

Footwear used by individuals with diabetes and a history of foot ulcer

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Abstract—Objective. To describe footwear preferences of people with diabetes and a history of foot ulcer from two large western Washington State healthcare organizations. **Methods.** As part of a clinical trial of footwear, self-reported information on footwear preferences, use, and cost were obtained from persons with diabetes and a prior healed foot ulcer for the year before their study enrollment. All participants' shoes were allocated into optimal, adequate, and dangerous categories based on design, structural and safety features, and materials. **Results.** The 309 males and 91 females in this study averaged 62 years of age. At baseline, men owned an average of 6 (+3) pairs of shoes, with an average purchase price of \$56, while women owned an average of 8 (+5) pairs, with an average purchase price of \$42. Women spent an average of 51% of their time in shoes in dangerous shoes compared to men who spent 27% of their time. Men and women spent nearly 30% of their time while out of bed in slippers, stockings, and barefoot. **Conclusions.** People with a history of diabetes and foot ulcers needed several styles of safe and attractive shoes for regular activities. Healthcare professionals

can provide patients with information on good footwear choices to help them select adequate shoes while avoiding dangerous shoes. This approach is more realistic than trying to move all people with prior foot risk factors or ulcers into uniformly optimal footwear, since recent evidence does not support this practice.

Key words: *diabetes mellitus, foot ulcer, footwear costs, shoes.*

INTRODUCTION

Footwear has been implicated as an extrinsic cause of foot ulcers in people with diabetes and high-risk foot conditions [1–4]. The pathways usually involve injury when a foot with impaired sensation and/or deformity experiences minor trauma or elevated plantar pressure, resulting in tissue damage [5]. In a descriptive and case control study, a footwear-related pivotal event resulted in amputation in 21 to 36 percent of the patients when ulcer etiology could be identified [6,7].

In people with diabetes and a prior foot ulcer, decreased reulceration was reported in several studies comparing patients wearing prescription footwear with those wearing their own footwear [3,8,9]. However, a recent clinical trial of footwear reported no statistically significant reduction in reulceration between patients

This material was based on work supported by the Rehabilitation Research and Development, Health Services Research and Development and the Seattle Epidemiology Research and Information Center, Department of Veterans Affairs, the National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Health, and the Centers for Disease Control.

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randomized to therapeutic footwear versus the control patients in their own footwear [10]. Despite the reported benefits of therapeutic shoes and inserts, compliance has been inconsistent with some patients deciding not to purchase or wear prescribed footwear [9,11]. General unattractive appearance, cosmetic unacceptability, limited shoe colors and styles, and a desire to wear slippers when indoors are reasons patients give for not wearing prescription shoes [11,12].

Footwear that is aesthetically acceptable to people with diabetes and prior foot ulcers has received little study in the United States. The aim of this descriptive paper is to quantify self-reported footwear preferences, use, and cost in diabetic patients who have a history of foot ulcer and do not have a severe foot deformity.

METHODS

We examined footwear preferences in this descriptive study of people with diabetes and a prior foot ulcer who participated in a clinical trial of footwear. Study males were enrolled from the Department of Veterans Affairs (VA) Puget Sound Health Care System, Veterans Health Administration (VHA), and males and females were enrolled from Group Health Cooperative (GHC) in Western Washington State between August 1997 and December 1998.

Study eligibility criteria included participants diagnosed with diabetes, ages 45 to 84; a history of a healed full-thickness foot lesion; no foot deformities requiring a custom shoe; shoe sizes 8 to 12 1/2 for men and 7 to 10 1/2 for women; and the ability to walk one block and climb one flight of stairs daily. Exclusion criteria were a prior lower-limb amputation of more than one digit; a foot lesion healed less than 1 month; a requirement of boots, custom shoes, custom inserts, or nontraditional footwear for daily activities; Charcot foot deformity; nonambulatory status; or a terminal illness that would make a 2-year survival unlikely. People with severe foot deformities were excluded because footwear provided as part of the randomized clinical trial could not safely accommodate them. Human subjects approval was received from both the University of Washington and GHC.

Measures

At enrollment, patients were interviewed about health and diabetes history, self-care practices, and activities of daily living. Study clinicians performed a standardized clinical foot exam on all participants and recorded deformities, skin and nail conditions, edema, peripheral pulses, and response to the 5.07 monofilament. Pictures of different types and styles of men's and women's footwear were used during the interview to elicit the types of footwear owned, the frequency worn during the last year, and the purchase price. In addition, a physical activity questionnaire quantified participants' physical activity during the previous 24 hours. This data included time in bed; time out of bed; shoes worn by type and style; and the time in slippers, stockings, and barefeet.

A shoe classification was developed for this analysis by adapting Tovey's criteria [13]. First, we characterized shoes as optimal, adequate, or dangerous. Criteria for optimal shoes were lace-ups made from quality forgiving materials with at least three to four eyes on each side, extra width across the metatarsal heads, extra depth in the toe box, low heels, and a padded tongue to firmly hold the foot. This type of shoe would accommodate minor and moderate foot deformities and edema. Examples of optimal shoes are over-the-counter therapeutic or custom shoes. Adequate footwear was defined as a cushioned shock-absorbing outsole, flexible uppers, a reasonable toe box, laces, and accommodative features. Examples of these shoes include walking, athletic, and casual lace-up shoes. Dangerous shoes were those with a shallow or narrow toe box, no laces, open toes or heels, and a heel height placing extra pressure on the ball of the foot. Examples of dangerous shoes are slip-on's, sandals, and thongs for both sexes; hard-soled dress shoes for men, and heels for women. All patients' shoes were grouped into these three categories for analysis.

Statistical Methods

We used descriptive statistics (SAS software) to analyze the baseline demographic characteristics of subjects by gender and the types of footwear owned and worn and to analyze the average purchase price [14]. Statistical tests were two-sided, with $p < 0.05$ considered statistically significant.

RESULTS

The 400 study participants included 187 VHA males (47 percent), and 122 GHC males and 91 GHC females (53 percent). The **Table** shows participants with an average age of 62 years and education of 14 years. The majority of participants were Caucasian (78 percent) and married (61 percent). No statistically significant differences were found between participants enrolled from VHA and GHC in average age, race, or years of education. Significantly more males reported disability than females (30.4 percent versus 8.8 percent). Prior diabetes outpatient education was reported by 68 percent of participants.

Two-thirds of participants had been diagnosed with diabetes ≥ 6 years. The average body mass index (BMI) was significantly higher in women than men (35.5 percent versus 32.2 percent). Clinical foot examination revealed 58 percent of participants were insensate to the 5.07 monofilament, 32 percent had moderate foot deformities that did not require custom shoes (hallux limitus, fixed claw toes, or bunions), and 10 percent had moderate or severe edema. Foot insensitivity and deformity were significantly less common in women than men.

Types of shoes owned and worn differed by gender. **Figures 1** and **2** show the percent of men and women owning each type of footwear, the average number of pairs of each type of footwear owned, and the estimated number of times each style was worn each week. The average purchase price is also included. In the year preceding study enrollment, men reported owning an average of 6 (+3) pairs of shoes. The types of shoes that men most frequently owned were walking (72 percent), casual (59 percent), and hard-soled dress shoes (54 percent). Both walking and casual shoes were worn an average of three times a week, while hard-sole dress shoes were worn less than once a week. Slippers were owned by 72 percent of men and worn an average of five times a week.

Women reported owning an average of 8 (+5) pairs of shoes (**Figure 2**). The three shoe types that women most frequently reported owning were sandals (73 percent), walking shoes (70 percent), and dress shoes with less than 1-inch heel (64 percent). Sandals were worn an average of 2.9 times a week, walking shoes 3.6 times a week, and dress shoes less than 1 time a week. Slippers were owned by nearly 80 percent of women and worn an average of five times a week.

Table.

Baseline characteristics of 400 participants in clinical trial of footwear in persons with diabetes.

Variable	Total			p Value
	Male (n = 309)	Female (n = 91)	Total (n = 400)	
Demographic Findings				
Average age (yr) (SD)	62.6 (9.9)	61.6 (10.6)	62.4 (10.1)	0.44
Average years of education (yr) (SD)	14.4 (3.0)	14.1 (2.7)	14.3 (3.0)	0.38
Race, Caucasian, Non-Hispanic (%)	77.3	80.2	78.0	0.56
Married/living together (%)	60.5	63.7	61.3	0.58
Source of Healthcare (%)*				
VA Puget Sound Health Care System (VHA)	60.5	—	46.8	—
Group Health Cooperative (GHC)	39.5	100.0	53.3	—
Disabled (%)	30.4	8.8	25.5	0.001
Retired (%)	39.5	44.0	40.5	0.45
Prior Diabetes Education (%)	67.8	68.9	68.2	0.84
Health and Foot Characteristics				
Type 1 diabetes (%)	5.8	8.9	6.5	0.30
Diabetes duration ≥ 6 yr (%)	67.0	66.7	66.9	0.94
Average body mass index (SD)	32.2 (6.4)	35.5 (8.2)	32.9 (7.0)	0.001
Insensate feet	62.7	43.3	58.3	0.001
Moderate foot deformity	34.7	21.1	31.7	0.014
Moderate or severe edema	10.7	7.8	10.1	0.42

VHA = Veterans Health Administration

SD = standard deviation

*Women were enrolled only from Group Health Cooperative.

		% Own	Average times/week worn	Average # pair owned	Average cost		% Own	Average times/week worn	Average # pair owned	Average cost
	54	0.7	1.3	\$82		13	3.4	1.2	\$15	
1. Wing tips or hard-sole dress shoes					7. Therapeutic off-the-shelf shoes					
	59	2.8	1.4	\$62		44	2.4	1.2	\$33	
2. Casual shoes					8. Sandals					
	40	1.0	1.1	\$86		17	2.5	1.0	\$9	
3. Work boots/shoes					9. Thongs					
	72	3.3	1.5	\$47		72	4.7	1.0	\$19	
4. Walking shoes (includes athletic)					10. Slippers					
	18	1.3	1.1	\$30	—	35	1.0	1.4	\$70	
5. Sneakers (canvas nonsupportive)					11. Other					
	46	1.9	1.3	\$57						
6. Loafers/slip-on shoes										

Figure 1.
Types of shoes owned and worn by 309 men with diabetes and a history of foot ulcers.

The average purchase price per pair for women's shoes was \$42. While the average cost per pair of men's shoes was higher (\$56 versus \$42), women owned more pairs of shoes than men, thus the average total cost for all shoes owned was \$366 for women and \$304 for men.

The footwear worn in the 24 hours preceding the baseline visit was classified into optimal, adequate, and dangerous categories as previously described. **Figure 3** shows less than 10 percent of men and women wore optimal footwear (over-the-counter therapeutic shoes) in part

because of study exclusion criteria of persons requiring custom shoes or custom inserts. Adequate footwear was worn more often by men than women (66 percent versus 43 percent). Half the women wore dangerous shoes at some time during the day compared to 27 percent of men.

According to the physical activity questionnaire, both men and women reported out-of-bed time at 15.5 hours a day. **Figure 4** illustrates patient's footwear when not in shoes. Men averaged 11.1 hours in shoes and 4.4 hours out of bed and not in shoes, specifically 1.1 hours

		% Own	Average times/week worn	Average # pair owned	Average cost		% Own	Average times/week worn	Average # pair owned	Average cost
		33	0.4	2.2	\$61		51	2.9	2.2	\$37
1. Dress shoe ≥1-inch heel					7. Loafers/slip-on shoes/flats					
		64	0.8	2.0	\$44		11	2.1	1.6	\$80
2. Dress shoe <1-inch heel					8. Therapeutic off-the-shelf shoes					
		39	2.3	1.6	\$55		73	2.9	1.8	\$43
3. Casual					9. Sandals					
		44	0.1	1.2	\$59		11	2.7	1.0	\$9
4. Boots					10. Thongs					
		70	3.6	1.4	\$47		79	5.4	1.1	\$19
5. Walking shoes (includes athletic)					11. Slippers					
		42	2.1	1.2	\$27	—	14	1.9	1.1	\$50
6. Sneakers (canvas nonsupportive)					12. Other					

Figure 2.

Types of shoes owned and worn by 91 women with diabetes and a history of foot ulcers.

barefoot, 1.2 hours in stockings, and 2 hours in slippers. Women averaged 10.7 hours in shoes and 4.8 hours a day out of bed and not in shoes, specifically 1.2 hours barefoot, 0.7 hours in stockings, and nearly 3 hours in slippers.

DISCUSSION

Study participants with a history of foot ulcer wore a variety of shoes for their normal activities. Men wore

walking and casual shoes most frequently, while women most often wore walking shoes. However, a high percentage of women owned and wore sandals. Averaging the time spent by shoe type before the clinical trial of footwear, study participants spent 6 percent in optimal shoes, 61 percent in adequate shoes, and 33 percent in dangerous shoes. Participants reported approximately 30 percent of out-of-bed time was spent in slippers, stockings, and barefoot. While slippers offer some foot protection, stockings offer little protection and increase the likelihood of falls.

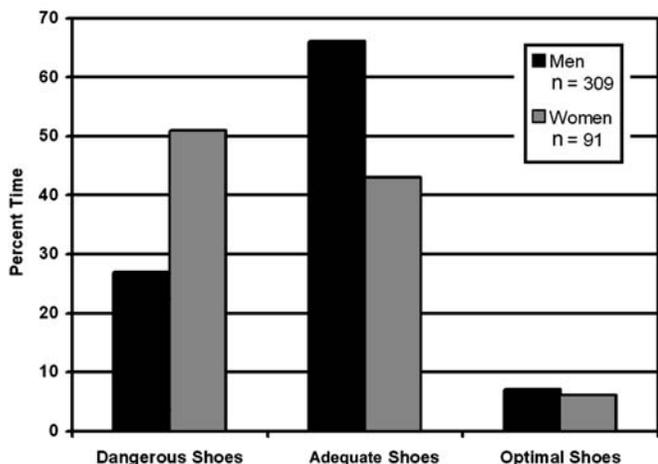


Figure 3. Percent time wearing optimal, adequate, and dangerous shoes at baseline.

Going barefoot is associated with minor trauma particularly in patients lacking foot sensation [4].

Therapeutic footwear has been widely promoted through guidelines and systems of care for people with diabetes and foot-risk conditions [15,16]. Many guidelines recommend therapeutic footwear for all people with diabetes and any foot-risk conditions, including a prior foot ulcer. Our data suggest people with a prior foot ulcer do not uniformly adhere to these recommendations and select their footwear from a variety of styles, shapes, and colors for different activities. Other research indicates dissatisfaction with prescribed footwear stems from improper fit; unacceptable appearance; high-cost; excessive time between ordering and receiving prescribed shoes; and limited colors, styles, materials, and durability [9,11,12].

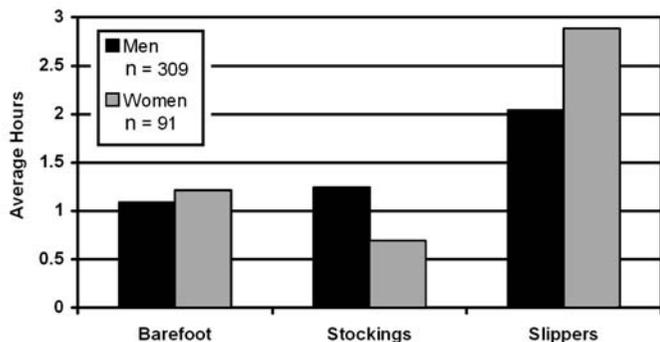


Figure 4. Time out of bed and not in shoes for men and women.

Limited research is available describing the characteristics of footwear that provide protection from foot ulcers in persons with diabetes. Tovey's shoe recommendations for people with diabetes and possibly insensate feet and/or moderately clawed toes were based on extensive experience working with people with insensate feet [13]. He recommended a broad and square toe box, low heels, lace-ups with three to four eyes per side, padded tongue, quality materials, light weight, and large enough to accommodate a cushioned insole. He stipulated that the presence of severe deformity, healed trophic ulcer, callosities, or pressure points required consideration of a custom shoe last and shoe [13]. Litzelman and colleagues quantitatively evaluated the association between footwear and foot lesions. They identified that healthcare professionals' recommendation for special shoes was significantly associated with the development of any foot lesion and their recommendation for appropriate width shoes was associated with more severe foot wounds [17]. Dahmen and colleagues recently published an algorithm for therapeutic footwear for persons with diabetes and peripheral neuropathy. While they identified shoe characteristics thought to be important for select foot characteristics, they provided no evidence linking shoe type and foot outcome [18].

Two clinical trials provided mixed findings on the efficacy of therapeutic shoes in preventing reulceration in people with diabetes and a prior foot ulcer [8,10]. An Italian study demonstrated one style of therapeutic footwear significantly reduced reulceration. A recently published clinical trial followed 400 Western Washington patients for 2 years and found no statistically significant difference in reulceration rates between people wearing study therapeutic shoes and/or inserts and those wearing their own footwear [10]. Findings from this study indicate that health professionals' careful attention to foot care may be more important than footwear but does not negate the possibility that special footwear is beneficial in people with diabetes and prior foot ulcers who do not receive close foot care.

This study has several limitations. First, this research excluded people who required custom shoes or custom inserts. Therefore, footwear preferences in people with severe foot deformities wearing custom shoes and inserts are not included. Second, 47 percent of the study population were male veterans, which may limit generalizing to some populations. Third, data on footwear owned and worn were self-reported and thus were subject to recall

bias. Although all participants had shoe pictures to assist them, some may have overlooked some shoes or not considered seasonal variation in reporting their footwear ownership and use.

CONCLUSION

In conclusion, people with prior foot ulcers indicated they need a variety in shoe types and styles. These individuals should be encouraged to use adequate footwear and minimize the time spent in dangerous footwear, stockings, and going barefoot. The combination of good foot care and adequate, acceptable, and reasonably priced footwear is important to ensure healthy feet in high-risk people with diabetes.

ACKNOWLEDGMENTS

Bruce Kilgore, Director Advanced Research and Development, NIKE, Inc., generously provided technical assistance, design, materials, and manufacturing guidance. Jeff Rodenbaugh provided outstanding assistance with programming.

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Submitted for publication May 6, 2002. Accepted in revised form June 17, 2002.