Effectiveness and Safety of Using Podikon Digital Silicone Padding in the Primary Prevention of Neuropathic Lesions in the Forefoot of Diabetic Patients

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Background: In diabetic patients with complications from peripheral neuropathy, the hyperpressure areas can rapidly lead to ulcerative lesions in the absence of protective sensation. Partial digital silicone orthoses could provide an innovative and functional therapeutic solution in the management of preulcerative areas of the forefoot in neuropathic diabetic patients. We clinically tested this hypothesis.

Methods: Digital off-loading silicone padding was prepared for 89 neuropathic patients with deformities and localized hyperkeratosis in the forefoot. After 3 months and in basal conditions, the number of areas of hyperkeratosis was evaluated together with the hardness of the skin, the number of active lesions, and any adverse events associated with use of the orthosis. The patients were compared to a control group of 78 randomized patients undergoing standard therapy. In a subgroup of 10 patients, a static and dynamic biomechanical evaluation was also conducted with a computerized podobarometric platform.

Results: Both the number of lesions and the prevalence of hyperkeratosis and skin hardness were significantly lower ($P < .01$) in the group treated with the silicone orthoses than in the control group. No adverse events were reported during the 3 months of observation. The podobarometric analysis highlighted a significant ($P < .001$) reduction of peak pressure in the areas undergoing orthotic correction.

Conclusions: Silicone padding is effective and safe in the prevention of lesions in neuropathic patients at high risk of ulceration and significantly reduces the incidence of new lesions in the 3-month follow-up period compared to standard treatment. (J Am Podiatr Med Assoc 99(1): 28-34, 2009)

Ulceration in the lower limbs of diabetic patients, commonly known as "diabetic foot," is the most frequent and severe chronic complication of diabetes and is attributable to an increase in the incidence of dysmetabolic pathology, caused by a change in lifestyle. The diabetic foot also represents by far the most frequent type of chronic ulceration.[1,2]

Although foot ulcers have a multi-factorial pathogenesis, peripheral neuropathy is the pathogenetic factor that most frequently determines the appearance of lesions. This is attributable to a reduction in the protective sensation and a localized increase in pressure caused by deformities induced by the motor component, above all in the forefoot, where the majority of lesions are located.[3,4] Furthermore, because of the minor amputations patients undergo for conservative reasons, recurrence of ulceration is even more common than the primary lesions, which poses particular management problems.[5]

The recent development of highly biocompatible materials, including silicone obtained by adding a cat-

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alyst to a base substance, has made it possible for removable orthoses to be produced that are capable of correcting or protecting localized hyperpressure areas as a consequence of deformity or partial amputation.[6]

The silicone orthoses can be classified into three groups according to their functions and therapeutic indications. Protective orthoses are designed for protecting hyperpressure areas of the forefoot without modifying its morphology (Fig. 1 A and B). Corrective orthoses are designed for reducing incongruous pressure determined by the nonstructural deformities of the forefoot (Fig. 1C). Additive orthoses are designed to reestablish the relationship between the residual components of the forefoot after partial amputation of toes (Fig. 1D).

The silicone used in producing orthoses is generally in the form of two distinct components: the base and the catalyst. With the new type of silicone (Podikon; Podolife, Rubano, Italy) catalysis takes place by mixing the base and catalyst, which are then added in predetermined precise proportions to achieve the desired final level of hardness.[7] Silicone orthoses are used because of the ability to rebalance the pressure loads on the areas at risk and reducing damage to the structure of the forefoot.[8,9]

The aim of this study was to evaluate the safety and effectiveness of using digital silicone orthoses in the management of preulcerative conditions of the forefoot in neuropathic diabetic patients.

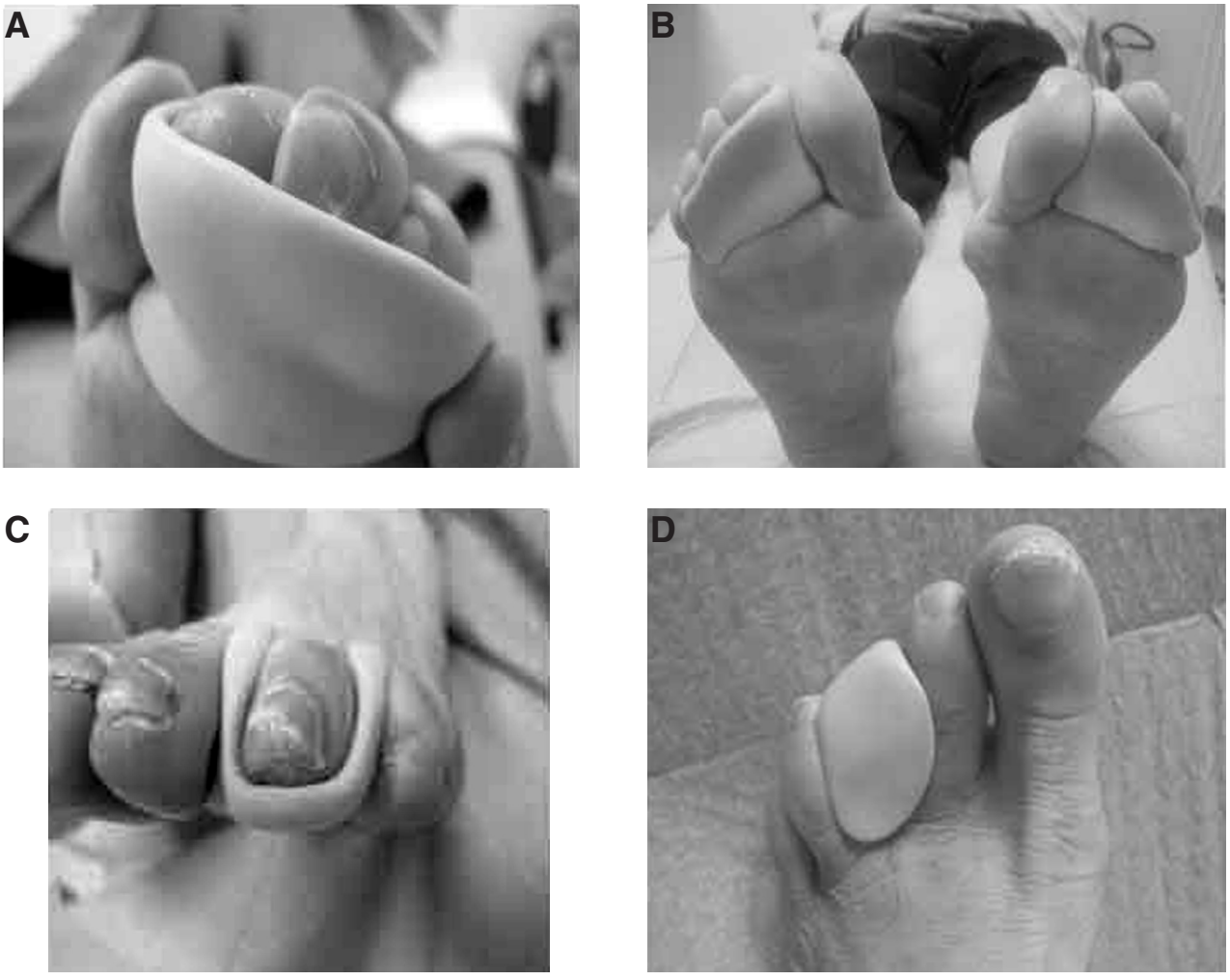

Figure 1. Different kinds of silicone orthoses. A and B, Protective orthoses designed to protect hyperpressure areas in the foot. C, A corrective orthosis designed to correct nonstructural deformities of the foot. D, Additive orthosis reestablishes correct morphology of the forefoot after minor amputation.

Materials and Methods

All patients attending the outpatient diabetic foot clinic between January 1, and July 1, 2005, were assessed for inclusion in the study. Inclusion criteria included age older than 18 years, diagnosis with type 1 or type 2 diabetes mellitus for at least 5 years, peripheral neuropathy documented by a threshold of vibratory sensitivity > 25 V measured in the hallux by a biothesiometer, and deformity or preulcerative conditions in the forefoot.

Exclusion criteria included active ulcerative lesions, peripheral macroangiopathy documented by a systolic pressure ankle/arm index < 0.9; local clinical symptoms (erythema, edema, increase in temperature, secretions, skin macerations, pain, or tenderness) or systemic symptoms (fever, leukocytosis) of infection; clinically visible rhagades or dyshidrosis, Charcot's neuroarthropathy in an active or stabilizing phase, and presence of peripheral neuropathies other than peripheral neuropathy.

After the patients gave informed consent, they were randomized into groups A and B, by means of a computer-generated randomizing list. The screening, randomization, and analysis processing are reported in Figure 2 for both groups. The patients in group A underwent a clinical exam to find the number and localization of hyperkeratosis and deformities. In particular, the presence of reduced articular motility in the toes was examined. The hardness of the skin was then measured in the areas with localized hyperkeratosis (Durometer mod. 3001 shore A; AFFRI, Induno Olona, Italy). The hardness of the skin was always determined by the same operator (V.S.), in the same place, and was photographed to guarantee future repetition of the exam using the same methods previously described by Piaggesi et al.[10] The patients then underwent, as is common practice in our diabetic foot clinic, mechanical keratolysis and complete elimination of the hyperkeratotic areas. Patients were then prescribed an accommodating soft insole and extra deep shoe as indicated in the international diabetic foot consensus form.[11]

After the preliminary evaluation, a digital orthosis was made to measure; Podikon 10 and 22 shores with silicone (Podolife, Rubano, Italy) were used. All orthoses were professionally manufactured. The type of orthoses (corrective, additive, or protective) to be made and its hardness (10 and 22 shores) varied by patient depending on the characteristics of the deformity treated and local conditions. Table 1 shows the general guidelines used.

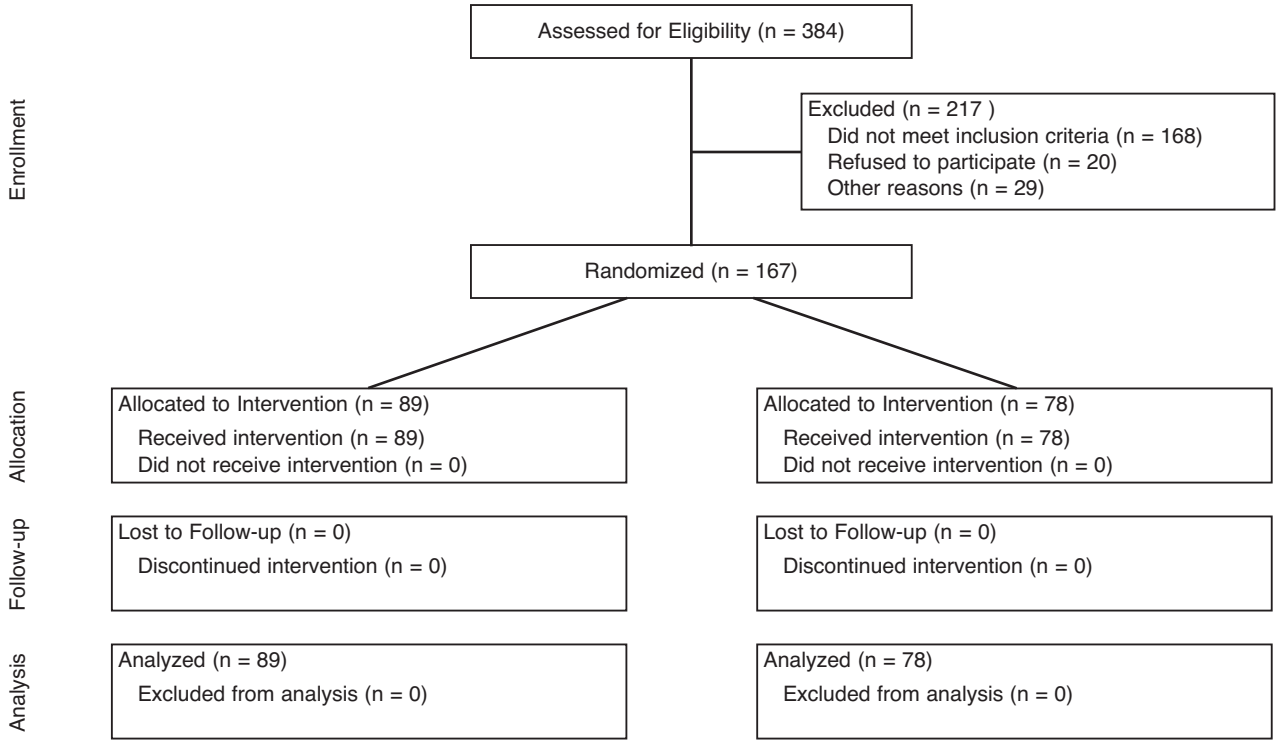

Figure 2. Consort diagram of the study.

Table 1. Clinical Features and Indications for Orthotic Treatment

Clinical Feature	Orthosis Type (Hardness)
Reducible deformities (claw toe, underlapping [curly] toe, hallux valgus) with areas of hyperkeratosis or hyperpressure	Corrective (22 shores)
Nonreducible deformity with hyperkeratosis or hyperpressure	Protective (10–22 shores)
Interdigital hyperkeratosis	Protective (10 shores)

The patients were reexamined 24 hours after the orthosis was prepared to check the position of the device and to see if their were any complications. The patients were also given instructions for managing the orthosis and were told to wear it continuously until the 3-month follow-up examination. During the follow-up examination, the same evaluations were carried out as at the initial examination of the study. The patients in group B underwent all the exams and procedures as in group A, except that they were not fitted with the orthotic protection. The evaluations at the beginning of the study and after 3 months were conducted by individuals other than those who prepared the orthosis and were, therefore, blinded to the treatment and the patients' group assignments.

The following parameters were evaluated at follow-up: the number and typology of deformities and hyperkeratosis, the appearance of ulcers during the 3-month observation period, the number and severity of undesirable effects from application of the orthotic protection, and skin hardness in the localized areas of hyperkeratosis.

A subgroup of ten patients in group A with a mean ± SD age of 72.4 ± 10.2, a duration of diabetes of 13.2 ± 5.2 years, and with a hemoglobin A_{1c} level of 7.4 ± 1.1% underwent a computerized baropodometric examination managed by specific software (Ecotechnology; Ecosanit, Anghiari, Italy).

The exam was conducted both statically and dynamically. In the static exam, patients were evaluated in bipedestation after a 30-sec adjustment period fixing on an infinite optic target at eye level. In the dynamic exam, ten steps were taken by each foot and the results of the average step, provided by the software, were recorded.

The baropodometric exam was conducted before and after application of the orthosis and allowed measurement of maximum peak pressures (kPa) at the points where the silicone device was applied. Other parameters taken into consideration in the baropodometric evaluation included the total surface of the foot (cm^2), the average weightbearing pressure (kPa), and the weight distribution of the forefoot and rearfoot compared to the total (%).

The data, shown as average ± SD, were analyzed with a χ^2 test for the dichotomic categories and variance analysis (ANOVA) and the Mann-Whitney test for the nonparametric data using commercial statistical software (Staview; SAS Institute, Cary, North Carolina). The significance limit was set at 5%.

Results

During the enrollment period, a total of 384 patients were screened, 216 met the inclusion crieteria, and 167 were actually enrolled and randomized into the two groups. Demographic and clinical information of the patients is shown in Table 2.

Of the 49 patients who were not enrolled, 27 lived too far from the clinic and were not able to attend the follow-up exams; 20 refused to give their consent to participate in the study; and two already had a silicone orthosis at the time of the first evaluation.

Hyperkeratosis was present in 93% of the patients in group A and in 91% of the patients in group B, and it was associated with deformities in virtually all patients in both groups. However, deformities in the absence of hyperkeratosis occurred in fewer than 10% in both groups. The area most affected by hyperkeratosis was the plantar area (61% in group A, 70% in group B) followed by the dorsal area (23% in group A, 20% in group B), and the interdigital area (11% in group A, 10% in group B). Stable deformities represented 20% of the total in group A and 18% in group B. There were no significant differences in skin hardness, measured in the areas with hyperkeratosis, be-

Table 2. Demographic and Clinical Characteristics of Patients Studied

	Group A	Group B
No. of patients	89	78
Type 1 diabetes	12	8
Type 2 diabetes	77	70
Age (y)[a]	58.2 ± 17.1	54.9 ± 18.2
Duration of diabetes (y)[a]	15.2 ± 8.9	16.4 ± 9.4
HbA_{1c} (%)[a]	8.2 ± 1.7	7.9 ± 0.9
VPT-Hallux (V)[a]	37.4 ± 10.2	34.1 ± 9.9
Deformity (%)	6	8
Hyperkeratosis (%)	5	6
Deformity and hyperkeratosis (%)	89	86

[a]Data are presented as mean ± SD.

Abbreviations: HbA_{1c}, hemoglobin A_{1c}; VPT, vibration perception threshold.

tween the two groups in basal conditions (71.7 ± 12.4 IU in group A versus 69.8 ± 16.1 in group B; P = .4271). Of the 89 orthoses prepared for the patients in group A, 68% were corrective, 21% were protective, and 11% were of a mixed type. Podikon 22 was used in 77% of the cases, and Podikon 10 was used in 23%.

At the 3-month evaluation, the prevalence of hyperkeratosis was significantly higher in group B than in group A (41% versus 84%, P = .0002). Skin hardness was significantly lower in group A compared to the baseline, but there were no significant differences in group B (Fig. 3).

No adverse events were reported in group A, although in 15 cases (16.8%), the orthosis was removed before the end of the 3-month period because of structural distortion caused by wear. In the 3-month observation period, one ulcer occurred in group A and 12 appeared in group B (1.1% versus 15.4%, P < .001). The results of the evaluations carried out with the computerized podobarometric exam on the ten patients in the subgroup before and after fitting of the orthosis are shown in Table 3.

Although changes were observed in all the considered parameters, only the reduction in maximum peak pressures reached a statistically significant level both in the static and the dynamic exam (P = .001). Other information obtained from the dynamic analysis on strength (17.4 ± 2.0 versus 17.5 ± 1.9 Kgf, P = .932) and integral pressure/time (165.5 ± 59.2 versus 118.7 ± 71.0 kPa/msec, P = .350) did not add significant information.

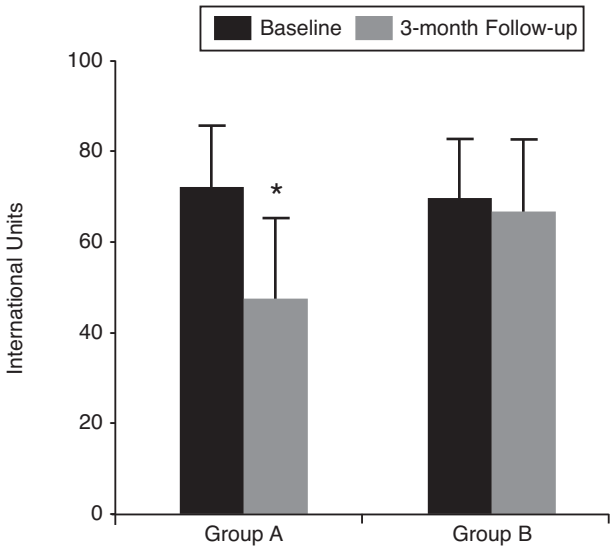

Figure 3. Measurement of hardness of skin with a durometer at baseline and at the 3-month follow-up in the two groups of patients. *P < .01

Discussion

Preulcerative conditions caused by diabetic neuropathy in the foot represent the most frequent cause of ulceration in diabetic patients.[12, 13] The presence of a loss of protective sensation and deformity caused by denervation puts the foot at risk for ulceration directly proportional to the gravity of the neuropathy and is quantifiable up to 18 times that of a diabetic individual without neuropathy.[14]

Hyperkeratosis represents, together with deformities, the most frequent and serious preulcerative condition in terms of lesion pathogenesis. A patient who has both sensory neuropathy and localized hyperkeratosis is 11 times more at risk for developing a lesion than a patient without hyperkeratosis. This increases to 56.8 times if the patient has had a previous lesion.[15]

The foot is at high risk of ulceration as far as neuropathic lesions are concerned, and recent studies have shown how lesions in the forefoot represent the majority of those affecting diabetic patients.[16] Our study has shown that use of a silicone orthosis is effective and safe in the prevention of lesions in neuropathic patients at high risk of ulceration and significantly reduces the incidence of new lesions in the 3-month follow-up period compared to standard treatment. The protective action of the orthosis reduces the formation of localized hyperkeratosis by redistributing peak pressures that occur in the areas most affected by deformity-related overloading.

The keratogenesis is affected by direct application of pressure representing nothing more than a compensatory attempt by the skin to counteract the excess pressure by increasing locally the rate of proliferation of keratinocytes.[17] Off-loading the pressure does in fact represent an indispensable precondition both for encouraging the tissue-repair mechanism, where active lesions are present, and for stopping the potential progression of preulcerative conditions toward lesions.[18, 19]

Although the gold standard in the case of neuropathic plantar ulcers consists of a nonremovable offloading device, some conditions, between and on the tip of the toes and the majority of pre- and postulcerative lesions, do not respond to the application of offloading casts and require different strategies.[20, 21] Being able to prepare ad hoc digital silicone orthoses widens the therapeutic possibilities of preulcerative conditions that are typical in the neuropathic diabetic foot.[22]

In our study, the use of digital silicone orthoses has allowed us to obtain a reduction in the number of incidents of hyperkeratosis in the patients treated. In those still present after 3 months of treatment, it has

Table 3. Results of Podobarometric Evaluation of Patients Studied

	Preevaluation	Postevaluation	*P* Value
Total surface of the foot (cm^2)	92.0 ± 16.7	132.6 ± 7.2	.254
Average weightbearing pressure (kPa)	97.7 ± 39.0	94.3 ± 26.5	.874
Weight distribution compared to the total (%)	25.9 ± 7.0	27.2 ± 3.5	.720
Weight distribution compared to the rearfoot (%)	23.4 ± 10.9	20.7 ± 3.8	.609
Static maximum peak pressure (kPa)	196.34 ± 5.3	98.57 ± 6.4	.001
Dynamic maximum peak pressure (kPa)	242.65 ± 6.6	152.97 ± 20.0	.001

also helped toward a significant reduction in skin hardness that is directly correlated to potential ulceration of lesions. This option is particularly important in light of identification of the toe area being at most risk for ulceration. This finding was demonstrated recently in the multicenter study *Eurodiale* conducted on a group of 1,300 patients throughout Europe, which demonstrated that the prevalence of lesions in the toes represents 55% of all lesions in patients with acute diabetic foot.[16]

The reduction of pressure in the points of overload in the forefoot such as hammer toe or hallux valgus, verified by the baropodometric exam notably lowers the risk of developing ulcerative and recurring lesions.[12] Furthermore, the patients treated did not show any undesirable effects associated with use of the orthotic device which, in fact, was very well tolerated. Safety of use and tolerance by the patients are fundamental elements in the use of any orthotic and rehabilitative device because they improve the patient's level of compliance, which is a significant variable in the effective use of the protection.[23] Digital silicone orthoses made with Podikon 10 and 22 can, therefore, be considered an effective and safe solution in the management of preulcerative conditions of the forefoot in patients with diabetic neuropathy who are at high risk for ulceration.

Acknowledgment: Podolife, the manufacturer of Podikon, for supplying free of charge all of the materials necessary for completing the study, and Ecosanit for generously allowing the use of Ecotechnology for the podobarometric evaluations.
Financial Disclosure: None reported.
Conflict of Interest: None reported.

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