LEST (Lower Extremity Strength Tester)

Product Design Specifications
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2/8/2019

Function:

During and after pregnancy, it is common for women to experience a loss of strength in the muscles of the pelvic girdle that can lead to pelvic instability. This can cause pain and discomfort, and new methods are continually being researched to relieve women of this condition during their pregnancy and the months afterwards. Currently, to determine if a patient has pelvic instability, a doctor has them perform a straight leg raise and rate the difficulty of doing so on a scale of 0-5, with a 5 being the highest difficulty. If the patient gives a rating of anything other than 0, the doctor then compresses the hips at the sides and has the patient try the straight leg raise again. If the extra pressure from the doctor makes the straight leg lift easier, this is indicative that the patient may have pelvic instability. One of our clients, Dr. Rita Deering, has performed comprehensive research that concluded that pregnancy has a significant impact on the strength of the pelvic girdle muscles. Presently, she is trying to quantitatively analyze the extent of the effect it has. Therefore, a device is needed to assess a maximal voluntary contraction (MVC) of the hip flexor (iliopsoas) and knee extensor (quadriceps, rectus femoris) muscles during a straight leg raise task to assess the loss of strength in the lower extremities of women both during and after pregnancy. This device will be completely portable and will have load cells implemented into the support posts to allow for the measurement of this MVC during testing.

Testing Procedure:

While laying down with their feet inside the area of the device labeled below, the subject will first perform an unassisted leg raise with one leg to fatigue it. The push plate will be in its lowest position (as shown), and both feet will be within the bars of the push plate, while one leg uses the area in between them to perform the fatiguing task. The leg not performing the fatiguing task will remain on top of the push plate so that the load cells can record in compression how much force that foot pushes down with. This fatiguing task will be performed until failure, which is achieved once the foot drops beneath 10 cm or excessive lumbopelvic motion occurs (measured by an air bladder underneath their lower back). Then, the push plate will be raised to an appropriate height and the fatigued leg will immediately perform a straight leg lift. The MVC produced by that leg will be recorded near the ankle of that leg. The leg that did not partake in the fatiguing exercise will rest on the bottom plate of the design, which does not interact in any

way with components fixed to the load cells. This process will then be repeated with the opposite leg on a separate day.

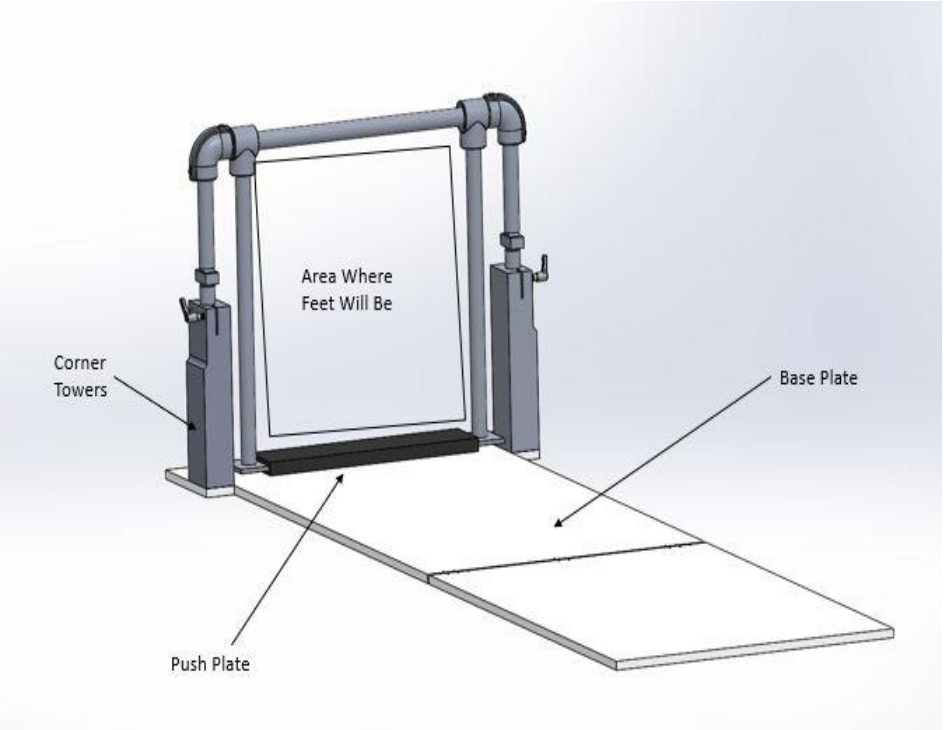

Figure 1: *Diagram of LEST Apparatus.*

Client requirements:

- Design must be completely portable in order to use in multiple research and clinical settings.
- The device must be strong enough to withstand the force of an MVC from an adult female performing a straight leg lift without breaking or losing function.
- The device must be in place and ready to use within a minute after subject's fatiguing task to prevent muscle recovery.
- Comfort (or a lack of) of the test subject must not limit the amount of force able to be produced.
    - Primary points where comfort must be considered include the base plate the subject will be laying down on and the push plate the subject will be both resting their feet on and pushing up against.
- A budget of $1000 must be kept; $488.16 is currently available after the first semester of design.
- The device must be designed so that it can be used when the patient is in a supine position.

- The subject should not be able to hold onto the device in any way, and secondary help from a doctor or different test subject should not be required to hold the device in place.
    - To prevent the design from flexing and disrupting data collection, suction cups will be used to help hold the apparatus to the floor.
- Load cells integrated into the design will be used to measure the MVC of the subject.
- All electronics shall be neatly organized and stored within the device so as to maintain an aesthetically appealing look and so that no wires/components disrupt the testing process.
- The surface of the design that the subject will press against with their ankle must not be uncomfortable to the point of causing pain, but must also not be too soft as to absorb the force of the MVC.
- The device must be conducive to the specific testing procedure detailed above.
- The design must completely integrate with the technology setup featured in the testing environment.
    - The Load Cell SST must be compatible with an A to D board and BNC cable.

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements:

- The device must have load cells integrated into it in order to accurately record the MCV of the test subject.
    - The load cells recognize forces from 0-300 N.
- All appropriate connections for the load cell to the data collection setup (SST, BNC cable, A to D board, Transducer Techniques software program) must be available during testing.
- The device will be used in UW-Health Research Park as well as other lab setting locations during the lifetime of the research project, and therefore must be completely portable.
- The device must not require any fixturing specific to a certain research location.
    - The weight of the test subject and suction cups will be used to hold the design in place.
- Must be able to withstand the force of a straight leg raise at maximum effort for an adult female.
    - This maximum force is estimated to be 264.8 N for a 30-year old female. [1]
    - Muscles involved: iliopsoas, quadriceps, and rectus femoris.
- The device must help to consistently and accurately measure the force of a lower body MVC (integrated load cells will measure the force produced).

- There must be adequate room within the device for the fatiguing task to be performed.
    - Both feet must be able to feet comfortable between the vertical supports holding the push plate in place. The subject will presumably hold their feet at hip width.
        - The average hip width of the adult American female is 12.16" [2][3]
- All portions of the device must be fully compatible with the specific testing procedure detailed above.
- Adjustment of the device (height of the push plate) must be fast and effective. Adjustable-position handles will be used on the corner towers to accomplish this.

b. Safety:

- Comfortable for patients to exert force without pain
- Able to easily accommodate patients of varying sizes, with the lower body size being of particular concern.
- Sturdy enough to avoid collapse and/or fracture from a lower body maximal muscle exertion of an adult female.
- No sharp or rough edges or protruding parts that could injure subjects as they use the device or the clients as they put the device in place.

c. Accuracy and Reliability:

- The device needs to contribute to an accurate reading from the force plate over multiple tests with varying patients (within 5% accuracy). This may require the ability to adjust on a per patient basis (in terms of height of apparatus).
- Testing of the device accuracy must be performed with weights that have been accurately measured. The force the weights exert on the push plate will then be measured in compression to ensure accuracy.
- The device should limit the area the patient can be situated in in order to maintain the position of the straight leg lift.

d. Life in Service:

- The two main locations the apparatus will be used are in UW-Health Research Park Clinic and the Badger Athletic Rehabilitation Training Center. However, it may be used in additional clinical settings.
- Needs to be available at any time of the day for extended periods of time. The number of cycles of MVC measuring is still yet undetermined.

e. Operating Environment:

- The device will be used and stored in a clinical setting.
- The largest chance for damage will likely occur during transport between clinics or while under stress from force applied by patient.
- Possible causes of failure could arise when subject is trying to get inside the apparatus and their leg/body collides with the apparatus in some way.

f. Ergonomics:

- Must be strong enough to easily withstand maximum contraction of hip flexor and knee extensor muscles of an adult female.
- Must allow a wide range of adult females to place feet into device
    - The interacting force bar needs to have enough space to accommodate a wide range of adult female ankles
        - Average ankle height = 3.058” [4][5]

g. Size:

- The apparatus must be wide and high enough to comfortably fit the lower legs/feet of any size adult female between its frame.
    - Average female hip width = 12.16”
        - Subjects will not have to hold their feet wider than hip width, so the vertical supports should be at least this width away from each other.
- The frame of the device will largely be sized based upon anthropometric data regarding the hip width and body length of the average American adult female.
    - The average hip height of the adult American female is 33.76” [2][3]
        - To ensure that the rear end of the subject holds down the entire apparatus, the folding joint of the base plate must be at least 33.76” from the end of the base plate the load cell apparatus is fixed to.
        - In this way, the rear end of the subject will pin the base plate to the ground.

h. Weight:

- The maximum weight of the device is 50 lbs, as it will need to be lifted and transported by one person between locations.
    - Weight reduction will be critical for ensuring the ease of use of the design.
    - Currently, the design weighs 47.41 pounds. The goal for this semester is to reduce the design to lower than 40 pounds.

i. Materials:

- No materials restrictions have been placed on this project as far as incompatibility with other equipment being used during the testing procedure.
- The frame is composed of aluminum rod with aluminum couplings at the corners.
- The base plate is made of HDPE with a foam mat on top for comfort.
    - The HDPE base plate was able to flex when an MVC was applied to the testing apparatus. This flexion should be reduced or gotten rid of by use of structural supports or alternative materials.
- The part of the device interacting with subject needs to be comfortable but not so soft that it absorbs the force of their MVC. A harder rubber material will likely be used.

j. Aesthetics, Appearance, and Finish:

- All seams, joints, and welds should be neat and aesthetically pleasing.
    - Professional looking coverings that accurately fit the dimensions of the design should be used, i.e. the yoga mat covering the base plate.
- There should not be any unfinished edges or contact points.
- No extraneous materials should be hanging down, protruding from, or in any way seen on the device.
    - All electronics (components and wires) must not impede the accuracy of data collection or interfere with the test subject in any way.
- The device's appearance should be comparable to the professional exterior of exercise equipment.

2. Production Characteristics

a. Quantity:

- One LEST will need to be produced.

b. Target Product Cost:

- A budget of $1000 dollars for this project has been set. Other competing designs have a cost of around $1000 dollars, so it would be preferred that our design does not reach that cost level.
    - $488.16 remain in the budget for improvements during the second semester of work.

3. Miscellaneous

a. Standards and Specifications:

- No FDA approval is required.
- No specific lab standards need to be met by the design, but it must be safe to use and prevent injury of the test subjects.

b. Customer:

- This design is not intended for commercial sale. For concerns of subjects utilizing the designs, please look below to "patient related concerns."

c. Patient-related concerns:

- Patient data confidentiality must be considered. The numerical value of MVC's of patients will be recorded, which is private information between the patient and the doctor performing tests.
- This device will be used for pregnant and postpartum women, so comfort is a major concern.
    - Subject must easily be able to perform the MVC test quickly after completing a fatiguing exercise.
- The testing of the apparatus involves creating a maximum force with certain muscles, so we want any surface of the device that a subject is pressing against to not cause them any pain or discomfort.
- All surfaces of the design must be relatively easy to clean between patient usage, in particular the mat covering the base plate.
    - No absorbent materials should be used.

d. Competition:

- MICROFET 2 MANUAL MUSCLE TESTING (MMT) HANDHELD DYNAMOMETER - $1,054
    - The Microfet 2 is an ergonomically-designed dynamometer that accurately measures the force produced by a certain muscle.
- Doctor's test-
    - A simple test that doctors use to measure if a patient has pelvic instability is to press against the sides of their hips and ask if that makes it easier for them perform the leg lift. If they say it does, they are considered to have pelvic instability.
- Training of whole leg waist abdominal muscle of lying on back power and test system - CN # 201520291327
    - This patent seemed to describe an apparatus that measured forces created similar to the ones in our testing procedure.

References

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[3] D. A. Winter, *Biomechanics and motor control of human movement*. Hoboken, NJ: Wiley, 2009.

[4] White, Robert M. (1982). *Comparative Anthropometry of the Foot.* [online] Available at: http://www.dtic.mil/dtic/tr/fulltext/u2/a126189.pdf [Accessed 10 Oct. 2018].

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