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Orthotic approach to prevention and management of diabetic foot: A narrative review

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Abstract

Diabetic foot is a common complication affecting more than one-fifth of patients with diabetes. If not treated in time, it may lead to diabetic foot ulcers or Charcot arthropathy. For the management of diabetic foot, shoe modifications and orthoses can be used to reduce pressure on the affected foot or provide the foot with increased stability. In addition, the shoe modifications and orthotic devices can relieve patient discomfort during walking. Appropriate shoe modifications include changing the insole material, modifying the heel height, adding a steel shank or rocker sole, and using in-depth shoes. Alternatively, a walking brace or ankle-foot orthosis can be used to reduce the pressure on the affected foot. The purpose of this narrative review was to provide a reference guide to support clinicians in prescribing shoe modifications and foot orthoses to treat diabetic foot ulcers and Charcot arthropathy.

Key Words: Diabetic foot; Foot ulcers; Charcot arthropathy; Shoes; Foot orthosis

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Core Tip: Footwear modifications and orthosis in diabetic foot management are aimed to prevent ulcers, protect the foot from external stimuli, and regulate the pressure on the foot. Types of shoe modifications include using an in-depth shoe, combination of insole materials, lifting the heel, applying a rocker sole, and applying an extended steel shank or flare or stabilizer. Orthosis includes prefabricated removable walking brace (such as control ankle motion walker, pneumatic walker, and conformer walking boot), Arizona ankle-foot orthosis, patellar-tendon-bearing orthosis, and Charcot restraint orthotic walker.

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INTRODUCTION

Diabetic foot is an infection, ulceration, or destruction of the tissues of the foot. It is associated with neuropathy and/or peripheral artery disease in the lower extremity of a person with diabetes mellitus [1]. The global annual incidence of diabetic foot ulcers in patients with diabetes was reported to be approximately 2%-5%, with a lifetime risk ranging from 15%-20% [2]. According to a report by the American Diabetes Association, 20% of patients with diabetes are hospitalized because of foot problems [3]. The main underlying causes of diabetic foot ulcer are peripheral neuropathy and ischemia due to peripheral vascular disease [4,5]. Once a foot ulcer develops, it may progress to foot infection, which if incurable, could eventually require limb amputation [4]. Most diabetic foot ulcers are caused by repetitive trauma due to weight-bearing or poorly fitting footwear, and ulcers often recur if the weight-bearing is not suppressed and the biomechanical abnormality of the foot is not controlled [5,6]. Prevention is important for effective management of the diabetic foot, with methods including continuous education and proper footwear for the patients with diabetes [6]. Such methods have been reported to prevent approximately 80% of all limb amputations due to diabetes [7]. Unfortunately, however, many patients are unaware of the diabetic foot, have never received proper education on its prevention, for example by wearing adequate shoes, or often receive treatment only after the problems, such as foot ulcers and neuropathic arthropathy, occur [8]. Therefore, it is essential for clinicians dealing with diabetic foot to be aware of the possible feet abnormalities due to diabetic complications and the importance of educating the patients with diabetes, including wearing the right footwear.

Another disease that can occur frequently as a complication of diabetes is Charcot arthropathy. The pathogenesis of Charcot arthropathy is not clearly known yet. It is believed to be a phenomenon in which the bone is weakened due to severe bone deficiency caused by autonomic nervous system abnormality or a local increase in blood flow to the bone [9]. Weakened bones are prone to fractures even under a very small weight, and the ligaments may also weaken, resulting in dislocation or subluxation [10]. Patients with Charcot arthropathy fail to sense pain in their limbs and continue to apply their weight, leading to bone deformity that further changes the normal force transmission path; this increases the chance of a fracture or dislocation and, consequently, deforms the weight-bearing part [11]. Over time, the process stops, and the deformity becomes permanent. Owing to the dislocation, the load cannot be distributed effectively and stably during walking, resulting in movement limitations, and the persisting bone protrusion eventually causes foot ulcers [12]. Furthermore, Charcot foot is characterized by a collapsed arch [9,10]. The non-surgical treatment for Charcot arthropathy is based on off-loading and edema control principles. The goal is to prevent the foot ulcers by minimizing mechanical stress, reducing edema, and creating structural stability, all of which help in restricting the weight-bearing and stabilizing the joint until the Charcot arthropathy is sufficiently controlled [5].

Orthoses play a very important role in treating diabetic feet that have already developed foot ulcers and Charcot arthropathy. Orthotic devices not only provide stability, limit the joint movement, and control foot deformity, but also relieve the load and evenly distribute the pressure on the foot. As a result, orthoses can effectively heal foot ulcers and control the symptoms of Charcot arthropathy. This review describes the management of diabetic feet using properly fitting shoes and orthoses.

FOOT ULCER CLASSIFICATION

Wagner classified foot ulcers from Category 0-3 based on the loss of protective sensation, foot deformity, and history of ulcer or ischemia [13]. Category 0 applies to cases where none of the following applies: Loss of protective sensation, deformity, callus, weakness, or history of ulceration or ischemia. Such cases are dealt with educating the patients on basic foot care and recommending conventional footwear. Category 1 solely involves the loss of protective sensation, and the use of in-depth shoes or

sneakers, non-molded soft inlays, and total contact orthoses is recommended. Category 2 involves foot deformity along with the loss of protective sensation and requires the use of in-depth shoes or sneakers, custom-molded foot orthoses, and external shoe modifications, if necessary. Category 3 involves all three factors, namely loss of protective sensation, foot deformity, and history of ulcer or ischemia, and requires custom-fabricated, pressure-dissipating accommodative foot orthoses, with additional recommendations for inlay-depth, soft-leather, adjustable-lacing shoes, and external shoe modifications, if necessary[13]. As illustrated above, the number of requirements for orthoses or properly fitting footwear and the complexity of prescriptions increase with the rising risk of foot ulcers.

ADAPTED FOOTWEAR

Ill-fitting footwear is a common cause of foot ulcers, whereas therapeutic footwear plays an important role in reducing the likelihood of foot ulcers[14]. Foot ulcers recur in about half the patients who wear shoes without modifications, compared to a recurrence rate of approximately 20% when an appropriate protective footwear is worn[5]. While prescribing adapted footwear for patients with diabetes, the goals are to protect the feet from the external environment, relieve excessive pressure, reduce impact and shear force, control foot deformity, and stabilize the movement[14]. The primary role of adapted footwear is to protect the feet from further harm by reducing the pressure on the affected area rather than treating the foot ulcers themselves and preventing their occurrence or recurrence[14,15]. The goal should be to reduce the pressure by at least 30% or to less than 200 kPa, where the pressure on the sole is the highest[16].

GENERAL PRINCIPLES FOR PRESCRIBING SHOES FOR PATIENTS WITH DIABETES

The shoe should conform to the shape of the foot, and there should be enough space inside, similar to an in-depth shoe. To determine the appropriate shoe size, the overall foot length, arch length, and foot width should be measured[17]. The shoes must be manufactured to accommodate the first and fifth metatarsophalangeal joints, which represent the widest part of the foot, while the shoe length should be such that there is a space of 1.3-1.6 cm between the longest toe and the tip of the shoe[17]. Additionally, the ball of the shoe should match in width with the ball of the foot, and the counter should not press the starting point of the Achilles tendon[8,17]. The insole should be removable and of triple-depth; leather insole is not recommended, as the primary aim is to minimize shear and friction[8]. The heel of the shoe is manufactured to be typically 2.5-5 cm high. If the height of the heel is over 5 cm, the pressure on the forefoot increases excessively[8,18]. Regarding the plantar surface, especially when the forefoot has an ulcer, a rigid rocker or a rigid rocker sole can reduce the pressure and help in healing of the ulcer[8]. It is recommended to purchase the shoes in the afternoon when the feet are swollen. In addition to checking the shoe size, the shoes must be tried on to check if it can correctly support the shape and the size of the feet when weight load is applied[8,17].

IN-DEPTH SHOE

In-depth shoes are usually blucher-type Oxford shoes that are 0.6-1.3 cm deeper than the conventional shoes. This extra space helps when using insoles and foot orthoses, which are necessary in cases of foot deformity due to Charcot arthropathy[8,17]. The in-depth shoes should have a light weight, good shock absorption capacity, and strong heel counter[8]. In the past, the upper material was mostly made of soft leather, but nowadays, breathable synthetic material is commonly used[8]. In addition, the relatively softer insoles are layered, and the lower the density of the insole, the more is the cushioning at the interface between the foot and the insole[19]. The insole is generally thermoformed to contour the patient's foot, and the outer sole is also modified to further reduce the pressure[19]. In addition to the Oxford shoes, sneakers may also be used. Sneakers have several advantages in terms of the depth, removable insoles, variety of ball widths offered by manufacturers, and diversity of design compared to that of the traditional Oxford shoes, allowing the patient to choose a model according to their personal preference[20]. When purchasing a ready-made footwear, the shoes should be modified if the foot deformity is severe. If the shoes cannot be modified, they must be custom-made[8].

SHOE INSOLE

Well-made custom insoles are necessary to properly distribute the pressure around the foot deformity. One of the ways is to increase the ambient pressure in order to relieve the pressure on a certain part of

the foot; however, this approach tends to be inaccurate and can result in damage to the foot because of an increase in the partial pressure[8]. The insole serves as the backbone of the shoe and secures the upper part to the sole[17]. The insole is manufactured in an accommodative form and divided into a soft, semi-rigid, or rigid material. Soft materials include cross-linked polyethylene foam, open-cell polyurethane foam, sponge rubber, and closed-cell expanded rubber. Although these soft materials are excellent for pressure distribution, they wear out quickly and have poor durability[21]. Semi-rigid materials include firm cross-linked polyethylene foam, ethylene vinyl acetate, and cork composite, which have a longer lifespan than the soft materials. They also function as a support in addition to providing shock absorption and cushioning. Semi-rigid materials are fabricated as custom insoles with three or more layers and typically used together with soft materials to provide a combination of support and compliance[22]. Soft and moldable polyethylene foam is used in the area beneath the plantar surface. Urethane polymer is used in the middle layer to prevent wear and absorb shock. Rigid ethylene vinyl acetate or cork is used as the bottommost layer for support and control of movement[8]. Insoles with rigid materials are made of thermoplastics, acrylics, and carbon fiber composites. Although they are highly durable and offer ample support and control, the rigid materials are difficult to modify and have much lesser shock absorption capacity and offer reduced cushioning and protection. In general, the use of rigid materials is contraindicated for patients with diabetes and neuropathy or a history of foot ulcers[23]. Compression paper or leather is commonly used to make insoles for patients with diabetes. The high-strength compression paper insoles are light in weight and inexpensive. Leather insoles are highly durable and adapt well to the plantar surface, absorb moisture, and provide excellent ventilation. However, the leather insoles are not always used owing to their relatively higher price and heavier weight compared to those of compression paper[17].

EXTERNAL SHOE MODIFICATIONS

Rocker sole

Rocker soles are an effective modification method for changing the plantar pressure and improving gait [17,24]. Rocker soles help to transition smoothly from heel-strike to toe-off without bending the shoe or foot. From the biomechanical perspective, this improves the overall gait by restoring the movement of the foot or ankle joint that was lost due to foot pain or deformation. This also relieves the pressure in a specific area of the plantar surface[8]. The apex of the rocker sole should be located proximal to the area where the pressure should be relieved, and the front end of the rocker sole should be arched from the proximal part of the metatarsal head to the distal end of the outsole. If there is an angle in the rocker sole instead of an arch, the gait will not be smooth[17]. Several types of rocker soles are available, all of which require appropriate modifications to meet the needs of the user. For example, the double rocker sole is a soft rocker sole without an outsole in the midfoot region. The forefoot rocker sole has a rocker angle only in the toe area. The heel-to-toe rocker sole has a rocker angle on both the heels and toes[16, 17].

Solid ankle cushion heel

The shoe heel provides stability to the foot heel and distributes the force applied on the foot to the entire sole[17]. The typical height of the shoe heel is 1.5-2 cm for men and 2.5-3 cm for women, but this could be modified according to the user's needs[25]. Most shoe heels are made up of rigid materials, but, if needed, a flexible heel may also be used to allow some plantar flexion[18]. A typical example is the solid ankle cushion heel (SACH), which has a wedge-shaped shock-absorbing material inserted into the heel. The SACH acts as a buffer during heel contact and mechanically increases the heel traction during the gait cycle, creating a smooth transition from heel-strike to toe-off[26]. Typically, the angle of the SACH is within 30°[17]. The SACH is indicated for patients with ankle or hindfoot stiffness due to metatarsal ulcers or Charcot deformity. It is also used in cases of degenerative arthritis or ankle fixation[17,26].

Extended steel shank

The extended steel shank, made of spring steel or carbon graphite, is located between the layers of the sole from the heel to the toes and serves to reinforce the midfoot region of the shoe[27]. The extended steel shank is typically used in combination with rocker soles to help improve their performance. In addition, the shank prevents the bending of the shoe, restricts the toe and midfoot movement, and further reinforces the driving force after a toe-off during gait[8,17]. However, since the extended steel shank can be easily bent owing to the properties of the material, thermoforming may also be combined for increased rigidity[17].

Flare and stabilizer

The flare and stabilizer modify the inside or outside of the shoe to stabilize the foot and serve as a support for the shoe[28,29]. A flare, typically made of ethylene vinyl acetate, is a structure added to the heel and sole of a shoe to widen the support surface of the shoe[17]. The flare, when used in combination with the rocker sole, also serves to increase the stability while walking[8]. A stabilizer is an

extension made of hardened resin or crepe that is added to the side of the sole to provide greater stability than flares do. A stabilizer is used for patients with severe instability on the medial or lateral side of the hindfoot or midfoot[30].

ORTHOSES

The International Working Group on Diabetic Foot (IWGDF) has published the off-loading guidelines for the appropriate treatment of diabetic foot ulcers[31]. According to this guideline, for people with diabetic ulcers, a removable knee-high off-loading device with an adequate foot-device interface should be selected as the first-choice treatment. Furthermore, a total contact cast (TCC) or a nonremovable knee-high walker is recommended depending on the patient's preference or the level of foot deformity. If nonremovable knee-high off-loading devices are contraindicated, a removable knee-high or ankle-high off-loading device is recommended[31].

Previous studies have reported that using a knee-high off-loading device is a faster treatment approach for foot ulcers than using other off-loading devices[32,33]. However, in actual clinical practice, knee-high off-loading devices are not commonly used, because they are contraindicated in at least half of the patients with diabetic foot ulcers with ischemia or infection[34]. Furthermore, many clinicians consider knee-high off-loading devices to be less effective than other types of devices[34]. However, according to the IWGDF guideline, since knee-high off-loading devices are contraindicated only in severe ischemia or infection, they can be used for mild or moderate ischemia or infection[31]. Additionally, TCC has traditionally been considered a gold standard off-loading treatment option, and knee-high off-loading devices are the first suggested option for patients with diabetic foot. Nevertheless, TCC and knee-high off-loading devices are under-used due to the perception that they are time-consuming to make and not cost-effective. However, since instant TCC and removable cast walkers are commonly used nowadays, it is necessary to improve the clinicians' expertise and awareness of orthoses that can be used in diabetic foot treatment[34-36]. Lastly, some barriers may be related to the patients themselves. The patients often perform weight-bearing activities at home that can strain their feet, as they misunderstand that off-loading treatment should be followed outside the home only[34,37]. Moreover, patients who fail to perceive the seriousness of diabetic foot ulcers are less motivated to use the off-loading devices[37,38]. These challenges can be addressed by educating the patients on their condition and the importance of the off-loading devices[35]. The poor mobility and stability that occur when patients use knee-high off-loading devices can also be problematic. The use of the device may result in a difference in length between the legs making it difficult to walk. For such cases, the shoe height, instead of the device, can be modified or mobility aids, such as a frame, can be used simultaneously[34]. The following paragraphs describe the off-loading devices available for diabetic foot ulcers and Charcot arthropathy.

NONREMOVABLE OFF-LOADING DEVICE

A typical example of a nonremovable walker is the TCC. The TCC is considered the standard treatment for managing neuropathic plantar ulcers and is also used to protect the foot in the early stages of vulnerability to Charcot fracture-dislocation[31,39]. The TCC relieves the pressure and load on the foot by distributing the weight across the entire sole and can prevent the risk of injury to bony prominences, such as the malleolus and tibia[40]. However, its limitations include the requirement of a skilled cast technician to apply the TCC appropriately, high manufacturing costs, and time-consuming process[40]. Moreover, the TCC is contraindicated in the very elderly and patients with infection or severe ischemia, visual or balance problems, varicose veins, or contralateral foot ulcers[40].

PREFABRICATED REMOVABLE WALKING BRACE

A prefabricated removable walking brace is used to treat diabetic feet with ulcers and Charcot arthropathy. The types of walking braces include the boot-type control ankle motion walker that controls ankle movement and uses an arch filler[41,42] (Figure 1A), the pneumatic walker that applies pneumatic pressure to reduce edema and prevent callus formation[43] (Figure 1B), and the conformer walking boot that consists of a molded inner liner that wraps around the foot and leg[44]. All walking braces consist of rigid rocker soles and a protective insole made up of materials such as Plastazote® foams, propylene terephthalate, and Spenco®. The walking braces are designed to immobilize all joints of the ankle and foot as would a TCC[8]. The general advantage of walking braces is that they are easy to wear, making it possible to manage the affected area at a relatively lower cost. However, if the foot deformity is severe, applying them can be difficult, and their large volume may reduce patient compliance[8].



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Figure 1 Types of refabricated removable walking brace and general appearance of orthosis. A: Control ankle motion walker; B: Pneumatic walker; C: Arizona ankle-foot orthosis; D: Patella-tendon-bearing orthosis.

ARIZONA ANKLE-FOOT ORTHOSIS

The Arizona ankle-foot orthosis (AFO) is mainly used for non-surgical management of posterior tibial tendon dysfunction or spastic deformity[45] (Figure 1C). It is also used in cases of ankle instability, arthritis, Charcot arthropathy, and diabetic peripheral neuropathy[8]. The Arizona AFO, typically custom-made from leather and polypropylene, extends proximal to the mid-axis of the tibia and distal to the metatarsal heads. The Arizona AFO plays a role in minimizing valgus alignment of the hindfoot, lateral calcaneal displacement, and dislocation of the medial ankle or restoring inadequate kinematics by supporting the calf and midfoot[46,47].

PATELLAR-TENDON-BEARING ORTHOSIS

The patellar-tendon-bearing (PTB) orthosis is used for partial weight-bearing of the lower extremities while restricting ankle movement[48] (Figure 1D). It supports the patellar tendon so that 60%-70% of the weight is supported by the knee joint and approximately 30% by the ankle joint[18]. A PTB orthosis can be applied to diabetic feet with fractures of the tibia or fibula, foot ulcers, and Charcot arthropathy[17]. The PTB orthosis is custom-made using a plastic-type brim based on the same principle as that used for making a PTB socket for below-knee prosthesis. The load is distributed to the ankle joint of the orthosis through the medial and lateral uprights. In general, the PTB orthosis is designed to restrict the movement of the ankle joint and provide internal and external stability[18]. Although this orthosis has the advantage of easily responding to changes in foot circumference caused by severe fluctuations in lower-extremity edemas, its heavy weight may limit patient compliance[8].

CHARCOT RESTRAINT ORTHOTIC WALKER

The Charcot restraint orthotic walker (CROW) is an orthosis manufactured to completely cover the feet and legs and can be applied to diabetic feet with Charcot arthropathy[8]. In Charcot arthropathy, it is used to prevent the development of ulcers by evenly distributing pressure to the entire leg and foot[49]. For a severe rocker sole deformity in the midfoot, it may be necessary to limit or eliminate the movement of the midfoot and hindfoot to restrict the entire foot and ankle joints. In this case, the CROW eliminates the movement of the foot and ankle joints, reduces the load and shear force applied to the foot, and protects the deformed foot from further damage[50]. The CROW orthosis is similar to a bivalved TCC and consists of a rigid polypropylene anterior and posterior shell with a dorsiflexion stop, heel lift, and rocker sole to counteract the nutcracker effect[8]. Since the CROW orthosis is fastened with a Velcro® strap, it is easy to detach, making it convenient for wound management, including wound cleaning[49]. However, as the CROW orthosis is bulky, it potentially limits patient compliance and sometimes leads to knee and lumbar pain due to immobility of the lower extremities[51].

CONCLUSION

In patients with diabetes, a foot ulcer or Charcot arthropathy is often the first step to amputation of the lower extremity, which becomes a major obstacle in the patient's life. To prevent foot ulcers, thorough and repeated patient education on diabetic feet is necessary in addition to preventive skin care and, above all, prescription of appropriate footwear. Once foot ulcers and Charcot arthropathy occur, it is extremely important to prescribe appropriate footwear and orthoses for the diabetic feet to effectively treat the foot lesion and prevent further deterioration. We believe that this review can serve as a reference guide for medical staff when prescribing appropriate footwear and orthoses for patients with diabetes.

FOOTNOTES

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