

Radial Extracorporeal Shock Wave Therapy Is Effective and Safe in Chronic Distal Biceps Tendinopathy

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Objective: To assess the efficacy and safety of radial extracorporeal shock wave therapy (rESWT) for chronic distal biceps tendinopathy (cDBT).

Design: Case-control study (level of evidence, 3).

Setting: SUN Orthopaedics and Sports Medicine.

Patients: Patients with a diagnosis of cDBT were recruited between January 2010 and February 2015.

Interventions: Patients received a single session of rESWT (2000 shock waves with energy flux density of 0.18 mJ/mm²) or other forms of nonoperative therapy.

Main Outcome Measures: Patients completed the visual analog scale (VAS), the modified QuickDASH (MQD) score, and the Roles and Maudsley (RM) score over a 12-month period.

Results: Forty-eight patients completed the final review at 12 months and were included in the study. Subjects ranged in age from 30 to 64 years. Mean pretreatment VAS scores for the rESWT and control groups were 8.3 and 8.5, respectively. Three and 12 months after inclusion in the study, the mean VAS scores for the rESWT and control groups were 3.4 and 5.6 ($P < 0.001$) and 2.7 and 4.7 ($P < 0.001$), respectively. Twelve-month follow-up MQD-Sports and

MQD-Work scores for the rESWT and control groups were 3.7 and 1.7 ($P < 0.001$) and 3.8 and 1.8 ($P < 0.001$), respectively. Differences in mean RM scores were statistically significant between groups at 3 months after the treatment. There were no significant complications.

Conclusions: Overall, rESWT is an effective and safe treatment for cDBT.

Clinical Relevance: Radial ESWT as a novel, effective, and safe treatment for cDBT.

Key Words: distal biceps tendinopathy, extracorporeal shock wave therapy, radial extracorporeal shock wave therapy, rehabilitation, sports medicine

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INTRODUCTION

Chronic distal biceps tendinopathy (cDBT) is characterized by activity-related antecubital elbow pain, weakness, and loss of function. The condition usually occurs in the dominant arm of middle-aged male adults.¹ Racquet sport athletes, wrestlers, weight lifters, archery athletes, body builders, and those whose job requires repetitive forearm rotation are at the risk.^{1–3}

Chronic DBT can be thought of as a stage in the continuum of the progression of tendinopathy to frank tendon rupture.⁴ There is often an acute phase (usually the result of repetitive microtrauma) that over time and without proper rest, progresses to the essential lesion of tendinopathy (a failed healing lesion) and ultimately loss of some function.^{1,3,4} The exact etiology and natural history of cDBT are unknown, as in many tendinopathies.⁵

Common symptoms include a deep, dull, burning pain localized to the antecubital fossa, which worsens several hours after activity and improves with rest. Difficulty with heavy lifting, pain after “arm workouts” with weights, and pain with using a screwdriver or pulling back an archery bow are typical patient complaints. Patients may experience decreased strength or endurance or both of elbow flexion and forearm rotation.¹ Supination is more often affected than flexion.^{4,6}

Traditional nonoperative treatment includes relative rest, activity modification, oral and topical anti-inflammatory medication, physical therapy modalities, stretching and strengthening,

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and splinting [note that some studies found that chronically overloaded tendons do not display enhanced inflammatory activity and nonsteroidal anti-inflammatory drugs (NSAIDs) may abolish the exercise-induced adaptive increase in collagen synthesis in human tendons].^{7,8} Steroid injections are avoided for the risk of further weakening a diseased tendon.¹ Although promising, the benefits of platelet-rich plasma protein injections remain unclear.⁹ These recommendations for treating cDBT are in line with general recommendations for the treatment of chronic tendinopathies (compare with the study of Loppini and Maffulli¹⁰).

Like other enthesopathies (ie, Achilles tendinopathy, lateral elbow tendinopathy, rotator cuff tendinopathy), response to traditional nonoperative treatment is varied and inconsistent. Symptoms can linger for an extended period, frequently over 1 year, and there are no consistently reliable disease-modifying treatments.¹

When nonoperative treatment fails, many authors recommend surgery.^{1,3,4} Surgery usually involves complete detachment and debridement of the diseased portions of the tendon followed by formal repair.^{11,12} Regarding technique, Bain et al¹³ recommended different techniques depending on the extent of tendon involvement. These authors suggested that disease limited to <50% of the tendon be treated with continued nonoperative management or with surgical debridement of the surrounding synovitis.¹³ Tendon degeneration/tearing of >50% should be treated with division of the remaining tendon, debridement, and formal repair.¹¹ Other authors recommended a similar technique.^{3,11}

Unfortunately, there are only a few published reports of successful surgical treatment of cDBT.^{3,11} The majority of these studies are small, retrospective, case series.^{3,11} Most authors reported favorable patient outcomes but also lengthy postoperative recoveries, prolonged time out of work, and not infrequent transient nerve palsies.^{3,11,14}

Radial extracorporeal shock wave therapy (rESWT) is a noninvasive procedure that was shown to stimulate regeneration and angiogenesis in treated tissues in mice.¹⁵ Radial ESWT has been used effectively to treat many types of tendinopathies and fasciopathies, including plantar fasciopathy, Achilles tendinopathy, patellar tendinopathy, greater trochanteric pain syndrome, proximal hamstring tendinopathy, lateral and medial epicondylitis, and calcifying tendinosis of the shoulder (eg, Refs. 16–22; among many others). Radial ESWT is very safe and often produces subjective and objective improvement several months after the treatment (for review see, eg, Refs. 23–26). Although there are some negative trials, there are now many randomized controlled trials (RCTs) that support the use of rESWT in these and other conditions.^{23–26} In particular, 24 RCTs on rESWT for tendinopathies have been listed in the PEDro database (www.pedro.org.au),²⁵ of which 19 RCTs found rESWT significantly better statistically than either placebo or alternative treatment modalities. (The PEDro database is a freely available database of more than 27 000 RCTs, systematic reviews, and clinical practice guidelines in physical and rehabilitation medicine.²⁷ For each RCT, review, or guideline, the PEDro database provides the citation details, the abstract, and a link to the full text, where possible. All RCTs listed in the PEDro database are independently assessed

for quality. All but 2 of the PEDro scale items are based on the Delphi list.²⁸ PEDro is currently the largest independent database on topics related to physical and rehabilitation medicine and is often used by investigators in Norway, Australia, and New Zealand; less so by other European and North American investigators).

It is of note that based on all studies on ESWT listed in the PEDro database, it was possible to identify application of local anesthesia and application of insufficient energy as main factors that can adversely affect the outcome of ESWT.²⁵ Another important factor that may adversely affect the outcome of ESWT is return to normal activities immediately after ESWT. The latter may have caused the negative outcome in the TOPGAME study on ESWT for chronic patellar tendinopathy in which no restrictions were given for either group with regard to sports participation,²⁹ whereas other authors who did not permit heavy activities, including sports, for 4 to 6 weeks after ESWT for chronic patellar tendinopathy—reported positive outcome.³⁰

Acknowledging (1) the inconsistent nature and variable efficacy of other nonoperative treatments, (2) the risks, missed work and sport participation, and the usual prolonged recovery associated with surgery, and (3) the proven effectiveness of rESWT in other types of tendinopathy, the aim of this study was to determine whether rESWT is safe and effective for the management of cDBT. Because no preliminary data were available, the null hypothesis of the present study was that a single session of rESWT is not an effective treatment for cDBT.

METHODS

Participants

The present study was a retrospective case-control study on patients who were derived from the clinical practice of the first author. From 01/01/2010 to 02/02/2015, all patients with an established diagnosis of cDBT who were treated by the first author were considered for inclusion in the study.

Initially, all patients underwent history taking and physical examination by the first author. The inclusion criteria of the present study included patients with a 6-month history of DBT refractory to other forms of nonoperative treatment, such as relative rest, a brief course of immobilization, physical therapy, analgesic medication, and soft tissue massage. In reality, DBT was defined as the insidious onset of deep, dull, antecubital elbow pain, point tenderness over the distal biceps tendon, and increased pain with resisted elbow flexion and forearm supination. All patients had a negative hook test as described by O'Driscoll et al.³¹ Furthermore, all patients had anteroposterior and lateral radiographs of the affected elbow to rule out tumors, end-stage elbow inflammatory or osteoarthritis, or loose bodies. Magnetic resonance imaging scans and ultrasound studies were performed on a case-by-case basis. Patients younger than 18 years, those with pregnancy, local infection, local tumors, rheumatoid arthritis, end-stage arthritis, loose bodies, prior elbow surgery, and unresolved fractures were excluded from the study.

After the diagnosis was confirmed, a thorough explanation of the various options, as well as the potential risks, benefits, and outcomes associated with the various options, took place for all patients. All patients who met the inclusion criteria and did not meet the exclusion criteria were offered (1) traditional nonoperative therapy consisting of physical therapy, a course of ibuprofen or naproxen, and a topical anti-inflammatory agent, (2) rESWT, and (3) surgery (note that offering NSAIDs was motivated by anticipated pain relief, despite the limited role of NSAIDs in tendinopathies^{7,8} but in view of the lack of alternatives). All patients were educated about their condition at their first clinic appointment.

After making an informed decision, those patients who chose to treat their conditions with rESWT were assigned to the rESWT group. Twenty-seven patients (28 elbows) were treated. One patient who had cDBT in both elbows and underwent bilateral treatment was excluded. Furthermore, there were insufficient follow-up data on 2 patients. Thus, 24 patients with 24 elbows with cDBT were available for analysis. These patients represented the rESWT group.

Thirty-two patients who chose to treat their conditions with traditional nonoperative methods were considered for inclusion in the control group. These patients were advised to (1) avoid activities that reproduced pain, (2) assess treatment progression based on a decrease in activity-related pain while performing activities of daily living, and (3) to use topical anti-inflammatory agents as a method for pain control twice per day for a period of 2 weeks and then on an as-needed basis. Patients were also directed to use either 600 mg of ibuprofen 3 times per day or 400 mg of naproxen 2 times per day for 2 weeks and then on an as-needed basis. All patients advised to take anti-inflammatory medications indicated that they took the anti-inflammatory medications as instructed.

Daily physical therapy exercises consisted of forearm, biceps, and shoulder stretching and strengthening. Stretches were held for a count of 4, followed by relaxation. Patients were advised to perform 10 repetitions, 2 times per day. Strengthening was performed using band exercises. Patients were advised to perform 3 sets of 8 to 12 repetitions with bands to strengthen the biceps, 2 times per day. No patient had severe worsening of symptoms after performing the stretching and strengthening exercises. Furthermore, all patients indicated that they had been compliant with their rehabilitation programs.

Physical therapy modalities, such as ice massage, manual massage, and ultrasound, were used on an as-needed basis. One patient developed a septic olecranon bursitis secondary to a laceration and was excluded. Two patients had concomitant lateral epicondylitis that ultimately required surgery and were also excluded. Furthermore, 5 patients were lost to follow-up. Thus, 24 patients with 24 elbows with cDBT were available for analysis. These patients represented the control group.

There were no statistically significant differences between patients in the rESWT group and those in the control group with respect to age and gender distributions, the affected side, mean duration of pain before treatment, mean visual analog scale (VAS) score, and mean Roles and Maudsley (RM) score at baseline (Table 1).

All patients in the rESWT group and those in the control group stated that they participated in some type of regular recreational sporting activity (ie, some form of noncompetitive exercise performed approximately 3–5 times per week) (Table 1). Furthermore, 10 of the patients in the rESWT group and 9 of the patients in the control group worked as laborers (ie, factory workers or manual gas-industry workers). Two of the patients in the rESWT group and 4 of the patients in the control group worked as farmers (Table 1). Other patients who chose to treat their conditions surgically (n = 2 patients) were not considered in the present study.

Study Design and Intervention

All patients signed an informed consent form. The details of the procedure and potential risks were discussed fully before treatment.

All treatments were performed by the first author, in a clinic setting, without anesthesia. A protocol shown to be effective in other clinical trials was used.^{18,19} A radial extracorporeal shock wave device (Swiss DolorClast; Electro Medical Systems, Nyon, Switzerland) was used in all instances. With this device, radial extracorporeal shock waves are produced after a projectile in a hand piece is accelerated by a pressurized air source and strikes a metal applicator with a diameter of 15 mm. The energy produced is transmitted to the skin as a radial shock wave through a standard, commercially available ultrasound gel. The waves are then dispersed radially from the application site into the surrounding tissues (see Figure 2A in Ref. 24).

Each patient received a single session of rESWT. Two thousand shock waves were applied with an air pressure of 4.0 bars [equal to an energy flux density (EFD) of approximately 0.18 mJ/mm²] at a frequency of 10 Hz. The total EFD of the treatment session was approximately 360 mJ/mm².

The procedure was performed with the patient seated on a clinic stretcher. A pillow was positioned under the elbow. The patient identified the area of maximal tenderness. This area was marked with a marking pen. The brachial pulse and biceps tendon were palpated. Conductive gel was applied to the skin overlying the palpable biceps tendon, the area of maximal tenderness, and the area of the biceps insertion. The applicator of the hand piece of the shock wave generator was placed in contact with the skin and aimed in a slight lateral and volar direction toward the area of maximal tenderness and biceps insertion, and away from the medially located brachial artery. The radial shock waves were primarily delivered in a volar to dorsal direction to the palpable biceps tendon, the region of maximal tenderness, and the region of the biceps insertion. Shock waves were applied in a circumferential pattern. Medial–lateral and superior–inferior movements of the applicator of the hand piece of the shock wave generator were restricted to an area of approximately 1 to 2 cm.

Postprocedure

On completion of the procedure, the treated elbow was assessed for hematoma, bruising, and swelling. The brachial pulse was palpated. All concomitant interventions were discouraged for 3 months after the treatment. Patients were

TABLE 1. Summary of Baseline Measures for Treatments Groups (n = 24 Each)

Characteristic	rESWT Group	Control Group	Comparison, <i>P</i>
Age, mean $\pm$ SEM (range), yr	49.2 $\pm$ 2.0 (30–64)	49.2 $\pm$ 2.0 (30–64)	1.0 (<i>T</i> test)
No. women (%)	3 (12.5)	2 (8.3)	1.0 (χ^2 test)
Affected side, n (%) left	12 (50)	11 (45.8)	1.0 (χ^2 test)
Duration of pain before treatment, mean $\pm$ SEM (range), mo	12.4 $\pm$ 0.9 (6–21)	10.5 $\pm$ 0.8 (6–20)	0.126 (<i>T</i> test)
VAS score, mean $\pm$ SEM (range), points	8.3 $\pm$ 0.17 (7–10)	8.5 $\pm$ 0.18 (7–10)	0.613 (<i>T</i> test)
RM score, mean $\pm$ SEM (range), points	4 $\pm$ 0 (4–4)	4 $\pm$ 0 (4–4)	1.0 (<i>U</i> test)
Sporting activity, n			
Weight lifting	9	8	
Archery	6	7	
Body building	3	2	
Arm wrestling	3	1	
Softball	1	3	
Golf	2	2	
Racquetball	0	1	
Patient occupation, n			
Manual laborer	4	3	
Gas line worker	4	3	
Farmer	2	4	
Factory worker	3	2	
Office worker	2	3	
Teacher	2	3	
Plumber	1	2	
Nurse	1	2	
Football coach	2	0	
Surgeon	2	0	
Homemaker	1	1	
Engineer	0	1	

allowed immediate range of motion. Patients were advised to avoid heavy lifting (>10 kg) for a period of 2 weeks. No other cointervention was used.

Activity was advanced as symptoms dissipated. Upper extremity forearm, biceps, and shoulder muscle strengthening was usually permitted 4 weeks after the treatment as dictated by the clinical response of decreased pain and improvements in the ability to perform activities of daily living.

Patients who worked in a sedentary occupation were allowed to immediately return to their pretreatment work status. The time to return to sports and unrestricted heavy labor was usually less than 6 weeks, and it was made on a patient-by-patient basis.

Outcome Measures

Outcome measures included the VAS score, the RM score, a modified QuickDASH Score-Sports (MQD-S), and a modified QuickDASH Score-Work (MQD-W). The VAS and RM scores were collected at baseline (BL) and 1 month (M1), 3 months (M3), and 12 months (M12) after inclusion into the study during the follow-up examinations. The MQD-S and MQD-W scores were calculated at M12.

On the VAS, 10 points indicated maximal unbearable pain, and zero points indicated no pain. Treatment success

was defined as individual improvement in VAS score by more than 60% at M3.

The RM score is a subjective 4-point patient assessment of pain and limitations of activity.³² With the RM score, 1 point indicated an excellent result with the patient having no symptoms. Two points indicated a good result with the patient significantly improved from the pretreatment condition and satisfied with the result. Three points indicated a fair result with the patient somewhat improved from the pretreatment condition and partially satisfied with the treatment outcome. Four points indicated a poor outcome with symptoms identical or worse than the pretreatment condition and dissatisfaction with the treatment result.

The MQD-S/Performing Arts module consists of 4 questions.³³ Each question assesses the degree of difficulty the responder has with some aspect of their sport or ability to use a musical instrument. Each question has 5 possible responses. A response of “1” indicates no difficulty with that particular item, whereas a response of “5” indicates the inability to perform the specified activity. Therefore, a MQD-S score of 1 indicates no difficulty, and a MQD-S score of 5 indicates severely diminished ability or inability to perform a particular activity. The

individual mean MQD-S score was obtained by determining the sum of the individual scores for each question and dividing by 4.

The MQD-W module also consists of 4 questions.³³ Similar to the MQD-S score, each question assesses the degree of difficulty the responder has with some aspect of their work. Each question also has 5 possible responses. A response of “1” indicates no difficulty with the specified activity, whereas a response of “5” indicates the inability to perform the specified activity. Like the MQD-S score, the individual mean MQD-W score was determined by adding the individual scores for each question and dividing by 4.

Statistical Methods

For all investigated parameters, mean and standard error of the mean were calculated at each time point (ie, BL, M1, M3, and M12, if applicable) separately for the patients in the rESWT group and those in the control group. Comparisons between patients in the rESWT group and those in the control group at baseline were performed with *t* Student's test (mean age of patients, mean duration of pain before treatment, and mean VAS score before treatment), Mann–Whitney *U* test (mean RM score before treatment), and χ^2 test (gender and affected side distributions). The development of mean VAS scores and mean RM scores after the treatment was investigated with repeated-measures analysis of variance (RM ANOVA) followed by post hoc Bonferroni tests for pairwise comparisons. Comparisons between patients in the rESWT group and those in the control group with respect to mean MQD-S scores and mean MQD-W scores at M12 were performed with the Mann–Whitney *U* test. Treatment success (ie, number of patients with individual improvement in VAS score by more than 60% at M3 and M12) was tested with Fisher exact test. In all analyses, an effect was considered statistically significant if its associated *P* value was smaller than 0.05. Calculations were performed using GraphPad Prism (Version 5.0 for Windows; GraphPad software, San Diego, CA).

Ethics

There is no local ethics board at the institution of the first author that could have approved the protocol of the present study. A corresponding letter of the Chairman of the Evangelical Community Hospital (Lewisburg, PA) is provided as additional file (see **Document, Supplemental Digital Content 1**, <http://links.lww.com/JSM/A119>). Therefore, the present study was performed as follows: once all data were available, they were made anonymous and sent to the last author who performed the statistical analysis. The last author has never visited the clinic of the first author and, thus, could not link the data to any patient. In this way, the present study was performed in full compliance with the guidelines of the local authorities of the University of Munich (Regierung von Oberbayern, Munich, Germany). The other coauthors have neither visited the clinic of the first author nor have they had access to any nonanonymous data.

RESULTS

Visual Analog Scale Scores

The mean VAS score of the patients in the rESWT group decreased from 8.33 ± 0.17 (mean $\pm$ standard error of the mean) at BL to 3.42 ± 0.32 at M3 and 2.67 ± 0.31 at M12, and of the patients in the control group, it decreased from 8.46 ± 0.18 at BL to 5.63 ± 0.23 at M3 and 4.67 ± 0.25 at M12. The differences in mean VAS score were statistically significant between patients in the rESWT group and those in the control group at M1, M3, and M12 but not at BL (RM ANOVA: $P_{\text{Treatment}} < 0.001$, $P_{\text{Time}} < 0.001$, and $P_{\text{Interaction}} < 0.001$; post hoc Bonferroni tests: $P_{\text{BL}} > 0.05$, $P_{\text{M1}} < 0.001$, $P_{\text{M3}} < 0.001$, and $P_{\text{M12}} < 0.001$) (Figure 1A).

Treatment Success

Fourteen patients (14/24 = 58.3%) in the rESWT group, but only 1 patient (1/24 = 4.2%) in the control group, showed individual improvement in VAS score by more than 60% at M3. At M12, 17 patients (70.8%) in the rESWT group and 4 patients (16.6%) in the control group showed individual improvement in VAS score of more than 60%. Differences between the groups were statistically significant at M3 ($P < 0.001$) and M12 ($P < 0.001$) (Figure 2). Accordingly, the null hypothesis was rejected.

Roles and Maudsley Scores

The mean RM score of the patients in the rESWT group decreased from 4 ± 0 at BL to 2.04 ± 0.19 at M3 and

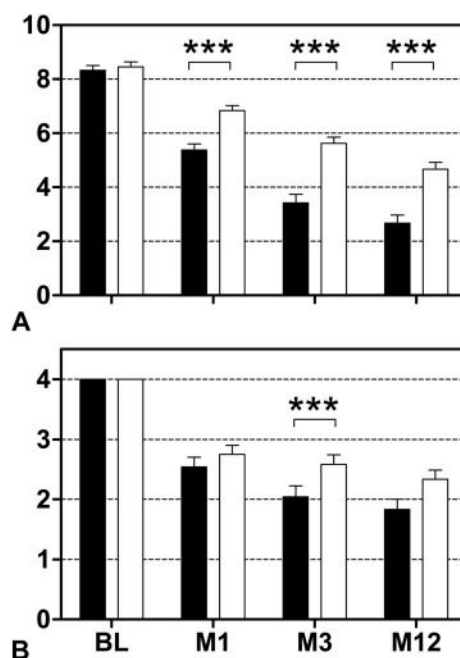


FIGURE 1. Mean and SEM of VAS scores (A) and RM scores (B) of patients in the rESWT group (closed bars) and those in the control group (open bars) at baseline (BL) and at 1 month (M1), 3 months (M3), and 12 months (M12) follow-up. Results of statistical analysis (post hoc Bonferroni tests) are indicated. *** $P < 0.001$.

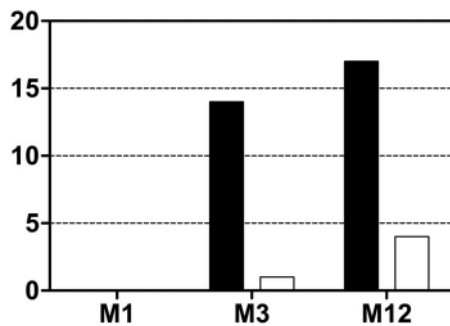


FIGURE 2. Number of patients in the rESWT group (closed bars) and those in the control group (open bars) with individual improvement in VAS score of more than 60% at 1 month (M1), 3 months (M3), and 12 months (M12) follow-up.

1.83 $\pm$ 0.17 at M12, and of the patients in the control group, it decreased from 4 $\pm$ 0 at BL to 2.58 $\pm$ 0.16 at M3 and 2.33 $\pm$ 0.16 at M12. The differences in mean RM score were statistically significant between patients in the rESWT group and patients in the control group at M3 but not at BL, M1 and M12 (RM ANOVA: $P_{\text{Treatment}} = 0.05$, $P_{\text{Time}} < 0.001$, and $P_{\text{Interaction}} = 0.028$; post hoc Bonferroni tests: $P_{\text{BL}} > 0.05$, $P_{\text{M1}} > 0.05$, $P_{\text{M3}} < 0.05$, and $P_{\text{M12}} > 0.05$) (Figure 1B).

Modified QuickDASH Scores-Sports

The mean MQD-S score of the patients in the rESWT group was 1.68 $\pm$ 0.13 at M12 and of those in the control group was 3.66 $\pm$ 0.08 at M12. This difference was statistically significant ($P < 0.001$) (Figure 3A).

Modified QuickDASH Score-Work

Patients in the rESWT group had a mean MQD-W score of 1.77 $\pm$ 0.13 at M12 and those in the control group had 3.84 $\pm$ 0.09 at M12. This difference was statistically significant ($P < 0.001$) (Figure 3B).

Occupation and Sporting Activity

All patients in the rESWT group and 20 of 24 patients in the control group were able to return to their preferred sports and did so at their preinjury levels. Of the 4 patients in the control group who did not return to their sports, 2 were weight trainers, 1 was a softball player, and 1 was a body builder. Time to return to sport was variable and ranged from 2 to 6 weeks.

Complications

There were 3 minor complications, all in the ESWT group. Two patients had pain during the treatment. The pain resolved after the completion of the procedure. One patient with a history of carpal tunnel syndrome had some increased tingling in the median nerve distribution after the treatment. The enhanced neurologic symptoms also resolved several hours after the treatment.

DISCUSSION

Tendinopathy is the most common cause of adult elbow pain.³ In order of frequency, the 4 most common elbow

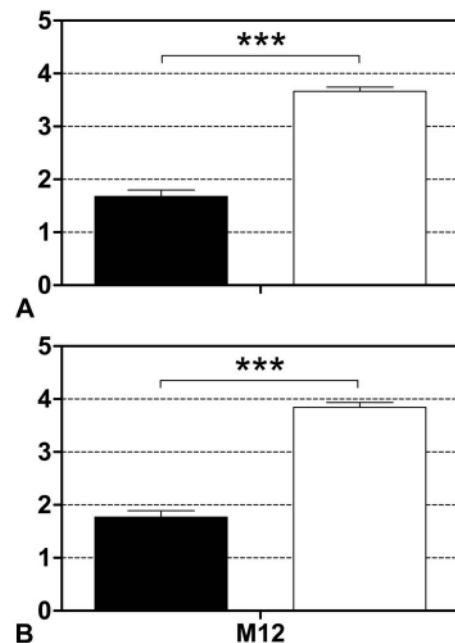


FIGURE 3. Mean and SEM of MQD-S scores (A) and MQD-W scores (B) of patients in the rESWT group (closed bars) and those in the control group (open bars) at 12 months follow-up (M12). Results of statistical analysis (T test) are indicated. *** $P < 0.001$.

pathologies defined by the location of the underlying tendinopathy are lateral elbow tendinopathy, medial elbow tendinopathy, DBT, and distal triceps tendinopathy.³ Each of these conditions may account for lost recreational time and work place dysfunction.

To our knowledge, the present study represents the largest series of patients with cDBT treated with rESWT (or ESWT in general) for which outcomes have been reported. The data demonstrate that patients with cDBT treated with rESWT reported statistically significantly decreased VAS scores (Figure 1A), statistically significantly better RM scores (Figure 1B), and statistically significantly greater functional scores (Figure 3) than control subjects. As was the case in prior rESWT tendinopathy trials, the majority of the improvement occurred by 3 months after the treatment.^{19,20,34} Of particular note was the substantial difference between the number of patients in the rESWT group and the number of patients in the control group who had positive outcome (calculated as individual improvement in VAS score by more than 60%) at M3 (58.3% vs 4.2%) and M12 (70.8% vs 16.6%). We are not aware of any other study on the treatment of cDBT with a comparable outcome. Furthermore, there were no substantial complications, and there was a high degree of patient satisfaction; no patient required re-treatment. These findings justify the use of rESWT for DBT.

One of the earliest descriptions of incomplete distal biceps tendon injury was that of Bourne and Morrey.³⁵ These authors labeled this disease process “partial tearing of the distal biceps tendon.” Although debatable, most investigators now believe that “partial tearing” of a tendon, as diagnosed by noting abnormalities on magnetic resonance imaging studies

and ultrasound studies, is more accurately described as “pathological tendinopathy.”³⁶ We favor the term “tendinopathy,” because it more accurately represents the pathophysiologic process and describes the clinical situation of pain, failed healing response of the tendon involved, and loss of function.

The literature is replete with studies regarding the use of ESWT to treat lateral and medial elbow tendinopathies. For instance, there are currently 18 highest-quality randomized controlled clinical trials on ESWT for lateral and medial elbow tendinopathies listed in the PEDro database (www.pedro.org.au).²⁵ However, the same is not true for cDBT. A literature search of the PEDro, EMBASE, and PubMed databases using the terms “shock wave therapy,” “ESWT,” and “biceps tendinopathy” revealed no studies. Indeed, we are aware of only 1 other publication, a case report of a single patient in whom calcific tendinopathy of the radial insertion of the biceps tendon was managed with 2 ESWT treatments.³⁷

Multiple studies have proven that ESWT is safe and effective in the treatment of upper extremity tendinopathies. Next to the 18 RCTs on ESWT for lateral and medial elbow tendinopathies listed in the PEDro database, there are currently 30 RCTs on ESWT for other upper extremity tendinopathies listed in this database.²⁵ Collectively, these RCTs have demonstrated that ESWT is effective and safe in the treatment of tendinopathies.

Although most clinical trials of rESWT on tendinopathies have yielded positive results, there remains uncertainty regarding the precise mechanisms of action of rESWT on treated tendons. In a recent review, Visco et al³⁸ summarized the current evidence of the biological effects of ESWT on tendons obtained in animal models, in vitro cell line systems, and primary cultured human tenocytes. These authors concluded that the majority of studies showed a dose-dependent destructive effect of ESWT, albeit at much higher EFD than used in the present study. Specifically, destructive effects of focused extracorporeal shock waves on tendons were observed after exposure of rabbit Achilles tendon to EFD of 0.28 mJ/mm² and higher,³⁹ rabbit quadriceps tendon to EFD of 0.5 mJ/mm² and higher,⁴⁰ and Shetland pony superficial digital flexor tendon to EFD of 0.14 mJ/mm².⁴¹ In contrast, the EFD of radial extracorporeal shock waves decreases by more than 50% already at a distance of 5 mm from the applicator.⁴² Accordingly, in the present study, distal biceps tendons were exposed to much lower EFDs than what considered destructive in animal models in the literature. On the other hand, Visco et al³⁸ also provided evidence that, in model systems, an optimal dosage of ESWT may have stimulatory effects on cell proliferation and the activation and enhancement of healing processes, such as motility of treated cells, neovascularization, collagen synthesis, and the expression of differentiation critical genes. Other studies in the model systems have suggested that a number of compounds, including cytokines and metalloproteinases, are important in ESWT-induced tendon healing.^{43–45}

All rESWT procedures of the present study were performed in the office of the first author on an outpatient basis and without anesthesia: local anesthesia application in the area of shock wave delivery may compromise the positive treatment effects of ESWT.^{24,25,46} Local anesthesia might

interfere with clinical focusing of the shock waves or, more likely, alter the neurogenic inflammatory response and antinociceptive effects associated with ESWT.⁴⁷

The findings of the present study can potentially have economic implications. Chronic DBT can have a substantial negative impact on work attendance and employment. A study documented that elbow tendinopathy was responsible for 11.7% of work-related injury claims in Washington State from 1987 to 1995, resulting in an average direct workers compensation cost of \$6593 per case.⁴⁸ In another study of work place absences, 5% of individuals with an elbow tendinopathy reported taking at least 1 sick day because of their elbow pain within the preceding year.⁴⁹

Decision making regarding specific rESWT protocols, energy levels, number of shock waves, number of treatments, interval of time between treatments, and total energy delivered are hindered by the diversity of published works. We chose to use a radial ESWT device over a focused ESWT device given the superficial location of the distal biceps tendon and proximity of the neurovascular structures to the tendon. We chose a treatment protocol that, in our experience, was effective for other forms of tendinopathy.^{18,19} Specifically, based on prior experience, we chose a single-treatment protocol, acknowledging that multiple treatment protocols have also been successful for various indications.^{16,17,20,22} Indeed, it is possible that the results from this study, although positive, might have been better had a multiple session protocol been used.

The present study is an audit of prospectively collected data and therefore has inherent limitations. First, there was no randomization and no placebo arm to this study, there was no blinding of the subjects and the physician who administered the therapy (which could not be achieved based on the study design), and there was no blinding of the assessors who measured the outcome. Second, the small number of patients could potentially confound the clinical results; however, the relative rarity of cDBT makes it difficult to conduct a study with a larger patient cohort. Third, imaging studies were not obtained for each patient. However, the symptoms and physical findings used to define cDBT in this study are generally accepted and considered appropriate for this condition.^{1,3,4,6,25} Finally, it remains unknown whether rESWT as applied in the present study caused tissue regeneration or just pain relief. Answering this question would require analysis of biopsies. However, the latter would turn a noninvasive treatment into an invasive procedure (it should be noted that in none of the studies on ESWT listed in the PEDro database,²⁵ biopsies were taken). Furthermore, adequate animal models of tendinopathies are not available to answer this question.

CONCLUSIONS

The present study suggests that the use of rESWT in patients with cDBT is safe and effective, leading to a significant reduction in pain and improvement in elbow function, without adverse effects. Clinicians should consider rESWT before surgical intervention in the management of cDBT.

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