Design of Rehabilitation Device for Increasing Micro Circulation in Diabetic People

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Abstract

The paper presents the design and fabrication of a new rehabilitation device for increasing micro-circulation/skin blood flow(SBF) in diabetic foot. The device is capable of transmitting vibration stimulation perpendicular to the area of the foot with an improved mechanism of varying amplitude and frequency of vibration. This device is unique in the sense that it is also capable of regulating the amplitude of vibration, which makes it more effective in curing foot ulceration ailments of varying degree. Diabetes Mellitus is spreading at a fast pace and is estimated to double by the end of this decade. One of the severe consequences associated with this ailment is chronic foot ulceration which if left untreated/ill-treated eventually leads to amputation of the limb. The medications available are not a favourable treatment for chronic conditions such as Diabetic polyneuropathy (DPN) as the side effects they cause can become more debilitating than the original pathology. The available vibration therapy devices till date, fail to produce desired curative results probably because of their distributed vibration and unregulated/uncontrolled vibration frequencies. This device not only induces controlled vibrations perpendicular to the foot with simultaneous amplitude and frequency modulation but is also cost effective.

Keywords
Vibration Therapy; Skin Blood Flow; Design; Fabrication; Frequency

1. Introduction
The most common causal pathway to diabetic foot ulceration involves the confluence of loss of sensation resulting in failure to detect repetitive pressure or trauma and abnormal foot structure or deformity producing sites of abnormally high pressure, usually over areas of bony prominence (Mueller et al. 1990 ; Brem et al. 2006). Persons with DM and signs of peripheral neuropathy have been shown to be 4 times as likely to have plantar ulcerations as those without neuropathy (Frykberg et al. 1998). Most treatment approaches involve non-prophylactic treatment with powerful medications such as antidepressants and anti-epileptics. Hyperbaric oxygen therapy may also help but is expensive. These treatments are not favourable for chronic conditions such as DPN, as the side effects they cause can become more enfeebling than the original pathology.

The blood micro-circulation is observed to be improved by vibration interventions with frequencies ranging from 20 to 50Hz, and 50Hz vibration may result in a greater increase in skin blood flow(Lohman et al. 2007, 2011; Lythgo et al. 2009). Furthermore, because of their reduced microvascular function, diabetics' SBF responses to vibration were less than those of healthy patients. Comprehending the situation, designing a device for providing vibrations, specifically for feet, with the required interventions is a great area to explore.

Nakagami et al. applied vibration of frequency 47 Hz to the ears of mice which promoted ulcer healing due to increase in SBF(Nakagami et al. 2007). The works of Yu et al. (2017) , Lohman et al(2007,2011) and Lythgo et al (2009) further provided credibility to use of low magnitude and high frequency (<50 Hz) vibrations in improving skin blood glow in lower limbs(Yu et al. 2017;Lohman et al. 2007, 2011;Lythgo et al. 2009). While Yu et al. (2017) work was based on providing continuous vibration, both Lohman et al. (2007,2011)and Lythgo et al. (2009) made use of short term intermittent vibrations for improving blood cell velocity in leg. Independent studies show that interval training therapy is more effective as compared to continuous training therapy, which was in fact, found to have adverse effect in certain cases (Wisløff et al. 2007; Ribeiro et al. 2010; Mitranun et al. 2014;Nakagami et al. 2007).The study by Maloney-Hinds et al. made use of vibration interventions at 30 and 50 Hz. The vibration interventions were applied to the forearm of healthy adults for 10 mins and skin blood blow (SBF) was measured for 10s after 1 minute therapy each time. The results showed significant improvement in SBF at both 30 and 50 Hz. However, improvement in SBF was shown to be higher at 50 Hz (Maloney-Hinds et al. 2008). Since, the SBF regulation mechanism in the upper limbs is different to the lower limbs, Malony-Hinds et al (2008) work was taken as basis for studies conducted on foot of diabetic and healthy adults to determine the effect of 5-min vibrations of 50 Hz with various rest period durations. It was found that short term (10 s) vibrations at 50 Hz frequency and an amplitude of 2 mm followed by 5 s or 10 s rest can significantly increase the SBF in both diabetic and healthy individuals (Ren W et al. 2019). Based on these experiments, we designed a device which can provide vibration therapy at wide range of frequency and amplitude.

Objectives
The objective of our device is to provide vibration in a single direction. We have developed a mechanism for varying amplitude (2 to 5 mm) and frequency of vibration. The device is supposed to provide point as well as surface vibration, hence a vibration plate along with vibration head is also modelled. The basic mechanism includes a cantilever beam, a cam and a movable vibration head[Figure1]. The centre of cam is attached with the shaft of a motor whose rotation speed can be varied. The rotation of cam leads to vibration of the beam which is hinged at one end. The beam is then connected with a movable vibration head. As the beam is hinge supported the amplitude of vibration varies as we move the vibration head away from the hinge. The initial frequency of vibration is kept at 50 Hz which can be varied as well. The vibration head is a hollow cylinder with outer and inner diameter as 10 mm and 5 mm respectively (Ren W et al. 2019). The vibration head provides vibration to the foot of patient. All the components are mounted inside a vibration box.

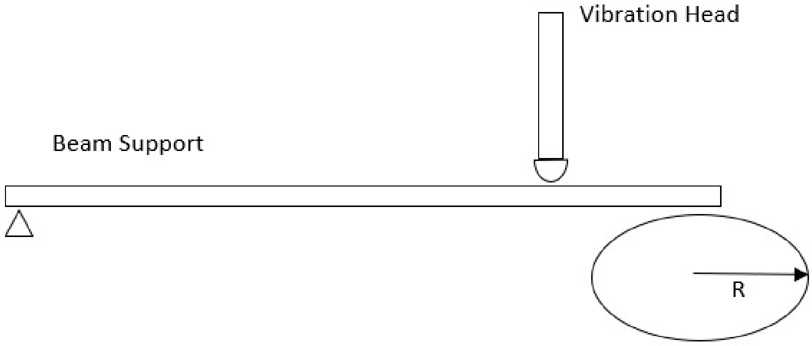


Figure 1. Basic sketch of mechanism to provide vibration

2. Literature Review
Persons with Diabetes Mellitus (DM) have been shown to be 4 times as likely to have plantar ulcerations as those without neuropathy (Frykberg et al. 1998). (Ghanassia et al. 2008) reported a diabetic foot ulcer recurrence rate of 60.9% and an amputation rate of 43.8% in a study of 89 hospitalized subjects. Nearly 50% of all people with DM have diabetic polyneuropathy making it one of the most common long-term complications of the disease.

Vibration Devices and Its Mechanism:
There are two broad mechanisms of Vibration Transfer: **Whole body vibration (WBV)**, in which mechanical vibrations are transmitted from the feet to the rest of the body using a vibrating platform, **and Focal muscle vibration** (FMV), where mechanical vibrations are applied to a localised point in muscles.
Studies have shown FMV produces better result in reducing muscle spasticity as compared to WBV. Whole-body vibration can cause fatigue, stomach problems, headache, loss of balance and "shakiness" shortly after or during exposure. (Canadian Centre for Occupational Health and Safety.)

Several vibration devices have been studied and designed by researchers:

Myovolt Vibration Device
It uses Focal muscle vibration technique. There are two models: three-actuator and two-actuator.(Ghazi et al 2021). A vibration intensity of 35–120 Hz, was used in previous studies (Murillo N. et al 2014).

Novafon Pro
It has two modes: Mode I (120 Hz) and Mode II (60 Hz). For each mode, intensity can be controlled by a rotating knob. Vibration can be provided by keeping the device above the forearm of subject and applying consistent pressure through the placement of a weighted securing strap(Ghazi et al 2021).

Linear Resonant Actuator/ Linear Vibration Motor

It is a precision vibration motor that produces an oscillating force across a single axis. It relies on an AC voltage to drive a voice coil pressed against a moving mass that is connected to a spring. When the voice coil is driven at the resonant frequency of the spring, the entire actuator vibrates with a perceptible force (Pujari et al. 2017).

Galileo Platform
It induces seesaw whole body vibrations. The Galileo platform oscillates around a central axis. A crankshaft principle on each side of the platform translates the rotating motion of the electro motor into a vertical displacement, inducing seesaw vibrations (Pel JJ et al. 2009).

Hand Tendon Vibration Device
The function of the device is to provide focal muscle vibration to tendons of hand and wrist muscles. It consists of five vibrator modules.
The above mentioned devices though having wide utility in providing WBV or FMV lack in providing variation of amplitude and a wide range of frequency variation and control. Also, The above mentioned devices however fail to provide claimed specifications regarding the vibrations and in turn least efficacy for the results for eg., Novafon Mode II was not 60 Hz, as claimed by the manufacturer. There is a large frequency drop in the Novafon vibration device in comparison with the other above mentioned devices when attached to body (not in free vibration). It can be attributed to the fact that the transducer is in direct contact with the body, and so the vibration mechanism and hence the driving (excitation) frequency can be physically hindered.This is different from typical vibration motor-based devices, where the vibration mechanism is enclosed, and the driving or excitation frequency cannot be physically hindered. Besides, these devices are expensive and therefore out of the reach of today's millennial population.

Taking the above mentioned limitations into consideration, we have devised the instrument which is capable of providing variation and control of amplitude and frequency both as well as the device is cost effective. The device will provide vibration without application of any constriction which often affects the frequency and intensity in the devices discussed above.

3. Methods
At the outset we selected the components in accordance to the mechanism capable of providing wide range of frequency and amplitude. A cantilever beam hinged at one end having slots grooved on its top surface in which a cylindrical vibration head can fit and move when desired to provide changed amplitude (displacement) has been selected as the most viable mechanism. The movement/vibration of the beam is brought about by the rotation of a cam about its axis fixed in the rotating shaft of a motor. The cam is connected to the shaft of motor and as the cam rotates it produces vibrations which are transferred via vibration head to the foot of the patient.
To provide a frequency of about 50 Hz (the following calculations were done:

Motor Calculations-
Pressure required = 9.45 kPa

Area of vibration = $\pi/4 \times [0.01^2 - 0.005^2]$

Force required = 0.55 N

Frequency of vibration needed = 50 Hz = 3000 RPM

Cam should rotate at half of this rpm, so RPM of motor = 1500 RPM

Torque generated by motor =

F × R = **0.55R N-m** (Where R is radius of cam)

Based on the results of frequency and torque calculations we chose the following criteria for the selection of motor which will be providing the required speed for the movement of cam, beam and vibration head:
Motor requirements:

Motor should produce sufficient torque and thrust (at least 0.55 N).
Motor should be able to produce 1500 RPM.
The motor must be compact and cost efficient.

After considering several motors which can produce 0.55 N torque, we chose DJI 2214 920KV BLDC Motor using the decision matrix in which we graded the parameters for efficient selection of motor that would work perfectly for our device as it is very compact, lightweight (60 gm), cost efficient and can produce required thrust and RPM.

Cam and Beam Calculations:

For DJI 2212 920 KV brushless DC motor

Shaft diameter = 6 mm
Length = 28 mm
Width = 28 mm
Height = 46 mm
Weight = 56 gm
Maximum thrust = 500 gm = 0.5 kg = 4.905 N
Maximum torque = 4.905 × shaft radius (i.e., 0.003 m)

= 0.0147 N-m = 1.47 N-cm

Now considering the force required is 0.55 N

Torque = F × R

0.0147/0.55

Hence, R_{max} =

Considering Factor of Safety (FOS) = 1.5
Actual thrust = maximum thrust/1.5 = 3.267

Actual torque = 3.267 × 0.003 = 0.0098 N-m

Actual R for the cam= 0.0098/0.55 = 1.78 cm

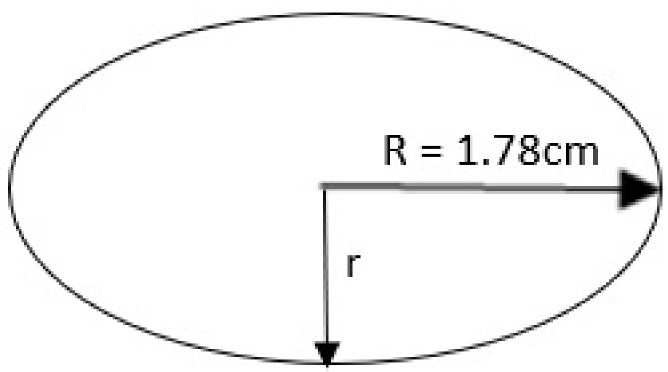


Figure 2 . Designed Cam

Further, we calculated ‘ r ’of cam and length ‘l ’of beam
We kept into consideration that amplitude of vibration will vary from 2 to 5 mm[Fig.3].

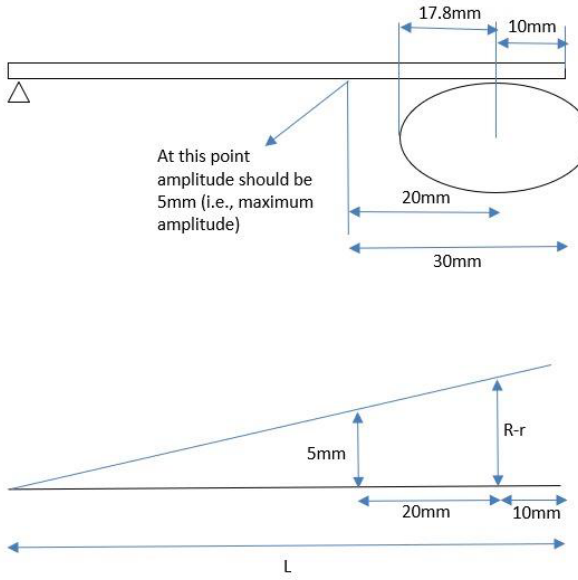


Figure 3. Schematic of Beam and Cam

Now, 5/(L - 30) = (R - r)/(L - 10),   where R = 17.8 mm[Fig. 2]

By putting values of ‘r ’we determined the length of beam. Also, considering average foot size of male and female, it’s length should be less than 90mm.

Case 1: Let (R - r) = 6 mm, i.e., r = 11.8 mm then, 5/(L - 30) = 6 /(L - 10)

L = 130 mm (which is more than 90 mm)

Case 2: Let (R - r) = 7 mm, i.e., r = 10.8 mm then, 5/(L - 30) = 7/ (L - 10)

Hence, L = 80 mm

So, the length of beam must be 80 mm and small radius ‘r ’of cam is 11.8 mm[Fig. 4].

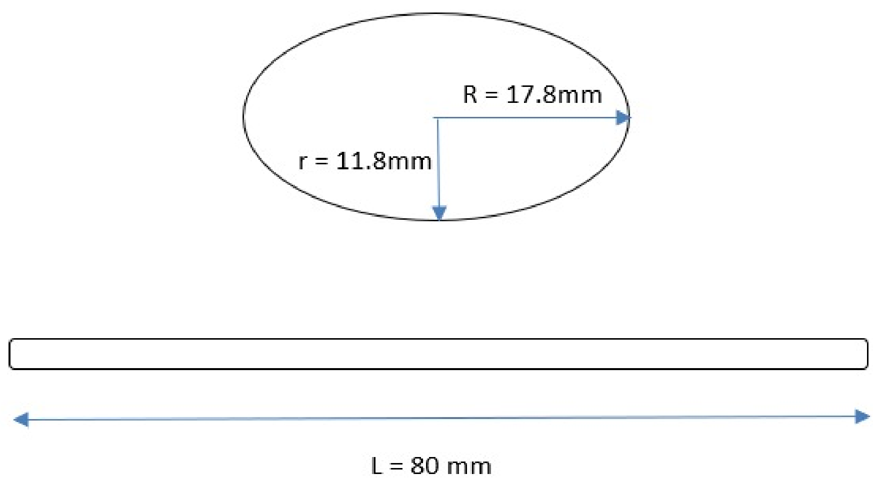


Figure 4. Final Design of Cam and Beam

Spring Calculation

Force generated by beam on spring = 0.55 N

Displacement required at the position where spring is mounted = 0.009mm
Spring Constant, K= 0.55/0.009 = 61.11 N/m

Prototype Modeling

To test the working of the vibration device, we created a model prototype. Based on the calculations of the cam, beam, and motor, the prototype is developed. When developing the vibration device, the dimensions of the electrical components that were to be installed in the vibration box were also taken into account. Modelling was done in 3D CAD design software SolidWorks[Figs. 5-10].

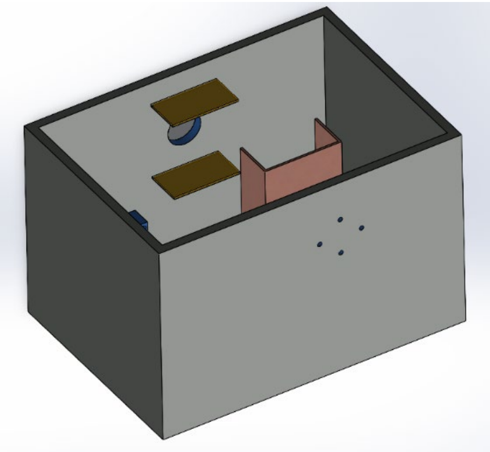


Figure 5. 3D CAD Model of Vibration Box

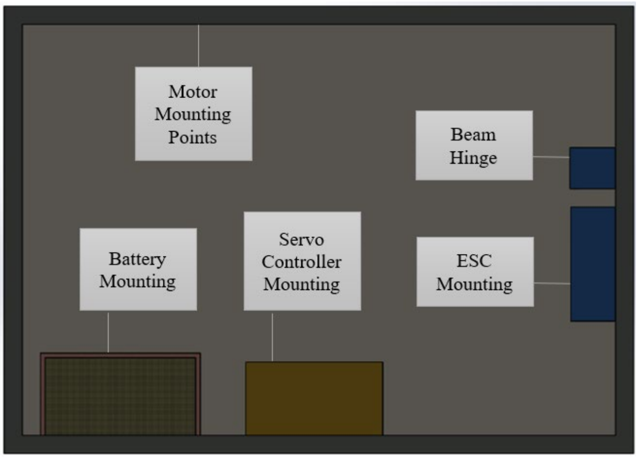


Figure 6. Vibration Box - Top View

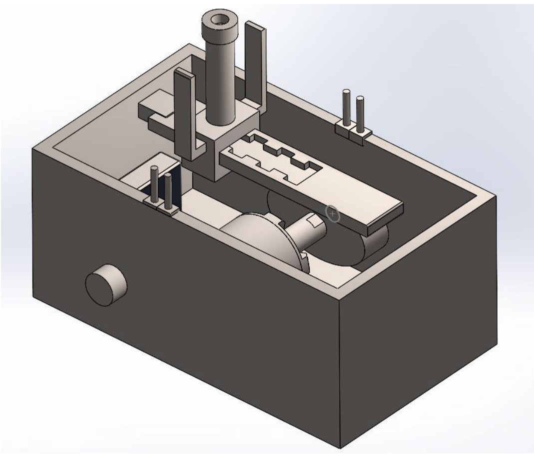


Figure 7. CAD of Vibration Device

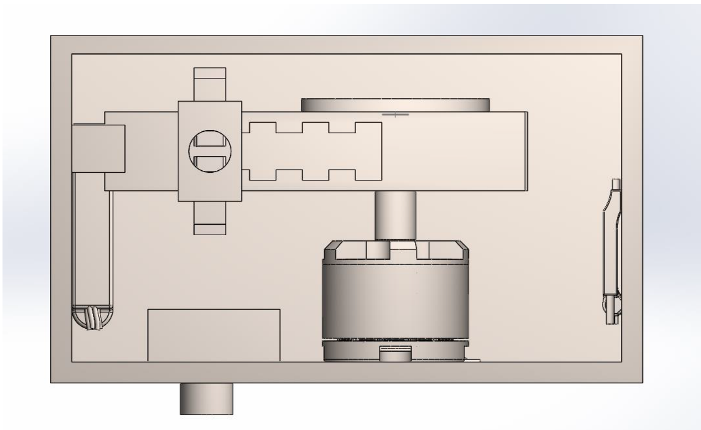
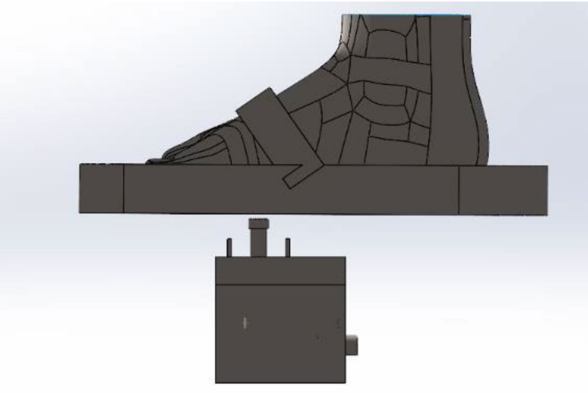


Figure 8. Sectional View - Top



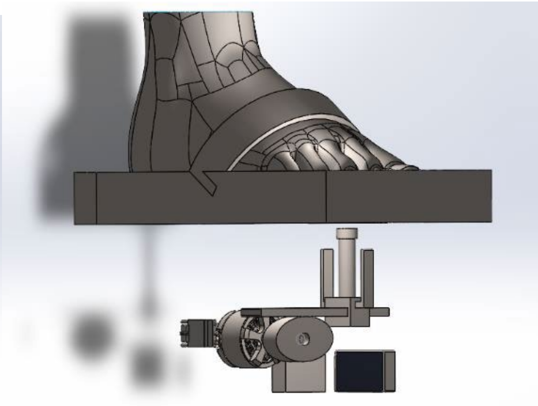
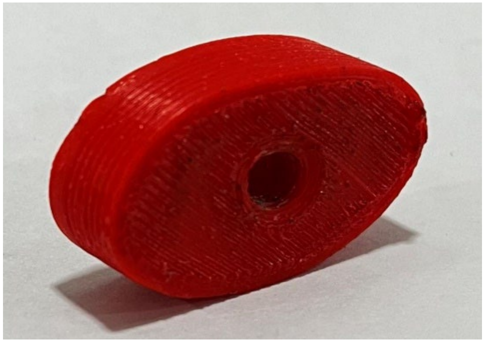


Figure 9. Full Assembly of Vibration Device & Foot Plate Figure 10. Exploded Assembly of Vibration Device



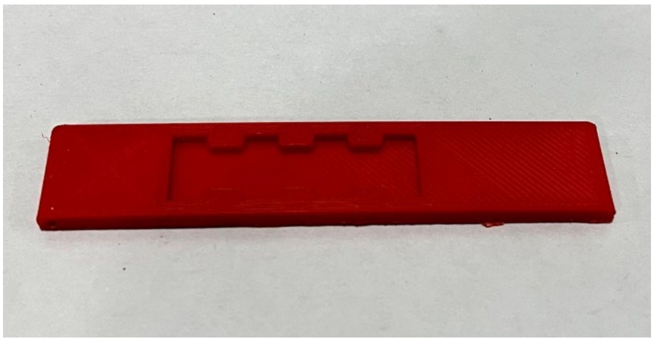


Figure 11. Cam Figure 12. Beam

The CAD models were used for 3D printing of various components viz. vibration head, cantilever beam, cam and the box in which all the components were mounted[Figs 11&12].

The speed of the BLDC motor is controlled with the help of an Electronic speed controller (ESC) by activating appropriate MOSFETs to create a rotating magnetic field so that the motor rotates. The ESC controller used in this project is SimonK 30A which has been chosen according to the motor.
In the initial experiment, a servo controller was used to vary the speed of the motor and power was supplied by a LiPo battery. As the BLDC motors are primarily used in drone development, the speed at which they rotate from the standstill position is quite high. In fact, much higher than the 1500 rpm required for providing 50 Hz frequency which is optimum for effective vibration therapy.Therefore, Arduino UNO was used to achieve lower speeds in a precise manner. A 10k ohm potentiometer knob is used in place of servo tester for varying the speed[Fig.13]. Arduino was fed with the code for speed control of the motor and calibration done to minimise and control the error. A speed range (maximum and minimum) was defined in the code for better control. Initially, we fixed our potentiometer knob on a protoboard to make multiple connections with the BLDC motor and ESC. The resistances of these components were taken into account and the Arduino UNO code was modified accordingly. When this experiment was found to be successful, soldering of the

wired connections was done and the setup was tested again. Using the Arduino, we generated the 50Hz Pulse Width Modulation (PWM) signal and according to the width of the pulse the ESC varied the motor speed from minimum to maximum RPM.

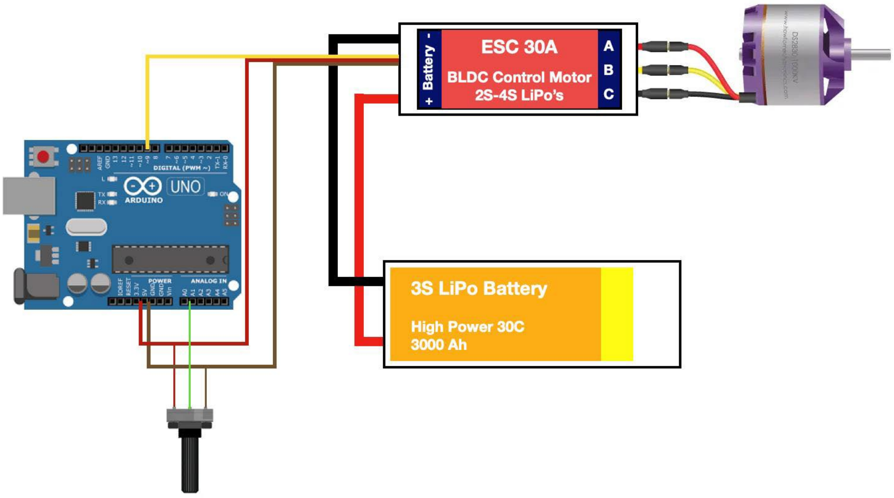


Figure 13. Circuit Diagram of the Speed Control Mechanism

Prototype Fabrication

We have developed a physical model to evaluate the functionality and viability of our vibration device.For the initial model, tin sheet was used to make the vibration box and mountings[Figs 14,15 & 16].

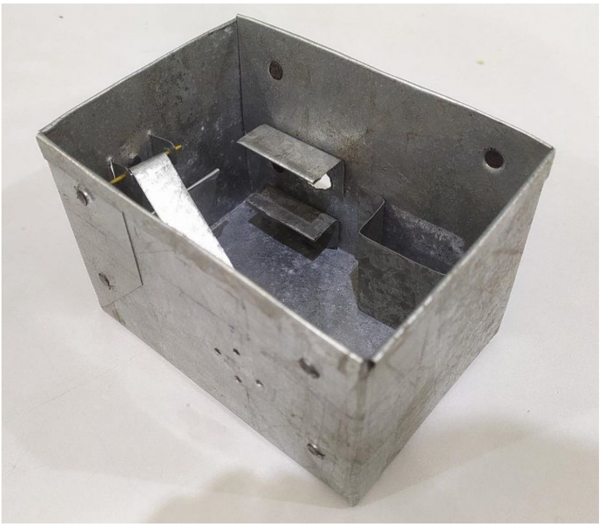


Figure 14. Vibration Box Prototype 1

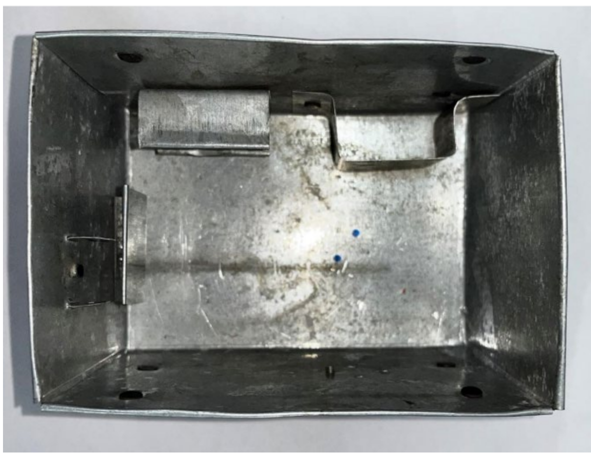


Figure 15. Vibration Box Prototype 1 – Top View

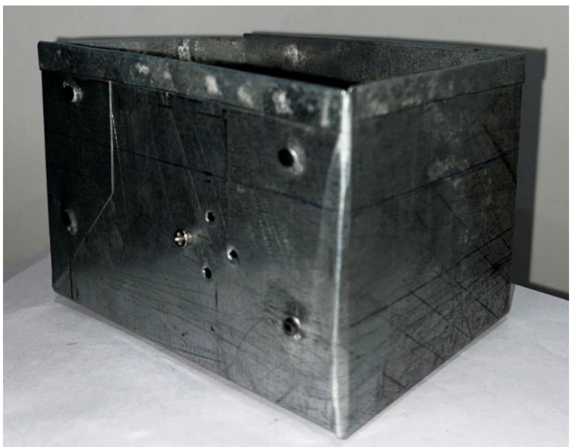


Figure 16. Vibration Box Prototype 1 – Side View

3D Printed Models for Prototype

We used 3D printing technique to fabricate cam and beam. The material used is Acrylonitrile Butadiene Styrene (ABS). The masses of cam and beam are 58 grams and 42 grams respectively[Figs 11&12].

Prototype 1 : Working Model

In prototype 1, all the components were mounted in the tin vibration box. Here, the method of speed control involved the use of a servo controller to vary the speed of the motor and power was supplied by a LiPo battery[Fig. 17&18].

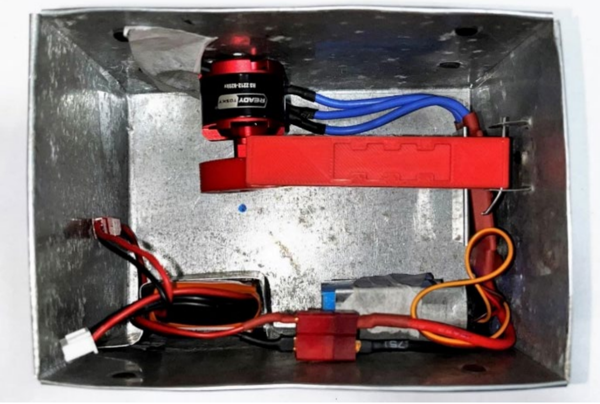


Figure 17. Working Assembly with Vibration Box

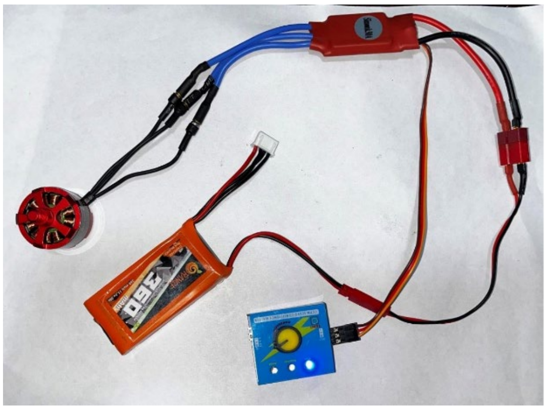


Figure 18. Connection of Electrical Components

Final Design of the Rehabilitation Device and its Components

In the first phase of fabrication of the prototype, certain flaws were identified which were troubleshot by bringing changes in the design of the components[Fig. 19]. Considering the design changes, we fabricated the final designs with the selected materials for each component using fused deposition modelling.

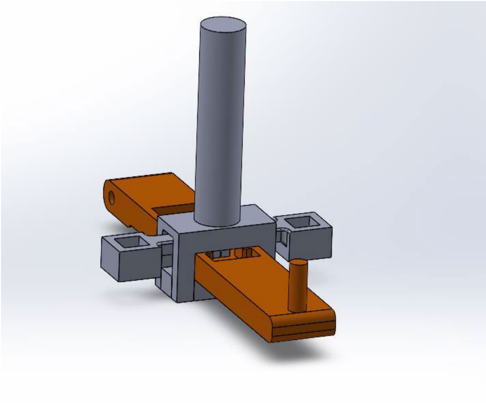


Figure 19. Vibration Head Assembly

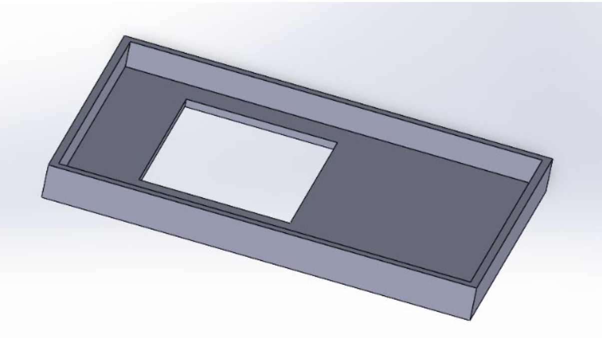


Figure 20. Vibration Box Lid

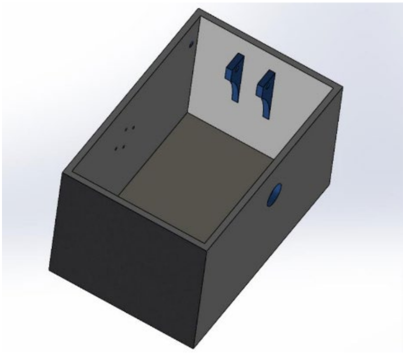


Figure 21. Vibration Box

Prototype 2: 3D Printed Rehabilitation Device

The updated CAD models were used for 3D printing of various components viz. vibration head, vibration box in which all the components were mounted[Figs 22&23]. After assembling the whole device, it was again tested and satisfactory results were achieved.

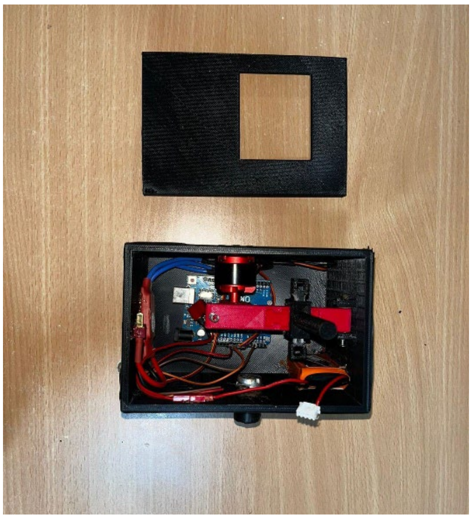


Figure 22. Open Top View of the Device

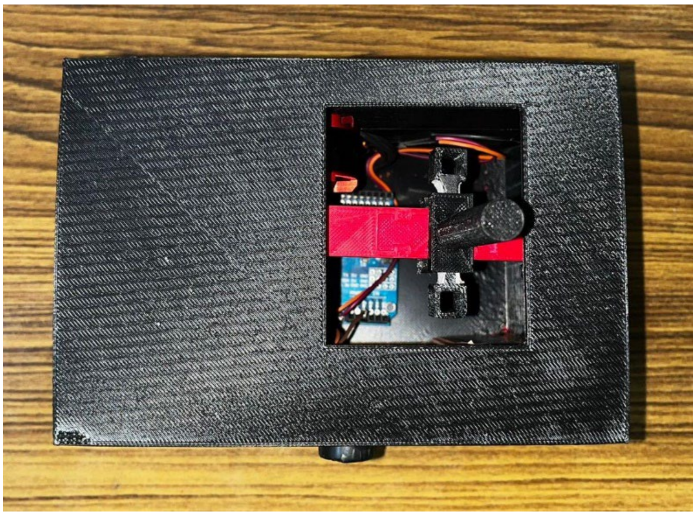


Figure 23. Top View of Device Assembly

As the final step, calibration was done by measuring the speed of the motor by tachometer and marking the knob positions for 1000 RPM and above. This will help us in providing the optimum speed required for vibration therapy which helps in improving the microcirculation of blood in the foot.

4. Results and discussions

We tested our device on few healthy subjects to verify it's functioning with respect to frequency and amplitude variation. We observed that the device has effectively transferred vibration to the foot at optimum frequency of 50 Hz. The amplitude variation is successfully achieved by manually changing the position of vibration head. The device will be used on patients in collaboration with ***Rajiv Gandhi Centre for Diabetes & Endocrinology, JNMC, AMU*** to test the developed device.

4.1 Proposed Improvements

The device can be improvised by using the LabView software to automate the frequency and amplitude control which will further simplify the device functioning.

5. Conclusion

Vibration therapy is a very effective alternative to conventional treatments in individuals with reduced SBF in the lower limbs especially in populations, such as those with insensitive feet, vulnerable to burns from thermal modalities. Numerous devices have been created to improve SBF in patients, but the majority of these devices do not entirely perpendicularly stimulate the patient's foot and do not have the ability to alter the amplitude. In order to address this issue, we modelled a device that would transmit vibration stimulation perpendicular to the area of the foot and allow for amplitude adjustment.

While designing our device we have also considered that it should be affordable to the millennials of our country, hence all the components used in our device are cost efficient.

In all, we have modelled a vibration device that will be delivering best results at a reasonable price.

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