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Validity of Instrument Assisted Soft Tissue Mobilization for Detecting Myofascial Adhesions through Secondary Diagnostic Ultrasound Analysis

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Validity of Instrument Assisted Soft Tissue Mobilization for Detecting Myofascial
Adhesions through Secondary Diagnostic Ultrasound Analysis

A Thesis

Presented to

The College of Graduate and Professional Studies
Department of Applied Medicine and Rehabilitation
Indiana State University
Terre Haute, Indiana

In Partial Fulfillment

of the Requirements for the Degree

Masters of Science

by

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Keywords: Instrument Assisted Soft Tissue Mobilization, Graston Technique, Diagnostic
Ultrasound, Myofascia, Fascial adhesions

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ABSTRACT

Context: many patients have pain and restricted motion due to myofascial adhesions. Clinicians use both manual and instrument assisted soft tissue mobilization (IASTM) techniques to treat myofascial adhesions. The main difference between manual therapies and IASTM is that IASTM claims that their instruments can accurately qualitatively detect myofascial adhesions through their resonance capability. However, the validity of this capability has yet to be researched. **Objective:** To determine the validity of using IASTM to detect myofascial adhesions through secondary diagnostic ultrasound analysis. **Design:** Correlational validity study. **Setting:** Athletic Training Laboratory. **Patients or other participants:** nineteen men (age = 22.4 ± 2.5) and eleven women (age = 21.2 ± 1.9). **Data collection and analysis:** From the thirty participants, one hundred adhesions were found and imaged. We calculated the percent level of agreement between the two rates, and then considered chance by using a κ coefficient to understand the relationship between the two rates of diagnostic us. **Results:** We identified an 83% level of agreement between raters. However, when chance was considered, we found a poor inter-rater reliability ($\kappa = 0.344$, $p < 0.001$). **Conclusions:** There is moderate evidence that IASTM is successful in quantitatively detecting myofascial adhesions. Sources creating instrument resonance other than myofascial adhesions may include blood vessels or adipose

nodules. Future investigation should further examine what specifically IASTM is detecting through its resonance, if not myofascial adhesions. **Key words:** instrument assisted soft tissue mobilization, Graston technique, diagnostic ultrasound, myofascia, fascial adhesions

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CHAPTER 1

INTRODUCTION

Many patients have pain and restricted motion due to myofascial adhesions. Clinicians use a variety of manual and instrument assisted soft tissue mobilization (IASTM) techniques to diagnose and treat myofascial adhesions. Gua Sha was the first instrument assisted technique dating back to ~220 BC⁽¹⁾. Since then, nearly twenty-five other instruments and similar or novel techniques have been developed based on the original Gua Sha philosophy. The main difference between manual therapies and IASTM is that IASTM claims that their instruments can accurately detect myofascial adhesions through their resonance capability. However, the validity of this capability has yet to be researched. The purpose of this research study is to determine the validity of using IASTM to detect myofascial adhesions through secondary diagnostic ultrasound analysis.

Research Question: Are IASTM instruments able to accurately determine the location of myofascial adhesions?

Hypothesis: IASTM instruments will be able to accurately determine the location of myofascial adhesions according to secondary diagnostic ultrasound analysis.

CHAPTER 2

REVIEW OF LITERATURE

This review will discuss fascia and fascial restrictions, several myofascial rehabilitation techniques and a summary of IASTM. Ultrasonography will also be explained as an objective measurement technique used to diagnose myofascial adhesions.

Search Strategy

The Pubmed, Pubmed Central, Medline, and SPORTDiscus database as well as individual online journals were searched for the following key words: Graston Technique, Graston Technique AND fascia, Myofascial adhesions, Ultrasonography, Ultrasonography AND fascia, Instrument Assisted Soft Tissue Mobilization Therapy (IASTM), Radiography AND fascia, ASTYM, STARR tool AND IASTM, Gua Sha, Massage AND fascia, Fusion AND fascia, Active Release Technique” (ART), foam rolling AND active release techniques.

Myofascial Restrictions

Fascia is a component of the connective tissue system ⁽²⁾. The term fascia can be described modestly as the continuous network of fibrous collagen-based tissue that surrounds individual muscles, muscle groups, blood vessels, organs and nerves⁽²⁻⁵⁾. Fascia has been referenced in a variety of ways. Gray often refers to the fascial complex as the extracellular matrix (ECM), though the terms collagenous network, connective tissue webbing, and fascial netting have also been used^(2, 6). For this study, the collagenous network will be referred to as

fascia, or more specifically, as myofascia. The term myofascia connotes both the inseparable nature of muscle tissue (myo-) itself as well as its corresponding connective tissue⁽²⁾. Specific histological information as well as properties pertaining to the nature of fascia will be discussed in the proceeding paragraphs.

Histology of Fascia

Myofascia is composed of specific cells, ground substance, and fiber types⁽³⁾. Because different types of collagen are shown to vary with mechanical force and strain, it is hypothesized that the functionality of fascia is dependent on the composition of the extracellular matrix, specific cells, and fiber filaments^(3, 7). Fiber orientation in fascia is important for its general functionality as observation has consistently found that reticulin, collagen, and elastin fibers orient themselves parallel to predicted lines of force in order to resist tension^(3, 8-10). A better understanding of reticulin, collagen, and elastin will elucidate the diversity and complexity of fiber orientation.

Reticulin is a very thin fiber that prevails in the embryo but is largely replaced by stronger, type III collagen in adults⁽²⁾. Reticulin fibers crosslink themselves in order to form a meshwork which provides cellular structure in the endoneurium, in the vascular walls, and in the smooth muscle⁽³⁾.

Collagen, a triple helix glycoprotein, is by far the most common protein found in the body and predominates in the fascial net^(2, 3). The number of collagen types in the human body is debatable; the Ross histology textbook and atlas currently recognizes twenty five distinct collagen types while Gordon recognizes twenty eight^(11, 12). Although type I collagen accounts for 90% of the body's collagen, fascia contains a variety of collagen combinations including

types I, III, IV, V, VI, XI, XII, XIV, XXI^(3, 11-14). Collagen is a necessary component because it provides resistance to tension and stretch which is a common occurrence in ligaments, tendons, sheaths, myofascia, and in deeper fascial layers^(3, 12).

Finally, Elastin, a protein in connective tissue, is found in areas of the body that require elasticity including the ear, particular ligaments, and the skin⁽²⁾. Elastic fibers found in the ground substance are also responsible for giving fascia its characteristic stretch^(3, 12, 14).

The cells found in fascia include fibrocytes (fibroblasts and myofibroblasts), adipocytes, and white blood cells^(2, 3, 5, 8, 15, 16). Fibroblasts are highly adaptable to their environment because of their ability to remodel in response to mechanical stimuli⁽³⁾. If increased mechanical stress or prolonged immobilization is endured, either DNA transcription of pro-collagen in the fibroblasts will change types or indistinguishable cell types will adapt to become more functional^(3, 16). It has been found that the molecular composition of the ECM is strongly correlated with locally induced mechanical stress. As a response to compressive forces in tendons and ligaments, the population of fibroblasts decreases while the number of chondrocytes increases^(3, 17, 18).

Myofibroblasts display contractile properties and contain actin-myosin filaments. It is unclear why this contractile ability exists, though in-vitro observations show that fascia may produce tension within the musculoskeletal system between 30 and 40N^(3, 19). An increase in the concentration of myofibroblasts may be responsible for several conditions including palmar fascial fibromatosis, plantar fascial fibromatosis, and adhesive capsulitis^(3, 20-23).

The ground substance is a watery gel made up of mucopolysaccharides or glycosaminoglycans⁽²⁾. These substances bind water to allow for the easy distribution of

metabolites in order to form part of the immune system barrier⁽²⁾. Proteoglycans form a continuous glue-like substance that helps bind cells together while still allowing for free exchange of substances responsible for survival⁽²⁾. In areas of the body where little movement occurs, the ground substance becomes more viscous and acts as a repository for metabolites and toxins⁽²⁾.

Fascial Plasticity

Plasticity allows fascia to be a responsive and versatile matrix, responding to the demands placed on it through rearrangement capability⁽²⁾. Fascia responds to a piezo-electric charge which then creates a stress on the structure and produces an electric current which signals either an augmented or reductive response⁽²⁾. This process is evident across the entire extracellular fibrous matrix. For example, when strain is placed on a muscle, a piezo-electric charge is induced not only within and around the muscle, but along the myofascial meridian as well⁽²⁾. When stretched, the muscle is capable of recoiling back to its initial resting length while fascia on the other hand, does not have recoil capabilities⁽²⁾. In general, muscle is able to deform elastically while fascia adapts plastically; once truly deformed, fascia will not go back to its original orientation^(2, 24, 25). When stretched too quickly, fascia will tear but when a slow stretch is created, the tissue was change plastically⁽²⁾.

To adapt to lines of pull, collagen molecules, secreted by fibroblasts, become polarized and orient themselves along the piezo-electric charge⁽²⁾. These collagen fibers then bind together with hydrogen bonds via the ground substance in order to form a new matrix⁽²⁾. In all, strain causes lines of piezo-electricity, which causes fascia to respond by laying down more collagen oriented in patterns of strain to ameliorate the resistance. Further more, when bodily movement or strain does not occur, fascia sits undisturbed and becomes more solid⁽²⁶⁾.

Integration of Fascia with the Rest of the Body

Fascia contains mechanoreceptors that convey information to the nervous system, thereby making the network the largest sense organ in the body⁽²⁾. The following receptors can be found within the fascial network: Ruffini endings, Pacini corpuscles, Golgi receptors, and free nerve endings⁽²⁾. These receptors receive and communicate information regarding vibrations, tangential (shear) force, load, stretch, and pressure⁽²⁾. Free nerve endings in the fascia act as both mechanoreceptors and nociceptors⁽²⁾.

Tensegrity

The term Tensegrity was first coined from the phrase “tension integrity” by R. Buckminster Fuller⁽²⁾. Fuller describes tension integrity as “a structural relationship principle in which structural shape is guaranteed by the finitely closed, comprehensively continuous, tensional behaviors of the system and not by the discontinuous and exclusively local compressional member behaviors. Tensegrity provides the ability to yield increasingly without ultimately breaking or coming asunder”^(2, 27).

Ultimately, there are two ways to support something: through tension or through compression⁽²⁾. Tensegrity creates an adjustment and proper balance between these two in order to produce a stable structure⁽²⁾. Generally bones are the primary compression forces while myofascia, certain bodily cavities, and cells act as tension members⁽²⁾. With the concept of tensegrity in mind, anatomical patterns or trains have been identified throughout the body⁽²⁾. These myofascial trains are described as continual bands that hold tensile strain patterns from bone to bone⁽²⁾. For example, an injury to the ankle can create long-term strain patterns throughout other areas of the body⁽²⁾.

When strain patterns of the extracellular fibrous matrix are found, a reduction in severity or a reversal is shown to be possible through manipulation or training⁽²⁾. In order for this to occur, two elements must emerge: 1) an opening of the injured tissue to facilitate fluid flow, muscular function, and a reconnection with the sensory-motor system and 2) an alleviation of the strain that caused the stress initially⁽²⁾. According to Ingber, an increase in tension of one of the members results in increased tension in members throughout the structure, even ones on the opposite side^(2, 28). This supports the idea that anatomical meridians, or trains, must be addressed fully as opposed to directing all treatment at a local level.

Fascial Treatment Options

The source of many debilitating medical conditions is the indirect pain caused by myofascial adhesions and consequent restrictions⁽²⁹⁾. Several forms of soft tissue mobilization therapies have been developed to alleviate myofascial pain. This review will include descriptions of the following: manual therapies including active release technique (ART) and massage therapy as well as instrument assisted soft tissue mobilization (IASTM).

Myofascial Release Technique

Myofascial release technique (MFR) is a manual strategy that targets both muscles and the fascial network⁽²⁶⁾. Bergert describes the technique as the art of feeling restrictions in the body's connective tissue system⁽²⁹⁾. Essentially, a trained clinician implements tissue-stretching techniques in order to regain musculoskeletal-system motion and to decrease associated pain⁽²⁶⁾. Mind and hands are combined in order to identify and treat abnormal tissue and restore its function. Because fascia is thixotropic in nature, movement, body heat, stretching, and massage tend to soften fascia making it a much more pliable structure⁽²⁶⁾. MFR is designed to use the

thixotropic nature of fascia in order to return it to its normal functionality. The technique works through a combination of pressure and stretching which causes friction thereby generating an increase in tissue temperature and energy⁽²⁶⁾. Indications for MFR include: structural imbalances, acute and chronic pain, muscle spasms, muscle guarding, and lack of mobility⁽²⁶⁾. Contraindications include malignancy or infection, acute fractures, obstructive edema, osteoporosis, degenerative joint disease, acute rheumatological conditions, cortisone therapy, blood thinners, and skin conditions⁽²⁶⁾. A review of literature conducted in 2009, shows that MFR is successful in alleviating pain, though the exact mechanism for how this is achieved is unknown⁽³⁰⁾. MFR is also efficacious in decreasing muscle spasm and increasing tissue extensibility, which is most likely due to its thixotropic nature⁽³⁰⁾.

Active Release Technique

Active release techniques (ART) was developed, refined, and patented by P. Michael Leachy who noticed that symptoms tend to be related to changes in soft tissue that can be felt through the hands. He observed how muscles, fascia, tendons, ligaments, and nerves respond to different forms of stress and was able to develop a successful technique from his findings. Clinicians who are getting trained in ATR are taught over 500 treatment protocols. Practitioners must become skillful in differentiating tissue texture, tension, and movement as well as be able to evaluate the movement of tissue relative to adjacent tissue. Active release technique is performed by shortening the tissue, applying a contact tension, and lengthening the tissue⁽³¹⁾. Precise tension and specific movement patterns are combined in an individualistic approach. ART used for chronic conditions that have resulted from acute conditions, micro-trauma, or from hypoxia.

Known research on ART is limited to pilot studies. A pilot study from 2004 looked at the effect of ART on quadriceps inhibition and strength. The researchers looked at 9 athletes who were currently suffering from anterior knee pain. Isometric strength and inhibition in the quadriceps were determined and ART treatment protocols for anterior knee pain. Results indicated that ART protocols did not reduce inhibition or increase strength in athletes with anterior knee pain⁽³²⁾. A later pilot study in 2005 aimed to determine whether or not ART is successful in increasing hamstring flexibility in healthy male participants. Twenty participants received ART on the origins and insertions of the hamstrings and dorsal sacral ligament. The sit-and-reach test was used before and after treatment protocols. Results indicate that a single ART treatment increases hamstring flexibility in healthy and active males⁽³³⁾. Lastly, a pilot study in 2006 examined changes in electromyography and a self-administered outcome measure after ART was applied to carpal tunnel patients. Five subjects were treated three times a week for two weeks with and ART protocol intended to affect the median nerve. There was significant improvement in the mean symptom severity and functional status scores of the Boston Questionnaire, though there was no significance found in the EMG analysis. Therefore, it can only be concluded that ART may an effective conservative management strategy though further research is needed before drawing conclusions⁽³⁴⁾.

Massage Therapy

Massage therapy, dating back as far as 2,700 B.C. in ancient Eastern China, is defined as “the practice of using touch to manipulate the soft tissues of the body”^(35, 36). As opposed to the other instrument and non-instrument assisted manipulations discussed thus far, massage therapy is also indicated for stress, tired or overworked muscles, relaxation, and promoting

general health. There are over 80 different types of massage including Swedish massage, deep tissue, reflexology, acupressure, sports massage, and neuromuscular massage. In sports massage compressive strokes, broad circular friction, and jostling strokes are implemented varying in depth, speed, and timing of the day (pre or post-event).

The techniques most commonly implemented during research come from Swedish massage and include combinations of effleurage, petrissage, tapotement, friction, and vibration. Effleurage, or stroking, is one of the more frequently used strokes in sports massage. Strokes are performed in the direction of lymph and venous flow and are typically used at the beginning of the session to prepare the patient or at the end for relaxation purposes. Petrissage, or kneading, takes place when muscle tissue is lifted away from underlying structures, is gently compressed, and then released. This stroke assists in the removal of metabolic waste and improves circulation. Tapotement, or percussion, is the repetitive light striking to the skin with the ulnar portion of the hands or with hands cupped. This is typically performed before sporting events with the goal of stimulating or energizing muscle tissue. Friction massage is a deep stroke that is either performed transversely or parallel to the fiber direction. The goal of friction massage is to initiate an inflammatory response in order to break down scar tissue, separate adhesions, increase circulation, or reduce trigger point activity. The final stroke is vibration, or shaking. It is a pre-event technique used to stimulate the targeted muscles and incorporates tremulous movements that result in shaking with the purpose of creating muscle relaxation and to increase circulation.

Instrument Assisted Soft Tissue Mobilization

Instrument assisted soft tissue mobilization therapy (IASTM) originates from the Traditional Chinese Medicine technique known as Gua Sha. This “scraping” technique dates

back to around 220 BC and is based on the theory of meridians and acupoints⁽¹⁾. Gua Sha involves using a smooth-edged instrument such as spoons, coins, jars, wood, bamboo, bone, or jade to intentionally create petechiae and ecchymosis (sha). Raising sha is theorized to remove blood stagnation and to promote normal circulation and metabolic processes⁽¹⁾.

IASTM today is much different than the traditional Gua Sha treatments. In the mid-1900s, David Graston, a pioneer of instrument assisted soft tissue mobilization, created a method and instruments for treating soft tissue injuries. Instead of the scraping technique that was meant to remove sha, the Graston technique was developed with the goal of detecting and alleviating adhesions. Using instruments to actually detect adhesions was a novel idea that set the technique apart from others⁽³⁷⁾. When creating the instruments, a variety of materials were originally used and qualitatively assessed. It was determined that stainless steel is able to generate the most vibration and would therefore trump other materials in detecting soft tissue adhesions and restrictions⁽³⁸⁾. Since its development, nearly thirty companies have marketed their own version of instruments (*see Appendix F*).

Various techniques and instruments have been developed in order to achieve MFR or an advanced form of MFR including instrument assisted soft tissue mobilization. Appendix E Summary of IASTM Research lists a few of many articles that discuss the outcomes of IASTM. Appendix F Summary of IASTM companies lists various IASTM instruments/tools from a variety of companies. Variance is shown in instrument composition, design, technique training and availability of training, as well as in instrument cost.

Fascial Imaging

Few methods exist for imaging fascia including magnetic resonance imaging (MRI),

computer assisted tomography (CAT scan) and diagnostic ultrasound. MRIs take advantage of the fact that different chemical elements are associated with different tissues in the body and use nuclear magnetic resonance to image the nuclei of atoms. MRI machines are large and expensive because they need to be able to induce a high intensity magnetic field. With CAT scans, a cross-sectional image is created by taking x-rays from various directions and calculating shapes and positions of objects blocking the x-rays. Diagnostic ultrasound, also known as sonography, exposes the body to high-frequency sound waves. When these waves come in contact with various structures, they reflect and produce an image. The average cost of an MRI is roughly \$5,000 dollars while the average cost of a CAT scan and diagnostic ultrasound is \$1,200-\$3,200 and \$100-\$1,000 respectively⁽³⁹⁾. CAT scans are disadvantageous due to the radiation associated with them. MRIs do not have radiation but they often take 45 minutes to an hour to complete depending on the body structure. Because diagnostic ultrasound is the least expensive option, is readily available at the institution, has no radiation, and is able to create real-time images, it will be used for this study and detailed in the proceeding paragraph.

Ultrasonography

Ultrasonography is a diagnostic imaging method in which sound waves are utilized to create real-time visualizations of internal body structures, including skeletal muscle, subcutaneous tissue, tendons, ligaments, and fascia⁽⁴⁰⁾. These images are formed by recording the echoes of ultrasonic waves that are directed into the tissues and reflected according to changes in tissue density⁽⁴¹⁾. Diagnostic ultrasound has greatly advanced in the past 10 to 20 years and is currently being used much more frequently to image musculoskeletal structures due to its low cost and noninvasive features⁽⁴²⁾. Other techniques are either insufficient at imaging

acute traumas or are too expensive and have limited availability i.e. magnetic resonance imaging⁽⁴²⁾.

While forms of manual therapy and IASTM are often successful at alleviating fascial adhesions, a quantitative relationship demonstrating the direct impact these techniques have on adhesion size has yet to be determined. IASTM claims that it is able to qualitatively detect fascial adhesions through vibration in the instruments; however, the truth of this statement is not understood and a quantitative measurement demonstrating the success of IASTM qualitative assessment has yet to be examined. While many other IASTM companies exist, Graston instruments were chosen for this study because of the technique's current popularity and because of the researcher's preference and training in the technique. In order to quantitatively measure the size of fascial adhesions, ultrasonography will be used.

Summary

Both manual and IASTM techniques have been utilized and shown to be successful at alleviating the indirect pain caused by myofascial adhesions. IASTM claims to be able to qualitatively access adhesions through the vibration of the instrument itself. Empirical evidence showing the success of this detection, however, does not exist. It is necessary to determine if IASTM is able to accurately detect adhesions in order to justify its use for this purpose.

CHAPTER 3

METHODS

Design

Correlational validity study

Participants

One hundred participants between the ages of 18 and 30 were recruited for this study. All participants will have fascial adhesions along the medial head of the gastrocnemius that are detectable with IASTM. Participants will be excluded if they possess any absolute contraindications for IASTM. If they have any relative contraindication they will be further evaluated to determine their eligibility. Absolute contraindications include open wounds, unhealed or unstable fractures, thrombophlebitis, uncontrolled hypertension, patient intolerance or hypersensitivity, hematoma, osteomyelitis, myositis ossificans, and hemophilia⁽⁴³⁾. Relative contraindications include: medications (anti-coagulants, steroids, hormone replacement therapy, NSAIDS), cancer, varicose veins, burn scars (mature scars 9 months post-healing), acute inflammatory conditions, kidney dysfunction, lymphedema, inflammatory condition secondary to infection, rheumatoid arthritis, pregnancy, osteoporosis, hemophilia, polyneuropathies, and unhealed uncomplicated fractures. Additionally, participants were excluded if they have an allergy to the emollient cream put forth by Graston Technique⁽³⁸⁾.

All participants provided written informed consent and completed a health history questionnaire.

Measurements and Instruments

Graston Technique Instrument

Graston Technique instrument 4 (GT4) was used for this study (*see figure 2*). This instrument is specifically designed to be used as a general scanning instrument for both convex and concave tissues. Although other instruments can be used for scanning, GT4 was chosen because the instrument is convex, which allows for more vibration when used on convex tissues, such as the gastrocnemius. The pressure of the instrument on the tissue was the weight of the instrument. The speed of the instrument scanning was approximately 3-4 inches of tissue per second. When scanning for adhesions, a sweeping stroke was implemented. A linear path starting near the origin of the gastrocnemius on the medial or lateral condyle of the femur and moving in a distal direction was used. If an adhesion was indistinguishable in this direction, then a sweeping stroke moving from distal to proximal took place. Scanning continued in all 4 directions (distal to proximal, proximal to distal, lateral to medial, and medial to lateral) until an adhesion was located.

GE LOGIQ e Portable Diagnostic Ultrasound

A diagnostic ultrasound machine (*see figure 3*) was used collect fascial dimension images and data. Under musculoskeletal settings, the knee setting was used to standardize all images. With these settings, the gain is set at 54, the frequency at 10.0 MHz, auto optimize at 92%, dynamic range at 81, E/A at 3/3, and the depth at 3.0 cm. A still image of the fascial adhesion was saved and immediately transferred to a USB drive for later analysis.

Procedures

Recruited participants will come to the athletic training laboratory dressed in attire that will allow easy access to the lower leg. Upon arrival, an oral presentation of informed consent will be conducted. After all questions are answered, participants will sign a written consent document that contained a written summary of what was presented and that also notes this information was presented orally. Participants will be screened to determine their eligibility to take part in the study by completing a health history questionnaire (HHQ) (*see Appendix C*). The HHQ focuses on questions regarding demographics, presence of lower extremity injury, and existence of general medication conditions that would contraindicate their participation. Participants will be asked if they have any known allergies to emollient cream (a list of ingredients will be orally listed to them). After completing the HHQ, the researcher will determine the eligibility of the participant (*see table 1 for timeline of procedure*).

The eligible participant will be asked to lie prone on the padded treatment table with both calves exposed and their foot relaxed and rested off the table. The participant will be instructed to lie in a motionless manner for the duration of the data collection. On the diagnostic ultrasound, a new patient will be created and the participant will be assigned a random patient ID number. This will ensure confidentiality in that all images saved on the diagnostic ultrasound and on the USB drive will not be able to get traced back to the participant.

A small amount of emollient will be applied topically to the entire area of the left and right gastrocnemius. GT4 will be used to scan the gastrocnemius at a 30-60 degree application angle⁽⁴³⁾. If any prominent myofascial adhesions are located, they will be marked with a dot

using a black permanent marker. Once the entire left and right gastrocnemius are scanned and marked, the process of obtaining an image will take place.

The area will be wiped clean of emollient with a towel and ultrasound gel will be applied to the same area. The head of the ultrasound will be placed directly over the marked adhesion and a still image will be taken, saved, and immediately sent to the USB drive. The ultrasound gel and permanent marker will be wiped clean using a towel. The ultrasound head and GT4 will be sprayed with Sanicide® and wiped clean.

All images will be analyzed at the conclusion of data collection. The images saved on the USB drive will be transferred to the laptops of two separate clinicians who are trained in using the diagnostic ultrasound. The clinicians will independently analyze the images and confirm whether or not the image was a myofascial adhesion.

Data and Statistical Analysis

We will calculate the percent level of agreement between the two raters, and then consider chance by using a κ coefficient to understand the relationship between the two rates of diagnostic US.

CHAPTER 4

Manuscript

INTRODUCTION

Fascia surrounds individual muscles, muscle groups, blood vessels, and nerves. When stress is placed on the body or when injury occurs, fascia can become stretched, or in severe cases, torn. When this takes place, the body responds by laying down more collagen and scar tissue is formed in the fascia. Scar tissue, also called adhesions or restrictions, can additionally be formed as a result of periods of immobilization or poor posture. Dehydration also has a direct effect on fascia, making it less pliable and unable to easily withstand tension and strain.

Clinicians use a variety of manual and instrument assisted soft tissue mobilization (IASTM) techniques to diagnose and treat myofascial adhesions. Gua Sha was the first instrument assisted technique dating back to ~220 BC⁽¹⁾. The original Gua Sha instruments were made from spoons, coins, jars, wood, bamboo, bone, or jade. The goal of Gua Sha was to intentionally create petechiae and ecchymosis (sha) by scraping the soft tissue. Raising sha is theorized to remove blood stagnation and to promote normal circulation and metabolic processes⁽¹⁾.

In the mid-1990s, David Graston, a pioneer of IASTM, created a method and instruments for treating soft tissue injuries. Instead of the scraping technique that was meant to remove sha, the Graston Technique® (GT) was developed with the goal of detecting and alleviating

adhesions. Using instruments to actually detect adhesions was a novel idea that set the technique apart from others⁽³⁷⁾. When creating the instruments, a variety of materials were originally used and qualitatively assessed. It was determined that stainless steel is able to generate the most vibration and would therefore trump other materials in detecting soft tissue adhesions and restrictions⁽³⁸⁾. Since the development of Graston Technique[®], nearly twenty-five companies have marketed their own version of the instruments and in some cases, have created their own technique. While the popularity of these instruments is on the rise, the empirical evidence for the validity of using IASTM to actually detect myofascial adhesions does not exist. Therefore, the purpose of this research study was to determine the validity of using the Graston Technique[®] to detect myofascial adhesions through secondary diagnostic ultrasound analysis.

METHODS

Participants

Thirty college-aged men (n=19 ;age = 22.4 ± 2.5) and women (n=11 ;age = 21.2 ± 1.9) with no current lower extremity injury participated. Recruitment took place by word-of-mouth and by utilizing fliers following approval of the research by the Indiana State University Institutional Review Board. All participants provided written informed consent, and because some participants may have also been regular patients cared for by the primary investigator, signed a dual role relationship form to avoid any coercion. The participants completed a health history questionnaire as well (*see Appendix C*).

Measurements and Instruments

Graston Technique Instrument

Graston Technique instrument 4 (GT4) (*see Figure 2*) was used for this study. This instrument is specifically designed to be used as a general scanning instrument for both convex and concave tissues. Although other instruments can be used for scanning, GT4 was chosen because the instrument is convex, which theoretically allows for more vibration or resonance when used on convex tissues, such as the gastrocnemius⁽⁴³⁾.

GE LOGIQ e Portable Diagnostic Ultrasound

A diagnostic ultrasound machine (*see Figure 3*) was used collect to fascial images. Under musculoskeletal settings, the knee setting was used to standardize all images. With these settings, the gain was set at 54, the frequency at 10.0 MHz, auto optimize at 92%, dynamic range at 81, E/A at 3/3, and the depth at 3.0 cm. A still image of the fascial adhesion was saved and immediately transferred to a USB drive for later analysis.

PROCEDURE

Recruited participants came to the athletic training laboratory dressed in attire that allowed easy access to the lower leg. Upon arrival, an oral presentation of informed consent was conducted. After all questions were answered, participants signed a written consent document that contained a written summary of what was presented and that also noted this information was presented orally. Participants then read and signed a Dual Role Relationship form. Participants were screened to determine their eligibility to take part in the study by completing a health history questionnaire (HHQ). The HHQ focused on questions regarding demographics, presence of lower extremity injury, and existence of general medication conditions that would contraindicate their participation. Participants were asked if they have any known allergies to

emollient cream (a list of ingredients were orally listed to them). After completing the HHQ, the researcher determined the eligibility of the participant.

The eligible participant was asked to lie prone on the padded treatment table with both calves exposed and their foot relaxed and rested off the table (*see figure 4*). The participant was instructed to lie in a motionless manner for the duration of the data collection. On the diagnostic ultrasound, a new patient was created and the participant was assigned a random patient ID number. This would ensure confidentiality in that all images saved on the diagnostic ultrasound and on the USB drive would not be able to get traced back to the participant.

A small amount of emollient was applied topically to the entire area of the left and right gastrocnemius. GT4 was used to scan the gastrocnemius at a 30-60 degree application angle using the pressure of the instrument only⁽⁴³⁾ (*see figure 5*). The speed of the instrument scanning was approximately 3-4 inches of tissue per second. When scanning for adhesions, a sweeping stroke was implemented. A linear path starting near the origin of the gastrocnemius on the medial or lateral condyle of the femur and moving in a distal direction was used. If an adhesion was indistinguishable in this direction, then a sweeping stroke moving from distal to proximal took place. Scanning continued in all 4 directions (distal to proximal, proximal to distal, lateral to medial, and medial to lateral) until the presence of an adhesion, or lack thereof, was decided.

If any prominent myofascial adhesions were located, they were marked with a dot using a black permanent marker (*see figure 6*). Once the entire left and right gastrocnemius were scanned and marked, the process of obtaining an image took place.

The area was wiped clean of emollient with a towel and ultrasound gel was applied to the same area. The head of the ultrasound was placed directly over the marked adhesion and a still image will be taken, saved, and immediately sent to the USB drive. The ultrasound gel and permanent marker was wiped clean using a towel. The ultrasound head was sprayed with Sanicide® and wiped clean.

All images were analyzed at the conclusion of data collection. The images saved on the USB drive were transferred to the laptops of two separate clinicians who were trained in using the diagnostic ultrasound. The clinicians independently analyzed the images and confirmed whether or not the image was a myofascial adhesion.

ANALYSIS

We calculated the percent level of agreement between the two raters, and then considered chance by using a κ coefficient to understand the relationship between the two rates of diagnostic US.

RESULTS

Rater 1 found 78% of the images to contain a myofascial adhesion while rater 2 noted 93% to have a myofascial adhesion (*see Appendix B*). We identified an 83% level of agreement between raters. However, when chance was considered, we found a poor inter-rater reliability ($\kappa = 0.344$, $p < 0.001$).

DISCUSSION

Graston Technique® (GT) is currently used by more than 16,000 clinicians in approximately 1,550 outpatient facilities. Furthermore, it is used by more than 234 professional

and amateur sports organizations and is included in the curriculum of 54 universities and colleges⁽³⁸⁾. GT is approved for continuing education for physical therapists, occupational therapists, certified hand therapists, chiropractors, and athletic trainers⁽³⁸⁾. It's important to note that these statistics represent GT alone and do not take into account other IASTM companies. If all companies were considered, these statistics would presumably grow. Undoubtedly, the use of IASTM in clinical practice is widespread and is shown to be a popular technique implemented in a variety of settings and used by an assortment of health care professionals.

IASTM claims that it can both diagnose and treat myofascial restrictions⁽³⁸⁾. Considering the prevalence of IASTM, it seems necessary to investigate both the validity and reliability of this claim. Plenty of research regarding the success of using GT for specific pathologies exists⁽³⁸⁾, however, there is no research validating the claim that GT can accurately detect myofascial adhesions through resonance capability. In order to prove that instrument vibrations can accurately detect a myofascial adhesion, a secondary form of diagnosis must exist to confirm the presence of the adhesion. Utilizing a form of diagnostic imaging is the logical method to confirm GT diagnoses. Magnetic Resonance Images (MRI) can cost upwards of \$5,000 dollars, require approval from a physician, and are time consuming⁽³⁹⁾. Computed Tomography (CT) averages \$1,200 to \$3,200 for each image and is less time consuming. Diagnostic ultrasound costs between \$100 and \$1,000 and is unique in its ability to take real-time images. With this in mind, it seems both logical and practical to utilize diagnostic ultrasound. Therefore, the purpose of this study was to determine the validity of using IASTM to detect myofascial adhesions through secondary diagnostic ultrasound analysis.

The results show that the two raters were in agreement 83% of the time. This seems relatively high, though when chance is taken into account, the κ is 0.344. Even though the statistics show that the level of agreement between the two raters is poor, the study is efficacious in stimulating many questions that future investigations may seek to answer. After the raters reviewed the images and statistics were gathered, images that both raters agreed that no myofascial adhesion was present were re-assessed by the investigators. The purpose of this was to determine other sources that may have been producing instrument vibration, i.e. blood vessels, nerves, lymphomas, etc.

Upon re-assessing the images, it was found that these other sources might include but not be limited to, blood vessels or adipose nodules. It was decided that the image was a myofascial adhesion if there were concrete gaps in the fascial layer (*see figures 10,11,12*). The images that did not show myofascial adhesions according to the raters often had a solid black circle beneath the myofascial layer or oblong-shaped circles that were present above the myofascial layer (*see figures 7 and 8*). The solid black circles are presumed to be blood vessels while the oblong-shaped circles are alleged adipose nodules. It remains unconcluded whether images rated as non-myofascial adhesions show an adipose nodule, a blood vessel, or another unknown structure. Figure 9 shows an image of brachial blood vessels in order to serve as a comparison to the solid black circles in figures 7 and 8. Figures 13 and 14 are images that the raters disagreed upon. This disagreement may exist as a result of the contrast in both level and type of experience the two raters have in viewing diagnostic ultrasound images.

The methods created in this study may serve as a guide for forthcoming investigators. Future studies should commission more raters with extensive experience, i.e. diagnostic

ultrasound technicians and radiologists. It is suggested that future researchers utilize a smaller instrument such as GT3 in addition to GT4 . GT4 should still serve as the initial scanning instrument to locate areas of vibration. GT3 can be used to increase precision of the exact location. The convex nature and smaller contact area GT3 features may allow adhesions to produce more pronounced resonance. With an amplified feel of the adhesions, clinicians may be able to more accurately diagnose a myofascial adhesion rather than confusing it with another source that is producing vibration.

Once validity of using IASTM to detect myofascial adhesions can be established, future studies may choose to utilize the tracing method on the diagnostic ultrasound. This would allow clinicians to quantitatively assess the precise size of the adhesion and determine a specific treatment protocol. This would also allow the clinician to chart treatment progress, as they would be able to compare the size of the adhesion over a given time. Even more, future studies can assess how various treatment times affect the size of the adhesion. The current treatment protocol is 30-60 seconds per adhesion⁽⁴³⁾ , though the basis for this protocol remains unknown. Furthermore, it's credible that if adhesions are distinctive in size, then they should be treated differently. It's important to know how long clinicians should be treating adhesions because if the 30-60 second protocol is too short to produce a decrease in adhesion size, then the treatment time must be extended. Conversely, if the 30-60 second protocol is too long, then knowing that shorter treatment times still produce the same decreases in adhesion size would save clinicians valuable time.

Researchers may also choose to compare GT instruments to other IASTM companies to determine which instruments are more effective in both diagnosing and treating adhesions. GT

argues that the stainless steel nature of their instruments is superior to other materials, though this has not been directly proven.

LIMITATIONS

The level of experience of the two raters in reading diagnostic ultrasound images could have contributed to the lack of agreement between them. Also, utilizing two investigators could have impacted the results as maybe more individuals reading the images may have increased inter-rater reliability. Another limitation may rest in the experience of the researcher using the diagnostic ultrasound. Finally, using a larger instrument like GT4 seemed to decrease the sensitivity the researcher felt in specifically locating the adhesion.

CONCLUSIONS

With the popularity of IASTM on the rise, investigating its validity must be examined in order to justify the use of this treatment modality. This is a novel investigation that used diagnostic ultrasound to examine the gastrocnemius myofascia. This study showed that there is moderate evidence that IASTM is successful in qualitatively detecting myofascial adhesions. Sources creating instrument resonance other than myofascial adhesions may have included blood vessels or adipose nodules. Future investigation should further examine what specifically IASTM is detecting through its resonance, if not myofascial adhesions. This is important because clinicians should feel confident in knowing exactly what they are treating. This study showed that what might feel like a myofascial adhesion through instrument resonance may not be which suggests that clinicians may not always be treating myofascial adhesions as intended. Once the validity of IASTM can be determined, future investigations can examine and establish

optimal treatment times per myofascial adhesion based on its original size. This would increase both the success of the treatment and its efficiency.

0-10 Min	10-11 Min	11-13 Min	13-15 Min
Oral presentation Informed consent document Dual Role Relationship form Health history questionnaire completed	Position participant and apply emollient	Scan area and locate adhesion(s) Mark adhesions with a black dot using a black permanent marker	Wipe off emollient and apply ultrasound gel Place ultrasound probe over marked adhesion and create a still image Save image under patient ID and immediately transfer image to USB drive

Table 1 Timeline of procedure

APPENDIX A: STUDY PARAMETERS

Ultrasonography - Ultrasound is the term used to describe frequencies above 30,000 Hertz.

Frequencies between 1 and 30 megahertz are typical for diagnostic ultrasound. Imaging depends on the recorded echoes of ultrasonic waves as they are directed into the tissues and reflected by tissue planes in areas of density change⁽⁴⁴⁾. Ultrasonography will be used to diagnostically create a 3D image of the adhesions and to quantify them individually⁽⁴⁰⁾.

Graston Technique (GT) - A patented form of instrument assisted soft tissue mobilization (IASTM) that is used by clinicians to detect and treat myofascial restrictions. There are 6 uniquely designed stainless steel instruments developed for a variety of injuries and for various areas of the body. The technique includes warm-up, treatment with the instruments, focused stretching, and low load exercises.

Fascial Adhesion - Fascia is a layer of fibrous connective tissue that surrounds muscles, blood vessels, and nerves. There are several layers of fascia including superficial, deep, and subserous (or visceral). The purpose of fascia is to reduce friction to allow muscles to easily glide over one another. Abnormal stress on the fascia causes the tissue to react by contracting and subsequently forming protective adhesions⁽²⁾.

Sweeping stroke - The sweeping stroke is characterized by the instrument contact points moving in one direction at the same rate in either a linear or a curvilinear path⁽⁴³⁾.

Assumptions, Limitations, and Delimitations

Assumptions

- Participants will answer health history questionnaire truthfully

Limitations

- Level of experience the two raters had in reading diagnostic ultrasound images
- Insignificant number of raters

Delimitations

- Using the Graston Technique instruments and not comparing it to other IASTM instruments techniques
- Participant demographics and generalizability
- Not including the full Graston Technique (protocol includes a brief warm-up exercise, treatment, stretching, strengthening, and ice)

APPENDIX B: STATISTICAL ANALYSIS

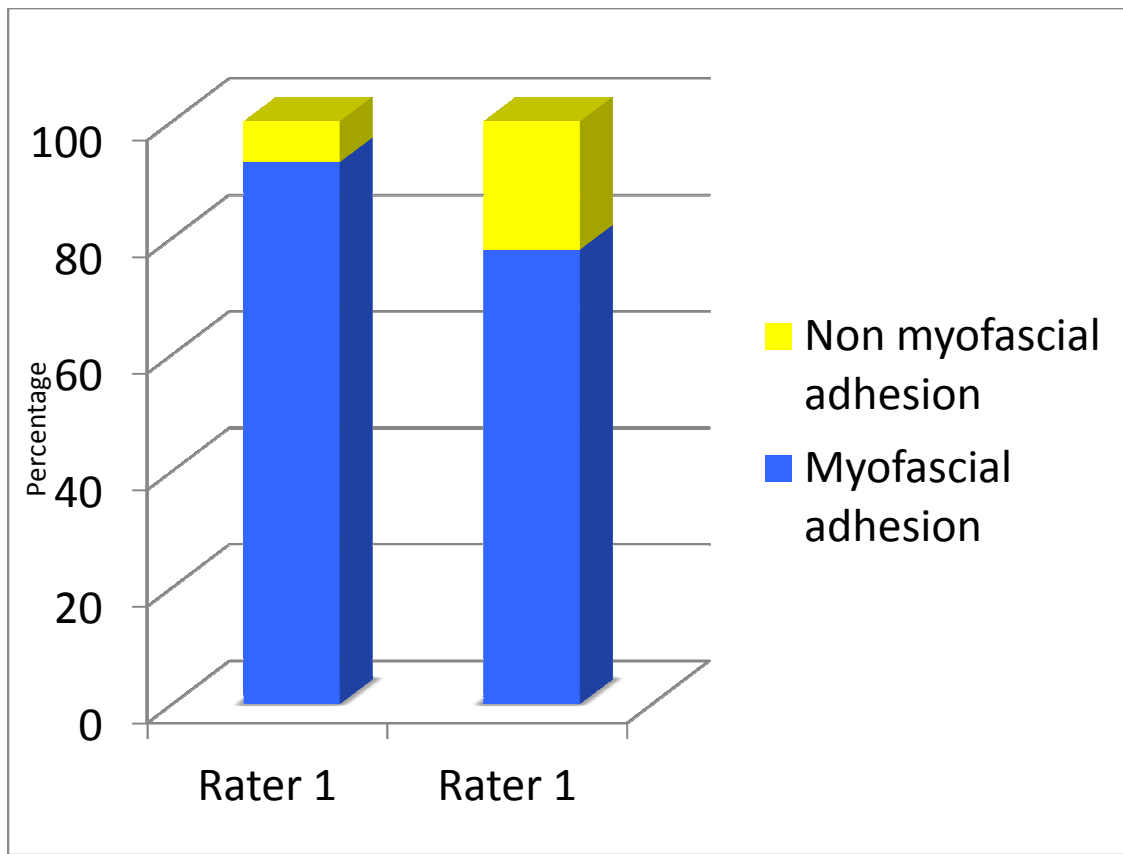


Figure 1. Comparing the number of myofascial adhesions to non myofascial adhesions.

Rater	Adhesion visible	No adhesion visible
Rater 1	78	22
Rater 2	93	7
Mean	85.5	14.5

Table 2 Level of agreement between raters.

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid -1.00	16	16.0	16.0	16.0
0.00	83	83.0	83.0	99.0
1.00	1	1.0	1.0	100.0
Total	100	100.0	100.0	

Table 3 Frequencies: Difference between raters.

	Value	Asymp. Std. Error ^a	Approx. T ^b	Approx. Sig.
Measure of Agreement Kappa	0.344	0.113	4.220	0.000
N of Valid Cases	100			

Table 4 Symmetric Measures.

Note: a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.



Figure 2. GT4.

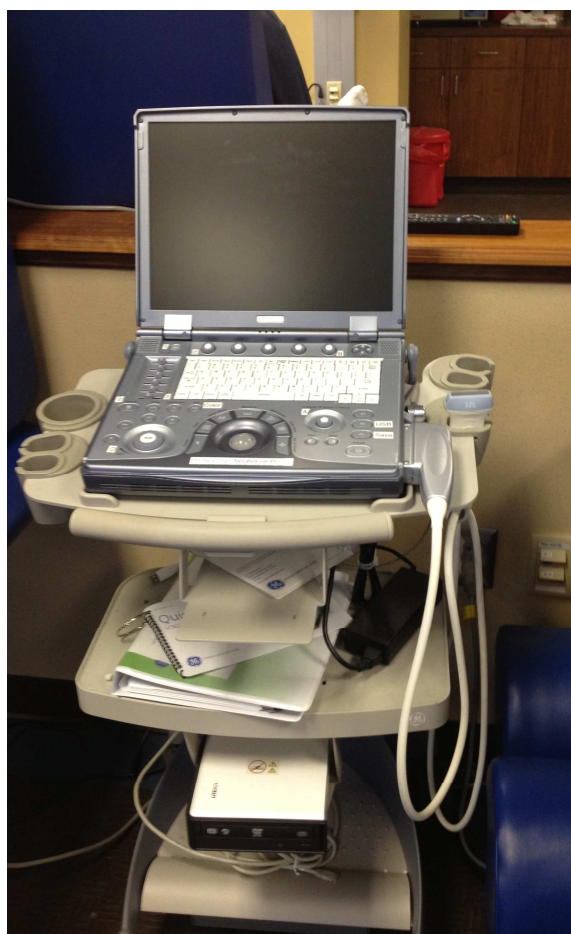


Figure 3. GE LOGIQ e Portable Diagnostic Ultrasound



Figure 4. Participant positioning

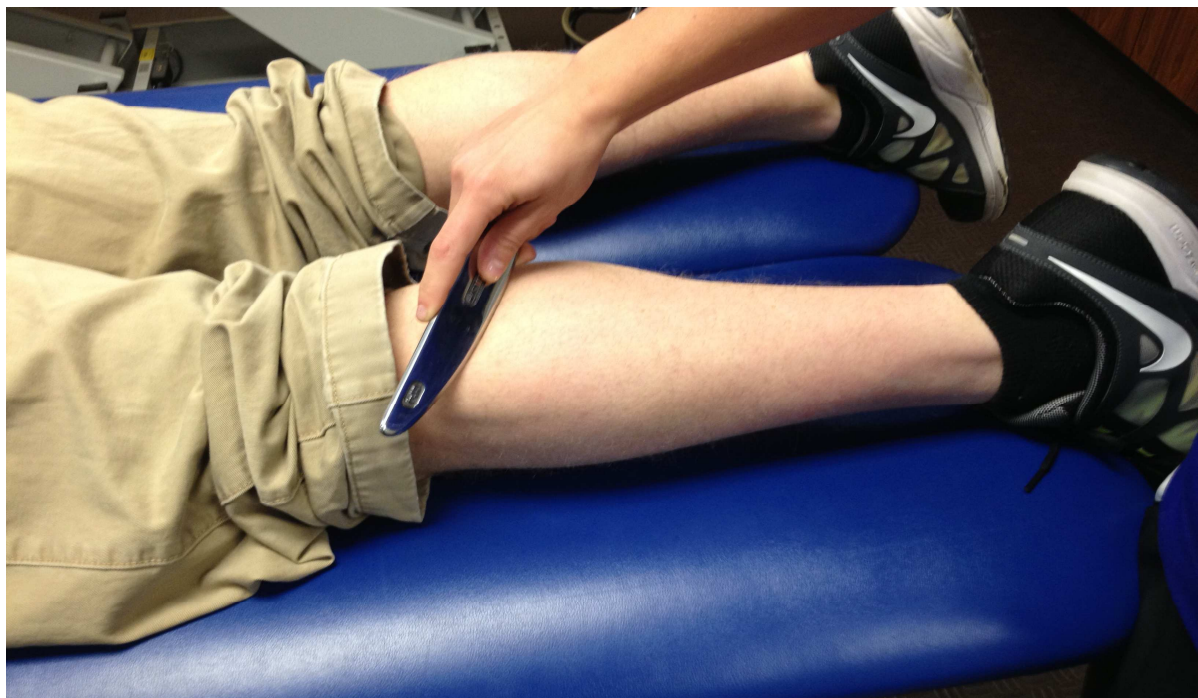


Figure 5. Instrument scanning.



Figure 6. Marked adhesion.

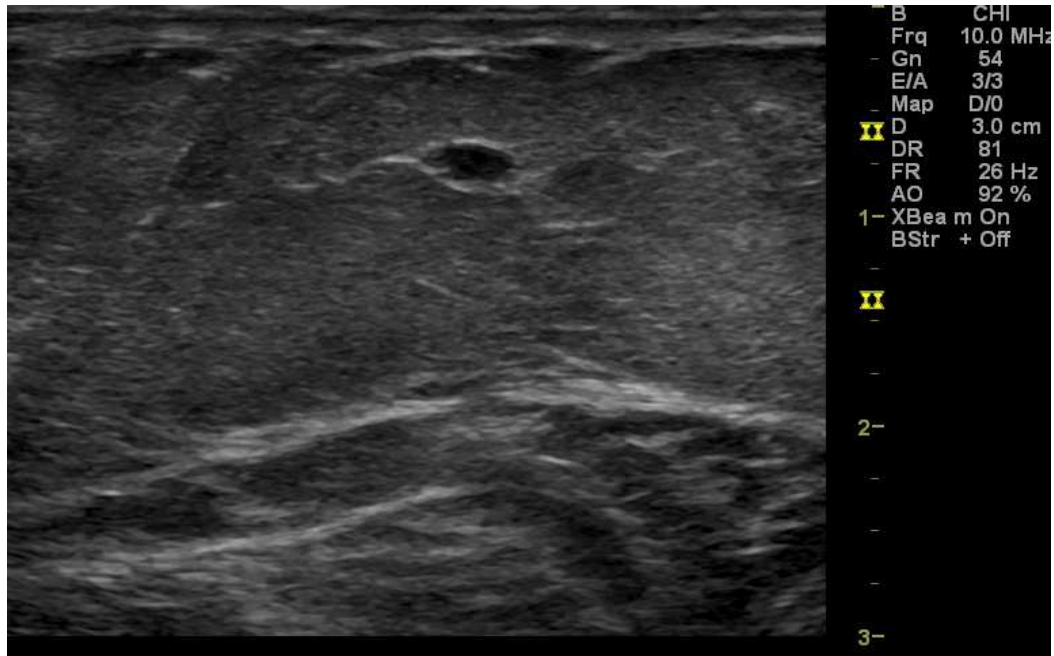


Figure 7. Non-myofascial adhesion.

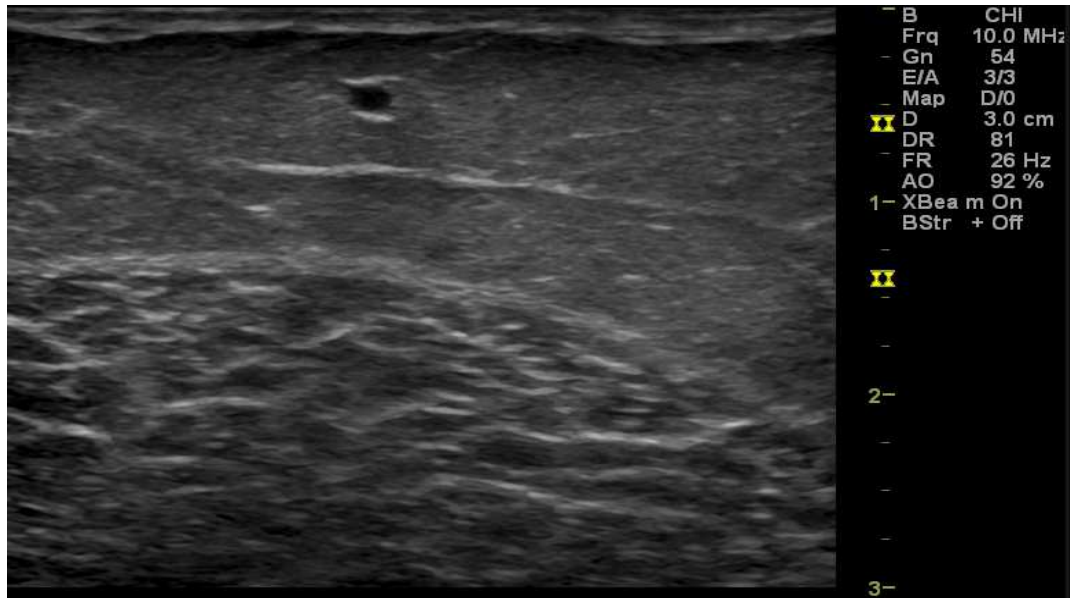
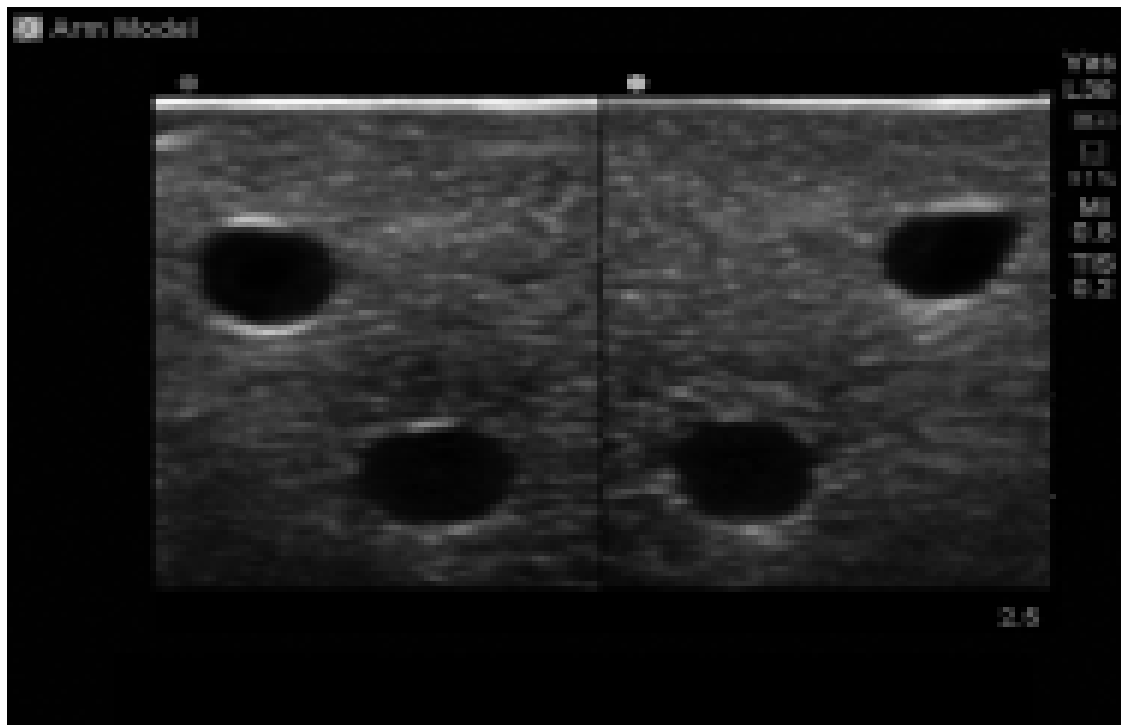


Figure 8. Non-myofascial adhesion.



(45)

Figure 9. Image of brachial arteries.

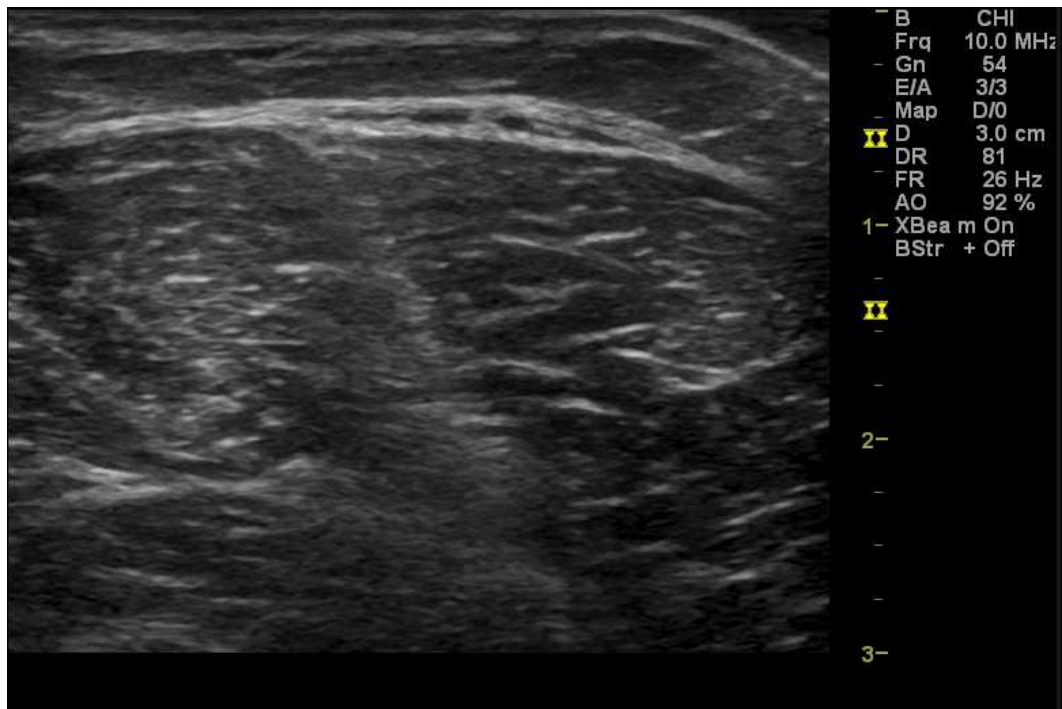


Figure 10. Image of myofascial adhesions.

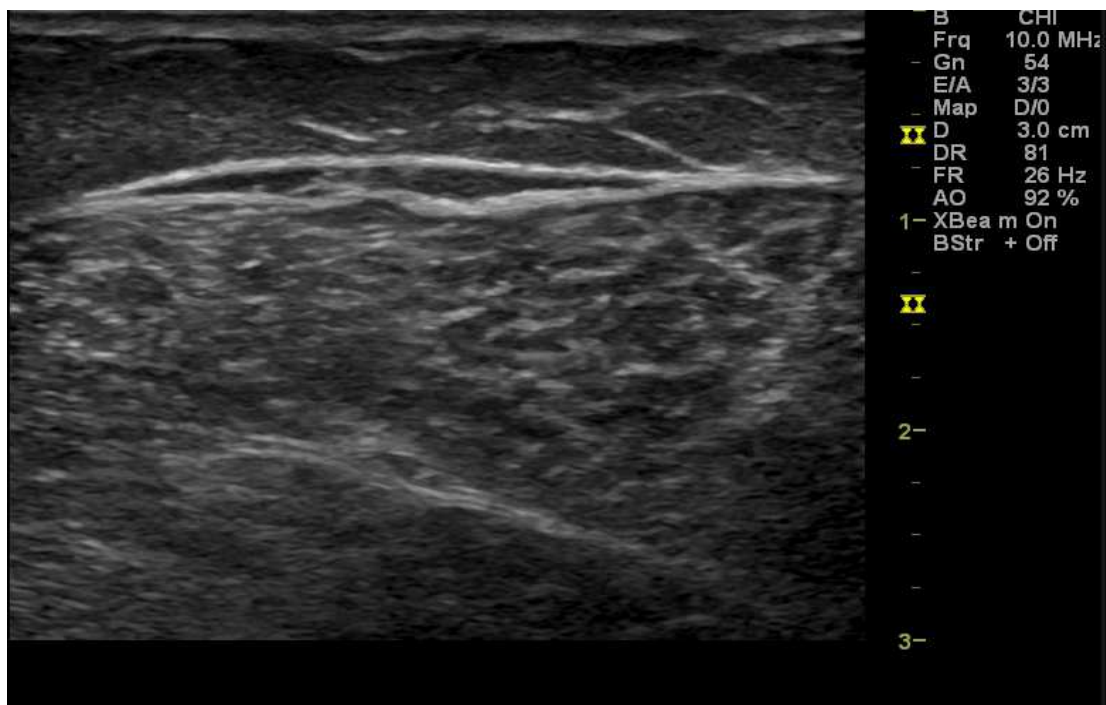


Figure 11. Image of myofascial adhesion.

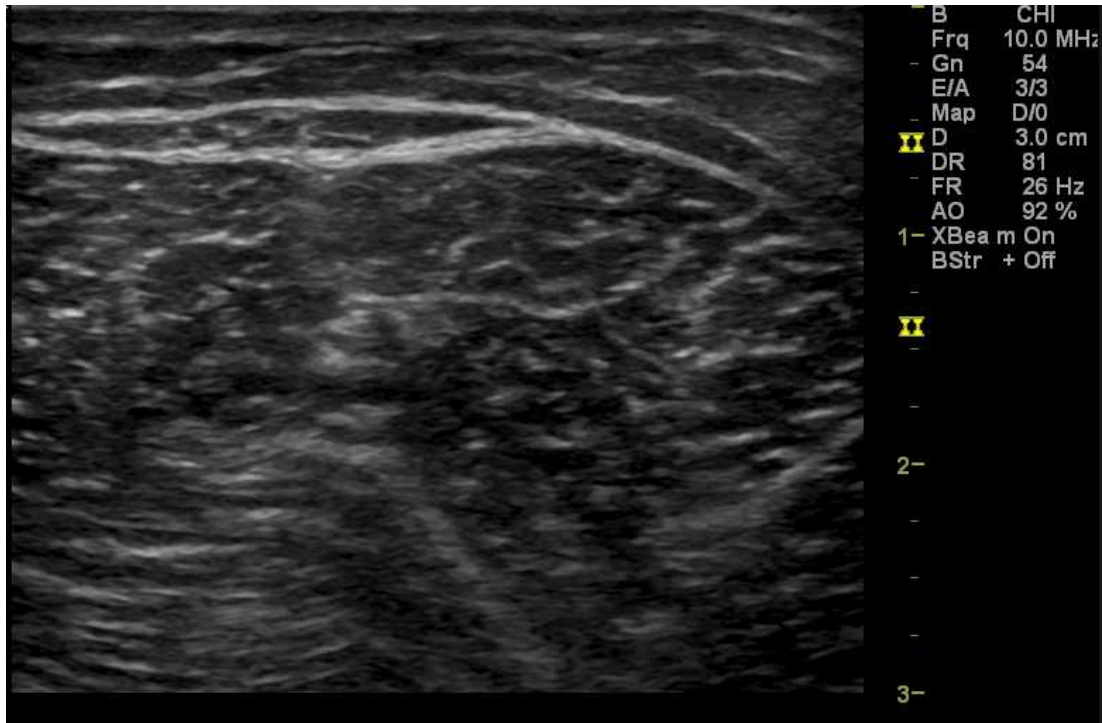


Figure 12. Image of myofascial adhesion.

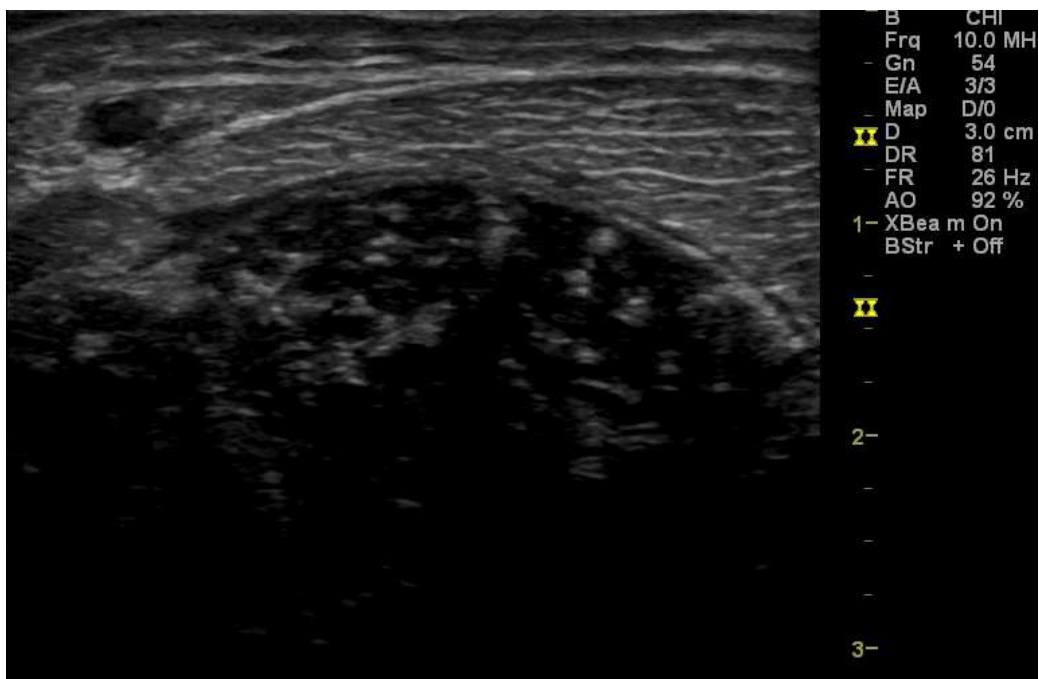


Figure 13. Image that the raters disagreed upon.

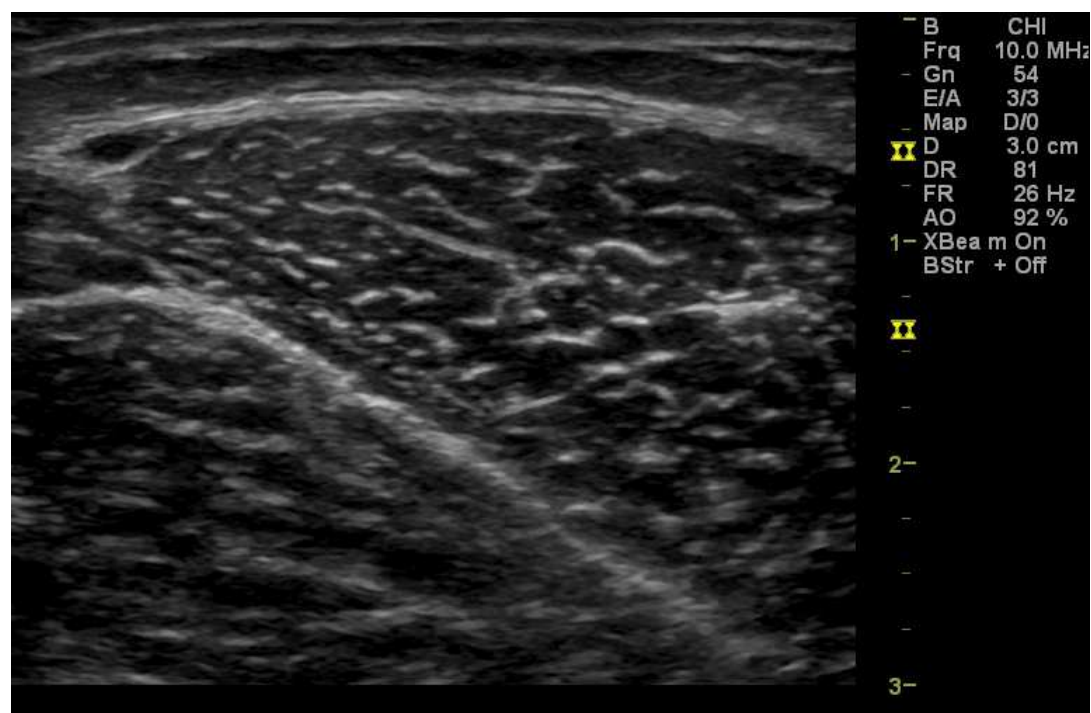


Figure 14. Image that the raters disagreed upon.

APPENDIX C: HEALTH HISTORY QUESTIONNAIRE

Health History Questionnaire

Please complete the following questions. Notify the researcher with any questions you may have or if you would like any further explanation.

1. What is your age? _____ (Write in)

2. Do you have a current lower extremity injury that prevents you from participating in physical activity? (Circle one)

Yes No

3. Please check any conditions that apply to you:

Red Flags/Absolute contraindications:

- ☐ Open wound- unhealed suture site/sutures
- ☐ Unhealed fractures
- ☐ Thrombophlebitis
- ☐ Uncontrolled hypertension

- ☐ Kidney Dysfunction
- ☐ Patient intolerance/Non-compliance/Hypersensitivity
- ☐ Hematoma
- ☐ Osteomyelitis
- ☐ Myositis Ossificans

Yellow Flags/Relative contraindications:

- ☐ Anti-Coagulant Medications
- ☐ Cancer
- ☐ Varicose Veins
- ☐ Burn Scars
- ☐ Acute Inflammatory Conditions (e.g. Synovitis)
- ☐ Inflammatory Conditions Secondary to Infection
- ☐ Rheumatoid Arthritis
- ☐ Pregnancy (consider inherent ligament laxity)
- ☐ Osteoporosis

4. Do you have an allergy to mineral oil or beeswax? (Circle one)

Yes No

5. Are you currently taking any medications (anti-coagulants, steroids, hormone replacement therapy, NSAIDS)? If yes, please specify in the space below.

APPENDIX D: INFORMED CONSENT

CONSENT TO PARTICIPATE IN RESEARCH

Validity of Instrument Assisted Soft Tissue Mobilization for Detecting Myofascial Adhesions through Secondary Diagnostic Ultrasound Analysis

You are asked to participate in a research study conducted by *Kaitlyn Silbaugh and Timothy Demchak* from the *Department of Applied Medicine and Rehabilitation* at Indiana State University. *This study is being conducted as a thesis.* Your participation in this study is entirely voluntary. Please read the information below and ask questions about anything you do not understand, before deciding whether or not to participate.

You have been asked to participate in this study because of your potential for muscular adhesions. In order to participate, there are inclusion and exclusion criteria that must be first examined through a health history questionnaire.

• **PURPOSE OF THE STUDY**

The purpose of this study is to determine if instrument assisted soft tissue mobilization (IASTM) is successful in detecting myofascial adhesions. Myofascia refers to connective tissue that surrounds each muscle. When injury or immobilization occurs, restrictions or painful adhesions can form in this tissue. Historically massage has been used to break up these adhesions and decrease pain. Recently, IASTM has been gaining popularity. It originally developed as a means for making massage easier for the clinician

by saving the use of their hands. It has been found however that these instruments, made of stainless steel, are able to amplify the feel of these adhesions so the clinician can get better feedback from them.

There are approximately 28 companies that have developed different versions of instruments with possible technique variations. One in particular, the Graston Technique, has been successful in the following: increasing range of motion, increasing blood flow, decreasing pain caused from adhesions, and in breaking up scar tissue and other restrictions. This study is looking at the ability of these instruments to feel for and diagnose myofascial.

• PROCEDURES

If you volunteer to participate in this study, you will be asked to do the following things:

Testing day:

Timeline of procedure

0-10 Min	10-11 Min	11-13 Min	13-15 Min
Informed consent Screening, briefing, health history questionnaire	Position participant and apply emollient	Scan area and locate adhesion	Use ultrasound to detect adhesion and create still image

0-10 Minutes: On the scheduled testing day, you should arrive wearing athletic shorts. You will be screened to determine your eligibility to take part in the study by completing a health history questionnaire (HHQ). The HHQ is focused on questions regarding demographics, lower extremity injury,

and on general medication conditions or allergies that would contraindicate your participation. After completing the HHQ, the researcher will determine if you are eligible to participate.

10-11 Minutes: If deemed eligible, you will be asked to lie face down on the padded treatment table with both calves exposed. For the duration of the session, you will be instructed to lie in a motionless manner. A small amount of emollient (cream) will be applied topically to one of your calves.

11-13 Minutes: A Graston Technique (see operational definition below) instrument will be used locate any adhesions, or bumps, along the tissue. Once a prominent adhesion is located, it will be marked with a small dot using a black permanent marker.

13-15 Minutes: The area will be wiped clean of emollient and ultrasound gel will be applied to the same area. The head of the ultrasound will be placed directly over the marked adhesion and a still image will be taken. The ultrasound gel will be wiped clean using a towel and the permanent marker will be removed using an alcohol swab.

Additional images may be taken if more than one adhesion is found upon the initial scanning process. This would increase your testing session by no more than 5 minutes.

If any soreness results from the procedure, you will be provided with ice to take home with you. The entire procedure from the time you enter the athletic training room to the time you leave will be no more than 20 minutes.

• **POTENTIAL RISKS AND DISCOMFORTS**

There is the small risk that you may develop minimal tenderness in the area that was scanned with the instrument. Be aware that this is completely normal and will be only temporary. If you do experience soreness, you will be given ice following the procedure and the researcher will instruct you to continue icing for 30 minutes, 2-3 times a day until soreness subsides. Typically soreness will last for only a day, though if discomfort persists longer than 48 hours, you will be referred to the Student Health Center at Indiana State University or to your family physician.

- **POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY**

There are no benefits to you and unfortunately, no compensation. However, the results of this study may change the way we diagnose muscular adhesions. If these instruments can accurately detect the adhesions like they claim to, patients would be saving significant time and money on alternative diagnostic imaging.

This study is not being conducted to improve your condition or health. You have the right to refuse to participate in this study.

- **CONFIDENTIALITY**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Each participant in the study will be assigned a random number to ensure that the participant is unidentifiable. Data will be collected using the diagnostic ultrasound. All adhesion images will be immediately transferred onto a USB drive. Only the researchers will have access to these images. When the research has been completed, all data will be stored indefinitely on the USB drive. Those who formally withdraw from the study will have their Health History Questionnaire immediately shredded and all images will be deleted from the USB drive. All Health History Questionnaires and Informed Consents will be kept in a locked file cabinet, in a locked room during the duration of the study. They will be kept there for three years at which point they will be shredded.

- **PARTICIPATION AND WITHDRAWAL**

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind or loss of benefits to which you are otherwise entitled. To formally withdraw, contact Kaitlyn Silbaugh via email or phone. In the event that you withdraw, your health history questionnaire will be shredded and any images will be deleted indefinitely.

You may also refuse to answer any questions you do not want to answer. There is no penalty if you withdraw from the study and you will not lose any benefits to which you are otherwise entitled.

- **IDENTIFICATION OF INVESTIGATORS**

If you have any questions or concerns about this research, please contact:

Kaitlyn Silbaugh

ksilbaugh@sycamores.indstate.edu

4137 Heritage Drive

Terre Haute, IN 47803

C: 612.710.2829

Timothy Demchak

Timothy.demchak@indstate.edu

567 North 5th Street

Terre Haute, IN 47809

C: 812.237.8496

- **RIGHTS OF RESEARCH SUBJECTS**

If you have any questions about your rights as a research subject, you may contact the Indiana State University Institutional Review Board (IRB) by mail at Indiana State University, Office of Sponsored Programs, Terre Haute, IN 47809, by phone at (812) 237-8217, or e-mail the IRB at irb@indstate.edu. You will be given the opportunity to discuss any questions about your rights as a research subject with a member of the IRB. The IRB is an independent committee composed of members of the University community, as well as lay members of the community not connected with ISU. The IRB has reviewed and approved this study.

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

Printed Name of Subject

Signature of Subject

Date

APPENDIX E: SUMMARY OF IASTM RESEARCH

Authors/Title	Purpose	Methods	Results	Conclusions
Looney et. al. ⁽⁴⁶⁾ Graston instrument soft tissue mobilization and home stretching for the management of planter heel pain: a case series	The purpose of this prospective case series was to describe the outcome of a set of patients with plantar fasciitis treated with Graston Instrument Soft Tissue Mobilization techniques (GT) and a home stretching program.	10 patients were treated with GT directed to the triceps surae, soleus, plantar fascia, and medial calcaneal tubercle. Participants received a maximum of 8 treatments over a time frame ranging from 3 to 8 weeks at a frequency of 1 to 2 sessions per week. Each patient was instructed to perform the stretching program at home 3 times daily	Prior to treatment, subjects had a mean duration of symptoms of 32.4 weeks. Patients were treated for an average of 6.9 visits. There was a significant improvement from baseline to follow-up for the Numeric Pain Rating Scale (P = .002) and Lower Extremity Functional Scale (P = .017)	The group of patients selected for this case series who were treated with GT and home stretching experienced clinically meaningful improvement
Hammer and Pfefer⁽⁴⁷⁾ Treatment of a case of subacute lumbar compartment syndrome using the Graston Technique	To discuss subacute lumbar compartment syndrome and its treatment using a soft tissue mobilization technique.	Case study: 59-year-old man with a one-year history of intense low back pain. GISM was administered on the hamstrings, sacrum, right hip lateral rotators, and low back region. Patient received six treatments and participated in a stretching regimen.	Patient was asymptomatic after 6 treatments and able to complete all tasks of daily living.	This case study demonstrates that GT may ameliorate subacute lumbar compartment syndrome.

Authors/Title	Purpose	Methods	Results	Conclusions
Gale Gehlsen⁽⁴⁸⁾ Fibroblast responses to variation in soft tissue mobilization pressure	To determine morphologic changes in the rat Achilles tendon after enzyme-induced injury with collagenase and subsequent pressure variations in ASTM therapy.	Thirty male white rats were randomly assigned to one of five groups with six animals per group: tendinitis (A), tendinitis plus light IASTM (B), tendinitis plus medium IASTM (C), tendinitis plus extreme IASTM (D), and control with surgery only (E). IASTM was performed for 3 min for six treatment sessions. The Achilles tendons were harvested 1 week after treatment.	Statistical analysis of the number of fibroblasts present indicated a significant difference ($P < 0.00$) between group D and all other groups.	The morphological evidence indicated that the application of heavy pressure promoted the healing process to a greater degree than light or moderate pressure.
Craig Davidson et al.(49) Rat tendon morphologic and functional changes resulting from soft tissue mobilization	To determine the effects of ASTM therapy on the morphological and functional characteristics of enzyme induced injured rat Achilles tendons	Four groups of five rats: (A) control, (B) tendinitis, (C) tendinitis + IASTM, (D) IASTM. Injury was induced, and the surgical site healed for 3 weeks. IASTM was performed on the Achilles tendon of groups C and D on days 21, 25, 29, and 33. Achilles were harvested.	Light microscopy showed increased fibroblast proliferation in the tendinitis plus IASTM treatment group	Although healing in rats may not translate directly to healing in humans, the findings of this study suggest that IASTM may promote healing via increased fibroblast recruitment

Authors/Title	Purpose	Methods	Results	Conclusions
Eric McLaughlin ⁽⁵⁰⁾ An Evaluation of the Effectiveness of the Modified Graston Technique on Reducing Edema Following an Acute Ankle Sprain	To evaluate the effectiveness of a modification of the Graston Technique on reducing edema following an acute ankle sprain.	Participants were randomly assigned to one of two groups. One group was treated with a traditional edema control protocol and the other group was treated with the traditional protocol plus modified GT. Edema was measured by water displacement prior to and after the treatment protocol on days 1, 3, 5, and 7 post injury.	There was no significant difference in edema control between the two groups. Achievement of full weight-bearing status for the group that received ISTM averaged one day sooner than that for the comparison group.	Utilizing GT with traditional edema control protocols may accelerate the rehabilitation of those with mild or moderate ankle sprains.
Warren Hammer ⁽⁵¹⁾ The effect of mechanical load on degenerated soft tissue	To present a form of therapeutic mechanical load, Graston Technique® in three case studies including supraspinatus tendinosis, Achilles tendinosis, and plantar fasciosis.	In each case study, case history and functional testing confirmed the presence of a condition characterized by degenerated soft tissue. Each condition was treated according to the GT protocol. GT is a patented form of treatment using stainless steel	The GT method resulted in the elimination of pain and normalization of the positive functional tests that revealed the conditions of supraspinatus tendinosis, Achilles tendinosis, and plantar fasciosis.	This method of mechanical deformation load on soft tissue lesions is unique for its ability to both detect and treat areas of degenerated tissue. It deserves further consideration for basic research.

APPENDIX F: SUMMARY OF IASTM COMPANIES

IASTM Tools	Year of Development	Composition	Description	Training	Cost
	2010	Composite metal injected plastic (heavier than aluminum and lighter than steel)	2 Instruments: #1 (12oz) and #2 (4.6oz)	No training available.	\$447.00
	1994	Stainless Steel	6 Instruments in a set. Each is comprised of convex/concave surfaces to mold to various contours of the body.	Module 1 Basic Training Module 2 Advanced Training Module 3 Advanced/Upper (Occupational Therapist or Certified Hand Therapist only)	Module 1 Basic Training: \$495.00 Module 2 Advanced Training: \$695.00 Module 3 Advanced/Upper Quadrant: \$450.00 Full instrument set: \$2,755.00 For OT/CHT instrument set: \$2,150.00 Fuzion I: \$1,295.00
	N/A	Aerospace aluminum (Fuzion I) or a polymer, mineral filled model (Fuzion II) depending on the design.	Designed to be an all-in-one multi-technique tool. The Fuzion I is much lighter in weight compared to the Fuzion II. Both models come in sizes small to extra large.	Do not need training to purchase. Training workshops and online training and forums are available. A fundamental instructional video and hand position manual are included with all purchases.	Fuzion II: \$475.00 Fuzion III Pink Demo: \$450.00 All sizes (small-extra large) are priced the same

IASTM Tools	Year of Development	Composition	Description	Training	Cost
IAM Tools (Instrument-Assisted Massage)     	2010	Grade 316 Stainless steel	6 Tools in total consisting of non-beveled and single and double beveled edges. Each tool is individually hand-crafted.	Do not need training to purchase. 3 hour training seminars are offered.	Training seminars are approximately \$80.00. Dolphin: \$554.00 Seahorse: \$438.00 Seal: \$524.00 Can Opener: \$469.00 2 in 1: \$312.00 Fin: \$453.00
Ellipse 	2011	Stainless Steel	All-in-one Tool. Double Beveled	No training required or offered for purchase or use of the tool.	\$199.00

IASTM Tools	Year of Development	Composition	Description	Training	Cost
Tecnica Gavilan 	2006	Stainless Steel	3 different instruments: Ala, Garra, and Pico. Each instrument has both concave and convex surfaces that are all double beveled.	Offers a 6-hour course to teach safe application of IASTM. Instruments are only sold to practitioners who have passed a course in IASTM (Tecnica Gavilan, FAKTR, Graston Technique, ASTM or ASTYM)	Working including instrument set: \$795.00 Workshop only: \$185.00 Set of instruments: \$750.00
Miyodac Therapy 	2012	Stainless Steel	7 different instruments of various sizes, treatment edges and weights.	No training or certification required for purchase. No specific training offered.	Student price: \$595.00 Achilles tool: \$479.20 Blade tool: \$477.20 Pen tool: \$319.20 Star tool: \$527.20 Trigger tool: \$479.20 Trigone tool: \$423.20 Wave tool: \$367.20 Complete set: \$1395.00
Adhesion Breakers 	2012	Stainless Steel	5 different tools comprised of convex and concave edges.	No training course required or offered.	AB1: \$185.00 AB2: \$170.00 AB3: \$165.00 AB4: \$160.00 AB5: \$160.00 Complete set: \$600.00

IASTM Tools	Year of Development	Composition	Description	Training	Cost
SASTM (Sound Assisted Soft Tissue Mobilization) 	2000	Aerospace ceramic polymer	The 8 instruments are designed on a square surface as opposed to a convex/concave instrument.	Certification required for purchase of instruments. Can be done either online prior to attending a seminar by completing an online test, or by attending a seminar and then purchasing instruments.	Purchase of instruments includes certification. Additional certifications require either \$250.00 per clinician or the attendance of a seminar for \$500.00. \$2500 for all 8 instruments. Stainless Steel model: \$465.00 Delrin Plastic model: \$195.00 Left handed versions available: add \$25.00 Stainless Steel: \$259.00 Aluminum: \$179.00
Narson Body Mechanic N6 	2006	Stainless Steel or Delrin Plastic	All-in-one instrument with convex, concave, and flat edges. Textured grip.	NO training required for purchase. No specific training offered.	Stainless Steel model: \$465.00 Delrin Plastic model: \$195.00 Left handed versions available: add \$25.00 Stainless Steel: \$259.00 Aluminum: \$179.00
Scimitar Tools 	2009	Stainless Steel or Aluminum	All-in-one tool. 6 different radius sizes. 7.375" long. 1.375" wide. 3/16" thick. Stainless Steel: 4oz. Aluminum: 1.74oz.	No training or certification required for purchase. No specific training offered.	Stainless Steel: \$259.00 Aluminum: \$179.00

IASTM Tools	Year of Development	Composition	Description	Training	Cost
	2012	300 grade stainless steel	All-in-one tool Multiple edges - some sharper than others	Upper and lower body instructional DVD (1 hour)	\$110.00 Student discount available
	Developed in 2001 On the market in 2011	Stainless Steel	Tools feature parabolic radius edges. They also feature both single and double bevel edges.	Currently developing a DVD and workshops. A detailed technique primer with IASTM background, research and 10 technique stroke descriptions is included for all orders.	Healing Edge I+: \$79.00 Healing Edge II: \$75.00 Healing Edge III+: \$135.00 Healing Edge III: \$95.00 Scar Tissue Release Detail Tool: \$75.00 Fascia Bar: \$75.00 Cyriax Friction Tool: \$75.00 Trigger Point Tool: \$35.00
	2005	Stainless Steel	All-in-one instrument with convex and concave edges.	No training or certification required for purchase. No specific training offered.	\$399.00

IASTM tools	Year of Development	Composition	Description	Training	Cost
i-assist tools 	N/A	316 grade stainless steel	All-in-one tool with convex and concave treatment edges. There is a distinct hook as well as flat edges and ridges. Matte textured surfaces exist in areas intended for grip.	No training or certification required for purchase. Workshop and background informational courses are being developed.	\$450.00
ASTYM 	1995	Polymer-resin composite	3 instruments that vary in shape, size, and treatment edges.	Must be certified in the technique in order to purchase instruments.	Per clinician over-time program: course \$995.00/clinician, \$360.00/instrument set, subscription fees 10 annual payments of \$700.00/clinician Per clinician one-time program: \$5000.00/clinician, instruments and subscription included Per site program: certification is \$995.00/clinician, instrument set is \$360.00, subscription is \$2000.00/year

IASTM Tools	Year of Development	Composition	Description	Training	Cost
FAKTR-PM (Functional and Kinetic Treatment with Rehab, Provocation and Motion) 	N/A	Stainless Steel	All edges are double beveled. F1: 6 5/8" long by 1 1/2" high. Weighs 7 oz. F2: 8 3/8" long by 1 3/8" high. Weighs 8 oz. F3: 8" long and 1 1/2" high. Weighs 7 oz. F4: 7 3/4" long and 1 7/8" high. Weighs 6 oz.	FAKTR is a concept, not a technique. Therefore, the training programs are extensive and teaches clinicians IASTM as well as other techniques. No training required for purchase of tools.	Classes are \$475.00. College Faculty and Student rate of \$420.00 Individual Instruments are \$295.00 Full Set of 4 instruments: \$999.00
BioEdge 		Stainless Steel	All-in-one instrument consisting of 3 different contoured edges. Weighs 14.8oz and measures 9.5" in length	No training required for purchase. Information video provided on company website.	\$425.00
Fibroblaster/Jack 	Developed in 2009 On the market in 2010	Stainless Steel	Fibroblaster: 4" in length and 4" in width. Weighs 8oz. Single Beveled Edge Jack: 6" in length and 2 1/2" in width	No training or certification required for purchase. No specific training offered.	Fibroblaster: \$125.00 Jack: \$125.00 Set: \$230.00 Student discount: \$75.00

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