

# Use of Pressure Offloading Devices in Diabetic Foot Ulcers

## Do we practice what we preach?

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**OBJECTIVE** — Pressure mitigation is crucial for the healing of plantar diabetic foot ulcers. We therefore discuss characteristics and considerations associated with the use of offloading devices.

**RESEARCH DESIGN AND METHODS** — A diabetic foot ulcer management survey was sent to foot clinics in all 50 states and the District of Columbia in 2005. A total of 901 geographically diverse centers responded. The survey recorded information regarding usage frequency and characteristics of assessment and treatment of diabetic foot ulcers in each center.

**RESULTS** — Of the 895 respondents who treat diabetic foot ulcers, shoe modifications (41.2%,  $P < 0.03$ ) were the most common form of pressure mitigation, whereas total contact casts were used by only 1.7% of the centers.

**CONCLUSIONS** — This study reports the usage and characteristics of offloading devices in the care of diabetic foot ulcers in a broadly distributed geographic sample. Less than 2% of specialists use what has been termed the “gold standard” (total contact cast) for treating the majority of diabetic foot ulcers.

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In the treatment of diabetic foot ulcers, pressure modulation, commonly referred to as “offloading,” is most successful when pressure is mitigated at an area of high vertical or shear stress (1). Common methods to offload the foot include bed rest, wheel chair, crutch-assisted gait, total contact casts, felted foam, half shoes, therapeutic shoes, and removable cast walkers (2). Although it is well known that pressure mitigation through offloading devices is crucial for the healing of plantar diabetic foot ulcers, there are, to the best of our knowledge, no reports in the literature that describe the characteristics and considerations associated with the use of pressure mitigation devices in a broad geographically diverse

sample of specialists. Therefore, the purpose of this study was to describe the characteristics and considerations associated with the use of offloading devices in foot clinics in the U.S.

### RESEARCH DESIGN AND METHODS

A diabetic foot management survey was sent to 5,200 private and academic practices and clinics in all 50 states and the District of Columbia in 2005. A total of 901 geographically diverse centers responded from 48 states and the District of Columbia. The data were analyzed by dividing the U.S. into four census regions (West, Midwest, South, and Northeast) based on regions described by the U.S. Census Bureau. The

survey recorded information about the usage frequency and characteristics of assessment and treatment of diabetic foot ulcers in each center.

**RESULTS** — Of the 901 respondents, 895 centers actively treated diabetic foot ulcers. The type and frequency of plantar offloading used is summarized in Figure 1. Of the 895 centers, shoe modifications (41.2%,  $P < 0.03$ ) were the most common form of pressure mitigation in  $>51\%$  of diabetic foot ulcer treatments. There were no significant regional differences in therapy. Total contact casts (TCCs) were used by only 1.7% of the centers for the majority of diabetic foot ulcer treatment, whereas 15.2% of the centers reported use of removable cast walkers. A total of 2.6% of the centers reported application of other modalities such as therapeutic shoes, and 12.3% of the centers reported use of complete non-weight-bearing (NWB) strategies such as crutches and wheelchairs for the majority of treatment. A total of 58.1% (520 centers) did not consider TCCs as the gold standard to offload the noninfected plantar diabetic foot ulcers. A total of 45.5% of the centers nationwide reported no use of TCCs as an offloading modality. Commonly reported factors affecting frequency of TCC usage included patient tolerance (55.3%), the time needed to apply the cast (54.3%), cost of materials (31.6%), reimbursement issues (27.5%), familiarity with method of application (25%), customizing parts (20.9%), staffing/ordering supplies (15.2%), and clinician coverage (10.6%).

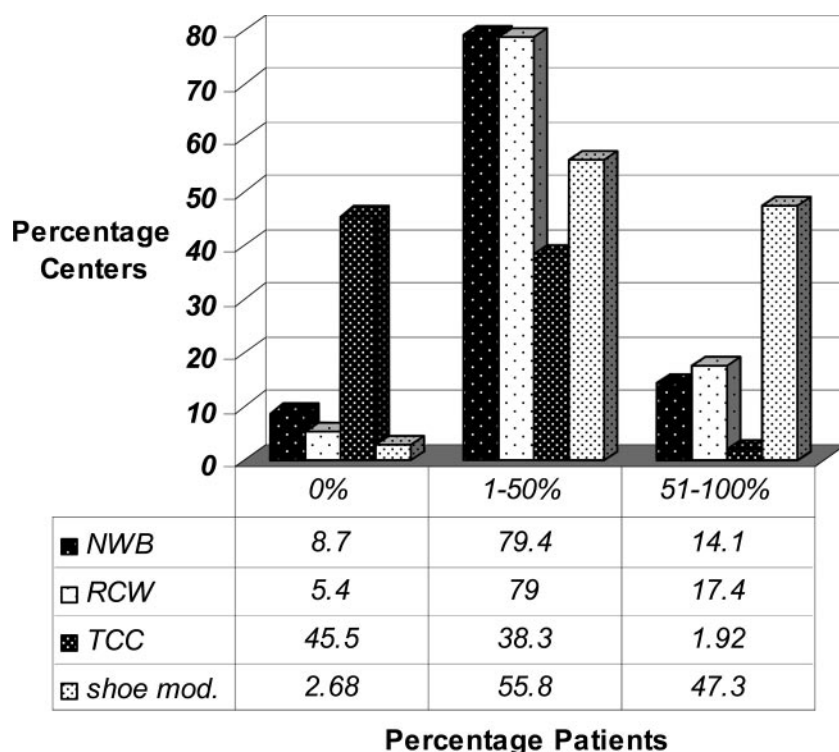
**CONCLUSIONS** — TCCs have been considered the gold standard by academicians and consensus committees alike (3); however, the results of this study suggest that this standard is actively used by merely 1.7% of centers for treatment of the majority of plantar diabetic foot ulcer treatment. Most of the centers (73.4%) used TCCs in  $<25\%$  of their patients, but (at best) intermittently. A further 45.5% of centers reported not using TCCs at all. This discrepancy between consensus doc-

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**Figure 1**—Type and frequency of plantar offloading used across 895 clinics.

uments, randomized controlled trials, and clinical reality may be secondary to a number of potential negative attributes that may discourage clinicians from using this modality. TCC application is time-consuming and often associated with a learning curve. Most centers do not have a physician or cast technician available with adequate training or experience to safely apply a TCC. Moreover, TCCs do not allow patients, family members, or health care providers to assess the foot or wound on a daily basis and are therefore often contraindicated in cases of soft tissue infections or osteomyelitis. Other patient complaints may include impaired activities of daily living, such as difficulty sleeping comfortably, and bathing difficulties while trying to avoid getting the cast wet. Certain designs of TCCs may also exacerbate postural instability (4).

Removable cast walkers (RCW) are, as their name implies, cast-like devices that are removable to allow for self-inspection of the wound and application of topical therapies that require frequent administration. Further, RCWs can be easily converted into an instant TCC (iTCC) (5). Wound healing efficacy and cost-effectiveness of iTCCs have been demonstrated in several randomized controlled trials (6,7). However, the results of this survey suggested that RCWs were

only used by 15.2% of the centers in the treatment of the majority of the wounds treated. Almost half of the centers (48%) used RCWs in <25% of plantar diabetic foot ulcers. The most likely explanation is the cost and lack of reimbursement associated with RCWs in the U.S. Most patients either cannot or are not willing to pay the extra money for the RCW, forcing clinicians to absorb the extra cost.

Whereas no offloading modality was used 100% of the time by the centers assessed, shoe modification was by far the most commonly used. This is despite data that suggests these are not effective means of offloading (8). Additionally, there are real concerns that an aperture applied around the wound based solely on visual cues may increase shear and vertical forces at the wound's periphery secondary to the "edge effect" (9). The popularity of shoe modifications may be secondary to many factors. Patients are often resistant to cast applications or the extra costs associated with RCWs. Clinicians are therefore compelled to use alternative methods such as shoe modifications that are less costly and reimbursable. Further, patients are often more tolerant of the slight modifications made to shoes with which they are familiar.

We are unaware of other reports in the medical literature that have reported

usage frequency and characteristics of offloading devices in the podiatric medical care of diabetic foot ulcers. Fewer than 2% of centers use what has been termed the gold standard (TCCs) for treating the majority of diabetic foot ulcers in this broadly distributed sample. Based on these findings, it is likely that although most specialists understand that amelioration of pressure, shear, and repetitive injury are principal tenets of diabetic foot ulcer care, the cost/benefit analysis, realities of maintaining a busy clinical practice, the available manpower, and reimbursement issues may influence clinicians to use less optimal pressure mitigation methods.

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