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The use of orthotic devices to correct plantar callus in people with diabetes

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Abstract

Foot problems are a major cause of morbidity in people with diabetes. Plantar callus is common and is a sign of abnormal foot pressures. Shear stresses at these areas of high foot pressures may ultimately result in ulcer formation. This study compared the effect on plantar callus of the use of rigid orthotic devices and conventional podiatric care. Twenty diabetic subjects participated in the study and were randomly allocated to conventional treatment ($n = 11$) or orthotic device treatment ($n = 9$). After 12 months the patients in the orthotic group showed a significant reduction in callus grade, whereas the conventionally treated group showed no significant change. There were no adverse effects from wearing the orthotic device. Rigid orthoses have a beneficial effect on plantar callus presumably through the lowering and redistribution of abnormal foot pressures.

Keywords: Plantar callus; Rigid orthoses; Diabetes

1. Introduction

Foot problems are a major cause of morbidity in people with diabetes and may result in lengthy periods of hospitalisation [1] and amputation [2]. Factors which predispose to the development of diabetic foot ulcers include sensory, motor and autonomic nerve dysfunction and small and large vessel vascular disease [3]. Biomechanical dysfunction resulting from changes in foot posture and leading to abnormal weight bearing is also important especially in the presence of sensory neuropathy [3].

Plantar callus is frequently observed in people with diabetes [4]. It is a result of hypertrophy of the stratum corneum with excess keratinisation [5] and indicates abnormal foot pressures. Plantar callus is an early sign of potential future problems in people with diabetes who often have other factors which place the foot at increased risk. The high dynamic vertical pressure and shear stress at the site of callus formation may ultimately result in ulcer formation [6–9]. In addition the presence of a callus produces a plantar prominence which will further increase the pressure in that area [10]. Although its removal reduces pressure at the site, pressures are not returned to normal [10].

Orthoses are externally applied devices which aim to decrease abnormal loads on the foot [11].

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Three basic types of orthotic devices are available: flexible supports, which include various felt, foam and rubber filler devices; semi-flexible supports which utilise firmer rubber compounds for posting and arch support; and rigid functional devices. Rigid orthotics are made from thermal pliable plastic fashioned from a cast taken of the foot in the neutral balanced position [12]. The more rigid the orthotic device, the more ideal functional control it provides for the foot contact shock absorbing phase during normal pronation, as well as midstance stability and propulsive thrust.

Traditional podiatric treatment of plantar callus involves paring of the hyperkeratotic skin, application of moisturisers and hypoallergenic padding. Since the underlying cause of the abnormal foot pressure is not corrected, callus reforms and treatment at regular intervals by a podiatrist is necessary. Since there are no data available on the optimal method for treating callus formation in people with diabetes, this study was performed to compare the traditional method of callus treatment with the wearing of a rigid orthotic device.

2. Subjects and methods

Twenty subjects with diabetes and plantar callus were recruited for the study. None had a past history of foot ulceration. There were five males and 15 females whose age ranged from 46 to 75 years with a mean (S.D.) of 66 (8) years. Duration of diabetes ranged from 1 month to 24 years with a mean (S.D.) of 8.4 (7.5) years and mean (S.D.) weight was 75 (10) kg. Two of the subjects were treated with diet alone, nine with oral hypoglycaemic agents and nine with insulin. Each gave informed consent to participate in the study.

Each subject was assessed by a podiatrist (LLM). The assessment included grading of the callus, a clinical assessment of lower limb biomechanics and gait analysis, measurement of vibration sensation with a Biothesiometer (Biomedical Instrument Company, Newbury, OH, USA) and Doppler studies of arteries in the feet using the Doppler Model 802-A (Parks Electronics Laboratory, Beaverton, OR, USA).

Subjects were randomally allocated to one of two groups: traditional treatment of callus by podiatrist ($n = 11$) or treatment with a custom made orthotic device ($n = 9$). Subjects were routinely assessed at 3-monthly intervals for 12 months.

Biothesiometer readings ranged from 13 to 50 mV with a mean (S.D.) of 24 (10). Eight subjects (five in the traditional treatment group and three in the orthotic treatment group) had evidence of neuropathy based on biothesiometer readings of > 20 mV. No subject in the orthotic treated group had severe neuropathy with the highest reading being 35 mV. One subject in the traditional treated group had a reading of 50 mV in both feet while the highest reading in the others with abnormal measurements was 38 mV. Stance and gait analysis showed that all subjects had mild pronation of both feet. No subjects had symptomatic peripheral vascular disease or absent dorsalis pedis and posterior tibial pulses.

It is our practice to grade the severity of plantar callosity according to the classification shown in Table 1. The classification takes into account the thickening of the keratin layer and the presence or absence of other pathology at the site of the callus. Subjects with Grade 4–6 callus were excluded from the study because of their need for podiatric treatment of the callus.

Plaster casts of the feet affected by callus formation were taken with the subtalar joint in its neutral position and the midtarsal joint maximally pronated [13]. The rigid orthotic device was made of Rohadur (Ozthotics, Randwick, NSW, Australia), a thermal pliable plastic which is pressed over the plaster cast which is balanced to allow for a predetermined position of the calcaneus. The device is further balanced by dental acrylic posts at the rearfoot in order to control contact, midstance

Table 1
Classification of plantar callus

Classification of callus	Description
Grade 1	Distinct area with minimal thickening of keratin layer
Grade 2	Moderate thickening of keratin layer
Grade 3	Marked thickening of keratin layer
Grade 4	Callus with haematoma
Grade 5	Callus with ulcer
Grade 6	Callus with infected ulcer

Table 2
Comparison of the clinical characteristics of the two groups of subjects participating in the study

	Orthotic group	Podiatry group
Age (years)[a]	63 ± 10	69 ± 6
Sex (M:F)	4:5	1:10
Duration of diabetes (years)[a]	10.7 ± 7.6	7.9 ± 6.6
Weight (kg)[a]	74.1 ± 6.5	76.2 ± 13.9
Treatment		
Diet	1	1
Oral agents	4	5
Insulin	4	5
Biothesiometer reading (mV)[a]	23.7 ± 12.1	24.6 ± 8.7
Number of calluses[a]	2.4 ± 1.0	2.9 ± 1.4

[a]Mean ± S.D.

and propulsive phases of walking. The orthotic devices are light and fit well into sports shoes. They extend from the heel to behind the metatarsal heads and do not interfere with toe movement during walking. Subjects were asked to wear the orthotic device for at least 7 h/day. Subjects provided with orthotic devices were reviewed after 1–3 weeks to ensure correct fitting of the device.

Subjects in the traditional treatment group attended the podiatrist for treatment of the callus at 3-monthly intervals, timed for soon after the study assessment visit. Subjects provided with orthotic devices did not have their callus debrided during the course of the study.

Calluses were photographed at entry to the study and after 12 months. For subjects in the conventional podiatry treatment group, the photograph was taken before the next scheduled routine podiatry visit. Photography was performed by qualified photographers from our Medical Illustration Unit. The photograph was taken from a standard distance from the foot using the same photographic equipment.

After 12 months the effect of the two forms of treatment was assessed by comparing the photographs of the callus. The callus was graded by consensus of the three authors who viewed the photographs together, blinded to the identity of the subject, the date of the photograph and the treatment mode.

2.1. Statistical analysis

The effect of the two modes of treatment was compared by analysing differences in callus grades after 12 months using Fischer's exact test. Group characteristics were compared using Student's *t*- and chi-square tests. A P value of < 0.05 was taken as significant.

3. Results

There were no differences between the two groups in mean age, body weight, duration of diabetes, treatment modes, biothesiometer reading or number of calluses (Table 2).

The subjects enrolled in the study had a total of

Table 3
Comparison of the number of calluses at entry to the study and at 12 months in the two treatment groups

	Orthotic group ($n = 9$)		Podiatry group ($n = 11$)	
	Initial	12 months	Initial	12 months
Number of calluses				
Left	13	12	15	15
Right	9	8	17	17
Total	22	20	32	32
Mean Callus Grade	1.9	1.2	1.6	1.7
Number of calluses				
Improved		16		2
Same		6		23
Worsened		0		7

64 Grade 1–4 calluses, 85% of which were located over the plantar metatarsal area. Each subject had at least one Grade 2 callus. The mean number and grade of calluses at entry to the study did not differ between the two groups (Table 3).

Callus grade improved in 16 of the 22 calluses in the orthotic treated group and remained unchanged in the other six. In the traditionally treated group, two of the calluses improved, 23 remained unchanged and seven deteriorated (five from Grades 1 to 2, one from Grades 2 to 3 and one from Grades 1 to 3) (Table 3). This difference was statistically significant ($P < 0.02$ Fischer's exact test).

There were no adverse events in people wearing the orthotic device. Minor adjustments were necessary soon after fitting of the devices in some subjects. There were no reported difficulties in wearing the device as instructed and the majority of subjects have continued wearing the device after the completion of the study.

4. Discussion

This study has shown that rigid orthotic devices result in a reduction in callus formation in people with diabetes and that orthoses were more effective than conventional podiatric treatment. Plantar callus often precedes the development of more serious foot problems especially in people with other risk factors. The neglected callus is the most frequent cause of ulceration brought about by mechanical factors [14]. Since they are painless, insufficient notice is taken by the patient of this common foot problem. Inflammation, subkeratotic haematoma and eventually tissue necrosis may occur below the callus resulting in a small cavity filled with serous fluid which eventually breaks through the surface with ulcer formation [14].

The orthotic device used in this study was made of Rohadur, a rigid, thermally pliable and durable plastic material. Although there is no accompanying padding, the careful moulding and fitting of the orthosis and adjustment of the device after fitting, ensure that it is well tolerated and does not cause pressure problems elsewhere in the foot. Orthotic devices can be accommodated in standard shoes although a number of our patients chose to wear sports shoes during their normal daily activities. Rigid functional orthoses should be avoided in people whose foot cannot be placed in the neutral position as they are likely to transfer the pressure point and create a problem elsewhere.

Other methods which have been shown to reduce abnormal foot pressures include the use of visco-elastic polymer material [15] and hosiery with specially designed high-density protective pads under the heel and forefoot [16,17], although pressures under the metatarsal heads remained abnormal. Shock absorbing inlay made of compressible material which regains its shape instantaneously when pressure is relieved has also been shown to reduce foot pressures by an average of 18% [18]. Foot pressures at the foot-orthosis interface were not formally assessed in our study because we did not have access to the necessary equipment. However, based on the findings of previous studies [15–19], it seems reasonable to assume that the reduction in callus thickness observed with the wearing of the orthotic device was the result of decreased pressure at the site of the callus, although specific measurement would be required to confirm this and to quantitate the magnitude of the reduction.

Sensory neuropathy is a common complication of diabetes and is an important risk factor for foot problems. Neuropathy results in abnormality of foot posture and pathologically high pressures under the metatarsal heads during standing and walking [3]. Some of our patients have evidence of mild asymptomatic neuropathy which is a recognised factor in producing abnormal biomechanical pressures in the foot. Furthermore, one study reported that 36% of diabetic patients with no clinical evidence of neuropathy had abnormal dynamic foot pressure recordings and that these patients had clear evidence of sensory dysfunction on nerve conduction studies [20]. We did not encounter any problems in the patients with mild neuropathy who were fitted with orthoses and their use in such patients may be particularly beneficial because of the increased risk of foot problems in the presence of neuropathy. However extreme caution is required with rigid orthotic

devices in people with severe neuropathy and in general their use should be avoided as a redistribution of pressure points may result in problems elsewhere in the foot.

The natural history of progression of callus formation from low grade to ulceration is not known. However during the course of this study progression to a higher callus grade occurred in some subjects in the conventional group despite routine podiatric treatment, whereas no progression to a higher grade was observed in the orthotic group.

The cost of the device used in this study was approximately $A100 which may limit the use of this type of orthotic device. We obtained the orthoses through a commercial manufacturer and the unit cost would be cheaper if made by a hospital Orthotic Department. Not all people with callus require orthoses but their use should be considered in people with severer grades of callus or frequent recurrence. Although the orthotic device is costly, it has favourable resource implications since, in the longer term, there would be a decrease in the frequency of visits to the podiatrist for treatment of uncomplicated callus enabling more diabetic people with high risk feet to receive appropriate care and education.

Foot problems are a major chronic complication of diabetes. A significant proportion are potentially preventable by the early detection and prompt treatment of reversible foot lesions. Plantar callus is a useful clinical sign and is indicative of abnormal biomechanical stresses in the foot. Rigid orthoses are an option for treating plantar callus and were found to be more effective than conventional podiatric treatment.

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