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THE APPLICATION OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) CAN BE USEFUL TO TREAT HYPERTENSION

by

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ABSTRACT

THE APPLICATION OF TRANSCUTANEOUS ELECTRICAL
NERVE STIMULATION (TENS) CAN BE USEFUL
TO TREAT HYPERTENSION

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Hypertension is the cause of several severe health conditions like heart attack, stroke, and heart failure. Pre-hypertension, mild hypertension, moderate hypertension, and severe hypertension are the four stages of hypertension. Currently, different types of medications like Thiazide diuretics, Angiotensin-converting enzyme (ACE) inhibitors, Angiotensin II receptor blockers (ARBs) are available in the market to lower the blood pressure. However, there are many side effects of the medications which have increased the demand of non-invasive techniques to lower the blood pressure. The existing non-invasive techniques are not effective for immediate results. Thus, we have designed a non-invasive bioelectronic blood pressure cuff to reduce the blood pressure.

The device consists of silicone rubber ring which was the housing of the TENS electrodes and TENS device. TENS device and TENS electrodes were connected via copper wire. The silicone rubber ring was fabricated with the help of ABS plastic mold by using injecting molding technique. After the fabrication of the device, all the components were assembled within the ring. Two separate prototypes were built for animal model and human model. The difference between the two prototypes were the position of the TENS device and the size of the ring. The prototype of the animal model was built to test the device in animals before testing it in humans. The partial testing of the device showed some convincing results that the device was working however, the conclusion could not yet be done due to COVID- 19 outbreak

TABLE OF CONTENTS

LIST OF ILLUSTRATIONS

LIST OF TABLES

Table Page

CHAPTER 1

INTRODUCTION

1.1 Background

Hypertension or high blood pressure is a common health condition of many people around the world. In this condition, people experience high pressure against their artery walls even during normal blood flow. It is one of the leading causes of several other health conditions like heart attack, stroke, and heart failure.

There are four stages of hypertension: Prehypertension (120/80 to 139/89) mmHg, Mild Hypertension (140/90 to 159/99) mmHg, Moderate Hypertension (160/100 to 179/109) mmHg and Severe Hypertension (180/110mmHg or higher). Smoking, drinking alcohol, unhealthy lifestyle, age, genetics, etc. are some of the causes of hypertension. Since hypertension is the cause of fatal health issues, it is very important to treat the condition on time. Thus, I along with my team have developed a non-invasive bioelectronic device which can lower the blood pressure of the patients by (5-20) mmHg in 10 minutes.

1.1.1 Current Treatment Methods to Treat Hypertension

Currently, the most common form of treatment for hypertension is the invasive therapy which involves different types of medications. There are different medications like Thiazide diuretics, Angiotensin-converting enzyme (ACE) inhibitors, Angiotensin II receptor blockers (ARBs) and many more are available in the market which can lower the blood pressure (Omudhome, 2019).

Similarly, there are two non-invasive therapies, also called non-drug treatment, available in the market which can lower the blood pressure of the patients with hypertension. RESPeRATE and Physiocue are the only two non-drug treatment methods available in the market to lower the blood pressure.

1.1.2 Limitations of Current Treatment Methods

Currently, the invasive treatment method involving the use of medications is popular for lowering the blood pressure of the patients with hypertension. However, the medications cause several side effects including feeling tired, weak, drowsy or lack of energy, diarrhea or constipation, dizziness or lightheadedness and many others. Thus, there is huge demand of non-invasive treatment method for lowering the blood pressure. However, the non-drug treatment methods currently available in the market are not effective enough for immediate results. For instance, RESPeRATE lowers the blood pressure via breathing exercise which yields the result after 3-4 weeks only, after the patients use the device continuously for 15 minutes regularly. Thus, it is not effective for immediate results.

1.2 Analysis of Need

Hypertension is the condition of elevated blood pressure which affects approximately one billion individuals worldwide. In the United States alone, about 46% of adults have hypertension which has increased morbidity and mortality every year. Since the treatment of the condition invasively with the help of drugs has a lot of side effects and the non-invasive treatment methods fail to provide immediate results, there is huge need of an effective non-invasive method of treatment which can overcome the limitations of the current treatment methods.

1.2.1 Significance of the Project

The development of bioelectronic medicine which can lower the blood pressure of the patients with hypertension helps to overcome the challenges of current treatment Methods. Our device consists of Transcutaneous Electrical Nerve Stimulation (TENS) device and TENS electrodes embedded withing the silicone rubber ring. With the help of TENS device and TENS electrodes, our device aims to stimulate Common Peroneal Nerve (CPN) in the upper calf region which transmits the electrical signal towards the cardiac center of the brain and lowers the blood pressure. Our device is expected to lower the blood pressure by (5-20) mmHg in 10 minutes, thus is effective for immediate results.

1.2.2 Objectives of The Project

The objective of the project is to develop a non-invasive bioelectronic device, a sleeve-like device, which can lower the blood pressure of the patients with hypertension by (5-20) mmHg in 10 minutes. To achieve that, our aim is to develop an elastic and durable ring consisting of TENS device, TENS electrodes and the connecting wire. The objective of the project is to develop a prototype which is accurate, cost effective, environmentally friendly and user friendly.

CHAPTER 2

DESIGN

2.1 Device Specifications

At the beginning of the project, the constraints were given to build a prototype. Two different prototypes: one for animal model and the other for human model, were built. The purpose of making a different prototype for animal model was to test the device on animals before testing on humans. Based on the constraints given, the prototypes were designed, and the physical and functional aspects of the prototypes are mentioned below:

2.1.1 Physical Aspects of the Project

Both animal models and human models have different parameters for their physical aspects which are mentioned below:

Table 2.1: Physical aspects of prototype for animal model and human model

Physical Aspect	Animal Model	Human Model
Dimension	Height- 10 mm Thickness- 4 mm	Height- 70 mm Thickness- 10 mm
Cost	$85/reusable unit	$100/reusable unit
Weight	25 g	205g
Operational Temperature	(0-40)^{0}C	
Power Requirements	Power source- 9 V battery, Resistance of the battery- 500 Ω, Frequency-Adjustable (2-150) Hz	

2.1.2 Functional Aspects of the Project

The device is expected to lower the blood pressure by (5-20) mmHg in 10 minutes. Thus, the operational time and blood pressure reduction are the functional aspects of the prototype.

2.2 Device Description

2.2.1 Components of the Device

The device is a sleeve-like design made up of silicone rubber ring that consists of TENS device, TENS electrodes and conducting wire.

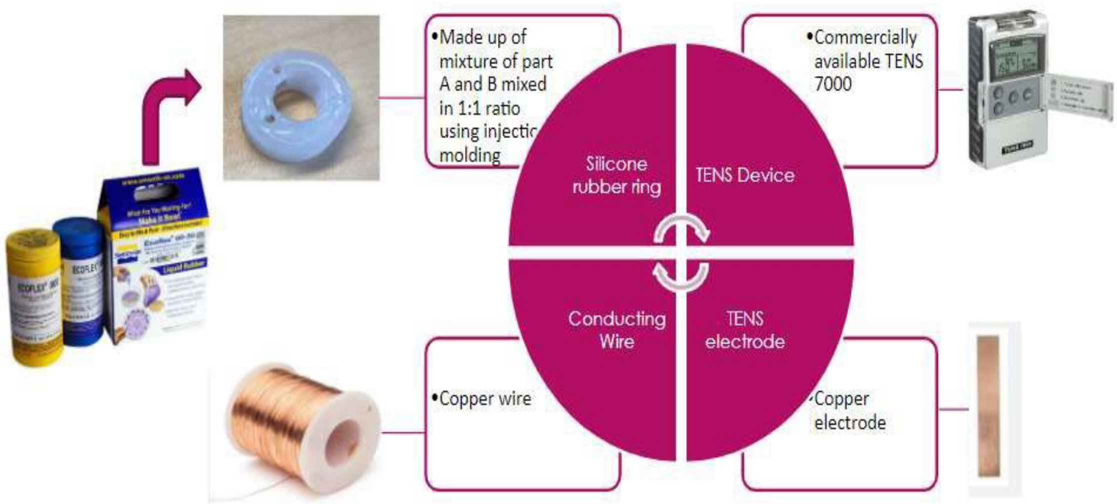


Figure 2.1: Illustration of the components of the device

The silicone rubber ring is made up of Ecoflex part A and part B mixed in the ratio 1:1. Commercially available TENS 7000 is used as the TENS device for our device which is the power source of the device. Copper wire is used as the conducting wire and the same wire uninsulated and hammered at the end is used the electrode for the device.

2.2.2 Detailed Description of the Device

Two separate models are built as per the constraints given. The purpose of making animal model is to test the device in rats first to confirm the working of the device before testing in humans. The difference between the two models is the size and the position of the TENS device. In animal model, the TENS device is outside of the silicone rubber ring which is connected to the TENS electrode inside the ring via copper wire. In the human model, the TENS device is embedded within the ring.

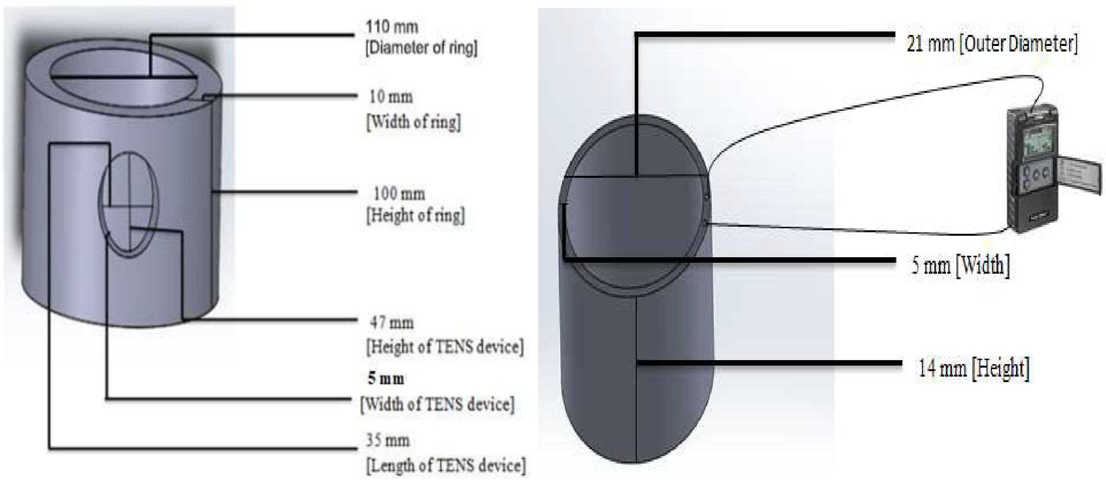


Figure 2.2: The detailed illustration of the dimensions of the human model with the space for TENS device (left) and animal model attached to the TENS device outside of the ring via copper wire (right)

CHAPTER 3

FABRICATION OF THE PROTOTYPE

The fabrication of the complete prototype was completed in two different stages which are explained below:

3.1 Fabrication of Silicone Rubber Ring

To fabricate the silicone rubber ring, injection molding technique was used. To do that, mold designs were made in SOLIDWORKS and the molds were printed in FABLAB UTA using ABS plastic. After that, Ecoflex part A and part B were mixed in 1:1 ratio and injection molding technique was used to fill the molds with the mixture. Then, the molds filled with mixture were first heated at 88 ^{0}F for 10 minutes and cooled down at room temperature for another 10 minutes. Finally, the silicone rubber rings of different diameters were obtained.

Figure 3.1: Silicone rubber rings of different diameters fabricated with the help of ABS plastic molds

3.2 Assembly of the Components

After the silicone rubber rings were fabricated, the TENS electrodes and copper wire were assembled into the fabricated ring. Silica glue was used to assemble them in the spaces created withing the ring.

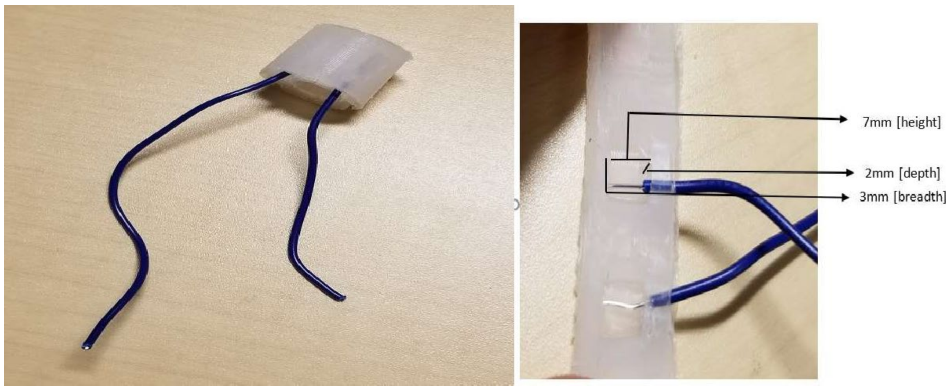


Figure 3.2: Assembly of the copper wire and the copper electrodes in the silicone rubber ring

Then, the wires were connected via soldering. The soldering was done in Maker's space UTA. Finally, the complete prototype for the animal model was obtained after the assembly of all the components. However, due to COVID-19 restrictions, human prototype could not be obtained, due to which few simulations were performed to check the device functionality in human.

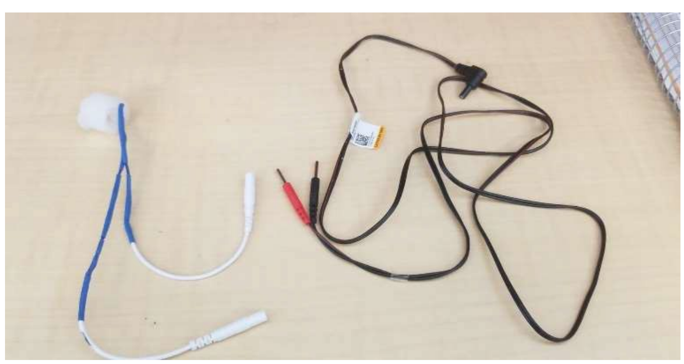


Figure 3.3: Final prototype for animal model after the assembly of all the components

CHAPTER 4

SIMULATIONS AND PROTOTYPE TESTING

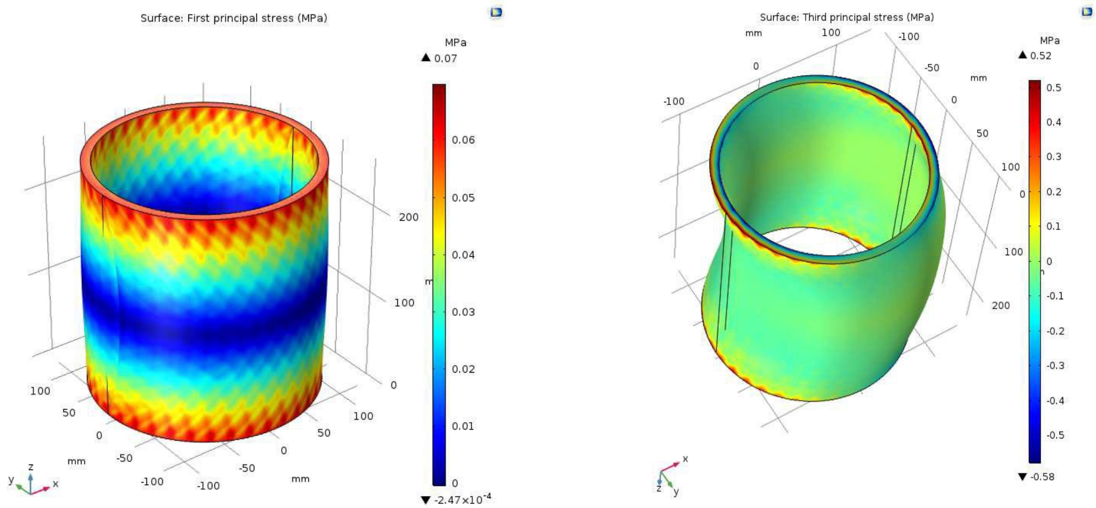
After the complete prototype was obtained, several simulations were done to confirm the working of the device. After that only, the testing of the device was done in animal model since only the prototype for animal was fabricated.

4.1 Simulations

Two different simulations were performed prior to testing the device in animal to confirm the working of the device. The two simulations are mentioned below:

4.1.1 COMSOL Simulation

COMSOL simulation was done to check the elasticity of the silicone rubber ring. We wanted to check whether the device could be used during walking or jogging. For that, the stress experienced by the ring during walking by a healthy 70 kg man was analyzed. The movements were analyzed during torsion and bending conditions. The stress graphs mentioned below show that the ring experiences very little stress during torsion and bending. Since the silicone rubber ring is a sleeve-like design that is slid on the upper calf region of the leg, it is very important for the ring to be elastic. The COMSOL simulation shows that the ring is very elastic, and it has fewer chances of distortion even when it is worn during walking or jogging.



Torsion Bending

Figure 4.1: COMSOL analysis of the stress experienced by the ring upon torsion and bending

4.1.2 ANSYS Simulation

The purpose of ANSYS Simulation was to check the effect of electrical nerve stimulation in the human body. We wanted to check the effect of a certain voltage of electrical stimulus introduced to the Common Peroneal Nerve (CPN). However, due to the complexity of the human body, we could not achieve what we had expected, and the simulation results were inconclusive.

4.2 Prototype Testing

After the fabrication of the complete protype, animal testing was done. However, before testing the device in animal model, the connectivity of the wires connected via soldering was checked using multimeter.

4.2.1 Testing of the Connectivity of the Wires

The wires were connected via soldering. It is very important to have the proper connection of the wires to ensure steady flow of current from the wires. Thus, we checked the connectivity of the wires with the help of multimeter.

4.2.2 Partial Prototype Testing in Animal Model

After the connectivity of the wires was tested, testing of the prototype for animal model was done.

Figure 4.2: Stimulation of CPN of rat model with the fabricated prototype for animal

Upon the stimulation of CPN with the help of the prototype, muscle twitching was observed in the rat model in all the attempts. It showed that the device is functional. The blood pressure reduction test was yet to be done. However, due to COVID- 19 outbreak, performing the rest of the tests to confirm the functionality of the device was not possible.

CHAPTER 5

CONCLUSION

The application of TENS device and TENS electrodes is useful to stimulate the Common Peroneal Nerve. However, due to the no in-person constraint, we were unable to check the device for actual blood pressure reduction test which was our primary goal. We were planning to try different frequencies and voltages to check the effect of each stimulation. Since, we did not have any laboratory access, we could not perform such testing that could verify that we met our primary goal which was to reduce the blood pressure of the hypertensive patients by (5-20) mmHg in 10 minutes. However, the secondary functions of the device, like elasticity of the ring and the stimulation of the nerve were verified, which have added value to our project.

5.1 Future Improvements

The device is a sleeve-like design which is slid onto the upper calf region. There is some chance that some of the silica gel might be lost while sliding the ring. Thus, to avoid that, the ring can be made with a hook and loop strap which makes the ring adjustable and secures the silica gel.

Likewise, the device can be made a closed loop. For that, a blood pressure (BP) testing device with Bluetooth settings which is sensitive to blood pressure can be made. The device also needs to be upgraded with Bluetooth settings. Once that is done, the patients do not have to worry about checking the blood pressure time and again.

Then, once the BP testing device receives the signal that the blood pressure of the patient is high, then the person can turn on the TENS device and our upgraded device will work to reduce the blood pressure.

CHAPTER 6

INDIVIDUAL AND GROUP CONTRIBUTIONS

There were three members including me in my group to complete the project. The tasks were assigned based on the expertise of each team member. There were some tasks which needed the contribution of all the group members, while there were some which I completed on my own. Below, I have mentioned my individual as well as group contributions that I was a part in to complete the project.

Table 6.1: Individual and group contributions

Individual Contributions	Group Contributions that I was involved in
1. Background research on Transcutaneous Electrical Nerve Stimulation (TENS) and its application in different areas of medical science	1. Fabrication and assembly of the components
2. Analysis of the working principle of the device	2. Testing of the prototype
3. COMSOL simulation	3. Preparation of presentations and reports
4. Determining the standards for the project	

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BIOGRAPHICAL INFORMATION

Rachana Kandel graduated with honors in Biomedical Engineering from University of Texas at Arlington in May 2020. With an aim to become a successful engineer in healthcare field, she came from Nepal to the United States of America in August 2016. She completed her bachelor's degree in Biomedical Engineering with a concentration in tissue engineering. Throughout her academic life, she was focused and passionate to learn new things. After joining UTA in August 2016, she was engaged with various organizations like Nepalese Student's Association at UTA (NSA@UTA) and Biomedical Engineering Student's Society (BMES) to enhance her leadership skills. Likewise, she worked in Nanomedicine Laboratory under Dr. Kytai Nguyen for a year to gain the laboratory experience. She has worked on many projects like designing a proposal for the treatment of brain cancer using nanoparticles, designing tissue engineered implants for repairing articular cartilage joints, developing non-invasive bioelectronic device for reducing blood pressure and many more. After her graduation, she is interested in working with a Biomedical engineering company for some time. After gaining some experience, her long-term goal is to work with World Health Organization (WHO) and to help the people around the world.