An investigation into the prescription procedures and material choice involved in the provision of bespoke foot orthoses for Diabetic patients.

**Introduction**

In 2008 it was estimated that 4.67% (2,440,000 people) of the population in England had diabetes (diagnosed and undiagnosed). This figure is expected to rise to 6.48% (3,605,000 people) by 2025, with this increase due to both the growing prevalence of obesity and the aging population (NHS National Diabetes Support Team 2008). There is a significant cost to the NHS on treating diabetes and its complications; it is reported as 5% of their total budget (Roberts 2007). Foot problems namely ulcers and amputations are common and serious complications seen in people with diabetes (Boulton 2004). This is a global issue with a leg lost due to diabetes every 30 seconds somewhere in the world (The Lancet 2005). However, it is important to note that these foot problems are not an inevitable consequence of having diabetes, as stated by Joslin (1934 cited in Boulton et al. 2006) ‘diabetic gangrene is not heaven-sent, but earth-born’. Factors such as peripheral neuropathy and arterial disease place the diabetic foot at high risk of ulceration but ulceration will only occur in the presence of some form of trauma. Extrinsic trauma for example ill fitting footwear or walking barefoot and stepping on a sharp object or intrinsic trauma such as repeated high pressures on parts of the foot during walking in the presence of neuropathy and/or peripheral arterial disease can result in the development of an ulcer (Boulton 2004, Sims et al. 1988).

Therefore, the use of an intervention that decreases foot pressures would make a reduction in the development of ulcers possible. Custom footwear and orthoses are interventions that have been used extensively by clinicians with diabetic patients considered at high risk of ulceration to reduce plantar pressure. Depending on their desired use orthoses are constructed to varying levels of shock attenuation and movement control characteristics which are achieved through the selection of an appropriate material/s. Whilst early orthoses were constructed from metal, wood, leather and fabric, contemporary materials predominantly include thermoplastic and thermosetting materials, foamed plastics, and viscoelastic polymers (Kogler 2007). This is due to advances in both material sciences and fabrication technology. Traditionally materials used for orthoses were heat molded, and therefore had to be a thermoplastic or thermosetting material, but with the introduction of CAD/CAM (Computer Aided Design/Computer Aided Manufacturing) technology orthoses can now be directly milled from a block of material.

Due to the vast range of materials now available to clinicians and the current paucity of information available to them on the characteristics of these materials making a well informed decision on material selection can prove difficult.

**Methodology**

The main objective of this study was to evaluate the clinical reasoning behind the prescription procedure with a particular emphasis on the choice of materials. To achieve this a questionnaire was developed within the biomechanics research group at Staffordshire University with the aim of investigating the prescription procedures involved in the provision of bespoke foot orthoses by Orthotists and Podiatrists.

This questionnaire is part of a research project which also includes laboratory testing of a selection of materials used in orthoses for diabetic patients. This research project is supported by Salts-Techstep under sKTP project (No: sKTP012).

There were four elements to this questionnaire; the clinicians’ profile, the type of devices they routinely prescribed, the material choices for these devices and the factors which affected their choice and finally whether the materials used were considered the most suitable for their purpose with a focus on diabetes.

In November 2009 29 questionnaires were distributed to clinical practitioners involved in the prescription and modification of footwear and insoles and who were identified as having experience of both traditional and CAD/CAM methods of manufacturing. 14 questionnaires were completed and returned for analysis.

**Results**

**Clinicians’ profile**

Half the respondents worked in hospital and acute settings with the remaining half from a combination of community and private clinics. The majority reported prescribing eleven or greater bespoke orthoses per month with a case load distribution and patient risk percentage as seen in Fig. 1 and 2 respectively.

Fig 1. Case load percentages for respondents.

Fig 2. Percentage of respondents’ case load defined as being “high risk”.

When asked about the casting technique they used, half selected foam box and half selected suspension plaster casting technique. However, the following question showed that 12 of the 14 reported varying their choice of technique according to the patient. In the follow up comments section respondents genrally stated that the purpose of the orthotic, for example amount of correction required, and the patients tolerance were the main factors in choice of casting technique. For example one respondant stated “It depends whether I am prescribing functional or accommodative orthoses. Also, time is a factor ..... sometimes (I) have to make do with a foam impression rather than neutral POP casts.” Respondents were also asked the rate the importance of time, cost, resources, training and receptivity of patients on their choice of casting technique with results shown in Fig. 3.

Fig 3. Ratings on importance of a number of factors on choice of casting technique.

The following three questions related to the availability of equipment in helping with biomechanical assessment (see Fig. 4, 5 and 6). Interestingly, only a few had a variety of equipment available to them with pressure mat being the most available to clinicians.

Fig. 4 Avalibility of equiqment to clinicians to assist in biomechanical assessment.

Fig. 5 Frequency of use of equipment for respondents who stated having equipment available to them.

Fig. 6 Ratings on importance of a number of factors on choosing to use/not use available equipment.

**Use and type of orthoses prescribed to diabetics**

When asked about the type of devices the clinicians predominantly prescribed to diabetics 6 used functional and accommodative devices in equal amounts whereas 4 predominantly used functional orthoses leaving three predominantly using accommodative devices (one respondent did not treat diabetics and so did not answer the questions relating specifically to diabetics). This is borne out in Fig. 7 showing that the majority of these experienced clinicians were comfortable in prescribing rigid foot orthoses for diabetics.

Fig. 7 Frequency of type of orthoses prescribed to diabetic patients.

**Material choices for diabetics and factors that affected this choice**

Fig. 8 details the materials chosen by the clinicians when prescribing orthoses for diabetics with Fig. 9. rating the importance of several factors in material selection. In summary, the respondents used a wide variety of materials with medium density EVA being useful in semi rigid and accommodative devices whilst polypropylene was the material of choice for the majority of rigid devices.

Fig. 8 Materials used based on type of orthotic

Fig. 8 Ratings on importance of a number of factors on material choice.

**Whether materials are sufficient for purpose**

The final section related to the materials themselves asking whether the choice of materials has changed significantly in the last 5 years with 5 respondents selecting yes and 8 choosing no. Some respondents choose to comment suggesting that materials have become more functional than cushioning, with two remarking on the introduction of Polyurethane as an option, and one suggesting that the materials are a better quality. When asked if they felt the range of materials available for orthoses provided to diabetics was appropriate the majority replied that it was.

**Conclusion**

In summary this questionnaire had experienced practitioners as respondents who were content to use any casting technique according to their patient’s needs. Generally respondents showed no reluctance in prescribing functional devices to their diabetic patients. Traditionally the aim of orthoses/insoles for diabetics has been to redistribute weight and provide cushioning (Edmonds and Foster 2005). When asked about the materials they were relatively satisfied with the range and quality of the materials available.

**References**

Boulton, A.J., Cavanagh, P.R. and Rayman, G., 2006. The foot in diabetes. 4th edn. United Kingdom: John Wiley & Sons Ltd.

Boulton, A. J. M. 2004. The diabetic foot: from art to science. The 18th Camillo Golgi lecture. *Diabetologia,* 47 (8), 1343-1353.

Edmonds, M.E. and Foster, A.V.M., 2005. Managing the diabetic foot. 2nd edn. USA: Blackwell Publishing.

Kogler, G.F., 2007. Materials and Technology. In: M.M. Lusardi and C.C. Nielsen, eds, *Orthotics and Prosthetics in Rehabilitation.* 2nd edn. USA: Elsevier, pp. 15-34.

NHS National Diabetes Support Team, ed, 2008. *Diabetes in England.*

Roberts, S., ed, 2007. *Working together for better diabetes care, clinical case for change.* Department of Health.

Sims, D. S., Cavanagh, P. R. and Ulbrecht, J. S. 1988. Risk factors in the diabetic foot: recognition and management. *Physical Therapy,* 68 (12), 1887-1902.

The Lancet. 2005. Putting feet first in diabetes. *The Lancet,* 366 (9498), 1674.