Comparison of conventional extracorporeal shock wave therapy and the new method of radial shock wave therapy in the treatment of calcaneal spurs

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Summary

In the 1980s extracorporeal shock waves were first used for the treatment of urolithiasis. Over the past few years extracorporeal shock wave therapy (ESWT) was introduced for the treatment of various orthopedic diseases including calcaneal spurs. The treatment proved to be an efficient alternative to surgery. However, a major drawback is availability and costs of extracorporeal shock wave machines. We developed a new device for treatment with radial shock waves and compared it to extracorporeal shock wave therapy.

50 consecutive patients were treated with the new device in 4 centers. Only patients with a minimum history of 6 months, at least two different unsuccessful conservative treatment approaches and clear indication for open surgery were included. History and results of the physical examination were recorded in detail. One to three treatments were performed without or in local anesthesia. Reexamination were scheduled after 1, 4 and 12 weeks, respectively, and included detailed physical examination and sorrow subjective scaling. These patients were cross-matched with 50 patients who had been treated with extracorporeal shock waves earlier.

Both the conventional as well as the new radial extracorporeal shock wave therapy yielded good clinical results. The success rates, defined as „good“ or „intermediate“ results and thus avoiding surgery was 80 and 82 % for the conventional and the new approach, respectively.

The new device for radial shock wave therapy is a successful alternative to open surgery as well as extracorporeal shock wave therapy. We developed a new therapy which seems equiefficient to other therapies, is non-invasive and economically very competitive.

Introduction

The introduction of extracorporeal shock waves for the treatment of urolithiasis revolutionized urinary stone therapy.[1, 2] Further applications were on other stones within the body such as gall bladder, pancreas and salivary gland stones.[3-5] We tested the effect on shock waves on wound and fracture healing in experimental models since 1986 and proved for the first time the osteogenetic potential of shock waves.[6-8] Knowing about the osteogenetic potential of shock waves we tested their effect in the treatment of pseudarthrosis.

In addition, since 1993 we treated tendinosis calcarea of the shoulder and plantar calcaneal spur based on shock wave effects on soft tissue described by others.[9-11].

Material and Methods

Shock wave treatment with pneumatically generated radial shock waves (Swiss DolorClast®)

The Swiss DolorClast® (EMS Electro Medical Systems, Switzerland) comprises a control unit and a handpiece which are connected via a flexible tube. The compressed air, which is drawn either form the hospital supply or from a separate compressor, is regulated in the control unit. In this way compressed air pulses of variable amplitude can be transferred to the handpiece; the control unit modulates the continuous compressed air supply at a frequency of 3 Hz before transfer to the handpiece via the connection tube.

Within the handpiece, the compressed air accelerates a projectile which strikes the base of a metal applicator. The force of the impact of the projectile on the applicator induces a shock wave in the latter. The tip of the applicator is positioned at the maximum point of pain using biofeedback.

Here 50 consecutive patients with treatments of calcaneal spurs were evaluated which are part of a multicentric, prospective, randomized, placebo-controlled study. Only patients with a minimum history of 6 months, at least two different unsuccessful conservative treatment approaches and clear indication for open surgery were included. History and physical examination were recorded in detail. One to three treatments were performed without or in local anesthesia. Reexamination were scheduled after 1, 4 and 12 weeks, respectively, with detailed physical examination and sorrow subjective scaling.

Exclusion criteria were a poor general level of health (Karnofsky index < 70), specific therapy during the last fourteen days, pregnancy, blood coagulation disorders, tumour growth when the region to be treated is affected, and systemic diseases which may be considered in differential diagnosis as possible causes of pain (e.g. collagenosis, rheumatic diseases).

These patients were cross-matched with 50 patients who had been previously treated with conventional extracorporeal shock waves.

Extracorporeal shock wave treatments

50 patients with plantar calcaneal spur had been treated earlier with extracorporeal shock waves. All patients suffered from pain with and without activity. Follow up was conducted with a patient questionnaire including a visual analogue scale for pain and activity of daily life.

General contraindications were blood coagulation disorders, pregnancy and tumour related pain.

Shock wave treatments were performed with 800 to 1000 shock waves at up to 0.20 mJ/mm^2. For shock wave generation an Ossatron (HMT, Switzerland), an MFL 5000 (Philips, Germany) or an Compact S (Dornier, Germany) were used. An integrated expandable water cushion with synthetic membrane was used for coupling in all machines. Positioning of the area of interest in the focus was x-ray guided with a C-arm.

Results

Both patients groups correlated well. Key demographic data are listed in Table 1. Only pain history was longer in the extracorporeal group; these patients had a health insurance dependent waiting time, while this was not the case in the radial ESWT study group.

Table 1: demographics

Parameter	Radial ESWT group	Conventional ESWT group
age (years)	50.4 ± 11.3	49.8 ± 13.4
sex		
female	36	34
male	14	16
location		
left	25	23
right	25	27
time of pain history (months)	23.7 ± 27.4	39.0 ± 26.5

A comparison of the symptomatology shows good homogeneity between both treatment groups (Table 2).

Table 2: symptomatology (%)

	Radial ESWT group	Conventional ESWT group
pain induced awakening	40	38
limitation in daily life	100	100
limitation in sport activities	78	74
limitation in professional activities	62	64
maximum walking time		
limited	50	54
unlimited	16	20
initial pain	28	24

The number as well as intensity of the extracorporeal shock wave treatment was initially determined empirically. Since their is no experience with the new treatment modality parameters were chosen arbitrarily and set down for this study. Treatment parameters are otherwise comparable between both groups with the exception of the use of local anesthesia (Table 3).

Table 3: treatment parameters

Parameter	**Radial ESWT group**	**Conventional ESWT group**
no. of shock waves	2000	800 - 1000
Anesthesia (%)		
None	90	18
Local	10	82
location (%)		
Left	50	46
Right	50	54
no. of treatments	1.9	1.8

After shock wave treatment no persisting clinically relevant side effects were seen in either group. In both groups irritation of the skin was seen in the majority of patients. Hematomas were observed in 3 patients after radial and in 8 after conventional extracorporeal shock wave therapy. Subjective pain classification after therapy was lower in the radial ESWT group.

Treatment success was evaluated in detail for the radial ESWT group after 1, 4 and 12 weeks (e.g. table 4, table 5) . However, only a patient questionnaire is available for the historical group of the conventional extracorporeal shock wave therapy after 12 weeks.

Table 4: night pain levels at examination (%) in the radial ESWT group

	none (0)	light (1-3)	Medium (4-7)	Heavy (8-10)
Before treatment	50	16	24	10
after 4 weeks	80	10	3	7
after 12 weeks	90	5	3	3

Table 5: pain without activity levels at examination (%) in the radial ESWT group

	none (0)	light (1-3)	Medium (4-7)	heavy (8-10)
Before treamtent	26	28	38	8
after 4 weeks	45	31	21	3
after 12 weeks	67	26	8	0

The mean overall success rate („completely satisfied" and „satisfied") for the radial ESWT group was 80 % and increasing with time (up to 94 % after 12 weeks). For the conventional ESWT group satisfaction rate was 82 % after 12 weeks (Table 6).

Table 6: patient satisfaction

	Radial ESWT group	Conventional ESWT group
Completely satisfied	78	66
Satisfied	16	16
not satisfied	6	18

No patient of the radial ESWT group would deny a repetition of the treatment (data for the conventional ESWT group is not available).

Discussion

Shock wave effects on bony tissue were investigated by Graff as early as 1986, when studying side effects of shock waves on tissue interposing shock waves during the treatment of ureteral and renal stones. He performed transmission measurements in vitro as well as treatments in vivo in pigs, rabbits and beagle dogs. While bleeding and necrosis as in a blunt trauma were seen at 48 hours, later an aseptic bone marrow necrosis and osteocyte damage as well as osteoneogenesis were observed. This represented the physiology of fracture healing without preexisting fracture.[9, 12-14] At the same time we studied the effect of shock waves on fractured healing and saw also osteoneogenesis thus stimulating fracture healing by shock waves.[6, 8] In a standardized fracture model this effect was verified.[15-18] Johannes found similar results.[19] In a pseudarthrosis model healing was enhanced by shock waves.[20] Other experiments using lower energies, however, did not demonstrate shock wave induced osteoneogenesis.[21, 22].

First clinical data on the treatment of pseudarthrosis with shock waves were reported by Valchanov.[23] 70 of 82 treatments have been reported as successful, however specification of patients, treatment and follow up are incomplete.[24] Bürger found only 35 % healing and 21 % callus formation in 37 patients.[25-29] In the same group Haist reported the importance of the pseudarthrosis type: while all patients with hypertrophic pseudarthrosis reached complete healing after shock wave therapy only 3 of 13 patients with atrophic pseudarthrosis had sufficient results.[30] Schleberger postulated stabilisation of the pseudarthrosis after shock wave treatment providing only axial pressure on the pseudarthrosis and achieved a treatment success in 41 of 45 patients.[31, 32] He recommended orthesis, but osteosynthetic material can be used, too, without compromising safety or success.[33, 34]. Our own data is the largest series of pseudarthrosis treated by extracorporeal shock waves with good success rates.

Soft tissue treatments (as for calcaneal spur) are subject of discussion. Energy densities vary.[35-38] We used higher energy levels in the extracorporeal group, which significantly reduced retreatment rate. Thus one might speculate that the treatment success correlates with a certain amount of energy used, which can be done in few treatments at a higher energy density or in more treatments at lower energy density. In our hands the higher energy density approach revealed stable succes rates for up to 4 years.

With the Swiss DolorClast® (pneumatically generated, radial extracorporeal shock waves) treatment results are comparable to our conventional extracorporeal experience. Although follow-up here presented is only 12 weeks, the first patients have reached the one year follow up and still keep the success rates of the conventional extracorporeal group.

Thus the new device seems to achieve good and durable results at a lower cost level.

Conclusions

Shock wave therapy for calcaneal spur is effective. It is non invasive and - in case of failure - does not compromise any invasive therapy. It has a low complication rate and can be performed on an ambulatory basis. As compared to the alternative surgical treatment, it is cost effective and has a very high patient acceptance.

The new device for radial extracorporeal shock wave therapy maintains the advantages of conventional extracorporeal shock wave therapy at least; in some clinical parameters it even seems to be superior. Economically, radial shock wave therapy with the Swiss DolorClast® is more cost effective.

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