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Abstract

Patients with diabetes and previous history of ulceration occupy the highest category of risk for reulceration and amputation. Annual recurrence rates of diabetic ulcerations have been reported as high as 34%, 61%, and 70% at 1, 3, and 5 years, respectively, with studies reporting 20% to 58% recurrence rate within 1 year. As the ever growing epidemic of diabetes expands globally, this sequelae of diabetic complication will continue to require increasing resources from the healthcare community to effectively manage. Recent data suggest that removal of preventative podiatric care from statewide reimbursement systems lead to significant and sustained increases in hospital admission (37%), charges (38%), length of stay (23%), and severe aggregate outcomes including amputation, sepsis and death (49%). The addition of comorbidities such as peripheral artery disease, poor nutrition, and non-adherence to preventive therapies not only increase a patient's likelihood for ulcer recurrence, but also cost of care and certainty of hospital admission. Currently, numerous efforts, guidelines, and industry generated products exist to prolong remission from ulceration; however, the clinical science for treating this patient population calls for much more effort. Despite this, data continue to suggest to demonstrate that appropriate follow-up care, shoe and insole modification, and patient education play a central role in reducing reulceration and amputation. Novel modalities for offloading and wearable sensor technologies offer the advantage of round-the-clock, patient specific and active response healthcare. These have the potential to detect, or even prevent, many wounds before they begin.

Keywords

diabetes, prevention, remission, ulcer, wound

The Potential Costs of Recurrent Ulceration

Both developed and underdeveloped nations alike loom on the edge of a global diabetes epidemic. The lifetime risk of a person with diabetes developing a foot ulcer is as high as 25%,¹ and diabetes is a diagnosis preceding 85% of all non-traumatic diabetic lower extremity amputations.¹ In 2001 alone, diabetes-related foot ulcers and amputations cost the US health care system an estimated \$11 billion.² This has risen to more than \$17 billion in 2013, surpassing the direct costs of the 5 most expensive cancers.³ Considering that previous works estimate the average cost per ulceration at nearly \$13 000,^{4,5} steps to prevent the initiation and recurrence of primary ulcerations should be a significant priority to the health care community.

Annual recurrence rates of diabetic ulcerations have been reported as high as 34%, 61%, and 70% at 1, 3, and 5 years, respectively, with recurrence rates as high as 20% to 58% within 1 year.^{6,7} Costs to treat diabetic patients with

active ulcerations are 1.5 to 2.4 times that of those without an ulcer.⁸ These costs inflate with the presence of peripheral arterial disease to nearly 4 times the cost of purely neuropathic wounds.⁹

Existing prevention methods have the potential to halve the risk of amputation for diabetic patients with a history of ulcer (Figure 1).¹⁰ It has been demonstrated that a 25% reduction in the incidence of foot ulcers through the use of basic preventative care would negate the cost of such program implementation.¹¹ The addition of comorbidities such

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Figure 1. A diabetic foot ulcer presents significant morbidity and mortality to patients. Proper wound care includes regular sharp debridement and offloading.

as poor vascular status, poor nutritional status, and noncompliance to preventative therapies not only increases the cost of care and likelihood for hospital admission but also greatly increases the likelihood for ulcerative recurrence requiring hospital admission.

What Are Our Current Strategies?

The American Diabetes Association guidelines recommend that all patients with diabetes see a podiatrist for foot screenings at least every 6 months, with those at heightened risk visiting at least every 2 months.¹² At these visitations, clinicians are tasked with evaluating the patient's continued risk for ulceration, resolving any ongoing complications, and augmenting the treatment strategy as necessary. As always, a patient's risks should be evaluated by a physician based on the most current literature. Reviewing a patient's neurological, vascular, and biomechanical status along with prior history of foot ulcers is necessary in creating an overall picture of a patient's ulcerative risk.^{12,13}

For a patient in ulcer remission, it is imperative to guide provider and self-care therapy with the mind-set of "active prevention." With this mindset, increasing patient knowledge regarding the importance of self-care is key to their overall success in remission. Current patient guidelines for



Figure 2. Custom molded diabetic footwear.

daily care include inspection of the feet, use of diabetic socks to reduce friction, foot exercises to promote circulation, and application of any medication or skin products as necessary. Patients also need to avoid self-damaging behaviors such as barefoot walking or using ill-fitting footwear, and should seek regular professional foot inspection and nail care.¹² The long term-management of blood sugar, diet, and exercise are absolutely fundamental, as elevated blood glucose levels have been shown to suppress inflammatory response. Therefore, in addition to regular patient monitoring of blood sugar levels, glycated hemoglobin (HbA1c) levels should be routinely reviewed and catalogued by medical staff.¹³

Reducing Peak Plantar Pressures

Repetitive stress on the foot, particularly in the presence of neuropathy or peripheral artery disease, is among the strongest risk factors for ulcer development, as a lack of sensation and decreased metabolic response render patients unable to organically detect repetitive stress and trauma to their plantar tissues. Confounding this presentation, patients with diabetes are shown to regularly have elevated peak plantar pressures.¹⁴⁻¹⁸ Therefore, constant plantar pressure redistribution is regarded as the most important therapy for managing a patient in remission.¹⁹ The in-shoe peak plantar pressure threshold of 200 kPa has been suggested as a reference to prevent foot ulceration. This threshold was obtained from patients with previous ulcer sites that have remained healed.²⁰ However, use of plantar pressure data to predict ulceration is problematic when used alone, as activity and activity collection likely play just as important a role.^{15,16,21-24}

Diabetic shoes (Figure 2) have demonstrated effectiveness at reducing ulcer recurrence by reducing peak plantar pressures and shear forces.^{25,26} Uccioli et al²⁷ found that 28% of



Figure 3. Total contact casts are the gold standard for offloading diabetic neuropathic wounds, yet are quite cumbersome for patients and take significant time and expertise to apply properly in the clinical setting.

patients wearing diabetic shoes experienced ulcer recurrence, in comparison to the 58% reulceration rate found in patients using normal shoe gear. These findings were reinforced by Busch and Chantelau²⁸ who found that therapeutic footwear significantly reduced reulceration. Therefore, it is strongly recommended that any diabetic with confirmed lower extremity polyneuropathy be transitioned to these devices.^{29,30}

Current logic and research driven literature refer to total contact casts (TCC; Figure 3) as the gold standard for wound offloading during active ulcerations caused by high peak plantar pressure.^{17,31} However, a study by Wu et al³² revealed that practice does not parallel the podiatric pulp, as only 1.7% of the 901 centers surveyed, and only 11% of 363 private podiatry practitioners surveyed utilize TCCs for primary offloading.³²⁻³⁴ Cavanagh and Bus¹⁹ also found clinicians worldwide resisting the implementation of TCC devices in the treatment of diabetic foot ulcerations presumably because of the increased time, cost, and expertise required in proper application.

Risks of Home-Based Self-Care

Home care treatment is not always reliably implemented. Patients experiencing cognitive impairment, visual loss,

larger body sizes, or other comorbidities limiting mobility may be unable to assess the condition of their own feet.³⁵ This is a dangerous situation, exacerbated by patients living by themselves, unable to solicit daily foot inspections. In tandem with a lack of adequate patient disease education, these home situations foster unintended ill compliance, confounding the outcomes of self-care modalities. Unfortunately, these indecorous situations are still regularly encountered in the diabetic population. Steps to increase surveillance and assessment, including correction of obstacles in the home care setting, are necessary to increase widespread improvement in remission rates.

The Role of the Multidisciplinary Team

One third of patients with diabetes also have a form of vascular disease, a comorbid factor that increases the likelihood of ulcerative recurrence by a factor of 10.²⁶ As the predominance of neuropathic ulcers continues to shift toward the neuroischemic, the increasing adoption of the “toe and flow” multidisciplinary model, where podiatry and vascular surgeons personify the backbone of a diabetes wound management team will see accelerated implementation.³⁶

A prospective study from 2008 found a 70% reduction in the total number of diabetes related amputations from 1995 to 2005 in the United Kingdom because of the introduction of the multidisciplinary team.³⁷ A study from Lithuania found patients receiving multidisciplinary care had a reulceration occurrence rate of 30.4% in comparison with a 58.4% rate of recurrence in the control group receiving individualized physician care.³⁸ Furthermore, recent data suggest that the removal of foot care from statewide reimbursement systems lead to significant and sustained increases in hospital admission (37%), charges (38%), length of stay (23%), and severe aggregate outcomes including amputation, sepsis and death (49%).³⁹

The inclusion of occupational therapists, physical therapists, and registered nutritionists further facilitates the respective home environment augmentation, mobility, dietary, and health style modifications necessary to reach the personalized goals of the high-risk diabetic patient.⁴⁰⁻⁴²

Surgical Modification

Ulcer recurrence is highly linked to deformities of the foot’s natural bony architecture. In these instances, surgical debridement of the offending bone is typically necessary to facilitate prolonged ulcerative remission.^{43,44} The most common deformities include hammertoes, local nerve entrapment, and tightness of the Achilles tendon. A 2003 study demonstrated that Achilles tendon lengthenings in tandem with TCC application reduced reulceration rates from 59% to just 15%, when compared to TCC application alone.⁴⁵ This followed a 1999 study showing a mean 28%



Figure 4. Smart Sox use fiber optic cables embedded within socks to warn the patient of peaks in plantar pressure. Warning messages are sent to the patient's wristwatch, instructing them to offload areas of high pressure.

reduction in peak plantar pressure with percutaneous Achilles tendon lengthening.⁴⁶

A smaller demographic of diabetic patients who have symptoms of nerve entrapment may benefit from nerve release surgery. Studies by Nickerson and Rader⁴⁷ and Garrod et al⁴⁸ have shown a reduction in recurrent ulcers in patients with diabetic neuropathy following surgical nerve decompression. This is believed to be a result of the reestablishment of plantar protective sensation following the release of nerve entrapment.⁴⁹ While this may not be a treatment modality for every patient with history of diabetic ulcer, it is at least a promising preventative treatment for the subgroup of patients with entrapment symptoms, who are medically stable for surgery.

Future Technologies and “Constant-Monitoring” Strategies

Perpetuating the concept of ulcerative “remission” is a key notion in framing both provider and patient goals for care.²⁹ In the near future, constant monitoring systems will seamlessly integrate themselves into patients' daily lives by means of wearable sensors and medical telemetry. Currently, calor, erythema, and high peak plantar pressure are some of the earliest known clinical markers for the inflammatory process that occurs prior to ulcer development.⁵⁰ “Intelligent” insoles or “smart” socks (Figure 4) could perpetually monitor these early indicators and alert the user or medical staff of a need for intervention. A 2007 randomized controlled trial from *Diabetes Care*, found that patients who did not use temperature monitoring were 4 times more likely to develop foot ulcer recurrence than those who did.⁵¹ These studies only hint at the possible global health savings that could be made possible following the ubiquitous implementation of such round-the-clock biomonitoring systems.

These concepts could also improve the design and construction of custom insoles and shoes. While insoles and

custom orthotics are shown to be useful in preventing the recurrence of ulcers, not every device can be created perfectly to each patient's unique anatomy. Additionally, physicians would no longer have to rely on neuropathic patients' subjective opinions on how the shoes or insoles “feel,” and could instead, use this objective data to fabricate patient specific devices.⁵² Devices using these construction methods have already undergone extensive investigation, demonstrating a 2-fold risk reduction for reulceration in patients as compared with the standard of care insoles.²⁵ Despite this, mainstream implementation in most practices has yet to occur.⁵³

As constant monitoring becomes forefront in patient specific-medicine, so will the implementation and expansion of 3-dimensional (3D) printing.⁵⁴⁻⁵⁸ Exoskeleton suits that have been 3D scanned and printed specific to a person's body have shown significant reduction in ground reactive forces.⁵⁹ Similar military exoskeletons increased the effective mobile distance of infantry while carrying increased equipment loads.⁶⁰ These devices could represent instant benefit to the frail or high-risk diabetic patient, allowing them uninhibited navigation of their daily activities, while simultaneously reducing plantar tissue impact and the stress of weight-bearing.

A different kind of exoskeleton, originally proposed for casting broken bones, could also benefit diabetic wound care. These 3D printed casts could advantage the gold standard TCC and non-weight-bearing casts, as computer-generated models could account for ideal plantar pressure distribution based on patient specific biomechanical and gait parameters.⁶¹ These modalities are still in development; however, their low costs of implementation and potential long-term medical costs make them exceptional options in the search for effective ulcer prevention.^{59,62}

Pearls and Lasting Comments on Ulcerative Remission

Maintaining remission is one of the most complex aspects related to the management of diabetic foot complications. The 5-year mortality rates, remission rates, and correlated morbidities are comparable to the most devastating forms of cancer. Whereas occurrence and recurrence are multifactorial etiologies, they are both a matter of biomechanics as well as sociomechanics.^{29,63}

Any lasting medical treatment or healing course is doomed without patient involvement. Recruiting the emotional and intellectual engagement of patients and other members of the patients' support team is challenging, yet patients are more adherent to treatment guidelines and follow up visits when clearly presented with the reasoning and logic behind physician course.⁶⁴ Much of the aims in the future of personalized medicine rest firmly in catered medical and surgical treatments.⁶⁵ We believe that an analogy to

cancer is apt in terms of personal and fiscal impact,⁶⁶ therefore, patient involvement should be central to prevention. Just as a regular breast cancer screening examinations may be important in identifying benign or sinister lesions, so too could regular foot examinations in detecting equally comorbid preulcerative calluses.⁶⁷

Much of the technologies mentioned in this article hold great promise for improving patient care. Physician practices and care strategies still demonstrate the best results when centered on interpersonal connections and interdisciplinary approaches. In the realm of treating diabetic foot complications, team and technique still transcend technology.

Declaration of Conflicting Interests

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