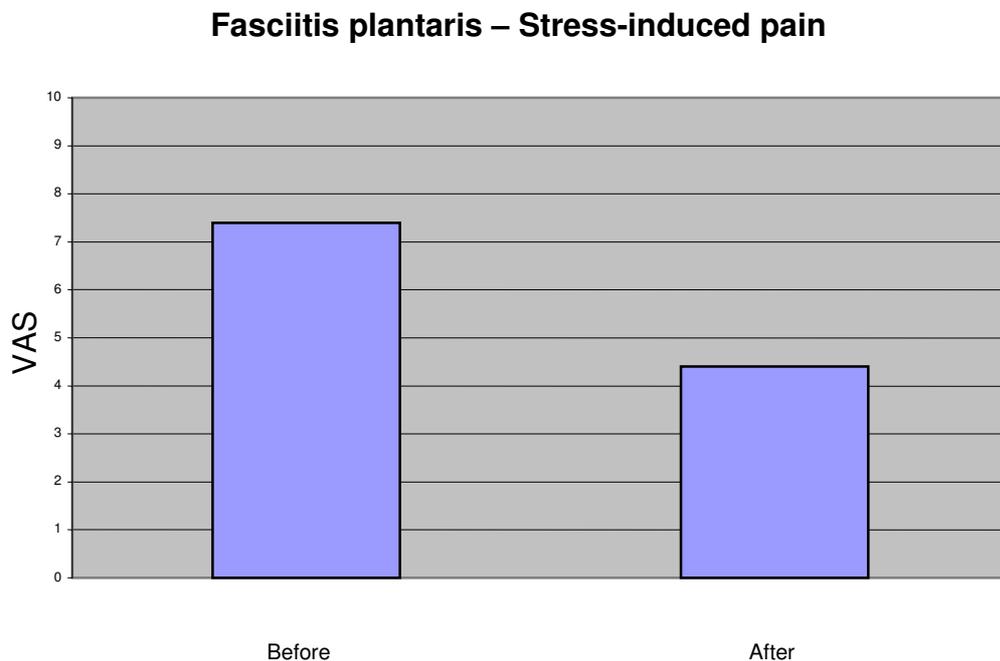


Fig. 1: Perception of stress-induced pain due to fasciitis plantaris before and after ESWT

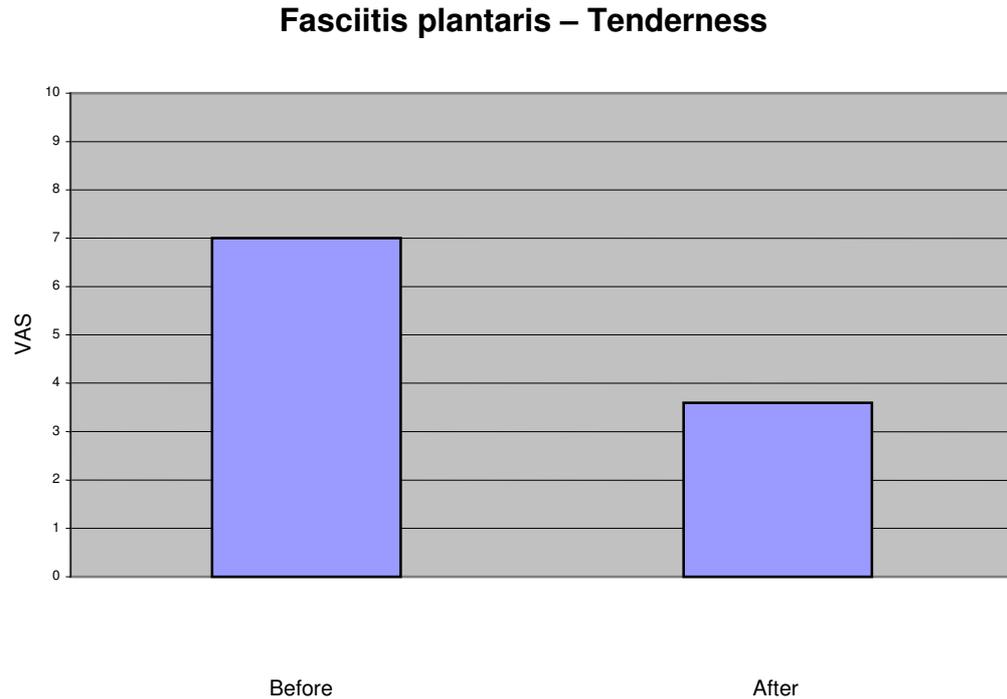


Fig. 2: Perception of tenderness due to fasciitis plantaris before and after ESWT

At the time of the follow-up examination 68% of the patients deemed the therapy to be very good or good, 31% were satisfied with the results and one patient was unsatisfied with the results a year after therapy. In 78% the capacities for athletic endeavors were the same as prior to the onset of the illness.

Moreover, there was a significant increase in the distance which patients with fasciitis plantaris could walk without experiencing pain. Thus the number of patients who could, prior to therapy, cover more than 200 m without pain was only 16; 68 patients indicated that after therapy they were able to walk more than 200 m without pain.

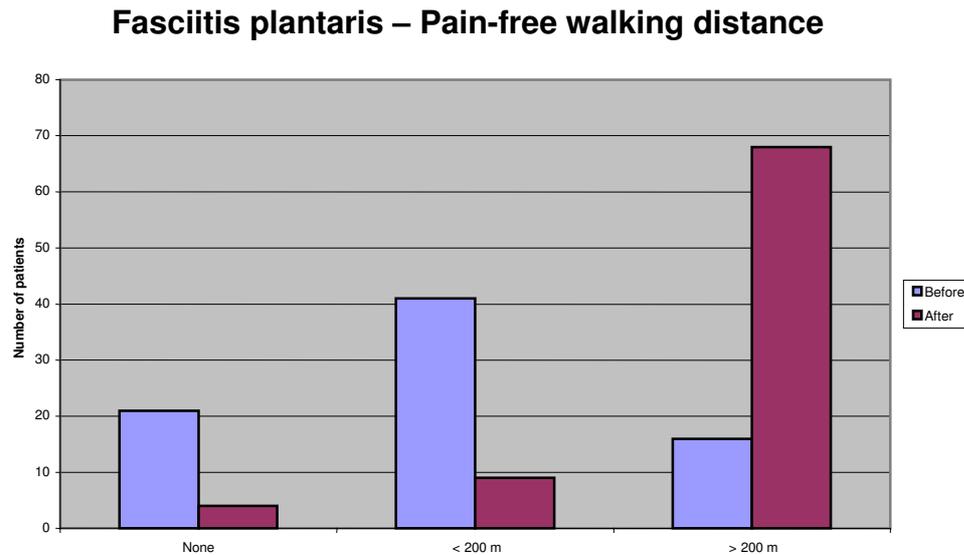


Fig. 3: Pain-free walking distance

82% of the patients used insoles at least part of the time. Beyond that, only 15% had undertaken ongoing conservative treatments in the form of physiotherapeutic exercises, for example. At the time of the follow-up examination none of the patients had had surgery on the heel. Moreover, no relevant side effects resulting from ESWT had been encountered by any of the patients.

Epicondylopathia humeri ulnaris (EHU)

During the past three years we have administered ESWT treatments to only four patients with EHU. It was not possible to conduct follow-up examinations for these patients in the framework of this study.

However, neither did any relevant side effects of the therapy occur in this group of patients.

Epicondylopathia humeri radialis (EHR)

Among those patients suffering from epicondylopathia humeri radialis and re-examined in the course of the present study, there was a significant reduction of tenderness and stress-induced pain.

Epicondylopathia humeri radialis – Pain at rest

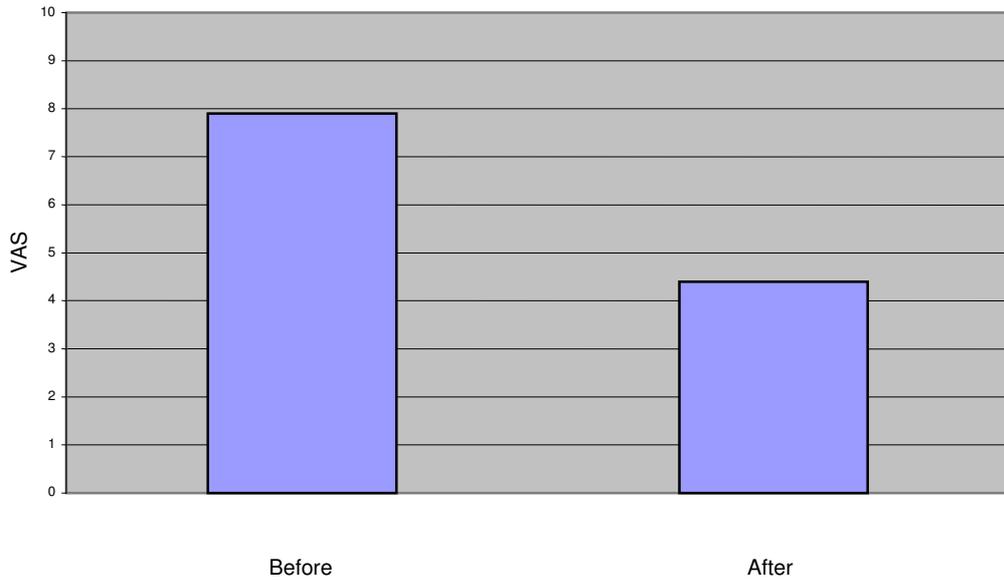


Fig. 4: Pain at rest

Epicondylopathia humeri radialis – Stress-induced pain

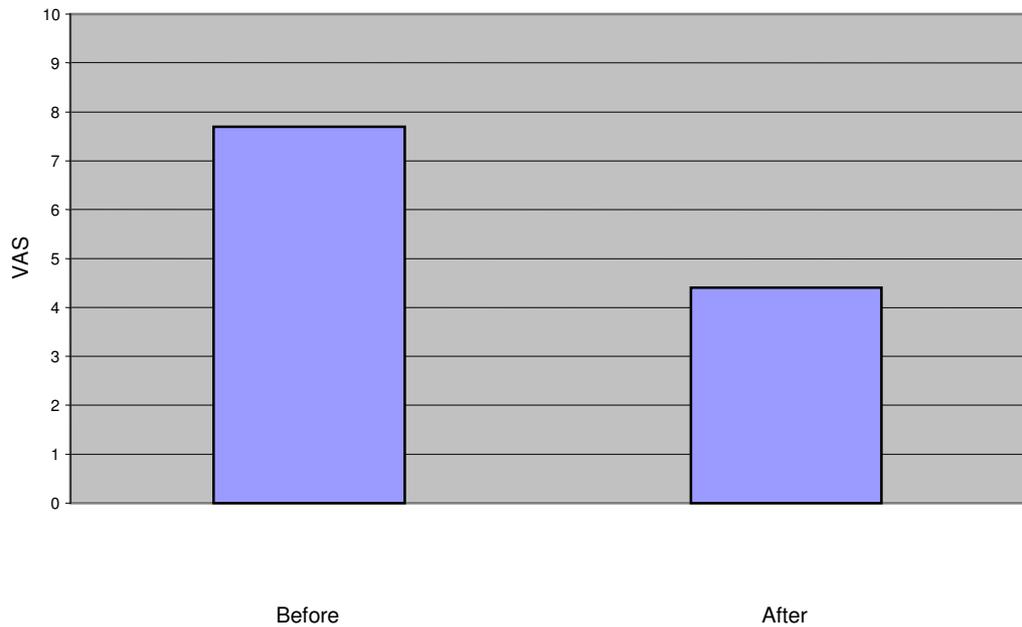


Fig. 5: Stress-induced pain

In this group of patients the pain sensed under loading or stress declined only by 1.9 points on the VAS, from 4.4 to 2.5.

In the current inquiry 72% of the patients stated that they were very satisfied with the therapy, while 17% found the therapy satisfactory one year after ESWT. Only one patient was dissatisfied with the therapy at this point in time.

Additional therapy was carried out for 25% of the patients. These were conservative measures in all cases and in the main physiotherapeutic treatments. The exercises which we had taught the patients, to be done at home, were carried out by 65% of the patients with greater or lesser regularity. None of the patients had to date had surgery on the elbow. Additionally, none of the patients encountered relevant side effects following ESWT.

46 of 56 patients were able to pursue athletic activities at a level equivalent to that prior to the onset of the illness.

Tendinosis calcarea

Of the 35 patients exhibiting tendinosis calcarea at the shoulder and who could be included in the follow-up examination, five patients indicated that, subsequent to ESWT, they had undergone surgical removal of the calcific deposit. These were counted as unsatisfied patients in the subjective evaluation. Over and above that, two patients indicated that they were not satisfied with the therapy. Three further patients were only "satisfied" with the therapy while 71% of the patients were very satisfied with the treatment. 28% of the patients indicated that they had continued conservative therapy following ESWT, these being exclusively physiotherapeutic treatments.

As far as pain at rest and under stress, the degree of pain relief which was found in the entire patient population and measured according to the VAS was not significant.

Tendiosis calcarea – Pain at rest

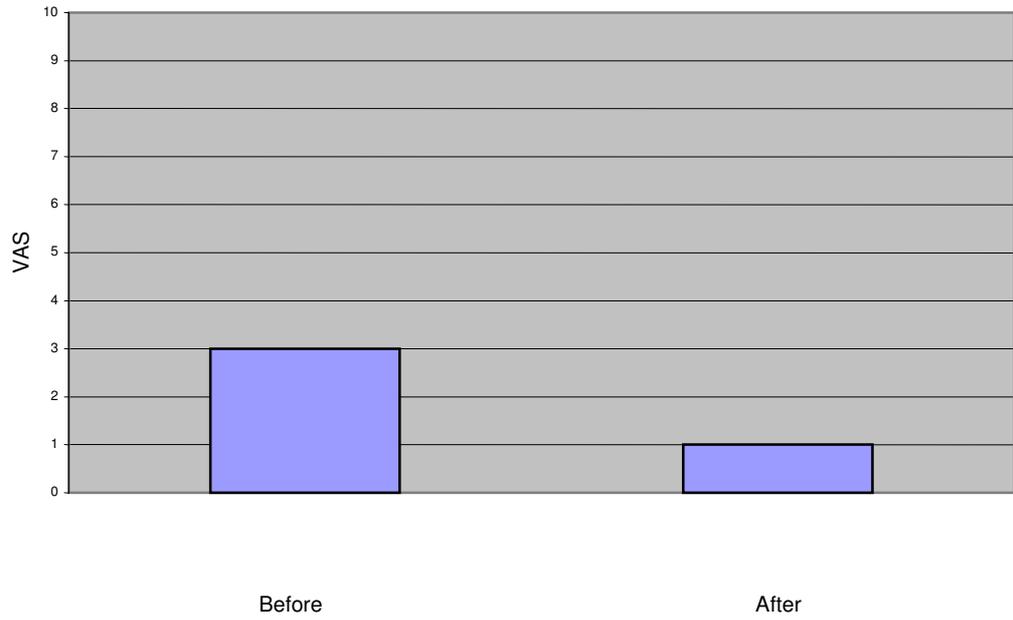


Fig.6: Pain at rest

Tendinosis calcarea – Stress-induced pain

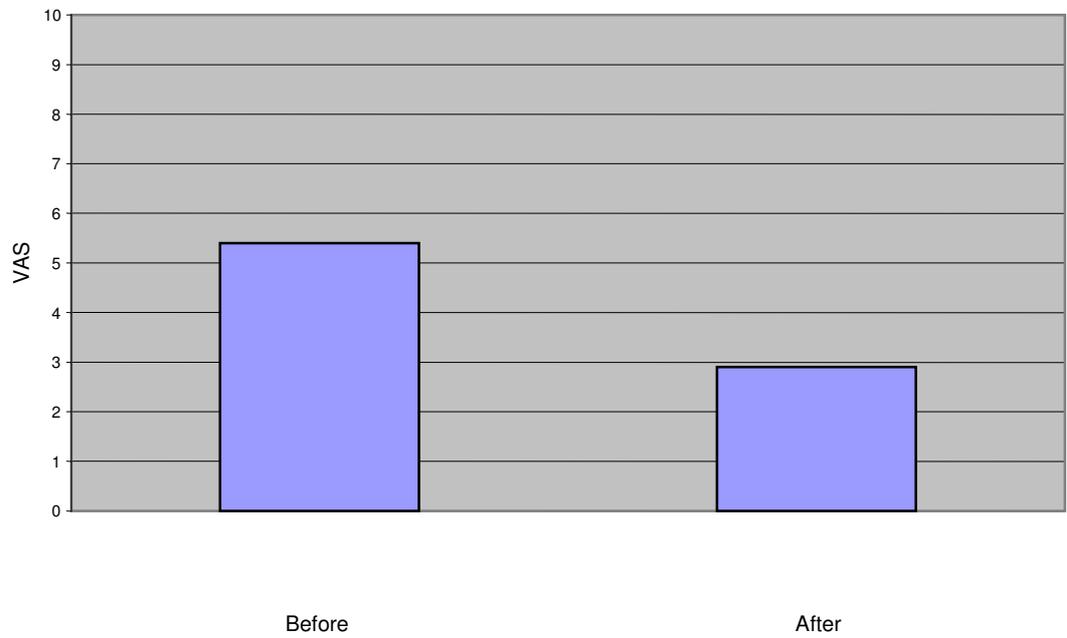


Fig. 7: Stress-induced pain

Our follow-up examination revealed that 78% of the patients had once again attained a level of athletic activity corresponding to that prior to the onset of the affliction.

In two of 35 patients there was localized reddening at the ESWT application point, persisting for a maximum of seven days but, however, subsiding without consequences and without further therapy. Beyond that there were no relevant side effects.

Pseudarthrosis

In 11 of 15 patients, examined five months after therapy on average, it was possible to discern bony bridge-over within the fracture line, both in the a.p. direction and in lateral X-rays and/or in the tomographic images which were taken. In four cases we could not discern any increasing knitting at the pseudarthritic cleft. We will take a closer look at these cases in the closing discussion. In none of the cases treated were there either local or systemic side effects. We could not, within the re-examination period, find any change in the in situ implants among those patients who had received osteosynthetic treatments.

Discussion

The efficacy of ESWT in treating fasciitis plantaris and epicondylopathia humeri radialis could be demonstrated in the present study. Right from the beginnings of ESWT for the locomotion system, the treatment of pseudoarthrosis by way of ESWT was among the standard indications recognized by DIGEST.

Due to the results now available and the very rare occurrence of side effects in our patient population, we recommend employing piezoelectric ESWT in the treatment of the DIGEST standard indications.

In the treatment of fasciitis plantaris it was found that our patient population experienced a significant reduction in pain at rest and under stress. These results correspond to current publications in the professional literature. The controlled studies (with placebos) by Ogden in 2001 was among the evidence which brought

about FDA approval of ESWT in the treatment of fasciitis plantaris in the United States.

No significant decrease in pain at rest and under stress could be demonstrated one year after ESWT in the treatment of epicondylopathia humeri radialis. In spite of this, 72% were satisfied with the therapy, reflecting the more open position in the literature. Here, too, the positive effect of therapy could be demonstrated.

In regard to tendinosis calcarea, our examinations were not able to achieve the good results reported for studies which Gerdesmeier carried out in 2002, with placebo control. Since there is a good surgical concept available as an alternate for this syndrome, this in contrast to the other syndromes described, this might explain the larger number of surgical interventions subsequent to ESWT.

Only studies without control groups are reported in the literature covering ESWT treatment of pseudarthrosis. These describe a success rate, with bony closure of the pseudarthrosis, for an average of 75% of all cases. Right from the implementation of ESWT for the locomotion system, the treatment of pseudarthrosis was among the standard indications recognized by DIGEST. The application of extracorporeal shockwaves induces microfracturing in the bony matter and subsequent cell proliferation with consecutive osteostimulation. ESWT is thus to be recommended for a fracture line of less than 5 mm, which was present in all those cases in our follow-up examination where knitting had taken place at the fracture.

Thus we recommend piezo-generated ESWT in treating fasciitis plantaris, epicondylopathia humeri radialis and tendinosis calcarea where pathology is indicated by sonographic examination and following the exhaustion of conservative therapy over at least four months, and in the therapy for pseudarthrosis prior to surgical correction.

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