White Paper

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Pressure Ulcers:
An Overview of a Painful Problem

Bruin Biometrics, LLC (BBI) is pleased to provide this series of white papers to help lay readers understand commonly debated topics in pressure ulcer research and clinical practice. These papers are the distillation of a comprehensive literature search and review, rather than the result of primary research.
Pressure Ulcers: An Overview of a Painful Problem

Introduction

Pressure ulcers, commonly known as bedsores, are a problem experienced internationally. They affect patient quality of life and impose a heavy resource and financial burden on healthcare systems.

A pressure ulcer is localized injury to the skin and/or underlying tissue usually over a bony prominence, such as a heel or an elbow (see Illustration I). This injury is caused by the inability of the skin and the supporting tissues to redistribute external pressure, including mechanical loading, friction, and shear (parallel force). Most pressure ulcers occur over bony prominences where there is less tissue for compression and the pressure gradient within the vascular network is altered. The most common anatomic location of all pressure ulcers is the sacrum (28.3%), followed by the heel (23.6%) and buttocks (17.2%) (see Illustration I). Based on the 2008 and 2009 International Pressure Ulcer Prevalence Survey, the overall prevalence of pressure ulcers was 12.3% across all care settings. Long-term acute care settings that serve patients with complex medical problems who require extended hospital stays have the highest overall prevalence of any care setting at 29.3%, with rehabilitation next at a range of 16.3% to 19.4%, and acute care settings at approximately 11.9%.

Pressure ulcers present a significant health and economic concern. They account for 60,000 deaths, 2.3 million incremental hospital days and an estimated $9.1-$11.6 billion per year of care costs in the United States. The cost of individual patient care ranges from $20,900 to $151,700 per pressure ulcer, which adds $43,180 to a hospital stay.
Similarly, in the United Kingdom, pressure ulcer care costs the healthcare system £2.1 billion per year ($3.4 billion). These costs are driven by nursing time to monitor, assess, and dress wounds, utilization of appropriate treatment therapies, as well as duration of hospital stay, based on the severity of the pressure ulcer. For example, the most severe pressure ulcers (Stage IV) require an average of 155 days recovery time and $129,248 for treatment of the ulcer and related complications during a single hospital admission. The result is an average hospital length of stay (LOS) that is 4.5 times longer than patients without pressure ulcers.

**Pressure Ulcer Classification**

The current standard of detection for pressure ulcers relies mainly on visual inspection. Visual inspection is used to detect and classify pressure ulcers according to the ulcer’s depth, width, degree of tissue loss, and presence of granulated tissue. The National Pressure Ulcer Advisory Panel (NPUAP) in conjunction with the European Pressure Ulcer Advisory Panel (EPUAP) categorizes pressure ulcers into one of six stages; 4 depth stages (Stages I-IV) and 2 additional stages to indicate deep tissue injury or an ulcer that cannot be classified. The NPUAP/EPUAP developed this classification system to ensure consistent and accurate wound categorization as a means to achieving proper treatment, as well as to help with diagnosis coding for reimbursement (ICD-9 and ICD-10 codes). Details about each stage are included in Table 1.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal or Healthy Skin</td>
<td>• Intact skin</td>
<td><img src="image1" alt="Normal Skin" /></td>
</tr>
<tr>
<td></td>
<td>• No visible bruising or skin discoloration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Skin is pain-free, and temperature is consistent across surface</td>
<td></td>
</tr>
<tr>
<td>Stage I: Non-blanchable erythema</td>
<td>• Intact skin with non-blanchable redness of a localized area, usually over a bony prominence</td>
<td><img src="image2" alt="Stage I" /></td>
</tr>
<tr>
<td></td>
<td>• Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue</td>
<td></td>
</tr>
<tr>
<td>Stage II: Partial Thickness Skin Loss</td>
<td>• Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough</td>
<td><img src="image3" alt="Stage II" /></td>
</tr>
<tr>
<td></td>
<td>• May also present as an intact or open/ruptured serum-filled or sero-sanguinous filled blister</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Presents as a shiny or dry, shallow ulcer without slough or bruising</td>
<td></td>
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</tbody>
</table>
Stage III: Full Thickness Skin Loss
- Full thickness tissue loss
- Subcutaneous fat may be visible but bone, tendon, or muscle is not exposed or directly palpable
- Slough may be present but does not obscure the depth of tissue loss
- May include undermining and tunneling

Stage IV: Full Thickness Tissue Loss
- Full thickness tissue loss with exposed bone, tendon or muscle
- Slough or eschar* may be present.
- Often includes undermining and tunneling†
- Category/Stage IV ulcers can extend into muscle and/or supporting structures such as fascia, tendon or joint capsule
- Exposed bone/muscle is visible or directly palpable

Unstageable: Full Thickness Tissue loss with Unknown Depth
- Full thickness tissue loss
- Actual depth of the ulcer is completely obscured by slough‡ (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed

Deep Tissue Injury (DTI) with Unknown Depth
- Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear
- The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue
- Evolution may include a thin blister or eschar over a dark wound bed
- Evolution may be rapid, exposing additional layers of tissue even with optimal treatment

Table 1: NPUAP/EPUAP Pressure Ulcer Classification System

Progression and Reverse Staging

Pressure ulcers do not always progress chronologically (through Stages I, II, III, etc.) in formation or healing. For example, tissue damage does not always present as Stage I pressure ulcer, which then develops into higher stage ulcer. In some instances, the first sign of a pressure ulcer is a deep III or IV ulcer, because the subcutaneous tissue can become necrotic before the epidermis erodes. This finding suggests that a small surface ulcer may in fact represent extensive subcutaneous damage.

Once a pressure ulcer develops, tissue damage is not easily reversed. Previously, it was generally accepted that a pressure ulcer would “reverse stage” throughout the healing process and be re-classified at a lower stage.

* Eschar: Dried, black, hard, necrotic tissue
† Tunneling: A tract heading away from the wound base in any direction
‡ Slough: Soft, yellow, brown, or gray material and is characterized by its stringy, adherent quality
(Stage IV becomes Stage III, then Stage II, Stage I, until the skin is again healthy). However, experts now dismiss this practice because it is physiologically incorrect. While pressure ulcers do heal to a progressively shallower depth, a healing wound is not filled by normal tissue; lost muscle, subcutaneous fat, and dermis is not replaced. Rather, the wound is replaced by scar tissue that is composed of endothelial cells, fibroblasts, collagen, and extracellular matrix. Therefore, it is not appropriate to say that a Stage II pressure ulcer will “heal” to a Stage I assessment. Instead, a pressure ulcer maintains its first classification stage, and the term “healing” is added as a prefix. For example, a Stage IV pressure ulcer that is improving is designated a “healing Stage IV” pressure ulcer; it is no longer “reverse staged” to Stage III or II.

Most Pressure Ulcers Are Avoidable

When a caregiver follows the guidelines for patient care that include repositioning bed-ridden patients approximately once every hour, the risk of developing a pressure ulcer dramatically decreases. In 2010, the National Pressure Ulcer Advisory Panel (NPUAP) hosted a multidisciplinary conference to establish consensus on whether or not pressure ulcers are avoidable. Eighty-two percent of the clinicians on the conference panel agreed that most pressure ulcers are avoidable. The instance when the development of a pressure ulcer was considered unavoidable—by a unanimous vote of all 24 panelists—was hemodynamic instability (a state requiring pharmacologic or mechanical support to maintain a normal blood pressure or adequate cardiac output), which is worsened by physical movement.

The rationale for agreeing that pressure ulcers are largely preventable stems from the fact that when a care-giver follows well-established guidelines for patient care, which include but are not limited to mobilizing patients regularly, ensuring proper nutrition, effectively managing moisture at the skin’s surface, the likelihood that a patient will develop a pressure ulcer dramatically decreases.

The Center for Medicare & Medicaid Services (CMS) also concluded that most pressure ulcers are avoidable. As of October 2013, CMS reimbursement for hospital-acquired Stage III and IV pressure ulcers will cease. Because pressure ulcers are reasonably preventable, CMS has deemed them “never events,” namely events that should never happen in a provider setting. Private insurers in the United States are also adopting these reimbursement restrictions. Similarly, the United Kingdom has adopted a zero tolerance approach toward pressure ulceration.
Failure to Detect Pressure Ulcers Have Serious Consequences

Forty-two percent of patients with a Stage I pressure ulcer progress to higher stages of ulceration. Treatment costs quadruple, from Stage I (£1,214 or approximately $1,966) to Stage II (£5,241 or approximately $8,485). A 1998 study found that Stage I ulcers deteriorated to a higher stage in 23.3% of the patients undergoing surgery lasting more than 4 hours. In acute care hospitals, more than 1-in-5 Stage I pressure ulcers deteriorated to higher stages in one week. The failure to identify a Stage I pressure ulcer during a skin assessment leads to increased incidence of Stage II ulcers, particularly in patients with darker skin tones. Acknowledged difficulties with commonly accepted practices of pressure ulcer detection help explain incidence rates.

1. **Sensitivity & Specificity**: Visual inspection, even when combined with paper and pencil risk assessment tools (e.g., Braden Scale, Norton, Waterlow) lack sensitivity and specificity (see Table 2). Differentiating between epidermal irritation and sub-epidermal injury becomes more a matter of individual perception than science.

<table>
<thead>
<tr>
<th>Tool</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Braden Scale</td>
<td>57.1%</td>
<td>67.5%</td>
<td>4.08</td>
<td>2.56-6.48</td>
</tr>
<tr>
<td>Norton Scale</td>
<td>46.8%</td>
<td>61.8%</td>
<td>2.16</td>
<td>1.03-4.54</td>
</tr>
<tr>
<td>Waterlow Scale</td>
<td>82.4%</td>
<td>27.4%</td>
<td>2.05</td>
<td>1.11-3.76</td>
</tr>
<tr>
<td>Clinical Judgment</td>
<td>50.6%</td>
<td>60.1%</td>
<td>1.69</td>
<td>0.76-3.75</td>
</tr>
</tbody>
</table>

*Table 2: Risk Assessment Tool Comparison*

2. **Dark Skin Tones**: Data show Stage I pressure ulcers are missed in patients with dark skin tones; instead, such patients develop four times as many Stage II pressure ulcers as compared to Stage I pressure ulcers.
3. **DTI and the Bottom-Up Formation model**: Stage II and higher pressure ulcers often occur suddenly without significant visual cues appearing on the skin surface in time to prevent them. Injury deeper in the tissue is the suspected cause. If surface ulceration is hard to detect, identifying injury deep in the tissue is near impossible without a method of interrogation.

The Bruin Biometrics Solution

Bruin Biometrics, LLC (BBI) has created the SEM Scanner, a diagnostic medical device intended to objectively detect pressure-induced tissue damage beneath the skin’s surface and measure the progression both of wound development and healing. Conceived by Barbara Bates-Jensen, PhD, RN, CWOCN, FAAN, one of the world’s leading wound care experts, the SEM Scanner is a hand-held, portable device that noninvasively detects levels of subepidermal moisture (SEM), a biophysical marker that is correlated with pressure ulcer formation and healing.

BBI believes that early detection of pressure ulcer formation is the best form of prevention. The SEM Scanner introduces an evidence-based, objective, method to pressure ulcer detection, enabling early intervention to treat tissue damage, and ultimately, prevent pressure ulcers.
Endnotes


Quintavalle, P. R., Lyder, C. H., Mertz, P. J., Phillips-Jones, C. and Dyson, M., 2006. Use of high-resolution, high-frequency diagnostic ultrasound to investigate the pathogenesis of pressure ulcer development. Advances in Skin Wound Care 19, pp. 498–505.


Harrow J.J. and Mayrovitz H.N., 2006. Initial assessment of tissue water content surrounding pressure ulcers in spinal cord injury patients. [Abstract]. Available at: <
