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A single application of low-energy radial extracorporeal shock wave therapy is effective for the management of chronic patellar tendinopathy

John P. Furia · Jan D. Rompe · Angelo Cacchio · Angelo Del Buono · Nicola Maffulli

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Abstract
Purpose Extracorporeal shock wave therapy (SWT) is effective for the management of chronic recalcitrant tendinopathy. The objective of the current study was to assess whether a standardized, single treatment SWT is effective for the management of chronic patellar tendinopathy
Methods Thirty-three patients with chronic patellar tendinopathy received low-energy SWT. Thirty-three patients with chronic patellar tendinopathy received other forms of non-operative therapy (control group). Evaluation was by change in Visual Analogue Scale (VAS), Victoria Institute of Sport Assessment score for patellar tendinopathy (VISA-P) score and by Roles and Maudsley Score.
Results Mean pre-treatment VAS scores for the control and SWT groups were 7.5 and 7.8, respectively. One month, 3 months, and 12 months after treatment, the mean VAS for the control and SWT groups were 6.7 and 4.3 ($p < 0.001$), 5.9 and 3.5 ($p < 0.001$), and 5.1 and 2.7 ($p < 0.001$), respectively. One month, 3 months, and 12 months after treatment, the mean VISA for the control and SWT groups were 50.7 and 65.5 ($p < 0.001$), 52.1 and 71 ($p < 0.001$), and 54.9 and 74.5 ($p < 0.001$), respectively. At final follow-up, the number of excellent, good, fair, and poor results for the SWT and control groups were 8 and 3 ($p < 0.001$), 17 and 10 ($p < 0.001$), 5 and 16 ($p < 0.001$), and 3 and 4 ($p < 0.001$), respectively. The percentage of patients with excellent ("1") or good ("2") Roles and Maudsley Scores (i.e. successful results) 12 months after treatment was statistically greater in the SWT group compared to the control group ($p < 0.001$).
Conclusion A single application of radial SWT is an effective treatment for chronic patellar tendinopathy.
Level of evidence III.

Keywords Shock wave therapy · Patellar tendon · Tendinopathy · Jumper's knee

J. P. Furia
SUN Orthopedics and Sports Medicine, 900 Buffalo Road, Lewisburg, PA 17837, USA
e-mail: jfuria@ptd.net

J. D. Rompe
OrthoTrauma Evaluation Center, 55130 Mainz, Germany
e-mail: profrompe@web.de

A. Cacchio
Department of Physical Medicine, Rehabilitation University of Rome "La Sapienza", 67100 Rome, L'Aquila, Italy
e-mail: angelo.cacchio@tin.it

A. Del Buono
Department of Orthopaedic and Trauma Surgery, Campus Biomedico University of Rome, Via Alvaro del Portillo 200, Rome, Italy
e-mail: a.delbuono@unicampus.it

N. Maffulli (✉)
Centre for Sports and Exercise, Barts and the London School of Medicine and Dentistry, London E1 4DG, UK
e-mail: n.maffulli@qmul.ac.uk

Introduction

Patellar tendinopathy is relatively common in jumping sports [1, 2], with a prevalence of 44.6 and 31.9 % in elite volleyball players and basketball players, respectively [9]. Symptoms can be debilitating, with impossibility to return to sport for long periods ranging from 6 months [4] to more than 2 years [9]. At times, symptoms may persist also in athletes who have retired [8]. Many treatment strategies have been advocated [10], but the management of patellar

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tendinopathy is still unclear [1]. Non-operative measures including rest, stretching, eccentric strengthening, physical therapies (ultrasound or iontophoresis), anti-inflammatory drugs, and bracing are often inconsistent and poorly evidence-based [1, 25–27], with more encouraging outcomes in patients with early symptoms [15]. Novel treatments involving platelet rich plasma injections, prolotherapy, and sclerosing treatments seem to be promising, but their effectiveness has not been unanimously supported by randomized, prospective, placebo-controlled clinical trials [11].

For surgical treatment of chronic patellar tendinopathy, numerous arthroscopic and open procedures have been described, but there is no agreement about the best option [2, 5, 10, 14]. Postoperatively, success rates greater than 80 % have been reported [2, 10], but some selection and assessment biases may have positively influenced outcome [3], often limited by the retrospective nature of these studies [5, 10, 14] and the absence of control group patients. In addition, postoperative recovery time may last [2, 3] up to 10 months [2].

Randomized controlled clinical trials have shown that Shock Wave Therapy (SWT) is effective for the management of tendinopathies and other soft tissue conditions [12, 13, 18–22].

The aim of this study was to determine whether low-energy SWT is safe and effective for the management of chronic patellar tendinopathy, arising from the hypothesis that this treatment improves patient outcomes with respect to baseline, with significantly higher effects than traditional conservative measures.

Materials and methods

This is a retrospective study on patients with chronic patellar tendinopathy who had undergone shock wave therapy at our institution between March 2008 and April 2009. These patients were compared with a control group of patients who had been treated with other conservative strategies. We informed all the patients about the different modalities of management of their condition, potential risks, benefits, and possible outcomes. Each patient gave the written consent. Control patients were selected blindly and were matched for age and gender with the patients of the SWT group. Inclusion criteria were history and physical examination positive for chronic patellar tendinopathy unresponsive to conservative measures including rest, anti-inflammatory drugs, ice, hamstring stretching and strengthening, physical therapy, bracing, and iontophoresis, with moderate-to-severe pain at the junction between the patella and patellar tendon, most in knee extension against resistance, and impaired function. Anteroposterior and lateral radiographs of the affected knee were helpful to rule out other causes of knee pain such as advanced osteoarthritis. Magnetic resonance imaging (MRI) scans and additional imaging studies were also performed.

Exclusion criteria included rheumatoid arthritis, generalized polyarthritis, local infection, pregnancy, tumours, age <18 years, end stage ipsilateral knee osteoarthritis (defined as severe knee joint space narrowing, joint sclerosis, and periarticular osteophytes), prior patellar tendon surgery, and previous fractures to the knee.

We included, in the SWT group, 33 (33 knees) of 37 patients who underwent SWT; 4 patients were excluded: 1 had undergone concomitantly SWT for the management of plantar fasciopathy, and 3 patients had not reached an adequate follow-up.

The control group included 33 patients treated with alternative non-operative measures. There were no intergroup differences in mean age (p = n.s.) or duration of symptoms (p = n.s.).

Occupation and sporting activities

Nineteen patients in the SWT and 16 patients in the control group practised regularly recreational sports (non-competitive exercise 3–5 times per week). Nine patients in the SWT group and 11 control patients undertook heavy physical work (i.e. they were heavy factory workers or manual labourers or in occupations that required extensive physical activity such as nursing and restaurant service).

Method of treatment

All patients gave a written informed consent. The senior author (J.F.) performed all the treatments in his office without anaesthesia using a radial shock wave device (Electro Medical Systems Swiss DolorClast, Munich, Germany), which produces shock waves by a projectile, accelerated with a pressurized air source, which strikes a 15 mm diameter metal applicator. The energy produced is then transmitted to the skin as a shock wave, through a standard, commercially available ultrasound gel. The waves are dispersed radially from the application site to surrounding tissues.

Each patient received a single low-energy administration with 2,000 shocks at a session of 4.0 bars (equal to an energy flux density of approximately 0.18 mJ/mm^2). The treatment frequency was 10 shocks/second; the total energy flux density per session was approximately 360 mJ/mm [2].

The procedure was performed with the patient seated with the knee at 90 ° of flexion after application of ultrasound gel on the skin overlying the distal pole of the patella and patellar tendon. The shock waves were directed from

Table 1 Mean VAS, VISA, and Roles and Maudsley Scores

Group	VAS				VISA				Roles/Maudsley			
	Pre	1	3	12	Pre	1	3	12	Pre	1	3	12
SWT	7.8	4.3	3.5	2.7	49.5	65.5	71.0	74.5	4	2.5	2.2	2.1
Control	7.5	6.7	5.9	5.1	49.3	50.7	52.1	54.9	4	3.3	2.9	2.7

VAS, $p < 0.001$ for each time point for shock wave therapy and control group

VISA, $p < 0.001$ for each time point for shock wave therapy group

SWT shock wave therapy group

anterior to posterior. This is a dynamic process in which the area of maximal tenderness is treated circumferentially, starting from the most painful site. The average size of the treated area measured 4–8 cm in width and 4–8 cm in length, and the time of treatment ranged from 4 to 8 min.

Postprocedure treatment

After the procedure, we assessed the presence of haematoma, bruising, and swelling, not allowing the patients to undergo additional, concomitant procedures for 3 months from the last SWT application. The patients were allowed to weight bear immediately with unrestricted range of motion, with no immobilization, and stationary cycling was recommended. Sedentary workers were allowed to return immediately to their pre-treatment work status. Soft jogging activities were started as tolerated 1 week after the treatment. The time to return to competitive sports and heavy labour occupations varied case-by-case.

Outcome measures

Visual Analogue Scale (VAS), the Victorian Institute of Sport Assessment (VISA) score [24], and the Roles and Maudsley (RM) [17] score were assessed before treatment and after this at 1 month, 3 months, and 12 months. Arising from previous studies reporting on SWT, we considered clinically relevant a two-point change in VAS [7] and a 10-point change in VISA.

The Roles and Maudsley Score is an extensively used subjective four-point patient assessment which considers pain and limitation of activity [17]: 1 point is an excellent result, with no symptoms; 2 points is a good result, with the patient significantly improved than pre-treatment and satisfied with the results; 3 points is a fair result, the patient is somewhat improved and partially satisfied with the treatment outcomes; 4 points indicates a poor condition, with little improvement after treatment and high dissatisfaction.

Statistical analysis

A power analysis showed that a sample size of 23 would be required to establish the statistical significance with $\alpha = 0.05$ and power $= 0.9$, with calculations based on the outcomes of SWT and non-operative treatment of chronic patellar tendinopathy. The paired student's t test and the χ^2 analysis were used to compare the means between groups. Significance levels for multiple comparisons were adjusted with the Bonferroni procedure. The significance level was $p < 0.05$. All analyses were conducted using SAS, version 8.2 (SAS Institute Inc, Cary, North Carolina).

Results

For all comparisons, the data met the assumptions for the statistical tests chosen. No inter-group differences in mean age ($p =$ n.s.) or mean duration of symptoms (p = n.s.) were recorded.

At 1 month from the treatment, the mean VAS score significantly improved from a baseline value of 7.8 ± 1.4 in the SWT treatment group and 7.5 ± 1.1 in the control group to a mean score of 4.3 ± 1.3 ($p < 0.001$) and 6.7 ± 1 ($p < 0.001$), respectively, (Table 1). Three months after the treatment, the mean VAS score improved further to 3.5 ± 1.2 ($p < 0.001$) for the SWT group and to 5.9 ± 0.8 ($p < 0.001$) for the control patients (Table 1). At 12-month follow-up, the mean VAS score was 2.7 ± 1.0 ($p < 0.001$) in the SWT treatment group and 5.1 ± 0.8 ($p < 0.001$) in the control group (Table 1). At each appointment, the patients undergoing SWT reported significantly better scores than controls ($p < 0.001$), with significantly greater change in VAS score after SWT administration ($p < 0.001$).

Victoria Institute of Sport Assessment score for patellar tendinopathy scores were significantly improved at 1 month, 3 months, and 12 months after treatment ($p < 0.001$), with significantly better results ($p < 0.001$) and greater change ($p < 0.001$) in VISA score for the SWT-treated patients than controls, at each appointment (Table 1).

Roles and Maudsley Score at the onset of the study, all SWT and control patients rated the condition of the affected knee as "4" (poor). The percentage of patients with excellent or good Roles and Maudsley Scores (i.e. successful results) at 1 month, 3 months, and 12 months after treatment was statistically greater after SWT treatment ($p < 0.001$ for each time point) (Table 1).

No patient complained of worsening from baseline symptoms in both the groups.

Fourteen of the 19 SWT-treated patients participating in sporting activity returned to pre-injury sport activity level; 11 of the 16 control patients who practised sports returned to sport at the same pre-injury level. The time to return to sport was variable, ranging from 1 week, for some volleyball players, to 12 months, for some runners. The 9 and 11 workers in the SWT group and control group, respectively, were able to return to their pre-injury occupations.

Minor complications occurred in 2 patients who complained of moderate pain during the treatment, with complete resolutions of the symptoms at the end of the treatment.

Discussion

The most important finding in the present study is that SWT is safe and effective up to 12 months from the last application, and provides significantly better results than current conservative care. Firstly introduced in the mid-1980s, SWT is safe, non-invasive, and effective for the management of chronic patellar tendinopathy [16, 26, 27]. Comparing outcomes of 13 patients undergoing surgery with those of 14 patients treated with SWT [16], significantly improved VISA and VAS scores were observed in both groups at 6-month follow-up, and the period of working inability was of 6.1 weeks for the surgically treated group and 0 for the SWT group [16]. In a randomized controlled clinical trial, the patients treated with SWT showed significantly increased satisfactory results than controls (27/30 patients or 90 % vs 12/24 patients or 50 %; $p < 0.001$), with significantly lower recurrence of symptoms (4 patients or 13 % vs 12 patients or 50 %; $p = 0.014$), and no systemic, local, and device-related complications. On the other hand, a study on 2 groups of athletes with early symptoms of patellar tendinopathy undergoing low-energy SWT (2000 impulses at a frequency of 4 Hz and energy flux density starting at 0.1 mJ/mm [2] and titrated according to pain tolerance) and placebo, evidenced no significant inter-group differences in VISA or VAS outcomes at any time point [29]. However, these athletes were mildly symptomatic, still able to participate in competition activities. We treated patients unable to compete, with low VISA-P scores. Our patients were advised to rest and interrupt temporarily their sporting activities. In a recent review reporting on outcomes of 204 patients (215 tendons) undergoing SWT treatment for chronic patellar tendinopathy [23], although methodological variations of the treatment protocols, satisfactory outcomes varied from 62 to 90 % of assessed patients, concluding that SWT is safe, promising in terms of pain relief and function recovery [23]. We reported results comparable to those observed in previous studies on SWT as treatment for chronic patellar tendinopathy [16, 23, 26, 27]. We evaluated the effects of a standardized, single treatment, low-energy protocol of *radial* SWT on a consecutive series of patients with chronic patellar tendinopathy resistant to other conservative measures and compared them with a matched control group. The SWT-treated group reported significantly better mean VAS and VISA scores at 1 month, 3 months, and 12 months from the treatment than the controls. In addition, most of these patients returned to pre-injury sport activities by few months from the SWT procedure. At 12-month follow-up, we recorded satisfactory results in 76 and 39 % of the SWT-treated and control patients, respectively, with no severe complications. We performed all SWT procedures in the office, without using anaesthesia. Previous studies reporting on SWT application in chronic plantar fasciopathy and Achilles tendinopathy have shown that the local injection of anaesthetics at the site of treatment may impair the positive effects of the treatment [6, 21], probably interfering with the delivery of the shock waves or, more likely, altering the neurogenic inflammatory response and antinociceptive effects following SWT.

Limitation of this study is its retrospective nature. Despite the relatively short follow-up, the effectiveness of SWT treatment was already evident at that time. The number of patients in the study was relatively small, but similar to prior studies on this subject. The functional improvement in the knee was assessed subjectively using VAS and functional scores, but no objective measures were utilized. In addition, we did not use ultrasound and/or MRI scans to confirm our clinical diagnosis [11, 21, 28].

We chose to use VAS, Roles and Maudsley, and VISA-P scores as outcome measures as these scores have been used extensively in prior studies on patellar tendinopathy, and the VISA-P is a validated score for the pathology at hand. While we agree that test–retest measurements are helpful, we felt that the size of this study, the common statistical tests used in this study, and the fact that this study was performed in a community clinical setting obviated the absolute necessity for performing this type of analysis. As was true in prior studies on this subject, we have limited the measurement accuracy to one decimal place, as scores were obtained in integers, and the mean scores yielded a number amendable to rounding to one decimal place. Data

analysis in prior published trials also adhered to this standard. While unlikely, we acknowledge the possibility for error based on rounding and, though unlikely, on our failure to perform test–retest measurements. Although this is a weakness of our study, we do not feel it is a "fatal flaw" as the study methodology is otherwise sound.

Shock wave therapy for the management of patellar tendinopathy is easy to perform in clinical setting, not risky for the patients and, requiring only one application, quick.

Conclusion

Traditional treatments of chronic patellar tendinopathy are generally lengthy, with frequent recurrences and, in many instances, provide no significant improvement of the symptoms. In our hands, low-energy radial SWT is safe and effective up to 12 months from the last application. Further randomized, prospective studies are needed to confirm our findings.

References

1. Alfredson H (2005) The chronic painful Achilles and patellar tendon: research on basic biology and treatment. Scand J Med Sci Sports 15:252–259
2. Coleman BD, Khan KM, Kiss ZS, Bartlett J, Young DA, Wark JD (2000) Open and arthroscopic patellar tenotomy for chronic patellar tendinopathy. A retrospective outcome study. Victorian Institute of Sport Tendon Study Group. Am J Sports Med 28:183–190
3. Coleman BD, Khan KM, Maffulli N, Cook JL, Wark JD (2000) Studies of surgical outcome after patellar tendinopathy: clinical significance of methodological deficiencies and guidelines for future studies. Victorian Institute of Sport Tendon Study Group. Scand J Med Sci Sports 10:2–11
4. Cook JL, Khan KM, Harcourt PR, Grant M, Young DA, Bonar SF (1997) A cross sectional study of 100 athletes with jumper's knee managed conservatively and surgically. The Victorian Institute of Sport Tendon Study Group. Br J Sports Med 31:332–336
5. Ferretti A, Conteduca F, Camerucci E, Morelli F (2002) Patellar tendinosis: a follow-up study of surgical treatment. J Bone Joint Surg Am 84:2179–2185
6. Furia JP (2006) High-energy extracorporeal shock wave therapy as a treatment for insertional Achilles tendinopathy. Am J Sports Med 34:733–740
7. Furia JP, Rompe JD, Maffulli N (2009) Low-energy extracorporeal shock wave therapy as a treatment for greater trochanteric pain syndrome. Am J Sports Med 37:1806–1813
8. Kettunen JA, Kvist M, Alanen E, Kujala UM (2002) Long-term prognosis for jumper's knee in male athletes. A prospective follow-up study. Am J Sports Med 30:689–692
9. Lian OB, Engebretsen L, Bahr R (2005) Prevalence of jumper's knee among elite athletes from different sports: a cross-sectional study. Am J Sports Med 33:561–567
10. Maffulli N, Longo UG, Denaro V (2010) Novel approaches for the management of tendinopathy. J Bone Joint Surg Am 92:2604–2613
11. Martens M, Wouters P, Burssens A, Mulier JC (1982) Patellar tendinitis: pathology and results of treatment. Acta Orthop Scand 53:445–450
12. Ogden JA, Alvarez RG, Levitt RL, Johnson JE, Marlow ME (2004) Electrohydraulic high-energy shock-wave treatment for chronic plantar fasciitis. J Bone Joint Surg Am 86-A:2216–2228
13. Ogden JA, Toth-Kischkat A, Schultheiss R (2001) Principles of shock wave therapy. Clin Orthop Relat Res 387:8–17
14. Orava S, Osterback L, Hurme M (1986) Surgical treatment of patellar tendon pain in athletes. Br J Sports Med 20:167–169
15. Panni AS, Tartarone M, Maffulli N (2000) Patellar tendinopathy in athletes. Outcome of nonoperative and operative management. Am J Sports Med 28:392–397
16. Peers KH, Lysens RJ, Brys P, Bellemans J (2003) Cross-sectional outcome analysis of athletes with chronic patellar tendinopathy treated surgically and by extracorporeal shock wave therapy. Clin J Sport Med 13:79–83
17. Roles NC, Maudsley RH (1972) Radial tunnel syndrome: resistant tennis elbow as a nerve entrapment. J Bone Joint Surg Br 54:499–508
18. Rompe JD, Cacchio A, Furia JP, Maffulli N (2010) Low-energy extracorporeal shock wave therapy as a treatment for medial tibial stress syndrome. Am J Sports Med 38:125–132
19. Rompe JD, Decking J, Schoellner C, Theis C (2004) Repetitive low-energy shock wave treatment for chronic lateral epicondylitis in tennis players. Am J Sports Med 32:734–743
20. Rompe JD, Furia J, Weil L, Maffulli N (2007) Shock wave therapy for chronic plantar fasciopathy. Br Med Bull 81–82:183–208
21. Rompe JD, Meurer A, Nafe B, Hofmann A, Gerdesmeyer L (2005) Repetitive low-energy shock wave application without local anesthesia is more efficient than repetitive low-energy shock wave application with local anesthesia in the treatment of chronic plantar fasciitis. J Orthop Res 23:931–941
22. Rompe JD, Schoellner C, Nafe B (2002) Evaluation of low-energy extracorporeal shock-wave application for treatment of chronic plantar fasciitis. J Bone Joint Surg Am 84-A:335–341
23. van Leeuwen MT, Zwerver J, van den Akker-Scheek I (2009) Extracorporeal shockwave therapy for patellar tendinopathy: a review of the literature. Br J Sports Med 43:163–168
24. Visentini PJ, Khan KM, Cook JL, Kiss ZS, Harcourt PR, Wark JD (1998) The VISA score: an index of severity of symptoms in patients with jumper's knee (patellar tendinosis). Victorian Institute of Sport Tendon Study Group. J Sci Med Sport 1:22–28
25. Visnes H, Bahr R (2007) The evolution of eccentric training as treatment for patellar tendinopathy (jumper's knee): a critical review of exercise programmes. Br J Sports Med 41:217–223
26. Vulpiani MC, Vetrano M, Savoia V, Di Pangrazio E, Trischitta D, Ferretti A (2007) Jumper's knee treatment with extracorporeal shock wave therapy: a long-term follow-up observational study. J Sports Med Phys Fitness 47:323–328
27. Wang CJ, Ko JY, Chan YS, Weng LH, Hsu SL (2007) Extracorporeal shockwave for chronic patellar tendinopathy. Am J Sports Med 35:972–978
28. Woodley BL, Newsham-West RJ, Baxter GD (2007) Chronic tendinopathy: effectiveness of eccentric exercise. Br J Sports Med 41:188–199
29. Zwerver J, Hartgens F, Verhagen E, van der Worp H, van den Akker-Scheek I, Diercks RL (2011) No effect of extracorporeal shockwave therapy on patellar tendinopathy in jumping athletes during the competitive season: a randomized clinical trial. Am J Sports Med 39:1191–1199