Pedal Pump Clinical Trial on Edema V1

Study Protocol & Statistical Analysis Plan

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Background

I am a Doctor of Osteopathic Medicine who has primarily practiced in the hospital. While caring for bed bound patients, I wished I had more time to use a technique I learned in medical school to help my patients. This desire has become the invention below.

The Pedal Pump is a device which engages the feet of patients while they are in bed. It provides gentle, on-and-off pressure to the feet, which, in turn, mobilizes the whole body in a rhythmic, calming manner. The invention is “patent-pending” and the design engineer is finishing the second round of the prototype. It is ready for research!

The proposed hypotheses of the Pedal Pump are based on the health benefits provided by normal walking. They include, but are not limited to…

Physiological Benefits
- Increase lymphatic flow within the body
- Increase blood flow back to the heart and into the tissues
- Increase intestinal peristalsis
- Increase kidney filtration
- Increase myofascial and musculoskeletal movement

Proposed Patient-Centered Benefits
- Decrease lower extremity fluid volume
- Increase survival rate in sepsis
- Decrease time to first bowel movement after surgery
- Decrease intestinal gas pain after laparoscopic procedure
- Decrease lower back pain
- Decrease neck pain

Proposed Hospital-Oriented Benefits
- Decrease length of hospitalization
- Decrease length of intensive care unit stay
- Decrease time to normalize lactic acid, white blood cell, and CRP lab values in setting of infection

Previous research on the osteopathic manual technique (also named Pedal Pump) has shown health benefits, specifically increasing lymphatic flow, decreasing lower extremity edema, and decreasing serum lactic acid after maximal exercise. However, due to the limitation of human practitioners, research has been limited. The Pedal Pump is now a device which facilitates consistency in treatment and allows for increased sample size in research.

Key Question for this first study: Is the Pedal Pump a feasible treatment for hospitalized patients?

Secondary question: Does the Pedal Pump decrease lower extremity edema?

This is a novel idea in its early stage of development, so we anticipate product advancements, further testing with larger population sizes, and future publications.

Welcome to Pedal Pump.

David McVay, DO
Hillcrest Medical Center Hospitalist, Tulsa, OK
Pedal Pump Device Inventor

Protocol Title: Hillcrest Pedal Pump Clinical Trial on Edema V1

Purpose:

The purpose of this trial is to evaluate the safety, feasibility, and preliminary effectiveness of bilateral Pedal Pump treatment in adults with bilateral lower extremity edema secondary to congestive heart failure (CHF), chronic venous insufficiency, kidney disease, or other fluid overload conditions. Participants will be randomly assigned to receive either active Pedal Pump therapy or a sham intervention, while outcome assessors remain blinded to treatment allocation to minimize measurement bias.

Study Design: This is a prospective, randomized, sham-controlled, assessor-blinded feasibility trial.

- Patients will lay with the head of the bed elevated at a 45-60 degree angle (i.e., in Fowler's position) for at least 10 minutes prior to being measured.
- Patients will receive either the treatment or the sham (detailed below).
- Patients will socialize, watch TV, read a book, use their phones or laptops, or otherwise spend their time how they prefer. However, unless there is an adverse outcome or the treatment needs to be aborted, they will keep their feet connected to the heel protector pillows which will be connected to the device during the entire 10 minutes.
- Patients will continue to receive diuretics and other treatment for lower extremity edema. Because the effects of medicines on lower extremity edema are usually seen in hours and not minutes. In other words, if a significant effect is shown within 10 minutes while the device is activated, then the effect would have been from the Pedal Pump's treatment in those 10 minutes.
- Treatment Group: The patients will experience...
    a. Being assisted to sit up in their beds. Their thighs, calves, and ankles being marked with a surgical marker at the locations and measured.
    b. The heel protector pillows attached to their feet and the Pedal Pump placed at the foot of the bed.
    c. Provided the treatment is tolerated by the patient, the Pedal Pump treatment being applied to both feet for 10 minutes continuously mobilizing their whole body in sufficient manner to see the nose move.
    d. The Operator turning off the device and removing it from the bed.
- Control Group (Sham): The patients will experience...
    a. Same as Treatment Group with the exact same device generating identical operational sounds and visible movement but it will not be close enough to the feet to produce sufficient displacement to transmit mechanical forces beyond the feet. The Pedal Pump will only contact the heel protector pillows enough to make the toes move but will not contact them enough to mobilize the legs or the entire body.
- Both groups will receive new measurements and surveys 45-60 minutes after the treatment, including asking them which group they believed they were included in (i.e. treatment vs. control) and their level of confidence in that belief.

Primary Endpoints:

- No serious adverse events in treatment group
- ≥95% treatment tolerability (≤5% "aborted" treatments)
- ≥1 cm change in average circumference

Secondary endpoints:

- No increase in pain or stress in ≥80% of the treatment group
- Greater decrease in pain or stress in the treatment group compared to the control group
- No adverse events in ≥80% of the treatment group

Number of Subjects:

- 60 patients for this first study:
    - 40 patients (⅔) receiving the Treatment and 20 patients (⅓) receiving the Sham.
    - Randomization will occur via 60 sealed envelopes shuffled and then distributed to the Operator. Randomization decreases bias, controls confounding variables, and increases internal validity.
    - Because this is a feasibility study, no formal power calculation was performed. A sample size of 60 participants is considered sufficient to estimate treatment variability, feasibility outcomes, recruitment rates, and preliminary effect sizes for future adequately powered randomized trials. Effect size estimates and confidence interval from this feasibility study will be used to calculate the sample size for a future definitive RCT.
    - The Sham will allow blinding to occur for the Assessors and for the patients, which will decrease bias.
- Blinding:
    - Patients will be blinded to knowing if they are in the Treatment Group or the Control Group; however, they may be able to ascertain which group depending on their insight into the purpose of the device and the experience of the Pedal Pump mobilizing the body or not.
    - Assessors (RN, CNA, etc) will be blinded.
    - Statisticians will be blinded.
    - Operators (persons who attach the device, turn it on, and detach it) will not be blinded.
    - At the end, Patients and Assessors will be asked: “Do you believe the patient was in the treatment group or the nontreatment (sham) group? How confident are you in your belief?”

Device Description and Engineering Safety:

- Device mechanism: Pushing on the feet
- Mechanical specifications: A 3D printed platform and casing with a motor inside and on-off switch outside of the casing. See video below for visual details.
- Power source is provided from a standard USA electrical outlet (120V)
    - Power cord includes an AC / DC Adapter
        - Input: 100-240V
        - Output: 20-24V with 3-5 amp input into motor
- Frequency/power: Device moves laterally with frequency of 1 cycle every 1.5 seconds and a max torque of 160 kg-cm.
- Contact materials: Patients' feet will contact the heel protector pillows only, which is made of Polyester, and then the heel protector pillows will contact the Pedal Pump platform.
- Safety: If a small internal piece of the device breaks, the patient will be protected by the device’s platform and then additional protection from heel protector pillows.
- Emergency Stop: If the patient has a need for emergent cessation of treatment, the patient can at any time move his or her feet away from the device (i.e. there is not any restraint placed on the patient’s feet). The Operator can also turn off the device at any moment.

Inclusion Criteria:

- Bilateral lower extremity edema of at least mild severity judged by the treating clinician to be due to CHF, chronic venous insufficiency, kidney disease, or other etiologies of fluid overload conditions.
- 18 years old or older
- Patients of any gender
- Medically stable
- Able to remain in Fowler position for 10 minutes
- Patients in the ER, observation, or admitted to the hospital for any period of time; outpatients (specifically CHF clinic patients)
- Patients must give informed consent to participate. The patient must be able to read the consent form (in English or Spanish) or give consent after the form is translated for the patient.

Exclusion Criteria:

- Patients using a hospital bed which has the scale on the foot board (e.g. Umano)
- Lymphedema (interstitial protein-built fluid)

- Lipedema (fat distribution)
- Pressure ulcers
- Active DVT (i.e. Patients who have signs of acute unilateral swelling must have a documented negative lower extremity venous duplex ultrasound within the current admission before they will be included in the trial.)
- Symptomatic peripheral vascular disease
- Wounds or infections in the feet, legs, buttocks, or back
- Weeping lymphedema or bullous cellulitis
- Uncontrolled hypertension (BP>180/110) in the recent 2 hours
- Uncontrolled hypotension (BP <80/45) in the recent 2 hours
- Heart rate greater than 110 or less than 45 in the recent 2 hours
- Leg or back surgery in previous 30 days
- Known pregnancy
- Severe osteoporosis/fracture risk

Recruitment:

- Provider referral
- PT or OT referral
- Nurse referral
- A team member will discuss the study with the patient and ensure all questions have been addressed prior to the patient voluntarily giving informed consent. A copy of the signed consent form must be given to the patient.
- Steps to make this happen:
    1. The Hillcrest Pedal Pump Investigation team will see which patients fit the criteria and send an Epic Chat message to the hospitalist, cardiologist, or otherwise treating provider.
    2. The provider will give approval via Epic Chat and, when possible, inform the patient that he or she may have this opportunity presented and the patient can accept or reject it.
    3. The Hillcrest Pedal Pump Investigation team will discuss the study with the patient and, if the patient agrees, will obtain informed consent.

Treatment:

- Patients will lay with the head of the bed elevated at a 45-60 degree angle (i.e., in Fowler's position)
- Patients will receive the Pedal Pump treatment applied to both feet for 10 minutes continuously, provided the treatment is tolerated by the patient.

Objective Measures: Assessments of the feet and legs will be taken pre-treatment (Minute 0), post-treatment (Minute 10), and follow-up (45-60 minutes after post-treatment):

- Feet observations: skin redness, bruising, swelling, numbness, capillary refill
- Bilateral Mid-Thigh Circumferences (15 cm above superior patella), Mid-Calf Circumferences (largest circumference), Ankle Circumferences (superior to the malleoli)
- The Assessor will use a skin marker to mark the location where he or she measured the first time, drawing lines above and below the measuring tape when applied to the ankle, calf, and thigh. He or she will use the same location for pre-treatment, post-treatment, and follow-up measurements. Each circumference measurement will be obtained in a duplicate. The average of the two measurements will be used for analysis.
- The measuring tape will not have slack and will not be so tight to cause pitting edema.



Subjective Measures: The below Symptoms will be rated by the patient pre-treatment, post-treatment, and at follow-up. Ratings range from 0 (none), 1 (mild), 2 (moderate), 3 (severe).

- Foot pain
- Ankle pain
- Knee pain
- Upper leg pain
- Low back pain
- Mid back pain
- Upper back pain
- Neck Pain
- Headache
- Nausea
- Stress level

Thresholds for clinically meaningful change:

- Circumference change ≥1 cm
- Pain, headache, nausea, or stress level changes ≥1 points

Treatment-related adverse events will be assessed by CTCAE v4.0 on a 1-5 scale:

- Grade 1 (Mild): Asymptomatic or mild symptoms.
- Grade 2 (Moderate): Minimal, local, or noninvasive intervention indicated.
- Grade 3 (Severe): Severe but not immediately life-threatening; hospitalization indicated.
- Grade 4 (Life-threatening): Urgent intervention indicated.
- Grade 5 (Death): Death related to the adverse event.

Adverse Events monitors will be such as, but not limited to:

- New pain
- Worsened pain
- Dizziness
- Blood pressure instability
- Skin irritation

- Muscle cramping
- Abdominal cramping
- Anxiety
- Nausea
- Syncope
- Chest pain of cardiac origin
- Sustained arrhythmia
- Stroke symptoms
- Hypoxia
- Hypotension

Treatment will stop immediately if a Grade 3, 4, or 5 adverse event occurs. The Operators and Investigators will keep record of the number of patients having adverse events and their severities.

Informed Consent will include:
- Study purpose
- Procedures
- Unknown risks
- Voluntary participation
- Withdrawal rights
- Data confidentiality
- Compensation procedures

Potential risks could include:
- Musculoskeletal strain
- Skin injury
- Nerve irritation
- Blood pressure changes
- Increased lower extremity edema
- Falls after treatment
- Aggravation of vascular disease

Patient Data will be obtained from the patient directly and/or from EPIC after the consent form is signed. Data collected will include:
- Age
- Sex
- Weight
- BMI
- Receiving IV diuretics
- Receiving oral diuretics
- Active CHF
- Active chronic venous insufficiency
- Acute kidney disease
- Chronic kidney disease and stage
- Active HTN
- MI history
- Stroke history
- Diabetes history
- Smoking 5+ years history
- Active pain

Referring Clinician Standards: If the patient may meet criteria and shows interest in participating, the referring clinician will message the Pedal Pump team.

Operator (Unblinded) Standards: All operators will be trained to the protocol as follows:

1. Operator's 1st Task:
    a. Obtain informed consent.
    b. Have the patient/representative answer the Pre-Treatment survey.
    c. Provide the Assessor with the Assessor paper.
2. *(Assessor's Pre-Treatment task then...)*
3. Operator's 2nd Task:
    a. Ensure the patient is in the correct position: laying with the head of the bed elevated at a 45-60 degree angle with feet uncrossed.
    b. Cover the heel protector pillows in new plastic bags and then position the patient's feet with socks inside the plastic-covered pillows.
    c. Place the device at the foot of the bed (use bed extender if needed). Plug it in.
    d. Turn the device on. Set a 10 minute timer.
    e. Obtain the additional past medical history and patient information. Write a short note in EPIC about the patient being a subject in the trial today.
    f. Turn the device off after 10 minutes.
    g. Remove the Pedal Pump device, the heel protector pillows, and discard the plastic covers.
4. *(Assessor's Post-Treatment task then...)*
5. Operator's 3rd Task:
    a. Have the patient/representative answer the Post-Treatment survey.
    b. Exit the room and sanitize the device using a "Purple Wipe" (i.e., Super Sani-Cloth® Germicidal Disposable Wipes): Any part that touches the patient, bed, floor, or other humans. Ensure the surfaces remain wet for 2 minutes for adequate sanitization.
6. *(Assessor's Follow-Up task then...)*
7. Operator's 4th Task:
    a. Have the patient/representative answer the Follow-Up survey.
    b. Tell the patient which group he/she was in. Thank the patient and Assessor.
    c. Upload the informed consent to the patient's EPIC chart. Copy it and give the copy to the patient. Then, store the originals in the physical folder in the pre-determined secure location.

Assessor (Blinded) Standards: All assessors will be trained to the protocol as follows:

1. *(Operator's 1st task then...)* Pre-Treatment Task:
    a. Assist the patient to sit up in bed.
    b. Mark with a surgical marker the locations where measurements will be taken.
    c. Record the Pre-Treatment objective data.
    d. Exit the room.
2. *(Operator's 2nd task then...)* Post-Treatment Task (within 0-5 minutes of device turning off):
    a. Re-enter the room.
    b. Record the Post-Treatment objective data.
    c. Set a 45 minute timer and exit the room.
3. *(Operator's 3rd task then...)* Follow-Up Task:
    a. Return to the patient's room 45-60 minutes after the treatment and record the Follow-Up objective data.

Investigators will include:

- Principal investigator: David McVay, DO
- Sub investigator(s): John Gemma, DO; Ezekiel Wang, MD

Data Storage and Analysis:

- The initial data will be written on paper by the patients and clinical assessors. Papers will be collected by the Hillcrest Pedal Pump Investigation team. Papers will be scanned into PDF for storage in a

HIPAA-compliant Google Drive Folder. The data collected (without patient identifiers) will then be manually uploaded to HIPAA-compliant Google Sheets or Microsoft Excel for statistical analysis by a blinded statistician.
- Investigators will use a Double Data Entry protocol (two different people type the data, and a system checks for mismatches) to ensure data integrity.

Statistical methods:
- Continuous variables (circumferences) will be analyzed by a blinded statistician using a paired t-test (pre vs. post) and an independent t-test or repeated measures ANOVA (analysis of variance) to compare the Treatment group directly against the Sham control group.
- The Subjective and Objective measures will be analyzed to establish standard deviation, *p*-values, and confidence intervals to define clinical significance.

Handling of missing data:
- If a patient or an assessor does not complete 20% or more of questions on the forms, the entry will be voided altogether.
- A Per-Protocol analysis will be used (i.e., analyzing only those who completed the full 10 minutes).
- If a patient requests to stop the intervention prematurely in case of emergency for personal reasons (not because of an adverse event), the data will not be submitted.

Pedal Pump Videos

HANDS-ON PEDAL PUMP DEMONSTRATED BY A MED SCHOOL PROFESSOR
YouTube Video: https://youtu.be/h11-aK6fx1E?feature=shared

Prototype 1.0

Click here to view a 1 minute demonstration video.

Updates to the Video for the Clinical Trial and future prototypes…

- Patients will be lying at an incline in the hospital bed (in 45-60 degree "Fowler's" or "Semi-Fowler's" position)

- Patients will be wearing Heel Protector Pillows, as shown here, covered in plastic.

Previous Research

PREVIOUS PEDAL PUMP RESEARCH FOR HANDS-ON TECHNIQUE
Pedal Pump helps the lymphatic system fight infections and decrease lower extremity edema
https://www.ncbi.nlm.nih.gov/books/NBK559051/

Pedal Pump decreases lower limb volume in healthy med students
https://pubmed.ncbi.nlm.nih.gov/36701752/

Use in sports medicine:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8761194/