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ANCHORING GASTRIC PACING AS THERAPY FOR OBESITY

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Obesity is an increasing health problem across the world. The gold standard treatment for morbid obesity is currently bariatric surgery but this is not without risks and is not suitable for all patients. Promising alternatives include gastric electrical stimulation, which has shown promising results in animals and in preclinical studies. However, challenges exist such as overcoming habituation and being able to adapt protocols to the individual and their needs.

A gastric pacemaker

Other gastric pacemakers have been reported in medical literature, but these devices are usually implanted by multi-incision laparoscopy, a relatively expensive and invasive procedure, and they usually use fixed gastric stimulation protocols. The Belgian team from the Polytechnic School of Brussels (ULB) aimed to solve all these limitations; "We try to have minimally invasive implantation and a way to counter habituation," says Antoine Nonclercq, project leader at the department BEAMS (Bio-, Electro- And Mechanical Systems) at ULB. The team developed a gastric electrostimulator system that is designed for minimally invasive implantation and remote programming and charging from outside the body. This allows the researchers to adapt the stimulation protocols to each individual, and to combat habituation, a declining response to repeated or prolonged stimulation.

Minimally invasive implantation and anchoring

To achieve minimally invasive and long-term implantation, the team came up with a novel system for anchoring the device into the muscular layer of the stomach wall.¹ This system allows the device to be implanted through a single percutaneous incision, and the team aim for an anchor that can remain in place for decades. "Normally, the stimulators are implanted laparoscopically, which is more invasive" says Nonclercq. "Our aim was to have percutaneous access smaller than 12 mm. This small diameter enables the percutaneous incision to be dilated rather than cut, reducing scarring."

The anchor system positioning the electrodes into the gastric wall is made up of two stainless steel needle electrodes and a flexible silicone body. During implantation, the needles are squeezed together and threaded through a trocar until they pierce the outer muscular layer of the stomach wall, taking care not to pierce all the way through to the inner mucosal layer. When the implantation tool is withdrawn, the flexible silicone springs back into shape and the anchor bites. "The two needles diverge with an angle so that they remain firmly attached to the stomach," explains Nonclercq.

After bench testing the anchor stability, the team implanted anchors into the gastric walls of six dogs using open surgery. This confirmed the long-term durability of the anchor over one year after implantation.¹ Next, the team tested the minimally invasive implantation in a dog cadaver, demonstrating proof of concept.

"The two needles diverge with an angle so that they remain firmly attached to the stomach."

Gastric pacing

Once the anchoring system was validated, the team hooked the electrodes up to the silicone-encapsulated electrostimulator,² implanted subcutaneously. The dogs were allowed a few weeks post-surgery to recover and get used to the device. Then the dogs underwent two 4-week periods where they either received adaptive electrostimulation or sham stimulation, while on a strictly monitored diet. Food intake reduced by 42% during the stimulation periods while weight increased by 10% during the sham periods. Stimulation also increased the frequency of gastric flow waves after eating. According to Nonclercq, this method could be a "minimally invasive, long-term, reversible, and adjustable alternative to bariatric surgery".

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Next steps

The team is working towards validating the device for clinical use. However, Nonclercq warns that there are several major steps and significant investment required before reaching the clinic. "In particular, the impact of stimulation on the electrode-body interface should be addressed," says Nonclercq, adding that "the clinical use of the stimulation methods will require adaptation." The dog study aimed to maintain initial body weight as a proof of concept. However, clinical use will have to be in conjunction with a trained dietician to adapt to the needs of the patient, be it weight loss or maintenance.

The team have made a head start by patenting their work with the help of their university Technology Transfer Office. This help was invaluable according to Nonclercq, explaining that patent writing is a field of expertise in itself.

"A minimally invasive, long-term, reversible and adjustable alternative to bariatric surgery."

Working together

Nonclercq leads a team of biomedical engineers but insists that collaboration is essential; "All our work is in partnership with medical doctors," he says, "the work is highly multidisciplinary; it's one of the challenges, but also its beauty." The project drew on expertise from a wide range of collaborators, all from different fields of medicine and engineering, to tackle diverse topics such as bioelectronics, minimally invasive devices, wireless charging, encapsulation, medical imaging and validation of the device *ex vivo* and *in vivo*.

Covid-19 was the other big challenge that occurred during the project, reported Nonclercq, noting that juggling practical experimentation with the pandemic restrictions was not easy.

Other applications

This electrostimulation system has a myriad of potential applications, particularly in other hollow organs such as the bladder. "We could use the minimally invasive procedure to place electrodes onto the bladder wall," says Nonclercq. This could help treat incontinence, for example in patients with incontinence due to spinal cord injury. The technique could even have applications in drug delivery according to Nonclercq. "There are many possibilities," he says, "even if we are most excited about obesity."

REFERENCES

¹ Debelle, A. et al. 2021. Optimization and assessment of a novel gastric electrode anchoring system designed to be implanted by minimally invasive surgery. *Medical Engineering & Physics*, 92, pp.93-101.

² Debelle, A. et al. 2021. Impact of adaptive gastric electrical stimulation on weight, food intake, and food intake rate in dogs. *Artificial Organs*.

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Careers

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