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Low-Energy Extracorporeal Shock Wave Therapy as a Treatment for Medial Tibial Stress Syndrome

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Background: Medial tibial stress syndrome (MTSS) is a pain syndrome along the tibial origin of the tibialis posterior or soleus muscle. Extracorporeal shock wave therapy (SWT) is effective in numerous types of insertional pain syndromes.

Hypothesis: Shock wave therapy is an effective treatment for chronic MTSS.

Study Design: Cohort study; Level of evidence, 3.

Methods: Forty-seven consecutive subjects with chronic recalcitrant MTSS underwent a standardized home training program, and received repetitive low-energy radial SWT (2000 shocks; 2.5 bars of pressure, which is equal to 0.1 mJ/mm²; total energy flux density, 200 mJ/mm²; no local anesthesia) (treatment group). Forty-seven subjects with chronic recalcitrant MTSS were not treated with SWT, but underwent a standardized home training program only (control group). Evaluation was by change in numeric rating scale. Degree of recovery was measured on a 6-point Likert scale (subjects with a rating of completely recovered or much improved were rated as treatment success).

Results: One month, 4 months, and 15 months from baseline, success rates for the control and treatment groups according to the Likert scale were 13% and 30% (P < .001), 30% and 64% (P < .001), and 37% and 76% (P < .001), respectively. One month, 4 months, and 15 months from baseline, the mean numeric rating scale for the control and treatment groups were 7.3 and 5.8 (P < .001), 6.9 and 3.8 (P < .001), and 5.3 and 2.7 (P < .001), respectively. At 15 months from baseline, 40 of the 47 subjects in the treatment group had been able to return to their preferred sport at their preinjury level, as had 22 of the 47 control subjects.

Conclusion: Radial SWT as applied was an effective treatment for MTSS.

Keywords: tendon injuries; medial tibial stress syndrome; shin splints; shock wave therapy

Shin splints—referring to pain and discomfort in the leg from repetitive running on hard surfaces or forcible excessive use of foot flexors—accounts for 6% to 16% of all running injuries and is responsible for as much as 50% of all lower leg injuries reported in select populations. Alternative terms to shin splints have been proposed over the years. Mubarak et al²ⁿ popularized the term medial tibial stress syndrome (MTSS), a condition that leads to pain in the posteromedial aspect of the distal two thirds of the tibia.

A diagnosis of MTSS specifically excludes exertional compartment syndrome and tibial stress fracture. It offers the most accurate description of the involved anatomy and presumed pathophysiology of this most common form of tibial stress injury.³ The hallmark of the physical examination in MTSS is palpable tenderness over a 4- to 6-cm area at the postero-medial margin of the middle to distal third of the tibia.³⁻¹¹,²⁶,³⁵,⁴¹,⁶⁸ Range of motion of the ankle and foot should not elicit pain. Passive stretch of the soleus, heel rises, and unilateral hopping may reproduce symptoms. Vascular and neurologic examinations produce normal results in subjects with MTSS.⁴⁴
Nonsurgical treatment for shin splints includes activity modification (relative rest). Other recommendations include icing, nonsteroidal anti-inflammatory medications, stretching and strengthening, and attention to biomechanical factors such as overpronation. Evidence for any of those is low.62 Very few people need surgery for shin splints. Surgery has been done in very severe cases of shin splints that do not respond to nonsurgical treatment. It is not clear how effective surgery is, however.28,31,68 Shock wave therapy (SWT) has been used successfully since the late 1980s for the management of various musculoskeletal disorders including plantar fasciopathy, Achilles tendinopathy, shoulder calcific tendinitis, lateral epicondylitis, and greater trochanter pain syndrome.8

Acknowledging the unpredictable response and frequent recurrences associated with traditional nonoperative treatment, the risks and prolonged rehabilitation associated with surgery, the recognition of an insertional malfunction as a potential source of pain, and the favorable results from prior studies involving SWT as a treatment for other forms of insertional enthesopathies, the aim of this study was to determine whether low-energy SWT is a safe and effective management modality for chronic MTSS.

PATIENTS AND METHODS

Before the study, the injury definition was decided and used throughout the study. Medial tibial stress syndrome was defined as (1) pain located on the medial border of the tibia during running or marching, (2) insidious onset of pain unrelated to any traumatic event, and (3) pain on palpation of the medial tibial border not localized to one spot. This was a pragmatic study conducted in a secondary-care setting. Consecutive subjects referred to the outpatient clinic for persisting MTSS were evaluated on the basis of a history and a physical examination, and checked for the study inclusion and exclusion criteria.

The inclusion criteria included subjects with an established diagnosis of unilateral chronic MTSS for at least 6 months before treatment who had failed at least 3 forms of traditional nonoperative measures for a minimum of 3 months. Traditional nonoperative therapies consisted of relative rest, muscle stretching and strengthening, anti-inflammatory medications, ice, a corticosteroid and/or local anesthetic injection, insoles, and orthoses.

The location of the pain was marked on a knee/shin diagram by all subjects, and the onset of pain was reported. All subjects had anteroposterior and lateral radiographs of the affected tibia including the knee and the ankle to rule out osteomyelitis, tumor, osteoarthritis, or fracture. In subjects for whom the diagnosis was ambiguous (17 of 47 subjects in the treatment group; 24 of 47 subjects in the control group), 3-phase bone scintigraphy and/or MRI was performed.

All subjects were examined to rule out exertional compartment syndrome (bilateral MTSS; complaint of cramping, burning, or pain over the involved compartment with exercise; comparison of physical and neurologic examination before and immediately after exercise when deemed necessary).53 Further exclusion criteria were rheumatoid arthritis, generalized polyarthritis, local infection, pregnancy, subjects with bleeding disorders, subjects with tumors, subjects younger than 18 years, subjects with end stage ipsilateral knee and ankle osteoarthritis (defined as severe joint-space narrowing, joint sclerosis, and peri-acetabular osteophytes), and subjects with prior knee or ankle surgery.

A total of 127 consecutive subjects with MTSS who presented to the investigator (J.D.R.) had experienced symptoms for at least 6 months and had tried at least 3 different forms of nonsurgical management without success. Therefore, they represented the minority of subjects with MTSS in whom a traditional nonsurgical treatment had failed. Those 127 subjects were the basis for the current study. As part of the initial evaluation, all subjects were given a thorough explanation of the various options, including financial burdens, as well as the potential risks, benefits, and outcomes associated with the various options.

A standardized home training program55 in combination with radial SWT was recommended, along with relative rest, to all 127 subjects. All subjects were informed in writing that they would have to expect no immediate effect from SWT; what side effects could occur with SWT (pain, bruising), what success rates had been reported with SWT in the management of other tendinopathies (50%-70%), and that they would have to pay for SWT on their own (total amount of $200).

After making an informed decision, 49 of 127 subjects (39%) chose to treat their condition with a home training program in combination with radial SWT. The remaining 78 subjects (61%) declined treatment with radial SWT. Those subjects were then treated with the home training program alone. All subjects gave informed consent. The details of the procedure and potential risks were discussed fully before treatment.

Treatment Group

Forty-nine subjects were treated consecutively. One subject underwent concomitant treatment of Achilles tendinopathy with low-energy SWT, and was excluded. There were insufficient follow-up data on 1 subject. Thus, 47 subjects with unilateral MTSS were available for analysis. These 47 subjects represent the treatment group. The subjects in the treatment group were managed with the following measures: relative rest, ice, and instructions to carry out rehabilitation exercises35 twice a day for 12 weeks. Shock wave treatment was performed at weeks 2, 3, and 4 after start of the 12-week home training program.

There were 28 women and 19 men in the treatment group, with a mean age of 41 years (range, 18-56 years). The average duration of the condition was 15 months (range, 8-24 months) (Table 1).
The home training program consisted of progressive slow exercises (calf stretching, Thera-Band [L. Artzt GmbH, Dornburg, Germany] stretching, heel raises, toe raises) with the following instructions.

Calf Stretch With Towel. Sitting on a firm surface with the injured leg straight in front of you, take a towel and loop it around the ball of your foot. Pull the towel toward you. Hold this position for 30 seconds. Relax. Repeat 3 times. When you do not feel much of a stretch anymore using the towel, start stretching the calf in the standing position described later.

Standing Calf Stretch. Facing a wall, place both hands at about eye level on the wall. Keep your injured leg back about 12 to 18 inches behind your uninjured leg. Keep your injured leg straight and your heel on the floor. Next, do a slight lunge by bending the knee of the forward leg. Lean into the wall until you feel a stretch in your calf muscle. Hold this for 30 to 60 seconds. Repeat 3 times.

Active Range of Motion of the Ankle. Sitting or lying down with your legs straight and your knee toward the ceiling, move your ankle up and down, in and out, and in circles. Do not bend your knee while doing this. Repeat 20 times in each direction. Push hard in all directions.

Anterior Compartment Stretch. Stand with 1 hand against a wall or chair for balance. Bend your knee and grasp the front of the foot of your injured leg. Bend the front of the foot toward the heel. You should feel a stretch in the front of your shin. Hold for 10 seconds. Repeat 10 times.

Thera-Band Strengthening Exercises for the Lower Leg: Resisted Dorsiflexion Flexion. Sit in front of a doorway with your legs outstretched. Anchor the Thera-Band in a door by tying knots in the ends and closing the knots in the door. Next, loop the Thera-Band around the forefoot of your injured leg. Pull your foot toward your body with the Thera-Band supplying resistance. Return slowly to the starting position. Repeat 10 times. Do 3 sets of 10.

Thera-Band Strengthening Exercises for the Lower Leg: Resisted Plantar Flexion. Sitting with your legs outstretched, put the tubing around the foot of your injured leg and hold the ends of the tubing in your hands. Gently press your foot down, stretching the Thera-Band. Return to the starting position. Repeat 10 times. Do 3 sets of 10.

Thera-Band Strengthening Exercises for the Lower Leg: Resisted Inversion. Sit on the floor with your uninjured leg crossed over your injured ankle. Hold one end of the Thera-Band in your hand and tie the other end in a loop. Place the loop around the forefoot of the injured leg and have the
band wrapped around the uninjured foot to provide an anchor. Move your injured foot inward with the Thera-Band providing resistance. Return your foot to the starting position. Repeat 10 times. Do 3 sets of 10.

**Thera-Band Strengthening Exercises for the Lower Leg: Resisted Eversion.** Sitting on the floor with both legs straight, have the Thera-Band looped around both feet. Slowly turn the injured foot outward, keeping the uninjured foot still. Return to the starting position. Repeat 10 times. Do 3 sets of 10.

**Heel Raises.** Balance yourself while standing behind a chair or counter. Raise your body up onto your toes, then slowly lower it. Repeat 10 times. Do 2 sets of 10.

**Toe Raises: Sitting.** Sit on a firm surface with your feet flat on the floor. Keep your heel on the floor and raise your toes off the floor. Repeat 10 times. Do 3 sets of 10. When the sitting exercise becomes easy, progress to the standing exercise, as described in the next paragraph.

**Toe Raises: Standing.** Standing with your feet flat on the ground, rock back to your heels and lift your toes off the floor. Hold this for 5 seconds. Repeat 10 times. Do 3 sets of 10.

All subjects in both the treatment and the control groups were given a practical demonstration of the exercises by trained physical therapists (6 instructional sessions, each 20 minutes long) and written instructions of home exercises.55

**Shock Wave Treatment**

All treatments were performed by the senior author (J.D.R.), in the senior author’s office, without local anesthesia. Shock wave treatment was performed at weeks 2, 3, and 4 after the start of the 12-week home training program. A radial shock wave device (Swiss DolorClast, Electro Medical Systems Nyon, Switzerland) was used in all instances. With this device, shock waves are produced after a projectile in a handpiece is accelerated by a pressurized air source and strikes a 15-mm diameter metal applicator.20,24,48,52 The energy generated is transmitted to the skin as a shock wave through a standard, commercially available ultrasound gel. The waves are then dispersed radially from the application site into the surrounding tissues.

Each subject received 3 low-energy treatments in weekly intervals. At each session, 2000 shocks were applied with a pressure of 2.5 bars (equal to an energy flux density of approximately 0.1 mJ/mm²). The treatment frequency was 5 shocks per second. The total energy flux density of the treatment session was approximately 200 mJ/mm².

The procedure was performed with the subject lying supine. Ultrasound gel was applied liberally to the skin overlying the medial tibial border and adjacent area. The shock waves were delivered in a medial-to-lateral direction. Shock wave application was a dynamic process. Using the principle of clinical focusing, the area of maximal tenderness was treated in a circumferential pattern, starting at the point of maximal pain. The average size of the area of treatment was approximately 2 to 4 cm wide and 4 to 8 cm long.

On completion of the procedure, the treated leg was assessed for hematoma, bruising, and swelling. All concomitant interventions were discouraged for 4 months after the last treatment. Subjects were allowed immediate weightbearing and unrestricted range of motion. No ambulatory aids were used. No immobilization or other co-intervention was used.

Subjects in the treatment group were invited to see the physician at weeks 2, 3, and 4 to check compliance with the training program by interview, and to receive radial SWT. Subjects in the control group were invited to see the physician after 2, 3, and 4 weeks to check compliance with the training program by interview, and to provide the same number of physician-subject contacts as in the SWT group. No diary was used to measure compliance as to completion of the home training program in either group.

All co-interventions were discouraged until the 4-month follow-up examination. For all groups, pain medication was allowed when requested (paracetamol, 2000-4000 mg/day). All subjects could contact the physician during working hours if they had questions about the training program.

After 6 weeks from baseline, the subjects were told to slowly return to their previous level of sports/recreational activity. Activity was advanced as symptoms dissipated. Subjects who worked in a sedentary occupation were allowed to immediately return to their pretreatment work status. Stationary cycling was permitted immediately after treatment. Easy running was permitted 1 week after the last treatment, as tolerated. The time to return to competitive sports and heavy labor occupations was made on a case-by-case basis.

**Assessment**

No disease-specific questionnaires are available for MTSS. Therefore, generic outcome measures (pain severity and recovery) were chosen as primary outcome measures. Written outcome assessments were recorded by each subject on a standardized form at baseline, 1 month, 4 months, and 15 months from baseline prior to seeing the physician at each visit. A nurse who was unaware of the intervention collected the forms and entered the responses into a database.

The primary outcome measurement was degree of recovery at 4 months compared with baseline, measured on a 6-point Likert scale (“completely recovered” to “much worse”). Success rates were calculated by dichotomizing responses. Treatment for subjects who reported themselves completely recovered or much improved was counted as success, and treatment for subjects who reported themselves “somewhat improved,” “same,” “worse,” or “much worse” was counted as failure.

Secondary outcome measurements were degree of recovery at 1 and at 15 months compared with baseline, measured on a 6-point Likert scale (completely recovered to much worse). Success rates were calculated by dichotomizing responses. Treatment for subjects who reported themselves completely recovered or much improved was counted as success, and treatment for subjects who reported themselves somewhat improved, same, worse, or much worse was counted as failure. Severity of pain during the past week was measured with a numeric rating scale (0 = no pain, 10 = very severe pain) at 1, 4 and 15 months from baseline.
The mean pretreatment NRS score for the SWT group was 8.1 ± 3.4. The mean pretreatment NRS score for the control group was 8.5 ± 3.1. One month after treatment the mean NRS score for the treatment group decreased to 5.8 ± 0.9. One month from baseline the mean NRS score for the control group was 7.3 ± 2.9. The between-group difference was statistically significant (P < .001).

Four months from baseline the mean NRS score for the treatment group decreased further to 3.8 ± 1.1. The corresponding NRS score for the control group was 6.9 ± 0.8. The between-group difference was statistically significant (P < .001).

Fifteen months from baseline the mean NRS score for the treatment group decreased further to 2.7 ± 0.9. The corresponding NRS score for the control group was 5.3 ± 2.6. The between-group difference was statistically significant (P < .001).

The mean difference of change between baseline NRS score and 1-month (2.3 and 1.2), 4-month (4.3 and 1.6), and 15-month (5.4 and 3.2) NRS scores was also compared. For each time point, the magnitude of the change in NRS score was significantly greater for the treatment group than the control group (P < .001 for each time point).

### Occupation and Sporting Activities

At 15 months from baseline, 40 of the 47 subjects in the treatment group had been able to return to their preferred sport. Twenty-two of the 47 control subjects had been able to return to their preferred sport. All SWT and control subjects who were able to return to their preferred sport did so at their preinjury level. Of the 7 SWT subjects who did not return to their preferred sport, 5 were runners, 1 played soccer, and 1 was a track athlete. Of the 25 control subjects who did not return to their preferred sport, 13 were runners, 3 played soccer, 9 were track athletes.
Time to return to sport was variable and ranged from 6 weeks for some soccer players to 6 months for some runners. Nine of the 10 SWT subjects and 5 of the 8 control subjects who worked as laborers or in occupations that required extensive physical activity were able to return in full to their preinjury occupations.

Compliance

All subjects had been checked for and encouraged to maintain compliance with the training program by interview after 2 and 4 weeks from baseline. At 4 months from baseline, 36 of 47 subjects in the treatment group reported to have performed the home training daily for 12 weeks, compared with 43 of 47 subjects in the control group.

Co-interventions

All co-interventions during the 4-month follow-up period were discouraged, but prescription of pain medication if necessary was allowed. Taking naproxen or paracetamol was closely related to failure of treatment. Fourteen of 17 subjects who failed in the treatment group and 30 of 33 subjects who failed in the control group requested taking the named analgesic drugs, but no other subjects did so.

Complications

There were only 10 minor complications. Eight subjects had pain during the shock wave treatment. The pain resolved after completion of the procedure. Two subjects had transitory reddening of the skin that resolved without intervention. There were no other complications detected during the examinations after treatment.

DISCUSSION

The pathophysiology of MTSS remains unclear. There is disagreement among authors on the cause of MTSS.5-8,12,46,58 Histologically, biopsy specimens reveal an inflammatory process with vasculitis that is consistent with periostitis. Although the soleus muscle may be the major contributing factor of MTSS, the flexor digitorum longus muscle and deep crural fascia also contribute to it, based on their sites of origin along the medial aspect of the tibia.6 Proposed risk factors associated with MTSS are increased foot pronation, increased muscular strength of the plantar flexors, increased varus tendency of the forefoot or hindfoot (or both), an abrupt increase in training intensity, inadequate calcium intake, hard or inclined (or both) running surfaces, inadequate shoes, and previous injury, although there is little objective evidence to support these opinions.6 **Women are at least twice as likely to develop MTSS as men, particularly if they have a body mass index of less than 21 kg/m².7,61,69 Studies have demonstrated a relationship between smaller tibial cross-sectional areas and tibial stress syndrome.5,64 Long bones with narrow diaphyseal widths will bend to a greater extent when loaded than those with wider diaphyses. This supports the tibial-bending theory of tibial stress injuries. This theory suggests that chronic repetitive loads that induce tibial bending cause bone stress around the site where maximum bending occurs. This corresponds to the most common location for MTSS. This theory also provides support for the pathophysiologic link between MTSS and tibial stress fracture.

The best way to diagnose MTSS remains unclear. Imaging procedures such as radiographs or MRI do not correlate well with clinical symptoms.67 Medial tibial stress syndrome is to be differentiated from tibial stress fracture in particular.15 Stress fractures are recognized as the continuum of changes from microfracture to frank fracture under excess stress. The differential diagnosis between these 2 diseases therefore is difficult in the early phase. Pain associated with tibial stress fractures typically is localized to the fracture site and is more proximal than that caused by MTSS. Palpation will elicit tenderness localized at the fracture site. However, the posteromedial aspect of the middle to distal third of the tibia should not be tender.8,35,65 Radiographs are not useful in the early phase of stress fractures,8 although they are useful in the late phase because they show periosteal reaction, callus formation, or sclerotic fracture line. High-resolution CT reliably shows cortical osteopenia with few small resorption cavitations.21-25 Coronal fat-suppressed MRI scans of subjects with stress fractures demonstrate an abnormally wide high signal in the localized bone marrow. In subjects with shin splints, the coronal fat-suppressed MRI scans show abnormally high linear signals along the medial posterior surface or along the medial bone marrow.2,59

The best management for MTSS remains unclear. Almost all athletes with shin splints can be treated nonoperatively with success.27,35,36,44 The American College of Sports Medicine recommends at least 7 to 10 days of rest from painful activities to treat MTSS.1 Nonsurgical treatment for shin splints includes activity modification, icing,1 nonsteroidal anti-inflammatory medications, stretching, and attention to biomechanical factors that might be correctable with insoles, orthoses,16,26,32,38 or antagonistic muscle strengthening, although there is little objective evidence to support these interventions.62 In most subjects, the pain subsides after several weeks of rest. Then, a gradual increase of activity is emphasized to prevent recurrence. Low-level training may begin, with subjects advised to warm up and stretch thoroughly before exercise and to increase training slowly.

Few people need surgery for shin splints. Surgery has been done in very severe cases of shin splints that do not respond to nonsurgical treatment.31 However, the effectiveness of surgery remains unclear. In the most recent uncontrolled case series, surgery significantly reduced pain levels by an average of 72% on the visual analog pain scale for 46 subjects who had failed nonsurgical therapy for at least 12 months. However, only 41% returned to their pre-symptom level of sports activity.58

**References 5, 7, 13, 35, 40, 44, 46, 69, 70,
There is no published article in a peer-reviewed journal on the use of extracorporeal SWT for MTSS. We were only able to identify 1 uncontrolled pilot study. Seventeen subjects with recalcitrant MTSS for 14 months received 5 applications of 2000 shocks of 2.5 bar (~0.1 mj/mm²) with a radial shock wave device. Within 12 weeks, exercise-related pain went down from 7.8 to 1.8 points on the NRS. Mean pain-free running time increased from 11 to 63 minutes.

The present study evaluated the effects of SWT on a consecutive series of subjects with MTSS who had not responded to at least 3 nonoperative forms of management. The outcome for the entire population was evaluated and compared with a well-matched control group. The mean NRS of the treatment group were statistically improved at 1 month, 4 months, and 15 months from baseline compared with the control group. The percentages of ratings 1 (completely recovered) or 2 (much improved) 15 months from baseline for the treatment and control groups were 76% and 37%, respectively. Forty of the 47 subjects in the treatment group and 22 of the 47 control subjects were able to return to their preferred sport. There were no significant complications, and no subject required additional SWT.

All radial SWT procedures were performed in the office without anesthesia. Prior studies involving subjects with chronic plantar fasciitis, Achilles tendinopathy, and lateral epicondylitis have demonstrated that local anesthesia application in the area of shock wave delivery compromises the positive treatment effects of SWT. Local anesthesia might interfere with clinical focusing of the shock waves or, more likely, alter the neurogenic inflammatory response and antinociceptive effects associated with SWT.

This study is a retrospective cohort study and, as such, has some inherent limitations that require consideration. There was no randomization and there was no placebo arm to the investigation. The length of follow-up was only 15 months from baseline. However, a positive treatment effect was already evident at this time. Finally, bone scintigraphy or MRI scans were not performed for each subject. However, the symptoms used to define MTSS are generally accepted and considered to be appropriate diagnostic descriptors of this condition.

Acknowledging these weaknesses, this series contributes valuable information. The results from this study add to the growing number of favorable reports that substantiate the efficacy of radial SWT as an effective treatment for chronic insertional pain syndromes.

CONCLUSION

Traditional treatment of MTSS is generally lengthy, associated with frequent recurrences, and in some cases, an unacceptable degree of improvement. This study demonstrates that low-energy radial SWT is safe and effective, that it can be used to treat subjects with chronic MTSS, and that satisfactory improvement is maintained for at least 1 year. Further prospective studies are needed to confirm this finding.

REFERENCES
