UCon; A noninvasive neurostimulation system specifically designed for genital nerve stimulation

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RESEARCH TYPE

Pure and Applied Science / Translational

ABSTRACT CATEGORY

Continence Care Products / Devices / Technologies

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#	Abstract 11
	Products, Devices and Innovative Therapies Scientific Podium Short Oral Session 2
	Thursday 8th September 2022
	09:35 - 09:42
	Hall K1/2
	New Devices · Neuromodulation · Overactive Bladder · Urgency Urinary Incontinence · Urgency, Fecal
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	IN-PERSON
PRESENTER	
N	**Nico JM Rijkhoff**
LINKS	

Abstract

HYPOTHESIS / AIMS OF STUDY

Neuromodulation is used to treat overactive bladder symptoms like urgency, frequency, and incontinence. In addition, nonobstructive urinary retention and fecal incontinence can also be addressed with neuromodulation. Clinically available neuromodulation therapies in urology and gastroenterology use either the sacral nerve roots or the posterial tibial nerve as target for stimulation. Another promising stimulation target is the dorsal penile/clitoral nerve (also called dorsal genital nerve (DGN)). Studies have shown that DGN stimulation can suppress detrusor contraction [1] and could thus be used to prevent incontinence when stimulation is started soon after the onset of a detrusor contraction (on-demand stimulation).

Studies on DGN stimulation have mostly used off-the-shelf components. These components are fine for short-term studies but have several drawbacks when doing long-term studies or when considering offering DGN stimulation as treatment. The main drawback is a relative bulky stimulator with too many buttons and programs. In addition, the stimulator usually lacks a way to quickly start stimulation, which is essential for on-demand stimulation.

Furthermore, there is the problem of the stimulation electrode. A stable long-term electrode-nerve interface is required but is difficult to obtain with off-the-shelf surface patches, especially in female patients.

In this project, we designed and build a neurostimulation system (both stimulator and electrode) for DGN stimulation.

STUDY DESIGN, MATERIALS AND METHODS

A literature study was conducted to draw up a list of stimulation parameters that are typically used in DGN stimulation. This resulted, in combination with our own experiences in DGN stimulation, in design specifications for the electrical capabilities of the stimulator. In addition, the stimulator had to be designed for patient-operated treatment offering convenient access to different stimulation modes, including quick access to on-demand stimulation.

A surface electrode for DGN stimulation had to be designed based on the local anatomy where also the large inter-person anatomical variation had to be taken into account. Human genitals vary largely in both shape and size. Beside gender differences there are large differences within the same gender, In addition, even dimensions can vary in the same person over the course of one day.

Several design criteria were taken into consideration including adhesive-, electrical-, and biocompatibility capabilities, mechanical integrity, comfort, and convenient to use for the patient. Especially, good adhesion to the moist mucosa and mechanical adaptation to the irregular surfaces of the genitals were important design criteria.

RESULTS

A small (69x53 mm, weight: 32 g), water tight, body worn, electrical stimulator for patient-operated treatment was designed and build (Fig. 1). It has a rechargeable battery with a capacity to last for a few days with normal use. There are only three buttons. One for ON/OFF, one for stimulation amplitude UP/DOWN and one for START/STOP On-demand stimulation. The following stimulation parameters are available: stimulation frequency: 20 Hz, pulse duration: 200 µs, pulse amplitude: 0-25 mA, maximum output voltage: 120 V. The stimulation pulses are rectangular, charge balanced and current controlled. The stimulator logs all stimulation sessions. Logs can be read by connecting the stimulator to a computer during follow-up at the hospital.
There are two operation modes: (1) Time-limited stimulation and (2) On-demand stimulation. Time-limited stimulation provides continuous stimulation for a set duration (15 min – continuous). On-demand stimulation provides 60 s of stimulation, which is initiated on-demand by pressing a button on the stimulator or on the remote control.
The remote control (27 mm diameter, weight: 5 g) (Fig. 1) has only one button and is powered by a button cell battery. It connects wirelessly to the stimulator using Bluetooth.
Dedicated DGN electrodes (19x21 mm, weight: 0.5 g) (Fig. 2) have been developed in collaboration with Axelgaard Manufacturing Co (California, USA). They are heart shaped and are suitable for use in both males and females. The electrodes consist of a silicone shell, a metal connector for the lead and, a customized hydrogel. The hydrogel (developed by Axelgaard Manufacturing Co) ensures optimal tissue friendliness and electrical properties along with biological safety. It has a thickness of 3 mm, and absorbs irregularities of the surface under the electrode. In this way both gender variances and variances within same gender or person can be handled by the same electrode. The triangular shape of electrode is specifically adapted for the female outer genital anatomy, which is most challenging. The pointy tip of the electrode is placed in the apex of prepuce/hood, with the two wings of the electrode extending down on the surface of the clitoral hood/clitoris and inner labia, depending on the dimensions of the individual anatomy.
UCon has been fully verified in all aspects relating to biocompatibility, electrical and mechanical safety, and usability and complies with relevant standards and regulations.

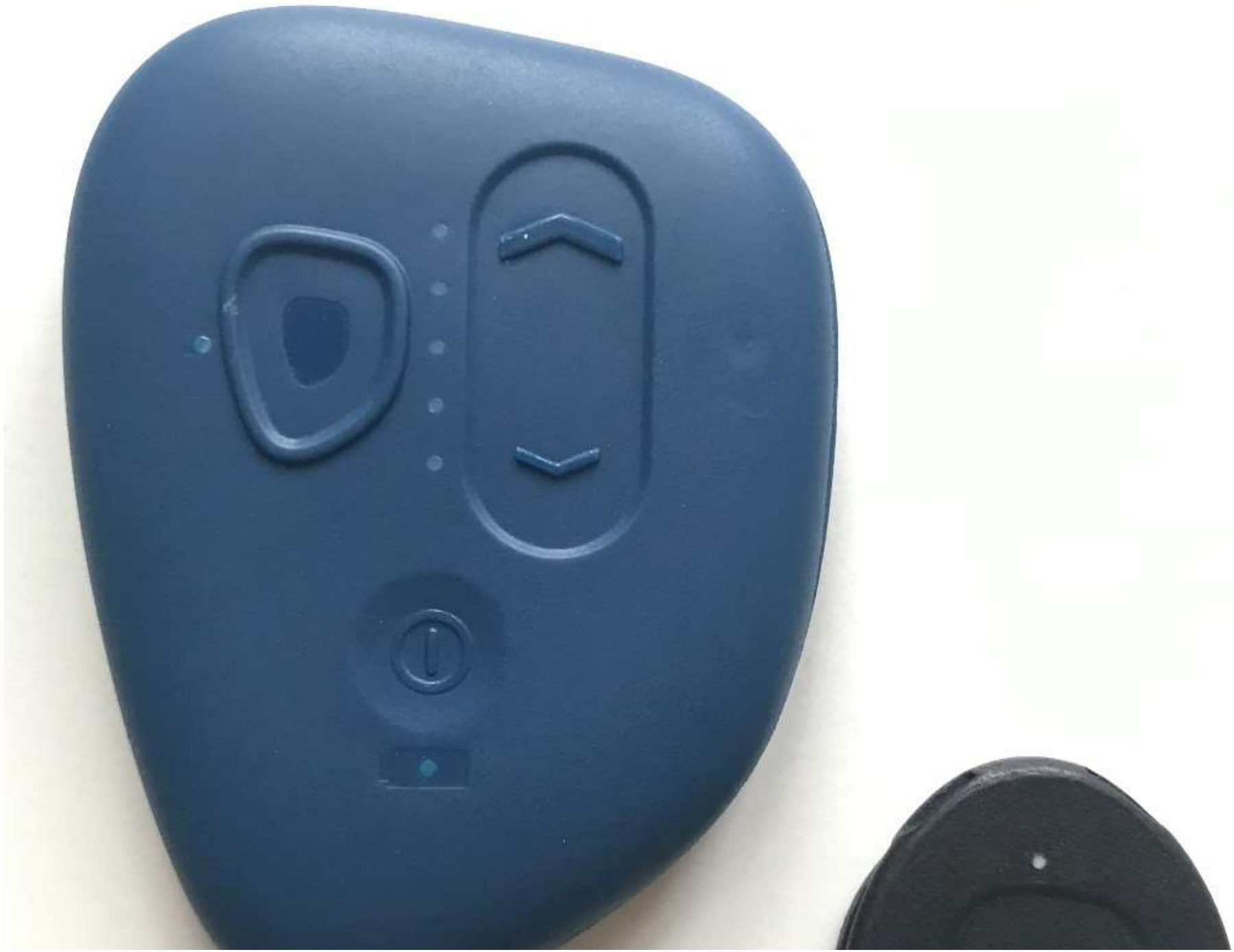
INTERPRETATION OF RESULTS

A complete neurostimulation device (UCon) has been designed and build for DGN stimulation. The main components are a stimulator, a remote control, electrodes, and leads. Bench tests and other required non-clinical tests have been conducted successfully so the device is ready to be tested in a clinical trial. It is expected that the availability of UCon would boost clinical research into DGN stimulation. In addition, UCon would allow DGN stimulation to become a medical treatment because the device has been developed according to requirements for regulatory clearance.

CONCLUDING MESSAGE

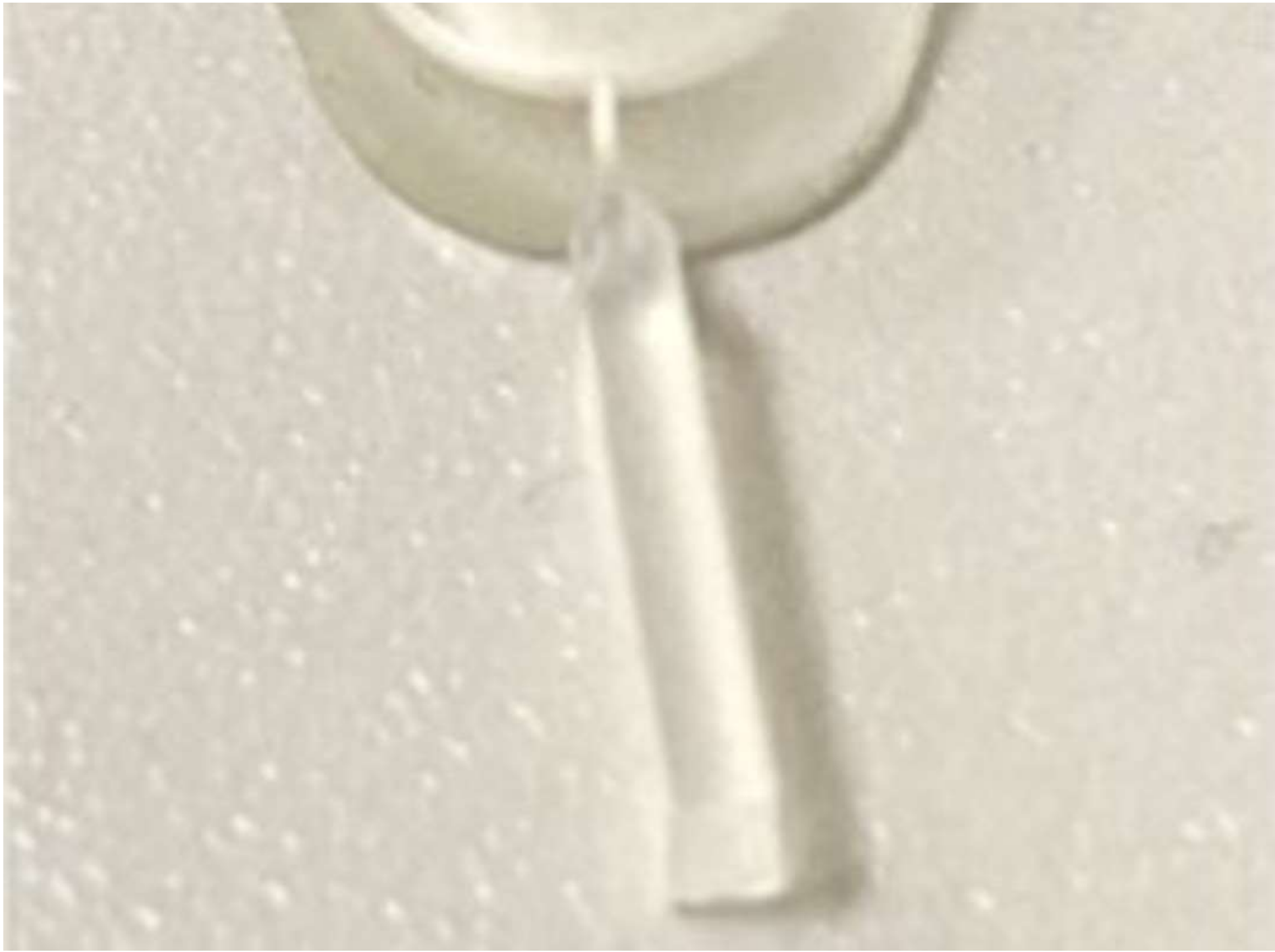
A non-invasive neuromodulation device for DGN stimulation has been build. All required verification tests were successfully completed. Approval for the first clinical study using UCon has been obtained from both the local medical device agency and the local medical-ethical committee. This study will enroll a total of 40 patients in 3 different hospitals and was initiated in March 2022.
Next steps involve development of a percutaneous electrode for DGN stimulation. This will be especially attractive for patients using on-demand stimulation because it would allow for a permanent electrode-nerve interface.

FIGURE 1



UCon stimulator and remote control

FIGURE 2



UCon surface electrode

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DISCLOSURES

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