

A Comparison of the Effectiveness of Radial Extracorporeal Shock Wave Therapy and Ultrasound Therapy in the Treatment of Chronic Plantar Fasciitis: A Randomized Controlled Trial

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Objective: To compare the effectiveness of radial extracorporeal shock wave therapy (rESWT) and ultrasound therapy (US) in the treatment of chronic plantar fasciitis.

Study Design: Randomized controlled trial.

Setting: Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital.

Material and Method: Thirty patients who were diagnosed with plantar fasciitis for at least 3 months and who had not responded to other forms of conservative treatment were recruited for this study. They were randomly divided into two groups of 15 patients. The rESWT group was treated with 1 session per week and the US group with 3 sessions per week, with both groups undergoing a total of 6 consecutive weeks of treatment. Visual analog scale (VAS) assessments were performed before and after treatment at 1, 3, 6, 12, and 24 weeks. The mobility subscale of the plantar fasciitis pain and disability scale (PFPS) was measured before and after treatment. Patient satisfaction was evaluated at the conclusion of the 6-week treatment protocol.

Results: VAS pain intensity scores were significantly decreased in both groups ($p < 0.001$), when measured after treatment at 1, 3, 6, 12, and 24 weeks. The VAS pain scores for the rESWT group dropped significantly more than those of the US group ($p < 0.001$). At the end of treatment, the PFPS mobility subscale scores in both groups were significantly decreased ($p < 0.001$). Similar to the VAS pain score outcome, the PFPS mobility subscale score for the rESWT group decreased significantly more than that of the US group ($p < 0.001$). Patient satisfaction was significantly higher in the rESWT group, relative to the US group ($p = 0.025$).

Conclusion: In chronic plantar fasciitis treatment, both rESWT and US were found to be effective in reducing pain and increasing mobility; however, statistical analysis showed that rESWT is significantly more effective than US.

Keywords: Plantar fasciitis, Radial extracorporeal shock wave therapy (rESWT), Ultrasound (US)

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Plantar fasciitis is the most common cause of inferior heel pain⁽¹⁾. It occurs in approximately 10% of the general population⁽²⁾. The most common age range is 40-60 years. Plantar fasciitis does not related to race or gender⁽³⁾. The causes of this disease remains unclear^(1,2). It is assumed that plantar fasciitis is caused by repetitive micro-trauma to the plantar fascia, with associating factors such as obesity, flat

feet, and tension in the Achilles tendon⁽¹⁻⁴⁾.

Diagnosis of plantar fasciitis is based on patient clinical history and physical examination. Patients typically present with heel pain when weight-bearing, especially with the first few steps in the morning or after periods of inactivity. The discomfort often improves after further ambulation. However, the discomfort often becomes worse at the end of the day in more severe cases, often limiting routine activity. Walking barefoot, walking on one's toes, or walking upstairs may exacerbate the pain. The patient usually experiences a maximum point of tenderness at the anteromedial aspect of the calcaneus⁽²⁻⁴⁾. Plantar fasciitis is a self-limiting condition with a good

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prognosis. Approximately 95% of patients experience symptom resolution within 12-18 months after undergoing conservative treatments⁽⁵⁾.

Surgery is generally recommended only after onset for at least 12 months and the failure of conservative treatment. Conservative treatments include padding and strapping, plantar fascia stretching exercises, shoe modifications, oral non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injection, and physical therapy methods⁽⁶⁾. Physical modalities include ultrasound therapy (US) and extracorporeal shock wave therapy (ESWT).

There are many reports in the literature that describe the physiological effects of therapeutic ultrasound. Published reports of only a few clinical trials have described conflicting conclusions. In 1996, Crawford F and Snaith M evaluated the therapeutic effects of therapeutic ultrasound in the treatment of plantar heel pain, as compared with sham ultrasound⁽⁷⁾. Both groups showed pain reduction (30% in the US group and 25% in the placebo group), but the results were not statistically significant. Although there is no evidence that strongly supports the effectiveness of therapeutic ultrasound, it remains the most common treatment routinely applied for plantar fasciitis and plantar heel pain⁽⁸⁻¹⁰⁾.

ESWT is a newer modality that is used for musculoskeletal pain therapy, including heel pain. In a 1998 controlled study, Perlick L and Boxberg W studied the effects of electrohydraulic ESWT (one treatment of 2,000 impulses) to reduce pain for plantar fasciitis. The results showed that ESWT was able to reduce pain scores significantly compared to the control group, after treatment at 12 weeks and 12 months ($p = 0.001$)⁽¹¹⁾. The effectiveness of electrohydraulic ESWT was a starting point from which new studies and technologies centered on musculoskeletal pain reduction have evolved. Most related controlled studies have reported a significant reduction in pain after 12 weeks of treatment⁽¹²⁻¹⁴⁾.

Both ultrasound therapy and ESWT are effective in the treatment of plantar fasciitis. In 2004, the RCT study by Kaewpinthong U showed that ESWT therapy reduced levels of pain significantly more than ultrasound therapy after treatment at 3, 6, and 12 weeks⁽¹⁵⁾. In 2007, Cheing GLY showed that 3 sessions using ESWT produced a greater reduction in heel pain than 9 sessions of ultrasound therapy over a three-week period⁽¹⁶⁾.

The more recently developed radial pressure wave ESWT (rESWT) is now also used for plantar

fasciitis. The shock waves produced by a pneumatic generator travel from the point of contact on the skin surface to the affected area. No local anesthesia is required at the treatment site, and only minor post-treatment complications have been reported^(17,18).

In clinical practice at the Department of Rehabilitation Medicine, Chulalongkorn University, the most effective commonly used modality prescribed for plantar fasciitis has been ultrasound therapy. Radial ESWT is a new modality in our department, with few doctors having patient treatment experience. In addition to favorable patient treatment results from rESWT, as well as good physician satisfaction, rESWT is a costly therapeutic alternative.

The objective of the present study was to compare the effectiveness of rESWT and US in chronic plantar fasciitis treatment. The primary objective was pain reduction, with patient foot, mobility function and overall patient satisfaction foot mobility being evaluated.

Material and Method

Setting

Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital.

Participants

From July 2010 to May 2012, patients with plantar fasciitis were recruited from the rehabilitation outpatient department. The inclusion criteria were as follows: age more than 18 years, diagnosis of plantar fasciitis more than 3 months with failure to respond to one conservative treatment (plantar fascia and gastrocnemius stretching exercise, shoe modification, or NSAIDs usage), and heel pain with first step walking in the morning greater than 5 on 10 cm visual analogue scale. The exclusion criteria were as follows: history of previous surgery or cancer of the heel, recent trauma, foot and/or ankle fracture, infection or other inflammation of the heel, neuro-vascular problems of the lower extremities, history of previous steroid injection less than 6 weeks, last ultrasound therapy less than 4 weeks, prior NSAID treatment less than 1 week, or contraindication to ESWT⁽¹⁷⁾ or ultrasound⁽¹⁹⁾.

Study design & randomization

The present study was a randomized controlled trial. The authors calculated the sample size based on the methodology of the RCT study by Kaewpinthong U. Fifteen patients were required for each group to detect a difference effectively between

the two groups, with a two-tailed α of 0.05 and $(1-\beta)$ of 0.80.

Block randomization was performed using a computerized random number generator for purposes of randomly assigning patients into two groups. A research assistant who was independent from the clinical treatment procedures performed in the present study was given possession of sealed opaque envelopes that contained random assignment numbers. Patients who met the eligibility criteria were then randomly assigned into the US therapy and rESWT therapy groups according to the randomly assigned number in the envelope selected.

Treatment procedures

All patients received the conventional rehabilitation program, which consisted of personal health care instructions (weight and activity control, self-foot massage, heat and cold application), plantar fascia and gastrocnemius muscle stretching exercise, and shoe modification for patients with flatfeet.

The rESWT group was treated with 1 session per week for 6 weeks with the application of radial extracorporeal, shockwave therapy always administered by the same physician. Swiss Dolorclast (EMS Electro Medical Systems SA, Nyon, Switzerland) equipment was used with a power hand piece transducer. Two thousand impulses were applied at a frequency of 10Hz and a pressure level of 2 bar. The ultrasound therapy group was treated with a Sonoplus 591 Enraf Nonius unit (Enraf-Nonius BV, Rotterdam, The Netherlands) at a frequency of 3MHz, intensity of 0.5-1 watt/cm², continuous mode, for 10 minutes. All sessions were administered by the same physical therapist; eighteen sessions were undertaken at a frequency of 3 sessions per week.

Outcome measures

Patients were assessed for heel pain at first-step walking in the morning by 100 mm visual analog scale⁽²⁰⁾ and for foot-mobility function by the mobility subscale of the plantar fasciitis pain and disability scale⁽²¹⁾ before treatment. All patients were asked personal care information questions relating to their condition, such as details regarding daily physical activity, plantar fascia and gastrocnemius muscle stretching exercises being performed, amount and type of pain relieving medications being taken, and complications of treatment. This line of questioning was performed each week before treatment and response data were recorded in the patient case record.

VAS scores for pain were assessed and recorded before treatment began and after treatment at 1, 3, and 6 weeks. VAS rating papers, sealed in opaque envelopes, were given to each patient. The papers were then returned to the assistant after being completed by the patient.

At 12 and 24 weeks, patients were interviewed by telephone and assigned a pain score. A foot mobility, function assessment using the mobility subscale of the plantar fasciitis pain and disability scale was performed before and after treatment. The authors selected specific items from the subscale that were common activities to all of the patients, including: No. 13) When you awaken, how many minutes must elapse before you can walk comfortably?; No. 15) Describe how much your pain affects you in different conditions: walking in the morning, walking barefoot, and standing after watching a movie; and, No. 19) Rate the limitations that your pain affects your daily life style.

Treatment satisfaction was assessed at the end of treatment by Likert Scale and rated as follows: 5 very satisfied, 4 somewhat satisfied, 3 neither satisfied nor dissatisfied, 2 somewhat dissatisfied, and 1 very dissatisfied. Treatment satisfaction, rating papers, sealed in opaque envelopes, were given to each patient. The papers were then returned to the research assistant after completion by the patient.

End of treatment criteria were VAS score less than or equal to 30 mm and completion of six sessions of treatment in the rESWT group or completion of eighteen sessions of treatment in the ultrasound group.

Ethical considerations

The present study was approved by the Institutional Review Board of Faculty of Medicine, Chulalongkorn University. All subjects were fully informed and written consent was obtained.

Statistical analysis

Statistical analysis was conducted using SPSS version 15.0 for Windows. Patient demographic data included age, sex, body mass index, flat feet, duration of pain, VAS, and the mobility subscale of the PFPS. Quantitative data were analyzed and presented as mean and SD. Qualitative data were analyzed and presented as percentage.

A comparison of VAS difference before and after treatment at 1, 3, 6, 12, and 24 weeks in each group was analyzed by repeated measures ANOVA and post-hoc analysis using the Bonferroni method. A confidence level of 95% ($p < 0.05$) was considered to be statistically significant.

A comparison of VAS difference before and after treatment at 1, 3, 6, 12, and 24 weeks between groups was analyzed by unpaired t-test. Statistical significance was defined as p -value <0.01 to minimize type 1 error of multiple comparison.

A comparison of the difference in the mobility subscale of PFPS score before and after treatment in each group was analyzed by ANOVA. A confidence level of 95% ($p<0.05$) was considered to be statistically significant.

A comparison of the difference in the mobility subscale of PFPS score before and after treatment between groups was analyzed by unpaired t-test. A confidence level of 95% ($p<0.05$) was considered to be statistically significant.

A comparison of treatment satisfaction before and after treatment between groups was analyzed by Mann-Whitney U test.

Results

Forty-seven patients were recruited for the present study. Seventeen patients were excluded due to diabetic neuropathy ($n = 2$), other heel pain not related to plantar fasciitis ($n = 3$), history of foot surgery ($n = 3$), history of steroid injection ($n = 4$), and VAS score less than 50 mm ($n = 5$). In due course, the 30 enrolled patients were randomly assigned to the rESWT and US groups, as shown in Fig. 1. There were no significant differences between the rESWT group and US group with regard to age, gender, body mass index, pain duration, flat feet, pain score, and mobility subscale of PFPS, as shown in Table 1.

All enrolled patients completed the treatment without complications. There was good patient compliance with the conventional rehabilitation programs. None of the patients took pain relieving medications during the period of research treatment. The results showed that pain scores decreased by

statistically significant levels in both groups at 1, 3, 6, 12, and 24 weeks. Pain score reduction in the rESWT group was significantly greater than that of the US group. The pain score difference between before and after treatment at 1, 3, 6, 12, and 24 weeks was significantly decreased in both groups, with more difference in the rESWT group than in the US group, as shown in Table 2.

The mobility subscale of PFPS between before and after treatment in each group was statistically reduced. The mean difference of the mobility subscale of PFPS in the rESWT group was more statistically reduced than in the US group, as shown in Table 3.

The patients in both groups rated their treatment satisfaction in only 2 of the 5 rating options, those being: “somewhat satisfied” and “very satisfied”. The very satisfied rating was selected by 80 percent of the rESWT group and 33.36 percent of the US group, with statistical differences shown in Fig. 2.

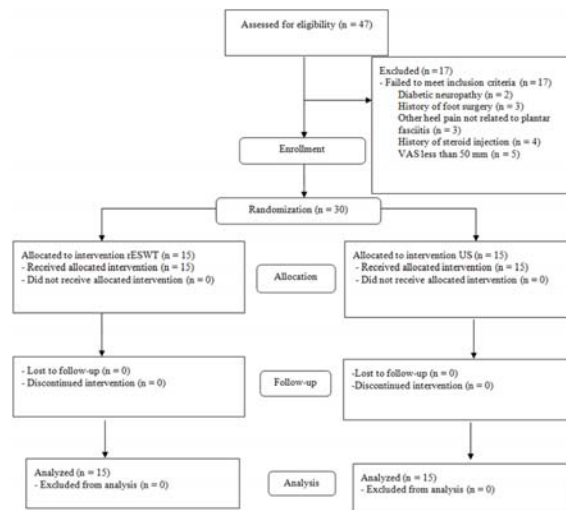


Fig. 1 Flow of patient participation in the study.

Table 1. Participant demographic data

Demographic data	rESWT ($\bar{x} \pm SD$)	US ($\bar{x} \pm SD$)	p -value
Age (years)	45.6 \pm 1.07	45.0 \pm 1.13	0.883
Gender (male:female)	4:11	2:13	0.871
Body mass index (kg/sqm)	26.03 \pm 1.99	25.67 \pm 2.06	0.63
Pain duration (years)	1.33 \pm 0.50	1.37 \pm 0.49	0.854
Flatfeet (n)	3	3	1
VAS score (mm)	85.86 \pm 0.98	87.27 \pm 0.95	0.693
PFPS (mobility)	11.00 \pm 1.07	10.73 \pm 1.03	0.493

Table 2. Mean and mean difference of VAS scores at before and after treatment at 1, 3, 6, 12, and 24 weeks

VAS score	rESWT ($\bar{x} \pm SD$)	US ($\bar{x} \pm SD$)	Difference between groups	<i>p</i> -value between groups
Baseline (before treatment)	85.86±0.97	87.27±0.95	1.40±0.35	0.693
After 1 week	62.87±0.74	74.93±1.00	12.07±0.32	<0.001
After 3 weeks	43.20±0.79	57.53±0.89	14.33±0.31	<0.001
After 6 weeks	24.00±0.72	39.33±0.84	15.33±0.29	<0.001
After 12 weeks	20.00±1.07	45.33±1.41	25.33±0.46	<0.001
After 24 weeks	16.00±1.30	48.00±0.1.61	32.00±0.53	<0.001
Difference before and after 1 week of treatment [95% CI]	23.00±0.29 [16.78-29.22]	12.33±0.09 [9.04-15.63]	10.67±0.30 [9.43-16.90]	<0.002
<i>p</i> -value	<0.001	<0.001		
Difference before and after 3 weeks of treatment [95% CI]	42.67±0.36 [34.83-50.51]	29.73±0.16 [24.10-35.37]	12.93±0.40 [4.76-21.10]	0.003
<i>p</i> -value	<0.001	<0.001		
Difference before and after 6 weeks of treatment [95% CI]	61.87±0.38 [53.67-70.07]	47.93±0.25 [39.24-56.62]	13.93±0.45 [4.62-23.25]	0.005
<i>p</i> -value	<0.001	<0.001		
Difference before and after 12 weeks of treatment [95% CI]	65.87±0.41 [57.02-74.71]	41.93±0.49 [24.75-59.12]	23.93±0.64 [10.86-37.00]	0.001
<i>p</i> -value	<0.001	<0.001		
Difference before and after 24 weeks of treatment [95% CI]	69.87±0.43 [60.71-79.02]	39.27±0.52 [20.87-57.66]	30.60±0.67 [16.80-44.40]	<0.001
<i>p</i> -value	<0.001	<0.001		

Table 3. Results of mobility subscale of PFPS

Mobility subscale of PFPS	rESWT ($\bar{x} \pm SD$)	US ($\bar{x} \pm SD$)	Mean of difference	<i>p</i> -value between groups	(95%CI)
Before treatment	11.00±1.07	10.73±1.03	0.27±0.38	0.493	[0.51-1.05]
After treatment	4.86±0.74	8.20±1.42	3.34±0.41	<0.001	[2.48-4.18]
Difference before and after treatment [95% CI]	6.13±1.24 [5.44-6.82]	2.53±0.99 [1.98-3.08]	3.60±0.41	<0.001	[2.75-4.44]
<i>p</i> -value in group	<0.001	<0.001			

Discussion

Chronic plantar fasciitis is a frustrating condition for both patients and physicians. The failure of conservative treatment may lead to surgery, which is associated with complication risks, such as flattening of the longitudinal arch, heel hypoesthesia, and rupture of the plantar fascia. Physical modalities are the first best option for patients before surgical options are considered and pursued. Although there was no evidence-based support that categorically proved its efficacy, ultrasound therapy has become the most generally used treatment for plantar fasciitis⁽²⁾. In the present study, patients were treated with ultrasound

therapy, with patient VAS pain scores showing significant reduction from the first week of treatment. Foot mobility function according to the PFPS mobility subscale also showed improvement at the end of treatment. These results support the effectiveness of ultrasound therapy in the treatment of plantar fasciitis.

The results of the present study show that rESWT was effective in reducing pain for plantar fasciitis, consistent with the findings of similar previous studies^(17,18,22). The positive effects of rESWT therapy appeared as early as week one of the treatment regimen and lasted long as 24 weeks. Although every similar study has been defined by a different treatment

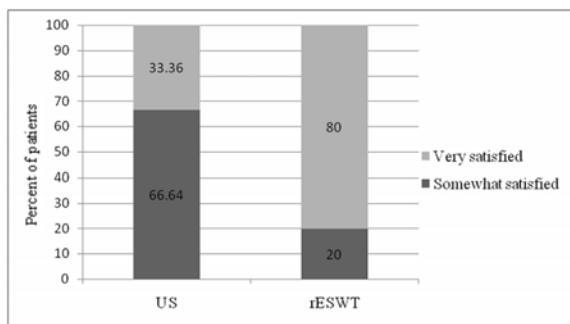


Fig. 2 Level of patient satisfaction with treatment.

protocol, the result of statistically significant pain reduction has been consistent. The present study used 2 bars of pressure, which was less than previous studies. This level of pressure had the effect of producing less pain for the patient, with comparable levels of treatment effectiveness. This lower level of treatment-related pain resulted in higher levels of patient compliance and also likely influenced overall patient satisfaction.

The present study demonstrated that ESWT is more effective than US in reducing pain for plantar fasciitis; results consistent with the findings of other related studies^(17,18). All previous studies compared ultrasound therapy with focused ESWT; however, the present study compared US to radial ESWT. Focused ESWT has higher tissue penetration power and impact force than rESWT. Alternatively, the energy generated by rESWT is delivered directly to the skin by converting pneumatic energy into shock wave energy. Maximum energy travels from the point of contact on the skin surface and is distributed radially into the tissue⁽²³⁾. As a result, a larger volume of tissue can be treated. This may provide some explanation as to why no complaints of pain or post-treatment complications were reported. Due to a lack of sufficient follow-up data and evaluation, the biological effects of rESWT therapy are not fully known or explained. The effects of hyperstimulation analgesia on an initial increase and subsequent decrease in substance P (SP)⁽²⁴⁾, explains the resulting pain reduction. Wang CJ attributed the long-term healing effects of rESWT to the stimulation and release of angiogenic growth factors and the in growth of neovascularization with a resulting improvement in blood supply, both leading to the repair of tendon and bone⁽²⁵⁾.

With a primary research focus on heel pain, few researches have also evaluated patient quality of

life using the Roles and Maudsley score, which showed improvement after rESWT therapy^(22,26). The authors of the present study were interested in common foot-related activities that are often limited or otherwise affected by plantar fasciitis. Accordingly, foot mobility function was assessed using the mobility subscale of PFPS. The results showed that both ultrasound and rESWT significantly reduced the mobility subscale score of PFPS at the end of treatment; however, the improvement in the rESWT group was significantly higher than that of the ultrasound group.

Treatment satisfaction was also evaluated. The results show levels of treatment satisfaction for rESWT therapy to be significantly higher than those of ultrasound therapy.

The result of rESWT therapy was more effective than US therapy, but the cost of treatment was higher. Per treatment cost of rESWT was more expensive than US (600 THB vs. 60 THB), but the number of required treatments was lower (6 vs. 18). The total cost of rESWT was roughly 3 times that of US (3,600 THB vs. 1,080 THB). Indirect costs of treatment (e.g. transportation, time off work) must also be considered. Given the efficacy of this treatment option, rESWT therapy should be considered, especially in cases of chronic plantar fasciitis. However, US therapy is a good treatment option for plantar fasciitis in health centers where rESWT is not available.

At present, there is no standard protocol for rESWT treatment of plantar fasciitis. Treatment outcomes may depend on machine types and treatment protocols. Future studies should consider focusing on protocol-specific factors, such as: type of transducer, impulse rate, frequency, pressure, and number of treatment sessions.

Conclusion

In chronic plantar fasciitis treatment, both rESWT and US were found to be effective in reducing pain and increasing mobility; however, statistical analysis showed that rESWT is significantly more effective than US.

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personal or professional conflict of interest with any aspect of the present study.

Potential conflicts of interest

None.

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เปรียบเทียบประสิทธิภาพของเครื่องกำเนิดคลื่นกระแทกเป็นจังหวะด้วยการบีบอัดอากาศกับเครื่องกำเนิดคลื่นเสียงความถี่สูงในการรักษาโรคพังผืดใต้ฝ่าเท้าอักเสบเรื้อรัง

นิภาภรณ์ คนเจน, ฐปกรณั์ แหนบนาค, ศิริพร จันทน์ฉาย

วัตถุประสงค์: เพื่อเปรียบเทียบประสิทธิภาพของเครื่องกำเนิดคลื่นกระแทกเป็นจังหวะด้วยการบีบอัดอากาศ (rESWT) กับเครื่องกำเนิดคลื่นเสียงความถี่สูง (US) ในการรักษาโรคพังผืดใต้ฝ่าเท้าอักเสบเรื้อรัง

รูปแบบการวิจัย: การวิจัยเชิงทดลองแบบสุ่ม

สถานที่: ฝ่ายเวชศาสตร์ฟื้นฟู โรงพยาบาลจุฬาลงกรณ์

วัสดุและวิธีการ: ผู้ป่วยจำนวน 30 รายที่เป็นโรคพังผืดใต้ฝ่าเท้าไม่น้อยกว่า 3 เดือน และไม่ตอบสนองต่อการรักษาแบบประคับประคองถูกแบ่งแบบสุ่มเป็น 2 กลุ่ม กลุ่มละ 15 คน กลุ่ม rESWT ได้รับการรักษาด้วย rESWT 1 ครั้ง ต่อ สัปดาห์ และกลุ่ม US ได้รับการรักษาด้วย US 3 ครั้ง ต่อ สัปดาห์ เป็นระยะเวลา 6 สัปดาห์ ประเมินระดับความปวดที่ก่อนและหลังการรักษาที่ 1, 3, 6, 12 และ 24 สัปดาห์ ประเมินด้านการเคลื่อนไหวของ PFPS ก่อนและสิ้นสุดการรักษา รวมทั้งประเมินความพึงพอใจหลังการรักษาที่ 6 สัปดาห์

ผลการศึกษา: ผู้ป่วยทั้ง 2 กลุ่มมีระดับความปวดลดลงอย่างมีนัยสำคัญทางสถิติ ($p < 0.001$) ภายหลังการรักษาที่ 1, 3, 6, 12 และ 24 สัปดาห์โดยเมื่อเปรียบเทียบระหว่างกลุ่ม ณ ช่วงเวลาเดียวกันพบว่า กลุ่ม rESWT มีระดับความปวดลดลงมากกว่ากลุ่ม US อย่างมีนัยสำคัญทางสถิติ ($p < 0.001$) และเมื่อสิ้นสุดการรักษา พบว่าค่าด้านการเคลื่อนไหวของ PFPS (mobility subscale of PFPS) ลดลงอย่างมีนัยสำคัญทางสถิติทั้ง 2 กลุ่ม ($p < 0.001$) โดยกลุ่ม rESWT มีค่าด้านการเคลื่อนไหวของ PFPS (mobility subscale of PFPS) ลดลงมากกว่ากลุ่ม US อย่างมีนัยสำคัญทางสถิติ ($p < 0.001$) ส่วนความพึงพอใจพบว่ากลุ่ม rESWT มีความพึงพอใจมากกว่ากลุ่ม US อย่างมีนัยสำคัญทางสถิติ ($p = 0.025$)

สรุป: Radial extracorporeal shock wave และ ultrasound มีประสิทธิภาพในการลดปวดและเพิ่มความสามารถ ในการเคลื่อนไหวในการรักษาโรคพังผืดใต้ฝ่าเท้าอักเสบเรื้อรังโดย rESWT มีประสิทธิภาพดีกว่า US
