Master's Thesis

# THE INTEGRATED DESIGN PROCESS OF A REHABILITATION EXERCISE SYSTEM: ELBOW JOINT REHABILITATION DEVICE AND SERVICE

JaeHan Park

Department of Creative Design Engineering

Graduate School of Creative Design Engineering, UNIST

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A thesis submitted to the Graduate School of Creative Design Engineering, UNIST in partial fulfillment of the requirements for the degree of Professional Master of Design-Engineering

JaeHan Park

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Approved by

Advisor KwanMyung Kim

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Jaehan Park

This certifies that thesis of Jaehan Park is approved.

01/11/2021

Advisor: KwanMyung Kim

Hwang Kim

Seungho Park-Lee

### ABSTRACT

This study employed a design agenda based on an integrated design process for a new rehabilitation exercise device and service system as a potential solution for treating upper-limb rehabilitation confronting the Korean rehabilitation treatment industry. For generating the design agenda, adopting a mixed design process consisting of both the main design process treating the overall process and the sub design process treating the phase process. Activities were conducted to define the design requirements while carrying out the design process. These activities included interviews with rehabilitation medical specialists at Kyungpook National University Hospital and Ulsan National University Hospital, visits to the occupational rehabilitation therapy room, and reviewing prior research surveys. This activity made it possible to understand the design requirements and trends in the design of upper-limb rehabilitation devices in Korea by extracting keywords and analyzing the collected information. A specialist in rehabilitation medicine at Kyungpook National University Hospital/Ulsan University, a company specializing in precision control, and a professor of design at Ulsan Institute of Science and Technology provided assistance and professional knowledge required in determining design the elements during the design process. The final result is divided into the interview result, the service system's design and the device's design within the service system. Several reasons were identified from interview results as to why a rehabilitation robot is not easily introduced and used in the Korean rehabilitation hospital based on four categories: medical environment, existing products, exercise, and hospital systems. The service system completed the concept design level. The device design was completed at the system-level design and partially the detail design. The device design's specific results include establishing the type of product, drawings, IF design contest entries, and patent applications. The expected effectiveness of the design agenda in this research is the introduction of Smart rehabilitation methods, improvement of medical welfare, reduction of work burden, quantification of diagnosis and prescription, and provision of customized training for patients. Rehabilitation medical professionals and precision control service providing companies showed the willingness to study further and commercialize the device design outcome. Through this study, one example is presented to designers in the Korean upper-limb rehabilitation device design field to employ design leadership to attract engineers or other groups of experts so that post-product concept design may be further studied.

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#### I. Research background and development strategy

#### 1.1 The background and purpose for developing the upper-limb rehabilitation device

According to the National Statistical Office (2018), Korea has entered the epoch of the Aging Society, with the proportion of the elderly population aged 65 or older exceeding 14 percent as of 2018. As a result, health problems in the elderly population are gradually increasing. According to a survey conducted by the Ministry of Health and Welfare (2017), the population of disabled people aged 65 or older has been steadily increasing to 38.8 percent in 2011, 43.3 percent in 2014, and 46.6 percent in 2017. Currently, about half of the elderly are suffering from various physical disorders including degenerative diseases. In addition, the National Insurance Corporation (2017) reported that the number of stroke patients, a typical degenerative disease, is on the rise, and 80% of stroke patients are in their 60s or older. From these data, we can see that the risk and significance of a stroke are gradually increasing.

Gangnam Severance Hospital (2006) define the word stroke as a disease caused by the blockage of blood vessels in the brain that prevents oxygen and nutrients from being supplied to brain cells, or by bursting brain blood vessels causing bleeding resulting in pressure or damage to the brain. Stroke has various symptoms depending on which brain function is damaged, but the paralysis of one arm/leg, sensory abnormalities, incorrect pronunciation, and visual impairment are typical. Among these, paralysis in one arm/leg is sometimes called *hemiplegia*. Repetitive training for upper and lower limb functions is introduced in rehabilitation treatment after determining whether the brain plasticity can be restored through intentional repetitive training to relieve the symptoms of hemiplegia (Hangil, S, Jaewon, B, Byungmo, O, & Tairyoon, H, 2014).

Today, robotic rehabilitation therapy is in the spotlight because it allows high repetitive training to restore upper-limb function (Hangil, S, Jaewon, B, Byungmo, O, & Tairyoon, H, 2014). There are various social and technical reasons why robot rehabilitation treatment is in the spotlight, but the main issue is the lack of health and medical staff to perform rehabilitation treatment (KISTEP, 2019). The *Medical Service Robot* published by KISTEP (2019) suggests that the number of babies born in Korea is expected to decrease over the next 22 years to 200,000 due to the low birth rate, and that the decreasing size of the productive population will lead to a shortage of medical personnel to prepare for an aging society. In addition, The Korea Institute for Health and Social Affairs (2015) predicted that there would be a shortage of about 110,000 health and medical personnel by 2030. However, the size of the supply shortage would decrease somewhat over time.

Robotic rehabilitation is not widely introduced in the actual rehabilitation environment. The reasons for this failure are low investment, small consumption markets, and high device costs due to complex factors such as problems in mass production (Minho, C, & Jinhwa, Y, 2013). In addition, rehabilitation

robots are being studied mainly for exoskeleton robots and foot-walking auxiliary (KISTEP, 2019). Therefore, the upper limb rehabilitation field remains stuck in a workforce-dependent therapy system where medical personnel utilize analog tools to diagnose and treat patients 1:1, as shown in Figure 1.



Figure 1. The figure shows that the medical staff treat the patient with 1:1 relationship using analog tool at the occupational therapy room (Source: National Rehabilitation Center, 2020)

In other words, the Korean rehabilitation industry faces two problems. One is the lack of health and medical personnel to perform upper-limb rehabilitation (KISTEP, 2019); the other is the high price of the device. Robots are not easily introduced and medical fees are not suitable (Minho, C, & Jinhwa, Y, 2013). The final purpose of this study is to present the results of a new rehabilitation exercise service system and device design which is based on a product design process to solve two problems existing in the domestic rehabilitation industry. However, due to the limitations of the research period, this study's scope was conducted up to Phase 3 Detail Design based on the product development process presented by Ulrich (2008), and partly to System-Level design. Therefore, the study's content consists of deriving design requirements, proposing system concepts, constructing the device design and use scenarios, and designing the device.



Figure 2. Product design process suggested by Ulrich (2008)

#### 1.2 Research and development process and strategy

Ulrich (2008) presented the product development process as an sequence of activities or stages of conceiving, designing and commercializing products. This sequence can be explained into six phases, shown in Figure 2. Phase 0 is the *Planning*, setting the goals of the project. Phase 1 is the *Concept Development*, identifying the needs of the target market and creating a concept. Phase 2 is the *System-Level Design*, determining the structure lay-out, the basic specification of the sub system. Phase 3 is the *Detail design*, determining the specification of the structure materials and allowance. Phase 4 is the *Testing and Refinement*, finding the potential or missed problems in the products through making a prototype. Phase 5 is the *Production Ramp-Up* process for accelerating the production such as checking the production line and finding the remaining problems. Each phase of the process does not necessarily take place sequentially, but can be parallel or repeated in parallel.

KwanMyung Kim (2014) categorized logical process models that specify the steps to be followed by the designer, how to proceed, and the appropriate actions for the designer at each stage as a prescriptive design process, one example being the design process model of Ulrich (2008). In addition, KwanMyung Kim(2014) explained that the prescriptive design process model is criticized for not reflecting the real design phenomena and introduced the *Process Chunk* concept for considering the reality factors. Process Chunk is described as small steps starting a new phase in another after the major task is completed through a series of sequential stages. Process chunk has some features such as initial input, internal iteration, final result, irreversibility.



Figure 3. Design process models suggested by Markus and Maver (Left) and Lawson (Right)

Tom Markus (1969) and Tom Maver (1970) recommended that the design process consider the order of analysis, synthesis, appraisal, and decision. They suggested the design process model shown on the left in Figure 3. Markus (1969) and Maver (1970) described the *Analysis* as including exploring relationships, finding patterns in available information, and identifying goals. *Synthesis* is a step forward

on the problem that can be called solution generating. *Appraisal* includes a critical assessment or evaluation of the solutions that run counter to the objectives identified at the Analysis stage.

However, Lawson, B (2006), explained that the design process that Markus (1969) and Maver (1970) presented has limitations that go from general to specific. In addition, Lawson, B (2006) claimed that the Markus/Maver's design process looks logical, but the reality is unrealistic because the design of the whole is sometimes changed by detail design. Then, he suggested a design model, shown on the right side of Figure 3.





Therefore, this study used the design processes model suggested by Lawson, B (2006), shown in Figure 4, to carry out a design outcome under the real surroundings. The development process consists of four elements: Information Collection, Analysis, Synthesis, Evaluation. *Information Collection* consists mainly of prior research, interviews with rehabilitation medical specialists, observation of occupational rehabilitation room while analysis, synthesis, and evaluation are repeated anytime. *Analysis* consists extracting keywords or contexts from information obtained at a specific stage and categorization. *Synthesis* is an element in designing based on the result obtained from the analysis or evaluation. Finally, *Evaluation* consists chiefly of obtaining feedback information about the design outcome through simplified usability testing or self-assessment, or being evaluated by experts involved developing the system, such as design, rehabilitation, electric part design.

For a feasible system design considering the specificity of the medical market, design strategy models such as the one shown in Figure 5 were adopted at both elements: Information Collection and Evaluation. It is a format where designers, who are the host of the system design, are assisted by rehabilitation medical specialists who can provide the information about design requirements and trends in the rehabilitation field as well as precise control service providing companies, who can help to design in



accordance with IEC 60601, a common standard for medical device design. Afterward, the design elements were supplemented by expert opinions from various fields and simple usability tests.

Figure 5. Design strategy model diagram

In other words, in this study, design processes shown in Figure 6 were carried out. The main-design process follows Ulrich's design process model (2008), but introduced the process chunk concept in each phase to reflect the actual design features. In addition, the sub-design process, carried out within each process chunk, was applied with the models of Lawson, B (2006) that repeat synthesis, analysis, and evaluation.



Figure 6. Main design process and sub design process

#### II. Prior development and research trends

#### 2.1 Existing upper-limb rehabilitation tools

Туре	Image	Features
		Price: Tens of thousands ~ Hundreds of thousands (Won)
		Space of use : Under 1m x 1m
Analog Tool		Degree of Freedom: 1 or 2 DoF
		■ Feedback: No
		■ Control: No
	1	■ Price: Serveral milions ~ Tens of millions (Won)
		■ Space of use : Over 1m x 1m
CPM Machine		Degree of Freedom: 1 ~ 3 DoF
		■ Feedback: No
		Control: Automatic Control
		Price: Tens of millions ~ Hundreds of millions (Won)
		■ Space of use : Over 2m x 2m
Rehabilitation Robot		Degree of Freedom: 1 ~ 3 DoF or More Dof
		Feedback: Virtual reality or Game interface
		Control: Automatic Control, Assistive Control

Table 1. Types of upper-limb rehabilitation tools and features

The tools used to diagnose and treat patients who require upper-limb rehabilitation can be classified in three categories: analog tool, Continuous Passive Motion (CPM) machine, and rehabilitation robots. Table 1 shows the typical shape and characteristics of these tools according to their type. Analog tools usually have the advantage of relatively low prices ranging from tens of thousands to hundreds of thousands of won and require less space for tool placement and storage. However, there are weaknesses such as limited degree of freedom in a product, no feedback to the user, and manual operation is required. The CPM machine usually costs millions to tens of millions of won and takes up relatively large space for layout and storage compared to analog tools. However, it has the advantages of performing exercise automatically and showing a relatively higher degree of freedom than an analog tool. Nevertheless, there is a limitation with no feedback factor to the user for rehabilitation and no function for assisting the user's force. In the case of rehabilitation robots, they usually show price trends ranging from tens of millions to hundreds of millions of won and take up more space for placement and storage than CPM machines. However, there is the advantage of interacting with users in the same way as virtual reality or games, and a high degree of freedom compared to other tools, as well as the ability to support user-force assistance.

#### 2.2 Domestic upper-limb rehabilitation design research trends

In order to design an upper-limb rehabilitation device to resolve problems in the domestic rehabilitation industry, this study identified prior research related to upper-limb rehabilitation device design in Korea. The research trend survey was conducted using DBpia, one of the most popular search sites for academic papers in Korea. To prevent a range of data investigations that was too broad, the scope of the preceding research targeted papers published between 2010 and 2020 using the keywords: upper-limb rehabilitation design, upper-limb rehabilitation development, and conducted system development or usability evaluations for the upper-limb rehabilitation movement. In the case of upper-limb rehabilitation design, the result was a total of 40 papers. A total of 43 papers were found for upper-limb rehabilitation development. After excluding duplicate papers, the results of 34 studies dealing with system development or usability evaluation for upper-limb rehabilitation movement were identified. As a result, research was obtained from three design journals and 28 engineering journals based on the subject classification categorized in DBpia.

Two of the three design journals conducted studies on human dimensions and operating ranges for developing CPMs for shoulders. The study in the other design journal conducted usability evaluations of wrist rehabilitation robots. Among them, the first author of the paper, who conducted the evaluation of wrist rehabilitation robots, majored in rehabilitation medicine. Therefore, it can be presumed that designers authored the two articles in the design journals.

The content of the 28 engineering journals mainly comprised element technologies, such as robot control methods, game contents, robot design and operating mechanisms for upper-limb rehabilitation. Of the 28 academic journals, there were two cases where the first author majored in design-related departments. There two cases dealt with basic experiments on rehabilitation treatment using Haptic devices and development of medical rehabilitation games using electromyography and gyroscope signals.

In other words, out of a total of 31 domestic journals dealing with system development or usability evaluation of upper-limb rehabilitation exercises, four were written by design-related majors, three of which covered basic research for designing rehabilitation exercise systems, and one with a research scope of system development (see Figure 7).



The ratio of the paper in Designer & Non-designer



#### **III. Design requirement definition**

Three activities were conducted to derive a design requirement for the upper-limb rehabilitation exercise system: interviews with rehabilitation medical specialists, field observations at the occupational rehabilitation room, and literature research. Because of the research period and surrounding constraints, there is a limitation in investigating data on all stakeholders related to the upper-limb rehabilitation exercise system, such as a patient who has a problem with their upper-limb, medical device manufacturers, and so on.

#### 3.1 Interview with rehabilitation medical specialists

The one-hour interviews were conducted with two rehabilitation medical specialists at the Kyungpook National University Hospital and Ulsan National University Hospital and focused on upper-limb rehabilitation method and environment. The reason for selecting rehabilitation specialists for interviews was threefold. First, the rehabilitation specialist is the most patient-facing medical person in the rehabilitation industry. Second, the rehabilitation specialist determines whether medical treatment is necessary or not depending on the patient's condition. Third, the rehabilitation specialist is a decision maker who could push to introduce and purchase a rehabilitation system for the hospital. HaeRan Shin (2007) maintained that in-depth interviews can produce rich and vivid research results, including analyzing a group's daily culture and interrelationships with individuals and groups. For that reason, an in-depth interview method was adopted—to discover and derive potential needs by collecting the rehabilitation field situation from the rehabilitation medical department doctor's point of view, problems in the hospital, problems of the current rehabilitation exercise tools, and so on.

The information obtained through the interview could be categorized into four sections: medical environment, existing products, exercise, and hospital systems (see Figure 8). *Medical environment* covers information on space shortages, medical stage limitations, the 1:1 patient-therapist relationship, and qualitative assessment. *Existing products* includes information on the appropriate size and price of the product and functions deemed unnecessary by the doctor. *Exercise* includes information on the exercise needed for upper-limb rehabilitation. Finally, *hospital systems* provides information on administrative procedures and economic perspectives in hospitals.

### Interview result

Medical environment	Existing product
Space shortage Medical stage limitation 1:1 Patient – Therapist relationship Qualitative assessment	Product size Product price Unnecessary function
Exercise	Hospital system

### Figure 8. Categorized interview result: Medical environment, existing products, exercise, hospital systems

Medical environment

■ Space shortage: Since the department of rehabilitation medicine is not a substantial department within the hospital, it is not allocated much space. Also, because other rehabilitation tools are competing for the available space, there is limited space for upper-limb rehabilitation.

Medical stage limitation: Full rehabilitation takes a long time, but actual patients' visits to the hospital are limited. It is sufficient only to perform exercises on a certain body part in certain stages. Unfortunately, most of the patients have difficulty in returning to a completely normal condition.

■ 1:1 Patient-therapist relationship: Most rehabilitation patients have difficulty making body movements during treatment. It causes them to keep requiring help from the therapist for management and protection.

■ Qualitative assessment: Medical staff utilize the Fugl-Meyer Assessment (FMA) scale to judge a patient's level of improvement. However, it depends on the doctor's subjectivity. As a result, some patients cannot go back to daily life after leaving the hospital.

• Existing products

■ Product size: Existing rehabilitation robots are too large to place in the occupational therapy room. This issue is directly related to the hospital's management of the patient rotation rate. The preferred size is a case that is smaller than a desk.

■ Product price: Ordinary rehabilitation robots are too much expensive to introduce in a hospital. The price range is from several million won to hundreds of million won for each.

■ Unnecessary function: Most of the patients who engaged in upper-limb rehabilitation exercises are older men with hemiplegia. Therefore, they prefer to exercise without looking at the monitor. Some patients appear dizzy and in pain.

Exercise

■ Exercise requirements: Required exercises for upper-limb rehabilitation depends on the patient's condition. Exercises include shoulder exercise, elbow exercise, wrist exercise, and finger exercise. Among these exercises, the shoulder and elbow require a relatively higher level of movement than the wrist and hand. Shoulder exercises contain elevation, abduction, and adduction. Elbow exercises contain flexion and extension and forearm supination and pronation.

Hospital systems

■ Administrative procedure: Since complex administrative procedures are required to purchase medical devices worth more than 5 million won, doctors also are reluctant to make requests for medical tools.

■ Economical perspective: Existing rehabilitation robots that include unnecessary functions like games that are too expensive and too large to place in hospitals. In other words, the price merited relative to space occupancy in the hospital is too high. Therefore,

most hospitals tend not to introduce the robot in their hospital. However, sometimes rehabilitation robots are purchased for utilizing as a symbol to promote the hospital.

#### 3.2 Observation of occupational therapy room

Observation of the occupational therapy room was conducted to determine the actual conditions of the upper-limb rehabilitation exercises. It is conducted without direct or indirect contact with occupational therapists and patients to observe the natural rehabilitation environment. There are two limitations to this observation. First is that taking pictures of the treatment situation is not allowed; therefore, providing descriptive information for this study depends on the author's writing and memory at that time. In addition, observation of the occupational therapy room could only be performed at the Daegu Fatima Hospital; therefore, the potential bias of the results needed to be extracted.

The observation of the occupational therapy room for rehabilitation indicated that It had an open space structure and contained rehabilitation equipment for various purposes. In addition, there were several rehabilitation patients and therapists, with one rehabilitation therapist in charge of each patient to lead the rehabilitation treatment. Also, there was no space for rehabilitation for specific purposes, such as upper-limb-rehabilitation.

#### 3.3 Literature research: Fugl-Meyer Assessment (FMA) scale

The rehabilitation medical specialists indicated that doctors use the Fugl-Meyer Assessment (FMA) to determine whether patients have been rehabilitated. Ministry of Health and Welfare and the New Health Technology Assessment Council (2019) described the FMA as a technique to evaluate the overall condition of stroke patients with motor disorders and to evaluate their treatment. In addition, Jung, Y.-I., & Woo, Y.-K (2018) explains FMA as a tool to assess the degree of physical recovery after stroke, including the shoulder, elbow, lower arm, wrist, and hand, and assess the hip, knee, and ankle of the leg. Furthermore, they also describe the FMA has three levels: two points are evaluated when the action is performed correctly, and one point is evaluated partially; zero points are assessed when it is not possible to perform. Figure 9 shows part of the upper-part assessment Fugl-Meyer (1965) suggested. Rehabilitation specialists ask a patient to make a specific motion/movement based on Fugl-Meyer Assessment during the rehabilitation exercise and then check the patient's point value point. When the patient achieves more than the specific scores, doctors recommend the patient leave the hospital.

```
UPPER EXTREMITY
        SHOULDER / ELBOW / FOREARM
   Α
 Ł
    Reflex-activity
                       Flexors
                       Extensors
I
   а
        Shoulder
                       Retraction
                       Elevation
                       Abduction
                      Outwards rotation
        Elbow
                      Flexion
       Forearm
                      Supination
    ь
       Shoulder
                      Add-/Inw.rotation
       Elbow
                      Extension .
       Forearm
                      Pronation
Ĩ
       Hand to lumbar spine
       Shoulder
                               0 - 90
                      Flexion
       Elbow 90°
                      Pro-/Supination
M
       Shoulder
                      Abduction 0°-90°
                      Flexion 90°-180°
       Elbow 0
                      Pro-/Supination
M Normal reflex-activity
  в
           WRIST
   Elbow 90° Wrist-stability
   Elbow 90° Wrist-flexion/extension
   Elbow 0
             Wrist-stability
   Elbow 0
             Wrist flexion/extension
   Circumduction
          HAND
  C
   Fingers Massflexion
   Fingers Massextension
   Grasp a
   Grasp b
   Grasp c
   Grasp d
   Grasp e
 D COORDINATION/SPEED
  Tremor
  Dysmetria
  Time
```

Figure 9. The part of Fugl-Meyer Assessment (Fugl-Meyer, 1965)

#### 3.4 System design requirements

Through interviews with rehabilitation specialists, visiting the occupational therapy room, and reviewing the research literature, customer/user's needs regarding the design were identified. Medical personnel requested quantitative assessment indicators and assistance with the device relative to carrying out their work. In addition, they wanted to have a device to manage many patients with a minimum number of staff and to be the right size and price—something that could actually be introduced to the hospital and used regularly. Discovering these needs allow the minimum requirements to be sorted out when designing the system. The requirements are classified into exercise, interaction, communication, price, and size. Among these, the exercise requirement should support elbow joint

internal/external rotation and elbow joint flexion/extension exercises, and a complex exercise that includes all four exercises. Interaction requirement should support the function of force compensation and feedback to the user and data visualization. In addition, service requirements should be prepared for collecting and transmitting patients' exercise data, prescription data transmission and reception, and a patient management function. The size of the product is required to be smaller than 1600 mm x 750 mm based on the maximum dimensions of the domestic desk size, as suggested by Yun-Keun, Lee & Hee-Seok, P and Dae-Seong, K (2009). Finally, it is recommended that the product supply price be less than five million won (see Table 2).

	Elbow joint internal rotation
	Elbow joint external rotation
Exercise	Elbow joint flexion
	Elbow joint extension
	Complex exercise
	Force compensation
Interaction	Feedback to user
	Data visualization
	Patient exercise data collection & transmission
Service	Prescription data transmission & reception
	Patient management
Price	Under 5 million (won)
Size	Under 1600 x 750(mm)

Table 2. Minimum requirements for upper-limb rehabilitation system design

#### **IV.** Concept design

#### 4.1 System concept design



## Figure 10 Data-based Smart diagnostic system consisting of medical staff-smart diagnose software-upper-limb rehabilitation device-patient

In this study, a Smart care system such as in Figure 10 is intended to solve the problem of lack of medical staff and high cost of rehabilitation robots. The system operates as follows.

- 1. The doctor treats the patient who visits the hospital and prepares the prescription.
- 2. Enter exercise prescription instructions into the computer according to the diagnosis results.
- 3. Exercise prescription data is transmitted from the Smart Diagnosis Assessment S/W to an intelligent upper-limb rehabilitation device.

- 4. Customized rehabilitation exercise programs work according to the prescription data.
- 5. The device collects data from the patient; for example, exercise history, the intensity of the exercise, and the condition of the patient's body part.
- 6. The collected data is stored on the server and passed on to the Smart Diagnosis Assessment S/W.
- 7. The Smart Diagnosis Assessment S/W converts the delivered data into information that can be used to diagnose patients.
- 8. Translated diagnostic information is passed to the doctor.
- 9. The doctor determines and diagnoses the patient's condition based on the transformed diagnostic information and data.

The Smart upper-limb rehabilitation device provides customized exercise dependent on the patient's condition, giving appropriate feedback to enhance the motivation for rehabilitation exercise. Three types of customized exercises are offered: active training, passive training, and assistive training. Active training involves the patient exercising independently, while in passive training, the machine automatically moves the patient's arm. In assistive training, the device generates resistance to the patient's movement. In addition, when the terminal is operating, the motor's current/voltage changes when the measurement method is adapted to observe and collect the patient's condition information in real-time and send it to the Smart Diagnosis Assessment software. Appropriate feedback provides information with the Smart Diagnosis Assessment software to enable partial non-face-to-face diagnosis and evaluation. In addition, one product can respond to both right-arm and left-arm patients.

Smart Diagnosis Assessment software collects information such as a history of the patient's rehabilitation exercise, intensity of rehabilitation exercise, and the affected part from the smart upperlimb rehabilitation device. Afterward, these data are processed into information such as recovery trends/strength improvement conditions of patients, and visualized data to make it easier for doctors to make a data-based objective judgment.

#### 4.2 Device design

#### 4.2.1 Device specifications

Within the system concept, the device plays the role of transmitting and receiving diagnostic/care records, collecting and receiving patient's exercise history, and providing exercise customized for the patient. Some elements are required to perform this kind of role: information storage and transmission element, device control, placing the arm, and the power resource for moving the arm. These elements can be expressed as components that compose the product. It can be implemented in the form of a

hardware module to transmit and control the information, arm-supporter, motor. These three factors are the key components of the product, and the presence and size/shape of these elements can have a great influence on determining the product concept in the future. Therefore, this study explores the process of deciding on the specifications of major factors.

To ensure that the hardware modules for storing and transmitting/controlling information were based on a professional background in engineering, the specifications were determined by consultation with Automotion, an electronic device control company. Automotion indicated a free space of 100 mm x 150 mm x 30 mm was sufficient to accommodate a hardware module capable of storing/transmitting, and controlling information.

The arm-support size can be limited to approximately 370 mm in length and 100 mm in width based on the human measurements provided by Size Korea (2020). These measures are based on data from the 7th Human Dimension Survey, which reported the length of elbows to fists of 95% of individuals over 65 years of age of the both genders surveyed, and the maximum hand width of 95% of over 65 years of age individuals of the total sexes surveyed in the 5th Human Dimension Survey. The maximum hand width was not found in the 7<sup>th</sup> Human Dimension Survey so the 5th Human Dimension Survey results were used.

To select the motor, prior materials related to the design and control of rehabilitation robots were investigated. Several short consulting with a medical specialist in the Kyungpook National University's rehabilitation treatment department and an electrical engineer at Automotion were conducted. In the prior research related to the human elbow, Harbo (2012) argued that the average maximum torque used for elbow flexion/extension is about 50 N-m. In terms of elbow rehabilitation robot design, Hansol, K & Gabsoon, K (2015) adopted the motor that is around 40 N-m. Minhyun Lee (2011) choose the 39 N-m motor, and Jaeho Kong (2018) selected a 30 N-m motor. However, for this study, with the help of Automotion, a motor with a rotational force of 10 N-m was selected. There were several reasons for this selection. For example, Hansol, K & Gabsoon, K (2015) showed that patients with no elbow muscle had around 2 N-m rotational force according to the results of an elbow rehabilitation exercise using an elbow rehabilitation robot. In addition, on the advice of the rehabilitation medical specialist, it was determined the exercise for rehabilitation does not require much strength because it is not a strength exercise. Moreover, there is a precedent for adopting the 14 N-m motor for developing rehabilitation robot system process for recovery exercise of elbow stiffness patient from the research conducted by the Jaekyeong, L & Jeongwan, L(2006).

#### 4.2.2 Device concept



Figure 11. The transition of the upper-limb rehabilitation device concept

After determining the specifications for the key components, the concept of the product was developed according to the parts. The product concept was presented in various types, reflecting the opinions and feedback from many people including the design department professor at the university, the rehabilitation medical specialists. Figure 11 shows the transition of the device concept relative to how to use the device, its operating mechanism, and its appearance.

The final product concept is the fourth picture in Figure 11. The product concept is best described as "A smart upper-limb rehabilitation device with a simplified function, that provides customized exercise for patients and provides quantitative evaluation criteria for medical staff at a low price and small enough to be used by placing it on a desk." There are several features. For example, without using additional tools, the device can treat patients with left arm or right arm exercise (see Figure 12). Users can easily adjust the display direction to fit their own viewing angle by pushing or pulling by one hand; the display can be rotated from a minimum of 0° to a maximum of 90°. The device can be controlled by touching the display.



Figure 12. How to apply to the left-hand or the right-hand with one device

#### 4.2.3 Device part

The device design was decided by conducting a simple usability evaluation on various design agenda to create an impression of a product that felt most comfortable to use. The usability assessment was conducted to identify usability problems or decide the design direction based on five users. This assessment method is based on the five-user rule. Nielsen & Landauer (1993) maintained that five users are sufficient to find the usability problems. Taking into consideration the research costs, five users could extract 85% of the overall usability problems.



Figure 13. Concept design of the arm support and the motor holder



Figure 14. Concept design of the bearing holder

Figure 13 and Figure 14 show the drawings of the various forms of arm supporter and motor/bearing holder. These design diagrams were evaluated by a group of five people from the design field including a designer or industrial design department student with more than four years of experience. The purpose of the evaluation is to determine the foam direction to can show the stability, professionalism, and

aesthetics factors. Among them, the overall styling direction of the product was decided by developing the selected diagrams.



Figure 15. Handle mock-up and short usability test

In the case of handle design, visual elements are important, but functional aspects and actual use are critical. Therefore, the simple five-user evaluation experiment was conducted to find which shape was best for grip among the designs in the 1:1 size mock-up. The user evaluation was conducted with five people who could hold the handle. The experiment was conducted on three different types of handle freely touched for 10 minutes; then, the grip was evaluated using a 5-point Likert scale. Based on the 5-point scale where 1 = very negative, 2 = negative, 3 = neutral, 4 = positive, and 5 = very positive, a column type was recorded as 3.6 points, a baby bottle type was 3.4 points, and the branch type was 1.8 points. As a result, the column type was adopted as the best handle shape design shown in Figure 15.

In this design concept, the counter-weigh part is used to minimize the reduction of the motor's life span, one of the key components, due to internal and external factors. Thus, the counter-weigh part is designed to minimize the life reduction of the motor in durability caused by forced rotary motion caused by external factors. De Leva, P. (1996) suggested that the weight of a human forearm and hand is about 2% of the total weight. The Size Korea (2020) presents data from the 7<sup>th</sup> Human Dimension Survey that report the average weight of individuals aged 65 or older, for all genders, is around 61.5 kg. Based on these two pieces of information, the weight of the forearm and hand of this group is around 1.2 kg. Therefore, with the weight of the forearm and hand set at 1.2 kg, the mass of the weight was adjusted to reduce the rotational moment affecting the motor since torque is affected by the position of the center

of the mass of the product and mass of the counter-weight. The characteristics of the material and the center of the mass of the product is based on the SolidWorks 2019. Torque is calculated based on the following constraints.

- 1. The motor is located in the center of rotation (0,0).
- 2. The motor rotates clockwise from the center of rotation.
- 3. Gravity  $(m/s^2)$
- 4. Ignore the friction between components.
- 5. The axis of rotation is fixed so that the displacement does not change

Figure 16 shows the physical characteristics and conditions when the *arm-supporter does not have a counter-weight* and compares the torque between *the arm-supporter alone* and *the arm-supporter with an arm*. The arm-supporter alone has a total mass is 0.32 kg, and the center of mass is located at the point (-215.62 mm, -3.2 mm). In the case of the arm-supporter with an arm, the total mass is 1.52 kg, and the center of mass is located at the point (-200.68 mm, 21.84 mm). Therefore, in each case, a torque of 0.069 N-m and 0.3 N-m is generated in a counterclockwise direction from the center of the rotation point.

Figure 17 shows the physical characteristics and conditions when the *arm-supporter has counter-weigh*' and compares the torque between the *arm-supporter alone* and the *arm-supporter with an arm*. In the case of the empty arm-support, the total mass is 5.13 kg, and the center of mass is located at the point (-2.89 mm, -19.93 mm). When the arm-supporter is holding an arm, the total mass is 6.33 kg, and the center of mass is located at the (-33.92 mm, -11.20 mm). Therefore, when the arm-supporter is empty, a torque of 0.014 N-m is generated in a clockwise direction from the center of the rotation point. When supporting an arm, a torque of 0.214 N-m is generated in a counterclockwise direction from the center of the rotation point. From these results, it can be seen that the amount of torque generated is smaller in the presence of a counter-weight. Since the magnitude of the torque is the magnitude of the force that gives resistance to the rotation of the motor, the minimized figure is ideal for minimizing the reduction in the durability of the motor due to forced rotation. In other words, adopting a counter-weight is advantageous in managing the life of the motor—a key component.



Figure 16. The no counter-weight case: Arm-supporter (upper) and Arm-supporter with arm (bottom)



Figure 17. The brass counter-weight case: Arm-supporter (upper) and arm-supporter with arm (bottom)



Figure 18. Paper prototyping and iteration

The overall size and display of the product were identified through self-evaluation by using 1:1 scale paper prototyping. The purpose of paper prototyping was to identify the elements that users thought were suitable for the user. As a result, the overall length was changed from 800 mm to 680 mm, and the display standard was changed from 5 in to 7 in. When an 800 mm length version device was placed on the desk, it was too large to place on a table and too far for the user to control the device. The 5 in display was too small to check the figure in the graphics.









Figure 20. Graphic-based user device using scenario

To realize the design, visual materials shown in Figure 19 and Figure 20 were provided to electronic device experts to enhance their understanding of the product concept and facilitate development. Details of Figure 20 are in Appendix 1.

#### V. Detail design

#### 5.1 Overall design



Figure 21. Upper-limb rehabilitation device modeling

Figure 21 displays 3D CAD modeling data generated in Solidworks (2019) that shows the overall shape of the device. The device consists of a handle, arm-support, counter-weight, body case, body basement, arm-support holder, bearing, bearing connection, bearing holder, motor, motor holder, motor connection, ball-caster, ball-caster holder, C-ring, display, display connection, motor stopper. Among them, the ready-made axle C-ring and the bearing connections that are important for compatibility with the 6200ZZ bearing were designed by referring to the specification table of each part.

#### 5.2 Part connection structure



Figure 22. Connection mechanism between the parts

Figure 22 shows the coupling structure of a part of a device. The main case of the device has a clear gap between the threaded Boss columns. This structure minimizes the gap between the main case and the base plate. In addition, the Korea Occupational Safety and Health Administration (2016) recommended the use of the minimum type of bolt nut to prevent complications including procurement, storage, and assembly. Therefore, the type of bolt used was limited to M3, M4 round-headed cross-bolt considering the device's size.



Figure 23. Connection mechanism between the parts

Running fit is applied to parts that need to be rotated, such as displays so that there is always clearance for relative motion. For components that do not require relative motion, such as bolts, a forced tight fit is applied.

#### 5.3 Medical device certification

Since this device design is a medical device that uses electricity, it is required to meet IEC 60601, a set of technical standards for the safety and essential performance of medical electrical equipment issued by the International Electrotechnical Commission (IEC).

For designing the device UI and instrument object, Paragraphs 4 and 7, 9 were the primary focus. IEC 60601-1:2012 Paragraph 4 discusses the general requirements for medical device design. IEC 60601-1:2012 Paragraph 7 discusses the requisites for marking/documentation of medical devices. IEC 60601-1:2012 Paragraph 9 discusses the mechanical hazards of medical devices. Among them, the device satisfied some part of paragraphs; specifically, 4.7 and 7.4 and 9.2.3, 9.3, 9,4.1.

IEC 60601-1:2012 Paragraph 4.7: Medical devices always require double safety. There is a feedback system to prevent any hazard from occurring, and there should be a countermeasure in the event the control does not work properly. A single failure condition is when either a control device or a contingency plan fails. The device should be designed to prevent unacceptable risks from occurring in this single failure condition during the expected service period (see Figure 24).



Figure 24. The example of satisfying the IEC 60601-1:2012 Paragraph 4.7

IEC 60601-1:2012 Paragraph 7.4: The symbol of the power switch shall be used for its function. On, Off, Toggle Power Switch, and Momentary Press Switch are examples shown in Figure 25. Units used in medical devices should be SI units (international units).



Figure 25. The example of satisfying the IEC 60601-1:2012 Paragraph 7.4

IEC 60601-1:2012 Paragraph 9.2.3: The design, layout, and protection shall be made to prevent accidental unintentional movement (see Figure 26).



Figure 26. The example of satisfying the IEC 60601-1:2012 Paragraph 9.2.3

IEC 60601-1:2012 Paragraph 9.3: Rough surfaces, sharp edges, and edges of medical devices that cause injury or damage shall be removed or covered (see Figure 27).



Figure 27. The example of satisfying the IEC 60601-1:2012 Paragraph 9.3

IEC 60601-1:2012 Paragraph 9.4.1: Medical devices and their parts intended to be placed on the floor or a table during normal use shall be designed so that they do not fall or move abruptly (see Figure 28).




#### VI. Prototyping and evaluation

#### 6.1 1st Prototyping and evaluation

A 1:1 scale pre-prototype was made to ascertain the structural problems of the device before building the main prototype. The main parts were printed out using 3D printing and assembled with ready-made products, as shown in Figure 29. Upon completion, a thorough examination was conducted to find the problems that occurred in the process of assembling and after assembling.



Figure 29. Prototyping for checking for design problems

One missing element was found during the design process, two problematic parts when combined, and one area required usability improvement.



#### 6.2 2<sup>nd</sup> Prototyping and evaluation

Figure 30. Trial product after checking problem

The 2<sup>nd</sup> prototype was made of the intended material and color after improving the problems found in the 1<sup>st</sup> prototype (see Figure 30). The 2<sup>nd</sup> prototype was given to four experts for an hour, allowing them to touch it freely. The group members were the two rehabilitation medical specialists, an electrical engineer at Automotion, and a design professor who works at the Ulsan National Institute of Science and technology. The information on usability problems and improvements was collected through indepth interview methods following the experts' examination. The collected information was categorized into durability issues, functional issues, usability issues, and management issues, as shown in Figure 31.

## Interview result

Durability issues	Usability issues	
Strap holder durability Arm support bending	Product clamping Handle control	
External force direction at the gear shaft	The size of the display	
Function issues	Management issues	

#### Figure 31. Categorized interview results: durability, usability, function, and management

• Durability issues

■ Strap holder durability: the structure of the part which secures the strap for securing the arm appears weak. Reinforce is required.

■ Arm support bending: the bending phenomenon occurs when force is given to the arm supporter part. Adding the reinforcement is recommended.

■ External force direction at the gear shaft: in the current structure, the motor is subjected to vertical drag, negatively affecting the motor. Structural improvement is required for the motor holder.

- Usability issue
  - Product clamping: the product can slip off the desk. A suitable solution needs to be found for securing it in place.
  - Handle control: controlling the location of the handle is inconvenient.
  - Size of the display: the 5 in display case may be inconvenient for the user during the exercise program.
- Function issue

Handle part: the handle would be better if it was possible to use it in a variety of ways, for example, grip method or interchangeable.

Recording and repetition of the specific action: it would be an interesting function if the device can store the fixed exercise program and the special exercise path of a specific patient.

• Management issue:

Material range: in terms of product management in the medical institution, some material is not preferred. For example, leather is a poor choice for product management because alcohol causes damage and leather fatigue.

#### VII. Result and discussion

#### 7.1 Design outcome

In this study, a new rehabilitation exercise device and service system was designed to solve problems facing the domestic upper-limb rehabilitation treatment industry including the shortage of medical personnel and the low penetration rate of rehabilitation robots due to the high price. These designs were carried out according to the design process model presented by Ulrich (2008) as the main design process, and the repetition of the work performed in areas corresponding to each phase was carried out using the design process model presented by Lawson, B. (2006) as a sub design process model. To define the design requirements during the process, activities such as interviews with rehabilitation medical specialists at the Kyungpook National University Hospital and Ulsan National University Hospital, visits to rehabilitation rooms, and reviews of prior research surveys were conducted. Through these activities, design requirements and design trends of upper-limb rehabilitation devices in Korea were identified. Professional knowledge required in determining design elements during the design process, design direction, and the result were derived through support and evaluation data from professionals in the specific fields. Specifically, rehabilitation medical specialists from the Kyungpook National University Hospital and Ulsan University Hospital, an electrical engineer with Automotion-the electric equipment control service provider-and an industrial design professor at the Ulsan Institute of Science and Technology provided guidance and expertise. The final outcome was divided into the design of the service system and the design of the device within the service system. The service system expressed in Figure 10 was designed during the Concept design phase. The outcome of device design within the service system is designed under the Detail design phase and partially designed in the System-Level design phase. The specific design outcomes of the device design include the prototype, CAD drawing, IF design contest entry materials, and patent applications. CAD drawing displays a detailed figure of the product and the BOM table showing the material in each part. Appendix 4 shows

the CAD drawings of the materials. The product concepts and use scenarios related to IF design contests are shown in Appendix 2 and Appendix 3. In addition, Appendix 2 shows the representative images of the device design. Figure 32 is one example of the materials shown in Appendix 2. Appendix 3 displays the design poster materials including background, problem, and solution. Finally, Appendix 5 contains an in-progress patent application and a related assessment report. The rehabilitation medical specialists and the experts at the Automotion Co. who helped with this research, expressed their willingness to follow up future work on this research, commercialize it, and will jointly apply for a patent to actualize the design.



Figure 32. The representative image of the outcome of the device design

#### 7.2 Expected effects

The upper-limb rehabilitation exercise system suggested in this study is expected to have four positive effects. First, reducing the burden on insufficient rehabilitation personnel. Second, quantification of diagnosis and prescription in the rehabilitation field. Third, patient-centered exercise training. Fourth, the introduction of Smart rehabilitation methods and promotion of medical welfare.

In reducing the burden of insufficient rehabilitation personnel by utilizing the automated tools, treatment of multiple patients can be efficiently delivered and managed at medical facilities with a small number of administrative personnel. For example, patient information can be provided by the device, and friction between therapist and patient can be reduced. It is expected that the occupational therapy room's working environment relative to upper-limb rehabilitation will change from the top picture in Figure 33 to the bottom picture.

In the case of quantification of diagnosis and prescription, medical personnel can diagnose, assess and prescribe the patient's condition more objectively and accurately by checking the patient's rehabilitation training status, exercise area, and exercise cycle quantitatively through the upper-limb rehabilitation exercise system. Moreover, doctors can free themselves from mental stress to judge the fine differences that may come from the qualitative evaluation system. It is also assumed that the patient can also check their degree of rehabilitation based on a numerical value, thereby strengthening their motivation for rehabilitation.

Patient-centered training allows patients to receive three types of exercise: Passive, Active, and Assistive, depending on their degree of rehabilitation. Through this process, the patient may overcome a relatively large number of limitations, thus increasing the motivation to rehabilitate the upper-limb.

Finally, it is expected that this device will be introduced to a relatively large number of hospitals to increase access to medical services for hemiplegia patients since it can be manufactured and supplied at a relatively low price compared to rehabilitation robots through the minimization of necessary functions.



Figure 33. Expected result from the suggested upper-limb rehabilitation system design

#### 7.3 Conclusion and discussion

In this study, the rehabilitation system and device were designed as outcomes. There are three contributions of this process.

First, the research boundary of industrial design has been widened in design research on rehabilitation devices used in the domestic upper-limb rehabilitation industry. Prior upper-limb rehabilitation device design studies are mainly focused on research to develop elemental technologies, basic studies that

could be used for further research, or usability studies to improve products. Among these, research to develop elemental technology is conducted by engineers while basic research and usability studies were conducted by designers. The essence of designers is creating artifacts tangible or not for improving the problem. However, today research conducted by designers does not play the essential role of creation, but mainly evaluates existing products or elements. In other words, designers don't design, but rather than play the role of evaluators. Such actions can be said to narrow the scope and authority of designers to perform on their own. Therefore, through this study, I want to expand the scope of research in industrial design by presenting examples of a designer's design in an upper-limb rehabilitation device in Korea.

Second, in product development, design can be used as one role model that takes leadership in product development. Domestic design research conducted in product development sometimes ends with concept design that only presents the function and shape of the product. However, in these cases, designers often fail to engage in post-concept design stages during the product development process. It fails to consider engineering elements, feasibility, production methods, and so on under the name of showing a vision. In this case, the final result may be produced, which is different from the concept intended by the designer. In other words, it occurs because leadership was employed in engineering and production from the design phase in the course of product development. Therefore, it is also necessary to design elements that can communicate with engineers to develop a product that can demonstrate the intended concept with leadership in the product development process. Consequently, it is important to communicate with engineering and other experts through specification definitions and presentation of working prototypes to implement functions and encourage products to be developed in line with their intended design.

Third, this study contributed to the industrial group by presenting designs that could be introduced in the rehabilitation industry. The design presented is based on consumer needs through observation of occupational rehabilitation rooms and interviews with rehabilitation doctors. As a result, Kyungpook National University Hospital and Ulsan National University Hospital received an offer to introduce the product after the completion of its development. Rehabilitation doctors said it would be beneficial to use with early-stage patients with severe paralysis and in welfare institutions for senior citizens.

In developing the products through this study, I realized how important it is to the design to have leadership in the development process. As a product planner, a designer is responsible for determining what value they can deliver to users and how to deliver this value. However, the value and delivery path can be changed at the production stage unintentionally. Therefore, designers need to have leadership and lead the product development process to communicate these important factors to users. For example, when the design elements and concepts were explained to an engineer who works at the Automotion Co., he was buried in cost-effectiveness and efficiency and argued the some design schema could distort

the original intention for the design. It was necessary to prevent this by designing the product's specifications in consideration of the engineering elements to communicate with the engineers. Therefore, I think it is essential for industrial designers to have engineering knowledge.

#### VIII. Limitations and future work

#### 8.1 Limitation of research

There are two limitations to this study. First, the interviews conducted at the preliminary stage of organizing the design requirements for the upper-limb rehabilitation were conducted only with rehabilitation medical specialists. Therefore, it was not possible to check the design requirements with the occupational therapist and patients who are the direct stakeholders of the upper-limb rehabilitation device. If a follow-up study is carried out, further interviews are required to identify these needs. Second, there were insufficient users for the usability evaluation. In this study, a short usability test was conducted with five users once for simply grasping the design direction or determination in a short time. It is difficult to assure that there was sufficient objectivity. For building more objectivity, it is necessary for a larger number of users to evaluate the usability at once or several times using the repetitive usability test. The repetitive usability test with five or six users is recommended in Nielsen and Landauer's (1993) model.

#### 8.2 Future works

This study explored only the partial prototyping stage; for a fully completed product, some future work is required. Representative future work can be categorized as the usability evaluation and improvement, elemental technology development, and medical device certification.

#### 8.2.1 Usability evaluation and improvement

After the additional production of prototypes designed in this study, a usability evaluation by medical specialists and patients at a medical center is required. Based on the usability evaluation result, the design of the device can be improved as indicated or completed.

#### 8.2.2 Element technology development

The method to control the motor and the technology to communicate with the device and servers within the medical institution are required to complete the product concept presented in this study. Further development is required to implement the device UI design.

Motor control should be managed to realize three kinds of exercise programs: Active exercise mode, Passive exercise mode, and Assistive exercise mode. For example, utilizing the voltage/current changing phenomena when the motor gets some resistance from human force. The communication function should save/send/receive information between the device and the medical center server. Device UI factors should be developed with Figure 19 and Figure 20 as guides.

#### 8.2.3 Medical device certification

Since the products presented in this study are devices belonging to medical devices, it is essential to repeat and study the development process for medical device certification. Therefore, procedures are required to modify and supplement design and technology to meet medical device certification standards. After medical device certification, it is necessary to introduce the product to the hospital and test the product on patients.

### **IX. Reference:**

- De Leva, P. (1996). Adjustments to Zatsiorsky-Seluyanov's segment inertia parameters. *Journal of biomechanics*, *29*(9), 1223-1230.
- Fugl-Meyer, A. R., Jääskö, L., Leyman, I., Olsson, S., & Steglind, S. (1975). The post-stroke hemiplegic patient. 1. a method for evaluation of physical performance. *Scandinavian journal* of rehabilitation medicine, 7(1), 13.
- Harbo, T., Brincks, J., & Andersen, H. (2012). Maximal isokinetic and isometric muscle strength of major muscle groups related to age, body mass, height, and sex in 178 healthy subjects. *European journal of applied physiology*, 112(1), 267-275.
- Hospital, G. S. (2006). Stroke. Retrieved from http://sev.iseverance.com/dept\_clinic/center/apoplexy\_center/faq/view.asp?con\_no=1074
- Kim, K.-M. (2014). Collaborative product design processes between industrial designers and engineering designers-A case study of six consumer product companies. (Ph.D), KAIST, KAIST. Retrieved from http://hdl.handle.net/10203/196959 (591756/325007 / 020085016)
- Kim, K., & Lee, K.-p. (2016). Collaborative product design processes of industrial design and engineering design in consumer product companies. *Design Studies*, *46*, 226-260.
- Lawson, B. (1997). How designers think: the design process demystified. 1997. In: Architectural Press, Oxford.
- Lawson, B. (2006). How designers think: The design process demystified. Oxford: Routledge.
- Markus, T. A. (1972). A doughnut model of the environment and its design. *Design Participation*. London, Academy Editions.
- Nielsen, J., & Landauer, T. K. (1993). A mathematical model of the finding of usability problems. Paper presented at the Proceedings of the INTERACT'93 and CHI'93 conference on Human factors in computing systems.
- Size Korea. (2020). 7 차 인체치수조사. Retrieved from https://sizekorea.kr/page/report/1.
- Ulrich, K. T. (2003). Product design and development. New York: Tata McGraw-Hill Education.
- 공재호, 하종립, 심유섭, 권용현, & 이학. (2018). 재활 치료 교육을 위한 Robotic

Manipulator 설계. 대한기계학회 춘추학술대회, 2257-2259.

국립재활원. (2020). 진료지원:물리작업치료과. In.

김한솔, & 김갑순. (2015). 힘측정기반 팔꿈치 재활로봇 설계 및 힘제어.

제어로봇시스템학회 논문지, 21(5), 413-420.

보건복지부. (2017a). 2017.4.02 보도자료: '뇌졸중'환자의 5 명 중 4 명은 60 세 이상.

Retrieved from

http://www.mohw.go.kr/react/al/sal0301vw.jsp?PAR\_MENU\_ID=04&MENU\_ID=0403&SEA RCHKEY=&SEARCHVALUE=&page=1&CONT\_SEQ=339009

보건복지부. (2017b). 2017 년 장애인실태조사.

보건복지부&신의료기술평가위원회. (2019). 푸글마이어 검사. (HTA-2019-24). Seoul:

보건복지부&신의료기술평가위원회 Retrieved from

https://nhta.neca.re.kr/nhta/publication/nhtaU0601V.ecg

- 서한길, 범재원, 오병모, & 한태륜. (2014). 편마비환자에서 로봇 보조 상지 재활치료의 효과. Brain & NeuroRehabilitation, 7(1), 39-47.
- 신혜란.(2007). 심층인터뷰 연구방법론: 타인에게 배우는 데이터 수집·분석기법. *국토*, 60-68.
- 안전보건공단. (2016). *볼트. 너트의 선정 및 체결에 관한 기술지침*. Retrieved from https://www.kosha.or.kr/kosha/data/guidanceDetail.do
- 이민현, 손종상, 김정윤, & 김영호. (2011). 편마비 환자의 재활운동치료를 위한 능동형 상지훈련시스템 개발. Journal of Biomedical Engineering Research, 32(1), 1-6.
- 이윤근, 박희석,& 김대성.(2009). 노동부고시와 KS 규격에 의거한 사무용 의자와 책상의

인간공학적 분석. *한국산업보건학회지,19*(1),16-24.

- 이재경, & 이정완. (2006). 팔꿈치 경직 환자의 회복운동을 위한 재활 로봇 시스템 개발. *대한기계학회 춘추학술대회*, 14-19.
- 전민호, & 이진화. (2013). 뇌질환 환자의 로봇 재활치료. Journal of the Korean Medical Association, 56(1), 23-29.
- 정영일, & 우영근. (2018). 뇌졸중 환자의 위팔 손상 수준에 따른 위팔 활동과 일상생활 활동의 예측도 분석-임상적 평가를 이용한 예비 연구. *PNF and Movement, 16*(3), 495-503.

40

통계청. (2019). 2019.03.22 보도자료: 2018 한국의 사회지표. Retrieved from

http://kostat.go.kr/portal/korea/kor\_nw/1/6/5/index.board?bmode=read&aSeq=373801&pageN o=&rowNum=10&amSeq=&sTarget=&sTxt=

한국과학기술기획평가원. (2019). 의료서비스 로봇.

한국보건사회연구원. (2015). 2015.04.01 보도자료: 보건의료인력 수급중장기 추계 결과

발표. Retrieved from

https://www.kihasa.re.kr/web/news/report/view.do?ano=8611&menuId=20&tid=51&bid=79

#### X. APPENDICES

## Appendix 1. Display UI design























Appendix 2. IF award materials (Presentative Images)





#### Appendix 3. IF award materials (Poster Images)







#### Difficult Self Assessment

Because of the two reasons above, patients find it difficult to check their condition by them-selves, as well as access pro-fessional care at hospitals.

#### & Low Accessibility



## 02 Solution

GOOPI tackles the three aforementioned issues by making data-based diagnoses, customizing programs, and treating several patients simultaneously.

#### Data-Based Diagnosis

Medical staff can check each patient's condition development through GOOPI remotely to give prescriptions accordingly.





#### Customizing Programs

GOOPI provides three different exercise programs depending on each patient's condition. These programs are active, assistive, and passive.

1	Active Exercise	1
S	Assistive Exercise	ŝ
%	Passive Exercise	Ę

#### • Simultaneous Treatment

GOOPI allows therapists to treat several patients at once. This helps to provide more medical service, therefore, increasing accessibility for elbow rehabilitation patients.



# 03

#### Main Components

GOOR's linear structure, which consists of a circle and a square, brings a simple, yet professional feel. The arm support is designed to give the user an intuitive idea of how to position the arm, while the circular part, provides a rotating context.



## **04** How to Use

GOOP's structure enables users to comprehensively rehabilitate both hands with one device by performing various exercises in three directions: horizontal, vertical, and diagonal.



#### Two-handed Design

Due to the adjustable Bottom Rotation, users can perform various exercises with GOOPI to rehabilitate both left and right hands' elbow muscles. The rotational display assists this two-handed design as well.



#### Movement Direction

The ergonomic shape of the Arm Support follows human arm shape, which makes it comfortable to perform various exercises with GOOPI, which includes not only horizontal elbow movements, but also vertical and diagonal ones.



## 05 Scenario

In the treatment process with GOOR potents pass through five stages: (1) first assessment, (2) prescription, (3) rehabilitation avercise, (4) data-based assessment, and (5) recover the 2nd, 3rd, and 4th stages form an iterative cycle, which eventually leads to albow recovery.



## 06 Effectiveness

Elbow rehabilitation patients can improve their well-being and quality of life by regularly exercising with GOOPI, thus, re-gaining their ability to do everyday activities on their own.



#### Before GOOPI

Elbow rehabilitation patients suffer from restricted arm movement, which hinders their well-being and autonomy in terms of performing everyday activities, since many of them often require repetitive elbow movements.

#### Rehabilitation with GOOPI

By performing various exercises with GOOPI, elbow rehabilitation patients can improve their elbow conditions from home easily.





#### After GOOPI

Elbow rehabilitation patients can freely perform basic activities in their day-to-day lives. These activities include movements involving the rehabilitated elbow muscles (ex. eating, raising objects, cleaning, etc).

## **07** Social Impact

GOOP's small and compact size allows patients to use it anywhere. After eating a medi at the table, while working at the dask or watching TV in the living room, users can do the prescribed rehabilitation training whenever and wherever they want. Even at small medical centers, GOOPI doesn't take alt of space to perform rehabilitation exercises in the same place at the same time.





Appendix 4. Product CAD drawings




























Appendix 5. Application for a patent

UNIST "발명인터뷰제" 평가 보고서				
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(대리	인 관리번호)	(PI	(PD20-380)	
11-1	명이 며치	사기계화키근 자키		
기술의 대하여	비밀을 유지	이할 것을 확약합니다	7.	
대하여	비밀을 유기	시할 것을 확약합니다 2020년 11월	ት. 17일	
기술의 대하여 성명	비밀을 유기	지할 것을 확약합니다 2020년 11월 평가분야	ት. 17일 전공분야/자격사항	서 명

본 평가는 UNIST의 직무발명에 대하여 발명인터뷰 및 기술평가를 통한 특허 심의기능 강화를 지원 함과 동시에 특허출원 단계에서부터 우수 발명을 체계적으로 발굴하고 발굴된 기술의 가치를 제고 하기 위한 기초자료로 활용하는데 그 목적이 있으며, 다른 용도로는 사용될 수 없습니다.

## I. 평가대상 발명 개요

발명의 명칭	상지재활치료 장치	
기술 분야	기계 / 제어	
대표 발명자	박재한	
평가일자	2020.11.17.	
기타 특이사항	선행기술조사보고서 첨부	

## Ⅱ. 평가결과

	기술 완성도(T1)	<u>9</u> 점(만점: 10)	
권리/기술성(T)	기술의 속성(T2)	<u>9</u> 점(만점: 10)	
	기술동향과의 부합성(T3)	<u>8</u> 점(만점: 10)	
	기술의 수명주기상 위치(T4)	<u>8</u> 점(만점: 10)	
	권리의 강도(T5)	<u>8</u> 점(만점: 10)	
시장성(M)	소계	_42_점(만점: 50)	
	상용화 가능성(M1)	<u>9</u> 점(만점: 10)	
	산업적 파급효과(M2)	<u>8</u> 점(만점: 10)	
	시장의 성장성(M3)	<u>9</u> 점(만점: 10)	
	기술수요 가능성(M4)	<u>9</u> 점(만점: 10)	
	시장진입 용이성(M5)	<u>8</u> 점(만점: 10)	
	소계	<u>_43_</u> 점(만점: 50)	
총계	<u>_85</u> 점(만점: 100)		

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