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The Use of Magnet Therapy for Wound Healing: A Feasibility Study

by

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies for acceptance, a thesis entitled "The use of magnet therapy for wound healing: A feasibility study" submitted by Mary C. Hill in partial fulfilment of the requirements of the degree of Masters of Nursing.

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ABSTRACT

The purpose of this study was twofold: 1) to determine if there was enough evidence to justify a larger study to investigate the effect of permanent magnet therapy on the healing of open abdominal surgical wounds; and 2) if such a study was feasible in terms of recruitment and implementation. The protocol called for sixteen participants; however, due to a range of recruitment and implementation problems nine were recruited and five completed the study. Participants were used as their own control: an active magnet and a sham were randomly positioned at each end of the abdominal wound and measurements were taken at intervals over two weeks. Although there was insufficient evidence to justify a larger study using this design, the information the study provided was most instructive. Identified challenges to study implementation are presented and suggestions are made that may prove useful to researchers creating future studies in this area.

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DEDICATION

I would like to dedicate this research to the individuals who participated. Thank you for trying something different and innovative. For your support, I am forever grateful.

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CHAPTER 1: INTRODUCTION

Surgical incisions that have opened following surgery, often due to infection (abscess) or separation of the fascia (dehiscence), present individuals with multiple and complex problems that can drastically affect their lives. Such problems as immobility, pain, excess drainage, disfigurement and varied treatment regimens present ongoing challenges to individuals living with these open wounds.

Despite the significant advances in perioperative and postoperative care over the past few decades, open abdominal surgical wounds continue to be a challenging complication. Wound dehiscence, for example, is associated with prolonged hospital stay and treatment, increased health care costs, and an associated mortality rate of 10% to 44% (Riou, Cohen, & Johnson, 1992; Makela, Kiviniemi, Juvonen, & Laitinen, 1995). Treatment modalities that facilitate and accelerate wound healing are therefore prime areas for nursing research. The search for alternative or adjuvant therapies that will enhance the rate of healing and decrease the cost of wound management is ongoing (Sheffet, Cytryn, & Louria, 2000). Laser treatment, electrical stimulation, hyperbaric oxygenation, maggot therapy, and more recently, non-contact radiant heat bandages are a few of the many suggested adjuvant therapies that facilitate wound healing (Houghton & Campbell, 1999). Research on the efficacy and effectiveness of most adjuvant therapies is limited, with few clinical studies and numerous design inadequacies (Broussard, Mendez-Eastman, & Frantz, 2000). The purpose of this study was to assess the feasibility of using magnet therapy, as another adjuvant therapy, to enhance the healing of open abdominal surgical wounds.

Very little scientific literature exists in the English language to support the growing use of complementary therapies for the treatment of various health problems (Szor & Holewinski, 2002). Magnets used in magnet therapy are easily accessible over-the-counter and from marketing distributors. Published reports suggest that magnet therapy increases circulation and nutrient supply to an affected area, reduces pain, increases melatonin, serotonin and enzyme production, alters cell conductivity and behaviour and inhibits the build up of cholinesterase (Szor, & Topp, 1998). Although magnet therapy has been used in the treatment of many conditions, a paucity of research exists on the use of magnets for wound healing. This study was designed to examine the effect of permanent magnet therapy on the healing of open abdominal surgical wounds and to determine the feasibility of doing such a study with a view to conducting a larger study if results indicate.

Magnetic Therapy

The two most common types of magnets are electromagnets and permanent magnets. An electrical current flowing through a solenoid cylindrical coil directed by a waveform generator creates the magnetism of electromagnets (Whitaker & Adderly, 1998). The waveforms are time varied, creating pulsed electromagnetic fields, or constant, creating static electromagnetic fields (Vallbona & Richards, 1999). Electromagnets or electromagnetic fields are only magnetized as long as the electrical stimulus is present.

The magnetic field of permanent or static magnets is created by the motion of electrons in the atoms of the material that compose the magnet, such as iron or nickel

(Whitaker & Adderly, 1998). Permanent magnets are configured as unipolar (magnets that have only one pole when applied to the skin) or bipolar (magnets have alternating north and south poles in a concentric pattern or grid when applied over the skin) (Vallbona & Richards, 1999). Gauss is a unit of measurement that indicates the strength of a magnetic field (Nikken, 1999). The gauss number represents the number of lines of magnetic force passing through an area of one square centimetre (Whitaker & Adderly, 1998).

Although there are differences between electromagnets and permanent magnets, it has been suggested that a similarity may exist (Whitaker & Adderly, 1998). The movement of an individual or even the movement of cellular fluid within the body may interact with the permanent magnet the individual is wearing to create a pulsed field (Whitaker & Adderly, 1998). This speculation is lacking research support, but if this theory is correct, significant similarities between permanent magnets and electromagnetic therapy may exist.

Research Questions

Is there sufficient evidence to justify a larger study to determine the effect of permanent magnet therapy on the rate of healing of an open abdominal surgical wound? Is such a study feasible?

Sufficient evidence may be determined by the following questions:

Justification

- Is there sufficient evidence of a positive effect to justify a future study?

- Are there any local effects (either positive or adverse) from the magnet placement on the skin and surrounding area?

Feasibility

- Is it possible to attain a sufficient number of participants with similar open abdominal surgical wounds?
- Is it feasible for the caregiver to perform the application of the magnets correctly and consistently?
- What comments may participants have on the application of magnets to their wound?

CHAPTER 2: LITERATURE REVIEW

A literature review was conducted using the data bases CINAHL, MEDLINE, CancerLit, Best Evidence, covering 1966 to present, using the key terms magnet therapy, biomagnetics, magnetism, magnetotherapy, electromagnetism and wound healing. Although studies exist on electromagnetic therapy and wound healing, only one study addresses the effects of permanent magnets on wound healing. In the following review, research relating to permanent magnet therapy will be more thoroughly presented, while studies relating to the effects of electromagnetic therapy on wound healing will be addressed only briefly.

Pulsed Electromagnetic Therapy

Many experimental studies have been published on the effect of electromagnetic fields, on various health conditions. Research using electromagnetic field therapy, for example, has been conducted on neurological disorders (multiple sclerosis, migraine, sleep, Parkinson's disease), bone and joint diseases (arthritis, femoral head necrosis, bone healing) and wound healing (cited in Vallbona & Richards, 1999).

The effects of magnetic fields on the vascular system are of particular interest to the area of wound healing as adequate circulation is essential for a wound to heal (Waldrop & Doughty, 2000). Alterations in chronic disease processes and in rates of wound healing with exposure to pulsed electromagnetic fields is a biologic phenomenon that is not well understood (Vallbona & Richards, 1999). Some studies indicate that exposure to electromagnetic fields increases peripheral blood flow (Erdman, 1960; Fenn, 1969;Ross, 1990). Of particular interest was a study conducted by Mayrovitz and Larsen

(1992) to determine the effects of pulsed electromagnetic field (PEMF) and vascular perfusion. The right forearm of nine participants was exposed to PEMF at a fixed radio frequency of 27.12 MHz with pulse duration of 65 microseconds for 45 minutes while seated in a temperature-controlled room. Baseline data and local skin blood perfusion and temperature were monitored on both forearms during treatment. Post treatment data revealed a significant treatment-time interaction ($p= 0.03$) with a significantly elevated perfusion in the treated arms after 40 minutes of treatment as compared to the control arms where there was no perfusion increase present ($p< 0.01$). This study indicates the possible connection between perfusion augmentation and PEMF treatment (Mayrovitz & Larsen, 1992).

Several studies have shown a beneficial effect of pulsed electromagnetic therapy on the healing of wounds (Itoh et al., 1991; Salzberg, Cooper-Vastola & Byrne, 1995; Cormorsan, Vasilco, Arghiropol, Parslaru, Jreanu, & Stelea, 1993; Goldin, Broadbent, Nancarrow, & Marshall, 1981;Kenkre, Hobbs, Carter, Holder, & Holmes, 1996). Although all these studies suggest that exposure to electromagnetic therapy caused an increase in the rate of wound healing, insufficient sample sizes, lack of randomization or a control group, lack of documentation of statistical analysis, or lack of control of variables, calls results into question. Research findings on the effects of electromagnetic fields in relation to wound healing are therefore inconclusive (Sheffet, Cytryn, & Lourie, 2000).

Permanent Magnet Therapy

Most of the studies of permanent magnet therapy have dealt with the effectiveness of magnets in the control of pain. Three studies (Vallbona, Hazlewood, & Jurida, 1997; Weintraub, 1998; Weintraub, 1999) indicate that the use of permanent magnets may be effective in pain relief while two studies (Collacott, Zimmerman, White, & Rindone, 2000; Hong et al., 1982) do not support these findings.

Vallbona, Hazlewood and Jurida (1997) used a double-blind randomized design to investigate the response of pain to permanent magnets in post polio patients. The researchers applied either active or placebo permanent bipolar magnets (varying in strength from 300-500 gauss) for 45 minutes over a selected point of pain using finger palpation to evaluated trigger point reaction. Results indicated that participants receiving the permanent magnets reported a decrease in pain of 4.4 points ($p < .0001$) on the McGill pain questionnaire when compared to the participants in the placebo group ($p < .005$).

Weintraub (1998) conducted two studies using permanent magnets on individuals with neuropathic pain. The pilot study applied magnetic footpads (475 gauss) for 24 hours a day, for a total of four months, to the feet of fourteen participants with peripheral neuropathies from diabetes and other etiologies. Results indicated 64 % of participants' experienced a clinical benefit (as measured by daily pain scores on a visual analog scale) from the magnetic footpads with 75% of the diabetic participants showing reduction or reversal of neuropathic symptoms. A more recent study by Weintraub (1999) investigated the effectiveness of magnetic footpads on individuals with neuropathic pain (both of diabetic and other etiology) using a randomized, double-placebo crossover design.

Magnetic footpads (475 gauss) and similar looking sham footpads were applied to nine non-diabetic participants with peripheral neuropathies and ten participants with advanced diabetic peripheral neuropathy over a four month period. Overall, 90% of the diabetic participants displayed statistically significant ($p < .05$) reduction and/or resolution of neuropathic pain compared to the 33% of the non-diabetic group ($p < .02$). Placebo effect was evident in all participants with the diabetic group displaying an effect of 38% compared to the non-diabetic group (22%).

Although these three studies (Vallbona, Hazlewood & Jurida, 1997;Weintraub, 1998; Weintraub, 1999) presented findings that indicated the effectiveness of using permanent magnets to reduce pain, the results must be interpreted cautiously. The studies lacked randomization or a control group, used various magnet strengths, lacked control of variables and lacked power due to insufficient sample sizes.

Two studies reported no significant pain relief with the use of a permanent magnet. Collacott, Zimmerman, White and Rindone (2000) conducted a randomized, double blind, placebo-controlled, crossover pilot study on the effects of a permanent magnet on chronic low back pain. Twenty participants (determined to provide 80% power at $p < .05$) were given either an active (300 gauss) or sham magnet applied for six hours a day, three days a week, for one week and then switched for the second week, with a one-week wash out period between the two treatments. The magnets (both active and sham) were worn for a total of 18 hours. The results indicated that neither the magnet nor the sham treatment ($p = .90$) achieved the prospectively determined reduction in pain intensity (2 point reduction on a visual analogue pain scale). This finding must be

interpreted cautiously because the magnet strength was weak and the subjects wore the magnets for a very short time compared with other studies. Similarly, Hong et al. (1982) were unable to determine a therapeutic effect with the use of a magnetic (1300 gauss) and sham necklace on the reduction of chronic shoulder and neck pain on 101 individuals. Subjects wore the necklace 24 hours per day for three weeks; data were collected using a pain scale (0-4) and electrodiagnostic tests.

Pertinent to vascular activity and wound healing, permanent magnetic pads (600 gauss) were found to significantly ($p < 0.01$) increase blood flow and soft tissue and bone growth when applied to the equine third metacarpus on eight horses (Kobluk, Johnston, & Lauper, 1994). Man, Man and Plosker (1999), conducted a double blind study on the influence of permanent magnetic field therapy on wound healing in suction lipectomy patients. Ten post lipectomy participants had magnets in the form of patches (150 – 400 gauss) placed over the operative region and 10 participants had similar sham magnet patches placed over the post operative region. Pain (visual analog scale), edema (0-10 scale), and discoloration or ecchymosis (0 – 10 scale) was evaluated at 1,2,3,4,7 and 14 days postoperatively. Results indicated that the treatment group had significant reductions ($p < 0.05$) in pain on postoperative day 1 through 7, in edema on days 1 through 4, and in discoloration on days 1 through 3 when compared with the control group.

Especially relevant to this proposed study was a case study on the use of magnet therapy to heal an abdominal wound. Szor and Topp (1998) presented a case study of a 51-year-old paraplegic woman with an abdominal wound that had been present for one

year. A magnet measuring 650 gauss was applied over the existing dressing treatment and was worn at all times with the exception of dressing changes. Within two weeks of the magnet intervention, surrounding scar tissue of the wound had changed from a red colour to a colour similar to the patient's skin and within four weeks the wound had healed completely. This case study by Szor and Topp (1998) calls for further research to investigate the therapeutic effects of magnet therapy as a non-invasive, painless, risk-free, and relatively inexpensive treatment option in wound healing. Although case studies lack generalizability, the in-depth information they provide lays a foundation for further research possibilities (Polit & Hungler, 1999; Yin, 1984).

Szor and Holewinski (2002) attempted a study using a randomized controlled double-blind design to investigate the effect of static magnetic therapy on the healing of diabetic foot ulcers. Data from this study could not be analyzed in any meaningful way because of the small sample size (37 subjects). The challenges in conducting the study and considerations for future research were presented.

A valuable resource was a book published by Jerabek and Pawluk (1998), Magnet Therapy in Eastern Europe. The authors compiled thirty years of magnet therapy research in Eastern Europe and reviewed the results. A description of the individual research results presented in the book was not included in this literature review because these studies were published in a foreign language and the authors provided a summary of the research results. However, the information provided by Jerabek and Pawluk (1998) on the mechanism of magnets, precautions and contraindications of magnet therapy were used in

the development of the study methodology and in determining the inclusion and exclusion criteria.

Conceptualization and Operationalization of the Variables

Magnet Therapy

The magnetic field of a permanent magnet is produced through the motion of electrons in the atoms of the material that compose the magnet (Whitaker & Adderly, 1998). The majority of the research studies have used bipolar magnets (magnets have alternating north and south poles in a concentric pattern or grid when applied over the skin) (Vallbona & Richards, 1999). The exact mechanisms of magnetic fields and how they interact with biological tissues to produce biological changes is unknown (Vallbona & Richards, 1999). Penetrability of the magnetic field through body tissue is difficult to measure, but it can be assumed that the measurement of intensity loss of a magnetic field flow through water is similar to the intensity loss through body tissue because of the high water content of body tissues (Vallbona & Richards, 1999). In addition, the magnetic field strength drops off rapidly with distance from the surface of the magnet; therefore permanent magnets have few risks relative to exposure duration (Jerabek & Pawluk, 1998). The application of magnetic fields has been supported by the World Health Organization (1987) as evidence indicates that adverse effects on human health are absent with exposure to static magnetic fields of up 20,000 gauss.

Five possible theories have been postulated on the biological effects of magnetic fields: 1) Solid-state theory of cellular function; 2) Theory of biologic closed electric circuits; 3) Association-induction hypothesis; 4) Ion cyclotron resonance theory; 5)

Resonance theory. These theories involve complex knowledge of other disciplines and to thoroughly explicate them is beyond the scope of this research proposal. Therefore, a brief description of the five theories is given in Appendix A.

Wound Healing

There are conflicting definitions of open abdominal surgical wounds. For the purpose of this study an open surgical wound included wound separations extending to the subcutaneous layer (personal communication, Dr. G. Hollar, March 13, 2001) or to all layers of the abdominal wall (dehiscence) (Riou, Cohen & Johnson, 1992).

Established standards have been developed on the care and treatment of open wounds. The value in providing a wound with a moist environment has been well documented (Ovington, 1999). Occlusive dressing (one type of moist wound dressing) can reduce and prevent infection, stimulate autolytic debridement, reduce wound pain, and stimulate the development of granulation tissue (Eaglstein & Falanga, 1997). Providing a moist wound environment and a standard dressing protocol for the abdominal wounds were included in this study.

A wound heals by the process of angiogenesis (formation of new blood capillaries), deposition of extracellular matrix or granulation tissue, and contraction of wound edges, and epithelialization (Robson, 1997). Wound healing was defined as healing that occurs by secondary intention as evidenced by granulation formation, epithelial cell migration towards the centre of the wound surface from the margins, smaller surface area of the wound and wound contraction (Morison, Moffatt, Bridel-Nixon & Bale, 1997). The expected outcome of wound healing is dependent upon the

conditions of the host including (Rolstad, Ovington, & Harris, 2000) decreased tissue perfusion, nutrition status, infection, diabetes mellitus, corticosteriods, and age (Waldrop & Doughty, 2000).

The progress and quality of tissue healing depends on the viability of tissue (West & Gimbel, 2000). Tissue injury disrupts vascular supply, rendering all wounds relatively hypoxic at the centre (Silver, as cited in West & Gimbel, 2000). Adrenergic vasoconstriction including cold, volume loss, and pain can decrease the availability of oxygen to the wound (Hopf et al, as cited in West & Gimbel, 2000), increasing the chance of postoperative infections (Kurz et al, as cited in West & Gimbel, 2000). The prime determinant of the competency of wound healing depends on the degree of tissue perfusion to the wound, which regulates the supply of oxygen (West & Gimbel, 2000). Other factors contributing to the potential for infection and failed healing are diabetes mellitus, pre-surgical morbidity, hypovolemia, and poor nutrition prior to surgery (West & Gimbel, 2000).

There are conflicting reports on the etiology of wound dehiscence. Riou, Cohen and Housten (1992) in their study of 2,761 patients found that 31 patients suffered from abdominal fascial wound dehiscence after major abdominal surgery. Significant risk factors included age over 65, wound infection, pulmonary disease, hemodynamic instability and ostomies in the incision (Riou, Cohen, & Housten 1992). Additional systemic risk factors that were found to be statistically significant included systemic infection, obesity, hypoproteinemia, hyperalimentation, malignancy, ascites, hypertension and steroid use (Riou, Cohen & Housten 1992). Risk factors not found to be important

included sex, type of surgical closure, type of incision, anemia, jaundice, diabetes, and foreign body in the wound (Riou, Cohen & Housten 1992). Makela, Kiviniemi, Juvoneneand, and Laitinen, (1995) found in their study of 48 patients with midline abdominal wound dehiscence that hypoalbuminemia, anemia, malnutrition, chronic lung disease, and emergency procedure were factors that were significantly associated with wound dehiscence. Vomiting, prolonged intestinal paralysis, repeated urinary retention, and increased coughing were additional statistically significant postoperative factors for the risk of wound dehiscence (Makela, Kiviniemi, Juvoneneand, & Laitinen, 1995). Nonsignificant variables included chronic heart disease, diabetes, obesity, alcoholism, preoperative intestinal obstruction, systemic and local infection, jaundice, use of steroids, type of incision, operating time, and type of wound closure (Makela, Kiviniemi, Juvoneneand, & Laitinen, 1995).

A higher incidence of wound dehiscence is reported with midline incisions (Lehman, Cross, & Partington, 1968; Reitamo & Moller, 1972; Keill, Keitzer, Nichols, Henzel, & DeWeese, 1973).), colon operations, emergency surgery, (Penninckx, Poelmans, Kerremans, & Beckers, 1979) and intra-abdominal infection (Graham, Stevenson, & McHenry, 1998). Mechanical factors that have been implicated in dehiscence include abdominal distension due to obstruction or ileus, retching, coughing, and vomiting (Haddad & Macon, 1980; Reitamo & Moller, 1972; Makela, Kiviniemi, Juvonene and, & Laitinen, 1995). Wound infection has been reported in many studies to have a higher incidence in the development of wound dehiscence (Riou, Cohen, & Johnson 1992; Reitamo & Mollar, 1972; Keill, Keitzer, Nichols, Henzel, & DeWeese,

1973). Cruse and Foord (1980) conducted a 10 year prospective study of surgical wounds at the Holy Cross Hospital and the Foothills Hospital in Calgary and found infection rates of 4.7% overall and 1.8% in the case of clean wounds. In addition, they found infection rates were higher in patients who were 66 years or older, taking steroids, obese, diabetic, malnourished and in those with longer pre-operative hospital stay, longer operation times, and those who had the insertion of wound drainage tubes (Cruse & Foord, 1980).

Age can also be a significant risk factor for wound infection and dehiscence (Cruse & Foord, 1980; Riou, Cohen & Housten 1992). Irvin (1981) found in a review of literature, that wound healing complications appear to be more prevalent in the older surgical patient. However, age alone is not an indicator of poor physiological health, and it is difficult to isolate aging as being detrimental to the healing process (Partridge, 1998). Healing in the aged should be viewed with in the context of the individual's psychological, physiological health (Partridge, 1998), concomitant medical conditions and polypharmaceutical use (Waldrop & Doughty, 2000).

In order to accommodate advancing age as a risk factor for open abdominal surgical wounds, the age of the participants for this study was broad, extending to the range of 18 years to 80 years. For the purpose of this feasibility study, the varied etiology of open surgical wounds and numerous extraneous variables (e.g. infection, obesity, steroids, diabetes, nutrition, vomiting, coughing, abdominal distension) were controlled by applying both an active magnet and a sham on each individual's abdominal wound, that is, by using the subject as his or her own control.

Magnet Strength

No literature exists to suggest the appropriate strength of magnet to be used to facilitate wound healing. Studies relating to the use of a permanent magnet to relieve pain used various strengths of magnets ranging from 300-1300 gauss (no rationale was given of the studies for the choice strength of magnet used). In the case study by Szor and Topp (1998), a 650 gauss magnet was placed on the abdominal wound. Therefore, the strength of the magnet that was chosen for this study was similar to the Szor and Topp's case study. For the purpose of this study, a 700 gauss bipolar magnet was used.

Many studies on the effect of electromagnetic therapy on wound healing have been published with promising results, but little research has been published on the effect of permanent magnets on wound healing. Open wounds provide many challenges for both the individuals who have them and the health care professionals who try to heal them. Therefore, the potential to facilitate and accelerate wound healing is beneficial for all those involved in the treatments. Permanent magnet therapy has the potential to be a safe, flexible and cost effect treatment because the patient can wear it at any time, it is mobile, and is a cheaper alternative to electromagnetic therapy. This study was intended to explore the feasibility and application of a permanent magnet to an open abdominal surgical wound and any possible effects on wound healing.

CHAPTER 3: RESEARCH DESIGN AND METHOD

From the review of the literature in chapter two it is evident that there is a paucity of literature in the area of permanent magnet therapy and wound healing. Therefore, this feasibility study was designed to examine the effects of permanent magnet therapy on the healing of open abdominal surgical wounds using the participant as their own control. In addition to quantitative wound measurements, qualitative data such as comments from participants and nurses, adverse effects to the skin caused by the magnets, and the ease and consistency of nurses implementing the study protocol was examined. The purpose of this chapter is to present the study design and method.

Study Population

The target population for this study were individuals with postoperative open abdominal surgical wounds (vertical or transverse in presentation), including wound dehiscence that measured 12 cm or greater in length. However, after five months of recruitment only three eligible participants had entered the study. Many potential participants had abdominal wounds that measured less than 12 cm and were not considered for the study due to the confinements of the inclusion criteria. After consultation with Dr. William Pawluk (member of supervisory committee and expert on magnet therapy) and the study supervisor, it was decided that the close proximity of the active magnet to the sham would not cause the sham to be magnetize. The length of the abdominal wound was therefore changed to 6 cm or greater to allow for more eligible participants. The inclusion criteria were modified to accommodate this change.

Inclusion and Exclusion Criteria

Inclusion criteria consisted of:

- Participants presenting with open abdominal surgical wound, either vertical, diagonal or transverse in presentation.
- Open abdominal surgical wounds that had occurred within 30 days of opening and were 6 cm or greater when measured in length.
- Participants between 18 years of age and 80 years of age.
- Participants who can communicate and understand English.
- Participants living in the Calgary area.

Exclusion criteria consisted of:

- Participants unable to give informed consent.
- Participants with electronic cardiac pacemaker, implanted pain modulators, insulin delivery systems, cochlear implants or defibrillators (magnet exposure directly over the devices may turn them off).
- Participants who are terminally ill or end stage disease.
- Participants with uncontrolled diabetes.
- Participants taking corticosteriods or other immunosuppressive drugs.
- Participants who are pregnant.
- Participants who have myasthenia gravis (may aggravate muscle weakness).
- Participants with conditions of active bleeding (studies in Eastern Europe reviewed by Jerabek and Pawluk, 1998, indicated a decrease in coagulation with

the use of magnetic fields varying in strength from 4000 Gauss to 250 000 Gauss).

- Cigarette smokers
- Participants receiving other adjuvant wound treatment therapies.
- Participants receiving radiation to abdominal area.
- Participants with hyperthyroidism; adrenal gland, hypothalamic and hypophyseal/pituitary dysfunctions which are clinically significant enough to be endocrinologically or physiologically symptomatic, may be over stimulated and lead to glandular exhaustion (evidence of this only found in Eastern European animal studies, (Jerabek & Pawluk, 1998).

Method

This feasibility study used a randomized, double blind, placebo-controlled, time series design. The participants, investigator, and individuals providing patient care were blinded to the identity of the magnets (active and sham) until after all participants had completed the 14 days of treatment. The research was conducted within the Calgary Health Region (CHR) acute care settings and the community. Participants who met the criteria and agreed to participate in the study became their own control with the placement of an active magnet at one end and an inactive sham at the other end of their wound. Data were collected for 14 days, with wound measurements taken once a week (day 1,7,14) for a total of three measurements. Participants were recruited as close to the time of the wound opening as possible and up to 30 days after opening. After 30 days it

was assumed by the investigator that complex health problems might be affecting the course of wound healing.

Treatment consisted of the application of a 700 gauss permanent bipolar magnet to one end of the wound. The active magnet was placed on either the top or bottom of the wound; the investigator, health care provider, and subject were blinded as to the placement of the active magnet on the wound. The centre of the wound was delineated by lines on the abdomen on either side of the wound using an indelible marker. The active magnet was centrally placed so that the middle of the magnet was aligned with the distal or proximal end of the wound and a sham, identical in appearance to the active magnet was applied to the other half of the wound in the same manner (Appendix B). In order to ensure consistent placement of the magnet on the distal and proximal ends of the wounds, half the circumference of the magnet was traced onto the healthy skin beyond the wound using an indelible marker (Appendix I). With each dressing change the magnets were placed in line with the semicircular tracings. As the wound healed, contraction occurred making the wound smaller, but magnets and shams remained in the original position throughout the study. The active and sham magnets were labelled "T" (top) and "B" (bottom) for vertical wounds or "L" (left) and "R" (right) for transverse wound. The magnets were cleansed with an alcohol swab and enclosed between two sterile transparent dressings. This kept the magnet free from contamination from wound exudates and ensured the placement markings ("T" and "B") remained on the magnet and sham. It also ensured that the magnets (which were clean, but not sterile) did not come into direct contact with the participants' skin and wound. Magnets were secured in place

using tape and remained in place at the proximal and distal ends of the wound at all times with the exception of dressing changes. Participants' dressing regimens were standardized to normal saline soaked gauze, and if necessary, mixed in hydrogel solution and lightly packed into the wound cavity, covered with dry gauze and pad, and secured with tape. This dressing protocol adhered to the principles of moist wound healing. Secondary dressings (dressings covering the wound, but not put into the wound) were changed as necessary to control wound exudates. Nurses changed the dressings as often as required to control wound exudates. Consistency in dressing technique was assured by educating the subject on the dressing technique and providing a written protocol to the subject and nurses caring for the wound (Appendix F). If the dressing protocol was to be changed, the site investigator was to be notified and the participant withdrawn from the study.

Instrumentation

The magnets (active and sham) used for this study measured 4cm in diameter and 3mm in thickness. For the purpose of determining the extension of the magnetic field radiating from the magnet edge, a 700 gauss magnet was assessed using the Magnetic Instrumentation Inc. Gaussmeter (model 7305). With the magnet lying flat on a surface the wand of the gaussmeter was a placed directly on top of the magnet and moved around the surface. Readings varied all over the magnet, but a 700 gauss measurement was attained when the wand was placed centrally on the magnet. When the wand was slowly moved away from the edge of the magnet, measurements showed a rapid decrease in strength (gauss) with no detection of a magnetic field (zero gauss) at approximately one

centimetre from the edge. Another instrument used to measure the magnetic field of a magnet is a compass, which is sensitive to magnetic fields. With the magnet lying flat on a surface the movement of the compass needle was used to detect the presence of the magnetic field by moving the compass towards the magnet. Using this technique, detection of movement of the compass needle occurred at approximately 4.5 cm from the magnet's edge. The discrepancy of the results of the two instruments was noted and it was decided that the more exact measurements from the gaussmeter would be used for this study.

The magnets used in the study were donated by a manufacturer (NuMagnetics Inc., Port Jefferson, NY). Sixteen active magnets and sixteen shams of identical size, weight, and shape, were placed in separate labelled packages. Active magnets and shams were delivered to an unbiased individual, who coded the active magnets with a dot using an indelible marker and covered with opaque tape. Opaque tape was also applied similarly to the sham magnets. Active magnets and shams were placed in separate envelopes and sealed. The active magnet envelopes and the sham envelopes were placed in two unlabelled separate boxes. Both boxes were given to the investigator. When a subject entered the study, an unbiased individual retrieved one envelope from each box and gave it to the investigator who applied the magnet-looking contents of each envelope (containing an active magnet or a sham) to each subject's abdominal wound. The codes identifying active magnets were not revealed until all patients completed the study. Participants were given the choice to keep the active magnet upon the completion of the study.

Sample and Recruitment

Sixteen participants were anticipated to be included in the study. Each participant was used as there own control with both an active magnet and sham applied to each end of the wound. The sample size was considered appropriate for this feasibility study because no previous data existed and the possibility of recruitment and implementation of the study design was unknown. Individuals with postoperative open abdominal surgical wounds (vertical or transverse in presentation), including surgical wound dehiscence comprised the study sample. Potential participants receiving treatment for open abdominal wounds were identified by physicians, Enterostomal Therapy nurses, assistant care managers, and nurses in acute care facilities or the community within the CHR. The site investigator was notified and visited potential participants to explain the study and provide an Introduction Letter (Appendix C) and a Participant Information Sheet (Appendix D) that explained the purpose and subject criteria of the study. An informed consent (Appendix E) was obtained from participants who agreed to participate in the study. The telephone number of the investigator was made available to all participants and nurses to answer any questions on the dressing protocol and research design. It was anticipated that recruitment was to occur over a two-month period, but due to the difficulty of finding potential participants that fit the inclusion criteria and other unforeseen problems, recruitment occurred over a period of ten months.

Data Collection Methods

The investigator collected data upon the start of the study (day 1) and weekly (day 7,14) for the duration of the 14 days of the magnet therapy. Baseline parameters included

demographic data (age, gender, weight), presence of co-morbid conditions, possible cause of wound, type of surgery, and duration of wound prior to the initiation of study (up to 30 days). Subjective assessment of wound appearance (including necrotic tissue and granulation tissue) was kept in a notebook. Wound healing was assessed by weekly measurement of the wound surface area (length x width-cm^2) and wound volume (length x width x depth, cm^3). The investigator used disposable paper rulers that were discarded after each measurement on day 1, 7, and 14. The length of the entire wound was measured in centimetres and the midpoint of the wound was established. At each assessment the length (from midline to end of wound) and width (the approximate middle point of each side of the wound) was measured in centimetres with the subject lying supine. Wound depth was measured at each assessment using a sterile depth gauge (sterile cotton tip applicator marked with wound depth and measured against ruler) at the midpoint of each side of the wound with the subject lying supine. These linear measurements provide an objective basis for the assessment of the overall dimensions of a wound, were inexpensive, readily available and caused minimal discomfort to the patient (Cooper, 2000). Three-dimensional linear measurements techniques (length, width, depth) for wounds are inherently imprecise, particularly with irregularly shaped wound beds, but serial measurements will reflect a tendency toward healing overtime (Cooper, 2000).

Participants were asked to write their comments on supplied paper (Appendix G) on the experience of having a magnet applied to their skin and wound. The investigator observed and kept notes on the effects and application of the magnets on the skin and

wound as well as the participants' verbal comments at each visit (day 1,7, and 14). In addition, caregivers were asked to write their comments on the ease of applying the magnets to the wound, ability to following the treatment protocol in a consistent manner and any other comments on this type of treatment (Appendix H).

Photographs of the wound were taken on day 1, 7, and 14 by the site investigator to monitor the progress of wound healing. These photographs supplemented the subjective assessment on the changes in the wound appearance throughout the 14 days of treatment. Photographs may be used for publication or presentation purposes to illustrate the results of the study.

Ethical Considerations

Participation in this research was voluntary. An information letter was distributed to all potential participants prior to the commencement of the study (Appendix D). If participants were interested in participating in the study, the investigator was notified and met with the subject, at a location convenient for the subject, where a verbal explanation of the study was given and questions will be answered. Those participants who agree to participate in the study were asked to sign an informed consent form (Appendix E). Participants were informed that they could withdraw from the study at any time without consequence.

There is no known risk of the use of magnet therapy to the patient. The World Health Organization has supported the applications of magnetic fields (1987). The magnets were enclosed within a sterile transparent dressing and were positioned on the distal and proximal ends of the wound. The magnets and shams were donated by a

manufacturer (NuMagnetics Inc., Port Jefferson, NY) and participants were able to keep their assigned magnets upon the completion of the study to use or discard as they wish.

Confidentiality was guaranteed by not referring to the participants by name in the database. Participants and photographs of wounds were identified solely by code. The code list, data, and photographs of the wounds were kept in a filing cabinet. The only person with access to the cabinet was the site investigator. The data, code list and photographs will be kept for a period of three years, upon which time they will be shredded and discarded appropriately.

Data Analysis

Dr. Tak Fung, a bio-statistician from the information Technology Services at the University of Calgary, was consulted for both the data analysis planning and statistical calculation phases of this project to ensure the appropriate application, accuracy and interpretation of statistical analysis. Data were entered into the statistical package for the Social Sciences (SPSS, Inc. 2001) twice, to ensure accurate data entry. The small sample size limited statistical analysis and therefore data were presented in a case study format to provide detailed descriptions of the participants and their experience of the study.

A one way repeated measures ANOVA was performed. The within subjects factors were interventions on two levels (active versus sham magnets) and day effects on three levels (measurements on day 1, 7, 14). The intervention by day interaction effect, day effects and intervention effects were tested. If there was a significant day by intervention interaction effect detected, this indicated that the day effect was changed

from intervention to intervention or vice versa. Testing of simple effect was performed if there was a significant day by intervention interaction effect. All statistical significance was based on an alpha level of 0.05.

In order to examine the effect of the magnet and sham treatments on wound healing, differences in within subjects means were analyzed for each visit using a pairwise t-test. The results are presented in Chapter 4.

Time Frame for this Study

The time frame for the study was anticipated to be approximately six months (Appendix I). Ethical approval was anticipated to take one month. The remaining five months was to be divided into three stages: recruitment (1 to 2 months), data collection (3 to 4 months), data entry and analysis (1 month). Recruitment and data collection took ten months at which time it was decided by the principle investigator and the site investigator to commence the thesis writing process using the data collected at that time.

CHAPTER 4: FINDINGS

Nine participants were enrolled over a 10-month period with only five completing the study. All participants who met the inclusion criteria and were approached to enter the study consented to participate. One subject withdrew due to extensive illness, excessive drainage from the wound and the loss of two of the magnets. One subject withdrew due to the development of a rash under one of the magnets, which was most likely caused by moisture being trapped between the magnet and skin. The third subject consented to be in the study, but her physician did not want her to continue. The final participant had to be withdrawn from the study because the nurses removed the markings on the magnets ("T" and "B") making consistent placement of the magnets impossible. Numerous participants were identified for the study, but did not meet the inclusion criteria for the following reasons:

- Lived outside of the Calgary area.
- Had abdominal wounds that were opened for more than 30 days
- Were receiving other adjuvant wound treatments or the wound had been pouched due to increased exudate drainage.
- Complicated abdominal wounds with fistulas draining fecal matter.
- Wounds surgically closed within the 2-week study period.

The purpose of this chapter is to present the results of the data analysis. To begin, the quantitative analysis of the wound measurements are provided. This section is followed by individual case studies of the five participants who completed the study.

Quantitative Analysis

All data were entered into the Statistical Package for the Social Sciences (SPSS, Inc. 2001) twice, to ensure accurate data entry. Participant 5 was not included in the test analysis for length because the measurements were not reliable. Wounds that presented horizontally with "R" and "L" were entered into the statistical package, re-labelled as "B" and "T" respectively. This was done to allow the statistical package to consistently analyze data from all the subjects. It was felt by the investigator that the orientation of the wound on the abdomen, whether horizontally or vertically, did not effect the measurements of length and depth of the wound.

In order to examine the affect of the magnet and sham treatments on wound healing, differences in within subject means were analyzed for each visit. Therefore, it was hypothesised that the magnet treatment would demonstrate greater decrease in both length and depth measurements. The within subject differences in means between the magnet and the sham were tested using a pairwise t-test. Overall, there was no significant effect for differences in sham and magnet means over the three visits. However, there was a trend that magnet measurements decreased more than the sham measure for length (Table 1). This was not seen in the depth measurements, where the sham measurements decreased more than the magnet at visit number three (Table 2)

As there was a decrease in length and depth measures in both the magnet and sham treatments, an additional analysis was done to investigate the mean differences over visits using a one-way repeated measure ANOVA for each group. This analysis showed a significant effect over visits for length measurements for the magnet ($F(2,6)=9.43$,

p=0.014), but there was no significant difference for the sham. The analysis of the depth measurement showed a significant main effect over visits for both the sham (F (2,6)=14.24, p=. 002) and the magnet (F (2,6)=5.09, p=0.037). This analysis of the data indicates that the wound did heal over the three-week study time (Appendix J). The differences of means revealed by the pairwise t-test indicate that the wound healing was independent of the magnet and sham treatment. A conclusion can be drawn that the magnet and sham treatment did not impede healing, nor did it enhance it.

It was concluded that the differences in measurements between the active magnet and the sham could not be interpreted in any meaningful way because of the lack of reliability in the length measurements and the small sample size. A statistician, who concurred with this interpretation, reviewed the data.

Table 1

Pairwise t-Test Indicating Mean and Standard Deviation (SD) for Wound Length Measured at Three Intervals (Visits)

	Wound Length (cm)					
	Magnet (n = 4)		Sham (n = 4)			
Visits	Mean	SD	Mean	SD	t(3)	p-value
Day 1	6.125	2.496	6.125	2.496	-	-
Day 7	5.425	2.948	5.625	2.983	0.700	0.534
Day 14	4.725	2.893	5.000	3.240	0.470	0.670

Table 2

Pairwise t-Test Indicating Mean and Standard Deviation (SD) for Wound Depth Measured at Three Intervals (Visits)

	Wound Depth (cm)					
	Magnet (n = 5)		Sham (n = 5)			
Visits	Mean	SD	Mean	SD	t(4)	p-value
Day 1	2.820	1.365	2.840	0.744	0.030	0.974
Day 7	2.000	1.275	1.980	0.705	-0.040	0.972
Day 14	1.600	1.012	1.280	0.909	-0.730	0.507

Case Studies

The five participants who completed the study will be presented in a case study format to provide a detailed description of the individual experiences and challenges that occurred in the study. In the following text the term "magnets" will refer to both the active magnet and the sham.

Participant 1

The first participant was a 42-year-old female weighing approximately 125 lbs. She had a bowel resection for adhesions and subsequently developed an intra-abdominal abscess. Her incision (vertical presentation) was incised, drained and packed with normal saline gauze. The participant entered the study eight days after the opening of the wound. On the first visit (day 1) the wound measured 11 cm and the base of the wound appeared red with granulation tissue. The skin surrounding her wound had a rash, which she stated

was itchy. An antifungal cream was applied. There was no noticeable wound exudate upon the removal of the previous dressing. The magnets were applied to her wound according to the study protocol.

On the second visit (day 7), the subject had responded well to the anti-fungal cream and the rash on the skin surrounding the wound had disappeared. The participant stated that the magnets were comfortable, but the bottom magnet had slipped downward away from the wound during a shower. Markings for measurement on the abdomen had faded and were reapplied at this time. The site investigator accidentally revealed the active magnet when she cleansed the magnet by using a metal forceps. The participant remained blinded to the placement of the active magnet.

The participant stated that her pain in the area of the wound had improved immensely since the magnets were applied. Prior to entering the study she stated she required pain medication more frequently than was prescribed by her physician. The following day after the magnets were applied, she no longer was "watching the clock" and had not required pain medication for five hours. She was using Tylenol # 3 less frequently during the day and only took a Percocet prior to dressing changes.

On the third visit (day 14), the participant stated that the magnets were comfortable, but the bottom magnet had occasionally slipped away from the placement marking. The participant had developed a skin rash under the tape used to secure the magnets. To avoid further skin irritation, a nurse had applied a dressing (duoderm) to the skin and the tape was secured to the dressing. Upon removal of the magnets a red line was noted on the skin demarcating the outline of the top magnet. The subject denied any discomfort

associated with this redness. The participant stated the bottom magnet pressed into her abdomen when sitting requiring a readjustment in position for comfort. Measurement markings on the abdomen had faded and were reapplied. The home care nurses stated that with the exception of the skin rash caused by the tape, they had no problems with the magnets.

The participant admitted at this visit that she had un-blinded herself the following day after the second visit by putting both magnets together on the night table when they accidentally fell off during the night. Worried that she had somehow magnetized the sham by putting the two discs together, she tested both magnets using a spoon. When she discovered that the spoon adhered to only one magnet, she reapplied the discs to their correct positions on the wound. She also acknowledged that her earrings on the bathroom counter had adhered to one disc. The subject insisted that prior to her un-blinding she was sure that the active magnet was on the bottom half of her wound because she did not feel any pain in that area as opposed to the constant discomfort she felt on the top half of the wound.

Markings on the skin for the magnet placement had disappeared and the midline marking was faint. The participant reassured the site investigator that she had reapplied the markings daily. It is likely that the markings faded and disappeared due to the normal saline dressing and daily showering. Upon completion of the study, it was revealed that the bottom disc was the active magnet.

Table 3

Wound Measurements for Participant 1

Visit	Treatment	Length from midpoint[a]	Width	Depth
Day 1	T	5.5cm	2cm	2cm
	B.[b]	5.5cm	3 cm	3cm
Day 2	T	4cm	1.5 cm	1.7 cm
	B.[b]	4cm	1.5 cm	2.5 cm
Day 3	T	2 cm	1 cm	1.1 cm
	B.[b]	3 cm	1 cm	1.6 cm

[a]Length of wound was measured from the midpoint marking of the wound to the distal point (bottom) or the proximal point of the wound (top). Therefore the top half and the bottom half of the wound from the midpoint marking have length measurements. [b]Active Magnet

Participant 2

The second participant was a 74-year-old female weighing approximately 170 lbs. She had undergone a laparotomy with resection of approximately15 cm of the terminal ileum. She developed an abscess under her incision (vertical presentation) three days later, which was incised and drained. Past medical history included: hypertension, depression/anxiety, Chronic Obstructive Pulmonary Disease, cholecystectomy, collagenous colitis, thyroidectomy and a right inguinal hernia repair. On the first visit (day 1), the subject had a very large gaping wound measuring 19 cm in length and 9 cm in width. Both the base of the wound and the sides were reddened and granulating, with the exception of a rope-like piece of necrotic tissue laying on the bottom left of the wound. The skin surrounding her wound was intact and healthy in appearance. The

participant entered the study five days after her wound had been opened. The magnets were applied to her wound according to the study protocol.

On the second visit (day 7), the participant stated she felt no other sensations in the wound since application of the magnets. She stated that there was no change in her wound pain. She indicated that the bottom magnet had fallen off three times onto the floor. The participant stated she was depressed due to hospitalization and having an open abdominal wound. She complained of itchiness under the bottom magnet. There was no indication of a skin rash when the magnet was removed. Since moisture trapped between the magnet and the skin may cause a rash and itchiness, one layer of gauze was placed under the bottom magnet for absorption purposes. The placement markings for the bottom magnet had disappeared. The other abdominal markings were reapplied. The wound base appeared pink in colour and the necrotic tissue had disappeared. Undermining at the wound edges was noted on the left side of her wound and measured 4 cm. Some necrotic slough was noted in this undermined area. A red demarcation on the skin from the top magnet was noted possibly due to the magnet being applied with too much pressure (Appendix K). Her surgeon had consulted plastic surgery to further assess and treat the wound. The site investigator contacted both surgeons and they agreed to continue with her present wound treatment until the completion of the study in one week.

On the final visit (day 14), the participant stated she had felt no differences or sensations from the magnet therapy. The participant was taking a new anti-depressant and was feeling better. It was discovered that the plastic covered side of the magnet (marked with the "T" or "B") had been placed face down on the abdomen, decreasing the magnets

effectiveness. In addition, both magnets had not been aligned to the placement markings on the abdomen. Again the top magnet left an impression on the skin in the form of a red semi-circular marking. The wound base appeared red with no necrotic tissue present. The participant felt the bottom magnet was the active magnet, but could not articulate why except that it had been "more trouble" because it had kept falling off. The bottom magnet was revealed to be the active magnet.

Table 4

Wound Measurements for Participant 2

Visit	Treatment	Length from midpoint[a]	Width	Depth
Day 1	T	9.5 cm	9 cm	3cm
	B.[b]	9.5 cm	9 cm	3cm
Day 2	T	10 cm	11.5 cm	1.3 cm
	B.[b]	9.5 cm	10.5 cm	1.0 cm
Day 3	T	9.5 cm	11.5 cm	0 cm
	B.[b]	8.5 cm	9 cm	1.3 cm

[a]Length of wound was measured from the midpoint marking of the wound to the distal point (bottom) or the proximal point of the wound (top). Therefore the top half and the bottom half of the wound from the midpoint marking have length measurements. [b]Active Magnet

Participant 3

Participant 3 was a 51-year-old female, weighing approximately 180 lbs. A hematoma had developed under the subject's abdominal incision following a hernia repair with mesh. Her incision was incised and drained and she entered the study four days after the wound was opened. Her past history included: two ceasarean-sections, each

resulting in infection of the incision and hematoma, a previous hernia repair with mesh, and an umbilical hernia repair. She smoked one package of cigarettes a day, had quit for her surgery, and resumed when she developed the open wound. It was decided by the site investigator to include the participant regardless of her smoking (an exclusion criteria) because of the difficulty with recruitment. Her incision was horizontal in presentation and measured 12 cm in length with no gaping of the edges, resulting in a 0 cm width measurement. The wound base appeared pink. The skin surrounding the wound was intact with some redness where the tape had been removed from the skin. Her dressings consisted of normal saline packing mixed with hydrogel. The subject complained of a "stinging" sensation on the left side of her wound especially with the application of the normal saline gauze. The magnets were applied to her wound according to the study protocol.

On the second visit (day 7), the participant felt the active magnet was on the left side of the wound stating, "there seems to be a feeling, but can't explain why." The nurse caring for the participant felt the active magnet was on the left side because the wound appeared to be healing better. The wound base appeared redder with granulation tissue. The participant stated the magnets were comfortable.

On the final visit (day 14), the participant reasserted her belief that the active magnet was on left side because she had "tingling and sharp knife-like" sensations. The participant stated there was no pain on the right side of the wound. The participant stated there had been an odour from the wound and an increase in drainage that was brown in colour. There was a small amount of white slough on the right side of the wound base.

The skin under both magnets was slightly reddened. When revealed, the active magnet was on right side of wound. The participant was shocked when this was revealed, as she was confident that the active magnet was on the left side. The subject kept the active magnet to put on the left side of her wound to help with the discomfort in that area. The subject assured the site investigator she would see her physician about the possibility of a wound infection.

Table 5

Wound Measurements for Participant 3

Visit	Treatment	Length from midpoint[a]	Width	Depth
Day 1	R[b]	6 cm	-	4cm
	L	6 cm	-	2.7cm
Day 2	R[b]	5.5 cm	-	4 cm
	L	5 cm	-	2.4 cm
Day 3	R[b]	5.4 cm	-	3.2 cm
	L	5 cm	-	2 cm

[a]Length of wound was measured from the midpoint marking of the wound to the distal point (bottom) or the proximal point of the wound (top). Therefore the top half and the bottom half of the wound from the midpoint marking have length measurements. [b]Active Magnet

Participant 4

This participant was a 33-year-old male weighing approximately 152 lbs. He had developed an abscessed incision (horizontal presentation) following surgery for a ruptured appendix, which resulted in a dehiscence of the wound and subsequent fistula from the bowel. The wound drained fecal exudates for approximately 3 months when he

returned to surgery for a diverting ileostomy and debridement of the wound. The participant entered the study four days after surgery, while still in the hospital. His past history included: a motorcycle accident resulting in a splenectomy, lacerated kidney, fractured bone, collapsed lung, closed head injury and pneumonia. The wound measured 7 cm in length and was transverse in presentation. The ileostomy was positioned directly above the wound and the pouch made it difficult to secure the magnets to either end of the wound. The wound appeared to have a red base, but was difficult to view because the area was extremely tender and manipulation of the wound caused the subject pain. The horizontal wound was situated in the patient's right lower quadrant of the abdomen. The skin of the abdomen above the wound was elevated due to a natural abdominal fold and presented higher than the skin of the abdomen below the wound. To maintain accuracy, the measurement for depth was taken using the level of the skin below the wound as a reference point. The participant received normal saline packing to the wound. The magnets were applied to his wound according to the study protocol.

On the second visit in hospital, the right side of the wound appeared to have decreased in length. An epithelial bridge had formed on the left side of the wound resulting in a small wound opening to the left of the bridge. This epithelial bridge developed exactly where the depth measurement had been taken on the previous visit. Therefore, the depth measurement was taken to the right of the epithelial bridge. The subject stated there was no pain in the wound and indicated he had no other feelings or sensations to report. The participant stated that the left magnet had slipped downward and out of place the day before. The midline marking on the wound had disappeared. The

wound base appeared red, but it was difficult to assess the small opening to the left of the epithelial bridge. The wound was draining a moderate amount of serous sanguineous fluid.

On the third visit (day 14) at the subject's home, the participant felt that the active magnet was on the right side of the wound because it was itchier. He had discovered the real magnet two days prior because it had stuck to the side of the kitchen sink when he was cleaning the magnets. Both magnets had been improperly placed too far away from the ends of the wound, especially the left magnet (Appendix L). The participant noticed some discomfort when the discs pressed into his abdomen, especially when he bent over or slept on his side with his legs drawn up. The midline marking on the abdomen had disappeared again. The subject stated that he had told his surgeon that he "really thought there was something" to the magnet therapy and it did actually help him heal. The participant thought the active magnet was on the right side of his wound because "it was more itchy". When revealed, the magnet on the right side of the wound was active.

Table 6

Wound Measurements for Participant 4

Visit	Treatment	Length from midpoint[a]	Width	Depth
Day 1	R[b]	3.5cm	0.8 cm	0.5cm
	L	3.5 cm	0.8 cm	2.5cm
Day 2	R[b]	2.7 cm	0.8 cm	1 cm
	L	3.5 cm (epithelial bridge)	0.8 cm	1.5 cm
Day 3	R[b]	2 cm	0.8 cm	0.4 cm
	L	3.5 cm	0.8 cm	1.0 cm

[a]Length of wound was measured from the midpoint marking of the wound to the distal point (bottom) or the proximal point of the wound (top). Therefore the top half and the bottom half of the wound from the midpoint marking have length measurements. [b]Active Magnet

Participant 5

This participant was a 79-year-old male weighing approximately 200 lbs. He had undergone a cystectomy for bladder cancer and ten days later his incision (vertical presentation) was incised and drained due to the formation of an intra abdominal abscess. The participant entered the study five days following the opening of his wound. His past history included: bowel cancer, TURP (Trans-Urethral Prostate Resection) and osteo-arthritis. The participant had used magnet therapy in the past for shoulder pain and felt the magnets were somewhat effective initially, but not for the long term. The subject was eager to enter the study in order to do "anything to heal the wound." The wound base appeared red and measured 6 cm in length. There was a moderate amount of yellow purulent exudate. The wound was being packed with normal saline gauze. The magnets

were applied to the wound according to the study protocol. The subject remained in the hospital.

On the second visit (day 7) in hospital the participant stated he did not think there "is anything to these magnets" and he thought, "it's a farce". The participant had no complaints about the magnet therapy and no other related feelings. He felt the bottom magnet pushed upward in his abdomen due to an abdominal fold. The abdominal markings had disappeared and the markings for magnet placement had faded. The participant had been transferred to a new unit within the hospital and all paperwork related to the study including the consent had been misplaced and was never found. New information sheets were given to the nursing staff. The participant stated he felt that the nurses "just don't know what to do with the magnets". He had told the nurses to reinforce markings on abdomen, but they seemed hesitant to do so. The nurse observed the dressing change and magnet placement at the time of this visit.

The site investigator received a call from a nurse on the participant's unit stating that wound drainage had increased three days ago and was now brown in colour. The family had requested that the magnets be removed because they felt the positioning of the magnets on the wound were impeding the numerous dressing changes the participant had to endure due to the increased drainage. The site investigator informed the nurse that the magnets could be removed and reapplied with each dressing change. Due to the apparent distress the family was having around the change in wound status, the site investigator visited the subject that afternoon (day 13) to take the final wound measurements. The participant felt that "the magnets were not helping, but not hindering either." On

examination, both discs were positioned incorrectly on the abdomen, approximately six inches from the distal and proximal end of the wound (Appendix L). The participant's wife commented that she felt the magnets were not in the right place and tried to move them over. There was no sign of the dressing protocol sheet in the room and the wife had not seen it for sometime. Markings on the abdomen for the disc placements had faded and the markings for the wound measurements had completely disappeared. The top magnet was no longer enclosed in the transparent dressing and the "T" marking on the top of the magnet was gone. The transparent dressing and the "B" marking remained on the bottom magnet. The participant indicated that he did not mind having the magnets on and did not know they were there. His daughter (a registered nurse) wanted the magnets to be removed due to the increased drainage from the wound and the potential of wound complications such as a fistula. It was revealed that the bottom magnet was active. The participant requested to keep the magnet so he could use it for his back discomfort.

Table 7

Wound Measurements for Participant 5

Visit	Treatment	Length from midpoint[a]	Width	Depth
Day 1	T	3 cm	2cm	4cm
	B.[b]	3 cm	2.5 cm	3.6cm
Day 2	T	2 cm	1.5 cm	3 cm
	B.[b]	2 cm	2 cm	1.5 cm
Day 3	T	1.85 cm	1.8 cm	2.3cm
	B.[b]	1.85 cm	1.9 cm	1.5 cm

[a]Length of wound was measured from the midpoint marking of the wound to the distal point (bottom) or the proximal point of the wound (top). Therefore the top half and the bottom half of the wound from the midpoint marking have length measurements. [b]Active Magnet

CHAPTER 5: DISCUSSION

The following discussion identifies some of the impediments and difficulties encountered in conducting this feasibility study. It is hoped that this information will be beneficial in the development of further wound research using larger sample sizes, a diversity in types of wounds, multi-centred sites and creative, innovative healing approaches.

Recruitment

The recruitment of sixteen participants for this feasibility study could not be achieved for a number of reasons. Based on the number of open abdominal surgical wounds seen by the investigator in her practice as an Enterostomal Therapy Nurse, recruitment of potential participants was not expected to be a problem. In reality, many unforeseen problems arose during the course of the study. For recruitment of participants, the site investigator was relying on the surgeons, nursing staff, and Enterostomal Therapy Nurses in both the community and acute care facilities. The expectation that hundreds of health care professionals would remain informed about the study and remember to contact the site investigator, in addition to their many responsibilities, was unrealistic. Regardless of the many recruitment tactics and the help of two student nurses, potential participants were unintentionally missed. It was an almost impossible task to penetrate all potential departments with information about the study, and reinforce this information regularly. On two occasions the site investigator was not given the opportunity to inform potential participants or their physicians of the study because the nurses had stated they were not interested in participating. It was difficult for the site investigator to control

what kind of information nurses gave potential participants and their physicians about the study resulting in decisions possibly being made with inaccurate information. The process of recruitment was found to be time consuming and required the site investigator to be physically and frequently present at each site, which was difficult due to work responsibilities and personal commitments.

Having an individual within each surgical unit, wound clinic and community setting, who had a vested interest in the research to identify participants would have been helpful. Many potential participants were identified on a surgical unit in an acute care facility because an individual who worked on the unit took an interest in the study. Szor and Holewinski (2002) cited several recruitment problems in their attempt to study the effects of magnetic therapy on the healing of diabetic foot ulcers. One of their suggestions was to have a study coordinator (when the investigator could not be present) whose primary focus would be to recruit potential participants, obtain consents, and follow-up on compliance of the research protocol with participants and caregivers. Szor and Holewinski (2002) further suggested having a multi-centred study for the recruitment of larger numbers of participants over a shorter period of time. Both of these suggestions would have been helpful in solving some of the recruitment problems in this study.

Support and Interest

Overall, health care professionals showed interest and support in this study. Many physicians were sceptical about the effects of magnet therapy on wound healing, but had no objections to their patients participating in the study. One physician did not want her patient to continue in the study due to reasons other than the magnet therapy. Most nurses

were genuinely interested in the study and eager to participate. Some nurses however, appeared irritated at recurring weekly phone calls to remind them about the study. Some individuals were found to have provided inconsistent responses with respect to the levels of interest in the study when the research assistants and the site investigator compared notes. On one occasion the site investigator was not informed that a nurse removed the magnets from a female participant due to a rash under a magnet and encouraged the participant to withdraw from the study. The participant informed the investigator of this decision a day after the magnets were removed.

It was discovered that regardless of the amount of education and information provided to the nurses about the study or the availability of the investigator, the success of the study relied on the nurses support and interest and their time to implement the study protocol. The following detailed example of one participant who was withdrawn from the study, illustrates the difficulties the nurses encountered when implementing the study protocol. This participant had to be withdrawn from the study on day 7 because the nurses repeatedly stated they did not know how to apply the magnets to the abdominal wound. Although the nurses had removed the transparent dressing enclosing the magnets and the "T" and "B" markings, they continued to apply the unmarked magnets to the wound. In addition, the dressing protocol had been misinterpreted by some of the nurses and the dressings applied incorrectly. The site investigator was informed on day six of the study by an ET nurse in the hospital, that the nurses were having difficulties with the dressing protocol. The site investigator talked to the nurse caring for the participant and was told she and the nurses could not find any information on the study. The dressing

protocol and study information were found at the front of the participant's chart and the phone number for the site investigator was taped to the front plastic cover of the chart. This example was extreme, but indicated to the site investigator that more frequent phone calls or visits to the unit to ask if there were any questions or concerns, may have alleviated comprehension problems regarding the study protocol.

Of interest, the site investigator found that when she informed health care professionals of the study she would elicit a more approving attitude toward her study if she downplayed the magnet therapy and the study outcomes. One physician stated that he doesn't "believe in those kind of therapies," but would assist in the recruitment of participants. One nurse stated after an information session about the study, that she was relieved that the site investigator was realistic about the study outcomes and not a fanatical advocate for alternative therapies. Another nurse stated she thought the study sounded like "witch-craft to me."

In addition, the approval of this study's research proposal by the Conjoint Health Research Ethics Board took approximately seven months. Very little was communicated to investigators as to why the process of approval was so delayed. The research proposal was sent to three outside evaluators for feedback. The investigators were eventually asked to meet with the Ethics Board to answer questions. Upon completion of this meeting, the board approved the research proposal. Although the reasons for the lengthy approval process cannot be confirmed, it was presumed that the Ethics Board was concerned with methodology. The Board wanted a more rigorous design including an experimental and control group. This is extremely difficult to accomplish when

conducting research on wounds because it is impossible to get a homogenous group of individuals with similar wounds and etiology. This issue would need to be resolved with another study design.

Wound Measurement Technique

Wound measurement was conducted using abdominal markings beside the wound indicating the mid-point of each wound and the midpoint of each half of the wound. Measurements of width, depth, and length were taken using these markings at each visit. Markings were made with an indelible marker, which faded over time due to exudates from the wound, dressing changes and bathing. The nurses did not consistently re-apply the markings when necessary on the abdomen. Therefore, all five participants had markings that faded substantially or disappeared altogether between each weekly visit. The site investigator reapplied new markings each week using the wound length at that visit which was usually smaller due to healing. This led to inconsistent wound measurements because the mid-point markers varied with each visit. Therefore, it was impossible to ascertain if there was a change in the length, width or depth of each half of the wound because there was no midline marking to use as a consistent reference point.

In retrospect, a different wound measurement tool that did not depend on nurses for accuracy should have been used. A computerized measurement tool (Computerized Photogrammetry by VERG Technologies, Ltd, Winnipeg, Manitoba Canada) is now available that captures and calculates wound dimensions using a digitized image of the wound (Goodman & Salcido, 2002). Although this can be a costly tool, it would provide consistent and accurate measurements of a wound over a period of time producing more

meaningful data. Other more technical measurement techniques to indicate wound healing with magnet therapy could be considered in a more rigorous study design, such as wound bed biopsy to measure microbiological changes in the wound and vascular studies to measure blood flow to the wound area. In addition, minimizing the number of caregivers caring for the wound would increase consistency of the research protocol. For example, wound care clinics, which typically have two to three nurses providing treatment, would create better compliance and consistency than an acute care facility where several caregivers were involved. As mentioned previously, an on-site study coordinator would also be helpful in this area.

The researcher tried to anticipate and control the many extraneous variables within this study, but it was discovered the major detriment to the study design was the reliance on nurses to follow instructions of the study protocol. This became an unanticipated factor that was not easily controlled within this study.

Mechanics and Blinding

The consistency of the placement of the magnets with each weekly visit became a problem. Magnets had a tendency to slip out of place or fall off due to increased moisture or exudates from the wound. Due to placement markings on the abdomen fading from week to week, the magnets were not always reapplied to the same position through out the study. Other problems with magnet placement included; magnets with the "T" or "B" being placed face down on the wound, magnets being placed on the abdomen no where near the wound, and the transparent covering on the magnets removed and the "T" and "B" markings subsequently washed off. With one participant in an acute care facility, two

magnets were lost between separate visits, both being the active magnet. It was suggested that because of the frequent number of dressing changes per shift, due to a large amount of wound exudate, the magnets could have been inadvertently discarded with the removal of the saturated dressings.

Some participants stated that the magnets on the lower part of their wound were uncomfortable, especially when sitting. This was due to the rigidity of the magnets being secured on the distal portion of a wound, low on the abdomen, usually in or near a natural abdominal fold resulting in the magnets pressing into the skin. Participants found that re-adjusting their position generally helped alleviate any further discomfort. In addition, to prevent magnets from slipping on the abdomen, they were secured tightly with tape, which sometimes caused discomfort to the participant and reddening of the skin under the magnets, probably due to pressure. A possible solution to this problem would be to use larger magnet pads that are flexible and would conform to the abdomen. These pads might be more comfortable for the participants and possibly adhere better to the abdomen because of their flexibility and greater coverage of surface area. These types of magnetic pads are presently available by a magnet manufacturer such as Nikken Inc. Several types of tape and dressings were used to secure the magnets to the wound, but it appeared the amount of exudate from the wound caused the slippage of the magnets rather than the type of securing device used.

Two participants inadvertently discovered which magnet was active, subsequently un-blinding themselves between day 7 and 14. The first participant of the study was concerned about affecting the sham magnet when she put the two magnets, back to back,

when they fell off during the night. She used a metal spoon in the morning to see if both magnets were active. Another participant was rinsing the magnet in a metal sink and accidentally dropped a magnet, which adhered to the sink. In addition, the site investigator un-blinded herself by cleansing the magnet during a dressing change using a metal forcep. Maintaining a double blind study when using magnets is a challenge as metal is pervasive in the hospital and in our surroundings, making it easy for the investigator and the participants to inadvertently reveal the active magnet. With subsequent participants, information was not provided regarding keeping the magnets six inches apart to avoid the sham from being magnetized by the active magnet. Although this procedure was recommended to the site investigator, it was discovered that the sham and the active magnet being in close proximity to each other did not cause the sham to become magnetized.

Feasibility and Justification

The purpose of this study was to assess the feasibility of using magnet therapy, as another adjuvant therapy, to enhance the healing of open abdominal wounds. The study results did not provide sufficient evidence of a positive effect of magnet therapy on the rate of healing of an open abdominal surgical wound. However, the results were dependant on the study design, which had some unexpected problems. The feasibility of the nurses to perform the application of the magnets correctly and consistently and the recruitment of sufficient number of participants with similar open abdominal wounds were difficult. As previously discussed, these problems could be resolved by having a study coordinator and using more advanced tools for wound measurements. In addition,

research on animal models should be considered to attain a more rigorous design and a controlled wound environment. This would provide evidence to justify further studies on the effect of permanent magnet therapy on wound healing. An animal model was considered for this study, but was not feasible for a variety of reasons, including cost. Moreover, it was felt to be important to use human subjects to examine the feasibility of the study, which would provide more applicable and practical information to be used by specialists in wound healing and future researchers.

Although, the quantitative results were not significant, the qualitative data indicated some potential areas for further study. The feedback provided by two of the study participants indicated that magnet therapy might have had a positive effect on pain relief in the wound area. Pain management and wound healing using magnet therapy could be further explored in future research.

Three of the participants believed that the magnet therapy was effective in healing their wounds. Although the study results did not reflect this belief, the psychological benefits of any treatment, whether physiologically effective or not, is an area that requires further investigation within the health field. Lastly, the study results did provide some indication that the application of the magnets could be uncomfortable with positioning and may produce minor skin irritations, all of which were easily resolved.

Overall, the qualitative data seemed to indicate that magnet therapy might have the potential to affect wound healing and pain relief. Although the statistical analysis indicated some significant results, these results cannot be interpreted because of the lack of reliability in the length measurements and the small sample size. While not statistically

meaningful, the findings may be suggestive of a magnet effect. Researchers designing larger studies can use the results of this study to avoid some of the pitfalls identified. In addition, the research study exposed health care professionals to magnet therapy and indicated that nursing research can and should be done in the area of complementary and alternative therapies. Many complementary and alternative therapies are readily available to the public; this exposure may encourage others to develop research to provide much needed scientific evidence for these therapies and treatments.

Conclusion

Individuals who experience open abdominal wounds are faced with multiple challenges that can drastically change their lives. Participants in this study experienced prolonged hospital stays, confinement to home for treatments, pain, disfigurement, loss of income and stress among other ongoing challenges in living with their open abdominal wounds. Therefore, all the participants were eager to participate in a study using magnet therapy that could potentially accelerate wound healing.

The idea for this study began when I took a university course, offered by the Faculty of Nursing on complementary and alternative therapies. I became interested in the potential healing effects of magnet therapy on the rate of wound healing. This therapy was non-invasive, relatively safe, potentially cost effective, simple to use, and did not limit a person's mobility. Furthermore, magnets were readily available through retail outlets to the public. Therefore, this feasibility study was developed to investigate the possibility of the effects of magnet therapy on of wound healing.

To conduct research on wound healing is challenging due to the many extraneous variables. No two wounds and their etiology are alike making a control and experimental group extremely difficult to attain. To attempt to do wound healing research using a complementary therapy, when very little research had previously existed created far more challenges than I could imagine. It was an undertaking that was both rewarding and frustrating at times, but provided an immense learning opportunity in understanding the process and challenges of conducting research. Although the findings did not indicate an effect of magnet therapy on wound healing, an innovative study design was developed and much information was gained for further research on magnet therapy.

Many different wound treatment modalities are used to enhance wound healing and innovative treatments are regularly introduced to the market. As a future Advanced Practice Nurse in Enterostomal Therapy, I believe that I have acquired a strong appreciation of the research process. I feel well prepared to evaluate the efficacy and effectiveness of the many wound healing treatments that are brought to the Enterostomal Therapy practice. Having experienced the challenges of research in wound healing using a complementary therapy, I have learned to broaden my perspectives, challenge my philosophy, expand my available options towards patient care, and seek innovative solutions to nursing practice problems. In addition, having had an opportunity to form interpersonal relationships with the study participants has provided me with a greater insight into their experiences and appreciation of what they are willing to endure to regain their lives. Difficulties with recruitment and the implementation of the study protocol, illustrated the importance of collaboration and cooperation with the

multidisciplinary team in providing treatments and quality of care to individuals. This, in turn, has impacted my approach and treatment of individuals with wounds and other problems related to my specialty.

The main objective of this study was to determine if such a study was feasible in terms of recruitment and implementation. The detailed information provided by the study and resolution of the methodological difficulties could result in future study designs that are more rigorous. As previously discussed, research on animal models may be considered to attain a more rigorous design and a controlled wound environment. Further studies are required on magnet and other complementary treatments to provide scientific evidence in support of therapies that are readily available to the public.

The purpose of this study was to assess the feasibility of using magnet therapy, as another adjuvant therapy, to enhance the healing of open abdominal wounds. Although, the results of this study may indicate that the application of magnet therapy to open abdominal wounds to enhance healing can be difficult, the experience of this research study provided me with far more challenges, information, knowledge, and insight than was ever thought feasible.

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APPENDIX A

Theories on the Biological Effects of Magnetic Fields

Five possible theories have been postulated on the biological effects of magnetic fields.

1. Solid-state theory of cellular function. This theory proposes that magnetic fields interact at the atomic and subatomic levels in biological systems and that micro regions within cells and molecules are sensitive to external magnetic fields leading to changes in enzymatic reactions, conduction velocity and cellular potentials (Vallbona & Richards, 1999).

2. Theory of biologic closed electric circuits. This theory postulates that because the human cardiovascular system serves as a conduit for the transmission of electrical energy to large areas of the body, a connection can be made that a magnetic field from either a permanent magnet or an electromagnetic device could also induce electrical currents with in the elements of the vascular systems in one area of the body and be transferred to other areas (Vallbona & Richards, 1999; Rubik, 1997).

3. Association-induction hypothesis. Magnetic fields could induce a change in the sensitive foci (cardinal sites) on molecules and when stimulated adequately could induce effects throughout the molecules cardinal sites that would lead to profound changes in physiological function (Vallbona & Richards, 1999). Another possibility of this

theory postulates that molecules within the blood, when exposed to a magnetic field, may be changed to a new conformational state, which may bring about the changes in physiologic function (Vallbona & Richards, 1999).

4. Ion cyclotron resonance theory. This theory suggests that there is a connection between the biological effects of electromagnetic fields (both static and alternating) on the ionic charge of ions such as calcium, potassium and magnesium. (Vallbona & Richards, 1999; Rubik, 1997).

5. Resonance theory. A major implication of this theory regarding the living state and electrogravitational mechanisms is that the application of a picotesla magnetic field may correct some neurological disorders.

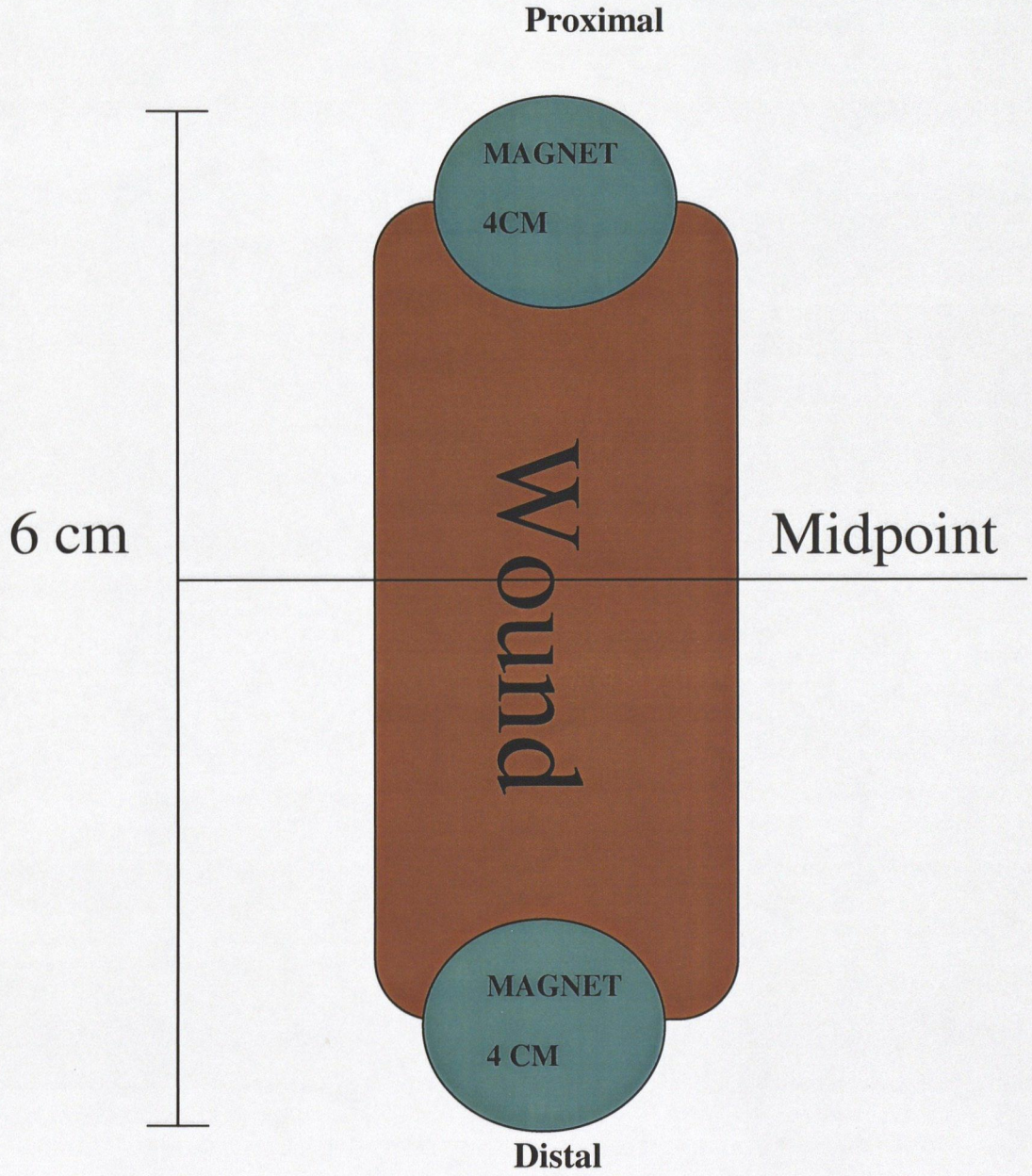
Water may also play a significant role in explaining the therapeutic effects of magnetic fields and further evaluation of the physical basis of this concept should be pursued (Vallbona & Richards, 1999).

The theory of biologic closed electric circuits and the effects magnetic fields on the vascular system is of particular interest to the area of wound healing. Alteration in chronic disease processes and in rates of wound healing with exposure to pulsed electromagnetic fields is a biologic phenomenon that is not well understood (Vallbona & Richards, 1999). Human and animal studies have indicated that increased peripheral blood flow results from exposure to electromagnetic and permanent magnet exposure (Erdmam, 1960; Fenn, 1969; Kobluk, Johnston, & Lauper, 1994). The effect of magnetic

fields on the vascular system is particularly pertinent to the area of wound healing because adequate circulation is essential for a wound to heal (Waldrop & Doughty, 2000)

APPENDIX B

Picture of Magnet Placement on the Wound



APPENDIX C

Introduction Letter for Surgeons, Physicians and other Recruitment Volunteers

A feasibility study to explore the use of magnet therapy on wound healing.

The purpose of this feasibility study is to determine the feasibility of using magnet therapy to enhance wound healing following an opening of an abdominal surgical wound.

The site investigator, Mary Hill, is a registered nurse and Enterostomal Therapist (specialty in wound, ostomy and incontinence care) who is a student in the Masters of Nursing program at the University of Calgary, Faculty of Nursing. She is highly experienced in managing wounds of the type examined in this study.

Despite the significant advances in perioperative and postoperative care over the past few decades, wound dehiscence after abdominal surgery continues to be a challenging complication which prolongs hospital stay and treatment, results in increased health care costs, and has an associated mortality rate of 10% to 44% (Riou, Cohen, & Johnson, 1992; Makela, Kiviniemi, Juvonen, & Laitinen, 1995). For this reason, wound care and treatment modalities that facilitate and accelerate healing are prime areas for research.

Magnet therapy is an alternative or adjuvant therapy that is reported to increase circulation and nutrient supply to an affected area, reduce pain, increase melatonin, seratonin and various enzyme production, alter cell conductivity and behaviour and inhibit the build up of cholinesterase (Szor & Topp, 1998). Although magnet therapy has been used for the treatment of many conditions, only one published case study has

examined the effects of magnet therapy and wound healing. Therefore, the purpose of this feasibility study is to determine the feasibility of using magnet therapy to enhance wound healing following an opening of an abdominal surgical wound.

Participants being sought for the study are individuals with an abdominal surgical incision (either vertical or transverse in presentation) that has opened due to infection or other causes. All open abdominal wounds must have occurred within thirty days of opening or dehiscence and measure 12 cm or more to be included in the study. All participants must be between 18 years of age to 80 years of age.

Excluded from the study will be participants unable to give informed consent, with an electronic cardiac pacemaker, implanted pain modulators, insulin delivery systems, cochlear implants or defibrillators, myasthenia gravis, conditions of active bleeding, terminally ill or end stage disease, uncontrolled diabetes, pregnant, cigarette smokers, taking corticosteriods or other immunosuppressive drugs, receiving other adjuvant wound treatment therapies, and receiving radiation to abdominal area. Also excluded will be participants with hyperthyroidism; adrenal gland, hypothalamic and hypophyseal/pituitary dysfunctions which are clinically significant enough to be endocrinologically or physiologically symptomatic.

Two discs (active magnet and sham magnet) will be applied at each end of the wound for the duration of 14 days according to a coded protocol. The investigator, health care provider and participants will not know whether the active magnet is placed on the top or bottom of the wound. Participants' dressing regimens will be standardized to normal saline soaked gauze mixed in hydrogel solution and lightly packed into the wound cavity,

covered with dry gauze and pad, and secured with tape. The type of secondary dressings (dressings covering the wound, but not put into the wound) may be changed as necessary to control wound exudates. A health care provider will change dressings as often as required to control exudates. Routine dressing changes, care, and dressing protocols will not change for the duration of the study. In the event that the dressing protocol has to be changed the site investigator will be notified and the participant will be withdrawn from the study. The site investigator will take wound measurements and photographs of the wound at the start of the study and weekly for the duration of the study (14 days). The site investigator will make subjective observations of local effects of the wound and note any comments from participants and caregivers regarding the magnet therapy. Participants and caregivers will be asked to write comments down about the experience of magnetic therapy.

There is no known risk of the use of magnet therapy. The application of magnetic fields has been supported by the World Health Organization (1987), which reported that there are no adverse effects of magnetic fields on human health.

Your cooperation in this study in helping to recruit potential participants is greatly appreciated. Results from this study will provide much needed information of magnet therapy and its potential effects on wound healing.

Please contact Mary Hill (site investigator) at 253-5659 if you have any potential participants who could participate in this study.

Note: Please contact Mary Hill for complete description of references.

APPENDIX D

Information Sheet for Participants

The purpose of this feasibility study is to determine the feasibility of using magnet therapy to enhance wound healing following an opening of an abdominal surgical wound. No research has been conducted, with the exception of a published case study, on the effects of magnet therapy and wound healing.

The site investigator, Mary Hill, is a registered nurse and Enterostomal Therapist (specialty in wound, ostomy and incontinence care) who is a student in the Masters of Nursing program at the University of Calgary, Faculty of Nursing.

If you agree to participate in the study, you will have two small, round discs (one active magnetic, one fake magnet) placed at each end of the wound for the duration of 14 days. The two discs will be secured on the top and bottom of your abdominal wound by tape. The investigator, health care provider and yourself will not know whether the active magnet is on the top or bottom of the wound. Routine dressing changes, care, and dressing protocols will not change for the duration of the study. A health care provider will change dressings as often as required to control exudates. If your physician requires that your dressing method should be changed, Mary Hill will be notified and you may be asked to withdraw from the study. The site investigator will take wound measurements at the start of the study and weekly for two weeks. Measurement of the wound entails measuring the size of your wound using a transparent measuring ruler and a sterile cotton tip applicator. The top, bottom and middle part of your wound will be delineated by making lines on your abdomen with an indelible marker. This will assist the health care

professional with the placement of the magnets when dressing is changed. Photographs of your wound will be taken at the beginning of the study and weekly, at the same time as wound measurements. The photographs will be used to monitor the wound healing progress. They may also be used in reports of the results in future publications and presentations. You will be asked to write any comments you may have regarding your experience on using magnet therapy.

There is no known risk to the use of magnet therapy. The application of magnetic fields has been supported by the World Health Organization (1987), with adverse effects on human health being absent with exposure to static magnetic fields of up to 20,000 gauss.

Confidentiality will be guaranteed by not referring to you by name in the database or on photographs of your wound. This anonymity is assured by assigning you a code that corresponds to your name. The code list will be kept in a locked filing cabinet. The only person with access to the cabinet will be the site investigator (Mary Hill).

You have the option of choosing to participating in the study or withdrawing from the study at any time. If you agree to participate in this study please advise your caregiver, nurse or physician of your interest. Mary Hill will contact you to set up an initial meeting to answer any questions you may have and to formally admit you as a participant into the study.

APPENDIX E

Consent Form

Consent for Participation in Research Study

A feasibility study to explore the use of magnet therapy on wound healing.

Principal Investigator: Dorothy Hughes RN, BA, MSc, Ph.D

Site Investigator: Mary Hill (Masters of Nursing Student) RN, BScN, ET

This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you a basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

The purpose of this feasibility study is to determine the feasibility of using magnet therapy to enhance wound healing following an opening of an abdominal surgical wound. You have been asked to take part because your incision (wound) is open, it is over 6 cm in length, and you have had it less than 30 days. If you agree to take part in the study you will have two small, round discs placed on top and bottom of your open wound for 14 days. One disc will be an active magnet, and one will be a fake magnet. There is no known risk to the use of magnet therapy. The investigator, health care provider and you will not know which is the active magnet until the end of the study. Your nurse or the investigator will change your dressing as necessary, following the method routinely used in treating wounds such as yours. This same method will be used each time your dressing

is changed. If your physician requires that your dressing method be changed, Mary Hill will be notified and you may be asked to withdraw from the study.

Mary Hill will visit you in the hospital or at home at the start of the study (day 1) and weekly (days 7,14) for a total of 3 visits. She will examine your wound, change the dressing if necessary, and take measurements (length, width and depth of your wound). A transparent ruler and sterile cotton tip applicator will be used to measure the wound. Photographs will be taken each time to monitor healing. The photographs may be used for publication of results or for presentations. Photographs will occur at the same time as wound measurements. You will be asked to write any comments you may have regarding your experience on using magnet therapy.

Confidentiality will be guaranteed by not referring to you by name in the database. You will be assigned a code number. Your name is associated with your code number only on a list that is kept in a locked filing cabinet. The only person with access to the cabinet will be the site investigator. Only your wound will be photographed, so no one will be able to identify you from the photo.

There will be no financial cost to you to participate in this study.

You will receive new and updated information during the course of the research as relevant.

The only direct benefit to you from being in this study is possible satisfaction from helping in this important research and contributing to scientific knowledge. Your wound might or might not heal faster. Taking part in this study is completely voluntary. If you decide not to take part, there will be no penalty to you. Your routine care will

continue as usual. You may drop out of the study at any time. There will be 16 people with open abdominal wounds in the study.

In the event that you suffer injury as a result of participating in this research, the physician responsible for your care will be notified for assessment and follow-up. There will be no compensation provided for you by the University of Calgary, the CHR, or the site investigator. You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. Your continued participation should be as informed as your consent, so you should feel free to ask for clarification or new information throughout your participation. If you have further questions concerning matters related to this research, please contact:

Site Investigator: Mary Hill

253-5659

Principal Investigator: Dr. Dorothy Hughes

Faculty of Nursing, University of Calgary

220-4650

If you have any questions concerning your rights as a possible participant in this research, please contact Pat Evans, Associate Director, Internal Awards, Research Service, University of Calgary, at 220-3782.

I have read the information in the accompanying information letter and in this consent and agree to be part of this study. I can withdraw from this study at any time and for any reason without affecting the relationship I have with any of the researchers.

Participant's Signature _____ Date_____

Investigator Signature _____ Date_____

Witness' Signature_____ Date_____

A copy of this consent form has been given to you to keep for your records and reference.

APPENDIX F

Information Sheet for Wound Dressing Protocol

To Whom It May Concern:

This patient is involved in a study on the impact of magnets on the rate of abdominal wound healing. There is a strict wound dressing protocol that must be adhered to for the duration of the study (14 days). The site investigator will be measuring the wounds on days 1, 7, and 14. Wound measurement will be coordinated as much as possible with dressing change on those designated days.

Wound Protocol

1. Prior to removing old dressing note the placement of the magnets on the ends of the wounds. Remove magnets (do not remove transparent dressing that magnets are enclosed in unless there is damage) and cleanse with normal saline. Put aside. Note: if transparent dressing (Opsite) needs changing, remove magnet, cleanse magnet with alcohol swab and place magnet between two new transparent dressing and seal (adhesive side to adhesive side). Do not disturb any markings or tape on the magnet.
2. Remove old dressing and packing.
3. Cleanse wound with normal saline.
4. Lightly pack wound with normal saline gauze,(and/or mixed with hydrogel).
5. Notice the semicircular markings on the skin above the distal and proximal ends of the wound. Place the magnet marked with a "T" on the proximal portion (top) of the wound so that the top half of the magnet is in line with the semicircular

marking on the skin. Place the magnet marked with a "B" on the distal portion (bottom) of the wound so that the bottom half of the magnet is in line with the semicircular marking on the skin. Secure magnets in place with tape (Mefix).

6. Cover wound with abdominal wound dressing (ABD Pad or other appropriate covering dressing) and secure with tape.
7. Change dressing as necessary to control exudates.

APPENDIX G

Comment Sheet for Participants

Please write any comments you may have on the experience of having magnetic therapy applied to your wound.

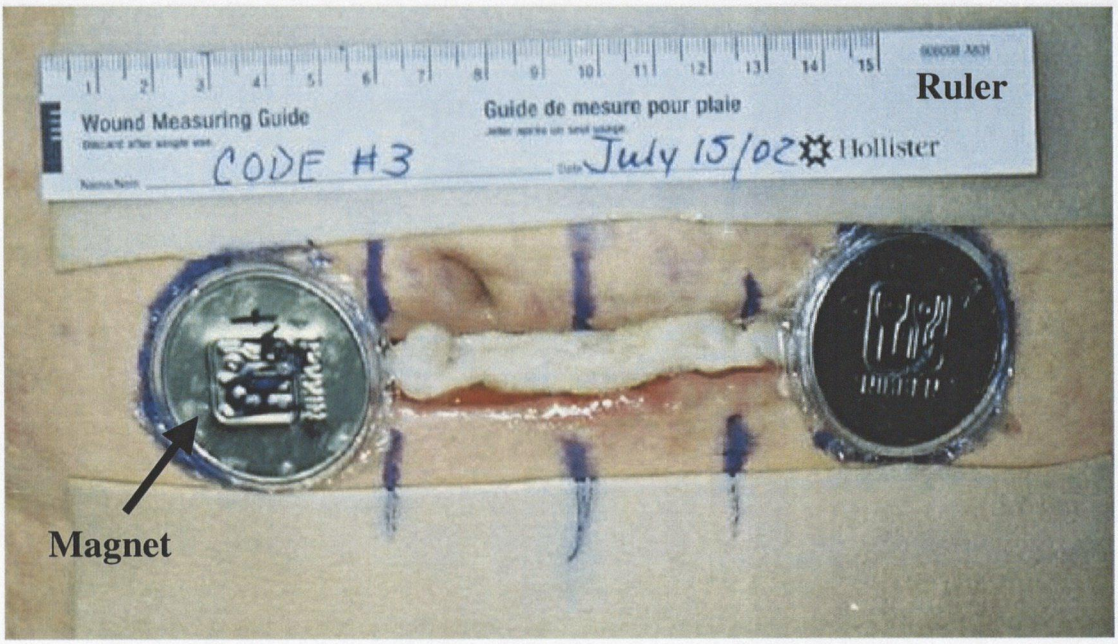
APPENDIX H

Comment Sheet for Caregivers

Please write any comments below on the ease of applying magnet therapy to the wound and any other comments you may have related to the application of this type of treatment.

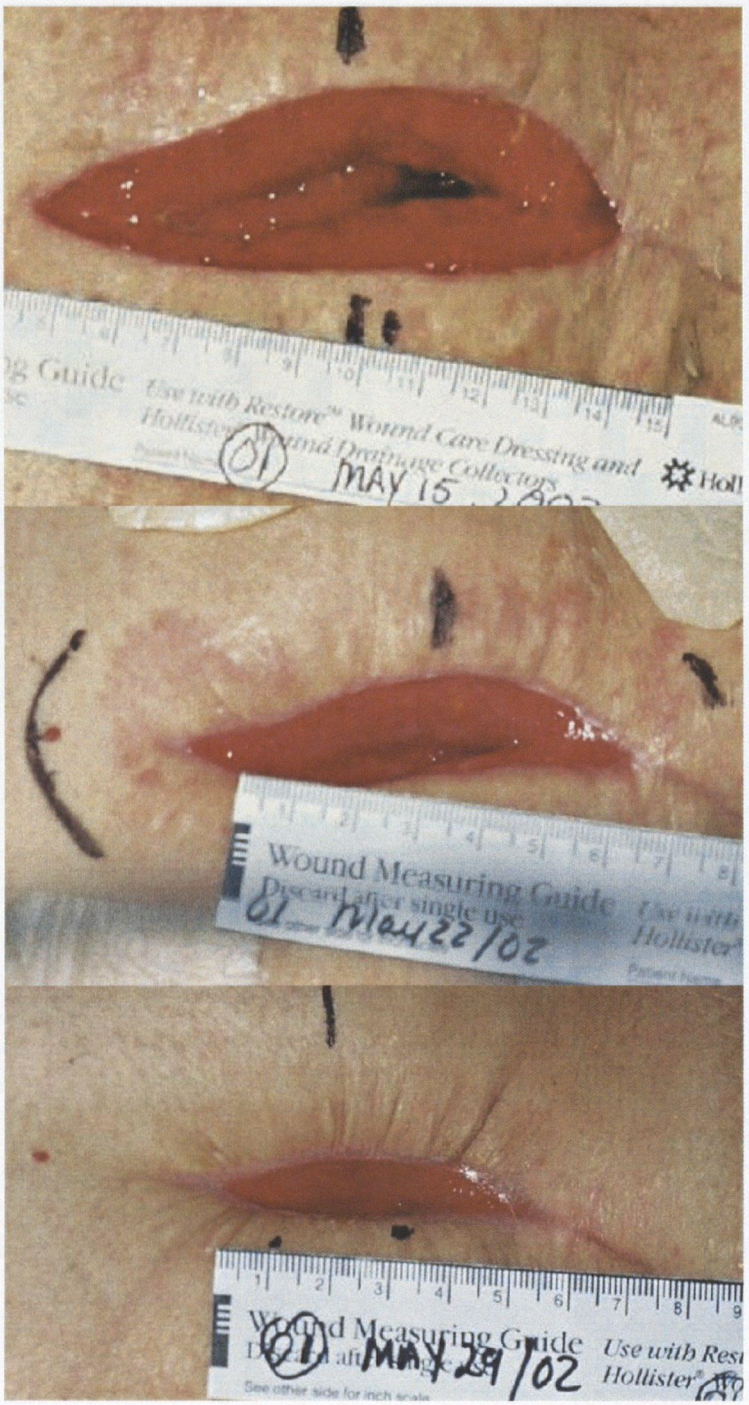
APPENDIX I

Photograph of Abdominal Wound with Magnets, Ruler and Markings



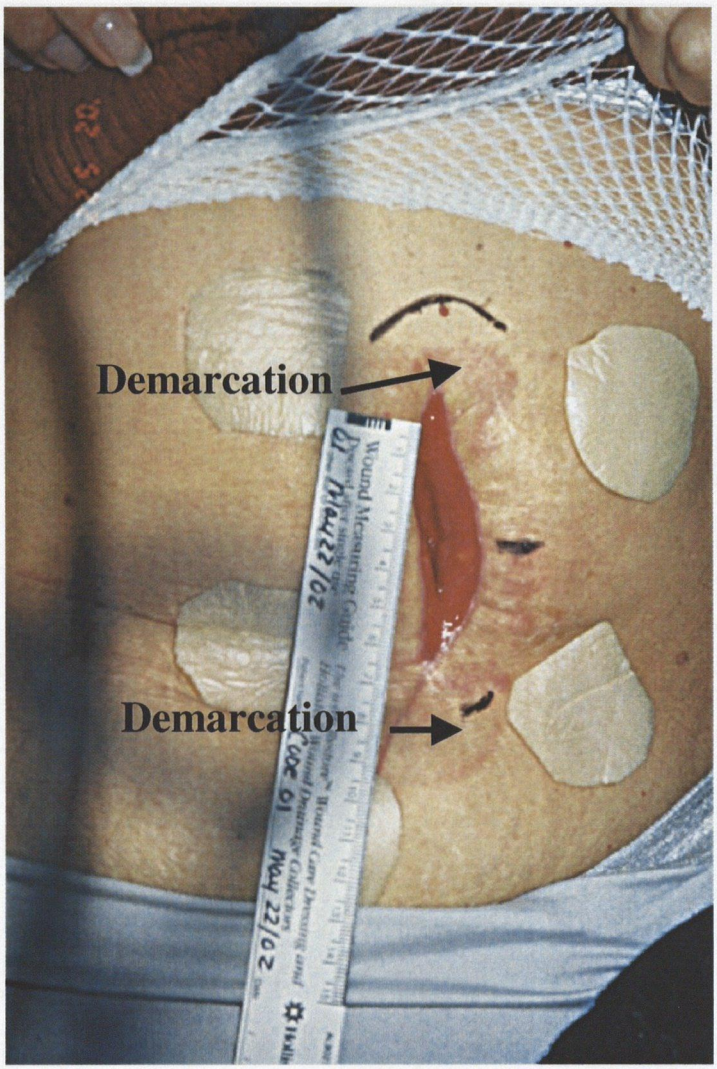
APPENDIX J

Photographs of Three Wounds, Taken at Day 1 (May 15), Day 7 (May22) and Day 14 (May 29), Demonstrating Absolute Measure of Healing



APPENDIX K

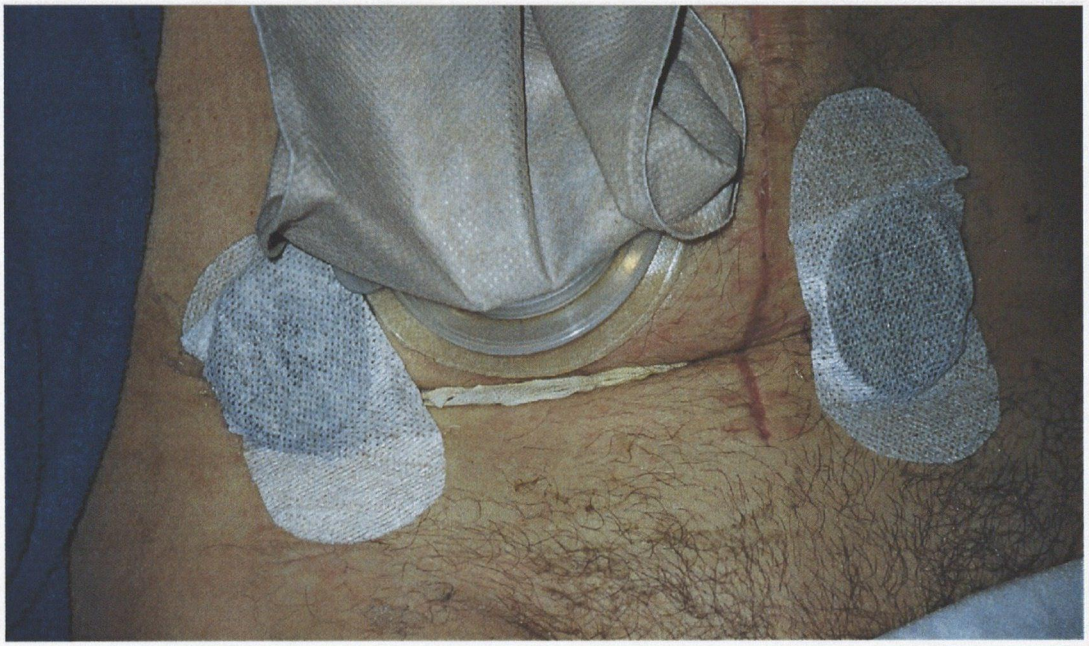
Picture of Magnet Demarcation on Abdomen



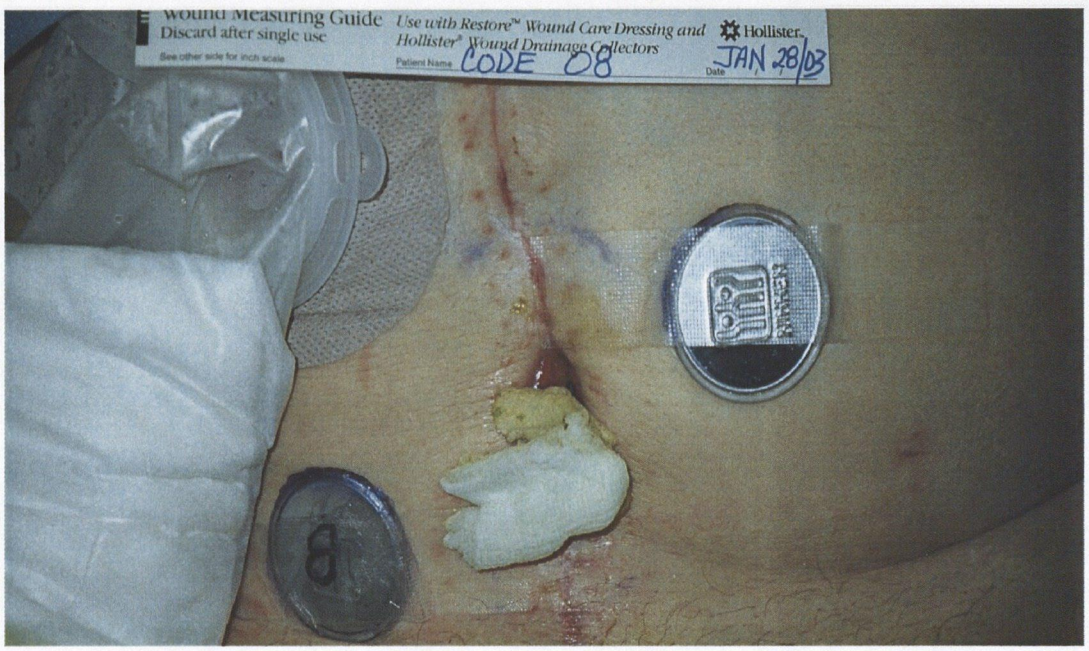
APPENDIX L

Pictures of Misplacement of Magnets

Participant 4



Participant 5



APPENDIX M

Letter of Approval: Conjoint Health Research Ethics Board

UNIVERSITY OF CALGARY

FACULTY OF MEDICINE

Office of Medical Bioethics
Heritage Medical Research Building/Rm 93
Telephone: (403) 220-7990
Fax: (403) 283-8524

2002-04-15

Dr. D. Hughes
Faculty of Nursing
University of Calgary
PF 2210
Calgary, Alberta.

Dear Dr. Hughes:

Re: A Pilot Study to Explore the Use of Magnet Therapy on Wound Healing
Student: Ms. Mary Hill Degree: MScN

GRANT ID: 15977

The above-noted thesis proposal and the consent form have been submitted for Committee review and found to be ethically acceptable. Please note that the Board has not received a revised analysis that appropriately reflects that the protocol is a pilot. However, to be considerate to the circumstance, the Board will approve the protocol with the requirement for a change to the analysis now only as a strong recommendation to your supervisory committee. Please also note that this approval is subject to the following conditions:

(1) a copy of the informed consent form must have been given to each research subject, if required for this study;
(2) a Progress Report must be submitted by 2003-04-15, containing the following information:
  (i) the number of subjects recruited;
  (ii) a description of any protocol modification;
  (iii) any unusual and/or severe complications, adverse events or unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, or complaints about the research;
  (iv) a summary of any recent literature, finding, or other relevant information, especially information about risks associated with the research;
  (v) a copy of the current informed consent form;
  (vi) the expected date of termination of this project;
(3) a Final Report must be submitted at the termination of the project.

Please note that you have been named as a principal collaborator on this study because students are not permitted to serve as principal investigators. Please accept the Board's best wishes for success in your research.

Yours sincerely,

Christopher J. Doig, MD, MSc, FRCPC
Chair, Conjoint Health Research Ethics Board

c.c. Dr. M. Reimer (information)
Ms. Mary Hill