

Effect of Magnetic Knee Wrap on Quadriceps Strength in Patients With Symptomatic Knee Osteoarthritis

Chung-Yao Chen, MD, Chia-Ling Chen, MD, PhD, Steele Chih-Chin Hsu, MD, PhD, Shih-Wei Chou, MD, PhD, Kun-Chung Wang, MD

ABSTRACT. Chen C-Y, Chen C-L, Hsu SC-C, Chou S-W, Wang K-C. Effect of magnetic knee wrap on quadriceps strength in patients with symptomatic knee osteoarthritis. *Arch Phys Med Rehabil* 2008;89:2258-64.

Objective: To determine the effects of magnetic knee wrap on isokinetic quadriceps strength in patients with painful knee osteoarthritis (OA).

Design: Randomized, double-blinded, placebo-controlled and before-after trial.

Setting: Rehabilitation clinic in a tertiary hospital.

Participants: Eligible patients (N=50) (mean age \pm SD, 66.0 \pm 8.6y) with mild to moderate knee OA were recruited from the outpatient department and 37 (74%) completed the trial. Only 3 (6%) withdrew due to study-related adverse effects.

Interventions: Wearing the active (n=24) or sham (n=26) magnetic knee wrap for 12 weeks.

Main Outcome Measures: The primary outcome measure was isokinetic quadriceps strength. Secondary outcome measures included the Health Assessment Questionnaire Disability Index (HAQ-DI) and the Health Assessment Questionnaire (HAQ) Pain Scale.

Results: Using intention-to-treat analyses, the peak isokinetic quadriceps strength increased significantly in the treated leg at 30°/s ($P=.007$) and 60°/s ($P=.022$) after wearing the magnetic knee wrap. Compared with baseline, the median strength increase for the treated leg in the study group significantly exceeded that in the control group at week 4 (.05Nm/kg vs $-.09$ Nm/kg at 60°/s, $P=.038$) and week 12 (30°/s, .09Nm/kg vs .04Nm/kg, $P=.044$; 60°/s, .17Nm/kg vs .02Nm/kg, $P=.031$). The HAQ-DI and HAQ Pain Scales improved significantly in both groups. Compared with baseline, the improvement at week 12 in terms of the HAQ-DI in the study group significantly exceeded that in the control group.

Conclusions: Magnetic knee wrap may significantly facilitate isokinetic quadriceps strength in patients with mild to moderate knee OA.

Key Words: Magnetics; Muscle strength; Osteoarthritis, knee; Quadriceps muscle; Rehabilitation.

© 2008 by the American Congress of Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation

OSTEOARTHRITIS IS A widespread, slowly developing disease, with a prevalence increasing with age.¹ Because 30% to 40% of persons over the age of 60 years have knee OA,^{2,3} it is likely to contribute greatly to disability in the general population because it limits the ability to walk, to rise from a chair, and to use stairs.⁴ The treatments for the knee OA include oral medication, intra-articular steroid or sodium hyaluronate injection, surgical management, and physical therapy (including therapeutic heat therapy, electrotherapy, muscular strengthening, knee brace, and insole usage). Pharmacologic agents commonly used in the treatment of OA are often costly, and possess numerous potential side effects that limit their use with many patients. In older patients, chronic use of NSAIDs is associated with a high frequency of adverse effects.^{5,6} Current evidence indicates that selective cyclooxygenase-2 inhibitors have important adverse cardiovascular effects that include increased risk for myocardial infarction, stroke, heart failure, and hypertension.⁷ Therefore, initial treatment should focus on nonpharmacologic approaches (eg, physical therapy, heat/cold, orthotics).⁸ Electromagnetic fields have been used therapeutically for 2000 years for various indications.⁹ Federal authorities in the United States do not currently regulate sales, but the marketed devices are not Food and Drug Administration approved. No adverse effects on human health have been observed with static magnets up to 2 Tesla^{10,11}; however, the efficacy of magnetic therapy has not been clarified in modern literature.¹²

Clinical trials evaluating magnetic therapy for knee OA have been limited and conflicting. Research into magnetic therapy

List of Abbreviations

AMI	arthrogenous muscle inhibition
CV	coefficient of variation
ES	effect size
HAQ	Health Assessment Questionnaire
HAQ-DI	Health Assessment Questionnaire Disability Index
ITT	intention-to-treat
IQR	interquartile range
mT	mTesla
NSAID	nonsteroidal anti-inflammatory drug
OA	osteoarthritis
ROM	range of motion
SMF	static magnetic field
VAS	visual analog scale
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

From the Departments of Physical Medicine and Rehabilitation (C-Y Chen, Hsu) and Orthopaedics (Wang), Chang Gung Memorial Hospital, Keelung; Department of Physical Medicine and Rehabilitation, Chang Gung Memorial Hospital, Taoyuan (C-L Chen, Chou); and Department of Physical Therapy, College of Medicine, Chang Gung University, Taoyuan (Chen, Chen, Hsu, Chou, Wang), Taiwan.

Supported by the Chung-Gang Medical Research Council (grant no. CMRPG23031).

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.

Reprint requests to Chung-Yao Chen, MD, Dept of Physical Medicine and Rehabilitation, Chang Gung Memorial Hospital, Keelung, No 222, Maijin Rd, Anle District, Keelung City 204, Taiwan, e-mail: jongyau2002@gmail.com.

Published online November 1, 2008 at www.archives-pmr.org.

0003-9993/08/8912-0017\$34.00/0
doi:10.1016/j.apmr.2008.05.019

generally may be divided into 2 areas: studies on pulsed electromagnetic fields and studies on SMFs. The pulsed electromagnetic field for the pain relief of knee OA has been reported to be effective in 3 double-blind placebo-controlled trials.¹³⁻¹⁵ But the pulsed electromagnetic field therapy is more expensive and significantly less available to consumers. Therapeutic magnets constructed with permanent magnets that generate SMFs have gained popularity in recent years. Eccles¹¹ reviewed several published, well conducted controlled trials and suggested that SMFs can induce analgesia. On the other hand, a recent systematic review by Pittler et al¹⁶ did not support the uses of static magnets for pain relief. However, Pittler pointed out in the same review that the evidence is insufficient to exclude a clinically important benefit for OA. To date, most studies use the 100-mm VAS for pain or the WOMAC¹⁷ as their outcome measurements. Hong et al¹⁸ studied the effect of a magnetic necklace on pain and reported that the placebo effect alone accounted for the 44% improvement observed in the control group. The placebo effect was reported to be significant and strongest when pain was the outcome.¹⁹ Besides, many placebo-controlled experiments are suspect because it is difficult to blind subjects to the presence of a magnet.¹² Indeed, it is impossible to blind subjects to their use of a nonmagnetic material because it will not stick to metal objects. Unfortunately, the types of trials that are particularly influenced by blinding are those with subjective outcomes or outcomes reported by patients (eg, quality of life instruments).²⁰ For reasons mentioned above, further studies on the therapeutic effects of SMF using more quantitative and objective outcome measures are warranted to decrease bias from the placebo effect and blinding.

Decreased quadriceps strength,²¹⁻²⁵ muscles imbalance,²⁶ impaired proprioception,^{24,27} and balance^{25,28} have been found in patients with knee OA. Among these, quadriceps strength is strongly associated with knee pain and disability.²⁹ The isokinetic strength measurement is a quantitative method and has good reliability in both healthy and arthritic patients.^{30,31} This work attempted to determine the therapeutic effect of magnetic knee wrap on isokinetic quadriceps strength in patients with mild to moderate knee OA throughout the 12-week treatment period.

METHODS

Participants

Patients with chronic knee pain were first screened consecutively based on specified selection criteria from the rehabilitation or orthopedic clinic in a tertiary care hospital. The diagnosis of knee OA was based on the clinical and radiologic criteria defined by the American College of Rheumatology.³² Because of the concern for compliance, we chose to recruit patients with mild to moderate knee OA (Ahlbäck classification³³ grade I). Patients who suffered from radiographically advanced knee OA (the Ahlbäck classification grade II–V) or marked knee effusion with limited ROM were excluded and given more aggressive combined therapy such as drugs, physical therapy, and even joint trapping/intra-articular steroid injection. Patients with cognitive impairment or active medical problems such as recent myocardial infarction and congestive heart failure were excluded because they were not suitable for isokinetic muscle testing. We did not recruit patients with metal knee implant or electronic devices such as pacemakers because of the possible interaction between magnetic fields and metal implants. Exclusion criteria also included pregnancy, inability to walk without assistance, joint infection, other diseases involving the knees, such as rheumatic/psoriatic arthritis,

Table 1: Demographic and Clinical Data of 42 Subjects Participating in the Study Using the ITT Model

Variable	Study Group (n=21)	Control Group (n=21)
Age (y)	64.2±6.8	66.1±8.7
Height (cm)	154.1±8.9	154.7±7.8
Weight (kg)	65.3±9.0	63.1±8.8
BMI (kg/m ²)	28.0±3.8	26.4±3.4
Men/women	4/17	5/16
Symptom duration (min)*	18 (3.5–42)	6 (3.3–21)

NOTE. Values are mean ± SD unless otherwise noted.

Abbreviation: BMI, body mass index.

*Median (IQR).

neurologic disorders, hip, and/or lumbar spine OA with referred pain to the study knee, history of intra-articular glucocorticoid, or hyaluronic acid injection 3 months prior to enrollment, and systemic connective tissue diseases. Table 1 shows the demographic and clinical data of the participants.

The investigation was approved by the hospital human research ethics committee. All participants received an explanation of the study and gave written informed consent before enrollment.

Procedure

This was a 1:1 randomized, double-blinded, and placebo-controlled study. The participants were asked to wear the knee wrap over the painful knee for 12 weeks. To determine the most severely affected leg, we asked subjects to identify the leg in which they experienced worse knee pain. If both knees were equally painful, the nondominant leg was chosen. The chosen leg was deemed the “treated leg.” All participants were requested to wear the knee wrap only on their designated knee for 12 weeks whenever they were awake except while bathing. The compliance to therapy was assessed by questioning how long the participants had spent wearing the knee wrap every day. During the 12-week study period, exercises with lower-limb muscle strengthening effect such as quadriceps strengthening exercises, jogging, mountaineering, bicycling, and treadmill training were prohibited. As far as possible, the medication and daily physical activities were kept constant, apart from small changes in mild analgesics such as acetaminophen and NSAIDs. Neither intra-articular/periarticular injections nor physical therapy were given during the study period.

Randomization and Blinding

A statistician generated the randomization sequence and placed the results in sequentially numbered envelopes. The randomization sequence was created using a permuted block sequence from a random number generator. A research assistant, who had no other tasks or patient contact throughout the study, conducted group assignment. The study coordinator conducted all other study procedures including enrollment and study visits. Procedures were designed to maximize blinding for all study participants and study personnel.

Magnetic Devices

Both sham and active magnetic knee wraps used in this study were manufactured by Nu-Magnetics Inc.^a The magnetic knee wraps are comprised of a reinforced and flexible magnetic rubber compound pressed into a sheet and cut into the shape of a knee wrap. The strength of the multipolar magnetic field is 35mT, as measured with a Lakeshore 430 gauss meter^b on the surface of the knee wrap. The effective field of the magnet

from the knee wrap surface is 17mm and the magnetic strength is reduced inversely with the square of the distance. Beyond 17mm, the magnetic field was measured in the range of the ambient magnetic field of the earth at about .50 gauss. The sham knee wrap was designed to be indistinguishable from the true magnetic wrap in size, shape, material, and balance; its gauss meter readings did not exceed the .50 gauss of the earth's magnetic field.

Outcome Measures

The outcomes were assessed by the same technician, before wearing the knee wrap, and at 1 week, 4 weeks, and 12 weeks while wearing the knee wrap, by analyzing quadriceps isokinetic strength of the treated leg and the 2-page Stanford HAQ.³⁴ Owing to circadian variations in OA pain perceptions, data were gathered on similar days of the week and at similar times of the day as far as possible.³⁵

Isokinetic quadriceps strength. The primary outcome measure was the quadriceps strength of the treated leg using the Biodex System 3 isokinetic dynamometer.^c The assessment was performed with the knee unwrapped. The pilot study showed that eccentric contractions were extremely uncomfortable and concentric knee flexion contractions more than 90° were usually painful for the study population. Therefore, only concentric contraction in limited ROM was examined. Before the evaluation, every participant was instructed regarding the basic principles of isokinetic assessments and performed a 15-minute warm-up. Participants' positioning on the dynamometer followed the protocol of the manufacturer, with the back supported and the hip flexed to approximately 80°. Trunk and thigh straps were fastened for stabilization. This study used a variation on the standard Biodex exercise protocol (Software Version 3.29 and 3.30)^c for isokinetic testing. At the beginning of the test the participants were allowed to familiarize themselves with the movement of each testing speed. The order of tests was: (1) knee extension/flexion concentric protocol at 60°/s, then (2) knee extension/flexion concentric protocol at 30°/s. Tests were started at 80° and performed through a joint arc from 80° to 20° (0°=full extension). The first and last 10° were subsequently deleted to account for the acceleration and deceleration of the dynamometer at the ends of the ROM, and also to account for possible inconsistent effort. Thus, force was measured between joint angles of 30° and 70°. Each subject was asked to perform 5 maximal repetitions without pause at each of the testing speeds. CV of the peak torque recorded from the 5 repetitions was calculated immediately to determine the reproducibility and trial was aborted if CV was greater than 15%. Aborted efforts were repeated in order to obtain the best possible representation of strength for each participant. The maximum number of trials for each test was 3. Thirty-second rest periods were imposed between trials. Sample data regarding power, velocity, and angle were computer analyzed. Gravity effect torque was calculated based on the subject's leg weight at a 30° angle. The concentric peak extension torque of the quadriceps was measured and expressed as a ratio relative to body weight (Nm/kg). Previous studies that evaluated the inhibited quadriceps strength of patients with knee OA using angular velocity of 30°, 60°, 120°, and 180°/s found that the inhibition on strength and the postrehabilitation improvement were more obvious at slower angular velocity.^{36,37} Together with the high standard required (CV<15%) and the concern of fatigue and pain in isokinetic testing, only 2 angular velocities (30° and 60°/s) were selected in this study.

Health assessment questionnaire. Secondary outcome measures were the change in the HAQ-DI and the HAQ Pain Scale during 12 weeks' follow-up. The HAQ^{38,39} was devel-

oped for arthritic conditions in general and the final version contains 20 items covering 8 categories of disability, which were combined to derive a single disability index ranging from 0 to 3. The low score indicates good health. A previous study⁴⁰ found that the HAQ-DI was more sensitive to the detection of disease progression of knee OA than the WOMAC.¹⁷ The HAQ Pain Scale was designed to assess the presence or absence of arthritis-related pain and its severity over the previous week. Pain was measured on a double-anchored VAS that was standardized to a length of 10cm. The scale ranged from 0 (no pain at the left anchor point) to 100 (severe pain at the right anchor point). Participants were instructed to place a vertical mark on the line to indicate the severity of their pain. The HAQ was given face-to-face in a clinical setting and has been validated.³⁴

Additionally, a test performed after the end of this study assessed masking and bias by asking participants whether they believed that a placebo or active device was used or whether they had no opinion.

Statistical Methods

Differences in quadriceps strength gain between the groups were considered clinically relevant. To determine the size of the 2 groups, a power analysis was conducted using preliminary data with an ES of 1, 2-tailed α of .05, and power of .8, which resulted in 18 patients per group. Based on an expected 30% dropout rate during the study, it was decided to recruit 25 participants per group.

We adopted an ITT approach in all analyses, and the last observation carried forward was used to impute data missing at follow-up. Additionally, a per-protocol analysis was performed to see if results differed. All tests were 2-tailed and an α level of .05 was considered to be statistically significant. The normality of the variables was evaluated using the Kolmogorov-Smirnov test. Data not normally distributed were expressed as median and IQR. Data produced by the HAQ-DI were subjected to nonparametric analyses. Baseline characteristics for both groups were compared using the Mann-Whitney *U* tests for continuous variables and the Fisher exact test for categorical variables. Within-group change during the 12-week period was assessed using the Friedman test and post hoc multiple comparisons of 4 visits were performed using the Student-Newman-Keuls test. For each participant, change scores of each outcome measure were calculated by subtracting the results of each follow-up assessment from those at the baseline. Change scores were calculated in order to make the between-group comparison using nonparametric statistics. Between-group differences in change scores and compliance at week 1, 4, and 12 were compared respectively using the Mann-Whitney *U* test. ES of strength increase was measured using the Cohen *d*. Baseline SD was used in the calculation of ES. All data analyses were performed using SPSS for Windows, version 10.0.^d

RESULTS

Between November 2004 and March 2006, 103 patients with chronic knee pain were screened. Of these, 50 were enrolled in the trial with 24 randomly assigned to the study group and 26 to the control group (fig 1). The mean age of the participants was 66 years (range, 44–81y). Of the enrolled participants, 13 (26%) withdrew during the study. The participants who withdrew were evenly spread across the groups, and their baseline characteristics were not markedly different from those with complete data. Among the dropouts, only 2 (4%) withdrew because they felt the treatment was ineffective and their data were included in the ITT model. Moreover, 8 (16%) of the

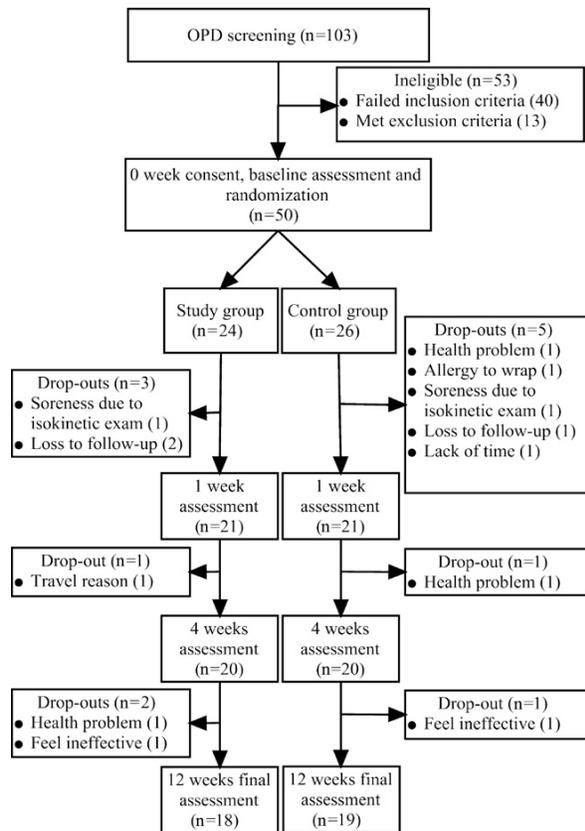


Fig 1. Trial protocol.

dropouts never received posttreatment assessment and were excluded from the ITT analyses. This left the remaining participants for the ITT analyses of 42 subjects (84%). No significant differences were found between the 2 groups at the baseline (tables 1 and 2).

The isokinetic quadriceps strength in the study group increased significantly at both angular velocities (30°/s, $P=.007$; 60°/s, $P=.022$) (see table 2). The post hoc analysis revealed

that the strength increase of the study group was noted as early as 1 week after the application of the magnetic knee wrap and peaked at the end of the investigation (see table 2). There was a trend ($P=.061$) that at week 1 the change scores of quadriceps strength at 60°/s in the study group exceeded those for the control group (table 3). Moreover, the change scores of quadriceps strength in the study group significantly exceeded those for the control group at week 4 (60°/s, $P=.038$) and week 12 (30°/s, $P=.016$; 60°/s, $P=.031$) (see table 3). At week 12, median increase in peak torque of 11% at 30°/s and 16% at 60°/s was noted in the study group and the ES of strength increase in the study group was .63 at 30°/s and .64 at 60°/s. No strength gain was noted in the control group.

The HAQ-DI and the HAQ Pain Scale was significantly decreased in both groups (see table 2). The change scores of the HAQ-DI in the study group at week 12 significantly exceeded those of the control group (see table 3). And there was a trend ($P=.063$) that magnetic knee wrap was more effective than the sham knee wrap in pain reduction at week 12 (see table 3).

The compliances between the 2 groups did not differ significantly except those at week 1 (study group: median compliance 6h/d, IQR, 4.25–9.5; control group: 10h/d, IQR, 6.5–12.5).

When the outcomes were reanalyzed using the per-protocol model, only 2 differences were identified relative to the ITT method. In the per protocol analyses, the differences of change scores in the HAQ-DI between the 2 groups at week 12 became nonsignificant ($P=.142$). Besides, it became a trend ($P=.053$) that at week 4 the change scores of quadriceps strength at 60°/s for the study group exceeded those for the control group.

Participants were asked after the end of the study to identify the treatment provided. Thirty-two (76%) participants responded. Of the 13 study group subjects responding, 2 (15%) believed they had active magnets, and 11 (85%) did not know. Of the 19 sham-device participants responding, 5 (26%) believed they had active magnets, only 1 (5%) believed they had sham magnets, and 13 (69%) did not know.

Drug use was similar between the study and control groups over the treatment period (analgesics, 30% vs 27%; NSAIDs, 24% vs 26%). No serious adverse effects occurred during the study and only 3 (6%) withdrew for study-related reasons. One case of skin irritation was reported in relation to the knee wrap as well as 2 cases of muscle soreness owing to isokinetic examination. The skin irritation disappeared after the wearing of the knee wrap was discontinued. The muscle soreness was mild and transient.

Table 2: Median Outcome Scores Over Time According to Group Allocation Using ITT Analyses

Variable	Group	Baseline	Week 1	Week 4	Week 12	Post Hoc [‡]
Q strength (Nm/kg)	SG [†]	1.07 (0.86–1.38)	1.02 (0.88–1.51)	1.04 (0.90–1.34)	1.12 (0.92–1.55)	a, b, c, d, f
	CG	1.18 (0.95–1.54)	1.14 (1.01–1.49)	1.15 (0.94–1.41)	1.07 (0.96–1.43)	
60°/s	SG [*]	0.90 (0.71–1.11)	0.89 (0.73–1.27)	0.90 (0.80–1.23)	0.97 (0.80–1.55)	c, e, f
	CG	1.02 (0.84–1.23)	0.97 (0.81–1.21)	0.97 (0.80–1.17)	0.95 (0.88–1.24)	
HAQ-DI (range 0–3)	SG [†]	0.25 (0.13–0.75)	0.25 (0.13–0.69)	0.13 (0.13–0.38)	0.13 (0.00–0.31)	b, c, d, e, f
	CG [*]	0.25 (0.00–0.63)	0.25 (0.06–0.50)	0.25 (0.00–0.50)	0.13 (0.06–0.44)	
HAQ Pain Scale [§]	SG [†]	50 (35–70)	40 (30–55)	30 (20–50)	20 (14–30)	a, b, c, d, e, f
	CG [†]	50 (40–60)	40 (30–40)	40 (30–40)	30 (25–40)	

NOTE. Data are median (IQR). Each group contains 21 participants. Abbreviations: CG, control group; Q, quadriceps; SG, study group.

^{*} $P<0.05$, [†] $P<0.01$; significant differences across time within the group using Friedman test.

[‡]Student-Newman-Keuls post hoc test: a, baseline versus week 1; b, baseline versus week 4; c, baseline versus week 12; d, week 1 versus week 4; e, week 1 versus week 12; f, week 4 versus week 12.

[§]100-mm VAS.

Table 3: Median Change Scores of Outcome Measures, Relative to the Baseline, According to Group Allocation Using ITT Analyses

Q Strength (Nm/kg)	Group	Week 1	Week 4	Week 12
30°/s	SG	0.08 (-0.04 to 0.22)	0.07 (-0.13 to 0.16)	0.09 (-0.01 to 0.25)*
	CG	0.01 (-0.04 to 0.17)	-0.02 (-0.10 to 0.09)	0.04 (-0.17 to 0.12)*
60°/s	SG	0.05 (-0.03 to 0.21)	0.05 (-0.07 to 0.26)*	0.17 (-0.02 to 0.31)*
	CG	0 (-0.12 to 0.08)	-0.09 (-0.14 to 0.11)*	0.02 (-0.14 to 0.16)*
HAQ-DI	SG	0 (0 to 0)	-0.13 (-0.13 to 0)	-0.13 (-0.38 to 0)*
	CG	0 (0 to 0)	0 (-0.06 to 0)	0 (-0.13 to 0)*
HAQ Pain Scale [†]	SG	-10 (-12.5 to 0)	-20 (-30 to -10)	-30 (-40 to -16)
	CG	-10 (-10 to 0)	-10 (-20 to 0)	-10 (-30 to 0)

NOTE. Data are median (IQR). Each group contains 21 participants. Negative signs represent a worsening for strength but an improvement for HAQ-DI and HAQ Pain Scale.

Abbreviations: CG, control group; Q, quadriceps; SG, study group.

*Statistically significant between groups ($P < 0.05$) using Mann-Whitney *U* tests.

[†]100-mm VAS.

All the knee wraps were retested using the same gauss meter at week 12, showing that the magnetic knee wrap had a mean strength of 33.2mT on the surface.

DISCUSSION

To our knowledge, this is the first investigation evaluating the therapeutic effect of magnetic knee wrap in knee OA by measuring isokinetic quadriceps strength instead of subjective measures such as the WOMAC and the VAS. As mentioned above, using these subjective measures has led to conflicting results found in most of the previous studies.^{10,11,16} Our findings that the magnetic knee wrap for knee OA might facilitate isokinetic quadriceps strength had not been scientifically documented before and has provided more objective and quantitative evidence supporting the usage of magnetic knee wrap.

The peak isokinetic quadriceps strength increased gradually after the application of magnetic knee wrap. Meanwhile, no improvement occurred in the control group. It was difficult to keep the CV less than 15% during the isokinetic testing if the participants were not cooperative and performing their maximal muscle contraction. Given that the quadriceps strength in the control group decreased mildly in the follow-up study (see table 3), it seems reasonable to suppose that the possible learning effect and placebo effect were minimized in this study by means of quantitative isokinetic testing with adequate control of CV. The significant strength increase at 30°/s at week 1 suggested that the magnetic knee wrap had a considerable immediate effect. The most notable strength increase occurred at week 12, which suggested that the effect on muscle strength might last for 12 weeks. The findings that strength increase of the study group at week 4 and 12 significantly exceeded that of the control group might support the potential role of SMF in strength recovery.

Various reasons exist for the facilitated quadriceps strength in the study group. Reduced inhibition, due to concomitant pain relief, is a possible explanation. With the improvement of the HAQ-DI, increased physical activities in the study group may prevent disuse atrophy, strengthen the muscle, and play a role in strength recovery of the treated leg. However, the mild decrease in quadriceps strength in the control group despite the pain reduction and the improvement of HAQ-DI suggests that physical activities were not the main reasons for strength recovery in the study group. During the treatment period, no low extremities strengthening exercises were actually performed by participants in both groups. Therefore, reduced AMI possibly related to the effect of SMF may be the other reason for strength recovery.

Muscle weakness in knee OA can be attributed to AMI,⁴¹ muscle fiber atrophy, or myopathic change.^{42,43} AMI results from the underlying inhibition of motoneurons by afferent signals from in and around the affected joint⁴¹ and is known to be the reason why efforts to restore strength are frequently unsuccessful even in the absence of pain. In the in vitro study using neuron from adult mouse, blockade of sensory neuron action potentials could be induced by an SMF in the 10mT range.⁴⁴ Cavopol et al⁴⁵ studied the cultured neurons from the dorsal root ganglion and estimated that the experimental threshold gradient and the calculated threshold field intensity of SMF for blockade of action potentials were approximately .02mT/mm and .02mT, respectively. Because the SMF (35mT) in this work has a presumed penetration of up to 17mm, indicating passage through the epidermal and dermal layers, which contain a rich network of nerves,⁴⁶ it is biologically plausible that SMF may inhibit and/or interrupt the firing of afferent signals, leading to decreased AMI and pain in our work. In other words, SMF may facilitate the inhibited quadriceps strength rather than directly strengthen the quadriceps.

The recovery in isokinetic quadriceps strength after the application of magnetic knee wrap is clinically comparable with other conservative treatments. A previous study found that the most pronounced effects of physical training on isokinetic quadriceps strength were seen after 3 months (median improvement: 20% at 30°/s).³⁶ Physiotherapy programs that emphasized motor control and function rather than lower limb strengthening for knee OA did not show a significant increase in quadriceps strength after the completion of 12-week therapy.⁴⁷ Accordingly, the quadriceps strength increase should be comparable between physical training and the application of magnetic knee wrap (16% at 60°/s). Intra-articular injection of hyaluronan was found to improve isokinetic quadriceps strength ranging from .27Nm/kg at 80°/s to .28Nm/kg at 240°/s 1 week after the completion of therapy.⁴⁸ However, Bayramoglu et al⁴⁹ reported no significant muscle strengthening 12 weeks after the injection. The mean strength recovery 12 weeks after the application of magnetic knee wrap ranged from .20Nm/kg at 30°/s to .21Nm/kg at 60°/s. Although the short-term effect is inferior to that of the viscosupplements therapy, magnetic knee wrap exerts a superior effect 12 weeks after the beginning of the therapy. The medium ES in strength increase at week 12 ranging from .63 at 30°/s to .64 at 60°/s further suggested that the use of magnetic knee wrap might be beneficial for patients with mild to moderate knee OA.

A recent review suggests that SMF can induce analgesia and pain relief was generally reported at gauss ratings of 40mT and

above.¹¹ Studies also found that multipolar magnets may more effectively reduce sensory afferent firing than unipolar or bipolar magnets, because they generate a deeper field gradient penetration.⁴⁴ These may be the reasons why multipolar static magnetic knee wrap of 35mT in this work can induce pain reduction. Besides, the effect on pain reduction in the study group was progressive and peaked at the end of the study. Pain reduction was also found in the control group. Small sample size, the effect of sham knee wrap per se, and limited follow-up duration might be the reasons for the nonsignificant difference in pain reduction between the 2 groups.

The application of magnetic knee wrap may improve HAQ-DI in patients with mild to moderate knee OA. The findings that the magnetic knee wrap decreased the HAQ-DI more effectively at week 12 than did the sham wrap are in agreement with the earlier findings that the WOMAC functional status improved in patients with knee OA after 2 weeks of SMF therapy.⁵⁰ Decreased pain and increased quadriceps strength may explain the improvement of the HAQ-DI in this investigation. However, the clinical significance of the improvement in HAQ-DI in our work is limited because the participants suffered from only mild disability (HAQ-DI=.25) at the beginning of the study. The improvement in pain and HAQ-DI in the control group was in agreement with the recent systematic review⁷¹ that suggested a sleeve has additional beneficial effect (WOMAC, function tests) for knee OA compared with medical treatment alone.

Most of the participants were cooperative and complied with our request not to test the magnetic property of their knee wrap. The questionnaire after study termination suggests that both groups remained blinded.

Study Limitations

Several important caveats exist to this study. First, the participants in this study suffered from knee pain caused by mild to moderate knee OA. Therefore, the experimental results may not apply to asymptomatic people with radiographic knee OA or patients with radiographically advanced knee OA (the Ahlbäck classification grade II–V). Second, the optimal strength of magnetic field and underlying mechanism of SMF therapy remains in question. The least time in a day for wearing the magnetic knee wrap to increase muscle strength is also underexplored. Third, the isokinetic muscle testing in this study only focused on slow angular velocity and limited ROM from 80° to 20°, excluding the eccentric contraction. Therefore, the facilitated quadriceps strength in this study may not be generalized to the activities involving eccentric quadriceps contraction or concentric quadriceps contraction in the squatting position or high angular velocity. Further study is warranted recruiting patients with more advanced knee OA, with longer follow-up period including the time after the magnetic knee wrap is discontinued, and measuring the effect of SMF on AMI to elucidate these questions and support the use of magnetic knee wrap in clinical practice.

CONCLUSIONS

Allowing for the caveats discussed above, the study has provided information suggesting that the application of the static, permanent magnetic knee wrap may produce a substantial recovery in isokinetic quadriceps strength. Considering its safety and relatively minimal cost, magnetic knee wrap thus can be used as an adjunct therapy of knee OA and may benefit prescribers by listing it as one of the choices of home therapy.

Acknowledgment: We thank Chieh-Ling Lin, BS, for her assistance in statistic analysis and data collection with this project.

References

1. Badley EM, Tennant A. Changing profile of joint disorders with age: findings from a postal survey of the population of Calderdale, West Yorkshire, United Kingdom. *Ann Rheum Dis* 1992;51:366-71.
2. van Saase JL, van Romunde LK, Cats A, Vandenbroucke JP, Valkenburg HA. Epidemiology of osteoarthritis: Zoetermeer survey. Comparison of radiological osteoarthritis in a Dutch population with that in 10 other populations. *Ann Rheum Dis* 1989;48:271-80.
3. Felson DT. The epidemiology of knee osteoarthritis: results from the Framingham Osteoarthritis Study. *Semin Arthritis Rheum* 1990;20:42-50.
4. Gur H, Kakin N. Muscle mass, isokinetic torque, and functional capacity in women with osteoarthritis of the knee. *Arch Phys Med Rehabil* 2003;84:1534-41.
5. Griffin MR, Piper JM, Daugherty JR, Snowden M, Ray WA. Nonsteroidal anti-inflammatory drug use and increased risk for peptic ulcer disease in elderly persons. *Ann Intern Med* 1991;114:257-63.
6. Gurwitz JH, Avorn J, Ross-Degnan D, Lipsitz LA. Nonsteroidal anti-inflammatory drug-associated azotemia in the very old. *JAMA* 1990;264:471-5.
7. Antman EM, Bennett JS, Daugherty A, Furberg C, Roberts H, Taubert KA. Use of nonsteroidal antiinflammatory drugs: an update for clinicians. a scientific statement from the American Heart Association. *Circulation* 2007;115:1634-42.
8. Griffin MR, Brandt KD, Liang MH, Pincus T, Ray WA. Practical management of osteoarthritis. Integration of pharmacologic and nonpharmacologic measures. *Arch Fam Med* 1995;4:1049-55.
9. Macklis RM. Magnetic healing, quackery, and the debate about the health effects of electromagnetic fields. *Ann Intern Med* 1993;118:376-83.
10. Vallbona C, Richards T. Evolution of magnetic therapy from alternative to traditional medicine. *Phys Med Rehabil Clin N Am* 1999;10:729-54.
11. Eccles NK. A critical review of randomized controlled trials of static magnets for pain relief. *J Altern Complement Med* 2005;11:495-509.
12. Finegold L, Flamm BL. Magnet therapy. *BMJ* 2006;332:4.
13. Trock DH, Bollet AJ, Dyer RH Jr, Fielding LP, Miner WK, Markoll R. A double-blind trial of the clinical effects of pulsed electromagnetic fields in osteoarthritis. *J Rheumatol* 1993;20:456-60.
14. Trock DH, Bollet AJ, Markoll R. The effect of pulsed electromagnetic fields in the treatment of osteoarthritis of the knee and cervical spine. Report of randomized, double blind, placebo controlled trials. *J Rheumatol* 1994;21:1903-11.
15. Jacobson JL, Gorman R, Yamanashi WS, Saxena BB, Clayton L. Low-amplitude, extremely low frequency magnetic fields for the treatment of osteoarthritic knees: a double-blind clinical study. *Altern Ther Health Med* 2001;7:54-64.
16. Pittler MH, Brown EM, Ernst E. Static magnets for reducing pain: systematic review and meta-analysis of randomized trials. *CMAJ* 2007;177:736-42.
17. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to anti-rheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;15:1833-40.
18. Hong CZ, Lin JC, Bender LF, Schaeffer JN, Meltzer RJ, Causin P. Magnetic necklace: its therapeutic effectiveness on neck and shoulder pain. *Arch Phys Med Rehabil* 1982;63:462-6.
19. Hrobjartsson A, Gotzsche PC. Is the placebo powerless? An analysis of clinical trials comparing placebo with no treatment. *N Engl J Med* 2001;344:1594-602.

20. Fergusson D, Glass KC, Waring D, Shapiro S. Turning a blind eye: the success of blinding reported in a random sample of randomised, placebo controlled trials. *BMJ* 2004;328:432.
21. Hayes KW, Falconer J. Differential muscle strength decline in osteoarthritis of the knee. A developing hypothesis. *Arthritis Care Res* 1992;5:24-8.
22. Lankhorst GJ, Van de Stadt RJ, Van der Korst JK. The relationships of functional capacity, pain, and isometric and isokinetic torque in osteoarthritis of the knee. *Scand J Rehabil Med* 1985; 17:167-72.
23. Wegener L, Kisner C, Nichols D. Static and dynamic balance responses in persons with bilateral knee osteoarthritis. *J Orthop Sports Phys Ther* 1997;25:13-8.
24. Hurley MV, Scott DL, Rees J, Newham DJ. Sensorimotor changes and functional performance in patients with knee osteoarthritis. *Ann Rheum Dis* 1997;56:641-8.
25. Messier SP, Glasser JL, Ettinger WH Jr, Craven TE, Miller ME. Declines in strength and balance in older adults with chronic knee pain: a 30-month longitudinal, observational study. *Arthritis Rheum* 2002;47:141-8.
26. Hortobágyi T, Westerkamp L, Beam S, et al. Altered hamstring-quadriciceps muscle balance in patients with knee osteoarthritis. *Clin Biomech (Bristol, Avon)* 2005;20:97-104.
27. Bennell KL, Hinman RS, Metcalf BR, et al. Relationship of knee joint proprioception to pain and disability in individuals with knee osteoarthritis. *J Orthop Res* 2003;21:792-7.
28. Hinman RS, Bennell KL, Metcalf BR, Crossley KM. Balance impairments in individuals with symptomatic knee osteoarthritis: a comparison with matched controls using clinical tests. *Rheumatology* 2002;41:1388-94.
29. O'Reilly SC, Jones A, Muir KR, Doherty M. Quadriciceps weakness in knee osteoarthritis: the effect on pain and disability. *Ann Rheum Dis* 1998;57:588-94.
30. Giles B, Henke P, Edmonds J, McNeil D. Reproducibility of isokinetic muscle strength measurements in normal and arthritic individuals. *Scand J Rehabil Med* 1990;22:93-9.
31. Noorizadeh Dehkordi S, Talebian S, Olyaei G, Montazeri A. Reliability of isokinetic normalized peak torque assessments for knee muscles in post-stroke hemiparesis. *Gait Posture* 2008;27: 715-8.
32. Altman R, Asch E, Bloch D, et al. Development of criteria for the classification and reporting of osteoarthritis. Classification of osteoarthritis of the knee. Diagnostic and Therapeutic Criteria Committee of the American Rheumatism Association. *Arthritis Rheum* 1986;29:1039-49.
33. Ahlback S, Rydberg J. [X-ray classification and examination technics in gonarthrosis] [Swedish]. *Lakartidningen* 1980;77: 2091-3.
34. Bruce B, Fries JF. The Stanford Health Assessment Questionnaire: a review of its history, issues, progress, and documentation. *J Rheumatol* 2003;30:167-78.
35. Bellamy N, Sothorn RB, Campbell J. Rhythmic variations in pain perception in osteoarthritis of the knee. *J Rheumatol* 1990;17:364-72.
36. Rogind H, Bibow-Nielsen B, Jensen B, Moller HC, Frimodt-Moller H, Bliddal H. The effects of a physical training program on patients with osteoarthritis of the knees. *Arch Phys Med Rehabil* 1998;79:1421-7.
37. Hurley MV, Newham DJ. The influence of arthrogenous muscle inhibition on quadriceps rehabilitation of patients with early, unilateral osteoarthritic knees. *Br J Rheumatol* 1993;32:127-31.
38. Bruce B, Fries JF. The Health Assessment Questionnaire (HAQ). *Clin Exp Rheumatol* 2005;23(5 Suppl 39):S14-8.
39. Koh ET, Seow A, Pong LY, et al. Cross cultural adaptation and validation of the Chinese Health Assessment Questionnaire for use in rheumatoid arthritis. *J Rheumatol* 1998;25:1705-8.
40. Bruce B, Fries J. Longitudinal comparison of the Health Assessment Questionnaire (HAQ) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). *Arthritis Rheum* 2004;51:730-7.
41. Young A. Current issues in arthrogenous inhibition. *Ann Rheum Dis* 1993;52:829-34.
42. Glasberg MR, Glasberg JR, Jones RE. Muscle pathology in total knee replacement for severe osteoarthritis: a histochemical and morphometric study. *Henry Ford Hosp Med J* 1986;34:37-40.
43. Nakamura T, Suzuki K. Muscular changes in osteoarthritis of the hip and knee. *Nippon Seikeigeka Gakkai Zasshi* 1992;66:467-75.
44. 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;16:20-32.
45. Cavopol AV, Wamil AW, Holcomb RR, McLean MJ. Measurement and analysis of static magnetic fields that block action potentials in cultured neurons. *Bioelectromagnetics* 1995;16:197-206.
46. Weintraub MI, Wolfe GI, Barohn RA, et al. Static magnetic field therapy for symptomatic diabetic neuropathy: a randomized, double-blind, placebo-controlled trial. *Arch Phys Med Rehabil* 2003; 84:736-46.
47. Bennell KL, Hinman RS, Metcalf BR, et al. Efficacy of physiotherapy management of knee joint osteoarthritis: a randomised, double blind, placebo controlled trial. *Ann Rheum Dis* 2005;64: 906-12.
48. Tang SF, Chen CP, Chen MJ, Hong WH, Yu TY, Tsai WC. Improvement of muscle strength in osteoarthritic knee patients after intraarticular knee injection of hyaluronan. *Am J Phys Med Rehabil* 2005;84:274-7.
49. Bayramoglu M, Karatas M, Cetin N, Akman N, Sozay S, Dilek A. Comparison of two different viscosupplements in knee osteoarthritis—a pilot study. *Clin Rheumatol* 2003;22:118-22.
50. Hinman MR, Ford J, Heyl H. Effects of static magnets on chronic knee pain and physical function: a double-blind study. *Altern Ther Health Med* 2002;8:50-5.
51. Brouwer RW, Jakma TS, Verhagen AP, Verhaar JA, Bierma-Zeinstra SM. Braces and orthoses for treating osteoarthritis of the knee. *Cochrane Database Syst Rev* 2005;25;(1):CD004020.

Suppliers

- a. Nu-Magnetics Inc, 6 Northwind Dr, Port Jefferson, NY 11777.
- b. MMT-6Jo4-VH; Magnet-Physics Inc USA, 770 W Algonquin Rd, Arlington Heights, IL 60005.
- c. Biodex Medical Systems Inc, 20 Ramsay Rd, Shirley, NY 11967-4704.
- d. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.