



ISCRR HORIZON SCANNING: TECHNOLOGIES TO PRIORITISE

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This ISCRR Horizon Scanning newsletter is intended 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 and mobility, and quality of life. Health-related innovations in the early stages of development, on the verge of diffusion, or not yet adopted into established health care systems but emerging in the next one to three years will be highlighted to help inform decision-makers on their adoption.

This newsletter is a result of a year-long collaboration between ISCRR and CADTH. CADTH received funding from ISCRR to develop, pilot, and evaluate a horizon scanning system. The topics presented in this pilot newsletter have gone through a rigorous filtering and prioritisation process. Forty technologies, treatments, and services were originally identified through horizon scanning activities. Through consensus agreement amongst VWA, TAC, and ISCRR representatives, the topics with the greatest potential to improve TAC and WorkSafe client outcomes were selected.

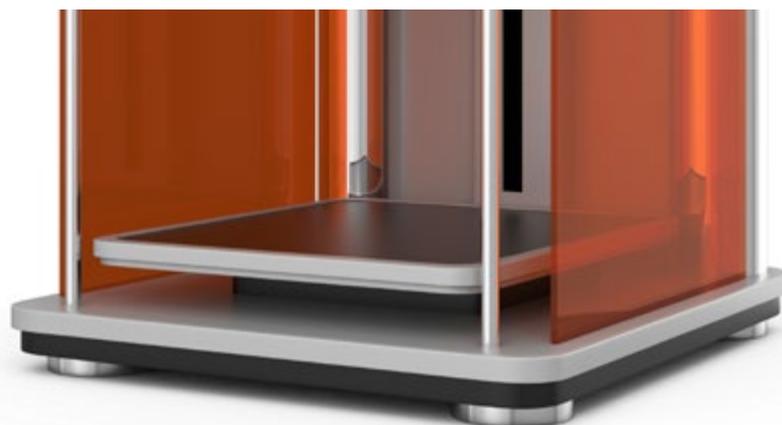
For more information on this collaboration or this newsletter, contact the Evidence Review Hub at ER.Hub@iscrr.com.au.

The topics covered in this newsletter –

- 3-D Printing for Manufacturing Prosthetics
- ReWalk Robotic Exoskeleton for Spinal Cord Injury
- The “Bionic” Ekso Robotic Exoskeleton for Paraplegia
- Mind-Controlled Prosthetic Arm Creates Possibilities for Those With Limb Loss
- Keyless Keyboard and Mouse for Those With Minimal Wrist and Hand Use
- Abdominal Functional Electrical Stimulation to Improve Respiratory Function After Spinal Cord Injury
- Unique Vacuum Suspension With the Sleeveless Vacuum Prosthetic Foot
- Epidural Stimulation Helps Paraplegics Regain Voluntary Control
- Dexmecamylamine (TC-5214) for Overactive Bladder
- Donated Human Tissue for Wound Healing

A joint initiative of





3-D Printing for Manufacturing Prosthetics

Researchers at the University of Toronto, in collaboration with Autodesk Research, are using 3-D printing techniques to produce cheap, fast, and easily customizable prosthetic sockets.

Sockets join limbs to prosthetics and are critical to ensuring proper and comfortable fits. The 3-D method allows researchers to create prosthetic sockets by producing a 3-D scan of a limb using an Xbox Kinect – motion-sensing body-recognition technology – and then creating a representation of a residual limb in Autodesk, a 3-D modelling software. A 3-D printer is then used to print the custom socket by building layer upon layer to create a 3-D solid object from a digital model.

Titanium, silicone, and nylon are commonly used materials for 3-D implants. Human tissue can also be printed from 3-D printers. Researchers are working on ways to use 3-D printing to create implants made of organic materials such as blood vessels, skin, and embryonic stem cells.

Prosthetics may be a lucrative market for 3-D printing, with the potential to improve the range and quality of

implants. Many manufacturers develop “one size fits all” prosthetics because it is expensive and impractical to design individual prosthetics. The main advantage of 3-D printing is higher customisation of geometric models. In some instances, it can accommodate almost exact replicas of an amputee’s remaining limb.

Three dimensional printing is a significantly more cost-effective means of creating prostheses. It also allows for more trial and error in the creation process because, compared to traditional manufacturing prototyping, it is low cost and quick. 3-D printing has the potential to disrupt the medical industry, particularly as costs for medical devices continue to rise. Once bio-printing and the 3-D printing of human organs and tissue becomes commercially viable, patients will have access to organs and implants that are printed using the size and organic structure that is required for their individual bodies.

This technology is developed by the University of Toronto and Autodesk Research. Other 3-D printed implants have been developed by numerous international small and medium-sized businesses.

Approved in Australia: No
Stage of development: Experimental
Setting for use: Residential



ReWalk Robotic Exoskeleton for Spinal Cord Injury

People with paraplegia may learn to walk again. The ReWalk system is a computer-controlled, exoskeleton, gait orthosis system that enables some patients with spinal cord injury (SCI) to sit, stand, and walk. The external frame is connected to a computer worn in a backpack and a remote control on a wristband. Crutches are also used to provide stability and balance.

The ReWalk was highlighted in *The Sydney Morning Herald* in a news report on April 1, 2014, when the company was looking for an Australian distributor. In the article, Dr. Peter New, Head of Rehabilitation at Monash Health and of the Caulfield Hospital's Spinal Rehabilitation Unit, was quoted as saying that these devices "... were an exciting development for patients with spinal injuries. 'Like many other things in medicine, this builds on other technologies and other things that have gone before but they have certainly taken it to a new level.'"

Several clinical trials of the device are currently in progress. Four clinical trials are recruiting patients with SCI to participate in observational and single cohort studies. In one small study of the device, all 12 patients had positive comments about the emotional and

psychosocial benefits of using ReWalk. Some patients reported pain relief, and improved bowel and bladder, function during the trial. However, the level of walking ability achieved varied between patients.

The ReWalk system offers two specific products. The ReWalk Rehabilitation is used in clinical rehabilitation settings and to test the feasibility of the device for certain patients. The ReWalk Personal is intended for everyday use, at home and at work, both indoors and outdoors.

The ReWalk was licensed by Health Canada in 2013. The US Food and Drug Administration (FDA) classifies the ReWalk as powered exercise equipment used for medical purposes, and is subsequently exempt from 510(k) premarket notification and premarket application procedures. It is available in Europe and Israel.

The institutional ReWalk-I reportedly costs approximately US\$105,000 and is manufactured by Argo Medical Technologies Inc.

The ReWalk is manufactured by Argo Medical Technologies.

Approved in Australia: No
Stage of development: Nearly established
Setting for use: Rehabilitation / Residential



The “Bionic” Ekso Robotic Exoskeleton for Paraplegia

The Ekso, like the ReWalk, is a gait orthosis system intended for individuals with spinal cord injuries resulting in lower extremity weakness to complete paralysis. The manufacturer calls the Ekso a “bionic suit” and a “gait training exoskeleton.” The externally worn “suit,” battery pack, and crutches attached to arm braces enables the user to stand and walk. The motor is used to power steps and a software program analyzes gait. A physiotherapist helps train the patient in using the device, from learning how to sit and stand, to how to walk. The Ekso suit weighs 45 pounds and is based on a system used by the US military.

The Ekso is available in North America and throughout Europe but, according to the manufacturer’s website, is not yet distributed in Australia. Clinical testing of the

system was carried out in 12 US rehabilitation hospitals in 2011 and 2012. Four clinical trials are underway, with completion dates in 2015 and 2016. The study designs of these trials include two single group assignments and two observational studies.

There are two other devices in development by Vanderbilt and Cyberdine.

The Ekso institutional line became available in 2012 and costs approximately US\$130,000. The company is working on a personal device that will cost from \$50,000 to \$75,000.

The Ekso bionic suit is manufactured by Ekso Bionics (formerly Berkeley Bionics) and has received US FDA approval.

Approved in Australia: No
Stage of development: Nearly established
Setting for use: Hospital



Mind-Controlled Prosthetic Arm Creates Possibilities for Those With Limb Loss

Arm amputees can now regain some of their lost fine-motor control with the new DEKA Arm System. The DEKA is the first mind-controlled prosthetic arm that, according to the manufacturer, can perform up to 10 movements simultaneously. The battery-powered device uses electrical signals from electromyogram (EMG) electrodes and is operated predominantly by foot controls. The EMG electrodes detect electrical activity generated by muscles involved in arm, wrist, and finger movements. The electrodes then send electrical signals to a computer processor in the prosthesis that translates the signals into specific movements.

The DEKA device is the same shape and weight of an adult arm and is intended to mimic normal fine-motor functioning. The device may increase functional independence and increase the performance of basic tasks and recreational activities.

A US Department of Veterans Affairs study involving 42 patients evaluated various generations of the DEKA Arm. Overall, feedback was positive, especially regarding refinements to the third-generation device that included improvements to wrist design, visual notification, foot control, end-point control, and cosmesis (physical enhancement and restoration). Another Department of Veterans Affairs study found that 90% of 36 patients using the device were able to perform new activities that they were unable to perform with their existing prostheses. These activities included using keys and locks, preparing food, self-feeding, using zippers, picking up small items like eggs and coins, and brushing and combing hair.

The DEKA Arm System is manufactured by DEKA Research and Development Corporation. It was FDA-approved in May 2014.

Approved in Australia: No
Stage of development: Nearly established
Setting for use: Residential



Keyless Keyboard and Mouse for Those With Minimal Wrist and Hand Use

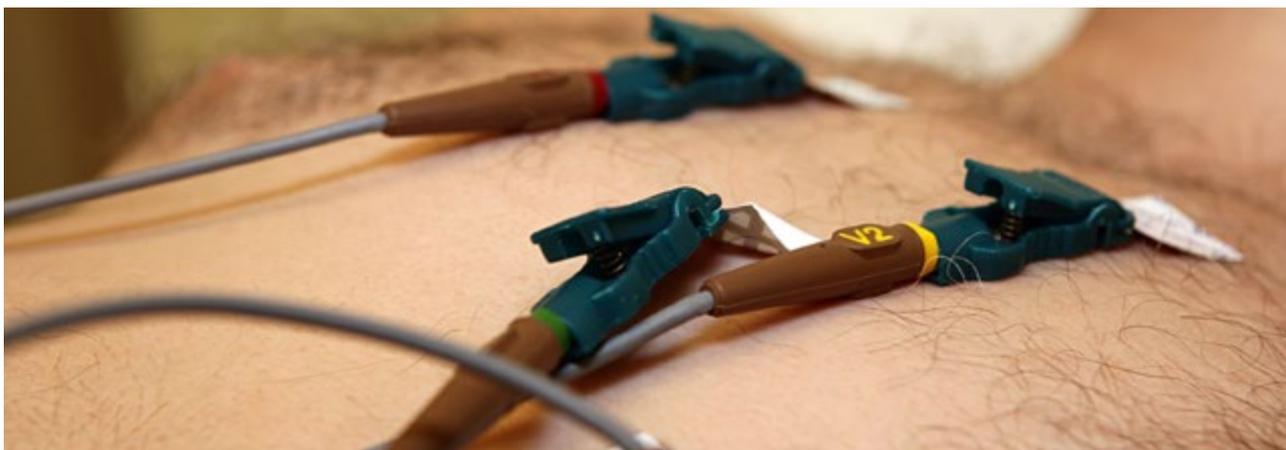
It is comfortable and very easy to use, portable, and minimises finger and wrist movement: The orbiTouch is a complete, ergonomic, 128-character keyless keyboard with integrated mouse.

Ideal for those with hand and finger injury, carpal tunnel syndrome, cerebral palsy, multiple sclerosis, traumatic brain injury, spinal cord injury (SCI), arthritis, and certain forms of autism, the orbiTouch eliminates the full employment of the finger and wrist motions needed to operate a keyboard. Instead, only the limited use of

hands and arms are needed to type on a keyboard, as two dome keys replace the QWERTY-type (US standard keyboard) keys to minimise hand and finger or wrist exertion.

The orbiTouch Keyless Keyboard requires no software installation. It is manufactured by orbiTouch Keyless Keyboard Inc./Blue Orb and costs approximately US\$400.00.

Approved in Australia: None required
Stage of development: Established
Setting for use: Residential



Abdominal Functional Electrical Stimulation to Improve Respiratory Function After Spinal Cord Injury

Tetraplegia (or quadriplegia) often affects respiration because the spinal nerves at the neck control the abdominal muscles. Respiratory infections and other respiratory complications are a major cause of morbidity and mortality in individuals with SCI. This is due to an accumulation of secretions in the lungs as a result of being unable to cough effectively. Some patients may require mechanical ventilation to breathe and some form of intervention to aid the removal of secretions in the airways.

The use of abdominal muscle training with functional electrical stimulation appears to improve the ability to cough. Abdominal functional electrical stimulation (AFES) may loosen lung secretions and lead to increased abdominal movement, which helps to stimulate cough peak flow. AFES can be applied consistently and

consequently may require less caregiver assistance.

A 2010 systematic review found evidence for "...the use of respiratory muscle training or electrical stimulation of the expiratory muscles to facilitate airway clearance in people with SCI..." As well, a 2013 feasibility study on changes in pulmonary function measures following AFES in 12 tetraplegic SCI patients showed significant improvements in forced vital capacity.

Neuromuscular electrical stimulation has been used for several years in combination with other interventions to improve respiratory function; further clinical trials of this treatment are underway.

Approved in Australia: N/A

Stage of development: Nearly established

Setting for use: Hospital / outpatient rehab



Unique Vacuum Suspension With the Sleeveless Vacuum Prosthetic Foot

While prostheses are a boon to amputees, they can also be a bane, causing discomfort, skin irritations, and socket issues. The Unity Sleeveless Vacuum prosthetic foot is intended to alleviate some of the issues by offering users the security of vacuum suspension without the sensation and restriction of a sleeve. According to the manufacturer, the device is unique in its ability to create distal vacuum, which helps to stabilise soft tissue volume and maintain effective suspension. The design of the device not only allows vacuum to be released quickly and easily, but it also may help to reduce the risk of proximal vacuum leakage and puncture issues associated with conventional “above-knee” vacuum methods.

Often, sleeves can restrict range of motion because they are bulky and prone to bunch behind the knee. They can also puncture, creating a vacuum leak in the process. The Unity system elevates vacuum within the socket without the use of a suspension sleeve. As well, the liner’s silicone construction provides more cushioning, more of an even distribution of pressure, and a closer distal fit.

The Unity Sleeveless Vacuum is manufactured by Össur.

Approved in Australia: Yes

Stage of development: Nearly established

Setting for use: Residential



Epidural Stimulation Helps Paraplegics Regain Voluntary Control

Neuromodulation of the lumbosacral spine may enable paralyzed individuals to voluntarily flex toes, ankles, and knees while the stimulator is active.

Surgically implanted electrodes send electrical currents to the spinal cord while patients are simultaneously engaged in specific motor tests involving their paralyzed legs. In addition to regaining some voluntary leg control, patients may also experience blood pressure control, body temperature regulation, bladder control, and sexual function.

A study of four SCI patients with the implanted stimulator found that each patient recovered some voluntary movement of their lower extremities. Other improvements to their overall health were also reported, such as

increased muscle mass, reduced fatigue, and dramatic improvements to their sense of well-being. The four participants had each been paralyzed for more than two years. Two of the participants had no sensation or cognition below the site of their injury and two had complete motor paralysis but some ability to experience sensation below the injury site. The study also incorporated daily training on a treadmill. Following training and epidural stimulation, all four patients performed voluntary leg movement on command while receiving electrical stimulation. They all had the ability to activate specific muscle groups and regulate the amount of activation while receiving stimulation. Patients regained some voluntary control within days of starting the stimulation.

Approved in Australia: No

Stage of development: Experimental phase 2

Setting for use: Outpatient rehab



Dexmecamylamine (TC-5214) for Overactive Bladder

Dexmecamylamine is a nicotinic channel modulator that has previously been studied for major depressive disorder. It is intended for both men and women, and represents a novel therapeutic approach for the treatment of overactive bladder.

According to the manufacturer, a completed clinical program with approximately 2,400 subjects in a different indication has resulted in a well-established safety and tolerability profile for dexmecamylamine. Their analysis of data from that program, as well as additional preclinical studies, revealed physiological findings that are consistent with marketed treatments for overactive bladder. In addition, dexmecamylamine is largely eliminated through the bladder unchanged, which supports the use of a low dose and creates the potential to minimise unwanted systemic effects.

A phase 2, double-blinded, randomised trial is currently underway to test the safety and effectiveness of dexmecamylamine compared with placebo in patients with overactive bladder syndrome. The study, which is designed to enroll approximately 750 patients, includes a three- to five-week screening period followed by a 12-week treatment period during which patients receive either one of three doses of dexmecamylamine (0.5 mg, 1 mg, or 2 mg) or placebo twice daily, randomised in a ratio of 2:1:1:1 (placebo, low dose, mid-dose, high dose).

Approved in Australia: No

Stage of development: Experimental phase 2

Setting for use: Residential



Donated Human Tissue for Wound Healing

Human tissue is now being used to facilitate the healing of a variety of non-healing wounds: TheraSkin is a “biologically active, cryopreserved real human skin allograft.” Processed from donated human tissue, it is harvested in 24 hours or less post-mortem from an organ donor who has cleared standard safety screening. It promotes wound healing by replicating cells and by apoptosis (programmed cell death), providing cellular and extracellular components with growth factors, cytokines, and collagen. It can be used to repair skin over wounds including those with exposed muscle, tendon, bone, and/or joint capsule (i.e., diabetic foot ulcers, venous leg ulcers, dehisced or reopening of surgical wounds, and pressure sores).

A retrospective cohort of 188 patients with either diabetic foot ulcer or venous leg ulcer evaluated the

relationship between wound size and the percentage of wounds closed after 12 and 20 weeks of TheraSkin application. The investigators found that only a few applications of TheraSkin grafts were required to achieve full wound closure. They reported that TheraSkin was a highly effective treatment in patients who had failed to show progression of healing after four weeks of traditional wound care.

A single-site, randomised controlled study is currently underway that compares TheraSkin with a bioengineered skin substitute for the treatment of venous leg ulcers.

TheraSkin is believed to be approximately 50% more cost-effective than using existing bioengineered, biologically active products.

Approved in Australia: No
Stage of development: Experimental
Setting for use: Hospital

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