Pressure Injuries.

The Current Clinical and Financial Burden

REHABTRONICS
TECHNOLOGY FOR RECOVERY

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Executive Summary

Pressure injuries are wounds caused by prolonged pressure. They generally occur on bony areas of the body such as the tailbone and heels and affect older, hospitalized adults with limited mobility and sensation.

There are six classifications of pressure injuries: Stages I-IV (representing progressively increasing tissue loss); Unstageable and Deep Tissue Injury. Pressure injuries often lead to cellulitis and gangrene (tissue death) but can lead to more life-threatening complications such as sepsis and death.

Injury management is nursing intensive and can lead to overcrowding and widespread infection in resource-strained facilities. Across North America, pressure injuries impact approximately 20% of hospitalized patients and increases baseline mortality rate. On average, a pressure injury more than doubles a patient's stay and substantially increases hospital expenses. For example, stage IV injuries and associated complications can exceed $120,000 in the US.

The most common approaches to prevention currently used are offloading pressure by turning patients every two hours and/or using pressure distributing mattresses. Both methods have shown limited efficacy. Treatment is limited to wound management and debridement at low stages, but higher stages require surgical intervention. Due to the high cost of treatment, there is a high demand for more effective preventative measures.

Pressure Injury Formation and Classification

Pressure injuries, also known as pressure ulcers or bedsores, are injuries to skin and underlying tissue that are caused by prolonged pressure.[1] They occur in soft tissue and skin surfaces over bony areas of the body, such as the heels and tailbone. These areas are prone to elevated external pressure, which disrupts blood supply and causes tissue damage. Pressure injuries generally impact people with limited mobility or sensation and can form within hours or days. Therefore, they are a significant problem in older hospitalized adults. **In the United States, pressure injuries are responsible for over 60,000 deaths annually, and the treatment of hospital-acquired pressure injuries costs over $12 billion annually.**[2]

There are six categories of pressure injuries: Stages I-IV, Unstageable, and Deep Tissue Injury (DTI).[3] Stage is determined based on clinical assessment. The numbered stages represent progressively greater tissue loss:

Stage I: Redness

Stage II: Skin breaking and blistering

Stage III: Injury extends into fatty tissue underneath the skin

Stage IV: Depth and damage extends to muscle and bone

Pressure Injuries Originate Deep Below the Skin

Although pressure injuries were previously thought to solely originate at the skin surface, they often originate deep below the skin at the bone-muscle interface. Prior to breaching the skin, these DTIs are very difficult to detect, but are marked by bruising and a purple appearance of the skin. They often go unnoticed until they break the skin, at which point they manifest as Stage 3 or 4 injuries, which are far more severe than the first two stages. A wound is considered unstageable if it is covered with a thick layer of dead tissue and pus that obscures the wound and prevents accurate stage differentiation.

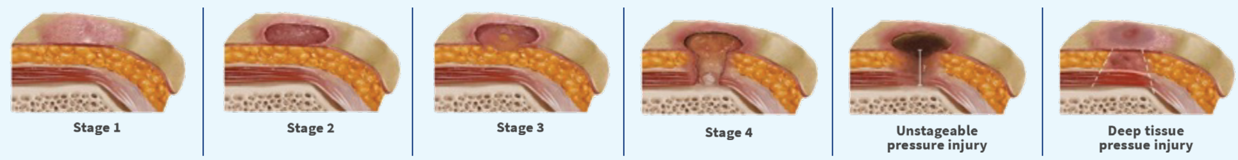

FIGURE 1 – SIX CATEGORIES OF PRESSURE INJURIES

Etiology of Pressure Injuries

Normal blood pressure within capillaries ranges from 20 to 40 mmHg; 32 mmHg is considered the average.[5] When external pressure exceeds capillary filling pressure, small blood vessels will narrow or block entirely, disrupting blood flow.

Capillary disruption is a complex sequential process. It forms the basic premise of pressure injury formation:[8-11]

Several risk factors act on soft tissue overlying bony areas (hips, heels, tailbone)

⇩

Pressure exceeds normal capillary filling pressure

⇩

Small blood vessels are blocked and torn, reducing blood flow and oxygenation

⇩

Tissue death (necrosis)

⇩

Pressure injury begins to form

Millions Suffer from Bed Sores in the United States:

2.5 million people each year

60K people die each year

UP TO **$120K** per patient in health care costs

Mechanism of Deep Tissue Injury

The mechanism of Deep Tissue Injury (DTI) formation at the cellular level depends on the extent of strain on the soft tissue.[8] For low-to-moderate strain, the lack of blood supply causes metabolic changes within deformed cells. This is followed by the accumulation of cell waste products and a decrease in pH (an acidic cell environment). In the case of high strain injury, there is direct deformation-related damage producing cell membrane failure and disrupting the cell structure. The outcome of both of these processes is cell death.

The combination of several risk factors can significantly accelerate injury formation. Tissue deformation can begin within 10 minutes of loading,[9] with pressure injuries starting to form as early as 1 hour after.[12] For lower risk patients, pressure injuries may develop over days or weeks.

Risk Factors Using the Braden Scale

Pressure injury risk is generally measured using the Braden Scale.[7] This scale evaluates patients on six variables noted in the table below, which compares a healthy individual with a high-risk patient.

Risk Category	Healthy Individual	High-Risk Patient	Disease Mechanism
Sensory Perception	Subconsciously adjusts weight in response to discomfort when sitting or asleep.	A patient with a spinal cord injury will not feel pain due to prolonged pressure. They may fail to adjust and relieve pressure.	Ischemia (inadequate blood supply)
Moisture	Uses proper hygiene and dries skin to prevent the accumulation of bacteria.	A patient with bowel incontinence may have elevated moisture at their lower back, leading to bacterial infection	Dermatitis (skin inflammation and breakdown)
Activity	Engages in consistent physical activity to ensure cardiovascular health and healthy capillary pressure.	An inactive or bedridden patient may experience poor blood flow to capillaries supplying skin and underlying tissue: minimal external pressure disrupts supply.	Ischemia (inadequate blood supply)
Mobility	Can move the body independently to relieve pressure when sitting or sleeping.	Wheelchair-bound or bedridden patients need help to alleviate pressure, delaying relief.	Ischemia (inadequate blood supply)
Nutrition	Maintains a balanced diet; circulating blood is rich in nutrients.	Poor nutrition interferes with the function of the immune system and collagen synthesis, slowing the wound healing process.	Low protein and vitamin content (limited regenerative factors)
Friction/shear	Quickly recovers from skin damage following abrasion. Subconscious adjustments and muscle contractions in response to deep tissue circulatory occlusion.	Bed or wheelchair transfer can cause friction and shear, accelerating tissue damage that leads to pressure injury. An inactive or bedridden patient may experience poor blood flow to capillaries supplying skin and underlying tissue: sheer forces disrupt blood circulation and tissue oxygenation.	Dermatitis (skin inflammation and breakdown). Ischemia (inadequate blood supply)

Moisture (which cause dermatitis) generally contributes to the first two stages of pressure injuries due to skin surface disruption. A lack of sensory perception, mobility, and activity produce ischemia: inadequate blood supply that causes a shortage in oxygen needed for tissue metabolism. Ischemia of soft tissue near bone-muscle interfaces is a major precipitating factor for the highly-severe Stage 3 and 4 injuries. Poor nutrition leads to a lack of regenerative factors in the blood; it increases the rate of injury formation and prevents effective healing. Friction/shear forces affect both the skin and underlying deep tissue. Friction forces on the skin can lead to skin abrasion and Stage I and II injuries. Sheer forces within deep tissue can restrict blood circulation leading to ischemia, DTI and Stage III, IV or Unstageable injuries.

Several common diseases also increase risk. Diabetes and obesity, for example, can impair wound healing, reduce blood flow, and raise the chance of infection.[1] Patients on immunosuppressive drugs also experience greater risk of infection.

Pressure Injury Complications

Pressure injuries can lead to several complications, some of which are life threatening.[1] A common complication is cellulitis, which is an infection of the skin and connected soft tissues.[4] If cellulitis is not treated, it may lead to tissue death (gangrene). The infection may spread to the bone (an infection called osteomyelitis) and reduce the function of joints and limbs. Long-term, non-healing wounds can lead to a type of skin cancer known as squamous cell carcinoma. In some cases, pressure injuries can lead to sepsis, shock, and death.

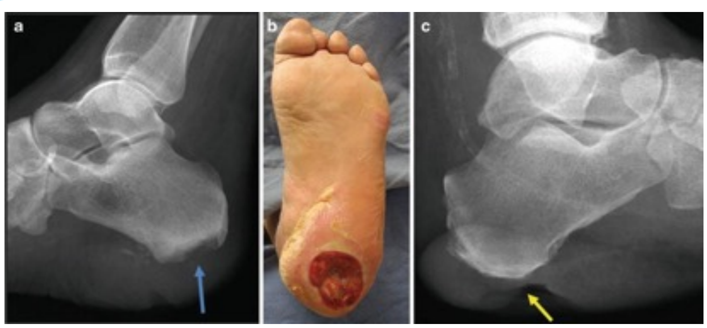

FIGURE 2 – OSTEOMYELITIS AT THE HEEL

A Constant Burden on Healthcare Teams

The prevention and treatment of pressure injuries can be nursing intensive.[5] Several studies suggest that pressure injury development is directly related to the ratio of patients to nurses and the average time spent at the bedside. In some care facilities, nurses spend upwards of two hours per patient, per day solely on pressure injury prevention.

At the health center level, a high prevalence of pressure injuries can lead to poor patient turnover, causing overcrowding and the lack of beds. These injuries also play a significant role in the spread of infection in the clinical area.[6] Therefore, with a lack of hygiene or proper nursing standards, pressure injuries can cause widespread disease. If injuries advance to Stages III or IV, they become a major burden for resource-strained facilities.

High Prevalence of Pressure Injuries is Costly

Canada

Particularly in frail, older adults, the estimated prevalence of pressure injuries across all healthcare institutions in Canada is 26%, with the following breakdown:[13]

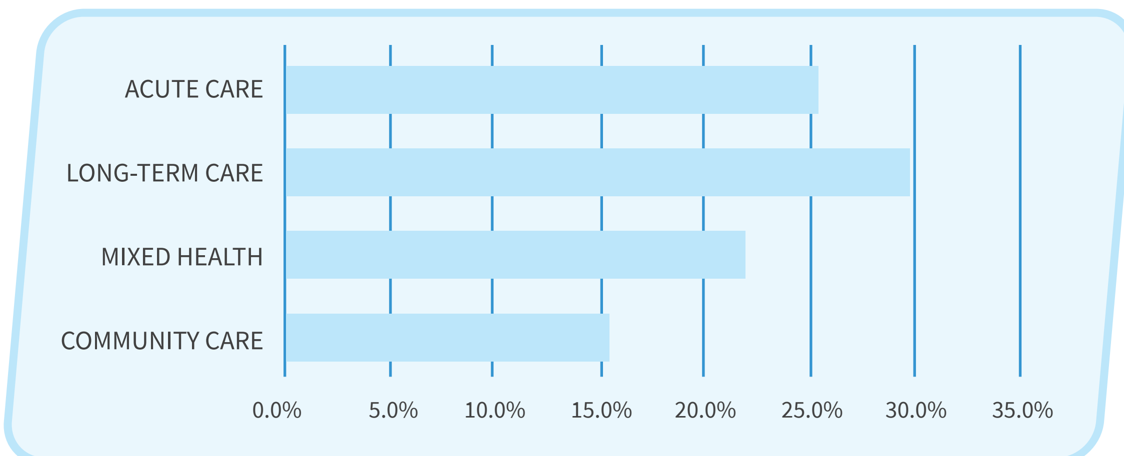

FIGURE 3 – PRESSURE INJURY PREVALENCE ACROSS CANADIAN HEALTH CENTERS

The highest reported rates of hospital-acquired pressure injuries occur in intensive care units (ICUs) and range from 14% to 42%.[14]

Pressure injuries are expensive. For patients over 65 in Canada, hospital-acquired pressure injury treatment costs range from $44,000 for Stage 2 to $90,000 for Stage 4.[15]

USA

Hospital-acquired pressure injuries affect more than 2.5 million patients in the U.S.[16/17] The prevalence of pressure injuries is up to 23% at long-term care and rehabilitation facilities and ranges from 10% to 41% in ICU patients.[17]

A 2012 Nationwide U.S. study evaluated the impact of pressure injuries on short-term inpatient outcomes:[17]

- Over 2x increase in mean length of stay (11.1 days vs. 4.6 days)
- Over 2x increase in mean total hospital charge ($72,000 vs. $32,200)
- Over 5x increase in mortality rate (9.1% vs. 1.8%)

A 2010 analysis in the American Journal of Surgery reported that the average hospital treatment cost for a Stage IV pressure injury and associated complications was over $120,000 in both hospital and community care settings.[18]

Given the large financial burden of treating pressure injuries, prevention is the preferred approach.

Current Approaches to Prevention and Treatment

Current Prevention – Turning and Repositioning

The most common preventative approach is frequently offloading pressure by turning and repositioning.[5] Patients that cannot turn or reposition themselves require assistance from nursing staff. The current gold standard is turning a patient at least every 2 hours. However, limited research has been conducted on the optimal turning frequency, and a “good turn” remains poorly defined. In some cases, tissue damage can occur when blood supply returns to tissue after prolonged lack of blood flow (reperfusion injury).[19] In addition, this approach is rarely compatible with critical/intensive care environments: for example, a patient requiring intubation cannot readily be turned to relieve pressure.

FIGURE 4 – A NURSE REPOSITIONS A HIGH-RISK PATIENT TO OFFLOAD PRESSURE

Current Prevention – Pressure-Redistributing Surfaces

A second approach is the use of pressure-redistributing surfaces. Dynamic mattresses and gel seat cushions are a significant expense for health centers attempting to reduce injury risk, and they demonstrate limited or no effectiveness in reducing pressure injury incidence.[20,21] Use of pressure-redistributing surfaces does not negate the requirement for turning and repositioning patients.

Aside from pressure reduction approaches, prevention involves the reduction of risk factors listed in the Braden Scale. Nurses can ensure patient skin is clean and dry on a regular basis.[5] Managing nutrition and supporting patients through mobility exercises can also prevent injury.[22]

Treatment – Wound Management

The treatment of pressure injuries is a combination of effective wound management and risk factor reduction.

Wound management begins with regular cleaning to remove any debris and bacteria that may delay healing.[5] Special dressings are used to protect against infection and support repair. Removal of dead tissue (debridement) is generally performed using a scalpel or laser.[15] If a bacterial infection is suspected, oral or topical antibiotics can be effective tools in wound management.

The treatment of high stage pressure injuries can be a challenging process, and often requires prolonged hospitalization. In rare cases, the wound may be unable to heal completely, and reconstructive surgery is required to restore function.[23] At these stages, greater emphasis must be placed on nutrition and hydration.

Modern treatment methods such as negative pressure wound therapy (vacuum placed over wound bed) and hyperbaric oxygen therapy (supplying excess oxygen in a sealed chamber) have shown poor efficacy compared to more invasive surgical techniques.[6] Currently, treatment incurs significant cost for both health systems and patients, making prevention efforts a major focus for nursing care.

Prelivia – A New Era or Pressure Injury Prevention

Prelivia is the first technology designed to prevent damage by restoring blood circulation and tissue oxygenation. The U.S. Food and Drug Administration provided 510 (k) Clearance for Prelivia in June 2021. Developed by Rehabtronics, Prelivia uses a patented neurostimulation technology that continuously increases local blood circulation. Studies have shown that Prelivia's unique technology increases tissue oxygenation by 28% and decreases 80% of pressure induced tissue damage. A caregiver applies electrodes to a patient's skin in the area that is at-risk for developing a pressure injury. Once activated, the electrodes deliver intermittent electrical stimulation (IES) to the tissue, which is painless. Unlike other systems that deliver electrical impulses, Prelivia delivers stimulation continuously without fatiguing muscles. Therefore, there are no time restrictions and Prelivia can be used 24/7 to keep tissue healthy in bedridden and chair-bound patients. Visit **www.rehabtronics.com** to learn more.

Prelivia Study Results

28%	80%	0
Increase in tissue oxygenation	**Decrease** in PI damage	**Bed sores** observed when use on High Risk Patients
28% tissue oxyengation : Gyawali, et. al., J Appl Physiol. 110 :246-255, 2011	80% reduction : Solis, et al., J Appl Physiol, 114 :286-296, 2013	0 bedsores: Ahmetovic, et al, Adv Wound Caref, 4(3): 192-201, 2015. Kane, et al, Adv Wound Caref, 6(4): 115-124, 2017

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Figures

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