

Usability Testing of Medical Device Based on Virtual Reality-Based Upper Limb Rehabilitation Software through Cognitive Walkthrough

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Usability Testing of Medical Device Based on Virtual Reality-Based Upper Limb Rehabilitation Software through Cognitive Walkthrough

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Abstract

Background: Intuitively recognizing risk factors caused by using software as a medical device is difficult because the interaction between the user and medical devices occurs in a virtual space. Therefore, user safety must be secured through usability enhancement using usability tests.

Objective: A formative evaluation was conducted to derive improvements in the usability and safety of virtual reality-based upper-limb rehabilitation software as a medical device in its prototype stage.

Methods: A formative evaluation was conducted using a cognitive walkthrough and survey. Occupational therapists (n = 6) who had some experience using medical devices similar to the upper limb rehabilitation software participated in the test, and quantitative and qualitative data were collected.

Results: Through formative evaluation, the following possible improvements in usability and safety were identified for the upper-limb rehabilitation software: 1) graphical user interface improvements for convenience of use, 2) natural user interface improvements, and 3) improvements in the user manual for better identification and understanding of product information and instructions.

Conclusions: The factors derived from this usability test will lead to improved upper-limb rehabilitation software, and better usability and safety of the product will be guaranteed by conducting formative and summative evaluations

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Original Manuscript

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Keywords: Usability; Formative Evaluation; Cognitive Walkthrough; Virtual Reality-Based Upper Limb Rehabilitation Software

Introduction

Background

Use errors that occur while using medical devices may often stem from poorly designed interfaces, as opposed to those that occur solely because of user mistakes [1]. Although not all user errors are attributable to design flaws, design-related issues can be mitigated by evaluating the usability of a device prior to commercialization [2]. Usability engineering processes are employed to identify predictable user errors before they manifest in clinical settings and cause harm [3,4].

In South Korea, the Good Manufacturing Practice regulations stipulate that usability engineering processes must confirm compliance with usability requirements before commercialization of medical devices, and this process must be conducted in adherence to the international usability standard [3,5]. Furthermore, given the close connection between medical devices and user safety, usability tests must be conducted before clinical use to ensure safety [6].

Specifically, usability testing based on risk management can be performed to ensure user safety and minimize errors in software use as a medical device [7]. Usability testing aids in identifying use errors and enhancing usability [8–10], and a user-centered approach that involves actual users is strongly recommended [11].

Usability tests can be categorized into formative and summative evaluations depending on the timing and purpose of the test [12]. Formative evaluations are conducted during product development to identify usability issues and improve design, whereas summative evaluations are performed during the final stage of product development, primarily using objective data analysis to validate the results [13]. Formative evaluations are often conducted using various methodologies such as cognitive walkthrough, task analysis, usability tests, and heuristic tests [14].

A cognitive walkthrough is an ideal method for evaluating software usability. It focuses on assessing the system from the perspective of a new user and is used to detect potential issues such as inconsistent interface actions or insufficient accuracy [15]. A cognitive walkthrough provides developers with insight into users' cognitive processes, enabling the creation of user-friendly interfaces. In addition, developers can make device designs more efficient, satisfying, and user-friendly through cognitive walkthroughs.

Virtual Reality-Based Upper Limb Rehabilitation Software

Motivating stroke patients to engage actively in rehabilitation treatments is crucial, and one of the motivational methods in rehabilitation treatment-virtual reality (VR) has emerged as an innovative tool for encouraging patients to participate in enjoyable and autonomous exercises [16]. Additionally, immersive VR environments promote better functional recovery, as they allow patients to undergo rehabilitation in a virtual environment that simulates the real world [17]. To meet the diverse needs and therapeutic goals of patients, specialized VR programs should be designed to offer individualized feedback and difficulty levels based on each patient's condition [18,19]. Furthermore, evaluating and improving the usability of VR-based rehabilitation tools is essential for providing user-friendly interfaces, aligning with patients' abilities and preferences, and ultimately enhancing their experience and acceptance of VR-based interventions [20].

Aim

The aim of this study was to conduct a formative evaluation focused on identifying potential improvements to enhance the safety and usability of the Rehabware Standard, which is an upper limb rehabilitation software medical device that is currently in its prototype stage. The scope of this study was limited to the formal evaluation of medical devices. IEC 62366 [4] suggests cognitive walkthrough as a formative evaluation method. We also used surveys involving occupational therapists who were the intended users of the device.

Methods

Overview

In this study, we used cognitive walkthrough and surveys to collect both quantitative and qualitative data from occupational therapists using upper limb rehabilitation software as a medical device. The study was approved by the Institutional Review Board of the Korea National Rehabilitation Center (NRC-2023-06-041).

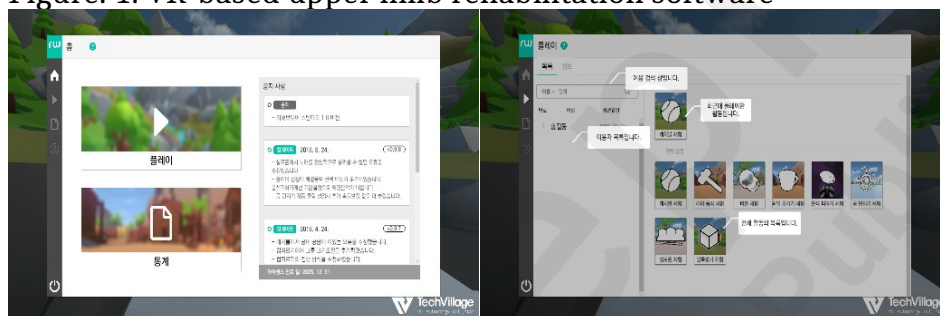
VR-Based Upper Limb Rehabilitation Software as a Medical Device

The Rehabware Standard by TechVillage Co., Ltd. is a VR-based upper-limb rehabilitation software used as a medical device for adults aged ≥ 20 years who are in the subacute phase of stroke recovery. It aims to improve upper limb functions, including those of the shoulder, elbow, forearm, wrist, and hand, through voluntary movements performed in a VR environment. The software operates by having users wear a head-mounted display (HMD)(Fig 1), effectively emerging them in a VR environment where they perform rehabilitation exercises.

This system offers eight distinct activities: 1. catching a ball, 2. hammering nails, 3. popping bubbles, 4. moving fruits, 5. avoiding meteors, 6. throwing balls, 7. for xylophone, and 8. stacking blocks. The intended users, namely occupational therapists, manipulate the software in clinical settings to help patients improve their upper-limb functionality.

The minimum computer specifications required to run the software were Windows 7 SP, Windows 8.1 or higher, and Windows 10, with a display resolution of $1,280 \times 720$ or higher. The recommended specifications are Microsoft Windows 10 Professional with a display resolution of $1,280 \times 720$. The hardware used was the VIVE Pro Full-Kit (including VIBE base stations and HMD).

Figure. 1. VR-based upper limb rehabilitation software



Participants

Six occupational therapists were recruited for the study. The inclusion criteria were an occupational therapist's license and prior experience with rehabilitation medical devices such as computerized cognitive rehabilitation programs. In addition, to demonstrate the Rehabware standard, mock patients were recruited because real patients must not use a medical device before they are certified by the MFDS. Three individuals without any prior experience using the Rehabware standard were selected as the mock patients. Before the test, all participants were informed of the aims, methods, and procedures of the usability test, and they filled out a consent form for participation.

Formative Evaluation Procedure

A formative evaluation was conducted in the Clinical Rehabilitation Testbed of the Korea National Rehabilitation Center. The total test duration per participant was about 1 h and 30 min. As the participants were unfamiliar with usability testing, the evaluators introduced the usability test process and explained its purpose and methods as well as product information.

The evaluators then asked them if they had prior experience with devices similar to those being tested. Next, the evaluators guided the participants on the use of the product by following a script that included a set of activities. The participants operated the software as a medical

device according to the instructions of the evaluators, and observers recorded their behavior and responses throughout the process. Following the test, the participants' satisfaction with the Rehabware Standard was assessed.

The formative evaluation was conducted in a simulated clinical setting designed to resemble the environment in which the Rehabware Standard is intended to be used (Fig. 2). The lighting, temperature, and humidity in the test room were measured prior to assessment. Lighting was maintained at 550 ± 100 lx, temperature of 24 ± 2 °C, relative humidity of $60 \pm 10\%$, and noise level of 50 ± 5 dBA.

Figure. 2. Test environment and scene



Cognitive Walkthrough

Cognitive walkthrough is a method used to assess how well users can navigate an interface without prior training or information on a medical device [21]. In this study, a cognitive walkthrough was conducted by six occupational therapists to evaluate the ease of navigation. The cognitive walkthrough scenario was structured as shown in Table 1.

Table 1. Use scenarios for cognitive walkthrough

No.	Task	Sub-task
1	Reviewing the user manual	1 Reviewing the user manual.
2	Checking components and power supply	2 Checking the HMD, controller, disposable face mask, PC set, and software in the PC. 3 Checking the product's power supply.
3	Launching the program	4 Launching the "RehabwareVR" icon and entering the password.
4	Creating patient information	5 Entering patient information. (Name (Gildong Hong), sex (male), date of birth (1980.09.07), characteristic (stroke_Rt.hemi), record (dominant hand_Rt)) 6 Providing instructions on patient data consent.
5	Donning the equipment	7 Instructing the patient to wear the disposable face mask, HMD, and controller.
6	Running the upper rehabilitation content	8 Selecting one of the upper limb rehabilitation exercises, explaining it to the patient, and running.
7	Running the content	9 Selecting the patient (Gildong Hong) and

		<p>configuring the catch ball activity. (Field of view: 2.0, distance: 12.0, angle: 45.0, cycle: 5.0, repetitions: 10) 10 Saving these settings as User Setting 3, then starting the catch ball activity. 11 After completing at least five repetitions, stopping the activity, modifying the environment settings, and rerunning the activity. (Position: top left, field of view: 2.0, distance: 10.0, angle: 50.0, cycle: 5.0, repetitions: 3) 12 Switching to the fruit transfer activity and running it. (Hand used to grip the cup: right hand, field of view: 2.0, time: 25.0, number of items: 5) 13 After completing the fruit transfer activity, proceeding with the bubble activity. (Field of view: 0.5, width: 2.0, height: 5.0, size: 5.0, number of items: 10.0, time: 45, Auto-click enabled.</p>
8	Updating patient information	14 Updating the patient information. (Name: Guklib Kim→Jaehwal Kim, condition: CVA→SCI)
9	Running contents after updating patient information	15 Selecting the patient (Jaehwal Kim) and starting the hammering activity. (Field of view: 0.5, number of nails: 5.0, repetitions: 6.0, time: 20.0) ⑩ After completing the hammering activity, switching to the meteor avoidance activity. (Field of view: 2.0, size: 1.0, speed: 6.0, cycle: 5.0, sensitivity: 1.0, number of items: 10.0) ⑪ Ending the session.
10	Doffing the product	⑫ Removing the HMD, controllers, and disposable face mask from the patient.
11	Reviewing statistical analysis results	⑬ Reviewing the data graph of the patient. ⑭ Reviewing the fruit transfer activity data for patient. ☐ Deleting the hammering activity data for patient.
12	Ending the program	☐ Ending the program.

Surveys

Prior to the formative evaluation, participants' personal information, clinical experience, experience with similar medical devices, and model names were recorded. Following the cognitive walkthrough, the participants filled out a survey form asking about their experiences with the Rehabware standard.

Results

Participant Characteristics

The clinical experience of the occupational therapists ranged from six months to six years, with an average of three years and nine months. In addition, they had prior experience using similar medical devices, such as Comcog and RAPAEEL (computerized cognitive rehabilitation programs), with their experience ranging from a minimum of two months to a maximum of five years (Table 2).

Table 2. General characteristics of participants

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No.	Sex	Age	Experience	Occupation	Experience using similar medical devices	Name of similar medical device
1	Female	28	Six years	Occupational therapist	Six months, twice a week	Comcog, RAPAEEL (Smart Glove, Smart pegboard)
2	Female	24	Six months	Occupational therapist	Two months, twice a week	RAPAEEL
3	Female	27	Five years	Occupational therapist	Five years, twice a week	Comcog, RAPAEEL, RehaCom
4	Female	25	Three years	Occupational therapist	Three years, once a week	RAPAEEL, Xbox
5	Male	27	Three years nine months	Occupational therapist	Two years, once a day	Comcog
6	Female	29	Five years eight months	Occupational therapist	One year, three times a month	Comcog, RehaCom

No.: Number

Cognitive Walkthrough Results

Twelve usability errors were identified using cognitive walkthrough. In Task 4, "Creating Patient Information," four errors were identified. In Sub-task 4.1, "Locating the Add Patient Icon," participants were confused as they could not find the icon leading to the screen for adding patient information. In Sub-task 4.2, "Registering Patient Information," participants hesitated when they had to enter such details as the diagnosis and dominant hand manually because moving to the next input field required a click on the mouse, as the Tab key shortcut did not work. In Sub-task 4.3, "Guiding Patients' Consent for Using Personal Information," participants skipped the data consent step and almost automatically pressed the confirm button without explaining the process of consent for using personal information to the mock patient.

In Task 7, “Performing the Activity,” five usability issues were identified. In Sub-task 7.1, “Selecting Activity,” participants attempted to select activities without first selecting the patient, which triggered a popup message indicating “No patient selected.” In Sub-task 7.2, “Configuring the Activity Settings,” participants committed multiple errors, including failure to estimate the virtual distance between the hand and the object within the virtual environment, and identifying which hand was being used for interaction. Furthermore, although the users clicked on the “User Settings” button, they failed to save the configurations. There were also challenges in adjusting precise decimal values using mouse clicks and dragging, and this time-consuming process delayed the therapeutic session. In Subtask 7.3, “Changing Activities,” participants switched activities without saving current data, which led to the loss of unsaved records. In addition, some therapists had difficulty adjusting the settings after completing an activity, as they were unsure whether they needed to press the confirm button before proceeding to the next activity. In Subtask 7.4, “Ending the Activity,” no usability issues were noted.

In Task 11, “Reviewing Statistical Analysis Results,” three errors were identified. In Subtask 11.1, “Reviewing Data Graphs,” no issues were observed. In Sub-task 11.2, “Reviewing Activity Data,” participants were unable to review the data because activity records were not saved, and there was inconsistency between the activity names on the playscreen and the statistical analysis screen, leading to further confusion. In Subtask 11.3, “Deleting Data” participants clicked on the pie chart and searched for a delete button on the detailed graph screen.

Survey Results

The survey assessing the usability of the UI showed that most participants rated usability as a score of 2 or lower, indicating ease of use on a five-point Likert scale (1: very easy, 5: very difficult) (Table 3).

Table 3. Survey results of usability of UI ($n = 5$)

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Usability of UI			M	SD
1. Reviewing user manual		Identifying information	1.67	0.82
		Comprehensibility	1.83	0.98
2. Checking the components		Differentiating between components	1.50	0.55
		Verifying connection and power	1.17	0.41
3. Launching the program		Launching the software	1.00	0.00
		Entering the password	1.00	0.00
4. Creating patient information		Creating patient information	2.17	0.75
		Consenting to the disclosure of personal information	1.67	1.03
5. Donning the product		Donning the product	2.00	1.10
		Instructions regarding the product	1.83	0.98
6. Running the content		Engaging in the content	1.50	0.55

7. Operating the contents	Explaining the contents	1.50	0.55
	Pausing the content	1.67	1.03
	Configuring detailed settings	2.17	1.33
	Changing detailed settings	2.17	1.33
	Ending the content	1.67	1.03
8. Updating patient information	Updating patient information	1.33	0.82
9. Configuring contents after changing the patient	Changing the patient	1.67	1.03
10. Doffing the product	Doffing the product	1.50	0.84
11. Reviewing statistical analysis results	Checking the graph	1.33	0.82
	Checking data	1.33	0.82
	Deleting data	1.50	1.22
12. Ending the program	Ending the software	1.17	0.41

1: Very easy; 5: Very difficult, M: Mean, SD: Standard deviation

Discussion

The following recommendations were suggested from the results of the cognitive walkthrough to enhance usability and user satisfaction with the interface of the Rehabware Standard. First, enhancements to the graphical user interface (GUI) are essential. A GUI facilitates more intuitive and efficient information presentation using graphics instead of text [22]. This study identified usability issues stemming from the lack of clarity in the “Add Patient” icon, underscoring the need for a more intuitive icon that clearly conveys its function. Additionally, improvements in typography, such as optimizing font size and color contrast, are necessary to enhance the readability of activity-setting screens.

Moreover, to streamline data entry, features such as pickers or steppers should be used to replace manual input across all patient information fields. Navigation between fields should also be optimized by enabling the use of the Tab key to facilitate field transitions and user input. Finally, the function controlling the buttons within the software must be displayed on the screen. When developing software-based medical devices, the GUI should aim to minimize the cognitive load and memory demands of users by incorporating a clear control mechanism and simplifying the operations[23].

Second, integrating natural user interface (NUI) elements could further enhance usability. NUI refers to an interface that relies on gestures rather than traditional input devices, such as a mouse or keyboard, to control content [24]. While the Rehabware Standard uses a gesture-based interface through HMD and its accessories(e.g., haptic device), the system does not distinguish between left and right, hindering therapists from properly administering therapy to

people with one-sided paralysis. To resolve this issue, the software should include automatic recognition of the orientation of the haptic device or manual configuration options to distinguish the affected side. In addition, therapists encountered difficulties in adjusting the virtual distance between the hand and objects on the therapist's monitor, indicating the need for better distance-control mechanisms in the VR environment. Therefore, a VR software interface should be created to ensure the ease of use by both therapists and patients.

Third, the UI design requires improvements to enhance the interaction between the medical device and its users. In this study, we observed that therapists employed inconsistent methods for adjusting settings and some failed to save their configurations before proceeding with the tasks. Although most medical device users are well-trained and experienced, errors can still occur when they rely heavily on their own prior knowledge. If the system can provide warning alerts when settings are unsaved or incorrect actions are detected, and provide confirmation prompts when actions are correct, unintended errors can be mitigated [25]. Therefore, warning alerts, confirmation popups, detailed instructions, and help guides within the software interface are recommended to prevent usage errors.

In addition to usability enhancement, privacy is a critical consideration in medical-device development [25]. Given that software as a medical device is often connected to other systems or databases via the Internet, data security must be rigorously managed to ensure confidentiality, integrity, and availability of sensitive information [26]. Thus, in addition to the issues identified in this study, it is essential to strengthen the cybersecurity of software-based medical devices to safeguard data.

Formative evaluation is a type of usability test conducted during the medical device development phase to improve product design. In this study, we conducted a cognitive walkthrough and surveys with occupational therapists as participants to explore potential areas for improvement in the Rehabware Standard.

Cognitive walkthrough is a usability test method used to systematically identify interactions between users and a system without prior knowledge of the system. It is particularly suitable for evaluating screen-based systems where users must actively navigate the interface [27]. Test tasks should be selected from the user's perspective, and the sequence of potential actions should first be outlined, followed by a step-by-step analysis of continuous actions to assess whether appropriate actions are taken at the correct moments. Successful interaction is determined by whether the system feedback helps users achieve their intended goals [28]. In this study, we identified usability issues that need to be addressed in the UI of VR-based upper limb rehabilitation software as a medical device.

This study not only identified some interface problems leading to improvements if corrected for the Rehabware Standard but also highlighted common UI elements that could be improved in the development of VR-based rehabilitation devices by conducting a cognitive walkthrough. However, one limitation of this study is that it mainly focused on the core functions of VR-based upper limb rehabilitation devices. Furthermore, although both healthcare providers administering therapy and patients receiving it were considered users, we did not include actual patients in the participation group. Nonetheless, the rehabilitation professionals involved in this study provided insights from the patients' perspective. Future research should broaden the scope of these tasks to conduct a more comprehensive analysis of the usability of the various features and activities.

Conclusion

Enhancing the UI of VR-based upper limb rehabilitation software as a medical device with a focus on ensuring a user-centered interface and promoting user convenience by addressing the identified UI errors and areas for improvement will facilitate the development of a device that fully meets user needs. A formative evaluation involving a specific user group was conducted based on the specific characteristics of the rehabilitation device, and the necessary enhancements must be made to adhere to the regulatory requirements governing medical devices. Subsequently, a summary evaluation of the final product should be conducted. These efforts will facilitate the commercialization of VR-based upper limb rehabilitation software that prioritizes both user safety and convenience. Moreover, enhancing the user-device interaction will improve the efficiency, safety, usability, and satisfaction of the device, ultimately enabling the development of a medical device that achieves error-free performance guaranteed by the system itself.

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Conflicts of Interest

The authors declare that they have no conflicts of interest.

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