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Radial Extracorporeal Shockwave Therapy (rESWT) is Non-Superior to Minimal-Dose rESWT for Patients with Chronic Patella Tendinopathy: A Double-Blinded Randomized Controlled Trial

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SUMMARY

Objective. Investigating outcomes for patients with chronic patella tendinopathy following radial extra-corporeal shockwave therapy (rESWT).

Methods. 22 patients with chronic patella tendinopathy were recruited for this DB-RCT from a single NHS Sports Medicine clinic. Participants were randomized equally to either 3 sessions of herapeutic-dose or minimal-dose rESWT respectively, alongside a structured and progressive home exercise program. Participants: 86% male, mean age 36.1 ± 12.5 years, symptom duration: 30.4 ± 32.7 months. Maximum 6-month follow-up, with interim data at 6-weeks, and 3-months.

Results. Improvements were seen in both groups, with an improvement of pain by about 35% across all time periods; these within-group improvements were seen at the interim (6-week, 3-month) and final (6-month) study period. However, no differences were seen between-groups at any time period, suggesting non-superiority of therapeutic over minimal-dose ESWT. There were no changes seen in markers of general health or levels of recorded physical activity.

Conclusions. Small sample sizes limit firm conclusions, but this study has failed to show any superiority of rESWT compared to minimal-dose rESWT in patients with chronic patella tendinopathy, when performed alongside a structured home exercise program (progressive loading, flexibility, and balance components). The findings from this study do not support the current recommendations, that of three sessions of radial-ESWT performed at weekly intervals at the maximally comfortably-tolerated dose.

Study registration. The study was registered prospectively on a publicly accessible database (ClinicalTrials.Gov - identifier NCT02546128).

KEY WORDS

Patella tendinopathy; extracorporeal shockwave therapy; outcome study; pain; rehabilitation; shock wave.

INTRODUCTION

Patella tendinopathy is most commonly reported in young, active, and often professional or elite-level athletes who undertake particular sports with repeated jumping and landing (1). One study reported an overall prevalence of 14% in athletes but reaching more than 30% in some sports including volleyball and basketball, affecting male athletes more than females, although precise risk factors remain elusive (1-3). However, patella tendinopathy can also affect people engaged in recreational sports or occupational activities, such as PE teachers or military populations (4), and who may be far less commonly studied than elite athletes. Patella tendinopathy presents with pain most commonly localized to the inferior pole of the patella (5). In a similar manner to other tendinopathies, this most typically occurs both at the onset of activity, and in a dose-related fashion with activity, with higher load/intensities being most provocative (6).

A range of different treatment strategies are employed in managing patients with patella tendinopathy. Rehabilitation programs include a slow concentric/eccentric program typically performed on a decline slope, heavy slow resistance programs (HSR), and progressive-loading exercises (PTLE) (7, 8). For those patients who fail to improve with rehabilitation, other options are used including the use of corticosteroid injections, high-volume injections (9), injections of blood products (autologous blood injections or platelet-rich plasma), extracorporeal shockwave therapy (ESWT) (10, 11), or surgery (12), all of which have a varied evidence base. There have been relative few comparative studies comparing different treatment options published to date. One cohort study suggests there may be greater improvements from autologous blood injections (ABI) compared to ESWT but relatively small numbers and the cohort nature of the study prevented firm conclusions (13). Other comparative work includes RCTs comparing corticosteroid injections, eccentric-based, or HSR-based rehabilitation and identified improvements in all groups, but mainly short-term improvements only in those who received steroid injection, and greater satisfaction in the HSR group, although tendon mechanical properties remained the same (14). Systematic reviews have suggested promising benefits from different treatments but have highlighted further research was needed to demonstrate their effectiveness, and reported that rehabilitation is the first-line treatment for patients with patella tendinopathy (15, 16).

ESWT generates inaudible high-energy sound waves and transmits through the skin to deeper tissues in an effort to promote recovery. In radial shockwave therapy (rESWT)/radial pressure-wave (RPW) this energy spreads aspherically covering a relatively broad area, expanding into deeper tissue as it loses power (17). Although variations exist between different studies, typically rESWT involves three treatment sessions, performed at weekly intervals, alongside a structured rehabilitation program (18). However, the evidence in support of ESWT in patients with patella tendinopathy may be uncertain (19), and this may be particularly the case when considering non-elite patients, or those with more chronic symptoms. Most research to date has included patients with relatively short duration of symptoms in whom natural resolution may be expected, or where the symptom duration is not clear (20, 21). The most recent systematic review have only included a couple of studies involving ESWT, and have suggested that ESWT may not be superior to sham-ESWT (15). A previous review involving 2 studies with focal-ESWT, but only a single study with radial-ESWT, demonstrated only slight improvements at 3-months and that one study showed ESWT to be no better than placebo (16). Given the limited number of reliable studies examining this treatment option, and questions about its clinical utility, further research may be required.

This study seeks to quantify any impact that three sessions of rESWT has for the treatment of patients with chronic patella tendinopathy, when added to a structured and progressive rehabilitation program, using validated measures of local pain/function, global function, and physical activity. The methods for this study are similar to sub-studies examining rESWT in patients with greater trochanteric pain syndrome or plantar fasciopathy previously reported (22, 23).

METHODS

Study outline

Patients were recruited for this double-blinded randomized controlled trial from a single NHS Sports Medicine clinic (UK), if they had symptoms of chronic patella tendinopathy, for a minimum of six-months duration, which had not improved sufficiently with a graded rehabilitation program (min 3-months). Participants were randomized evenly to receive three rESWT treatment sessions performed at weekly intervals at one of two strengths, using an Intelect RPW ESWT machine (DJO Global Chattanooga). In the intervention group, the bar strength (energy level) was increased to the maximum, comfortably-tolerated dose for the individual patient, whereas the control-group received sessions at the lowest possible energy dose from this rESWT machine, hereafter called minimal-dose rESWT. Alongside rESWT, both groups received identical, structured and progressive, home rehabilitation program (described below). This started before rESWT commenced and continued throughout study inclusion.

The study duration was six-months, with interim data at six-weeks and three-months, using a range of patient-reported outcome measures at baseline and follow-up. All patients were blind to treatment group, and were reviewed by clinicians blinded to treatment allocation.

Inclusion/exclusion criteria

Inclusion criteria

Minimum age 18-years old at enrolment, localized pain for minimum six months duration, with pain reproduced on localized palpation of the proximal patella tendon at its patella insertion, previous structured rehabilitation program (including eccentric strengthening and balance components) for a minimum of 3-months, and ultrasound or MRI evidence suggestive of patella tendinopathy (24).

Exclusion criteria

Inability or unwilling to undertake the graded rehabilitation exercise program. Local corticosteroid injection within three months) or current anticoagulation (potential increased risk

rupture). Previous or current partial or full thickness tears of the patella tendon (to avoid risk of further injury).

Consent and randomization

Patients were identified during routine care and the study, and its objective was discussed with those that met the inclusion/exclusion criteria. Written patient information leaflets were provided to support this discussion and a cooling-off period of at least 24 hours was given prior to study recruitment. A screening log was not kept as this study was open to all patients meeting the study criteria.

Following consent, participants were randomized by the study nurse equally to intervention or control groups using Sealed Envelope software (www.sealedenvelope.com, ©Sealed Envelope Ltd.). The same nurse administered the rESWT sessions and subsequently remained independent throughout the rest of the study period.

Interventions and blinding

Three sessions of rESWT, performed weekly for three weeks, was performed using an Intelect RPW ESWT machine (DJO Global Chattanooga). This was administered by a single nurse practitioner, following a standardized protocol.

Intervention group

2,000 rESWT shocks per treatment at 15 Hz. The bar strength (energy level) was performed as per manufacturer recommendations with the energy dose (bar strength) at the maximal comfortably-tolerated level, rather than a single specified pressure setting. The mean value of the pressure waves generated was 2.2 ± 0.2, 2.7 ± 0.2, 3.2 ± 0.2 bar for the 1st, 2nd and 3rd treatment sessions respectively, with the strength varying between patients.

Control group

The lowest energy settings from this commercially available machine were used. 500 shocks were undertaken per treatment (one-quarter of the intervention group) at a frequency of 15.0 Hz (same as intervention group). The bar-pressure was set at 1.4 for all 3 treatments (approximately half that of the intervention group), representing approximately a one-eighth dose or rESWT.

Blinding

Participant and observer blinding took place in this DB-RCT. Participants were advised that the sensations felt during rESWT treatment were variable. Study participants' views of the rESWT device were obscured by patient positioning and the study nurse made efforts to mask the strength of the administered rESWT treatment by enquiring about comfort levels and altering/appearing to alter the rESWT settings based on patient responses. Members of both groups had identical aftercare following rESWT, including the initial advice, use of analgesia, and the rehabilitation program. Participants were reviewed by observers blinded to treatment group allocation.

At the six-month time-point, participants consulted with the lead investigator after they had completed the final study questionnaires. Study un-blinding happened during this consultation. No accidental un-blinding occurred during the study period. Participants reporting that they had not improved sufficiently for them at the end of the study (six-month point), were potentially eligible for further treatment outside of the study based on patient preferences and clinical reasoning.

Rehabilitation program

Before rESWT was carried out, a home-based rehabilitation program was taught to all study participants, who were shown how perform and progress these throughout their study inclusion. The loading component of this program consisted of body-weight eccentric-concentric load on a decline slope, which were slowly progressed as tolerated throughout study duration. The program also included balance and proprioception exercises. Exercise techniques were assessed at interim appointments by treating clinicians, and any necessary corrections were made. Participants were provided with written material to facilitate rehabilitation progression.

Outcome measures

Participants completed a bespoke study questionnaire at baseline (within 24 hours of rESWT) and repeated this at the follow-up visits (6-week, 3-month and 6-month) which comprised different outcome measures. Participants were asked using a 0-10 numerical rating scale (NRS) for their levels of self-reported pain on average and pain at its worst. Additionally, this questionnaire included validated Patient-Reported Outcome Measures (PROMs) for patella tendon pain/function with Victoria-Institute of Sport Assessment-Patella (VISA-P) (25, 26) questionnaire. An assessment for possible neuropathic or centralized pain was made with painDETECT (27-29) and the Central Sensitization Inventory (CSI) (30, 31), respectively. Global function was assessed via EQ-5D-5L (32, 33). Physical activity levels were recorded via two vital signs physical activity questions (34, 35). This study questionnaire took an average of 20 minutes per appointment for the participant to complete, and participants were advised of this at the outset.

The primary outcome measure was the between-group change in pain on average from baseline to 6-months (using the 0-10 NRS); the other outcome measures were secondary to this.

Statistical analysis

Using results from other published research for self-reported changes in levels of pain, and with a minimum clinical important difference of between 0.9 and 2.0 points (36, 37), an *a priori* power calculation (power set at 0.95 and α set at 0.05), calculated 34 participants in total were required. Unfortunately, the COVID-19 pandemic and other external factors made study recruitment more challenging than expected at the outset. However additional in-study data after 20 completed participants led to queries about treatment effectiveness, and study recruitment was halted after 22 completed with data reported as found.

Data were collated prospectively and analyzed with SPSS v27 (IBM SPSS Statistics). Statistical significance was set at $p < 0.05$. All data were analyzed on an intention to treat basis. Missing Value Analysis (MVA) was not undertaken. Data are displayed as mean ± SD.

Normality of data was assessed using Shapiro-Wilk test. Normally distributed data were analyzed with parametric testing, and non-parametric testing undertaken for data that were not normally distributed. Independent t-tests, or chi-square tests, analyzed baseline data to demonstrate comparability of groups. Between-groups analysis was undertaken with non-parametric testing to identify if a significant difference in outcome occurred between the two groups at either the final (6-month), or at the interim time points. As secondary analysis, within-groups comparisons (follow-up time-points *vs* baseline) were undertaken using paired-samples t-tests or related-samples Wilcoxon Signed Rank tests.

Ethical considerations

This project is a sub-study of a larger suite of tendon intervention projects assessing effectiveness of radial ESWT in several different tendon conditions, run as independent sub-studies with the same methodology. The study was given a favorable opinion from an NHS Research Ethics Committee (REC ref 15/EM/0122 – Date of approval: March 30, 2015) and had all necessary local site approvals. Ongoing reporting to, and monitoring by, the host Sponsor (UHL NHS Trust) was undertaken (UHL study id 11401 / EDGE ref 41336).

RESULTS

22 participants with chronic patella tendinopathy were enrolled in this study having met the formal inclusion/exclusion criteria. The mean age of the participants at baseline was 36.1 ± 12.5 years; 86% were male. No participants were professional athletes, all were/had been either recreationally physically active, or active during their occupations (*e.g.*, PE teachers) or both. There was a mean duration of 30.4 ± 32.7 months (range 9 months-10 years) of symptoms prior to enrolment (range: 6 months-20 years). All patients had previously undertaken a home exercise program prior to study enrolment, all had tried regular analgesia, and 18% (4/22) had previously tried specific podiatry-manufactured insoles. 9% (2/22) had received a corticosteroid injection as a part of their previous treatments, neither receiving any benefit. No patients had previously received high-volume injection, injections of blood/blood products, or surgery. As part of enrolment criteria, all participants had received either an ultrasound assessment (14/22) or MRI (11/22), additionally 18% (4/22) had also received an x-ray in the 3-months preceding enrolment.

13 participants were randomized to the intervention group and received maximally-comfortably tolerated radial ESWT, 9 to the control group (receiving minimal dose radial ESWT), and all participants completed the three sessions of rESWT as expected. There were no significant differences recorded between participants in the intervention and control groups for their demographics (**table I**), or baseline PROMS (**table II**). One participant in the intervention group missed their initial 6-week interim study follow-up appointment, but all participants attended the 3-month interim appointment, and all participants completed the final 6-month follow-up as planned. Information for study recruitment is detailed in the included CONSORT 2010 Flow Diagram (**figure 1**).

Table I. Demographic information for study participants.

	Intervention group (recommended-dose rESWT) (n = 13)	Control group (minimal-dose rESWT) (n = 9)	P-value
Age (years)	34.5 ± 6.9	38.3 ± 18.2	0.495
Gender (male/female)	12M/1F (92% male)	7M/2F (78% male)	0.329
Symptom duration (months)	32.4 ± 32.3	27.6 ± 35.0	0.742

Data shown are mean ± SD.

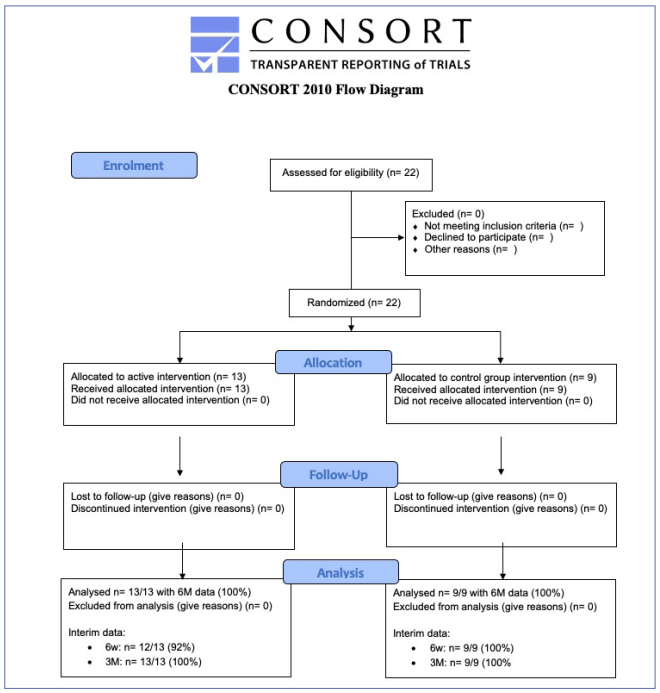

Figure 1. CONSORT Flowchart for rESWT RCT study..

For the patella tendinopathy group as a whole, there was an overall significant improvement in the measure of self-reported average pain (0-10 NRS) from 6.2 ± 1.8 at baseline, to 4.5 ± 1.9 at 6-weeks (p = 0.002), 4.1 ± 2.1 at 3-months (p < 0.001), and 3.6 ± 2.4 at 6-months (p < 0.001). The VISA-P score improved from 40% ± 16% at baseline, to 49% ± 14% at 6-weeks (p = 0.047), 52% ± 20% at 3-months (p = 0.002), and 51% ± 22% at 6-months (p = 0.014). These figures for the study as a whole exceeded the minimally important clinical difference (MCID) for both outcome measures.

Within-groups

The baseline and follow-up values for the different study parameters are displayed in **table II** for the primary outcome measure of the self-reported average level of pain. In addition, **table II** displays values for the question of the reported pain at its worst, as well as the validated PROMs: VISA-P, painDETECT, CSI, EQ-5D %health value, and the number of active minutes per week recorded by the vital signs questions. **Table II** display the between-groups statistical significance value at each time point, with any within-group changes from baseline of statistical significance being highlighted using asterisks.

There were statistically significant within-group improvements in the primary outcome measure, the self-reported average pain, at the 6-month (final) outcome, as well as the two interim time-points for both members of the intervention and control group (all p < 0.05). There were inconsis-

Table II. Self-reported data at baseline and follow-up.

		Baseline	6-weeks	p	3-months	p	6-months	p
Average pain (0-10)	I	6.3 ± 1.7	4.6 ± 1.7*	0.702	4.2 ± 1.7**	0.695	4.2 ± 2.7*	0.235
	C	5.9 ± 2.1	4.3 ± 2.2*		3.9 ± 2.7*		2.7 ± 1.6**	
Pain at its worst (0-10)	I	7.7 ± 2.0	6.8 ± 1.6	0.571	6.8 ± 2.2*	0.500	6.5 ± 2.4	0.096
	C	7.5 ± 2.4	6.1 ± 2.1**		5.6 ± 2.9*		4.8 ± 2.3*	
VISA-P	I	43.2% ± 15.9%	49.1% ± 10.0%	0.512	53.7% ± 16.9%**	0.697	51.1% ± 24.0%	0.734
	C	34.8% ± 14.4%	48.0% ± 20.2%		50.0% ± 25.2%		49.6% ± 20.3%	
painDETECT	I	10.2 ± 4.4	8.3 ± 3.7	0.305	7.8 ± 2.8*	0.185	8.9 ± 5.4	0.754
	C	14.3 ± 5.7	12.5 ± 7.5		11.5 ± 6.6**		8.9 ± 7.3*	
CSI	I	18.0% ± 13.9%	18.8% ± 9.8%	0.181	20.0% ± 14.3%	0.792	18.3% ± 12.4%	0.754
	C	26.1% ± 10.8%	24.5% ± 10.2%		20.8% ± 10.1%		21.2% ± 8.6%	
EQ-5D %health	I	74.7% ± 15.2%	73.3% ± 13.4%	0.851	74.5% ± 10.8%	0.916	71.2% ± 24.5%	0.702
	C	73.6% ± 11.5%	71.9% ± 15.4%		72.3% ± 19.7%		67.0% ± 21.0%	
Vital signs – active minutes per week	I	111.9 ± 149.7	139.6 ± 148.1	0.624	135.0 ± 122.5	0.916	218.0 ± 263.4	0.602
	C	71.7 ± 67.7	80.1 ± 61.5		111.3 ± 59.4		109.6 ± 100.5	

Data shown are mean ± SD; I: Intervention group (*i.e.*, recommended-dose rESWT n = 13, n = 12/13 at 6 w, n = 13/13 at 3 M, n = 13/13 at 6 M); C: control group (*i.e.*, minimal-dose rESWT, n = 9, n = 9/9 at 6 w, n = 9/9 at 3 M, n = 9/9 at 6 M). Statistical significance was calculated between data at baseline and the different follow-up time-points respectively, comparing intervention and control groups (non-parametric Mann-Whitney U-Test P-value displayed.) Within-group comparisons between baseline and follow-up time points was undertaken using either paired t-tests or Wilcoxon tests, and statistical significance is denoted by the use of asterisks within that row (*p < 0.05, **p < 0.01, ***p < 0.001); VISA-P: (%scale), higher value indicates less pain / better function; painDETECT: (range 0-38), with lower score indicating lower likelihood of neuropathic pain; CSI: (%scale), lower score indicates lower likelihood of centralised pain component; EQ-5D: health (%scale), higher score indicates better self-rated global health.

tent improvements in any of the other studied parameters. Self-reported worst pain improved significantly for both groups at 3-months ($p < 0.05$), but in the control-group only at the 6-week, and 6-month time point. VISA-P improved in the intervention group significantly at 3-months ($p < 0.01$), but not at the other two time points, and improvements did not reach significance for the control group at any studied. The other secondary measures of the presence of possible neuropathic pain (painDETECT) revealed significant changes from baseline at the 3-month point in both groups, but in the control group only at 6-months. The marker for centralized pain (CSI) did not show any changes from baseline at any of the follow-up periods. There were no changes in the marker of self-reported health from the EQ-5D, or levels of physical activity as recorded by the two vital signs questions.

The minimally clinical important difference (MCID) for 0-10 pain scale is reported at 0.9 - 2.0 points (36, 37). The lower of these two values was exceeded in both groups at the 6-week period, and the higher value exceeded in both groups at both the 3-month and 6-month point. There was an improvement in the recording of self-reported average pain of 2.1 points in the intervention group (33%) and 3.2 points in the control group (46%) at the final 6-month time-point. These indicated clinically significant results, as well as the aforementioned statistically significant within-group improvements.

Between-groups

Although there were a number of improvements in the within-group analyses, the between-groups analysis showed no significant differences between groups for any variable studied. No statistically significant between-groups differences were identified for the primary outcome measure of self-reported level of average pain at 6-months ($p = 0.235$), or at the interim time-points of 3-months ($p = 0.695$), or 6-weeks ($p = 0.702$). Additionally no differences were seen for the other secondary measures of worst pain or the validated VISA-P for local pain/function or any of the other secondary measures assessing neuropathic or centralized pain, global function, self-reported health, or physical activity at any time-point. These data are all displayed in **table II**.

Side-effects

The side-effect profile of the rESWT treatment was very favorable; no significant untoward events, such as hematoma formation, pain preventing completion of treatment protocol, or patella tendon rupture were reported during the study period. No participants in either group reported any significant erythema, bruising, numbness, or increased stiffness after any of the rESWT treatment sessions.

DISCUSSION

This study has shown no differences between the intervention and the control groups for any of the outcome measures studied, *i.e.*, no superiority of one treatment protocol from another. There were no benefits seen in the group who received three sessions of radial shockwave therapy, performed at weekly intervals at the recommended dose, compared to a group who received minimal-dose rESWT treatment protocol utilizing used one-quarter of the number of shocks which were performed at about half of the pressure (*i.e.*, approximately one-eighth of the dose), therefore although this study has reported within-group improvements for measures of pain and function, the lack of between-group differences that were seen, demonstrates that the benefits that were seen were not as a result of the energy level of the shockwave therapy that was delivered.

This study therefore does not support the treatment dose recommended, that of three sessions of extra-corporeal shockwave therapy delivered at the maximum comfortably-tolerated dose. This finding is in line with that of previous reviews which have questioned the role of ESWT in patients with patella tendinopathy (15, 16, 19), and further demonstrates this in a particular population with a long history of symptoms.

Statistically significant within-group improvements were seen in measures of self-reported average and worst pains, which may replicate some benefits seen post-ESWT in other published works (11, 38), although pain was often improved, rather than cured. Benefits were not consistently seen in the VISA-P questionnaire which has been developed to give a standardized method of quantifying symptoms (25, 26). However, this questionnaire with its emphasis on self-reported sport function, which accounts for 30 out of a maximum of 100 points has come under criticism recently with a systematic review highlighting low-quality evidence of sufficient relevance and inconsistent comprehensibility (39, 40). It may be that alternative patient-reported outcome measures are needed, or further evidence to support the validity and usefulness of VISA-P across populations.

Looking at the overall study groups, despite improvements reported in levels of pain comparing pre/post data, the levels of physical activity reported through the use of the vital signs questions did not show any change, suggesting that the pain itself was not necessarily the barrier to activity that it was subjectively believed to be. However, the heterogenous range of activity levels, represented by the broad standard deviations, may obscure analysis for this point with the numbers that were recruited. Similarly, there were no significant pre/post improvements in the %health scale for the EQ-5D questionnaire which represents global health, indicating that any changes may be only local rather than have more generalized benefits.

This study used broad inclusion criteria to replicate a real-world approach and recruited patients from a single NHS clinic assessing the effectiveness in a group of patents with often very chronic symptoms, who had not improved with a range of treatments previously. This study recruited patients who were slightly older than those represented in several previously published studies, with a mean age of 36.1 years, compared with studies recruiting most participants in their 20 s (11, 38, 41). Additionally, in this study participants were recreationally-active, rather than elite athletes, without the same pre/rehabilitation that elite athletes benefit from. Lastly the participants in this study and had an average duration of symptoms of two-and-a-half years prior to the rESWT therapy. This is often a poorly reported variable in some published studies, however has a great importance due the recognized expected improvements in symptoms over 6-12 months for many patients with many different tendinopathies. Any of these factors could at least hypothetically have had an influence on the outcomes that were seen. However, these are more representative of a population presenting to routine healthcare services, and may give more generalizable findings than several other studies previously published.

Radial ESWT was well tolerated in this study, with all patients receiving the expected rESWT treatment as per study protocol and no patients reporting any significant side-effects from the treatment. All but one participant attended all of the interim appointments, and all participants attended the final appointment (**figure 1**). This low loss-to-follow-up rate improves the analysis and findings identified.

There are several recognized limitations of this double-blinded RCT which need to be considered, however the data presented here does not support the current rESWT treatment regime. This study was relatively small, recruiting 22 patients in total, and the study could have been under-powered to identify a significant between-groups difference, given an *a priori* power calculation suggesting that 34 participants may have been needed. This study is larger in number than at least one other study investigating this treatment and which suggested positive benefits for patients with patella tendinopathy (42). However, there are two other published studies which were larger in size than this one and, similarly to this, have not shown benefit (11, 41) leading to uncertainty of any benefit from this treatment modality in this population in the published literature. The sample size chosen at the study outset was challenging, and this not met which is acknowledged. This however was based on assumptions about any potential differences that could be seen, which were not identified during in-study analysis. The study had some recruitment issues during the phases of COVID lockdowns leading to slower recruitment than expected, however in-study power calculations and in-study analysis suggested that a statistically significant or clinically significant result was not going to be identified and a decision was taken to cease study recruitment and formally analyze with the results obtained to disseminate this knowledge more broadly. It may be that a larger, multi-center study, could seek to replicate findings here in real-world secondary care clinic settings to further demonstrate the lack of appreciable difference between therapeutic and sham radial-ESWT. The publication of this study's data can also support future work in this area, including any meta-analysis which may seek to bring together data from several smaller studies.

In addition, through the blinded randomization process undertaken in this study allocated the blocks that were chosen randomized 13/22 participants to the intervention group, compared to 9/22 to the control group. Analyses have not shown differences at baseline or follow-up, but these numbers could potentially have influenced the results seen in this study, and this is acknowledged.

The reasons for the lack of differences in outcomes following either three sessions of rESWT at recommend dose or minimal dose remain unknown at this time. It is possible that the (within-groups) benefits seen in this study were as a result of time itself, or from the rehabilitation exercises undertaken. However, as the participants had symptoms for an average of two-and-a-half years which were resistant to rehabilitation prior to study inclusion, these factors may be less likely for the (within-groups) benefits that were seen, some of which reached statistically significant and clinically significant levels even only 6-weeks after treatment and continued throughout the 6-months follow-up. Some participants had scored relatively low on baseline NRS scores for pain, and this could potentially have had an influence as other research in another tendon condition has suggested that better results are seen in those with the worst pain (43). It is not known if the inclusion of participants with fewer symptoms at baseline could have had an impact, and subgroup analysis is not reliably possible with small umbers recruited here.

It is recognized that this study did not utilize a true placebo group and to attempt to blind participants the control group received minimal-dose ESWT. It at least theoretically possible that this could have had an influence on the results that were seen, *i.e.*, the beneficial effects can be seen from minimal-dose ESWT. This approach used the same study design as used in other studies investigating patients with greater trochanteric pain syndrome (22) or plantar fasciitis (23). This approach was chosen pragmatically to give some element of patient-blinding to strengthen the study design. To investigate this further, a single-blinded (observer-blinded) study could be undertaken comparing outcomes following rESWT plus rehabilitation in this clinical population with chronic symptoms to a group receiving rehabilitation only, although

this weakens the robustness of a double-blinded study design. Alternatively, a study could use this same rESWT machine with acoustic shielding inserted between the transmitter head and the patient, potentially allowing a double-blinded design. Conversely it may be that greater dose of ESWT is required for a therapeutic effect to be seen in patients with (chronic) patella tendinopathy, *i.e.*, the dose received by the intervention group in this study was too low. The evidence underlying the specific treatment recommendations is unknown, particularly as a dose-dependent effect has been demonstrated for focal-ESWT but this relationship is less clear for rESWT (44). Uncertainties still remain as to the number of rESWT sessions, or the intensity at which these should be performed, for benefit. It is at least possible that differences may be found between-groups if an increased number of treatment sessions were to be used, but this question cannot be answered from this study design, and would need to be the focus of further works. Furthermore, it is at least theoretically possible that this machine could be in some way less effective than other rESWT machines used in previous studies. However, this is a specific medical device, licensed for this indication, so it is unclear if this is likely. A comparative study between two different rESWT machines could seek to address this consideration. A final alternative may be that rESWT does not have a clinically significant benefit with this cohort of patients with patella tendinopathy, and that this condition may not respond as favorably to this treatment as other tendinopathy conditions may. These questions cannot be fully answered by this study and could be the focus of further works.

CONCLUSIONS

Although the relatively small sample sizes may limit detailed analysis or limit the conclusions that can be reached, this study has not shown any difference in outcomes between the two groups. As such it suggests that the currently recommended radial shockwave treatment regime may not be correct and further studies may be needed to explore these concepts further. Given the uncertainties of benefit shown in this study and in other published studies, if this treatment is to be undertaken, the authors recommend that this treatment should be performed within studies which can investigate the possibility of any dose-effect, or what, if any, factors could predict individual response to treatment for patients with chronic patella tendinopathy.

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DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

PCW: recruitment, interim reviews, final assessments, data analysis, writing – original draft. CD: randomization, rESWT procedures, writing – original draft, writing – review & editing. RC: interim reviews, writing – original draft, writing – review & editing. All authors contributed to the writing of the manuscript. There are no other specific acknowledgements to give for this research.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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