

Vertical pressure reduction with customised insoles in the prevention of recurrent foot ulceration in patients with peripheral neuropathy

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INTRODUCTION

It is well documented in the literature that people with peripheral neuropathy secondary to diabetes mellitus are at risk of developing foot ulceration (Delbridge, 1985, Ctercteko, 1981). The structural changes that commonly develop in the neuropathic foot result in increased pressure over bony prominences. This overloading has been identified as one of the leading causes of neuropathic ulceration (Veves, Murray, Young and Boulton, 1992). However, numerous other factors such as soft-tissue thickness, joint mobility, skin integrity, duration and velocity of loading and patient attitude towards their condition may also be implicated, suggesting a multi-factorial aetiology to neuropathic ulcer formation (Landsman and Sage, 1997, Day and Harkless, 1997).

Historically, a variety of clinical methods such as felt padding, total contact casts and orthoses have been utilised to re-distribute pressure away from ulceration (with a view that excessive/damaging underfoot pressures are a major causative factor in neuropathic ulceration). Furthermore, such modalities have been used as a preventative management strategy against re-ulceration (Guzman et al, 1994). The effectiveness of the management has usually been evaluated by the clinical outcome, ie the healing of ulceration and the prevention of further re-ulceration of that site. However, very little systematic measurement of how much pressure is being re-distributed from a given area has been undertaken. The purpose of this study was to evaluate the amount of pressure which was re-distributed from a previously ulcerated site by using various customised insoles. In addition, the duration and velocity of loading over these areas was evaluated.

METHOD

Eight participants (four with a history of unilateral ulcers and four with bilateral ulcers) with a history of diabetes mellitus and peripheral sensory neuropathy were evaluated. All participants had had previous plantar neuropathic ulceration which had been healed for two months or more. Before inclusion into the study, vascular status was assessed to determine that blood supply was adequate for healing. As a component of their management each participant was wearing customised insoles, which had been fashioned to redistribute pressure away from the previous area of ulceration in an attempt to maintain the healed state. Data were taken using the F-Scan (Tekscan®, Boston, MA) in-shoe pressure measurement system. Calibration was performed according to the manufacturers guidelines. Each participant underwent three pressure measurement trials both with and without the customised insoles. Trial scores were averaged to obtain one value per parameter for each participant. The parameters evaluated in this study are listed in Table 1 below.

Table 1. List of parameters measured.

PARAMETER MEASURED	ABBREVIATION
Vertical peak pressure without insole	PPNI
Vertical peak pressure with insole	PPWI
Duration of loading without insole	DURNI
Duration of loading with insole	DURWI
Velocity of loading without insole	VELNI
Velocity of loading with insole	VELWI
Pressure time integral without insole	INTNI
Pressure time integral with insole	INTWI
Total contact surface area without insole	SANI
Total contact surface area with insole	SAWI

RESULTS

Data was analysed using two-tailed paired t-tests to calculate the differences in the mean values between the with and without insole conditions for each of the parameters listed in Table 1 above. A statistically significant difference was found in 3 out of 5 variables tested at an alpha level of 0.05 as presented in Table 2 below.

Table 2. Results of paired t-tests.

	MEAN X-Y	PAIRED t VALUE	PROB. (2 TAIL)
PPNI V's PPWI	-2.525	-3.116	0.0098
DURNI V's DURWI	-.074	-1.274	0.2291
VELNI V's VELWI	-3.03	-1.75	0.108
INTNI V's INTWI	-0.625	-2.693	0.0209
SANI V's SAWI	33.5	3.857	0.0027

From this analysis it is evident that the custom made insoles reduced peak pressure under the previously ulcerated areas $p < 0.01$. However, the raw data demonstrates a large range of values between participants were obtained in relation to pressure reduction, from as much as 7.5 Kg/cm^2 (93% reduction in pressure) to as little as 0.2 Kg/cm^2 (6% reduction in pressure). Surface area $p < 0.01$ and pressure / time integral $p < 0.05$ also reached statistical significance. Velocity to peak loading (change in pressure with time, $\Delta P / \Delta t$) and duration of loading did not prove to be statistically significant $p > 0.05$.

DISCUSSION

Whilst the reduction in vertical peak pressure under the previously ulcerated foot sites with and without orthotic is statistically significant, clinically, what is interesting to note is the large variability in the amount of pressure reduction between subjects. That is some participants had relatively large pressure redistribution whilst others had negligible amounts. This raises important questions regarding the multifactorial aetiology of neuropathic ulceration and the relative impact of a variety of factors. For example the differences in weight bearing surface area which were highly significant in the present study. Less significant was the pressure / time integral while duration and velocity of loading did not reach significance which would suggest that the role of these factors may not be as important

in management of the neuropathic ulcer. In conclusion the authors recommend further research to clearly delineate the role of vertical pressure reduction in combination with other factors in the healing of neuropathic ulceration.

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