

CRITICAL REVIEW. PART 3.

Therapeutic footwear – still a Cinderella service? A critical review of the literature

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ABSTRACT

Background

That specialist therapeutic footwear has some clinical benefits has been demonstrated, but for these clinical benefits to be achieved the patient has to wear them. However, varying degrees of patient satisfaction with this footwear have been reported leading to non or low use. There have been reports and recommendations for changes to address this problem. The purpose of this review therefore is to explore if these recommendations have impacted on patient care in improved patient satisfaction and use of the footwear.

Method

An electronic and hand search for papers from 1992 to 2006 was carried out.

Results

Ten papers investigating patient satisfaction and compliance with this footwear were reviewed, and six papers investigating the impact of the footwear service on these factors were also reviewed.

Discussion

There is still a problem of specialist therapeutic footwear not being worn. Research has focussed on the footwear itself and/or the service that provides it. There has been no research that has investigated the relationship between the patient and practitioner, and the influence of this on the patient's engagement in this intervention. A deeper understanding of the patient's experiences of being provided with this footwear is needed, and this may reveal factors that can influence the patient's decision to wear the footwear.

BACKGROUND

Research has demonstrated some clinical benefits of specialist therapeutic footwear in terms of, for example, lowered incidence of foot reulceration in patients with diabetes, and improved walking speed and pain reduction in patients with rheumatoid arthritis (RA)¹⁻⁹. Despite conclusive good-quality evidence to support its use, clinicians utilise this footwear with an associated expenditure of approximately £20 million per year,¹⁰ and it is generally agreed that this footwear has some clinical benefit. For this footwear to contribute to good foot health it has to be worn by the patient to a level at which the potential for maximum foot health benefits are achieved. However, it is known that there are varying degrees of patient dissatisfaction with this footwear, resulting in the footwear being used selectively or not at all, ending up as 'shoes in the cupboard'.¹¹

Patient satisfaction and compliance with specialist footwear has consistently been reported to be low from the late 1960s to the early 1990s. Dixon & Franklin¹² found that 50% of 70 patients were dissatisfied with their footwear. Haslock & Wright¹³ however found that only 17% of patients in their study complained of problems, but this

study was carried out by the people that provided the footwear, which may have influenced the patients' responses. An independent survey of patients with a variety of foot problems, commissioned by the Department of Health,¹⁴ found that, whilst 82% of all the patients were satisfied overall, most had some negative comments about the footwear, with poor communication between the prescribing clinician and the orthotist and then between the orthotist and the shoe maker being a fundamental problem.

Further to this study, Park & Craxford¹⁵ found that, although 90% of the 71 patients responding to their questionnaire experienced some relief of symptoms, 50% had some criticism about their footwear such as poor cosmetic acceptability, difficulty getting the shoes on, being too heavy and uncomfortable and in some cases not wearing the shoes at all (7%). Costigan et al¹⁶ found that, of the 82 patients interviewed in their study, 12% had stopped wearing their shoes within 36 months after being fitted with them and 51% were dissatisfied with poor appearance and difficulty getting the shoes on, these being the main reasons for poor compliance. This early work is potential evidence of patients having to compromise in that, although some benefits are recognised resulting in overall satisfaction, there are still major patient-focussed issues that result in patients being dissatisfied with specific aspects of the footwear, resulting in low use, selective use or them not being worn at all.

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The views of consultants who prescribe this footwear have also been sought. Lord & Foulston¹⁷ surveyed 1696 consultants who were currently prescribing footwear at that time, with 48% stating dissatisfaction primarily in the speed of delivery, its suitability, and the training of staff in the prescribing and dispensing of it. A response to this paper reassures the authors that response rate of less than 50 % from the consultants probably represents the ‘honest’ half, who may not feel qualified to answer the question on suitability,¹⁸ and highlights the fact that there is little, if no, training for the ‘prescriber’ of the footwear, and this need should be addressed.

In 1996 the Department of Health commissioned a study to investigate the problems highlighted by the previous research.¹⁹ The authors of this report identified the same problems as the previous work and further described the service that provided specialist footwear as “rudderless and uncoordinated” and that it was a ‘Cinderella service’. This report made several recommendations for improvements in both the footwear and the service with the aim of improving both patient satisfaction and clinical outcomes.

The purpose of this review therefore is to explore if these recommendations have impacted on patient care in improved patient satisfaction and use of the footwear.

METHOD

The following databases were electronically searched for all papers related to specialist therapeutic footwear (1992-March 2006).

- PubMed
- Embase
- Medline
- Cinahl

The Cochrane database of systematic reviews
 The Cochrane register of Controlled trials
 Current controlled trials at

<http://www.controlled-trials.com>

UK National Research Register

<http://www.update-software.com/national/>

The following journals were hand searched

- The British Journal of Podiatry*
- The Foot*

Search Terms

- Footwear AND compliance
- Footwear AND use
- Footwear AND patient satisfaction
- Footwear AND service
- Footwear AND orthotic service
- Footwear AND surgical appliances

Inclusion/exclusion criteria

All studies that reported patient satisfaction or dissatisfaction and/or compliance with specialist therapeutic footwear were included. Only studies published in the English language and studies less than 1 year old were included for review (Table 1). Ongoing work was not included in the review as the author recognises that the peer-review process is an effective process for screening the quality of research, and its relevance to practice.

PATIENT SATISFACTION WITH THERAPEUTIC FOOTWEAR

Since the Salford Report¹⁹ there are indications of continued patient dissatisfaction with therapeutic footwear, leading to poor compliance or low levels of usage (Table 1). Newson *et al*²⁰ interviewed 40 patients who had been supplied with specialist footwear for a variety of reasons. They used a structured questionnaire and found that 62% complained of the overall appearance of the footwear and 37% were unable to put the shoes on without help. Lack of time for assessment, no information and no follow-up appointment were also identified as being problem areas that contributed to the failure of the footwear to meet the needs of the patient. These problems concur with those identified in the Salford Report¹⁹. It may be that there had been no time to embrace the recommendations made by the report before this work was published. Philipsen²¹ investigated 74 patients attending an orthopaedic clinic and found that, although 38% patients reported some benefit, 17% had no benefit or had deteriorated and 7% developed ulcers whilst using their specialist footwear. Although overall there was benefit with improved comfort there were areas of concern to patients such as poor cosmesis.

A questionnaire²² sent to 137 subjects with rheumatoid arthritis (RA) had a return rate of 97. Twenty four percent had discontinued using their footwear within 12 months of them being supplied indicating that some problems with the footwear occur over time. A problem using questionnaires acknowledged by the authors is incompleteness and poor return. The patients who failed to complete the questionnaires may also be the most dissatisfied or non-complaint with their footwear and this could have an effect on the validity of the results. However this study does highlight the complexity of providing patients with an intervention that is outwardly visible as well as the functional aspects of getting the shoes onto the feet.

Stewart²³ also investigated footwear usage in patients with RA. She perceived that this group of patients were more difficult to fit with footwear due to foot deformity and associated pain. The questionnaire was sent to 96 patients, with 86% responding with fully or partially completed questions. The author demonstrated that overall satisfaction with prescription footwear in patients with RA deformity was high, but again this was

Patient satisfaction with Footwear (general)	Patient satisfaction with footwear (diabetes)	Patient satisfaction, with footwear (rheumatoid arthritis)	Footwear service
Newson <i>et al</i> 1992 ²⁰ Philipsen <i>et al</i> 1999 ²¹	Knowles and Boulton 1996 ²⁵ Armstrong <i>et al</i> 2001 ²⁶ Bas Van de Weg 2002 ²⁷ MacFarlane and Jensen 2003 ²⁸ Johnson <i>et al</i> 2006 ²⁹	Herold and Palmer 1992 ²² Stewart 1996 ²³ Van der Esch, Heijmans and Dekker 2003 ²⁴	Bowker <i>et al</i> 1992 ¹⁹ Boer and Seydel 1998 ³¹ British Society of Rehabilitation Medicine (1999) ³² Baker and Leatherdale 1999 ³³ Williams and Meacher 2001 ³⁴ Emery and Borthwick 2002 ³⁵

Table 1 – Summary of papers selected for the review.

Author/year/country	Sample Characteristics	Method	Results
Newson <i>et al</i> 1992 ²⁰ UK	40 patients (variety including polio, Osteoarthritis, rheumatoid arthritis, foot deformity, amputation, CVA)	Questionnaire	62% complained of appearance 37% complained of difficulty getting the shoes on
Phillipsen <i>et al</i> 1999 ²¹ Denmark	74 patients from an orthopaedic dept	Questionnaire	38% some benefit but complaints of poor appearance and comfort 17% found no benefit 7% developed ulcers
Herold and Palmer 1992 ²² UK	137 patients 79 RA	Questionnaire	24% stopped wearing them within 12 months
Stewart 1996 ²³ UK	96 patients with RA (86% responded)	Questionnaire	<u>Overall satisfaction</u> 29% very satisfied; 50% satisfied; 16% dissatisfied; 5% very dissatisfied <u>Satisfaction with style</u> 24% very satisfied; 49% satisfied; 16% neither satisfied or dissatisfied; 7% dissatisfied; 5% dissatisfied
Van der Esch, Heijmans and Dekker 2003 ²⁴ Netherlands	640 patients RA 223 responded OA 187 responded	Questionnaire	46% of the RA patients possessed footwear (30% overall - walking aids including walking sticks did not use them –unfortunately did not separate out the non-use of footwear
Knowles and Boulton 1996 ²⁵ UK	Diabetes 50	Interview	22% regular wearers 18% disliked style 38% wore slippers indoors
Bas Van de Weg 2002 ²⁷ Netherlands	Diabetes 75 Other 172 (71% responded)	Questionnaire	20% wore their footwear always compliant: 46 diabetes; 57 controls often compliant: 33 diabetes; 30 controls non-compliant: 21 diabetes; 13 controls
MacFarlane and Jensen 2003 ²⁸ USA	161 patients (31% responded)	Questionnaire	90% reported that they thought that footwear was important 63% liked wearing them but: 24% complained about appearance 24% complained about lack of comfort 14% complained about the weight
Johnson <i>et al</i> 2006 ²⁹ UK	Diabetes with history of ulceration/amputation -15 Practitioners- 15	Interviews	Differing perspectives in terms of expectations, usage and fit

Table 2 Patient (and practitioner) satisfaction with therapeutic footwear

associated with selective use of the footwear. Stewart²³ also highlighted that when the patients were asked about the weight of the shoes it was unclear whether there were problems with the actual weight of the shoe or whether it was the visual appearance of weight that was a problem.

An investigation into the possession and use of footwear²⁴ in a random sample of 640 patients with RA or osteoarthritis (223 RA, 187 OA) revealed that 46% of the patients with RA possessed specialist footwear. However 30% did not use it on a regular basis. The authors concluded that this non-use was associated with less need and negative clinical and patient-centred outcomes.

The first study to explore different footwear for use at home²⁵

found that of 50 interviewed patients with diabetes only 22% were regular wearers (which they defined as wearing the shoes all day) but that 38% wore slippers indoors. In substantiation of this, Armstrong²⁶ reported that high-risk patients were less likely to wear their prescribed footwear at home than when outside. As such patients are more active when in the home this non-compliance may well be important in the causation of ulceration.

Bas van de Weg²⁷ conducted a postal questionnaire of 75 patients with diabetes and 172 controls with a good response rate (71%). One fifth of the patients in this study complied with their footwear but the author acknowledged that this could have been an under representation as the non-responders could have been

non-compliant. Compliance was defined as wearing the shoes from morning to evening. The author highlighted the need to provide the patient with information on the possible consequences of non-compliance, and suggested that this type for footwear should only be provided to patients who were motivated to wear it (and in this study the fact that the patients contributed a payment towards the footwear may have increased compliance). He further suggested that a pragmatic individualistic approach to patients who require footwear is required and may involve the provision of special insoles in trainers as an alternative in achieving better long-term results.

A questionnaire survey of patients with diabetes was carried out by Macfarlane & Jensen,²⁸ exploring the patients' use of specialist footwear. The content of the questionnaire is detailed and justified but, like the other previous studies, how the questions were formulated is not described. Only 31% (n=50) of the patients surveyed responded and some of the questions were not completed but annotated, indicating the problem of not piloting the questionnaire. The authors do discuss the implication of poor usage and suggest that, in addition to poor cosmesis, the lack of perceived value of the shoes may be a contributory factor.

A recent qualitative study by Johnson et al²⁹ carried out semi-structured interviews with 15 patients with a history of diabetes-related foot ulceration and/or amputation and 15 practitioners, and demonstrated differing perspectives in terms of expectations, shoe-wearing behaviour and difficulties fitting feet that are constantly changing shape. They recommend that the patient's needs be taken into consideration in shoe provision.

THE INFLUENCE OF FOOTWEAR SERVICE STRUCTURE ON PATIENT SATISFACTION AND USAGE OF FOOTWEAR

The provision of this specialist therapeutic footwear starts with the prescribing clinician who is often a consultant.³⁰ There are no clinical guidelines in the UK to define who should have this footwear and who should make the decision to have it resulting in lack of clarity as to the purpose and objective of this intervention. Boer & Seydel³¹ found that consultants and rehabilitation practitioners in the Netherlands had differing views and knowledge about the objectives of specialist footwear, and there were differences in the types of foot problems they would refer for specialist footwear. However, overall they agreed that patients with RA and diabetes would have positive health benefits but there was no mention of factors in relation to the patient's perspective. This study identified a need for education amongst the prescribing practitioners with regards to product knowledge and what clinical benefits could be expected.

In the UK there are currently a wide range of footwear service structures and many issues with regards to training and professional roles in its provision.³²⁻³⁷ This perhaps is a reflection of the lack of clear evidence for one service structure being more effective than another. The traditional model for footwear services is characterised by a footwear prescription from a medical consultant being fulfilled by a commercial orthotist working in isolation from the other clinicians. There is little allocated appointment time, no monitoring of patient and clinical outcomes and little choice or written information for the patients. This type of service still exists in the UK despite the recommendations¹⁹ for the development of multidisciplinary working with clear lines of communication, appropriate training for individuals, dedicated managerial time and being more focussed on the needs of the patients. The Salford Report¹⁹ also suggested that services should be audited for outcomes that were patient focussed, but there has been little attempt to achieve this.

The only study to investigate differences between a traditional and a contemporary (multidisciplinary) footwear service model

was carried out by Williams & Meacher,³⁴ and evaluated patient perceptions of footwear and services. The contemporary service is characterised by referral from any practitioner, pre-assessment screening for suitability by a podiatrist, allocated clinical appointment time with the orthotist to discuss footwear options, active engagement of the patient in all decision making, regular footwear and patient monitoring, and written information to supplement verbal advice/explanations. Fifty-five patients were interviewed by a researcher who was blinded as to which service the patient attended. The multidisciplinary footwear service resulted in greater usage of the footwear and more patient satisfaction.

This work supports that of Lord & Foulston¹⁷ who concluded from their study that continuity of care and supervision is vital throughout the prescription process and beyond to ensure that any difficulties with the footwear are overcome. In conjunction with this is providing the patient with adequate information about the purpose and function of their footwear so that they do not have unrealistic expectations. Philipsen²¹ also found that when patients were well informed about the purpose and function of the footwear they appeared to have more benefit than those who were not well informed. However, out of the 74 patients in this study, only 9% had a follow-up appointment to have their footwear checked.

A questionnaire study carried out in a multidisciplinary footwear clinic for patients with diabetes revealed that 83.5% of patients reported that they wear their footwear all the time with only 3.8% reporting that they never wore them at all.³³ This would suggest that patients are more likely to wear their shoes when they are provided in this setting, however, self-reported levels of usage are unreliable and other methods of monitoring usage may reveal different results. However, there is an indication from this study that patients who received footwear from a department where they had they already received foot care may well have perceived the footwear to have more value as it was associated with a familiar department and personnel, and part of a process that was already valued.

Emery & Borthwick³⁵ investigated patient and practitioner views of three footwear services. They used questionnaires with patients, with a 71.7% response rate, and semi-structured interviews with four health professionals. They investigated three clinical settings, a diabetes clinic, a rheumatology clinic and a multidisciplinary rheumatology footwear clinic. The authors identified three main areas of importance from both the patient and practitioner responses: the review of footwear following supply, lack of formal objective measures of clinical effectiveness and poor communication. This paper supports previous work that there are problems in these key areas and that whatever the type of service there appears to be a continued and persistent problem with usage of therapeutic footwear as a health intervention.

In a review of a multidisciplinary foot clinic in rheumatology,³⁷ recommendations were made for a dedicated foot clinic to include as a minimum a consultant, an orthotist and a podiatrist and possibly a physiotherapist. An audit of this service with regard to clinical outcomes has not been carried out as yet but there was high use of specialist footwear, with 47 of the 109 patients being provided with specialist footwear. This model may be important in ensuring that the right patients receive footwear as an intervention and, as already identified by Williams and Bowden,³⁸ there is an unmet need, with some patients who would benefit being overlooked by the professionals looking after other aspects of their care.

DISCUSSION

That therapeutic footwear achieves clinically focussed outcomes is not disputed as there is some evidence in the literature that this is so.¹⁻⁹ However, despite the recommendations for improvements in service delivery and improving the design of the footwear, there remains a problem with specialist footwear still not meeting

all the needs of all patients. The choice of research method and the particular focus of the research could be the reason.

The majority of the studies to date have used patient satisfaction surveys and questionnaires as a tool for assessing patients' reactions to therapeutic footwear as an intervention. It is assumed that levels of patient satisfaction are the barometer that indicates both the patient focussed and clinical success of the footwear. In reality what we find from these studies is that, despite overall satisfaction in the patients who continue to wear the footwear, there are still issues in relation to some aspects of the footwear itself. However, as most of the studies reviewed do not describe how the questionnaires were formulated it is possible that they were practitioner or researcher-focussed questions rather than patient-focussed questions, i.e. the focus of the questions could have been what the researchers thought should be asked rather than what patients felt was important and this could have introduced bias in the results. Therefore using questionnaires may be one reason why the real problems with footwear from the patient's perspective have not been uncovered.

All these studies assume that compliance with footwear is linked to satisfaction and that satisfied patients wear their footwear according to the expectations of the clinician. Indeed, compliance in respect of specialist footwear usage is difficult to define. The issues influencing compliance are complex and include psychological, physical and social elements, and any definition is based on whether it is the clinicians' or patients' perspective but has been described as 'the extent to which a patient's behaviour coincides with medical or health advice.'³⁹ This definition assumes that patients should do what clinicians tell them to do and that this equates to positive health outcomes. As compliance is not a problem until it is sufficiently low as to render effectiveness less than efficacy and looking at this from a patient centred perspective, compliance is an outdated term. We should perhaps replace this with 'appropriate health behaviour to achieve the maximum health benefits where the patient has informed choice or usability.'

Jannick developed a self-administered questionnaire to assess the usability of specialist shoes in patients with orthopaedic foot problems.⁴⁰ Usability is defined by the International Organisation for Standardisation (ISO) as 'the extent to which a product can be used by specific users to achieve goals with effectiveness, efficiency and satisfaction in a specified context of use'. The questionnaire comprises four effectiveness items (pain, instability, callus, and wounds), one efficiency item (putting on and taking off shoes) and seven satisfaction items (pinch, slip, weight of shoes, cold feet, perspiration, maintenance, and cosmetic appearance). Jannick concludes that adding efficiency and satisfaction factors to effectiveness factors informs more about the usability of this intervention with the specific focus being on the footwear itself. This is a major move forwards in acknowledging the complexity of footwear as an intervention in respect of clinical outcomes in relation to usability factors that are patient focussed.

Within the definition of usability, effectiveness is the accuracy and completeness with which users achieve specific goals. Perhaps, therefore, this is better than talking about 'compliance', for example, in a person who is able to walk to the shops without pain, satisfaction is defined as the comfort and acceptability of use and can be assessed in terms of attitudes to using the product, such as how patients feel about the appearance of their shoes and the level of comfort provided. The context of use refers to the physical and social environments in which a product is used.

Measurement of usability is particularly important in light of the complexity of the interactions between the patient and their goals, and the elements of the context of use. This can result in different levels of usability for the same product when used in different contexts.

A clear recommendation is made for improved communication between the prescribing clinician and the orthotist, and the

orthotist and the footwear technician, with the aim of improving the footwear and the outcome for patients. Interestingly though, improved communication between the orthotist and the patient has not been mentioned, either because there was no perceived problem in this area or because this had not been identified as a problem.

The research has looked at the footwear itself and/or the service in general and, although practitioner/patient relationships are alluded to in respect of communication, the effectiveness of the consultation between the patient and practitioner has not specifically been investigated. Despite the service structure, this therapeutic relationship may have the greatest influence on patient usage and satisfaction with specialist footwear.

We cannot ignore the importance of the clinical encounter and its influence on whether the patient is satisfied or not, and this incorporates satisfaction with the footwear. Without a 'good' clinical encounter patients feel disenfranchised from the health care process. This disenfranchisement would be expected to lead to dissatisfaction with the clinical encounter and so potentially low compliance. There is already some direct evidence of the importance of monitoring and reviewing footwear in improving compliance. Baker & Leatherdale³³ reported that compliance was improved in patients because of the regularity with which footwear was checked. This checking was a constant reinforcement of why they are wearing the footwear and re-motivated the patient. Williams & Meacher³⁴ demonstrated that patients attending a footwear clinic based in the department where they had their foot care may well have perceived the footwear to have more value as it was associated with a familiar department and personnel.

The patient's role in health care is generally changing from that of a passive recipient to an active participant, and in this respect patient expectations are that they should be able to make informed choices⁴¹. Providing information to empower a patient is aimed at enabling a person to gain greater control over a situation, i.e. enabling patients to become equal partners in the care and treatment process instead of being the traditional passive partner subservient to the healthcare professional.⁴² Lack of perceived control in chronic and disabling diseases such as RA may lead to non-compliance as a choice, which in effect is the only way that patients gain control if it is not facilitated by the health care professional.

The importance of practitioner-patient communication is described by Street:⁴³ 'in spite of sophisticated technologies for medical diagnosis and treatment, talk remains the primary means by which the physician and patient exchange health information. It is also the way that practitioners evaluate patient comprehension'.

RECOMMENDATION FOR CLINICAL PRACTICE

Several key areas emerge from this critical review that may improve outcomes for patients and clinicians alike:

- Patient involvement in the design or choice of design should be encouraged in an attempt to increase acceptance of the footwear.
- Patients should be aware of the purpose of this footwear and what it will potentially look like before they are referred for it.
- Supported choice not to have the footwear should be allowed by the referring practitioner.
- Therapeutic footwear should be provided through the service that provides specialist foot care so that the patient recognises that it is part of a whole package of foot care.
- Attention should be made to what patients wear around the home.
- Use of this footwear and both clinical and patient focussed outcomes should be monitored.

RECOMMENDATION FOR FURTHER RESEARCH

There has been no study that explores in depth the patient's feelings, opinions, attitudes and perceptions of being provided with therapeutic footwear, nor has there been any study that investigates the impact of the therapeutic relationship and the practitioners involved in its provision on the levels of patient engagement in the use of this footwear. These two aspects are the focus of current research by the author of this review using a qualitative research approach.

CONCLUSION

Since the Salford Report¹⁹ there is evidence that some of the recommendations have been embraced, but changes are localised and evaluated only to a limited extent. This review further reinforces the key recommendations made by this report and the studies published since. Despite these recommendations there are indications of continued patient dissatisfaction with therapeutic footwear, leading to poor compliance or low levels of usage. Appropriate qualitative research methods should be employed to gain a deeper understanding of the patient's perspective of wearing this footwear. When this is achieved, it may provide the solution of raising the status of the footwear and the service that provides it to more than a 'Cinderella service', and patients may be happier to wear the footwear with the potential health benefits being achieved.

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