# The Design and Fabrication of a Rehabilitative Device for Medial Tibial Stress Syndrome

*Supplemental Handout for the*
*Final Presentation - Major Qualifying Project*

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**Abstract of Project:**

There is currently no device on the market today that mimics the rehabilitative benefits of professionally applied athletic tape to treat the symptoms of medial tibial stress syndrome (MTSS) and is available to the average consumer. The goal of this project was to address this need by designing and fabricating a device to give the user similar rehabilitative benefits as professionally applied athletic tape, whilst being accessible and affordable to the common injured person. The scope of this project includes individuals who need relief from the symptoms of medial tibial stress syndrome but do not have regular access to professional care. Those within that population include, but are not limited to, hobby runners, military personnel and active persons. The device also aimed to be customizable to meet individual user needs, cost-effective, and easily applicable. The final device resembled a sock and incorporated two different athletic fabrics and velcro to mimic athletic tape by pulling the muscle in specific directions. Various testing and statistical analyses were performed to ensure that the materials used in making the device could withstand the various forces and conditions.

# Rehabilitative Device for Medial Tibial Stress Syndrome Survey

The purpose of this survey is to quantify the efficiency of medial tibial stress syndrome rehabilitative device designed as part of a Major Qualifying Project by Sandra Duarte (BME), Madison Stahl (BME), Carly Whittle (BME) advised by Prof. Tiffiny Butler PhD ATC. You will be asked a series of questions and asked to complete a set of exercises, including walking ⅛ mile, running ⅛ mile and 10 jumps, over the course of two days.

**1. What is your age? _____**

**2. What is your sex?**

☐ Female ☐ Male ☐ Other _____

**3. What sport do you play? _____**

**3. On average, how many hours do you exercise per week?**

☐ 0-3 hours ☐ 4-6 hours ☐ 7-10 hours ☐ 11+ hours

**4. How many days per week do you typically exercise?**

☐ 0 days ☐ 1-2 days ☐ 3-4 days ☐ 5-7 days

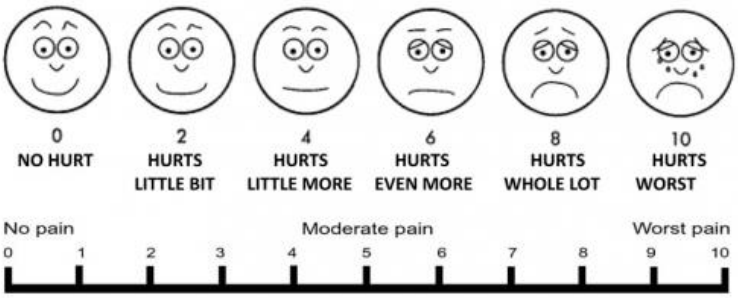
**5. What types of exercises do you do?**

_____

_____

_____

**4. Please refer to the scale below for the following questions:**




The following image as sourced from https://www.ortho-neurocenter.com/pain-scale

**4a. Based on the pain rating scale, what is your pain <u>before</u> applying the device?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

**4b. Based on the pain rating scale, what is your pain <u>after</u> applying the device?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

**4c. Based on the pain rating scale, what is your pain <u>after</u> applying the device and <u>after completing the exercises</u>?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

**5. After a rest period while still wearing the brace, are you experiencing any pain?**

☐ Yes ☐ No

**6. Are you experiencing any pain after taking the brace off?** ☐ Yes ☐ No

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***To be filled out by the researchers***

**Test Conductor Name: _____**

1. Before applying the device: ☐Circulation ☐Feeling ☐Motor
2. After applying the device: ☐Circulation ☐Feeling ☐Motor
3. Comments:

_____
_____
_____
_____
_____
_____
_____

# Informed Consent Agreement for Participation in a Research Study for All Participants

**Investigators: Sandra Duarte, Madison Stahl, Carly Whittle**

**Contact Information: gr-MTSSMQP@wpi.edu**

**Title of Research Study: The Design and Fabrication of a Rehabilitative Device for Medial Tibial Stress Syndrome**

**Sponsor: Worcester Polytechnic Institute Department of Biomedical Engineering**

**Introduction:**
You are being asked to participate in a research study. Before you agree to this, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks or discomfort that you may experience as a result of their participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

**Purpose of the study:** We are a group of senior biomedical engineering students here at Worcester Polytechnic Institute (WPI). We are conducting this to test and gain feedback on our device for our MQP and to see if users with the diagnosis of Medial Tibial Stress Syndrome will benefit from our device. We are not providing treatment or diagnosis. There are few orthotic devices on the market today that aid in the rehabilitation of active individuals with Medial Tibial Stress Syndrome (MTSS); however, those on the market have not been effective in reducing the symptoms of MTSS or have required professional advisement and application. The most effective products available utilize therapeutic athletic tape to strategically pull the tibialis posterior muscles, creating a sling that allows for the user to resume regular activity whilst protecting the injured muscle. We have created a device that incorporates the athletic tape technology for the treatment and rehabilitation of MTSS that regular consumers can use without the need for taping knowledge or access to an athletic trainer.

**Procedures to be followed:** We have selected you for testing because you identified as someone with MTSS. We will use your feedback to continue to improve our design. Again, we are not providing treatment or diagnosis. We are only asking for your feedback on this device. This test will take place in a public setting in the WPI Recreation Center. The test will be given over a two-day period. On one day, there will be an exchange of basic information, a physical exercise test without the device, and a question and answer period. One the second day, there will be the same physical exercise test with the device, and a question and answer period. The two days will be similar in activity for consistency purposes. For example, we want to avoid having test one on an off-day and test two on a day with a demanding practice. The physical tests will include a walking lap and a running lap around the WPI Recreation Center Indoor Track, followed by jumping in place ten times. If you are comfortable, one of the researchers will examine your circulation, feeling, and motor ability after the test. This examination will be done by touching your foot and lower leg. We ask that you give honest and thoughtful answers to our questions. There are no right or wrong answers. An outlined step by step procedure is shown below.

1.) Day One: You will complete the physical test without the device consisting of walking a lap around the indoor track (1/8th mile), running a lap around the indoor track (1/8th mile), and jumping in place 10 times (5 minutes).

2.) The researcher will ask you some follow-up questions about your experience guided by the survey (3 minutes)

3.) You along with the researchers will then arrange a day and time for Day 2, where the previous steps will be repeated, with the exception that the device will be worn for the entire physical exam.

**Risks to study participants:** If you are uncomfortable with a question, you do not need to answer it. If you are comfortable, we will take notes as you perform the test. The physical tests require no more than what you would normally do in your sport, but you may stop the test for any reason at any point with no penalty.

**Benefits to research participants and others:** There are no immediate benefits to the participant. However, this testing will help us understand what improvements need to be made to our device. Our goal is to create a device that incorporates the athletic tape technology for the treatment and rehabilitation of MTSS that regular consumers can use without the need for taping knowledge or access to an athletic trainer. Our primary objectives for the device include being effective, affordable, and safe. Our secondary objectives are for the device to be comfortable, washable, simple, and customizable.

**Record keeping and confidentiality:** The paper copies of our collected data will be scanned and uploaded into Microsoft OneDrive. Only the researchers will have access to this information and the researchers will need to login with their WPI credentials to access the information. Once all of the paper copies are uploaded, the paper copies will be kept in a locked cabinet in Professor Tiffiny Butler's office at the Oasis House. This information is very valuable to us, and we will also respect your privacy. We will not record your name, however, we will record your age and sex. This means that the age will be connected to your response, but you will not be identifiable. "Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or its designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you."

**Compensation or treatment in the event of injury:** This research does not involve more than minimal risk of injury or harm. You do not give up any of your legal rights by signing this statement.

**For more information about this research or about the rights of research participants, or in case of research-related injury, contact:** gr_MTSSMQP@wpi.edu. The contact information for the IRB Manager; Ruth McKeogh, Tel. 508 8316699, Email: irb@wpi.edu; and Human Protection Administrator; Gabriel Johnson, Tel. 508-831-4989, Email: gjohnson@wpi.edu.

**Your participation in this research is voluntary:** Your refusal to participate will not result in any penalty. You may decide to stop participating in the research at any time without penalty or loss of benefits. The project researchers retain the right to cancel or postpone the experimental procedures at any time they see fit.

**By signing below,** you acknowledge that you have been informed about and consent to being a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____ Date: _____

Study Participant Signature

_____

Study Participant Name (Please print)