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An attempt at objective and subjective evaluation of the therapeutic efficacy of focused and radial shockwave applied to symptomatic heel spur

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Purpose: The experiment was designed to evaluate and compare the efficacy of focused shockwave and radial shockwave in symptomatic heel spur treatment. Postural balance tests were used to ensure the objectivity of evaluations. *Methods*: Forty three patients with symptomatic heel spur were divided into two comparative groups that received respectively focused shockwave therapy (the FSWT group; 2000 impulses, 4 Hz, 0.4 mJ/mm^2) and radial shockwave therapy (the RSWT group; 2000 impulses, 8 Hz, 5 bars + 2000 impulses, 8 Hz, 2.5 bars). Each patient received 5 treatments at weekly intervals. Before therapy started and 1, 3, 6 and 12 weeks after it ended, the intensity of pain experienced by the patients was assessed and static balance tests were performed on a force platform. *Results*: Successive measurements showed that the intensity of all kinds of pain under consideration was decreasing gradually and statistically significantly in both groups. The percentage reduction in pain intensity was similar between the groups. The standard deviation of the COP in the anterior-posterior and medial-lateral directions, 95% confidence ellipse area and COP velocity kept varying throughout the experiment, but in none of the groups changes were statistically significant. *Conclusions*: Focused shockwave therapy and radial shockwave therapy improve the well-being of patients with symptomatic heel spur significantly and comparably. Posturography cannot deliver unambiguous data for tracking changes that the two therapies induce in these patients.

Key words: *treatment, ESWT, symptomatic heel spur*

1. Introduction

Spurs are osteophytes protruding from bones into soft tissue that can grow in various sites [1]. The most common type of a spur (the inferior heel spur) develops from the medial process of calcaneus towards the forefoot [18]. Many inferior heel spurs are asymptomatic [18], but patients reporting painful heels are not infrequent [22].

Reports from experiments point to a high probability of a heel spur and plantar fasciitis being concomitant. In one experiment, 17 of 19 patients (89%) had a heel spur as well as plantar fasciitis [12], but the situation should not be regarded as common.

Plantar fasciitis is a degenerative condition of the plantar fascia caused by repetitive injuries to the site of the attachment of the plantar fascia to the medial process of the calcaneus [5] and the most frequent cause of heel plain in adults [21].

Symptomatic heel spur can be managed using different therapies, both conservative and surgical [5]. The wide range of conservative therapies includes focused shockwave therapy and radial shockwave

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therapy, which are different in that focused shockwave allows the greatest value of energy flux density to be achieved at the selected depth inside the pathologically affected tissue, whereas energy carried by radial shockwave is the greatest right under the emitter and declines as it travels through tissues [17].

According to the available reports, extracorporeal shockwave therapy (ESWT) is generally effective in treating symptomatic heel spur. However, standard protocols for focused and radial shockwave therapies have not been developed yet [7], [9]–[11], [15], [16], [20]. Reports comparing their effectiveness are also few.

The effectiveness of heel pain treatment can be evaluated using subjective methods (e.g., VAS [9], [10], [20], Roles' and Maudsley's scoring system [9], [15], and the Foot Function Index [16]) and objective methods, but studies where the latter were used are few [16].

This experiment was designed to evaluate and compare the therapeutic efficacy of focused shockwave and radial shockwave in treating symptomatic heel spur. Posturographic tests were conducted to obtain objective data on the treatment results.

2. Materials and methods

Ethics statement

Ethical approval for the experiment was granted by the Local Research Ethics Committee of the Medical University of Silesia (reference No KNW/0022/KB1/158/10). All participants signed written informed consent forms.

Participants

The participant inclusion criteria were the following: (1) typical tenderness at the site of the attachment of the plantar fascia to the medial process of the calcaneus, (2) pain at the first step in the morning, (3) pain felt in the weight-bearing limb after a period of inactivity during the day, (4) a heel spur of any size shown in an X-ray image or ultrasound scan, and (5) heel pain of at least 3 months in duration.

Patients meeting the following criteria were excluded from the experiment: (1) neurological diseases, (2) nerve entrapment, (3) younger than 18 years of age, (4) pregnancy, (5) general infection, (6) local infection of the lower extremity, (7) a neoplastic disease, (8) skin inflammation of the lower extremity, (9) ulceration of the lower extremity, (10) being on anticoagulants, (11) physical therapy received in the past six weeks, (12) corticosteroid injections received in the past six weeks, (13) diabetes, (14) Reiter's syndrome, (15) gout, (16) ankylosing spondylitis, rheumatoid arthritis or other rheumatoid diseases, (17) unhealed foot injuries, (18) knee joint or ankle joint dysfunction, (19) a pace maker, (20) heart rhythm disorders, (21) inefficiency of the circulatory system, (22) surgical intervention in the foot, (23) pain in both heels.

The approved patients were randomly divided into two comparative groups that received respectively focused shockwave therapy (the FSWT group) and radial shockwave therapy (the RSWT group). The baseline characteristics of patients in both groups are presented in Table 1.

Table 1. The baseline characteristics of patients by group

Demographic details	FSTW $n = 21$	RSWT $n = 22$
Sex (male/female)	10/11	15/7
Age [kg] ($\bar{X} \pm$ SD)	53.05 ± 13.80	52.09 ± 10.84
Height [cm] ($\bar{X} \pm$ SD)	168.8 ± 9.9	173.5 ± 10.1
Body mass [kg] ($\bar{X} \pm$ SD)	79.38 ± 12.02	86.68 ± 17.55
Duration of symptoms in months ($\bar{X} \pm$ SD)	8.9 ± 8.6	8.3 ± 7.0
Affected extremity (right/left)	13/8	14/8

Procedures

Focused shockwave therapy was applied without anaesthesia using a Piezowave device with a piezoelectric head made by Richard Wolf GmbH to patients lying face down on a table. Before treatment commenced, the tenderest point on patient's heel was located by manual palpation. The point was subsequently applied 2000 impulses at a frequency of 4 Hz and energy flux density of 0.4 mJ/mm^2. Each patient in the FSWT group received 5 procedures at weekly intervals.

In the RSWT group, shockwave therapy was applied to patients lying in the same position, also without anaesthesia. In this case, the device was a Gymna-Uniphy's ShockMaster 500 with a pneumatic emitter. The most painful site of the patient's heel was located by manual palpation before treatment. First 2000 pulses (8 Hz, 5 bars) were applied to the identified site and then another 2000 pulses were delivered to the heel and sole of the foot at a pressure reduced to 2.5 bars. Each patient in the RSWT group underwent 5 procedures at weekly intervals.

Measures

Before treatment started and 1, 3, 6 and 12 weeks after it ended, pain intensity was assessed by items from the pain subscale of the Foot Function Index [4] (the worst foot sole pain, pain at the first step in the morning, pain walking barefoot, pain standing barefoot, pain walking with shoes, pain standing with shoes, pain walking with orthotics, pain standing with orthotics, and end-of-day pain) and static balance tests were performed on a force platform.

Pain intensity was assessed with a 0–10 VAS scale where 0 stood for "no pain" and 10 for "the worst pain imaginable".

Posturographic tests were carried out on a standardly configured AccuGait force platform made by AMTI. The data it generated were analysed using the NetForce software package. Prior to the tests, all patients underwent the Romberg and Unterberger tests in order to exclude the presence of any neurological conditions that might bias the tests' results. A posturographic test consisted of six one-minute measurements taken at 30 second intervals. The protocol required participants to stand motionless and relaxed in an upright posture for the length of the test. For the first 3 measurements, participants stood with eyes open and for the next 3 with eyes closed. Statistical analysis was applied to the mean values of the parameters recorded in each set of measurements. Before measurements started, the geometrical centre of the platform and lines dividing it vertically and horizontally into halves were marked on it. The participants were asked to place their right and left foot on respectively the right side and the left side of the platform so that the midpoints of their feet were opposite the geometrical centre of the platform. During the first three measurements, participants were asked to look straight ahead so they could not correct their posture.

In both comparative groups, the following parameters were analysed:

- standard deviation of the COP, separately for the anterior-posterior (SD_{AP}) and medial-lateral (SD_{ML}) planes,
- 95% confidence ellipse area,
- COP velocity (Vel).

Percentage change in pain intensity was calculated using the formula

$$X\,[\%] = \frac{(X_p - X_k)}{X_p} \times 100\,[\%]$$

where

X – percentage change in pain intensity,

X_p – average pain intensity before treatment,

X_k – average pain intensity 12 weeks after treatment.

Statistical analysis

To investigate the distribution homogeneity of patients' characteristics (age, body mass, height, the duration of the condition) and of all selected parameters, the Mann–Whitney U test was used. The distribution of the other characteristics (BMI, gender, right or left limb affected) was analysed with the two-sided Fisher's exact test. The level of statistical significance adopted for all tests was $p \leq 0.05$.

Because most characteristics were found not to have a normal distribution, statistical analysis was based on non-parametric tests.

Changes inside groups were examined using Friedman's ANOVA test and the Bonferroni post-hoc test. Changes between groups were compared using the Mann–Whitney U test. The level of significance in all tests was $p \leq 0.05$.

3. Results

The treatment groups were homogenous regarding the distribution of their baseline characteristics. Successive measurements showed that pain intensity was decreasing gradually and statistically significantly, regardless of whether radial shockwave or focused shockwave was applied. Pain intensity changes in patients walking and standing with orthotics were analysed for 9 individuals in the FSWT group and 9 individuals in the RSWT group, because the other patients did not use orthotics (Table 2). The other kinds of pain were analysed for changes in intensity in all patients. Analysis showed that percentage change in pain intensity was comparable between the two groups (Table 3).

Table 2. VAS for pain in both groups (mean ± SD)

	Baseline	Week 1	Week 3	Week 6	Week 12
1	2	3	4	5	6
The worst pain					
FSWT	7.9 ± 1.9	4.7 ± 2.6**	3.6 ± 2.5**	3.1 ± 2.2**	2.5 ± 2.3**
RSWT	8.4 ± 1.8	5.8 ± 2.7**	4.8 ± 2.3**	4.1 ± 2.4**	2.8 ± 1.9**
Pain at the first step in the morning					
FSWT	6.9 ± 2.7	4.1 ± 3.0**	3.3 ± 2.5**	2.8 ± 2.2**	2.3 ± 2.3**
RSWT	7.1 ± 2.4	4.4 ± 2.5**	3.7 ± 1.9**	2.9 ± 1.6**	1.9 ± 1.5**
Pain walking barefoot					
FSWT	5.4 ± 2.3	3.5 ± 2.3**	3.0 ± 1.8**	2.5 ± 2.0**	1.6 ± 1.7**
RSWT	6.5 ± 2.1	5.3 ± 2.5**	4.1 ± 2.4**	2.8 ± 2.3**	2.1 ± 2.2**
Pain standing barefoot					
FSWT	5.8 ± 2.4	3.2 ± 2.8**	2.5 ± 2.5**	2.0 ± 2.2**	1.7 ± 2.2**
RSWT	4.2 ± 2.3	2.6 ± 2.3**	2.4 ± 2.0**	2.1 ± 2.1**	1.4 ± 1.5**

1	2	3	4	5	6
Pain walking with shoes					
FSWT	6.6 ± 2.5	3.8 ± 3.0**	3.0 ± 2.5**	2.3 ± 2.3**	1.7 ± 2.2**
RSWT	5.2 ± 2.2	3.3 ± 2.0**	2.6 ± 1.7**	2.1 ± 1.5**	1.4 ± 1.3**
Pain standing with shoes					
FSWT	5.8 ± 2.3	3.2 ± 2.8**	2.7 ± 2.5**	2.1 ± 2.2**	1.6 ± 2.0**
RSWT	4.1 ± 2.1	2.6 ± 1.9**	2.1 ± 1.5**	1.9 ± 1.6**	1.3 ± 1.3**
Pain walking with orthotics					
FSWT	4.7 ± 1.9	1.1 ± 0.9**	1.1 ± 0.9**	0.7 ± 0.9**	0.7 ± 0.9**
RSWT	4.2 ± 1.6	2.3 ± 1.4**	2.0 ± 1.0**	1.7 ± 0.9**	1.3 ± 0.7**
Pain standing with orthotics					
FSWT	3.4 ± 1.2	0.8 ± 0.7**	0.7 ± 0.7**	0.6 ± 0.7**	0.6 ± 0.7**
RSWT	2.7 ± 1.2	1.3 ± 1.0*	1.1 ± 0.8**	0.8 ± 0.7**	0.6 ± 0.7**
End-of-day pain					
FSWT	7.4 ± 2.3	4.4 ± 3.0**	3.6 ± 2.6**	3.1 ± 2.5**	2.6 ± 2.7**
RSWT	6.6 ± 2.2	4.4 ± 2.4**	3.7 ± 2.3**	3.2 ± 2.2**	2.2 ± 1.6**

Note: the post-hoc Bonferroni *t*-test against the baseline.
* $p < 0.01$, ** $p < 0.001$.

Table 3. Percentage change in pain intensity in both comparative groups

	FSWT	RSWT	*p*
The worst pain	69.2 ± 26.4	66.3 ± 20.4	>0.05
Pain at the first step in the morning	65.2 ± 30.6	74.2 ± 23.4	>0.05
Pain walking barefoot	71.3 ± 31.9	69.5 ± 26.9	>0.05
Pain standing barefoot	73.6 ± 33.3	59.9 ± 37.0	>0.05
Pain walking with shoes	75.7 ± 30.0	70.4 ± 26.3	>0.05
Pain standing with shoes	74.4 ± 29.4	61.4 ± 33.8	>0.05
Pain walking with orthotics	79.3 ± 28.6	66.2 ± 13.8	>0.05
Pain standing with orthotics	78.7 ± 27.4	81.5 ± 22.7	>0.05
End-of-day pain	65.6 ± 37.8	67.2 ± 21.9	>0.05

The Mann–Whitney U-test.

The standard deviation of the COP (in both planes), 95% confidence ellipse area and COP velocity kept varying over the length of the experiment, but changes were statistically not significant in either the FSWT group or the RSWT group (Tables 4 and 5).

Table. 4. Change of the level of stabilographic parameters in FSWT group

Parameters	Baseline (1)	1 week (2)	3 weeks (3)	6 weeks (4)	12 weeks (5)	$p < 0.05$ between: 1–2 1–3 1–4 1–5 – insignificant change
SD_{AP} [cm] (EO)	0.51 ± 0.21	0.49 ± 0.28	0.47 ± 0.20	0.46 ± 0.16	0.50 ± 0.17	–
SD_{ML} [cm] (EO)	0.33 ± 0.15	0.25 ± 0.08	0.31 ± 0.11	0.26 ± 0.10	0.30 ± 0.11	–
Vel [cm/s] (EO)	1.76 ± 0.49	1.81 ± 0.57	1.80 ± 0.54	1.74 ± 0.45	1.84 ± 0.64	–
95% CEA [cm^2] (EO)	6.25 ± 4.50	4.20 ± 3.13	5.04 ± 3.57	4.35 ± 2.94	4.72 ± 2.26	–
SD_{AP} [cm] (EC)	0.53 ± 0.30	0.51 ± 0.19	0.49 ± 0.18	0.51 ± 0.25	0.52 ± 0.17	–
SD_{ML} [cm] (EC)	0.36 ± 0.21	0.30 ± 0.13	0.32 ± 0.12	0.30 ± 0.11	0.34 ± 0.11	–
Vel [cm/s] (EC)	1.55 ± 0.31	1.57 ± 0.45	1.60 ± 0.37	1.71 ± 0.79	1.68 ± 0.40	–
95% CEA [cm^2] (EC)	6.41 ± 5.47	6.36 ± 8.27	5.61 ± 4.01	5.63 ± 5.24	4.94 ± 2.47	–

Note: the post-hoc Tukey's *t*-test against the baseline. Abbreviations: EO – eyes opened, EC – eyes closed, SD_{AP} – standard deviation of the COP in anterior-posterior plane, SD_{ML} – standard deviation of the COP in medial-lateral plane, Vel – COP velocity, 95% CEA – 95% confidence ellipse area.

Table. 5. Change of the level of stabilographic parameters in RSWT group

Parameters	Baseline (1)	1 week (2)	3 weeks (3)	6 weeks (4)	12 weeks (5)	$p < 0.05$ between: 1–2 1–3 1–4 1–5 – insignificant change
SD_{AP} [cm] (EO)	0.56 ± 0.16	0.56 ± 0.18	0.53 ± 0.19	0.51 ± 0.14	0.49 ± 0.15	–
SD_{ML} [cm] (EO)	0.35 ± 0.13	0.37 ± 0.19	0.33 ± 0.14	0.33 ± 0.14	0.34 ± 0.13	–
Vel [cm/s] (EO)	1.96 ± 0.59	2.02 ± 0.55	1.99 ± 0.47	2.01 ± 0.45	2.10 ± 0.65	–
95% CEA [cm^2] (EO)	6.38 ± 2.98	6.50 ± 3.92	5.48 ± 3.26	5.39 ± 2.91	5.75 ± 3.51	–
SD_{AP} [cm] (EC)	0.57 ± 0.17	0.60 ± 0.20	0.54 ± 0.16	0.52 ± 0.13	0.51 ± 0.14	–
SD_{ML} [cm] (EC)	0.44 ± 0.15	0.46 ± 0.16	0.44 ± 0.22	0.41 ± 0.15	0.38 ± 0.15	–
Vel [cm/s] (EC)	1.73 ± 0.43	1.93 ± 0.82	1.70 ± 0.49	1.67 ± 0.39	1.66 ± 0.38	–
95% CEA [cm^2] (EC)	7.80 ± 4.42	8.80 ± 5.57	6.60 ± 4.75	6.34 ± 3.90	6.51 ± 3.45	–

Note: the post-hoc Tukey's *t*-test against the baseline. Abbreviations: EO – eyes opened, EC – eyes closed, SD_{AP} – standard deviation of the COP in anterior-posterior plane, SD_{ML} – standard deviation of the COP in medial-lateral plane, Vel – COP velocity, 95% CEA – 95% confidence ellipse area.

4. Discussion

The experiment has shown that the effectiveness of both focused shockwave and radial shockwave is good and comparable. In the observation period, the intensity of all kinds of pain was decreasing gradually and statistically significantly in both comparative groups.

Many researchers who chose focused shockwave or radial shockwave to treat patients with heal pain also managed to considerably reduce its intensity. The results in the treatment groups were compared with placebo groups [7], [9], [11], [15] or a conservative therapy group [10], but the effectiveness of the therapy was evaluated using only subjective methods.

Only Lohrer et al. [16] compared the effectiveness of focused shockwave and radial shockwave applied to patients with plantar fasciitis and performed objective tests regularly used in sport science (single leg drop and long jump, single limb posturometry and isokinetic testing), to assess the patients' neuromuscular performance. The results of their experiment pointed to focused shockwave as being more effective for managing heel pain.

The results of our experiment are relatively consistent with the results obtained by van der Vorp et al. [24], who used focused shockwave and radial shockwave to treat patellar tendinopathy and found their effectiveness to be comparable.

COP measurements on a force platform are frequently chosen to assess postural stability in quiet standing in healthy people (young [6], [19] and elderly [2]) and in people with Parkinson's disease [23], injuries [8], etc. There are many parameters with which postural stability can be assessed, among which standard deviation of the COP in the anterior-posterior and medial-lateral planes, COP velocity and 95% confidence ellipse area [6], [14] are commonly preferred.

Because the support base area in humans is very small relative to height, their postural balance can be easily disturbed. In quiet standing, the respiratory movements of the chest, heart beat, blood circulation and other factors cause the centre of body mass on which the stability of the upright posture depends to vary constantly and randomly in the anterior-posterior and medial-lateral planes. Other exogenous and endogenous factors [2], [25] can also affect the values of postural parameters, for instance, heel pain is believed to be likely to affect the COP signal.

In this and other experiments, patients with symptomatic heel spur felt pain while walking or standing. It is possible that a standing patient pain could ease pain in the weight-bearing heel by shifting the COG (Centre of Gravity) towards the forefoot and thereby decreasing load on the heel. This strategy, however, is likely to increase load on the ankle joint and make the posterior lower leg muscles work harder. In this case, posturography would probably show a major change in the sagittal sway and in other posturographic parameters (including COP velocity and 95% confidence ellipse area). Lower pain intensity after treatment should allow the COG to go back towards the heel again and the posterior lower leg muscles to relax, causing a change in the amount of sway. Although post-treatment measurements consistently showed the intensity of all kinds of pain to decrease gradually and statistically significantly, such changes were not observed.

In humans, postural stability in the frontal plane is determined by two-legged stance and relatively limited mobility of the joints of the lower extremities in this direction [13]. Small lateral sway in the frontal plane is also ensured by an appropriately large support base area that depends on the size of the feet and the distance between them. If postural stability of a standing person depended exclusively on the biomechanical factors, it would be the greatest if the body mass were equally distributed between both feet [3]. Persons with heel pain may tend to move their COG towards the painless foot, a likely result of which would be significant change in the amount of sway in the frontal plane and in other posturographic parameters mentioned above. As in the previous case, with pain intensity reduced by treatment, it could be expected that the COG would return to the midpoint of the distance between the feet and that the range of sway would change as a result. None of these changes was observed in the experiment, though.

Perhaps the pain patients felt during quiet standing at different stages of our experiment was not strong enough to activate some of the described mechanisms, or perhaps heel pain does not considerably affect posturographic parameters. It is noteworthy, however, that the mean values of parameters considered were low and comparable with those obtained for healthy people [6].

The results of our experiment were not compared with the results presented by other researchers, because of a failure to find other experiments where posturography was used to evaluate patients with symptomatic heel spur for changes caused by the selected therapy.

According to the results of this experiment, the effectiveness of focused shockwave therapy and radial shockwave therapy in treating symptomatic heel spur is good and comparable. However, posturography failed to generate hard data with which their effectiveness could be verified. Dynamic tests on a force platform would probably provide more information.

5. Conclusions

1. The therapeutic effect of focused shockwave therapy and of radial shockwave therapy applied to patients with symptomatic heel spur is statistically significant and comparable.
2. Posturography cannot generate unambiguous data for tracking changes that the two therapies cause in these patients.

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Conflict of interest

The authors declare that they have no conflict of interest.

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