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ORIGINAL REPORT

PERCEIVED USABILITY AND USE OF CUSTOM-MADE FOOTWEAR IN DIABETIC PATIENTS AT HIGH RISK FOR FOOT ULCERATION

Mark L. J. Arts, PhD[1], Mirjam de Haart, MD, PhD[1], Sicco A. Bus, PhD[1], Jan P. J. Bakker, MD, PhD[2], Hub G. A. Hacking, MD[3] and Frans Nollet, MD, PhD[1]

From the [1]Academic Medical Center, Department of Rehabilitation, University of Amsterdam, Amsterdam, [2]Medisch Centrum Alkmaar, Department of Rehabilitation, Alkmaar and [3]St Antonius Hospital, Department of Rehabilitation, Nieuwegein, The Netherlands

Objective: **To assess the perceived usability and use of custom-made footwear in diabetic patients who are at high-risk for foot ulceration, and to elucidate the determinants of usability and use.**

Design: **Survey.**

Subjects: **A total of 153 patients with diabetes, peripheral neuropathy, prior plantar foot ulceration and newly prescribed custom-made footwear, recruited from 10 Dutch multidisciplinary foot clinics.**

Methods: **The Questionnaire of Usability Evaluation was used to assess the patients' perception of weight, appearance, comfort, durability, donning/doffing, stability, benefit and overall appreciation of their prescription footwear (all expressed as visual analogue scores). Data on priorities for usability and footwear use (in h/day) were obtained from patient reports. Multivariate logistic regression analysis was used to assess determinants of usability and use.**

Results: **Median (interquartile range) score for overall appreciation was 8.3 (7.1–9.1). Scores ranged from 6.5 (4.5–8.6) for weight to 9.6 (6.3–9.9) for donning/doffing. Footwear comfort was listed most often (33.3%) as the highest priority. Footwear use was <60% of daytime (where daytime was defined as 16 h out of bed) in 58% of patients. The only significant determinant of footwear use was the perceived benefit of the footwear ($p = 0.045$).**

Conclusion: **Perceived usability of footwear was mostly positive, although individual scores and priorities varied considerably. Footwear use was low to moderate and dependent only on the perceived benefit of the footwear. Therefore, practitioners should focus on enhancing the patient's appreciation of the therapeutic benefit of custom-made footwear.**

Key words: therapeutic footwear; diabetic foot; patient satisfaction; adherence; perceived usability; ulcer prevention; pedorthic shoes; footwear comfort.

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Correspondence address: Dr. Sicco A. Bus, Academic Medical Center, University of Amsterdam, Department of Rehabilitation, PO Box 22660, NL-1100 DD Amsterdam, The Netherlands. E-mail: s.a.bus@amc.uva.nl

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INTRODUCTION

Foot ulceration often occurs in patients with diabetes mellitus who have peripheral neuropathy, and this condition significantly increases the risks for infection and lower-extremity amputation (1–3). Patients who are at high risk for developing a foot ulcer are often prescribed custom-made therapeutic footwear (4). However, despite preventative treatment, foot ulcers frequently recur (5).

To prevent pressure ulcers effectively, therapeutic footwear needs to be worn. Our own trial on footwear effectiveness and data from others showed that, when properly offloading footwear is worn for the majority of the day, the risk for foot ulcer recurrence can be significantly reduced in patients with diabetes (6, 7). However, several studies show a low use of therapeutic footwear in this patient population: only 22–36% of patients use their footwear frequently (> 80% of daytime, i.e. time out of bed) (12–14). This seems to be considerably lower than in patients with rheumatoid arthritis or degenerative foot disorders (8, 9). This difference in footwear use between patient groups may be mediated by the role of peripheral neuropathy, which prevents diabetic patients from properly "feeling" the effect of their prescription footwear (e.g. in relieving plantar foot pressure), and thus these patients may value their footwear differently from patients with intact foot sensation.

The perception of footwear usability, involving aspects such as weight, appearance, comfort and benefit, has been shown to affect footwear use (10–15). Insight into perceived usability is therefore important in order to understand, and eventually to improve, patient behaviour in wearing therapeutic footwear. However, data on perceived footwear usability in diabetic patients at high risk for foot ulceration is scarce and its association with footwear use is not clear. This study therefore aims to explore the perceived usability and use of custom-made footwear in diabetic patients who are at high risk for plantar foot ulceration, and to find determinants of perceived usability and footwear use.

PATIENTS AND METHODS

Subjects

A total of 153 patients with diabetes were recruited from the multidisciplinary diabetic foot clinics of 10 Dutch hospitals that participated in a larger study into the effectiveness of custom-made footwear

(7). Baseline socio-demographic and clinical characteristics were recorded. All patients had loss of protective sensation due to peripheral neuropathy and had a plantar foot ulcer that had healed in the 18 months prior to the study. Loss of protective sensation was verified by the inability to sense the pressure of a 10 g Semmes-Weinstein monofilament at at least 1 of 3 plantar foot sites tested: hallux, first metatarsal head, and fifth metatarsal head, or the vibration of 25 V or more measured at the dorsal hallux using a Bio-thesiometer (16). Feet were examined for the presence of deformity, which was classified as "none", "mild", "moderate" or "severe" (Table I). Exclusion criteria were: active ulceration, inability to walk unaided for at least 100 m, bilateral amputation proximal to the tarso-metatarsal joint, and inability to follow study instructions. All patients provided written informed consent prior to the start of the study. The medical ethics committees of each participating centre approved all study procedures.

Custom-made footwear

Footwear was prescribed by a rehabilitation specialist and manufactured by an orthopaedic shoe technician, both experienced in diabetic foot care. Most prescribed footwear was fully customized ($n = 131$), the rest was semi-customized, i.e. prefabricated extra-depth shoes with custom-made insoles ($n = 22$). During prescription, patients could express their personal preferences for certain footwear characteristics, such as colour, type of closure, and style, provided that biomechanical function was not jeopardized. Fully customized shoes were mostly ankle-high shoes (79%), and in other cases high shoes (i.e. midtibia level, 8%) or low shoes (i.e. below the ankle, 13%). Semi-customized shoes were mostly low shoes (73%); the other 27% was ankle-high. All shoes had leather uppers and closures were either laces (77%) or straps (23%). Prior to footwear delivery, patients were given verbal and written information regarding the importance of wearing therapeutic footwear. At footwear delivery, patients were further instructed to wear their shoes during all walking and standing activities and to avoid barefoot walking.

Perception of footwear usability

Three months after delivery, when patients were accustomed to their footwear (17), perceived usability of their footwear was assessed using the Questionnaire of Usability Evaluation (QUE) (18). The QUE has been developed and valued as a valid and reliable tool to assess perceived usability of therapeutic footwear in patients with degenerative foot disorders (18). The QUE is a self-completed questionnaire that assesses the following footwear usability items: overall appreciation, weight, appearance, comfort, stability, benefit (at home and at work), sole thickness, maintenance and durability, donning/doffing, and pain. Questions regarding perceived pain were omitted due to the loss of protective sensation in all patients. Patients scored each item using a visual analogue scale (VAS), where 0 represented the most negative perception and 10 the most positive perception.

The QUE was also used to assess footwear use, which was reported in days per week (i.e. "never", "1 day per week", "2–3 days per week", "4–5 days per week" or "6–7 days per week") and then in h per day (i.e. "never", "1–4 h per day", "4–8 h per day", "8–12 h per day" or "more than 12 h per day"). In addition to the QUE, patients were asked to prioritize footwear usability aspects by answering the questions: "Please list all footwear usability aspects that you find important" and: "Which of these listed aspects do you find most important?"

Data analysis

For each QUE item, VAS scores ≥ 8 were classified as "good", ≥ 6 and < 8 as "acceptable", and < 6 as "poor". Footwear use was recalculated per patient as the mean number of hours per day, by multiplying the median reported hours per day with median reported days per week, and dividing the outcome by 7 days. For example, a patient reporting to use the footwear "8–12 h per day" and "4–5 days per week" had a mean footwear use of $10 \times 4.5/7 = 6.4$ h per day. To calculate footwear use as percentage of daytime (i.e. time out of bed), daytime was assumed to be 16 h per day. Based on previous data (6), patients with footwear use $< 60\%$ of daytime were classified as "low-to-moderate users", and $\geq 60\%$ as "frequent users".

Statistical analysis

Descriptive analyses were performed for each QUE item and for footwear use. Median values and interquartile ranges (IQR) were calculated for each QUE item and for footwear use, as scores were not normally distributed across patients. Univariate and multivariate logistic regression models were built to assess determinants for each QUE item, for which scores on each QUE item were dichotomized based on the median score. Factors entered into the model were patient characteristics (gender, age, level of education, body mass index, foot deformity level, diabetes duration, and diabetes type) and footwear characteristics (type of footwear, i.e. fully or semi-customized, footwear height, presence of a shaft support, and history of custom-made footwear use, i.e. first user or experienced user). Univariate and multivariate logistic regression models were also built to elucidate the determinants of footwear use ("low-to-moderate use" vs "frequent use"). Factors entered into the model were identical to those mentioned above, with the addition of the median VAS scores on each QUE item. Multivariate models were performed in a backward stepwise fashion ($p < 0.05$), for which entry into the model was determined by significance ($p < 0.10$) in the univariate analysis. All statistical analyses were carried out using IBM SPSS Statistics for Windows, version 19.0 (IBM Corp. Released 2010. Armonk, NY, USA).

RESULTS

Baseline socio-demographic and clinical characteristics are summarized in Table I. Median VAS scores and percentage of patients scoring "good", "acceptable" or "poor" for each QUE item are shown in Table II. Median VAS score for overall appreciation of the footwear was 8.3. Across all QUE items, median VAS scores ranged from 6.5 (for weight of the shoe) to 9.6 (for donning/doffing). Footwear appearance showed the highest percentage of "good" scores (67%), whereas weight showed the highest percentage of "poor" scores (45%). Almost

Table I. *Baseline characteristics*

Variable	Outcome
Patients, *n*	153
Male/female, *n*	127/26
Age, years, mean (SD)	62.9 (10.3)
Caucasian/non-Caucasian ethnicity, *n*	147/6
Diabetes type (1/2), *n*	45/108
Diabetes duration, years, mean (SD)	17.1 (13.5)
Body mass index, kg/m^2, mean (SD)	30.7 (5.7)
HbA1C, %, mean (SD)	7.5 (1.5)
Vibration perception threshold, V, mean (SD)	44.1 (11.8)
Foot deformity[a], *n*	
None/mild/moderate/severe	6/52/67/28
Education level, *n*	
Low/medium/high	86/27/40
First-time prescription/previous prescription, *n*	79/74

[a]Level of deformity: none: no deformity or amputation; mild: pes planus, pes cavus, hallux valgus, hallux limitus, hammer toes, and lesser toe amputation; moderate deformity: hallux rigidus, claw toes, hallux or ray amputation, and prominent metatarsal heads; severe deformity: Charcot foot, forefoot amputation, and pes equines.
V: volt; SD: standard deviation; HbA1C: glycated haemoglobin.

Table II. *Scores for each item of the Questionnaire of Usability Evaluation (QUE)*

QUE item	Score Median (IQR)	Poor (VAS <6) %	Acceptable (VAS 6–8) %	Good (VAS >8) %
Overall appreciation	8.3 (7.1–9.1)	13.9	25.4	60.7
Weight	6.5 (4.5–8.6)	45.0	16.7	38.3
Appearance	7.2 (5.0–8.9)	19.8	13.1	67.2
Comfort	8.5 (7.1–9.3)	13.6	23.1	63.3
Sole thickness	7.9 (5.3–9.2)	31.6	25.7	42.8
Maintenance	8.7 (5.9–9.3)	24.6	13.1	62.3
Durability	7.9 (6.8–8.9)	20.8	30.0	49.2
Donning/doffing	9.6 (6.3–9.9)	26.5	10.2	63.3
Stability	8.8 (6.6–9.6)	20.5	18.9	60.6
Perceived benefit (home)	8.5 (5.3–9.4)	27.0	12.5	60.5
Perceived benefit (work)	8.4 (4.9–9.6)	30.6	16.7	52.8

VAS: visual analogue scale; IQR: interquartile range.

14% of patients scored "good" on all usability items and 3% of patients scored "poor" on all items.

The results from the logistic regression analyses of perceived usability are shown in Table III. Level of education was the only determinant of overall footwear appreciation, with patients with a lower level of education having a higher appreciation than patients with a higher level of education. Perception of shoe weight was better in older than younger patients and better when patients wore low shoes, shoes without a shaft support, or semi-customized shoes, of which only shoe height remained a significant determinant in the multivariate analysis. Perception of footwear appearance was better in older than younger patients and better in patients with a lower level of education than those with a higher level of education, and was further determined by shoe height and the presence of a shaft support. In the multivariate analysis, the factors age and education level remained significant determinants. Shoe type was the only factor that significantly determined the perception of comfort (semi-customized more comfortable than fully-customized). Donning and doffing was perceived as easier in patients with a shorter than longer duration of past foot ulcers and with less severe than more severe foot deformity, but none of these factors remained significant in the multivariate analysis. Patients with type 1 diabetes and with longer-standing diabetes perceived their footwear as more beneficial in the house compared with patients with type 2 diabetes and those with shorter duration of diabetes, whereas younger patients perceived their footwear as more beneficial at work than did older patients (none remained significant in multivariate analysis).

Comfort was reported as the highest priority of all footwear usability aspects by 33.3% of patients (Table IV). Footwear appearance was reported as the highest priority by 16.3% of patients, and foot protection by 4.1% of patients.

Table III. *Univariate and multivariate logistic regression analyses of perceived usability for each item of the Questionnaire of Usability Evaluation (QUE)*

	Univariate analysis		Multivariate analysis	
Variable per QUE item[a]	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Overall appreciation				
Education (low – medium – high)	0.515 (0.330–0.804)	0.003	Not applicable[d]	
Weight of the shoe				
Age, years	1.043 (1.005–1.083)	0.026		
Shoe height (low – ankle-high – high)	0.199 (0.006–0.098)	0.014	0.595 (0.393–0.902)	0.014
Shaft support (absent – present)	0.434 (0.161–1.067)	0.098		
Shoe type (semi – fully customized)[b]	0.402 (0.142–1.140)	0.087		
Appearance				
Age, years	1.044 (1.005–1.083)	0.025	1.039 (1.000–1.079)	0.048
Education (low – medium – high)	0.607 (0.393–0.938)	0.025	0.641 (0.412–0.997)	0.049
Shoe height (low – ankle-high – high)	0.706 (0.478–1.043)	0.080		
Shaft support (absent – present)	0.418 (0.156–1.124)	0.084		
Comfort				
Shoe type (semi – fully customized)[b]	0.284 (0.098–0.823)	0.020	Not applicable[d]	
Donning/doffing				
Ulcer duration	0.938 (0.873–1.008)	0.079		
Foot deformity (ranked none to severe)	0.486 (0.238–0.994)	0.048		
Benefit (at home)				
Diabetes type (I–II)	0.430 (0.207–0.891)	0.023		
Diabetes duration (years)	1.013 (0.989–1.038)	0.091		
Benefit (work)[c]				
Age, years	0.942 (0.887–1.002)	0.058	Not applicable[d]	

[a]All variables with *p*-values <0.10 in the univariate analyses were entered in the multivariate analysis per QUE item. Variables with *p*-values ≥0.10 were discarded from the Table. Variables containing more than 2 categories (such as shoe height) were treated as ordinal variables (i.e. low=1, ankle-high=2, high=3). There were no significant variables found in the univariate analyses for the QUE – items "sole thickness", "stability", "maintenance" and "durability", and these are therefore not listed in the table.

[b]Shoe type "semi" represents semi-customized shoes; shoe type "fully" represents fully customized shoes.

[c]Only scores of employed patients were included.

[d]Multivariate analyses were not applicable when only 1 variable was significant in the univariate analyses.

95% CI: 95% confidence interval; OR: odds ratio.

Table IV. *Priority list on perceived usability of footwear aspects*[a]

Listed usability aspects	Times listed *n* (%)	As most important *n* (%)
Comfort	84 (22.3)	49 (33.3)
Fit	62 (16.5)	16 (10.9)
Appearance/style	40 (10.6)	24 (16.3)
Support	32 (8.5)	14 (9.5)
Weight	29 (7.7)	9 (6.1)
Functionality	26 (6.9)	9 (6.1)
Protection	20 (5.3)	6 (4.1)
Donning/doffing	19 (5.1)	1 (0.7)
Pain reduction in the foot	17 (4.5)	7 (4.8)
Stability	10 (2.7)	3 (2)
Perspiration	5 (1.3)	2 (1.4)
Quality	4 (1.1)	2 (1.4)
Other	12 (3.2)	3 (2)
Total	360 (100)	145 (100)

[a]Eight of the 153 included patients did not complete this part of the questionnaire.

Patients wore their shoes for a median of 9 h/day (IQR 6–13 h). Fifty-eight percent of patients were classified as "low-to-moderate users", and 42% as "frequent users". In univariate logistic regression analysis, a higher degree of neuropathy (VPT) and higher VAS scores for perceived maintenance of the footwear, perceived benefit at work and perceived benefit at home were significantly associated with more frequent footwear use (Table V). Of these factors, only perceived benefit of the footwear at home remained a significant determinant in the multivariate analysis.

DISCUSSION

The majority of diabetic patients in this study, who are at high risk for developing foot ulcers, perceived the usability of their custom-made footwear as acceptable to good. However, footwear use was low, with 58% of patients wearing their prescription footwear for less than 60% of daytime hours. The only factor in this study that determined footwear use was the perceived benefit of wearing prescription footwear at home. These findings suggest that improving perceived usability will generally not have a large impact on footwear use in this patient group. Addressing the benefit of footwear by educating patients more effectively about the therapeutic value of custom-made footwear is therefore indicated to improve footwear use.

Patients were least satisfied with the weight of their shoes, which is a known problem with custom-made therapeutic footwear (13, 14). Shoe height significantly determined perception of weight. High shoes are common in custom footwear prescriptions, and because these are mostly provided for functional purposes, this is not an aspect that can be changed easily. The use of different, lighter-weight materials in footwear manufacturing may reduce shoe weight without jeopardizing shoe function. The factor that best determined overall appreciation of footwear and footwear appearance was the level of education, with patients with a higher level of education giving lower scores. This unprecedented finding shows that level of education should be taken into account when the goal is to improve these items in high-risk diabetic patients. Most usability items were given higher scores than found in studies on stock diabetic footwear (14, 19) or in studies on patients with other foot disorders wearing custom-made footwear (8, 9). This suggests that diabetic patients at risk for ulceration are more positive about custom-made than off-the shelf footwear, and more positive than other patient groups wearing similar footwear. However, we cannot rule out the influence of methodological differences between studies in this comparison, such as the use of different types of questionnaires or some studies limiting their assessments to footwear aesthetics and comfort. These comparisons should therefore be explored further in future research.

Many different footwear usability aspects were listed as being important for the patients. This suggests that communication about personal preferences and priorities is important in footwear prescription, as other studies have also shown (11, 13, 19, 20). To our surprise, shoe comfort was reported most frequently as the highest priority aspect, rather than items such as foot protection or appearance. Williams & Nester (14) stressed the role of appearance in footwear usability, but their tested patients were approximately 8 years younger than our patients. Since we found age to be a determinant of the perception of footwear appearance, this may explain the differences between their study and ours. Shoe comfort as highest priority in patients who have lost protective foot sensation stresses the potential ambiguity in the meaning of "comfort", where pa-

Table V. *Univariate and multivariate logistic regression analyses of footwear use*

Variable	Low-to-moderate users ($n=89$)	Frequent users ($n=64$)	p	OR	95% CI
Univariate analyses					
VPT, V, mean (SD)	43.3 (11.8)	46.8 (7.7)	0.048	1.036	1.000–1.073
Perceived maintenance, median (IQR)	8.6 (4.9–9.2)	8.9 (7.8–9.5)	0.059	1.045	0.995–1.327
Perceived benefit at home, median (IQR)	7.9 (4.8–9.1)	9.0 (8.0–9.7)	0.017	1.142	1.024–1.273
Perceived benefit at work, median (IQR)	7.6 (4.4–9.7)[a]	9.4 (7.9–10.0)[b]	0.023	1.217	1.027–1.441
Multivariate analysis					
Perceived benefit at home			0.045	1.272	1.001–1.620

All variables with p-values <0.10 in the univariate analyses were entered in the multivariate analysis. Variables with p-values ≥ 0.10 were discarded from the table.

[a]Based on $n=39$, [b]$n=33$ subjects who were employed at the moment of assessment.

VPT: vibration perception threshold; V: volts; OR: odds ratio; SD: standard deviation; IQR: interquartile range; 95% CI: 95% confidence interval.

tients may interpret this as referring to walking comfort more than to shoe fit. Others found that patients with different foot disorders relate footwear comfort more to an improvement in walking (11). Since we suggest that this is also the case in the current study, shoe design and manufacturing should facilitate comfort of walking, something that may be easier to achieve with semi-customized than with fully customized footwear.

Foot protection was reported by only 5% of patients as a priority, and by only 4% as the highest priority aspect, while foot protection is the primary reason to prescribe custom-made footwear for high-risk diabetic patients. This demonstrates the low level of comprehension and/or appreciation of this primary goal of prescription footwear, even though patients received information about this at footwear delivery. It is possible that patients understand the primary goal, but nevertheless value more the footwear's ability to provide comfort. More effective information and education addressing the therapeutic benefit of wearing custom-made footwear is thus required.

Only 42% of patients were classified as frequent users of their prescription footwear (worn > 60% of daytime). This proportion is quite low considering the high risk of developing a foot ulcer in these patients, who all have peripheral neuropathy and a recently healed foot ulcer, and many of whom have foot deformity. A recently completed trial on custom-made footwear effectiveness from our group suggests that when adequately offloading custom-made footwear is worn more than 80% of the steps taken, a significant reduction in risk of plantar foot ulcer recurrence can be achieved (7). In correspondence with these data, Chantelau & Haage (6) showed earlier that the risk of developing foot ulcers may be substantially reduced when properly offloading footwear is worn for more than 60% of daytime hours. Because only a minority of patients in the current study achieved this threshold, non-adherence is a major issue in this patient population, and this topic requires further research and more emphasis in clinical practice. Footwear use in the current study is comparable to results of earlier studies on diabetic patients (14, 19), which confirms that use is considerably lower than in other patient groups (8, 9). Associations between perceived usability and footwear use were weak, which shows that footwear use is difficult to predict from data on perceived usability. Thus, a satisfied patient does not guarantee proper footwear use.

Perceived benefit of wearing the footwear was the only significant determinant of footwear use and has been recognized before as important determinant among patients with various foot disorders (10, 13–15). "Benefit at home" was the only significant determinant of footwear use in the multivariate model. "Benefit at work" dropped-out as determinant in the model, perhaps because few patients were employed. The lack of protective foot sensation may have negatively affected perceived benefit of footwear, and with that footwear use. As a comparison, patients with rheumatoid arthritis receive direct feedback on the benefit of their footwear because they sense pressure and pain. For the same reason, improving awareness and motivating neuropathic patients to wear their footwear (more often) may be more difficult (12, 21–23). More evidence on the efficacy of worn custom-made footwear in preventing ulceration would support a more effective approach to improving awareness and motivation. Prescription of specific protective footwear for use indoors may be another option to improve perceived benefit and footwear use in neuropathic diabetic patients (12, 13, 24).

A limitation of the methodological setup was that we used a questionnaire that has not been validated for diabetic patients (18). This demonstrates itself by questions regarding perception of "comfort" and "benefit at work", which are less straightforward in a patient group that is neuropathic and mostly unemployed. Nevertheless, we considered the QUE to be sufficiently suitable and more appropriate than, for example, face-to-face interviews because of the use of VAS scores. A second limitation was that only a minority of patients wore semi-customized shoes (14% of total group). Although the influence of shoe type was assessed in the logistic regression analysis, results from this analysis should be considered with caution since these results may not be generalizable to all patients wearing semi-customized footwear given the small sample involved. Finally, footwear use was assessed subjectively based on patient self-reports, which might have affected the accuracy and reliability of the data. Objective methods to measure footwear use are preferred and have become available during the course of this study (25). We recommend using such methods in future investigations.

In conclusion, in diabetic patients at high risk for ulceration, perceived usability of custom-made footwear was acceptable to good, but individual perceptions varied greatly. Footwear use was lower than desired in this patient group and was determined only by how patients perceived the benefit of using custom-made footwear, in particular for use at home. Patients prioritized usability mostly towards footwear comfort, while foot protection was mentioned as a priority by only 1 in 20 patients. These outcomes stress the importance of addressing the issues of perceived benefit of therapeutic footwear and foot protection, by educating patients more effectively on the therapeutic value of custom-made footwear. This may be crucial to improve footwear use and better protect the foot against complications.

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