# Effectiveness of Diabetic Therapeutic Footwear in Preventing Reulceration

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**OBJECTIVE** — To review the evidence for the effectiveness of therapeutic footwear in preventing foot reulceration in individuals with diabetes and foot risk factors.

**RESEARCH DESIGN AND METHODS** — We conducted a structured literature review based on a Medline search for studies of therapeutic footwear that examined prevention of reulceration. Nine published articles were identified. Characteristics of the study population, components of the intervention, and level of adherence were evaluated. U.S. Preventive Services Task Force criteria for evaluating research were applied to rate each study on study design and internal validity.

**RESULTS** — Risk ratios in all studies assessing the association between therapeutic footwear and reulceration were below 1.0, suggesting some protective footwear benefit. However, in the most rigorous experimental study, no statistically significant benefit was observed between control patients wearing their own footwear and intervention patients wearing study footwear. Annual reulceration in these studies' control groups ranged from 8.4 to 59.3%. In patients with severe foot deformity or prior toe or ray amputation, observational studies suggested a significant protective benefit from therapeutic footwear.

**CONCLUSIONS** — Therapeutic footwear has been used for decades as one of many strategies to prevent reulceration in patients with diabetes and foot risk factors. The findings of several studies reporting statistically significant protective effects from therapeutic footwear may have been influenced by several design issues. When considering the appropriateness of therapeutic footwear recommendations for moderate-risk patients, clinicians and patients should jointly explore individual strategies to decrease events that lead to foot ulcers.

*Diabetes Care* 27:1774–1782, 2004

Preventing foot ulcers in individuals with diabetes is a major clinical objective for diabetes care providers because foot ulcers can lead to lower-limb amputations. In a study of causal pathways to amputation, Pecoraro et al. (1) reported that ulcers preceded 84% of diabetes-related amputations. In 1997, 68% of U.S. amputations were in individuals with diabetes. Of these diabetes-related amputations, 53% involved toes and feet and 47% were at the transtibial or transfemoral level (2). Efforts to prevent ulcers and reulceration may avoid serious sequelae that reduce patients' quality of life and increase their health care costs (3).

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Received for publication 17 October 2003 and accepted in revised form 1 March 2004.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.



Published strategies for preventing reulceration include multidisciplinary foot care, debridement of callus and nails, patient self-management education, and therapeutic footwear because foot ulcers and amputations have been attributed to poorly fitting footwear (1,4–7). Therapeutic footwear was publicized as a way to prevent ulcers, amputations, hospitalizations, and costs when Congress approved this benefit contingent on a demonstration study showing cost savings or cost neutrality (8,9).

Clinical recommendations for people with diabetes include provision of special footwear to individuals with diabetes and foot risk factors (10–13). Footwear benefits have been widely promoted and accepted in the clinical community despite limited experimental evidence on the effectiveness of therapeutic footwear in preventing foot reulceration (14). The purpose of this article is to review the evidence for the effectiveness of therapeutic footwear in preventing reulceration in people with diabetes and to discuss factors influencing study findings.

## RESEARCH DESIGN AND METHODS

— A Medline search was conducted for studies of therapeutic footwear and reulceration in individuals with diabetes from 1980 to the present that included the following keywords: "diabetes" or "footwear" AND "ulcer" or "treatment" or "costs" or "amputation" or "shoes." This initial search yielded 393 citations published in the English language. The articles were classified into two general categories according to the type of intervention: *1*) footwear used with other interventions and *2*) footwear or footwear reimbursement as the primary intervention.

We included for further consideration all randomized and nonrandomized controlled trials, analytic studies, and descriptive studies examining prevention of reulceration in people with diabetes. Studies that examined surrogate outcomes such as plantar pressure reduction and ulcer treatment strategies (e.g., total contact casting, bivalve boots, and healing sandals) or first ulcers were excluded. Studies were retained if the therapeutic

**Table 1—*U.S. Preventive Services Task Force System for Evaluating Evidence***

| Study design rating | Study design | Internal validity ratings |
|---|---|---|
| I | Randomized clinical trial | Assignment of Good, Fair, or Poor based on clarity of the intervention(s), acceptable randomization, absence of selection bias in nonrandomized studies, addressing loss to follow-up, adjusting for potential confounders, and addressing all important outcomes. |
| II-1 | Well-designed controlled trial without randomization | |
| II-2 | Cohort or case-control analytic study (with control group) | |
| II-3 | Multiple time series or dramatic results in uncontrolled experiments | No validity ratings assigned for studies rated II-3 or III. |
| III | Descriptive study | |

Source: ref. 19.

footwear intervention included either off-the-shelf therapeutic shoes with custom or generic inserts or custom shoes with custom inserts. Therapeutic off-the-shelf footwear are preassembled shoes with an adjustable depth insert, whereas custom shoes are shoes that are built based on a replica or mold of a patient's foot (15). References from all published therapeutic footwear articles, one Cochrane review, and two National Health Service Health Technology Assessments were cross-referenced to ensure capture of all relevant literature, but no additional studies were identified (16–18).

Each study was uniformly abstracted for information on study design and research methodology, sample characteristics, randomization, control groups, reulceration risk, type of intervention, and clinical findings. The project team independently rated each article on study design and internal validity using criteria from the U.S. Preventive Services Task Force, as described in Table 1 (19). The risk of reulceration in each study sample was based on the patients' history of foot ulcers (moderate risk) and/or a history of severe foot deformities and prior amputations (high risk).

**RESULTS** — Nine published articles on therapeutic footwear for individuals with diabetes that examined prevention of reulceration were identified. These articles included two randomized and one nonrandomized controlled trial, two analytic studies, and three descriptive studies. Two articles reported findings from the same randomized controlled trial (8,9).

### Multifactoral interventions including therapeutic footwear

Three studies used interventions with multiple components to examine the effect of therapeutic footwear on ulcer outcomes (Table 2) (4,6,20). The purpose of a descriptive study by Edmonds et al. (6) was to evaluate the role of a specialized diabetic foot clinic on limb survival. The multidisciplinary team consisted of a physician, consulting orthopedic and vascular surgeons, chiropodists, nurses, and a shoe fitter. One of many services offered was a pair of custom shoes. Edmond's patients were divided into two groups: a neuropathy group, 16% of whom had either a Charcot deformity or ray amputation at baseline, and an ischemic group, who lacked foot pulses and of whom 65% had ankle jerks. Tight ill-fitting footwear was identified as the most frequent precipitating factor for 68% of the neuropathy group and 88% of the ischemic group. The custom footwear was accepted and worn by 58% of the neuropathy group and 57% of the ischemic group. The remainder in both groups either did not receive or did not wear the custom shoes and served as the referent group.

The intervention included foot assessments, debridement, wound care, treatment of infection and edema, arteriography as necessary, and patient education on foot care practices at every visit. The average follow-up visit intervals approximated 3.5 weeks during ulcer healing and 7.5 weeks after healing. After initial healing, 121 of the original 148 neuropathy group patients were further observed for 26 months. Four patients underwent transtibial amputation, and 23 other patients were not followed. Of patients in the neuropathy group who wore therapeutic footwear, 26% reulcerated compared with 83% of patients in the referent group (risk ratio 0.31, 95% CI 0.24–0.46). In the ischemic ulcer follow-up group, 25% of individuals wearing custom shoes reulcerated compared with 83% of the referent group (0.30, 0.22–0.53) (6).

These findings suggest a benefit of therapeutic footwear for high-risk patients but are not definitive because the study design did not randomize patients and used a nonoptimal reference group, and the multifactor intervention precludes the separation of footwear benefits from other intervention benefits. The study design was rated II-3 because of its descriptive nature.

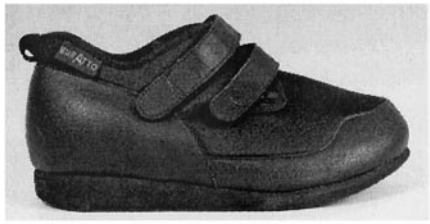
Dargis et al. (4) conducted a study in Lithuania to determine if a multidisciplinary approach to foot care would reduce reulceration and amputations compared with standard care over a 2-year period. All patients had a previous neuropathic ulcer and no peripheral vascular disease, Charcot deformity, or prior amputation; thus, they were at moderate risk of reulceration. Intervention group patients received care at a multidisciplinary clinic in a rehabilitation hospital in the city of Kaunas. The intervention included provision of extra-depth shoes and plastazote, multiform, or silicone inserts; foot care education; and follow-up visits at least every 3 months for debridement, callus removal, wound dressing changes, nail cutting, and foot care reeducation. The control group patients, drawn from seven clinics in other areas of Lithuania, received the standard of care for those outlying areas and follow-up visits every 3 months (4).

Over the 2-year follow-up, 30.4% of the treatment group in the multidisciplinary clinic developed recurrent ulcers compared with 58.4% in the control group (risk ratio 0.51, 95% CI 0.31–0.80). The intervention, inclusion criteria, and loss to follow-up were clearly presented. The clinical care and footwear interventions appeared to be provided by the same staff. The following question remains: To what extent was the footwear effect confounded by other interventions in the multidisciplinary clinic, the nonrandom treatment assignment, nonadherence with footwear, and regional practice variation between the central

**Table 2—*Multifactor studies to prevent lower-extremity reulceration in persons with diabetes***

| Author, year, site | Study design and average follow-up | Inclusion criteria | Intervention | Study groups | Sample characteristics | | | | Findings | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Average | | Average diabetes duration (years) | | |
| | | | | | *n* | Age (years) | Male (%) | | Clinical* | Ratings† |
| Edmonds, 1986, U.K. | Descriptive study; ~2.2 years | Treated in diabetic foot referral clinic | Therapeutic footwear (Dru shoe) with plastozote insoles or custom shoe inserts, patient education, foot assessment, wound care, debridement, follow-up visit every 3.5 weeks on average during ulcer episode | Neuropathic | 86 | 59 | 47 | 16 | 26% of neuropathic patients wearing footwear vs. 83% of patients in own footwear reulcerated (RR 0.31, 95% CI 0.24–0.46)‡ | Study design: II-3 |
| | | | | Noncompliant | 35 | 59 | 47 | 16 | | Internal validity: NA |
| | | | | Ischemic | 52 | 69 | 53 | 15 | 26% of ischemic patients wearing footwear vs. 83% of patients in own footwear reulcerated (RR 0.30, 0.22– 0.53)‡ | |
| | | | | Noncompliant | 18 | 69 | 53 | 15 | | |
| Dargis, 1999, Lithuania | Cohort study; control subjects in seven clinics in other regions of Lithuania; 24 months | Previous history of ulcer, neuropathic disability, palpable foot pulse, no past history of amputation, no Charcot foot | Multidisciplinary clinic foot care; extra-depth shoes with plastazote, multiform or silicone insoles; foot care education in both arms; follow-up every 3 months | Intervention | 56 | 59 | 48 | 14 | 30% in intervention clinic reulcerated | Study design: II-2 |
| | | | | Control | 89 | 59 | 47 | 16 | 58% in control clinic (odds ratio 0.31; RR 0.51, 0.31–0.80)‡ amputation: 7 vs. 14% | Internal validity: Fair |
| Uccioli, 1995, Italy | Two-site controlled trial with alternate allocation; 12 months | Prior foot ulcer and no current ulceration, no minor or major amputation, and no major foot deformities | Therapeutic footwear with custom molded insole; education; follow-up visit at 6 months | Intervention | 33 | 70 | 60 | 17 | 27.7% in intervention group reulcerated | Study design: II-1 |
| | | | | Control | 36 | 60 | 64 | 18 | 58.3% in control group (odds ratio 0.26; RR 0.47, 0.23–0.90)‡ | Internal validity: Fair |

*Risk ratios (RRs) presented from original article unless otherwise indicated (‡). †U.S. Preventive Services Task Force Study design ratings from Table 1.



*Uccioli Study Shoe Worn By Men and Women (20)*

*Chantelau Study Shoe Worn By Women (21)*

*Reiber Study Shoe Worn By Women (24)*

**Figure 1—***Examples of footwear from three studies of therapeutic footwear.*

treatment hospital and outlying control clinics? The Dargis study was assigned a II-2 study design rating and a Fair internal validity.

In the third multifactor intervention study, 69 men and women with previous foot ulcers or at high risk for reulceration at two clinical sites in Italy were alternatively assigned to a footwear intervention or a control group to determine if Podiabetes shoes specially designed for diabetic patients by Buratto could prevent foot reulceration (20). The same design shoes with tri-density inserts were provided to 33 intervention men and women at two sites (Fig. 1). Patient education on foot care and appropriate footwear was provided to both groups, and patients were seen at 6 months to assess footwear adherence and receive new footwear. The study did not use randomization, but rather used alternate treatment allocation; thus, it received a II-1 study design rating (Table 1).

Ulcer occurrence was unevenly distributed over time, with 30% of control patients' ulcers occurring within the first 2 months. After 1 year of follow-up, 27.7% of patients who received study footwear reulcerated compared with 58.3% of patients who wore their own footwear (risk ratio 0.47, 95% CI 0.23–0.90). The authors did not specify whether there was any separation of foot care from the footwear intervention, which could lead to contamination of the intervention. This study is generalizable to moderate-risk patients of both sexes wearing one shoe style (Fig. 1). The internal validity of this study was rated as Fair based on a lack of information on loss of patients to follow-up and potential contamination of the footwear intervention with foot care.

### Therapeutic footwear as the primary intervention

Six studies examined the singular effect of therapeutic footwear or reimbursement for footwear on the prevention of reulceration (Table 2). Chantelau et al. (21,22) conducted two descriptive studies of therapeutic footwear as the primary intervention on patients with diabetic foot complications (a history of polyneuropathy, limb ischemia, foot ulceration, or prior forefoot or toe amputation) in a German population at moderate to high risk of reulceration. Both studies were assigned a II-3 study design rating because of their descriptive nature. In the 1990 study, 50 consecutive patients with "diabetes foot syndrome" were recruited from an outpatient diabetes foot clinic. Of these 50 patients, 72% had prior foot ulcers and 30% had a prior toe or forefoot amputation. The clinical course of these patients was observed after the provision of custom shoes with cork, plastazote, and leather insoles (Fig. 1). After 25 months, 41 patients survived (21). Patients who wore their custom shoes daily were significantly less likely to have reulceration compared with patients who wore their custom footwear infrequently (risk ratio 0.48, 95% CI 0.29–0.79).

Chantelau's second descriptive study tracked 51 patients with a history of neuropathic foot ulcers, including some patients from the 1990 study, to assess the influence of patient's footwear adherence on reulceration risk (22). All 51 patients were provided custom shoes with plastazote, neoprene, and poron inserts (Fig. 1). There were 37 patients who were considered compliant because they wore their therapeutic footwear at least 60% of the time (Table 2). The referent group included individuals who were noncompliant. At 20 months, 8% of compliant patients reulcerated compared with 38% of noncompliant patients (risk ratio 0.23, 95% CI 0.05–0.98). At 40 months, 54% of the compliant patients reulcerated compared with 100% of the noncompliant patients (22). Even the compliant high-risk population experienced high reulceration rates.

Two published studies provide results from the Medicare Therapeutic Shoe Demonstration (8,9). A randomized trial of reimbursement for footwear was mandated in the same legislation that instituted the Medicare footwear benefit. The Congressional mandate required a 2-year trial to determine whether the footwear benefit was cost neutral to Medicare and a 2-year extension to examine cost increases should cost savings not be found in the first 2 years. The mandate explicitly defined the primary outcome not as a clinical benefit but as a "one-tailed test of cost savings" (8). Patients were randomized to receive either a benefit that would reimburse 80% of the cost of therapeutic shoes or no footwear reimbursement.

These two studies were assigned a study design rating of I because of their randomized controlled trial design.

Between August 1989 and October 1991, 1,711 patients were assigned to the treatment group and 1,717 were assigned to the control group. Participants were from California, Florida, and New York and were followed for 12 months for foot complications including amputations (8). Amputation rates were not significantly different between the two groups (risk ratio 1.42, 95% CI 0.88–2.30). At the end of the trial in October 1992, 4,373 patients had been randomized and enrolled for an average of 20 months. The study sample was at moderate to high risk of reulceration because 59% of participants had prior foot ulcers and 25% had prior amputations (9).

There were no utilization or cost differences between the two groups at 1 year (8), which may have been due to an observed effect size and a sample size that were much smaller than expected. The observed difference in cost was much lower than the expected 6% difference, which reduced study power from 80 to 23% (assuming equal variances and a 0.10 significance level) and reduced the likelihood of rejecting the null hypothesis. The reduction in power was also compounded by the use of one-tailed tests to assess cost differences, which reduced the type I error (rejecting the null hypothesis when the null is true). In the final report to Congress, Wooldridge et al. (23) stated that the study would have needed 247,000 beneficiaries to achieve statistical significance for the actual cost difference observed in their sample. Thus, not only was the effect size lower than expected, but also study enrollment was far below target (4,373 patients were enrolled instead of the 27,500 patients expected).

Lack of power also affected the analyses of amputation as the outcome. Had the sample size been 27,500 as originally planned and had the same amputation rates been observed, the higher amputation rate in the treatment group would have been statistically significant, running counter to the expected clinical footwear benefit. Given the low adherence in obtaining footwear (32% of patients in both groups already owned therapeutic footwear) and the limited study population, the study was assigned a Poor internal validity rating (Table 3). Despite these issues, Medicare initiated a footwear benefit in 1993 without either efficacy or effectiveness studies.

Reiber et al. (24) conducted a randomized trial designed to determine if extra-depth and extra-width footwear and two types of inserts would reduce reulceration in 400 patients with a reported history of foot ulcers but no lower-extremity amputations of more than one digit and no requirement for custom footwear. The study randomized patients into one of three groups: 121 patients were provided three pairs of therapeutic shoes (Fig. 1) and three pairs of customized cork and neoprene inserts; 119 patients were given three pairs of therapeutic shoes and three pairs of prefabricated polyurethane and nylon inserts; and 160 control subjects wore their own footwear (Table 2). Lightweight terrycloth house slippers were provided to all study participants to equalize the "out-of-shoe" exposure (24).

This randomized clinical trial was assigned a study design rating of I. Two-year follow-up results indicate that therapeutic shoes did not significantly reduce reulceration comparing the intervention and control patients (risk ratio 0.88, 95% CI 0.51–1.52, for the cork insert group; 0.85, 0.48–1.48, for the prefabricated insert group). The study team assigned a Good internal validity rating because of information on loss to follow-up, footwear nonadherence, uniform shoe outsoles, assessment of important outcomes, and the use of intention-to-treat analysis. A limitation of this study was only 58% of patients lacked sensation to the Semmes-Weinstein monofilament at baseline and 66% at the study's end, so this study could be characterized as having patients at moderate risk of reulceration. In response to suggestions in two letters to the editor that footwear might have been protective for patients lacking sensation (25,26), a subset analysis of individuals lacking sensation at baseline showed no significant difference between groups regarding benefit of therapeutic footwear and both types of inserts (27).

The final study by Busch and Chantelau (28) tracked 92 insured patients in Germany with a prior ulcer, diagnosed diabetes with complications, polyneuropathy, or peripheral vascular disease but no foot deformities. This analytic study was given a II-2 study design rating. All patients were prescribed off-the-shelf therapeutic footwear between June 1999 and June 2001, 60 of whom obtained it because their insurer agreed to cover part of the footwear costs. Patients in the control group wore their own footwear because their insurer denied footwear coverage. Patients were tracked until reulceration or study end at 42 months. One-year follow-up results indicate that therapeutic shoes significantly reduced reulceration (risk ratio 0.25, 95% CI 0.12–0.51). The internal validity of this study was rated as Poor based on nonrandomization, uncertainty on whether insurance denial was a proxy for insurance differences or lower incomes, the absence of multivariate analysis, and a lack of information on footwear adherence.

Diabetic footwear was discussed in two published reviews of clinical trials to prevent ulceration or reulceration (16,17). In a 2001 Cochrane Collaboration review of published trials, Spencer (16) concluded that poor methodology prevented the recommendation of any type of footwear. Majid et al. (17) reviewed published and unpublished trials of ulcer prevention and treatment for the Health Technology Assessment Program in the U.K.'s National Health Service and concluded that no current treatment strategy had a sufficient evidence base to support widespread adoption.

Clinical findings from the reported studies are summarized by annual incidence, risk ratios, and 95% CIs for studies that presented these parameters or provided data to permit these calculations (29,30) (Table 4). A striking finding is the sevenfold variation in reulceration among the control populations. The risk ratio of amputations in the Wooldridge studies (8,23) was calculated to be 1.42 (not significant), and the annual incidence of amputations per 100 subjects was 2.6 in the intervention group and 1.8 in the control group (not reported).

**CONCLUSIONS** — Risk ratios in studies assessing the association between therapeutic footwear and reulceration are uniformly below 1.0. However, two clinical trials (8,24) found no significant protective benefit of therapeutic footwear, while analytic and descriptive studies reported significant protective findings. There are six fundamental issues important in evaluating footwear and reulceration findings: *1*) the heterogeneity in study design, *2*) patient reulceration risk, *3*) follow-up and study outcome criteria,

**Table 3—*Studies of therapeutic footwear to prevent lower-extremity reulceration in individuals with diabetes***

| | | | | | Sample characteristics | | | | Findings | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Average | | | | |
| Author, year, site | Study design and average duration | Inclusion criteria | Intervention | Study groups | *n* | Age (years) | Male (%) | Average diabetes duration | Clinical* | Ratings† |
| Chantelau, 1990, Germany | Descriptive study; 25 months | Neuropathy diabetes clinic, prior healed ulcer, no severe peripheral vascular disease | Bespoke shoe with cushioned insole | Combined | 41 | 59 | 62 | 17 years | 42% of patients wearing shoes daily reulcerated vs. 87% of patients who did not wear shoes daily (RR 0.48, 95% CI 0.29–0.79) | Study design: II-3<br>Internal validity: NA |
| Chantelau, 1994, Germany | Descriptive study; 20 months | Attended foot clinic for 4 years, no ischemic foot lesions | Footwear with plastazote, neoprene, and poron inserts (protective bespoke) | Overall | 51 | 63 | 58 | 20 years | Compliant patients had more foot care and less reulceration (8 vs. 38% at 20 months, RR 0.23, 0.05–0.98)‡ (54 vs. 100% at 40 months) | Study design: II-3<br>Internal validity: NA |
| | | | | Compliant (60% of time) | 37 | — | 60 | — | | |
| Wooldridge 1994 and 1996, U.S. | Randomized controlled trial; 12 months | Hospital admit for diabetes foot issue in 3 years before demonstration; CA, FL, or NY residents in 8/89–10/92 | 80% reimbursement for therapeutic footwear | Intervention benefit | 1,711 | 70 | — | 59% >10 years | Reulceration outcomes not reported | Study design: I |
| | | | | Control | 1,717 | 70 | — | 59% >10 years | Amputation (RR 1.42, 0.88–2.30)‡ | Internal validity: Poor |
| Reiber, 2002, U.S. | Randomized controlled trial; 24 months | Diabetes diagnosis, age 45–84 years, history of foot lesion or infection, can walk, no prior lower-extremity amputation of ≥2 digits, no unhealed lesion, no special footwear or terminal illness | Therapeutic shoes; custom insole; polyurethane insole; slippers; follow-up visit every 17 weeks | Shoe + cork insert | 121 | 61 | 78 | 65% >6 years | No significant reulceration differences between cork and control groups (RR 0.88, 0.51–1.52) or polyurethane and control groups (0.85, 0.48–1.48) | Study design: I<br>Internal validity: Good |
| | | | | Shoe + polyurethane insert | 119 | 62 | 77 | 65% >6 years | | |
| | | | | Control | 160 | 63 | 77 | 70% >6 years | | |
| Busch and Chantelau, 2003, Germany | Cohort study with control subjects whose insurer denied footwear coverage; up to 42 months | Clinic patient from 6/99 to 12/31/01, prior foot ulcer, insured, diabetes with polyneuropathy and/or peripheral vascular disease | Off-the-shelf therapeutic shoe; standardized insole; soft uppers without stiff toe-caps | Shoe | 60 | 62 | 52 | 12 years | 15% of patients with shoes reulcerated at 1 year vs. 60% of patients without shoes (RR 0.25, 0.12–0.51)‡ | Study design: II-2<br>Internal validity: Poor |
| | | | | Control | 32 | 67 | 56 | 15 years | | |

*Risk ratios (RRs) presented from original article unless otherwise indicated (‡). †U.S. Preventive Services Task Force Study design ratings from Table 1.

**Table 4—*Annual incidence and risk ratio for reulceration from seven therapeutic footwear studies***

| | Treatment group | | | Control group | | | | Annual incidence of ulcers per 100 subjects | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Event | No event | Total | Event | No event | Total | Risk ratio (95% CI) | Intervention group | Control group | Intervention group | Control group |
| Edmonds, 1986* | 22 | 64 | 86 | 29 | 6 | 35 | 0.31‖ (0.24–0.46) | 11.8 | 38.2 | — | — |
| Edmonds, 1986† | 13 | 39 | 52 | 15 | 3 | 18 | 0.30‖ (0.22–0.53) | 11.1 | 37.0 | — | — |
| Dargis, 1999 | 17 | 39 | 56 | 50 | 39 | 89 | 0.51‖ (0.31–0.80) | 15.2 | 28.1 | — | — |
| Uccioli, 1995 | 9 | 24 | 33 | 21 | 15 | 36 | 0.47‖ (0.23–0.90) | 27.3 | 58.3 | — | — |
| Chantelau, 1990 | 11 | 15 | 26 | 13 | 2 | 15 | 0.48 (0.29–0.79) | 20.3 | 41.6 | — | — |
| Chantelau, 1994 | 3 | 34 | 37 | 5 | 9 | 14 | 0.23‖ (0.05–0.98) | 4.9 | 21.4 | — | — |
| Reiber, 2002‡ | 18 | 103 | 121 | 27 | 133 | 160 | 0.88 (0.51–1.52) | 7.4 | 8.4 | — | — |
| Reiber, 2002§ | 17 | 102 | 119 | 27 | 133 | 160 | 0.85 (0.48–1.48) | 7.1 | 8.4 | — | — |
| Busch and Chantelau, 2003 | 9 | 51 | 60 | 19 | 13 | 32 | 0.25‖ (0.12–0.51) | 15.0 | 59.3 | — | — |

*Neuropathic group. †Ischemic group. ‡Custom insert and therapeutic shoe group. §Prefabricated tapered polyurethane insert and therapeutic shoe group. ‖Odds ratios and risk ratios presented from original article unless otherwise indicated.

*4*) characteristics of intervention shoes and inserts, *5*) adherence with study footwear and foot protection when patients are out of their study footwear, and *6*) concurrent nonfootwear interventions.

First, randomized clinical trials are recognized as the gold standard for estimating treatment effects and are assigned the highest study design rating by the U.S. Preventive Services Task Force (19,31). Only two studies of the eight published articles in this review were randomized clinical trials (8,9,24). Given the uncertain knowledge about disease course and the usual large variations in biological measures, it is difficult to determine on the basis of uncontrolled clinical observation whether a new treatment has altered an outcome and, if it has, to what extent. A clinical trial provides an opportunity to make a judgment because the control group ideally is comparable to the intervention group in every way except for the intervention being studied (32).

The strategy of using noncompliant patients as the footwear comparison group is suboptimal. These patients may have other characteristics that suggest less attention to health care recommendations and other characteristics dissimilar to the intervention group. Tantalizing findings from these descriptive studies often show regression to the mean when tested using a more rigorous study design. The final point about clinical trials is the use of accepted publication strategies such as the "Beyond CONSORT criteria" to allow uniform discussion of study protocols, strategies for randomization, participant flow, follow-up, and methods to ascertain the outcome (33).

Second, reulceration risk (influenced by patient inclusion and exclusion criteria) varied widely across studies. Some studies included patients with severe foot deformities (e.g., Charcot abnormalities and prior toe or ray amputations). Perhaps the best evidence supporting this observation is the sevenfold variation in annual ulcer incidence observed in the control population (Table 4). In populations with very high annual ulcer incidence, it is far easier to achieve significant reductions with intervention strategies than in populations with low rates.

Third, optimally, studies will specify regular follow-up protocols, account for all study patients, and have independent observers determine the outcome. Failure to account for the entire study population and the assessment of the outcome by the same providers delivering the intervention introduces potential for bias.

Fourth, the characteristics of intervention shoes and inserts used in each study differed, which could have influenced reulceration rates. Differences include the shape of the lasts, the inserts, the materials, and the manufacturing techniques. Not surprisingly, the footwear had different esthetic appeal, as demonstrated by the footwear from the Uccioli, Chantelau, and Reiber studies in Fig. 1 (20,21,24). All of these shoe and insert characteristics have the potential to influence reulceration rates.

Other pivotal events leading to reulceration include minor environmental trauma, self-care injury, and progression of vascular disease that would not necessarily be affected by the provision of therapeutic footwear. One study provided slippers to intervention and control patients to balance the out-of-footwear exposure to minor trauma (24).

Fifth, patient adherence strongly influences the benefit of a footwear intervention. Chantelau et al. (21,22) indicated that 63% of patients followed for 2 years wore their shoes every day and that 72% of patients followed over 4 years wore their shoes at least 60% of the time. In the trial by Reiber et al. (24), 85% of patients in the two intervention groups were compliant in wearing therapeutic shoes.

Failure to obtain or wear recommended therapeutic footwear underestimates the clinical benefit of footwear in an intention-to-treat analysis (34,35). In the Medicare Therapeutic Shoe Demonstration, only 71% of the intervention group eligible for reimbursement actually obtained therapeutic shoes, and only 23% of this 71% in the treatment group renewed their prescription in the following year (8) (Table 3). Three years after the Medicare demonstration started, 85% of beneficiaries in the treatment group had therapeutic footwear, but only 61% reported wearing therapeutic shoes outside of the home (9).

The low rate of footwear acquisition in Medicare may be affected by the re-

quirements that a Medicare beneficiary with diabetes has to meet to obtain reimbursement: *1*) have Medicare Part B coverage, *2*) currently be under a doctor's comprehensive plan of care for diabetes, and *3*) have a history of foot ulceration, partial or complete amputation of the foot, peripheral neuropathy with evidence of callus formation, foot deformity, or poor circulation.

In a study of English clinic diabetic patients, Knowles and Boulton (36) found that only 22% of patients wore therapeutic footwear regularly. In light of data on the acquisition and use of footwear, it is not surprising that the reported clinical benefits of therapeutic footwear have been equivocal when study design and internal validity are considered.

Sixth, three studies had multifactorial interventions that combined footwear with other nonfootwear interventions. The benefit of preventive callus, nail care and other foot care, multidisciplinary consultation, and patient self-management could not be separated from the sole provision of footwear. Further, the potential to contaminate the intervention by mixing foot care and footwear interventions is present in several of these studies.

In conclusion, results from the descriptive and alternate allocation studies are encouraging. However, after factoring in study design principles, appropriate comparison groups, and complete follow-up, the evidence is less compelling. It is a popular belief that therapeutic shoes and inserts should be dispensed freely to all patients with diabetes; however, there is not consistent evidence to support this practice. The community concerned with the prevention and treatment of diabetic foot complications is faced with a dilemma. In light of the evidence, health care providers should carefully evaluate the evidence for footwear apart from foot care and education. Finally, providers and patients should jointly explore individualized strategies to decrease the events that give rise to foot ulcers.

**Acknowledgments**— This study was funded by the Department of Veterans Affairs.

The helpful comments from Eric Johnson and reviewers are greatly appreciated.

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