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The Short-Term Effects of Magnetic Insoles on Pain and Function in a Population with Lower Extremity Osteoarthritis: A Pilot Study

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THE SHORT-TERM EFFECTS OF MAGNETIC INSOLES ON PAIN AND FUNCTION IN A POPULATION WITH LOWER EXTREMITY OSTEOARTHRITIS: A PILOT STUDY

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This Scholarly Project, submitted by Janice Holth, Jennifer Surma, and Sarah Barendt in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Faculty Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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PERMISSION

Title
The Short-term Effects of Magnetic Insoles on Pain and Function in a Population with Lower Extremity Osteoarthritis

Department
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Degree
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TABLE OF CONTENTS

LIST OF FIGURES..................................................................................................................v
LIST OF TABLES.......................................................................................................................vi
ACKNOWLEDGEMENTS.............................................................................................................vii
ABSTRACT.................................................................................................................................viii

CHAPTERS
I. INTRODUCTION..................................................................................................................1
II. LITERATURE REVIEW..........................................................................................................4
III. METHODS...........................................................................................................................18
IV. RESULTS.............................................................................................................................23
V. DISCUSSION/CONCLUSION.................................................................................................29

APPENDICES
A. VAS..................................................................................................................................35
B. SF-36v.2................................................................................................................................37
C. Advertisement.......................................................................................................................44
D. IRB Human Subjects Review Form.....................................................................................46
E. Foot Assessment....................................................................................................................53
F. Participant Survey................................................................................................................55
G. Consent Form.......................................................................................................................57
H. Wearing and Activity Log....................................................................................................60

REFERENCES............................................................................................................................62
LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>95% Confidence Intervals of the Means for Pain Scores</td>
<td>25</td>
</tr>
<tr>
<td>2.</td>
<td>95% Confidence Intervals of the Means for Physical Aggregate Scores</td>
<td>27</td>
</tr>
<tr>
<td>3.</td>
<td>95% Confidence Intervals of the Means for Mental Aggregate Scores</td>
<td>28</td>
</tr>
</tbody>
</table>
# LISTS OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Participant demographics</td>
<td>24</td>
</tr>
<tr>
<td>2. Pain Means and Standard Deviations</td>
<td>25</td>
</tr>
<tr>
<td>3. Physical Aggregate Means and Standard Deviations</td>
<td>27</td>
</tr>
<tr>
<td>4. Mental Aggregate Means and Standard Deviations</td>
<td>28</td>
</tr>
</tbody>
</table>
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CHAPTER I
INTRODUCTION

Worldwide, 70-90% of the population use alternative medicine for pain relief.¹ There are many forms of alternative medicines that are becoming popular with people experiencing pain. Most alternative therapies do not require invasive surgeries or use of medications. One form of alternative medicine that people use is magnetic therapy. Americans spend more than $500 million annually on magnets to treat pain.² The estimated amount spent on magnetic therapy worldwide is $5 billion.² Many people purchase magnets in stores or over the internet to use on their own without consulting a health care provider.³ However, many of the forms of alternative medicines, including magnets, do not have significant evidence to prove that they do indeed work.

For hundreds of years, magnets have been used to alleviate pain. Magnets are said to improve fibromyalgia,⁴ fracture healing,⁵ carpal tunnel syndrome,⁶ pelvis pain,⁷ diabetic foot pain,⁸,⁹ multiple sclerosis,¹⁰ osteoarthritis (OA),¹¹ chronic low back pain,¹² rheumatoid arthritis pain,¹³ and tinnitus.¹⁴ Magnets have even been acknowledged to help physical performance¹⁵ and increase range of motion.¹⁶ Philpott & Taplin¹⁷ showed that magnetic therapy can improve mood. Magnets are used in shoe insoles, heel inserts, mattress pads, bandages, belts, pillows/cushions, bracelets, and other jewelry.² There has been some published research on the effects
of magnetic therapy but more is needed for the safety of the consumers. The medical community would benefit from more research on magnetic therapy in order to prove and standardize the treatment options.

Purpose

The purpose of this study was to evaluate the short-term effects of magnetic insoles on lower extremity (LE) OA pain and function.

Research Questions

1. Is there a significant difference in pain when an individual uses magnetic insoles?
2. Is there a significant difference in function as self reported on the Short Form-36v2 (SF36) when an individual uses magnetic insoles?

Significance

The significance of this study was to assess if magnetic insoles decrease pain and increase functional abilities in people with OA of the LE.

Null Hypotheses

1. There is no significant difference in perceived level of pain with use of a magnetic insole, a nonmagnetic insole, and no insole.
2. There is no significant difference in perceived level of function under the conditions of wearing a magnetic insole, a nonmagnetic insole, or no insole, as self-reported in the SF-36v2 in the physical and mental aggregate scores.
Alternate Hypotheses

1. There is a significant difference in perceived level of pain with using a magnetic insole, a nonmagnetic insole, and no insole.

2. There is a significant difference in perceived level of function under the conditions of wearing a magnetic insole, a nonmagnetic insole, or no insole, as self-reported in the SF-36v2 under the physical and mental aggregates.
CHAPTER II
REVIEW OF LITERATURE

Osteoarthritis

Osteoarthritis is defined as "a chronic joint disorder characterized by degeneration of joint cartilage and adjacent joints that can cause joint pain and stiffness."\(^{18}\) Osteoarthritis is also described by Goodman, Boissonnault, and Fuller\(^{19}\) as a slow, progressive degeneration of joint structures including articular cartilage and bone, with joint space narrowing.\(^{19}\) Two out of 3 people in the United States over the age of 35 have signs and symptoms of OA. Due to the profound effects on the joints, many people with pain associated with OA seek medical and non-traditional approaches to pain management and improvement of function, including the use of magnetic therapy.

The primary cause of OA has been found to be a defect in the articular cartilage which leads to degenerative changes in the articular surfaces of the weight bearing joints such as the hips and knees. Secondary causes of OA include trauma, infection, hemarthrosis, osteonecrosis, or other pathological conditions.\(^{19}\) Described by Goodman, Boissonnault, and Fuller\(^{19}\) as being driven by mechanical forces but mediated by biomechanical processes, OA is an active disease process and generally not the result of general "wear and tear" on a joint. The disease process begins with the loss of cartilage which leads to joint inflammation and bony overgrowth with
osteoophyte development. As there is no cure for OA, joint changes then lead to muscle weakness and atrophy, ligamentous laxity, and joint pain. Signs and symptoms of this disease process include: pain, deep ache, stiffness, crepitus, swelling, and decreased flexibility of the joint. Although often relieved by rest, these symptoms can greatly impact a person’s life and lead to the necessity for medical treatment.

The most prevalent risk factors of OA are age, poor weight control, muscle weakness, joint laxity, decreased bone density, genetics, local biomechanical factors, and a life of inadequate diet and lack of exercise. In many cases, serious injury of a joint, especially the hip, has been found to lead to OA of the joint. Sport activities can lead to degenerative changes of OA if they are high intensity, high impact, repetitive, and include twisting of the lower extremities.

Factors placing individuals diagnosed with OA at high risk for decreasing function include proprioceptive inaccuracy, knee pain intensity, and a high Body Mass Index (BMI). Factors which increase a person’s functional ability with OA include strength, mental health, high self-efficacy, increased social support, and a greater amount of aerobic exercise per week. Many of the people diagnosed with OA experience the need to reduce the amount of exercise and weight bearing activities in their lives due to pain in their joints. This sedentary lifestyle leads to increased weight and/or obesity, which puts more stress on the joints and begins a continuous destructive cycle. Combined with decreased lower extremity function, this cycle has been shown to increase the chances of osteophyte development in a 5 year study.
Reducing the effects and progression of OA is a primary goal of treatment. Adequate amounts of Vitamin D and Vitamin C in the diet as well as early diagnosis and intervention has been found to slow the disease process. Traditionally prescribed medications to decrease pain and degenerative changes associated with OA include COX-2 inhibitors, nitric oxide synthesis inhibitors, antioxidants, bone growth promoters, metalloproteinase and cytokine inhibitors, and gene therapy. Additional medications can include aspirin, corticosteroids, intramuscular and intra-articular steroid injections. Additional recommendations to increase functional ability include weight control and exercise combined with strength training. Self management techniques that are increasing in popularity include TENS, acupuncture, hot and cold packs, pacing of activities, relaxation techniques, yoga, Tai Chi, goal setting, food supplementation such as glucosamine, and the use of walking aids or insoles. Another therapy becoming popular for patients with painful OA is aquatic exercise which has been proven to reduce pain in weight-bearing joints. With the expanding popularity of these pain-reducing therapies, people are also trying other alternative therapies such as magnetic energy for pain reduction and improved function.

Magnets

Humans have been utilizing the power of magnetism for thousands of years. A lodestone (magnetite) mine dating back 100,000 years was located in Africa where magnetite was used in foods, potions, and creams to alleviate many different conditions. It is thought that many civilizations, including the Chinese, Egyptians, Hebrews, Indians, and Greeks used magnets to cure illnesses, heal various conditions,
and relieve pain. In 1000 A.D., a Persian physician documented the use of magnets to relieve gout, muscle spasms, and other disorders. Although the shape and size of magnets have changed, the basic principal in a magnetic therapy has remained the same. Natural (permanent) magnets are composed of a north pole, which has a negative charge, and a south pole which has a positive charge. Opposite poles attract each other and like poles repel. Magnets are able to produce their magnetic fields without an electrical current being present. Today, over 100 million people worldwide use magnetic therapy to counter the effects of pain, stress, and various conditions on the body. In Japan, magnetic therapy is popular due to research findings that show magnets to be effective for the treatment of pain. A natural magnetism exists in objects such as the loadstones used in Africa, the human body, and the sun. Dr. Kyoichi Nakagawa, director of Tokyo’s Isuzu Hospital, believes that the proven decreasing magnetism of the sun causes a magnetic deficiency syndrome in the body which increases the population’s need for additional magnetism in their lives. Symptoms he has associated with this syndrome include migraines, lack of energy, insomnia, general stuffiness, aches, pains, lower back problems, memory loss, and changes in heartbeat and blood chemistry. It is these factors that Nakagawa believes are the fundamentals behind the disease processes today and leads to the need for the application of magnetic therapy on the human body.

Factors that can influence the effects of a magnetic field on the body include the duration of time the magnetic device is in contact with the body, strength and polarity of the magnet, geometric configuration, depth of penetration, and anatomical placement. The recommended duration of magnetic therapy use for the therapeutic
effect of magnetism to occur varies by study. However, most studies agree that there is an immediate effect on the body when magnets are applied to it.\textsuperscript{6, 10, 11, 12, 13, 14, 28}

When assessing length of time for effects to occur, it is important to consider the strength and polarity of the magnet because these factors can alter the affects on the individual. It is also important to consider factors such as age, the length and condition of the disorder, climate, and response of the body because these factors can affect the participants’ response to magnetic treatment. Depending on these factors, treatment times can vary from seconds to months. Several studies report bodily changes due to magnetic therapy to be present after two weeks of utilizing the therapy.\textsuperscript{7, 11, 29}

Polarity of a magnet refers to the direction of the magnetic force.\textsuperscript{30} It has been shown that the negative polarity is safe for treatment of most disorders, especially when using high strength magnetic fields for a long exposure.\textsuperscript{3, 30} Negative magnetic energy is used to normalize human cellular metabolic function, heal tissues, and calm the human body.\textsuperscript{30} When positive magnetic energy is used incorrectly, or overused, it can cause adverse effects on the tissues, or cause traumatic side effects such as altering nerve conduction or blood flow.\textsuperscript{14}

Magnetic fields pass freely through the body; the penetration of a magnetic field is directly related to the mass and the strength of the magnet.\textsuperscript{14, 17} The strength of a magnet depends on the material used, shape, weight, size, and polarity. A gauss meter measures the strength of the magnet by the amount of iron-weight it can lift. A gauss unit (G) is the force of attraction that is measured at the surface of a magnet.\textsuperscript{14} In order for magnetic therapy to be effective, research shows that the strength should
be at least 500 G. An example of an insole, sold by American Magnet, has 15 alternating vertical bands of 100G each in the positive and negative fields. This alternating polarity produces a magnet with a weak strength of 100G over all.

Geometric configuration patterns of magnetic fields within a magnetic therapy device can include parallel lines, circles, triangular-board, or checkerboard patterns. The arrangement of the magnets used in products influences the strength of the magnets overall. The strongest pattern proven effective for a magnetic insole is a triangular-based grid. The magnetic insoles produced by American Magnet utilize a parallel line configuration. A study aimed to test the effectiveness of arrangements of static magnetic fields found that a whole-body, negative-field sleep pad reduced pain to a greater extent than a sham mat containing magnets of varying polarity. However, participants using either of the magnetic pads experienced improvements in functional status, pain intensity, and tender points.

The effects of magnets on the human body are not proven in every case; however, many effects are theorized to occur in individuals treated with magnetic therapy. These effects include balancing the equilibrium between cell death and growth, increasing blood flow while increasing the delivery of oxygen and nutrients to the tissues, dilation of blood vessels, increase the production of white blood cells, reducing fluid retention and inflammation, and increasing connective tissue relaxation. It is also important to take into account the possibility of these effects causing unforeseen complications with pre-existing conditions. Magnetic therapy is not recommended for everyone. Contraindications include women who are pregnant as there is unknown effects on the fetus, consumers with an implanted device such as
an insulin pump, pacemaker, defibrillator, TENS unit, or cochlear implants should not use magnets due to the possibility of disruption of the magnetically controlled features of the devices, people who use a medication patch which magnetism may effect the delivery of the medication. Those persons taking anticoagulants or have a platelet disorder, Myasthenia Gravis, or hyperthyroidism should not use magnetic therapy due to the increased bleeding that can occur with application of magnetic fields. This caution also applies to persons with infections or wounds which may be adversely affected by the magnetic field. Magnetic therapy is also not recommended for those persons with cancer due to the increased circulation and possible spread or metastasis within the body. There are some potential side effects that have been reported from improper use of magnets, such as headaches, pain, insomnia, seizures, digestive problems, toxin release, tumor growth, dizziness, hyperactivity, and medication interactions.32

Magnetic Therapy and OA

Research shows conflicting results in the effectiveness of magnetic therapy for relief of pain from OA. One study reviewed 3 randomized control trials of pulsed electromagnets used on patients with OA of the knee and of the neck which demonstrated that magnets had a small to moderate effect on knee pain and a much smaller effect on neck pain.28 The researchers concluded that the current limited evidence does not show a clinically important benefit of pulsed electromagnets for treating OA of the knee or neck and that there is a need for larger trials to prove whether significant benefits do exist.28
Another trial utilizing pulsed electromagnet therapy with OA had participants use a placebo device or a Pulsed Electro Therapy (ET) device placed on or between the knees for 10 minutes 3 times per day.\textsuperscript{33} Pulsed ET significantly reduced pain, over a 6 week period in the treatment group, and did not produce any adverse effects. No improvements were noted with the placebo-treated group. The authors suggested further studies are needed to assess Pulsed ET for OA and other conditions.\textsuperscript{33}

A third method of using pulsed electromagnetic therapy had participants with OA of the knee lay on a pulsed electromagnetic mat or a sham mat for 30 minutes twice a day for 6 weeks. At the end of the 6 week trial, physical function scores were significantly improved for the treatment group compared with the sham group while pain and stiffness decreased for both groups.\textsuperscript{34} Therefore, no significant difference in pain and stiffness was found between the groups.\textsuperscript{34}

In a study utilizing static magnetic fields for treatment of pain associated with OA of the knee gave subjects a knee sleeve which either contained magnets, or was a placebo sleeve without magnets. Knee pain was measured at 4 hours, 1 week, and 6 weeks. There was a statistically significant improvement in pain in the treatment group at 4 hours, but no significant difference was found at 1 week or 6 weeks.\textsuperscript{33} This study indicates that a 1 week or 6 week wearing period had no effect on knee pain compared to a 4 hour assessment.

Marketing campaigns for magnetic insoles target individuals with diagnoses of OA of the foot, knee, and hip although limited research is available to determine the validity of the claims. Research concerning heel pain, however, has demonstrated results of decreased pain and increased function.\textsuperscript{35} One study that assessed the effects
of magnetic insoles on plantar heel pain found no significant differences in pain outcomes between participants who received either shoe insoles containing a magnet or insoles that were identical except for having no magnet. Participants wore the insoles at least 16 hours per week for 2 months and kept a daily pain diary to measure outcomes. Both groups experienced significant improvement in morning foot pain and in enjoyment of their jobs although no significant differences were found between treatment groups.35

Various magnetic therapy devices have been researched to analyze their effect on pain and function in people with OA. It is due to the limited research available concerning static magnetic fields for the improvement of pain and/or function in persons with OA that further research is needed to evaluate magnetic therapy use in this population. Assessments used for the evaluation of pain and function in persons with OA are also key to the research of magnetic therapy's effects on a person and vary widely in their use in clinical settings.

Evaluation Measures for Pain

Several effective pain measures have been identified for various populations including the verbal, numerical, or line graph Visual Analog Scale (VAS),36 verbal or written reports,37 the McGill Pain Questionnaire,37 the modified pain chart,37 and pain diaries.37 The VAS (Appendix A) has been proven valid and reliable with many populations of people in pain38 and those with chronic pain36 such as the pain caused by changes associated with OA. Two versions of the VAS include the absolute and comparative scales.36 The absolute scale represents a person's pain at that moment in time while the comparative scale allows comparisons to previous scores to show
changes in pain over time.\textsuperscript{36} The absolute scale has demonstrated greater reliability in clinical testing than the comparative scale.\textsuperscript{36} Barker, Lamb, Toye, Jackson, and Barrington\textsuperscript{39} used the VAS pain rating scale to compare pain felt by people with OA and the radiographic findings indicating the disease progression. The researchers found that pain scores had greater clinical correlations with physical functioning than radiographic scoring.\textsuperscript{39} A study evaluating the effects of an aquatic exercise program on participants OA pain used the VAS to evaluate changes in pain over the course of the study.\textsuperscript{24} The VAS is widely used in OA literature to assess the pain felt by people with OA and the changes experienced through treatment.\textsuperscript{24,35,39}

Evaluation Measures for Function

Radiographic scoring or grading of OA of the lower extremities is often done prior to joint replacement surgeries to assess the degree of OA involvement in the joint but may not be the optimal choice for analyzing changes in function of the persons with OA.\textsuperscript{22,39} The Kellgren and Lawrence scale of radiographic grades indicates the level of pathology from 0 to 4 with zero being no osteoarthritis development and 4 being severe involvement.\textsuperscript{39} Although these techniques are commonly used by surgeons, Barker, Lamb, Toye, Jackson, and Barrington,\textsuperscript{39} studied patients prior to joint arthroplasty and discovered that there were considerable variations in function, pain and power among participants with the same radiographic score. Two studies have found that pathological level of involvement or radiographic findings are not predictive of patient pain or function with OA leading to the necessity of the development of other testing procedures.\textsuperscript{39,40}
Reproducible physical function tests which diagnose and track the effects of OA on the body include on-the-spot marching, walking up and down stairs, completing a maximum number of straight leg raises, and a repeated chair stand exercise. These examinations have been designed to assess the functional impact of OA on the person as a whole. They have also been proven to be effective in evaluating changes in patient’s function through the course of treatment or disease progression.

Also effective for tracking changes in function and health are self-report, health related quality of life (HRQOL) questionnaires such as the Short Form-36 (SF-36) (Appendix B), which make it easy for a patient and therapist team to assess a patient’s progress in treatment. The SF-36 is a self reporting questionnaire covering a person’s functional abilities and perceived quality of life. The second version of the Short Form-36, the SF-36v.2, was developed to be a more “international version” of the first edition and contains improved instructions and item wording, improved layout, increased comparability for cultural and translational adaptations, and an adapted 5-point scale as opposed to the original 7-point scale. The SF-36v.2 is recommended for population surveys, outcome research studies, controlled clinical trials, and clinical practice with individual patients. Questions on the SF-36v.2 are rated to indicate the level at which the participants health has effected different aspects of their life over the past week. For example, Question 1 asks “In general, would you say your health today is:” with response options: “1. Excellent, 2. Very Good, 3. Good, 4. Fair, or 5. Poor.” Norm-based scoring algorithms have been
developed and researched to maximize reliability and validity of the SF-36v.2 making it a standardized test which is accepted in many fields.42

Salaffi, Carotti, and Grassi43 conducted a study which compared the Western Ontario and McMaster University (WOMAC) OA-specific questionnaire with the more broad SF-36. Their findings indicate that the WOMAC may be the instrument of choice when assessing only the consequences of knee and hip OA in elderly patients.43 The SF-36 was found to be better at assessing general function, non-muscular co-morbidities and physical limitations in this population.43 Both the WOMAC and the SF-36 are self-reporting questionnaires with the WOMAC covering only the participants' perception on their pain, stiffness, and physical functional disabilities.43 Due to the multiple effects that magnets have on the body and the likelihood of co-morbidities, it is important that assessments of many factors are included in this study, leading to the utilization of the SF-36 as the functional assessment measure. Davey, Edwards, and Cochrane44 proved the SF-36 to have test-retest reliability in participants with lower extremity OA. The mental health and role-functioning areas of the SF-36 have been proven to accurately predict physical function outcomes in participants with OA in a 3 year study.20

The SF-36v.2 assesses general health and quality of life including all parts of the body including the feet. Foot pathologies range from infections and ulcers, to deformities and cancers, making it important that feet are assessed whenever something new is added to the shoe.45 Also, co-morbidities such as diabetes are common in people with OA and it is highly recommended that foot health be assessed regularly to prevent skin breakdown and monitor sensory changes.
Foot Screenings

Routine foot screenings are important for the vast majority of the older population due to the rising number of people with diabetes and the fact that there is no treatment available for peripheral neuropathy caused by diabetes. It is estimated that 15% of all hospital admissions for diabetic patients are related to peripheral infections. By identifying those at risk for ulceration, preventative measures can be taken to avoid any changes in peoples' feet prior to complications or diabetic diagnosis. To identify those at high risk of ulceration, it is imperative that an effective screening tool is designed for screening purposes. A common device used to assess lack of protective sensation in many populations is the Semmes-Weinstein monofilaments. This set of 20 nylon filaments with standardized lengths and diameters, which buckle at a designated, reproducible force. Authorities recommend that 10 sites are tested on each foot with 9 sites on the plantar surface and 1 site between the first and second toes to assess all dermatomes on the foot. Singh et al found that only 4 testing sites are needed to adequately assess sensation changes and has proven reliable in detecting changes in 90% of the population.

In addition to sensation testing, assessments for foot pathologies including ulcerations, pedal pulses, and deformities are needed for people with OA of the LE. Ulcers of the feet occur when continuous trauma is applied to a specific area leading to a loss of protective adipose tissue. Nutritional supply to the area is then diminished in people with vascular disorders or may occur through neuropathy. Infections may cause few if any symptoms leading to delay of treatment and increasing involvement of surrounding tissues. The warm, moist environment
experienced by feet when confined in shoes for several hours each day increases the likelihood for infections.\textsuperscript{48} It is also important that pedal pulses be assessed due to the prevalence of Peripheral Artery Disease in the aging population and the effects of this disease on a person’s feet. Although truly absent pedal pulses can only be assessed using Doppler technology, notations of diminished or absent pulses with palpation should be referred to a physician for further assessment.\textsuperscript{45} Absent, diminished, and normal pulses identified with palpation is a standardized and reproducible physical assessment.\textsuperscript{45} Although unlikely in smaller vessels, bruits in the artery should also be recorded if present.\textsuperscript{45} Common foot deformities include hallux valgus, claw toes, and nail pathologies which may become worse with the addition of something in the shoe\textsuperscript{48} such as an insole.

Magnetic insoles are believed to benefit people with foot, knee, hip, and low back pain through the magnetic properties described previously. Because it is common for OA to affect these joints of the LE, magnetic therapy may be a modality to assess when analyzing various treatment options for people diagnosed with OA. Therefore, it is the focus of this study to evaluate the short-term effects of magnetic insoles on pain and function in people with OA of the LE.
CHAPTER III

METHODS

Subjects

Subjects were recruited by advertisement (Appendix C), word of mouth, and personal acquaintances of researchers. During the initial phone conversation with potential subjects, general qualification questions were asked and size of shoe was obtained from the participants. Insoles were purchased prior to each participant's first meeting based on the size each had reported during the initial conversation.

Potential subjects were informed of details of the study and given the opportunity to ask questions and discuss concerns prior to deciding to participate in the study.

Approval for the use of human subjects for this study was obtained from the University of North Dakota Institutional Review Board. (Appendix D)

Ten people volunteered to participate in the study, 2 were excluded due to time conflicts and not meeting inclusion criteria. Eight subjects (3 males, 5 females; mean age of 55.85 years) met the necessary criteria to be included in this study:

1. Previously diagnosed with OA in one or more joints in their LE
2. Age 18 years or older
3. Physical pain in the lower extremity
4. No implanted metal device in the foot or ankle
5. No pacemaker, cochlear implant, or other implanted device which have possible adverse affects from external magnetic field

6. No known myasthenia gravis, hyperthyroidism, platelet disorder, spinal neoplasm, cancer, or pregnancy at the time of the study

7. Not on anticoagulant medications

8. No evidence of adverse findings in the foot examinations and not currently using foot orthotics

9. Participants must also be able to rate their pain on the Visual Analog Scale (Appendix A) and complete the SF-36v2 Functional Assessment Questionnaire (Appendix B).

Subjects were not excluded from this study due to prior joint arthroplasty of the knee or hip or current use of over-the-counter or prescription medications.

Instrumentation

At the beginning and end of each 2 week insole-wearing period, participants completed the VAS, SF-36v.2, and had their feet assessed by the investigators. Pain was assessed using the 0-10 VAS with 0 signifying no pain and 10 equaling the most extreme pain they can imagine experiencing at that time. The VAS has been established as valid and reliable.38

The SF-36v.2 is a self-report questionnaire used in assessment of perceived physical and mental functioning prior to and during the wearing periods. The SF-36v.2 contains 36 questions with 1-3 and 1-5 ratings for functional abilities. Research has demonstrated that the SF-36v.2 is useful in assessing functional changes over time in people diagnosed with OA.42,43,44
Participants' foot health data was collected using a foot assessment (Appendix E) devised by the investigators to assess skin and nail integrity, sensation, and circulation. Adverse reactions of the feet in these areas would have been identified by this assessment.

Procedure

Potential participants completed a Participant Survey (Appendix F) which was used in assessment of inclusion criteria and resultant demographical analysis. Once potential subjects were screened for the inclusion criteria and agreed to participate in the study, each participant signed the Consent Form (Appendix G) and were given a copy for their records. The individuals recruited for participation in this study were informed that their participation was voluntary and that they could withdraw at any point during the study without consequences. Subjects then completed the pain assessment on the VAS, the SF-36v2, and received the initial foot assessment. Eligible participants were randomly assigned to 1 of 2 groups depending upon which insoles they were to wear first, magnetic or non-magnetic.

The magnetic insoles were those produced by American Magnet and had a cumulative strength of 100G. The insoles were made up of 15 bands of alternating polarity running the length of the insoles. Five participants wore these insoles during the first wearing period. The non-magnetic insoles were Dr. Scholls Cushion Insoles. Three participants wore the non-magnetic insoles during the first wearing period.

For the initial meeting, participants were asked to wear the shoes in which they would wear the insoles at least 8 hours each day during the study. The
investigators then fit participant’s shoes with the insoles which each had been randomly assigned to wear. If needed, the insoles were cut to fit the size of the shoes. Once fit of the insoles had been established, each participant was given a Wearing and Activity Log (Appendix H) on which they were asked to record the hours they wore their shoes with the insoles each day and general activities performed while wearing the shoes with insoles.

After 1 week, each participant was called by an investigator and was asked to rate their pain on the VAS. Participants were questioned about the fit of the insoles to identify possible adverse affects which may have been caused by the insoles. The participants were given the opportunity to ask any questions that had come up over the past week.

At the end of 2 weeks, participants met with a researcher, reported their pain on the VAS, and completed the SF-36v2. Participants’ feet were assessed at this time to identify any adverse affects that may have occurred during the insole wear. Participants also turned in their completed Wearing and Activity Log to the researcher.

For a period of at least 1 week following the first trial, no insoles were worn by the participants. At the end of this time period, each participant returned to be refit with the opposite type of insoles from the type worn during the first 2 weeks of the study. Each subject gave a pain rating on the VAS, filled out the SF-36v2, and received a new Wearing and Activity Log. The foot assessment was completed by the investigators at that time to assess any changes that may have occurred during the
previous time frame and to identify any reason for the participant to be discontinued from the study.

Following a week of wearing the second pair of insoles, each participant was again called by an investigator. Participants were given the opportunity to express any concerns and were asked for a pain rating on the VAS. Participants were questioned about the fit of the insoles to identify any possible adverse affects caused by the insole wear.

At the end of the second 2 weeks, each participant was assessed by an investigator for a final time. Pain was reassessed with the VAS, and overall function was reassessed with the SF-36v2. Participants also turned in their Wearing and Activity Logs to the investigators. Participants’ feet received the final foot assessment at that time to ensure they had maintained the health of their feet and had no adverse affects caused by the insoles. Participants were allowed to keep the insoles they wore as compensation for completing the study.

Data Analysis

Transformation of data was completed following the standardized procedure for analyzing the SF-36v.2, and statistical analysis was completed using the Statistical Package for Social Sciences (SPSS) version 11.5. The independent variables identified for this study were the type of insoles worn by the participants. The dependant variables were the participants’ pain and level of function. Univariate Analysis of Variance (ANOVA) with a repeated measures design was completed for pain on the VAS and the 2 factors, physical and mental aggregates, identified through completion of the SF-36v.2.
CHAPTER IV

RESULTS

Subjects

All 8 participants completed the study; demographics are presented in Table 1. All participants’ self-reported wearing times averaged above the recommended 8 hours per day for the total 2 weeks in each wearing condition. No mean difference (x= 9.62, SD=1.87) was found in the hours participants wore the magnetic or nonmagnetic insoles. Thus leading to the conclusion that the hours worn did not effect data analysis and had no alternate effect on the participants’ pain or function data.

Pain

The means and standard deviations for pain scores were not statistically significant for demonstrating a decrease in participants’ pain during the study (Table 2). Pain scores were entered and analyzed using the univariate, repeated measures, ANOVA. The tests of between-subjects effects of pain revealed no significant difference between participants who wore magnetic or non-magnetic insoles during either of the 2 wearing periods [F(5,19)=1.382, p=.275, power=.381] (Figure 2). The insoles the participants wore, magnetic or nonmagnetic, had no effect on participants’ pain level during either of the 2-week wearing periods or during the no-insole wearing period.
<table>
<thead>
<tr>
<th>Demographic</th>
<th>Number of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>3</td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
</tr>
<tr>
<td>OA:</td>
<td>8</td>
</tr>
<tr>
<td>Hip and knee pain</td>
<td>4</td>
</tr>
<tr>
<td>Hip, knee, and low back pain</td>
<td>1</td>
</tr>
<tr>
<td>Knee pain only</td>
<td>3</td>
</tr>
<tr>
<td>Joint Arthroplasty:</td>
<td>2</td>
</tr>
<tr>
<td>Unilateral hip arthroplasty</td>
<td>1</td>
</tr>
<tr>
<td>Bilateral hip arthroplasty</td>
<td>1</td>
</tr>
<tr>
<td>Medications used for pain relief:</td>
<td>6</td>
</tr>
<tr>
<td>Tylenol</td>
<td>3</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>1</td>
</tr>
<tr>
<td>Aleve</td>
<td>1</td>
</tr>
<tr>
<td>Flosomex</td>
<td>1</td>
</tr>
<tr>
<td>None</td>
<td>2</td>
</tr>
<tr>
<td>Previous magnetic insole use</td>
<td>0</td>
</tr>
<tr>
<td>Participant beliefs in magnetic therapy for pain control:</td>
<td></td>
</tr>
<tr>
<td>Believed in magnetic therapy</td>
<td>2</td>
</tr>
<tr>
<td>Did not believe in magnetic therapy</td>
<td>2</td>
</tr>
<tr>
<td>Did not respond</td>
<td>4</td>
</tr>
</tbody>
</table>
Table 2: Pain Means and Standard Deviation

<table>
<thead>
<tr>
<th>Time, Insole</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial, no insole</td>
<td>3.63</td>
<td>2.26</td>
</tr>
<tr>
<td>First wear, non-magnetic insole</td>
<td>2.33</td>
<td>1.15</td>
</tr>
<tr>
<td>First wear, magnetic insole</td>
<td>3.80</td>
<td>1.30</td>
</tr>
<tr>
<td>Post break, no insole</td>
<td>2.63</td>
<td>2.13</td>
</tr>
<tr>
<td>Second wear, non-magnetic insole</td>
<td>3.6</td>
<td>1.95</td>
</tr>
<tr>
<td>Second wear, magnetic insole</td>
<td>2.00</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Figure 1: The 95% confidence intervals of the means for pain scores reveal no significant statistical change in that the intervals overlap greatly and represent no change between the reported pain before or after any of the insole use.
Function

There was no significant difference between the physical (Table 3) or mental (Table 4) aggregate means and standard deviations of the magnetic and nonmagnetic insole wearings. Tests of between-subjects effects on the transformed physical aggregate scores revealed no statistically significant difference in physical scores between wearing times \[F(5,19)=.695, p=.634, \text{power}=.199\] (Figure 3). Also, tests of between-subject effects on transformed mental aggregate scores revealed no statistically significant changes in mental scores between wearing times \[F(5,19)=.338, p=.884, \text{power}=.115\] (Figure 4). Therefore, perceived health and role function was unaffected by the insoles worn by the participants.

Foot Assessments

The Foot Assessments that were completed at the beginning and end of each insole wearing period showed objective changes with only 1 participant. The monofilament tests for sensation and the dorsal/pedal pulses assessment showed no changes with any participant. However, the skin integrity check showed changes in one participant. One participant developed blisters on her feet during the first week of the second wearing time, the magnetic insole period. This participant was not removed from the study because she chose to continue wearing the insoles and reported her pain was unaffected by the blisters which were almost healed by the final assessment.
Table 3: Physical Aggregate Means and Standard Deviations

<table>
<thead>
<tr>
<th>Time, Insole</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial, no insole</td>
<td>39.59</td>
<td>7.43</td>
</tr>
<tr>
<td>First wear, non-magnetic insole</td>
<td>38.87</td>
<td>6.32</td>
</tr>
<tr>
<td>First wear, magnetic insole</td>
<td>41.43</td>
<td>5.80</td>
</tr>
<tr>
<td>Post break, non insole</td>
<td>40.79</td>
<td>6.45</td>
</tr>
<tr>
<td>Second wear, non-magnetic insole</td>
<td>41.52</td>
<td>7.04</td>
</tr>
<tr>
<td>Second wear, magnetic insole</td>
<td>42.92</td>
<td>3.07</td>
</tr>
</tbody>
</table>

Figure 2: 95% confidence interval of the means of each test condition regarding physical aggregate scores. As this visual representation of the data depicts the error bars overlapping, this demonstrates that the difference between the means in not statistically significant for the conditions.
Table 4: Mental Aggregate Means and Standard Deviations

<table>
<thead>
<tr>
<th>Time, Insole</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial, no insole</td>
<td>53.14</td>
<td>7.89</td>
</tr>
<tr>
<td>First wear, non-magnetic insole</td>
<td>58.16</td>
<td>1.09</td>
</tr>
<tr>
<td>First wear, magnetic insole</td>
<td>53.09</td>
<td>6.41</td>
</tr>
<tr>
<td>Post break, no insole</td>
<td>53.97</td>
<td>5.08</td>
</tr>
<tr>
<td>Second wear, non-magnetic insole</td>
<td>52.03</td>
<td>5.49</td>
</tr>
<tr>
<td>Second wear, magnetic insole</td>
<td>58.84</td>
<td>3.30</td>
</tr>
</tbody>
</table>

Figure 3: Data demonstrates that with small sample size and overlapping effort bars, the 95% Confidence Intervals of the means were not statistically significant between testing conditions.
CHAPTER V
DISCUSSION/LIMITATIONS AND CONCLUSION

The use of magnetic and non-magnetic insoles for pain relief and improvement of function in people with OA pain was not supported by the findings in this study. Statistical data revealed that there was no significant difference in pain or function as reported on the VAS and/or SF-36v2 under any of the testing conditions. Participants experienced no statistically significant changes in pain or function from initial testing to after wearing magnetic or non-magnetic insoles, and after a no-insole wearing period. Both mental and physical aggregate scores on the SF-36v2 revealed no statistical change between conditions. This evidence supports the null hypothesis; magnetic and non-magnetic insoles had no effect on pain and function in people with OA in this study.

Participant factors which could have affected the outcome of this study include: age range of participants and effects of OA on their person, activities engaged in, beliefs in magnetic therapy, and additional personal choices in regards to how they wore their insoles. Additional factors that could have influenced results include: evaluation procedures, small sample size, length of time and time of year that the insoles were worn, strength of the magnets, and the fact that the study was not blinded. Individually or in combination, all of these factors had the potential to limit
the effects of magnetic insoles on the participants’ pain and/or function during the study.

The age of participants in this study was approximately 55 years, and because of the small sample size, no statistical data was done to determine age related OA changes. With OA, the longer the person has pathological changes within the joint, the more intense the symptoms may become over time. The participants’ initial severity of pain (x: 3.63, SD: 2.26) may have had an effect on the results when assessing changes of pain and function.

Participants’ daily activities were not restricted during the study, only the 8 hours of daily insole wear time was recorded and reported by the participants. Although participants were asked to fill out logs to assess their average activities, these activities were not controlled, and many participants were not descriptive of their activities on the forms. This difference in activities may have made an impact in their pain and function. Subjects may have been more active these summer months or had different types of activities in their lives. This activity could have caused increased or decreased pain and changes in functional abilities. Future studies may wish to standardize activities or consider a pedometer to track level of activity of the participants over the course of the study.

This study was not blinded, and the subjects knew which insole they were wearing during each time period. Preconceptions of alternate therapy could have had a psychological effect on subjective data. On the initial survey, a question asked if each believed in magnetic therapy. Four participants chose to leave this question blank, 2 reported positive feelings towards magnets use for pain relief, and 2
disagreed with the potential pain relief qualities of magnetic therapy. (Table 1) The researchers did not attempt to influence participants’ beliefs during the initial intake or during the course of the study.

The participants also provided limitations for this study; they made personal choices that may have influenced data reporting. For example, one participant chose to wear her insoles with her sandals. Although recommended to wear shoes, this participant developed blisters from gluing her insoles to the bed of her sandals to make them stay put. Another participant, who did not wear orthotics at the start of the study, chose to insert her insoles over orthotics at some point during the first week of the magnetic insole wear. This change could have affected the position of the insole relative to the foot. Specific initial instruction for participants regarding these unanticipated actions or guidelines for researchers’ data inclusion following in these types of circumstances would benefit future studies on insole use.

Data was reported subjectively by the participant, and there were no objective recordings done to ascertain diagnosis and progression. Objective data, such as radiographs or physical function testing, may have demonstrated changes due to the insoles that the participants were unaware of in their subjective reports. Investigators did not request that participants provide written proof from their physicians of the diagnosis of OA, and no functional tests were performed to quantify the extent of OA involvement in the participants’ LE. Pain is difficult to measure since it is subjective and depends on multi-causative factors.

The small sample size decreased power in data analysis. A larger sample size may be warranted to demonstrate the effects on a population with OA. Also, no
analysis was done on the placebo effect in this study. A blinded study may have altered participant’s self-reported pain and function differences.

The subjects wore the magnetic insoles for 2, 2-week time periods with a minimum of 1 week break between wearing periods. Although researchers have used a 2-week time frame and stated that significant differences in subjects symptoms were found, the results of this study do not support the findings that a 2 week time period is sufficient for demonstrating changes in pain and/or function. Pain and function scores may have shown greater changes with a longer wearing period. Due to the subjects wearing the insoles during different times of year, weather may also have had an effect on symptoms along with the shoes participants chose to wear during this time period.

Other factors that had the potential to influence results were the magnetic strength of the insoles, configuration, and polarity. Compared to the recommended 500 G strength of magnetic insole, the strength of the American Magnet insoles were weak, measuring only 100 G. A triangular-based grid configuration has also proven most effective for magnetic therapy treatments. This study used the American Magnet insoles which were arraigned in a parallel band configuration. Negative polarity is recommended to increase human cellular metabolic function, heal tissues, and calm the human body. The American Magnet insoles consisted of alternating bands of positive an negative polarity.

Clinical Implications

Due to the high number of people using magnetic therapy, it is important for health providers to be educated and aware of the effects of magnetic therapy. Patients
who may be using alternative therapies, such as the use of magnetic therapy, may not be aware of possible side effects and contraindications to the therapy they have chosen to apply to their body. By encouraging patients to report alternative therapy use to providers, providers can discuss research with their patients on what has been shown to be effective and minimize potential adverse affects. With many types of pain relief available, it is important for clinicians to be aware of the available uses and effects of these therapies.

Conclusion

Under this study's conditions, we found no significant difference in pain with the use of magnetic insole, nonmagnetic insole, and no insole. We also found no significant difference in function under the conditions of wearing a magnetic insole, nonmagnetic insole, or no insole as self-reported on the SF-36v.2 under the physical and mental aggregate scores. Statistical analysis revealed that no significant difference was found in mental and physical aggregate scores during any of the wearing periods. This data demonstrated that the participants in this study felt no decreases in pain or increases in functional abilities during this study as reported on the VAS and SF-36v.2.

As we discovered with this study, manufacturers are marketing products to groups of people who may not experience any significant change in their pain or functional abilities due to the product they purchase. Providers may be asked to educate patients on the potential effects of these therapies so that consumers can make educated decisions about what they choose to use on their body. As people today are increasing their use of alternative therapies, including magnetic therapy, it
is important that more evidence based research is done to determine the possible effects and benefits of these therapies. Potential areas for further research include: age of participants, activities participants engage in, length of time the magnets are worn, strength of the magnets, and a larger sample size. Additional evaluation procedures to examine the involvement of OA in the participants' LE and functional testing may also be considered.
Magnetic Insoles  
Participant Pain Questionnaire

ID #: ______

Circle the number that describes your pain today:

<p>| | | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>None</td>
<td>Some</td>
<td>Moderate</td>
<td>A Lot</td>
<td>Severe</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

For each of the following questions, please mark an \( \square \) in the one box that best describes your answer.

1. In general, would you say your health is:

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ \square ]</td>
<td>[ \square ]</td>
<td>[ \square ]</td>
<td>[ \square ]</td>
<td>[ \square ]</td>
</tr>
</tbody>
</table>

2. Compared to one year ago, how would you rate your health in general now?

<table>
<thead>
<tr>
<th>Much better now than one year ago</th>
<th>Somewhat better now than one year ago</th>
<th>About the same as one year ago</th>
<th>Somewhat worse now than one year ago</th>
<th>Much worse now than one year ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ \square ]</td>
<td>[ \square ]</td>
<td>[ \square ]</td>
<td>[ \square ]</td>
<td>[ \square ]</td>
</tr>
</tbody>
</table>

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SF-36\textsuperscript{®} is a registered trademark of Medical Outcomes Trust.
3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th>Yes, limited</th>
<th>Yes, limited</th>
<th>No, not limited</th>
</tr>
</thead>
<tbody>
<tr>
<td>a lot</td>
<td>a little</td>
<td>at all</td>
</tr>
</tbody>
</table>

- **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports
- **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
- Lifting or carrying groceries
- Climbing several flights of stairs
- Climbing one flight of stairs
- Bending, kneeling, or stooping
- Walking more than a mile
- Walking several hundred yards
- Walking one hundred yards
- Bathing or dressing yourself
4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>

- **Cut down on the amount of time you spent** on work or other activities

- **Accomplished less than you would like**

- **Were limited in the kind of work or other activities**

- **Had difficulty performing the work or other activities (for example, it took extra effort)**

5. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems (such as feeling depressed or anxious)**?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>

- **Cut down on the amount of time you spent** on work or other activities

- **Accomplished less than you would like**

- **Did work or other activities less carefully than usual**
6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. How much bodily pain have you had during the past 4 weeks?

<table>
<thead>
<tr>
<th>None</th>
<th>Very mild</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Very Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>A little bit</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>

\[\text{1. Did you feel full of life?}\]

\[\text{2. Have you been very nervous?}\]

\[\text{3. Have you felt so down in the dumps that nothing could cheer you up?}\]

\[\text{4. Have you felt calm and peaceful?}\]

\[\text{5. Did you have a lot of energy?}\]

\[\text{6. Have you felt downhearted and depressed?}\]

\[\text{7. Did you feel worn out?}\]

\[\text{8. Have you been happy?}\]

\[\text{9. Did you feel tired?}\]

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>

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11. **How TRUE or FALSE is each of the following statements for you?**

<table>
<thead>
<tr>
<th>Definitely true</th>
<th>Mostly true</th>
<th>Don't know</th>
<th>Mostly false</th>
<th>Definitely false</th>
</tr>
</thead>
</table>

- I seem to get sick a little easier than other people.
- I am as healthy as anybody I know.
- I expect my health to get worse.
- My health is excellent.

**THANK YOU FOR COMPLETING THESE QUESTIONS!**
Have you been diagnosed with Osteoarthritis of the knee or hip?

Do you have pain associated with your Osteoarthritis?

Are you not currently seeking treatment for your pain?

Would you like to assist in furthering research on Magnetic Insoles and their effect on pain and functional abilities?

If you answer yes to the above questions you may be eligible to participate in our study and receive free foot screenings.

For more information contact Janice and Jenny at 772-7600
University of North Dakota Human Subjects Review Form

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University’s policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the “IRB Checklist” for additional guidance.

Please provide the information requested below:

Principal Investigator: Dr. Sue Jeno, PT, Janice Holth, Jenny Surma, Sarah Barendt
Telephone: 701-777-2831  E-mail Address: sujeno@medicine.nodak.edu
Complete Mailing Address: P.O. Box 9037, UND Dept. of Physical Therapy, Grand Forks, ND 58202

School/College: University of North Dakota  Department: Physical Therapy

Student Adviser (if applicable): Dr. Sue Jeno
Telephone: 701-777-2831  E-mail Address: sujeno@medicine.nodak.edu
Address or Box #: P.O. Box 9037, UND Department of Physical Therapy

School/College: University of North Dakota  Department: Physical Therapy

Project Title: The Short-term Effects of Magnetic Insoles on Pain and Function in a Population with Lower Extremity Osteoarthritis: A Pilot Study

Proposed Project Dates: Beginning Date: May 23, 2005  Completion Date: May 23, 2006 (Including data analysis)

Funding agencies supporting this research: University of North Dakota, Department of Physical Therapy

(A copy of the funding proposal for each agency identified above MUST be attached to this proposal when submitted.)

Does the Principal Investigator or any researcher associated with this project have a financial interest in the results of this project? If yes, please submit, on a separate piece of paper, an additional explanation of the financial interest (other than receipt of a grant)

YES or X NO

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

Type of Project: Check “Yes” or “No” for each of the following.

X YES or NO New Project  YES or X NO Dissertation/Thesis

YES or X NO Continuation/Renewal  X YES or ____ NO Student Research Project

YES or X NO Is this a Protocol Change for previously approved project? If yes, submit a signed copy of this form with the changes bolded or highlighted.

YES or X NO Does your project involve medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.

YES or X NO Does your project include Genetic Research? If yes, refer to Chapter 3 of the Researcher Handbook for additional guidelines regarding your topic.

YES or X NO Does your project include Internet Research? If yes, refer to Chapter 3 of the Researcher Handbook for additional guidelines regarding your topic.

YES or X NO Will subjects or data be provided by Altru Health Systems? If yes, submit two copies of the proposal. A copy of the proposal will be provided to Altru.

X YES or ____ NO Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or will assistance with the data collection be obtained from another organization?
If yes, list all institutions:  Valley 400, Center Court Fitness, Select Therapy and Fitness, Grand Forks Senior Citizens' Center

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands their involvement in that study, and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and, if possible, should be printed on letterhead.

Subject Classification: This study will involve subjects who are in the following special populations: Check all that apply.

- Minors (< 18 years)
- Prisoners
- Persons with impaired ability to understand their involvement and/or consequences of participation in this research
- Adults > 18 years with diagnosed osteoarthritis of the hip and/or knee

For information about protections for each of the special populations, refer to Chapter 5 of the Researcher Handbook.

This study will involve: Check all that apply.

- Deception
- Radiation
- New Drugs (IND)
- Non-approved Use of Drug(s)
- Recombinant DNA
- None of the above will be involved in this study

I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as minors, prisoners, pregnant women/fetuses).

Magnetic therapy has been used for centuries for healing and reduction of pain from the ancient Greek usage of Loadstones to Mesmer's usage of magnetic iron rods. The effects of magnets on the human body include: reduction of fluid retention and inflammation, decreased pain, and increased circulation. In today's markets it is possible to buy magnetic devices ranging from jewelry to mattress pads and from insoles to horse blankets. Magnetic insoles are marketed as being used for reducing pain in feet, legs, joints, and low back. Osteoarthritis pain is also closely correlated with decreased function. The purpose of this study is to evaluate the short-term effects of magnetic insoles on lower extremity osteoarthritis and function. The study will include 14 participants with osteoarthritis, 2 randomly assigned groups of 7, who will wear over-the-counter magnetic insoles or generic non-magnetic insoles for 2 weeks. For one week no insoles will be worn, and then the groups will switch and wear the other type of insole for 2 weeks. Function, pain, and foot status will be assessed prior to, during, and after treatment. Our goal is to evaluate the beneficial use of magnets to apply them to this patient population in a therapeutic setting.

II. Protocol Description

Please provide a succinct description of the procedures to be used by addressing the instructions under each of the following categories. Individuals conducting clinical research please refer to the "Guidelines for Clinical-Research Protocols" on the Research and Program Development website.

1. Subject Selection.

a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects. If incentive payments will be made to anyone for enrolling participants, describe the incentive package.

Participants who have diagnosed lower extremity osteoarthritis will be voluntarily recruited from various local organizations including: Valley 400, Center Court Fitness, Select Therapy and Fitness, Grand Forks Senior Citizens' Center using fliers (see attached) put up at these establishments.

b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above.

Flyers will be posted in various churches, organizations, and fitness centers around the area to find subjects willing to participate in this research. Once potential subjects contact the investigators, a consent questionnaire will be administered to ensure participants are at minimal risk and qualified to meet the standards required to be included in the research. Subjects selected from the population will have physician diagnosed osteoarthritis of the hip(s) and/or knee(s) to fulfill our research goal to find out if magnetic insoles have any effect on pain and function in people with this condition and to
further conclude if magnetic therapy may be used as an aspect of treatment to improve the lives of people with osteoarthritis.

c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.

Exclusion criteria include: persons who are pregnant, have a pacemaker, cochlear implant, implanted insulin pump, or TENS unit, have open sores or are on anticoagulant medications, have a history of platelet disorder, myasthenia gravis, hyperthyroidism, autoimmune inflammatory disease, spinal neoplasm, cancer, and those individuals who fail an initial foot examination. Pregnant women are excluded because at this time the effects of magnets on fetuses are unknown. Those persons with implanted devices are excluded due to the fact that the magnetic fields may disrupt these devices. Due to the increased circulation that can be caused by magnets and the possibility of increased bleeding, those persons with open, bleeding sores, are on anticoagulants, or have a history of platelet disorder or cancer are excluded. People who fail the foot exam, or any subsequent foot exams throughout the study, will be excluded due to increased risk of co-morbidities and possible risks to further harm their foot health by using new orthotics for shoe wear.

d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.

Approximately 14 participants are needed, with 7 participants randomly assigned in each of two groups. Fourteen participants was the amount chosen because this is a pilot study and statistical analysis needs to be performed on the data collected from these subjects. The number of subjects will be used to add power and validity to the statistical analysis of this study.

e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.

The results found with this study may either indicate further research or show no effects on pain and function in people with lower extremity osteoarthritis.

2. Description of Methodology.

a) Describe the procedures used to obtain informed consent.

Prior to testing, participants will be asked to read and sign the attached consent form, and they will be provided with a copy of this form for their records.

b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research.

This study will take place in a private room at the University of North Dakota School of Medicine and Health Sciences in the Physical Therapy department, staffed by the investigators. The funding for this study is from the UND Department of Physical Therapy and the investigators.

c) Indicate who will carry out the research procedures.

Procedures will be carried out by Janice Holth, Jennifer Surma, and Sarah Barendt under the supervision of Dr. Sue Jeno, PT.

d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

Participants are asked to wear the shoes which they will wear for at least 8 hours each day during the study. During the first day of evaluation they will be asked to complete a pain assessment on the Visual Analog Scale (VAS), SF-36v2 functional questionnaire, receive an initial foot examination, and sign the consent form. The participants will be given a copy of the consent form at that time. The investigators will then make a photocopy or tracing of their insoles to be worn for the study. The investigators will fit their shoes with the insoles which have been randomly assigned to them. Once fit has been established, each will be given a wearing and activity log which they will be asked to record the hours they wear their shoes with the insoles each day and general activities performed while wearing the shoes with insoles. We ask that they try to wear them at least 8 hours per day during this study. This part of the study will take approximately 30-45 minutes. After one week we will call each participant to ask for a pain assessment on the VAS and check the fit of the insoles. This will take approximately 5 minutes.
At the end of two weeks, we will reassess their pain on the VAS, and overall function by completing the SF-36v2. We will ask that they bring their wearing and activity log. The participation in this step should last approximately 20-30 minutes.

For a period of at least 1 week following the first trial, no insoles with be worn by the participants. At the end of this week, they will return to be refit with new insoles. They will give a pain assessment on the VAS, fill out the SF-36v2, and receive a new wearing and activity log. This step’s participation should take approximately 30 minutes.

Following a week of wearing the second pair of insoles, we will call each participant to ask for a pain assessment on the VAS and check the fit of the insoles. Participation in this call should take approximately 5 minutes.

At the end of these 2 weeks, we will again reassess their pain on the VAS, and they will fill out the SF36v2. We will ask that they bring their wearing and activity log. Their feet will receive a final assessment at this time to ensure they have maintained the health of their feet. This portion of the study will take approximately 30 minutes.

e) Describe audio/visual procedures and proper disposal of tapes.

f) Describe the qualifications of the individuals conducting all procedures used in the study.

Dr. Sue Jeno is on faculty in the PT Department and has training in the procedures utilized in this study. Janice Holth, Jenny Surma, and Sarah Barendt are second year students in the Doctor of Physical Therapy program at the University of North Dakota. They have taken coursework and are taking courses that give them the competency to perform the research proposed to fulfill their educational research project required to graduate from this program. They have been trained in the proper techniques of foot assessment and administration of the SF-36 and Visual Analog Scale for pain.

g) Describe compensation procedures (payment or class credit for the subjects, etc.).

The compensation for participation in this study will be the 2 pairs of insoles worn during the study and foot screenings.

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.


a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.

The risks associated with this study are minimal, but these risks will be monitored and controlled. Limited physical risks could include foot pain, blisters, or tingling. Emotional risks may include the subjects becoming slightly discouraged if anticipating an improvement in their condition and these benefits are not achieved. Proper subject screening and foot assessments will be completed prior to the study to minimize these possible risks.

b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.

To maintain confidentiality, participants are identified by a numerical code only with data stored in separate, locked cabinets within the Department of Physical Therapy. Information will only be presented in aggregate form and identifiable only to the investigators and advisor of this study for data analysis purposes.

4. Subject Protection.

a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).

Subjects will be informed of the procedures, purpose, and time involved in this study prior to participation. Subjects will sign a consent form and be provided a copy for their records. Subjects will be informed that they may withdraw from the study at any time without any repercussions. Foot assessments will be performed prior to and throughout the study to maintain foot quality and ensure participants who enter the study have healthy feet. Fit of insoles will also be reassessed throughout the study to prevent potential risks associated with wearing the insoles.

b) Describe procedures you will implement to protect confidentiality (such as coding subject data, removing identifying information, reporting data in aggregate form, etc.).
To maintain confidentiality, participants are identified by a numerical code only and data will be stored separate from consent forms in locked file cabinets within the Department of Physical Therapy. Information will only be presented in aggregate form and identifiable only to the investigators and advisor of this study.

c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.

Each subject will be provided a copy of the consent form personally from the investigators at the first visit, prior to beginning the study.

d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.

Describe:
1) the storage location of the research data (separate from consent forms and subject personal data)
2) who will have access to the data
3) how the data will be destroyed
4) the storage location of consent forms and personal data (separate from research data)
5) how the consent forms will be destroyed

Data will be stored separate from consent forms in locked file cabinets within the Department of Physical Therapy. The only people who will have access to this information being the investigators, advisor, and IRB auditing staff. Data will be kept for three years after the completion of the study, at which time the information will be shredded.

e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.).

In the event that this research activity results in a physical injury, medical treatment will be readily available, including first aid, emergency treatment and follow-up care as it is to any member of the general public in similar circumstances. Payment for any treatment must be provided by the subject or the subject’s third party payer, if applicable.

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

In the unlikely event that this research activity results in injury, medical treatment will be available, including first aid, emergency treatment and follow-up care as it is to the general public in similar circumstances. The person and their third party payer must provide payment for any such treatment.

III. Benefits of the Study
Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). Please note: payment is not a benefit and should be listed in the Protocol Description section under Methodology.

Advancement of research in the area of the use of magnetic insoles in the therapeutic setting is the ultimate goal of this study. The participants will learn about magnetic therapy and potentially experience its positive effects on their osteoarthritis pain and function. The knowledge gained in this study may aid all involved in their future decisions regarding the use of magnetic therapy.

IV. Consent Form
A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects. Refer to the RD&C website for further information regarding consent form regulations.

Please note: Regulations require that all consent forms, and all pages of the consent forms, be kept for a minimum of 3 years after the completion of the study, even if the subject does not continue participation.

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signatures:

(Principal Investigator) Date: 

(Student Adviser) Date: 

51
REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW
University of North Dakota Institutional Review Board

Date: 5/6/2005  Project Number: IRB-200505-363

Principal Investigator: Jeno, Sue; Holth, Janice; Surma, Jenny; Barendt, Sarah

Department: Physical Therapy

Project Title: The Short-Term Effects of Magnetic Insoles on Pain and Function in a Population with Lower Extremity Osteoarthritis: A Pilot Study

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on May 9, 2005 and the following action was taken:

☑ Project approved. Expedited Review Category No. 4
☑ Next scheduled review must be before: May 8, 2006
☑ Copies of the attached consent form with the IRB approval stamp dated May 9, 2005 must be used in obtaining consent for this study.

☐ Project approved. Exempt Review Category No.
☐ This approval is valid until as long as approved procedures are followed. No periodic review scheduled unless so stated in the Remarks Section.
☐ Copies of the attached consent form with the IRB approval stamp dated must be used in obtaining consent for this study.

☐ Minor modifications required. The required corrections/additions must be submitted to RDC 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.)

REMARKS: Any unanticipated problem or adverse occurrence in the course of the research project must be reported within 72 hours to the IRB Chairperson or RDC by submitting an Unanticipated Problem/Adverse Event Form.

Any changes in protocol or Consent Forms must receive IRB approval prior to being implemented. You must submit a Protocol Change Form with all revised research documents to include changes to protocol, consent forms, or supportive materials, with the appropriate signatures, to Research Development and Compliance for review and approval.

PLEASE NOTE: Requested revisions for student proposals MUST include adviser's signature. All revisions MUST be highlighted.
☑ Education Requirements Completed. (Project cannot be started until IRB education requirements are met.)

cc: Chair, Physical Therapy; Dean, School of Medicine

Signature of Designated IRB Member
UND's Institutional Review Board

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 RDC to obtain the required documents.

(Revised 07/2004)
APPENDIX E
Magnetic Insoles
Foot Assessment

ID # __________

1. Are the nails thick, too long, ingrown, or infected with fungal disease? Y N

2. Note foot deformities

<table>
<thead>
<tr>
<th>Toe deformities</th>
<th>L</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bunions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Charcot foot</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foot drop</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prominent Metatarsal Heads</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amputation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specify date, side and level</td>
<td>___________</td>
<td></td>
</tr>
</tbody>
</table>

3. Pedal Pulses: (fill in the blanks with a “P” or “A” to indicate present or absent).

<table>
<thead>
<tr>
<th>Post. Tibial</th>
<th>L</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsalis Pedis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Skin Condition: (Measure, draw in and label on foot diagram)

| C = Callus | S = Swelling |
| PU = Pre-ulcerative lesion | U = Ulcer |
| R = Redness | D = Dryness |
| W= Warmth |

5. Protective Sensation: label with + if participant can feel 4.5 g. monofilament or – if participant can not feel filament in circled areas.

Recommend Referral? Y N
APPENDIX F
Magnetic Insoles
Participation Survey

ID#:__________________
Birthday:__________
Gender: M F
Height:__________
Weight:__________
Shoe Size:__________

Do you have osteoarthritic pain in your hip(s) or knee(s)? Yes No

In which joint(s) is your osteoarthritic pain?______________________________

Are you currently seeking medical treatment for your osteoarthritic pain?: Yes No

How would you describe your pain today? ________________________________

How long have you been experiencing this pain? __________________________

What Medications are you currently taking? ______________________________

Have you ever worn magnetic insoles? Yes No

Do you believe in magnetic therapy for relieving pain? Yes No

Have you had a joint arthroplasty/replacement? Yes No

If yes, which joint(s)? _____________________________________________

Please Circle any that apply to you:

- Pregnant
- Pacemaker
- Cochlear Implant
- TENS unit
- Insulin Pump
- Platelet Disorder
- Spinal Neoplasm
- Cancer
- Myasthenia Gravis
- Hyperthyroidism
- other implanted device
The Short-term Effects of Magnetic Insoles on Pain and Function in a population with Lower Extremity Osteoarthritis: A Pilot Study

Participant Information and Consent Form

You are invited to participate in a student research study conducted by Janice Holth, Jennifer Surma, and Sarah Alberts Barendt and faculty advisor, Dr. Sue Jeno, PT of the University of North Dakota Department of Physical Therapy. The purpose of this study is to evaluate the effects of magnetic insoles on pain and function of people with osteoarthritis.

Healthy individuals who do not meet any of the exclusion criteria can be included in this study. Reasons to be excluded from this study include: persons who are pregnant, have an implanted devise, have open sores or are on anticoagulant medications, have a history of platelet disorder, myasthenia gravis, hyperthyroidism, autoimmune inflammatory disease, spinal neoplasm, cancer. The effects of magnets on the involved structures with these diagnoses are detrimental to the health of the participant or are unknown at this time leading to the exclusion of these individuals. Also, if problems are noted during initial foot assessment, participants will also be excluded.

You will be asked to come to the Dept. of Physical Therapy 4 times during the study. During the first day of evaluation you will be asked to sign this consent form and complete the participant survey as well as the pain and function questionnaires. You are asked to wear or bring the shoes you plan on wearing for the study so the investigators can assess size and fit your shoes with the insoles randomly assigned to you, magnetic or non-magnetic. A foot assessment will be completed at this time to assess sensation and possible complications to wearing the insoles. This part of the study will take approximately 30-45 minutes of your time.

You will be given a wearing and activity log which you will be asked to record the hours you wear your shoes with the insoles each day and general activities performed while wearing the shoes with insoles. We ask that you try to wear these shoes with the insoles for at least 8 hours per day during this study. After one week, you will receive a phone call from one of the investigators who will ask about your pain and make sure the insoles still fit. At the end of two weeks, you will return to UND and we will again reassess your pain and overall function. We will ask that you bring your wearing and activity log to the investigators. You will again complete the pain and function questionnaires and a foot assessment will be done to make sure no changes or sores have occurred. The participation in this step should last approximately 20-30 minutes.

You will then spend at least one week without any insoles. After which, you will return to be refit with new insoles, either magnetic or non-magnetic. You will have your feet reassessed and receive a new wearing and activity log. This step’s participation should take approximately 30 minutes. After one week, you will again receive a phone call from one of the investigators to assess your pain and the fit of the insoles. At the end of two weeks, we will reassess your pain and overall function and one last time. We will ask
that you bring with you to UND, your wearing and activity log and you will again complete the pain and function questionnaires. Your feet will be reassessed at this time to ensure health of feet has been maintained. This portion of the study will take approximately 30 minutes. You will be able to keep the insoles you wore as part of this study.

The benefits to you, the participant, is possibly experiencing the effects of magnetic insoles, as well as assisting in medical research which will further the knowledge on the legitimate uses for magnetic insoles with persons experiencing pain from osteoarthritis. This study will last 6 weeks, and your compensation will be the insoles worn in this study.

The anticipated risks associated with participation in this study are minimal and may involve changes in the condition of your feet. We request that you wear socks with your shoes and contact the investigators immediately if you feel any discomfort. The foot assessments are designed to minimize the risk of these problems. If any problems are developing during the study, you will be removed from the study and referred as necessary. Basic first aid or emergency treatment will be available as needed as it would be for the general public and any medical attention will not be covered by this institution and will have to be covered by you or your third party payer. To maintain confidentiality, all personal data will be assigned a numerical code, and data from this study will be stored in locked file cabinets within the Department of Physical Therapy for three years, after which time it will be shredded. Only the researchers, the advisor, and people who audit IRB procedures will have access to the data.

Your participation in this study is completely voluntary. Your decision whether or not to participate in this study will in no way change any future relations with UND. If you do choose to participate in this study, you or the researches can choose to terminate participation at any time without penalty. There are no anticipated costs for participation in this study and you will receive a copy of this consent form for you records.

If you have any question or concerns about this study at any time, please do not hesitate to contact Dr. Sue Jeno at 777-2831, Janice Holth and Jennifer Surma at 772-7600, Sarah Alberts Barendt at 885-5110, or Research Development and Compliance at 777-4279.

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. MY SIGNATURE INDICATES THAT, HAVING READ THE ABOVE INFORMATION; I HAVE DECIDED TO PARTICIPATE IN THE RESEARCH PROJECT.

Participant __________________________ Date __________________________

Phone Number and best time to reach you
APPENDIX H
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REFERENCES CITED


49. SPSS Version 11.5. (SPSS, Inc., Chicago, Ill.)