MAGNOTHERAPY – CLINICAL EVIDENCE OF EFFECTIVENESS: With particular reference to Magnopulse products

by

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Foreword

This document is intended to give the reader a summary of the evidence for the efficacy of static magnets, particularly in the arena of pain reduction. Many broad claims have been made for magnotherapy and these have probably served only to undermine the true merit of magnotherapy. This brief overview has been constructed to draw attention to the scientific and published evidence for benefit from Magnotherapy and also to draw attention to those magnet products that are tried and tested.

About the author

Dr. Nyjon Eccles BSc PhD MBBS MRCP. - obtained his medical qualifications in1992 from UCL Medical School in London and his MRCP in 1997. He had also graduated previously with a PhD in Pharmacology in 1992. Dr Eccles is primarily a general and naturopathic physician and has a special interest and experience in complementary supportive treatments that promote well-being and recovery. He runs a private clinic in Harley Street, London called *The Chiron Clinic* where he is also involved with Medical Infrared Thermal Imaging technology and its application in the screening of pain syndromes and Breast Cancer.

He has helped to research and develop an apparatus called Stresserve over the last 4 years and is the senior Clinical advisor to Harley Street Stress Services.

He spends much of his time in research and has written many papers and scientific reviews on a wide range of topics including “Stress Measurement” and “Stress measurement in the Workplace”. He has a longstanding interest in Magnet therapy and has also written several dossiers recently on the efficacy of “Magnet therapy” including a “A Systematic review of randomised control trials of static magnets for pain relief” and “A Scientific Review of Static Magnets in Wound Healing”. In addition he has been responsible for organising and conducting several double blind clinical trials in Magnotherapy. His work in respect of the latter is mentioned and summarised in this document.

What is Magnotherapy?

Application of a magnetic field, either by way of a static or electromagnet, for therapeutic purposes.

Electric and Magnetic fields

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.
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 (the electrical currents) across the cell membrane is very likely.*

How do magnetic fields work?

Existing scientific evidence suggests that there appear to be two principle ways that magnets reduce pain.
1. Magnets can reduce local tissue acidity (due to a neutralisation of positively charged protons responsible for acidity), which contributes to pain, the consequence of this being a
2. Secondary increase in circulation and local tissue oxygenation

They also seem to inhibit nerve transmission of pain signals (reduced membrane depolarisation and inhibition in transmission…. means that the nerves that are responsible for conducting pain do not fire so easily).

How do they promote wound healing?

As long ago as 1792, Galvani observed that injured tissues generated small electrical currents. Becker measured these injury currents in bone and others have measured them in injured soft tissue (Wolcott et al, 1969). Electrical stimulation has been used to facilitate wound healing for more than 30 years (Carey & Lepley, 1962).
The beneficial effect of static magnets may be due to promotion of the so-called injury current that is generated rapidly at a wound site after injury.

Magnet power

It is generally believed 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).

Magnet Safety
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).

Specific conditions Magnotherapy has an effect on

Pain and swelling
Wound healing and leg ulcers
Period pain/PMS

Benefits

Natural, drug free
Pain reduction
Improved quality of life (due to pain reduction and greater mobility)
Cost saving implications for NHS

The Evidence

The following section draws together all the evidence for the efficacy of magnets, in particular within the field of pain relief and wound healing. It begins with a review of the historical evidence that would support a beneficial effect and then moves on to the published and unpublished scientific evidence as well as current clinical trials that are in progress.

Historical Evidence

Magnetic therapy was used in Ancient Egypt, then by Physicians such as Hippocrates and Galen(2^{nd} century BC).
It was used in the Middle Ages by Paracelsus (1493-1542).
In the 1^{st} century BC Chinese physicians discovered and recorded the effect that changes in the earths magnetic field have on health.
By 1000 AD Persian physicians were documenting the use of magnets to relieve spasm and treat gout.
Magnetic cures for gout, arthritis, poisoning and baldness are documented in many medieval works.

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" 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.

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. So popular were the devices at this time that the 19^{th} 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.

1842 Irish doctor William Stokes and American doctor John Bell were obtaining successful results with their primitive biomagnetic treatments ay 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).

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.

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".

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.

Recent epidemiological studies (Jauchem & Merrit,1991; Milham,1982) analyzing cancer deaths in relation to electromagnetic field (EMF) exposure. Foster (1992) reported a small but significant relation between occupational EMF exposure and leukemia. 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 leukemia (Savitz et al, 1998) .The general concordance of these results has led many investigations to revisit the EMF problem.

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). 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.

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 is important in its aetiology.

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.

Circumstantial evidence for magnetic influence on the body

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).

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).

<u>Credibility of Manufactures– MagnoPulse</u>

Need for credible products by credible manufacturers
Diligent companies – MagnoPulse the leader
Do not make broad and dubious claims that are not evidence-based
Approach: Focus on specific problems that people suffer from
Sponsor well conducted clinical trials

Products listed as medical devices (MDA Class I, Class II applied for)
MagnoPulse products (LadyCare, LegCare, UlcerCare, SleepCare)
Aim of product design- safe but optimally effective

CLINICAL TRIALS

A Systematic review of randomised control trials of static magnets for pain relief - Dr Nyjon Eccles BSc MBBS PhD MRCP

Overall 9 of the 12 studies reported a significant analgesic effect due to static magnets (more details of these 12 studies are shown in the appendix to this document).

Of 8 of the better quality studies, 7 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).

MAGNOPULSE SPONSORED TRIALS

LadyCare Double blind clinical trial demonstrates effectiveness to relieve period pain- Dr Nyjon Eccles BSc MBBS PhD MRCP

Thirty-five women who suffered regular dysmenorrhoea were randomly allocated to either a specially designed *LadyCare* static magnet or a control (attenuated power magnet) group and studied over one cycle.

There was a significant reduction ($p< 0.02$) in pain in the LadyCare group compared to the placebo group. Mean pain score differences (McGill pain score before – pain score after device) were 18.06 ± 3.96 (mean ± SE) in the LadyCare group and 4.83 ± 3.24 in the placebo group. This represented an average of 53% reduction in pain in the LadyCare group compared with an average of 15% pain reduction in the Placebo group. Seventy percent of the subjects in the LadyCare group had at least a 50% reduction in pain, 47% of whom had a > 75% reduction in pain.

There was also a reported alleviation of associated irritability in the LadyCare compared to the placebo group ($p=0.056$). More of the placebo group than the LadyCare group reported "side effects" from which we conclude that there were no significant side effects to be reported in the LadyCare group.

Other Magnopulse-sponsored double blind trials in progress

LADYCARE/ ENDOMETRIOSIS TRIAL (in collaboration with the SHE Trust).
To further investigate the efficacy of LadyCare as a treatment of endometriosis. To be completed by January 2004.

ULCERCARE TRIAL
To investigate the efficacy of Magnopulses' UlcerCare to expedite chronic leg ulcer healing. To be completed by January 2004.

Magnopulse-sponsored Randomised customer surveys

1. Survey of to Determine the Longterm Effects of *LadyCare* Static Magnets on Dysmenorrhoea (Period pain) - Dr Nyjon.K.Eccles & Derek R. Price

193 women who had purchased LadyCare were surveyed randomly over the telephone. Most of the 193 women surveyed suffered form primary dysmenorrhoea with an average pain duration of 11.6 years.

The key findings were as follows:

Long-term persistence of analgesic effect of LadyCare to relieve period pain was suggested from the survey with 90% of those using LadyCare for more than 1 year still having pain relief.

93 of the women surveyed were asked if they had noticed any side effects from wearing LadyCare. None of the 93 women had experienced any side effects. The majority of respondents, 73%, had been using the LadyCare for at least 7 months and 31% had used LadyCare more than a year.

Average pain level was 8.2 0.11 on a scale of 1-10 before LadyCare and 5.6 0.19 after LadyCare. This difference was highly statistically significant ($p<0.0001$). There was also a statistically significant reduction ($p < 0.0001$) in the consumption of painkillers before (10.26 0.44) and after (6.67 0.37) using LadyCare.

LadyCare also produced highly significant reductions in symptoms associated with menstrual periods such as irritability ($p< 0.0001$), breast tenderness ($p< 0.0001$), bloating and water retention ($p<0.0001$) and a significant reduction in spots in those who experienced these as a menstrually related symptom.

Average days off work were 6.8 0.58 before LadyCare and 3.1 0.46 after LadyCare. This difference was again highly statistically significant ($p<0.0001$) and represents a reduction of 54% in time taken off work.

73% of respondents in the survey said that they would recommend LadyCare to a friend. This figure is consistent with the previous results in this survey, as well as data obtained from the double blind trial and a large body of anecdotal evidence indicating that LadyCare is effective in 75% of users.

The survey set out to assess whether LadyCare is safe and efficacious with long-term use. The results suggest an affirmative answer to both these questions with about 90% of women reporting persistence in efficacy with long-term use and no women at all experiencing any side effects.

2. A Survey of to Determine the Effectiveness of *Magnopulse LegCare* Static Magnets on Leg pain and Swelling - Dr Nyjon.K.Eccles & Derek R. Price

A telephone survey was conducted of 202 randomly selected users of *Magnopulse LegCare* static magnet leg wraps. The majority of the patients, 67%, using the LegCare used it for knee pain. Average duration of pain was 87.2 months with a range 1 to 600 months. Forty-five percent of respondents had associated leg swelling.
The key findings were as follows:

96% of respondents said there was a reduction in leg pain after wearing the device. There was an average of 73% reduction in leg pain after wearing the LegCare. This reduction in pain was highly statistically significant ($p<0.0001$).

85% of those who responded had a reduction in pain of at least 50%. Furthermore, 31% had no pain at all after wearing the device and 49% had a reduction in pain of 70% or more.

The majority, 75%, had a noticeable reduction in pain within 14 days of wearing the LegCare. More than half (54%) of LegCare users required no further treatment for their leg pain.

Of those who had swelling, 72 of the original 202, 73% reported a reduction in leg swelling after wearing the LegCare. The average reduction in leg swelling after wearing the LegCare was 71%. This reduction in leg swelling was highly statistically significant ($p < 0.0001$).

65% reported an improvement in quality of life after wearing LegCare of which 10% were much better.

No respondent reported any worsening of health from wearing the device.

3. A Survey of to Determine the Effectiveness of *Magnopulse UlcerCare* Static Magnets on Leg Ulcer Healing and Leg pain - Dr Nyjon.K.Eccles & Derek Price

A telephone survey was conducted of 160 randomly selected users of *Magnopulse UlcerCare* static magnet leg wraps. Average ulcer duration was 49 months i.e. just over 4 years. The device had been worn for an average of 4 months at the time of the survey.

The key findings were as follows:

A highly significant reduction ($p < 0.0001$) in ulcer size of 68% was achieved over the treatment period. Forty one percent (41%) of patients experienced complete ulcer healing with only 11% of patients had no effect on ulcer size. The average time to heal in those that had complete healing was 3.9 months.

72% of those with associated swelling had a reduction in swelling after wearing UlcerCare with an average reduction in swelling of 71%. This reduction in swelling was highly statistically significant, $p < 0.0001$.

84.5% had a reduction in associated leg pain with UlcerCare. This reduction in pain was highly statistically significant, $p < 0.0001$. There was a statistically significant reduction in painkiller consumption after using UlcerCare ($p< 0.030$), with 57% of patients no longer taking painkillers at all.

The majority, 54.5% reported an improvement in ability to perform daily tasks with 64% reported an improvement in the quality of life. This was at least in part due to less pain, less restriction and greater mobility.

APPENDIX

A Systematic review of randomised control trials of static magnets for pain relief - A Summary -

Dr Nyjon K. Eccles BSc MBBS PhD MRCP

Since 1977 there have been 12 double blind placebo-controlled trials of static magnets in the treatment of pain syndromes.
Nine of the 12 studies reported a significant analgesic effect due to static magnets. Of the 10 better quality studies with 3 points 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).
These studies are now generating curiosity, interest and reduced scepticism amongst the Medical fraternity. Summaries of the 12 studies are shown below.

Vallbona et al (1997) showed a significant pain reduction in his study of 50-post polio syndrome patients after 45 minutes exposure to static magnets.

Kanai et al (1998) in their study of 85 subjects and 22 controls showed that small samarium-cobalt magnets compared with dummy magnets 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. This suggests a gradual increase in blood flow.

Man et al (1999) looked at the effect of unidirectional static ceramic magnet patches over a 14-day period in 20 patients who had undergone surgical liposuction. Patients were assessed at day 1,2,3,4,7 and 14 post surgery. 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.

Diabetic peripheral neuropathy is a painful condition described as disabling, intractable and progressive and for which conventional pharmaceuticals such as non-steroidal ant-inflammatory drugs, analgesics, anticonvulsants and tricyclic anti-depressants are ineffective. However, in a double blind placebo-controlled crossover study of 24 patients who had failed to improve with conventional therapy, Weintraub (1999) demonstrated a significant reduction in pain in 90% of patients using static magnetic insoles.

In another randomised double blind crossover study Holcomb et al (2000) demonstrated significant pain reduction after 24 hours in 54 patients with either chronic back or knee pain.

Brown and colleagues (2000) in their study of chronic pelvic pain were able to show a 60% reduction in pain scores (as assessed by the McGill pain questionnaire) after 4 weeks, with a 33% reduction in pain at 2 weeks; emphasising the importance of treatment duration for some types of pain in eliciting significant effect.

Alfano et al (2001) demonstrated significant reduction in fibromyalgia pain intensity over a 6-month period by the use of magnetic mattresses in their study of 119 fibromyalgia sufferers.

Segal et al (2001) studied 64 patients with rheumatoid arthritis who despite medications had persistent knee pain by taping either static magnets or placebos to the knee for 1 week. They found a significant reduction in pain in the magnet group ($p<0.0001$). Subjects also reported a reduction in global disease activity of 33%.A three-month follow-up questionnaire indicated even greater improvement.

A double blind study crossover trial on a sample of 107 women, aged 18-45, with menstrually- related pelvic pain 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.

Three studies failed to show significant pain relief and these are summarized below.

Collacott et al (2000) in their study of static magnets in 20 elderly subjects with chronic low back pain were unable to demonstrate a statistically significant effect with magnets of 300 gauss worn for 6 hours a day, 3 days per week, alternate weeks. The authors rightly acknowledged that a stronger magnet might be needed to penetrate deeper to the source of the pain.

A study of pain thresholds on the back of the hand in 16 subjects failed to show any effect of magnets applied for 5 minutes (Harper & Wright, 1977). Not only is this inadequate time duration to observe any effect of a static magnet, but also the authors do not state the power of the magnet used.

Hong et al (1982) studied the effects of magnetic necklaces of 1300 gauss power on 101 volunteers over a 3-week period. They were divided into 4 groups (with pain vs without pain matched with either magnetic or non-magnetic necklaces). 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.

Overall, these controlled studies support the wealth of anecdotal reports from patients, not to mention the reports from animal studies, that static magnets can provide effective analgesia.

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