

Radial shock wave therapy for lateral epicondylitis: a prospective randomised controlled single-blind study

G. SPACCA ¹, S. NECOZIONE ², A. CACCHIO ¹

Aim. Despite the lateral epicondylitis or tennis elbow is a common cause of pain in orthopaedic and sports medicine, the results of the different modalities of conservative treatment are still contradictory. The purpose of this study was to evaluate the efficacy of radial shock wave therapy (RSWT) in the treatment of tennis elbow.

Methods. In a prospective randomized controlled single-blind study, of 75 eligible patients, 62 with tennis elbow were randomly assigned to study group and control group. There were 31 patients in the study group and 31 patients in the control group. Both groups had received a treatment a week for 4 weeks; the study group had received 2 000 impulses of RSWT and the control group 20 impulses of RSWT. All patients were evaluated 3 times: before treatment, at the end of treatment and to 6 months follow-up. The evaluation consisted of assessments of pain, pain-free grip strength test, and functional impairment.

Results. Statistical analysis of visual analogue scale (VAS), disabilities of the arm, shoulder, and hand (DASH) questionnaire and pain-free grip strength test scores has shown, both after treatment and to the follow-up at 6 months, significant difference comparing study group versus control group ($P < 0.001$). Statistical analysis within the groups, showed always statistically significant values for the study group. Also the control group showed statistically significant differences for some analyzed parameters. Nevertheless such differences resulted to be more statistics that not clinics as it showed the percentage of satisfied patients in the study group

¹Physical Medicine and Rehabilitation Unit
Department of Neuroscience
San Salvatore Hospital, L'Aquila, Italy
²Clinical Epidemiology Unit
Department of Internal Medicine and Public Health,
University of L'Aquila, L'Aquila, Italy

(87% post-treatment; 84% follow-up) in comparison with that of the control group (10% post-treatment; 3% follow-up), and the number needed to treat (NNT) that is of 1.15 at post-treatment and of 1.25 to the 6 months follow-up.

Conclusion. The use of RSWT allowed a decrease of pain, and functional impairment, and an increase of the pain-free grip strength test, in patients with tennis elbow. The RSWT is safe and effective and must be considered as possible therapy for the treatment of patients with tennis elbow.

Key words: Lateral epicondylitis - Tennis elbow - Radial Shock Wave Therapy - Elbow pain.

Lateral epicondylitis of the elbow is a common cause of pain in orthopaedic and sports medicine. Lateral epicondylitis of the elbow has many analogous terms, including lateral tennis elbow, elbow pain, tendonitis of the common extensor origin, and peritendonitis of the elbow. We used in this study the term of "tennis elbow". The symptoms include pain and tenderness over the lateral epicondyle of the humerus and pain on gripping or dorsiflexion against resistance of the wrist, middle finger, or both.

The aetiology and pathophysiology of tennis elbow remain unknown; nevertheless, the multifactorial aeti-

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Address reprint requests to: Dr. A. Cacchio, Dipartimento di Neuroscienze, Unità Operativa Complessa di Medicina Fisica e Riabilitazione, Ospedale "San Salvatore" di L'Aquila, Via Natali 1, 67100 Coppito-L'Aquila, Italy. E-mail: angelo.cacchio@tin.it

ology has been invoked by some authors and the predisposing factors are aging, chemical, vascular, hormonal, and hereditary factors.¹

The most common reasons for tennis elbow pain are local injury due to overuse, and muscular imbalance. Overuse syndrome has even been suggested as a factor, although a degenerative rather than inflammatory process has been demonstrated in histologic examination of the extensor aponeurosis, most frequently at the origin of the extensor *carpi radialis brevis* muscle of patients with this disorder.^{2, 3} Despite the clinical diagnosis is easy, the treatment is often difficult.⁴

The most common complaints of subjects with tennis elbow are pain and decreased grip strength, both of which may affect daily living, job or sport activities.⁵

Treatment of patients with tennis elbow is generally conservative, ranges from nonsteroidal anti-inflammatory drugs, physiotherapy with ultrasound and laser therapy, stretching and strengthening exercises, to local steroid injection. Surgical intervention is required for elbow that are resistant to conservative management. However, both conservative and operative treatment have not shown consistent and promising results.^{1, 6-9}

The therapeutic modality of extracorporeal shock wave therapy (ESWT) has been object of previous studies that have shown the effectiveness of the ESWT in the short term for treatment of epicondylitis of elbow.^{2, 10-13}

Actually, the standard indications in the musculoskeletal system are plantar fasciitis, elbow's epicondylitis and calcifying tendinitis of shoulder.¹⁴

Recently, radial shock wave therapy (RSWT) has been introduced for the treatment of insertion tendinopathies such as tennis elbow,¹⁵ plantar fasciitis with or without heel spur,¹⁶ and calcifying tendinitis of shoulder.¹⁷ The results of these studies, that used RSWT, have not shown differences in comparison with the results obtained with ESWT.

The rationales of the treatment with the shock waves in the treatment of the tendinopathies include the promotion of soft tissue healing,¹⁸ achieve relief from pain through inhibition of pain receptors.¹⁹ However, mechanisms by which shock waves promote tissue healing, and analgesic effects are still unknown and a matter of speculation.²⁰

In the RSWT the shock wave is produced pneumatically through the acceleration of a projectile inside the handpiece, unlike the ESWT where the shock wave

is produced by electrohydraulic, piezoelectric and electromagnetic systems.

Pressure waves generated by pneumatic mechanism are transmitted radially from the tip of applicator to the target zone, decreasing in energy proportional to the third power of the penetration depth in the tissue.¹⁷ In the RSWT the focus doesn't centre on the target zone, as in the ESWT, but in the tip of the applicator.

However, despite different methods exists to produce the shock waves, their therapeutic effectiveness seems not to be influenced by their methods of production.¹⁷

The RSWT can be compared to the low- or medium-energy ESWT. Low- and medium-energy are definitions derived by the ESWT classification done by some authors²¹⁻²³ according to the ESWT focus energy flux density (FEFD). Low-energy shock waves have an FEFD of up to 0.08 mJ/mm², medium-energy an FEFD of up to 0.28 mJ/mm², and high-energy have an FEFD up to 0.6 mJ/mm².

Due to possible tissue damage caused by high-energy shock wave (FEFD >0.28 mJ/mm²), as showed by Rompe *et al.*²² in rabbit Achille's tendon, the treatment of soft-tissue injuries with ESWT has been made with a low- medium- energy (FEFD <0.12 mJ/mm²), in almost all the studies present in literature. In theory, therefore, the RSWT should also be able to achieve therapeutic effects in tennis elbow.

The purpose of our study was to evaluate the therapeutic effectiveness of RSWT employment on the treatment of tennis elbow, using a prospective randomized controlled single-blind study. The goals of the used treatment are to decrease the pain, to reduce the functional impairment and to improve the strength of the elbow's muscles.

Materials and methods

From November 2002 to July 2003, of 75 eligible patients (Figure 1) 4 did not meet inclusion criteria, 6 had met exclusion criteria, and 3 refused to participate, thus only 62 consisting of 32 men and 30 women with an average age of 46.92±9.26 years (range 31-65) were recruited for this prospective randomized controlled single-blind study in which we use the RSWT for the treatment of tennis elbow. In 43 patients the right elbow was affected, and the left elbow in the remaining 19. The average duration of the condition

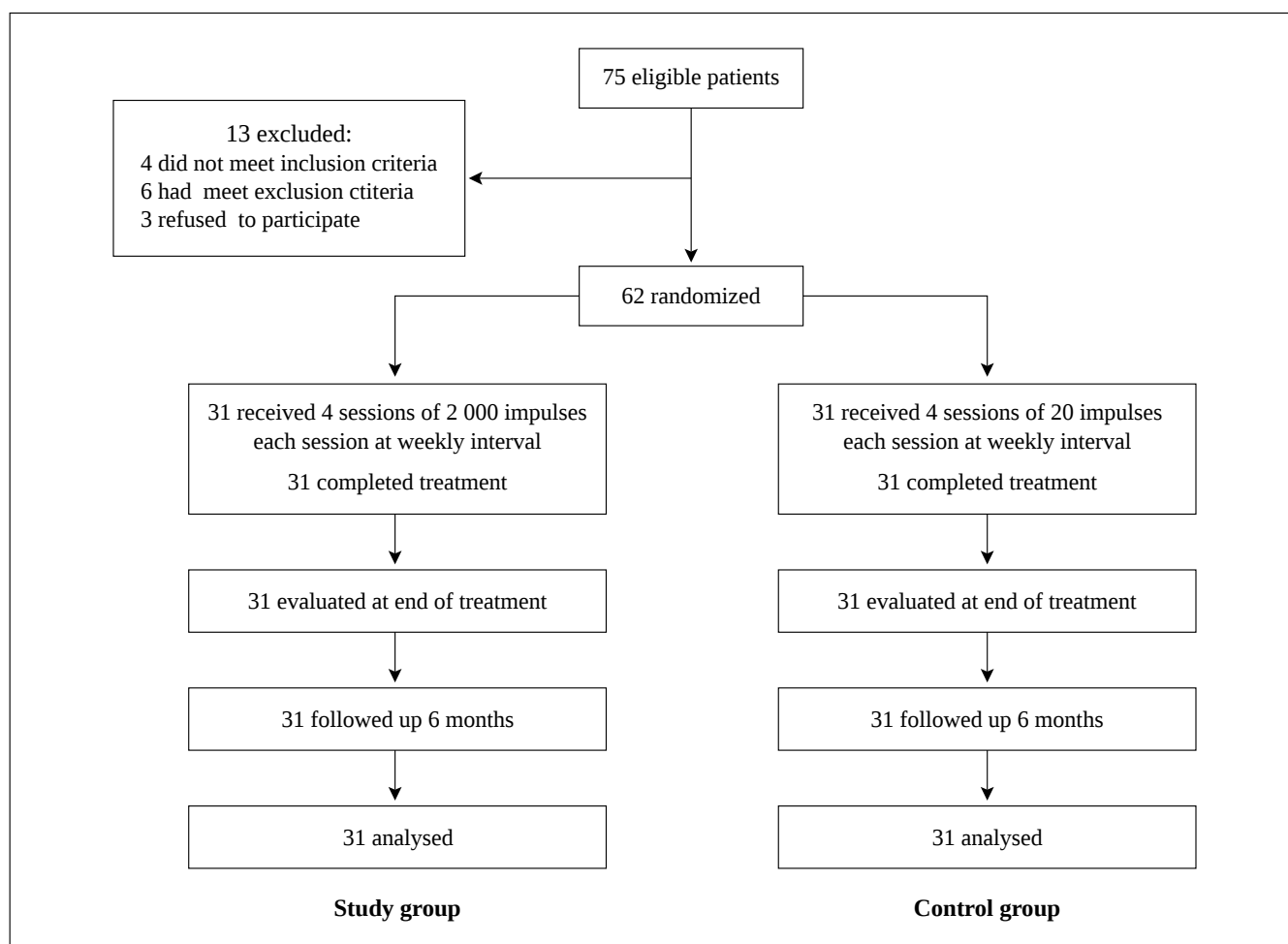


Figure 1.—Flow diagram of study.

was 10 months (range, 12-22 months). Inclusion criteria were: clinical diagnosis of lateral epicondylitis of the elbow confirmed by diagnostic imaging (ultrasound or magnetic resonance imaging), duration of symptoms for a least 10 months; pain with a visual analog scale (VAS) score ≥ 3 cm, failed previous conservative treatments included nonsteroidal anti-inflammatory drugs, cortisone injection, physical therapy, exercise programs, and the use of a functional elbow brace. Exclusion criteria were: pregnancy, implanted pacemaker, blood coagulation disorders, assumption of anticoagulants drugs, skeletally immature patients, inflammatory or neoplastic disorders, pathologies in the shoulder and/or neck, and treatment with corticosteroid injections in the last 4 weeks.

Informed consent was obtained and potential risks were explained to the patients. Patients who met the eligibility criteria were randomly assigned, by the use of computer-based 1:1 randomization scheme to study or control groups. The subjects had been randomly divided in 2 groups, and both groups had been formed of 31 subjects. The study group of 31 subjects average age 46.82 ± 9.52 years (range, 34-65 years), the control group with 31 subjects average age 47.03 ± 9.15 years (range, 31-62 years).

Treatment procedure

In this study, we used the Physio Shock Wave Therapy (Pagani Elettronica, Milano, Italy) consisting

of a control unit, a handpiece with 3 different applicators: 8 mm, 10 mm, 15 mm, and a medical air compressor. The compressor creates a pneumatic energy that is used to accelerate a projectile inside the handpiece. When the projectile strikes the applicator, a shock wave is created that is distributed radially from the tip of the applicator to the pain zone. The control unit modulates the intensity, the frequency which are expressed respectively in bar, and hertz, and the number of impulses.

All patients were seated with the shoulder and elbow respectively abducted of 45° and flexed of 90°, with the forearm leaned on a plan, and the shock wave applicators was positioned perpendicular to the site of insertion of wrist's extensors muscles, on the lateral epicondyle. No local anaesthetics or analgesics drugs were administered before or during the treatment.

The treatment with low-energy shock wave is recommended for the patients with tendinopathies.²² There is no consensus on appropriate doses of shock wave and treatment parameters remain empirical. However, 1 000 to 2 000 impulses of an EFD from 0.01 up to 0.28 mJ/mm² are usually recommended and applied¹¹⁻¹³ 3 times at weekly intervals.

The choice not to employ a classical placebo group but a group, that we can define "less active same therapy" group, has been due to the previous published study^{12, 13} that use ESWT in the same manner, for treatment of tennis elbow. Moreover, some authors^{11-13, 17, 22} affirm that the effectiveness of the shock wave therapy is dose-dependent, therefore, we can hypothesize that 20 impulses don't produce some physiological effect, and we are able, moreover, to verify this assertion.

Also, not using local anesthesia has been necessary to maintain the perception of the impulses from the patient.

Study group

All patients in the study group have received 4 sessions, 2 000 impulses for each session of RSWT that were applied using a 15 mm applicator, a pressure and a frequency were respectively: 1.2 bar and 4 Hz for 500 impulses, and 1 bar and 10 Hz for 1 500 impulses.

The treatment area was prepared with coupling gel (aquasonic 100, Parker laboratories, Fairfield, NJ, USA) to minimize the loss of shock wave energy at the interface between applicator tip and skin.

Control group

All patients in the control group have received 4 sessions, 20 impulses for each session of RSWT that were applied using a 15 mm applicator, a pressure and a frequency were respectively: 1.2 bar and 4 Hz for 5 impulses, and 1 bar and 10 Hz for 15 impulses.

The treatment area was prepared with coupling gel (aquasonic 100, Parker laboratories, Fairfield, NJ, USA) to minimize the loss of shock wave energy at the interface between applicator tip and skin.

Outcome measures

All patients were evaluated 3 times: before therapy (pre-treatment), at the end of therapy (post-treatment) and to 6 months (follow-up). The decision to set the follow-up to 6 months is based on the hypothesis of Haake *et al.*²⁴ about the possibility of spontaneous improvement of painful symptoms in a longer period.

The examination consisted of assessments of pain, pain free grip strength test, and functional impairment. Assessment of pain at rest, provoked by palpation, and evoked by resisted wrist dorsiflexion (Thomsen test) was done by a VAS range from 0 (no pain) to 10 (maximum pain). On the basis of the studies by Stratford *et al.*²⁵ showing on subjects with lateral epicondylitis, maximum grip strength test less reliable, less valid, and less sensitive to change than pain-free grip strength test, we have used for our evaluation of the strength this last procedure. The pain-free grip strength test was performed in the involved side with the elbow extended by a Jamar Dynamometer (Preston Healthcare, Jackson, USA). Functional impairment was assessed with the disabilities of the arm, shoulder, and hand (DASH) questionnaire developed by the Upper Extremity Collaborative Group (UECG).²⁶

The primary end point was the reduction of 3 points in the pain VAS at rest, provoked by palpation, and evoked by resisted wrist dorsiflexion (Thomsen test).

The secondary end points were the reduction of 20 points to functional impairment DASH questionnaire, improvement of 5 kg to the pain-free grip strength test. Also subjective satisfaction for treatment and number needed to treat (NNT)^{27, 28} were evaluated.

Statistical analysis

Statistical analyses were performed using the SAS 8.2 (SAS Institute Inc., Cary, NC, USA) All analyses of the

outcomes were performed according to the principle of intention-to-treatment. Friedman two-way ANOVA by ranks was used to compare difference within the group in different time. For the pain-free grip strength test we have tested the normality with the Shapiro test, and verified that only 3 variable resulted normal we have decided to apply also in this case a no-parametric test. Post-hoc comparison was done by Wilcoxon's rank sign test for dependent samples, and by Wilcoxon's rank sums test for independent samples, as appropriate. Significance levels for multiple comparisons were adjusted with the Bonferroni procedure. Moreover the NNT^{27, 28} was evaluated to allow a clinical translation of the statistical results. The NNT is expressed in terms designed to help decide whether the intervention might be valuable in clinical practice.²⁸ For example, when comparing treatment X and treatment Y, an NNT score of 5 for treatment X indicates that, on average, after treating 5 patients, treatment X will have achieved one more positive outcome than if treatment Y had been used.²⁸

Results

There were no device-related problems, and no systemic or local complications. The baseline characteristics that were similar and without statistic significance for both groups are shown in Table I. All patients were re-assessed after treatment period and at 6 months follow-up. There have been no withdrawals, so the total of the 62 recruited patients has completed the study.

Pain (primary outcome)

Friedman two-way ANOVA of all pain scores analysed (at rest, provoked by palpation, and at Thomson test) demonstrated a significant effect of treatment ($P<0.0001$) and a significant treatment-time interaction ($P<0.0001$). Post-hoc comparison demonstrated a significant differences between study and control groups ($P<0.0001$) after treatment and at the 6 months follow-up. Comparing the same parameter, before and after treatment within each group, a statistically significant reduction (improvement) is shown (Table II) in the study group ($P<0.001$) and a statistically significant increment (worsening) in the control group ($P<0.0001$) both after treatment that at the 6 months follow-up.

TABLE I.—*Baseline characteristics of both groups.*

Characteristics	Study Group	Control Group
Patients (n)	31	31
Age	46.82±9.52*	47.03±9.15*
Duration (mo)	12±4.95*	13±5.03*
Male/Female (n)	16/15	16/15
Treatment side (right/left)	27/18	23/22
DASH functional impairment (5 th -95 th percentile)	38.5 (35-44)	38 (36-43)
Pain-free Grip Streght test (kg) (5 th -95 th percentile)	38 (32-41)	37 (32-41)
Pain (VAS range 0-10 cm)		
At rest (5 th -95 th percentile)	4.5 (2-7)	4.5 (2-8)
Provoked by palpation (5 th -95 th percentile)	8 (4.5-9.5)	7 (4.5-9)
At Thomsen test (5 th -95 th percentile)	5.0 (2-8.5)	4.5 (2-8)

Values are median and (5th-95th percentile)

* Values are mean ± standard deviation

TABLE II.—*Pain Scores (VAS 0-10 cm) before and after treatment, and at 6 months follow-up in the Study and Control Groups.*

Score	Study Group Median (5 th -95 th)	Control Group Median (5 th -95 th)	P value
<i>Pain at rest</i>			
Before treatment	4.5 (2-7)	4.5 (2-8)	0.635*
After treatment	0.5 (0-1.5)	5 (2-8.5)	<0.001*
P value	<0.001**	<0.001**	
Follow-up	0.5 (0-2)	6.5 (3-9)	<0.001*
P value	<0.001***	<0.001***	
<i>Pain provoked by palpation</i>			
Before treatment	8 (4.5-9.5)	7 (4.5-9)	0.647*
After treatment	0.5 (0-3)	8.5 (5.5-9.5)	<0.001*
P value	<0.001**	<0.001**	
Follow-up	1 (0-3)	8 (5-9)	<0.001*
P value	<0.001***	<0.001***	
<i>Pain at Thomsen Test</i>			
Before treatment	5.0 (2-8.5)	4.5 (2-8)	0.413*
After treatment	0.5 (0-2.5)	5.0 (2.5-8)	<0.001*
P value	<0.001**	<0.001**	
Follow-up	1.0 (0-3)	6.5 (2.5-9)	<0.001*
P value	<0.001***	<0.001***	

*Comparison between Study and Control Groups before, after treatment, and 6-months follow-up

**Comparison between before and after treatment within each group

***Comparison between before treatment and 6-months follow-up within each group

Pain-free grip strength test (secondary outcome)

Friedman two-way ANOVA demonstrated a significant effect of treatment ($P<0.0001$) and a significant treatment-time interaction ($P<0.0018$). Post-hoc com-

TABLE III.—*The mean values of Pain-free Grip Strenght Test in the Study and Control Groups.*

	Study Group Median (5 th -95 th)	Control Group Median (5 th -95 th)	P value
Pre-treatment	38 (32-41)	37 (32-41)	0.224*
Post-treatment	50 (37-60)	38 (33-42)	<0.001*
P value	<0.001**	0.012**	
Follow-up	46 (34-56)	36 (32-44)	<0.001*
P value	<0.001***	0.269***	

*Comparison between Study and Control Groups before, after treatment, and 6-months follow-up

**Comparison between before and after treatment within each group

***Comparison between before treatment and 6-months follow-up within each group

TABLE IV.—*The mean values of DASH functional impairment scale in the Study and Control Groups.*

	Study Group Median (5 th -95 th)	Control Group Median (5 th -95 th)	P value
Pre-treatment	38.5 (35-44)	38 (36-43)	0.804*
Post-treatment	13 (8-19.5)	36 (32-41)	<0.001*
P value	<0.001**	<0.001**	
Follow-up	10 (6-16.5)	34.5 (31-39)	<0.001*
P value	<0.001***	<0.001***	

*Comparison between Study and Control Groups before, after treatment, and 6-months follow-up

**Comparison between before and after treatment within each group

***Comparison between before treatment and 6-months follow-up within each group

parison demonstrated a significant differences between study and control groups ($P<0.0001$) after treatment that at the 6 months follow-up. The statistical analysis within each group showed, post-treatment, (Table III), a statistically significant increase of pain-free grip strength test scores both in the study group ($P<0.001$) and in the control group ($P=0.012$); however this increase is clinically significant only for the study group as it showed the percentage of satisfied patients in the study group (87% post-treatment; 84% follow-up) in comparison with that of the control group (10% post-treatment; 3% follow-up), and NNT that is of 1.15 at post-treatment and of 1.25 to the 6 months follow-up. Moreover a reduction of the values reached in the post-treatment was shown to the 6-months follow-up. Nevertheless the study group maintained a value of pain-free grip strength test statistically significant ($P<0.001$) in comparison to the pre-treatment value, contrary to the control group that didn't show statistically significant differences ($P=0.269$) for the same comparison.

TABLE V.—*Subjective satisfaction and NNT in the study and control groups.*

	Study Group (No.=31)	Control Group (No.=31)	NNT (95% CI)
<i>Post-treatment</i>			
Satisfied	27 (87%)	3 (10%)	1.15 (1.08-1.60)
Unsatisfied	4 (13%)	28 (90%)	
<i>Follow-up</i>			
Satisfied	26 (84%)	1 (3%)	1.25 (1.08-1.45)
Unsatisfied	5 (16%)	30 (97%)	

NNT: number needed to treat; 95% CI, 95% confidence interval

DASH functional impairment (secondary outcome)

Friedman two-way ANOVA demonstrated a significant effect of treatment ($P<0.0001$) and a significant treatment-time interaction ($P<0.0018$). Post-hoc comparison demonstrated a significant differences between study and control groups ($P<0.0001$) after treatment that at the 6 months follow-up. Comparing the same parameters, before and after treatment within each group, a statistically significant reduction is shown (Table IV) in the study group ($P<0.001$). Also the control group showed a statistically ($P<0.001$) but not clinically significant reduction as it showed the percentage of satisfied patients in the study group (87% post-treatment; 84% follow-up) in comparison to that of the control group (10% post-treatment; 3% follow-up), and the NNT that is of 1.15 at post-treatment and of 1.25 to the 6 months follow-up.

Overall satisfaction (secondary outcome)

The subjective satisfaction of patients and the NNT have shown in Table V.

Discussion

As shown by some authors 1, 2, 9, 11-13, 15, 16 most patients responded to conservative treatment with only 7.3% of the 1 213 patients requiring surgery.¹ Then, the primary treatment for patients with tennis elbow is conservative. Despite this, it is not yet well defined which is the treatment of choice. In fact, the conservative treatments range from nonsteroidal anti-inflammatory drugs, functional bracing, physical therapy, to cortisone injection. Furthermore, some authors 6-8, 10, 20, 24 contest the effectiveness of the conservative

treatments, and others have found the results of non-operative treatment to be inconsistent, and with the insufficient evidence to support one treatment over others.

Currently, ESWT shows a little smaller success rate of surgical treatment, and surgery can be done if the ESWT also fails.^{2, 11-13}

Although the ESWT mechanism of action is not yet known, some authors^{2, 10-16} have used the ESWT in the treatment of the tennis elbow bringing good results.

It has been postulated that shock waves provoked an intense stimulation (hyperstimulation) which activates the fibres of small diameter which project to cells in the periaqueductal grey area, that activate a serotonergic system which modulates transmission of pain stimuli through posterior horns. This causes a raising of the patient's pain tolerance above their existing original pain level. Furthermore, ESWT causes a localized metabolic reaction, due to increased vascularity and less formation of adhesions, that occur promoting natural healing process.^{11, 12, 29}

Recently, RSWT has been introduced for the treatment of insertion tendinopathies such as plantar fasciitis with or without heel spur, and tennis elbow.¹⁵ Straub *et al.*¹⁶ using RSWT, in a 12 month follow-up study with more than 200 patients, showed an overall treatment success of up 83% for the tennis elbow and 81% for the plantar fasciitis.

Despite the RSWT has been introduced at the end of the 90s, currently still no randomised clinical study has been conducted for appraising their effectiveness and safety in the treatment of tennis elbow.

To our knowledge, our study is the first randomized, single-blind, less active same therapy-controlled, of RSWT for this condition.

A direct comparison of the various study results with one another is difficult, due to the use of different device, with different mechanisms of output of the shock wave, and of the different dosage of energy flux employees. However, our study, in which we use RSWT, showed similar results of previous studies, that used ESWT.¹¹⁻¹³

This randomised controlled study has shown that between the 2 groups the differences of the values for each analyzed parameter, such as VAS, pain-free grip strength test, and DASH scores, were always statistically significant. Moreover to improve the clinical translation of these statistic results we have investigated the subjective satisfaction of the patients and the NNT, both post-treatment and at the 6 months follow-up. In

this manner we have ascertained that even if the analysis within each group showed statistically significant values, these were not necessarily translated in a clinical improvement, appreciable from the patients. In fact, despite the statistically significant results, in the DASH value in the control group, which received 4 sessions of 20 impulses each session at weekly interval, only 3 patients (10%) after treatment and 1 patient (3%) to the 6 -months follow-up were satisfied of the received treatment. Contrary to the study group, which received 4 sessions of 2 000 impulses each session at weekly interval, the satisfied patients were 27 (87%) after treatment and 26 (84%) to the 6 month follow-up.

Rompe *et al.*^{12, 13} reported a good or excellent outcome in 48% of 50 patients with chronic tennis elbow who were treated with 3 000 impulses of shock wave therapy and acceptable results in 42% at the final review at 24 weeks, in comparison with 6% good or excellent outcome and 24% acceptable outcome in 50 patients treated with 30 impulses.

Accordingly to Rompe *et al.*^{12, 13} our results confirm that the effectiveness of the shock wave therapy, independent of the system of shock waves generation, is dose-dependent.

Krischek *et al.*² using low-energy ESWT had found excellent and good results in 60% and 62% of patients with tennis elbow respectively at 6 months and 1 year. Wang *et al.*³⁰ have had 91% complete or nearly complete resolution of pain in patients with lateral epicondylitis of the elbow after shock wave treatment, compared with no improvement for any patients of control group. Melegati *et al.*³¹ have obtained good results with an increase of the functionality, appraised with the total elbow scoring system (TESS), and a decrement of the pain, appraised with the VAS, using 2 different positionings of therapeutic head of shock waves: lateral tangential and back tangential in 2 groups of 21 and 20 patients respectively. Ko *et al.*¹¹ in a series of 53 patients (56 elbows) treated with medium-energy ESWT (0.18 mJ/mm²) have shown to have, at 6 weeks, the following results: 36.7% excellent or good, 38.8% acceptable, and 24.5% unchanged. To 12 weeks the rate of success is become of 57.9% excellent or good, 36.8% acceptable, and 5.3 unchanged. Haake *et al.*²⁴ analyzing the results of their double-blind, prospective, randomized, multicenter study, they conclude that the ESWT results are not superior to the placebo in the treatment of lateral epicondylitis. Nevertheless,

some considerations can be made related to the Haake's study: a) although it was a large multicenter study, different procedures and parameters of treatment were used; b) both the local anesthesia before the treatment, and anti-inflammatory drugs during and in the 3 following days of the treatment was used. These conditions can modify the results and induce to wrong conclusions. In fact, also with the methodological limits (presence of a group less effectiveness therapy rather than placebo) and with the use of a different device (RSWT) from those employees in the Haake's study, the results of our study as those of other authors,^{12, 32} who use a more correct study methodology (presence of a true control group and use of similar device to the Haake's study), have shown a real effectiveness of the shock waves in the treatment of the lateral epicondylitis.

Although the lack of a true placebo-control group can represent a limit of our study, our results showed that the RSWT are comparable, both in the effects that in the effectiveness to low-energy ESWT, in the treatment of tennis elbow. Also, as shown for low-energy ESWT, RSWT have the advantage that can be done without local anaesthesia.

Moreover, as low-energy ESWT the RSWT have smaller risks of adverse effects, compared to high-energy ESWT, in the treatment of the tendinopathies, as shown by the previous studies of Rompe *et al.*²² in which high energies (>0.28 mJ/mm²) caused damage and necrosis of the rabbit tendon tissue.

Conclusions

This study has shown: a) RSWT effectively reduce pain and increase grip strength and elbow function, without device-related adverse effects. Moreover, the results observed after the treatment were maintained over the following 6 months; b) the results of the present randomised controlled study are comparable with those of previous ESWT and RSWT studies; c) the cumulative time-dependent effect, shown for the ESWT, independent of the system of shock waves generation, are also present in the RSWT; d) the RSWT, as shown for low-EFD ESWT, have the advantage that can be done without anaesthesia, reducing the risks of local or systemic adverse effects; e) RSWT is a new therapeutic modality that is safe and effective in the treatment of patients with tennis elbow.

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