ISCRR
Institute for Safety, Compensation and Recovery Research

HORIZON SCANNING

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NEWSLETTER

Technologies to Prioritise

The Institute for Safety, Compensation and Recovery Research (ISCRR) Horizon Scanning program is designed to identify new and emerging health technologies, treatments and services that may have the potential to improve the lives of people affected by transport accidents or work-related illnesses and accidents. The technologies, treatments and services are anticipated to have a significant impact on client care, safety, independence, function, mobility and quality of life. The health-related innovations presented are selected from technologies in the early stages of development, on the verge of diffusion or not yet adopted into established health care systems. The technologies are estimated to emerge in the Australian market within one to three years.

The nine innovations presented in this newsletter have gone through a rigorous filtering and prioritisation process. They originated from a list of thirty-eight innovations that were identified through horizon scanning activities. Through consensus agreement amongst representatives from the Transport Accident Commission (TAC), WorkSafe Victoria (WorkSafe) and Monash University (ISCRR), the innovations were prioritised and selected as those with the greatest potential to improve TAC and WorkSafe client outcomes.

The clinical evidence and regulatory status of the innovations featured in the newsletter will be monitored on an ongoing basis.

For more information on ISCRR, The Horizon Scanning program or this newsletter, contact
ISCRR.horizon.scanning@monash.edu

TECHNOLOGIES INCLUDED IN THIS NEWSLETTER

A joint initiative of

WorkSafe VICTORIA
TAC Transport Accident Commission
MONASH University

Non-invasive ultrasound technique for the treatment of severe brain injury

Despite increasing rates of survival after severe brain injury, a number of patients do not fully recover. Some patients wake in a vegetative or minimally conscious state and there are very limited treatment options for these patients. A new non-invasive ultrasound technique called low-intensity focused ultrasound pulsation is being investigated for the treatment of severe brain injury.

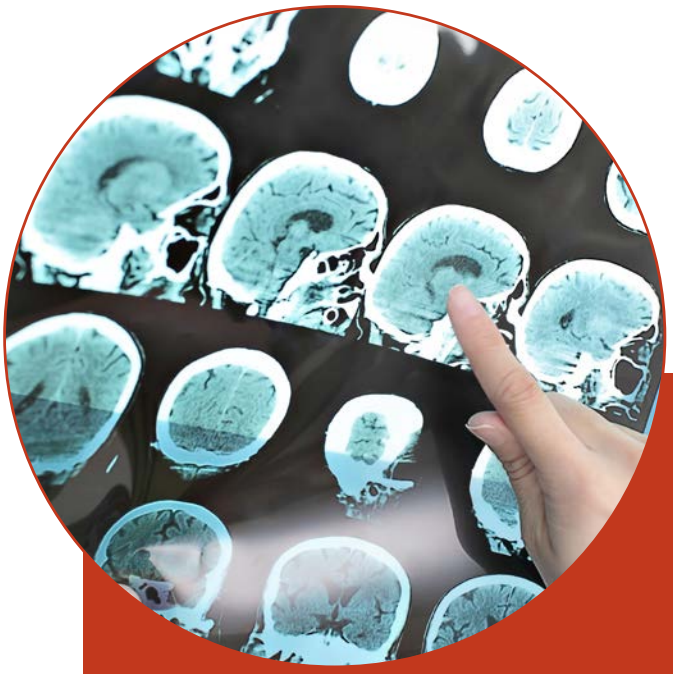
This new technique involves the use of a device that produces a small sphere of acoustic energy that can be targeted at different regions of the brain to excite nerve tissue. The treatment targets the thalamus; a part of the brain that has a key role in consciousness, sleep and alertness.

As part of the first in human study to test the feasibility, safety and initial effectiveness of this technique, it has been used in a 25-year-old coma patient. The device (BXPulsar 1001, BrainSonix) was placed on the side of the patient's head, 19 days post-injury. Ultrasound energy was applied to the thalamus in 30 second bursts, repeated 10 times within a 10 minute period. Prior to the procedure, the patient showed only minimal signs of being conscious and of understanding speech.

Within three days of treatment he had regained consciousness and full language comprehension and could reliably communicate by nodding or shaking his head. Five days following the procedure the patient attempted to walk. The results are promising, however, it is not possible to determine if the patient improved spontaneously.

A clinical trial, due for completion in 2017, is being conducted by the University of California, Los Angeles and is expected to enrol 15 patients. The trial will inform the feasibility of a full-scale clinical trial. If successful, this new technique may provide an alternative for people with severe brain injury for whom there are currently very few treatment options.

Developer: BrainSonix Inc.
www.brainsonix.com



Australian approval status: Not approved

Stage of development: Experimental

Setting for use: Acute care

Transcutaneous electrical spinal cord stimulation to improve function following spinal cord injury

Neurostimulation is a new strategy currently under investigation in the management of spinal cord injury. Neurostimulation (sometimes also referred to as neuromodulation) uses gentle electrical currents to stimulate the spinal cord. Research has given hope that neurostimulation applied to the injured spinal cord can improve function.

NeuroRecovery Technologies Inc. has developed an implantable epidural spinal cord stimulation system and a non-invasive transcutaneous (through the skin) spinal cord stimulation system to provide functional recovery for individuals with spinal cord injury.

The non-invasive system involves transcutaneous stimulation of the spinal cord using a proprietary prototype device. The device delivers an electrical current to the spinal cord via electrodes placed on the skin of the lower back and near the tail bone. This approach uses specific stimulation parameters that do not elicit pain even when energies required to transcutaneously reach the spinal circuitry are used. The procedure eliminates the need for surgery to implant the electrodes and stimulator.

A study has shown that five men, each paralysed for more than two years, were able to voluntarily generate step-like movements following treatment with transcutaneous electrical spinal cord stimulation. The men participated in a series of 45-minute sessions, once per week for 18 weeks. In addition to the stimulation, the men also received several minutes of conditioning each session, during which their legs were moved manually. For the final four weeks of the study the men received the drug buspirone, which has been shown to induce locomotion in animals with spinal cord injury. Because the men responded so quickly to the therapy, it is believed the stimulation may have awakened dormant connections between the brain and the limbs.

Studies investigating whether non-invasive transcutaneous electrical spinal cord stimulation can improve function including hand and arm, lower limb and bladder function are currently underway. Trials are expected to be completed between 2016 and 2018.

Project Edge, launched in September 2016, is a collaboration between the University of Technology Sydney, SpinalCure Australia and Spinal Cord Injuries Australia to establish the first neurostimulation research program outside of the USA. Subject to securing funding, Project Edge will be involved in Australian trials to further investigate the use of transcutaneous stimulation in spinal cord injury. (www.projectedge.org.au)

Developer: NeuroRecovery Technologies Inc.
www.neurorecoverytechnologies.com

Australian approval status: Not approved

Stage of development: Experimental

Setting for use: Rehabilitation

NeuroLife neural bypass system to restore movement following quadriplegia

A new technology has been developed that allows paralysed patients to regain conscious control of their fingers, hand and wrist. The technology bypasses damaged areas of the nervous system so the brain can communicate directly with the muscles. Surgeons implant a small chip on the brain's motor cortex; the part of the brain responsible for nerve impulses that initiate voluntary movement. The chip transmits information from the brain, through sophisticated decoding software, to a customised forearm cuff containing electrodes that stimulate the muscles for specific movement. The technology interprets thoughts and brain signals, bypasses the injured spinal cord and enables direct communication with arm and hand muscles.

A trial is currently underway at Ohio State University to assess whether the NeuroLife neural bypass system (also referred to as neural bridging system) can allow participants with quadriplegia to move a paralysed limb using their thoughts. The study is expected to enrol five patients and is due to be completed in 2018.

The first patient to be enrolled in the trial was a 24-year-old male who was paralysed from the shoulders down as a result of a diving accident. In 2014, the man underwent precise implantation of a small computer chip (Utah microelectrode array, Blackrock Microsystems) on his motor cortex. Following surgery, the man participated in sessions up to three times per week where he was trained to use the system. After two months the man was able to open and close his hand with his thoughts. With more training he is now able to perform more sophisticated movements and functional tasks relevant to daily living such as picking up a spoon, stirring a coffee, swiping a credit card and holding a phone to his ear. A second patient is expected to start in the study during 2016.

Limitations of the current system mean that it can only be used in the laboratory. The system needs to be recalibrated each session and this is a time-consuming and technical process. In addition, the system does not allow the user to feel the objects they are manipulating. Sensory feedback from the hand would enable the user to adjust their grip strength more effectively. The developers hope to evolve the system so it can be used by individuals at home.

Developer: Batelle
www.battelle.org

Australian approval status: Not approved

Stage of development: Experimental

Setting for use: Rehabilitation

UPnRIDE mobility device

Sedentary wheelchairs are associated with a detrimental impact on physical and mental health, and on productivity and social inclusion. A standing position however, provides exercise for paralysed limbs and alleviates many of the health problems associated with long-term wheelchair use. The UPnRIDE mobility device was designed to provide upright mobility and is suitable for most wheelchair and scooter users, including paraplegics, quadriplegics and people suffering from traumatic brain injury. The device was designed to provide upright mobility to people who cannot use robotic exoskeletons such as the ReWalk walking device.

The UPnRIDE is a convertible wheelchair that brings users from a sitting position to an upright position. The device is reported to provide fully-functional standing and sitting mobility, improving health and enhancing social inclusion. It is unique in that it provides users with full functional mobility in an upright position both indoors and outdoors on a variety of surfaces, including sloping surfaces. According to the manufacturer, features include:

- jointed braces and harnessing straps for safe support for users
- auto-balancing and unchanged centre of gravity for constant stability algorithms to minimise the risk of hazardous situations
- a design for easy maneuverability.

The device was launched in September 2016 and is expected to be available commercially from early 2017 for approximately US$30,000. The developer is currently working to obtain regulatory clearance for marketing and is conducting two clinical trials. One trial is being conducted at Israel's Sheba Medical Centre and the other with the U.S. Department of Veterans Affairs in New York.

Developer: UPnRIDE Robotics
www.upnride.com

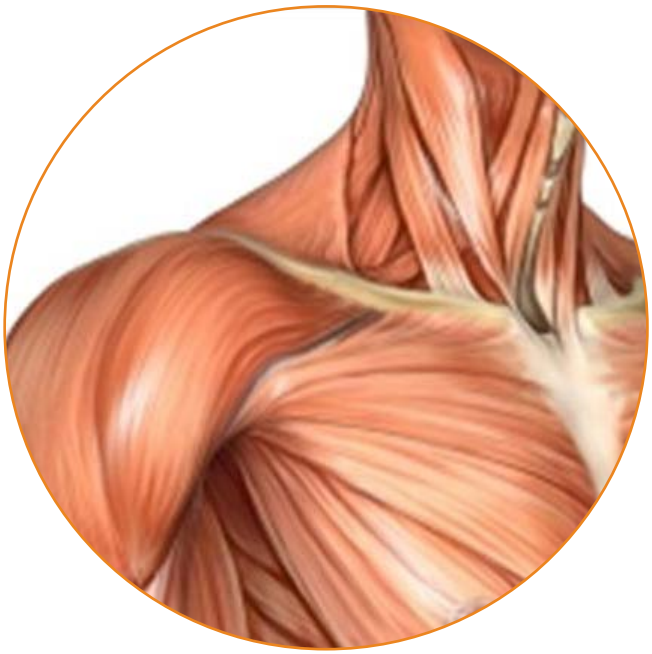
Courtesy of UPnRIDE Robotics

Australian approval status: Not approved

Stage of development: Not known

Setting for use: Home care / Rehabilitation

Biological scaffolds to treat muscle loss from severe musculoskeletal injuries



Severe musculoskeletal injuries, such as those that occur after traumatic injury, are often associated with a loss of muscle and can result in life-long disability. Skeletal muscle has the ability to regenerate after injury, allowing injured areas to be replaced with functional muscle. However, in instances where large volumes of muscle are lost following trauma, regeneration fails and muscle is replaced by scar tissue. This process is known as volumetric muscle loss. The reconstruction of tissue following this type of injury is often not possible and there is a limited ability for tissue regeneration and healing because structures involved in repair pathways are also compromised. Current treatment options include physical therapy, braces and tendon or muscle transfers, which often do not restore strength and function.

Biological scaffolds have been suggested as a regenerative approach for these types of injuries. Biological scaffolds made from extracellular matrix are implanted devices that provide structural and biochemical support on which tissue grows. These devices provide a scaffold that is replaced by the subjects' own tissue over time. The scaffolds are composed of animal derived collagen and proteins that surround the cells in animals. No living cells are found in these scaffolds. Extracellular matrix devices are made by many commercial manufacturers and have been used for a variety of reconstructive surgical procedures for an extended period of time.

A study was conducted at the University of Pittsburgh School of Medicine and the McGowan Institute for Regenerative Medicine to investigate the effects of implantation with extracellular matrix biological scaffolds in individuals who suffer from injury with loss of skeletal muscle tissue. Participants underwent surgical implantation at the site of missing muscle with biological scaffolds derived from pig tissue. Aggressive physical therapy commenced between 24-48 hours after surgery and continued for 24 weeks. Results from the first thirteen patients showed significant improvement in strength and range of motion as well as evidence of skeletal muscle regeneration. By six months after implantation, patients showed an average improvement of 37.3% in strength and 27.1% in range of motion tasks, compared with pre-operative performance. The patients had previously failed to respond to conventional treatment for their muscle injury.

Australian approval status: Not approved

Stage of development: Not known

Setting for use: Acute care

iBOT two-wheel motorised wheelchair

The iBOT powered-wheelchair has a number of features distinguishing it from most powered wheelchairs. The iBOT was designed to provide increased freedom, flexibility and independence for users. It is for indoor and outdoor use and functions to provide mobility on smooth surfaces and inclines and movement across obstacles and uneven terrain including curbs, grass, gravel, sand and shallow water. Users can ascend and descend stairs with or without assistance. The wheelchair incorporates technology that monitors and responds to changes in movement to keep the user upright and stable at all times. In addition, the iBOT can raise its occupants to the eye level of people standing nearby and provide mobility in a seated position at an elevated height of approximately six feet.

The iBOT powered-wheelchair was originally developed in a partnership between DEKA Research and Development, and Johnson and Johnson, and was approved by the United States Food and Drug Administration in 2003. The iBOT originally sold for US$25,000, a prohibitive price tag that forced production to halt in 2009.

A partnership was announced in May 2016 between DEKA and Toyota to develop and launch the next generation of the iBOT. The new design is much slimmer and will be enhanced by 15 years of improvements in technology, which will also contribute to a reduced price.

There is currently no information about the availability of the second generation iBOT or its price.

Developer: DEKA Research and Development and Toyota
www.dekaresearch.com/innovations

Australian approval status: Not approved

Stage of development: Not known

Setting for use: Home care / Rehabilitation

Riluzole for the treatment of acute spinal cord injury

Spinal cord injury is a devastating event resulting in severe neurological deficit, loss of function and deterioration in quality of life. There are currently no effective therapies known to improve neurological and functional recovery. Spinal cord injury involves a primary mechanical injury, followed by a secondary injury involving many signalling pathways that results in further damage. There is an opportunity to preserve remaining viable nerve tissue by reducing the development of secondary injury and therefore improve post-injury outcomes. Riluzole is a drug that has effects on the pathways involved in the development of secondary injury, which makes it a promising neuroprotective treatment option for spinal cord injury.

Riluzole is an anticonvulsant drug approved by the United States, Canadian and Australian authorities for the treatment of amyotrophic lateral sclerosis (ALS). It has been shown to slow the progression of motor neuron loss and improve survival in these patients. Riluzole has an established safety profile from its use in ALS. A phase I trial of riluzole for acute spinal cord injury was completed in 2011 and provided safety and pharmacokinetic data (how a drug is absorbed, distributed, metabolised and excreted).

This trial suggested neuroprotective benefits of riluzole.

Patients with cervical injuries treated twice daily with riluzole orally or by nasogastric tube, within 12 hours of injury for 14 days, had greater improvements in impairment than a comparison group that received usual care.

On the basis of these results, a phase II/III randomised controlled clinical trial assessing the role of riluzole in treating acute cervical spinal cord injury began in January 2014. The trial plans to enrol 351 patients and is expected to be completed in 2018. As of August 2016, 40 patients had been enrolled.

Australian approval status: Not approved (not approved for spinal cord injury)

Stage of development: Investigational

Setting for use: Acute care

StimQ Peripheral Nerve Stimulator System for the relief of severe difficult to manage persistent pain

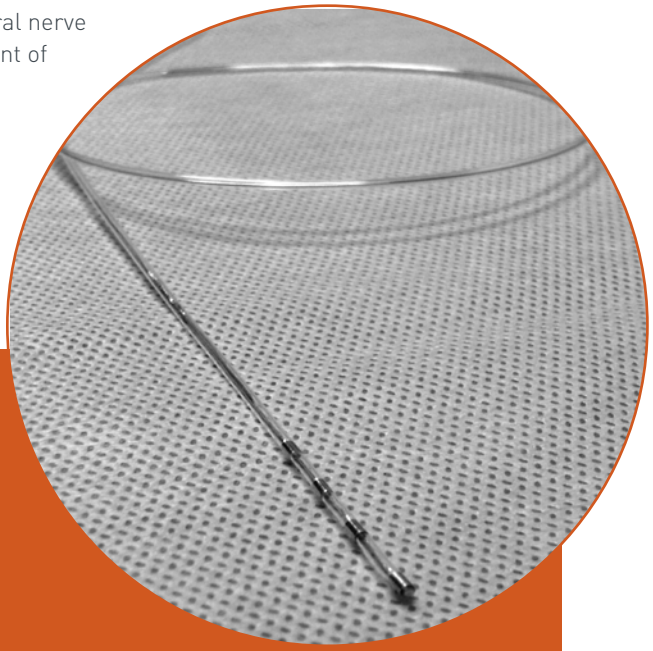
The StimQ System is an implantable peripheral nerve stimulation system used to provide therapeutic relief for persistent, intractable (difficult to control) pain of peripheral nerve origin (nerves outside the brain and spinal cord). The system can be used alone or in combination with other therapies as part of a multidisciplinary approach. The therapy employs pulsed electrical current to create an electrical energy field that acts on peripheral nerves in the limbs and torso to alter the transmission of signals that lead to the perception of pain in the brain. The system is comprised of a small implantable stimulator (Freedom-8A / Freedom-4A Stimulator) and an externally worn transmitter which is used to wirelessly power the stimulator. The stimulator is less than 5% of the size of other standard implanted options.

The manufacturer claims that the StimQ System is the world's first wireless, fully programmable peripheral nerve stimulator neuromodulation device. It can be implanted through a standard needle-sized insert or small incision next to peripheral nerves where the pain is originating. This is unlike other products on the market, which require general anesthesia, a large surgical incision and placement of electrodes and an internal battery within the body.

No studies of the effectiveness of the StimQ Peripheral Nerve Stimulator System could be identified. An ISCRR evidence review conducted in 2015, concluded that, due to a lack of high-quality, controlled primary studies, there is insufficient evidence to support the use of peripheral nerve stimulation for the treatment of persistent pain. If these technologies are shown to be effective, the StimQ System may provide a minimally invasive option in the management of persistent pain.

The StimQ System received United States Food and Drug Administration approval in March 2016 and is being marketed in the USA. It is expected to be available in the United Kingdom during 2016. It is estimated that the product will be available in Australia in 2017, pending Therapeutic Goods Administration marketing approval.

Manufacturer: Stimwave Technologies
www.stimwave.com



Courtesy of Stimwave Technologies

Australian approval status: Not approved

Stage of development: Nearly established

Setting for use: Acute care / Home care

SPRINT Peripheral Nerve Stimulation System for acute and persistent pain

Globally, healthcare systems are investigating therapies to manage pain while reducing the use of opioids. It has been reported that in the United States, almost 25% of patients who start opioids for pain relief progress to episodic or long-term use. The SPRINT Peripheral Nerve Stimulation System (also known as the Smartpatch System) was developed to span the treatment gap between pharmacological treatment and surgery to provide a drug-free, minimally invasive, reversible pain therapy.

The SPRINT System is a minimally invasive, peripheral nerve stimulation system designed to provide relief for acute and persistent (chronic or long-term) pain. The system consists of a threadlike lead and a matchbox-sized wearable stimulator. The lead is inserted through the skin with a fine needle, and connects externally to a wearable stimulator. The stimulator delivers an electrical current through the lead, which stimulates peripheral nerves to achieve localised pain relief. Unlike other peripheral nerve stimulation systems, SPRINT does not require permanent implantation and is designed to be withdrawn without surgery at the end of the treatment period. The system can be implanted in an outpatient setting.

Small studies have shown that the SPRINT System achieved significant pain reduction and improvements in quality of life in patients with post-stroke shoulder pain or post-amputation pain in the lower limbs. Larger, more robust studies examining pain experience, functionality and adverse events are needed.

Clinical trials are underway in the treatment of post-amputation pain and for the treatment of pain following total knee replacement. Both of these trials are due for completion in 2017.

The SPRINT System received United States Food and Drug Administration approval in April 2016 for use of up to 30 days in the back and/or extremities for the symptomatic relief of chronic intractable pain and acute pain, including post-surgical and post-traumatic pain.

The system received European CE mark and Australian Therapeutic Goods Administration approval in 2013 to treat chronic shoulder pain.

Manufacturer: SPR Therapeutics
www.sprtherapeutics.com

Australian approval status: Not approved (Approved for chronic shoulder pain only)

Stage of development: Nearly established

Setting for use: Acute care / Home care

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