*Acta Orthop. Belg.*, 2008, **74**, 98-101

*ORIGINAL STUDY*

# Extracorporeal shock-wave therapy (ESWT) with a new-generation pneumatic device in the treatment of heel pain
# A double blind randomised controlled trial

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**Although low-energy extracorporeal shock wave therapy (ESWT) is widely used to treat a variety of soft tissue disorders, no precise algorithm has been accepted in clinical management. Furthermore, the clinical use of a new generation pneumatic device has not yet been evaluated.**

**We performed a double blind randomised controlled trial on a group of 25 patients with heel pain from chronic plantar fasciitis, to assess the efficacy of ESWT. The main outcome measure was the patients' subjective assessment of pain by means of a Visual Analog Scale (VAS) and the Roles and Maudsley Score before ESWT, early after treatment and six months later.**

**There appeared to be a significant placebo effect with low-energy ESWT in patients with heel pain, and there was also lack of evidence for the efficacy of ESWT when compared to sham therapy.**

**Keywords** : extracorporeal shock wave therapy (ESWT) ; chronic plantar fasciitis ; visual analog scale (VAS) ; Roles and Maudsley Score.

## INTRODUCTION

Extracorporeal shock wave therapy (ESWT) is a well-known method which was first introduced in the treatment of renal calculi about three decades ago (*2*). ESWT was subsequently also used in the treatment of delayed bone union and nonunion (*2*). It has now become an alternative method in the management of some soft tissue disorders such as tendonitis of the rotator cuff, tennis elbow, plantar fasciitis and others (*1,3,6,7,9,10*).

A wide application of this method was possible due to the introduction of a new generation of devices. A pneumatic ESWT device has been used in our clinical trial.

Detailed indications, contraindications and technical parameters of ESWT in treatment of soft tissue conditions have not been established yet (*1,3,6, 7,9,10*). The aim of the study was to evaluate, in a double blind randomised controlled trial, the early results with the new ESWT pneumatic device in the treatment of plantar fasciitis by means of a Visual Analog Scale (VAS) and the Roles and Maudsley Score.

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No benefits or funds were received in support of this study

## PATIENTS AND METHODS

Twenty-five adult patients with plantar fasciitis which had been symptomatic for a mean time period of 28.3 months were included in the study. Exclusion criteria were local inflammation or infection, local arthritis, neurological disorder, pregnancy, tumour, presence of a cardiac pacemaker or anticoagulant therapy.

In total 25 patients were included in the study, of which 14 (56.0%) were females. The mean age of the whole group was 51.8 ± 12.5 years. The mean age of male and female patients was respectively 50.2 years (SD = 15.2) and 51.1 years (SD = 8.6).

The placebo group (group 0) included 9 patients (5 females, 4 males), and the treated group (group 1) 16 patients (9 females, 7 males). The mean age in group 0 and group 1 was respectively 51.7±14.3 years (range, 29 to 70) and 51.9 ± 11.9 years (range, 33 to 72). Mean ages in group 1 and group 0 did not differ significantly ($p = 0.89$).

All patients had previously received conservative treatment, without success : 3/9 in group 0 (33.3%) and 13/16 in group 1 (81.2%) had been given medication (mostly NSAID's), most of them twice a day. Twenty four subjects (96%) had been submitted to physiotherapy. Twenty three (92%) had been given corticosteroid injections.

No additional treatment was allowed during the six months observation period.

Subjects were assessed by a blinded observer prior to ESWT sessions.

We used a standardised survey in order to evaluate the patients' status before implementation of ESWT. This survey included : personal data of the patient, medical history, precise anatomical localisation of pain, former treatment and additional diagnostic workup (radiographs, CT, NMR).

Patients were randomly distributed between two groups by drawing of lots and were not informed of the randomisation results.

Extracorporeal shock waves were applied using a new generation pneumatic device (Swiss DolorClast ; EMS, Nyon, Switzerland). Common ultrasound gel was used as a contact medium between the applicator (∅ = 15 mm) and the skin at the point of the most intensive pain. The energy flux density was 0.16 mJ/mm$^2$ (2.5 bar).

All the treated patients (group 1) received 500 shock waves during the first session and 2000 shock waves in two further sessions at 3 days intervals. In group 0, sham therapy was used : the pattern of sessions was the same but the energy flux density was reduced almost to zero.

ESWT was performed by an orthopedic surgeon who was not involved in the selection of the patients and was not aware of the technical parameters of the device (energy flux density to be applied), which were administered before each session by a blinded observer.

Patients were aware of the trial methodology. After being informed of ESWT principles each patient signed a consent form.

All patients completed a visual analog score (VAS) in which 0 mm was no pain and 100 mm the worst imaginable pain before each ESWT session and six months after the last session.

Roles and Maudsley modified scores were also completed before each session and six months after the last session by an independent observer.

The 25 patients completed three ESWT sessions and were evaluated and considered for the statistical analysis of early results.

Fisher's test, Mann-Whitney's test and ANOVA were used for statistical analysis. A level of $p < 0.05$ was accepted as significant.

## RESULTS

There was no significant difference between group 0 and 1 with respect to the duration of symptoms before treatment ($p = 0.36$) (table I).

In group 0, 3/9 patients (33.3 %) had been given medication (mostly NSAID's), most of them twice a day, versus 13/16 (81.2%) in group 1 ; the difference was significant ($p = 0.03$).

A change greater than 50% in the VAS for pain (VAS before trial/VAS after 6 months) was observed respectively in 44.4% (4/9) of patients in the control group and in 56.2% (9/16) in the treated group ; the difference is not significant ($p = 0.44$).

The values of VAS before trial (VAS 1) were not significantly different between group 0 and 1 ($p = 0.75$) (table II).

The changes in Roles and Maudsley score values in the two groups between the early and late assessment after treatment ($p = 0.22$, table III) were not significantly different ; there was also no significant difference between group 0 and group 1 with respect to the VAS changes noted between the early and late assessment ($p = 0.15$) (table IV).

A significant decrease in VAS values was observed in group 0 and 1 between assessments

Table I. — Duration of symptoms in group 0 and 1 (days)

| | N | Days | | | | |
|---|---|---|---|---|---|---|
| | | mean | median | minimum | maximum | SD |
| GROUP 0 | 9 | 21.0 | 24.0 | 1.0 | 48.0 | 16.4 |
| GROUP 1 | 16 | 35.6 | 27.5 | 1.0 | 180.0 | 43.2 |

Table II. — Values of VAS before trial (VAS 1) in group 0 and 1

| | N | mean | median | minimum | maximum | SD |
|---|---|---|---|---|---|---|
| GROUP 0 | 9 | 45.7 | 45.0 | 6.0 | 95.0 | 32.8 |
| GROUP 1 | 16 | 52.2 | 52.0 | 30.0 | 77.0 | 12.9 |

Table III. — Change in Roles and Maudsley scores in group 0 and 1

| | GROUP | Δ -1 | Δ 0 | Δ +1 | Δ +2 | Δ +3 | |
|---|---|---|---|---|---|---|---|
| N | 0 | 0 | 6 | 0 | 3 | 0 | 9 |
| % | | 0.0% | 66.7% | 0.0% | 33.3% | 0.0% | |
| N | 1 | 2 | 5 | 4 | 4 | 1 | 16 |
| % | | 12.5% | 31.2% | 25.0% | 25.0% | 6.2% | |
| N | ∑ | 2 | 11 | 4 | 7 | 1 | 25 |

Table IV. — Change in VAS between assessment at one month and 6 months comparing group 0 and 1

| | N | mean | median | minimum | maximum | SD |
|---|---|---|---|---|---|---|
| GROUP 0 | 9 | -1.78 | -10.00 | -44.00 | 88.00 | 44.42 |
| GROUP 1 | 16 | -28.25 | -31.00 | -68.00 | 10.00 | 26.06 |

after one month and after 6 months assessment ($p < 0.001$) (fig 1).

## DISCUSSION

In a large number of reports describing the role of ESWT in the treatment of soft tissue disorders, the data concerning inclusion criteria, methods of study, parameters of shock-wave as well as instruments used for outcome evaluation have varied considerably. In a majority of studies, electrohydraulic or electromagnetic shock waves generators were used *(7,10)*. Our paper concerns the new generation device which, due to its mobility, may be used on an outpatient clinic basis. The main advantage of this new device is a size of the cap which allows for very precise application of shock wave energy. The point of application was established according to the clinical assessment as the most painful point on palpation. Other authors have presented methods based on radiographs, NMR and CT. As a method of assessment of the treatment, VAS was used because of its wide use, which enables comparison of our results with other studies *(4,5,11)*. The Roles-Maudsley score was also used to increase the level of objectivity of assessment *(8)*.

In our double blind randomized controlled trial, the groups compared were small though very homogenous. The groups differed to a minor extent in terms of conservative treatment given before the trial. Before our trial VAS were statistically comparable in both groups.

We have observed a change in VAS over 50% (VAS before trial/VAS after 6 months) in about 50% of patients in both groups, but there was no significant difference between the two groups.

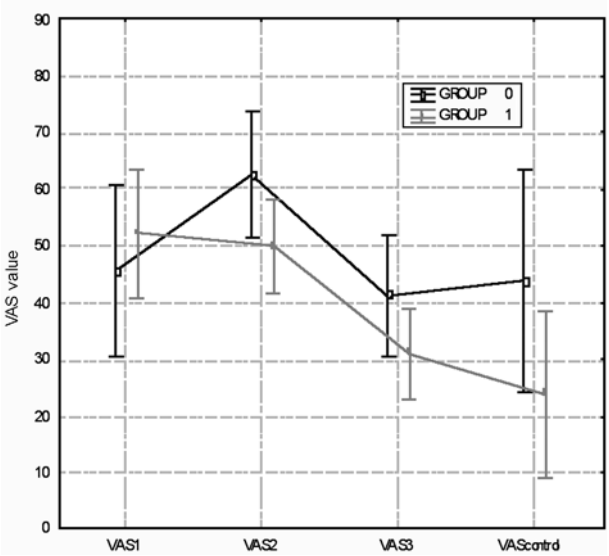


***Fig. 1.*** — Significant decrease in VAS values for pain was observed in group 0 and group 1 between assessments before ESWT application and at 6 months ($p < 0.001$).There was no significant difference between the changes noted in group 0 and 1 (VAS 1 - before first ESWT session, VAS 2 - before second ESWT session, VAS 3 - before third ESWT session, VAS control - at 6 months).

It appears that a placebo effect was the most important independent factor influencing the final result after six months. We observed a significant decrease in VAS values in groups 0 and 1.

## CONCLUSIONS

There appears to be a significant placebo effect with low-energy ESWT in patients with heel pain, and there is also a lack of evidence for its efficacy compared to sham therapy.

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