INSPIRE FOUNDATION
Funding Research into Spinal Injury

Project BIONIC BLADDER Restoring bladder & bowel control after Spinal Cord Injury

RESTORING CONTROL WITH QUALITY OF LIFE

Spinal Cord Injury (SCI) paralyses muscles and cuts off sensation; these life changing consequences are permanent and very challenging to manage. No two cases of SCI are identical, and they can vary in severity. Although the ability to walk can often be lost, and sometimes the ability to grasp or move ones arms, there is one guarantee, **SCI always effects bladder and bowel control**. Commonly this involves losing the ability ‘to empty’ when required and the development of uncontrolled overactivity, leading to incontinence. These consequences can be devastating to individuals’ quality of life and dignity and for those unfortunate enough to experience SCI, there is no question **Restoration of bladder and bowel control is a key priority.**

OUR SPECIFIC AREA OF INTEREST

The INSPIRE Foundation is supporting research at **Oxford and Bath Universities** aiming to use neurostimulation techniques to control the bladder and bowel. This would allow people with SCI to either prevent incontinence or empty the bladder or bowel at the flick of a switch. Where existing treatments can aid and improve symptoms, the current gold standard of treatment still involves catheterisation with the significant risk of ongoing infections that goes with this. Neurostimulation may be applied on demand to artificially restore control and does not exhibit side effects. This project will focus on refining stimulation waveforms for this application and implementing them on an existing implantable device, such that they are available to people with SCI as promptly as possible.

OUR RESEARCH TEAM

Dr Ben Metcalfe PhD MEng FHEA – Deputy Head of the Department of Electronic and Electrical Engineering at the University of Bath and Principal Investigator (PI)

Professor Alex Green FRCS, MD, BSc, MB BS – Consultant Neurosurgeon, Nuffield Department of Clinical Neurosciences, University of Oxford and Oxford University Hospitals NHS Foundation Trust

Professor Tim Denison DPhil MBA MS PhD – Professor, MRC Brain Network Dynamics Unit, University of Oxford, ex-VP of Research and Core technology team at Medtronic and global leader in neuromodulation

Ms Deepti Bhargava MD – Consultant Neurosurgeon, The Walton Centre NHS Foundation Trust

Dr Sean Doherty MEng PhD – Research Fellow at University College London (UCL) and the London Spinal Cord Injury Centre, SARS Advisor to Finetech Medical Ltd, Lead System Engineer at Amber Therapeutics Ltd, Owner of a Spinal Cord Injury

Dr Nicolas Granger DVM PhD DECVN FHEA FRCVS – Associate Prof at Bristol University & Consultant Neurologist at CVS Referrals

Above Left: Professor Alex Green and team with an SCI patient at the **University of Oxford.**

Above Right: **PI Dr Ben Metcalfe** presenting his work to **HM Queen Elizabeth II** alongside the **Lord Lieutenant of Somerset Mrs Annie Maw** who suffered a spinal cord injury in 2002.

Right: Research Fellow Dr Sean Doherty receives the INSPIRE Foundation PhD Scholarship from the late **Baroness Masham of Ilton at the House of Lords.**

SACRAL ANTERIOR ROOT STIMULATION SYSTEM – CURRENT SIDE EFFECTS

Sacral anterior root stimulation (SARS) devices are occasionally implanted to enable bladder control. However, as things stand, the nerves that carry sensation from the pelvic region are necessarily cut during implantations to remove reflex bladder and sphincter contractions that cause incontinence and dangerous voiding. However, this is unacceptable to many patients because it abolishes reflex erection and ejaculation, and is destructive – the latter becoming an increasingly important factor as the prospects for spinal cord regeneration improve. It may also cause sphincter and pelvic floor weakness in men and women, and in a minority of patients, stress incontinence. Therefore, electing for SARS requires careful consideration, and for those living with SCI who do have reflex erections/ejaculation and remaining sacral sensation, the downsides often outweigh the positives of predictable and safe bladder function, even if catheters and medication continue to be used.

BIONIC BLADDER - Future Research

This project brings together several strands of Engineering and Neuroscience and aims to use novel waveforms to replicate the effects of cutting sensory nerves, without the loss of sensation, reflex erections and ejaculations. **Importantly our advances would avoid the need to cut the sensory nerves and thus avoid doing further harm post SCI**. As the research team has already conducted significant background work, this should be possible with only minor updates to the existing SARS device, enabling speedy translation. We expect the results from this project to feed into a pilot trial offering next-generation SARS devices to trial.

HOW MUCH, HOW LONG AND WHERE?

While our medical research will primarily be conducted at the **University of Oxford,** this 2 year project costing **£213,146** and is being coordinated using additional facilities at the **University of Bath, Bristol and UCL.** The cost is needed to cover research staff, equipment purchase, travel and consumables for the duration of the testing phase with 5 SCI participants and salaries for clinical staff. Device development support from a medical device company will be covered and some equipment will be loaned from them.

WHY ARE WE APPROACHING YOU?

There is no Government or NHS funding for research into SCI and we rely on donations from grant making trusts, foundations and other charitable organisations. We absolutely dependent on the generosity of these bodies without which our research programme, uniquely focused on improving the lives of the 50,000 people living with SCI in the UK, would simply cease! Our current programme of eight projects is costing **£1.41m.**

HOW THE EXPECTED OUTCOME WILL BENEFIT THE SPINAL CORD INJURED

"Restoration of bladder control is a top priority to the SCI population, where incontinence and catheter associated infections may be regular and are extremely detrimental to individuals' quality of life. Our research is exciting as it involves the translation of techniques into new devices that may provide on demand control of the bladder and bowel. The fact that neuromodulation can be used on-demand, to immediately suppress an unwanted contraction of the bladder or trigger a wanted contraction, distinguishes it from existing therapies. We are in the early stages of trialling this technique in hospital labs. Looking to the future there is evidence that this is a technique that may be used by people with many pathologies either in combination with or instead of pharmaceutical therapies. Bionic bladder will give us strong proof-of-concept evidence of neurostimulation's potential; if successful, good baseline data will be harnessed to seek further funding for larger bodies to run a randomised controlled trial."

Dr Ben Metcalfe (Bath University)
Principal Investigator
Project BIONIC BLADDER (funded by INSPIRE) January 2024

'…researching independence, quality of life and dignity after spinal cord injury…'