

No difference in effectiveness between focused and radial shockwave therapy for treating patellar tendinopathy: a randomized controlled trial

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Abstract

Purpose The aim of the study was to compare the effectiveness of focused shockwave therapy (FSWT) and radial shockwave therapy (RSWT) for treating patellar tendinopathy.

Methods Patients were randomized into two groups. One group received three sessions of FSWT, and the other group received three sessions of RSWT. Both groups also received an eccentric training programme. Follow-up measurements took place 1, 4, 7 and 14 weeks after the final shockwave treatment. The primary outcome measure was the Victorian Institute of Sport Assessment-Patella (VISA-P) questionnaire. Secondary outcome measures were pain during ADL, sports activities and the decline squat.

Results Forty-three subjects (57 tendons) were included in the study. Twenty-one subjects (31 tendons) received FSWT, and 22 subjects (26 tendons) received RSWT. Both groups improved significantly on the VISA-P score, but there were no differences in improvement between the FSWT group (15 points on the VISA-P) and the RSWT group (9.6 points, n.s.). This was also the case for the secondary outcome measures.

Conclusion There were no statistically significant differences in effectiveness between FSWT and RSWT. It is therefore not possible to recommend one treatment over the other on grounds of outcome. Both groups improved

significantly, although it is questionable whether this difference is clinically relevant.

Level of evidence II.

Keywords Patellar tendinopathy · ESWT · Randomized controlled trial · Jumper's knee

Introduction

Patellar tendinopathy is a chronic knee injury that is often therapy resistant [8, 10]. Conservative and surgical treatments of patellar tendinopathy are not always successful; hence, new treatment options are being developed [9]. One of these treatments is extracorporeal shockwave therapy (ESWT). A systematic review of the literature concluded that ESWT is a safe and promising treatment for patellar tendinopathy, but that further research was necessary, especially as different shockwave devices were used [22]. The review identified seven studies, six of which used a traditional focused shockwave device. The remaining study used a radial shockwave device, a technology that has been introduced more recently [12]. One might expect a difference in effectiveness since there are differences between the technologies of FSWT and RSWT [18]. As described elsewhere, waves for FSWT can, depending on the device, be generated by means of electrohydraulic, electromagnetic and piezoelectric mechanisms [15]. In all three generation methods, a wave is generated in water inside the applicator (in this case by means of an electromagnetic mechanism), and this wave is subsequently focused by a lens and transmitted into the tissue. Waves for RSWT are generated by accelerating a projectile, by means of compressed air, through a tube, at the end of which it hits an applicator that makes contact with the skin. Because of

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these differences in generation, there are important differences between the waves that each technology produces. First, radial shockwaves have a more superficial effect, as the maximal energy is reached at the skin, compared to focused shockwaves which reach a maximal energy in the focus that is located deeper into the body tissues [14]. Second, it has been shown that pressure waves generated by RSWT from a fundamental point of view cannot be called shockwaves because they lack the characteristic physical features of shockwaves such as a short rise time, a high peak pressure and nonlinearity [3].

Like most clinical effect studies, *in vitro* studies looking at the effects of ESWT on tissue also most often use focused shockwave devices. However, in sports medicine and physical therapy clinics in the Netherlands, radial shockwave therapy (RSWT) is used to treat patellar tendinopathy by far more practitioners (in a ratio of 4:1) than focused shockwave therapy (FSWT) [20]. This may be related to the fact that these devices are more affordable. There is thus a discrepancy between the results of scientific research on treating patellar tendinopathy with ESWT, which is mostly based on studies with FSWT, and clinical practice, where the use of RSWT is more common. The aim of this study is therefore to fill this gap by comparing the effects of FSWT and RSWT for the treatment for patellar tendinopathy.

Materials and methods

The TOPSHOCK study was a randomized controlled trial with blinded outcome assessors and blinded participants and a follow-up of 14 weeks, conducted in the Netherlands (trial number NTR 2774). The study took place at the Center for Sports Medicine of University Medical Center Groningen between May 2010 and October 2011. Approval was obtained from the local medical ethics committee (Number 2009/322) prior to the study. Participants provided verbal and written informed consent before the study. A complete description of the study protocol has been published before [21].

Population

Subjects who visited the Sports Medicine Center of University Medical Center Groningen and were diagnosed there with patellar tendinopathy by experienced sports medicine specialists and were asked to participate in the study. Subjects aged between 18 and 50 were regarded eligible if they reported a history of pain in the patellar tendon or its insertions in connection with training and/or competition. These symptoms had to be present for at least 3 months, there had to be palpation tenderness of the patellar tendon,

and the VISA-P (Victorian Institute of Sport Assessment-Patella) score had to be below 80 points. The diagnosis was primarily based on history and clinical examination; however, in case of doubt with regard to diagnosis, imaging techniques such as radiographs, ultrasound and MRI were used to rule out other knee pathology or increase the likelihood of patellar tendinopathy. Acute knee or patellar tendon injuries, chronic joint diseases and other coexisting knee pathology, knee surgery or injection therapy in the preceding 3 months, daily use of drugs with a putative effect on patellar tendinopathy (e.g. non-steroid anti-inflammatory drugs) or use of anticoagulants were reasons to exclude subjects.

Treatment

An independent researcher from another department did a computerized randomization of participants to one of the treatment groups to receive either FSWT or RSWT, both in combination with personally instructed eccentric decline board training. Treatment allocation was concealed from the subjects and the outcome assessors at all times during the trial. Shockwave treatment was applied with a Storz Duolith SD1 (Storz Medical AG, Tägerwil, Switzerland) that can deliver both (electromagnetic) FSWT and RSWT. Both groups received three ESWT sessions from the same physical therapist (M.H.) with a 1-week interval. During each session, 2,000 pulses were delivered at 4 Hz and an intensity of 0.12 mJ/mm² to the FSWT group and at 8 Hz and an intensity of 2.4 bar to the RSWT group. The intensities that were used during FSWT (0.12 mJ/mm²) and RSWT (2.4 bar) were comparable (personal communication with manufacturer, May 2010). If both legs of subjects were treated, they received the same treatment for both legs.

All subjects performed an eccentric exercise programme that started 2 weeks after the final ESWT treatment. This programme consisted of performing single-leg squats on a decline board and was based on the recommendations of Visnes et al. [24]. Three sets of 15 repetitions twice a day for 5 days a week had to be performed. Subjects received instructions on how to execute the exercises. They were advised to experience some pain, around 4 on a visual analogue scale (0 = no pain, 10 = worst pain ever), during the execution of the squats. If less pain was experienced, they were advised to increase the load by using a backpack with extra load. Subjects were advised to reduce sports activities during the treatment period and the first weeks after treatment.

Measurements

Primary outcome was improvement on the VISA-P questionnaire at the final follow-up [23, 26]. This questionnaire asks for pain, function and sports participation in subjects with patellar tendinopathy and is a measure of the severity

of patellar tendinopathy and is a reliable instrument with good test–retest reliability [26]. The score on the VISA-P questionnaire ranges from 0 to 100 points, with 100 points indicating complete symptom-free sports participation. The questionnaire was completed at baseline and 1, 4, 7 and 14 weeks after the final treatment. Secondary outcome measures were VAS pain score (ranging from 0.0 to 10.0) during ADL, during sports activities and during the decline squat and the subjective rating of improvement. These secondary outcome measures were collected 7 and 14 weeks after the final treatment, because subjects visited the clinic at these moments and physical tests could be administered. Subjects completed the VISA-P questionnaire at 1 and 4 weeks at home. Pain experienced during the ESWT treatment was also measured using a VAS pain score. All outcome measures were collected by blinded outcome assessors. Subjects also completed a Web-based logbook in which they reported the number of training sessions and matches they participated in as well as their compliance with the eccentric exercise programme.

Statistical analyses

Analyses were performed according to the intention-to-treat principle (last observation carried forward), using SPSS, version 18. Group means of VISA-P and VAS scores were calculated with an accuracy of one decimal. Generalized estimating equations (GEE) analyses were performed on the continuous outcome variables. With this method, it is possible to control for within-subject correlated data, as is the case for subjects that had treatment for both legs. Covariates included in the analyses were: duration of symptoms, hours of training during the first 5 weeks of the study, number of match events during the first 5 weeks of the study, number of days per week that the eccentric training programme was performed, and the baseline value of the dependent variable. Chi-square tests were performed for discrete variables. Baseline, treatment and logbook data were analysed using independent sample *t* tests.

Sample size was calculated based on the VISA-P score 12 weeks after the last ESWT treatment. A difference in the VISA-P score of 15 points at the end of the study (14 weeks) was considered to be clinically relevant. Based on a previous study of Lian et al. [11], a baseline score of 64 points was expected in symptomatic subjects with an SD of 19 points. With a power of 80 % and an alpha of 5 %, 28 tendons per group were needed to detect a clinically relevant difference.

Results

Forty-three subjects (57 tendons) were randomized over the two treatment groups (Fig. 1). Bilateral symptoms were

present in 14 subjects. Characteristics of the study population are shown in Table 1. One subject dropped out of the study after the first follow-up. One subject (FSWT) received an injection with corticosteroids in the tendon at his own request, after being told of the risks and side effects. Another subject (RSWT) received an injection with corticosteroids in the infrapatellar bursa. Both injections were given between the last treatment and the final follow-up. For these two subjects, the values of the last measurement before the injection were carried forward. For three subjects, the ESWT protocol had to be adjusted because they could not tolerate the pain (Fig. 1). In the FSWT group, one subject received all three treatments at an intensity of 0.07 mJ/mm² instead of 0.12 mJ/mm², and for one subject, the intensity was adjusted to 0.10 mJ/mm² but only during the first treatment, whereas the second and third treatments were given at an intensity of 0.12 mJ/mm². For one subject in the RSWT group, the intensity was adjusted during the first treatment from 2.4 bar to 1.8 bar. Treatments 2 and 3 were administered according to the protocol. All participants were included in the analyses (intention-to-treat).

Primary outcome measure

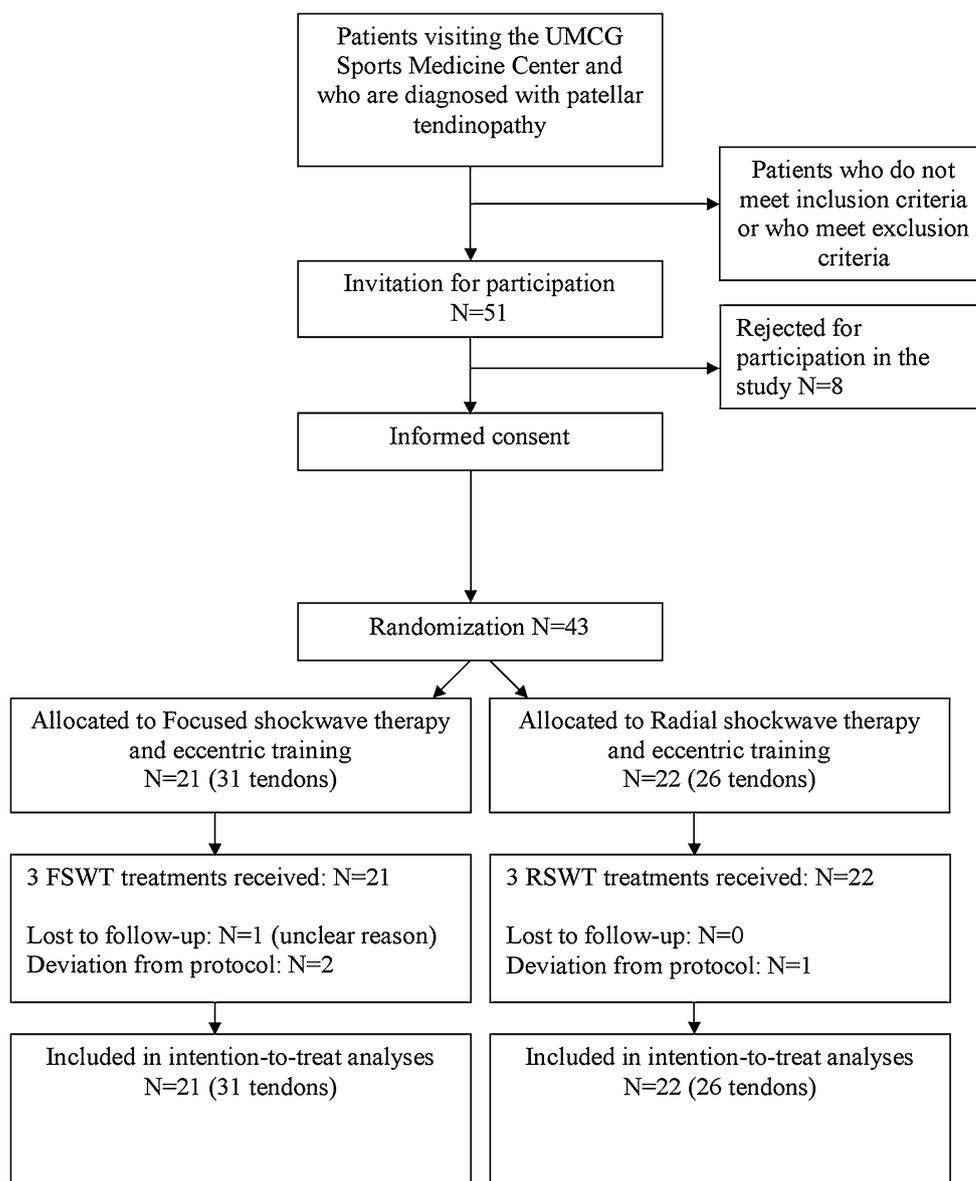
There was no difference between treatment groups in improvement on the VISA-P questionnaire after 14 weeks (n.s.) or any other follow-up time point. The main analysis showed that the FSWT group (15 points) as well as the RSWT group (9.6 points) improved significantly on the VISA-P questionnaire ($p < 0.01$; Table 2).

Secondary outcome measures

There were no significant differences in the amount of improvement on pain during ADL, pain during sport and pain during performance of the decline squat between treatment groups (Table 2). Both groups improved significantly over time on these measures. There was no difference between the FSWT and the RSWT group in the percentage of subjects that indicated improvement of symptoms after 7 weeks (60 vs. 59 %, $\chi^2 = 0.04$, n.s., based on the 42 subjects who completed the study) and 14 weeks (65 vs. 75 %, $\chi^2 = 0.29$, n.s.; based on the 42 subjects who completed the study) nor in pain experienced during the shockwave treatment (VAS score: 4.9 ± 2.3 vs. 4.2 ± 2.5 , n.s.).

Logbook

There was no difference between the FSWT group and the RSWT group in the amount of training during the first 5 weeks (2.5 ± 2.9 vs. 1.6 ± 1.4 , n.s.), the number of

Fig. 1 Flow of participants throughout the trial

match events during the first 5 weeks (0.04 ± 0.10 vs. 0.11 ± 0.27 , n.s.) and the number of times they performed the 5-days/week eccentric exercise programme (3.2 ± 2.2 days per week vs. 3.8 ± 1.6 days per week; n.s.).

Discussion

The most important finding of the present study was that there is no statistically significant difference in the effectiveness of FSWT and RSWT for treating patellar tendinopathy. This is the first randomized controlled trial to compare the effectiveness of FSWT and RSWT in the treatment for patellar tendinopathy. Both groups improved significantly over the 14-week follow-up period, but there were no differences between groups in VISA-P scores, in

VAS pain scale scores or in the rating of subjective improvement. Neither were there differences between groups in VAS pain scale scores during administering of the treatment. For this reason, it is impossible to recommend one treatment over the other based on outcome of treatment or feasibility.

Overall, the effectiveness of ESWT for patellar tendinopathy remains a matter of debate [8]. A recent systematic review of the literature on the effectiveness of ESWT identified studies that had rather good treatment results, but a variable methodological quality. Based on this literature, it was concluded that ESWT seems to be a safe and promising treatment for patellar tendinopathy [22]. A recent non-randomized retrospective study found ESWT to be more effective than other procedures [6]. However, a recent RCT found no effect of ESWT for patellar

Table 1 Baseline characteristics of the study population

	FSWT <i>n</i> = 21 (tendons = 31)	RSWT <i>n</i> = 22 (tendons = 26)	Total group <i>n</i> = 43 (tendons = 57)	Difference between groups
Age (years)	28.8 ± 10.3	33.4 ± 10.7	31.1 ± 10.7	n.s.
Men/women	16/5	16/6	32/11	
Height (cm)	182.2 ± 8.8	180.5 ± 8.5	181.3 ± 8.6	n.s.
Weight (kg)	80.5 ± 10.3	78.4 ± 15.6	79.4 ± 13.2	n.s.
BMI	24.2 ± 2.5	23.9 ± 3.8	24.1 ± 3.2	n.s.
Training h/wk	3.3 ± 4.1	1.8 ± 1.6	2.5 ± 3.2	n.s.
Playing and training load compared to before injury: same load/reduced load	4/17	4/18	8/35	
Duration of symptoms (in months for all tendons)	32.3 ± 28.7	38.6 ± 56.9	35.2 ± 43.5	n.s.
Unilateral/bilateral	11/10	18/4	29/14	
Location of pain (proximal/mid-tendon/distal)	30/0/1	23/0/3	53/0/4	n.s.
Primary sport	5 Soccer 3 Basketball 2 Running 2 Volleyball 1 BMX 1 Field hockey 1 Fitness 1 Handball 1 Jiu-jitsu 1 MMA 1 No sport 1 Rowing 1 Tennis	6 Running 6 Volleyball 4 Soccer 2 Fitness 1 Cycling 1 Korfbal 1 Tennis 1 Ultimate frisbee		

Table 2 Outcome measures at baseline and during follow-up for both treatment groups

Measure	Time	FSWT	RSWT	Difference with pre-treatment (95 % CI) ¹		<i>p</i> -value
VISA-P	Baseline	48.6 ± 18.7	48.8 ± 17.2			
	1 week	53.7 ± 17.2	53.9 ± 16.0	0.0	(−7.4 to 7.5)	n.s.
	4 weeks	54.1 ± 16.3	58.1 ± 18.2	−3.8	(−10.7 to 3.1)	n.s.
	7 weeks	59.6 ± 16.9	53.5 ± 21.5	6.3	(−1.2 to 13.9)	n.s.
VAS-ADL	14 weeks	63.6 ± 24.2	58.4 ± 22.1	5.4	(−3.8 to 14.6)	n.s.
	Baseline	3.9 ± 2.4	3.7 ± 2.3			
	7 weeks	2.7 ± 2.1	2.8 ± 2.3	0.4	(−1.1 to 1.8)	n.s.
VAS-sport	14 weeks	2.0 ± 2.0	2.1 ± 2.1	0.3	(−0.9 to 1.5)	n.s.
	Baseline	6.1 ± 2.6	6.0 ± 2.4			
VAS-1 single-leg decline squat	7 weeks	4.6 ± 3.0	4.4 ± 2.8	0.0	(−1.1 to 1.1)	n.s.
	14 weeks	3.3 ± 3.0	4.0 ± 2.6	0.9	(−0.2 to 2.0)	n.s.
	Baseline	3.3 ± 3.4	3.5 ± 2.3			
VAS-10 single-leg decline squats	7 weeks	2.5 ± 3.3	3.2 ± 2.5	0.5	(−0.6 to 1.6)	n.s.
	14 weeks	2.5 ± 3.4	2.4 ± 2.6	−0.3	(−1.5 to 0.8)	n.s.
	Baseline	4.4 ± 3.3	4.1 ± 2.2			
VAS-10 single-leg decline squats	7 weeks	3.2 ± 3.5	3.6 ± 2.6	0.7	(−0.4 to 1.7)	n.s.
	14 weeks	3.4 ± 3.5	3.0 ± 2.7	−0.1	(−1.1 to 1.0)	n.s.

^a Positive values for the differences indicate a larger improvement for the FSWT group

tendinopathy [25]. The improvement of 15.0 and 9.6 points for the FSWT and RSWT group respectively on the primary outcome measure of the present study, the VISA-P questionnaire, was also rather disappointing, as we defined a change of 15 points as the minimal clinically relevant difference. More randomized trials with a transparent design studying different treatment protocols are therefore necessary to determine the exact role of ESWT as treatment option for patellar tendinopathy.

The aim of the present study, however, was not to answer the question of whether ESWT is effective for patellar tendinopathy, but to compare the effectiveness of two ESWT methods. The choice for this research question was motivated by the discrepancy we have previously noted between “science”, in which mainly the effectiveness of FSWT is studied, and “practice”, where primarily RSWT devices are used by practitioners and physical therapists in the Netherlands [20]. One might expect a difference in effectiveness because of the differences between the technologies of FSWT and RSWT [3]. Despite this, there are no *in vitro* studies available that compare the biological effects of both methods, and there is only one clinical study that has previously compared the clinical effects of FSWT and RSWT. In that study, subjects with plantar fasciitis received either three sessions of either FSWT or RSWT with the same device as in the present study [13]. A very small difference on a pooled outcome measure in favour of FSWT was found. This pooled measure was a combination of eight variables, including the functional foot index and neuromuscular performance tests. Because of this pooling of variables, it is difficult to understand what this difference means, and it is also questionable whether this difference has clinical relevance. On theoretical grounds, a difference in favour of FSWT might have been expected since the plantar fascia is a thick tissue that is located deeper into the body and FSWT is supposed to act deeper than RSWT. The same hypothesis can be applied to patellar tendinopathy, since the most common location for patellar tendinopathy is the proximal posterior part of the patellar tendon [1]. In the present study, however, no differences were found between FSWT and RSWT either. Based on the study by Lohrer et al. [13] and the present study, at the moment there is no evidence of clinically relevant differences in effectiveness between the two ESWT technologies.

For these reasons, other aspects may have to be considered in the decision of which device to use. One such consideration may be the amount of pain that is experienced by subjects during treatment. In the present study, we found no difference in the pain experienced during FSWT and RSWT. A difference would have been obvious, since it is known that the experienced pain is related to the pressure field generated by the ESWT device [17], and the

pressure fields of the two ESWT technologies are very different. Then, there is the economic aspect to consider. A calculation of the costs for both methods shows that the costs of RSWT are lower than those of FSWT (personal communication with supplier, January 2012). Variable costs for an RSWT treatment of 2,000 pulses are around 20 % of the costs of FSWT. The yearly depreciation costs are also lower for RSWT, around 70 % of those of FSWT.

The present study has some strengths and limitations. Strengths were the use of a randomized controlled design, the fact that the design was previously published, blinding of patients as well as outcome assessors, use of multiple outcome measures, and application of both FSWT and RSWT with the same equipment. Another strength is that subjects completed a weekly logbook, with results that indicate that instructions to reduce load during the first weeks of the trial were followed. A limitation was that no firm conclusions can be drawn with regard to the effectiveness of ESWT because no placebo or control group was studied. Another limitation is that treatment results might be influenced by the fact that more subjects in the FSWT group had bilateral patellar tendinopathy. It has been suggested that there are differences in the aetiology of unilateral and bilateral patellar tendinopathy [4, 5, 7], although others found no differences between these populations [19]. Even if there are differences in aetiology though, this does not necessarily mean that the treatment would affect subjects with unilateral and bilateral patellar tendinopathy differently. By using GEE as a statistical method, we controlled for the fact that some of the subjects were treated on both legs. This is often omitted in studies that treat subjects on two limbs, and it may bias the results as scores of the limbs of one subject are correlated [2, 16].

The present study found no differences in effectiveness between FSWT and RSWT for the treatment for patellar tendinopathy. Based on the limited clinical improvement, the decision to use SWT for the treatment for patellar tendinopathy remains controversial; besides that, the choice for one of the two available technologies, FSWT and RSWT, does not appear to be an important contributing factor for clinical outcome.

Conclusion

There is no difference between FSWT and RSWT for chronic patellar tendinopathy in addition to eccentric training. Both treatment groups showed a slight improvement after treatment, although it is questionable whether this difference is clinically relevant. Based on the present clinical results, it is impossible to recommend one ESWT treatment over the other in terms of effectiveness, but on economic grounds, RSWT seems to be more cost-effective.

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