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RESEARCH ARTICLE

A Personalized 3D-Printed Hand Prosthesis for Early Intervention in Children With Congenital Below-Elbow Deficiency: User-Centered Design Case Study

LUIS CCORIMANYA[1], (Graduate Student Member, IEEE), MODAR HASSAN[2], (Member, IEEE), REIKO WATANABE[3], TOMOYUKI UENO[4], YASUSHI HADA[3], AND KENJI SUZUKI[2], (Senior Member, IEEE)

[1]Graduate School of Systems and Information Engineering, University of Tsukuba, Ibaraki 305-8577, Japan
[2]Faculty of Systems and Information Engineering, University of Tsukuba, Ibaraki 305-8577, Japan
[3]University of Tsukuba Hospital, Ibaraki 305-8576, Japan
[4]Ibaraki Seinan Medical Center Hospital, Ibaraki 306-0433, Japan

Corresponding author: Luis Ccorimanya (ccorimanya@ai.iit.tsukuba.ac.jp)

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ABSTRACT The adoption of prosthetic hands by children with congenital upper limb deficiency from a very early age has benefits in terms of reducing prosthesis abandonment, improving body image, and mitigating developmental and physiological complications that arise from the underuse of the deficit arm. However, current hand prostheses present drawbacks that make them not suitable for very young children. This study investigates the design requirements of a prosthesis for very young children with congenital below-elbow deficiency using a user-centered design (UCD) approach. The UCD puts the child at the center of the design process, with parents as mediators between the child and the design team. The study was conducted with an interdisciplinary team over three years, with several prototypes developed for different growth stages of the child. This paper presents the adopted UCD approach and its timeline, the iterative prototypes of the prosthesis developed throughout the study, and the final prototype with a focus on its child-friendly features. Finally, the paper describes the design requirements concluded from the study and the authors' recommendations for implementing prosthetic hands in below-elbow early intervention.

INDEX TERMS Auditory biofeedback, children, congenital below-elbow deficiency, design implications, early intervention, hand prosthesis, in-liner electrodes, myoelectric control, user-centered design.

I. INTRODUCTION

Congenital limb deficiency has adverse effects on child development. This impairment may lead children to a range of behavioral, emotional, and social issues [1], affecting their quality of life. Around 4 per 10,000 infants in Japan are born with this deficiency, occurring more often in the upper limbs [2]. A congenital upper limb deficiency means the partial or entire malformation of the arm since birth. Prosthetic hands can improve the overall well-being of children with upper limb deficiency. Previous investigations have demonstrated that the early adoption of hand prostheses, preferably under two years of age, benefits the children's physical [3] and psychosocial health [4], creates a body image of the prosthesis [5], increases the acceptance rate [6], and leads to more prolonged use of the hand prosthesis [7].

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Generally, hand prostheses are divided into three categories. First, aesthetic hand prostheses intend to look like natural hands. Eshraghi et al. [8] developed a functional low-cost cosmetic prosthesis that allows object grasping with a novel alloy-wire-reinforced structure. Despite their life-like appearance, aesthetic prostheses do not offer the same functionality for object manipulation as the more advanced prostheses [9]. Second, body-powered prosthetic hands are actuated by movements of the remaining upper limb joints or by the shoulders. Nowadays, due to 3D-printing technology, it is feasible to develop low-cost and scalable prostheses for children [10] to meet their rapid growth. However, body-powered prostheses can be challenging to operate, awkward, and heavy [11]. Third, electrically powered prosthetic hands are more advanced thanks to the use of motors and batteries. They can be upgraded to myoelectric prostheses with integrated electromyography (EMG) electrodes to improve the control interface. The Electrohand 2000 [12] is the current state-of-the-art myoelectric hand prosthesis for children. It offers natural and intuitive control owing to the myoelectric control, and it possesses a firm grasp and wide opening due to its motor and mechanical design. Nevertheless, it is heavy, expensive, and not scalable. Also, training the child to contract voluntarily the muscles suited for EMG control may need several sessions [13].

The previous literature suggests that children face various challenges when using hand prostheses, depending on their type. Prior investigations [14], [15], [16] have identified challenges associated with prosthesis use in children. These challenges include the prosthesis' weight, discomfort, durability, and limited usefulness. The origin of these challenges is not investigated in detail. It is likely due to the design that focuses on the intended functionality rather than ease of adoption from children's perspective.

This work attempts to address the issues that hinder the adoption of prosthetic hands for early intervention by employing the User-centered design (UCD) process. The target users are 2- to 6- years old children with congenital below-elbow deficiency. The scientific contribution of this work are the gathered design implications for developing a hand prosthesis for early intervention of children and the concrete implementation example of a prosthetic hand for a child with congenital forearm loss or deformation.

Moreover, the proposed prosthesis aimed to accomplish the following objectives:

i. Perform simple actions such as grasping lightweight and small objects, Figure 1a, to provide the child with the needed functionality [17].
ii. Assist the intact hand in case of two-handed manipulation, Figure 1b, to increase the perceived usefulness of the prosthesis and improve the child's capacity for myoelectric control [18].
iii. Help in the EMG training to make it easier for the child to control myoelectric prostheses [19].

FIGURE 1. Child using the proposed hand prosthesis for (a) grasping small and light objects, (b) assisting the intact hand, and (c) comparing with the intact hand.

iv. Serve as a *transitional prosthesis* for a later, more functional prosthetic hand. In this way, it can help to increase the muscle strength and range of motion (ROM) of the remaining upper limb [20].

CLINICAL RELEVANCE

Pediatric myoelectric prosthetic hands in Japan are regarded as *special prostheses* under the Japanese health insurance system [21]. This means that myoelectric prosthetic hands for training cannot be provided to the children, although proof of mastery of the prosthesis or potential benefit are prerequisites for acquiring a prosthesis later with the insurance system.

The number of training sessions is relative. It depends on various factors, such as age and level of deficiency. From the therapists' clinical experience, 2-3 years of training is required to prove a child's ability to use a myoelectric prosthetic hand effectively. This time frame goes according to Hubbard et al. [13], considering that the training sessions are held once a month in the Rehabilitation department of the University of Tsukuba Hospital. Nevertheless, such training is often not viable due to issues such as the high cost of training myoelectric prostheses, maintenance, and the need to update the socket multiple times to fit the child's growth stages.

Most children with congenital hand or forearm defects can use their residual limbs well to perform activities of daily living. However, it is desirable to perform two-handed movements to avoid the overuse of the intact arm [22], and asymmetrical body posture [23] and its secondary effects, such as the risk of falling [24]. Additionally, the acquisition of two-handed movements brings the possibility of performing movements that cannot be performed with one hand or movements that the child has abandoned.

In cases where training was possible using conventional myoelectric prosthetic hands, the younger the child's age, the more difficult it was to communicate with the child. In addition, children often showed aversion to cumbersome prosthetic hands. Therefore, in clinical practice, there is a need for a myoelectric prosthetic hand that is affordable, lightweight, scalable, and easy to use to enable early prosthetic training for children with upper limb deficiencies [10], [25].

II. METHODS

A. USER-CENTERED DESIGN

UCD is an iterative design process in which the designer focuses on the target users and their needs at each stage of the process [26]. The principal advantage is that it involves the target user in the design process, which leads to the development of technologies that are highly compatible with the target user.

In the field of prosthetics, earlier investigations have reported the successful use of the UCD approach to find out the prosthesis' context of use and requirements through surveys [27], questionnaires [28], interviews [29], and workshops [30]. Furthermore, Dimitrov et al. [31] and Fligliola et al. [32] developed upper limb prosthetic hands using a UCD approach. The results indicated that these prototypes are more appealing to the recipients. Similarly, Laffranchi et al. [33] developed the Hannes hand prosthesis through a holistic design approach to replicate the critical biological properties of the human hand.

Regarding children involved in the UCD process, Fails et al. [34] reviewed the current UCD methods and techniques employed for involving children in designing new technologies for children. Druin et al. [35] described extensively the roles that children can play in the UCD process, which are: *user*, *tester*, *informant*, and *design partner*. Also, Scaife et al. [36] pioneered working with children as *informants*, proposing a preliminary methodological UCD framework. Finally, Almeraj et al. [37] proposed a UCD methodology and techniques to work with visually impaired children. The target users, children with disability, are analogous to this study. Nevertheless, there is no literature about using the UCD process to develop prostheses for children with upper limb loss or deformation.

ADOPTED USER-CENTERED DESIGN

Based on the preceding works, a UCD framework was adopted to develop a child hand prosthesis suitable for early intervention. In the proposed methodology, the child plays the role of *informant* because children as informants can offer input before developing a prototype and feedback after its development for the next iteration [35]. In this way, more information can be gathered to develop the desired prosthetic hand. However, it was not possible to treat the child as a regular informant due to the child's young age in the present study. The child was considered as *indirect informant*, which means that her needs and responses were gathered through observation and from the parents who acted as *mediators* between the child and the research team. The proposed UCD process, shown in Figure 2, consisted of four phases:

- Phase 1: Understand the context of use

The first phase of the proposed UCD process is about understanding the context of use of a child's hand prosthesis for early intervention: to define what for and under what conditions the child will use the hand prosthesis. The UCD technique *User Observation* was employed. It consists of

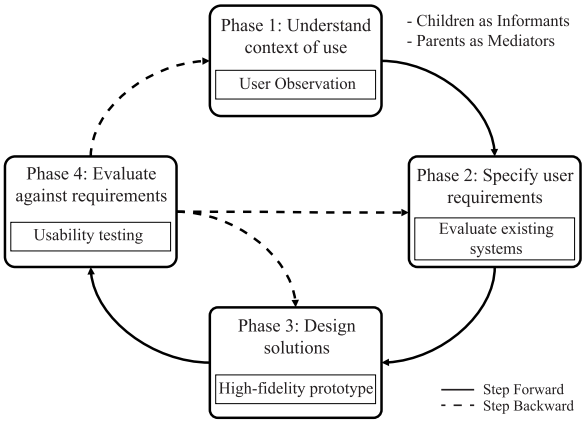


FIGURE 2. The proposed UCD process scheme for children with congenital upper limb deficiency.

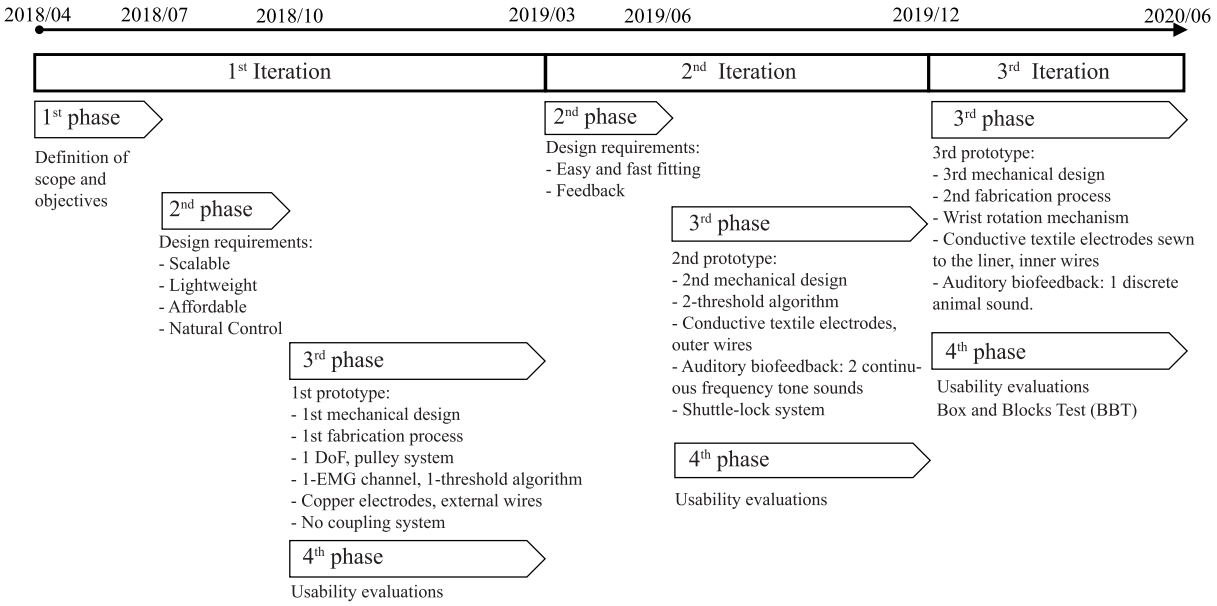


FIGURE 3. Timeline of the case study.

studying the child's behavior in specific contexts and environments.

- Phase 2: Specify user requirements

The second phase is to specify the child's requirements for the hand prosthesis in the scope of the context of use defined in Phase 1. *Evaluate existing systems* is an excellent technique to observe and assess the child's performance using an existing hand prosthesis. Hence, it helps to gather the design requirements needed to develop a child hand prosthesis suitable for early intervention.

- Phase 3: Design solutions

The third phase consists of designing and developing a prosthetic hand prototype based on the design requirements explored in Phase 2. In this stage, developing a *High-fidelity prototype* ensures that the tested device appears and functions as the final desired one.

- Phase 4: Evaluate against requirements

The final phase is to assess the prototype developed in Phase 3 and to verify whether it fulfills the design requirements discovered in Phase 2. In this last step, *Usability testing* methods will be helpful to discriminate the essential requirements from the extra ones. In addition, it can identify the ease of use of different prosthetic prototypes. The UCD process is concluded if a prototype meets the design requirements.

B. THE CASE STUDY

This work is part of a research project being conducted in collaboration with the Rehabilitation Department of the University of Tsukuba Hospital. A partial work of this project has already been published [38]. The research team consists of engineers, physical therapists, and prosthetists.

The study patient was a 4-year-old (at the beginning of this research) girl with congenital below-elbow deficiency on the right arm. Prior to this study, the child had previous experience using hand prostheses. From 2 to 3 years old, she used a custom-made body-powered prosthetic hand. The trials were held under the supervision of physical therapists and prosthetists who belong to our work team. Then, from 3 years old, she uses a myoelectric hand prosthesis, the Electrohand 2000 developed by Ottobock, thanks to a health care program from the local prefecture.

All the examinations with the patient were held at the Rehabilitation department, and all the procedures were approved by the Clinical Research Ethics Review Committee at the University of Tsukuba Hospital (under Application No. H29-071).

The UCD process was grouped into three major iterations to explain this study more effectively. In each iteration, phases 3 and 4 were held in parallel. This is because several evaluation sessions were conducted when designing the prosthesis prototype for each iteration, making minor adjustments and improvements to the prototype between the sessions, and only significant changes between the iterations.

The timeline of this study representing the iterations, the corresponding phases, and the outcomes found in each phase is presented in Figure 3. Then, the developed prototypes and the UCD process schemes for the different iterations are presented in Figure 4 and Figure 5, respectively. Finally, the functional schematics of the prosthesis prototypes are shown in Figure 6. The iterations are explained as follows:

1) ITERATION 1

The UCD process for the first iteration is presented in Figure 5a. It included all the phases since it was the first iteration.

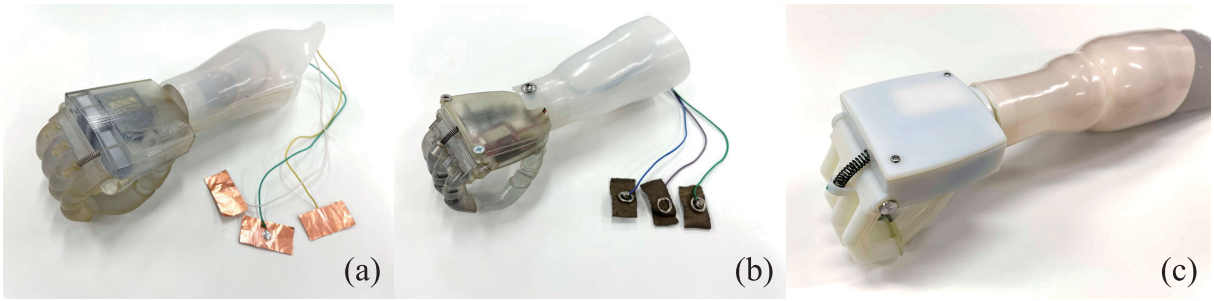


FIGURE 4. Hand prosthesis prototypes at the (a) 1st iteration, (b) 2nd iteration, and (c) 3rd iteration.

1.1) PHASE 1

For the first three months of this study, the child and the parents were cited once a month to the rehabilitation department. Each session was divided into two parts, 30 minutes each. In both parts, the parents were asked to tell the child that she could play with the various toys available in a playroom designed to rehabilitate children at the hospital. The toys were of different shapes, sizes, and weights.

For the first part, the child did not wear any hand prosthesis to examine how she interacted with the toys using the intact hand and the stump together. For the second part, the child wore a custom-made body-powered prosthesis developed by a local prosthetics company. The reason was to know if the child would consider the prosthetic hand to play with the toys. We observed and took notes about the child's behavior while playing. Additionally, videos were recorded for later analysis and discussion with the entire team. In the following sessions, the observations were discussed with the parents.

While the child was not using a hand prosthesis, we noticed that she used mainly the intact hand to interact with the toys around her. However, when the object was too big or heavy, she began to use the stump to assist the intact hand. The parents confirmed that this behavior is present in her daily life. Then, while the child was using the body-powered prosthesis, we observed that she continued using mainly the intact hand. The parents mentioned that the body-powered prosthesis was heavy and bulky for her despite being customized to her body. Also, they pointed out that she felt the prosthesis control was not comfortable.

The team's observations and the parents' opinions and feedback concluded that a hand prosthesis for young children should not target to replace the missing limb but to assist the intact hand. This means that the prosthesis should allow the child to perform simple actions like grasping light and small objects and serve as an assistance device for the intact hand in case of two-handed tasks.

In addition, the prosthesis control should be more sophisticated than the body-powered prosthesis, assuming that myoelectric control is the best option. However, it is well-known that there are difficulties regarding EMG-based control adoption and training. Therefore, a hand prosthesis for early intervention in children with congenital below-elbow deficiency should focus on EMG training, serving as a transition from no prosthesis or body-powered prostheses to advanced myoelectric prostheses.

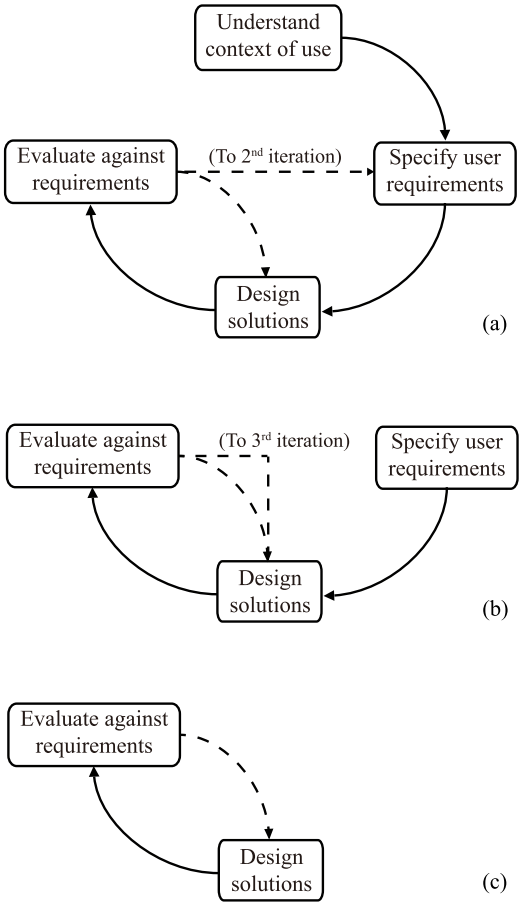


FIGURE 5. The UCD process schemes for the (a) 1st iteration, (b) 2nd iteration, and (c) 3rd iteration.

1.2) PHASE 2

For the next three months, the child and her parents were cited again to the rehabilitation department. Once a month for 1 hour per session. In the first half of the sessions, evaluations were conducted to examine the child's interaction with toys of

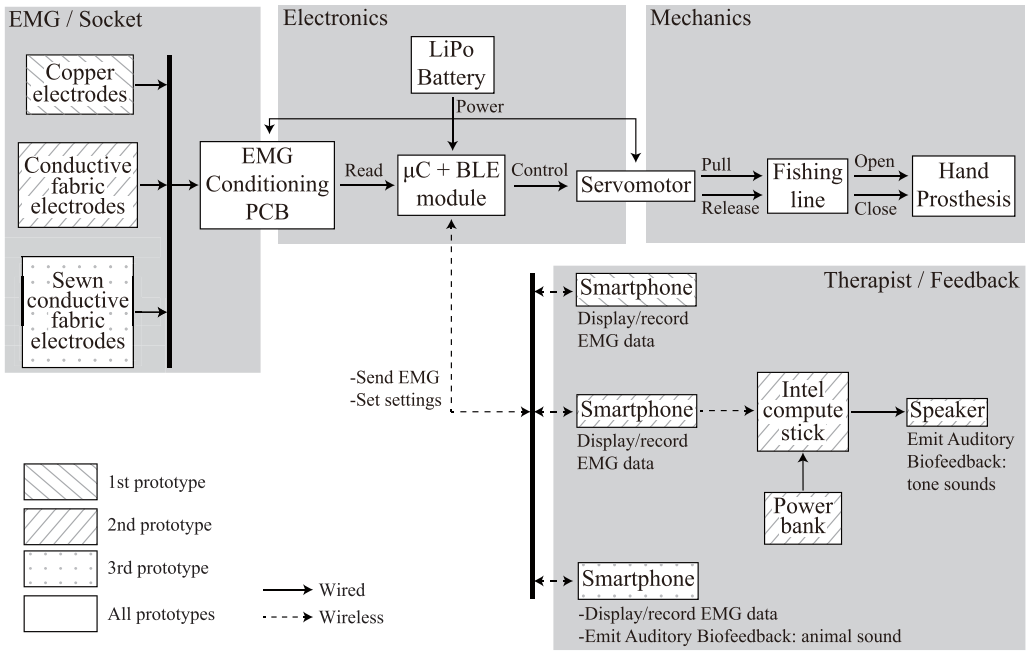


FIGURE 6. **Functional schematics of the 1st, 2nd, and 3rd prototypes. The gray shaded areas indicate the different subsystems of the hand prosthesis.**

different sizes, shapes, and weights similar to the first phase. The difference was that the child wore the current state-of-the-art prosthesis, Electrohand 2000. During the evaluations, we closely examined the child's performance while wearing the prosthesis. Also, videos were recorded for later analysis. In the second half, meetings with the parents were held to ask for their opinions and feedback. It is important to mention that the child interacted and talked with her parents during the experiments. Therefore, they better understood how she felt about the prosthesis and translated it for us in more specific terms.

The Electrohand 2000 size was for 3 to 6 years old children, appropriate for the child during this case study. However, we observed that she had difficulties using the prosthesis. The parents were inquired about this issue and they responded that the child felt that the prosthesis was somewhat bulky and heavy. This may be because the Electrohand 2000 prosthesis is only available in fixed sizes and weights. In addition, the prosthesis material and actuator are heavy by default. Thus, it was concluded that an ideal hand prosthesis for children must be *scalable* to match the child's age perfectly and *lightweight* to suit very young children.

The anthropomorphic characteristics differ among different populations. Japanese people tend to be smaller compared to European Americans [39] and other Asians [40]. This study defines a hand prosthesis as scalable if the design can cover the range of 2-year-old Japanese children to 6-year-old American children. The hand length was considered the most important measurement to match. It was measured from the wrist to the tip of the middle finger. Lin et al. [40] proposed proportional relationships between height and other body parts for Asian people. The hand length-to-body height ratio average was 0.11. The height data of Japanese and American children were obtained from Suwa et al. [41] and Fryar et al. [42], respectively. Results indicated that the hand prosthesis should be able to be scaled from 9.7 cm to 13.1 cm in length to be considered scalable for early intervention. A range of $\pm 10\%$ of the intact hand size was considered acceptable.

The hand prosthesis is perceived heavier because its weight, including the socket, is supported only by the stump, causing discomfort because of the excessive pressure on the stump [43]. Therefore, the prosthesis should be lighter compared to the intact hand weight. In this study, a hand prosthesis is defined as lightweight if it weighs 20% less than the intact hand. Only the hand was considered for comparison because the forearm weight fluctuates depending on the level of deficiency. Clauser et al. [44] estimated that the hand weight-to-body weight ratio was 0.0065. Japanese children weigh less than American children [39], so their weight was considered as reference. The weight data of Japanese children were obtained from the same database for height [41]. Results indicated that the hand prosthesis to be considered lightweight for early intervention should be lighter than 65 g for 2 years, 76 g for 3 years, 86.4 g for 4 years, 97 g for 5 years, and 110.8 g for 6 years.

Moreover, we observed that the child could control the myoelectric prosthesis successfully. The parents mentioned that she was confident using the prosthesis and had no significant inconveniences. Thus, the hand prosthesis control should be *myoelectric* to offer natural control to the child. Nevertheless, it is important to mention that the child

had previous experience using prostheses, such as the custom body-powered prosthesis and the Electrohand 2000, which undoubtedly contributed to this outcome. Therapists noticed that the child had less difficulty adjusting to the Electrohand 2000 than the custom body-powered prosthesis despite the myoelectric prosthesis being more complex. The parents confirmed this and stated that the prior training with the body-powered prosthesis helped the child get used to wearing and using hand prostheses. In addition, they added that the success of using the body-powered prosthesis increased her determination to use the more advanced Electrohand 2000.

Finally, the Electrohand 2000 is the most advanced child prosthesis but also the most expensive one, about $14,000. To have an economically viable intervention at any stage of children's rapid growth, the entire cost of the prosthesis should be *affordable*. All myoelectric prostheses are imported in Japan, which drives the cost up to $15,000 [45]. Also, aesthetic prostheses cost around $3400 in the local market [46]. There is no literature regarding pricing policy for child hand prostheses. In this study, a hand prosthesis that costs in the range of $1,000 - 2,000 was considered affordable for early intervention. It was assumed that developing a proper myoelectric hand prosthesis is not possible below this price range. The coupling system was also accounted for in the overall cost as it is required to attach the hand prosthesis to the stump.

1.3) PHASE 3

In the following six months, the prosthetic prototype was developed under the design requirements found in the previous phase. The first developed prosthesis is shown in Figure 4a, and its overview is detailed in Figure 7.

The mechanical design of the prosthesis was divided into the palm, fingers, and thumb. The palm was designed to be hollow to fit the actuator and the electronic components inside. However, it was only possible to place the actuator inside the palm in this first design, Figure 7. The other electronic components were placed in the empty space of the socket. The index, middle, ring, and little fingers were connected to move as one unit. The thumb was designed to provide grip along with the index and middle fingers. It was fixed to the palm with a screw. The opening angle of this prototype was 45°.

3D scanning and 3D printing technologies and an easy fabrication process were used to develop the first prototype. First, the intact hand was scanned for complete measurement. Then, the dimensions were introduced to the pre-designed prosthesis model in 3D CAD software. Finally, the prosthesis was 3D printed using the Object 350 Connex 2 3D printer and Polyjet resin material, both from Stratasys. Nevertheless, the prosthesis design can be printed with affordable desktop-size FDM 3D printers without any modification, using ABS, PLA, or TPEG materials.

The prosthesis had only 1 degree of freedom (DOF), opening and closing, to reduce the number of actuators and, thus, its overall size and weight. It was possible thanks to the developed pulley system conformed by a servomotor, a mechanical spring, and a fishing line. In this prototype, the chosen servomotor was the micro servo SG90 from Tower Pro with torque (τ) = 0.12 Nm, a spring with spring constant (k) = 0.5 N/mm, and a 0.14 mm fishing line of maximum tension = 15 lb. The resting position of the prosthetic hand is closed, thanks to the spring. The pulley system is detailed in a later section.

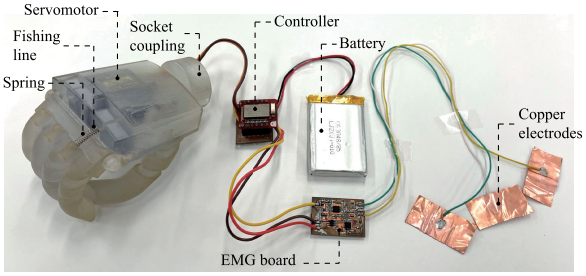


FIGURE 7. 1st prosthesis prototype overview.

The servomotor was selected as the actuator because of its high torque/power consumption ratio. The BLE nano v1.5, a development board with a built-in microcontroller and Bluetooth Low Energy (BLE) from RedBearLab, was in charge of controlling the prosthesis and supporting wireless communication. A compact 3.7 V, 380 mAh LiPo battery was selected to power the system with the help of the built-in voltage regulator present in the BLE nano.

This prototype did not have a stump-prosthesis coupling system to conduct evaluations at the earliest. The stump was only attached to the socket by pressure, Figure 8a.

The electrodes were made of flexible, thin copper sheets connected to the control board via external wires. Since there is only 1 DOF, a 1-channel EMG with three electrodes was used to control the prosthesis. A straightforward 1-threshold algorithm for the prosthesis opening was implemented to reduce the computational cost. The EMG signal was recorded and displayed in real-time using Bioroid, Figure 9, a custom smartphone application developed internally. The control settings, such as the gain and the threshold, were set with the smartphone application, Figure 9a.

1.4) PHASE 4

As mentioned before, the usability evaluations were held in parallel with the design and development of the prosthesis. The child and the parents were cited to the rehabilitation department. Once a month for 1 hour. The tests were conducted as in phases 1 and 2, but this time the child wore the developed prosthesis to play with the toys. Then, meetings with the parents were held similar to the second phase. The results for the first prototype were promising but with some drawbacks in the myoelectric control and the wearing of the prosthesis that are explained as follows.

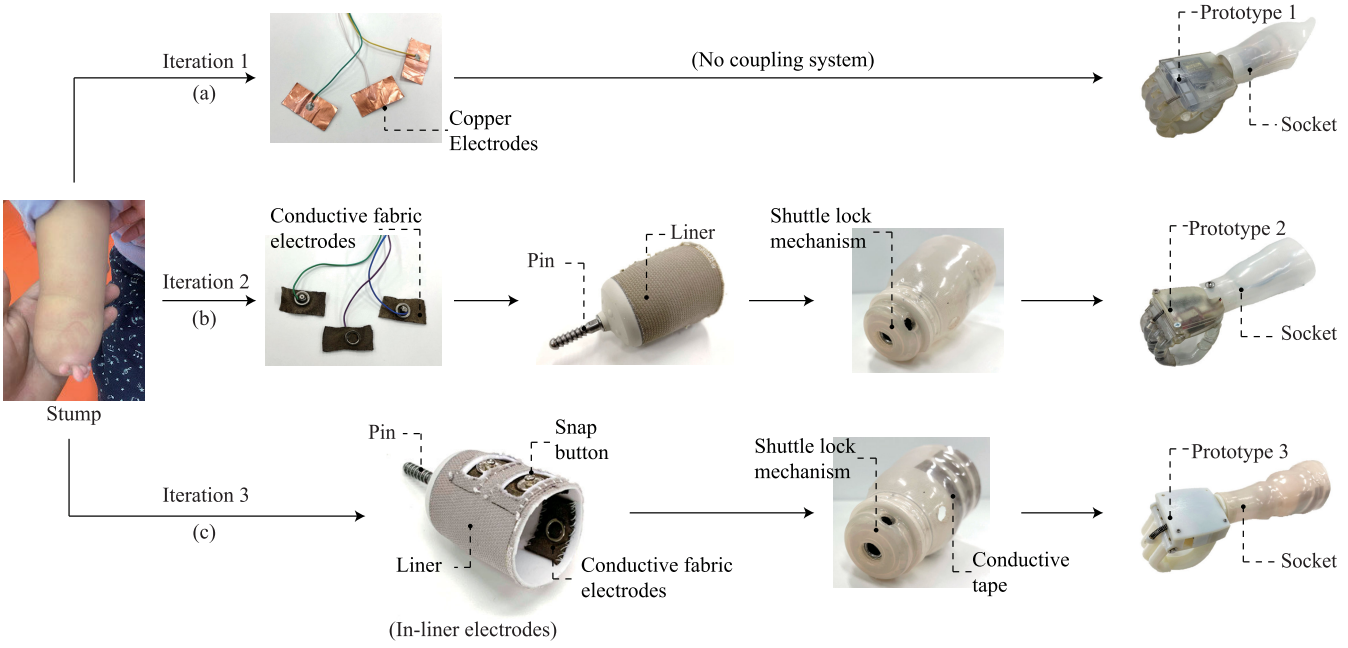


FIGURE 8. Evolution of the coupling system.

Thanks to 3D scanning and 3D printing technologies, it was possible to develop a *lightweight*, *scalable*, and anthropomorphically proportioned hand prosthesis. The weight of the prosthesis was 85.1 g, less than 80% of the intact hand weight, 86.3 g, for a 4-year-old Japanese child. The prosthesis length, measured by adding the palm and middle finger lengths, was 11 cm. It was comparable to the intact hand of the child. Moreover, the hand prosthesis was generated in the range of 2-year-old Japanese children to 6-year-old American children, considering the previous databases. In all cases, the hand prosthesis met the requirements of being lightweight and scalable. It is important to mention that the dimensions were manually changed in the prosthesis model to generate the prosthesis in different sizes.

Further, thanks to the 3D printing material and low-cost electronic components, the prosthesis prototype was significantly more *affordable* than the commercial options. For the cost estimation, the prosthesis fabrication was quoted with a 3D printing manufacturing company that uses FDM 3D printer and TPEG material. The PCBs fabrication was quoted in a company as well. The socket was manufactured by the same prosthetics company that developed the custom body-powered prosthesis. The total cost was about $600.

The 1-EMG channel proved to be sufficient to perform the opening of the prosthesis. The child could control the myoelectric prosthesis but was not stable. During the evaluations, the child often inadvertently opened or closed the prosthesis. The electronic noise might have affected the EMG signal reading. Thus, the 1-threshold algorithm needed to be improved.

An important finding was that the prosthesis was uncomfortable to wear for the child. The child's stump was only

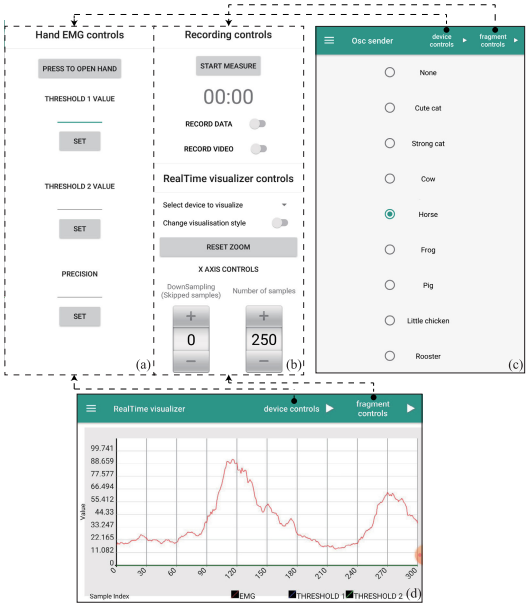


FIGURE 9. Bioroid smartphone application. (a) The opening threshold (threshold 1), closing threshold (threshold 2), and gain (precision) are set in the control settings. (b) The EMG measuring and recording are started and stopped from the recording settings. (c) The different animal sounds are selected from the auditory biofeedback interface. (d) The EMG signal and the opening and closing thresholds are displayed in the real-time visualizer.

attached to the hand prosthesis by pressure. The parents stated that the child felt uncomfortable having her skin in contact with the hard surface of the socket. Also, during the evaluations, the stump came out of the socket due to the lack of a coupling system. Finally, the wires of the electrodes were outside the socket, which disturbed the child when using the prosthesis.

2) ITERATION 2

A second iteration, Figure 5b, was carried out to address the drawbacks of the first prosthetic prototype. This iteration did not include the first phase because the results of the first iteration did not mean to change the scope and boundaries of this research. Thus, the UCD process was performed from the second phase. tHE procedures for each phase of this iteration are the same as those conducted in the first iteration.

2.1) PHASE 2

This second phase was conducted for three months after finishing the first iteration. Two more design requirements were identified in addition to confirming the previous ones.

The developed prototype of the first iteration did not have a stump-prosthesis coupling system which made the prosthesis uncomfortable to wear and use. Moreover, this phase demonstrated that the air pressure coupling system of the Electrohand 2000 made the fitting process somewhat slow and cumbersome. Thus, providing an improved coupling system was important to not cause discomfort to the child, which is a reason for prosthesis abandonment [14].

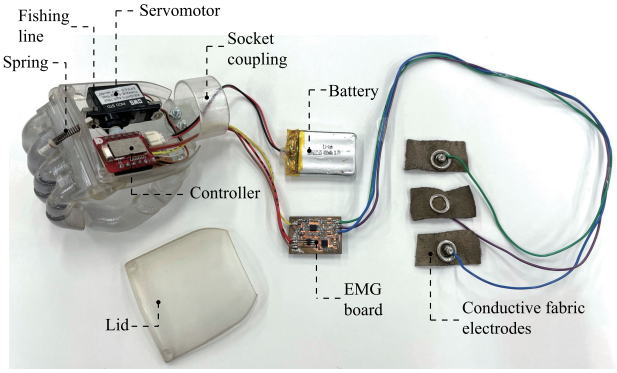
The second finding was the need for feedback. The child was able to control the Electrohand 2000 without major problems. However, she showed little interest in using it. During the evaluations, the child used only the intact hand to play with the toys unless a two-handed task was required. The frequency of use was similar to that of the body-powered prosthesis. The parents mentioned that the child did not find the Electrohand 2000 entertaining. We hypothesized that the addition of feedback had the potential to catch the child's attention. Additionally, the child can be taught how to use and control the myoelectric prosthetic hand through the use of feedback [47].

2.2) PHASE 3

For the following six months, phases 3 and 4 were held simultaneously. The second prosthesis prototype is shown in Figure 4b, and its detailed overview is in Figure 10.

The mechanical design was similar to the first prototype. The main difference was that the palm structure was split, adding a lid on the top. This second design required less material and added more space inside the palm. Thus, the control board was also placed inside the palm, Figure 10a. However, the EMG acquisition board and the battery were still located in the socket. The pulley system components were upgraded to provide a firmer grasp. The newly selected servomotor was the Pico STD from GWS with $\tau = 0.06$ Nm; a spring with $k = 1$ N/mm; and a 0.242 mm fishing line of maximum tension = 30 lb. The fabrication process was identical to the first iteration.

The control algorithm was upgraded to a 2-threshold algorithm to address the electronic noise presented in the first prototype. One threshold is for the prosthesis opening, and the second threshold is for the closing. Additionally, the copper electrodes were replaced with conductive fabric electrodes because they are flexible, thin, stretchable, and durable.



(a) Mechanics, electronics, and EMG electrodes.

(b) Auditory biofeedback (tone sounds).

FIGURE 10. 2nd prosthesis prototype overview.

The shuttle lock system was used to join the child's stump to the prosthetic hand. This coupling system is widely used in prosthetic applications because it provides good suspension through the connection of the liner with the shuttle lock mechanism, Figure 8b. The Iceross Upper-X Locking from Ossur was used as a liner.

Auditory biofeedback was implemented due to the design priority of being friendly to the child and the therapists' suggestion. They commented that auditory biofeedback could be more attractive to children, catching their attention. As a first attempt, frequency tones were used, referencing the work conducted by Tsubouchi et al. [48]. Two different tones with predefined frequencies were emitted to continuously indicate the two states of the prosthesis: open and close. The sound was computed using the SuperCollider software and the Intel Compute Stick, and produced by a speaker, Figure 10b.

2.3) PHASE 4

The results of the second prototype were better compared to the first one. They are described as follows.

The weight of the second prosthesis was 68 g which was less than 80% of the intact hand weight, 97 g, of a 5-year-old Japanese child. It was even lighter than the first prototype because the new design required less 3D printing material. The prosthesis length, 11.8 cm, matched the child's intact hand length. Similar to the first prototype, it was possible to generate manually the second prosthesis prototype for the range of 2-year-old Japanese children to 6-year-old American children. In all cases, the second prosthetic prototype met the requirements to be scalable and lightweight for early intervention. The total cost increased to $1,550 because of the commercial liner. However, it is still within the range considered affordable in this study.

The EMG control stability of the prosthesis was improved owing to the 2-threshold algorithm. The algorithm was able to recognize better the child's intention to open or close the hand prosthesis. Thus, the child could grasp and lift objects with fewer failures.

As expected, the shuttle lock system made the prosthesis fitting easier and simpler. The child donned and doffed the proposed prosthesis in less time than the Electrohand 2000. Additionally, the new fitting system was comfortable to wear. The parents said that the liner softly covered her stump, avoiding contact between her skin and the prosthesis. Nevertheless, the wires of the electrodes were still outside the socket, which caused discomfort while using it and reduced the prosthesis aesthetics.

The auditory biofeedback was not appealing to the child as expected. The parents mentioned that she was unpleased by the continuous tone sounds. The child might have not been related to those artificial due to her young age. The therapists suggested replacing the tones with child-friendly sounds to catch the child's attention. Additionally, they recommended producing the sound discreetly rather than continuously to make it easier to comprehend.

Finally, a bottleneck was identified in the fabrication process. It was necessary to 3D scan the child's intact hand in person to get the necessary measurements to 3D print the hand prosthesis. This limited the capacity to update the prosthesis in terms of size and weight at different growth stages, which can cause discomfort to the child while using a prosthesis that does not fit her.

3) ITERATION 3

A third and last iteration, Figure 5c, was conducted to address the issues with the auditory biofeedback, the fabrication process, and the external wires of the electrodes. This iteration held phases 3 and 4 in parallel for the last six months of the present study. It was decided only to meet the previously found design requirements to have an adequate final prosthesis prototype and then to begin with the assessments and experiments related to performance and technical evaluation.

3.1) PHASE 3

The third and final prosthesis prototype and its overview are shown in Figure 4c and Figure 11, respectively.

The mechanical design was improved. It was more anthropomorphic and had a wider opening, 60°, to enable grasping medium-sized objects. Also, all the electronic components, including the acquisition board and the battery, were placed inside the palm structure since it was more spacious than the second prototype design. The thumb was attached to the palm structure by 3D printing them together. For a third time, the grasping force of the pulley system was improved. The new components are the digital micro servo DS09AMD from Hyperion with $\tau = 0.32$ Nm, a spring with $k = 2$ N/mm, and a 0.40 mm fishing line of maximum tension = 80 lb.

The prosthesis opening and closing sequences are displayed in Figure 12. The resting position of the prosthetic

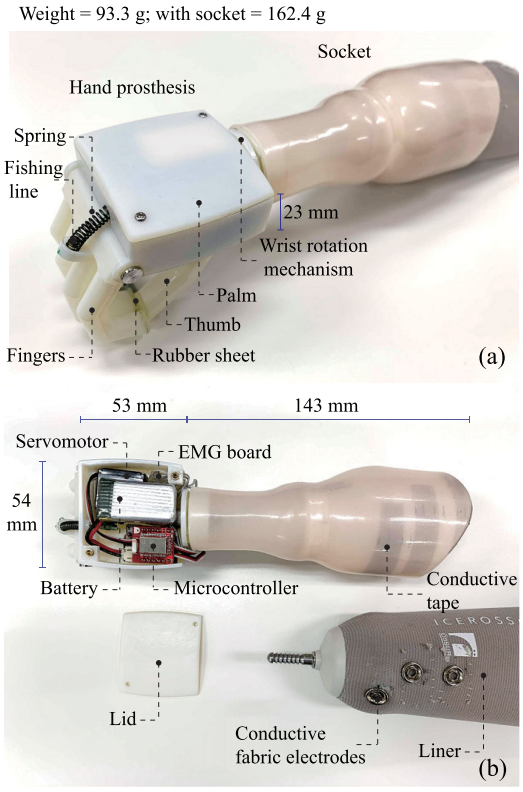


FIGURE 11. Overview of the developed hand prosthesis: (a) mechanics, and (b) electronics and EMG electrodes.

hand was closed due to the mechanical spring. When the child contracted her muscle, the servomotor rotated clockwise, tensioning and pulling the fishing line connected to its shaft. Thus, the spring was compressed, and the prosthesis was opened. When the child relaxed her muscle, the servomotor rotated counterclockwise, returning to its original position. Then the mechanical spring was uncompressed, closing the hand prosthesis.

An additional feature was added to the prosthesis based on the recommendation of the therapists: a wrist rotation mechanism. It was conformed by two rubbers and a screw. The rubber sheets were placed on the palm and socket surfaces attached during the assembly by a screw that passed through their centers. The force to overcome the friction between the surfaces and rotate the hand was adjusted by the screw.

The conductive fabric electrodes were sewn inside the liner, Figure 8c, to eliminate the external wires. The referenced work was done by Daly et al. [49]. With this improvement, the wires were placed inside the socket without compromising the prosthesis' comfort while using it. The EMG signals traveled from the conductive fabric electrodes to the control board through the contact between snap buttons connected to the electrodes and conductive tapes wired to the control board.

The block diagram of the EMG signal acquisition and processing system is described in Figure 13. This system was formerly developed in our laboratory. It is based on widely used EMG processing techniques. The EMG signal

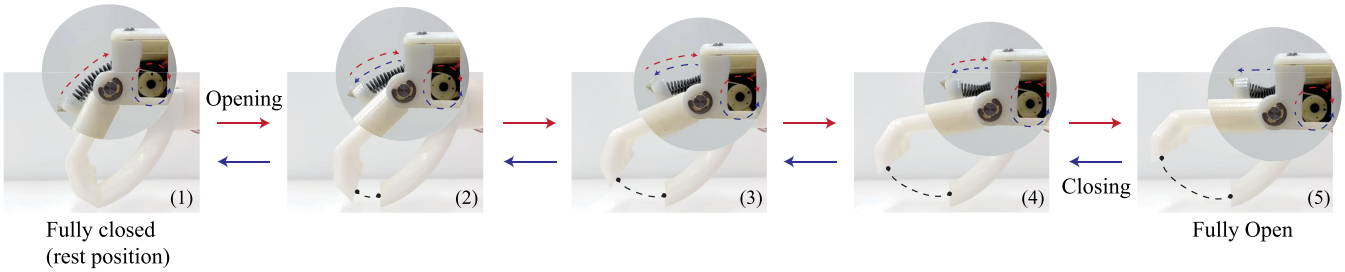


FIGURE 12. Opening/closing sequence of the prosthesis. The opening movement goes from (1) to (5). In the opening, the servomotor rotates clockwise pulling the fishing line and compressing the spring. The closing movement goes from (5) to (1). In the closing, the servomotor rotates counterclockwise releasing the fishing line and decompressing the spring.

acquisition and processing consisted of two stages: analog and digital. The EMG electrodes were placed on the child's trained muscle and the elbow as reference. In the analog stage, the EMG signals were subtracted and amplified with a gain of 1000 by the INA333 instrumentation amplifier. Then, the resulting signal was filtered by a 160 Hz RC low-pass filter. A driven right leg (DRL) circuit was implemented in the reference circuit to reduce the common-mode interference. In the digital stage, the resulting signal was read with a sampling frequency of 500 Hz. Then, the signal was filtered by a second-order band-pass Butterworth filter (20-150Hz) and a second-order band-stop Butterworth filter (50Hz). Subsequently, the signal was rectified, and it was smoothed by a moving average (MAV) filter with a window size of 100ms (50 samples). Finally, the processed signal was custom amplified and displayed in real-time on a smartphone by Bioroid, Figure 9d.

The auditory biofeedback was improved from tones to child-friendly animal sounds following the recommendation of the therapists. The animal sounds are familiar to children, potentially catching children's attention and encouraging them to use the hand prosthesis. The sound emitted was discrete instead of continuous to make it easier to understand. Since the default position of the prosthesis was closed, the discrete animal sound was assigned to the opening movement. This prototype produced the sound by Bioroid, eliminating the extra hardware of the second prototype. The child chose her desired animal sound from a list in the smartphone interface, Figure 9c. When the child contracted her muscle to open the prosthesis, the smartphone produced the chosen animal sound for 1 second to indicate the hand was opening.

The fabrication process was made remote based on [50] to avoid the in-person 3D scanning of the child's intact hand. Moreover, parametric dimensions were used to make the fabrication process easier and faster. Marlene et al. [51] investigated using parametric dimensions to fabricate 3D-printed hand prostheses. Results showed that the fabrication process was easy and highly customized. First, the parents were asked to measure only the palm length of the child's intact hand. Then, this dimension was introduced to the new 3D parametric model, and the resulting design was printed. The palm width and the middle finger length were calculated from the palm length. The proportions between these dimensions were estimated based on collected anthro-

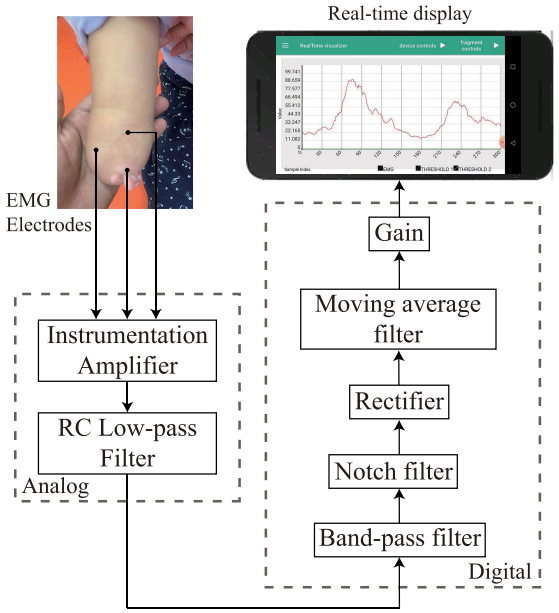


FIGURE 13. Block diagram of the EMG signal acquisition and processing.

pometric hand data of Asian children [52]. The lengths of the index, ring, and little fingers were calculated from the middle finger length based on the cross-sectional database obtained by Hohendorff et al. [53]. The proposed relationships are presented in Figure 14. The middle finger diameter was also selected from the previous database [53]. Then, the diameters of the index, ring, and little fingers were calculated by subtracting 1, 2, and 3 mm from the middle finger diameter, respectively [51]. The palm thickness was 25 mm by default to place all electronic components inside the palm. The thumb was the only element that was not parametric. It was designed to provide a secure grip with the index and middle fingers when the prosthesis was closed.

3.2) PHASE 4

The new mechanical design allowed the child to grasp medium and light-sized objects. Also, the wrist rotation mechanism was useful for grasping objects with a difficult-to-grasp orientation.

The prosthesis fabrication was faster and more straightforward due to the remote measurement and the parametric dimensions based on the palm length. The parents stated that measuring the child's palm length was effortless.

The prototype's weight was 93.3 g, lighter than 80% of the hand, 110.8 g, of a 6-year-old Japanese child. The total hand prosthesis length was 12.5 cm, matching the child's intact hand length. Thanks to the parametric design, the other hand dimensions also matched, as seen in Figure 1c. Also, the parametric prosthesis model was successfully scaled to the range of 2-year-old Japanese children to 6-year-old American children. In all cases, the third prototype met the requirements to be scalable and lightweight for early intervention. It is important to mention that, in this prototype, it was only necessary to change the palm length dimension to obtain a new prosthesis model. In previous prototypes, all dimensions were changed manually. The total cost of the third prosthesis was about $1,600, so it was considered affordable for early intervention.

The soft in-liner electrodes made the prosthesis's donning and doffing more comfortable. The parents added that the fitting was faster and simpler.

The results of the third prototype's auditory biofeedback were as expected and promising. The parents commented that the child enjoyed using the prosthesis since the animal sounds caught her attention. The therapists observed the same outcome and added that auditory biofeedback could improve the EMG training methodology for children with congenital forearm loss.

The UCD process was concluded since the third prototype met the design requirements.

III. PERFORMANCE ASSESSMENTS

A. EMG SIGNAL

A recording of the EMG signal while the child was using the developed prosthesis during a usability evaluation is shown in Figure 15. The instances when the prosthesis was closed or opened during the evaluation are indicated at the top. The opening and closing thresholds that determined the prosthesis behavior are shown with the set values during the evaluation. The dash-dotted lines indicate a prosthesis motion from the recorded EMG data, whereas the dashed lines are from the recorded videos. The triangles and squares represent the prosthesis opening and closing delays, respectively. Overall, the graph shows an adequate control performance by the child. However, it also shows significant issues: involuntary opening and closing motions (unstable area), and varying delays between the EMG signal activation/deactivation and the corresponding prosthesis motion (gray area).

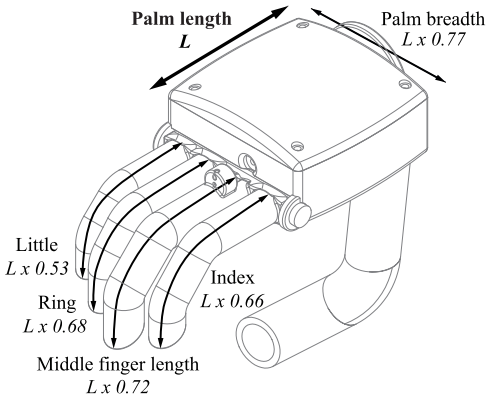


FIGURE 14. Hand prosthesis parametric design.

B. DESIRED AND UNDESIRED MOVEMENTS

The desired and undesired motions, *unpredictability*, of the proposed prosthesis were assessed under a protocol proposed by Chadwell et al. [54]. The opening movement was only evaluated because the child's muscle contraction was to open the prosthesis. The tests were conducted on a non-disabled male because it was difficult to ask the child to perform mundane tasks accurately. The participant wore an arm sleeve with conductive fabric electrodes sewn to it to replicate the condition of the in-liner electrodes. The hand prosthesis was attached to the participant's wrist. First, the desired opening movements were assessed. The participant was told to put the forearm in two positions: 45 degrees above, $+45°$, and below, $-45°$, the horizontal line of the arm, $0°$. In each position, the participant was instructed to open the hand prosthesis. Ten trials per position. Second, as for the undesired opening movements, the subject was instructed to move the forearm between the two previously defined positions, $+45°$ and $-45°$, keeping the prosthesis closed. 12 transitions in total. An undesired movement was considered if the prosthesis was opened during a transition.

The participant performed correctly 9 and 8 opening movements at the $+45°$ and $-45°$ positions, respectively. Also, there was only one undesired opening movement during the $+45°/-45°$ transitions. Overall, the prosthesis control performance was satisfactory. The prosthesis responded correctly to the desired movements from the user. The undesired opening movements might have been due to insufficient arm sleeve pressure, resulting in a deficient electrode-skin contact. This contact can be enhanced by the socket in the case of a patient. For further work, the electrode-skin contact pressure will be improved by adding foam behind the conductive tapes, Figure 8.

C. ELECTROMECHANICAL DELAY

The electromechanical delay was defined as the time elapsed since the muscle was contracted until the prosthesis started opening [54]. For this assessment, the EMG signal was manually triggered by touching the electrode located in the middle of the muscle. The delay was calculated by video analysis.

The electromechanical delay of the hand opening was 145 ms. The obtained delay is higher than the optimal controller delay, which range is 100 - 125 ms [55]. However, it can be considered adequate considering that the proposed prosthesis aims to be a *transitional prosthesis*.

D. BOX AND BLOCKS TEST

The widely-used Box and Block Test (BBT) was conducted by the child using the proposed prosthesis, Figure 16,

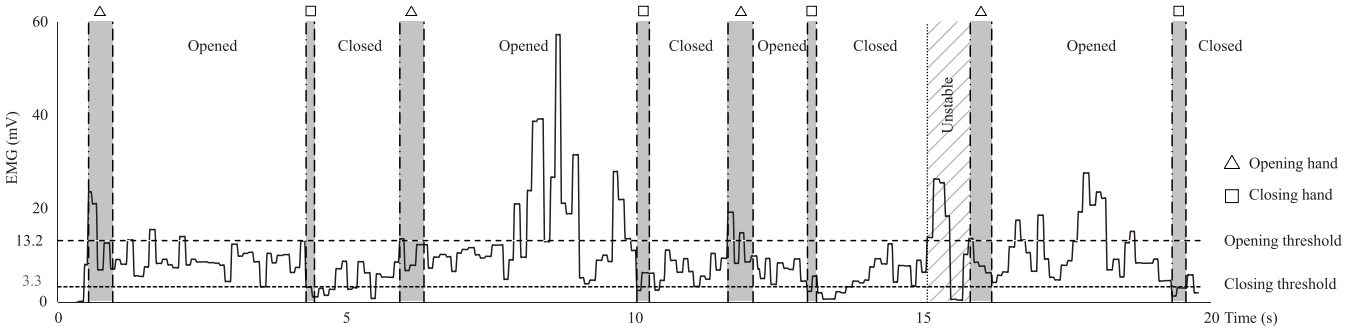


FIGURE 15. EMG recording during usability evaluation.

and the Electrohand 2000. The protocol was based on Mathiowetz et al. [56]. One 1-minute BBT was held per prosthesis. The child moved 12 and 17 blocks using the proposed prosthesis and the Electrohand 2000, respectively. Since the child uses the Electrohand 2000 in her daily life, this result was reasonable. The proposed prosthesis will be able to offer similar gross manual dexterity to the Electrohand 2000 with more training.

E. GRIP FORCE AND OPENING DISTANCE

The grip force applied by the fingers and the opening distance between the thumb and the fingers are shown in Table 1 for each developed prosthetic prototype. The grip force and opening distance were measured five times with a digital force gauge and a caliper at each servomotor angle position. The mean values are presented in the table.

As expected, the grip force and the opening distance increased as the servomotor rotated owing to the pulley system. The force applied by the fingers increased between iterations since the pulley system components were upgraded progressively. The opening distance in the first two prototypes was similar because there were no major changes in the design of the fingers. The opening angle was 45° in both cases. The opening distance in the third prototype was greater than the previous prototypes due to its mechanical improvements. The opening angle was 60°. The maximum grip force and opening distance were 5.1 N and 43.6 mm, respectively.

F. FULL OPENING AND CLOSING TIMES

The full opening and closing times, Table 2, meant the times it took for the prosthesis to open or close fully. For the analysis, videos of the prosthesis opening and closing were recorded. Five measurements for each movement. The mean values are presented in the table.

In all prototypes, the prosthesis closing was faster than the opening. This was because the prosthesis was rapidly closed by the spring, while the servomotor overcame the spring force slower to open the prosthesis. The full opening and closing times increased between iterations since the spring and servomotor were upgraded progressively, increasing the grip force but slowing the movements. The last prosthesis prototype's full opening and closing times were 460 ms and 356 ms, respectively.

FIGURE 16. The child performing the box and blocks test using the developed prosthesis.

IV. DISCUSSION

The results showed that the developed prosthesis is suitable for conducting early intervention in children with congenital below-elbow deficiency. The UCD approach was crucial because it involved the child in the design process, which was the key to defining the design requirements. All the components are located inside the palm, making the prosthesis suitable for any level of deficiency.

The developed prosthetic hand is a myoelectric prosthesis that intends to be used for early intervention in children with congenital forearm loss, and that performs the following tasks:

i. Perform simple tasks such as grasping lightweight and medium-sized objects.
ii. Assist the intact hand in case of a two-handed manipulation.
iii. Serve as a transitional prosthesis, which means to be a bridge between no prostheses or body-powered prostheses and advanced myoelectric prostheses.
iv. Help the child in the EMG training.

The key feature of the developed prosthesis is to be child friendly, which facilitates its adoption by the child. The proposed hand prosthesis was designed to be scalable,

TABLE 1. Grip force and opening distance according to the servomotor rotation angle. (P = Prototype).

Servo (%)	Force (N)			Opening distance (mm)		
	P1	P2	P3	P1	P2	P3
0	0.13	0.30	0.2	0	0	0
25	0.25	0.63	0.67	6.70	6.83	9.0
50	0.41	0.98	1.33	13.0	13.0	19.0
75	0.59	1.5	2.35	15.5	20.4	32.2
100	1.0	2.1	5.1	23.4	23.0	43.6

lightweight, and anthropomorphic. As a result, it is possible to provide an aesthetic hand prosthesis with the appropriate size and weight for each stage of the child's growth.

In addition to the inexpensive 3D printing material, the electronic components were also low-cost. This makes the hand prosthesis affordable, being economically viable to provide multiple hand prostheses during the different growth stages of the child. In future work, the cost is planned to be reduced by fabricating the socket and liner using 3D scanning, 3D printing, and flexible material.

The shuttle-lock coupling system and the in-liner electrodes provide easy, fast fitting and comfortable wearing. The child was able to don and doff the liner and the prosthesis by herself. The liner and the sewn conductive textile electrodes were soft to the child's skin and could adjust to the shape of the remaining limb, providing comfort while wearing the prosthesis. This is a significant benefit compared to rigid EMG electrodes. However, the electronic noise should be addressed in future work.

The auditory biofeedback showed to be appealing to the child. The therapists were optimistic about the preliminary tests. They commented that it has the potential to improve the EMG training methodology because it encourages the child to use the hand prosthesis. This concept is consistent with the literature where auditory biofeedback can help cognize EMG signals [48] and improve the EMG learning methodology [57]. Additionally, it can be intuitive and improve the sensory feedback in myoelectric prostheses [58]. However, it can make the child stand out in natural-use environments such as classrooms. In future work, the effects of using auditory biofeedback in such places will be investigated.

The remote measurement and the use of parametric dimensions simplified the fabrication method of the prosthesis. Additionally, the estimated parametric dimensions were appropriate. The developed prosthesis is comparable in terms of size with the child's intact hand, Figure 1c. All dimensions are calculated from the palm length except for the thumb, which is custom designed to obtain a proper grip. The viability of the thumb's parametric design will be researched in future work. Our vision is to develop an open-source parametric prosthesis to automate the design process fully. The goal is to design a prosthesis that can be assembled with minimal technical expertise to be easily deployable in healthcare institutions.

The proposed prosthesis could be controlled without significant difficulties by the child. One notable issue was the unstable functioning that happened during the usability tests.

TABLE 2. Full opening and closing times for each prototype.

	Prototype 1	Prototype 2	Prototype 3
Full opening time (ms)	167	540	460
Full closing time (ms)	140	347	356

The noise in the electronic system and the low signal-to-noise ratio (SNR) of the conductive fabric could be the main reasons. This problem needs to be fixed through improvements to the conductive fabric quality and the signal processing algorithm. Adopting double differential electrodes and adaptive thresholding methods can also improve the stability of the EMG control of the prosthesis.

Finally, the technical features of the developed prosthesis with the Electrohand 2000 and the Cyborg Beast Hand are compared in Table 3. The data was collected for 6-year-old child prostheses. The proposed hand prosthesis is the lightest, 93 g, and is considered affordable, $1,600. The Electrohand 2000 is certified for clinical use by a commercial company, which increases its final price. However, the comparison between the base materials indicates that the proposed prosthesis would be more affordable even when considering the cost of commercialization, in addition to the advantage of being scalable. The proposed prosthesis has a bigger opening distance, 43.6 mm, than the Electrohand 2000, 35 mm, which is adequate for grasping small and medium size objects. Additionally, the developed prosthesis owns myoelectric control as the Electrohand 2000, whereas the Cyborg Beast Hand is body-powered. On the other hand, it is necessary to increase the grip force of the proposed prosthesis. During the experiments, the grip force was adequate to hold light objects but inadequate for heavier objects. Therapists advised increasing the grip force to allow the child to interact with more objects. The prosthesis' grip force will be improved by increasing the spring stiffness constant and using a servomotor with higher torque.

1) LIMITATIONS

The limitations of this study are as follows: First, the discovered design criteria were confirmed with only one child. In future work, the proposed prosthesis and the design conclusions will be tested and verified with a larger sample of children to establish general design requirements for the development of prostheses for children with congenital below-elbow deficiency. Second, only two hand prostheses were used to specify the child's requirements. In further iterations, other hand prostheses will be evaluated during phase 2 of the UCD process to possibly find out more design-related requirements.

V. DESIGN IMPLICATIONS

Through the experience gained in this study, design implications were derived for developing hand prostheses suitable for early intervention in children with congenital below-elbow deficiency. These are summarized as follows:

TABLE 3. Technical comparison among the Electrohand 2000, the Cyborg Beast hand, and the developed prosthesis.

	Electrohand 2000 [59]	Cyborg Beast hand [10]	Proposed prosthesis
Cost ($)	14,000	50	1,600
Weight (g)	115	140	93
Opening width (mm)	35	-	43.6
Maximum grip force (N)	35	-	5.1
Control	Myoelectric	Body-powered	Myoelectric

A. GENERAL REQUIREMENTS

A prosthetic hand for children with congenital below-elbow deficiency should be a simple myoelectric prosthesis that achieves the following objectives:

- Perform simple grasping tasks.
- Assist the intact hand in two-handed tasks.
- Help the child in the EMG training.
- Serve as a transitional prosthesis.

B. SPECIFIC REQUIREMENTS

A hand prosthesis suitable for early intervention with children with congenital forearm loss should possess the following key and child-friendly design features:

- Scalable: Provide a hand prosthesis with the appropriate size and weight for each stage of the child's growth.
- Lightweight: Be suitable for children from a very early age.
- Affordable: Be economically viable to provide the prosthesis continuously during the child's growth.
- Myoelectric control: Offer the child natural control of the prosthesis.
- Easy and fast coupling: Make the fitting process easier and faster, and decrease the burden of wearing the prosthesis.
- Child-friendly feedback: Improve the EMG training method, trigger and maintain the child's interest in using the prosthesis.
- Soft EMG electrodes: Be comfortable for the child during prolonged prosthesis use.
- Automated and remote design process: Simplify the prosthesis fabrication.

C. FABRICATION GUIDELINE

Additionally, a fabrication guideline is suggested to develop hand prostheses for children with below-elbow loss remotely:

- First, the parents measure the palm length of their child.
- Second, the dimension is entered into an open-source parametric prosthesis model in 3D CAD software. The result is the prosthesis 3D design with the corresponding dimensions.
- Third, the prosthesis parts are 3D printed by a practitioner or using an online service.
- Forth, the socket and the coupling should be designed by a prosthetist.
- Fifth, the soft electrodes, the electronics, and the mechanical components are obtained online.
- Finally, the parents assemble the prostheses by themselves following the provided instructions.

VI. CONCLUSION

A novel hand prosthesis for early intervention in children with congenital below-elbow deficiency was developed under the UCD process. The proposed prosthesis possesses decisive implications for design that make it suitable to conduct early intervention and facilitate its adoption by children.

The developed prosthetic hand is scalable. It matches the hand size of children in the range of 2 to 6 years old. Also, the proposed prosthesis is lightweight. It weighs less than 80% of the hand of 2- to 6- years old children. The model for a 6-year-old child weighs only 93.3 g. The overall cost is $1600 which makes it affordable. In the Box and Blocks Test, the score of the proposed prosthesis is 12 blocks. Finally, the opening width and the maximum grip force are 43.6 mm and 5.1 N, respectively.

In future work, we will address the limitations of this study and the technical issues and continue improving the hand prosthesis. Additionally, we will conduct comparative studies to verify the effectiveness of the developed auditory biofeedback. Finally, we plan to develop a fully parametric 3D hand prosthesis design and share it as open-source material.

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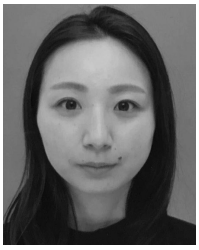
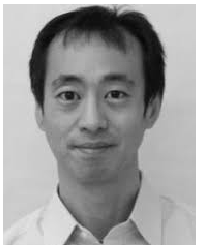
LUIS CCORIMANYA (Graduate Student Member, IEEE) received the B.S. degree in mechatronics engineering from the Pontifical Catholic University of Peru, Lima, Peru, in 2015, and the M.E. degree from the University of Tsukuba, Ibaraki, Japan, in 2020, where he is currently pursuing the Ph.D. degree in engineering. From 2015 to 2017, he was a Research Assistant with the Biomechanics and Applied Robotics Research Laboratory, Pontifical Catholic University of Peru. From 2017 to 2018, he was a Research Student with the University of Tsukuba. His research interests include assistive and rehabilitation technologies, particularly, upper limb prostheses.

MODAR HASSAN (Member, IEEE) received the B.S. degree in engineering from Tishreen University, Latakia, Syria, in 2009, and the M.E. and Ph.D. degrees in engineering and the M.S. degree in medical sciences from the University of Tsukuba, Tsukuba, Japan, in 2013, 2016, and 2016, respectively. From 2010 to 2011, he was a Lecturer in mechatronics with Tishreen University. From 2016 to 2021, he was a Postdoctoral Researcher with the University of Tsukuba, where he is currently an Assistant Professor with the Faculty of Engineering, Information and Systems. His research interests include assistive robotics, wearable devices, esports and para-esports, orthotics, prosthetics, biomechanics, and motor control.

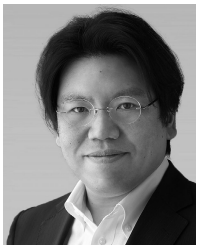


REIKO WATANABE received the B.S. degree in occupational therapy from the Nihon Institute of Medical Science. She received the Occupational Therapist License, in 2011. Currently, she is an Occupational Therapist with the Department of Rehabilitation, University of Tsukuba Hospital, Tsukuba, Japan. Her research interests include the investigation of new methods and tool for early rehabilitation, prosthetic interventions for children with congenital limb deformities, toy, biosignal, and the biofeedback-based gamification of rehabilitation methods for children.



TOMOYUKI UENO received the M.D. degree from the University of Tsukuba, in 2001. He is currently an Associate Professor with the Faculty of Medicine, University of Tsukuba. He is also affiliated with the Koga/Bando Clinical Education and Training Center, University of Tsukuba Hospital, and the Department of Rehabilitation and Neurology, Ibaraki Seinan Medical Center. He is a member of the Japanese Society of Neurology, The Japanese Association of Rehabilitation Medicine, and The Japanese Society of Prosthetics and Orthotics. His research interests include the development of robot-assisted rehabilitation methods for persons with central nervous system disorders, the development of robotic orthotics for gait support in daily life, and the development and verification of novel prosthetic hands for children.

YASUSHI HADA received the Ph.D. degree from the University of Tsukuba, in 1991, and the Doctor of Medical Science degree from Teikyo University, Tokyo, Japan, in 2006. He was a Visiting Research Fellow with the Division of Clinical Neurophysiology, Department of Neurology, The University of Iowa, from 1997 to 1999. Currently, he is a Professor with the Department of Rehabilitation Medicine, Faculty of Medicine, University of Tsukuba. His research interests include topics related to rehabilitation medicine, clinical neurophysiology, sports medicine for persons with physical disabilities, the robot-assisted rehabilitation of persons with gait disorders, and the development of novel orthotic and the prosthetic solutions for rehabilitation and for support of daily life activities.



KENJI SUZUKI (Senior Member, IEEE) received the B.S. degree in physics, and the M.E. and Ph.D. degrees in pure and applied physics from Waseda University, Tokyo, Japan, in 1997, 2000, and 2003, respectively. He is currently a Full Professor with the Center for Cybernics Research, and a Principal Investigator of the Artificial Intelligence Laboratory, Faculty of Engineering, University of Tsukuba, Tsukuba, Japan. He was a Visiting Researcher at the Laboratory of Musical Information, University of Genoa, Genoa, Italy, and the Laboratory of Physiology of Perception and Action, College de France in Paris. His research interests include augmented human technology, wearable robotics and devices, biosignal processing, social robotics, and affective computing.