Published in final edited form as:

Arch Phys Med Rehabil. 2010 July ; 91(7): 1098–1104. doi:10.1016/j.apmr.2010.02.013.

Static Magnetic Field Therapy for Carpal Tunnel Syndrome: A Feasibility Study

Agatha P. Colbert, MD, Marko S. Markov, PhD, Nels Carlson, MD, William L. Gregory, PhD, Hans Carlson, MD, and Patricia J. Elmer, PhD

Helfgott Research Institute of the National College of Natural Medicine, Portland, OR (Colbert, Markov, Gregory, Elmer); Research International, Williamsville, NY (Markov); Department of Orthopaedics and Rehabilitation, Oregon Health & Science University, Portland, OR (Carlson N, Carlson H).

Abstract

Objectives—To assess the feasibility of conducting trials of static magnetic field (SMF) therapy for carpal tunnel syndrome (CTS), to collect preliminary data on the effectiveness of two SMF dosages and to explore the influence of a SMF on median nerve conduction.

Design—Randomized, double blind, sham controlled trial with 6-week intervention and 12-week follow-up.

Setting—University hospital outpatient clinics

Participants—Women and men (N=60), ages 21–65, with electrophysiologically-confirmed CTS diagnosis, recruited from the general population.

Interventions—Participants wore nightly either neodymium magnets that delivered either 15 or 45mTesla (mT) to the contents of the carpal canal, or a non-magnetic disk.

Main Outcome Measures—Symptom Severity Scale (SSS) and Function Severity Scale (FSS) of the Boston Carpal Tunnel Questionnaire (BCTQ) and 4 median nerve parameters: sensory distal latency, sensory nerve action potential amplitude, motor distal latency and compound motor action potential amplitude).

Results—58 of 60 randomized participants completed the study. There were no significant between-group differences for change in the primary endpoint SSS or for FSS or median nerve

© 2010 The American Congress of Rehabilitation Medicine. Published by Elsevier Inc. All rights reserved.

Correspondence to Agatha P. Colbert, MD, National College of Natural Medicine, 049 SW Porter St., Portland, OR 97201. acolbert@ncnm.edu Reprints are not available from the authors.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Presented in part at the Symposium for Portland Area Research on Complementary and Alternative Medicine (SPARC), April 18, 2009, Portland, OR, the North American Research Conference on Complementary and Integrative Medicine (NARCCIM), May 12–15, 2009, Minneapolis, MN, and the American Association of Naturopathic Physicians, August 19–22, 2009 Tacoma, WA.

ClinicalTrials.gov Identifier: NCT00521495

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated.

Suppliers:

a. Norso Magnetics, PO. Box 311, Bracey, VA

conduction parameters. For the SSS and the FSS each group showed a reduction at 6-weeks indicating improvement in symptoms.

Conclusions—This study demonstrated the feasibility and safety of testing SMF therapy for CTS. There were no between-group differences observed for the BCTQ or median nerve parameters following 6 weeks of SMF therapy. Significant within-group, symptomatic improvements of the same magnitude were experienced by participants in both active and sham magnet groups. Future studies are needed to optimize SMF dosimetry and resolve issues related to the use of sham controls in SMF trials.

Keywords

Carpal Tunnel Syndrome Magnetic Field Therapy; Magnetics; Rehabilitation

(SMF therapy is frequently used by the general public as a self-care intervention to treat pain. Recent data on sales of therapeutic magnets show US consumers spend more than \$350 million on these products each year (Data Monitor Research-2000). Despite the widespread use of permanent magnets limited data on their safety and efficacy is available. Providing consumers with information they need to make informed decisions about their use of complementary and alternative medicine, including SMF therapy, is identified as an area for priority research by the National Center for Complementary and Alternative Medicine (NCCAM) <http://nccam.nih.gov/about/plans/2005/strategicplan.pdf>

CTS, a chronic painful condition that may be responsive to SMF therapy, has a prevalence of 0.1–3.8% in the general population.¹ Although surgical release is recommended as an effective treatment for moderate to severe CTS <http://www.aaos.org/research/guidelines/CTTreatmentguide.asp>, many patients seek less invasive, alternative approaches for symptom control.^{2–3} A recent systematic review concluded that of the physical modalities commonly used to treat CTS there is moderate (level 2) evidence for the effectiveness of wrist splints and limited or conflicting evidence for yoga, laser and ultrasound.⁴ Only two previous human studies that applied permanent magnets over the site of the carpal canal are available.^{5–6} One study involving 8 hands, showed a therapeutic benefit of SMF^{5–6} but major methodological flaws limit the credibility of both studies including: lack of electrophysiological confirmation of CTS diagnosis⁶; suboptimal SMF dosing regimen⁶; small numbers of hands treated⁵, short duration of follow-up^{5–6} and inadequate blinding⁵.

A few basic science studies suggest the biological plausibility for evaluating SMFs to treat the compressed median nerve in the carpal canal. SMFs enhanced neurite growth in the presence of growth factor⁷ and blocked sensory neuron action potential firing in cell culture.⁸ In addition, the application of an SMF reduced edema formation in a rat model.⁹

In view of the widespread popularity of SMF therapy and some degree of evidence for a biological effect it is reasonable to evaluate the clinical effectiveness of SMF for CTS. Before initiating a full scale randomized controlled trial, however, several methodological challenges need to be resolved.

Our objectives in conducting this pilot study therefore, were to: determine the feasibility of recruiting and retaining compliant CTS participants for an SMF study; obtain preliminary data on the effectiveness and safety of two active magnets and a control sham magnet and; explore whether electrophysiological recovery of the median nerve occurs as a result of applying a permanent magnet over the carpal canal for six weeks.

Methods

Participants

The institutional review boards of the National College of Natural Medicine and the OHSU approved the study protocol. All enrolled participants provided written, informed consent. Data collection and participant follow-up took place at the OHSU Orthopaedics and Rehabilitation Clinic and the Oregon Clinical and Translational Research Institute in Portland, OR from February 2006 to January 2008.

Participants were recruited from university hospital outpatient clinics and from among the general public via newspaper advertisements, flyers posted in local businesses and postings on the research web sites of OHSU and National College of Natural Medicine. Included in the study were women and men between 21 and 65 years of age, who had clinical evidence of CTS (hand or wrist pain with paresthesiae or numbness in any or all fingers, predominating in a median nerve distribution and especially occurring at night for at least the past 3 months), a baseline BCTQ SSS >2 and electrophysiological evidence of median nerve compression within the carpal canal¹⁰ (median sensory distal peak latency >3.5 ms at 13 cm, median nerve distal motor onset latency >4.2 ms at 7 cm, median-ulnar across palm latency difference ≥0.5ms, median-radial to thumb latency difference ≥0.7ms, median-ulnar to ring finger latency difference ≥0.4ms).

Participants were excluded if their symptoms did not fit criteria for the clinical diagnosis of CTS, had previous surgery for CTS on the involved wrist, had previously used magnets, were unwilling to discontinue use of wrist splints or other CTS therapies during the 18-week study period, had insulin-dependent diabetes, were taking narcotic medication, had a medical condition that might confuse the diagnosis of CTS or interfere with the participant's ability to comply with the research protocol, or were involved in CTS related litigation or a workers' compensation claim.

Study Design

This study was a 3-arm randomized, double-blind, sham-controlled clinical trial. Once deemed eligible, participants were randomized to receive 6 weeks of treatment with one of three devices. This was followed by a 12-week no-treatment follow-up period designed to determine the persistence of any effect of the treatments. At the outset, participants were told that the study's intent was to compare the effectiveness of three different strength magnets. They were not informed of the true study hypothesis i.e., that we were comparing two different strength magnets to a non-magnetic sham control.

Randomization

Following screening, participants who met the eligibility criteria went through a 2-week run-in period to assure that they did not exhibit sensitivity to the tegaderm tape used to affix the treatment device; to assess the likelihood of their completing the treatment protocol elements and; to obtain two BCTQs separated by two weeks which would serve as the baseline SSS value. Random assignment to one of three groups followed a computer generated stratified randomization schedule in permuted blocks of five, based on gender, and severity of symptoms as scored on the baseline SSS. Subjects were given their assigned treatment device by a research assistant blinded to group allocation.

Active and control interventions

The three treatment devices were: a unipolar neodymium magnet (2.5cm diameter × 0.3cm thick) magnetized to deliver a SMF of either ~15–20 mT or 45–50 mT to the contents of the carpal canal at a depth of 2.4cm from the magnet's surface, or a non-magnetized aluminum

disk (2.5cm diameter $\times$ 0.3cm thick) that delivered 0 mT. The side of the active magnet facing the skin attracted the south pole-seeking needle of a compass and was defined as the “north pole” of the magnet in accordance with the convention used by magnetotherapy practitioners (Lhasa OMS 2009 Medical Supplies catalog p28). When using a unipolar magnet, magnetotherapists typically apply this side of the magnet to treat chronic painful conditions. The appearance of the active and control devices was identical.

Participants were instructed to apply their device when going to bed at night and to remove it each morning for a period of 6 weeks. This treatment regimen of nighttime-wear only was intended to enhance masking by reducing participants’ opportunities for discovering the magnetic properties of their device.

Magnet quality assurance—The active magnets and sham disks were manufactured to our specifications by James Souder^a. All devices were sent to the laboratory of the study biophysicist (MSM) who recorded magnetic flux density measurements 2.4cm from the center surface of each magnet using a 2100 T model KiloMTmeter. Any magnet with a surface field strength that varied by more than 5% from the manufacturer’s rating was discarded. After the magnetic field strength was recorded each disk was placed in an individual Styrofoam insert, fitted to a plastic box (8 $\times$ 9 $\times$ 13cm). The boxes were labeled with a magnet ID number. The study biophysicist defined the ID codes for the magnets, designating them as Group A, B, or C. The ID codes were concealed from all other study personnel until completion of the trial. The biophysicist had no contact with the participants at any time.

Outcome measures—The primary outcome measure was the SSS of the BCTQ.¹¹ The BCTQ is a two part validated, self-administered questionnaire that includes questions on symptom severity (SSS) and functional status (FSS). Questions are scored on a 5-point Likert scale with “1” representing no symptoms and “5” representing very severe symptoms. Secondary outcome measures included: the FSS of the BCTQ and four median nerve conduction parameters: peak distal sensory latency, amplitude of median nerve action potential, onset distal motor latency and amplitude of median nerve compound action potential.

To minimize inter-examiner variability¹², all NCS were performed by one of two experienced electromyographers who had received similar electrodiagnostic training and were currently practicing in the same OHSU electrodiagnostic laboratory. All NCS were performed using the same instrument, a Keypoint EMG system (Alpine Biomed Corp., 1700 Newhope Suite B, Fountain Valley, CA 97208). Skin temperature of the upper extremity was monitored and maintained at 33 to 34 degrees Celsius at the time of testing.

Compliance with the intervention and hours of device wear was assessed from a participant completed daily log. Safety of the treatments was determined using a participant completed symptom questionnaire and from participants’ spontaneous reports of adverse events throughout the trial. Outcomes were measured at baseline, at the end of the treatment period (6 weeks), and after a 12-week, no-treatment follow-up period (18 weeks).

Blinding strategies

Participants were not informed that they had a one in three chance of receiving a non-magnetized disk. We took several measures to maintain blinding in the study personnel. With the exception of the biophysicist, none of the study personnel opened the plastic box that contained the magnet. The study statistician who generated the randomization was blinded as to which group, A, B, or C, corresponded to which treatment condition. Study investigators and personnel who were involved with participant treatment, follow-up, and

measurement were blinded to treatment assignment. A research assistant whose sole responsibility was to distribute the magnet devices was employed to further assure blinding to treatment assignment. When distributing the magnet devices, the research assistant selected the plastic box with the contained device indicated by the random allocation sequence and gave it to the participant with instructions for applying, removing and storing the device. Participants were instructed to affix the disk to the skin over the site of the carpal tunnel with circular tegaderm adhesive each night and remove it in the morning. (Figure 1.) The research assistant did not touch the device and had no knowledge of its magnetic properties.

The success of our blinding strategies was evaluated with a post treatment questionnaire and a debriefing interview. At their last study visit each participant completed a questionnaire that asked which strength magnet they believed had been assigned and if they had tested the treatment device for magnetic properties. In addition, after all participants completed the study a debriefing interview was conducted to inform them that they may have had a non-magnetic device and to ask, in view of this knowledge, whether they thought their device was an active magnet or not.

Statistical Methods—Effectiveness of the SMF therapy was evaluated using an intent-to-treat analysis, employing the last observation carried forward method. For the primary outcome, a one-way ANOVA was used to compare between-group differences for the change in the SSS from baseline to the 6 week end of treatment measure and for the baseline to 18 week follow up measure. For the secondary outcomes, similar one-way ANOVAs were used to compare between-group differences for change in the FSS and change in NCS from baseline to 6 weeks and from baseline to 18 weeks. To account for the many tests performed the alpha level was set at the more conservative $p < .001$. All alpha levels below .10 are reported so that any (likely spurious) trends can be noted. For ancillary analyses, paired t tests were used to assess within-group changes, pre- to post-intervention for the SSS and FSS scores at 6 weeks and 18 weeks. Chi-square analyses were used when data were of a categorical nature.

Results

The three groups were comparable at baseline for demographic characteristics and BCTQ and nerve conduction parameters with no significant between group differences. (Table 1.) The study population was composed of 75% percent women and the mean age of the group was 50 years.

A total of 315 people were initially screened by telephone interview (Figure 2), and 60 individuals were enrolled in the study. The majority of enrolled participants (67%) were identified from responses to local newspaper advertisements.

Numbers for analysis

Two of the 60 enrolled participants (3%) withdrew before study completion, one from the 15mT group and one from the 45mT group. All 60 participants were included in the intent-to-treat analysis.

Compliance with wearing the treatment device: the majority of participants reported in their daily logs that they wore their device every night, only 7% reported not wearing the magnet on one or two nights out of the required 42 nights of magnet wear. 94% of participants completed their daily logs. 95% of the study visits and questionnaires were completed for both the BCTQ and NCS at 6 and 18 weeks. This study visit completion rate was similar across all groups.

Success of blinding

Among those study completers who received an active magnet (N=38) 45% reported deliberately testing or inadvertently discovering the magnetic properties of their device (Figure 3). Of the 20 participants in the 0mT sham group, only one person tested the device and thought it was magnetic. 15% of this group said they suspected their device might have been non-magnetic, but did not test it.

Adverse events

One participant reported a minor exacerbation of musculoskeletal pains on the first day of magnet (45mT) wear. These symptoms resolved spontaneously after 2 days. Two participants developed a skin rash under the tegaderm adhesive. The rashes cleared with the application of a topical ointment during the day. No serious adverse events were reported.

Effectiveness

For the primary endpoint, each treatment group showed a reduction in the SSS of the BCTQ during the 6-week intervention period indicating an improvement in symptoms with some of the initial reductions maintained during the 12-week no-treatment follow-up period (Table 2). There were no significant between-group differences in change in SSS from 0 to 6 weeks, or from 0 to 18 weeks. Similarly, each treatment group showed a reduction in the secondary outcome, the FSS of the BCTQ, during the 6-week intervention period indicating an improvement in function, but there were no significant between-group differences in the change in FSS from 0 to 6 weeks, or from 0 to 18 weeks. For the four measured median nerve conduction parameters there were no significant within or between-group differences for any parameter at either 6 or 18 weeks. (Table 3) Additional ancillary analyses, (paired t-tests), showed that the pre-to post- intervention improvements for the SSS of the BCTQ were significant within each of the three groups at 6 weeks, $p < .001$ for each of the three groups, and at 18 weeks, $p < .008$ for the 15mT group, $p < .001$ for each of the other two groups.

Discussion

This study demonstrated the feasibility of recruiting and retaining compliant participants for an RCT to evaluate SMF therapy for CTS. We also found that 15mT and 45mT SMFs can be safely applied to the contents of the carpal canal for a 6-week period. The primary outcome measure of CTS symptoms improved after 6 weeks of treatment to a similar degree in the sham control group and two active magnet groups. At 18 weeks, 12 weeks after the treatment had ceased some but not all of the apparent treatment benefits were still observed in all three groups. The timing and magnitude of change for these variables was similar across all groups.

In order to achieve a high level of internal validity we used standardized measurements and follow-up protocols and employed a double-blind randomization with a sham control. Our population was well characterized with regard to the diagnosis of CTS. Of particular note, we restricted our enrollment to those participants with electrophysiologically-confirmed median nerve compression within the carpal tunnel and were able to precisely quantify the SMF dose delivered to the contents of the carpal tunnel. Our findings of significant pre- to post-symptomatic improvement in each of the three study groups, needs to be accounted for. A variety of explanations including natural progression of the disease, a placebo effect or regression to the mean are possible. A particularly strong placebo effect is known to be associated with the use of injections, surgery and novel medical devices and cannot be ruled out in this study.¹³ We took steps in our measurement protocol to minimize regression to the

mean for our primary outcome; at outset we averaged two BCTQ questionnaires, administered two weeks apart, to obtain a more representative baseline SSS measure.

In addition to these oft cited explanations for why a control group improves to the same extent as the experimental group we considered the possibility that our sham device, although non-magnetic, was not inert. The aluminum disk chosen as our control may have exerted some unintended effects on a clinically relevant acupuncture point (PC 7) over which the disk was affixed. In addition, positioned as it was over the palmar aspect of the wrist the disk also prevented the extremes of wrist flexion. It is possible that the mild mechanical pressure exerted with nightly application stimulated an important acupuncture point and/or that the placement of the disk at the base of the hand simulated the effect of a simple wrist splint.

In retrospect, we believe that our efforts to maximize participant blinding may have compromised our SMF dosing regimen. Participants in our study were allowed to wear their devices only during the hours of sleep (7–9 hours per 24 hours) for six weeks, whereas participants in a previous, less well controlled study, reportedly experienced symptomatic and electrophysiologic improvement after wearing their magnets continuously 24 hours per day for 30 days.⁵ Within the field of magnet therapy there are few studies to guide the selection and use of SMF dosimetry and treatment regimens. Thus several other components of our SMF dosing regimen may have been less than optimal. We evaluated only two SMF strengths (15mT and 45mT). We were unable to test any alternate magnetic field strengths, durations of magnet wear, types of magnets, or magnetic polar configurations within the scope of this study.

Wrist splints are often prescribed, along with recommendations for activity modification, as a first line of treatment for CTS. The magnitude of changes on the SSS of the BCTQ that we observed in our study are similar to improvements reported in non-sham controlled studies of wrist splints for CTS.^{14 15 16 17} Compared to our mean SSS changes of 0.7 in the 15mT and 0.8 in the 45mT groups Mishra found a significant SSS pre to post change of .39.¹⁷ Walker et al demonstrated an improvement of 0.7 in full time splint wearers and .59 in the night time only wearers.¹⁵ Manente et al reported a SSS reduction of 1.2 in participants who wore the MANU hand brace compared to no treatment while the mean SSS improved by 0.88 in another study that compared the MANU to a wrist splint group who experienced a 0.78 improvement.¹⁴

In this study we wanted to evaluate an objective outcome measure (NCS) and explore a potential disease modifying effect of SMF by testing before and after median nerve electrophysiological parameters. Basic science researchers have reported enhanced neurite growth⁷ and blockade of sensory nerve potential firing⁸ which suggests that SMFs under certain conditions can influence neural tissue. Our participants experienced no significant within- or between- group improvements in median nerve electrophysiology. This may be because SMFs do not facilitate median nerve repair in the carpal tunnel or because our SMF dosimetry may have been suboptimal.

Success of blinding

Blinding participants in clinical trials that involve the use of a permanent magnet is challenging because magnetic properties are so easily discovered. We used a participant blinding approach (masking to study hypothesis) that is endorsed by the CONSORT group for use in non-pharmacological studies.¹⁸ We can be relatively confident that blinding was successful because the majority of participants in each group thought they had a real magnet. (Figure 3). 45% of participants who had active magnets either tested or discovered the magnetic properties of their devices. Yet, only one person in the sham group deliberately

tested her device and no one in that group inadvertently discovered that the device was not magnetized. However, in future long term studies the likelihood that people in the sham group will test their devices for magnetic properties is high.

Future directions

This study has highlighted many challenges of conducting randomized controlled trials that involve the use of permanent magnets. A wide variety of SMF dosing parameters need to be evaluated, including the assessment of different types of permanent magnets, such as flexible magnets and ferrite magnets, as well as neodymium magnets; testing SMFs of different field strengths and polarities; and the application of magnets for different durations of time and frequencies of application. In addition SMF dosing regimens need to be optimized for each medical condition to be evaluated. Of vital importance is the need for a sham control device that is believable to participants but confirmed to have no physiological effect. Finally, as an alternative to RCTs, future consideration should be given to comparative effectiveness studies which may provide more useful information to clinicians with regard to whether one physical modality, such as wrist splints, is more likely to benefit patients than another, such as static magnetic field therapy.

Conclusions

This study established the feasibility of treating CTS with SMF. Participants in the active magnet groups and the control group experienced clinically relevant improvement after 6 weeks of treatment, but no significant between- group differences in outcome measures were demonstrated. Our goal was to obtain information that would better inform the general public about the safety and effectiveness of two SMF dosages for CTS. We demonstrated the short term safety of these SMF dosages but based on the results of this pilot study we are still unable to inform patients that SMFs are either effective or ineffective for treating CTS.

Acknowledgments

The authors wish to express their appreciation to Tracy Edinger, ND, Elizabeth Arnall, BS and Heather Schiffke, MATCM for their assistance in participant recruitment, data collection, data handling and participant follow-up in this project. We also thank James Souder, BS for contributing his expert knowledge on magnetic materials and for his willingness to custom manufacture the permanent magnets used in this study.

Supported by the National Institutes of Health/National Center for Complementary and Alternative Medicine (grant no. AT003293) and Oregon Clinical and Translational Research Institute (grant no. UL1 RR24140 01).

List of Abbreviations

BCTQ	Boston Carpal Tunnel Questionnaire
CTS	carpal tunnel syndrome
FSS	function severity scale
ID	identification
OHSU	Oregon Health & Science University
SMF	static magnetic field
SSS	symptom severity scale

Reference list

1. Atroshi I, Gummesson C, Johnsson R, Ornstein E, Ranstam J, Rosen I. Prevalence of carpal tunnel syndrome in a general population. *Jama* 1999;282(2):153–158. [PubMed: 10411196]
2. Verdugo RJ, Salinas RA, Castillo JL, Cea JG. Surgical versus non-surgical treatment for carpal tunnel syndrome. *Cochrane Database Syst Rev*. 2008;(4) CD001552.
3. Bland JD. Treatment of carpal tunnel syndrome. *Muscle Nerve* 2007;36(2):167–171. [PubMed: 17534984]
4. Piazzini DB, Aprile I, Ferrara PE, Bertolini C, Tonali P, Maggi L, et al. A systematic review of conservative treatment of carpal tunnel syndrome. *Clin Rehabil* 2007;21(4):299–314. [PubMed: 17613571]
5. Weintraub MI, Cole SP. Neuromagnetic treatment of pain in refractory carpal tunnel syndrome: An electrophysiological and placebo analysis. *J Back Musculoskel Rehabil* 2000;15:77–81.
6. Carter R, Aspy CB, Mold J. The effectiveness of magnet therapy for treatment of wrist pain attributed to carpal tunnel syndrome. *J Fam Pract* 2002;51(1):38–40. [PubMed: 11927062]
7. Siskin B, Midkiff P, Tweheus T, Markov M. Influence of static magnetic fields on nerve regeneration in vitro. *Environmentalist* 2007;27(4):477–481.
8. McLean MJ, Holcomb RR, Wamil AW, Pickett JD, Cavopol AV. Blockade of sensory neuron action potentials by a static magnetic field in the 10 mT range. *Bioelectromagnetics* 1995;16(1):20–32. [PubMed: 7748200]
9. Morris CE, Skalak TC. Acute exposure to a moderate strength static magnetic field reduces edema formation in rats. *Am J Physiol Heart Circ Physiol* 2008;294(1):H50–H57. [PubMed: 17982018]
10. Robinson LR, Micklesen PJ, Wang L. Optimizing the number of tests for carpal tunnel syndrome. *Muscle Nerve* 2000;23(12):1880–1882. [PubMed: 11102914]
11. Levine DW, Simmons BP, Koris MJ, Daltroy LH, Hohl GG, Fossel AH, et al. A self-administered questionnaire for the assessment of severity of symptoms and functional status in carpal tunnel syndrome. *J Bone Joint Surg Am* 1993;75(11):1585–1592. [PubMed: 8245050]
12. Chaudhry V, Cornblath DR, Mellits ED, Avila O, Freimer ML, Glass JD, et al. Inter- and intra-examiner reliability of nerve conduction measurements in normal subjects. *Ann Neurol* 1991;30(6):841–843. [PubMed: 1789696]
13. Kaptchuk TJ, Goldman P, Stone DA, Stason WB. Do medical devices have enhanced placebo effects? *J Clin Epidemiol* 2000;53(8):786–792. [PubMed: 10942860]
14. De Angelis MV, Pierfelice F, Di Giovanni P, Staniscia T, Uncini A. Efficacy of a soft hand brace and a wrist splint for carpal tunnel syndrome: a randomized controlled study. *Acta Neurol Scand* 2009;119(1):68–74. [PubMed: 18638040]
15. Walker WC, Metzler M, Cifu DX, Swartz Z. Neutral wrist splinting in carpal tunnel syndrome: a comparison of night-only versus full-time wear instructions. *Arch Phys Med Rehabil* 2000;81(4):424–429. [PubMed: 10768530]
16. Manente G, Torrieri F, Di Blasio F, Staniscia T, Romano F, Uncini A. An innovative hand brace for carpal tunnel syndrome: a randomized controlled trial. *Muscle Nerve* 2001;24(8):1020–1025. [PubMed: 11439376]
17. Mishra S, Prabhakar S, Lal V, Modi M, Das CP, Khurana D. Efficacy of splinting and oral steroids in the treatment of carpal tunnel syndrome: a prospective randomized clinical and electrophysiological study. *Neurol India* 2006;54(3):286–290. [PubMed: 16936391]
18. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med* 2008;148(4):295–309. [PubMed: 18283207]

Figure 1.
Placement of permanent magnet on wrist

Figure 2.
CONSORT Participant enrollment and flow chart

Figure 3.
Success of blinding

Table 1

Baseline Characteristics of Enrolled Participants

	0mT (control) (n=20)	15mT (n=20)	45mT (n=20)	p *
Age , mean $\pm$ SD, y	51.8 $\pm$ 5.1	50.0 $\pm$ 11.4	47.6 $\pm$ 8.7	.33
Women , no. (%)	15 (75)	15 (75)	16 (80)	.91
Race no. (%)				
White	17 (85)	19 (95)	18 (90)	.57
African-American	1 (5)	0 (0)	0 (0)	.36
American Indian or Alaska Native	1 (5)	0 (0)	1 (5)	.60
Unknown	1 (5)	1 (5)	1 (5)	1.0
Ethnicity no. (%) Hispanic	3 (15)	1 (5)	1 (5)	.42
BMI (kg/m ²) $\pm$ SD	28.4 $\pm$ 8.7	29.4 $\pm$ 7.4	31.0 $\pm$ 10.6	.71
Baseline BCTQ SSS mean $\pm$ SD	2.9 $\pm$.6	2.9 $\pm$.6	3.0 $\pm$.5	.77
Baseline BCTQ FSS mean $\pm$ SD	2.3 $\pm$.7	2.1 $\pm$.7	2.4 $\pm$.7	.43
Median nerve parameters				
SDL (msec) mean $\pm$ SD	4.4 $\pm$.8	4.2 $\pm$.5	4.7 $\pm$.9	.14
MDL (msec) mean $\pm$ SD	4.9 $\pm$ 1.1	4.9 $\pm$.9	5.0 $\pm$.8	.87
SNAP amplitude (μ volts) mean $\pm$ SD	17.1 $\pm$ 8.5	19.0 $\pm$ 7.7	16.0 $\pm$ 11.6	.60
CMAP amplitude (mvolts) mean $\pm$ SD	5.4 $\pm$ 1.9	5.9 $\pm$ 2.9	5.7 $\pm$ 2.2	.78

Detailed description

BMI=Body Mass Index, BCTQ =Boston Carpal Tunnel Questionnaire, SSS= Symptom severity scale, FSS=Functional severity scale, SDL=sensory distal latency (peak), MDL=motor distal latency (onset), SNAP= sensory nerve action potential, CMAP=compound motor action potential.

* The exact p value is provided for either chi-square or ANOVA tests of overall differences between groups at baseline for the variable listed.

Table 2

Mean Change from baseline to 6 weeks and 18 weeks by treatment group for the Boston Carpal Tunnel Questionnaire Symptom Severity Scale and Functional Severity Scale

Treatment Group				
	0mT (control) n=20	15mT n=20	45mT n=20	
	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD	Between group ANOVA [§]
BCTQ-SSS				
Baseline	2.9 $\pm$.6	2.9 $\pm$.6	3.0 $\pm$.5	
6 weeks	2.0 $\pm$.8	2.1 $\pm$.7	2.2 $\pm$.5	
18 weeks	2.3 $\pm$.7	2.4 $\pm$.8	2.3 $\pm$.8	
Change B- 6 weeks	0.9 $\pm$.9 (p=.001)*	0.7 $\pm$.6 (p=.001)*	0.8 $\pm$.6 (p=.001)*	(p=.689)
Change B-18 weeks	0.6 $\pm$.7 (p=.001)*	0.5 $\pm$.8 (p=.008)	0.7 $\pm$.6 (p=.001)*	(p=.463)
BCTQ-FSS				
Baseline	2.3 $\pm$.7	2.1 $\pm$.7	2.4 $\pm$.7	
6 weeks	1.7 $\pm$.4	1.7 $\pm$.5	1.8 $\pm$.6	
18 weeks	1.8 $\pm$.6	1.9 $\pm$.8	2.0 $\pm$.8	
Change B- 6 weeks	0.7 $\pm$.8 (p=.001)*	0.5 $\pm$.7 (p=.008)	0.6 $\pm$.6 (p=.001)*	(p=.686)
Change B-18 weeks	0.5 $\pm$.8 (p=.001)*	0.2 $\pm$.8 (p=.006)	0.4 $\pm$.6 (p=.001)*	(p=.722)

Detailed description

BCTQ=Boston Carpal Tunnel Questionnaire

SSS = Symptom Severity Score.

FSS = Functional Severity Score.

[§]Between group analysis of variance

6 weeks = end of treatment period

18 weeks = follow-up visit after a 12 week no treatment period

* Paired t test for within group analysis, p value is significant

Table 3

Mean Change from baseline to 6 weeks and 18 weeks by treatment group for median nerve conduction parameters

Treatment Group				
	0mT (sham) n=20	15mT n=20	45mT n=20	
	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD	Between group ANOVA [§]
SDL (msec)				
Baseline	4.4 $\pm$.8	4.2 $\pm$.5	4.7 $\pm$.9	
6 weeks	4.2 $\pm$.9	4.2 $\pm$.5	4.7 $\pm$ 1.0	
18 weeks	4.3 $\pm$.9	4.3 $\pm$.7	4.8 $\pm$ 1.2	
Change B- 6 weeks	.2 $\pm$.3 (p=.022)	.1 $\pm$.2 (p=.326)	0 $\pm$.4 (p=.872)	(p=.160)
Change B-18 weeks	0 $\pm$.4 (p=.685)	-.1 $\pm$.5 (p=.345)	-.1 $\pm$.6 (p=.493)	(p=.768)
SNAP (μvolts)				
Baseline	17.1 $\pm$ 8.5	19.0 $\pm$ 7.7	16.0 $\pm$ 11.6	
6 weeks	18.2 $\pm$ 7.7	18.5 $\pm$ 8.3	16.0 $\pm$ 8.8	
18 weeks	18.3 $\pm$ 7.9	16.9 $\pm$ 6.3	16.2 $\pm$ 10.3	
Change B- 6 weeks	1.0 $\pm$ 6.4 (p=.474)	.5 $\pm$ 7.0 (p=.734)	0 $\pm$ 6.0 (p=.974)	(p=.734)
Change B-18 weeks	-1.2 $\pm$ 7.4 (p=.488)	2.2 $\pm$ 7.3 (p=.202)	-.3 $\pm$ 4.1 (p=.773)	(p=.226)
MDL (msec)				
Baseline	4.9 $\pm$ 1.1	4.9 $\pm$.9	5.0 $\pm$.8	
6 weeks	5.0 $\pm$ 1.3	5.1 $\pm$ 1.6	5.0 $\pm$.8	
18 weeks	5.1 $\pm$ 1.3	5.2 $\pm$ 1.0	5.2 $\pm$ 2.4	
Change B- 6 weeks	-.2 $\pm$.5 (p=.203)	-.2 $\pm$ 1.2 (p=.429)	.1 $\pm$.6 (p=.626)	(p=.533)
Change B-18 weeks	-.3 $\pm$.5 (p=.045)	-.3 $\pm$.8 (p=.149)	-.1 $\pm$.3 (p=.070)	(p=.744)
CMAP (mvolts)				
Baseline	5.4 $\pm$ 1.9	5.9 $\pm$ 2.9	5.7 $\pm$ 2.2	
6 weeks	5.9 $\pm$ 1.9	5.1 $\pm$ 2.6	5.6 $\pm$ 2.7	
18 weeks	5.9 $\pm$ 3.0	4.8 $\pm$ 2.1	4.3 $\pm$.7	
Change B- 6 weeks	-.6 $\pm$ 1.9 (p=.227)	.8 $\pm$ 2.5 (p=.174)	.2 $\pm$ 2.0 (p=.721)	(p=.167)
Change B-18 weeks	-.5 $\pm$ 2.3 (p=.298)	1.1 $\pm$ 2.2 (p=.042)	0 $\pm$ 1.5 (p=.953)	(p=.049)

Detailed description

SDL= median nerve sensory distal latency (peak)

SNAP=sensory nerve action potential (amplitude)

MDL=motor distal latency (onset)

CMAP=compound motor action potential (amplitude)

6 weeks = end of magnet wear

18 weeks = follow-up visit.

There were no significant between- group differences at 0–6 weeks, 6–18 weeks or 0–18 weeks in any of the outcome measures.