Mass General Brigham

Institutional Review Board
Intervention/Interaction Detailed Protocol

Principal Investigator:	Adam Landsman, DPM, PhD
Project Title:	A test of efficacy and foot position alteration in patients wearing Good Feet arch supports for the treatment of pain
Version Date:	09/15/22
Version Name/Number:	GF-20222

For Intervention/Interaction studies, submit a Detailed Protocol that includes the following sections. If information in a particular section is not applicable, omit and include the other relevant information.

1. Background and Significance

Foot orthoses are arch supports that can be worn in the shoes, and are designed to relieve pain by providing support to various areas of the foot to eliminate or reduce excessive mechanical forces. Most commonly, these devices are used as part of the treatment protocol for a variety of common foot ailments including painful plantar fasciitis and pronation. A variety of musculoskeletal pains have been shown to be reduced, and stability in ambulation can be improved by adding arch support to the shoes (1-9). Most importantly, previous studies have demonstrated that the structure of the foot can be altered, and with that the function of the foot, when orthoses are used.

A study by Nawoczenski, et al (1) used an electromagnetic tracking device to record the relative position and orientation of the hallux relative to the calcaneous during walking, with and without an arch support. This system verified that the position of the first metatarsal in particular varied depending on the arch support worn. Utilizing a forefoot pressure transducer, Yung-Hui, et al (2) showed that the magnitude of forefoot pressure could be changed by varying the height of the heel from 1.0 to 7.6cm, and that the amount of forefoot pressure could be modulated with the addition of various types of shoe inserts and arch supports. With arch supports, they showed a decrease in impact force of 33.2%, and a reduction in heel pressure and forefoot pressure by about 24%. They found that arch supports increased the level of comfort that these subjects had during walking as compared to those without arch supports.

Foot orthoses have also been shown to impart stability to the ankle and subtalar joints. Tochigi, et al (3) demonstrated a reduction in abnormal ankle internal rotation in a cadaveric mechanical testing study in which the talofibular and interosseous talocalcaneal ligaments were resected. Kitaoka, et al (4) also examined cadaveric specimens by simulating midstance loading of the foot while mechanically loading five tendons to simulate weightbearing. Using a magnetic tracking system, they demonstrated that arch alignment improved significantly when an orthosis was used. In a separate cadaveric study by Kitaoka, et al (7), they measured the effects of orthoses on arch height and stability. In their study, they demonstrated changes in the metatarsal to talar abduction angle,

dorsiflexion and eversion of the forefoot, eversion of the calcaneal talar joints, and talotibial dorsiflexion at the ankle. They also demonstrated a statistically significant increase in arch height as well as greater stability in simulated stance position.

A study involving 206 military personnel was conducted by Mundermann, et al (5), to examine the frequency of stress fractures and mechanical injuries when non-custom arch supports were worn. Their study tracked various measures of injury and comfort, and demonstrated that soldiers who wore arch supports had significantly higher level of comfort and a 13% lower incidence of stress fractures then soldiers who did not. Furthermore, they identified morphological features of the foot that played a role in overall comfort when wearing arch supports.

The impact of arch supports on lower back pain has also been studied previously. Kelaher, et al (6) showed that subjects wearing a non-custom, prefabricated semirigid orthoses experienced a reduction in low-back discomfort after 2 months, as compared to subjects who wore a simple cushioning device.

A video tracking system was used by Cornwall, et al (7) to demonstrate transverse tibial rotation as a reflection of calcaneal inversion in study subjects walking with various types of orthotic devices. Their study showed that orthotics can decrease maximum tibial internal rotation and velocity while walking. Thus, they concluded that modifications performed at the level of the sole of the foot (i.e. arch supports) can have a mechanical effect on the function of more proximal structures, such as in the ankle and leg.

Finally, this principal investigator previously published a related study in 2009 (8), which examined the effect of over-the-counter foot orthoses on several parameters including flexible foot deformities (i.e. hammertoes, and hallux valgus), as well as foot, knee, hip and back pain. Balance was also examined. In the previous study, radiographs were used to document variations in arch height, intermetatarsal angle, hallux abductus angle, metatarsal declination angle, calcaneal inclination angle, and sesamoid position, and several statistically significant differences were documented with and without arch supports. In addition, center of pressure measurements were also used to document shifts in center of mass with time, as a measure of stability while standing. There was also a statistically significant improvement in stability when arch supports were used. Symptomatic changes were also measured, and that study demonstrated significant improvement in arch and back pain, and reduction in knee pain.

The goal of the current study is to improve and extend our 2009 study, but introducing much more sophisticated measures for the parameters of interest. In 2009, we had concerns about the accuracy of some of the measures on radiographs. In the current study, both weightbearing radiographs and weightbearing CT scans will be utilized to gain a more accurate appreciation for the changes in morphology in three dimensions, that are anticipated. Subjective measures of pain were based on unvalidated scales and are replaced by only validated assessment tools. The previous study did not allow for standardization of shoes while the current study provides study shoes as well as insoles to all subjects.

The value of this study to patients who suffer from the most common foot ailments is evident. Arch supports are a simple treatment option for a variety of conditions including hallux valgus, metatarsalgia, pes plantar fasciitis, and may also be helpful for chronic ankle, knee, and back pain. Arch supports are a highly cost effective and potentially helpful way to manage a variety of simple conditions that may be otherwise treated surgically. The investigators hope that this study will demonstrate a safe, effective, and inexpensive way to help manage some of the most common foot ailments.

2. Specific Aims and Objectives

The objective of this study is to measure the structural changes that occur in the foot when wearing arch supports, and how these changes correlate with overall relief of common structural-related foot ailments; plantar fasciitis, metatarsalgia, and/or hallux valgus

Specific Aim #1:
Measure any changes that occur in the position and alignment of the foot bones relative to one another using weight bearing radiographs and weight bearing CT scans, with and without over-the-counter arch supports under the sole of the feet.

Hypothesis: Arch supports (orthoses) will alter the positioning and alignment of the bones of the foot when standing. Any changes will be measurable in three dimensions, using both weight bearing CT scans and standard anterior-posterior and lateral radiographs.

Specific Aim #2:
Demonstrate if there is a correlation between symptomatic relief of painful foot conditions including hallux valgus, pes planus, metatarsalgia, as well as low back, knee and ankle pain using validated clinical scores and quality of life measures.

Hypothesis: Painful foot conditions as well as certain types of low back, knee, and ankle pain will improve when subjects wear over-the-counter arch supports on a regular basis, as demonstrated by validated subjective scoring.

3. General Description of Study Design

This study is a single armed prospective case series designed to evaluate the efficacy of treating common structural-related foot ailments (i.e. plantar fasciitis, metatarsalgia, and/or hallux valgus) with a high quality non-custom made arch support. It is believed that these conditions are the result of inadequate or poorly fitted arch supports resulting in a lack of structural correction in the foot while weight bearing. Over-the-counter insoles are believed to counteract the shortcomings in foot structure that result in these painful conditions. In this study, it is proposed that changes in foot morphology can be measured quantitatively using weight bearing CT Scan (Computerized Tomography) and X-rays of the subject with and without the arch supports. Subjects will also answer questions from a validated series of questionnaires pertaining to their foot condition and generalized health and activity level.

The study is a minimal risk study, with all subjects receiving the arch supports being investigated. There is no placebo offered. Initial evaluation of all subjects will include all imaging and measurements. Collection of subjective responses will occur after 4 weeks, 8 weeks, and 12 weeks of treatment.

4. Subject Selection

A total of 50 subjects will be enrolled. Subjects must meet the following inclusion and exclusion criteria:

Inclusion

1. Men or women ≥ 18 and ≤ 65 years of age

2. The subject is able and willing to comply with study procedures and a signed and dated informed consent is obtained
3. Subjects diagnosed with symptomatic hallux valgus and/or plantar fasciitis and/or metatarsalgia.
4. Patient has had foot pain for at least 30 days.
5. Willing and able to utilize insole when walking for 90 days.
6. BMI ≤ 35
7. Able to walk up to 0.5 miles without difficulty, in a 24-hour period.

Exclusion

1. Inability or unwillingness to comply with study procedures
2. Gross asymmetry in feet, where shoe size differs by 2 or more full sizes between right and left foot
3. Subject has had a CT performed within the last 30 days, for any body part.
4. Prior partial or total amputation of a foot
5. BMI < 35.
6. Unilateral or bilateral foot deformity that would hinder the fitting of an over-the-counter arch support, such as active Charcot foot or Charcot with boney prominence
7. Ulcers or open sores on either foot
8. Currently wearing custom shoes or insoles.
9. Currently ambulating with a cane, crutches, walker.
10. Currently using any type of foot or ankle brace, and/or having used a brace in the last 30 days.
11. Pregnancy

Subject Recruitment:

Subjects will be recruited from the clinicians in the Division of Podiatry under the Department of Orthopaedics. Additionally, the sponsor, Good Feet Worldwide has a trade store the MGH service area, and will allow us to promote the study at their location with an advertisement poster. Potential subjects from the trade store will be referred to our clinics for screening and, when appropriate, recruited for the study.

Potential subjects will contact the principal investigator, Dr. Adam Landsman for preliminary screening and if they are able to satisfy the basic criteria, will be invited for formal screening. If qualified, they will be enrolled to begin the study. In order to avoid any undue pressure, all potential subjects who are patients of one of the Investigators will be given the option to do any or all of the following:

- Offer patients the opportunity to take home the Consent Form, and call back if they wish to participate
- Offer to connect the patient with other health care providers to discuss participation.

All study subjects will be screened and evaluated at the Foot and Ankle Clinic at MGH Waltham. Screenings and enrollments will take place on Tuesdays and Wednesdays, during dedicated research time.

The conditions being examined here are common among all races and genders, and enrollment is open to all. There have been limitations placed on subject age, as this age group is most likely to experience the conditions being studied.

5. Subject Enrollment

Prescreening is done by telephone, and is performed by the Principal Investigator or one of the research assistant. The following script is used to make a preliminary determination of eligibility. Before asking any other questions, the following questions and points will be discussed with the potential study subject:

- *Is this a good time to talk?*
- *Would you be willing to answer questions about your health and medical history to find out if you might qualify for the study? Some of the questions may make you feel uncomfortable. You can stop at any time.*
- *I will record your answers in writing, but only collect detailed contact information if you qualify for the study and want to schedule an in person visit.*
- *The risk of allowing us to collect and record your name with your answers is a loss of confidentiality. We will take reasonable steps to protect the confidentiality of your information.*
- ***May I begin?***

This is a study to evaluate the effect of arch supports on people with one or more of the following conditions: Bunions (also known as hallux valgus), Heel pain (also known as plantar fasciitis), metatarsalgia (pain across the ball of your foot), and/or lower back pain that gets worse with walking around. Do you have any (or all) of these conditions, and have these symptoms been present for at least 30 days?

· No

o Thank you for your interest. You do not qualify to participate in this study but if you like, you may leave your name with us to participate in future studies.

· Yes

Before I describe the rest of the study to you, I have a few more questions to determine if you qualify.

Are you between the ages of 18 and 65 years old? Do you weigh less than 300 lbs.?

· No

o Thank you for your interest. You do not qualify to participate in this study but if you like, you may leave your name with us to participate in future studies.

· Yes

Have you had surgery to your feet previously (not including toenail procedures)? Have you ever had any part of either foot amputated?

· Yes

o Thank you for your interest. You do not qualify to participate in this study but if you like, you may leave your name with us to participate in future studies.

· No

Is the difference in shoe size between your two feet 2 or more full sizes?

· Yes

o Thank you for your interest. You do not qualify to participate in this study but if you like, you may leave your name with us to participate in future studies.

· No

Do you currently wear custom-molded orthotics, or have you worn them in the last 30 days?

· Yes

o Thank you for your interest. You do not qualify to participate in this study but if you like, you may leave your name with us to participate in future studies.

· No

Have you ever been diagnosed with Neuropathy?

· Yes

o Thank you for your interest. You do not qualify to participate in this study but if you like, you may leave your name with us to participate in future studies.

· No

Allow me to tell you a little more about this study. We will be looking at the effect of arch supports on a variety of conditions, including bunions, metatarsalgia, plantar fasciitis, knee, hip, and/or lower back pain. We want to determine if wearing arch supports might help to relieve pain associated with these conditions.

In order to participate, you will be asked to go to come into the Good Feet store to be fitted for the arch support kit and for a new pair of shoes. You will then be referred to the Foot and Ankle clinic at Massachusetts General Hospital in Waltham, where you will receive the shoes and arch supports and be enrolled into the study.

There will be a total of 4 visits that are required. The first visit is the longest and will take approximately 2 hours. The 2nd, 3rd, and 4th visits are only expected to take about 45 minutes.

At the first visit, the doctor there will also examine your feet and discuss your medical history with you. You will then be asked to sign a consent form to participate in the study.

After signing the consent form, you will receive your new arch supports and your new shoes. They will then do a series of tests that include:

o Standing Catscan (CT scan) of both feet, with and without arch supports

o Standing X-rays of both feet, with and without arch supports

o You will be asked to complete a questionnaire

During the 2nd, 3rd, and 4th visits, you will be asked to complete the questionnaire again, and the doctor will examine your feet.

If you decide to participate in the study, you will receive the arch supports and shoes at no cost to you. You may keep these after the study as well. In addition, we can reimburse you for any travel costs. You will receive a check for $200 at the end of the study . If this sounds like something that you would be willing to do, I will need to get a little more contact information from you so that I can schedule your visits.

After preliminary screening, potential study subjects will be scheduled for an in-person meeting and evaluation, in order to review the study expectations. Subjects who are not registered in the MGB system will be asked to register prior to their first appointment. All subjects will be informed that their ability to receive treatment in our clinic will not be influenced by whether or not they participate in this study. Once we have reviewed the study plan, eligible subjects will be asked to sign an informed consent that will be given on an paper or and iPad via RedCap and signed, to be administered by the Principal or Co-investigator, and signed in the presence of a witness. Study subjects do not have to sign the consent on the spot, and may take the form with them, if they decide they would like to review at home, before signing.

Any subjects drawn from the principal and co-investigator's practice will be given clear indications that they are under no obligation whatsoever to participate in this study, and that either way, it will not hinder their ability to continue to be treated by the investigator.

Non-english speaking study subjects, can review information with the help of a medical translator. Translated documents will be provided as needed. The Short Form consent process will be used to obtain consent from non-English speaking study subjects.

Informed Consent

Informed consent will be obtained from each subject before any procedures or assessments that would not otherwise be required for the care of the subject are done and after the aims, methods, anticipated benefits, potential hazards, and insurance arrangements in force are explained and the subject has been given sufficient time to ask questions and consider participation in the study. It will also be explained to the subjects that they are free to refuse entry into the study and free to withdraw

from the study at any time without prejudice to future treatment. It is permissible for a third person (e.g., a family member) to be present during the explanation of the study.

The written informed consent form is to be in compliance with Code of Federal Regulations (CRF) 21 Part 50.27 and Good Clinical Practice (GCP) guidelines. The Sponsor will approve the informed consent and all amendments to the informed consent prior to submission to the IRB/Ethic's Committee. A copy of the informed consent document to be used will be submitted by the Investigator to the IRB/Ethic's Committee for review and approval prior to the start of the study. The original signed consent is retained in the subject's study records, and a copy is provided to the subject and placed in medical record.

Study participants are not being offered anything of significant value that may be viewed as coercive in nature, and is appropriate for the time and effort commitment requested from all study subjects.

6. STUDY PROCEDURES

Table 1: Schedule of Visit Activities

Study Procedures	**Screening and Treatment**	**Follow-up Visits (Every 28±3 days)**		
	Week 0	Week 4	Week 8	Week 12
	Visit 1	Visit 2	Visit 3	Visit 4
Informed Consent	X			
Inclusion/Exclusion Criteria	X			
Medical History and Demography	X			
Urine Pregnancy test for women	X			
Physical Exam (incl Ht & Wt)	X	X	X	X
Selection and fitting of insoles	X			
Clinical assessment of Foot Function	X	X	X	X
Weightbearing CT w & w/o insoles	X			
Weightbearing X-ray w & w/o insoles	X			
Administer VAS, OFS exam	X	X	X	X
Review Diary		X	X	X
Schedule subsequent visits	X	X	X	
Record Adverse Events		X	X	X

a. <u>Screening / Baseline</u> – Visit 1 (Day 1)

Informed consent must be obtained from each subject before any study procedure can commence. The consent form will be given on an IPad via RedCap signed on paper. The subject will sign and date the Informed Consent Form and undergo the following evaluations/procedures:

Medical History and Physical Assessment

- Determination of eligibility based on inclusion/ exclusion criteria
    - Urine pregnancy test for all women. Pregnant women are not eligible to participate.
- Demographics (date of birth, gender, race) will be recorded
- Medical history: relevant medical history, including history of current disease, and information regarding underlying diseases will be recorded.
- Physical exam will be performed and results recorded
- Height and weight will be measured and recorded.
    - Calculate subject's Body Mass Index

Foot Assessment

- Clinical evaluation of feet will be performed by Podiatrist Study Investigator
    - Classification of foot type
    - Pathologies and painful conditions will be identified
    - Additional ancillary conditions will be included in the history
        - Back, Knee, and Ankle pain along with associated diagnoses and prior treatments
        - Dermatologic conditions
        - Neurovascular measurements
    - Assessment of standard shoe gear
    - Generalized foot appearance (i.e. edema, tender areas, etc.)
    - Basic gait assessment

Subjective Pre-Treatment Assessment:

- VAS (Visual Analog Scale) and OFS (Orthopedic Foot Score) data collected to determine pre-treatment levels of pain and function. The following validated questionnaires will be completed by each study subject.
    - ACFAS Universal foot Evaluation
    - AOFAS Outcome score
    - Oswestry Low Back Disability score
    - Pain Intensity Score
    - Global Health Test
    - Pain Interference
- Pre-treatment assessment to be completed on day one.
- Subjects will describe their immediate impressions without and with the arch support in place.

Insole Selection

- Based on clinical assessment, properly sized set of arch supports and properly fitted athletic shoes will be dispensed to the study subject. Fit and comfort will be confirmed before proceeding with other data collection steps.

Baseline Measurements

- Each subject will have one weight bearing CT and one weight bearing X-ray series (AP/Lateral) taken barefooted and a second series taken with the selected arch support in place. Subjects are enrolled sequentially, and there is no placebo group.
- Image analysis will compare position and alignment of bones of the foot to measure differences in positioning with and without arch supports, using CT and X-ray. X-ray measurements will include intermetatarsal angles, hallux abductus angle, sesamoid position, metatarsal declination angle, calcaneal inclination angle, talocalcaneal angle, calcaneocuboid angle, and overall morphology. CT measurements will be used to determine the 3-dimensional positioning of the foot bones, and will document the change in position that occurs with and without arch support.

Logging of Activities and Symptoms

- Study subjects will be issued a diary and they are to record the following data on a weekly basis. The diary will be sent to the patient via email and RedCap links.
    - Estimated distance walked (Those able to count steps are encouraged to do so.).
    - Activities of Daily Living
    - Symptoms, and level of pain rated on a VAS scale.
    - Compliance with wearing of insoles and athletic shoes

b. Treatment Phase

We will be conducting follow up surveys via email and RedCap links with patients.

Monthly follow up (End of weeks 4, 8, and 12)

- Confirmation of eligibility based on inclusion/ exclusion criteria
- Medical history: New or relevant changes to medical history, including history of current disease, and information regarding underlying diseases will be recorded
- Review of logged data from daily diary
- Completion of physician re-assessment and OAS and VAS scoring.
- Validated questionnaires will be completed at each of the 3 follow-up visits.
    - ACFAS Universal foot Evaluation
    - AOFAS Outcome score
    - Oswestry Low Back Disability score
    - Pain Intensity Score
    - Global Health Test
    - Pain Interference
- Record any Adverse Events
- Clinical photographs will be taken with and without the arch support in place, while barefooted.

c. Study Completion/Termination

When the subject completes the study, voluntarily withdraws, is withdrawn for any reason, the study is terminated, or the Investigator is no longer able to locate the subject, the reason for the withdrawal will be reported along with any relevant information concerning the device, subject condition or death.

All subjects withdrawn from the study due to an adverse event, or have an adverse device effect or serious adverse event at study completion, will be followed until the adverse device effect or serious adverse event is resolved, a resolution is no longer expected or it returns to baseline.

Treatment Discontinuation

After completing the estimated 12-week visit requirements, the subject will be considered to have completed the study. In all cases of withdrawal, the date and the reason for withdrawal are to be documented.

Primary Endpoint

The primary endpoint is the change in symptoms when arch supports are worn, as compared to baseline. Change in symptoms and relief of pain will quantified based on subjective completion of validated questionnaires. Data from the questionnaires will provide a reliable assessment of symptomatic relief from the foot ailments being evaluated.

Secondary Endpoint

The secondary endpoint is the change in foot morphology when shoe inserts are worn. The change to be documented is the acute change that occurs in the boney structure of the foot when it is supported with the orthosis. A critical part of the analysis is to demonstrate if there are measureable changes in foot morphology when supported, and to determine if those changes correlate with symptomatic changes in the study subject's foot condition.

Remuneration

Study subjects will not be paid to participate in this study. However, all participants will receive new orthoses and new shoes, and will be permitted to keep these items at the conclusion of the study. Also, all study participants will receive up to $50 to reimburse them for any travel expenses related to the study. We would like to pay the participants by check on the date of their visit, if permitted to do so.

Sharing of Data and Confidentiality

All data will be kept within the confines of MGH. Since there are no other sites involved in the study, no outside investigators will have a need for access to the data.

7. Risks and Discomforts

The risks include discomfort during walking and/or standing, and can include bruise and/or blister formation, exacerbation of existing foot pain, tightness in shoes, temporary foot or leg cramps, bruising of the foot. X-rays and CT scans will be taken, and these tests involve very low levels of radiation. All of the devices being used in this study are currently available for purchase without a prescription, and are being used in the manner in which they were intended.

There are no new applications being explored for either the insoles or shoes that the study subjects will receive during this study. There are no unusual or excessive risks to study subjects, and all procedures being performed on subjects are already in use for diagnostic and treatment purposes.

8. Benefits

Historically, when these conditions (plantar fasciitis, hallux valgus, metatarsalgia) are treated with arch supports, they have responded with significantly less pain, and in many cases, helped the subjects to avoid surgical correction. We expect that the subjects who participate in this study will show signs of improvement in symptoms. They will also benefit from a highly focused medical examination of their

feet. Future patients will benefit from this study by knowing that arch supports are a safe and effective treatment for these foot ailments. The study may also help to optimize arch support design in the future.

9. Statistical Analysis

Statistical plan is for a one-way repeated measures ANOVA to compare the parameters with participants with and without arch-support insoles for each slope. We anticipate using SPSS for Windows (SPSS Science Inc., Chicago, IL, USA) for the statistical analyses. Levene's test will be used to test the homogeneity of the variances. A Kolmogorov-Smirnov test will be used to evaluate the normality of the data, a Wilcoxon test will be used when the data are not normally distributed. The significance level was set at $\alpha = 0.05$. The effect size (ES) for the difference from baseline will be calculated for each variable as a measure of the practical relevance of the significance using Cohen's *d*; ES values between 0.20 and 0.49 are considered small, those between 0.50 and 0.79 are considered moderate, and those 0.80 and above are considered large.

10. Monitoring and Quality Assurance

In order to insure subject safety, all data will be reviewed at each study visit, including a thorough review of the study subject diary. This will occur on a monthly basis. In addition, study subjects will have the unlimited opportunity to contact the Principal Investigator to discuss any concerns or complications, at any time. The Principal investigator will be responsible for assessing any risks or complications, and will discontinue the study if any related complications occur.

In this study, the DSMB will be composed of other physicians from the PI's department who are not participating in the study. Members of the DSMB will meet bi-weekly to discuss and review all research data pertaining to safety in the current study, until the completion of the study. This group will also be responsible for maintaining the integrity of all recordkeeping. All adverse events will be reported to the DSMB, Partners' IRB and Study Sponsor.

Study Monitoring will be performed in accordance with ICH E6-GCP, sponsor's SOPs, the protocol, and applicable local regulations. According to ICH E6-GCP, the sponsor or the authorized personnel on behalf of the sponsor may audit the investigational site to compare raw data, source data, and associated records with the interim or final report of the study to assure that data have been accurately reported. The investigators will accept that regulatory authorities may conduct an inspection to verify compliance of the study with GCP.

11. Privacy and Confidentiality

- ✓ ☐Study procedures will be conducted in a private setting
- ✓ ☐Only data and/or specimens necessary for the conduct of the study will be collected
- ✓ ☐Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)

- ☐ **N/A** Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
- ✓ ☐Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
- ✓ ☐Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
- ✓ ☐All electronic communication with participants will comply with Mass General Brigham secure communication policies
- ✓ ☐Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
- ✓ ☐All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens
- ✓ ☐The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research
- ✓ ☐Additional privacy and/or confidentiality protections

The investigators will assure that the privacy of the subjects, including their personal identity and all other personal medical information, will be maintained at all times. In CRFs and other documents or material submitted to the sponsor, subjects will not be identified by their names, but by an identification code (e.g., initials and study allocated number). Personal medical information may be scrutinized for the purpose of verifying data recorded in the CRF. The monitors, properly authorized persons on behalf of the sponsor, the quality assurance unit, or regulatory authorities may do this. Personal medical information will always be treated as confidential.

The Investigator will maintain the confidential subject identification list, that will not to be made available to the Sponsor, including subject's, study Identification and medical record numbers to link records. The subject should be informed that the data will be stored and analyzed by computer, that local and Federal regulations for the handling of computerized data will be followed and that identification of individual subject data will only be possible for the Investigator and the monitor. The subjects will be identified in the Case Report Form with subject number and initials. The Investigator should inform the subject that the records relevant to the study may be inspected by the study Sponsor, the FDA, or other persons as required by law.

12. References

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9. Landsman, A, DeFronzo, D, Anderson, J, Roukis, T: Scientific assessment of over-th-counter foot orthoses to determine their effects on pain, balance, and foot deformities. J Amer Pod Med Assoc, 99; 206-15, 2009.

APPENDIX A

Data Monitoring Committee / Data and Safety Monitoring Board Appendix

- *To be completed for studies monitored by Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) if a full DMC/DSMB charter is not available at the time of initial IRB review.*
- *DMC/DSMB Charter and/or Roster can be submitted to the IRB later via Amendment, though these are not required.*

A Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) will be convened for safety monitoring of this research study. The following characteristics describe the DMC/DSMB convened for this study (Check all that apply):

- ✓ ☐The DMC/DSMB is independent from the study team and study sponsor.
- ✓ ☐A process has been implemented to ensure absence of conflicts of interest by DMC/DSMB members.
- ✓ ☐The DMC/DSMB has the authority to intervene on study progress in the event of safety concerns, e.g., to suspend or terminate a study if new safety concerns have been identified or need to be investigated.
- ✓ ☐Describe number and types of (i.e., qualifications of) members:
  2 Doctors of Podiatric Medicine (DPM) who are familiar with the use of orthoses and are also familiar with foot pathology will serve as the members of the DSMB. Both members have completed their CITI training, and have prior experience in research.
- ✓ ☐Describe planned frequency of meetings:
  Bi-weekly meetings

- ✓ ☐ DMC/DSMB reports with no findings (i.e., “continue without modifications”) will be submitted to the IRB at the time of Continuing Review.

- ✓ ☐ DMC/DSMB reports with findings/modifications required will be submitted promptly (within 5 business days/7 calendar days of becoming aware) to the IRB as an Other Event.