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A Designers' Perspective on Additive Manufactured Smart Wearables for Paediatric Habilitation

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Abstract

The aim of the paper is to identify from the perspective of designers, what is required to optimally design smart habilitation devices for additive manufacturing, whilst ensuring a high quality multi-user experience. Semi-structured interviews were conducted with designers to identify the key requirements to develop such devices. The outcome of this study will provide a preliminary framework for designers to take advantage of the state-of-the-art of design for additive manufacturing in order to meet the expectations of multiple users of smart devices for pediatric occupational therapy.

Keywords: additive manufacturing, co-design, user experience, smart wearables for peadiatric habilitation

1. Introduction

Designing for additive manufacturing (AM) is considered as a less constraining task compared to designing for conventional manufacturing processes. Presently, AM has become more multifaceted by incorporating embedding of electronics, printing with multiple materials and in multiple axis, amongst other novel mechanisation, capable to manufacture a wider range of products. However, engineering designers might find it more challenging to design such products due to novel technologies. Thus, Design for Additive Manufacturing (DfAM) is being considered to enhance the development of products and optimally design devices for 3D printing (Vaneker et al., 2020).

Apart from these challenges, medical field designers have to take into consideration end-users' requirements, as well as the respective regulations and standards to make sure the 3D printed device is safe and satisfies the customers' needs. Typically, various individuals interact with medical devices, both directly and indirectly. Similarly, Smart WEarables for Paediatric Habilitation (SWEPH), have multiple users including; the child who is undergoing habilitation, their legal guardian and the occupational therapist. These important stakeholders, amongst other individuals, generate various requirements which designers must abide with to deliver an optimal device that caters for their individualistic needs and ensures a high quality user experience (UX). A separate study, carried out by the author, was conducted to identify what shall be incorporated in the design of SWEPH to generate positive emotions for its respective users. Four one-to-one sessions were conducted with children with cerebral palsy, whilst three focus groups with twenty-one stakeholders were organised with groups of occupational therapists, legal guardians of children with cerebral palsy and a mix of experts. This separate study revealed that; co-designing with relevant stakeholders is essential to design SWEPH. Furthermore, motivation is necessary to entice children during therapy. In this respect personalisation in the design of paediatric habilitation devices, which can be achieved with AM, plays a key role.

In view of this context and the multidisciplinary aspects of additive manufactured SWEPH, this study will address the research question "*To what extent do engineering designers require a proactive design support tool to design smart wearable habilitation devices for additive manufacturing, and at which stage of design process would it deem fit?*" The outcomes of this study aim to address this question led to the development of a preliminary framework for engineering designers to take advantage of the state-of-the-art of the DfAM and design a device which generates a UX. The focus of this study is on SWEPH intended to be worn on the upper limb.

This study is part of the overall data collection means to develop and evaluate the design support tool as depicted in (Figure 1). The main focus of this paper is the study with designers. Other preliminary evaluation studies were conducted with children and a mix of experts. The study with children was conducted to generate an initial idea of the children's feedback on additive manufactured SWEPH. 3D printed parts of an upper limb SWEPH, as part of an ongoing project, were presented to three typically developing children to collect their feedback. Subsequently, the outcomes of this evaluation study were discussed in a one-day workshop with a mix of experts, including three qualified occupational therapists and five engineers. These studies will be considered to support the findings of the study conducted with the designers.

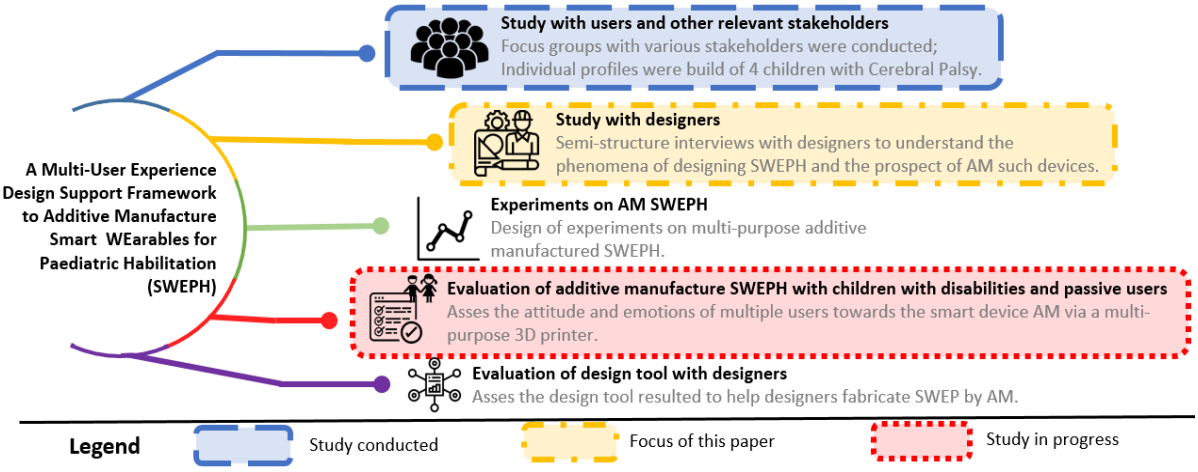

Figure 1. Key studies forming part of the overall data collection to develop and evaluate the design support tool

The following section introduces any related work in-line with the scope of this study. Section 3 describes the method used to gather insights from the designers, followed by the resulted requirements in Section 4. Section 5 proposes a preliminary framework to design SWEPH by AM, followed by a brief discussion in Section 6. Ultimately, a conclusion is drawn in Section 7.

2. Related Work

Designing medical devices demands a structured methodology, complying with the national regulations and following the standards necessary to ensure a safe product for the end-users. This applies as well to devices used during paediatric occupational therapy to help therapists deliver their sessions and reach their clients' full potentials. Martínez and Avilés (2020) present a methodology to design rehabilitation devices by following a systematic process, starting from identification of the problem up to prototyping, however overlooking the use of AM.

Recently, AM is becoming more commonly utilised in the rehabilitation field to design products, from prosthesis and orthoses to more complex devices such as therapeutic devices as well as hearing aid parts (Lee et al., 2019; Effendi et al., 2020; Sabarish et al., 2021). As AM is maturing, it is essential to follow a structured framework to manufacture high-end products. Yeong and Chua (2013) present a quality management framework to additive manufacture medical devices. This framework emphasises the significance of abiding by regulations and standards, initiating from data and software input to understanding and continuous verification of the process, however it overlooks the benefits of AM.

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Meanwhile, Ricotta et al. (2020) present a new approach to design customised orthosis via AM, following a reverse engineering methodology. Their study highlights the advantages of customisation and flexibility offered by AM, however it does not include the participation of relevant stakeholders.
Other recent studies on AM rehabilitation devices highlight the importance of co-designing with relevant stakeholders, especially with active users and medical professionals. Perera and Ranasinghe (2018) conducted a study with various stakeholders of habilitation products for children with hemiplegic cerebral palsy, to use their insights in order to design therapy assistive products. However, they overlook the fabrication process of their designs in particular AM. On the contrary, Thorsen et al. (2019) consider AM while following a co-design approach to identify the primary users' needs and design the product accordingly. Correspondingly, De Carvalho Filho et al. (2019) highlight the importance of rehabilitation professionals' participation when designing such devices with AM. The mentioned studies identify the importance to follow a co-design approach when designing rehabilitation devices by AM, focusing on the usability of the device, with limited acknowledgement to UX. In addition, designing with children is more challenging due to their short attention span (Markopoulos and Bekker, 2003) and the fact that they struggle to verbalise their thoughts (Hannah et al., 1998). Furthermore, recent studies endorse the utilisation of DfAM to strategically 3D print cheap and optimal products. Kumke et al. (2016) developed a DfAM framework to continuously support design engineers throughout the design process of developing products for AM. This framework is quite generic and does not incorporate previously mentioned aspects of SWEPH requiring the integration of electronics, unlike the passive products aforementioned.
The above review indicates that whilst DfAM and the co-design approaches are being adopted in the development of additive manufactured devices for rehabilitation, studies which take in account SWEPH and the corresponding perspective of designers to fabricate such devices, are lacking. Thus, this paper will address this gap by identifying from the perspective of engineering designers what is required to design such smart products for AM and propose a preliminary framework inspired by the requirements identified, DfAM, and UX design.

3. Method

Semi-structured interviews were used as the main data collection method to explore the phenomena of engineering designers to develop SWEPH. The interviews involved their experience with respect to designing medical devices, AM, UX design, their insights on involving stakeholders. Furthermore, part of the interview was dedicated to identify the designers' requirements of a framework to help them design such devices for AM. A pilot study of the interview was conducted to determine whether any changes in the questions and flow were required. The questions and layout were adjusted according to the feedback obtained. During the interviews, small-scale quantitative data was collected via ranking questions and Likert scales. The order of the rank questions was shuffled to reduce chances of bias between interviewees. Correspondingly, the Friedman test was used to compare the means of the ranked elements, with the null hypothesis stating that the mean rank does not vary if the p-value is lower than 0.05. Meanwhile, thematic analysis was conducted to identify important themes and patterns throughout the qualitative data recorded.

3.1. Thematic Analysis

The method proposed by Braun and Clarke (2006) was followed by initially transcribing each recording and familiarising with the script by re-reading. Subsequently, each transcript was coded via NVivo statistical and qualitative data analysis software (released in March 2020), by two researchers for validation and homogeneity. Once the coding was generated from both researchers, an inter-rate reliability (IRR) factor was outputted to determine the extent of which the coding is correctly representing the end-goal. The IRR resulted equated to be 0.875, which presents a high agreement between the researchers. Successively, the codes identified were grouped into themes and presented in Section 4.

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3.2. Participants

Eight engineering designers participated in this study, including one female. The number of interviewees fall under the recommended range of participants by Polkinghorne (1989) to explore a phenomenon. Experience of these designers varied between 1 to 35 years (M = 11.13 years; SD = 11.67). The participants originated from different countries across Europe and the United States, with the majority coming from the United Kingdom, two of which emigrated to the United States and Australia. Finding participants specifically on the development of 3D printed SWEPH was challenging. Therefore, although all the participants had previous experience in designing medical devices, their experience varied from designing assistive technology, rehabilitation wearables and products for children, to specialising in AM.

4. Identified Themes

AM prospect to fabricate SWEPH

AM SWEPH brings a lot of advantages as compared to conventional manufacturing methods, allowing for cheap and quick iterations in the design. The fast manufacturability of AM allows designers to rapidly print their design in a few working days, since children would quickly outgrow the device. Nevertheless, AM permits alterations in case the child outgrows a preceding design. Additionally, it allows for customisability to manufacture one-off personalised devices to cater for the individual's specific needs, while design complexity and flexibility encourages designers to develop novel designs.

Although AM has the aforementioned advantages, two designers pointed out that in their opinion 3D printing has not yet reached its full potential for them to consider it over conventional processes to achieve a high-end product for their client. Three of the designers interviewed highlighted that they rarely take in account AM when they are designing a medical product, whilst the majority agreed that they commonly use AM for prototyping and testing purposes only.

Despite this, designers encounter various challenges when designing products for AM. The major three challenges, as graded via a ranking question between eight presented challenges were; embedding of electronics, obtaining a good surface finish and 3D printing with multiple materials. Meanwhile, the least distressing challenge according to the designers is post-processing. Although being quite subjective depending on the part, the majority agreed that it is quite easy to finalise a product if it is designed and printed appropriately. The Friedman test shows that there is no significant difference between the mean ranks obtained ($\chi^2(7) = 12.04$ and $p = 0.049$). Vaneker et al. (2020) identified few assembly design rules with respect to traditional 3D printers, as well as post-processing means to obtain a good surface finish, whilst Vaezi et al. (2013) highlight various difficulties when AM multiple material parts.

When it comes to embedding the electronics of SWEPH, designers indicated that it is still quite a challenge for them to implement electronics during/after 3D printing. Their favoured means to embed electronics are post-additive manufacturing assembly and remote assembly through a multipurpose printer, both preferred over start-stop assembly. The Friedman test resulted a $\chi^2(2) = 4.75$ and $p = 0.024$, concluding that there is no significant difference between the mean ranks of the electronics embedment in additive manufactured products. Designers highlighted that post-additive manufacturing and remote assembly process are more favourable as they permit maintenance on the electronics via disassembly of the parts. Meanwhile, for the latter, the majority of the steps are automated, with reduced idle time and not requiring much labour input, making it ideal for high quantity sales. Furthermore, it was identified that majority of the designers were not familiar with this technology, which might have influenced their responses. In opposition, start and stop assembly requires labour involvement to insert electronics while the printer is idle and electronics are permanently embedded inside the device, restricting maintenance.

Design of UX for additive manufactured SWEPH

The sole purpose of SWEPH is to improve the quality of life of the end-user. AM paediatric habilitation devices indirectly impacts the child's experience, due to prospects of personalisation. Personalisation results in ownership of the device, especially when the child is actively involved during the design process to help develop the device. Customisation of the device promotes attractiveness and helpfulness

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for habilitation as it caters for individual's needs, personal likings and gender consideration. Designers ranked ease of use and fun as the most important criteria, followed by attractiveness and helpfulness, to generate a high quality UX for children. The Friedman test showed that there is a marginal difference between the mean ranks of the UX criteria presented, since $\chi^2(9) = 21.02$ and $p = 0.0026$.

With respect to AM factors, it was unclear whether AM aspects have a direct impact on the child-product interaction. Three designers emphasised that AM might impact device comfortability due to its layer thickness and surface finish. For instance, staircase effect would be uncomfortable for the child. Additionally, designers remarked that if the device is poorly designed the child might end up getting frustrated and will avoid interact with it again. Furthermore, ergonomics aspects such as size, fit and weight of the device are important to avoid causing discomfort and fatigue.

On another note, AM can as well impact the UX of the passive users interacting with the device. Designer's emphasised that occupational therapists are influenced by AM since they can have bespoke devices for their clients, making it more efficient for them to achieve their client's functional goals. Similarly, parents' might be impacted by the customisability aspects of AM, since the device would cater for their child's individualistic requirements affecting their UX indirectly. Through the element of customisability both the parents and occupational therapists can benefit from it, since the child will be motivated to engage with the device and hence promoted to habilitate. Motivation is an important ingredient to have an effective therapy session with children (Ziviani et al., 2013) as it helps to maximise the output of therapy, whilst customisability would allow to modify the device according to the child's needs and desires, encouraging them to interact more with the device. Therefore, understanding what the users want and empathising with them by avoiding what upsets them and implementing what subjectively, makes the device attractive and fun for them, can help motivate them to use the device.

Another impactful element of UX, is social inclusion. Designers noted that in case of SWEPH the design should be as minimally visible as possible, yet designed to be a product which children can proudly wear. This is crucially important if the device will be utilised in social environments, such as school.

An important criterion of UX is usability (Bitkina et al., 2020) and was the focus of related studies aforementioned in Section 2. Usability of SWEPH is impactful on all users who interact with such devices. Although in case of children, they might have other priorities when interacting with the device, such as fun, parents and occupational therapists would prioritise efficiency and effectiveness, since they will base their experience on the resulted outcome. Thus, apart from evaluation from the children's perspective with respect to their experience, it is important to test the usability of the additive manufactured device, and ensure that it meets the initial design goals of its various users.

In addition to the outcomes of the study with designers, preliminary findings of the evaluation study with children showed that all participants preferred 3D printed modes of attachments (refer to Figure 2), as long as they had a good quality surface finish, to avoid irritating their skin. Furthermore, bulky designs, such as parts 2 and 3 in (Figure 2), were not favoured as they were rather invasive for the children's hands. This highlights the significance of DfAM to cleverly design and manufacture the device and avoid preventable obtrusions and discomforts.

Multiple stakeholders' insights on additive manufactured SWEPH

One of the main themes discussed during the interviews conducted was the involvement of stakeholders in the development of SWEPH. Due to its multidisciplinary aspects, it is highly unlikely for designers to be able to have knowledge in the field of habilitation to design the device unassisted. Designers highlighted that requirements of relevant stakeholders need to be generated and confirmed in the initial staging of the design process. Respectively, the stakeholders' input is required in the various stages of the design process of paediatric habilitation devices. The main stakeholders identified during this study included the children, their parents, the occupational therapists, as well as the designers themselves. As aforementioned, the state-of-the-art also imposes the importance of co-designing with the primary users of passive additive manufactured assistive devices (Thorsen et al., 2019), and rehabilitation professionals (De Carvalho Filho et al., 2019), as well as with the parents of children for passive habilitation device design (Perera and Ranasinghe, 2018). Other stakeholders who play an important role in the development of additive manufactured SWEPH include the client who

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proposes the development of such devices, electrical engineers and 3D printer technicians, amongst others. All these individuals play an important role to supply optimal additive manufactured SWEPH.

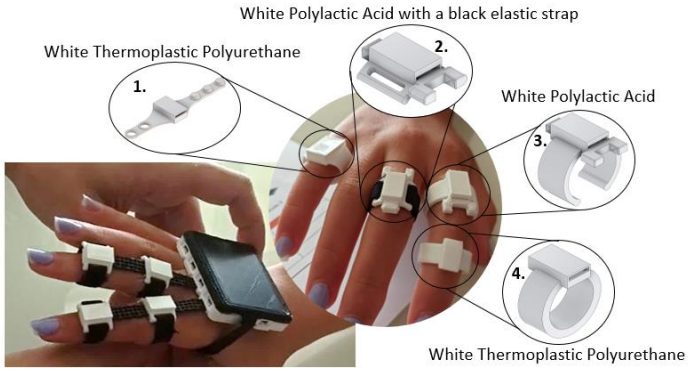

Figure 2. Exemplar SWEPH components produced by fused deposition modelling

Due to the complexity of the end-user and the various variables one needs to consider, part of the designer's tasks is to prioritise the respective requirements accordingly and find a balance between the stakeholders considered. It was highlighted that balancing requirements of various stakeholders and their implementation depends on the level of experience of the designer. Meanwhile, the majority of the designers agreed that they find it relatively easy to implement stakeholders' requirements in their design. The interviewees recommended that the stakeholders' requirements should be considered during the early stages of the design process to reduce the number of iterations made in the design at a later stage (Shirzad et al. 2015). Hence, it was emphasised that it is important to consider the appropriate stakeholders throughout the design process, whilst ensuring that their requirements are met and high quality multiple users' experiences are obtained. Ultimately, it was acknowledged that although the designers input is significant as part of the holistic design process of SWEPH, their requirements should not be prioritised above the users' needs, and not get abstracted of its main objectives.
Furthermore, during a discussion with multiple experts in one of the separate studies aforementioned in (Figure 1), feedback on additive manufactured SWEPH was obtained to determine what needs to be improved to satisfy users' needs and desires. Occupational therapists provided further input from their experience on how the device could be improved to help them reach their clients' functional goals. The main aspects discussed regarded the obtrusiveness of the device with the children's movements and ensuring the 3D printed means of attachments were adequate to secure the device with the child's hands.

Themes related to the design process of SWEPH and its respective challenges

Based on their experience the eight designers depicted that to design SWEPH they require a structured design process. During this study the key steps to develop medical devices were discussed in relation to fabricating SWEPH, since they fall under medical device classifications. Tasks such as benchmarking and literature search were highlighted as important means to get an initial idea of what needs to be designed, together with the necessary studies with end-user and other relevant stakeholders to identify their requirements. Taking a user-centred approach, designers must make sure to identify the subjective requirements of the end-user who will be using the device, building a profile for each individual client. A key tool to generate a profile of the child in query is the International Classification of Functioning, Disability and Health (ICF) checklist of the World Health Organization (2003), to identify their disability and functional abilities. In the following stage design concepts are generated and respectively the best concept or two are identified. Meanwhile, in the embodiment stage the designs are defined with further detail, considering manufacturability and assembly/disassembly. The next phase of the design process involves the validation of the design to ensure it is up to standard and in-line with the regulatory bodies, concluding the documentation and conducting evaluation studies with the stakeholders to get their feedback on the device. Other important aspects discussed with regard to the design process include regulations, standards, prioritising the International Organisation for Standardisation (ISO) 13485, prototyping and necessary iterations, amongst other. A list of design tools used in medical device development, which were also suggested for SWEPH,

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include; quality function deployment (QFD), product design specification (PDS), Pugh matrix and Failure modes and effects analysis (FMEA).

The process to design SWEPH is not a straight forward progression, as designers face various challenges. The majority of challenges revolve around the end-user, such as finding participants due to a limited population, ethical constraints due to the vulnerable individuals involved, and keeping in touch with them. In case of SWEPH, personalisation plays a vital role to ensure that the device is in in line with the child's specific needs and likings, thus regular interaction with the users is important for the designer no to lose track of the users' requirements. The designers emphasised that designing with children increases the number of requirements as compared to designing with adults, especially when designing for disability (Hannah et al, 1998; Markopoulos and Bekker, 2003). Additionally, designers remarked that they are frequently restricted with time and cost. In case of SWEPH, time is critical since children outgrow their devices in a short period, hence, designers need to make sure the final product is delivered to the user in time. Other struggles identified include problem formulation for whom they are designing and what actually needs to be designed to tackle the end-users needs, not only their wants.

5. A Preliminary Framework to Assist Designers Develop Additive Manufactured Smart Wearables for Paediatric Habilitation

Considering the phenomena studied and its outcomes discussed in the previous section, a structured design process solution can fill in the gap in literature to assist designers overcome the aforementioned challenges and constraints, and meet their requirements. The solution will be considering the multidisciplinary aspects of paediatric habilitation devices, DfAM, UX, whilst taking a co-design approach to manufacture optimal SWEPH for occupational therapy intervention. The goals of this process is to ultimately generate a high quality UX for the potential users of the designed device.

The designers interviewed recommended that the framework should be implemented as early as possible in the design process, to be used as a reference throughout the various design stages in order to avoid losing sight of the initial goals generated. Moreover, it was emphasised that DfAM should be incorporated between conceptual and embodiment stages to take advantage of the AM reach its potential. Similarly, Kumke at al. (2018) targeted the conceptual and the initial steps of embodiment stage to leverage AM potentials and implement DfAM.

During this study the designers were asked to rank what they wish such framework incorporated. Out of ten factors presented, the designers prioritised the following five features respectively; to identify UX aspects for children, to identify UX aspects of other users, to identify requirements of relevant stakeholders, to adhere with applicable regulations and standards, and determine how to embed electronics during AM. Four designers highlighted that the other aspects should still need to be consider, for instance generating initial designs, identifying AM parameters and implementation of tailor-made characteristics. The Friedman test resulted $\chi^2(9) = 22.96$ and $p = 0.0036$, concluding that there is a marginal difference between the mean ranks of the factors presented.

Taking in account the aforementioned data and themes identified in Section 4, a preliminary framework to guide designers to develop SWEPH by AM. The framework (see Figure 3) takes an iterative co-designing approach from the beginning of the design process with relevant multiple stakeholders who will be interacting with the device; the children, their parents and occupational therapists. A profile of the child with physical limitations will be considered in the initial stage to design the device accordingly to their individualistic needs and desires, taking in consideration UX criteria as highlighted in Section 4. This applies as well to the passive users who will be interacting with the device to take in consideration their interaction with it. Transitioning from the conceptual design stage to the embodiment stage is supported by the implementation of the DfAM to develop the device purposely for AM, reducing superfluous material, omit costs, implementation of AM rules and identify the most suitable AM parameters. Additionally, as identified in Section 4, it will consider multi-material parts printing, embedding of electronics and surface finish to tackle the AM challenges prioritised by the designers. DfAM guide would especially benefit novice designers who do not have substantial background on 3D printing. The framework incorporates the ISO13485 standard for the quality management of medical devices, to ensure that the user's and regulatory body's requirements

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are met. Additionally, it suggests to identify and comply with regulations and other standards from the initial stage of the design process. This goes in-line with the study by Yeong and Chua (2013) who emphasised the significance of standards and regulations when AM medical devices. Additionally, the framework considers verification and validation, abiding with the proposed framework by Balzan et al. (2021) to verify and validate additive manufactured bespoke medical devices.

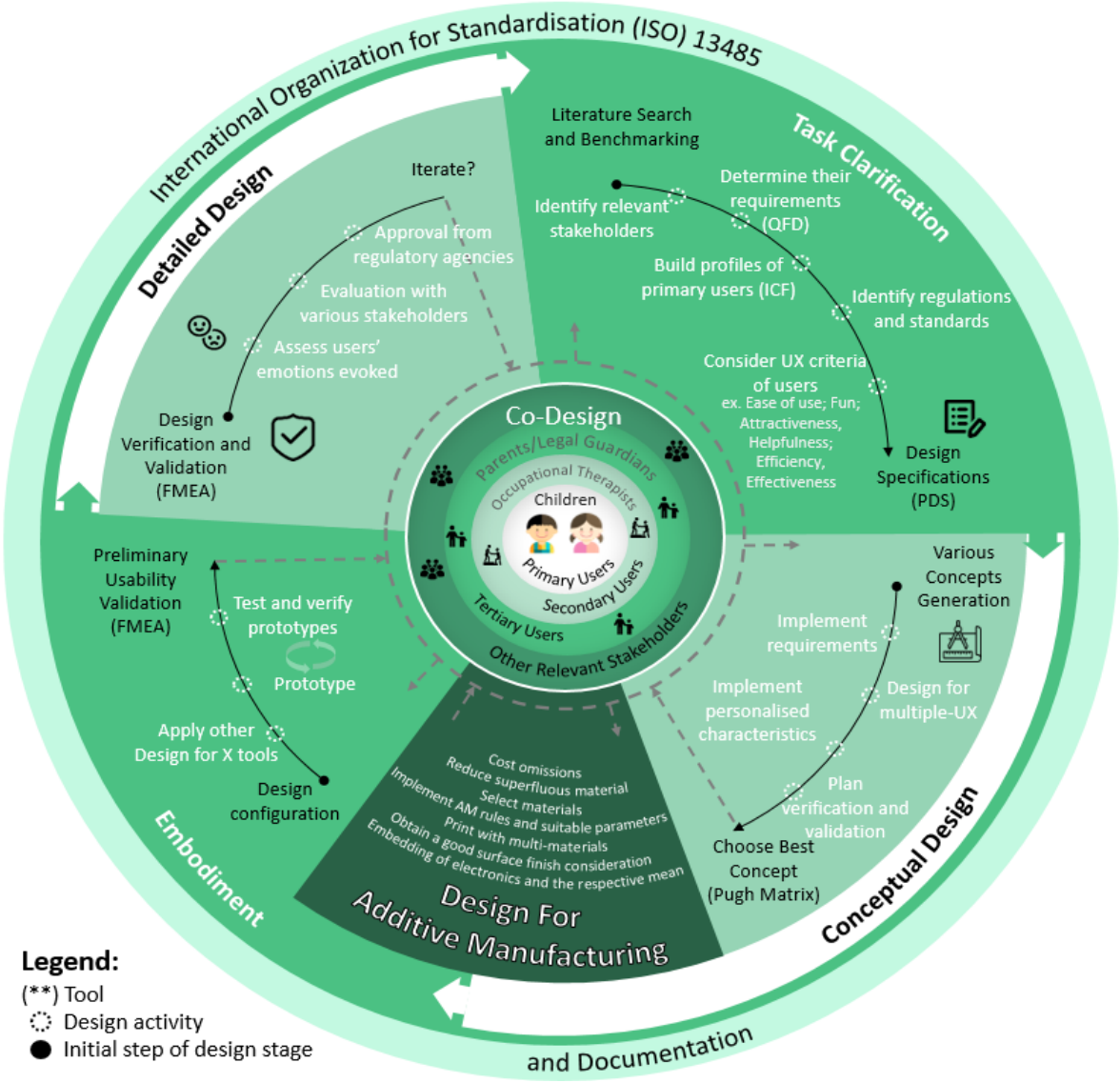

Figure 3. Preliminary framework to design additive manufactured SWEPH

All of the designers favoured that the framework should be presented as a computer-based support tool, instead of a paper-based format, as it would be better accessible and provide more in-depth specifications, as well as for enhanced communication in a team-based environment. Ultimately, the majority of the interviewees agreed that such framework would be suitable for both novice and experienced designers to guide them during the design of SWEPH for AM. In fact, seven of the designers concluded that they would always refer to such a framework as it would be useful for them to not overlook any important parameters to design such devices.

6. Discussion

The framework developed differs from the state-of-the-art as currently there are no structured processes to design SWEPH fabricated by AM. The presented framework considers what the designers need to optimally design paediatric habilitation devices for AM. Co-designing with multiple stakeholders is

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suggested, including the primary, secondary and tertiary users' requirements, as well as other relevant stakeholders. Fundamental differences to previous literature publications include the involvement of DfAM and UX design for multiple users. Respectively, according to the designer's feedback DFAM was incorporated between the conceptual and embodiment design stages.

The main limitation of this study is its sample size to validate both the qualitative and quantitative data obtained. Although the sample size is small, the results from this study correlates with the separate study conducted by the author with multiple stakeholders of upper limb SWEPH for children with cerebral palsy. The element of co-designing with active and passive users was highlighted as an important aspect when designing paediatric habilitation devices. This proceeds in line with what Shirzad et al. (2015) proposed through a user-centred approach by frequently involving relevant stakeholders to help design physical therapy devices. The customisability AM offers goes in-line with the personalised aspects to consider when designing such devices. In the aforementioned study, it was identified that children are highly motivated and engaged during therapy when the device is personalised according to their likings and specific needs. This aspect is also a great advantage for occupational therapists to achieve their clients' individual goals. Similarly, Ko et al. (2015) define a structured design process which incorporates both DfAM and design for personalisation, to take advantage of the customisability offered by AM. Apart from personalisation and motivation, AM prospects the ability to achieve key characteristics of SWEPH, if designed properly. Such characteristics recommended by various stakeholders include durability, lightweight, designed-to-size to fit securely on the children's hands, and simplicity, to avoid unnecessary complications. DfAM shall help the designers achieve a device with the identified characteristics and satisfy the respective individuals who interact with it.

What could have been noted during the execution of the interviews, was that the origin and work background impacted some of their responses. For instance, the participants who live or worked in US prioritised a lot the implementation of standards and complying with regulations due to the medical device regulatory bodies system in US. A future step of this study would be to determine the impact of the framework on designers when developing 3D printed smart paediatric habilitation devices. Prior to this, further studies need to be conducted to strengthen the resulted tool, as presented in (Figure 1). The output of these studies will help determine what affects the UX of both passive and active users, and thus what needs to be incorporated as part of the framework to obtain a high quality UX via DfAM.

7. Conclusion

In this paper the phenomena to design additive manufactured SWEPH purposes was remarked by analysing the qualitative data obtained from a study with engineering designers. The key contribution of this study are the themes identified on AM SWEPH, UX, multiple stakeholders' input and the respective design process and challenges. From these themes a preliminary framework was generated. It recommends a co-designing approach, which differs from the state-of-the-art by the simultaneous consideration of multiple users' experience design and DfAM. The resulted framework will provide a reference for designers to optimally develop SWEPH for AM, to generate a high quality UX for multiple users. The framework is still in its preliminary stages and it will be validated through future studies with designers.

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