Original Article

Low Intensity Permanent Magnets in the Treatment of Chronic Lumbar Radicular Pain

Suzan Khoromi, MD, MHS, Marc R. Blackman, MD, Albert Kingman, PhD, Athos Patsalides, MD, Leigh Ann Matheny, RN, Sandra Adams, PT, Arthur A. Pilla, PhD, and Mitchell B. Max, MD

National Institute of Mental Health (S.K.), National Center for Complementary and Alternative Medicine (M.R.B.), National Institute for Dental and Craniofacial Research (A.K., M.B.M.), National Institutes of Health (A.P., L.A.M., S.A.), Bethesda, Maryland; and Department of Biomedical Engineering, Columbia University (A.A.P.), New York, New York, USA

Abstract

We assessed the pain-relieving efficacy of static magnetic fields produced by 200 Gauss (G) magnets compared with 50 G magnets in a double-blind, randomized, two-phase crossover study in patients with chronic lumbar radicular pain. The surface field strengths of the magnets were 200 and 50 G. Phase I included four random periods of two-week duration: two periods with 200 G, one period with 50 G, and one period of "no treatment." The magnets were positioned either vertically or horizontally in standard lumbosacral elastic corsets. Phase II consisted of two five-week periods with the most effective magnet from Phase I and its corresponding 50 or 200 G device. The primary outcome was average daily leg pain score (0–10 scale) in each period of Phase II. Thirty-eight of 40 randomized patients completed Phase I, and 28 of 31 Phase II participants completed the study. In Phase I, pain scores did not differ significantly between 200 and 50 G magnets. Phase II average leg pain scores tended to be lower with 200 vs. 50 G magnets (3.2 ± 2.1 for 200 G vs. 3.9 ± 2.2 for 50 G magnets [$P = 0.08$]) after excluding one unblinded patient. The relative treatment effect of the 200 G magnets appeared to increase throughout the five-week period. Although these data cannot rule out a chance effect, the positive trends suggest that larger, longer-duration, sham-controlled trials with 200 G magnets be considered in patients with chronic lumbar radicular pain. J Pain Symptom Manage 2007;34:434–445. *© 2007 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.*

Key Words

Magnet therapy, chronic lumbar radicular pain, chronic sciatica

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Address reprint requests to: Suzan Khoromi, MD, Section on Developmental Genetic Epidemiology, National Institute of Mental Health, National Center for Complementary and Alternative Medicine, 35 Convent Drive, Bldg. 35, #1A102 (MSC-3720), Bethesda, MD 20814, USA. E-mail: khoromisu@mail.nih.gov

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Introduction

Lumbar radiculopathy is typically associated with sciatica, a sharp and shooting pain along the distribution of the sciatic nerve. Despite a population prevalence of 4.5%,[1] there are no proven drug treatments for chronic sciatica and few clinical trials. Nonpharmacological therapies, including chiropractic manipulations, physical therapy, exercise, transcutaneous electrical stimulation, and magnetic devices, are commonly used in such patients.

During the past decade, consumers have increasingly used magnets for sciatica and other pains, spending an estimated $5 billion worldwide.[2,3] Most field strengths range from 5 to 5,000 Gauss (G), well within the World Health Organization recommended safe exposure range.[4] The effects of magnets have been studied in patients with chronic neck and shoulder pain,[5] osteoarthritis of the knee,[6] plantar fasciitis,[7] postpolio pain,[8] fibromyalgia pain,[9,10] chronic low back pain,[11] and painful diabetic neuropathy.[12] To our knowledge, only one prior study has reported the effects of magnet treatment in patients with chronic sciatica.[13] In that study, 100 patients with chronic sciatica pain were exposed to pulsating magnetic fields of extremely low intensity (0.1−0.3 G) plus standard medication treatment for 14 days. They exhibited a small but significantly greater pain reduction, based on interval to pain relief and/or painless walking, compared to control subjects who received standard treatment alone. Static magnetic fields offer several advantages over pulsating fields, including their suitability for continuous usage, ease of application, simpler design, and low cost.

The goals of this study were to assess whether permanent magnets of 200 G surface field strength alleviate sciatica pain as compared to 50 G magnets, whether 50 G magnets are superior to standard treatment, and whether these devices are well tolerated in this patient population. Our hypothesis was that the effect of the 50 G magnets would not differ from standard treatment and that 200 G magnets would be superior to 50 G magnets.

Methods

Participants

This study was conducted at the Clinical Center of the National Institutes of Health. The protocol was approved by the Institutional Review Board of the National Institute for Dental and Craniofacial Research. Patients were recruited between August 2002 and December 2003 via advertisements in the Washington Post newspaper. The advertisement solicited adults with radiating back pain, leg pain, or a history of pinched nerve or disc disease in the lower back. Each respondent's eligibility was first assessed via telephone screening questions, followed by an outpatient history and physical examination performed by the principal investigator (SK), who enrolled the subjects. All study participants gave written informed consent.

Inclusion criteria were 1) age between 18 and 75 years at the start of the study; 2) average leg pain of at least 4/10 on a verbal numerical scale of 0−10, with 0 representing no pain and 10 representing worst possible pain, present five days per week or more for at least three months; 3) evidence of lumbar radiculopathy, based on the presence of pain in one or both buttocks, thighs, or legs and at least one of the following features on the side corresponding to pain: sharp and shooting pain below the knee, pain evoked by straight leg raising to 60 degrees or less, decreased/absent ankle reflex, weakness of muscles below the knee, sensory loss in an L5/S1 distribution, or imaging (magnetic resonance imaging [MRI], computerized tomography [CT]/myelogram) evidence of nerve root compression in the lower lumbar region; 4) willingness to refrain from making changes in the type and dose of medications taken for sciatica during the study; 5) ability to understand the study measures and be mentally capable to give consent to participate in the study (based on an eighth grade level); 6) willingness to keep a log of pain level and documentation of compliance with wearing of magnetic back device; and 7) (for women of reproductive age) a pregnancy test at baseline and adequate contraception during the study.

Exclusion criteria were 1) patients with pacemakers or mechanical heart pumps; 2) pregnancy or breast-feeding; 3) presence of pain of greater intensity in any other location than the low back or the leg; 4) history of fibromyalgia as described by Wolfe;[14] 5) pain attributable to malignancy, inflammatory arthritis, or infection; 6) spinal instability defined by

a finding of Grade II spondylolisthesis or greater on plain radiography, CT scan, or MRI; 7) presence of other medical condition presenting with numbness and pain in the legs, such as diabetic polyneuropathy and peripheral vascular disease; or 8) history of spinal fusion with spinal rods inserted in the lower lumbar spine.

Imaging and Laboratory Evaluation

Patients submitted an MRI of the lumbosacral spine taken within one year of study enrollment, or an MRI was performed at the NIH Clinical Center upon study entry. A neuroradiologist blinded to each patient's symptoms reviewed the films, commenting on degenerative disc or joint disease and other findings contributing to low back pain or radiculopathy according to definitions and classifications proposed by the American Society of Neuroradiology.[15]

Patients were assessed as having lateral recess syndrome, neural foraminal stenosis, canal stenosis, or their combination if their clinical findings and MRI offered a consistent anatomical explanation of their root symptoms resulting from compression of roots due to degeneration of joint, facet, and/or disc. Patients with evidence of degeneration but no visible root compression were classified as degenerative disc disease and/or degenerative joint disease. Patients with no abnormality were classified as within normal limits. Laboratory evaluation included a complete blood count with differential sedimentation rate, antinuclear antibody titer, and rheumatoid factor to exclude inflammatory arthritis, cancer, and spinal infection. Patients completed a 15-item questionnaire, the Patient Health Questionnaire-15, devised by Kroenke et al.,[16] to assess for multisomatoform disorder.

Experimental Protocol

Phase I. The first phase was intended to select the optimal orientation of the magnet for a longer-term intervention (Phase II). Study patients were randomized to four periods of two-week duration each while continuing their stable medical treatment (Fig. 1). Each patient was randomized to two periods of 200 G treatment and one period of 50 G treatment in addition to a "no treatment" period. Patients were asked to wear magnetic belts eight hours during waking hours and to document in their diary the number of hours they had used the belt each day. The magnetic belts consisted of the following:

- Four permanent 200 G magnets oriented parallel to the spinal axis (vertical, [V]),
- Four permanent 200 G magnets oriented perpendicular to the spinal axis (horizontal, [H]),
- Four 50 G magnets oriented vertically, and
- Four 50 G magnets oriented horizontally.

The magnets were ceramic and were made from strontium ferrite. Each of them weighed 0.15 lb and were three inches long, two inches wide, and 1/8 inch in thickness (Dowling Magnets Company, Sonoma, CA). Active and sham magnets were axially magnetized (one pole per face) with an average surface field of 200 and 50 G, respectively. The north-facing pole of each magnet (geographic south pole) faced the skin surface for both active and sham belts.

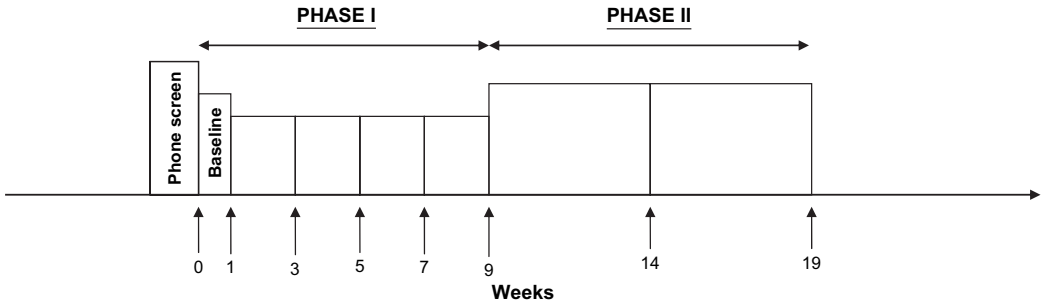

Fig. 1. Phase I consisted of two periods of 200 G magnetic devices, one period of a 50 G magnetic device, and a no treatment period. Phase II was a crossover of the preferred device from Phase I and its corresponding 200 or 50 G device.

The 200 G strength was chosen for the surface magnetic field strength so that the static field at the level of the nerve roots was approximately 20 times the ambient magnetic field of the earth, that is, 5–10 G, in accord with field strengths that have reportedly relieved pain in published studies.[17–19] We sought to design a control treatment with no therapeutic effect as compared to "no treatment" that would appear as similar as possible to the 200 G magnets. We, therefore, produced a 50 G device by demagnetizing 200 G magnets to this field strength, at which small metal objects likely to be encountered by the patients (e.g., paper clips) were weakly bound to the belt. Details of the magnetic field measurements can be found in the Appendix. The magnetic fields at 9 cm were 6.5 ± 0.46 and 1.6 ± 0.14 G for the 200 and 50 G magnets, respectively. We thought the low field strength produced by the 50 G magnet was unlikely to strongly affect the generation or transmission of pain impulses, but were willing to accept a small biological effect to preserve enough of an observable magnetic effect to blind the patients.

Magnets placed vertically or horizontally produced the same magnitude and orientation of the magnetic field relative to the spine and spinal nerve roots. The two magnet orientations were used in Phase I to determine which device was more comfortable and to make it more difficult for patients to decipher the blinding scheme. The magnets were encased in a plastic cover to keep them waterproof and to allow the patients to wash their belts during study participation. Four magnets were sewn in two parallel sets, with two on each side of the spine, into standard lumbosacral elastic corsets commonly used by the NIH Rehabilitation Medicine Department for treating mechanical back pain. The magnets in each pair were 3.5 cm apart from each other across the spine. The magnets were sewn into the lower portion of the corsets over the area most closely matched to the L4, L5, and S1 nerve roots, which are most commonly irritated in chronic sciatica.

During the "no treatment" period, both the participants and the study personnel were unblinded. All study personnel except for the senior author (MM) were blinded to the protocol sequences in Phases I and II, as well as to the strength of the belts worn by the patients. At the end of Phase I, the research participants returned to the NIH outpatient clinic for a follow-up visit. Patients who were interested in continuing the study were then randomized to Phase II by the senior author, who had no patient contact.

Phase II. Phase II of the study also incorporated a randomized, double-blind, crossover design consisting of two treatment periods of five-week duration, one each with a 200 and a 50 G belt (Fig. 1). If one of the two 200 G magnet belts from Phase I was found to have the best pain score, this was chosen and matched with its corresponding H or V 50 G belt for Phase II of the study. For patients who preferred a 50 G belt or the no treatment period, and who were interested in continuing the study, the senior author selected the 200 G belt with the lowest pain scores from Phase I, and randomized the patient to this belt and its corresponding 50 G V or H belt. If the subject's pain scores were equal across all of the four periods and he/she chose to complete the study, he/she was randomized to one of the 200 G devices and its corresponding 50 G belt. Subjects were randomized to the belts in a crossover design. In Phase II, all 200 and 50 G magnets were matched in direction. During the first period of Phase II, 13 subjects were randomized to 200 G and 14 subjects to 50 G magnets. At the conclusion of Phase II, the patients were asked if they would like to have a belt made for them for their individual use, and they were given a belt of their liking at no cost.

Outcome Measures

Each day at bedtime, patients rated their pain during the last 24 hours using a 0–10 numerical scale.[20] They were asked to assess pain in six separate categories: average back, leg, and overall pain (leg and back), and worst back, leg, and overall pain. To answer the leg pain questions, people who had pain in both legs were asked to rate pain on the worse side. At the end of each period, patients mailed back their pain diaries to the study nursing staff, and the information was entered into a database. Subsequently, the study nurses mailed out devices during periods 2, 3, and 4

of Phase I. Patients returned to the Clinical Center at the end of Phases I and II.

In the original protocol, we specified the primary outcome to be the comparison of mean scores for average leg pain during the last two weeks of each period of Phase II using 200 and 50 G magnets. A mean score for each patient was calculated from the 14 daily scores, which used to determine the group mean for the treatment. We used data from the last two weeks of each period in order 1) to minimize any potential carryover effect and 2) to keep the number of component pain scores (7−14) consistent with those used in Phase I. It has been shown that an average of 7−14 component pain scores is much more accurate than a single pain score, but using more than 14 scores does not improve accuracy.[21] Other secondary outcome measures obtained at the end of each period of Phase II only were 1) global pain relief (leg and back pain combined) using a categorical pain scale rating overall pain outcome as worse, no relief, slight, moderate, a lot, and complete relief; 2) the Oswestry Low Back Pain Disability questionnaire;[22] 3) the Beck Depression Inventory;[23] and 4) the 36-item Short Form of Health Survey (SF-36), a general health status instrument that measures the social, mental, and emotional dimensions of health and illness.[24] Side effects elicited during weekly phone interviews were rated for severity as mild, moderate, or severe.

Blinding and Randomization

The senior author established the treatment code and marked the belts V1, V2, H1, and H2. V and H referred to the magnets being horizontal and vertical, and the numbers referred to the study code for magnet strength. He also verified that the 200 G magnets bound a paper clip strongly and the 50 G magnets weakly. In addition, he assigned balanced sequences to patients in Phase I according to Latin squares and used random numbers to assign treatment orders in blocks of four during Phase II. Between uses by different patients, all belts were checked by one of the research assistants who did not have patient interaction to ensure that the magnets had not lost their magnetic field strength. All patients were given a blinding questionnaire at the end of each period in Phase II. The questionnaire asked 1) which belt they thought they were assigned to; 2) what they based this opinion on; 3) whether they had tried to see if the belt contained magnets; and 4) if they had tested the magnets, how they had checked this and what result they had obtained. Prior to filling out the blinding questionnaires, the patients were reassured by the study nurse that in case they had checked the belt this would not disqualify them from continuing the study and receiving a free belt, if they so desired, at the end of the trial. It was decided that the data for any patient who had broken the blinding by checking the strength of the magnetic belt would be excluded from the analysis because such patient's results might create a bias favoring the 200 vs. 50 G belts.

Statistical Analysis

In Phase I, there were two distinct sequence types having three and four distinct sequence orders, respectively, comprising the four-period crossover design with unequal numbers of subjects among sequences. Carryover and period effects were evaluated separately for pairs of crossover periods within the four-period crossover design. Graphical methods were used to access the degree of parallelism among average daily pain scores within and between sequence types over the four treatment periods, separately, for the six patient pain outcome scores. Pain scores for the horizontal and vertical 200 G treatment periods during Phase I were similar, as were those for the horizontal and vertical 50 G periods. Therefore, they were pooled and analyzed using a two-way analysis of variance model. Paired *t*-tests were performed comparing change scores for the 200 vs. 50 G magnet group, and the 50 G vs. "no treatment" periods for each of the six pain outcomes. Phase II used a balanced two-period crossover design. Tests for period and carryover effects were performed. Tests for the 200 and 50 G magnets were performed using crossover differences for each of the six pain outcomes.

Sample Size

Because the primary outcome score of the study was based on Phase II results, we estimated sample size for Phase II to be 28 patients for alpha = 0.05 and beta = 0.20 using the sample size formula for a crossover study.[25]

We used 2.9 as the standard deviation for the difference between 200 and 50 G treatments based on a drug trial of patients with chronic low back pain,[26] given the paucity of randomized controlled trials of magnet treatment. We set the effect size at 1.6 on a scale of 0–10. This corresponds to approximately 30% pain reduction between 200 and 50 G magnets, a clinically meaningful difference.[27]

Side Effects

The study nurses contacted the patients once a week by phone to elicit any adverse effects and check for patient compliance with keeping a daily log of pain and wearing the belt.

Results

Study Patients

Of 305 phone responders, 246 reported either back pain alone, pain location and quality that were typical of myofascial pain in the lower extremities (localized stiffness and dull aching pain), or were not interested in the study. These findings are consistent with the reported frequency of musculoskeletal etiology for low back pain seen in the primary care setting.[28] Fifty-four of the 63 respondents with radiating leg pain who were willing to participate in the trial met the inclusion and exclusion criteria. Table 1 shows that the demographic features among Phase I and Phase II completers were similar.

Forty-seven of the 54 patients who were qualified for the study were randomized to Phase I. Three dropped out during Period 1, three during Period 2, and one patient dropped out during Period 3 (Fig. 2). Of the 40 patients who completed Phase I, 10 chose not to go on to Phase II, of whom six were not interested in continuing the study and four dropped out for personal reasons (two relocated, one changed job, and one had a changed work schedule). Thirty of 40 Phase I completers entered Phase II, of whom two dropped out after randomization. Thus, the dropout rate was 13% during Phase I and 7% during Phase II. No pain data were available for these patients. One participant told the investigator at the end of Phase II that he had deliberately tested the magnetic force of the belts with a paper clip and identified the stronger and weaker belts. Because of this unblinding, we excluded this subject from the primary analysis. The original design of the study protocol included an intent-to-treat analysis, but this was abandoned due to the haphazard pattern in missing diaries for some participants. We excluded these subjects and

Table 1
Demographics in Phase I and Phase II Completers

	40 Phase I Completers	28 Phase II Completers
Sex (M:F)	18:22 (45%:55%)	13:15 (46%:54%)
Age (years)		
Median	60	57
Range	30–78	30–78
Work status		
Employed	19/7	14/5
unemployed	(48%/18%)	(50%/18%)
Disabled	2 (5%)	1 (4%)
Retired	11 (28%)	8 (29%)
Unknown	1 (2.5%)	0 (0%)
Pain duration (years)		
Median	4.5	5
Range	0.4–44	1–30
MRI diagnosis	N/A	
NFS		3 (11%)
CS		7 (25%)
LRS		2 (7%)
DJD/DDD		4 (14%)
Within normal limits		2 (7%)
CS/LRS		2 (7%)
CS/LRS/NFS		4 (14%)
CS/NFS		4 (14%)
Physical signs		
Sensory change	30 (75%)	20 (11%)
Weakness	14 (35%)	8 (29%)
Straight leg raising	28 (70%)	17 (61%)
Reflex change	11 (28%)	5 (2%)
Previous pain medications		
Nonsteroidal anti-inflammatory medications	24 (60%)	16 (57%)
Opioids	7 (18%)	3 (11%)
Anticonvulsants	0 (0%)	0 (0%)
Antidepressants	7 (18%)	5 (18%)
NCV/EMG		
Participants with no studies	30 (75%)	23 (82%)
Participants with studies	10 (25%)	5 (18%)
Findings		
No abnormal findings	0	0
Denervation in distribution of:		
L5 nerve root	7 (18%)	3 (11%)
S1 nerve root	3 (7%)	2 (7%)

NFS = neural foraminal stenosis; CS = canal stenosis; LRS = lateral recess syndrome; DDD/DJD = degenerative disc disease/degenerative joint disease; NCV/EMG = nerve conduction velocity/electromyography.

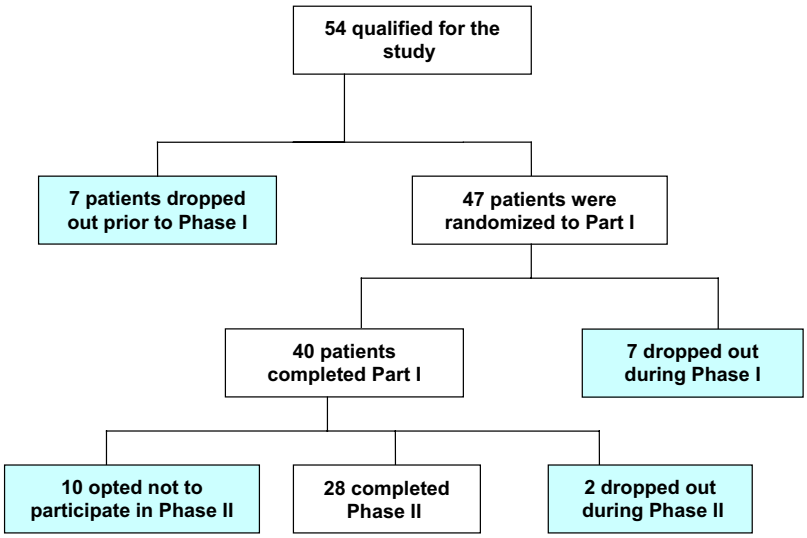

Fig. 2. Study algorithm.

performed a per protocol analysis. Results below are based on the 40 Phase I completers and 27 Phase II completers who were compliant with the protocol.

Effects of Treatment

Primary Outcome. The primary outcome, average daily leg pain score (0–10 scale) in each period of Phase II, was 3.2 ± 2.1 for 200 G magnets (mean $\pm$ SD) as compared with 3.9 ± 2.2 for 50 G magnets ($P = 0.08$). This difference corresponds to an 18% pain reduction produced by the 200 G compared to the 50 G treatment (Table 2). The patient who unblinded himself reported a 44% reduction in average leg pain with the 200 G belt compared to the 50 G belt. Including this patient in the analysis resulted in a P value for average leg pain reduction of 0.06.

Secondary Outcome. In Phase II, global pain relief scores were better for patients receiving 200 vs. 50 G magnets ($P < 0.0002$, Wilcoxon Signed Rank test for comparison across the six-category scale; $t = 3.88$, $P = 0.0007$ using parametric t-test) (Table 3). Thirteen patients gave the same global pain relief rating with 200 and 50 G magnets, nine rated the 200 G magnets as one grade better, four rated the 200 G magnets as two or more grades better, and none rated the 50 G magnets as better.

During Phase I, there were no significant differences in pain reduction in any of the pain scores in patients receiving 200 vs. 50 G magnets (Table 4). During Phase II, pain reduction was significantly better using 200 G magnets for average overall (21%) and worst overall pain (17%) (Table 2). Fig. 3 illustrates that, in Phase II, the mean of average leg pain scores during treatment with the 200 G magnet continued to drop during Weeks 3, 4,

Table 2
Pain Outcome Scores in 27 Blinded Phase II Completers

Pain	Baseline	200 G	50 G	200–50 G	*P* value	95% CI	% Reduced[a]
Average leg	4.6	3.2	3.9	−0.7	0.08	[−2%, 36%]	18
Average back	5.1	3.7	4.1	−0.4	0.31	[−9%, 27%]	10
Average overall	4.7	3.4	4.3	−0.9	0.02	[3%, 37%]	21
Worst leg	5.6	4.0	4.4	−0.4	0.23	[−7%, 26%]	9
Worst back	6.3	4.3	5.0	−0.7	0.11	[−3%, 31%]	14
Worst overall	5.80	4.0	4.8	−0.8	0.04	[1%, 32%]	17

[a]% Reduced refers to percent pain reduction when comparing 200 to 50 G magnet.

Table 3
Global Pain Relief in Phase II

	200 G Magnet					
50 G Magnet	Worse	None	Mild	Moderate	A Lot	Total
Worse	0	1	0	0	1	2
None	0	1	2	1	0	4
Mild	0	0	6	4	2	12
Moderate	0	0	0	3	2	5
A lot	0	0	0	0	3	3
Total	0	2	8	8	8	26

This table matches the number of patients within each category of the global pain relief scale for both the 50 and 200 G magnets. For example, there were four patients who experienced mild pain relief with the 50 G and moderate relief with the 200 G magnet ($P < 0.0002$, Wilcoxon Signed Rank test, for comparison across the six-category scale).

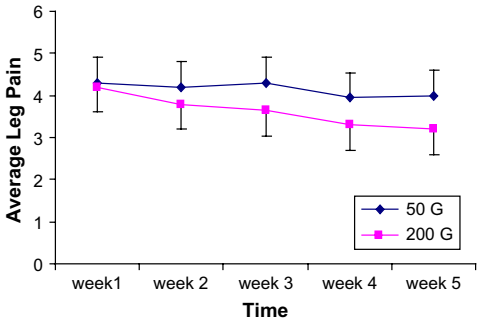

Fig. 3. Average leg pain over both periods of Phase II. Each point represents the mean of average leg pain for each week of treatment with 50 and 200 G during Phase II for the 27 blinded patients.

and 5 wearing the 200 G belt, albeit without reaching statistical significance. For the 50 G magnet, this drop leveled off after Week 2.

In regard to measures of quality of life, there were no significant differences ($P = 0.23$) between the mean scores on the Beck Depression Inventory or the Oswestry Disability Index (paired $t = 0.90$, $P = 0.811$) for patients using the 200 and 50 G magnets. Similarly, after adjustment for multiple comparisons, SF-36 scores were not significantly different between the two treatment groups (Table 5).

Patient Belt Preferences. At the conclusion of the study, 96% of the patients requested a belt to be made for them for long-term usage, with 82% of these patients requesting the 200 G magnet belts.

Period and Carryover Effect. No carryover or period effects could be detected during Phase I when comparing pairs of periods ($P > 0.05$). Graphical inspection for carryover effect and period effects was consistent with the multiple two-period crossover approximate analyses of the average and maximum pain scores in Phase I when comparing each possible paired combination in Phase I. In Phase II, P values were 0.77, 0.93, and 0.54 for the carryover, period, and orientation effects of average leg-pain scores, respectively.

Side Effects. No patient withdrew from Phases I or II because of an adverse effect associated with either treatment. One study completer reported a sensation of heat and fatigue while wearing the 50 G belt during Phase I.

Blinding. Three patients did not fill out blinding questionnaires. Fifteen Phase II completers based their correct guess on pain relief, and one patient based his correct guess on checking the belt. Eight patients based their false guesses on pain relief and one patient based his false guess on the side effect he attributed to a magnetic treatment. Nurses based their correct guesses on pain relief for 16

Table 4
Phase I Magnet Data for One Week of Treatment in 40 Phase I Completers

	Baseline[a]	200 G	50 G	No Rx	% Reduced[b] (200−50 G)	*P* value[c]	% Reduced[d] (50 G−No Rx)
Average leg	4.3	3.4	3.5	3.9	4	0.11	9.8
Average back	4.8	3.9	4.1	4.4	4.5	0.28	5.4
Average overall	4.5	3.8	4.0	4.4	4.9	0.21	0.2
Worst leg	5.3	4.2	4.3	4.6	2	0.42	6.7
Worst back	6.0	4.8	5.2	5.2	8	0.07	0.5
Worst overall	5.5	4.6	5.0	5.3	6.6	0.08	5.6

No Rx = No treatment.
[a]Baseline values were obtained before either intervention was started (at the beginning of the total 10 weeks).
[b]% Reduced refers to percent pain reduction when comparing 200 to 50 G magnets.
[c]The *P* values were generated from the analysis of the pain scores and not from percent pain reduction.
[d]% Reduced refers to percent pain reduction when comparing 50 G magnets to no treatment.

Table 5
SF-36 Scores for the Two Treament Groups

	Baseline	200 G	50 G	*P* value
Physical functioning	48	59	51	0.02
Social functioning	68	79	73	0.13
Role limitations (physical)	41	64	50	0.10
Role limitations (emotional)	54	85	62	0.01
Body pain	38	60	46	0.01
Mental health	72	78	74	0.13
Vitality	48	55	53	0.43
General health perception	62	70	65	0.14

P values relate to comparisons of 50 to 200 G magnets. None of the *P* values are significant when corrected with a Bonferroni test for multiple comparisons.

patients. For one patient they were uncertain, and for eight patients their incorrect guesses were based on pain relief.

Placebo Effect. Based on percent pain reduction (Table 4) during the no treatment period, placebo effect ranged from 1% to 10% for the six pain scores during Phase I.

Discussion

In this randomized trial, five-week treatments with 200 G magnets reduced average leg pain, the primary outcome, by 18% compared with 50 G magnets (95% CI: −2% to 36%, $P = 0.08$). Because the 95% confidence interval includes zero, these data do not rule out an effect entirely due to chance. However, our findings of several significant differences in secondary measures were encouraging. The average and worst pain scores during Phase II (Table 2) were superior with the 200 G magnets, as were the global pain ratings. In addition, Fig. 3 indicates the difference in pain scores between 200 and 50 G magnets increased from Week 1 through the final week of treatment, without reaching statistical significance. It is possible that the analgesic effect of this magnetic treatment has a cumulative effect or a slow onset and that a longer treatment period would have shown a significant effect for the primary outcome. Differences in adipose or muscle tissue superficial to the target area may also explain why some patients experienced more pain reduction than others. Such anthropometric differences between the two groups or the longer duration of treatment periods of five weeks in Phase II, as compared to two weeks in Phase I, may explain the differences between 200 and 50 G magnets in Phases I and II.

Several limitations may have been present in this study. Although the 50 G "sham" was instrumental in obtaining proper blinding as attested by the blinding questionnaire scores, the field delivered by the 50 G magnet at the 9 cm depth may have exerted a small treatment effect, thereby reducing the size of the true treatment difference between the 200 and 50 G devices. Lack of differences between "no treatment" and 50 G magnets in Phase I, however, suggests that any such effect may be small or negligible. The 50 G device also produced fields in the 10−20 G range on superficial lumbar muscles, which lie toward the lower range of magnetic fields that may exert an analgesic effect on musculoskeletal structures.[4] Thus, the full effect of the 200 G device (Appendix) may not have been properly tested at the level of the musculoskeletal tissue.

We would conjecture that any bias due to study dropouts (7% during Phase II) or unblinding was relatively minor. None of the correct guesses for patients and nurses alike were based on side effects. In addition, there was no evidence of carryover or period effects during either phase.

The sample size was relatively small,[29] but similar sample sizes previously used by our team in drug trials of patients with neuropathic pain have yielded statistically significant results for modestly effective treatments.[30,31] Recruiting patients through newspaper advertisement may also have created a bias by selecting subjects favorable to alternative treatments. In addition, 6 of the 10 Phase I completers who dropped out of the study prior to Phase II may have withdrawn due to lack of pain relief, which could have resulted in an enhanced effect in Phase II.

Large placebo effects are commonly ascribed to pain treatments,[32] especially complementary and alternative treatments.[33] However, to distinguish true placebo effects from regression to the mean, "no treatment" periods are needed. Meta-analyses of such studies have lowered estimates of the magnitude of the placebo effect.[34,35] In Phase I of our study, the difference between pain scores with the 50 G magnet and no treatment condition represents the sum of true placebo effects and possible electromagnetic effects of 50 G devices on pain. This total

effect, 1%−10% on various measures, suggests that the placebo effect was small (Table 4).

Although there is a substantial literature describing how electromagnetic fields may affect biological systems,[36] few studies have focused on how magnets may affect nerve root sensitivity. Static magnetic fields have been reported to exert a direct effect on calcium binding to calmodulin and secondary messenger enzymes (kinases, etc).[37] Certain electromagnetic fields cause a significant increase in calcium efflux from chicken brain tissue in vitro (0.05−0.38 G).[38] Calcium is the key transducer of neuronal membrane potential changes into specific cellular actions and neurotransmitter release at the synaptic level, and, therefore, could dampen neuronal hyperexcitability and its cellular accompaniments. Magnetic fields from 0.2 to 10 G with large spatial gradients (approximately 10 G/mm) have been reported to increase the inhibitory threshold of electrically stimulated sensory neurons in vitro.[17,18]

Two previous clinical studies have shown that magnets may be associated with modest improvement in neuropathic pain. The study of sciatica patients by Thuile and Walzl was described above.[13] In the other study, multipolar, 450 G, permanent magnetic insoles were associated with pain relief in a multicenter, randomized controlled trial of patients with painful diabetic neuropathy.[12] One attractive aspect of treatment with magnets is the absence of adverse effects, as supported by our study and those previously published.[12,13]

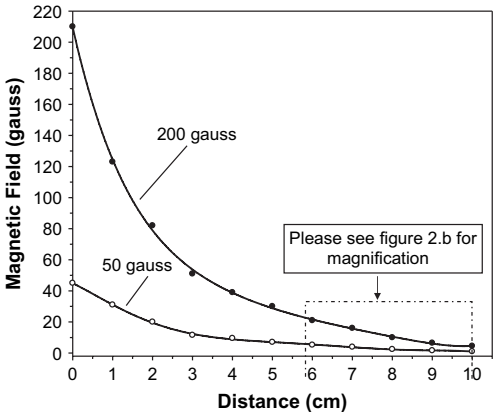

Fig. 4. Decay of the magnetic field along the *z*-axis (perpendicular to the magnet surface) for typical 200 and 50 G magnets used in this study. The magnet field at 9 cm was 6.5 and 1.6 G for the 200 and 50 G magnets, respectively.

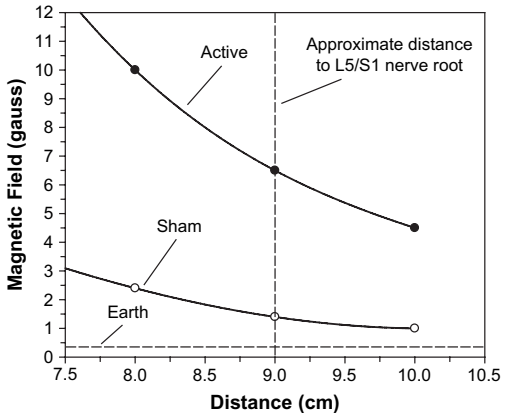

Fig. 5. Expanded view of the magnetic field decay along the *z*-axis (perpendicular to the magnet surface) for typical 200 and 50 G magnets used in this study. Vertical dashed line shows the approximate distance of the L5 and S1 nerve roots from the skin surface. For reference, the earth's magnetic field, 0.3 G in the study location, is shown (horizontal dashed line).

This randomized, controlled, double-blind study showed a nonsignificant trend toward leg pain reduction in patients with chronic sciatica exposed to magnets of 200 vs. 50 G strength. The use of 50 G magnets achieved the goal of proper blinding, which is an important issue in magnet studies, but may have partially masked the true effect of the 200 G magnets on radicular pain. A longer duration of treatment may have increased the effect of 200 vs. 50 G magnets (Fig. 3). In addition, three of the secondary outcomes, global pain relief, average overall and worst overall pain score hint that overall pain in patients with chronic sciatica may be responsive to treatment with 200 G magnets. Studies of larger size and longer duration should be considered to explore the effects of 200 G or stronger magnets compared with novel sham magnet devices that offer superior blinding without deep tissue effects.[39]

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Appendix

Magnetic Field Measurements for Study Devices

The 200 G strength was chosen for the surface magnetic field so that the static field at the level of the nerve roots was approximately 20 × ambient, that is, 5–10 G. The earth's magnetic field in this geographic location is 0.32 G. Thus, at the level of the nerve roots, the 50 G magnet applied a magnetic field approximately 1 G above the ambient magnetic field. Magnetic field measurements were carried out by placing the magnets horizontally in a specially constructed gantry, which allowed computer controlled motion to ±0.1 mm in all three axes of a 3D Hall Effect probe having 1 mm spatial resolution (Sentron Model 3RT). Probe movement along the *z*-axis was computer controlled and data were sampled with a 12-bit A/D converter. All magnetic field measurements represent an average of 100 samples at each distance and are accurate to ±0.1 G. The curves shown in Figs. 4 and 5 represent the magnetic field at distances along the *z*-axis starting on the surface in the center of each magnet. Curve fit was cubic, as expected: To a first approximation, the depth of penetration of the magnetic field into tissue was reduced inversely with the cube of the small dimension of the magnet (two inches in this study). All magnets were checked prior to assignment by a research assistant independent of the study team with a hand-held Gaussmeter (model manufacturer).