AN INTERPRETIVE PHENOMENOLOGICAL STUDY OF USER EXPERIENCES OF THERAPEUTIC FOOTWEAR

ANITA E WILLIAMS

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University of Salford

Institute for Health & Social Care research

School of Health Care Professions

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"Caminante no hay camino. Se hace camino al andar".

Traveller there are no paths, paths are made by walking.

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ABSTRACT

Therapeutic footwear is provided to patients with the primary aims of reducing foot pain and improving foot health. Therefore, it is of concern that patients choose not to wear it. This choice has been attributed to its poor appearance. However, there may be other reasons for this choice and the reasons may be more complex than previously acknowledged. Therefore, the aim of this study was to investigate the users' experiences of this footwear. In the context of this study the 'users' are women with rheumatoid arthritis.

This study was based on an interpretive phenomenological approach (IPA) that employed conversational style interviews to gather data. Ten women with RA and experience of wearing the footwear were recruited and following ethical approval the interviews were carried out, transcribed, organised and analysed.

Five organising themes emerged as findings. These were the participants:

- feelings about themselves,
- · feelings about the footwear,
- unmet needs and expectations,
- behaviour with the footwear and
- feelings about the consultation with the practitioner.

The final, global theme was that the patient/practitioner consultation has a powerful influence on the women's feelings about themselves, the footwear, their expectations of it and their behaviour with it. This study has provided insight into their experiences of this footwear in that, unlike any other intervention, it replaces something that is normally worn and is part of an individual's perception of self and their perception of how others see them. The footwear impacts more on women's emotions than previously acknowledged and in addition, it has been found that the consultation influences their emotions and behaviour with the footwear. As well as improvements in footwear design and the service that delivers it, the training of the practitioners in a more patient focussed consultation

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style could improve the women's experience and engagement in the footwear as a health intervention, as well as something that is 'worn'.

CHAPTER 1 FRAMING THE THESIS

CHAPTER 1 - FRAMING THE THESIS

1.1 Introduction

The purpose of this introductory chapter is to provide a brief, but essential, background to the subject area for this thesis and the influences on me as the author that have led to the inception, and development of this research. The origin of these influences emerged from my clinical practice that included wide experience of managing patients with systemic diseases, such as diabetes and rheumatoid arthritis that placed the lower limb at risk of infection, ulceration, gangrene and ultimately limb loss. An important aspect of management in the prevention of these devastating problems was the provision of therapeutic specialist footwear. I will also introduce my developing thoughts about professionally based research and how this has influenced my ideas for the basis of this work. These areas will be explored later in the thesis following the critical review of the literature appertaining to the subject area, exploration of the literature on research methodology and the further development of my research philosophy. Thus, as well as the academic work contained in this thesis, I will also demonstrate my professional journey.

1.2 Background to 'Therapeutic Footwear'.

Since ancient man created footwear as protection from injury and the provision of warmth and comfort, there is an inescapable liaison between the foot and its protective footwear. Therefore, in the management of patients presenting with symptoms associated with foot pathology, footwear has to be considered both in the causation of foot pathology and in the treatment of it. Inappropriate footwear is a factor in the development of painful lesions such as corns and callus, which in healthy individuals do not affect the morbidity of the lower limb or are considered life threatening.

However, in patients presenting with systemic diseases, such as diabetes and rheumatoid arthritis (RA) the morbidity of the lower limb may be compromised. The complications associated with these diseases that impact on the foot are a compromised vascular supply, loss of protective sensation and altered architecture of the foot. These complications place the foot at risk of ulceration, infection and ultimately amputation. The patient's choice to use footwear that is deemed unsuitable by practitioners is known to be a factor in the cause of limb and life threatening foot ulceration in these patients (Firth et al 2007, Apelqvist et al 1990). This footwear is deemed inappropriate by practitioners if it is unable to accommodate the foot deformity without placing excessive forces on the skin and underlying structures. If the skin is unable to withstand these forces, it is likely to ulcerate particularly when there is loss of the protective sensation that would alert the patient to these damaging forces (Firth et al, Dahmen et al 2001, Edmonds et al 1996). Due to deformity, it may not be possible for the patient to find suitable footwear from retail outlets. So, the option is to have specialist therapeutic footwear supplied through the National Health Service (NHS) in the United Kingdom and through other agencies in other parts of the world.

This therapeutic footwear may be 'bespoke', which is made to the specific dimensions of the foot and is generally reserved for patients with major foot deformity. In cases of mild to moderate foot deformity, 'stock' footwear is supplied as a cheaper alternative to bespoke. This 'stock' footwear is available in a variety of extra deep and wide fittings that are not available through the usual retail suppliers. This therapeutic footwear is provided through the NHS Appliance or Orthotic Services, and the clinicians who measure and supply this footwear are orthotists. Historically this footwear was supplied to patients who had congenital problems affecting the feet such as talipes and acquired foot deformity as a result of conditions such as polio. At that time foot surgery was not as advanced as it is now and so this footwear was the only option available to ensure that these patients had symptomatic relief and improvements in mobility. As these patients came under the specialist area

of orthopaedics, the footwear was termed 'orthopaedic' or 'surgical' footwear. In the last twenty years the prevention of these conditions and also the management of these conditions have improved and this has resulted in a decline in these patients requiring this type of footwear.

Over the same period, this decline has been countered by the increase in the number of patients with diabetic foot complications requiring the footwear provided by the NHS (DOH 2001) so, shifting the need. In addition to patients with diabetes, there is increasing support from both clinicians and national guidelines (ARMA 2004) for therapeutic footwear to be provided to patients with rheumatoid arthritis. This group of patients are collectively termed 'high risk'. This means that they are at risk of ulceration, local and systemic infection, amputation and ultimately loss of life. The shift in the types of patients being provided with this footwear means that orthotists are now presented with patients who have chronic systemic diseases that are complex with regards both the diseases and their management. The manufacturers of this footwear have made efforts to take into account the specific requirements of the 'high risk' patient group in the functional design of the footwear and in the materials used in its construction with several manufacturers using the term 'diabetic footwear'. Indeed the terminology used to describe this footwear has changed generally from 'surgical' or 'orthopaedic' to 'therapeutic' footwear that could be viewed as a more positive term in respect of focussing on its intended outcome of achieving the desired positive therapeutic benefits for this patient group.

Therapeutic footwear has received the attention of researchers who have identified that there are clinical benefits in terms of lowered incidence of foot

re-ulceration in patients with diabetes (Chantelau, Kushner and Spraul 1990, Chantelau and Haage 1994, Wooldridge and Moreno 1994, Wooldridge et al 1996, Reiber et al 2002, Busch and Chantelau 2003), and improved walking speed, pain reduction and improved foot health in patients with RA (Moncur and Ward 1990, Fransen and Edmonds 1997, Williams, Rome and Nester 2007). However, for this footwear to contribute to good foot health it has to be worn sufficiently to have a

therapeutic effect. Patients have to be happy to wear it, but their satisfaction and compliance with therapeutic footwear has consistently been reported to be a problem from the late 1960s to the early 1990s by such authors as Dixon and Franklin (1968), Bainbridge (1979), Park and Craxford (1981), and Costigan et al (1989). The Department of Health commissioned Bowker et al (1992) to investigate the low levels of satisfaction and compliance highlighted by the previous research. They confirmed the earlier findings, but took the themes further by describing the service that provides specialist footwear as "rudderless and uncoordinated" and a 'Cinderella service'. The term 'Cinderella service' in this context, describes the lack of attention, funding, managerial support and development of the services that provide the footwear.

1.3 Influences from Clinical Practice

As a clinician managing high risk foot disease, I was aware of the problems associated with the footwear and the service that delivers it. This awareness emerged around the same time as Bowker et al (1992) published their report. It awakened unease in me in relation to my own professional practice. At this time I supported many patients requiring foot care who had been supplied with therapeutic footwear by the Surgical Appliance Service. A number of patients wore the footwear and as a result had improvements in their foot health and levels of comfort. However, there were many who chose not to wear the footwear, either because it had contributed to their foot problems or because they did not like the appearance of it. My concern was that whilst some patients benefited from it as an intervention, some had developed serious problems such as ulceration by wearing it and further to this was the waste of resources because of those patients choosing not to wear it. Bowker et al (1992) had made several recommendations for improvements in both the footwear and the service that provides it, with the aim of improving patient satisfaction, usage and clinical outcomes. They recommended the development of multidisciplinary footwear clinics to achieve these aims. The recommendations made by Bowker et al (1992) resonated with my own thoughts as to what would improve the service for the patients attending my clinic.

Armed with information about the problems experienced by patients and the financial cost to the hospital of the footwear not being worn, together with the passion that we needed to improve the patients' experience, the multidisciplinary footwear clinic was established in 1993. The features of the clinic were in line with recommendations made by the authors of the Salford Report (Bowker et al 1992). This multidisciplinary service was audited and compared with the traditional surgical appliance clinic in the domains of clinical outcomes, footwear usage and patient satisfaction. It was found that although the multidisciplinary service was more successful than the traditional service at achieving positive outcomes in the these domains, there were still 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' (Williams and Meacher 2001) and a financial drain to the service budget.

The expenditure associated with Orthotic services nationally around that time was approximately £20 million per year (Audit Commission 2000), with footwear taking up an estimated 60% of this NHS spend. The Disabled Living Foundation (1991) summarised work investigating the problems associated with the supply of footwear. They identified that the 'non use' of this footwear was between 20% and 50% and that this could equate to £2 million waste per year. This waste does not take into account the additional cost associated with the impact of poor foot health, limb and life threatening foot complications, not to mention the suffering and socioeconomic impact on individuals and their families.

The waste of resources coupled with concern for the deterioration of foot health in the high risk patients attending my own clinic, resulted in personal feelings of frustration. This 'frustration' was with the patients for not wearing the footwear, but also with me, as I perceived that I was failing as a practitioner. On reflection the 'professional frustration' I was feeling was perhaps the result of how I had been trained as a

chiropodist in the late 1970's. As a novice practitioner, I was influenced largely by my professional training. The training at that time was based on the medical model of care (Beck 2004) that focuses the practitioner on the presenting clinical problem and its management rather than the whole patient. Beck (2004) identified that medical training supported the ethos that the practitioner was the owner of all knowledge, and that the patient either did, or did not do as they were instructed. In the context of clinical practice and the footwear service, if the patient did not do as instructed, they were labelled as 'non-compliant'. The act of labelling the patient in this way appeared to further reinforce professional power and resulted in the patients being passive recipients of the footwear. From this observation, I developed unease about this situation and its impact on the lack of patient compliance with the footwear. It was an area of both clinical and professional interest to me, but I also considered it an area worthy of research. The desire to research this area became a focus for me, particularly as previous research had repeatedly made the same recommendations and had not generally resulted in any improvement for the users of the footwear.

However, before I focussed on the purpose of the research idea, I needed to understand more about the influences on patient behaviour and the terms associated with health behaviour such as compliance, non-compliance, adherence and concordance. Patients' health behaviour with respect to therapeutic footwear is therefore a central theme of the work presented in this thesis.

1.4 Professionally Based Research

Health care services are driven by the need for evidence (Sacket et al 1996) to prove that there are definite clinical benefits to the interventions provided and that adverse effects are identified before their acceptance into clinical practice. This is evidenced through the establishment and work of agencies such as the Cochrane Collaboration and the National Institute for Health and Clinical Excellence (NICE) who aim to influence clinical practice and the quality of health care through the implementation of quidelines that are based on research evidence. The need for evidence to support

podiatry and foot care interventions as being both effective and safe, has provided the focus of most research in the last ten years. This research has been carried out by a small number of podiatrists with established national reputations (Woodburn et al 1996, 2000, and 2002 [a and b], Nester et al 2000, 2001 [a], and 2001 [b] and Rome et al 1998, 2000 and 2001). These pioneers in research have generally approached clinical questions from a positivistic stance using quantitative methods such as Randomised Controlled Trials (RCT). As a practitioner I held these researchers in great esteem as being 'scientific' and I considered their results both impressive and indisputable. However, with a developing research interest, expertise and experience of carrying out an RCT (Williams, Rome and Nester 2007), this research influenced my developing thoughts on both the focus of research in this area and the research methods employed.

1.5 Influences from experience of quantitative research

Reflecting on the experience of carrying out an RCT (Williams, Rome and Nester 2007), I discovered that I had found it hard to be the objective researcher that I perceived to be the requirement of this type of research. I realised that in addition to the quantitative data collected, I had listened to what the subjects of this study had to say. I was concerned that the process of the RCT had not captured this, as I considered that it provided me with significant insight into their experiences and perceptions. These experiences and perceptions were not captured by the research methods that I adopted for this study, such as the validated objective health status measures (Budiman-Mak et al 1991, Bennett and Patterson 1998). This was really interesting to me as this desire to explore the participants experiences appeared to align with my clinical approach to patients, with the focus being on the person in the context of their problem rather than the problem alone. This approach had developed over a number of years of clinical experience of working with patients with complex, chronic diseases such as Rheumatoid Arthritis and diabetes. Working in a wider multidisciplinary team, I was further influenced by other practitioners' approaches. In particular, I was influenced by the nurses and occupational therapists, who demonstrated concern for the psychological, social and spiritual needs of the patients.

Reflecting on the influences on my clinical practice and the experience gained from carrying out an RCT became pivotal in developing my thoughts on an appropriate research approach. The fact that there was information that was not being captured provided me with the motivation to explore how I *could* capture the patient's subjective views, experiences and feelings, as I perceived that these could potentially influence their behaviour with the footwear. I considered that such experiences might be more valuable than the outcome of the RCT, and yet to date I had ignored them. These considerations provided further focus and an enhanced desire to explore this problem area.

1.6 Problem Identification

The patient's engagement with therapeutic footwear is clearly an important area to research as the problem of lack of compliance or low usage is still evident and previous research has not answered the question of "why don't patients wear their therapeutic footwear?" However, and more importantly, no one has asked the question "what are the patient's experiences and feelings about being provided with therapeutic footwear?" If their experiences and feelings are explored, the factors limiting the use of this footwear might be revealed. In an era where 'patient centred care' is a sound bite of the National Health Service, being patient centred in both clinical and research terms in this specific area has not been achieved.

The frustrations and the disquiet that I experienced in both the clinical setting, and much later in a research environment, have provided me with the motivation to formulate and consolidate my ideas for this thesis. These ideas have emerged from reflection on my clinical practice, early research experiences and the professional role of research. In addition to these factors, who I am as a person, with an empathic approach to the patients in my care and a desire to impact on their lives in a positive

way, has also been a driver to the further exploration and investigation of patients' health behaviour with respect to the appearance footwear.

All my experiences as a clinician and as a novice researcher have provided me with the ability to maximise the opportunity to explore this problem area. The focus is an attempt to discover the potential solutions that will contribute to improving the experience for both the patient and the practitioners involved in the provision of this footwear.

1.7 Summary

This chapter has provided the background into the influences that have led me to the purpose of this thesis and the investigation embedded in it. In this Chapter, I have described the influences from my clinical practice, my knowledge and experience of therapeutic footwear as an intervention. Further to this I have demonstrated my awareness of professionally based research. These influences generated the disquiet, concern and passion that have become the driving force for this work with the ultimate aim of improving the patients' experiences of this footwear. Improving the patients experience has the potential to influence their engagement with it and positively impact on foot health, thereby improving their overall quality of life.

The subsequent chapters of this thesis will reveal a journey that includes both the research itself and the milestones of learning. These milestones are the improved knowledge of the subject area and research methods, but more importantly the further development of my own philosophy and beliefs that underpin this research as a worthy activity.

That therapeutic footwear has the potential for contributing to positive health benefits was a belief that was supported by my interpretation of the evidence as a clinician. This interpretation was based on each author's findings and conclusions and not my

own critical review of this literature. In order to support my belief that therapeutic footwear did have the potential to improve foot health, and to explore factors that may have influenced the focus for this thesis, the first stage of the journey was to critically evaluate the research in this area. The next chapter is therefore a critical review of the literature exploring the clinical benefits of therapeutic footwear in the main patient groups being provided with this footwear, that is, those with diabetes and those with rheumatoid arthritis.

CHAPTER 2

CLINICAL BENEFITS OF THERAPEUTIC FOOTWEAR

CHAPTER 2 - CLINICAL BENEFITS OF THERAPEUTIC FOOTWEAR

2.1 Introduction

The two main groups of patients with whom I had most contact with as a clinician and who were thought of as benefiting from therapeutic footwear are those with diabetes and those with rheumatoid arthritis. Although both these two diseases have the potential to have major impact on the structure and function of the foot (Apelqvist et al 1990, Kerry et al 1994), they are different in respect of the subjective symptoms of the disease. Patients with rheumatoid arthritis are more likely to complain of pain as their main symptom (Turner et al 2007) and patients with diabetes are more likely to experience loss of sensation in their feet because of peripheral neuropathy (Masson et al 1989). Due to these differences a review of the literature on the clinical effectiveness of therapeutic footwear has been divided into two parts, one reviewing the literature on those with diabetes and the second those with rheumatoid arthritis.

2.2 Background

Both diabetes and rheumatoid arthritis are chronic, systemic diseases that have the potential to significantly affect the vascular status, tissue viability and structure of the foot. Therapeutic footwear is considered an important part of maintaining and improving foot health and quality of life and is a key feature of maintaining mobility and through this, independence, socialising and wellbeing. Furthermore, the need for this type of footwear by specific groups of patients has been identified (DOH 2001, ARMA 2004) as playing a role in reducing the impact of foot problems in the large numbers of people suffering from these diseases and their complications.

The United Kingdom has an estimated 1.3million people diagnosed with diabetes mellitus which accounts for £48 billion of the National Health Service annual budget. It is further estimated that 15% of people diagnosed with diabetes develop foot ulcers associated with neuropathy, ischaemia or both (Benvenuiti et al 1995). Ulceration of the diabetic foot is known to have serious consequences including infection, gangrene and amputation of the lower limb (Larson et al 1995). The estimated prevalence of foot problems associated with diabetes mellitus ranges from 20% in the early stages of disease to 90% in the late stages (Benvenuiti et al 1995).

Preventing foot ulceration is a priority for any health care practitioner involved in the care of patients with diabetes. Callus formation often precedes the development of neuropathic ulcers and it is known that foot ulceration precedes 84% of diabetes related lower limb amputations (Pecoraro et al 1990). Callus tends to form at pressure points in ill-fitting shoes, compounded by the effects of neuropathy on patterns of weight bearing. There are studies to support the belief that inappropriate footwear, purchased by patients in retail outlets is the cause of foot ulceration. Apelqvist et al (1990) identified footwear as the precipitating cause in the majority of toe ulcers and a significant number of lesions elsewhere in the foot and more recently McGill et al (2005) found that footwear trauma were the precipitating factor in 54% of ulcers in their study of two hundred and fifty patients with diabetic neuropathy. Therefore, therapeutic footwear is often recommended by clinicians in the attempt to minimise the trauma often associated with the patients own retail footwear.

Rheumatoid arthritis (RA) is common, affecting around 1% of the UK population (Symmons et al 1994). Once initiated, the persistent synovitis so characteristic of RA causes progressive joint damage and disability, the result being a progressive deterioration in affected patients' quality of life, and an estimated cost of £1.3 billion annually in the UK (Van Jaarsveld et al 1997). A number of studies have described the common structural and functional changes in the foot affected by rheumatoid arthritis (Sharma et al 1979, Minns and Craxford 1984), and there are reports of up to 89% of RA patients having some form of foot pathology (Vidigal et al 1975).

O'Connell (1998) and Michelson (1994) both identified forefoot pain as being the most frequent and severe foot problem affecting the gait and mobility of people with RA. In RA patients, reduced MTP dorsal flexion mobility induces changes in the walking parameters (Laroche et al 2006). Painful valgus deformity of the rear foot is associated with changes in the 3D kinematics affecting eversion at the ankle joint complex and internal rotation of the leg (Woodburn et al 2002 a). Further to these structural and functional problems, it has been identified by Firth et al (2007) that vasculitis, which is often associated with rheumatoid arthritis, is a primary factor leading to foot ulceration in this patient group.

The management goals for the patient with RA foot problems are pain management, preservation of foot function and prevention of ulceration. Two therapeutic components that are central to achieving these goals are footwear and foot orthoses (Diamonte and Light 1982, Jacobs 1984, Gerber and Hunt 1985, Frieberg and Moncur 1991, Marks and Myerson 1997). The provision of therapeutic footwear is described as a key in reducing the impact of pain and improving mobility (Bouysset et al 2005). Shrader (1999) identified that nearly every article published on the management of foot problems associated with the RA foot mention footwear as an important consideration in the management of these problems.

However, although this footwear is recommended in these two patient groups there is lack of clarity as to the potential foot health benefits. The objective of this literature review therefore is to identify and evaluate the evidence for the clinical effectiveness of therapeutic footwear for those with diabetes and rheumatoid arthritis.

2.3 Method

Anita Williams - An Interpretive Phenomenological Study of User Experiences of therapeutic Footwear – January 2008

The search terms were selected from both my experience in this specialist area and from the preliminary background reading of the subject area. The search terms were:

Diabetes AND Specialist footwear Rheumatoid arthritis AND Therapeutic

Diabetes AND Therapeutic footwear footwear

Diabetes AND Orthopaedic footwear Rheumatoid arthritis AND Orthopaedic

Diabetes AND Prescribed footwear footwear

Diabetes AND Shoes Rheumatoid arthritis AND Prescribed

Diabetes AND Footwear footwear

Diabetes AND Footwear and ulceration Rheumatoid arthritis AND footwear

Rheumatoid arthritis AND Specialist Rheumatoid arthritis AND shoes

footwear

The following databases were electronically searched using these search terms, for all articles related to specialist therapeutic footwear in relation to the patient groups of diabetes and rheumatoid arthritis (1986-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

Randomised controlled trials (RCT's), controlled clinical trials (CCT's), case controlled studies, and cohort studies were included. Papers were excluded that related to non-specialist therapeutic footwear or adaptations to non-specialist footwear. This review focuses on the use of therapeutic footwear in adults and therefore studies in children/adolescents were excluded. Only studies published in the English language and studies that were less than twenty years old were included for review. Work accepted for publication though not currently in press was included in this review to ensure that the reader is aware of recent and ongoing work. Ongoing work is not included in the review as the author recognises that the peer review process is an effective process for screening research.

Studies that fulfilled the inclusion requirements were reviewed and summarised. Each study was described in terms of patient characteristics, study type and design, description of the footwear and if other interventions were included such as foot orthoses, outcome measures and summary of conclusions drawn from the study. The quality of the studies was assessed according to the classification system described by Prior (2005) (Table 2.1)

Table 2.1 Grading system for recommendations in evidence based guidelines (Prior 2005)

Grades of recommendations

- A Requires at least one randomised controlled trial (RCT) as part of a body of literature of overall good quality and consistency addressing the specific recommendations.
- B Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation or systematic review of case control or cohort studies.
- C Based on non-experimental descriptive studies (e.g. correlation or case control studies.)
- D Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality.

2.4 Results

2.4.1 Papers reviewed

Six studies (Table 2.2) examined the effect of therapeutic footwear as a primary intervention in the prevention of re-ulceration in the diabetic foot. In addition, three studies investigated therapeutic footwear as a component of multifactor intervention or a 'package' of foot care, including callus debridement and foot health education and there were three systematic reviews of the literature in this area (Table 2.2)

| Table 2.2 – Papers selected for the critical review of therapeutic footwear as an intervention in the Diabetic foot | | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--|--|--|
| Studies investigating therapeutic footwear as a primary intervention: Studies investigating therapeutic footwear as a component of a package of foot care | | | | |
| Chantelau, Kushner and Spraul 1990 | Edmonds et al 1986 | | | |
| Chantelau and Haage 1994 | Uccioli et al 1995 | | | |
| Wooldridge and Moreno 1994 | Dargis et al 1999 | | | |
| Wooldridge et al 1996 | | | | |
| Reiber et al 2002 (a) | Systematic reviews: | | | |
| Busch and Chantelau 2003 | Spencer et al 2001 | | | |
| | Majid et al 2000 | | | |
| | Maciejewski et al 2004 | | | |

Four studies (Moncur and Ward 1990, Fransen and Edmonds 1997, Chalmers et al 2000, Williams, Rome and Nester 2007) and two systematic reviews (Egan et al 2003, Farrow et al 2005), investigated the impact of footwear as an intervention in the rheumatoid arthritis (RA) patient (Table 2.3).

Table 2.3 Papers selected for the critical review of therapeutic footwear as an intervention for the rheumatoid foot

Systematic reviews

Egan et al 2003 (Cochrane review)

Farrow et al 2005 (systematic review)

Studies investigating therapeutic footwear as a primary intervention

Moncur and Ward 1990

Fransen and Edmonds 1997

Chalmers et al 2000

Williams, Rome and Nester 2007

2.4.2 Therapeutic footwear as a primary intervention for re-ulceration in the diabetic foot.

Six studies (Table 2.2) examined the effect of therapeutic footwear as a primary intervention in the prevention of re-ulceration (Chantelau, Kushner and Spraul 1990, Chantelau and Haage 1994, Wooldridge and Moreno 1994, Wooldridge et al 1996, Reiber et al 2002 (a), Busch and Chantelau 2003). These studies will now be reviewed in detail.

Chantelau (1990) and Chantelau and Haage (1994) conducted two descriptive studies on patients with complications associated with diabetes (polyneuropathy, limb ischaemia, foot ulceration or prior forefoot or toe amputation) in a German population considered to be at risk of re-ulceration.

In their 1990 study, Chantelau recruited fifty consecutive patients with diabetic foot syndrome from a diabetes foot clinic. Of these fifty patients 72% had previous foot

ulceration and 30% had toe or forefoot amputation and all had peripheral neuropathy and/or peripheral vascular disease. None of the patients had active ulceration. Patients with Charcot and other foot deformities were excluded. These patients were provided with custom made therapeutic shoes with cork, plastazote and leather insoles. After twenty-five months, forty one patients remained in the study. Compliance with the footwear was monitored subjectively by checking the shoes for evidence of wear and by interview. There was lack of detail of the interview content and how the questions were arrived at. Also, the definition of the patient as being either a regular or irregular wearer of the footwear was subjective relying on patients self reported use and evidence of shoe wear. It is unclear whether the specific activities were undertaken whilst wearing the shoes. Those who wore their shoes daily (regular wearers) were significantly less likely to have ulceration compared with patients who wore them infrequently (irregular wearers). The authors indicate that there might be difficulty in generalising the results to the whole population. However, this was the first study to attempt to evaluate the effectiveness of therapeutic footwear and it provided a catalyst for further research in this area.

Chantelau and Haage's (1994) descriptive study followed fifty one patients with a history of neuropathic foot ulcers (including some of the patients from the 1990 study) to assess the influence of patients' footwear adherence on the risk of reulceration. Patients with ischemic foot lesions were excluded. All patients were provided with custom made shoes with plastazote, neoprene and poron insoles. Foot care was provided along with the footwear, but this was provided to the patients whenever they wanted and this may have had an influence on the reulceration rate with those patients attending more frequently receiving more foot care. However, the authors do report that the patients who were the most compliant with the footwear were also more compliant with foot care and acknowledge the influence of the foot care on the outcomes of the study. Thirty seven patients were considered compliant because they wore their therapeutic footwear at least 60% of the time and at twenty months only 8% of the compliant patients re-ulcerated. The authors of this study also highlight the effect of wear on the effectiveness of the

properties of the footwear and recommend that patients should have two pairs at any given time. This is useful in support of clinical practice, as often patients are only supplied with one pair (Williams and Meacher (2001) by the service that traditionally supplies the footwear, or may not receive foot care in combination with the footwear.

Two studies by Wooldridge (1994 and 1996) in the United States, investigated the impact of financial reimbursement for therapeutic footwear purchases on levels of footwear usage. Patients were randomised to receive either a benefit that would reimburse 80% of the cost of therapeutic shoes or no reimbursement (they could purchase the footwear at their own cost if so desired). The study sample was large, with 1,717 assigned to the control group and 1,717 to the intervention group. Fifty nine percent had prior foot ulcers and 25% had prior amputations and therefore the sample could be described as being moderate to high risk. They were followed for 12 months for foot complications. Amputation rates were not significantly different between the two groups. At the end of the study 4,373 patients had been enrolled for an average of 20 months. There was low uptake in obtaining footwear, so funding did not increase ownership. However, 32% of patients in both groups already owned therapeutic footwear. Footwear ownership across both groups at follow up was 85% for the intervention group and 55% for the control group with footwear usage reported as 61% for the intervention group and 37% for the control group. Despite the inconclusive evidence from this study, Medicare continued to provide financial reimbursement for this patient group, recognising that this footwear is important to this patient group.

Reiber (2002 a) conducted a randomised controlled trial to determine if extra depth and extra width footwear (Fig 2.1) and two types of insoles would reduce reulceration in four hundred patients with previous foot ulcers.



Fig 2.1 Therapeutic footwear (Reiber 2002 a p2552)

Patients were randomly allocated into one of three groups: 121 subjects were given three pairs of therapeutic shoes and three pairs of customised cork and neoprene insoles; 119 subjects were given three pairs of therapeutic shoes and three pairs of prefabricated polyurethane and nylon insoles and 160 control subjects wore their own footwear. The method of randomisation is not described. Lightweight slippers were also provided to all the study subjects. Two year follow up results indicate that therapeutic shoes did not significantly reduce ulceration comparing the intervention to the control groups. The incidence of ulceration was reported to be 15% in group 1 (cork insole) and 14% in group 2 (prefabricated insole) respectively and 17% in the control group. The information provided on the loss of subjects to follow up, footwear non-adherence and the use of 'intention to treat' analysis provides good internal validity.

A limitation of Reiber's study was that only 58% of the subjects demonstrated sensory neuropathy at baseline and 66% at the end of the trial, so this study could be characterised as having patients with only a low or moderate risk of re-ulceration. However, a further analysis of the subset of patients lacking sensation showed no significant difference between groups regarding the benefit of therapeutic footwear (Reiber 2002 b). They concluded that this study does not provide the evidence for the widespread use of therapeutic footwear in patients with low to moderate risk of re-ulceration. Further to this, they suggest that careful attention to foot care by health care professionals may be more important. However they do acknowledge that therapeutic footwear may be beneficial in high risk patients or for those who do not receive regular foot care.

A prospective cohort study carried out by Busch and Chantelau (2003), reported on a series of 92 patients with a history of foot ulcers. They were randomised to extra depth shoes with a rocker bottom sole and standard (non-custom) insole or to their own shoes. The extra depth shoes are described in detail and in addition to the rocker outer sole and the shock absorbing insole, the shoes had soft uppers and no

stiffness in the toe caps. The allocation was non random in that the control group consisted of 32 subjects whose insurance company would not provide therapeutic footwear. The authors acknowledge that they considered it unethical to deny a group of patients the protective footwear and so justify this choice of group allocation. The two groups were comparable in terms of type of diabetes, peripheral neuropathy, peripheral vascular disease the only slight difference was that the control group was slightly older (Mean age -control 67 yrs, intervention group 62 years) and all were considered high risk for re-ulceration. Patients were followed up until the end of the study at 42 months or until re-ulceration.

One year follow up results in Busch and Chantelau's (2003) study, demonstrated that the therapeutic shoes significantly reduced the incidence of re-ulceration (Risk ratio 0.25, 95% CI 0.12-0.51). However, the internal validity of this study is poor due to the non-randomisation, the absence of multivariate analysis, and the lack of information on compliance with the footwear. There is no information on the suitability of the footwear worn by the control group. Foot care was not standardised, with the patients accessing this service as and when they felt they required it. However, the authors do report that both groups accessed foot care equally.

A summary of the results of the review of this and the previous papers is contained in Table 2.4

Table 2.4 Studies investigating therapeutic footwear as a primary intervention for re-ulceration in the diabetic foot.

| Author/ Year/ country | Study design/ duration | Inclusion criteria | Intervention | Sample characteristics | Results | grade |
|----------------------------------------------------------------------------|---------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| Chantelau, Kushner and Spraul 1990 Germany | Descriptive study 25 months | Severe peripheral Neuropathy and/or peripheral vascular disease, prior healed ulcer, | Bespoke shoe with rocker sole and cushioned insole | N=41 Age(yrs) 59 Male(%) 62 Diabetes duration(yrs) 17 | 42%of patients wearing shoes daily re-ulcerated vs. 87% who did not wear their shoes daily RR 0.48, 95% CI 0.29-0.79 | С |
| Chantelau and Haage 1994 Germany | Descriptive study 20 months | Attended foot clinic for 4 yrs, no ischemic foot lesions | Bespoke shoe with rocker sole and cushioned insoles | N=51 Age(yrs) 63 Male(%) 58 Diabetes duration (yrs) 20 | Compliant patients (>60% of daytime use) at 20months had more foot care and less ulceration [8 vs38%] (RR 0.25, 95% Cl 0.12-0.51 | С |
| Wooldridge and Moreno (1994) and Wooldridge et al 1996) USA | RCT 12-20 months | Fifty nine percent had prior foot ulcers and 25% had prior amputations Randomised into Intervention group 80% reimbursement for cost of footwear and control group self funded footwear | 80% reimbursement for cost of therapeutic shoe v no reimbursement for the cost of therapeutic shoe | Intervention n=1717 Age (yrs) 70 Males (%) no information Diabetes duration (yrs) 59%>10yrs Control n =1717 Age (yrs) 70 Males (%) no information Diabetes duration (yrs) 59%>10yrs | Amputation rates were not significantly different between the two groups (risk ratio 1.42 95% CI 0.88-2.30). Footwear ownership Intervention group 85% Control group 55% Footwear usage Intervention group 61% Control group 37%. | A |
| Reiber 2002 US | RCT 24 months | Diabetes, age 45-84yrs, history of foot lesion or infection, no prior amputation of>2 digits, no unhealed lesion, no special footwear | Bespoke shoes, rocker sole + cork insole or + Polyurethane insole + slippers | N=121 Age(yrs) 61 Male(%) 78 N=119 Ag(yrs) 62 Male(yrs) 77 | No significant re- ulceration differences between the cork and the PU insole (cork- RR 0.88, 0.51-1.52; PU RR 0.85,0.48-1.48 | А |
| Busch and Chantelau 2003 Germany | Prospective Cohort study 42 months | Clinic patient from 1999 to 2001, previous foot ulcer, insured, polyneuropathy and/or peripheral vascular disease | 'Stock' therapeutic shoe, soft uppers no stiff toe cap rocker sole, standard flat cushioned insole | Intervention group N=60 Age (yrs) 62 Males(%) 52 Diabetes duration(yrs) 12 Control group N=32 Age(yrs)67 Males (%) 56 Diabetes Duration (yrs) 15 | 15% of patients with shoes re-ulcerated at 1 yr vs. 60% of patients without shoes (RR 0.25, 0.12-0.51) | В |

2.4.3 Therapeutic footwear in multi-factorial interventions for re - ulceration in the diabetic foot.

Three studies investigated multi-factorial interventions on ulcer outcomes and included therapeutic footwear as one of the interventions (Edmonds et al 1986, Uccioli 1995, Dargis et al 1999) (Table 2.2).

The first is a descriptive study by Edmonds et al (1986) who evaluated the role of a specialist foot clinic in reducing lower limb amputations. The multidisciplinary team included a physician, consultant orthopaedic and vascular specialists, podiatrists, nurses and a 'shoe fitter'. The subjects in this study (n=239) were divided into two groups: those with neuropathy (16% had Charcot deformity or ray amputation at baseline) and an ischemic group. Inappropriate footwear was identified as being the most frequent precipitating factor in foot ulceration. However, the criteria for grading the footwear as being appropriate or not was not described in detail. Therapeutic footwear was provided and worn by 58% of the neuropathy group and 57% of the ischemic group with the remainder being the control group. The package of care received by all the subjects in this study was, foot assessment, callus debridement, wound care, treatment of infection, and foot health education.

After two years the amputation rate was reduced by 50%. In the neuropathy group wearing therapeutic footwear 26% re-ulcerated compared with 83% of patients in the control group. In the ischaemic group 25% re-ulcerated compared with 85% of the control group. These findings suggest that for high risk patients, therapeutic footwear may be of benefit. However, the multi-factorial intervention makes it impossible to separate the benefits of therapeutic footwear from the other interventions.

A study of sixty nine patients with a history of foot ulceration or at high risk of reulceration, but no history of amputation was carried out at two clinical sites in Italy by Uccioli et al (1995). The subjects were alternately assigned to a control or an intervention group. The control group wore their own footwear but these were checked for suitability prior to the onset of the study. Shoes specially manufactured for the diabetic foot with tri-density insoles, soft thermo-formable leather with semi-rocker soles were provided to subjects in the intervention group.

Patient education was provided to both groups and patients were followed up at six months to check footwear adherence and receive new footwear. It is not clear how adherence was assessed or evaluated. The study did not use random allocation but used 'alternate treatment' allocation. Ulcer occurrence was 30% in the first two months in the control group. After one year follow up, 27.7% of the intervention group had ulcerated compared with 58.3% of the control group. There was no information on the patients lost to follow up and potential contamination of the effect of footwear as an intervention, because foot care was not standardised. The authors concluded that individuals with significant foot deformities should be considered for customised shoes, but in the absence of significant deformities, high quality well fitting non-prescription footwear seems to be a reasonable option.

Dargis et al (1999) also investigated the effect of the multidisciplinary approach in the reduction of ulceration and amputation compared with standard care over a two year time period. All the patients had a history of neuropathic ulceration but no peripheral vascular disease, foot deformity or amputation. These subjects were therefore deemed at moderate risk of re-ulceration. The multidisciplinary interventions included extra depth shoes and plastazote, multiform or silicone insoles, foot care education and callus debridement every three months or less. Other interventions included wound care, nail care and foot health education. Over the two year period 30.4% of the multidisciplinary group developed ulceration compared to 58.4% in the control group. The intervention, inclusion criteria and loss to follow up were presented clearly. However, it is unclear what the influence of the other interventions had on the success or failure of the footwear. Other problems with this study are the non-randomisation of subjects, lack of reporting on usage and

non-adherence with the footwear and the variations in clinical treatments. However, despite the weaknesses of this study, the authors indicate that therapeutic footwear does appear to have a beneficial effect in preventing re-ulceration, even in those with a moderate risk.

A summary of the studies investigating therapeutic footwear in multi-factorial interventions for re-ulceration is contained in Table 2.5

Table 2.5
Studies investigating therapeutic footwear in multi-factorial interventions for re-ulceration in the diabetic foot

| Author, year, Country | Study design and duration | Inclusion criteria | Intervention | Sample characteristics | Results | grade |
|------------------------------------------------|-------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| Edmonds et al 1986 UK | Descriptive study ~26 months Follow up 3.5 weeks average during ulcer episode | Diabetic foot clinic attendee | Stock footwear (Dru shoe) with plastazote or custom made insoles, patient education, wound care (inc debridement) | Neuropathic compliant N = 86 Age(yrs) 59 Male(%) 47 DD(yrs) 16 Neuropathic non- compliant N = 35 Age(yrs) 59 Male(%) 47 DD(yrs) 16 Ischaemic compliant N = 52 Age(yrs) 69 Male(%) 53 DD(yrs) 15 Ischaemic Non- compliant N = 18 Age(yrs) 59 Male(%) 48 DD(yrs) 14 | Neuropathic patients 26% compliant vs 83% non-compliant re-ulcerated (RR0.31, 95% CI 0.24-0.46 Ischaemic patients 26% compliant vs 83% of non-compliant re-ulcerated (RR 0.30 95% CI 0.53 | С |
| Uccioli et al 1995 Rome and Milan, Italy | Two site controlled trial 12 months Follow up 6months | Prior foot ulcer, no current foot ulcer, no minor or major ulceration No major foot deformity | Therapeutic footwear with a custom moulded insole; education Control group own footwear | Intervention N = 33 Age(yrs) 70 Male(%) 60 DD(yrs) 17 Control N = 36 Age(yrs) 60 Male(%) 64 DD(yrs) 18 | 27.7% Intervention group re-ulcerated compared with 58.3% in control group (RR 0.47 95% CI 0.23- 0.90) | В |
| Dargis et al 1999 Lithuania | Cohort study (7 clinics) 24 months. Follow up every 3 months | Neuropathy, previous history of ulcer, palpable foot pulse, no amputation, no Charcot | Multidisciplinary foot care, extra depth shoes with plastazote, multiform or silicone insoles, foot care education | Intervention N = 56 Age(yrs) 59 Male(%) 48 DD(yrs) 14 Control N = 89 Age(yrs) 59 Male(%) 47 DD(yrs) 16 | 30.4% re-ulcerated intervention group compared with 58.4% in the control group (RR 0.51 95% CI 0.31-0.80). | В |

Therapeutic footwear is included in three published reviews on the prevention of ulceration and re-ulceration in the diabetic foot. Majid et al (2000), in a review of both published and unpublished studies of ulcer prevention and management concluded that there was insufficient evidence to support its widespread adoption. Further to this, Spencer (2001) concluded that poor methodology prevented conclusive evidence for recommendation of footwear as an intervention for prevention of ulceration. However, it was indicated that there was weak evidence for this footwear in prevention of re-ulceration. In a recent review of studies investigating therapeutic footwear in prevention of re-ulceration (Maciejewski et al 2004), the authors conclude that although two clinical trials found no significant protective benefit of therapeutic footwear, analytic and descriptive studies reported significant protective benefits. Re-ulceration risk varied widely across all the studies with some including major foot deformity. Maciejewski et al (2004) commented on the effect of this major foot deformity in a seven-fold variation in annual ulcer incidence, in that populations with a high annual ulcer incidence, it is easier to demonstrate a significant effect of the intervention in reducing ulceration than those with a low incidence.

Despite inconclusive evidence, therapeutic footwear does appears to have a role in prevention of re-ulceration, particularly when combined with other foot health interventions such as foot care and foot health education.

2.4.4 Therapeutic Footwear as an intervention for the Rheumatoid Foot

Four studies (Moncur and Ward 1990, Fransen and Edmonds 1997, Chalmers et al 2000, Williams, Rome and Nester 2006) and two systematic reviews (Egan et al 2003, Farrow et al 2005) investigated the impact of footwear as an intervention in the rheumatoid arthritis (RA) patient (Table 2.3).

The small randomised controlled trial by Fransen and Edmonds (1997) investigated the use of extra depth shoes by patients with RA. The randomised open controlled study investigated thirty participants (15 intervention and 15 controls) on stable drug treatment but with foot pain of at least 1 year's duration. All participants were said to have rheumatoid arthritis but no classification criteria was used to define a definitive diagnosis. Patients with severe cardiac, pulmonary or neurological disease that might influence gait were excluded as were patients who had recently undergone surgery. All the participants' baseline characteristics are described and they all completed the Health Assessment Questionnaire (HAQ) (Kirwan and Reeback 1986). The experimental group used extra-depth shoes and the control group their own shoes. The trial was followed by a repeated measures analysis utilising the control participants. Participants who wore the shoes for two months demonstrated significant improvements in physical function, walk pain, stair pain, and pain free walk time without an increase in walking aids or arthritis medication, compared to those who wore their own footwear. The participants with the shortest disease duration had the greater percentage improvement in walk pain and HAQ scores, suggesting that early intervention would have the most impact on the patients overall quality of life in relation to walk pain reduction and physical function. There was no change in non-weight bearing pain, subjective wellness or fatigue. The quality score given by the reviewers (Farrow et al 2005) for this study was a low score of 2 out of 5 on the Jadad scale (Jadad et al 1996). However, the results do support the use of therapeutic footwear in patients with symptoms associated with rheumatoid arthritis.

A subsequent study by Chalmers et al (2000) investigated 28 RA patients with the minimum of two subluxed metatarso-phalangeal joints (MTP) and MTP joint pain as the most significant problem. The patients received, in random order, three interventions for 12-week trials, separated by 2-week washouts. The interventions were: supportive shoes worn alone, supportive shoes worn with semi-rigid orthoses (Subortholen), or soft orthoses (Plastazote). The outcome measures were the Robinson Bashall Functional Assessment [RBFA] (McCloy et al 1987), which consisted of standing, walking and stair-climbing scales; the walking and stair-

climbing components of the Toronto Activities of Daily Living measure [TADL] (Helewa et al 1982), the time to walk a distance of 50 feet; lower extremity joint count; MTP joint count; and pain. There was no difference between the use of extradepth shoes alone and extra-depth shoes with soft insoles. Semi-rigid insoles with extra-depth shoes provided a lower level of pain for the user than extra-depth shoes alone over the 12 week period. When the patients wore the soft insoles in extra depth shoes there was no difference between these and extra depth shoes alone. However the patients' preferences were recorded and following experience of all three combinations, nearly 50% preferred the soft insoles in extra depth shoes with the rest preferring the semi rigid insoles in extra depth shoes. Those who chose soft insoles had similar pain using both types of insoles, whilst those choosing semi rigid foot orthoses experienced more pain with soft insoles. The significance of this study is that it demonstrates the importance of the insole in specialist footwear as a therapeutic component of the footwear rather than footwear alone and the importance of the patient's perceptions as to what interventions are likely to be most beneficial regardless of objective outcome measures.

The Cochrane review by Egan et al (2002) concluded that there was evidence from the two studies (Fransen and Edmonds 1997, Chalmers et al 2000) that extra depth shoes and moulded insoles decrease pain on weight-bearing activities such as standing, walking and stair-climbing.

The quality score of the Chalmers study by the reviewers (Farrow et al 2005) was again a low score of 2 (Jadad et al 1996), but concurring with the conclusions of the Cochrane Review (Egan 2002) they conclude that extra depth shoes, especially if combined with foot orthoses are likely to be beneficial. Interestingly they also comment that in the case of surgical procedures there was little reporting of the 'harm' that occurred to subject being studied e.g. infection, delayed wound healing thrombosis and this was seen as important to report. However in comparison to the surgical studies reviewed, they state that 'harm' is not a problem with foot orthoses or therapeutic footwear. The lack of recognition that this may possibly be an issue

may be due to the studies being reviewed not mentioning potential harm. However, a study carried out after the reviews were published by Williams et al (2007), did identify that therapeutic footwear can potentially cause adverse effects on the foot health of individuals and that this would lead to the footwear not being used.

This study (Williams et al 2007), compared a traditionally designed therapeutic shoe with a new footwear design based on patients opinions from a previous study (Williams and Nester 2006) Eighty patients were randomly assigned to either an intervention group with the new design of footwear (Figure 2.2) or the control group with the traditional design of footwear.



Figure 2.2 – Therapeutic footwear (Williams et al 2007)

The footwear design features were described in detail. Patients completed two specific health related quality of life scales, the Foot Health Status Questionnaire (Bennett and Patterson 1998), and the Foot Function Index (Budiman-Mak et al 1991), both at baseline and after 12 weeks. This trial was non-blinded, but as the outcome tools were self completed by each subject, bias was minimized. Both the specific health-related quality of life scales demonstrated significant improvement from baseline to week 12 with the intervention group (p<0.05). There was no significant difference in both specific health-related quality of life scales after week 12 with the traditional group (p>0.05). However, only 36 completed the trial with ten patients (9 in the control group) refusing the footwear outright and thirty-four patients withdrawing from the study after the footwear was supplied due to either non-footwear related problems or adverse incidents related to the footwear. Whilst the

high drop out rate, particularly from the control group may be seen as a limitation, it reflects the clinical reality that many patients choose not to wear the footwear they are provided with. Deciding not to wear the footwear at the time of provision in the control group is an important result of this study. This study highlights the complexity of factors which impact on the clinical outcomes from this footwear in respect of personal issues for patients, such as cosmesis, the perceptions of others regarding their footwear and the stigma of foot deformity and disability.

Williams, Rome and Nester (2007) concluded that improvement in pain, foot health and patient satisfaction with the new design of footwear indicates the importance of patient involvement in the design process and throughout the process of supplying and monitoring the footwear. The fact that the new design shoe was based on patient's involvement in the design process in a previous study (Williams and Nester 2006) may be the most important factor in its success in this patient group.

A summary of all the studies selected for this section of the review are detailed in Table 2.6.

| Author/year/c | Study duration | Inclusion criteria | Intervention | Sample Characteristics | Results | grade |
|---------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| Moncur and Ward 1990 USA | Survey Questionnaire 3months- 5months | Definite diagnosis of RA, previous demonstrable compliance with footwear interventions | Heat mouldable shoes with insoles | 25patients females age range 35-74 | Baseline level of comfort in own shoes 20 self reported improved walking Adverse incidents reported | С |
| Fransen and Edmonds 1997 Australia | RCT 8 weeks | Stable drug treatment foot pain of at least 1 year's duration. Rheumatoid arthritis Exclusions Patients with severe cardiac, pulmonary or neurological disease recent surgery. | Intervention group Extra depth off the shelf footwear Control group own footwear | 30 22 females 8 males 2 withdrawal | Weight bearing pain decreased and an improvement in HAQ scores Intra group changes in completers In intervention group - VAS pain walking reduced(mean 17.2 p=0.0001) VAS pain climbing stairs (mean 18.4 P=0.0001) Controls-no significant change | А |
| Chalmers et al 2000 Canada | RCT cross over design 12 weeks each intervention with 2 weeks wash out period between the interventions | Diagnosis of RA, Minimum 2 subluxed MTP joints bilaterally and MTP joint pain as most significant foot problem | Extra depth shoes with semi rigid orthoses (subortholen) v extra depth shoes and soft orthoses (plastazote) v shoes alone | 21 females (mean age 63 yrs) 3 males (mean age 60yrs) Mean disease duration 15yrs 4 withdrawal | Changes in mean VAS foot pain Shoes alone = 0.05 Soft orthoses = 0.01 Rigid orthoses = 1.87 between group P=0.027 There was no difference in the RBFA TADL, 50 foot walking time or foot joint counts | А |
| Williams, Rome and Nester 2006 UK | RCT 12 weeks | RA of five years or more duration, foot deformity, difficulty in being able to obtain suitable retail footwear and self-reported foot pain | Control group Traditional design shoe with flat insole Patient centred design shoe with moulded insole | 80 recruited 36 completed 50 female 30 male mean disease duration (years) for all patients was 17.07 +/- 14.41 | FFI between group Baseline p = 0.52 12 weeks = p < 0.01 FFI Baseline -12 weeks Intervention p < 0.05 Control p = 0.41 FHSQ between group Baseline p>0.05 12 weeks (p<0.05) FHSQBaseline-12weeks Intervention p<0.05 Control group p>0.05 | А |

2.5 Summary

Although therapeutic footwear is often provided for patients with diabetes, particularly after one episode of foot ulceration, overall there is limited good quality evidence for its therapeutic effect. Research is limited, with many of the studies lacking in quality and rigour. Most of the studies reviewed had small sizes in relation to the method chosen, were non-randomised, non-blinded and had differing study designs. These factors made comparisons difficult. In addition, there were differences in patient groups with regards patient inclusion, and baseline characteristics. However, despite the problems in study design, therapeutic footwear does appear to have an important contribution in the prevention of re-ulceration in both these patient groups particularly when combined with other foot related interventions.

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In contrast, that therapeutic footwear can be of benefit to patients with RA is supported by reasonable evidence (Fransen and Edmond 1997, Chalmers 2000, Williams, Rome and Nester 2007). These benefits include reduction in pain, increased mobility, and improved foot health.

2.6 Conclusion

Although the evidence for therapeutic footwear as a health intervention is inconclusive due to differing methodology and in some cases small sample sizes, overall, there are good indications that patients with diabetes and patients with rheumatoid arthritis do benefit from the provision of therapeutic footwear particularly when combined with other foot care interventions. In particular, in patients with RA the improvements in painful symptoms and foot health are significant.

The conclusion that I make from this review is that therapeutic footwear is effective, particularly in patients with RA, painful symptoms and poor foot health.

In addition to this, the results of previous work, (Williams and Nester 2006) indicate that those patients with diabetes and those with RA have differing needs from their therapeutic footwear. Patients with diabetes focus on its appearance and patients with RA being more concerned with comfort and reduction of pain. Therefore, given these benefits, it is of concern that patients chose not to wear the footwear. This choice has been observed in clinical practice and in the research evaluating its effectiveness. In order to explore the reasons for this choice, the next chapter is a review of the literature that explores factors that may influence the patients' behaviour with the footwear.

CHAPTER 3

FACTORS INFLUENCING THE PATIENT'S BEHAVIOUR WITH THERAPEUTIC FOOTWEAR

CHAPTER 3 - FACTORS INFLUENCING THE PATIENT'S BEHAVIOUR WITH THERAPEUTIC FOOTWEAR

3.1 Introduction

Research has demonstrated some clinical benefits of specialist therapeutic footwear in terms of for example, lowered incidence of foot re-ulceration in patients with diabetes (Chantelau, Kushner and Spraul 1990, Chantelau and Haage 1994, Wooldridge and Moreno 1994, Wooldridge et al 1996, Reiber et al 2002[a], Busch and Chantelau 2003), improved walking speed, and pain reduction in patients with rheumatoid arthritis (RA) (Moncur and Ward 1990, Fransen and Edmonds 1997, Chalmers et al 2000, Williams, Rome and Nester 2007) and improved foot health (Williams, Rome and Nester 2007). It is generally agreed that this footwear has some clinical benefit particularly in patients with RA (Williams, Rome and Nester 2007) with practitioners utilising this footwear as a foot health intervention.

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 engagement with this footwear, resulting in the footwear either being used selectively or not at all and ending up as 'shoes in the cupboard' (Williams and Meacher 2001). Therefore, the purpose of this exploration of the literature is to review the evidence for the influences on the patients' behaviour with therapeutic footwear.

3.2 Background

Patient satisfaction and 'compliance' with specialist footwear has consistently been reported to be low from the late 1960s to the early 1990s. Dixon and Franklin (1968) found that 50% of 70 patients (with Rheumatoid arthritis - RA) were dissatisfied with their footwear. Contrastingly, Haslock and Wright (1969) found that only 17% of RA patients in their study complained of problems. However, this study was carried out

by the people that provided the footwear, which may have influenced the patient's response. An independent survey of patients with a variety of foot problems. commissioned by the Department of Health (Bainbridge 1979) found that whilst 82% of all the patients were satisfied overall, most had some negative comments about the footwear. Bainbridge (1979) identified that poor communication between the prescribing clinician and the orthotist, and then between the orthotist and the shoe maker were the fundamental problem. Further to this study, Park and Craxford (1981) found that although 90% of the 71 RA 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 al (1989) found that of the eighty two patients (general foot problems) 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 as being the main reasons for poor 'compliance'. This early work is potential evidence of patients having to compromise. Compromise occurs in that although some benefits are recognised resulting in overall satisfaction, there are still major issues that result in patients being dissatisfied. The dissatisfaction relates to specific aspects of the footwear resulting in low use, selective use or them not being worn at all.

The views of consultants prescribing this footwear have also been sought. Lord and Foulston (1989) 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 the less than 50 % response rate from the consultants probably represents the 'honest' half, who may not feel qualified to answer the question on suitability (Rowley 1989) and highlights the fact that there is little, if no training for the 'prescriber' of the footwear and this need should be addressed.

Recognising the concerns with this footwear, the Department of Health commissioned a study by Bowker et al (1992), with the purpose of investigating the problems highlighted by the previous research. 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. These were, more information for patients, review appointments, effective management of the referral process and budget and patient involvement.

Therefore, the purpose of this review of the literature is to explore if the recommendations made by Bowker et al (1992) have impacted on the factors that influence patient satisfaction and their behaviour with the footwear.

3.3 Method

The following search terms were identified from reading the literature in relation to the clinical effectiveness of the footwear and also from previous knowledge of the services that provide the footwear:

- Compliance and footwear
- Compliance, footwear and therapeutic
- Compliance, footwear and surgical
- Compliance, footwear and orthotic services
- Patient satisfaction and footwear
- Patient satisfaction, footwear and therapeutic
- Patient satisfaction, footwear and surgical
- Patient satisfaction, footwear and orthotic services

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

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PubMedMedline

EmbaseCinahl

- The Cochrane database of systematic reviews
- The Cochrane register
- UK National Research Register

The following journals were hand searched

The British Journal of Podiatry
 The Foot

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 which were less than fourteen years old were included for review. Ongoing work is 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.

3.4 Results

3.4.1 Papers reviewed

Sixteen papers were selected for the review (Table 3.1). Of these, ten were in relation to patient satisfaction (2 involving patients with 'general' foot problems, five involving patients with diabetes and three involving patents with rheumatoid arthritis). The remaining six papers were in relation to footwear services. Compliance was an issue in all these papers, both in relation to patient satisfaction with the footwear and the service that delivers it.

| Table 3.1 Papers selected for the critical review of studies investigating factors | | | | | |
|------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
| that influence the clinical benefits of therapeutic footwear | | | | | |
| Patient satisfaction with Footwear (general) | Patient satisfaction with footwear (diabetes) | Patient satisfaction, with footwear (rheumatoid arthritis) | Footwear service | | |
| Newson et al 1992 Philipsen et al 1999 | Knowles and Boulton 1996 Armstrong et al 2001 Van de Weg 2002 MacFarlane and Jensen 2003 Johnson et al 2006 | Herold and Palmer 1992 Stewart 1996 Van der Esch et al 2003 | Bowker et al 1992 Boer and Seydel 1998 British Society of Rehabilitation Medicine (1999) Baker and Leatherdale 1999 Williams and Meacher 2001 Emery and Borthwick 2002 | | |

3.4.2 Patient satisfaction with therapeutic footwear

Since the Salford Report (Bowker et al 1992) there are indications of continued patient dissatisfaction with therapeutic footwear leading to poor compliance or low levels of usage.

Newson et al (1992) interviewed forty 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 which contributed to the failure of the footwear to meet the needs of the patient. These problems concur with those identified in the Salford Report (Bowker et al 1992). It may be that there had been no time to embrace the recommendations made by the report before this work was published. Philipsen (1999) investigated seventy four

patients attending an orthopaedic clinic found that although 38% patients reported some benefit, 17% had no benefit or had deteriorated and 7% developed ulcers whilst using their therapeutic footwear. Although there was improved comfort overall, there were areas of concern to the participants of this study, such as poor cosmesis.

A questionnaire (Herold and Palmer 1992) sent to one hundred and thirty seven subjects with rheumatoid arthritis (RA) had a return rate of ninety seven. 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, Herold and Palmer (1992) do highlight the complexity of providing patients with an intervention which is outwardly visible as well as the functional aspects of getting the shoes onto the feet.

A subsequent study by Stewart (1996), also investigated footwear usage in patients with RA. The author 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 ninety six patients with 86% of these responding with fully or partially completed questions. She demonstrated that overall satisfaction with prescription footwear in patients with RA deformity was high but again this was associated with selective use of the footwear. Stewart (1996) also highlighted that when the patients were asked about the weight of the shoes it was unclear whether the problems with weight were the actual weight of the shoe or whether it was the visual appearance of weight which was reported as being a problem.

An investigation into the possession and use of footwear (Van Der Esch et al 2003) in a random sample of six hundred and forty patients with RA or osteoarthritis (223 RA, 187 OA) revealed that 46% of the patients with RA possessed therapeutic 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 use of different footwear for use at home in relation to satisfaction (Knowles and Boulton 1996) 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 Armstrong et al (2001) monitored activity with therapeutic footwear and reported that even though they were more active in the home, the patients were less likely to wear their prescribed footwear at home than when outside. Although not related directly to satisfaction, this lack of compliance highlights a problem that may well be important in the causation of foot ulceration.

Van de Weg (2002), conducted a postal questionnaire with 75 patients with diabetes and 172 controls, with a good response rate of 71%. One fifth of the patients in this study complied with their footwear but the author acknowledges that this could be an under representation as the non-responders could be non-compliant. They defined compliance as wearing the shoes from morning to evening. The authors highlighted the need for providing the patient with information of the possible consequences of non-compliance and also suggest that this type for footwear should only be provided to patients who are motivated to wear it. Also, 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 and Jensen (2003) 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 al (2006) who carried out semi structured interviews with 15 patients with a history of diabetes related foot ulceration and/or amputation and 15 practitioners. They demonstrated differing perspectives in terms of expectations, shoe wearing behaviour and difficulties fitting feet which are constantly changing shape. They recommend that the patient's needs are taken into consideration in shoe provision.

A summary of all the papers in relation to patient satisfaction is contained in Table 3.2

| Table 3.2 Patient satisfaction with therapeutic footwear | | | | |
|----------------------------------------------------------|----------------------------|---------------|---------------------------------------------|--|
| Author/year/Country | Sample characteristics | Method | Results | |
| N | 40 patients (variety | | 62% complained of appearance | |
| Newson et al 1992 UK | including polio, | Questionnaire | 37% complained of difficulty getting the | |
| | Osteoarthritis, rheumatoid | | shoes on | |
| | arthritis, foot deformity, | | | |
| | amputation, CVA) | | | |
| Philipsen et al 1999 | | | 38% some benefit but complaints of poor | |
| Denmark | 74 patients from an | Questionnaire | appearance and comfort | |
| | orthopaedic dept | | 17% found no benefit | |
| | | | 7% developed ulcers | |
| Herold and Palmer 1992 | | | 24% stopped wearing them within 12 | |
| UK | 137 patients 79 RA | Questionnaire | months | |
| Stewart 1996 | | | Overall satisfaction | |
| UK | 96 patients with RA (86% | Questionnaire | 29% very satisfied;50% satisfied;16% | |
| | responded) | | dissatisfied;5% very dissatisfied | |
| | | | Satisfaction with style | |
| | | | 24% very satisfied;49% satisfied; 16% | |
| | | | neither satisfied or dissatisfied;7% | |
| | | | dissatisfied;5% dissatisfied | |
| Van der Esch et al 2003 Netherlands | 640 patients | | 46% of the RA patients possessed | |
| Netricianos | RA 223 responded | Questionnaire | footwear (30% overall - walking aids | |
| | OA 187 responded | | including walking sticks did not use them – | |
| | | | unfortunately did not separate out the non- | |
| | | | use of footwear | |
| Knowles and Boulton | | | 22% regular wearers | |
| 1996 | Diabetes 50 | Interview | 18% disliked style | |
| UK | | | 38% wore slippers indoors | |
| Van de Weg 2002 | | | 20%wore their footwear | |
| Netherlands | Diabetes 75 | Questionnaire | always compliant: 46 diabetes;57 controls | |
| | Other 172 | | often compliant : 33diabetes 30 controls | |
| | (71% responded) | | non-compliant : 21 diabetes 13 controls | |
| MacFarlane and Jensen | | | 90% reported that they thought that | |
| 2003 ²⁸ | 161 patients [31% | Questionnaire | footwear was important | |
| USA | responded] | | 63% liked wearing them but | |
| | | | 24% complained about appearance | |
| | | | 24% complained about lack of comfort | |
| | | | 14% complained about the weight | |
| Johnson et al 2006 ²⁹ | Diabetes with history of | Interviews | Differing perspectives in terms of | |
| UK | ulceration/amputation -15 | | expectations, usage and fit | |
| | Practitioners- 15 | | | |

3.4.3 Footwear services

The provision of this specialist therapeutic footwear starts with the prescribing clinician who is often a consultant. 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 and Seydel (1998) found that in the Netherlands, consultants and rehabilitation practitioners 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 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 training and professional roles in its provision (British Society of Rehabilitative Medicine 1999, Baker and Leatherdale 1999, Williams and Meacher 2001, Emery and Borthwick 2002, Orthotic Pathfinder Report 2004, Helliwell 2003). This perhaps is a reflection of the lack of clear evidence for one of the service structures being more effective than others. The traditional model of footwear service 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 recommendations by the Salford Report (Bowker 1992) 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 Report also suggested that

services should be audited for outcomes which were patient focussed but there has been little attempt to achieve this.

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 (Baker and Leatherdale 1999). 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. Still, 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 is associated with a familiar department and personnel, and part of a process that was already valued.

One study that aimed to investigate differences between a traditional and a contemporary (multidisciplinary) footwear service model was carried out by Williams and Meacher (2001), who evaluated patient perceptions of footwear and services. The contemporary service is characterised by referral from any practitioner, preassessment 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 and Foulston (1989) 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. Philipsen (1999) 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.

Further to the study by Williams and Meacher (2001), Emery and Borthwick (2002) investigated patient and practitioner views of three footwear services. They used questionnaires with patients with 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 research supports previous work that there are problems in these key areas and that what ever the type of service there appears to be a continued and persistent problem with usage of therapeutic footwear as a health intervention.

In an attempt to rectify some of the known problems, Helliwell (2003) established and reviewed a dedicated foot clinic that included a consultant, an orthotist and a podiatrist with access to 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 (2004) there is an unmet need with some patients who would benefit being overlooked by the professionals looking after other aspects of their care.

3.5 Summary and developing thoughts

Despite the recommendations for improvements in service delivery (Bowker et al 1992) and improvements in the design of the footwear (Williams and Nester 2006,

Williams et al 2007) there remains a problem with specialist footwear still not meeting all the needs of all the patients.

It may be that the research to date has not influenced widespread changes in practice due to the choice of research methods and the particular focus of the research. The majority of the studies have used patient satisfaction surveys and questionnaires as a tool for assessing the patient's reaction 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 rather than patient focussed questions. That is, the focus of the questions could have been what the researchers thought should be asked rather than what patients feel is important and this could have introduced bias to the results. Therefore the choice of using questionnaires may be one reason why the real problems with the 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' (Anon 1979). 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 (Anon 1997) and looking at this from a patient centred perspective, compliance is an outdated term.

Perhaps the term 'compliance' should be replaced with 'appropriate health behaviour', which in terms of specialist footwear is 'usage' sufficient to achieve the maximum health benefits and where the patient has informed choice. These thoughts are in line with Jannick (2004) who developed a self-administered questionnaire to assess the usability of specialist shoes in patients with orthopaedic foot problems. Within the definition of usability, effectiveness is the accuracy and completeness with which users achieve specific goals and perhaps this is more appropriate than talking about 'compliance'. For example, if a person 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 e.g. 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 and highlights the potential influences on footwear usage.

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. Jannick (2004) concludes that adding efficiency and satisfaction factors to effectiveness factors informs more about the usability of this intervention. This is a major move forwards in respect of acknowledging the complexity of footwear as an intervention in respect of clinical outcomes in relation to usability factors that are patient focussed.

A clear recommendation from most of the studies reviewed is for improved communication between the prescribing clinician and the orthotist and then the orthotist and the footwear technician with the aim of improving the footwear fit and appearance. 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 that this had not been identified as a problem.

Research into patient compliance with footwear has considered 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 be the greatest influence on patient usage and satisfaction with specialist footwear and may have been the factor in the multidisciplinary clinic (Williams and Meacher 2001) where dialogue between the orthotist and the podiatrists facilitated inclusion of the patient in discussions and choices.

The importance of the clinical encounter cannot be ignored and its influence on whether the patient is satisfied or not. Without a 'good' clinical encounter patients may well 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. Effective communication is an essential component in the achievement of a good clinical encounter and therefore good clinical outcomes. The importance of practitioner-patient communication is described by Street that,

'...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'. (1991 p23).

This two way communication is required to support the patient's changing role in their own health and health care. The patient's role 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 choices (Ong et al 1995). Providing information to empower a patient is aimed at enabling a person to gain greater control over a situation, that is, enabling patients to become equal partners in the care and treatment process instead of being the traditional passive partner subservient to the healthcare professional (McIver 1993). Lack of perceived control

in chronic and disabling diseases such as rheumatoid arthritis may lead to noncompliance as a choice which in effect is the only way that patients gain control if it is not facilitated by the health care professional.

To date, there has been no study that explores the impact of the practitioners involved in its provision on the levels of patient engagement in the use of this footwear nor the patient's feelings, opinions, attitudes and perceptions of being provided with therapeutic footwear.

3.6 Conclusion

Since the Salford Report (Bowker 1992) 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. In particular, in patients with RA, where we know there is the potential for reduction in pain and improvements in foot health (Fransen and Edmonds 1997, Chalmers 2000 and Williams, Rome and Nester 2007), it is of concern that patients are not satisfied with the footwear and demonstrate a lack of compliance with it.

The persistence in the literature of measuring compliance through patient satisfaction and vice versa, has led to an assumption that these are inextricably linked. In addition and most importantly, there is lack of consistency as to what compliance actually means in the context of therapeutic footwear. Some describe it as wearing the footwear all day, some 'the majority of the time', but all imply that the patient does as the practitioner tells them to do. The meaning of compliance and the factors that influence it may be more complex than these studies describe.

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Therefore, the term 'compliance' is explored further in the next chapter as are other terms in relation to health behaviour with the aim of gaining a deeper understanding of the whole concept of an individual's behaviour associated with health interventions.

CHAPTER 4 HEALTH BEHAVIOUR

CHAPTER 4 - HEALTH BEHAVIOUR

4.1 Introduction

Poor patient compliance with health care has been a focus of concern since health care emerged as a distinct profession. Hippocrates is reported to have said,

'[the physician] should keep aware of the fact that patients often lie when they state that they have taken certain medicines' (Sacket as cited in Haynes et al 1979 p2).

Since this ancient recognition of the problem, the extent to which a person's behaviour does (compliance), or does not (non-compliance) coincide with medical or health advice is increasingly recognised as a major consideration in the management of patients in a variety of health care settings. In this chapter, I will explore the health behaviour terminology, compliance, adherence and concordance, the different perspectives on health behaviour, specific models of health behaviour in relation to general health interventions and specifically therapeutic footwear.

4.2 Background

Surveys of health care practitioners (HCP) indicate that one of the most stress inducing aspects of their practice is that of patient non-compliance (Haynes 1979). It is often considered that the patient is attempting to inhibit treatment efficacy, the blame being directed towards the patient. Non-compliance is seen as a barrier to effective health care and therefore as having implications for the health of patients, effective use of resources, how HCP evaluate their own effectiveness and for the evaluation of the clinical efficacy of treatments. This problem applies to many interventions and has been demonstrated to be of consistent concern for services providing therapeutic footwear as an intervention and has warranted the publication

of a Department of Health commissioned study by Bowker et al (1992). Bowker et al (1992) focussed on the problems with the design of the footwear and the service that delivers it as being the cause of patient non-compliance.

The clinical, economic and academic reasons explain in part why the issue of patient non-compliance is such a major focus of concern and investigation for and by health care providers. Indeed, research into non-compliance has increased over the last 40 yrs, with over 60,000 citations since 1980 relating to compliance. However despite this concern and the potential impact of non-compliance or poor compliance on health outcomes, the definitions of the behaviour associated with 'compliance' remain problematic as are the methods of assessment of the factors that contribute to it and its measurement. Indeed studies of compliance often do not define compliance or have differing definitions resulting in a lack of consensus. For example, non-compliance can mean not complying at all, low levels of compliance, inappropriately complying or over complying. The process of seeking, receiving and following a treatment and advice has many stages and many opportunities for non-compliance. For example in the area of therapeutic footwear it could be breaking appointments, not collecting the footwear, or not using it as advised by the practitioner.

The average rate of non- compliance with medical advice generally, is stated to be about 40% (DiMatteo 1994). That is, two out of every five patients fail to comply sufficiently with their health care regimens to achieve health benefits. However, percentages may underestimate non-compliance because most studies have included in their samples only people who agreed to participate. It is possible that people who do not participate may differ in important ways from those who do, that is, it is possible that motivated individuals are more likely to be compliant. Also, the compliance rates cited do not reflect the range of 'compliance' behaviours, that is, some patients comply exactly, some not at all and probably most to one degree or other. Therefore there is no clear picture of the scale or impact of compliance and non-compliance with health care generally or in particular areas such as therapeutic

footwear. However, compliance or rather the lack of it, in itself is not the problem. Compliance is only one issue in a plethora of factors that impact on health. One important factor is that health interventions don't always result in health benefits and the reasons for this are also multi-factorial. The complexity of health behaviours and the influences on them will be explored in the following sections in which I scope the literature in these areas.

4.3 Health Behaviour Terminology – from 'Compliance to Concordance'

There are varied terms to describe a patient's health behaviour in relation to the interventions and the health advice that practitioner's provide. These terms include compliance, adherence and concordance. They all have different meanings and involve different processes in relation to the behaviour, and these will now be explored.

Compliance, as a term in relation to health behaviour has been defined as;

'...the extent to which patients' behaviour coincides with medical or health care advice' (Sacket as cited in Haynes et al 1979 p2), conversely, non-compliance has been defined as;

"...a failure to comply with instructions or advice given by health care professionals (Sacket as cited in Haynes et al 1979 p2).

Roberson (1992) critiques this definition in that it assumes that medical advice is good for the patient or that rational patient behaviour means following advice precisely. There is also an assumption in relation to this definition that health interventions equate to health improvement and also views the patient as a passive recipient of treatment. Although in the area of therapeutic footwear provision there is evidence that there are potential, positive health outcomes (Williams, Rome and

Nester 2007), the lack of compliance demonstrated by some studies (Park and Craxford 1981, Stewart 1996) may be due to the patient being passive in accepting this footwear through lack of options for any other intervention or loss of choice as to whether to have it or not.

The differing definitions of *non*-compliance includes those patients who do not comply at all, those who partly comply or those who over comply. Non-compliance is therefore a term that has a range of dimensions. An inadequate level of compliance may be defined as;

"...the point below which the desired preventative or therapeutic result is unlikely to be achieved with the medication (or intervention) prescribed" (Sarafino 1994 p301).

O'Harahan and O'Malley (1981), suggest that the term non-compliance should only be used where failure to comply is of a nature that appreciably interferes with the goals of treatment, and that the threshold for this goal is different for different interventions and for different patients. For example, some drugs are still effective with 80% compliance and outcomes of many interventions are difficult to measure precisely as in the physical therapies (Dracup and Melis 1982). Indeed with regards to footwear as an intervention, the level of compliance is often viewed as wearing the footwear the majority of the time (Park and Craxford 1981), but there has been no study that quantifies the amount of wearing time with health gain. Therefore there is an assumption that the longer the footwear is worn the better the foot health.

Most of the 'compliance' literature generally, focuses on improving compliance for clinical and economic reasons. However it could be argued that the concern about non-compliance is also related to issues of professional power, status and control. To a large extent medical knowledge tends to be founded, justified and legitimised in terms of what Friedson (1986) terms 'formal knowledge'. Formal knowledge is inherently accepted by patients as being credible because of the status of the producers of that knowledge. The dominance of medical and other health care

practitioners (HCP) and their position of definers of health/illness and appropriate treatment is reinforced and legitimised through various legislative measures and policy. This ethos has underpinned healthcare and for many years has perpetuated the notion of a dominant professional and a dependent patient. The behaviour of non-compliance challenges these professional beliefs and is often perceived as deviant and irrational with the patient being labelled as a 'problem' patient.

Adherence is another term related to the degree to which patients carry out health care actions, but adherence has different connotations to the term compliance. It is often used interchangeably with the term compliance but implies a different role for the patient. Compliance places the patient in a passive role. In contrast, the term adherence implies more patient agreement in the chosen intervention or advice implementation and sticking to the agreed regimen to achieve optimum clinical benefit (Dunbar- Jacob et al 2000). It is suggested that the term adherence reduces the attribution of greater power to the HCP in the practitioner-patient relationship, and implies more agreement (Joffe 2000). However, the balance of power is still with the HCP (Haynes 1979, Fitzgerald Miller 2000). In patients with chronic disease it has been seen that increasing the time scale between appointments decreases adherence (Simmons et al as cited in Dunbar-Jacob 2000) implying that patients require supervision and control by the HCP in order for the optimum clinical benefit to be achieved. This may also be the case with adherence with therapeutic footwear as it is known that when it is provided through a foot care service that monitors its use, compliance (adherence) is improved (Baker and Leatherdale 1999, Williams and Meacher 2001).

In 1998, The Royal Pharmaceutical Society changed the terminology used in relation to patients and medication from compliance to 'concordance', which in their definition suggests agreement and harmony (Marinker 1998). More recently this term has been used in government policy papers (DOH 2000, DOH 2006) but to date, less so in research. The essential factors of 'concordance' are the patient as a decision maker with the professional as an empathic facilitator. The fundamental

difference between concordance and compliance (also adherence) is that concordance focuses on the consultation process rather than on the outcome of the consultation. Compliance refers to a specific patient behaviour, for example 'did the patient take their medication in accordance with the wishes of the health care professional?' For this reason, it is possible to have a non-compliant (or nonadherent) patient. It is not possible to have a non-concordant patient, only a consultation between two parties can be non-concordant (Weiss and Britten 2003). A concordant relationship is very much about the patients having considered choice (Dracup and Meleis 1982), is 'patient centred' and the patient and practitioner have shared power. The ethos of patient empowerment is driven by NHS policy. The National Health Service Plan (DOH 2000) suggests that more power and information should be available to patients. Indeed the Department of Health states that HCP's should 'attempt to see things through the patients' eyes' (DOH 2006), but despite attempts to evaluate therapeutic footwear through patient questionnaires, there is little evidence of this occurring in the research setting or in the services that provide the footwear.

It could be said that the different terms, compliance, adherence and concordance essentially define three different models of how patients engage in health care and exhibit health behaviours and habits. There are differences in the processes involved and each has a different perspective both with regard to the action involved and who has the primary control (Table 4.1).

| Table 4.1 Health Behaviour – Control and action | | | | |
|-------------------------------------------------|-----------------------------------------|----------------------------------------------|--|--|
| | Decision maker/primary control | Action involved | | |
| compliance | HCP | Patient instructed | | |
| adherence | HCP and patient | Agreement by patient | | |
| concordance | Patient centred with HCP as facilitator | Patient makes informed and considered choice | | |

In conclusion to this exploration of terms, I suggest that concordance is a process that takes into account many factors and influences. Within this process, compliance and adherence as health behaviour may be the result of this process. The value of a concordant relationship between the practitioner and the patient, in the context of therapeutic footwear, has never been explored or evaluated. This relationship is dependent on an acknowledgement of the perspectives of the patient and the practitioner and whether their focus is on the health behaviour associated with the intervention or the outcome of the intervention.

4.4 Health behaviour perspectives

Health related behaviours can be viewed from either an outcome or process perspective (Vermeire et al 2001) (Table 4.2). For example, whether or not a patient takes their medication or sticks to a calorie restricted dietary regime is process oriented. Health gain from the medication or weight loss from a diet is outcome focussed. Wearing therapeutic footwear is the process and increased foot health is the potential outcome. Health related behaviour can be seen about going through the process independently and irrespective as to whether the outcome is achieved.

However, health related behaviours, whatever the definition or the balance of patient/practitioner power should be linked to the health outcomes, for example a study investigating the effect of a particular medication on lowering of blood pressure found that 80% compliance reduced the blood pressure whereas 50% compliance did not. In this case compliance was defined by process, that is 80% compliance and the outcome which is the lowering of blood pressure (Dracup and Meleis 1982). We do not know how often or for how long therapeutic footwear has to be worn to achieve foot health benefits. However, it is difficult to draw similarities between medication and footwear. Footwear is an item that is normally worn as an item of clothing and so behaviours with it may reflect desires and habits that have formed over a lifetime rather than instruction from the practitioners.

| Table 4.2 Health Behaviour Perspectives | |
|-----------------------------------------|-------------------------------------------------------------------------------------------------------------|
| Health Behaviour | Perspective |
| COMPLIANCE | PROCESS irrespective of outcome eg take medicine every day as instructed |
| ADHERENCE | PROCESS eg take medicine every day as agreed |
| CONCORDANCE | PROCESS and OUTCOME eg take medicine as negotiated, health benefits reviewed and re negotiated as required. |

The way that patients view health care advice and exhibit health behaviour is changing. It is changing in that they have their own knowledge and beliefs and bring these with them to the consultation. This now influences the way that patients and health care practitioners (HCP's) interact. The focus on professional/patient interactions, in many studies of compliance and adherence has assumed that professionals are the major source of beliefs regarding health and behaviour related to health. Health behaviour has been viewed in terms of the appropriate use of professionals and the treatments that they offer. However, various researchers have found that the influences on health beliefs and health behaviour are much wider than this (Stimson 1974, Conrad 1985). They have shown that patients actively evaluate treatments, in light of beliefs about treatments, the nature of health, measures that improve health and the use of treatments. Individuals are often in the patient role for only a fraction of their lives, yet the influence of these brief encounters with the professional world is presumed to be of paramount importance by HCP's. From a professional perspective this is no surprise as it is rare that HCP's follow their patient's from the professional setting into the patient's wider world.

In addition to not seeing the patient in their 'own world', HCP's may underestimate the patients own knowledge. The identification of a 'lay referral system' as noted by Calnan (1987) has shown that individuals engage in a complex process even before consulting health care professionals. This involves assessment of their own health needs, the use of significant others and various self-motivated measures to increase their health. The individual may then seek professional help having already made judgements about their own needs, treatment and expectations of professionals. However, in my own experience of footwear services it is unlikely that individuals seek to be referred for this footwear (Williams and Meacher 2001, Williams and Nester 2006) but rather seek help for specific foot problems. It is the HCP who determines whether therapeutic footwear should be provided.

It might be expected that patients with disabling or life-threatening health problems are more likely to adhere to medical regimens than those with less serious illnesses. Whether this idea is correct seems to depend on whose perspective it is viewed by. Physicians perceive that patients with serious illnesses are no more likely to adhere than those with milder health problems (Becker and Rosenstock 1984). In contrast, when comparisons are based on the patient's evaluation of the seriousness of their illness the patients who rate as having serious illness show better adherence to their treatment (Becker and Rosenstock 1984). It is possible to relate this to the area of therapeutic footwear because if patients do not know the seriousness of not wearing their footwear, such as the potential for foot ulceration and life threatening infections then they are not going to value their footwear in that it is essentially a preventative treatment.

Most studies of patient compliance generally have failed to consider patients as being evaluative and critical in their use of treatments, being more focussed on the objective external variables that may account for non-compliance such as age, gender and disease type. These studies have concentrated on the professionals' expectations and definition of compliance (or adherence), also whether the patient complied or not and not what they did instead. This is the case in therapeutic

footwear research where the non-compliant patients are not described in terms of their alternative footwear style or behaviour.

The ways in which individuals give meaning and definition to their own behaviour based on beliefs, expectations and constructs have on the whole not been considered in research terms. The view of patients as passive recipients of health care is based on the belief of professionals as 'experts' and about the expected efficacy of the treatments prescribed. The concept of compliance presented through most of the literature can also be seen as an ideology about the professional beliefs about what is appropriate health related behaviour for patients. The use of non-compliance as a negative label does not allow for any other behaviour which differs to a greater or lesser extent from the professional's instruction or advice.

However, the alternative approach that is emerging is for the HCP to view the patient as an active participant in their own health care with negotiation as the basis of the professional-patient relationship (DOH 2005, 2006). In contrast to the compliance model that puts the HCP at the centre of control and is process orientated, the new perspective, which is essentially the concordance model, puts the patient at the centre and is more focussed on the outcome. Because the concordance model takes into account the variety of influences and behaviours in relation to health, it is complex. By understanding this complexity and the defined stages in changing health behaviour, (Prochasca and DiClemente 1984) and the influences on health related behaviour, HCP's are becoming better placed to achieve concordance.

In the modern NHS the focus on the terms compliance and non-compliance and adherence are clearly inappropriate in terms of process and health related outcomes. The concordance model is an essential component of the new ethos of the NHS with the HCP and patient partnership and a shift in the balance of power from the HCP towards the patient. Perhaps however we should move away from these terms that describe only part of health behaviour and simply refer to 'health

behaviour'. I suggest that health behaviour can therefore be defined in positive terms as being;

"...appropriate health behaviour, over a suitable timescale and at a level which achieves optimum and measurable health gain".

In the context of therapeutic footwear the relationship between usage and health gain is described in terms of reduced pain, increased mobility and improved foot health. However we are not sure how the achievement of these fit with the established models or the beliefs of individuals.

4.5 Models of Health Belief and Health Behaviour

The concerns with behaviour change that has the potential to lead to health benefits, have culminated in a number of models that assess how knowledge, attitudes and beliefs get transferred into health related actions that are sustainable and result in health benefits.

The Health Belief Model [HBM] (Rosenstock et al 1988) suggests that an individual's decision to engage in specific health related behaviour results from minimum levels of knowledge about the behaviour and of motivation to practice it. This can have major implications as to whether the patient engages with health advice and interventions. The patient must see themselves as vulnerable to the condition, see the condition as threatening to them, convinced of the efficacy of the proposed interventions and must see few difficulties in understanding the recommended action they must undertake. The latter two variables can be summarised as the benefits and barriers associated with the change in behaviour. The patient is prompted to act either by external factors such as the mass media or health practitioner or by internal prompts such as painful symptoms. This may be the motivating factor in the use of therapeutic footwear but we know that despite the benefit of reducing symptoms patients still chose not to engage in it.

Despite the attempts of the HBM as a whole to predict good health behaviour and outcomes, it only describes part of the process which leads to changes in health related behaviour. However a key element of it is important. This element is that a person needs to feel personally vulnerable to the health problem before any action can be considered. Patients who do not recognise health risk, either because of lack of information or being optimistically biased do not engage with health behaviour change. Although not defining a process to health gain, the HBM does identify some of the prerequisites for behaviour change that will ultimately facilitate behaviour change and potentially result in health benefits.

A further set of health belief models are concerned with factors that constitute people's intention to practice particular health behaviour. These models arose because of the thought that the HBM fails to consider the translation of beliefs into action and leaves out crucial social factors. The 'social' factors include the individuals' desire for approval from others in their health related behaviours. An example of this is the Theory of Planned Behaviour [TPB] (Ajzen as cited in Kuhl and Beckmann 1985) that looks at people's intention to carry out certain health related behaviours assuming that intention is related to actual behaviour change. A development on the TPB intention-behaviour link has been devised by Gollwitzer (1993). In the TPB the effective translation of intention into changes in behaviour lies with strong intention. Gollwitzer divides intention into the overall goal to do something and the specific 'when' and 'where' of fulfilling this intention, termed 'implementation intention', and found that when implementation intentions are formed, people are significantly more likely to perform the behaviour intended than when such intentions are not performed.

There is some evidence (Pitts 1996) that a further factor feeds the translation of knowledge into action. This factor is the development of health habits which are said to be good predictors of health actions. A health habit is a health behaviour that is well established and is carried out semi-automatically, for example, the first three to

six months are critical to the process of becoming a regular exerciser and if this can be established for six months it is likely to continue. It is unclear whether this can be applied to therapeutic footwear use. The footwear is very visible and for patients to wear it they have to like it. Liking it may mean its appearance, its comfort, and/or its contribution to improved comfort. Without these outcomes, no amount of continued use is going to reinforce and sustain footwear wearing time.

The HBM and theories of behaviour change go some way to describing some of the factors required in the process of achieving positive changes in health related behaviour. However they are somewhat limited in the way that they tend to focus on why the patient doesn't change their health behaviour and are viewed as a linear progression with a start and end point rather than a cycle.

The Trans-theoretical Approach or Stages of Change Model [TASCM] (Prochaska and Di Clemente 1982 and 1984) expands on the stages previously described and has been demonstrated as being effective at changing a range of health care behaviours. It is based on a cycle of 5 stages, pre-contemplation, contemplation, preparation, action and maintenance. This model takes a positive approach towards finding how people change rather the negative approach of why people do not change. Patients may go through the cycle several times before they change their behaviour getting on and off at any stage. An important aspect of this model is the raising of patients' awareness through information. If patients are not knowledgeable as to why they need to change their health behaviour they cannot make choices about their care or self care unless they have this information. Concentrating on the positive aspects that a change in health behaviour can bring can empower the patient to move to the next stage. Elements of the HBM may be relevant in the precontemplation stage as it is here that people evaluate the costs and benefits of the health behaviour. The link between intention and behaviour change (TPB) may be relevant to the contemplation and preparation phases. However, the Stages of Change Model is dynamic and appears to hold the key to behaviour change over the traditional models. The TASCM provides the key stages in behaviour change. It is

essential that these are taken into account in the process of achieving concordance with the ultimate aim of improving health related behaviour sufficiently to achieve maximum health gains.

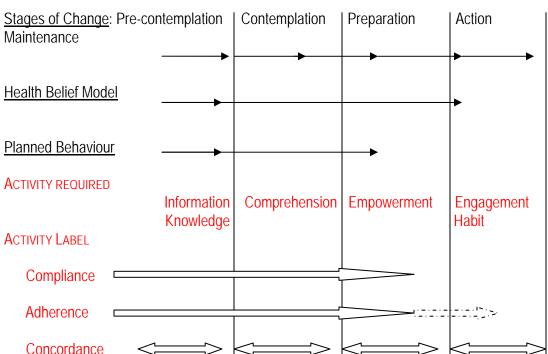


Figure 4.1 Stages of Health Behaviour Change and Health Related Activity

To achieve clarity as to the meaning of compliance and non-compliance, these terms have been explored, as have other terms relating to health behaviour. Health behaviour, in relation to both process and outcome has been clarified with consideration to the roles of the patient and the practitioner and in the context of therapeutic footwear.

Thoughts have emerged from the literature reviews on patient behaviour with the footwear (Chapter 3) and the exploration on health behaviour terminology, that unlike any other health intervention, therapeutic footwear replaces something that is normally worn and is therefore different to all other interventions. This dual role of

footwear therefore may influence the patients' behaviour with it. However, there are possibly other influences that will now be explored fully in the following sections.

4.6 Influences on health behaviour

Each patient is unique in themselves, their experiences and the influences upon them as individuals. Therefore, there is potential for these factors to influence an individual's engagement in good health behaviour and/or the use of specific health interventions that practitioners provide. The purpose of the following sections is to explore these factors with consideration as to how they influence the use of interventions, including therapeutic footwear.

The influences of patient specific factors, information given to them, their perceptions of health, and their level of control and power will be explored. The practitioner/patient relationship, communication between them and the qualities of the practitioner will also be examined as potential influences. The strategies for improving health behaviour and ways of evaluating it will be discussed with the aim of providing knowledge on this area. This is necessary in the context of the aim of this thesis in that a practitioner's role should include being influential on the patients health behaviour in a positive way and to evaluate the patient's behaviour with the intervention provided.

4.6.1 Patient factors

The strategies for behaviour change all refer to intra-personal effects, which echo the ideology that health is a personal responsibility. However, health choices are not related purely to internal factors. They are also linked to external factors such as financial status, employment and social class (French and Adams 1986). An

example of this is the behaviour of smoking, which does not correlate with knowledge, but with specific norms and pressures within people's social groups.

The health of a nation and thereby an individual's health is also linked with policy level decisions (DOH 2006). This varies between different health issues and involves, for example with alcohol abuse: identification of high risk groups, provision of interventions, changing beliefs about alcohol and altering the laws controlling use. Therefore, health status is not purely a function of individual choice, but also of social group norms and policy decisions. Demographic variables such as age, sex, marital status, social class and disease factors are poor indicators of the level of health related behaviour. Although some associations have been found the results are often inconsistent between studies (Vermeire et al 2001, Cluss and Epstein 1985, Haynes et al 1976). However a combination of these factors shows a stronger association to health behaviour (Korsch, Fine and Negrete 1978) that in most studies is defined as compliance.

Age, when associated with different types of illness appears to affect compliance in different ways, for example among child and adolescent diabetics, adolescents were less compliant with dietary advice than children (Varni and Babarni 1996). For adult arthritis patients 47% of 55-84 yr olds and only 28% of 34-54 yr olds made no medication errors in several weeks of monitoring with middle aged people with busy lives making the most errors (Park et al 1999). Lack of adequate knowledge is an important cause of poor compliance in the elderly (De Geest et al 1998). The complexity of the regimen and poor communication are often mentioned as common causes of non-compliance in older patients with memory disorders, which make them unable to follow complex sets of instructions (Donovan and Blake 1992). Although age is reported in some studies into therapeutic footwear use they have not specifically identified age as a factor in non-compliance with therapeutic footwear. However, it has been identified that with retail footwear, younger females are more concerned with the appearance of the footwear (Joyce 2000).

It is suggested by De Geest et al (1998) that support from the family and social network is essential for compliance particularly in the elderly. Social isolation is a risk factor for non-compliance not just because of the lack of social support but also because of a higher incidence of depressive symptoms in socially isolated individuals. Depression negatively influences illness perceptions and consequently the behaviour in relation to compliance with the rapeutic regimens. Depression may be associated with reduction in cognitive functioning essential to remembering and following through treatments. A systematic review of 12 articles on depression and 13 on anxiety (Di Matteo et al 2000) concludes that depression leads to noncompliance with health care advice and interventions whereas anxiety has an unclear relationship to adherence. The association between depression and nonadherence was significant with an odds ratio of 3.03 (95% confidence interval 1.96-4.89) and concluded that compared with non-depressed patients the odds are three times greater that depressed patients will be non-adherent with medical treatment recommendations. Evidence of strong co-variation of depression with medical noncompliance suggests the importance of recognising depression as a risk factor for poor outcomes among patients who might not be adhering to medical advice. Di Matteo et al (2000) recommend that recognition of depression could help the physician manage his or her frustration with patient non-compliance and thus improve the physician-patient relationship. Also for patients with chronic disease, screening for depression might prove to be a useful identifier for potential barriers to positive health related behaviour and use of interventions such as therapeutic footwear. No study into non-compliance with therapeutic footwear has considered the link between depression and lack of its use. However, patients with chronic diseases such as rheumatoid arthritis are more at risk of depression (Dickens et al 2002) and therefore depression may need to be a consideration in clinical practice and in research.

The current health care system in the UK was created in an era predominated by acute illness where the delivery of care centred on accurate diagnosis and treatment to cure the condition with little role for the patient except as passive recipients of

care. This concept was identified by Parsons (as cited in Brady 1998) as the classic 'sick role' with the only obligation of the patient being to seek help and co-operate with the physician to get well. In return the people in the sick role were relieved of work and family obligations. This still may be appropriate in emergency and acute care situations. However, chronic diseases now dominate the resources of health care system and the roles of the patient and practitioner are changing. At most only 50% of people with chronic disease comply with doctor's recommendations irrespective of disease, treatment or age (Dunbar-Jacob et al 2000). Compliance and persistence are poor in patients with diseases with a high or moderate risk of death especially in conditions like hypertension where the treatment side-effects are greater than the symptoms which are often none.

The complexity of chronic disease management sometimes requires day to day adjustment in response to individual circumstances. Therefore compliance in the traditional sense is neither possible nor successful in the long term in chronic disease management. Patients with chronic diseases such as Rheumatoid Arthritis (RA) are less compliant with treatment over time (Feinberg 1988). The consequences of poor health related behaviour with medical interventions or advice may be serious in this patient group including exacerbation and progression of disability, development of secondary complications, more frequent medical emergencies and unnecessary prescription of drugs and failure of treatment. The very nature of the disease can mitigate against good health related behaviour in RA. The natural course of the disease in most patients is characterised by exacerbations and remissions. These may occur regardless of the treatment regimen. Therefore if a patient suffers an exacerbation of symptoms despite engaging with a prescribed regimen or conversely improves when not complying subsequent positive health behaviour may be adversely affected. Brady (1998) suggests that patients with chronic disease require active self-management. This self-management role involves several tasks including using medications correctly, changing behaviours to improve symptoms or slow disease progression, interpreting and reporting symptoms accurately, adjusting to new social and economic circumstances, coping

with emotional consequences, and participating in treatment decisions. This also involves patients' self evaluation of the disease process and making modifications to their management plan with support from the HCP.

Patients are unique individuals who are a combination of a multitude of variations in age, sex, educational, economic, physical and psychological health. Particularly in chronic diseases patients need to be able to modify their treatments and self management in light of changes in their individual circumstances and disease status. However, to be able to do this they need information.

4.6.2 Information, Knowledge, and Comprehension

Information, knowledge and comprehension are central to engaging the patient in partnership with the health care practitioner (HCP). However, these terms are often used interchangeably but actually have very different meanings. Information is 'something told', knowledge is 'awareness gained by experience, a range of information, with understanding, and comprehension is 'the act or capability of understanding' (Oxford Dictionary 2002). Information alone cannot change behaviour, knowledge alone cannot change behaviour and comprehension relies on information and knowledge. Therefore all these are inextricably linked and in isolation are ineffective at influencing the process of behaviour change. Health interventions and advice have traditionally been given to patients with a considerable quantity of information in the belief that this would change people's behaviour. This belief is flawed in that there is an assumption that if the patient knows what to do they are likely to do it. Psychologists have established that although knowledge is a necessary component in behaviour change strategies it is not sufficient in isolation (Leventhall and Cleary 1980). It has already been established that there are other factors that influence health behaviour, potentially in a negative way, so knowledge and understanding are not the solution, even though they are a prerequisite. It is not clear from the research into therapeutic footwear if the participants in these studies understood why they were provided with the

footwear, although in the multi-disciplinary footwear clinics it has been identified as one of the factors that increased compliance over a traditional model (Williams and Meacher 2001).

Evidence-based *patient choice* is defined as offering patients research based information and the opportunity to influence decisions about their treatment and care. This has yet to be achieved generally in health care and may be so in the services that provide specialist footwear. Holmes-Rover (2001) advocates 'evidence-based' patient choice and a high degree of patient involvement in clinical decision making, but points out that time constraints during the consultation necessitate the information be available before and after the consultation. She suggests that although health care professionals can access systematic reviews, this information might not be meaningful for patients and a patient decision template for treatment options might be successful. Systematic reviews would inform the options, probabilities and sometimes outcome descriptions. This template or module (Table 4.3), in essence would map out the patient's key questions and the information required for the patient to make an informed decision.

| Table 4.3 - Decision Template for Treatment Options (adapted from Holmes-Rover 2001) | | | |
|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|------------------------------------------|--|
| REQUIRED ELEMENT | KEY PATIENT QUESTIONS | INFORMATION PROVIDED | |
| Clinical condition reported | What are the characteristics of my disorder | Details of clinically | |
| | /disease/diagnosis? | important sub groups | |
| Patient decision situation | What are the different ways this | Options for surgical treatments, medical | |
| | disorder can be treated? | treatments, watchful waiting, | |
| | | complementary therapies | |
| For each treatment option: | | | |
| Treatment processes | What kind of treatment is it? | Mode and duration of treatment, | |
| | How much time does it involve? What do | nature of patient involvement | |
| | I have to do to undergo this treatment? | | |
| Outcomes and probabilities | What are the chances of improvement | Rates for different outcomes over | |
| | over the next x days/weeks/months/ | various times, absolute number improved, | |
| | years or over my lifetime | improvement rate | |
| Value tradeoffs | Side effects, length of life v quality of life, descriptions of other patients' experiences? | Material for clarification of values | |

These patient choice modules (Table 4.3) aim to contribute to the higher standards of informed consent and patient participation in decision making. However, it is recognised (Holmes–Rover 2001) that training in the implementation of these modules is required but once in place would actually reduce the complexity and burden of providing information and :

'...enhance the health system's capacity to provide high quality health care to an informed public' (Holmes-Rover 2001 p667)

The patient choice modules encourage a patient focussed approach and aim to identify the patients' priorities and values. It is known that there is a difference between what consultants and patients priorities are.

An observational study of 79 patients with a variety of rheumatological diagnoses by Kwoh and Ibrahim (2001) investigated patient preferences. They found that patients were found to differ in their choices of what they considered important health and symptom status outcomes and that the physicians often fail to identify these choices. They assessed physical, mental, social and symptom status. However, patient's opinions may change over time depending on their health status and the patients selected for the study had a variety of diagnoses, although they were all chronic conditions (rheumatoid arthritis, osteoarthritis or low back pain). It may be that if they had chosen one condition to observe at a particular stage in their disease then the patient's preference may have been the same. There was also a mix of males and females in the group. It could be that there are distinct differences in patient preferences dependent on gender but this was not explored in this study. The study also only observed 4 consultants who might have co-incidentally have had the same style of assessing patients and therefore the results cannot be generalised.

Despite these criticisms this study does indicate that there may be differences between what patients want and what consultants perceive the patients want. Even in:

'.....this era of cost containment and limited resources correct identification of patient preferences for important outcomes is essential.......Taking patient preferences into account when selecting among many options may lead to increased patient satisfaction and compliance, thereby yielding maximum benefit.....' (Kwoh and Ibrahim 2001 p375).

This is particularly so when patients present with extensive and complex problems. A decision making template may be useful in the area of therapeutic footwear. Often the decision is made by the referring practitioner and the footwear is 'prescribed', although increasingly the patient is referred to the dispensing practitioner who then makes the decisions often independently of the patient and without consultation as to the patient's preferences (Williams and Meacher 2001). Failing to consider patient preferences may obscure factors that are important to them, thereby contributing to patient dissatisfaction.

Attempts to improve engagement in positive health related behaviour by giving information to increase patient's knowledge and ensure comprehension have been the focus of health care and studies for many years. When this fails the patient is often viewed as ignorant or forgetful when the information is not acted upon. Rather than attempting to help the patient achieve positive health behaviour the literature is primarily concerned with teaching professionals how to manipulate patient's behaviour. Scheid-Cooke (1993) terms this manipulation 'benevolent coercion'. Many writers have focussed on the doctor's communication to the patient rather than communication between the two and suggest that the use of information giving is a method of coercion. Ley (1988) suggests that there is a significant relationship between understanding, memory, satisfaction and compliance. However, a study by Cohen (1979) found that half of the physician's statements were forgotten

immediately after a visit therefore losing information, and the transfer of this into knowledge and comprehension. Kwoh and Ibrahim (2001) recommend that practitioners ask what patient's treatment preferences and priorities are before giving the patient information and patients are more likely to remember when this is done. Self-efficacy is an important determinant of health because not only are efficacy beliefs predictive of future health behaviour but because self-efficacy can potentially be influenced through clinical interventions such as patient information and education. However it is acknowledged by Kirwan et al (2005) that the measurement of the impact of self efficacy is difficult with the available measurement tools.

The persuasive impact of the health message or information is dependent on both cognitive (knowing and intuition) and emotional factors. As footwear is perceived to be an item of clothing and therefore part of an individual's body image or perception of self and expression of sexuality it may be that emotions invoked through this being provided in another setting compared with normal retail footwear purchases interferes with the information provided. Also if the message given invokes fear then this will impact on the individual's ability to comprehend. While the models of health belief and behaviour focus on a cognitive reasoned approach, another focus could be the emotive approach. This is perceived as fundamental to persuasion in both the psychological and health promotion literatures. There is a strong argument for using emotion such as fear and humour in engaging people in behaviour change. Classic health education relied heavily on generating high levels of fear (Kirscht and Haefner 1973) and this was consistent with the authority and status of the 'expert' resulting in fearsome messages. The use of fear actually had little effect on health behaviour change, although the general public views that fear shocks people out of complacency, for example the UK AIDS campaign. However, there is little current evidence to support the use of emotion to motivate behaviour change. At the opposite end of the spectrum there are those who believe that people protect themselves from the anxiety with defence mechanisms such as denial. This links with the HBM that if fear evoking health messages lead to defensive denial the 'not me' response is likely to follow with no change in behaviour as a result.

Evidence for the effect of humour on health messages is virtually non-existent despite its substantial use in practice. Its use reflects a change in approach to more of a marketing influenced one in which positive messages are favoured (Ben Sira 1981). One advantage of humour is that it produces laughter, which may be perceived as a reward, which in itself is a component of the process of persuasion.

The way that information is provided emphasises the importance of the clinical encounter and the interaction between the practitioner and the patient. This is a potential influence on patients' experiences of being provided with footwear and therefore possibly their potential to use it.

4.6.3 Patient Control and Power

The balance of power in the patient / practitioner relationship has been touched upon in relation to models of health care. I will now explore power as a concept to illuminate its importance to the individual and health behaviour as it is not clear if the balance of power is with the patient.

Power in this context, is the ability of an individual to produce behaviour change in another. Power is the means by which A gets B to do something and in the health care setting, models exist to explain this. Lukes (1974), describes three dimensions of power:

- 1. A forces B to do something
- 2. A controls the agenda in any interaction with B
- 3. A controls the world as B sees it

First dimensional power might be used appropriately in emergencies or when patients are very distressed or unconscious and do not want or cannot discuss

options. Second dimension power is exercised when the conversation is deliberately steered towards or from certain topics. Further to this with third dimension power. the advantages of a treatment or its complications may be emphasised in a way that influences the patients' apparent choices. This might be used when there is lack of time, poor ambience between the patient and the HCP or poor listening skills. It is perceived that many HCP claim to present the facts to patients in an unbiased way and allow them to make their own choice. This is how they see that they shift the balance of power in favour of the patient (Canter 2001). This might involve discussion and the patient might then make a choice but the whole encounter is firmly placed within a conventional biomedical framework and there is no place for other treatment options such as herbal medicine, acupuncture and other complementary medicines. In reality there may be no difference between the three dimensions as the power may stay with the practitioner but the patients' experience of it may be different. Time is highlighted as an issue in footwear services and therefore the balance of power has to sit with the practitioner who is forced to complete certain tasks within a certain appointment time (Williams and Meacher 2001)

A critique of Lukes' (1976) model of power is that it assumes only two parties. In reality HCP's may consult with other HCP's and patients consult with others such as friends, family and other resources. Nestel (2001) highlights the fact that decisions are rarely made in isolation as patients may consult several doctors or other health care practitioners and there may be social influences, economic influences and religious and cultural influences. She points out that models of power usually assume two parties and do not consider these additional influences. She suggests that if HCP's are practicing patient-centred medicine then the issue of power is irrelevant. Patient choice implies that the doctor will actively seek out the patient's desire to make decisions about their own health care.

Horder and Moore (1990) suggest that the more the patient is in control the better the outcome and Brady (1998) suggests that the patient's role in health care is changing from a passive recipient to that of an active participant. Empowering patients is different to educating them, it is about increasing their control and becoming equal partners in the care and treatment process instead of being the traditional passive patient, subservient to the HCP. Further to this, Coulter (2002) suggests that doctors and patients are equals but with different expertise. This statement is challenged by McQueen (2002) who suggests that clinical effectiveness depends on the practitioner understanding the patients' beliefs and expectations, but that patients are not equals and their beliefs do not have the ontological status of medical knowledge. McQueen (2002) further suggests that denial of the status of doctors and of the medical tradition of research is false democracy. However, it could be argued that although health care practitioners have a general knowledge of the condition, patients have a personal knowledge therefore it should be an equal partnership even though they have differing ontological perspectives. Milburn (2001) as cited in McMurray and Cheater (2003), states that:

"... patient's have a right to be involved in their care and that the balance of power should be away from doctors and shift exclusively in favour of the patient." (pg 65)

However, this idea that power can be shifted from one individual to another particularly with the asymmetry of knowledge and expertise that are inherent in the patient-practitioner relationship could result in unnecessary tests, unnecessary medication and untested therapies (McQueen 2002).

The concordance model advocates a sharing of power in the practitioner-patient relationship. It takes into account the patients perspective, acknowledging that the patient has expertise in their experience of the illness and this is different to practitioner knowledge but is of equal relevance and value in terms of deciding on the best management. A concordant consultation is one in which both these views are included in the decision making process regarding management which is contrasted with the paternalistic approach with the patient in a passive role and obedient to the practitioners' instructions. Paternalism however is still acceptable in

the concordance model as long as it reflects the patient's preference and this has been elicited during the consultation. Practitioners often assume that the patient wants a paternalistic approach. However, research suggests that professionals are often unable to accurately assess a patient's preferred role in decision making (Strull et al 1984)

Donovan and Blake (1992) found that some patients chose not to comply with instruction as a way of expressing their attempts to cope with their disease and as a way of having control and power over at least something in their life. Lack of perceived control in chronic diseases such as Rheumatoid Arthritis may lead to non-compliance, but is in effect the only way that patients gain control. There is the opinion that medical power is intrinsic to medicine and arises from the process of socialisation that induces a submission to medicine. We are generally born in hospital, receive assessments, investigations and treatments there or in other clinical facilities and many will die in hospital. Another aspect of the medical power debate is that if practitioners are practising patient focussed care then power doesn't come into the equation at all and the aim is to achieve a shared relationship between the patient and the practitioner. The problem that prevents the adoption of patient centred care lies with how practitioners have been educated.

4.6.4 Health care practitioner – patient relationship

Vermiere et al (2001) in their review of the literature found 200 different doctor, patient, and encounter related variables but none of them were consistently related to or fully predictive of compliance. Although many correlations were weak the possibility of a causal relationship is often suggested.

There may be several aspects of the patient/HCP interaction that facilitate improved health behaviour. Although physician's characteristics are not related to 'adherence' (DiMatteo 1993), there do appear to be ways in which the interaction can produce greater adherence. Thom et al (1999) have found that trust experienced in relation

to the practitioner predicts (self reported) adherence and concludes that there is a link between adherence and the patient's trust of and satisfaction with the physician.

The style of the practitioner in the interaction can have a major impact on 'adherence' to health care advice. An effective style is one that encourages patients to express their concerns (Noble 1987 as cited in Myers and Midence 1998). This 'patient focussed' style can be taught (Aspergren 1999) but evidence of the adoption of training in this area has been lacking. The same authors also suggest that adherence also improves if the relationship style is friendly rather than business like. Recall of information as well as adherence is improved if the doctor is emotionally supportive and treats the patient as partner in the exchange. A collaborative rather than authoritarian style is also more democratic. A style in which patients are asked how they are performing with the regimen (process focussed) works better than questions where adherence is assumed (outcome focussed). In line with the Social Learning Theory (Rosenstock 1988) the health practitioner who reinforces past successes, ensuring that advice is understood is likely to facilitate adherence. The quality of such a discussion in which value differences are aired produces the best adherence results (Noble 1998). Physicians often describe the nature of decisions to their patients but less often discuss the risks and benefits and according to Braddock et al in 1997, rarely assess patient understanding.

In 1995, The Royal Pharmaceutical Society looked at ways to reduce the waste of patients not taking their medication (Marinker 2004). Initially it was thought to be a problem of non-compliance, since some patients forget, do not understand instructions, or stop taking medication once they start to improve (Barber 2002). However, studies showed that many patients were actively choosing not to take their medication (Coleman 2005). It became clear that the problem was occurring during the consultation. This situation was immensely frustrating for both the traditional, authoritarian doctor faced with a patient who chose to reject sound, evidence-based treatments and, for the patient who felt that s/he was not being heard. There was a lack of concordance between the directions of the doctor and the behaviour of the

patient. Doctors are trained to make medical decisions by balancing the risks and benefits of various treatment options. It soon became clear that patients follow a similar process but their understanding of the situation may be clouded by many more factors (Horne et al 2004). (Figure 4.2)

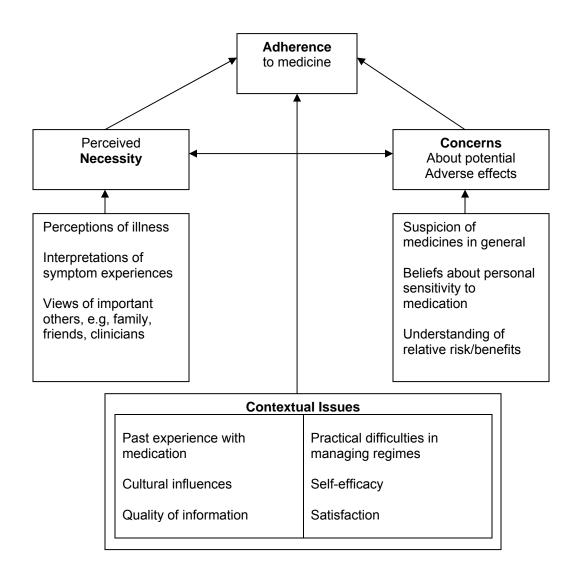


Figure 4.2 Influences on patient decision making and adherence to treatment (Horne et al 2004)

The doctor/patient consultation can be described in terms of a market place transaction seeing the patient as a consumer choosing to 'purchase' health care, and that:

'...In spite of sophisticated technologies for medical diagnosis and treatment, talk remains the primary means by which the physician and patient exchange health information. ...however this is often fraught with problems'. Stewart and Roter (1989 page 63)

Ferninan (2001) reinforces the thought that paternalistic attitudes have to stop, HCP communication skills have to improve and they need training in these skills during their professional education to ensure that shared decision making takes place. There have been no studies that have investigated the patient/ practitioner interaction or the patients' experiences of it in relation to being provided with therapeutic footwear. However, there is evidence from the literature in other areas as identified here that it has the potential to influence the patients' health behaviour and engagement in interventions. Effective communication appears to be the key to achieving this and therefore this aspect of the consultation will now be discussed.

The importance of doctor / patient communication is described by Street (1991) who emphasises the influence of communicative styles and personal characteristics. Sarafino (1994) suggests that one of the reasons for poor communication may be that the patient is worried about a symptom may casually mention it in the hope that the doctor agrees that it is nothing or that patients cannot describe their symptoms. Sarafino (1994) further suggests that doctors should enhance their interview skills ask questions and check for comprehension or patients could fill out a simple questionnaire about symptoms. Communication problems between HCP and patients have been demonstrated and studies have found that many patients are dissatisfied with the information given to them (Coulter et al 1998, Ong et al 1995, Stewart 1995). The focus of the HCP on the disease and not the person has been blamed for this breakdown in communication.

Patient centred approaches to care are increasingly promoted as being the key to improved health outcomes. The concept of 'patient centred medicine' was introduced into the medical literature in the mid 1950's by Balint (1955). This concept has its roots within the paradigm of holism, which suggests that people need to be seen in their biopsychosocial entirety and draws attention to the patients' as individuals. However, despite this concept being available for such a length of time, there is little consensus regarding the meaning of patient centred medicine (Table 4.4).

Table 4.4. Definitions of Patient Centred Medicine

| Byrne 1976 | An approach whereby the HCP uses the patients knowledge and experience to |
|------------------|-----------------------------------------------------------------------------------------------|
| | guide the interaction within the consultation |
| McWhinney 1989 | The physician tries to enter the patients world, to see the illness through the patients eyes |
| Stewart 1995 | Identifies 6 related components |
| | Exploring both the disease and the illness experience |
| | 2. Understanding the whole person |
| | 3. Finding common ground regarding management |
| | 4. Incorporating prevention and health promotion |
| | 5. Enhancing the doctor patient relationship |
| | 6. Being realistic about personal limitations and issues such as time and other resources |
| Mead 2000 | Identifies 5 dimensions |
| | The extension of the scope of medicine to psychological and social levels |
| | Understanding the patients experience of the illness |
| | 3. Sharing of power and responsibility |
| | 4. The 'therapeutic alliance' developing a relationship based on care, sensitivity & empathy. |
| | 5. The doctors self awareness and the attention to emotional cues in the relationship. |
| Lewin et al 2003 | 1.HCP sharing control of consultations, decisions about interventions or the |
| | management of the health problems with patients |
| | 2.HCP focus on the patient as a person rather than solely on the disease |

Different elements of patient centred care may be different in different situations and to different stakeholders for example health providers and health consumers may have different concerns, the providers being concerned with adherence and outcomes and the consumers more concerned with knowledge and the consultation.

Patient centeredness is increasingly advocated despite relatively poor understanding of the effect of different interventions to promote it. Communication between the HCP and patient is an element of patient centred care which has been examined in more detail. A review to ascertain whether the quality of HCP-patient communication impacts on health outcomes identified 21 randomised controlled trials (Stewart 1995). Most of these studies demonstrated a correlation between effective communication and improved health outcomes. If patient centred care is seen to be desirable in its own right, evidence is still needed as it may have varying acceptability and impact depending on the health care setting, the patient, the health problem and the culture.

A review of 135 studies by Lewin et al (2003) concluded that overall, there is fairly good evidence for those interventions that aim to promote patient centred care, lead to a significant increase in patient centeredness in the consultation process. This was indicated by a range of measures relating to clarification of the patients concerns, communication about treatment options, and levels of empathy. However, none of the studies used measures to assess patient centeredness as there is no gold standard measure for this. There is also evidence from this review, that training HCP in patient centred approaches may impact positively on patient satisfaction with care however it was difficult to quantify the benefits of this on health outcomes. Lewin et al (2003) make several important recommendations:

- Future trials need to assess (not only the effect of HCP training) but the effects of changing the organisation of care in promoting patient centred care.
- A definition of patient centred care needs to be widely acceptable and used in effectiveness studies
- The development of a gold standard measure for patient centeredness
- Involvement of consumers in the design, planning and delivery of interventions to promote patient centred care should include issues seen as important by consumers for quality of care.

Although providing a vehicle for improved communication and a 'balance of power' shift, concordance may seem to be problematic to some HCP's. It is possible that patients may reject what may be considered 'best' clinical practice even when they have been fully informed as to the nature and consequences of the decision. In these situations concordance does not detract from the autonomy of the HCP to document such events fully or to refuse to supply a treatment which is considered unsafe. However, the HCP may feel at risk of litigation should a patient who has refused treatment suffer as a result. However, Levinson (1997) conducted a study amongst physicians who had a previous history of malpractice claims and those with no previous malpractice history. They found that physicians with no previous history of malpractice claims had better communication consultation skills, using more facilitative talk such as soliciting the patient's opinion and encouraging them to talk.

A major concern with HCP's is that the achievement of a concordant relationship and through this to elicit patients' opinions could lead to long consultations and be impractical. However, there is some evidence that discussion of patient's views does not necessarily lead to longer consultations (Belle Brown 1989) and may save time in the longer term through resolution of misunderstandings. As the HCP gets more proficient at this and in the area of therapeutic footwear, the time invested in the consultation would be negated by the fact that there would be less waste in footwear not worn.

Social modelling (Bandura 1986) and positive reinforcement create effective health messages. Within this perspective the patient who depicts the adoption of the behaviour change acts as a model for those observing it. Role models who have socially desirable characteristics such as power, sex appeal and courage can be influential. In light of the interpersonal emphasis HCP's are in a particularly good position to influence health choices because they act as high status models and have the potential to reinforce health-enhancing behaviours in a face-to-face setting.

Canter (2001) describes a concept of medical power which includes legitimate and charismatic power. Individual clinicians may exercise each of these types of power in different proportions so that each has his distinctive consultation style. It may be that being charismatic is more desirable in the modern NHS than being coercive. However it is possible that charismatic doctors may do harm to patients who remain thankful for it or indeed that patients are grateful for any attention.

Generally, neither the HCP nor the patient are taught the skills that enables them to carry out their role in disease management. They rely on intuition, convenience and habits (Clark and Gong 2000). These authors recommend that health behaviours need to be understood and debated by both parties to effectively achieve health gains. They suggest that many barriers to effective communication occur during the consultation. Patients may feel that they are time wasting, omit details they deem unimportant, and do not understand medical terms. Poor communication is traditionally measured in terms of patients' inability to recall doctors' instructions with patients failing to recall between one third and one half of the statements given to them by doctors (Di Matteo 1994). However, methods to measure recall that rely on direct recall do not take account of the meaning imbued in statements. This may not incorporate patients' intentions and may lead to false conclusions and erroneous impressions.

4.6.5 Strategies for Improving Health Related Behaviour

There have been efforts to identify the factors that improve the patient's experience and influence the health outcomes achieved from the consultation and the intervention. Clark and Gong (2000) suggest improving communication between the HCP and the patient through:

- Making eye contact with the patient,
- Eliciting the patient's fears/concerns,

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- Construct reassuring messages that alleviate fears,
- Address immediate concerns,
- Engage the patient through open ended questions,

•

- Tailor the treatment through negotiation, use non-verbal encouragement and verbal praise for achievements,
- Review long term plans and
- Help the patient plan in advance for decision making (such as using a diary).

Bien, Miller and Tonigan (1993) describe the ingredients of successful behaviour change that positively affects health and concluded that six elements constituted an effective intervention when they occur together. These elements offer a viable 'package' for HCP hoping to change the behaviours of their patients. They are:

- feedback/telling the person of their personal risk
- the person taking responsibility for change
- clear advice from the expert to change
- a menu of options as to how one can go about change
- empathy in terms of the style of the advice giver
- enhancement of the patient's sense of personal control and optimism.

In 2001 an initiative, in the form of the Task Force on Medicines Partnership took on the role of promoting the concept of concordance (Shaw 2004). A tri-pillar model was developed which has been widely accepted and details the requirements of achieving a concordant relationship. (Figure 4.3)

Concordance

A process of prescribing and medicine-taking based on partnership

Patients have enough knowledge to participate as partners

Patients are offered information about medicines which is clear, accurate, accessible and sufficiently detailed.

The information provided is tailored to individual patients' needs

Education programmes empower patients to take responsibility for their own health

Prescribing consultants involve patients as partners

Patients are invited to talk about their priorities, preferences & concerns about medicine taking, & the proposed treatment. These are explored openly

Professionals explain the rationale for, and the characteristics of the proposed treatment.

Patients and health professionals jointly agree on a course of treatment which reconciles as far as possible the professional's recommendations and the patient's preferences.

The patient's and professional's understanding of what has been agreed is checked

The patient's ability to follow the agreed treatment is checked

Patients are supported in taking medicine

All appropriate opportunities are used to discuss medicines issues (e.g. patients' interactions with doctors, pharmacists, and nurses)

Health professionals share medicines information effectively with each other

Medications are reviewed regularly with patients' participation.

Practical difficulties in taking medicines are addressed

Figure 4.3 Requirements for a concordant relationship (Shaw 2004).

For many GPs, this required radical changes in their consultation techniques. It meant accepting that the only person able to change a patient's behaviour is the patient, and that sometimes the decision reached would be that the patient refused the best treatment option (Jordan 2002). It was realised that the factors that underpinned the development of a concordant approach in the context of patients taking prescribed drugs, could have a wider use. Over recent years the Department of Health has focused on the adoption of a more patient-centred approach for all HCP's. The Patients' Charter (DOH 1995) and later, the NHS plan, (DOH 2000) outline the responsibility of HCP's to explain the benefits and risks of treatment options in all aspects of health care.

Further to this, the Wanless Report (Wanless 2002) found that those patients who participated in choosing and making decisions about their own care have better results. This shows that for any Healthcare Professional, achieving concordance with patients is a necessary aspect of modern healthcare delivery.

4.6.6 Assessing Health Related Behaviour

The factors that influence health behaviour and therefore the potential for health improvement are complex and inter-related. There are multiple influences that shape the patients' perceptions and agenda before they enter the consultation. Further to this, the qualities of the practitioner, the patient and practitioner interaction, and the exchange of information between the two are possibly pivotal in influencing health behaviour and in the context of therapeutic footwear, patients' engagement with it.

The complexity of these influences on health related behaviour, such as compliance and non-compliance has prevented the development of a gold standard method of measurement of it. The lack of a valid method for measurement is by itself a major barrier to 'compliance research' (Morris and Schulz 1992). The relationship between positive health related behaviour and the level of health benefit needs to be clarified.

Various methods have been used to assess compliance and adherence with treatments, drug treatments in particular. Some of these methods are complex such as checking blood concentration and serum levels of drugs (Jack 1980).

Health care practitioners are now expected to act in a 'concordant' way yet the true benefit of concordance is still unclear. There are no measures or units of 'concordance' so it cannot be quantified or associated with any measurable outcome. Therefore evidence of improved patient outcomes, improved health behaviour even improved patient compliance associated with concordance is still to

emerge. Evidence of the cost effectiveness of concordance is even further away. However, concordance has led to perceived improvements in adherence and satisfaction (Little et al 2001). Therefore it is right for HCP's to continue to pursue patient centeredness, where concordance is the 'mantra' that focuses the practitioner on being non-judgemental, treating patients as equals, eliciting patient's concerns and facilitating their informed decisions.

4.7 Summary

From my exploration of the literature, I now have clarity that compliance is only one facet of health related behaviour. In isolation, compliance may be seen to be about issues of professional power and control where non-compliance is seen as deviancy, with the patient as a passive recipient rather than an active participant. In reality, levels of compliance can be as varied as the factors that influence it and therefore health gain is equally varied.

Patients, especially those with chronic illness, make decisions about their treatments that fit into their own beliefs and personal circumstances. Labelling them as non-compliant is inappropriate in this era where 'patient empowerment' should be the mantra of every health care practitioner involved in the care of people with chronic diseases. Improvements in health behaviour are dependent on the many factors (Fig 4.4) that have been demonstrated in other areas to be of significant influence.

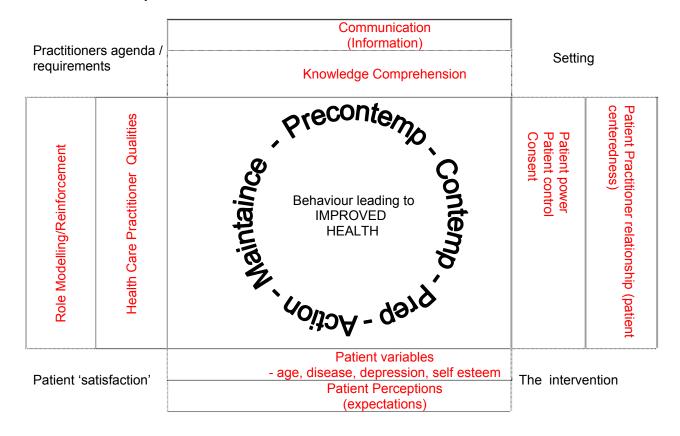


Figure 4.4 Factors that influence health behaviour

In the context of therapeutic footwear the areas highlighted in red have not been investigated.

Implicit in our interest in enhancing patient behaviour is the assumption that doing so is important to health outcomes. In the context of therapeutic footwear, before we reach the point of investigating what level of negative health related behaviour leads to poor health outcomes and what level of positive health related behaviour leads to good health outcomes, we need to understand the interplay between the patient and the practitioner. It is possible that each condition and each practitioner-patient pair involve different factors that affect positive health related behaviour. There may be specific factors in relation to this clinical encounter that may need investigation in the area of therapeutic footwear and the patients' behaviour with it.

Vermeire (2001) comments that most 'compliance' research has focussed on the extent and determinants of non-compliance and suggests that one of the reasons for the lack of progress in this area is the absence of two crucial factors, the patients perspective and the health care practitioners perspective. For this reason, one of the objectives of the research contained in this thesis will be to discover how this relationship influences the patient's experience of being provided with therapeutic footwear. It may be that something is revealed about this relationship that relates to the patients engagement and behaviour with the footwear.

4.8 Conclusion

This chapter has provided an exploration into health behaviour terminology, the different perspectives on health behaviour, and specific models of health behaviour in relation to general health interventions. This knowledge has further influenced my own personal perspective and how it relates to therapeutic footwear as an intervention

Armed with the knowledge from the reviews of the literature (Chapter 2 and 3) and the literature that has informed my understanding of the influences on health behaviour, I have consolidated the ideas and perspective for the planned research. The next chapter reveals these ideas in the form of a theoretical framework. This framework provides clarity and focus for the intended research and concludes with the specific purpose, aim and objectives of the research.

CHAPTER 5 THEORETICAL FRAMEWORK

CHAPTER 5 - THEORETICAL FRAMEWORK

5.1 Introduction

This chapter pulls together the key findings from the literature reviews on the clinical effectiveness of therapeutic footwear, patient engagement and satisfaction with it and influences on health behaviour in the context of therapeutic footwear. The knowledge obtained from this part of the thesis has further influenced my thoughts and beliefs in relation to patients' behaviour with therapeutic footwear. These findings and the thoughts that this work has provoked, provide the theoretical framework for the planned study. A theoretical framework is needed as;

"...research without theory does little to advance knowledge....the study that lacks theoretical rationale lacks the substance and fails to answer the 'so what' question. The findings just sit there, begging to be hitched to something....the saddest thing about atheoretical studies is that they describe events in isolation from a context that allows the results to be generalised" (Downs 1994).

Therefore, the following sections bring to the foreground each aspect of the theory that has contributed to the developing focus of the study. These aspects are;

- The clinical effectiveness of therapeutic footwear
- Patients' behaviour with therapeutic footwear
- Patient factors
- The patient –practitioner relationship

This framework underpins the process of further defining the specific problem to be investigated and the rationale for its focus. These aspects will be returned to in the discussion section of the thesis when the findings from the study will be explored.

5.2 Clinical effectiveness of Therapeutic footwear

Despite therapeutic footwear having the potential to reduce pain, improve comfort and levels of activity, patients often chose not to wear it

In contrast to patients with diabetes, the primary foot symptom for patients with rheumatoid arthritis (RA) is foot pain. There is conclusive evidence that therapeutic footwear contributes to positive symptomatic benefits for patients with RA. These benefits are reduced pain, improved foot health and improved general mobility and were identified by Fransen and Edmonds (1997), and later by Williams, Rome and Nester (2006). Although cosmesis is a factor identified by Stewart (1996) resulting in low compliance in patients with RA, when compared to patients with diabetes, cosmesis is of less importance than comfort (Williams and Nester 2006).

Given the potential benefits to patients with RA identified by Fransen and Edmonds (1997), and Williams, Rome and Nester (2007) together with the patient's desire for comfort above the appearance of the footwear (Williams and Nester 2006), it is of concern that patients with RA do not wear it.

5.3 Patient's behaviour with the rapeutic footwear

Previous research has investigated why patients with RA do not wear their footwear and link this choice to their level of satisfaction.

The previous research by Park and Craxford 1981, Bowker et al 1992, Herold and Palmer 1992, and Stewart 1996, has mainly focussed on the numbers of patients satisfied with therapeutic footwear, and the numbers of patients wearing them, with some superficial attempt to explore what the problems are that lead to patient dissatisfaction. This previous work appears to be focussed on what the researcher thinks is the problem (Park and Craxford 1981, Stewart 1996) using questionnaires

as the tool to collect data, therefore making assumptions that we know enough to be able to ask the right questions to understand why footwear is not used.

Patient involvement and opinions in the design process of this footwear can improve levels of acceptability (Williams, and Nester 2006) and therefore the patients' choice to wear it. Further to this, in a subsequent study (Williams, Rome and Nester 2007) it was observed that the participants were at the centre of the 'consultation' with the researcher and that this also had the potential to influence their behaviour with it. From this and previous research, it could be concluded that the patient's choice to wear therapeutic footwear is a combination of acceptable designs (Williams and Nester 2006) and appropriate service delivery (Williams and Meacher 2001). These aspects have been addressed to a limited degree in some services (Williams and Meacher 2001), but there still remains the reported problem of low usage of this footwear.

Work by Williams and Nester (2006) demonstrated that 'being satisfied' is more complex than 'being' or not being' satisfied. In their study, even those patients who chose a footwear design that they were satisfied with, there were aspects of the footwear with which they were not satisfied. Satisfaction, therefore has not been defined in the context of therapeutic footwear and the factors influencing it may be complex, including factors in relation to the patients themselves.

5.4 Patient factors

There are potentially many intrinsic factors that influence a patient's health behaviour.

The literature review carried out in Chapter 4 has provided information that some of the main intrinsic 'patient focussed' factors that influence health related behaviour are chronic disease, depression and social isolation. These factors pose the greatest challenge to practitioners as they have the potential to impact on the achievement of the appropriate behaviour that contributes to positive health benefits.

Depression is associated with chronic diseases such as rheumatoid arthritis. Dickens et al (2002) identified that depression is more common in patients with RA than in healthy individuals and that this may be attributable to the levels of pain they experienced. Di Matteo et al (2000) identified from a meta analysis of the literature that depression leads to poor levels of engagement in treatments. Social isolation has been identified as a result of the physical disability caused by joint damage in RA (Borman et al 2007). This isolation and lack of support by family and friends is suggested by De Geest et al (1998) as a contributory factor in poor engagement in treatment.

The complexity of chronic disease, depression and subsequent social isolation, may be linked to the patients' engagement with therapeutic footwear. Additionally, in the context of general footwear (Joyce 2000) females are known to have concerns over the appearance of their footwear. In the context of therapeutic footwear, it is not known how these factors influence footwear use or indeed if these factors are considered by the practitioners providing the footwear.

5.5 The patient – practitioner relationship

The interaction between the patient and the practitioner is influential in achieving a shared understanding and through that increasing the potential for positive health behaviour.

There has been a fundamental shift in respect of responsibility for the health of individuals that has being driven by the Department of Health (DOH 2000). No longer are patients seen as passive recipients of health care delivered by

practitioners with formal knowledge and power (Friedson 1986). In relation to patients' health behaviour the focus is moving away from 'compliance', which is outcome focussed to the process of concordance. The development of a concordant relationship may achieve different levels of compliance, so one term doesn't replace the other. Dracup and Meleis (1982) identify that to achieve a concordant relationship requires a rebalancing of the power between the patient and the practitioner.

In contrast to the traditional medical model of care (Beck 2004), the biopsychosocial approach (Engel 1977 and 1980) incorporates a sharing of power and the development of a partnership that supports patient choice. This approach involves considering what is happening to the patient outside the consultation in a broader psychological and social context and also the complexity of the problems that patients bring with them to the consultation. This approach is particularly relevant for patients with chronic long term conditions such as rheumatoid arthritis, where choices in the management of the condition are vital due to the fluctuating course of the condition (Gupta et al 2007).

In the context of therapeutic footwear, it is unclear if there has been a change in mindset from the 'medical model' approach (Beck 2004) to the biopsychosocial approach (Engel 1977 and 1980) in the therapeutic relationship. Further to this, no study has explored the patients' feelings about their interaction with the practitioner and how this impacts on their behaviour.

5.6 Summary of the theoretical framework

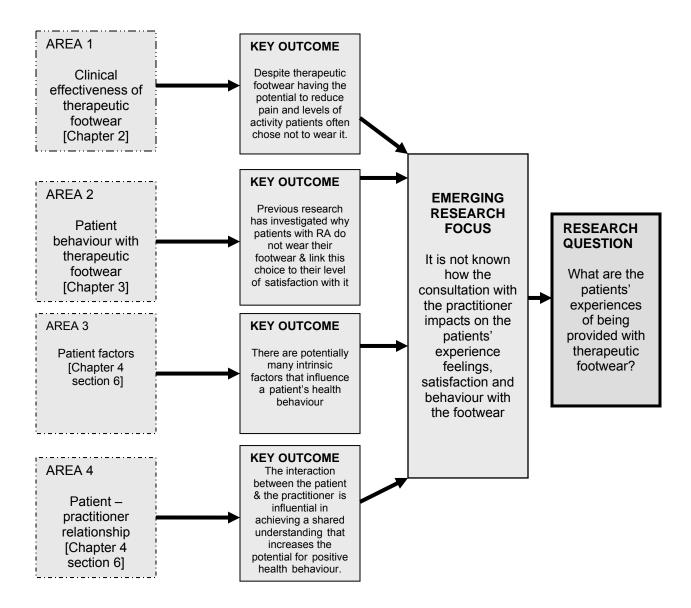
Having completed an extensive literature review and returning to the original question, it is clear that none of this research has fully answered the question of, "why don't patients wear their therapeutic footwear?" No previous research has explored the patients' experiences of this footwear and therefore we do not have a clear understanding of the problem from the patients' perspective as users of this

footwear. This basic knowledge is missing, so, the question that needs to be asked is;

"...what are the patients' experiences of being provided with therapeutic footwear?"

With this question being the focus, it is timely to define the purpose of the study through defining the specific aims and objectives that have emerged in relation to the key summary points of the literature reviews (Figure 5.1 Summary of the Theoretical Framework).

Figure 5.1 Summary of the Theoretical Framework



5.7 Aim and Objectives of the Study

The aim of my research is to discover the users' experiences of therapeutic footwear. In this context the 'users' are females with Rheumatoid arthritis.

The objectives are to explore the;

- 1. users' experiences of being provided with and *wearing* therapeutic footwear,
- 2. influences that affect the users' choice to wear or not to wear the footwear, and
- 3. users' experiences of *the practitioners* involved in the provision of this footwear.

A secondary aim was to explore the practitioners' opinions of the user responses. In this context, the practitioners were orthotists.

As previous, quantitative research approaches to this area focus on the problem and the intervention objectively and not the patient's subjective experience, a qualitative approach may provide insight and understanding as to where the problems are. This methodology will now be explored, described and justified in the context of the aim and objectives of the planned research.

CHAPTER 6 METHODOLOGY

CHAPTER 6 - METHODOLOGY

6.1 Introduction to methodology

This chapter will detail the research approach, and the methods and procedures employed for both the collection of data and the analysis of the data. However, as Koch (1996) suggests, the philosophical basis of any study needs to be detailed for the reader to understand how both the research approach and methodology are appropriate to the research aim and objectives. As qualitative methods of research differ in their theoretical underpinnings and philosophical orientations (Willis 2007), I will identify and reflect further on the influences on me, both as a professional and as a person. This reflective process will clarify my beliefs and 'world view' of research and how this aligns with the purpose and approach to this study and the chosen methodology.

I will now explore the influences on the developing research approach that includes my growing awareness of the historical context and current orientation of health research, the influence of clinical experience and the influence of gender on the research approach. Further to this reflective process I will analyse how these have influenced the development of my world view of research and subsequently how this impacts on the research in this thesis.

6.2 Influences on the research approach

6.2.1 The historical context and current orientation of health research

In this section, I will explore the historical context of health research with regard to the practitioners' approach to health care practice and how this has influenced the focus of this research. Further to this, the current orientation of health research will be described in relation to the profession of podiatry and the influences of this on my own perspective.

Within medical research, the focus has generally been on the physical manifestations of the disorder, its pathogenesis and the numerous and diverse drugs that aim to manage the symptoms and influence the disease process (Ong and Richardson 2006). This 'medical research' is generally on a group of patients with a particular condition or symptoms and uses measurable clinical outcomes together with a research method that is appropriate to this type of investigation. Quantitative methods such as randomised controlled trials and cohort studies have been chosen to achieve the aim of testing the clinical effectiveness of a multitude of health care interventions. The importance of these methods is emphasized by the research hierarchy of evidence with the randomised controlled trial being the 'gold standard' (Glasziou et al 2004).

For the quantitative researcher to achieve the 'gold standard', objectivity is desired. To achieve this objectivity, control of the variables, strict inclusion criteria, randomisation and statistical analysis are required. This approach is underpinned by the positivist paradigm, which, as described by Willis (2007), is that in which the nature of reality is material and external to the human mind, and that the methods and resulting data are viewed as scientific and objective. Popper (1959) commented on this positivist belief in that:

"....through well constructed experiments you could arrive at the truth about something as there is always the possibility that the data gathered do not represent reality, therefore it is easier to disprove a hypothesis than prove it beyond doubt" (page 66).

Prior to Popper, Dilthey (1883 as cited in Willis 2007) suggested that the aim of positivist research is to discover generalisations and laws based on statistical averages. In contrast to this positivist aim, Dilthey believed that we should understand an interpretive understanding of the individual or type and that this understanding should be holistic. My own beliefs align with Dilthey in that researchers need to consider that the participants in health research have a multitude of complex feelings, beliefs, and experiences. This has the potential to influence the outcomes of research whatever method is employed.

Recently, the 'patient's experience' and the use of qualitative methods has become more acknowledged by the medical community particularly when researching patients with chronic diseases (Ong and Coady 2006, Ong and Richardson 2006). As practitioners and researchers, we should not underestimate the ability of an individual to observe, reflect and analyse their own feelings and experiences. Providing an opportunity for patients to vocalise their feelings and experiences to someone who listens has the potential to be a rich source of information. This information is valuable for both research and clinical purposes. Thomas (2005) asserts that phenomena that exist as feelings such as courage, anger, fear, sadness and loss can reveal the patient's experience of disease conditions and their impact in respect of their biological, psychological and social needs. This in turn affects the patient's behaviour and this behaviour may well be influential in achieving the good health outcomes that practitioners strive to achieve.

In striving to achieve good health outcomes, practitioners follow the rules of practice that are generated by research evidence (Howard et al 2003) and in this respect, the term 'evidence based practice' has become the cornerstone of clinical governance within health care services. Evidence-based practice is becoming the foundation of every health care professional's clinical decision making and although professional practice can be viewed as a subjective activity, to achieve objectivity this research has to be carried out as a separate activity or by an objective and independent researcher. However, Black (1994) identifies that quantitative research, and therefore the evidence based practice that this produces may not be focussed on the issues relevant to patients. This is apparent in the area of therapeutic footwear where quantitative research methods have failed to reveal the factors inherent in the patients' experience that may influence their behaviour with the footwear. In my own experience of quantitative research (Williams, Rome and Nester 2007) I observed that patients were revealing information that was not captured by quantitative methodology. This focus on quantitative methods has, in part, been driven by both the ethos of specific health professions and what these professions require from research.

The health care professions that are allied to medicine, which includes my own profession of podiatry, are relatively young professions that emerged following the

World Wars. Formal training for podiatrists was recognised in the late 1950s and it took a number of years for research to be recognised and valued as validation for our health care interventions. The development of the profession, both in its scope of practice and the notion that this practice is scientific has been recognised by the medical world generally as evidenced by podiatry researchers achieving publications in highly rated peer reviewed journals (Woodburn et al 1996, 2000, and 2002 [a and b], Nester et al 2000, 2001 [a], and 2001 [b] and Rome et al 1998, 2000 and 2001). This research activity and recognition has accelerated in the last decade. Therefore, these pioneers in podiatry research who started their research journeys with the desire to be 'scientific' followed in the path of the medical practitioners and researchers. It could be said that they were forced to follow where the opportunity was and this was the route to break through into research as a professional activity. They chose a quantitative approach that considered measurable outcomes as vital in investigating the profession specific health care interventions but on the whole these did not capture the patient's experience of their condition nor the interventions that we thrust upon them.

The quantitative approach to research within podiatry was underpinned by the professional training that was originally based on the medical model of care (Beck 2004). This resulted in conditions being treated with little consideration to the influences and factors outside of the clinical environment, with patients:

"...being viewed as malfunctioning machines and their complaints as problems to be solved using a linear hypothetico-deductive thought process" (Thomas 2005 p64)

This is in contrast to current thought in the podiatry profession. This thought is to have a more 'holistic person centred approach' to patients which, not only takes into account their general health problems but also their social and psychological needs. There has been an extension of the role of podiatrists from providing localised foot care treatments to being a specialist in the assessment and diagnosis of the myriad of systemic and structural complications associated with systemic and often chronic diseases. This change in professional ethos and the focus of podiatry education in how we view our patients has been influenced by the work of writers such as Prochasca and DiClemente (1982, 1984). This change in focus embraces the bio-

psycho-social model (Engel 1980) in acknowledgement that there are other influences, which impact on the health of individuals other than our interventions. The whole approach to patient care is becoming patient focussed and holistic with the balance of power with the patient and 'negotiation' being the mantra of the consultation (DOH 2006).

In relation to my own early experience of research, despite my holistic approach to clinical practice it was initially difficult to embrace qualitative paradigms. This resulted in an over eagerness to focus on the research process rather than the underlying philosophy in an attempt to produce results that will withstand the critique of the audiences to whom this research will be presented. The knowledge base that supported my practice was influenced by the notable quantitative researchers such as Woodburn et al (1996, 2000, and 2002 [a and b]), Nester et al (2000, 2001[a and b]) and Rome et al (1998, 2000 and 2001) who were the pioneers of podiatry research and whom I admired. There was tension between who I was as a practitioner with a holistic approach and who I was influenced by as a researcher and this tension took some time to resolve. Intuitively I knew that the positivistic paradigm did not fit with the purpose of my intended study and I needed to reflect on my own world view.

During this time of tension, a pivotal moment occurred when I overheard a conversation one day that had an impact on my thoughts about research. A business man was speaking to a female colleague about a commercial product promotion. The part of the conversation that struck me was his closing comment:

"...well remember my dear...reality is nothing and perception is everything". (Anonymous 2005)

Analysing this statement, I started to grasp the notion that reality is only how the individual perceives it and in that respect, reality can only be seen through the individual's perception not from my observation or 'measurement' of their behaviour. This is in contrast with the positivist view of the world that Guba (1990) identifies as being 'out there' and available for study in the static form. Further to this, the aim of

quantitative research to be generalisable cannot capture the uniqueness of a patient's perceptions and the complexity of influencing factors.

In this section I have explored the historical context of health research and the influence of professionally based research on my own research paradigm. The notion that a holistic approach to clinical practice could be transferred into the research setting was both liberating and exciting. This was in anticipation that in the context of therapeutic footwear, this approach could provide the answers that previous research had not been able to achieve. Further to these thoughts, I also realised that my clinical practice and experiences of it have also influenced my world view. Therefore, this is now explored and made transparent because of the influences on my research philosophy and approach to this area of research.

6.2.2 Influence of clinical experience -Novice to expert clinician

I believe that as a health care practitioner, who we are and how we develop is a complex interplay between the knowledge and skills that develop through clinical experience. This belief aligns with that of Merleu-Ponty (1962) who describes achieving experience through knowledge and skill as achieving 'maximum grip'. As humans we constantly try to perceive and manipulate situations to achieve the best view of the world, the best and safest existence and the most pleasurable experiences. The ability to do this depends on our learning from experiences and an 'intentional arc', which includes 'know how' and an ability to respond to and reflect on situations (Schon 1983, 1987). My growing professional knowledge, skill and responsiveness to reflexivity in practice, contributed to my development from a novice to an expert practitioner. In addition, this development included an ability to embrace a new approach to the clinical encounter that was different to how I had been trained. In essence this was a transition from the ethos of the medical model of care to a 'holistic' approach.

The adoption of the holistic approach (Engel 1977) to the clinical encounter in which all the patient's needs were considered not only gave me information about how these needs impacted on them but it created a relationship between me and the

patient. In this relationship I felt that trust, friendship and empathy emerged to a level where I viewed the patient's decisions almost as my own. The potential clinical outcomes became less of a focus but this did not mean them becoming less important, it meant that my approach to the patient allowed them to decide at what level they wanted the positive health benefits in relation to their expectations, needs and choices. I realised that whatever the clinical outcome the patient's choice was important and I relinquished my dominating professional power so that ownership of the decision making became the patients. This transition involved me becoming a support to the patient in their decision making and an advocate when they needed a voice.

This transition was before the term 'patient centred' became a 'sound bite' of the National Health Service (DOH 2005, DOH 2006). This was a fundamental philosophical shift in the sense of moving away from how I had been taught as a student with what I now know as the 'medical model' of care, to the biopsychosocial approach that encompasses social and behavioural aspects of health (Engel 1977). This change in my personal philosophy emerged from my early professional career through to becoming an experienced practitioner. This change led to a number of questions in relation to the therapeutic footwear that I supplied to patients attending my clinic. I questioned the reported 'satisfaction' with the footwear and if it equated to the patients being totally happy with it. Satisfaction questionnaires are often administered by the service that delivers it and the questions formulated by the practitioners who deliver the patient care. The patients' responses therefore may be influenced by this and the fear that negative responses may influence their future care will provided results that are not a true reflection of the situation.

Further to this, I also questioned that if the patients had the choice to wear this footwear, would they choose to wear it. Choice in life is important and often patients with chronic disease have lost choice in their lives due to the effects of the disease on their abilities to carry out the normal activities of daily living. In addition to these questions that were emerging, new knowledge obtained from the review of the literature into health behaviour provided me with the knowledge of the influences on it. I realised that there were potentially other influences on the patient's choice to wear the footwear or not. Most previous research has focussed on the appearance

of the footwear and not explored other influences. The clinical encounter between the patient and the practitioner is the opportunity for patients to have a voice but it is not known in this area if they do have a voice and if they are listened to. The ultimate question of why patients chose not to wear their footwear once it is provided still remained unanswered. All these questions that arose from my clinical experience of this area have contributed to the developing focus of this research.

My holistic approach to patient care created questions that were different to those posed by previous research. I had achieved a level of understanding from the patient's perspective using a holistic approach to clinical practice. I also noticed that being a female practitioner had an influence on the clinical consultation compared to my male colleagues in that the patients consistently revealed to me how they felt about their footwear. With this in mind I will now explore the influence of gender on the planned exploration of patients' experiences of being provided with therapeutic footwear.

6.2.3 Influence of gender on the research approach

Despite the implementation of a multidisciplinary footwear clinic that had all the features recommended by the Salford Report (Bowker et al 1996), it became apparent to me that we were still failing patients (Williams and Meacher 2001), particularly the female patients.

As a clinician and later as a researcher, I reflected on what it must feel like to be the recipient of this footwear. I concluded that I would experience public self consciousness as described by Hale et al (2007), feel unfeminine and therefore would be probably be one of the patients who would not wear their footwear regardless of the consequences to the health of my feet. These feelings can be described as an empathic response and has been described by laquinta and Larrabee (2004) as being an important aspect of an effective relationship between the patient and the practitioner. The women's concern for body image resonates with me, as does the knowledge of how shoes contribute to body image and feelings of sexuality. There was a tension arising between me as a woman and me as a

practitioner. I became aware of myself as a therapeutic tool for negotiating and encouraging engagement in the use of this footwear, whilst realising that it was not ideal in appearance. Also, I realised that compared to the normal choice that women have when they purchase retail footwear, there was no choice in the therapeutic footwear either in the styles or whether to have it or not. My feelings of empathy for these women and the intuition that things could be improved for them continued to drive me to the ultimate goal. This goal was that the experience of being provided with therapeutic footwear, the footwear itself and the possible health benefits should and could be improved for these women.

During the process of reflecting on the impact of gender on clinical practice I discovered feminist theory in relation to research. Harding (1987) identified ways in which feminist researchers can transform research methodology and hence the impact of research findings. There are certain aspects of Harding's beliefs which align with mine. First, she views that the objectivity of quantitative research methodology hides the biases and experiences that guide the research, whether we acknowledge them or not. She proposes that open acknowledgement of the subjectivity of our research actually increases the objectivity of the research through being transparent as to what our beliefs and influences are. Second, she views feminist research as being emancipatory allowing a particular group to take control of their lives. This view fits with my belief that patients should be the centre of the consultation and that they should have a voice, and hence choice in their care. Finally, she suggests that change can be influenced by reflexivity as a component of research.

My ability to reflect in practice led to the emergence of several questions that had not been answered, either in the clinical or research setting. Being female is a powerful tool in data collection and analysis. In line with other female researchers such as Hale (2007), I feel that being female has advantages when researching female participants using qualitative methods. Being a female researcher has advantages in the area of therapeutic footwear in that I can empathise with these women and that this empathy has the potential to enable these women to have a voice. An exploration of how best to achieve this led me to a stage in the journey where I considered the various research approaches and philosophies associated with them.

This resulted in the culmination of the influences that contributed to my own research paradigm.

6.2.4 Development of Personal Research Philosophy

The development of my research beliefs or 'world view' arose from self reflection and awareness of my professional and personal horizon, plus reflection on my experience of quantitative research methods. This development led to the culmination of all these influences into a personal research philosophy. This then guided me to explore qualitative methodology and specifically interpretivist phenomenology in respect of the focus of the research being on patients' experiences.

Reflecting on my previous experience of quantitative research, I struggled with the rigid processes and objective detachment involved. I also viewed this as being inappropriate for this area of study. I realised that it would be difficult to be objective in my approach to research in this context; it did not fit well with me as a person with a concern for the well being of individuals and who I was as a clinician with a holistic approach to patients and their needs. I found that I could not ignore the emotional dimensions of patient's experiences in the research context and considered that to be 'person centred' in clinical practice should be transferred to a research approach. In this situation, I viewed the researcher as co-operating and collaborating, with a blurring of the gap between the researcher and the researched. This 'blurring' equalises the power balance inherent in a positivist approach, resulting in the researched expressing their valued thoughts and views with the researcher being the vehicle for that to happen.

I was very clearly travelling in the direction towards qualitative research, but before I travelled any further I felt that it was desirable to consolidate my understanding of the concepts, beliefs and terminology associated with it. During my journey through the philosophical jungle of research approaches I stumbled across a perspective on what research is. This perspective assisted my understanding of the difficulties and problems associated with being a researcher and provided a realisation that it is a:

'.....strenuous and devoted attempt to force nature into the conceptual boxes supplied by professional education" (Kuhn, 1962 p145)

This definition resonated with my thoughts that positivist research, in its striving for objectivity did indeed force nature into conceptual boxes. Some writers such as Denzin and Lincoln (1994) may argue that this process of boxing nature does not fit comfortably with the more fluid approach of the qualitative, interpretivist researchers. However, this perspective described by Kuhn (1962) had impact on me in respect of what my research was and was not to be about. I recognised that this was more than just choosing a research method that seemed to be appropriate to obtaining data in order to provide answers to the identified problem. I realised that I would have to be devoted to my task and in that respect required the development of intellectual strength and ability to explore and understand the concepts associated with these approaches. In that respect I recognised that there were the conceptual 'boxes' that Kuhn described and the contents were the different research paradigms and their differing ontological and epistemological views of the world. I consider that the fluidity that Denzin and Lincoln (1994) describe relates to the ability of the researcher to be flexible in their approach to data collection and the interpretation of the data produced rather than the concepts that define the overall research approach.

Emerging from these thoughts is the notion that it is not desirable to conduct objective research in this area. This notion is in line with the beliefs of Kant (1781) who stated that you cannot be objective about subject matter,

"...because we become pre-wired, so to speak, with 'categories of understanding' that then influence our perceptions." Kant (1781) translated by Guyer and Wood (1998).

These thoughts were explored further by Dilthey (1883 as cited in Willis 2007) who argued that to achieve true understanding of a subjective phenomenon requires a holistic, rather than atomistic process. He emphasised that observations do not exist separate from our conscious activities and that we must think in order to know reality. Further to this Dilthey felt that we should undertake an interpretive understanding of the individual or type. Therefore, in order to know the reality of

patients experiences of therapeutic footwear, the concern is not to provide results that can be generalised to a wider population but rather to develop a deeper understanding of patients' experiences.

Heidegger (1927) also proposes abandonment of the search for generalisable truths and laws to concentrate on local understanding about human behaviour. Heidegger further suggests that the interpretivist ontological position is that there is no reality except in what we perceive in our heads and what is perceived through our senses. Further to this, Merleau-Ponty (1962) suggests that although our perceptions of things and therefore reality, is very individualistic, we are humans who communicate and have understanding of each other. Therefore it is impossible to have a totally unique version of reality but a core belief of the interpretive paradigm is that reality is socially constructed.

The belief that reality is socially constructed has become the basis of interpretivist research paradigms. An example of this is phenomenology that focuses on the subjectivity and relativity of reality, continually pointing out the need to understand how humans view themselves and the world around them. Following Kant (1781), phenomenologists distinguish phenomena, which are the perceptions appearances from the point of view of a human, from noumena, which are what things really are. Greenhalgh and Taylor (1997) describe the interpretive paradigm as attempting to interpret phenomena in terms of people's subjective interpretation of experience and reality. Therefore, it is the aim of the researcher to enter the world of the individual whilst acknowledging the impact of the research process. The researcher is part of the research process in that they have experiences and perceptions of their own. This research process is, I believe, one that involves a relationship between the researcher and the researched that requires trust and respect for each other. I feel that to be the recipient of another person's most innermost thoughts, feelings and opinions is a privilege but also a responsibility. The responsibility lies with the researcher to use these thoughts appropriately in their interpretation of them.

For Denzin and Lincoln (1994) the collection and interpretation of qualitative data on people is inherently subjective and no matter how close we come to meeting the technical standards of research techniques the result is not an objective report of the truth of the matter. This could also be said of positivist research, especially when it comes to the interpretation of data, despite the statistical tests employed. Denzin and Lincoln (1994) also point out that we also use subjective values to decide whether a study warrants our attention and suggests that the values we use to make that decision are ideological, political, moral and personal. Hale et al (2007) support this notion and suggest that these choices introduce subjectivity into any research approach, even those using a quantitative approach. However, in qualitative research this subjectivity is acknowledged with the researcher becoming an integral part of the process and outcome.

These thoughts led me to explore the research approaches that would provide me with the most appropriate method for this study. Willis (2007) suggests that 'research approaches' can be defined by the method chosen and by the philosophy underpinning that approach. Exploring a definition of philosophy, this is;

"...the use of reason and argument in seeking truth and knowledge of reality especially the causes and nature of things and of the principles governing existence, the material universe, perception of physical phenomena and human behaviour...," (Oxford English Dictionary 2002)

Based on this definition, I further consolidated my thoughts around my own philosophical stance or 'world view'. My philosophy emerged from my belief that reality is different from person to person, particularly in respect of my role and the patient's role in healthcare. However, I do acknowledge that there are some commonalities in that through dialogue we develop a shared understanding. My concern over the emotional aspects of healthcare and further to this, my holistic approach to care, can be considered to be useful in the exploration of the wholeness of the patients' experience. I believe that in the clinical situation, patients should feel empowered to make decisions and choices in their care. Like the clinician, the researcher is the vehicle to empower the participant and this liberating process should allow the participant to reveal true feelings.

The influences from professional training, clinical practice, and research experience have been explored as has the influence of gender on the development of my current philosophy or 'world view' of research. I have considered how my beliefs align with an interpretivist phenomenological paradigm and this is summarised in Figure 6.1.

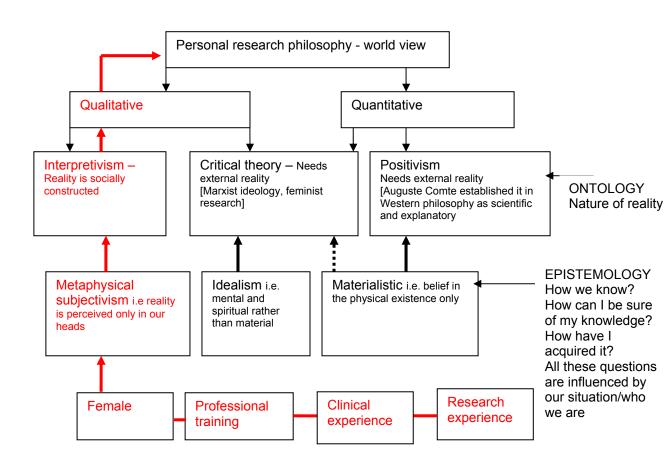


Figure 6.1Development of personal research philosophy

6.3 Justification for the Research Approach

Having explored the factors that defined my own research philosophy I then needed to look for a research approach that would be suitable for the aim and objectives of the planned study. Through reading the literature about different qualitative methods, I was further convinced that this was the right approach.

Qualitative research, in contrast to the quantitative approach, obtains insight and deep understanding not through establishing causality, but through improving comprehension by utilising an interpretative, naturalistic approach to its' participants (Denzin and Lincoln, 1994). Further to this, Greenhalgh (2001) suggests that the strength of a qualitative research approach lies in its internal validity, that is, its closeness to the truth and it touches the core of what is occurring rather than skimming the surface. As previous research had not explored patients' experiences of being provided with therapeutic footwear in any depth, an interpretive phenomenological approach was chosen as the most appropriate to achieve the aim and objectives of the planned study. I will now explore this approach in order to justify why it has been adopted for this study.

The methods used in phenomenological research provide an understanding of the lived experience of humans 'through their eyes' (Heidegger 1927). It makes the distinction between what things are and how they are seen and with the belief that consciousness and physical existence are not separate therefore feelings can and do influence behaviour. It is a particularly useful method with which to begin when studying a new area in order to identify issues that warrant further research or an area where a new perspective is needed. In the area of therapeutic footwear previous work has failed to answer the question of why patients do not wear their therapeutic footwear and therefore a new perspective is needed.

Phenomenology as a research method has a brief history in the field of rheumatology (Ryan 1996) but there are different interpretations and modifications of phenomenological philosophy (Omery 1983). For clarification and justification for the phenomenological approach to this study, I will explore its origins.

Descriptive phenomenology was developed by Husserl (1931) who was known as the father of phenomenology. His work broke away from the purely positivist orientation of the science and philosophy of his day, giving weight to subjective experience as the source of all of our knowledge of objective phenomena. Husserl's phenomenology emerged from the Cartesian philosophy of the mind and the mind-body split (known as *cogito ergo sum* "I think, therefore I am"). This phenomenology came to mean the study of phenomena as they appear through consciousness

(Koch, 1995), with intentionality being a key element of his work. Intentionality is the notion that the main characteristic of consciousness is that it is always intentional and it is how humans relate to objects within our consciousness. Husserl's belief was that every mental phenomenon is characterised by the intentional (or mental) existence of an object within it. We are always conscious 'of something'. Smith and Woodruff Smith (1995) suggest that this intentionality, in the context of phenomenology, describes the human mind reaching out and into the objects of which it is conscious.

Central to Husserl's argument was that experience as perceived by human consciousness has value and should be scientifically studied in order to understand it. It was asserted that the researcher should 'return to the things themselves' and to the 'essences' that constitute consciousness and perception of the human world (Husserl, 1931). Husserl argued that a scientific approach was needed to illuminate and describe the essential objects or 'essences' of lived experiences as a means to understanding. These objects of interest have been described as 'primordial phenomena' that exist within a 'primordial consciousness' (Husserl, 1931), that is, they are objects of our consciousness that have not been previously reflected on or judgements made about them. It is this search for the object of consciousness that Landgrebe (1973) suggests makes Husserlian phenomenology objective. Husserl's background as a quantitative researcher had clearly influenced his thoughts and this is illustrated by his aim for objectivity that aligns with the positivist paradigm.

With my personal research beliefs I had concern that objectivity was not desirable in the context of the planned research as an objective approach to researching the area of therapeutic footwear had not provided all the answers as evidenced by the continuing problem. With this concern in mind, I then explored the writings of Heidegger (1927) who was a student of Husserl and further to this, the writings of Gadamer (1989).

In contrast to Husserl's search for objectivity, Krell (1999) describes Heidegger's (1927) belief that each individual has a subjective viewpoint and interpretation of their experience depending on past experiences, culture, social status and their knowledge base. Therefore, not only do humans have a consciousness, but are

orientated towards time and space. Mulhall (1996) further illuminates this by stating that the only way to fully understand phenomena is to consider it within its context and the significance it holds for the individual. In contrast to Husserl who suggested that to achieve objectivity one should 'bracket' ones preconceived ideas, Heidegger believed that it was impossible and in fact undesirable to suspend ones previous understandings because one cannot stand outside of the world. This has been identified by Linge (1976) as the most prominent difference between descriptive and interpretive phenomenology. The notion that we should be adding to previous knowledge not replacing it aligns with my thoughts on the value of these ideas as a contribution to the research process rather than a weakness of it.

Therefore, the strict 'bracketing' of past experiences, knowledge and beliefs found within Husserl's descriptive phenomenology is considered to be both impossible and undesirable in this investigation because of previous clinical practice, professional experience and knowledge of previous research. Most health care practice today is based on the philosophy of reflective practice whereby reflecting on action in builds knowledge and understanding (Schon, 1987; 1983). Merleau-Ponty (1962) tells us that,

".....the life of consciousness – cognitive life, the life of desire or perceptual life – is subtended by an 'intentional arc', which projects round about us, our past, our future, our human setting, our physical, ideological and moral situation" (Merleau-Ponty 1962 p136).

I believe that we cannot deny this 'intentional arc' and to 'bracket' this previous knowledge and understanding, would, I believe result in an automated and sterile research process. This would have resulted in difficulty in defining the focus of the research, the analysis of the findings in relation to previous work and the philosophical thoughts that have emerged through this thesis. One important thought is that Heideggerian values have the potential to influence health care practice. Inherent emotions that are deemed inappropriate for health care practitioners to have and indeed encouraged to subdue as being unprofessional may create a barrier to gaining an understanding of the patient's perspective. If this barrier can be removed in the research context with the aim of achieving a greater understanding of

the patient's problems, then this could be transposed into clinical practice to achieve the same result. This thought will be returned to in the discussion section of this thesis.

Following on from the rejection of the concept of bracketing, the beliefs that are at the core of interpretive phenomenology are 'Dasein' and the hermeneutic circle. Mulhall (1996) described Heidegger's notion of 'Dasein' meaning the entity that human beings are. Further to this, Krell (1999) describes how Heidegger questions the nature of 'being'. 'Being' means what it is to be a person and that no experience can be understood without reference to contextual understanding, since people are 'in' and 'of' the world. When viewing Heidegger's concept of personhood and 'Dasein', Leonard (1994) highlighted five points that help to clarify Heidegger's ontological concerns regarding what it means to be a person and how the world is intelligible to that person (Table 6.1)

Table 6.1 Heidegger's views of what it means to be a person (Leonard 1994)

Each person has their own world which is taken for granted until reflected upon and analysed.

Each person has a 'being', in which things have value and significance and examining this context is the means of understanding.

Each person is self-interpreting, in that they interpret experiences and knowledge in an attempt to understand themselves.

Each person is embodied, but not in the Cartesian view of possessing a body, embodiment enables human to experience their actions in the world.

Each person is 'in' time.

This view provided me with clarity as to how individuals view the world 'in time'. It provided me with confidence to know how people reflect. This is important in the planned investigation as they will not just be describing events that occurred in the past but a reflection on them over time. With this in mind we have to accept that

feelings at one point in time may be different at another point in time and that the language to describe this may be different and have different meaning to individuals.

Interpretive phenomenology has also been described as philosophical hermeneutics (Linge, 1976). The term hermeneutics has its origins in the 17th century when it was introduced as a method of biblical interpretation. The two assumptions that are associated with hermeneutics are that humans experience the world through language and that this language provides both understanding and knowledge (Dowling, 2004). Heidegger's goal was to uncover the nature of human understanding. He argued that 'truth and method' are at odds with each other and was critical of rigorous 'scientific' method which he believed that correctly interpreting text meant recovering the original intention of the author who wrote it. However, Gadamer (1989) argued that people have a 'historically effected consciousness' and that they are embedded in the particular history and culture that shaped them. Therefore interpretation of text involves a 'fusion of horizons' described by Leonard (1994) where the researcher finds the ways that the text articulates with their own background. Therefore, essentially, hermeneutics involves cultivating an ability to understand things from another's point of view.

Interpretive phenomenology extends Heidegger's introduction of the historicity of 'Dasein' and proposed that the interpreter should work in a 'hermeneutic circle' (Gadamer 1989). This begins with the interpreters reflecting on and analysing their own background, understanding and prejudices to develop self-awareness of their own 'horizon' or historicity (Gadamer 1989). This then facilitates the interpreter in analysing the text with a more open mind and remaining true to the data of the inquiry when interpretations are made. Leonard (1994) suggests that this self-reflection and awareness should continue throughout the interpretative process until the 'fusion of horizons' occurs. This relates to the process by which the new meaning that has been generated or revealed from the data is fused with the previous understanding or prejudices to produce new knowledge or understanding (Gadamer, 1989; Linge, 1976).

In summary, the aim of the interpretive phenomenological approach is to determine what an experience means for that person through exploring dialogue and the interpretation of that dialogue to reveal feelings and meaning. Morse (1991) succinctly describes it as being inductive, meaning that experience and perception is elicited from the participant's not the researcher's perspective, but with consideration to the researcher as the research tool.

The exploration of the philosophy of phenomenology has provided me with a greater understanding and confidence as to how my beliefs align with the interpretive phenomenologists. These beliefs are that to achieve a holistic perspective of the subject then a holistic approach is required and that the unique experience and knowledge that I have adds value to the research process. The next step was to consider the most appropriate method of collecting the data for the purpose of this study. Further to this I will describe the research process and the method of analysing the data.

6.4 The Data Collection Tool

This section will detail the rationale for the choice in the data collection tool for this investigation. The researcher's perspective will be highlighted and the selection criteria for the participants described. Further to this, all procedures will be detailed and ethical issues will be discussed

The application of an interpretive phenomenological approach requires a suitable data collection method. How people feel, based on experience, and how they behave are interlinked (Prochasca and DiClemente 1984). People are a valuable source of information about themselves, their environment, culture, lifestyle and they are capable of expressing their feelings and behaviours with some clarity (Lederman1990). We have to acknowledge that experiences occur over time, but these definitely have an impact on how we feel at any given point in time. Burns and Grove (2001) suggest that one method of exploring these experiences is to use interviews as the research tool in which, the data takes the form of conversations, words and meanings. Further to this, Silverman (1993) suggests that semi structured interviews are said to be empowering, as they allow the subject to articulate their own views and raise issues.

Pope et al (2002) and Mulhall (1996) both identify the advantage of using semistructured compared to structured interviewing, in that it allows a flexible approach where the participant is encouraged to talk about issues that are most important or 'authentic' to that person. It allows the participant within the research context to be in control and therefore in a position of power. Both Bryman (2001) and Melia (2000) identify that the researcher also has the flexibility to respond and ask new questions depending on the interviewees' responses The researcher and respondent are therefore allowed to 'participate in' the interview, which facilitates a collaborative and open environment and a more in-depth, authentic and detailed picture of their experiences (Gadamer 1989, Sjostrom and Dahlgren 2002). Further to the semistructured interview, a conversational style of interview allows even more fluidity with the interviewer asking key questions when the dialogue from the participant dries up or if they wander off the subject for too long. Willis (2007) suggests that this style also allows the interviewer to check the meaning of the participant's responses and can therefore add to the rigour of the study. This method fits perfectly with the philosophy of interpretive phenomenology and my own research belief that a holistic person centred approach is necessary to obtain the participant's perspective. Therefore, to achieve the aim and objectives of this study a conversational style of interview was chosen as the method of collecting data.

There are a number of disadvantages to using interviews to gather data and the main issue that was particularly pertinent to this study was social desirability response bias as identified by Fielding (1998). People who are engaging in socially unacceptable behaviour or have not adhered with healthcare interventions are more susceptible to researcher obtrusiveness and therefore are more likely to distort their responses (Polit and Hungler, 1999). However, Fielding, (1998) suggested that interviews are advantageous in comparison to questionnaires when the topic is sensitive or complicated, because explanations and information can be given. I attempted to counteract social desirability response bias by putting the participants at ease by using a warm and friendly manner during the interviews and ensuring a neutral or non-judgemental demeanour as suggested by Polit and Hungler (1999).

Another disadvantage of interviews identified by Fielding (1998) is that they rely on the interviewee having the knowledge and perception necessary to answer the questions. I addressed this issue by using a purposive sample of patients as suggested by Pope, Royan and Baker (2002). All the patient participants had all been prescribed therapeutic footwear, so they had the knowledge and experience necessary to ensure adequate data was collected.

Having chosen a conversational style of interviewing I have explored the potential weaknesses and ways of dealing with these, to minimise their influence. I will now discuss how the researcher's perspective needs to be considered in the process of collecting the data.

Although the tool of choice for the collection of data was interviews, it could be said that the interviewer is the research tool. In this respect, as the researcher has preconceived ideas that have emerged through clinical practice in this area, previous research and also her own perspective as a female interviewing females, this needs to be described and acknowledged. It is inconceivable that these interviews should be carried out by someone with no knowledge of footwear and the services that provide it or with no views at all on the subject area. To allow the reader to contextualise the findings of this research, I have been transparent as to my previous clinical and research experiences and the journey that has influenced my beliefs and developing approach to this study in Chapter 1 and in the conclusions of Chapters 2-4.

6.5 The Participants and Recruitment Procedure

In clinical or experimental quantitative research, it is considered 'gold standard' to ensure that a truly random sample is recruited so that the results reflect, on average, the condition of the population from which that sample was drawn. In qualitative research we are not interested in an 'average view' of a patient population; we want to gain an in-depth understanding of the experience of particular individuals or groups. Therefore I deliberately sought out individuals who fitted selection criteria that emerged from the theory underpinning this research (Chapter 5 section 5).

Corben (1999) describes this as being crucial in this type of research as it is important that the reader of the research is clear who the research is carried out on and why.

The patient group chosen for this study are females with rheumatoid arthritis, as defined by Arnett et al (1988) who have experience of wearing therapeutic footwear. It is known that this patient group have complex disease symptoms and complications that require addressing when therapeutic footwear is provided. We know that females generally make their footwear choices based on appearance over what they know to provide comfort (Joyce 2000) and that there is a problem with specialist footwear in this patient group (Stewart 1996). However, no previous studies have explored in depth the patients' feelings in relation to the footwear, the service or the patient / practitioner interaction and the influence of this on the patient's engagement and use of therapeutic footwear.

The criteria that emerged from the theoretical framework for this study, was used in the selection of patient participants who were recruited from four hospitals in one locality in the North West of England. The Surgical Appliance Officer in each of the four hospitals identified patients who fulfilled the criteria of the sampling framework. The patients were identified from the Appliance service records.

The following inclusion criteria were applied:

- Listed on orthotic service records
- Attended a clinic appointment for footwear within the last six months
- Received specialist footwear from the orthotic services
- Reported at their last appointment that they were satisfied with the footwear
- A diagnosis of rheumatoid arthritis (Arnett et al 1988) of more than 3 yrs duration
- Female gender

Over a recruitment period of four weeks, eleven potential participants who met the criteria were sent letters and information leaflets about the planned study. Out of these eleven, ten women agreed to take part. The one patient refusing did so

because of a planned hospital admission. In order to explore if there were any differences in experiences between the genders, three males were subsequently recruited from three of the hospitals as an exploratory part of this study.

6.6 Ethical Considerations.

The ethical considerations for this research will now be discussed. These are wider than the concerns for potential risks that participants of research have to consider before giving consent, although this aspect will also be discussed.

De Reave (1996) suggests that the first and most important ethical aspect of any planned research is the reason for doing the research in the first place. This is important as it could be considered unethical to carry out research with people if that research had already been carried out. If the information or the answers to a research question can be answered elsewhere, then to carry out research just for the sake of doing it would be unacceptable, particularly if there was a risk of harm. In the case of this study, the reason for doing it is that despite previous research in this area, it has failed to provide the answers and thereby solve the problem of low patient engagement in therapeutic footwear. Therefore, it can be justified why this research is taking place.

In relation to research methodology, De Reave (1996) highlights the importance of ensuring that the participants do not have their time wasted. In this respect, it is important to have the most appropriate method for the purpose of the research so that unnecessary procedures or inappropriately long contact with the participants is avoided. In addition, the benefits and harms of the research process and outcome need to be recognised and harms minimised. Polit and Hungler (1999) discuss the potential benefits and harms of research in relation to the ethical issues of research. The ethical issues are based upon the ethical principles of beneficence, non-maleficence, and autonomy.

Beneficence is the principle that the benefits of the research to the participants will be maximised (Polit and Hungler, 1999). Within the current study I reiterated that

there might not be direct benefits to the participants personally, but that the study would be of benefit to the service and patients in the future, as the findings would inform service improvements. However, there was the potential for the interviews to be a positive experience for the participants. This is in respect of the interview being a vehicle for allowing them to have a 'voice' and express their concerns and experiences. Therefore, the interviews may be a therapeutic experience.

Polit and Hungler (1999) describe non-maleficence as relating to the issue of minimising harm or exploitation of the participants. The risk of physical harm to the participants in this study was minimal, although as Steinke (2004) points out, emotional harm is a potential risk when interviewing. In this study there was the potential for emotional harm if the participants became embarrassed or upset when talking about a lack of engagement in the use of the footwear. I addressed this by explaining to the participants prior to obtaining informed consent and commencing the study, that if they felt uncomfortable or distressed that they could stop the interview at any time and it would not be restarted. This, however, was not deemed necessary during any of the interviews. I also identified potential support mechanisms through the Patient's Advisory and Liaison Service (PALS).

Social harm, as described by Ford and Reutter (1990) may have resulted from confidential information being made public. However, this risk was addressed by maintaining confidentiality at all times throughout the study. Consent forms were the only place where the participant's names were used. On all other written data relating to the study the participants name was replaced with a pseudonym. The original consent forms were stored in a secure locked place, accessible only by me. All digital recordings were destroyed immediately after transcription and analysis and it is planned that the coded interview transcripts will only be stored for 15 years in accordance with current NHS Trust policy. Only myself, as researcher had access to the information gathered during the interviews, although with the participants' consent, the anonymised data was shared with my research supervisors, and one additional 'researcher' for the purposes of peer review. In addition, the transcripts were used as case studies to ascertain the practitioner's interpretation and responses. I also obtained the participants' consent to use anonymised quotations in the final report and reserved the right to publish results. Finally, permission was

asked to take digital photographs of their footwear to illustrate the type of footwear worn and to further illuminate the case studies for the purposes of disseminating the findings of this investigation in presentations and publications (Appendix I Participant Letter and Information; Appendix II – Participant Consent Form).

Steinke (2004) suggests that respect for autonomy relates to the principle that prospective participants have the right to decide voluntarily whether to participate in a study. The prospective participants in this study were given detailed information regarding the aim and consequences of the study and opportunities to ask questions before consent was given (Appendix I – Patient Information). Recruitment was by invitation letter rather than face to face, it was voluntary and adequate information was provided regarding the risks and benefits of the study before informed consent was obtained (Appendix II) and confidentiality assured. They were also informed of their right to withdraw from the study at any time, without adverse effects or implications for their future care. This right is supported by authors such as Ford and Reutter (1990). De Reave (1996) suggests that appropriate access to participants involves maintaining their autonomy. That the participants in this study were interviewed in their own home, possibly contributed to their feeling of autonomy and had the effect of equalising the power balance between the researcher and the researched. De Reave (1996) highlights the importance of the participant knowing to whom they are giving their consent and personal information to. She raises an important point that often the researcher is a health professional and if the participant is aware of this it might influence their decision to take part in the research. In this study this issue is addressed by the participants being informed that the researcher was an academic member of the university but who had experience of working in footwear services.

De Reave (1996) considers that it is important that during the process of disseminating the findings of research, that the researcher is responsible for possible 'harm' caused to individuals or groups reading the findings. In this case, the practitioners to whom the findings and recommendations relate to could become distressed as it could be perceived that they are being criticised. In presenting the findings, I will make assurances that the aim of the research was not to find fault, but to find reasons for the patient's lack of engagement in the footwear. The resulting

recommendations for clinical practice could facilitate an improved experience for the practitioners as well as the patients.

Ethical approval for this study was sought and gained from the Central Office for Research Ethics Committee, which provided an objective analysis of the relevance and adherence to ethical considerations and advice regarding patient information and consent.

In summary, a humanistic approach to the ethical considerations for this study, acknowledges the importance of the participant's feelings. Also, that it is essential to acknowledge that emotional damage is of no less concern than potential physical damage, for example, from research involving interventions such as drugs. With the ethical considerations being described, I will now detail the data collection procedure for both the patient participants (6.7) and the practitioners (6.8)

6.7 Data collection procedure – patient participants

Reassurance was given to each potential participant, that if they declined to be involved in the study, that this would not affect their future treatment. Those that were interested in taking part in the study were asked to contact the researcher (AW) to arrange a convenient date and time for the interview to take place at their own home.

Following my personal introduction and provision of identification, further clarification as to the purpose of the study was given and the opportunity for the participants to ask questions was provided. Informal conversation took place to put the participants at their ease. Formal written consent was obtained and all participants agreed to proceed to the interview. To achieve continual informed consent, I further assured the participants that they could stop the interview at any time and withdraw from the study if they so wished and receive support at this time. There were no third parties present during the interview

The patients were described in terms of age, occupation, duration of rheumatoid arthritis disease, and general health status using the Stanford Health Assessment form (Bruce and Fries 2003), type of therapeutic footwear and duration of wear time. These details were gathered in order to provide a full description of the sample. This is required so that the reader of the research findings could decide for themselves how transferable the results would be and so that they can contextualise the findings of the study.

I asked an initial question, "tell me about your experiences of being provided with and wearing specialist footwear". Dependent on the patient's responses further trigger questions were planned so that the dialogue could be kept going if the conversation came to a halt or if the participant wandered off the subject of footwear for too long.

These included:

- 'How did you feel when you first wore the footwear?'
- 'How do you feel about it now?'
- 'What impact has the footwear had on your ability to do the things you want to do?'.
- 'Are there any aspects of the footwear that you would like to comment on?';
- 'Are there any aspects of the service which you would like to comment on?'
- 'Are there any aspects about the practitioner that you would like to comment on?'

These were rarely used as the interviews continued on the theme of footwear and the participants told their stories with little need for prompting. This fluid approach to questioning sat easy with me as I had experience of using this approach in the clinical context.

The participants were interviewed for approximately 60-90 minutes each using a 'conversational' interview style. This length of time enabled the participants to feel relaxed and able to talk openly and honestly (Polit and Hungler, 1999; Slevin and Sines, 1999). The interviews were recorded using a digital voice recorder and field notes were made with regards to the participant's body language and facial

expression, such as sadness and the way the dialogue was said, such as increased volume or demonstration of anger. The participants were given the opportunity to have the original copy of the recording if they so wished, but all declined.

Pseudonyms were used to replace the participants' names to achieve anonymity. The interviews were transcribed verbatim immediately after the interviews by myself, so that I could start to fully immerse myself in the meanings in the text. A personal reflective account of each interview was completed, in order to consider my experience of the interview process. This was so that I could maintain transparency as to my role in both the collection of the data and in the analysis of it.

6.8 Data Collection Procedure – Practitioner participants

The transcripts and recordings of the patient participant interviews were read and listened to by four orthotists. These are the professionals who supply patients with therapeutic footwear. As the profession is male dominated with very few female orthotists those recruited were three male and one female. The primary purpose of this was to identify any aspect of the therapeutic relationship that was of interest and significant when compared to the participant's responses. I also felt that this was a necessary process in order to achieve credibility of the data collected initially, particularly in the eyes of the orthotist practitioners that this work may have impact on.

It was impossible to trace the actual orthotists involved in the provision of footwear to the patient participants due to the contracting arrangements under which orthotists are employed. Therefore, the orthotists were selected at random from mailing list of orthotists from their professional body with the selection based on NW and Yorkshire postcodes for ease of travel. They had been qualified for an average of 12 years (range 5 years to 20 years).

They were recruited by the researcher (AW) with the first four orthotists agreeing to take part. Reassurances were made about confidentiality and anonymity with regards to their comments on the transcripts. The background to the study was

described and the philosophical approach to the research explained. The method of subject recruitment was described so that the orthotists were clear that the patients had been recruited by the Surgical Appliance Officers, that the patients were reported as being satisfied and were reported to be wearing their footwear. The aim of this was to reassure the orthotists that the patient participants had not been sampled for the reason of being dissatisfied and therefore that bias had not been introduced to the study. All this information was also contained in an information sheet about the study and all the orthotists signed a consent form (Appendix III Practitioner Letter and Information Sheet and Appendix IV Practitioner Consent Form). I explained to them the purpose of reading the transcripts and listening to the recordings. Apart from this, no discussion about the transcripts took place between the researcher and the orthotists or between the orthotists.

The orthotists were then asked to listen to the patients' dialogue as though the participants were talking to them. Then they were asked to identify and highlight written text of significance in relation to what they thought was important to the participant and to themselves as practitioners. There was no conferring between the practitioners and the whole process took six hours to complete on two separate days for each of the orthotists.

I have described in detail the procedures for collecting the data from both the patient and practitioner participants. I will now detail how the data collected were analysed

6.9 Data Analysis

The interpretive phenomenological approach used for this study and as highlighted by Moustakas (1994), has aimed to determine what an experience means for the participants and provide others with an understanding of it. Because the participants have described experiences from the past I feel that it has to be recognised that some reflection is occurring and the memory of experiences does change over time. However, this does not weaken the participant's response as feelings and experiences from the past affect feelings and behaviour in the present and therefore the impact of these are firmly in the present.

This interpretive approach adopts a holistic perspective with the focus being the whole experience and in this respect it is used to increase understanding. In describing the whole experience to the researcher, the person's feelings and the behaviour associated with those feelings provides the researcher with insight into the experience, but the perception of the experience is the person's view not the researcher's (Morse 1991). In addition, I acknowledge that I believe that although the participants are sharing their own unique experience, as a woman with concern for my own body image, I can empathise with these feelings and this in turn influences my beliefs but enables me to see things through the participants' eyes. As I am the research tool I have explored the influences on me as a person (Chapter 1; 1.3 and Chapter 6; 4.3) so that there is clarity as to my own philosophy and this enables the reader to consider the data collection process and the process of data analysis in the context of these beliefs.

The method of data analysis needed to be appropriate to the interpretive phenomenological research approach of my research to allow the true meaning of the data to be identified (Gadamer 1989, Priest, 2002). Denzin and Lincoln (1994) view interpretive data analysis as;

'...an art; it is not formulaic or mechanical. It can be learned, like any form of story telling only through doing.......fieldworkers can neither make sense of nor understand what has been learned until they sit down and write interpretive text, telling the story first to themselves and then to significant others and then to the public.' (Denzin and Lincoln 1994 p 502).

Therefore, the following is an account of the analytical process that revealed the findings of this study.

6.9.1 Analysis of the participants' transcripts

Immediately following each interview I reflected on the experience from my standpoint and summarised what the key areas were in the interview that had impacted on me. These are presented in the chapter that presents the findings. I then began the process of analysis by listening to the interview recording first and then transcribing each interview verbatim with pauses in dialogue and field notes added at the appropriate part of the interview transcript. I ensured that I made notes of voice intonation, pauses when the participant was thinking and any other incidents that occurred during the interview period. The transcription was done on the same day as the interviews so that all the information was dealt with in a timely and consistent way.

Structured analysis occurred after transcription of all the interviews using an interpretive hermeneutical approach. I analysed the text with regard to Heidegger's concept of 'Dasein' and my own pre-assumptions and beliefs (Heidegger 1927). This ensured that I remained true to the phenomenological philosophy of gaining a holistic understanding of the participants' experiences of being 'in' and 'of' the world (Krell 1999, Mulhall 1996). I rejected the option of using an electronic method of extracting data from the transcripts. My thoughts following an exploration of this option were that it would be too constraining and mechanistic and would not take into account my own experience of being 'in' the participants' world. I read each transcript several times to identify codes in line with an analytical tool which is a way of organising a thematic analysis of qualitative data (Attride-Stirling 2001). This analytical tool facilitates the discovery of themes at different levels and then the structuring and depiction of these themes, which are the features of any hermeneutic analysis. Thematic frameworks do not provide an analysis of data but organise the data so that it can be analysed (Attride Stirling 2001). This systematic technique uses more than intuition and whilst it is recognised that analysis of qualitative data is a necessarily subjective process, it is necessary to have a method of organising and exploring the data that allows the discovery of meaning which is the basis for understanding of 'others' experiences.

The full process of organising the data was done in three stages in line with the recommendations made by Attride- Stirling (2001). The first step was to reduce the text into meaningful text segments using a coding framework. The coding framework was based on the theoretical background which formed the basis for this study and also recurrent issues which arose from the text itself. Included in this first step is the extraction of text segments which apply to the codes. These text segments aid analysis and their use is supported by authors such as Bryman and Burgess (1994) and Miles and Huberman (1994).

The second step in organising the data was identification of themes. This was done by re-reading the text segments within the context of the codes under which they have been classified, abstracted from the full text. This procedure allowed identification of underlying patterns and structures. The themes are then refined into themes which are specific enough to be discrete and non- repetitive and broad enough to encapsulate the ideas contained in numerous text segments.

The third step consisted of arranging the themes into similar coherent groupings consisting of a distinct and final global theme supported by the organising themes which comprise the basic themes. The final stage was to describe the network and explore it and it is here that the analysis of the findings took place

The initial codes and constructs condensed from the interviews were checked by an independent researcher who confirmed the reasonableness and consistency of each stage of the data analysis. She initially explored one script in depth for codes and themes. These were checked against my own interpretation to see if there were any differences in interpretation of the text. Minor differences were discussed and agreement was achieved. She then read the other transcriptions and from this confirmed the reasonableness of extracted meanings and agreed the interpretation of the themes. This verification process is supported by Giorgi (1995), who suggests that there are universals open to intersubjective verification and when applied to analysis of data, Giorgi suggests makes it 'scientific'. This is more of a positivist perspective and is not shared by most interpretivists. However, in this study this approach was considered because of the community to which the results would be presented. This community is more entrenched in the positivist paradigm and so

intersubjective verification was employed to ensure that the results stood as being credible.

The content of the interviews was also discussed with my academic supervisors before returning to the participants for confirmation of validity of the transcriptions. There was minor additional material from some participants but this had already been covered by others. The participants confirmed that the transcriptions were a true account of their thoughts. The benefits of this however are questionable (Koch and Harrington 1998). The reason for this is that the recoded interviews were transcribed verbatim guaranteed accuracy of the words and there is no evidence that this actually enhances the quality of the data analysis. However, it has become custom and practice in an attempt to add rigour to the study. Two participants were slightly concerned that they appeared to have complained too much but agreed that the transcript was true. I reassured both these participants that the information was confidential and that they would remain anonymous so that their future management would not be affected.

Exemplars or extracts of text are used as a presentation strategy. This allows the reader to visualise the person in the situation (Benner 1994, Malpas 1992). It ensures that the written analysis remains an authentic interpretation of the text and that the phenomena are shown or displayed to the reader (Gadamer 1989). Heidegger (1927) defined phenomena as 'what shows itself in itself'. By showing examples of the phenomena to the reader this allows further interpretation and understanding of the text and the true 'authentic' nature of the experiences to be revealed (Gadamer 1989). The provision of these examples supports the trustworthiness of the findings (Hággman-Laitila 1999).

6.9.2 Analysis of the practitioners' opinions

The issues that were deemed to be important by the practitioners were identified from the transcripts and the voice recordings of the participants. However, rather than identifying themes in relation to the participants experiences, they sought to explain the problems that they had from their own perspective. These explanations

were consistent between the practitioners except for issues to do with the consultation. The analysis of these data and a record of all the comments are presented in the chapter on the findings of the investigation.

6.10 Summary of Methodology

This chapter has provided an exploration of the influences, philosophical underpinning and justification for the method employed for the collection and analysis of the data. The method of data organisation and analysis has been described in detail to provide clarity for the reader as to how the themes were formulated from the codes and meaning extracted from the text. I will now present the findings that are the result of the data analysis process.

CHAPTER 7 FINDINGS FROM THE ANALYSIS

OF THE DATA

CHAPTER 7 - FINDINGS FROM THE ANALYSIS OF THE DATA

7.1 Introduction

The focus for this research has been the users' experiences of therapeutic footwear in line will the original aim of the study;

'The aim of my research is to discover the users' experiences of therapeutic footwear';

The participants in the study were women with rheumatoid arthritis, and I also interviewed three men as an exploratory part of the investigation. The aim of this was not to draw direct comparisons between the genders but to explore if there were any commonalities or differences that may be of value or interest to the main aim of the study.

In line with the suggestion by Silverman (1993), I would estimate that around 70% of the data extracted from the transcripts had relevance to the subject area. It has to be accepted that, as in any dialogue there is a certain amount of erroneous material or 'dross', but this is a characteristic of semi-structured or 'conversational' interviewing and is necessary to obtain the information required. Attempting to stem the participant's dialogue that contained erroneous material may have put constraints on the interview and essential areas missed. Therefore, it is acceptable that the transcripts contained dialogue that was not relevant to the purpose of the interview. Interestingly though, Playle (2000) suggests that what may initially be seen as erroneous material or 'dross', sometimes emerges as very relevant contextual information following in-depth analysis of the data. In agreement with Playle (2000), I consider that it is important have an iterative approach that involves returning to the transcripts as many times as possible in order to 're-listen' to the dialogue. This ensures that important meanings and phrases are not missed during the process of data organisation and analysis.

This chapter will present the data from the extracted codes and issues discussed by the participants, through to the basic themes and organising themes. A global theme that is formulated at the final stage of analysis is then presented. Each theme is illuminated by extracts or exemplars from the text of the transcripts. These are used so that the reader can experience the words spoken by the participants. This presentation style adds to the trustworthiness of the data, but also allows the reader to explore their own interpretation of the text in relation to that of the researchers. In this respect, it is acknowledged that there are other interpretations in relation to who is reading the text. Whilst this is true, I have been transparent as to the influences on me as a practitioner, researcher and person and how these influences have made me ideally placed to explore the data fully and in depth. To support the trustworthiness of the data analysis process, the extracted text has been agreed upon by an independent researcher and the supervisors for this study.

Therefore, the findings of this research are presented as analysis of the data and exemplars extracted directly from the transcripts to illuminate each theme. A commentary on each of the themes is carried out to provide initial thoughts to be explored further in the discussion chapter.

7.3 Findings from the female Participants

The participants' demographics, disease duration, and health assessment scores (HAQ) (Kirwan and Reeback 1986) are shown in Table 7.1. The purpose of describing the participants in this way is so that the reader can contextualise the findings in relation to the participants. It is possible that factors such as age, occupation, disease duration and general health status could impact on their experiences of the footwear. These factors have been presented in this study though not analysed as this was not the aim of the study. However, some of these factors will be highlighted in the recommendations for further research.

Table 7.1 Female participants' demographics

| Patient | DOB / age | occupation | RA Durat ion (yrs) | HAQ | Type of footwear/ wearing time (yrs) |
|---------|-------------|---------------------------------------|--------------------|-----|--------------------------------------------|
| Lily | 08/10/37 69 | retired early- self employed | 10 | 3 | bespoke - 8 yrs |
| Rose | 29/01/53 53 | welfare officer | 10 | 1.5 | bespoke - 6 yrs |
| Daisy | 10/02/47 59 | shop worker | 9 | 1.7 | stock shoes 4 yrs |
| Heather | 10/10/39 67 | retired early -Mill worker | 22 | 3 | bespoke- not worn wearing flip flops |
| Daphne | 06/03/39 67 | retired early - chemist | 19 | 2 | bespoke - not worn wearing retail |
| Gladys | 03/04/30 76 | retired early –shop worker | 26 | 2.5 | bespoke 5 yrs |
| Lena | 06/03/62 44 | teaching assistant | 9 | 1 | Bespoke -5 yrs |
| Sylvia | 16/03/49 55 | shop worker | 15 | 1.5 | stock - 7 yrs |
| Anne | 16/07/33 53 | Retired early - librarian | 17 | 2.5 | stock- 6 yrs |
| Monica | 10/02/59 47 | Retired early – worked in off licence | 8 | 2.5 | stock shoes- 3 yrs |

All but two of the patients were wearing their footwear every day and for the majority of the time. The two patients who were not wearing their shoes had attempted to wear them and had been back to the practitioner on several occasions for the fitting problems to be resolved. As these problems had not been resolved they had given up trying. Interesting though, together with the others, these two patients were considered to be satisfied with the footwear and therefore it was assumed by the orthotic services that the footwear was being worn.

7.3 Findings from the female participants

Exemplars are presented from the transcripts to illustrate the issues discussed and the themes that emerged from the analysis. Tables 7.2 - 7.6 detail the analysis of the transcripts from the extracted codes to organising themes. A commentary on each of the themes is presented to highlight certain issues. Table 7.7 then summarises the organising themes and demonstrates the emergence of a global theme from the female participants.

7.3.1 Theme 1 - Feelings about 'self'

'Naughty Amelia Jane - Enid Blyton'

The women expressed how they saw themselves as being 'bad'. This badness has connotations of being 'naughty'. As in the case of Naughty Amelia, the repetition and reinforcement of a label has the effect of it becoming reality even if it is not true:

- "... I hate this arthritis ...it has taken over my body...when I look in the mirror ...and I try not to these days... I don't recognise myself (looks sad)...I feel and look rubbish most of the time...my hands and feet are the worst...these big bunions...these are really **bad**" Heather
- "...the pain...yes the pain is the worst thing and then how you look makes it worse...you feel fed up and then the pain is worse...I don't feel feminine...my feet are particularly **bad**" Lily
- "...I feel and look rubbish most of the time. I don't feel feminine or sexy any more...especially how my feet look...they look really **bad**awful...". Anne

"..Your body is unrecognisable it changes so quickly and there is no control...it's how it looks... it's how you appear to others... you look different and can't do the things you want to...my hands are **bad** enough but I don't like to show my feet either...they are ugly and wide ..like a man's and I can't get shoes to fit" Daphne

The women expressed feelings about how they felt that their feet were visibly different from other women. This visibility was identified as being how the feet looked and how the feet impacted on their ability to walk 'normally' and look normal, because of the pain, as Lily revealed:

"...Hate them! [her feet].. They are the worst thing about the arthritis... they take over my life...they are the one thing that stop me going out...well if your knees or hands are bad you can about manage ...but foot pain well that is different...you can't walk right and people notice." Lily

"I don't like my feet much....they are the thing that stop me walking normally and I feel...well...that everyone can see that I can't walk normally...I have learned to fight the pain to try and walk better...then that shows in your face..." Rose

Although pain is a personal experience, it becomes visible in how it impacts on both their appearance and their function. This results in the self consciousness expressed by these women:

- "...I can't walk normally...I limp and that makes me feel...well...very visible and self conscious" Gladys
- ""...I can't walk normally... If you shuffle around people notice and (thinks for a time)......it shows in your face..." Monica
- ..." I hate going out... I feel that people notice that I am struggling to walk at a normal speed... I feel that the world is speeding past

me and that makes me different...I feel very self conscious... I don't go out much..."Anne

The limitation of functional abilities is of concern in relation to 'others' such as partners, children and work colleagues, both in respect of not being able to do the things they used to and how this appears and impacts on the 'others' as revealed by Sylvia, Lena and Daisy:

"...I sometimes can't do the things I need to do at work.....I can lift some things but then can't walk with them because the extra weight puts stress on my feet...I try....I really do try...if you don't walk normally people notice...that makes me feel different...people are kind but I would rather they didn't notice" Sylvia

" I was worried that the children would notice that some days I don't walk as well...they haven't said anything but I worry in case they notice." Lena [teaching assistant]

"...when I am out shopping with my daughter I feel like I am lagging behind...sometimes I have to stop and then she is way ahead of me...I am sure people notice and wonder what's wrong with me..." Daisy

These women also described the affect of the disease on appearance, describing it as premature aging and losing years out of their life. Frustration with the loss of control over changes in their bodies and the loss of the 'normal' process of aging was evident:

"...well it shows in your face...the pain you know...maybe because you are stood on them...makes you self conscious as well...I look and feel like an old lady". Daisy [age 59]

- "...I felt I had a...this thrust on me...that I jumped from 40 straight to being in my 60's" Sylvia [age 55]
- "...you know I don't think anyone really understand how this takes over your life...I have lost some of my most important years....talk about growing old gracefully." Gladys [age 76]
- "...I feel and look older than I should...this happens suddenly not slowly like it should so you get gradually used to it.." Rose [age53]

Fear for the future for themselves and other people in their lives was expressed by most of the women interviewed:

- "...pain shows in your face...makes you look old and I feel ...when I look in the mirror god what must my husband think...and then I worry about the future..." Monica
- "...I worry that I can keep on working...I need to be active and have interesting things to talk to my family about" Lena
- "...I don't want to be a burden on my family...they do so much already...can't imagine what would happen to me if they were not here...I wonder about that and it makes me anxious...they have their own lives don't they?" Heather

The process of organising the codes, issues and basic themes that resulted in this organising theme is detailed in Table 7.2

Table 7.2 Organising Theme 1 - Feelings about 'self'.

| Codes | Issues discussed | Basic Themes | Organising Theme |
|--------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Loss Grief Sadness Anger Guilt Image Stigma Sexuality Bad Relationships Restriction Concern Fear | Consider that the changes are bad Loss of femininity Loss of sexuality. Premature aging. Visible disease Self image Public perception of self. Social isolation. Loss of control. Social disgrace Disease progression. Lack of improvement. Deterioration of feet Guilt about the Impact on others. Fear for their future. | Changes in appearance invoke feelings grief, sadness & anger at the loss of femininity & sexuality Visible disease and the emotions invoked result in stigma and social isolation, restricting activities and impacting on relationships. All this is viewed by the women as 'bad' Loss of control of the effect of disease on their bodies results in fear for their future, both for themselves and others. | Feelings about self |

Commentary on Theme 1

I didn't anticipate that the participants would initially talk about themselves, their feet and the impact of rheumatoid arthritis on their bodies as the focus of the study was footwear. Also, the opening question to the interviews asked about their experience of therapeutic footwear. Clearly though the participants' feelings and emotions about the effect of the disease on their bodies and its visible appearance invoked very strong emotions through their descriptions of it and in the way that it was said. The emotions of anger, anxiety, loss and sadness, were expressed in what they said and how they said it, for example when they talked about loss they said it with sadness in their voice, but they also said that they were sad. This demonstrates not only the inescapable association between feet and its protective footwear, but also the inescapable association between their visible disease and feelings about themselves.

The participants described their feet as being 'bad'. This has connotations in respect

of the value that individuals have of themselves. The term 'bad' in relation to a person usually describes their behaviour, often naughty behaviour. If these participants believe that they are bad, which is a negative label, and then they don't perceive themselves as 'good'. Being 'good is a positive label that is given as a reward for good behaviour, particularly in children. Feeling 'bad' could be perceived to be a punishment and could contribute to their low self esteem. These women had concern for the effect that they had on others in their life and this invoked feelings of guilt, sadness and anger, that they were a burden, in particular with partners and children.

7.3.2 Theme 2 – Feelings about the footwear

'These boots are made for walkin.......' Nancy Sinatra

Issues discussed about the footwear itself formed the second theme. The function of footwear is not just as protection or for 'walkin' in, they are part of image and sexuality. The women in this study had issues with the appearance of the footwear in that it made them feel less sexy and feminine, in essence the footwear had more of a male appearance. The negative feelings and emotions expressed about their feet and then their footwear were reinforced by the reaction of 'others' to their footwear. Again, the emotions of shame, sadness, and anger that were identified as being associated with their feet were identified with the footwear.

Further to this these feelings, the women considered themselves as being visibly different whilst wearing the footwear and this impacted on how they viewed themselves and how they viewed that others saw them, as Rose expresses;

"...The shoes....as soon as I see a person I can say oh yes she's got hospital shoes on...I compare my boots with other people and they are more feminine and pretty and that makes me feel sad". Rose This sadness is also expressed by Daisy;

"I think I knew that the shoes had to... well...like...treat my feet...its like wearing a splint....I have some of those for my hands...but shoes are different...they are meant to make you look nice...in my early 20s I used to wear sexy stilettos...no chance now even if I don't walk in them (looked sad)". Daisy

Further to this, Heather and Daphne express anger and humiliation;

"I felt very tearful the first time I had the shoes...humiliated....I would get dressed up and then I feel like a clown... just don't feel dressed...I feel untidy...that makes me angry". Heather

"...the first time I wore them at home...the look of horror from my family...well that was that...I felt humiliated and angry... they are in the attic if you want to see them...a waste if you ask me" Daphne

Despite all these negative emotions, these women expressed gratefulness;

"...the first pair was a pair of shoes which were really old fashioned sort of old women's shoes if you will...and I felt....I felt I should be grateful..."

Lena

"... you feel sort of...well...masculine because they are a bit clunky and that makes me feel sad...I would just love a decent pair of shoes...don't look in shoe shops ...that makes me feel worse...still I am grateful that I have something to wear" Anne

"...I didn't really want to wear these but have to...no choice...I don't like the look of them...really don't... and hope that no-one notices...I hide my

feet as much as I can...my family are good...they say that its more important that I have no pain, so I am grateful for that at least..." Sylvia

Feeling 'bad' about the footwear reinforces the feeling of 'badness' about their feet and themselves (Theme 1). Further to this, this emotion was reinforced by the referring practitioner;

"...the first pair were no use at all and they looked bad...when I went back to see the doctor he pulled a face and said that they weren't right for my feet...I could have told him that...made me feel dreadful...it was they way he looked at me and then I was angry at the waste and how it had made me feel bad" Monica

The process of organising the codes, issues and basic themes that resulted in this organising theme is detailed in Table 7.3

Table 7.3 Organising Theme 2 – Feelings about the Footwear

| Codes | Issues discussed | Basic Themes | Organising Theme |
|-----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Labelled Visible Anger Shame Sadness Stigma Bad Gender Grateful Humiliation | Loss of femininity. Loss of sexuality. Loss of choice Premature aging Being visibly different to others. Self image Social disgrace Being grateful Feeling bad Influence of 'others' comments | Therapeutic footwear is visibly different to the retail footwear generally chosen by women and is considered as 'bad' Footwear plays an important role in women's appearance of self and public perception of self. Footwear contributes to the powerful emotions associated with loss of femininity and premature aging and these emotions are influenced by 'others' Despite there being issues to do with the appearance of the footwear, the participants feel obliged to be grateful | Feelings about the footwear |

Commentary on Theme 2

It is already known from previous studies (Stewart 1996, Park and Craxford 1981) that patients often dislike their footwear sufficiently to stop them wearing it. In this study all but two of the participants wore their footwear. However, despite the majority continuing to wear their footwear, the effect of it still invoked very powerful negative emotions such as anger, shame, sadness and feeling 'bad' (Table 7.3). These emotions have apparently much more impact on these women than the opinion of 'disliking' the shoes and are the same as when they were talking about their feet and themselves. In addition there was evidence of some of the women feeling humiliated by having to wear them but nevertheless most expressed gratefulness that something had been tried. This 'gratefulness' is possibly what previous 'satisfaction' questionnaires have measured. Further to this there was concern and anger at the waste of resources. In addition to the two women that chose not to wear their footwear some had experienced several attempts to get the shoes right and one participant had been supplied with one successful pair with regards reduction of pain but subsequent pairs had failed to achieve this.

Again, the description of the footwear as 'bad' mirrors how these women feel about themselves and implies that they value themselves less than someone who feels and is labelled as 'good'. Emerging thoughts here are that there is a difference between the understanding as to what the purpose of the footwear is by the practitioner and the participant, with the focus for the practitioner being footwear for 'walkin' in and the focus for the participant being footwear as part of their body image.

7.3.3 Theme 3 – Unfulfilled Needs and Expectations

'I can't get no...satisfaction' Mick Jagger

Dissatisfaction was expressed by these women in respect of their needs and expectations that were not met. The participants expectations were not set by the referring practitioner and therefore these women had mixed expectations of how the footwear would appear and what the aims of the footwear were in relation to for example, achievement of pain reduction or improvement of mobility. These women were clear as to what they wanted from the footwear, as Daisy says;

"...just to have some shoes that look nice AND take the pain away...that's what I thought they would do...there are many days even they don't help with the pain.. but I cant get any others on and I have to work..." Daisy

Some had expectations to do with function and there was fear and concern about deterioration:

"...I said well... my constant nightmare is that one day I will find my ankle trailing along the floor... you know and he said this is what we are trying to prevent... it doesn't seem to have done that really... this is 8 years of being wearing special shoes..." Lily

Often, these women didn't know what to expect, but they were clear about their own needs, as Lena, Daphne and Sylvia explain;

"I knew that I needed a support underneath...I could feel the pressure from the bones of my foot in the arch...I used to pad this up myself and it felt better..." Lena

"...they were too low and I felt like I was falling in them...my balance isn't good and I need a small heel.... you know just half an inch higher

would have helped my balance...they were just too low...and ... I did expect them to look more like shoes I would buy..."Daphne

"..didn't know the system or what I could expect...but I knew I needed some shoes which were supportive for my ankles and with room for my toes..." Sylvia

When the footwear did not meet their expectations, this created disappointment, dissatisfaction, sadness and also guilt that it was their own fault and a waste of NHS resources;

"I expected the shoes to be plain but didn't expect them to be so ugly... although I looked at the pictures when they were put on my feet they looked awful...I know my feet are bad and this makes it difficult for the fitter..... I nearly cried....felt guilty... they had been ordered so I took them...went home and cried" Heather

"I don't need to go out that much so I expected to get softer pair for around the house so I can get around easier...I had a fall last year and that shook me up...the shoes...well they are very sturdy and well made...not suitable for use in the home but do wear them when I go out....[how often?] oh...about once a fortnight..." Gladys

"...I didn't expect boots...thought I was having shoes...I don't know why I had boots...maybe to support the ankles...would have been better with shoes though as I struggle with the heaviness of these as I am quite weak in my legs..." Rose

The process of organising the codes, issues and basic themes that resulted in this organising theme is detailed in Table 7.4.

Table 7.4 Organising Theme 3 – Unfulfilled needs and expectations

| Codes | Issues discussed | Basic Themes | Organising Theme |
|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Disappointment Frustration Expectation Needs Sadness Dissatisfaction Anger Grateful Guilt Failure | High expectations Needs not being met. Grateful for anything. Guilt that they haven't succeeded with the footwear. Guilt about the waste of resources. No identification of needs or expectations | Expectations are high and when these are not met, emotions of frustration, disappointment and sadness are invoked. When expectations are not met the participants assumed responsibility for the failure of the footwear and feel guilt for the waste of resources Despite the disappointment and unfulfilled expectations they are grateful that 'something' has been tried. | Unfulfilled needs and expectations |

Commentary on Theme 3

These women had little explanation given to them before being sent for the footwear by the referring clinicians and therefore had developed their own expectations in the absence of information. They had invariably identified what they thought their needs were and these were linked to the expectations about what they would receive. When they spoke about their consultation about the footwear, this emerged as a separate theme. However, in relation to this theme and in respect of their own perceived needs they did identify that there was no dialogue taking place during the consultation with the referring practitioner.

In addition to their expectations, it is clear that they had their own experiences and knowledge of their foot problems, their footwear and their own considered opinions as to what would help them. The opportunity to explore these opinions and expectations had been missed by the referring and dispensing practitioner.

This process should have included these women in the decision making process and therefore would have possibly made them feel important. This process of providing the practitioner with vital clues to the most appropriate features and function of the footwear, this feeling of 'importance' could also then been part of the women's whole experience of being supplied with the footwear and then the importance of the footwear itself.

The expectations of these women were not matched by their experience of the footwear. There is evidence that they blame themselves for the failure of the footwear and therefore feelings of guilt are invoked about the waste of resources.

7.3.4 Theme 4 – Behaviour with the footwear

'Cinderella hasn't got a dress and can't go to the ball' - Charles Perrault

The impact of this footwear on the lack of choice in clothes is loss of femininity, expressed through how it affects their behaviour and choices. The female participants, who had chosen to wear the footwear, did acknowledge that it improved their mobility in respect of reducing foot pain. However, it did restrict activities, particularly those perceived as social ones where feeling feminine and wearing feminine clothes was deemed important. There was evidence of compromise, with the footwear influencing the types of clothes worn. Trousers were viewed as being more suitable to wear with the footwear but this was seen as restricting choice.

Supported 'compromise' by the practitioner was not evident at all. This 'compromise' could involve informing and supporting these women as to when it was essential that the footwear needed to be worn and when alternatives could be worn for low activity, low impact, social use. It could be said that some of these women would have struggled to obtain footwear of this type but there was evidence of them trying and succeeding as in the case of Lena, Daphne and Anne.

"I can't complain as I feel my mobility would not be as good without these...Its important to be mobile and pain free...on a day to day basis they are just about ok...but when I go out I do wear sandals then pay for it after." Lena

"I was so ashamed of the shoes I would rather have the pain and squash my feet into something better or stay indoors with nothing on them than to have to wear them...I can tell you this cant I?" Daphne

"...some days I wear them and some days I don't. It depends what I am doing...if I am home I tend to wearing nothing on my feet...is that bad? If my arthritis is Ok sometimes I can get more normal shoes on if its bad then I don't go out particularly if it's a dressy thing...then I get cross because I feel I am missing out" Anne

This decision making results from a risk/benefit evaluation by these women. When they cannot do this it invokes emotions of frustration, sadness and shame. These emotions clearly impact on the behaviour of these women, particularly social behaviour;

"...Not nice...No not nice at all.....I hide my feet under the table...they weren't nice they were awful..... and I felt ungrateful...but I cant wear what I want to and that makes me sad." Sylvia

"...I don't go out much...not because I cant...its because I am ashamed of my footwear...I cant wear decent clothes and then these...so I choose to stay in..."Gladys

"...I stay at home a lot...I struggle to get shoes on some days...I have some trainers that are OK and go with pants. I would have really liked some decent shoes to go out in but those...I would have hidden away forever if they were the only ones" Heather

"....I don't go out much...I can't get normal shoes on ...I am stuck with these...I can go shopping but I don't go to family do's...that makes me sad". Lily

There is evidence of compromises in choice of clothing, in fact it is not clothing of 'choice' but of 'need' and again this impacts on their social activities;

"Well I suppose that I have a pair of shoes I can wear when things get really bad and at least I have something to put on my feet if I get really desperate... they do restrict what you can wear though, I do tend to wear trousers a lot and I would love to wear a feminine dress...can't complain really.". Monica

"Don't go out much but sometime makes me feel like crying and I panic when I do get an invite ... I think oh gosh these boots". Rose

These women feel that they cannot discuss issues to do with clothing and in effect they were 'voiceless' when it came to expressing how the footwear restricts choices, as Monica reveals;

" I don't want to wear these shoes with dresses as they look ridiculous... I don't feel that they understand what the shoes do ...I would like to say but don't feel that I can.." Monica

"... I wanted to ask if there were some more fashionable shoes but felt that I couldn't ask...it would seem ungrateful...." Lily

The process of organising the codes, issues and basic themes that resulted in this organising theme is detailed in Table 7.5

Table 7.5 Organising Theme 4 – Behaviour with the footwear

| Codes | Issues discussed | Basic Themes | Organising Theme |
|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| Sadness Shame Frustration Restriction Powerless Resigned Compromise Accepting Loss of choice Social isolation Voiceless | Restriction of social activities Lack of choice in clothes. Loss of role in social settings. Social isolation Resigned to being different to others Feel should not complain | Loss of choice in footwear impacts on self image resulting in restriction of activities & social isolation. The choice in footwear options is only resumed when the participants choose not to wear them. This is considered bad behaviour & invokes feelings of guilt The lack of 'voice' and feeling that hey should not complain results in unsupported compromise with footwear behaviour | Behaviour associated with the footwear |

Commentary on theme 4

As in the first two themes, the emotions of shame, sadness, and anger (Table 7.5) were identified as being associated with the impact of this footwear on the females' activities. This is particularly so when it comes to social activities. It is clear that this footwear has a significant impact on these women's choice to engage in social activities and can lead to isolation, further reinforcing feelings of sadness and anger. There is an apparent loss of voice when it comes to opinions or 'complaining' about the footwear and its impact. This results in these women compromising with their footwear behaviour to improve their choice. This choice is unsupported by the practitioner. Despite the footwear increasing mobility in some of these women, it certainly restricts activities either through its direct visual appearance or through the impact on the choice of clothes worn. This further reinforces that footwear is an item of clothing and is a significant part of perception of self and public perception of self.

7.3.5 Theme 5 – Feelings about the consultation

'...it's good to talk' - British Telecom

It is generally acknowledged and supported through the 'sound bites' of advertisements that communication, or 'talk', is good, but there were concerns raised by the participants that there was little communication between the practitioner and the participant.

Statements and meaning in relation to the participants' feelings about the dispensing practitioner formed the fourth theme. It was expressed that they had trust in the practitioner's skills in the assessment and dispensing of the footwear;

"... you do believe what you lot tell us ...I mean you are the experts...."Rose

"... I didn't question their expertise...they are the experts...my feet are difficult" Anne

Further to this, two female participants described the practitioner as being a 'nice person', which was linked to them visibly trying options if there were issues or problems with the fit of the footwear. However, there were several negative attributes identified by most of the female participants, for example, being dismissive of the patients concerns, labelling the patient in negative terms as 'bad' and having poor communication skills.

"There was no discussion....if fact I don't really think it mattered what I thought ...just said I had bad feet and that made me feel ashamed". Daisy

"I don't feel there was a two way conversation about what was available and how much say I had in what was going on ...". Sylvia

"... I find it difficult to... to understand if they are taking in what I say.

They need to understand what we need, but to look at it from a professional point of view with respect of the problem feet thereforethey need to understand the whole picture..."Heather

There was no opportunity for these women to have a voice about the initial problems with the footwear;

"They were too low and I felt like I was falling in them...my balance isn't good and I need a small heel.....I was in and out in two minutes...told I would get used to them...it was because I had been wearing higher heels..." Daphne

The female participants perceived that the practitioners lacked knowledge about RA, pain and their needs in relation to footwear.

"I think generally there is not much understanding about how rheumatoid arthritis affects the person...well...we are people aren't wewe are just not a pair of feet we have feeling... and sometimes I feel that they (practitioners) just don't understand....". Lily

The recurring expressions of shame, sadness, and anger that are evident in the first three themes were expressed by the females as being associated with the consultation. Additional emotions of guilt and feelings of powerless were also expressed. The labelling of the feet as 'bad' is evident again;

"I had chosen two pairs that I liked and after he had measured me he said I couldn't have those and pointed out a pair in the catalogue ... I asked if I could perhaps try the other and he said there was no point as my feet were really bad... made me feel guilty and ashamed". Heather

"I am sorry I have moaned about the shoes.....they are expensive you know...he did tell me that...I think) he was trying to make me feel quilty and get me to wear them... " Monica

"I don't need...how can I say? (thinks) sympathy is wrong...it makes me feel...well its not helpful...condescending...its not a positive thing at all...makes me feel pathetic and powerless and now it makes me angry". Rose

The nuances of the non-verbal aspects of the therapeutic relationship were perceived as important by the women involved, with the practitioner's body language, such as head scratching or looking concerned, being mentioned as reinforcing these feelings.

"He pulled a face when he saw my feet....that made me feel... ashamed really..... and upset...I went home and cried...I felt...well...humiliated". Lily

"I just felt that I was a lot of trouble to him...there was a lot of sighing and head scratching and then when he said my feet were difficult... I felt awful" Gladys

However, there were some positive comments about the consultation

"...he listened to what I had to say which made me feel important...I then felt ... that we could work together" Lena

"... When there were problems with the shoes he really tried to sort them...I was grateful for him trying" Monica

The positive comments appeared to impact on the participants experiences in a positive way.

The process of organising the codes, issues and basic themes that resulted in this organising theme is detailed in Table 7.6

Table 7.6 Organising theme 5 – Feelings about the consultation

| Codes | Issues discussed | Basic Themes | Organising Theme |
|------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
| Understanding Trust Control Power Knowledge Discussion | Understanding the patients' experience of the disease and its impact. Needs being understood | Lack of opportunity to explain their experience of disease, its impact and their needs results in the participants feeling of not being important and reinforces the balance of power with the practitioner | |
| Listening Communication Importance Dismissive Grateful Effort Disappointment | Acknowledgement of their needs. Two way communication Feeling of importance Power with the practitioner. Patient being voiceless. | The lack of opportunity to explore options & have choice disempowers these participants resulting in them feeling voiceless. Practitioner attitude and their communication skills influence the participants feeling of self worth and importance. | Feelings about the consultation with the practitioner |
| | Trust in the practitioners skill Visible effort of trying. Grateful that something has been tried | The visible effort of trying was valued by the participants and this invoked the feeling of being grateful. The participants had trust in the practitioners' skill. When the footwear didn't meet the participants' expectations this trust was broken. | |

Commentary on theme 5

Even the patients who were generally 'satisfied' with their footwear revealed negative issues to do with the consultation. All except two of the participants had experience of several practitioners (orthotists) and some comments were particular to an experience that they had with one orthotist.

The female participants' perception of the practitioners' attitude, comments and body language, tended to reinforce the negative view of their foot problems and issues in relation to the footwear. The female participants' feelings about themselves, their experience of RA and the foot problems associated with the RA, and their expectations of the footwear are on the whole not considered by the practitioner. There is little evidence of dialogue or active questioning by the

practitioner. Therefore, a therapeutic relationship through the sharing of 'knowledge' is not established.

These participants considered components of a patient focussed communication style to be important in the development of a good relationship. These components include good listening skills, explanation, checking patient understanding, allowing for questions, and being non-judgemental. Demonstrable knowledge of RA, its impact and the effect of pain on these women would have further aided the establishment of a partnership and thereby possibly have the effect of increasing their confidence in the practitioner. Further to this, the acknowledgement by the practitioners that these women are the 'experts' in their own problems has the potential to improve their perception of their own importance within this clinical encounter.

Another concern identified by the female participants, were the practitioner's body language, facial expressions and verbal labelling of the patients feet as being really bad. These factors reinforce the patient's negative feelings about themselves and guilt at being perceived as a 'difficult' patient. Sympathy is seen as unhelpful and condescending, thus reinforcing the balance of power with the practitioner. There was evidence of the use of the emotion of guilt to encourage one woman to wear the shoes by using the cost of the footwear as an incentive. In this case, this illuminates that professional power can be used in an attempt to influence the use of this footwear. It may be argued hat it is important for the patient to know the cost of the footwear, but this would be better placed at the beginning of the process so that the patient can chose not to engage in it rather than as a tool to enforce its use and thereby reinforce feelings of guilt and gratefulness.

7.3.6 Global theme

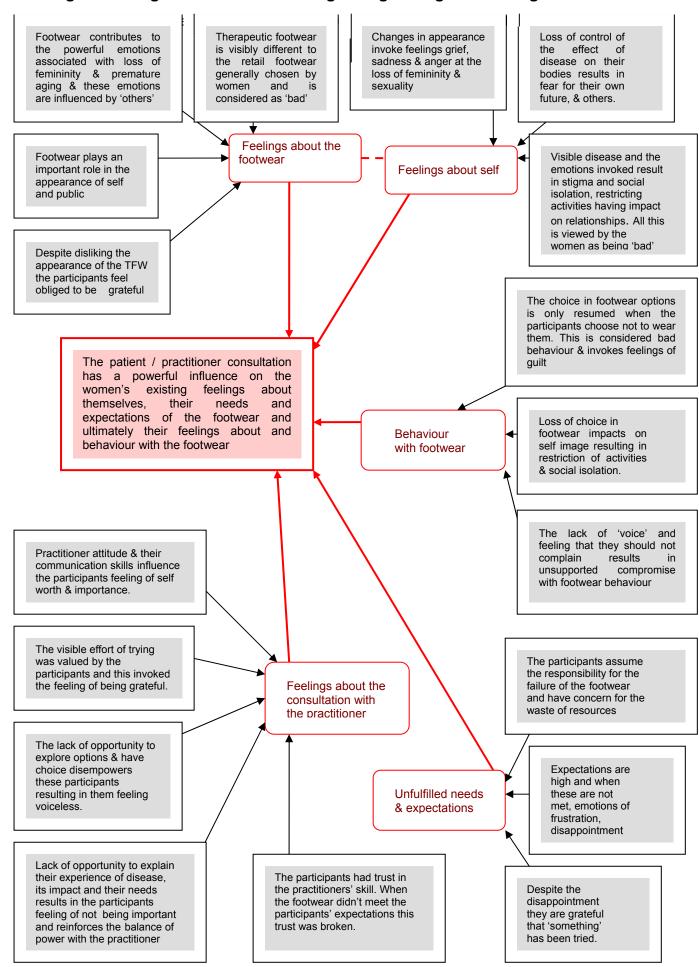
The overall or 'global' theme of the findings emerged through the framework used for analysis (Attride- Stirling 2001). The words or codes extracted from the dialogue and the text and the issues discussed were organised into eighteen

basic themes (Tables 7.2- 7.6). These were then condensed into five organising themes and finally the global theme emerged from these (Table 7.7). The global theme identifies the core or central meaning from the findings. The global theme is that the patient / practitioner consultation has a powerful influence on the women's existing feelings about themselves, their needs and expectations of the footwear and ultimately their feelings about, and behaviour with, the footwear (Table 7.7). Further to this, the organisation of the findings and how the themes and organising themes relate to the global theme are demonstrated in Figure 7.1.

Table 7.7 Global theme

| Organising theme | Global theme |
|----------------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| Feelings about self | |
| 2. Feelings about the footwear | The patient / practitioner consultation has a powerful influence on the women's existing feelings about |
| Unfulfilled needs and expectations | themselves, their needs and expectations of the footwear and ultimately their feelings about and |
| Behaviour with the footwear | behaviour with the footwear |
| Feelings about the consultation with the Practitioner | |

Figure 7.1 Organisation of the findings – organising themes to global theme



7.3.7 Additional information obtained from analysis of the transcripts

The focus of the analysis was the identification of the problems that contribute to the lack of engagement in therapeutic footwear as a health intervention. However, some additional information was extracted from the transcripts which is of importance and worthy of reporting and discussion. These results emphasise that the participants had clear ideas about what would have improved the service, and therefore what would have contributed to their experience. Further to the women's ideas, it is evident that through this research process these women were encouraged to have a voice. The importance of this is clear in the depth of information that this process has achieved. Although it is a research process, the features of this could be transposed into the clinical situation.

The female participants were very clear and precise about what would have improved their experience. The opportunity for time to consider their options before being referred for the footwear, to have more information on which to base their choices and to be able to voice their opinions were identified by the female participants as factors of importance, as Daisy reveals:

" I would have liked more choice as to whether to have the footwear in the first place... I felt I didn't have time to consider whether I wanted it or not....just....well...went along with what the doctor said".

In addition, knowing that they were being listened to through positive feedback and affirmation of what they had said by the practitioner was identified as an extremely important factor in the consultation. Monica identifies that being able to talk and have someone listen is important and when this does not happen, creates sadness:

"It is good to talk to someone who listens even though there is nothing that can be done...if you understand it helpstrouble shared I suppose and all that....I feel very sad that I wasn't listened to...if I had it might have been better."

Negative emotions such as anger and guilt were a result of not being listened to, as Daphne reveals:

"I think that the fitter....well any health person needs to listen to us more...I don't feel I was listened to about the footwear and now I feel guilty that I don't wear them...what a waste...that makes me angry." Daphne

Heather succinctly describes the importance of communication in that:

"Communication is a big word it is a very...you know... knowing what's available...that alone ...if I had known what was going on yeah definitely knowing what is available and a two way thing...it didn't happen...made me feel sad"

That these women had the perception that they were not listened to invoked emotions of sadness and anger. The statement that communication is a big word emphasises its importance to these women and will therefore be considered when making recommendations for improvements to the clinical encounter.

The female participants in this study identified the importance of the practitioners acknowledging that they were the experts in their own experience of RA, as Sylvia describes:

"...you assume they know their job but we know our bodies don't we ..! know what will work....and it's not just a matter about what will work for our bodies ...it has to feel right.....look right and ...well it's more about how we feel in the head isn't it?.."

Acknowledgement that the females had unique knowledge and expertise in their own disease would have made them feel important and included in the process, would

have enhanced their experience and perhaps avoided some of the negative emotions. In all cases, this acknowledgement was not reported as happening.

That the practitioners were experts in their job (often seen as the practitioner 'making' the footwear) was mentioned by two participants:

"...he is very skilled making shoes... Anne

"...the shoes...he made them beautifully but they didn't fit and were just too hard...." Heather

However this was questioned by a number of the female participants, as Monica states:

".....well they know their job....don't they?"

On the whole therefore, when the footwear failed, the participants felt that it was their own fault and this feeling was reinforced by the practitioners saying that they had 'difficult feet'. The failure of the footwear and the transfer of the responsibility of this to the participant invoked the emotions of disappointment, sadness and guilt.

7.3.8 Summary of the findings from the female participants

The impact of the participants' feelings and emotions about themselves, the footwear, the unmet expectations and the practitioner was also demonstrated in their reported behaviour with the footwear. The feelings and emotions were demonstrated both in words and in the way they were spoken. There was evidence in all the eight females currently wearing the footwear that they had had to make a compromise between their appearance and comfort. In all cases, the footwear clearly restricted the types of clothes that they wore and in this respect restricted activities such as social activities. Most female participants behaved as passive recipients of the footwear with no opportunity to voice their opinions or reject the option of footwear before the process of supplying it was started. This loss of voice was apparent throughout the process of being referred for and receiving the therapeutic footwear.

Some identified that they needed more time to consider footwear as an option before being referred. Two participants took the option of not wearing the footwear at all but this left them with the emotion of anger invoked by the waste and a feeling of guilt. Knowledge about footwear by the referring consultant and their teams is reported by the participants of this study as being of benefit in supporting informed choices at the point of referral.

7.4 Findings of the exploratory interviews with the male participants

Previous work has identified that there are not the issues and problems with male gender perceptions of therapeutic footwear compared with females (Williams and Nester 2006) in relation to its appearance. Despite this, and as previous research has focussed on females (Stewart 1996) it was considered useful to explore the possibility that the males may have revealed important aspects of their experience that would possibly contribute to the aims and objectives of this study. There was no intention to directly compare the female and male responses, but rather to generally illuminate any differences or commonality between the two genders. These interviews revealed very little with regards to any problems and therefore any potential solutions to the problem of patients not choosing to wear this footwear. The male participants had much less to say about their experience in general and were happier overall with the footwear provided and how it was provided. The male participants' demographic details, details of disease duration, general health status and type of footwear are contained in Table 7.8.

Table 7.8 Male participant demographics

| Patient | DOB / age | occupation | RA Duration (yrs) | HAQ | Type of footwear / wearing time (yrs) |
|---------|-------------|---------------------------------|----------------------|-----|---------------------------------------|
| | | retired early from police force | _ | | stock shoes - 4 yrs |
| James | 16/3/50 56 | | 8 | 1.5 | 3.00 × 3.1000 × 3.10 |
| Henry | 10/10/32 74 | retired office worker | 10 | 2. | bespoke shoes - 8 yrs |
| Coorgo | 07/11/45 61 | retired postman | 0 | 1 5 | stock shoes - 5 yrs |
| George | 07/11/45 61 | | 8 | 1.5 | , |

None of the male participants talked about the appearance of their feet with regards to the visible changes occurring due to the arthritis. Just one of the male participants, Arthur, made a comment about the visible impact of the footwear and this was a positive comment in relation to walking speed:

"I can walk faster in these shoes, which is good so I don't hold people up.."

This response is different than the females, who talked about the visibility of the footwear as an item of clothing and about being different to others. The main focus of the male participants was the construction of the footwear and the fact that it was free, as Arthur and George state:

"I am really pleased with these shoes ...to have a pair of hand made shoes makes you feel great..." Arthur

"... oh this footwear is great...good and strong and my toes are comfy now because they have soft linings in them ...they're hand made you know." George

None of the male participants revealed that they changed their behaviour because of the footwear not did they mention any aspect of their experience that needed improving.

This was an exploratory group, so the results should be considered with caution. Possibly a younger male group may have had more to say about body image and the effect of the footwear. Perhaps because they wear trousers and footwear of this type is more acceptable with this clothing, the issues of appearance and loss of choice in clothes was not an issue at all. The only problem was with one participant who expressed problems in the summer whilst on holiday as the shoes made his feet hot. He still wore them and was not bothered about wearing shoes with shorts.

"...I struggle in the summer though when my feet get hot and try to wear sandals but can't walk in them as good as these so I just get on with it...even with shorts they look ok" James

They all expressed trust in the skill of the orthotists and described them as 'friendly' and 'nice chaps'. There was an air of camaraderie between the male participants and the male orthotists.

"The chap that makes them is good at his job...supports Man U (football team) too so we get on great!" John

The male participants did not mention the requirement for the practitioners to have knowledge of their condition. The only negative comment was that two of the participants expressed concern that they got to know one practitioner and then they moved to another hospital. This reflects the known problems with continuity inherent in the contracting arrangements for these practitioners with the National Health Service.

7.5 Findings from the practitioners

Several issues were identified by all four orthotists as being important in explaining the female participants' responses and as having impact on the patients' experiences of being provided with the footwear. The issues were,

- Lack of time to assess patients' needs other than the presenting medical problem.
- Consider that females with RA are very difficult to please, because the footwear
 has to match the deformities of the feet. The foot deformity results in footwear that is
 not acceptable aesthetically. However, the practitioners felt that they did their job if
 the footwear fulfilled the clinical requirements.

- Lack of patient compliance with the use of the therapeutic footwear was viewed as the patients' choice and an inevitable problem due to the aesthetics of the footwear.
- Lack of options for the practitioner feeling obliged to 'do something'
- Lack of footwear choice for the practitioner contracting dictates the manufacturer and types of shoes available
- Not feeling part of the wider 'team' of health care practitioners, therefore alternatives to footwear were not considered or explored.
- Needing an effective consultation style, but that lack of training in specific consultation skills may have contributed to some of the issues identified by the participants.

Most of the comments made by the practitioners were to do with issues in relation to the service. For example, lack of time, lack of choice and not feeling part of a team. Therefore, it can be concluded that the practitioners' focus on the service structure is the main factor that influences the participants' experiences of being provided with this footwear. Whilst acknowledging the constraints of this on their practice, it perhaps shifts the responsibility for the participants' negative experiences to the service rather than accepting ownership of the problems identified in relation to the practitioners themselves.

The practitioners did identify the need for an effective consultation style, although two of the practitioners stated that they had lots of experience in consultations and that this was something that couldn't be taught and that it developed from experience. Although the participants in this study did identify some positive aspects of the practitioners' consultation style, for example, good listening skills, visibly trying and demonstrating understanding, these were not identified by the practitioners. There was no acknowledgement by the practitioners of the complexity of the patient with regards their medical, social, psychological needs or the complexity of their own professional role as described by the MRC (2000).

In addition to their specific professional role with regards providing interventions, all health care practitioners have a psychotherapy role and a training role. Further to this, it is acknowledged that these roles have the potential to influence health behaviour and behaviour with health interventions (MRC 2000).

On the whole, it is perceived that the practitioners involved in the management of the participants and the practitioners who read the transcripts are using the ethos that supports the medical model of care (Beck 2004) and on the whole ignore the psychological and social issues that affect the lives of these patients.

7.6 Summary

This chapter presents the results of the data analysis and exemplars from the transcripts to highlight each theme. Interesting factors that have emerged from the data analysis have been identified and discussed within the commentary on each theme. These factors will now be expanded upon and explored in relation to theory in the following discussion chapter.

CHAPTER 8

DISCUSSION ON FINDINGS

CHAPTER 8 - DISCUSSION ON FINDINGS

8.1 Introduction

The key areas covered by previous work on therapeutic footwear are patient satisfaction with the footwear (Park and Craxford 1981, Herold and Palmer 1992, Stewart 1996), the impact of different models of service provision on patient compliance with the footwear (Baker and Leatherdale 1999, Williams and Meacher 2001), and the footwear itself (Williams and Nester 2006, Williams, Rome and Nester 2007). Further to this previous, largely quantitative work, the findings of this interpretive phenomenological study have revealed some extremely important issues in addition to what is known from the existing literature where quantitative approaches have been used.

The aim of discovering the 'users' experiences of therapeutic footwear, has been achieved through the objectives of the study. How these relate to the findings of the study is shown in Figure 8.1 and demonstrates the complexity and the inter-relating factors that are part of that experience.

The analysis of the interviews has revealed a richness of data about the female participants' feelings, perceptions and behaviour associated with the footwear, some interesting aspects in relation to the exploratory interviews with the male participants and the practitioners' responses to the female participants' responses. In addition and unexpectedly, this study has revealed the participants feelings and emotions about themselves and their feet. This demonstrates the inextricable liaison between feet and footwear.

Another interesting facet to this research is that the participants who were recruited for this study were considered satisfied by the service that provided the footwear. All previous research has focussed on the reasons why dissatisfied patients do not wear their footwear The reason for choosing 'satisfied' participants was to discover their experiences and also the factors that influenced their choice to wear the footwear or not.

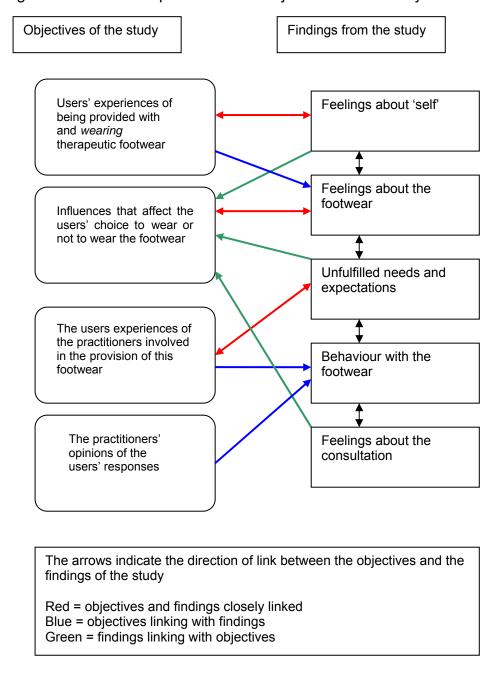


Figure 8.1 Relationship between the objectives of the study and the findings

However, before the results of this study are discussed, it is important to highlight potential limitations to the study, so that the reader can read this section with confidence that these issues have been considered and addressed. These issues are specifically, potential bias through participant selection, sample size, data

saturation and researcher bias,. A reflective commentary and discussion on further quality aspects to this study are contained in Chapter 9 (Section 9.2- 9.7)

8.2 Potential limitations to the study

8.2.1 Sample

I purposefully sought participants who fitted inclusion criteria and have been explicit in the reasons for choosing this group. This concurs with the thoughts of Greenhalgh and Taylor (1997) who suggest that in qualitative research we are not interested in an "on average" view of a patient population. We want to gain an in depth understanding of the experience of particular individuals, therefore random selection is unsuitable. To reiterate, women with Rheumatoid arthritis were chosen because there is a known problem with therapeutic footwear this patient group (Stewart 1996). Stewart (1996) found that the women in her study were dissatisfied, so I chose women that were deemed satisfied in order to explore their experiences and if there were reasons that influenced their footwear wearing habits. An additional thought was that if I had chosen dissatisfied participants this would have introduced bias to the results of the study in respect of pre-empting 'bad' experience. Returning to the research question 'what are the users' experiences of wearing therapeutic footwear?', I wanted to explore their experiences of wearing the footwear and as we know that dissatisfied patients do not wear their footwear, this would not have been an ideal group to study.

Data saturation is an issue in qualitative research in that it is difficult to identify the participant numbers at the beginning of the research. The use of an iterative approach to the data collection ensures that participant recruitment can cease once it is apparent that no new information is being revealed by interviewing additional participants. In contrast to Ryan et al (2003) who recruited forty participants, the recruitment in this study ceased at ten. The lead author in the Ryan et al (2003) study acknowledges that saturation occurred at around fifteen. The drive to recruit larger numbers than required for qualitative research in healthcare is possibly because the audiences that view this research are mainly from a positivistic

background. These audiences have concern for the rules of quantitative methods. This is despite the acknowledgement that the purpose of qualitative research is to discover deeper meaning rather than generalisable results, there is still persistence in applying the rules of quantitative research to qualitative research. This has had an impact on qualitative researchers, as Greenhalgh and Taylor (1997) state that:

'Failure to recognise the legitimacy of this approach has, in the past, led critics to accuse qualitative researchers of continually moving their own goalposts' (Greenhalgh and Taylor 1997 p 741).

With respect to the number of participants in this study, I aimed to remain true to the philosophical underpinning of the phenomenological approach in that its purpose is to obtain insight and deep understanding. This is achieved, not through establishing causality with larger numbers, but through improving comprehension about a few (Denzin and Lincoln, 1994).

8.2.2 Researcher bias

The interpretive phenomenological approach (Heidegger 1927) to this study is much more than a description and interpretation of the participants' experiences. It requires that the researcher enters into the participants' world and in this respect the data obtained is embedded in a unique hermeneutic circle (Gadamer 1989). As I have knowledge of subject area of this study and with clinical experience of the problems with therapeutic footwear it could be argued that the results could be biased. However, I have been fully transparent to the reader of this work as to my background and influences on me as a practitioner, researcher and as a person in Chapter 1. Additionally, in order to ensure that the work was not biased, I chose a 'conversational' interviewing style that encourages the participant to talk freely about their experiences. This style, identified by Mays and Pope (2000 and 1995) as having minimal 'guidance' through the interviews by the researcher's questions, ensures that the dialogue is mostly that of the participant. This 'conversational style of interviewing is in contrast to Ryan et al (2003) who used semi-structured interviews with a number of set questions. The structuring of questions may have

reduced the opportunity for the revelation of deep feelings and opinions obtained from this 'conversational' method. The questions in my study were used primarily as prompts when the conversation halted for a long period or if the participant wandered off the subject for too long.

I will now discuss the findings of this study in relation to both the original objectives and the literature that formed the theoretical framework for this work. In addition, the findings that are new and either sit outside of the theoretical framework or add to it, will be discussed and explored in relation to additional literature. The purpose of this is to highlight the key findings of this work that have the potential to influence both clinical practice and further research.

8.3 The female participants

8.3.1 Feelings about themselves

In this study all the women spoke about themselves in relation to the disease and how it had affected their feet and the function of their bodies. This was not anticipated, as the opening interview question guided the participants to reveal their experiences of wearing therapeutic footwear. Clearly this was an important aspect and an area of concern for them. This concern is supported by MacSween et al (2004) and Gutweniger et al (1999) who identified that chronic disabling disease such as RA impacts on the individual in respect of altered body image, low self esteem, and loss of independence, depression and anxiety.

These factors have the potential to affect the individuals' perception of 'self' and their public perception of 'self' (MacSween et al 2004). Therefore they affect how the individual engages in therapeutic interventions that can be intrusive in the normal day to day situations in people's lives. According to Lempp et al (2005), the level of this impact may vary according to gender, age, beliefs, understanding, perceptions and personality. Previous experience also appears to affect patients' attitudes towards their illness history and its underlying causes, the potential for a cure, prescribed medication, self medication and their usage of complementary health

therapies. With this in mind, Lempp et al (2006) recommend that all these should be explored with patients and that education programmes and other interventions should incorporate the patient's own belief systems and values.

Additionally, the onset of an illness such as rheumatoid arthritis is described by Bury (1982) as being a disruptive event or critical situation that influences the structures of everyday life'. He highlights the impact of this disruption on the plans that individuals have for the future and describes this as a 'biographical disruption'. This concern for their planned future is highlighted by Heather:

"...I don't want to be a burden on my family...they do so much already...can't imagine what would happen to me if they were not here...I wonder about that and it makes me anxious...they have their own lives don't they?"

However, despite this concern, Bury (1982) found that patients with RA were hiding their illness from their family either actively or inadvertently due to disbelief and anxiety. This 'hiding', ultimately involves rearranging their personal and social involvements so that the visible affect of RA on the function of their bodies is less evident to others. Further to this, the necessary physical ability to carry out work related activity, the stigma associated with chronic illness and the lack of tolerance by others is described by Bury (1982) as being contributory to an individual's ability to mobilise resources. However, the view adopted by Bury (1982) is critiqued by Williams (2000) in that it does not take into account other possibilities such as illness being an existing part of an individual's biography and draws in the concept of life being reflective on positive and negative events. The thoughts of Williams (2000) align with those of Merleau Ponty (1962) in that who we are now and how we view our current existence is based on an 'intentional arc' that is made up from experiences from the past and present. Nevertheless, the description of the onset and continued impact of illness as a biographical disruption (Bury 1982) is clearly in evidence for the participants of this study.

The complexity of an individual's health problem is more than disease itself and their experience of it. It includes the effect of the disease on the individuals' feelings and emotions, how these in turn affect their health behaviour and their perceptions about

the interventions we provide. The women in this study demonstrated feelings about their bodies and described their feet and their bodies as 'bad'. This term has connotations in respect of the value that they have of themselves, as it is more associated with behaviour that is described as 'naughty' and therefore warrants punishment. This feeling in relation to the feet has never been identified as 'naughty' before but is clearly an issue to do with their perceptions of themselves in relation to body image.

The changes in appearance invoke feelings of grief, sadness and anger at the loss of femininity and sexuality, described as premature aging by Daisy (age 59):

"...well it shows in your face...the pain you know...maybe because you are stood on them...makes you self conscious as well...! look and feel like an old lady...,"

and, as in Anne's case, as losing identity as a female both in how she feels and looks:

"...I feel and look rubbish most of the time. I don't feel feminine or sexy any more...especially how my feet look...they look awful...".

Gutweniger et al (1999) identified the strong link between body image, poor function invoking feelings of being handicapped due to the inability to carry out certain important bodily functions and tasks. Further to this, Vamos (1990) identified a strong desire to hide or change the body both in its actual appearance and its functional appearance by women with a disability. The visibility of the disease and the emotions invoked result in social stigma and social isolation, restricting activities and impacting on relationships, as Anne reveals:

..." I hate going out... I feel that people notice that I am struggling to walk at a normal speed... I feel that the world is speeding past me and that makes me different... I feel very self conscious... I don't go out much..."

In addition to the medical label officially assigned to the individual as highlighted by Wade and Halligan (2004), the visibility of rheumatoid arthritis also labels these

women as being different. This labelling is in addition to the disease label assigned to them at diagnosis. The visibility of disease affects the quality of an individual's interaction in several life domains, such as work, family and social life. MacSween et al (2004) suggest that this in turn impacts on their perception of their own self worth or self esteem. The ability to carry out these interactions and the ability to carry out certain tasks are related to self esteem (Ryan 1996) and mental well being (MacSween et al 2004). However, certain tasks can be of more importance to one individual than the next. For example, an ability to continue working may be more important to one person whereas an ability to cook may be of more importance to another. MacSween's (2004) study highlighted the link between physical self perception and adherence in physical activities. This adherence may be important in the rehabilitative process and clinical management and therefore a tentative link is made here between self perception and engagement in therapeutic footwear use. If self esteem is increased in other domains such as the ability to work, this may impact on feelings about the footwear.

Loss of control over the effects of disease on their bodies, results in feelings of fear for the future. This fear is for both themselves and others, as Heather relates:

"..! don't want to be a burden on my family...they do so much already...can't imagine what would happen to me if they were not here...! wonder about that and it makes me anxious...they have their own lives don't they?"

In the exploratory part of this study, the males did not raise issues to do with their feet as being important. This is in contrast to the females who have concern for the visibility of disease, the loss of femininity and also the roles women have as carers and homemakers, as well as workers. Compared with the men, the women demonstrated concern for how their feet impacted on function in relation to their roles. This highlights the complex link between visible disease in relation to appearance, poor function and the inability to complete tasks.

That the female participants initially focussed on their feet as an issue, highlights the inseparable combination of feet and footwear, with the footwear reinforcing their already negative feelings about their perception of self. This negative perception is

known to exist in this patient group (Gutweniger 1999) and in this situation could be compounded by the visibility of therapeutic footwear.

8.3.2 Feelings about the footwear

In the normal context of use, footwear is required to meet a person's needs as defined in the retail context in that footwear is chosen and is worn as an item of clothing. This is quite different to the specialist 'therapeutic' footwear which is supplied by the NHS as an intervention to 'use' rather than an item that is 'worn'. This being the case, the usual choice of which footwear to wear is automatically being taken away from the patient since their existing choice of retail footwear has been deemed unsuitable for their foot health needs and it is known that the replacement of their existing footwear is often without the patient's pre-emptive request or involvement in the decision (Williams and Meacher 2001).

Further to this, it can be interpreted that the patient has far less control and influence in the choice of specialist footwear compared to their usual retail purchase. This is likely to disengage the patient because they are being told that their previous choice of footwear was wrong, and we know what is best for them. This disengagement, by default, confines the patient to the role of passive recipient with no choice rather than the active participant who chooses. Often, the only choice the patient has is whether to wear the specialist footwear once it has been supplied. This is supported by evidence (Park and Craxford 1981, Herold and Palmer 1992, Stewart 1996, Williams and Meacher 2001) that patients frequently choose not to wear this footwear after it is supplied. This indicates that in the context of the consultation, the practitioner has failed to establish the patient as an active participant in the decision making before the footwear is supplied.

The footwear itself and its impact on restricting their choice in clothes could be seen as a contributing factor to the female participants' social isolation that is evident in people with chronic disease (Whalley et al 1997, Treharne et al 2005). Footwear plays an important role in the women's appearance of themselves and their 'public perception of self', as Rose described:

"...The shoes....as soon as I see a person I can say oh yes she's got hospital shoes on...I compare my boots with other people and they are more feminine and pretty and that makes me feel sad".

Footwear therefore can be seen to contribute to the powerful emotions associated with the loss of femininity, premature aging and loss of control associated with the disease as described by the participants and in previous studies (Ryan 1996). The loss of choice and hence control over their footwear choices further reinforces the poor self esteem already evident. Even though there were negative comments and emotions revealed about the footwear, most of the women, even those not wearing the footwear felt grateful for something that had been tried, as Lena describes:

"...the first pair was a pair of shoes which were really old fashioned sort of old women's shoes if you will...and I felt....I felt I should be grateful..."

Despite being thought of as being 'satisfied' by the service that provided the footwear, the females in this study revealed aspects with which they were not satisfied. However, they demonstrated gratitude for the practitioners' interventions. This appreciation and gratefulness may be what is reported in previous questionnaires as satisfaction (Park and Craxford 1981, Herold and Palmer 1992, Stewart 1996). This implies that they are not entirely satisfied, but feel that they should be grateful for anything even if it is not satisfying all the aspects associated with footwear use. It has been shown by these previous studies that satisfaction is associated with compliance with the footwear. However, no study has actually defined what satisfaction is and there is an assumption that satisfaction is related to the footwear being used to a sufficient level to optimise foot health and also that satisfaction implies that all the patients' needs are being met. Williams and Nester (2006) identified that these needs range from comfort and ability to walk more 'normally' to those needs associated with the visual appearance of the footwear (Williams and Nester 2006).

That the female participants had concern for the visual appearance of their footwear was not surprising as it is known that women generally favour fashion over foot

health (Joyce 2000). However, women with RA have demonstrated more concern for comfort (Williams and Nester 2006) and that if this is the priority then the therapeutic footwear has to be worn and a compromise occurs over the appearance of the footwear. Another issue that has emerged is that the practitioners view the footwear as a foot health intervention and as an inanimate object. If we agree with Merleau-Ponty (1962) that an inanimate object can become part of the person and who they are, then footwear is not an inanimate object. Once the footwear is on the foot it is a visible part of that person. This is where there is a discrepancy between the views of the patient and the practitioner.

8.3.3 Behaviour with the footwear

The key principles that formed the theoretical framework for this study included the known facts that therapeutic footwear can be clinically effective, in that it has the potential to reduce pain, thereby improving comfort and levels of activity in this patient group (Fransen and Edmonds 1997, Williams, Rome and Nester 2007). We know from previous work that some patients chose not wear the footwear at all and many wear it selectively (Park and Craxford 1981, Herold and Palmer 1992, Stewart 1996). This choice is deemed inappropriate by the clinicians providing it and this behaviour is termed non-compliance. The effect of this 'labelling' is that it shifts the responsibility to the patient and further assigns another label to the individual. The patient is labelled by the disease, in this instance, rheumatoid arthritis. Further to this they are labelled by the visibility of the disease and the footwear. Then they are being labelled in negative terms in relation to their health behaviour with the footwear as being non-compliant.

This non-compliance is not what the practitioners want and there is an expectation that patients will wear this footwear once it is provided. This expectation is founded on the ethos that the patient will do as instructed by the practitioner and that choice is not considered. In the normal context, footwear is chosen for its many functions in relation to activity and appearance. Women in particular (Joyce 2000) choose a variety of styles according to their activities and also evaluate the 'cost/benefits' of such choices. If footwear becomes an intervention or treatment then patients should understand the benefits of wearing it in relation to their levels and types of activity.

Supported choice would enable the patient to feel in control of their situation. In this respect they may be more likely to engage in it when it is really needed, such as for high impact, long duration activities.

Two female participants in this study chose not to wear the footwear at all and had relegated the footwear to 'shoes in the cupboard' as described in a previous study (Williams and Meacher 2001). This choice also reflects the results of other work that identified that one in six pairs of shoes are not worn (Disabled Living Foundation 1991). This choice was not taken lightly by the two female participants, and it was evident that this action invoked feelings of anger because their expectations had not been met. Despite the footwear being free, all the female participants recognised a cost to the NHS and therefore when they chose not to wear it they felt guilty and angry at the waste.

Indeed, in this study the participants revealed that they had high expectations from the footwear with regards comfort, function and appearance. Although it is known that meeting expectations is not necessarily related to satisfaction, as expectations change throughout the process of receiving health care (Thomson and Sunol 1995), in the case of being supplied with therapeutic footwear this may not be so. Meeting their expectations initially was seen as important by the participants in this study. These expectations may have arisen from their own perceptions of what the footwear should achieve, but the referring practitioner may well have influenced the participants' expectations. This may reflect a lack of understanding about therapeutic footwear as an intervention by the referring practitioner and this may arise due to lack of communication between the two practitioners or the fact that many dispensing practitioners work in isolation with little opportunity for joint discussion and dialogue with the referrers. Understanding and acknowledging the patient's expectations by the dispensing practitioner may be one of the factors that should form the basis of the initial consultation about the footwear. In this study, the participants reported that they lacked the opportunity to express this and this lack of 'voice' was also identified as a problem associated with other issues that were of importance to them.

The participants of this study not only revealed their opinions about the footwear, their expectations of it and their behaviour with it but revealed the strong emotions that are associated with these aspects. These emotions are considered negative ones and in respect of the footwear, mirror the emotions these women expressed about their feet. So it could be assumed that the footwear reinforces the already negative emotions experienced by these women about themselves and their feet. If the practitioner demonstrated understanding about this and attempted to reassure the patient about the appearance of their feet and the footwear, professional power could be used in a positive way as we already know that significant 'others' can influence how we feel about ourselves (Bandura 1986, Canter 2001).

8.3.4 Feelings about the consultation

The focus of much of the female participants' dialogue during the interviews was around the consultation with the dispensing practitioner. Although two of the participants described the dispensing practitioner as a 'nice person' and demonstrated a concern for solving issues to do with the fit of the footwear, the majority discussed negative aspects. The body language of the practitioner and their attitude reinforced both the female participants' negative feelings and guilt at being perceived as a 'difficult' patient. This possibly reinforces the balance of power with the dispensing practitioner and would not encourage open and shared dialogue. In some cases the participants perceived the practitioner as using guilt about the cost of the footwear to encourage its use. It is not clear whether the cost of the footwear is a legitimate area to discuss as it places guilt as the primary motivation to wear them rather than the patient choosing to wear them. Guilt is a negative emotion and again reinforces the balance of power with the dispensing practitioner.

The participants expressed that they perceived the dispensing practitioner as having little or no knowledge of RA and the impact of pain. Whether these practitioners did have knowledge of RA is not known but the importance is that they did not demonstrate this to the patient. The lack of opportunity to explain their experience of disease, its impact and their needs results in the participants feeling of not being important and reinforces the balance of power with the practitioner. In addition, the

lack of opportunity for the participants to have a voice detracts from the development of a therapeutic relationship. This problem is augmented by the lack of continuity of care by the dispensing practitioners due to the service contracting arrangements whereby the practitioner may be different at each patient visit.

Empathy was identified in this study as being important as it demonstrated that the practitioner had an understanding of the condition and the effect of it on their lives. The participants also suggested that sympathy was "condescending". When exploring these terms it could be said that there are similarities between them in that they both involve a sinuous association between two people. However, there are subtle differences in both the definition and power of these two terms. Sympathy is defined as:

"...the act of sharing...in an emotion or sensation or condition of another person..." (p 1236 Oxford English Dictionary 2002)

Whereas empathy is defined as:

"...the power of identifying oneself mentally with, and so fully comprehending a person" (p383 Oxford English Dictionary 2002).

On closer analysis of the meanings of these two words, sympathy is about sharing an emotion whereas empathy involves a process of understanding another person's experience. In addition, sympathy in every day language is used to convey an expression of pity or sorrow for the pain and distress of someone who has suffered loss. The connotation of its use in the clinical context is one which further places the individual on the receipt of the sympathy in a position of weakness. This position of weakness reinforces the lack of voice that these women feel in this environment.

In this era of 'patient centred care' where patient empowerment is considered to be the mantra of every healthcare practitioner, a state of concordance between the patient and the practitioner is considered to be the route to achieving both good clinical outcomes and improving the patient's decision making and experience (DOH 2006). In other areas there is evidence that this approach improves the situation for the patient and practitioner alike (Lewin et al 2003). That a patient's decision about their level of involvement is important to the achievement of concordance has been highlighted (Treharne et al 2006) and this level of involvement may be different depending on whether the patient perceives the issue to be an everyday decision or an important medical decision (Neane et al 2005). Footwear may be seen as an everyday decision, that is, a clothing choice rather than an intervention and therefore the importance of involvement in the consultation as highlighted by Ryan et al (2003) may not be perceived by these women to be appropriate in the context of footwear that is viewed by the practitioner as being an intervention.

This disparity of understanding between the practitioner and the patient may be where the essence of the problem with therapeutic footwear lies. It has been demonstrated that generally there is evidence of discrepancy between the patient's and practitioner's views on the importance of disability, physical function and pain (Suarez Almazor et al 2001, Hewlett et al 2001), with the practitioners focusing on the physical manifestations and management of the disease. The ability of practitioners to acknowledge the patient's problems from their perspective has been seen as the key to providing support and reassurance (Donovan and Blake 2000) and therefore possibly the patient's feelings of importance and the importance they assign to footwear as an intervention.

Shared information and understanding is pivotal in the quality of the relationship between the practitioner and the patient (Leventhal et al 1997) and to achieve this effectively practitioners need to demonstrate empathy, friendliness, interest and concern. Roter et al (1998) further identify these factors as being important and the combination of these affective components are seen to be more effective than a single focus. Taking appropriate action or engaging in appropriate health behaviour is not based on objective factors but subjective perceptions about the perceived social consequences. This is a balance between the costs and the benefits and in a way equates to self management in which the patient is the problem solver. Therefore footwear could be seen as self management and its use dependent on the patient's perceived goals. If this is the case then the practitioner needs to ascertain what these goals are and to do this requires the establishment of a good relationship between the practitioner and the patient. In support of this notion, patients with RA

do see themselves as partners in their own health care (Lempp 2006). Paying attention to not just the pathology but the whole context of the problem including both social and psychological perspectives leads to a deeper understanding and a more effective outcome (Foster et al 2003).

It is acknowledged that there is more to the therapeutic relationship than the intervention in that what goes on during the consultation does have an effect on the effectiveness of the intervention. Paterson and Dieppe (2005) highlight this by suggesting that in randomised controlled trails the effect of the consultation on the placebo group grossly underestimates the treatment effect of the intervention. The effect of the consultation may be why both treatment and placebo groups are often seen to improve. Perhaps then, the intervention is the vehicle for some other more vital aspect of care such as listening and demonstrating empathy and that this alone has a positive effect. In a previous study into two different service models of providing therapeutic footwear (Williams and Meacher 2001), it is possible that the success of the multidisciplinary model over the traditional model was more about the practitioner's qualities rather than the type of service that the practitioner works in.

The processes of information gathering, facilitating patient choice, and information giving have been identified by Williams and Meacher (2001) as being the main factors that influenced the patients' experience of the multidisciplinary setting in a positive way. The practitioner is pivotal in this but Williams and Meacher (2001) did not provide an account of the effect of the interaction between the two practitioners involved in the multidisciplinary clinic or how this influenced the patients' perception of their experience. It is possible that the dialogue between the practitioners facilitated a 'thinking aloud' that the patients could hear whereas in isolation this 'thinking' is possibly not shared. This would account for the patients' perception in this current study that the practitioners involved had no understanding of their condition. This 'thinking aloud' could be part of the interaction with the patient so that they feel included in the decision making. However, as most of the participants in this current study indicated that they were not listened to or felt 'voiceless', the lack of encouragement by the practitioner for the participants to speak demonstrates the lack of 'patient focus'.

The way that the participants relayed their concerns over the consultation could possibly have been affected by previous experiences with other practitioners and therefore their expectations of the consultation. Lempp et al (2005) conducted a small qualitative study (26 patients) to look at the experiences and views of patients with Rheumatoid Arthritis regarding the guality of health care they received in primary and secondary care. They found that four main factors influence patient's perceptions about the staff who care for them and the treatment options available namely: their past experiences with the NHS; their own health beliefs; professional attitudes (e.g. listening to patients, receiving feedback on disease processes), and finally the 'organisational aspects (e.g. good communication between health professionals), which would make their visits to the outpatient clinic easier. Further to this, the participants in Lempp et al's study (2005) focused on the impact that rheumatoid arthritis had on their personal relationships, changes in body image, impact on their working lives, discrimination and stigmatism, and loss of role within society. Crucially these patients were of the view that many of these problems were unknown or their impact undervalued by the health professions.

In this study, the consultation between the participants and the dispensing practitioner was identified as a vital component affecting whether the patients engage in the use of specialist footwear. Ryan et al (2003) identified that the relationship between the patient and the practitioner is seen as a partnership in which information, feedback on progress, support and empathy by the practitioner is necessary to influence the patient's perceptions of control in a positive way. It is already known that the clinical encounter with the practitioner is perhaps the most important factor in the patient's engagement with health interventions (Horder and Moore 1990). Street (1991) identifies that:

"... in spite of sophisticated technologies for medical diagnosis and treatment, talk remains the primary means by which the physician and patient exchange health information".

Although good communication skills alone are not identified as being as important as trust, expertise, liking and respect (Roter 2004), to achieve all these desirable

aspects to a consultation, effective communication and a concordant relationship is required.

Establishing a concordant relationship through effective communication, facilitates the patient's control over choices and their subsequent engagement in the intervention (Ong et al 1995). The nature and composition of the clinical consultation about specialist footwear is potentially a significant factor influencing whether the patient chooses to wear it or not. Most participants in this study behaved as passive recipients with apparently no opportunity to choose to reject the option of footwear before they are referred to the dispensing practitioner by the referring practitioner. Therefore, the source of the problem with specialist footwear could be perceived to be at the point of referral with the template for the balance of power set at this event as being with the practitioner.

Knowledge about specialist footwear by the referring practitioner and engaging with the patient in the decision to refer is a pivotal moment at which the patient either becomes a passive recipient or an active participant using information to make considered choices. To promote positive health behavior, the balance of power in the patient/practitioner relationship needs to shift towards the patient so that they are not a passive recipient but become an active participant in the decision making (Ong et al 1995).

It is clear that the participants of this study both desired and needed to be involved in the decision making and to be allowed to 'have a voice' in this situation. To enable this 'voice' requires a relationship with the practitioner that encourages the patient to voice their opinions, concerns and choices. This could be facilitated by the practitioner through a demonstrating empathy and understanding of the patient's condition and concerns. The participants in this study found their 'voice' during the research process and voiced definite ideas about what would have made their experience better.

8.3.5 Opinions on improving the experience

The female participants demonstrated knowledge about their foot problems and had opinions as to what would have helped if they had been listened to. The possession of this knowledge identifies them as experts of their own problems, which in turn leads to the expectation that they should have strong control and a sense of ownership in the decision making process. The imbalance of the existing process supports their role as passive recipients with no control and therefore it is not surprising that control is only regained in the choice of wearing, or not wearing the footwear once it has been dispensed.

That patients are experts in their own condition, is recognised specifically in patients with RA. However, in conjunction with this they need information and guidance that enables them to make informed choices of service providers and the treatments they offer (ARMA 2004).

At the point of referral for these women there was no choice and from that point onwards the only choice was ultimately whether they wore the footwear or not. Despite this loss of choice, there was evidence of trust in the dispensing practitioner to know their job with reference to the footwear itself and they were perceived as the experts in this footwear. This has been demonstrated to be important in the establishment of trust between the patient and the practitioner (Roter et al 1998) in a variety of settings. However, it is perceived in this situation that although there is an innate trust that practitioners have a skill in the intervention that they supply to the patient, communication, dialogue and listening are the key to the establishment of the level of trust that allows the patient to have a 'voice' about the intervention.

Establishing the patients' expectations and needs is a vital stage in patient assessment and this should be the focus for the consultation. As practitioners, the desired outcomes from our interventions may be very different to what the patient wants. In this instance, it may not be a reduction in pain or increasing mobility that is important to the patient but rather, improving their appearance by disguising the deformity of their feet or improving the visual aspect of their walking style.

8.4 The male participants

Although a small number, it was interesting to carry out exploratory interviews with the three male participants. A younger male group may have had more to say about body image but normal attire for males is trousers and this is seen as appropriate for use with this type of shoe. Indeed some of the women in the study chose to wear trousers in an attempt to create a visual appearance of 'normality'. The male participants did not discuss body image issues at all nor did the footwear impact on their behaviour.

They described the practitioners as 'friendly' or 'nice chaps' almost describing an air of camaraderie between the male orthotists and the male participants. Perhaps being of the same gender is one factor that rebalances the power in this relationship, although there is no work on gender issues within the therapeutic relationship. There were no emotional responses from the male participants but they did express that they had engaged in social chat, for example about football. This social chat did not appear to take place in the female group, but may be vital in encouraging discussion within the consultation.

8.5 The Practitioner responses

There was disparity between what the female participants expressed, and the practitioners' interpretation and opinion of their transcripts. Most of the aspects identified as having an impact on the patients experience were to do with the service. These aspects were, lack of time with each patient, lack of choice in footwear due to contracting arrangements, working in isolation and lack of choice for them as practitioners in that they felt obliged to do something once the patient had been referred to them. These problems have been identified in studies and reports (Williams and Meacher 2001, Orthotic Pathfinder Report 2004, Bowker 1992). Clearly there was concern over the patients' experiences and comments but this was a very defensive approach identifying constraints and problems with the service as reasons for these.

Although the practitioners identified that they lacked training in consultation skills during their professional training, two of them said that these skills developed through clinical experience. However, there is some evidence that physiotherapy practitioners (Turner and Whitfield 1999) and podiatry practitioners (Bellamy 2007) are more influenced by their original training than critically appraising the literature or through clinical experience. As clinical experience can be defined as:

"'Making the same mistakes with increasing confidence over an impressive number of years' O'Donnell (1997) as cited in Issacs and Fitzgerald (1999),

and as there is no evidence to support that years of clinical experience increase the effectiveness of the consultation, changing the behaviour of practitioners has been highlighted as an area for further attention and research (Marteau et al 2006). There is some evidence, however, that supports the effectiveness of these consultation skills being taught in medicine (Aspergren 1999, Cooper and Hassell 2002).

The practitioners in this study did not identify the factors that made for a good consultation. This is in contrast to the patient participants who had very clear opinions as to what was lacking and what was needed. In relation to the participants they did not comment the reported feelings about themselves, their expectations or the footwear in relation to how important this information would be in their clinical decision making. They did however have a long discussion about how difficult it is to please female patients with RA as it was difficult to get footwear to fit these 'very bad feet' and it was this that resulted in non-compliance or 'bad behaviour' with the footwear.

Inherent emotions that are deemed inappropriate for health care practitioners to have and indeed encouraged to subdue as being unprofessional may create a barrier to gaining an understanding of the patient's perspective. If this barrier can be removed in the research context with the aim of achieving a greater understanding of the patient's problems, then this could be transposed into clinical practice to achieve the same result.

8.6 Summary

In the context of the female participants' experiences and the practitioner responses to these experiences there are emerging issues that contribute to the patients' experience of being provided with this footwear. These experiences and the emotions associated with them influence whether they wear the footwear or not.

What the female participants think that the practitioner needs in addition to their profession specific practical skills, are effective communication skills, an ability to listen, and appropriate body language. Demonstrating that they value the patient, effective information giving, being non-judgemental, non-labelling, providing feedback, and checking levels of understanding and expectations are considered vital. These factors are essentially what are contained in the Calgary Cambridge model (Kurtz and Silverman 1996). Demonstration of empathy and knowledge of the patients' general health and impact of specific problems would increase the patients' confidence in the practitioner. Additionally, a demonstrable understanding of the impact of the footwear, the patients' perception of self and their public perception of self and acknowledgement that the patient is an expert in their own health problems would contribute to the patients' feelings of importance and equalize the balance of power in the relationship.

So, in summary, the patient / practitioner consultation has a powerful influence on the women's existing feelings about themselves, their needs and expectations of the footwear and ultimately their feelings about, and behaviour with the footwear.

CHAPTER 9

REFLECTION ON THE INTERPRETIVE PHENOMENOLOGICAL APPROACH TO THE STUDY

CHAPTER 9 - REFLECTION ON THE INTERPRETIVE PHENOMENOLOGICAL APPROACH TO THE STUDY

9.1 Introduction

In context of the area and focus of this investigation, an interpretive phenomenological approach has provided me with the ability to gain insight into the reality of the users' experiences and perceptions of being provided with therapeutic footwear. I have obtained a richness and depth of data that have been presented through themes and supported with exemplars. The exemplars support the trustworthiness of the data, and also allow the reader to have an insight into the users' experiences.

The strength of my research is the convergence of personal knowledge of current issues with therapeutic footwear, the intuition that the work is timely and right, a concern for the theoretical concepts and the philosophical approach to this work. The interpretive phenomenological approach to this study has combined both a description and an interpretation of the participants' experience in the context of their life, revealing not only their thoughts, but also the emotions associated with their experiences. Further to the participants' sharing of their 'own world' with me, I have organised and interpreted their dialogue in relation to my own experience and existing literature, entering into a hermeneutic process that has formed the basis of the findings of this investigation.

A further strength of this research is that I have been both transparent (Priest 2002) and reflective about decisions made throughout the research. This process has also been described as 'openness' by DeWit and Ploeg (2006). This openness has ensured that I have remained true to the data with acknowledgement of the fusion of the literature, my beliefs and the data. This process is supported by Krell (1999) and Hággman-Laitila (1999) as being essential in qualitative research and is in line with the thoughts of Gadamer (1989). Gadamer suggests that the most important aspect of this type of research is not showing us what to do with 'method' but explores what is 'going on' during it and is part of this reflective process.

In this chapter, I intend to reflect on and discuss the emerging issues and thoughts that have emerged throughout the research process in relation to both the methodology and my development as a researcher. First, I will discuss general issues in relation to qualitative research approaches and the value of this to this study.

9.2 Qualitative methodology

The process of choosing a qualitative research approach, carrying out the research itself and then reflecting on it, has triggered some thoughts as to the place of this methodology within health care research. The purpose of this is not to evangelise about qualitative research methods over quantitative methods but to identify its importance in health care research.

It is apparent, from the number of studies published that employ quantitative methods that the medical community place high value on the numerical data produced by these studies. However, it has been identified by Chambers (2000) that this focus is not as relevant to the real issues that are important to patients, practitioners and other stakeholders in healthcare. However, over the last decade, qualitative research approaches have become more evident in medically orientated journals. Within the field of rheumatology, authors such as Hale, Treharne and Kitas (2007), Ong and Richardson (2006), Ong and Coady (2006), Quandt and Acury (1997), and Ryan (1996) have both used and supported the use of qualitative methods as being appropriate for capturing the patients' experiences of disease and their experiences of health care interventions.

The importance and value of qualitative research is supported by the changing ethos of the Department of Health (DOH 1995, 1999, 2003) to being more 'user' focussed. At a clinical level, this ethos requires the development of a 'partnership' that is achieved through a concordant relationship between the patient and the practitioner. This gives the patient, the 'user' of health care a voice in the decision making (DOH 2006). Therefore, whilst it is acknowledged by authors such as Hale et al (2007), that

we need quantitative methods to produce 'scientific' evidence for our interventions, they emphasise that we also need to link this evidence with the patients' experiences. Then, we may have a more holistic view of both the problems being investigated and the interventions we provide in the management of these problems.

A more holistic approach to research is crucial to building the body of evidence to support what practitioners do, how they do it, who they do it to and how it is evaluated. As Chambers (2000) suggests, rather than debating about the merits or demerits of quantitative and qualitative research methods we should chose the most suitable approach and method for both the area to be researched and the research question. Not only do we need a range of methods in order to understand the complexities of health care, but an understanding of the philosophy of research, not just by the researchers, but by the practitioners who embrace the evidence and change their clinical practice accordingly. Through research activity, it is generally agreed that researchers and the results of their research can influence clinical practice. However, they can also influence a profession's philosophical standpoint. The qualitative research approach has become a strong clinical and professional influence for nurses, but this has yet to be achieved for podiatrists or orthotists. In recent years, there have been attempts to inform the podiatry profession of the benefits of this research approach (Redmond, Keenan and Landorf 2002, Chambers 2000), but with no attempts within the orthotics literature. It has yet to be accepted as having the same status as quantitative research by researchers and practitioners from these professions.

Qualitative approaches are particularly suited to exploring and identifying the experiences of patients and issues to do with health and healthcare in the context of the patient's 'own world'. This sort of notion is supported by Black (1994) who suggests that the increasing use of qualitative methods generally in healthcare may have occurred because quantitative methods have provided either the wrong answers or no answers to important questions in both clinical care and service delivery. This is the case in the area of therapeutic footwear as despite recommendations emerging from previous research (Salford Report 1992, Williams and Meacher 2001) that are in place in clinical practice, the problem of poor levels of usage still persists. So clearly this previous work has not answered the question,

"why patients choose not to wear the therapeutic footwear?" Further to this, all previous research into this area has ignored the complexity of chronic disease, the impact of this on the individual and therefore the complexity of providing footwear as a health intervention.

Black (1994) suggests that due to the complexity of chronic diseases, and the perceived cavern between what practitioners think patients' needs are and the patients' perception of their own needs, there is no single research method that can answer all the questions or provide solutions. This concept is supported by the Medical Research Council (2000), who acknowledges the potential benefits of all research methodologies. With regard to the researchers themselves, Seale (1999) argues that researchers should have respect for the sheer variety of theoretical and methodological positions. Further to this, Seale (1999) argues that researchers develop a 'craft skill' that leads to the development of their own style and that this is acceptable if the decisions for this are explicit when reporting the results of their research. With regard to this study, the rationale for the choice of methodology has been made clear and I have aimed to remain true to the interpretive phenomenological approach. However, due to the uniqueness of my own beliefs I have my own style and therefore have developed a 'craft skill' in the approach to this research.

The interpretive phenomenological approach (Heidegger 1927) to this study is much more than a description and interpretation of the participants' experiences. I am immersed in the subject area of this study and in this respect I am well placed to enter into the data produced by the interviews. As my background is acknowledged my interpretation of the data in this study is embedded in a unique hermeneutic circle (Gadamer 1989). This 'uniqueness' has resulted in the emergence of my own style that has been successful in revealing both new issues and new perspectives on existing issues. These issues, together with evidence from the existing literature have created a clearer picture as to where the problems lie and also more importantly, what the potential solutions are. The findings of this study provide a different facet to the work of previous researchers in this area; rather it adds to the body of evidence and has ensured that an important aspect that has been previously ignored has now been explored. This has created a humanistic view of the problem

rather than just the practitioners' view. However, marrying this with the positivistic view of this problem area has created a more holistic perspective and understanding.

Having explored thoughts that have emerged about qualitative research in the professional context and thoughts about the value of this approach to this area of study, I will now provide an account of thoughts in relation to the data collection tool.

9.3 Data Collection Tool

A conversational style of interviewing has allowed the participants to be able to speak freely and it has enabled me to discover their deeper feelings and thoughts. In agreement with Mays and Pope (2000 and 1995), this method had the effect of equalising the balance of power between the researcher and the researched and created an environment that encouraged them to talk freely about their experiences. In contrast to Ryan et al (2003) who used semi-structured interviews with a number of set questions, I chose a more conversational style to create free flowing narrative. The structuring of questions may have reduced the opportunity for the revelation of deep feelings and opinions obtained from this less structured method. The questions in my study were used primarily as prompts when the conversation halted for a long period or if the participant wandered off the subject for too long. Ryan et al (2003) justified their choice of a semi-structured approach because she found that the participants in her study could not focus on the subject matter with unstructured interviews. However, in contrast to this opinion and in support of my choice, Koch (1998) advocates an open questioning style such as 'What is it like being...?' and further to this suggests that openness is crucial to obtaining the full story of the participant.

Overly mechanistic and systematic data collection may be confining and may limit the trustworthiness of the data by missing subtle truths in the data. Conversely, it might be said that not having structure may have left some areas uncovered. I had knowledge from previous studies about the problem areas but the aim of my study was to discover new ones or a different perspective on existing ones. The aim was

also to obtain the participants responses with as little interference or bias from me as the researcher defining the questions. Heidegger (1927) believed that to understand the characteristics of human existence in the world you have to be in it. Adopting an interpretative phenomenological approach has allowed me to enter into the participants experiences without being prescriptive and influential on the stories that they reveal about their world. This approach has provided the patient with a voice to reveal their feelings, emotions and thoughts. These have been essential in developing a true understanding of the problem area.

In the context of the interview itself, it could be said that the researcher is the research tool rather than the interview. As the researcher is the facilitator of the interviews it is difficult to separate the two and the interaction between the researcher and the participant has the potential to influence the data. I will now explore the influence of the interaction between the researcher and the participants on the research process.

9.4 Interaction between the researcher and participants

There are several issues that emerged through the experience of carrying out these interviews. Researcher bias is an area of concern in which the rigor of qualitative research methods can be challenged as being:

"...anecdotal, impressionistic and strongly subject to researcher bias (Koch and Harrington 1998 p184)

However, although it is important to consider the overall expressions of rigour used for quantitative research methods, they are philosophically inappropriate for qualitative research. The goal of quantitative research, informed by the positivist world view, is finding the epistemological single truth. In contrast, Koch and Harrington (1998) suggest that the goal of interpretive phenomenology is an increased understanding of the multiple interpretations of the meaning of human experience. The whole concept of carrying out research is much more than the fundamental activity of collecting data. Researchers have their own world views and

approach their research with their own beliefs and presumptions and for that matter, their own hypotheses. An interpretivist approach allows the researcher to take into account the effect of their previous experiences that have formed their world view and to be transparent in this process so that the reader can be fully aware of their standpoint and beliefs (Koch and Harrington 1998). Paley (2005) draws an analogy between cognitive illusions and error (as viewed as different perceptions) in all forms of research. He uses as an example for the Muller Lyer Illusion (Figure 9.1) to illustrate that although we have the knowledge that the lines are the same length, the perception is that they are different.

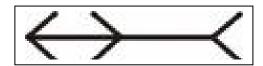


Figure 9.1 Muller Lyer Illusion

Paley (2005) uses the Muller Lyer illusion to distinguish between realities as they really are and realities as they seem. We have to acknowledge that there are multiple realities and that reality exists in one's mind and is therefore subjective. Therefore, he suggests that objectivity is impossible in all forms of research. Exploring the quest for objectivity in research, Paley (2005) quotes a description of objectivity by Lincoln and Guba (2003), who describe it as:

"...a chimera: a mythological creature that never existed" (p197)

Although objectivity is not attainable, nor indeed desirable in phenomenological investigations, it is important for the reader of the research findings to be able to ground this work in the context of the researcher's influences and views of the world. One of the strengths of this research is the reflective account of the influences on me as the researcher and embracing them in a way that enhances the research. This notion is supported by the work of Reason (1988) when he describes a skill known as 'critical subjectivity as the:

"...awareness in which we do not suppress our primary subjective experience nor do we allow ourselves to be overwhelmed and swept along by it; rather we raise it to consciousness and use it as part of the enquiry process." (p147)

This supports the notion that I am the primary research tool and can therefore be said to be more insightful when it comes to interpreting the transcripts and in analysing the data. In interpretive phenomenological analysis the researcher's aim is to enter the lived experiences of the participants (Heidegger 1927) rather than describing the participants' experiences objectively as suggested by Husserl (1931). This is achieved through listening to the participants' narratives during the data collection, transcribing the data, interpreting the transcripts, organising the data and finally describing the characteristics of the phenomenon.

Although I have experience of interviewing patients as a practitioner I initially found the role of research interviewer different. I felt that I was entering more into the participants' world than in the clinical situation, where the balance of power was with me as the practitioner. In the clinical situation I still had to retain control over the dialogue so that essential areas of the patients' assessment were covered within the time constraints. In the research situation, I realised that this control had to be relinquished if the participant is to feel that they can speak freely. Further to this, I observed that the participants found the experience emancipatory and that they had been given the opportunity to find their 'voice' about issues of importance to them about their footwear experiences. The participants expressed that this 'voice' was something new to them and asked if it was appropriate to reveal their true feelings, as expressed by Rose;

"...I can say this to you can't I?......It is OK to tell you this..."

Providing participants with the opportunity to reveal their feelings is a vital and beneficial part of the process of qualitative research and is acknowledged by writers such as Sherman (1994) and Koch et al (1994). Listening to the participant's 'voice' provides information in order for the researcher to understand an area or phenomenon, but it can also be therapeutic for the participants in that it allows marginalised groups to have a voice.

It could be said that women who are receiving health care, in a male dominated medical profession are marginalised. In this area there are more male practitioners involved in the provision of therapeutic footwear than females. The balance of power is not just with the practitioner because of their position of power as a practitioner but also a result of male dominance within the profession represented in this study. Gutweniger et al (1999) identifies that the marginalisation of women in health care may be further emphasised by the effect of chronic disease on the appearance of the body, the public perception that these women have of their bodies and the social stigma and vulnerability associated with it. Listening to these women during the research process appeared to be the key to them finding their voice and revealing their innermost feelings and thoughts. This 'listening' needs to be transferred into the clinical encounter and although as practitioners, we talk about patient centeredness perhaps we 'hear' our patients but don't truly 'listen'.

In my reflective account of the influences on me as a researcher (Chapter 1) I explored gender as a factor that may have influenced the planned research. I was also transparent about me as the research tool both in the data collection and data analysis parts of this study. I did not set out with the purpose of labelling this research as 'feminist' but it has emerged that I did have epistemological concerns about this fact and the influence of this on both the process and outcome of the study. The interpretive phenomenological approach was developed by Heidegger (1927) who was male and although I remained true to the philosophical underpinning of this approach I acknowledge that my approach to this research has been influenced by my gender and professional experience.

In relation to an individual's experience being unique to that individual (Heideggar 1927) and Gadamer's (1989) philosophy of individuals being 'in and of the world', as human beings we do have shared experiences. Much of what the participants revealed resonated with me both as a woman and as a practitioner. When the participants revealed that they felt sad, I felt sad; when they revealed that they felt angry, I was angry; when they expressed loss I felt that loss. The result of this was that I experienced empathy with these women. An example of this is when one participant reported feeling humiliated by the practitioner. She expressed shame and sadness at the reaction of the practitioner to her feet:

"...He pulled a face when he saw my feet....that made me feel... ashamed really.....
and upset...I went home and cried...I felt...well...humiliated". Lily

I felt sad and angry that she had been treated in this way. There was a tension between me as a researcher and as a practitioner. I found it hard not to discuss potential solutions, and although I could empathise it was outside of my remit to reaffirm that this was unacceptable as this may have caused further distress. In the context of the research, the subjective feelings invoked in me could be viewed as an influence affecting the rigor of the study. However, it can be considered as the first steps into Heidegger's (1927) 'hermeneutic circle' that acknowledges historicality and involves exploring my past and present feelings, acknowledging that these feeling exist and that I had my own world view and experiences to draw upon. What I was doing was what Gadamer (1989) describes as 'establishing prejudices', which should not be seen as an obstacle in pursuit of truth. Koch 1994 concurs with this:

"...Prejudices are the conditions by which we encounter the world as we experience something. We take value positions with us into the research process. These values, rather than getting in the way of research, make research meaningful' Koch 1994 p977

In this respect, the interviews were a 'shared' experience and this occurred in a very intimate and safe environment in which these women could share their experiences and not only demonstrate concern for themselves but also for others in the same situation. Most of the women agreed to take part in the study because they felt that it would help 'others' in the same situation. The beneficial aspect of being involved in a study of this type not only provides an opportunity for the participants to voice their opinions but it also provides a feeling of 'being important'. This was seen in a study investigating the experience of one woman's experience of living with chronic pain by Eichblat (1996):

"... it gave me a warm feeling to be involved in this process...I feel validated somehow..." (Eichblat 1996 p27 as cited in Koch 1998 p1186)

Providing the participants with 'a voice' was an important outcome in this study that was not anticipated. The realisation that this had happened in the research context, and the fact that it has been missing in the clinical context for these women was a pivotal point. It has become a driver in the formation of the recommendations to be made in the final chapter of this thesis.

I have discussed the issues in relation to the interaction between and the roles of the researcher and the researched. The researcher's role is vital in the analysis of the data and this will now be explored.

9.5 Data Analysis

I chose to transcribe and analyse the interviews manually, rather than using electronic methods of organising and interpreting the data. This was because I wanted to have the opportunity of immersing myself in the words, phrases and stories of the participants. This insightful analysis is an important part in the whole process of the analysis and presentation of the findings and is supported by Quandt and Arcury (1997). Simply relying on transcripts provided by others eliminates many of the contextual clues that guide analysis and promotes further investigation. The way the words were spoken was important as I had concern for the emotional dimension of what was being said not just the words themselves. An example of this was that participants expressed anger because they said that they were angry:

"....I would get dressed up and then I feel like a clown... just don't feel dressed...I feel untidy...that makes me angry". Heather

However, some participants expressed anger in the way that they spoke and didn't necessarily express anger as a word:

"...we are people aren't wewe are just not a pair of feet we have feeling... and sometimes ... I feel that THEY (practitioners) JUST DON'T understand....". Lily

I had concern that understanding and meaning may be lost using an electronic method and that carrying it out manually provided me with the opportunity to view the transcripts in light of the theoretical framework and my own philosophical stance. This facilitated the opportunity for new information and themes to be quickly identified.

As a researcher using an interpretive phenomenological approach I became aware of my duty not just to ensure that I had paid attention to the rigor of my research during the research process but that I would have to defend the rigor of my research in the public domain. In revisiting the literature, a critical appraisal of rigor in interpretive phenomenological research by De Wit and Ploeg (2006) concluded that the rigor and integrity of this type of research can be achieved through the use of a framework for evaluating rigor. I will now explore this framework in relation to my study.

9.6 Evaluation of Rigour

The first two aspects of this framework described by De Wit and Ploeg (2006) for evaluating rigour, relate to the process of research. The first aspect, 'balanced integration' is a concept that describes both the in-depth intertwining of the philosophy within the method and the results and also a balance between the voice of the study participants and the interpretation of their voice.

I have explored the philosophy underpinning the research method and my own philosophy in the appropriate sections of this thesis. In addition I have provided a balance between providing the reader with exemplars of the participants 'voices' and my interpretation of their narratives. In this respect I have achieved 'balanced integration'. Using exemplars as a presentation strategy allows the reader to visualise the person in the situation (Krell 1999, Benner, 1994; Malpas, 1992). It ensures that the written analysis remains an authentic interpretation of the text and that the phenomena are shown or displayed to the reader (Gadamer, 2004). Heidegger defined phenomena as 'what shows itself in itself'. By showing examples of the phenomena to the reader this allows further interpretation and understanding

of the text and the true 'authentic' nature of the experiences to be revealed (Gadamer, 1989). Hággman-Laitila, (1999) suggests that the provision of these examples also supports the trustworthiness of the findings.

Another important factor supporting the trustworthiness of this study is that debriefing was carried out with supervisors and advisors who were well informed about the subject matter and the research approach. The various aspects of the data collection method were debated at length with exploration of the underpinning personal philosophical beliefs and the influences that shaped them. Discussion about the interpretation of the text, the choice of exemplars and the organisation and interpretation of the data further added to the trustworthiness of the data (Hággman-Laitila 1999, Corben 1999). Utilising periods away from the fieldwork for reflection and consultation with peers helped to maintain a focus on the quality issues associated with this research (Britten et al 1995).

9.7 Research outcome

With respect to the research outcome, the expressions of rigor (Dewit and Ploeg 2006) are 'concreteness', 'resonance' and 'actualisation'. 'Concreteness' is an expression of rigor that is demonstrated through the writing of the results that allow the reader to sinuate what they are reading about the phenomena to their own experiences of the world. 'Resonance' is about how the expressions of the participants invoke similar feelings in those reading it. This enables a 'grasp' of what the experience is like and further enhances the ability of the reader to enter the world of the participant. Koch (1998) also identifies this as being an important aspect of interpretive phenomenological research in that, patient stories:

"...are spurs to the imagination, and through our imaginative participation in the created worlds, empathic forms of understanding are advanced." (p 1183 Koch 1998)

This empathy and understanding does not end with the conclusion of the study. 'Actualisation', as described by Dewit and Ploeg (2006) is when the study does not

end but continues to be interpreted by and influence readers in the future. Evaluation of the achievement of these three aspects can only be done through conferring with the readers of this work initially such as peers and project supervisors and later through the readers of work published in the public domain.

The methods employed to ensure rigor deal mostly with issues to do with the method and presentation of the findings. In respect to the philosophical underpinnings of this study, it has to be remembered that:

"...there is no single, timeless truth existing 'out there' independent of particular perspective or method waiting to be discovered by means of scientific procedures..." (Grenz 1996 p106 as cited in Koch 1998)

The ontological concept of 'being in the world' (Gadamer 1989) can only apply to the present so what has happened in the past is contaminated by influences that have occurred since the event. As Koch (1998) succinctly states:

"...Because we stand in the world we can never escape our historical context..." (Koch 1998 p 1188)

Therefore, we live in a world of competing interpretations based on the historical context and the present reality. We also have a shared reality of the world we live in, the experiences and emotions that we have. Because of this we can experience a fusion of horizons at the intersection between the participant and the researcher. Through the process of acknowledging this and comparing the similarities and differences of the participants and the researchers' experiences, the interpreter of this research engages in a hermeneutic process. This process has been described as a 'conversation' between both past and present experiences by Grenz (1996 as cited in Koch 1998), with the research being an interaction between a historically produced text and a historically produced researcher. Within this process the researcher and the researched move between their backgrounds of shared meaning to a more focussed understanding. This process is important in order that the reader understands the origins of the recommendations made within this thesis.

The culmination of this thesis will provide a number of recommendations for clinical practice and for further research. This post doctoral research has emerged as a direct result of the study contained in this thesis but also from the development of my research skills and confidence in my own philosophical stance as a researcher. This journey has changed me as a person, a practitioner and as a researcher. Therefore, before I make final recommendations I consider it timely to reflect on this journey.

9.8 A Reflective account of the researchers 'Journey'.

I will now consider how my knowledge, philosophical stance and thoughts have developed and matured through the process of producing this thesis.

Coming from a positivistic background, I was entrenched in the systematic and methodological processes that quantitative research approaches demand. This focus on the methodological issues resulted in a preoccupation with an attempt to apply positivistic principles to my research approach. This resulted in a distraction of, for example, considering random selection of participants without considering whether this was necessary or appropriate to my research area. The driver for this was that I knew that I would have to defend my work to an audience entrenched in the positivistic paradigm. This audience, which elevates quantitative methodology to the pinnacle of the 'quality triangle', may well view interpretive qualitative studies as being less worthy and:

"...being at best an interesting adjunct to real science and at worst nothing more than 'subjective' musings or simply anecdotal."

(Hale et al 2007 p140)

Following the numerous discussions with my research supervisors and an exploration of the literature on the various philosophical approaches to research, I realised that an overly mechanistic data collection could prevent the discovery of the hidden and subtle meanings in the data. The planning of the methodological aspects of this study was like the beginning of a journey in which:

"... I was naïve. I didn't yet know that the answers vanish as one continues to travel, that there is further complexity, that there are more inter-relationships and more questions" Kaplan (1996 page 146)

The above quote by Kaplan (1996), describes how I felt at the beginning of the study. Once I had let go of my positivistic background and desire for objectivity, I discovered the excitement that an exploration of qualitative approaches can invoke. I was no longer confined by the strict and objective 'rules' and a journey of discovery into the reality of the patients' world had begun.

Following a review of the literature associated with qualitative approaches, the discovery of the inter-relationships, complexities and the emergence of further questions, convinced me that this approach was the right one for this area of investigation. However, my pursuit of a 'method' then became another distraction. As Koch and Harrington (1998) identify, the attraction of this for new researchers is that 'method' comes with rules to follow and therefore makes the research endeavour a safer endeavour.

With my focus being on the methods of data collection and much less on the underpinning philosophy and indeed, my own developing philosophy, this resulted in a period of confusion and dissatisfaction. However, I then spent some time exploring the work of the main writers who had influenced qualitative research (Kant 1781, Comte 1853, Dilthey 1883, Heidegger 1927, Husserl 1931, Gadamer 1989) and then examined how my beliefs aligned with theirs (Heidegger 1927, Gadamer 1989). This was a pivotal time during the preparation work for this study. I felt that I was now getting to grips with both the ontological and epistemological underpinning for my research and that this aligned with the interpretive phenomenological paradigm. I felt more confident that I would be able to defend my approach to this research with the passion and confidence that this had invoked in me as a researcher. This confidence was further reinforced by the writings of Willis (2007). Willis identifies that it is important to adhere to one paradigm and then this drives the research without compromising its philosophical underpinnings or research approach or method, whilst acknowledging that there is some flexibility in choice of data collection and data analysis tools.

The specific quality issues to do with the methods of collecting and analysing the data have been discussed but one of the most important general issues is whether the findings of a study are worth paying attention to (Denzin and Lincoln 1994). Patient compliance with therapeutic footwear has received attention from previous researchers (Fisher and McClellan 1989, Herold and Palmer 1992, Stewart 1996, Fransen and Edmonds 1997, Baker and Leatherdale 1999, Williams and Meacher 2001, Emery and Borthwick 2002) and authors of reports (Disabled Living Foundation 1991, Bowker et al 1996) who have both sought to identify the problem and make recommendations for service organisation and footwear design. Despite this level of research activity, improvements in footwear design (Williams and Nester 2006) and in the service (Williams and Meacher 2001, Emery and Borthwick 2002, Helliwell 2003) there has remained a persistent problem of patient dissatisfaction and low usage of this footwear. So, this problem area has been worthy of further attention using an alternative research approach. Eisner (1997) called this 'worthiness', 'instrument utility' or 'usefulness' and suggested that this is the most important test for a qualitative study. The usefulness may be that:

"...A study may help us understand a situation that would otherwise be enigmatic or confusing...," (Eisner 1997 p58)

or assist in understanding people's past experiences better. Eisner also uses an analogy to describe the advantages of this approach in that:

"Guides, more than maps, are closely associated with the utilities of qualitative studies. Unlike maps, qualitative studies are general, they are not mathematically scaled to match the territory, and they are more interpretive and narrative......guides call our attention to aspects of the situation or place we might otherwise miss." (Eisner 1997 p59)

Therefore, an interpretive phenomenological approach has provided an exploratory 'guide' that has allowed me to travel much further into the complex jungle of this particular subject area. This journey into the participants' experiences has revealed more about known areas and more importantly has discovered new areas that to

date have not been discovered. I will now summarise with an overall conclusion and make recommendations for future research and clinical practice.

CHAPTER 10

CONCLUSION AND RECOMMENDATIONS

CHAPTER 10 - CONCLUSION AND RECOMMENDATIONS

10.1 Concluding messages

To provide clarity as to how I have fulfilled the purpose of this work, I will now focus on the key areas and messages that are the culmination of this thesis.

The approach adopted in this study has allowed the participants to acquire a 'voice' regarding their experiences of therapeutic footwear and has also revealed their opinions as to what would have improved their experience. This 'voice' has revealed that therapeutic footwear, unlike any other intervention replaces something that is normally worn and is part of an individual's body image. In contrast to the male participants, this footwear has an impact on the women's identities in respect of their perception of themselves, how they appear to others and in the roles that they have to perform. It impacts significantly on their ability and desire to fulfil a social role, where it is important to look and feel as a woman. The footwear has the potential to invoke and then reinforce the negative emotions such as sadness and anger, already felt by these women. These negative emotions contribute to their poor perception of 'self' and how they believe that people view them. In addition to the emotions expressed, the women used the term 'bad' in respect of themselves and the footwear. The feeling of being 'bad' impacts on their ability to have a 'voice' and maintains the balance of power during the consultation with the practitioner.

Lack of demonstrable empathy with these women by the practitioners and not being perceived as listening to them contributes to the powerlessness that these women feel. This is in conflict with the current ethos of the NHS (DoH 2006). The DoH supports the notion that patients should have a voice and that the balance of power in the practitioner-patient relationship with regards to decision making should be with the patient. One of the fundamental issues that has emerged from this research is that footwear has a dual role. To the women it is something to be worn as part of body image and sexuality, but to the male practitioners it is a health intervention that has specific clinical goals and outcomes. When these goals are not achieved the women are labelled as non- compliant. This non-compliance could be called 'bad'

behaviour and this is further illuminated by the guilt that these women feel when they don't chose to wear the footwear.

Non-compliance was identified by the practitioners as behaviour in these women, but the reasons that contributed to this were mainly to do with the configuration of the service such as lack of time for the consultation and contracting arrangements limiting the practitioners' choices. However, they did identify and acknowledge that effective communication skills are important during the consultation.

The patients' consultation with both the referring practitioner and the dispensing practitioner are pivotal moments that have the potential to influence whether the patients chose to wear the footwear or not. If a more patient centred approach is adopted in all aspects of the referral and dispensing process, we can then evaluate whether more patients chose to be referred for this footwear, and chose to wear it. Further to this aspect, consideration for the social requirements of this footwear in addition to the clinical goals should be considered by everyone involved in the provision of this footwear. These include the practitioners, the footwear manufacturers, the service that funds the footwear and the policy makers that define both the design of this footwear and where this footwear is supplied.

A qualitative approach to this problem area has provided both a deeper understanding from the female 'users' perspective and this has provided some key findings that have the potential to influence both future research and practice. Despite being considered a neophyte research approach within the professions of podiatry and orthotics, it has provided an opportunity to seek and obtain the answers that were previously elusive to practitioners and researchers alike. The change in ethos of clinical practice in these professions from the medical model of care to a more holistic approach may be the driver for qualitative research approaches to become more prominent. Additionally, it is now considered vital to involve users in the development of research themes and proposals (MRC 2000). There should be no hierarchy of importance in the value of different research methods and approaches. They are all valuable, and 'blended' together can provide answers to the complex questions and problems that emerge from clinical practice. Once this is accepted, we will have a greater confidence that we are providing the 'right things, to

the right patients, in the right way', thereby ensuring that they have the right experience and the right health outcome.

10.2 Key points

- Therapeutic footwear impacts on women's perception of their bodies and their feelings and emotions much more than previously acknowledged, even in those who are considered as 'satisfied' with this footwear. This influences their activities, particularly social activities more than previously considered.
- There is conflict in the perceptions of these women and the practitioner as to the role of the footwear. In effect it has a dual role. To the women it is something to wear and to the practitioner it is a medical intervention. There is acknowledgement by these women that the footwear should improve their foot health but there is a desire for it to be visibly acceptable. The achievement of this was considered difficult or even impossible in this patient group by the practitioners.
- Despite the participants of this study being recognised by the service that provides the footwear as being 'satisfied' there were aspects of the footwear and the consultation with which they were not 'satisfied'. However, the participants were 'grateful' and perhaps this gratefulness is what the traditional satisfaction questionnaires measured. Therefore, patient 'dissatisfaction' has been grossly under reported in previous studies. The involvement of users in both footwear design and service provision may result in changes that will meet the patients' expectations and improve the patients feeling of being satisfied.
- Being understood and being able to voice their opinion has the potential to increase the patients feeling of importance during the consultation. This feeling may shift the balance of power from the practitioner to the patient in the development of a 'concordant' relationship. The patients 'voice' has the potential to reveal to the practitioner the factors that need considering in the provision of this footwear. Consideration of these factors may positively influence the patients choice to wear

the therapeutic footwear in an appropriate way to maximise the opportunity for improved foot health.

The practitioners focussed on the medical problems of the participants rather than
the impact of these on their emotions, their needs and their roles. The training of
practitioners in a more patient focussed consultation style may improve the patients
experience and engagement in the footwear as an intervention as well as something
that is 'worn'.

These key messages will now be expanded on in respect of making recommendations for further research. These research ideas are as a result of the work contained in this thesis and will be carried out as post-doctoral research. However, there are some recommendations that have the potential to influence clinical practice in a relatively short time scale.

10.3 Recommendations for clinical practice

Practitioners need to acknowledge that therapeutic footwear has a dual role. Despite it being a therapeutic intervention, it remains an item of clothing and hence part of the patient's perception of themselves. All the practitioners involved in the process of referral and supply of this footwear should demonstrate empathy and an understanding of the effect of this footwear on the individual emotionally.

The referring practitioners need have an understanding of how foot problems impact on an individual with regard to their appearance as well as function. A discussion with the patient of the limitations of this footwear in respect of its appearance prepares the patient for making an informed choice as to whether to be referred or not. In the case of a patient rejecting footwear, options such as foot surgery should be explored.

The dispensing practitioners need to discuss the therapeutic aims of the footwear with the patient before the footwear is ordered. This discussion with the patient

needs to include the possibility of negotiation and compromise as to the design of the footwear and when it is used. To enable this to occur, the development of a concordant relationship needs to be established. This consultation style and effective consultation skills should be integrated into undergraduate and postgraduate training for all practitioners involved in the provision of specialist footwear and to patients. Involving people with chronic diseases in some of the education on specific diseases, for example rheumatoid arthritis may improve the practitioner's understanding of the disorder and its impact on the individual in the training environment.

There is a need for the development of a defined care pathway that is patient focussed from the outset so that choices and decision are made before the patient is referred to the dispensing practitioner. Medical consultants and their teams should be provided with education into this area particularly those working with the patients who require this footwear, such as in rheumatology and diabetes clinics.

An understanding by the service providers, that the process of assessing, measuring and fitting therapeutic footwear is a complex process that requires an appropriate amount of time. Time is required for the practitioners to listen to the patients in respect of their needs and expectations and then to communicate an understanding of this back to the patient. This holistic approach will enable the practitioners to understand the complexity of the problems and associated emotions that these patients experience. Not only should this patient focussed approach support the development of a good relationship with the patient and improve the practitioners' experience but achieve both clinical and patient focussed outcomes. Once it is recognised that footwear is a complex intervention that requires time to provide, then it will not be relegated to the 'Cinderella service' as it was described by Bowker et al (1992).

10.4 Recommendations for further research

Several questions and further research ideas have emerged from this thesis that will be pursued as post doctoral research. The three main areas are the;

- consultation between the patient and the practitioner,
- design of the footwear and
- service model / location that supplies the footwear.

While the concept of concordance ties in with current moves to 'patient centeredness' in the NHS, the benefits of this in relation to the rapeutic footwear provision needs to be evaluated. In this context, four main questions emerge:

- What are the influences on the practitioners' consultation style?
- What are the components of a 'gold standard' consultation from both the practitioner's and patient's perspective?
- Does an effective consultation in the context of therapeutic footwear necessarily lead to improved foot and general health?
- Can patients be provided with a 'preferences' tool that would facilitate information giving and information gathering during the consultation?

Knowing what the influences are on the practitioners' consultation style and what both they and the patients consider to be the components of a gold standard consultation are the starting point for identifying where changes need to be made. These changes can potentially be addressed in the undergraduate education of these practitioners. This could be further supported with consultation techniques being embedded in the formal adoption of reflective practice by these practitioners. Once an effective consultation style is identified and embedded in clinical practice we can then evaluate if it improves the patients experience and impacts on improved foot and general health. With regard to the choices that patients should be making, a footwear preferences tool could be developed to enable the patient to communicate what they think they need and what their preferences are before they enter into the consultation with the dispensing practitioner. This tool could then be evaluated in respect of both the patient's and practitioner's perspective and the clinical outcomes.

The design of the footwear is generally based on the specific clinical requirements of this footwear in relation to foot protection, foot function and foot health. This has resulted in designs that focus on fitting criteria rather than the aesthetics of the footwear. In recent years there have been improvements in the design features of the footwear which, the manufacturers claim make it less obviously visible as therapeutic footwear. However, the women in this study have revealed that that this footwear is still visible as being different and would not be their footwear of choice. Apart from one study (Williams and Nester 2006), the patients opinions and suggestions for the design of this footwear have not been explored. Improvements in design that take on board the users requirements together with modern manufacturing techniques and advances in the materials used in the construction of retail footwear, there is potential to exploit these in therapeutic footwear manufacture. The specific questions that have emerged in relation to the footwear itself are:

- Can retail design features be incorporated into the design of therapeutic footwear?
- How do the specific fitting features of this footwear relate to improvements in foot protection, foot function and foot health?
- Can new materials and designs improve the appearance of the footwear to an extent that the patients chose to wear it?
- Can new designs incorporating the clinical (fitting) requirements with the patients (design) requirements achieve the reported clinical benefits of existing therapeutic footwear designs?

Having the right footwear designs that meet the requirements of the clinician and the patient may be the crucial factor in influencing the patients' acceptance and experience of wearing this footwear. The consultation with the practitioner and the footwear itself, have been issues revealed by the participants of this study.

Although the setting in which, the footwear is provided was not mentioned by the participants of this study, I have reflected on all of the potential influences on the patients' experiences and this additional factor has emerged from these thoughts. In the retail context, the experience of purchasing footwear is very different to receiving it in a clinical context. The environment is different in that the variety of footwear designs are available to see, feel and try on. This allows the 'purchaser' of this footwear to make choices on design and fit, usually in a comfortable environment where they take as much time as is required to make the decision to purchase the footwear. Two questions arise in relation to this aspect;

- What are the patients' thoughts of the environment that this footwear is provided in?
- Would the patient experience be enhanced if this footwear was provided through a service that incorporated some of the features normally associated with the retail environment?

Having identified further research questions in relation to the areas of the consultation, the design of the footwear and the service that supplies the footwear, it is possible that these could become discrete studies in themselves. These questions have emerged from my research and I consider them as important as the findings of the study. This importance is in respect of how further research has the potential to provide more answers. However, for this research to influence practice and improve the patient experience, the results of this research have to be taken on board by the manufacturers, the practitioners and the service providers. To effectively instigate change in this area will not be as simple as informing them of the findings and recommendations from this research. As my ultimate purpose in carrying out this research was to influence change and improve the experiences of patients in this area, I need to explore ways of instigating change. The factors that make change happen are that the people involved in that change need to identify the problems themselves, but most importantly agree their own solutions. The importance of these factors in achieving change is supported by authors such as Scott et al (2003).

Therefore, as post-doctoral research, I propose to utilise a 'world café' research approach that will enable the exploration of this area by the people involved in it. This approach is supported by the philosophical components of an action research methodology that involves problem solving and change management in the natural setting. As Willis (2007) identifies, the researcher gives up some control in order to do this research in the natural (in this instance, clinical) setting with the focus being the identification of solutions to the practical problems. The process of action research is participatory and collaborative in that the participants are involved in the design, execution and analysis of the study. As described by Grundy and Kemmis (1982 as cited in Grundy (1988) pg 267):

"... In action research, all actors involved in the research process are equal partners, and must be involved in every stage of the research process..."

In addition to the users of the footwear and the practitioners involved in supplying it, I suggest that in addition to these two main stakeholders, representatives from the footwear industry, referring practitioners and service managers are included. This planned research builds on what I have already discovered from the work contained in this thesis and will maximise the opportunity for implementing change in this area to the benefit of the users of this footwear.

10.6 Overall Conclusion of the thesis

The completion of the work required for this thesis and the research contained in it has been crucial in enhancing my knowledge and developing thoughts on the complex aspects of therapeutic footwear as a health intervention. In addition, I have developed a deeper understanding of the influences on health behaviour and how these transpose to behaviour with footwear. Further to this acquisition of knowledge and the development of a deeper understanding, I now have clarity as to how the influences on me as a person, a clinician and as a researcher have formed my current 'world view'.

This 'world view 'and the beliefs associated with it have aligned with the interpretive phenomenologists. In this respect, I have experienced, for the first time, the use of an interpretivist method of data collection and data analysis. The exploration of the underpinning philosophies of the various research approaches has revealed not only the methods of which, I had no previous knowledge or experience of, but also a different way of thinking about research as a scholarly activity. These thoughts have emerged through reading the literature and texts associated with this area but also through debate with my academic supervisors, advisors, and colleagues. As this thesis is the culmination of a personal journey, I will return to an extract from the work of Kaplan (1996), who describes himself at the beginning of his own journey:

"... I was naïve. I didn't yet know that the answers vanish as one continues to travel, that there is further complexity, that there are more inter-relationships and more questions" Kaplan (1996 page 146)

Kaplan's thoughts express how I felt at the beginning of this work and at certain points throughout. I feel that I have achieved the aim of the research embedded in this thesis, which was to discover the users' experiences of being provided with and wearing therapeutic footwear.

These experiences involve a complexity of factors that I have been able to both identify and understand the inter-relationships of these factors. I have discovered some of the answers that are vital for the development of further research and also have the potential to influence practice by dissemination through publication and conference presentations. The planned post-doctoral research will further enhance the opportunity of instigating changes in practice thereby achieving the ultimate aim of improving the users' experience of this footwear, their engagement with it and therefore achieve the desired benefits of improved symptoms, foot health and overall quality of life.

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APPENDIX I

PARTICPANT LETTER AND INFORMATION SHEET

Anita Williams Directorate of Podiatry University of Salford Frederick Road Salford M6 6PU



0161 295 7027

date

Dear Patient

Re: An investigation into users experiences of prescribed therapeutic footwear

You are being invited to take part in this research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to consider you involvement in this research and decide whether or not you wish to take part. It would be helpful if you would contact the researcher, Anita Williams within two weeks from the date you are given this information

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| Thank you for reading the attached information. |
| Yours Faithfully |
| Anita Williams |

PATIENT INFORMATION SHEET

Study title:

An investigation into users' experiences of prescribed therapeutic footwear

1. What is the purpose of the study?

There is known to be a problem with low usage and patient dissatisfaction with prescribed therapeutic footwear which is provided by the National Health Service. Previous studies have suggested that there are several possible reasons for the low usage and patient dissatisfaction with this footwear. Both the quality of the footwear and the service which provides it has been identified as potential problems. However no one has looked at all of these issues from the patient's perspective and how these issues can influence the patient's choice to use the footwear.

The purpose of the study is to investigate these factors from the patient's perspective in an attempt to ultimately improve the patient's experience of being provided with and use of this footwear. This study is for an academic piece of work for a PhD thesis. The researcher (Anita Williams) is a lecturer and part time PhD student at the University of Salford. She has worked for the NHS previously and has extensive experience in foot problems and footwear.

2. Why have I been chosen?

You have been chosen because you have had experience of being provided with prescribed therapeutic footwear from the Appliance Department or Orthotic Service at your local hospital.

3. Do I have to take part?

Taking part in the research is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

4. What will happen to me if I take part?

You will be contacted by the researcher whose details appear at the end of this information sheet. She will arrange to visit you at home. The time and day will be entirely to suit your own commitments but the study will take part between October 2005 and October 2006. You will be interviewed by the researcher about your experiences of being provided with footwear through the hospital. The interview will take no longer than one hour and thirty mins, unless you chose to discuss your experiences for longer, in which case this time can be extended or the researcher will arrange to see you again. The interview will be recorded on a digital recorder If you wish to keep the original recording of the interview you will be given a copy at the end of the study. If you do not wish to keep it the recording will be destroyed.

5. What are the possible disadvantages and risks of taking part?

If you have had a bad experience of being provided with this type of footwear you may feel angry or upset. The researcher carrying out the interview is sensitive to your wishes and if you feel that you do not wish to continue with the interview it will be stopped and you will have the opportunity to withdraw from the study completely

6. What are the possible benefits of taking part?

The benefits may be that the study will ultimately improve the patient's experience of being provided with NHS footwear and if you have had a bad experience, may feel better taking to the researcher about it

7. Will my taking part in this study be kept confidential?

All information which is collected during the interviews and group work will be kept strictly confidential. Any information about you will have your name and address removed so that you cannot be recognised from it.

8. What will happen to the results of the research study?

Once the research is complete the work will be published in professional journals and a report written for the hospitals involved. A summary of this report will be sent to you for your own information. The patients who have contributed to the study will not be mentioned by name in any paper, report or presentation at conferences. You may be asked by the researcher if it is permissible to photograph your feet and/or your footwear. If you do not wish for this to happen then you can refuse. The photographs will be used only in presentations of this research or in publications in scientific or medical journals.

9. Contact for Further Information

Anita Williams
University of Salford,
Directorate of Podiatry,
Frederick Road,
Salford M6 6PU

0161 295 7027 a.e.williams1@salford.ac.uk

If you agree to take part in the study you will be asked to sign a form (example attached) where you give your consent (written agreement) to taking part in the study. This does not mean than you cannot withdraw at any time if you so wish. You will be provided with a copy of the consent sheet which you sign. Thank you for reading this Information sheet and considering your inclusion in this study

Anita Williams (Researcher)

APPENDIX II PARTICIPANT CONSENT FORM

Centre Number: Patient Identification Number for this trial:



CONSENT FORM

Study Title: An investigation into users experiences of prescribed therapeutic footwear

Name of Researcher: Anita Williams

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| | I confirm that I have read and uthe above study and have had the | | dated 24/09/05 | rsion 2) for |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|----------------|---------------|
| | I understand that my participati without giving any reason, with | on is voluntary and that I am free out my medical care or legal right | | ne |
| 3. | I understand that the interview will be listened to by the researcher responding to the permission for the research 4. I agree to take part in the above | onsible for this study er to have access to the tape rec | - | |
| | Name of Patient | Signature | Date | |
| | Name of Person taking consent (if different from researcher) | Signature | Date | |
| | Researcher | | Date | Signature |

1 copy for patient; 1 for researcher; 1 to be kept with hospital notes

APPENDIX III

PRACTITIONER LETTER AND INFORMATION SHEET

Anita Williams
Directorate of Podiatry
University of Salford
Frederick Road
Salford M6 6PU

0161 295 7027

date



Dear

Re: An investigation into patients experiences of prescribed therapeutic footwear

You are being invited to take part in this research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Please contact me if there is anything that is not clear or if you would like more information. Take time to consider you involvement in this research and decide whether or not you wish to take part. It would be helpful if you would contact the researcher, Anita Williams within two weeks from the date you are given this information

Thank you for reading the attached information.

Yours Faithfully

Anita Williams



PRACTITIONER INFORMATION SHEET

Study title:

An investigation into users' experiences of prescribed therapeutic footwear

1. What is the purpose of the study?

There is known to be a problem with low usage and patient dissatisfaction with prescribed therapeutic footwear which is provided by the National Health Service

Previous studies have suggested that there are several possible reasons for the low usage and patient dissatisfaction with this footwear. Both the quality of the footwear and the service which provides it has been identified as potential problems. However no one has looked at all of these issues from the patient's perspective and how these issues can influence the patient's choice to use the footwear.

The purpose of the study is to investigate these factors both from the patient's and practitioner's perspective in an attempt to ultimately improve the patient's experience of being provided with and use of this type of footwear.

This study is for an academic piece of work for a PhD thesis. The researcher (Anita Williams) is a lecturer and part time PhD student at the University of Salford. She has worked for the NHS previously and has extensive experience in foot problems and footwear.

2. Why have I been chosen?

You have been chosen because you are a practitioner who provides the footwear to patients

3. Do I have to take part?

Taking part in the research is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your role as a practitioner within the Appliance/Orthotic Service

4. What will happen to me if I take part?

You will be contacted by the researcher whose details appear at the end of this information sheet. She will arrange to visit you at a time and day which fits in with your own commitments. The study will take part between October 2005 and October 2006.

You will be asked to listen to some recordings of patients stories about their footwear experiences and will also view the written transcripts from these recordings. You will then be asked to highlight issues that you think are important and then your opinions about the transcripts and recordings will be sought.

5. What are the possible benefits of taking part?

The benefits may be that the study will ultimately improve the patient's experience of being provided with NHS footwear and the possibility that this research will influence your clinical practice.

6. Will my taking part in this study be kept confidential?

All information which is collected during this work will be kept strictly confidential. Any information about you will have your name and address removed so that you cannot be recognised.

7. What will happen to the results of the research study?

Once the research is complete the work will be published in professional journals and a report written for the hospitals involved. A summary of this report will be sent to you for your own information. The patients or practitioners who have contributed to the study will not be mentioned by name in any paper, report or presentation at conferences.

8. Contact for Further Information

Anita Williams
University of Salford,
Directorate of Podiatry,
Frederick Road,
Salford M6 6PU

0161 295 7027

a.e.williams1@salford.ac.uk

If you agree to take part in the study you will be asked to sign a form (example attached) where you give your consent (written agreement) to taking part in the study. This does not mean than you cannot withdraw if you so wish at any time. You will be provided with a copy of the signed consent sheet Thank you for reading this Information sheet and considering your inclusion in this study Anita Williams (Researcher)

APPENDIX IV PRACTITIONER CONSENT FORM

WERSING OF WALFORD

Centre Number:
Patient Identification Number for this trial:

CONSENT FORM

 $\textbf{Study Title:} \ \textbf{An investigation into users' experiences of prescribed the rapeutic footwear}$

Name of Researcher: Anita Williams

| | Please initial box | | | | |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|------|--|--|
| | I. I confirm that I have read and understand the information sheet dated 24/9//05 (version 2) for the above study and have had the opportunity to ask questions. | | | | |
| | 2. I understand that my participati without giving any reason, with | on is voluntary and that I am free out my medical care or legal righ | | | |
| 3. | I understand that the results of this study will be used for presentations and publications | | | | |
| | 4. I agree to take part in the above | e study. | | | |
| | Name of Patient | Signature | Date | | |
| | Name of Person taking consent (if different from researcher) | Signature | Date | | |
| | Researcher | Signature | Date | | |

1 copy or participant; 1 for researcher;