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Electromagnetic Transduction Therapy for Achilles Tendinopathy: A Preliminary Report on a New Technology

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ABSTRACT

A parallel prospective feasibility study was performed on 53 patients with chronic mid-portion Achilles tendinopathy (age 44.7 ± 9.1 years). Of the 53 patients, 28 (active group) were treated using a new electromagnetic (pulsed electromagnetic field) transduction therapy device (Cellactor® MT1) and heel cushions. The device produces an electromagnetic field of 80 milliTesla; a total of 8 treatments was performed within 4 weeks in an outpatient setting, without anesthesia, immobilization, or rest. A control group of 25 patients with a similar duration of symptoms was treated with heel cushions only. At the 12-week assessment point, the visual analog scale scores in both groups had significantly decreased, although the active group had significantly improved visual analog scale scores compared with those of the controls. The Role-Maudsley scores had also significantly improved in both the active and the control groups ($p < .00001$ and $p = .0002$, respectively). Electromagnetic transduction therapy could potentially be a useful modality for the treatment of Achilles tendinopathy. It should be compared with the current reference standard of extracorporeal shockwave therapy/radial soundwave therapy with similar level I, II, and III studies.

Achilles tendinopathy is one of the most common overuse sports injuries, with 7% to 9% of runners affected in a given year, with a lifetime incidence of 40% to 50%. Also, >24% of competitive athletes will develop this condition (1). Causation remains elusive, in part, because it is multifactorial (2). Intrinsic factors are involved such as tendon degeneration and calcification, with disruption of collagen and posterior calcaneal deformity (i.e., Haglund's) (2–4). Extrinsic causes include shoe gear with a lower heel height, excessive speed work or interval training, hill running, and ballistic sports (2).

Achilles tendinopathy is classified as mid-portion (i.e., the main body or watershed region) and insertional. The present study focused on a novel therapy for the mid-portion of the Achilles tendon. Achilles tendinopathy can further be delineated as tendinosis and paratendinosis (2,5,6). Nonoperative treatment outcomes vary with the use of different modalities such as insoles, eccentric exercises, injections, and extracorporeal shockwave therapy/radial soundwave therapy (ESWT/RSWT) (7–11), with ESWT/RSWT showing the highest level of evidence (7). The present study sought to test for a feasibility study using electromagnetic therapy for mid-portion Achilles tendinopathy.

Electromagnetic therapy, specifically pulsed electromagnetic fields (PEMFs), has been studied for bone and soft tissue indications. The electromagnetic field strength is measured in milliTesla (mT), which can range ≤150 mT. The typical PEMF field strength for bone stimulators is ≤8 mT (12). With PEMFs, an oscillating frequency of 120 Hz can create a tissue penetration of 18 cm. Using an impulse release frequency of 3 Hz and a single impulse duration of 140 μs, no temperature increases will occur in the tissue. This was studied by Krath et al (Krath et al, Effect of high intensive electromagnetic transduction therapy on osteoinduction of human bone marrow mesenchymal stem cells; in review). They showed higher mRNA expression of type collagen I, alkaline phosphatase, osteocalcin, vascular endothelial growth factors, and bone morphogenic protein-2 in mesenchymal tissue cells treated with 150 mT. This level is much higher than that used in typical PEMF treatments by >10-fold. Other investigators have studied the effects of PEMFs on human tenocytes in vitro with a similar increase in factors beneficial to healing (13). It has been documented that for PEMFs to be beneficial, the field strength must be >10 mT (14,15).

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Conflict of Interest: Drs Gerdesmeyer, Klueter, Harrasser, and Krath received a device from Storz Medical for the study.

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The current evidence for electromagnetic therapy is evolving. In 2016, Page et al (16) reported the current levels of evidence in Cochrane Reviews of electrotherapy for rotator cuff tendinopathy. With the introduction of newer electromagnetic devices, other studies are being performed to evaluate the effects on rotator cuff tendinopathy (Gerdesmeyer et al. Electromagnetic transduction therapy and shockwave therapy in rotator cuff tendinopathy: a prospective randomised controlled trial; in review). This technology might be effective for other soft tissue pathologic entities. With Achilles tendinopathy so prevalent, we designed a preliminary study to determine whether PEMFs have a beneficial effect for this condition. This study would serve as a feasibility study for a future randomized study comparing electromagnetic therapy and other modalities, such as ESWT.

Patients and Methods

Patients with mid-portion Achilles tendinosis were prospectively studied. None of the patients had paratendinopathy. The present study was designed as a prospective parallel group trial. All study patients were advised not to change their activity level and not to add any other therapeutic regimen such as nonsteroidal anti-inflammatory drugs, physical therapy such as stretching and eccentric exercises, ESWT/RSWT, and so forth, other than what was recommended for the study. Contraindications for this therapy included an implanted pacemaker, coagulopathy, and a history of neoplasm in the same limb. The inclusion criteria were chronic (>6 months) symptoms and a follow-up period of 12 weeks after therapy. The exclusion criteria were a history of previous surgery to the affected Achilles tendon, neuropathy, inflammatory arthropathy/enthesopathy, and failure to comply with treatment protocol.

A total of 53 patients met the criteria. Their average age was 44.7 ± 9.1 years. Of the 53 patients, 28 (active group) received high-energy electromagnetic transduction therapy (EMTT™) and used heel pads with a 1-cm heel cushion. The control group of 25 patients who also had chronic mid-portion Achilles tendinopathy received just the heel pads with a 1-cm heel cushion as their only intervention. The active group received EMTT™. EMTT™ was applied twice weekly, with a total of 8 sessions within a period of 4 weeks with the Cellactor® MT1 device (Storz Medical AG, Tägerwilen, Switzerland Fig. 1). Each treatment was performed for 20 minutes at 80 mT, with an impulse frequency of 3 Hz and an electric power of 30 kV by a single provider. No anesthesia was used. These patients also used identical heel pads with a 1-cm heel support, the same as for the control group. No other immobilization, braces, or rest (downtime) was required.

At 12 weeks after EMTT™, data analysis was performed, using a visual analog scale (VAS) as the primary endpoint and the Roles-Maudsley (RM) score as the secondary endpoint, both of which have been validated by previous studies (7,8). Statistical analyses were also performed. The sample size calculation was based on the model of stochastic superiority within the parametric Student *t* test or nonparametric Wilcoxon-Mann-Whitney test for the primary and secondary outcome measures, depending on the distribution of the data. To analyze the distribution of the 2 treatment groups, we used the Shapiro-Wilk test. A value of $p < .025$ (1-sided) was considered statistically significant.

Results

At baseline, we found no difference in the affected side, body weight, or duration of pain. In the present study protocol, the control group (13 right and 12 left tendons; mean age 45.0 ± 8.5 years) was treated with a 1-cm heel cushion. The active (study) group underwent EMTT™ and also wore a 1-cm heel cushion. The EMTT™ plus heel cushion (active) group (18 right and 10 left tendons, mean age 43.6 ± 9.4 years) showed a significant pain reduction. No difference was found between the VAS score of the 2 groups at baseline ($p = .37$) nor in age. The VAS score in the control group decreased from 6.6 ± 1.3 at baseline to 4.9 ± 1.6 after 12 weeks ($p < .01$). The VAS scores for the EMTT™ plus heel cushion group also had decreased significantly within the 12-week period from 6.9 ± 1.3 at baseline to 3.6 ± 2.0 at the last follow-up point ($p < .01$). The difference between the active EMTT™ group and control group was statistically significant in favor of the combined EMTT™ plus heel cushion group ($p < .01$).

The pretreatment RM score for the control group was 3.68 ± 0.48, which had decreased to 2.92 ± .78 at 12 weeks ($p = .0002$). The pretreatment RM score for the EMTT™ plus heel cushion group was 3.61 ± 0.5 and had decreased to 2.57 ± .92 at 12 weeks ($p < .00001$). No significant difference was found between the 2 groups in the RM scores at 12 weeks ($p = .14$).

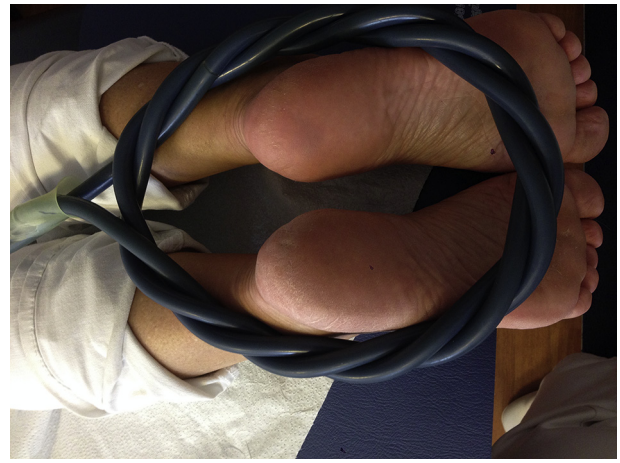


Fig. 1. Demonstration of treatment for bilateral Achilles tendinopathy.

One patient in the control group opted for surgery, because he could not tolerate the pain experienced during treatment. No other complications occurred. Some patients reported minor temporary redness. The data are summarized in Figs. 2–6.

Discussion

The results of the present study have shown that using a high level of PEMFs (or EMTT™) to treat chronic mid-portion Achilles tendinopathy can significantly decrease VAS scores and improve RM scores in the short term compared with just using heel cushions. The therapy is advantageous, because it does not require anesthesia, immobilization, or rest ("downtime"). The intervention can be performed on an outpatient basis, which is also of benefit. The finding that heel

	Pre-Tx Symptoms	Pre-RM	Pre-EMTT VAS	Post RM	Post-EMTT VAS
Mean Mos	11.61	3.61	6.96	2.57	3.61
SD	5.65	0.5	1.29	.92	2.01

	excellent	good	fair	poor
Baseline	0	0	9	19
12 weeks	4	7	13	4

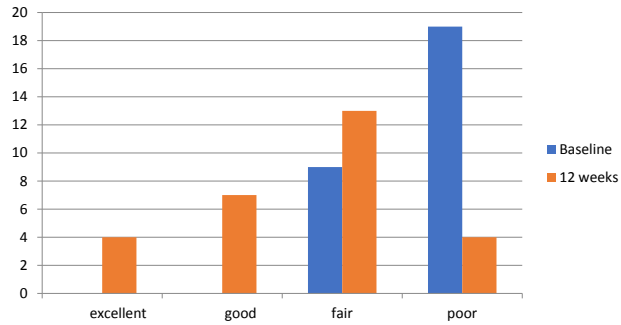


Fig. 2. Outcomes for the active group (electromagnetic transduction therapy [EMTT™] and heel cushions; n = 28). Mos, months; Post-EMTT, after EMTT; Post RM, Roles-Maudsley score after treatment; Pre-EMTT, before EMTT; Pre-RM, Roles-Maudsley score before treatment; Pre-Tx, pretreatment; SD, standard deviation; Tx, treatment; VAS, visual analog scale.

	Pre-Tx Symptoms	Pre RM	Pre-Tx VAS	Post RM	Post-12 wks VAS
Mean Mos	10.96	3.68	6.64	2.92	4.88
SD	6.15	0.48	1.29	.78	1.60

	excellent	good	fair	Poor
Baseline	0	0	8	17
12 weeks	1	5	13	5
drop out for surgery	1			

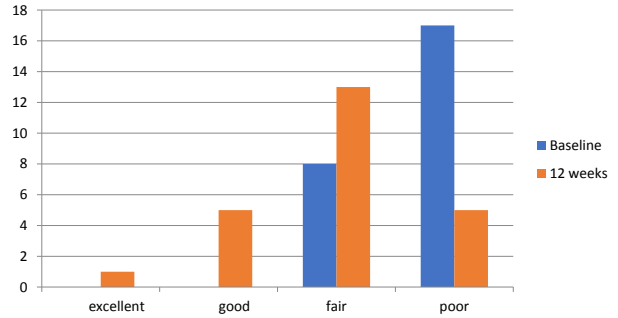
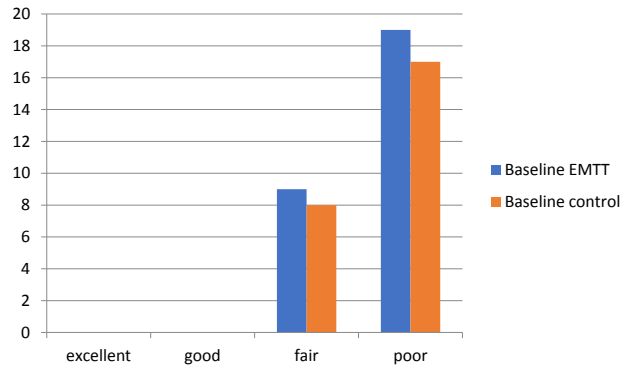


Fig. 3. Outcomes for the control group (heel cushions alone; n = 25). Mos, months; Post-12 wks, after 12 weeks; Post RM, Roles-Maudsley score after treatment; Pre-RM, Roles-Maudsley score before treatment; Pre-Tx, pretreatment; SD, standard deviation; Tx, treatment; VAS, visual analog scale.

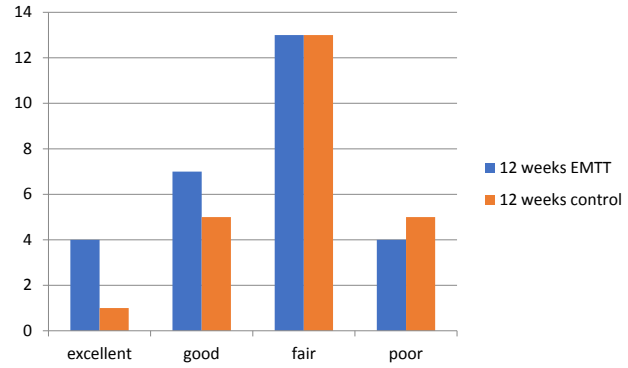
cushions alone significantly improved the scores is interesting. The heel cushion size of 10 mm in the present study appears thicker than that used in other studies, which typically used a lower thickness (17).

Other types of electromagnetic modalities have been critically studied for soft tissue injury in humans; however, these have typically involved the shoulder (14,16). The modality most stringently studied for mid-portion Achilles tendinopathy is ESWT/RSWT, the reference standard (7,8). In 2009, Rompe et al (18) showed that combining RSWT with eccentric exercises improved the outcomes for Achilles tendinopathy patients in a level 1 study. Similarly, Saxena et al (8) showed significant improvement with RM scores with noninsertional Achilles tendinopathy. Their patients' RM scores improved from approximately 3.5 to 1.5. In the present study, the improvement of RM scores was not as great (approximately 2.5 to 3). However, the duration of pretreatment symptoms and the shorter assessment period might have been factors in the poorer outcomes.



	excellent	good	fair	poor
Baseline EMTT	0	0	9	19
Baseline control	0	0	8	17

Fig. 4. Baseline comparison between the 2 groups. EMTT™, electromagnetic transduction therapy.

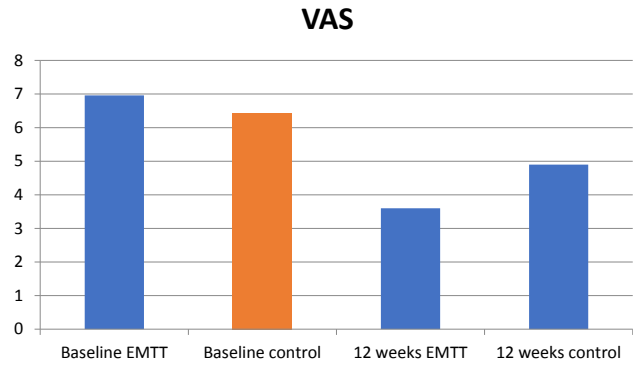


	excellent	good	fair	poor
12 weeks EMTT	4	7	13	4
12 weeks control	1	5	13	5

Fig. 5. Outcomes for both groups at 12 weeks after treatment. EMTT™, electromagnetic transduction therapy.

A recent study evaluated ESWT with and without EMTT™ for rotator cuff tendinopathy, with better outcomes for the latter group (Gerdesmeyer, et al. Electromagnetic transduction therapy and shockwave therapy in rotator cuff tendinopathy: a prospective randomised controlled trial; in review). In the present study, it was encouraging that significant improvement at just 12 weeks can be achieved.

In conclusion, the present study was designed as a feasibility study to determine the effect size and tolerance of EMTT™ for patients with longstanding Achilles tendinopathy. As such, this report is limited and conveys biases that have not been scientifically controlled. A prospective randomized study would be a welcome addition to the literature, with an additional treatment arm of adding ESWT/RSWT.



	VAS MW	SD
Baseline EMTT	6.96	1.3
Baseline control	6.44	1.3
12 weeks EMTT	3.6	2
12 weeks control	4.9	1.6

Fig. 6. Visual analog scale (VAS) scores from before treatment and 12 weeks after treatment had significantly improved in both groups ($p < .01$), with the active group (electromagnetic transduction therapy [EMTT™]) experiencing statistically significant improvement compared with the control group ($p < .01$). MW, Mann-Whitney.

Eccentric loading should also be compared. The thickness of the heel cushion would also be interesting to evaluate. Patients in such a study should also be evaluated for 1 year after therapy to allow comparison with similarly constructed studies.

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