Integrating Advanced Wound Care: A Key Component of Diabetes Disease Management

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Summary

Diabetic foot problems are frequent, and associated with high costs. Treatment modalities for diabetic foot ulcers range from simple and expensive options, such as pressure relieving shoes, to costly amputations. A multidisciplinary approach to preventing and treating diabetic foot problems has proved to be cost saving. Implementing such an approach will save money and improve clinical outcomes.

Key Points

- Diabetic foot problems are a significant, costly issue.
- Keys to treatment are debridement and off-loading.
- Vacuum therapy is a useful and cost-effective adjunct for healing foot ulcers.
- Disease management programs to prevent diabetic foot ulcers improve clinical outcomes and reduce costs with early returns on investment.

DIABETES AND ASSOCIATED FOOT PROBLEMS are a significant public health problem. Foot problems are common in diabetic patients and result in extensive hospitalization, disfiguring surgery, lifetime disability, and a diminished quality of life. One out of seven U.S. healthcare dollars is spent on diabetes care. Ten percent of Medicare beneficiaries have diabetes but account for 27 percent of the cost. Diabetic foot problems account for 6 percent of hospital admissions for diabetes and 20 percent of hospital days.[1]

A diabetic's lifetime risk of developing a foot ulcer is greater than 15 percent. The cumulative three-year incidence is 6 percent. Fifteen percent of patients who develop a foot ulcer also will develop osteomyelitis. About 15.6 percent of foot ulcers will result in an amputation. In a Medicare study seven years ago, the two-year attributable cost per diabetic foot ulcer was $28,000.[1] Thus, foot problems are not only frequent, but also costly.

Foot ulcers occur in diabetics for many reasons. The major reasons include neuropathies that prevent the patient from detecting injury to the foot, differences in wound healing, and the presence of peripheral arterial disease. The pathways to foot ulceration are illustrated in Exhibit 1.[2] With a loss of feeling from neuropathy, the patient does not feel pain from an injury to the foot. Because of a lack of awareness, the patient does not rest the area or treat the injury. Continuous repetitive stress on the injured site will lead to a foot alteration and abnormal healing. Chronic diabetic foot wounds have been shown to have abnormal healing because of inflammatory excess, growth factor deficiency, bacterial bio-burden, and cellular senescence.

Peripheral arterial disease (PAD) as a result of atherosclerosis is very common in patients with diabetes. Diabetes increases the risk of PAD more than other factors such as smoking, hyperlipidemia, hypertension, and hyper-homocysteinemia.[3,4] Significant PAD decreases blood supply to the foot. Small-vessel disease and large-vessel disease PAD both contribute to the development of diabetic foot ulcers (Exhibit 2).

Patients with diabetes can be stratified into risk groups for developing ulcers (Exhibit 3).[5,6] As a patient increases in risk group, his or her risk of having a foot ulcer increases.

There are seven major treatment modalities for diabetic foot ulcers. These include off-loading debridement, wound dressing, treatment of infection, vascular reconstruction, healing enhancers, and amputation. Off-loading and debridement are the keys to healing ulcers. Off-loading is taking pressure off the ulcer site through bed rest and off-loading appliances such as total-contact casts, can walkers,

Exhibit 1: Pathways to Foot Ulceration

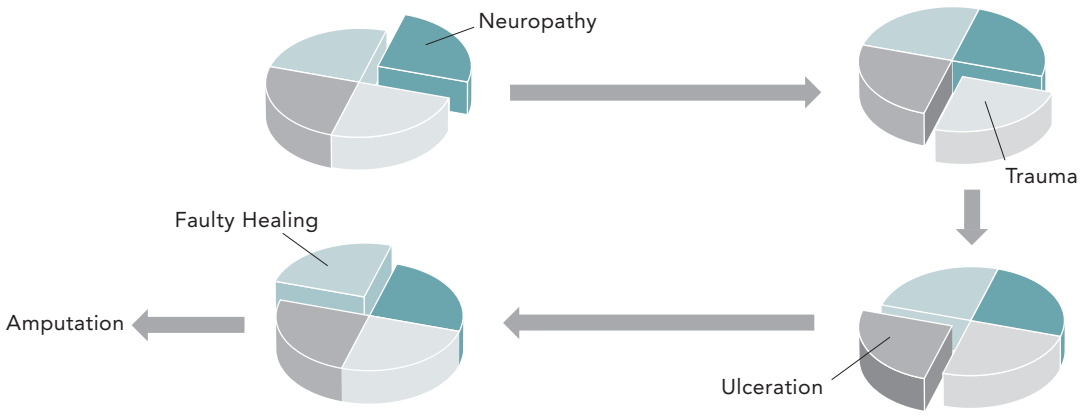
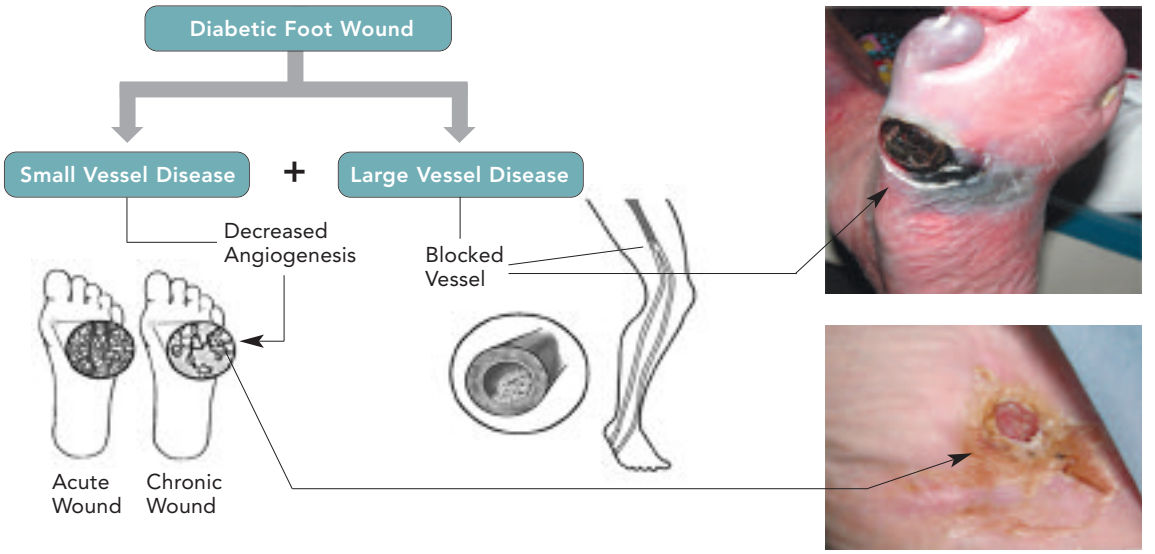


Exhibit 2: Combined Effects of Small and Large Vessel Disease



felted-foam dressings, and surgical shoes (Exhibit 4). Debridement is removing necrotic tissue from the ulcer. This can be done with enzymes applied to the site or mechanically with cutting. The goal of debridement is to convert a chronic wound into an acute wound. Frequently removing necrotic tissue, along with off-loading, promotes wound healing. Another effective treatment is the use of dressings to provide a moist wound environment to enhance growth of new skin cells, prevent trauma, and minimize risk of infection.

Infected ulcers require more aggressive treatment than non-infected ones. Osteomyelitis, gangrene and amputation all can result from infected ulcers. Limb-

Exhibit 3: Diabetic Foot Risk Classification

Risk Category	Description	Odds Ratio (95% CI)
0	No neuropathy, no peripheral vascular disease	—
1	Neuropathy, no deformity or peripheral vascular disease	1.7 (0.7–4.3)
2	Neuropathy and deformity and/or peripheral arterial disease	12.1 (5.2–28.3)
3	History of foot ulceration or lower extremity amputation	36.4 (16.1–82.3)

Exhibit 4: Off-loading Appliances

threatening, infected ulcers with extensive cellulitis, deep abscesses, osteomyelitis and/or gangrene need to be carefully debrided. Wound cultures should be taken. Broad-spectrum intravenous antibiotic therapy is also necessary. Osteomyelitis requires treatment with antibiotics for six weeks. Surgical resection of the infected bone may be required, and will allow a shorter course of antibiotics.

Trying to preserve a severely infected or gangrenous foot or leg is termed limb salvage. Limb salvage approaches include aggressive broad-spectrum antibiotics, debridement of all necrotic tissue, revascularization of critically ischemic areas with various surgical procedures, staged surgical closure of the wound, and use of a healing enhancer such as a vacuum pressure device to enhance wound closure. If limb salvage fails, amputation is the next option.

A vacuum pressure device being used in limb salvage is the vacuum-assisted closure (VAC) therapy system. The VAC device provides intermittent or continuous suction to a special dressing that fits over the wound. This approach promotes healing by enhancing granulation tissue formation, drawing the wound together, helping promote flap and graft survival, removing interstitial fluid and infectious material, and providing a closed, moist environment.

One study of the VAC system evaluated and compared outcomes and resource-utilization costs for treating a 162 diabetic foot-ulcer patients who underwent forefoot amputations. Patients were randomly treated with either the VAC device or moist wound healing. Fifty-six percent of the VAC therapy system patients healed, compared to 39 percent of the moist wound healing group.[7] The time for healing was 60 days with the VAC therapy system compared to 88 days for the moist wound group.[7] In a retrospective cost analysis of resource utilization data from this study, direct costs for patients treated with the VAC therapy system was on average $8,826 lower than costs for moist-wound therapy. Patients healed with the VAC therapy system had an average $12,852 lower direct cost than patients healed with moist-wound therapy.

Other healing enhancers can be used as adjuncts to the therapies discussed above to improve healing of diabetic ulcers. These include recombinant human platelet-derived growth factor (Regranex®) and skin substitutes (living bilayer skin substitute [Apligraf®], and human fibroblast-derived dermal substitute [Dermagraft®]). In studies, these three agents have been shown to heal more diabetic foot ulcers faster than conventional therapy with moist dressings alone.[8-10]

Amputation may be a preferable course in selected patients as an alternative to prolonged unsuccessful limb salvage treatment. Indications for amputation include uncontrolled overwhelming infection, pain not manageable with analgesics, and extensive necrosis of the foot that prohibits adequate function.

Optimal care of diabetic foot ulcers requires use of a treatment protocol. This protocol should be evidenced based, and should utilize sound surgical and/or bio-mechanical principles. The clinical experience of a multidisciplinary team is invaluable in treating diabetic foot ulcers. The team should include an endocrinologist, a podiatrist, a vascular surgeon, and a primary care provider for each patient. The expected result of such a treatment protocol should be the expectation of the healing of ulcers in the

absence of infection or ischemia. Diabetic foot ulcers should be at least 35 to 50 percent healed using the standard care of debridement and off-loading by four weeks. If this result does not occur, a change in therapy is required such as using an adjunct treatment such as VAC therapy or a skin substitute.

Ulcers recur in 50 percent of patients who have an ulcer history. Prevention of recurrent ulcers requires regular provision of routine foot care, patient education, and provider education. Routine medical foot care includes examination of the feet for deformities or other issues that may lead to ulcers, trimming of nails, sensory testing, and provision of therapeutic shoes. Patients with diabetes need to understand how to care for their own feet. Providers need to understand how to treat diabetic ulcers. To prevent recurrences, prophylactic surgery in selected patients to correct foot deformities causing areas of pressure may be necessary.

Programs for preventing and treating diabetic foot ulcers can improve quality of care easily and inexpensively. Caring for diabetic feet does not require expensive technology. Quality care for a diabetic foot would result in significant savings for the payer. Multidisciplinary team approaches to diabetic foot care have reported statistically significant reductions in morbidity and cost.[11]

Lavery and colleagues implemented a lower-extremity disease management program consisting of screening and treatment protocols for diabetic members of a managed care organization.[12] Screening consisted of evaluation of neuropathy, peripheral vascular disease, deformities, foot pressures, and history of lower extremity pathology. They stratified patients into low- and high-risk groups, and implemented preventive or acute-care protocols. Utilization was tracked for 28 months and compared to 12 months of historic data prior to implementation of the disease management program. After implementation of the disease management program, the incidence of amputations decreased 47.4 percent, from 12.89 per 1000 diabetics per year to 6.18.[12] The number of foot-related hospital admissions decreased 37.8 percent, from 22.86 per 1000 members per year to 14.23.[12] The average inpatient length-of-stay was reduced 21.7 percent, from 4.75 to 3.72 days.[12] Additionally, there was a 69.8 percent reduction in the number of skilled nursing facility admissions per 1000 members per year and a 38.2 percent reduction in the average length of stay in a skilled nursing facility, from 8.72 to 6.52 days.[12] This study demonstrates that a population-based screening and treatment program for the diabetic foot can dramatically reduce hospitalizations and improve clinical outcomes.

Developing a disease-management program to prevent and treat diabetic foot ulcers fits in with the future of healthcare—an era of pay for performance. The National Committee for Quality Assurance (NCQA) with the American Diabetes Association is developing an expert consensus of diabetic foot examination performance measures. One objective is to identify the essential components of a diabetic foot examination such as sensory testing. Currently, the NCQA Health Plan Employer Data and Information Set (HEDIS) measures that a foot examination occurred but does not record the content of the examination.

Conclusion

Although diabetic foot ulcers are costly both in terms of money and quality of life, implementing a disease management program can provide significant financial and clinical outcome returns. Such a program should be evidence-based and multidisciplinary. **JMCM**

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References

1. Ramsey SD, Newton K, Blough D. Incidence, outcomes, and cost of foot ulcers in patients with diabetes. *Diabetes Care.* 1999; 22:382-387.

2. Pecoraro RE, Reiber GE, Burgess EM. Pathways to diabetic limb amputation. Basis for prevention. *Diabetes Care.* 1990;13:513-21.

3. Newman AB, Siscovick DS, Manolio TA, Polak J, Fried LP, Borhani NO, Wolfson SK. Ankle-arm index as a marker of atherosclerosis in the Cardiovascular Health Study. Cardiovascular Heart Study (CHS) Collaborative Research Group. *Circulation.* 1993;88:837-845.

4. Lee AJ, MacGregor AS, Hau CM, Price JF, Rumley A, Lowe GD, Fowkes FG. The role of haematological factors in diabetic peripheral arterial disease: the Edinburgh artery study. *Br J Haematol.* 1999;105:648-654.

5. Peters EJ, Lavery LA; International Working Group on the Diabetic Foot. Effectiveness of the diabetic foot risk classification system of the International Working Group on the Diabetic Foot. *Diabetes Care.* 2001;24:1442-7.

6. Lavery LA, Armstrong DG, Vela SA, Quebedeaux TL, Fleischli JG. Practical criteria for screening patients at high risk for diabetic foot ulceration. *Arch Intern Med.* 1998;158:157-62.

7. Armstrong DG, Lavery LA, Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. *Lancet.* 2005 12;366:1704-10.

8. Regranex® package insert. Raritan, New Jersey: Ortho-McNeil Pharmaceutical, Inc. May 2005.

9. Apligraf® package insert. Canton, MA: Organogenesis Inc. March 2005.

10. Dermagraft® website. www.dermagraft.com Accessed January 3, 2007.

11. Reiber GE. Diabetic foot care. Financial implications and practice guidelines. *Diabetes Care.* 1992;15 (Suppl 1):29-31.

12. Lavery LA, Wunderlich RP, Tredwell JL. Disease management for the diabetic foot: effectiveness of a diabetic foot prevention program to reduce amputations and hospitalizations. *Diabetes Res and Clin Practice.* 2005;70:31-37.