Issues in device development education in collaboration with medical institutions

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Abstract

In collaboration with engineering educational institutions and medical institutions, we are providing manufacturing education that cannot be experienced only on campus through the development of medical support equipment. After trial and error, we established a curriculum as an assistive technology course with six units as one package. This course consists of 2 units of classroom lectures and 4 units of seminar subjects. However, it is a special course in addition to the curriculum of the conventional department, and the students feel a heavy burden. This is a common problem in many manufacturing subjects. During class time, it is necessary to have time to be conscious of today's goals based on the results of the previous session. In addition, time to prepare for work and time to clean up at the end are necessary. Therefore, the amount of time spent on manufacturing is very limited during class hours. As a result, students are also required to engage in extracurricular activities. This is the reason for the low number of participants.

Based on these, we will clarify the significance of this special course and discuss the results of examining solutions to these issues. In the manufacturing of medical-engineering collaboration, it is important to first create prototypes for discussion and to embody the issues for quantifying the design specifications. In addition, in order to maintain the motivation of students, it is important not to embody the idea as the goal, but to conduct a demonstration experiment with the product and evaluate the effect quantitatively. In addition, we will discuss the importance of close cooperation between medical and engineering coordinators, production staff, and staff in the medical field, as well as quantitative evaluation criteria as the final goal.

Keywords: *different needs from three standpoints, prototype, masked needs, endless development, quantitative evaluation criteria*

Introduction

In the field of hands-on education, there has been an increasing focus on two-dimensional (2D) fabrication methods such as problem-solving through programming and design using three-dimensional computer-aided design (3D CAD). In the real world, the use of 3D CAD is becoming mainstream in order to omit the mockup production process and simplify trial and error, so it is important to incorporate manufacturing using such tools in educational settings. However, I think there are prerequisites for this. In other words, when people who are manufacturing or who have experience of manufacturing are promoting manufacturing with each other, using these tools is effective in various ways, such as shortening time and enabling sufficient discussion.

On the other hand, it is very important for students who have little experience in manufacturing to know how difficult it is to give shape to their ideas, that is, to embody their ideas. In this paper, "manufacturing" is defined as "problem solving with a clear purpose and a set goal."

"Manufacturing" and " Crafting" are different. Crafting is the realization of ideas through processing and assembly, while manufacturing is the determination of design specifications, the proposal of solutions that satisfy those specifications, and the definition of problem solving through the realization of these proposals. Furthermore, manufacturing is the simplest when there is only one target for the creator to consider. In other words, the target purchases and becomes a user. For example, make a pencil for writing or a cup for drinking. In such cases, the problem is solved if the purpose of a pencil that writes easily, a cup that does not leak, etc. is achieved. Next, there are two types of target users. For example, school bags. In this case, the purchaser is the presenter, such as a parent, and the user is the child. As a result, design specification conflicts are increasing. For example, a contradiction in purpose arises, such as things that are heavy but cheap rather than light and strong. In addition, in the case of manufacturing through medical-engineering collaboration, another point of view increases. In other words, users have different needs, such as business operators, patients (users), and purchasers (facility/maintenance side). And conflicting problems become a three-way street.

In order to carry out manufacturing (problem solving) that satisfies such needs, there are several issues that must be overcome. However, tackling such high-hurdle issues has a highly effective aspect as manufacturing education.

In this paper, we discuss issues related to development education in medical-engineering collaboration based on our previous experience. We then provide what we have learned about what it takes to overcome the challenges of incorporating this meaningful medical-engineering device development education into the curriculum.

Education curriculum

We offered a two-year, six-credit training curriculum for device development in collaboration with medical institutions. Each unit consists of 15 sessions and each session is 90 minutes. The first year is 1 credit for lectures and 1 credit for seminars. In the second year, 3 credits of exercises and 1 credit of lectures are offered. These five subjects are as follows:

(1): Introduction to Assistive Technology: IAT,
(2): Practice in Assistive Design: PAD,
(3): Practice in Clinical Equipment development: PCED,
(4): Assistive Technology and Co-op: CPAT,
(5): Introduction to Medical Welfare Technology: IMWT.

IAT : Introduction to Assistive Technology

In the IAT course, the curriculum focuses on gaining a physiological understanding of disabilities and learning approaches to functional compensation. The program has set the following three objectives. (1) Regarding welfare devices, there are cases where the needs to be addressed may conflict among the purchaser (management), operator (caregiver), and the individuals directly involved (patients) who have physical contact. Understanding and being able to explain what constitutes an "usable product" in light of these perspectives and developing products accordingly. (2) Acquiring knowledge of human characteristics (ergonomics) and understanding and explaining their applicability to future development and other areas.
(3) Understanding and explaining how the shape of objects and the work environment can affect the human body differently.

PAD : Practice in Assistive Design

In the PAD course, students collaborate with medical institutions to generate ideas and receive feedback from the field in response to their needs. The course has set the following three objectives. (1) Understanding the engineering process and being able to generate problem-solving proposals that incorporate fail-safe and foolproof considerations. (2) Delivering presentations that are understandable and convincing to non-engineers.
(3) Generating ideas from the perspectives of three types of customers (end-users): the purchaser, operator, and individuals who directly benefit from the assistive technology devices.

PCED : Practice in Clinical Equipment development

The PCED course applies and improves the knowledge gained in the PAD. Bring your ideas to life through functional prototyping. This course has three goals: (1) Enhancing existing designs with industrial design elements while meeting the required functionality. (2) Understanding and incorporating fail-safe and foolproof principles into the design process. (3) Building functional prototypes and preparing comprehensive reports documenting the development process.

CPAT : Assistive Technology and Co-op

In the CPAT course, the products developed by PCED are used in cooperation with medical institutions, evaluated, and further improved. It is also intended to be re-evaluated and brushed up. This course has three goals:
(1) Understanding and applying the experimental planning based on the "Ethical Guidelines for Medical Research Involving Human Subjects" to conduct product evaluations in actual medical settings. (2) Understanding and utilizing the non-verbal communication effectiveness between the developed products and the clinical environment.
(3) Being able to consider improvements based on evaluations and checks.

IMWT : Introduction to Medical Welfare Technology

In the IMWT course, students gain hands-on experience in creating products for clinical settings and learn about the development of project proposals, experimental plans, and other related documents. The course has set the following four objectives.
(1) Understanding and applying the social security system in Japan. (2) Understanding the symptoms of diseases such as dementia and recognizing the considerations that need to be taken into account to address associated social issues. (3) Understanding the concept of biofeedback and being able to apply it.
(4) Understanding the specifications and quality assurance in the development of welfare and medical devices and being able to apply them.

Device Development through Collaboration between Medical and Engineering Fields

In this section, we will explain the development of a detachable voice input nurse call device as a case study conducted through collaboration between PAD, PCED, and CPAT.

Background of the Development

Nurse call devices are commonly used to connect caregivers and nurses with patients, especially those with severe limb paralysis. However, the widely available nurse call systems are typically button-operated, which poses difficulties for individuals with cervical spinal cord injuries who have limited hand movement. Consequently, patients with cervical spinal cord injuries resort to alternative methods such as breath-activated switches or point-touch switches. Nevertheless, these switches require precise positioning adjustments to accommodate the patient's subtle movements, resulting in the need for frequent readjustments during caregiving. Therefore, there is a demand for a simple method that allows patients with cervical spinal cord injuries to operate nurse call devices without relying on hand movements or breath activation.

In recent years, inclusive design principles, considering the usage by minority groups, have been increasingly applied in device development. AI speakers, which have become more affordable and are widely used in households, are an example of this trend. Building upon this, Suzuki et al. [1] developed a voice-activated nurse call device that can be operated both through voice commands and manual interaction, without modifying the existing nurse call systems in hospitals. In a preliminary study, a self-controlled study was conducted comparing the developed device with point-touch switches traditionally used by

cervical spinal cord injury patients. The evaluation criterion was the setup time of the development machine and the reference machine. Ten rehabilitation staff members in charge of environmental preparation participated in this study. As for the experimental procedure, we prepared the device until the simulated patient could initiate a nurse call, and conducted a comparative test using the developed device and the conventional device. The staff who participated in this comparative trial suggested that there is a possibility of changing to a positive response to the introduction of AI speakers. This indicates the importance of inclusive design that considers not only users but also operators.

However, the average setup time for the developed product was 78 seconds, which was 1.5 times longer than the results of the comparative test. Therefore, improvements in devices that are easier to set up have been found to be necessary.

Development Objective

The purpose of this development is to replace the existing nurse call system without tools and without the need for advance directives from nurses. Also, it is to develop a device that can be installed within 50 seconds. The device should allow for both voice and manual operation, facilitating use in a variety of hospital rooms.

Design specification

The design specifications are as follows.

(1) The overall dimensions of the device must fit within the desktop space of 100mm x 100mm. (2) It must be able to respond to various types of nurse calls within hospitals. This means broad compatibility with existing nurse call systems. (3) Easy installation without tools. In addition, the burden on healthcare workers should be minimized. In other words, the target installation time until nurse call activation by voice operation is within 50 seconds.

Result: Developed device

Figure 1 shows the developed and manufactured device. This device allows for direct manual activation of the nurse call button. Additionally, it incorporates a solenoid for operating the nurse call via voice commands. The device includes a clamp for adjusting the mounting position of the solenoid and nurse call. The plate shown in the figure is a clearance plate designed to facilitate easy adjustment of the mounting positions of the solenoid and nurse call. Figure 2 presents the equipment used and the operational flow. For the voice-activated nurse call, the AI speaker used is the Google Nest Mini (98mm in diameter, 42mm in height). A hub mini (65mm in height, 65mm in width, 20mm in height) is used as a substitute for a remote control to transmit the voice signal to the solenoid via Bluetooth. To activate the nurse call using the AI speaker, the user needs to say "OK Google, turn on the nurse call."

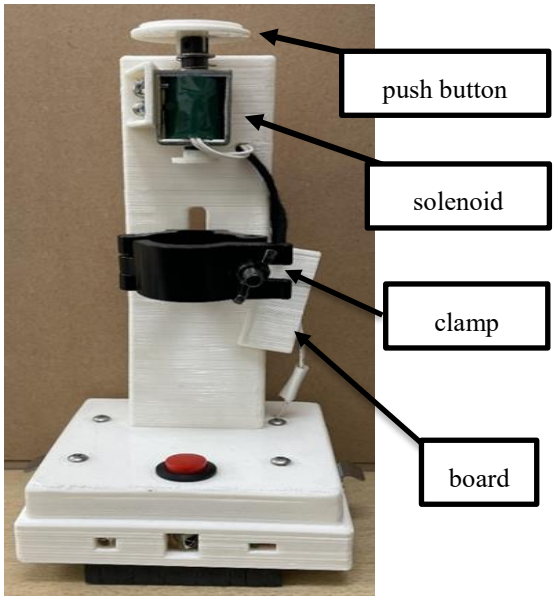


Figure 1 Developed equipment

Innovations and Improvements for Time Reduction during Installation

When patients are changed or rooms are switched, it becomes necessary to attach the device to the nurse call system beside the bed. In such cases, it is crucial that non-engineer nurses can easily set up the device without receiving instructions. To address this, a card illustrating the installation and operation methods, as shown in Figure 3, is affixed to the device itself. This eliminates the need to search for a manual or memorize the installation process, making it easier for nurses to set up the device.

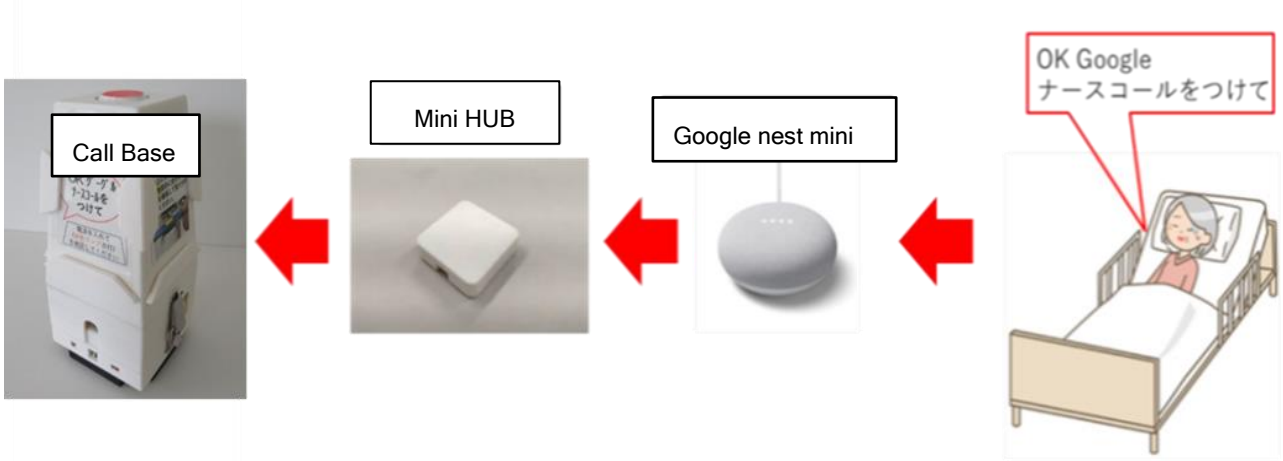


Figure 2 The equipments used and the flow of operations

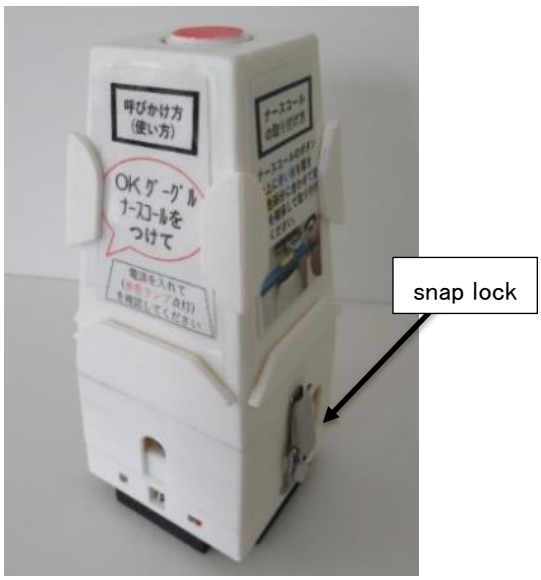
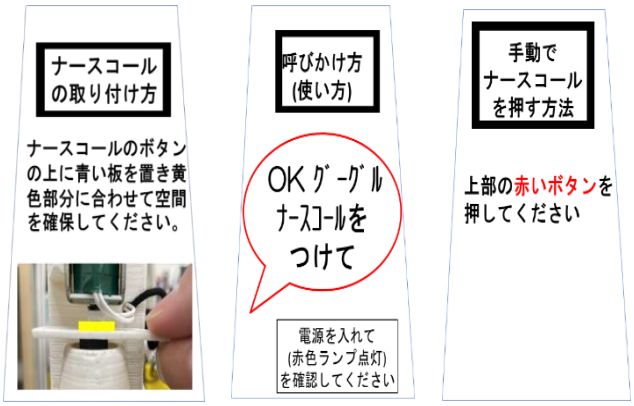


Figure 3 Appearance of development equipment

Figure 4 depicts the three cards attached to the device. Figure 4(a) illustrates the method of attaching the nurse call system, Figure 4(b) provides instructions on how to use it with voice commands, and Figure 4(c) explains the operation method for manual use. These innovations allow even patients and their families who encounter the device for the first time to easily understand how to use it.



(a) (b) (c)

(a) mounting arrangement, (b) how to call, (c) how to push

Figure 4 Display boards

Furthermore, as shown in Figure 5, in previous research cases, the device cover was fixed with four screws. In the device developed this time, as depicted in Figure 3, it is secured with a snap lock. This one-touch removal of the cover reduces the time required for nurse call setup, enabling time-saving benefits.

The installation of the nurse call button can be challenging due to the varying length of the solenoid and the distance required to activate the nurse call. Therefore, it is necessary to ensure a consistent distance during installation. To address this, we have equipped a clearance plate, as shown in Figure 6, which allows for easy installation at regular intervals. By placing this plate on the nurse call button and securing it with a clamp, it becomes easy to set up. Additionally, it is important to use specific words when addressing the AI speaker to ensure proper functionality. Therefore, we attached an explanation card to the terminal body so that even first-time users can make calls without hesitation (Fig. 4(b)).

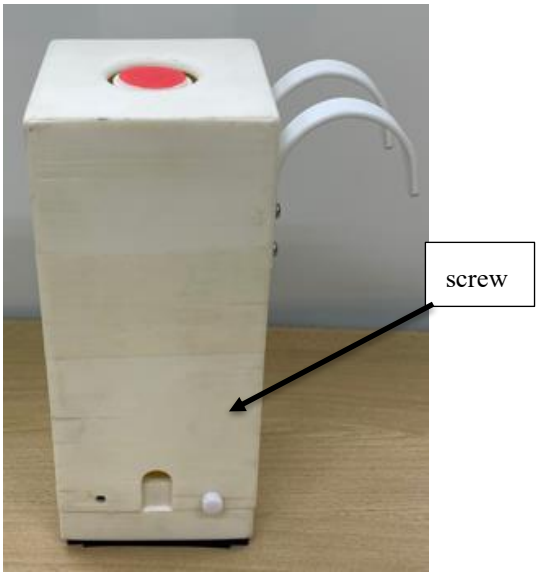


Figure 5 Equipment developed in previous research

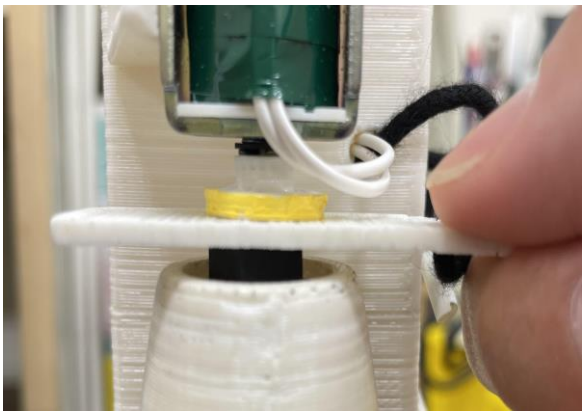


Figure 6 Spacing adjustment between solenoid and button

Effectiveness Verification

We measured and compared the installation times of the developed device and the conventional equipment that shown Fig.5. The participants for measuring the installation time of the conventional equipment were ten physical therapists, occupational therapists, and speech-language pathologists working at Matsuyama Rehabilitation Hospital.

The participants for measuring the installation time of the developed device were ten fifth-year students from National Institute of Technology, Niihama College.

This verification was conducted with the approval of the Ethics Committee at Matsuyama Hospital.

Validation Method

The verification method involved measuring the time taken to complete the following four steps:

(1) Removing the cover of the nurse call device,
(2) Adjusting and installing the nurse call at the appropriate height,
(3) Attaching the cover
(4) Speaking to the AI speaker and operating the nurse call.

After measurement, the average installation time of the

two devices is calculated, and the difference between the average values is tested for significance. We also calculate the effect size for the difference.

Validation Results

The results are shown in Figure 7. The installation time in the control experiment refers to the installation time when using the conventional equipment, while the installation time in the intervention experiment refers to the installation time when using the developed device.

The average installation time for the conventional equipment was 73.4 ± 18.5 seconds, while the average installation time for the developed device was 48.2 ± 7.1 seconds, resulting in a 25.2-second improvement compared to the conventional equipment.

To examine the difference in means between the two groups, an unpaired t-test was performed, revealing a significant difference (p=0.0018).

Furthermore, we need to consider whether this is a meaningful effect size. The standardized effect size "Δ_0" is determined by equation (α), where "$\bar{x}_i$" represents the mean of the intervention group, "$\bar{x}_0$" represents the mean of the control group, "$\bar{u}_i$" represents the unbiased standard deviation of the intervention group, and "$\bar{u}_0$" represents the unbiased standard deviation of the control group.

$$\Delta_0 = \frac{|\bar{x}_i - \bar{x}_0|}{\sqrt{\frac{\bar{u}_i^{\,2} + \bar{u}_0^{\,2}}{2}}} \qquad (\alpha)$$

The unbiased standard deviation "$\bar{u}_i$" of the intervention group was 7.1, and the unbiased standard deviation "$\bar{u}_0$" of the control group was 18.5. Substitute this into equation (α).

$$\Delta_0 = \frac{|\bar{x}_i - \bar{x}_0|}{\sqrt{\frac{\bar{u}_i^{\,2} + \bar{u}_0^{\,2}}{2}}} = \frac{|48.22 - 73.38|}{\sqrt{\frac{7.1^2 + 18.5^2}{2}}} \cong 1.8$$

As a result, the standardized effect size "Δ_0" was 1.8. The benchmark for standardized effect size is considered high when it exceeds 0.8, indicating a significant difference in improving the installation time (time reduction). Therefore, it can be concluded that the development of a simplified attachment-type voice nurse call device achieved the following : (1) A nurse call can be made within 50 seconds without explanation. (2) Easy to operate even for first-time users (3) Easy to install without tools.

Based on these results, it can be said that the creation of a product that satisfies the design specifications has been accomplished.

Discussion

Initially, the requested installation method from the medical institution was to attach the device to the bedside railings. However, it was found to be inconvenient in practice as the railings were frequently removed during caregiving and nursing tasks. As a result, it was decided to develop a stationary-type device, which allowed for seamless usage in caregiving without any hindrance. Additionally, during the development process of the detachable voice input device, although the functionality met the specified requirements, numerous unforeseen issues occurred. These included the number of power sources and methods for adjusting the volume, which required repeated improvements. From these experiences, it became evident that the physical realization of an idea is crucial in medical-engineering collaboration. By basing discussions on the real prototype, various hidden needs, challenges, and the addition of functionalities could be revealed.

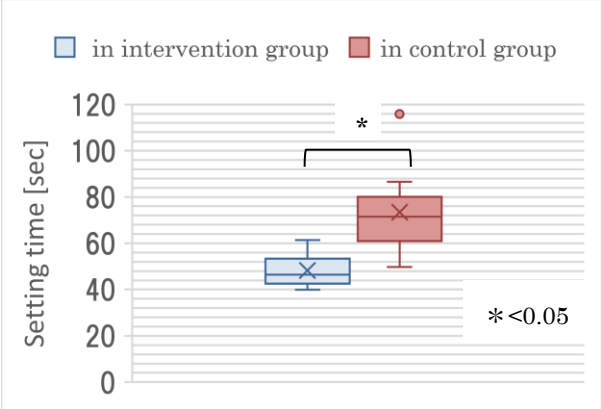


Figure 7 Comparison of installation work time

Therefore, even if the design specifications are not clear, it is important to materialize improvement ideas based on the needs of the field in order to explore hidden needs. In other words, it is crucial for us to create prototypes without spending excessive time initially.

Next, let's consider incorporating medical-engineering collaborative device development education into the curriculum, which can provide students with numerous learning opportunities. Students may feel that improvement requests from the field are endless. Additionally, it can be challenging to evaluate the efforts made by students as tangible outcomes.

Hence, providing objective evaluations based on actual usage in numerical form can alleviate project failures and mitigate the burden on students. Through continuous iterations of improvements, students can experience a sense of accomplishment.

Furthermore, during device development, when intense discussions occur between the hospital and engineering sides, the focus sometimes shifts from prioritizing usability for patients to emphasizing convenience for hospital staff. This is because in medical-engineering collaboration, users are divided into operators, patients (end-users), and purchasers (facilities/maintenance), each having different needs. Consequently, when evaluators of the developed product differ, contrasting evaluations and opinions often arise, resulting in conflicting viewpoints.

In order to create products that satisfy multiple needs and address challenges, it is necessary to first determine the minimum design specifications for each user. Products that significantly prioritize one specification often lower the satisfaction of other users. For example, there are often trade-offs between ease of installation and durability. Therefore, objective evaluation criteria that satisfy each

user are crucial. These criteria serve as the goal of product development and provide students with motivation to strive towards achieving them. On the other hand, conducting experiments with patients, nurses, and other healthcare professionals in real-world settings requires numerous procedures. Obtaining objective evaluations in medical institutions necessitates following various research protocols involving human subjects, which can be time-consuming and financially costly.

However, learning these procedures is essential for engineers. It is an area that has been difficult to incorporate into traditional technical education at industrial colleges. Therefore, I believe that collaboration between medical and engineering fields is highly valuable in product development.

Conclusion

Through the implementation of an educational program focused on collaborative medical-engineering product development, we have obtained the following conclusions.
(1) It is important to materialize ideas without spending too much time, even if the design specifications are not initially clear. Creating a prototype based on these materialized ideas is crucial for exploring masked needs.
(2) The focus should be on conducting empirical experiments with the created prototypes rather than solely on the fabrication process (materializing ideas). Evaluating the effectiveness quantitatively through these experiments is essential.
(3) Close coordination between coordinators from the medical and engineering fields, as well as collaboration with healthcare staff in the clinical setting, is crucial. Setting the final goal, which includes establishing quantitative evaluation criteria, is of utmost importance.

Acknowledgments

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