



Adherence to Therapeutic Diabetic Footwear: Determinants and Considerations

Compliance is often complicated by psychological and cultural factors that transcend the functionality of these shoes.

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Diabetes mellitus is the sixth leading cause of death in North America¹ and also poses a socioeconomic burden.^{2,3} In 2017 alone, the United States spent \$327 billion dollars in medical costs for the treatment of diabetes.⁴ This rise in treatment cost is due to the increased prevalence of the disease.⁵ Patients with diabetes have up to a 25% lifetime risk of developing a foot ulcer.⁶ The recurrence rate for diabetic foot ulcers is reported to be 40% within one year after ulcer healing and almost 60% within three years of ulcer healing.⁷ The formation of diabetic foot ulcers predisposes a patient to potential lower extremity amputation.⁸

In 85% of amputations, there is a foot ulceration that precedes it.⁸ Patients with diabetes and peripheral neuropathy can develop foot ulcers by repetitive cycles of physical stress placed on the feet during weight-bearing activities.⁹ Off-loading allows for the redistribution of physical stress on osseous prominences and high stress areas of the foot.¹⁰ Off-loading principles entail decelerating the foot onto the ground to decrease the impact of ground reactive forces on the skin¹¹ and is one of the key tenets to the healing of diabetic foot ulcers and the prevention of new wounds.⁹

Reducing Plantar Pressure

There are various types of interventions to reduce plantar pressure in patients with diabetes. Custom off-loading footwear and orthoses are associated with a decrease in ulcer recurrence when compared to standard off-the-shelf shoes and orthoses.¹² The prescribed footwear should either reduce the overall pressure

are prone to infection and is contraindicated in patients with critical ischemia.¹⁵

RCWs

Another modality that falls under the classification of ankle-high, off-loading devices is the removable cast walker (RCW). RCWs maintain the ankle at a 90-degree angle al-

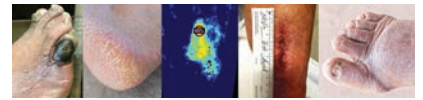
Behavioral health disorders have proven to be a barrier in the care for patients with diabetes.

values to less than 200 kPa throughout the foot, or have plantar pressure mitigation of at least 30% at the peak pressure zones of the foot.¹²

In the treatment of an active foot ulcer, a non-removable knee-high off-loading device such as the total contact cast (TCC) is considered by many to be the gold standard.^{9,13,14} In a study conducted by Begg and colleagues, the walls of the TCC reduced plantar contact area by keeping the foot suspended, thereby minimizing pressure to about 30% of plantar load.¹³ The TCC, however, may not be the best option for patients who

lowing for decreased pressure on the forefoot.¹⁶ While studies show that RCWs have similar¹⁷ or even higher¹⁸ forefoot plantar pressure mitigation when compared to the TCC, patient compliance with the device tends to be poor.^{9,19} RCW's ease of application concomitantly allows for patients to remove the off-loading modality when they so choose resulting in low adherence in RCW use.²⁰ RCWs can be made irremovable to increase patient adherence through securing the cast in place with a cohesive bandage, plaster, or fiberglass.¹⁶

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Determinants of Adherence to Therapeutic Diabetic Footwear

Patient adherence is an essential part of treatment efficacy. This is made evident by a meta-analysis comparing TCCs, irremovable cast walkers, and RCWs, concluding that TCCs and irremovable cast walkers resulted in significantly improved ulcer healing in contrast with RCWs due to the forced compliance associated with irremovable devices.²¹ Studies show that only 22-28% of patients with diabetic foot disease wear their prescribed therapeutic footwear more than 80% of the time.²² This reduced adherence results in decreased healing efficacy of the prescribed footwear and is complicated by a myriad of factors including physical, social, and psychological.

Mental Health and Diabetes

Studies suggest that mental health conditions and patient perception of their health condition can play a role in the adherence of patients with diabetes to their prescribed therapeutic footwear.²³ Behavioral health disorders have proven to be a barrier in the care for patients with diabetes. Some studies show that patients with diabetes and comorbid behavioral health disorders receive poorer quality diabetic care and are less likely to receive Hemoglobin A1C and low-density lipoprotein-cholesterol (LDL-C) tests in comparison to those diagnosed with diabetes alone.²³

Behaviors associated with patient self-perception of their condition can also influence adherence to diabetic therapeutic footwear. Patients who perceive their wounds to be less severe are less likely to adhere to their off-loading devices whereas those with osseous pedal deformities are more likely to be compliant to the prescribed footwear.²⁴

While fear of amputation can increase adherence measures, clinicians should encourage better health goals that align with a patient's personal motivating factors to promote a more positive outlook regarding the patient's ulcer healing progress.⁷ Depression is another behavioral health

disorder that can influence patient behavior. A study that analyzed the relationship between depression and diabetic self-care noted three deficiencies in patients with both diabetes and depression, including high non-adherence rates to oral hypoglycemic medicines, notable lack of physical activity, and inadequate clinical monitoring of glycemic control.²⁵

While these patients received physician-initiated services, including Hemoglobin A1C, microalbuminuria, and retinopathy exams, behavioral changes secondary to depression negatively influenced adherence to diabetic patient self-care. This included patients neglecting the following practices: wearing prescribed thera-

are other factors in assessing patient use of diabetic therapeutic footwear. Patients tend to adhere to wearing their prescribed footwear outside of home rather than in-home where most of the ambulation actually occurs.²⁶

Interestingly, greater day-to-day variation in activity was positively associated with adherence.²⁸ This is likely because patients with greater variability in their activity tend to spend more time away from home. Studies also show that patients wore their prescribed footwear significantly less during weekends than weekdays,²⁶ and non-adherence was highest during the late-evening, night, and early-morning hours, when patients are more likely to walk on hard

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peutic footwear, examining feet for indications of impending ulcerations, avoiding walking barefoot, and attending foot care appointments.²⁵

Footwear Design

The appearance and appeal of footwear design may also be a limiting factor to adherence, especially for female patients. In a study conducted by Jarl and colleagues,²⁶ women were shown to have worse diabetic health than men. Female patients with diabetes reported negative attitudes toward the appearance and price of therapeutic footwear, despite their increased need to adhere to the use of an off-loading device. Women disliked the shoes, reporting an impact on their self-image due to the large size and unfeminine appearance of the therapeutic footwear.^{26,27}

In the study, both men and women preferred conventional shoes over therapeutic shoes when it came to the appearance and weight of the shoe; however, both men and women felt that therapeutic shoes were more comfortable in practical use.²⁶ Variability in daily activity and location of use

bathroom or kitchen floors.²⁸ These factors further amplify the problem of increasing cumulative stress on an inadequately protected foot in an environment where patients spend more of their time and feel safest.²⁸

Other predictors of adherence relate to patient comfort when utilizing the off-loading footwear. Patient adherence may potentially be impacted by the effect of off-loading modalities on the kinetic chain of the lower extremity and subsequent altered gait characteristics.²⁹ Rocker bottom soles, a common feature of off-loading devices, have been shown to result in increased center of mass and center of pressure sway in patients without diabetes;¹⁰ this device-induced instability may be of concern in those with ambulatory deficits associated with diabetic peripheral neuropathy. Certain off-loading devices have thick soles that induce limb-length discrepancies, resulting in postural instability and lateral flexion at the L5 to S1 joint and leading to low back pain and noncompliance with wearing removable off-loading devices.³⁰

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When induced with a limb length discrepancy of 2 cm or greater, Nahas and colleagues noted an increase in peak total foot pressure in the shorter limb, specifically the area beneath the second to fifth metatarsal heads resembling that of a supinated foot.³¹ Another study assessed postural stability in a group of high-risk patients with diabetes using various off-loading modalities including TCC with cast boot, TCC with a rubber heel, RCW, half shoes, and canvas shoes.

The study noted that a TCC with a heel resulted in significant instability when compared with all other modalities.³² Moreover, postural stability was found to be a powerful predictor of noncompliance in a prospective multicenter international study when participants with diabetic foot ulcers were monitored for more than one month.²⁹ Patients with higher body mass index were also found to be less adherent.²⁸

This non-compliance may reflect their overall difficulty with stabil-

as medical interventions is challenging for most patients and can require considerable time and education.²⁷ Patients may feel more comfortable at certain times of day, or days of the week in wearing their prescribed therapeutic device, and having reminders in real time may potentially increase adherence.²⁸

The study concluded that implementation of a monitor device can potentially help improve patient adherence, and the incorporation of adherence monitoring into standard clinical care would likely be beneficial. Accessing patient adherence data, however, can be considered an invasion of privacy and potentially

Studies have shown a significant positive correlation between more appealing footwear and higher adherence.

Adherence has traditionally been assessed through subjective means of patient self-reporting, or via semi-quantitative method of observing the wear and tear of prescribed therapeutic footwear.²² These methods, however, lack sensitivity, accuracy, often result in missing data, and may increase the risk of reporting bias.²² Moreover, adherence is most appropriately obtained during

implicate ethical dilemmas relating to data accessibility, insurance utilization of such data, and influence on patient care.³⁴ Nevertheless, the use of objective adherence monitoring offers great potential, and new studies assessing and validating the use of smart devices to improve adherence to off-loading continues to date.

Disparities in treatment plans between patients with both diabetes and behavioral health disorders and those with diabetes alone pose serious health risks for those diagnosed with mental health-related conditions.²³ Patient and provider education can account for these disparities in practice and is essential to target to help improve diabetic footcare outcomes. A qualitative study regarding diabetic therapeutic footwear noted differing perspectives between healthcare professionals and patients in terms of expectations and reality of preventive behavior.³⁵

Counseling patients on wearing their footwear can help address fears or perceived ideologies surrounding the idea of therapeutic footwear in public. The positive association between the perceived benefit of diabetic shoes and adherent use of the shoes³⁶ further supports the role of improved patient education in patient adherence.

To date, much of the effort in evaluating and improving off-loading devices has narrowly focused on the devices' pressure mitigation efficacy while the user experience with these devices is generally overlooked.¹⁰

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There are improved ways to measure patient adherence to therapeutic footwear with patients receiving real-time reminders or notifications through their mobile devices.

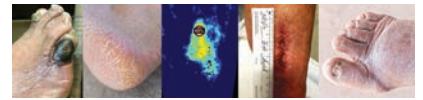
ity, and therefore resistance to the use of modalities that may further alter their gait and balance. While current research offers some insight into the determinants and predictors of patient adherence to therapeutic footwear, a 2016 systematic review concluded that there are currently too few studies in the literature to draw any definitive conclusions.^{10,33}

Considerations for Improving Patient Adherence

Adherence to therapeutic diabetic footwear is often complicated by psychological and cultural factors that transcend their functionality.²⁶ The transition from the everyday perspective of footwear as items of clothing to a medical perspective of footwear

ambulation, when pressures on the foot are highest.²⁸

In light of new technological advancements, there are improved ways to measure patient adherence to therapeutic footwear with patients receiving real-time reminders or notifications through their mobile devices. This may help with increased adherence in a home environment since adherence tends to be lowest at home despite patients being significantly more active.²² In a study conducted by Bus and colleagues, an adherence monitor was used to measure patient adherence to therapeutic footwear. The adherence monitor is small enough to fit inside a patient's shoe, and is composed of two temperature sensors, a data logger, and battery.²²



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The appearance, cost, and weight of therapeutic footwear are determining factors to patient adherence.¹⁴ Studies have shown a significant positive correlation between more appealing footwear and higher adherence.²⁸

A study involving individuals with diabetes who had previously received a prescription for therapeutic footwear identified style as the most important factor with respect to their footwear.³⁷ Manufacturers of diabetic footwear may consider possible new designs that may take away the stigma associated with diabetic therapeutic footwear in public. If the design of therapeutic footwear can be structured to align with new fashion trends or the addition of customizable parts, it might incline both male and female diabetic patients to adhere more to wearing their footwear.

Patient stability and biomechanical changes of the entire kinetic

chain are also important factors that should be considered and addressed appropriately to help increase patient adherence.^{29,38} Future studies regarding psychological and sociological influences on patients' perception of their diabetic foot condition are needed to further elucidate the effects of patient education and other interventions on patient adherence and potentially improve the prescription for and the use of therapeutic footwear.

Conclusion

Adherence to therapeutic diabetic footwear plays a critical role in the healing of foot ulceration and prevention of re-ulceration in individuals with diabetes. Adherent use of off-loading footwear remains a challenge, and improvements in the user experience with these devices may result in improved adherence. Educational gaps may be addressed through patient counseling and creation of personal treatment goals. By

doing so, it eliminates the constant fear of amputation. This tends to increase adherence.

It is recommended that caregivers specifically encourage patients to consistently wear their prescribed footwear whenever possible.³⁸ Patient comfort is an incredibly important aspect in addressing barriers in the treatment and prevention of diabetic foot ulcers. Effective communication between clinicians and patients can result in overall improved health outcomes. A better understanding of the patients' perception of their condition and factors affecting adherence have great value in guiding clinical practice, and provide an excellent basis to make way for improved adherence rates. **PM**

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