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# **A Systematic review of randomised control trials of static magnets for pain relief**

**Dr Nyjon Eccles BSc MBBS PhD MRCP**

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# **ABSTRACT**

## **Objectives**

To establish whether there is evidence for or against the efficacy of static magnets to produce analgesia.

## **Methods**

A review of the historical use of Magnotherapy was undertaken by way of introduction. A systematic literature review was undertaken of studies that compared the use of static magnets with an appropriate control for the treatment of pain. Study methods, their quality and outcome were also reviewed. The putative mechanism by which static magnets may elicit a physiological effect is also reviewed.

## **Results**

Overall 9 of the 12 studies reported a significant analgesic effect due to static magnets. Of the 10 better quality studies with 3 points (Table 2 & 3) or more on the quality assessment, 7 were positive and 3 were negative. In 2 of the negative studies there are major concerns over adequacy of magnet power for the type of pain ( 300 gauss for chronic back pain, Collacott et al, 2000), a query raised by the authors themselves, and of duration of exposure (5 minutes in Harper & Wright, 1977). The latter authors also failed to state the power of the magnet used in their study. If these 2 studies are excluded on the grounds of inadequate treatment then 7 out of 8 of the better quality studies demonstrated a positive effect of static magnets in achieving analgesia across a broad range of different types of pain (neuropathic, inflammatory, musculoskeletal, fibromyalgic, rheumatic and post-surgical).

## INTRODUCTION

It has been known for some time that the behavior of certain types of biological materials are influenced by magnetic fields (Reno & Nutini, 1963). Subtle magnetic fields can produce a physiological effect. For example, pico-tesla range electromagnetic fields have been shown to have significant effects on nerve regeneration (Turing, 1952).

Electrical activity exists in the body at all times e.g. the beating heart. The heart is the biggest electromagnetic field generator in the body (Eyster et al, 1933). Mechanical loading of bones generates electrical currents. The discovery of magnetic material (deposits of magnetite) in the human brain may suggest that we are physiologically designed to respond to magnetic fields (Kirschvink et al, 1992).

It has been postulated that pathological state may result from misalignment of sub-microscopic magnetic fields from their natural state and that applying a magnet allows for a physiological re-orientation of order and coherence in molecules. We now know that wound and hard tissue repair process involves electric currents. Becker & Selden (1985) proposed the existence of an electromagnetic system in the body that controlled tissue healing. When the electrical balance of the body is disturbed by an injury, an injury current is generated, with the resultant shift in the body's current triggering a set of biological repair systems. As healing progresses the injury current diminishes to zero.

It has been noted from Space flight that deprivation of the electromagnetic wave between the earth's surface and the ionosphere leads to abnormal body functioning (Owen, 1986)

The following historical review highlights some of the recorded evidence of the therapeutic use of magnets. I am indebted to the excellent review and treatise of electromagnetic fields published by Dr. Roger Machlis (1993).

For more than 2000 years effects of magnets and low frequency electromagnetic fields on biological processes have been debated. Magnetic therapy was used in Ancient Egypt, then by Physicians such as Hippocrates and Galen and in the Middle Ages by Paracelsus. The use of magnets to treat musculo-skeletal disorders such as gout and muscle spasms dates back thousands of years to the Greeks, Persians and Chinese physicians. The Greek philosopher Aristotle was perhaps the first person in recorded history to mention the therapeutic properties of natural magnets in the 3rd century BC. In the 2<sup>nd</sup> century BC, Galen, the Greek physician and writer, applied natural magnets to different parts of the body. Consequently lodestone (naturally occurring magnetic iron ore) bracelets, amulets and other devices began to appear. In the 1<sup>st</sup> century BC Chinese physicians discovered and recorded the effect that changes in the earth's magnetic field have on health. By 1000 AD Persian physicians were documenting the use of magnets to relieve spasm and treat gout. Plato claimed that it was Euripides who first coined the term "magnet" and attributed magnetic force to a kind of mineral soul within the stone. (Quinan, 1885).

Peter Peregrinus is credited with writing the first major postclassical discourse on magnetism in 1289, describing in great detail the use of the magnetic compass. Magnetic

cures for gout, arthritis, poisoning and baldness are documented in many medieval works. (Mourino, 1992).

Paracelsus (1493-1542). Investigated the medicinal properties of lodestones in the treatment of epilepsy, diarrhoea and hemorrhage. Pharmacists in Europe were using powdered lodestone in elixirs for topical application. William Gilbert (1544-1603) a physician to Queen Elizabeth I, wrote in his book *De Magnete* (1600) (Butterfield J, 1991) hundreds of detailed experiments on electricity and terrestrial magnetism- and debunking many quack medicinal uses of the magnet. By the mid 18<sup>th</sup> century durable high power magnets were available throughout Europe. Czech Jesuit Maximillian Hell published a treatise on magnetism in 1762 and his work inspired interest from a younger University colleague Franz Anton Mesmer (1734-1815). He was trained in mathematics, medicine and law and his doctoral thesis "*Dissertatio physicomedice de Planetarum influxu*" in 1766 dealt with the effects of gravitational fields and cycles on human health. He coined the term "animal magnetism" based on his theories that gravitational forces were able to produce a sympathetic magnetic flux capable of profound neuropsychomatic and constitutional effects. He conducted preliminary clinical trials of these theories in 1774 and in 1775 published his first medical treatise entitled "*On the medicinal uses of the magnet*". His term "animal magnetism" was coined to describe magnetic forces which he believed could become misaligned leading to physiological asynchrony and that restoration of these malaligned forces could restore health. His methods became popular throughout the salons of Europe. In 1784 a controlled study performed by Antoine Lavoisier, Guillotin and Benjamin Franklin concluded that the efficacy of magnetic healing occurred only in the patient's mind. Mesmer challenged them to allow patients with refractory neuropsychiatric illness to be randomly allocated to either his treatment or the best alternative medical treatment that they could offer, but they refused, affirming that they did not discount the possible beneficial effects of Mesmer's therapy, but more its basis as a objective biophysical force. Whilst in France, Mesmer's work was labeled as quackery he had stimulated enough interest elsewhere to generate clinical research in the field.

In 1795, a Connecticut physician Elisha Perkins developed a therapeutic device based on magnetism and electromedicine. Based on testimonial evidence and satisfied customers, Perkins was awarded a U.S. patent for the device from the government. His son Benjamin acquired a British patent for the device. It was thought by many, and indeed gained a reputation, to be one of the great therapeutic marvels of the turn of the century. Attempts by the medical establishment in Europe and the U.S. to discredit the device were met with charges of physician greed, professional arrogance and deliberate restriction of "alternative health care approaches". By the time of Perkins death in 1799, electromagnetic medicine was well established in the treatment of many different diseases. So popular were the devices at this time that the 19<sup>th</sup> century has been referred to as "the Electromagnetic era of medical quackery".

The work of Christian Oersted in 1820 and Michael Faraday and Joseph Henry firmly launched the concept and application of electro-magnetism. (Mourino, 1991). In 1842 Irish doctor William Stokes and American doctor John Bell were obtaining successful results with their primitive biomagnetic treatments at Dublin's Meath Hospital.

In 1843 Reverend Jacob Baker postulated in his pamphlet "*Human Magnetism*" a vital fluid pervading all natural objects, providing forces of electricity and magnetism and serving as a vital link between mind and body. (Baker,1843).

He believed that mobilization of this force could be produced by the will or by external magnetic fields and could, when activated, effect cure from many diseases, including epilepsy, asthma and even cancer. In the 1880's Dr. C. J. Thacher was responsible for the development of "magnetic garments" with which he claimed to be able to cure anything including paralysis. A pamphlet put out by his company explained that the vigor of life in plant, animal and man was almost entirely dependent on the magnetic energy of the sun.

Another doctrine put forward by proponents of magnetic theory at the time was that the iron content of blood made it the primary magnetic conductor of the body and that of the blood's ability to absorb magnetic power from the atmosphere was compromised by unhealthy living. There was evidence that by the late 19<sup>th</sup> century the medical establishment was beginning to accept the role of electromagnetism in the treatment of some diseases, although the concept was still controversial.

In 1887, Robert Bartholow's textbook "*Medical Electricity*" reported that the magnetic and electric currents induced by placing magnets on the skin resulted in the "very extensive subjective impressions of heightened organic activity..... these results were so uniform that there seemed to be no doubt of their genuineness".

Controlled trials performed at the turn of the century produced less convincing results of the efficacy of electromagnetism. This contradictory data made it difficult for the medical establishment to either condone or restrict the practice of magnetic healing. By the time of the Second World War, it would seem that the physiologic effects of electromagnetic fields were no longer catching the attention of the academic medical journals. However at this time Russian army doctors were using magnets following limb amputation to promote wound healing. In 1959, Kyoichi Nakagawa MD, a leading authority on therapeutic effects of magnetism on the human body discovered that some symptomatic conditions respond favourably to magnetic therapy when other modalities fail. Barnothy in the 1960s reviewed all the available data leading to his published two volume work entitled "*Biological effects of magnetic fields*" in 1969. Some of the "in vitro" work that he reports on suggests strongly that magnetic fields, at least at a cellular level, have subtle physiologic consequences.

The advent of Magnetic Resonance Imaging (MRI) in recent years has given the concept of magnetic interaction with the human body more credibility. MRI exposes the body to magnetic fields of the order of 1-2 Tesla (10 to 20,000 gauss).

*In conclusion, the historical evidence highlights the debate over the efficacy of magnetism to achieve positive health effects. However, much of this debate seems to focus on the physiologic basis of the effect rather than of investigating the evidence of a real effect.*

The debate on physiologic influence of biomagnetism has been somewhat re-awakened by more recent epidemiological studies (Jauchem & Merrit,1991; Milham,1982)

analyzing cancer deaths in relation to electromagnetic field (EMF) exposure. A small but significant relation between occupational EMF exposure and leukaemia was reported by Foster in 1992. Other studies have reported of other health risks such as male breast cancer, chromosomal abnormalities, and several other health hazards. (Michaelson, 1987). A number of important studies have concluded a small but significant relation between childhood domestic EMF and leukaemia (Savitz et al, 1998) .The general concordance of these results has led many investigations to revisit the EMF problem.

One of the prices that we pay as technology advances is an increase in electromagnetic pollution. Our environment of power lines, and ever increasing populous of mobile phones and computers has led to controversies over the effect of this electromagnetic pollution on our health.

Geomagnetic storms are associated with an increase in the number of cases of myocardial infarction (Brecus et al, 1995; Androva et al, 1982). Small mammals and humans deprived of natural geomagnetic oscillations suffer ill-health (Wever, 1973). The dysregulation of these natural fields by technological devices emitting artificial fields and radiations have been reported to have adverse effects on health (Wertheimer & Leeper, 1979; Savitz & Wachtel, 1988; Hardell & Holmberg, 1995). Electromagnetic fields have been shown to alter EEG signals, alter DNA synthesis, reduce melatonin synthesis, reduce immune response, increase messenger RNA transcription rate, alter enzyme activity and influence the blood brain barrier.

Conversely, positive effects on health have been described of magnetic fields of only a few hundred nanoTesla with frequencies in the range of 7 to 8 Hz.

*If indeed high-energy electromagnetic fields can disrupt human physiology it perhaps challenge us to wonder if more subtle magnetic fields could have a health enhancing effect. We should rather than being dismissive, examine more carefully the potential interaction of magnetic fields with the body's biorhythms. Maybe our ancestors were stumbling on something that could be of immeasurable benefit to us both now and in the future.*

The purpose of this article was to systematically review the evidence for the efficacy of static magnetic fields in the treatment of pain.

The public acceptance of magnet therapy (and alternative/complementary therapy in general) far outweighs its acceptance by the medical community. We live in an era where evidence-based medicine is vogue. By this we mean evidence of effectiveness or benefit over and above "the placebo". As with all treatments it is important to know that they are efficacious but also that they are safe. The Japanese have used magnets for years to treat chronic fatigue syndrome and have suggested that an increase in environmental electromagnetic pollution and/or progressive inability to be energized by the earth's magnetic field (Rosch, 1998) is important in its aetiology. The Yellow Emperor's Canon of Internal Medicine, some 4,000 years ago also talks about stones and heat and magnets working over acupuncture meridians. In the last 2 decades the Japanese have been using magnets to relieve pain.

There is little doubt that oscillating electromagnetic fields can relieve pain and inflammation but static magnets are motionless magnetic fields until recently there have been very few studies of the efficacy of static magnetic fields in pain.

There are many anecdotal reports of effective pain relief from static magnets from users including athletes (White,1998) and physicians (Weintraub,2000) and unpublished reports of increased healing and reduced pain by physicians (Barnothy,1964; Henren,1997; Ruibal,1997). In 1938, Dr Hanson reported pain relief on himself after application of a static magnet. Estimate worldwide profits from sales of static magnets exceed \$5 billion annually. A quest for analgesia would appear to be a major part of these sales and it is hard to believe that devices that were ineffective could sustain this level of turnover. After 2,000 years of deliberation, the jury is still out. A bone growth stimulator, which works by electromagnetism, has an 80% success rate in promoting the union of non-healing fractures and has FDA approval (Bassett et al,1982). A similar device has also been approved for aiding female incontinence (Galloway et al,2000). Armed with this information one would have expected a huge interest in the potential further applications of electromagnetic fields to promote healing in other clinical situations but this field does not appear to occupy a significant proportion of Medical Research. Most early research on magnets took place in Europe but the research in North America is now expanding.



## **METHODS**

A search was performed of scientific journals from 1966 to May 2002 of the following databases: MEDLINE 1966 – 05/2002, EMBASE 1989 – 04/2002, LIFE SCIENCES 1990 – 03/2002, APPLIED & COMPLEMENTARY MEDICINE 1985 – 05/2002, SPORTS DISCUSSIONS 1830 – 04/2002. Search terms used were: *magnets, magnetotherapy, pain, analgesia, blood flow and circulation*. In addition Internet searches were performed in *google* using the same terms. The search resulted in over 150 articles and two Proceedings. These were all reviewed in detail and in particular the randomized double blind trials. Original articles were obtained, and all references were scanned for further relevant articles.

### **Study selection**

All articles were included which reported a randomized controlled trial in which subjects with pain were randomly allocated to either active treatment or placebo. No language restrictions were applied. Studies with no statistical comparisons were excluded. No exclusions were made for type of pain. For each study, trial design, randomization, blinding and handling of dropouts were recorded, inclusion and exclusion criteria were also noted as were details of treatment and control procedures, main outcome measures and study results.

### **Number of Subjects**

Number of subjects in the key studies ranged from 14 to 119. Five studies used less than 30 subjects, one study employed 45 subjects. The remaining studies examined 50 or more subjects with 4 studies testing 100 or more.

### **Quality assessment**

The quality of the studies was assessed by the system of Jadad et al (1996). Points were awarded in the following manner: study described as randomized, 1 point with an additional point for the appropriate method and a deduction of 1 point for an inappropriate randomization method; both subject and evaluator blinded to intervention, 1 point; description of withdrawals and dropouts, 1 point. A further point was deducted if the blinding procedure was described and inappropriate.

## RESULTS

### Description of studies

The searches revealed 17 possibly relevant studies of which 5 were excluded for the reasons given in Table 1.

**Table 1.** Reports of studies of static magnet therapy for pain retrieved from literature searches but excluded from the systematic review with reasons for their exclusion

<i>Author (date)</i>	<i>Reason for exclusion</i>
Nakagawa (1976)	? controlled or randomized, insufficient data
Shapiro (1987)	Case reports only
Fisher (1988)	Case reports only
Toysa (1998)	Case reports only
Borsa & Ligget (1998)	Single blind

In the 12 remaining studies subjects had the following types of pain: acute pain induced by heat, chronic shoulder and neck pain, post-polio pain, low back pain (in 2 studies), post-surgical wound pain, intractable neuropathic pain, chronic knee and back pain, fibromyalgic pain, rheumatoid arthritic knee pain, chronic pelvic pain and monthly dysmenorrhoea (see Table 2).

Subjects were recruited from various sources: a rehabilitation clinic (Collacott et al, 2000), healthy volunteers (Harper & Wright, 1977), patients scheduled to undergo surgery (Man et al, 1999), clinical referral and media announcement through a university-based clinic (Alfano et al, 2001), recruitment from Medical clinics (Holcomb et al, 2000; Weintraub, 1999; Kanai et al, 1998; Vallbona et al, 1997), medical centers combined with community-based rheumatology and orthopaedic centers, and volunteers of unspecified origin (Hong et al, 1982; Brown & Parker, 2000).

### Quality of Studies

Two studies gained the maximum score of 5 (Collacott et al, 2000; Alfano et al, (2001), 4 studies scored 4 points (Weintraub, 1999; Segal,2001; Hong et al,1982; Vallbona et al, 1987), 4 studies scored 3 points (Harper & Wright, 1977; Man et al,1999; Holcomb et al, 2000; Kanai et al 1999) and the remaining 2 studies scored 2 and 1 respectively (RSSL study, 2001; Brown et al, 2000). The procedure reported for randomization was only reported in 4 of the 12 studies (see Table 3). Subject blinding was reported on in 11 of the 12 studies and assessor blinding was clearly reported in 9 of the 12 with 3 studies not clearly stating this (Kanai et al, 1998; Brown et al, 2000; RSSL study, 2001).

## Outcomes

Overall 9 of the 12 studies reported a significant analgesic effect due to static magnets. Of the 10 better quality studies with 3 points (Table 2 & 3) or more on the quality assessment, 7 were positive and 3 were negative. In 2 of the negative studies there are major concerns over adequacy of magnet power for the type of pain (300 gauss for chronic back pain, Collacott et al, 2000), a query raised by the authors themselves, and of duration of exposure (5 minutes in Harper & Wright, 1977). The latter authors also failed to state the power of the magnet used in their study. If these 2 studies are excluded on the grounds of inadequate treatment then 7 out of 8 of the better quality studies demonstrated a positive effect of static magnets in achieving analgesia across a broad range of different types of pain (neuropathic, inflammatory, musculoskeletal, fibromyalgic, rheumatic and post-surgical). Table 2 summarises all the key studies in more detail including, the study designs, quality, number of subjects, methodology, endpoint measures and results and a further more detailed explanation of the 12 key studies is given below.

Post polio pain syndrome is notoriously difficult to treat, associated with diffuse muscle and joint pains in 76% of sufferers and increased susceptibility to nociceptive stimuli. Vallbona et al's study (1997) recruited 50 patients with post polio syndrome who reported muscular and arthritic pain. All patients had significant pain for at least 4 weeks. Assessment of pain was made by palpation of trigger points before and after application of the device. Magnetic devices were of alternating polarity and between 300 to 500 gauss power. Placebos were identical but with inactive magnets. Baseline pain levels were also assessed by the McGill Pain Inventory. Only one area of reported pain, that being most sensitive to palpation, was evaluated, even though multiple sites may have been present. An active trigger point associated with the site of pain was elicited by pressure with a blunt object. Patients were asked to rate their pain on palpation on a scale of 1 to 10. A randomly chosen device was then taped over the area for 45 minutes thereafter it was removed and pain reassessed at the trigger point. Patients who received the active device experienced an average pain score decrease of  $4.4 \pm 3.1$  ( $p < 0.0001$ ) on the 10 point scale. Those with the placebo devices experienced a decrease of  $1.1 \pm 1.6$  ( $p < 0.005$ ). The proportion of patients in the active device group who reported a pain score decrease greater than the average placebo effect was 76%, compared with 19% in the placebo device group ( $p < 0.0001$ ). They were able to demonstrate a significant analgesic effect of static magnets against the syndrome.

Kanai et al (1998) studied 85 subjects patients with low back pain (duration not specified); the pain being confirmed by thermal imaging and 22 controls. 180mT (1800 gauss) small samarium-cobalt magnets were applied to painful region for 3 weeks. Dummy magnets of 10mT (100 gauss) applied to the control subjects in the same region. Pain was assessed at 1, 2 and 3 weeks by VAS and by thermal imaging. Magnets compared with dummy magnets (10mT) improved low back pain significantly after 1 week. This improvement was associated with a significant increase in the lowest

temperatures on thermographic images at 2 and 3 weeks. The authors suggested that this represented a gradual increase in blood flow.

Diabetic painful peripheral neuropathy is an intractable and progressively disabling condition. A randomised double blind placebo controlled crossover study on 19 subjects using multipolar magnetic foot pads (475 gauss) was conducted over a period of 4 months by Weintraub (1999). All patients had failed to improve with conventional pharmacological treatments (e.g. analgesics, NSAIDs, anti-convulsants, tricyclics). Acupuncture had also been tried in a few individuals. Ten subjects had diabetic peripheral neuropathy and 9 had non-diabetic peripheral neuropathy. The study design entailed 4 phases. After initial neurological and electrodiagnostic evaluation, patients randomly received an active magnetic foot insole for one foot and a similar appearing sham insole on the other foot. Subjects scored their pain by a VAS in both feet twice a day. After 30 days the sides of the active and sham insoles were switched for an additional 4 weeks. At the end of this month, the subjects received two new active magnetic insoles (475 gauss) and continued for a further 8 weeks rating their pain level twice daily. No new pharmacological interventions were allowed. Patients were evaluated on a monthly basis by the same assessor. Motor, sensory and reflex functions were also assessed. Nerve conduction velocities were also investigated in the common peroneal and posterior tibial nerves. Improvement was significantly more pronounced in the diabetic cohort, 90% versus 33%, at the end of 4 months ( $p < 0.02$ ). Severe axonal damage was demonstrated in the diabetic cohort compared with only mild demyelinating changes in the non-diabetic group and these differences seemed to be predictive of clinical success and responsiveness.

Man et al (1999) looked at the effect of unidirectional (negative pole against the skin) static ceramic magnet patches of 150-400 gauss over a 14-day period in 20 patients who had undergone surgical liposuction. The same surgeon performed all the procedures. The devices were applied immediately post-operatively overlying the areas that had been suctioned and left in place for 14 days. The treated areas were assessed at day 1,2,3,4,7 and 14 post surgery by the same blinded observer. Discolouration and oedema were assessed on a scale of 1 to 10 and pain was assessed by a VAS. Several observations were made including significantly less discolouration at days 1, 2 and 3 and significantly less oedema at days 1-4 in the magnet group compared to controls. There was significantly less pain between days 1-7 (37-65% reduction) compared with the control group and this was confirmed by the consumption of less analgesics in the magnet group.

A 4-week application of a 500 gauss unidirectional static magnets to trigger points for 24 hours a day in 14 women with chronic pelvic pain of non-specified duration. This was conducted as a 2 week double blind with a 2 week single blinded extension. Pain was assessed by McGill pain inventory and the Pain disability index. The study demonstrated a 50% reduction in the level of pain in 60% of subjects after 4 weeks compared with a 33% reduction in the level of pain after 2 weeks. This study emphasises the importance of duration of exposure, particularly in chronic pain syndromes (Brown et al, 2000).

A randomized double blind crossover study Holcomb et al (2000) compared the effect of a quadripolar static magnet device, 200mT (2000 gauss), against an identical non-

magnetic placebo on 54 patients with chronic back and knee pain. Diagnosis was based on physical and radiographic findings. All patients underwent x-rays of the lumbar spine to demonstrate evidence of degenerative disc or joint disease. Patients with knee pain also received x-rays of the affected knee. All 13 patients with knee pain in the study had confirmed osteoarthritis. Patients were randomly assigned to one of two treatments; either magnet or placebo and then these treatments were reversed after a 7 day washout period and 24 hour reassessment of pain scores. Outcome measures were pain scores as determined by VAS and a verbal rating scale (VRS). Pain assessments were made after 1, 3 and 24 hours after the device application. The magnet group was found to have a significant reduction of pain scores compared with the placebo group ( $p=0.030$ ).

Alfano et al (2001) studied the effects of magnetic and placebo mattresses on the pain of fibromyalgia. All 119 subjects met the 1990 American College of Rheumatology criteria for fibromyalgia. The subjects were divided randomly into 4 groups. Subjects in Functional group A were exposed to a mattress of 3,950 gauss with the magnets arranged in a unipolar and uniform manner, whereas those in Functional group B were exposed to a mattress of 750 gauss with the magnets arranged with varied space and varied polarity. Subjects in the 2 sham groups used mattresses that were identical in appearance and texture to the functional pads except that they contained inactive magnets. Subjects in the usual care group continued with their established treatment regimens. Primary outcome measures were the change in pain scores (on an 11 point scale) at 3 and 6 months in functional status (fibromyalgia impact questionnaire), pain intensity ratings and a tender point pain intensity score (summation of pain ratings from palpation of tender points, tender point count). A single physician performed the tender point assessment and was blinded to all treatment group assignments. There was a significant difference among groups in pain intensity ratings ( $p=0.03$ ) with Functional pad A showing the greatest reduction from baseline at 6 months. All 4 groups showed a decline in the number of tender points, but the difference among the groups was not significant ( $p=0.072$ ). Whilst there was a significant reduction in pain intensity in Functional group A, the trend for improvement in functional improvement in the active treatment groups was not significant ( $p=0.23$ ).

Segal et al (2001) studied 64 patients with rheumatoid arthritis who despite medications had persistent knee pain by taping either static magnets (190 millitesla, 1900 gauss) or placebos (1 steep field as opposed to 4 steep field gradients in the active treatment group) to the knee for 1 week. Control devices looked identical except that they contained only one instead of 4 magnets (72mT, 720 gauss). Subjects had to meet the criteria defined by the American Rheumatism Association (1987) classification of Rheumatoid arthritis and had to have a baseline pain score of at least 40/100 on a VAS. Assessments of disease activity, ESR, CRP, range of motion, examination for tenderness and swelling, patients' assessment of physical function and the The Modified Health Assessment Questionnaire (MHAQ) for difficulty with activities of daily living were also assessed. These assessments were made at 1 hour, 1 day and 1 week after placing the devices in situ. Each subject was also give a pain diary and asked to log their pain scores in the morning and evening each day. Baseline pain scores in treatment and control groups were similar (61/100 and 63/100 respectively). A greater reduction in reported pain was sustained through the 1 week follow-up (40.4% and 25.9%) and corroborated with the diary pain

scores ( $p < 0.0001$  for each vs baseline). However comparison between the two groups demonstrated a statistically insignificant difference ( $p, 0.23$ ). They found a significant reduction in pain in the magnet group ( $p < 0.0001$ ). Subjects in the active treatment group also reported a reduction in global disease activity of 33% as compared with a 2% decline in the control group ( $P, 0.01$ ). After 1 week 68% of the treatment group reported feeling much better, compared with 27% of the control group. No significant differences were measured in serum inflammatory markers. In this study both test and placebo magnets were active magnets, which is likely to explain the lack of statistical difference despite the occurrence of significant pain reduction compared to controls without magnets. A three-month follow-up questionnaire indicated even greater improvement. The authors admit to a dose-comparative study rather than a placebo-controlled study.

A double blind study crossover trial on a sample of 107 women, aged 18-45, with regular menstrually related pelvic pain was conducted with an outcome measure of a 5 point pain assessment scale completed 3 times a day during menses. This study showed a small but significant reduction in pain compared with placebo on days 2 and 3 of the menses after application of a specially designed neodymium magnet (2000 gauss) was applied to the pubic region at the time of onset of pain. Anecdotal evidence suggests that the same magnet was more effective in relieving pain when it was applied one or two days prior to the onset of menses (unpublished observations).

The following 3 studies failed to show any analgesic effect of magnets compared with placebo.

Collacott et al (2000) used a randomized placebo control procedure to compare the effect of a 300 gauss bipolar magnets with an identical sham magnet. Twenty patients were studied with chronic back pain due to degenerative disease and this was confirmed radiographically beforehand. Their pain was assessed using a visual analogue scale (VAS) and the McGill pain inventory. Range of motion of the lumbo-sacral spine was also assessed by the same observer. All subjects followed the treatment protocol for 2 weeks: 1 week with magnets and 1 week with sham devices, with a 1 week washout period between the two treatment weeks. Devices were applied for 6 hours per day, 3 days a week. Assessments were made after the first day's treatment and then after each week. They were unable to demonstrate a statistically significant effect of magnets compared with sham treatments on any of the outcome measures.

Hong et al (1982) studied the effects of magnetic necklaces of 1300 gauss power on 101 volunteers, 46 males and 55 females. Forty- nine of the subjects were without pain but 52 had chronic neck and shoulder pain periodically or consistently for more than 1 year. They were divided into 4 groups (with pain vs without pain matched with either magnetic or non-magnetic necklaces). Necklaces were worn for 24 hours per day for 3 weeks. All subjects were told that they would receive a treatment with a magnetic necklace for 3 weeks. Subjective evaluation of pain was performed before and at the end of 3 weeks. Results did not reveal a significant analgesic effect of the magnetic necklace (52% improvement) compared with placebo (44% improvement). The significant placebo effect was commented on by the authors who found that almost all their subjects believed that

their necklaces were magnetized. Interestingly, proximal conduction times in the ulnar nerve were significantly reduced in subjects without pain but were unchanged in subjects with pain. The authors suggested that this differential effect may represent an action on healthy (without pain) compared with diseased (patients with pain) nerves.

A small study to assess pain thresholds to heat in the back of the hands of 16 healthy volunteers, before and after application of a wrist magnet was performed by Harper & Wright (1977) The magnetic power of the bracelet was not noted. Each volunteer acted as his or her own control being tested 5 times with and without the bracelet. The order in which the bracelets were worn was randomized. They were unable to demonstrate a significant change in pain threshold due to the magnetic device.

# **INSERT TABLES 2 & 3 HERE**

**TABLE 2. Randomised controlled trials of static magnets in the treatment of pain: study characteristics and results**

**TABLE 3. Jadad Scoring System to measure methodological quality**



## DISCUSSION

Seven out of 8 of the better quality randomised control studies, excluding 2 with inadequate treatment protocols; demonstrate effective analgesia by static magnets. In general the methodological quality of the studies, as assessed by the 3 criteria of the modified Jadad score for clinical trials was good with 10 of the 12 trials scoring 3 or more out of the possible 5. Perhaps what is equally impressive is the broad variety of types of pain that appeared to respond including neuropathic, inflammatory, musculoskeletal, fibromyalgic, rheumatic and post-surgical pain. None of the studies reported any side effects with magnets.

The 12 key trials are outlined above in Table 2. Magnets were applied as necklaces, footpads, mattresses, patches or straps. Magnet power varied from 150 to 3,950 gauss. Pain relief was reported at gauss ratings of 400 and above. The study showing no effect used a magnet of 300 gauss rating.

Duration of exposure ranged from 45 minutes to prolonged wear for 6 months. Studies demonstrating significant relief used a minimum exposure of 45 minutes. One study where no significant relief was observed used exposure times of 6 hours per day for 3 days on alternate weeks. The latter study used a magnet of 300 gauss power for treating chronic back pain. Consensus of opinion on this study, including the authors themselves, was that this was probably too weak a magnet to address pain of this nature. In any case the intermittent exposure may also have contributed to the lack of efficacy in this particular type of chronic pain. Another study (Harper & Wright, 1977) showing no effect on pain thresholds in healthy volunteers used a very short exposure time of 5 minutes to the magnet.

Clearly, one of the problems with magnet studies is in identifying the power of the magnet to use. Very few studies, in fact none of the studies reviewed here, gave an estimate of the magnetic field penetration. We know that quoted magnetic power of commercial magnets tends to be grossly overestimated. There is therefore a need to identify accurately magnet power measurement both in terms of the magnet surface power and also field penetration. From the present studies, it would appear that for pain relief static magnet power should be at least 400 gauss and probably needs to be greater when deeper tissue penetration is required.

It is difficult to perform a truly double blind study using magnets because of the obvious interaction of the magnet with metallic objects. It would be easy for subjects or blinded observers to confirm which one was the live magnet. As reported by Hong et al (1982), most of their subjects believed that they were being given a magnetic necklace and the authors suggest that this fact alone accounted for the 44% improvement observed in the placebo group. It is therefore important when performing studies to give no clue that magnets are being used at all and that the study is designed to test a “metallic device”. One study tried to get around this by using a magnet of 25% strength of the test magnet (i.e. 500 gauss compared with 2000 gauss) as placebo (Segal et al, 2001). This “placebo” also produced significant relief to the degree that there was no significant difference between placebo and control. There was however a significant difference between magnet and non-magnetic controls.

### *Magnetic device: some considerations*

Strength, source, polarity and size of magnets and duration of exposure should be taken into consideration (Owen, 1986; Barnothy, 1964). The optimum magnetic field strength is unknown and this is complicated by the fact that different cells or cellular components seem to have different thresholds of response to magnetic fields (Pilla, 2000). Nakagawa (1995), from his experience and work with magnets in Japan, concluded that magnets need to exceed 500 gauss strength to be effective on the human body. Magnetic power is expressed in modern units of tesla (T) but the older unit of gauss is still used. 1 telsa is equivalent to 10,000 gauss. The earth's magnetic field is 0.5 Gauss (1/10,000 tesla). Most commercial static magnets have powers of less than 1,000 gauss (0.1 tesla). Moreover, gauss readings are often found to be much lower than manufacturers' claims (less than 20% of the claimed power in some cases) (Blechman et al, 2001). Also, the surface of a magnet usually has non-uniform gauss readings.

One of the limitations of magnet therapy in the past has been the use of relatively low magnetic power for weight ratios of ferrite-based magnets. The advent of neodymium/boron/iron magnets in the 1980s allowed for high magnetic field to weight ratios making therapeutic devices significantly more practical and portable. They also have the advantage of retaining their magnetism for decades.

Field flux density is often greater at the edges compared with the centre of the magnet (Blechman et al, 2001). The field strength is proportional to the square of the distance from the magnetic source. The strength falls off rapidly from the body surface. This makes it difficult to assess penetrability. A non-uniform field results in tissues after application to the skin surface (Pilla, 2000). Devices that utilise a directional plate to focus the magnetic effect in one direction are therefore potentially useful. The degree of sub-dermal decay varies with different magnetic alloys (Blechman et al, 2001)

The optimum treatment duration is also not established and positive results have been obtained from 45 minutes to 24 hours (Grigat et al, 2000).

Some feel that the polarity of the magnet that faces the skin may have a differential effect (Owen, 1986). Most of the double blind studies cited in this review have employed the south pole of the magnet adjacent to the skin. There is still debate over whether application of north or south poles determines the nature of the effect. According to Vallbona (1999) both bipolar (alternating north and south poles in concentric pattern or a grid) and unipolar (one pole at the surface applied to the skin) magnets are effective in pain relief. Some have hypothesised that multi-polar magnets may generate deeper field gradient penetration than either unipolar or bipolar magnets (Weintraub, 2000).

Magnetic fields are not impeded by bone and other structures.

### *Static magnet safety*

The evidence that certain electric and magnetic fields augment DNA synthesis has been met with concern over cancer risk. This concern is largely directed at pulsed electromagnetic fields, and in particular continuous exposure to high voltages e.g.

overhead power lines, electric blankets etc (Trock, 2000). No adverse effects on human health have been observed with static magnets up to 2 Tesla or 20,000 Gauss (WHO, 1987). (Vallbona et al, 1997; Jonas, 2000). Magnet therapy practitioners usually recommend that once the magnet has done its job it should be removed, allowing the body to heal itself naturally. Magnetic fields can alter rate of chemical reactions and in some circumstances can enhance conventional drug treatments necessitating a dose reduction in the latter. There is however a paucity of research in this area. Consultation with a Medical practitioner is recommended if regular medication is being taken. Magnetic fields of 2 and 7 Tesla produced no teratogenic effects in pregnant mice (Wagner et al, 2000). However, some studies have reported effects on young animals. It therefore seems prudent to avoid magnets in pregnancy and young children less than 3 months (Coghill, 2000). It is also recommended that magnets should be avoided in pacemaker wearers and those who have metal implants or who wear insulin syringe drivers.

### *Putative mechanisms of action?*

Atoms are spinning magnets and therefore must interact with each other. It is logical to assume that magnetic fields can influence the charged state of biological systems (Adey, 1986). Living systems maintain magnetic profiles in the range of  $10^{-7}$  Gauss to  $10^{-12}$  Gauss. Faraday's law states that a magnetic field will exert a force on a moving ionic current. Ionic currents across cell membranes are fundamental to maintenance of cellular integrity and cell communication. Ionic effects e.g. changes in ion binding have been described with magnetic fields as low as 0.1 to 1 microtesla (Muehsam & Pilla, 2000). Healthy cells seem to have greater electrical charge than unhealthy cells (Owen, 1986). Cellular health and efficient function is to a large degree dependent on the maintenance of correct ionic gradients across the cell membrane. These ionic gradients are maintained by continuous inputs of energy. Most of the chemical energy of our body is used up to re-establish ion gradients, gradients that keep metabolic processes going, including cell signalling mechanisms. Important examples include Na/K transporters, which can either be antiporters, coupling the counter movement of Na and K ions across membranes, or symporters, moving Na<sup>+</sup> and K<sup>+</sup> synchronously and unidirectionally to the same side of the membrane. **All electrical currents generate magnetic fields and all magnetic fields cause a change in electrical potential. Therefore, an interaction of magnetic fields with ion fluxes across the cell membrane is very likely.** That electrical fluxes are important in healing is evident from studies on bone deformation and wound healing. Compression of bone generates a negative electrical potential. Furthermore, the cells are responsive to alteration in externally applied DC electrical fields (Basset & Becker, 1962; Markov, 1995; Jaffe & Vanable, 1984).

### *Change in ion flux and alteration of membrane potentials*

It has been postulated that magnetic fields exert their effects by an action on the ion pumps in the cell membrane; particularly those involved in pumping calcium, sodium and potassium ions such as sodium-potassium-ATPase and calcium-ATPase (Itegin, 1995; Burkhart & Burkhart, 2000; Aceto et al, 1982; Gualtierotti, 1964). The interaction with calcium ions may be important in their proposed circulatory enhancement effects

(Horowitz, 2000). Changes in tissue calcium concentration have been described after static magnetic field exposure (Itegin et al, 1995; Flipo et al, 1998). It has also been postulated that magnets encourage the supply of negative charges to cells thereby restoring cellular resting membrane potentials (Weinberger et al, 1996).

Low amplitude electromagnetic fields alter the threshold for electrical stimulation in nervous tissue (Scherlag & Yamanashi, 2000). There is evidence of pain signal inhibition by this mechanism (McLean et al, 1995 and Cavopoli et al, 1995). Significant reductions in nerve conduction times have been reported in the ulnar nerves of subjects wearing magnetic necklaces 24 hours a day for 3 weeks (Hong et al, 1982).

Static magnets have been postulated to alter sodium/potassium concentrations leading to an increase in resting membrane potentials. The potential consequence of this would be reduced membrane depolarisation and inhibition in transmission of pain impulses and therefore analgesia (Borsa & Liggett, 1998; Lednev, 1991 and Olney et al, 1990).

Magnets may create a field that alters how pain signals are transmitted (Hawkins, 1998).

Static as well as electromagnetic fields boost ATP production in the test tube (Rosch, 1998). This effect may be mediated by magnets affecting the pH difference across the mitochondrial membrane. This pH difference results from positively charged hydrogen ions being pumped out of the mitochondrial membrane to maintain an electrical potential across the membrane of 220 mV; crucial to driving energy production.

An increase in the synaptic cleft has also been described i.e. the gap between nerve endings and their target tissue, raising the possibility of a biomechanical as well as a bioelectric action of magnetic fields (Itegin et al, 1995).

### *Magnets and circulation*

Increased blood perfusion and skin temperature have been observed in human arms exposed to pulsed magnetic fields (Mayrovitz & Larsen, 1992). There are several studies that suggest a similar effect may be elicited by static magnetic fields.

In a microphotoelectric pletysmographic study of rabbit ear circulation in anaesthetised rabbits, static magnets of 0.25-tesla strength were observed to cause a 20% increase of circulation in the face of a 10-15% decrease in circulation in control rabbits (thought to be due to either anaesthetic and/or stress) (Gmitrov et al, 2002). Increased rat skin fold circulation has been measured for 5 minutes after exposure to an 8-tesla static magnet. This was followed by a gradual return to control levels (Ichioka et al 1998).

Static magnet fields of 0.2-0.35 tesla (1,500 gauss) applied to the carotid artery sinus baroreceptor region was found to produce significant macro-circulatory effects in reducing blood pressure and modified micro-circulation (Gmitrov, 2002). There was a time delay of 40 minutes before the effect was observed. In other animal studies it has been suggested that the pain relief due to static magnets may be accounted for by an increase in circulation and there was evidence that this circulatory increase may be elicited by enhanced cholinergic vasodilator neurotransmission or by an anticholinesterase action to prevent breakdown of the vasodilator acetylcholine

(Takeshige & Sato, 1996). Serum cholinesterase in rats is inhibited by static magnetic fields (Gorczyńska & Wegszynowicz, 1989).

Migration of erythrocytes (red blood cells) has been described along a magnetic field (Saygih et al, 1992). Others have reported a blood viscosity lowering effect of magnets (Cisarik, 1986).

In contrast mini magnets (0.005-0.3 tesla) had no significant effect on buccal mucosal blood flow (Saygih et al, 1992). The aim of this study was to establish whether or not magnets had any untoward effects on blood flow or blood cells. The authors concluded that there were no harmful effects on either blood flow or on blood cells. No detectable effect of static magnets of 500 gauss on human skin blood perfusion, as assessed by laser Doppler flowmetry or laser Doppler imaging was detected over a period of 36 minutes exposure (Mayrovitz et al, 2001). However, Kanai's double blind study (1998) showed that back pain sufferers had colder areas, as assessed by thermal imaging, in painful areas and that these warmed after 2 to 3 week application of static magnets. The increase in temperature paralleled pain relief. These findings would suggest that static magnets can increase blood flow but that their ability to achieve this may have variable time-dependence.

Blood oxygen changes have been described in both directions in magnetic fields (Kutrumbus & Barnes, 2000).

***There is certainly evidence that static magnets can increase blood flow. It is not certain whether this is their primary action or whether this effect is secondary to ionic changes that favour an increase in blood flow.***

#### *Other postulated mechanisms of action*

Induction of immune and vascular responses (Alfano et al, 2001)

Cyclical changes in the physical state of water (Beall et al, 1976). Sixty percent of the body is water, 2/3 of this being within the cells and 1/3 outside the cells.

A postulated effect on the pineal gland leading to a cascade of effects on several biological outputs such as melatonin, serotonin and various enzymes (Szor & Topp, 1998).

An anti-inflammatory action. Reduced experimental synovitis has been described in rats. Ten rat hind joints were injected with zymosan, a chemical agent that induces synovitis over a 3-week period. Application of a static magnet field to the floor of the rat's cages (3,800 gauss) significantly ( $p < 0.002$ ) reduced the inflammatory score by 50%. This anti-inflammatory effect may explain the benefits of magnets to promote healing in osteoarthritis. A rapid normalization of erythrocyte sedimentation rate (ESR), a non-specific measure of inflammation, was achieved by exposure to a constant magnetic field in an inflammation model in rabbits (Bassett et al, 1982).

## CONCLUSION

Twelve double blind placebo controlled trials are summarised above. Seven of 10 studies indicate that static magnets are effective in relieving pain. Two of the studies showing no effect are flawed, one by Collacott et al (2000), by not using sufficient magnetic power. The authors themselves were fully aware that the absence of any effect may well have been due to the low power of the magnets they used in their study (300 gauss). Moreover other studies, as summarized above, have shown an analgesic effect of static magnets in low back pain. The second study of the 3 showing no effect by Harper & Wright (1977) is flawed by using much too short an exposure time to the magnet (5 minutes). We also do not have the benefit of knowing the power of the magnet in this study. Hence 7 out of 8 studies demonstrate a positive effect of static magnets in pain relief.

There is a wealth of historical evidence, albeit not in the form of controlled trials, of physiological and therapeutic effects of magnetic fields in humans. Some of the possible mechanisms by which they may induce these effects have been reviewed. In the light of all this data taken together and in particular the largely positive outcome of this systematic review of the existing randomized controlled trials, it is time that we looked more closely and seriously at this apparently non-invasive modality for relieving pain and indeed at the whole concept of the way that subtle magnetic and electromagnetic fields may benefit human physiology.

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# **APPENDICES**

**LadyCare Health Products Ltd**  
**24 Emery Road**  
**Bristol**  
**BS4 5PF**

18<sup>th</sup> March 2002

Dr N Eccles  
The Chiron Clinic  
121 Harley Street  
London  
W1G 6AX

Dear Dr Eccles

Further to our very interesting telephone conversation last week, we can confirm that we are delighted to help your current work on magnetic pain relief. We have been trying for some time to build as much evidence as possible for the effectiveness of our LadyCare device and have been collating our anecdotal evidence as a single file. Included in this are a short report from a school nurse and the results of a mini survey with the British Association of Women Police.

Of course, all of this is meant to support the placebo controlled trial that was carried out by RSSL on the LadyCare device. I have copied this study to you separately.

By the way, you may care to contact Mr. D. Price of Magno-Pulse Ltd (Tel. 0117 9710 710) as he may have other studies and evidence that may be of use to you. In the meantime, I look forward to meeting you in the near future.

Yours sincerely,

Adrian Burley  
Director  
LadyCare Health Products Ltd

# **LADYCARE ANECDOTAL EVIDENCE**

## **1. British Association of Women Police\* Trial results of LadyCare**

### **Background**

LadyCare has been registered as a Class 1 medical device, and is proven to help alleviate menstrual pain. LadyCare represents a long overdue breakthrough in safe, drug-free pain management.

39 BAWP members have conducted their own trials since the Nottingham PDD with very positive results – 93% of returned questionnaires reported that LadyCare relieved the usual period pain. Please refer below:

<b>Questions</b>	<b>Answers</b>		
	<b>Yes</b>	<b>No</b>	<b>N/A</b>
1. Usually suffer 2 days+ of monthly pain?	93%	7%	
2. Usually use painkillers?	93%	7%	
3. Able to reduce painkillers with LadyCare use?	86%	14%	
4. LadyCare reduced the normal pain?	93%	7%	
5. Benefit felt within an hour?	93%	7%	
6. More energy during use?	43%	57%	
7. Improved concentration during use?	71%	29%	
8. Able to resume activities previously restricted during period?	57%	43%	
9. LadyCare was comfortable to wear?	86%	14%	
10. Reduced mood swings?	57%	29%	14%

\* **British Association of Women Police** – A National Organisation concentrating on the welfare, development and support of all female staff within the Police Force.

### **Typical Comments from Triallists**

“Fantastic product, excellent results”

“It’s a necessity not a luxury”

“Total pain relief within 20 minutes”

“Very impressed – no water retention”

“I wouldn’t like to be without it”

“Excellent, after years of suffering”

“Totally banished any bloating”

“Most effective when used in advance”

“LadyCare is definitely something I will pass on to friends.” - Inspector

“...would recommend to others – found it helped my headaches and bloating prior to period and only took 2 lots of painkillers instead of a whole box!” – Sergeant

“It certainly made life much easier and appeared to help.” – CID

## **2. Cannock Chase High School, Staffordshire: School Nurse Report – 2002**

“Last summer I went to R.C.N. Headquarters to attend the Independent School Nurses Conference for the first time. Little did I realise the consequences I would have of picking up a “magnet” at one of the exhibitors’ displays.

I am the school nurse at Cannock Chase High School, a mixed secondary comprehensive school in south Staffordshire with a roll of 1800 pupils. I am employed directly by school and work full time in the school’s medical room.

Most days, I will see girls who are distressed and unable to function, some even to the point of collapse due to menstrual pain. I find it incredible to believe that we have developed sanitary towels and tampons to give women independence and freedom but have not yet found effective pain relief. I have seen girls who due to ignorance and innocence have taken a second dose of analgesic 30 minutes after the first dose because they were still in pain. Girls who need to have one or two days in bed due to the severity of pain have required medical notes for the Local Education Authority for their parents to avoid being fined £2000 for repeated poor attendance. The prospects educationally, psychologically and personally for these young women I believe **are** poor unless we can offer a choice to change. We, as nurses have an ethical and moral duty to be pro-active in that change.

Drug choices are limited — paracetamol rarely relieves pain totally, ibuprofen and mefenamic acid should be taken with food to reduce the possible side-effect of gastrointestinal disturbances. I do not know many teenagers that eat well and regularly, also when in pain, their appetite is further decreased. Lastly when these drugs are prescribed, are we fully informing patients of possible side-effects? In today’s litigious society, we are the holders of such information, should we not be sharing it?

Having always had an open mind regarding the use of “alternative” therapies, I believe that conventional medicine can be complemented. So when I picked up the LadyCare. I was immediately interested. The company producing it LadyCare Health Products Ltd, offered to let me have a device free of charge to trial at school.

The LadyCare device comes in two parts - the main magnet is approximately 3.5cm in diameter and encased in smooth plastic. For maximum effect it is positioned over the uterus (or the point of pain) and secured in place by a second smaller magnet with the briefs between both magnets. It **reportedly** works by increasing the blood supply to the localised area, thus reducing the build up of lactic acid and hence the reduction of muscular cramping of the uterus.

I returned to school, but was unsure how I was going to offer the trial to pupils, when a member of the teaching staff came to the medical room with period pain - I offered her the use of a LadyCare and she found that it “definitely made a difference in the early stages of her period” and the minor cramps/discomfort she usually felt went completely”. This gave me confidence, faith and belief, to offer the LadyCare to pupils.

I had concerns about directly offering it to pupils — I envisaged an irate parent asking, “What was I asking pupils to shove down their knickers?” Therefore my first aim was to gain parental interest and consent. Over the next few months when girls came into the medical room with period pain I also gave them information to take home and discuss with their parents. I encouraged them to return the following month to have a free trial.

LadyCare Health Products were in regular contact and provided all the information I would need — leaflets, newspaper articles and testimonials. Their support was always very genuine and any problems we encountered they were ready to listen and even modified the design. Several incidents occurred with the first design of LadyCare, which clipped to the briefs: once the device ended up on the classroom floor — that teacher really does want to remain anonymous! And one member of staff felt so energetic during her period, whilst dusting she got too close to the television screen and de-magnetised the screen. This was simply rectified by turning the set off overnight.

Soon I found that girls were telling their friends how effective the device was and they would come and ask to borrow it. If these pupils were Year 9 and above (aged 13 upwards) I felt that they were Gillick competent and I accepted this as consent, ensuring I told them how to use the LadyCare and that they took written information with them, for their parents. For pupils in Years 7 & 8 I gave information and asked parents to contact me if more information was required.

Staff and pupils were asked to complete a questionnaire after use: these are some of their comments: Catherine, aged 14 “The pain eased dramatically” and “my parents say that my mood swings have mellowed”. Helen aged 16 “may sound daft, but feel more confident at that time of the month”. Helen’s mother said that “her mood swings have really improved and the fact that she does not need so much pain relief is beneficial.” Katie, aged 11, has only known severe pain since starting her periods at age 9, said “the pains aren’t as bad anymore and “I can do anything without having to sit out or worry.” Teaching staff that took part in the trial were enthusiastic too, finding it to be “discreet” and “pain is significantly lessened.” Some were still taking analgesia but less often. One member of staff had seen her GP with severe breast tenderness; he had advised her that it was a hormonal problem. She used the LadyCare for a few weeks and now says. “the problem has completely gone”.

Wearing the Lady Care constantly at least 24 hours before the period is due has shown to have the most benefit with pain relief. Those pupils that have used LadyCare for three months or more have noticed an improvement in mood swings and generally felt happier. Over twenty pupils and staff have trialled the LadyCare and only two found it of little or no benefit, though both commenced use when pain was deeply established.

One local GP, when asked for his opinion by a parent about LadyCare said it was all in the head — he went on to prescribe her daughter menefamic acid. Which is a shame because even if it had “just worked in her head” surely it would be better than filling her with drugs?

Overall I have been extremely impressed and have seen young women gain confidence and take control of their lives with the use of the LadyCare. I just wish I had discovered

this product prior to having a hysterectomy at the age of 36 for crippling pain with endometriosis. We are in the 21st century; surely we need to embrace new concepts of menstrual pain relief for today's women, instead of reaching for the medicines in the first instance.

### **3. Letter from DF, Glasgow - 12 June 2002**

I would be honoured if you used my e-mail to encourage potential users. There may be others like myself who have tried other pills and potions on prescription which have not worked, apart from medication to stop periods altogether. These medications which I have been on in the past have caused weight gain and the need for bone scans to check my bone density. Your product offers hope to others and cuts out the GP prescriptions which are not only a waste of money but a waste of the GP's time and our own. My next option would be to have a hysterectomy but it looks as though I have been saved from the knife thanks to my little magnet!

I have no objection to your PR Company contacting me as I feel that more women should know about this wonderful device. I work in Glasgow Royal Infirmary and have already passed on information about your product to colleagues and also to fellow sufferers in another Glasgow hospital where I used to work.

Your product came to my attention by reading the "Woman" magazine and I did feel that this well established magazine would not "rubber stamp" the LadyCare product if there was no evidence to support it. Had I not been a regular reader of "Woman" I would most certainly have continued to suffer (and my family!) for some considerable years or until it was deemed necessary for radical surgery.

### **4. Received by email: from AV - April 2002**

"LadyCare, My Heroes"

I have been using the LadyCare magnet for 3 months now as I can no longer take NSAIDS for the pain as a result of stomach ulcers. I had an awful few months of struggling with daily life during my period trying to manage on paracetamol - which are no good!! When I read about the LadyCare in the Daily Mail I was intrigued. I hit your web site and ordered straight away.

I can honestly say that the LadyCare is the best thing in the world - the first month I still needed paracetamol but at least they actually worked. Now I don't even need to take anything to stop the pain or the cramping and it doesn't wake me up in the night. These are all things I could not say prior to using the magnet and it's good to have continual pain relief rather than have painkillers time out on you.

Bravo LadyCare! That's what I say, sell it to all women everywhere it really is every woman's dream! (well maybe no periods at all is!!)

## **5. Received by email: from AV**

I first heard it mentioned on Newsbeat on Radio One at teatime. They were interviewing 6th form students who were extolling the virtues of this magnet. This was sometime around October 2001 and I trailed every search engine on the internet to try and find it.

Having forgotten all about the report on the radio some 4 months later my mum had read an article in the Daily Mail female section specifically regarding alternative remedies for period pain, It didn't give the web address for yourselves, however I inputted the LadyCare name into "Ask Jeeves" and your address came up.

I have passed the web address onto a colleague and I keep telling my girlfriends how great it is. I think you should think about selling them in Boots the Chemist, spread the faith!! I'm a cynic, but if you're in pain like me both with the cramps and with stomach ulcers you will try anything. Please do use my quotes, anything to encourage us women to not suffer!

## **6. Letter from GA, Effingham – 21/10/01**

Dear Sir

I'm writing to thank you for this great relief in LadyCare. I live a very busy and stressful life being a chef. So no time for pains, moodswings and headaches. LadyCare answered my prayers and I can now get on with my life and job. After using it twice now I'd recommend it to anyone.

## **7. Letter from JB, Dudley – 7/1/02**

Re: LadyCare

I have tried the above for two months now. First month I thought fluke, second month again no pain. I just hope it carries on the same, as it is saving me a small fortune, in not having to buy Nurofen tablets. The girls I work with cannot believe the difference, normally I'm doubled over with cramps. So THANK YOU! to whoever came up with the idea, as it has made it easier for me and those I have to work with. Thank you again.

## **8. Letter from DB, East Horseley – 24/11/00**

I have recently purchased a "LadyCare" from you. I have found it to be incredibly beneficial. I suffer from extreme symptoms of endometriosis, which is completely debilitating. I have to admit I have only used your magnet once but I was amazed by the results. I had virtually no pain, which on other occasions has been extremely acute. Many thanks.



### **9. Letter from PK, Wembley – 16/3/01**

It's a god-send to me and to my daughter who no longer takes time off school because of cramps.

### **10. Letter from JM, Chippenham – 15/11/01**

I am more than happy to endorse your product. I was one of those very sceptical people – How on earth can a magnet stop the pre-menstrual pains that I get in my tummy and also in my breasts? I was spending approx. £25 a month on Evening Primrose oil capsules and various lotions and potions and thought that I might as well give your product a trial, but only after reassurance that I would have a full refund if it didn't work! I am delighted to say that it started to work almost immediately – I now have no pain in my breasts at all, and my tummy pains are greatly reduced. I no longer use Evening Primrose oil or lotions and potions, so after my initial outlay I am now saving £25 a month. I cannot recommend or praise your product highly enough and have told many people about it including my Doctor and Consultant.

### **11. Letter from WN, Leatherhead – 19/7/00**

I am writing in praise and in gratitude for the LadyCare. Within half an hour of using it for the first time I had relief from period pain and I have not had to endure the debilitating pain since. I also have the Magno-Pulse wristband which gives me great relief from arthritic pain in my arms. With a hectic life as a teacher and as a dancer in my leisure time, both items have enabled me to function more fully and effectively at the age of 56. When not using my LadyCare for period pain relief, I have attached it to the area over my hips and obtained relief from the considerable hip pain I suffer. Maybe this is an idea you could develop further. I would heartily recommend this product to others and would not be without them at my advanced time of life in order to maintain a healthy and active lifestyle.

### **12. Letter from WG, Devizes – 2/8/00**

I recently purchased a "LadyCare" for my Granddaughter. I must say she is more than delighted with it! Instead of taking two days off of school she is able to attend and take part in sports etc which the pain prevented before. I myself have already noticed a lot of benefit.

### **13. Email from YW – 3/4/01**

I just wanted to say what an amazing product the LadyCare is. Even painkillers only gave a modicum of relief, which only lasted for a few hours. The only painkiller which was in any way effective was Ibuprofen, and this risked complications with my asthma. Since using the LadyCare I have not had to take a single painkiller at THAT time – it

really is a fantastic product. Many, many thanks!

**14. Email from AR – 24/8/00**

Just to say thank you for the lady care magnets that you sent me they really seem to have made a difference to the amount of pain I suffer during my period, I suffer from pelvic congestion and they really seem to help.

**15. Letter from JG, Cumbria – 7/1/00**

Thank you for sending my LadyCare back to me so prompt. I didn't realize how much relief it has given me until I had to do without it.

**16. Letter from UJ, Somerset – 22/1/002**

A brilliant product which has helped me enormously.

**17. Letter from Mr EK, Somerset – 18/3/02**

Once again would like to say I find it invaluable for my arthritis.

**18. Letter from DL, Chippenham – 3/5/02**

I have worn this LadyCare for a couple of years and am sure it has been of great benefit to me.

**19. Letter from JJ, Bristol – 4/4/02**

Having used my LadyCare for several months now. I have been extremely pleased to find that it lives up to your claims and I have recommended it to family and friends, together with mentioning your other products.

**20. Letter from SH, West Malling – 18/4/02**

I have had very good results whilst using my LadyCare – after many years of needing strong painkillers during menstruation I am now drug free!

**21. Letter from AB, East Boldon – 20/3/02**

May I say this has been an excellent product which has saved my seventeen-year-old daughter drugs and pain.

**22. Letter from LP, Pulborough – 24/1/02**

Your LadyCare has helped me tremendously.

**23. Letter from SB, Wilmslow – 10/3/02**

This was purchased for my daughter and she found it a marvelous product which enabled her to avoid taking time off school and spending long periods of time on the settee dosed up with painkillers and with a hot water bottle clutched to her stomach.

**24. Letter from NH, Poole – 5/5/02**

The magnet is used by my 14 year old daughter who since December has not had to miss her usual one day a month from school, so for this we say thank you and it really does work!

**25. Comment from MM, Yorkshire**

My daughter has found the 'LadyCare' wonderful

**26. Comment from D, Surrey**

I have found LadyCare to be incredibly beneficial. I suffer from extreme symptoms of endometriosis which is completely debilitating. I have to admit I have only used it once but I was amazed by the results. I have had virtually no pain which on other occasions has been extremely acute.

**27. Comment from VG, Wiltshire**

Delighted with LadyCare instead of taking at least 2 days off of school, my granddaughter is now able to attend and participate in sporting activities which the pain prevented before.

**28. Comment from AR**

I suffer from pelvic congestion and 'LadyCare' really seems to help.

**29. Comment from 38. Comment from VL, Middlesex**

I am happy to tell you that whereas my thirteen-year-old daughter's periods were extremely heavy with clotting, she now has a fairly normal cycle. She has not taken a single Feminax tablet since she began wearing the LadyCare.

**30. Comment from JT, Penicuik**

No pain at all no feeling down and snapping at my family, I also found that I had a much more regular flow, I will not hesitate to rave about 'LadyCare' to anyone who will listen. Thank you again for your high-class products and service

### **31. GB, Pontefract**

Proved invaluable, well worth the money.

### **32. Letter from DN, London – 23/3/02**

Thanks to you I have my life back each month.

### **33. More LadyCare Comments**

- Very impressed and pleased with the results.
- Brilliant product which has saved me (even though I initially thought it was expensive) a lot of money on herbal remedies and painkillers so it's nice not to put anything into my body for a change, so no side effects great. Thanks. Good Luck.
- Only had it for the last two months. First time I think I used it too late when I had already suffered with cramps for about 36 hours. The damage was done perhaps. **It** didn't make any difference. Last month was much better – used it from first show and only resorted to paracetamol (normally use Nurofen Plus).
- The first month that I used LadyCare the relief was practically instant – I had no pain at all.
- LadyCare has relieved my menstruation pain greatly. Although it has not completely eradicated the pain it has enabled me to carry on through the day and most importantly I haven't had to take any painkillers. Can also say that my blood flow is much smoother and it is not so clotty. I also don't have the feeling of total exhaustion.
- Although I have to say I was sceptical, LadyCare definitely helps relieve the pain, and whereas before using it, I had to take time off work as I felt so ill, I have now used it twice and both times I was able to carry on working – considering I do outdoor, manual work – I think that is a real test for LadyCare. I don't take any painkillers now and they really didn't help anyway. I am really quite amazed at this product!
- Yes, I would continue to use LadyCare, it is absolutely brilliant. I have told all my family and friends how good it is. I would highly recommend it to any woman who suffers from menstrual pain. Now my daughter will not have to suffer menstrual pain when she starts her periods. She will definitely be trying LadyCare.
- I did not have a migraine during my period which I have had despite all different trials of medication for 10 years. If this is a pure coincidence then it was a nice one. I will continue to use the device and wait and see!
- I have recommended it to ALL my friends!
- I have endometriosis and I get two types of pains, a cramping pain in which it stopped

while using it, but didn't stop the sharp stabbing pain unfortunately.

- I still have to use painkillers, but with the LadyCare as well, it's a great help.

- It is a very good device. Excellent, helped me a lot.

- My problem was feeling dizzy and very disorientated. I had tried different tablets from the doctor but nothing helped until I tried the Magno-Pulse. I no longer have days off work every month.