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## Use of custom-made orthopaedic shoes

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Document Version Publisher's PDF, also known as Version of record

Publication date: 2011

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA): Netten, S. J. J. V. (2011). Use of custom-made orthopaedic shoes. s.n.

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Download date: 21-06-2022

## summary

Custom-made orthopaedic shoes (OS) can only be of benefit if they are actually used. OS are prescribed for patients with a wide variety of pathologies, however, it is not clear if these patients use their OS. Evidence concerning use of OS and factors that may be associated with their use is scarce. Therefore, the aim of this thesis was to evaluate use of OS, and to evaluate which factors are associated with use of OS.

Use of OS can be defined based on frequency of use (e.g. per day, week, or month), duration of use (e.g. in hours per day), environment of use (e.g. indoors, outdoors), or task of use (e.g. work, leisure). Frequency or duration of use can be measured for any patient, irrespective of the specific situation of that patient. In this thesis, use was defined in three frequency categories: frequent use (4-7 days/week), occasional use (1-3 days/week), and non use (never using OS).

Use of OS has been associated with factors of its usability. 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' (ISO, 9241-11). In this thesis, both patients' expectations and patients' experiences on factors of usability of OS have been evaluated within the three domains of the ISO definition: effectiveness, efficiency, and satisfaction.

As start of the research of this thesis, a questionnaire was developed to measure use and usability of OS (*Chapter 2*). Development of this questionnaire, the Monitor Orthopaedic Shoes (MOS), was based on a literature search, expert interviews, two expert meetings, and exploration and testing of its reproducibility.

MOS comprises two parts: A pre-part (34 questions), measuring several outcome variables three months before patients' first-ever pair of OS are delivered, and measuring patients' expectations on the most relevant factors of usability of OS. And a post-part (39 questions), measuring several outcome variables three months after patients' first-ever pair of OS are delivered, and measuring patients' experiences on the most relevant factors of usability of OS. High reproducibility scores (Cohen's kappa > 0.60 or intra class correlation > 0.70) were found in all but one question of both parts of the final version of MOS. It took patients about fifteen minutes to complete one part of MOS.

It was concluded that MOS is a practical and reproducible question-

naire that can measure use and the most relevant factors of usability of OS from a patient's perspective.

With the post-part of MOS, use of OS and the association between use and the most relevant factors of usability of OS was evaluated (*Chapter* 3). A group of 339 patients with different pathologies was recruited by twelve orthopaedic shoe companies in the Netherlands. Mean age of these patients was  $63 \pm 15$  years, 38% were male, and all patients received their first-ever pair of OS.

Three months after delivery, 81% of the patients used their OS frequently (4–7 days/week), 13% occasionally (1–3 days/week), and 6% did not use their OS. Associations were found between use and all measured factors in all three domains of usability (effectiveness, efficiency, satisfaction; p-values varied from <.001 to .028). Patients who used their OS more often had a more positive opinion regarding all measured factors of usability of OS.

It was concluded that it is essential to take all factors of usability of OS into account when prescribing and evaluating OS. The effectiveness of OS (e.g. a change in pain after OS), the efficiency of OS (e.g. the ease of walking with OS), and the satisfaction with OS (e.g. the patient's opinion of the cosmetic appearance of OS) are all relevant in relation to use of OS

In *Chapter 4*, the objective was to evaluate the association between patients' expectations on the most relevant factors of usability three months before delivery and use of OS three months after delivery of patients' first-ever pair of OS. Answers on the pre-part and the post-part of MOS from the same 339 patients were used.

Patients' expectations on the most relevant factors of usability were not associated with use of OS (p-values range: .106 to .607), but the difference between expectations and experiences was (p-values range: <.001 to .012). Patients whose expectations were met by their experiences were more likely to use their OS. There was no communication of patients' expectations with the medical specialist or orthopaedic shoe technician in 34% and 25% of the patients respectively.

It was concluded that patients' expectations should not be much higher than their experiences. This implies that communication between patients and prescribing clinicians about their expectations is crucial. However, around a quarter of the patients reported no such communication, which indicates that a potential gap in communication may exist. between short-term outcomes and long-term use were evaluated in the research in *Chapter 5*. One and half years after delivery of their first-ever pair of OS, a shortened version of MOS was sent to all patients who were using their OS after three months. A questionnaire was returned by 269 patients. Mean age of these patients was  $63 \pm 14$  years, and 38% were male.

After 1.5 years, 87% of the patients still used their OS (78% frequently (4-7 days/week) and 9% occasionally (1-3 days/week)); 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 eight out of ten short-term outcomes of factors of usability of OS (p-values range: <.001 to .046). Largest differences between users and non-users were found for scores of the short-term outcomes of the fit of OS and communication with the medical specialist and orthopaedic shoe technician (effect size range: .16 to .46).

It was concluded that patients with worse short-term outcomes of usability of their OS are more likely to use their 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 non-users for communication with the medical specialist and orthopaedic shoe technician stresses the importance of this communication in relation to use of OS.

In the last research of this thesis, the importance of factors of usability of OS to individual patients was evaluated, and the influence of these factors on a patient's decision to use OS (*Chapter 6*). In a qualitative study, 23 patients (10 male) with different pathologies were interviewed. All patients had received OS two to four months before the interview. The semi-structured interview covered three domains: factors of usability of OS, communication and service of prescribing clinicians, and the opinion of others. Data was analyzed using the framework approach.

An improvement of walking was the most important factor of usability for individual patients. The importance of other factors of usability of OS varied between patients, irrespective of patient characteristics. Good communication and service of prescribing clinicians increase patients' satisfaction, and can thereby positively influence their decision to use OS. In relation to the other two domains, the opinion of others was deemed to be less important. Finally, patients indicated they had to accept their OS. When OS are not accepted, patients are likely to decide not to use them.

It was concluded that a patient's decision to use OS is influenced by

acceptance of OS. This can be positively influenced by reaching an improvement of walking, by positive outcomes on other factors of usability important to an individual patient, and by good communication and service of prescribing clinicians.

In *Chapter 7* the results of the research of this thesis were integrated according to the 'Conceptual model for predicting assistive technology (AT) usage', and themes for future research and the implications for clinical practice were discussed.

From the final model of this thesis (see Figure 3 of Chapter 7), it can be seen that use of OS is influenced by acceptance of OS. Acceptance of OS is influenced by the perceived relative advantage of OS and by contextual factors. The perceived relative advantage of OS is determined by weighing of the perceived benefits of OS and perceived benefits of parallel intervention options on three factors of usability that may be important for an individual patient (improvement of walking, cosmetic appearance, ease of use) and on quality of life. Contextual factors are factors as communication and service of prescribing clinicians that influence acceptance of OS, and thereby indirectly influence use of OS. When OS are being used, the impact of OS is determined by outcomes of the three factors of usability that may be important for individual patients. The impact of OS determines the perceived benefits. The perception of these benefits is weighed against the perceived benefits of parallel treatment options, to determine again the perceived relative advantage. With that, the decision to use OS or not is recurring over time.

Three themes emerged that warrant future research. More research is needed on communication between patients and prescribing clinicians, and on the association between use of OS and psychosocial factors as quality of life. As third theme for future research, it was explored if use of OS can be predicted before delivery by future research based on models from social science. It was concluded that the Perceived Attributes Theory seems to have limited possibilities, whereas the Theory of Planned seems to have good possibilities to predict use of OS before delivery.

In clinical practice, focus during prescribing and manufacturing of OS should be patient-centred, and not product-centred. Good communication between patients and prescribing clinicians is crucial, to find the most optimal solution taking patients' preferences, expectations, and acceptance of their OS into account.