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Design and pilot testing of the DVA/Seattle Footwear System for diabetic patients with foot insensitivity

Gayle E. Reiber, PhD; Douglas G. Smith, MD; David A. Boone, CP; Michael del Aguila, MS; Robert E. Borchers, MS; David Mathews, CP; Aaron W. Joseph, MS; Ernest M. Burgess, MD, PhD
Prosthetics Research Study, Seattle, WA 98122; the Departments of Health Services, Epidemiology, Orthopaedic Surgery, and Rehabilitation Medicine, University of Washington, Seattle, WA 98195; VA Puget Sound Health Care System, Seattle, WA 98108; Harborview Medical Center, Seattle, WA 92122; NIKE, Inc., Beaverton, OR 97005

Abstract—Clinical epidemiology studies suggest the majority of lower limb amputations were preceded by a minor traumatic event, often footwear-related, and lower limb ulcers. To reduce foot trauma and ulcers, the diabetic patient with foot insensitivity has unique footwear needs. To address these needs for patients not requiring custom shoes, the DVA/Seattle Footwear System was developed. The six components of this system include: 1) a specially designed shoe last based on the geometry of the diabetic foot and research findings on foot regions at highest risk of ulceration, 2) a depth-inlay shoe, "Custom Stride™ by PRS," designed to be paired with either a custom-fabricated cork insole or a preformed polyurethane insole, 3) a laser digitizing system that captures 3-D plantar foot contours, 4) DVA/Seattle ShapeMaker™ software adaptation for modifying plantar surface contours and applying free-form and template modifications to increase or relieve loading, 5) software that translates files into code used by a milling machine to define the cutting path and carve cork blockers into custom insoles, and 6) a preformed polyurethane insole thicker than a typical insole to accommodate the extra volume and the interior dimensions of the shoe.

A 6-month pilot cross-over trial of 24 diabetic male veterans without prior foot ulcers was conducted to determine the feasibility of producing, and the safety of wearing, these depth-inlay shoes and both types of insoles. During the first 4 weeks, patients were assigned to the study shoes and one type of insole. During the next 4 weeks, they wore the other type of insole, and during the final 4 months, they chose which pair of insoles to wear with the study shoes. Over 150 person-months of footwear observation revealed no breaks in the cutaneous barrier with use of either cork or polyurethane insoles and the study shoes. Patient compliance with the footwear was 88%. Patients were highly satisfied with the appearance, stability, and comfort of the shoes and the comfort of both types of insole. However, 75% of the patients noted that the study shoes felt heavier than their customary shoes. Further research is needed to determine the long-term effectiveness of footwear in prevention of foot ulcers in the population at highest risk for diabetic reulceration and amputation.

Key words: automated fabrication, depth-inlay shoes, diabetes, insoles, neuropathy, orthoses.

INTRODUCTION

The average annual number of lower limb amputations performed for individuals in short-stay hospitals between 1989 and 1992 was 105,000. Over half of these amputations were performed for persons with diabetes, even though such individuals comprise only 3 percent of the United States population (1). A Seattle VA study found that most persons with amputation could identify a pivotal event starting the causal chain that led to their amputation, and for nearly half the initiating event was footwear related (2). In 84 percent of these causal chains, foot ulcers were present. Similar footwear and foot ulcer findings have been reported by other investigators in their diabetic clinical and research populations (3,4).

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Address all correspondence and requests for reprints to: Dr. Gayle Reiber, VA Puget Sound Health Care System (152), 1660 South Columbian Way, Seattle, WA 98108.

Peripheral neuropathy has been observed in half of the patients with a 20-year duration of diabetes (5,6). Results from a 1994 VA Health Services Study of 732 diabetic general internal medicine patients indicated that 60 percent of patients reported lower limb numbness and over 40 percent reported no pain sensation in their feet. In addition, nearly 40 percent of these patients reported knowing nothing, a little, or needing to know more, about selecting proper footwear (7).

Patients with foot insensitivity are at high risk for developing foot ulcers, due to unperceived tissue damage caused by repetitive mechanical stresses (3,5). Many diabetic individuals with insensate and mildly deformed feet could benefit from insoles that provide relief in high plantar pressure surface areas, paired with shoes that provide extra width across the metatarsal heads and extra depth in the toe box (8,9).

Off-the-shelf insoles are made from a variety of materials of different durometer hardnesses to provide comfort and shock absorption and to accommodate the foot. In contrast, custom insoles are made from a model of the foot of the patient to accommodate fixed deformities and areas at risk of damage, and to control flexible deformities with support and stability (10). Custom insoles can also redistribute plantar pressure, reduce shock and shear, accommodate, stabilize, and support foot deformities, limit joint motion, and improve biomechanical alignment. Insole technologies range from traditional plaster casting and hand-crafted insoles to automated contact and noncontact measurement devices linked to computer-aided design work stations and numerically controlled milling machines (11).

Available depth-inlay shoes for men are generally oxford-style and provide an additional one-quarter to three-eighths of an inch (0.635 to 0.953 cm) depth throughout the shoe to accommodate an insole and/or a foot with structural deformities. However, patients have complained that depth-inlay shoes are unattractive, expensive, or not durable (12). Interior dimensions of many depth-inlay shoes have not been designed for exact pairing with custom insoles. An imprecise insole-shoe interface has been reported to result in ulcers in some patients with insensate feet (13).

The DVA/Seattle Footwear System was developed to address the unique footwear needs of diabetic patients with foot insensitivity who do not require custom shoes. This system includes 1) a novel shoe last design, 2) design and production of a special depth-inlay shoe, the Custom Stride™ by Prosthetic Research Study (PRS) that is designed to be paired with customized cork or preformed polyurethane insoles, 3) a laser digitizing system that captures the three-dimensional (3-D) contour of the plantar surface of the foot, 4) adaptation of DVA/Seattle ShapeMaker™ software for modifying the 3-D computer model of the foot according to the needs of the patient, 5) a computer-controlled carver to fabricate the custom cork insoles, and 6) a polyurethane insole designed to conform to the interior dimensions of the shoe but without patient-specific customization. Development and pilot-testing of this system in a population of 24 diabetic veterans with diminished foot sensation was undertaken to compare the safety and effectiveness of the fabricated cork insole with that of the preformed polyurethane insole paired with this depth-inlay shoe.

METHODS

DVA/Seattle Footware System Development

The DVA/Seattle Footware System is an integrated approach for creating footwear for diabetic individuals with foot insensitivity who do not require custom shoes. The PRS team and collaborators from NIKE, Inc. began with a traditional shoe last that incorporated findings from 1) basic research at PRS into the relationship of foot morphology to shoe-last shape, 2) our previous research at the VA Puget Sound Health Care System, Seattle, and patient care experience on the most common foot ulcer sites that led to lower limb diabetic amputations, 3) findings from a 1993 PRS footwear pilot study of 30 diabetic men whose size 10 feet were scanned with a Cyberware laser scanner to digitize the 3-D surface of their feet and ankles, 4) analysis of the foot shapes and an averaging of the findings with customized software, 5) clinical and wear test experience of from 3 to 8 months on the 30 men while they wore commercial NIKE walking shoes or cross-trainers, 6) results from a footwear preference survey of 76 diabetic veterans, and 7) clinical observations[1] (11,14). None of the available commercial lasts were a good match; therefore, a hybrid was created using the hindfoot of one last, the forefoot of another, and the addition of over 20 quantitative modifications to the contour of the last to accommodate shape characteristics of the large group of diabetic patients with insensitivity and minor-to-moderate foot deformities.

[1]Reiber G, del Aguila M, Weitz R, et al. Footwear practices and preferences among a group of outpatient diabetic veterans. Unpublished data.

Based on clinical and laboratory data of the study team, three major modifications were made to a standard size 9 last for this depth-inlay shoe: 1) extra width and height were added in the toe box to accommodate the metatarsal heads and to allow for hyperextension and hyperflexion of metatarsophalangeal and proximal interphalangeal joints; 2) increased depth was added throughout the length of the shoe; and 3) a rocker bottom was added to reduce gait-induced plantar stress.

This depth-inlay, blucher style, front-laced shoe is shown in **Figure 1**. The upper is made from high quality cowhide leather to foster breathability, retain shape, minimize the time needed for break-in, and provide durability. The outsole unit is molded from urethane by the Meramec Group (Sullivan, MO), with a rocker bottom that allows a smooth rolling motion from heel to toe with normal gait to decrease motion in the tarsal-metatarsal joints.

Figure 1.
New depth-inlay shoe, "Custom Stride™ by PRS."

Thirty pairs of prototype shoes were manufactured by Cole-Haan (Portland, ME, a subsidiary of NIKE, Inc.) using cement construction methods. With a traditional outsole, the extra forefoot volume incorporated into the study shoe would have resulted in an unattractive shoe, with a high, boxy profile. To circumvent this problem and provide additional lateral support, the lasted upper was sunk deeply into the outsole, which has high side walls to minimize the appearance of the extra depth added to the waist and instep. This depth-inlay shoe accommodates the volume of the inserts and is adaptable for diabetic patients with minor plantar and dorsal structural abnormalities.

The technique developed by the team to measure the plantar contours of the foot uses a laser digitizer (Cymavision, patent pending). Wearing white stockings to enhance contrast, the patient stands with nominally equal weight-bearing and knees in full extension on a 21-in (53.3-cm) platform with a clear plate. Each foot is then optically digitized through the plate. The laser digitizer has no moving parts and measures the plantar surface of the foot in less than 0.5 of a second, with an accuracy of ± 0.5 mm in measurement of depth.

The digitized data are subsequently imported into a modified version of the DVA/Seattle ShapeMaker software (15), where free-form modifications and prescription templates are applied to the 3-D digitized image to create custom insoles. The template modifications (stored shape manipulations based upon physical landmarks, such as the metatarsal heads) incorporate information based on the foot pathology, contours, and the findings from the clinical foot exam, to either increase loading or provide relief to key areas. **Figure 2** shows the regions used in the template to modify areas of the plantar surface. This process is analogous to the Automated Fabrication of Mobility Aids (AFMA) system developed by members of this team to design and modify prosthetic sockets (15).

Once the 3-D shape has been defined in software, the remaining task is to manufacture the insole. Rubberized cork blanks, formed so the bottom of the blank conforms perfectly to the bottom surface of the interior of the shoe, are provided by the Meramec Group. Cork is used because of its machinability and its material properties subject to little set or deformation. Each insole blank is machined by a 3-axis, computer-numerically-controlled (CNC) milling machine (Light Machines Corp., Manchester, NH) using software that translates the DVA/Seattle ShapeMaker file into directions that define the cutting path. A podiatrist, certified prosthetist, or orthotist fits the insoles to the feet of the patient, making minor modifications by hand as needed. Finally, the insole is covered with a 1.5-mm layer of foam-backed nylon tricot top cover to provide a cushioning interface between the foot and insole. The top cover material is thin to minimize obscuring even slight modifications. **Figure 3** shows the cork blocker, carved insole, and finished insole with top cover. All of the steps involved in the DVA/Seattle Footware System to provide patients with custom insoles (clinical exam, digitization, shape modification, insole carving, and fitting) are performed in less than 2 hours.

The standard study insole is made of a closed cell polyurethane foam, and is thicker than insoles used in

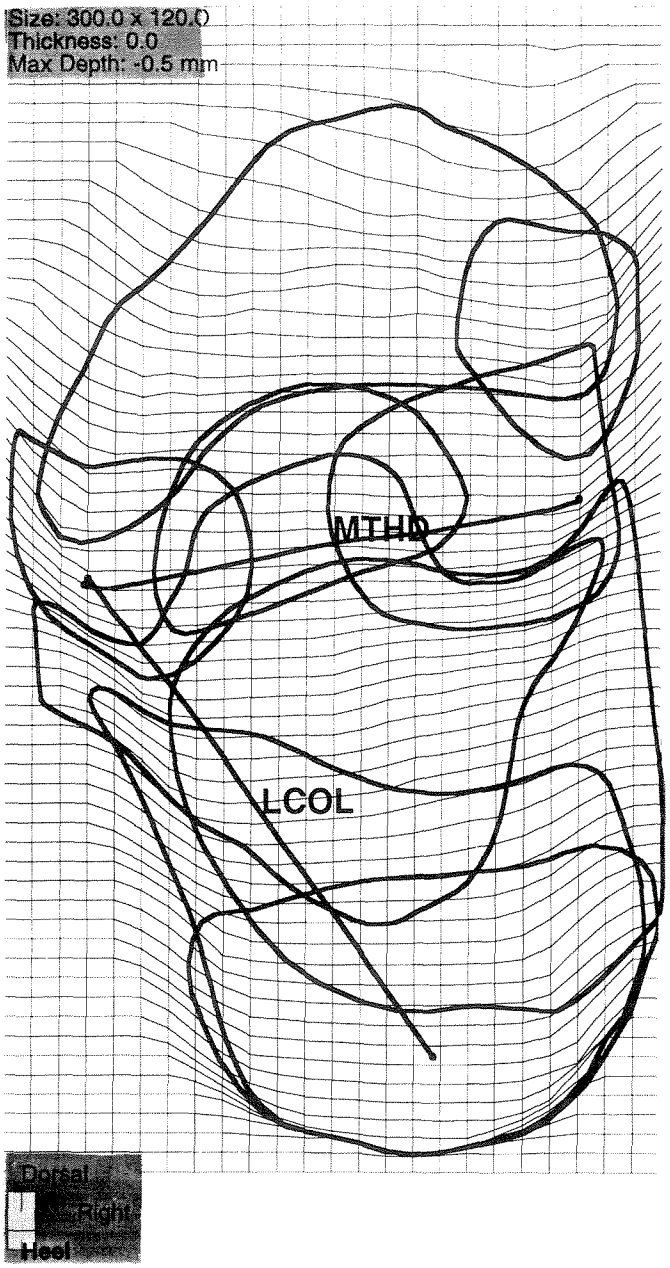

Figure 2.
Template regions for modification of the 3-D digitized foot image.

commercial walking shoes in order to accommodate the interior dimensions of this depth-inlay shoe, and to provide cushioning for the feet (9,10,12). This insole is not based on the digitized form of the foot; rather, it is molded to conform exactly to the interior plantar contour of the shoe, as shown on the left side of **Figure 4.**

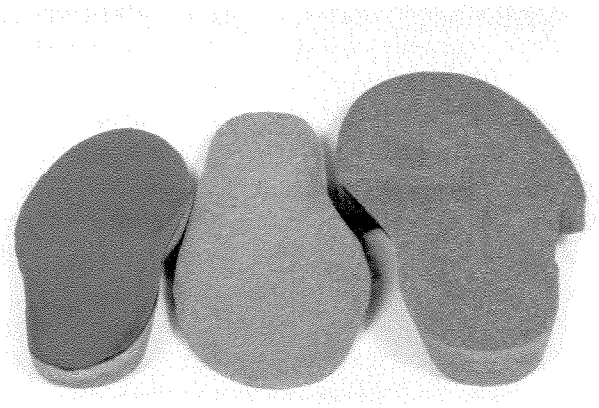

Figure 3.
From left to right: finished cork insole, carved insole without top-cover, and cork blocker.

Pilot Study

A 6-month prospective non-randomized, cross-over study (16) of the Custom Stride shoe and insoles using the DVA/Seattle Footware System was conducted at PRS from January to October 1995. The primary outcome of interest was a break in the cutaneous barrier of the foot as assessed by direct observation by study personnel and graded using the Seattle Wound Classification System (14).

Study patients were 24 diabetic males, ages 45–84, who received regular health care at the Seattle VA Medical Center, had no prior history of foot ulcer or

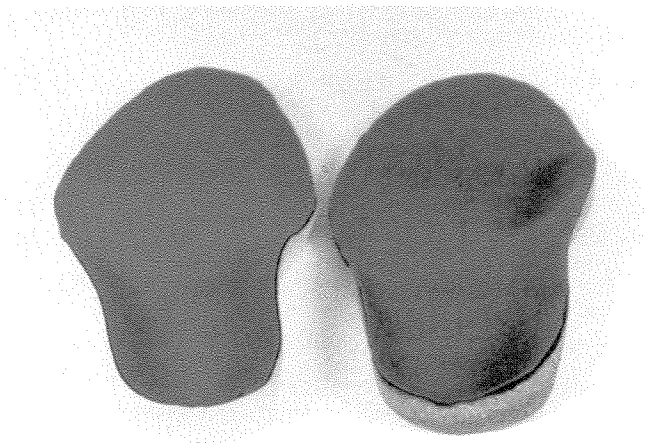

Figure 4.
Preformed polyurethane insole on left and customized cork insole on right, to be used with the Custom Stride™ by PRS shoe.

amputation, could ambulate at least 8 blocks per day, wore 10–10 ½-size shoes, and were willing to provide informed consent and agree to the study requirements. Patients were excluded from the study for any of the following: 1) prior lower limb amputation, 2) current or prior foot ulcer or Charcot foot deformity, 3) current nonambulatory status, 4) current requirement for boots, custom shoes, or nontraditional footwear for activities of daily living, 5) current requirement of supplemental oxygen, or 6) current or past alcohol or substance abuse history that could interfere with study compliance.

Patients were identified from the investigators' prior studies at PRS and the VA Puget Sound Health Care System, Seattle. A letter describing the study was sent to patients who met the age, diabetes, and foot ulcer criteria, asking them to contact the investigators if they were interested in participating. It was stressed that patients would need to continue with their regular health care provider(s) for health and foot care.

Study Measures

Patients were evaluated by a multidisciplinary team. At baseline, each patient received a clinical examination of the lower limbs, and both feet were digitized. Questionnaires were administered to obtain information on health history, diabetes, quality of life, and a 24-hour recall of physical activity. Patients were initially assigned to one of the two insole types to be used in the depth-inlay study shoe: customized cork or standard preformed polyurethane. Ten-minute walking fit tests of the shoes and insoles were conducted on each patient during the initial appointment, and each was given instruction regarding break-in of the new shoes and insoles. Within 1 week of the baseline visit, patients were re-evaluated to assess the fit of the insole.

Patients wore one type of insole in the study shoe for 4 weeks, and then crossed over to the opposite type insole for the next 4-week period. The major study outcome variable was dichotomous (never/ever ulcerated) for each insole type. Patient satisfaction with the footwear was assessed during the first 2 months of the study through specific questions regarding appearance, comfort, stability, and weight. At the beginning of study month three, all patients were requested to select the insoles of their choice to wear in the study shoes for the next 4 months. During months three to five, patients received a monthly phone call to address footwear compliance, foot problems, and lesions. At the end of month six, all patients were again clinically evaluated by the study team and their feet digitized for comparison with the baseline findings. Study visits and data collection during this 6-month period followed the research protocol. Regular assessments included shoe function, patient compliance, level of physical activity, insole adequacy, needed modifications, changes in insole, shoe material characteristics, and the adequacy of the shoe/insole interface.

RESULTS

Table 1.
Description of pilot study population at baseline prior to assignment to shoes/insole combinations (n = 24).

Characteristic	Value
Demographic	
Mean age (s.d.)	66.0 (9.3)
% Caucasian	92.0
% Education ⩾ 12 years	88.0
Clinical	
Body Mass Index* (s.d.)	28.6 (3.9)
% DM clinical duration > 10 years	43.7
% with clinical neuropathy in at least one foot	60.0
% with bunion, hammer toes, or claw toes	40.0
Footwear	
% using off-the-shelf insoles	36.0
% using custom insoles	32.0
% with extra-depth shoes	4.0
% using custom shoes	0
Foot-care	
% who regularly break in new shoes	52.0
Number of times/week wash feet, average (s.d.)	5.0 (2.7)
Number of times/week examine feet, average (s.d.)	5.9 (3.4)

* Body Mass Index = (weight kg)/(height m)^2.

Table 1 shows select patient characteristics at study enrollment. These patients were older (mean age 66), predominantly white (92 percent), and fairly well educated. Forty-four percent of these patients reported a clinical duration of diabetes over 10 years; 60 percent were found to be clinically neuropathic in at least one foot at baseline, and 40 percent presented with one or more mild foot deformities. Before study enrollment, about one-third (36 percent) were using off-the-shelf insoles and another third (32 percent) custom insoles. Only one patient (4 percent) was currently using depth-inlay shoes. Study patients reported frequent foot self-examination and foot care.

Table 2 provides findings on clinical and technical outcomes observed in over 150 person-months of shoe

and insole wear. Within 1 week of using polyurethane insoles, six patients were determined to be at risk of dorsal skin ulceration; therefore, their insoles were thinned to relieve pressure on the dorsal surface of their toes. Minor adjustments were made to the cork insoles after fabrication (e.g., adjustment of heel height). There were no breaks in the cutaneous barrier in any patient during the study. One patient presented at 6 months with an interdigital fungal irritation that was determined to be unrelated to the study insole or shoes.

When patients were questioned about insole preferences at study week 8, almost 21 percent preferred cork, 54 percent preferred polyurethane, and 25 percent had no preference. At week 26, there was no statistically significant difference in insole preference, with 45 percent preferring cork, and 55 percent preferring polyurethane.

Table 2.
Clinical findings in 24 diabetic patients testing the DVA/Seattle Footware System.

	Insole type	
Characteristic	**Cork**	**Polyurethane**
Breaks in Cutaneous Barrier	0	0
Other Adverse Events		
Blisters	0	0
Callus	1	0
Interdigital fungal infection	1	0
Redness on dorsal aspect of toes requiring insole modification	0	6
Mean number of modifications to insole	0.76	0.80
% of modifications for clinical reasons	0	32.0
Insole preference at study week 5*	20.8	37.5
Insole preference at study week 8*	20.8	54.2
Insole preference at study week 26*	45.0	55.0

*41.7% and 25% had no insole preference at study weeks 5 and 8 weeks, respectively.

Table 3 describes various measures of patient satisfaction with the shoes and insoles. Patient satisfaction with the appearance of the shoes was 88 percent, 96 percent indicated the shoes were comfortable, and 100 percent reported both types of insoles were comfortable. A feeling of stability in these shoes was reported by 96 percent. However, 75 percent noted that the study shoes were heavier than those they usually wore.

Patient compliance was assessed both through an interviewer-administered activity log and a single question regarding proportion of time in study footwear and of total time in any footwear. **Table 3** documents the patient compliance at 88 percent at the end of the first month, a level maintained through the end of the second study month. To corroborate patient self-report of compliance, during the telephone contact at the end of study month three, the interviewer asked both the patient and the patient's partner the same questions about footwear compliance. With a Pearson correlation coefficient of 0.93 ($p<0.0001$), agreement between patient and partner was high (17).

Table 3.
Patient satisfaction with footwear in 24 diabetic patients testing the DVA/Seattle Footwear System.

Characteristic	**Percent**
Liked appearance of shoes	88
Felt shoes were comfortable	96
Felt insoles were comfortable	100
Felt stable in footwear	96
Felt footwear was heavier than shoes normally worn	75
Compliance with footwear	
% reporting wearing study shoes of total time with anything on feet - week 4	88
% reporting wearing study shoes of total time with shoes on feet - week 8	88
Correlation between patient and partner reporting on shoe/insole use, study month 3	0.93 ($p<0.001$)

DISCUSSION

The DVA/Seattle Footware System represents a significant advance in design and production of footwear for diabetic individuals with foot insensitivity who do not require custom shoes. This integrated system includes a high quality, attractive depth-inlay shoe, based upon the shape of feet of 30 diabetic males, which was modified into an accommodative last. This shoe has been designed to be paired with either a customized cork or a preformed polyurethane insole. Technical assistance from colleagues at NIKE, Inc. facilitated the design and manufacture of this state-of-the-art footwear, using quality materials, methods, and manufacturing techniques. The AFMA system previously used for automated fabrication of prostheses has been adapted to customize and carve the cork insoles (15).

Combinations of shoes and insoles developed as part of this system were provided to 24 veterans with diabetes

who participated in a 6-month cross-over trial. During 150 person-months of observation, there were no foot lesions or other footwear-related adverse events. Patients were highly satisfied with the shoe and insole appearance, comfort, and stability. Though the majority of patients were clinically neuropathic, they were able to provide subjective impressions of this footwear. The insole preference for these patients was 55 percent for polyurethane compared to 45 percent for cork. This difference was due largely to the perception of greater cushioning in the polyurethane insole. It is encouraging that patient insole preferences were nearly evenly divided, since the study represented one of two patient populations (peripheral neuropathy, foot deformity and no ulcer history) for which the footwear was designed. The polyurethane insoles were intended to be worn by those diabetic patients not requiring insole customization. The second population consists of patients with a history of foot ulcers who are at high risk of reulceration. For these patients, the clinician-prescribed cork insole will allow customized relief in high plantar pressure areas and other modifications based upon patient foot geometry and physical findings. In the future, it is envisioned that clinicians will be able to specify the insole best suited for their patient, whether it be preformed or custom milled.

This pilot study demonstrates the ability to provide patients with customized footwear in a timely fashion with no short-term adverse events. The study was not designed to test the different material properties of semi-rigid or soft materials (cork or polyurethane). However, the 6-month wear-test by these 24 patients showed that the performance of both materials was excellent.

From the outset, this depth-inlay shoe incorporated the expressed footwear needs, preferences, and practices of veterans into the design of the shoe upper and outsole. Thus, the 88 percent patient compliance with footwear during the first 2 study months is higher than rates reported in other studies (18,19). Previous observational studies and a randomized trial indicated that the use of therapeutic footwear decreases the risk of reulceration in patients with diabetes (3,4,20). Yet reports indicate many patients who received therapeutic footwear did not use it as prescribed, largely for aesthetic reasons, thereby negating its potential benefit (3,18,19).

In conclusion, this study demonstrates that diabetic patients who are at risk for foot ulceration and do not require custom shoes may benefit from this type of footwear. Further research is needed to determine the long-term clinical efficacy and effectiveness of depth-inlay shoes, custom insoles, and generic preformed insoles in the prevention of diabetic foot reulceration in patients at high risk for limb loss.

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