Biofeedback in partial weight bearing: Usability of two different devices from patient's and physical therapist's perspective

Masterthesis

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“ONDERGETEKENDE

Remko van Lieshout,

bevestigt hierbij dat de onderhavige verhandeling mag worden geraadpleegd en vrij mag worden gefotokopieerd. Bij het citeren moet steeds de titel en de auteur van de verhandeling worden vermeld.”

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SAMENVATTING

Achtergrond: Sommige patiënten mogen het been na een trauma of operatie tijdelijk niet volledig belasten. Doorgaans worden zij geïnstrueerd in partieel belasten door een fysiotherapeut. Het gebruik van biofeedbacksystemen om de naleving van instructies te verhogen, lijkt veelbelovend. SmartStep en OpenGo Science zijn biofeedbacksystemen die real-time feedback geven. Voor een succesvolle implementatie is onder meer een goede bruikbaarheid van de systemen vanuit gebruikersperspectief van belang.

Doelstelling: Beschrijven van de bruikbaarheid van SmartStep en OpenGo Science vanuit het perspectief van patiënt en fysiotherapeut tijdens de gesuperviseerde revalidatie van patiënten die na trauma of operatie zijn voorgeschreven met partieel belasten.

Methode: In een concurrent triangulatie mixed-methods ontwerp, werden kwalitatieve en kwantitatieve gegevens verzameld en geanalyseerd. Bruikbaarheid werd onderverdeeld in gebruikersprestaties, tevredenheid en acceptatie. Patiënten voorgeschreven met partieel belasten en hun fysiotherapeut werden gevraagd om SmartStep en OpenGo Science te gebruiken tijdens gesuperviseerde revalidatie. De Bruikbaarheid werd kwalitatief getest door een hardopdenk-methode en een semi-gestructureerd interview en kwantitatief getest m.b.v. de System-Usability-Scale (SUS) en gesloten vragen. Voor de kwalitatieve gegevens werd een thematische inhoudsanalyse gebruikt.

Resultaten: Zes patiënt-fysiotherapeutduo's participeerden in de studie. De mediane SUS-score voor patiënten en fysiotherapeuten voor SmartStep was respectievelijk 69 en 64 en voor OpenGo Science respectievelijk 83 en 84. Scores boven de 70 werden beschouwd als een ten minste aanvaardbare bruikbaarheid. De kwalitatieve resultaten laten zien dat de gebruikers gemengde gevoelens en percepties hebben t.a.v. tevredenheid en acceptatie.

Conclusie: Dit onderzoek geeft inzicht in de bruikbaarheid van twee biofeedback systemen tijdens de gesuperviseerde revalidatie vanuit het perspectief van patiënt en fysiotherapeut. De algehele bruikbaarheid van beide perspectieven lijkt tenminste aanvaardbaar voor OpenGo Science en niet aanvaardbaar voor SmartStep te zijn.

Implicatie: Met deze bevindingen kan SmartStep en OpenGo Science worden verbeterd. Toekomstig onderzoek zou zich moeten richten op de bruikbaarheid van biofeedbacksystemen in de onbegeleide revalidatie thuis voor onderzoek en klinische praktijkdoelstellingen.

Trefwoorden: Bruikbaarheid, Biofeedback, Belasting, Orthopedie, Technologie

ABSTRACT

Background: Partial weight bearing is frequently instructed by physical therapists in patients after lower-limb trauma or surgery. The use of biofeedback devices seems promising to improve patient's compliance with these instructions. SmartStep and OpenGo Science are biofeedback devices that provide real-time feedback. For a successful spreading of use, usability of the devices is a critical aspect and should be tested from a user's perspective.

Aim: To describe the usability from therapist's and patient's perspective of Smartstep and OpenGo Science to provide feedback on partial weight bearing during supervised rehabilitation of patients after lower-limb trauma or surgery.

Methods: In a convergent mixed-methods design, qualitative and quantitative data were collected. Usability was subdivided into user performance, satisfaction and acceptability. Patients prescribed with partial weight bearing and their physical therapists were asked to use SmartStep and OpenGo Science during supervised rehabilitation. Usability was qualitatively tested by a think-aloud method and a semi-structured interview and quantitatively tested by the System Usability Scale (SUS) and closed questions. For the qualitative data thematic content analyses were used.

Results: Six duos of a physical therapist and a patient participated. The median SUS scores for patients and physical therapists were for SmartStep 69 and 64 and for OpenGo Science 83 and 84, respectively. Scores above 70 were considered as at least passable usability. The qualitative data showed that there were mixed views and perceptions from patients and physical therapist on satisfaction and acceptability.

Conclusion: This study gives insight in the usability of two biofeedback devices from the patient's and physical therapist's perspective. The overall usability from both perspectives seemed to be at least passable for OpenGo Science and not passable for SmartStep.

Implication: With these findings SmartStep and OpenGo Science can be improved. Further research should investigate the usability of biofeedback devices when used at home for research and clinical practice purposes.

Keywords: Usability, Biofeedback, Weight bearing, Orthopaedics, Technology

INTRODUCTION

Restrictions of lower-limb weight bearing are frequently instructed in patients after orthopedic trauma or surgery such as lower-limb fractures or osteotomies [1]. Weight bearing (WB) is often restricted to protect the injury site or surgical construct from too much stress that may lead to failure. [2-4]. Conversely, the rationale for gradually advancing WB is that repetitive loads can stimulate bone growth and healing. [1-3]. Therefore, it is commonly recommended that a rehabilitation program should include WB restrictions, which are gradually reduced as healing occurs [1,5].

Usually, physical therapists (PTs) train patients to comply with WB instructions, using tactile feedback or bathroom scales[1,6]. However, these methods do not represent dynamic activities (e.g. walking) and are not accurate in training patients to comply with partial weight-bearing (PWB) instructions [5-9]. Previous research shows that it is difficult for patients to comply with WB instructions [1,5,7,9-13]. Reasons for non-compliance include (1) the difficulty to judge the load placed on the lower-limb, and (2) the use of inadequate training methods to achieve controlled PWB [1,7,11,13]. Technological advances have resulted in the development of several commercially available biofeedback devices that are capable of offering real-time feedback on PWB in dynamic situations [1,5,6,11]. Examples of such biofeedback devices are SmartStep and OpenGo Science. Both devices are intended to be used in supervised clinical settings by PTs and patients. These devices use different technology to measure WB and provide real-time feedback. Both biofeedback devices seem promising to improve training and compliance to WB instructions because of providing real-time feedback. Thereby, SmartStep has already been used in several studies on PWB[10,14-16]. OpenGo Science, recently developed, does not interfere with natural gait by using insoles without external modules attached to the body. Both devices are completely wireless.

Although these devices seem promising, the use of technology in daily practice is often not as successful as predicted, due to lack of technology acceptance in patients and healthcare professionals [17]. Several studies have outlined that involvement of the user in the development and evaluation of technology is needed for successful spreading of use [17-19]. Therefore, usability of a product has been considered as an important critical aspect of the interaction between user and product [20]. A mismatch among the users' needs or expectations and the abilities of the biofeedback device can considerably undermine the user-product interaction. According to De Bleser et al. usability refers to the quality of a system towards ease of learning, ease of use, and user satisfaction and should be tested from a user's perspective[21]. In this case the intended users are PTs and patients after orthopedic trauma or surgery. Besides involvement of the intended users, usability of the systems should be tested in the specific context in which it is used, including the tasks users intend to perform [22]. To date, there are no studies that have met these requirements.

Therefore, the aim of this study was to describe the usability from physical therapist's and patient's perspective of SmartStep and OpenGo Science for feedback on partial weight bearing during supervised rehabilitation of patients after orthopedic lower-limb injury or surgery.

METHODS

Design

A convergent mixed methods design was used to evaluate the usability of the Biofeedback devices from patient's and PT's perspective. Qualitative and quantitative data were collected and analyzed during a similar timeframe[23].

Participants

Participants consisted of duos of a physical therapist (PT) and their patient. Participants were recruited by purposive sampling at four different physical therapy settings in the Netherlands, including private practices, rehabilitation centers, rehabilitation departments of nursing homes and orthopedic departments of hospitals. The aim was to recruit a group of participants that was heterogeneous with respect to therapy setting, orthopedic condition, age, sex and education level. A diverse selection of participants and settings facilitates a broad spectrum of usability input[21]. A sample size of at least five participants was considered as sufficient because earlier research has shown that observing four or five participants discovers 80% of a product's usability problems[24]. PTs were eligible if they: trained patients in PWB, worked at earlier described settings and were not influenced concerning the devices by a direct colleague who participated in the study. Patients were eligible if they fulfilled all the following requirements. They had to be: prescribed with PBW (with a maximum load of 50% body weight) by a doctor because of lower-limb (orthopedic) trauma or surgery; referred to physical therapy; able to walk with crutches; aged 18 years and older; wearing shoes, sized between 38 and 45 (measured by the Continental European System). Patients were excluded when one or more of the following applied: diagnosed with cognitive impairments that prevent the understanding of instructions or the performance of the assigned tasks; not able to wear shoes (e.g. because of edema); having other disorders that interfered with normal gait performance; no good understanding of the Dutch language; diagnosed with central and peripheral neurologic disorders; having a severe hearing impairment (not able to hear the feedback sounds). All participants gave their written informed consent.

Biofeedback devices

Table 1 shows an overview of the characteristics of SmartStep and OpenGo Science Appendix 1 shows a more detailed description of both biofeedback devices.

Table 1

Characteristics of the biofeedback devices

	Biofeedback devices	
Characteristics	**OpenGo Science**	**SmartStep**
Sensor type	capacitive pressure sensor	silicon pressure sensor
Number of sensors	13	2
Load range per sensor (unit)	0 - 40 (N/cm^2)	0 – 25 (N/cm^2)
Feedback type	audio or haptic	audio
Connectivity Sensor(s)-FB unit	wireless to SP	via tubes
Sampling frequency	5 to 100 hertz	40 hertz
Data transfer	wireless or cable to PC	wireless to PC
Data storage time	5 to 48 hours*	10 minutes

Note. FB = feedback, SP = smartphone, PC = personal computer

* data storage time depends on the chosen sampling frequency

Data collection

Patient characteristics as age, gender, educational level, bodyweight, shoe size, type and location of orthopedic surgery, PWB prescription were collected. For PTs the following characteristics were collected: age, gender, physical therapy setting, and experience in instructing PWB.

To evaluate usability, the conceptual framework for testing electronic adherence monitoring devices of De Bleser et al. was used [21]. This framework divides usability from user's perspective into three categories: user performance, satisfaction and acceptability. User performance refers to safe and effective use of a device[21]. Satisfaction refers to user-reported advantages, disadvantages, problems experienced when using the device and how much users liked or disliked the device[21]. Acceptability relates to whether the device will be used in the real world[21]. User performance was studied using three methods: (1) counting user errors during the performed tasks; (2) timing user tasks in seconds; (3) asking participants to think aloud while performing tasks. A think-aloud method is commonly used in usability research, especially when users are confronted for the first time with a device[21,25-27]. This method is used to make explicit what users thoughts and experiences are when performing a specific task. The think-aloud process was videotaped. To investigate aspects of satisfaction and acceptability, patients and PTs were assessed by also using the think-aloud method and by a semi-structured interview. An interview guide with closed questions about satisfaction and acceptability was employed to provide structure to the interviews (see Table 5 and 7). During the interview participants were asked to explain their answers. Satisfaction questions were based on the D-quest[28]. Acceptability questions were based on the acceptability concept described in De Bleser et al. [21,29] Semi-structured interviews were audio-recorded.

To evaluate overall usability, patients and PTs were assessed with the System Usability Scale (SUS)[22] shown in Appendix 2. This questionnaire consists of 10 statements that are scored on a 5-point Likert scale, ranging from "strongly agree" to "strongly disagree". The overall SUS score ranges from 0 to 100, where higher scores represent better usability. According to the study of Bangor et al. scores above 70 can be considered as at least passable[30]. It is a simple and reliable method, widely used in usability evaluation [30]. The English SUS shows a good internal consistency: between studies Cronbach's alpha ranged from 0.85 to 0.91[30]. Construct validity was tested by factor analysis and showed that the 10 statements on the scale address just one dimension "overall usability" [30].

Procedures

The biofeedback devices were integrated in two therapy sessions. So duos of patient and PT could experience these devices. Usability from patient's and PT's perspective were assessed separately to prevent bias. First the patient was instructed by the researcher and underwent the measurements. In a second session, the PT instructed the patient and underwent the measurements. The two sessions lasted respectively 60 and 90 minutes. In Appendix 3 the measurement procedures for both perspectives are described. The devices were used in two different equally occurring orders (SmartStep - OpenGo Science and the reversed order). The duos were allocated randomly to one of the two testing orders by letting the patient draw blindly one slip of paper without replacement.

Data analysis

Descriptive statistics were used to describe participant characteristics and to describe usability measured by (1) the SUS-questionnaire, (2) the interview's closed questions, and (3) the counted usability problems.

The video- and audiotaped data from the think-aloud session and the interview were transcribed verbatim. Thematic content analysis was used. Meaningful comments regarding usability were identified and grouped into thematic categories. This was done by one researcher and checked by a second researcher. For quotations for which no agreement was found, a third researcher was consulted till consensus was reached among researchers. Qualitative data analysis was conducted with NVivo for the Macintosh version 10.1.1 (QSR International, Doncaster, Australia).

Both quantitative and qualitative data were merged together for analysis and comparison.

Ethical issues

The study was approved by the Medical Ethics Research Committee of the University Medical Center Utrecht, the Netherlands (approved in april 2015, METC-protocol number 15-080/C). The study was conducted according to the principles of the Declaration of Helsinki *(*version: 64th WMA General Assembly, Brazil, October 2013).

RESULTS

Participant characteristics

Six patients (67% female) between 26 to 70 years and six PTs, working in different physical therapy settings with an average experience (in instructing PWB) of 10 years participated in this study. Characteristics of the study population are presented in table 2.

Table 2 Characteristics of the study population

Characteristics	
Patients (N=6)	
Male / Female: n/n [%/%]	2/4 [33/67]
Age [years]: mean [range]	52 [26-70]
Body weight [kg]: mean [SD]	75 [62-100]
Shoe size*: median [range]	40 [38-45]
*Educational level***	
Low: n [%]	3 [50]
Secondary: n [%]	3 [50]
High: n [%]	0
Type of surgery	
Elective surgery: n [%]	4 [67]
Trauma surgery: n [%]	2 [33]
Location of surgery	
Hip: n [%]	4 [67]
Knee: n [%]	2 [33]
Physical therapists (N=6)	
Male / Female: n/n [%/%]	5/1 [83/17]
Age [years]: mean [range]	35 [29-39]
Experience** [years]: mean [range]	10 [4-14]
Type of physical therapy setting	
Private practice: n [%]	4 [67]
Rehabilitation center: n [%]	0
RD of nursing home: n [%]	1 [17]
OD of hospital: n [%]	1 [17]

Note. RD = rehabilitation department, OD = orthopedic department

* Shoe size was measured in the units of Continental European System

** A person is defined as low educated if their highest education level is primary education or preparatory secondary vocational education, (vmbo), secondary vocational education, level 1 (mbo 1), general secondary education, basic level (avo onderbouw). A person is defined as secondary educated if their highest education level is higher secondary general education (havo), pre-university education (vwo), secondary vocational education level 2, 3, 4 (mbo 2, 3, 4). A person is defined as highly educated if their highest education level is higher vocational education (hbo), university bachelor (BA), university masters (MA) or doctor (dr.).

*** Experience expressed in years of instructing Partial weight bearing in patients with orthopedic conditions

Overall perceived usability

The results of the SUS for both biofeedback devices are shown in Table 3. SmartStep and were considered as at least passable by respectively three and five patients. For the PTs, respectively three and five participants considered SmartStep and OpenGo Science as at least passable.

Table 3 Perceived overall usability for both biofeedback devices measured on the SUS

	SUS Score	
Biofeedback device	**Median**	**Range**
Patients		
SmartStep	69	55 - 90
OpenGo Science	83	50 - 90
Physical therapists		
SmartStep	64	40 - 75
OpenGo Science	84	43 - 90

Note. SUS = System Usability Scale, maximum score = 100

Categories of usability

User performance

Table 4 shows the time registration of the cluster of tasks performed with the biofeedback devices, a description of user errors, and the number of errors that occurred during the tasks. The results show that there were not many errors made by the patients. However, three out of six patients could not attach SmartStep's control unit around the ankle independently due to hip surgery (hip flexion was not allowed past 90 degrees). When looking at the PTs we see that, for SmartStep, four out of six PTs experienced problems in inflating the air pockets of the insole. After a cue all participants managed to complete the task. For OpenGo Science, there were a lot of connectivity errors between the insoles and the PC or smartphone. Eventually, each participant succeeded in connecting the insoles with the PC and smartphone (some with cues or help from the researcher). All PTs managed to prepare SmartStep and OpenGo Science for use during PWB instructions within respectively 12 and 6 minutes.

Table 4 User performance for both the biofeedback devices

Cluster of tasks	User	User performance		
		Time* [Range]	Description of user errors	Errors n **[%]
SmartStep				
Putting on the device	Patients	107 [90-130]	Not able to put on the insole and the control unit around the ankle independently because of hip surgery (limited hip flexion was allowed)	3 [50]
	PTs	206 [112-255]	Air pockets of the insole are not inflated because PT forgot to close the ventil	4 [67]
			Not getting the tubes disconnected from the control unit	1 [17]
			Control unit was attached around the ankle upside down	1 [17]
Instructing PWB	PTs	560 [422-669]	Connection control unit with PC failed because PT forgot to activate the control unit.	1 [17]
			Investigator had to help PT to remember the steps that has to be performed to use SmartStep during PWB instructions.	1 [17]
			Recording PWB could not be started because PT did not know how to save the patient file	1 [17]
			Patient's foot was not lifted when PT inflated and calibrated the insole	1 [17]
Monitoring PWB	PTs	118 [74-153]	-	
OpenGo Science				
Putting on the device	Patients	112 [78-130]	Wrongly placing the battery in the insole	3 [50]
			Not able to put on the shoes with insoles independently because of hip injury (limited hip flexion was allowed)	1 [17]
	PTs	97 [79-126]	-	
Instructing PWB	PTs	200 [112-337]	Not getting the insole connected with the smartphone	1 [17]
			During instructing PWB, accidentally the upper threshold on the smartphone was adjusted.	1 [17]
			During instructing PWB, connection between insole and smartphone was lost without a clear reason.	
Monitoring PWB	PTs	407 [240-635]	Insoles did not connect with PC because PT forgot to select the right insole size.	6 [100]
			Insoles did not connect with PC because PT forgot to put batteries in both insoles	1 [17]
			Insole did not connect with PC because PT tried to connect one insole instead of two insoles (two insoles is required)	1 [17]
			When saving a patient file the software jammed	1[17]
			When trying to connect the insoles with the PC the software jammed, possible because PT clicked multiple times while the program was busy to process the previous command.	1[17]
			Connection failed because insole was still connected with another host (smartphone), and insole cannot be connected with multiple hosts	1[17]

Note. PTS = physical therapist, PWB = partial weight bearing, - = no errors
* Average time expressed in seconds
** Number of errors across all participants

Satisfaction

The results of the closed satisfaction questions are shown in Tables 5. In general, overall satisfaction with SmartStep, perceived by patients was at least 'quite satisfied' for four patients and the satisfaction with OpenGo Science was at least 'quite satisfied' for all patients. For PTs, overall satisfaction with SmartStep and OpenGo Science was perceived as at least 'quite statisfied' by respectively three and all participants.

Satisfaction extracted from the think-aloud data and the open questions, is illustrated by thematically categorized examples of quotes from patients and PTs shown in Appendix 2. The results show mixed views and perceptions from patients and PTs on satisfaction. For SmartStep, in general, patients were satisfied with the wearable comfort and the effectiveness. The views were mixed for satisfaction with the feedback, ease of use and intrusiveness. Some patients experienced SmartStep as an intrusive device because of the control unit around the ankle and the amount of beeps. Further they disliked the inability to attach the control unit by themselves. Concerning OpenGo Science, in general, patients were satisfied with the wearable comfort, ease of use and intrusiveness. More specific, patients liked the use of normal looking and feeling insoles and the use of a smartphone. The views were mixed for satisfaction with feedback and effectiveness. Some patients disliked the impossibility to simultaneously watch the exact amount of loading on the smartphone and walk with crutches. Some patients disliked the numerous beeps and that no WB data was stored on the smartphone. Satisfaction from a PT perspective differs for SmartStep and OpenGo Science. For SmartStep, in general, most PTs were satisfied with the effectiveness and they expressed mixed feelings concerning feedback, wearable comfort, ease of use and intrusiveness. Especially, comments on SmartStep's feedback varied at lot. Some PTs liked that it was possible to preset a lower and upper threshold, whereas others had some concerns about the auditory feedback. With respect to the ease of use, more than half of the PTs said that there were a lot of steps before they could actually use SmartStep. Regarding OpenGo Science, most PTs were satisfied with the wearable comfort, ease of use and intrusiveness. More specific, they liked that the insoles were without external modules attached to the body, and could be connected with a smartphone. PTs perceptions were mixed with respect to OpenGo Science's feedback and effectiveness. Most PTs liked that both audio and haptic feedback was possible. Some PTs disliked that a feedback signal was only provided when the upper threshold was exceeded and most PTs regret that feedback via smartphone was not available during recording WB via the PC.

Table 5 Patient and physical therapist satisfaction with the biofeedback devices measured on a five-point Likert scale

Question	BFD	Number [%] of participants				
		VS	QS	MLS	NVS	NSA
PATIENT SATISFACTION						
1. How satisfied are you with the feedback provided by the device?	SM	1 [17]	5 [83]	0	0	0
	OG	4 [67]	2 [33]	0	0	0
2. How satisfied are you with the (wearable) comfort of the device?	SM	0	5 [83]	0	1[17]	0
	OG	5 [83]	1 [17]	0	0	0
3. How satisfied are you with the ease of use of the device?	SM	1 [17]	2 [17]	2 [33]	1 [17]	0
	OG	3 [50]	3 [50]	0	0	0
4. How satisfied are you with the degree to which the device helps you to take the right amount of weight bearing (on the affected lower-limb)?	SM	4 [67]	2 [33]	0	0	0
	OG	2 [33]	4 [67]	0	0	0
5. How satisfied are you with the device, overall?	SM	1 [17]	3 [50]	1 [17]	1 [17]	0
	OG	4 [67]	2 [33]	0	0	0
PHYSICAL THERAPIST SATISFACTION						
1. How satisfied are you with the feedback provided by the device to your patients?	SM	0	4 [67]	1 [17]	1 [17]	0
	OG	3 [50]	3 [50]	0	0	0
2. How satisfied are you with the ease of use of the device?	SM	0	2 [33]	3 [50]	1 [17]	0
	OG	3 [50]	3 [50]	0	0	0
3. How satisfied are you with the degree to which the device helps you with instructing patients in partial weight bearing	SM	2 [33]	3 [50]	0	1 [17]	0
	OG	1[17]	5 [81]	0	0	0
4. How satisfied are you with the degree to which the device helps you with monitoring patient's weight bearing	SM	1 [17]	3 [50]	2 [33]	0	0
	OG	2 [33]	1 [17]	2 [33]	1 [17]	0
5. How satisfied are you with the adjusting options of the device	SM	1 [17]	1 [17]	4 [67]	0	0
	OG	2 [33]	3 [50]	1 [17]	0	0
6. How satisfied are you with the device, overall?	SM	0	3 [50]	2 [33]	1 [17]	0
	OG	4 [67]	2 [33]	0	0	0

Note. BFD = Biofeedback device, VS very satisfied, QS = quite satisfied, MLS = more or less satisfied, NVS = not very satisfied, NSA = not satisfied at all, SM = SmartStep, OG = OpenGo Scie

Acceptability

The results of the closed acceptability questions are shown in the Tables 7. In this section only the main acceptability results are presented. Regarding acceptability from the patient's perspective, the results show that five patients answered the question whether they would recommend SmartStep to other people in a similar situation (prescribed with PWB) with at least 'probably'. For OpenGo Science all patients answered this question with at least 'probably'. Looking at willingness to pay a contribution for the biofeedback device, patients responded more negatively concerning SmartStep in comparison with OpenGo Science. In the former case three patients answered with at least 'probably', whereas in the latter case five patients responded with at least 'probably'. Regarding acceptability from PT's perspective Table 7 showcased the following: Just one PT would recommend SmartStep at least 'very probably' to colleagues and all PTs would recommend OpenGo Science 'very probably' to colleagues. Furthermore three PTs wanted to purchase SmartStep at least 'probably' and all the PTs wanted to purchase OpenGo Science at least 'probably'. Reasons for non-acceptance of SmartStep emerging from the interview were: complexity of the device, intrusiveness of a control unit around the ankle, intrusiveness of the audio feedback and the availability of more usable devices.

Table 7

Patient and physical therapist acceptability of the biofeedback devices measured on a five-point Likert scale

Question	BFD	Number [%] of participants				
		D	VP	P	PN	VPN
PATIENT ACCEPTABILITY						
1. Would you recommend this device to other people in your situation?	SM	1 [17]	2 [33]	2 [33]	1 [17]	0
	OG	0	4 [67]	2 [33]	0	0
2. If you are in a similar situation in the future, do you intend to use this device again in supervised rehabilitation	SM	1 [17]	4 [67]	0	0	1 [17]
	OG	1 [17]	5 [83]	0	0	0
3. If you are in a similar situation in the future, do you intend to use this device also in the rehabilitation at home	SM	1 [17]	2 [33]	1 [17]	0	2 [33]
	OG	2 [33]	3 [50]	1 [17]	0	0
4. Would you be willing to pay a contribution for the use of this device	SM	1 [17]	1 [17]	1 [17]	1 [17]	2 [33]
	OG	3 [50]	1 [17]	1 [17]	1 [17]	0
5. What would be the amount in euros you are willing to contribute?		Number of patients		Median [range]		
	SM	6		56 [0 – 150]		
	OG	6		88 [10 – 150]		
PHYSICAL THERAPIST ACCEPTABILITY						
1. Would you recommend your colleagues to use the system	SM	0	1 [17]	4 [83]	1 [17]	0
	OG	0	6 [100]	0	0	0
2. Would you like to use this system in the future in the supervized rehabilitation	SM	0	2 [33]	2 [33]	2 [33]	0
	OG	0	5 [83]	1 [17]	0	0
3. Would you like to use this system in the future in the home rehabilitation	SM	0	0	1 [17]	4 [67]	1 [17]
	OG	0	3 [50]	2 [33]	1 [17]	0
4. Do you want to purchase this device in the future for use it your patients?	SM	0	1 [17]	2 [33]	3 [50]	0
	OG	0	4 [67]	2 [33]	0	0
5. What would be the amount in euros you are willing to pay?		Number of PTs		Median [Range]		
	SM	6		300 [250-1250]		
	OG	6		500 [300-2000]		

Note. BFD = Biofeedback device, D= Definitely, VP=Very Probably, P=Probably, PN=Probably Not, VPB= Very Probably Not, SM = SmartStep, OG = OpenGo Science, PTs = physical therapists

DISCUSSION

This study described the usability from PTs and patient's perspective of the biofeedback devices, SmartStep and OpenGo Science when used for feedback on PWB during supervised rehabilitation after lower-limb injury or surgery.

In general, the overall usability measured on the SUS suggested that SmartStep was not passable and OpenGo Science was at least passable from both patient's and PT's perspective. This classification is according to the study of Bangor et al[30]. They stated that products that are at least passable, score above 70 on the SUS.

Looking at user performance, all PTs managed to prepare SmartStep within 12 minutes and OpenGo Science within 6 minutes for use during PWB instructions. Six minutes seems reasonable instead of the 12 minutes since most PTs have 30 minutes per patient. Furthermore, SmartStep showed usability problems with inflating the insole's air pockets and OpenGo Science showed some connectivity issues. All problems were solved with cues or help from the researcher. It should be noted that time spent to prepare the devices and found usability problems, are expected to decrease when PTs are properly trained in using the devices.

Satisfaction data show that there are mixed views and perceptions from patients and PTs. For SmartStep, the quantitative data showed that patients were the least satisfied with "ease of use" and "overall satisfaction". This could be explained by the qualitative data, some patients experienced SmartStep as an intrusive device because of the control unit around the ankle and the amount of beeps. They also disliked the multiple operating steps and that they were not capable to attach the control unit by themselves due to hip surgery. This is in line with Fu 2014 who mentioned that SmartStep is besides its effectiveness, a complex and auditory intrusive device [5]. Concerning OpenGo Science, the quantitative data showed patients were quite satisfied with all examined satisfaction aspects. Patients scored especially high on satisfaction with wearable comfort. This is in line with the qualitative data showing that all patients expressed positive feelings regarding the insoles. PT satisfaction differed more than patient satisfaction. For SmartStep, quantitative data showed, that PTs were the least satisfied with ease of use, adjusting options and with overall satisfaction. This might be explained because the majority of the PTs indicated that there were a lot of steps before they actually could use SmartStep and besides disliked the intrusiveness of the device (e.g. amount of beeps heard and control unit around the ankle). Regarding OpenGo Science, the quantitative data showed that most PTs were the least satisfied with monitoring patient's WB. This might be explained by half of the PTs dislike that feedback via smartphone was not available during recording WB via the PC. Furthermore, the quantitative data showed that all PTs were at least quite satisfied with OpenGo Science. The qualitative data suggests that especially satisfaction with wearable comfort, ease of use and intrusiveness of OpenGo Science contributes to this good overall satisfaction.

In general, patient acceptability for SmartStep and OpenGo Science was good. When looking at PT acceptability, the data about intention to purchase in the future suggested poor acceptability for SmartStep and good acceptability for OpenGo Science. Thereby, it should be noted that PTs were not informed concerning the real price of SmartStep and OpenGo Science. This could have influenced the acceptability because high costs could undermine acceptance as being a critical determinant of technology acceptance[31].

The quantitative satisfaction data suggested that patients and PTs were mostly satisfied with the feedback provided by the biofeedback devices. However, during the think-aloud sessions and the interviews patients and PTs expressed different needs and expectations about feedback. For example, some participants preferred to receive only feedback when they exceeded an upper WB threshold, others preferred to receive also feedback when WB was within the target zone. Perhaps, the limited feedback options of the devices don't match with the different users' needs and expectations. Previous studies indicate that biofeedback devices have to be flexible in the way that they are able to adapt to users' feedback needs and learning phase[32-33]. Sigrist et al. suggested in their theoretical review that motor learning should start with real-time feedback during the motor task execution[32]. Subsequently, real-time feedback should be switched to a lower frequency or changed to postponed feedback to facilitate automation of the movement[32]. Furthermore, they suggested that self-controlled feedback offers a possibility for adapting feedback to the current phase of the learner. Therefore, it highly involves and motivates the learner and may also promote self-efficacy[32]. Effectiveness of real-time and post-response feedback in learning a PWB skills was investigated by Winstein et al[33]. They suggested that practice with real time feedback is beneficial for immediate performance but not for learning of PWB skills. For long-lasting learning the skill, post-response feedback is more effective[33].

A strength of the current study was that usability of the biofeedback devices was investigated with involvement of the intended users and tested in the specific context in which it should be used. Hereby, a clear view was provided what users experiences were when using the different devices. Another strength of this study is that mixing qualitative and quantitative evaluation methods ensures comprehensive data collection and avoids needless a priori assumptions [21,25,27].

However, some limitations should be mentioned. A limitation could be the short time participants worked with the devices. This may have affected the results. More time with the devices may result in a better user performance or effectiveness and a more positive user satisfaction. For instance, AL-Maskari's study showed that better user performance resulted in a greater user satisfaction[36]. It should also be noted that testing the two devices in one session may have influenced the results. Although participants were asked not to compare the devices much of the participants verbally used the other device as reference in the usability testing. This could have affected the usability negatively or positively depending of the superiority or inferiority of the reference device.

Another limitation could be the sample size. The question arises whether the sample size of 5 duos of patient-PT is still sufficient to discover 80% of a product's usability[24] when measuring at different settings. For instance, patient characteristics for patients treated in a rehabilitation department of a nursing home differ from patients treated in a private practice. Characteristics of patients in a rehabilitation department of a nursing home concern their high age, having multiple impairments, and their orthopedic problem is mostly status after hip surgery or fracture(s) [37,38]. Probably, these patients have different needs and encounter different usability problems than patients from a private practice. Therefore, retrospectively reviewed, recruiting 5 duos per setting would have been better to feel confident in discovering 80% of the usability problems.

Important implications for future use and development of SmartStep and OpenGo Science are: Integrate more feedback options in both devices. In particular for SmartStep: Make it less intrusive by changing the auditory feedback and the visibility of the control unit or use some other sensor technology, and make it easier to attach the control unit. For OpenGo Science, make the system less sensitive for user errors, offer the possibility to connect the insoles with multiple hosts simultaneously so WB measurements and feedback via smartphone can be combined, and consider to use a feedback unit that can be worn, for instance a smartwatch, so patients and PTs can see the actual amount of WB easier.

This study only provides information on the usability during supervised rehabilitation. However, there is a growing need from clinical practice and research for biofeedback devices that provide real time biofeedback and can collect data in daily life. Further research should investigate the usability of biofeedback devices that can be used at home for clinical practice and research purposes.

CONCLUSION

The results of the current study give insight in the usability of two biofeedback devices from patient's and physical therapist's perspective when used in supervised rehabilitation of patients after lower-limb trauma or surgery. The overall usability of SmartStep from both perspectives seemed not passable. OpenGo Science seemed at least passable from both perspectives. Further research should also investigate the usability of biofeedback devices when used at home for research and clinical practice purposes.

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Appendix 1

OpenGo Science (Moticon, Munich, Germany) consists of wireless sensor insoles for data measurement, analysis software, an ANT radio stick for wireless transmission, and a WB application for a smartphone. Each insole has thirteen pressure sensors, which cover 60% of the insole area, a triaxial acceleration sensor and a temperature sensor. The WB application for the smartphone is used to preset an upper threshold for WB and to provide real-time audio or haptic feedback. The analysis software enables to record and analyze WB data. In live mode, the sensor insoles transmit the data directly to the PC.

SmartStep (Andante medical devices Ltd, Beer Sheva, Israel) consists of flexible insoles containing two separate air pockets (one for the forefoot and one for the hind foot). Tubes are used to inflate/deflate each pocket and to connect the pockets to microprocessor control unit, that is worn around the ankle. The microprocessor control unit contains two pressure sensors and is also functioning as a feedback unit by producing an audio signal when a preset WB value is reached. A Software application on a PC is used to preset upper and lower WB thresholds and to record and analyze WB data. In the online mode, SmartStep communicates via wireless Bluetooth USB adapter with a computer.

System Usability Scale

	Strongly disagree 1	2	3	4	Strongly agree 5
1. I think that I would like to use this system frequently					
2. I found the system unnecessarily complex					
3. I thought the system was easy to use					
4. I think that I would need the support of a technical person to be able to use this system					
5. I found the various functions in this system were well integrated					
6. I thought there was too much inconsistency in this system					
7. I would imagine that most people would learn to use this system very quickly					
8. I found the system very cumbersome to use					
9. I felt very confident using the system					
10. I needed to learn a lot of things before I could get going with this system					

Appendix 3

Procedure patient's perspective:

First, measurement procedures were explained to the patient and patient characteristics were collected. Before the usability testing began, patients watched an instructional video to explain the think-aloud method based on an example. Patients were asked to use the biofeedback devices one after the other during a training session in which PWB with crutches was practiced. Patients were asked to complete a cluster of specific tasks with the devices. Before executing a particular cluster of tasks, patients watched an instructional video with an explanation of device functions regarding the task to perform. The clusters of tasks were: putting on the device and using the biofeedback device during PWB. Patients were asked to think aloud when carrying out the tasks. Patients were encouraged to think aloud by using standardized phrases. The session was videotaped. After completion the session with the other device started, following the same procedures. Subsequently, patients were asked to fill in the SUS questionnaire for both the biofeedback devices, followed by a semi-structured interview that took approximately 20 minutes.

Procedure PT's perspective:

In general, the procedures for the PT's perspective were the same as for the patient's perspective. It also started with an explanation about the measurement procedures, collection of participant characteristics and they also watched instructional videos. Only the PT's tasks were different from the patient's tasks: the PT had to program the devices. The clusters of tasks for PTs were: putting on the device, preparing and using the device for instructing PWB, and preparing and using the biofeedback device for monitoring PWB. Subsequently, PTs were also asked to fill in the SUS questionnaire for both biofeedback devices and were interviewed afterwards.

APPENDIX 4

Examples of patients' and physical therapists' comments on the usability of biofeedback devices thematically categorized.

Thema	Comment (type of participant and number)
Feedback	***SmartStep***
	"You are getting a clear signal when you are loading according to the target load, that is good". (patient 1) "I felt that the numerous feedback beeps were disturbing". (patient 3) "I like that the system warns you when you are putting too much or too little weight on the leg. And I'm satisfied with the feedback beeps, the beeps are clear". (patient 5) "Though feedback beeps are clear and work properly, I do think that haptic feedback is more convenient than a beep. Especially when you go outside". (patient 6) "The feedback provided by SmartStep is usable for patients". (PT 2) "Too much auditory information, beeps, not pleasant for me as a physical therapist and for the patient" (PT 3) "If someone is loading the leg properly, you hear with every step a beep. I think SmartStep beeps too much. Perhaps usability is better when SmartStep only beeps depending on whether the lower or upper threshold is exceeded." (PT 4) "More or less satisfied with the feedback. No beep, single and double beeps give a direction to the patient, respectively increasing, maintaining or decreasing weight bearing, that seems absolutely useful. But the difference between a single and a double beep is maybe difficult to hear for elderly and persons with hearing problems". (PT 5) "I'm satisfied with the feedback. It is an advantage that you can preset a lower and a upper weight bearing threshold. The feedback sounds are clearly heard. But you are hearing a lot of beeps and the sounds are very annoying. You even hear one beep when you are loading properly. I think this can be demotivating to patients". (PT 6)
	OpenGo Science
	"This device beeps too quickly, I deliberately try to put little weight on my leg but it still beeping frequently". (patient 5) "The feedback sounds are clear". (patient 6) "The system gives immediate feedback to the patient when she/he is loading too much. that is quite convenient. I would have liked when it also provided feedback if the patient loaded the leg to little". (PT 1) "It is nice you can choose between audio and haptic feedback, because I can imagine the hearing continuous beeps can irritate eventually". (PT 2) "I like the audio feedback, especially that it is only present when the patient puts to much load on the leg". (PT 4). "For patients it is clear that beeps are only heard when the upper weight-bearing threshold is exceeded. With this patient the beeps were a bit demoralizing because with almost every step the patient exceeded the threshold so the beeps were continuously present" (PT 5) "The ability to provide audio and haptic feedback as well is nice. It is a calm sound and you change the feedback to vibrations so only the patient is provided with the feedback". (PT 6) "Perhaps it is a pity when using the smartphone the patient does not know the exact amount of weightbearing or threshold exceedance, Nameley, the smartphone is in the patient's pocket and the sounds do not give an indication". (PT 6)

Wearable comfort	***SmartStep***
	“The insole and control unit around the ankle does not feel comfortable” (patient 2) “Insole and control unit around the ankle fits good”. (patient 3) “I don’t even feel that there is an insole inside the shoe”. (patient 5) “The insole feels fine in the shoe. you can barely feel it”. (patient 6) “I can imagine that I device around the ankle is cumbersome, it is also relatively large especially when the patient has thin legs”. (PT 3) “The insole is inserted fairly easy, but I have the impression the insole is not fitting properly in the shoe”. (PT 3) “The insole is not so comfortable for the patients, that is a disadvantage”. (PT 4)
	OpenGo Science
	“The insole feels good, you really do not notice that you have it in your shoe”. (patient 1) “The insole feels comfortable and the insole is wireless”. (patient 2) “Insoles feel comfortable”. (patient 3) “The insoles look and feel like normal shoe inlays”. (patient 4) “You hardly notice that you have an insole in your shoe”. (patient 6) “Pressure insole look like normal insole, seems comfortable for patients”. (PT 4)
Ease of use	***SmartStep***
	“There are a lot of actions you have to perform before you can use SmartStep”. (patient 1) “It is not easy to put on the control unit because I have a mobility limitation in my hip”. (patient 4) “It is a disadvantage that I need some help with putting the device on. Due to hip surgery I’m not able to flex the hip so far and cannot put it on by myself”. (patient 5) “Attaching SmartStep’s control unit around the ankle is an unhandy activity when you have had hip surgery. I’m not able to attach the control unit by myself”. (patient 6) “SmartStep is easier to use then I expected based on the way it looks”. (PT 1) “I think that putting on the device and presetting the device is too time consuming”. (PT1) “With the analysis software you can precisely see how much someone has loaded the leg, I like that.” (PT 2) “I can preset a lower and upper threshold, and I can look back in the analysis software precisely how someone loaded the leg regarding the thresholds, it's really nice system”. (PT 1) “Too many actions before you can actually use de feedback device, not easy to use”. (PT 3) “The analysis software is informative, it works fast, gives a clear reflection of the weight bearing and it is positive that weight bearing is expressed in kilograms”. (PT 3) “Usability of the analysis software is super, you can see how the patient is responding to the audio feedback, and you can watch the saved weight bearing data”. (PT 4) “Attaching the tubes with the control unit and placing the insole in the shoe is easy to do”. (PT 5) “First impression of the analysis software is that is looks practical”. (PT 5) “You have to undertake quite a few actions before you can start using the system, such as pumping up the insole, attaching the control unit, connecting the insole…….. These actions cost considerable time“. (PT 6(“I like the compliance diagram in the software. This summary can help you to stimulate patients to achieve better compliance rates” (PT6)

	OpenGo Science
	"It's an easy to use device, you connect the insole with your smartphone put the insole in your shoe, and you are ready to go". (patient 2) "I need a person to help me with the smartphone, I'm not used to it". (patient 3) "Easy to use system, it is wireless, has no tubes or control unit attached around body parts, just insoles and gives feedback via your smartphone, perfect". (patient 4) "The insole is easily placed in the shoe and there are no straps or other things around the ankle, that's nice". (patient 5) "The battery connection plate in the insole looks very vulnerable and fragile. And you have to have fine motor skills to put in the coin cell battery". (patient 5) "You have to have pockets to carry the smartphone. Thus, that's a problem because I don't have pockets right now. And you have to be handy with a smartphone and I myself am not. So that's an issue too, but if someone helps me then it will succeed". (patient 5) "It is difficult to preset the exact weight-bearing threshold in the smartphone app with the slider. Apart from using the slider it should be convenient if you could type in the threshold directly". (patient 6) "OpenGo Science is easy to use, easy to wear, simple, it works with a Smartphone and nowadays everyone can handle a smartphone. It seems like a good system". (patient 6) "The insole and smartphone are easy to use in daily practice" (PT 1) "Although I'm not familiar with the analysis software it is easy to use". (PT 1) "OpenGo Science seems easy to use, it can be connected with your smartphone and nowadays almost everyone has a smartphone". (PT 2) "Device is easy to use and real-time feedback via the smartphone is good". (PT 3) "I'm inclined to watch the amount of kilograms on the smartphone but it is difficult to instruct the patient in PWB and watch the kilograms on the screen simultaneously". (PT 3) "Analysis software on the PC seems extremely useful to analyze weight bearing, but I would have liked weigh bearing measurements expressed in kilograms instead of Newton". (PT 3) "Device is easy to use during partial weight-bearing instructions and it seems also usable for the rehabilitations at home". (PT 4) "OpenGo Science is quickly applied, easy to use and no long explanations are needed for patients. There are no wires attached, just put the insoles in the patient's shoe and ready to go". (PT 5) "Concerning the weight-bearing app, it is a challenge to set the slider for the upper threshold on the exact amount of kilograms. It is working very precisely" (PT 5) "I'm very satisfied, it is easy and quick to use. Just place the insole in the shoe, turn on the smartphone and there you are". (PT 6)

Effectiveness	***SmartStep***
	"SmartStep works, every time you put too much weight upon the leg you heard a beep". (patient 2) "the system helps you to load the leg according to the instructions". (patient 3) " I can hear the beeps clearly and it helps you to comply with weight-bearing instructions". (patient 4) "I'm satisfied with SmartsStep, it does what it has to do." (patient 5) "It is difficult to feel how much weight you put on your leg by yourself. I think SmartStep is very useful in dealing with this problem".(patient 6) "I think SmartStep is usable in daily practice, the control unit is not heavy and attached to the outside of the ankle and small enough that it does not interfere with the crutches". (PT 2) "I thinks it is a usable system that helps the patient to comply with partial weight-bearing instructions" (PT 4)
	OpenGo Science
	"Sometimes it is unclear whether you put enough weight on your leg because you are walking with crutches and smartphone is in your pocket". (patient 1) "This devices gives me a feeling of safety, I now know when I'm loading to much". (patient 3) "It is a pity the smartphone did not store data. I can't look back in the smartphone how much load I placed on my leg. When I walked with crutches and tried to comply with the weight-bearing instructions I could not manage to also look on the smartphone for the kilograms, I only heard the beeps" (patient 4) "I think the system is usable for supervised rehabilitation and maybe even for use at home". (PT 2) "When recording patient's weight bearing the biofeedback from the smartphone is not available, I would have preferred to also use the smartphone's feedback during the measurements". (PT 3) "It is impractical that feedback via the smartphone can not be provided to the patient when the insoles are collecting data or are connected with the PC. Without feedback we immediately see that this patients loads to much". (PT 4) "Although monitoring weight bearing via the PC looks pretty good, I do not understand why you would not combine data collection via the PC and feedback via smartphone. Now it is not possible. When you are collecting data it is not clear for the patient how much he or she loads the affected leg. Combining these functions seems more convenient". (PT 5)
Intrusiveness	***SmartStep***
	"With the tubes and control unit around the ankle it looks like you are on parole from prison". (patient 2) "you look like a crook with an electronic ankle bracelet. However, it is easy to use and helps you in your recovery." (patient 4) "Although you don't really feel the control unit around the ankle, the idea of having something around the ankle is strange. Especially, when you would go outside. I think I won't like that". (patient 6) "It is quite a device and it is really visible. When used in practice is not necessarily a thing, but used outside it is". (PT 6)
	OpenGo Science
	"The insoles looks like podiatric insoles, that is fine because I'm familiar with podiatric insoles". (patient 2) "You cannot see that you patient is wearing a device, top". (PT 6)

Note. PT = physical therapist