CLINICAL MANAGEMENT extra

SPECIAL ISSUE PRESSURE INJURIES

Reexamining the Literature on Terminal Ulcers, SCALE, Skin Failure, and Unavoidable Pressure Injuries

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GENERAL PURPOSE:

To synthesize the literature regarding skin injuries that are found in patients at the end of life and to clarify the terms used to describe these conditions.

TARGET AUDIENCE:

This continuing education activity is intended for physicians, physician assistants, nurse practitioners, and nurses with an interest in skin and wound care.

LEARNING OBJECTIVES/OUTCOMES:

After completing this continuing education activity, you should be better able to:

1. Define the terms used to describe pressure injuries and skin changes at the end of life.

2. Discuss the concept of skin failure as applied to end-of-life skin injuries and implications for practice.

ABSTRACT

This article synthesizes the literature regarding the concepts of "terminal" skin injuries that are found in patients at the end of life, including Kennedy terminal ulcers, Skin Changes At Life's End, Trombley-Brennan terminal tissue injuries, and skin failure. Also included is a discussion of avoidable and unavoidable pressure injuries as defined and differentiated by the Centers for Medicare & Medicaid Services and the National Pressure Ulcer Advisory Panel. To help clarify the controversy among these terms, a unifying concept of "skin failure" that may occur with an acute illness, chronic illness, or as part of the dying process is proposed. This proposed concept of skin failure is etiologically different than a pressure injury, although pressure injury and skin failure can occur concomitantly. These proposed concepts require further research and validated diagnostic criteria. Consensus around appropriate terminology is essential to reduce confusion among stakeholders and ensure appropriate patient care.

KEYWORDS: acute skin failure, avoidable pressure injuries, chronic skin failure, end-stage skin failure, Kennedy terminal ulcer, KTU, pressure injuries, pressure ulcers, SCALE, Skin Changes At Life's End, skin failure, TB-TTI, terminal ulcers, Trombley-Brennan terminal tissue injury, unavoidable pressure injuries

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INTRODUCTION

Through the collective efforts of research, clinical experience, clinical guidelines, expert consensus, and numerous professional organizations' endeavors, the knowledge base for interprofessional team members to prevent and treat pressure injuries has increased. Over the years, several terms and concepts have been associated with pressure injuries, especially those that occur under specific circumstances.

The authors review the literature for these concepts, including terms for pressure injuries in palliative care and for patients who are at end of life. The three terms that are initially discussed are Kennedy terminal ulcer (KTU),[1–3] Skin Changes At Life's End (SCALE),[4–6] and Trombley-Brennan terminal tissue injury (TB-TTI).[7,8] They are presented in the order in which they were published.

Next, the concept of skin failure[9–21] will be discussed. The use of this term represents an attempt to provide a unifying hypothesis for skin changes at the end of life and other acute states that compromise skin integrity. Finally, the idea of avoidable versus unavoidable pressure injuries is considered, along with the debate as to whether KTU, TB-TTI, SCALE, and skin failure are avoidable or unavoidable.[22–34] The Centers for Medicare & Medicaid Services (CMS) has separated the skin changes associated with the dying process from pressure injuries that may be avoidable versus unavoidable.[27] Therefore, the evolution of the definitions of avoidable versus unavoidable pressure injuries from CMS and professional organizations will be included.[22–27]

Over the years, the terms and concepts covered in this CME article have sparked discussion, controversy, and debate. The authors will strive to report the literature as objectively as possible. With this examination, the authors aim to (1) gather what is known about this topic, (2) assess the need for consistent terminology,[35,36] (3) evaluate the interrelationships among these concepts, (4) propose a model unifying these concepts, and (5) provide a springboard for continued dialogue.

PRESSURE INJURIES IN PALLIATIVE CARE/ PATIENTS AT END OF LIFE

In the mid-19th century, Jean Martin Charcot recognized that certain decubitus ulcers precede death, and he termed this lesion the "decubitus ominosus."[37] In the late 1980s, clinicians described clinical skin changes that were occurring in patients who were at the end of life. One initial description was the KTU.[1] Subsequently, authors have attempted to clarify this phenomenon[2,3] by providing data about pressure injuries or other signs of skin compromise, including ulcers that occur in patients at the end of life.[7,8] Additional publications have reported

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expert consensus concerning these skin changes in persons at the end of life.[4–6] By examining this literature, the authors' aim is to clarify the different terms used to describe pressure injuries and other skin changes in patients at the end of life. Consistent terminology is needed for this skin phenomenon. Table 1 summarizes key information from the literature about KTU, skin failure, acute skin failure (ASF), SCALE, and TB-TTI. The authors will present a more complete synopsis in the following sections.

KENNEDY TERMINAL ULCER

At the first National Pressure Ulcer Advisory Panel (NPUAP) conference, Karen Lou Kennedy presented her clinical observations and data about skin injuries in the 500-bed intermediate care facility where she was employed. The pressure ulcer committee members in her Indiana facility believed that their pressure ulcer rate was below the reported rate in the literature of 15% to 20% for nursing home residents at that time.[1] These data led the committee to examine retrospective data from September 1983 through December 1988. Initially, their analysis included only stages 2 through 4 ulcers and calculated the prevalence to be between 1.23% and 5.34%. Interestingly, they noticed slight monthly variations, with the lowest incidence of pressure ulcers occurring in December and the highest in October. In January 1989, stage 1 pressure injuries were also included in the analysis, which increased the prevalence rate by 0.2%.[1]

The committee members then investigated how long residents lived after developing a pressure injury and found that 55.7% died within 6 weeks. They coined the term "Kennedy terminal lesion."[1] Kennedy and colleagues noticed that residents who had a sudden appearance of a red, yellow, or black bilateral pear-shaped ulcer predominantly on the sacrum or coccyx seemed to be at increased risk of impending death (Figure 1).[1]

These data inspired further investigation into the number of residents who died and whether they had pressure injuries. Kennedy[1] published one retrospective case review of residents with a total of 95 pressure injuries from 1983 to 1988; 51 of the patients died. The percentage of residents with a pressure injury who died ranged from 3.61% (3 out of 83) in 1984 to 20.79% (21 out of 101) in 1988.[1] For those who died, the most prevalent location of pressure injuries was the coccyx (23.4%), followed by the hip (17.4%), and finally the heel (14.8%). Other Kennedy terminal lesion locations were detected on the buttocks (11.6%) and ischium (6.2%).[1] Once these "Kennedy terminal lesions" appeared, life expectancy was reported to be between 2 weeks and several months, with 55.7% dying within 6 weeks of the discovery of these ulcers.[1] The physiologic mechanism(s) by which these lesions occurred was not known, but Kennedy hypothesized that it was part of the dying process that caused these skin changes. The data also revealed that those who did not die were more likely to have skin breakdown on the left buttocks, right ankle, or right ischium.[1] This led to Kennedy speculating that *bilateral* skin breakdown could be an indicator of increased morbidity and that it warranted further research to explore this observation.[1]

Among healthcare professionals, these terminal lesions eventually became known as KTUs. The literature is not clear as to whether KTU should be considered a pressure injury or a separate skin problem that also occurs over a bony prominence, making differentiation difficult from a "typical" pressure injury.

No further data could be found in the published literature. However, www.kennedyterminalulcer.com includes additional information, including treatment suggestions and a definition of a KTU: "a pressure ulcer some people develop as they are dying."[2]

3:30 Syndrome

The KTU website also includes information about a phenomenon called "3:30 syndrome."[3] Kennedy has posted on the KTU website that 3:30 syndrome is a variant of the KTU; it presents differently and more quickly, often within few hours. It can appear as little black spots that look like "specks of dirt or dried bowel movement."[3] Alternatively, these can mimic skin that has been colored with a black or purple marker, presenting as a black, flat (macular) patch of intact skin with a possible blister in a unilateral location. As the hours progress, the patch becomes larger and can quickly become almost the size of a quarter, 50-cent piece, or silver dollar.[3]

Examples of this phenomenon often begin with normal skin on first examination in the morning (intact, no color changes) when the patient is moved from his/her bed to a chair. At around 3:30 pm, when the patient is placed back in bed, the skin has a blackened discoloration and other potential surface changes, thus the name "3:30 syndrome." When the nurse examines the discolored skin, it seems difficult to believe it evolved over just 6 to 8 hours in a chair. The life expectancy of a patient with 3:30 syndrome is often as short as 8 to 24 hours (Figure 2).[3]

In 2010, Yastrub[38] argued that a KTU is different from a pressure injury because it is attributable to hypoperfusion (local ischemia) of the skin rather than pressure. She cautioned clinicians to correctly distinguish between a KTU and a pressure injury because it can assist in setting realistic wound healing goals.[38] In 2016, Miller[39] expressed his opinion that the concept of the KTU is problematic because it requires factors other than pressure to explain both the development and progression of these pressure injuries in persons with terminal conditions. His assessment of the KTU was that it is based on observation without a proven physiologic mechanism.[39] He introduced the idea that systemic physiologic effect and local stressors, rather than just terminal status, may explain these ulcers.[39] Dr Miller

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Table 1.

THE LITERATURE AT A GLANCE: A SUMMARY OF TERMINAL ULCERS, SCALE, AND SKIN FAILURE CONCEPTS

Term (Year Published)	Definition	Characteristics/Comments	Evidence/References
KTU (1989)	The KTU is shaped like a pear; predominately on the coccyx or sacrum. Red, yellow, and black. Onset of a KTU is sudden.[1]	Life expectancy from 2 wk to several months.[1] Other locations include hip, heel, ischium. Additional shapes: butterfly, horseshoe. Borders are irregular. Presenting characteristics are a larger area with superficial depth.	One retrospective case review in long-term care from 1983–1988 (51 patients who died) after clinical observation of skin changes[1]
Skin failure	An event in which the skin and underlying tissue die; attributable to hypoperfusion that occurs concurrent with severe dysfunction or failure of other organ systems.[14]	Can be categorized as chronic, end stage, or acute.[14] Life expectancy can vary. Generally over a bony prominence but can occur anywhere on the body. This condition is unavoidable in most instances. It is unclear whether this condition is independent of KTU, TB-TTI, or DTI.	One retrospective study of outcomes (180-d mortality) in 74 individuals. Brown[11] found PI development rates of 66.7% in intensive care, 75% in acute, and 66.7% in long-term care. No deaths were directly attributable to presence of a PI.[11]
ASF (2006)	Describes the hypoperfusion state that leads to tissue death that occurs simultaneously to a critical illness.[16]	Statistically significant and independent predictors for ASF in ICU patients from the logistic regression model were pulmonary artery disease, mechanical ventilation for more than 72 h, respiratory failure, liver failure, and severe sepsis/septic shock[16]	One retrospective case-control study[16] in two magnet medical centers in northeast US (N = 450). Mean length of stay was 9 d; mean Braden Scale score on admission to ICU was 14. Of all 450 patients, 150 had PIs; of those, 82 patients (54.7%) had sacral PI. Half of the PIs (n = 75, 50%) were staged as DTI. Stage 2 (n = 43, 29%) was the next most common. The majority of PIs (n = 101, 67%) developed in the first week of ICU admission.[16]
SCALE (2008)	A mnemonic used to describe a group of clinical phenomena.[5] "Physiological changes that occur as a result of the dying process may affect the skin and soft tissues and may manifest as observable (objective) changes in skin color, turgor, or integrity, or as subjective symptoms such as localized pain."[5]	The changes can be unavoidable and may occur with the application of appropriate interventions that meet or exceed the standard of care.[5] Recommended: research to identify the mechanisms for the proposed decreased hypoperfusion and oxygenation of the skin and soft tissues.[5] Further, distinguish skin and soft tissue damage associated with SCALE from other skin disorders not associated with skin organ compromise or the end of life.[5]	Modified 3 phase Delphi process used to develop 10 consensus statements originally drafted by 18 key opinion leaders, which were then reviewed by 49 international reviewers (2008),[4] and 52 international reviewers reached consensus on the 10 final statements (2010)[5] Review article with a case review of a long-term care resident[6]

(continues)

Table 1.

THE LITERATURE AT A GLANCE: A SUMMARY OF TERMINAL ULCERS, SCALE, AND SKIN FAILURE CONCEPTS, CONTINUED

Term (Year Published)	Definition	Characteristics/Comments	Evidence/References
TB-TTI (2010)	Spontaneously appearing skin alterations (rapid evolution, speed of enlargement and progression, appearance in areas of little to no pressure such as shins and thighs, and mirror imaging found in patients at the end of life). Unavoidable occurrence—one that is related to organ failure at the end of life.[8]	Bruise-like appearance (pink, purple, or maroon color); may be butterfly pattern. Can be linear striations on legs that extend downward or on thoracic or lumbar spine that present horizontally. May or may not be over bony prominence. Skin remains intact and does not break down. Can be confused with a DTPI.	Retrospective chart reviews from a 10-bed palliative care unit after clinical recognition of the skin changes (2010; N = 22)[7] Larger retrospective study (2012; N = 80)[8]

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Abbreviations: ASF, acute skin failure; DTI, deep tissue injury; DTPI, deep tissue pressure injury; ICU, intensive care unit; KTU, Kennedy terminal ulcer; PI, pressure injury; SCALE, Skin Changes At Life's End; TB-TTI, Trombley-Brennan terminal tissue injury.

Figure 1.

KENNEDY TERMINAL ULCER

Figure 2.

3:30 SYNDROME

then introduced a new term, Miller pressure equivalent injuries, and called for more research.[39]

Schank[40] later refuted Miller's assumptions, citing the work of Charcot and the CMS guidelines as reinforcing the phenomena of terminal ulcers such as the KTU associated with an increased risk of mortality. She also emphasized the need for more research regarding this concept.[40]

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SKIN CHANGES AT LIFE'S END

A group of 18 international key opinion leaders met in 2008 to review the evidence, literature, and expert clinical experiences known at that time about previously proposed concepts of KTU and skin failure. From this initial meeting, 10 consensus draft statements emerged. These were disseminated at professional conferences held between September 2008 and June 2009, in a 2008 peer-reviewed journal,[4] on the panel sponsor's website, and 49 international reviewers were asked to evaluate each statement in the consensus document.

After a modified Delphi process, the revised 10 statements were reviewed by another 52 international stakeholders who also had to reach 80% agreement (strongly agree, somewhat agree) for each of the final 10 consensus statements (Table 2).

A part of the original purpose of the SCALE panel was to clarify the clinical observation that skin breakdown in patients at the end of life may not be attributable to substandard healthcare. Advocating that these skin changes found in patients at the end of life could not be prevented was (and still is) an important notion. This also applied to unavoidable pressure injuries at the end of life. This was an important inclusion because nonpayment of additional money for a pressure injury diagnosis may result for US hospitals if an individual develops a pressure injury during his/her hospitalization.

Several key statements from the SCALE document[5] require further clarification. The panel's recommendations stated that the physiologic changes of dying can cause unavoidable skin and soft tissue changes despite care interventions that meet or exceed the standard of care. The SCALE concept represents the loss of skin integrity from any of a number of factors, including but not limited to equipment or devices, incontinence, chemical irritants, chronic exposure to body fluids, skin tears, pressure, shear, friction, and/or infections. Additional risk factors for SCALE include general health issues such as weakness and suboptimal nutrition (Table 2).

Diminished tissue perfusion (local ischemia), impaired skin oxygenation, decreased local skin temperature, mottled discoloration, and skin necrosis are all part of the SCALE process and may evolve into skin failure if two or more internal organs are also involved. Clinical care must also include patient-centered concerns that should be addressed, including pain and activities of daily living.

The SCALE document recommended that a total skin assessment should be performed regularly to document all areas of concern, consistent with the wishes and condition of the patient and their family, friends, and support persons. Providers are encouraged to pay special attention to bony prominences and skin areas with underlying cartilage. These bony areas of special concern include the sacrum, coccyx, ischial tuberosities, trochanters, scapulae, occiput, heels, digits, nose, and ears. They are further encouraged to describe the skin or wound abnormality exactly as assessed to avoid diagnostic errors. Consultation with a qualified healthcare professional is recommended for any skin changes associated with increased pain, signs of infection, skin breakdown (when the goal may be healing, although it is often maintenance of existing changes), and whenever the patient's circle of care expresses a significant concern.

The probable skin change etiology and goals of care should be determined as outlined in Table 2 with the 10 SCALE statements. Expectations around the patient's end-of-life goals and concerns should be communicated among the members of the interprofessional team and the patients as well as their circle of care. The discussion should include the potential for SCALE including other skin changes, skin breakdown, and pressure injuries.

To summarize the SCALE document, pressure injuries may be an unavoidable part of the dying process, but other skin injuries can also exist simultaneously. There are degrees of skin impact during the dying process, and not everyone with SCALE has skin failure. Skin compromise can exist without the published definitions of skin failure. To put the SCALE document in perspective with the other sections of this document, providers must also examine the organ failure literature, dermatologic literature, and an important Swedish study.

The Swedish Study

In 2017, Carlsson and Gunningberg[41] reported on "the predictors for development of pressure ulcers (injury) in end-of-life care." This was a retrospective, descriptive, and comparative study design of the Swedish National Quality Registry using logistical regression for statistical analysis. All deceased patients older than 17 years (n = 60,319) registered in the Swedish Register of Palliative Care during 2014 were included. The data were used to develop predictors for developing pressure injuries at the end of life.

The results documented that all healthcare facilities except general palliative home care had a significantly higher incidence of pressure injuries than did the nursing homes (Tables 3 and 4). The study included at-risk populations for the development of pressure injuries that are not always recognized in all healthcare system analyses, including individuals with diabetes and those in a postfracture state, with an infection, or with multiple diagnoses/comorbidities (eg, diabetes). From these data, they have identified chronic diseases, infections, and acute injuries that are not documented in other studies as potential risk factors. For example, some persons with dementia often may wander and are less likely to remain in bed or one position. These patients had significantly fewer pressure injuries. Further, pain

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Table 2.
THE 10 SCALE STATEMENTS[5]

1. Physiological changes that occur as a result of the dying process may affect the skin and soft tissues and may manifest as observable (objective) changes in skin color, turgor, or integrity or as subjective symptoms such as localized pain. These changes can be unavoidable and may occur with the application of appropriate interventions that meet or exceed the standard of care.
2. The plan of care and patient response should be clearly documented and reflected in the entire medical record. Charting by exception is an appropriate method of documentation.
3. Patient-centered concerns should be addressed including pain and activities of daily living.
4. Skin Changes At Life's End are a reflection of compromised skin (reduced soft-tissue perfusion, decreased tolerance to external insults, and impaired removal of metabolic wastes).
5. Expectations around the patient's end-of-life goals and concerns should be communicated among the members of the interprofessional team and the patient's circle of care. The discussion should include the potential for SCALE, including other skin changes, skin breakdown, and PrUs.
6. Risk factors, symptoms, and signs associated with SCALE have not been fully elucidated, but may include
   - weakness and progressive limitation of mobility;
   - suboptimal nutrition, including loss of appetite, weight loss, cachexia and wasting, low serum albumin/prealbumin level, and low hemoglobin, as well as dehydration;
   - diminished tissue perfusion, impaired skin oxygenation, decreased local skin temperature, mottled discoloration, and skin necrosis;
   - loss of skin integrity from any of a number of factors, including equipment or devices, incontinence, chemical irritants, chronic exposure to body fluids, skin tears, pressure, shear, friction, and infections; and
   - impaired immune function.
7. A total skin assessment should be performed regularly and document all areas of concern consistent with the wishes and condition of the patient. Pay special attention to bony prominences and skin areas with underlying cartilage. Areas of special concern include the sacrum, coccyx, ischial tuberosities, trochanters, scapulae, occiput, heels, digits, nose, and ears. Describe the skin or wound abnormality exactly as assessed.
8. Consultation with a qualified healthcare professional is recommended for any skin changes associated with increased pain, signs of infection, skin breakdown (when the goal may be healing), and whenever the patient's circle of care expresses a significant concern.

(continues)

Table 2.
THE 10 SCALE STATEMENTS,[5] CONTINUED

9. The probable skin change etiology and goals of care should be determined. Consider the 5 P's for determining appropriate intervention strategies:
   - prevention
   - prescription (may heal with appropriate treatment)
   - preservation (maintenance without deterioration)
   - palliation (provide comfort and care)
   - preference (patient desires).
10. Patients and concerned individuals should be educated regarding SCALE and the plan of care.

Abbreviations: PrU, pressure ulcer; SCALE, Skin Changes At Life's End.

was associated with more pressure injuries. The presence of an intravenous drip or enteral feeding (more commonly used in acute care institutions) was associated with a significantly decreased likelihood of developing pressure injuries.[41] Although this study cannot prove causation, and findings may not be generalizable to all healthcare systems, it is a valuable resource for future prospective research.

Organ Failure and Dermatologic Skin Area/ Severity Indexes

The SCALE document clearly stated that other situations such as multiple organ failure were beyond the scope of the SCALE panel document. Multiorgan dysfunction or failure described by Irwin and Rippe[42] is defined as the "presence of altered organ function in acutely ill patients such that homeostasis cannot be maintained without intervention. It usually involves two or more organ systems." Not all patients with SCALE necessarily have multiorgan failure, but research is needed to document the severity and extent of injury that may accompany SCALE. The authors of the present article will use examples to illustrate recognized quantitative models for other organ compromise that could be used to create a model for the skin.

Kidney disease represents a purely quantitative model for organ failure. To determine renal failure, glomerular filtration rate is calculated using the serum creatinine, age, body size, and gender. This is an objective measurement to determine kidney failure based on various levels of compromise.

For governments or policy makers to accept skin failure as a framework of unavoidable skin injury at the end of life and not subject these changes to penalties for substandard healthcare, it would require diagnostic criteria that reflect area and extent of injury. Dermatologists have utilized scores for research on treatment effectiveness that combine these components. The

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Table 3.
INCIDENCE OF PRESSURE ULCERS/INJURIES IN DIFFERENT HEALTHCARE SETTINGS[41]

Criteria	Time	Nursing Home, %	Short Stay at Nursing Home, %	Specialized PC Inpatient Unit, %	Hospital, %	General PC Home Care, %	Specialized PC Home Care Unit, %
Stages 1-4 PI	On admission	6.9	16.2	19.0	13.8	11.0	10.2
	At death	16.8	20.8	29.7	19.6	18.6	23.5
	Difference	+ 9.9	+4.6	+10.7	+5.8	+7.6	+13.3
Stage 3 or 4 PI	On admission	2.3	4.6	4.1	3.5	2.6	2.4
	At death	4.9	5.6	6.2	3.9	4.6	5.1
	Difference	+2.6	+1.0	+2.1	+0.4	+2.0	+3.7

Abbreviations: PC, palliative care; PI, pressure injury.
Palliative care had a significantly higher incidence of PIs than nursing homes; patients admitted to nursing homes may have time for their PIs to heal prior to death.

body surface area could be calculated similarly to burn score formulas, with the hand and fingers representing approximately 1% of the total body surface, or as in the rule of nines.[43]

Another diagnostic option is the Psoriasis Area and Severity Index, which is often used to assess new treatments, including newer biologic agents.[44] Areas of psoriasis are given a 0 to 4 score for each of three clinical criteria: erythema, thickness of the scale, and thickness of the lesions. Other more complicated scoring systems also exist; for example, scoring for atopic dermatitis[45] bases 60% of the score on the intensity of the injury, 20% for the area, and 20% for symptoms (pruritus and insomnia). The potential components for a proposed preliminary skin failure score are provided in Table 5.

TROMBLEY-BRENNAN TERMINAL TISSUE INJURY

Over a decade after the KTU was first described, a different team of clinicians published data regarding skin manifestations observed in persons in the last hours/days/weeks of their life. Trombley and Brennan noticed skin alterations that spontaneously appeared on patients in their inpatient palliative care unit. A 2010 retrospective chart review of 22 patients revealed

Table 4.
SYMPTOMS ASSOCIATED WITH PALLIATIVE END-OF-LIFE CARE[41]

Demographics	Findings
Type of facility	• Prevalence of PI ranged from 6.9% in nursing homes to 19% in specialized PC inpatient units
	• Highest PI prevalence at death was 29.7% (PC inpatient unit)
	• In hospitals, patients experienced the highest rates of pain, anxiety, death rattles, parenteral/enteral feeds
Age	• Older age is a predictor of PIs
	• Gender—no difference
Medical conditions	• General PC home care is not significantly related to development of PIs.
	• Patients with the following conditions were at a higher risk of PIs: cancer, neurological disease, diabetes mellitus, post fractures, multiple diseases, infections
	• Dementia was significantly associated with lower incidence of PIs.
Length of stay	• Pain was associated with a higher likelihood of developing PIs (possibly because caregivers are reluctant to turn patients), but better pain control reduces PI incidence and vice versa
	• Nausea decreases PI incidence; relief of nausea increases PI incidence
	• Patient loss of decision-making ability increases PI incidence
	• IV drip or enteral feeding is associated with decreased PI occurrence

Abbreviations: PC, palliative care; PI, pressure injury.

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pink, purple, or maroon bruiselike butterfly-shaped skin alterations.[7] These lesions do not progress to a pressure injury. This chart review was expanded to include an additional 58 patients. All of these terminal tissue injuries developed despite the staff's prevention strategies. Researchers also identified linear striations on patient legs that often extended downward. Horizontal striations may also be observed on the thoracic or lumbar spine. These skin alterations were noted both over bony prominences and elsewhere, including on the thigh. These lesions often had a mirror-image pattern in patients at end of life. These skin alterations appeared spontaneously, evolved rapidly, and could appear in an area of little to no pressure (Figure 3). The research team cautioned that these terminal tissue injuries could be confused with a deep tissue injury (which they were not) but rather were an unavoidable occurrence related to internal organ and skin compromise for persons at the end of life. In addition, they noted in a few patients that when the center of the wound was devoid of color, death often occurred within 2 hours.[7] The hospital named these terminal tissue injuries after the researchers (TB-TTI).[7]

A related 2012 study of 80 patients revealed that 79 had intact skin without any exudate. Researchers concluded that the 500 observed changes could not be attributed to gaps in care.[8] Another retrospective chart review of an additional 86 patients corroborated earlier results. The median time from identification of the injury until death was 36 hours (M.R.B., unpublished data, December 2018). The pooled results indicated that 75% of the patients exhibiting a TB-TTI died within 72 hours of the first identification of these skin changes (M.R.B., unpublished data, December 2018). A further unpublished multisite study involving several hospitals within the health system is now in progress, and a National Institutes of Health grant has been submitted to continue this work.

SKIN FAILURE

Skin failure is a concept that has ignited passion and opposing opinions among healthcare professionals. One of the earliest proposals that the skin as an organ could fail was published by John La Puma[10] in 1991. It was part of his remarks at a 2-day 1991 conference about the Agency for Health Care Policy and Research's clinical guideline, *Prediction, Prevention and Early Treatment of Pressure Ulcers in Adults*.[10] Dr La Puma remarked, "The skin is the largest organ of the body. If the heart, lungs, and kidneys are showing signs of failing, isn't it logical that the skin would also show signs of failing? Why is a pressure ulcer considered a sign of inadequate healthcare, when symptoms of heart disease or lung disease or kidney disease are not? In the terminally ill patient, a pressure ulcer may only be a sign of physical decline and mortality."[10]

In 2000, Witkowski and Parish[12] also published a similar belief that "If the heart, lungs, and kidneys are failing, is it not logical that the body's cover would also show signs of failure?" The concept of skin failure was once again brought to the forefront in presentations and publications by Langemo and Brown.[14] Their expert opinion was based on a systematic review of literature published between 1984 and 2015, where seven articles were identified and explicated with clinical observation. Langemo[14] defined skin failure as "an event in which the skin and underlying tissue die due to hypoperfusion that occurs concurrent with severe dysfunction or failure of other organ systems." Three types of skin failure were described: acute, chronic, and end stage. Acute skin failure occurs concurrently with an acute illness such as septic shock or myocardial infarction; chronic skin failure occurs concurrently with a chronic condition such as multiple sclerosis or a malignancy, and end-stage skin failure occurs concurrently with end-of-life issues such as renal failure, pulmonary fibrosis, and

Table 5.
PROPOSED SKIN DAMAGE/FAILURE MODEL

	Skin Damage	Loss of Normal Skin	Factors for Comparing Skin Damage	Symptoms and Possible Correlations to Skin Damage
1	Localized external injury	<10% injury	• Infections • Ischemia (gangrene) • Pressure injuries • Edema • Moisture-associated skin changes • Purpura • Skin tears • Blisters	Pain ($P < .001$) only significant value in Swedish study[42] Nausea = less PI ($P < .5$) but relief of nausea = ↑PI Not significant: • Confusion • Anxiety • Death rattles • Shortness of breath
2	Mild	11%–25%		
3	Moderate	26%–50%		
4	Severe	51%–75%		
5	Skin failure	76%–100% or localized severe disease, Skin Changes At Life's End, and multiorgan failure		

This proposed model is modified from the renal failure model, Psoriasis Area and Severity Index, and score for atopic dermatitis and is presented to stimulate discussion and research.
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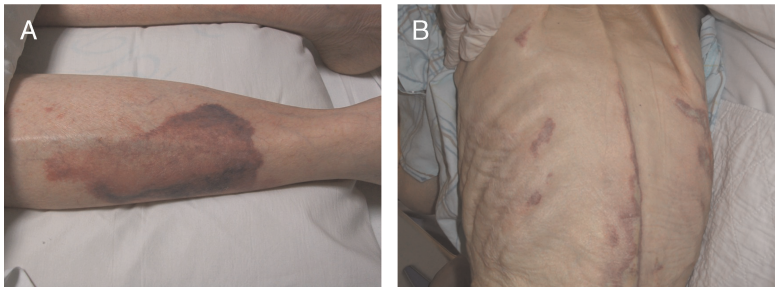
Figure 3.
EXAMPLES OF TROMBLEY-BRENNAN TERMINAL TISSUE INJURY



A, RIGHT LEG. B, BACK. © MS BRENNAN.

so on.[14] Other authors began to show interest in engaging with the concept of skin failure—both for and against.[11–21]

Levine[18] built on Langemo's definition by proposing that skin failure is "the state in which tissue tolerance is so compromised that cells can no longer survive in zones of physiologic impairment such as hypoxia, local mechanical stresses, impaired delivery of nutrients, and buildup of toxic metabolic byproducts." This includes pressure injuries, wounds that occur at life's end and in the setting of acute illness, and multisystem organ failure.[17] Levine[17] believes that skin failure is "an emerging concept that clarifies current trends in clinical practice" and "will lay the foundation for common nomenclature and open new directions for research." Levine[17,18] uses skin failure as a unifying concept that encompasses broader etiologies including pressure injury, KTU, TB-TTI, SCALE, and so on. The position of Langemo and many others in the wound care arena is to clarify that a pressure injury has pressure and/or shear as its etiology, whereas pressure is not a necessary component of skin failure. Langemo and Brown[14] go on to note that skin failure and pressure injury can occur concomitantly on the same individual. Despite this research and key opinion leader commentaries, there is currently no agreed-upon definition of skin failure.

Acute Skin Failure

Empirical evidence regarding ASF is limited. One "clinical conundrum" is defining and identifying skin failure in acutely ill hospitalized patients.[16] To provide some evidence to answer this question, Delmore and colleagues[16] have published data from 552 ICU patients in the US to predict the development of ASF. They used Langemo's definition and refined it slightly to state it is "the hypoperfusion state that leads to tissue death that occurs simultaneously to a critical illness."[16] This retrospective case-control study sorted the data into several categories: disease status, physical conditions, and conditions of hospitalization. Their ICU patients results revealed that peripheral arterial disease, mechanical ventilation for more than 72 hours, respiratory failure, liver failure, and severe sepsis/septic shock were statistically significant and independent predictors of ASF.[16] The authors expressed concern that there is no clear-cut diagnostic criteria for ASF: "in certain populations, such as the critically ill patient, the phenomenon of ASF may be occurring and with the current level of evidence, these ulcers may be incorrectly identified as PrUs."[16]

As one of the few data-based articles, this is an important contribution to ASF research and serves as a stimulus for further inquiry. Olshansky[19] agreed with statements made by Delmore et al[16] and gave examples of potential skin failures that appear randomly over the body, including Stevens-Johnson syndrome, necrotizing fasciitis, pemphigus, and epidermolysis bullosa. However, these diseases often occur without other organ failure. He agreed with Delmore and colleagues that ASF is not a pressure injury and called for the wound and dermatology communities to work together to create a uniform definition and diagnostic criteria for skin failure.[19]

TERMINAL ULCER TERMINOLOGY

Controversy exists regarding which term (KTU,[1–3] TB-TTI[7,8]) is best to describe terminal lesions or whether these lesions, such as the lesser known Miller pressure equivalent injuries, are even terminal lesions.[39] According to the KTU website,[2,3] the KTU is a particular type of pressure injury seen in patients at the end of life. It states that the KTU "can start out larger than other pressure ulcers, are usually more superficial initially and develop rapidly in size, and depth and color."[2,3]

Levine believes that terminal ulcer terminology, including SCALE, has limited application because of variability in late life trajectories and longer life spans in today's healthcare environment, such as with artificial life support that can prolong the dying process.[46] He believes that nomenclature associated with "end of life" is intrinsically problematic because this period is complex, often prolonged, and difficult to define and does not include breakdown in critical care settings that may share similar

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mechanisms. Levine's solution is to recast these terms under the umbrella of the prognostically neutral term "skin failure" that is consistent with concepts of tissue physiology in other organ systems.

Although the literature may not always agree as to whether or not KTUs, SCALE, or TB-TTIs are pressure injuries, many clinicians and researchers believe that these skin injuries are not pressure injuries and can be unavoidable as part of the dying process. The CMS agrees with this stated belief and does provide some guidance in long-term care (LTC) settings (Supplemental Table, http://links.lww.com/NSW/A20). For example, according to the CMS, when a clinician determines that a patient has a terminal ulcer (mostly known as Kennedy ulcers), then this is no longer considered a pressure ulcer and is not coded in the pressure ulcer section of the Minimum Data Set (MDS) 3.0.[27]

There are no CMS statements regarding terminal skin injuries in acute care or in the Resident Assessment Instrument manual for LTC, long-term acute-care hospitals, or inpatient rehabilitation facilities. However, there are statements in the CMS's *State Operations Manual: Guidance to Surveyors for Long Term Care Facilities* about pressure ulcers (F686, 483.25(b) Skin Integrity, 483.25(b)(1)).[27] They became effective on November 28, 2017, and indicate that terminal ulcers can be a clinical phenomenon that are part of the dying process.[27]

Beyond reimbursement, other quandaries related to terminology exist. One of the controversies is how to accurately diagnose any terminal ulcer, because often they can only be retrospectively diagnosed (ie, after patient death). It is also unclear whether any terminal ulcers have healed; this is not reported in the peer-reviewed literature. Further, as alluded to in previous sections, there is controversy over whether terminal ulcers are pressure ulcers. Because these terminal lesions (as such) may be in areas exposed to pressure, pressure may be a factor in their development.

AVOIDABLE VERSUS UNAVOIDABLE PRESSURE INJURIES

Another debate central to these complex concerns is whether KTU, TB-TTI, SCALE, and skin failure are avoidable or unavoidable. By reviewing and synthesizing the literature on this topic, the authors' intent is to summarize and introduce criteria for determining whether or not these skin phenomena, in addition to pressure injuries, are avoidable.

Early in the wound care literature, authors began to propose the idea that some or even all pressure ulcers were preventable or unavoidable. In the 19th century, Jean Martin Charcot believed that pressure ulcers were unavoidable given damage to the central nervous system, with the assumption that there were "neurotrophic fibers" that went directly from the brain and spinal cord to the skin.[37] Because they could not be prevented, they were deemed unavoidable.

In November 2004, after a 3-year review of the existing literature and opportunity for public comment, the CMS revised its guidance for surveyors in LTC, using the term "unavoidable." The intent of the CMS guidance was that residents should not develop a pressure ulcer while in LTC unless the resident's condition was such that the ulcer could not be prevented:

> *Based on the comprehensive assessment of a resident, the facility must ensure that (1) a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were* ***unavoidable****; and (2) a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.*[47] [emphasis added]

This language clearly indicated that based on some residents' clinical condition, some pressure injuries could be designated as unavoidable or not preventable. The CMS defined unavoidable as follows: "Unavoidable means that the resident developed a pressure ulcer even though the facility had evaluated the resident's clinical condition and pressure ulcer risk factors; defined and implemented interventions that are consistent with resident needs, goals, and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate."[47] In turn, the CMS defined avoidable as follows: "'Avoidable' means that the resident developed a pressure ulcer and that the facility did not do one or more of the following: evaluate the resident's clinical condition and pressure ulcer risk factors; define and implement interventions that are consistent with resident needs, resident goals, and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate."[47]

Note that the four criteria listed in both definitions are the same except that in one instance the facility did all of the specified tasks (unavoidable), and in the other, the facility did not do one or more of the required care items (avoidable). Therefore, determining if a pressure injury is unavoidable is a *process* that includes assessment and evaluation of patient condition and risk factors, as well as a clearly defined and implemented individualized plan of care that was monitored, evaluated, and revised as appropriate.

In 2010 and 2014, the NPUAP held a series of conferences to further explore the notion that not all pressure injuries could be avoided. Soon after the NPUAP consensus conference held in 2010 at the Johns Hopkins Medical Center, the CMS definition of unavoidable pressure injury was broadened so it was applicable to all care settings.[23] This was accomplished by consensus of the 24 national and international professional organizations in attendance at the conference. Stakeholders replaced the words "facility" with "provider," and "resident" with "individual."[23] Further, there was 100% agreement among stakeholders that not all pressure injuries

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were avoidable,[23] particularly when the ability of the body to reperfuse the tissue is limited or inadequate. There was 83% agreement that the condition called skin failure exists, and 100% indicated that skin failure was not the same as a pressure ulcer.[23] Further, "the panelists recognized that no formal diagnostic criteria exist for skin failure. They supported that skin failure is a documentable condition and that skin failure is not the same as a pressure ulcer. There was no vote taken on Kennedy terminal ulcers as either a documentable pressure injury, or a low profusion association lesion."[23]

The second NPUAP International Consensus Conference on avoidable versus unavoidable pressure injuries was held in 2014, again at the Johns Hopkins Medical Center.[24] National and international experts from 25 stakeholder organizations as well as an audience of more than 400 individuals explored the multifaceted issue of pressure ulcer unavoidability within a systemic, scientific, organ-system framework. The attendees also considered the complexities of *nonmodifiable* intrinsic and extrinsic risk factors for unavoidable pressure injury and came to an 80% or greater consensus on a number of such factors. The resulting 2014 NPUAP Unavoidable Pressure Injury document was based on a review of hundreds of research articles that provided scientific evidence behind unavoidable risk factors for pressure ulcer development.[24]

The year 2017 saw updates to two documents regarding avoidable/unavoidable pressure injuries, one by the Wound, Ostomy and Continence Nurses Society[26] and the other in a CMS State Operations Manual Appendix that updated its guidance to surveyors regarding the definition of avoidable and unavoidable pressure injuries.[27] The bolded terms (emphasis added) were added to the original CMS definitions and are current as of October 1, 2018.[27]

"Avoidable" means that the individual developed a pressure ulcer/**injury** and that the facility did not do one or more of the following: evaluate the individual's clinical condition and risk factors; define and implement interventions that are consistent with individual needs, goals, and **professional** standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate. "Unavoidable" means that the individual developed a pressure ulcer/**injury** even though the facility had evaluated the individual's clinical condition and risk factors; defined and implemented interventions that are consistent with individual needs, goals, and **professional** standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.

Given the current state of the literature, more research is needed to identify which factors in the development of pressure injuries are modifiable and which are not. There is currently no validated algorithm to determine whether a pressure ulcer is unavoidable.[48] However, the concept of unavoidable pressure injury is supported by definitions from the CMS, NPUAP, and Wound, Ostomy and Continence Nurses Society, and consensus from conferences and in the literature supports the phenomenon of skin failure as distinct from pressure injuries.

CONCLUSIONS

Through synthesis of the literature on these concepts, it is clear that while there is agreement that skin changes at end of life are real clinical phenomena seen in practice, the pathophysiology of skin changes in dying and palliative care patients is incomplete. There is also the need to agree on definitions and terms and to begin to define diagnostic criteria for skin failure as well as skin changes at end of life. Having multiple terms to describe these phenomena can be confusing and may impede communication among clinicians, especially across disciplines. It may also be puzzling to payors and regulators.

Coming to consensus will be best accomplished in an interprofessional forum, regardless of professional licensure, specialty, or practice care setting. Terminology needs to be consistent and subject to validation in the clinical setting. This article provides a platform for further dialogue.

PRACTICE PEARLS

- The physiologic understanding of KTU, TB-TTI, SCALE, and skin failure is incomplete.
- Kennedy terminal ulcer, TB-TTI, and SCALE are considered to be unavoidable in persons at end of life.
- Skin failure is clinically distinct from pressure injury.
- There is a need to agree on definitions and terms and to begin to define diagnostic criteria for skin failure and skin changes at end of life.

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