

Challenges for the design of an endoscopically implanted electrostimulator

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Abstract

Gastrointestinal stimulator implants have recently shown positive results in helping obese patients to achieve healthier nutrition. However, to place the implant, the patient currently needs to go through a surgical procedure. Endoscopic implantation has the benefit over laparoscopies and bariatric surgeries to be non-invasive. It could be used to place the gastric stimulator in the stomach. However, the implant then needs to go through the oesophagus, which implies new constraints on the size and the weight of the device. This paper presents a project that aims to design such an implant and assess the electrical and mechanical challenges involved in such a design.

Keywords: *gastric electrical stimulation, endoscopic implantation, obesity.*

Introduction

Obesity has reached epidemic proportions globally, with at least 2.6 million people dying each year as a result of being overweight or obese. Today, one billion adults are overweight (BMI above 25) and more than 300 million are obese (BMI above 30). In almost half of OECD countries, 1 in 2 people is now overweight or obese. If recent trends continue, projections suggest that more than 2 out of 3 people will be overweight or obese in some OECD countries within the next 10 years (Fig. 1) [1].

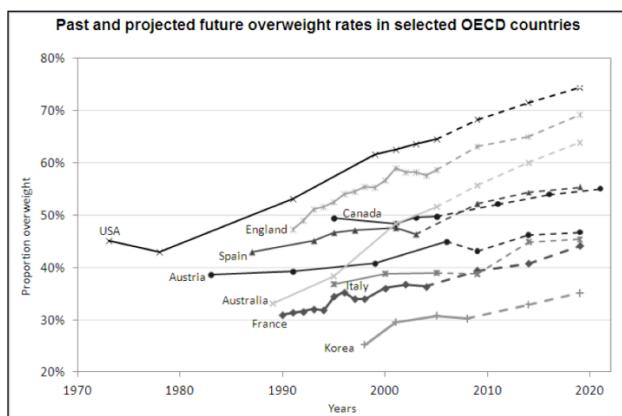


Fig. 1: Past and projected future overweight rates in selected OECD countries [1]

Gastric electrostimulation is a technique used to fight obesity. Gastrointestinal stimulator implants have recently shown positive results in helping obese patients to achieve better nutrition and are being clinically tested [2] [3]. Current implants consist of an implanted housing composed of a

receiver or a battery providing the power and a stimulator. The housing is placed in a subcutaneous pocket. To place the implant, the patient needs to undergo a surgical procedure (such as laparoscopy), which is expensive, requires a long recovery time and presents risks for the patient. In particular, to place the electrodes in the stomach wall, the surgeon needs to go through a thick layer of fat, which is risky for the patient. Implanting the device by endoscopy would avoid such a surgical procedure.

This paper presents a project that aims to design such an implant and assess the electrical and mechanical challenges involved in such a design.

Main challenges of the project

An endoscopically implanted gastric stimulator has to fulfil various requirements. First, due to the passage through the oesophagus, the device cannot exceed a diameter of 18mm and a maximum volume of 5 cm³. The large housings used for current implants are therefore unsuitable. Second, the device needs to have adequate anchoring in the stomach to avoid migration or detachment. This requirement is particularly delicate as the layer of the stomach used to attach the implant may be thin and as the implant needs to withstand stomach contractions. Third, the device must resist highly acidic environment (the pH in the stomach can be as low as 1), which imposes considerable limitations on the packaging. Fourth, the device needs to be easily placed using endoscopic tools. For instance, the electrode should be embedded in the implant as in situ connections and sutures are

difficult to perform by endoscopy. Fifth, the system's power supply should not be cumbersome neither require too regular endoscopies to recharge the batteries.

Work achieved

The whole system is currently under development. The stimulation protocol, the output stage design, the anchoring system and the power supply have been assessed and are detailed in this section.

Choice of the stimulation protocol

The protocol will be based on the Implanted Gastric Stimulation (IGS) from Medtronic, which already showed good results when implanted near the pylorus [2] [3] (note that the published results were achieved with a subcutaneous implant connected to electrodes placed next to the pylorus) and requires less energy than most current stimulators. Stimulation will only occur during mealtimes (3 to 4 hours per day).

The IGS protocol (Fig. 2) is a subthreshold and unconditional stimulation. It consists in stimulating periodically with a train of pulses without generating Gastric Slow Waves (GSW).

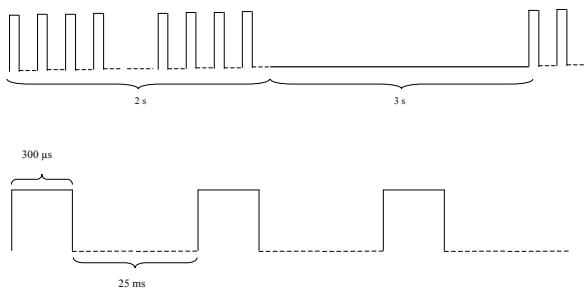


Fig. 2: Stimulation protocol from Enterra by Medtronic (above, two seconds train of pulses provided every five seconds and below, a train of pulses composed of 300 μ s pulses occurring every 25ms)

Electrodes are located near the pylorus to stimulate in the opposite direction to the GSW, at 40Hz, a frequency superior to the natural frequency of the GSW (3 waves per minute). The stimulation induces a decrease of the peristaltism and a feeling of satiety.

Output stage design

The output stage consists in a current source delivering 10mA pulses to the patient. One of the major challenges is the miniaturization of the circuit. Usually, blocking capacitors are used to protect the patient against DC current during single fault failure. However, the size of the blocking capacitor is considerable so a promising alternative was chosen instead. It consists in using high

frequency switching [4] to allow using smaller blocking capacitors while insuring patient protection.

The design of the anchoring system

Natural contractions and the thin layers (a few millimetres) of the stomach make the anchoring difficult. The device may drift over time because of quick cicatrization and renewal of the tissues. Various issues have been previously raised such as migration and detachment [5], difficult removal [6] and limited degrees of freedom in endoscopy [7].

The pyloric sphincter has been chosen to anchor the device as it is quite thick (5 to 7 mm), hard (muscle layer) and easily located. Besides, stimulation in the pylorus with long pulses already proved its effectiveness to treat morbid obesity in dogs [8]. Furthermore, the most common used position for implantable gastric stimulation is located just 2cm away from the pylorus.

The chosen design, to fix the implant on the pyloric sphincter, relies on using a type of "piercing" (Fig. 3) to make the anchoring easier. To place the implant, the pylorus is stretched and the device is inserted through the muscle. The sharp tip pierces the sphincter and allows the abutting member to be clipped. The pylorus can then be released.

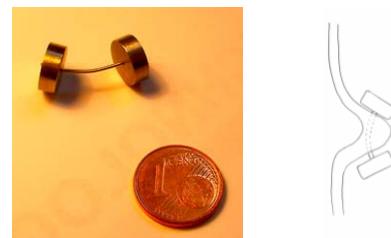


Fig. 3: Inert implant (left) and implant in the pylorus (right)

A flexible body has been chosen to reduce the stress endured by the device during stomach movements (stronger contractions occur at the pyloric sphincter) and to ensure a good contact of the electrodes. This idea has been patented by our group (Priority Date: 2009/05/08; Application number: PCT/EP2010/056378).

Choice of the power supply strategy

The power supply is to be integrated inside one of the abutting members of the implant to limit the size of the whole device. Its weight is therefore limited to 1g and volume to 360 mm³. The power consumption needed to achieve the stimulation protocol proposed is about 200 μ W. Various options for the power supply of the implant are being considered.

Batteries are attractive as they do not need external circuitry. However, they would require regular endoscopies to be replaced or reloaded and the energy available is limited by the size of the implant.

Transcutaneous inductive powering requires achieving an inductive link across a large layer of fat (around 10 centimetres). Furthermore, an external powering system is required which may be cumbersome and impede the comfort of the patient.

Human energy harvesting avoids both regular endoscopy and the need for an external powering system. An energy conversion system based on an electromechanical transducer has been proposed by our group [9]. It showed that, considering the low level of physical activity of an obese patient, only about 100nW could be harvested in this way. Further studies are ongoing to improve the energy harvesting method, for instance relying on breathing movements.

Further work

Our first aim is to complete the development of a working prototype. Three major steps are needed to achieve this goal.

First, the anchoring of an inert implant will be tested in three dogs during three months. This implant has been realized with two titanium disks linked by a flexible body.

Second, a prototype to stimulate the stomach at the pylorus will be developed. It will first be tested on a dead animal stomach and should assess the functionality of the stimulation.

Third, the prototype will be tested in an animal model while monitoring food intake and energy expenditure, as well as animal weight. This will assess the physiological impact of the defined stimulation protocol at the pylorus. Impacts on the duodenum will also be observed.

Further work will include clinical trials and reaching regulatory approval (CE Mark, etc). If the conclusion is favourable, the method will be transferred to a company.

At the end of this project, we hope to propose a functional gastric implant that will treat obesity noninvasively. Obese patients would then only

need outpatient operation, without risking bariatric surgery, to benefit from this cure.

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