STUDY PROTOCOL

Improvement of 3D-printed Prostheses Design and Development of Home-based Training Module via Participatory Research Design: A Report on a Comprehensive Study Protocol

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ABSTRACT

Introduction: A prosthetic limb technology has grown tremendously in the past few years, offering hope for increased functioning and better quality of life to people with upper limb amputation. However, the phenomenon of prosthetic rejection remains a challenge, particularly among paediatric users because of the prosthesis-related factors in functionality and appearance as well as the training and prosthetics services. Aim: One solution is to involve an Occupational therapist (OT), engineer (3D printed prosthesis expert), prosthesis user (experienced child), and their parent in designing the prosthesis. However, these collaborations have not been implemented as intended in the engineering field. Hence, this current study aimed to report on a comprehensive study protocol based on 3-corner collaborative design in order to develop and improve three-dimensional (3D) printed upper limb prosthesis design and a home-based self-care training module. **Methods:** The 3D upper limb prosthesis and training module was designed using a 3-corner collaborative design (participatory design approach). The participatory design process (involved experienced children with transradial deficiency; parent; OT and engineer) and data collection techniques included semi-structured interviews, participant observation, the Delphi technique, and face-to-face discussion. **Discussion:** The 3-corner collaborative design (participatory design approach) process helped us design an interactive platform to design a new 3D printed upper limb prosthesis features such as sizes, weight, control, and obtaining information on training that possible to manufacture tailor-made, customized, and personalized parts according to the users' deficiency; making them more suitable for the development of prostheses for each user, which must be customized. **Trial Registration:** Ethical approval was granted by The National Medical Research Register Committee, with a study code of NMRR-19-4219-51664.
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INTRODUCTION

In recent years, there has been enormous progress in the world of prosthetics for people with upper limb impairments, giving hope for improved functionality and a better quality of life (1). However, the phenomenon of prosthesis rejection remains a challenge, especially among paediatric users due to prosthesis-related factors related to its functionality, appearance as well as the training and prosthetic services (2). Although much progress has been made in the field of upper limb prostheses and a wide range of prostheses are available, many people still choose not to use their prosthesis. A systematic review on 25 years of literature by Biddiss and Chau (2007) (3) found that the average refusal rates for children were 45% and 35% for body-powered and powered prostheses respectively, while the average refusal rates for adults were significantly lower reported at 26% and 23% respectively. The survey shows that the elements of comfort and function of the prostheses were important factors for their use or rejection.

Prosthesis training is a necessary step in helping prosthesis users to integrate the prosthesis into his/her daily life and achieve independence (1). Prosthetic training often starts with 'control training' and the first step of control training is to help the user to discover how to open and close a prosthetic hand. When the prosthesis user has achieved basic control of his/her prosthesis, the training can shift to the process of 'use training'. Use training focuses on refinement and use of the prosthesis. The use of activities during training not only improves immediate performance, but also promotes the learning of a prosthetic skill (4). The goal of training is to help the user to use the prosthesis efficiently and demonstrate a

natural movement pattern.

An optimal upper-limb prosthetic training must be structured to facilitate treatment for functional gains and elevate children's productivity in social contexts (5). It has been widely reported that training modules have played a key role in the success of prosthesis usage among children. More importantly, articles highlighted that lack of training with the prosthesis or flawed quality of the training modules resulted in non-use of the prosthesis (1, 6, 7). On top of that, training is touted to be a crucial element in developing the capability to use myoelectric prostheses in everyday life (1, 8).

Research demonstrates the pressing need of a tailor-made training module for these patients, without which prosthesis failure and limited use of advanced functions will remain a problem (6, 9, 10). Several studies found the reason behind this issue may be due to insufficient training (1, 6, 10, 11). Also, the abandonment in the use of a prosthesis due to dissatisfaction with its intended function is a commonly reported problem (9). It is extremely important for the patients to be trained, preferably at an early-stage of post-surgery, to use prostheses within the context of their activities.

Recently, companies such as Ottobock and iLimb (Touch Bionic) have made it possible for amputees and therapists to access a training protocol. However, these modules focus solely on helping adults master complex daily tasks (managing finances and medications, food preparation, housekeeping, laundry) to assist them to live independently in the community. Meanwhile, children will struggle to apply the aforementioned protocol in daily life as unlike adults, children only require basic self-care skills for eating, bathing, maintaining personal hygiene, grooming, dressing and toileting.

To be able to use a prosthesis in daily life, the training must be conducted in a real-world setting (12). In this regard, children may lack a standardized training program to carry out daily activities. To reduce upper limb prosthesis rejection rates, it is important to understand the reasons behind the rejection or non-use of the devices. Many studies have attempted to determine the key reasons for prosthesis rejection, reporting both functional and non-functional criticisms from users. However, many of these studies relating to prosthesis use involve limited feedback from the users themselves. One solution for giving prosthesis users and parents a better opportunity to expressed their dissatisfaction with the mechanical robustness of the prosthesis may be 3-corner collaborative design (participatory design approach) that employ interactive platform that can facilitate user, their parents, OTs and engineer in developing effective prosthesis design and training programme that useful to potential users. It is the responsibility of the researcher to understand the viewpoints of the user through methods which enable them to express their opinions (13, 14, 15, 16).

In the case of developing a 3D printed upper limb prostheses for children, this will include the user and their parents as well as the OTs working with the child (peadiatric and orthopedic), as well as the engineer who are an expert in 3D printed prosthesis design and development. A cross-functional team is important in this approach to ensure that children's novel ideas can be gleaned (13). Advances in 3D printing permit rapid development of new and inexpensive prostheses in response to participants' views. 3D printing facilitates an iterative approach to device development which is central to this study. The prototypes were developed using 3D printing, which is a form of Rapid Prototyping Technology (RPT). RPT provides a means of quickly producing solid, 3D prototypes from Autodesk Fusion360 software and manufactured in the 3D Printed laboratory located in the Department of Biomedical Engineering, Faculty of Electrical Engineering, Universiti Teknologi Malaysia. A combination of both desktop and industrial-grade 3D printer Ender2Pro FDM were used during the prototyping. This enables a complete prototype to be created in one printing process. An iterative approach is fundamental when it comes to incorporating participants' views into the prosthesis design. Four research questions are composed:

RQ 1: What is the cause of rejection on experienced upper limb deficiency children and their parents on the current upper limb prosthesis using qualitative technique?

RQ 2: Could the 3-corner collaborative design (participatory design approach) methodology used to develop and improve upper limb prosthesis using iterative prototyping (using 3D printing)?

RQ3: What is the effective element in a home-based self-care training module with grasping and lifting hand coordination test for children who use an upper limb prosthesis?

RQ4: What is the validity of the home-based self-care training module using qualitative technique (content and face validity)?

The aims of the current study were to investigate the cause of rejection on experienced upper limb deficiency children and their parents on the current upper limb prosthesis; to improve upper limb prosthesis design using qualitative technique and iterative prototyping (using 3D printing) and to develop home-based self-care training module with grasping and lifting hand coordination test for children who use an upper limb prosthesis within the 3-corner collaborative design (participatory design approach) methodology.

It was hypothesized that the 3-corner collaborative design (participatory design approach) methodology able to get the best solution for our clients' problems and able to improve 3D-printed prostheses design which possible to manufacture tailor-made, customized, and personalized

parts according to the users' deficiency, making them more suitable for the development of prostheses for each user, which must be customized. Furthermore, it was also hypothesized the training module able to aid the children fitted with the prostheses in daily practice. Our hypothesis was based on previous study shows that interdisciplinary teamwork (participatory design approach) can increase the innovativeness and quality of the solution due to dissimilar ways of looking at a problem (17, 18).

The current study responds to the high non-use rates and dissatisfaction by involving children, thier parent and other cross-functional team in the development of new 3D printed upper limb prosthesis design and home-based self-care training module. In this research protocol, the cause of rejection of current 3D printed upper limb prosthesis will be explored, focusing on a collaboration with 3D-printing experts in particular, with the overall goal to understand how the collaboration between OTs, 3D-printing experts and child and their parent could look like and how this collaboration can be facilitated in develop and improve a new design of 3D printed upper limb prosthesis and home-based self-care training module.

METHODS

3-corners collaborative design cycle (participatory design) has been used to design, develop, and gain feedback of new 3D printed upper limb prosthesis design. The study was divided into three phases, as shown in Figure 1.

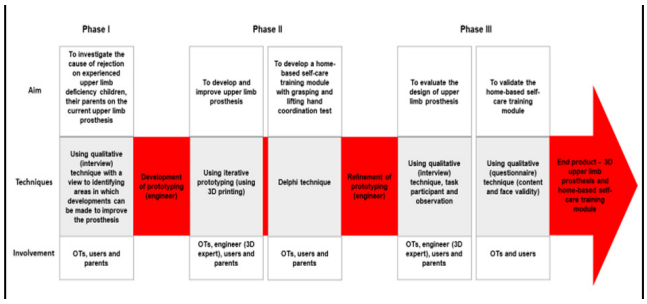

Figure 1: 3-corners collaborative design cycle (participatory design) has been used to design, develop, and gain feedback of new 3D prosthesis design. The study was divided into three phases. The aim, data collection techniques, and participatory for each phase is shown in the figure.

Ethical considerations

Ethical approval for the various stages of this study was granted by The National Medical Research Register Committee, with a study code of NMRR-19-4219-51664. All participants signed an informed consent form prior to their involvement in the study.

Theoretical framework

As per the framework in this study, a 3-corner collaborative design cycle which is a collaborative design methodology by Paulovich (2015) (16, 17) was adopted in determining the OTs role in order to ensure that our clients are using their upper limb prosthesis effectively. The 3-corner mutually beneficial design cycle is founded on the idea that rather than using participatory techniques to develop the complete product, each player takes on a skill-driven function while still actively engaging in important design choices. It may be assumed that occupational therapists (OTs) would play the position of the healthcare professional, and the 3D-printing specialist (i.e., an engineer) would probably take the function of the designer.

Seven phases make up the 3-corner collaborative design cycle. In order to develop a plan, the OTs must first examine the client's needs and requirements and then communicate this information with an engineer. Concept and design development are tasks that fall predominantly under the purview of the engineer in steps two and three, respectively. The OTs converses with the client at this period to explore different choices and offer input to the engineer within the time specified. Prototyping is the next step the engineer takes which then the item is assessed (step 5) and the OT and client decide if the item is a viable solution (step 6) or whether a redesign is required (step 7).

Design

The study followed a multi-stage design using semi-structured interviews (with thematic analysis) to understand children's and parents' views on current 3D printed upper limb prosthesis, develop new 3D printed prosthesis design responding to these views and gain feedback on the prosthesis.

Phase I: identify the cause of rejection

Phase I had one aim:

(I) To investigate the cause of rejection on experienced upper limb deficiency children and their parents on the current upper limb prosthesis using qualitative technique (interview) with a view to identifying areas in which developments can be made to improve the prosthesis design.

Recruitment

In phase I, experienced upper limb deficiency children and their parents were recruited from the research lab at School of Biomedical Engineering and Health Sciences (SKBSK) research department by the social enterprise. The inclusion criteria were as follows: that participants needed to be aged between 7 and 12 years, had a unilateral transradial deficiency and at least six months of experience with 3D printed myoelectric upper limb prostheses; be willing to be interviewed for approximately 60 minutes about personal experiences and feelings. Meanwhile the exclusion criteria are as follows; subjects who have significant uncorrectable visual deficits, major communication or neurocognitive deficits, skin conditions prohibiting prosthetic wear, or have an electrically controlled medical device.

Participants in phase I of the study comprised the following groups:

(I) Children diagnosed with Transradial (below-elbow) unilateral congenital limb absence or traumatic deficiency, aged between 7 to 12 years old and their parents;

(II) Occupational therapists.

The phase I recruitment process ended up with a total of 9 participants: 3 experienced children, 4 parents, and 2 occupational therapists.

Data collection techniques

Qualitative interview was chosen to achieve in-depth understanding of users' rejection on current 3D printed hand prosthesis. The question was developed in English, prior to conducting the interview and was translate during the study. It was translated to Bahasa Melayu by native speakers. All of the interviews were conducted by an experienced therapist whose native language matched the participants' native languages. The first author was present at all of the interviews and intervened if necessary. The first author and interviewer do not know these three participants and no relationship was established between the first author and interviewer and any of the participants before the interviews.

The first author and the interviewer introduced themselves at the beginning of each interview session, explaining their role and the goal of the study. Subsequently, demographics and general anamnesis were noted before open question were asked about reasons for prosthetic rejection. The interviews were recorded with a smartphone and field notes were taken. Children could be interviewed alone or with parents if they felt more comfortable. At interview commencement, parent was reminded that children should attempt to answer on their own, but they could augment answer of their children, if necessary, to encourage further dialogue. Children were given an information sheet to explain the interview process. Parent and children were each asked a separate set of questions, with the same topic.

Phase II: development of new prosthesis design and module

Phase II had two aims:

(I) To develop and improve upper limb prosthesis design using qualitative technique and iterative prototyping (using 3D printing) within the 3-corner collaborative design (participatory design approach) methodology.

(II) To develop a home-based self-care training module with grasping and lifting hand coordination test for children who use an upper limb prosthesis using Delphi technique.

Recruitment and baseline characteristics

Recruitment of participants in phase II took place in the Unit of Occupational Therapy at Hospital Tuanku Ja'afar Seremban, Malaysia. Twelve Occupational Therapists (OTs) were selected according to the following criteria with the following characteristics;

(I) Certified Occupational Therapist;

(II) Over three years of service in pediatric or orthopedic;

(III) Having valid credentialing in the field;

(IV) Knowledgeability and experience in the study area.

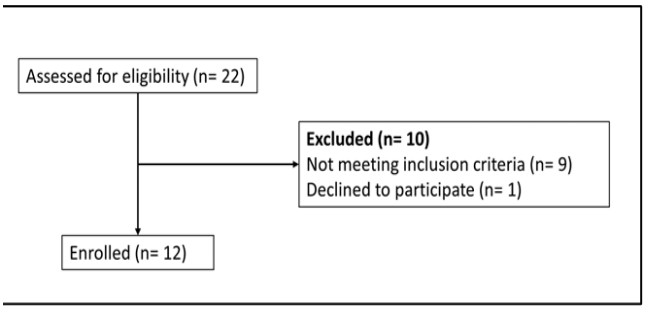

Figure 2: Flowchart phase II.

Figure 2 shows a flowchart of the recruitment process of related Occupational Therapists. According to Dalkey (19), it is deemed adequate to engage more than 10 expert panels in Delphi-oriented research for robust outcomes. Ziglio (20) suggested that a satisfactory outcome can be attained even with small number of panels in the range of 10-15 people. In this study context, 12 OTs were initially contacted for participation in consensus development and all the participants duly agreed to participate.

Data collection techniques

A three-round Delphi technique was implemented. Round one involved (1) a literature search, and (2) a review of an existing user manual, and experiences of 12 OTs specializing in pediatric and orthopedic was obtained by rating the proposed components using a Likert scale from a range of 1 to 5 in round two of the study. An analysis of consensus, stability, and agreement was then performed according to the characteristics of relevance, clarity, simplicity and sufficiency in round three. Fleiss kappa statistical test was used to measured strength of agreement.

Phase III: gain feedback of new design and validate module

The aim of phase III was to:

(I) To evaluate the new design of 3D upper limb prosthesis using qualitative technique (interview).

(II) To validate the home-based self-care training module using qualitative technique (content and face validity).

Recruitment and baseline characteristics

In phase III, the number of experienced children, parents and OTs were selected based on the following criteria (the recruitment criteria are exactly the same as in phase I and II):

(I) Three children diagnosed with Transradial (below-elbow) unilateral congenital limb absence or traumatic deficiency, aged between 7 to 12 years old and their parents:
(II) Twelve certified OTs with over three years of service in pediatric or orthopedic, valid credentials and knowledgeability and experience in the study area.

Data collection techniques

This stage's goal was to verify the items on the shortlist that were generated by the three-round Delphi procedure. Twelve occupational therapists (each from 12 state in Peninsular Malaysia) were invited to participate in the validation process. All items of the shortlist were assessed for validity in terms of relevance, clarity, simplicity, and sufficiency of items, the rating utilized a four-point scale for each content validation. Rating of 1 and 2 indicated negative classification while 3 and 4 implied positive classifications. The validity assessment of each and every question had to be agreed upon by the entire expert panel. In the events of doubt in regard to the inputs, an online discussion meeting was conducted to validate the final module document with an emailed validation sheet (content as well as face validity). Furthermore, this online discussion was set up to provide an opportunity to the researcher to explain and answer/clear the doubt.

Data analysis

Phase I

The data analysis began while the authors were still conducting the interviews (21). The reason for this was that the ongoing analysis could reveal relevant follow-up questions in the next interview that might provide more information-rich answers or a deeper understanding of what the participants were trying to convey (22). The interviews were analysed using thematic analysis following Clarke and Braun's (2015) (23, 24) six-phase process where each process contributes to a systematic and comprehensive analysis of qualitative data. The first phase consists of familiarizing oneself with the data and then, in the second phase, creating initial codes. The third phase then organizes these initial codes into potential themes, which are reviewed and refined in the fourth phase. In the fifth phase, the final themes are defined and named, while the sixth and final phase consists of writing a coherent narrative that reflects the essence of the identified themes.

The interviews were transcribed verbatim, and the authors familiarized themselves further with the data by reading over the transcript multiple of times. The authors then coded and put one interview together and coded the remanding interviews separately. Then authors reviewed each other's coding and recoded if needed. The authors then segment the data correlated to the codes to start searching for patterns and possible themes. Proceeding this, the authors reviewed each other's themes and renamed or redefined them were differences of opinions occurred.

To minimize analysis biased due to a prior knowledge and preconceptions, a research team of an Occupational therapist, author and an engineer (prosthesis design expert) completed the coding and analysis of interviews. Open coding was initially used to code the transcribed interviews. The research team then met to discuss and build consensus on the codes for each statement within each interview. Disagreements in coding were arbitrated during these meetings. Initial codes were used to identify central themes through reduction, a process of distilling the essence of a phenomena that is an essential aspect of phenomenology (23, 24). Finally, transcripts were reviewed to locate central themes and text that reflected each theme. Our analytical codes were developed directly from participant transcripts.

Phase II

Questionnaires were used in the Delphi technique as a data collection tool. The DATAtab web-based statistics software and excel 2010 software were used for data analysis. The consequences of the Delphi round of the review were analyzed by utilizing middle and interquartile range (IQR). This study uses the IQR values to determine the consensus level of the expert panels whether it is high (IQR 0 to 1.00), moderate (IQR 1.01 to 1.99) or no agreement (IQR > 2.00) while the median indicates the dimension of understanding where a median of 4 to 5 indicates high agreement, 2.01 to 3.99 suggests moderate agreement while anything less than that points to no agreement (25, 26).

Phase III

In this phase, author performs the Pearson correlation statistical test, also known as Pearson’s r, to analyze the statistical significance of the final outcome. This test basically measures the linear relationship between the Delphi rounds based on the outcome of the panels’ consensus. As the Delphi technique consists of several rounds of inter-related questionnaires hence it is extremely important to determine the correlation between each of these rounds whether there is consistency in terms of the panels’ consensus between each round. The test produces values ranging from -1 (negatively correlated), 0 (no correlation) and 1 (positive correlation). On top of that, Fleiss’ kappa, the most suitable analytical statistic tool to evaluate the degree of agreement of three or more participants, is also used to measure the level of agreement among the panellists in this study (27, 28). Like the majority of correlation coefficients, this one also assumes a minimum value

of 0 and a maximum value of 1. The scale used in the DATAtab software was used in the analysis of the Fleiss' kappa values.

DISCUSSION

This protocol adopted a *3-corner collaborative design cycle* (participatory design), involving children (experienced user), their parents, Occupational therapists, and engineer (3D prosthesis expert) throughout the process. This study demonstrated how a 3-corner collaborative design cycle (participatory design) can help to produce better prosthesis design in order to improve children functionality by taking the experiences of the child and parent as a starting point. This approach allowed us to develop a novel prosthesis design and training module that is child-centered, takes into account the perspective of the child, parent and OTs and integrates with engineer's expertise. Hence, by involving multiple parties, we were able to develop a 3D printed upper limb prosthesis focusing on optimizing the experience of children and their parents while working with available resources.

Current study represents the first stage in the development of new design of upper limb 3D printed prosthetic: continual, iterative development will be required to reach the stage at which they can be commercially manufactured. However, involving users from this early stage ensures that the point of departure for the design is from the users' own views, experiences and expertise. The previous work (1, 9, 29) reported that prostheses for children need to be lighter, more comfortable, more useful and more attractive. Using this methodology has also highlighted that prosthesis should be safe, quick and easy to use; and natural (in both appearance and movement). When developing prostheses, it is important to be aware of issues that are relevant to all users, as they may affect the use or non-use of the devices (13). From previous published studies, engineer and OTs have expressed the belief that involving children and parents in designing and choosing prostheses leads to feelings of ownership and, subsequently, reduces non-use of devices (15). This demonstrates the value of involving children and their parents in the development of prosthesis and training generally. The children and their parents demonstrated an ability to engage fully in the study and share unique insights which may not have been gleaned through other methods.

Prior investigations have revealed a study gap in the body of knowledge about the training module for utilizing a prosthetic hand for children. A thorough analysis of the existing materials and journals found a lack of adequate explanation and direction for clinically educating child users of multigrip hand prosthetics. Pre-prosthetic, integration, control training, and activity training are the four basic training stages that have been recognised in the literature and are referenced in the majority of publications; nevertheless, there are few comprehensive guidelines on how to carry out these training phases. This knowledge gap highlights the necessity for more study and the creation of thorough training guidelines in order to improve the training procedure and the results for people utilising multigrip hand prosthetics. Paediatric treatments have shifted in recent years from using traditional clinical facilities to conducting therapy sessions in the patient's home (30). Children are involved in therapeutic activities under the direction of their parents or other carers inside the familiar surroundings of their own residences as part of home programs and interventions. This method has shown to provide effective learning and significant improvements in overall function (30). These results provide credence to the idea that home intervention, particularly in the context of prosthesis usage, can promote healthy relationships and improve functionality in a range of daily living tasks for kids.

Hence, the implication of this study, we presume that the application of the collaborative 3-corner design cycle (participatory design) and 3D printing (rapid prototyping) can greatly contribute to the development process of upper limb prostheses, as we have shown in this study. In addition, 3D printing and rapid prototyping technologies have contributed to the ability to produce customised or user-tailored parts that are much more accurate compared to the conventional manual prosthetic process (13). Engineers (3D expert), occupational therapists, and researchers might potentially reduce future rejection of upper limb prosthetic devices by addressing the underlying causes behind their rejection. The results of this study can serve as a valuable reference for the advancement of prosthetic design and device development, addressing specific areas of concern and meeting the needs of users.

Limitations

Our study had several limitations. First, as the training module emphasized consultation activities with occupational therapists and the researcher did not include the opinions of OTs in health clinic and engineering experts. Although the expert panels encompassed occupational therapists specializing in pediatric and orthopedic, the overall number of pediatric and orthopedic specialists was significantly large. As such, our OTs may not have been representative. Our expert was not fully representative of the Malaysia population of OTs in other ways as well: OTs in health clinics were underrepresented. Thus, this standard might not effectively reflect the perspectives of all OTs.

Additionally, we wanted to briefly address the fact that this module focused on occupational therapists' perspectives activities and thus, we did not include child/family feedback on the training module design. It explicitly was not our intention to diminish the role of the child/family in designing the training module.

However, it was our aim to focus on the perspective of OTs in designing home-based self-care training in general, and not with regard to specific amputation cases. Yet, all activities in the training module were designed to be functionally useful and as fun as possible. The expert panel aimed to develop activities that could be performed at home with readily available equipment (e.g. cups, balls, spoon, and bottle). Nevertheless, a recommendation for future research is to further detail and experiment with workable collaborative design processes and to explicitly involve clients in such research.

Finally, it should be noted that this manual was primarily structured for children with functional upper-limb prostheses to execute basic activities, meaning that the components might not be relevant to counterparts with non-functional upper-limb and cosmetic prostheses.

CONCLUSION

More research is required to determine whether working together between children, parent, OTs and 3D printing experts can lead to the practical implementation of 3D printed upper limb prosthesis. The process of collaboration is still in its early stages. The study's framework can be used as a reference to help researchers and occupational therapists understand how 3-corner collaborative design might spread throughout the field of occupational therapy in order to develop and improve three-dimensional (3D) printed upper limb prosthesis design and a home-based self-care training module. One possible interpretation of this trend could be a partnership involve a cross-functional team that consists of an Occupational therapist (OT), engineer (3D printed prosthesis expert), prosthesis user (experienced child), and their parent. Overall, it can be said that initiative is required to advance the concept of collaboration between cross-functional team. The ultimate goal of this effort is to determine how 3-corner collaborative can result in designing 3D printed upper limb prosthesis that are more precisely customized to meet the needs of individual clients.

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