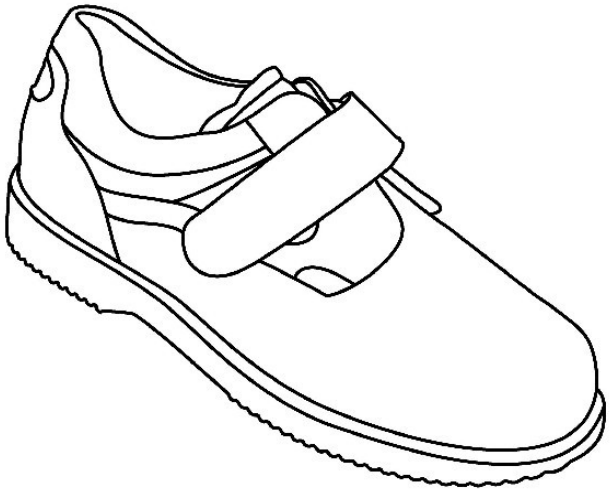
Clinical study of the LucRo®-shoe



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Shortcut

SDS: Stock „diabetic“ shoe

EVA: Ethylen-Vinyl-Acetat

PIVD: peripheral ischaemic vessel disease

PNP: Polyneuropathy

1. Summary

Aims: Diabetic patients with podopathy (diabetic foot syndrome) may need protective footwear, be it customized or industrially produced stock “diabetic” shoes (SDS). The effectiveness of each type pf “diabetic” shoe needs to be proven clinically, e.g. in terms of prevention of foot ulceration. The following study assesses a new German SDS, the LucRo shoe, which consists of rocker-shaped walking sole, a standardized shock absorption insole, and soft uppers without stiff toe-caps. The LucRo SDS has been registered as a Medicinal Product according to the European Community Guideline 93/42/EC.

Methods and patients: A total of 92 high-risk diabetic patients (mean age of 63 years, and a duration of diabetes of 13 years) with healed foot ulcer were recruited prospectively over 31 month; 87 patients suffered from polyneuropathy, 24 patients had peripheral ischaemic vessel disease. One group of patients (n=60) received the LucRo SDS and wore them, while the remaining patients (n=32) did not receive the SDS and were forced to use their normal footwear. This allocation reflects the haphazard reimbursement policies of the individual patients’ health insurances, and is in accordance with the current German legislation. The patients were followed-up to 42 month until the first foot ulcer relapse or the end of the study.

Results: There were no differences between the groups concerning age, sex, type and duration of diabetes, prevalence of polyneuropathy and peripheral ischaemic vessel disease, frequency of foot care and mortality rate. The first year annual rate of foot ulcer relapses was significantly different between the groups: 60% without SDS versus 15% with SDS. The overall cumulative ulcer-free survival was significantly greater with SDS ($p < 0.0001$, log rank test).

Conclusion: The LucRo stock “diabetic” shoe has shown to be highly effective in the prevention of foot re-ulceration in high-risk patients with diabetic podopathy.

2. Introduction

Footwear significantly affects the course of the diabetic foot syndrome (diabetic podopathy). If unsuitable, footwear injures the feed, thereby increasing the risk of amputation in patients with loss of protective sensation. If appropriate, footwear can protect the feet from such lesions. Mismatch between foot and shoe, and “normal” shoe design or materials are causally involved in nearly 80% of all foot lesions that precede amputations in diabetic patients (1). Empirical criteria for the making of special “diabetic” protective footwear have already been devised some time ago (2). However, intervention studies with diabetic footwear are rare, and the proof of its efficacy in terms of clinical endpoints, e.g. prevention of foot ulceration, is still scarce (3). Clinical trials on “diabetic” footwear in free-living patients are difficult to perform: some patients would reject them, for cosmetic reasons, while others would wear them only temporarily (4, 5). However, one of the main problems is the lack of standardization of “diabetic” footwear, and the lack of standardization of the diabetic feet regarding size and shape (6). Previous reports have claimed clinical benefits for some stock “diabetic” shoes, however, there were limitations within the methodology utilized (5, 7 – 9). Due to the fact that to date there is no unequivocal clinical proof as to the effectiveness of “diabetic“ stock shoes, the German health insurance companies generally do not cover the costs of SDS prescription, whereas they are legally obliged to reimburse any kind of prescribed medication. However, on demand some of the approximately 500 various local, regional, and industry-based-health insurances would reimburse approximately 170 EURO for each pair of “diabetic” stock shoe, which is about 2/3 of the total costs. It is not publicly known, which insurances do r do not reimburse the costs for “diabetic” stock shoes; and likewise, neither have the insurances followed their reimbursement policies consistently over time. Thus, the attitude of the German health insurances as to the reimbursement is purely haphazard. The rate of foot ulcers can be appreciably high (58%-100% per year) in unprotected high-risk patients with a history of diabetic foot lesions (9, 10). Treatment with protective footwear can lower this rate considerably (3, 9, 11, 12), which makes a randomized, placebo-controlled trial with an unprotected control group of high-risk patients problematic. The following study was therefore conducted with a cohort of health insurances beneficiaries, to whom their insurance companies - by chance – either provided or withheld “diabetic” stock shoes by covering or not the costs.

3. Study design, patients, materials and methods

3.1 Study design

The study was single centered, prospective cohort study, using health insurance based data, and practice registry and case notes. The study assessed the effects of particular stock „diabetic“ shoe on the rate of foot ulcer relapses in patients with diabetic podopathy. Approval from the local ethics committee was obtained.

3.2 Patients

The patients included in the study all belonged to a large practice oft who internists specializing in diabetology. The practice is located in an industrial city in western Germany (approx. 600.000 inhabitants), and is caring for about 2000 patients with diabetes. The patients were selected from the practice's patients registry according to the following criteria: they had to be beneficiaries of a state-approved or private health insurance, had to have diabetes with complications (ICD-no. 10.7(type-1 diabetes) or ICD-10 no. 11.7(type-2 diabetes)), and hat to have received treatment for a foot ulcer (according to the practice's application for reimbursement for wound care (general practitioners procedures' numbers 2002, or 2004, or 2020, or 2021 wound care)). The foot ulcer had to be healed completely by that practice (see below). The Patients hat to have polyneuropathy (PNP) and/or periphal ischamic vessel disease (PIVD); major foot deformations and limitations in mobility of foot joints had to be absent. A particular type of stock footwear (see below) had to be prescribed within 4 weeks after healing of the ulcer between June 1999 and June 2001; the patients had to remain attached to the practice until the end of the study 31.12.2001.

A total of 92 patients met the inclusion criteria and were followed for ulcer relapses. Their clinical characteristics are summarized in Table 1.

Tab. 1: Clinical characteristics

	Stock „diabetic“ shoe - SDS		
	withheld*	provided*	p-value
Patients with SDS prescription, n	32	60	
Gender (w/m), n	18/14	31/29	n.s.
Age, years	67 (50; 74)	62 (54; 73)	n.s.
Known duration of diabetes, years	15 (6; 23)	12 (5; 15)	n.s.
Length of follow-up, month §	5 (2; 19)	19 (8; 25)	< 0.05
Patients with:			
Type-1 diabetes, n (%)	3 (9 %)	5 (8 %)	n.s.
Type-2 diabetes, n (%)	29 (91 %)	55 (92 %)	n.s.
PNP, n (%)	29 (91 %)	58 (97 %)	n.s.
PIVD, n (%)	8 (25 %)	15 (25 %)	n.s.
Ulcer relapse, n (%)	25 (78 %)	12 (20 %)	< 0,001
Visits to the practice per patient month, n	1.0 (0.6; 1.5)	0.8 (0.5; 1.2)	n.s.
Foot care sessions, per patient and per month, n	0.6 (0.1; 0.7)	0.5 (0.1; 0.6)	n.s.
Patients deceased during follow-up, n (%)	1 (3 %)	4 (7 %)	n.s.

*due to withholding/providing reimbursement by individual patients‘insurance companies.

Medians (Interquartile range) or numbers (n) or percent (%) as indicated.

n.s. = not significant

§ = until ulcer relapse, death, or end of the study

3.3 Definitions

- **Polyneuropathie (PNP)**

PNP was diagnosed using the Rydel-Seiffer tuning fork (13); a vibration sensation < 5/8 at the first metatarsal head was taken indicative of PNP.

- **Peripheral ischaemic vessel disease (PIVK)**

PIVD was diagnosed using a continuous wave 8 mHz Doppler device; an ankle/arm pressure index <1.0 or an abnormal flow-profile suggestive of collateral circulation was taken as indicative of PIVD.

- **Foot ulcer**

A foot ulcer was defined as any partial or complete disruption of the skin (Wagner stage 1-2), with or without inflammation. Healing of an ulcer was defined as complete closure of a lesion with durable skin, leading to the cessation of wound care.

3.4 Stock „diabetic“ shoes (SDS)

To all patients, the same brand of industrially made SDS was prescribed (LucRo, Schein Orthopädie Service KG, Remscheid/Germany), which had basically the same design, but varied in colors and versions for men and women.

Other particular features of the LucRo shoes were as follows:

- Three widths (small, medium, large)
- Stiff, convex walking sole („rocker bottom“) from EVA and rubber (Softgummi)
- Very soft upper of three layers (from inner to outer: cloth, rubberfoam, leather) without any kind of toe cap
- A shock-absorbing standardised, non-moulded insole comprising of three components (rear part 6mm Lunasoft, 42° Shore A hardness; anterior part 6mm Lunaflex, 20° Shore A hardness, covered with 3mm thick p², 17° Shore A hardness)

The outline of the anterior part of the insole is shaped less triangular, but more rectangle (Fig. 1), fitting reasonably to the dimensions of the feet of elderly persons (6) and corresponding with the shape devised by Helbig at al. on the basis of anthropometric measurements in healthy men (14). A picture of such SDS is shown in Fig. 2.

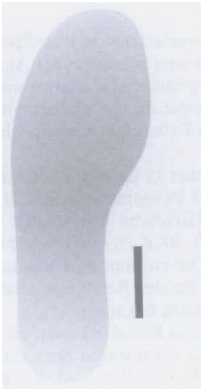

Abb. 1: Insole outline of the „diabetic“ LucRo® shoe. Size 39, French system.

The bar corresponds to 5 cm.

Abb. 2: The LucRo®-shoe (Version for women). The upper is easily deformable.

The softness of the upper- which is easily deformable, see Fig. 2- is required to avoid toe pressure strain. The rocker-bottom decreases peak plantar pressures beneath the metatarsal heads and prolongs pain-free walking distances in cases of PIVD (15) and the insole acts by cushioning the planta pedis in the forefoot area (where most pressure strain occurs during walking). These items (3) had been recommended by Tovey (2) on empirical grounds. Furthermore, the LucRo shoe was designed along earlier experiences with other brands of German SDS (5, 8, 11). When the LucRo SDS was introduced to the market in 1999, they represented the 3rd generation of German SDS. The LucRo SDS has been registered as an approved medicinal product class 1, in confirmation with the European Community Guideline 93/42 EC.

By contrast to these SDS, normal fashion shoes (e.g. Oxford style) mostly have only one width which is too narrow for most diabetic feet (6), have a (stiff) toe cap and hard insoles (3).

3.5 Allovation of stock „diabetic“ shoes (SDS)

To all patients at least one pair of SDS was prescribed, providing the foot shape was suitable for the SDS at the shoe-fitting. The prescription was given to one single retailer (Innova-med. Inc., Haan/Germany), who then by letter applied to the patient's insurance companies for reimbursement. In all cases, he as well as the patients, received response letters of either approval or decline by their insurances. While 15 insurances (including Allgemeine Ortskrankenkasse and various Betriebskrankenkassen) of 60 approved reimbursement of approximately 2/3 of the total costs of approx. 250 EURO, 4 insurances (Deutsche Angestelltenkrankenkasse, Technikerkrankenkasse, Bundesknappschaft, Betriebskrankenkasse Hoesch) of 32 patients categorically declined to reimburse any part of the costs. The former 60 patients did receive the SDS from the retailer and the practice. If the patients were satisfied by the first pair of SDS, one or two more pairs were prescribed and the appropriate reimbursement received.

3.6 Statistics:

Analyses were carried out using Kaplan-Meier life-table analysis, log-rank test, Kruskal-Wallis test and chi square test. Medians are reported with interquartile ranges; 95% confidence intervals were calculated when appropriate. $P<0.05$ was considered statistically significant.

4. Results

The patients were followed prospectively from the date of the prescription of SDS until ulcer relapse or end of the study 31.12.2001 for up to 42 month. During follow up, 5 patients had died, 1 patient with and 4 patients without ulcer relapse. The causes of death (coronary event, suicide, cancer) were unrelated to the diabetic podopathy. The patients differed in the ulcer relapse rates according to whether or not they had received SDS; otherwise, the patient characteristics were similar (Table 1). The 32 patients without SDS were followed until ulcer relapse or end of the study for a median (interquartile range) of 5 (2; 9) month. In the first year of follow-up, 19 patients (60% (95 Cl 43-77%)) had experienced an ulcer relapse and 6 more patients in the remaining time. The 60 patients with SDS were followed for 19 (8; 25) month. In the first year of follow-up, 9 patients (15% (95% Cl 6-24%)) had experienced an ulcer relapse and 3 more patients in the remaining time ($p<0,001$ versus patients without SDS). The absolute risk reduction by the SDS treatment in the first year was 45% (95 Cl 24-64%)

and the number-needed-to-treat was 2, 2 patients per year to prevent one foot ulcer relapse. The ulcer-free proportions of patients over time are depicted in Fig. 3.

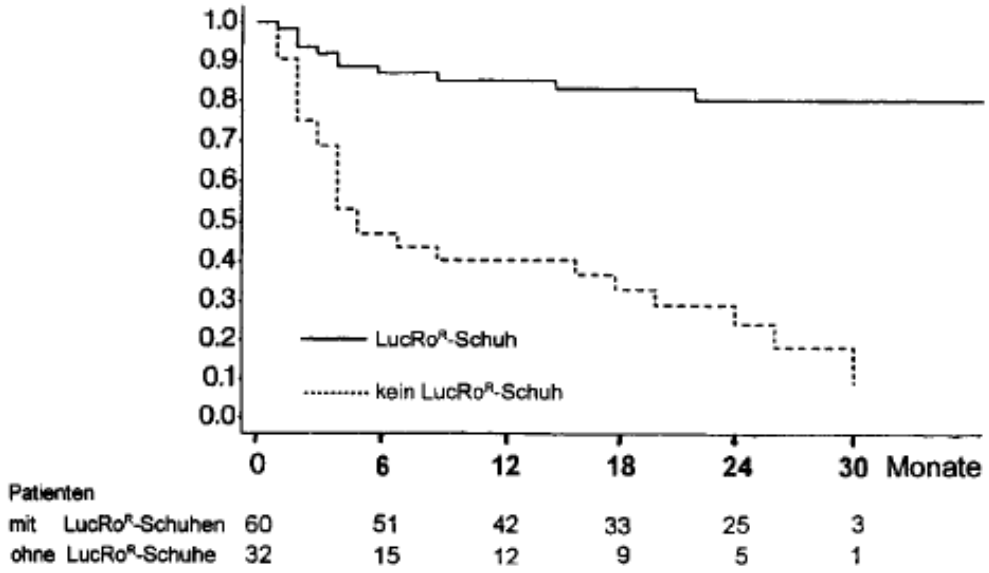

Fig. 3: Proportion of of patients without ulcer (event-free-patients) over time after

Kaplan-Meier. Log-Rank-Test $p < 0{,}001$

5. Comment

The present data confirms that stock „diabetic“ shoes (SDS) with a particular performance can significantly reduce the incidence of foot ulcer relapse in high-risk patients with diabetic podopathy (without foot deformity). The brand of SDS used in the present study, LucRo, has shown similar treatment effects as another brand, Podiabetes by Buratto, which is no longer on the marked (9). The present study is one of the largest controlled trial on prescribed SDS, with a control group of high-risk patients forced to continue with their self-selected non-protective normal footwear. Although all German citizens are legally charged similar health insurance fees and the insurances are legally obliged to reimburse for every medical prescription of state-approved medication and treatment irrespective of the patients' socioeconomic status, the control patients were - by chance – denied SDS by their health insurance companies. As SDS to date have not been officially approved, the health insurances have the right to refuse to pay anything, or to generously reimburse 2/3 of the costs. Withholding reimbursement for SDS by the insurances means that patients do not get it as prescribed. As such inconsistencies unpredictably occur within as well as between the various German health insurance companies, this situation provided an ideal allocation basis with very little potential for bias. The study design deemed even more appropriate as a randomized clinical trial with a placebo-group appeared to be unjustified (16, 17), because of the notoriously poor performance of normal footwear in high-risk patients. Moreover, data material generated by health insurances is increasingly used for analyses of patient outcomes (18, 19).

The study patients were apparently very satisfied with their SDS, as 95% of them applied for a second and a third pair. A high compliance rate, may, thus have contributed to the high effectiveness of the LucRo shoe. Previous studies have shown a correlation between the effectiveness of protective "diabetic" footwear and the length of time the patients were wearing the shoes (5, 11). The present study, however, did not address in particular the length of time the SDS were worn.

As far as foot care is concerned, all patients were offered podiatry (trimming nails and cutting calluses) by the practice staff. However, it was left at the patients' discretion how often they would show up podiatry. In the present study, patients of both groups exhibited roughly the same frequency of podiatry and of visits to the practice in general (Table 1).

„Footwear has never commanded much attention among the medical profession and many doctors do not realize how prescribing comfortable shoes can transform their patients' lives"[20].

Footwear may be extremely cumbersome to study in clinical terms, because it may require prolonged use to show a result (21), might not be very effective (22), or it might decrease the patients' compliance (23). Therefore, many researcher have resorted to surrogate endpoints instead, e.g. to the reduction in plantar pressure by certain kinds of footwear (3, 22, 24), or to a formal evaluation (25). However, the results were not unequivocal (3, 20, 24) and controversies remain (26). Caution is, therefore, required when judging the potential benefits of some protective footwear for diabetic patients at-risk. The clinical proof of the effectiveness, e.g. by preventing foot lesions, remains the gold standard for the evaluation of "diabetic" footwear. This holds true not only for SDS, but also for custom shoes (11) which, to our knowledge have never been studied rigorously in controlled trials.

Finally it must be emphasized that the beneficial effects of LucRo shoes have been obtained in high-risk patients with polyneuropathy and/or peripheral ischaemic vessel disease, who have an extremely high rate of spontaneous re-ulceration of up to 100% per year. It remains to be demonstrated, whether these shoes will also protect patients with spontaneous 7% annual ulcer incidence, which is the incidence rate in "low-risk" diabetic patients without any prior foot ulceration (27). Previous studies with different types of special "diabetic" footwear failed to demonstrate a significant reduction in foot ulcer rates in such "low-risk" patients (28, 29, 39). In 240 low-risk patients without polyneuropathy using special footwear, Reiber at al. (3=) have shown recently unchanged foot ulcer rates, while shoe inducted foot ulcer rate was reduced in 160 high-risk patients using special footwear with particular insoles (9 out of 47 ulcers), as compared to normal footwear (19 out of 27 ulcers) (31).

The prevention of re-ulceration in patients with diabetic podopathy is highly cost-effective, as foot ulceration increases the treatment costs per patient by 10.000 to 16.000 US-Dollars (32), while the costs for 3 pairs of SDS in our study were about 700 US-Dollars. Rangnarson-Tennvall et al. have calculated that high-risk patients a comprehensive prevention program with regular podiatric care and SDS is cost-effective, if it reduces the foot ulcer incidence by at least 25% (33).

In conclusion, the present data indicate that a particular brand of stock „diabetic“ shoe, the LucRo shoe, is effective in reducing the incidence of foot ulcer-relapses by 45% in the first year in high-risk diabetic patients with a polyneuropathy and/or ischaemic vessel disease and a history of foot ulceration. The unequivocal effectiveness of the SDS utilized in the present study (like another brand of SDS in a previous study (9)) warrants that future trials on “diabetic” footwear in high-risk patients should be run as head-to-head comparisons (16, 17), e.g. with a LucRo shoe as reference, rather than as “placebo”-controlled trials.

Conflict of interest statement:

E. Chantelau is a beneficiary of the health insurance *Allgemeine Ortskrankenkasse*;

he has recieved honoraria for consulting the health insurances *Bundesverband der Betriebskrankenkassen, Essen/Germany* and *Allgemeine Ortskrankenkassen Bundesverband, Bonn/Germany*. K. Busch has no conflict of interest.

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