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Extracorporeal shockwave therapy (ESWT) in Achilles tendinopathy. A long-term follow-up observational study

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Aim. **The etiology, pathogenesis and natural course of Achilles tendinopathy are not yet completely known. Various forms of therapies, either conservative or surgical, have been proposed for its treatment. In the last few years, extracorporeal shockwave therapy (ESWT) has been proposed in the treatment of these tendinopathies and has shown encouraging short-term results. The purpose of this type-C study was to evaluate the effectiveness of ESWT in the symptomatic treatment of Achilles tendinopathies over time.**

Methods. **One hundred five patients (127 tendons) aged between 18 and 74 years (mean age 47.8) were enrolled in this study. All patients underwent clinical and instrumental diagnosis (ultrasonography, magnetic resonance imaging and X-rays) in order to identify presence, location and seriousness of the specific tendinopathy. The symptomatology was classified using the Visual Analogical Scale (VAS) and according to a five-stage clinical evaluation range. Shock wave treatment was applied with an electromagnetic shock wave generator. The protocol consisted in an average of four sessions (minimum three, maximum five), at a 2/7-day interval. In each session 1 500-2 500 impulses were administered with an energy varying between 0.08 and 0.40 mJ/mm2. All patients were evaluated before therapy and two months after the last ESWT session. Also, all patients were assessed and evaluated at medium-term (6 to 12 months), and 121 patients also at long-term (13 to 24 months).**

Results. **Authors obtained satisfactory results in 47.2% of cases (60 out of 127 tendons) at two-months follow-up, which increased to 73.2% at medium-term follow-up (93 out of 127 tendons), and then reaching 76% in the last evaluation (92 out of 121 tendons).**

Conclusion. **The outcome of the described shock wave treatment appears to be satisfactory and confirms the role of this alternative treatment in the management of the tendon disorders.**

KEY WORDS: Extracorporeal shock wave therapy - Tendinopathy - Achilles tendon - Physical therapy modalities.

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The etiology, pathogenesis and natural course of Achilles tendinopathy are not yet completely known. Histologically, there are no inflammatory cells, but increased amounts of interfibrillar glycosaminoglycans and changes in the collagen fibre structure and arrangement are usually seen. *In situ* microdialisys has confirmed the absence of inflammation. Achilles tendinopathy is most often seen among recreational male runners aged between 35 and 45 years, and it is most often considered to be associated with overuse. However, this condition is also seen in patients with a sedentary lifestyle.[1]

Various forms of treatment, either conservative or surgical, have been proposed for its treatment.

In the last few years extracorporeal shockwave therapy (ESWT) has been proposed in the treatment of Achilles tendinopathies and has shown encouraging short term results. ESWT has the advantage of being painless, non-invasive, well-tolerated by patients and has no collateral effects. Therefore, it could be a valid alternative to surgical treatment.[2-4]

Conflicts of interest.—All authors certify they did not sign any agreement with a commercial interest related to this study.

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TABLE I.—*Classification of Achilles tendinopathy according to symptoms.*

Classification	Symptoms
Stage 0	No pain
Stage 1	Pain only during sport with no limitation of sport performance
Stage 2	Pain during sport, limiting sport participation, and sometimes at rest (particularly on rising in the morning)
Stage 3	Pain also during daily activities
Stage 4	Intolerable and constant pain

The purpose of this type-C study (prospective study without a control group but with adequate analysis and follow-up of sufficient scope and duration) [5] was to evaluate the effectiveness of ESWT in the symptomatic treatment of Achilles tendinopathies over time.

Materials and methods

Between December 1997 and January 2005, 122 patients (105 males and 17 females) affected by Achilles tendinopathy were treated with ESWT.

Inclusion of patients was discussed with the local Ethical Committee. A randomized placebo-controlled study could not be permitted in relation to the fact that patients were paying for ESWT treatments. Lack of a control group for ethical reasons is often found in similar published studies.[6-10]

The inclusion criteria included a clinical history of Achilles tendon pain for at least six months and a minimum of three months' conservative treatment administered without benefit for at least four weeks before shock wave treatment. Patients who underwent physical therapy in the four weeks prior to ESWT were not included in this study (three patients), as well as those who had taken non-steroidal, anti-inflammatory medication the previous week (two patients). Exclusion criteria also included other associated pathologies such as polineuropathies (one patient), previous surgical treatments of the ankle affected by Achilles tendinopathy (six patients) and patients lost at short-term follow-up (five patients).

One hundred five patients were enrolled in this study (89 males and 16 females), 22 of which with bilateral pathology, for a total of 127 tendons. The patients' age ranged from 18 to 74 years with an average of 47.8±12.4 years. All patients were involved in various sports activities: 10 as professionals (9.5%), 63 as amateurs (60%) and 32 practicing sports occasionally but at least once a week (30.5%).

Diagnosis was made following clinical criteria and instrumental procedures (X-rays, magnetic resonance imaging and ultrasonography -US-), which helped to recognise 84 cases affected by insertional tendinopathy (66.1%) and 43 cases affected by non-insertional Achilles tendinopathy (33.9%).

Moreover, X-rays showed calcium deposits in 25 cases, 23 of which in the insertion region, and 2 cases observed in the context of the Achilles tendon.

Evaluation methods consisted of a classification scale graded from 0 to 4 used to evaluate pre- and post-treatment subjective symptoms. All patients were requested to estimate their pretreatment subjective symptoms and the current status of their treated Achilles tendon [11] (Table I). More recent cases were evaluated with Victorian Institute of Sport Assessment-Achilles questionnaire, which is validated for Achilles tendon problems,[12] but these results could not be included in the current study for uniformity with older results.

Shock wave treatment was applied using an electromagnetic shock wave generator produced by STORZ Medical AG, Tägerwilen, Switzerland). All patients underwent an average of four sessions (minimum three, maximum five), with an average two-day rest period (from two to seven days.), with an energy of 0.08-0.33 mJ/mm^2 for tendon belly tendinopathies and of 0.12-0.40 mJ/mm^2 for insertional calcific tendinopathy (optical fiber hydrophone measurements). The treatment was given with 1 500-2 500 impulses for each session using an ultrasonic guidance to focus the shock waves on insertional tendinopathy or midportion tendinopathy or calcified area. Treatments were administered without anesthesia. In 11 cases, after a first standard treatment cycle, patients who did not respond adequately underwent a second identical cycle. At the end of treatment, patients were asked not to return to sports activities for a minimum of three weeks and not to assume any medical therapy. Complete return to sports activities took place in accordance with the athlete's pain tolerance and the absence of clinical signs.

All patients were evaluated before therapy and two months after the last ESWT session. Also, all patients were assessed and evaluated at medium-term (6 to 12 months), and 121 patients were also evaluated at long-term (13 to 24 months).

TABLE II.—*Classification of results.*

Results	Symptoms
Excellent	Stage 0 at the time of follow-up
Good	Stage 1 with a post-treatment improvement of at least two stages
Fair	Improvement but the final result was stage 2 or higher
Poor	No improvement

Evaluation of post-treatment results was made on the basis of the average Visual Analogue Scale (VAS) score and of the subjective clinical evaluation range. The results were classified with the criteria shown in Table II.[13] In conclusion, excellent plus good results were considered as satisfactory and fair plus poor results as not satisfactory.

The statistical analysis of the results (P<0.05) used Student's t test for parametric variables and U Mann-Whitney and Wilcoxon test for non-parametric variables. SPSS version 14 software package was used for data analysis.

Results

The mean values according to the VAS scale were evaluated at different stages and are shown in Figure 1.

A significant average improvement (P<0.01) of the initial pain symptomatology (7.49±1.6) can be observed two months after the end of treatment (4.75±2.9). The mean value of the VAS scale decreases further in patients at medium-term (2.88±3.1) and is constant at long-term follow-up (2.6±3.3).

Figure 2 shows mean values using subjective clinical evaluation range (Stage 0 through 4) at different stages. A noticeable improvement is shown starting two months after the end of treatment (mean 1.78±1.2) (P<0.01) and continuing at medium-term evaluation (mean 1.07±1.2), while at long-term follow-up the improvement is unchanged (mean 0.93±1.2).

Finally, we obtained satisfactory results in 47.2% of cases (60 out of 127 tendons) at two-months follow-up, increasing to 73.2% at medium-term follow-up (93 out of 127 tendons), and reaching 76% in the last evaluation (92 out of 121 tendons) (Table III).

We achieved better results in tendinopathies of the main body of Achilles tendon compared with those obtained in insertional tendinophaties at two-month follow-up (satisfactory results in 60.5% of non-insertional tendinophaties *vs* 43.7% of insertional tendinophaties; P<0.05), at medium-term follow-up (satisfactory results in 77.7% of non insertional tendinophaties *vs* 42.3% of insertional tendinophaties; P<0.05), and at long-term evaluation (satisfactory results in 75% of non-insertional tendinophaties *vs* 37.4% of insertional tendinophaties; P<0.01).

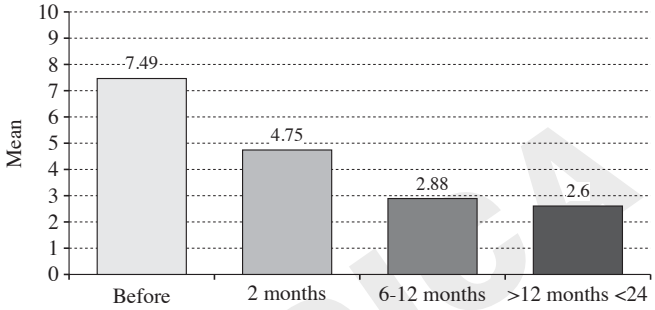

Figure 1.—Mean values according to the VAS scale at different stages.

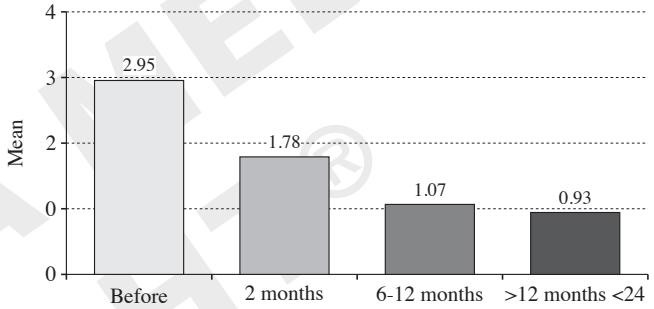

Figure 2.—Mean values using clinical evaluation scale at different stages.

TABLE III.—*Results at different follow-up.*

Follow-up	N. of tendons	Satisfactory	Unsatisfactory
2 months	127	47.2%	52.8%
Medium term (2-12 months)	127	73.2%	26.8%
Long term (13-24 months)	121	76%	24%

Regarding calcific tendinitis, 25 cases were treated. The bone spurs remain unchanged.

Discussion

Few prospective studies are available in literature regarding conservative therapies in Achilles tendinopathy. Such conservative rehabilitation treatments have

been proposed by several authors as initial therapeutical strategy [14-16] and include a combination of rest, medication (non-steroid anti-inflammatory drugs or corticosteroid injections), orthotic treatment, stretching [17] and various forms of physiotherapy.

Promising results have been obtained with eccentric training in athletic patients, with satisfactory results at medium-term follow-up.[18, 19] Eccentric exercises seem to be ineffective in sedentary patients with Achilles tendinopathy.[20]

Concerning physical therapies, a recent comparative study has matched the results of cryoultrasound therapy *vs* those obtained with Laser CO_2 and Tecar therapy. Cases treated with cryoultrasound therapy have shown a more significant variation in VAS score than those treated with with Laser and Tecar therapy.[21]

In recent studies, instrumental and immunohistochemical investigation showed neovascularization in Achilles tendons with painful tendinosis but not in normal, pain-free tendons. Neovascularization was observed in the area with tendon changes and it is probably related to the pain symptomathology.[22] Ultrasound-guided sclerosis of neovessels with polidocanol in painful chronic Achilles tendinosis has permitted a large number of cases (80%) to remain pain-free for a long period of time (two years) without significant risk of tendon rupture.[23]

In a recent double-blind randomized study, the efficacy of local injections of sclerosing and anesthetic substances have been compared and the sclerosing substance has been clearly demonstrated to lead to significant pain reduction.[24]

Furthermore, both eccentric calf muscle training and use of sclerosing injections showed a decrease in neovascularization in a study conducted with US and color-Doppler.[17]

These new therapeutic frontiers, however, leave unanswered questions regarding the role and the significance of neovascularization in a region that always seemed to be hypovascular due to low oxygen supply and, therefore, with a reduced tissue regeneration potential. Further prospective work with longer follow-up is, therefore, necessary to confirm the validity of these therapies and the hypothesis that the biological stimulus of shock waves goes beyond a mere antalgic effect.

In the last decade, focused ESWT has been used in the treatment of tendinopathies. Despite its success in clinical application in the treatment of soft tissues and orthopedic pathologies, the exact mechanism of ESWT is not yet fully understood. Several authors suggest that its effect can be ascribed to the transduction of the acoustic shock wave signal into a biological signal.

Studies performed through the evaluation of hystological and biomechanical parameters on animals showed that ESWT induces tissue regeneration and facilitates tendon healing after trauma. These experimental studies have pointed out significant increase in neovascularization, reduced adhesion formation and increase in hydroxyproline levels on tendon tissues treated with ESWT. In addition, in the tendons treated with ESWT, a greater force is required to damage the tendon when compared with the control group.[25, 26]

Biopsies performed on canine Achilles tendons 4 and 8 weeks after treatment with ESWT showed neovascularization growth and blood supply improvement, a result that was not found in the control group.[27] In a later study, neovascularization in the bone-tendon junction was confirmed by the presence of such angiogenic markers as vessel endothelial growth factor, endothelial nitric oxide synthase and by endothelial cell proliferation indicated by proliferating cell nuclear antigen (PCNA). The results showed earlier release of angiogenic growth factors and increase in neo-vessels and tissue proliferation about four weeks after treatment, that persisted for up to 12 weeks.[28]

The efficacy of ESWT is strictly related to energy level and number of impulses used during treatment.[29] Effects of ESWT appear, in fact, to be dose-related.

Some authors have noted that the use of energy flux densities of 0.28 mJ/mm^2 on Achilles tendons treated with ESWT showed no evidence of tendon damage and that changes were reversible in four weeks, while higher energy levels (0.60 mJ/mm^2) showed lesions of the tendon and paratendon tissue. In addition the authors revealed an increase in tendon diameter and an inflammatory reaction, which did not completely disappear after four weeks.[28] Other authors have indicated the presence of tendon lesions with the use of energy flux range between 0.42 and 0.50 mJ/mm^2.[30]

To evaluate the effects on tendon healing of different intensity impulses of extracorporeal shock wave, some authors gave a single treatment (0.16 mJ/mm^2) to rat tendons in which Achilles tendinitis had been induced through a collagenase injection at tendon junction. The group that received ESWT with 200 impulses showed biomechanical and biochemical character-

istics of tendon healing, PCNA, neovascularization and elevated expression of growth factors (TGF-B1 and IGF-1) two weeks after treatment. On the other hand, ESWT treatment with 500 and 1 000 impulses showed inhibitory effects on tendon repair. These studies confirm that harmful effects of ESWT on tissues are dose-related. The limitation of these studies is that results obtained on animal models cannot be utilized for human purposes, as animal soft tissues (such as rats and rabbits, etc.) could be more sensitive to ESWT.[31]

In our study we used a medium-low energy flux density and different energy levels for insertional tendinopathies and tendon belly pathologies. Higher levels of energy (0.12-0.40 mJ/mm^2) were used in insertional tendinopathy, since the focal zone is the tendon-bone junction and related calcifications, if any, while in tendon belly pathologies a lower energy level was used (0.08-0.33 mJ/mm^2).

While several studies are available in literature on the effects of ESWT on animal models, fewer are the clinical studies. Moreover, a comparison with studies reported in literature concerning the efficacy of ESWT in Achilles tendinopathy is difficult because treatments were administered with different generators using different levels of energy and different number of impulses. Also, clinical results were evaluated with different criteria.

In a study conducted on patients with chronic Achilles tendinopathy treated with ESWT, 60% of satisfactory results were noted after three years of follow-up.[32] A recent study with control group [2] was carried out to determine the efficacy of ESWT for the treatment of adults with chronic insertional Achilles tendinopathy. Twelve months after treatment, the number of patients with successful Roles and Maudsley scores was statistically greater in the ESWT group compared with the control group (P>0.0002), with 83% of ESWT group patients having a successful result.

In another study authors compared the results of ESWT with those of surgery at one year follow-up.[4] Even though the satisfactory results shown by surgery (84%) were higher than those obtained with ESWT (72%), these latter results are very encouraging. In this study satisfactory results were obtained in 77% of insertional tendinopathy cases and in 85% of tendon belly cases. In spite of some differences in the typology of patients and in follow-up, these results match those of a study carried out by La Sapienza University School of Medicine:[11] after surgery and at an average follow-up of 11.5 years (range 5-18 years) results were satisfactory in 88% of cases. The same study showed a lower percentage of satisfactory results in insertional tendinopathies (77%) when compared to tendon belly pathologies (85%), a characteristic noted in our ESWT case history, with smaller satisfactory results (excellent and good) in the insertional tendinopathies in comparison to those obtained in tendon belly pathologies at two months after the end of treatment and at medium-term follow-up (P<0.05), at medium-term (P<0.05) and at long-term follow-up (P<0.01). In our opinion, the unsatisfactory results obtained with shock wave in treating insertional tendinopathy compared to tendon belly pathologies may be associated to the multifactorial nature of this pathology, that may include various lesions such as Haglund's heel, bursitis, upper calcanear spur, degenerative and metaplastic phenomena of the bone-tendon junction.

In spite of the absence of a control group, as in other studies published in international literature,[6-10] the results obtained in our experience are encouraging for the long-lasting improvement of pain symptomatology, without collateral effects.

These results would suggest to wait at least one year after treatment before considering surgery and to evaluate the possibility of administering additional treatments when satisfactory results have not been obtained. In our experience, ESWT treatment does not prejudice surgery and may even improve the tendon's condition for surgery.

However, the conservative management approach is hardly tenable with serious or professional athletes, for which pressure is high to return to activity as soon as possible. These cases, if a quick response to ESWT is not observed, are normally scheduled for surgery without further wait.

Presently, low- and medium-energy ESWT is used only after failure of conventional therapies while, on the basis of our experience, it can be evaluated as first-approach therapy, due to lack of contraindications and collateral effects. In fact, patients in this study that did not respond successfully to treatment, later underwent surgery with no harm whatsoever.

Finally, the response to treatment seemed not to be influenced by the presence of calcifications, which did not show any radiological evidence of modification after the treatment

Conclusions

Although Achilles tendinopathy has been studied extensively, there is a clear lack of properly conducted scientific research to clarify its etiology, pathology, natural history and optimal management.

As mentioned before, limitations of this study are: absence of a control group undergoing a placebo therapy and impossibility to achieve 100% patient recall. At present, this study is continuing with the adoption of a control group undergoing alternative treatment, focusing also on shock wave related modifications evidenced by diagnostic means.

Despite these limitations, the study showed the positive effect of extracorporeal shock wave therapy in the treatment of the tendinopathy, and the results obtained in our experience are encouraging in the light of the long-lasting improvement of the pain symptomatology reached without collateral effects.

However, a prospective randomized, clinical trial with a control group and the standardization of physical and technical treatment parameters seems to be necessary for a classification of ESWT as evidence-based medicine.

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