2004

The Effect of Ionized Bracelets on Pain and Function in Individuals with Arthritis

Jamie Gullickson
University of North Dakota

Josh Hamilton
University of North Dakota

Amy Hebl
University of North Dakota

Rachel Hoffman
University of North Dakota

THE EFFECT OF IONIZED BRACELETS ON PAIN AND FUNCTION IN INDIVIDUALS WITH ARTHRITIS

By

Jamie Gullickson
Josh Hamilton
Amy Hebl
Rachel Hoffman
Bachelor of Science in Physical Therapy
University of North Dakota, 2003

A Scholarly Project

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine and Health Sciences

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Master of Physical Therapy

Grand Forks, North Dakota
May
2004

This Scholarly Project, submitted by Jamie Gullickson, Josh Hamilton, Amy Hebl, and Rachel Hoffman in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

Michelle LaBrecque
(Graduate School Advisor)

Thomas Mau
(Chairperson, Physical Therapy)

PERMISSION

Title	The Effect of Ionized Bracelets on Pain and Function in Individuals with Arthritis
Department	Physical Therapy
Degree	Master of Physical Therapy

In presenting this Scholarly Project in partial fulfillment of the requirements for a graduate degree from the University of North Dakota, we agree that the Department of Physical Therapy shall make it freely available for inspection. We further agree that permission for extensive copying for scholarly purposes may be granted by the professor who supervised our work, or in her absence, by the Chairperson of the department. It is understood that any copying or publication or other use of this Scholarly Project or part thereof for financial gain shall not be allowed without our written permission. It is also understood that due recognition shall be given to us and the University of North Dakota in any scholarly use which may be made of any material in our Scholarly Project.

Signature Jamie Sullickson Date 12.19.03

Signature [signature] Date 12-19-03

Signature Amy Hall Date 12-19-03

Signature Rachel Hoffman Date 12-19-03

TABLE OF CONTENTS

LIST OF TABLES

Table

ACKNOWLEDGEMENTS

We would like to thank Michelle LaBrecque, our advisor, for all of the guidance and insight that she gave us throughout our scholarly project. We appreciate her work in procuring the Balance Bracelets for this project, for without this, we wouldn't have been able to complete this research study. Next, we would like to give special thanks to Dr. Renee Mabey and Dr. Richard Landry for guiding us through the never-ending statistical analysis portion of this project. We would also like to thank Marge Berger, CEO of Nutritional Health Services, LLC, Balance Bracelet division, for her generous donation of bracelets used in this study. We would also like to thank Rene Sawyer for the donation of envelopes and stamps.

Last but not least, we would like to thank our families, friends, faculty, and classmates for the love and support that they have shown us throughout this process. These past three years will never be forgotten and will be cherished forever in our hearts.

Thank you.

ABSTRACT

Arthritis is a prevalent condition found throughout the entire population. Manifestations of this disease can lead to increased pain in multiple joints leading to decreased functional mobility and limitations in activities of daily living. Ionized bracelets have become an increasingly popular non-traditional, conservative treatment for decreasing pain and improving well-being in persons with multiple diagnoses and body system involvement. Very little research has been conducted on the effects of ionized bracelets; therefore, additional research needs to be conducted to validate these theories.

The purpose of our study is to determine the effect of ionized bracelets on pain and function in individuals diagnosed with arthritis. Fifty subjects over the age of 18 and diagnosed with arthritis were recruited to participate in this double blind, randomized controlled trial. The subjects were required to wear either an ionized or placebo bracelet for a four week time period. A prescreening questionnaire was used to collect general demographic data and as a screening tool to exclude those with any pathology/conditions that could have been adversely affected by the ionized bracelets. Subjects were randomly divided into two groups (19 ionized, 31 placebo). Subjects rated their pain using the Visual Analog Scale (VAS) and measuring functional activities using the Short Form 36 (SF-36).

Statistical analysis using a mixed groups factorial ANOVA showed no significant interaction of treatment groups and time as related to pain and function. In the ionized

group, a significant difference was found using a paired t-test when evaluating the main effects of time on the Bodily Pain subset in the SF-36, but not in the VAS. This group showed a decrease in pain over the four week course. A significant level of improvement of function was also found in the Vitality and Social Functioning subsets of the SF-36. This significance was found only in the placebo group, not in the ionized. In the General Health subset of the SF-36 a significant difference was found when looking at both ionized and placebo groups together, but no significance was found when analyzed separately.

With so many inconsistencies, the results of this study have illustrated the need for further research regarding the effects that ionized bracelets have on arthritic pain and function. Further research should focus on more precise single variables such as pain as opposed to multiple factors, such as pain and function. These studies should be performed with larger sample sizes and over longer periods of time. Only as research accumulates will consumers be able to make informed decisions regarding the use of alternative therapies such as ionized bracelets.

CHAPTER I

INTRODUCTION

In recent times ionized bracelets have become increasingly popular as a form of alternative therapy to decrease pain and improve a person's quality of functional living. Despite the magnitude of public interest in these therapies, most are under researched and lack sound evidence-based theories. This is not deterring the consuming public from spending millions of dollars each year towards alternative methods. In fact, a survey indicated that four out of ten Americans used some form of alternative medicine in 1997.[1,2,3] This amounts to an estimated 629 million visits to alternative practioners, compared to 388 million visits to a primary care physician. [1,2,3]

Alternative therapies indicate a very complex thought process involving many different schools of thought and beliefs including ancient Chinese medicine and practices. These ancient practices can be best understood and appreciated only after periods of study, which will enhance one's understanding of the methods of alternative medicine.

Problem Statement

To date, there is only one study in literature on the effects of ionized bracelets for pain relief. There is no documentation to report if functional activities are changed by wearing an ionized bracelet.

Purpose

The purpose of this study is to determine the effect of ionized bracelets on pain and function in individuals eighteen years and older diagnosed with arthritis. While wearing an ionized Balance Bracelet© and completing surveys that will include the visual analog scale and SF-36, pain and function will be monitored over a four week period.

Significance of Study

This study is important to the profession of physical therapy because of the many patients with arthritis that are treated with physical therapy modalities. With many different options for pain control on the market including ionized bracelets, it is important as clinicians to gain baseline knowledge and understanding of these alternative practices. This will better enable physical therapists to answer questions or concerns raised by patients.

Research Questions

Research Question #1: Does the ionized bracelet decrease pain?

Research Question #2: Does the ionized bracelet increase functioning with activities of daily living?

Research Question #3: Is there a difference in pain and activities of daily living when an individual is given a placebo bracelet?

Hypothesis

Null Hypothesis: There is a significant difference in pain and function with activities of daily living between individuals with an ionized bracelet or a placebo bracelet over a four week period.

Alternative Hypothesis: There is not a significant difference in pain and activities of daily living between individuals with an ionized bracelet and a placebo bracelet over a four week period.

CHAPTER II

LITERATURE REVIEW

Alternative Medicine

In today's society, many people are finding inadequate relief from conventional medicine. In turn, many of them are relying on the fast growing alternative medicine market to address their needs both physically and spiritually. In 1997, consumers in the United States spent a conservatively estimated 27 billion dollars out of pocket for alternative therapies.[1,4]

A major contributing factor for this growing trend is dissatisfaction with western medical outcomes. Gesler and Gordon[5], authors of *Alternative Therapies,* discussed three major reasons for this growing dissatisfaction. To further examine the first factor is to address how western medicine is known for being able to cure infectious, contagious diseases and manage medical emergencies and trauma. It fails, however, to show the same success in chronic conditions such as pain, arthritis, and heart diseases.[5,6] The primary focus has been to look for cures instead of focusing on preventative measures, such as looking at underlying lifestyle-related causes that produce chronic illnesses and disease. In a study conducted by Eisenberg and Kessler [4], they found that 83 percent of people who used an unconventional therapy had also sought treatment for the same problem from a medical doctor, but failed to show improvement, and led them to a different alternative. Of this 83 percent, only 72 percent reported their use of alternative

therapies to their physicians.[4] For many people, hospitals and physicians seem to categorize people according to a disease or label which results in a cold, impersonal environment. Many health professionals have regarded the mind and body as two separate components but the Chinese theory argues that all aspects of the human body including mind, body, and soul, need to be addressed to maintain a healthy balance.

The second factor is the aging of our nation, often referred to as the Baby Boomer generation. Baby Boomers have a mind set that aging has a negative effect on their persona and are willing to try anything to reverse or delay the aging process. This explains why more and more people are willing to pay out of pocket expenses and try alternative therapies. [4,5,6]

The third and final factor is that people are looking for total body wellness, including body and mind. Alternative practitioners tend to spend more time with their patients emphasizing healer/patient relation, where physicians tend to spend less time with their patients and focus on a cure for the specific disease process.[5]

Arthritis Overview

In 1997, a national survey showed that 26% of individuals with self-reported arthritis had used a complementary and alternative therapy in the past twelve months.[2] The same survey indicated that nearly two thirds of rheumatology patients use complementary and alternative therapies. Osteoarthritis, (OA) is defined as a "chronic joint disorder characterized by degeneration of joint cartilage and adjacent joints that can cause joint pain and stiffness".[5,6,8] Chief causes of osteoarthritis are age, excess weight gain, general wear and tear, and a lifetime of inadequate diet and exercise. [5,6,8] In the general population, two out of three persons over the age of thirty five will present with

some sign of osteroarthritis.[8] Some of the first symptoms to appear are pain that is described as deep and aching. OA symptoms may present as early morning stiffness, stiffness following periods of rest, pain that worsens with joint use, soft tissue swelling, and creaking and cracking of joints with movement.[5,6,8] As these problems progress, the joint will become less mobile and this restricted mobility will become a hindrance to the individual. This is where most of the functional limitations present problems for most people and often the individual can develop some degree of disability. [5,6,8]

Rheumatoid Arthritis, (RA) is defined as "an autoimmune disease in which joints, usually including those of the hands and feet, are symmetrically inflamed, resulting in swelling, pain and tenderness often resulting in the eventual destruction of the joint's interior".[7] The synovial tissue is unable to lubricate the joints and does not allow the joints to move pain free. The first signs and symptoms of rheumatoid arthritis are inflammation in symmetrical joints, typically the smaller joints such as the hands, fingers, and toes. [6,7] The joints will quickly become enlarged and deformed as the disease progresses and often leads to some degree of decreased functional ability. [6,7]

Another factor that can contribute to symptoms of both osteoarthritis and rheumatoid arthritis is the influence that weather has on the individual's pain level. Research has shown that weather can influence the intensity of pain.[9] A study conducted by Strusberg, Mendelberg, Serra, and Strusberg[9] found a statistical significance that correlated with pain and temperature. The study consisted of 151 patients with OA, RA, fibromyalgia and a control group. Low temperature, high atmospheric pressure, and relative humidity correlated to increased pain in RA. The OA group had a correlation in

pain with low temperature and high humidity. The control group found no correlation in pain and temperature. The study supports the fact that weather does influence pain, but pain can not be a predictor for weather changes.[9]

Traditional treatments for osteoarthritis and rheumatoid arthritis pain have primarily included exercises, over-the-counter and prescription medications, modalities (such as thermotherapy, cryotherapy, transcendental nerve stimulation), surgery, and weight reduction.[7,8,10] These treatments can be initiated by a wide variety of healthcare professionals including physicians, chiropractors, physical therapists, occupational therapists, and pharmacists. The wide spectrum of professionals can be frustrating for the consumer especially if they are not getting adequate pain relief from the multiple prescribed treatments.

Many obstacles can stand in the way of a successful treatment outcome due to the pain that exercise entails. Many people become sedentary which can lead to an increase in weight which presents with more stress for the already stressed and painful joints. Many people have problems resulting from competitive younger years, such as sports and athletics, which can cause the degeneration to begin earlier in life. Success has been found with surgical methods, but due to individuals' anxiety of the procedure and fear of severe pain that will accompany the surgery, the individuals are hesitant to pursue this route.[8,10]

History of Chinese Medicine

Traditional Chinese medicine has existed since the sixth century. This approach of healing is based on the opposite and complimentary forces commonly referred to as "yin" and "yang."[5,11,12,13,14,15] According to Chinese beliefs, the entire universe is made

up of things that are yin and yang.[13,14,15] Every concept of life and environment, action, object, or aspect of time consists of these two opposing energies. Characteristics of yin include cold, darkness, night, slow, moistness, autumn, winter, rest or that which is inside or female. On the contrary, yang is associated with heat, brightness, day, fast, dryness, spring, summer and that which is outside or male.[12,13,14,15] Imbalances of the yin and yang are thought to arise from inactivity or over-exertion of a certain body organ, the individual's mind, or the environment. To maintain health, it is essential to balance the body's yin and yang.[11,12,13,14,15]

The concept that is essential to Chinese medicine is the role of *qi* (pronounced chee and sometimes referred to as *chi* or *ch'i*) which is the vital energy that flows through the body. *Qi* works to maintain the health and vitality of the individual while also regulating the physiological functions of the body.[11,12,13,14,15] A closer examination of how vital energy is distributed through the body has revealed that it is circulated through pathways called meridians. It is speculated that there are fourteen continuous energy meridians, twelve of which run bilateral, with the other two running unilateral along the midline of the body.[12,16]

Disorders and aliments contribute to the interruption of these energy meridian channels. A direct link of the imbalance of flow can be caused by an injury or trauma that often results in pain. Through diagnostic procedures, the individual's *qi* is assessed, looking for any excessive or deficiency in his/her vital energy. Chinese therapies are incorporated to remove the obstruction or obstacle that is prohibiting normal flow and function. Examples of these therapies that aim to balance the *qi* are acupuncture, magnetic concepts, ionization, and herbal remedies.[6,11,12,13,14,16]

Ionization Theory

A new area of alternative medicine, with minimal research documented, is the use of ionized wrist bracelets for pain relief and improved energy. According to promotional information from the manufacturer, the bracelets act on the nervous system of the body, absorbing excess static electricity.[17] Based on the same Chinese principles as acupuncture, the bracelets help to balance the body's yin and yang to promote total body health and wellness.[17,18,19]

In 1887, Heinrich R. Hertz in Palla de Malloraca, Spain discovered this phenomenon known as the principle of self-induction.[17,18,19] By definition, the principle of ionization involves an induction effect which is set up between the organism and the bracelet.[18,19] The organism induces certain energy onto the bracelet. If this energy is in the frequency band of the bracelet, then the bracelet starts generating energy of opposite charge to that produced by the organic perturbation or affliction. This in turn will change cells that lack energy to their biological normality. Although the definition can be vague, the complete ionization process is a secret process not revealed in its' entirety by the manufacturer.[17,18,19]

The manufacturer recognizes that there are multiple negative ions in the environment such as air pollution, stress, and anxiety which causes bioenergetic imbalances. To maintain well-being, these imbalances must be eliminated. The optimum ratio of ionic balance is for every five positive ions, there are respectively four negative ions. The bracelet works to recharge the fatigued cells, restoring the bioenergetic equilibrium of the body.[17,18,19]

Previous Research

After a thorough literature review was conducted, only one published study was reported on the use of ionized bracelets versus a placebo.[3] The Mayo Clinic of Jacksonville, Florida conducted a randomized double-blind trial using ionized wrist bracelets versus a placebo bracelet to assess the effects on musculoskeletal pain. The study involved six hundred and ten subjects with pain in at least one of twelve body parts. The bracelets were worn for a four week period with subjects self-reporting a pain score on a ten point scale. The results concluded that there was statistically significant improvements in pain scores with both groups. There was no statistical difference obtained between the groups wearing the placebo bracelet versus the ionized bracelet.[3]

Placebo Effect on Research

In looking at the efficacy of any type of therapy outcome, the main goal is to have the patient report an improvement in status. However, the main question remains; is the improvement from a placebo effect or from the specific treatment intervention? By definition from Gotzche[20], "the placebo effect is the difference in outcome between a placebo treated group and an untreated control group in an unbiased experiment". Factors that can stimulate placebo responses can be either provider or patient based. The provider can influence responses by compassion, warmth, attitude, decreasing anxiety and self-awareness. These can all be associated with positive outcomes of a placebo or an active treatment. A double blind study was conducted by Shapiro et al[21], and demonstrated that a physician who delivers care in an enthusiastic, caring manner will develop better rapport with the patient, thus attributing to a higher level of comfort and confidence that leads to better treatment outcomes.

No specific personality, demographics, or other guiding characteristics can determine if a patient is going to respond to treatment versus a placebo. There are many factors that can influence a response, either positive or negative, including patient expectations, patient attitude toward the provider and the treatment, and patient compliance to a treatment. [20,21,22] Studies have shown that with placebos, if a patient has a clear understanding of what the treatment is suppose to achieve, those patients often report the same symptom relief that is suppose to be elicited by the actual treatment.[21,22] The effort of the provider to clearly and compassionately provide treatment to a person, especially with anxiety towards an illness, can have a positive outcome and allow for the placebo effect to occur. Studies have reported that improved compliance of patients, especially in alternative therapies, can be attributed by an array of different things. Cost is most likely an out-of pocket expense when using alternative therapies, therefore the patient commits to the treatment. The fact that most people who choose to use alternative therapy for pain relief can elicit a placebo response in and of itself.[20,21,22]

With many explanations to why a placebo works, it exemplifies the need to pursue studies where placebos are used. The success of any treatment can be determined by many things, including factors that are controlled by the provider, the patient, the mind, and/or the body.

CHAPTER III

METHODS

The final approval for this study was obtained from the University of North Dakota Institutional Review Board for the use of human subjects. A copy of the human subjects review form is located in Appendix A. During the recruitment process, the researchers informed the individuals that participation was voluntary. They were also informed that they could drop out at any point during the study without consequences. Details of the study were explained to the individuals and they were given the opportunity to address questions and concerns prior to deciding to participate. Those participating in the study signed an Information and Consent Form developed by the researchers. The subjects were given a copy of the consent form, with the original copies kept locked in the UND PT department. The original forms will be destroyed three years after completion of the study. A copy of the Information and Consent Form is located in Appendix B.

Subjects

This study consisted of 50 subjects (17 males, 33 females) who were recruited through word of mouth, advertisement (see Appendix C), enlisting members of local arthritis support groups throughout Grand Forks and the surrounding area, and personal acquaintances of the researchers and faculty advisor. Inclusion criteria consisted of the following: 1) subject self-report of osteoarthritis or rheumatoid arthritis previously

diagnosed by a physician, 2) subject was 18 years of age or older, 3) subject had no implanted medical device (such as a pacemaker), 4) subject had no known allergies to non-plated metals, 5) subject did not work with high voltage machinery, and 6) the subject must have been able to read and complete a series of questionnaires.

Subjects were not excluded from this study because of over the counter or prescription medication usage for their arthritic pain. Subjects were encouraged to continue their prescribed medication regime as directed by their physician. Changes in medications were tracked throughout the study. Decisions regarding the subjects' inclusion in the study (data collected from each subject through completion and return of surveys) were made in the final statistical analysis. If the participant lost their bracelet during the four week study, they were excluded from the study. Participants were able to keep the bracelets after the research was completed. Those given a placebo bracelet to wear for the four weeks were given a truly ionized bracelet after the study was completed.

Instrumentation

Data was collected through surveys completed by the subjects at set intervals throughout the study. The initial Short Form 36 Health Survey (Appendix D), the Visual Analog Scale (Appendices E, G, H, I), and a questionnaire created by the researchers to specifically measure items not covered on the previously mentioned surveys (Appendix E) were used and completed. The VAS was used at each interval of this study including the initial questionnaire, One Hour, Two Week, and Four Week Pain and Medication Questionnaires (Appendices E, G, H, I)

Short Form 36 Health Survey (SF-36)

Health-related quality of life outcome measures have improved over time, benefiting from continued use and research, and resulting in enhancements to both the science and technology of health outcome surveys.[23] The SF-36 is a survey that measures the quality of life as related to the general health of a person. This survey is a practical and reliable method to obtain general outcomes of health in a variety of settings, measuring the following eight different domains: 1) Physical Functioning, 2) role limitations due to physical health (Role-Physical), 3) Bodily Pain, 4) General Health perceptions, 5) Vitality, 6) Social Functioning, 7) role limitations due to emotional problems (Role-Emotional), and 8) Mental Health.

Validity

Validity is described as "the degree to which an instrument measures what it is purported to measure; the extent to which it fulfills its purpose".[24] In a study by Kosinki M et al.[25] in 1999, the SF-36 was found to be valid in measuring the effects of osteoarthritis (OA) and rheumatoid arthritis (RA) on general health. The study also found the SF-36 to be valid for measuring generic health outcomes for trials using alternative treatments for OA and RA. The study compared patients with arthritis to the general U.S. population. The patients with arthritis scored significantly less on all eight scales ($P < 0.0001$) of the SF-36, although the mental health measure was not statistically significant.

Reliability

Reliability is the extent to which measures give consistent and accurate results.[26] Ware[26] looked at 14 studies that tested the reliability of the SF-36 on patients with a wide range of diagnoses including AIDS, orthopedic conditions, renal disease, and diabetes. All scores exceeded the accepted standards for measures used in group comparison. For each individual scale, the median of the reliability coefficients of all the studies equaled or exceeded .80, except the social functioning scale. These results support the use of the SF-36 in studies of health status. The physical functioning scale was the most reliable, as it consistently exceeded the .90 standard of reliability.

Visual Analog Scale (VAS)

This scale provides an easy way for patients to measure subjective estimates of pain intensity. Patients rate their pain on a horizontal line that represents a continuum of their pain symptoms, ranging from "pain as bad as it could be" to "no pain" with severe, moderate, and slight along the continuum.[27]

Validity

McCormack et al[28] completed a critical review of studies testing the validity of the VAS. They reported that the VAS ensured validity when compared with several other tests. They found a .75 correlation between the VAS when printed vertically and a four-point descriptive scale rating pain as slight, moderate, severe, or agonizing. Correlations of .89 to .91 were also found between vertical and horizontal VAS scales given to a group of 100 and 104 rheumatic patients. A group of patients who were

repeatedly tested showed a correlation of .81 between the VAS and a five-point verbal rating scale. The VAS was also compared to the McGill Pain Questionnaire and correlations ranging from .6 to .63 were obtained.

Reliability

McCormack et al[28] also completed a study testing the reliability of the VAS. In this study the VAS was tested for repeatability and both horizontal and vertical scores were compared among one hundred rheumatology patients. A correlation between scores of .99 was found, with the horizontal scale scores slightly but not significantly lower than the vertical scores. When retest reliability was tested with both literate and non-literate patients, the VAS was found to be more reliable in the literate group. Reliability in the literate group was .94 compared to .71 in the non-literate group.

Pain Rating Questionnaire

The researchers of this study created this questionnaire in order to obtain information that could not be attained through the SF-36 or the VAS. This questionnaire included the subject's type of arthritis (OA or RA), specific joints affected by the arthritis, any changes in medication (prescription and over-the-counter) usage throughout the four weeks, and any additional information/comments that the subjects had regarding their pain, function, etc. The reliability and validity of this survey have not been established, however, the researchers believed the information acquired through this survey was important in measuring the effects of the bracelet on the pain and function of the subjects.

Procedure

After the recruitment of 50 subjects, they were randomly placed into two groups. Group 1 (n=19) were given true ionized bracelets and group 2 (n=31) were given placebo bracelets. This study was conducted as a double blind study; the researchers, faculty, and the subjects did not know who received the ionized versus placebo bracelets until the four weeks were completed. Both groups wore the bracelets for four weeks. Each subject met initially with one of the researchers at a convenient location. At this meeting, the participants were given instructions on how to complete the forms and surveys throughout the four weeks. The initial prescreening questionnaire (including the VAS), Information and Consent form, the SF-36, and questionnaire created by the researchers were completed at this initial meeting. The subjects then completed the remaining surveys on their own time on pre-determined dates set by the researchers at the initial meeting. The patients were then instructed on the proper wearing and care of the bracelet before having the bracelet fitted and adjusted by the researcher. A handout with information on how to wear and care for the bracelet (see Appendix F) was also given to the subject. One hour after the fitting and adjustment of the bracelet, the subjects were required to fill out a One-Hour Pain Rating questionnaire (see Appendix G). After two weeks, the subjects completed a Two-Week Pain Rating questionnaire (see Appendix H). At the end of the fourth week, the subjects completed the Four-Week Pain Rating questionnaire (see Appendix I) and the SF-36. Different colored surveys were used to differentiate the Two and Four Week questionnaires. For the easy return of questionnaires, subjects were provided with self addressed stamped envelopes. Phone

calls were made and/or e-mails were sent to the subjects one to two days prior to the scheduled date to remind them to complete and return their surveys.

Data Analysis

The statistical analysis was performed using SPSS Version 11.0[29]. A mixed groups factorial ANOVA was used to determine differences in pain between the two treatment groups over a period of four weeks. The independent variables were the treatment groups and the dependent variables were the pain levels reported on the VAS. A mixed groups factorial ANOVA was again used to determine the differences in functional levels between the two treatment groups during the four weeks. The independent variables were the treatment groups and the dependent variables were the scores reported on the SF-36. An ANCOVA was performed on the pain and functional level measures to confirm the findings produced by ANOVA. If significance was found, a paired t-test was used to look at the main effects of time and treatment group to determine where the significance came from. The significance level used throughout this research was α=.05. Results of the data analysis will be discussed in greater detail in Chapter IV.

Reporting Results

Upon completion of this study, a copy of this scholarly project was given to Balance Bracelet, a division of Nutritional Health Services, LLC, and the advisor for this scholarly project. A copy of this study will also be given to the Harley E. French Library of the Health Sciences at the University of North Dakota. This study was completed in partial fulfillment of the requirements for the University of North Dakota School of Medicine and Health Sciences Program of Physical Therapy.

CHAPTER IV

RESULTS

Results were compiled from 38 out of 50 subjects who participated in this study. Data from seven subjects was not used in the final statistical analysis due to the low number of rheumatoid arthritis diagnoses. The data from four other subjects was not used because they had both types of arthritis, with one also having psoriatic arthritis. One subject was not included because he/she received the bracelet and surveys later than the other subjects and therefore was unable to return the surveys within the necessary data collection time frame. The researchers decided to only use the data from the osteoarthritis group only due to the higher numbers in both placebo and ionized groups. The sample size for the rheumatoid arthritis subjects was not large enough to have adequate statistical power.

A mixed groups factorial ANOVA was performed to examine the effects of the treatment groups and time upon the VAS pain measurements. In reporting the VAS, an increase in score means indicates a decrease in pain. Table 1 shows the means for each condition of the design. There was no interaction of treatment groups and time as related to pain ($F(3, 108) = 1.15$, $p = .33$, $Mse = 122.59$). There was also no significance for either main effect of group ($F(1, 36) = 1.18$, $p = .28$) or time ($F(3, 108) = 1.34$, $p = .27$).

A mixed groups factorial ANOVA was performed to examine the effects of the treatment groups and time upon the subset measurements of the SF-36. Table 2 shows

the means for each condition of the design. There was some variation in the sample sizes within each subset. This was dependent on whether the subject completed every question within each subset. If subjects did not complete each subset in its entirety, their scores were not used to calculate the statistics for that subset. There was no interaction of treatment group and time as related to function for any subset. Table 3 shows the statistical results of each subset of the SF-36. Significance was found for the main effects of time in four of the eight subsets (Vitality, Bodily Pain, Social Functioning, and General Health). Paired t-tests were run on each of the four subsets in which there was significance to determine whether the significance was from the ionized or placebo group. Vitality and Social Functioning showed a significant increase in the placebo group. Bodily Pain showed a significant increase in scores which indicated a decrease in pain in the ionized group. Significance was found in the General Health subset when the placebo and ionized groups were analyzed together but not when analyzed separately. Table 4 shows the results of the paired t-tests for each of the four subsets showing significance.

In summary, the only finding related to the use of ionized bracelets in this study was a decrease in Bodily Pain over the course of four weeks. Vitality and Social Functioning showed an improvement, however, this was only in the placebo group. General Health showed an improvement in both treatment groups collectively, but not separately.

Table 1. Pain Scores from the VAS by Treatment Groups

Time	Treatment Groups	Mean	Standard Deviation	Number
Initial	placebo	53.22	19.92	26
	ionized	46.11	11.98	12
One Hour	placebo	58.53	17.98	26
	ionized	47.74	18.50	12
Two Week	placebo	57.07	19.67	26
	ionized	52.99	16.95	12
Four Week	placebo	53.67	17.66	26
	ionized	52.54	17.77	12

Table 2. Subset Means and Standard Deviations from The SF-36 by Treatment Groups

SF-36 Subset	Time	Treatment Group	Mean	Standard Deviation	Number
Physical Functioning	Initial	placebo	41.65	11.56	26
		ionized	42.83	11.50	12
	Four Week	placebo	41.33	11.24	26
		ionized	43.53	11.37	12
Role-Physical	Initial	placebo	44.00	10.19	24
		ionized	43.80	8.82	12
	Four Week	placebo	46.14	10.51	24
		ionized	45.02	10.49	12
Bodily Pain	Initial	placebo	41.19	7.81	25
		ionized	38.03	6.26	12
	Four Week	placebo	41.72	7.15	25
		ionized	42.12	6.79	12
General Health	Initial	placebo	46.93	9.29	25
		ionized	46.82	9.13	11
	Four Week	placebo	44.75	9.29	25
		ionized	44.96	9.13	11
Vitality	Initial	placebo	47.97	9.05	25
		ionized	45.33	10.12	12
	Four Week	placebo	50.84	10.00	25
		ionized	48.19	11.54	12
Social Functioning	Initial	placebo	46.40	12.13	24
		ionized	47.76	10.99	12
	Four Week	placebo	50.49	10.00	24
		ionized	50.49	10.09	12
Role-Emotional	Initial	placebo	50.37	9.02	24
		ionized	47.78	13.31	12
	Four Week	placebo	49.72	10.75	24
		ionized	48.10	11.95	12
Mental Health	Initial	placebo	51.13	9.72	25
		ionized	49.77	10.77	12
	Four Week	placebo	52.82	8.05	25
		ionized	50.00	12.65	12

Table 3. Interaction and Main Effects ANOVA Results For the SF-36 Subsets

SF-36 Subset	Source	Degrees of Freedom	F	Significance
Physical Function	Interaction	1, 36	.304	.585
	Time	1, 36	.042	.839
	Treatment Group	1, 36	.190	.666
Role Physical	Interaction	1, 34	.129	.722
	Time	1, 34	1.728	.197
	Treatment Group	1, 34	.039	.844
Bodily Pain	Interaction	1, 35	2.5	.123
	Time	1, 35	4.188	.048*
	Treatment Group	1, 35	.371	.546
General Health	Interaction	1, 34	.026	.874
	Time	1, 34	4.337	.045*
	Treatment Group	1, 34	.000	.988
Vitality	Interaction	1, 35	.000	.997
	Time	1, 35	5.882	.021*
	Treatment Group	1, 35	.646	.427
Social Functioning	Interaction	1, 34	.190	.666
	Time	1, 34	4.749	.036*
	Treatment Group	1, 34	.037	.848
Role Emotional	Interaction	1, 34	.235	.631
	Time	1, 34	.026	.873
	Treatment Group	1, 34	.321	.574
Mental Health	Interaction	1, 35	.343	.562
	Time	1, 35	.600	.444
	Treatment Group	1, 35	.414	.524

*significance at $p<.05$ level of significance

Table 4. Paired T-tests For Main Effects of Time For Each Treatment Group

SF-36 Subset	Treatment Group	Time	n	Sample Mean	Standard Deviation	t	Degrees of Freedom	Power
Vitality	Placebo	Initial	25	47.67	9.05			
		Final	25	50.84	10.00	-2.461	24	.021*
	Ionized	Initial	12	45.33	10.12			
		Final	12	48.19	11.54	-1.186	11	.261
Bodily Pain	Placebo	Initial	25	41.19	7.81			
		Final	25	41.72	7.15	-.364	24	.719
	Ionized	Initial	12	38.03	6.26			
		Final	12	42.12	6.79	-3.330	11	.007*
Social	Placebo	Initial	24	46.40	12.13			
Functioning		Final	24	50.49	10.00	-2.129	23	.044*
	Ionized	Initial	12	47.76	10.99			
		Final	12	50.49	10.09	-1.254	11	.236
General Health	Placebo	Initial	25	46.93	9.34			
		Final	25	44.75	9.29	1.943	24	.064
	Ionized	Initial	11	46.82	9.99			
		Final	11	44.96	9.13	1.304	10	.222

*significance at $p<.05$ level of significance

CHAPTER V

DISCUSSION AND CONCLUSION

The overall correlation in this study between ionized bracelets and their effect on pain according to the visual analog scale was not statistically significant, regardless if the bracelet was ionized or a placebo. Four of the eight Short-Form 36 subsets including Physical Functioning, Role-Physical, Role-Emotional, and Mental Health demonstrated no change for either ionized or placebo bracelet groups.

Statistics demonstrated change over time in four out of the eight subsets of the Short Form-36 when analyzed separately. The subset title of Bodily Pain reported a level of change in the ionized bracelet group with an increase in function in relation to pain. The subset groups of Vitality and Social Functioning reported a significant level of improvement of function in the placebo bracelet group. The General Health subset group reported a significant increase with both ionized and placebo bracelets when analyzed together, as one group. When analyzed separately, no significance was found in the ionized or placebo bracelet groups in the General Health subset. These findings may be explained by several factors including the age of the subjects, the individual's subjective report, placebo effect, variability of weather, time frame of the study, preconceptions of alternative therapies, and the total number of subjects in this study.

In this study, participant's age ranged from 29 to 87 years old. This is a very large range of age difference in subjects. No formal statistical analysis was performed to compare age groups, due to the small sample size. This could have contributed to the outcome of the study because arthritis is a disease process that usually progresses as a person ages. Consideration for follow-up studies would be to look at age in more specific ranges to see if it truly does play a factor in pain and function.

The subjects gave a self-report of the number of years diagnosed with either osteoarthritis or rheumatoid arthritis, but from this data, the severity of the arthritis was not clear or measurable. Subjects who presented with chronic arthritis had a better chance to see a larger decrease in pain versus a newly diagnosed subject with minimal initial pain who would not have the chance for extensive pain relief. Due to the variance of geographical location of the subjects, the weather could have influenced the subjective pain and function scales. Research shows that weather can have an effect on arthritic pain.[9] Although the regional geographical location was relatively similar, the day to day weather patterns could have enhanced the symptoms from subject to subject.

The time frame for this study was conducted over a four-week period. Although the manufacturer states that results can occur within this time period, they also report that results may be minimal and require a longer wearing time to notice the full benefits of the ionic bracelet. Another aspect to consider is the position the bracelets were worn on the wrist. For purposes of validating and standardizing the study, the bracelets were to be worn on the right wrist with the terminals facing up. This is described by the manufacturer as the position where most people experience the best results and benefits. The manufacturer also advises individuals to change the position of the bracelet if no

changes were noticed after 72 hours. In this study, that information was not given to the subjects in order to help decrease the variance of the study and not to confuse the participants.

An additional area that could have contributed to the results of this study could be the preconceptions of alternative therapies that the subjects had. If subjects had used an alternative therapy prior to participating, they may be more likely to believe in the gains and benefits of the ionic bracelet. On the other hand, if subjects believed that there would be no change or that the bracelets did not hold any power, they would not be as open-minded to any improvements or changes. The researchers did not provide any manufacturer's information about the possible effects the bracelets could display, in order to help eliminate preconceptions about the bracelets. To help eliminate this factor, researchers encouraged all participants to report their honest and truthful answers. As stated earlier, most people that purchase or use forms of alternative medicine fall into the Baby Boomer population.[4,5,6] This population includes people born between 1950 and 1962 and accounted for 40% of the participants in this study. There was no question asked regarding whether the subjects had tried an alternative therapy method in the past, making it hard to determine if any preconceptions were held by these subjects.

Many preconceptions could have lead to the placebo effect that occurred in the placebo bracelet group, as the group showed change and improvement over time in two SF-36 subsets, Vitality and Social Functioning. Many factors could have contributed to this, including the subject's expectations of the bracelet, the subject's attitude towards the researchers, and the subject's compliance to the study.[20,21,22] Due to the vast advertisements and publications available, some of the subjects could have been exposed

to and were aware of the expected effects of the bracelets. Research has shown that this knowledge can lead individuals to report symptom relief regardless of which treatment they received, either placebo or real. [20,21,22]

Clinical Implications

Because of the increasing number of people choosing to use alternative therapies, it is important for all healthcare providers to be educated and be aware of their effects. It is dually important for patients to report to a medical doctor or health care provider, any forms of alternative therapy that they are using in addition to their prescribed treatment. This is important in to order to help prevent any unwanted side effects that could occur. If professionals are well informed of alternative therapies, they would more accurately be able to answer any questions, concerns and/or properly know where to direct the patient for further information and clarification. It is important to encourage the patient to report all forms of treatment or therapy they are receiving so the most appropriate intervention can be safely provided.

Limitations

A number of limitations were recognized that could have influenced the results of this study. Because this was a double blind study and there was randomized distribution of the bracelets, an uneven number of ionized versus placebo bracelets were given out. This resulted in 31 placebo bracelets and 19 ionized bracelets being used in this study. Of the seven subjects with rheumatoid arthritis, six received an ionized bracelet and only one received a placebo bracelet, thus not allowing for statistical analysis to be completed on this sample size and also eliminating these subjects from the overall study and statistical report.

All data collected was per participant's subjective report. To eliminate the variance of the participant's subjective report as much as possible, all subjects were encouraged to be truthful and honest in their reporting. The subjects were required to fill out and send back all surveys. Although the researchers took steps to ensure proper education for completing all forms, some were returned incomplete. The incomplete sections were unable to be included or analyzed in this study. This could have been a factor when determining significance for all participants in this study as a whole, but not separately for the ionized or placebo bracelet groups. A larger sample size could have helped to eliminate this problem.

To be included in this study, participants were required to have been diagnosed by a physician with OA or RA. Researchers did not require written documentation and relied solely on the subject's report.

There is a definite need for future studies on ionized bracelets. Prior to this study there has only been one study conducted looking at the effects of ionized bracelets.[15] These bracelets are easily accessible to the general public, yet they are not federally mandated. Because ionized bracelets are not federally mandated, there are very few restrictions on the claims made by manufacturers, therefore opening the window for false claims and leaving little room for evidenced based research.

Other research should include objective information such as range of motion, strength, and endurance. A study including objective information could sufficiently increase the evidence based data for ionic bracelets because it would rely on the professional collection of data instead of the subject's perceptions.

To better interpret the effects of the bracelet on the body, it is beneficial to understand the ionization process. Research in this area would help to support the claims of the manufacturer and also to enhance the validity of the effects while using the bracelets. In this study, the researchers were unable to measure the amount or intensity of ionization in each individual bracelet. The researchers relied on the manufacturer to provide the bracelets with the precise ionization level and bracelet identification as either ionized or placebo.

Further studies should limit the sample size to one group of arthritis versus looking at both osteoarthritis and rheumatoid arthritis. Although they share many similarities, they are both very different disease processes. Studies should focus on one area of interest versus looking at multiple areas when assessing the effects of the ionized bracelets. By limiting the variables prior to the research, the researchers could have reduced the number of subjects whose data was unable to be used in this study. In future studies, researchers should avoid case studies or low subject enrollment and work towards larger sample sizes, which will enhance the statistical power of the study.

Conclusion

Although significance was found in multiple subsets of the Short Form-36, the significance between the ionized and placebo bracelets was very inconsistent and unable to confirm the study's hypothesis. Even though the SF-36 bodily pain subset displayed a statistically significant decrease in the ionized group, this was very small and not enough to confirm the hypothesis that the ionized bracelets decrease pain. The Visual Analog Scale is found to be a more reliable and valid tool for measuring pain when compared to the Bodily Pain subset of the SF-36. The Bodily Pain subset measures pain related to

level of functioning while the VAS measures the intensity of pain. The statistics used for the VAS showed an outcome of no statistical difference for either the ionized or placebo group. When analyzing all of the statistics, no overall benefit of decreased pain or improved function was found with wearing the ionized bracelet. Although some individuals who participated in this study did see improvement and benefits when wearing the ionized or placebo bracelet, it was not shown through statistical analysis.

Based on inconsistent variables throughout this study, it is not possible to determine true effectiveness or ineffectiveness of the ionic bracelets. In the era of people using more and more ionized bracelets for therapeutic reasons, more substantial evidence based research is needed to help enhance and protect the consumer.

APPENDIX A

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 the Office of Research and Program Development (ORPD), 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: Michelle LaBrecque (advisor), Amy Hebl, Rachel Hoffman, Jamie Gullickson, Josh Hamilton

Telephone: (701) 777-2831 E-mail Address:mlabrecq@medicine.nodak.edu

Complete Mailing Address: 501 N. Columbia Road, PO Box 9037, Grand Forks, ND 58202-9037

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

Student Adviser (if applicable): Michelle LaBrecque

Telephone: 701-777-6389 E-mail Address:mlabrecq@medicine.nodak.edu

Address or Box #: University of North Dakota Physical Therapy Department P.O. Box 9037, Grand Forks, ND 58202-9037

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

Project Title: The Effect of Ionized Bracelets on Pain and Function in Individuals with Arthritis

Proposed Project Dates: Beginning Date: 6-01-03 Completion Date: 12-19-03
(Including data analysis)

Funding agencies supporting this research: Marge Berger, CEO of Balance Bracelet, has donated 25 ionized bracelets and 25 placebo bracelets for this scholarly project.

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

___ YES or _x_ NO 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)

If your project has been or will be submitted to another Institutional Review Board(s), please list those boards below along with the status of each proposal.

_____ Date submitted: _____ Status: ___ Approved ___ Pending

_____ Date submitted: _____ Status: ___ Approved ___ Pending

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 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: Grand Forks YMCA

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)
_____ UND Students
_____ Prisoners
_____ Pregnant Women/Fetuses
_____ Persons with impaired ability to understand their involvement and/or consequences of participation in this research
_x_ Other Individuals 18 and older who have a medical diagnosis of arthritis

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
_x_ None of the above will be involved in this study
_____ Stem Cells
_____ Discarded Tissue
_____ Fetal Tissue
_____ Human Blood or Fluids
_____ Other
_____

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).

Arthritis is a prevalent condition found throughout the entire population. Manifestations of this disease can lead to increased pain in multiple joints leading to decreased functional mobility, and limitations in activities of daily living. Ionized bracelets have become an increasingly popular non-traditional, conservative treatment for decreasing pain in multiple diagnoses and body systems. Ionized bracelets act on the nervous system to absorb static electricity. The static energy is the result of an imbalance between positive and negative ions. The bracelets have been made available through a generous donation by Balance Bracelets, a Mallorca, Spain based company with the registered trademark for the bracelets. Balance Bracelets claims that if there is pain in an area of the body, there may be too much static energy in that particular area. By wearing a bracelet it will consume the excess energy, therefore helping to relieve pain and increase abilities/or function. With the focus of physical therapy in today's health care being on evidence-based practice, the purpose of this research is to identify the effects of ionized bracelets on arthritic pain and function. Human subjects will either wear a placebo bracelet that has been de-ionized or a fully ionized bracelet and complete surveys prior to study, at one hour, at two weeks, and at four weeks in order to determine the effects of ionized bracelets on pain and functional activities. The resulting data will assist in continuing the current knowledge base for the use and the effects of ionized bracelets.

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 Office of Research and Program Development website.

1. Subject Selection.

It is anticipated that the subjects will be recruited from the city of Grand Forks, surrounding communities, and personal acquaintances over the age of 18 years old with a diagnoses of arthritis from a medical doctor. The subjects self-report of medically diagnosed arthritis sufficient to continue in the study. Researchers will recruit subjects by word of mouth, attending support groups associated with arthritis, and advertisements. Subjects will be contacted by telephone, in person, mail and email. The subjects will be randomly divided into two samples of twenty-five subjects. One sample will represent 25 subjects wearing a fully ionized bracelet, with the other sample being 25 subjects wearing placebo or non-ionized bracelets. Involvement in the study will be voluntary and informed consent will be obtained through a signed consent form before any testing will be performed. Each subject will be selected based on the following criteria: 1) a diagnosis of arthritis from a medical doctor of any nature found in any joint of the body and 2) have the ability to fill out and return the following, required questionnaires: the SF-36, the Visual Analog scale, and a pain rating /medication questions related to their arthritic joint(s). Subjects will be excluded from this study if they have a pacemaker or other electronic devices, work with high-voltage machinery, or have an allergy to non-plated metal, due to the adverse effects that could occur while wearing an ionized bracelet. Subjects will not be excluded from this study due to over the counter or prescription medication use, subjects are encouraged to continue their prescribed medication regime unless directed by the physician. Changes in medication will be tracked on each of the four surveys throughout the study. Decisions regarding the subject's availability in the study will be made in the final statistical analysis. This study is not considered to be inclusion or exclusion criteria but as looking at it as preliminary analysis. Up to fifty participants will partake in this scholarly project as statistical data suggests a large number of participants in order to get adequate reliability.

2. Description of Methodology.

Prior to testing, the participants will read, be competent and independent in decision-making, and sign the informed consent form to participate in this study. A signed copy of the consent form will be given to the participant. The research will be conducted through returned questionnaires. The principle investigators, UND physical therapy students under the direction and supervision of their advisor (Michelle LaBrecque), will perform the following research procedures: 1) initial meeting with the participants to fill out the initial questionnaire, and the short-form 36 2) fitting and adjustment of the bracelet to ensure proper application; 3) patient education and information including a handout regarding use and maintenance of the bracelet. Student researchers and subjects will not know who has received an ionized versus placebo (non-ionized) bracelet until the 4 week study is completed. Following one hour the participants will fill out the one-hour pain ratings questionnaire, after two weeks the participants will fill out the two week pain rating questionnaire, and after four weeks of bracelet use in the study, the short-form 36 and the four week pain rating questionnaire will be completed. Phone calls will be made by the researchers to the participants two days before the survey are due, to remind them to fill out and send in the surveys. Time arranged for initial meeting is approximately 60 minutes, and subsequent questionnaires will take approximately 10 to 15 minutes to complete. Different colored paper will be used to differentiate time scale for return of questionnaires as well as self addressed envelopes for ease of survey return. Participants will be able to keep the bracelets after research has been completed. If the participant shall lose their bracelet during the four week study the participant will have to be excluded from the study.

The researchers carrying out the research are physical therapy students at the University of North Dakota Physical Therapy Department who have been trained in the procedures stated above. All procedures will be completed under the direction and supervision of advisor Michelle LaBrecque who is a licensed PT.

Attachments: Attachments include informed consent, questionnaires and surveys, patient instruction handouts, initial information and advertising recruitment.

3. Risk Identification.

The risks associated with this study are minimal, but these risks will be monitored and controlled. Limited physical risks could include unknown allergy to surgical stainless steel, and possible headache due to the location of the bracelet. Emotional risks might include subjects anticipating an improvement in their condition and become discouraged if no benefits are achieved. No financial risks or liabilities will be placed on the subjects. Proper subject screening and education by the researchers will control physical and emotional risks.

Respect for the individual will be ensured by informing the subjects that all information will be kept confidential. There will be no direct way to link the participants' responses and data sheets to the consent forms.

4. Subject Protection.

Confidentiality will be maintained by using assigned numbers and not attaching the subjects' names to the reported data. The participant will be required to sign two consent forms prior to testing. One copy will be issued to the participant and one will be kept in the participants file for legal protection. The research data and consent forms from this study will be stored in separate locked cabinets in the Physical Therapy Department at the University of North Dakota. This information will only be available to the investigators conducting this study. The research data will be kept for at least three years after the completion of the study and will be discarded appropriately. In the event that this research activity results in physical injury, medical treatment will be available as it is available to a member of the general public in similar situations. Should injury occur during the testing process the participants would be encouraged to seek proper medical attention. All individual expenses will be the responsibility of the individual and his/her third party payer. The University of North Dakota, Balance Bracelets, and the researchers are not responsible for any such injury or treatment. At any time if questions or concerns arise subjects will be able to contact investigators or advisor by telephone. If at any time the subject chooses to leave the study there will be no penalty.

III. Benefits of the Study

This study is designed to determine the effect of ionized bracelets on pain and function in individuals with arthritis. The investigators of this study feel the results of this study will develop a baseline for future research studying individuals with deficits, such as pain and decreased function with a variety of diagnoses.

Minimal research exists relating to the use of ionized bracelets on arthritic pain and function. The goal of the study is to provide further information and create awareness of ionized bracelets as an alternative, non-invasive therapy for pain control and relief.

Further benefits for the subjects may include decreased pain and improved functional abilities, and potential for decrease arthritis medications per their physician. Ionized bracelets are expensive to purchase to the individual, however, the bracelets will be free of charge to our subjects.

IV. Consent Form

Informed consent will be obtained through an information and consent form (see attached form). All individuals participating in this study will be competent and independent in their decision-making and will sign the consent form in relation to participation in the study. Subjects will be provided with a copy of the consent form at the initial test session. Once the subject and one of the investigators sign the form, a photocopy will be made and then given to the subject. Subjects may withdraw from using the bracelet at any time without any repercussions of consequences.

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:

Requirements for submitting proposals:
Additional information can be found at the ORPD website at **www.und.nodak.edu/dept/orpd**

Original Proposals and all attachments should be submitted to the Office of Research and Program Development, P.O. Box 7134, Grand Forks, ND 58202-7134, or brought to Room 105, Twamley Hall.

Prior to receiving IRB approval, researchers must complete the required IRB human subjects' education. Please go to http://www.und.nodak.edu/dept/orpd/regucomm/irb/Default.htm for more information.

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the ORPD website regarding required copies and IRB review categories, or you may call the ORPD office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company's protocol must be provided.

Please Note: Student Researchers must complete the "Student Consent to Release of Educational Record".

Revised 4/14/03

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

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD[1]

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

The study to which this release pertains is

_____

_____

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

_____

Date Signature of Student Researcher

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

APPENDIX B

Reference #:_____

Information and Consent Form

Title: The Effect of Ionized Bracelets on Pain and Function in Individuals with Arthritis

You are invited to participate in a study conducted by Jamie Gullickson, Josh Hamilton, Amy Hebl, and Rachel Hoffman, students in the Masters of Physical Therapy program at the University of North Dakota. The purpose of this study is to determine the effects of ionized bracelets on pain and function in individuals with arthritis. This will be measured by surveys inquiring differences in pain and functional levels throughout the course of the study.

Participants will be randomly assigned into two groups. Half of the subjects will receive a placebo (non-ionized) bracelet and half will receive a true ionized bracelet. You or the student researchers will not know if your bracelet is ionized or non-ionized. If you would like to know which bracelet you wore you may contact us at the end of the four week study. (see phone numbers on the second page)

There are certain criteria that subjects must follow to guarantee correct performance of their bracelet. You **should not** participate in this study if you: have an implanted medical/electronic device, such as a pacemaker; or you have allergies to metal (bare, nonplated or coated). If selected, you **should not wear** the bracelet in these circumstances: in a tanning bed, while working with high voltage machinery, in contact with other metals (i.e. watches), or during medical examination and treatment with electronic instruments, especially x-ray. You **should wear** the bracelet at all times including in the shower or bathing, and while sleeping. Participants are encouraged to continue with any current medical treatments and their normal daily routine including exercise, leisure activities, hobbies, etc. Participants must know that these bracelets are not a cure for arthritis.

Your participation in this study will require you to wear the ionized bracelet for four weeks and complete a total of eight surveys. Two surveys will be completed before putting on the bracelet; two surveys after wearing the bracelet for one hour; two surveys after wearing the bracelet for two weeks, and the final two after four weeks of wearing the bracelet. If you lose your bracelet during the four week time period, you will be excluded from the study.

On the first day of your four-week participation in this study you will be informed on the proper use and wearing of the bracelet as well as proper care of the bracelet. You will be fitted for the bracelet and given a packet of surveys for the entire four-week study. Before putting on the bracelet you will be required to fill out a short survey relating to your pain and functional activities that you perform in your daily routine. After one hour you will fill out another survey about your pain level. We anticipate this initial meeting to take approximately one hour. We also encourage you to write any comments on this study, your pain and functional level, and thoughts throughout the four weeks.

Reference #:_____

You will benefit from participating in this study by being able to keep the bracelet after the study is completed, and knowing that you enable us to fulfill our research requirements. Although the length of time that your ionized bracelet will work depends on you the individual, the effects can last from 12-24 months.

The results of this study will be confidential, and the number assigned to you will be known only by the investigators to identify the data. There will be no way to identify you as a subject. The results will be stored for three years after the study has ended, unless they are required for continuing studies. Your participation is voluntary, and you may discontinue participation at any time during the four weeks without any penalty. Whether or not you participate in this study will in no way reflect your relationship with the Physical Therapy Department, the University of North Dakota, or Balance Bracelets.

The investigators involved will be available to answer any questions or concerns you may have about this study. You may contact the investigators by calling Jamie at 701-777-9968, Josh at 701-746-8175 or 701-740-1523, Amy at 701-775-7143, Rachel at 320-394-2138 or 701-777-9968, and Michelle 701-777-2831. A copy of this consent form is available to all participants in this study. If you are interested in the results of this study, please feel free to contact Michelle LaBrecque at 701-777-2831 in the spring of 2004. You may also contact ORPD (Office of Research and Program Development) at 701-777-4279 if you have question or concerns regarding the research design.

As with any form of non-traditional medicine, there are risks of injury. An injury could include a rash due to an unknown allergy to the metal on the bracelet. Another risk you could face could be an emotional risk due to anticipating improvement in your condition when there is no improvement. If you decide to participate, you are free to discontinue at any time until the data collection is completed. In the event this research activity results in physical injury, you and/or your third party payer must provide the cost of medical treatment, as the investigators, the University of North Dakota, and Balance Bracelets cannot be held liable.

I HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND CONSENT FORM. ALL OF MY QUESTIONS HAVE BEEN ANSWERED AND I AM ENCOURAGED TO ASK ANY QUESTIONS THAT I MAY HAVE OF THIS STUDY IN THE FUTURE. MY SIGNATURE INDICATES THAT I HAVE READ THE ABOVE INFORMATION, AND I HAVE DECIDED TO PARTICIPATE IN THE RESEARCH PROJECT.

_____ _____

Participants signature Date Investigators signature Date

APPENDIX C

Do you have Arthritis?

Do you know somebody who does?

You could possibly qualify to participate in a study wearing ionized bracelets.

We are looking for participants ages 18 and up to be involved in this study.

If you would like to wear an ionized bracelet to see if it helps with your arthritic pain
OR
would like more information about this study please contact:

Amy at 775-7143

Amy 775-7143	Amy 775-7143	Amy 775-7143	Amy 775-7143	Amy 775-7143	Amy 775-7143	Amy 775-7143	Amy 775-7143	Amy 775-7143	Amy 775-7143

APPENDIX D

Your Health in General

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully, and mark an ☒ in the one box that best describes your answer. ***Thank you for completing this survey!***

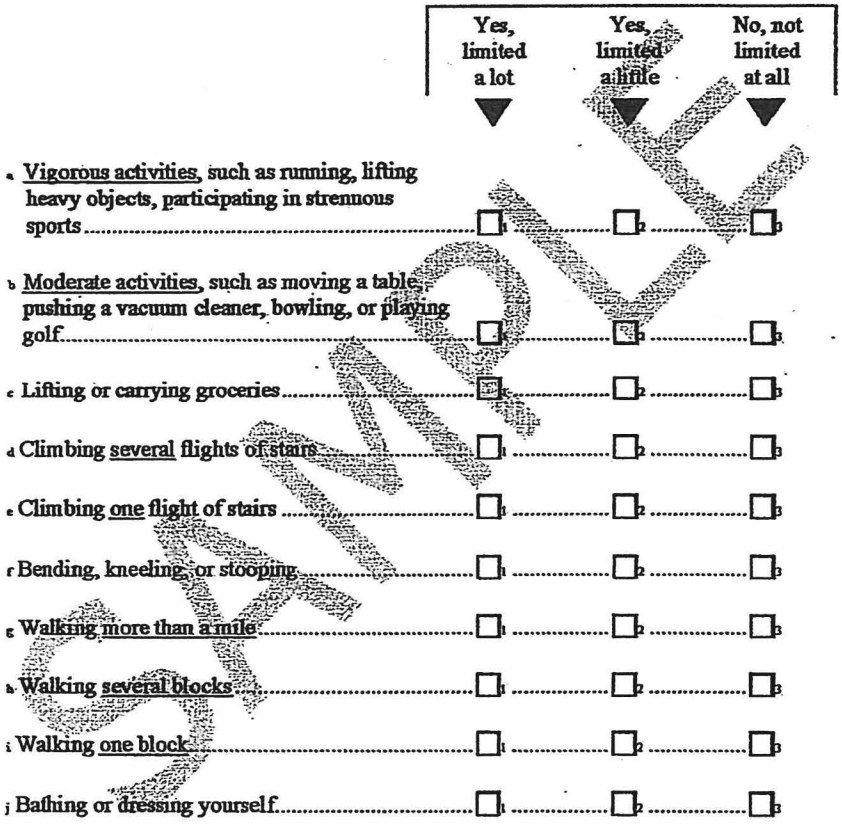
1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. **The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?**



	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking more than a mile	1	2	3
h. Walking several blocks	1	2	3
i. Walking one block	1	2	3
j. Bathing or dressing yourself	1	2	3

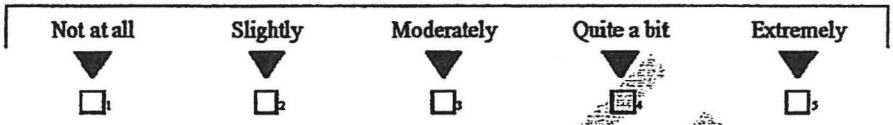
4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
a. Cut down on the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Were limited in the kind of work or other activities	1	2
d. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks, 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)?

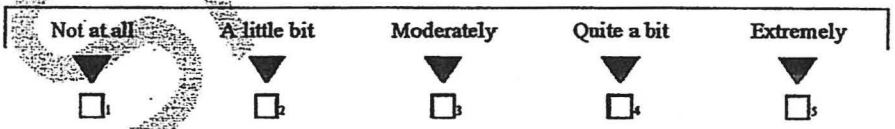
	Yes	No
a. Cut down on the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Did work or other activities less carefully than usual	1	2

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?



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

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



9. **These questions are about how you feel and how things have been with you during the <u>past 4 weeks</u>. 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 <u>past 4 weeks</u>...**

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of pep?	☐1	☐2	☐3	☐4	☐5	☐6
b. Have you been a very nervous person?	☐1	☐2	☐3	☐4	☐5	☐6
c. Have you felt so down in the dumps that nothing could cheer you up?	☐1	☐2	☐3	☐4	☐5	☐6
d. Have you felt calm and peaceful?	☐1	☐2	☐3	☐4	☐5	☐6
e. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5	☐6
f. Have you felt downhearted and blue?	☐1	☐2	☐3	☐4	☐5	☐6
g. Did you feel worn out?	☐1	☐2	☐3	☐4	☐5	☐6
h. Have you been a happy person?	☐1	☐2	☐3	☐4	☐5	☐6
i. Did you feel tired?	☐1	☐2	☐3	☐4	☐5	☐6

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

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐1	☐2	☐3	☐4	☐5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

THANK YOU FOR COMPLETING THESE QUESTIONS!

APPENDIX E

Reference #:_____

Initial Questionnaire

1. Have you been diagnosed with arthritis by your physician? YES NO

2. What is your gender? (Circle one) **Male** **Female**

3. What is your age in years? Please print on the line _____

4. How long have you been diagnosed with arthritis in years?

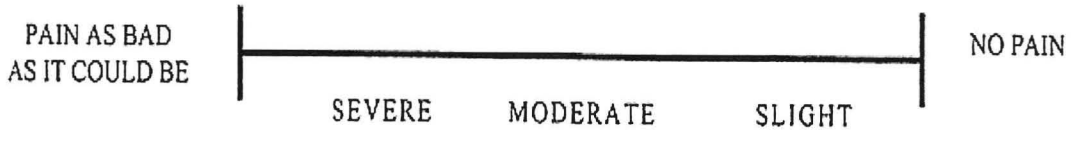
   Please print on the line _____

5. Do you have Rheumatoid arthritis or Osteoarthritis? Please circle one

6. Where in your body do you have arthritis? Please put one check where you have arthritis, then please put another check to the area where you experience pain most of the time(if left **and** right sides are affected, check both):

	Right	Left
Neck	____	____
Mid-Back	____	____
Low Back	____	____
Shoulder	____	____
Elbow	____	____
Hand/Fingers	____	____
Hip	____	____
Knee	____	____
Ankle	____	____
Foot/Toes	____	____

7. Mark on the line below how you would rate your pain most of the time



Reference #:_____

8. Do you have a pacemaker? YES NO

9. Do you have other implanted electronical devices? YES NO

   If yes please list _____

10. Are you allergic to metals? YES NO

    Please list any other allergies that you have:

_____

11. Do you work around high-voltage machinery or medical equipment including x-rays or MRI? (Airport x-ray is acceptable) YES* NO

12. Are you on any over-the-counter medications for pain relief?

    YES NO

    If yes, please list the over-the-counter-medications:

    _____

    _____

11. Are you on any prescription medications for pain relief?

    YES NO

    If yes, please list the prescription medications:

    _____

    _____

*if yes, the investigator will explain the procedures you must follow if you still wish to participate in the research study

We thank you for your time in completing this questionnaire. Please return this form to your investigator when completed. Certain answers on this form may exclude you from our study.

APPENDIX F

All you need to know about your bracelet

Do's and Don'ts

Do try to wear your bracelet all the time- especially while sleeping or exercising.

Do not wear the bracelet if you have an electronic or medical device such as a pacemaker.

Do not wear the natural finish bracelet if you are allergic to surgical stainless steel.

Do not continue to wear the bracelet if any type of discomfort occurs after the bracelet is worn.

Do not wear while using electric blankets, magnetic products, or tanning beds.

Do not wear any other metals or a watch ON THE SAME WRIST as the bracelet. Rings may be worn on the same wrist as your bracelet.

Do not allow the ends of the bracelet to come in contact with one another.

If your bracelet is too loose you can push the terminals closer together but you would want them a pinky width apart from each other.

Your bracelet may discolor if exposed to chlorine water but this will not change the effects the bracelet has.

Do not set your bracelet on electronic devices such as computers, or microwaves.

Do not wear your bracelet in a tanning bed.

Do not wear your bracelet during medical examination and treatment with electronic instruments **especially during an X-ray**.

Do not put bracelet into a pocket full of change.

APPENDIX G

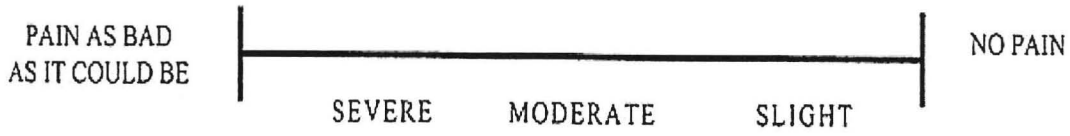
One Hour Pain Ratings

Reference #_____

1. Did your pain increase, decrease, or not change since you last rated your pain? Please check all that apply, including which side of body:

	Right	Left	Increase	Decrease	No Change
Neck	_____	_____	_____	_____	_____
Mid-back	_____	_____	_____	_____	_____
Low Back	_____	_____	_____	_____	_____
Shoulder	_____	_____	_____	_____	_____
Elbow	_____	_____	_____	_____	_____
Hand/Fingers	_____	_____	_____	_____	_____
Hip	_____	_____	_____	_____	_____
Knee	_____	_____	_____	_____	_____
Ankle	_____	_____	_____	_____	_____
Foot/Toes	_____	_____	_____	_____	_____

Mark on the line below how you would rate your pain most of the time (since you last rated your pain).[1]



If there are any other comments you would like us to know about your symptoms or your bracelet please feel free to add below.

27. Visual Analog Scale. Functional Toolbox. University of North Dakota

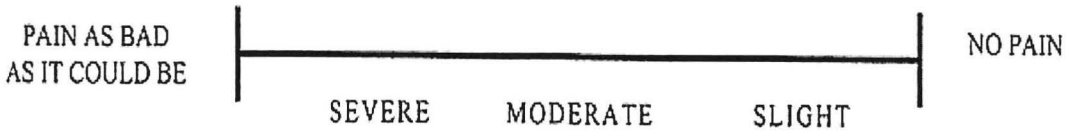
APPENDIX H

Week 2 Pain and Medications Questions Reference #__

1. Did your pain increase, decrease, or not change since you last rated your pain? Please check all that apply, including which side of body:

	Right	Left	Increase	Decrease	No Change
Neck	_____	_____	_____	_____	_____
Mid-back	_____	_____	_____	_____	_____
Low Back	_____	_____	_____	_____	_____
Shoulder	_____	_____	_____	_____	_____
Elbow	_____	_____	_____	_____	_____
Hand/Fingers	_____	_____	_____	_____	_____
Hip	_____	_____	_____	_____	_____
Knee	_____	_____	_____	_____	_____
Ankle	_____	_____	_____	_____	_____
Foot/Toes	_____	_____	_____	_____	_____

Mark on the line below how you would rate your pain most of the time (since you last rated your pain).[1]



27. Visual Analog Scale. Functional Toolbox. University of North Dakota

Week 2 Pain and Medications Questions Reference #__

2. Have you made any changes in your pain medications during the study? YES NO

   If yes please list _____

   _____

3. Over the course of this study, do you feel any medication (prescription or over the counter) changes have been a factor in your results of pain or function?

   YES NO

If yes please explain _____

_____

If there are any other comments you would like us to know about your symptoms or your bracelet please feel free to add below.

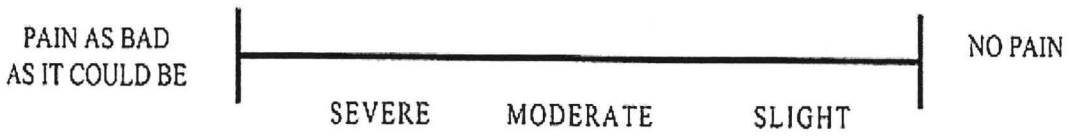
27. Visual Analog Scale. Functional Toolbox. University of North Dakota

APPENDIX I

Week 4 Pain and Medications Questions Reference #_

1. Did your pain increase, decrease, or not change since you last rated your pain? Please check all that apply, including which side of body:

	Right	Left	Increase	Decrease	No Change
Neck	_____	_____	_____	_____	_____
Mid-back	_____	_____	_____	_____	_____
Low Back	_____	_____	_____	_____	_____
Shoulder	_____	_____	_____	_____	_____
Elbow	_____	_____	_____	_____	_____
Hand/Fingers	_____	_____	_____	_____	_____
Hip	_____	_____	_____	_____	_____
Knee	_____	_____	_____	_____	_____
Ankle	_____	_____	_____	_____	_____
Foot/Toes	_____	_____	_____	_____	_____



27. Visual Analog Scale. Functional Toolbox. University of North Dakota

Week 4 Pain and Medications Questions Reference #_

2. Have you made any changes in your pain medications during the study? YES NO

   If yes please list _____

   _____

3. Over the course of this study, do you feel any medication (prescription or over the counter) changes have been a factor in your results of pain or function?

   YES NO

If yes please explain _____

_____

If you feel there are any other comments you would like us to know about your symptoms or your bracelet please feel free to add below.

27. Visual Analog Scale. Functional Toolbox. University of North Dakota

REFERENCES

REFERENCES

1. Eisenberg DM, Davis BR, et al. Trends in alternative medicine use in the united states 1990-1997. *JAMA*. November 1998; 280(18):1569-1575.
2. Felson DT, Lawrence RC, et al. Osteoarthritis: new insights. *Ann Intern Med.* November 2000;133(9):726-737.
3. Bratton RL, Montero DP, et al. Effect of "ionized" wrist bracelets on musculoskeletal pain: a randomized, double-blind, placebo-controlled trial. *Mayo Clin Proc.* November 2002; 77:1164-1668.
4. Eisenberg DM, Kessler RC, et al. Unconventional medicine in the united states; prevalence, cost and patterns of use. *N Engl J Med.* January 1993; 328(4):246-252.
5. Gordon R, Nienstedt B, et al. Alternative Therapies. New York, NY: Springer Publishing Company; 1998.
6. Chopra D. Alternative Medicine: The Definitive Guide. Tiburon, CA: The Burton Goldberg Group; 1997.
7. Berkow R, Beers M, et al. Merck Medical Manual of Medical Information. Whithouse Station, NJ: Merck Research Laboratories; 1997
8. Moskowitz, Howel, et al. Osteoarthritis Diagnosis and Management. Philadelphia, PA: W.B. Saunders Company; 1984.
9. Strusberg I, Mendelberg RC, Serra HA, Strusberg AM. Influence of weather conditions on rheumatic pain. *J Rheumatol.* 2002 Feb; 29(2): 335-8.

10. Schattenkirchner M. New Trends in Osteoarthritis. Basal Switzerland: S Karger AG; 1982.

11. Cassileth B. The Alternative Medicine Handbook; The Complete Reference Guide to Alternative and Complementary Therapies. New York, NY: W.W. Norton and Company; 1998.

12. Charman RA. Complementary Therapies for Physical Therapists. Oxford, UK: Butterworth Heinemann; 2000.

13. Marti J. The Alternative Health and Medicine Encyclopedia. Detroit, MI: Visible Ink Press; 1995.

14. Spencer J, Jacobs J. Complementary/Alternative Medicine; An Evidence Based Approach. St. Louis, MO: Mosby Incorporated; 1999.

15. Charman R. Complementary Therapies for Physical Therapists. Woburn, MA: Butterworth-Heinermann; 2000.

16. Micozze MC. Fundamentals of Complementary and Alternative Medicine. New York, NY: Churchill Livingstone; 1996.

17. Nutritional Health Services LLC; Balance Bracelet Division. [package insert]. St Helena, SC;2003.

18. Similar findings have been noted by Grupo Rayma S.A. and by Marge Berger CEO (written communications September 2003).

19. Rayma. Live A Better Life Balance and Harmony. Available at http://www.raymabracelet.com. Accessed September 9,2003.

20. David P. Understanding the Placebo Effect in Complementary Medicine. New York, NY: Churchill Livingstone; 2001.

21. Turner JA, Deyo RA, et al. The importance of placebo effects in pain treatment and research. *JAMA.* May 1994; 271(20):1609-1614.

22. Kaptchuk TJ. The placebo effect in alternative medicine: can the importance of a healing ritual have a clinical significance. *Annals of Intern Med.* June 2002; 136(11):817-825.

23. SF-36v2™ Health Survey. QualityMetric Incorporated. Available at: http://www.qualitymetric.com/products/surveys/SF36v2.shtml Accessed on October 15, 2003.

24. Currier DP. Elements of research in physical therapy. 3rd ed. Baltimore MD: Williams and Wilkens; 1990. 171

25. Kosinski M et al. The SF-36 health surveys as a generic outcome measure in clinical trials of patients with osteoarthritis and rheumatoid arthritis: relative validity of scales in relation to clinical measures of arthritis severity. *Medical Care.* 1999 May; 37(5 Suppl); MS10-22.

26. Ware JE. SF-36 Health Survey: Manual and Interpretation Guide. Quality Metric Incorporated. 2002. Lincoln, RI: 7.1-7.7.

27. Lewis CB, McNemey T. Clinical measures of functional outcomes- "the functional outcomes toolbox". McLean, VA: Learn Publications.

28. McCormack HM, del Horne DJ, Sheather S. Clinical applications of visual analog scales: 2. a critical review. *Psychol Med.* 1988; 18. 1007-1019.

29. SPSS, Inc. SPSS Base 11.0 for Windows User's Guide. Chicago, IL: SPSS, Inc; 2002.