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DEVELOPMENT OF AN AUTOMATED TRANSCUTANEOUS ELECTICAL ACUSTIMULATION DEVICE SYNCHRONIZED WITH RESPIRATION FOR TREATING GASTROESOPHAGEAL REFLUX DISEASES

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ABSTRACT

Gastroesophageal reflux disease (GERD) is a common digestive disorder that usually has symptoms including reflux, heartburn, pain when swallowing, etc. Evolving from traditional needle acupuncture and electroacupuncture (EA), transcutaneous electrical acustimulation (TEA) becomes a popular method for treating GERD with its non-invasive intervention feature. Recently, an even more effective method synchronized with respiration in TEA is emerging. However, the current procedure for conducting synchronized TEA (STEA) treatment is mostly based on patients' manual synchronization, which can generate a big delay or error in the synchronization, significantly compromising the effectiveness of this method. To solve this issue, this research presents a novel STEA device that can automatically detect the user's respiration wave and synchronize with the breath to conduct TEA. With this automated synchronization device, the patients can inhale and exhale with an uninterrupted and normal respiration pace while receiving the TEA treatment, largely simplifying the treatment procedures and enhancing the effectiveness of the method. The system of the STEA device consists of a chest strip respiration sensing element, a stimulation point identifier, and a stimulation current generator. Experiments were conducted to verify human respiration detection, electrical current generation and synchronization. The results demonstrated the feasibility, effectiveness and reliability of the automated device system.

Keywords: Gastroesophageal reflux disease, synchronized transcutaneous electrical acustimulation, automated, respiration.

NOMENCLATURE

Gastroesophageal reflux disease	GERD
Electroacupuncture	EA
Transcutaneous electrical acustimulation	TEA
Synchronized TEA	STEA

1. INTRODUCTION

Gastroesophageal reflux disease (GERD) is a common digestive disorder that occurs when the stomach acid frequently flows back into the upper esophagus[1]. This acid reflux can irritate the lining of the patients' esophagus, creating discomfort and even severe pains. Patients usually experience common signs and symptoms including heartburn (a burning sensation in the chest), regurgitation of food or sour liquid, chest pain, difficult swallowing, disrupted sleep, etc.[2]. This can significantly disturb patients' quality of health-related life and

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cause a large economic burden for the patients and health systems. According to a systematic review[3], it approximates that 18.1%-27.8% of the population in North America are suffering from GERD, and the prevalence in other continents are severe as well with 8.8%–25.9% in Europe, 2.5%–7.8% in East Asia, 8.7%–33.1% in the Middle East, 11.6% in Australia and 23.0% in South America.

The major pathological cause of GERD is the failure of the anti-reflux barrier that allows abnormal reflux to enter the esophagus[4]. From a surgical perspective, the disease is a mechanical disorder, which is caused by the incompetency of the lower esophageal sphincter (LES), a gastric emptying disorder, or failed esophageal peristalsis[5]. Therefore, using surgery to restore the function of the anti-reflux barrier becomes one of the major treatment methods for GERD. The surgical method, especially the laparoscopic surgery for GERD, has shown promising effectiveness with 90% of long-term symptoms improvement[6]. However, the surgical method has high side effects, such as osteoporosis, community-acquired pneumonia, dysphagia, flatulence, and gas-blat syndrome, significantly impacting patients' life quality and increasing ongoing costs[7]. Moreover, although the impairment of LES is considered as the major cause of GERD from a surgical perspective, the exact nature of the anti-reflux barrier is not understood thoroughly. Clinical experience indicates that the pathophysiological abnormalities also involve altered visceral hypersensitivity, impaired autonomic function, and abnormal central processing, which cannot be treated effectively with a surgical method[8].

Acupuncture has been demonstrated to be an effective method for treating various gastrointestinal diseases and has been applied in treating GERD[9]. Electroacupuncture (EA), a modified form of conventional acupuncture method by adding electrical current on the acupuncture needles, has also been demonstrated to be effective in ameliorating the symptoms in GERD[10]. Both conventional acupuncture and EA methods require high-skilled medical professionals to conduct the procedures as the needles need to be inserted accurately through patients' skin. Transcutaneous electrical acustimulation (TEA), a noninvasive and needless method, applies a low-intensity electrical current to acupuncture points with attached electrode pads. This method has been demonstrated to be of high effectiveness to improve gastrointestinal mobility abnormalities and vagal activities for GERD treatment[11]. Moreover, with its noninvasive and self-administrated features, the therapy can be conducted at home and at any time as needed, making the therapy more effective and cheaper. Recently, an even more effective method by synchronizing respiration with TEA is emerging. Led by Dr. Gengqing Song, one of the authors of this paper, the direction of exploring the effectiveness for this synchronized TEA (STEA) has been proceeded in several human subject experiments and clinical trials[12-14]. However, the current procedure of synchronization with respiration in STEA is mainly based on patients' compliance that the patients need to use their own sensation to feel the start of electrical stimulation and then breathe the air to follow the stimulation. This manual synchronization has an ununiformed delay and requires the patients to cooperate tightly in a long term, highly compromising the effectiveness of STEA treatment and increasing patients' cognitive burden.

To enhance the effectiveness of STEA in GERD treatment and move STEA into a practical application level, this paper presents the development of a novel STEA device that could automatically detect the user's respiration wave and synchronize it to conduct acustimulation. With this automated synchronization device, the patients can inhale and exhale with an uninterrupted respiration pace while receiving the TEA treatment, largely simplifying the treatment procedures and enhancing the effectiveness of the method. The system of the STEA device physically consists of a chest strip respiration sensing element and a stimulation current generator. With its small size and a don-doff design, the device is convenient for home self-operation, largely reducing the cost of GERD treatment. Experiments were conducted to verify human respiration detection, electrical current generation and synchronization. The results demonstrated the feasibility, effectiveness, and reliability of the automated device system.

2. METHOD

This paper presents the development of a novel STEA device that can automatically do an intermittent stimulation while being synchronized with the user's breath. This section illustrates the design requirements, structure of the device, respiration wave detection, and the stimulation control system.

2.1 Design parameters and preparation

The procedure of the synchronization mainly includes identifying the start of inhalation, immediately starting the stimulation at the beginning of the inhalation and lasting the stimulation for an interval of time before the end of exhalation. There are two main types of methods to measure the breath rate and waveforms, including a contact-based type and a contactless breath way[15]. The contact-based type usually involves wearing a strip with a strain-gage pressure sensor, a thermistor-based sensor, or a capacitive sensor to measure the chest expansion. The contactless monitoring approach usually used camera-based computer vision, ultra-wide band, or infrared thermography signals to measure the chest expansion remotely. The contactless method is expensive as it needs advanced electrical components and technologies. Thus, our design focuses on a contact-based type sensor that is convenient for a user to wear and detach and has a lower cost. The design approach in this paper for respiration measurement is prone to use a low-cost strain-gage pressure sensor and embed it into a Velcro attach strip.

There are different kinds of stimulation waveforms, mainly including monophasic square waveform, biphasic square waveform, and sine waveform. Studies show no big difference in the effectiveness of pain management among different types of waveforms[16]. Currently, there are no studies on the difference of effectiveness for GERD among different waveforms; thus, we can choose the simplest monophasic square wave as an objective stimulation waveform based on the

assumption that there is no difference of effectiveness on GERD treatment among different waveforms as well. According to the electricity types, stimulators can be categorized into two types, including constant current and constant voltage stimulators. As the constant voltage stimulator has an advantage in easing users' discomfort[17], the design in the paper will choose to use this type. Based on the clinical experience of our physician co-author in this paper and meta-analysis of current publications related to GERD treatment, the amplitude of the voltage needs to be controlled below 20 V, and the pulse of the square waveform need to have an adjustable frequency in the range of 1 Hz-200 Hz[18].

2.2 Overview of the design

Fig. 1 shows the concept of the presented STEA system. The system physically consists of a stimulation controller, a chest strip sensor, and electrode pads. The procedures of the automated control mainly include respiration sensing and stimulation identification and electrical waveform generation. We designed a novel chest strip sensor that is to extract the force information $\boldsymbol{f}$ of the expansion of the chest during breathing. Once the information is extracted, the respiration parameter vector $\boldsymbol{u}$, including the period and calibrated force will be updated and sent to a stimulation identifier. The stimulation identifier will identify the start point of the inhalation and generate a command $\boldsymbol{y}$ and send it to a stimulation driver to start the stimulation electricity generating. The stimulation will last for a certain time within each respiration cycle.

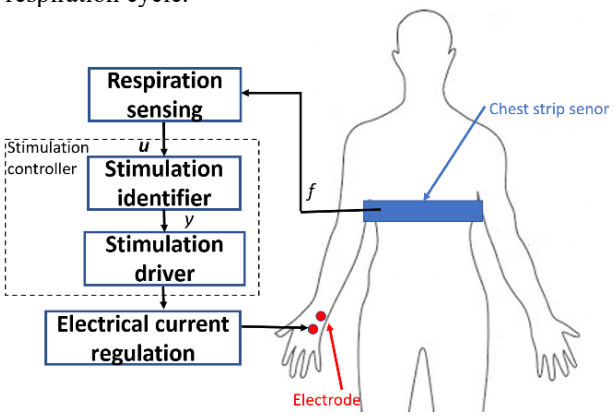


FIGURE 1: CONCEPT SKETCH OF THE STEA SYSTEM

A prototype is made as shown in Fig. 2. The stimulation controller is covered by a plastic shell with 120 mm in length, 100 mm in width and 30 mm in height. It has a weight of 228 grams. With this size and weight, it has a significant advantage in portability. The chest strip sensor is made with Velcro strip embedded around with a strain-gage force sensor, which is convenient for the users to wear and take off. The stimulation controller is installed with standard power female adapters that can be convenient to connect with the chest strip sensor and electrodes.

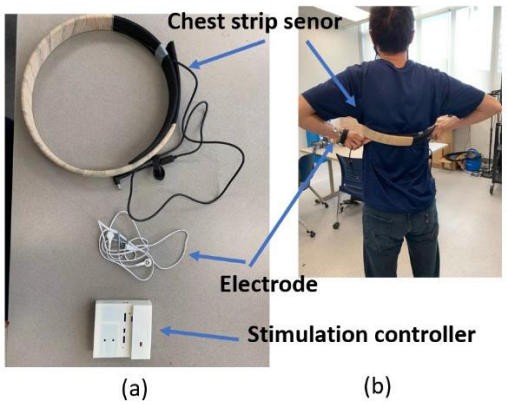


FIGURE 2: PROTOTYPE: (a) OVERVIEW OF THE STEA; (b) APPLICATION

2.3 Respiration sensing and stimulation identification

The chest strip sensor is a typical flexible force sensitive resistor (strain-gage type) which produces a voltage change induced by the pressure generated by the movement of the chest expansion. Though the sensor can be accurately calibrated and measures the force with a high precision, only using the magnitude of the measured force is difficult to identify the start point of the inhalation as the force magnitude is sensitive to the users' body sizes, respiration variation, the fastening positions on the chests and users' movement. Therefore, a novel algorithm is needed to model the respiration and identify the start point of stimulation so that the sensing and identification can be universal for different users and robust to the aforementioned factors. Here we designed a novel algorithm based on the slope of the detected respiration waves. As can be seen in Fig. 3, although the force magnitude is changing due to respiration variation, the slopes still have the same pattern. Based on this observation, we designed an algorithm to detect the slope pattern instead of the force magnitude to identify the start point of the inhalation.

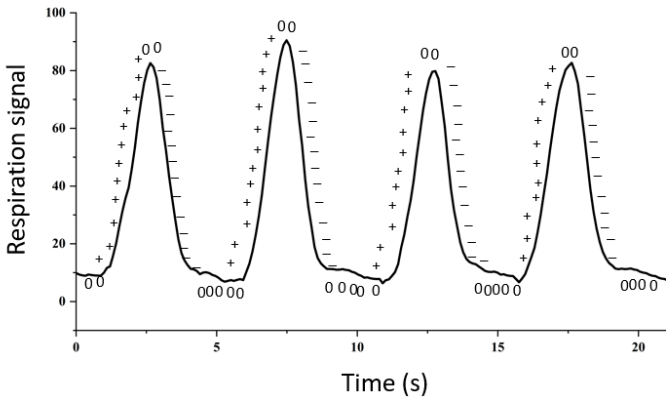


FIGURE 3: RESPIRATION WAVES WITH PATTERNS

As can be seen in Fig. 3, the increase of the sensed force is coded as positive "+", a flat of the sensed force as zero, and a decrease as negative "-". Observation shows that "0 0 +" always appears at the start of the inhalation, thus identified as the start of stimulation.

2.4 Control system

The flow of the signal and circuit is also shown in Fig. 4. The signal obtained by the respiration sensor is transferred into the system through an Analog-to-Digital Converter (ADC) for calculation. The respiration sensing model and the stimulation identifier is built within the internal flash memory in a microcontroller. A PIC32MX microchip is used to establish the control system. An extra flash memory is used to store the respiration wave and stimulation data for further analysis. The stimulation command is sent into the output circuit through a Pulse-width modulation (PWM). AA batteries are used to provide the power, and a power management system is established to maintain a sustainable, efficient and safe use of the power. The physical hardware of the circuit is as shown in Fig. 5.

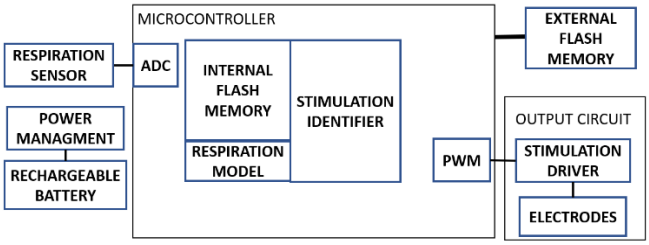


FIGURE 4: CIRCUIT DIAGRAM

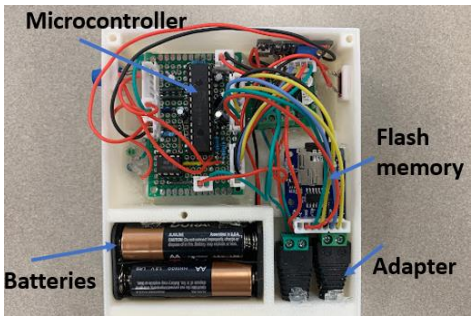


FIGURE 5: PROTOTYPE OF THE CIRCUIT

3. EXPERIMENTS AND RESULTS

3.1 Experiment Descriptions

To evaluate the functionality of the presented STEA device, a benchtop testing was conducted. The main objectives of the experiment are to verify whether expected stimulation pulses are generated, and the synchronization is performed with high accuracy. A human user wore the respiration strip sensor on the chest, and breathed in a relaxation state. The electrode pads were connected with a 470k-ohm resistor to best simulate the impedance of human skin. The stimulation is set to last two seconds in each respiration cycle. A standard oscilloscope was used to displace and store the electrical signal of the chest expansion and the stimulation pulses. The setup is as shown in Fig. 6. After the first one-minute experiment, a second human user slightly changed the respiration rate and adjusted the amplitude of the stimulation pulse in order to verify the reliability of the presented system.

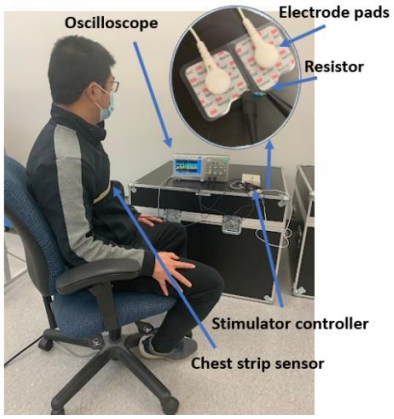
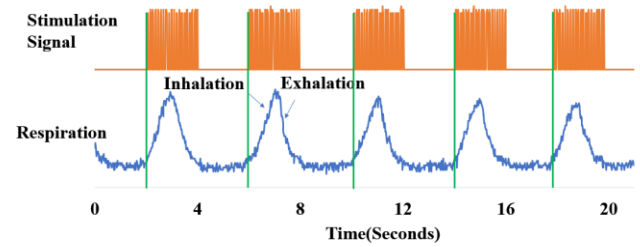


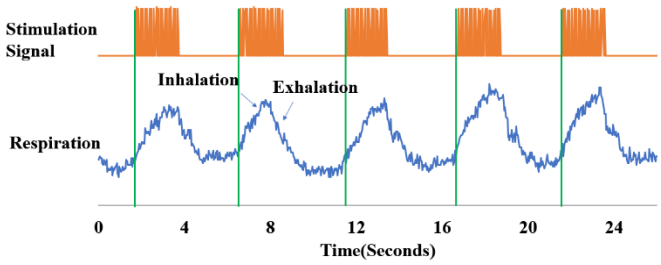
FIGURE 6: EXPERIMENT SETUP

3.2 Experiment results

As can be seen in Fig. 7 (a), the stimulation pulses with constant voltage amplitude start immediately after the inhalation with minor delay. Based on the recorded data in the one-minute operation, the average time delay between the start point of stimulation and the actual start inhalation measured by the chest strip sensor is around 0.066 seconds. Compared to a regular respiration cycle (around 4 seconds here), this minor time delay reflects a high accuracy of synchronization, demonstrating the functionality of the presented STEA device. In the second experiment with variable respiration parameters, the same success of stimulation pulse generation and synchronization is shown in Fig. 7 (b), demonstrating the reliability of the present system.



(a)



(b)

FIGURE 7: EXPERIMENT RESULTS: (a) FIRST EXPERIMENT; (b) SECOND USER WITH DIFFERENT RESPIRATION PACES

CONCLUSION

To explore an enhanced treatment method, this paper presents the development of a novel automated transcutaneous

electrical acustimulation device which automatically synchronizes the user's breath and generates required stimulation electrical waves. A convenient and home-base respiration sensing strip with a novel identification algorithm is presented. Experiment was conducted with real human respiration sensing, and the results demonstrated that the control system can generate expected electrical waveforms, synchronize the respiration with neglectable delay, and provide reliable function. Future work will conduct clinical trials on human subjects to further verify effectiveness of the respiration synchronization approach in treating with GERD and add more functions and features (e.g. constant current mode, and sine waveform) to the device.

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REFERENCES

[1] Vakil, N., Van Zanten, S.V., Kahrilas, P., Dent, J., and Jones, R., 2006, *The Montreal definition and classification of gastroesophageal reflux disease: a global evidence-based consensus.* Official journal of the American College of Gastroenterology| ACG. **101**(8): p. 1900-1920.

[2] Lacy, B.E., Weiser, K., Chertoff, J., Fass, R., Pandolfino, J.E., Richter, J.E., Rothstein, R.I., Spangler, C., and Vaezi, M.F., 2010, *The diagnosis of gastroesophageal reflux disease.* The American journal of medicine. **123**(7): p. 583-592.

[3] El-Serag, H.B., Sweet, S., Winchester, C.C., and Dent, J., 2014, *Update on the epidemiology of gastro-oesophageal reflux disease: a systematic review.* Gut: p. 871-880.

[4] Giorgi, F.D., Palmiero, M., Esposito, I., Mosca, F., and Cuomo, R., 2006, *Pathophysiology of gastro-oesophageal reflux disease.* Acta Otorhinolaryngol Ital. **26**(5): p. 241-246.

[5] Stefanidis, D., Hope, W.W., Kohn, G.P., Reardon, P.R., Richardson, W.S., and Fanelli, R.D., 2010, *Guidelines for surgical treatment of gastroesophageal reflux disease.* Surg Endosc. **24**: p. 2647–2669.

[6] Lin, D.C., Chun, C.L., and Triadafilopoulos, G., 2015, *Evaluation and management of patients with symptoms after anti-reflux surgery.* Diseases of the Esophagus. **28**(1): p. 1-10.

[7] Ganz, R.A., 2016, *A Review of New Surgical and Endoscopic Therapies for Gastroesophageal Reflux Disease.* Gastroenterology & Hepatology. **12**(7): p. 424-431.

[8] Miwa, H., Kondo, T., Oshima, T., Fukui, H., and Tomita, T., 2010, *Esophageal sensation and esophageal hypersensitivity - overview from bench to bedside.* J Neurogastroenterol Motil. **16**(4): p. 353-362.

[9] Zhu, J., et al., 2017, *Acupuncture for the Treatment of Gastro-Oesophageal Reflux Disease: A Systematic Review and Meta-Analysis.* Acupuncture in Medicine. **35**(5): p. 316-323.

[10] Zhang, C., Guo, L., Guo, X., Guo, X., and Li, G., 2012, *Clinical curative effect of electroacupuncture combined with zhizhukuanzhong capsules for treating gastroesophageal reflux disease.* Journal of Traditional Chinese Medicine. **32**(3): p. 364-371.

[11] Hu, Y., Zhang, B., Shi, X., Ning, B., Shi, J., Zeng, X., Liu, F., Chen, J.D., and Xie, W.-F., 2020, *Ameliorating Effects and Autonomic Mechanisms of Transcutaneous Electrical Acustimulation in Patients With Gastroesophageal Reflux Disease.* Neuromodulation: Technology at the Neural Interface. **23**: p. 1207-1214.

[12] Song, G.-Q., Zhang, N., Shi, R., Chen, J., and Chen, J., 2014, *Improvement of Gastric and Autonomic Function With Synchronized Transcutaneous Electroacupuncture in Healthy Subjects With High Fat Diet.* Gastroenterology. **146**: p. S843.

[13] Song, G., Sarosiek, I., Bashashati, M., Sun, Y., Chen, J., and McCallum, R., 2015, *Needleless Transcutaneous Electroacupuncture in Synchronization With Breathing for Treating Nausea in Patients With Idiopathic Gastroparesis.* American Journal of Gastroenterology. **110**: p. S758.

[14] Liu, Z., Lu, D., Guo, J., Liu, Y., Shi, Z., Xu, F., Lin, L., and Chen, J.D.Z., 2019, *Elevation of Lower Esophageal Sphincter Pressure With Acute Transcutaneous Electrical Acustimulation Synchronized With Inspiration.* Neuromodulation: Technology at the Neural Interface. **22**: p. 586-592.

[15] Roudjane, M., Bellemare-Rousseau, S., Khalil, M., and Gorgutsa, S., 2018, *A Portable Wireless Communication Platform Based on a Multi-Material Fiber Sensor for Real-Time Breath Detection.* Sensors. **18**: p. s18040973.

[16] Hingne, P.M. and Sluka, K.A., 2007, *Differences in Waveform Characteristics Have No Effect on theAnti-Hyperalgesia Produced by Transcutaneous Electrical NerveStimulation (TENS) in Rats With Joint Inflammation.* The Journal of Pain. **8**(3): p. 251-255.

[17] *Foundations of Electrical Stimulation*.Lane Community College; Available from: https://media.lanecc.edu/users/thorpeb/pta101lab/FoundationsofEstim/FoundationsofEstim_print.html.

[18] Johnson, M., 2007, *Transcutaneous electrical nerve stimulation: mechanisms, clinical application and evidence.* Reviews in pain. **1**(1): p. 7-11.