Wearable neuromodulation devices to manage urinary incontinence subsequent to Spinal Cord Injury

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Spinal Cord Injury's bladder problem

Spinal cord injury (SCI) seriously disrupts the function of the lower urinary tract, affecting storage and voiding of urine. SCI can result in overactivity of the bladder (NDO), which often leads to chronic issues with urinary incontinence [1].

Incontinence and Quality of life

A 2010 study of London Spinal Cord Injury Centre outpatients reported 56% had incontinence on a minimum of a monthly basis, found to negatively influence quality of life measures [2].

Urodynamic assessment of bladder overactivity

Measuring bladder pressures whilst filling the bladder enables us to quantify bladder activity. The figure below shows an uncontrolled detrusor contraction resulting in leakage.

What is Neuromodulation?

Neuromodulation is the 'activity in one neural pathway modulating the pre-existing activity in another through synaptic interaction'. Electrical stimulation of sensory nerves is a common method of applying neuromodulation.

Neuromodulation and the bladder?

Previous research has shown neuromodulation's capacity to acutely inhibit episodes of NDO in persons with SCI. This may present a method of managing incontinence using a wearable device.

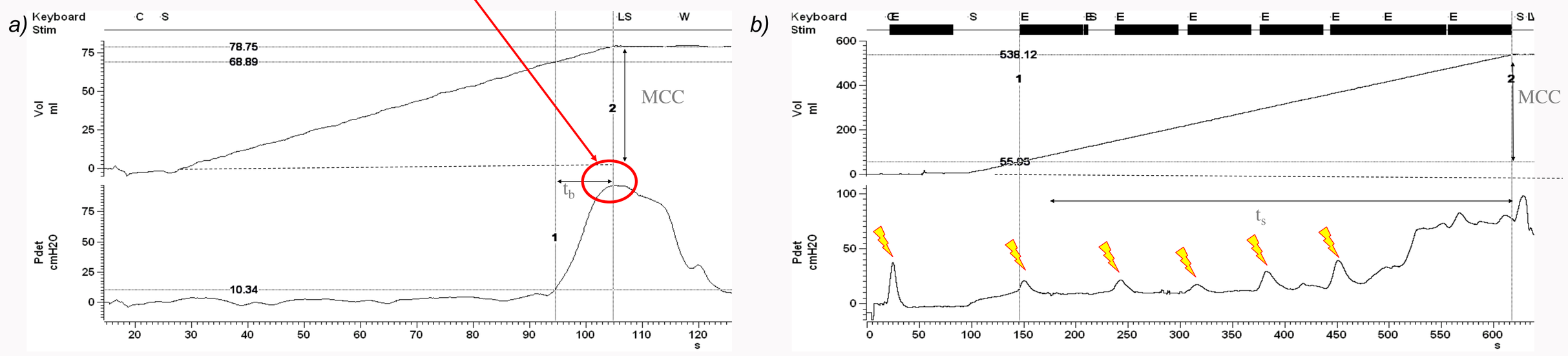

Figure 1. Graphs from a) baseline and b) with Genital Nerve Stimulation cystometry showing volume infused and P_{det} in one participant

Assessing acute effect and comparing stimulation sites

Stimulation of several anatomical sites is reported to reduce bladder overactivity in neurogenic cases [3]. However, validity in SCI and agreement on the acute effect of stimulating each site have not been achieved. We conducted a urodynamic investigation of n=8 people with SCI and bladder overactivity, comparing stimulation at each of the sites in figure 2, to assess the acute effects.

- Only DGNS produced a significant change in bladder capacity (+118ml±124).
- Stimulation of the genital nerve was seen to suppress detrusor contractions when applied at sufficient amplitude.
- For clinical implementation patient selection will be key to effective use, intact reflexes are necessary.
- No significant changes in capacity or visual suppression of NDO seen during stimulation of other sites.

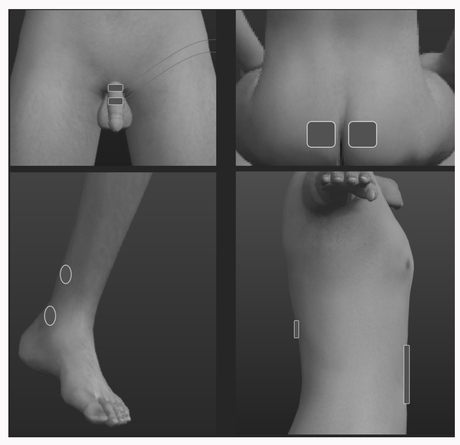

Figure 2. Simulation sites electrode positioning. a) Dorsal Genital Nerve (DGNS) b) Sacral Roots (SRS) c) Posterior Tibial Nerve (PTNS) d) Spinal Cord (SCS)

A wearable neuromodulation device?

The ability to switch off or delay a detrusor contraction presents an opportunity to develop a wearable device that may be used to reduce incontinence events.

Problems

There have been several issues identified in previous short trials of surface DGNS for management of incontinence. Variable **levels of sensation to trigger stimulation, abundance of wires, lack of easy access to stimulation triggers, unknown best regimes** and surface electrode design all present issues. We have implemented a system to look at some of these, figure 4.

Pilot study

We have recently begun a pilot study using DGNS over a week with SCI participants. Outcome measures are a digital bladder diary, ICIQ and ambulatory urodynamics compared to baseline values generated in a preceding week.

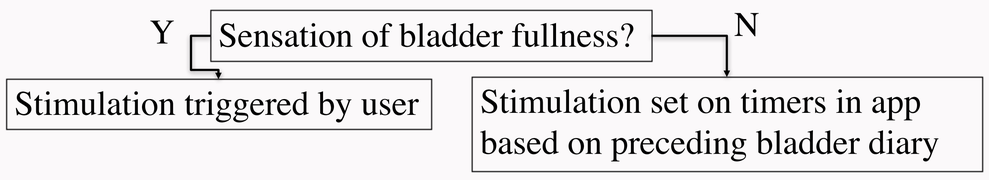

Figure 3. Set-up of neuromodulation system triggers for SCI is dependent on residual sensation

Conclusions

- Bladder overactivity following SCI may be acutely suppressed by stimulating the genital nerve
- Transcutaneous stimulation of the other 3 sites outlined in figure 1 showed no effect on NDO
- Potential for an effective wearable device exists, we are investigating further.

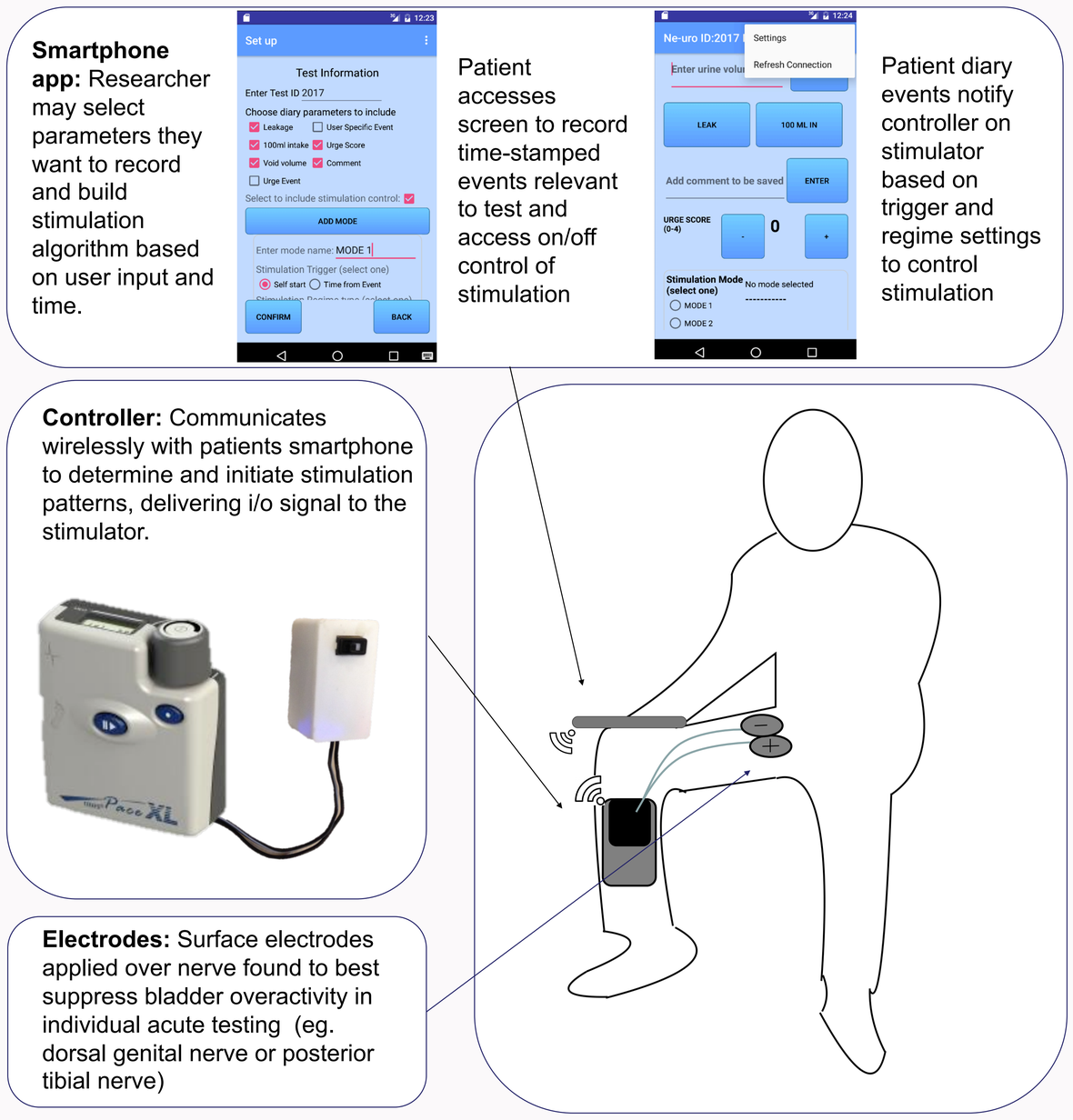

Figure 4. An overview of the system components and their position relative to the patient.

References

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2. Liu, C.W. et al., 2010. The relationship between bladder management and health-related quality of life in patients with spinal cord injury in the UK. Spinal Cord, 48(4), pp.319–324.
3. McGee, M.J., Amundsen, C.L. & Grill, W.M., 2015. Electrical stimulation for the treatment of lower urinary tract dysfunction after spinal cord injury. The Journal of Spinal Cord Medicine, 38(2), pp.135–146.

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