Advances in Diabetic Foot Management: The Clinical Effectiveness of Foot Orthoses Prescribed to Control and Reduce Diabetic Foot Pathology

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ABSTRACT

The aim of this article is to examine the beneficial effect of pre-formed foot orthoses and computer generated foot orthoses in the management of the diabetic foot, and to establish which patients would benefit most from such a treatment. The evidence suggests that these interventions are efficacious and acceptable to patients, and could be made available more quickly than traditional bespoke foot orthoses, reducing costs and waiting times, and giving immediate protection against pressure related tissue injury.

Control of plantar pressure and loading is critical in the management of the foot in diabetes, both for the healing and prevention of foot ulcers. This article quantifies the effect that both simple insoles and pre-formed foot orthoses, have on plantar pressure loading parameters. Also, it examines the patient's perception and compliance with the intervention. In addition, a small clinical study of chronic diabetic foot ulcer patients treated with foot orthoses generated from their dynamic plantar pressure data indicates that this is a highly successful future treatment.

The findings from the two studies described in this article support a novel alternative to provide pressure off-load in diabetic feet, obviating the need for complex casted foot orthoses in many cases. In addition the article identifies the patients who are most likely to benefit from such interventions. This will help to simplify the management of the diabetic foot.

INTRODUCTION

In England, more hospital beds are filled with people who have diabetic foot complications, than are filled with all other diabetic complications combined.[1] Diabetes may alter both the musculoskeletal and soft tissue mechanics in a manner that elevates plantar pressure and makes tissue damage more likely,[2] causing non-resolving neuroischaemic ulcers at weight bearing sites.[3] Most of the skin injuries seen on the feet of patients with diabetic neuropathy occur on the plantar surface, frequently at the sites of highest pressures under the foot. On average, patients with diabetes have higher pressures under their feet than persons without diabetes.[4] Increased plantar pressure has been associated with recent or current ulcers, and with risk of amputation.[5-7] In British studies, diabetic foot ulcer prevalence has ranged from 5.3% to 7.4%,[8,9] and among persons with diabetes, approximately 15% will develop a foot ulcer during their lifetime.[10,11] Recurrence rates for diabetic foot ulcers are 35-40% over three years and 70% over five years.[12]

These ulcers can have serious consequences. They are highly susceptible to infection, which may spread rapidly, causing overwhelming tissue destruction.[13] 5-15% of people with diabetic foot ulcers require lower extremity amputation, usually because of gangrene; foot ulcers precede 85% of amputations in people with DM in the United States (U.S).[14,15] Up to two-thirds of non-traumatic amputations in the US are in people with DM whose ulcers have progressed to gangrene.[16]

Management of foot ulcer patients usually includes increasing the area of foot-ground contact and stabilisation of the foot via foot orthoses (special insoles).[3,17] Viscoelastic polymers have proven efficacious in several studies, Boulton[18] demonstrated that the addition of viscoelastic polymer inserts decreased focal pressure by about half. Other work has indicated that polyurethane gel, when utilised in foot orthoses, is more effective in reducing shear than foam materials.[7] However, systematic scientific evaluation to determine the validity of the use of foot orthoses as an effective clinical intervention for diabetic foot disease has been limited, with no randomised clinical trials, and has consisted almost exclusively of bespoke foot orthoses individually fabricated for each patient measured only when new,[17,19,20] rather than pre-formed "off the shelf" foot orthoses.

In addition, little assessment has been made of the patient's satisfaction with this form of interventive therapy. Studies have indicated that foot orthoses should be beneficial in improving the long-term prognosis in the diabetic foot.[21] However, people continue to fail to wear them, preferring to risk recurrent ulceration - this behaviour has not been fully investigated.

Table 1: Average findings over the six month period

	Orthoses total foot	Cleron Total foot	Difference in means	Regionalised data where orthoses significantly superior to cleron
Reduction in mean peak plantar pressure	100 kPa (22%) p<0.001	60 kPa (16%) p<0.05	Orthoses better p<0.001	1st MPJ (p<0.05) 3rd,4th,5th MPJ's (p<0.008) medial & lateral heel (p<0.01)
Reduction in pressure-time integral	33 kPaSec (16%) p<0.412	18.5 kPaSec (10%) p<0.289	No significant difference P<0.053	3rd,4th,5th MPJ's (p<0.01) Increased: medial midfoot (p<0.01)
Increase in contact area	13 cm^2 (11%) p<0.001	3 cm^2 (2%) p<0.01	Orthoses better p<0.001	1st MPJ (p<0.05) 2nd MPJ (p<0.001) medial & lateral midfoot (p<0.01) medial & lateral heel (p<0.01)

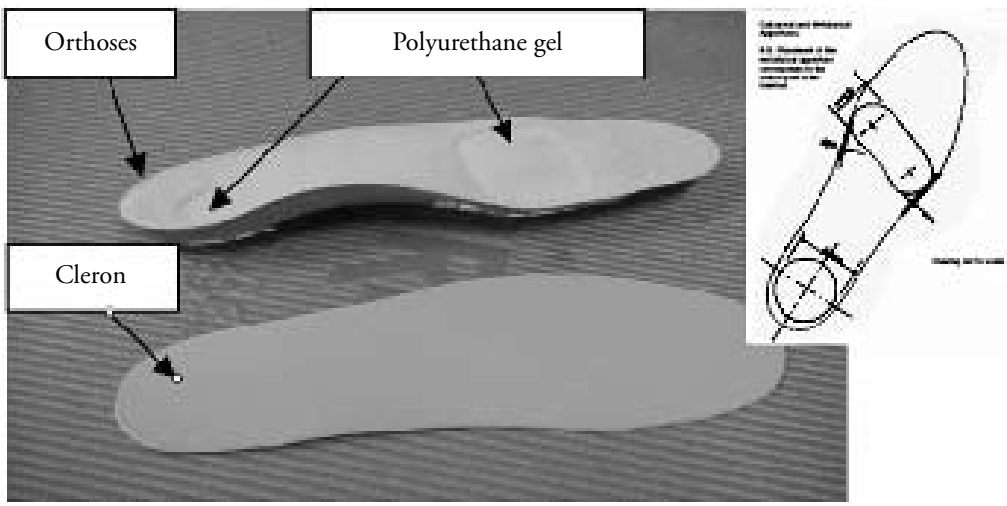

Fig. 1 : Picture and schematic of foot orthosis and insole

METHODOLOGY

A prospective randomised clinical control trial was performed. 117 subjects with Type I and II diabetes within United Bristol Healthcare NHS Trust, referred by their podiatrist, were randomly assigned preformed polyurethane gel and ethylene vinyl acetate foot orthoses (Langer Biomechanics Group (UK) Ltd, Stoke-on-Trent) or simple 3mm cleron (open cell polyurethane foam) insoles (Footwear Findings Ltd, Somerset, U.K), to wear in their own footwear (Fig. 1). Medical, neurological, vascular, and biomechanical status was assessed in each subject using a standard form. Vertical plantar pressure, pressure-time integrals, and contact area was measured using a Pedar in-shoe pressure measuring system (Novel gmbh, Munich, Germany). Pressures were recorded in both standardised orthopaedic shoes (Ken Hall Parma Shoes) and in the subjects' own shoes. Wearer perception of foot health was assessed using the Bristol Foot Score self-completion questionnaire, which was specially developed for this study.[22] Compliance was assessed using a diary of wear, in which the subject recorded when they did not wear the foot orthoses or insoles. Data were recorded at zero, three and six months.

Subjects

103 (35 female, 68 male, age range 18-75 years) completed the trial. Subjects excluded if; concurrent medical condition likely to affect their ambulatory status, unable to walk for 30 metres unaided, active foot ulceration and/or infection, severely oedematous feet or amputations, and wearing bespoke orthopaedic footwear. To take part in the study subjects had to be wearing footwear, which was adequate to accommodate the foot orthoses or insoles.

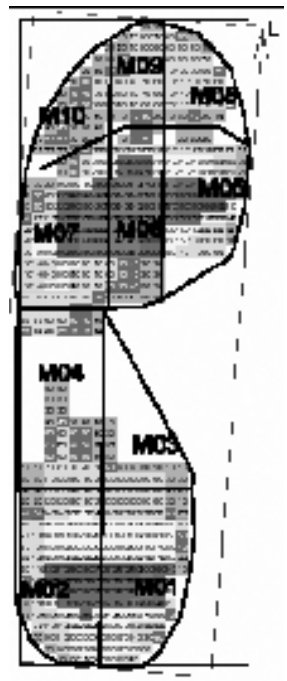

Fig. 2: Standard foot division mask applied to all plantar pressure data

Protocol

10 left and 10 right footsteps were analysed for each data situation, and the footsteps were divided into regions using the PRC standard mask (Figure 2), Novel WIN software (Novel gmbh). Statistical analysis was performed using SPSS for Windows™, significance accepted at the 5% level.

RESULTS

On average over the six-month study period the foot orthoses achieved a 22% (100kPa) (p<0.001) reduction in mean peak pressures and a 16% (33KPas) (p<0.412) reduction in pressure-time integral. The insoles achieved a 16% (60kPa) reduction (p<0.05) in mean peak pressures and a 10% (18.5kPas) reduction (p<0.298) in pressure-time integral. Mean contact area increased by 11% (13cm^2) (p<0.001) in the foot orthoses group, and increased by 2% (3cm^2) (p<0.01) in the insole group (Table 1).

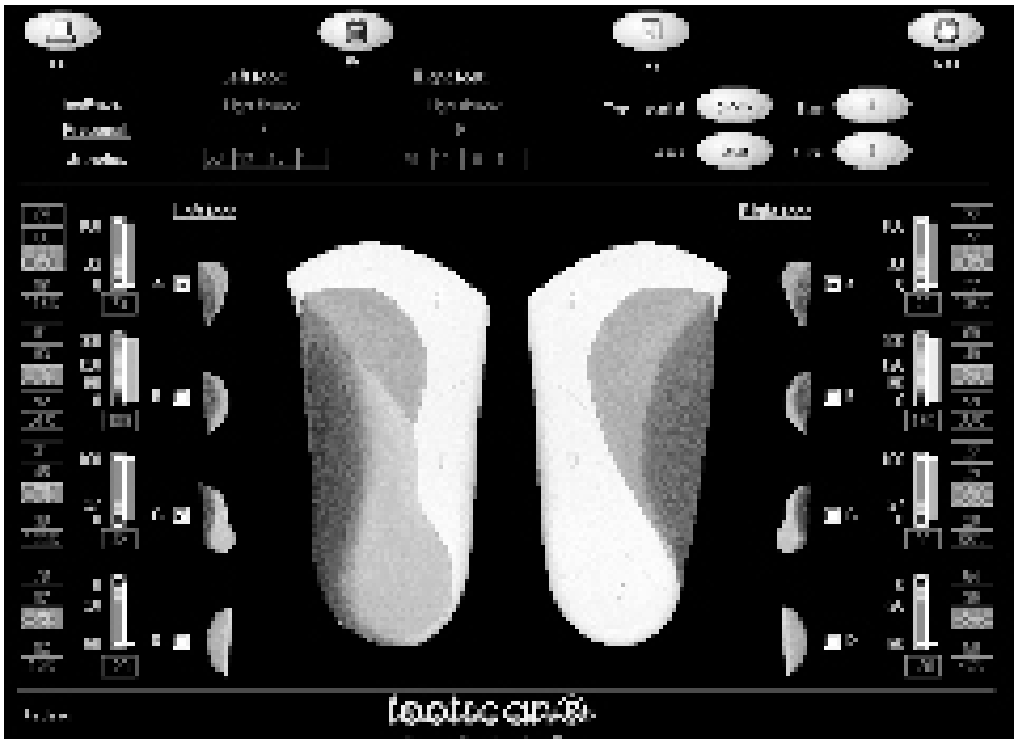

Fig. 3 : D3D computer generated orthoses

Table 2 : Summary of all patients treated with D3D computer generated foot orthoses

Type of Diabetes	Age	Sex	Foot Type	Ulcer Location	Ulcer Duration	*Outcome*
II	62	Female	Cavus	R/1st MPJ	5 years	Healed
I	58	Male	Cavus	L/4th MPJ	10 years	Healed
I	50	Male	Cavus	B/1st IPJ's	2 years	Healed
II	66	Male	Planus	L/5th toe	3 years	Died
I	39	Female	Planus	Neuropathic pain	1 year	Pain free
I	47	Male	Planus	B/4th & 5th toes	6 months	Healed
I	69	Male	Cavus	B/1st MPJ's	12 years	Re-ulceration
I	38	Female	Planus	L/2nd MPJ & toe	4 years	Re-ulceration
II	60	Male	Planus	B/1st MPJ's & IPJ's	5 years	Healed
I	36	Male	Planus	R/1st IPJ	3 years	Healed
I	52	Male	Cavus	L/1st &R/4th MPJ's	8 years	Healed
II	51	Male	Rectus	R/1st MPJ	1 year	Healed
II	60	Male	Planus	R/2,3,4th MPJ's	5 years	Healed
II	48	Male	Planus	L/2nd & 3rd MPJ's	4 years	Healed

ANOVA indicated that increasing subject age led to a decrease in peak plantar pressures, while duration of diabetes and history of ulceration led to an increase in the pressure-time integral. Being randomised to foot orthoses as opposed to cleron increased the contact area.

Due to the influence of soling materials peak pressures (mean 16% foot orthoses, mean 12% cleron) and pressure/time integrals (mean 21% foot orthoses, mean 20% cleron) were always lower and contact areas (mean 8% foot orthoses, mean 9% cleron) always higher in the subjects own footwear with either of the two insoles, when compared with values obtained in the standard footwear.

Perception of foot health as recorded by the Bristol Foot Score, demonstrated a trend of improvement, which was significant ($p<0.001$) only in the foot orthoses group.

From the diary of wear 84% of the foot orthoses group and 60% of the insoles group claimed to wear the intervention constantly.

DISCUSSION

The study indicated that both interventions were effective, this is valuable as the simple cleron insole is frequently utilised in the management of the diabetic foot, but its use has been poorly validated. The pre-formed foot orthoses proved to be as effective as bespoke casted foot orthoses have proven in other studies, this is also important as these would be easier and quicker to issue to patients. The findings from this study also indicate which patients would benefit most from the foot orthoses; this should enable more effective prescription.

The Bristol Foot Score results and low drop-out rate in the study, is an indicator of the patient's satisfaction. This is probably largely due to the patients being able to wear their own footwear with the intervention. New ulceration during the study only occurred in the cleron insole group, affecting three people, this could indicate that the foot orthoses were better at ulcer prevention, but much larger numbers would be needed over a longer period to test this.

CONCLUSION

The study provides new evidence for the efficacy of simple plantar cushioning in people with diabetes, and suggests that foot orthoses do not always need to be bespoke, and are best targeted at those with a longer duration of diabetes and/or a history of ulceration. Also, the perceived improvement in foot health measured with the foot orthoses indicates that they may improve wearer compliance. The study also indicates the effect of the soling material on the plantar pressure parameters recorded, leading to the recommendation that patients wear their own footwear with cushioned soles wherever possible, and that orthopaedic footwear should also be provided with cushioned soles.

CLINICAL STUDY: ORTHOSES COMPUTER GENERATED FROM PLANTAR PRESSURE DATA IN THE MANAGEMENT OF DIABETIC FOOT ULCERS

A convenience sample of 14 patients with non-healing diabetic foot ulcers and/or chronic neuropathic pain, were treated with foot orthoses generated using their dynamic plantar pressure data (Table 2). Walk data were collected using the RSscan International (Belgium) 0.5 metre pressure platform sampling at 350 Hz, a total of four left and four right footsteps were collected per patient. Using RSscan International D3D software, foot orthoses were designed for each patient. The D3D principle is based on a study of 25,000 different feet worldwide measured by RSscan International. With the use of different casts they have built up a 3D (three dimensional) model that is now used to determine four different arch heights. In practice, two different basic orthotic shells are built using a moulding technique combining high pressure and high temperature on EVA materials. By using a B-correction under the medial arch, 4 different arch heights can be accommodated. The elements A, B, C and D are used to obtain a natural unroll of the foot. (See Figure 3)

A full-length low-density EVA top cover was utilised in all cases to cushion and accommodate deformities. 10 of the 14 patients treated with these foot orthoses have completely healed (Table 2). This study provides further evidence for the efficacy of functionally dynamic foot orthoses, in changing plantar loading parameters in the diabetic foot. These foot orthoses are produced from computer generated information and use standardised components, making them simple and repeatable.

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