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A Cost-Effective Electrical Stimulation Device for Non-Pharmacological Pain Management During Pregnancy

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Abstract

Pain related to pregnancy is due to the physical changes that occur in a woman's body to accommodate the growing fetus. Pain management during pregnancy requires a balance between effective relief and the safety of the mother. Presently, pain management includes medication and therapy methods. Non-pharmacological methods should be prioritized over pharmacological methods to relieve the pain due to the adverse side effects of medication on both the mother and the fetus. In this study, a novel electrical stimulation device is designed and developed for non-pharmacological pain management during pregnancy. The device provides biphasic electrical pulses noninvasively using electrode pads. The device can be used by both pregnant females and females suffering from period cramps. The designed and developed device is cost-effective, portable, and modular. In the future, the device can be made smart by controlling it via the mobile application using wireless communication. It can also be integrated into therapeutic systems for maternal care.

1. Introduction

Around 20 – 90 % of pregnant women suffer from low back pain [1]. It is a mild pain in most cases, yet one-third of the females experience severe pain [2]. It has the highest prevalence in the third trimester of pregnancy [3]. It is a significant concern in the public health sector. 56% of the working women took sick leave during the first 32 weeks of pregnancy, out of the normal 40 – 42 weeks. While 25% of working women require long-term leave due to pregnancy pain [4]. This pain is caused by to combination of various factors, including mechanical, hormonal, and circulatory [5][6][7]. A hormone called relaxin is released during pregnancy, causing ligament laxity that induces changes in the facet joints, back muscles, and ligaments [2]. Extra mechanical strain is applied on the back as the centre of gravity shifts forward during pregnancy [6][7]. The pain is assessed using the questionnaire by medical practitioners for pregnant subjects [8][9][10].

Many pregnant women face sleep difficulties. In a study, the researchers examined how pregnant women with sleep difficulties responded to acupressure and low-frequency transcutaneous electrical nerve stimulation in terms of their quality of sleep. 42 pregnant women received interventions twice a week for 6 weeks. There were no significant changes in scores before or after the interventions [11]. In a study, pharmacological and non-pharmacological methods were compared. The comparison involved 300 pregnant women. Electrical stimulation reduced pain significantly when compared to paracetamol, and it is also safer than the use of pethidine because that drug has appreciable negative effects on the mother and the fetus [12]. Electrical stimulation can help relieve stress and depression [13]. It can also be used by females suffering from pain during periods [14]. Transcutaneous electrical nerve stimulation is a safe and effective substitute for pharmaceutical choices like pethidine [15].

A comparison between non-pharmacological methods indicates that electrical therapy is useful to relieve pain [16]. Researchers evaluated the effectiveness of electrical stimulation in the initial phase of labor. 326 pregnant women participated in the study. The visual analog scale was used to quantify the main outcome, the intensity of labor pain, at several intervals, such as 30, 60, and 120 minutes after the intervention, as well as 2–24 hours following delivery. In comparison to the control group, the experimental group reported a shorter active labor phase and noticeably lower pain scores. The findings indicate that electrical stimulation is a useful non-pharmacological method for easing pain [17]. In a study, researchers focused on assessing the electrical stimulation during childbirth. Three groups of laboring women participated in a randomized controlled experiment. Intensity of pain, length of labor, satisfaction with childbirth, and neonatal health indices are among the outcomes. The usefulness of transcutaneous electrical nerve stimulation in treating early labor pain and enhancing patient satisfaction in term women is indicated by the investigation results [18].

The world of science and technology is evolving day by day. A safe and secure communication can be made possible using the algorithm for cognitive radio networks [19]. Reinforcement learning can be used for unmanned aerial vehicles to have smart flight [20]. Breast cancer can be classified using the histological images by the aid of deep learning [21]. Biomedical signals can be simulated for testing and optimization of hardware design [22][25]. Vanilla GAN can be used for data augmentation [23]. A portable device can be used to detect preterm labor in early stages of gestation in women [31]. Electrooculography can be useful for the detection of stress [24]. These studies reflect different aspects of innovations in their own domains. Using electrical stimulation for pregnancy pain management is also an innovative approach, reducing the need for medication and ensuring the safety of mothers and babies.

In a study, before and after usage of electrical stimulation is compared including 263 of the 272 women. The pain scores were significantly lower, i.e., 7.09 vs 6.74, with $p = 0.02$. Furthermore, 72% of women said they would use it again, 80% said they would recommend it, and 78% said it helped them manage their pain. It is an inexpensive, low-intervention method of treating labor pain that gives women a sense of control and may enable them to stay at home longer before requiring hospitalization [26]. In another study, the pain management during medication abortion is assessed in a randomized trial. The results showed that electrical stimulation is an effective non-pharmacological method to relieve pain [27].

Episiotomy is a procedure that involves surgery after childbirth. It is very painful process. Electrical stimulation can be used to reduce the post-surgical pain. A study highlights a review including the data of 6 databases. The results shows that it is significant compared to control groups and reduce pain as early as 1 hour after the episiotomy [28]. Considering the fact that it is a surgical procedure, electrical stimulation is a better and safe option. There is a high teratogenic risk while using medication for treating headache. Electrical stimulation devices are a better option for reducing the pain in migraines. It is better alternative in pregnancy [29]. In a study, researchers reviewed 11 studies. 1576 participants were included. Visual analog scale was used to assess the pain. The frequency of electrical stimulation was set to 15 – 100 Hz during the active labor phase when cervical dilation was 6 cm. The results indicated that electrical stimulation is better and safer option for noninvasive management of pain [30].

In this work, a portable and cost-effective electrical stimulation device has been designed and developed to offer non-pharmacological pain relief specifically tailored for women, with a primary focus on pregnant women experiencing labor pain and individuals suffering from menstrual cramps. The device functions by delivering biphasic electrical pulses through noninvasive electrode pads placed on the skin, which stimulate peripheral nerves to modulate pain perception based on the principles of Transcutaneous Electrical Nerve Stimulation. This study aims to avoid the use of dangerous pharmacological methods for pain management. Hence, reducing dependency on analgesics and minimizing the risk of complications, particularly during pregnancy. A non-pharmacological electrical stimulation device has the potential to be upgraded into a smart therapeutic system by integrating wireless communication modules such as Bluetooth or Wi-Fi. This would allow remote control and real-time monitoring via a mobile application, enabling personalized pain management plans and seamless integration with digital maternal care platforms. Furthermore, data logging and cloud-based analytics could be incorporated to monitor pain relief patterns and improve treatment outcomes over time.

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2. Methodology

2.1 Hardware Components

Design and development of an electrical stimulator requires various components that include a microcontroller, a boost converter, a potentiometer, and an L293D dual H-bridge IC. The initial prototype is first developed on a breadboard, followed by prototyping it on the PCB. The driving IC, named L293D H-bridge IC, offers the switching power required to produce the biphasic waveform. The IC is a good fit for this application because of its high output current capabilities, broad supply voltage range of 4.5V to 36V. It makes it possible to precisely adjust the polarity of the waveform, which is essential for generating the intended biphasic signal. The logic design of the circuit makes sure that the two timers cooperate to create a steady and tunable waveform, which makes the system adaptable to applications that call for certain amplitude and frequency characteristics. Two 54-bit timers of a small-sized microcontroller, Seeed Studio Xiao ESP32-S3, are used to generate a biphasic waveform. The first timer, Timer0, manages the biphasic waveform's positive and negative peaks, while the second timer, Timer1, controls the interval between these peaks. This synchronization makes it possible to create the perfect biphasic waveform with tunable parameters. Figure 1 shows the general block diagram representation of the electrical stimulation circuit for pain management. The duration for stimulation is usually 250 microseconds with a current up to 2 milliamperes and voltage ranging from 30 – 60 volts. For stimulation to be successful, this component makes sure the pulses are given with the right magnitude and direction. The stimulation intensity may be precisely controlled by using a trimmer potentiometer (2kΩ), which provides adjustable resistance for fine-tuning the pulse amplitude. By increasing the input voltage, the XL6009 boost converter ensures that there is enough power for the stimulation procedure. Biphasic electrical stimulation is made possible by this meticulously constructed circuit, which consists of these interrelated parts.

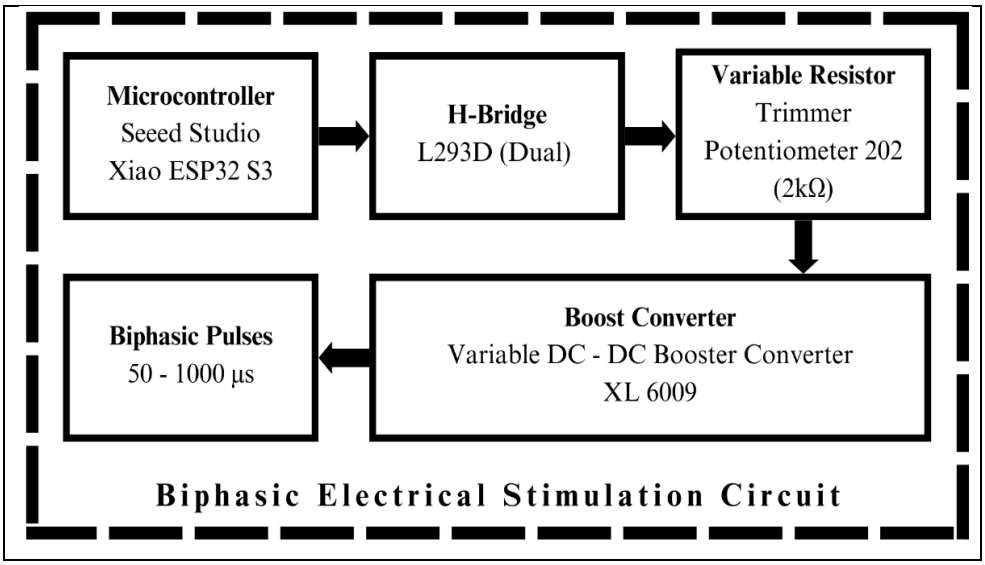
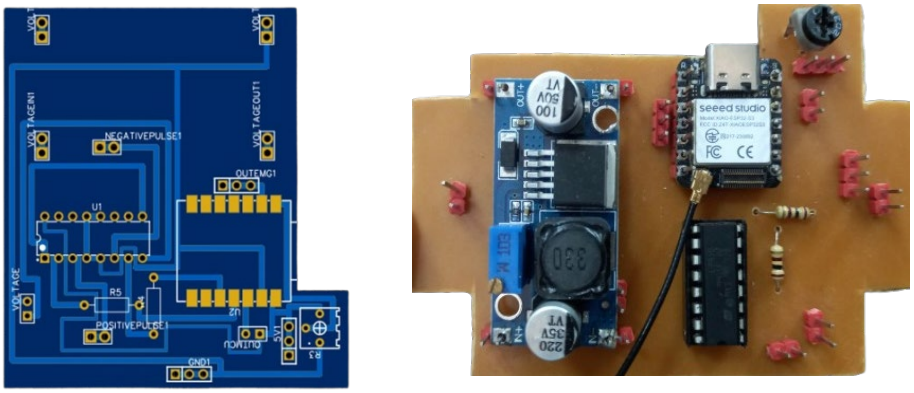


Fig. 1 *General block diagram representation of biphasic electrical stimulation circuit*

2.2 Printed Circuit Board

As shown in Figure 2 (a), a laser-produced single-layer printed circuit board with dimensions 88.77 mm in length and 63.26 mm in width is used to build the circuit. Effective signal routing is given priority in the design, and the L293D IC is positioned near the microcontroller to reduce signal interference and guarantee peak performance. The traces are kept thick to provide thermal resistance against the high voltages. The Printed Circuit Board with the through-hole components mounted on it is shown in Figure 2 (b). The 88.77 mm long by 63.26 mm wide PCB design is ideal for through-hole component installation to provide dependable electrical connections, sufficiently thick paths for enduring high voltages.



(a) (b)

Fig. 2 *PCB (a) Layout; (b) Biphasic electrical stimulation PCB*

2.3 Power

The purpose of a charging and power distribution circuit is to effectively distribute voltage to different parts of an electronic system and control the charging of a power source, such as a rechargeable battery. It is developed to supply operating voltage to the microcontroller and the electrical stimulator PCB. Figure 3 displays a block schematic of a charging and power distribution circuit intended to supply voltage to different parts of a portable device. A 3.7V Lithium-Ion rechargeable battery, which acts as the circuit's main energy source, is at its core. When connected to an external power source, a TP4056 charging module is in charge of effectively recharging the battery. The circuit's entire power supply is managed by a power button, most likely an SPST (Single Pole Single Throw) switch. A distribution module distributes the battery's electricity to the different parts after it has been turned on. This module controls the power flow and guarantees effective use, frequently combining PCBs and a microcontroller. To convert the battery's voltage to higher levels (5V, 8V, or 12V) as needed by various system components, a DC-DC boost converter—more especially, the CKCS BS01—is essential. The device functions independently and recharges simply thanks to this adaptable circuit design, which offers a dependable and effective power solution for a variety of applications.

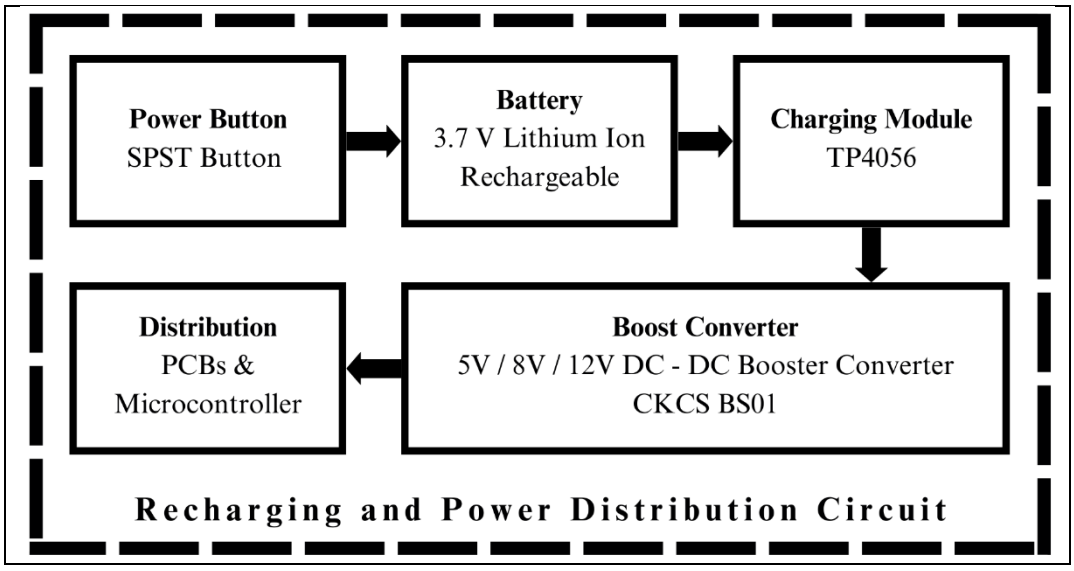


Fig. 3 *Power distribution circuitry with rechargeable battery*

2.4 Device Case

A popular 3D printing technique called fused deposition modelling, often referred to as fused filament fabrication, produces things by layer-by-layer extrusion of molten thermoplastic filament. The filament is deposited onto a build platform by a heated nozzle moving in accordance with a computer-generated design. The 3D shape is progressively constructed as each layer cools and solidifies, creating a strong link with the one before it. The way we design and make things has been completely transformed by 3D printing, and Polyethylene terephthalate

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glycol, commonly known as PETG or PET-G filament, has become a common option for 3D printing the cases. PETG may be post-processed to provide a variety of finishes and comes in a broad spectrum of colors. Because of these characteristics, PETG is perfect for 3D printing a wide range of cases, including those for smartphones, tablets, electronics, and specially made cases for certain gadgets. By using PETG, 3D printing provides a sustainable and adaptable method of producing fashionable and protective cases, lowering dependency on conventional plastics and fostering a more environmentally responsible future. 3D CAD version of casing for device is shown in Figure 4. Connectors, switches, or other user interfaces are probably accessible through the cutout on one side. The model has a rectangular base, but one side has a more detailed cutout. Dimensions are 55 mm in height, 225 mm in length, and 90 mm in width.

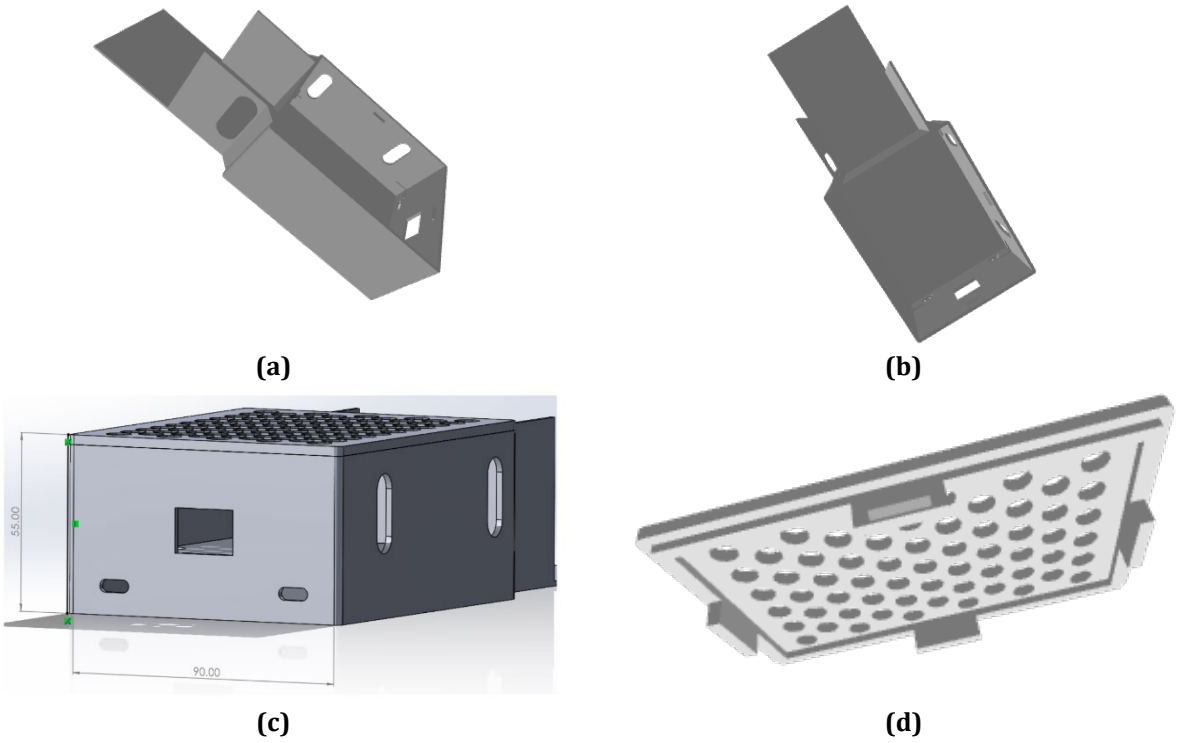
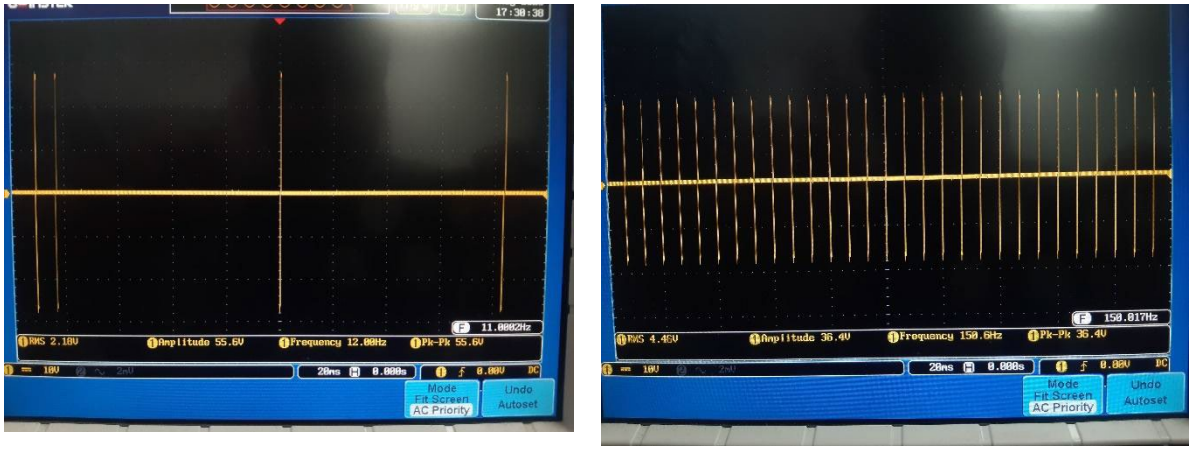


Fig. 4 *Views of CAD model of device from different angles*

3. Results

A biphasic pulse waveform produced by timer interrupts on a digital oscilloscope is seen in Figures 5 (a) and (b). Transcutaneous Electrical Nerve Stimulation therapy frequently uses this particular pulse form, especially to treat pregnancy-related discomfort. Compared to monophasic pulses, biphasic pulses reduce the possibility of tissue damage and skin irritation, making them the preferred option for TENS devices. To maximize the therapeutic impact for pregnant women who are in discomfort, the oscilloscope's exact timing and amplitude of the pulses may be changed. The waveform is consistent over time, and its parameters, like amplitude, pulse width, and frequency, can be changed accordingly. Furthermore, the safety limits for current are kept under 2 mA. This is the safe range for current output in electrical stimulators and can be used by the user without any harmful effects. The current limiter is used to limit the current within this range. As far as the cost is concerned, electrical stimulators available commercially are quite expensive compared to this 10 USD prototype while providing the exact same customizable features like adjustable amplitude (intensity), frequency, and pulse width. The price range of commercially available Omron, Beurer, and Corebelt stimulator ranges between 30 – 250 USD. Therefore, the proposed initial prototype is quite cost-effective and the cost can be further reduced if it is developed on a mass scale. Besides being affordable, this prototype is also easy to use and portable, making it a great option for home-based therapy with guidance from a healthcare provider. Its compact size and battery-powered design mean that pregnant women can use it comfortably without needing to visit a clinic every time. Users can also adjust the intensity, frequency, and pulse width to match their comfort level, allowing for more personalized and effective pain relief. In the future, features like wireless connectivity and a mobile app could be added to let doctors monitor progress remotely and help users track their sessions. This budget-friendly biphasic stimulator offers a practical and accessible solution for managing pregnancy-related pain.



(a) **(b)**

Fig. 5 *Variation of amplitude and frequency of biphasic pulses (a) 55V & 12Hz; (b) 36V & 150Hz*

The device's printed circuit board is shown in Figure 6. It combines a microcontroller, power supply, potentiometer, and electrode pads onto a single PCB, is intended to help manage pregnancy pain. The device's pulse production, timing, and intensity are all managed by the microcontroller. Through the electrode pads, the patient receives biphasic electrical pulses from the pulse generator. The proposed prototype is a compact, custom-designed portable stimulator for therapeutic applications, featuring electrode pads for delivering electrical stimulation to the body. The central controller is the Xiao ESP microcontroller, which manages signal generation and device control. An L293D IC functions as a motor driver to regulate the current flow to the electrodes. A boost converter increases the voltage to suitable levels required for stimulation, and a potentiometer is included to manually adjust the output intensity. The circuit provides positive and negative output terminals connected to two electrode pads, enabling controlled electrical pulses for therapeutic or diagnostic use. The system is designed to deliver biphasic electrical stimulation, where current alternates between positive and negative phases. This approach ensures balanced charge delivery across the tissue, minimizing the risk of skin irritation, tissue damage, or electrode corrosion, making it especially suitable for prolonged and safe neuromuscular or pain-relief therapies.

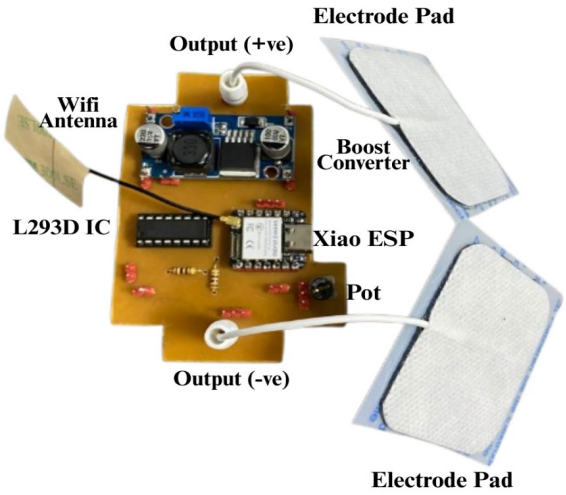


Fig. 6 *PCB of electrical stimulation device*

The model is carefully examined for faults before 3D printing, support structures are added where necessary, and print settings such as layer height and infill density are established. The model is exported as an STL file, a common format for 3D printing, when it is ready.

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The device is shown in Figure 7.

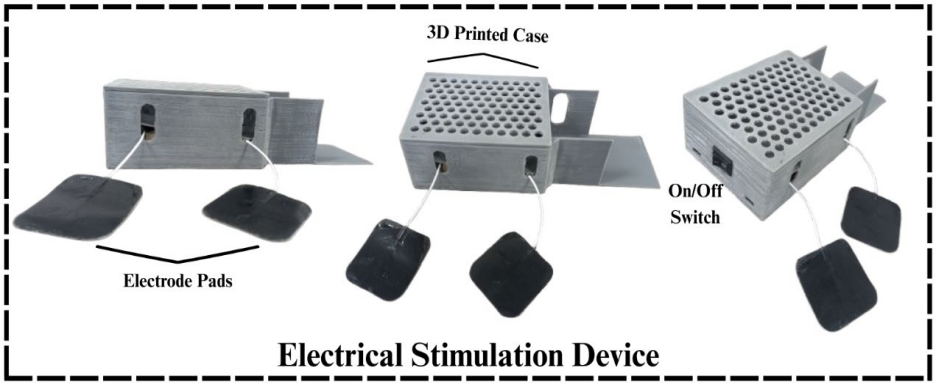

Fig. 7 *Electrical stimulation device*

4. Discussion

The development of a cost-effective and portable biphasic electrical stimulation device for non-pharmacological pain management during pregnancy addresses a significant clinical need in maternal healthcare. Given the high prevalence of pregnancy-related pain, especially in the lower back during the third trimester, the demand for effective, non-drug-based therapeutic alternatives is substantial. Pharmacological interventions, though effective, carry inherent risks for both the mother and the fetus. Hence, non-pharmacological alternatives, particularly electrical stimulation, provide a safer and often more acceptable option. This study demonstrated the successful initial design and implementation of a biphasic electrical stimulation device using low-cost, readily available hardware components. The core of the system, the ESP32-S3 microcontroller and the L293D H-bridge IC, ensures the precision and reliability of the generated waveforms, which are critical for therapeutic efficacy and user safety. A boost converter is used to boost the voltage, accordingly, using the potentiometer connected to it. The design of the PCB is optimized to minimize the line frequency noise and avoid overheating.

The key points that make this different from other devices include affordability, small size, and modularity. It is scalable as it can be made using the readily available hardware components. Unlike many clinical-grade stimulators that are bulky and expensive, this design is both scalable and suitable for home usage. Its rechargeable battery enhances its portability for daily pain management. The effectiveness of electrical stimulation in managing pregnancy and menstrual pain is well-supported in the literature [11][14][16][18]. Several randomized trials and observational studies have highlighted the reduction in pain intensity, improved maternal satisfaction, and reduced dependency on pharmacological agents such as pethidine [12][15][17]. It is effective in providing women with better autonomy and confidence. In the future, this device will be tested on real subjects once it is approved by the medical device regulatory body. Therefore, the assessment of safety, comfort, and real-world efficacy will be done during the clinical trials.

This device also has the potential to make a big difference in places where medical resources are limited. In many rural or underserved areas, pregnant women often don't have access to reliable pain relief due to the high cost of medication or a lack of nearby healthcare facilities. Since this biphasic stimulator is affordable, easy to use, and non-invasive, it could be a great alternative in such settings. It gives women more control over their own pain management without the need for drugs, which can be especially helpful when medical supervision is limited. Because the design is simple and modular, it can be easily repaired or adapted using locally available parts. With basic guidance from healthcare workers, this device could be part of community health programs, helping more women manage pregnancy-related pain safely and effectively.

There are some applications in which this work can be used in the future. For example, the integration of wireless modules such as Bluetooth or Wi-Fi would allow real-time monitoring, control via a mobile app, and cloud-based data analysis. These features would facilitate personalized treatment plans, remote therapies, and continuous tracking of pain patterns, contributing to improved maternal health facilities. However, the study does have limitations. While the device is developed in an optimized way as a research prototype, clinical validation in a larger and diverse patient population is needed to assure therapeutic efficacy, safety, and durability. User feedback, ergonomic considerations, and device comfort during prolonged use must also be assessed in future trials.

Besides the benefits mentioned above, another significant change in the healthcare of modern mothers that can be seen by the creation of this biphasic electrical stimulation device is the focus on accessibility, safety, self-control, and technological empowerment. The movement towards domestic treatment equipment has significantly increased within the past ten years due to the escalating cost of hospital care, non-availability of

specialized care in country areas as well as the international preference of non-pharmacological forms of care. This device resonates well with these worldwide healthcare trends as it provides a therapeutic modality that is clinically relevant and does not necessitate the use of specialized medical infrastructure to be used on normal practice. In addition, the application of biphasic pulses is one of the design options that strengthen patient safety. Biphasic waveforms can be used to reduce the chances of electrochemical reactions at the skin-to-electrode interface, an issue which is often linked to monophasic stimulation. This may cause burns, skin irritation or tissue fatigue caused by repeated delivery of unidirectional current which results in ion build-up. Such accumulation is eliminated through the balanced charge distribution in biphasic stimulation which makes the therapy sessions longer and safer and more comfortable particularly in pregnant women who tend to have an increased sensitivity to skin contact. Also, biphasic pulses increase muscle recruitment and activation of sensory nerves and reduce discomfort which is necessary to follow up home-based therapy protocols.

One more point that should be discussed is that the proposed prototype has a high level of customization. The restrictable frequency, amplitude and pulse width options provide the healthcare provider with the means of sliding the adjustable stimulation parameters to suit the unique pain profile of an individual patient. Pain associated with pregnancy differs significantly among the women with some complaining of lower back pain, others complaining of pain in the pelvic girdle, sciatica type pain or overall muscular tension. The availability of equipment allowing the possibility of fine-tuning the nature of stimulation guarantees that the therapy will be patient-centered and personalized. Longitudinal treatment also occurs well under customization since the intensity of pain varies among the stages of pregnancy; a device with a flexible nature avoids over stimulation or under treatment. Technically, the application of inexpensive but high-performing devices such as the ESP microcontroller and L293D driver can be used to prove the fact that medical-grade functionalities do not have to be prohibitive in their expenses. This presents a possibility of increasing the scope of biomedical engineering research in low- and middle-income nations where costly hardware is a frequent issue. It can allow students, researchers, and clinicians to continue improving and validating the device, which will result in a long-term medical innovation ecosystem. Besides, the design is modular, which promotes prototyping and experimenting. Individual modules can be modified (e.g. the motor driver can be replaced by a special H-bridge that is specifically bio-stimulation-capable, or more sophisticated boosting circuitry can be added) without necessarily redesigning the whole system.

PCB design factors are also important in enhancing performance of the devices. Reduced line frequency interference, optimization of trace length, and sufficient separation of high current and low current channels are some of the factors that lead to signal stability. These hardware optimizations are such that the pulse delivered does not generate noise spikes, distortions and unwanted frequency artifacts, which can affect the therapeutic effectiveness. The delivery of clean waveforms is particularly relevant to the stimulation of the superficial nerves or nerve fibers of muscles since uncontrolled variations of the waveforms may cause discomfort or erratic treatment results. Society is of a larger view also. Pregnant women in most regions of the world lack access to routine services of pain management because of logistical, financial, or cultural reasons. Ailments like low back pain during pregnancy that goes unattended by most due to its perceived normalcy during gestation are not given a proper clinical care. Consequently, women are also left alone to treat discomfort on their own, and it can result in lower mobility, a higher level of stress, and a lower quality of life. Such a device, which can be carried anywhere, is not only affordable but is also user-friendly, can make the practice of pain-relief become democratic in the sense that the therapeutic apparatus will be in the hands of those who need it the most. This empowerment does not only help to alleviate maternal discomfort but can also lead to improved fetal outcomes because it helps to decrease stress-related physiological reactions.

In subsequent models, the addition of wireless communication features will be able to add a significant improvement in the function and effect of the product. As an example, mobile application could be supported by Bluetooth connectivity to enable a user to monitor their pain score progress, duration of session, stimulation parameters being used and perceived effectiveness. An equipped version with Wi-Fi capability would enable the clinician to remotely track the usage patterns or even change the therapeutic recommendations. Large-scale, anonymized data collection in future may be facilitated by cloud integration and aid researchers in delving into the pain patterns of the populations in the context of pregnancy. All these aspects of the personalized healthcare ecosystem mean that the real-time feedback and constant monitoring are used to detect the complications or the use of ineffective pain management methods early. Although the current design is very promising, it has a number of limitations that have to be noted. As the prototype is still in the preclinical phase, the assertions about its therapeutic utility are founded on known literature and principles of electrical stimulation in lieu of the actual patient response. To test the levels of comfort, long-term tolerability, ease of use, and real-world efficacy, clinical testing will be needed. The impact of various stimulation profiles on various pain conditions should also be studied in such studies to confirm the flexibility of the device between patients with different needs. The other constraint is the lack of sophisticated safety measures like auto-shuts or electrode removal sensors, or skin impedance sensors. These are not the features required to develop the prototype, but critical ones that can enable the medical deployment to receive regulatory approval.

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Technically, the proposed device is enhanced in its reliability with proper PCB design considerations, such as thick copper traces to withstand high voltages, placement of components to reduce as much as possible the electromagnetic interference of components, and separation of low-power control circuitry and high-voltage stimulation paths. The current-limiting mechanism present in it makes sure that stimulation does not exceed the commonly agreed 2 mA limit of safety in clinical standards of neuromodulation. Also, the rechargeable lithium-ion battery prevents the need to use mains power, which adds further level of user safety and portability. All these design solutions add to a strong and secure stimulation platform that can be used throughout the course of pregnancy.

The other important difference of the proposed work is its affordability and applicability to the low resource healthcare settings. The prototype costs a total of about 10 USD as a component cost and this is much lower than commercial devices that cost between 30 USD and more than 250 USD. The cost savings is done without undermining the essential therapeutic parameters including the integrity of the waveform, the safety current limits and the compliance to the voltage requirements. The reason is that the device is relatively inexpensive, which means that it can be used especially in developing countries and rural environments in maternal care where people frequently lack access to pharmacological pain treatment and highly qualified medical institutions. The proposed system would be consistent with the global maternal health goals of minimizing unnecessary exposure to medications during pregnancy as they facilitate safe and home-based pain management.

The proposed system has a number of technical and practical strengths in comparison to commercially available transcutaneous electrical nerve stimulation (TENS) devices. Commercial products like Omron, Beurer, and Corebelt are usually fixed stimulation-based models with a restricted range of parameter customization, and often aim at the general pain reduction, but not at pregnancy-specific needs. Contrastingly, the suggested device will allow adjusting pulse amplitude, frequency and pulse width separately using a microcontroller-based architecture. Such degree of tailoring is necessary because the pain that accompanies pregnancy is highly differentiated in terms of intensity and location in different body parts depending on the gestation period. In addition, the biphasic waveform gives the benefit of charge balance across the tissue-electrode interface to minimize the potential of skin irritation and electrochemical tissue damage, which is a continued concern in a number of monophasic stimulators cited in literature that are of low cost.

The device is also based on manual control using a potentiometer thus creating the risk of operator error especially to those who are not conversant with electrical appliances. As an illustration, the pulse amplitude should not be adjusted too high to result in discomfort. The following version of the device should include preset modes, i.e. mild pain, moderate pain, or pelvic pain relief, as it would be easier to control and would be safer. Such modes have the capability of automatically setting ideal ranges of frequencies and amplitudes in accordance with set therapeutic standards. Lastly, the eco-friendly design options, including rechargeable batteries and biodegradable electrode materials, might be also used to contribute to the sustainability and acceptance of the device. With environmental responsibility becoming a growing principle in the global healthcare systems, the use of green materials and reduction of electronic waste could become the necessary aspects of the development of medical devices. This device is an important initiative to enhance the pain management options available to women during pregnancy and perhaps to other patients at large since it is cheap, convenient, customizable, and safe.

5. Conclusion

In conclusion, a solution in the form of a device that is a practical, cost-effective, and scalable solution to a common and often undertreated problem, pregnancy-related pain, is proposed. The electrical stimulation device designed here demonstrates strong potential as a non-pharmacological, user-friendly, and portable tool for pain management. Its affordability makes it a promising non-pharmacological substitute for pregnancy pain management, particularly in home care and low-resource clinical environments. Future work should focus on extensive clinical testing, user interface development, and integration into broader maternal health systems. If validated in clinical settings, the device could contribute meaningfully to improving the quality of life for women by offering a safe, accessible, and empowering method of pain relief during critical stages of pregnancy.

The paper describes the design and development of a biphasic, portable, and customizable, and economic bipolar electrical stimulation device designed to manage the non-pharmacological pain during pregnancy. The proposed system combines safety-oriented generation of waveforms, modular hardware design, and cost to overcome significant constraints of commercially available stimulators. Outside of pain management during pregnancy, the device demonstrates promise in the implementation of the device in other areas of life including the treatment of menstrual pain and postnatal pain. In the future, the development will be aimed at clinical validation, ergonomics optimization, and the introduction of intelligent functions such as wireless connectivity and mobile app support. As it is further validated, the suggested device will be a scalable solution to maternal pain management, especially in low- and middle-income locations where the availability of safe and affordable technologies used in healthcare is a problem.

Clinically and safety wise, biphasic electrical stimulation will be used in the proposed device; this is a significant design decision that is in line with the existing norms of neuromodulation. Biphasic waveforms facilitate equal charge delivery at the skin- electrode interface thus reducing the risk of tissue polarization, skin irritation and electrode degradation when used over long periods. The feature is especially important with pregnancy, where physiological sensitivity is extremely high, and safety margins have to be stringent. Additional measures to keep the stimulation within acceptable therapeutic limits include the provision of current-limiting circuits and the regulated increase of voltage. Consequently, the proposed system satisfies functional requirements and proves to be highly focused on the safety of both the mother and the fetus, which is one of the primary concerns of the non-pharmacological interventions in obstetric care.

In addition to the direct use of the proposed electrical stimulation device, it can be a part of a greater transformation of the healthcare system to be patient-centered and technology-enabled. The device enables autonomy and decreases the need to use pharmacological interventions and repeated visits to the clinic because it provides users with a safe and self-managed option of pain management. This method is especially applicable in the contemporary healthcare where the focus is on the preventive care, distant treatment, and therapeutic decisions. As it evolves, such as with data logging, clinician feedback loops and integration with digital maternal health platforms, the device may be integrated into an intelligent pregnancy care ecosystem. This kind of integration would not only contribute to the individual treatment outcomes but also be useful in the population level in understanding the trend in pain management, which would eventually be used in improving maternal health approaches and evidence-based clinical decision-making.

This study develops a solid base on the derivation of cheap, safe, and purpose-specific electrical stimulation systems to suit maternal care. Although the current research is based on hardware design, validation of the waveform, and feasibility, the upcoming research would emphasize on complete clinical trials that would determine the therapeutic efficacy at various periods of pregnancy and the different degrees of pain. Other guidelines are the integration of adaption stimulation algorithms, more safety measures like impedance monitoring and automatic shut off system, and adherence to international standards of medical device regulation. Through the progressive development in these directions, the proposed device could become a prototype of a clinically applicable solution, which will add to the sustainable, equitable, and technology-based approach of pain management in the contemporary healthcare systems.

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Conflict of Interest

We declare that there is no conflict of interests regarding the publication of the paper.

Author Contribution

The authors confirm their contributions to the manuscript as follows: ***Study conception and design:*** *Muhammad Omar Cheema, Zia Mohy Ud Din, Jahan Zeb Gul;* ***Data collection:*** *Muhammad Omar Cheema, Zia Mohy Ud Din;* ***Analysis and interpretation of results:*** *Muhammad Omar Cheema, Zia Mohy Ud Din, Jahan Zeb Gul;* ***Draft manuscript preparation:*** *Muhammad Omar Cheema, Jahan Zeb Gul, Fawad Salam Khan;* ***Critical review and final approval:*** *Zia Mohy Ud Din, Fawad Salam Khan, Mohd Norzali Haji Mohd. All authors reviewed the results and approved the final version of the manuscript.*

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