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Manufactured Shoes in the Prevention of Diabetic Foot Ulcers

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OBJECTIVE — To evaluate the efficacy of manufactured shoes specially designed for diabetic patients (Podiabetes by Buratto Italy) to prevent relapses of foot ulcerations.

RESEARCH DESIGN AND METHODS — A prospective multicenter randomized follow-up study of patients with previous foot ulcerations was conducted. Patients were alternatively assigned to wear either their own shoes (control group, C; $n = 36$) or therapeutic shoes (Podiabetes group, P; $n = 33$). The number of ulcer relapses was recorded during 1-year follow-up.

RESULTS — Both C and P groups had similar risk factors for foot ulceration (i.e., previous foot ulceration, mean vibratory perception threshold >25 mV). After 1 year, the foot ulcer relapses were significantly lower in P than in C (27.7 vs. 58.3%; $P = 0.009$; odds ratio 0.26 [0.2–1.54]). In a multiple regression analysis, the use of therapeutic shoes was negatively associated with foot ulcer relapses (coefficient of variation = -0.315 ; 95% confidence interval = -0.54 to -0.08 ; $P = 0.009$).

CONCLUSIONS — The use of specially designed shoes is effective in preventing relapses in diabetic patients with previous ulceration.

D iabetic patients with a history of neuropathic plantar ulceration have abnormally high pressure under the foot while walking. Peaks of pressure occur most frequently under the metatarsal heads and correlate with the sites of ulceration (1). A wide variety of footwear has been proposed to reduce pressure peaks and prevent ulceration (2–5), but there are few objective experi-

mentally derived data to support the effectiveness of most shoe therapy (3,6–8). No studies have evaluated the efficacy of manufactured shoes in preventing foot ulceration. The aim of our work was to evaluate the effectiveness of manufactured shoes (Podiabetes by Buratto, Italy), made according to Towey guidelines (4), in preventing relapses of foot ulcerations in high-risk diabetic patients.

RESEARCH DESIGN AND METHODS

— This prospective study was performed in two teaching hospitals (Rome and Milan). Only patients with previous foot ulceration and those considered to be at high risk of foot ulceration (9) were included in the study. They were randomized to wear either their ordinary nontherapeutic shoes or therapeutic shoes with custom-molded insoles. Initially, patients fulfilled the following criteria: 1) absence of ulceration, 2) absence of previous minor or major amputations, and 3) absence of major foot deformities such as Charcot joints. All patients received the same educational guidelines on foot care and general information on the importance of appropriate footwear (i.e., proper size, durability, and sole). The patients in the control group were free to wear ordinary shoes unless clearly dangerous. The same follow-up protocol was applied to both groups. Use of the specific footwear was rated as infrequent, occasional, frequent, or continuous; and the state of the shoes was assessed after 6 months, when a second pair was given. The patients were considered to have had an ulcer relapse either when a new ulcer appeared in the site of the previous one or when a new foot ulcer appeared in a different area.

Study sample

A total of 69 patients were enrolled (43 men, 26 women): 33 wore therapeutic shoes (Podiabetes group [P]), and 36 wore their own nontherapeutic shoes (control group [C]) (Table 1). Peripheral neuropathy was evaluated by vibratory

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ABI, ankle/brachial index; CI, confidence interval; VPT, vibratory perception threshold.

Table 1—Characteristics of the patients

	n	M/F	Age (years)	Duration (years)	Type I/II
Podiabetes	33	20/13	59.6 ± 11	16.8 ± 12.7	8/25
Control	36	23/13	60.2 ± 8.2	17.5 ± 8	9/27

perception threshold (VPT) and peripheral vascular disease by ankle/brachial index (ABI).

Characteristics of shoes and insoles

The shoes were designed according to Towey guidelines (4): super-depth to fit customized insoles and toe deformities and soft thermoformable leather with semi-rocker soles. The customized insoles were shaped by cast using Alcapy, a material derived from PPT (Professional Protective Technology, Deer Park, NY), to relieve local pressures and Alcaform, a material derived from plastazote, to absorb high-pressure points.

Statistical analysis

All results are expressed as means ± SD. Statistics were calculated using an Apple Macintosh computer programmed with a standard statistical package (Statview). Analysis of variance and multiple regression analysis were performed as indicated. χ^2 test was used to compare the ulcer relapse frequencies among groups. *P* values <0.05 were considered signifi-

cant. The incidence of an ulcer was taken as the incidence of first ulcer relapse only.

RESULTS—ABI (1 ± 0.2 in C and 0.95 ± 0.2 in P) and VPT (31 ± 12 mV in C and 33 ± 9 in P) indicate the same risk for foot ulceration in both groups. Figure 1 reports the cumulative incidence of relapses during a 12-month observation period. In the C group, there was a high incidence of relapses during the first 2 months of observation, reaching 30%. A further increase was observed during the following 4–5 months, reaching values higher than 50%. P group showed a relatively low incidence during the first 7 months, followed by a small increase after that time. The percentage of relapses over 1 year was 58.3 in C group and 27.7 in P group (*P* = 0.009; odds ratio = 0.26; 95% confidence interval [CI] = 0.2–1.5). The use of therapeutic shoes was negatively associated with foot ulcer relapses (coefficient of variation = -0.315; 95% CI = -0.54–-0.08; *P* = 0.009) in a model of multiple regression analysis adjusted for age, sex, type of diabetes, duration of disease, HbA_{1c}, retinopathy, nephropathy, ABI, and VPT. The mean ulcer-free time was longer in P than in C group (9.1 ± 3.7 vs. 3.7 ± 3.1 months; *P* < 0.02). No differences with respect to age, duration of disease, or risk factors for foot ulceration were observed for patients with or without foot ulcer relapses in both the C and P groups. No differences in the use of therapeutic shoes (always rated as frequent or continuous) were recorded between patients with or without relapses in the P group.

ulcer prevention program. Patients with severely deformed feet require custom-molded shoes (6–8), and patients with minor foot deformities may benefit from using athletic shoes (3,8). Other patients at high risk may benefit from wearing special shoes, while not requiring expensive custom-made shoes. Some companies have marketed shoes for diabetic patients, but there are no comparative data establishing their absolute or relative efficacy.

Our study indicates the efficacy of manufactured shoes with customized insoles in preventing reulceration in a group of patients at similar risk. In previous works, the ulcer relapse rate reported using customized shoes (6,7) is more or less similar to that obtained in our experience with manufactured shoes that cost five times less. The availability of therapeutic footwear at low cost may contribute to its diffusion.

In our country, the public health service covers the expense of therapeutic shoes only in a very limited number of cases, and in our protocol, the presence of a control group without special shoes is justified by the need for information for the National Health Service to reimburse a larger number of patients for special shoes. Another point relates to the quality of products marketed for the diabetic community. In a survey of their local footwear retailers, Masson et al. (10) found that only 1 out of 22 shops provided any information about the needs of diabetic patients in their staff training programs. On the other hand, the American Diabetes Association clearly indicates in its position statement (11) that "if unfamiliar with therapeutic footwear, the health-care provider should seek assistance from a qualified footwear specialist." This underlines the fact that there may be cases in which medical professionals and/or shoe manufacturers are unable to either prescribe or make shoes for diabetic patients. In these cases, prescribed footwear may be useless when not outright dangerous (12). The availability of manufactured shoes with an established positive effect

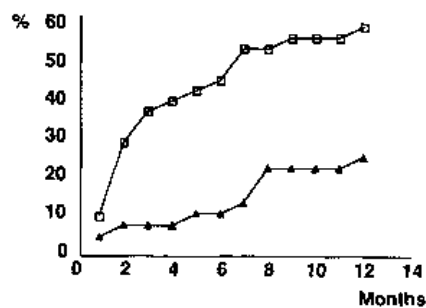


Figure 1—Cumulative incidence of foot ulcer relapses in control (□) and Podiabetes (▲) groups during 12 months of observation.

DISCUSSION—The provision of proper footwear is a cornerstone of any

on ulcer relapses may represent an additional opportunity in terms of ulcer prevention.

The relapses in the treated group may not be attributed to compliance in wearing therapeutic shoes, and we cannot exclude that in some occasions the insoles did not completely relieve the pressure peaks. The availability of devices to measure internal foot pressure will allow us to further elucidate this matter.

In conclusion, our comparative data establish the efficacy of specially manufactured shoes in preventing ulcer relapses in high-risk diabetic patients. Use of these shoes is recommended in order to reduce ulceration and consequently the amputation rate in the diabetic population.

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