

# Comparison of Radial Versus Focused Extracorporeal Shock Waves in Plantar Fasciitis Using Functional Measures

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## ABSTRACT

**Background:** Recent literature shows evidence for effective treatment for plantar fasciitis using either focused or radial shock waves. Up to now no research has been available which compares these different procedures. We hypothesized ( $H_0$  Hypothesis) that for plantar fasciitis, outcomes following focused or radial shock wave treatment were equal. **Materials and Methods:** For this pilot study, 39 patients suffering from recalcitrant plantar fasciitis were randomized in two groups. Treatment was performed in three sessions. Once a week 2000 impulses of radial (0.17 mJ/mm<sup>2</sup>) or focused (0.20 mJ/mm<sup>2</sup>) shock waves were applied. Efficacy was determined by multivariate analysis of eight single variables including changes in Foot Functional Index, neuromuscular performance (Single leg drop and long jump, postural stability, isokinetic testing), and by a composite score from baseline to 12 weeks followup. Multivariate Wilcoxon tests (Wei-Lachin procedure) and formal meta-analytic procedure with adjustment for subgroups was performed to determine the adjusted effect sizes with their corresponding confidence intervals. **Results:** The overall result ("Crude Pooling") shows "small" superiority of the focused extracorporeal shock wave therapy (MW = 0.55, LB-CI = 0.4644). Adjusted for age the focused treatment exhibited "more than small" superiority (MW = 0.59, LB-CI > 0.5) and this result is statistically significant (LB-CI = 0.5067, benchmark for equality = 0.5). **Conclusion:** This study provides some evidence for focused extracorporeal shock wave treatment being superior to radial extracorporeal shock wave therapy for recalcitrant plantar fasciitis.

## Level of Evidence: I, Prospective Randomized Study

**Key Words:** Heel Pain; Plantar Fasciitis; Focused Extracorporeal Shock Wave Therapy; ESWT; Radial Extracorporeal Shock Wave Therapy

## INTRODUCTION

Plantar fasciitis is not typically found in athletes and its etiology seems to be multi-factorial.<sup>21</sup> Nevertheless 12.7% of elite runners suffer from it at some time.<sup>18</sup> Elevated body mass index, higher age, reduced ankle dorsiflexion, abnormal foot posture, and tight Achilles tendon are discussed as intrinsic risk factors.<sup>21,28</sup> In the USA, one million patients (3.8 per 1,000 persons) diagnosed with plantar fasciitis visit a physician per year.<sup>29</sup> Irrespective of the method of treatment, 80-90% of the patients become asymptomatic within 10 months.<sup>21</sup>

Stimulated by the work of Graff et al.<sup>13</sup> high energy focused extracorporeal shock waves were introduced in conservative orthopaedics in 1991 as an additional means to induce healing in pseudarthrosis.<sup>35</sup> Application of this technology for treatment of plantar fasciitis was initially reported in 1995.<sup>7</sup> At that time and during the following decade extracorporeal shock wave therapy was performed under local or regional anesthesia and the area to treat was defined to be 0.5 cm to 1 cm in diameter at maximum.<sup>7</sup> This small area of interest was to be located by fluoroscopy or (later) by ultrasound.<sup>9</sup> Meanwhile, biofeedback application has been shown to result in superior outcome.<sup>32</sup> In 2001, radial extracorporeal shock wave therapy was introduced for the treatment of plantar fasciitis.<sup>33</sup> Focused shock wave devices electromagnetically, electropneumatically, or piezoelectrically<sup>9</sup> generate energy which is transmitted to a small region of interest (focus) with the maximum energy level developing some cm subcutaneously. On the other hand radial shock wave devices are pneumatically actuated, develop their maximum energy at the skin surface and distribute it radially into the tissue.<sup>10</sup> An advantage of this method is that an extended volume of tissue can

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The study was funded by Storz Medical AG, Tägerwilten, Switzerland.

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be treated.<sup>24</sup> Thereby the maximum energy is found at the interface between skin and transducer and is reduced in a quadratic function related to penetration depth.

Up to now, evaluation of outcome following extracorporeal shock wave therapy has been performed exclusively by subjective measures like VAS<sup>34</sup> and standardized questionnaires (SF-36<sup>5</sup>, Roles and Maudsley Score<sup>30</sup>). Testing for neuromuscular performance, which is a standard in sport science, has not yet been implemented as a measure for outcome following extracorporeal shock wave therapy. We therefore questioned if there was a difference in efficacy following radial versus focused extracorporeal shock wave therapy for plantar fasciitis.

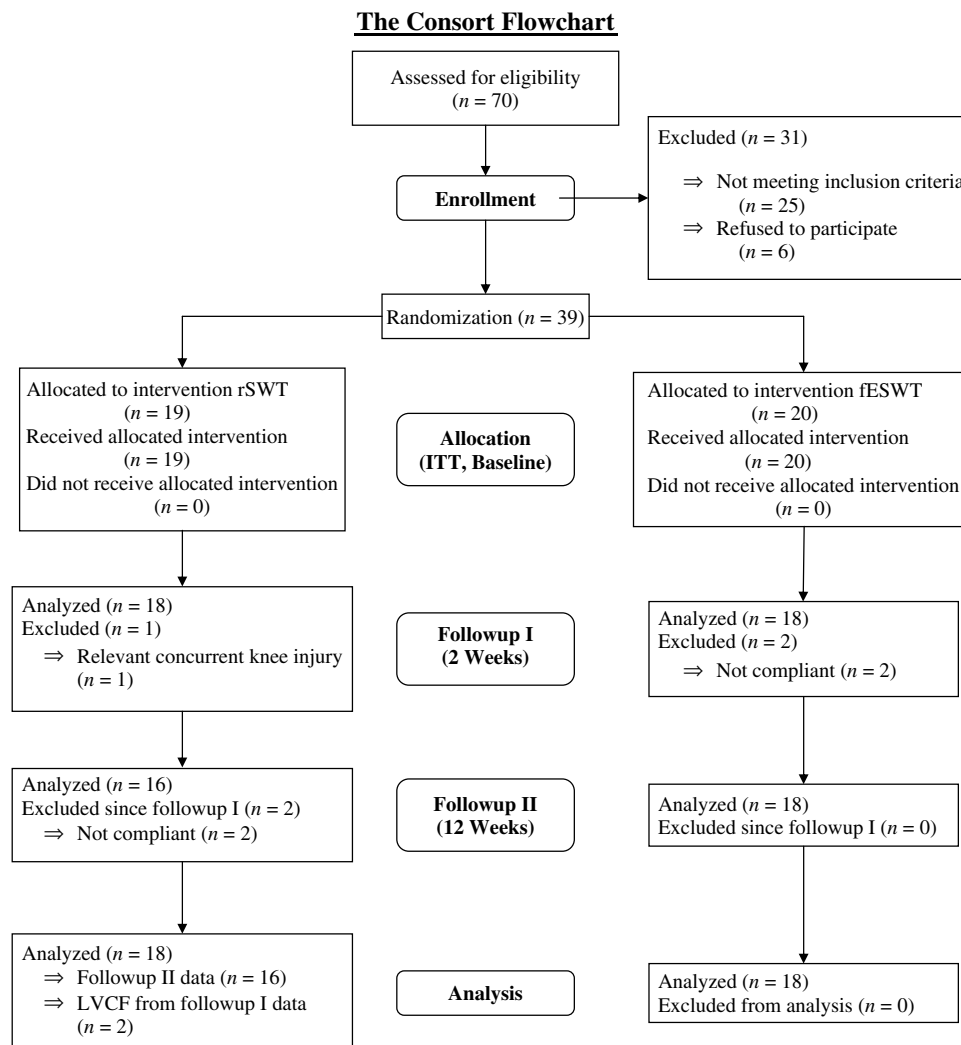
## MATERIALS AND METHODS

This study was approved by the local ethics committee.

In a single center parallel group design, 39 patients were randomized to either radial or focused extracorporeal shock wave therapy. Patients and screening and followup investigators were blinded with respect to the specific treatment group (double blinding). Shock waves were applied by a physician who was not involved in screening or followup evaluation.

### Patients

The study was advertised in the local press. Seventy patients contacted the study center and were consecutively screened (Figure 1). Thirty-nine patients in a “fair” or “poor” condition with respect to the Roles und Maudsley Score<sup>30</sup> were considered eligible for the study. Inclusion and exclusion criteria were evaluated by telephone or during a screening visit (Table 1). Anthropometric baseline data were recorded during the screening visit including age, sex, height, weight, body mass index, shoe size, dominant leg, dominant hand, and radiographic evidence of a heel spur.



**Fig. 1:** Consolidated Standards of Reporting Trials (CONSORT) flow chart for the patients through the study. rESWT, radial extracorporeal shock wave therapy; fESWT, focused extracorporeal shock wave therapy; ITT, Intention-to-Treat Population; LVCF, Last Value Carried Forward; rSWT, radial shock wave therapy.

**Table 1:** Inclusion/Exclusion Patient Criteria**Inclusion criteria**

1. Plantar fasciitis on one side clinically proven by:
  - Typical focal tenderness at the medial plantar fascia origin
  - Typical load dependent plantar pain (VAS for pain >5)
  - Typical “morning pain” (pain on first getting up) elicited by the first few steps
2. History >3 month resistant to conservative treatment by:
  - NSAR
  - Local cortisone injection(s)
  - >Six physiotherapy sessions (local massage, ultrasound, electrotherapy, stretching, tape)
  - Night splint
  - Orthotic shoe inserts
3. Roles and Maudsley Score = 3–4 (26)
4. Heel spur proven or not by radiographs
5. Age >18 years
6. Written informed patient consent following detailed information about the study
7. willingness to refrain from additional treatment interventions during the course of the study (exception: orthotic shoe inserts which were in use for more than 2 months)

**Exclusion criteria**

1. Local and systemic neurologic disorders (including sciatica)
2. Rheumatologic disorders
3. Malignant disease
4. Lower extremity bone disorders (osteomyelitis, Paget)
5. Posttraumatic axial misalignment of the lower extremity (calcaneal fractures)
6. Systemic Cortisone treatment
7. Diabetes mellitus
8. Coagulopathies
9. Pregnancy
10. Bilateral plantar heel pain

Thirty-nine patients were randomized to either focused ( $n = 20$ ) or radial ( $n = 19$ ) shock wave treatment. In the “focused” group the median age was 45.0 (range, 34.0 to 71.0) years, median height was 1.79 (range, 1.60 to 1.90) m, median body weight was 85.0 (range, 60.0 to 115.0) kg, median body mass index was 26.0 (range, 20.3 to 39.10), and median French shoe size was 42 (range, 38 to 44). In the “radial” group the median age was 52 (range, 38 to 68) years, median height was 1.74 (range, 1.57 to 1.88) m, median body weight was 86 (range, 59 to 100) kg, median body mass index was 27.4 (range, 20.4 to 38.10), and average French

shoe size was 41.5 (range, 38.5 to 44.0). Male/female ratio was 12/8 in the “focused” and 11/8 in the “radial” subgroup. The right leg (right hand) was dominant in 12 of 20 (18/20) in the “focused” group and in 14 of 19 (19/19) in the “radial” group. Radiographic evidence for a plantar heel spur was present in 16 of 20 in the “focused” and in 17 of 19 in the “radial” group. The baseline analyses showed more than “small” group differences with regard to age, height and body mass index.

**Treatment**

Shock waves were applied with the Duolith SD1 device (Storz medical, Tägerwilten, Switzerland) providing electromagnetically generated focused or pneumatically driven radial extracorporeal shock waves. Treatment was performed to the point of maximum tenderness over the medial plantar fascia insertion in three sessions via biofeedback, with one week interval. 2000 impulses (frequency = 10 Hz) were applied per session. Energy flux density was 0.20 mJ/mm<sup>2</sup> for patients in the “focused” group while “radial” shock waves were transmitted with 0.17 mJ/mm<sup>2</sup> corresponding to a 3-bar energy level setting.

**Study procedure**

After the screening visit and enrollment a patient could be treated, or had to wait for treatment until the end of the 4 weeks “washout phase” following conservative treatment by local injections (corticosteroid and/or local anesthesia), electrotherapy, ice, heat, massage and antiinflammatory drugs. Stretching and orthotics implemented more than 4 weeks prior were allowed to be continued. Immediately before the initial treatment (baseline) efficacy variables of the study were tested (Foot Functional Index, Single leg drop and long jump, postural stability, isokinetic testing). The treating physician allocated the patient to the “radial” or “focused” group following a computer generated random list (BiAS 8.4, Frankfurt/Main, Germany) and performed the initial treatment. One and 2 weeks later ( $\pm 3$  days), two more treatment sessions were offered, if the patient further suffered from relevant pain. Followup investigations were performed 2 and 12 weeks after the last shock wave treatment repeating the baseline measures.

**Outcome instruments**

Main efficacy outcome of the study was determined by formal meta-analytic pooling procedure of eight single variables, including changes in Foot Functional Index and in neuromuscular performance (Single leg drop and long jump, postural stability, isokinetic testing).

The Foot Function Index (FFI) is a foot specific validated questionnaire, which measures the influence of pain, disability and activity restriction on function.<sup>4</sup> Originally designed to study rheumatoid arthritis patients without fixed foot deformities,<sup>4</sup> reliability was demonstrated also for patients with different foot complaints without systemic

disease.<sup>1</sup> It was already implemented in a previous study for plantar fasciitis.<sup>22</sup> The patient administered questionnaire has been translated in an expert consensus meeting (authors of the study).

We introduced neuromuscular performance tests to objectively evaluate functional outcome after dorsal calcaneocuboid ligament repair.<sup>23</sup> As pain affects function<sup>11</sup> it seemed reasonable to use these functional tools to objectively evaluate neuromuscular performance in the course of the rehabilitation. A specific validation for plantar fasciitis, however, has not yet been performed.

*Single leg drop jumps:* jumping height was calculated from the time interval between single leg take off from a height of 16 cm with the hands fixed to the hips and landing (contact mat, Biovision® Wehrheim, Germany).

*Single leg long jumps:* from single leg stance take off and landing took place on the same foot and the covered distance was measured. Patients initially accommodated to both jumping techniques. The best of three trials for each leg was further analyzed. These tests were validated in subjects with normal and anterior cruciate ligament deficient knees and following anterior cruciate ligament reconstruction.<sup>2,27</sup> In a previous study the reliability of the single-leg drop and long jump as well as ICC  $\geq$  0.95.<sup>23</sup>

*Single limb posturometry:* This test is validated for differentiating between functionally unstable and stable ankles.<sup>19</sup> Involuntarily, the stance plate of a Posturomed® system (Haider Bioswing, Pullenreuth, Germany) was medio-laterally perturbed 25 mm. The patient (upright standing, open eyes, directed straight ahead) was asked to stabilize the system as fast as possible. The path of the center of gravity was recorded for 20 s. The best of three trials of either leg was used for further consideration.

*Isokinetic testing:* To quantify the muscular status of the ankles, isokinetic testing has proven to be reproducible.<sup>16</sup> We used a standard concentric/concentric dorsi-/plantarflexion ankle protocol at 30 degrees/second and 120 degrees/second, respectively (Biodex System 3 PRO, Biodex Medical Systems, New York, NY). Peak torque values were calculated from this data for either ankle.

#### Statistical analyses

Minimizing the required assumptions is a recommended approach for confirmatory statements on efficacy,<sup>20</sup> especially in small sample sizes. Thus, a nonparametric assessment of treatment effects was chosen as the primary analysis method.

The baseline analyses showed more than “small” group differences with regard to age, height and body mass index. While the group differences with regard to height (median 1.79 m versus 1.74 m) and body mass index (median 26.0 versus 27.4) may be regarded as clinically negligible, the (statistically not significant) difference in age of 7 years might be of prognostic value. Thus, special stratified analyses have been performed using the overall median of

the Intention-to-Treat population (ITT) as a cutoff for dichotomization resulting in a “low age” subgroup (less than 50 years) and a “high age” (more than 50 years) subgroup. The statistical analyses were performed using Testimate, version 6.4. Figures have been created using ScienceGraph, version 4.9. Meta-analytic pooling procedures<sup>15</sup> have been performed using MetaSub, version 1.3.6. This software is fully validated according to FDA 21 CFR part 11 (all software by idv, Gauting, Germany). For missing values at the final visit the last value carried forward technique has been applied.

Due to potentially relevant baseline inhomogeneities with regard to age, a formal subgroup pooling was performed by means of formal meta-analysis in order to investigate the adjusted overall effect across subgroups. The effect size analyses were made by applying the Wilcoxon-Mann-Whitney test (univariate and multivariate) which provides the Mann-Whitney estimator (MW).

Statistical significance was determined by the confidence interval approach:<sup>17</sup> if the lower bound of the two-sided 95.0% confidence interval (LB-CI) was lying above the benchmark for equality, statistical significance was shown (LB-CI > 0.5). The relevant benchmarks for the Mann-Whitney estimator (MW) were:<sup>6</sup> 0.29 = large inferiority, 0.36 = medium sized inferiority, 0.44 = small inferiority, 0.50 = equality, 0.56 = small superiority, 0.64 = medium sized superiority, 0.71 = large superiority. MW estimators of 0.36 (or less) or 0.64 (or more) for medium-sized inferiority or superiority, respectively were regarded as clinically relevant (Table 2).<sup>6</sup>

For variables measured on both sides of the body, the intraindividual differences have been used. With regard to Foot Functional Index, the sumscore (comprising pain, disability, and function subscales) has been used. Missing final values have been replaced by last value carried forward technique.

#### RESULTS

In the “focused” group the median FFI was 36.0 at baseline and 11.5 at followup ( $p = 0.0027$ ). In the “radial” group the median FFI was 37.3 at baseline and 14.7 at followup ( $p = 0.0013$ ). Within the neuromuscular performance tests, statistically relevant changes from baseline to followup were found in the “radial” group for the single limb posturometry (median at baseline, 66.2 mm; median at followup, 38.6 mm;  $p = 0.0159$ ), and for the isokinetic plantarflexion testing in 30 degrees/second (median at baseline 44.7 Nm, median at followup 52.5 Nm;  $p = 0.0432$ ). In the “focused” group single limb posturometry improved from baseline (median, 87.7 mm) to followup (median, 44.3 mm;  $p = 0.0814$ ), and the isokinetic plantarflexion testing in 30 degrees/second increased from 43.7 Nm (median) at baseline to 48.7 Nm (median;  $p = 0.1297$ ) at followup.

**Table 2:** Statistical Methods Overview/Explanation

Overview of Statistical Methods	
'Crude' Pooling	<ul style="list-style-type: none"> <li>• Evaluation of all intention-to-treat-analysis patients.</li> </ul>
Wilcoxon-Mann-Whitney test	<ul style="list-style-type: none"> <li>• Group comparisons with regard to each of the eight efficacy criteria (univariate analyses)</li> </ul>
Multivariate, directional Wilcoxon-Test (Wei-Lachin Procedure)	<ul style="list-style-type: none"> <li>• Group comparisons with regard to the combination of all eight efficacy criteria (multivariate analyses)</li> </ul>
Mann-Whitney statistic (MW = Mann - Whitney estimator)	<ul style="list-style-type: none"> <li>• Nonparametric effect size</li> <li>• Relevant benchmarks for effect size (MW) according to Cohen: 0.29 = large inferiority, 0.36 = medium-sized inferiority, 0.44 = small inferiority, <b>0.5 = equality</b>, 0.56 = small superiority, 0.64 = medium-sized superiority, 0.71 = large superiority</li> </ul>
'Subgroup' Pooling (Formal Meta-analytic Approach)	<ul style="list-style-type: none"> <li>• Evaluation as described for "crude pooling", but this time <i>within</i> each subgroup (age below or over 50 years) followed by <i>formal pooling</i> of the subgroup results by meta-analytic procedures (Hedges-Olkin)<sup>15</sup>. The resulting effect sizes are adjusted for baseline differences (age).</li> </ul>
Confidence interval approach for significance (ICH E9) <sup>17</sup>	<ul style="list-style-type: none"> <li>• Statistical significance is shown if the lower bound of the confidence interval is lying above the benchmark for equality (0.50).</li> <li>• Confidence interval: two-sided 95.0%</li> </ul>

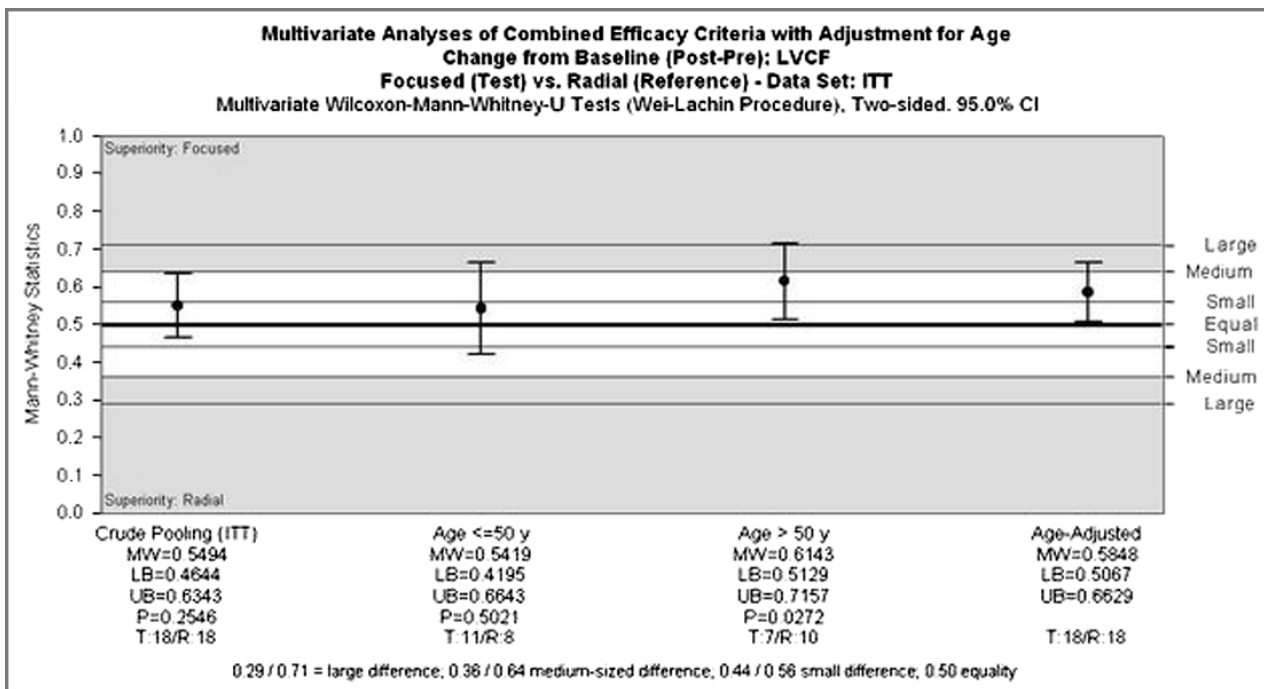
The overall result (crude pooling) in the full intention to treat population (ITT) shows "small" superiority of the focused as compared to the radial shock wave treatment (Figure 2). The result adjusted for age subgroups indicates "more than small" superiority of the focused treatment. The adjusted result with formal meta-analytic pooling was statistically significant (LB-CI = 0.5068, benchmark for equality

= 0.5, confidence interval approach, exploratory interpretation). In addition to the adjusted result there was also statistically significant superiority within the single "high age" subgroup (exploratory interpretation) (Figure 2). With respect to the eight single outcome variables, focused treatment was superior in six out of eight parameters. More than "small" (up to "medium-sized") superiority was shown for the focused technique in four single variables (single leg drop jump, isokinetic testing for plantarflexion at 30 degrees/second, and isokinetic testing for dorsiflexion and plantarflexion at 120 degrees/second). "Medium-sized" superiority for the focused group was found in isokinetic dorsiflexion testing at 120 degrees/second. Focused shock wave group was inferior in isokinetic dorsiflexion testing at 30 degrees/second (MW = 0.48) and for single leg long jump testing (MW = 0.42) (Figure 3).

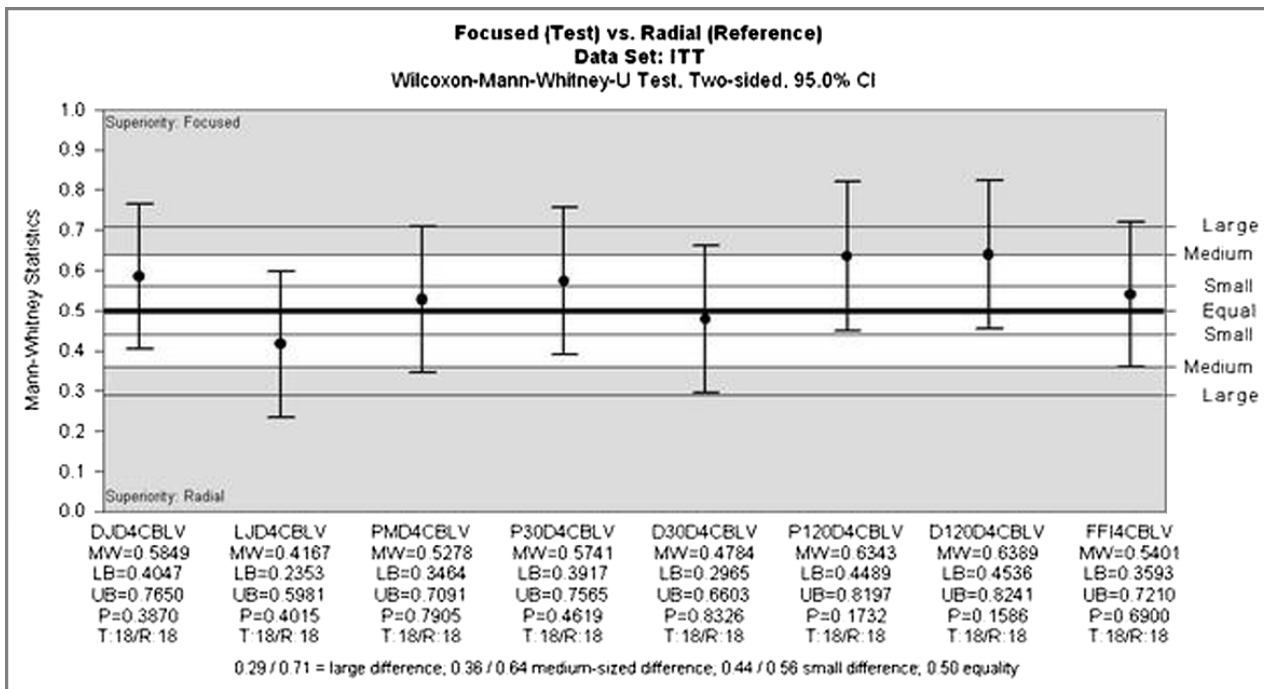
Considering patient's age, five out of eight measures in the "low age" group and seven out of eight variables in the "high age" group were superior for the focused shock wave treatment (Figure 4, A and B).

## DISCUSSION

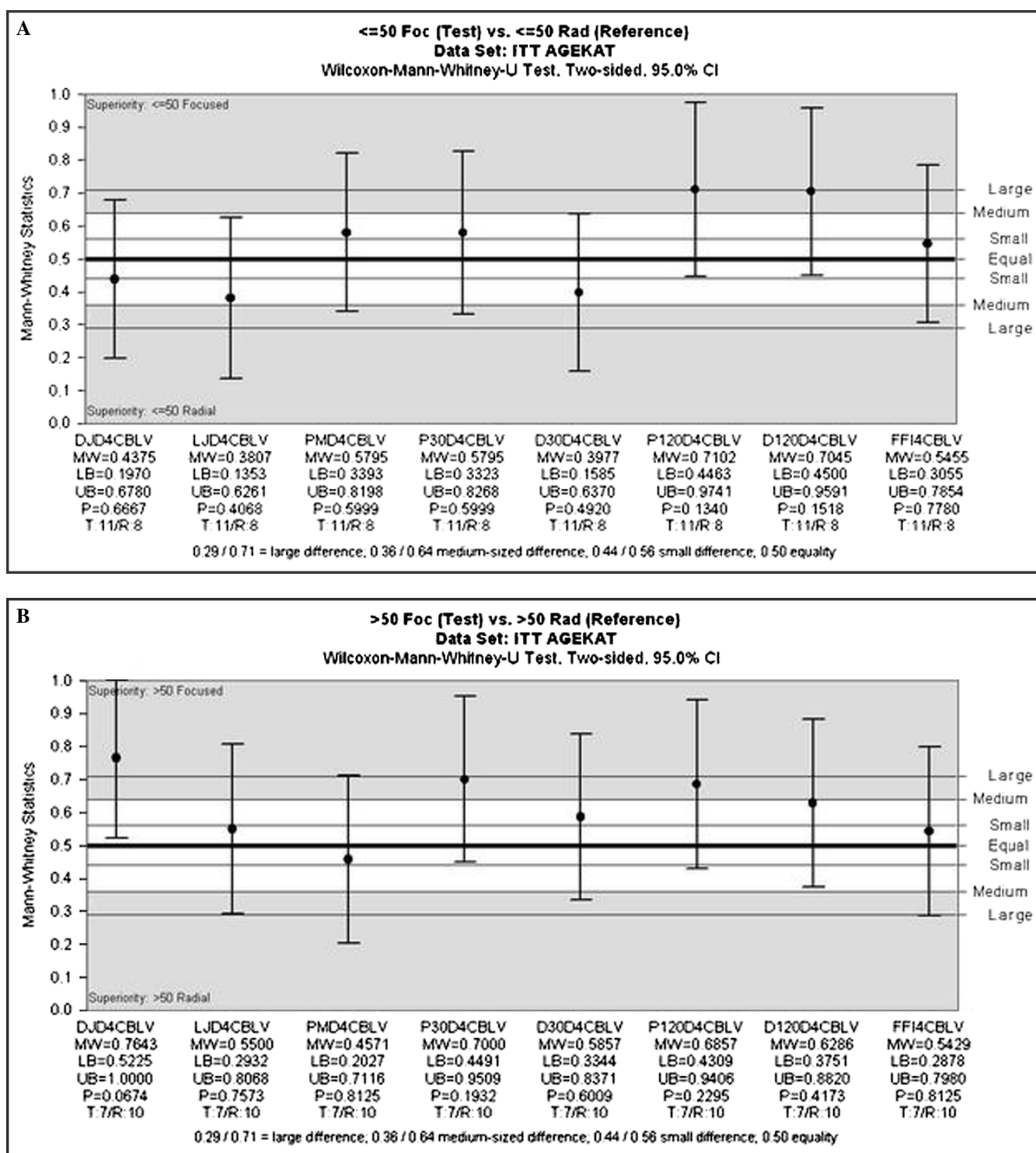
Historically, mainly focused shock waves have been used for treatment of recalcitrant plantar fasciitis.<sup>31</sup> There is only one recent placebo controlled and double blind trial available demonstrating the effect of radial shock waves compared to a placebo treatment.<sup>8</sup> Both methods have not been compared up to now. The device used for the present study integrates a focused and a radial shock wave generation as well. It is marketed not only in Europe, but worldwide and FDA approval (PMA) for the USA is pending. The present pilot study revealed some indication for superiority of the focused extracorporeal shock wave treatment as compared to the radial extracorporeal shock wave treatment. Combining all tested variables, resulted in a superior outcome for the group treated with focused shock waves. After adjustment for age, this overall efficacy was statistically significant for the full ITT population as well as for the "high age" (more than 50 years) subgroup. In a review of the literature, formal meta-analysis could not be performed due to considerable methodological heterogeneity between studies. Nevertheless, these authors concluded that well designed studies were found to be more prone to show favorable results for the respective extracorporeal shock wave treatment groups.<sup>31</sup> Most earlier randomized trials revealed no beneficial effect of extracorporeal shock wave therapy compared to placebo.<sup>3,14</sup> As recently demonstrated, these results were most likely biased by the use of local anesthesia as biofeedback controlled aiming of the shock waves to the most tender area has been shown to improve treatment results.<sup>32</sup> Considering only randomized and double blinded trials, a superior outcome of extracorporeal low energy shock waves on patients suffering from intractable



**Fig. 2:** Final changes from baseline of main efficacy variables (combined evaluation). Results of Multivariate Wilcoxon tests and formal Meta-Analytic pooling procedure with adjustment for subgroups. LVCF, Last Value Carried Forward; ITT, Intention-to-Treat Population; CI, Two-Sided 95% Confidence Interval; MW, Mann-Whitney Estimator (Effect Size Measure); LB, Lower bound of the Two-Sided 95% Confidence Interval; UB, Upper bound of the Two-Sided 95% Confidence Int; P, p value; T, Test subgroup (“focused”); R, Reference subgroup (“radial”).



**Fig. 3:** Final changes from baseline of main efficacy single variables, Results of Exact Wilcoxon-Mann-Whitney tests. ITT, Intention-to-Treat Population; CI, Two-Sided 95% Confidence Interval; MW, Mann-Whitney Estimator (Effect Size Measure); LB, Lower bound of the Two-Sided 95% Confidence Interval; UB, Upper bound of the Two-Sided 95% Confidence Int; P, p value; T, Test subgroup (“focused”); R, Reference subgroup (“radial”). DJD4CBLV = Drop jump change from baseline last value carried forward. LJD4CBLV, Long jump change from baseline last value carried forward. PMD4CBLV, Posturomed change from baseline last value carried forward. P30D4CBLV, Isokinetics Plantarflexion 30 degrees/second change from baseline last value carried forward. D30D4CBLV, Isokinetics Dorsiflexion 30 degrees/second change from baseline last value carried forward. P120D4CBLV, Isokinetics Plantarflexion 120 degrees/second change from baseline last value carried forward. D120D4CBLV, Isokinetics Dorsiflexion 120 degrees/second change from baseline last value carried forward. FFI4CBLV, Foot Functional Index change from baseline last value carried forward.



**Fig. 4:** Final changes from baseline of main efficacy single variables, last value carried forward, Results of Exact Wilcoxon-Mann-Whitney tests. Subgroups “low age” (A) and “high age” (B). Cut off point, 50 years. ITT AGEKAT= Intention-to-Treat Population Categorized for Age Subgroups; CI, Two-Sided 95% Confidence Interval; MW, Mann-Whitney Estimator (Effect Size Measure); LB, Lower bound of the Two-Sided 95% Confidence Interval; UB, Upper bound of the Two-Sided 95% Confidence Int; P, p value; T, Test subgroup (“focused”); R, Reference subgroup (“radial”). DJD4CBLV =Drop jump change from baseline last value carried forward. LJD4CBLV, Long jump change from baseline last value carried forward. PMD4CBLV, Posturomed change from baseline last value carried forward. P30D4CBLV, Isokinetics Plantarflexion 30 degrees/second change from baseline last value carried forward. D30D4CBLV, Isokinetics Dorsiflexion 30 degrees/second change from baseline last value carried forward. P120D4CBLV, Isokinetics Plantarflexion 120 degrees/second change from baseline last value carried forward. D120D4CBLV, Isokinetics Dorsiflexion 120 degrees/second change from baseline last value carried forward. FFI4CBLV, Foot Functional Index change from baseline last value carried forward.

plantar fasciitis as compared to placebo treatment was consistently present.<sup>8,12,22,25</sup>

There is only one randomized controlled trial available in the literature comparing high (0.56 mJ/mm<sup>2</sup>) and low (0.12 mJ/mm<sup>2</sup>) intensity focused extracorporeal shock wave therapy and no difference was present.<sup>22</sup> A reduced pain level however was reported for patients who additionally exercised three times or more per week and received high intensity treatment.<sup>22</sup>

We present the first randomized controlled study comparing the outcome following focused or radial shock wave therapy applied with identical energy flux densities. Some evidence for a better outcome in the focused group has been found even with the small number of patients available in this study and the results further were age dependent.

No generally agreed evaluation instrument exists. The question, which instruments are relevant for baseline and follow up evaluation in extracorporeal shock wave therapy studies, is not adequately addressed in the literature. Outcome measuring instruments in extracorporeal shock wave therapy studies traditionally evaluate the subjective condition of the patients. Most often subjective pain scales like the VAS<sup>34</sup> are used and have been applied extensively in evaluation of extracorporeal shock wave therapy effects.<sup>31</sup> Additionally, attempts have been made to compress the structure under investigation by a specific device which allowed for a standardized pressure. The resulting pain again was judged by the patient on VAS.<sup>24</sup> However, there is no validated disease-specific instrument available for plantar fasciitis even if standardized foot specific questionnaires like the FFI<sup>4,22</sup> and generic tools like the Short Form-36 Health Survey (SF-36)<sup>5</sup> or the Roles and Maudsley Score<sup>30</sup> have rarely been implemented and were combined to measure outcome.<sup>8,14,22</sup> We used the FFI score consisting of a pain scale which is composed of eight specific pain questions (worst foot pain, foot pain 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). One article introduced ultrasound plantar fascia thickness measurement as a means for objective outcome measures. While thinner plantar fascias predicted less pain after treatment, a significant reduction of the mean plantar fascia thickness from 4.6 mm to 4.2 mm ( $p < 0.05$ ) was detected only for the low intensity treatment group.<sup>22</sup> Even if the reliability of the measurements were confirmed, this difference is clinically irrelevant.

Functional testing is recommended and has been validated to assess functional limitations following knee ligament injuries and during the course of the rehabilitation.<sup>2,26,27</sup> This is the first study evaluating extracorporeal shock wave therapy effects relying not only on patient administered subjective data. It seems reasonable that pain limits function of a specific structure or functional unit. Conversely, pain reduction as a consequence of treatment is assumed to

improve performance irrespective of any specific training. Theoretically, the functional neuromuscular capacity of patients suffering from plantar fasciitis is therefore important as well. In this context, we implemented different tests for complex neuromuscular performance using active (isokinetics, single leg long jump) and reactive (single leg drop jump) muscular performance and postural control (posturography). Nevertheless, even these tests are limited by the actual patient's motivation. Establishing combined efficacy criteria resulting from subjective scores and neuromuscular measurements may lead to more robust assessment of the effects of extracorporeal shock wave treatment.

One weakness of the present study is the small number of patients leading to large confidence intervals of the single outcome variables with corresponding imprecision of the univariate results. Also, a group difference with regard to age (7 years) was detected in the baseline investigation. Further analysis showed that subjects older than 50 years had a better outcome. The results additionally may be biased by a "learning curve" from baseline to followup, as our reliability testing was performed with young and healthy subjects active in high level competition sports who are more familiar with these activities.<sup>23</sup> Besides this, further placebo controlled validation and reliability testing with respect to extracorporeal shock wave therapy and specific pathologies has to be performed not only for the presented functional tests but also for all previously applied instruments like VAS. The obtained results should be confirmed by further clinical studies with larger patient numbers.

## CONCLUSION

Focused extracorporeal shock wave therapy may be superior compared to radial extracorporeal shock wave therapy in plantar fasciitis using the same low intensity energy flux densities. However, validation in large scale trials are needed for any superiority outcome measure in the evaluation of extracorporeal shock wave therapy.

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