〈 Clinical Research 〉

Shockwave Therapy Associated With Eccentric Strengthening for Achilles Insertional Tendinopathy

A Prospective Study

Nacime Salomão Barbachan Mansur, MD, Tiago Baumfeld, MD, Fernando Villalon, MD, Bruno Takeshi Aoyama, Fabio Teruo Matsunaga, Paulo Roberto Dias dos Santos, Bruno Schiefer dos Santos, and Marcel Jun Sugawara Tamaoki, MD

Abstract: Background. *The usual initial treatment for insertional Achilles tendinopathy is nonsurgical. Yet there is no standard conservative treatment for Achilles insertional tendinopathy. Shockwave therapy (SWT) has become a reliable option for the management of this illness over the past years. The aim of this study is to report the effectiveness of low-energy SWT associated with an eccentric strengthening protocol in 19 consecutive patients.* Methods. *This is a prospective study with 19 patients aged between 26 and 72 years diagnosed with insertional Achilles tendinopathy. The protocol consisted of SWT associated with eccentric exercises for 12 weeks. All patients were evaluated on the first day and after 24 weeks (final follow-up) with the Victorian Institute of Sports Assessment–Achilles (VISA-A) score, visual analogue scale (VAS), American Orthopaedic Foot and Ankle Society (AOFAS) questionnaire, and by algometry. At the last follow-up, patients were also assessed for adherence to the protocol, complications and final outcome (in their perception as success or fail).* Results and Conclusion. *Fifteen (79%) patients were fully adherent to the Alfredson protocol, and 13 (68%) patients considered the treatment protocol successful. At the last evaluation, patients demanded higher pressure on calcaneus to trigger pain (algometry 1), reported less pain when the algometer was applied with 3 kg (algometry 2), had less global pain (VAS), and had higher AOFAS and VISA-A scores. This study evidences that eccentric loading associated with SWT can dramatically improve patients' symptoms. We can conclude that eccentric loading associated with SWT is an effective treatment for Achilles insertional tendinopathy.*

Levels of Evidence: *Therapeutic, Level III: Prospective cohort*

Keywords: high-energy shockwaves; Achilles tendon; tendinopathy; insertional; eccentric loading; Alfredson protocol

> "Calcaneus tendinopathy develops due to the combination of intratendinous degenerations caused by prolonged low-grade inflammatory status and erratic healing."

Calcaneus tendinopathy develops due to the combination of intratendinous degenerations caused by prolonged low-grade inflammatory status and erratic healing. It can be divided anatomically as

DOI: 10.1177/1938640019826673. From UNIFESP–Escola Paulista de Medicina, São Paulo, SP, Brazil. Address correspondence to: Tiago Baumfeld, MD, Rua dos Pampas, 990, Torre 1/Apto 1701, Prado, Belo Horizonte, MG 30411-030, Brazil; e-mail: tiago.baumfeld@gmail.com.

insertional and noninsertional tendinopathy.[1-3] When the disease occurs within 2 cm of the tendon attachment on the calcaneus tuberosity, it is considered an insertional tendinopathy.

Diagnosis is strongly suggested when pain is reproduced by palpation of the distal tendon and insertion site on the calcaneus. Increase in tendon volume and local hyperemia also supports diagnosis.[1-4] Differential diagnosis like tumors and stress fractures can be excluded with ultrasonography and radiography. Ultrasound will also show signs of tendon disease.

Initial treatment based on eccentric strengthening of the tendon has been shown to have 82% success rate in return to previous activities when considering noninsertional tendinopathy alone.[5,6] However, in insertional disease, results are less impressive, ranging from 32% to 67% return to previous activity levels,[2-4] demanding a different approach to the problem.

Extracorporeal shockwave therapy (SWT) has been used for more than 30 years, proving to be a safe and efficient way to treat kidney stones.[7,8] Both low-energy[9-11] and high-energy[9,12] shockwaves are being used to treat several other conditions like pseudo-arthrosis[13,14] and other kinds of tendinopathy with interesting results.[15-18]

Within this context and based on recent evidence, SWT has been proposed as a viable and promising option to be used when classic nonsurgical treatment fails, but prior to surgery referral.[19-21] However, clinical data are still insufficient to indicate SWT as a worldwide consensus.[15,20]

The authors foresee good to excellent results in the combination of an eccentric strengthening protocol and low-energy SWT. Thus, the objective of the present study is to demonstrate the superiority of the combination of both strategies, and to report results of this approach in 19 consecutive patients.

Materials and Methods

This is a prospective study with 19 patients, 8 women and 11 men, ranging in age from 26 to 72 years, diagnosed with insertional Achilles tendinopathy. Patients included had pain on palpation of the last 2 cm of the Achilles tendon and also in its insertion site into the bone, associated with correspondent tendon volume increase on ultrasound.

Exclusion criteria were patients with prior foot and ankle surgery, peripheral vascular diseases, peripheral neuropathy, systemic inflammatory disease, noninsertional tendinopathy, previous tendon infiltration, pregnancy, blood coagulation disorders, and presence of local infection. All patients were enrolled in a single tertiary center for the same treatment protocol after signing an informed consent. This study was approved by our hospital's ethics committee.

Treatment consisted of SWT sessions (Figure 1) associated with an eccentric exercise protocol (Figure 2). Patients had to perform 20 minutes cold compresses, 3 times a day with a minimum 2-hour interval between them. They all received the same pain killer prescription protocol. Their base sporting activities were interrupted in the first 8 weeks of treatment. After 4 weeks, they were free to run on flats, perform cycling, and to do water activities as long as they were painless. After the eighth training week, more complex sporting activities were gradually restarted as long as they also remained pain free.

All patients were evaluated at the first day and after 24 weeks (final follow-up) with the Victorian Institute of Sports Assessment–Achilles (VISA-A) questionnaire (VISA-A) score, visual analogue scale (VAS), American Orthopaedic Foot and Ankle Society (AOFAS) score, and with algometry. We used a digital pressure algometer (Wagner Force One Model FDIX 50TM, Wagner Instruments), which measures pressure in kg/cm^2 with an accuracy of ±0.2%. Pressure was applied manually to the area of interest using a 1-cm^2 rubber tip fixed to the gauge. Algometry values were registered as the minimum strength to generate pain (algometry 1) and as the pain (VAS) triggered by the algometer with a strength of 3 kgf × cm^2 (algometry 2). At the last follow-up, patients were also assessed for adherence to the protocol, complications and the final outcome (in their perception as success or fail).

Figure 1.

Shockwave being applied to the Achilles tendon insertion.

Figure 2.

Eccentric exercise.

Statistical analysis was performed with the GRETL software (2017). Student's *t* test was used to compare pre- and postoperative data. Subsequently, repeated-measures multivariate analysis of covariance was administered to test for covariations and main effects. A *P* value <.05 was considered significant.

Shockwave Therapy

Starting 1 week after clinical diagnosis (first intervention), SWT was repeated once every 2 weeks (second and fourth weeks). The patients were placed on a stretcher in the supine position. They all used ear muffs with their feet pointing toward the shockwave machine. The tendon insertion was marked with ink and moisturized with ultrasonography gel, reference points were the highest bulging site or the penultimate transversal skin crease. Radial shockwaves were applied with a BLT600 equipment (BTL Medical Technologies, Markham, Ontario, Canada), with 2000 to 3000 pulses, 7 to 10 Hz frequency, and 1.5 to 2.5 bar of intensity per application.

Eccentric Exercises

Two days after the first SWT session, patients started a 12-week Alfredson eccentric strengthening protocol.[22-24] The exercises were explained to the patients by the assistant doctor and they also received a detailed booklet regarding the protocol. Exercises started on ground level from a flexed ankle (tiptoes) followed by passive ankle extension (dorsiflexion). They were repeated 15 times in each series. There were 3 series with extended knees and 3 series with knees flexed at 20°.

The eccentric phase with the affected limb had to be performed slowly, while the patient contracted the muscles and increased the distance between the attachment and insertion points. Only the nonaffected member did the concentric stage (upward). Patients were told that the objective's fulfillment and the quality of the exercise are indicated by the discomfort felt on the calf after the series. As soon as the exercises became pain-free, patients were encouraged to add a load of 5 kg in a backpack.

Results

Table 1 describes the data of the 19 patients enrolled in this study. The average age was 51 years, with 13 (68%) white individuals. All patients in this study completed the protocol, with no complications. Fifteen (79%) patients were fully adherent to the Alfredson protocol, and 13 (68%) patients considered the treatment protocol successful. Adherence to the Alfredson protocol increased 6.5 times the chance of having a successful outcome (P = .01). Average body mass index was 29.20 kg/m^2 and it did not influence the outcome (P = .13). Gender and ethnicity did not affect the outcome either (P = .10 and P = .67, respectively). Two patients reported use of quinolone, which did not influence the outcome (P = .08).

Table 2 highlight the statistical comparative data. We can notice that at the end of the protocol, the patients demanded higher pressure on calcaneus to trigger pain (algometry 1), referred less pain when the algometer was applied with 3 kgf × cm^2 (algometry 2), had less global pain (VAS), and had higher AOFAS and VISA-A scores. All these differences were statistically significant.

Discussion

Insertional Achilles tendinopathy is frequent and affect both athletes and sedentary population. An improper healing response seems to cause the disease. In the affected tissues, we find degenerative changes and a low inflammatory reaction. The condition is painful, decrease athletic performance and might even impair the patient's daily activities. Up to 16% of patients abandon their sports activities due to the insertional Achilles tendinopathy.[2]

Usual conservative treatment includes physical therapy and exercises, but this approach still lacks good clinical results. One of the preferred exercise programs is the eccentric strengthening, which has excellent results in the noninsertional tendinopathy but does not offer the same reliability and effectiveness in insertional tendinopathy. Thus, we still do not have any reliable conservative treatment standard increasing the number of surgeries performed in these patients, which carry a financial burden as well as a myriad of complications like infection, wound dehiscence, tendon rupture, and nerve damage.[4]

In the quest for an adequate healing stimulation for these tissues, several alternatives were tried like infiltration, electrostimulation, and sclerotherapy. None of them proved to be successful and the search for cheap, practical and safe ways of inducing tissue reparation continues. By stimulus of soft tissue healing in behalf of angiogenesis and by enhancing the diffusion of cytokine molecules, SWT has become a reliable option on the approach of this illness.[11]

Shockwaves release angiogenic markers and recruit mesenchymal stem cells inducing neovascularization[10,11,25] by a still unknown molecular mechanism.[12,14] These newly formed vessels improve blood circulation and improving tissue regeneration at the tendon-bone junction. Separate lines of inquiry suggested that SWT, relative to placebo therapies, induce a higher increase of mechanical resistance and higher concentration of markers of collagen synthesis (ie, hydroxyproline and pyridinoline), which are important components of the healing process.[9,10,13]

Shockwaves have few complications, transitory hyperemia being the most frequent.[19] Five percent of patients report pain after high-energy shockwaves, but it normally ceases at the end of the treatment.[21] Tendon rupture was described in literature in only 1 study[26] that reported 2 cases of elderly patients in a population of 49 cases. The authors could not find a true relation between the therapy and the events. Rasmussem et al[27] has done a randomized placebo-controlled clinical trial with 48 patients and 12 months of follow-up, comparing the use of radial SWT after 4 weeks of

Table 1.

Descriptive Data.

Patient No.	Gender	Body Mass Index (kg/m^2)	Race	Age (Years)	Adherence to Alfredson Protocol	Outcome	Algometry 1 (kgf × cm^2)		Algometry 2 (VAS)		VAS		AOFAS		VISA-A	
							Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1	Female	25	White	44	Good	Success	2.03	4.04	8	3	5	0	75	95	95	95
2	Female	32	White	60	Partial	Fail	2.97	2.22	9	9	8	8	47	38	6	13
3	Female	26	White	53	Partial	Fail	3.45	2.02	7	9	8	9	49	44	43	12
4	Male	27	White	54	Good	Success	1.8	6.02	6	1	1	3	87	100	80	82
5	Male	26	Non-white	49	Good	Success	3.2	6.8	8	3	7	0	73	92	47	88
6	Male	31	Non-white	36	Good	Success	2.36	2.54	9	6	6	5	41	47	32	45
7	Female	37	White	44	Good	Success	1.9	7.06	8	0	8	0	66	88	53	84
8	Male	29	White	53	Partial	Fail	5.66	4.84	4	3	4	3	70	70	57	55
9	Female	39	White	53	Partial	Fail	3.28	6.9	1	1	4	2	68	75	17	45
10	Male	35	Non-white	55	Good	Fail	2.2	2.94	9	6	3	7	72	54	27	40
11	Male	22	Non-white	49	Good	Success	7.38	8.32	0	0	0	0	82	97	77	74
12	Male	21	White	44	Good	Success	28	5.16	5	2	4	1	73	87	80	96
13	Male	25	White	58	Good	Success	4.12	6.45	6	1	6	0	47	97	59	70
14	Male	25	Non-white	43	Good	Success	4.26	2.2	5	1	5	2	77	87	59	71
15	Male	27	White	26	Good	Fail	2.7	4.84	9	6	8	7	41	70	47	5
16	Female	28	White	52	Good	Success	2.12	2.46	3	4	3	3	85	85	60	84
17	Female	32	White	64	Good	Success	2.36	4.76	3	3	6	1	49	90	7	80
18	Male	29	Non-white	73	Good	Success	3.78	6.12	2	3	6	5	55	75	62	64
19	Female	28	White	43	Good	Success	3.6	6.6	7	1	8	4	51	75	24	86

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Society; VAS, visual analogue scale; VISA-A, Victorian Institute of Sports Assessment–Achilles.

Table 2.

Statistical Analysis for the Outcome Measures.

Scores	Average		*P*
	Pre-Treatment	Post-Treatment	
Algometry 1	3.55	4.65	.013
Algometry 2	4.77	3.41	.023
VAS	5.26	3.16	.009
AOFAS	63.58	77.56	.004
VISA-A	49.05	62.58	.044

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Society; VAS, visual analogue scale; VISA-A, Victorian Institute of Sports Assessment–Achilles.

conservative treatment, including stretching and strengthening. SWT group had less pain and better function. Kearney et al[4] conducted a systematic review of the literature looking for evidences concerning calcaneus insertional tendinopathy treatment. They found only 1 article[21] that used high-energy therapy, and, nevertheless, the work was limited by the small sample and the methodology inconsistencies.

While isolated shockwave treatment has shown encouraging results during the past years, they were not definitive. Adjuvant administration of the Alfredson protocol proved to be a reliable combination in the noninsertional presentation of this disorder in some studies.[22-24,27] Our study, though not placebo controlled, gives great evidence that eccentric loading associated with SWT can improve dramatically patients' symptoms, as we found significant improvement in clinical scores and in objective and subjective pain measures. It is noteworthy that our patients' perception success rate (68%) is comparable to the results of literature, but even the patients who classified the treatment as a failure had improved when we look to the objective measures used as outcomes. We can notice that at the end of the protocol, most of the patients demanded higher pressure on calcaneus to trigger pain (algometry 1: 3.55 kgf × cm^2 pretreatment vs 4.65 kgf × cm^2 posttreatment). They referred less pain (VAS) when the algometer was applied with 3 kgf × cm^2 (algometry 2: 4.77 pretreatment vs 3.41 posttreatment) and had less global pain (VAS: 5.26 pretreatment vs 3.16 posttreatment). All these differences were statistically significant.

It is also worth mentioning that our patients got high clinical scores at the end of the protocol, improving AOFAS scores from 63.58 to 77.56 and VISA-A scores from 49.05 to 62.58, with statistical significance. We can highlight that SWT was not the only treatment modality that contributed with these good results, as adherence to the Alfredson protocol increased 6.5 times the chance of having a successful outcome.

Because of our consistent findings, we believe that adding SWT to the eccentric strengthening can lead to a successful management of the Achilles insertional tendinopathy while avoiding complications and financial burden of surgical treatment. The strengths of this study results are its prospective methodology, the combined procedures, and the use of many trustable outcome measures to corroborate the results. The limitations of this study are its short follow-up, the single-center study, and the lack of a placebo-controlled group. Also, we could not evaluate objectively the adherence to the Alfredson protocol as this outcome was derived from patients' view.

Therefore, we can conclude that eccentric loading associated with SWT is effective for treating insertional Achilles tendinopathy. The strategy combination showed promising and consistent results in a very heterogenic population. Further studies, with a longer follow-up period, randomization, and a placebo-controlled group are required to confirm this and to ascertain this approach as a viable option in dealing with this prevalent condition.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: Project granted with government funding (CNPq [Conselho Nacional de Pesquisa–National Research Council] under the protocol number 8094833648737701).

Ethical Approval

This study was approved by the São Paulo Federal University (UNIFESP) Ethics Committee (No.: 1373481).

Informed Consent

All patients provided informed consent.

Trial Registration

Not applicable. FAS

ORCID iDs

Nacime Salomão Barbachan Mansur https://orcid.org/0000-0003-1067-727X
Tiago Baumfeld https://orcid.org/0000-0001-9244-5194

References

1. Hartog BDD. Insertional Achilles tendinosis: pathogenesis and treatment. *Foot Ankle Clin*. 2009;14:639-650. doi:10.1016/j.fcl.2009.08.005

2. Irwin TA. Current concepts review: insertional Achilles tendinopathy. *Foot Ankle Int.* 2010;31:933-939. doi:10.3113/FAI.2010.0933
3. Magnan B, Bondi M, Pierantoni S, Samaila E. The pathogenesis of Achilles tendinopathy: a systematic review. *Foot Ankle Surg.* 2014;20:154-159. doi:10.1016/j.fas.2014.02.010.
4. Kearney R, Costa ML. Insertional Achilles tendinopathy management: a systematic review. *Foot Ankle Int.* 2010;31:689-694. doi:10.3113/FAI.2010.0689
5. Sayana MK, Maffulli N. Eccentric calf muscle training in non-athletic patients with Achilles tendinopathy. *J Sci Med Sport.* 2007;10:52-58.
6. Sussmilch-Leitch SP, Collins NJ, Bialocerkowski AE, Warden SJ, Crossley KM. Physical therapies for Achilles tendinopathy: systematic review and meta-analysis. *J Foot Ankle Res.* 2012;5:15. doi:10.1186/1757-1146-5-15
7. Guilherme G, Travaglini PT, dos Santos JBG, de Seixas AMT, Flávio F. Efeito de ondas de choque na placa de crescimento de coelhos. *Acta Ortop Bras.* 2005;13:31-34. doi:10.1590/S1413-78522005000100008
8. Maffulli G, Hemmings S, Maffulli N. Assessment of the Effectiveness of Extracorporeal Shock Wave Therapy (ESWT) for Soft Tissue Injuries (ASSERT): an online database protocol. *Transl Med UniSa.* 2014;10:46-51.
9. Hsu RW, Hsu WH, Tai CL, Lee KF. Effect of shock-wave therapy on patellar tendinopathy in a rabbit model. *J Orthop Res.* 2004;22:221-227.
10. Wang CJ, Huang HY, Pai CH. Shock wave-enhanced neovascularization at the tendon-bone junction: an experiment in dogs. *J Foot Ankle Surg.* 2002;41:16-22.
11. Notarnicola A, Moretti B. The biological effects of extracorporeal shock wave therapy (ESWT) on tendon tissue. *Muscles Ligaments Tendons J.* 2012;2:33-37.
12. Chen YJ, Wang CJ, Yang KD, et al. Extracorporeal shock waves promote healing of collagenase-induced Achilles tendinitis and increase TGF-beta1 and IGF-I expression. *J Orthop Res.* 2004;22:854-861.
13. Chen YJ, Kuo YR, Yang KD, Wang CJ, Huang HC, Wang FS. Shock wave application enhances pertussis toxin protein-sensitive bone formation of segmental femoral defect in rats. *J Bone Miner Res.* 2003;18:2169-2179.
14. Wang CJ, Chen HS, Chen CE, Yang KD. Treatment of nonunions of long bone fractures with shock waves. *Clin Orthop Relat Res.* 2001;(387):95-101.
15. Hart L. Shock-wave treatment was more effective than eccentric training for chronic insertional achilles tendinopathy. *Clin J Sport Med.* 2009;19:152-153. doi:10.1097/01.jsm.0000347357.41069.27
16. Mani-Babu S, Morrissey D, Waugh C, Screen H, Barton C. The effectiveness of extracorporeal shock wave therapy in lower limb tendinopathy: a systematic review. *Am J Sports Med.* 2015;43:752-761. doi:10.1177/0363546514531911
17. Rompe JD, Furia J, Maffulli N. Eccentric loading versus eccentric loading plus shock-wave treatment for midportion Achilles tendinopathy: a randomized controlled trial. *Am J Sports Med.* 2009;37:463-470. doi:10.1177/0363546508326983
18. Rompe JD, Nafe B, Furia JP, Maffulli N. Eccentric loading, shock-wave treatment, or a wait-and-see policy for tendinopathy of the main body of tendo Achilles: a randomized controlled trial. *Am J Sports Med.* 2007;35:374-383.
19. Al-Abbad H, Simon JV. The effectiveness of extracorporeal shock wave therapy on chronic achilles tendinopathy: a systematic review. *Foot Ankle Int.* 2013;34:33-41. doi:10.1177/1071100712464354
20. Furia JP. Extracorporeal shockwave therapy in the treatment of chronic insertional Achilles tendinopathy [in German]. *Orthopade.* 2005;34:571-578.
21. Furia JP. High-energy extracorporeal shock wave therapy as a treatment for insertional Achilles tendinopathy. *Am J Sports Med.* 2006;34:733-740.
22. Fahlström M, Jonsson P, Lorentzon R, Alfredson H. Chronic Achilles tendon pain treated with eccentric calf-muscle training. *Knee Surg Sports Traumatol Arthrosc.* 2003;11:327-333.
23. Mafi N, Lorentzon R, Alfredson H. Superior short-term results with eccentric calf muscle training compared to concentric training in a randomized prospective multicenter study on patients with chronic Achilles tendinosis. *Knee Surg Sports Traumatol Arthrosc.* 2001;9:42-47.
24. Ohberg L, Alfredson H. Effects on neovascularisation behind the good results with eccentric training in chronic mid-portion Achilles tendinosis? *Knee Surg Sports Traumatol Arthrosc.* 2004;12:465-470.
25. Wang CJ, Wang FS, Yang KD, et al. Shock wave therapy induces neovascularization at the tendon-bone junction. A study in rabbits. *J Orthop Res.* 2003;21:984-989.
26. Costa ML, Shepstone L, Donell ST, Thomas TL. Shock wave therapy for chronic Achilles tendon pain: a randomized placebo-controlled trial. *Clin Orthop Relat Res.* 2005;440:199-204.
27. Rasmussen S, Christensen M, Mathiesen I, Simonson O. Shockwave therapy for chronic Achilles tendinopathy: a double-blind, randomized clinical trial of efficacy. *Acta Orthop.* 2008;79:249-256. doi:10.1080/17453670710015058