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Static magnets – what are they and what do they do?

Magnetos estáticos – o que são e para que servem?

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Abstract

Introduction: Therapeutic static magnets have gained wide community acceptance for neuromusculoskeletal pain relief in many countries yet, apart from strong anecdotal reports of benefit, there is a paucity of scientific evidence for their use. **Objectives:** In this review we describe the physical characteristics of traditional and commonplace unipolar and bipolar static magnets as well as newer quadripolar magnetic arrays; discuss what is known of the physiological effects of static magnets and the strength of the literature; and make suggestions for targeted future research for static magnets in the management of neuromusculoskeletal pain conditions.

Key words: magnetotherapy; pain; static magnets; quadripolar magnetic arrays.

Resumo

Introdução: A magnetoterapia estática conquistou ampla aceitação da comunidade para alívio da dor neuromusculoesquelética em diversos países. No entanto, com exceção de relatórios anedóticos de seus benefícios, há uma grande escassez de evidências científicas para seu uso. **Objetivos:** Nesta revisão, descrevemos as características físicas dos tradicionais magnetos estáticos unipolares e bipolares comuns, assim como os mais recentes conjuntos magnéticos quadripolares; discutimos o que se conhece sobre os efeitos fisiológicos da magnetoterapia estática e o suporte da literatura; e fazemos sugestões para futuras pesquisas direcionadas à magnetoterapia estática no controle de condições de dor neuromusculoesquelética.

Palavras-chave: magnetoterapia; dor; magnetos estáticos; magnetos quadripolares.

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Introduction

Magnetic devices have been used for treating human ailments since the 16th century[1]. Magnetic fields of varying strengths are employed in such diverse applications as energy production, transportation, information storage and medical imaging. Most modern magnets are much more powerful than the Earth's magnetic field. A magnetic field occurs perpendicularly to an electric field; it is generated in two ways[2]. Firstly, a magnetic field is created when electrically charged particles flow through a coiled or looped conductor producing one of two field types: static or time-varying[2]. A static field forms with direct current, while a pulsating time-varying field is generated by alternating current[3]. Secondly, electrons within certain materials have their own intrinsic magnetic fields that, when summed vectorially, give a net magnetic field. Such permanent magnets do not require a motile electric current. Static fields from permanent magnets are the subject of this review.

The SI unit for magnetic field strength is the Tesla (newton per ampere-meter) (where 1 Gauss=10^{-4} Tesla). The authors will describe magnetic field strength in units of Tesla (T) or milliTesla (mT), and convert Gauss to Tesla when citing the work of others. To put field strength into perspective, the fields of Magnetic Resonance Imaging devices are in the order of 1.5 to 3 T, while the earth's field is less than 0.05 milliTesla (mT). Therapeutic magnetic devices used for pain relief typically generate magnetic fields of 11-500 mT[4]. It can be useful to remember that the field strength is inversely proportional to the cube of the distance from the surface of the magnet.

Magnetic fields can be represented diagrammatically so that the density of lines reflects the strength of the magnetic field[2]. Field lines form closed loops, emerging from the negative (South) pole of the magnet and enter through the positive (North) pole (e.g., Figure 1A). Field strength is the amount of force exerted by the magnet on charged particles within the field. For example, iron filings will align with the field to reveal patterns in the lines of force (e.g., Figure 1B). Field patterns vary with different orientations of the poles in arrays of magnets e.g., bipolar magnets and quadripolar magnetic arrays. The distinction may be important since the unique field pattern is reported to be the basis of effect for devices such as quadripolar magnetic arrays.

Static magnet therapy is classified under CAM Methodology #3 - Energy, by the US National Institutes of Health Centre for Complementary and Alternative Medicine[5]. Commonly, weak static therapeutic magnetic devices are made of ferrite (typically <0.4 T) with a single positive and negative pole. While there is no such thing as a 'unipolar magnet' the term is used to describe the application of one pole to the area to be treated, e.g., Figure 1A. For a bipolar application both poles are in contact with the part to be treated, such as with a horseshoe magnet[6].

Modern therapeutic magnets are constructed of synthetic alloys with inherently strong, permanent, static fields. Magnetic alloys are categorized by the material content. Compounds of aluminum, nickel and cobalt (alnico) are sometimes mixed with iron, copper or titanium to create field strengths of up to 0.15 T. Rare earth or super (lanthanoid) magnets when blended with neodymium and sometimes iron and boron are typically of 0.2 to 1.2+ T, or, with samarium cobalt can be even stronger, up to 3.4 T.

Magnets have become popular with the lay public for the management of acute (including post-operative) and chronic pain in humans, racehorses and domestic pets. During the last two decades coinciding with the development of the quadripolar magnetic array, community expectations of magnetic therapy

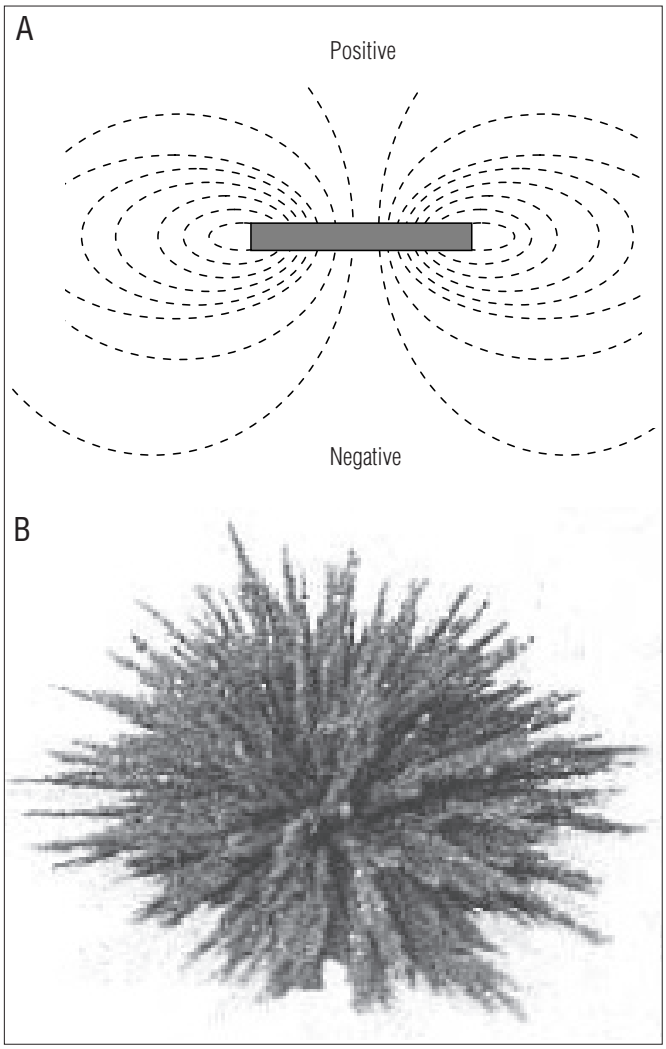

Figure 1. Representation of a bipolar static magnet. A: Bipolar disc-shaped magnet (lateral view) with field lines projecting from the negative pole and entering the positive pole. B: Pattern produced in iron filings by a bipolar magnet.

have increased due to anecdotal claims of 'miraculous' healing reported in the media. Such reports have created a multibillion-dollar, consumer-driven industry worldwide, while the evidence for use of these devices remains anecdotal and insufficient for acceptance by conventional healthcare practitioners[7].

Controversy surrounding the therapeutic efficacy of static magnets was highlighted in a vigorous discussion in the online reader response section to an editorial appearing in the British Medical Journal[8]. The matter of evidence for (and against) applications of static magnets evokes strong opinions which are sometimes driven by commercial interests and at other times lacking in scientific rigor. However, the quality of research in this field is steadily improving. Herein, we have restricted our discussion to static magnetic fields, and attempt to understand the literature related primarily to clinical populations with symptoms of pain of musculoskeletal origin. We compare the physical characteristics of bipolar and quadripolar magnetic arrays, investigate their purported physiological effects (which necessarily requires an incomplete review of laboratory models), and discuss the results of clinical studies using static magnets.

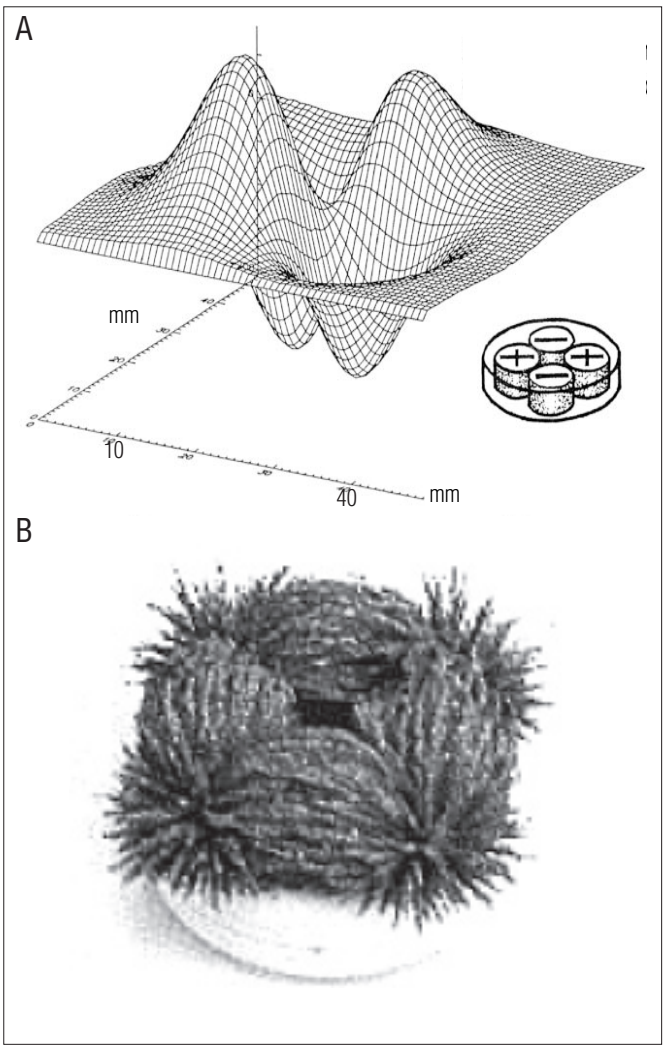

Figure 2. Representation of a quadripolar magnetic array. A: Field map of a quadripolar magnetic array. The magnet arrangement within the device is shown in the lower right corner (Extract from McLean et al.[7]). B: Pattern produced in iron filings by a quadripolar magnetic array.

What are bipolar static magnets and quadripolar magnetic arrays?

Permanent static magnets come in a wide range of shapes and sizes (e.g., disc and bar-shaped magnets), field strengths and patterns. Many traditional therapeutic magnets are disc or coin shaped (Figure 1), often embedded in personal jewelry, mattress and pillow covers, orthopedic external supports such as neck collars and back braces, which are available to the public 'over the counter' and with few instructions for application.

A 'quadripolar' magnetic array is usually composed of four magnetic discs, arranged with alternating polarity within a hypoallergenic plastic casing (Figure 2A). Pairs of positive and negative poles repel each other across the midline of an "X" while being attracted to the neighboring opposite pole. Manufacturers of quadripolar devices suggest that the alternating attraction and repulsion force creates a 'magnetic void' in the centre of the array. The result is 'steep field gradients' purported to produce effects beyond those of simple bipolar static magnets[9]. Figure 2 illustrates the magnet arrangement within a quadripolar magnetic array and the field map produced by scanning 3mm above the device with a gaussmeter; and the resultant field pattern in iron filings. Comparison between Figures 1 and 2 demonstrates that the bipolar and quadripolar magnetic arrays appear to be substantially different.

The magnets of a quadripolar array are typically constructed from magnetic alloys, measuring less than 3 cm in diameter, weighing approximately15 grams, and generating a field of approximately 200 mT. The manufacturers recommend that quadripolar magnetic arrays are applied directly to the skin in specific locations around a painful area and left *in situ* as required[10].

Physiological effects of static magnets

Low strength static magnetic devices are marketed not only to provide pain relief but also to address a wide range of signs and symptoms including reduction in swelling, induction of more restful sleep, stress relief and for anti-infective properties. Charged particles in body fluids flowing through a magnetic field will drift further apart (the Hall effect) and paramagnetic elements such as oxygen or aluminum will reorientate to magnetic lines of force[11]. However these effects are transient, minute, and may not be clinically important. Hypotheses proposed

for therapeutic effects of static magnets include altering radical dependent biochemical processes, or lipid membranes, and exerting forces on cell intermediates or charged particles such as electrolytes[12]. These mechanisms may alter the firing rate of neurons, change the rate of enzyme-mediated reactions, affect calcium channels, or increase local blood circulation[12,13]. However, the supporting evidence for any of these effects is not strong[4] and the issue of effect mechanism remains vexatious. Information regarding possible mechanisms of effect would assist in defining the specific conditions for which static magnetic field therapy may have benefit, optimize its application and thus promote improved research.

A common claim is that therapeutic magnets result in physiological thermal effects that promote tissue healing. Sweeney et al.[14] conducted a study to determine if skin or intramuscular temperatures were altered with the application of flexible therapeutic magnets to the quadriceps muscle for 60 minutes. The study was a repeated-measures, placebo-controlled design (n=13) and the results showed that neither skin nor intramuscular temperatures were significantly different across the three treatments at any time. The authors emphasized that the results of their study contradict one of the fundamental claims made by magnet distributors.

The primary physiological effect attributed to exposure by static magnetic fields is that of change in blood flow and circulation[eg,15]. An effect on blood flow has been verified in studies of rats using 8 T whole body exposure[16], and in rabbits using 0.25 T in ear chamber experiments[17]. The results have led to the magnetic field effects being described as biphasic, i.e., causing vasodilation when resting blood vessels are constricted prior to magnet application; and vasoconstriction when blood vessels are dilated in the area of the magnetic field[18].

In humans, there are few studies that have specifically investigated the clinical or physiological effects of static magnetic fields. A randomized, double-blind, placebo-controlled crossover study examined the effects of static magnets on resting forearm blood flow and vascular resistance in young, healthy men[15]. The results of the study demonstrated that the average blood flow was not significantly different between the magnet and placebo conditions after 10, 20 and 30 minutes of treatment application (P>0.05).

Clarity regarding physiological effects has only become evident in recent times in a series of studies in which Mayrovitz[19-21] have investigated the effects of static magnetic fields on aspects of microcirculation and skin blood perfusion. After a number of attempts using different protocols, Mayrovitz and Groseclose[21] were the first to use locally applied static magnets to demonstrate an effect on human skin blood perfusion noting an unexpected reduction in this outcome measure. The authors concluded that the reduction in skin blood perfusion was likely to be related to the biphasic responses noted earlier in rat studies[16]. This finding raises the possibility that investigating static magnetic energy in experimental models of pain is unlikely to be successful if there is no pathology, in particular no vascular component.

Magnet therapy and neuromusculoskeletal pain management

Ratterman et al.[4] carried out a review of scientific peer-reviewed publications regarding magnetic therapy and found that while magnetic therapy was gaining popularity, the scientific evidence to support its efficacy in pain management was lacking. A more recent systematic review by Pittler, Brown and Ernst[22] concluded that the available evidence does not support the use of static magnets for pain relief. We have further updated the search, and a summary of relevant literature of static magnets (of varying configurations) is presented in Table 1 (with an indication of study designs, range of pain conditions and experimental samples utilized, number of subjects, inclusion of placebo, polarity, application times, outcomes and study limitations).

Due to the fact that the devices are distinctly different in field characteristics, we have separated published studies of quadripolar magnetic arrays and presented these in Table 2 along with results from an *in vitro* study of this device.

We employed an inclusive approach to the literature search using as broad a range of search terms as possible to identify as many references to static magnetic therapy in case studies as well as clinical reports, and controlled trials. We searched Medline, PubMed, CINAHL, Web of Science and OVID as well as the grey literature through electronic sources (such as Google Scholar). Reference lists were cross-referenced in order to identify as many relevant sources as possible. The search had no start date limitation but was restricted to reports published by June 30, 2008. No language limits were set although the capacity to interpret non-English language reports was restricted by the translation resources available to the authors. Only full-text sources were considered. *A priori* search terms were not limited to any particular type of pain conditions although, to ensure that the search was comprehensive, a number of searches were cross-referenced with specific search terms limited to musculoskeletal pain. No restrictions were placed on study designs or methodologies. Subsequent to the completion of the literature search, *post hoc* limitations were set for reporting purposes to exclude non-neuromusculoskeletal conditions.

The following discusses, in more detail, the outcomes from some of the known research and then distils the information for consideration of further research.

Table 1. Studies of static magnet therapy for the treatment of neuromusculoskeletal pain[§] (Study numbers: Bipolar magnets: 6; Multipolar magnets: 1; Unipolar magnets: 4; Not stated: 10).

Year/ Author	Study Design	Sample	N	Magnet Strength☼/ Polarity & Number	Application Time	P or WM	Results	Limitations
1982 Hong[23]	Randomized, double-blind experiment	Males/females pain free vs chronic shoulder/ neck pain >/= 1 year	101	1300 G (130 mT); polarity not stated; necklace of up to 11 magnets	24 hr per day for 3 wk	Yes	*Significantly decreased pain intensity and frequency in both groups; *ulnar nerve conduction time reduced in subjects without pain	Power of sample size not stated; effectiveness of blinding; questionable contact of magnets with skin due to necklace design
1997 Vallbona, Hazelwood & Jurida[24]	Double-blind randomized clinical trial	Males/females post polio trigger point pain	50	Ranging between 300-500 G (30-50 mT); bipolar; various	45 min	Yes	**Significant pain relief with magnets greater than with placebo (MPQ)	Effectiveness of blinding; small sample size; non-standardized magnet protocol
1997 Caselli et al.[25]	Non-blinded, randomized controlled trial	Males / females with plantar heel pain	34	500 G (50 mT) at surface; polarity not stated; insoles	4 wk	Yes	No significant differences in foot function index	Effectiveness of blinding; small sample size
1998 Borsa & Liggett[26]	Single-blind, placebo study with repeated measures design	Males/females of healthy condition, induced pain	45	0.07 T (700 G / 70 mT); polarity not stated; single flexible magnet	Not stated	Yes	No pain improvement either group (VAS)	Single-blind component; small sample size
1998 Kanai et al.[27]	Double-blind randomized clinical trial	Males / females with low back pain	107	180mT (1800 G); polarity not stated; 35-40 magnets	3 wk continuous	Weak magnet (10mT)	**Significant differences in pain, numbness, ROM, muscle tenderness	Clarity of blinding protocol
1999 Weintraub[28]	Randomized, double-placebo control, crossover trial	Male/females Peripheral neuropathy of diabetic & non-diabetic origin	19	475 G (47.5 mT); multipolar insole (sham & active in cross-over; then 2 active insoles)	24 hrs per day for 30 days for each phase of trial. Total magnet time = 12 wk	Yes	*Significantly reduced burning pain, tingling and numbness in diabetic group only (VAS)	Lack of a double-blind component; small sample size; heterogeneity of subject diagnoses; no wash-out period between active and sham phases
1999 Colbert et al.[29]	Double-blind randomized pilot trial	Females with fibromyalgia	25	1100G (110 mT) at surface; unipolar; 270 magnets within mattress pad of 4cm	Nightly (sleep) for 16 wk	Yes	*Significant decrease in pain, sleep improvement, fatigue, total myalgic score, daily functioning, pain distribution in magnet group (VAS)	Lack of control of time on magnet or positions used, small sample; lack of gender balance; difference in body weight among magnet and placebo group subjects (control>magnet); concurrent treatments not controlled; effectiveness of subject blinding

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Year/ Author	Study Design	Sample	N	Magnet Strength☼/ Polarity & Number	Application Time	P or WM	Results	Limitations
2000 Collacott et al.[30]	Randomized, double blind, placebo controlled, crossover pilot study	Male/female chronic degenerative low back pain	20	ave 300 G (30 mT); bipolar; single large flexible magnet	6 h per day for 3 days per week for 1 week (Total 18 h for both sham and magnets)	Yes	No pain relief or increase in ROM (VAS and Pain Rating Index)	Small sample size; lack of gender equality (males=19, females=1); heterogeneous pathologies for diagnoses of LBP; uncertain success of subject blinding
2001 Alfano et al.[31]	Double-blind randomized controlled trial	Fibromyalgia	119	(1) 395mT (3950 G), 0.6-0.3mT at skin; unipolar; multiple magnets in a mattress grid pad (number unspecified) (2) 750 G (75mT); bipolar; multiple magnets in mattress egg-crate pad	Unspecified sleeping / exposure times	Yes (?weak field still present after sham magnets demagnetized)	*Significant differences in pain intensity level but no differences in number of tender points, functional status or tender point pain intensity	Uniformity and strength of field between intervention devices
2002 Pope & McNally[32]	Double-blind randomized controlled trial	Males / females with self-reported repetitive strain injury	45	245mT (2450 G); polarity not stated; wrist bracelet with 1 magnet	30 min	Yes	No significant difference in pain scores or typing ability between magnet and placebo; *significant difference in pain and typing ability between magnet/placebo groups and control groups	Gender imbalance (females more than males); placebo intervention not disclosed to subjects; low subject numbers
2002 Carter et al.[33]	Double-blind randomized controlled trial	Carpal tunnel syndrome	30	100mT (1000G) at surface; polarity not stated; 4 flexible magnets @ 2500 G and 1 disc magnet @ 10,000 G to form a single unit	45 min	Yes	Significant reduction in pain in both groups with no significant difference between groups	Small sample size; 2 week interval between intervention and follow-up VAS ratings after a relatively short intervention period
2002 Hinman et al.[34]	Double-blind randomized controlled trial	Chronic knee pain - Osteoarthritis	43	1.08T (10800 G / 1080 mT); unipolar; n=4	Variable: individualised by subject according to pain	Yes	*Significant differences in pain, physical function and gait speed	Questionable statistical power and underlying subject pathology; non-standardized application time; gait speed measurement not standardized
2003 Winemiller et al.[35]	Double-blind randomized controlled trial	Plantar heel pain; 80 female; 21 male	101	2450 G (245 mT); bipolar; insoles	At least 4 h per day, 4 days per wk for 8 wk	Yes (weak field (2.2 G) present in sham magnets)	No significant differences at 4 and 8 wk	Gender imbalance; efficacy of subject blinding

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Year/ Author	Study Design	Sample	N	Magnet Strength☼/ Polarity & Number	Application Time	P or WM	Results	Limitations
2003 Weintraub et al.[36]	Multi-centre, double-blind randomized controlled trial	Diabetic peripheral neuropathy	259	450 G (45 mT); bipolar (magnetized strontium ferrite powder); insole	24 hr per day for 4 mo	Yes	*Significant difference at 3rd and 4th month for burning pain, numbness and tingling, and exercise-induced foot pain	Inability to maintain blinding in subjects; uncertainty regarding compliance of continuous wearing of insole devices
2004 Kanai et al.[37]	Double-blind randomized controlled trial	Males/females with frozen shoulder	40	130mT (1300 G); polarity not stated; 12 magnets	3 wk continuous	Yes	*Significant differences in ROM, pain, pain on palpation and night pain; *significantly raised skin & deep body temperature	Broad range of condition duration and acuity / chronicity (1 wk to 36 yr); efficacy of blinding
2004 Wolsko et al.[12]	Double-blind randomized controlled trial	Knee osteoarthritis	26	40-850 G (4-85 mT); unipolar; 4 magnets inserted in a sleeve plus 64 partially de-magnetized magnets	Initially 4 hr then at least 6 hr per day for 6 wk	Yes – weak field magnet <0.65 G	No difference in WOMAC at 6 wk; *significant difference in VAS at 4 h; efficacy of placebo strategy was confirmed	Small group numbers (pilot trial); differences in severity of knee OA between groups
2004 Harlow et al.[38]	Double-blind randomized controlled trial	Hip / knee osteoarthritis	194	Grp 1: 170–200 mT (1700-2000 G); Grp 2: 21-30mT (210-300G); Grp 3: 69-196mT (690-1960 G); polarity not stated; unspecified number of magnets inserted in wrist bracelets	Continuous wear during waking hours for 6 wk	Yes – one group had true non- magnetic placebo; another group had weak magnetic field)	*Significant differences in WOMAC and VAS at 12 wk but not at 4 wk (compared to placebo but not when compared to weak magnetic field)	Efficacy of blinding; contamination of placebo group by active magnets supplied by manufacturer as placebo magnets
2005 Mikesky et al.[39]	Double-blind randomized placebo-controlled trial	Males/females with induced delayed onset muscle soreness	20	750 G (75 mT); polarity not stated; 3 disc magnets	Continuous wear for 1 wk (except when bathing)	Yes	No significant difference	Effectiveness of blinding
2005 Reeser et al.[40]	Double-blind randomized, within-subject placebo-controlled trial	Males/females with delayed onset muscle soreness	23	350 G (35 mT); polarity not stated; one large magnet to cover muscle of interest	45 min magnet treatment on 4 consecutive days	Yes	No significant difference	Low subject numbers as outcomes measures demonstrated some variability
2005 Winemiller et al.[41]	Prospective, double-blind randomized placebo-controlled trial	Male/females with non-specific foot pain	83	2450 G (245 mT)(mean surface strength=192 G / 19.2 mT); bipolar circular array; insole	At least 4 hr per day, 4 days per week for 8 weeks	Yes – placebo field strength <5 G	No significant differences at 4 or 8 wk	Heterogeneity of foot pain diagnosis; uncertainty of blinding; compliance with wear.

§excluding pain of other origins e.g., pelvic, visceral etc; *p>0.05; **p>0.01; P=Placebo; WM=weak magnet; MPQ=McGill Pain Questionnaire; VAS=Visual Analogue Scale. ☼Field strengths as reported by authors – not converted to Tesla.

Table 2. Studies of quadripolar magnetic arrays in the treatment of pain (including clinical and *in vitro* studies).

Year/ Author	Study Design	Sample	N	Magnet Strength☼/ Polarity & Number	Application Time	P or WM	Results	Limitations
1991 Holcomb, Parker and Harrison[1]	Multi-centre, randomized, 2 x 2 cross-over pilot study	Males / females with chronic low back or knee pain	54	200 mT (2000 G)	Continuous for 24 hr with 7 day washout	Yes	*Significant reduction in (low back and knee) pain at 1 and 24 hr but not at 3 hr; increased use of analgesia in placebo group	Not peer reviewed (available on website only); Efficacy of blinding; low subject numbers with heterogeneity of diagnosis (some subjects had both back and knee pain)
1995 McLean et al.[42]	In vitro cell culture study of effect of quadripolar array on blockade of neuron action potential	Mouse dorsal root ganglia in cell suspension medium	493 neurons	40-90 mT (ave 71 mT) (400-900 G); alternating polarity; 4 magnet array vs 1 & 2 magnets	200-250 s	n/a	Failure of action potential firing in 66% of cells when exposed to the 4 magnet array – effect attributed to field gradient rather than field strength	Accuracy of exposure of targeted neurons in cell suspension to magnetic field and thus to measurement of action potential
1999 Segal et al.[43]	Double-blind randomized controlled pilot trial	Males / females with rheumatoid or psoriatic knee arthritis pain	16	190 mT (1900 G); alternating polarity; 4 devices	Continuous for 1 wk	Yes	*VAS pain & function significantly improved	Low subject numbers; efficacy of blinding; more females than males; no control group
2000 Holcomb et al.[44]	2 x Single case studies	1) 3 yr history of lumbo-sacral and abdominal pain 2) 6 mo history of thoraco-lumbar and genital pain	2	Field strength not stated; alternating polarity; 3 devices	Continuous as required	n/a	1) 90% reduction in pain within minutes 2) Significant reduction in pain within 10 min Both patients' pain relief was maintained in the long term with continued application	Results of single case studies cannot be extrapolated more generally
2001 Segal et al.[45]	Multi-site, double-blind randomized controlled trial	Rheumatoid arthritis	64	190 mT (1900 G); alternating polarity; 4 x 4 magnet array in single device	Continuous for 1 wk	Weak unipolar magnet up to 72 mT	**Significantly less pain in treatment group compared to control group; *Greater reduction in global assessment of disease activity	Low subject numbers; cultural differences in mixed subject group

*p>0.05; **p>0.01; P=Placebo; WM=weak magnet; MPQ=McGill Pain Questionnaire; VAS=Visual Analogue Scale. ☼Field strengths as reported by authors.

Neuromusculoskeletal pain management with bipolar static magnets

Vallbona, Hazelwood and Jurida[24] conducted a study to determine if the chronic pain experienced by post-polio patients could be relieved by the application of magnetic devices over an identified painful trigger point. The study is reviewed here in detail as it is commonly used as a basis to promote magnetic products. Vallbona, Hazelwood and Jurida[24] designed a double-blind, randomized clinical trial of 50 patients diagnosed with post-polio syndrome and self-reported muscular and arthritic pain. The McGill Pain Questionnaire was used to measure subjective pain levels experienced following firm application of a blunt object over an active trigger point. Placebo or active magnetic devices (30 - 50 mT) were applied to the affected area for 45 minutes to identify if the magnets had analgesic effects. Patients in the active device group experienced an average reduction in pain score of 4.4 +/-3.1/10 ($p<0.0002$) while those with the placebo device experienced a decrease of 1.1 +/-1.6/10 ($p<0.005$).

Vallbona, Hazelwood and Jurida[24] concluded that application of magnetic devices over painful trigger points in participants with post-polio pain results in significant and prompt relief of pain, however the results of the study should be viewed with caution due to a lack of adequate experimental controls. For example, the researchers did not measure nor standardize the pressure applied to trigger points before and after application of the magnetic device, hence the dependent variable may not have been reliably measured. Secondly, the mean age of participants in the experimental group was lower and there were twice as many women than in the control group. The possible effects of age and gender were not matched across groups. The results of the above study are yet to be reproduced.

More recent studies are indicative of the conflicting results noted for magnet research. Alfano et al.[31] tested the effectiveness of therapeutic magnets in individuals with fibromyalgia. The randomized, placebo-controlled study investigated sleep pads with static magnetic fields compared to placebos and usual treatment, in decreasing patient pain perception (pain intensity ratings, tender point count and tender point pain intensity score) and improving functional status (Fibromyalgia Impact Questionnaire) after six months of treatment. All groups showed improvements in functional status, pain intensity level, tender point count and tender point intensity. With the exception of pain intensity level, the improvements observed in the real magnet groups did not differ significantly from the placebo group or usual care group ($p=0.25$). The results of the above study did not show strong evidence for the efficacy of therapeutic magnets.

A study by Hinman, Ford and Heyl[34] aimed to determine the effects of static magnets on the level of pain and functional limitation associated with chronic knee pain from degenerative joint disease. A double-blind, randomized controlled trial was conducted in which subjects with chronic knee pain wore pads containing magnets or placebos over the knee joint for two weeks. The results revealed a significantly greater improvement in ratings of pain and physical function in the group wearing magnets ($P=0.002$). In another randomized, controlled trial that investigated the effects of magnetic insoles on plantar heel pain, the investigators found that wearing magnetic insoles daily for 8 weeks did not provide significant reductions in daily foot pain and employment performance when compared to placebo[35]. In contrast, Wolsko et al.[12] found in a randomized, placebo-controlled trial that magnets showed statistically significant reductions in osteoarthritic knee pain compared to placebo treatment ($P<0.05$) at four hours but not at 6 weeks.

The results of our search demonstrate that the literature relevant to static magnet therapy is increasing and that of the 20 clinical studies that have investigated the efficacy of magnets on neuromusculoskeletal pain, 11 studies have shown at least some benefit for a variety of outcome measures. Beyond this observation, it is difficult to be more definitive about the effects, and pooling of data is not possible due to the disparate nature of the studies and protocols utilized.

Neuromusculoskeletal pain management with quadripolar magnetic arrays

As outlined earlier, quadripolar magnetic arrays produce a magnetic field pattern substantially different to that produced by traditional therapeutic magnets. As such, research pertaining to quadripolar magnetic arrays and their effects on pain are considered separately herein (Table 2). The available research on quadripolar magnetic arrays is more limited than reported for traditional therapeutic magnets, reflecting the fact that the devices are comparatively new and have been subject to patent controls until recent times.

There are few clinical studies that have examined the hypoalgesic effects of quadripolar magnetic arrays[1,43,44]. Statistically significant reductions in pain have been noted and are discussed below. Despite some positive findings, skepticism exists regarding the efficacy of using quadripolar magnetic arrays in the treatment of pain. In particular, a number of studies have been carried out by researchers with affiliations and financial interests with the manufacturer rather than by independent investigators. As well as the factors noted earlier regarding physical parameters of magnets, known studies of quadripolar magnets present various inadequacies such as the

lack of placebo or control conditions, inadequate control of confounding variables and insufficient subject numbers.

Clinical studies

In one of the first pilot studies using quadripolar magnetic arrays, Holcomb, Parker and Harrison[1] investigated the ability of the devices to reduce pain in 54 patients with chronic low back and knee pain using a 2x2 randomized, double blind, cross-over design. Patients received one of two treatments consisting of either quadripolar magnetic arrays followed by placebo or vice versa. Base line and post-treatment measures of pain at one, three and 24 hours were obtained using the Visual Analogue Scale (VAS) and Verbal Rating Scale. Also, data was collected on analgesic and mood altering drug use during the treatment periods.

Prior to treatment the average pain rating was 52.9 +/-23.3 points (mean +/-standard deviation). With application of the devices, pain reduced by an average of 8.11 +/-3.38 points more than the placebo treatment (p=0.03). Treatment with quadripolar magnetic arrays reduced pain levels at all three time points, although only the one and 24 hour differences were statistically significant (p=0.032 and 0.03, respectively). There were no statistically significant differences in the amount of analgesics used during the treatment and placebo conditions (p=0.087). The results of this study suggest that quadripolar magnetic arrays might be effective in reducing low back and knee pain.

In a pilot study examining the efficacy of quadripolar magnetic arrays (190 mT) as an adjunct therapy for joint pain in patients with inflammatory (rheumatoid or psoriatic) arthritis and persistent knee pain, Segal et al.[43] measured a range of dependent variables (including patient's and physician's global assessments of disease activity (GADA), Westergren Sedimentation Rate (WSR), range of motion of the knee by goniometry, tenderness, swelling, patient's assessment of physical function, VAS and the modified Health Assessment Questionnaire (MHAQ) for difficulty in daily activities). The dependent variables were measured before and at consistent time intervals up to one week after placement of the magnets. Four quadripolar magnetic arrays were applied to the knee over the suprapatellar and infrapatellar bursae and over the medial and lateral collateral ligaments. The authors found that knee pain was reduced significantly on average by 67% compared to base line after one week of treatment with the devices (p<0.006). In addition, there was a statistically significant reduction in the rheumatologists' GADA rating (p<0.0005). Nearly all patients offered "extremely positive feedback" concerning the benefits obtained with the devices and elected to continue using the devices on completion of the study. The limitations of the study included the lack of a placebo or control condition and a high ratio of female to male participants (8:1).

Holcomb et al.[44] conducted a case study of two adolescents with debilitating, drug-resistant, chronic pain of the low back and abdomen with intermittent pain of the genitalia, diagnosed on MRI with intervertebral disc disease. Both patients had undergone multiple evaluations by several specialists and surgery without pain relief. In both patients, treatment with quadripolar magnetic arrays provided rapid relief of symptoms that was sustained for more than two years. The devices were taped to the skin over the pain associated spinal levels. One patient reported a rapid 90% reduction in pain while the other reported a "rapid and notable" (not quantified) reduction in pain. Adjusting the placement of the magnetic devices controlled recurrent pain. Holcomb et al.[44] reported that one of the patients gradually decreased his dependence on the devices and remained virtually pain free for the following 24-month follow-up period. Although the results seem remarkable and describe application of the devices in a clinical setting, the anecdotal nature of the results in single case reports means they cannot be used to extrapolate more broadly.

Holcomb et al.[44] claim that the success of quadripolar magnetic arrays is a common experience with more than 2000 people being treated with the magnetic devices, alone or in combination with medication, for low back pain over a period of ten years. The authors state that approximately 80% of patients received sufficient benefit to continue treatment. Many became pain free within minutes to hours, while others took weeks to months to achieve acceptable pain levels. Approximately 20% of patients with low back pain were reported by Holcomb et al.[44] to receive no benefit from treatment with quadripolar magnetic arrays. Such impressive claims in the absence of definitive research results require verification under controlled clinical trial conditions.

In addition to the problems identified later in this review, numerous other matters may have confounded the results of studies investigating quadripolar magnetic arrays. These factors include insufficient control over confounding variables, poor study design, insufficient subject numbers and gender inequality. Overall the research on quadripolar magnetic arrays is encouraging however the studies need to be replicated with large randomized controlled trials and by investigators without affiliations and financial interests in the manufacturer of the devices.

In vitro studies

The mechanism of hypoalgesic effects of quadripolar arrays reported in previous studies remains unsubstantiated.

Results from *in vitro* studies suggest that the analgesic effects of quadripolar magnetic arrays are due to strong magnetic field gradients moving membrane components such as voltage-sensitive ion channel proteins, or changing the phosphorylation state of ion channels in sensory neurones, consequently reducing or blocking action potential (AP) firing[42,46].

The first published study of cellular effects using quadripolar magnetic arrays, found that exposure of adult mouse dorsal root ganglion cells in culture to a 10 mT quadripolar field reduced or blocked action potential (AP) firing[46]. AP firing was stimulated by brief 1-3 msec pulses of depolarizing current. The reduced or blocked AP firing was reversible with slow recovery of firing occurring over several minutes. Arrays of four magnets with like polarity (i.e., all positive or all negative) (32-35 mT) reduced AP firing but resulted in fast recovery of firing following removal of the field. An alternating dipolar array (13.7 mT) or a single magnet had no effect. The neurons utilized resembled mechanoceptive and nociceptive neurons in humans suggesting the results observed could be applicable to the human nervous system. Complete blockage of APs was achieved in 83% of the 'nociceptive type' neurons and 92% of the 'mechanoceptive type' neurons within 3-7 minutes[46].

In another study, the same researchers examined the AP blocking effects of quadripolar magnetic arrays and found that 66% of stimuli failed to elicit an AP in neurons in cell culture when exposed to an 11 mT field compared to less than 5% during the control period ($p<0.02$)[42]. The number of firing failures was maximal after approximately 200-250 seconds of exposure to the field and returned gradually to baseline over 400-600 seconds following removal of the magnets. The authors proposed that a direct or indirect effect on the conformation of AP generating sodium channels could account for these results[42] however there have been no molecular or cellular studies to confirm this claim.

McLean et al.[42] determined several features of the biological effects caused by quadripolar arrays. These include the finding that maximal reduction of action potential firing in the quadripolar field required several minutes to evolve (indicating time dependency) and recovery of action potentials occurred over minutes after removal of the field. Other field patterns had different or no effects ($p>0.05$). A single magnet (88 mT) or two magnets of alternating polarity (28 mT) had no significant effect. To determine if the gradient of the field or the field strength was the principal determinant of the reduction of AP firing, a weaker quadripolar array was produced which had 1% of the field strength of the original array. It was noted that the weaker array reduced action potential firing as much as the stronger array. McLean et al.[42] propose that the effectiveness of the quadripolar magnetic array is due to the steep gradient between the centre of the array and the magnetic poles and not the strength of the magnet. To date, it seems no *in vivo* nerve conduction studies have been performed to establish a link between *in vitro* effects and the analgesic responses observed in pain studies.

In the above studies, quadripolar magnetic arrays were placed at a distance of 0.5 to 1cm from neurons in cell culture. There is no literature to suggest that similar AP blocking effects would occur with the device placed further from neurons. Hence, the findings may not be applicable *in vivo* when distances between the skin surface, where the device is applied, and the sensory neurons carrying nociceptive or mechanoceptive signals may be greater than 0.5-1cm. This is of particular importance in clinical settings where patients will have varying amounts of soft tissue overlying nerves. Nerves pass close to the skin surface in various locations; however studies of the pain relieving effects of quadripolar magnetic arrays have found relief of pain when applying the device over more deeply located nerves. In Holcomb et al.[44] case study of two patients with severe pain from intervertebral disc disease discussed earlier, the devices were applied at the skin surface, a distance that may be two or three times greater than that used in laboratory studies. The factor of distance from magnet to target tissue raises the possibility that another mechanism may be responsible for the analgesic effects that have been observed in previous studies.

It is clear that much research remains to be done in order to identify effect mechanisms and clinical outcomes for both static magnets and magnetic arrays. A range of research design and methodology factors that may influence research outcomes is discussed below.

Methodological and design-related issues for static magnet research

The examples of research findings of static magnetic therapy cited herein and the effects on pain related measures demonstrate the disparate nature of magnet studies. Some of the issues influencing research outcomes have been raised in the discussion of quadripolar magnet arrays. Although authors generally have attempted to design randomized, placebo-controlled studies, the variety of approaches used has not resulted in clear outcomes. One of the main factors complicating interpretation of results is that there are many 'dosing' and application variables to consider when applying magnetic therapy, e.g., polarity, field strength and penetration, and perhaps configuration of field patterns.

Despite the general observation that there is some evidence to support the use of magnets for neuromusculoskeletal pain,

it is not yet possible to define the application parameters contributing to reported beneficial outcomes. This is exemplified by the fact that in 50% of the studies reviewed, the polarity of the magnets investigated was not stated (or at least unclear) and a variety of magnet types was utilized (e.g., magnet insoles, magnetic discs etc). Moreover, the number of magnets used varies widely from one study to the next (ranging from a single magnet through to 270 individual magnets, and in some cases not specified), as does the method of application (e.g., mattress underlays, necklaces etc).

In relation to magnet characteristics, the issue of field strength is an obvious variable. Few authors have recognized the variable and attempted to describe the field strength at the surface of the magnet device or at a distance from the device in order to quantify how much energy is delivered to the target tissue. A close inspection of the available literature suggests that this factor remains a probable confounding variable in relation to outcomes and would appear to be a mandatory requirement in future design and reporting of magnetic therapy research. In the studies listed in this review, field strength varied from 4 mT to 1080 mT.

The magnet application period is another factor potentially contributing to disparate results. As noted in the available literature in Table 1, application times ranged from as little as 30 minutes up to many weeks of continual application. Clearly this aspect of dosing is critical to clarify, if magnet therapy is to be considered as a legitimate non-pharmacological method of pain relief. Time of magnet application may have a bearing on factors such as immediacy of effect, sensitivity of neural structures (e.g., accommodation) and carry over of responses (which may have a bearing on wash-out periods in cross-over study designs). All of these factors require further research as contributing elements in studies of efficacy. Additionally, the placement of magnets can be specific (i.e., precisely placed over tender points) or general (as in magnetic blankets).

Arguably, the most important variable in clinical studies is that of an adequate placebo device permitting effective blinding. This factor can be controlled where the study methodology incorporates a short supervised magnet application period such as in a clinical laboratory setting. However, such a methodology may result in an inadequate period of application. Where a methodology tests extended periods over many hours of application over days or weeks, it becomes more difficult to control either accidental or intentional loss of blinding by the research participants, and makes imperative the inclusion of an adequate placebo. To preserve blinding, some researchers have gone to elaborate lengths such as: constructing sham magnets[12], using metal shielded or capped magnets[38], demagnetizing active magnets[47], and deliberate deception of research subjects as to the status of the control group[32]. The variety of ways in which this aspect of magnet research has been dealt with, is indicative of the problematic nature of this issue – one which needs to be addressed satisfactorily if the therapy is to be adequately investigated.

The disparate nature of the results of magnet research raises the possibility that there is some form of dose-responsiveness related to magnet therapy (perhaps a threshold for dose exists) and that by combining factors such as application time, polarity and field strength improved outcomes may result. Such factors should arguably be studied in cheaper laboratory (e.g., animal or experimental) models of pain to substantiate efficacy and matters related to dosing parameters before continuing with expensive clinical research in patient populations with questionable outcomes.

Conclusion

In a review of the known literature presented herein, it is not yet clear if static magnets have a significant role to play in the effective management of neuromusculoskeletal pain although some of the research is encouraging. If the clinical studies presented in this review are combined (Tables 1 and 2) then 13 of 24 clinical studies investigating neuromusculoskeletal pain have demonstrated at least some efficacy using static magnetic therapy. However, there are significant issues related to dosing parameters and physical characteristics, as well as effect mechanisms that remain to be clarified prior to conducting further expensive clinical studies which are unlikely to demonstrate an effect until the methodological issues are attended to.

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