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Meal-Assistance by Robot Suit HAL using Detection of Food Position with Camera

Hiroaki Kawamoto, Tomoya Shiraki, Tasuku Otsuka and Yoshiyuki Sankai

Abstract— **Meal-assistance is necessary for patients with upper limb paralysis caused by diseases such as cerebrovascular disorder and cervical cord damage. We have developed the upper limb type HAL (HAL-UL) to assist the arm movement during a meal for people with upper limb paralysis. HAL-UL achieves reaching movements according to pre-generated trajectories. Furthermore, for meal assistance it is required to provide the reaching movement for various locations, shapes, and amounts of food. Therefore, the purpose of this research is to achieve the detection the food position by HAL during meal-assistance using image processing and to verify its effectiveness. A camera is installed overhead to detect the image of the food on the table. Then the locations of the food pieces are detected using image processing. A microphone is installed as a command interface for the user to command the dish number. Finally, the optimal trajectory to the location is selected from pre-generated reaching trajectories. To determine the effectiveness of the proposed method, an eating experiment was performed. A subject wore the HAL-UL in front of a table, and 4 dishes with different types of food were prepared. Then, the image of the food was processed, the food locations were detected, and the optimal reaching trajectories were selected. According to the determined trajectories the HAL-UL provided eating movement support for the subject. Therefore, the effectiveness of the proposed method was determined and we confirmed the HAL-UL for meal-assistance may be used successfully for the actual meal-assistance.**

I. INTRODUCTION

Meal-assistance for physically challenged people who have difficulties to eat by themselves is important to keep them active in their daily life. In standard meal-assistance, a care-giver brings the food to the personfs mouth, but to do so 3 times a day for many people brings a great burden to the caregivers. In order to reduce this burden, care robots for eating have been developed [1]-[4]. These robots are equipped with a manipulator to bring the food to the peoplefs mouth. The role of these robots is thought to be similar to caregivers in terms of providing food to the physically challenged people. At the same time many patients prefer to eat on their own. In order to meet this request, it is necessary to support their upper limb motion while eating, i.e., their disabled arms are directly assisted to eat. The support for the eating motion provides a self-reliant method for eating which would help to restore their Quality of Life (QoL). In addition, daily arm exercise through meal-assistance would contribute to the prevention of disuse syndrome. In our group, we have developed the Robot Suit HAL (Hybrid Assistive Limb) [5]-[8], which is a wearable robot to support and enhance the human physical functions. Recently, a lower limb version to support walking, standing up etc. has been developed. A similar wearable robot for the upper limbs could be designed to assist a disabled personfs arms and hands for eating. Therefore in this paper, we propose to develop an upper-limb type HAL (HAL-UL), which includes arm and hand support, to be used for meal-assistance and to evaluate its basic operation.

Section II describes the HAL-UL. In section III a food position detection algorithm is presented, and in section IV motion control including an interface to communicate

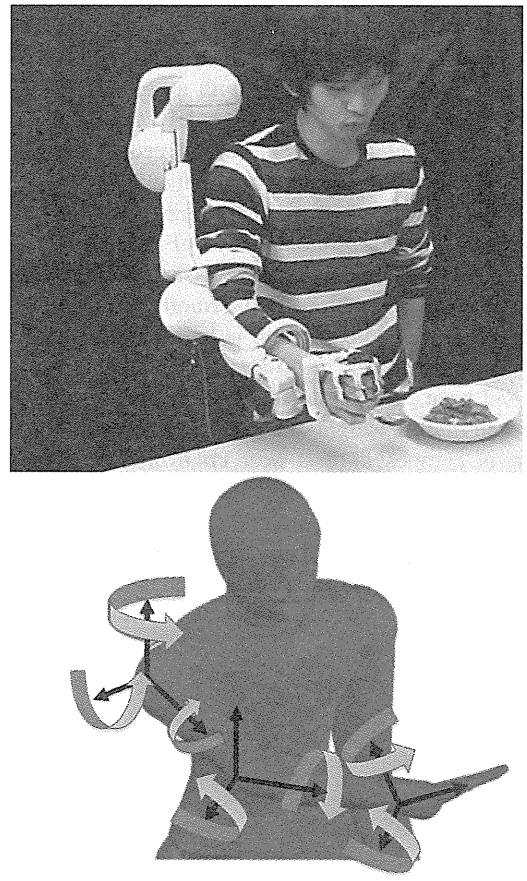

Fig. 1. HAL-UL and rotation axis. HAL-UL contains 3 Degree-of-Freedom (DoF) on shoulder joint, 1DoF on elbow joint and 3DoFs on wrist joint.

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the wearer's intention to the HAL for meal-assistance is presented, followed by the experiments conducted with an able-bodied person and the results in section V. Section VI discusses the effectiveness of the HAL-UL and the paper closes with the conclusion in section VII.

II. UPPER-LIMB TYPE HAL FOR MEAL-ASSISTANCE

A. Mechanism

The upper-limb type HAL (HAL-UL) is a wearable system that enables physically challenged user to take a meal by his own hand by assisting his arm with an exoskeleton. Figure 2 shows the appearance of the HAL-UL. The exoskeleton of the HAL-UL contains 3 Degrees-of-Freedom (DoF) in the shoulder joint, 1 DoF in the elbow joint and 3DoF in the wrist joint. Each joint contains a power unit to actuate the joint. The human upper limb contains 7DoF and with the above set of DoF the HAL-UL enables assisting all joint motion of the human upper limb. Furthermore, a grasp-assistance system developed in our group is built into the hand of the HAL-UL and performs grasp-assistance. The user sits on the chair and wears the HAL-UL. The HAL-UL is fixed to the chair such that its weight is not felt by the user. The control system is composed of a host controller, communication units, and motor drivers, which were all developed in our group. Each power unit contains a potentiometer for the angle measurement. The angle data obtained by the potentiometer is sent to the host controller through the communication unit after which the host controller sends the control order to each motor driver.

B. System configuration

In order to realize meal-assistance with HAL-UL, the detection of food positions on the table and a command interface are required. The meal-assistance system proposed in this research is realized by integrating a camera for image processing and a microphone interface into the HAL-UL. Figure 3 shows the system configuration of HAL-UL. The computer that performs the image processing and the voice interface communicates with the controller of HAL-UL by TCP/IP to transmit the processing result.

III. DETECTION OF FOOD POSITION

It is necessary to first carry the hand to the food in order to eat it. Position, shape and quantity of food change while eating. In these situations, HAL has to estimate the position of the food to carry the hand to the food that the wearer wishes to eat. We use camera image processing to estimate the position of the food. A camera is attached to the chair onto which HAL is installed (Fig. 3). An image of the dishes and food taken from above is processed. The estimation of the food position is realized through the following steps.

A) *Detection of dishes*
B) *Mask processing to extract dishes*
C) *Extraction of food parts*
D) *Labeling, processing and center position estimation of food pieces*

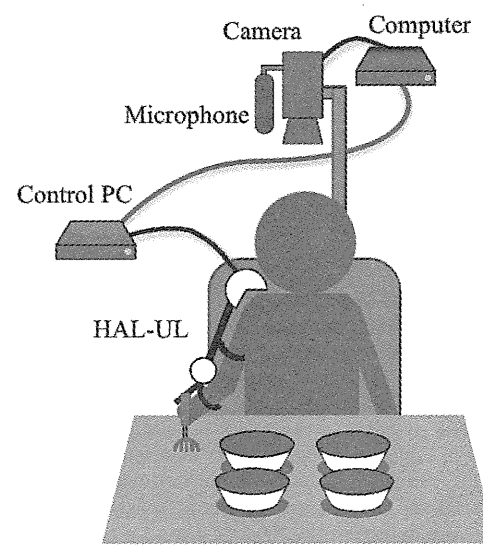


Fig. 2. Configuration of whole system

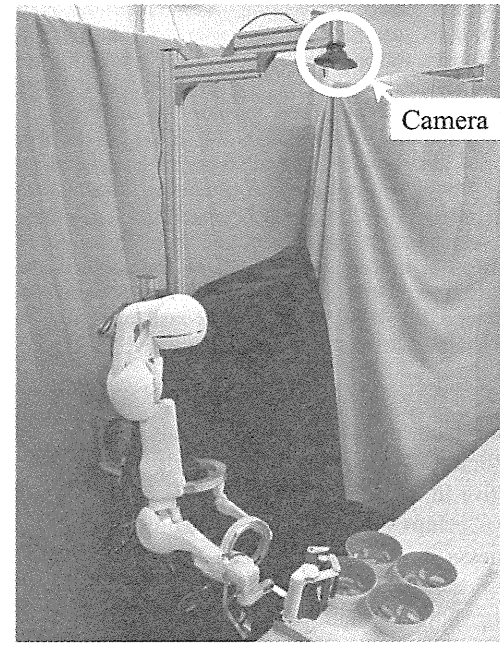


Fig. 3. A camera is attached to the chair onto which HAL is installed

The image processing for each step is done as follows.

A. Detection of dishes

Color information based on the RGB color space of the dishes would be influenced by a change of light source. The accuracy of the position detection by image processing using RGB color information may therefore be impaired. Thus, we adopt HSV color space to detect the position of the dishes in order to reduce false detections due to a change of light source. HSV represents color as three parameters, hue, saturation, and lightness. It is quickly possible to convert RGB color space to HSV. Surfaces of the dishes are extracted by

image binarization using hue information. We used circular dishes in blue color. The hue of the dishes is 220. In this research a hue between 210 and 230 is binarized as 1, and other values as 0.

B. Mask processing to extract dishes

The range for the detection of the position of the food is in the inner side of the dishes because the food is on the dishes all the time. Here, we describe a method for mask processing to eliminate the outside region of the dishes from the detection range of the food. First, an outline of the dish is extracted as a circular form from the binarized image by using Hough transformation. Hough transformation is popularly applied as an image processing technique to detect a line or circle from an image [10]. In the Hough transformation of a circle, the central coordinate and radius are identified. Circles passing through an image point (X_i, Y_i) are unlimitedly present. The central coordinate (X_c, Y_c) and the radius r are plotted using the parameters of the three-dimensional Hough space by using the following equation.

$$(X_i - X_c)^2 + (Y_i - Y_c)^2 = r^2 \quad (1)$$

For each image point, this plot is calculated (vote). As a result, the point obtaining the most votes in Hough space is the parameter of the circle which is identified by Hough transformation. Actually, the amount of calculations for the parameters of the circle is enormous because of the three-dimensional space. In this research, the Hough transformation for a circle is conducted on the condition that the parameter of the radius is known because the size of the dishes can be identified from the image. Finally, the central coordinate is identified by Hough transformation. Based on this result, the image mask containing the extracted dishes is obtained as shown in Fig. 4(a)-(d).

C. Extraction of foods

Binarization is performed to extract the food parts from the image masked in B. The colors of the dishes is binarized as 0, and the rest as 1. As a result, the pixel range containing the food can be extracted. However, it is difficult to extract white color foods by using hue. So, binarization is processed by using saturation as well as hue. In this research, the image is binarized as 1 if the saturation is less than 5. Figure 4(c)-(g) shows the image containing the extracted food parts.

D. Center position estimation of food

First, regions containing food are extracted by binarization of food colors within the dishes. Next, labeling of each region is performed using 8-connectivity for the extracted regions. The labeling procedure using raster scan based 8-connectivity is described as follows.

a) *While scanning in horizontal direction from the upper left of the image, a white pixel without labeling is set as the target pixel.*

b) *If the upper pixel or the upper left pixel above the target pixel is labeled, the same label is set to the target pixel. However, if the label of the target pixel differs from the left pixel, it is memorized in a lookup table that these labels have a connective component.*

c) *If the upper pixel and the upper left pixel above the target pixel are not labeled, and the left pixel is labeled, the label of left pixel is set to the target pixel.*

d) *If the upper, the upper left and left pixel for the target pixel are not labeled, a new label is set to the target pixel.*

e) *a), b) and c) are repeated until all white pixels are labeled.*

After the labeling is finished, the label numbers memorized in the lookup table are updated to minimize the amount of label numbers as shown in Fig. 5. After the update of the

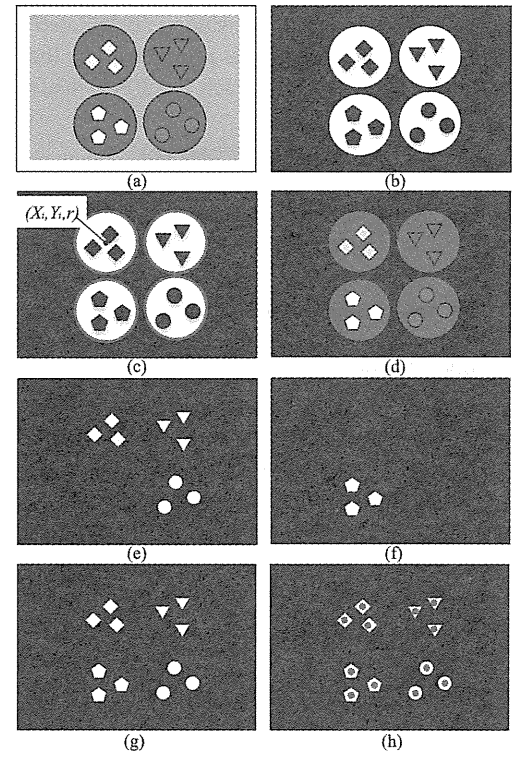


Fig. 4. Steps of Image processing.

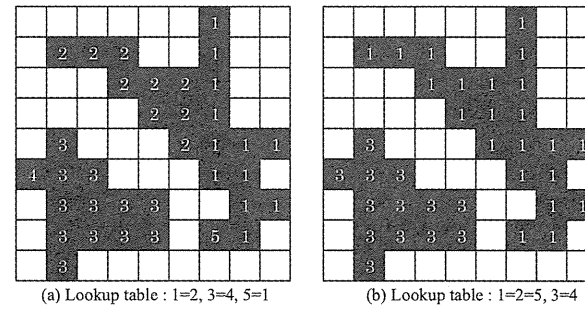


Fig. 5. Raster scan and Labering

labeling is finished, the center position is calculated for each food region. The center position is represented by the average location value of the pixels of each label(Fig. 4(h)).

IV. Motion control

The eating motion supported by HAL is based on the kinds of food that people are normally able to take with one hand. This motion is divided into four phases as follows (Fig.6).

1) *Keep the hand at the initial position*
2) *Carry the hand to a piece of food located on the table in front*
3) *Pick up the food*
4) *Carry the hand to the wearerfs mouth and return the hand to the initial position*

Of these, phases 2), 4) are reaching motions to carry the hand to a target position, whereas 3) is a picking up motion with a fork. Control methods for each motion are explained below. Moreover, the interface required to communicate the wearer's intention to HAL is explained.

A. Reaching motion

During eating the reaching motions to carry the hand to the food and back to the mouth are repeatedly performed. The reaching motions of the upper-limb type HAL realize human-like motion trajectories. Practically, at first the hand trajectories are calculated from the minimum jerk model. The trajectories obtained from the model resemble the normal reaching motion of human arms. Secondly, the calculated hand trajectories are transformed into joint trajectories by inverse kinematics. HAL then achieves the actual reaching motion by trajectory tracking control based on the reference joint trajectories. However, if the hand trajectories and the joint trajectories would be calculated in real time, the eating motion support could not be performed smoothly because of the enormous amount of calculations. In order to solve this problem, we prepared reference trajectories according to a set of reaching positions in advance. In this motion control system, a square table (210[mm] $\times$ 210[mm]) is divided into 64 square grids, the center of each grid field is set to be one of the target positions. The reference trajectory for each target is then calculated. Here, HAL chose the trajectory for each target position based on the image processing algorithm as described in Section III.

B. Wrist motion

After the hand reaches a target food position, the food can be picked up by using a fork or spoon. At that time the hand posture is controlled by HALfs wrist, which contains three degrees of freedom. In this research, the food is picked up by pricking it with fork. The hand posture is controlled to direct the edge of the fork vertically into the food. After carrying the hand to the mouth, the edge of the fork with the food is controlled by the wrist to move in the direction of the mouth.

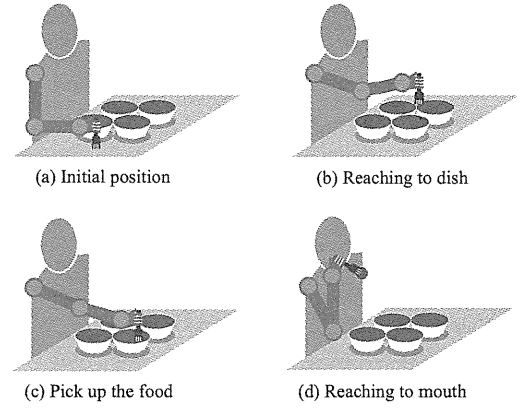


Fig. 6. Steps in Eating motion

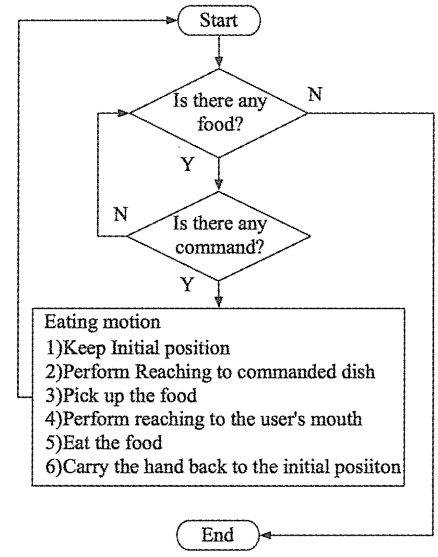


Fig. 7. Operation flow

C. Interface

During the meal assistance, HAL should pick up the food that the wearer wants to eat. Therefore, it is important to communicate the wearer's intention to HAL. We adopted an audio interface through which HAL can determine the reference trajectory based on the wearer's voice. The wearer communicates the desired food to HAL by speaking the number corresponding to the positions of the dish on the table. In this research, we prepared four dishes on the table, with the dish located in upper left labeled as number 1, upper right as 2, left lower as 3, and right lower as 4. Figure XX shows the relationship between the dishesf positions and labeling numbers. We adopted Julius for SAPI made by Microsoft Corporation as the voice-recognition system.

D. Operation flow

Based on above, the meal-assistance with HAL-UL is achieved through iteration of the following steps. Figure 7

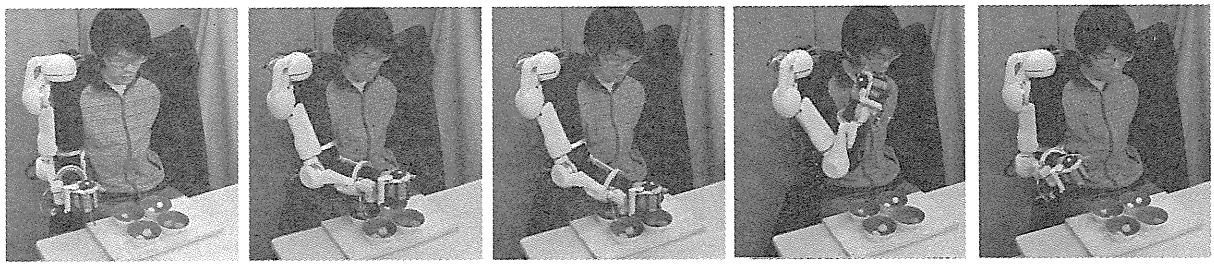


Fig. 8. Eating motion through the experiment

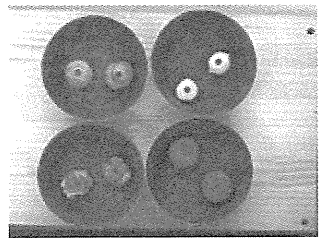
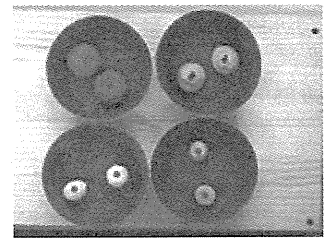
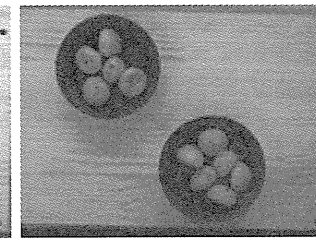
	Case1	Case2	Case3
Food Placement			
Quantity	8	8	11
Trials of Reaching	8	9	11
Success rate	100%	89%	100%

Fig. 9. Result of experiment.

shows the operation flow of the meal-assistance with HAL-UL.

1) *Detect positions of dishes and foods by proposed image processing*
2) *Wearer commands the dish number by voice*
3) *Carry the hand to the commanded dish*
4) *Pick up the food with the fork*
5) *Carry the hand to the userfs mouth*
6) *Wearer eating the food*
7) *Carry the hand back to the initial position*

V. EXPERIMENTAL VERIFICATION

A meal assistance experiment using HAL-UL is conducted in three different conditions, varying by food and location. The radius of the food used in the experiment are 25[mm]-40[mm]. The trial subject is an able-bodied male. We asked him to loosen up and relax during the motion support, and to speak the numbers labeled on the dishes. The number of eating motions for each food number (success rate) is measured in the experiment. The sequence of eating motions is shown in Fig.8. Food locations, food names, number of different food, number of eating motion, and success rate are shown in tableYY. The result of the experiment was a success rate of 100% for cases 1 and 3, and 89% for case 2.

VI. DISCUSSION

In case 2, HAL-UL did not pick up the food once. When the fork contacted the food, it rolled away due to the error between the detected center position and the actual center position. However, meal-assistance would be achieved by the current version of HAL-UL because the success rate of the eating motion is hight. In this experiment, it was possible to pick up pieces of food from 25 mm to 40 mm in size because the grid interval, which indicates the resolution of reaching motion, was set to 30 mm. It is possible to deal with smaller foods if the grid interval was adjusted more finely.

VII. CONCLUSIONS

In this research, we proposed an image processing algorithm for the detection of food positions for the upper-limb type HAL (HAL-UL). A camera is installed overhead to detect the separate pieces of food on the table. The system then detects the food position using image processing. Furthermore, a microphone is installed as an command interface so that the user can command the desired dish number using his voice. In an experiment with a relaxed healthy person and actual food we verified that the HAL-UL could detect the food position and perform the meal-assistance operation according to the user's command. As

a result, the effectiveness of the proposed method could be verified and we confirmed it will be possible to use the HAL-UL for actual meal-assistance.

VIII. ACKNOWLEDGMENTS

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Development of Upper-limb type HAL and Reaching Movement for Meal-Assistance

Tasuku Otsuka, Ko Kawaguchi, Hiroaki Kawamoto, and Yoshiyuki Sankai

Abstract— **Having a meal is one of the most basic human activities. There are several hundred thousand patients with upper limb disorders in Japan, who need to be nursed when eating. By letting the patients to perform meals with their own arms, it is expected to promote a more independent life and improvement in their quality of life. In our group we have researched and developed Robot Suit HAL, which is an assistive system to expand, intensify and support human physical function by wearing it. The purpose of this research is developing the upper-limb type HAL(HAL-UL) for meal-assistance. In this paper, we develop a hardware which is able to perform reaching movements of an end-point position and a control method for it. The structure of the HAL-UL has a shoulder joint (three-degree-of-freedom) and an elbow joint (one-degree-of-freedom). The shoulder joint encompasses a ring-shaped rotation mechanism with gears for rotation. Furthermore, a grasp-assistance system is built in the forearm of HAL-UL and performs grasp-assistance. The whole system is fixed to a chair so that weight applied on the user. The control method used for reaching operation is the trajectory tracking control method. In order to calculate a smooth trajectory and the target angles considering the human range of motion, we propose a trajectory calculation method using weighted-pseudo-inverse-matrix and minimum jerk model. The effectiveness of it is investigated through experiments with a healthy person and the HAL-UL actualized reaching movements for meal-assistance.**

I. INTRODUCTION

Meal-assistance for upper extremity paralysis patients who have difficulties to eat by themselves is important to keep active in their daily life. In standard meal-assistance, a caregiver brings the food to the people's mouth. The caregiver bears a great burden of meal-assistance. In order to reduce this burden, care robots for eating have been developed.[1]-[4]. These robots are equipped with a manipulator to bring food to the people's mouth. The role of these robots is thought to be similar to caregivers in terms of providing food to the physically challenged people.

On the other hand, patients prefer to eat on their own. In order to meet this request, it is necessary to support the upper limb motion while eating. That is, their disabled arms are directly assisted to eat. The support for the eating motion provides a self-reliant method for eating which would help to restore their Quality of Life (QoL). In addition, daily arms exercise though meal-assistance would contribute to the prevention of disuse syndrome.

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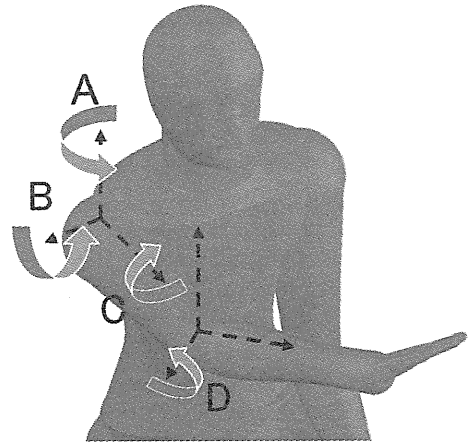


Fig. 1. Definition of rotation axis. The HAL-UL assists these 4 degree of freedoms. A: shoulder adduction-abduction, B: shoulder flexion-extension, C: upper arm medial-lateral rotation and D: elbow flexion-extension

In our group, we have developed the Robot Suit HAL (Hybrid Assistive Limbs)[5]-[8], which is a wearable robot to support and enhance the human physical functions. Recently, a lower limb version to support walking, standing up etc. has been developed. A similar wearable robot for the upper limbs could be designed to assist the disable person's arms for eating. Therefore in this paper, we propose to develop an upper-limb type HAL(HAL-UL) to be used for meal-assistance and evaluate its basic operation.

Section II describes the HAL-UL. In section III the autonomous controller is presented, followed by the experiments conducted with an able-bodied person and the results(section IV). Section V discusses the effectiveness of the HAL-UL and the paper is closed by a conclusion in section VI.

II. UPPER-LIMB TYPE HAL FOR MEAL-ASSISTANCE

A. Specifications

The upper-limb type HAL(HAL-UL) is wearable system that enables taking a meal on his own arm by assisting his arm with an exoskeleton. Therefore, it is required not only to perform meal-assistance but also to wear the system without user's load. In order to realize meal-assistance with HAL-UL, the following conditions are listed as required specifications for the HAL-UL

1) *Assist user's each joint movement by wearing it*
2) *Obtain enough Range of Motion(ROM)*
3) *Calculate adequate angle trajectories considering human ROM to control it*
4) *Assist grasping spoons, forks, and containers*
5) *Move the hand to the point on the desk and carry the food to user's lip*

In this research, first we developed a hardware and a control method that satisfy conditions 1)-3). Next, we verified through a basic experiment with a healthy person that the hardware satisfies conditions 4) and 5).

B. Design of HAL-UL

The HAL-UL is an wearable robot arm system for assisting the user's upper limb movement by wearing it. For this study we defined the assisted moment axis arrangement as shown in Fig. 1. In order to provide a comfortable user experience and avoid mechanical problems, it is necessary to design the robotic arm structure to avoid spatial interference between the exoskeleton, the actuators and the user body. The power units are installed in the exoskeleton along each of the human arm joints, providing power assistance for elbow and shoulder joints. For safety reasons, we also designed the hardware of HAL-UL to satisfy the ROM required for meal-operation while not exceeding human maximum ROM.

1) Joints arrangement of shoulder: Human shoulder joint is represented by a ball joint which contains three degree-of-freedoms(DOF); adduction-abduction(Fig. 1:A), flexion-extension(Fig. 1:B), and medial-lateral rotation(Fig. 1:C). In order to provide power assistance to the movement of the ball joint, three actuators are attached to the exoskeleton structure. The actuator which assists adduction-abduction joint is allocated in the upper part of shoulder and is positioned horizontal relative to the ground as shown in Fig. 2. This actuator does not need nod to support gravity at the seated position because the rotation axis is corresponding in the direction of gravity. Moreover, it is advantageous in respect of the energy efficiency because the meal operation consists of a lot of horizontal movement on the desk. The flexion-extension joint is allocated at the outer side of the shoulder. The medial-lateral rotation joint is arranged to match the long axis of the upper arm to the rotation axis of HAL and we developed rotation mechanism that considered easiness of wearing. The upper arm rotation mechanism is described as follows.

2) Upper arm rotation mechanism: In order to provide power assistance for the medial-lateral rotation movement of the upper arm(Fig. 1:D), we developed the ring mechanism as shown in Fig. 3. The mechanism can do a lateral rotation of 5[deg] and medial rotation of 90[deg]. It is difficult for upper limb disorders patients to pass the arms through the fixed ring mechanism. Because of that we designed the ring structure with a part cut off so that the user can insert the arm inside the rotation mechanism.

The arm of the user is locked inside the exoskeleton by rotating a partially cut ring spur wheel around the arm and closing the gap in the exoskeleton. The proposed ring spur

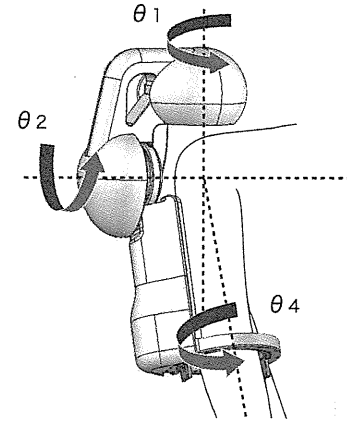


Fig. 2. Joint arrangement of shoulder joint. Three axes are orthogonal in one point.

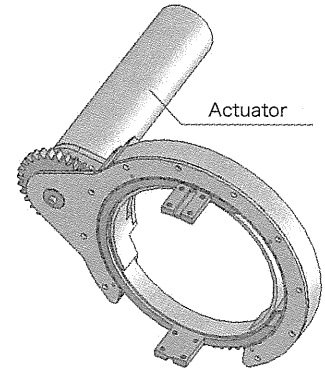


Fig. 3. Upper arm rotation mechanism. A ring spur wheel makes turn round frame.

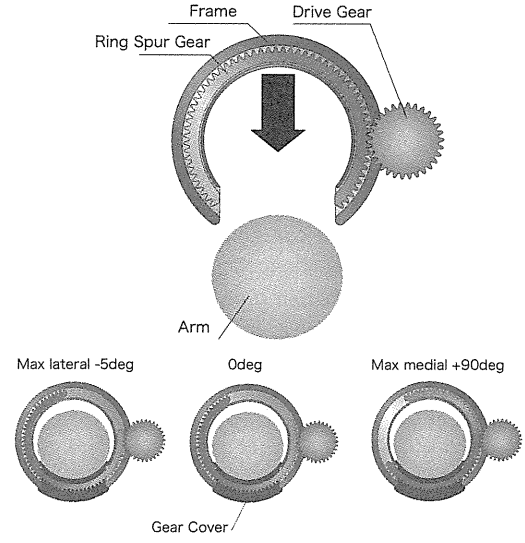


Fig. 4. Detaching and driving image. Users can put them arm from cut part. It has 5[deg] for the lateral rotation, and it has 90[deg] for the medial rotation.

wheel locking mechanism is shown in Fig. 4. When the cutting part of the frame and the ring spur gear are overlapping the arm can be inserted or removed from the part. The detaching method is shown in Fig. 4. After Inserting the arm an actuator rotates ring spur gear and the cutting lack is shut and a cover is attached. By using this mechanism, it can be expected to become easy to wear the system for upper limb disorder patients.

3) Joint arrangement of elbow: The elbow actuator is allocated outside of the body corresponding to the rotation axis of the elbow joint as shown in Fig. 5. The structure of the forearm is connected to the upper arm rotation mechanism and the grasp-assistance system can be attached to the forearm.

4) Grasp-assistance system: The grasp-assistance system[9] developed in our group is applied to support the grasping tableware (Fig. 6). It contains tendon drive with an electrical motor and wire provides assistive grasping for the low grip patients. The system is connected on the forearm of HAL, and performs the grasp-assistance by the instruction from HAL. Only the hand of the user is fixed to HAL-UL by this grasp-assistance system.

C. System configuration

The developed HAL-UL is shown in Fig. 7 . The user sits on the chair and wears the HAL. The HAL-UL is fixed to the chair and weight is not applied on the user. Moreover, the range of motion of each joint was confirmed with a user wearing it. The figure is shown in Fig. 8. The control system is composed of the host controller, the communication unit, and the motor driver which are developed in our group. Each power unit contains a potentiometer for the angle measurement. The angle data that the potentiometer obtained is sent to the host controller through the communication unit and the host controller operates and sends the control order to each motor driver (Fig. 9). The control method and the control order are described in the following section.

III. CONTROL METHOD

In this paper we focused on drinking motion support in various meal activities. In this chapter, firstly, we divide the drinking motion into some phases and relate these phases to reaching motion and grasping motion. Secondly, we explain control method of reaching motion and grasping motion.

A. Drinking motion

The drinking motion supported by the HAL-UL is based on the kinds of drink that people are normally able to take with one hand. This motion is divided into five phases.

1) *Carry the hand from an initial position to a container including a drink located on a table in front*
2) *Grasp the container*
3) *Carry the hand to the wearer's mouth*
4) *Carry the container back to the table after drinking*
5) *Return the hand to the initial position*

Of these, phases 1), 3), 4) and 5) are reaching motions to carry the hand to a target position, whereas 2) is a grasping

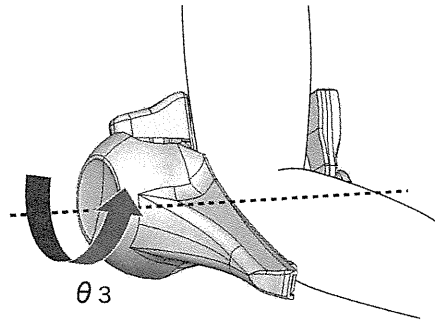


Fig. 5. Joint arrangement of elbow joint

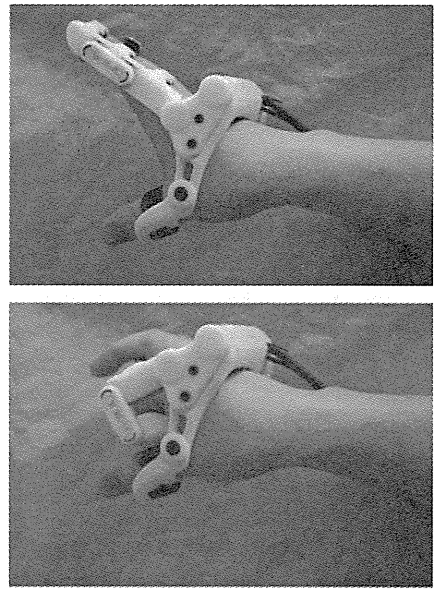


Fig. 6. Grasp-assistance system. It enables providing grasp-assistance with one motor and wire.

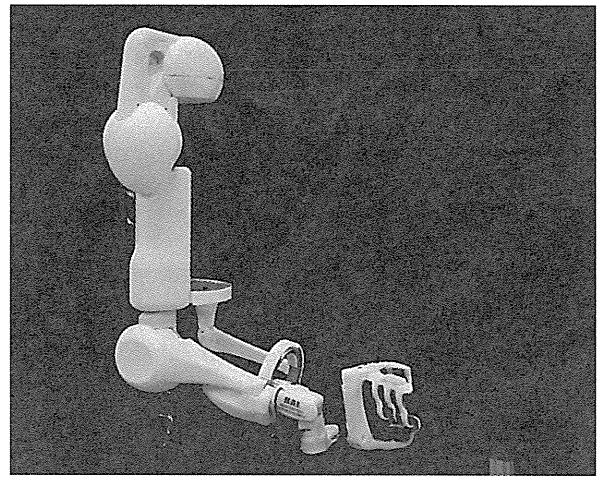


Fig. 7. Appearance of HAL-UL

motion for the container. Control methods for each motion are explained follow.

B. Reaching Motion Control

Here we describe the motion control method for 1), 3), and 4). A target hand trajectory from initial position to target position is calculated based on the minimum jerk model. Trajectories obtained from this model resemble the normal reaching motion of human arms. In this model, the trajectories are followed by minimizing the performance function as shown in the following equation. Where $\boldsymbol{x} = (x(t), y(t), z(t))$ is the hand trajectories.

$$P = \int_0^{t_f} |\dddot{\boldsymbol{x}}|^2 dt \tag{1}$$

where t_f is the time to arrival at the target points. For the following initial conditions $\boldsymbol{x}(0) = \boldsymbol{x}(t_f) = 0$, $\dot{\boldsymbol{x}}(0) = \dot{\boldsymbol{x}}(t_f) = 0$, $\ddot{\boldsymbol{x}}(0) = \ddot{\boldsymbol{x}}(t_f) = 0$, the minimum jerk trajectory is defined by a 5th order derivative as shown in the following equation.

$$\boldsymbol{x}(\tau) = \begin{cases} x(\tau) = x_0 + (x_0 - x_f)(15\tau^4 - 6\tau^5 - 10\tau^3) \\ y(\tau) = y_0 + (y_0 - y_f)(15\tau^4 - 6\tau^5 - 10\tau^3) \\ z(\tau) = z_0 + (z_0 - x_f)(15\tau^4 - 6\tau^5 - 10\tau^3) \end{cases} \tag{2}$$

where $\boldsymbol{x}_0$ and $\boldsymbol{x}_f$ are the starting position and ending position respectively, and τ is t/t_f $(0 \leq \tau \leq 1)$.

In order to control each joint angle, a target angle trajectory is calculated from the target hand trajectory by calculating the inverse kinematics based on the Jacobian. However, in this case the trajectory for one joint cannot be calculated because with the total amount of degrees of freedom for the upper limb of HAL there is one redundancy. We therefore use a pseudo inverse matrix to calculate the target angle trajectory. A weighted pseudo inverse is adopted to obtain the angle trajectory on the basis of the human joint range of motion. This calculation algorithm to obtain the angle trajectory from the hand trajectory is described as follows.

Step 1 *Discretize the target hand trajectory* $\boldsymbol{x}(\tau)$ *by step size* Δt.

$$\tau_{i+1} = \tau_i + \Delta t,$$

$$\boldsymbol{x}_{i+1} = \{x(\tau_i + \Delta t), y(\tau_i + \Delta t), z(\tau_i + \Delta t)\}. \tag{3}$$

Step 2 *Calculate the target distance from* x_i *to* x_{i+1}

$$\Delta \boldsymbol{x} = \boldsymbol{x}_{i+1} - \boldsymbol{x}_i. \tag{4}$$

Step 3 *Calculate the weighted pseudo inverse matrix of the Jacobian. Where the weighted matrix* $\boldsymbol{W}$ *is a* 4×4 *positive definite symmetric matrix and the* a_i *and* b_i *is the limitation of joint angle.* w_i *becomes 0 when* θ *approaches limit value. Therefore,* $\Delta\theta$ *also decrease by weighted matrix* $\boldsymbol{W}$ *and realizing joint angle limitation.*

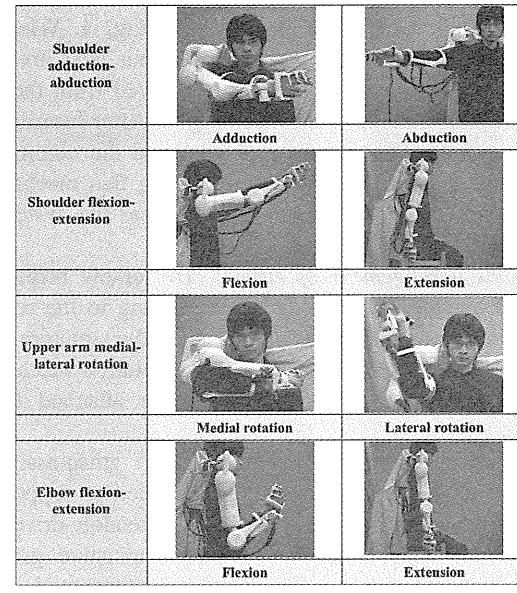


Fig. 8. Joint range of motion of HAL-UL

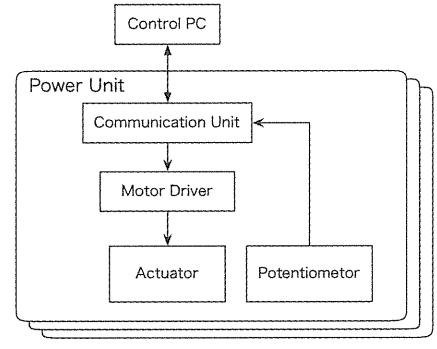


Fig. 9. Control system is composed of the host controller, the communication unit, and the motor driver. The host controller send command to each power unit.

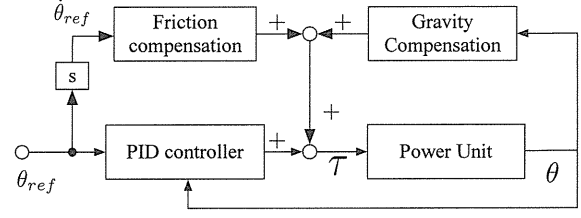


Fig. 10. Assistive torque is generated by using a PID control based on the target angle trajectory. Moreover, the motion control is further improved by adding a gravity and friction compensation controller.

$$\boldsymbol{J}^{+} = \boldsymbol{W}^{-1}\boldsymbol{J}^{T}(\boldsymbol{J}\boldsymbol{W}^{-1}\boldsymbol{J}^{T}), \tag{5}$$

$$\boldsymbol{W} = \begin{bmatrix} w_1 & 0 & 0 & 0 \\ 0 & w_2 & 0 & 0 \\ 0 & 0 & w_3 & 0 \\ 0 & 0 & 0 & w_4 \end{bmatrix}, \tag{6}$$

$$w_i = -(\theta - a_i)(\theta - b_i). \tag{7}$$

Step 4 *Calculate the angle displacement vector* Δq_i

$$\Delta \boldsymbol{q}_i = \boldsymbol{J}^{+}\Delta \boldsymbol{x}. \tag{8}$$

Step 5 *Renew the joint angle vector*

$$\boldsymbol{q}_{i+1} = \boldsymbol{q}_i + \Delta \boldsymbol{q}_i. \tag{9}$$

The target angle trajectory is obtained by iterative calculation from step 1 to step 5.

The assistive torque for each power unit is generated by using a PID control based on the target angle trajectory. Moreover, the motion control is further improved by adding a gravity and friction compensation controller as shown in Fig. 10.

C. Grasping motion control

The grasp-assistance system is independent from HAL-UL and the grasping and releasing operations are conducted according to the signal from the HAL. The HAL-UL does not contain the function to identify the holding object at the present stage, therefore, in this study the timing of the grasping operation is performed according to the preset timing. The grasp-assistance system grasps the container when the hand reaches the container and releases it when the hand go back to the first position.

IV. EXPERIMENT & RESULTS

A. Protocol

We performed an experiment to confirm basic function of developed HAL-UL and trajectory calculating method. The experiment was performed with relaxed healthy person. The tasks are followings (Fig. 11).

1) *Reach to the bottle on the desk*
2) *Grasp the container*
3) *Reach to the user's mouth*
4) *Go back to first position and put the container*

The position of the bottle is decided beforehand, and does reaching to the position. Whether each joint follows to the targeted value from the generated trajectory and whether it operates safely with human wearing HAL is confirmed.

B. Result

Figure 12(a) shows reaching and grasping motion in the experiment. Figure 12(b) shows target joint angles and obtained joint angles. As a result of the experiment, the target operation was achieved. The generated joint angle does not exceed human joint range of motion by the proposal method.

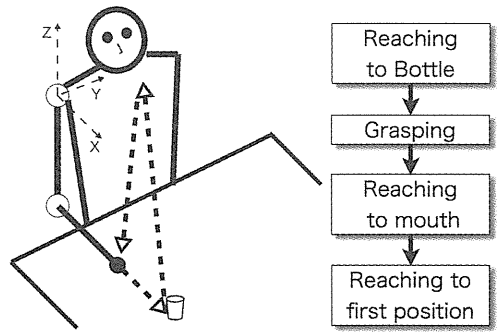
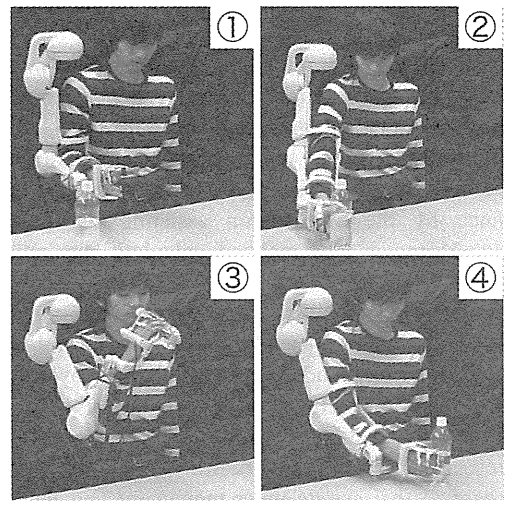
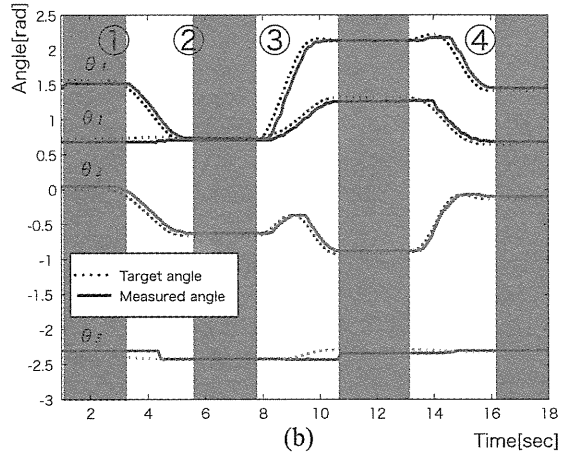


Fig. 11. Protocol of the experiment. The tasks are followings, 1) Reaching to the bottle on the desk. 2) Grasping the bottle, 3) Reaching to the userfs mouth, 4) Going back to first position



(a)



(b)

Fig. 12. Result of experiment. (a) shows reaching and grasping motion in the experiment. (b) shows target joint angles and obtained joint angles. Each power unit followed generated target angle and reaching operation was achieved.

V. DISCUSSION

Each power unit performed reaching and grasping operation by rotating accordingly to the calculated angles. The fundamental capabilities of the HAL-UL were verified by the correct performance of the reaching and grasping operations. The reaching operation is performed by manually setting the target point on the desk. The trajectory and target angles are autonomously generated by the proposed method. Therefore, by implementing an interface for setting the target food position on the table, reaching operation of meal assistance could be executed. The large error margin of θ_3 is attributed to the large mechanical friction of the numerous rotation mechanisms. Moreover, the posture of the spoon and the glass cannot be arbitrarily changed because there is no degree of freedom of the wrist, and this could represent an obstacle in an actual meal. This problem can be solved by adding an extra degree of motion through a wrist support mechanism.

VI. CONCLUSIONS AND FUTURE WORKS

In this research, we proposed wearable hardware which enables reaching operation in meal and trajectory calculation method by developing an upper-limb type HAL(HAL-UL) for meal-assistance. The developed hardware contains 4DOFs and a grasp-assistance system and performs meal-assistance by the exoskeleton assisting the userfs limb directly. Moreover, we realized calculating a smooth trajectory and the target angle which does not exceed the human range of motion by proposing a trajectory calculation method with weighted-pseudo-inverse-matrix and minimum jerk model. In the fundamental experiment by the relaxed healthy person, we verified that each joint could follow to the trajectory calculated by the proposed method and performed the prescribed operation. In future works, we will develop a mechanism that assists wrist movement and the interface to actually perform meal assistance with the cooperation of actual patients.

VII. ACKNOWLEDGMENTS

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Stepwise Process of Clinical Trials in Safety-Conscious Development of Human Assistive Robots

Koji Hasebe, Hiroaki Kawamoto, Akira Matsushita, Kiyotaka Kamibayashi, and Yoshiyuki Sankai

Abstract— **Recent advances in the study of human assistive robots have led to requests for ethical review for clinical trials during the development process. In this environment, many developers have found it difficult to understand the criteria for these ethical reviews. One of the basic reasons for this difficulty is the methodology in robotics. That is, trials in the development of robotics are characterized as exploratory rather than confirmatory, with the current design being rapidly altered to achieve the final product. However, from the ethical and scientific viewpoints, it is requested to plan serial trials so that the objectives gradually shift from exploration to confirmation. That is, aspects of the design should be gradually fixed throughout the development process, and in the latter stages trials should be conducted that confirm the merits of a fixed design. To address this problem, we proposed a development process for human assistive robots in our previous work with the intention of helping developers identify the current phase of development and plan suitable experimental protocols. Based on this, in this paper we present a more refined approach that considers a stepwise process for developing the final product with enough safety measures to protecting users.**

I. Introduction

A. Background and Motivation

According to recent advances in human assistive robots[1], such as intelligent wheel chairs, prosthetic limbs, and wearable robots, clinical trials are becoming more common. Consequently, developers (robotics researchers and engineers) are being requested to undergo ethical reviews for their trials. However, in this environment many developers conducting clinical trials find it difficult to understand the criteria for ethical reviews, such as the requirement to clearly state the primary objectives, hypotheses and endpoints of their trials.

There may be several possible causes for this difficulty. One plausible explanation is a lack of experience with ethical reviews on the part of the developers, as ethical reviews have been limited to clinical research typified by areas such as drug development. However, the most basic reason is the methodology that characterizes the development process in robotics. In general, experiments are conducted to evaluate an idea for improving the current design. Depending on the outcomes of these experiments, the design is altered and further experimentation is planned to evaluate this revision. This short-term trial-and-error cycle continues iteratively until achieving the final product. Thus the experiments throughout the development process may be characterized as exploratory rather than confirmatory.

However, to make trials ethically acceptable and scientifically sound, researchers are being required to follow a stepwise approach as established in medicine. In the development of a medical product, the main experimental objective gradually shifts from exploration to confirmation. In addition, the design is gradually fixed in the process, and in particular is not changed during the latter confirmatory phases. The underlying principles in this stepwise approach follow such well-known guidelines as the Nuremberg Code [14], the Belmont report [15], the Declaration of Helsinki [17], and the Code of Federal Regulations [1]. In the specific case of drug development, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) [6] provides a unified standard for the European Union, the United States, Japan, and so on. On the other hand, guidelines have been issued for the development of medical devices, such as the Investigational Device Exemption (IDE) by the FDA [16], Medical Device Directive (MDD) in the EU [2], and ISO 14155 [8]. In these documents, requirements for the protection of trial subjects and the scientific soundness of trials are stated, but no stepwise approach like that in the ICH guideline is outlined.

B. Objective of this paper

To address the problem explained above, we proposed in [4] a development process for human assistive robots. This process was intended to help developers identify the current phase in their development and plan experimental protocols which comply with both ethical and scientific requirements. Our proposed process is similar to that in the ICH guidelines, but is adjusted to the context of human assistive robots to reconcile the differences between robotics and medicine. The main features of our process are as follows.

Our process consists of five temporal phases named Phases 0 to IV. Throughout these phases, trials are conducted stepwise and the objectives gradually shift from exploration

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[1]In this paper, "human assistive robots" are robots for supporting or enhancing human activities. In other words, the scope of our discussion is limited to Class B of the Global Harmonization Task Force (GHTF) [3]. Consequently, invasive devices are beyond the scope of this paper.

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to confirmation. Also, trial subjects shift from the developers themselves to patients, that is, the intended users of robots. In the early phases, design changes in short-term trial-and-error cycles are allowed to facilitate smooth development. In addition, the developers can avoid ethical review (in Phase 0), or they are recommended to prepare experimental protocols with a range of possible deviations according to expected design changes (in Phase 1). In contrast, design changes are forbidden in later phases, and if modification is required, the experimental protocol must be revised and reviewed through the ethical board.

However, apart from the ethical and scientific requirements, developers are also required to plan a series of trials to confirm and demonstrate that the final product is both effect and meets the necessary safety criteria. To satisfy requirements of this kind, Yamada et al. [18] proposed a stepwise development process focusing on safety considerations. The process in that paper consists of three temporal stages, Stages 1 to 3, where the safety measures are gradually implemented. Thus the objectives of the trials shift from evaluation of effectiveness to confirmation of safety. In addition, with each new stage, a major design change takes place according to the results of a series of trials.

The objective of this paper is to refine the development process introduced in our previous work [4] by integrating it with the stepwise process in [18]. The central idea behind this integration is to map each stage of Yamada et al.'s development process to the corresponding part of our process, so that each stage consists of a series of phases specified in [4].

The process proposed in this paper aims to realize the following improvements. First, our process is appropriate and directly applicable to the development of human assistive robots, and makes the criteria for ethical review more understandable for developers. Moreover, in comparison with the process previously proposed in [4], the process presented in this paper is consistent with the ideal safety-conscious development process. Second, our process may also help the IRB (Institutional Review Board) understand the approach taken in engineering research. That is, our process is intended to bridge the methodological gap between robotics and medical science. Finally, our process forms a basis for guidelines on the development of human assistive robots with high levels of safety. This formulation will be our main topic of study in the future.

This paper is organized as follows. Section II overviews the process defined by the ICH's guideline [6] for clinical trials in the development of a new drug. Section III presents the phase-based development process for human assistive robots. Section IV overviews the process introduced by Yamada et al. [18] and then explains the mapping of the latter to the former. Finally, Section V concludes this paper.

II. Overview of the Drug Development Process

The ICH guideline for clinical trials [6] outlines the principles and practices for the development of new medicinal products and has been adopted by the regulatory bodies of the European Union, the United States, Japan, and so on. For example, the Ministry of Health, Labour and Welfare (MHLW) in Japan has published the guideline [11] for clinical trials based on [6]. For the protection of trial subjects and to ensure the scientific soundness of experiments, the ICH guideline suggests that drug development is ideally a logical, stepwise procedure. To describe the development process as a stepwise approach, four temporal phases named Phases I to IV are defined as follows.

Phase I: This phase is the initial stage of studies on humans. The most typical target of this trial is human pharmacology. This trial aims to assess the safety, tolerability, and actions of drugs. Each trial may be conducted on a small group of healthy participants, certain types of patient, or both. These trials typically includes studies to estimate the safe dose range, side effects, pharmacokinetics, pharmacodynamics and potential therapeutic benefits of the drug.

Phase II: The most typical function of this part of the trial is therapeutic exploratory investigations. This phase is designed to explore the effectiveness of the drug, as well as to assess its safety in patients with the disease or condition that is the target of the trial. Furthermore, trials in this phase are performed on a larger group of patients on a gradual basis and dose escalation designs are often used. The goals of this phase are to determine doses and regimens for the Phase III trials and to evaluate potential endpoints, therapeutic regimens, and target populations for further study.

Phase III: This phase is conducted to confirm the therapeutic value of the drug or treatment. The trials in this phase aim at a definitive assessment of how effective the drug is, compared with current gold standard treatments for large groups of patients. These trials are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended recipient population. Phase III trials should provide an adequate basis for marketing approval and explore the dose-response relationships and the responses in wider populations, in different stages of the disease or in combination with other drugs.

Phase IV: This phase starts after the drug is approved. The studies in this phase delineate additional information including the drug's safety, efficacy, and dose definition. A variety of studies in this phase are on the therapeutic use and benefits, without routine surveillance studies.

III. Phase-Based Development Process for Human Assistive Robots

A. Overview

To incorporate the stepwise development process into the development process for human assistive robots, one of the most important issues is the dilemma between the admissibility of design changes and the requirements for ethical acceptability. This is, as explained in Section I, due to the process for robot development, in which repeated design

changes in the development process are essential. Particularly in the early stages, short-term cycles of design changes are necessary to achieve a first prototype. Consequently, requiring developers to prepare ethical reviews for each design change would be a great obstacle to smooth development. However, there is an inevitable need for a third party to check the safety of trial subjects and the scientific soundness of experiments.

To address this dilemma, we take a compromised approach. From the viewpoint of protecting trial subjects and ensuring scientific soundness of the experiments, our proposed process consists of four temporal phases named Phase 0 to III. This classification of clinical trials according to when the trials occurs during development is similar to the development process defined in the ICH's guideline. Thus, in our process, the objectives of experiments are gradually shifted from exploratory to confirmatory. However, in the earlier stages, namely Phase I and Early Phase II, changes in the robot's design as well as of the experimental protocols are allowed whenever the safety of these changes has been explained and documented in the preceding ethical review. In addition, we consider a preliminary phase named Phase 0 to further smooth the development process. This phase is characterized as development of a first prototype by repeating short-term cycles of experiments, where the trial subjects in this phase of these experiments are the developers themselves. In contrast to Phases 0 and I, design changes are not allowed in Phase II. This requirement will force the developers to establish suitable hypotheses and endpoints for the current stage of the development process.

B. Development process for Human Assistive Robots

We shall now give a detailed explanation of our proposed process, describing the project timescales, expected objectives, human trial subjects, and clinical test items for each of Phases 0 to III. To clarify our ideas, we assume that the target robots are for people with disabilities, such as wheel chairs, or power assisted robots to support walking or eating, but they is also directly applicable to the other types of human assistive robots.

Phase 0: The goal of this phase is to develop an initial prototype of an intended assistive robot to be used for the experiments in successive phases. The development of the prototype is usually conducted in development cycles with iterative refinements of the design by experiment and hazard analysis. In the development cycle, the basic design idea is confirmed by experiments using a simple trial model. The current design idea is then partly modified or determined based on the results of these experiments. Again, the next experiments are conducted to confirm the previous modification, and such an iteration of experiments and refinements is continued until the initial prototype aimed at is achieved.

Typical hypotheses and endpoints in Phase 0 are determined to confirm whether the prototype performs as intended by the specifications.

The trial subjects in this phase are the developers themselves. Since they have enough knowledge of safety measurements in the use of their device for experiments, we consider that the safety of the experiments is ensured only by their recommendations, or by using check lists or hazard analysis methods, instead of by ethical review.

Phase I: For this phase the design and specification of the prototype are confirmed and refined by experiments with trial subjects other than the developers. Analogous to Phase I in the ICH's guideline, the trial subjects are able-bodied adults, both to make the experiments safer and to facilitate fault identification. The control parameters in the experiments, such as torque, speed, and degrees of freedom of the device, are gradually increased within a range that ensures the safety of trial subjects. During the series of experiments, the performance of the prototype is enhanced to the level of its intended use. The typical hypotheses and endpoints in this phase are determined to confirm whether the performance and safety of the prototype meet the intended design specifications.

As in the case of Phase 0, the design of the prototype in this phase is still often improved. In contrast to Phase 0, though, an ethical review is required for each experiment because the trial subjects are third persons. However, as previously mentioned, subjecting the developers to an ethical review for each design change would be a tiresome procedure for both the developers and the ethical review board. Thus, in this phase, it is recommended that the developers prepare the experimental protocol with a range of possible deviations according to the expected design changes, such as the possibility of replacement of actuators, control programs, and so on. To ensure the trial subjects' safety, the developers should conduct a hazard analysis of the series of experiments described in the protocol. The developers may then freely change the protocol to the extent that has already been allowed by the ethical review.

Phase II: This phase is the first stage in which the trial subjects are persons with disabilities. This phase is divided into two temporal sub-phases as follows.

In Early Phase II, the experiments assume mock situations for a variety of practical uses. For example, in the case of rehabilitation robots, the training procedure or a period of use are investigated using the current prototype. The effectiveness of the prototype is also explored across a wide range of disorders. More precisely, at the beginning of this phase, the trial subjects are patients with mild and stable symptoms. The number of subjects is gradually increased, as is the level of their disabilities.

Through these experiments, the current design is changed if the results of the experiments indicate room for improvement not identified in the preceding phases. Thus, as in Phase I, design changes are allowed only within a range where safety is ensured in advance by the ethical review. Clearly, a thorough hazard analysis of experiments in this phase is crucial and requires consideration of the disabilities of trial subjects as well as the results of experiments in the preceding phases. At the end of this phase, the design of the prototype is fixed, and throughout the later phases it cannot be changed.

	Subjects	Modification	Ethical review
Phase 0	Developers	Allowed	Unnecessary
Phase I	Able-bodied persons	Allowed	Necessary
Early Phase II	Persons with wide range of disabilities	Allowed	Necessary
Late Phase II	Persons with focused disabilities	Not allowed	Necessary
Phase III	Persons with focused disabilities (scaled-up version of Phase II)	Not allowed	Necessary

TABLE I
SUMMARY OF THE DEVELOPMENT PROCESS

In contrast to the exploratory approach taken in Early Phase II, in Late Phase II the experiments are characterized as confirmatory studies. For this purpose, experiments are conducted using a prototype with a fixed design. The effectiveness is verified using groups of trial subjects with focused disabilities, since this is considered to be more effective in establishing the usage of the proposed robot. In addition, the number of subjects is larger than in Early Phase II, and reproducibility with statistical significance is verified. The hypotheses and endpoints in this phase are thus determined to verify the effectiveness for trial subjects, rather than to investigate it.

Modifications of design and specification in each trial are forbidden. Thus, if modification is required in a series of trials, it is necessary to revise the experimental protocol and review it through the ethical board again.

Phase III: Phase III is the stage that confirms suitability and decides the final specification and usage as a product. If the detailed specification and usage of the robot is fixed from the results of the Phase II trials, the development proceeds to the next phase. To improve the degree of accuracy of the evaluation, the experiments in this phase are conducted in various institutions with as many disabled persons as possible.

IV. Refinement of the Stepwise Process

In the previous subsection, we discussed how our stepwise process protects subjects in clinical trials. However, if we apply this process to actual robot development, we should also consider the incorporation of safety devices into the intended robot. According to Yamada et al. [18], it is not in general reasonable to equip a prototype with all the required safety features from the early stages of development of human assistive robots (see also [5] for a case study of safety construction processes). Rather, in the early stages the main objective is to demonstrate the effectiveness of the robot, and the required safety devices are then gradually introduced and safety is ensured by trials in the later stages. Thus, it is important to investigate how to protect trial subjects against possible harm caused by a prototype which is not fully equipped with safety devices.

In this section, we first introduce the stepwise development process from Yamada et al. [18], focusing on safety construction. We next integrate this process with our phased process in a coherent manner, thereby refining our proposed process.

A. Safety Construction Process

In Yamada et al. [18], the ideal development process for safety construction consists of the following four stages[2].

Stage 0: In this stage, the conditions and environment for use of the intended robot are fixed, and risk assessment for this supposed use is conducted. The main objective of experiments is to demonstrate effectiveness rather than safety, and thus safety measures against previously identified risks are kept to a minimum.

Stage 1: Following the previous stage, the main objective of this stage is to identify possible hazards and demonstrate effectiveness, but this is conducted in more realistic environments. Finally, the results of risk assessment are reviewed. From a ethical viewpoint, the development process cannot continue to the next stage unless the estimated benefits outweigh the risks.

Stage 2: Prior to the experiments in this stage, the safety integrity level and required safety measures are determined according to the results of risk assessment from the previous stage. The objectives of this stage are to design and develop the appropriate safety devices, evaluate reliability, and detect defects in the prototypes. These activities follow ALARP (As Low As Reasonably Practicable) on instrumental grounds. The trial subjects are now ideally the target users (that is, the patients), but such a trial is not allowed by ethical boards unless the benefits outweigh the risks.

Stage 3: In addition to the safety devices developed in the previous stage, safety devices are continuously developed as long as the product achieves the safety integrity level. In addition, the final safety demonstrations are conducted before product release.

B. Safety-Conscious Phased Development Process

As we have seen in the previous subsection, Yamada et al.'s [18] process describes a robot development process

[2]In [18], their process originally consists of Stages 1 to 3, but they implicitly assume a preliminary stage prior to Stage 1. Thus, in this paper we call this Stage 0 and treat it as an independent stage.

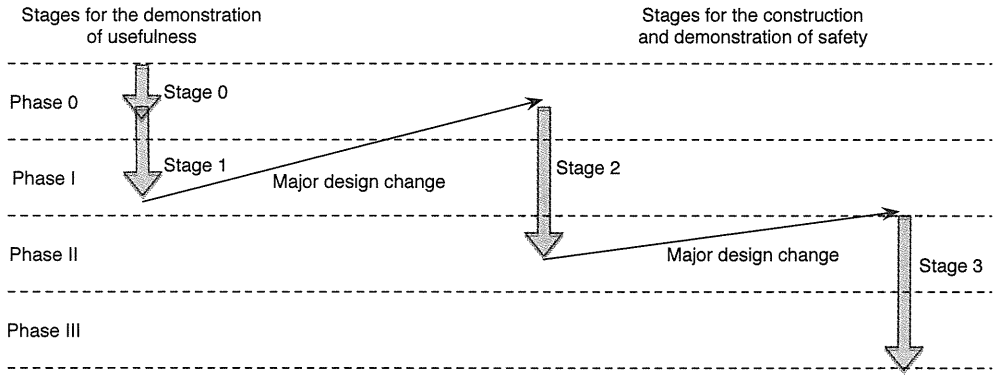

Fig. 1. Integrated Development Process

from a broader viewpoint, and each stage can therefore be mapped to a part of our process. In addition, according to the case study by Homma et al [5], major design changes were required at the end of Stages 1 and 2. In terms of our phased process, a major design change induces back-tracking to a suitable phase. From these observations, the development process we obtain by integrating the process from Yamada et al. [18] with ours can be depicted as in Fig 1. Here, the vertical arrows represents Stages 0 to 3 and are mapped to parts of our phased process.

Stage 0 is mainly mapped to Phase 0. In this stage, experiments are conducted mainly in the developers' laboratory and the trial subjects are the developers themselves. As previously stated, ethical reviews are not mandatory in this stage. Instead, the safety of trial subjects is guaranteed by minimal measures, such as an emergency shutdown system or risk assessment by means of check lists or simple hazard analysis. The main objective of these trials is to evaluate the effectiveness of the intended robot. A prerequisite for continuing to the next stage is risk assessment, but any prototypes have not yet been equipped with safety devices and so assessment is mainly based on specification documents.

Stage 1 is mapped to later Phase 0 and Phase 1. In this stage, experiments are conducted in the laboratory and the main objective is again to demonstrate the usefulness of the robot. However, if the ethical board agrees that the benefits are sufficient in comparison with the possible hazards, trials with persons outside the laboratory are permitted.

Stages 2 and 3 are mainly mapped to Phases 1 to 3, but experiments may be partly conducted in Phase 0 due to major design changes. In these phases, the main objectives shift to safety considerations. That is, development of safety devices and evaluation of safety are carried out. The trials are conducted in more realistic situations with patients with the disease or condition that the intended robot targets. As previously explained, the number of trial subjects as well as the level of disease are gradually increased.

To close the explanation of our proposed process, we would like to give some remarks on the usefulness of the process for both the developers and the IRB.

On the one hand, it is important for the developers to identify the current position so as to plan the experiments in the development process. This may help to clarify hypotheses and endpoints suitable for the current position. For later phases, it may also help avoid unnecessary exploratory experiments, which are often included as a function of this particular style of engineering research. On the other hand, it is important for the IRB to understand that the development process consists of iterative short-term cycles of experiments and design changes. Although we should consider the protection of trial subjects, it would be a major obstacle to smooth development if each experiment is subjected to a fixed protocol of ethical review. Instead, we introduce Phase 0 as a preliminary phase where the safety of trial subjects (that is, the developers themselves) is guaranteed without an ethical review. In addition, we also propose allowing flexible changes of design and experimental protocols if the safety of these changes has already been explained and documented in the preceding ethical reviews.

V. Conclusions

In this paper, we have proposed a development process for human assistive robots, which is intended to be a reference for developers planning serially conducted clinical trials. The process classifies clinical trials into four temporal phases, Phases 0 to III, where the objectives of the trials gradually shift from exploration to confirmation. In addition, we also integrated this phased process with a standard safety-conscious development process, thereby making it possible for the developers to identify the current position in the safety construction process.

Our stepwise process is similar to the ICH guideline, but is adjusted to the context of robotics. Our process would facilitate the positioning of clinical trials in a phased experimental sequence for developers, which is expected to help the understanding of experimental objectives and endpoints in the planning of the experimental protocol. Furthermore, our process aims to provide a common language for the developers of robotics and the IRB.

The process presented in this paper is still under development and has room for improvement. To accomplish our process as a guideline for the development of human assistive robots, many details still need to be determined. To achieve this target, we are currently considering a development process for a wearable robot suit called HAL [12], [13]. In addition, it would be worthwhile considering the consistency of our process with safety standards such as Guide 51 [10], IEC 61508 [7], and ISO 13482 under formulation [9]. This will also be investigated as a part of our future research.

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of chronic exercise and the G-CSF that application to noninvasive regenerative therapy is expected. *Method:* Male 5/6-nephrectomized WKY rats were divided into five groups according to the following treatments: 1) no treatment (C); 2) exercise with treadmill running (20m/min for 60 min/day, 5 days/week) (EX); 3) G-CSF (5 micro g/kg/day, sc); 4) EX+G-CSF; and 5) sham operation (S). The rats were then treated for 12 weeks. *Results:* The 24 h-urinary excretion of protein, serum creatinine in the EX+G-CSF group, and the blood urea nitrogen in the G-CSF and EX+G-CSF groups were significantly lower than those in the C group. The index of glomerular sclerosis (IGS) in the EX, G-CSF and EX+G-CSF groups were significantly lower than that in the C group. The IGS in the G-CSF and EX+G-CSF groups were significantly lower than that in the EX group. The expression of α-smooth muscle actin in the glomerulus was the lowest in the Ex+G-CSF group. *Implications/Impact on Rehabilitation:* These results suggest that both chronic exercise and G-CSF have renoprotective effects in CRF model. They also suggest that the simultaneous treatment of chronic exercise and G-CSF can enhance endurance with the renoprotective effects.

No. 303

GAIT TRAINING OF A SPINAL CORD INJURY PATIENT USING ROBOT SUIT HAL

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Objective: Our goal is to enhance the quality of life of persons with motor disabilities by means of an active motion support system that assists the impaired motion in a way that matches as much as possible to the motion of able-bodied persons. To this end we developed the Robot Suit HAL (Hybrid Assistive Limb) to actively support and enhance the human motor functions. The objective of this research is to investigate the effectiveness of the rehabilitation of a person with spinal cord injury using HAL. *Method:* The HAL can be controlled using the Voluntary Control method or the Autonomous Control method. Voluntary Control provides physical support according to the wearer's voluntary muscles activity. Autonomous Control provides a predefined functional motion based on recorded motion patterns from able-bodied persons. In this research, we used Voluntary Control for a person with spinal cord injury. The subject was a 69 years old man who was diagnosed with spinal canal stenosis. He has difficulty flexing his right hip and knee joints during the swing phase as well as extending these joints during the standing phase. The trials were organized in one-hour sessions, which were performed twice a week for eight weeks. In the trials, gait training with the HAL was performed on a treadmill. *Results:* The gait training was evaluated by comparing the time and step count of the 10 m walk test, before and after the eight-week gait training. The walking speed was higher and the step count was decreased after the eight weeks. *Implications/Impact on Rehabilitation:* The HAL allowed the patient to provide motion support voluntarily, which improved walking ability. This research suggests the HAL may be effective as active rehabilitation devices.

No. 304

DIFFICULTIES IN EVERYDAY TECHNOLOGY USE AFTER BRAIN INJURY: ASSESSMENT USING THE EVERYDAY TECHNOLOGY USE QUESTIONNAIRE (ETUQ)

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Objective: To reveal difficulties people with brain dysfunction have using Everyday Technology (ET) in their daily life. We also consider how to solve some of these problems through technology. *Method:* The participants were five cases with higher brain dysfunction living at home after brain injury. Neuropsychological testing was conducted using the Wechsler Adult Intelligence Scale - 3rd edition (WAIS-III), the Wechsler Memory Scale - Revised (WMS-R), and the Behavioural Assessment of Dysexecutive Syndrome (BADS). Everyday life at home was assessed through semi-structured interviews with them and their caregiver. We assessed ET with the Everyday Technology Use Questionnaire (Rosenberg et al, 2009), Japanese version: ETUQ-Kobe. *Results:* They use 29 to 36 items of the 100 items included in the ETUQ-Kobe. The items that they felt difficult using were microwave ovens (using switches, or forgetting to remove items), gas stoves (adjusting the gas-level), air conditioners (switching between heating and cooling modes), etc. We classified the cause of problems in ET use as: prospective memory disorder (such as forgetting to take out laundry from the washing machine), attention disorders (such as forgetting flush a toilet), and executive function disorders (such as don't understand the operational procedure of remote control). We also developed the support system for the problem caused by impaired attention "forgetting flush toilet water". *Implications/Impact on Rehabilitation:* For people with higher brain dysfunction, some ET items are difficulty due to their complex procedures, or due to forgetting, although they can operate that item. Some items can be used if appropriate prompts or stimulation are provided.

No. 305

THE EFFECT OF POSTOPERATIVE SWALLOWING REHABILITATION ON SWALLOWING FUNCTION AND QOL IN PATIENTS WITH HEAD AND NECK CANCER

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Objective: Postoperative swallowing dysfunction is thought to impair quality of life (QOL) in patients with head and neck cancer surgery. However, few studies have thoroughly investigated about the relation among swallowing dysfunction, QOL and swallowing rehabilitation. This study evaluated the effect of postoperative swallowing rehabilitation on postoperative swallowing function and QOL. *Method:* Subjects were 27 patients who underwent surgery for head and neck cancer at the Tohoku University Hospital between 2006 and 2009. Thirteen patients received postoperative swallowing exercises for 2 months were served as REHA group. Fourteen patients who did not receive postoperative swallowing exercises were served as Control group. Assessment of Frenchay Dysarthria Assesment test (FDA), speech intelligibility, swallowing function and The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire H&N35 (QLQ-H&N35) was conducted at just before the operation 1(before the rehabilitation), and 3 months (after the rehabilitation) after surgery. *Results:* In REHA group, FDA score improved significantly as compared with Control group. With regard to the QLQ-H&N35, score for Open mouth, pain, social contact score improved in REHA group. Performing postoperative swallowing exercises produces improvements in post treatment swallowing function in patients with surgery for head and neck cancer. *Implications/Impact on Rehabilitation:* Postoperative rehabilitation, especially postoperative swallowing exercises may be effective in improving swallowing dysfunction and QOL in patients with head and neck cancer surgery.

No. 306

IN-HOME REHABILITATION SUPPORT PHYSICIAN SYSTEM

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事例紹介

ロボットスーツHALの安全技術

Safety Techniques in Robot Suit HAL

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1. はじめに

ロボットスーツHAL（以下HAL）は，サイバニクス研究から生まれた装着型のロボットである．HALは装着者の生体電位信号を読み取り，その信号に従った制御を行うことで，装着者の身体運動を補助する仕組みを持っている．

歩行など下肢動作の補助を目的とした下肢型のHALは，“ロボットスーツHAL福祉用”（以下，HAL福祉用）として，CYBERDYNE社によって実用化された．CYBERDYNE社は継続して各種安全技術の開発に取り組み，製品の改良・製造をすすめ，2010年春より本格的にレンタル販売・サポートを展開している．

本稿では2011年現在，普及初期にあるHAL福祉用に用いている安全技術および安全に対する取り組みを概説する．またHAL福祉用に備えられた安全機能と，IEC 61508-1 [1]などで注目されている機能安全の関連を解説する．最後に装着型ロボット一般に共通して適用可能な安全コンポーネントの可能性について考察する．

2. HAL福祉用の安全技術

HALはその特性上，人体に密着して電気的に動作し，力学的な効果を人体に及ぼすシステムである．このようなシステムは一般的ではないため，安全技術について十分に検討し，適宜対応していく必要がある．

HALのような新しい機器を安全に設計するには，リスクアセスメントに基づく開発手法を適用するのが適切と考えている．リスクアセスメントに基づく開発手法は，国際安全規格（ISO 12100-1 [2], IEC 61508-1 [1], IEC 60601-1 [3]など）でも要求されており，標準的な方法と言える．

リスクアセスメントでは，開発しようとする製品に対して，予見できるハザード（“危険源”と訳される）を列挙し，その発生確率を割り当てる．次に，列挙されたハザードに対して，人へ与えうる危害を列挙し，その重大さを割り当てる．最後に割り当てられたハザードの発生確率と危害の重大さを組み合わせて，リスクレベルを割り当てる．

この割り当てられたリスクレベルが，開発する際の指標となる．リスクの高いものから，ハザードの発生確率を下げる対策や，危害の重大さを下げる対策（“リスク低減方法”と呼ぶ）を講じ，開発内容に盛り込んでいく．対策の結果として残留するリスクが受容可能なレベルまで下がると期待できるならば，実際の開発を進めることになる．

リスクアセスメントの各段階について記録に残すことで，すべての予見できるリスクと，それに対して施した対策のリストが得られることになる．このリストは，対策漏れの有無や，対策の妥当性を検証するための重要な資料となる．

CYBERDYNE社におけるHAL福祉用の開発では，リスクアセスメントを実施し，それに基づいてリスク低減方法を検討し，開発に反映していった．以下に，CYBERDYNE社の開発で行った方法を解説する．

リスク管理計画：リスクアセスメントをどのように行うかを計画した．ハザードの発生確率，危害の重大さのレベル，リスクレベルの定義を行い，リスクレベルの決定法としてリスクマトリクス法を計画した．リスク低減方法の検討と実施の手順および，残留リスクの受容性判断基準を定めた．リスク管理を行う製品ライフサイクルの特定を行った．

ハザード分析：下肢型HALのプロトタイプ開発時に明らかとなったハザードと，予見できるハザードを列挙した．

体型がHALに合わない，装着部と皮膚の摩擦，許容できない関節運動，不安定な姿勢，コンポーネントの故障などが，HAL福祉用に特徴的なハザードだった．ここでは発生確率の割り当ては行わなかった．

初期リスク評価：ハザードごとに初期リスクを評価する場合，管理すべき項目数が増大してしまう．そこで，各ハザードの結果として生じる危険状態（装着者が晒される関節部へ過負荷，装着部の圧迫など）を列挙した．原因となるハザードが複数あるため，列挙された危険状態の発生確率の割り当てには幅を持たせた．

次に，危険状態の程度によって危害が異なるとして，予

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