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The Effects of Magnetic Insoles on Lumbar Flexion

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THE EFFECTS OF MAGNETIC INSOLES ON LUMBAR FLEXION

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This Scholarly Project, submitted by Kari Braaflat, Becky Cox, Angela DeLaCruz, and Heather Skarsgard in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(Faculty Preceptor)

(Graduate School Advisor)

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ABSTRACT

Magnets have been used for therapeutic purposes for hundreds of years. Today, magnetic devices and other alternative therapies are more popular than ever among the general public. The effect of these magnetic devices is dependent on several variables including strength, depth of penetration, placement, time exposed to the magnetic field, and polarity. There are many proposed theories on how magnets affect the body, but there is little research to support them. One of the theories proposed is that magnets alter connective tissue elasticity and allow greater range of motion (ROM). Additional research needs to be conducted to validate or negate these proposed theories.

The purpose of this study was to evaluate the effects of magnetic insoles on lumbar flexion. The study also evaluated the placebo effect of having knowledge of the theoretical effects of a strong magnetic insole on lumbar flexion measurements.

Thirty-eight subjects between the ages of 20 and 49 participated in this double blind study. A participant survey was used to collect general demographic data and as a screening tool to exclude those with any pathology and/or conditions that could have been adversely affected by the magnets or testing procedure positions/movements. For Trial 1, active flexion at the lumbar spine was measured by the double inclinometer method at baseline and on each of the three different sets of insoles. Two sets of insoles contained magnets, each of which was of a different strength, while the third insole did

not contain any magnets. The measurements were repeated in Trial 2 to evaluate the placebo effect. No significant difference was found when comparing lumbar ROM across the three insoles for either trial. A significant difference was found in ROM for lumbar flexion between males and females on all insoles.

Although this study found no increase in lumbar flexion when standing on magnetic insoles, these results cannot be carried over to other possible effects of magnetic devices. The results of this study have provided additional information regarding the effects of magnetic devices on healthy subjects and have illustrated the need for further research on the various magnetic devices that have become so popular.

Future research may further evaluate the effects of magnet therapy by including individuals with impairments, other magnetic devices, various magnet placement methods, and various treatment durations. Only as research accumulates will consumers be able to make informed decisions regarding the use of magnetic devices as an alternative therapy.

CHAPTER I

INTRODUCTION

People are always looking for new and different ways to help themselves both improve and maintain their health. One example of this is the use of magnets for health promotion and wellness. Magnets, used by many early civilizations as a remedy for a variety of ailments, are currently experiencing a comeback among the average consumer. The simplicity of magnet therapy is what makes it so attractive to consumers; it requires no medication or invasive surgery to treat a medial problem or condition.

In 1997, an estimated 83 million adults used at least one alternative medical therapy.[1] The National Center for Complementary and Alternative Medicine, which was established in 1998 through the National Institutes for Health, averaged more than 460,000 hits per month on its website during the first half of 1999. Worldwide, the public has spent more than $5 billion on magnetic devices alone.[2] There is little evidence of the efficacy of magnet therapy and with all of the interest and money being spent on this form of therapy, there needs to be more substantial evidence that they do in fact have therapeutic value.

Magnet therapy is the application of magnets or magnetic force in treating diseases.[3] Magnetic devices of various types are being marketed to and purchased by the general public. Devices ranging from necklaces to shoe insoles and everything in between are used to relieve the consumer's pain complaints and increase range of motion

(ROM). These devices are being sold alongside other drugstore items to anyone who wishes to purchase them, without regard to the individual's health status.

Although the public has embraced the concept of magnetic devices, there is still much confusion among the general public concerning the appropriate application and use of them. As alternative therapies, such as magnet therapy, join mainstream medical practice, the public needs to be aware of the effectiveness, or lack there of, precautions, and contraindications of these therapeutic modalities. It is the responsibility of the medical and scientific communities as well as the manufacturers and marketers to produce information regarding the proven uses of magnets, which may include using them to treat pain, disease processes, and increase ROM. Scientific studies are also needed if magnet therapy is to achieve government regulation and become part of standardized medical care.

Purpose

The purpose of this study was to determine if there was a difference in the amount of lumbar ROM attained when standing on magnetic shoe insoles.

The research study aimed to answer the following questions:

1. Is there a significant difference in lumbar ROM when an individual is standing on magnetic insoles?
2. Is there a significant difference in lumbar ROM between different strengths of magnetic insoles?
3. Is there a significant difference in lumbar ROM between genders when standing on magnetic insoles?

4. Is there a significant difference in lumbar ROM when an individual is given specific information (placebo effect) about magnets?

Significance

The significance of this study was to determine if magnetic insoles affect ROM, specifically flexion, at the lumbar spine. Baseline knowledge about magnet therapy and its relationship to ROM in the healthy population was gained through this study.

Hypotheses

1. There is a significant difference in lumbar ROM when an individual is standing on magnetic insoles.
2. There is a significant difference in lumbar ROM between different strengths of magnetic insoles.
3. There is a significant difference in lumbar ROM between genders when standing on magnetic insoles.
4. There is a significant difference in lumbar ROM when an individual is given specific information about magnets.

CHAPTER II

LITERATURE REVIEW

History

The use of magnets is recorded in the history of many different cultures. The first writings can be traced back to as early as 2000 B.C. when Chinese healers were said to use magnetic lodestones (natural magnets) on the body to correct unhealthy imbalances in the flow of Qi (chi), or energy.[4,5] An ancient Chinese medical text describes the application of magnetic stones at specific sites on the body for healing purposes.[5] Ancient Hindu, Egyptian, Persian, and Tibetan writings also refer to the use of lodestones. Even Cleopatra was said to have worn a lodestone on her forehead to prevent aging.[4,6]

Literature reports that the first person documented to recognize that all magnets had a north and a south end was an Italian man named Peregrinus.[5,7] In 1289, he used the term "polus" to refer to the unique ends of the magnet. Today we refer to these ends as poles. In 1600, Sir William Gilbert wrote the first scholarly attempt to explain the nature of magnetism and how it differed from the attractive force of static electricity. Gilbert allegedly used magnets to relieve the arthritic pains of Queen Elizabeth I. He was also the first to recognize that the earth was actually a large lodestone with a north and south pole.

In England during the 18th century, the development of new magnets that were more powerful than lodestones renewed interest in the potential healing power of magnets.[5,8,9] According to many articles on the history of magnets, Maximilian Hell, the chief astronomer at the University of Vienna, was one of those interested in the medicinal uses of magnets. Hell claimed that steel magnets could be used to cure several ailments. Through his work, Hell sparked the interest of one of his colleagues, Franz Anton Mesmer. Mesmer, a controversial figure of his time, came up with the theory of "animal magnetism". He felt that he could "magnetize" wood, paper, water, or anything by touching them through his own animal magnetism. He felt that regular magnets simply served as conductors to facilitate the flow of "universal fluid" from him to the patient.

In the 1800s magnetic and electric forces were linked together, and their practical applications were explored through electromagnetic turbine technology as a source of limitless power.[8] This generated much excitement among the public, who felt that there was potential in the human uses of magnetism.

A number of studies on magnets and magnet therapy were conducted throughout the early 1900s, but the application of magnetic fields to the human body for medicinal purposes faded.[9] This is most likely due to reports that came out of the Edison Laboratory, an influential institution at that time, which stated that magnetism had no effect on the human body. Throughout the late 1900s, magnets as a therapeutic treatment again surged in popularity as people looked for alternative methods to treat their ailments. Today, magnetic devices are used in the treatment of many diseases and physical

problems including pain and decreased ROM though there is limited research to validate these theories.

Research

Companies that market and sell magnetic devices claim that they can relieve pain, increase ROM, and have a therapeutic effect on a wide variety of diseases and conditions. A way to evaluate these claims is to review the results reported in published studies.

Japan has been one of the countries on the forefront of magnet research. According to a translation of a Japanese article on "Magnetism and Living Bodies," there was a reasonably high rate of success with the use of ferrite permanent magnet bracelets, which were worn by research participants to relieve shoulder stiffness.[9] Another Japanese research team compared the effectiveness of magnetic bracelets and nonmagnetic bracelets worn by patients with stiff shoulders. A considerable difference in perceived level of pain/stiffness was found in the group that wore the magnetic bracelets.[9]

More recently, research was conducted in Japan by three hospitals: San-ikukai Hospital, Tokyo Communication Hospital, and Kouseikai Suzuki Hospital.[4] The study was headed by Dr. Kazuo Shimodaira, and it reviewed the effect of magnetic mattress pads on the subjects' complaints. The subjects in the experiment had complaints of back and neck pain, insomnia, and fatigue. This double blind study used 375 magnetic mattress pads and 56 nonmagnetized mattress pads as placebos. At the end of the study, it was found that 301 subjects reported a decrease in their symptoms, while 74 subjects reported no results with the use of the magnetic mattress pads. The Japanese translation

did not indicate if there was a significant difference when comparing the magnetic and nonmagnetic mattress pads.

A double blind pilot study conducted by Baylor College of Medicine and the Institute for Rehabilitation and Research in Houston sought to determine if there was an effect in the chronic pain of 50 post-polio patients when a magnet was applied to an identified trigger point.[10] A magnetic or placebo device was applied to the affected area for 45 minutes. The subjects were to identify pain areas and rate the pain on a scale of 1-10 before and after treatment. The results indicated a significantly lower average pain score in those that received the magnetic device treatment as compared to those who received the placebo device.

The effects of magnet therapy on depression have also been an area of research.[11] One study conducted by George et al.[11] placed magnets over a particular area of the heads of 12 adults diagnosed with depression. A small electrical pulse was sent through the magnet for 2 seconds. After a period of 2 weeks (10 treatments), the researchers found that the subjects who were treated with magnets had significantly improved mood as compared to those who received the placebo treatment.

All of the previously mentioned studies have shown favor for the positive effects of magnets. There have also been several studies conducted that have found no effect with magnet therapy. For example, in a case report by Dexter,[12] it was found that magnet therapy was ineffective for the treatment of snoring and obstructive sleep apnea syndrome. Collacott et al.[13] conducted a randomized double blind, placebo controlled, crossover pilot study with 20 patients with chronic low back pain. The patients were

exposed to real and inactive magnets during alternate weeks for 6 weeks. They wore the magnet for 6 hours a day, 3 days a week. The magnets were applied to the surface of the skin and held on by an abdominal binder. They found that there was no difference in the reported pain or mobility between treatment times.

The New York College of Podiatric Medicine[14] conducted a study on patients with heel pain. The study included 19 patients that wore a molded insole containing magnetic foil, and 15 patients who wore the same type of insole with no magnetic foil. Approximately 60% of the patients in each group reported improvement. These results suggest that the magnetic foil did not benefit the patient.

There has not been enough reliable testing to determine the effectiveness of magnet therapy. The scientific community needs to respond to this and provide the public with information as to whether research shows favor for or against the use of magnets. This will provide the public with the knowledge to make informed decisions regarding their use of magnet therapy. In order to better understand the effects of magnet therapy, a more comprehensive look at magnets and their interaction with biological systems will be covered in the following sections.

How Magnets Are Formed

Lodestones are formed when molten lava that contains iron or iron oxide cools and becomes magnetized by the magnetic force of the Earth.[15] As this occurs, the molten particles of iron twist around to align with the magnetic poles of the Earth. Then, as the lava solidifies, the iron particles become trapped in this orientation.[15,16] As an alternative to naturally formed magnets (lodestones), industry has made it possible to produce

magnets of different size, shape and strength. Magnets are made by using alloys and adding ground iron as the primary ingredient.[15] This mixture is heated to the melting point and poured into molds. Most magnet therapy products today contain these inexpensive ferrite magnets.

Over the course of the twentieth century, other magnets have been developed that are even stronger than iron magnets. These twentieth century magnets include alnico magnets first produced in the 1930s, ferrite and ceramic magnets introduced in the 1950s, and rare-earth magnets developed in the 1970s and 1980s.[8] The most powerful magnet currently made is a neodymium magnet, which is at least a hundred times more powerful than the iron magnets available in the preceding century. This type of magnet is made by adding neodymium and boron to the base ingredient of magnets, iron.[15] Neodymium is only available in small amounts, and these magnets tend to be smaller in size when compared to other magnets.

Regardless of the type of magnet, or how it was formed, any magnet can affect human tissue. The degree of effect is dependent on several variables that are outlined in the next section.

Magnetic Field Variables

Several variables may alter the effect of a magnetic field on the human body. These variables include: (1) geometric configuration pattern of polarity; (2) strength; (3) depth of penetration; (4) anatomic placement; (5) duration of exposure; and (6) direction or polarity.[9,16,17]

Geometric configuration

Geometric configuration patterns of magnet polarity may include circles, parallel lines, triangular-board, or checkerboard patterns.[5] The increased effectiveness of these patterns are based on the fact that the geometric configurations multiply the strength of the magnets. The triangular-board patterns are considered the strongest pattern available for magnetic insoles (Figure 1).

Strength

The strength of a magnet is measured by the amount of iron-weight it can lift or by a gauss meter.[18] A gauss unit (G) is the force of attraction that is measured at the surface of the magnet.[15] The strength of a magnet is dependent on the material used, weight, shape, size, and polarity.[5,18] Research indicates that in order to be effective for therapeutic purposes, magnet strength should be at least 500 G.[9,19] This can be compared to a refrigerator magnet which has a strength of 10 G.

Magnetic force diminishes as distance from a magnet increases according to the inverse square law ($F=1/r^2$, where "F is the force and "r" is the distance).[15] This indicates that if the distance from the magnet is doubled, then the intensity of the magnet drops to one-quarter of its former value.

Depth of Penetration

The penetration of a magnet is directly related to the strength and the mass of the magnet. The stronger and larger the magnet, the deeper the depth of penetration.[16,18] Magnetic fields are unique in how they pass freely through all body structures. Unlike

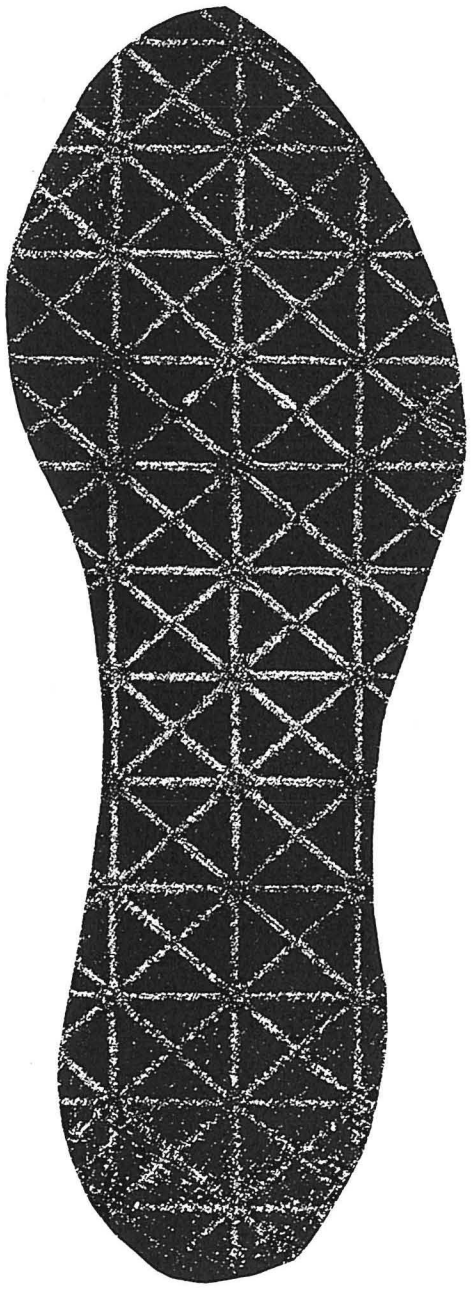

Figure 1. Representation of triangular-board pattern of magnets in an insole. Reprinted with permission from Nikken, Inc.

magnetic fields, sound, electricity, heat and x-rays are blocked by bone, slowed down by skin resistance, or absorbed when encountering soft tissue and muscle.[5]

Anatomic Placement

Literature indicates that accurate placement of the magnet is crucial for the desired therapeutic effect.[5] The three major anatomic placement sites for magnets when used for therapeutic effects are: 1) over acupuncture points, 2) over areas of referred pain, and 3) directly over local sources of pain.

Acupuncture is a system of treatment that was established in China and is based on the premise that health is dependent on circulation of vital energies through prescribed pathways in the body.[5] The vital energy is called Qi and is derived from two opposing forces: yin and yang. When these forces are not balanced, the natural flow of Qi is blocked and results in illness. The vital energy of Qi flows through channels called meridians, which are related to specific organs. Acupuncture points are the locations where meridians approach the surface of the body and where an acupuncturist inserts needles (Figure 2). It is believed that magnets activate meridians and acupuncture points and can be just as effective as acupuncture in normalizing the flow of Qi.

Magnets can be used to treat both local and referred pain. In treating referred pain, placement of the magnets on the local and the referred areas of pain is required for effective therapeutic intervention with magnets.[5] Treatment of localized pain involves placing magnets directly over the painful site.

Again, due to the inverse square law, it is important that the magnet is placed close to the skin.[15] Magnets are often sewn into garments such as braces or lumbar belts,

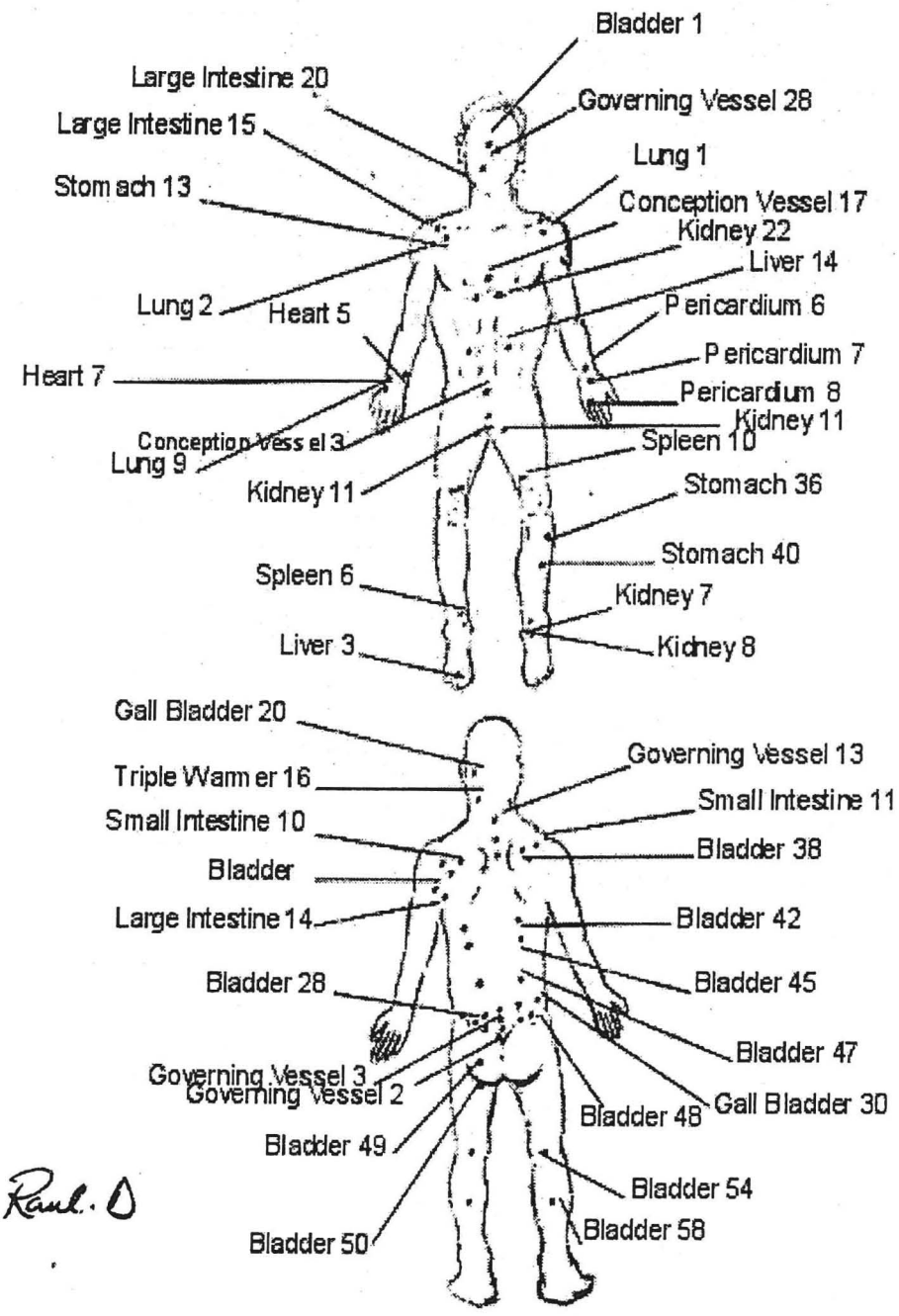

Figure 2. Acupuncture points.

encased in shoe insoles, or made into jewelry such as bracelets and necklaces. Placement of magnets around joints such as the wrist, knee, hip or ankle work the best by placing magnets on all sides of the joint.[5] Magnet placement for the treatment of spine pathologies requires placement over the spine or just lateral to the spine so that the magnet has an effect on the acupuncture points as well as the local painful points. If the problem is generalized, such as general fatigue, hypertension, or widespread arthritis, then magnetic jewelry, magnetic beds, or magnetic shoe inserts are believed to be helpful.[15]

Treatment Duration

The literature varies in the recommended effective treatment duration with the use of magnets. Most literature recommends that magnets should be worn in cycles, rather than 24 hours per day, to prevent adaptation.[5,15,18] Adaptation is a physiological phenomenon that takes place when the body has adjusted to the magnetic force field and the therapeutic effectiveness may diminish in the tissue.[5] Continuous usage of magnets over several months may cause symptoms to return in what is called a "habituation effect."

The duration of treatment with magnets also depends on the strength and polarity of the magnet. One research study indicates that rather than providing relief, applying strong magnets of positive polarity for a period of longer than 10 minutes per day can become a stress factor for the individual.[18] Only upon medical advice should treatment go beyond 10 minutes per day with strong, positive polarity magnets. This same study recommended that a maintenance regimen of one-half hour to one hour per day using

negative magnetic application was helpful once there had been an initial success with magnet therapy. Other research indicates that negative polarity magnets can be worn 24 hours per day until pain relief occurs, with magnet therapy discontinued for a 3 day period after 3 weeks of continuous use to allow the patient's body to regain homeostasis.[5]

The duration of treatment and the period of relief from magnet therapy vary according to certain factors, such as: length of the illness, age, nature of disease, eating habits, response of the body, and climate conditions. With magnet therapy, results may take effect immediately, or may occur within minutes, hours, days, weeks, or months depending on the above factors.

Polarity

The polarity of magnets refers to the direction of magnetic force.[15] The Law of Polarity states that opposite poles attract each other and like poles repel each other.[16,18] Magnets are either polarized as unipolar or bipolar. Unipolar magnets have one side polarized with negative energy (north pole) and the other side polarized with positive energy (south pole).[16,17] The terminology of "positive" and "negative" energy, has no reference to "good" or "bad," but instead, refers to the laws of physics and electricity.[16]

Magnets are considered bipolar if the same side of a magnet is polarized with both positive and negative energy. Bipolar magnets can have alternating north and south poles in a concentric pattern or grid.[17] North pole electrons spin counterclockwise generating negative magnetic energy while south pole electrons spin clockwise generating positive magnetic energy.[16]

It is agreed upon by several researchers that negative magnetic energy is the polarity that is safest in treating most illnesses, particularly when long-term or accumulative exposure occurs at a higher gauss.[5,16,18] Negative magnetic energy is said to normalize human cellular metabolic function that is out of balance and to heal tissues.[16] This type of magnetic energy is also thought to "calm" human body systems. See Table 1 for a list of the effects of positive and negative magnetic energy.

Positive magnetic energy is not utilized on biological systems as often as negative magnetic energy.[18] Researchers feel that when positive field energy is used incorrectly or overused, it can have an adverse effect on tissues (Table 1). It has been shown that positive field energy, continued in a chronic state, causes fatigue and energy collapse. It has also been stated that when using positive energy, it is safer to use lower gauss strength due to the potentially detrimental effects. Using negative magnetic energy in conjunction with the positive energy may counter the potential for adverse effects.[16]

Magnetic Effects on the Human Body

The exact mechanisms of the interaction of magnetic fields with biologic tissues that result in functional changes are unknown at the present time. Yet, magnets have been shown to have several different effects on the human body.[17] The following are reported effects of magnetic fields on living organisms: 1) increased connective tissue relaxation, 2) increased blood flow, 3) increased oxygen carrying capacity, 4) maintained pH balance of various body fluids, 5) reduced inflammation and fluid retention, and 6) normalized sodium pump.[18]

Table 1. Effects of Negative Magnetic Energy vs. Positive Magnetic Energy[10,11,14]

Negative Magnetic Field Energy (North Pole)	**Positive Magnetic Field Energy (South Pole)**
➢ Normalizes and calms body systems	➢ Disorders body systems
➢ Anti-stress (slows heart rate slightly)	➢ Over-stimulates
➢ Micro-organisms/parasites inhibited	➢ Micro-organisms/parasites overgrow
➢ Fights infection	➢ Promotes infection
➢ Supports biological healing	➢ Inhibits biological healing
➢ Increases cellular oxygen (indirect evidence)	➢ Decreases cellular oxygen (indirect evidence)
➢ Reduces inflammation	➢ Can increase inflammation
➢ Pulls fluids and gases	➢ Pushes fluids and gases
➢ Reduces fluid retention	➢ Increases intracellular edema
➢ Relieves pain	➢ Increases pain
➢ Normalizes acid base balance	➢ Acidic metabolic response
➢ Reduces/dissolves fatty deposits & reduces scar tissue	➢ Encourages fatty depositing
➢ Promotes bright, happy affect & stimulates production of melatonin by pineal gland	➢ Promotes dull, depressed affect
➢ Promotes mental acuity and reasonableness & restores physical and mental energy	➢ Promotes mental over activity and unreasonableness & decreases physical and mental energy
➢ Encourages deep, restorative sleep	➢ Stimulates wakefulness and stimulates over activity

Increased connective tissue relaxation has been one reported effect of magnetic fields on the body.[18] Connective tissue provides and maintains form in the body, as structure is its main function.[20] The major constituent of this type of tissue is the extracellular matrix, which is composed of protein fibers, tissue fluid, and amorphous ground substance. Joint capsules, ligaments, areolar tissue, bone, and tendons are all classified as connective tissue structures. When considering connective tissue structures around a joint, an increased relaxation in connective tissue due to exposure to magnetic fields can cause these structures to stretch, resulting in an increase in the available motion at that joint.

Blood flow increases by attracting and repelling charged particles within the blood. This causes a generation of heat and allows blood vessels to dilate.[19] Another way the rate of blood flow increases is by the relaxation of connective tissues.[5] This increase in blood flow and relaxation of connective tissue have been stated as reasons for relief of pain and soreness.[16]

Magnet therapy causes an increase in the oxygen carrying capacity of the blood by increasing the pH.[18] This occurs by increasing the body's negative magnetic field. The result is that the blood is charge-induced and creates more hydroxyl (OH-) ions, which combine with other ions to raise blood pH to an alkaline level. In effect, excess acid must either be eliminated or neutralized, to prevent toxic conditions in the cell.[5] Negative magnetic energy is alkalinizing and normalizes pH, relieving symptoms which result from acidic conditions such as: allergies, toxic states, insect bites, acid indigestion, chemical hypersensitivity, pain, and sore musculature after exercise.[16]

Magnets have also been found to reduce inflammation and fluid retention.[16] Magnetic fields cause a potential energy difference of sodium and potassium ions between the external and internal fluids. This allows the nutrient channel to open more readily, allowing a more optimal flow of fluids between the external and internal cellular environments.[18] This flushes away molecules that are causing pain and inflammation at the site.[5]

There are two types of fluid retention (edema) in body tissues: 1) intracellular and 2) extracellular. Under direct negative magnet therapy, intracellular edema clears rapidly. This is due to the magnet normalizing the functions of the sodium pump (charged sodium ions leaving the cell and charged potassium ions entering the cell). Extracellular inflammatory edema in closed spaces is relieved by physically placing negative magnetic energy to the side of the affected area. This "pulls" the fluid from the encapsulated area, relieving edema and pressure.[16]

Precautions/Side Effects

Magnetic fields have varying effects on a person's health. If used properly, magnets have been reported to improve health without causing side effects.[18] Although the chance of side effects is low, there are still some potential effects that may come from improper use of magnets. Side effects that have been reported include headaches, pain, toxin release, insomnia, tumor growth, seizures, digestive difficulties, hyperactivity, dizziness, and medication interactions.[16,18]

Improper use of magnets may be encountered with the use of the wrong polarity, too long of a duration, too strong of a magnet, incorrect placement of the magnet, or

overmedication due to the combination of medications with the magnet. The precautions that should be followed in order to minimize side effects, which include:

- It is not advised to use magnets on the abdomen or around the uterus area during pregnancy to prevent any adverse affects on the growing tissues of the fetus.[5,15,16,18,19]
- Individuals with defibrillators, pacemakers, or other implanted devices should not use magnets. A magnet may interrupt the function of these devices.[5,15,16,18,19]
- Magnetic energy should not be used for 60-90 minutes after meals to allow normal peristalsis to take place.[16,18,19]
- Magnetic beds should not be used 24 hours daily if an individual is ill. The magnetic bed could suppress adrenal function and the individual may experience a slow energy recovery.[16,18]
- Magnetic devices should be removed while bathing to avoid accumulation of oil residues or perspiration under the magnet.[18]
- It is advised not to put magnets over major open wounds or bleeding wounds since magnets are thought to increase circulation.[15,16]
- Positive magnetic energy is not to be utilized unless under medical supervision. Positive magnetic energy can stimulate growth of tumors & microorganisms. It may also over stimulate brain activity producing hallucinations, hyperactivity, addiction, insomnia and seizures.[15,16,18]

- It is stated that conditions such as cancers, tumors, or infections should be treated with negative pole only. Once the inflammation of the infection has passed then a person may benefit from positive magnet energy under supervision.[15]
- It is not advised to use strong magnets around the head, neck, glands, or organs for long periods of time.[15]
- It has been shown that applying large magnets over 1,000 G strength to the head for more than 10 or 15 minutes at a time could put the endocrine system out of balance or produce headaches.[15]

It is important that the general public recognizes these precautions/side effects, so that they are aware of the potential complications of magnet therapy or effects of the magnets before they make the decision of whether or not to use them.

The Lumbar Spine

Due to the effects of magnets on connective tissue, a review of the structure and function of the joints of the lumbar spine will be covered in this section. The spine is an extremely complex system of interconnecting joints, each of which is surrounded by a connective tissue joint capsule. The entire complex is supported by ligaments that limit both flexion and extension of the spinal column. Movement of the spinal column enables an individual to move appropriately in order to interact with the environment. This area is also a common site of injury and pain in the general population. For all these reasons, the use of magnet therapy to decrease pain and increase function is an attractive alternative to more invasive surgical and pharmaceutical therapies in treating conditions

of the lumbar spine. A more complete analysis of lumbar spine mechanics is required to understand the potential effects of magnets on this area of the body.

Structure and Function

The lumbar spine consists of 5 vertebrae and intervertebral discs, 10 zygapophysial joints (facets), and ligamentous structures. The lumbar vertebral body is massive, with the transverse diameter and height being greater than the anterior-posterior diameter and height.[21] The vertebral bodies act as support structures that bear the majority of the compressive forces in an erect posture.[22] There are intervertebral discs between each of the vertebra which also help bear the static compressive load in an erect posture (Figure 3). The disc consists of the annulus fibrosus, nucleus pulposus, and cartilage plates and acts as a shock absorber for the forces that are imposed upon the spine.

Each facet joint is a synovial joint surrounded by a connective tissue capsule that functions in guiding and restraining spinal movement.[22] These joints are oriented in the sagittal plane with a distinct concave-convex arrangement.[23] The convex inferior joint surface is situated medial to the superior joint surface and faces anterolaterally. The concave superior joint surface faces posteriorly and medially (Figure 3). Other connective tissue structures that support the facet joints and control movement of the spinal column include the anterior longitudinal ligament, posterior longitudinal ligament, ligamentum flavum, interspinous ligaments, and supraspinous ligaments (Figure 4).

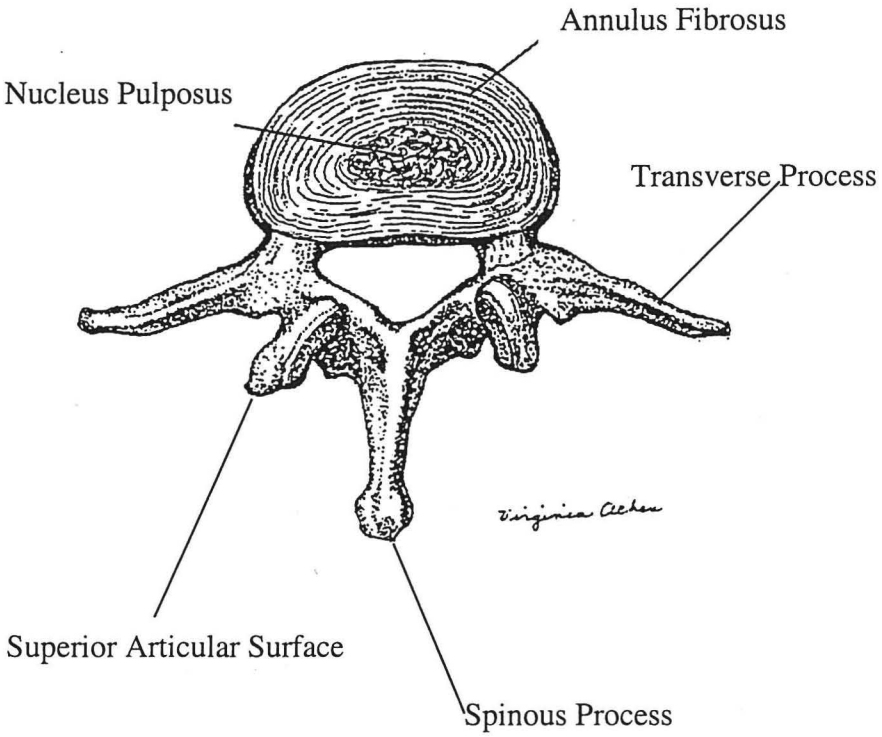

Figure 3. Lumbar vertebra and intervertebral disc. Reprinted with permission from the University of North Dakota. *Anatomy for Allied Health.*

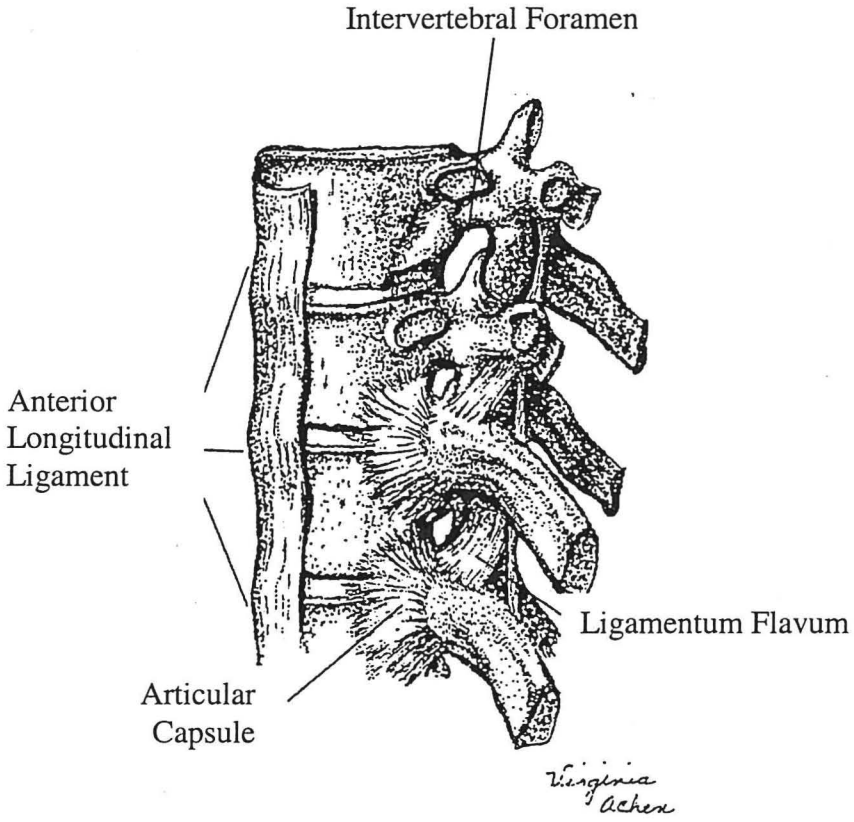

Figure 4. Supportive structures of the lumbar spine. Reprinted with permission from the University of North Dakota. *Anatomy for Allied Health.*

Movement of the Lumbar Spine

Minimal rotation is allowed in the lumbar spine due to the orientation and shape of the facet joints.[24] The main movements allowed in the lumbar spine are flexion and extension in the sagittal plane. In vertebral flexion, the superior vertebrae anteriorly tilts and glides causing a widening of the intervertebral foramen and a separation of the spinous processes.[21] Intervertebral discs influence vertebral flexion as the annulus fibrosis is compressed and bulges anteriorly, while the posterior portion of the disc stretches and resists separation of the vertebral bodies. Although the amount of vertebral tilting is partly dependent on disc size, it is also limited by tension in the interspinous and supraspinous ligaments that resist separation of the spinous processes. Also imposing control over excessive flexion is the passive tension in the facet joint capsules, posterior longitudinal ligament, ligamentum flavum, posterior annulus, and the back musculature. Magnet therapy is reported to relax the connective tissue, which would theoretically allow an increase in lumbar flexion.

Measurement of Range of Motion

There are many methods available for assessing lumbar ROM. Techniques for measuring lumbar flexion include the double inclinometer method,[25] Schober skin distraction method and its various modifications,[26] and the finger-tip-to-floor test.[27] The double inclinometer method is often the preferred method for obtaining accurate and reproducible lumbar flexion measurements in an inexpensive and practical way.[25] This is due to its accuracy in measuring a specific spine segment's mobility without being confounded by motion above and below the assessed points. The double inclinometer

method has the advantage of measuring spinal movement in degrees, which makes assessing ROM more accurate since the underlying motion is angular in nature.[26]

In literature, the reported "normal" values of spinal ROM in asymptomatic subjects vary according to what is used as a measuring instrument.[28] It is reported that when using the double inclinometer method, normal lumbar flexion ranges for females and males vary according to age with males demonstrating greater values (Tables 2 and 3).[26]

Movement of the lumbar spine requires appropriate functioning of all the structures involved in order to have normal, pain free motion. When any of the structures of the lumbar spine become disrupted, the result can be pain and limitations in motion. Due to the high costs associated with low back pain rehabilitation, alternatives such as magnet therapy have gained favor in the general public. In theory, relaxation of connective tissue through the use of magnetic fields should make this type of therapy a reliable alternative to more invasive intervention strategies. Due to the lack of scientifically based articles on this subject, no research was found documenting the effects of magnets on ROM in the lumbar spine.

Magnetic insoles are a readily available form of magnet therapy, and easily accessible to the general public. They are advertised to relieve pain and improve motion, but empirical evidence on the efficacy of these claims is yet to be established by scientific inquiry. This research study was designed to answer the question of whether or not magnetic insoles affect lumbar ROM in healthy subjects.

Table 2. Normal Ranges for Female Lumbar Flexion Angle[26]

Age Range	N	Mean (deg)	SD (deg)
15-24 years	161	26	9
25-34 years	143	24	8
35-65 years	136	22	8

Table 3. Normal Ranges for Male Lumbar Flexion Angle[26]

Age Range	N	Mean (deg)	SD (deg)
16-24 years	122	33	9
25-34 years	295	31	8
35-44 years	159	28	8
45-65 years	110	26	8

CHAPTER III

METHODS

Subjects

Forty-three subjects between the ages of 20 and 49 with no impairments or known history of back problems participated in this study. All subjects were recruited on a voluntary basis through the use of advertisements posted on informational bulletin boards within the School of Medicine and Health Sciences at the University of North Dakota. This study was approved by the University of North Dakota Institutional Review Board and designated as project number IRB-200105-234 (Appendix A).

Prior to participation in the study, the subjects completed a survey (Appendix B) regarding inclusion/exclusion criteria, and signed a consent form (Appendix C). Exclusion criteria were established according to the precautions associated with the use of magnets and with the required body positions of the testing procedure (Table 4).

The study was completed at the Physical Therapy Department within the University of North Dakota's School of Medicine and Health Sciences. Subjects were asked to wear loose fitting clothing that would not impede movement and allow free exposure of the lower thorax, lumbar spine, and sacrum. To ensure privacy and confidentiality of the participants, the testing was performed in a closed room. The subjects were not compensated for participation in this study.

Table 4. Exclusion Criteria for Subject Participation[11,14]

Criteria	Rationale for Exclusion of Subjects
Pregnancy	Unknown effects on fetus
Mechanical devices (i.e. pacemakers, insulin pumps, etc.)	Possible disrupted function of device
Open wounds	Potential of increased circulation which would exacerbate pre-existing condition
History of platelet disorders	
Using anti-coagulation medications	
History of cancer	To avoid stimulated tumor growth
History of back pain/problems (i.e. fused spine, Paget's disease)	To avoid possible exacerbations of pre-existing condition
Autoimmune disorders/Hyperthyroidism	
Intolerance of forward bent position	Required testing procedure

Instrumentation

Inclinometers

Measurements were obtained using the double inclinometer method.[25] This method was chosen because it has shown substantial validity and reliability with measurement of lumbar flexion.[26,29] The inclinometers (ISOMED, Inc., P.O. Box 22248, Portland, OR 97269-2248) used were fluid pendulum, and uni-level (Figure 5).[30]

The actions of the participants and testers were standardized to ensure consistency. The measurements were obtained by two researchers, one who measured ROM at the T_{12} spinous process (Tester A), and the other measured ROM at the S_2 spinous process (Tester B). Each inclinometer was positioned so that the spinous process was midline between the adjustable legs of the instrument. Both inclinometers were aligned vertically in the sagittal plane (Figure 6). Total lumbar ROM was calculated by subtracting the measurement obtained at S_2 from the measurement obtained at T_{12}. The methodology required three consecutive measurements to be within $\pm$ 10% or 5°, whichever was greater, of each other in order to be valid.[25] If these requirements were not met within six measurements, the subject was eliminated from the study.

Reliability

A pilot study of lumbar flexion measurements was completed prior to the initiation of the present research study to determine the reliability of Testers A and B in using the inclinometers. Intra-rater reliability for total ROM measurement (T_{12} - S_2) was found to be good (ICC = .94).[31] Intra-rater reliability was also good for both Tester A at the T_{12} spinous process (ICC = .99) and Tester B at the S_2 spinous process (ICC = .84).

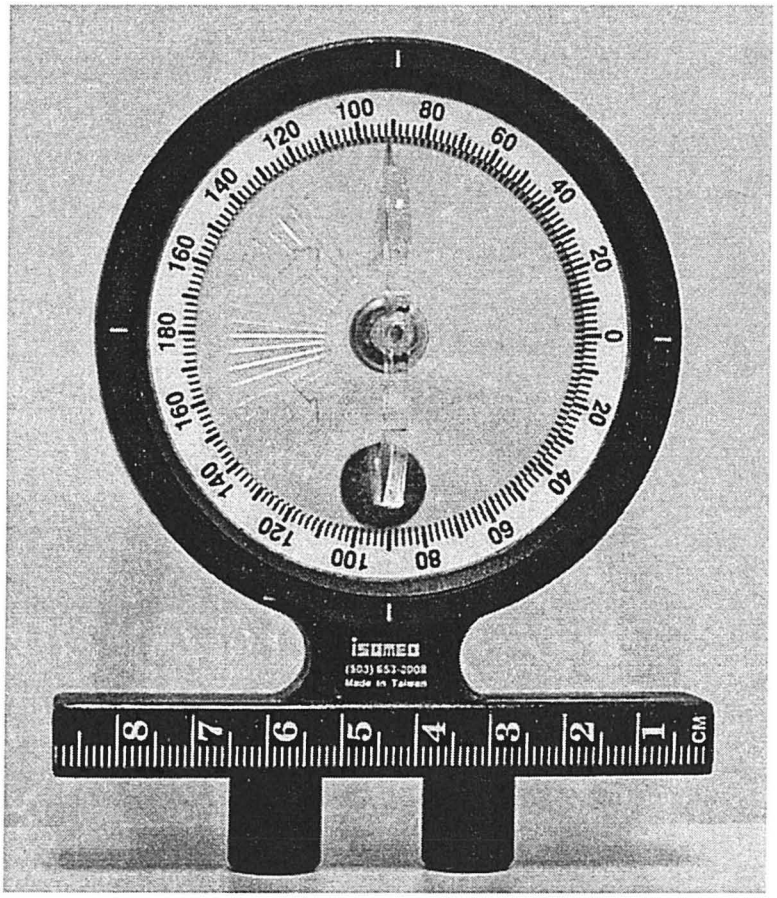

Figure 5. Uni-level inclinometer.

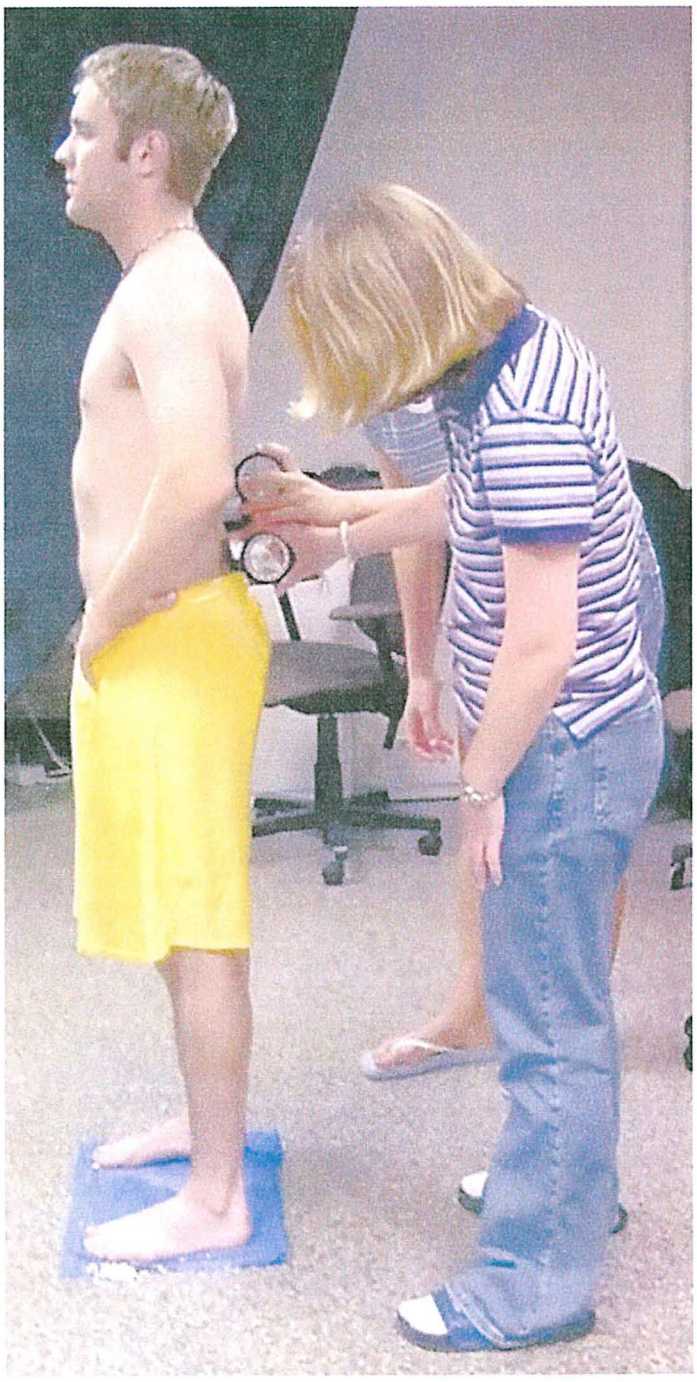

Figure 6. Alignment of the inclinometers on the spinous processes of T_{12} and S_2.

Insoles

The insoles were obtained from two different companies. Insole A was from Nikken Inc. (15363 Barranca Parkway, Irvine, CA 92618) and insoles B and C were from Dr. Scholl's (Schering-Plough, 2000 Galloping Hill Rd. Kenilworth, NJ 07033-0530). Prior to the study, the insoles were measured with a gauss meter in the Engineering Department at the University of North Dakota. The instrument used was the Gaussmeter Model 610 (F.W. Bell, 6120 Hanging Moss Rd. Orlando, FL 32807). Insole A (Figure 7) contained 71 unipolar magnets (strong magnetic insole). Thirty-seven of these magnets were oriented with the north pole (negative magnetic energy) facing up, and they ranged in strength between 140 and 265 G. Thirty-four of the magnets in insole A were oriented with the south pole (positive magnetic energy) facing up and ranged in strength from 120 to 170 G. Insole B (Figure 8) contained 7 unipolar magnets (weak magnetic insole). Four magnets in insole B were oriented with the north pole facing up, and strengths were measured between 105 and 120 G. The remaining 3 magnets were oriented with the south pole facing up and strengths measured between 85 and 115 G. In both insoles, the orientation of the magnets was generally alternated between the north and south poles. Insole C contained no magnets.

Procedure

Two sets of measurements were obtained in this study. The first set of measurements (Trial 1) evaluated lumbar flexion at baseline and on each of the three insoles. The second set of measurements (Trial 2) evaluated the effect of the subjects having knowledge that an insole contained strong magnets and that magnets may increase

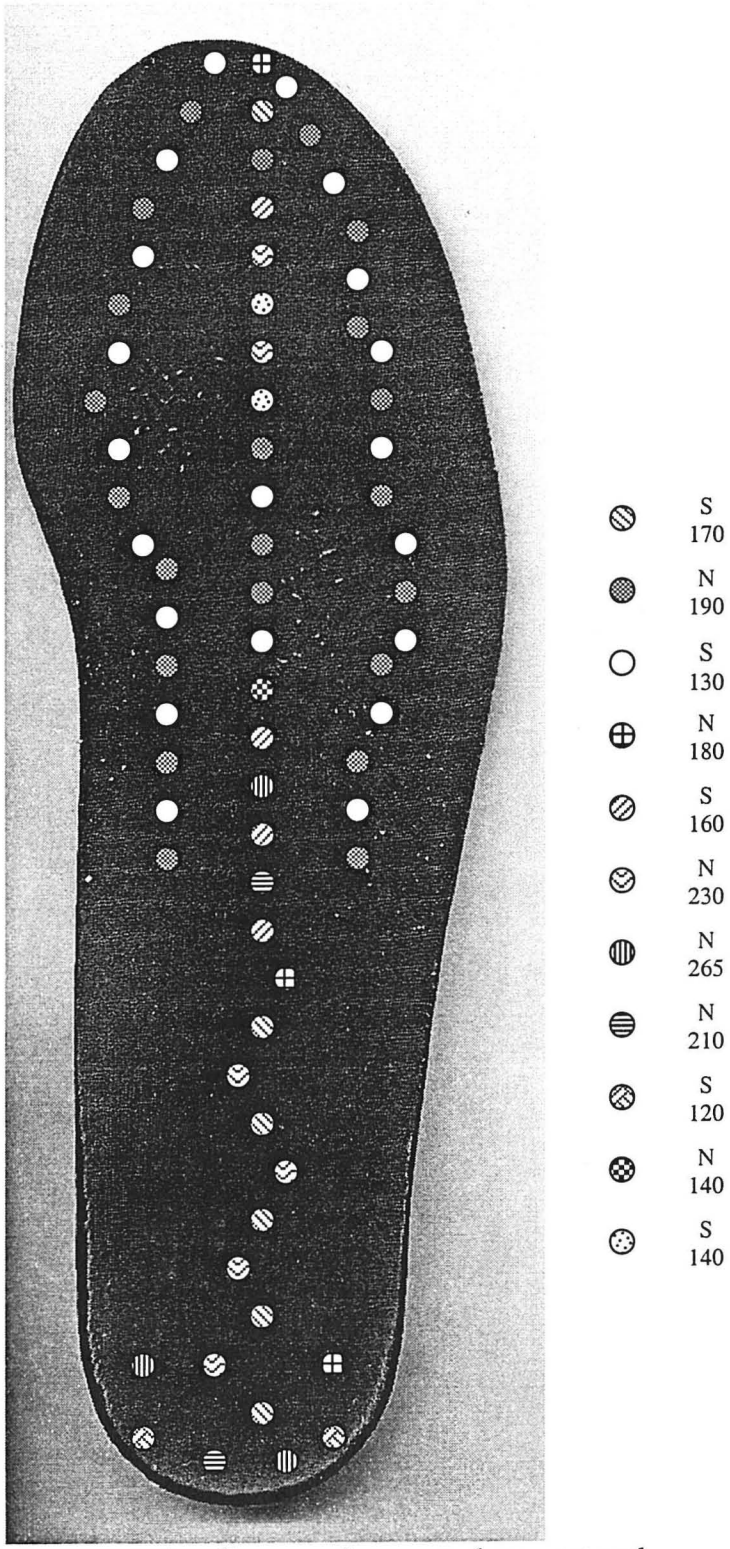

Figure 7. Representative diagram of magnet placement and strength of insole A as measured by a gauss meter.

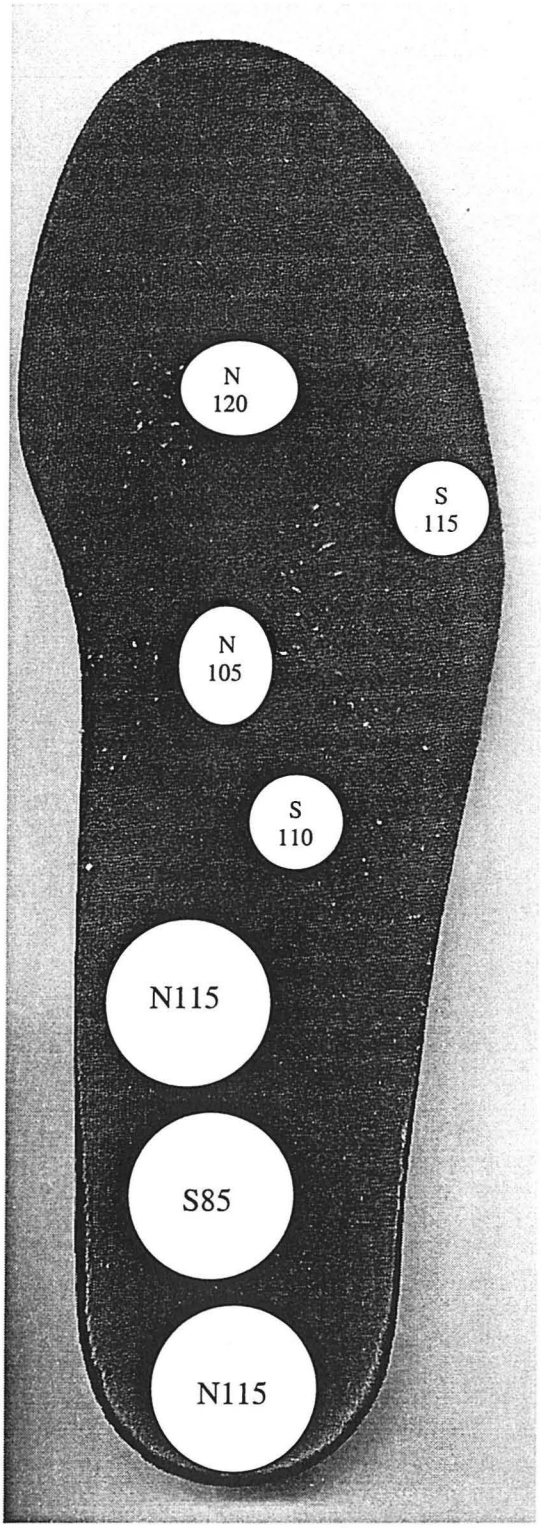

Figure 8. Representative diagram of magnet placement and strength of insole B by a gauss meter.

ROM (placebo effect). Four researchers (A,B,C,D) were involved in the study. Testers A, B, and C remained in the testing room during measurement procedure, while Tester D was outside of the room. Testers A, B, and C obtained and recorded measurements. Tester D provided the subjects with necessary information prior to each trial, administered the consent form and participant survey, and led the subjects through the stretching protocol. Tester D was the only tester with knowledge of the identification of the insoles prior to measurements. The insoles were placed on the ground by an individual not involved with the testing procedure prior to the testers or subjects coming into contact with them. Each insole was covered with self-sticking felt to mask any difference in texture. Each pair was then inserted in a cloth cover to prevent visual identification of the type of insole. A layer of plastic wrap was placed over the cloth covers and changed between subjects for sanitary purposes. The insoles were identified as 1, 2, or 3 and arranged in numerical order (Figure 9). The insoles were randomly ordered for each day of data collection. This double blind method ensured randomization and unbiased measurements by the testers, and unbiased subject performance.

After the survey was completed and the consent form was signed, each subject was asked to perform a warm-up, which consisted of 3, 30-second static, sustained stretches for forward flexion of the lumbar spine in a standing position. The subject was then instructed to lay prone on a plinth while the T_{12} and S_2 spinous processes were marked with a wax pencil by Tester C. Spinous processes were located by palpation of the iliac crests and identification of the vertebral level by Tester C. Palpation of the

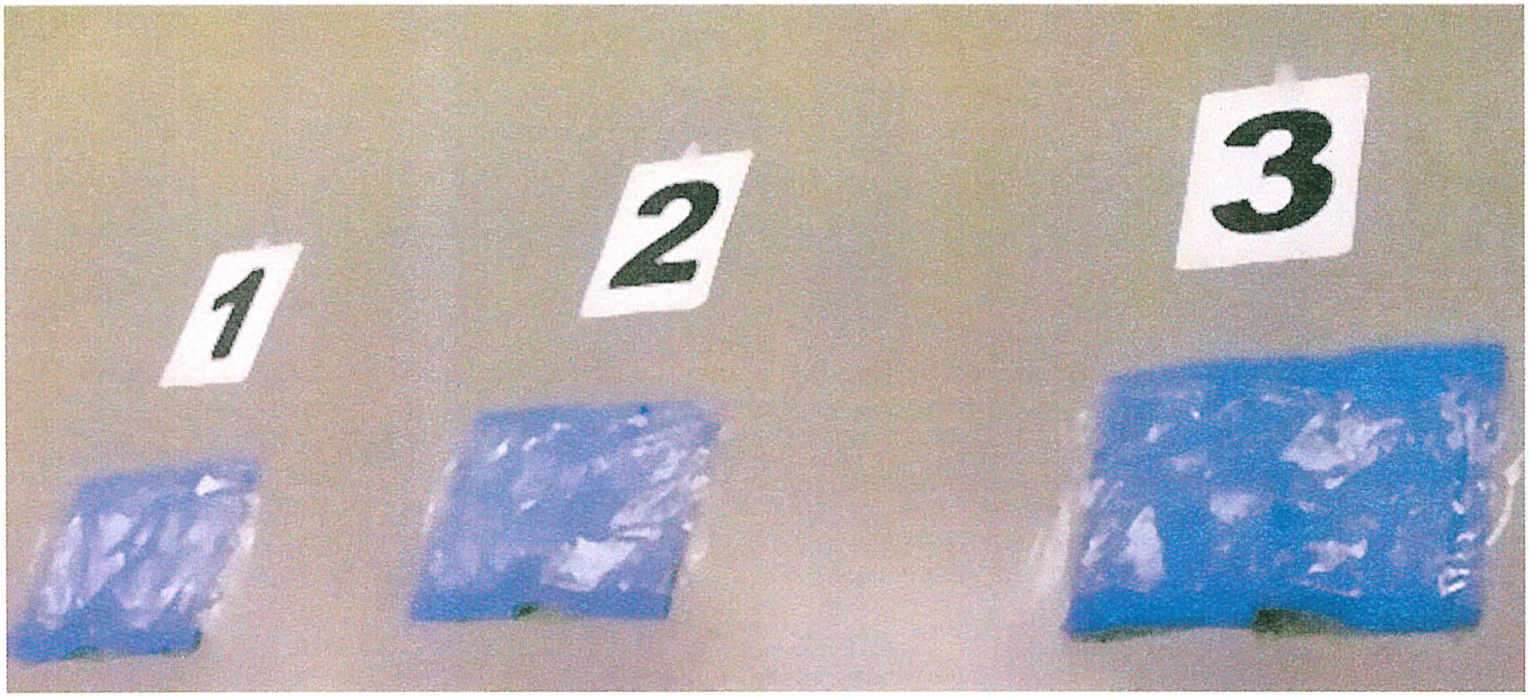

Figure 9. Floor arrangement of insoles within cloth coverings.

spinous processes continued to determine the location of T_{12} and S_2. The subject's clothing was adjusted to expose the necessary structures in the low back area. Male subjects removed their shirts. For female subjects, the back of the shirt was tucked into the bra strap. The subject's waistband was adjusted just below the level of the posterior superior iliac spine. Measurements were performed in a closed room to accommodate subject modesty.

Prior to beginning the test procedure for Trial 1, the subject was asked to draw a card from a pile containing the numbers 1, 2, and 3. The number drawn by the subject determined at which insole the subject would start the test procedure. A baseline measurement of lumbar spine flexion was taken while the subject stood barefoot on level ground, followed by measurements on each insole, which started with the number drawn and continued in numerical order (i.e. 2, 3, 1). For each measurement taken, the subjects were instructed to stand upright with their weight evenly distributed between both feet. The subjects were instructed to keep their knees straight and hands placed on their hips at all times during the measurements. Both inclinometers were positioned, aligned in the sagittal plane, and zero readings were obtained while the subject stood in a neutral position. The subject was then asked to actively bend forward as far as possible. Tester A asked the subjects if they could go any further before inclinometer readings were recorded on the data collection form (Appendix D). The subject returned to an upright position between each measurement. When measurements were completed, the subject was asked to leave the testing room for further instructions regarding the next part of the study.

Prior to obtaining measurements for Trial 2, the subject was told that a particular pair of insoles contained the strong magnet to evaluate the placebo effect. Each subject was informed that magnets are said to increase ROM. Due to the double blind nature of this study, neither the testers nor the subjects were allowed to know the true identification or location of the insole types. The actual identification of the insole that the subjects were told contained the strong magnet was relevant only for data collection purposes and was known only by Tester D. The subjects were told to repeat the testing procedure and to again try equally hard at all insoles, but a feeling of increased ROM at a particular insole was possible due to the effects of the magnets. The subjects were instructed not to relay any of the information just given to them to anyone else throughout the testing procedure. The subject then returned to the testing room and drew another card. Measurements were repeated at each insole (baseline measurement was not repeated), and again started at the insole indicated by the card.

Data Analysis

SPSS 10.0 statistical software[32] was used to perform data analysis. A repeated measures ANOVA with a significance level of $\alpha = .05$ was used for measurements of Trial 1 to determine differences in ROM between the 3 types of insoles, and between men and women. The independent factors were insole type and gender, and the dependent variable was lumbar ROM. A repeated measures t-test with a significance of $\alpha = .05$ was used to analyze the measurements obtained in Trial 2 that evaluated the placebo effect. The independent variable was the level of knowledge regarding the type of insole and the dependent variable was lumbar ROM.

CHAPTER IV

RESULTS

Results were compiled from a total of 38 out of 43 subjects who participated in this study. Data from 5 subjects were unable to be used in the final statistical analysis due to their ROM values being inconsistent within the maximum of 6 repetitions available. The study consisted of 21 female and 17 male participants between the ages of 20 and 49 years. The mean age was 23.7 years with a median age of 22.5 years. ROM values for the different groups are shown in Tables 5 and 6 and graphically represented in Figure 10.

A Repeated Measures ANOVA was used to determine if there was a significant difference in ROM measurements across the 4 test conditions. The 4 test conditions for each trial were: baseline measurement with no insole, placebo insole measurement (no magnet), weak magnetic insole measurement, and strong magnetic insole measurement.

No significant difference was found when comparing the means of the ROM values for all subjects across the 4 test conditions, $F(3,144)=0.063, p=0.962, \alpha=0.05$. There was also no significant difference found in ROM measurements between the different insole types across the 4 test conditions, $F(3,144)=0.067, p=0.978, \alpha=0.05$. When the subjects were divided by gender and their means were compared across the 4 test

Table 5. ROM Values Between Males and Females

Groups	Gender	Mean (degrees)	Standard Deviation	t-score
ROM, baseline, no insole	Males	56	7	3.131
	Females	47	9	
ROM, insole, no magnet	Males	57	6	3.187
	Females	48	9	
ROM, insole, weak magnet	Males	55	7	2.720
	Females	48	8	
ROM, insole, strong magnet	Males	57	6	3.663
	Females	47	8	

Table 6. ROM Values Between 1st and 2nd Trials

Groups	**Mean (degrees)**	**Standard Deviation**	**t-score**
ROM, trial 1, no magnet	52	9	-0.439
ROM, trial 2, no magnet	52	8	
ROM, trial 1, weak magnet	51	8	-0.0506
ROM, trial 2, weak magnet	51	8	
ROM, trial 1, strong magnet	51	8	0.401
ROM, trial 2, strong magnet	51	8	

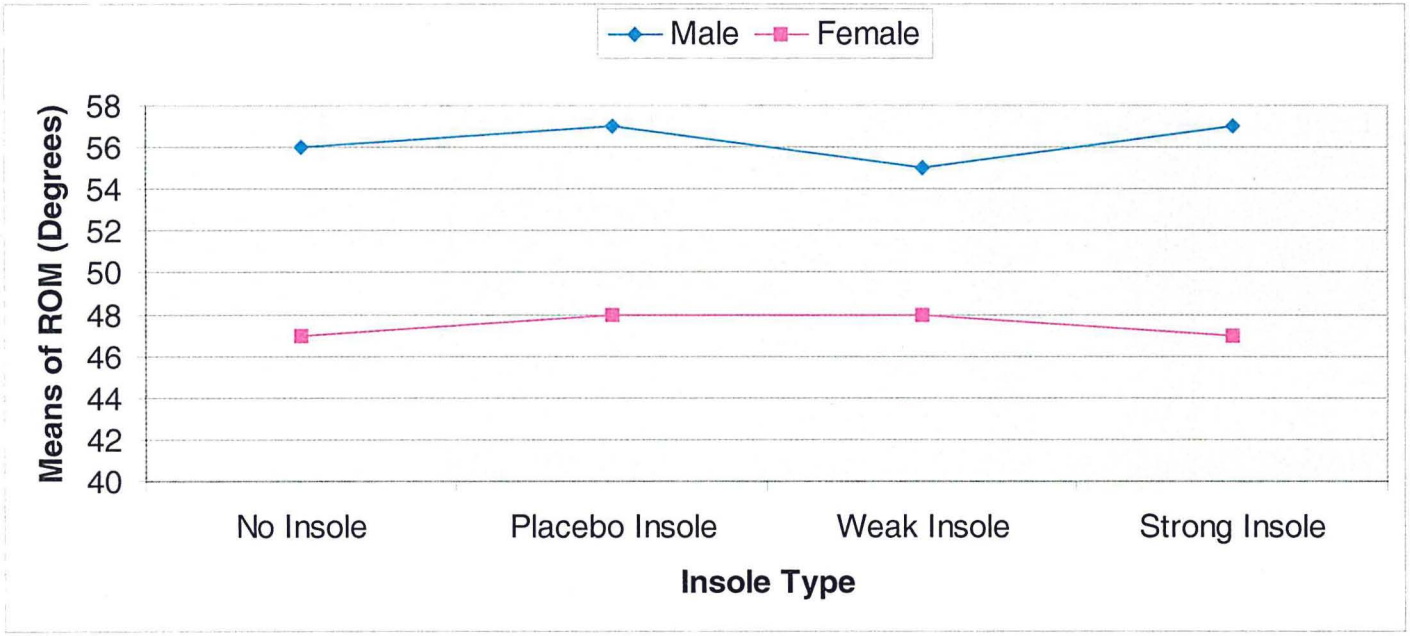

Figure 10. Interaction between gender and insoles.

conditions, a significant difference was found with males demonstrating greater ROM than females, $F(1,144)=45.815, p=0.000, \alpha=0.05$.

A Repeated Measures t test was used to compare ROM measurements of Trial 1 and Trial 2. When comparing the results of Trial 1 and Trial 2 at each insole, no significant differences were found at the insole with no magnet, $t(37)=-0.439, p=0.663, \alpha=0.05$; the insole with the weak magnet, $t(37)=-0.506, p=0.616, \alpha= 0.05$; nor at the insole with the strong magnet, $t(37)=0.401, p=0.691, \alpha= 0.05$.

CHAPTER V

DISCUSSION AND CONCLUSION

The overall correlation in this study between magnetic insoles and their effect on lumbar ROM was not statistically significant. There was also no significant difference in ROM on any of the insoles regardless of the strength of the magnets. These findings may be explained by several factors including lack of pathology or limitation of ROM in the lumbar spine, magnet placement, and time spent on the insoles.

The exclusion criteria established in this study were designed to result in a testing sample of healthy adults without any pathology of the lumbar spine that may inhibit full ROM. Without limitations, the subjects may have been incapable of demonstrating any marked improvements in their ROM when measured on the magnetic insoles. In addition, the effect of the magnets on the connective tissues in the lumbar spine may have been insufficient to show any significant increases in ROM.

Research indicates that the strength of a magnet is affected by the distance the area to be effected is from the magnet.[5,15] The results of this study suggest that the distance between the magnetic insoles and the lumbar spine may be too great to produce desired results. Although the magnetic insole manufacturers suggest that the magnets increase ROM throughout the body, some of the literature suggests that the magnet needs to be placed at or near the site of the desired effect.

Research is inconsistent regarding the appropriate duration of exposure to a magnetic device to achieve a therapeutic effect. The amount of time the participants in this study were in contact with the magnetic insoles was approximately 1 to 3 minutes, which was dependent on the number of repetitions needed for accurate measurement. When the insoles were obtained for this study, the distributor from Nikken Inc., the company that produced the stronger set of magnetic insoles, suggested that the magnetic insoles would produce their effect instantaneously. No published research, nor the results of this study support this claim. Furthermore, this study only evaluated the effect of magnetic insoles on lumbar flexion. The results for the lumbar spine do not necessarily indicate a lack of effect at other joints in the kinetic chain for the same exposure time.

The results did show a significant difference between men and women and the amount of lumbar ROM they were able to achieve. Male subjects demonstrated greater ROM in lumbar flexion than females. These results are consistent with other studies and norms for lumbar flexion.[28,33] Studies that have evaluated lumbar ROM in men and women have found that lumbar flexion is generally greater in males, and extension, rotation, and lateral flexion are generally greater in females. Possible explanations for this finding may include structural differences between males and females, or flexibility differences between genders in other musculature involved in forward flexion of the spine (i.e., hamstrings). Although males demonstrated greater lumbar flexion, neither gender showed significant differences in ROM when standing on the magnetic insoles.

The results found that the placebo effect did not contribute to the performance of the participants. Individuals who had no known impairments or previous back injuries

were used as subjects in this study. If the magnets had had the effect of "loosening" the connective tissue structures around the lumbar spine, it would be expected that even these reportedly "normal" subjects could have achieved additional ROM. This was not seen in this study as all subjects performed equally on all 3 insole types and between Trials 1 and 2.

Limitations/Future Research Considerations

One limitation of this study may have been tester proficiency with the double inclinometer method. Every attempt was made to reduce this error by completing a pilot study to provide the testers with practical experience with inclinometers and to measure intra-rater reliability. Good reliability was found within the testers in the pilot study.

The sample in this study consisted of individuals without limitations in lumbar ROM. Future research may consider using a testing sample of individuals with limited ROM with and without accompanying pain. If the subjects without impairments of this study were unable to gain ROM due to normal structural limitations, magnetic insoles may have the effect of increasing motion for an individual with limited ROM due to connective tissue impairments.

Another variable of magnet therapy that needs further research is the duration of exposure to the magnets. Research shows varying theories regarding the optimal amount of time necessary for desired results. Future research may evaluate various magnetic devices and various diseases/ailments in determining the appropriate duration of exposure as well as the varying effects of strength and polarity.

Other research projects may include evaluating various joints, various directions of motion at each joint, a larger sample size, and various magnet placement methods. Magnet placement methods may include placing the magnet directly over the joint with limited ROM, placing the magnet directly over referred and/or local sites of pain, or placing magnets at acupuncture points or along meridians.

While this study evaluated the effects of magnetic insoles on lumbar flexion ROM, future studies are needed to evaluate the effects of magnetic insoles at the joints nearest to the insoles (i.e., ankles, knees). In order to assess ROM of the ankle and/or knee while weight bearing on the insoles, one possible method may be to evaluate functional activities that involve extreme ranges of motion in the joint(s) to be tested utilizing motion analysis.

Conclusion

Manufacturers have claimed that magnetic devices can relieve pain, promote connective tissue relaxation and elasticity, and have therapeutic effects on many diseases and ailments. One of these claims was evaluated by this study to determine specifically if magnetic insoles would increase lumbar ROM. This research study concluded that there was no significant difference in lumbar flexion ROM in normal, healthy subjects when standing on magnetic insoles. Although this study specifically found no effect on lumbar flexion ROM, we cannot extrapolate other possible benefits of magnetic devices on the body from these results.

The insoles used in this study are easily accessible to the general public including individuals with and without physical impairments. Additional research needs to be

conducted to validate or negate the proposed effects of magnetic devices. Magnetic devices are not limited by government regulations, so there has been very little restriction on the claims made by the manufacturers. Since the general public may not be aware of government regulations, the average consumer may have difficulty distinguishing between the proposed and research based effects of magnetic devices. Government regulations would force manufacturers of magnetic devices to provide scientific research on the effects of their products before placing them on the market, providing consumers with more realistic and research based advertisements.

APPENDIX A

x EXPEDITED REVIEW REQUESTED UNDER ITEM ____ (NUMBER[S]) OF HHS REGULATIONS
___ EXEMPT REVIEW REQUESTED UNDER ITEM ____ (NUMBER[S]) OF HHS REGULATIONS

UNIVERSITY OF NORTH DAKOTA HUMAN SUBJECTS REVIEW FORM FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED PROJECTS INVOLVING HUMAN SUBJECTS

Please include ALL information and check ALL blanks that apply.

PRINCIPAL INVESTIGATOR: Dr. Sue Jeno, Kari Braaflat, Becky Cox, Angela Kiefat, Heather Skarsgard **TELEPHONE:** 701-777-2831 **DATE:** 3/20/01

ADDRESS TO WHICH NOTICE OF APPROVAL SHOULD BE SENT: P.O. Box 9037, Dept. of Physical Therapy, UND

SCHOOL/COLLEGE: Medicine (E.g., A&S, Medicine, EHD, etc.) **DEPARTMENT:** Physical Therapy **PROPOSED PROJECT DATES:** 3/01/01-5/1/02 (Month/Day/Year)

PROJECT TITLE: The Effects of Magnetic Insoles on Lumbar Flexion

FUNDING AGENCIES (IF APPLICABLE): Not Applicable

TYPE OF PROJECT (Check ALL that apply):

x NEW PROJECT ___ CONTINUATION ___ RENEWAL ___ DISSERTATION OR THESIS RESEARCH x STUDENT RESEARCH PROJECT

___ CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT

DISSERTATION/THESIS ADVISER, OR STUDENT ADVISER: Dr. Sue Jeno

PROPOSED PROJECT: ___ INVOLVES NEW DRUGS (IND) ___ INVOLVES NON-APPROVED USE OF DRUG ___ INVOVLES A COOPERATING INSTITUTION

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATION, PLEASE INDICATE THE CLASSIFICATION(S):

☐ MINORS (<18 YEARS) ☐ PREGNANT WOMEN ☐ MENTALLY DISABLED ☐ FETUSES ☐ PERSONS WITH

☐ PRISONERS ☐ ABORTUSES ☒ UND STUDENTS (>18 YEARS)

IF YOUR PROJECT INVOLVES ANY HUMAN TISSUE, BODY FLUIDS, PATHOLOGICAL SPECIMENS, DONATED ORGANS, FETAL MATERIAL, OR PLACENTAL MATERIALS, CHECK HERE ____

IF YOUR PROJECT HAS BEEN\WILL BE SUBMITTED TO ANOTHER INSTITUTIONAL REVIEW BOARD(S), PLEASE LIST NAME OF BOARD(S): _____

Status: ____ Submitted; Date _____ ____ Approved; Date _____ ____ Pending

1. ABSTRACT: (LIMIT TO 200 WORDS OR LESS AND INCLUDE JUSTIFICATION OR NECESSITY FOR USING HUMAN SUBJECTS.)

The use of magnets for therapeutic purposes has been a treatment of choice for many musculoskeletal conditions for hundreds of years in many European countries and China. Recently, it has become more popular in the United States with many people choosing to try this alternative therapy. The effects of magnets coincide with many of the effects of modalities (ultrasound, hot packs, E-stim) used in the physical therapy setting. Effects of magnets include: reducing fluid retention, reducing inflammation, relieving/decreasing pain, increasing circulation, and normalizing acid base balance[1]. Often times, pain can be a limiting factor in the amount of displayed range of motion (ROM). So by decreasing or relieving pain, there will be an increase in ROM. The purpose of this study is to determine the effects of magnetic insoles on lumbar flexion in a healthy population. The study will involve 100 non-impaired subjects between the ages of 18 and 50. The subjects' active lumbar flexion range of motion will be measured by the double inclinometer method at baseline and while standing on three different insoles. Two pair of insoles are magnetic, each set being of different strengths, and the third set will be nonmagnetic insoles. In order to accurately assess range of motion of the lumbar spine with an inclinometer, human subjects must be used. We hope to use the results of this study to show a beneficial use of magnets and the implementation of magnets as an adjunct to therapeutic treatment.

PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. **PROTOCOL:** (Describe procedures to which humans will be subjected. Use additional pages if necessary. Attach any surveys, tests, questionnaires, interview questions, examples of interview questions (if qualitative research), etc., the subjects will be asked to complete.)

Subjects:

One hundred non-impaired subjects between ages 18 and 50 with no known history of back problems will participate in the study. All subjects will be recruited voluntarily within the University of North Dakota. Prior to participation in the study, subjects will complete a survey regarding inclusion/exclusion criteria, and sign a consent form. Exclusion criteria will include: history of back pain/problems, fused spine, pregnancy, people possessing any of the following: pacemaker, cochlear implants, insulin pump, using a TENS unit on a regular basis, taking anti-coagulant medications, open/bleeding wounds, or a history of any of the following: platelet disorder, myasthenia gravis, hyperthyroidism, severe autoimmune inflammation, spinal neoplasm, Paget's disease, inflammatory back pain and cancer. Also subjects will be excluded if they report light headed/faint feelings with bending forward or if they cannot tolerate repeated movements requiring sustaining a head down, forward bent at the waist position for a period of approximately 5 seconds each repetition. Subjects who are possibly pregnant will be excluded because the effects of magnets on the fetus are not known at this time. Subjects with mechanic devices such as pacemakers, cochlear implants, insulin pumps, and TENS units will be excluded because the magnets may interrupt the function of these devices. Magnets have been found to increase circulation so subjects will be excluded if they presented with open/bleeding wounds, had a history of platelet disorder or if they were currently taking anti-coagulant medication. Positive magnetic energy can stimulate the growth of tumors so subjects will be excluded if they have a history of cancer. The project will be completed at the physical therapy department within the University of North Dakota's Medical School. Subjects will be asked to wear loose fitting clothing that will not impede movement and will allow free exposure of the lower thorax, lumbar spine and sacrum. Privacy will be considered and addressed by measuring subjects in a private room. The subjects will not be compensated for participation in this study.

Methods:

Subjects will be asked to perform a warm-up consisting of sustained lumbar flexion stretches for 30 seconds, 3 times prior to testing. The subjects range of motion will be measured utilizing a double inclinometer method in four separate test conditions- baseline and standing on three separate insoles. The magnetic insoles being used come from different companies. Insole A is from the Nikken company and Insole B is from Dr. Scholl's. Both insoles were measured with a gauss meter at the University of North Dakota's Engineering Department. Insole A consisted of 71 magnets within the insole, with the north poles measuring between 190-265 gauss and the south poles measuring between 120-170 gauss. Insole B consisted of 7 magnets within the insole with the north poles ranging 90-120 gauss and the south pole's strength ranging from 85-115 gauss. In both insoles, the north and south poles were alternated in position. The nonmagnetic insole is also from Dr. Scholl's and has no magnets within it. These insoles will be placed on the ground by an outside individual prior to the testers or subjects come in contact with them, so neither the testers nor the subjects will know which insoles contain the magnets. This double blind method will ensure randomization and unbiased measurements by the testers.

To obtain ROM measurements, a double inclinometer method will be used to measure lumbar flexion. The order of measurement will be randomly assigned to each subject. The T12 and S2 spinous processes will be marked with a wax pencil for easy reference. The subject will stand upright with knees straight and weight evenly distributed between both feet, hands placed on the hips. The first inclinometer will be placed over the T12 spinous process with the middle of the inclinometer directly over the spinous process. The second inclinometer will be placed over the S2 spinous process, again with the middle directly over the spinous process. Both inclinometers will be aligned in the sagittal plane and zero readings will be obtained. The subject will then be asked to actively flex forward as far as possible and both inclinometer readings will be recorded. The sacral inclinometer measurement will be subtracted from the T12 measurement to obtain the true lumbar flexion angle. The subject will then return to neutral trunk position. This procedure will be repeated until three consecutive measurements are obtained that are within $\pm$ 10% or 5° of each other, whichever is greater[2]. However, a maximum of six measurements will be performed on each subject in each test condition. If three consecutive measurements fitting the above criteria are not obtained within the six measurements, the subject's data will not be used for this study.

The subject's will be asked to repeat the same test procedure after a 10-minute break to measure the placebo effect. Prior to entering the testing area, the subjects will be told that the one set of insoles contains a strong magnet and will greatly improve their range of motion. Due to the double blind nature of the study, only the individual who places the insoles prior to testing will be aware of which insoles are actually the strong magnets.

Data Analysis:

Descriptive statistics describing the subject's will be reported. The data collected during the experiment will be compiled for each of the insoles used in this study. Results will be analyzed utilizing traditional descriptive and analytical statistics.

3. **BENEFITS:** (Describe the benefits to the individual or society.)

This study will potentially lead to the advancement of research in the area concerning the use of magnets in a physical therapy setting and as an alternative therapy. The subjects that participate will learn about the proposed benefits of magnets and their effects on range of motion. The results from this study may aid the subjects and others in future decisions about whether to use magnets as a source of therapeutic intervention.

4. **RISKS:** (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to protect the confidentiality of data obtained, debriefing procedures, storage of data, how will be stored (long date must be a minimum of three years), final disposition of data, etc.)

Potential risks to subjects include the possibility of minor muscle soreness from the act of flexing at the spine several times during the trials. This risk is very minor as the motion being performed is performed during activities of daily living. To minimize the risk each subject will perform a brief warm-up consisting of range of motion and stretching for the lumbar spine.

The subjects in this study will be identified by a numbered code only. The names of the subjects will not be used in any reports using the results of this study. Any information gathered in connection with this study and that can be identified with the subjects will remain confidential and will be disclosed only with the subjects permission. Only the investigators will know the numbered code identifying the data.

Data will be stored at the University of North Dakota in the Department of Physical Therapy in the office of Dr. Sue Jeno. It will be placed in a secured cabinet for a period of three years from the time of completion, after which time it will be shredded.

5. **CONSENT FORM:** Attach a copy of the **CONSENT FORM** to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no **CONSENT FORM** is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur.

   Describe where signed consent forms will be kept and for how long (must be a minimum of 3 years), including plans for final disposition or destruction.

The consent forms will be kept in Dr. Sue Jeno's office, which is located in the Department of Physical Therapy at the University of North Dakota. It will be placed in a secured cabinet for a period of three years from the date of completion of the study. After this period of time the information will be shredded.

Please see attached form.

Reference:

1. Philpott WH, Taplin S. *Biomagnetic Handbook A Guide to Medical Magnetics The Energy Medicine of Tomorrow.* Choctaw, OK: Enviro-Tech Products; 1990:6, 27.
2. Cocchiarella L, Anderson GBJ. The Spine. In: *Guides to the Evaluation of Permanent Impairment.* 5th ed. United States: AMA Press; 2000:402-403.

6. For **FULL IRB REVIEW** forward a signed original and fifteen (15) copies of this completed form, including fifteen (15) copies of the proposed consent form, questionnaires, examples of interview questions, etc. and any supporting documentation to the address below. An original and 19 copies are required for clinical medical projects. In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company's protocol must be provided.

Office of Research & Program Development
University of North Dakota
Grand Forks, North Dakota 58202-7134

On campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105 Twamley Hall.

For **EXEMPT** or **EXPEDITED REVIEW** forward a signed original, including a copy of the consent form, questionnaires, examples of interview questions, etc. and any supporting documentation to one of the addresses above. In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

SIGNATURES:

Principal Investigator	Date
Project Director or Student Adviser	Date
Training or Center Grant Director	Date

(Revised 2/2000)

STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UND Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your "Human Subjects Review Form."

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD[1]

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board's access to those portions of my educational record which involve research that I wish to conduct under the Board's auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit. The study to which this release pertains is _____

_____

_____

I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation.

_____ _____

Date Signature of Student Researcher

[1]Consent required by 20 U.S.C. 1232g.

REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW

University of North Dakota Institutional Review Board

Date: April 30, 2001 **Project Number:** IRB-200105-234

Name: Sue Jeno, Kari Braaflat, Becky Cox, Angela Kiefat, Heather Skarsgard **Department/College:** Physical Therapy

Project Title: The Effects of Magnetic Insoles on Lumbar Flexion

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on May 4, 2001 and the following action was taken:

☐ Project approved. **EXPEDITED REVIEW** Category No. _____
Next scheduled review is on: _____

☐ The attached consent form dated _____ is the **only consent form which may be used for this study.**

☒ Project approved. **EXEMPT REVIEW** Category No. 2
This approval is valid until June 1, 2002 as long as approved procedures are followed. No periodic review scheduled unless so stated in the Remarks Section.

☒ The attached consent form dated May 4, 2001 is the **only consent form which may be used for this study.**

☐ Project approved **PENDING** receipt of corrections/additions. These corrections/additions should be submitted to ORPD for review and approval. **This study may NOT be started UNTIL final IRB approval has been received.** (See Remarks Section for further information.)

☐ Project approval **deferred. This study may not be started until final IRB approval has been received.** (See Remarks Section for further information.)

☐ Project **denied.** (See Remarks Section for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairperson or ORPD.

PLEASE NOTE: Requested revisions for student proposals MUST include adviser's signature.

Kathy Small 5-4-01

cc: Sue Jeno, Adviser

Signature of Designated IRB Member
UND's Institutional Review Board

Date

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact ORPD to obtain the required documents.

(Revised 2/2001)

APPENDIX B

ID # _____

Magnetic study participation survey

Birthdate: / /
Gender: M or F

Height:
Weight:

1. Is there any chance that you could be pregnant? _____
2. In the past year have you experienced any significant back pain or needed to seek medical attention for back problems? If yes, explain: _____

   _____
3. Do you have any of the following? Circle all that apply:

   Pacemaker Cochlear implants Fused spine

   Tens unit Insulin pump
4. Have you been diagnosed with any of the following? Circle all that apply:

   Platelet disorder spinal neoplasm Cancer

   Myasthenia Gravis Paget's disease Hyperthyroidism

   Inflammatory back pain severe autoimmune inflammation
5. Are you taking any medications at this time? If so explain: _____

   _____
6. Are you on any Anti-coagulant drugs? If so explain: _____
7. Do you have any open, bleeding wounds? _____
8. List any relevant surgeries you've had: _____
9. Do you get light headed when changing positions? _____
10. Do you have any problems bending forward at the waist or holding that position?

    _____

APPENDIX C

I.D. #____

INFORMATION AND CONSENT FORM
Lumbar Flexion Range of Motion Study

Principle Investigators: Dr. Sue Jeno, Kari Braaflat, Becky Cox, Angela Kiefat, and Heather Skarsgard from the Department of Physical Therapy at the University of North Dakota

You are being invited to participate in this study of the lumbar spine (low back) range of motion. the purpose of this study is to determine effects of various insoles on low back range of motion. We hope that the results of this study will aid Physical Therapists in the treatment of decreased back motion. We also hope to provide a basis for future research that may be of use to Physical Therapists in involved in treatment of patients with decreased motion.

You were chosen because: 1- of your age, 2-lack of back pain, 3- exclusion criteria, and 4- your willingness to participate in this study.

As a subject for this study, you will be asked to go to the Physical Therapy Department at the University of North Dakota, located in the Medical Science North Building. We expect participation to last approximately 30 minutes. Prior to testing, a pre-specified stretching exercise will be performed. You will then be asked to stand on three different sets of shoe insoles and perform bending at the waist. This motion will be measured and recorded. Magnetic devices may be utilized during the measurements. You will be asked to do this at each set of insoles. Subjects are asked to wear loose fitting clothing that will not impede movement and will allow free exposure of the lower and middle back. We will honor your privacy and address this issue appropriately.

Although the process of physical performance testing always involves some degree of risk, the investigators in this study feel that,, because this is a commonly performed motion, the risk of injury or discomfort is minimal. Minor muscle soreness may result following the repeated activity. However, to reduce this, you will be taken through a brief warm-up of forward bending at the waist prior to the testing procedure.

Your name will not be used in any reports of the results of this study. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. The investigator or participant may stop the experiment at any time if the participant is experiencing discomfort, pain, or any other symptoms that may be detrimental to his/her health. Your decision whether or not to participate will not affect your future relationship with the University of North Dakota. If you decide to participate, you are free to discontinue participation at any time without prejudice.

The investigators involved are available to answer any questions you have concerning this study. In addition, you are encouraged to ask questions concerning this study that you may have in the future. Questions may be answered by calling Dr. Sue Jeno at (701) 777-2831 or Heather Skarsgard at (701) 777-9880. If you have any other concerns, contact the University of North Dakota Institutional Review Board at the Office of Research and Program Development at (701) 777-4279. At your request you will be given a copy of this form for future reference.

In the event that this research activity results in physical injury, medical treatment will be available as it is to a member of the general public for similar circumstances. You and your third party payer must provide payment for any such treatment.

All of my questions have been answered and I am encouraged to ask any questions that I may have concerning this study in the future. I have read all the above and willingly agree to participate in this study as it is explained to me by Kari Braaflat, Becky Cox, Angela Kiefat, and Heather Skarsgard.

_____

Subject's Signature **Date**

_____

Witness's Signature **Date**

APPENDIX D

Data Collection Form

Date ID #

Baseline	T12	S2	T12-S2
Measurement 1			
Measurement 2			
Measurement 3			
Measurement 4			
Measurement 5			
Measurement 6			

Insole____	T12	S2	T12-S2
Measurement 1			
Measurement 2			
Measurement 3			
Measurement 4			
Measurement 5			
Measurement 6			

Insole____	T12	S2	T12-S2
Measurement 1			
Measurement 2			
Measurement 3			
Measurement 4			
Measurement 5			
Measurement 6			

Insole____	T12	S2	T12-S2
Measurement 1			
Measurement 2			
Measurement 3			
Measurement 4			
Measurement 5			
Measurement 6			

(Placebo) Insole____	T12	S2	T12-S2
Measurement 1			
Measurement 2			
Measurement 3			
Measurement 4			
Measurement 5			
Measurement 6			

(Placebo) Insole____	T12	S2	T12-S2
Measurement 1			
Measurement 2			
Measurement 3			
Measurement 4			
Measurement 5			
Measurement 6			

(Placebo) Insole____	T12	S2	T12-S2
Measurement 1			
Measurement 2			
Measurement 3			
Measurement 4			
Measurement 5			
Measurement 6			

APPENDIX E

Kari Braaflat
University of North Dakota
PO Box 9037
Grand Forks, ND 58202

December 9, 2001

Clifton Jolly
Advent Communications
Dallas, TX

Dear Mr. Jolly:

We are writing to request permission to reproduce a copy of the triangular board patterned insole. The figure would be used in our Scholarly Project, which is part of our graduate requirements for a Master in Physical Therapy degree from the University of North Dakota, Grand Forks, North Dakota.

Six copies will be made for the following uses: Graduate School, Physical Therapy Library, and for each of us to have a copy of the Scholarly Project. The figure will be referenced as a source from Nikken. Please fax a copy of this to UND at 701-777-4199.

Thank you for your attention to this request.

Sincerely,

Kari Braaflat, SPT
Department of Physical Therapy
Grand Forks, ND 58202

Approval is given to Kari Braaflat, Physical Therapy student at the University of North Dakota, for copying the above figure for educational purposes outlined above.

Date Thu, 06 Dec 2001 14:47:38 -0800
From "Clifton H. Jolley, Ph.D." <clifton@adventcommunications.com>
To klettenm@medicine.nodak.edu
Reply-To clifton@adventcommunications.com
Subject Re: magnetic insoles
Parts Message Source

Happy to comply.

Send the waiver ... and please copy me with your report when it is completed.

APPENDIX F

Consent for Taking and Publication of Photographs

Name: Ryan Stromme

Location: University of North Dakota

Date: 7-9-01

In association with Kari Braaflat, Becky Cox, Angela Kiefat, and Heather Skarsgard's study entitled "The Effects of Magnetic Insoles on Lumber Range of Motion," I consent to the researchers using photographs of me, which may be published under the following conditions:

1. The photographs shall be used if the researchers, Kari Braaflat, Becky Cox, Angela Kiefat, and Heather Skarsgard deem that medical research, education or science will be benefited from their use. These photographs may be published and republished, separately or in connection with each other, in professional journals or medical books provided that in any such publication or use I shall not be identified by name.

2. The aforementioned photographs may be modified or retouched in any way the researchers deem necessary.

Signed _____ Date 7/9/01

Witness _____ Date 7/9/01

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REFERENCES CITED

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