

Use of and satisfaction with ankle foot orthoses

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Use of and Satisfaction with Ankle Foot Orthoses

Holtkamp FC^{1*}, Wouters EJM¹, van Hoof J¹, van Zaalen Y¹ and Verkerk MJ^{2,3}

¹Fontys University of Applied Sciences, Institute of Allied Health Professions, Dominee Theodor Fliednerstraat 2, 5631 BN Eindhoven, The Netherlands

²Eindhoven University of Technology, Department of Industrial Engineering & Innovation Sciences, PO Box 513, 5600 MB Eindhoven, The Netherlands

³Maastricht University, Department of Arts and Social Sciences, PO Box 616, 6200 MD Maastricht, The Netherlands

Abstract

Objective: The aim of this study was to obtain insight in specific elements influencing the use, non-use, satisfaction, and dissatisfaction of ankle foot orthoses (AFOs) and the presence of underexposed problems with respect to AFOs.

Methods: A questionnaire was composed to obtain information from AFO users to investigate the variables associated with satisfaction and the relation between these variables. A specific feature of this study was the systematic analysis of the remarks made by the respondents about their AFO. Quantitative data analyses were used for analysing the satisfaction and qualitative analyses were used analysing the remarks of the respondents. A total of 211 users completed the questionnaire.

Results: Our survey showed that 1 out of 15 AFOs were not used at all. About three quarters of the AFO users were satisfied and about one quarter was dissatisfied. Females and users living alone reported relatively high levels of dissatisfaction, especially in the field of dimensions, comfort, weight, safety and effectiveness. Dissatisfaction with respect to off-the-shelf AFOs for the item durability was higher than that for custom-made AFOs. In the delivery and maintenance process the items 'maintenance', 'professionalism' and 'delivery follow-up' were judged to be unsatisfactory. A large number of comments were made by the respondents to improve the device or process, mainly by the satisfied AFO users. These comments show that even satisfied users experience many problems and that a lot of problems of AFO users are 'underexposed'.

Conclusion: To improve user satisfaction, the user practice has to be identified as an important sub-process of the whole orthopaedic chain especially in the diagnosis and prescription, delivery tuning and maintenance, and evaluation phase.

Keywords: Ankle foot orthosis; Assistive devices; Design; Evaluation; Integrated orthopaedic design model; Non-use; Use; User satisfaction.

Introduction

In the pursuit of better products and more satisfied patients, the orthotic field is constantly evolving by improving existing and developing new devices such as ankle foot orthoses (AFOs). Despite many efforts by professionals in development and innovation in AFOs, three important problems can be defined in AFOs: non-use, dissatisfaction, and underexposed problems [1-6]. This study focuses on these three problems.

Studies on the use and non-use show large differences between various types of orthoses. Jannink [7] observed a percentage of non-use of orthopaedic shoes from 8 to 75% and de Boer et al. [8] a percentage of 48% of non-use of functional wrist orthoses for persons with rheumatoid arthritis. The non-use of assistive aids is mainly caused by neglecting the specific needs of users, the change in function after delivery, and the limitations caused by the prescribed aids [1]. The phenomenon of non-use is strongly influenced by the expectations of the patient and his/her environment. Personal characteristics such as age, sex, and living environment also play an important role [9-10]. It is remarkable that many patients choose not to use their device, despite the fact that non-use hinders daily activities and social participation [4,5-11].

It is generally acknowledged that satisfaction and dissatisfaction with orthopaedic devices have two components: the satisfaction and dissatisfaction with the product and the satisfaction and dissatisfaction with the process [12]. In order to be able to determine and manufacture a custom-made or, instead, choose an off-the-shelf AFO, the whole process from diagnosis and prescription, design, manufacturing,

delivery and maintenance, to user experience, is of importance. In particular, the aspects where information of the patient should be retrieved or evaluated are important.

Satisfaction is positively influenced by product design, functioning and cosmesis [1]. Bosman et al. [13] observed that service provision and delivery by the orthotic service provider are also important satisfaction elements in the process. One would expect that patients who report a high satisfaction use their device without serious problems. However, Jannink et al. [14] reported a number of serious deficiencies in the performance of AFOs despite the fact that the overall satisfaction was 8.1 (scale 1-10). In other words, even a high satisfaction rate may cover up underexposed problems.

In the literature, there are two studies about the non-use of, the dissatisfaction with and underexposed problems concerning AFOs. Bulley et al. [15] from a qualitative study based on focus group interviews, reported reasons for dissatisfaction as: 'uncomfortable,

***Corresponding author:** Fred Holtkamp, Fontys University of Applied Sciences, Dominee Theodor Fliednerstraat 2, 5631 BN Eindhoven, The Netherlands, Tel: +31 651942732; Email: f.holtkamp@fontys.nl

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cumbersome, inflexible, difficulties in finding appropriate shoes with the AFO and remains in place even when not needed' (p.229). The researcher stated that although technological developments advance on a daily basis, the satisfaction and use do not appear to improve at the same pace. Magnusson et al. [16] reported pain associated with use of the device and difficulties ambulating on challenging surfaces as an important reason for dissatisfaction in their study. The object of this study is to obtain insight into the specific elements that influence use and non-use, satisfaction and dissatisfaction of AFO users, and the presence of underexposed problems with respect to AFOs.

Methods

Participants

The quantitative part of the study was based on a questionnaire. The questionnaires were sent to 500 AFO users by five P&O service providers, who were geographically spread over the Netherlands. The selected service providers employed prosthetists and orthotists, who had received a university-level education and had experience or were familiar with scientific or applied research. AFO users were randomly selected from the database of the providers [17]. All participants younger than seven years of age, with an insufficient knowledge of the Dutch language, or using the AFO no longer than three months, were excluded. Both custom-made as well as off-the-shelf AFOs were included. No additional exclusion criteria were formulated.

Outcome measures

The outcome measures determined in this study were different variables of satisfaction with the product: use, safety, durability, and ease of use [18], comfort and effectiveness [19], and the process: delivery, maintenance, professionalism, follow-up after delivery, and services in general.

For this study we used a questionnaire composed out of four existing and validated questionnaires [13,20-22]:

The survey by Jannink is a questionnaire for usability evaluation of orthopaedic shoes [13]. It distinguishes four effectiveness items, one efficiency item and seven satisfaction items.

The D-quest is a survey for measuring satisfaction about the product and process. It consists of twelve items: user-friendliness, maintenance, effectiveness, durability, adjustment, comfort, delivery process, professional services, weight, safety and size [20,22].

The EuroQol 5 dimension descriptive self-completion system (EQ-5D) is a survey of mobility of amputees in Activities of Daily Living (ADL) [23,24]. It comprises five items: mobility, self-care, usual activities, pain/discomfort and anxiety/depression [23]. Respondents made an estimation of their health status by ticking the most appropriate statement in each of the five items. In this study, the mean health status was used as an outcome measure.

The mobility survey: a questionnaire for environmental and personal characteristics [25]. It consists of items related to the living environment and use of assistive aids, including use of stairs, bicycles, walking sticks, frames and walkers.

These four questionnaires were supplemented with 16 newly-developed questions in order to obtain additional information about the AFO device itself and the use of this device. Face validity of this part of the questionnaire was checked by applying a so-called member check, also known as a respondent validation. Member check was applied by comparing the results of the questionnaire to the open questions and

remarks of the participants to check the internal validity [26].

The combination of these questionnaires resulted in an 88-item called Design in Orthopaedic Engineering Questionnaire for Usability Evaluation of Orthoses (DOE-quest) (Appendix 1). In summary (Table 1), the complete DOE-quest is divided into:

Questions 1-7 are general questions regarding gender, age, living situation, education;

Questions 8-17 are related to the AFO product and process (developed by the researcher);

Questions 18-37 are related to AFO use (derived from Jannink [7]);

Questions 38-45, 46-58, 59-66 are related to mobility (standing, walking, other activities (partly derived from Jannink [7] and partly developed by the researcher));

Questions 67-81: the D-Quest; [20];

Question 82 is related to the AFO product and process (developed by the researcher). Respondents were asked to name three items of which they think that improvements could be made on the AFO;

Questions 83-87: the EQ-5D [24];

Question 88: suggestions for comments on or improvement of the AFO, included as a blank comment field. This field was used to provide additional information with respect to the AFO (developed by the researcher).

Ethics

The research was conducted within the boundaries set by the Helsinki declaration and approved by the Fontys Committee of Ethics in Research, Eindhoven, The Netherlands [27]. Participants were informed by means of an information letter and could withdraw from the study at any moment in time. All participants signed the informed consent document. If participants were younger than 18 years, informed consent was also given by their parents or guardians. Written permission was obtained from Euro Qol for use of the EQ-5D.

Data analysis

All statistical analyses were carried out in SPSS 21.0. Descriptive statistical analysis, such as frequencies and percentages, were applied. The answer possibilities 'satisfied' and 'completely satisfied' were combined in the analysis and defined as satisfied, and 'completely dissatisfied', 'not satisfied' and 'average dissatisfaction' was defined as dissatisfied. The total number of satisfied and dissatisfied respondents per item was used to calculate the percentages. The answers of the summary questions of the DOE-quest were not taken into account in calculating the average percentages.

A logistic regression analysis was performed. The relative contribution (association) of the categorical variables, sex, age, living arrangement, education, body mass index (BMI) and AFO type, on the outcome (whether satisfied or unsatisfied) was calculated for the D-Quest items.

Blank comment fields were used to retrieve information about the underlying cause of discontent. Respondents were offered the possibility to describe additional requirements and recommendations of interest for the design process of AFOs and to indicate why they were dissatisfied. For the qualitative analysis the comments were sorted into four groups of comments by: non-use and satisfaction (interpreted as: no problems experienced), non-use and dissatisfaction (major problems

Question Numbers	Amount	Topic	Subject	Relation to Satisfaction			
				General	Product	Process	Answer Type
1-7	7	User	Gender, Age, Living situation, Education	1-7			Open; dich.; 3/5 m.c.
8-17	10	User	AFO product and process (developed by the researcher)		8, 10,17	9,11-16	3 or 5 m.c.
18-37	20	Product	AFO use (derived from Jannink 2004)		18-37		3 or 5 m.c.
38-45	8	Product-User	Standing (derived from Jannink 2004)		38-45		dich. cat. VAS
46-58	13	Product-User	Walking (derived from Jannink 2004)		46-58		dich. cat. VAS
59-66	8	Environmental	Other activities in AFO use (derived from Jannink 2004 and developed by the researcher)		59-66		dich. cat. VAS
67-81	15	Product and Process	D-Quest (Demers et al. 1996)		67-75	76-81	5-Point Likert Scale
82	1	Product and Process	Respondents suggestions for improvement product and or process (developed by the researcher)		82	82	Open
83-87	5	Health	The EQ-5D (Devlin, Krabbe 2013)	83-87			3-Option Answer
88	1		Respondents suggestions for any other comment (developed by the researcher)		88	88	Open
Legend	dich.	Dichitome (Yes/No)					
	m.c.	Multiple Choice					
	cat.	Categorical (3 or 5 Answer Possibility)					
	VAS	Visual Analogue Scale (10 cm)					
	5-pLs.	Five Point Likert Scale					
	3-opt.	Three Options					

Table 1: Summary content DOE Questionnaire.

experienced), use and dissatisfaction (major problems experienced) and use and satisfaction (underexposed problems experienced) [28]. Denomination of the group 'non-use and satisfaction' may be confusing but used here in line with the followed structure. The four groups were analysed, labelled and classified into five main items in line with the topics of the questionnaire. These items were: health, product, user practice, functionality and process.

The item 'health' contains personal factors (pain, sense confinement, inflammation, skin damage, chafing and transpiration).

The item 'product' contains all elements related to dimensions, weight, size, finish, adjustability, materials, construction and durability. Environmental issues like acceptance, expectations, influence of the environment, looks, cosmesis, ambient conditions, damage, fitting, effectiveness, colour, ease of use, safety, comfort are covered in the item 'user practice'.

The item 'functionality' is related to handling the AFO in daily practice and contains items such as lacing, freedom of movement, energy cost and hygiene.

The item 'process' covers the whole process of assessment and follow-up, evaluation, repairs, individual support, as well as involvement of the patient in the process, finance and professionalism of the staff.

The analyses were made by two independent researchers. Final classification of the comments was based on consensus. In case of disagreement a third researcher was involved. The grouped comments were counted and the frequency of each grouped comment was calculated.

Results

First, the general respondent characteristics and the satisfaction with the product and process are described. Thereafter, the recommendations and comments given by the respondents are presented.

Respondents characteristics

In total 123 males (58%) and 87 females, with a mean age of

48.8 (SD=25.0) (normally distributed), completed the questionnaire (response rate of 44%). For one participant gender was not reported. Twenty per cent of the respondents were younger than 18 years. Eighty four per cent were living with others. Sixty nine percent of respondents indicated that they received education at basic level, 19% at a higher level (medium) and 4% at university level (high). The respondents' mean (BMI) was 24.6 (SD=5.2), representative of a normal population [29]. The range of the EQ-5D scores (n=190) was .71 (SD=0.22) reflecting a representative group of the respondents population with respect to health problems [24]. Of the AFOs 84% were custom-made (Table 2). For six respondents the AFO type was unknown. Diagnoses leading to the AFO prescription were wide-ranging, and included cerebrovascular accident, cerebral palsy, multiple sclerosis, spinal disc herniation, osteophytes (bone spurs), et cetera.

Product and process dissatisfaction: The results of the DOE-quest part showed a total mean score of satisfaction of 3.82, (range 1 completely dissatisfied – 5 completely satisfied), (SD=0.87) on the AFO as a whole and a 3.95 (SD=0.79) for service in general (Table 3A).

In general, dissatisfaction rates for AFO design and use ('product') and process of delivery and maintenance (processes) were 26% and 20% respectively (Table 3B).

Females, people under the age of 18 and people living alone scored 30%, 33% and 30% respectively on dissatisfaction regarding the AFO as a whole.

At the level of product dissatisfaction, statistical significant associations between sex and dimension, and sex and comfort were found. Females were very dissatisfied over dimensions (OR=0.41, p=0.008) and comfort (OR=0.44, p=0.014) (18% and 48% respectively). People living alone showed a statistical significant association for the items, safety (p=0.031) and effectiveness (p=0.046). On the other hand people not living alone were more dissatisfied over the weight of the AFO (p=0.025).

The item durability showed a statistical significant association in favour of the custom-made AFO (OR=4.1, p=0.018).

n=211				
Category	total	%	SD	% missing values
Gender				0.4
Male	123	58		
Female	87	41		
Mean Age	49.8		24	
Living Situation				2
Alone	32	15		
Not Alone	174	84		
Education*1				10
Primary And Secondary Education (Level 1,2,3)	144	69		
Higher Education (Level 4,5)	36	17		
University (Level 6,7,8)	9	4		
BMI				3
Underweight	28	13		
Normal Weight	72	34		
Overweight	81	39		
Obese	24	11		
EQ5D mean	0.71	0.22		10
Diagnoses				3
Cerebro Vascular Accident	49	23		
Cerebral Palsy	20	9		
Multiple Sclerosis	12	6		
Spina Bifida	3	1		
Poliomyelitis	5	2		
Neuromuscular Diseases	13	6		
Trauma / Injury	13	6		
Spinal Disc Herniation	30	14		
Plantar Fasciitis	2	1		
Bone Spur	4	2		
Other Causes	53	25		
AFO type				2.8
Off-the-shelf	29	14		
Custom-made	176	84		

*1 According to National Qualification Framework

Table 2: User related characteristics.

Dissatisfaction with the 'delivery and maintenance process' was mainly found for the items maintenance, professionalism and delivery follow-up.

People living alone showed a statistical significant association with maintenance (OR=0.40, p=0.020). Females, people living alone, and people with a higher BMI showed statistical significant associations (OR=0.28, p=0.005, OR=0.30, p=0.027, OR=0.31, p=0.025) for dissatisfaction with respect to professionalism. The delivery follow-up showed a significant association for dissatisfaction for people living alone (OR=3.45, p=0.012) and custom-made orthosis (OR=0.09, p=0.027). People with a BMI>25 were dissatisfied over service in general (OR=0.28, p=0.012).

For AFOs as a whole, the least dissatisfied group were males and users with a high level of education. The most dissatisfied group were users below 18 years of age, females, and people living alone.

The DOE-quest items that the respondents considered most important were ease of use (110 times) comfort (95 times), effectiveness (76 times), weight (67 times) and safety (57 times).

Remarks and recommendations of users and non-users: The

starting point for the identification of the remarks was at the level of use (non-use) and (dis)satisfaction. In response to the questionnaire, a total of 185 remarks and recommendations were made by 92 respondents concerning the product and process satisfaction. Respondents were given the opportunity to add a maximum of three remarks or recommendations.

Four groups were identified: non-use and dissatisfied with remarks defined as 'major problems', non-use and satisfied with remarks defined as 'no problems', use and dissatisfied, remarks defined as major problems, and use and satisfied. In this last group the remarks were defined as 'underexposed problems' (Figure 1). The comments were coded into keywords and labelled as being within one of the five main groups; health, product, user practice, functionality and process (Table 4).

Examples of remarks made by the respondents were: 'I never have been informed about the colour options of the AFO', or 'the AFO is damaging my clothes', or 'I wish that the material used was more permeable for moisture because I sweat a lot and it affects the skin of my foot', 'the AFO shouldn't break down so fast', or 'the AFO doesn't fit very well, I do need to use extra bandages'. Remarks such as 'I was never informed about the colour options', 'There was no follow up', 'They didn't really listen to my wishes', were labelled as 'involvement' within the main group 'process'. 'Damaging clothes' was labelled as 'damage' and is within user practice, as is 'fitting'. Remarks with respect to 'transpiration' were classified within 'health'. In this coding process each remark was individually analysed and labelled. The labelled remarks were then counted.

Non-use and dissatisfied: The group 'non-use and dissatisfied' consisted of 3% of the respondents and 5% of the comments. In total 10 remarks were made; 1 respondent reported 3 comments and 3 respondents 2 comments each. Comments made by the respondents were related to issues such as pain and chafing. One remark was made about AFO-induced inflammation. Critical comments were also made about comfort and dimensions.

Non-use and satisfied: The group 'non-use and satisfied' consisted of 4% of respondents and 3% of the comments. The comments made by respondents were mostly positive such as 'The AFO has helped me well' and 'I do not need the orthosis anymore'.

Use and dissatisfied: The group 'use and dissatisfaction' consisted of 12% of respondents and 30% of the comments. About half of the respondents reported two and the other half of the respondents reported three comments. In the group 'health', pain and chafing were mentioned as reasons for dissatisfaction. Also, with respect to the AFO itself, 17 comments were made about items that should be improved such as size, weight, used materials, adjustability, finish, and durability. Twenty four comments referred to user practice with many comments about improvement of the comfort, ease of use and fitting. In the group 'functionality' recommendations were made about the handling of the AFO and the amount of required energy to use the AFO. Complaints about the follow-up, and not being involved in the design process, were classified part of the process item.

Use and satisfied: The group of satisfied users consisted out of 30% of the respondents. This group made the majority of all comments: 113 remarks, which is 62% of all remarks made. The item about which the greatest number of remarks were made was user practice; 52 in total. Most of the remarks referred to comfort and ease of use. These were the subject of many recommendations. Some respondents mentioned damaged clothing and furniture when using the AFO.

Personal and AFO characteristics		Orthosis design and use characteristics																										
		dimensions			weight			adjustment			safety		durability		ease of use		comfort		effectiveness		AFO (whole)							
3a		D-quest	mean	sd.	3,750	0,956	4,000	0,772	3,660	0,895	4,010	0,644	3,950	0,751	3,790	0,909	3,610	0,913	3,920	0,833	3,820	0,865						
3b		%	OR	CI (p)	%	OR	CI (p)	%	OR	CI (p)	%	OR	CI (p)	%	OR	CI (p)	%	OR	CI (p)	%	OR	CI (p)						
dissatisfaction mean (%)		17			12			17			16			18			24			20			26					
sex	male	15	0.41	0.21-0.79	14	0.37	0.31-1.55	18	0.73	0.36-1.49	13	1.17	0.46-2.96	18	1.28	0.54-3.023	20	0.84	0.40-1.79	30	0.44	0.24-0.85	15	0.66	0.29-1.48	22	0.62	0.30-1.25
	female	18		(.008)	10			16			15			15			27			48			30			22		
age	< 18	9	0.76	0.26-2.22	8	1.34	0.42-4.24	8	1.29	0.45-3.77	21	2.00	0.58-6.84	18	1.48	0.42-5.26	33	2.42	0.83-7.20	44	2.24	0.84-5.96	20	1.37	0.43-4.40	33	1.32	0.46-3.78
	≥ 18	24			15			25			12			16			19			35			24			17		
arrangm.	alone	12	1.76	0.71-4.38	10	3.06	1.15-8.11	8	2.32	0.94-5.72	23	3.30	1.12-9.75	14	0.82	0.24-2.77	21	1.07	0.36-3.21	53	2.23	0.91-5.48	27	2.76	1.02-7.48	30	1.98	0.78-5.06
	family	26			14		(.025)	26			12		(.031)	17			23			34			25			16		(.046)
education	basic	15	0.85	0.41-1.76	5	1.47	0.61-3.56	17	0.86	0.40-1.83	19	1.88	0.68-5.24	17	0.88	0.35-2.24	23	0.78	0.34-1.90	42	0.93	0.45-1.90	31	1.33	0.55-3.23	27	1.01	0.46-2.21
	higher	17			9			17			9			16			23			36			23			16		
BMI	< 25	17	0.88	0.44-1.77	10	1.68	0.76-3.74	17	0.95	0.22-1.73	23	0.84	0.33-2.16	21	1.86	0.81-4.26	23	1.05	0.49-2.26	40	0.89	0.45-1.74	19	1.06	0.47-2.41	25	0.84	0.40-1.74
	≥ 25	16			17			17			14			14			22			36			23			17		
AFO type	off-the-shelf	11	1.21	0.49-3.00	9	0.76	0.23-2.53	14	0.62	0.22-1.73	15	1.39	0.40-4.81	36	3.41	1.24-9.44	26	1.33	0.47-3.73	44	1.10	0.44-2.77	21	0.77	0.24-2.54	21	0.64	0.22-1.88
	custom made	27			17			30			14			14		(.018)	23			36			27			18		

Personal and AFO characteristics		Delivery and maintenance characteristics														
		delivery		maintenance		professionalism		delivery follow-up		services in general						
3a		D-quest	mean	sd.	4,040	0,813	4,000	0,816	4,090	0,811	3,930	0,854	3,950	0,789		
3b		%	OR	CI (p)	%	OR	CI (p)	%	OR	CI (p)	%	OR	CI (p)	%	OR	CI (p)
dissatisfaction mean (%)		14			20			18			23			20		
sex	male	10	0.50	0.20-1.24	18	0.43	0.18-1.07	11	0.28	0.12-0.68	22	0.64	0.28-1.44	19	0.51	0.22-1.16
	female	17			23			25		(.005)	23			22		
age	< 18	16	1.07	0.24-4.91	21	1.72	0.44-6.73	15	1.60	0.37-7.01	14	0.26	0.05-1.31	15	0.47	0.11-2.01
	≥ 18	13			19			18			25			21		
living arrangm.	alone	13	1.27	0.38-4.23	30	4.00	1.24-12.9	23	2.70	0.89-8.21	38	3.54	1.32-9.50	27	2.46	0.87-6.94
	family	14			18		(.020)	17			20		(.012)	18		
education	basic	11	0.56	0.20-1.58	17	0.54	0.19-1.54	12	0.30	0.11-0.87	20	0.87	0.382-2.01	17	0.77	0.32-1.86
	higher	15			22			23		(.027)	25			22		
BMI	< 25	12	0.90	0.35-2.31	18	0.79	0.31-2.03	10	0.31	0.11-0.86	18	.55	0.23-1.30	11	0.28	0.10-0.76
	≥ 25	14			20			22		(.025)	26			25		(.012)
AFO type	off-the-shelf	11	0.75	0.20-2.81	16	0.42	0.08-2.06	19	0.74	0.21-2.64	12	0.09	0.01-0.76	15	0.25	0.51-1.20
	custom made	14			21			17			25		(.027)	21		

Table 3: Satisfaction in general (3a) and associations to dissatisfaction (3b) per component on AFO design and process characteristics.

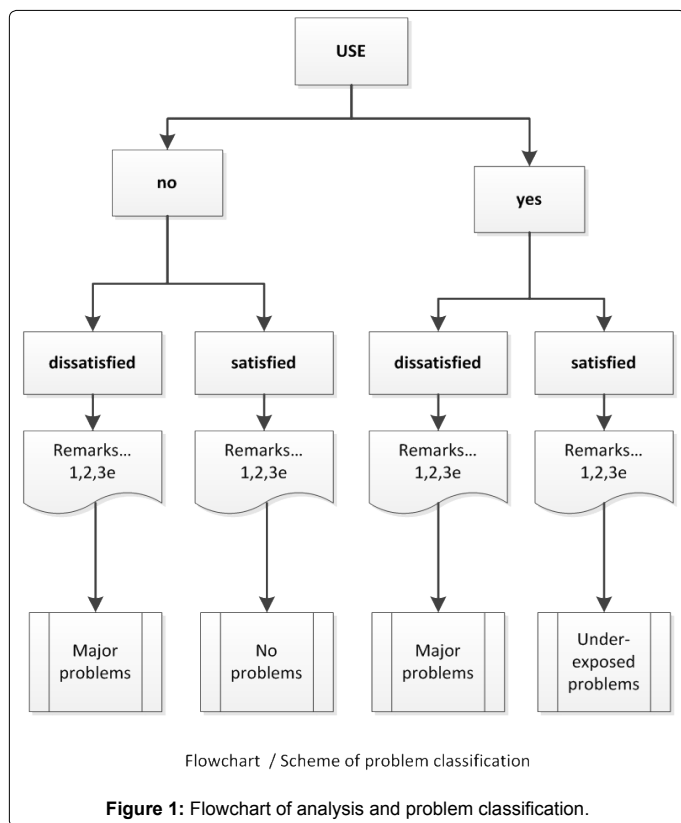
Label	Number of respondents	Number of remarks made by respondents	% of respondents who made remarks	Number of remarks per main item					Total remarks	% of total remark
				Health	Product	User Practice	Functionality	Process		
		Remark 1/2/3		Pain, Sense Confinement, Inflammation, Skin damages, Chafing	Dimensions, Weight, Size, Finish, Adjustability, Materials, Construction, Design, Durability	Looks, Cosmesis, Ambient Conditions, Damage, Fitting, Effectiveness, Colour, Ease Of Use, Safety, Comfort	Handling, Lacing, Freedom Of Movement, Energy Cost, Hygiene	Follow-Up, Maintenance, Evaluation, Assessment, Involvement, Finance, Professionalism		
Non-use and dissatisfied	14	6/ 3/1	3	3	4	3	0	0	10	5
Non-use and satisfied	9	3/1/1	2	3	1	1	0	0	5	3
Use and dissatisfied	41	24/21/12	12	5	17	24	3	8	57	30
Use and satisfied	142	59/36/18	30	9	35	52	9	8	113	62
Total	206	92/61/ 32	47	20	57	80	12	16	185	100

Table 4: Item categories of respondents remarks.

For effectiveness, the fitting and the way the AFO looks is mentioned often. The second largest group consisted of remarks about the product; 35 in total. Respondents made suggestions for improvements of the materials used (11 remarks), the dimensions (5 remarks), and the overall design (5 remarks), durability, adjustability, weight and finish of the AFO. In the group 'health' pain and chafing caused by the

AFO was mentioned often (9 remarks). Safety, lacing, handling and effectiveness were issues raised for the functionality group with nine recommendations made. The subjects of items mentioned in the group process were comparable with those from the group use and dissatisfied.

Summary: main dissatisfaction categories: In all of the four distinguished groups (non-use and dissatisfied, non-use and satisfied,



use and dissatisfied and use and satisfied) most observations made by the respondents were classified in the items 'product' and 'user experience' with 57 (30%) and 80 (43%) remarks respectively.

Discussion

The data presented in this study cover a wide geographic area of the Netherlands. A great variety of foot and ankle problems were reasons for the prescription of an AFO to patients, either custom-made or off-the-shelf. Existing AFO satisfaction surveys mostly focussed on use and satisfaction with the AFOs. From this study, by focusing on the non-use, dissatisfaction, and comments made by the users, new insights have come to the fore.

General satisfaction

In our study we found that a quarter of the respondents were dissatisfied about their AFO. Four out of nine elements in the 'orthotic design and use' (i.e., 'product') and three out of five elements in the 'process delivery and maintenance' (i.e., 'process') scored high percentages of dissatisfaction. Comfort was an aspect significantly differing in terms of percentage from overall satisfaction in an unfavourable manner. Our data are in agreement with data reported in literature. For example, previous studies of the Health Care Insurance Board in the Netherlands (CVZ) showed a mean overall rating of orthopaedic device user satisfaction of 80% [16]. The study of Malkin et al. [30] showed that 73% of their respondents considered their AFO 'very' or 'fairly helpful'. Also in that study 27% of the respondents stated that the AFO was not helpful. More recently, Chen et al. [31] and Arfoui et al. [32] found comparable results with respect to overall satisfaction. This is in line with our result, which show approximately the same number of users to be not satisfied. It is recognised by the same studies that satisfaction is influenced by the product quality and

the process of delivery, but these studies did not indicate exact causes of dissatisfaction.

A number of user characteristics relates to the dissatisfaction with the AFOs design and use, and process. The results found in this study are comparable with earlier studies [29-31] that include descriptions of user types. Women are apparently more critical about their bodies and issues that affect them such as cosmesis and appearance of the device. In addition, younger users, who have less self-reliance [33] and less experience with the shortcomings of the healthcare system, have higher expectations that cannot always be fulfilled, compared to older users [34]. People living alone depend in all aspects on the reliability and effectiveness of their AFO since one may assume that help is not directly available in case it is needed. These findings are supported by our results. The above items can be summarized under the term user practice. Apparently, thorough knowledge of this user practice is of great importance [35].

In our opinion, the percentages of dissatisfaction for all users are that high that efforts for improvement have to be focussed on at least these parts of the orthopaedic process, where information is obtained from the patient.

Remarks: Major problems and under-exposed problems

In this study we systematically investigated the remarks made by respondents. Remarks could be made after answering all 81 questions. One may assume that, after answering all questions, the remarks made reflect topics that greatly concern people. To our knowledge, no systematic study of the remarks made by respondents has been reported in the literature.

The four groups of respondents revealed a lot of information. The comments of the group 'non-use and dissatisfaction' clearly shows that parts from the whole process from diagnostics and prescription, design, manufacturing, delivery and maintenance, to user experience, in particular these parts where information of the patient should be obtained, failed. The comments of the group 'non-use and satisfied' shows an opposite picture: these users were satisfied because the therapy had ended or the AFO was no longer needed.

The group 'use and dissatisfied' reported serious problems. All remarks showed that important information and feedback from the patient during the whole process was not used to improve performance. The group 'use and satisfied', the majority of the respondents (75%), reveal the existence of many underexposed problems. One would expect that this group might vouch for a trouble-free use. However, our study shows that even the group of satisfied users still reports serious problems. This group made 113 remarks (62% of all remarks). Even the 'fully' satisfied users (13%) have serious comments that should be taken into account. Most of the comments were related to the product design and the environment in which the AFO had to be used. These remarks and recommendations show that 'satisfaction' distracts our attention from existing problems of users.

In this study we used four questionnaires and combined this with a number of additional questions regarding use and environment into one large complete questionnaire (DOE-quest). Our study, however, shows that the comments made by the users reveal new and important information, especially with regard to the product itself and the user practice. Therefore, it is of the utmost importance, not only in surveys, but also in daily practice, to give the patient the opportunity to make comments.

The remarks made by non-users (satisfied, dissatisfied) and users

(satisfied, dissatisfied) showed that the main categories of dissatisfaction refer to the 'user practice' and 'product'. Lower numbers of remarks belong to the categories 'health', 'process' and 'functionality'.

From all these observations five conclusions can be drawn. First, in orthopaedic practice it appears that too little attention is paid to the experience of the user. It suggests that the experience of the user is not analysed systematically and that user practice is not seen as being integrated in the whole orthopaedic chain. Second, it shows that the prosthetist, orthotist, pays too little attention to the technical aspects of the product in relation to the experiences of the user. It seems that 'hard' aspects of the product (technical functionality) are considered more important than the 'soft' aspects of the product (user functionality). Third, the 'self-proclaimed' fully satisfied users provide important and valuable information revealed by the remarks they made, which can help to improve the product and process. Fourth, analysing the remarks made by the respondents systematically provides the orthotist a wealth of extra information which can be used to improve the product and the process. Finally, the research showed that the orthopaedic chain does not yet work in an optimal way. It should not be accepted by the professional that 6% of the respondents do not use the AFO because they are dissatisfied, and that one-fourth of the AFO users is dissatisfied overall. In addition, this study showed that satisfied users also report serious problems that can be associated with the user practise. This shows that a) the user experience has to be identified as an important part of the whole orthopaedic chain, b) the feedback loops in the whole chain have to be closed, and c) the quality standards in this field have to be defined much more from the perspective of the user and the standard of the performance has to be raised from 'good' to 'excellent'. In summary, when the whole sector succeeds in integrating user experiences in the whole chain the performance of this chain for all groups of users will be improved considerably.

To increase the level of satisfaction with respect to the outcome of the analysis and additional comments made by the surveyed AFO users it is recommended to pay more attention to product and delivery process in general and more specific to the user practice. Patient assessment, evaluation and the frequency of this evaluation, also after delivery, can provide valuable information. Listening to the needs, concerns and experiences of the patients after delivery of orthopaedic devices by incorporation of the DOE-quest at several prosthetic and orthotic service providers, may help to increase the level of satisfaction. Thus, with the aid of future research, a large database should be filled out which can be used to retrospectively identify factors related to the product and user experience

Apart from creating a database, it is also worthwhile to define an integrated orthopaedic design model in which underlying mechanisms used in the design process are defined. Future studies that combine user practice with the AFOs biomechanical effect in relation to user satisfaction so as to verify if, and how many, of the AFOs are not fitted optimally (from a biomechanical perspective), can make user practice and satisfaction more explicit.

For this reason, future challenges for prosthetists, orthotists, lie in optimizing and recalibrating the whole orthopaedic device process. This process, visualised in Figure 2, consists out of a number of sub processes (SP): SP1 concerns diagnosis & prescription. Diagnosis and prescription are actually regarded as two separate parts, but in daily practice they are intertwined. SP2 relates to the design, SP3 is about the manufacturing, SP4 concerns the supply, tuning and maintenance, and finally, SP5 refers to evaluation and the user experience of the AFO. The various sub processes are important because in every part of the process specific information is available and needed but not always noticed.

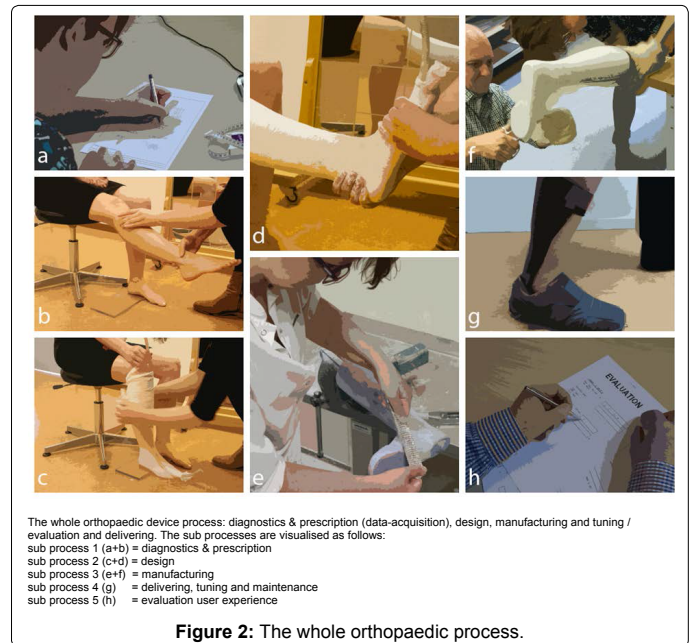


Figure 2: The whole orthopaedic process.

In the diagnosis and prescription phase important information about the user is acquired. This is especially the phase when the user will share his information about user practice and daily use. In the evaluation phase this information should be checked.

The challenge lies in understanding this whole chain. An adequate design model should be developed which involves therapists, physicians, prosthetists, orthotists and users in the design and evaluation process.

This study also has some limitations. Participants were selected from five service providers. It is possible that participants from other service providers might yield different results. While the sample is diverse in terms of age and heterogenic in diagnosis and the sample size is sufficient to estimate item difficulties, it is not large enough to discern differences in sub-groups of specific AFOs. In this study with respect to dissatisfaction, no distinction has been made between the different types of AFOs.

Although parts of the questionnaire were validated, the questionnaire as a whole has not been validated. However the questionnaire was checked for face validity by applying a member check. The questionnaire used in this study consists partly out of newly developed questions. Additional work must be conducted to demonstrate the validity of the DOE-quest. In future studies with respect to satisfaction and user practice also the perspective of the prosthetist and orthotist should be subject of research.

Conclusion

In general, it seems that the use of AFOs and the overall satisfaction is high. However, from the perspective of the individual user the data are far less favourable: 1 out of 15 AFOs is not used at all and about 25% of the AFO users are dissatisfied.

Even the satisfied users made a large number of important comments that suggest an underexposed dissatisfaction. We recommend to improve user satisfaction, the user practice has to be identified as an important sub-process in the orthopaedic chain especially in the diagnoses and prescription, delivering - tuning- maintenance, and evaluation phase.

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Participant follow-up: The authors have no plans to notify the study participants of the publication of this article because of a lack of contact information.

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