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Non-Invasive and Wireless Treatment of Obstructive Sleep Apnea via Electrical Stimulation Method

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***Abstract*—Obstructive sleep apnea defined as a medical condition caused by loss of muscle tone in upper airway dilator muscles. There are various treatment methods exist for this condition both invasive and non-invasive, but they all have their weaknesses and strengths. Electrical stimulation method seems to be the most promising non-invasive method in terms of efficiency and adherence rate. This study introduces a low-cost, easy-to-use and wireless novel device to treat obstructive sleep apnea based on electrical stimulation method. The developed device uses an accelerometer to track respiration and apnea episodes and when an apnea episode is detected delivers a small electric current to dilator muscles to make them regain their muscle tone, thus treating obstructive sleep apnea. The device also communicates with a smartphone application to keep a recording of respiration and apnea data to enable further studying of data by medical professionals and researchers.**

Keywords—obstructive sleep apnea; accelerometer; Bluetooth low energy; electrical stimulation; respiration signal processing

I. INTRODUCTION

A. Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) is a medical condition which is caused by irregular closure of upper airways of persons during sleep. The electrical activity of the muscles that dilate upper airways decrease when a person falls asleep, resulting in a reduced muscle tone and constricted pharyngeal lumen. In some cases, this constriction leads to snoring, and if upper airways completely get blocked by these muscles, to OSA. OSA causes irregular breathing patterns which lead to interruption of sleep cycles [1], snoring, choking, daytime sleepiness and fatigue [2]. Although there are further studies required to determine a causal relationship, OSA is also linked with glucose intolerance, diabetes, metabolic syndrome [3], hypertension [4], and coronary heart disease [5]. OSA is common among middle-aged people, which affects about 4% of male and 2% of female individuals [6]. There are various invasive and non-invasive methods already in use or in research for treatment of OSA.

Continuous positive airway pressure (CPAP) treatment is the most widely available treatment option for OSA [7]. In CPAP treatment, patients are continuously given air generated by a compressor unit nearby through a mask that has been strapped on their faces that covers their nose and mouth. Use of CPAP treatment regulates breathing pattern during sleep by preventing the collapse of the airways [2], thus normalizing sleep architecture, reducing sleepiness during the day as well as eliminating other health issues related to OSA [7]. Although CPAP is widely available and accepted as a standard treatment for OSA, it has some shortcomings. 1/3 of patients quit treatment within the 5 years they start the treatment mainly due to the overall discomfort associated with the treatment [8]. Another study specifies that CPAP treatment adherence rates are around 30 to 60% [7], meaning that up to 70% of the patients quit the treatment although they should have been continuing. Reasons for low adherence rates are mainly linked to the discomfort that's associated with the use of the device since it heavily restricts patient movement, generates noise while in use and its cost. Due to the low adherence rates, the effectiveness of CPAP treatment is reduced [9] and to negate this, alternative treatment options for OSA exist.

B. Alternative Treatments for Obstructive Sleep Apnea

Treatment options for OSA other than CPAP can be grouped into a few main categories: oral appliance (OA) therapy, surgical therapy, electrical neurostimulation therapy of the hypoglossal nerve stimulation (HGNS) and electrical stimulation therapy (ES).

OA is a non-invasive treatment option designed for prevention of collapsing by altering tongue and jaw position and it improves upper airway configuration [10]. Various studies [11]–[13] have reported improvement in oxygen saturation [14], REM sleep time and arousal index [15]. Adherence rates for OA are also higher than CPAP, 76% in 1 year and 62% after 4 years [10]. OA treatment has also its downsides, they're mainly side effects such as dryness in the mouth, irritation of the gums, tooth pain and excessive salivation. These side effects are usually temporary and experienced differently from patient to patient. In some cases, side effects are persistent, and this persistence leads to abandonment of the treatment [16].

When it comes to surgical therapy, various methods exist such as Maxillo-Mandibular Advancement (MMA), Soft Palatal Procedures, Laser-Assisted Uvulopalatoplasty (LAUP) [17]. Although the results of surgical procedures are promising, there's lack of standardization and there are complications related to invasive operations, so further data is needed to evaluate and accept surgical therapies as standard means of treatment of OSA [18].

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GNS is an emerging invasive method of treatment and it has been studied by several researchers and companies over the last decade [19]. HGNS is based on stimulation of the twelfth cranial nerve, hypoglossal nerve, which innervates all intrinsic and extrinsic muscles of the tongue but palatoglossus. HGNS treatment is done via a device which has a stimulator, a sensing lead, and a stimulation lead. Leads are implanted to sense breathing and stimulate the hypoglossal nerve to clear obstruction without causing arousal [20]. Stimulation of hypoglossal nerve activates genioglossus muscle, which extends the base of the tongue [21]. This extension opens the obstructed airway. The main downside for HGNS is its cost. Cost for the device itself, as well as clinical evaluation and pre and post-operation costs, are estimated to be 250 to 270000 SEK whereas a CPAP device and its clinical procedures cost only about 8000 SEK [20]. HGNS has also some severe adverse effects such as tongue soreness, abrasions, and weakness which are rare.

The last category, ES therapy is non-invasive and used to stimulate the muscles that dilate upper airways to keep upper airways open during sleep. Over the last decade, this method has been developing, presenting an encouraging option for treatment of OSA [22]. Dilator muscles can be stimulated via different waveforms with different frequencies and amplitudes as well as they can either be delivered continuously or intermittently. While there is not a standardized waveform and frequency currently does not exist, recent findings have been promising enough to establish a baseline for future work using this method [22].

C. *A New Approach to Upper Airway Stimulation Therapy*

Taking into consideration of all the treatment methods for OSA mentioned above, ES seems to have a promising application area due to its non-invasive and easy-to-apply nature. Even though HGNS is being heavily studied by both researchers and companies, it remains an expensive method of treatment and it has surgery-related complications since it's an invasive method. OA and surgical therapy are overshadowed by CPAP and they seem to lack a strong potential for replacing it since they offer little improvement over CPAP treatment in terms of patient comfort and ease-of-use.

To present an innovative, easy-to-use, comfortable and affordable treatment option for OSA, a novel device based on electrical stimulation method is implemented. The device offers a wireless, low-cost and energy-efficient two-component solution both to detect apnea episodes and to clear obstruction of upper airways by stimulating dilator muscles.

II. METHODS

A. *Detecting Obstructive Sleep Apnea Episode*

Detection of apnea episode is done via a belt that is tied on the subjects, covering the right lumbar region, umbilical region and left lumbar region (Fig. 1). The belt consists of an accelerometer (TDK InvenSense MPU6050), a Bluetooth Low Energy (BLE) capable system-on-chip (SoC) (Nordic Semiconductor nRF51822) and a coin cell battery (CR2032).

The belt moves away from and moves towards the subject, corresponding to their breathing pattern. This movement of the belt is continuously detected by the accelerometer delivered to SoC over Inter-Integrated Circuit (I^2C) protocol.

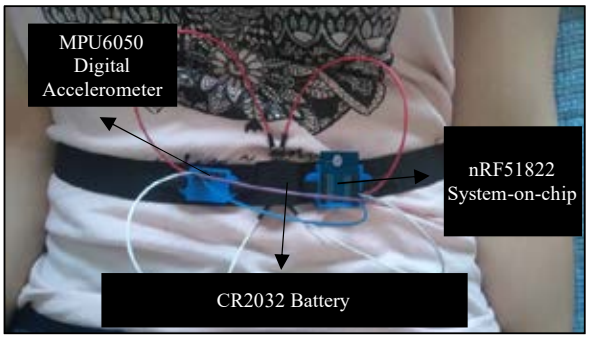

Fig. 1. Overview of apnea detection system.

The accelerometer is set to ±2 g(m/s^2) range to get a more accurate measurement and an on-board digital low-pass filter (DLPF) is set to 5 Hz cutoff frequency to remove noise such as pulse and electromyography signals. Considering that an adult person breathes about 12 to 20 times per minute [23], breathing frequency of an adult person in rest is about 0.2 to 0.33 Hz, so on-board DLPF is enough to remove a significant amount of unrelated biological signals.

Although most of the noise can be removed via internal DLPF of the accelerometer, there is still some noise present since the breathing signal frequency is quite low in comparison to other biosignals. To address this, an initial calibration is done each time before the device is used. To perform the initial calibration, subjects are asked to stand still while holding their breath in the supine position for 5 s. During this time a measurement is acquired from the accelerometer and mean of this data is calculated. This data is an offset error which is to be removed from each measurement that's acquired from the device in normal use for that particular subject for a session.

SoC continuously analyzes the data that it receives and checks whether the movement is stopped for 10 s. If it's determined by the SoC that the movement is stopped for 10 s, it's interpreted that apnea episode is ongoing and sends a stimulation warning to the SoC in the neck circuitry via BLE by changing corresponding attribute value of BLE characteristic.

B. *Delivering Electrical Stimulation Upon Apnea Episode*

Stimulation is done via a circuit that sends small electrical current when apnea episode onset is detected (Fig. 2).

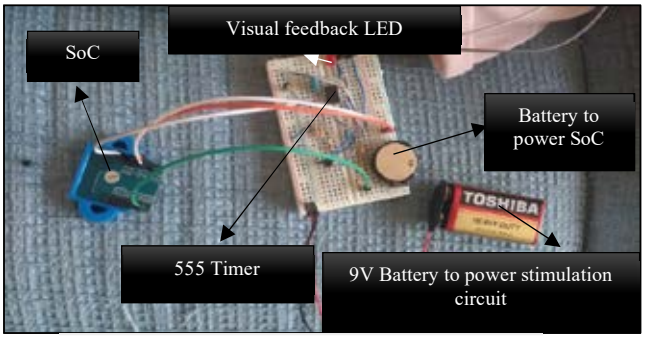

Fig. 2. Overview of stimulation circuit.

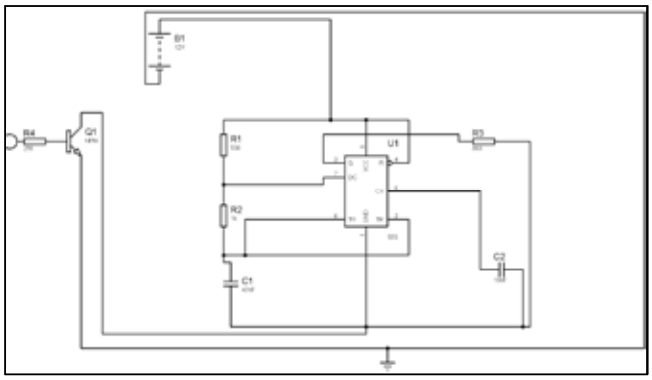

Fig. 3. Circuit diagram of stimulation circuit.

The circuitry on the neck has the same SoC and the battery as the apnea detection belt, it also includes a stimulation circuit (Fig. 3) and electrodes attached to that circuit.

Stimulation circuit contains 4 resistors, 2 capacitors, a 9V battery, a LED and a 555 pulse generator (LM555). LM555 is set to run in astable mode via capacitors and resistors connected to it to deliver a steady flow electrical current. The circuit delivers approximately 4 mA of current with 12 kHz frequency that lasts about 80 µs. The LED in the circuit is used to give visual feedback whenever the circuit delivers a stimulation.

In order to trigger the circuit as soon as apnea episode onset is detected, a binary junction transistor (BJT) is used and biased to run in switch mode. This BJT keeps the circuit closed as long as a 3.3 V from SoC is not present in its base leg. 3.3 V from SoC puts the BJT in saturation to complete the circuit with 9 V battery and deliver stimulation.

C. Complementary Smartphone Application

To keep a record of breathing patterns, respiration count and frequency, apnea episodes and to share them with other concerned parties such as medical professionals, a smartphone application is developed using Android Studio in Java Programming Language for Android Operating System devices (Fig. 4).

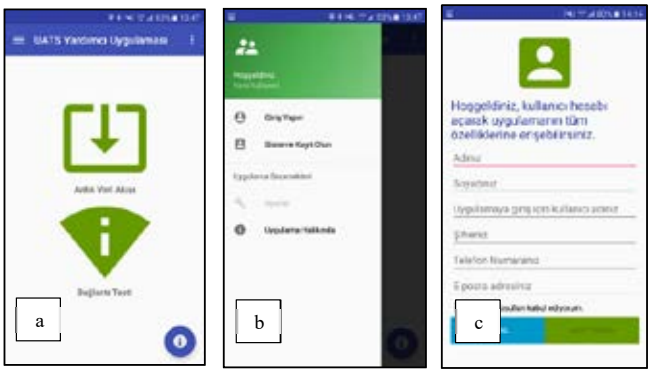

Fig. 4. Screenshots from the application (a) Overview, (b) Main menu, (c) Creation of a new user account.

The application receives and records accelerometer data in real-time from the SoC in the belt. Then the application displays this data graphically in its user interface to provide visual information to its users. Recorded data is kept in an encrypted online database and on the mobile device to enable future diagnostic studies by researchers and medical professionals. Users of the device can also display their data by accessing their accounts with a password.

III. Results

Respiration pattern and an OSA episode can successfully be detected by the device (Fig. 6). According to Fig. 5, the Y- axis of the accelerometer detected respiration more precisely than the other axes. This is mainly due to the positioning of the subjects as they were lying in the supine position. Oscillating regions of the plot (0-35 s), (55-87 s), (108-127 s), (151-166 s) indicate normal breathing pattern and static regions (36-54 s), (88-107 s), (108-150 s) indicate moments where breathing has voluntarily been stopped by the subject, a simulation of apnea episode. Fig.

Fig. 5. Respiration data acquired from BIOPAC temperature transducer (airflow vs. time).

5 shows how a similar breathing pattern acquired from BIOPAC Temperature Transducer (SS6L) as a comparison.

Respiration data acquired from the developed device seems to be consistent with the data acquired from commercial BIOPAC device. This shows that the belt can successfully acquire respiration data from a subject without substantial noise that affects overall signal quality enough to miss any simulated apnea episodes or breathing cycles. Results also confirm that the smartphone application can successfully receive data from the SoC in the belt via BLE and can record the data it acquires to be displayed and analyzed later on by related persons.

IV. Conclusion

Advantages and shortcomings in various treatment methods for OSA are well documented in existing studies carried out by researchers and companies. CPAP is and has been considered to be a standard treatment method for OSA, but its adherence rates are low mainly due to the discomfort associated with its use, resulting in poor long-term treatment efficiency. Currently, there's an ongoing interest in improving OSA treatment, especially for invasive methods. While invasive methods offer a better way of treating OSA, they're costly and they come with complications related to surgery. Electrical stimulation, however, offers a non-invasive, easy-to-apply and affordable treatment option.

In order to provide an affordable, easy-to-use and comfortable treatment method for OSA, a novel device is developed based on electrical stimulation method. The device features a belt that has an accelerometer that can track the abdominal movement of subjects, thus their respiration. If the respiration stops as a result of apnea onset for 10 s, the SoC in the belt sends a warning to SoC on the neck via BLE to initiate delivery of electrical stimulation. Circuitry on the neck delivers

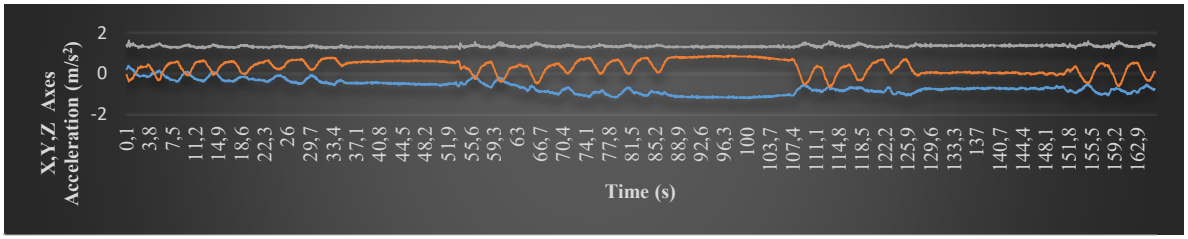

Fig. 6. A 3 minute respiration data received from a volunteer, healthy subject.

a small amount of electrical current to stimulate the dilator muscles to end the apnea episode. A complementary smartphone application is also developed to record respiration data to enable their future analysis as well to be used as a diagnostic information by medical professionals. Data are saved both locally and on a server with encryption. The application can show respiratory patterns, respiration frequency and detected apnea events in real-time.

In all tests that have been performed, the device was able to detect breathing patterns correctly as well as apnea events. Stimulation from the neck circuitry could be delivered correctly in the case of respiration of the subject stops and a visual feedback received from the device that stimulation has been delivered. The complementary application also works as intended, it was able to connect to SoC on the belt via BLE and could receive, process and display respiration data in real-time.

As a future use case scenario, medical professionals can log on to their accounts to view their patients' data that they have recorded at their home to use their respiration data in their diagnosis process. Future studies can be carried out to perform tests in controlled studies with OSA patients to ensure the device works as intended on real patients and can treat upper airway obstruction via electrical stimulation.

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REFERENCES

[1] J. F. Garvey, M. F. Pengo, P. Drakatos, and B. D. Kent, "Epidemiological aspects of obstructive sleep apnea," *J. Thorac. Dis.*, vol. 7, no. 5, pp. 920–929, 2015.

[2] A. Nicolini *et al.*, "Non-invasive ventilation in the treatment of sleep-related breathing disorders: A review and update," *Rev. Port. Pneumol.*, vol. 20, no. 6, pp. 324–335, 2014.

[3] P. Lévy, M. R. Bonsignore, and J. Eckel, "Sleep, sleep-disordered breathing and metabolic consequences.," *Eur. Respir. J.*, vol. 34, no. 1, pp. 243–60, Jul. 2009.

[4] K. Narkiewicz and V. K. Somers, "Obstructive sleep apnea as a cause of neurogenic hypertension.," *Curr. Hypertens. Rep.*, vol. 1, no. 3, pp. 268–73, Jun. 1999.

[5] D. Martinez *et al.*, "Sleep apnea is a stronger predictor for coronary heart disease than traditional risk factors.," *Sleep Breath.*, vol. 16, no. 3, pp. 695–701, Sep. 2012.

[6] P. Terry Young, P. Mari Palta, P. Jerome Dempsey, M. . James Skatrud, P. Steven Weber, and S. B. M.D., "The Ocurrence of Sleep-Disordered Breathing Among Middle-Aged Adults," *N. Engl. J. Med.*, 1993.

[7] B. W. Rotenberg, D. Murariu, and K. P. Pang, "Trends in CPAP adherence over twenty years of data collection: A flattened curve," *J. Otolaryngol. - Head Neck Surg.*, vol. 45, no. 1, pp. 1–9, 2016.

[8] J. Steier *et al.*, "Continuous transcutaneous submental electrical stimulation in obstructive sleep apnea: a feasibility study.," *Chest*, vol. 140, no. 4, pp. 998–1007, Oct. 2011.

[9] N. B. Kribbs *et al.*, "Objective Measurement of Patterns of Nasal CPAP Use by Patients with Obstructive Sleep Apnea," *Am. Rev. Respir. Dis.*, vol. 147, no. 4, pp. 887–895, 1993.

[10] K. Sutherland *et al.*, "Oral appliance treatment for obstructive sleep apnea: An update," *J. Clin. Sleep Med.*, vol. 10, no. 2, pp. 215–227, 2014.

[11] H. Gotsopoulos, C. Chen, J. Qian, and P. A. Cistulli, "Oral Appliance Therapy Improves Symptoms in Obstructive Sleep Apnea," *Am. J. Respir. Crit. Care Med.*, 2002.

[12] C. D. Johnston, I. C. Gleadhill, M. J. Cinnamond, and W. M. Peden, "Oral appliances for the management of severe snoring: A randomized controlled trial," *Eur. J. Orthod.*, 2001.

[13] A. Mehta, J. Qian, P. Petocz, M. A. Darendeliler, and P. A. Cistulli, "A randomized, controlled study of a mandibular advancement splint for obstructive sleep apnea.," *Am. J. Respir. Crit. Care Med.*, vol. 163, no. 6, pp. 1457–61, May 2001.

[14] N. Petri, P. Svanholt, B. Solow, G. Wildschiødtz, and P. Winkel, "Mandibular advancement appliance for obstructive sleep apnoea: Results of a randomised placebo controlled trial using parallel group design," *J. Sleep Res.*, 2008.

[15] J. Blanco, C. Zamarrón, M. T. Abeleira Pazos, C. Lamela, and D. Suarez Quintanilla, "Prospective evaluation of an oral appliance in the treatment of obstructive sleep apnea syndrome.," *Sleep Breath.*, vol. 9, no. 1, pp. 20–5, Mar. 2005.

[16] F. R. de Almeida *et al.*, "Long-term compliance and side effects of oral appliances used for the treatment of snoring and obstructive sleep apnea syndrome.," *J. Clin. Sleep Med.*, vol. 1, no. 2, pp. 143–52, Apr. 2005.

[17] S. M. Caples *et al.*, "Surgical modifications of the upper airway for obstructive sleep apnea in adults: a systematic review and meta-analysis.," *Sleep*, vol. 33, no. 10, pp. 1396–407, Oct. 2010.

[18] O. M. Vanderveken *et al.*, "Development of a clinical pathway and technical aspects of upper airway stimulation therapy for obstructive sleep apnea," *Front. Neurosci.*, vol. 11, no. SEP, pp. 1–12, 2017.

[19] S. ok Hong, Y.-F. Chen, J. Jung, Y.-D. Kwon, and S. Y. C. Liu, "Hypoglossal nerve stimulation for treatment of obstructive sleep apnea (OSA): a primer for oral and maxillofacial surgeons," *Maxillofac. Plast. Reconstr. Surg.*, vol. 39, no. 1, 2017.

[20] J. Hedner *et al.*, "Hypoglossal nerve stimulation (HGNS) for treatment of obstructive sleep apnea Hedner J , Ejnell H , Grote L , Liljegren A , Sjögren P , Svedmyr S , Wikberg Adania U , Jivegård L Hypoglossal nerve stimulation (HGNS) for treatment of obstructive sleep a," 2015.

[21] R. J. Gupta, D. Kademani, and S. Y. C. Liu, "Upper Airway (Hypoglossal Nerve) Stimulation for Treatment of Obstructive Sleep Apnea," *Atlas Oral Maxillofac. Surg. Clin. North Am.*, vol. 27, no. 1, pp. 53–58, 2019.

[22] M. F. Pengo and J. Steier, "Emerging technology: Electrical stimulation in obstructive sleep apnoea," *J. Thorac. Dis.*, vol. 7, no. 8, pp. 1286–1297, 2015.

[23] C. Chourpiliadis and A. Bhardwaj, *Physiology, Respiratory Rate*. 2019.