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Original Research

Efficacy of Extracorporeal Pulse-Activated Therapy in the Management of Lower-Extremity Running-Related Injuries: Findings From a Large Case Cohort

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ABSTRACT

Running is one of the most popular sports worldwide, with many health benefits. Injuries are also common, with running-related injuries reported in up to 79% of runners annually. Extracorporeal shockwave treatment can be used to treat soft tissue conditions, with the strongest level of evidence for management of plantar fasciitis. However, most studies have focused on nonathletes or studied a single condition, and few investigations have reported outcomes for extracorporeal pulse-activated therapy. In this case series, we evaluated the outcomes of 94 runners receiving extracorporeal pulse-activated therapy for lower-extremity running-related injuries, including plantar fasciitis and lower-extremity tendinopathy (Achilles, posterior tibialis, patellar, hamstring). We hypothesized that most runners with foot and ankle injuries would respond favorably to treatment and that success rates would be similar across conditions. Overall, 74 runners (79%) met their respective minimal clinically important difference for functional outcome measures, with no differences in response by age, sex, body mass index, or chronicity of condition. Further, no differences were noted in proportion achieving the minimal clinically important difference between foot and ankle (Achilles, posterior tibialis, and plantar fascia) compared with proximal injuries (53 [84.3%] versus 31 [72%], $p = .15$). A mean of 4 treatments resulted in achieving the minimal clinically important difference, with 95% achieving it by 5 treatments. No differences in bars of pressure, frequency, or other aspects of treatments were observed to predict response. Our findings suggest that a majority of runners with lower-extremity injuries respond favorably to extracorporeal pulse-activated therapy, including those with foot and ankle injuries.

Running is one of the most popular forms of sport and exercise worldwide. In 2013, there were 19 million runners who crossed the finish line in U.S. running events covering all distances (1). However, running-related injuries (RRIs) are common within the sport. A 2007 systematic review by van Gent et al (2) found that the overall annual incidence of RRIs was up to 79%. Of all RRIs, foot and ankle conditions of Achilles tendinopathy, plantar fasciitis, and medial tibial stress syndrome are among the common forms of injury, along with more proximal injuries including both hamstring and patellar tendinopathy (3).

Typical treatments for most injuries include activity modification, oral anti-inflammatory drugs, and physical therapy. However, a portion of runners with RRIs have pain refractory to treatment (4–6). Other forms of intervention, including corticosteroid injection, are often considered after trials of these conservative measures. The utility of corticosteroids for these conditions is limited, given the degenerative etiology of most tendon and soft tissue conditions and concern for tenotoxicity (7). Orthobiologics such as platelet-rich plasma (PRP) have been proposed to stimulate tissue healing; however, the success of PRP for treatment of tendon conditions is inconsistent (8–10).

Extracorporeal shockwave treatment (ESWT) is an alternative form of treatment for soft tissue conditions. Current evidence supports its use in the management of soft tissue injuries, with arguably the highest level of evidence seen in management of plantar fasciitis (11,12). Additionally, success rates in the treatment of Achilles tendinopathy combined with eccentric loading were reported as high as 83% in 1 study (13). The best reported outcomes for success in athletes were observed in the treatment of proximal hamstring tendinopathy, with 80% achieving preinjury level return to sports. ESWT involves the production and delivery of mechanical energy to target tissue and is further classified as either focused (F-SWT) or radial (R-SWT). R-SWT uses a ballistic mechanism via the use of compressed air to accelerate a projectile to the end of a tube, where it strikes an applicator. Upon striking the applicator, a pressure wave is produced that propagates and expands radially into

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the target tissue. Although the exact mechanism of action remains unknown, there are a number of proposed direct effects of shockwaves on damaged tissue as well as indirect effects of shockwaves on the regulation of local metabolic and inflammatory milieu (11,14,15).

Studies of efficacy of treatment with the R-SWT method of Extracorporeal Pulse-activated Therapy (EPAT) for lower-extremity tendinopathies and plantar fasciitis are limited, with most studies evaluating nonathletes and treatment of a single condition. Further, studies comparing the efficacy of ESWT for foot and ankle conditions to other injuries has also not been reported. The purpose of this report is to present the results of EPAT in the treatment of 94 athletes with RRI. We hypothesized that a majority of runners would improve, with no differences expected by anatomy between foot and ankle and more proximal injury locations. Exploratory outcomes included accounting for anthropometric characteristics that may influence results (age, sex, and BMI) and treatment characteristics associated with success (number of treatments, intensity, and frequency).

Methods

Approval for this study was obtained from our institution's quality improvement advisory board, and institutional review board approval was waived by the institution. The population studied was runners with lower-extremity RRI who presented to the outpatient running medicine clinic of the senior author (A.S.T.). Chart review from August 2017 to September 2019 of all patients receiving EPAT for a RRI was performed by 3 authors (D.R., M.M., A.S.T.). Clinical data obtained included injury, clinical and treatment characteristics, demographics, and functional outcomes. An RRI was defined as a condition that interfered with normal training and ability to compete for >7 days (16). The forms of RRI evaluated in the study were defined as foot and ankle conditions of Achilles tendinopathy, posterior tibialis tendinopathy, or plantar fasciitis; non−foot and ankle conditions were hamstring and patellar tendinopathy. Inclusion criteria were (1) primary diagnosis of a RRI and (2) completed baseline and follow-up functional outcome measures. To exclude the influence of other sources of pain and injury on outcome, we did not include runners receiving treatment for multiple conditions simultaneously (such as both patellar tendinopathy and plantar fasciitis), runners with presence of other conditions including joint disease, and surgery within the past 6 months.

Shockwave Procedure

Treatments were performed using the Storz Extracorporeal pulse activation technology (EPAT®) device (Storz Medical, Tägerwilen, Switzerland). All patients with hamstring tendinopathy received a minimum of 4 sessions with the goal to meet 4 bars of pressure (17). For all other conditions, EPAT was applied over a minimum of 3 weekly sessions, with additional sessions as needed to obtain maximum clinical response. Frequency and pressure ranged from 12 to 15 Hz and 2 to 5 bar, largely dictated by patient comfort and using the principle of clinical focusing (targeting sites of pain with treatment). No topical or regional anesthetic was applied during treatment, and patients were instructed to refrain from use of nonsteroidal anti-inflammatory medications and icing during treatment through final follow-up.

Functional outcome measures were collected at baseline, following initial treatment series (typically after sessions 3 and 4) and during clinic visits through the final follow-up. Victorian Institute of Sports Assessments (VISA) questionnaires comprise 8 questions assessing limitations in ability to participate in sport, and scores range from 100 (asymptomatic) to 0 points. The Foot and Ankle Ability Measure (FAAM) is divided into 2 subscales, Activities of Daily Living (ADL) and Sport. The ADL subscale ranges from 84 (no limitations) to 0 points, and the Sport subscale ranges from 32 (full performance, asymptomatic) to 0 points. Runners were offered further treatment with EPAT at follow-up visits, which were usually scheduled 6 to 8 weeks after completing initial treatment. Treatment success was defined as reaching the minimal clinically important difference (MCID), a measure of improved function. The following outcome measures were used:

1. VISA – Achilles (VISA-A) for Achilles tendinopathy (18). A change of 12 points was used for the minimal clinically important difference, as this is one of the most frequently used values for midportion etiologies, and 6.5-point MCID for insertional etiologies (19,20).
2. VISA – Hamstring (VISA-H) for hamstring tendinopathy (21). A change in 22 points was used for the MCID (21). Criteria for midportion and distal hamstring injuries has not been described; the same value of 22 was assigned for MCID.
3. VISA – Patella (VISA-P) for patellar tendinopathy (22). A change in 13 points was used for the MCID (23).
4. FAAM for plantar fasciitis and tibialis posterior tendinopathy. A change in 8 points for ADL subscale and 9 points for Sport subscale were used for the MCID (24). Runners who met either the ADL or Sport subscale value were assigned as meeting MCID.

Statistical Analysis

Descriptive statistics were used to evaluate variable frequencies. Percentages or means and standard deviations are reported. The primary outcome was evaluating the proportion of runners meeting the MCID for each condition and differences in characteristics between responders versus nonresponders. Two-sample unpaired t tests and chi-squared tests were used to evaluate for differences between continuous and categorical variables using Stata (R.G.), version 16 (StataCorp, College Station, TX). Statistical significance was defined at the 5% ($p \leq .05$) level.

Results

Initially, 142 runners in total who received treatment with EPAT for RRI were identified on chart review. Of those, 15 were excluded for not completing a follow-up outcome questionnaire, and 33 were excluded for treatment of an alternative condition or multiple separate areas treated concurrently. This resulted in a population of 94 runners (Table 1). The population contained runners treated for foot and ankle conditions (Achilles tendinopathy, n = 27, 29%; plantar fasciitis, n = 17, 18%; tibialis posterior tendinopathy, n = 7, 7.5%) and proximal injuries (hamstring tendinopathy, n = 36, 38%; patellar tendinopathy, n = 7, 7.5%) (Table 2). Eighty-five patients (90%) completed prior physical therapy, and mean duration of symptoms exceeded 1 year in length. In addition to EPAT, each runner was recommended to complete physical therapy, or when describing correct exercises, encouraged to continue a home exercise program at the time of EPAT, given evidence suggesting that combined ESWT with tissue loading may improve efficacy of treatment (13). In general, activity recommendations were to run and perform cross-training as tolerated.

No differences in meeting the MCID for functional outcomes were found for foot and ankle conditions compared with proximal lower-extremity conditions (53 [84.3%] versus 31 [72%], p = .15). Mean functional outcome changes from baseline to final follow-up increased for all conditions analyzed (Fig. 1 and Fig. 2). Seventy-four (79%) patients met respective MCID values for the treated condition, with 95% of these runners meeting the MCID by 5 EPAT treatment sessions (Fig. 3). Three of these patients met the MCID for only 1 subscale of the FAAM. There were no differences in bars of air pressure (3.35 ± 0.77 and 3.59 ± 0.6 bar; p = .19) or frequency (14.99 ± 0.05 and 14.96 ± 0.14 Hz; p = 0.43) during treatment that predicted response for responders versus nonresponders, respectively. As expected, a higher number of treatments were performed on runners who did not meet

Table 1
Anthropometric characteristics of treatment responders versus nonresponders (N = 94)

	All	Responder	Nonresponder	p Value
n (%)	94 (100)	74 (78.7)	20 (21.3)	
Age (y)	39.7 ± 14.16	38.8 ± 13.94	42.9 ± 14.84	.25
Sex				.94
Male	43 (45.7)	34 (45.9)	9 (45)	
Female	51 (54.3)	40 (54.1)	11 (55)	
Body mass index (kg/m^2)	22.9 ± 3.85	22.7 ± 3.85	23.7 ± 3.83	.33
Symptom duration (mo)	14.3 ± 18.93	13.2 ± 16.22	18.5 ± 27.21	.28
Prescribed physical therapy	78 (86.7)	63 (88.7)	15 (78.9)	.27
No. of shockwave treatments	4.22 ± 1.6	3.99 ± 1.22	5.1 ± 2.40	.01*
Longest distance race completed				
5,000 m to half-marathon	32 (34)			
Marathon	53 (56.4)			
Did not report	9 (9.6)			

Data are mean ± standard deviation or n (%).
* Significant at $p < .05$.

Table 2
Characteristics of responders versus nonresponders by condition (N = 94)

	All	Responder	Nonresponder
Proximal hamstring tendinopathy	32	22 (69)	10 (31)
Age (y)	43.3 ± 15.8	42.8 ± 15.8	44.5 ± 16.4
Female sex	22 (68)	15 (68)	7 (32)
Body mass index (kg/m^2)	21.5 ± 3.0	21.5 ± 3.4	21.4 ± 1.9
Symptom duration (mo)	16.2 ± 22.7	12.4 ± 12.9	25.4 ± 36.8
Bilateral symptoms	6 (19)	4 (67)	2 (33)
Distal/mid-hamstring tendinopathy	4	3 (75)	1 (25)
Age (y)	44.3 ± 11.7	48 ± 11	33
Female sex	1 (25)	0	1 (100)
Body mass index (kg/m^2)	26 ± 6.2	22.9 ± 1.1	35.1
Symptom duration (mo)	5.5 ± 3.7	5.7 ± 4.5	5
Bilateral symptoms	0		
Insertional Achilles tendinopathy	11	10 (91)	1 (25)
Age (y)	37.7 ± 12.2	36.0 ± 11.4	55
Female sex	5 (45)	5 (100)	0
Body mass index (kg/m^2)	24.2 ± 3.5	24.1 ± 3.6	25.9
Symptom duration (mo)	21.8 ± 19.4	19.2 ± 18.3	48
Bilateral symptoms	2 (18.2)	2 (100)	0
Mid-portion Achilles tendinopathy	16	13 (81)	3 (19)
Age (y)	37.4 ± 13.9	36.7 ± 15	40.3 ± 8.5
Female sex	7 (44)	7 (100)	0
Body mass index (kg/m^2)	23.4 ± 4.0	22.9 ± 4.0	35.4 ± 4.3
Symptom duration (mo)	11.4 ± 10.7	11.9 ± 11.8	9.3 ± 3.1
Bilateral symptoms	4 (25)	3 (75)	1 (25)
Patellar tendinopathy	7	6 (86)	1 (14)
Age (y)	34.1 ± 16.1	36.7 ± 16.1	19
Female sex	0	0	0
Body mass index (kg/m^2)	26.1 ± 2.5	26.3 ± 2.7	24.4
Symptom duration (mo)	26.9 ± 36.6	29.3 ± 39.4	12
Bilateral symptoms	2 (29)	2 (100)	0
Tibialis posterior tendinopathy—FAAM ADL	7	6 (86)	1 (14)
Age (y)	31.7 ± 12.9	28.2 ± 9.8	53
Female sex	5 (71)	4 (80)	1 (20)
Body mass index (kg/m^2)	21.1 ± 4.4	21.1 ± 4.9	20.6
Symptom duration (mo)	6.6 ± 1.8	6.3 ± 1.9	8
Bilateral symptoms	0	0	0
Tibialis posterior tendinopathy—FAAM sport	7	5 (71)	2 (29)
Age (y)	31.7 ± 12.9	30.6 ± 13.4	34.5 ± 16.3
Female sex	5 (71)	4 (80)	1 (20)
Body mass index (kg/m^2)	21.1 ± 4.4	18.9 ± 2.8	26.6 ± 2.0
Symptom duration (mo)	6.6 ± 1.8	6.2 ± 2.1	7.5 ± 0.7
Bilateral symptoms	0	0	0
Plantar fasciitis—FAAM ADL	17	11 (65)	6 (35)
Age (y)	40.9 ± 11.5	39.7 ± 10.8	43 ± 14.5
Female sex	11 (65)	7 (64)	4 (36)
Body mass index (kg/m^2)	23.1 ± 3.9	22.9 ± 4.7	23.4 ± 2.6
Symptom duration (mo)	8.5 ± 6.6	7.6 ± 5.2	10 ± 8.9
Bilateral symptoms	1 (6)	0	1 (100)
Plantar fasciitis—FAAM sport	17	12 (71)	5 (29)
Age (y)	40.9 ± 11.5	37.6 ± 9.6	48.8 ± 14.2
Female sex	11 (64)	8 (73)	3 (27)
Body mass index (kg/m^2)	23.1 ± 3.9	22.5 ± 4.5	24.6 ± 1.8
Symptom duration (mo)	8.5 ± 6.6	9.2 ± 6.8	6.8 ± 6.5
Bilateral symptoms	1 (6)	0	1 (100)

Data are n (%) or mean ± standard deviation.
Abbreviations: ADL, activities of daily living; FAAM, foot and ankle ability measure.

MCID (because of the goal to achieve treatment response by further sessions of treatment).

Discussion

The purpose of this investigation was to evaluate the efficacy of EPAT within a population of running athletes for the management of RRI. In this population of 94 runners, a majority (78%) achieved improvement in function as quantified by achieving MCID. The MCID was met after a mean of 4 sessions, corresponding to time of mean 3.8 ± 2.5 weeks from initiation of treatment. To date, most ESWT studies have looked at outcomes typically a minimum of 3 months after treatment conclusion, when full effects are expected to be achieved. The literature on short-term outcomes is more limited, although Dedes et al (25) found significant improvement in pain and functionality immediately after treatment, including for plantar fasciitis and Achilles tendinopathy. Our results expand on findings of improved function during early treatment and were within a population of running athletes. No major complications were observed during active EPAT treatment. One patient did suffer plantar fascial rupture 6 weeks after treatment in the setting of running a marathon and prescription of a Medrol dose pack by a different provider.

Achilles tendinopathy and plantar fasciitis are among the most common RRIs, although posterior tibialis tendinopathy is also observed in runners (3). Most foot and ankle conditions are initially managed nonsurgically, with Achilles tendinopathy treated with progressive eccentric loadings, whereas mainstays for plantar fasciitis include stretching of both the calf muscles and plantar fascia and intrinsic foot muscle strengthening (26). Nearly half of patients receiving conservative treatment for Achilles tendinopathy have poor success (4). Likewise, 20% of patients with plantar fasciitis will fail to respond completely to conservative treatment within 12 months (5). Many of these patients will consider further treatments, including surgery. Shockwave offers an alternative, noninvasive treatment, with 1 recent review grading the existing level of evidence for ESWT to be “good and fair” for Achilles tendinopathy and plantar fasciitis, respectively (12). Most studies in the review used focused on shockwave (12), especially for plantar fasciitis, and none of them specifically studied the running population. A 2003 randomized controlled trial by Rompe et al (27) randomized 45 recreational athletes with >1 year of plantar fasciitis who ran ≥30 miles/week and had failed ≥3 conservative treatments to active low-energy F-SWT or sham treatment. They found low-energy F-SWT to be significantly more effective than sham at 6 and 12 months. Separately, success with combined shockwave and eccentric exercises was achieved in 83% of patients treated with Achilles tendinopathy (13). Within our running population treated, 83.4% of all runners met MCID. This is notable, as 90% of the cohort had physical therapy before considering EPAT.

The most commonly treated site in our study was the proximal hamstring tendon complex. Proximal hamstring tendinopathy (PHT) represents a relatively small percentage of overall hamstring injuries, yet it is more common in distance runners and is attributed to repetitive eccentric loading (28). Whereas the mainstays of conservative treatment for PHT include early pain control, correction of pelvic malalignment, soft tissue mobilization, and progressive hamstring strengthening with gradual return to running, there remains no consensus on the optimal treatment strategy (28,29). The 1 prior study of R-SWT in athletes across sports identified 80% of those receiving R-SWT and none in the conservative treatment arm returning to preinjury level at 3 months (17). In the present study, MCID using VISA-H scores was achieved in 69% of runners. Although a different measurement is used for outcome, our results are comparable to prior results (17) and suggest that EPAT may be effective for treatment of hamstring tendinopathy in runners.

Similar to hamstring tendinopathy, we also observed that most runners responded favorably to treatment of patellar tendinopathy. The rate of this injury in athletes has been reported as 14.2% annually, particularly in sprinters (30). ESWT may be considered for the treatment of patellar tendinopathy in athletes (31). A case-control study identified improved visual analog score and VISA-P at all time intervals (1, 3, and 12 months) after a single application of R-SWT compared with no improvement in the population receiving conservative treatment (32). Peers et al (33) found comparable long-term functional outcomes between ESWT and surgery for recalcitrant disease. In contrast, randomized controlled studies have not shown favorable response of shockwave treatment. Jumping athletes treated during the season did

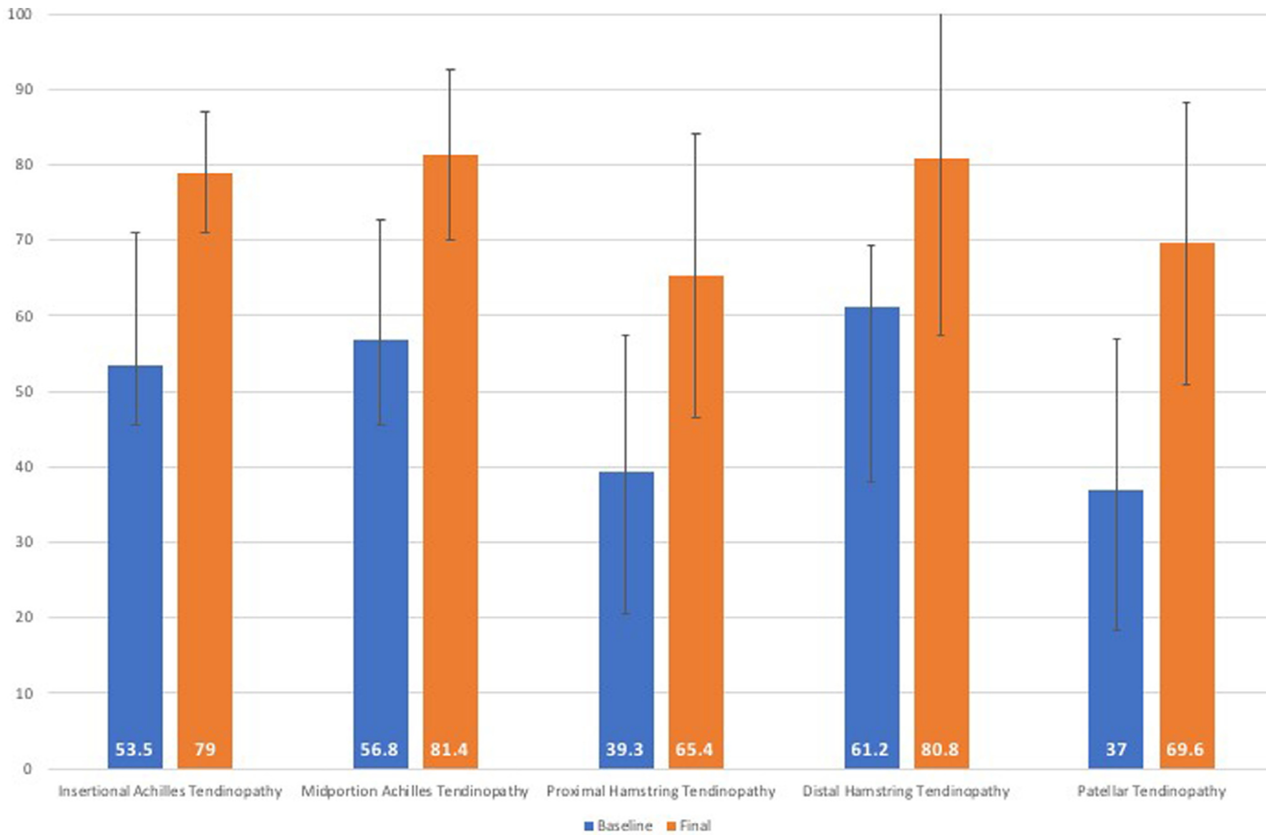

Fig. 1. Victorian Institute of Sport Assessment outcome changes (n = 43). Mean and standard deviations on functional outcomes of baseline and final follow-up scores.

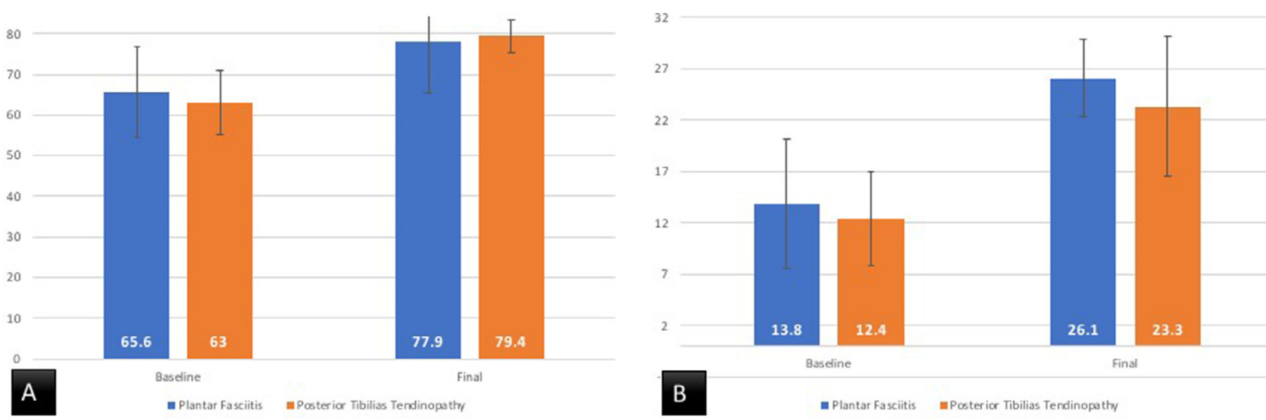

Fig. 2. Foot and ankle ability measure outcome changes (n = 51). Mean and standard deviation scores on functional outcomes of baseline and final follow-up foot and ankle ability measure activities of daily living subscale (*A*) and sport subscale (*B*).

not have improved functional outcomes (34). Van der Worp et al (35) found no difference between F-SWT and R-SWT when treating patellar tendinopathy. Although limited by sample size and study design, our cohort saw overall improvements in functional status, suggesting that runners may respond well to EPAT.

There are several limitations in our study. Our study design is limited by lack of a true control group to measure the effect isolated to EPAT. Nearly all runners had prior PT, with RRIs averaging 1 year of duration, and were active during treatment, arguing that natural history would not explain the improvements observed. Additionally, while each patient was diagnosed clinically by a single physician, we did not have confirmatory imaging available for each of the included patients. EPAT required out-of-pocket costs, which may result in selection bias for those who chose to complete treatment. Notably, the results of our study reflect combined response to both EPAT and performing exercises, as runners were referred back to physical therapy or advised to continue home exercises, as the combination of progressive tissue loading during ESWT has been shown to have improved efficacy (13). Despite these limitations, our study included consecutive patients treated with EPAT to minimize selection bias. Our findings add to limited studies that evaluated athletes, use of EPAT, or comparison across conditions. Number of treatments of EPAT was based on runner preference, with shared decision making with the provider. The study design allowed for evaluating the influence of a

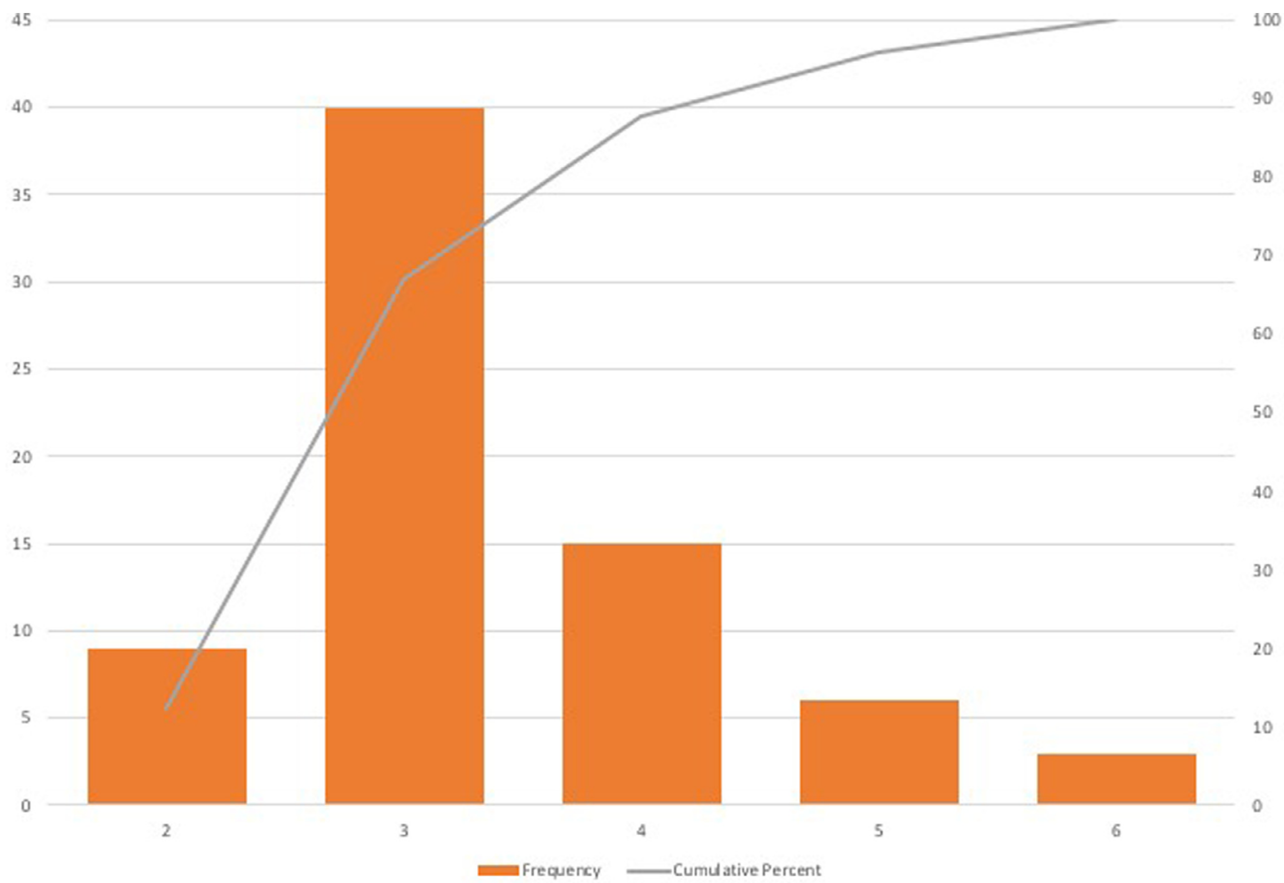

Fig. 3. Number of treatments to minimal clinically important difference (n = 74). Number of patients meeting their respective outcome measure's minimal clinically important difference by cumulative treatment number.

greater number of sessions to achieve success, and 95% of runners met MCID by 5 treatment sessions. Bars of air pressure and frequency during treatment (in Hz) did not influence treatment, arguing that clinical focusing is effective to guide management. Further studies on optimal timing and dosing of treatment are needed; our study would suggest that 5 treatments may be considered for most conditions.

In conclusion, our findings suggest that a majority of runners receiving EPAT may optimize clinical response to treatment of various overuse injuries of the lower extremity. Foot and ankle conditions responded similarly to proximal injuries in our running cohort. The high rate of success with EPAT suggests that runners with overuse lower-extremity injuries may consider this treatment given the favorable safety profile and improved function. These results may aid in the development of future randomized controlled trials or prospective cohort studies focusing on overuse lower-extremity RRIs.

Acknowledgments

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