

Long-term use of custom-made orthopedic shoes: 1.5-year follow-up study

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Abstract—This study investigated long-term use of custom-made orthopedic shoes (OS) at 1.5 years follow-up. In addition, the association between short-term outcomes and long-term use was studied. Patients from a previously published study who did use their first-ever pair of OS 3 months after delivery received another questionnaire after 1.5 years. Patients with different pathologies were included in the study ($n = 269$, response = 86%). Mean age was 63 ± 14 years, and 38% were male. After 1.5 years, 87% of the patients still used their OS (78% frequently [4–7 days/week] and 90% occasionally [1–3 days/week]) and 13% of the patients had ceased using their OS. Patients who were using their OS frequently after 1.5 years had significantly higher scores for 8 of 10 short-term usability outcomes (p -values ranged from <0.001 to 0.046). The largest differences between users and nonusers were found for scores on the short-term outcomes of OS fit and communication with the medical specialist and shoe technician (effect size range = 0.16 to 0.46). We conclude that patients with worse short-term usability outcomes for their OS are more likely to use their OS only occasionally or not at all at long-term follow-up.

Key words: foot disorders, long-term use, medical devices, orthopedic shoes, orthotics, patient satisfaction, rehabilitation, shoes, usability, usability outcomes.

INTRODUCTION

Custom-made orthopedic shoes (OS) are prescribed to a wide variety of patients to prevent or diminish foot and/or ankle problems or to improve gait [1]. OS are frequently prescribed in, for example, England and Wales (200,000 pairs prescribed in 2000; 52 million inhabitants) [2] and the Netherlands (50,000 pairs prescribed in 2006; 16 million inhabitants) [3]. For OS to be effective and maximize the positive health benefits, it is essential that they are actually used.

Recently, we found that most OS are used shortly after delivery [4]. However, short-term use of an assistive technology (AT) does not necessarily lead to long-term use [5–6]. After an introductory period, patients have to accept the need for the AT and conclude that it will be useful to them in the future in order to continue their use of it [5–6]. Studying AT use from a longitudinal perspective is valuable as it allows one to look beyond short-term

Abbreviations: AT = assistive technology, MOS = Monitor Orthopedic Shoes, OS = custom-made orthopedic shoes.

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use and consider time-related changes [7]. For OS, no studies have been published in which the continuation of short-term use into long-term use has been examined.

A conceptual framework for AT in general has been developed, proposing that long-term use depends on short-term outcomes [5]. For OS, short-term usability outcomes are associated with short-term use. For example, more benefits of OS with regard to walking capacities, wound healing, and pain reduction; more comfort and ease of use of OS; and a more positive opinion on the cosmetic appearance of the OS have all been associated with higher levels of use [4,8–11]. Whether these short-term outcomes are associated with long-term use as well is not known.

The present study is a follow-up of a previously published study in which short-term use (3 months after delivery of a patient's first pair of OS) was investigated [4]. The first aim of the present study was to investigate the long-term use of OS 1.5 years after delivery of a patient's first pair. The second aim was to determine the association between short-term usability outcomes and long-term use of OS.

METHODS

Procedures

A shortened version of the Monitor Orthopedic Shoes (MOS) [12] was sent as a follow-up measurement to patients from a previously published study [4] 1.5 years after delivery of their first-ever pair of OS. If patients did not respond within 1 month, the questionnaire was sent again as a reminder.

Patients

In a previously published study, 339 patients of 12 different Dutch orthopedic shoe companies who were provided with OS were included [4]. Inclusion criteria were (1) first-ever pair of OS, (2) 16 years of age or older, (3) able to read Dutch, and (4) able to complete the questionnaire without help related to cognitive or physical impairments. The 21 patients who did not use their OS after 3 months were excluded from analysis in this study, although a questionnaire was sent to them to ask if they were still not using their OS. Seven more patients were excluded: six patients had died and one patient had had a bilateral amputation.

Of the 311 eligible patients, 269 completed the shortened MOS after 1.5 years (response rate = 86%). Mean age of the patients included in this study was 63 ± 14 years, and 38 percent were male. Of these patients, 63 had diabetes mellitus, 46 rheumatoid arthritis, 196 an unspecified foot disorder, 17 a muscular disease, and 86 another disorder (e.g., cerebral vascular accident, spinal cord injury, psoriasis, leather allergy). Disorders were indicated by patients themselves, and it was possible to indicate more than one disorder. Age, sex, and disorders of the patients included in the study were comparable with the nonresponders. Reasons for nonresponse were not known.

Outcome Measures

The extended version of the MOS is a practical and reproducible questionnaire that can be used for a wide range of patients with foot problems [12]. However, most of the questions on the extended version were not relevant for this research. We therefore used a shortened version of the MOS. This version consisted of four questions (Appendix, available online only). Two questions regarding the frequency and daily duration of use of OS were identical to questions in the extended version of the MOS. One question regarding the number of pairs of OS a patient was provided was added. For patients who did not use their OS, one question was added to ask for the reason of nonuse. Patients were given space for other remarks.

We defined three categories of OS use: frequent use (4–7 days/week), occasional use (1–3 days/week), and nonuse (not using OS). Nonuse was divided into two categories: nonuse due to dissatisfaction with aspects of the usability of the OS and nonuse due to physical changes that have made using OS not possible or necessary anymore. Even though nonuse due to physical changes might be related to the usability of the OS, it is not always possible or reliable to interpret it as such. More important, it has been stressed that these are two different kinds of nonuse [13–14]. For analyses, we included only patients who did not use their OS because of dissatisfaction with aspects of the usability.

Scores for short-term (after 3 months) usability outcomes for a patient's first-ever pair of OS from our previous study were used [4]. Usability is "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction, in a specified context of use" (International Organization for Standardization, 9241-11). Within these domains, the following aspects were measured: change in walking

capacity, wound healing, change in pain, and change in sprains (domain effectiveness); donning and doffing OS, fit of OS, ease of walking with OS, and weight of OS (domain efficiency); and cosmetic appearance of OS and communication with the medical specialist and the shoe technician (domain satisfaction).

Statistical Analysis

We assessed differences between the three groups with a Kruskal-Wallis test or chi-square test. The first was used because of nonnormal distribution of the data. We performed post hoc analyses to assess differences between the groups separately. We used a Mann-Whitney *U*-test for scale measures with a nonnormal distribution of the data and calculated the effect size with the following formula: effect size = $Z/(n_1 + n_2)$ [15]. We analyzed data using SPSS for Windows, version 16.0 (SPSS Inc; Chicago, Illinois).

RESULTS

Of the patients who used their OS after 3 months, 87 percent ($n = 234$) used their OS at the 1.5-year follow-up as well (78% [$n = 211$] frequently [4–7 days/week] and 9% [$n = 23$] occasionally [1–3 days/week]) and 13 percent ($n = 35$) ceased using their OS; 57 percent ($n = 20$) of this nonuse was due to dissatisfaction with the OS (Table 1). The patients who used their OS frequently had a significantly longer daily duration of use than the patients who used their OS occasionally; significantly more men than women frequently used their OS (Table 1).

The continuation of short-term use into long-term use is shown in Table 2. Of the patients who frequently used their OS after 3 months, 84 percent continued to do so after 1.5 years. In contrast, only 23 percent of the patients who used their OS occasionally after 3 months continued to do so; 46 percent of these patients used their OS frequently after 1.5 years, whereas 26 percent of these patients ceased using their OS because of dissatisfaction with the usability (Table 2). Three of the fifteen responding patients who did not use their OS after 3 months used their OS frequently after 1.5 years (results not shown in Table 2). These three patients indicated in their open answers that they continued trying, after discarding their first pair, until the usability of their second pair was satisfactory.

The scores for 8 of 10 short-term usability outcomes for the OS were significantly higher for patients who

were using their OS frequently at the 1.5-year follow-up (Table 3). The largest differences between patients who used their OS (both frequently and occasionally) and those who ceased using their OS were found for scores of fit of OS and communication with both the medical specialist and the shoe technician (post hoc analyses; Table 3). The largest differences between patients who frequently and those who occasionally used their OS were found for scores on change in pain, weight of the OS, and cosmetic appearance of the OS (post hoc analyses; Table 3).

DISCUSSION

In the present long-term follow-up study, we found that 87 percent of the patients who used their OS at short term still used their OS after 1.5 years and 13 percent of the patients ceased using their OS. Of this nonuse after 1.5 years, 57 percent was due to dissatisfaction with the usability of the OS. We further found that high scores for 8 of 10 short-term usability outcomes were significantly associated with long-term use. Patients who ceased using their OS after 1.5 years had the lowest scores for short-term outcomes concerning the fit of their OS and communication with both the medical specialist and shoe technician. Patients who used their OS only occasionally after 1.5 years had, in comparison with those who used their OS frequently after 1.5 years, significantly lower scores for short-term outcomes concerning change in pain, weight of the OS, and cosmetic appearance of the OS.

This is the first study in which long-term follow-up of OS use was investigated. The rates of long-term use found support the conclusion that nonuse of OS is not a major problem in the Netherlands, neither at short nor at long term [4,16]. However, not all patients continued to use their OS, which indicates room for improvement. More than half of the patients who ceased using their OS did so because of dissatisfaction with aspects of the usability of their OS. This dissatisfaction was indicated at long-term follow-up; however, it could also be seen in lower scores for short-term usability outcomes. This association between short-term outcomes and long-term use is in line with a conceptual model for AT in general [5].

In order to discuss the clinical implications of these findings, we must discuss some limitations of this study first. The scores for short-term outcomes that were used in this study were for a patient's first pair of OS only. After 1.5 years, patients have usually been provided with a

Table 1.

Patient characteristics, categorized with regard to frequency of use of their custom-made orthopedic shoes (OS) 1.5 years after delivery. Values are % (*n*) or otherwise indicated. Frequent use = using OS 4–7 days/week, occasional use = using OS 1–3 days/week, nonuse = not using OS.

Characteristic	Frequent Use (78%; <i>n</i> = 211)	Occasional Use (9%; <i>n</i> = 23)	Nonuse (13%; <i>n</i> = 35)	<i>p</i> -Value*
Sex				
Male	42 (89)	13 (3)	31 (11)	0.02
Female	58 (122)	87 (20)	69 (24)	
Age (years)† (mean ± SD)	64 ± 14	64 ± 14	59 ± 17	0.20
Main Reason‡				
Pain	54 (114)	74 (17)	63 (22)	NA
Wounds	9 (19)	4 (1)	6 (2)	
Foot Deviation	24 (51)	4 (1)	20 (7)	
Leg Length Difference	2 (4)	4 (1)	0 (0)	
Other	11 (23)	13 (3)	11 (4)	
Pairs of OS Provided				
One	5 (11)	30 (7)	54 (19)	NA§
Two	66 (140)	57 (13)	26 (9)	
Three	23 (48)	13 (3)	6 (2)	
Four	5 (10)	0 (0)	0 (0)	
Five	1 (2)	0 (0)	0 (0)	
Missing	0 (0)	0 (0)	14 (5)	
Daily Duration of Use (hours/day)				
>12	39 (81)	4 (1)	—	<0.001
8–12	31 (66)	9 (2)	—	
4–8	22 (47)	26 (6)	—	
1–4	8 (17)	61 (14)	—	
<1	0 (0)	0 (0)	—	
Reason for Nonuse				
Dissatisfaction with Usability				
Effectiveness	—	—	17 (6)	NA
Comfort	—	—	40 (14)	
Physical Changes¶				
Positive	—	—	17 (6)	NA
Negative	—	—	23 (8)	
Missing	—	—	3 (1)	NA

Note: Percentages may not add to 100 because of rounding.

**p*-Value for differences between frequent users, occasional users, and nonusers is shown.

†Age at moment of first measurement, i.e., 3 months before delivery of patient's first pair of OS.

‡Main reason was indicated by patients themselves.

§Chi-square test was not applicable because more than 25% of cells had expected count <5.

¶Positive changes mean that patients do not need their OS anymore; negative changes mean that patients were not able to use their OS anymore.

NA = not applicable, SD = standard deviation.

second and sometimes third pair of OS. The usability of a patient's second or third pair may be different, yet this difference was not taken into account. All OS are fully custom-made, and even though the same individual model cast is used, variation between the pairs is always possible. This could, for example, be seen in the three patients who discarded their first pair, yet are now using their subsequent

pair frequently. The usability of the pair(s) of OS a patient is currently using might be more important than the short-term outcomes of a previous pair. However, we still found a strong association between the usability of the first pair and use at follow-up. This might imply that the first experiences a patient has with OS are important with regard to the use of future pairs.

Table 2.

Continuation of short-term use into long-term use. Values are % (*n*). Short-term use = use after 3 months, long-term use = use after 1.5 years, frequent use = using OS 4–7 days/week, occasional use = using OS 1–3 days/week, nonuse = not using OS.

Short-Term Use	Long-Term Use				Total [†]
	Frequent Use	Occasional Use	Nonuse* [†]		
			Dissatisfied	Physical	
Frequent Use	84 (195)	6 (15)	5 (11)	5 (12)	100 (233)
Occasional Use	46 (16)	23 (8)	26 (9)	6 (2)	100 (35)

Note: Percentages are shown within short-term use. Percentages may not add up to 100 because of rounding.

*Nonuse could be due to dissatisfaction with aspects of usability or to physical changes that have made using OS not possible or necessary anymore.

[†]One patient is missing because reason for nonuse was not known.

OS = custom-made orthopedic shoes.

Table 3.

Association between long-term use of OS and short-term outcomes of aspects of usability. Values are median (interquartile range) or % (*n*) or as indicated.

Outcome	Freq (78%; <i>n</i> = 211)	Occ (9%; <i>n</i> = 23)	Non* (7%; <i>n</i> = 20)	<i>p</i> -Value [†]	Post Hoc Analyses					
					Freq–Non		Freq–Occ		Occ–Non	
					<i>p</i> -Value [‡]	ES	<i>p</i> -Value [‡]	ES	<i>p</i> -Value [‡]	ES
Effectiveness										
Change in Pain (skin) [§] (<i>n</i> = 128; 14; 12) [¶]	86 (65.25–95)	61 (43.25–88.75)	53 (50.25–70)	0.007	0.01	0.21	0.01	0.19	0.88	0.04
Change in Pain (muscles) [§] (<i>n</i> = 121; 19; 17) [¶]	92 (64–93)	59 (42–75)	71 (50.5–84)	0.001	0.06	0.14	0.001	0.25	0.23	0.20
Change in Sprains [§]	91 (76.5–97)	95 (78–98)	83 (55–98)	0.49	0.62	0.05	0.28	0.10	0.37	0.19
Efficiency										
Donning/Doffing OS [§]	75 (51–89)	74 (40–85)	51 (28–93)	0.29	0.24	0.08	0.26	0.07	0.94	0.01
Fit of OS [§]	86 (71–94.75)	85.5 (69.5–94.5)	39 (16.75–77.75)	<0.001	<0.001	0.27	0.99	0.00	0.003	0.46
Ease of Walking with OS [§]	83 (66–93)	65.5 (43.75–89.75)	48.5 (18.75–83.25)	<0.001	<0.001	0.25	0.23	0.15	0.13	0.24
Weight of OS [§]	48 (27–53)	27 (18–48)	49 (23–52)	0.03	0.82	0.01	0.007	0.18	0.09	0.27
Satisfaction										
Cosmetic Appearance: Patient's Opinion [§]	61.5 (47–81)	49 (18–69)	51 (23–76)	0.02	0.17	0.09	0.007	0.18	0.52	0.10
Cosmetic Appearance: Other's Opinion										
Very Ugly or Ugly	7 (14)	22 (5)	10 (2)	NA**	—	—	—	—	—	—
Neutral	39 (83)	35 (8)	45 (9)		—	—	—	—	—	—
Attractive or Very Attractive	40 (85)	30 (7)	25 (5)		—	—	—	—	—	—
Do Not Know or Missing	14 (29)	13 (3)	20 (4)		—	—	—	—	—	—
Communication with Medical Specialist [§]	85 (66.5–93.75)	87 (62–95)	68 (51.75–73.75)	0.01	0.002	0.22	0.94	0.01	0.08	0.29
Communication with Shoe Technician [§]	87 (73–94)	85 (75–96)	68 (49.25–90)	0.046	0.01	0.16	0.86	0.01	0.048	0.30

Note: Percentages many not add to 100 because of rounding.

*Only patients who did not use their OS anymore and were dissatisfied with usability of their OS were taken into account; patients who did not use their OS because of physical changes (*n* = 14; 5%) or for whom a reason for no use was missing (*n* = 1) were not taken into account.

[†]*p*-Value for difference between three groups is shown.

[‡]*p*-Value for difference between two groups is shown.

[§]Scores could range from 0 (most negative score possible) to 100 (most positive score possible).

[¶]Not all patients had wounds, pain, or sprains; therefore, number of patients for these questions is indicated for each group respectively.

**Chi-square test was not applicable because more than 25% of cells had expected count <5.

ES = effect size, Freq = frequent use (using OS 4–7 days/week), NA = not applicable, Non = nonuse (not using OS), Occ = occasional use (using OS 1–3 days/week), OS = custom-made orthopedic shoes.

Another limitation is the skewed distribution of patients over the three groups. A large majority of patients used their OS frequently, whereas only a small percentage used them occasionally or not at all. This is clearly a positive result from a clinical point of view. However, the comparison between the groups might be affected by the skewed distribution. Because the differences between the groups were rather large, in our opinion this effect will be small. Further, it was not possible to perform multivariate analyses or to calculate odds ratios. A larger group of patients should be studied to overcome these problems.

This study has two important clinical implications. The association found between short-term outcomes and long-term use implies that it is important to monitor patients for longer periods. All patients in this study were using their OS after 3 months; however, for some patients this short-term use did not continue into long-term use. Patients with worse short-term outcomes are more likely to use their OS less or not at all after 1.5 years follow-up. Patients who are not satisfied with aspects of the usability of their OS should be monitored closely to prevent them from using their OS less or not at all after the first few months. Attention needs to be paid to these patients in clinical practice.

Patients who ceased using their OS gave communication with both the medical specialist and the shoe technician significantly lower scores. This again stresses the importance of this communication in relation to the actual use of OS [14,17–19]. It can be hypothesized that patients who are dissatisfied with the communication are less willing to return to the medical specialist or shoe technician in order to change their OS when they do not fit perfectly. These patients are probably more likely to stay at home and stop using their OS. Further research into the intricacies of the communication between patient, medical specialist, and shoe technician is needed. In clinical practice, attention should be paid to patients who are dissatisfied with the communication to prevent them from not using their OS long-term.

CONCLUSIONS

We conclude that a large majority of patients is still using their OS at long-term follow-up. This long-term use is associated with positive short-term usability outcomes for a patient's OS; patients with worse short-term

usability outcomes for their OS are more likely to use OS only occasionally or not at all at long-term follow-up. This implies that these patients should be monitored closely, even when OS are used in the short term. The large differences found between users and nonusers for communication with the medical specialist and shoe technician again stresses the importance of this communication in relation to the use of OS.

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