Formative Evaluation of an Electrically-Powered Orthopedic Exerciser: A Focus Group Interview Study

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Abstract

Background: Errors while using medical devices, owing to flaws in the user interface design and implementation, can be a risk for users. Accordingly, increasing emphasis is being placed on usability evaluations by actual users in the design and development stages of medical devices to minimize the risk factors that may cause usage errors. Moreover, a usability evaluation is a mandatory requirement for medical device regulations in countries that follow the IEC 60601-1 standard.

Objective: This study aimed to conduct a formative evaluation using focus group interviews (FGIs) and satisfaction surveys with healthcare professionals in the field of rehabilitation medicine to identify areas for improvement to enhance the safety and convenience of an electrically-powered orthopedic exerciser, a lower-extremity medical rehabilitation device, in the prototype stage.

Methods: Quantitative and qualitative data were collected through formative evaluation conducted using FGIs and satisfaction surveys with participants; participants consisted of rehabilitation doctors (n=5) and physical therapists (n=5) with experience in using similar medical devices.

Results: During the formative evaluation, the following three categories were derived to reduce exerciser usage errors: 1) product upgrades to ensure safety, 2) hardware and software improvements for convenience of use, and 3) improvement of the manual for better identifiability and understanding of the product and instructions.

Conclusions: Improvement areas to ensure safety, convenience of use, and clarity of instructions were identified through a formative evaluation based on FGIs and satisfaction surveys with healthcare professionals with experience in using similar medical devices. The factors derived from this formative evaluation are expected to contribute to the development of an improved electrically-powered orthopedic exerciser, and repeated formative and summative evaluations of the improved version will eventually lead to the development of a safe medical device.

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Original Paper

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Keywords: Formative Evaluation; Usability; Electrically-powered Orthopedic Exerciser; Focus Group Interview

Introduction

Background

Electrical medical equipment refers to electrical devices or products that come in contact with or are involved in delivering energy to patients. The equipment must comply with the IEC 60601 safety

standards [1]. In particular, IEC 60601-1-6 (usability) is a standard applied mandatorily to evaluate devices and prevent injuries to patients, for example through usage errors, for all medical devices in the developmental stage [2,3]. For usability (IEC 60601-1-6), a usability engineering process must be applied in compliance with the IEC 62366 [4,5].

According to the IEC 62366, the usability evaluation is divided into formative and summative evaluations, which should be performed throughout the development process [6,7]. A formative evaluation is performed starting at the initial design stage to explore the strengths, weaknesses, and unexpected errors in user interface (UI) design. A summative evaluation is performed on the completion of UI development to obtain objective evidence that the UI can be safely used [7]. In usability evaluations, different methodologies are applied depending on the purpose of the evaluation and the stage at which it is performed. Therefore, it is important to employ appropriate evaluation methodologies at each stage [8].

Formative evaluations are performed repeatedly from the device-design stage to manage the risks associated with convenience of use and usability. Moreover, since the device must be designed and modified after reflecting on the evaluation results, obtaining feedback from actual users is an appropriate evaluation method [9]. A focus group interview (FGI), a method used in formative evaluation, is employed to identify the perspectives and opinions of actual users regarding the use of a medical device, which can be used to evaluate the device prototype during the design stage [10,11].

Medical device designers design devices by focusing on their safety and usability in compliance with the IEC 62366 standards to minimize risks and improve the overall quality of the device design [12]. Compliance with these standards is also essential in terms of medical device regulations and market entry. Rebless Pro, an electrically-powered orthopedic exerciser currently under development, is a lower-extremity rehabilitation device designed to reconstruct lower-extremity muscles and restore lower-extremity joint motion, considering the limitations of continuous passive motion (CPM) devices and lower-extremity rehabilitation robots. Quality improvement through a formative evaluation is required for Rebless Pro, which is currently in the prototyping stage.

Electrically-powered orthopedic exerciser

An electrically powered orthopedic exerciser is an electrically-powered device used for the reconstruction of muscles and restoration of joint motion [13]. A CPM device, a prime example of an electrically-powered orthopedic exerciser, prevents stiffness and stimulates the regeneration of joint tissues by providing continuous passive exercise to patients with musculoskeletal disorders [14]. Electrically-powered orthopedic exercisers with various added functions, including a knee CPM device controlled and monitored using a mobile phone application, and an upper extremity rehabilitation CPM device with added active exercise functions are currently being developed [15,16]. The objective of this study was to conduct a formative evaluation of Rebless Pro, a CPM device currently under development in Korea. Rebless Pro is a medical device with a tablet-based controller that combines active and recorded passive exercise functions for knee and ankle rehabilitation.

Aim

This study aimed to identify areas of improvement to enhance the safety and convenience of Rebless Pro during its design phase. Therefore, the scope of this study was limited to the formative evaluation of the device design, which was conducted using FGIs and satisfaction surveys with healthcare professionals working in the field of rehabilitation medicine, who are actual prospective users, in compliance with the IEC 62366.

Methods

Overview

In this study, FGIs and questionnaire surveys were conducted to collect quantitative and qualitative data on an electrically-powered orthopedic exerciser. This study was approved by the institutional review board of the National Rehabilitation Center (NRC; NRC-2023-03-020).

Electrically-powered orthopedic exerciser prototype

The device evaluated was the Rebless Pro (H Robotics Inc., Incheon, Republic of Korea) (medical device class 2 in Korea), which is an electrically-powered orthopedic exerciser that provides the knee and ankle full range of motion (ROM) and active/passive exercise for the restoration of lower extremity motion in patients with neurological or musculoskeletal disorders (Figure 1). The Rebless Pro, a prototype in the device design stage, consists of a main unit and a tablet-based controller.

The intended users are physical therapists and rehabilitation medicine specialists, while the intended recipients are patients with neurological or musculoskeletal disorders, such as reduced joint ROM caused by lower-extremity joint and muscle paralysis or contracture, who require restoration of motor function and strengthening of the weakened muscles.

Figure 1. Electrically-powered orthopedic exerciser

Participants

Participants, consisting of five doctors and five physical therapists, were recruited through peer referral and a bulletin board announcement at the Clinical Rehabilitation Testbed of the NRC. All participants had experience using a CPM-based rehabilitation device and at least one year of clinical experience. The entire formative evaluation process, including the FGIs, was conducted separately for the doctor and physical therapist groups.

Formative evaluation procedure

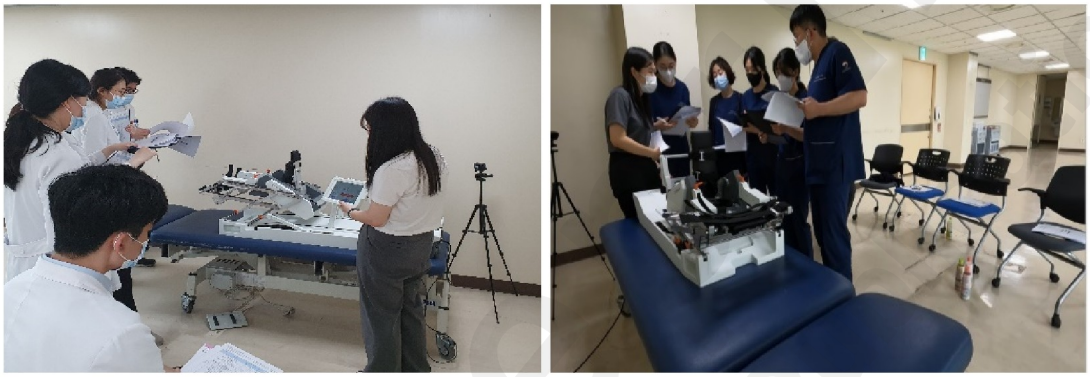
A formative evaluation was conducted at the Clinical Rehabilitation Testbed of the NRC. This consisted of one session per group for 90 minutes. The evaluator introduced the assessment to participants who may have been unfamiliar with usability evaluations and informed them about product evaluation, objectives, and methods. After confirming that the participants understood the details of the evaluation, consent for voluntary participation and video and audio recordings were obtained from each participant. The evaluator then provided the user manual for the Rebless Pro to the participants. After confirming that the participants had studied the information on the Rebless Pro, the evaluator investigated the participants' experiences in using similar devices and the names of these devices. The evaluator then conducted a demonstration of the task scenarios along with the FGIs and surveys of satisfaction with the Rebless Pro.

For the formative evaluation, the physical therapy environment in which Rebless Pro was used was

simulated, and the device was set up on a Bobath table (Figure 2). The luminous intensity, temperature, and relative humidity of the evaluation sites were measured before formative evaluation. The luminous intensity was 550±100 lux, temperature was 24±2 ℃, relative humidity was 50±10%, and noise was 50±5 dBA. The actual scenes of the evaluation are shown in Figure 3.

Figure 2. Test environment

Figure 3. Scenes of the evaluation



Focus group interviews

FGIs were used for qualitative data collection. The evaluator designed scenarios for eight tasks (37 sub-tasks) based on a user manual (Table 1). The evaluator provided product demonstrations according to product demonstration scenarios and conducted FGIs on the Rebless Pro. The participants observed the Rebless Pro and presented their opinions on risk factors and areas of UI improvement that were predictable or identified through the product demonstration.

Table 1. Use scenarios for rehabilitation medical staff

Use scenarios	Task description
Task 1. Turn on the power	
Sub-task 1	Connect the power cable plug to the main unit connector and press the “ON” sign on the power switch to turn on the device
Sub-task 2	Check the controller power and select “Start exercise now”
Sub-task 3	Select the exercise area, direction, method, and type from the controller home screen
Task 2. Length and position setting	
Sub-task 4	Unlock the main unit and check the lock menu on the controller display
Sub-task 5	Use a tape measure to measure calf and thigh lengths

Sub-task 6	Input the calf and thigh measurements into the controller
Sub-task 7	Load the affected area of the imaginary patient on the main unit
Sub-task 8	Lock the main unit and check the lock menu on the controller display
Sub-task 9	Set the initial position angle
Task 3. Active exercise	
Sub-task 10	Set the angle range for exercise (flexion-30, extension-110), exercise intensity (flexion-15, extension-15), and duration of exercise (20 min)
Sub-task 11	Start the exercise and pause after 3 min
Sub-task 12	Restart the exercise and finish after 3 min
Sub-task 13	Check the exercise record screen and return to the initial angle
Task 4. Passive exercise	
Sub-task 14	Select the item area (knee), direction (right), method (passive), and type (exercise) from the tablet home screen
Sub-task 15	Reset the length and position
Sub-task 16	Set the angle range for the exercise (flexion-30, extension-110), wait time (10 s), exercise speed (5), and duration of exercise (20 min)
Sub-task 17	Start the exercise and pause after 3 min
Sub-task 18	Restart the exercise and finish after 3 min
Sub-task 19	Check the exercise record screen and return to the initial angle
Task 5. Active range of motion (ROM) measurement	
Sub-task 20	Select the item area (ankle), direction (left), method (active), and type (ROM measurement) from the tablet home screen
Sub-task 21	Reset the length and position
Sub-task 22	Start measuring the active ROM
Sub-task 23	Finish measuring the active ROM
Sub-task 24	Check the active ROM measurement results on the screen and return to the home screen
Task 6. Passive ROM measurement	
Sub-task 25	Select the area (ankle), direction (left), method (passive), and type (ROM measurement) from the tablet home screen
Sub-task 26	Reset the length and position
Sub-task 27	Set the angle range for the exercise (flexion-30, extension-110, and speed–5)
Sub-task 28	Start measuring the passive ROM
Sub-task 29	Finish measuring the passive ROM
Sub-task 30	Check the passive ROM measurement results on the screen and return to the home screen
Task 7. Recorded exercise	
Sub-task 31	Select the item (direction–left and type–recorded exercise) from the tablet home screen
Sub-task 32	After starting the recording, instruct the patient to move the device
Sub-task 33	After completing the recording, edit the exercise portion to set it
Sub-task 34	Start the recorded exercise
Sub-task 35	Finish 3 min after starting the recorded exercise
Sub-task 36	Check the exercise result screen
Task 8. Turn off the power	
Sub-task 37	Turn the power off on the controller, then turn the power off on the main unit

Surveys

Before the FGIs were conducted, the participants' personal information, clinical experience, experience using similar medical devices, and their model names were investigated. After the FGIs, satisfaction surveys of the Rebless Pro were conducted to collect the quantitative data. The satisfaction survey consisted of 51 items on the ease of using the UI and three items on information comprehensibility and identifiability. The survey items were rated on a 5-point Likert scale ranging from 1 (very difficult) to 5 (very easy).

Results

Participant characteristics

In the doctor group, clinical experience ranged from 1 year and 3 months to 2 years and 3 months. Experience in using similar medical devices ranged from 3 months to >1 year. In the physical therapist group, the clinical experience ranged from 7 to 28 years, and experience using similar medical devices was >1 year for all members (Table 2). All members of both groups had experience using electrically-powered orthopedic exercisers, such as MOTOmed and CPM, but all were using the Rebless Pro for the first time.

Table 2. General participant characteristics

No.	Sex	Age	Experience	Occupation	Experience using similar medical devices	Name of similar medical device
1	Female	29	2 yr 3 mo	Doctor	1 yr, > once a day	MOTOmed
2	Female	27	2 yr 3 mo	Doctor	1 mo, once a day	CPM
3	Male	26	2 yr 3 mo	Doctor	6 mo, once a day	MOTOmed
4	Female	28	1 yr 3 mo	Doctor	4 mo, once a day	MOTOmed
5	Male	25	1 yr 3 mo	Doctor	3 mo, twice a day	MOTOmed
6	Female	51	28 yr 10 mo	Physical therapist	1 yr, 3 times a day	MOTOmed
7	Male	40	14 yr	Physical therapist	1 yr, once a day	MOTOmed
8	Female	36	9 yr 10 mo	Physical therapist	1 yr, once a day	MOTOmed
9	Female	32	9 yr 6 mo	Physical therapist	1 yr, once a day	MOTOmed
10	Female	29	7 yr 3 mo	Physical therapist	1 yr, 3 times a day	MOTOmed, CPM

No.: Number

Focus group interviews

From the FGIs, three key factors and seven sub-factors were derived as possible improvements to the Rebless Pro. The three key factors were as follows: 1) product upgrades to ensure safety, 2) hardware

and software improvements for convenience of use, and 3) improvement of the manual for better identifiability and understanding of the information (Table 3).

Table 3. Subjects of the focus group interview results

Subject	Suggested Solution
(1) Product upgrade to ensure safety	Improve the exterior Fasten the device Adjust the motor for exercise speed and resistance
(2) Improvements for convenience of use	Improve the hardware UI Improve the software UI
(3) Improvement of the manual for better identifiability and understanding of the information	Input details about the intended patient group and medical indications Input details about device use and operation

UI: User Interface

Product upgrade to ensure safety

The participants prioritized patient safety and suggested the following potential risks and improvements to the Rebless Pro:

The exterior requires improvement as the device has a complex structure and accidents may be caused through items getting caught on its exterior.
The device should be fastened to the table, but force applied by the therapist should allow it to slide or move. The device should be secured using an anti-slip pad.
Patients may complain of pain because the speed of the basic exercise may be too fast. The initial position angle should be adjusted while the device is being fitted.
Movement speed needs to be more finely adjusted.
The operating exercise speed should be shown on the controller display.
The basic resistance intensity of the device may be too high for the patient to counteract.
There is a high likelihood of errors occurring during ROM measurement, and measurement range errors may occur.

Hardware and software improvements for convenience of use

For user convenience and ease of use, the following hardware and software improvements to the Rebless Pro were suggested:

The power (ON, OFF) button should be repositioned.
The emergency stop button should be repositioned, and separate buttons should be provided for the patient and therapist.
The material of the fastening strap where the device is secured to the patient should be changed.
Noise from the motor may interfere with the treatment of other patients. The motor noise should be adjusted.
As this device is provided to the patient by medical staff, the wording of the instructions should be improved to make it easier for patients to understand (instead of using medical terminology).
The information about intensity and stiffness sensitivity is provided only in the manual. It is cumbersome to have to refer to the manual while using the device. A pop-up window with a summary of each function should be added to the controller display.
Control icons, such as up and down arrows, should be presented more clearly on the display.

Improvement of the manual for better identifiability and understanding of the information

Participants suggested the following improvements to the Rebless Pro manual to allow better identifiability and understanding of information by users:

Detailed information about the contraindications for intended patient groups, stages of life and age groups, specific criteria for applicable patients, and the patient's position when fitting the device should be provided.
With respect to use of the device, calf/thigh measurement criteria, exercise intensity criteria based on Manual Muscle Test or Modified Ashworth Scale standards, and clear exercise speed criteria should be provided.

Satisfaction

The satisfaction survey findings on the ease of use of the UI showed that out of 51 items, 7 and 17 items scored ≤ 4 points in the doctor and physical therapist groups, respectively (Table 4).
The satisfaction survey findings on the identification and understanding of information showed that out of three items, those that scored ≤ 4 points were none in the doctor group and two in the physical therapist group (Table 5).

Table 4. Survey results on ease of use of the user interface

No.	Survey item	Responses from rehabilitation doctors		Responses from physical therapists	
		M	SD	M	SD
1	Check the user manual	4.6	0.55	3.8	0.45
2	Check the exterior of the product	4.6	0.55	3.6	1.14
3	Connect the power cable plug to the main unit connector and press the "ON" sign on the power switch to turn on the device	4.6	0.55	4.6	0.55
4	Check the controller power and select "Start exercise now"	4.6	0.55	4.4	0.89
5	Select the exercise area, direction, method, and type from the controller home screen	4.8	0.45	4.4	0.89
6	Unlock the main unit and check the lock menu on the controller display	4	1.00	3.8	1.30
7	Use a tape measure to measure calf and thigh lengths	4	0.71	3.2	1.30
8	Input the calf and thigh measurements into the controller	4.6	0.55	3.4	1.34
9	Load the affected area of the imaginary patient on the main unit	4.2	0.84	3.8	1.30
10	Set the initial position angle	4	0.71	3.4	0.89
11	For active exercise, select "Start the	4.6	0.55	4.2	0.84

	test”				
12	For active exercise, select “Start exercise on completion”	4.6	0.55	4.2	0.84
13	For active exercise, set the angle range for active exercise	4.4	0.89	4.0	1.22
14	For active exercise, set the pace for a single session	4.2	0.84	4.2	0.84
15	For active exercise, set the exercise intensity	4	0.71	4.4	0.55
16	For active exercise, set the duration of exercise	4.6	0.55	4.4	0.55
17	For active exercise, select “Start exercise”	4.8	0.45	4.4	0.55
18	For active exercise, select “Pause”	4.6	0.55	4.4	0.55
19	For active exercise, select “Finish exercise”	4.8	0.45	4.4	0.55
20	For active exercise, check the exercise result screen	4.8	0.45	4.4	0.89
21	For passive exercise, select the exercise area, direction, method, and type from the controller home screen	4.6	0.55	4.4	0.89
22	For passive exercise, set the length and position	4.6	0.55	3.8	1.30
23	For passive exercise, set the angle range for exercise	4.4	0.89	4.2	0.84
24	For passive exercise, set the wait time	4.8	0.45	4.2	0.84
25	For passive exercise, set the exercise speed	4.6	0.55	4.2	0.84
26	For passive exercise, set the duration of exercise	4.6	0.55	4.2	0.84
27	For passive exercise, select “Start exercise”	5	0.00	4.2	0.84
28	For passive exercise, select “Pause”	4.8	0.45	4.2	0.84
29	For passive exercise, select “Restart exercise”	4.8	0.45	4.2	0.84
30	For passive exercise, select “Finish exercise”	5	0.00	4.2	0.84
31	For passive exercise, check the exercise result screen	4.8	0.45	4.4	0.89
32	For active range of motion (ROM) measurement, select the exercise area, direction, method, and type from the controller home screen	4.2	0.45	4.4	0.89
33	For active ROM measurement, set the length and position	4	0.71	3.4	1.52
34	Start active ROM measurement	3.6	1.14	4.0	1.00
35	Finish active ROM measurement	3.8	0.84	4.0	1.00
36	For active ROM measurement, check the test result screen	4.4	0.55	4.4	0.89

37	For passive ROM measurement, select the exercise area, direction, method, and type from the controller home screen	4.4	0.55	4.4	0.89
38	For passive ROM measurement, set the length and position	4.4	0.55	3.4	1.52
39	For passive ROM measurement, set the angle range for exercise	4.4	0.55	3.8	1.30
40	Start passive ROM measurement	4.4	0.55	4.0	1.00
41	Finish passive ROM measurement	4.4	0.55	4.0	1.00
42	For passive ROM measurement, check the test result screen	4.4	0.55	4.4	0.89
43	For recorded exercise, select the exercise direction and type from the controller home screen	4.4	0.55	4.2	0.84
44	For recorded exercise, set the length and position	4.4	0.55	4.2	0.84
45	For recorded exercise, select “Start recording”	4.4	0.55	4.2	0.84
46	For recorded exercise, select “Finish recording”	4.4	0.55	4.2	0.84
47	For recorded exercise, edit the recorded exercise portion	4.4	0.55	3.8	1.30
48	For recorded exercise, set the duration of exercise	4.4	0.55	4.2	0.84
49	For recorded exercise, start and finish the exercise	4.4	0.55	4.2	0.84
50	Stop operating the main unit and controller	4.4	0.55	4.4	0.55
51	Press the “OFF” sign on the power switch to turn off the device	4.6	0.55	4.6	0.55

M: Mean, SD: Standard Deviation, No.: Number

Table 5. Survey results on identifiability and understanding of information

No.	Survey item	Responses from rehabilitation doctors		Responses from physical therapists	
		M	SD	M	SD
1	Were you able to clearly see the exterior markings on the product (e.g., label, button signs, etc.)?	4.4	0.55	3.0	2.00
2	When using the controller, were you able to check the operational status of the screen?	4.6	0.55	4.4	0.89
3	Was the user manual helpful?	4.4	0.55	3.8	0.45

M: Mean, SD: Standard Deviation, No., Number

Discussion

Principal Results

A formative evaluation is a usability evaluation performed to improve the design of a medical device under development. To gain qualitative and quantitative insights into the course of the development of the Rebless Pro, an electrically-powered orthopedic exerciser, a formative evaluation was conducted. This was achieved using FGIs and satisfaction surveys with rehabilitation medicine professionals who had experience using other electrically-powered orthopedic exercisers.

FGIs enable individuals to freely express their own experiences and engage in discussions using not only their own knowledge but that of others, thereby providing diverse perspectives and detailed information on a specific topic [10]. Moreover, FGIs are used to identify and analyze expert responses as experts share information and experience in using a particular product or service. Therefore, FGI findings may be used to develop or improve products and services [17].

Motorized medical devices can cause unintended movements by the patient or user, potentially leading to discomfort or injury [18]. Because the operator of the Rebless Pro is a medical professional and the user is a patient, the participants in this study prioritized patient safety and presented opinions on improvement of the exterior structure of the device and upgrades to the device fastening, exercise speed, and resistance strength. These points suggest that patient and operator safety is crucial when designing a rehabilitation device and that the product should be upgraded to ensure safety.

A previous study mentioned that devices using robotic technology should be equipped with at least one emergency stop button that is easily accessible to the user [19], and another study reported that an emergency stop system should be installed to prioritize user and patient safety in the event of device malfunction or user error [20]. On the basis of their own experience using similar medical devices and the product demonstration, the participants in our study indicated the need for the emergency button to be redesigned and repositioned so that it would be more visible and easily accessible to medical staff or patients in the event of an emergency. Consequently, we determined that the emergency stop system of a medical device has a direct impact on the ability to prevent device malfunction and that it plays an important role in ensuring device safety and efficacy.

The Rebless Pro is operated mostly by medical staff; however, the patient is the primary wearer of the device. Therefore, the participants suggested that the wording of the manual should consist of terms that can be easily understood by the patient, rather than medical terminology. This is consistent with findings of a previous study that reported that the ability to operate the device quickly and accurately is important; however, it is also important that the UI be written in simple terms to enable the user to use the device intuitively and consistently [21]; these findings suggest that the UI design should consider the use by novices.

From an ergonomic perspective, the medical device design should consider not only convenient usability but also possible injuries due to repeated strain and physical defects of individuals [22]. The key to the CPM is its ability to deliver the same movement as the actual human body through human lower-extremity ROM and accurate alignment [23]. As in previous studies, the need to mark the joint ROM and axes on the surface of the medical device was suggested in this study as an area of improvement for electrically-powered orthopedic exercisers, considering the individual physical factors of each patient.

The user manual of a medical device is important not only for usability but also for identifying and understanding information [24]. The user manual explains device operation, maintenance, and troubleshooting, which can potentially affect patient safety [25]. The participants in this study also requested specific information regarding specific operating standards and clear information about the intended patient groups, including contraindications and applicable age. Based on previous and the present studies, the construction of a high-quality user manual is essential for the effective use of the

device.
It is believed that the satisfaction survey results showed an average score of ≥ 4 points for most items regarding ease of use of the UI because data were collected on the basis of product demonstration. The findings also showed that satisfaction with information identification and degree of understanding were lower in the physical therapist group than in the doctor group. In rehabilitation medicine, doctors and physical therapists form a collaborative, multidisciplinary team; however, rehabilitation doctors are responsible for establishing the overall treatment plan, whereas physical therapists specialize in assessing motor problems and providing rehabilitation training [26–28]. The satisfaction scores may have been lower for physical therapists than for rehabilitation doctors because physical therapists assigned scores for identification and understanding of the Rebless Pro on the basis of their own experience. These findings confirm that when developing a medical device, the intended users should be clearly defined so that they can satisfy the information identifiability and understanding requirements.
Because continuous formative evaluations of improved medical devices are important to ensure their efficacy [29], repeated formative evaluations are required for the commercialization of our high-quality electrically-powered orthopedic exerciser. Improving the UI to reduce errors that may cause serious harm is recommended to enhance device efficacy and safety.

Limitations

Owing to the nature of rehabilitation devices, both the medical staff who use the device to provide rehabilitation therapy and the patients who receive the therapy are considered users. One limitation of this study is that it did not include patients who were potential users of the Rebless Pro. Nonetheless, the participants in this study, consisting of healthcare professionals in the field of rehabilitation medicine, also presented their opinions from the patient's perspective.

Conclusions

If improvements are made considering the safety of the electrically-powered orthopedic exerciser, information identifiability and understanding, and ease of use according to the risk factors and identified areas of improvement of the UI, the device can be developed to meet the needs of its users. Repeated formative evaluations that include diverse user groups selected on the basis of the characteristics of the rehabilitation device and the execution of necessary improvements should lead to a summative evaluation of the final product and meet the device development regulations. Such efforts are expected to lead to the commercialization of an electrically-powered orthopedic exerciser that considers safety and convenience of use by actual users.

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Conflicts of Interest

None declared.

Abbreviations

CPM: continuous passive motion
NRC: National Rehabilitation Center
ROM: range of motion
UI: user interface

FGI: focus group interview

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