



# You Can't Manage What You Don't Measure

A proactive approach is needed to protect individuals with at-risk skin and to prevent additional damage.

BY DESMOND BELL, DPM, CWS, FFPM RCPS (GLASG)

## The Economic Impact and the Scope of the Problem

The economics of chronic wounds, whether they be related to diabetes, vascular, pressure, or other conditions, has been a growing problem for decades. Resources are expended on healing wounds, but the problem of preventing them and their recurrence is arguably more expensive and poses even more challenges than taking a wound to closure during the initial episode.

A significant number of Medicare recipients are afflicted with wounds, representing an ever-growing burden on our healthcare system. Nearly 15% of Medicare beneficiaries (8.2 million) had at least one type of wound or infec-

tion to manage wounds more efficiently, non-traumatic lower extremity amputation rates continue to rise. There has been a steady increase in amputation rates since 2012 and 2015, the analysis first presented in January 2019 in *Diabetes Care* by Geiss, Yanfeng, et al.<sup>5</sup>

Not surprisingly, the stress placed on the healthcare system from diabetes and diabetic foot ulcers (DFUs) is significant. The utilization patterns and the questionable beneficial impact of many products used to treat DFUs has resulted in scrutiny by the Centers for Medicare & Medicaid Services (CMS) and private payors to the point that sweeping changes are anticipated in terms of reimbursement to physicians and other health care providers. In a time where sustainability is a consideration across multiple areas, whether the environment or how we produce goods, the ability to continue this delivery of healthcare regarding diabetic foot ulcers in its present state does not seem sustainable.

Addressing the underlying aspects is critical in the successful management of diabetic skin. However, a broader approach must be considered to address DFU prevention on a larger scale, one that requires a proactive versus a reactive approach to this high-risk population. Understanding risk factors and aggressive intervention on the “front end” is critical in preventing people with diabetes from converting into patients with diabetic foot ulcers.

The pathophysiology of DFU development is well documented, with traits such as reduced perfusion via macro or micro circulation, decreased protective sensation due to peripheral neuropathy, drying of skin due to

*Continued on page 78*

## Autonomic nerve dysfunction and its impact on the degradation of overall skin function is a major contributing factor in both development and recurrence of DFUs.

tion (not pneumonia). Surgical infections were the largest prevalence category (4.0%), followed by diabetic infections (3.4%). Total Medicare spending estimates for all wound types ranged from \$28.1 to \$96.8 billion.<sup>1</sup> Margolis et al. estimated that the prevalence of diabetic foot ulcers among Medicare beneficiaries with diabetes is about 8%.<sup>1,2</sup> Assuming a prevalence of diabetes in this population of 28%, this would equate to 2.2% for the entire Medicare population.<sup>1,3</sup>

The spending on diabetic foot ulcers parallels the continued increase in diabetes as well as the aging of our population. In 1996, we had approximately 16 million people in the US living with diabetes. Most recent estimates based on analysis during 2021, we now have approximately 38.1 million diabetics over the age of 18 (or 14.7% of all US adults). Additionally, an estimated 97.6 million people aged 18 or older have pre-diabetes (38% of the adult US population) and among those 65 years or older, 27.2 million (48.8%) have pre-diabetes, according to Centers for Disease Control annual statistics.<sup>4</sup>

Adding to the overall concerns is that despite the spending, development and use of advanced technologies

## New Concepts and Studies

*“Clinical Innovations” is PM’s ongoing series of articles dedicated to introducing new concepts, technologies and studies to the podiatric community. Readers should be aware that Podiatry Management does not specifically endorse any of the technologies, concepts, or products being discussed.*



autonomic neuropathy, underlying structural deformity, and disproportionate shearing and focal pressure, among them. Autonomic nerve dysfunction and its impact on the degradation of overall skin function is a major contributing factor in both development and recurrence. Understanding how such nerve impairment leads to dry, cracked skin and diminishment of the skin's protective barrier is important. However, the ability to measure objectively the level of such dysfunction is imperative to clinical decision-making when formulating a proactive care plan to enhance skin function. Simply instructing a patient to apply a skin cream to their feet every day is an ineffective strategy at best.

Patient engagement that includes the use of diagnostic tools are likely under-utilized for any number of reasons. From the physician perspective, following clinical guidelines or expert recommendations can also be challenging if access to resources poses obstacles. These two components of DFU prevention and recurrence require an objective approach, and one that is evidence-based.

### Action Plan

Identifying the at-risk foot begins with a detailed history documenting diabetes control, smoking history, exercise tolerance, history of claudication or rest pain, and prior ulcerations or amputations. A thorough examination of the

feet should be performed annually in all people with diabetes and more frequently in at-risk individuals.<sup>6,7,8</sup>

We know that many patients in this at-risk population have some degree of neuropathy. Diabetic neuropathy is a diagnosis of exclusion. One estimate is that up to 50% of diabetic peripheral neuropathy may be asymptomatic.<sup>9</sup> The most common early symptoms of neuropathy are induced by the involvement of small fibers and include pain and dysesthesia (unpleasant sensations of burning and tingling). Evaluation to assess small fiber involvement is typically achieved via the pin-prick test or by temperature assessment.<sup>9</sup>

If not recognized and if preventive foot care is not implemented, people with diabetes are at risk for injuries as well as diabetic foot ulcers (DFUs) and amputations. Recognition

---

---

## One symptom of diabetic autonomic neuropathy is sudomotor dysfunction, which presents as either increased or decreased sweating.

---

---

and treatment of autonomic neuropathy may improve symptoms, reduce sequelae, and may improve quality of life.<sup>9</sup>

One symptom of diabetic autonomic neuropathy is sudomotor dysfunction, which presents as either increased or decreased sweating. Screening for symptoms of autonomic neuropathy includes asking about symptoms of orthostatic intolerance (dizziness, lightheadedness, or weakness with standing), syncope, exercise intolerance, constipation, diarrhea, urinary retention, urinary incontinence, or changes in sweat function.<sup>9</sup>

Decreased moisture due to sudomotor dysfunction can lead to cracking of skin, thereby reducing the protective barrier function of the skin, and allowing for not only potential ulcer formation, but also increasing the ability of micro-organisms to enter the body. Superficial cellulitis is an example of a skin infection commonly found in diabetics, where no obvious open ulceration exists. The disruption of the skin's integrity allows bacteria access to the inner layers of the skin, resulting in infection often caused by staphylococcus or streptococcal organisms. Quantifying the extent of skin dryness or moisture can allow a physician to more accurately prescribe or recommend optimal topical skin protectants or barriers.

The SKIN-CARS (Coalition for At-Risk Skin) consensus panel published recommendations for persons with "at-risk" skin, along with steps to promote enhanced function. Additionally, a proactive approach is needed to protect individuals with at-risk skin and prevent additional damage.<sup>10,11</sup>

Among their recommendations, all persons should have an evaluation to determine if they have at-risk skin; persons identified with at-risk skin should have initial comprehensive and ongoing assessments to develop care strategies that include prevention and risk mitigation; and persons

*Continued on page 79*



with at-risk skin should have individualized care strategies aimed at the maintenance or improvement of skin barrier function and/or the prevention of skin alterations.<sup>10</sup> Restoring the skin barrier function and adequate skin hydration is extremely important to prevent the recurrence of skin damage, even when all symptoms have resolved.<sup>10,12</sup> Studies have shown that emollients rich in lipid content can accelerate the regeneration of skin barrier function.<sup>10,13</sup> Some lotions and cream emollients contain both humectants and occlusives, in which the humectant will draw the moisture into the epidermis and the occlusive will ensure that it remains there.<sup>10,13</sup> Humectants help to trap moisture in the skin and reduce water loss from evaporation.<sup>10</sup> For optimal efficiency, moisturizers should be applied immediately after bathing and at least once daily.<sup>10,11,12</sup> An additional application is necessary for enhanced barrier function.<sup>10</sup>

### LEAP Vitals Can Be Part of the Solution

Regardless of whether as an initial preventative measure, or as an intervention to prevent re-ulceration, it is always easier to prevent a wound than it is to treat one.

Consider also that in instances where a DFU has healed, the injury sustained to the skin at that location comes with it a decrease in tensile strength of the new skin. It has long been held that upon full remodeling after healing, repaired skin has approximately 80% of its original tensile strength. Repeated trauma to the same site as in the case of a recurrent DFU adds to the likelihood of suboptimal repair and additional risk of re-ulceration.

Analogous to the taking of general health vital signs such as blood pressure, temperature, weight, and pulse oximetry/oxygen saturation, “vital signs for the skin” adds a measurable dimension to an assessment where a patient at high-risk for developing a DFU is concerned. Addressing skin integrity, specifically where autonomic neuropathy is present, requires more than a general assessment that dry or cracked skin is present. The LEAP (Lower Extremity Amputation Prevention) Vitals® (Arche Healthcare) includes use of diagnostic tools to objectively assess the ex-

tent of skin compromise due to autonomic neuropathy, including both temperature and extent of skin moisture (Skin Moisture Index). In the clinical setting, a podiatric physician or medical assistant uses the Arche LEAP Vitals Kit (DermaStat® and IRStat®) to assess the skin moisture and temperature levels of the patients with diabetes and used thereafter as part of an ongoing proactive LEAP strategy. If DermaStat shows a “very dry/dry reading”, (Figure 1) or if IRStat identifies a “hot spot” > 4° difference between surrounding tissue or identifies a > 10° difference between limbs indicating a potential vascular issue, the patient is put into the Arche LEAP Vitals Protocol.

Continuous measuring, monitoring and managing of the diabetes patient’s potential for developing a diabetic foot wound because of their Skin Moisture Index (SMI) or skin temperature differences results in ongoing measurements. Specifically, the IRStat (temperature) and the DermaStat (SMI) are used to quantify each. Where abnormal readings are noted, the additional use of the Neuropad, a small patch-like device, is utilized to evaluate sudomotor dysfunction and its connection to autonomic functionality.

At-risk individuals should be assessed at each visit and should be referred to foot care specialists for ongoing preventive care and surveillance. The physical examina-

*Continued on page 80*



Figure 1: DermaStat results

tion can stratify patients into different categories and determine the frequency of these visits.<sup>6,9</sup>

The problems presented when managing diabetic foot ulcers are extensive, and therefore, no single solution exists that on its own will reduce lower extremity amputations. Changing behaviors of patients and physicians may be the single most important factor in this effort, and may also be the simplest of all interventions, yet adoption of new habits is a struggle, as most people are reluctant to change, even when the benefits are understood. Using tools to help them in the process of developing new habits is essential, as admonishing someone to “try harder”, or in this case, to inspect their feet daily, will not likely be advice that is well-received.

Positive feedback is an important factor for patient “buy-in” of any treatment plan. Describing to patients the detail of a plan is far less effective than showing them

---

---

### **Preventing limb and life-threatening amputations is not just a noble ambition, it is an area of medicine whose need is critical.**

---

---

their results, and compliance is likely to be greater, along with outcomes. Providing patients with visual feedback in both clinic and home settings is part of the benefits of using the LEAP Vitals assessment tools.

For physicians, there must be financial incentives beyond patient well-being before changes are likely to be made within an existing practice. Whether they be a patient or physician, then, for adoption of new behaviors to proceed, we must provide tangible resources and tools that provide relevant feedback to help them accomplish their goals.

Physicians whose practice has a clear vision and purpose are likely to hold greater satisfaction on all levels, including financial. Preventing limb and life-threatening amputations is not just a noble ambition, it is an area of medicine whose need is critical. Palpating of pulses or checking between a patient’s toes is not a Comprehensive Diabetic Foot Examination, and therefore, more objective methods are required to achieve DFU prevention and ultimately, a greater impact on lower extremity preservation among this high-risk population.

Engagement of the patient is critical. Successful outcomes cannot come from a unilateral approach where the physician is solely responsible for all aspects of care, from assessment to treatment. At home and remote monitoring can make the patient’s engagement more achievable when the proper tools are easy to use and provide the necessary information that allows for early intervention when a potential problem has been identified. Daily monitoring of the skin is more likely to occur when objective visual feedback is achieved. “You Can’t Manage What You Don’t Measure”. *PM*

*Continued on page 81*

## References

<sup>1</sup> Nussbaum, Samuel R. et al. An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. *Value in Health*, Volume 21, Issue 1, 27–32

<sup>2</sup> Margolis DJ, et al. Prevalence of diabetes, diabetic foot ulcer, and lower extremity amputation among Medicare beneficiaries, 2006 to 2008: Data Points #1. 2011 Feb 17. In: *Data Points Publication Series* [Internet] 2011 Agency for Healthcare Research and Quality (US) Rockville, MD

<sup>3</sup> Centers for Medicare and Medicaid Services (CMS) Chronic Conditions among Medicare Beneficiaries, Chartbook, 2012 Edition. CMS Baltimore, MD

<sup>4</sup> CDC. National Diabetes Statistics Report. 2024. <https://www.cdc.gov>

<sup>5</sup> Geiss LS, Yanfeng L, et al. *Diabetes Care* 2019 Jan;42(1):50-54

<sup>6</sup> ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 12. Retinopathy, neuropathy, and foot care: Standards of Care in Diabetes—2023. *Diabetes Care* 2023;46(Suppl. 1):S203–S215

<sup>7</sup> Boulton AJM, Armstrong DG, Albert SF, et al.; American Diabetes Association; American Association of Clinical Endocrinologists. Comprehensive foot examination and risk assessment: a report of the task force of the foot care interest group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists. *Diabetes Care* 2008;31:1679–1685

<sup>8</sup> American Diabetes Association Professional Practice Committee. Retinopathy, neuropathy, and foot care: Standards of Care in Diabetes—2024. *Diabetes Care* 2024;47 (Suppl. 1):S231–S243

<sup>9</sup> Schaper NC, van Netten JJ, Apelqvist J, Bus SA, Hinchliffe RJ; IWGDF Editorial Board. Practical guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update). *Diabetes Metab Res Rev* 2020;36(Suppl. 1):e3266

<sup>10</sup> Morgan M, Milne C, et al. At-Risk Skin: 21 Consensus Statements From the Coalition for At-Risk Skin. Supplement to *Wound Management & Prevention*. November 2022

<sup>11</sup> Beeckman D, Campbell J, LeBlanc K, et al. Best practice recommendations for holistic strategies to promote and maintain skin integrity. February 28, 2020. *Wounds International*. Accessed March 7, 2022. <https://www.woundsinternational.com/resources/details/best-practice-recommendations-holistic-strategies-promote-and-maintain-skin-integrity>

<sup>12</sup> Purnamawati S, Indrastuti N, Danarti R, Saefudin T. The role of moisturizers in addressing various kinds of dermatitis: a review. *Clin Med Res*. 2017;15(3-4):75-87. doi:10.3121/cmr.2017.1363

<sup>13</sup> Ersser SJ, Maguire S, Nicol N, Penzer R, Peters J. Best practice in emollient therapy: a statement for healthcare professionals. *Dermatol Nurs*. 2012;11(4):S1-S19.



**Desmond Bell, DPM, CWS, FFPM RCPS (Glasg)** is the Founder and President Emeritus of “The Save A Leg, Save A Life” Foundation, a multi-disciplinary non-profit organization dedicated to the reduction in lower extremity amputations and

improving wound healing outcomes through education, evidence-based methodology and community outreach. He also serves as Chief Medical Officer of Omeza, an evidence based medical technology company and consumer healthcare products company initially focused on healing chronic wounds and preventing their recurrence.