

## EFFICACY OF A STATIC MAGNETIC DEVICE AGAINST KNEE PAIN ASSOCIATED WITH INFLAMMATORY ARTHRITIS

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[In collaboration with and supported by the Holcomb Medical Research Institute]

Potential Conflicts of Interest: Dr. Holcomb is a major stock holder and Dr. McLean is a minor stock holder in the company that manufactures the magnetic devices used in this study. This manuscript was submitted to an Oversight Committee appointed by the Vice Chancellor of the Medical School.

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### To The Editor:

Electromagnetic fields have been used therapeutically for 2000 years, for indications ranging from headaches to gout (1). There is considerable evidence that steady direct current and time-variant electromagnetic fields are produced by living bone through metabolic activity and piezoelectric activity upon bone deformation respectively (2). Pulsed electromagnetic fields (PEMF) have been used for acceleration of fracture and osteotomy healing. These effects have been shown to be mediated by reduction of osteoclastic resorption of bone, increased vascularization and increased rate of bone formation by osteoblasts, and these mechanisms have been studied on cellular and gene transcription levels (3). Placebo-controlled trials have shown decreased pain and improved functional performance in patients with osteoarthritis of the knee with PEMF therapy (4). However, relatively few clinical studies have examined the effects of static magnetic fields.

In this study, we examined the efficacy of treatment with a static magnetic field generator as adjunctive therapy for the joint pain in patients with inflammatory arthritis. The MagnaBloc (MB; U.S. patent no 5,312,321) is a non-invasive non-significant risk device, consisting of four permanent magnets arrayed with alternating polarity in a hypoallergenic plastic case. The MagnaBloc™ is approximately 3.5 centimeters in diameter, weighs approximately 30 grams and generates a magnetic field of 190 millitesla. This device reduced mechanical low back pain (5,6) and knee pain significantly more than placebo. Much larger time invariant magnetic fields like those produced by magnetic resonance imaging devices have not been shown to be harmful to man or animals (10,11, 12).

This study was designed to evaluate a protocol for use in a large double-blind, placebo-controlled study. The principal outcome measure was pain intensity in patients receiving MB therapy compared to baseline level of pain. In addition to assessment for anti-nociceptive and anti-inflammatory effects, this study also assessed the effect of MB treatment on the level of physical functioning.

Volunteers for this study included patients over the age of eighteen with inflammatory arthritis (rheumatoid or psoriatic arthritis) and persistent knee pain despite appropriate use of medications. The trial enrolled a cohort of 18 patients, drawn from a population consecutively presenting with the complaint of knee pain to their rheumatologist at Medical Specialists of Nashville or the Arthritis and Joint Replacement Center at

Vanderbilt University Medical Center in Nashville, Tennessee during the 6 week period beginning August 31, 1998. Subjects included 16 females, 2 males, 16 Caucasians, and 2 African Americans, with an average age of 65.1 years-old.

Patients were excluded if they had a cardiac pacemaker, prosthetic knee, unstable neurological condition, or morbid obesity. The magnetic field produced by the MagnaBloc™ device can interfere with cardiac pacemakers. Morbid obesity results in technical difficulty both in affixing the devices and in field penetration of the fat layer which surrounds the nerve. Changes in analgesics were not allowed during the trial.

Design of this study followed ACR recommended core set of disease activity measures for rheumatoid arthritis clinical trials (13). The following assessments were made: patient's and physician's global assessments of disease activity (GADA); Westergren Sedimentation Rate (WSR); range of motion of the knee by goniometry; examination for tenderness; examination for swelling; patient's assessment of physical function; 100mm horizontal visual analogue scale for pain (VAS); and, the Modified Health Assessment Questionnaire (MHAQ) for difficulty in daily activities (14,15).

Patients with inflammatory arthritis who met inclusion criteria and consented to participation were included. The rheumatologist conducted a standardized joint examination, including assessment of tenderness and swelling and measurement of range of motion of the joint by goniometry. A Global Assessment of Disease Activity (GADA) was made by the rheumatologist by placing a mark on a 100mm line. Patients reported baseline levels of pain on a Visual Analog Scale for pain (VAS), and completed the Modified Health Assessment Questionnaire (MHAQ). Westergren Sedimentation Rate (WSR) was assessed.

With the patient seated and the leg flexed 90 degrees at the knee, four MB devices were applied: over the suprapatellar and infrapatellar bursae and over the medial collateral and lateral collateral ligaments to broadly cover joint swelling and inflamed synovium. Devices were affixed to the skin around the joint by double-stick adhesive tape and reinforced with Transpore™ (3M) tape over each device.

One hour and 1 day after placement of the devices, MHAQ and VAS were repeated. Subjects were instructed to leave the devices taped in place until the 1 week follow-up visit. One week after placement of devices, subjects were reassessed with GADA, ROM, VAS, WSR, and MHAQ, and devices were removed. This study was conducted with the approval of the Vanderbilt Committee for the Protection of Human Subjects.

Sixteen of 18 subjects completed the protocol. At entry, subjects reported an average difficulty with activities of daily living of 50.6 mm on a 100-mm line. By the follow-up visit, the average level of difficulty was 26.5/100mm ( $p<0.002$ ). Prior to treatment, knee pain averaged 43.4/100mm (range 7-86/100mm). At the 1 hour follow-up, pain ratings in the treated joint averaged 24.1/100mm with a range of 2-59/100mm ( $p<0.005$ ), and by one day, the average pain rating was 27.4/100 with a range of 1-57/100mm ( $p<0.047$ ). At the one week follow up, the average pain score was 14.7/100mm with a range of 1-40/100mm ( $p<0.006$ ). Average levels of difficulty and pain are shown in Figure 1. For this patient population, the MHAQ results at baseline, 1 day and 1 week showed a slight decline in ability to complete activities of daily living, from 1.74 to 1.49 ( $p=0.12$ ) to 1.41 ( $p=0.07$ ). On other scales, at the one hour follow up, 59% of patients reported feeling better or much better than before treatment, and at the one week follow up visit, 87% reported feeling better or much better than before receiving magnetic therapy.

Subjects entered with a rheumatologist's GADA average rating of 42.2/100mm, and by the 1 week follow-up visit the average rating decreased to 15.6/100mm ( $p<0.0005$ ). Initial assessment revealed tenderness in the affected joint in 84%, and objective swelling of the joint in 53% of patients. These assessments decreased to 20% and 33% respectively at the 1-week assessment. The average Westergren Sedimentation Rate for patients did not significantly change over the week, 37.5-mm per hour at entrance and 33.8-mm per hour after one week of treatment. Goniometry measurements for functional range of motion in the treated joints did not significantly change over the week.

Statistical analysis was performed using the Wilcoxon Signed Rank test for non-parametric comparison of 2 paired observations, comparing each time-point to baseline.

In this pilot study, knee pain was reduced, on average, 67% during treatment with static magnetic devices over 1 week and this was a statistically significant reduction compared to baseline. Nearly all patients offered extremely positive feedback concerning the benefits that they attained with MagnaBloc™ therapy.

Of 15 patients who completed the trial, 14 elected to continue use of the MagnaBlocs™ due to the significant amount of relief they attained during the one-week trial. One patient elected to not continue use due to development of a rash under the tape. The 2 patients who did not complete the study complained of discomfort in sleep (N=1) and frequent spontaneous detachment of the devices (N=1). Continued open use should provide useful information about how to optimally place and attach the devices.

Assessment of efficacy in pain studies is confounded by daily fluctuations in pain intensity; standardized, as opposed to individualized, placement of devices; and, co-medication, which though constant could have variable efficacy in the face of fluctuating pain. One deficiency of this pilot study was that there was not a placebo group for comparison. Subjects and rheumatologists were informed that subjects would be assigned to either a MB or a magnetic placebo group. However, all patients in fact received active MB devices. Through initiation of a placebo-controlled study, it should be possible to control for the effects of having devices attached to the knee as well as subjects being under observation for a week. Future studies, incorporating a placebo-control, will also allow a comparison between treatment periods of subjects receiving placebo treatment for a week followed by open use with MB devices. This would also permit assessment for continued effect past 1 week in patients receiving MB devices. In order for the sedimentation results to be more accurately evaluated, it will be necessary to examine data collected during the randomized, placebo-controlled continuation of this study.

The mechanistic basis for these promising results is not entirely understood. The array of four permanent magnets of alternating polarity in each MB produce magnetic fields with regions of steep gradients that block firing of sodium-dependent action potentials of sensory neurons in cell culture (7, 8, 9). The same array has been shown to block calcium-dependent responses to capsaicin and sodium-dependent action potential firing simultaneously in the same neurons (16). A spatially homogeneous static magnetic field has been shown to reversibly reduce calcium current in the pituitary derived GH3 cell line (17). Conformational changes within the ion channels and/or neuronal membranes may explain these findings.

The results of this pilot study are encouraging and validate this protocol for use in study of magnetic therapy in the treatment of inflammatory arthritis. These results justify continuation of this study in a randomized, double-blind, placebo-controlled manner in order to characterize further the therapeutic potential of the MagnaBloc™ for treatment of inflammatory arthritis.

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