Usability of custom-made orthopaedic shoes

in patients with degenerative disorders of the foot

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CONTENTS

CHAPTER 1

Introduction and outline of the thesis

1.1 INTRODUCTION

The human foot is a complex structure designed for standing, and walking which can be labelled as the basic elements of activities of daily life e.g. sports, work, and household chores. Even though the foot can be stated as the basis of the human body, it is also very vulnerable. In the Netherlands it is estimated that about 200,000 people per year consult their general practitioner because of foot complaints not attributable to an accident[1 2]. Surveys have reported a 10-24 % prevalence of self-reported foot abnormalities in adults, with the highest rates being found in women and in people of 65 years of age and older[1-3] . A lot of these foot complaints are the result of degenerative changes of the foot. Degenerative disorders of the foot are defined in this thesis as: “a foot with anatomical abnormalities and disorders as a consequence of a biomechanical disbalance, which lead to primary arthrosis deformans of one or more joints of the ankle and/or foot region and/or chronic inflammation of peri-articular structures”. As a consequence of these abnormalities pain and very often callus occur.

Today, serious degenerative disorders of the foot are treated both surgically and by orthopaedic shoes. Many different surgical techniques (for different anatomical parts of the foot) have been introduced during time. For example, more than 100 techniques have been introduced for correction of hallux valgus[4 5]. In uncontrolled case series, good clinical results have been reported in 80% to 90% of patients who have undergone surgery[6 7]. From an historical point of view, orthopaedic shoes were developed to treat the casualties of the world wars. As a consequence of several foot injuries normal shoes were adapted or custom made shoes were fabricated for these deformed feet[8]. Many aspects regarding material and construction of orthopaedic shoes for different foot problems have improved since.

This thesis focuses on custom-made orthopaedic shoes used to treat degenerative disorders of the foot. In general, clinicians and orthopaedic shoe technicians aim at redistributing plantar pressure over the plantar surface by means of orthopaedic shoes or shoe adaptations. Supported by a broad

variety of technical tools (e.g. Harris mat, podobarograph, or plantar pressure measurement systems), clinicians and orthopaedic shoe technicians try to get a better understanding of the distribution of the plantar pressure. At the moment, the relationship between plantar pressure and foot complaints is not clear[9].

Unfortunately, it is known in clinical practice that there is considerable non-use of the orthopaedic shoes and shoe inserts provided varying from 8% to 75% [10-16]. However, the exact amount of non-use of orthopaedic shoes in the Netherlands is not clear, also no overview is available regarding the extent to which orthopaedic shoes are evaluated and by which measurements. The treatment of degenerative disorders of the foot is still mainly based on clinical evidence and 'trial and error' and only limited on evidence based medicine. No clear evidence is available regarding associations between usability factors and actual use of orthopaedic shoes, nor can future use be predicted by rehabilitation specialists and orthopaedic shoe technicians.

The definition of usability as stated by the International Organisation for Standardisation (ISO) forms the framework for this research project. Within the ISO, usability is defined as: "the extent to which a product can be used by specific users to achieve goals with effectiveness, efficiency, and satisfaction in a specified context of use"[17 18]. This definition has it's origin in the information and communication technology in which it was used to develop computer systems. Soon after, this concept was also used to develop every day products used in general populations. Nowadays it is more and more widely recognised that the growing number of older people and people with disabilities require special needs in product design[19]. Usability of rehabilitation devices has been identified as one important factor in enabling older people and people with disabilities to continue to be independent and to profit from (rehabilitation) technologies.

The main aim of this thesis is to gain a better understanding of the associations between usability factors (effectiveness, efficiency, satisfaction, and context of use) and the actual use of custom-made orthopaedic shoes in

patients with degenerative disorders of the foot. The main research questions answered in this thesis are:

1. Which usability factors (effectiveness, efficiency, satisfaction, and context of use) are associated with actual use of custom-made orthopaedic shoes?
2. Can actual use be predicted by usability factors and personality factors?
3. What is the relationship between plantar pressure parameters and foot pain in patients with degenerative disorders of the foot?

1.2 OUTLINE OF THE THESIS

In chapter 2 a systematic review was described to determine the methodological quality of studies evaluating orthopaedic shoes and orthopaedic shoe provisions. The second aim of this systematic review was to gain a better understanding to what extent evaluation studies regarding orthopaedic shoes, prescribed for patients with degenerative disorders of the foot, rheumatoid arthritis, diabetes mellitus and neurological foot disorders, focus on the aspects of the International Organisation for Standardisation (ISO) definition of usability, i.e. effectiveness, efficiency, satisfaction, and context of use.

In these evaluation studies, more and more questionnaires are being used to establish the usability of rehabilitation technological aids. This is also the case in studies evaluating orthopaedic shoes prescribed for patients with degenerative disorders of the foot. Although several instruments currently exist to measure pain and disability associated with foot problems or to measure patient satisfaction and acceptance of rehabilitation aids, none of the above-mentioned questionnaires quantifies all aspects of the usability - effectiveness, efficiency, satisfaction and context of use - of orthopaedic shoes. Therefore we have developed a self reported questionnaire, the Questionnaire for Usability Evaluation (QUE) of orthopaedic shoes. In chapter 3 we described how the QUE was developed and assessed the reproducibility and responsiveness of the instrument. The QUE was used for the study described in the chapters 4, 5, and 6.

In chapter 4 the results are described of a multicentre, prospective cohort study. In this study the actual use of orthopaedic shoes in 100 consecutive patients with degenerative disorders of the foot was investigated. The main objective of this study was to identify usability factors which are associated with the actual use and non-use of orthopaedic shoes, based on the parameters of the ISO definition of usability: effectiveness, efficiency, satisfaction, and context of use (research question 1).

In chapter 5 we concentrated on the prediction of actual use of custom-made orthopaedic shoes (research question 2). No clinical data are available at the moment by which clinicians and orthopaedic shoe technicians can predict future use of orthopaedic shoes. If potential non-users can be identified early in the rehabilitation process, clinical decisions can be made to redirect the treatment meeting the needs of the patients. Within this study usability factors as well as psychosocial factors are studied. Although the role of those factors as determinants of device usage has been recognized, the relationship between these factors and actual use of rehabilitation devices are not well understood.

In chapter 6 we described the evaluation of the effectiveness of custom-made orthopaedic shoes, in terms of pressure and pain, in patients with degenerative disorders of the foot. Additionally, the relationship between plantar pressure parameters and foot pain was studied (research question 3).

In chapter 7, some methodological issues will be discussed, from a more general point of view. In addition, the clinical implications of our findings for the management of custom made orthopaedic shoes and it's relevance for the different stakeholders e.g. patients, medical specialists, orthopaedic shoe technicians, health insurance companies, and the (local) government will be discussed. Finally, advice for further research regarding the usability of orthopaedic shoes is described.

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CHAPTER 2

A systematic review of the methodological quality and extent to which evaluation studies measure the usability of orthopaedic shoes

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2.1 ABSTRACT

Objective: To determine the methodological quality of studies evaluating orthopaedic shoes and orthopaedic shoe provisions. To what extent do studies evaluating orthopaedic shoes, prescribed for patients with degenerative disorders of the foot, rheumatoid arthritis, diabetes mellitus and neurological foot disorders, focus on the aspects of the International Organisation for Standardisation (ISO) definition of usability, i.e. effectiveness, efficiency, satisfaction, and context of use?

Design: Systematic review

Methods: A systematic literature search was performed to identify randomized controlled trials (RCTs) concerning orthopaedic shoes and orthopaedic shoe inserts. The methodological quality of the studies was assessed independently by two raters, based on the 19 items of the "Maastricht-Amsterdam criteria list". The studies were assessed against the parameters of the ISO definition of usability.

Results: 11 RCTs were included. The methodological scores ranged from eight to 14 out of 19 possible points. 11 studies focused on the effectiveness of the orthopaedic shoes and orthopaedic shoe provisions, two of which reported outcome measures and conclusions related to the efficiency of the studied orthopaedic shoes and orthopaedic shoe provisions. Four studies reported some form of patient satisfaction and only three studies paid attention to the context of use.

Conclusions: The methodological quality of the RCTs as assessed according to the 19 different criteria, varied considerably. The present review shows that current scientific literature concerning the usability of orthopaedic shoes focuses mainly on effectiveness, at the expense of the other domains of usability, i.e. efficiency, satisfaction, and context of use.

2.2 INTRODUCTION

Foot problems are a common health problem in the general population. Epidemiological surveys show a prevalence of self-reported foot problems of 10% to 24%, with the highest rates being found in women and in those who are 65 years of age and older[12]. However, the estimated prevalence of foot problems within disease specific groups, such as patients with rheumatoid arthritis (R.A.), patients with diabetes mellitus (D.M.), and patients with neurological disorders, is much higher, ranging from 20% in early stages of the disease to 90% in late stages[3]. These foot problems may restrict ambulation, limit activities, and influence participation in daily life.

For the above-mentioned foot problems orthopaedic shoes are prescribed, especially in serious cases. Unfortunately, it is known in clinical practice that there is considerable non-use of the orthopaedic shoes and shoe inserts provided varying from 8% to 75%[4-10]. Obviously, these orthopaedic shoes and shoe inserts are not always that usable. Besides this, the amount of non-use is unsatisfactory for rehabilitation specialists and patients as well as for insurance companies because of the unnecessary costs. It is for this reason that comprehensive evaluations of orthopaedic shoes should be methodologically sound and focus on all aspects of usability. The results of studies with a poor methodological quality should be interpreted with caution because of the possible bias involved.

Usability is defined in the International Organisation for Standardisation (ISO) 9241-11 as “the extent to which a product can be used by specific users to achieve goals with effectiveness, efficiency, and satisfaction in a specified context of use”[11 12]. It was in the computer world that the term usability was first introduced. It led to a human-centred design of computer systems. Later, the definition of usability also became important in developing everyday products – i.e. consumer products, or equipment used by the general public. Nowadays it is more and more widely recognised that the growing number of older people and people with disabilities requires special needs in product design. Better usability has been identified as one important factor in enabling older people and people with disabilities to continue to be independent and to profit from (rehabilitation) technologies[13]. Within the definition of usability,

effectiveness is the accuracy and completeness with which users achieve specified goals. For example, a patient is able to walk to a supermarket without foot pain. The resources that are expended in relation to the accuracy and completeness with which users achieve goals are assessed to determine efficiency. Relevant resources may include mental or physical effort (for example, independently putting on and taking off orthopaedic shoes), time or financial costs. Satisfaction is defined as the comfort and acceptability of use, and can be assessed in terms of attitudes to using the product (for example, how do patients feel about the cosmetic appearance or measure of perspiration in their orthopaedic shoes?). Finally, the context of use refers to the physical and social environments in which a product is used[11] [12]. Measurement of usability is particularly important in view of the complexity of the interactions between the patient and his goals and the elements of the context of use, which can result in significantly different levels of usability for the same product when used in different contexts.

Insight into the usability of orthopaedic shoes, can be obtained from the results of several randomized controlled trials (RCTs) described in the literature. The objective of the present review was to address the following research questions:

1. What is the methodological quality of the studies evaluating orthopaedic shoes and orthopaedic shoe provisions?
2. To what extent do studies evaluating orthopaedic shoes, prescribed for patients with degenerative disorders of the foot, rheumatoid arthritis, diabetes mellitus and neurological foot disorders, focus on the aspects of the ISO definition of usability, i.e. effectiveness, efficiency, satisfaction, and context of use?

2.3 METHODS

This systematic review was based on an analysis of the literature on the evaluation of orthopaedic shoes and orthopaedic shoe provisions for patients with degenerative disorders of the foot, rheumatoid arthritis, diabetes mellitus and neurological foot disorders. Articles were sought in MEDLINE (1970-2002), EMBASE (1970-2002), PiCarta (1970-2002) and the database of the Cochrane Field 'Rehabilitation and Related Therapies'. PiCarta is a search-engine by means of which searches can be performed in a number of integrated databases containing bibliographic records, table of contents data and hyperlinks to full text and web pages. Currently the Dutch-Union Catalogue, NetFirst, and Online Contents are included in PiCarta (http://picarta.pica.nl).
The following keywords were used: shoe(s), footwear, insole, insert, usability, utility, usage, usefulness, effectiveness, efficiency, ease of use, comfort, (personal) satisfaction, acceptance, foot, feet, lower extremity, degenerative, osteoarthritis, diabetes mellitus, D.M., rheumatoid (arthritis), R.A. neurologic. The MEDLINE search strategy is described in Appendix 1 and is adapted to suit the other databases. In addition to this literature search, the references of relevant publications were carefully checked.

The initial selection of the articles was based on the title and the content of the abstract. The following inclusion criteria were applied by two researchers: (1) studies evaluating orthopaedic shoes and orthopaedic shoe provisions prescribed for patients with degenerative disorders of the foot, rheumatoid arthritis, diabetes mellitus and neurological foot disorders; (2) only studies designed and reported as randomized controlled trials; (3) published, full-length articles; (4) language: English, German, French or Dutch; (5) published between 1970 and 2002. This systematic review only included RCTs because these are considered to have the most robust study design with the least risk of bias in the results.
The application of these selection criteria resulted in the exclusion of studies which focused on healthy subjects, and the evaluation of orthopaedic shoes provided for people with knee, hip, or back problems. Evaluation studies in

which the effectiveness of orthopaedic shoes was determined by foot pressure measurements and gait-analysis were also excluded. In this review orthopaedic shoes are defined as custom-made orthopaedic shoes and off-the-shelf orthopaedic footwear. Orthopaedic shoe provisions refer to shoe inserts and adaptations to ordinary shoes.

The methodological quality of the selected studies was assessed independently by two raters (MJ and HvD) based on the “Maastricht-Amsterdam criteria list” for the assessment of the methodological quality of RCTs. The 19 criteria contained in this list concern patient selection, intervention, outcome measurements, and statistics[14] (see Appendix 2), and could be rated as "don't know" if the available information was unclear or insufficient. If the available information was sufficiently clear, criteria were rated as "yes", indicating adequate methods, or "no" indicating inadequate methods or potential bias. Each "yes" is scored as one point, and therefore a maximum of 19 points is possible. In case of disagreement, consensus was reached by discussion.

Studies, which fulfilled the selection criteria, were assessed against the ISO definition of usability, examined on the following four parameters: effectiveness, efficiency, satisfaction and context of use. The result of each study was summarised as either '+' (refers to a positive relationship between the study and the parameters of the ISO definition of usability) or '-' (no relationship) by the same two raters (MJ and HvD). Any disagreements were to be resolved by discussion or, if necessary, by consulting a third reviewer. An inventory was also made of the diagnostic groups (patients with degenerative disorders of the foot, R.A., D.M. or neurological disorders).

2.4 RESULTS

The systematic literature search in MEDLINE, EMBASE, PiCarta, and the database of the Cochrane Field ‘Rehabilitation and Related Therapies’ resulted in the identification of 17 RCTs, 11 of which fulfilled the selection

criteria and were included in the present review[9 10 15-23] (Table 1 and 2). Six RCTs were excluded because they focussed on healthy individuals.

The size of the experimental groups in the 11 studies ranged from 12[16] to 121 [10] patients. The number of patients included in the control groups ranged from 7[16] to 160[10]. Five studies focused on patients with the following degenerative disorders of the foot[16-19 23]: plantar heel pain syndrome[16], painful metatarsalia[17 18], proximal plantar fasciitis[19], and hallux valgus[23]. Patients with D.M. resulting in neuropathic foot ulcerations were included in four studies[10 15 20 22], and the remaining two studies included R.A. patients with foot deformities[9 21]. No studies concerning disorders of the foot arising due to disordered motor control were identified.

Six trials studied the usability of orthopaedic shoes[9 10 15 20-22], two of which compared orthopaedic shoes with 'ordinary' shoes[9 15]. Four studies compared orthopaedic shoes with alternative orthopaedic shoes containing different types of casts[20 22], or different types of inserts[10 21]. Four trials compared different types of insoles, varying in material and construction properties[16-19]. One study compared the results of treatment with the insole/cast and treatment with surgery in patients with hallux valgus[23].

As many as 10 different outcome measures were used in the five studies that assessed the usability of orthopaedic shoes for patients with degenerative disorders of the foot (see Table 1 and 2). All studies used at least 4 different outcome measures, and all studies measured the amount of pain reduction achieved by the use of orthopaedic shoes. Three studies[16 17 19] used the Foot Function Index to establish the impact of foot complaints on 'activity limitation', 'pain', and 'disability'.

Within the group of D.M. patients as many as eight different outcome measures were used to assess the usability of orthopaedic shoes. In all of these studies the incidence of foot ulcers was used as a primary outcome measure, and two studies[20 22] also measured the amount of time during which the foot ulcers decreased. As many as eight different outcome measures were used in the two studies[9 21] evaluating orthopaedic shoes prescribed for R.A. patients. Both studies measured the amount of pain reduction achieved by wearing the orthopaedic shoes and the patient's physical functioning. It was not always clear what the primary outcome measures were.

Table 1 Characteristics and methodological scores of 11 RCTs investigating the usability of orthopaedic shoes or orthopaedic shoe provisions

Study	Patients	Diagnosis	Age Mean (SD)		Intervention
			Experimental	Control	Experimental
Uccioli et al., 1995	E = 33 C = 36	D.M. / previous foot ulcerations	E = 59.6 (11)	C = 60.2 (8.2)	Therapeutic shoes (Podiabetes)
Caselli et al., 1997	E = 19 C = 15	Plantar heel pain syndrome	Total group median (range) 43 (28-59)		PPT/ Rx Firm molded insoles containing a magnetic foil
Caselli et al., 1997	E1 = 16 E2 = 12 C = 7	Painful lesser meta- tarsal keratoses	total group median (range) 42 (23 – 65)		E1=Viscoped insole E2=Poron insole
Fransen and Edmonds, 1997	E = 15 C = 15	Rheumatoid Arthritis	E = 59.1 (14.2)	C = 60.1 (8.9)	Off-the-shelf orthopaedic footwear
Kelly and Winson, 1998	E = 18 C = 15	Metatarsalgia	E = 51 (17-75)	C = 51.5 (33-81)	Bauerfiend Viscoped® Insole
Pfeffer et al., 1999	E1 = 42 E2 = 51 E3 = 50 E4 = 47 C = 46	Proximal plantar fasciitis	median (range) E1 =48.5 (23-69) E2 = 49.5 (30-75) E3 = 44 (27-69) E4 = 48 (26-76)	C = 47 (25-81)	E1=Custom orthosis E2=Silicone orthosis E3=Rubber orthosis E4=Felt orthosis
Carvaggi et al., 2000	E = 24 C = 26	Neuropatic foot ulcers	E = 59.2 (9.9)	C = 60.5 (10.7)	Therapeutic shoes

Control	Follow-up	Relevant outcome measures	Authors' conclusions
Ordinary shoes	1 year follow-up every month	Use of therapeutic shoes Incidence of foot ulcers	The use of specially designed shoes is effective in preventing relapses in diabetic patients with previous ulceration.
PPT/ Rx Firm moulded insoles without a magnetic foil	4 weeks	Foot function Pain Disability Activity restriction	The PPT/ Rx Firm molded insole is effective in treating heel pain. The magnetic foil offered no advantage.
No insole	4 weeks	Foot function Pain Disability Activity restriction	Insole therapy used after debridement of lesser metatarsal keratoses improved foot function.
No intervention	2 months	Pain Physical function Gait parameters (velocity, cadence, stride length)	The footwear group (E) improved in all measured variables. In contrast, the control group demonstrated a slight deterioration.
Langer Bleuline® Insole	8 weeks	Subjective improvement VAS pain Estimated walking distance Compliance Peak pressure	The Langer Bleuline® Insole is more efficacious (subjectively and objectively), more economical and better tolerated by patients.
C=Stretching only	8 weeks	Foot function Change in overall pain Change in pain during specific circumstances Hours spent standing	A prefabricated shoe insert, in conjunction with a stretching programme, is more likely to produce improvement in symptoms of proximal plantar fasciitis.
Total off-loading cast made with fibreglass	30 days	Ulcer area Time reduction ulcer area Number of ulcers healed Side-effects Patient acceptance	Significance difference in reduction speed of neuropatic ulcers treated with fibreglass cast The elimination of side-effects and high patient acceptance.

Table 1 Continued

Study	Patients	Diagnosis	Age Mean (SD)		Intervention
			Experimental	Control	Experimental
Chalmers et al. 2000	E = 24 C = 24	R.A. / MTP metatarsalgia	men: 63 (2) women: 60 (10)		Cross-over design E1= Supportive shoe E2= Supportive shoe, soft orthoses E3= Supportive shoe, semi- rigid orthoses
Armstrong et al., 2001	E1 = 19 E2 = 20 E3 = 24	D.M. neuropathic foot ulcerations	E1 = ? E2 = ? E3 = ?		E1 = Total –contact cast E2 = Removable cast walkers E3 = Half shoes
Torkki et al.2001	E1 = 71 E2 =69 C = 69	Hallux valgus	E1 = 48 (10) E2 = 49 (10)	C = 47 (9)	E1 = Surgery E2 = Orthosis
Reiber et al., 2002	E1= 121 E2= 119 C=160	D.M. / foot ulceration	E1 = 61 (10.1) E2 = 62 (10.1)	C = 63 (10.0)	E1 = Therapeutic shoes, cork inserts E2 = Therapeutic shoes, pre-fabricated inserts

	Follow-up	Relevant outcome measures	Authors' conclusions
Control			
	12 weeks per intervention	VAS pain VAS treatment effectiveness Lower extremity joint synovitis Lower extremity function Treatment preference Daily wearing time Material compression	Semi-rigid orthoses worn in supportive shoes is an effective treatment for metatarsalgia. Supportive shoes alone or with soft orthoses did not provide pain relief for metatarsalgia.
	12 weeks/ or wound healing	Proportion of wound healing Wound healing as function of weeks Activity level Comfort	The total-contact cast seems to heal a higher proportion of wounds in a shorter amount of time.
C = waiting list	Evaluation 6 and 12 months after intervention	Duration of foot pain Pain intensity during walking (VAS) Patient assessment global improvement No. of painful days Cosmetic disturbance Footwear problems Functional status Treatment satisfaction Ability to work Costs Assessment	Surgical osteotomy is an effective treatment for painful hallux valgus. Orthoses provide short-term symptomatic relief.
	3, 6, 12 months	Overall health Foot and functional status Physical activity Amount out of bed time Incidence of foot ulcer	There is no evidence to support a widespread dispensing of therapeutic shoes and inserts to diabetic patients without severe foot deformity with a history of foot ulcer. Careful attention to foot care by health care professionals may be more important.

The scores for methodological quality ranged from eight[16 17] to 14[23] out of 19 possible points (see Table 2). Only one study reported that the treatment allocation was concealed[23]. Blinding of the outcome assessor was reported in two studies[10 21], and blinding of the care-giver was reported in one study[18]. None of the studies reported blinding of the patients for the intervention. Only two studies described certain adverse effects of the orthopaedic shoes[20 22]. There was disagreement between the two raters (MJ and HvD) on 19 out of 209 (9.1%) of the items assessing the methodological quality of the 11 RCTs studied. Consensus on these items was reached by discussion between the two raters, so the third rater was not consulted.

Table 2 Methodological scores of 11 RCTs investigating the usability of orthopaedic shoe provisions

Study	Methodological scores				
	Total (max 19)	Patient selection (max 4)	Intervention (max 5)	Outcome measurement (max 7)	Statistics (max 3)
Uccioli et al., 1995	9	2	2	3	2
Caselli et al., 1997	8	1	2	3	2
Caselli et al., 1997	8	2	1	3	2
Fransen , Edmonds, 1997	9	1	1	4	3
Kelly and Winson, 1998	13	3	3	4	3
Pfeffer et al., 1999	12	2	3	4	3
Carvaggi et al., 2000	10	3	2	4	1
Chalmers et al. 2000	11	2	2	5	2
Armstrong et al., 2001	12	3	2	5	2
Torkki et al.2001	14	4	2	5	3
Reiber et al., 2002	13	3	2	5	3

The 11 studies, which fulfilled the selection criteria, were assessed against four parameters (effectiveness, efficiency, satisfaction and context of use) of the ISO definition of usability (see Table 3). The overview is based on the chosen outcome parameters and the conclusions of the authors of the selected articles (see Table 1).

There was disagreement between the two raters (MJ and HvD) on 6 out of 44 (13.6%) of the items. Consensus on these items was reached by discussion between the first two raters, so the third rater was not consulted.

All of the 11 evaluation studies that were included focused on the effectiveness of orthopaedic shoes. Those with a study population of patients with degenerative disorders of the foot or patients with R.A. all focussed on pain reduction. Studies evaluating the usability of orthopaedic shoes for

patients with D.M. focused primarily on prevention of re-ulceration or decreasing the incidence of foot ulcers.

Only one trial studied aspects of efficiency. Torkki et al. (2001)[23] measured the usability of orthopaedic shoes in terms of footwear problems and costs. Patient satisfaction with orthopaedic shoes was measured in five studies[18 20-23]. In respect of the context of use, three trials measured the amount of pain patients experienced during activities in their material environment (e.g. walking around the house, walking on uneven ground, going up and down stairs).

Table 3 Overview of studies evaluating the usability of orthopaedic shoes in relation to parameters of the ISO definition of usability

Author	Effectiveness	Efficiency	Satisfaction	Context of use
Ucciolli et al., 1995	+	-	-	-
Caselli et al., 1997	+	-	-	+
Caselli et al., 1997	+	-	-	+
Fransen and Edmonds, 1997	+	-	-	-
Kelly and Winson, 1998	+	-	+	-
Pfeffer et al., 1999	+	-	-	+
Caravaggi et al., 2000	+	-	+	-
Chalmers et al., 2000	+	-	+	-
Armstrong et al., 2001	+	-	+	-
Torkki et al., 2001	+	+	+	-
Reiber et al., 2002	+	-	-	-
Total	11	1	5	3

(+) refers to a positive relationship between the published study and the parameters of the ISO definition of usability. (-)means that no attention was paid to that parameter of the ISO definition of usability.

2.5 DISCUSSION

To increase the use and usability of orthopaedic shoes, comprehensive evaluation studies should be methodologically sound and focus on all aspects of usability.

In this systematic review the scores for methodological quality of the included RCTs ranged from eight to 14 out of 19 possible points. No weights were assigned to the methodological criteria, because these would be entirely

arbitrary. It was not always clear whether failure to meet a criterion was due to imperfections in the execution of the study or to incomplete reporting.

Several forms of bias could have influenced the results of the various trials, indicating that the results should be interpreted with caution. In studies evaluating orthopaedic shoes or orthopaedic shoe provisions it is difficult to blind the care-providers, patients and outcome assessors. Furthermore, it is very important to gain insight into the use of co-interventions. Only five studies avoided the use of co-interventions, or mentioned the possible influence of co-interventions on their study results. Moreover, especially when pain reduction is the primary outcome measure, the influence of medication (e.g. anti-inflammatory drugs) should be taken into account.

In this systematic review the results of the individual RCTs that met the selection criteria have been summarised as they were presented by the original authors. Two raters, who were not blinded, assessed the methodological quality of the included studies. Blinding of the raters was not considered to be feasible because both raters already had considerable knowledge of the literature included in the review, and would recognise most of the studies, even if blinded.

With respect to the second aim of this systematic review, it can be concluded that comprehensive evaluation studies concerning orthopaedic shoes or orthopaedic shoe provisions focus mainly on the effectiveness aspect of the ISO definition of usability. Rarely are outcome measures chosen to assess the efficiency of use, patient satisfaction, and the influence of the context of use on usability.

Questionnaires are mainly used to establish the usability of orthopaedic shoes or orthopaedic shoe provisions. Three RCTs used the Foot Function Index (FFI), which measures the impact of foot complaints on foot function[2 7 24] in terms of pain, disability, and limitation of activities. All of the items are rated on a Visual Analogue Scale (VAS) and have satisfactory clinemetric properties[2 7 24].

Other researchers used questionnaires that were specifically developed for their study, instead of the more generally applied questionnaires, but provide no information about the properties and methodological quality of these questionnaires. However, none of the questionnaires quantified all aspects of

usability (product characteristics, user characteristics, effectiveness, efficiency, satisfaction, and context of use) with regard to orthopaedic shoes. Future comprehensive evaluation studies should use measurement tools that assess the effectiveness, efficiency, satisfaction and context of use in order to increase the usability of orthopaedic shoes and shoe inserts.

Acknowledgements

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APPENDIX 1 Literature search, combination of keywords

# 1	Shoes [MeSH] shoe*or footwear or insole* or insert*
# 2	Usability or utility or usage or usefulness
# 3	Effectiveness or efficiency [MeSH] or ease of use or comfort or personal satisfaction [MeSH] or satisfaction or acceptance
# 4	Foot [MeSH] or feet or lower extremity
# 5	Degenerative or osteoarthritis [MeSH]
# 6	Diabetes mellitus [MeSH] or D.M.
# 7	Rheumatoid [MeSH] or rheumatoid arthritis or R.A.
# 8	Neurologic*
# 1	# 2
# 1	# 3
# 1	# 4
# 1	# 5
# 1	# 6
# 1	# 7
# 1	# 8

All keywords (also MeSH terms) are searched as text words or All fields.
The literature search was limited to randomized controlled trials [ptyp].

APPENDIX 2 Maastricht-Amsterdam criteria list for the assessment of methodological quality

Patient selection

a.	Were the eligibility criteria specified?	Yes / No / Don't know
b.	Treatment allocation	
1)	Was a method of randomization performed?	Yes / No / Don't know
2)	Was the treatment allocation concealed?	Yes / No / Don't know
c.	Were the groups similar at baseline regarding the most important prognostic indicators?	Yes / No / Don't know

Interventions

d.	Were the index and control interventions explicitly described?	Yes / No / Don't know
e.	Was the care-provider blinded for the intervention?	Yes / No / Don't know
f.	Were co-interventions avoided or comparable?	Yes / No / Don't know
g.	Was the compliance acceptable in all groups?	Yes / No / Don't know
h.	Was the patient blinded for the intervention?	Yes / No / Don't know

Outcome measurement

i.	Was the outcome assessor blinded for the intervention?	Yes / No / Don't know
j.	Were the outcome measures relevant?	Yes / No / Don't know
k.	Were adverse effects described?	Yes / No / Don't know
l.	Was the withdrawal/drop-out rate described and acceptable?	Yes / No / Don't know
m.	Timing follow-up measurements	
1)	Was a short-term follow-up measurement performed?	Yes / No / Don't know
2)	Was a long-term follow-up measurement performed?	Yes / No / Don't know
n.	Was the timing of the outcome assessment in both groups comparable?	Yes / No / Don't know

Statistics

o.	Was the sample-size for each group described?	Yes / No / Don't know
p.	Did the analysis include an intention-to-treat analysis?	Yes / No / Don't know
q.	Were point estimates and measures of variability presented for the primary outcome measurements?	Yes / No / Don't know

CHAPTER 3

Questionnaire for Usability Evaluation of orthopaedic shoes: Construction and reliability in patients with degenerative disorders of the foot

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3.1 ABSTRACT

Objective: To develop a self-report questionnaire for patients with degenerative disorders of the foot to evaluate the usability of their orthopaedic shoes, and to assess the reproducibility and responsiveness of the instrument.

Design: The development of the Questionnaire for Usability Evaluation (QUE) of orthopaedic shoes was based on a literature search, structured expert interviews, and a ranking procedure. A cross-sectional study was carried out to determine the reproducibility and internal consistency of the questionnaire.

Setting and subjects: The study population comprised 15 patients with degenerative disorders of the foot who had worn their orthopaedic shoes for at least three years and 15 patients with degenerative disorders of the foot who had never wore orthopaedic shoes, but would receive them within a month.

Results: Within the questionnaire four effectiveness items (pain, instability, callus, wounds), one efficiency item (putting on and taking off shoes), and seven satisfaction items (pinch, slip, weight of shoes, cold feet, perspiration, maintenance, cosmetic appearance) were developed. All items in the questionnaire met the test-retest criteria. The smallest real difference (SRD) ranged from 0.23 to 3.82 cm on a Visual Analogue Scale (10 cm). Cronbach's alpha's for the domains of pain and instability ranged between 0.70 and 0.92.

Conclusions: The QUE should provide a good rationale to assess the usability of orthopaedic shoes and can be considered reliable.

Keywords:
Shoes, osteoarthritis, usability, questionnaire

3.2 INTRODUCTION

Degenerative disorders of the foot are very common in older individuals. Population surveys have reported a 10-24% prevalence of self-reported foot abnormalities in adults, with the highest prevalence being found in women and in those of 65 years of age and older[1]. These foot complaints and abnormalities (e.g. hallux valgus, claw toes, metatarsalgia) may restrict ambulation, limit activities, and influence the participation of these people in daily life. For the above-mentioned degenerative disorders of the foot, orthopaedic shoes can be prescribed, especially in serious cases. A key feature of orthopaedic shoes is their usability.

Usability is defined in ISO 9241-11 as “the extent to which a product can be used by specific users to achieve goals with effectiveness, efficiency, and satisfaction in a specified context of use”.

Within the definition of usability, effectiveness is the accuracy and completeness with which users achieve specified goals. For example, a patient is able to walk to a supermarket without foot pain. The resources that are expended in relation to the accuracy and completeness with which users achieve goals are assessed to determine efficiency. Relevant resources may include mental or physical effort (for example, independently putting on and taking off orthopaedic shoes), time or financial costs. Satisfaction is defined as the comfort and acceptability of use, and can be assessed in terms of attitudes to using the product (for example, how do patients feel about the cosmetic appearance or measure of perspiration in their orthopaedic shoes?). Finally, the context of use refers to the physical and social environments in which a product is used. Measurement of usability is particularly important in view of the complexity of the interactions between the patient and his goals and the elements of the context of use, which can result in significantly different levels of usability for the same product when used in different contexts[2].

Insight into the use and usability of rehabilitation technological aids, can be obtained from the results of several evaluation studies described in the literature[3]. In these evaluation studies, more and more questionnaires are being used to establish the usability of rehabilitation technological aids. This is

also the case in studies evaluating orthopaedic shoes prescribed for patients with degenerative disorders of the foot. One such questionnaire is the Foot Function Index (FFI), which measures the impact of foot complaints on foot function[4 5]. The foot function is measured in terms of pain, disability and limitation of activities. All of the items are rated on a Visual Analogue Scale (VAS), and have satisfactory clinimetric properties. The FFI has been used in several studies, both in selected patient groups with generalized diseases (rheumatoid arthritis, osteoarthritis) and in patients with more localized foot complaints (heel pain, forefoot pain)[4 5]. However, because the FFI focuses only on the foot function, no evaluation can be made of the usability of the orthopaedic shoes, as defined in ISO 9241-11.

Another questionnaire, the SERVQUAL (SERVice QUALity measurement scale), can be used to assess patient satisfaction with orthopaedic shoes[6]. In this questionnaire, consumer interests and experiences are assessed on a 5-point Likert scale. The questionnaire contains 30 items, covering five domains: tangibles, reliability, responsiveness, assurance and empathy. The SERVQUAL was used in the National Health Service in the United Kingdom, in rehabilitation, in hospital services, in nursing services and other health care services[6]. The subscales of the SERVQUAL were found to be internally consistent, and have a satisfying content validity and reliability.

Other researchers have used questionnaires that they have specifically developed for their study, instead of more generally applied questionnaires. Caravaggi et al.[7] measured patient acceptance of a therapeutic shoe using a VAS. Torkki et al.[8] used a self-designed questionnaire that measured the duration and intensity of foot pain, ability to work, cosmetic disturbance, footwear problems, health-related quality of life, satisfaction and costs related to foot care. Kelly and Winson[9] evaluated the use of ready-made insoles in the treatment of metatarsalgia. The assessment included a questionnaire consisting of VAS pain scores, estimated walking distance and VAS symptom relief scores. Fransen & Edmonds[10] evaluated the effectiveness of off-the-shelf orthopaedic footwear for people with rheumatoid arthritis using a questionnaire to assess chronic foot pain, in terms of self-reported pain and physical functioning. No further information about the properties and methodological quality of these questionnaires is available.

Although several instruments currently exist to measure pain and disability associated with foot problems or to measure patient satisfaction and acceptance of rehabilitation aids, none of the above-mentioned questionnaires quantifies all aspects of the usability (effectiveness, efficiency, satisfaction and context of use) of orthopaedic shoes. The purpose of this study was to develop a self-report instrument (questionnaire) to measure all aspects of the usability (effectiveness, efficiency, satisfaction, context of use) of orthopaedic shoes in patients with degenerative disorders of the foot, which is reliable with regard to reproducibility and homogeneity.

3.3 METHODS

Development of the Questionnaire for Usability Evaluation (QUE) of orthopaedic shoes

Collection of items

The development of the Questionnaire for Usability Evaluation (QUE) of orthopaedic shoes is based on the standard methodology for the development of questionnaires for research purposes, i.e. a literature search, structured expert interviews, and a ranking procedure. In the literature search, articles and reference books were sought in MEDLINE (1970-2001), EMBASE (1970-2001) and the database of the Cochrane Collaboration Field 'Rehabilitation and Related Therapies', using the following combinations of keywords: foot, ankle, osteoarthritis, claw toes, hammer toes, hallux valgus, metatarsalgia, plantar fasciitis, calcaneal spur, calcaneal bursitis, plantar fibromatosis, flat foot, cavus foot, shoes, orthopaedic shoes and orthopaedic footwear. In addition to this search, the reference lists of relevant publications were carefully checked. The initial selection of articles was based on the title and the content of the abstract. The following inclusion criteria were applied by two researchers (MJ and JdV): [1] studies concerning the evaluation of orthopaedic shoes and degenerative disorders of the foot; [2] published, full-length articles; [3] language: English, German or Dutch. The literature search resulted in the identification of 5 reference books[11-15] and 18 articles[16-33]. Based on this literature search it can be stated that the concept of usability in

respect to orthopaedic shoes have been explored only superficially. Little formal knowledge is therefore available. In order to obtain additional information from clinical practice, structured expert interviews were held with a group of rehabilitation specialists (n=10), orthopaedic surgeons (n=3), orthopaedic shoe technicians (n=10) and patients with degenerative disorders of the foot (n=10). These experts (specialists and patients) were interviewed about (foot) problems and aspects regarding orthopaedic shoes at the effectiveness, efficiency, satisfaction and context of use level relevant for the specific experts.

Selection and ranking of items

The same experts (n=33) were asked to rank the usability items, based on two criteria: subjective experienced incidence of these usability items in clinical practice, and measure of relevance. The literature search, the expert interviews and the ranking procedure resulted in a list of 12 usability items, which could be measured by means of a questionnaire. These 12 items are: pain during daily activities, stability during daily activities, callus, wounds, pinch, slip, and weight of shoes, cold feet, perspiration, putting on/taking off shoes, maintenance, and cosmetic appearance.

Based on these 12 items the first version of the QUE of orthopaedic shoes was developed, consisting of two parts (*QUE pre-test* and *QUE post-test*). The QUE pre-test should be completed before patients receive their orthopaedic shoes. It measures the current state of subjective experienced foot problems and shoe problems while the patient is still wearing ready-made shoes, and also measures the expectations patients have with regard to their orthopaedic shoes they will receive. The QUE pre-test consists of 67 questions distributed over the 12 usability items. Pain during daily activities (standing, walking, climbing stairs, riding a bicycle, activities of daily life and work) [18], stability during daily activities (standing, walking, climbing stairs, riding a bicycle, activities of daily life and work) [21], callus [3], wounds [3], pinch [3], slip [3], weight of shoes [3], cold feet [3], perspiration [3], putting on/ taking off shoes [3], maintenance [2], and cosmetic appearance [2].

The QUE post-test measures the current state of subjective experienced foot and shoe problems of a patient who wears orthopaedic shoes, and has to be

completed after the orthopaedic shoes have been worn for at least three months. The QUE post-test consists of 45 questions distributed over 12 items. Pain during daily activities [12], stability during daily activities [14], callus [2], wounds [2], pinch [2], slip [2], weight of shoes [2], cold feet [2], perspiration [2], putting on/taking off shoes [2], maintenance [2], and cosmetic appearance [1].

Face validity (whether the questions, on the face of it, appear to be measuring the variables they claim to measure) was reviewed by experts from various fields: rehabilitation medicine, rehabilitation research, human movement sciences and orthopaedic shoe technology.

Response format

The QUE pre-test and the QUE post-test consist of questions at a dichotomous level (yes/no) and questions at an interval level (VAS). Each VAS question consists of a 100-mm line bounded by two anchor phrases denoting the extremes of possible answers. Patients indicated their answers by making a mark across the line. Pilot-testing indicated that the respondents understood the direction of the choices and how to fill in the answers.

Reliability characteristics of the QUE for orthopaedic shoes

The QUE pre-test and QUE post-test for orthopaedic shoes were tested for reliability, in terms of reproducibility and internal consistency. Reproducibility is defined as the ability to measure attributes in a reproducible and consistent manner when administered on several occasions to stable subjects (34). Internal consistency refers to the statistical coherence of the scale items.

Study population

Thirty patients were recruited from the outpatient clinic of a rehabilitation centre. Inclusion criteria were: 1) degenerative disorders of the foot; 2) wearing orthopaedic shoes for at least three years (n=15; experienced group, who will fill in the QUE post-test) or will be wearing them within a month (n=15; inexperienced group, who will fill in the QUE pre-test); 3) able to read Dutch; 4) over 18 years of age; and 5) in a stable phase of the degenerative foot disorders.

Design of the test-retest reproducibility study

Patients filled in the first version of the QUE pre-test and QUE post-test in the outpatient clinic of a rehabilitation centre twice, with an interval of 2 weeks. No clinically relevant changes in the patients' health status were expected to be found during this two-week interval. Because of the diversity of the questions, the age of the study population (elderly people), and the time required to complete the QUE (+/-30 minutes), it was expected that at the second occasion patients would not remember their first responses.

Data-analysis

Reproducibility

Reproducibility refers to the agreement in scores between two measurements. This is quantified with Cohen's kappa and the intraclass correlation coefficient (ICC). Cohen's kappa represents the proportion of agreement. In general, with a kappa value of less than 0.40, the agreement is considered to be poor to fair, 0.41-0.60 indicates moderate agreement, 0.61-0.80 good agreement, and when kappa exceeds .80 the agreement is very good. The intraclass correlation coefficient (ICC) is often preferred over the Pearson's correlation as a measure of reproducibility, because it combines systematic and random errors into one statistic. In this study the ICC (absolute agreement, two-way random) model was used, measuring the degree of absolute agreement among measurements[36]. To detect longitudinal changes in time the standard error of measurement (SE_m) was calculate. The SE_m provides an interpretation of the magnitude of this within-subject variability, which is also known as the error variance[34]. SE_m is calculated according to:

$SE_m = \sqrt{MS_{error}}$ [35]

Assuming that the two measurement errors are independent of each other, an interval or error band can be calculated, expressing the uncertainty of the difference between the two true scores. The difference between both measurements should be at least $1.96*\sqrt{2}*SE_m$ to be 95% confident of a real difference between the true scores. The quantity $1.96*\sqrt{2}*SE_m$ is called the 'Smallest Real Difference' (SRD), and indicates the point where the difference

between two consecutive assessments exceeds the measurement error or 'noise'.

Homogeneity

Homogeneity refers to the statistical coherence of scale items, and can be expressed in Cronbach's alpha correlation coefficients. This coefficient is based on the (weighted) average correlation of items within a scale, and indicates whether each item in the scale is contributing to the variance in the overall score. The internal consistency was only computed for the pain and instability items. The pain items consists of several sub-items (pain during standing, walking, climbing stairs, riding a bicycle, activities of daily life and work). Instability also consists of several sub-items (instability during standing, walking, climbing stairs, riding a bicycle, activities of daily life and work). The other items (callus, wounds, pinch, slip, weight, cold feet, perspiration, putting on/taking off, maintenance, and cosmetic appearance) have no sub-items. Internal consistency is considered to be good if Cronbach's alpha is higher than 0.70. However, because of the small study population (n=15) the computed Cronbach's alpha's in this study will only give an indication of the internal consistency of the pain and instability items.

3.4 RESULTS

Study population

The characteristics of the study population are summarised in Table 1. There was no difference between the inexperienced group (n=15) and the experienced (n=15) group in age ($p = 0.289$) or gender ($p = 0.705$). The inexperienced group had a mean age of 61.5 years (SD: 14.4 years) and the experienced group had a mean age of 55.8 years (SD: 14.3 years). Both groups consisted predominately of women (9 females in the inexperienced group and 10 females experienced group) who were not working for various reasons. The most common reasons were that they had retired because of age or disability. The level of education was also comparable between the two groups.

Table 1 Characteristics of the study population (n=30)

	'Inexperienced group' (n=15)	'Experienced group' (n=15)
Mean age (SD)	61.5 (14.4)	55.8 (14.3)
Gender		
Male	6 (40%)	5 (33%)
Marital status		
Never married		3 (20%)
Married	11 (73%)	12 (80%)
Widowed or divorced	4 (27)	
Living alone	4 (27%)	3 (20%)
Level of education		
Primary school	5 (33%)	8 (53%)
Secondary school	7 (47%)	4 (27%)
High school	1 (7%)	1 (7%)
College	2 (13 %)	2 (13%)
Employed	2 (13%)	4 (27%)

Reproducibility

In this test-retest study, three aspects of reliability were examined. In Table 2 these reliability aspects are listed for the 'inexperienced group', who filled in the QUE pre-test questionnaire, which had 20 questions at a nominal level that correlated significantly ($p<0.05$). Questions, which did not correlate significantly or were not relevant for 75% or more of this study population, were removed from the questionnaire. The Cohen's Kappa of 9 questions was between 0.60 and 0.80 ($p<0.05$), which can be regarded as good, and for 11 questions the Cohen's Kappa was above 0.80 ($p<0.05$), which can be regarded as very good. In the 'inexperienced group' one person did not fill in the questions at interval level. As a consequence this person is left out the analysis for the calculation of the ICC and the SRD. The ICC for the interval items regarding the effectiveness ranged between 0.726 and 0.996, and for items regarding satisfaction it ranged between 0.835 and 0.990. Both of these ranges were considerably high. However, the SRD showed ranges of 0.42 to 2.67 for items of effectiveness implying that differences in VAS scores over 0.42 to 2.67 cm should be found before it can be concluded that there is a detectable change in effectiveness beyond measurement error can be concluded. The SRD for the item of efficiency showed a range of 1.22 to 2.44, and for the item of satisfaction a range of 0.70 to 2.70.

Table 2 Psychometric summary of the 'unexperienced' QUE pre-test scales (n=15)

Domain	No. of Items nominal	Cohens''s Kappa	Internal consis-tency	No. of Items interval	ICC (n=14)	SRD (n=14)	Internal consis-tency
Effectiveness							
Pain	6	0.6 - 1.0	0.87	9	0.87 – 0.99	0.42 - 2.60	0.90
Instability	7	0.71 - 1.0	0.82	9	0.75- 0.99	0.99 - 2.67	0.85
Callus	1	0.88		2	0.94 – 0.95	1.99 - 2.15	
Wounds	1	0.73		2	0.72 – 0.98	1.80 - 1.86	
Efficiency							
Putting on and taking off	1	0.77		2	0.76 – 0.98	1.22 - 2.44	
Satisfaction							
Pinch	1	1.0		1	0.99	1.09	
Slip	1	0.6		2	0.95 - 0.99	0.70 - 1.60	
Weight	1	1.0		2	0.89 – 0.98	1.46 - 2.08	
Cold feet				1	0.98	1.36	
Perspiration	1	1.0		2	0.91 – 0.93	2.11 - 2.42	
Maintenance				2	0.78 – 0.81	2.47 – 2.70	
Cosmetics				2	0.84 - 0.91	2.60 - 2.64	

* a= 0.05; ICC = intraclass correlation coefficient; SRD = Smallest Real Difference

Table 3 lists the reliability aspects for the 'experienced group' of 15 patients who filled in the QUE post-test questionnaire. Twenty-one questions at a nominal level correlated significantly ($p<0.05$). The Cohen's Kappa of 14 questions was higher than 0.80 ($p<0.05$), and can be considered as very good. For six questions the Cohen's Kappa was between 0.61 and 0.80 ($p<0.05$), which can be considered as good. One question, experienced instability during ‘climbing stairs’ can be considered as moderate, with a Cohen's Kappa between 0.41 and 0.60 ($p<0.05$). In the 'experienced group' also one person did not fill in the questions at interval level. As a consequence this person is left out the analysis for the calculation of the ICC and the SRD. The ICC for interval items regarding the effectiveness of orthopaedic shoes ranged between 0.853 and 0.999, and for items regarding satisfaction it ranged between 0.839 and 0.994. Both ranges were considerably high. The SRD showed a range of 0.15 to 2.62 for items of effectiveness, so differences in VAS scores over 0.15 to 2.62 cm should be found before it can be concluded that there is a detectable change in value of use beyond measurement error. For the items of satisfaction, a range of 0.66 to 2.62 is found, implying that differences in VAS scores over 0.66 to 2.62 cm should be found before it can be concluded that the changes were not caused by measurement error.

Table 3 Psychometric summary of the 'experienced' QUE post-test scales (n=15)

Domain	No. of Items nominal	Cohen's Kappa	Internal consis-tency	No. of Items interval	ICC (n=14)	SRD (n=14)	Internal consis-tency
Effectiveness							
Pain	5	0.7 – 0.89	0.70	6	0.94 - 0.99	0.15 - 2.62	0.90
Instability	6	0.52 - 1.0	0.82	7	0.85- 0.99	0.97 - 2.03	0.92
Callus	1	0.87		1	0.95	2.54	
Wounds	1	0.87		1	0.94	2.04	
Efficiency							
Putting on and taking off	1	0.63		1	0.94	0.47	
Satisfaction							
Pinch	1	0.84		1	0.96	1.85	
Slip	1	1.0		1	0.99	0.66	
Weight	1	1.0		1	0.97	1.06	
Cold feet	1	0.82		1	0.84	2.40	
Perspiration	1	0.60		1	0.95	2.09	
Maintenance				2	0.97 – 0.98	1.00 – 1.81	
Cosmetics				1	0.89	2.62	
Amount of use							
Days a week	1	1.0					
Hours a day	1	0.69					

* a= 0.05; ICC = intraclass correlation coefficient; SRD = Smallest Real Difference

Homogeneity

In Table 2 the internal consistency of the pain and instability items are listed for the 'unexperienced group', who filled in the QUE pre-test questionnaire. However, because of the small study population (n=15) this can only give an indication of the internal consistency of the pain and instability items. The Cronbach's alpha for pain and instability items at a nominal level (yes/no) ranged from 0.82 to 0.87, and for pain and instability items at an interval level (VAS-scores), it ranged from 0.85 to 0.90.

In Table 3 the internal consistency of the pain and instability items is listed for the 'experienced group', who filled in the QUE post-test questionnaire. For pain and instability items at a nominal level (yes/no), Cronbach's alpha ranged from 0.70 to 0.82, and for pain and instability items at an interval level (VAS-scores), it was between 0.90 and 0.92.

The Cronbach's alphas for pain are based on 6 sub-items (pain during standing, walking, climbing stairs, riding a bicycle, activities of daily life and work). The Cronbach's alphas for instability are based on 7 sub-items

(instability during standing, walking, walking on a rough surface, climbing stairs, riding a bicycle, activities of daily life and work).

3.5 DISCUSSION

Assessment of person-perceived usability is essential when evaluating rehabilitation interventions such as orthopaedic shoes. In this study, usability was defined as “the extent to which a product can be used by specific users to achieve goals with effectiveness, efficiency and satisfaction in a specified context of use”. There is no available questionnaire which quantifies all aspects of the usability of orthopaedic shoes. The purpose of this study was to develop a questionnaire to measure the usability of orthopaedic shoes in patients with degenerative disorders of the foot, based on the ISO 9241-11 definition of usability, which was reliable with regard to reproducibility and homogeneity.

The development of the QUE for orthopaedic shoes was based on a literature search, structured expert interviews, and a ranking procedure. Since the purpose of this literature search was to make an inventory of possible items regarding the usability of orthopaedic shoes, no assessment was made of the methodological quality of the studies. Based on the systematic review it can be stated that the concept of usability in respect to orthopaedic shoes have been explored only superficially. To overcome publication bias 33 ‘experts’ in the field of orthopaedic footwear were asked to provide additional information gained from their own clinical practice. It should be mentioned that this additional information is valid for the Dutch situation, and needs to be further examined before extrapolation to other countries. Since the literature does not report any data on the incidence of the usability items, the ranking of these items was carried out by the same experts and based on their experiences in clinical practice. An epidemiological study would be recommended to identify objective rates of incidence.

The literature search, the expert interviews and the ranking procedure resulted in a list of 12 items to assess the usability of orthopaedic shoes.

Based on these 12 items, the Questionnaire for Usability Evaluation of orthopaedic shoes was developed, consisting of two parts (QUE pre-test and QUE post-test). The QUE pre-test (final version) consists of 56 questions, and measures different aspects of foot complaints and the expectations unexperienced people have with regard to the effectiveness, efficiency, satisfaction and context of use of their orthopaedic shoes. The QUE post-test (final version) consists of 45 questions, and measures different aspects of foot complaints and the experience people have with regard to the effectiveness, efficiency, satisfaction and context of use of their orthopaedic shoes. Pilot-testing indicated that the patients understood the direction of the choices and how to fill in the answers. Within this pilot-study patients filled in the questionnaire and were interviewed about the comprehensibility, direction of choices and how to fill in the answers stated in the questionnaire afterwards. However this was not formal tested. Face validity was based on the experts' judgement of the items. The experts came from various fields: rehabilitation medicine, rehabilitation research, human movement sciences and orthopaedic shoe technology. In future studies the currently available questionnaire needs to be examined by linking the items to the ICF reference framework. In this manner it is possible to link the QUE to other already existing instruments.

The test-retest reliability of the QUE was also satisfactory, compared with the reliability of the Dutch version of the FFI (ICC: 0.70- 0.83). However, the FFI focuses only on the foot function, and does not provide any information about the usability of orthopaedic shoes.

Reproducibility coefficients, expressed as a dimensionless number between 0 and 1, do not lend themselves to a straightforward interpretation. For this purpose the smallest real difference (SRD) is better suited. The SRDs, are expressed in the same dimensions as the questions in the QUE pre-test and QUE post-test.

In this study some of the SRDs were found to be relatively large (up to 27% of the total VAS scale). However this is not a problem, because patients with degenerative disorders of the foot have severe pain before they are provided with orthopaedic shoes, which results in high VAS scores. The goal of prescribing orthopaedic shoes, however, is to reduce a lot of the pain they experience during their daily activities.

The other way to test the reliability of a questionnaire is to calculate Cronbach's alpha. The internal consistency (based on Cronbach's alpha) of the QUE was also satisfactory, compared with the FFI (a□0.88 to 0.94) and the SERVQUAL (a□>0.70). However, it should be mentioned that, because of the small study population (n=30), the Cronbach's alphas calculated in this test-retest study give only an indication of the internal consistency of the pain and instability items. Further investigation in a larger study population will be necessary to draw firm conclusions with regard to the internal consistency. It is then also possible to analyse the results using other psychometric methods including factor or principle component analysis.

Based on this study, it can be concluded that the QUE assesses all aspects of the usability (effectiveness, efficiency, satisfaction and context of use) of orthopaedic shoes, which no other questionnaire does. Four items were developed within the domain of effectiveness (pain, instability, callus and wounds), one item was developed within the domain of efficiency (putting on and taking off orthopaedic shoes) and seven items were developed within the domain of satisfaction (pinch, slip, weight of shoes, cold feet, perspiration, maintenance and cosmetics). All the above-mentioned items relate to various different aspects of the context of use. Furthermore, the QUE can be considered as a reliable questionnaire with which to assess the usability of orthopaedic shoes, also compared with other, more generic questionnaires. The multidimensional structure of the QUE should provide a good rationale to evaluate the usability of orthopaedic shoes.

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APPENDIX

Domain	Items	Description of the items
Effectiveness		
	Pain during daily activities	- Pain during stance - Pain during walking - Pain during climbing stairs - Pain during riding a bicycle - Pain during activities of daily life - Pain during work, labour
	Instability	- Instability during stance - Instability during walking - Instability during walking on uneven ground - Instability during climbing stairs - Instability during riding a bicycle - Instability during activities of daily life - Instability during work, labour
	Callus	- Corns are small hard conical hyperkeratosis due to friction and pressure - Callus are thickenings of keratin due to pressure
	Wounds	- Abnormality/ damage of skin texture (e.g. ulceration, color)
Efficiency	Putting on and taking of orthopaedic shoes	- The amount of problems a patient experiences while putting on and taking of their orthopaedic shoes
Satisfaction	Pinch	- The sticking, squeezing of the shoe
	Slip	- The occurrence of slipping of the heel in the shoe
	Weight	- The experienced (subjective) weight of the shoe
	Cold feet	- The occurrence of cold feet
	Perspiration	- The occurrence of perspiration
	Maintenance	- The experienced difficulties in the maintenance of orthopaedic shoes (e.g. polishing, cleaning, repairing)
	Cosmetic appearance	- Do patients find their shoes ugly or beautiful?

CHAPTER 4

Use of orthopaedic shoes in patients with degenerative disorders of the foot

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4.1 ABSTRACT

Objective: To study the actual use of orthopaedic shoes in patients with degenerative disorders of the foot and to identify factors which are associated with use and non-use, based on the parameters of the International Organisation for Standardisation (ISO) definition of usability: effectiveness, efficiency, satisfaction, and context of use.

Design: Multicentre, prospective cohort study.

Setting and subjects: 100 consecutive patients with degenerative disorders of the foot were included from the outpatient clinics of seven rehabilitation centres in the Netherlands.

Main outcome measures: Usability was assessed by means of the Questionnaire for Usability Evaluation of orthopaedic shoes.

Results: 23 out of 93 patients with degenerative disorders of the foot wear their orthopaedic shoes less than three days per week after three months of follow up. Factors significantly associated with the actual use of orthopaedic shoes are increase in stance duration (effectiveness; OR= 2.14), decrease in skin abnormalities (effectiveness; OR= 1.35), problems experienced with putting on and taking off orthopaedic shoes (efficiency; OR= 0.46), and cosmetic appearance of orthopaedic shoes (satisfaction; OR= 1.54).

Conclusions: We can learn more about the usability of orthopaedic shoes by adding efficiency and satisfaction factors, and not only focussing on the effectiveness factors.

Keywords:
Shoes, degenerative, usability

4.2 INTRODUCTION

Degenerative disorders of the foot are very common in older individuals. The associated foot complaints and abnormalities (e.g. hallux valgus, claw toes, metatarsalgia) may restrict ambulation, limit activities, and influence participation[1-3]. Orthopaedic shoes can be prescribed, for the above-mentioned degenerative disorders of the foot, especially in serious cases. The prescription and provision of orthopaedic shoes mainly takes place on an empirical basis, and therefore greatly depends on the individual experiences of clinicians and orthopaedic shoe technicians. Moreover, several conflicting opinions can also be found in the literature with regard to when it is necessary to prescribe orthopaedic footwear and what features of shoe-design are necessary to obtain protective benefits[4]. Nowadays, in clinical practice shows there is a high rate of non-use of orthopaedic shoes and orthopaedic shoe provisions varying from 8% to 75%[5-11]. It is obvious that such a high rate of non-use is unsatisfactory.

Insight into the use and usability of orthopaedic shoes can be obtained from the results of several evaluation studies described in the literature. Usability is defined by the International Organisation for Standardisation (ISO) 9241 as "the extent to which a product can be used by specific users to achieve goals with effectiveness, efficiency, and satisfaction in a specified context of use"[12 13].

Based on the results of a systematic review which focussed on methodological quality and the extent to which evaluation studies measure different aspects of usability, it can be concluded that randomised controlled trials carried out to evaluate orthopaedic shoes or orthopaedic shoe provisions focus mainly on the effectiveness level of the ISO definition of usability[14]. For patients with degenerative disorders of the foot, the effectiveness is usually determined according to the levels of pain reduction, foot function, walking distance, stance duration, and activity limitation. Outcome measures are rarely chosen to assess the efficiency of use, patient satisfaction, and the influence of the context of use on usability.

As there is no available data on the various aspects of usability of orthopaedic shoes, which may influence a patient's decision to use or not to use the

orthopaedic shoes, the objective of this study is to investigate the amount of use of orthopaedic shoes made by patients with degenerative disorders of the foot and to identify usability factors which are associated with the actual use and non-use of orthopaedic shoes, based on the parameters of the ISO definition of usability: effectiveness, efficiency, satisfaction, and context of use.

4.3 METHODS

Setting and subjects

A group of 100 consecutive patients with degenerative disorders of the foot were enrolled from the outpatient clinics of seven rehabilitation centres and rehabilitation departments of university hospitals in the Netherlands from September 2001 to February 2003. Patients were invited to participate after the project had been explained to them and they had signed a disclosure form and informed consent. Inclusion criteria specified that patients: (1) have degenerative disorders of the foot; (2) receive custom-made orthopaedic footwear; (3) are able to read and understand Dutch; (4) are older than 18 years.

Degenerative disorders of the foot are defined as: “a foot with arthrosis deformans of one or more joints of the ankle and/or foot region and/or chronic inflammation of peri-articular structures”[15]. Based on this definition, the following are considered to be degenerative disorders of the foot: arthrosis of ankle/subtalar and midtarsal joints, achillis tendinitis, plantar fasciitis/fibromatisis, tibialis posterior tendinitis, hallux valgus, prominent or subluxed MT-heads, hallux rigidus, claw toes, and hammer toes. The rehabilitation specialists, associated with the seven participating centres established the presence of degenerative disorders of the foot in the participating patients according to the above-mentioned definition.

The exclusion criteria were: (1) active foot infections; (2) inability to walk without the aid of a wheelchair; (3) previous experience with orthopaedic shoes; (4) prescribed off-the-shelf orthopaedic footwear.

Custom-made orthopaedic shoes

Within the present study, custom-made orthopaedic shoes are defined as complete individually manufactured low or high shoes with medical technical facilities (Figure 1a, 1b). The Appendix shows the anatomy of a custom-made orthopaedic shoe. The most important functions of custom-made orthopaedic shoes are support, correction, and immobilisation of the deformed foot. To create an individually manufactured orthopaedic shoe, various data are necessary. In the Netherlands, the orthopaedic shoe technician uses a blue-print of the foot, a plaster cast of the foot, and a vacuum footprint. An individual last is then manufactured, and this is used to make a plastic proof shoe, with which the clinicians and orthopaedic shoe technicians can detect pressure points and can study the patient's gait cycle. Based on the results of this proof shoe, the real custom-made orthopaedic shoe is manufactured. As a consequence, none of the custom-made orthopaedic shoes worn in this study are the same. The custom-made insoles that were used in these custom-made orthopaedic shoes were made of Plastazote and PPT. Plastazote is a foamed polyethylene with a closed-cell construction, and PPT is an open-cell, porous, firm foam material which relieves local pressure, labelled as a "high energy-absorbing substance".

Figure 1a Complete individually manufactured low orthopaedic shoes

Figure 1b Complete individually manufactured high orthopaedic shoes

Study design

The study was conducted as a multi-centre prospective cohort study. Subjects were assessed twice. The baseline assessment took place one month before the patient received custom-made orthopaedic shoes, and the follow-up measurement was three months after delivery of the custom-made orthopaedic shoes. After the delivery of the custom-made orthopaedic shoes patients were instructed to gradually accustom themselves to wearing the orthopaedic shoes during the first two weeks. No further instructions were given.

Measurements

Questionnaire for Usability Evaluation of orthopaedic shoes (QUE): The QUE focuses on all aspects of usability (effectiveness, efficiency, satisfaction and context of use) of orthopaedic shoes, and consists of two parts (QUE-pre and QUE-post)"(unpublished observations)"[15]. The QUE-pre measures different aspects of foot complaints and the expectations of unexperienced patients with regard to the effectiveness (pain, instability, skin abnormalities), efficiency (putting on/ taking off), and satisfaction (stick, slip, weight of shoes, cold feet, perspiration, and cosmetic appearance) of their orthopaedic shoes in their context of use. The QUE-post measures different aspects of foot complaints and the patient's experience with regard to the effectiveness, efficiency, satisfaction, and context of use while wearing orthopaedic shoes. Face validity (whether the questions, on the face of it, appear to be measuring the variables they claim to measure) was reviewed by experts from various fields: rehabilitation medicine, rehabilitation research, human movement sciences, and orthopaedic shoe technology. Furthermore, the QUE is considered to be a reliable (reproducible and internally consistent) questionnaire for assessment of the usability of orthopaedic shoes[13].

Statistical analysis

Differences between users and non-users of orthopaedic shoes at baseline were assessed with an independent t-test (α=.05) for scale measures and by a chi^2 test for nominal measures. In addition, an exploratory univariate analysis was performed to identify demographic characteristics, effectiveness,

efficiency, and satisfaction factors associated with the actual use of orthopaedic shoes. To identify effectiveness factors the difference between the QUE-post and the QUE-pre scores was calculated; to identify efficiency and satisfaction factors only the QUE-post scores were analysed.

Demographic characteristics, and effectiveness, efficiency, and satisfaction factors with p-values exceeding 0.20 in the univariate analysis, were excluded from the multiple logistic regression model. Factors associated with the actual use of orthopaedic shoes in the exploratory univariate analysis were also tested for collinearity before being included in a multiple logistic regression model. The factors were selected on the basis of the results of the univariate analysis and the previously published results of other studies. Contributions to the model are reported as odds ratios. All analyses were performed with SPSS, version 11.5.

4.4 RESULTS

Patient characteristics

Three months after the delivery of their orthopaedic shoes, patients with degenerative disorders of the foot were asked: “how many days per week do you wear your orthopaedic shoes?” Patients who wore their orthopaedic shoes less than three days per week were classified as non-users of orthopaedic shoes. Based on this criterion, 70 patients (70.0%) were classified as users of orthopaedic shoes after three months and 23 patients (23.0%) were classified as non-users. Seven patients (7.0%) were lost to follow-up for various reasons: one patient died, the overall health status of two patients deteriorated to such an extent that orthopaedic shoes were no longer required, two patients underwent surgery within the follow-up period, and two patients dropped out for no known reason. Table 1 gives a summary of the baseline characteristics of users and non-users. No significant differences were found, ($p > .05$) with regard to age, foot pain, instability, and skin abnormalities. However, actual users had more prominent MT-heads ($p = 0.032$).

Table 1 Summary of baseline characteristics of users and non-users

Variable	Users (n=70)	Non-users (n=23)	p-value
Age (years)	58.2 (15.5)	63.8 (13.6)	0.123
Gender			
male	34 (36.6)	4 (4.3)	0.008
female	36 (38.7)	19 (20.4)	
Degenerative disorder (n)*			
arthrosis	26	6	0.987
achillis tendonitis	2	0	0.492
plantar fasciitis	3	0	0.397
tibialis posterior tendonitis	0	0	-
hallux valgus	30	10	0.072
prominent MT-heads	45	14	0.032
hallux rigidus	26	8	0.325
claw toes	25	8	0.115
hammer toes	14	4	0.160
Foot pain (VAS**)	4.9 (2.4)	4.5 (2.5)	.459
Instability (VAS**)	2.4 (2.6)	3.4 (3.0)	.140
Skin abnormalities (VAS**)	3.9 (3.5)	4.3 (3.7)	.655

*More than one degenerative disorder per person can be present.
Values are mean ±SD or n (%); **VAS: 0 = slight, 10 = severe

Multivariate analysis of factors associated with actual use of orthopaedic shoes

An exploratory univariate analysis was performed to identify demographic characteristics, and effectiveness, efficiency and satisfaction factors associated with the actual use of orthopaedic shoes. Factors with p-values exceeding 0.20 in the univariate analysis or, with a low prevalence in this study population, were excluded from the multiple logistic regression model that was used to examine the associations of the following variables with the use of orthopaedic shoes: gender, age, increase in stance duration, decrease in pain, decrease in skin abnormalities, putting on/ taking off orthopaedic shoes, amount of stick of orthopaedic shoes, weight of orthopaedic shoes, amount of perspiration in orthopaedic shoes, and cosmetic appearance of the orthopaedic shoes (Table 2). The following variables were excluded from the multiple logistic regression model because of their high p-values ($p>0.2$): living status, decrease in instability, amount of slip, amount of cold feet, and measure of maintenance. Increase in walking duration was excluded from the model because of its strong association with increase in stance duration. Moreover, most people with degenerative disorders of the foot are elderly, and they walk only short distances and perform mainly indoor activities.

Table 2 Multiple logistic analysis of demographic characteristics, effectiveness, efficiency, and satisfaction factors associated with orthopaedic shoe-use

Variable	Users	Non-users	Odds Ratio	95% CI
Demographic				
gender			5.09	0.95 – 27.39
- male	34 (36.6)	4 (4.3)		
- female	36 (38.7)	19 (20.4)		
age	58.2 (15.5)	63.8 (13.6)	0.98	0.93 – 1.02
Effectiveness				
increase in stance duration	1.57 (2.74)	-.217 (2.4)	2.14	1.19 – 3.85
decrease in pain	2.2 (2.4)	-0.1 (3.1)	1.41	0.99 – 2.00
decrease in skin abnormalities	2.1 (3.3)	0.2 (2.9)	1.35	1.02 – 1.80
Efficiency				
putting on / taking off o.s.	0.4 (1.3)	1.5 (3.0)	0.46	0.26 – 0.82
Satisfaction				
amount of stick o.s.	0.9 (2.1)	2.1 (3.6)	1.13	0.78 – 1.64
amount of weight o.s.	2.1 (3.2)	1.1 (2.6)	1.11	0.81 – 1.53
amount of perspiration o.s.	2.1 (3.1)	1.4 (3.1)	1.23	0.92 – 1.64
cosmetic appearance o.s.	5.7 (2.8)	4.7 (3.0)	1.54	1.10 – 2.15

Values are mean ±SD or n (%); Effectiveness, efficiency, and satisfaction items are measured on a Visual Analogue Scale (VAS: 0 = slight, 10 = severe). o.s.= orthopaedic shoes.

When considering variables at the effectiveness level of usability of orthopaedic shoes, users of orthopaedic shoes show a significantly greater increase in stance duration (OR= 2.14; p= 0.012) and decrease in skin abnormalities (OR= 1.35; p= 0.038) compared to non-users of orthopaedic shoes. With regard to the efficiency level of usability of orthopaedic shoes, the users of orthopaedic shoes had less problems with putting on/taking off their orthopaedic shoes than non-users (OR= 0.46; p= 0.008). Finally, with regard to satisfaction, the cosmetic appearance of orthopaedic shoes was found to be more attractive by the users than by the non-users (OR= 1.54; p= 0.012).

Gender (OR= 5.09; p= 0.058) and decrease in pain (OR= 1.41; p= 0.056) were also found to be associated with the actual use of orthopaedic shoes, but not significantly (p> 0.05).

The overall fit of the logistic model was 56.3%. The variables of gender, age, increase in stance duration, decrease in pain, and decrease in skin abnormalities had an R^2 of 34.9%. Addition of the efficiency variable putting on and taking off orthopaedic shoes increased the R^2 to 43.3%, and addition of satisfaction variables increased the R^2 with another 13%.

4.5 DISCUSSION

The results of this study indicate that, after three months, 23 out of 93 patients with degenerative disorders of the foot wear their orthopaedic shoes less than three days a week. Previous studies have reported a great variety in the rate of non-use, ranging from 8% to 75%. This variety can partly be explained by the different criteria used to define non-use and the difference in the duration of follow-up, varying from three months[11] to 5 years[8]. Scherer[11] reported that approximately one third of all rehabilitation aids are not used within the first three months after delivery. Phillips & Zhao[10], however, found that non-use of rehabilitation aids occurred mostly within a year after delivery. The difference in the reported rates of non-use can also be explained by differences in the study populations. The amount of non-use has predominantly been studied in patients with diabetes mellitus[9] [16] and rheumatoid arthritis[17]. These are populations in which severe and multiple disabilities (e.g. visual, behavioural, cognitive, inflammations) play an important role.

A potential source of bias lies in the fact that patients tend to give socially desirable answers to questions about the amount of use[18]. This social desirability bias could result in an underestimation of the total amount of non-use found in this study.

With regard to demographic factors, only the univariate analysis showed a strong association between gender and orthopaedic shoe-use. Male patients tend to use their orthopaedic shoes more often than female patients. No association was found between age and orthopaedic shoe- use in the present study, but Sykes et al.[8] found differences in use between different age-groups. In their study the median use under the age of 18 was more than the median use in adult patients.

Effectiveness variables that were found to be associated with orthopaedic shoe-use are: increase in stance duration, decrease in pain, and decrease in skin abnormalities, although decrease in pain was not significantly associated. These results may indicate that, as a result of the changed shape of the foot, degenerative foot disorders are often painful on weight bearing to the extent that ambulation is severely restricted, thus greatly limiting the ability to perform even the basic activities of daily living. Several studies have reported

evidence that orthopaedic shoes (custom- made or off-the-shelf) decrease the pain with weight-bearing activities such as standing and walking[19-25].

With regard to the efficiency factors, a strong association was found between problems experienced with putting on and taking off orthopaedic shoes and the actual amount of use. Patients who experienced fewer problems with putting on and taking off their orthopaedic shoes wore them more often than those who experienced many problems. These findings can be explained by the fact that most patients with degenerative disorders of the feet are elderly people with a diminished physical (cardiovascular, bone, joint, and muscular) status. For these elderly people, putting on and taking off orthopaedic shoes costs a lot of energy and coordination, and this additional effort makes considerable demands on their physical resources.

Within the satisfaction domain a significant association was found between cosmetic appearance and actual use of orthopaedic shoes. Patients who considered their orthopaedic shoes to be attractive wore them more often than those who consider them to be “ugly”. These findings are supported by the results of previous research[24 26 27].

The overall fit of the logistic model (R^2) was 56.3%. Until recently, most comprehensive evaluation studies regarding orthopaedic shoes focussed mainly on the aspects of effectiveness. In the present study a multiple logistic model comprised of demographic and effectiveness variables (gender, age, increase in stance duration, decrease in pain, and decrease in skin abnormalities) had an R^2 of 34.9%. Based on the ISO definition of usability, efficiency and satisfaction variables also need to be studied within a specific context of use. Adding the efficiency variable “problems with putting on and taking off orthopaedic shoes” to the logistic model increased the R^2 to 43.3%. Adding the satisfaction variables to the overall logistic model increased the R^2 with another 13%, mainly due to adding the cosmetic appearance variable. These findings indicate the importance of adding efficiency and satisfaction variables to effectiveness variables when studying the usability of orthopaedic shoes. However, the results of this study must be interpreted with some caution. They are only applicable to groups of patients who are similar to the study population. Within other disease-specific groups, such as patients with diabetes mellitus, rheumatoid arthritis or neurological disorders, additional

factors may also play an important role.

In conclusion, we can learn more about the usability of orthopaedic shoes by adding efficiency factors and satisfaction factors and not only focussing on the effectiveness factors.

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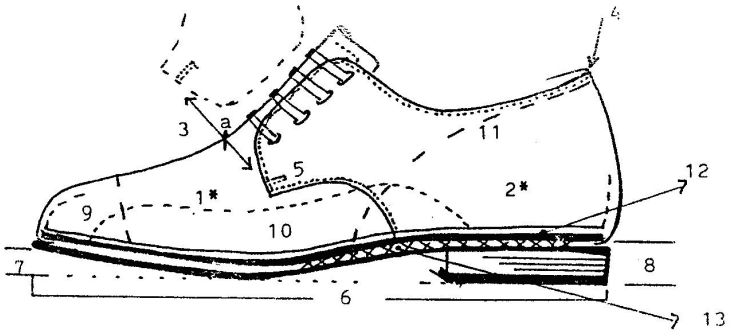
APPENDIX **Anatomy of a custom-made orthopaedic shoe (source: Postema et al. 1991[28])**



1* - 2*	=	The upper shoe
3	=	The instep, the space needed to get the forefoot into the shoe
4	=	The heel grip, the point of grip of the foot/heel
5	=	The (medial/lateral) quarter point
6	=	The shoe bottom, consisting of insole, shank, outer sole and heel
7	=	Toe spring, distance between the sole and the ground, measured at the toe of the shoe
8	=	Heel height
9	=	Toe stiffener
10	=	Lining
11	=	Heel counter
12	=	Insole
13	=	Shank

CHAPTER 5

Prediction of actual use of custom-made orthopaedic shoes in patients with degenerative disorders of the foot is not possible

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Submitted

5.1 ABSTRACT

Objective: The question addressed in the present study is: to what extent can usability factors (effectiveness, efficiency, satisfaction, and context of use) and psychosocial and behavioural factors related to pain, measured at baseline, predict the actual use of orthopaedic shoes in patients with degenerative disorders of the foot.

Design: Multi-centre, prospective cohort study.

Setting and subjects: 100 consecutive patients with degenerative disorders of the foot were included from the outpatient clinics of seven rehabilitation centres in the Netherlands.

Main outcome measures: Baseline characteristics were assessed with the Questionnaire for Usability Evaluation (QUE) and the Multidimensional Pain Inventory – Dutch Language Version (MPI-DLV).

Results: Three months after the delivery of their orthopaedic shoes 70 patients (70%) were classified as users of orthopaedic shoes and 23 patients (23%) were classified as non-users. Seven patients were lost to follow-up. Only gender was associated with the actual use of orthopaedic shoes (OR = 4.486 (1.384 – 14.537). Based on usability factors, and pain related psychosocial factors, no significant associations with actual use of orthopaedic shoes were found.

Conclusions: Prediction of actual use of orthopaedic shoes is not possible on the basis of usability factors and pain related psychosocial factors. Clinicians and orthopaedic shoe technicians need to monitor patients after the delivery of their orthopaedic shoes. In cases of non-use, refined adaptations should be made to the orthopaedic shoes, taking into consideration patient characteristics and patient experiences.

Keywords:

Orthopaedic shoes, degenerative, foot pain, usability

5.2 INTRODUCTION

In Western industrialized societies, degenerative disorders of the foot are common and the prevalence of these foot disorders (e.g. hallux valgus, claw toes, metatarsalgia) increases with age [1]. As a consequence of changes in the shape of the foot, degenerative disorders of the foot are often painful during standing and walking, which greatly interferes with the activities of daily life [1-3]. Serious degenerative disorders of the foot are currently treated with surgical techniques and/or orthopaedic shoes, which can be prescribed by a general practitioner, an orthopaedic surgeon, or a rehabilitation specialist. The prescription and provision of orthopaedic shoes mainly takes place on an empirical basis and therefore depends to a great extent on the individual experiences of the clinicians and orthopaedic shoe technicians.

Unfortunately, according to the literature there is a high rate of non-use of orthopaedic shoes and orthopaedic devices varying from 8% to 75% [4-12]. It is obvious that this high rate of non-use is unsatisfactory and it is also a great burden on societal expenditure and health care costs. The total costs of medical aids were estimated at €□627 million in the Netherlands in 2001. Approximately 15% of these total costs can be attributed to the production of prosthetics and orthotics, including the manufacture of orthopaedic shoes[13].

In an attempt to identify factors that are associated with the actual use of orthopaedic shoes in patients with degenerative disorders of the foot, a recent prospective cohort study addressed the relationship between usability factors (effectiveness, efficiency, satisfaction, context of use) and actual use[14]. The outcomes were increase in stance duration, decrease in skin abnormalities, problems experienced with putting on and taking off orthopaedic shoes, and the cosmetic appearance of orthopaedic shoes.

Today, no predictors are available by which clinicians and orthopaedic shoe technicians can predict the future use of orthopaedic shoes. If potential non-users can be identified early in the rehabilitation process, clinical decisions can be made to adapt the treatment to meet the needs of the patients. In addition to usability factors, pain related psychosocial factors might also play an important role in the actual use of orthopaedic shoes. However, although the role of pain-related psychosocial factors as determinants of device usage

has been recognized, the relationship between these pain-related psychosocial factors and the actual use of rehabilitation devices is still not clear [15 16].

The question addressed in the present study is: to what extent can usability factors and pain-related psychosocial factors predict the actual use of orthopaedic shoes in patients with degenerative disorders of the foot.

5.3 METHODS

Setting and subjects

From September 2001 to February 2003, patients with degenerative disorders of the foot (n = 100) were recruited from the outpatient clinics of seven rehabilitation centres and rehabilitation departments of university hospitals in the Netherlands. The protocol was approved by the local Human Ethics Committee and all patients signed a disclosure form and gave written informed consent. Rehabilitation specialists, who were associated with the participating centres included patients for participation if they: (1) had degenerative disorders of the foot; (2) had a prescription for custom-made orthopaedic footwear; (3) were able to read and understand Dutch; and (4) were over 18 years of age.

In the present study, degenerative disorders of the foot include: arthrosis of ankle/subtalar and midtarsal joints, achillis tendinitis, plantar fasciitis, tibialis posterior tendinitis, hallux valgus, prominent or subluxed metatarsal heads, hallux rigidus, claw toes, hammer toes.

The following patients were excluded: (1) patients with Rheumatoid Arthritis, Diabetes Mellitus or neurological disorders; (2) patients who had active foot infections; (3) patients who were unable to walk without wheelchair assistance; (4) patients who already had experience with orthopaedic shoes; (5) patients who would receive off-the-shelf orthopaedic footwear.

Study design

The study was conducted as a multi-centre prospective cohort study. Baseline assessment was performed one month before the patients received their custom-made orthopaedic shoes. The follow-up measurement, to assess

actual use, was performed three months after delivery of the custom-made orthopaedic shoes. Patients were asked: “how many days a week do you wear your orthopaedic shoes?” Actual use of orthopaedic shoes was measured on an ordinal scale, and the possible answer categories were: never, 1 day a week, 2-3 days a week, 4-5 days a week, or 6-7 days a week.

Measurements

Questionnaire for Usability Evaluation of orthopaedic shoes (QUE): The QUE was developed to study the usability (effectiveness, efficiency, satisfaction, and context of use) of orthopaedic shoes [17]. With the QUE, different aspects of foot complaints during activities of daily life can be studied. It also measures the expectations people have with regard to the effectiveness (pain, instability, and skin abnormalities), efficiency (putting on/ taking off), and satisfaction (stick, slip, weight of shoes, cold feet, perspiration, and cosmetic appearance) of orthopaedic shoes in their context of use. The response format is a Visual Analogue Scale (VAS: 0 = slight, 10 = severe). Face validity was reviewed by experts from the fields of rehabilitation medicine, rehabilitation research, human movement sciences, and orthopaedic shoe technology. Furthermore, the QUE can be considered as a reliable and internally consistent questionnaire with which to assess the usability of orthopaedic shoes[17].

Multidimensional Pain Inventory – Dutch Language Version (MPI-DLV): The MPI-DLV is designed to assess the psychosocial and behavioural aspects of pain [18]. The questionnaire consists of 61 questions, and is divided into three parts. Part 1 gives information about pain experience and the influence of pain on several aspects of daily life (pain severity, interference, life control, affective distress, and support). Part 2 measures the extent to which the patient experiences the reactions of significant others (e.g. partner) towards their pain as punishing, concerning or distracting. Part 3 assesses participation in three categories of daily activities (household chores, outdoor work, and social activities) and a composite score ‘general activity’. With the MPI-DLV, four profiles of pain patients can be identified: dysfunctional, interpersonally distressed, adaptive coper, and average. The dysfunctional type (DYS) reports high levels of pain severity, greater pain-related

interference in daily life, high levels of affective distress, low levels of life control, low activity levels, and a supportive environment. The interpersonally distressed type (ID) is characterized by a high degree of pain severity, high levels of affective distress, and low levels of life control. Furthermore, a low level of environmental support is also characteristic of this type. The adaptive coper (AC) reports less pain severity, lower levels of affective distress, higher activity levels, and less pain-related interference in daily life, compared to the DYS and ID types. The environmental support is lower than of the DYS type, but considerably higher than that of the ID type. The average type (AV) has characteristics between the other three types. In general, the AV type experiences the least suffering compared to the DYS and ID types. Patients who can not be classified into one of the above-mentioned profile types are classified as anomalous. Lousberg concluded that the MPI-DLV is a reliable and valid measurement instrument[18].

Statistical analysis

Three months after delivery of their orthopaedic shoes, the cohort of patients was divided into users and non-users. Users were defined as patients who wore their orthopaedic shoes three days a week or more, and non-users were defined as patients who wore their orthopaedic shoes less than three days a week.

Baseline characteristics were investigated by exploratory univariate analysis to identify demographic characteristics, effectiveness, efficiency, satisfaction factors, and MPI factors associated with the actual use of orthopaedic shoes. Associations were reported as Odds Ratios (OR) and their 95% Confidence Interval (CI). Factors were selected on the basis of the results of the univariate analysis and the previously published results of other studies. All data were analyzed with the SPSS Statistical Package for Windows 11.5. A p-value < 0.05 was considered to be statistically significant.

5.4 RESULTS

Demographic characteristics

Three months after the delivery of their orthopaedic shoes, 70 patients (70%) were classified as users of orthopaedic shoes and 23 patients (23%) were classified as non-users. Seven patients (7%) were lost to follow-up for a diversity of reasons. One patient died, the overall health status of two patients decreased in such way that orthopaedic shoes were no longer required, two patients underwent surgery within the follow-up period, and two patients dropped out for no known reason. Table 1 lists the demographic characteristics of the users and non-users at baseline. No significant associations were found with regard to age, living status or level of education. In the present study only gender was found to be associated with actual use (OR = 4.486 [1.384 – 14.537]).

Table 1 Demographic characteristics

	Users (n=70)	Non-users (n=23)	OR	95% CI
Mean age in yrs (sd)	58.2 (15.5)	63.8 (13.6)	0.974	0.941 – 1.009
Male : Female (n)	34 : 36	4 : 19	4.486	1.384 – 14.537
Living status			1.299	0.450 – 3.743
Living alone	22 (31)	6 (26)		
Living with others	48 (69)	17 (74)		
Level of education			1.956	0.698 – 5.481
≤ Primary school	15 (21)	8 (35)		
> Primary school	55 (79)	15 (65)		

Values n (%)

Usability factors associated with actual use of orthopaedic shoes

The results of the univariate analysis are listed in Table 2. No significant associations were found between actual use and effectiveness, efficiency, and satisfaction factors measured at baseline. Furthermore no significant associations were found when effectiveness, efficiency, and satisfaction factors were analyzed in a multiple logistic regression analysis.

Table 2 Baseline effectiveness, efficiency, and satisfaction factors associated with actual use of orthopaedic shoes

	Users (n=70)	Non-users (n=23)	OR	95% CI
Effectiveness				
Duration in stance	4.0 (3.5)	4.0 (4.0)	1.002	0.879 – 1.141
Duration in walking	4.4 (3.2)	4.3 (3.7)	1.013	0.872 – 1.176
Foot pain with ordinary shoes	4.9 (2.4)	4.5 (2.5)	1.073	0.882 – 1.305
Expected foot pain with o.s.	2.8 (2.1)	2.8 (1.8)	0.986	0.776 – 1.254
Instability with ordinary shoes	2.5 (2.6)	3.4 (3.0)	0.885	0.750 – 1.045
Expected instability with o.s.	3.0 (2.3)	3.0 (2.2)	1.014	0.798 – 1.287
Skin abnormality in ordinary shoes	3.9 (3.5)	4.3 (3.7)	0.967	0.845 – 1.105
Expected skin abnormality in o.s.	2.7 (2.4)	3.3 (2.5)	1.105	0.877 – 1.393
Efficiency				
Amount of problems with putting on/ taking off ordinary shoes	1.1 (2.6)	1.3 (2.9)	0.977	0.821 – 1.163
Expected amount of problems with putting on/taking off in o.s.	1.9 (2.4)	2.1 (2.9)	0.967	0.803 – 1.164
Satisfaction				
Amount of stick in ordinary shoes	3.4 (3.9)	4.9 (4.2)	0.913	0.812 – 1.027
Expected amount of stick in o.s.	1.4 (2.1)	2.0 (2.5)	1.129	0.868 – 1.468
Amount of slip in ordinary shoes	0.5 (1.9)	1.16 (2.9)	0.884	0.729 – 1.072
Expected amount of slip in o.s.	1.3 (1.2)	4.1 (3.8)	1.630	0.842 – 3.158
Amount of weight of ordinary shoes	0.9 (2.5)	1.1 (2.6)	0.970	0.809 – 1.164
Expected amount of weight of o.s.	3.6 (1.9)	3.9 (2.7)	0.935	0.740 – 1.182
Amount of cold feet in ordinary shoes	1.1 (2.0)	0.6 (1.3)	1.183	0.868 – 1.611
Expected amount of cold feet in o.s.	1.9 (2.2)	2.3 (2.1)	1.073	0.863 – 1.335
Amount of perspiration in ordinary shoes	2.1 (3.2)	2.0 (3.7)	1.013	0.877 – 1.169
Expected amount of perspiration in o.s.	3.1 (3.1)	2.3 (2.8)	1.105	0.924 – 1.321
Expected cosmetic appearance of o.s. (ugly - beautiful)	6.5 (2.7)	6.3 (3.1)	1.031	0.868 – 1.224
Expected durability of o.s.	8.2 (1.6)	8.1 (2.0)	1.057	0.795 – 1.405

Values are mean VAS ±SD; o.s.= orthopaedic shoes

MPI – DLV factors associated with actual use of orthopaedic shoes

The baseline characteristics of the two groups showed no significant association between the four MPI-DLV patient profiles (Table 3) and actual use of orthopaedic shoes (OR= 1.151 [0.770 – 1.722]; p = 0.459).

Table 3 MPI-DLV patient profiles for users and non-users

	Users (n=59)	Non-users (n=17)	Total
MPI			
Dysfunctional	9	5	14
Interpersonally distressed	9	4	13
Adaptive coper	10	1	11
Average Type	24	6	30
Anomalous	7	1	8

The results of the univariate logistic analysis that was performed to identify baseline MPI-DLV categories associated with the actual use of orthopaedic shoes (Table 4), also revealed no significant associations. Furthermore, no significant associations were found using a multiple logistic regression model. Seventeen patients could not be included into the analysis because they did not fill in part 2 of the MPI-DLV as a consequence of their living status (e.g. single, widow).

Table 4 Baseline MPI-DLV categories associated with actual use of orthopaedic shoes

	Users (n=59)	Non-users (n=17)	OR	95% CI
MPI				
Pain severity	3.22	3.03	1.152	0.715 – 1.856
Interference	2.76	2.79	0.979	0.616 – 1.555
Life control	4.58	4.29	1.144	0.786 – 1.664
Affective distress	1.78	2.06	0.829	0.527 – 1.304
Support	3.81	3.33	1.183	0.851 – 1.646
Perceived freq. of punishing	0.96	0.83	1.103	0.669 – 1.816
Solicitous	2.70	2.82	0.937	0.631 – 1.393
Distracting responses	2.72	2.58	1.051	0.751 – 1.471
General activity	2.70	2.79	1.218	0.663 – 2.238

5.5 DISCUSSION

After a three-month follow-up, 23 (24.7%) out of 93 patients who participated in this study, wore their orthopaedic shoes for less than three days a week. These results confirm the findings of other studies [4-10]. The non-users are of particular interest, because their abandonment of the orthopaedic shoes has implications for shoe prescriptions. The question addressed in the present study was: to what extent can usability factors and pain related psychosocial factors, measured at baseline, predict the future use of orthopaedic shoes in patients with degenerative disorders of the foot.

The results of this study show that no significant associations could be found between actual use and characteristics measured at baseline with the QUE and the MPI-DLV.

Therefore, no relationship was found between the usability factors, and pain related psychosocial factors and the actual use of orthopaedic shoes. These results are also supported by the results of previous studies focusing on the relationship between psychosocial factors and the actual use of rehabilitation devices. The only two studies that were identified were carried out by Scivoletto et al.[15] and Rogers et al. [16]. Rogers et al. studied the user characteristics of a long-handled bath sponge, and found that non-users perceived greater control over their disability and pain, but that sociodemographic factors did not play a role[16]. Scivoletto et al. found a significant relationship between extroversion and non-use of a reciprocating gait orthosis, but their data were preliminary[15]. Nonetheless, this lack of evidence might also be due to publication bias, because studies reporting on strong (often statistically significant) prognostic ability are more likely to be published.

A recent prospective cohort study reported longitudinal changes in several usability factors[14]. These changes were found three months after the delivery of orthopaedic shoes, and were associated with the actual use of orthopaedic shoes. Based on a multiple logistic regression model, gender (male), age (increasing age), increase in stance duration, decrease in pain, decrease in skin abnormalities, less problems with putting on and taking off orthopaedic shoes, and a positively rated cosmetic appearance were significantly associated with the actual use of orthopaedic shoes. An association between longitudinal changes and actual use of rehabilitation devices had also been reported in previous studies [19 20]. A plausible explanation for these findings can be found in Skinner's theory of operant conditioning [21 22]. Based on this theory, it can be assumed that people with degenerative disorders of the foot are more likely to wear their orthopaedic shoes if they experience an increase in stance duration, a decrease in pain, and a decrease in skin abnormalities (positive experiences). When people do not experience these positive results of wearing orthopaedic shoes, it is plausible that this will lead to non-use. This non-use of orthopaedic shoes, as a consequence of not solving the patient's

foot problems, will be increased by a lack of ease in wearing the shoes. In order to increase actual use, patient experiences with regard to the effectiveness, efficiency, and satisfaction of the orthopaedic shoes need to be translated into material and construction principles on the basis of which shoe adaptations can be made.

With regard to the methodological quality of prognostic studies, Altman describes a list of factors relating to internal validity [23]. These factors concern the characteristics of patient samples, follow-up period, outcome parameters (objective, unbiased, fully defined, and appropriate), prognostic variables, method of analysis, and treatment subsequent to inclusion in the cohort. Most of the criteria were met in the present study. We studied a well defined cohort, but excluded patients with severe cognitive problems. In clinical practice there is no doubt about the lack of rehabilitation potential in these patients and their bad functional prognosis [24]. Altman also states that a sufficiently long follow-up period is important in relation to the internal validity of prognostic studies. Scherer reported that approximately one third of all rehabilitation aids are not used within the first three months after delivery [7]. We therefore chose a follow-up period of three months. Phillips & Zhao, however, found that non-use of rehabilitation aids occurred mostly within a year after delivery [4]. Based on these arguments, further investigation is needed after a one-year follow-up. The third and fourth factors described by Altman concern the outcome and prognostic variables. Both outcome measures, the QUE and MPI-DLV, were shown to have sufficient psychometric characteristics (e.g. face validity, reproducibility, internal consistency) to assess the usability of orthopaedic shoes and the pain-related psychosocial characteristics of the patient, respectively. The last factor mentioned by Altman, regarding standardization of the treatment, was not applicable in the present study because custom-made orthopaedic shoes are individually manufactured based on the foot deformities of the patient[23]. The choice of these shoe characteristics is made by the rehabilitation specialists and orthopaedic shoe technicians.

In conclusion, clinicians and orthopaedic shoe technicians need to monitor patients after the delivery of their orthopaedic shoes. In cases of non-use, refined adaptations should be made to the orthopaedic shoes, taking into consideration patient characteristics and patient experiences.

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CHAPTER 6

Effectiveness of custom-made orthopaedic shoes in the reduction of foot pain and foot pressure in patients with degenerative disorders of the foot

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Submitted

6.1 ABSTRACT

As a consequence of changes in the shape of the foot, degenerative disorders of the feet are often painful during standing and walking. In general, clinicians try to redistribute plantar pressure over the plantar surface by means of orthopaedic shoes or shoe adaptations. However, the relationships between plantar pressure and foot pain in patients with degenerative disorders of the foot are not clear.

The goal of this study was to evaluate the effectiveness of custom-made orthopaedic shoes, in terms of pressure and pain, in patients with degenerative disorders of the foot. Additionally, the relationship between plantar pressure parameters and foot pain was studied, with special emphasis on metatarsal heads 2-3, which are the most relevant in degenerative foot disorders.

77 consecutive patients with degenerative disorders of the foot were recruited from the outpatient clinics of seven rehabilitation centres and rehabilitation departments of university hospitals in the Netherlands.

Visual Analogue Scales were used to measure foot pain during several conditions (standing, walking, climbing stairs, activities of daily life and work). Foot pressure parameters were obtained by means of an in-shoe foot pressure measurement system.

Custom-made orthopaedic shoes significantly decreased subjectively experienced pain by at least 23%, and significantly reduced average pressure under all foot regions by at least 9%, indicating not only a redistribution of pressure but also a decrease in plantar pressure. Based on these results, it can be concluded that custom-made orthopaedic shoes are effective in reducing foot pain and foot pressure.

6.2 INTRODUCTION

Degenerative disorders of the foot are very common in older individuals. Surveys have reported a 10-24 % prevalence of self-reported foot abnormalities in adults, with the highest rates being found in women and in people of 65 years of age and older[1-3]. Degenerative disorders of the foot are defined as: “a foot with anatomical abnormalities and disorders as a consequence of a biomechanical disbalance, which lead to primary arthrosis deformans of one or more joints of the ankle and/or foot region and/or chronic inflammation of peri-articular structures”[4]. Based on this definition the following disorders of the foot are characteristic of the degenerative foot: arthritis of the ankle/subtalar and midtarsal joints, achillis tendinitis, plantar fasciitis, tibialis posterior tendinitis, hallux valgus, prominent or subluxed metatarsal heads, hallux rigidus, claw toes, and hammer toes. As a consequence of the changed shape of the foot, degenerative disorders of the foot are often painful during standing and walking, which are basic elements in all sorts of activities in daily life.

It is assumed, that as a result of bone deformity, callus, and deformity of the plantar pads, the plantar pressure distribution has changed[5]. In general, clinicians try to redistribute plantar pressure over the plantar surface by means of orthopaedic shoes or shoe adaptations. This is mostly a process of trial and error based on empirical knowledge, in which the orthopaedic shoe or inlay is often adjusted on the basis of the patient’s comments regarding pain relief and comfort. More and more, in-shoe pressure measurement systems are being used to obtain objective information concerning the pressure distribution between foot sole and shoe. However, the relationships between foot pressure and foot pain in patients with degenerative disorders of the foot are not clear. One study that was identified addressed the relationship between pain and different foot pressure parameters in the rheumatoid foot[5]. The authors found that the average pressure may be a useful indicator in the management of the rheumatoid foot, but that further study is required to improve understanding of the relationship between rheumatoid foot mechanisms and pain. Another investigation, carried out by Postema et al.,[6] studied the effects of orthoses in relieving metatarsalgia. They found that

custom-made orthoses were more effective than ready-made orthoses, but they did not find any relationship between peak pressure and pain.

The goal of this project was to study the effectiveness of custom-made orthopaedic shoes, in terms of foot pressure and foot pain, in patients with degenerative disorders of the foot. Additionally, the relationship between plantar pressure in patients with degenerative disorders of the foot and foot pain was studied, with special emphasis on metatarsal heads 2-3, which are the most relevant in degenerative foot disorders.

6.3 METHODS

Subjects

A total of 77 consecutive patients with degenerative disorders of the foot were recruited from the outpatient clinics of seven rehabilitation centres and rehabilitation departments of university hospitals in the Netherlands, from September 2001 to February 2003.

The inclusion criteria specified that patients: (1) had degenerative disorders of the foot accompanied by foot pain; (2) had a prescription for custom-made orthopaedic footwear; (3) were able to read Dutch; and (4) and were older than 18 years. The rehabilitation specialists, associated with the seven participating centres established the presence of degenerative disorders of the foot.

The exclusion criteria were: (1) patients with Rheumatoid Arthritis, Diabetes Mellitus or neurological disorders; (2) patients who had active infections; (3) patients taking analgesics; (4) patients who are wheelchair-bound (5) patients who had already had experience with orthopaedic shoes; (6) patients who would receive off-the-shelf orthopaedic footwear.

Measurements

Visual Analogue Scales (VAS) were used to measure foot pain in several situations (standing, walking, climbing stairs, activities of daily life and work). The VAS consisted of a straight, horizontal line, 100 mm in length bounded by

two anchor phrases (‘little pain’ and ‘severe pain’). The line was not divided into any sections.

To measure plantar pressures an in-shoe pressure measurement system (Novel GmbH, Munich, Germany; Pedar-mobile expert version 129wo; novel-win version 08.7) was used. It has been demonstrated that this Pedar in-shoe pressure measurement system is reliable and valid[7]. Insoles consisted of 256 matrix-configured sensors, each of which was sampled at 50Hz. With the aid of a calibration device, all sensors in the insoles were individually calibrated with air pressure, in a computer-aided procedure. Calibration occurred every three months, as prescribed by the manufacturer.

As it is likely that there is a relationship between the two individual feet, it was decided to focus only on the right foot in this study. In the middle of a longer walkway (10 m), six steps of each measured trial were studied, thereby excluding start and end effects. The walking duration of each trial was determined by summation of these six steps, and the *median* walking duration was calculated over seven trials. Compared to the mean walking time, the *median* walking time is less sensitive for outliers. Three of the seven trials adjacent to this median walking duration were further analysed. For each of these three trials the median step-time was calculated, and the step with the median step-time and the step most similar to this median step-time were selected.

The EMED Pedar Link programme was used to select these six steps (two steps x three trials) for further analysis in the EMED Multimask Evaluation programme. Pressure parameters were calculated for each of the following foot regions: lateral hindfoot (LH), medial hindfoot (MH), lateral midfoot (LM), medial midfoot (MM), 1st metatarsal head (MTH1), 2nd and 3rd metatarsal heads (MTH2-3), 4th and 5th metatarsal heads (MTH4-5), hallux (H), toes 2-5 (T2-5). For each region, an average score from 6 steps was calculated for peak pressure, average pressure, and pressure-time integral. Peak pressure (P_{max}; N/cm^2) is defined as the maximum pressure that occurred in each region. The pressure-time integral (P_{TI}; N.s/cm^2) equals the area under the pressure-time curve. The average pressure (P_{av}; N/cm^2) per region was calculated by dividing the pressure-time integral by the time in that particular region.

The prescription of custom-made orthopaedic shoes for patients with degenerative disorders of the foot is based on the hypothesis that excessive pressure under the foot causes pain. More specifically, pain in the forefoot (under the metatarsal heads) is the problem that is most frequently mentioned [6]. In addition, the centre of pressure (the point on the ground through which a single resultant force appears to act) starts at the back of the heel on the lateral side and runs along the middle of the foot to the metatarsal heads 2-3, where it moves medially, ending at the hallux (Figure 1). In order to select the pressure parameter (P_{max}, P_{TI} and P_{av}) most closely associated with walking pain, pressure parameters at the point of intersection (the metatarsal heads 2-3 region) were studied.

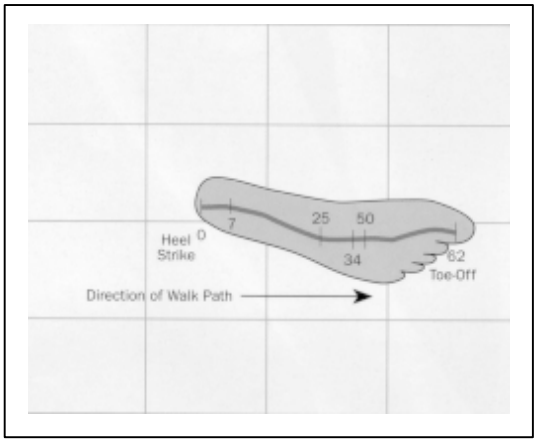

Figure 1 Direction of centre of pressure

Custom-made orthopaedic shoes

In the present study, custom-made orthopaedic shoes are defined as complete individually manufactured low or high shoes with medical technical facilities (Figure 2a, 2b). The orthopaedic shoe technician uses a blue-print of the foot, a plaster cast of the foot, and a vacuum footprint to manufacture an individual last. The individual last is used to make a plastic proof shoe, with which the clinicians and orthopaedic shoe technicians can detect pressure points and can study the patient's gait cycle on an empirical base. After this

evaluation the real custom-made orthopaedic shoe is manufactured. All custom-made orthopaedic shoes were provided with custom-made insoles. In the present study the insoles were made of Plastazote and PPT. Plastazote is a foamed polyethylene with a closed-cell construction, and PPT is an open-cell, porous, firm foam material which relieves local pressure, labelled as a "high energy-absorbing substance"

Figure 2a Complete individually manufactured low orthopaedic shoes

Figure 2b Complete individually manufactured high orthopaedic shoes

Procedures

The study was conducted as a cohort study. Each patient was examined by a rehabilitation specialist who explained the project. The protocol was approved by the local Human Ethics Committee, and all subjects signed a disclosure form and informed consent. Subjects were assessed twice: a baseline assessment was made of the patients wearing their present footwear (T0), one month before receiving custom-made orthopaedic shoes, and a follow-up measurement was made 3 months after delivery of the custom-made orthopaedic shoes (T1).

At T0 and at T1 the measurement insoles were positioned according to the manufacturer's protocol. Each subject was allowed 5 minutes to get used to the measurement insoles. Measurements were taken during 7 separate trials along a straight, level walkway. The subjects walked at a self-chosen, comfortable walking speed. Patients were allowed to use their personal walking aids, e.g. walking stick, crutch. The VAS was used to measure foot

pain at T0 and T1. Patients completed the VAS at home prior to the foot pressure measurement.

Statistical analysis of data

The effectiveness of custom-made orthopaedic shoes, in terms of pressure and pain in patients with degenerative disorders of the foot, was evaluated by means of a paired sample T-test.

To select the pressure parameter (P_{max}, P_{TI} and P_{av}) most closely associated with walking pain, pressure parameters in the metatarsal heads 2-3 region were studied by calculating the within-subject correlation coefficients[8]. The within-subject correlation is defined as the correlation between foot pressure under MTH 2-3 and walking pain within the subjects. This correlation is calculated as the correlation coefficient between the within-subject deviation scores.

6.4 RESULTS

Patient characteristics

Table 1 gives a summary of the baseline characteristics of the study population. Three months after the delivery of their orthopaedic shoes, 64 patients (83.0%) wore their orthopaedic shoes more than three days per week and 13 patients (17.0%) wore their orthopaedic shoes less than three days per week.

Table 1 Summary of baseline characteristics of study population

Variable	n=77
Age (years: mean (sd))	60.5 (14.8)
Gender	
male	30 (39)
female	47 (61)
Degenerative disorder (n)*	
arthrosis	30
achillis tendonitis	2
plantar fasciitis	2
tibialis posterior tendonitis	0
hallux valgus	35
prominent MT-heads	58
hallux rigidus	34
claw toes	32
hammer toes	18

*More than one degenerative disorder per person can be present.

The mean step-time wearing ordinary shoes was 0.756 (0.152) seconds, while wearing orthopaedic shoes the mean step-time was 0.708 (0.130). A paired T-test indicated a significant difference in step-time between walking with ordinary shoes and walking with orthopaedic shoes (T= 3.265, p= 0.002). However, the increase in velocity was 6.4%.

Foot pain

The data were analysed to investigate whether custom-made orthopaedic shoes had any effect on subjective perceptions of foot pain during standing, walking, climbing stairs, activities of daily life and work. The mean and standard deviation VAS scores are listed in Table 2. For all situations (standing, walking, climbing stairs, activities of daily life, and work), pain significantly decreased by at least 23% within three months when patients wore orthopaedic shoes instead of their ordinary shoes.

Table 2 Comparison of pain during standing, walking, climbing stairs, activities of daily life, and work activities between ordinary shoes and orthopaedic shoes

Activities	Ordinary shoes	Orthopaedic shoes	Pain decrease (%)	p
Pain during standing	6.3 (2.7)	3.5 (3.2)	44	.000
Pain during walking	7.1 (2.6)	5.5 (2.5)	23	.001
Pain during climbing stairs	3.4 (3.8)	2.2 (3.2)	35	.007
Pain during activities of daily life	5.2 (3.2)	3.1 (3.5)	40	.000
Pain during work activities	3.9 (3.9)	2.1 (3.2)	46	.000

Associations between foot pain during walking and foot pressure parameters

The highest correlation was found between average pressure and walking pain (Table 3).

Approximately 27% (R^2) of the variability could be attributed to the observed association between average pressure and walking pain.

Table 3 Correlation between pressure variables in metatarsal heads 2-3 region and walking pain

Variable	Correlation coefficient (95%-CI)
Peak pressure (N/cm^2)	0.444 (0.307 - 0.563)
Pressure-time integral (Ns/cm2)	0.360 (0.213 - 0.490)
Average pressure (N/cm^2)	0.521 (0.396 - 0.628)

The effect of custom-made orthopaedic shoes on average pressure in 9 foot regions

Analyses of the effect of orthopaedic shoes on plantar pressure focussed on the average pressure within each region. A paired T-test was used to study the effect of custom-made orthopaedic shoes on average pressures for nine regions under the foot. Table 4 shows the mean (standard deviation) average pressure data for 77 patients walking with ordinary shoes and orthopaedic shoes. Three patients were excluded from further data-analysis because of technical problems with the measurement equipment. The paired T-test indicated that the average pressure under all nine regions significantly decreased by at least 9 % when wearing custom made orthopaedic shoes instead of ordinary shoes.

Table 4 Average pressure data (SD) for all regions per shoe type*

Foot region	Ordinary shoes	Orthopaedic shoes	Pressure decrease (%)	p
LH	10.9 (2.5)	9.9 (3.4)	9	.021
MH	11.1 (3.0)	9.2 (2.1)	17	.000
LM	9.7 (2.6)	8.7 (1.7)	10	.001
MM	9.7 (3.12)	8.6 (2.0)	11	.001
MTH1	12.1 (5.6)	9.6 (3.4)	12	.000
MTH2-3	11.9 (3.9)	9.6 (2.9)	19	.000
MTH4-5	9.5 (3.7)	8.4 (2.8)	12	.002
Hallux	12.1 (5.5)	9.6 (3.0)	21	.000
Toes 2-5	10.5 (4.0)	8.9 (2.6)	15	.000

* Average pressure is presented as N/cm^2

6.5 DISCUSSION

The results of this study show that custom-made orthopaedic shoes significantly decrease foot pain during standing, walking, climbing stairs, activities of daily life, and working activities by at least 23% within three months. Such results have also been reported in several other studies, which found that orthopaedic shoes (custom-made or off-the-shelf) decreased pain during weight-bearing activities such as standing and walking[9-16].

The present study also indicates a significant difference in step-time (closely related to an increase in walking speed) between walking with ordinary shoes and walking with orthopaedic shoes. This increase in walking speed is likely to

affect plantar pressure. Previous studies have reported higher plantar pressures as a result of higher walking speeds[7 17]. In the present study, however, it was decided not to standardize walking speed but to allow patients to walk at their normal comfortable walking speed, and to use step-time as an outcome parameter. According to Cavanagh and Ulbrecht[18], this is more meaningful than attempting to make the patients conform to a set of conditions which may be unnatural for them. Consequently, the pressure parameters measured during walking with orthopaedic shoes must be interpreted with the increase (6.4%) in walking speed in mind.

Treatment of degenerative disorders of the foot generally aims at redistributing the plantar pressure by means of different types of materials incorporated in the insoles. When considering the effectiveness of orthopaedic shoes in terms of plantar pressure, the results of this study show a remarkable decrease in average pressure of at least 9 % under all nine foot regions, indicating not only a redistribution of plantar pressure, but also a 'loss' of overall pressure, despite the increase in walking speed. This decrease in overall pressure was also observed in several other studies[5 6]. However, these studies did not report results for the entire foot. Several mechanisms might have caused the 'loss' in overall pressure found in this study. The in-shoe pressure measurement system measures only plantar pressure during the stance phase of the gait cycle. It is not possible to measure plantar pressure during the swing phase with the currently available in-shoe pressure measurement systems. Moreover, most of the custom-made insoles used in this study were made of Plastazote and PPT. Plastazote is a foamed polyethylene with a closed-cell construction. PPT is an open-cell, porous, firm foam material which relieves local pressure, labelled as a "high-energy absorbing substance"[19 20]. Previous research had already indicated the effects of different types of materials in reducing plantar pressures during the stance phase of the gait cycle[19-21].In addition, Brodsky at al.[21] found that under laboratory conditions Plastazote and PPT reduced the force transmitted, indicating the shock-absorbing properties of the materials. These shock-absorbing properties result not only in a decrease in plantar pressure during the stance phase, but also in a certain time-delay before the material returns to its original form. Therefore, as a consequence of this time-delay, part of the

absorbed pressure might be released during the unloading phase and the swing phase, in which the plantar pressure can not be measured.

The aim of this project was to study the relationship between plantar pressure (peak pressure, average pressure, pressure-time integral) and foot pain in patients with degenerative disorders of the foot.

Although the average pressure correlated best with walking pain, the correlation accounted for only 27% (R^2) of the variability. Other factors - physical, psychological and sociological - could also play a role in pain sensation. A number of previous studies have investigated the relationship between pressure variables and pain. Postema et al.[6] studied the effect of orthoses in relieving metatarsalgia. They concluded that custom-moulded insoles and a rockerbar result in a substantial redistribution of pressure, as expressed by the peak pressure and force impulse. However, they found no statistically significant correlation between peak pressure, force-time integral and pain. Hodge et al.[5] also found no relationship between peak pressure and pain, but they did find a moderate ($r= 0.562$) and statistically significant ($p< 0.05$) relationship between average pressure and pain. They stated that although peak pressure might be the variable of interest in management of the insensate foot, because of its relationship to mechanical damage und ulceration, average pressure appeared to be the more important variable in the management of pain. Hodge et al.[5] provided a plausible explanation for this observation. Based on studies carried out by Garell et al.[22] and Greenspan[23] they stated that, unlike mechanoreceptors, nociceptors respond slowly to increases in pressure. It is plausible that brief duration peak pressures are insufficient to cause the high frequency discharges from nociceptors that are necessary for the perception of pain.

Based on these results of the present study, it can be concluded that custom-made orthopaedic shoes are effective in reducing foot pain and foot pressure.

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CHAPTER 7

General discussion and conclusions

7.1 GENERAL DISCUSSION

It is estimated that in the Netherlands approximately 200,000 people per year consult their general practitioner because of foot complaints that are not attributable to an accident [1 2]. Many of these foot complaints are the result of degenerative changes in the foot, which can be alleviated by means of (custom-made) orthopaedic shoes.

Unfortunately, it is well known in clinical practice that there is a considerable amount of non-use of orthopaedic shoes [3-9], but the exact extent of non-use of orthopaedic shoes in the Netherlands is not clear. No overview is yet available of the extent to which orthopaedic shoes are evaluated, or by which methods, and there is no clear evidence with regard to associations between usability factors (effectiveness, efficiency, satisfaction, and context of use) and the actual use that is made of custom-made orthopaedic shoes. Future use can therefore not be predicted by rehabilitation specialists or orthopaedic shoe technicians.

The present research has clarified some of these issues. Some methodological issues will be discussed from a more general point of view, and the clinical implications of the findings for the management of custom-made orthopaedic shoes will also be discussed, together with their relevance for the various stakeholders e.g. patients, medical specialists, orthopaedic shoe technicians. Some recommendations for further research regarding the usability of custom-made orthopaedic shoes are also made.

Methodology

Variation in non-use

In the literature, a considerable amount of non-use of orthopaedic shoes and shoe inserts is reported, varying from 8% to 75% [3-9]. This variation can partly be explained by the conflicting opinions with regard to the prescription of (custom-made) orthopaedic shoes and the specific shoe-design features that are necessary to achieve protective benefits. As a result, custom-made

orthopaedic shoes are manufactured according to a wide range of principles. Another plausible explanation for this reported variation in non-use of orthopaedic shoes can be found in the different criteria used to define non-use. A recent literature search gave an overview of the reported definitions of non-use of rehabilitation technological aids [10]. Scherer compared several studies in which non-use of assisted devices was investigated, and found that an average of about one-third to one-half of the devices are not used [9]. The most simplistic definition of non-use was proposed by Phillips and Zhao [8], who dichotomized actual use into yes versus no. However, most authors adopt a more refined definition of non-use [9 11 12]. Scherer makes a distinction in several degrees of non-use, ranging from full-time use to partial use. Parker and Thorslund use three categories to define actual use: the device is used correctly, the device is used incorrectly, and the device is not being used [13]. Finally, the term functional use is often used in clinical practice, but it is not well-defined. Further research, for example based on a Delphi Method, needs to be carried out to define non-use in terms of frequency of use, duration of use per day, average use, and use during various activities, etc. With the Delphi Method, the opinions of individual experts on a certain topic can be combined to reach consensus. By means of a questionnaire, experts are asked to give their opinion about the actual use of orthopaedic shoes. The results are then summarized and, based on these results, a revised questionnaire is developed for the expert group. The expert group is usually given at least one opportunity to re-evaluate its original answers, based on examination of the group response. It is also possible to re-evaluate the individual findings by means of group meetings. Based on this method, consensus could be reached with regard to the definition of (functional) use of orthopaedic shoes.

Literature analysis

As mentioned in the Introduction, the main goal of this thesis was to gain a better understanding of the associations between usability factors (effectiveness, efficiency, satisfaction, and context of use) and the actual use of custom-made orthopaedic shoes by patients with degenerative disorders of the foot. To achieve this goal, a systematic literature analysis was first

performed to assess the extent to which current evaluation studies focus on all aspects of the ISO definition of usability, i.e. effectiveness, efficiency, satisfaction, and context of use[14]. Additionally, a search was made in the literature for prognostic factors regarding the actual use of rehabilitation technological aids, in particular orthopaedic shoes. These factors formed the starting point of the item pool for the development of the Questionnaire for Usability Evaluation of orthopaedic shoes.

In general, the additional value of systematic reviews is that they provide an overview in which the findings of original articles are summarized in a systematic manner. Through a clearly formulated goal, research question, and methods section, the literature research becomes reproducible and verifiable. Most systematic reviews reported in the literature focus in particular on randomised controlled trials (RCTs) because these are likely to provide more valid and reliable information than other sources of evidence when addressing aspects of therapeutic efficacy [15]. To identify factors associated with the actual use of orthopaedic shoes and any possible prognostic factors, non-randomized longitudinal studies were also investigated. However, it was even more difficult to identify all longitudinal non-randomized evaluation studies by searching the literature in a systematic way than it was to identify RCTs. It is probable that studies reporting strong, often statistically significant associations are more likely to be published (publication bias) than studies with negative results [16]. Moreover, there is no widely acknowledged optimal strategy for searching the literature for longitudinal evaluation studies. There is also a need for guidelines to assess the quality of these longitudinal studies and optimal search strategies for non-randomised trials need to be developed. As a consequence of this lack of consensus, we reported only the RCTs in our systematic review, but other study designs were also used to create an item pool as a starting point for the development of a questionnaire.

Clinical implications

The Questionnaire for Usability Evaluation

In this thesis, a description is given of the construction and reliability analysis of the Questionnaire for Usability Evaluation of orthopaedic shoes (QUE). The QUE was developed because there was no existing questionnaire which quantified all aspects of the usability (effectiveness, efficiency, satisfaction and context of use) of orthopaedic shoes. The QUE was found to be a reliable (reproducible and internally consistent) questionnaire, with which to evaluate the usability of custom-made orthopaedic shoes [17].

The QUE was developed as a research tool to evaluate the usability of orthopaedic shoes. In the near future the QUE can also be applied in clinical practice as an assessment and monitoring instrument. During the first consult of a patient with degenerative disorders of the foot, an inventory can be made of foot pain and instability problems during various activities e.g. standing, walking, climbing stairs, daily activities, and work. Moreover, an inventory can also be made of the patient's expectations with regard to the orthopaedic shoes and their context of use. However, in its present form the QUE is far too extensive, and needs to be shortened into a checklist. This will increase its practicability in clinical practice.

An additional advantage of such a checklist, which will provide an inventory of patient characteristics, is that it will ease the pressure on rehabilitation specialists and orthopaedic surgeons. As is already the case in other diagnostic fields of rehabilitation (e.g. spinal cord injury, multiple sclerosis) in several European countries and in the United States of America, nurse practitioners can assist the physicians in the diagnosis and treatment of patients. These nurse practitioners work closely with doctors to provide high quality individualized care for their patients. By filling in this checklist the nurse practitioner can make a differential diagnosis and a treatment policy which can serve as a starting point for the prescription of (custom-made) orthopaedic shoes by the rehabilitation specialist or orthopaedic surgeon.

After the delivery of the orthopaedic shoes, during the check-up, the nurse practitioner can make a follow-up inventory to objectify the increase or decline in the patient's foot problems. The patient's experience with the orthopaedic shoes in terms of efficiency (problems with putting on and taking off the orthopaedic shoes) and satisfaction (cosmetic appearance) can also be assessed in a simple way by means of the QUE. An additional advantage of this monitoring process could be the effect of making the patient aware of the increase or decline in foot problems since the delivery of the orthopaedic shoes.

In future studies, the currently available QUE also needs to be examined by linking the items, based on the International Organization for Standardization (ISO) definition of usability to the International Classification of Functioning, Disability and Health (ICF) reference framework[18]. In this way it is possible to link the QUE to other already existing instruments. As a consequence, it can also be modified to assess the usability of other rehabilitation devices. Linking the domains of the ICF framework to the terminology used by the ISO also has other advantages for health care. The ISO's principal activity is the development of technical standards making the development, manufacturing and supply of products and services more efficient, safer and cleaner. The ICF describes how people live with their health condition and gives a classification of health and health-related domains that describe body functions and structures, activities and participation. Since an individual's functioning and disability occurs within a context, the ICF also includes a list of environmental factors. Linking the ICF to the ISO might therefore be beneficial for the development and evaluation of technological rehabilitation aids made for people with impairments of body functions.

Factors associated with actual use

The results of this study show no significant associations between actual use and characteristics measured at baseline with the QUE and the Multidimensional Pain Inventory – Dutch Language Version (MPI-DLV). Therefore, no relationship was found between usability factors and pain-related psychosocial factors and actual use of custom-made orthopaedic shoes[19]. The results of the present study are supported by the findings of

some previous investigations in which the relationship between psychosocial factors and actual use of rehabilitation devices was studied [20 21]. However, the present study did show longitudinal changes in usability factors[22]. Based on a multiple logistic regression model, gender (male), age (increasing age), increase in stance duration, decrease in pain, decrease in skin abnormalities, less problems with putting on and taking off orthopaedic shoes, and a positive opinion of cosmetic appearance were significantly associated with actual use of custom-made orthopaedic shoes. These changes were found three months after the delivery of the orthopaedic shoes. An association between longitudinal changes and actual use of rehabilitation devices has also been reported in previous studies [23 24].

A plausible explanation for these findings can be found in the behavioural sciences. According to Skinner's theory of operant conditioning, people learn to act as a function of consequences [25-27]. The basic principle of this theory is the repetition of behaviour as a consequence of pleasant stimuli (positive reinforcers). People intend to show behaviour which leads to positive results but when they experience no results or negative results, the behaviour will be avoided or will be abandoned. Based on this theory, it can be stated that people with degenerative disorders of the foot are likely to wear their custom-made orthopaedic shoes (behaviour) if they experience an increase in stance duration, a decrease in pain, and a decrease in skin abnormalities (positive reinforcers). As a consequence an important task for the rehabilitation specialist, orthopaedic surgeon, and orthopaedic shoe technician is to give realistic information about the expected benefit of the orthopaedic shoes and to provide a good orthopaedic shoe. Within this framework it also needs to be stressed that the foot complaints will not disappear from one day to another, and that patients sometimes need time to accustom themselves to their new (orthopaedic) shoes in gradually. Furthermore, non-use of orthopaedic shoes, as a consequence of failure to solve foot complaints, will be increased by a lack of comfort. As a consequence of the association found between problems with putting on / taking off of the orthopaedic shoes and actual use, it is recommended that new construction principles should be developed to improve the comfort of orthopaedic shoes. Due to an increase in comfort,

(custom-made) orthopaedic shoes would also become beneficial for patients with additional problems e.g. physical, mental or cognitive impairments.

The use of foot pressure measurements

A broad scala of new technologies are currently being developed and evaluated within the field of rehabilitation. The use of these new technologies, which should increase the quality of health care and reduce the pressure on rehabilitation professionals, is stimulated by the government as well as by the health care professionals themselves. The main goal is to integrate these new technologies in rehabilitation care. One example is a foot pressure measurement system. Foot pressure measurement systems can play a supportive role in objectifying the quality of custom-made orthopaedic shoes and the materials used to reduce or redistribute plantar pressure in relation to the foot problems. There is consensus, both in clinical practice and in the literature, that plantar pressure relief is the main goal in treating serious degenerative disorders of the foot. In general, clinicians try to redistribute plantar pressure over the plantar surface by means of orthopaedic shoes or shoe adaptations.

More and more, in-shoe pressure measurement systems are being used to obtain objective information concerning the pressure distribution between foot sole and shoe. Currently however, these foot pressure measurement systems are mainly used for scientific purposes and to a lesser degree in clinical practice, because the relationship between dynamic foot pressure parameters, foot complaints and shoe construction and materials is not clear. In the present study a modest correlation ($r = 0.521$ (0.396 - 0.628)) was found between average pressure beneath the 2^{nd} and 3^{rd} metatarsal heads and foot pain when walking. These results are supported by Hodge et al., who also found a modest relationship between average pressure and pain in rheumatic patients[28]. Based on these findings, we suggest that clinicians and orthopaedic shoe technicians should focus on the average plantar pressure in the management of painful degenerative feet. It should be mentioned that these findings are based on the measurement of vertical forces. In future studies the effect of shear forces on painful feet also needs to be investigated.

Despite this increasing knowledge about the relationship between plantar pressure parameters and foot complaints, there is no consensus among clinicians and orthopaedic shoe technicians about which shoe characteristics are the most effective in treating the above-mentioned foot problems. Following Postema et al and Praet and Louwerens, more research needs to be carried out to investigate the relationship between shoe design and pressure reduction[29] [30]. Postema et al. concluded that custom-moulded insoles and a rockerbar result in a substantial redistribution of pressure, as expressed by the peak pressure and force impulse, in patients with metatarsalgia[29]. However, they found no statistically significant correlation between peak pressure, force-time integral and pain. Praet and Louwerens also concluded that custom-made orthopaedic rocker-bottom shoes are the most effective method for reducing the pressure underneath the neuropathic forefoot[30], but no clear relationships were found between contact area, shaft height and reduction in plantar pressure.

7.2 GENERAL CONCLUSIONS

Our multi-centre prospective cohort study showed that, after three months, 23 out of 93 patients with degenerative disorders of the foot wore their custom-made orthopaedic shoes less than three days a week.

Based on the ISO definition of usability, the following effectiveness variables were found to be associated with orthopaedic shoe-use: increase in stance duration, decrease in pain, and decrease in skin abnormalities, although for decrease in pain the association was not significant. With regard to the efficiency factors, a strong association was found between problems with putting on and taking off the orthopaedic shoes and the actual amount of use. Patients who experienced fewer problems with putting on and taking off their orthopaedic shoes wore them more often than those who experienced many problems. Within the domain of satisfaction, a significant association was found between cosmetic appearance and actual use of the orthopaedic shoes. Patients who considered their orthopaedic shoes to be attractive wore them more often than those who considered them to be “ugly”.

The overall fit of the logistic model (R^2) was 56.3%, of which 34.9% was at the expense of the domain of effectiveness (increase in stance duration, decrease in pain, and decrease in skin abnormalities). These findings indicate the importance of adding efficiency and satisfaction variables to effectiveness variables when studying the usability of orthopaedic shoes.

It is not possible to predict the actual use of orthopaedic shoes on the basis of usability factors and pain-related psychosocial factors. As a consequence, clinicians and orthopaedic shoe technicians have to provide adequate orthopaedic shoes – type, material, construction, cosmetic appearance, etc. – and need to monitor the patient after delivery of the orthopaedic shoes. In case of non-use, refined adaptations should be made to the orthopaedic shoes in accordance with patient characteristics and patient experiences. In addition to improving the usability of the orthopaedic shoes after three months, these factors can also be used in the process of prescribing a second pair of orthopaedic shoes.

Within this research project a study was made of the effectiveness of custom-made orthopaedic shoes, in terms of pressure and pain, in patients with degenerative disorders of the foot. Custom-made orthopaedic shoes significantly decreased subjectively experienced pain by at least 23%, and significantly reduced average pressure under all foot regions by at least 9%, indicating not only a redistribution of pressure but also a decrease in plantar pressure. We currently recommend that clinicians and orthopaedic shoe technicians focus on the average plantar pressure during the management of painful degenerative feet.

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SUMMARY

Usability of custom-made orthopaedic shoes in patients with degenerative disorders of the foot

Surveys have reported a 10-24% prevalence of self-reported foot abnormalities in adults in Western industrialized society, with the highest rates being found in women and in people of 65 years of age and older. As a consequence of these foot abnormalities (e.g. hallux valgus, claw toes, metatarsalgia), degenerative disorders of the foot develop, which are often painful during standing and walking, and interfere greatly with the activities of daily life. Orthopaedic shoes can be prescribed for the above-mentioned degenerative disorders of the foot, especially in serious cases. Unfortunately, it is well known in clinical practice that there is a considerable amount of non-use of the orthopaedic shoes and shoe inserts that are prescribed, varying from 8% to 75%. It is obvious that such a high rate of non-use is unsatisfactory, and puts a great burden on societal and health care costs.

The treatment of degenerative disorders of the foot is still mainly based on clinical evidence and 'trial and error', and only to a limited extent on evidence-based medicine. No clear evidence is available with regard to the associations between usability factors and the actual use of orthopaedic shoes, nor can future use be predicted by rehabilitation specialists or orthopaedic shoe technicians.

The definition of usability according to the International Organization for Standardization (ISO) forms the framework for this research project. The ISO defines usability as: "the extent to which a product can be used by specific users to achieve goals with effectiveness, efficiency, and satisfaction in a specified context of use".

The main aim of this thesis is to gain a better understanding of the associations between usability factors (effectiveness, efficiency, satisfaction, and context of use) and the actual use of custom-made orthopaedic shoes by

patients with degenerative disorders of the foot. The main research questions that are addressed this thesis are:

1. Which usability factors (effectiveness, efficiency, satisfaction, and context of use) are associated with actual use of custom-made orthopaedic shoes?
2. Can actual use be predicted by usability factors and personality factors?
3. What is the relationship between plantar pressure parameters and foot pain in patients with degenerative disorders of the foot?

In the General Introduction (Chapter 1) the problem definition, the aims of this thesis, and the research questions are described.

Chapter 2 presents the results of a systematic review. The objective of this systematic review was to determine the methodological quality of studies evaluating orthopaedic shoes and orthopaedic shoe provisions. The aim was also to assess the extent to which studies evaluating orthopaedic shoes, prescribed for patients with degenerative disorders of the foot, rheumatoid arthritis, diabetes mellitus and neurological foot disorders, focus on the aspects of the ISO definition of usability, i.e. effectiveness, efficiency, satisfaction, and context of use. Based on this systematic review, it can be concluded that the methodological quality of the studied randomized controlled trials, as assessed according to 19 different criteria, varied considerably. The present review also showed that current scientific literature on the usability of orthopaedic shoes focuses mainly on effectiveness, at the expense of the other domains of usability, i.e. efficiency, satisfaction, and context of use.

Chapter 3 describes the development a self-report questionnaire for patients with degenerative disorders of the foot, to evaluate the usability of their orthopaedic shoes and to assess the reproducibility and responsiveness of the instrument. The development of the Questionnaire for Usability Evaluation (QUE) of orthopaedic shoes was based on a literature search, structured expert interviews, and a ranking procedure. A cross-sectional study was carried out to determine its reproducibility and internal consistency. The QUE

is based on four effectiveness items (pain, instability, callus, wounds), one efficiency item (putting on and taking off the shoes), and seven satisfaction items (pinch, slip, weight of shoes, cold feet, perspiration, maintenance, cosmetic appearance). Furthermore, the QUE is considered to be a reliable (reproducible and internally consistent) questionnaire for the assessment of the usability of orthopaedic shoes.

There is no available data on the various aspects of usability of orthopaedic shoes, which may influence a patient's decision as to whether or not to wear the orthopaedic shoes. The objective of the study described in Chapter 4 was therefore to investigate the amount of use of orthopaedic shoes made by patients with degenerative disorders of the foot, and also to identify usability factors which are associated with the actual use and non-use of orthopaedic shoes, based on the parameters of the ISO definition of usability: effectiveness, efficiency, satisfaction, and context of use. The results of this study showed that, after three months of follow-up, 23 out of 93 patients with degenerative disorders of the foot wore their custom-made orthopaedic shoes less than three days per week. Factors significantly associated with the actual use of orthopaedic shoes are increase in stance duration (effectiveness; OR= 2.14), decrease in skin abnormalities (effectiveness; OR= 1.35), problems with putting on and taking off orthopaedic shoes (efficiency; OR= 0.46), and the cosmetic appearance of orthopaedic shoes (satisfaction; OR= 1.54). These findings indicate the importance of adding efficiency and satisfaction variables to effectiveness variables when studying the usability of orthopaedic shoes.

No predictors are yet available to help clinicians and orthopaedic shoe technicians predict the future use of orthopaedic shoes. If potential non-users can be identified early in the rehabilitation process, clinical decisions can be made to redirect the treatment to meet the needs of the individual patient. Chapter 5 addresses the question of the extent to which usability factors (effectiveness, efficiency, satisfaction, and context of use) and pain-related psychosocial factors, measured at baseline, can predict the future use of orthopaedic shoes in patients with degenerative disorders of the foot. Based

on this study, it was concluded that it is not possible to predict the actual use of orthopaedic shoes on the basis of usability factors and pain- related psychosocial factors. As a consequence, clinicians and orthopaedic shoe technicians have to provide adequate orthopaedic shoes – type, material, construction, cosmetic appearance, etc. – and need to monitor the patient after delivery of the orthopaedic shoes. In case of non-use, refined adaptations should be made to the orthopaedic shoes in accordance with patient characteristics and patient experiences.

To objectify these refined adaptations foot pressure measurement systems are currently available. It is presumed that, as a result of bone deformity and soft tissue atrophy the normal plantar pressure distribution has changed. Clinicians aim to reduce plantar pressure by distributing forces more equally over the plantar surface by means of orthopaedic shoes or orthopaedic shoe provisions. However, the relationships between foot pressure and foot pain in patients with degenerative disorders of the foot are not entirely clear. The goal of the study described in Chapter 6 was to evaluate the effectiveness of custom-made orthopaedic shoes, in terms of pressure and pain, in patients with degenerative disorders of the foot. The relationship between plantar pressure parameters and foot pain was also studied, with special emphasis on metatarsal heads 2-3, which are the most relevant in degenerative foot disorders. It was concluded that wearing custom-made orthopaedic shoes significantly decreased subjectively experienced pain by at least 23%, and significantly reduced average pressure under all foot regions by at least 10%, indicating not only a redistribution of pressure but also a decrease in plantar pressure. A modest correlation was found between average pressure beneath the 2nd and 3rd metatarsal heads and foot pain when walking.
In the General Discussion in Chapter 7, some methodological issues are described from a more general point of view. Aspects of the diversity in definitions of non-use of rehabilitation devices are discussed, and certain methodological issues pertaining to systematic reviews, search strategies and study designs are also addressed. Subsequently, the clinical implications of the findings for the management of custom-made orthopaedic shoes are discussed, together with their relevance for the various stakeholders e.g.

patients, medical specialists and orthopaedic shoe technicians. The possible role of the QUE in the diagnosis and the prescription of orthopaedic shoes is explained, and it is also suggested that the QUE could be used to monitor the patients after the delivery of their orthopaedic shoes. With regard to the factors that were found to be associated with the actual use of orthopaedic shoes, a plausible explanation is given, based on the theory of operant conditioning. Finally, it is suggested that foot pressure measurement systems can play a supportive role in objectifying the quality of the custom-made orthopaedic shoes and the materials used to reduce or redistribute plantar pressure in relation to the foot problems.

SAMENVATTING

Bruikbaarheid van orthopedische schoenen (type A) bij patiënten met degeneratieve voetafwijkingen

Onderzoek heeft aangetoond dat in de Westerse maatschappij degeneratieve voetafwijkingen relatief veel voorkomen, waarbij op basis van zelfgerapporteerde voetklachten prevalenties worden vermeld van 10% tot 24%. De hoogste prevalentie van voetklachten wordt waargenomen bij vrouwen en bij personen ouder dan 65 jaar. Degeneratieve voetafwijkingen, zoals hallux valgus, klauwtenen en metatarsalgie veroorzaken vaak pijn tijdens het gaan en staan. Hierdoor worden de activiteiten van het dagelijks leven soms ernstig verstoord. In deze gevallen kan orthopedisch schoeisel verstrekt worden. Helaas blijkt uit de klinische praktijk dat niet-gebruik van orthopedisch schoeisel relatief veel voorkomt, variërend van 8% tot 75%. Het is duidelijk dat dit hoge percentage niet-gebruik onbevredigend is en daarnaast verantwoordelijk voor aanzienlijke maatschappelijke en gezondheidszorgkosten.

De behandeling van degeneratieve voetafwijkingen door middel van orthopedisch schoeisel is voornamelijk gebaseerd op klinische ervaring en ‘trial and error’ en slechts voor een klein deel op wetenschappelijke bewijsvoering. Er is geen onomstotelijk bewijs voor associaties tussen verschillende bruikbaarheidsfactoren en daadwerkelijk gebruik van orthopedisch schoeisel. Tevens is het voor revalidatieartsen, orthopedisch chirurgen en orthopedisch schoentechnici niet mogelijk om toekomstig gebruik, dan wel niet-gebruik van orthopedisch schoeisel te voorspellen.

De definitie van bruikbaarheid, zoals gehanteerd door de “International Organisation for Standardisation” (ISO), vormt het raamwerk voor dit proefschrift. Binnen de ISO wordt bruikbaarheid gedefinieerd als: “de mate waarin een product door een specifieke gebruikersgroep op een effectieve en efficiënte manier naar tevredenheid gebruikt kan worden binnen een bepaalde gebruikerscontext”.

De belangrijkste doelstelling van het in dit proefschrift beschreven onderzoek is het inzicht te vergroten in mogelijke associaties tussen bruikbaarheidsfactoren (effectiviteit, efficiëntie, satisfactie en gebruikerscontext) en het daadwerkelijk gebruik van individueel vervaardigde orthopedische schoenen bij patiënten met degeneratieve voetafwijkingen te vergroten. De belangrijkste vraagstellingen van dit onderzoek zijn:

1. Welke bruikbaarheidsfactoren (effectiviteit, efficiëntie, satisfactie en gebruikerscontext) zijn geassocieerd met het daadwerkelijk gebruik van individueel vervaardigde orthopedische schoenen?
2. Is het mogelijk daadwerkelijk gebruik van individueel vervaardigde orthopedische schoenen te voorspellen op basis van bruikbaarheidsfactoren en persoonlijkheidsfactoren?
3. Is er een relatie tussen voetdrukparameters en voetpijn van patiënten met degeneratieve voetafwijkingen?

In de algemene inleiding (hoofdstuk 1) worden de probleemstelling, doelstelling en vraagstellingen van het in dit proefschrift beschreven onderzoek vermeld.

In hoofdstuk 2 worden de resultaten van een systematische review naar de methodologische kwaliteit van evaluatiestudies ten aanzien van orthopedische schoenen dan wel schoenvoorzieningen beschreven. Tevens is beoordeeld in welke mate evaluatiestudies van orthopedische schoenen - verstrekt voor patiënten met degeneratieve voetafwijkingen, reumatische voetafwijkingen, patiënten met diabetische voeten en patiënten met neurologische voetwijkingen - zich richten op de verschillende bruikbaarheidsfactoren (effectiviteit, efficiëntie, satisfactie en gebruikerscontext) zoals vermeld door de ISO. Op basis van deze systematische review kan worden geconcludeerd dat de methodologische kwaliteit van de bestudeerde ‘randomised controlled trials’ (beoordeeld volgens 19 verschillende criteria) aanzienlijk varieert. De systematische review toont tevens aan dat de huidige wetenschappelijke literatuur aangaande de bruikbaarheid van orthopedisch schoeisel zich met name richt op de effectiviteit van de orthopedische schoenen ten koste van de

andere bruikbaarheidsfactoren zoals de efficiëntie, satisfactie en gebruikerscontext.

In hoofdstuk 3 wordt een vragenlijst beschreven die ontwikkeld is om de bruikbaarheid van orthopedische schoenen te evalueren bij mensen met degeneratieve voetafwijkingen. Deze “Questionaire for Usability Evaluation of orthopaedic shoes” (QUE) is tot stand gekomen op basis van een literatuurstudie, deskundigeninterviews en een wegingsprocedure. De QUE is opgebouwd uit een viertal effectiviteit-items (pijn, instabiliteit, eelt- en drukplekken en wondjes), één efficiëntie-item (aan- en uittrekken van orthopedisch schoeisel) en zeven satisfactie-items (knellen, slippen, gewicht van de schoenen, koude voeten, transpiratie, onderhoud en cosmetiek van de schoenen). Een cross-sectionele studie is uitgevoerd om de reproduceerbaarheid en de interne consistentie vast te stellen. Gebleken is dat de QUE een betrouwbare (reproduceerbare en intern consistente) vragenlijst is om de bruikbaarheid van orthopedisch schoeisel vast te stellen.

Omdat er geen gegevens bekend waren inzake de verschillende bruikbaarheidsaspecten van orthopedisch schoeisel, die de patiënt doen beslissen om het schoeisel wel of niet te gaan gebruiken, is in hoofdstuk 4 beschreven welke bruikbaarheidsfactoren geassocieerd zijn met het daadwerkelijk gebruik, dan wel niet-gebruik van orthopedische schoenen. De resultaten van deze studie laten zien dat 23 van de 93 patiënten met degeneratieve voetafwijkingen hun orthopedische schoenen minder dan 3 dagen per week dragen. De volgende factoren zijn significant geassocieerd met het daadwerkelijk gebruik van orthopedische schoenen: toename in staduur (effectiviteit; OR = 2,14), afname in huidafwijkingen (effectiviteit; OR = 1,35), problemen met het aan- en uittrekken van orthopedisch schoeisel (efficiëntie; OR = 0,46), en het cosmetische uiterlijk van orthopedische schoenen (satisfactie; OR = 1,54). Deze bevindingen geven het belang aan van de toevoeging van efficiëntie- en satisfactiefactoren in relatie tot de bruikbaarheid van orthopedische schoenen.

Momenteel zijn er geen voorspellende factoren beschikbaar aan de hand waarvan clinici en orthopedisch schoentechnici het toekomstig gebruik van orthopedisch schoeisel kunnen voorspellen. Indien potentiële niet-gebruikers van orthopedisch schoeisel in een vroeg stadium van het revalidatieproces geïdentificeerd zouden kunnen worden, kunnen klinische beslissingen aangaande de behandeling mogelijk worden bijgestuurd overeenkomstig de wensen van de patiënt. In hoofdstuk 5 is de mate beschreven waarin bruikbaarheidsfactoren (effectiviteit, efficiëntie, satisfactie en gebruikerscontext) en pijngerelateerde psychosociale factoren het toekomstig gebruik van orthopedisch schoeisel kunnen voorspellen. Het bleek niet mogelijk toekomstig gebruik van orthopedisch schoeisel te voorspellen door middel van bruikbaarheidsfactoren en pijngerelateerde psychosociale factoren. Daarom is het noodzakelijk dat clinici en orthopedisch schoentechnici adequaat schoeisel – type, materiaal, constructie, cosmetiek, etc – verstrekken én het proces na aflevering van het orthopedisch schoeisel goed bewaken. In het geval van niet-gebruik moeten verfijnde aanpassingen aan het orthopedisch schoeisel gedaan worden, waarbij zowel de karakteristieken van de voet als patiëntervaringen in overweging moeten worden genomen.

Om deze verfijnde aanpassingen aan het orthopedisch schoeisel te objectiveren is voetdrukmeetapparatuur beschikbaar. Verondersteld wordt dat de plantaire druk verandert als gevolg van botdeformatie en weke delen atrofie. Clinici en orthopedisch schoentechnici proberen veelal door middel van orthopedisch schoeisel de plantaire druk te reduceren door de inwerkende krachten meer evenredig over het plantaire oppervlak te verdelen. De relatie tussen de verschillende voetdrukparameters en voetpijn zijn echter niet geheel duidelijk. Het doel van de studie, zoals beschreven in hoofdstuk 6, is het effect van orthopedisch schoeisel bij patiënten met degeneratieve voetafwijkingen te evalueren in termen van voetdruk en voetpijn. Tevens is de relatie tussen verschillende voetdrukparameters en voetpijn bestudeerd. Hierbij is de nadruk gelegd op de regio metatarsale 2-3. Deze regio speelt vaak een belangrijke rol bij patiënten met degeneratieve voetafwijkingen. Op basis van deze studie kan geconcludeerd worden dat individueel vervaardigd

orthopedisch schoeisel de subjectief ervaren voetpijn verlaagt met minimaal 33% en dat de gemiddelde voetdruk ($P_{average}$) onder de gehele voet is afgenomen met minimaal 10%. Dit duidt niet alleen op een redistributie van de plantaire druk, maar ook op een afname van plantaire druk als gevolg van individueel vervaardigd orthopedisch schoeisel. Daarnaast is er een bescheiden positieve correlatie gevonden tussen de gemiddelde voetdruk ($P_{average}$) onder metatarsaal regio 2-3 en voetpijn tijdens lopen.

In de algemene discussie (hoofdstuk 7) wordt een aantal methodologische punten vanuit een bredere optiek aan de orde gesteld. Allereerst wordt de verscheidenheid aan definities betreffende niet-gebruik van revalidatiehulpmiddelen bediscussieerd. Daarnaast wordt een aantal methodologische principes beschreven in relatie tot systematische reviews, zoekstrategieën en onderzoeksdesigns.

De klinische betekenis van de onderzoeksresultaten voor patiënten, medisch specialisten en orthopedisch schoentechnici wordt bediscussieerd. Allereerst wordt de mogelijke rol van de QUE als diagnostisch instrument beschreven. Daarbij wordt voorgesteld de QUE te gebruiken om de patiënten te volgen na de aflevering van hun orthopedisch schoeisel. Vervolgens wordt op basis van de ‘theory of operant conditioning’ naar een verklaring gezocht voor de gevonden associatie tussen verschillende bruikbaarheidsfactoren en het daadwerkelijk gebruik van orthopedisch schoeisel. Aansluitend wordt gesuggereerd dat voetdrukmeetapparatuur in dezen een ondersteunende rol kan spelen om de kwaliteit van de (individueel vervaardigde) orthopedische schoenen te objectiveren. Tevens lijkt voetdrukmeetapparatuur van belang om relaties tussen verschillende materiaalsoorten en de afname in plantaire druk vast te stellen bij personen met ernstige voetproblematiek.

CURRICULUM VITAE

Michiel Jannink werd geboren op 19 april 1975 in Nijverdal en is opgegroeid in Wierden. Na het volgen van de middelbare school op het PIUS X college te Almelo studeerde hij Bewegingswetenschappen aan de Rijksuniversiteit Groningen (RUG). De studie Bewegingswetenschappen – afstudeerrichting revalidatie en gehandicaptenzorg – werd afgerond in maart 1998. Na een kleine 2 jaar gewerkt te hebben als Trainer Fysieke Arbeid bij het Bureau voor Fysieke Arbeid begon hij in januari 2000 als wetenschappelijk onderzoeker bij Roessingh Research and Development te Enschede. In mei 2000 is hij gestart met zijn promotieonderzoek binnen het ZonMw programma revalidatie technische hulpmiddelen.

Naast zijn werk als wetenschappelijk onderzoeker bij Roessingh Research and Development heeft Michiel bij het EMGO-instituut het postdoctorale onderwijs Epidemiologie gevolgd. Momenteel werkt hij als wetenschappelijk onderzoeker bij Roessingh Research and Development binnen het onderzoekscluster Functieherstel Technologie aan de onderzoekslijn Virtual Reality en Robotica binnen de revalidatie. Binnen deze onderzoekslijn werkt hij aan de projecten “Actieve revalidatie”, “Virtual Reality and Neglect” en “SCOMOSI, de ontwikkeling en evaluatie van een scootmobiel simulator”. Daarnaast maakt hij deel uit van de projectgroep “Innovatiecentrum voor Revalidatietechnologie” en is hij projectleider van het ZonMw project “Het gebruik van revalidatie hulpmiddelen bij 1e en 2e generatie Turken in Nederland: knelpunten?”.

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