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Design and Fabrication of a Moist Heat Therapy Device for Treating Non-specific Low Back Pain

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Abstract: *In this paper, the design and fabrication of an electronic moist heat therapy device is described for administering heat therapy treatment for non-specific low back pain (LBP). The device which is handy and low weight, incorporates low cost components such as a PIC16F microcontroller, a potentiometer to manually adjust voltage supply to the heater, a temperature sensor, a seven-segment display, a 12VDC power supply, and a heater component made up of a number of serially connected ceramic sealed resistors. In addition to these components, the device also incorporates a Bluetooth feedback system for temperature management through a third party electronic device like a mobile phone. Initial results obtained from the device show its advantages over the use of traditional hot water bottles which temperature cannot be regulated. The device is capable of maintaining target temperature required for effective heat therapy for non-specific LPB, without any concerns of heat loss or subsequent fall in temperature.*

Keywords: *Non-specific low back pain, moist heat therapy, Microcontroller, potentiometer, Bluetooth, and ceramic sealed resistors*

1. Introduction

Low Back Pain (LBP) is a common musculoskeletal disorder causing huge humanitarian and economical costs (van Middelkoop et al., 2011). It refers to spinal and para spinal symptoms in the lumbosacral region (Koes et al, 2010; Andreisek et al., 2013) and is often classified as acute (short term), sub-acute (intermediate) and chronic (long-term) according to duration of pain. Low back pain is typically described as specific or non-specific. Non-specific LBP is described as a “mechanical” back pain of musculoskeletal origin in which symptoms vary with physical activities. A wide range of terms are used for nonspecific mechanical induced pains, these include: low back pain/strain/sprain, lumbago, facet joint syndrome, sacroiliac syndromes, segmental dysfunction, somatic dysfunction, ligamentous strain, and myofascial syndrome. These typically involve processes in the muscles and/or ligaments that are difficult to be reliably identified by physical examination or diagnostic testing (Emch and Modic, 2011).

When injury occurs to soft tissues, inflammation occurs in which chemical mediators are released that not only induce an inflammatory response, but also sensitise nociceptors (pain receptors) and other somatosensory components of the nervous system. Some of these inflammatory mediators include: serotonin, cytokines, bradykinine and prostaglandins. Nociceptors transmit nerve signals that travel through the spinal cord to the brain, where the sensation of pain is recognised. At the same time, neurotransmitters initiate a spinal reflex that increases muscle motor activity and tonicity at the site of injury, leading to a reflexive muscle contraction. If persistent, the increase in muscle tone can cause painful muscle spasms, which can lead to further tissue damage due to decreased blood flow and oxygen (hypoxia) to the surrounding tissues. Pain in turn increases. This injury process is called the pain-spasm-pain cycle (Nadler et al., 2004). This cycle must be interrupted to prevent further tissue injury and to reduce the sensation of pain. Body weight also contributes to back pain due to the muscles being overworked, since approximately 50% of the body weight acts to compress the lumbar spine in upright postures, it adds strain to the muscles and ligaments in the back. Much greater force arises from tension in the Para spinal muscles which stabilise the spine. In order to compensate for extra weight, the spine can become tilted and stressed unevenly, extra stomach weight also pulls the pelvis forward and strains the lower back, thereby creating pain.

Superficial heat has been used for centuries to manage such pain occurring in the lower back region with specific goal of relieving pain, altering the physiologic processes underlying tissue healing, and affecting the plasticity of connective tissue, including muscle, tendon, ligament, and joint capsule. Traditionally, such modalities include; hot water bottles, heated stones, soft heated packs filled with grain, poultices, hot towels, hot baths, saunas, steam, heat wraps, heat pads, electric heat pads and infra-red heat lamps (Qaseem et al., 2017, Ajibola and Folorunso, 2017). Thermo receptors (special temperature-sensitive nerve endings) are activated by changes in skin temperature, these receptors initiate nerve signals that block nociception (the pain signal processing that results from a noxious stimulus) within the spinal cord.

Topical modalities applied with physical support activate another type of specialised nerve endings called proprioceptors. Proprioceptors detect physical changes in tissue pressure and movement. Proprioceptor activity also inhibits the transmission of nociceptive signals to the brain. The activation of these receptors within the spinal cord reduces muscle tone, relaxes painful muscles, and enhances tissue blood flow. The primary goal of heat therapy is therefore to alter the tissue temperature in a targeted region over time for the purpose of inducing a desired biological response such as pain relief (analgesia) and increase in tissue metabolism (Nadler et al., 2004).

2. Literature Review

2.1 The Physiological Effect of Heat Therapy

Heat therapy, also known as thermotherapy is the use of heat in the treatment of pain and other similar health conditions. Thermotherapy consists of application of heat or coldness for the purpose of changing the cutaneous, intra-articular and core temperature of soft tissue with the intention of improving the symptoms of certain conditions (Brosseau et al., 2003, Nadler et al., 2004). It is useful for the treatment of musculoskeletal injuries and soft tissue injuries. Using heat as a therapeutic intervention decreases pain in joint and muscle as well as soft tissues (Petrofsky et al., 2013, Nadler et al., 2004). The primary objective of heat therapy is the expansion of blood capillaries, increased blood flow to the affected area that provides nutrients and oxygen for better healing.

The application of thermotherapy leads to increasing the extensibility of collagen tissues, decreasing joint stiffness, reducing inflammation, edema (swelling), and aids in the post-acute phase of healing, and increasing blood flow. The increased blood flow to the affected area provides proteins, nutrients, and oxygen for better healing (William, 2008). It also results in increase in soft tissue flexibility, muscle resistance, easier and better contraction of smooth muscles, and improvement in the muscles motor function (Szymanski, 2001). Besides, thermotherapy triggers decline in pain especially low back pain through inhibiting pain signal and pressure exerted on the back muscles (Nadler et al., 2003).

In addition, when hot water bottle (especially in case of providing deep heat) is used, it leads to distraction of a person's focus from his/her pain, muscle relaxation, and hence pain relief. Continued thermotherapy leads to alleviating pain in people with acute low back pain, which decreases muscle seizure or spasm and resolves inability (Nadler et al., 2003; Kent, 2006).

The application of moist heat is a routinely prescribed therapy in today's medical field. The body's physiological response to moist heat is dilation of the blood vessels, causing an increase in the blood flow to the area under treatment. Increased local circulation enhances recovery by flushing away the waste products and bringing in fresh blood cells to the treatment area. Moist heat is exceptionally useful in treating back pain caused by muscle spasms from strain and tension. It can also temporarily alleviate pain associated with arthritic and musculoskeletal conditions. The increased blood flow can help relax muscles in spasm and help maintain joint and muscle flexibility.

Heat stimulates the cutaneous thermoreceptors that are connected to the cutaneous blood vessels, causing the release of bradykinin which relaxes the smooth muscle walls resulting in vasodilation. Muscle relaxation occurs as a result of a decreased firing rate of the gamma efferent, thus lowering the threshold of the muscle spindle fibres and increasing afferent activity. There is also a decrease in firing of the alpha motor neuron to the extrafusal muscle fibre, resulting in muscle relaxation and decrease in muscle tone (Sands et al., 2013; Steven et al., 2003).

For therapeutic modalities to be effective, it must have the capacity to produce desirable effects at the intended tissue depth (Ajibola and Folorunso, 2017). The maximal effect of energy occurs when its rays strike the body at a right angle since some of the rays are reflected away from the target site as the angle deviates from right angle, thereby reducing the level of absorption. According to Filip Struyf et al 2014, this phenomenon is guided by two basic laws; the Cosine law for conduction and the Inverse square law for radiation;

The Cosine law states that as the angle deviates from 90 degree, the energy varies with the cosine of the angle.

$$\begin{aligned}&\textit{Effective energy}\\&\quad = \textit{Energy} \times \textit{cosine of the angle of incidence}\end{aligned} \tag{1}$$

The inverse-square law states that if the rays strike the tissues at a right angle, the power intensity per unit area from a point source varies inversely according to the square of the distance from the source. According to the inverse square law, the intensity of radiant energy striking the tissues is directly proportional to the square of the distance between the source of the energy and the tissues:

$$\textit{Intensity of radiant energy, } E = E_s/D^2 \tag{2}$$

Where,

E_S amount of energy produced by the source,
D^2 square of the distance between the target and the source,
E resulting energy absorbed by the tissue.

However, for radiant energy, a difference of ±10^{o}C from the right angle is considered to be within acceptable limits. This means that each time the distance between the energy and the tissue is doubled, the intensity of the energy received by the tissue is reduced by a factor of four.

Superficial heat modalities convey heat mainly by conduction or convection, it elevates the temperature of the tissues and provides the greatest effect at 0.5cm or less from the surface of the skin. As a vasodilator, heat should be avoided in tissues with inadequate vascular supply, in case of acute injury, in bleeding disorders (because heat would increase bleeding), in tissues with a severe lack of sensitivity, and in scars (Benzon et al., 2013).

The amount of heat flow through tissue varies with the type of tissue, and is called thermal conductivity. Changes in surface tissue temperature caused by superficial heating agents depend on the intensity of heat applied, time of heat exposure, thermal medium for surface heat. Heat therapy is delivered by three mechanisms: conduction, convection, and conversion. Superficial heat is usually conductive heat (e.g., hot water baths, electric heating pads, warm compresses), methods for providing convective superficial heat include; fluidotherapy, whirlpool, moist air baths, and hot air baths. Conversion heating involves the conversion of one energy form (e.g. light, sound) into another (heat). Superficial heat is produced by heat lamps or radiant light bakers, with heat being transferred when the conveying medium (light energy) is converted to heat energy at the skin surface. Some of the factors that determine the extent of the physiologic response to heat are; level of tissue temperature (usually 40-45 ºC), duration of the tissue temperature increase, the rate of increase in the tissue temperature, and size of the area being treated.

Generally accepted evidence dictates that the duration and temperature range of heat therapy should be dependent on the level of injury, and clinical rationale (Hartzell et al., 2012; Prentice, 2002; Starkey, 2004). In low back pain, tissue heat transfer is dependent on body weight (Savastano et al., 2009; Petrofsky et al., 2009; Stephen et al., 2014). It is therefore necessary to be able to regulate and monitor the rate of temperature increase so as to tailor the application of the heat therapy device to individuals, to ensure patient safety, ease of application, control of heating and maintenance of target temperature.

This paper focuses on an electronic moist heat therapy device intended for treating non-specific LBP, it uses a manually adjusted potentiometer to set the desired temperature, allowing for a more effective user control of the device as the temperature will not exceed the limit set by the user. Controlled increase in thermal temperature is important in the case of injured muscles to increase tissue elasticity, thereby allowing the muscle to elongate and resist further injury (Lund et al., 2017; Angilletta et al., 2010; Arnason et al., 2008; Bazett-Jones et al., 2008), and also to prevent burn as a result of overheating. This (controlled increase) is important to limit the risk of tissue damage and is dependent on the use of a controller which is designed to force the temperature treatment progression at the desired temperature and minimise the treatment time required (Robert et al., 2005). Other heat modalities have no means of regulating or monitoring the tissue temperature through a third-party device and are therefore not effective as there is a constant need to interrupt the process of therapy to adjust for a rapidly decreasing temperature since the desired temperature cannot be maintained.

2.2 Benefits of Topical Heat Therapy

Some of the benefits provided by topical heat therapy may be mediated directly in the brain. Functional brain imaging research (Kang et al, 2011) has revealed central effects of non-noxious skin warming with increased activation of the thalamus and posterior insula of the brain. In addition, innocuous tactile stimulation of the skin activates the thalamus and S2 region of the cerebral cortex. These direct effects on the brain may mitigate the sensation of pain in the brain, thereby providing pain relief. A 1ºC increase in tissue temperature is associated with a 10% to 15% increase in local tissue metabolism (Tristan et al., 2012). This increase in metabolism aids the healing process by increasing both catabolic and anabolic reactions needed to degrade and remove metabolic by-products of tissue damage and provides the milieu for tissue repair.

Topical heat treatment applied directly on the skin increases both deep tissue temperature and blood flow. Mahajan et al. (2010) informed that heating pad treatment on the skin of the lower back region at 40ºC increases deep muscle tissue temperature by 5ºC, 3.5ºC, and 2ºC at muscle tissue depths of 19mm, 28mm, and 38mm below the surface of the skin, respectively. Conductive topical heat treatment of the knees of healthy subjects increased popliteal artery blood flow by 29%, 94%, and 200% after 35 minutes of treatment with heating pad temperatures of 38ºC, 40ºC, and 43ºC, respectively (Struyf et al., 2014; Erasala et al., 2001; Mendiguchia et al., 2013) demonstrated that deep tissue blood flow was found to increase 27%, 77% and 144% in the trapezius muscle of healthy volunteers with heating pad treatments, resulting in skin temperature increases of 38ºC, 40ºC and 42ºC, respectively.

The latter two studies show a two to threefold increase in deep tissue blood flow with moderate levels of conductive topical heat treatment applied directly to the skin. In addition, it was reported that a significant increase in trapezius muscle conduction velocity, most likely due to increased tissue blood flow, occurred with hot pack treatment at moderate temperatures (Cramer, et al., 2012).

Continuous application of low-level heat therapy (LLHT) directly on the skin has been shown to be safe and therapeutically effective in treating musculoskeletal disorders. According to Paul Kennedy et al. (2017), a randomised controlled clinical trial evaluating the effects of a wearable medical device that provided eight hours of continuous LLHT for the treatment of delayed onset muscle soreness of the quadriceps muscles showed significant increases in pain relief after eight hours of heated knee wrap wear at temperatures of 38ºC and 40ºC compared with a control group that wore unheated control wraps on both knees.

The same procedure has also been found to be effective for treating acute muscular low back pain especially those associated with menstrual pain. Using the same approach, Steiner et al. (2000) showed that if continuous LLHT is applied for eight hours per day over three consecutive days significant increase in pain relief persisted in the heat-treated group twenty-four hours after all treatments were stopped compared to an unheated control treatment. Akin et al. (2001) demonstrated that continuous low-level heat therapy with a wearable medical device applied directly on the skin of the lower abdomen for 12 hours per day for two days, provided significant pain relief in patients with dysmenorrhea when compared to a control group wearing an unheated device.

Continuous LLHT is also effective for the treatment of wrist pain associated with strains, sprains, and osteoarthritis. In their work, Michlovitz et al. (2002) showed incremental pain relief with eight continuous hours of topical heat treatment for three consecutive days compared with placebo treatment. Pain relief progressively increased with each successive day of therapy and persisted in the heat-treated group on the fourth and fifth day after all treatments were stopped. The therapeutic benefit of heat therapy in subjects with wrist pain included a significant increase in grip strength after three consecutive days of LLHT, which remained two days after all treatment had stopped. Similar therapeutic benefits were observed in subjects with carpal tunnel syndrome.

2.3 Safety of Heat Therapy

Heat therapy is safe when used within the treatment time recommended. Heat can be used to alleviate pain, muscle spasm caused by ischemia that may be relieved by heat, which increases blood flow to the area of injury. Inflammation and swelling are decreased through some of the direct effects of heat application such as increasing metabolism, reducing oxygen tension, lowering pH level, increasing capillary permeability, and releasing histamine and bradykinin thereby causing vasodilation.

Thermotherapy should be used with caution in patients with diabetes mellitus, multiple sclerosis, poor circulation, spinal cord injuries, and rheumatoid arthritis because it may cause disease progression, burns, skin ulceration, and increased inflammation (Nadler et al., 2004, Hurley et al., 2008).

When using thermotherapy, the skin should be protected in heat-sensitive or high-risk patients, especially over regions with sensory deficits. Caution should be used with products generating high intensity heat (greater than 45ºC), such as with Hydro collator packs or electric heating pads. Application time should be restricted for modalities that heat to high intensity levels. Other contraindications include application of heat immediately after an injury, over the eyes or genitals, over the abdomen during pregnancy, and over active infections.

2.4 Heat Therapy in Combination with Modified Physical Activity

Heat should be applied as prescribed on the sore area for a short duration in a position of comfort to assist with pain management. Modified activity should be encouraged as bed rest is not recommended, such activities should be carefully introduced as the patient begins to recover from the worst of the back-pain episode but cold therapy is not recommended (Norris, and Matthews, 2008). As bed rest has been de-emphasised, a more active approach to physical activity has been recommended. These recommendations are similar to those at the turn of the past century when the "disuse syndrome" was viewed as a prominent cause of low back pain (Henschke et al., 2009). The most common situations to avoid are prolonged sitting or standing, to avoid prolonged sitting at work or in a vehicle, patients should be instructed to get up at regular intervals (every 30 minutes) to walk and move their backs, because changing positions can increase pain, attention while getting up or sitting down and doing it slowly may avoid recurrent back spasm.

Low-stress aerobic activities, especially walking, is the best early activity. Patients should generally avoid strenuous activity, such as heavy lifting, climbing, or jogging until symptoms are improving over a period of a few days. Patients with acute low back pain may experience small benefits in pain relief and functional benefits from advice to stay active. The fear that activity will increase the pain is common in acute low back pain sufferers, in most people this will recede as the individual finds that he or she can maintain at least some level of activity. Fear-avoidance beliefs can be defined as a dysfunctional interpretation that physical or social activity will worsen the pain and/or cause harm. Individuals with these beliefs may be identified early in the course of their low back pain episode as those who state these fears about continued activity. They frequently believe that complete avoidance of activity or even bed rest is necessary to heal, individuals who demonstrate fear-avoidance should be informed of the potential harm of no activity and the dangers of deconditioning and should be urged to return to modified work (Damian Hoy et al., 2014; Henschke et al., 2009).

3. Materials and method

The individual components that make up the device and their principles of operation are briefly discussed. The circuit is powered by a 12V dc battery supply. The microcontroller is the core of device's processing unit, it gives command to all other components of the device based on its programming. The temperature sensor reads the temperature and displays it on a screen, while a second screen displays the time. This device is programmed to self-regulate and shut down once it completes the duration of therapy imputed through the timer potentiometer, this serves as a safety mechanism to prevent overheating or burns.

The temperature potentiometer is manually adjusted to set the desired temperature, this allows for a more effective control of the device as the temperature will not exceed the limit set by the user. There is also a Bluetooth feedback system option for controlling and monitoring through a third-party device like a smart phone. The heater is made up of a number of ceramic sealed resistors which are serially connected, they are small and arranged in such a way as to provide heat to a targeted region of the body without the burn hazard associated with typical heaters. The heater heats up the water contained in the rubber pouch, this water medium transfers heat to a concentrated area of the lower back tissues through an insulated cotton cloth material. The complete block diagram and circuit diagram of the device are illustrated in Figures 1 and 2, respectively.

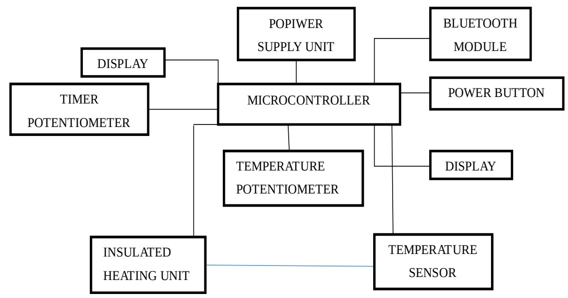

Figure 1. Schematic Block diagram of the device

3.1 Wire-Wound Ceramic Composition Resistors

This type of resistor is made up of resistance wire which is intended for making electrical resistors. In many situations, the stability of the resistor is of primary importance, and thus the alloy temperature coefficient of resistivity and corrosion resistance that play a large part in material selection. When resistance wire is used for heating elements, high resistivity and oxidation resistance is important. Sometimes, resistance wire is insulated by ceramic powder. Ceramic powder helps to control the resistive value of resistors.

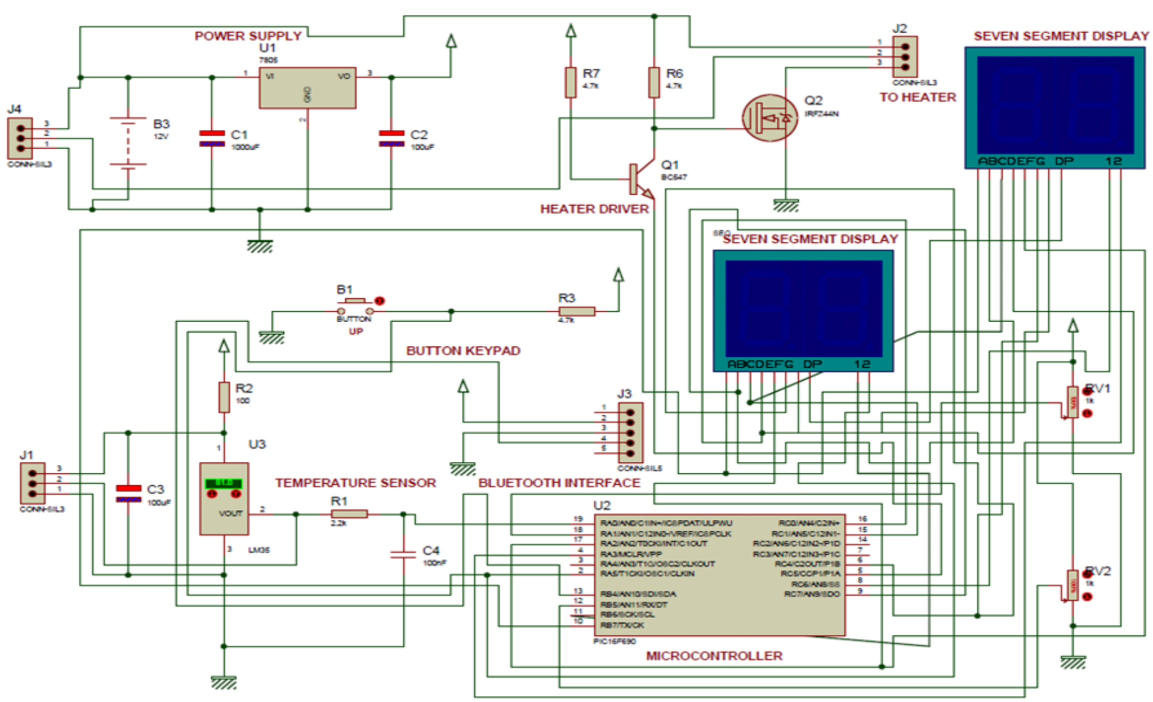

Figure 2. Circuit diagram of the device

Ceramic is also an excellent heat conductor, this property of ceramic allows the cores of the resistor to endure low to moderate power electrical current without overheating and becoming damaged, because of its insulation and thermal properties, ceramic is used to externally insulate and provide greater thermal endurance to some types of resistors. The most common of these resistors are made of resistive wire spun around a ceramic core and then encased in a block or cylinder of ceramic material. The higher the ratio of carbon in the mix, the lower the resistive value the ceramic resistor will have. A higher ratio of ceramic on the other hand will mean a higher resistive value of the resistor.

3.2 Microcontroller (PIC16F689)

The control of the circuit is accomplished through the use of a microcontroller, the PIC16F689, which can be programmed from a PC using the C programming language. The microcontroller delivers commands to the heat therapy device circuitry. The PIC is a family of modified Harvard architecture microcontrollers derived from the PIC1650, the name PIC initially referred to Peripheral Interface Controller. PIC devices generally feature: Flash memory (program memory, programmed using MPLAB devices), SRAM (data memory), EEPROM memory (programmable at run-time), Sleep mode (power savings), Watchdog timer.

3.3 LM-35 Precision Centigrade Temperature Sensor

The LM- 35 precision centigrade temperature sensor is used to measure tissue temperature during the application of heat therapy. It is a precision integrated circuit temperature sensor with an output voltage linearly proportional to the centigrade temperature. The LM-35 sensor has an advantage over linear temperature sensors calibrated in degree kelvin as the user isn't required to subtract a large constant voltage from the output to obtain a convenient centigrade scale. The sensor doesn't require any external calibration or trimming to provide typical accuracies of ±¼ºC at room temperature and ±¾ºC over a full -55ºC to +150ºC temperature range. The low output impedance, linear output, and precise inherent calibration of the LM 35 make the interfacing to the readout control circuitry especially easy. The LM-35 is rated to operate over a temperature range of -55 ºC to +150 ºC; it is therefore suitable for this work.

3.4 Potentiometer

A potentiometer is a three-terminal resistor with a sliding or rotating contact that forms an adjustable voltage divider, it is essentially a voltage divider used for measuring electric potential (voltage); the component is an implementation of the same principle, hence its name. Potentiometers are rarely used to directly control significant amounts of power (more than a watt or so), instead they are used to adjust the level of analog signals (for example volume controls on audio equipment), and as control inputs for electronic circuits. User-actuated potentiometers are widely used as user controls, and may control a very wide variety of equipment functions.

3.5 Heater Driver (MOSFET – IRFZ44N)

The heater driver / actuator is designed to limit the amount of current delivered to the heater and control the consequent working rate of the heater. The heater temperature control provides a periodic control signal having a substantially constant peak to peak magnitude and an average value dependent on a sensed temperature to be regulated. The rate of heating is proportional to the applied current. The power dissipated by joule heating in the heater is proportional to the square of the current. Thus, an increase in current above a certain value will result in overheating of the device. It is therefore important to carefully control the current that is applied to the heater. It would be advantageous to provide a temperature control circuit for the heater that operates in a nonlinear fashion. A further advantage to using such a circuit is that it operates using the same voltages already present in the circuitry for the device being protected. This design provides a power MOSFET–IRFZ44N control circuit for driving the heater.

3.6 HC-05 Bluetooth Module

Signal transmission from the heat pad to a third-party device for monitoring and management during thermotherapy is accomplished through the use of an HC-05 Bluetooth module. Bluetooth transmission is chosen over radio frequency transmission due to frequent interference which occurs when using RF transmission. The HC-05 module is an easy to use Bluetooth SPP (Serial Port Protocol) module designed for transparent wireless serial connection set-up, it is used to transmit data from the heat therapy device to a third-party feedback device for temperature monitoring and management.

3.7 Seven-Segment Display

Temperature display on the heat wrap is accomplished through the use of a seven-segment display. A seven-segment display (SSD) or indicator is a form of electronic display device for displaying decimal numerals that is an alternative to the more complex dot matrix display. It is widely used in digital clocks, electronic meters, basic calculators, and other electronic devices that display numerical information.

4. Results and Discussion

A heat therapy device using moist heat for providing analgesia through the use of an electrical resistive heating material was developed. The modality can be strapped to the lower waist of the patient in the manner as a waist bag. Figure 3 shows pictures of the control unit and also that of the insulated heating unit detached from the control unit.

(a) (b)

Figure 3: (a) Device control and monitoring unit and (b) Device heater section detached from the control unit

4.1 Results Analysis

Ten young adults participated in the research after agreeing to sign the informed consent forms, and participation in this research was entirely voluntary. The device was placed on the lower back region of selected participants and the duration of exposure ranged between 30 to 45 minutes per therapy session. The heating element of the device was not in direct contact with the surrounding tissues at any time as it was sealed within the water containing pouch through which heat was conducted to the lower back. The study population was fairly selected across age groups without sexual preferences, but subject with increased risk of complications such as people who suffer with ailing cardiovascular systems, spinal cord injuries and rheumatoid arthritis to avoid disease progression, burns, skin ulceration, and increased inflammation. The risks attached with use of the device were minimal as measures were taken to greatly reduce such risks. Some of these measures include:

1. An insulated heat wrap containing the heating unit which is placed on the lower back.
2. A temperature controller which controls the treatment progression at the desired temperature and minimises treatment time.
3. A Bluetooth monitoring and feedback system which constantly monitors the temperature of the device.
4. A power safety system that automatically switches off the device once the treatment time is complete.

Initial results from the device are shown in Figure 4. The results obtained from the moist heat therapy device reveal that from an ambient temperature of 34 ºC, temperature increases steadily to its peak temperature at point A, which is the desired temperature for applying therapy during the first five minutes of therapy, it then remains steady from that point A to point B and beyond throughout the rest of the therapy application.

A plateau effect occurs after peak temperatures are reached; this plateau effect is seen over the rest of the heat application. The heat therapy device is able to maintain its peak value temperature beyond 15 minutes after point A as the device is regulated, the heater shuts off automatically when it reaches its peak / pre-set temperature of 45 ºC and switches back on as it falls below this temperature to ensure that the temperature required to elevate the core muscle temperature is constant and maintained to aid in relieving pain and muscle spasm. The rate of heat loss is slower as device monitors and regulates fall in temperature so that the heat lost to the tissue and environment is replaced continually by the heater.

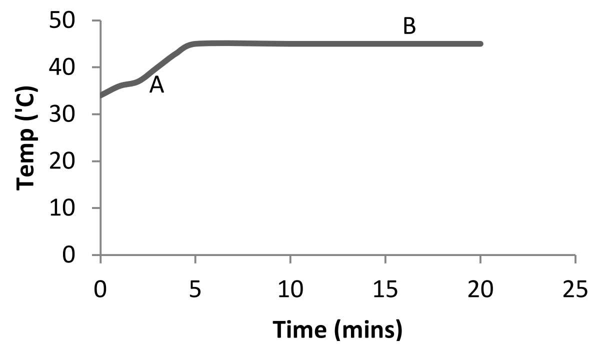

Figure 4: Heating rate for moist heat therapy device

Figure 5 shows experimental results from the traditional method of hot water bottle. An initial temperature of warm water at 60 ºC is used as a starting value at point A as it is considered adequate for therapy, temperature falls rapidly to a temperature of 32 ºC at point B over a period of one hour as seen on the graph and continues to fall towards room temperature, it then remains constant as the modality loses heat rapidly to the immediate environment considering that the rate of heat loss is not regulated.

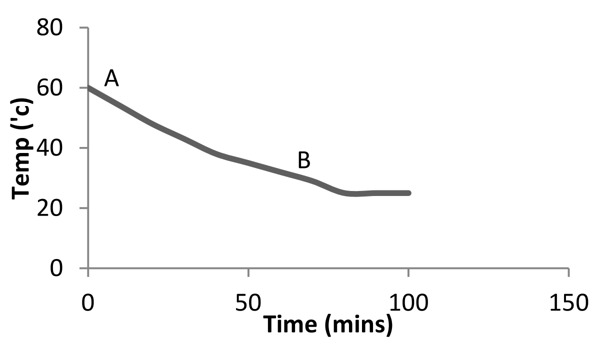

Figure 5: Heating rate for hot water bottle

During heat transfer to the body, the greatest degree of elevated temperature occurs in the skin and subcutaneous tissues within 0.5 cm of the skin surface.

In areas with adequate circulation, temperature increases to its maximum within 6 to 8 minutes of exposure. Muscle temperature at depths of 1 to 2 cm increases to a lesser degree and requires a longer duration of exposure (15 to 30 minutes) to reach peak values (Everett B. Lohman et al, 2012). Intense heat must therefore be applied for a duration of 15-30 minutes for effectiveness. Results show that this modality is not effective in the resolution of low back pain as the rate at which heat is lost fast to the immediate environment, and the thermal conductivity of body is not being replaced in any way. This leads to a reduction in the intensity of the heat applied over time and prevents effective penetration of the tissues to aid in pain relief. The efficacy of heat therapy in low back pain depends on the modality through which heat is applied, as a modality with unregulated rate of heat loss and fall in temperature will prove ineffective in relieving low back pain. A regulated moist heat therapy device in relieving low back pain is effective as the rate of heat loss and subsequent fall in temperature are addressed by constant monitoring and regulation by the device. Figure 6 shows the temperature gradient of electronic heat therapy device versus hot water bottle.

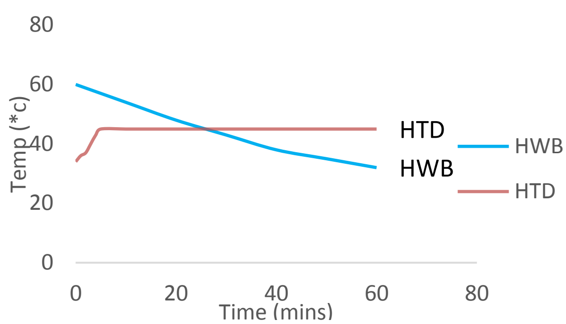

Figure 6: Temperature gradient of an electronic heat therapy device versus hot water bottle

4.2 Market Potential and Cost Analysis

The market potential is quite high for this innovative device particularly in low resource countries. According to a systematic review (Louw et al., 2007), the average lifetime prevalence of LBP in Africa among adolescents was 36%, and 62% among adults. In an urban population in southwestern Nigeria, a prevalence level of between 32-85% was reported (Omokhodion, 2004). A similar study in a teaching hospital in eastern Nigeria showed that out of every 10% of orthopedic patients, 82.1% of adult patients with LBP had LBP of mechanical or non-specific origin (Omoke and Amaraegbulam, 2016), and is within the range of 80% - 90% documented for developed or high-income nations. This shows that LBP of mechanical origin is predominant in Nigeria which has an estimated population of about 186 million (according to the 2017 revision of the World Population Prospects). Approximately 50% of Nigerians are urban dwellers, with the proportion of people between the ages of 15 and 65 years comprising 53.2% of the total population (United Nations, 2012).

The market potential of the device = No. of buyers × qty. purchased by the average buyer × price of 1 unit of the product.

The number of buyers was calculated using an estimated prevalence level of 80% of the adult urban population (53.2%) of a total population of 186 million.

Number of buyers = 0.8 × 0.532 × 186,000,000 = 7,916,160.

The design for this device incorporates low cost components which makes it easily affordable in poor resource countries where access to sophisticated medical equipment is rare. The total cost of the prototype amounts to about $105. However, the final prototype did not benefit from the cheapest industrial prices. The cost summary was done for an estimated 1000 units at $20,000, excluding the extrinsic expenses and chances for discounts, and reductions due to better market experience. The price values were taken from several component distributors. Shipping and handling were not included. Similar products in western markets would cost an upward of $500, making it rather difficult for an average person in a poor resource country to be able to afford such a device.

5. Conclusion

Findings have shown that relief from low back pain depends on the duration (time) and intensity at which heat is applied. The ability to provide improved heat therapy device for the application of thermotherapy is emerging as a preferred option for pain management among sufferers of mechanical low back pain, as physicians and physiotherapists are opposed to complete dependence on prescription drugs/opioids. The development of an electronic heat therapy device is coming at a time when we need a means of monitoring and quantifying the long term physiological response of individuals, and also overcome some limitations of the traditional methods of administering thermotherapy. The developed moist heat therapy device certainly has numerous advantages over traditional methods of heat therapy using hot water bottles particularly in areas of effective heating control and accuracy in maintaining the target temperature, real-time monitoring of tissue temperature during therapy, and over all patience safety.

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