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## Patients' expectations and actual use of custom-made orthopaedic shoes

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**Objective:** To investigate the association between patients' expectations and the actual use of custom-made orthopaedic shoes.

**Design:** A prospective cohort study with internal comparison.

**Setting:** Twelve orthopaedic shoe companies.

**Patients:** During six months, consecutive patients who were provided with their first ever pair of orthopaedic shoes and aged 16 years or older were recruited. A total of 339 patients with different pathologies were included (response 67%). Mean (SD) age of the patients was 63 (15) years, and 129 patients (38%) were male.

**Main measures:** A practical and reproducible questionnaire, measuring: frequency of use of orthopaedic shoes, patients' expectations and experiences of aspects of the usability of orthopaedic shoes, and communication about patients' expectations.

**Results:** Patients' expectations were not associated with the use of orthopaedic shoes (*P*-values range: 0.106 to 0.607), but the difference between expectations and experiences was (*P*-values range: <0.001 to 0.012). The expectations of patients who frequently used their orthopaedic shoes were in concordance with their experiences, whereas the expectations of patients who did not use their orthopaedic shoes were much higher than their experiences. There was no communication of patients' expectations with the medical specialist or orthopaedic shoe technician in 34% and 25% of the patients respectively.

**Conclusions:** In relation to the actual use of orthopaedic shoes, it is crucial that patients' expectations are not much higher than their experiences.

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## Introduction

Custom-made orthopaedic shoes are assistive technologies, prescribed to a wide variety of patients to prevent or diminish foot and/or ankle problems.<sup>1</sup> Orthopaedic shoes are frequently prescribed in, for example, England and Wales (200,000 pairs prescribed in 2000; 52 million inhabitants),<sup>2</sup> and in the Netherlands (50,000 pairs prescribed in 2006; 16 million inhabitants).<sup>3</sup> For any assistive technology to be effective, it is essential that they are actually used, to maximize the potential to contribute to positive health benefits.

The use of orthopaedic shoes has been associated with many aspects of their usability, which 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 (ISO), 9241-11). Positive experiences with the effectiveness (e.g. less pain) or the efficiency (e.g. comfortable shoes) of the orthopaedic shoes, or the satisfaction of the patient, have all been associated with more frequent use.<sup>4-7</sup> These associations have all been established retrospectively, three months to two years after delivery of the orthopaedic shoes.<sup>4-7</sup> Patients' expectations have not been taken into account, even though patients' expectations can seriously affect the use of an assistive technology.<sup>8-10</sup>

Little is known about patients' expectations of orthopaedic shoes. To the best of our knowledge, there is only one study; the authors concluded that the use of orthopaedic shoes could not be predicted based on expectations.<sup>11</sup> However, the experiences of the patients were not taken into regard in that study. When considering the evidence for research in assistive technologies in general, it has been stressed that the difference between expectations and experiences is associated with the use of an assistive technology, rather than the expectations.<sup>8,9</sup> Expectations which are in concordance with experiences promote use of an assistive technology, and non-use is higher when expectations are not met by experiences.<sup>8,9</sup> With the limited evidence available, more insight into the association between patients' expectations and the actual use of orthopaedic shoes is needed.

The aim of this study was to investigate the association between patients' expectations and the actual use of orthopaedic shoes three months after delivery.

## Methods

### Procedures

During a six month period, patients were recruited by 12 orthopaedic shoe companies to participate in this study. A specially developed questionnaire consisting of a pre-part and a post-part was used.<sup>12</sup> During the visit where foot measurements were taken, the orthopaedic shoe technician handed the pre-part over to patients who gave written informed consent. Personal data of these patients were sent to the researchers. The pre-part had to be completed and returned to the researchers before actual delivery of the orthopaedic shoes. Three months after delivery of the orthopaedic shoes, the researchers sent the post-part to all patients who completed the pre-part.

Patients who did not complete either the pre- or the post-part of the questionnaire within a month were contacted by telephone once by the researchers in order to ask for the reason of delay and possible problems, and were asked to complete the questionnaire. The procedures were approved by the local Medical Ethics Committee.

### Patients

Consecutive patients of 12 orthopaedic shoe companies who were provided with their first ever pair of orthopaedic shoes, during a six month period, were included. Patients who were provided with a subsequent pair of orthopaedic shoes were excluded, because there is a large difference between patients who receive orthopaedic shoes for the first time and patients who receive a subsequent pair of orthopaedic shoes, especially with regard to their expectations.<sup>13</sup> Other inclusion criteria were: (i) 16 years of age or older; (ii) able to complete the questionnaire without help related to cognitive or physical impairments.

## Outcome measures

We used the Monitor Orthopaedic Shoes, which is a practical and reproducible questionnaire that can be used for patients with a wide range of disorders.<sup>12</sup> The Monitor Orthopaedic Shoes consists of a pre-part and a post-part with multiple choice and visual analogue scale questions. The pre-part was designed to measure the current situation, patients' expectations of the most relevant aspects of the usability of their orthopaedic shoes, and the communication regarding their expectations with the medical specialist and the orthopaedic shoe technician. The post-part was designed to measure use and the experiences of the usability of their orthopaedic shoes, and to measure the difference between expectations and experiences. For the purposes of this study, the results concerning patients' expectations and concerning the difference between expectations and experiences were used.

Three categories of use of orthopaedic shoes were defined: frequent use (4–7 days/week), occasional use (1–3 days/week), and non-use (not using orthopaedic shoes). We further asked patients to indicate the average daily duration of use in hours. Use of orthopaedic shoes was not further specified into activities during which orthopaedic shoes were used or location of use (e.g. indoor vs. outdoor use).

Within the domains of usability as defined by the ISO, the following aspects were measured: change in walking capacity, wound healing, change in pain, and change in sprains (effectiveness domain); fit of orthopaedic shoes, ease of walking with orthopaedic shoes, weight of orthopaedic shoes (efficiency domain); cosmetic appearance of orthopaedic shoes (satisfaction domain).<sup>4–7</sup>

The difference between expectations and experiences was obtained in two ways. For items in two of the domains, effectiveness and satisfaction, the score on the post-part of Monitor Orthopaedic Shoes (experiences; range 0–100) was subtracted from the score on the pre-part of Monitor Orthopaedic Shoes (expectations; range 0–100). The score of the difference between expectations and experiences could range from –100 to 100; a negative score meaning that expectations were higher than experiences, a positive score vice versa.

For items in the efficiency domain, the difference between expectations and experiences was directly asked in the post-part of the Monitor

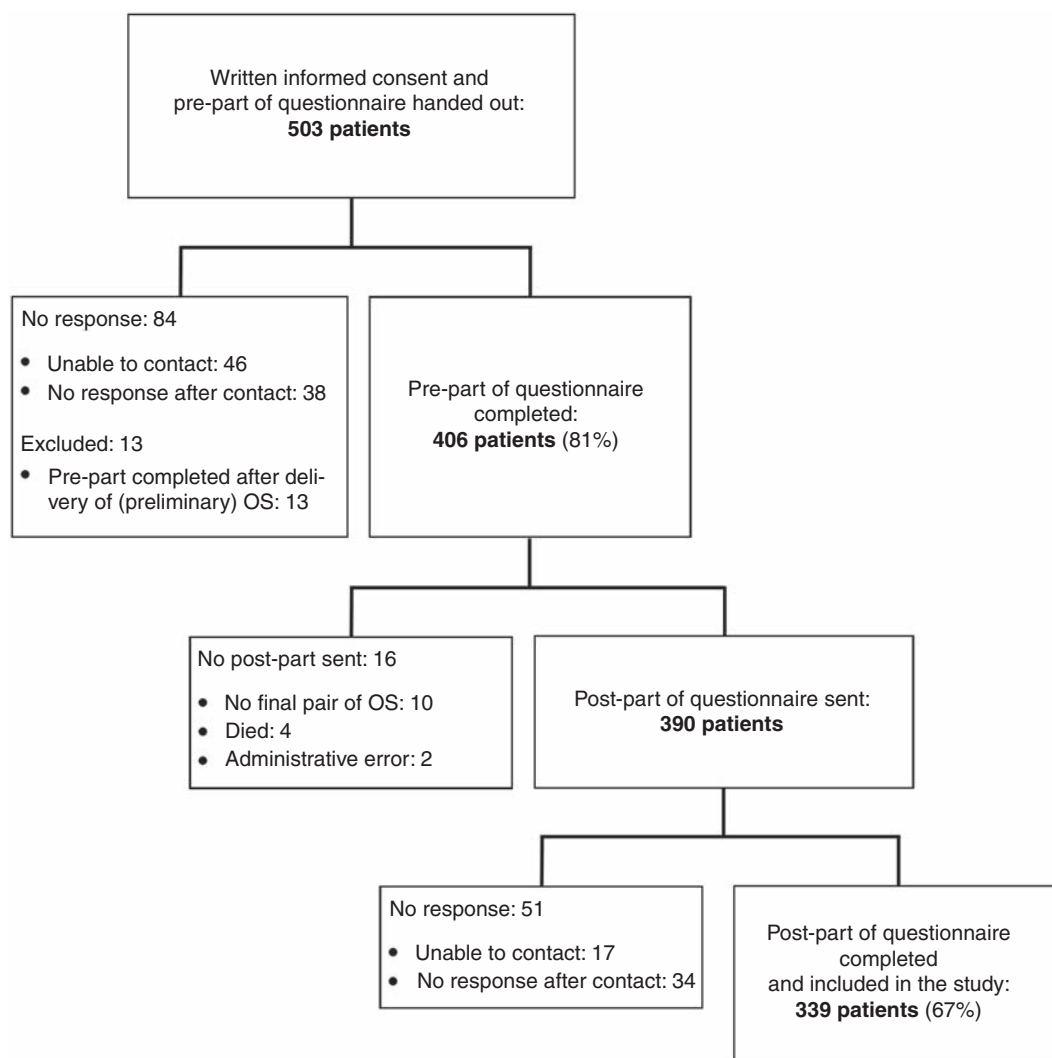
Orthopaedic Shoes. This was a deliberate choice during the development of the Monitor Orthopaedic Shoes. Experts (both orthopaedic shoe technicians and experienced patients) indicated that patients only have a general expectation that aspects of the efficiency of orthopaedic shoes will be good, since orthopaedic shoes are fully custom-made and based on an individual model cast of their foot. They also indicated that patients are very well capable of indicating after delivery if there was a difference between the expectations they had and their actual experiences. The score of this question (range 0–100) was adjusted, so that the score of the difference between expectations and experiences of items in the efficiency domain could range from –100 to 100 as well; a negative score meaning that expectations were higher than experiences, a positive score vice versa.

## Statistical analysis

Differences between the three groups were assessed with a Chi-square test or Kruskal-Wallis test. The latter was used because of non-normal distribution of the data. Post-hoc analyses to assess differences between the groups separately were performed using a Mann-Whitney U test, and by calculating the effect size with the formula (effect size =  $Z/\sqrt{(n_1 + n_2)}$ ). Data were analysed using SPSS for Windows, version 16.0 (SPSS Inc. Chicago, Illinois, United States of America).

## Results

The patient flow is shown in Figure 1. The mean (SD) age of the 339 patients included in the study was 63 (15) years, and 129 patients were male (38%). Of these patients, 85 had diabetes mellitus, 60 rheumatoid arthritis, 237 an (unspecified) foot disorder, 23 a muscular disease, and 104 another disorder (e.g. cerebral vascular accident, spinal cord injury, psoriasis, leather allergy, and others). Disorders were indicated by patients themselves, and it was possible to indicate more than one disorder. Age and gender of the patients included in the study were comparable with the non-responders (patients who gave written informed consent but did not complete both



**Figure 1** Patient flow. OS = custom-made orthopaedic shoes.

parts of the questionnaire; mean (SD) age 59 [17] years and 41% male), and with all patients of the orthopaedic shoe companies to whom a first ever pair of orthopaedic shoes was provided in the same six months (data obtained via management of the orthopaedic shoe companies; mean (SD) age 63 [17] years and 39% male).

We were able to contact 34 of the 51 patients who did not respond to the post-part of the questionnaire. Reasons indicated for not responding

were lack of interest ( $n=15$ ), lack of time ( $n=10$ ), not using orthopaedic shoes and dissatisfied ( $n=3$ ), not using orthopaedic shoes because of change in medical situation ( $n=2$ ), questionnaire missing in post ( $n=2$ ), and no reason specified ( $n=2$ ).

Three months after delivery of orthopaedic shoes, 275 patients (81%) used orthopaedic shoes frequently (4–7 days/week), 43 patients (13%) used orthopaedic shoes occasionally (1–3 days/week),

**Table 1** Patient characteristics, categorized with regard to the frequency of use of their custom-made orthopaedic shoes

		Frequent use (n = 275; 81%)	Occasional use (n = 43; 13%)	Non-use (n = 21; 6%)	P*
Gender	Male	110 (40%)	16 (37%)	3 (14%)	.061
	Female	165 (60%)	27 (63%)	18 (86%)	
Age (years)	Mean ± SD	63 ± 14	63 ± 17	63 ± 12	.998
Main reason <sup>†</sup>	Pain	147 (54%)	30 (70%)	12 (57%)	NA <sup>§</sup>
	Wounds	25 (9%)	1 (2%)	0 (0%)	
	Foot deviation	62 (23%)	5 (12%)	4 (19%)	
	Leg length difference	7 (3%)	0 (0%)	2 (10%)	
	Other	34 (12%)	7 (16%)	3 (14%)	
General health <sup>‡</sup>	Improved	51 (19%)	3 (7%)	6 (29%)	NA <sup>§</sup>
	No change	194 (71%)	34 (79%)	11 (52%)	
	Deteriorated	28 (10%)	5 (12%)	3 (14%)	
	Missing	2 (1%)	1 (2%)	1 (5%)	
Daily duration of use (hours/day)	>12 hours	65 (24%)	2 (5%)	NA	<.001 <sup>¶</sup>
	8 – 12 hours	93 (34%)	1 (2%)		
	4 – 8 hours	83 (30%)	14 (33%)		
	1 – 4 hours	29 (11%)	20 (46%)		
	< 1 hour	1 (.5%)	6 (14%)		
	Missing	4 (.5%)	0 (0%)		

Note: values are *n* (%) or otherwise as indicated. Frequent use = using orthopaedic shoes 4–7 days/week; Occasional use = using orthopaedic shoes 1–3 days/week; Non-use = not using orthopaedic shoes; NA = not applicable; \*: the *P*-value for the differences between the three groups is shown. <sup>†</sup>: the main reason for prescription of orthopaedic shoes was indicated by patients themselves. <sup>‡</sup>: general health refers to the change in general health (not the feet specifically) between pre- and post-measurements. <sup>§</sup>: a Chi-square test was not applicable because more than 25% of the cells had an expected count less than 5. <sup>¶</sup>: the *P*-value for the difference between frequent and occasional users only is shown, as this was not applicable for non-users.

and 21 patients (6%) did not use orthopaedic shoes. There were no significant differences between the patient characteristics of the three groups (Table 1). Patients who use their orthopaedic shoes frequently have a significantly higher daily duration of use than patients who use them occasionally (Table 1).

There were no associations between patients' expectations and the use of orthopaedic shoes three months after delivery (Table 2). In contrast, the difference between patients' expectations and experiences had a significant association with the use of orthopaedic shoes (Table 3). The expectations were in concordance with the experiences for patients who used their orthopaedic shoes frequently, whereas expectations were much higher than experiences for patients who did not use their orthopaedic shoes; the differences between expectations and experiences for patients who used their orthopaedic shoes occasionally fell in between the other groups (Table 3).

No communication about their expectations was reported by 112 (34%) and 83 (25%) patients

to the medical specialist and the orthopaedic shoe technician, respectively (Table 4). Of the patients who did report discussion of their expectations with the medical specialist and the orthopaedic shoe technician, 115 (54%) and 142 (58%) patients, respectively, reported higher expectations afterwards; 2 (1%) and 6 (2%) patients reported lower expectations after discussion (Table 4). In total, 272 (87%) patients indicated that they had input concerning the cosmetic appearance of their orthopaedic shoes. No differences were found between patients who use their orthopaedic shoes frequently, occasionally, or not at all (*P*-value range: 0.226 to 0.917; results not shown).

## Discussion

In this study, the association between patients' expectations and the actual use of orthopaedic shoes was investigated. It was shown that there is no association between patients' expectations

**Table 2** Patients' expectations, categorized with regard to the frequency of use of their custom-made orthopaedic shoes

	Frequent use (n = 275; 81%)	Occasional use (n = 43; 13%)	Non-use (n = 21; 6%)	P*
Walking capacity				
Will improve	171 (65%)	24 (56%)	13 (62%)	.607
Will stay the same	89 (34%)	17 (40%)	8 (38%)	
Will deteriorate	5 (2%)	2 (5%)	0 (0%)	
Missing	10	0	0	
Wounds				
Will heal	41 (84%)	8 (80%)	0	NA
Will stay the same	8 (16%)	2 (20%)	0	
No wounds	223	33	17	
Missing	3	0	4	
Change in pain (skin) <sup>†</sup> (n = 120;16;6) <sup>‡</sup>	86 (71.5; 94)	86 (77; 95)	66.5 (58.75; 84.75)	.166
Change in pain (muscles) <sup>†</sup> (n = 182;28;8) <sup>‡</sup>	83 (72; 93)	82 (65.5; 91.75)	72.5 (66.75; 87)	.334
Change in sprains <sup>†</sup> (n = 111;15;3) <sup>‡</sup>	89 (78; 96)	86 (73; 92)	77 (70; 79)	.106
Cosmetics: patient's opinion <sup>§</sup>	53 (47; 75)	52.5 (31.75; 71.25)	54 (31; 63)	.511
Cosmetics: other's opinion				
Very ugly or ugly	29 (11%)	8 (19%)	3 (14%)	.333
Neutral	95 (35%)	12 (28%)	10 (48%)	
Attractive or very attractive	31 (11%)	3 (7%)	1 (5%)	
Do not know or missing	120 (44%)	20 (47%)	7 (33%)	

Note: values are n (%) or median (IQR); Frequent use = using orthopaedic shoes 4–7 days/week; Occasional use = using orthopaedic shoes 1–3 days/week; Non-use = not using orthopaedic shoes; NA = not applicable; \*: the P-value for the differences between the three groups is shown; †: expected change in pain/sprains is shown, scores could range from 0 (much more pain/sprains) to 100 (much less pain/sprains); ‡: not all patients had pain or sprains; therefore the n of patients for these questions is indicated, for each group respectively; §: scores could range from 0 (very ugly) to 100 (very attractive).

**Table 3** The difference between patients' expectations and experiences, categorized with regard to the frequency of use

	Frequent use (n = 275; 81%)	Occasional use (n = 43; 13%)	Non-use (n = 21; 6%)	P*	Post-hoc analyses <sup>‡</sup>					
					Freq.–Non.		Freq.–Occ.		Occ.–Non.	
					P <sup>†</sup>	ES	P <sup>†</sup>	ES	P <sup>†</sup>	ES
Change in pain (skin) <sup>‡</sup> (n = 120;16;6)	–1.5 (–19;10.75)	–1 (–21.75; 4.5)	–48.5 (–74.25; –17.25)	.012	.003	.26	.622	.04	.022	.49
Change in pain (muscles) <sup>‡</sup> (n = 182;28;8)	–2.5 (–19; 10)	–8 (–45.75; 1.5)	–47.5 (–58.75; –21.5)	<.001	<.001	.25	.018	.16	.048	.33
Change in sprains <sup>‡</sup> (n = 111;15;3)	2 (–7; 12)	–1 (–22; 12)	–25 (–61; 17)	.544						
Cosmetic appearance <sup>§</sup>	1 (–12; 18)	3 (–25.75; 10)	–20.5 (–41.25; –3.75)	.004	<.002	.19	.144	.09	.047	.27
Fit of orthopaedic shoes	58 (9; 82)	24 (–35; 52)	–5 (–83.5; 40)	<.001	.001	.20	<.001	.21	.116	.21
Walking with orthopaedic shoes	58 (9; 84)	6 (–37;69)	–86 (–91; –60)	<.001	<.001	.38	.001	.19	<.001	.59
Weight of orthopaedic shoes	0 (–34; 50)	–28 (–75; 5)	–64 (–82; –8)	<.001	.001	.19	<.001	.20	.274	.04

Note: values are median (IQR) or as indicated. Scores could range from –100 to 100; a negative score meaning expectations > experiences, a positive score meaning experiences > expectations; ES = Effect Size; Freq. = Frequent use = using orthopaedic shoes 4–7 days/week; Occ. = Occasional use = using orthopaedic shoes 1–3 days/week; Non. = Non-use = not using orthopaedic shoes; \*: the P-value of the difference between the three groups is shown; †: the P-value of the difference between the two groups is shown; ‡: not all patients had pain or sprains, therefore the n of patients for these aspects is indicated, for each group respectively; §: patients' own opinion of the cosmetic appearance of their orthopaedic shoes is shown.



**Table 4** Communication about patients' expectations

	<i>n</i> = 339
Communication with medical specialist	
Quality of communication*	87 (73.5; 95)
Communication about expectations	
Yes	220 (66%)
No or cannot remember	112 (34%)
Missing	7
Expectations after communication	
Higher expectations	115 (54%)
Lower expectations	2 (1%)
No change	52 (25%)
Did not have expectations	42 (20%)
Missing	9
Communication with orthopaedic shoe technician	
Quality of communication*	90 (78; 96.5)
Communication about expectations	
Yes	249 (75%)
No or cannot remember	83 (25%)
Missing	7
Expectations after communication	
Higher expectations	142 (58%)
Lower expectations	6 (2%)
No change	67 (27%)
Did not have expectations	37 (13%)
Missing	2
Input concerning cosmetic appearance?	
Yes	272 (87%)
No	41 (13%)
Missing	26

Note: values are median (IQR) or *n* (%). \*: quality of communication is the patient's opinion of how well the medical specialist or orthopaedic shoe technician listened, scores could range from 0 (listened very badly) to 100 (listened very well).

and the use of orthopaedic shoes. In contrast, an association was found between the use of orthopaedic shoes and the difference between expectations and experiences: the expectations of patients who frequently used their orthopaedic shoes were in concordance with their experiences, whereas the expectations of patients who did not use their orthopaedic shoes were much higher than their experiences. Around one quarter of the patients reported that there was no communication of their expectations with the medical specialist or the orthopaedic shoe technician. In line with research regarding assistive technologies in general, this research implies that, for orthopaedic shoes to be used, it is crucial that patients' expectations are not much higher than their experiences.<sup>8,9,14,15</sup>

To place the current findings into perspective, it is necessary to first discuss some limitations of this study. The difference between expectations and experiences was obtained in two ways. This makes it difficult to compare the scores of the separate items, and might bias the results. However, in a study where the measurement approach of patients' expectations was investigated, it was concluded that there are no differences between these two methods.<sup>16</sup> Further, the trends and the association with the use of orthopaedic shoes was the same for all measured aspects, independent of the way they were obtained. Because patients' expectations are not associated with use, we would recommend for research purposes to only measure the difference between expectations and experiences directly at follow-up, as this is less time-consuming and overcomes the problem that patients only have general expectations for some aspects.

Caution should be taken when interpreting the results concerning communication, as only a few aspects of communication were measured and no insight was obtained into 'what' was being communicated. Future studies using a qualitative approach may provide more in depth insight into the intricacies of the communication between the patient and the orthopaedic shoe technician and medical specialist.<sup>17</sup>

Another limitation is the small number of patients who did not use their orthopaedic shoes after three months. Such a low rate of non-use is clearly a positive result from a clinical point of view. However, it makes comparison between the three groups harder because of the skewed distribution. Because the differences between the groups were rather large for all aspects, including more patients would in our opinion result in finding the same effects with larger effect sizes.

A possible bias may have resulted from the 33% non-responders. However, characteristics of patients included in the study were comparable to all patients who were provided with a pair of orthopaedic shoes in that period and to the non-responders. Further, we phoned patients who did not respond to the post part to check if non-response was related to non-use or dissatisfaction. Only a few did not use their orthopaedic shoes and even less did not respond because of dissatisfaction; all other patients did use them and had

reasons for not responding that were not related to the outcomes. If there is a bias from the non-responders, it is in our opinion only small.

This study has important implications for research and clinical practice. Future research should aim to find predictors of use, as patients' expectations have no predictive value. Prediction of use is worthwhile, as this can save time and energy from patients, medical specialists, and orthopaedic shoe technicians. A possibility that has been proposed in a recently developed, but not yet validated, model for prediction of use of assistive technologies,<sup>18</sup> is research based on sociological theories like the theory of planned behaviour<sup>19</sup> and the diffusion of innovations theory.<sup>20</sup> To validate this model and to find predictors of use, future research should be patient-centred and focus on the perceived relative advantage of orthopaedic shoes.<sup>18</sup>

Concerning clinical practice, this study underlines the importance of patients' expectations. This again stresses the shift that should be made in clinical practice, from a focus on the technical qualities of the orthopaedic shoes, to a patient-centred focus.<sup>17,21,22</sup> An orthopaedic shoe that is technically perfect, yet does not meet the patients' expectations, will most likely not be used.<sup>23–25</sup> Both the medical specialist and the orthopaedic shoe technician should focus on exploring and understanding the expectations a patient has of their orthopaedic shoes. An estimate can then be made if these expectations will be met by the experiences that patient is likely to have. If not, adjustments can be made in time, which will then promote the use of the orthopaedic shoes.

Communication is the only way in clinical practice to explore and understand patients' expectations, and this communication has been shown to be important in relation to the latter use of the orthopaedic shoes.<sup>10,17,22,24</sup> Our finding that around one quarter of the patients reported no communication of their expectations with the medical specialist or the orthopaedic shoe technician indicates that a potential gap exists between what a clinician may be trying to communicate and what the patient actually perceives or understands. Awareness of this gap, and subsequent improvements in communication, may promote the use of an assistive technology.

### Clinical messages

- Patients' expectations are not associated with the use of orthopaedic shoes, whereas the difference between expectations and experiences is.
- Patients' expectations were much higher than their experiences after delivery for patients who did not use their orthopaedic shoes.
- There is little communication about patients' expectations between the patient and the medical specialist or orthopaedic shoe technician.

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### Competing interests

None declared.

### Contributors

All authors contributed to initiating and designing the study, monitoring progress, deciding on the analytic strategy, and writing the paper. The corresponding author is the guarantor and takes

ultimate responsibility for the accuracy and honesty of the report and the morality of the study.

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