

Smart-e-Pants for the Prevention of Pressure Injuries in the Spinal Cord Injury Population: Horizon Scanning Brief

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Background

Pressure injuries (PIs) originate at the surface of the skin and progress inward, or at the deep bone and muscle level and progress toward the skin surface. The outside-in ulcers develop due to skin abrasion, poor nutrition or hygiene, and excessive skin moisture or dryness. Inside-out ulcers develop due to the accumulation of pressure where soft tissue is trapped between a bony area and an external surface.¹ This pressure causes damaging levels of mechanical deformation in the tissue and deprives it of oxygen. Individuals and their caregivers are usually unaware that the latter type of PI has developed. Once skin signs are visible, extensive damage of the underlying tissue has already presented.¹ The most common area for PIs to develop, accounting for more than 70% of all occurrences, is the ischial tuberosity or sacrum region.²



Technology Overview

Scientists at the University of Alberta in Canada have developed underwear that electrically stimulates the skin and is designed to fit into existing care routines. The underwear, Smart-e-Pants, is intended to prevent the development of PIs of the ischial tuberosity and sacrum. The underwear is fitted with electrodes that generate tiny pulses of intermittent electrical stimulation (IES). The IES works by contracting muscles and redistributing surface pressure away from the bony prominences. This movement relieves accumulated pressure and mechanical deformation, and boosts blood supply and oxygen to the region. The electrical current is mild, lasts approximately 10 seconds, and is generated once every 10 minutes. These periodic contractions mimic the subconscious postural adjustments performed by able-bodied individuals in response to discomfort while sitting or lying down.³

The device consists of a stimulator pack that is held in place in a detachable pocket at the waist, either a fabric or incontinence-protective undergarment (designed to replace underwear), and self-adhesive electrodes that are placed into mesh panels in the undergarment. The stimulator generates the IES pattern that is transmitted to the electrodes, and the electrodes deliver the stimulus to the skin.³ The lifespan of the stimulator is approximately three to five years. The undergarment for continent individuals lasts as long as regular underwear and is single-use for incontinent individuals. Electrodes for continent individuals can be used for several days. For incontinent individuals, the electrodes will likely be single-use. The undergarment allows for the pre-placement of the electrodes. This makes it easy for the device to be put on and removed, a process that takes less than 10 minutes.³

According to the manufacturer, training costs are comparable to existing practice for the management of PIs. A brief training session is required to familiarize users with the device and how to recognize an adequate muscle contraction to ensure optimal electrode placement.

Clinical Indication

Patients who are immobile (e.g., those confined to a bed or wheelchair) or who cannot move certain parts of their bodies are at high risk of developing PIs. This includes the elderly, patients in intensive care units, individuals in long-term care, and individuals with spinal cord injury (SCI).

Potential for Impact

Safety: Recently published evidence suggests that the Smart-e-Pants system is safe and well accepted by patients.³ As such, it is anticipated that it will improve patient safety compared with existing PI management practices.

Quality of Life: The pain, discomfort, and distress associated with a PI can have a significant impact on the physical, psychological, emotional, spiritual, social, and financial well-being of patients. PIs can also limit a patient's independence because they require extra caregiver attention. Consequently, this device is anticipated to have a significant positive impact on patient quality of life.

Delivery of Care: The effort involved in preventing and managing PIs requires action by many members of a patient's care team. Subsequently, this device may be able to help eliminate the need for significant human resources.

Cost: Given the large financial burden of treating PIs after they have developed, it may be more economical to prevent them from occurring. The prevention of PIs is believed to be 2.5 times more economical than treatment.³

Clinical Effectiveness

A Canadian safety and feasibility study published in 2014 tested the Smart-e-Pants technology on 48 participants at risk of deep tissue ulcers.³ Testing was conducted over a four-week period in four health care settings: an acute rehabilitation unit of a general hospital, a tertiary rehabilitation hospital, a long-term facility, and home care. Outcomes measured included skin reaction to long-term stimulation, demands on caregivers, stability of induced muscle contraction, and acceptability as part of the users' daily routine

Each subject received treatment with the device for 12 hours a day, four days a week, for four weeks or upon discharge. Study results suggest that the treatment is safe and well accepted by patients in all four clinical settings. PIs were not observed in any of the participants. There were no differences between the clinical setting in patient positioning, ease of finding optimal stimulation site, and patient acceptance. Patients and caregivers did not find the application disruptive and suggested it was acceptable as part of their daily routine. Nearly 100% of patients agreed that the device was a feasible preventive method for deep tissue ulcers.

Safety

In the safety and feasibility study, adverse skin reactions were minimal. The application of electrodes directly to the skin caused skin redness in some patients, but this disappeared within 30 minutes. Two minor skin tears occurred in incontinent patients with compromised skin quality. These tears were attributed to the tape used to secure the electrode edges. To resolve this issue, a more suitable tape was used when needed and a mesh panel for electrode placement was built into the garment.

Setting for the Technology Use

The system can be used throughout the continuum of care, in an acute rehabilitation setting, a subacute setting, long-term care, and those at risk in the community.

Regulatory Approval

This is not approved anywhere yet. Canadian approval is anticipated for late 2015, US and European approval for early 2016, and Australian approval for 2017.

Cost

According to the manufacturer of the Smart-e-Pants technology, the stimulator pack will cost around C\$200.00. The target daily cost of consumables depends on continence and clinical environment, but is anticipated to be approximately C\$10.00 per day.

References

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