Master's Thesis

Ergonomic Evaluation and Design Process for Healthcare Products : A Case Study of Patient Transfer Design

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Approved by

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ABSTRACT

Inpatient falls are a critical issue in healthcare facilities. Up to 30% of such falls result in injury, which may in turn lead to impaired rehabilitation and co-morbidity in mental and physical health. One of routine activities that poses high risks of falls of patients is a within-facility patient transfer. Within-facility patient transfer is a high-risk task not only for patients but also for care-givers. Care-givers frequently transfer patients from bed to a wheelchair or wheelchair to bed manually, and it can cause musculoskeletal injuries of the care-giver. Various aid devices such as a powered patient lifter have been introduced to improve the safety of patient transfer and to assist care-givers, but they have not been widely used due to their bulky size and slow operation.

To overcome such problems, one of medical robot manufacturers in Korea developed the functional prototype of a semi-powered patient lift and transportation device. The device is equipped with a forward leaning seat to allow easy loading and unloading patients without manual lifting. Since the functionality and usability of the prototype has not been evaluated, it was necessary to conduct thorough evaluation both in fields and laboratory and to come up with redesign goals and strategies. Therefore, this study was aimed to evaluate the functionality and usability of the prototype using various ergonomic evaluation approaches and to redesign the prototype based on the results of the evaluation.

In the evaluation process, various methods have been used to understand and identify care-givers' needs, interaction patterns between the prototype and patients, and safety issues when operating the prototype inside and outside patient rooms through user interview and field observation studies at hospitals. To evaluate the biomechanical advantages over traditional manual transfer methods, a human-subject experiment was also conducted with quantitative assessment of muscle activities, foot reaction forces and transfer time. Then, using the findings of the evaluation, redesign ideas have been made and the prototype has been upgraded to reflect the ideas. The upgraded prototype was evaluated again at hospitals to confirm whether the changes improved the functionality and usability of the device.

In this paper, detail procedures for the evaluation and redesign are explained, with related problems and challenges. Also, some ideas for improving the evaluation/redesign processes for healthcare products are proposed for future research and development.

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1. INTRODUCTION

1.1 Research Background

1.1.1 Fall accidents at healthcare facilities

Falls of inpatient are critical problem in hospital. It can be considerably dangerous because the frequency of falls is much higher in hospital than for people living in their own homes (Hayes, 2004). The study of Joint Commission on Accreditation of Healthcare Organizations reports that the fatal falls account for 4.6% of the sentinel events (Beyea, 2005). According to the study of Kang et al, 59% of fall occurred in the patient room when they move without assistance of care-givers (Kang at al., 2015). Thus, many research analyzed the factor of falls and fall-related injuries in hospital (Healey et al., 2004; Kinn et al., 2001; Perell et al., 2001). Up to 30% of such falls may result in injury, such as from bruises and minor injuries to severe wounds of the soft tissues and bone fractures, all of which may in turn lead to impaired rehabilitation and co-morbidity. Falls are also associated with higher anxiety and depression scores, loss of confidence and post-fall syndrome. They are associated with an increased length of hospital stay and higher rates of discharge institutional care over a long period. Not only is it costly for individual patients and for hospitals, but it may result in anxiety among complaints or litigation from patients' families.

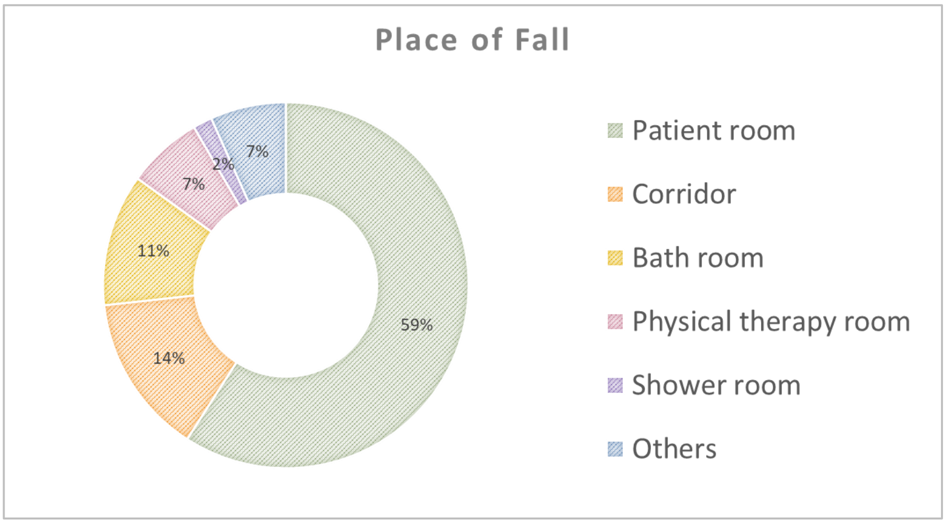


Figure 1. Place of Fall (Retrieved from Kang at al., 2015)

1.1.2 Patient transfer and work-related musculoskeletal disorders of nursing personnel

Fortunately, falls have considered as a predictable and preventable accident. Hospitals used to diagnose fall risk of each patient by using fall risk assessment tool and take care of them who are in a group of particularly vulnerable to for it more specially. In addition, hospitals recommend that they should be assisted by care-givers whenever they move.

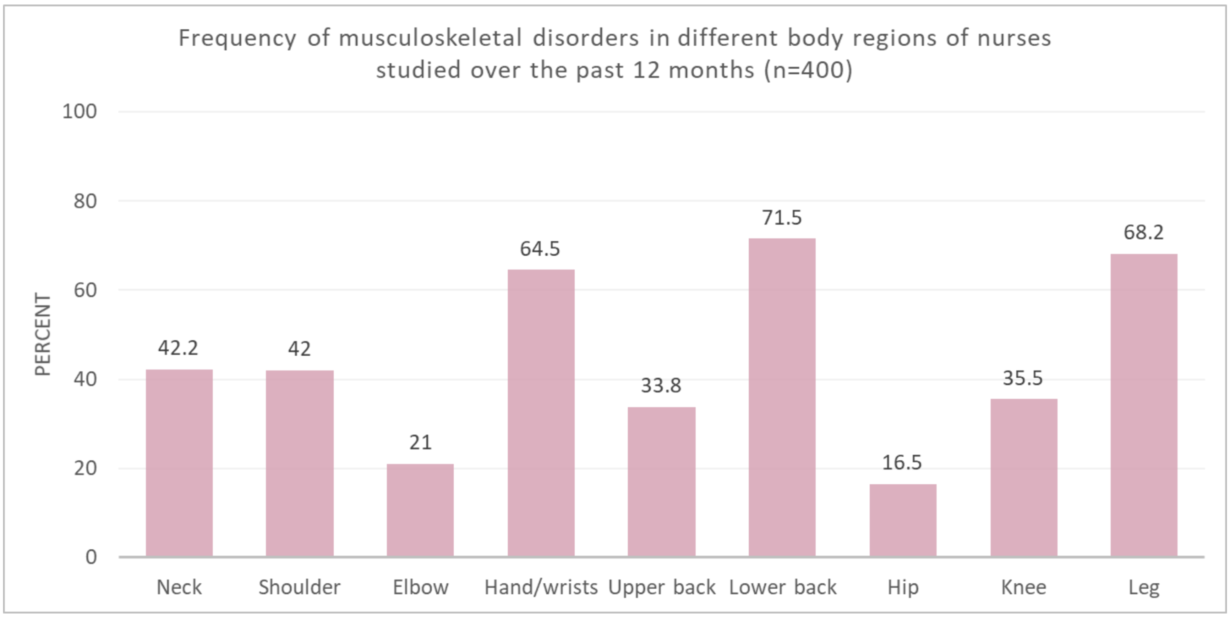


Figure 2. Frequency of musculoskeletal disorders in different body regions of nurses studied over the past 12 months (n=400). (Retrieved from Avedini at al., 2015)

Therefore, the most important task of nursing personnel is patient transfer. Especially, the second ranked one among the more frequently reported tasks are transferring the patient from bed to wheelchair or vice versa (Knibbe and Friele, 1996). Likewise, wheelchair is the most used assist device in hospital because it is light in weight and easy to use and store. However, it should require manual lifting. In real hospital environment in Korea, the number of transferring between bed and wheelchair is over 40 times and it included most of the harmful factors of work-related musculoskeletal disorders (WMSD), such as high repetitiveness, awkward posture, and use of strong force. According to previous research about WMSD of nursing personnel, prevalence of low back pain reported 85.5% of worker when they transfer manually without assist equipment. The study by National Institute of Occupational Safety and Health (NIOSH) reported that the prevalence of WMSD among nursing and care facilities was 3.2% that is the highest among other occupational groups. The 12-month prevalence of back pain among nurse (35-80%) exceeds that range found for other occupational groups (27-65%) (Burdorf, 1992).

1.1.3 Assist devices for WMSD prevention in patient transfer

Many transfer assist devices have been developed in order to aid transfer task more safely and prevent WMSD of nurses. There are various types of non-powered devices, such as a transfer belt, a sliding board and sheet, pivot disc, etc. Nevertheless, hardly have they used in Korea when transferring because of burdensome and time-consuming process.

Figure 3. Types of patient lift. Clockwise from top left: a mobile floor lift, a fixed bed lift, a fixed ceiling lift, a free-standing track lift, a fixed bed lift, and a sit-to-stand lift.

Besides those, the most widely used transfer device in hospital is a patient lift (Figure 3). It is stated by law that general hospitals should equip a patient lift at each ward. It is used to assist care-givers to hoist patient with limited mobility from a bed, wheelchair, shower, or toilet and safely transfer them to a different location. There are a mobile floor lift and stationary overhead lift using electric, hydraulic or manual power. It can reduce mental and physical stress of both patient and nursing personnel.

Despite there are diverse types of patient lift, they still require that complex and time-consuming procedures. Also, it should be moved slowly and require other assistant to prevent from swaying which may cause dizziness while transferring. That is, two or more care-givers are required for transferring one patient by using the lift. Hence, in real hospital environment in Korea, they are hardly used for transferring task.

Although there was an abundance of research which recommended use of assistive device for reducing fall risk of inpatient and WMSD of nurse, existing devices have critical limitation as listed above. To be useful in real environment, a new device or method needs to be introduced.

1.1.4 New patient transfer device

Figure 4. CarryBot (Manufacturer: Hyndai Heavy Industries Co., Ltd., Korea)

Name	Carrybot
Driving Mechanism	Powered wheel mechanism
Weight Support Mechanism	2 DOF(Tilting + Elevation)
Maximum Load	150kg
Moving Speed	1.1 ~ 1.7 km/h
Available Time	Standby mode: 48 hours / Driving mode: 4 hours
Safety Device	Seat belt / Handle For Patients/ Emergency Stop Button

Table 1. CarryBot Specification

Thus, Robotics Research Department in Hyundai Heavy Industries Co. developed a patient lift and transportation device. The new device, named ‘CarryBot’, is equipped with a powered drive mechanism and applied new transferring mechanism mimicking piggyback by a 2 DOF robot system. Two linear actuators can adjust the height and angle of seat fitted with hospital environment, such as bed, toilet and wheelchair. According to reduce the difference of height between two products, it enables to transfer a patient not by lifting but by sliding toward the seat and carry the patient while seated. Additionally, the figuration of seat was designed ergonomically by empirical analysis with researchers in laboratory. Thus, it was expected that more secure, faster and comfortable transferring.

1.2 Potential problems of new patient transfer

There are potential issues that limit the actual use of the CarryBot at hospitals. The main cause is the lack of proper user research. Specific issues are listed below:

First, target users have not been clearly identified and studied. The CarryBot developers did not explicitly define the users of the robot. They assumed that it would replace conventional wheelchairs at hospitals. However, the CarryBot cannot be used for some patients whose abdomen or chest areas are treated. Hip surgery patients cannot also use the robot. In the former case, the thorax should not be pressed, and in the latter case, the leg angle should always be maintained at 15 degrees or more. Therefore, the target users should be further subdivided and investigate their exact problems and needs.

Second, design requirements were invalid. There are two group of users; one is patient and the other is nursing staff. However, developers considered opinions from doctors and nurses at general hospitals at the design phase. They have not considered how nursing staff or other care-givers transfer patients at hosiptals. Design requirements must include the needs for all users and environments. Otherwise, the design direction may be incorrect.

Third, the specification of robot was set incorrectly. Developers have tested their original prototypes with healthy 30-40 male researchers who pretended patients and care-givers. For this reason, the final specification of the robot was not appropriate for real patients and care-givers. Particularly, it is necessary to reflect the characteristics of patients who are sensitive to seat friction or pressure and have extreme physical conditions compared with the general public. Otherwise, it is inconvenient to use and can cause injury.

1.3 Research objectives

The main objectives of this study were to introduce how we have redesigned the CarryBot through field and lab evaluation processes and to propose, based on our experiences, a better approach for designing healthcare equipment, specifically for patient handling and aid devices. Below steps were followed to come up with the proposed process.

First, we quantitatively evaluated whether the piggyback design of the CarryBot can lessen physical loads of nursing personnel during patient transfer. The new design was originally suggested to allow easy and fast patient transfer, but it has not been confirmed during the design and development phases. According to the results of quantitative evaluation, we have setup redesign specifications and applied them to the upgrade processes.

Second, we conducted actual user research, including field user survey and observations at hospitals to identify problems and issues of using the CarryBot at hospitals. The developers have not conducted proper user research and field evaluation. It was not known how real users use the device and how they interact with the device at patient rooms or other places at hospitals. Through our user research and field evaluation, we have identified key requirements and goals for redesign.

Third, we have studied various scenarios of user-product interactions and product-environment interactions. We have collected anthropometric data of target users, reviewed existing regulations and guidelines, and measured dimensions of hospital patient rooms to determine detail specifications and dimensions of the redesigned CarryBot.

1.4 Full Flow Chart of Research

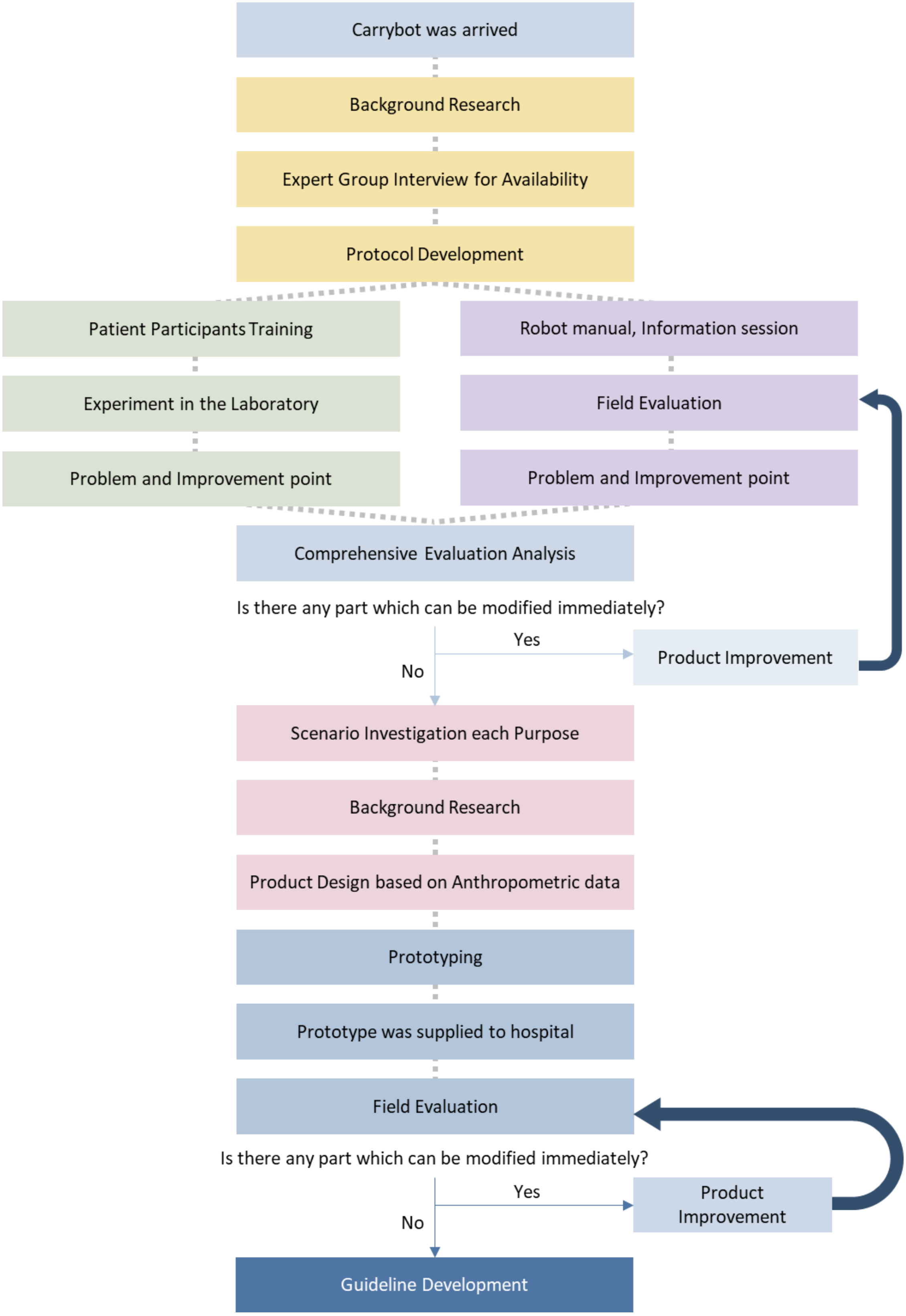


Figure 5. Full flow chart of the research

2. REDESIGN PROCESS

2.1 Background Research

Background research was necessary because there is no experience in terms of patient transfer product including CarryBot before. This procedure aimed to examine background knowledge with regards to general hospitals, patients, and transfer assistive devices and develop a user protocol in accordance with CarryBot which proposed new mechanism.

2.1.1 Guideline Research about Assist devices in the hospital

There are many types of devices which can assist nursing personnel when they transfer patients in the hospital. Among them, the most used products were picked out and the purpose and user manual were investigated. The investigated devices can be divided broadly into two groups such as manual and powered devices.

Figure 6. Assist devices used in general hospitals and nursing home.

Figure 6 shows manual devices, such as a wheelchair, transfer board, sliding mat, and gait belt. These products are used with wheelchair, that is to say that they assist transfer between bed and wheelchair. For example, the transfer boards, also called sliding boards, help individuals move from one location to another and prevent slips and falls. It also aids caregivers in moving others with limited mobility, while reducing their own risk of leg or back injury. Likewise, the gait belt and pivot disc are used when a nurse transfers a patient between wheelchair and beds for preventing falls and musculoskeletal injuries.

The most used powered assist device is a patient lift (Figure 3) because it is defined by law that general hospital should equip with the patient lift each ward. The mobile lift of floor based lift is best-selling item because it is cheaper than other design and is able to be used in various location with a number of patients in and out of the ward.

2.2.2 Expert focus group interview

This interview was aimed to collect the information related to the needs and expectations of users (nursing personnel) and environment (general hospital) and to conduct a brief usability evaluation with regard to applicability. Four nurses who completed curriculum about patient transfer and had experience as a nurse practitioner over 1,000 hours were recruited from Ulsan University in Korea. Two nurses participated in the interview, and a total of two FGI sessions were conducted. The experimental environment was set included a motorized adjustable bed, shower chair which has a similar dimension with toilet, and various assist devices such as a wheelchair, CarryBot, transfer board, sliding mat, and gait belt.

Figure 7. Expert interview environment set up. The shower chair was placed as a substitute for the toilet and the difference between two products was within 3cm.

The interview was consisted of question and answer, discussion, demonstration sessions with a participant who played a role as an elderly people who has risk for falls due to the lack of strength and balance. The entire interview was recorded for two hours. The basic questions were prepared in advance for a smooth interview and consisted of applicability, additional purpose, user manual development and training, improvement ideas and precautions.

Figure 8. Nurses demonstrated patient transfer in various ways during expert focus group interview

The results of the interview were as follows.

- Piggyback designs were not suitable for patients who underwent surgery on the upper body because they caused unavoidable pressure around the breast and abdomen.
- It can be useful at home as well as at home when it is light.
- Current operating method was not intuitive, so that nursing personnel have to take time to get used to it.
- It could be used not only within, but between wards such as patient room, toilet, shower room, therapy room and etc.

- Almost patient transfer is managed by porters and there is a day schedule. Thus, when a patient wishes to move except for transfer schedule, he/she must wait until the porters have time.

2.2.3 User manual development

Since CarryBot proposed a new mechanism, piggyback, it was necessary to develop a proper manual how to safely move the patient in a proper holding way. It was made referred to many assist devices manual and based on the results of focus group interview. This included the components, operation method, transferring method and precautions.

Figure 9. Process of protocol development.

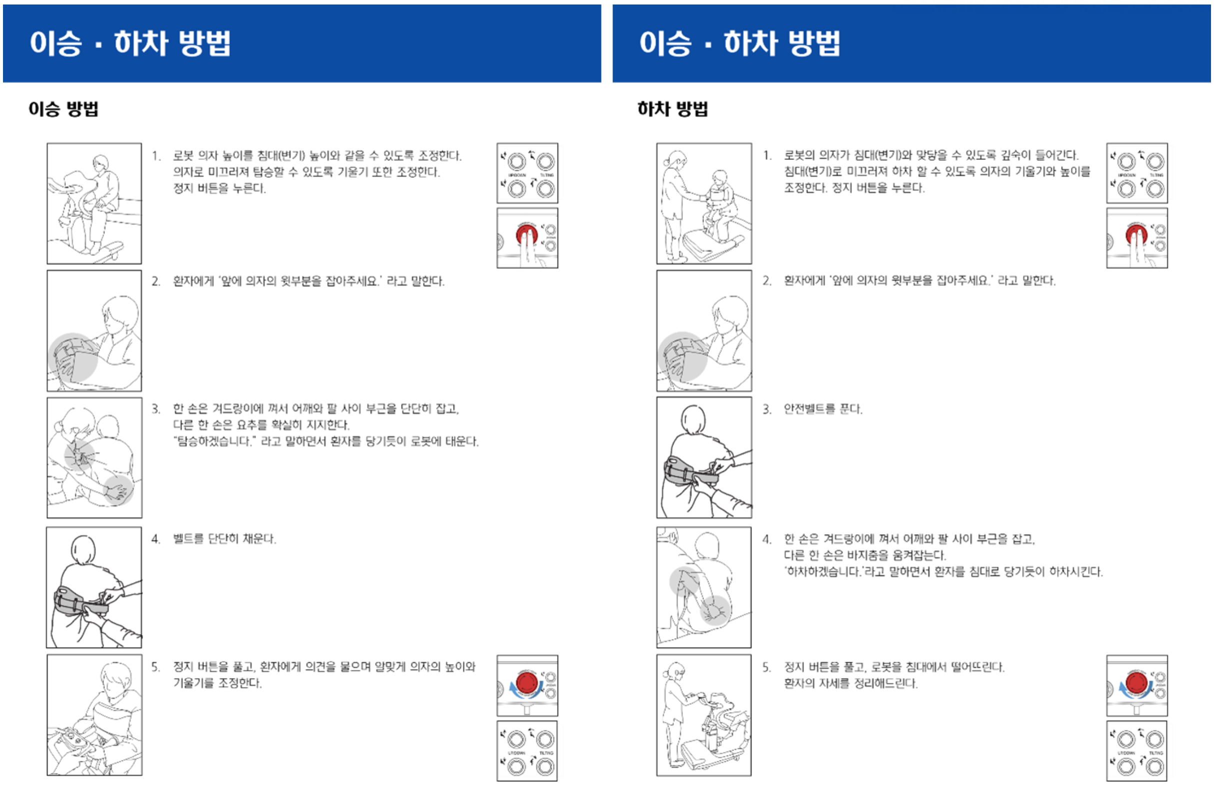


Figure 10. Transfer methods between bed and the robot in the user manual

Figure 11. Illustration of CarryBot in the user manual included description of each components, controller button, and operation methods.

2.2 Experiment for effectiveness verification of piggyback mechanism

2.2.1 Objectives

CarryBot suggest new transferring mechanism; piggyback. The robot provided seat with powered height and angle adjustability and it helped to transfer a patient not by lifting but by sliding toward the seat due to diminish difference between two objects. However, new mechanism had not been verified whether the method provides good assistant and ergonomic advantage to nursing personnel than wheelchair or not. The experiment was conducted to quantitatively compare usability between CarryBot and wheelchair and investigate the excellence using muscle activity, plantar pressure and transfer time.

2.2.2 Methods

Experimental design

The experiment was designed with multiple variable and multiple levels. The independent variable is the patient handling equipment, wheelchair and CarryBot, and type of task, loading and unloading. There are four condition; bed to robot, robot to bed, bed to wheelchair and wheelchair to bed.

Dependent variable is upper body muscle activity, plantar pressure of nurse and transfer time. To collect quantitative data of muscle activity, electromyographic (EMG) signals were obtained bilaterally from eight muscle sites on upper body. The muscle sites were selected to assess the relative physical demands of patient handling at common sites of injury such as neck, shoulder, low back, and upper arm without disturbance on transferring holding method. Mean, max and cumulative values were used to assess average levels of muscle activity, peak demands on the muscle and total amount of muscle activity during tasks, respectively. Plantar pressure was obtained using insole sensors in same slip-on which has flat insole and outsole. These data were used to analyze how much patient weight were applied to nurse during tasks. The pressure of left, right, and sum of both feet were used to assess the load and imbalance. Transfer time were measured from start to end each task for how long it takes. The time are closely related with product usability because time saved means less fatigue accumulation.

Participants

Twenty females with no previous history of musculoskeletal disorders were recruited for the role as a nurse. All participants were not a nurse but university students at Ulsan National Institute of Science and Technology who had not be learned how to handle patients (Table 2). A patient participant was temporarily hired for this research and had practiced the role for three months. The patient was assumed to elderly who has risk for falls due to the lack of strength and balance.

Role	# of Participants	Age	Height, cm	Weight, kg
Nurse	20	22.2 (1.5)	158.0 (7.5)	54.1 (6.6)
Patient	1	22	160.0	57.0

Table 2. Subject demographics. Mean(SD) are presented.

Manually transferring from bed to CarryBot

CarryBot was placed perpendicular to the bed and the wheels were locked. The height of seat was adjusted same with that of the bed. The nurse stood near the patient with feet shoulder width apart then left hand grasped the patient under the axillae around upper arm and the other hand held tightly their shirts and pants at the same time. Count three then the nurse pushed the patient toward the bed with zigzag motion until they seated comfortably on the bed.

Manually transferring from CarryBot to bed

The basic setting, such as height, angle, and placement, of CarryBot was same as the procedure from bed to CarryBot. The nurse stood near the patient with feet shoulder width apart. There is a little difference to the grip that one hand grasped the patient under the axillae around upper arm and the other hand supported patient's clothes around low back. Count three then the nurse pulled the patient toward the robot. Lastly, the angle of seat was leaned forward until the patient feels comfort.

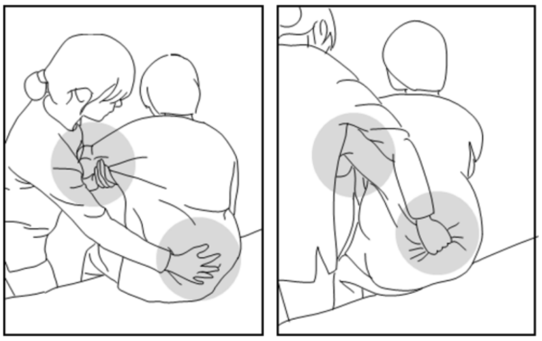


Figure 12. Grip during transfer to/from CarryBot

Manually transferring from bed to wheelchair

The wheelchair was placed with 45 degrees to the bed and the wheels were locked. The footrest was put in an upright position. The nurse stood facing the patient with one food facing the patient and the other foot in the direction of the move. Then the nurse got close up to stand as close as she can to the patient. Then, bent her knees, keep their back straight and grasped the clothes of patient around patient's low back with two hands. In synchronization using a gentle rocking motion they pulled the patient toward themselves, shifted their weight to the foot facing the direction of the move and pivoted to avoid twisting. Lastly, nurse should put them down slightly and push them keeping the grip until the patient leans back enough in the wheelchair.

Manually transferring from wheelchair to bed

The procedures used for transferring patient from bed to wheelchair were very similar to those used for transferring from wheelchair to bed. At the last step, nurse put seated deeply a patient at the bed with zigzag motion.

Testing protocol

Participants were provided with a written consent form describing the research protocol that had been approved by the university's Institutional Review Board. The participant was asked to review the form and ask any question about the experiment prior to signing. The experimenter measure the height and weight of participants. They learned and practiced enough how to move a patient and the use of equipment via an instructional video and from an experimenter.

Prior to locating EMG electrodes, the dead cell on eight muscle sites were removed with ethyl alcohol swab and the hair were shaved if necessary. EMG electrodes were placed over both sides of biceps brachii (BB), lateral deltoid (LD), upper trapezius (UT) and elector spinae at the level of L4 (L4). After a few minutes of rest, the reference EMG which meet the following requirement were collected for 30 seconds; (1) stand straight up, (2) natural foot width, (3) face forward, (4) no movement, and (5) relax. For each muscle, the value that elicited mean of middle 10 seconds data was used for normalize the trial data for the given muscle.

The participant changed their shoes to the experimental footwear inserted insole sensors. Prior to data acquisition, the pressure sensors were calibrated to the participant's weight.

Figure 13. The placements of EMG and insole sensors

The four transferring were learned by the printed protocol and demonstration session, then participants were given much practicing time for 20 minutes. When they completely learned the techniques, three minutes of rest was provided before main experiment recording.

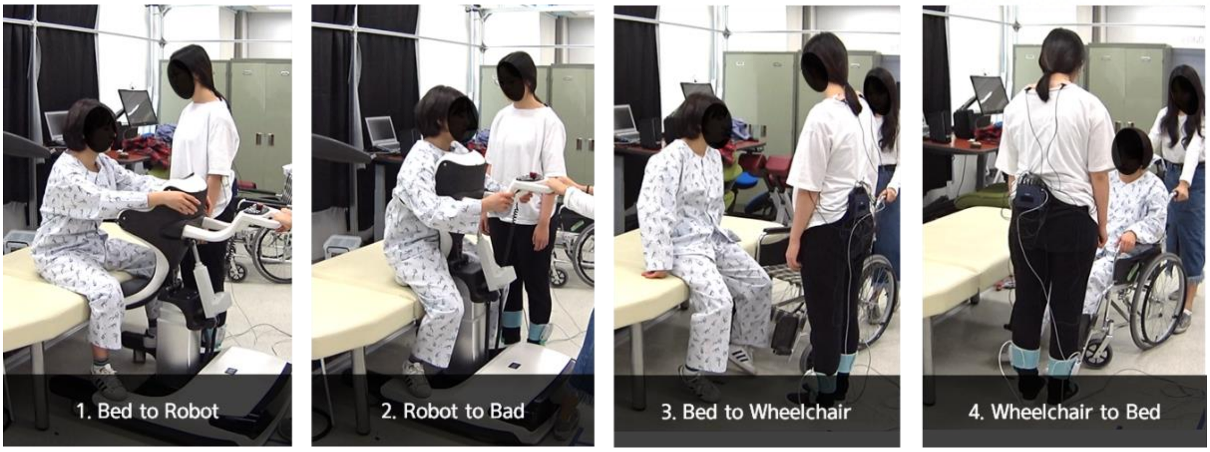


Figure 14. Start positions each four conditions

Four experimental conditions were proceeded with the sound of ‘start’ to ‘end’ and repeated 3 times (total 12 trials). All data were recorded from ‘start’ to ‘end’ and the order of conditions was randomized. The pace of participant’s movement was not controlled, but they were asked to move naturally not fast or slow of purpose. At least 1 minute of rest was provided between each trial. The total time required from participants was 1 to 1.5 hours, which included the consent process, task practice, EMG set-up, and data collection.

Data collection and processing

EMG data were collected at 2048 Hz, using a multi-channel EMG system (Flexcomp system, Thought technology, Canada). The data were rectified and band pass filtered (10Hz high pass, 500Hz low pass and 2nd order Butterworth filter). Then, the data were notch filtered at multiples of 60 Hz. These filtering were processed through a MATLAB program. The task EMG data for each muscle were normalized by reference EMG. Therefore, the unit of normalized EMG would be identified as how much times muscle activity are increased based on reference EMG.

The plantar pressure data were obtained at 100 Hz, using the F-Scan system (Tekscan Inc., Boston, USA). Average and peak values were extracted. Transfer time was measured in the EMG system.

For each trial, mean, max and cumulative values were determined for each muscle. The mean EMG indicates the average of muscle activity for task. The max EMG means the peak value of the moment when the patient's weight shift to nurse. The cumulative EMG considered task duration so it means the total usage of muscle during the task.

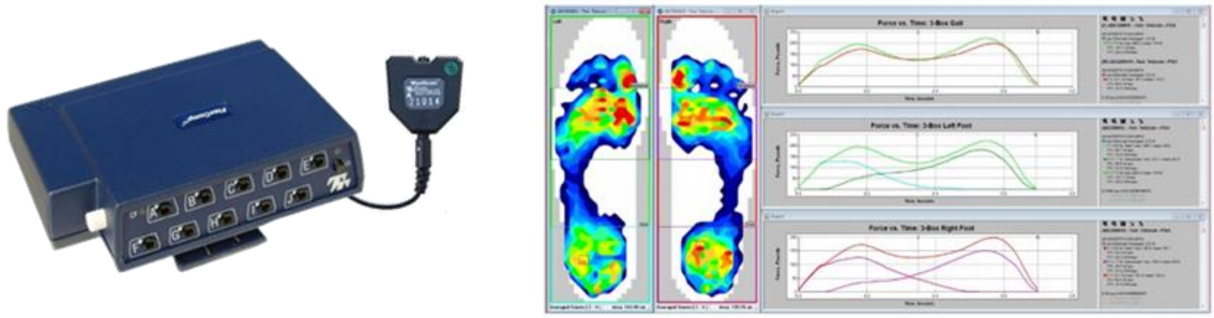


Figure 15. Flexcomp EMG system and F-Scan software

Statistical Analysis

The normalized EMG data of getting on and off tasks were analyzed separately. ANOVA procedures were used to examine the effects of type of patient handling equipment on muscle activity. Pairwise comparisons of conditions were conducted with the Tukey post hoc test.

2.2.3 Results

EMG

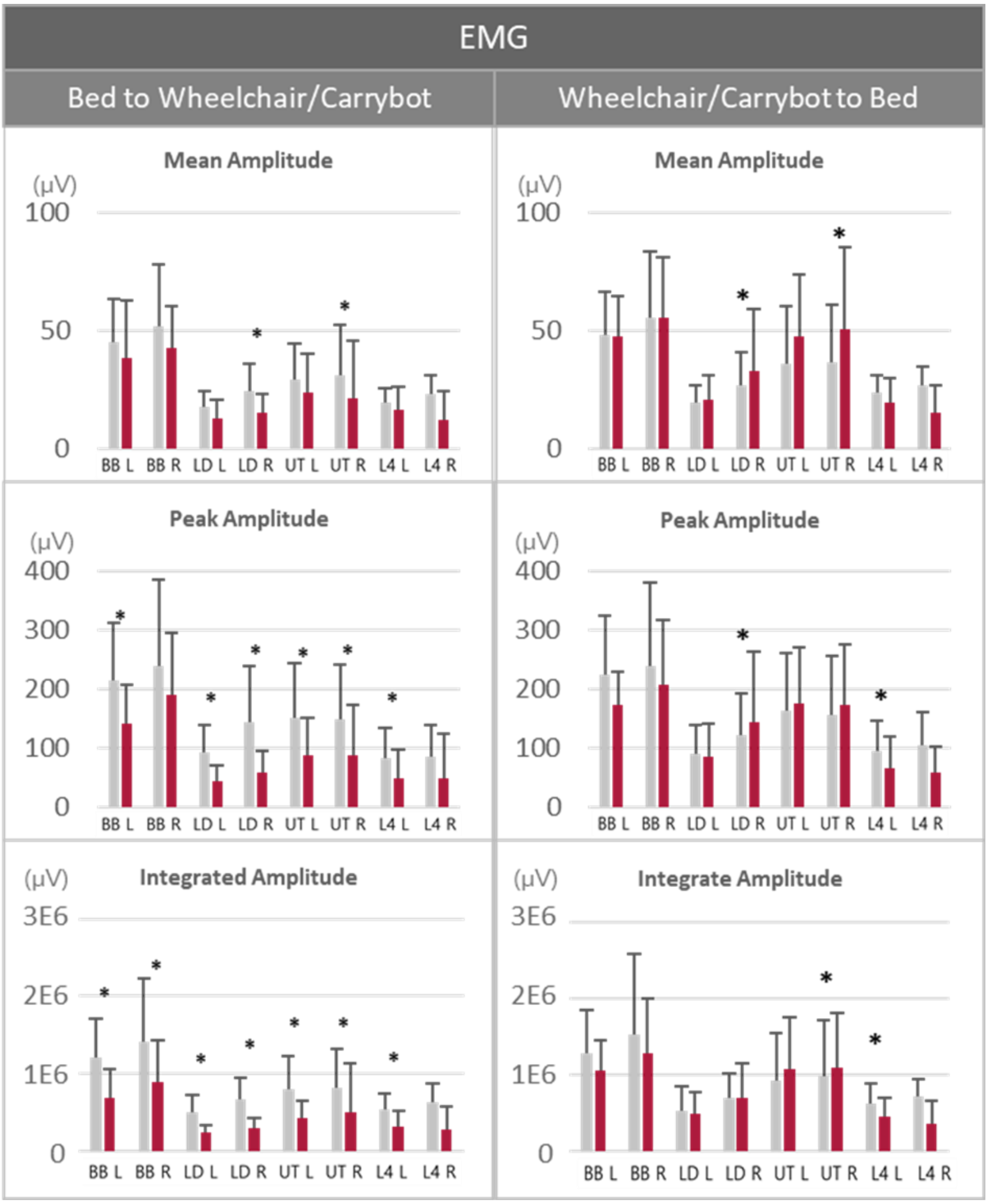


Figure 16. Mean, peak, integrated EMG amplitudes. Left column shows the result of task from CarryBot/wheelchair to and right column shows the one from bed to CarryBot/wheelchair.

Notes: F statistic degree of freedom = (1,188). BB L left biceps brachii, BB R right biceps brachii, LD L left lateral deltoid, LD R right lateral deltoid, UT L left upper trapezius, UT R right upper trapezius, L4 L left erector spinae of L4 level, L4 R right erector spinae of L4 level. * Significance level at $P < 0.05$

	Bed to robot/wheelchair			Robot/wheelchair to bed		
	Mean EMG	Max EMG	Cumulative EMG	Mean EMG	Max EMG	Cumulative EMG
BB L	0.05	4.15	7.28	0.11	2.19	1.44
	0.830	0.044*	0.008**	0.746	0.141	0.233
BB R	1.30	1.62	7.09	0.18	0.46	0.17
	0.256	0.205	0.009**	0.669	0.497	0.683
LD L	1.42	20.03	24.44	0.07	0.55	0.63
	0.236	0.000**	0.000**	0.793	0.459	0.430
LD R	11.27	24.75	33.13	5.44	5.15	1.58
	0.001	0.000**	0.000**	0.021*	0.025*	0.212
UT L	1.36	8.00	14.02	2.64	0.13	0.55
	0.247	0.006**	0.000**	0.107	0.724	0.461
UT R	8.63	18.26	14.73	8.47	3.19	4.35
	0.004**	0.000**	0.000**	0.004**	0.077	0.039*
L4 L	1.79	17.70	27.92	2.33	9.98	6.93
	0.184	0.000**	0.000**	0.130	0.002**	0.010*
L4 R	0.15	1.32	0.08	0.62	0.41	0.55
	0.696	0.253	0.780	0.433	0.524	0.458

Table 3. Outcome of statistical analysis of mean, max and cumulative electromyographic data. F-values (top) and p-values (bottom) are provided.

* Significance level at $P < 0.05$

** Significance level at $P < 0.01$

For ‘bed to robot/wheelchair’ tasks, the effect of equipment was highly significant on two, six, and seven muscles, for mean, max, and cumulative EMG. Except L4 R, each comparison. The robot with wheelchair showed significantly lower muscle activity when the robot was used ($p<0.05$). In contrast to this, for ‘robot/wheelchair to bed’ tasks, the effect of equipment was Significant on only two muscles for all results. Exceptions to L4 L, the EMG for LD R and UT R, when the robot was used elicited higher activity than wheelchair ($p<0.05$).

Significant effects of transfer method on mean EMG amplitude were found on the right lateral deltoid and the right upper trapezius muscles (Fig. 14). When transferring from bed, participants used the two muscles significantly more when using the robot. To the contrary, when transferring to bed, participant used the same muscles significantly less when using the robot ($p<0.05$).

Difference in the peak and integrated EMG between the two methods was more pronounced when transferring to bed. When using the robot, significantly less peak and integrated EMG values were observed from all muscles but the right biceps brachii and lumber extensor muscles ($p<0.05$).

Plantar pressure

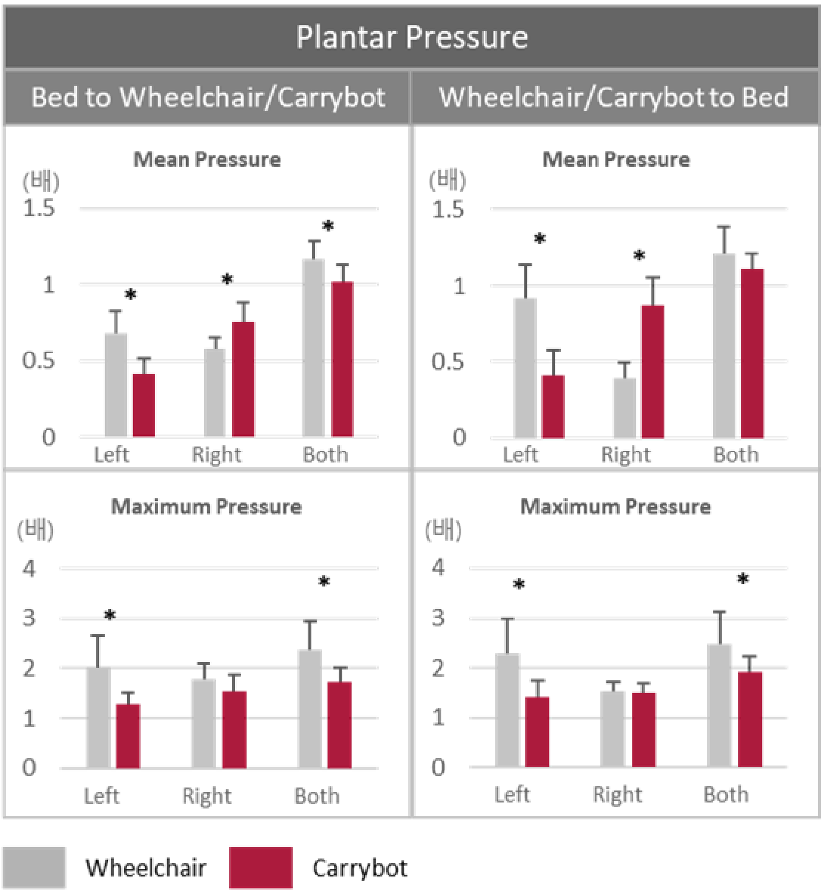


Figure 17. Mean and maximum plantar pressure each left feet, right feet and sum of foot. Left column shows the result of task from bed to CarryBot/wheelchair and right column shows the one from CarryBot/wheelchair to bed (* p<0.05)

Significant effects of transfer method on mean plantar pressure were found on left, right, and both. Except to right plantar pressure on peak pressure, the load from patient weight were decreased when transferring using CarryBot. To the contrary, all peak pressure was decreased when using CarryBot. There are significant differences of left feet than right. According to both pressure, total load from patient weight was decreased.

Transfer time

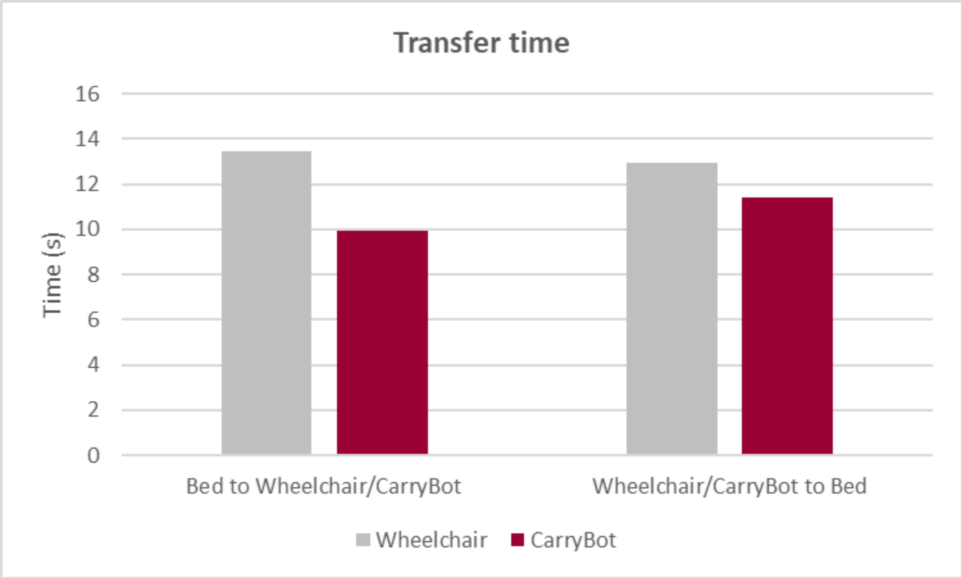


Figure 18. Mean transfer time

There is significant difference between transferring by wheelchair and CarryBot. When transferring from bed to CarryBot, participants spent 9.9 sec, while transferring to a wheelchair tool 3.6 sec more in average. Similarly, it took 11.4 sec in average when transferring from the robot to bed, and transferring from the wheelchair took 1.6 sec more. It may not seem to have much of a benefit. However, there is a great effect on reducing fatigue accumulation in the long term.

2.2.4 Conclusion

This study has shown that CarryBot and wheelchair had a variety of differences of 20 participants in upper body muscle activities, plantar pressure and transferring time. As the result, less force was used and less weight from patient was dealt when using a robot to load a patient when using a wheelchair. In contrast, when the robot was used have higher muscle activity than wheelchair during getting off trial. This result suggests the robot should be modified more effectively especially getting off task.

2.3 Field Evaluation

2.3.1 Objective and field training session

In the previous study, the design requirements and specifications were determined through an empirical analysis in the research team consisted of a few medical personnel. Thus, it was hard to reflect some problem and needs of actual user. In this procedure, user research included ergonomic advantage and usability evaluation of the robot has been conducted to come up with design improvement ideas by using the prototype. More specifically, this process was aimed to understand user characteristics, environment, tasks and workflow of the robot, then propose comprehensive problem and needs for design requirements.

Prior to qualitative field evaluation, training session was proceeded in the three hospitals. Total 85 medical staff were participated from two hospitals and one nursing home in Korea. It consisted of manual distribution, demonstration, and question and answer session.

Figure 19. Field education consisted of manual distribution, demonstration and Q&A sessions

2.3.2 Methods

Six nursing personnel, two porters, two nursing aids, and two nurses, were recruited from two general hospitals and one nursing home in Korea. Hospitals included one respiratory medicine ward and orthopedics ward of two large general hospitals which have over 1500 beds. They routinely transferred patient between bed and wheelchair over 40 times per day. All participants were fully trained and instructed in terms of CarryBot in advance. The robot was provided to each hospital and the participating nursing personnel used the robot for two weeks for their routine patient transferring. During the period, they recorded their and patient's opinions on a diary chart and were interviewed individually twice a week regarding pros and cons of the robot. The key contents of interview are as follow.

- Purpose and Problem by usage
- Character and suitability for patient, nursing personnel, and environment
- Storage problem
- Ease of use
- Price and Design

2.3.3 Results

In addition, they were shadowed by experimenters in order to observe how they use the robot for their routine patient transfer and discover potential problem and needs. The shadowing was partially recorded without patient's portrait rights. There are similar feedback and opinions regarding prototype from general hospital and nursing home (Table 4). In addition, the result was classified the design factor and components.

	General Hospital	Nursing Home
Feedback	The seat's forward-looking seat design and height adjustment possibilities were positively assessed by the patient, assisting the nursing workforce without manual lifting. Very little force when transferring over long distances. It was difficult to get into the hospital because it was bulky, slow, heavy, and difficult to maneuver. It has contributed to a more sophisticated improvement of the image of the hospital.	The seat's forward-looking seat design and height adjustment possibilities were positively assessed by the patient, assisting the nursing workforce without manual lifting. The forward tilted seat design allows nursing staff to move the elderly more easily and safely than a wheelchair. The dimensions of the sheet must be modified. There were many very weak elderly people in the nursing home. Minor pressure and friction can cause pain.
Opinion	Once the adjustable paper size has been developed, it can be used in pediatric wards. The robot should be mounted on the IV stand (drip stand).	In a typical nursing home, a small robot without a power drive system is suitable because there is little long-distance movement.

Table 4. Feedback and opinion from general hospital and nursing home.

2.3.4 Direction of design improvement

There are various problem and user needs derived from the field evaluation. In conclusion, the direction of design improvement could be summarized as follow.

First, all components which was directly contacted with patient must be ergonomically designed. Especially, seat, seat belt, and other components can cause painful pressure on the patient due to improper dimensions, so patient body size must be considered. Therefore, all dimension of components should be determined by considering anthropometric data such as hip width, breast width, etc. In addition, appropriate accessories should be added to induce stable and comfortable neutral posture during transferring. Since user is patient not healthy person, the materials and shape of the robot should be determined accordingly.

Second, there are many problems in the control part. Transferring by CarryBot took twice time than wheelchair and it can cause to be reluctant to use it. Thus, the speed must be increased to at least current transferring speed by wheelchair. Additionally, it should equip with components for prevention of collision caused by increasing speed such as a warning horn, bumper etc. The controller provided less elaborate maneuver that caused anxiety to patient. It needs to be improved so that it can run more smoothly.

Third, the overall size and weight, which directly affect the applicability, must be reduced. Although the difference in size between the robot and the wheelchair, CarryBot, which needs to be operated with a joystick, is too hard to use in tight room sizes. Another reason was nursing personnel were not familiar with powered control system and it could lead to an accident such as collision and falls. Heavy weight, nearly 70kg, also affects the robot to control. Therefore, this requires a more intuitive driving mechanism while reducing overall size and weight.

2.3.5 Conclusion

Although the above design improvement directions are suggested, the specific design should be considered as a result of quantitative experiments and data as well as these results.

2.4 Design Improvement

2.4.1 Direction Determination of Design Improvement

When the results of experiment and field test were combined, a light and intuitive manual driving model was preferred to the current hospital environment rather than the powered driving model. The powered driving model was suitable for hospitals to implement fully ‘Comprehensive Nursing Care’ due to the large size and weight because they have a motor and a battery which accounts for a large part of the weight. Additionally, it has been identified to develop improved design in two directions, such as short and long distance. Likewise, usage must be departmentalized and the manual driving model should be improved first.

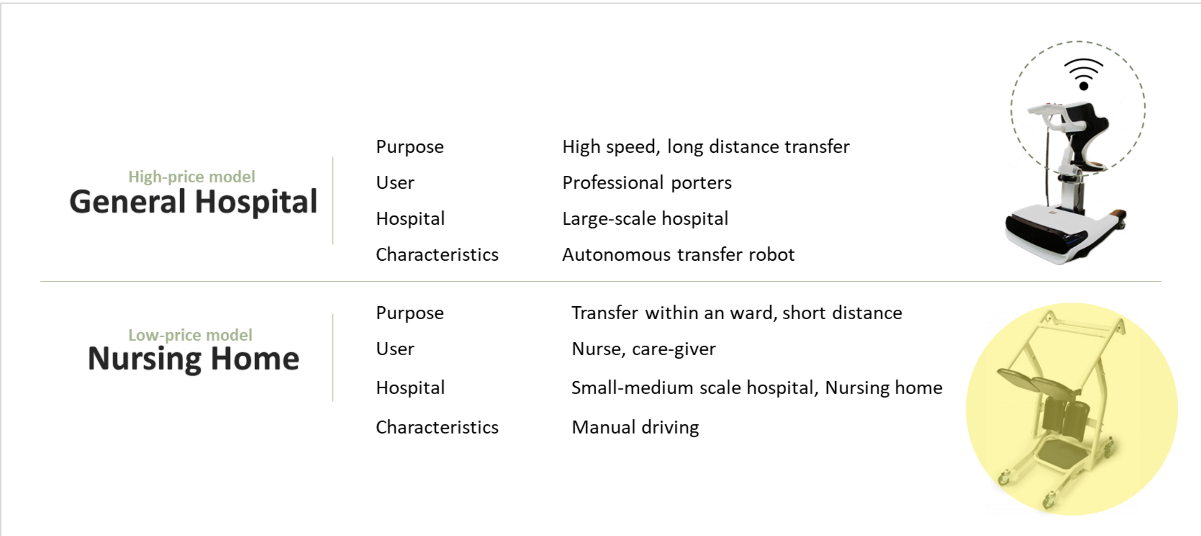


Figure 20. Departmentalized target user group

2.4.2 Design Requirements

In order to reflect the problem and needs from the results of experiment and field test, the improvement design should satisfy following requirements.

- Ergonomic design for neutral posture during use.
- Ease of use: driving, change directions
- Stable posture
- Proper dimension for patients
- Maximum speed is over 4km/h
- Additional devices: IV stand, urine colleting pouches, chart etc.

2.4.3 Design Specification

Following above design requirements, improvement design ideas were drawn from the brainstorming session and research in terms of anthropometric data, material, and shape. A new design had been developed with below specific improvements.

Seat

- Products leaning forward design were searched such as tattooist chair, harness, baby sling, massage chair, and weight training equipment and the dimension and figuration were referred.
- The dimension and shape of CarryBot were determined using anthropometric data of women from 50 to 89 years, which account for 70% of inpatient.
- Sectioned detachable cushion pads were applied to allow various patients to properly adjust and control specific areas.
- The forearm and chin supports were added in order to induce comfortable piggyback posture without any strength of patient.

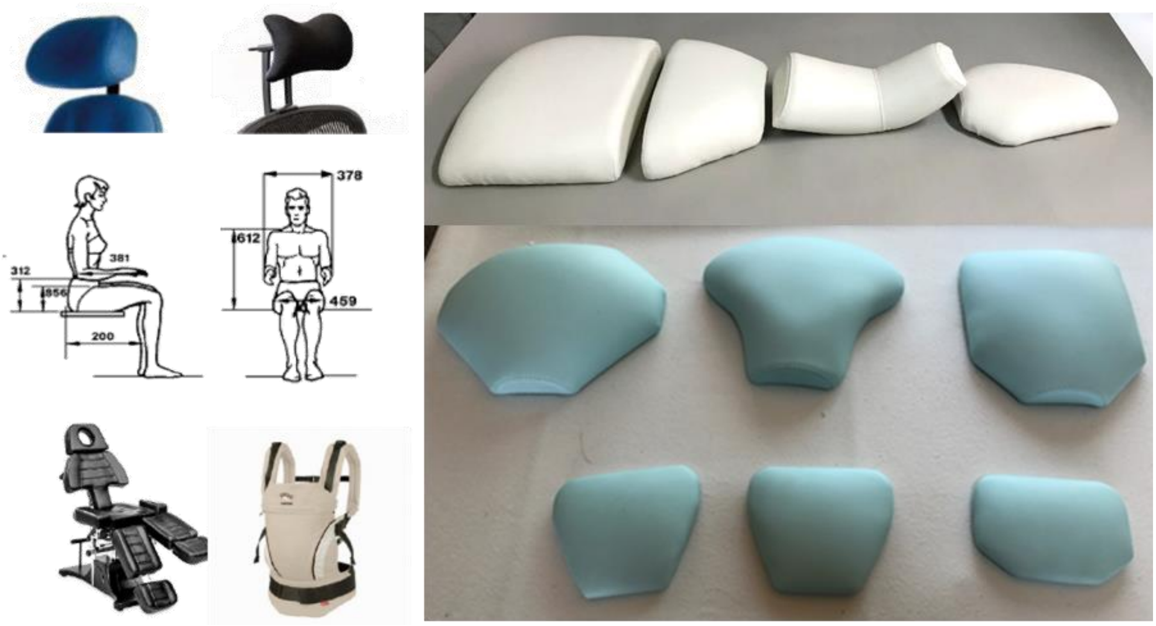


Figure 21. Various type of sectioned detachable cushion pads received ideas from ergonomic chair, baby carrier, tattooist chair, and etc.

Control part

- Both remote and attached controllers were applied so that it allows easy access not for patient but for nursing personnel

Driving part

- Powered drive mechanism has been removed.
- Total weight was diminished through the frame was punched and the weight of motor and battery decreased.
- A change of direction was improved through motorized wheels was changed to four caster wheels.
- Front two wheels can lock the direction for long distance transferring.
- The ergonomic designed handle was added which can use from every direction to nursing personnel and provide function as a safety bar when patient get on and off the robot to avoid side falls.

Outline/figuration

- Range of height should be from 35cm to 75 cm because it reflected from height of toilet to motorized patient bed.
- A radius of rotation should be under 85cm due to average distance between beds in patient room.

2.4.4 Prototyping

Based on the design requirements and specification, prototype was redesigned and developed. Figure 22 illustrates components of the final design.

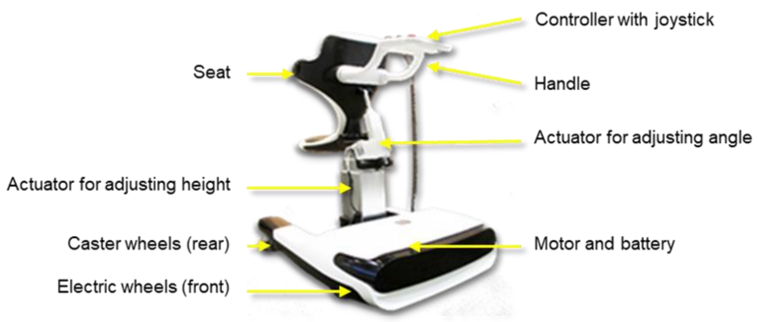
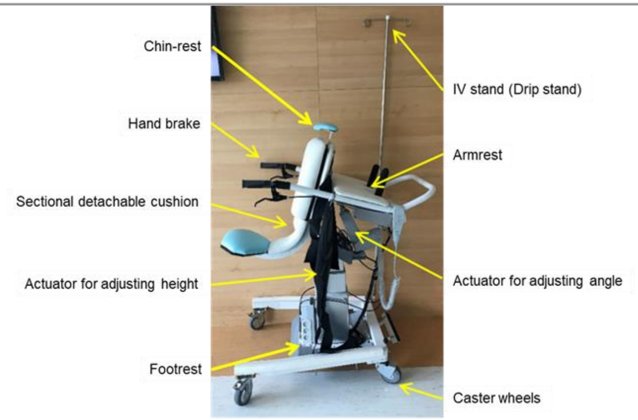
Existing Prototype	Redesigned Prototype
	
Feedback from Field Test and User Research	**Design Improvement**
Heavy weight	Reduced weight except for powered drive system
Bulky size	Dimension setting considering patient room environment
Slow operating speed Difficult to maneuver	Freely adjustable speed and intuitive operation by manual drive
Not compatible with other devices used in hospitals (IV stand, urine colleting pouches, oxygen tank, and etc.)	Add accessory to be compatible with other devices used in hospitals
Restricted patient Uncomfortable chair Low stability due to small seat size	Sectioned detachable cushion pads for improving usability Chair size and shape determined by reflecting anthropometric data Add arm and chin support for patient comfort
Cumbersome seat belt	Apply simple aircraft seatbelt

Figure 22. Final design and components of redesigned prototype

2.4.5 Field Evaluation

Through develop the prototype, almost figuration has been modified. Thus, the newly developed prototype was tested again to confirm whether the design improvements meet the needs of patient and nursing personnel. Same participants were recruited again for comparing with the pervious design at same hospitals. It also was conducted for two weeks by using same user study methods, diary, observation, shadowing, video recording and interview, as before. Likewise, questions of interview were prepared in advance.

Positive feedbacks

- The manual operation model has been evaluated to be more intuitive, faster and smoother than motorized operation model.
- Sectioned detachable cushion pads have been rated positive reviews and there is no gender difference
- The adjustable handle height induced a more neutral posture to the nursing personnel, so the load on the waist was estimated to be reduced compared to previous designs and wheelchairs.
- If the patient is leaning against the forearm and chin supports, they can sit comfortably without unnecessary force.

Negative feedbacks

- Still, the robot was considerably heavier than a wheelchair.
- The brake should operate more smoothly because the robot rattled by a sudden stop. It can cause anxiety and inconvenience to the patients.
- The seatbelt fastening process should be simpler. Both the patients and the nursing personnel evaluated that it took a long time to wear the seatbelt.
- The prototype must slow down because they rumbles when crossing the threshold.

2.4.6 Conclusion

Generally, all six nursing personnel rated the redesigned prototype positively. These evaluations indicated that it solved previous problem and met user requirements. Resolving remaining issues in the following design has a significant impact on the usability and user satisfaction. Furthermore, this process has opened the possibility to look forward to the future design.

3. DISCUSSION

3.1 Cause of the Problems in Previous Product Development Process

Inadequate user research has created an unnecessarily complicated and huge robot. The robot has been transformed into a simple device through a redesign process. The most fundamental cause of this problem is that the researchers did not investigate actual users and environments. That is, they had not performed a proper user research. The researchers heard the issue of transferring patients from the medical staff and reflected their requirements in the product. However, patient transfer is actually performed by professional porter or caregiver, not by medical staff. Therefore, the researcher had proceeded whole process with insufficient understanding of them. As a result, CarryBot did not reflect actual users' opinions at all. In order to develop a product that meets the actual usage scenarios, we need to investigate the problems and needs of real user, professional porter and care-giver, to reflect the requirements. If so, actual the most problems of the robot could be prevented through the process.

If we go back to the first stage of this device development, it is strongly recommended to develop the product for nursing home first. In the general hospital, there are many acute patients and unexpected situations occur frequently. Additionally, each hospital has different system and environment. Thus, there are many difficulties in conducting user research or evaluating finished prototype. Therefore, it is more appropriate to develop the device specialized in patients for nursing home firstly because it has many chronic rather than acute patients and has a relatively monotonous system. In other words, it has an environment where user research can be conducted more smoothly than the general hospital. Developing a product that fits in a nursing home and then improving the design for a general hospital can provide a more practical and safe product for the patient and save time and money.

3.2 Problems from Inappropriate Context research

User

The specification of previous prototype was set by an empirical method in which healthy 30- to 40-year-old men in the lab repeatedly used the robot. For this reason, the final specification was not appropriate for the patient. Particularly, it is necessary to reflect the characteristics of patients who are sensitive to friction or pressure and have extreme physical conditions compared with the general public. Otherwise, it is inconvenient to use and can cause injury.

Environment

Researchers in Hyundai robotics laboratory had not researched directly hospital environment, so they referred from the government regulation. It specified in the regulation that the distance between beds should remain above 1.5m. They developed the robot in accordance with it. In reality, however, there are significant difference that the average of spaces in three field test hospitals was 0.95m. Thus, the robot was too big to use in patient room and the field test was hardly conducted. This problem could be prevented by researching hospital environment directly. They did not implement user research and this resulted in waste time and money. Likewise, there are government regulations, but because it was enacted without considering the reality, it is difficult to find a hospital that fully complies with the requirements. Thus, it sternly recommended to conduct the environment research directly by developer.

Almost hospital scheduled patient transfer in advance. For example, in the rehabilitation wards of field test hospitals, the porter should transfer a patient between bed and wheelchair every 5 minutes. Thus, the patients waited for their turn and it is hard to require other transfer except for schedule. Considering this situation, patient transfer assistive device can be more practical.

Technology

The researchers in Hyundai had pondered over the function of Carrybot in order to naturally mimic a piggyback posture. However, the procedure to verify that this mechanism is useful to the user is missing. This can be confirmed in a quantitative or qualitative evaluation.

3.3 Essential Considerations

More exhaustive user research

Users could be divided two groups and one of them were patients. Generally, patients are weaker mentally and physically compared to the public. Almost of them may be an extreme user. A small stimulus such as a little pressure and friction is not a problem for the public whereas patients can feel pain and be injured by it. Therefore, when developing patient related products, every detail must be considered and keep in mind that the threshold of patients is low.

Active cooperation of hospital

Although the field test is necessary, it is really difficult that an experimenter who is not a medical professional survey and observes patients directly. In this research, when observing patients in the hospital, many patients were reluctant to be surveyed and they acted unnaturally. Nevertheless, it is not good idea to evaluate a product only by healthy person because it may lead awkward result. In this condition, the best solution is that nursing personnel who always attend and are familiar with a patient conduct user study by themselves. That is, they directly ask a question to patients. This method are a great help to induce actual behavior and gather opinion naturally. If possible, experimenters prepare a list of questions for nursing personnel in advance and involve directly them as active in the user research as a co-researcher.

Trust building by quantitative data

Furthermore, the product should give great trust to users, patient and nursing personnel, in order to gather many feedback. Patients generally have much more fear than the public and nursing personnel always pay attention to them. If they experienced a little fault of product during riding, they would think that the product was dangerous, felt the fear about sentinel events and not want to use it again. Therefore, the product should be completely verified through experiment and regulation before the field test. Then, the quantitative data could be helpful to persuade users more effectively.

Relations between user and product

It might be better to develop the robot in an automobile company rather than heavy industrial company because the former has researched and considered interaction between product and user very finely not only its function and effectiveness but also comfort and emotion. At least, if an ergonomist who is familiar with human-centered design process took part in developing process at the beginning, it would have shown better results.

Regulation

It is necessary to obtain the government's approval as a medical device. Before the permission, it is not supposed to test in real hospital. Therefore, it is important to get ready to approval from Korea Food and Drug Administration at the beginning, to use allowed material and to consider the regulation during the process.

3.4 Proposed product design process

Based on this study, we propose a new product redesign process (Figure 23). It was created with reference to the engineering product design process and user-centered design process (Abras at al., 2004; Cross at al., 1989). Hospitals are a very conservative group, so they tend to avoid change if they are not sure. Therefore, researchers must ensure that they understand and confirm the user, environment, and regulations before conducting a field assessment. The flowchart includes important contents for appropriate user study and essential consideration. For example, development of electric products should consider the government regulation from the beginning. In addition, hospitals have very different environments and system, so direct user research is required. We hope that this process will help prevent unnecessary trial and error and help you develop more practical products.

3.5 Research Contribution

Potential contributions of this research to the development of healthcare product are summarized as below:

- Traditional user research and market analysis for consumer product design do not work well for the development of healthcare products, especially for patient-care equipment. Designers should consider various aspects of patients as well as users (care-givers) when designing and planning the healthcare products.
- User research at the early stage of design/development process should include proactive field observation to understand the unique limitations of various healthcare facilities and relevant safety code and regulations. That is, it is critical to evaluate 'user-product-environment' interactions.
- It is critical to conduct quantitative ergonomic evaluation as well as qualitative usability evaluation to validate the functions and benefits of the product. The validation results can be used to certify the product in terms of the functionality and safety of the product.

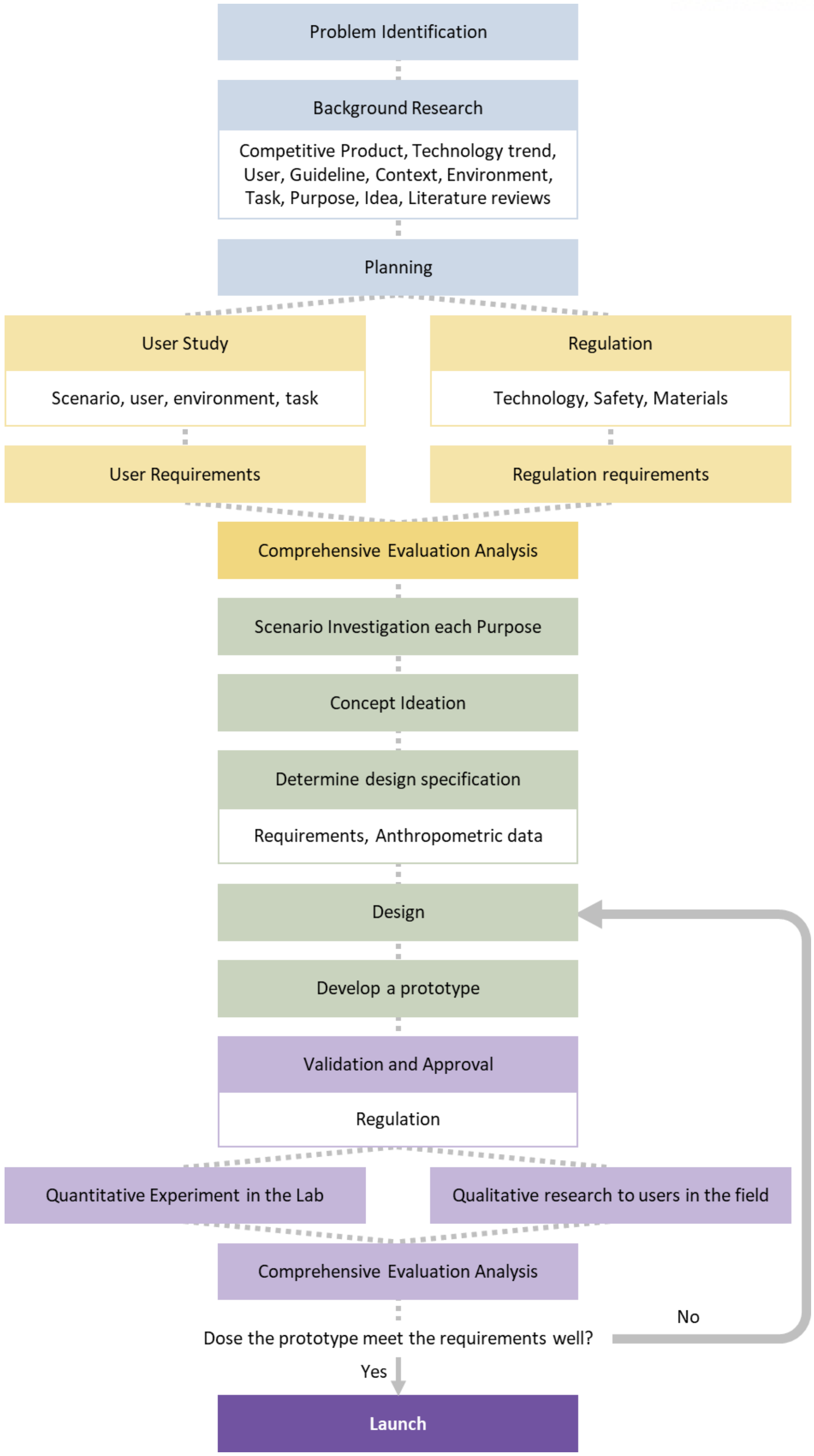


Figure 23. Proposed product design process specialized for patients.

4. CONCLUSION

In this study, ergonomic advantage and usability of a new patient transfer aid prototype has been evaluated to come up with design improvement ideas. Both ergonomic evaluation and qualitative user research highlighted that the prototype could help care-givers transfer patients more safely with less physical efforts compared when transferring using a conventional wheelchair. However, several critical usability issues have also been identified from the user research, and therefore, design modifications have been made to address the user requirements. The newly developed prototype was tested again at various hospitals to confirm whether the design improvements meet the needs of care-givers and patients. In the last field test, the redesigned prototype has been proved to be more useful and safe than original prototype.

CarryBot was originally developed by a major domestic corporation. They had developed this robot for three years, based on solid human resources made up of several robot researchers and medical doctors. However, the result was not acceptable to real users (patients, care-givers) at hospitals. The main causes of the problem were the development of the product without understanding the actual user and the lack of proper consideration of real hospital environments. Thus, in this study, based on our experience, we proposed a new product design/development process to avoid such problems in future healthcare product developments.

Healthcare product development, specifically for developing patient aid devices at hospitals, needs careful and thorough user research both quantitatively and qualitatively at the very early stage of design processes. Users of healthcare products are diverse in their physical and cognitive abilities, and such aspects can be a serious limiting issue when using the products because of safety and cost. In addition, it should be studied where the products are used, how the products interact with the environments, and whether the interaction would comply with existing regulations and codes. Hospitals have very strict regulations for patients' safety. Healthcare products that do not meet the regulation will fail even without any field evaluation.

We hope that our proposed design process would help future developers of healthcare products and guide them how to apply ergonomic user and product evaluation methods throughout the process.

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