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Research article

One Session of Extracorporeal Shockwave Therapy-Induced Modulation on Tendon Shear Modulus is Associated with Reduction in Pain

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Abstract
The aim of the study was to examine the immediate effect of 1 session of extracorporeal shockwave therapy (ESWT) on patellar tendon stiffness and to explore the relationship between the change in tendon stiffness and the pain intensity. Thirty-four male athletes aged 22.2 ± 3.8 with patellar tendinopathy were recruited. The participants were randomized into ESWT and sham groups. The ESWT group received 1500 impulses of ESWT at 4 Hz with maximal tolerable pain intensity and the sham group received intensities below 0.08 mJ/mm^2. Supersonic Shearwave Imaging (SSI) was used to measure tendon shear modulus (an index of tissue stiffness), and a visual analogue scale was used to quantify the pain intensity during compression with 10 lb (4.535 kg) pressure directed on the most tender part and then during a single-leg declined-squat test. A significant reduction in tendon shear modulus (from 57.4 ± 25.5 kPa to 40.6 ± 17.6kPa, $p = 0.001$) was detected in the ESWT receiving ESWT with an intensity from 0.13 - 0.33 mJ/mm^2 but not the sham group (from 47.7 ± 17.1 kPa to 41.0 ± 12.7 kPa; $p = 0.06$). In the ESWT group, the change in tendon shear modulus was associated with the change in the intensity of pain during single-legged declined-squat test ($\rho = 0.55$; $p = 0.023$) but not pressure pain ($p > 0.05$). These findings suggest that one session of ESWT induces reduction of tendon stiffness in volleyball and basketball players with patellar tendinopathy. The reduction in tendon stiffness is associated with reduction in pain during single-legged declined-squat test.

Key words: Tendon shear modulus, extracorporeal shockwave therapy, patellar tendinopathy, single-leg decline squat test.

Introduction

Patellar tendinopathy (PT) is one of the most common injuries in sports involving jumping (Lian et al., 2005). Clinically, patients complain of pain localized at the proximal insertion of the patellar tendon, particularly during squatting and landing after jumping (Cook et al., 2000). Its prevalence has been reported to be as high as 32% to 45% in athletes involved in jumping sports, (Lian et al., 2005) and the incidence rate is higher in males than females (de Vries et al., 2015). Most importantly, the condition is often prolonged and causes an early cessation of an athletic career (Kettunen et al., 2002).

Extracorporeal shockwave therapy (ESWT) is one of the modalities for reducing pain and improving function in individuals with PT (van Leeuwen et al., 2009; Everhart et al., 2017). Extracorporeal shockwaves are acoustic waves characterized by a high positive peak pressure of short duration followed by a lower-magnitude tensile wave (Rompe et al., 1998). The energy flux density represents the amount of acoustic energy passing through a 1mm^2 area per impulse, ranging from < 0.08 mJ/mm^2 to 0.6 mJ/mm^2. The early prospective cohort study from Rompe et al. (1998) have demonstrated that ESWT induced a significantly greater improvement of function in patients with chronic PT when compared with conservative treatment. However, two recent systematic reviews on the effectiveness of ESWT for PT have contrasting recommendations. Korakakis et al. (2018) commented that ESWT is no better than placebo for subjects with PT. On the other hand, Everhart et al. (2017) regarded ESWT as an effectiveness intervention for PT. The authors also observed a dosage-effect on ESWT-induced treatment efficacy. When applied with an intensity between 0.17 and 0.25 mJ/mm^2, ESWT has shown greater effects on functional recovery than control, (Wang et al., 2007) and has similar effects on pain reduction as injections of platelet-rich plasma at 2 months post-intervention (Vetrano et al., 2013; Erroi et al., 2017). In contrast, when high intensity therapy (0.25 mJ/mm^2 to 0.42 mJ/mm^2) was prescribed, no significant difference in functional improvement was detected between the ESWT and control groups. Taken together, these studies may suggest that the effects of ESWT are dose dependent; and the treatment range is between 0.17 and 0.25 mJ/mm^2. However, Thijs et al. (2017) could not detected better results on pain during declined-squat and function when ESWT was prescribed at 0.20 mJ/mm^2. One possible explanation could be on the difference in activity level between the treatment and control groups. In their study, the type of sports participation between the treatment and control groups was not compared. This is problematic because loading on the patellar tendon would be difference in different sports (Zhang et al. 2015). In order to further elucidate the effectiveness of ESWT, sport participation needed to be one of the controlled factors.

The pain mechanism of tendinopathy is unclear. Pathophysiological changes such as an ncrease in substance P and in-growth of nerves near the neo-vessels; as well as pathomechanical changes such as mal-function in collagen slidings are being proposed as the source of pain associated with tendinopathy (Vasta et al., 2016; Zhang et al., 2011). Recent studies has demonstrated an increase in patella tendon shear modulus (an index of tendon stiffness) in patients with chronic PT than control (Coombes and Tucker, 2018; Zhang et al., 2014) with the amplitude of tendon shear modulus associated with the intensity of activity-related pain in tendinopathic tendon (Coombes and Tucker, 2018). In this connection, the therapeutic effects of ESWT on nerve conduction and vascularization have been

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reported. ESWT was found to induce an improvement of nerve conduction and a faster rate of axonal regeneration on peripheral nerve in rat. (Hausner et al., 2012); as well as an upregulation in vascularization in the Achilles tendon-bone junction on healthy dogs and rabbits (Wang et al., 2002; Wang et al., 2003), and a down-regulation in vascularity in patients with supraspinatus tendinopathy (Notarnicola et al., 2011). ESWT-induced modulation on the mechanical properties of tendinopathic tendon has not been established (Zhang et al., 2014; Wang et al., 2003).

In a recent study, Lee et al. reported a greater decrease in patellar tendon stiffness when ESWT was applied in the initial 6 weeks of an eccentric exercise program (by 29%) than exercise alone (by 12%) (Lee et al., 2020). The group difference, however, was not statistically significant. In this study, tendon stiffness was measured using ultrasound and a dynamometer and such a measurement method could not record localized or regional measurement of tendon properties. Pathology in patellar tendinopathy commonly occurs in the proximal region of the patellar tendon. (Kulig et al., 2013) A question therefore arises whether ESWT could modulate regional tendon stiffness and whether regional modulation on tendon stiffness would be related to symptomatic changes. Such findings would help to explore the mechanical effects of ESWT on the tendon of individuals with tendinopathy.

The primary aim of the present study was to examine the immediate effect of 1-session of ESWT on tendon shear modulus. The second aim was to explore whether the change in tendon shear modulus would associate with the change in the intensity of pain during pressure- and single-legged declined-squat tests. We hypothesized that 1-session of ESWT could reduce tendon shear modulus at the proximal portion of the patellar tendon and the changes in tendon shear modulus would be positively associated with reduction in the intensity of pain in patients with patellar tendinopathy.

Methods

Thirty-four male athletes aged 22.2 ± 3.8 with PT were recruited from the local university and community basketball and volleyball teams. Only males were recruited, because PT is more prevalent in male athletes (de Vries et al., 2015). The sample size was calculated based on the first 5 participants receiving ESWT. The G-power was calculated using pre-ESWT and post-ESWT values of the mean and standard deviation of tendon elastic modulus. Taking alpha at 5% and power at 80%, the estimated sample size per group should be 24. The inclusion criteria were as follows: 1) between 18 and 35 years of age; 2) persistent pain for at least 3 months; 3) maximum intensity of pain in the previous week ≥ 3 using a visual analogue scale (VAS) with 0 as no pain and 10 as the worst pain; 4) Victorian Institute of Sport Assessment-patellar score (VISA-p) less than 80; 5) pain and tenderness on palpation in the inferior pole of the patella or during a loading test using single-leg squatting or jumping (Zwerver et al., 2010); and 6) thickening of the proximal part of the patellar tendon with areas of hypoechoic signals (Kulig et al., 2013). Exclusion criteria were history of corticosteroid injection and previous surgery to the lower limb. All recruited patients were physically screened by an experienced sports physical therapist with 13 years of clinical experience. Ultrasound imaging was captured by a second physical therapist with 3 years of experience of ultrasound scanning after attending a certified musculoskeletal ultrasound course. The present study was approved by the Human Subjects Ethics Sub-committee of the administrating institution, and all participants gave their written informed consent before the study. All procedures adhered to the Declaration of Helsinki.

Figure 1 shows the study flow diagram. After collection of demographic information such as age, weight, height as well as sports-related information on training hours per week. Participants were randomized into treatment and sham groups. A simple randomization procedure was performed using sealed identical non-opaque envelopes marked inside with “ESWT” or “sham”. After picking up an envelope, the subject handed it to the physiotherapist providing the intervention. The patient did not know the type of intervention. He was informed that the shockwave machine would cause some noise and pain might or might not be provoked. Tendon stiffness before and immediately after the intervention by another physiotherapist who did not know the type of intervention. The test was conducted in a room with room temperature controlled at 25℃.

Supersonic Shearwave Imaging (SSI) was conducted using an Aixplorer® ultrasound unit (Supersonic Imaging, Aix-en-Provence, France) in conjunction with a 50 mm linear-array transducer at 4-15 MHz frequency to measure patellar tendon shear modulus (an index of tissue stiffness) (Zhang and Fu, 2013). The musculoskeletal acquisition mode was used with the temporal averaging (persistence) and spatial smoothing set to medium and 6, respectively. The elastic images were taken at 1 Hz. A single operator (ZJZ) performed all scans to eliminate inter-rater variability. He had attended musculoskeletal ultrasound course and familiarized with the equipment for 3 years before data collection. He was also unaware of the type of intervention.

Participants were examined in supine position with 30° of knee flexion. The knee was supported on a firm towel and a custom-made ankle stabilizer was used to keep the leg in neutral alignment on the coronal and transverse planes. The scanning procedures were adopted from our previous studies (Zhang and Fu, 2013; Zhang et al., 2017). The B-mode was used to place the transducer head aligned in the longitudinal plane with the collagen fibers of the patellar tendon. When a clear image of the patellar tendon was captured, the shear wave elastography mode was then activated. The transducer was placed on the skin with light pressure on top of a generous amount of coupling gel, perpendicular to the surface of the skin. The ultrasound probe was kept stationary, aligned longitudinally with the patellar tendon for 8-12 seconds during the acquisition of the SSI map (Zhang and Fu, 2013; Zhang et al., 2017). Three longitudinal images were captured for the tendon of each knee for off-line analysis. The region of interest was first defined by a rectangular box of 13.5 mm×12.5 mm (the largest size provided by the manufacturer) distal to the apex of the patella and with the patellar tendon located within its center part. The diameter of the Q-box was defined by the thickness of the tendon (Figure 2). Test-retest reliability was conducted in 11 participants on the same day at two sessions with one hour apart. The intra-rater reliability was 0.98 (95% CI: 0.93-0.99) and the minimal detectable difference is 13.7 kPa (Zhang and Fu, 2013).

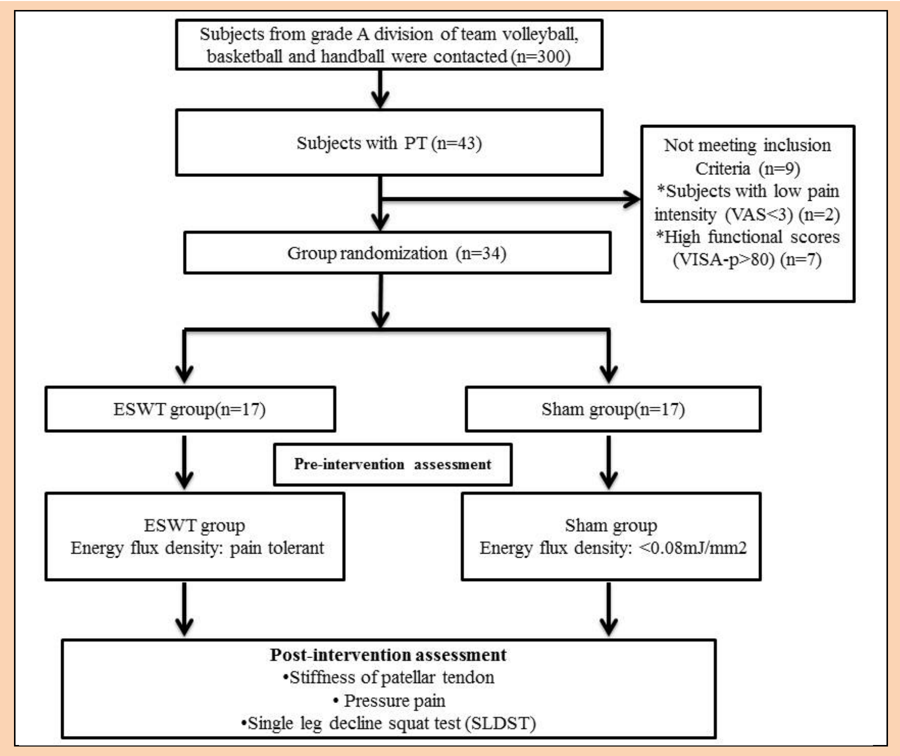

Figure 1. Flow chart of the experimental procedure.

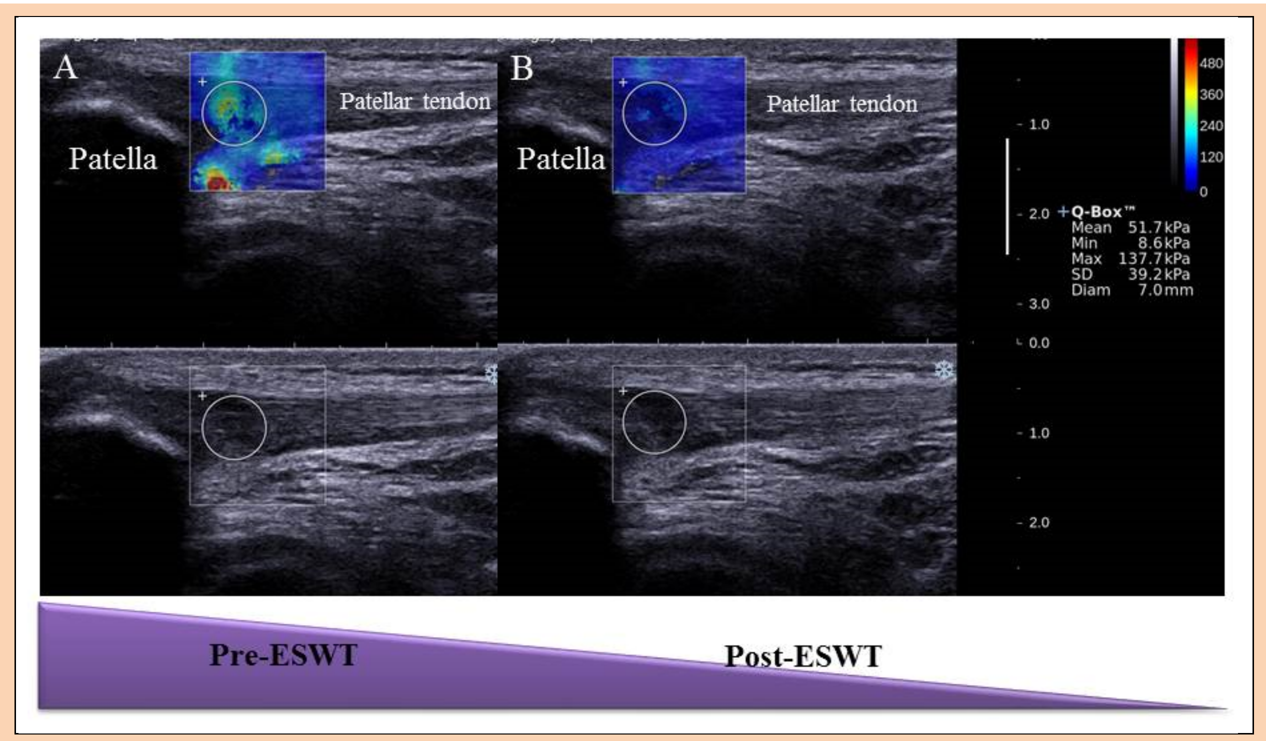

Figure 2. Images of patellar shear modulus at pre-ESWT and post-ESWT. Upper images show color-coded box presentations of patellar tendon shear modulus superimposed on grey scale sonograms of the patellar tendon. Each circle indicate the region of interest and its corresponding shear modulus is demonstrated under the Q-Box on the right. Bottom images represent grey scale sonograms of patellar tendon on the identical scan planes. ESWT denote Extracorporeal shockwave therapy.

Pressure pain was measured by a hand-held algometer (manufactured by pdt, Rome, Italy). Pain was provoked through a rubber disc at the end of the algometer. The participant was placed in a supine position with 30° of knee flexion on a treatment table. The most painful area on the proximal patellar tendon was determined by palpation and then a 10 lb (4.535 kg) force was applied via the algometer onto this area (van Wilgen et al., 2011). The intensity of pain being provoked was reported using a visual analogue scale (VAS) from 0 to 10, with 0 indicating no pain, and 10 indicating the worst pain during testing. The algometer has been demonstrated to have good intra-tester reliability for pain pressure threshold among patients with PT and the intensity of pain captured with a constant pressure can be helpful in the evaluation of clinical interventions (van Wilgen et al., 2011).

The single-leg declined-squat test was conducted after assessment of pressure pain (Kongsgaard et al., 2006; Zwerver et al., 2007). The patient was required to stand on a single leg on a 25° decline board and was instructed to bend the knee until pain was elicited. The magnitude of the first onset of pain was rated using the VAS and referred as activity-related pain.

The ESWT was delivered at a Rehabilitation Clinic by a physical therapist (WCL) with 13 years of clinical experience. The participants were in a supine position with the treated knee supported at 30° of flexion. The most painful site (the same as the pain-pressure measurement site) on the patellar tendon was palpated and marked. Focused ESWT was delivered by a Storz Minilith SL1 lithotrypter machine (Storz Medical, Switzerland) at the marked site at each participant's maximal tolerable pain intensity. Contact gel was applied between the patellar tendon and the applicator to minimize the loss of shock wave energy (Figure 3). In the treatment group, 1500 impulses at maximum tolerable pain were delivered at 4 Hz. (Wang et al., 2007; Chow and Cheing, 2007). Initial 500 impulses was used to determine the maximal_tolerate pain. The EFD was computed according to the conversion table from the manufacturer. An energy level below 0.08 mJ/mm^2 (below the therapeutic energy level of 0.17 mJ/mm^2) was delivered at the same frequency and with the same number of impulses to the sham group. For subjects with bilateral symptoms, the more painful side during the previous 7 days was selected for intervention.

Descriptive statistics (mean and standard deviations) were used to describe the physical characteristics of the ESWT and sham groups, and the outcome variables before and after intervention. The data normality of these variables was assessed using the Shapiro-Wilk test. Independent *t* tests were used to compare the demographic data of the ESWT and sham groups. Repeated measure analysis of variance was used to assess differences on tendon shear modulus with time (before and after intervention), within the 2 groups (ESWT and sham) with type of sports as covariate for the treated leg. With significant interaction between group and time, paired-*t* tests were used for before and after intervention changes in the treated and sham groups. Spearman correlation coefficient tests would be used to assess association between actual and percentage changes in tendon shear modulus and intensity of pressure- and single-legged decline-squat pain in the intervention group. The software SPSS version 17.0 (SPSS Inc, Chicago, IL) was used to perform the statistical analyses.

Figure 3. Set-up of subject and equipment for Extrocorporeal shochwave therapy.

Table 1. Subject characteristics. Values are reported as mean±standard deviation.

Variables	ESWT group (n=17)	Sham group (n=17)	*P* Value
Age, year	21.1 ± 2.2	23.2 ± 4.7	0.108*
Weight, kg	76.6 ± 6.6	72.8 ± 5.8	0.086
Height, m	1.82 ± 0.06	1.79 ± 0.06	0.121
Body mass index, kg/m^2	23.1 ± 1.5	22.9 ± 2.1	0.699
Training intensity, hours/w	5.9 ± 2.7	4.9 ± 2.2	0.244
Training years, y	8.1 ± 2.4	9.5 ± 4.3	0.251
Duration of symptom, months	36.3 ± 21.9	28.1 ± 27.7	0.341
VAS	7.2 ± 1.5	6.6 ± 1.7	0.313
VISA	55.5 ± 14.3	59.3 ± 8.8	0.393

VAS: visual analogy scale; VISA: Victorian Institute of Sport Assessment. *Non-parametric test was used because normality test using Shapiro-Wilk test with p = 0.004.

Results

Figure 1 shows the recruitment procedure. Within 18 months, we recruited 43 participants. Seven participants (VISA-p score > 80) and 2 participants (VAS < 3) were excluded from this study. Therefore, the final number of subjects was 34. The characteristics of recruited participants are reported in Table 1. There was no significant difference in age, BMI, training intensity, and training history as well as duration of PT-associated symptoms between groups (all $p > 0.05$). There were not significant group differences on pre-intervention tendon shear modulus ($p = 0.20$)

In the intervention group, the treatment intensity ranged from 0.13mJ/mm^2 to 0.33mJ/mm^2. The majority (15 out of 17) had treatment intensity below 0.25 mJ/mm^2. The number of participants was 8, 6, and 1 for treatment intensity of 0.13mJ/mm^2, 0.17mJ/mm^2, and 0.22 mJ/mm^2 respectively. In the sham group, the treatment intensity was standardized at <0.08mJ/mm^2.

Significant time (p = 0.00) and time*group effect (p = 0.022) were observed on tendon shear modulus with sport (basketball and volleyball) as co-variate. Post-hoc analysis indicated significant reduction in tendon shear modulus by 26.7%4 ± 19.1% in the ESWT group (p = 0.001) and not significant difference in tendon shear modulus in the sham group by 8.4%4 ± 24.7% (p = 0.06) (Table 2).

A significant positive correlation was found between change in tendon shear modulus and intensity of single-legged declined-squat pain (ρ = 0.55; p = 0.023) (Figure 4a). Percentage change in tendon shear modulus was significantly related to percentage change of intensity of single-legged declined-squat pain (ρ = 0.53; p = 0.028) (Figure 4b). Hence, a greater reduction in tendon shear modulus was associated with a greater reduction in pain when performing single-legged decline squat. Such relationship could not be detected between change in tendon shear modulus and with pressure pain (p > 0.05).

Table 2. **Pre- and post-ESWT patellar tendon shear modulus, pressure pain and activity-related pain. Values are reported as mean± standard deviation.**

		ESWT group (n=17)	Sham group (n=17)
PT shear modulus (kPa)	Pre-ESWT	57.4±25.5	47.7±17.1
	Post-ESWT	40.6±17.6	41.0±12.7
	Mean difference (95% CI)	16.8±16.0	6.7±13.7
	P	0.001	0.06
Pressure pain	Pre-ESWT	7.0±1.4	6.4±2.0
	Post-ESWT	6.2±1.8	5.7±2.2
Single leg declined board pain	Pre-ESWT	5.1±1.6	5.2±2.0
	Post-ESWT	4.5±1.7	4.3±2.0

PT: patellar tendon; MD: Mean difference, ESWT: extracorporeal shockwave therapy.

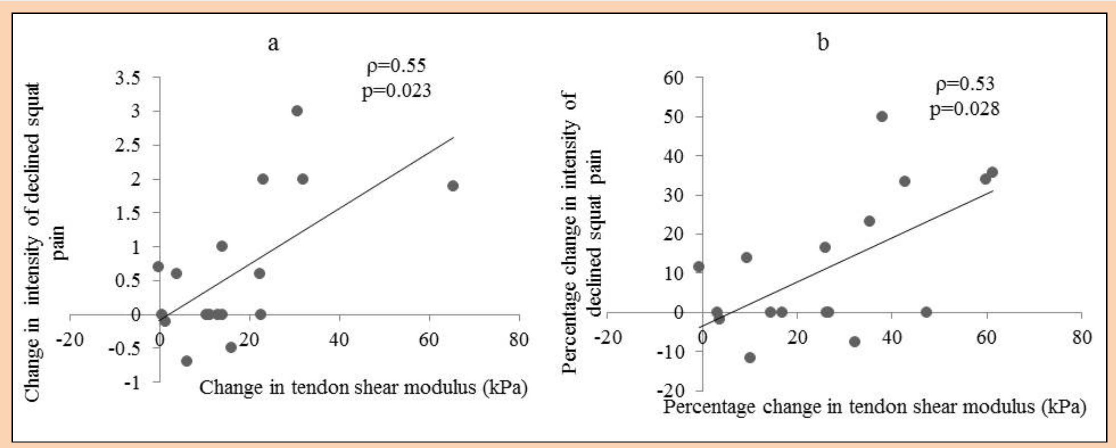

Figure 4. **Significant positive correlation was found between (a) change in tendon shear modulus and intensity of pain during single leg decline squat and (b) percentage change in tendon shear modulus and percentage change of intensity of pain during single leg decline squat test in subjects with patellar tendinopathy after 1-session of extracorporeal shockwave therapy.**

Discussion

Findings from this study indicate that 1-session of ESWT could induce significant reduction on patellar tendon shear modulus (an index of stiffness) in male athletes particiapting in basketball and volleyball. Furthermore, change in tendon shear modulus and pain when performing single-legged declined- squat test are related.

The patellar tendon shear modulus was significantly reduced by 29.5% after 1 session of ESWT. The reduction was greater than the minimal detectable difference (13.7 kPa). Reduction in the sham group was 6.7 kPa (by 8.4%). To our knowledge, this is the first study reporting ESWT-induced significant modulation on tendon stiffness in tendinopathic tendon. Lee et al. (2020) was the first group to explore possible effects of ESWT combined with eccentric exercise on tendon stiffness in athletes involving in jumping sports. The research team used ultrasound with dynamometer that assessed stiffness of the whole tendon and could not detect significant effect of ESWT on tendon stiffness. In this connection, ESWT was prescribed at the most painful spot at the proximal part of the tendon (about 5mm from the inferior pole of the patellar), regional measurement on tendon stiffness might be more sensitive in detecting the intervention effects. In this study, we used shear-wave elastograph to quantify tendon shear modulus (as an index of tendon stiffness) at the proximal patellar tendon. Findings from the current study demonstrated significant reducing in tendon stiffness at the proximal patellar tendon when ESWT was applied at the painful site located at the proximal patellar tendon.

Why ESWT can modulate tendon stiffness? In an animal study, a significant increase in the expression of lubricant was found after 1 session of ESWT. The authors proposed that the mechanical impact or the upregulation of TGF-β1 expression from the extracorporeal shockwaves could stimulate the increase in lubricant expression. An increase in this expression might reduce tendon stiffness when measured at the site where the shockwaves were applied (Zhang et al., 2011). In another animal study, Chen et al. (2004) reported a significant increase in tendon temperature after 1 session of therapeutic ultrasound (acoustic waves) by 5°-8°C. An increase in 3°-4°C could induce an increase in tendon extensibility (Lehmann et al., 1970; Larsen et al., 2005). In a human study, Alegre et al. (2016) reported an increase in patellar tendon stiffness of 25% after the temperature dropped by about 17°C. The authors suggested that cooling-associated increase in tendon stiffness might be related to changes in the intrinsic material properties of collagen fibrils as well as a change of the viscoelastic properties of the tendon's gel-like ground substance. Extracorporeal shockwaves are acoustic waves, and the acute reduction in tendon stiffness after ESWT might also relate to an increase in tendon temperature, similar to that from therapeutic ultrasound. Further research is required to assess the temperature change and its association with tendon stiffness induced by ESWT.

In a cross-section observation study, we found an increase in regional tendon shear modulus at the proximal patellar tendon in athletes with patellar tendinopathy than healthy controls (Zhang et al., 2014). In the pathological group, the tendon elastic modulus was found significantly related to the intensity of self-perceived pain during single-legged declined-squat test. In order to delineate the cause and effect relationship, we conducted pre- and post-ESWT measurements on these two outcome measures. Findings from the present study demonstrated that a reduction in tendon stiffness is associated with a reduction in the intensity of self-perceived pain during single-legged declined-squat test in subjects receiving one session of ESWT. The relationship between tendon stiffness and activity-related pain is further substantiated.

ESWT is a modality for reducing pain and improving function for patients with PT that might be dose dependent. Based on a systematic review on the effectiveness of extracorporeal shockwave therapy in common lower-limb conditions, Korakakis et al. (2018) concluded that ESWT-induced insignificant effects in pain scores, and patient-rated pain reduction at short and mid-term follow-up on patellar tendinopathy. The authors, however, pointed out that such results might associate with a non-linear dose-response relationship for ESWT. In an earlier review paper, Everhart et al., (2017) observed that significant effects of ESWT on pain reduction was reported in studies using energy flux density between 0.17 – 0.25 mJ/mm^2. Treatment dosage seems to be one of the determining factors that depends on energy flex density and number of shocks. The optimal treatment dosage, however, has not been decided, and the most effective protocol has not been established (Everhart et al., 2017). The recommended treatment dosage from the International Society for Medical Shockwave Treatment was below 0.25 mJ/mm^2 for 1000-2400 impulses for 1-5 sessions. In this study, the maximum tolerable pain was used as the criteria for treatment intensity and the number of shocks was standardized at 1500 impulses. Findings from this study indicated that majority (88%) of patients received treatment intensity within the recommended treatment dosage. Aside from treatment dosage, demographic background relating to tendon loading is another factor to be considered. Thijs et al. (2017) found not significant effects of ESWT on pain and VISA-P score in subjects participating in a variety of sports. Our group has reported significant difference on tendon stiffness among healthy sedentary, athletes participating in volleyball and basketball games (Zhang et al. 2015). It is important to include sport as one of the co-variate when assessing the efficacy of ESWT.

Limitations

This study aimed to evaluate the acute effects of 1 session of ESWT. Long-term follow-ups are also important in assessing the treatment efficacy of ESWT. A minimum of 3 months is generally used in assessing the treatment efficacy of ESWT. The cumulative effects of ESWT on tendon stiffness and their relationship with treatment efficacy is another issue to be explored. It is not known whether the reduction in tendon stiffness would be increased with repeated applications of ESWT. Further research is suggested to examine the cumulative effects of ESWT and the treatment efficacy. Secondly, all of the athletes were suffered from pain at the proximal region where ESWT was applied. Findings from this study might not be generalized to other regions of patellar tendon. Male athletes were recruited for this study because PT is more prevalent in male athletes (de Vries et al., 2015). Findings from this study cannot only be generalized to the females because of the morphological differences between the two genders.

Conclusion

We conclude that a single session of ESWT induced significant reduction in tendon stiffness. A reduction in tendon stiffness is associated with a reduction in self-perceive pain during the single-leg decline squat test. Such findings suggest ESWT-induced modulation of tendon mechanical properties and activity-related pain are related in male athletes with patellar tendinopathy.

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Key points

- One session of ESWT induced a reduction in tendon stiffness among athletes with PT.
- The reduction in tendon stiffness is related to self-perceived pain
- Such findings may be one of the mechanisms of ESWT for treating PT.

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