ISCRR
Institute for Safety, Compensation and Recovery Research

HORIZON SCANNING

Issue 3 / July 2016

# 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 ten innovations presented in this newsletter have gone through a rigorous filtering and prioritisation process. They originated from a list of forty 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

# AST-OPC1 for the treatment of acute spinal cord injury

There are currently no approved treatments that can restore neurological function and reverse damage to the spinal cord following spinal cord injury. Current spinal cord injury treatment options focus on preventing further injury and are designed to improve mobility, function and pain.

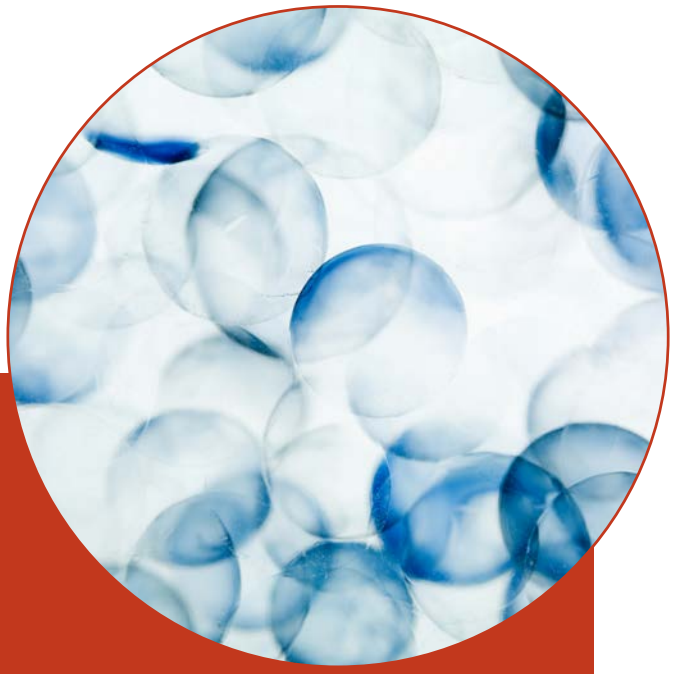
AST-OPC1 is a population of cells derived from human embryonic stem cells developed as a therapeutic strategy for spinal cord injury repair. AST-OPC1 cells are reported to act through multiple repair pathways to restore nerve conduction and function. AST-OPC1 may provide the opportunity to restore some motor function; increasing self-care and lessening daily care needs following spinal cord injury.

In an early-stage safety and feasibility trial, five patients with neurologically complete thoracic spinal cord injury were administered AST-OPC1 as a single injection into the injury site between 7 – 14 days after injury. The study showed that in four of the five patients the size of the injury site was reduced suggesting the treatment may reduce spinal cord tissue deterioration in the long term. During this trial, no serious side effects were noted.

Following the success of the first trial, a second trial was initiated to further evaluate AST-OPC1 in patients with cervical spinal cord injury. The second trial, the SCi-Star clinical trial, was initiated in 2015 and is due for completion in 2018. This trial will evaluate the safety and efficacy of a single treatment with AST-OPC1 administered 14 – 30 days after injury. The study will also assess the impact on hand and arm function.

AST-OPC1 received United States Food and Drug Administration Orphan Drug Designation in February 2016. The purpose of this designation is to advance the evaluation and development of products that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions.

AST-OPC1 is being developed by Asterias Biotherapeutics, United States.



**Australian approval status: Not approved**

**Stage of development: Experimental**

**Setting for use: Acute care**

# Indego powered exoskeleton

Wheelchairs are currently the primary devices used to restore some degree of mobility in people who have experienced a spinal cord injury resulting in paraplegia. However, long-term wheelchair use is associated with thinning bones, pressure sores, and subsequent complications relating to the urinary, cardiovascular, and digestive systems. Furthermore, wheelchairs are unable to restore upright mobility (walking) or allow users to climb stairs. Wearable powered exoskeletons have the potential to increase mobility and freedom to individuals with paraplegia.

The Indego powered exoskeleton has a set of computer-controlled, motorised leg braces that restore the ability to walk with crutches. It is designed for patients with paraplegia who are able to use their hands and shoulders and who have good bone density and cardiovascular health. Patients control movement by leaning forward to walk and leaning backward to slow down or stop. There are two models of the Indego system, one intended as a therapeutic tool for use in a rehabilitation setting and the other which is designed as a personal assistive walking device for use at home or in the community.

The Indego system is promoted as having several unique features that facilitate usability and independent operation. This includes the modular, lightweight design that allows it to be put on, taken off and adjusted to fit without assistance as well as allowing for rapid set-up and easy transportation. The system can be worn while seated in a standard wheelchair.

A clinical trial assessing the safety and effectiveness of the Indego device in restoring upright mobility for individuals with spinal cord injury under a variety of conditions was completed in late 2015. A trial to assess and measure the impact of the Indego device as a therapeutic tool in a rehabilitation setting is expected to commence in mid-2016.

The Indego system is approved for clinical and personal use in the United States and Europe. The Indego system has United States Food and Drug Administration clearance and European CE marking (certified as fit for its stated purpose and meets relevant safety legislation). In the United States the Indego is priced at approximately US$80,000 for the personal unit, prices in Europe may vary.

The Indego is manufactured by Parker Hannifin Corporation, United States.

*Courtesy of Parker Hannifin Corporation, USA*

**Australian approval status: Not approved**

**Stage of development: Nearly established**

**Setting for use: Rehabilitation / Home and community**

# Cross-linked hyaluronic acid for the treatment of neuropathic pain

Neuropathic pain occurs when nerves are damaged by disease or injury, causing them to misfire and send pain signals to the brain. Neuropathic pain is usually described as shooting, stabbing, burning or an electrical shock, and is often worse at night. The pain is often severe and can be difficult to treat, with many sufferers experiencing little relief or unwanted side-effects from currently available pharmacological treatments such as antiepileptics, antidepressants and opioids.

Cross-linked hyaluronic acid has shown promise as a potential new treatment for neuropathic pain. In its natural form hyaluronic acid is a liquid that is broken down in the body within a day. Cross linking chemically binds the individual chains of the acid so it is changed into a gel that is broken down over a period of 6 to 12 months. Cross-linked hyaluronic acid injections are commonly used as fillers in cosmetic surgical procedures and are available in Australia commercially as Juvéderm (Allergan) and Restylane (Galderma).

The first trial to assess the safety and effectiveness of cross-linked hyaluronic acid for the treatment of neuropathic pain has recently been completed. The study involved 15 patients with 22 different pain syndromes who had experienced persistent neuropathic pain for an average duration of 5.5 years. Following targeted injection of cross-linked hyaluronic acid into the painful area (including face, spine, shoulder, elbow, wrist, thigh and feet) all patients reported pain relief. Pain, assessed using a self-reported measure of pain intensity, decreased from an average of 7.5/10 before treatment to 1.5/10 after treatment. The average time to achieve pain relief was 24 hours and the average duration of pain relief was 7.7 months. The study was presented at the American Academy of Pain Medicine meeting in March 2015.

The mechanism of action of cross-linked hyaluronic acid in reducing neuropathic pain is not fully understood but may include blunting the unwanted spontaneous nerve signals and an anti-inflammatory effect.

A patent for the novel indication and technique for use of cross-linked hyaluronic acid in the management of pain was granted in November 2015.

**Australian approval status: Not Approved**

**Stage of development: Experimental**

**Setting for use: Acute care / Primary care**

# Keeogo motorised assistive walking device

Keeogo is a motorised assistive walking device or exoskeleton which consists of a set of computer-controlled, motorised leg braces designed for individuals experiencing a lack of endurance, reduced muscle strength or pain as a result of injury or chronic illness. Keeogo is designed to assist with certain types of mobility issues such as difficulties with walking endurance, climbing stairs, carrying an object for a short distance or standing for a long period of time. Keeogo is not intended for individuals with spinal cord injury resulting in complete paralysis.

Keeogo utilises sensors at the knee and hip joints to detect the user's intended movement and applies adjustable motorised power to complement the user's own muscle strength. To use the Keeogo device, individuals must have the ability to initiate movements in walking, sitting, standing, squatting, crouching, kneeling and stair climbing as well as the ability to walk without assistance from another person and maintain the necessary balance and core strength.

The benefits of Keeogo are currently under investigation and have not yet been clinically proven. The manufacturer claims the intended functional benefits for individuals with mobility impairments wearing Keeogo on a regular basis include the ability to remain active, the ability to work, improved safety and stability, improved accessibility, the potential to prolong the onset of wheelchair use, overall independence and freedom. Intended clinical benefits include improved endurance, musculoskeletal health, balance, posture, bladder/bowel function, bone health, mental health and increased circulation.

The manufacturer states that a clinical trial to assess the effectiveness and safety of Keeogo for community and home mobility use is currently underway.

Keeogo is commercially available in Canada and costs C$40,000 to purchase or C$1,000 per month to rent.

The Keeogo is manufactured by B-TEMIA, Canada.

*Courtesy of B-TEMIA*

**Australian approval status: Not approved**

**Stage of development: Investigational**

**Setting for use: Rehabilitation / Home and community**

# Telehealth for the treatment of post-traumatic stress disorder (PTSD)

Although effective evidence-based psychotherapies are available for treating post-traumatic stress disorder (PTSD), many sufferers fail to receive the care they need. Two factors that contribute to this are a lack of access to providers due to distance and the perceived stigma associated with openly seeking mental health resources. A model that incorporates telemedicine-facilitated psychotherapy could remove geographical constraints and could offer discreet treatment.

The Telemedicine Outreach for PTSD program was developed to enhance access and engagement in evidence-based psychotherapy and pharmacotherapy for remote veterans. The model employed an off-site PTSD care team (tele-psychiatrist, tele-psychologist, tele-pharmacist, and tele-nurse care manager) and used telemedicine technologies (telephone, interactive video and electronically shared medical records). Services were delivered to individuals at home or at a local community based clinic.

Following the successful evaluation of this approach, the United States Veterans Health Administration intend to deploy the intervention nationally. To support the national deployment, an implementation project commenced in April 2016 to evaluate the clinical effectiveness of the intervention and the cost and effectiveness of different implementation strategies. The study will finish in 2019.

Results from a recent trial support the models of telehealth that are being developed for the treatment of PTSD. The study demonstrated that evidence-based psychotherapy delivered as home-based telehealth was safe and effective with outcomes comparable to treatment delivered in person. The study showed that 70% of participants reported a good relationship with their provider, 79% would recommend telehealth to a fellow patient and 46% reported missing fewer appointments.

The models that are being developed may be applicable to PTSD resulting from other types of trauma including serious accident or injury.

**Australian approval status: Not approved**

**Stage of development: Investigational**

**Setting for use: Telehealth**

# Regenerative treatment of complete traumatic spinal cord injury with a surgical implant (SC0806)

Spinal cord injury from trauma or disease is referred to as complete or incomplete based on whether any movement or sensation occurs at or below the level of injury. People with incomplete injuries retain some sensory function and may have voluntary motor activity below the injury site. Following a complete injury there is a total lack of sensory and motor function below the level of injury, even if the spinal cord was not completely severed. Currently there are no regenerative therapies available that restore spinal cord function in injuries classed as complete spinal cord injuries.

SC0806 is a new treatment designed to recreate a functional spinal cord and is based on the regeneration of functional nerves at the injury site. SC0806 is a drug/device combination comprising a biodegradable implant loaded with fibroblast growth factor and peripheral nerve grafts. The implant is surgically implanted into the injured spinal cord to reconnect viable nerves on either side of the injury. Fibroblast growth factor is reported to work through multiple repair pathways to support nerve cell survival and regeneration. The implant is administered together with robot assisted walking training.

SC0806 received Orphan Drug Designation in Europe in 2010 and by the US Food and Drug Administration in 2011. The purpose of this designation is to advance the evaluation and development of products that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions.

The first in-human trial of SC0806 commenced in 2015 and is expected to be completed in 2019.

SC0806 is being developed by BioArctic Neuroscience AB, Sweden.

**Australian approval status: Not approved**

**Stage of development: Experimental**

**Setting for use: Acute care**

# Granulox haemoglobin spray for the treatment of chronic wounds

Pressure ulcers are common in individuals with limited mobility and / or sensation. Despite effective interventions for the prevention and management of pressure ulcers, many do not heal and become chronic wounds.

Oxygen is essential for wound healing and is required to both minimise further tissue damage as well as promote healing of the damaged tissue. A major cause of slow wound healing is an inadequate level of oxygen supply in the wound itself.

Granulox (also known as HEMO2SPRAY) is a new treatment shown to speed healing of slow-healing wounds such as foot ulcers, leg ulcers, pressure ulcers and post-surgical wounds. The active ingredient is haemoglobin which acts as an oxygen transporter. Haemoglobin binds oxygen from the surrounding air, improving oxygen availability in the wound bed and enhancing the activity of the pathways within the damaged cells required for wound-healing. Granulox is sprayed directly onto the wound at every dressing change and is intended to be used in addition to standard wound care.

There have been several evaluations of the effectiveness of Granulox to promote healing of chronic wounds. In one study, following 6 months' treatment for chronic wounds in the lower limb, 93% of patients in the Granulox treatment group reported wound healing compared with only 7% of patients in the standard care group. A second study in patients with chronic venous leg ulcers reported a wound size reduction of 53% following 13 weeks of Granulox compared with a wound size enlargement of 21% in patients who received only standard wound care. More recently, a study conducted in patients with pressure ulcers reported that wound size was reduced in 94% of wounds following 4 weeks of treatment, and 82% of wounds were healed following 12 weeks treatment. Granulox was also shown to reduce wound pain in 90% of patients in this study.

Granulox has European CE marking (certified as fit for its stated purpose and meets relevant safety legislation) and is available in the United Kingdom and Europe.

Granulox is manufactured by infirst Healthcare, United Kingdom / SastoMed, Germany.

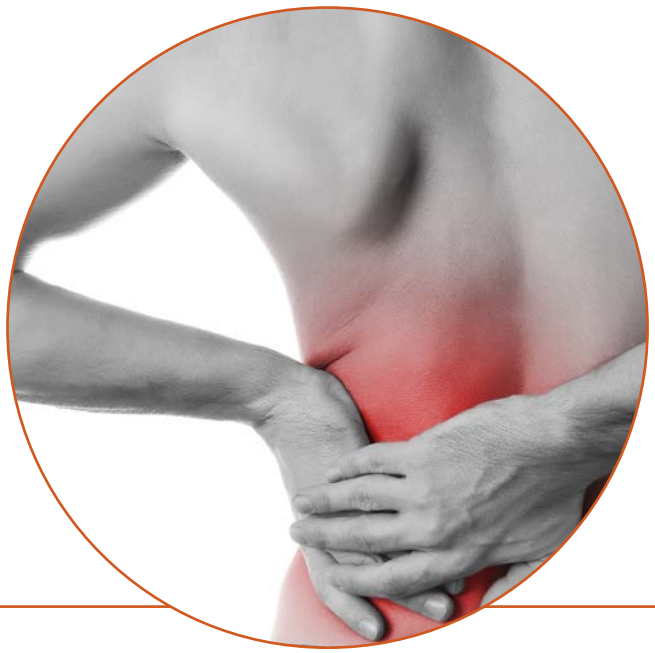

*Courtesy of infirst Healthcare Ltd*

**Australian approval status: Not approved**

**Stage of development: Nearly established**

**Setting for use: Acute care / Rehabilitation / Residential care / Home and community**

# Model of care for people with acute low back pain



Low back pain is recognised as a major cause of disability in Australia. A key problem in the management of low back pain is the number of people who develop chronic low back pain following an acute episode. Studies have shown that 48% of those reporting an episode of acute back pain still experience pain and disability after three months and almost 14% remain unrecovered at 12 months. There is an expectation that early appropriate care may reduce such a transition.

Current data reveals that treatment approaches involve several deviations from guideline recommendations including the liberal use of spinal imaging, opiate analgesia and recommendations of bed rest. The NSW Agency for Clinical Innovation Musculoskeletal Network have developed a model of care for the management of people with acute low back pain to support the implementation of the commonalities of the numerous management guidelines that exist. The model of care is essentially a primary care based model that will be supported as required by specialty clinicians and the broader NSW health system. The key objectives of the model are to reduce the pain and disability associated with acute low back pain.

The model has been developed for people aged 16 years and over who present to their general practitioner or emergency department with a new episode of acute low back pain of less than three months' duration that was preceded by one month of no pain. The model provides different care pathways for people with acute low back pain using three triage classifications: i) Non-specific low back pain, ii) Low back pain with leg pain, iii) Suspected serious pathology.

The model of care is underpinned by ten key principles for the management of people with acute low back pain: 1) Assessment: history and examination, 2) Risk stratification, 3) Patient education, 4) Active physical therapy encouraged, 5) Treatment with simple analgesic medicines, 6) Judicious use of complex medicines, 7) Cognitive behavioural approach, 8) Imaging limited to cases of suspected serious pathology, 9) Pre-determined times for review, 10) Timely referral and access to specialist services.

The draft model of care was first published in October 2015 and implementation and evaluation will be undertaken over a period of 12 to 24 months. In the first instance the model of care will be trialled in four NSW Local Health Districts. Evaluation of the model of care over time will help refine and contribute to the final version.

**Australian approval status: Not required**

**Stage of development: Other (Trial implementation)**

**Setting for use: Primary care**

# Neuro-Spinal Scaffold for the treatment of acute spinal cord injury

Currently there are no approved therapies that successfully reverse the damage that occurs as a result of a spinal cord injury.

The Neuro-Spinal Scaffold is a porous bioresorbable polymer device that is inserted surgically into the spinal cavity caused by traumatic spinal cord injury. The scaffold provides the spared spinal tissue with structural support and protection from further damage and also provides a supportive matrix to facilitate nerve healing and regrowth. The scaffold should be implanted as early as possible after injury (within 96 hours) to reduce the tissue damage that occurs during the acute phase of injury in order to preserve as much nerve connection as possible. The scaffold breakdowns within the body over the course of weeks to months.

The INSPIRE Study was initiated in 2014 to investigate the safety and potential benefit of the Neuro-Spinal Scaffold for the treatment of complete thoracic spinal cord injury. The American Spinal Injury Association Impairment Scale describes a person's functional impairment as a result of their spinal cord injury and is a five-point scale (A to E). At the time of enrolment in the INSPIRE study all individuals were classified as grade A (having a complete spinal cord injury with no motor or sensory function below the level of injury). The developer reports that four of the first six patients (67%) enrolled in the study demonstrated an improvement of at least one grade on the scale by 6 months. It is reported that historically fewer than 16% of patients with complete thoracic spinal cord injuries have grade improvements on the scale by 6 months post-injury. The developer also claims to have demonstrated significant improvements in motor, sensory and bowel and/or bladder function in these patients.

The INSPIRE study is ongoing and is expected to be completed in 2017. Plans are underway to initiate a second study to investigate the Neuro-Spinal Scaffold in cervical spinal cord injuries.

The Neuro-Spinal Scaffold is being developed by InVivo Therapeutics, United States.

**Australian approval status: Not approved**

**Stage of development: Experimental**

**Setting for use: Acute care**

# Guideline-based clinical pathway of care for the treatment of whiplash injury

Whiplash-associated disorders carry large health and economic costs. Recovery after whiplash injury remains poor, particularly for those who experience high levels of pain and disability following injury. An online clinical prediction tool that enables early risk classification of people with whiplash into low, medium and high risk of non-recovery, was recently developed. At the same time a new clinical pathway of care was developed in Australia based on these risk categories.

The clinical pathway of care involves minimal care for those stratified at low risk of non-recovery. It is recommended that individuals at low risk of ongoing pain and disability receive up to three sessions of guideline-based advice and exercise with their primary healthcare provider. For those identified at medium to high risk of developing ongoing pain and disability, the pathway recommends early referral to a specialist clinician who will conduct a more in-depth physical and psychological assessment. The specialist will liaise with the original primary healthcare provider and determine one of three further pathways of care: 1) Liaise with and monitor care under the primary carer, 2) Take over and provide specialist care for a short period, 3) Refer for alternative care.

A clinical trial is currently underway in New South Wales and Queensland to evaluate whether the clinical pathway of care provided according to the estimated risk of non-recovery improves health outcomes while remaining cost-effective. Outcomes will be compared to those achieved following usual care provided by the primary healthcare provider based on clinical judgement. It is anticipated that the trial will be completed in 2019. The trial is funded by a partnership grant from the National Health and Medical Research Council, New South Wales Motor Accidents Authority and the Motor Accidents Insurance Commission of Queensland.

Depending on the outcomes from the trial, the new clinical pathway of care has the potential to change clinical practice for whiplash-associated disorders.

**Australian approval status: Not required**

**Stage of development: Investigational**

**Setting for use: Primary care**

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