Original articles: "Der niedergelassene Chirurg, vol. 6,No. 4/2002" G. Haupt, R. Diesch, T. Straub, E. Penninger, T. Frölich, J. Schöll, H, Lohrer, T. Senge



Translation from the German Language

Summary

Plantar fasciitis, often called "heel spur" has a prevalence of more than 0.5 million in Germany alone. Numerous conservative treatments are known. Recently, shockwave treatment has been discussed. In this paper, we present radial shockwave therapy: it reduces the device in size and costs; shockwaves are coupled into the body by direct contact.

103 patients participated in the study and were randomised to verum or sham treatment. Follow-up examinations scheduled 1, 4 and 12 weeks after therapy; therapy could be repeated twice. In all symptom complexes (pain when walking, pain at rest, night-time pain) and in the subjective rating, the verum was slightly superior to the sham treatment.

Radial shockwave therapy enriches the therapeutic options for plantar fasciitis, without causing the high costs of conventional shockwave therapy.

Keywords: heel spur, plantar fasciitis, radial shockwave therapy.

Introduction

The prevalence of plantar fasciitis, or "heel spur", in Germany is between 500,000 700,000. Lateral X-rays in Caucasians showed plantar and/or dorsal heel spurs in 15.7% of people, 11% of whom were affected bilaterally [32]. The incidence rises with age and is comparable on different continents such as Europe, Africa and America [2]. The primary symptom is pain, often in combination with active or passive restriction of motion [3,9,14]. A large number of conservative treatments are described [30,40,41]. Ultrasound [10,37], iontopheresis [16] and low-energy laser [12] achieve only a placebo effect level. Physical therapy, steroid injections and non-steroidal anti-inflammatory drugs are used. Surgery is recommended only when conservative measures have failed [1].

The introduction of extracorporeal shockwaves for the treatment of urolithiasis has revolutionised the treatment of urinary calculi [4,5]. Further applications focus on other calculi such as gallbladder, pancreatic and salivary gland stones Since 1986, we [28,34,35]. have been testing the effect of shockwaves on the healing of wounds and bone fractures in experimental models demonstrated the osteogenetic

potential of shockwaves for the first time [21-23]. This led to the treatment of pseudarthrosis with shockwaves. Finally, in recent years, soft-tissue conditions such as calcareous tendinitis of the shoulder, lateral and medial epicondylitis and plantar fasciitis have increasingly been treated [7,15,31].

In 1996, over 60,000 of these treatments were carried out in Germany, yet the data situation is still unsatisfactory. In addition, it means a considerable economic strain, because devices to generate extracorporeal shockwaves generally cost substantial sums of money.

Shockwaves can also be generated pneumatically (Lithoclast). These, too, were first used in urology (for endoscopic stone crushing). This method is much more affordable. Our own experimental studies of the soft tissues and bones of rabbits and monkeys after treatment with radial shockwaves showed results that match those obtained after treatment with extracorporeally generated shockwaves. Therefore, the shockwaves produced using both principles of generation can be assumed to be comparable. The paper presented here studies the effect of pneumatically generated radial shockwaves in plantar fasciitis.

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Table 1: Demographic data					
		Total	Verum group	Control group	
Age (years)		50.4 +/- 11,7	50,4 +/- 11,3	50,6 +/- 12,3	
Women		77	39	38	
Men		26	16	10	
Right side		49	27	22	
Left side		54	28	26	
History (in months)		24 +/- 27,5	23,7 +/- 27,4	24,6 +/- 28,1	

Materials and methods

The Swiss DolorClast (EMS Electro Medical Systems, Switzerland) consists of a control device and a handpiece, connected by a flexible tube. The device is a development on the Swiss LithoClast, a device for endoscopic stone treatment [27,42]. Animal-experimental findings in rabbits and Macaque

monkeys provided the basis for this development [19].

A control device regulates the metered discharge of technically pure compressed air (filtered for 5 mm) to the handpiece, supplied either by a hospital compressor, if available, or by a separate compressor. In this way, the compressed air pulses are transmitted with variable amplitude to the handpiece; the control device adjusts the constant-

ly compressed air supply at a frequency of 3 Hz before this is transmitted to the handpiece via the connection tubing.

In the handpiece, the compressed air accelerates a projec

tile, which strikes the underside of a metal applicator. The force of the impact of the projectile on the applicator produces a shockwave in this transmitter. The

Table 2: Symptoms and findings (%)					
	Total	Verum group	Control group		
Night-time pain	32,0	36,4	27,1		
Restrictions in daily life	95,1	92,7	97,9		
Restrictions during sport	66,0	74,5	56,3		
Occupational restrictions	52,4	58,2	45,8		
Maximum walking time	0,0	0,0	0,0		
Restricted	57,3	49,1	66,7		
Not restricted	14,6	16,4	12,5		
Pain at the start of sports activity	23,3	27,3	18,8		
Flushing	1,0	0,0	2,1		
Overheating	1,9	0,0	4,2		
Swelling	6,8	3,6	10,4		
Scarring	1,0	1,8	0,0		
Injection sites	1,0	1,8	0,0		
Pes valgus	21,4	20,0	22,9		
Pes varus	35,9	30,9	41,7		
Pes planus	39,8	34,5	45,8		
Pes cavus	2,9	0,0	6,3		

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atraumatic tip of the applicator is positioned at the point of maximum pain, determined by patient biofeedback (see Fig. 1).



Fig. 1: Treatment of plantar fasciitis

Patients

103 consecutive patients with plantar calcaneal tendoperiostitis were studied as part of a mul-

ticentre prospective randomised placebo-controlled study. Only patients with at least a sixmonth history, with at least two different unsuccessful attempts at conservative treatment and with a clear indication for surgery were enrolled.

The exclusion criteria were a poor state of general wellbeing (Karnofsky Index < 70), a specific therapeutic approach during the previous fourteen days, pregnancy, blood-clotting disorders, tumour growth in the region to be treated, and systemic diseases that could be regarded as possible sources of the pain in the differential diagnosis (for example, collagenosis or rheumatic conditions).

The patients were randomised into the verum or control group. Both groups received identical treatment, but in the control group the construction of the de-

vice was modified in such a way that no shockwaves were transmitted. Up to three treatments were carried out with or without local anaesthesia. Follow-up examinations were carried out after one, four, twelve and fiftytwo weeks.

In patients in the control group, if symptoms persisted after four weeks, the code was broken and they were allowed to change over to the treatment group.

The record forms were completed by the treating orthopaedic or general surgeons in question and entered anonymously into the computer (dbase) at the study centre, and then analysed with the aid of SPSS.

Results

55 patients were randomised to the verum group and 48 to the control group. Demographic data (cf Table 1) as well as the symptoms and admission data (cf Table 2) were comparable in the verum and control groups.

The treatments were carried out at an initial pressure of 4 bar with 2,000 shockwaves. Local anaesthesia was required in five patients (9%) in the verum group and three patients (6%) in the control group. In the immediate post-operative period, local symptoms were observed (cf Table 2), all of which had disap Follow-up examinations were carried out in 84 patients after

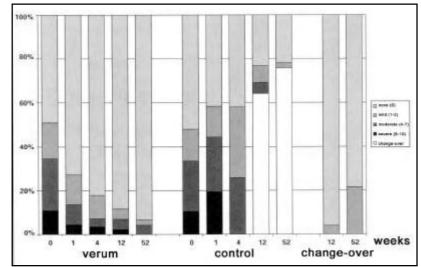


Fig. 2: Night-time pain

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100%
60%
40%
20%
0 1 4 12 52 0 1 4 12 52 12 52 weeks
verum control change-over

Fig. 3: Pain at rest

52 weeks. Night-time pain, pain at rest and pain when walking improved significantly in the treatment group (see Figs. 2, 3 and 4). An increasing improvement over the entire follow-up period was noticed. In the con-

trol group, no substantial change was noticeable between the baseline and the follow-up examinations. Patients who dropped out of the control group after four weeks due to the persistence of symptoms and were

100%
80%
40%
40%
20%
0 1 4 12 52 0 1 4 12 52 12 52 weeks
verum control change-over

Fig. 4: Pain at walking

then given the real treatment achieved results akin to those obtained by the patients in the primary treatment group.

Restrictions of walking time and in daily life were persistent in 36 and 34 per cent respectively in the verum group, with 52 and 50 per cent for sport and occupation respectively, although the extent of the restriction had decreased significantly. The comparative values in the control group were all over 70 per cent.

When asked after one week, the vast majority of patients said that they would have the treatment again. This was unchanged in the verum group. In the control group, this figure fell after four weeks and again after twelve weeks (see Fig. 6). This correlates with patient satisfaction: after twelve weeks, over 90 per cent of patients noticed an improvement, and over 60 per cent were entirely satisfied. This was true of only ten per cent in the control group (see Fig. 7).

Discussion

In the last 30 years, the influence of many physical factors on the healing processes of bones and soft tissues has been studied. The use of extracorporeal shockwaves in the treatment of urolithiasis brought a

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100%
80%
60%
40%
20%
0 1 4 12 52 0 1 4 12 52 12 52 weeks
verum control change-over

Fig. 5: Agreement to further treatment

new physical medium into medicine [4,5].

With shockwaves, effects can be achieved in the body without the use of a scalpel. It became a natural progression to use extracorporeal shockwaves in the treatment of other intracorporeal concrements, too.

From 1985 onwards, gallbladder, pancreatic and salivary gland calculi were treated with shockwaves [28,34,35]. Common to all of these therapeutic

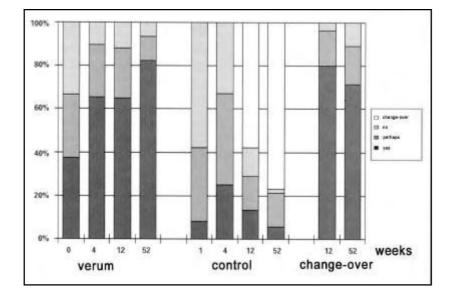


Fig. 6: Agreement to further treatment

approaches is shockwave-generated destruction.

Shockwaves were first used in 1986 to stimulate healing processes instead of to destroy stones. Low shockwave dosages showed a stimulating high but inhibitory effect on the healing of superficial skin wounds in the pig [20]. An osteoneogenetic effect of shockwaves was also demonstrated. and led to the use of shockwaves in the treatment of pseudarthrosis . [11, 15, 17, 18, 22, 24, 25, 36, 38, 39].

In plantar fasciitis, hardly any conservative and surgical procedures have been the subject of multicentre controlled studies. Therefore, it is difficult to assess their value. However, conservative treatment should certainly be attempted first. The patient population presented here had undergone a minimum of two conservative therapeutic attempts and had at least a 6month history of the condition, i.e. it was a negative selection. Shockwave therapy planned in place of surgical treatment.

The side effects of radial therapy are equivalent to those of conventional extracorporeal shockwave therapy with transient pain, petechial bleeding or subcutaneous haematoma in up to four per cent [26]. However, local symptoms are much more common with radial therapy.

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This is attributable to the lower penetration area of the energy. After one week, no side effects whatsoever were evident any longer, and none of the patients developed neurological disturbances. Therefore, local irritation does not appear to be of lasting clinical significance.

The subjective success rates with conventional extracorporeal shockwave therapy are quoted as 50 to 75 per cent [6,8,29,33]. Radial shockwave therapy achieves success rates in the same range or even slightly above. A placebo effect can be ruled out by comparison with the control group.

The essential difference between this and conventional shockwave therapy lies in the minimisation of the amount of equipment required and the clear reduction in associated costs. Both forms of shockwave therapy also do not interfere with future surgery, if required, in non-responders.

The use of shockwaves in orthopaedics is controversial. The lack of studies is the main focus for criticism [13]. For this reason – and out of fear of a dramatic increase in treatment figures – the statutory health-insurance funds have so far refused to reimburse treatment costs, even though the data on competing conservative and surgical procedures is no clear-

er. Yet, the few prospective randomised studies of shockwave therapy in orthopaedics that do exist prove the effectiveness of this treatment in plantar fasciitis.

Radial shockwave therapy allows costs to be reduced, while providing at least equivalent effectiveness. This makes this therapy attractive compared with conservative and particularly surgical procedures, from the perspective of both patients and costs.

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