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The Effect of Low Dose Extracorporeal Shock Wave Therapy (ESWT) on Plantar Fasciitis: A Trial Study in Queen Mary Hospital
低劑量體外衝擊波治療(ESWT)對足底筋膜炎的影響 - 在瑪麗醫院的試用研究

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ABSTRACT

Background/Purpose: To assess the efficacy of low-energy extracorporeal shockwave therapy (ESWT) for the treatment of plantar fasciitis.
Methods: This was a prospective case series study that was performed at the Department of Orthopaedics, Queen Mary Hospital, Hong Kong. Twenty-one symptomatic feet in 16 patients with persistent symptoms of plantar fasciitis despite 3 months of conservative treatment were recruited in November 2008. All patients received five sessions of low energy ESWT and their corresponding 10-point visual analogue scale scores were recorded before and after each treatment sessions for each symptomatic foot. The patients were assessed for up to 6 months post-treatment.
Results: The mean visual analogue scale scores reduction for pain on first step in the morning, daily activities, and heel compression test were 2.62 (44.3%), 3 (38.3%), and 1.6 (36.8%), respectively, post-treatment. The analgesic effect was maintained in 52.3% (n = 11) of the patients at 6 months post treatment.
Conclusion: Low energy ESWT was shown to be an effective outpatient treatment option for patients with plantar fasciitis.

中 文 摘 要

目的: 為了評估低能量體外衝擊波治療(ESWT)為足底筋膜炎的治療的功效。
設計: 前瞻性病例系列。
單位: 骨科，瑪麗醫院香港。
方法: 16個患有足底筋膜炎(共21隻腳)，接受3個月保守治療但症狀持續存在的病人在2008年11月被招募參加研究。所有病人接受低能量體外衝擊波治療(ESWT)5次，並記錄每隻腳在治療前後對應的疼痛分數(以10點視覺模擬評分法VAS記錄)。所有病人在治療後6個月都會接受再評估。
結果: 在早晨第一步，日常活動和腳跟壓力試驗中，平均治療後VAS評分減少疼痛為2.62（44.3%），3（38.3%）和1.6（36.8%）。鎮痛效果能夠在治療後6個月保持的有52.3%（11例）。
結論: 低能量體外衝擊波治療是治療足底筋膜炎的有效治療選擇。

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Introduction

Shockwaves are energy waves generated in water medium characterized by rapid expansion and vaporisation. The highly amplified soundwave expands in three dimensions, forming a cone with the maximum pressure at the wave front.[1,2] The attenuation of wave fronts subsequently causes an abrupt rise and fall of air pressure that can causes high tension at the surface of calculus, resulting in structural crack.[1–4] The application of shockwaves was used successfully for the treatment of urinary and biliary calculi in the 1980s but it was not until the 1990s that the use of extracorporeal shockwave therapy (ESWT) was adopted for the treatment of various tendinopathies.[1,2,5]

The exact mechanism by which ESWT relieves tendon-associated pain is not known. It is postulated that shockwaves may have an initial analgesic effect by altering the permeability of neuron cell membranes. A higher stimulus is required to trigger an action potential in the sensory neuron.[1,2,4,5]

Another postulated theory is that ESWT may cause increased blood flow to the treated site and induce an inflammatory-mediated healing process in damaged tendons by disrupting avascular, damaged tissues, and encouraging revascularization, release of local growth factor, and the recruitment of appropriate stem cells to the area.[2,4,6]

Plantar fasciitis is the most common cause of heel pain in the adult population and a small subset of patients has symptoms that are refractory to conservative management for months to years. Patients with such disease typically report a sharp heel pain that is worse on the first step in the morning and towards the end of the day.[7,8] Many studies in the past involving ESWT on plantar fasciitis were highly variable in their study designs and treatment regimens and thus conclusive evidence regarding the optimal treatment protocol is still lacking.[9–18] Most studies involving ESWT on plantar fasciitis employ high-energy shockwaves that are believed to have a higher clinical efficacy. However, the associated discomfort in high-energy ESWT often requires the use of local anaesthesia that could be more cumbersome to the patient.[13,14,18] The present study aims at studying the effect of a low dose ESWT system on plantar fasciitis in a local population.

Methodology

Patients

Patients with clinical diagnosis of plantar fasciitis that have failed conservative management (nonsteroidal anti-inflammatory drugs, stretching exercises, heel pads, and night splints) of at least 3 months were recruited from the specialist clinic of the Orthopaedics and Traumatology unit of Queen Mary Hospital, Hong Kong, between 1 November 2008 and 30 November 2008. For our study, plantar fasciitis was clinically defined as moderate to severe heel pain upon the first few steps in the morning that gets worse with continued weight bearing. The pain and tenderness should be located in the medial tubercle of the calcaneus without obvious signs and symptoms of other differentials of heel pain such as stress fractures, osteomyelitis or hindfoot arthritis. Radiographs of the involved foot were taken for patients whose clinical diagnosis was uncertain to exclude other causes of heel pain. The daily activities are our patients all required walking on level ground, stairs, and slopes for $\geq$1 hour daily. Those who met the specific inclusion and exclusion criteria listed in Table 1 were referred to the Physiotherapy Department of the hospital for assessment of feasibility of treatment.

Informed consent was obtained for all patients who met the inclusion and exclusion criteria, prior to the start of treatment. Possible adverse effects were explained to them.

The machine

The Swiss DolorClast® Classic shockwave therapy system (E.M.S. Electro Medical Systems S.A., Nyon, Switzerland) (Figure 1) was used in this trial study. This is a pneumatically generated ESWT system capable of generating impulses with different working pressures. The working pressure was converted into energy density based on the conversion graph presented in the operation manual of the ESWT unit. A 10 mm radial probe treatment head was used for all patients (Figure 2).

Outcome measures

A 10-point visual analogue scale (VAS) for heel pain was taken before and after each treatment session: while taking the first step in the morning; while doing daily activities (walking on level ground, stairs and slopes, standing); and when applying pressure. Follow-up telephone interviews regarding VAS scores at first step in the morning and during daily activities were conducted at 3 months and 6 months post treatment. The 3-month and 6-month scores were compared to those taken at the end of the fifth ESWT sessions for each individual foot. Any deterioration in VAS scores from either parameter during telephone follow-up was taken as a loss of the initial improvement. The total percentage reduction in VAS scores at the end of five treatment sessions was also calculated as a ratio of change in VAS score divided by the pretreatment

Table 1
Recruitment criteria

Inclusion criteria	Exclusion criteria
Age >18 y	Rheumatoid arthritis or systemic diseases
History of plantar heel pain for >3 mo	Diabetes mellitus or metabolic diseases
Failed conservative treatment including physiotherapy treatment	Tendon rupture
	Neurological or vascular diseases
	Hyperthyroidism
	Active malignant disease with or without metastases
	Osteomyelitis
	Chronic infections
	Systemic long term use of steroid
	Underlying immunocompromised disease
	Severe respiratory or cardiac disease
	Pregnancy
	Use of warfarin
	Previous surgery around treatment area
	Severe respiratory or cardiac disease
	Unsuccessful prior extracorporeal shockwave therapy

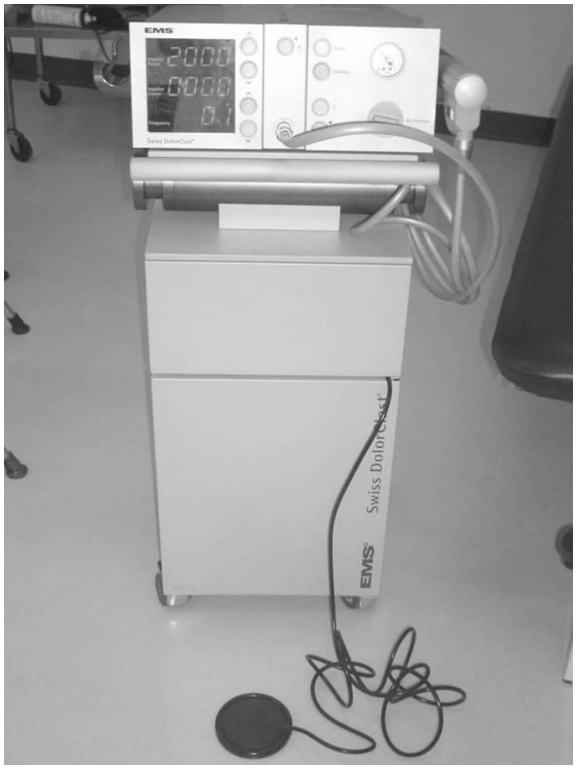

Figure 1. The Swiss DolorClast® Classic shockwave therapy system.

baseline VAS value. In categorising degree of improvement amongst our patients, they were arbitrarily divided into four groups based on percentage of VAS reduction after five treatment sessions: mild improvement (0–20%); moderate (21–40%); good (41–60%); very good (61–80%); and excellent (81–100%).

The treatment regimen

All patients received a total of five treatment sessions by a trained physiotherapist in each session. Each patient was asked to lie in the prone position with a pillow supported under the abdomen and the heel. The area with maximal tenderness was localized by palpation and marked with an "X" by a pen. ESWT was then directed to this area of maximal tenderness (Figure 3). Ultrasound gel was used as the coupling medium between the head and the patient. The patients were asked to rank their pain level

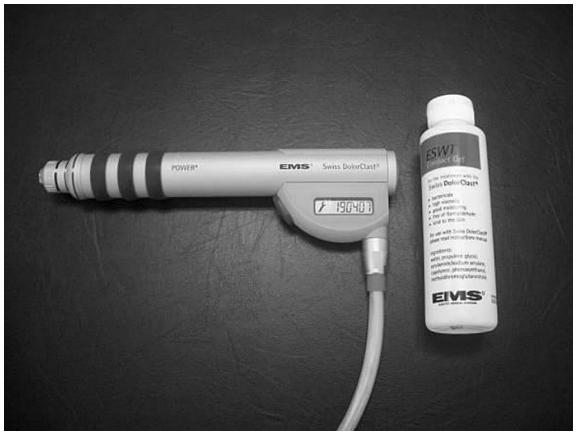

Figure 2. The 10-mm treatment head and gel: E.M.S. Power + Handpiece.

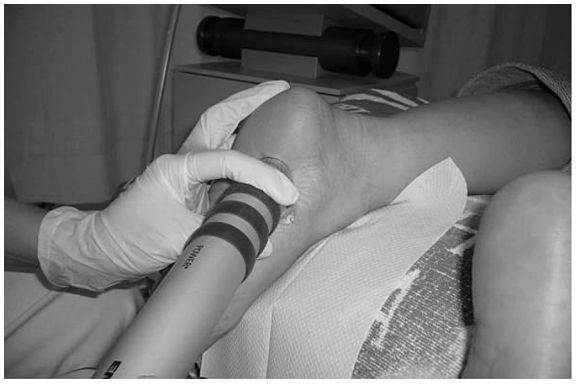

Figure 3. Treatment head directing towards the most painful site.

according to the VAS corresponding to the three parameters by our physiotherapist before and after each treatment sessions and their scores were recorded.

Each patient received a total of 2000 impulses to their symptomatic foot (4000 impulses in bilateral cases) in each session of treatment with an air pressure of 0.8–2.0 Pa, which is equivalent to an energy level of 0.08–0.16 mJ/mm^2. During the first treatment session, around five discrete impulses were given to each patient as a trial. If no adverse effect was experienced, the remaining 1995 impulses were then administered in a continuous fashion with a frequency of 8 pulses/s interrupted by three brief periods of rest after every 500 impulses (1st rest period after 495 impulses). The treatment probe was redirected towards the most painful area during each rest period. Treatment sessions were given 3–7 days apart. No local anaesthesia was given before any sessions for any patient.

Statistical analysis

All statistical analyses were performed using SPSS for windows (version 15.0; SPSS Inc., Chicago, IL, USA) and Microsoft Excel. The average reductions in pain score and their respective percentage reductions after each ESWT sessions were calculated.

Results

Sixteen patients with 21 diseased feet meeting our inclusion and exclusion criteria were recruited. They have all had symptoms of plantar fasciitis for at least 3 months that have failed to resolve by various conservative treatment modalities. The majority of our patients were female (11:5) and their age ranged from 35 years to 71 years (mean age 54 years). They had all successfully undergone five sessions of ESWT according to our treatment protocol.

The average pain score for the first step in the morning showed a stepwise improvement after every treatment session, and the mean reduction of VAS scores in all our symptomatic feet after five sessions was 2.62, averaging a 44.3% improvement (Figure 4). The mean VAS score for pain on daily activities also showed a similar decline in pain scores after each treatment session, with a comparable reduction of mean VAS score of 3 or 38.3% equivalent at the end of five treatment sessions (Figure 5).

On a slightly more objective assessment of the heel pressure test, there was also a consistent trend of pain reduction immediately after every treatment session (Figure 6). The mean reduction of VAS pain score across each treatments was 1.6 (36.8%).

Concerning the distribution of different percentiles of improvement on daily activities and on heel pressure test, moderate to excellent reduction of localized heel pain was observed in the

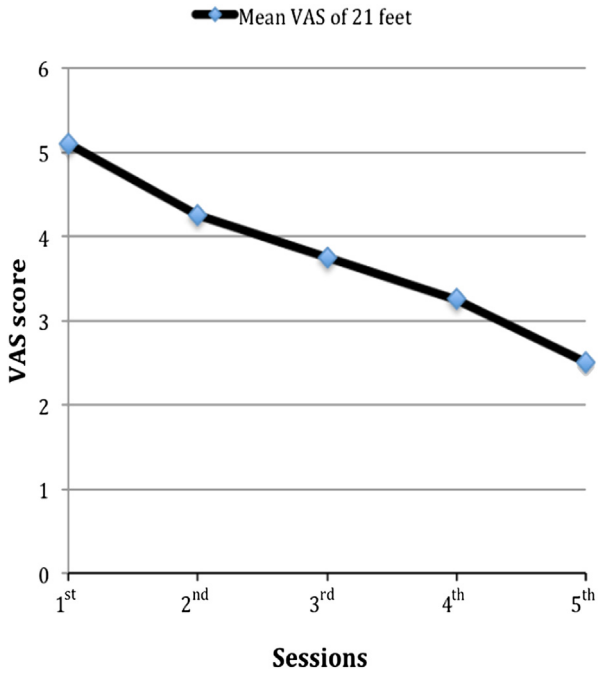

Figure 4. Pain improvement on first step in the morning. Mean visual analogue scale reduction of 2.62 (44.3%) after five sessions.

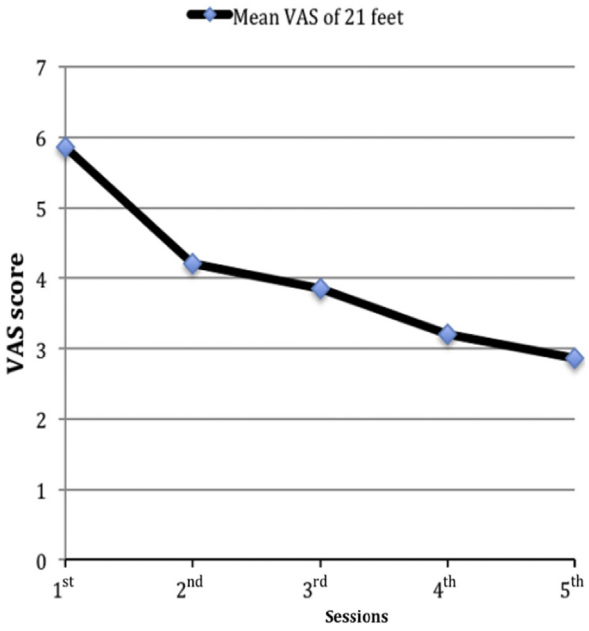

Figure 6. Pain improvement on heel pressure test. The mean visual analogue scale reduction was 1.6 (36.8%) after five treatment sessions.

majority of our studied sample. With 71.4% ($n = 15$) of the total number of feet showing improvement in the moderate to excellent categories ($\geq$21% in reduction of VAS scores) for pain on the first step in the morning and on the heel pressure test, and 61.9% ($n = 13$) of the total number of feet showing improvement for pain on daily activities.

Telephone interviews conducted as early as 2 weeks post-treatment revealed a mean improvement in VAS score by 42.3% in terms of pain at first step in the morning and on daily activities across all 16 patients in all their symptomatic feet (minimum improvement of 10% and a maximum of 90%).

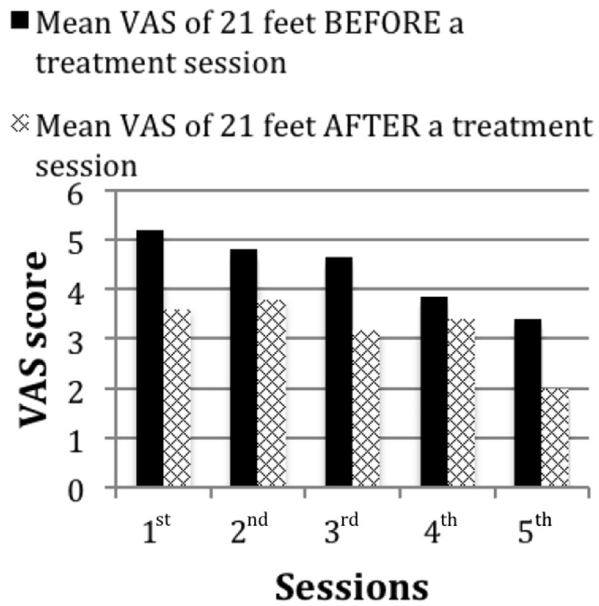

Figure 5. Pain improvement on daily living. Mean visual analogue scale reduction of 3 (38.3%) after five treatment sessions.

In terms of assessing the longer-term efficacy via our telephone follow-up, 66.7% ($n = 14$) of the total number of feet was able to maintain the post-fifth session VAS score at 3 months, while 23.8% ($n = 5$) deteriorated (Figure 7). Of the group able to maintain their initial improvement at 3 months, three diseased feet lost the initial improvement at 6 months, while 11 went on to maintain the initial improvement at 6 months (52.3% of total number of symptomatic feet). One patient with bilateral symptomatic feet was lost to follow-up at 3 months. No adverse effect was reported by any patients in our study.

Discussion

Plantar fasciitis is the most common cause of heel pain, and an estimated 10% of the population develops this condition throughout their lifetime. The aetiology of plantar fasciitis is poorly understood.[7] Proposed pathological processes including thickening

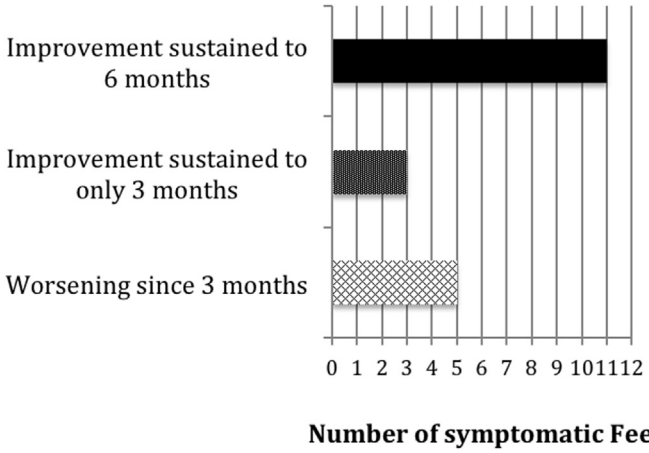

Figure 7. Maintenance of improvement in 3 months and 6 months: 3 months, 66.7% ($n = 14$) and 6 months, 52.4% ($n = 11$).

of the proximal fascia, decreased vascularity, peritendinus inflammation, loss of normal elasticity, and alteration of nociceptor physiology all may play roles in the development of this disorder.[8] Common studies attribute plantar fasciitis to a fascial degenerative disorder rather than an active inflammatory cause.[8] Associated risk factors for such condition are female sex, obesity, limb-length discrepancy, pronated foot type, and prolonged weight bearing at work.[7,19–21]

Plantar fasciitis is self-limiting and 90% of the cases are curable by conservative means such as orthotics, night splints, nonsteroidal anti-inflammatory medications, and stretching exercises.[7,8] However, due to the lack of strong supportive evidence, there is currently no standard treatment protocol for plantar fasciitis.[12,18,22,23] Cases that are recalcitrant to treatment often lead to dissatisfaction, particularly for athletes.

For recalcitrant plantar fasciitis, surgical release of the plantar fascia remains the last resort and its usually considered after 6–12 months of unsuccessful treatment. However, success rate is variable and often associated with surgical morbidities and time loss from work.[24–26] For such reasons many patients have to live with the burden of pain in cases of failed treatment of plantar fasciitis.

An alternative noninvasive treatment modality for plantar fasciitis is the use of ESWT. The application of ESWT in musculoskeletal conditions was first popularized in Europe in the 1990s for conditions such as shoulder tendinitis, tennis elbow, followed by fracture nonunions, and plantar fasciitis.[1,2,4,5] The device is a derivative of devices similar to that used for lithotripsy and relies on delivery of shockwave energy in soft tissues to produce its clinical effect. There are currently four different groups of devices (electrohydraulic, electromagnetic, piezoelectric, and pneumatic) with different methods of shockwave generation that can potentially result in different clinical efficacies.[1,4,23] The exact mechanism by which ESWT reduces pain for recalcitrant plantar fasciitis is poorly understood but many have postulated it to be due to mechanisms such as tissue neovascularization induction, nerve conduction modulation through impact on membrane permeability, and activation of endogenous opioid system.[1,2,6,27,28] As an alternative to surgery for recalcitrant plantar fasciitis, ESWT has the advantage of offering comparable success rate in a much shorter recovery time and minimal risks.[5,23,24]

Since the late 1990s, different case control and randomized controlled trials of ESWT on recalcitrant plantar fasciitis were conducted with different degrees of success. Maier et al[29] found excellent to good results based on the modified Roles and Maudsley's score in 36 out of 48 heels in their series at 29 months. While another prospective series published in 2000 reported that 33 out of 41 patients with recalcitrant plantar fasciitis were either symptom free or significantly better at 12 weeks after treatment with ESWT.[30] In 2002 Ogden et al[18] performed one of the first randomized double-blinded case controlled studies on ESWT for plantar fasciitis. The study involved 119 patient in the treatment group and 114 in the control group. After a single application of high energy ESWT, successful result was found in 47% of the treatment group vs. 30% of the control group.[18] This study had then paved the way for the approval by the Food and Drug Administration for the use of ESWT on plantar fasciitis. Although there is a trend from most studies suggesting the use of a higher energy of ESWT (i.e., $\geq$0.2 mJ/mm^2) in more frequent sessions (i.e., $\geq$3 sessions)[5,11,14,16–18,31] in order to achieve a better outcome, much debate today still exists regarding the optimal treatment protocols in terms of energy density, energy dosage, number and frequency of treatment sessions. The heterogeneity in study designs and outcome measurements makes any comparisons difficult, thus quality evidence of ESWT on plantar fasciitis is still lacking.

Our study showed that ESWT is able to reduce the pain caused by plantar fasciitis. The most irritable symptoms, the pain over the heel in the first step in the morning, is significantly reduced after the treatment was started. The average magnitude of pain reduction in all our measured categories ranges from 38.6% to 44.3%, which is similar to the magnitude of pain reductions reported in established studies.[11,12,14,16,18,29,31,32] However, direct comparison of our findings to major studies is difficult at this point without the use of similar scoring systems such as Roles–Maudsley and Foot Functional Scores. Another observation among our patients is the window of clinical durability of ESWT. Although the majority of our patients (66.7%) were able to maintain their clinical improvement by 3 months, the percentage dropped to 52.3% by 6 months. One possible reason for this *wearing off* effect of the initial improvement may be the regeneration of sensory fibres as early as 3 weeks in an animal study after treatment with ESWT.[33,34] As one postulated mechanism of ESWT on plantar fasciitis relief is through sensory nerve degeneration, any nerve regeneration could certainly nullify the initial analgesic effect. Another reason for the *wearing off* effect could be explained by angiogenesis model in an animal study by Wang et al[35] in 2002. In their study involving dog Achilles tendon, they were able to demonstrate an increase in certain medicated growth factors and neovessels, which peaked at 4 weeks and declined after 12 weeks.[35] This concurs with the findings in our studies that the majority of our patients were able to retain the analgesic effect in 3 months but a portion of them regressed as time lapsed to 6 months. If angiogenesis in the plantar fascia is crucial to the alleviation of symptoms in plantar fasciitis, then any loss of this affect after a predictable time lapse will lead to recurrence of symptoms.

Although ESWT has been slowly gaining acceptance for the use of plantar fasciitis, the upfront and maintenance cost of the machine could be an obstacle to many who will question its cost/benefit effectiveness. As with any new technique, the initial cost of treatment would be high, which we would expect to generally decrease over time as it becomes more widely utilized. Since the cost-benefit effectiveness is variable in terms of patient load and all hidden cost must be accounted for in evaluating the cost/benefit ratio, it is not within the scope and not the aim of this study to perform such an analysis. However, future studies on cost effectiveness of ESWT may prove to be valuable from an administrative standpoint. Although we cannot demonstrate a curative effect of ESWT on plantar fasciitis, as only 52.4% of the patients in our study were shown to have a sustainable analgesic effect at 6 months, it is nevertheless shown to be a viable form of treatment for symptomatic control in plantar fasciitis. Furthermore, most our patients including those who deteriorated at 6 months were generally satisfied with the initial improvement and indicated that they would prefer additional ESWT treatments again if offered the chance.

As opposed to high-energy shockwaves that have been used in most studies, we believe that the low-energy shock waves used in our study are effective in symptomatic alleviation of plantar fasciitis, with the advantage of minimizing side effects such as patient discomfort, erythema, periosteal detachment, and even small fractures that have been reported.[1,2]

Aside from the small sample size and short follow-up period, other limitations of our study were the lack of a control population and the use of more objective pain and functional assessment scores described above, which would allow for a more direct comparison to results from major trials. In addition, the possibility of selection bias could be introduced in our study when a 3-month instead of a 6-month cut-off period of threshold was used as a recruitment criterion for selection of patients who had failed prior conservative treatments. Plantar fasciitis typically resolves in

6–18 months, and an earlier cut-off time-line for recruitment in our study could introduce a self-improvement effect, enrolling patients with symptoms that would otherwise improve with time. However, as surgical release for plantar fasciitis is usually not considered until at least 6 months of failed treatment (i.e., recalcitrant cases), the use of ESWT can help patients alleviate symptoms and reduce the chance of development into recalcitrant cases that may in turn require more invasive treatment. Although radiographs were obtained for most of our studied patients, another improvement in our study would be to obtain radiographs for all patients during recruitment, as it is necessary and good clinical practice to exclude other conditions of heel pain thoroughly before properly diagnosing and initiating the treatment of plantar fasciitis. In terms of outcome measurement, the use of VAS score alone in our case in our assessment criteria certainly has its limitations as it is often considered nonlinear and subjective, opening the possibility of recall bias. However, the VAS is a simple measurement especially for the elderly and has been validated as a reliable measurement for pain in musculoskeletal disorders. Although almost all of our patients with documented VAS improvement were satisfied with the outcome, the addition of other assessment tools such as the Roles–Maudsley score, Foot Functional Index, and SF-36 health survey can certainly be considered in future studies for a more comprehensive outcome measure, as such tools can allow for better assessment of symptomatic improvement and overall level of patient satisfaction than VAS score alone.

Conclusion

Our study has illustrated the positive efficacy of ESWT in treatment of plantar fasciitis. The use of low energy pneumatic ESWT over five sessions of 2000 impulses of 0.16 mJ/mm^2 appears to be a safe alternative to other conservative modalities in symptomatic control of plantar fasciitis. Its use demonstrated a time-dependent relationship with an effective durability period, with an early positive clinical effect seen as early as 2 weeks in the majority of the symptomatic feet that can be sustained to at least 6 months in 52.4% of our series. The positive results of our study support its use as a viable noninvasive treatment modality for plantar fasciitis and may reduce the chance of development of recalcitrant plantar fasciitis.

Conflicts of interest

All authors declare no conflicts of interest.

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