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ORIGINAL RESEARCH ARTICLE

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Revolutionizing Spinal Care: 3D Printing a Customized Ultrasound-Reinforced Orthosis for Scoliosis Treatment

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Abstract: The spine is a critical component of the human body, supporting balance, flexibility, and natural movement. However, scoliosis, a condition where the curvature of the spine exceeds 10 degrees, can lead to health complications. In this research, we designed and 3D printed a customized orthosis using the Blender program, supported by ultrasound sensors controlled by an Arduino UNO circuit. Our innovative approach aims to accelerate healing and alleviate pain in patients with scoliosis. This study serves as a starting point for the development of research in the orthotic treatment of scoliosis of the spine by integrating two treatment techniques at the same time. Our ultrasound-reinforced orthosis represents a significant advancement in spinal care, offering a promising solution for scoliosis treatment.
Keywords: Spinal orthosis; Ultrasound waves; Scoliosis; 3D printing.

1. Introduction

Orthopedic appliances include precision and creativity in the design and manufacture of external orthoses (orthotics) as part of the patient's treatment process, and orthotic devices work to control weak or deformed areas of the body of a physically disabled person. Orthotic devices can be used on different areas of the body including the upper and lower limbs, the skull, or the spine[1].

Common orthotic interventions include scoliosis orthotic devices, HALO devices used in life-threatening neck injuries, and ankle-foot orthoses used in the rehabilitation of children with cerebral palsy[2]. Recently, orthoses have been designed to significantly realign the spinal bones in patients with postural scoliosis[3]. Scoliosis treatment methods have gradually developed with the advancement of scientific techniques, and a lot of research and scientific applications have been carried out in this field, until orthotic devices have become one of the important therapeutic devices used in the medical field.

There has been some research and experiments conducted in this field. Bidari *et al*.[4] compared braces made in the traditional way with those made through two computer-aided design and numerical analysis techniques: CAD-CAM, and CAD-FEM (Computer-Aided-design, Finite Elements modeling). The ideal shape of scoliosis braces made using digital fabrication methods was reached in the anterior plane, and in the sagittal plane, where it was found using digital simulation that the printed braces were found through digital simulation to be more effective than traditional braces in the sagittal plane[4]. In the context of using ultrasound in the treatment process and relieving pain resulting from the orthotic process, recent studies investigated the use of ultrasound in relieving lower back pain[5]. It seems that ultrasound therapy is one of the safe and effective methods used in orthopedic and vertebral treatments in addition to traditional methods such as exercise[6], and electrical stimulation therapy[7]. It has been shown that ultrasound therapy can be applied in two modes, continuous or pulsed, and while the continuous mode delivers ultrasound waves non-stop throughout the treatment period, the discontinuous mode delivers pulses of waves and echo processing to deliver intermittently ultrasound for medical imaging that It transmits pulses of ultrasound and processes the echo that reflects the condition and elasticity of the tissue[8]. In general, ultrasound therapy expresses unidirectional energy delivery using the tip of the crystal probe towards the area of injury with a frequency between 1 and 3 MHz and intensity between 0.1 W/cm^2 and 3 W/cm^2[9]. A number of studies were undertaken including one on a sample of between 30 and 445 people, ranging in age from 31 to 56 years. The duration of treatment ranged from 3 weeks to six months, using several types of treatment. Six randomized clinical trials that evaluated the effectiveness of ultrasound therapy on lower back pain were included. It was shown that therapeutic ultrasound was more effective than other methods in reducing pain associated with the central nervous system[8-11].

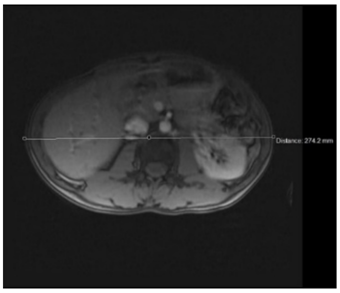
Lou *et al*.'s study[12] was titled “Ultrasound-assisted Brace Casting for Adolescent Idiopathic Scoliosis”, where twenty-six people participated in this pilot study distributed as 17 in the control group and 9 in the intervention group. The results indicated the effective role that the 3D ultrasound system can play as a radiation-free method for determining the optimum pressure level and location to obtain the best intra-brace stimulus correction during brace casting. The average number of radiographs per subject taken before final brace implementation with the intervention group was significantly lower than the control group. The safety of using ultrasound in the treatment process and not causing any harm to the patient was confirmed through studies and research, including calibration and electrical safety studies using therapeutic ultrasound for orthopedic, where the study of Daniel *et al*.[13] aimed to determine the extent to which the ultrasound equipment used by Chiropractors to calibrate conditions, electrical safety standards, and evaluate the frequency of ultrasound therapy use. A cross-sectional study tested 45 ultrasound machines to determine the extent to which the ultrasound equipment used by Chiropractors complied with conditions, electrical safety standards, and evaluated the frequency of ultrasound therapy use. It was found that a large proportion of ultrasound machines in chiropractic clinics presented a slightly increased wave intensity to the patient. The aim of the research is to speed up the healing process and relieve pain in patients with scoliosis, as this research serves as a starting point for the development of ultrasound-assisted orthotic treatment of scoliosis by integrating two treatment techniques simultaneously.

2. Orthosis Design

2.1 The Studied Case

A magnetic resonance images series was obtained using a device (SIEMENS MAGNETOM Symphony at 1.5 T, Al-Bassel Hospital, Tartus, Syria) of a 32 male patient with lumbar scoliosis and converted into 3D models using Blender software. **Figure 1** shows the magnetic resonance image of the patient, and outlines the studied section in which the measurements have been performed.

A



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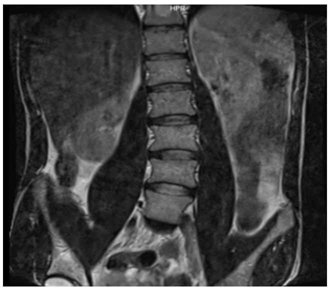

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Figure 1. Magnetic resonance imaging (MRI) of the studied case, highlighting the presence of scoliosis in both the sagittal and axial planes. (**A**) The sagittal plane showing the studied section (**B**) The axial plane section studied. (**C**) The whole studied case showing the scoliosis in the sagittal plane.

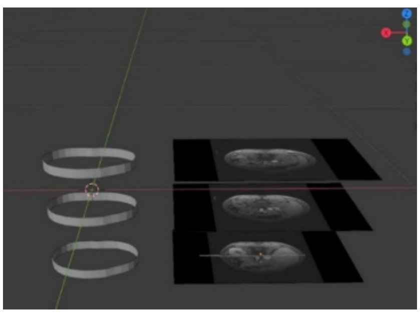
2.2 The 3D Design

The 3D model of the customized orthosis was created based on the patient's medical image obtained through magnetic resonance imaging (MRI). The MRI allowed us to study the case and determine the design considerations related to the geometry, size, and materials that would be necessary for creating a successful 3D model. Working in 3D design allowed us to have a close understanding of all the details of the model, ensuring that it was tailored to the patient's unique anatomy and provided effective support for their scoliosis condition.

At this stage, the 3D model was built by locating the decompression and scoliosis sites on the patient's medical image, as shown in **Figures 1A and B**. The 3D model provided a visualization of the affected area of the spine, enabling us to design an orthosis that provided targeted support and promoted bone remodeling and tissue regeneration.

2.3 The Slicing of the Model

After taking the cross-sections and surrounding them using the Blender program, for each section of the patient’s body as in **Figure 2A**, the sections were connected to each other, taking into account the real distance between the sections (2 mm), then a mechanical pressure point was created using the opposite pad of scoliosis, and two holes corresponding to the pressure pad were created to install the ultrasound generator to treat muscle contraction that causes scoliosis, as shown in **Figure 2B**.



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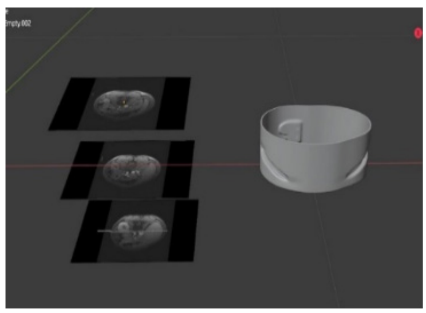

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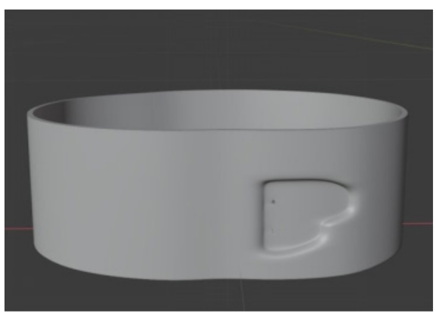

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Figure 2. Design of scoliosis orthosis. (**A**) The contour outline on different slices used to produce the 3D model. (**B**) The assembly of different slices into a unified numerical and personalized model. (**C**) The overall resulting model after assembling the separated slices.

2.4 The 3D Printing

The design of the customized orthosis was transferred to the 3D printer software in STL format. This allowed us to create a digital model of the orthosis that could be used to manufacture the device without any human intervention. The 3D printing process was automated, starting from the measurements obtained from the patient to the manufacture of the device.

The use of 3D printing technology enabled us to create a customized orthosis that closely matched the anatomical shape of the installation area. The error rate in the final product was very small, ensuring that the orthosis fit the patient's unique anatomy and provided effective support for their scoliosis condition.

Figure 2C shows the final shape of the orthosis after 3D printing. The orthosis was designed to provide targeted support to the affected area of the spine, promoting bone remodeling and tissue regeneration. The use of 3D printing technology allowed us to create a customized orthosis that was both effective and non-invasive, providing a promising treatment option for patients with scoliosis.

2.5 US Wave Sensor Adaptation Circuit Design

The ultrasonic sensors are controlled by the Arduino UNO circuit in order to speed up the healing process and relieve the patient's pain. In this research, we programmed the Arduino circuit connected with the ultrasonic sensors through a set of commands and instructions written in Arduino C that aims to give a command to the ultrasonic sensors. An audio signal starts transmitting waves for 10 minutes through the ON/OFF button, with a text message displayed on the LCD screen stating that exposure to waves has started.

The exposure to the waves is switched off after the expiry of the exposure time (10 minutes) automatically through a timer with a warning beep to indicate the termination of the exposure process. The start time of exposure to the waves is determined by the doctor in coordination with the patient at his home to ensure his comfort and not to move him to medical centers. **Figure 3** shows the diagram of the circuit. It consists of the following components:

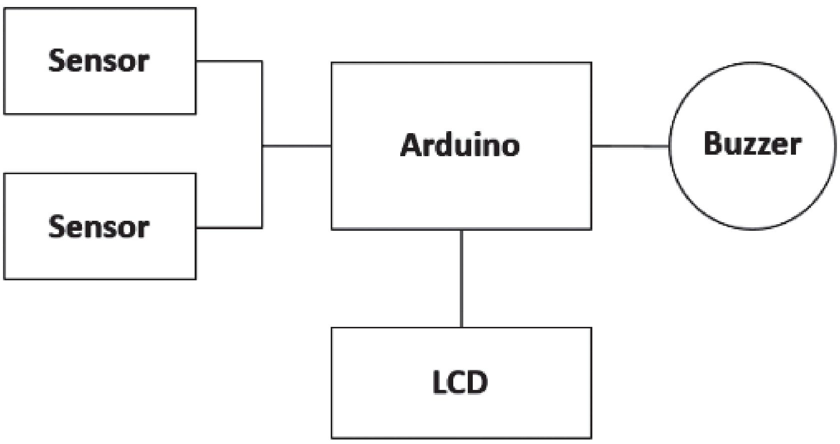

Figure 3. Circuit diagram.

2.5.1 Ultrasound Source (US Sensor)

In our study, the ultrasound sensor (shown in **Figure 4A**) was a critical component of the treatment system. The sensor was placed on the contracture muscles that were causing scoliosis, next to the mechanical pressure point with a corrective effect for scoliosis through the orthosis. By placing the ultrasound sensor at the site of scoliosis, we were able to deliver ultrasound waves directly to the affected area at a frequency of 3 MHz, promoting bone remodeling and tissue regeneration. The ultrasound waves had a corrective effect on scoliosis by enhancing the mechanical pressure provided by the orthosis and accelerating the healing process. The ultrasound sensor itself was a small, lightweight device that could be easily positioned on the patient's body. The sensor was designed to transmit and receive ultrasound waves, enabling it to both deliver the treatment and monitor its effectiveness. The use of the ultrasound sensor provided a non-invasive and painless treatment option for patients with scoliosis, eliminating the need for more invasive procedures and reducing the risk of complications.

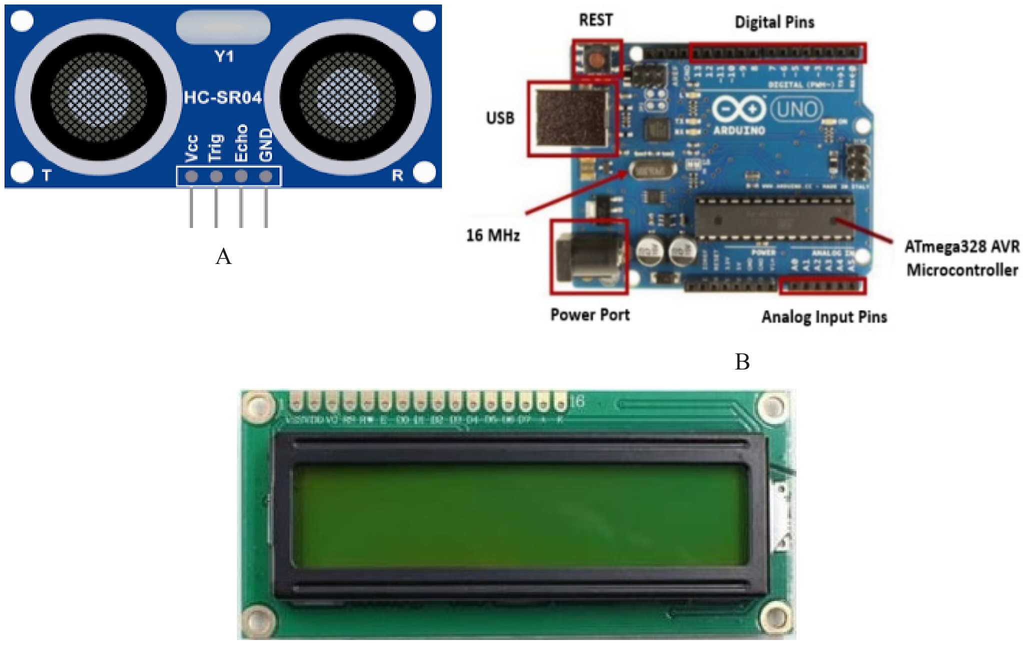

Figure 4. Arduino components used to form the acquisition and treatment system. (**A**) Ultrasonic part used to send the waves used in bone remodeling. (**B**) Arduino Mega system used to control all inputs and peripherals of the system. (**C**) LCD system used to input the parameters and display the progress of the treatment.

2.5.2 Control Unit

In our study, we used the Arduino circuit as shown in **Figure 4B** to control the ultrasound signal transmission and monitor the treatment process. The Arduino circuit is a development board that is equipped with a software environment for the AVR controller from Atmel. The circuit is open-source, meaning that anyone has the right to use and modify its programs and give different operating commands to all circuits connected with it. This made it easy for us to customize the operation of the circuit to suit our specific requirements. The appropriate electrical supply to the controller was secured by using a battery to provide the supply voltage (Vs 5+). The use of a battery as a power source ensured that the circuit could be used in a portable and flexible manner, making it suitable for use in a clinical setting. The battery also provided a stable supply voltage, ensuring that the circuit operated reliably and accurately.

2.5.3 Display Screen

In our study, we used an LCD screen (shown in **Figure 4C**) to display the status of exposure to ultrasonic waves. The use of the LCD screen provided real-time feedback to the user, enabling them to monitor the progress of the treatment and ensure that it was functioning correctly. The LCD screen was connected to the Arduino circuit and was powered using appropriate electrical feeding to display the relevant information. The information displayed on the LCD screen included the start and end time of the treatment, the current status of the treatment, and any error messages that may have occurred during the treatment process. The use of an LCD screen provided a user-friendly interface for patients and healthcare professionals, and helped to ensure that the treatment was delivered accurately and effectively.

2.5.4 Clinical Application Software

The treatment protocol in our study was installed programmatically within the Arduino circuit, which was connected to the ultrasound sensor. The circuit was programmed to operate via a start button, which initiated a 10-minute exposure period. During this time, the ultrasound signals were transmitted through the orthosis and into the affected area of the spine. The exposure period was automatically ended through a timer and an alarm that worked automatically to indicate the termination of the ultrasound exposure. This ensured that the treatment duration was consistent and standardized across all patients. Once the exposure period was completed, the circuit automatically turned off the ultrasound signal, ensuring patient safety and preventing overexposure to the ultrasound waves. The use of an automated treatment protocol enabled us to ensure accurate and consistent treatment delivery, which is critical for effective treatment outcomes.

2.6 Final Scoliotic Spinal Orthosis

After the previous steps, the full design and settings were completed and a miniature orthosis model assisted by ultrasound technology was ready to be applied. The goal of this model was to speed up the healing process of scoliosis and reduce the pain caused by the mechanical stress of the correction process using the orthotic device. The ultrasound-assisted miniature orthosis was designed to provide targeted support to the affected area of the spine, promoting bone remodeling and tissue regeneration.

Figure 5 shows the shape of the ultrasound-assisted miniature orthosis device. The device was designed to be compact and non-invasive, making it easy to wear for extended periods. The ultrasound technology incorporated into the device provided a painless and effective treatment option for patients with scoliosis.

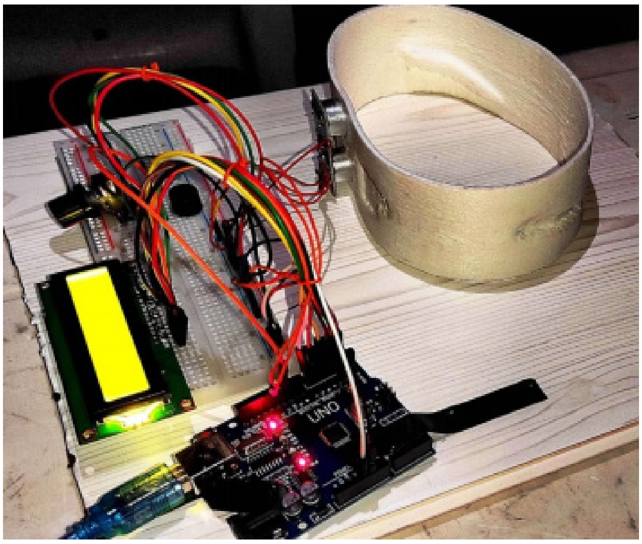

Figure 5. The overall scoliotic spinal orthosis. The components work together to form an integrated system capable of transmitting and processing ultrasound signals, controlling the treatment process, and displaying critical information to the user.

3. Summary and Conclusion

In this prototype, we combined two treatment techniques to address the challenges of treating scoliosis. Based on previous studies and theoretical principles, we developed a customized orthosis (specifically, a lumbar scoliosis case orthosis) supported with ultrasound to accelerate the healing process and alleviate the pain caused by the mechanical pressure. The successful implementation of this integrated system represents a significant advancement in orthotic and support devices that can support the recovery of medical problems.

Our innovative approach represents a significant step forward in developing orthosis and support devices that leverage cutting-edge technology to improve patient outcomes. However, further research is needed to fully evaluate the efficiency of this treatment technique in different pathological groups, as well as assess the accuracy and influence of sensor parameters. We believe that continued research in this area will lead to the development of even more effective and personalized orthosis and support devices, thereby improving patient outcomes and quality of life.

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Author's Contributions

All authors attest that they meet the current International Committee of Medical Journal Editors (ICMJE) criteria for Authorship.

Availability of Supporting Data

Data are available on request from the corresponding author.

Conflict of Interest

The authors declare no conflict of interest.

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