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Design and Implementation of Bone Wax Application Device

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Abstract

The basis of this research paper is a Diploma Thesis and presents the process of designing and implementing an innovative device to combat bone haemorrhage. The device is based on a patented idea that proposes heating the hemostatic wax, which is already used in cases where bone haemorrhage needs to be addressed, and its application through a special device. The device was fabricated following a thorough examination of the existing procedures of bone haemorrhage hemostasis. After defining the key factors that needed to be considered so that this device could be innovative yet effective in various conditions, without compromising the patient's safety, the device was fabricated following a thorough examination of the existing procedures of bone haemorrhage hemostasis. The results demonstrate the device's efficacy in the experimentation phase while pointing out the room for improvement. Thus, the fabricated device could impact the approach to bone hemostasis treatment and could be applied to various fields, from orthopedic surgeries and neurosurgeries to combat and emergency medical aid.

1 Introduction

Technology brings forth novel advancements that push the boundaries of innovation and progress. Medical science employs these innovations to provide the optimum medical care, resulting in the least possible side effects. The evolution in both technology and medical science fields has been rapid over the past decades. The research delves into the theoretical background of haemorrhage treatment with the utmost goal of establishing the basis for implementing a device that acts as an assistive medical tool, improving the procedures and the quality of treatment.

Comprehending the bone's internal structure is crucial, as it facilitates a better grasp of the reasons behind the need for hemostasis. Being porous and traversed by veins, while being the source of production of the red blood cells, bones when ruptured, result in blood loss and bleeding. The implications of that blood loss can be increased healing time but can also be more severe when not treated accordingly. During surgeries, blood loss can also obscure the view of the inflicted areas and increase the difficulty of the procedure.

The aim of the Diploma Thesis[1] was the research, design and development of a device for applying bone wax, based on the general idea that the initial patented idea [2] described. The main functions of the

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device should be the heating and the extracting of the bone wax to deal with the haemorrhage of bones.

2 Theoretical Background and Literature Review

Currently, there are several ways of addressing bone haemorrhage, using a unique mixture of beeswax and paraffin, forming the hemostatic bone wax[3], [4]. The medical personnel apply this mixture, called bone wax, by "heating" and forming the hemostatic bone wax, with their hands, to be malleable and ready to be applied to the wounded area. Therefore, it is time-consuming and results in an increased difficulty of application. Furthermore, the hemostatic bone wax prevents the complete restoration of bone tissue to the areas where it has been applied, introducing undesirable consequences.

The objectives of implementing a bone wax application device were:

- Easier application procedure
- Sterile device and hemostatic bone wax
- Portable and easy-to-use operatio
- Capabilities of increased accuracy of treatment with less material applied
- Ability to access difficult wounded areas
- Reusability
- Emergency response on site
- Employable under extreme conditions

Some characteristics, temperature of the bone wax, materials of the device, and portability, were also defined through the research to make the device easy to use and safe for the patients. Osteonecrosis [5] is the necrosis of bone tissue and in that case, a limiting factor that needed to be considered was the heat applied. Osteonecrosis occurs at 50oC and it is a temperature that should not be applied to the patient's body by the device. The device's sterilisation was considered, and specific materials were selected. The design includes removable parts, which can be sterilised before use and discarded.

3 Methodology

To achieve the aforementioned objectives and fabricate the final device Figure 2-C, the implementation of the device went through certain stages. First, the theoretical background had to be studied and considered as the primary source of providing the necessary information on how the device should operate. The theoretical background consisted of research in medical science and the applications and studies of hemostatic bone wax[4]. After that, the circuitry was experimentally designed only for controlled heating. The feedback was positive and after that, some experimental circuits were designed and adjusted accordingly, to come up with the final design that implements all the necessary features. Then the casing and the extruding mechanism were designed in 3D CAD software. The next step was to 3D print all the necessary components and test fit while checking the functionality. Following that, the device was fabricated from all the individual components and then the code was composed to enable the device to work according to the needs defined by the research that had been done. To ensure optimal performance of the device, testing and experimentation were carried out. This involved measuring power consumption, amperage, and operation times. Based on the results, adjustments will be made in

subsequent steps to enhance the device's functionality.

3.1. Circuitry Design

The requirements for ease of use, portability, heating and extrusion of the bone wax, provided the core for determining the design of the circuits. The need for portability resulted in choosing batteries as the power source, while the heating procedure set forth the need for batteries capable of providing high current. The battery of choice was a 26650 Li-ion battery, providing up to 30 Ampere at a nominal voltage of V_{Nom} = 3.7V. Hence, it was crucial to have a charging and Battery Management System (BMS). The ICs of choice to have optimal performance, while reducing size, were the TP4056 as the charging IC and the DW01 as the BMS.

The microcontroller responsible for performing the different tasks, calculations and temperature control, was the STM32g030f6P6 microcontroller and was chosen because of its capabilities (Pulse Width Modulation pins, Timers, etc.), the number of I/O (input/output pins) that it had and the input voltage requirements.

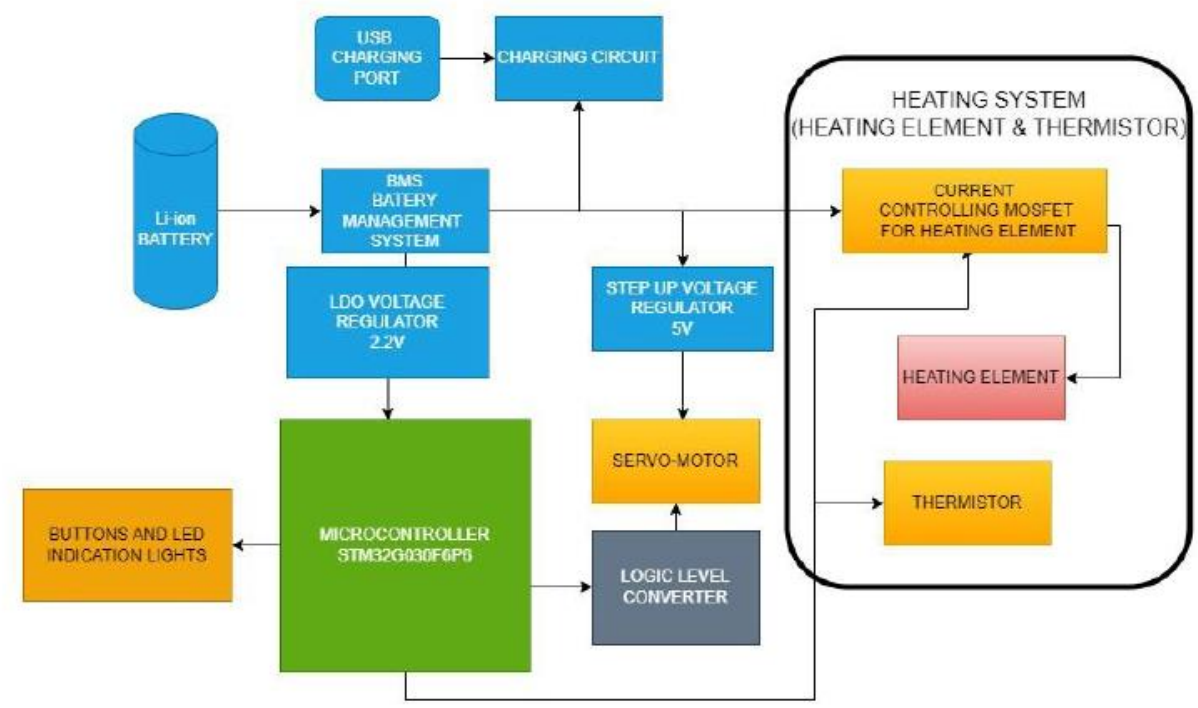

Figure 1: Block Diagram of the Circuit

A stable power supply to the microcontroller had to be considered for best performance and accurate temperature control, for that reason a circuit of low voltage dropout voltage regulator was added providing 3.2V to the microcontroller. A step-up voltage regulator, with an output of 5V, was also added to provide the voltage to the servo-motor, which is responsible for the extruding procedure, which needed 4-6V. Having a low-power microcontroller meant that the logic level was shifted towards the 3V and a need for a logic level shifter emerged to communicate with the servo-motor that had a 5V logic level.

The high current requirement of the heating element was taken into account. Using a MOSFET the current

can be regulated through the microcontroller. That way it was possible to use PID and PWM to control the heating procedure more accurately. The low voltage provided by the battery was crucial for selecting the MOSFET and the $V_{GSthreshold}$ should be close to the minimum voltage of the battery, which is 2.4V, so that the full potential of the battery can be used. The CSD16340Q3 was chosen and provides up to 20A of current with a $V_{GSthreshold} \approx 0.85V$, $I_{ds} = 250\mu A$.

3.2. Printed Circuit Board (PCB) Design and Fabrication

Following the completion of the theoretical circuit design, the subsequent stage was the fabrication of the circuit in its physical form. The PCB was crafted by utilising online PCB design software, a 3D model produced is shown in Figure 2-A, followed by printing and soldering of various components. Initially, the first versions of the PCB were printed for testing purposes. To check only the heating procedure, and various components and eventually to check for any problems. The final version was sent to an external manufacturer to be printed and after that, the PCB was hand-soldered with the use of a handmade solder plate.

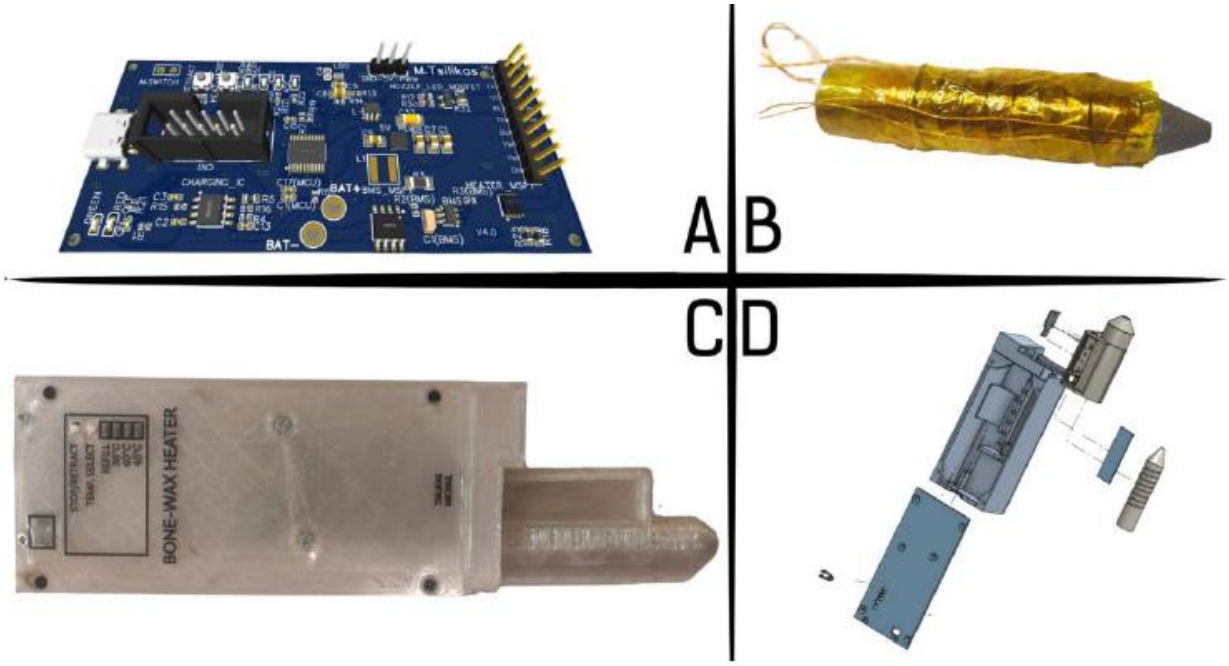

Figure 2: **A.** 3D Preview of PCB **B.** Heating Chamber **C.** The Final Device **D.** 3D Preview of Device`s Parts

Heating displacement through the copper pads was taken into consideration and dual-layer PCB was chosen for the prototype to decrease the size of the board and to make it more accessible for testing. The components used were Surface Mount Technology (SMT) to decrease the size and produce a compact and efficient result.

3.3. 3D Casing Design and Mechanical Extrusion

To create a device that meets specific requirements, 3D CAD software was utilised to design a custom casing and mechanical extrusion mechanism. The device needed to house all the electronic components PCB, buttons, LEDs, battery and the extrusion mechanism with the servo-motor. These parts had to be

snugly fit and secured in place to make the most out of the available space. Incorporating a detachable nozzle that holds the bone wax, heater element, thermistor, and extrusion button was a crucial aspect of the device's design. This feature enhances ease of use and promotes sterility. The chosen detachable mechanism uses a linear slot where parts slide and lock together through friction. Meanwhile, electrical connection happens through female and male connectors found on the two individual pieces that fit and slide together.

3.4. 3D Printing Parts

The materials selected are crucial to the construction and performance of the device. Considering heat and sterilisation, the device needed to be manufactured with strong, yet lightweight materials that can be sterilised easily. The best choice was aluminium for its strength, smooth and easily sterilised surface, as well as its self-sterilizing characteristics[6] and ability to conduct heat efficiently. However, during the prototyping phase and due to cost consideration, the material chosen was PET-G and only the container of the bone wax was manufactured with aluminium. All the parts shown in Figure 2-D were printed in a 3D printer except from the wax container that was sent to an external manufacturer to be 3D printed, but in aluminium.

3.5. Device Assembly

With all the essential components at hand, the assembly of the device is initiated. The SMT components were soldered to the final PCB and inserted into designated positions. PCB was fitted with soldered wires connecting the servo-motor, buttons, LEDs, battery and the female connector.

As shown in Figure 2-B the bone wax container was covered in Kapton tape to make it electrically non-conductive. After that the Nichrome wire, acting as the heating element, was wrapped around the container in prefabricated slots. The thermistor also had to be mounted by special non-electrically conductive heat-transferring glue. Along with one button and two inspection LEDs, all the components were soldered to the male connector and fitted to the detachable nozzle part. The final device as shown in Figure 2-C has dimensions of 21cm length, 6.1cm width and 4.2cm height.

3.6. Code Composition

The code was composed in the Cube IDE software for the microcontroller. In order not to halt the code execution, interrupt functions were used to detect the press of buttons and the proper function of the PID controller alongside the PWM generation. The code checks if the temperature selection button is pressed. If pressed, the button initiates the heating procedure (PID controller, PWM generation, temperature calculation). When the temperature reaches the desired temperature the corresponding LED lights up continuously declaring that the device is ready for extruding the bone wax. Using an interrupt, the device detects when the extrude or stop button is pressed and acts accordingly. To change the detachable nozzle, the user needs to press the refill button, and then the extruding piston returns to the refill position and awaits the user’s action.

Lastly, the code incorporates some safety features. The device checks for hazardous temperatures above 49^{o}C and if it detects a temperature greater than 49^{o}C stops all actions. In the design a magnetic sensor was placed on the main body of the device, detecting if the nozzle is present, and if it is not the device deactivates until the nozzle is placed in its proper position.

4 Results

Experimenting and assessing the device was done in a controlled environment, of 25°C and 38% humidity, to receive results that provide a clear understanding of the performance.

Time to heat in each of the three different predefined temperatures:

- 35°C → 20 seconds
- 40°C → 29 seconds
- 45°C → 50 seconds

To test the device in extreme conditions it was inserted in a freezer (-17°C) for 3 hours, so the inner core of the bone wax could reach the desired -17°C of the freezer, and then the heating procedure was initiated. At the same time, an oscilloscope and a temperature sensor monitored the temperature and the voltage levels. With the selected temperature being 45°C, the time the device needed to reach the desired temperature was 2 minutes and 35 seconds.

Additionally, an experiment of continuously heating at each of the heating temperatures was conducted to test the consumption of the device and its performance. As presented in Figure 3 the device starts drawing a current of around 3.5A until it reaches the selected temperature. After that, it draws small amounts of current, around 200mA to sustain the selected temperature.

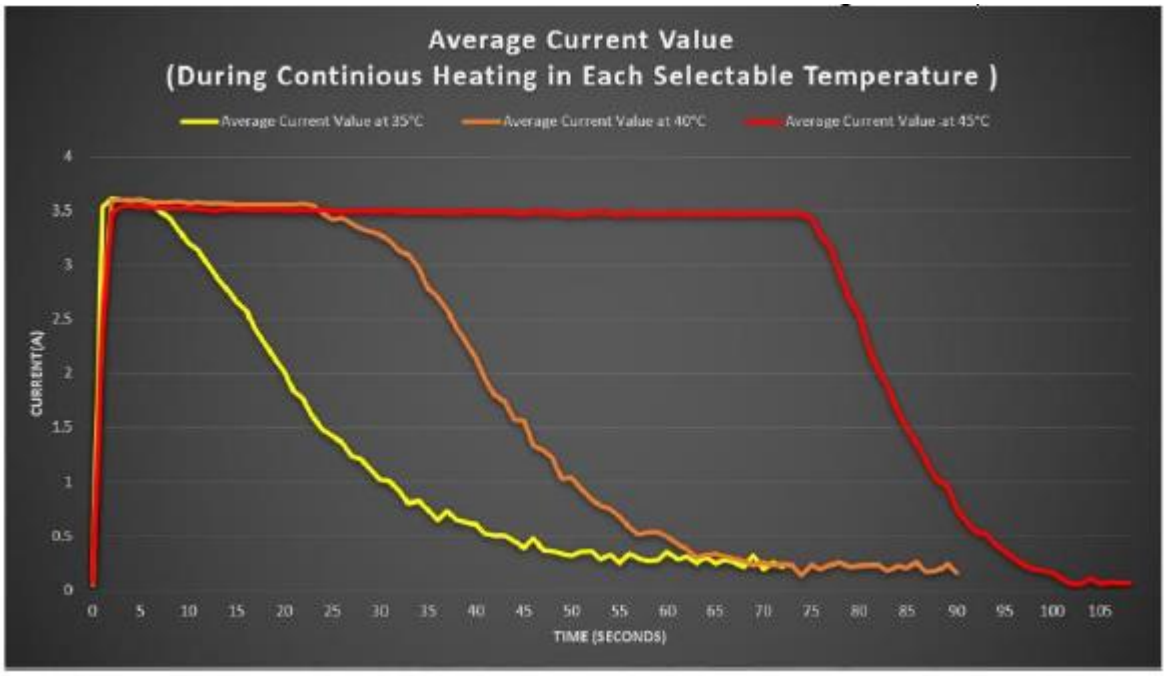

Figure 3: Continuous Heating, Average Current

Considering all of the above, it is concluded that the device is capable of performing the tasks that it was designed to do while being portable and able to operate when the temperature varies from -17°C to 40°C according to the tests.

There is room for improvement and the procedure of optimizing the device commenced. The final device

will be using aluminium and will optimize the performance of the microcontroller to limit the current consumption while decreasing the size of the device.

5 Conclusion

The objective of designing and implementing a device to apply bone wax has been achieved. The device possesses the necessary features, which were determined through research on the medical use of bone wax for hemostasis. The device implemented is just a prototype, improvements and further research and clinical trials are needed to reach its final form.

The PCB will be improved by the use of 3 layers so that the copper traces will cover less distance, thus improving performance and freeing space for the components to be oriented more compactly.

The material of choice for the outer shell will be aluminium, decreasing the thickness of the outer walls and consequently, the size of the device, while having more strength and better sterilization properties.

The battery has a performance that is more than sufficient. However, by decreasing its capacity, the size of the final device would be reduced, which is crucial for creating a portable medical device.

As an ongoing process, research, trials, and experimentation provide ample feedback, allowing for continual improvement.

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