Use of Pressure Offloading Devices in Diabetic Foot Ulcers: Do We Practice What We Preach?

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*Purpose:* Pressure mitigation is crucial for the healing of plantar diabetic foot ulcers (DFU). Characteristics and considerations associated with the use of offloading devices are discussed.

*Methods:* A DFU 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 DFU in each center.

*Results:* Of the 895 respondents that treat DFU, shoe modifications (41.2%, p<0.03) were the most common form of pressure mitigation while total contact casts (TCC) were used by only 1.7% of the centers.

*Conclusions:* This study reports the usage and characteristics of offloading devices in the care of DFU in a broadly distributed geographic sample. Less than 2% of specialists use what has been termed the “gold standard” (TCC) for treating the majority of DFU.
In the treatment of diabetic foot ulcers (DFU), pressure modulation, commonly referred to as “offloading,” is most successful when pressure is mitigated at an area of high vertical or shear stress. Common methods to offload the foot include: bed rest, wheelchair, crutch assisted gait, total contact casts, felted foam, half shoes, therapeutic shoes, and removable cast walkers. Although it is well known that pressure mitigation through offloading devices is crucial for the healing of plantar DFU, 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 United States.

METHODS
A diabetic foot management survey was sent to 5200 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 United States into four census regions (West, Midwest, South, and Northeast) based on regions described by the US Census Bureau. The survey recorded information about the usage frequency and characteristics of assessment and treatment of DFU in each center.

RESULTS:
Of the 901 respondents, 895 centers actively treated DFU. The type and frequency of plantar offloading used is summarized in Table 1. Of the 895 centers, shoe modifications (41.2%, p<0.03) were the most common form of pressure mitigation in more than 51% of DFU treatments. There were no significant regional differences in therapy. Total contact casts (TCC) were used by only 1.7% of the centers for the majority of DFU treatment while 15.2% of the centers reported use of removable cast walkers. 2.6% of the centers reported application of other modalities such as therapeutic shoes, and 12.3% of the centers reported employment of complete non-weightbearing (NWB) strategies such as crutches and wheelchairs for the majority of treatment. 58.1% (520 centers) did not consider TCC as the gold standard to offload the non-infected plantar DFU. 45.5% of the centers nationwide reported no use of TCC 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%)

DISCUSSION
TCC have been considered the gold standard by academicians and consensus committees alike, however, the results of this study suggest this standard is actively employed by merely 1.7% of centers for treatment of the majority of plantar DFU treatment. Most of the centers (73.4%) used TCC in less than 25% of their patients, but (at best) intermittently. A further 45.5% centers reported not utilizing TCC at all. This discrepancy between consensus documents, 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, TCC 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 TCC 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, RCW 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 RCW 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%) employed RCW in less than 25% of plantar DFU. The most likely explanation is the cost and lack of reimbursement associated with RCW in the United States. Most patients either cannot, or are not willing to, pay the extra money for the RCW forcing clinicians to absorb the extra cost.

While no offloading modality was utilized 100% of the time by the centers assessed, shoe modification was by far the most commonly utilized. 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 RCW. 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 DFU. Fewer than 2% of centers use what has been termed the “gold standard” (TCC) for treating the majority of DFU 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 DFU care, the cost/benefit analysis, realities of maintaining a busy clinical practice, the available manpower, reimbursement issues may influence clinicians to use less optimal pressure mitigation methods.
REFERENCES:
Pressure Offloading Devices in Diabetic Foot Ulcers

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<th>Percentage Centers</th>
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<td>79.4</td>
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<td>ULCW</td>
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<td>Other mod.</td>
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Percentage Patients