

## BIOMAGNETICS IN THE TREATMENT OF HUMAN PAIN - PAST, PRESENT, FUTURE

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### ABSTRACT

A 2x2 randomized double-blind cross-over study was done to assess the efficacy of the Magna Bloc in reducing low back and knee pain in 54 patients at two centers. The Magna Bloc is a magnetic treatment device which contains a quadripolar permanent magnet system. Pain was assessed using visual analog scale, ranging from zero (no pain) to 100 (maximal pain). Prior to any treatment the average pain rating was  $52.9 \pm 23.3$  points (mean  $\pm$  standard deviation). With treatment, the Magna Bloc<sup>TM</sup> reduced pain by an average of  $8.11 \pm 3.38$  points more than did the placebo treatment ( $P=0.030$ ). If confirmed, this would suggest that the Magna Bloc is effective in reducing chronic low back and knee pain. *biomagnetic therapy, magnetics, pain-therapeutics, cross-over study*

### INTRODUCTION AND HISTORICAL BACKGROUND

The prevalence of chronic pain is not known. It is wide spread and is in many ways the single worst symptom for a patient to suffer. Data from a variety of sources suggests that annually in the United States and many other industrialized nations, between 25 and 30% of the population have chronic pain.<sup>1</sup> In addition to the pain itself, it affects the patient's mood, ability to function, to work, and personal and family life.

Since earliest recorded history, legions of physicians and other healing professionals have applied numerous treatments to prevent, alleviate, or cure the cause of pain. Often these attempts to ease pain and suffering were ineffectual. These treatments have included the use of magnetics. Such devices were used as early as the 16th century, when William Gilbert (1544-1603) of Colchester used magnetics to treat Elizabeth I of England. Gilbert's classic book *De Ma2net* remains a landmark in the history of science because of its recognition of a difference between static electricity and magnetism.<sup>2</sup>

The use of magnetic devices is currently viewed, with skepticism. It seems likely that the Austrian physician Franz Anton Mesmer (1734-1815) is the main reason for this attitude. The proponent of a theory of "animal magnetism," he soon was the subject of debate in every European capital. It is most important to note that the debate was at least as much about him personally as about his theories. His magnetic institute was investigated by a special commission of the French medical establishment. His work was ultimately debunked and Mesmer lost all credibility.<sup>3,4</sup>

Because of the cloud over Mesmer's work, other work in the therapeutic use of magnets has been ignored. For example, in 1842 Stokes and Bell in their two volume treatise *Lectures on the Theory and Practice of Physics* report on experiments conducted at Dublin's Meath Hospital "with a view to ascertain the effects of a powerful magnet on the human body."<sup>5</sup> They reported that the patients treated for pain demonstrated relief of pain and restoration of function. "The application of the magnet was followed by a very rapid subsidence of the morbid symptoms, and the patient got well in a few days."<sup>5</sup>

Given the well accepted and widespread use of magnetic imaging techniques, it seems unarguable "that a magnet should act on the human body is neither extraordinary nor incredible."<sup>5</sup> This paper presents results of a pilot study of a new magnetic device to reduce pain.

### MATERIALS/METHODS

#### Study Design

We conducted a randomized cross-over study to assess the efficacy of a unique static magnetic device, the Magna Bloc, to reduce pain. Fifty-four patients suffering from chronic lower back pain or chronic knee pain were studied in two medical centers. After receiving informed consent, patients were randomly assigned to one of two treatment orders: the Magna Bloc in the initial period, with a similar control device without magnetic properties in the second period, or vice versa. Baseline measurements were obtained using both the Visual Analogue Scale<sup>6-17</sup> (VAS) and a verbal rating scale<sup>6,7,10,13,14,18,19</sup> (VRS) after which the device was placed in the appropriate location. In both scales, zero indicates no pain. In the VAS, the maximum score is 100, while in the VRS, the maximum score is 10. Measurements were repeated with the device in place at one, three, and twenty-four hours after treatment began. The device was removed after twenty-four hours of treatment.

Following a minimum seven day washout period, assessments were made before application of the second treatment and at one, three, and twenty-four hours after treatment was begun. Data on analgesic drug and mood affecting drug use was collected during both treatment periods.

Although neither the physician nor the patient was informed which treatment was applied in each treatment period, the Magna Bloc is strongly magnetic. Thus, either the physician or the patient could have discovered which treatment was being applied in each period. In order to minimize this possibility, precautions were taken to protect the blind.

The study was approved by the relevant institutional review boards.

#### Patient Characteristics

Forty of the 54 patients (74.1%) were treated at one center. Forty-one of the 54 patients (75.9%) were treated for back pain. Four of these patients were also treated for knee pain. Thirty-three of the patients (61.1%) were female. Ages ranged from 25 to 86 years (median: 66; interquartile range: 54-73) and the duration of illness ranged from four months to 30 years (median: 5.5 years; interquartile range: 2-11 years).

#### Description of Device

The Magna Bloc is a quadripolar static magnetic field device (U.S. patent pending). The device is constructed of a hypoallergenic, molded plastic casing which is applied to the surface of the skin over nerve fibers so that they lie in proximity to nerve bundles or ganglia. The device weighs approximately 30 grams and is approximately 3.5 cm in diameter. The magnetic energy measures 200 millitesla.

#### Diagnostic Criteria

Each patient entered the study only after a detailed work-up was completed by the investigator. The work-up included a thorough medical history, including previous diagnostic work-up(s) and treatment(s) for the condition, and a physical examination. A thorough pain history was elicited, including the distribution, quality, and temporal characteristics at the time of onset and during the interval between onset at the time the patient was being evaluated.

Diagnosis was based on physical and radiographic findings.<sup>20</sup> All patients received a lumbar-sacral spine series to demonstrate radiographic evidence of degenerative disc or joint disease. Patients with knee pain also received x-rays of the affected knee.

Laboratory tests included a CBC, electrolytes, erythrocyte sedimentation rate, arthritis profile, and a urinalysis. These studies were done to screen for secondary causes of osteoarthritis.

Of the 41 back pain patients who were studied, 30 had pain primarily of musculoskeletal origin and 11 patients had pain primarily of neuropathic origin. Specific diagnoses included degenerative disc and joint disease, osteoarthritis and nerve entrapment secondary to post-surgical scarring. All 13 patients treated with knee pain had arthritis. Four of the 13 patients treated for knee pain had post-traumatic arthritis.

#### Method of Treatment

Back pain was treated by placing Magna Bloc in each of the following anatomical positions:

- In the mid-line over the spinous process of the first lumbar vertebra (L1);
- Approximately 1/4" towards the mid-line from a point of reference at the protuberance of the posterior superior iliac spine. The actual placement for the magnet should be at the level of the L3 spinous process and it should be bilateral. (That is on either side of L3);
- Over the superior aspect of L4 in the mid-line; Bilaterally over the protuberance of the posterior superior iliac spine;
- Over the junction of the proximal 1/3 and the middle 1/3 of the coccyx.

Knee pain was treated by placing a Magna Bloc :

- Over the joint space for knee pain laterally;
- Medially to the knee;
- One inch inferior and anterior to the proximal head of the fibula.

### Statistical Analysis

The analysis follows the sequential approach suggested by Jones and Kenward<sup>21</sup> for a 2x2 crossover study with baseline measurements. With this approach, the possibility of a first order carry-over effect is tested by comparing the baseline results in the two periods. Depending on the result of this test, a second test statistic is calculated to assess whether there is a treatment-by-period interaction. If neither test appears significant, then a direct test of the effect of treatment is possible using the within person differences between the two treatment periods, ignoring the baseline measurements. To eliminate period effects, the treatment effect is calculated from the mean results separately for each treatment order, rather than as a simple average over all patients. Thus, the overall treatment effect is not the weighted average of results in subgroups. As suggested by Jones and Kenward, a P-value of 0.10 (two-sided) was used to screen for first order carry-over effects and interactions. A P-value of 0.05 (two-sided) was used to indicate statistical significance when testing for treatment efficacy. Analysis was done for each of the three follow-up measurements (one, three and twenty-four hours) separately and for the average of the three outcomes. The average is equivalent to the overall test for treatment efficacy in a repeated measures analysis of variance.

Since the results available on the VAS and VRS are both bounded, analyses was done both on the original scale and using a logit-type transform to avoid the limited range on the measurements. As there was evidence that the results are not normal in either case, statistical significance is determined using a Wilcoxon Rank Sum Test, the non-parametric analog of a unpaired t-test. Since results were consistent with both the VAS and VRS for both the original scale and the logit transformed scale, only results from the original VAS scale are reported.

Medication data consisted of the specific drug and dosage taken during the twenty-four hour treatment periods. In order to reduce this data to a manageable amount, the data was collapsed to the total number of times that a analgesic (narcotics; non-narcotics; nonsteroidal anti-inflammatory drugs) was taken and the number of times that a potentially mood affecting drug (anti-depressants; muscle-relaxants; sedatives) were taken. Drugs were classified based on their primary therapeutic modality, according to the Physicians's Desk Reference.<sup>22</sup> After summarizing the medication data, it was possible to compare the number of doses taken by a subject in both periods. Assuming that the two treatments were equal, one would expect that equal numbers of subjects would use more medication on the active period (compared to the placebo period) as would use more medication during the placebo period (compared to the active period). This can be tested using a sign test. Individuals using the same amount of drug in the two periods are ignored in this analysis, since they are uninformative for a difference between two periods.

### RESULTS

There was no statistically significant association between treatment orders for the basic demographic data (age, sex, site), or baseline medical history (diagnosis, duration of illness). There were differences between the two centers in age of patient (Hillsboro 9.5 years older than Parkway; P = 0.016).

Males had a substantially longer duration of illness than females (6.5 years longer than females; P=0.005). The baseline pain level on the VAS before active treatment was 52.2 ± 26.9 (mean ± standard deviation) and 53.8 ± 25.2 before placebo treatment. Although 33 (61.1%) of the 54 patients received placebo in the first period, this was not statistically significantly different from the ideal allocation of 0.067. There was no evidence for first-period carryover or for an interaction of treatment and period (P>0.50 for all tests).

Table 1 shows the effect of treatment at each time point (including baseline) and the average effect over time for all 54 patients combined. Also shown are the results for each diagnostic group separately. A minus sign indicates that the pain level is less when the patient is treated by Magna Bloc than during the placebo period. Treatment with the Magna Bloc reduces pain level at all three time points, although only the one and twenty-four hour differences a statistically significant (P=0.032 and 0.030, respectively). The average effect (mean: -8.11; standard error of estimate: 3.38) is also statistically significant (P=0.023). Similar results were found in both diagnostic groups.

The difference between the three time points is not statistically significant (P>0.15 using a repeated measures analysis of variance).

Diagnosis	Number	Pretreatment	1 hour	3 hours	24 hours	Average
All	54	-0.31 ±3.23	-5.59±3.93*	-6.78±3.53	-11.96 + 5.24*	8.11 ±3.38*
Back	41	-0.49±3.29	-6.00±4.85	-8.42±4.41	-10.56±6.39	-8.32±4.22
Knee	17	-0.04±7.31	-2.64±6.06	-1.05±3.97	-17.76±8.18	-7.15 ±4.13

.01sPs0.05 (Wilcoxon Rank Sum Test, Two-sided)  
Entries are mean effect on the visual analog scale (treatment - placebo) ± standard error of effect

Because of the small size of the pilot study, none of the differences between subgroups, defined by gender, center, age group (< 66, ≥66), or duration of illness (<5.5 years, ≥5.5 years), were statistically significant. However, substantial pain reduction is not found in all of the subgroups shown in Table 2. The difference between Hillsboro females and the other center-gender subgroups was statistically significant at the three hour observation (P=0.0230), but the average effect was not significantly different (P>0.15). Comparing all four center-gender groups, the difference at three hours was not statistically significant (P=0.086).

Results for pain medications and for mood medications are provided in Tables 3 and 4 respectively. These tables show the number of subjects using no medication in either period (the "none" group), taking the same number of doses in both periods (the "same" group), and the number of subjects consuming more medication during one treatment than the other (A>P, meaning more doses of medication taken with active treatment; P>A, meaning more doses taken with placebo treatment).

TABLE 2 Effect of Treatment on Reported pain by Subgroup						
Diagnosis	Number	Pretreatment	1 hour	3 hours	24 hours	Average
<b>Gender</b>						
Male	21	-2.61±3.96	-13.32±5.55	-15.21±6.26	-16.89±5.66	-15.14±4.36
Female	33	1.14±4.73	-00.81±5.27	-01.51±4.07	-08.86 ±7.87	-03.72±4.70
<b>Center</b>						
Hillsboro_	40	-2.30±4.27	-8.19±03.65	-9.06±4.21	-16.71±05.02	-11.32±3.21
Parkway	14	5.04±2.82	1.06±11.31	-0.44±6.68	-00.69±13.53	-00.02±9.12
<b>Age</b>						
Young_	26	-2.46±4.66	00.85±6.28	-03.38±4.78	-09.69±7.72	-04.17±5.12
Old	28	0.38±4.78	-13.43 ±4.86	-12.24 ±5.43	-13.88 ±7.78	-13.18±4.68
<b>Duration of illness</b>						
Shorter	27	-0.28±5.42	-7.64±5.09	-5.71±4.95	-13.93 ±7.36	-9.09±4.57
Longer	27	-0.39±3.72	-1.39±5.80	-6.14±4.84	-08.61±7.72	-5.39±4.83
<b>Center-Gender</b>						
H-M	16	-4.07±4.88	-11.20±06.35	-13.40±07.41	-17.17 ±06.09	-13.92±04.45
H-F	24	-1.12±6.46	-06.18±04.55	-06.17 ±05.16	-16.41±7.36	-09.59±04.57
P-M	05	2.42±3.72	-19.75±13.80	-20.67±14.26	-15.83±16.99	-18.75±13.91
P-F	09	5.98±2.32	11.70±15.04	10.25±04.51	06.53 ±18.59	09.49± 10.82

Entries are mean effect on the analog scale (treatment-placebo) ± standard error of effect

TABLE 3 Results for Analgesics Back and Knee Diagnosis Combined			
	Both sites	Hillsboro	Parkway
none in either period	16	14	2
same in both periods	10	08	2
more during active period	09	06	3
more during placebo period	19	12	7

TABLE 4 Results of Mood Affecting Medications Back and Knee Diagnosis Combined			
	Both sites	Hillsboro	Parkway
none in either period	35	28	7
same in both periods	09	07	2
more during active period	05	02	3
more during placebo period	05	03	2

For both sites of pain combined, nine patients used more analgesics during the active treatment than during the placebo treatment compared to 19 patients using more analgesics during the placebo period than during the active period. This difference, although suggestive that less medication was taken during the placebo period, is not statistically significant ( $P = 0.087$ , using a two-sided test). Similar results were found for analgesic usage for back pain in both centers and in the Hillsboro center only. Neither of these differences were statistically significant ( $0.10 > P > 0.05$ , two-sided).

There was no evidence for differences between the two treatment groups for mood affecting drugs.

## DISCUSSION

The results of this pilot study suggest that Magna Block may be effective in reducing back and knee pain in patients. The Magna Block reduced pain by an average of 8.11 points (standard error of the effect: 3.38) on the visual analog scale compared with the control treatment. The largest improvement was at the measurement with 24 hours of treatment, where the improvement was 11.96 points (standard error of effect: 5.24). Results were similar for both diagnostic groups. The data suggests that the improvement increases with time, but this difference was not statistically significant.

Patients were observed to use less analgesics during the active Magna Block treatment than during the placebo treatment. Together, these two results suggest that treatment reduced reported pain levels at twenty-four hours, without increased use of either analgesics or mood affecting medication. Because of the small size and preliminary nature of the study, it is not possible to determine whether pain reduction is limited for specific groups of patients, although there is some weak evidence to suggest this. Although there was a statistically significant difference between females in one center and the other patients (male in the same center and all patients in the other center), this is the most extreme difference found, so it is very possible that it arose by chance.

Attempts were made to ensure that both the physician and patient were blind to the treatment being applied, but patient blindness cannot be assured in this study. Although we have no reason to believe that there were systematic attempts by patients to identify which device was used, this possibility cannot be ruled out. Since the measurements of pain are patient self-reports, knowledge of the treatment could bias our results. As such, it is necessary to confirm these results in other rigorously controlled clinical trials.

Although our current data suggest that this device reduces lower back and knee pain, the future of biomagnetics in medicine is uncertain. Limited evidence suggests that the common mediator of the therapeutic magnetic effect may be a critical, universal organelle: the cell membrane.<sup>23</sup> If this observation is valid, then appropriate electromagnetic forces may favorably affect many pathophysiologic processes.

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