Summary

✓ Pressure ulcers are a serious health problem for many patients, and treating those ulcers incurs substantial health care costs.

✓ Most pressure ulcers are preventable.

✓ Initial studies suggest that muscle stimulation delivered through electrodes in a specially designed undergarment — Smart-e-Pants — may reduce the risk for developing pressure ulcers in the sacrum (area at the base of the spine). This could improve care of individuals confined to beds or wheelchairs.

✓ Initial studies of the device have been short-term, non-randomized ones carried out in a small number of patients. The studies mainly measured pressure relief and patient and caregiver acceptability of the technology.

✓ The Smart-e-Pants device would be used in addition to standard care practices, such as pressure relief mattresses, wheelchair cushions, repositioning, and skin care.

✓ The technology is still undergoing clinical trials and is not yet commercially available.

Background

Pressure ulcers are injuries to the skin or underlying tissue caused by pressure, shear, or friction.\(^1\) They are common in individuals with reduced mobility or sensation, such as those who are bedridden or confined to wheelchairs.\(^2,3\) The US National Pressure Ulcer Advisory Panel defines a pressure ulcer as “an area of unrelieved pressure over a defined area, usually over a bony prominence, resulting in ischemia, cell death, and tissue necrosis.”\(^4\) Pressure ulcers, also known as bedsores or decubitus ulcers, may form externally, from the skin inwards (due to pressure, abrasion, poor nutrition or hygiene, or excessive moisture or dryness of the skin), or internally, from the soft tissue outwards (due to the accumulation of pressure between a bone, the adjoining tissue, and the supporting surface).\(^5\)

Most pressure ulcers are assessed with a four-stage classification system developed by the US National Pressure Ulcer Advisory Panel. This system categorizes ulcers into one of four stages, from intact reddened skin to severe wounds extending beyond the skin into the subcutaneous tissue (stage III) or involving the muscle, tendon, or bone (stage IV), with two additional categories for “suspected” and “unstageable” wounds.\(^4,6\)

Pressure ulcers that affect the deep tissue may not be recognized until the wound is externally visible, by which time extensive injury may have occurred.\(^5\) These ulcers often develop from the constant pressure between the ischial tuberosities (the pair of sitz or “sitting bones” of the pelvis) and the surrounding tissue in individuals confined to beds or wheelchairs. Up to 70% of pressure ulcers develop on the hips or buttocks.\(^4\)

In Canada, the estimated incidence of pressure ulcers is approximately 15% in community care, 22% in mixed care, 25% in acute care, and 30% in non-acute care facilities.\(^7\) The prevalence of pressure ulcers in all Canadian health care settings is estimated to be 26%.\(^7\)
Individuals with spinal cord injuries are particularly affected by pressure ulcers. An estimated 86,000 Canadians have spinal cord injuries and there are more than 4,300 new cases of spinal cord injury in Canada each year. The prevalence of pressure ulcers in individuals with spinal cord injuries ranges from 14% to 33%. More than 85% of individuals with spinal cord injuries will develop a pressure ulcer at least once during their lifetime.

Because they are painful and debilitating, pressure ulcers have a negative effect on physical, psychological, and social domains of quality of life. Pressure ulcers are an adverse event that also increases the risk for further adverse events, including infection, osteomyelitis (infection of the bone), sepsis, and death. A summary of recent UK National Institute for Health and Care Excellence (NICE) guidance notes that not only do pressure ulcers “… increase mortality, result in extended hospital stays, and consume substantial health care resources, they are often an example of avoidable harm.” In 2008, the US Centers for Medicare & Medicaid Services (CMS) adopted a nonpayment policy for the costs of treating stage III and IV pressure ulcers that develop in hospital — these are now considered “never events” or preventable, hospital-acquired conditions.

Patients with pressure ulcers need additional medical care and have longer hospital stays for wound treatment and to prevent recurrence. Severe pressure ulcers may require months or years of wound care treatments, including surgical interventions, such as muscle flaps or skin grafts.

Due to the intensive treatments involved, pressure ulcers are costly. An Ontario study estimated that the net hospitalization costs of treating hospital-acquired pressure ulcers in patients older than 65 years ranged from $44,000 for stage II pressure ulcers to $90,000 for stage IV pressure ulcers. This study also determined that the treatment costs of pressure ulcers that developed before individuals were admitted to hospital ranged from $11,000 for a stage II pressure ulcer to $18,500 for a stage IV pressure ulcer. A small Canadian study (n = 12) of the cost of caring for community-dwelling individuals with pressure ulcers due to spinal cord injury found an average monthly cost per patient of $4,745 (ranging between $3,400 and $18,000).

Several economic analyses have concluded that, despite the additional costs of the interventions, effective pressure ulcer prevention offers overall cost savings. For example, recent Ontario cost-effectiveness analyses determined that providing pressure redistribution mattresses to all long-term care residents would be cost-effective. Using pressure support overlays on operating tables for patients undergoing lengthy surgical procedures and for elderly patients in the emergency room would also be cost-effective. These interventions could reduce overall hospital costs and improve patient care. When multi-faceted interventions are used, the development of most pressure ulcers can be prevented.

A recent commentary in CMAJ (the journal of the Canadian Medical Association) noted, “… one under-recognized opportunity for both reducing health care expenditures and improving patient care is better prevention of pressure ulcers.” The prevention and treatment of pressure ulcers is now an accepted indicator of health system quality and patient safety. Prevention is essential because successfully treating pressure ulcers is costly and difficult.

# The Technology

Researchers at the University of Alberta are studying the use of intermittent electrical stimulation (IES) to relieve accumulated pressure and improve tissue oxygenation in patients at risk for pressure ulcers. In the past, different modes of electrical stimulation have been used to promote pressure ulcer wound healing, but the Smart-e-Pants technology is intended to prevent pressure ulcers. Smart-e-Pants incorporates electrodes into specially designed underwear that delivers electrical stimulation to the underlying muscles. The device consists of:

- The underwear — a cotton and Lycra fabric, similar to biking shorts, with a front zipper to accommodate patients needing catheterization, markers on the thighs to guide alignment, and belt loops for the electrode leads
- The surface electrodes — two for each buttock, contained in mesh panels on the back of the pants
- A small, battery-operated stimulator — housed in a pocket at the waist

When activated, the electrodes deliver 10 seconds of stimulation every 10 minutes, causing the gluteal muscles to contract and redistribute seating pressure. The stimulation achieves an effect similar to the subconscious fidgeting and shifts in body positioning that individuals without mobility issues make to relieve pressure. The longer period of no stimulation (measured in minutes) relative to the stimulation period
(measured in seconds) minimizes muscle fatigue. In addition to redistributing pressure, the regular muscle activation improves tissue oxygenation, which also helps to prevent pressure ulcers.

Various styles of the Smart-e-Pants undergarments have been developed, including modified designs for incontinent patients.

**Regulatory Status**

PrevBiotech is the company working to bring the Smart-e-Pants technology to market (http://www.prevbiotech.com). Efforts to obtain Health Canada and US Food and Drug Administration regulatory approval are under way, and the developers expect Smart-e-Pants will be commercially available in 2015.

**Patient Group**

Elderly residents in nursing homes; individuals in long-term care; those with diabetes; and individuals confined to beds or wheelchairs due to spinal cord injuries, head trauma, or musculoskeletal disease are particularly at risk for developing pressure ulcers, but all patients are potentially at risk. In addition to the constant pressure, the muscle atrophy and poor tissue oxygenation associated with many of these conditions further increases the risk of developing pressure ulcers.

With an aging population and rising rates of diabetes, the number of patients at risk for pressure ulcers is likely to increase.

**Current Practice**

Many different interventions are used to reduce the risk for developing pressure ulcers. Some interventions are labour intensive, such as timed repositioning or turning of patients by nursing staff. Other interventions involve costly equipment, such as specialized beds and mattresses.

Current guidelines recommend the use of an interprofessional team using multiple interventions to prevent pressure ulcers. These interventions include careful patient assessment, pressure relief through repositioning and the use of cushioned support surfaces, ensuring adequate nutrition and fluid intake, and meticulous skin care regimens for cleansing, moisturizing, and protection. Recent Canadian guidelines for the prevention and management of pressure ulcers in people with spinal cord injuries also note the importance of involving the patient in self-management interventions (such as weight-shifting manoeuvres for those in wheelchairs).

**Methods**

**Literature Search Strategy**

A peer-reviewed literature search was conducted by an information specialist using the following bibliographic databases: MEDLINE, PubMed, Embase, and the Cochrane Library (2014, Issue 11). Grey literature was identified by searching relevant sections of the CADTH Grey Matters checklist (http://www.cadth.ca/resources/grey-matters). No methodological filters were applied. Conference abstracts were excluded from the search results. The search was limited to English language documents published between January 1, 2010 and December 8, 2014. Regular alerts were established to update the search until March 9, 2015.

**Study Selection Criteria**

Published studies that assessed the use of the Smart-e-Pants technology were selected for the review of clinical evidence. Studies of alternative devices or methods for pressure ulcer prevention and other sources were also included, where appropriate, to place this technology in the context of current clinical practice.

**The Evidence**

One of the pilot studies for Smart-e-Pants investigated the use of two different regimens of IES in 17 patients with spinal cord injuries. Surface electrodes (rather than the prototype undergarments) were used to deliver the stimulation to the gluteus maximus muscles. The researchers found evidence that both regimens of stimulation reduced surface pressure over the ischial tuberosities and increased tissue oxygenation. The range of pressure reduction varied between participants, depending on the wheelchair cushions used and their level of body fat, but all patients experienced pressure reduction. These findings were similar to those of earlier IES studies conducted in able-bodied participants.

The largest published trial to date reported the results of a single-group safety and feasibility study of a prototype of the Smart-e-Pants undergarments. During this trial, the investigators noted that the prototype undergarment was not suitable for patients with incontinence and a new undergarment was subsequently designed for these
patients.) This study included 48 participants in acute and tertiary rehabilitation hospitals, long-term care, and homecare who were at risk of developing deep tissue injury pressure ulcers. Each study patient received IES for 12 hours per day, four days per week for four weeks, or, in hospital patients until discharge. (Some patients chose to continue using the system after hospital discharge.) In the safety and feasibility study, IES was administered to the gluteal muscles through pairs of surface electrodes on each side of the buttocks. Incontinent patients had the electrodes placed directly on their skin, while continent patients received the IES with electrodes placed both directly on the skin and as contained in the Smart-e-Pants undergarments.

The main outcome measures for the study were the demands on caregivers (effort and time involved in placing the electrodes, setting the stimulator, and checking for muscle contractions once it was activated); daily skin monitoring after removal of the device; system performance (stability of the electrodes and sustainability of muscle contractions); and patient acceptability of the system in their everyday life. Most caregivers rated the effort required as “easy” (74% in long-term care settings, 79% in homecare settings, and 87% in rehabilitation settings). Muscle contractions were more difficult to elicit and detect in patients with greater muscle atrophy due to age or a longer history of immobility. In all health care settings, the time it took to put on the Smart-e-Pants (less than 18 minutes) and to remove them (usually less than 10 minutes, including the documentation time for completing the daily trial questionnaire) was deemed acceptable by patients and their caregivers. Very few skin reactions were noted, either with direct application of the electrodes or with use of the garment. When asked whether they found the electrical stimulation to cause irritation, distraction, or discomfort, almost all patients in all care settings (in 96% of 648 IES sessions) responded “not at all” or “very little.”

For most study patients and caregivers, use of the undergarment made the system less cumbersome to use. Six patients reported that the use of IES reduced the pain they experienced while sitting for long periods. None of the study patients developed a pressure ulcer during the time they used the IES system.

To date, more than 70 patients have used the Smart-e-Pants undergarment. Most patients used the device for a one-month period (a few patients have continued to use it for up to 16 months), 12 hours per day, in various settings, including rehabilitation units, long-term care settings, and at home. Comments from patients with spinal cord injuries who used the Smart-e-Pants during the early clinical trial indicate they find the technology easy to use, and some patients reported additional benefits, such as reduced pain, decreased spasticity, reduced fluid retention in the legs, and stronger muscle contractions.

Shorts that deliver IES to both the gluteal and hamstring muscles have been tested in small pilot studies (n = 10) by Dutch researchers using technology developed by US-based Axiobionics. The researchers concluded that providing electrical stimulation to both the gluteal and the hamstring muscles provided better pressure relief around the ischial tuberosities.

A 2014 systematic review included five studies that looked at the longer-term effect of electrical stimulation on pressure ulcer prevention in individuals with spinal cord injuries. Three of the five studies found beneficial changes with electrical stimulation; for example, increased muscle thickness, reduced seating pressure, improved tissue oxygenation and sitting tolerance, or a decreased incidence of pressure ulcers. The two other studies found no statistically significant difference with electrical stimulation; however, these studies only had a short follow-up period (eight or 12 weeks), in comparison with the studies that found benefit (which included a follow-up period of more than one, two, and five years). However, the quality of the evidence was generally weak (mostly case reports or case series, and only one randomized controlled trial that was considered to be of good quality). They concluded that the evidence of the long-term benefits of electrical stimulation in preventing pressure ulcers was still inconclusive.

The 2014 National Pressure Ulcer Advisory Panel guidelines concluded there was sufficient evidence of effectiveness to consider the use of electrical stimulation to prevent pressure ulcers in patients with spinal cord injuries.

The Canadian Best Practice Guidelines for the Prevention and Management of Pressure Ulcers in People with Spinal Cord Injury recommend that the use of electrical stimulation be considered to decrease ischial pressure and increase blood circulation. (Note that the supporting evidence was mainly from studies of electrical stimulation delivered through implanted devices.)
The current evidence on the Smart-e-Pants technology indicates it can reduce surface pressure and improve tissue oxygenation. Whether Smart-e-Pants can prevent pressure ulcers has not yet been demonstrated in longer-term randomized controlled trials. A phase 2, multi-centre clinical trial of Smart-e-Pants is reportedly under way. Researchers at the Universities of Alberta and Calgary are also planning a study to assess the potential cost savings of the technology.

### Adverse Effects

Some patients (ranging from 1% to 24% in the different health care settings) experienced minor skin irritation that resolved within 30 minutes after removal of the electrodes that had been placed directly against the skin. Two incontinent patients with compromised skin quality had minor skin tears: one was an elderly long-term care resident with fragile skin and the other was a middle-aged patient who experienced the tear when the clinical tape used to secure the electrode edges to her skin was removed. Both of these patients had the electrodes directly against their skin. None of the patients who wore the Smart-e-Pants undergarments containing the electrodes experienced adverse effects.

In a recent systematic review of electrical stimulation for pressure ulcer prevention and treatment, only four of 16 studies reported on adverse events. No patients in these four studies experienced adverse events.

### Administration and Cost

Smart-e-Pants is intended for use by patients in all health care settings: acute care hospitals, rehabilitation, or long-term care facilities, as well as at home.

Because Smart-e-Pants is not yet commercially available, the cost is not yet known. Published estimates of the potential cost of the Smart-e-Pants range from C$500 to C$2,000. The main cost will be the stimulator pack. Once the electrodes are removed, the underwear is washable and reusable, and may cost approximately C$70.

### Concurrent Developments

The 2014 US National Pressure Ulcer Advisory Panel guidelines include assessments of the evidence on new preventive and treatment interventions, including microclimate control using special support surfaces that adjust the levels of moisture, evaporation and heat dissipation against the skin, prophylactic polyurethane foam dressings, and the use of silk-like fabrics (instead of cotton) to reduce shear and friction.

NICE recently issued guidance on the use of Parafricta bootees (socks) and undergarments made of this special fabric to reduce the risk of pressure ulcers. The guidance concluded that these garments “…show potential to reduce the development and progression of skin damage caused by friction and shear in people with, or at risk of, pressure ulcers. Research is recommended to address uncertainties about the claimed patient and system benefits of using the garments.” Preliminary studies of new fabrics for bedding, underpads, patient gowns, and coverlets indicate that these can reduce heat, moisture, and friction against the skin and may help prevent pressure ulcers. Other research into “smart textiles” includes the use of biosensors to detect chemical changes that may indicate pressure ulcer formation. New types of pressure-relieving mattresses are also commercially available, such as Dolphin System beds and overlay pads that simulate fluid immersion to relieve pressure.

Implanted neuromuscular electrical stimulation devices, intended for long-term use in individuals with spinal cord injuries, are also under investigation.

### Rate of Technology Diffusion

The Smart-e-Pants technology has not yet been used outside of research studies.

### Implementation Issues

The additional staff time required to help patients position and remove the Smart-e-Pants may be a consideration for health care facilities.

Although further evidence is needed, the Smart-e-Pants technology may be an important advance in pressure ulcer prevention.

### References


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