Implantable Airflow Sensor and Vagus Nerve Stimulation for Chronic Asthma Treatment (2022)

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***Abstract*—Those suffering from difficult to severe asthma are more likely to reject established medicinal therapies and so require alternative treatments to relieve symptoms. Airway smooth muscle (ASM) is controlled by the parasympathetic nervous system, via two physiologically distinct Vagus Nerve pathways. Appropriate electrical stimulation of these pathways induces ASM relaxation and airway dilation. This study introduces a closed-loop system able to sense bronchoconstriction in patients via a bronchial air-flow sensor, and instigate Vagus Nerve Stimulation (VNS) in order to relieve symptoms. The included processor, signal processing unit, and stimulating electrode are all fully implanted, and the device displays wireless charging and data transmission capability. Logic behind device design and fabrication are described, and results demonstrate effective mechanisms of the implant components. Additionally, mock surgical/X-Ray images are provided to illustrate how a clinician can interpret and recognize a CT scan from an implant patient.**

***Index Terms*—Asthma, implantable feedback, vagus nerve stimulation(VNS), airflow sensor, wireless charging**

I. Introduction

Asthma is a breathing condition characterized by respiratory symptoms such as shortness of breath, chest tightness, wheezing and variable expiratory airflow limitation. The main contributor to these symptoms is over-active bronchial smooth muscle, which constricts stochastically or in response to environmental conditions such as allergens or temperature, narrowing the airway and reducing airflow [1]. Often asthma is mild and resolves after adolescence, but cases can range from mild to severe and can persist into adulthood. Traditional treatments include inhalable fast-acting relieving medicines (short acting beta-agonists) that act directly on muscle cells to reduce intracellular calcium and cause relaxation, and daily preventative corticosteroids that reduce symptom frequency. However, some patients reject these medicines; this is much more common in difficult-severe asthma cases. Asthma is much more dangerous for these individuals as symptoms cannot be easily controlled, hence there is a need for the development of alternative therapies that can relieve symptoms. Smooth muscle tone is controlled by the parasympathetic nervous system via physiologically distinct pathways on the Vagus Nerve [2]. It has been shown that, by using VNS to stimulate particular regions of the VNS, we can induce bronchodilation [3]. Hence, we propose an implanted closed-loop device design, able to sense asthma related bronchoconstriction, and administer VNS to relieve disease symptoms.

Manuscript received 16 December 2022. Date of publication 16 December 2022; date of current version 16 December 2022. This work was supported in part by Hanyang University in part by Implantable Electronic Medical Devices and Technology Research Council. This article was recommended for publication by Professor Dr. YeiHwan Jung upon evaluation of the reviewers' comments. Jinhee Hwang, Jonathan Madar, and Sun-young Park are with the Hanyang University, Seoul, Republic of Korea (e-mail: jhher1757@hanyang.ac.kr; je2madar@hnaynag.ac.kr; sunyounge95@hanyang.ac.kr).

II. Feedback System

Figure 1 illustrates the implant feed-back system with a basic block diagram. Air flow through the lungs is measured by a catheter flow-sensor placed in the Bronchi. This feeds information, via a lead, to a signal processing/power-supply unit located near the surface of the skin on the neck. By analyzing the breathing curve shape produced from the flow-sensor, this unit triggers stimulation of the Vagus Nerve when appropriate, via an attached electrode. This relaxes the bronchioles, allowing more air to flow through the lungs, which is subsequently sensed by the flow sensor again and forwarded to the processing unit, completing the loop. The position of the processing unit also allows for wireless charging, as well as wireless data-transfer with an external device. Overall, this system can provide non-intrusive therapy for those suffering from severe asthma, or those that reject typical therapeutics.

III. Device Design

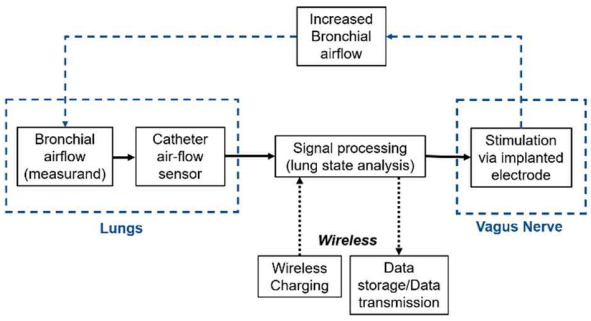


Fig. 1. Block diagram of the implants feedback system.

A. Sensor

Figure 2a shows the design of the bronchial air-flow sensor. The flow rate is measured through a variable piezoresistor that changes according to the flow rate. Four cantilever-like hairs flex in response to respiratory air-flow, inducing a measurable piezoresistance. Figure 2b shows how drag is effectively induced across the cantilevers. From the blue regions of slower air, we can see that drag is induced on the cantilevers. Figure 2c shows the relative deflection of each cantilever as the device was being rotated 180 degrees. We can see a consistent relationship in the deformation of the cantilevers, allowing flow-rate to be sensed irrespective of flow direction. This sensor is housed on a small catheter tube with legs (Figure 4b) allowing for sturdy insertion into the airway with minimal disruption to the internal bronchi walls.

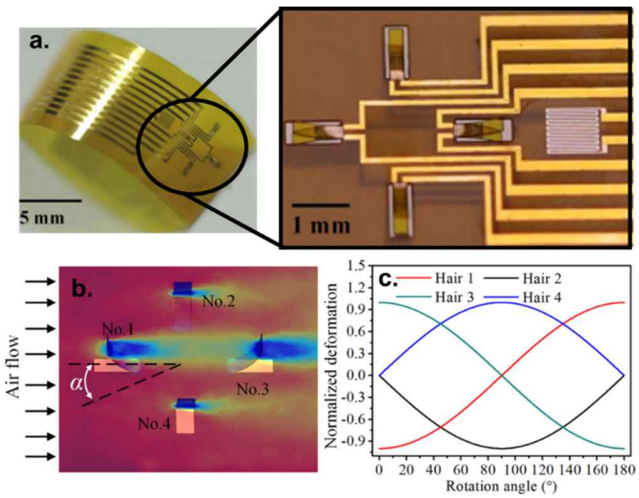


Fig. 2. (a) Schematic diagram of flow sensor (b) Simulation of air flow distribution of constant air flowing across the sensor (c) bending test result according to hair position.

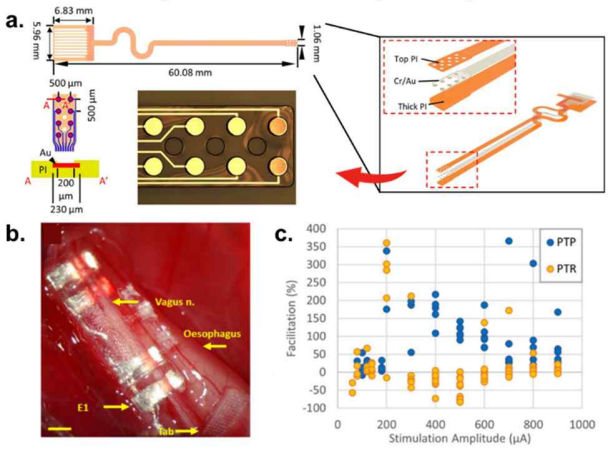


Fig. 3. (a) Schematic diagram of vagus nerve stimulator (b) Image of a stimulator implanted over the vagus nerve (c) Bronchial tidal volume according to stimulation amplitude.

B. Stimulation

Figure 3a shows the electrode design for VNS. It is constructed from a layer of chrome and gold, with pi used for encapsulation. Figure 3b shows the electrode inserted *in situ*. The measured respiratory flow rate following VNS of varying current amplitudes can be seen in Figure 3c. The result that electrical stimulation of 400-600 microamperes was effective can be seen in Figure 3c.

IV. Result

Figure 4 illustrates what the components of the implant should look like after surgery. 4a and 4b show images of the bronchus before and after insertion of the airflow sensor. Figure 4c pictures a mock CT scan of what the implanted electrode would be expected to look like. We can see the stimulating electrode attached to the Vagus Nerve, with its wires leading back to the processing unit positioned near the skin surface on the neck. You can also see the wire trailing down from this processing unit towards the sensor implanted in the bronchi.

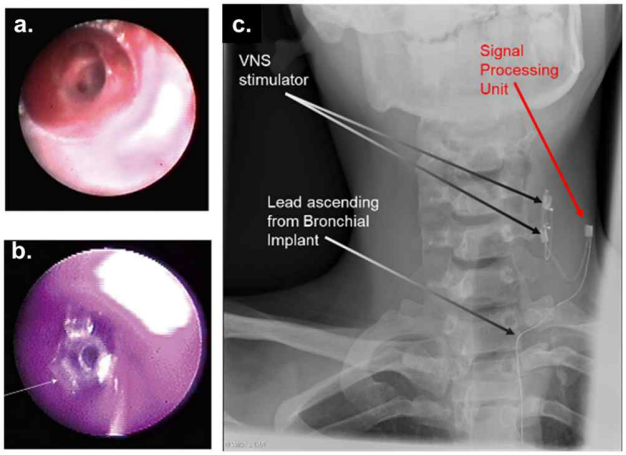


Fig.4. Image of a sensor implantation in bronchi (a) before and (b) after (c) mock CT image of stimulator electrodes attached on the vagus nerve.

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