Developing a Wireless Device for the Research of Practical Neuromodulation Techniques to Treat the Neurogenic Bladder

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***Abstract*— Neuromodulation of peripheral nerves has long been viewed as a viable alternative treatment modality for suppressing Neurogenic Detrusor Overactivity (NDO). Research has continued over decades yet translation into patient use remains elusive. Questions have been asked as to the long term efficacy of continuous stimulation and a viable system using conditional stimulation has so far not been realised. Herein lies an opportunity for the research and development of a practical, non-invasive, neuromodulation system to treat NDO. To do so, further investigation of practical stimulation triggers and regimes is necessary. This paper presents the design of a wireless device for flexible delivery and assessment of stimulation techniques outside of the laboratory.**

I. Introduction

Supra-sacral spinal cord injury (SCI) causes serious disruption to the function of the lower urinary tract, often resulting in Neurogenic Detrusor Overactivity (NDO) and Detrusor Sphincter Dyssynergia (DSD). These two conditions affect the storage and voiding phases of the micturition cycle and can lead to both high intra-detrusor pressures and incontinence [1]. The impact of SCI on the bladder is keenly felt in the SCI population and research into this area is consistently cited as a priority [2].

Urological management goals are to protect the upper urinary tract and maintain continence. This is achieved by reducing NDO. Current management techniques do this pharmacologically, surgically or with implanted electrical stimulation devices. All have associated risks and side effects that may render them ineffective or unfavourable. Neuromodulation is an alternative treatment for NDO that takes advantage of the still intact lumbosacral spinal pathways following SCI, using electrical stimulation of the Sacral or Pudendal nerves to suppress bladder activity and promote continence [3]. Transcutaneous neuromodulation techniques have been investigated for decades yet no system has been offered to SCI community [4].

Continuous stimulation has been shown to be effective at suppressing NDO in a laboratory setting but its clinical implementation is limited by problems of power consumption and the potential habituation of reflexes. Conditional stimulation, applied as NDO occurs, has been shown to be as effective [5] and may offer the advantage of reducing the problems mentioned above. The problem with this approach lies in implementing a conditional stimulation system. The chronic measurement of bladder activity has been a subject of much frustration and of ongoing research [6].

Other avenues have been explored to avoid the need for this measurement. Acute and more chronic tests of user initiated stimulation (UIS) and semi-conditional stimulation have reported favourable results [7]-[9]. These results suggest an effective device could be implemented that is not wholly conditional and that further research into alternative stimulation triggers and regimes is warranted.

This paper outlines the development of a device to aid research into the efficacy of neuromodulation in the ambulatory environment, with the capability to wirelessly deliver and assess a range of stimulation regimes and triggers. We will use this tool to design and assess practical methods of delivering neuromodulation to treat NDO through everyday life.

II. Design

To be capable of controlling and assessing stimulation regimes the design consists of two main components, a controller for a commercially available stimulator (Odstock Medical stimulator (OMS)) and a app-based user interface, for researchers and patients to input and read information (see figure 2). Stimulation parameters of pulse frequency, pulse width, shape and amplitude are set on the commercially available stimulator and will be based on previous acute evaluation of response to neuromodulation in each user.

The user interface, delivered through a smart device based app, functions in three modes (illustrated in figure 1). First for the researcher or clinician to input the stimulation regime and trigger type they wish to implement along with relevant test information. This is loaded from the user interface to the controller, to complete the stimulation algorithm. Secondly, it offers a patient interface to be used for stimulation on-off control and diary entry of relevant information. Thirdly to collate the diary and stimulation data captured for a post test review and export. This data will be time-stamped in sync with simultaneously recorded ambulatory urodynamic data to allow review of stimulation tests against objective data.

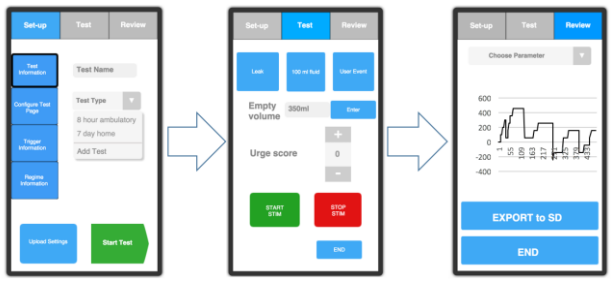

Figure 1. Initial designs for User Interface. From left to right - 1. Parameter and information input 2. Patient diary and control interface 3. Review and export window

The role of the controller is to turn the stimulation on and off at the correct times, to deliver the program set by the researcher. This controller will be constructed from a microcontroller, Bluetooth module, RTC, SD module and power supply directly connected to the OMS through a single cable. The core stimulation algorithm is stored and actioned

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here, informed by specific parameters relating to stimulation regimes and triggers sent to the controller wirelessly from the user interface. This wireless communication between the controller and app-based user interface will be achieved using Bluetooth technology. The controller will be located with the OMS, during tests it need not be accessed by the patient. The user interface, with its patient diary function, should be easily accessible. Fig. 2. outlines the components in the system and their interactions.

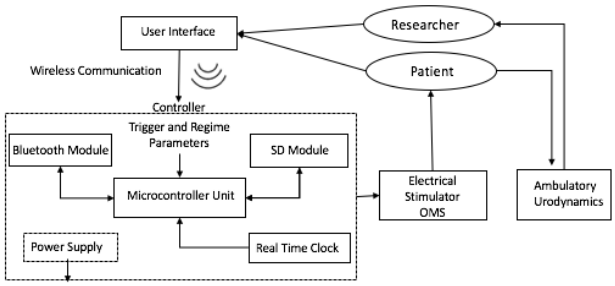

Figure 2. Block diagram of system outlining components and interactions relative to both patient and researcher

Ambulatory urodynamic data, when relevant to a study, will be captured concurrently using a commercially available device. This involves measuring detrusor pressure (P_{det}) over the course of a study. Abdominal (P_{abd}) and vesicle (P_{ves}) pressures are recorded from pressure transducers attached to urethral and rectal catheters, P_{det} is then calculated as P_{ves}-P_{abd}. Previous research [10] has concentrated on conditional stimulation, relying on ambulatory urodynamic measurements to deliver stimulation in response to an increase in pressure. However, indwelling pressure measurement is not a long-term solution. The design presented here takes a different approach, using detrusor pressure measurement as an objective outcome measure as opposed to an active component in our system. Patient diary inputs and stimulation times will also be recorded. This will enrich the ambulatory urodynamic data to lead to a better understanding of the effects of each tested stimulation mode.

Constraints placed on the design of the controller relate to size, power consumption and safety. In addition, the user interface must address usability constraints. We have currently based specifications on being able to support seven day studies in the home environment. Users will range in mobility from wheelchair users with limited hand dexterity to walking users with full hand function. The design must accommodate all, throughout activities of daily living.

III. Discussion

The main considerations in the design of this device have been to allow the user to maintain a true to life environment and to allow input flexibility whilst ensuring relevant data is captured. By developing a modular system, we aim to enable a future add-on for collection of urodynamic data within the same system. The option is also left open for greater use of software in the process, integrating the available data into one place may allow a more holistic view of outcomes and provide a basis for designing a more intelligent system.

Use of a wireless system will allow the whole assessment to take place with the stimulator in place, minimising the burden on the user and the risk of the system dislodging during activities of daily living. Untethered control allows easier access to the on-off control for the user, particularly users with limited hand dexterity who may also benefit from the use of a touchscreen user interface.

There are multiple regimes and triggers that may be suitable for effectively delivering stimulation. A key point in designing this device is to enable this range to be accessed and adapted through one common platform. This is particularly challenging in a population with such wide ranging requirements, where it is probable that individual adaptation of stimulation parameters and delivery techniques would be necessary. In this version, the device will provide a framework to assess semi-conditional, user initiated and timing based stimulation. The flexibility to modify, combine and add new trigger or regime paradigms will be built in. This flexibility will be used to develop a truly translational neuromodulation device, where personalised stimulation modes may be developed for individuals.

The device is currently under development and a prototype will be presented at the conference. It is intended to be used in ambulatory neuromodulation trials at London Spinal Cord Injuries Centre (LSCIC). Should this study be successful in identifying a practical neuromodulation paradigm, we will expand our prototype's capabilities and evaluate its suitability for clinical use.

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