

Pedal Pump Clinical Trial on Edema V2

Principal Investigator: David McVay, DO

Hillcrest Medical Center

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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 we are finishing our 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.

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Protocol

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

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) as the only cause of edema
- Lipedema (fat distribution) as the only cause of edema
- 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
- Leg or back surgery in previous 30 days
- Known pregnancy
- Severe osteoporosis/fracture risk

Potential patients will be identified via:

- 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.

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) and post-treatment (Minute 10-15):

- 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. The Assessor will use the same location every time.
- The measuring tape will not have slack and will not be so tight to cause pitting edema.



Thresholds for clinically meaningful change:

- Circumference change ≥ 1 cm at any leg location

Informed Consent will include:

- 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 will include:

- Age
- Sex

Referring Clinician: If the patient may meet criteria and shows interest in participating, the referring clinician will message the Pedal Pump team which will notify the Operator and Assessor working that day.

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

1. Operator's 1st Task:
 - a. Obtain informed consent.

- b. 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. Ensure knobs are in correct position. Turn the device on. Set a 10 minute timer.
 - e. Write a short note in EPIC about the patient being a subject in the trial today. Copy informed consent twice. Place one copy into the patient's paper chart at the desk and give one copy to the patient.
 - 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. 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.
 - b. Tell the patient which group he/she was in. Thank the patient and Assessor.
 - c. Gather the Assessor, Operator, and Informed Consent papers. 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. Mark with a surgical marker the locations where measurements will be taken.
 - b. Record the Pre-Treatment objective data.
 - c. 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.

Research

The study will be submitted to [ClinicalTrials.gov](https://clinicaltrials.gov) before enrollment begins.

Investigators will include:

- Principal investigator: David McVay, DO
- Sub investigator(s): Curtis Marti, OT; Jesse Gurley, OT

Primary Endpoints (Outcomes):

- No Treatment-Related Adverse Events Scoring 3, 4, or 5 on the CTCAE v4.0 scale
- ≥95% treatment tolerability (≤5% "aborted" treatments)
- ≥1 cm change in lower extremity circumference at any leg location

Secondary Endpoints (Outcomes):

- <20% of Treatment Group having Treatment-Related Adverse Events scoring 2 per CTCAE v4.0

Number of Subjects:

- 30 patients for this study:
 - 20 patients (2/3) receiving the Treatment and 10 patients (1/3) receiving the Sham.
 - Randomization will occur via 30 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 30 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 will be blinded.
 - Statisticians will be blinded.
 - Investigators may be blinded if not performing the Operator role as well.
 - Providers will be blinded.
 - Operators (persons who attach the device, turn it on, and detach it) will not be blinded.
 - At the end, 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?

Study Design:

- 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 engaging 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 being attached to their feet and the Pedal Pump being 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)
 - a. Same as Treatment Group with the exact same device generating identical operational sounds and visible movement but the patient's body will not be close enough to the device 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 immediately (within 0-5 min.) after the treatment.

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.

- We will use a Double Data Entry protocol (two different people type the data, and a system checks for mismatches) to ensure data integrity.
- A blinded statistician will analyze the data.

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 to compare the Treatment group directly against the Sham control group.
- We will analyze the Subjective and Objective measures to establish standard deviation, *p*-values, and confidence intervals to define clinical significance.

Handling of missing data:

- If an assessor does not complete 30% or more of questions on the forms, the entry will be voided altogether.
- We will use an Intention-to-Treat Analysis (i.e., analyzing all subjects' data to discover how the device may be experienced in real life by different hospitalized subjects).

Device Description and Engineering Safety

- Device mechanism: Applying a cephalad-directed load to the plantar surfaces of the feet without causing dorsiflexion.
- 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 second and a max torque of 160 kg-cm.
- Contact materials: Patients' feet will be in socks of the patient's choice which will contact the plastic covers of the heel protector pillows (made of Polyester). The heel protector pillows inside the plastic covers 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.

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](#).

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/>