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A Novel User-Centred Framework for the Holistic Design of Therapeutic Medical Devices

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Abstract

Numerous and complex sequence of activities in medical device development often result in time consuming and expensive engineering processes. In this study, patient and designer requirements were identified and integrated within a novel framework which supports medical device design through a consolidated understanding of user-experience whilst directly coalescing the applicable regulatory requirements in terms of product compliance and certification. This assists in the development of safe and reliable products which reflect the need for increased usability considerations during design.

Keywords: user-centred design, product design, user experience, biomedical design

1. The Medical Device Design Landscape

The medical device industry is gradually adopting a fresh mindset in exploiting User-Centred Design (UCD) principles in the design of products aimed at improving the quality of life. Research shows that adopting a user-centred approach early in the design process helps in designing safe and clinically effective medical devices, which are easy and satisfying in terms of usability (Chandran et al., 2020). Abela et al. (2021) showed that medical device design (MDD) tends to focus predominantly on the safety and efficacy of devices, often without involvement of the affected user or any consideration of user-product interaction. This is particularly evident in the design of therapeutic products, such as with rehabilitative or assistive technology (AT) where the intended purpose is often to sustain or enhance the functional capabilities of the user. In this regard, the application of UCD principles in the design of therapeutic products tends to be advantageous in exploiting functionality in that user ergonomics and human factors become central to the design in hand (Mohammed et al., 2017). Furthermore, additional physiological benefits to patients and users can be achieved by adopting UCD principles during CAD modelling, Rapid Prototyping (RP) and testing (Mohammed et al., 2015). Nonetheless, there is little research on the methods for user involvement in healthcare design (Surma-aho et al., 2021). Research shows that the benefits of implementing UCD principles in MDD are not backed by adequate guidance to successfully conduct design activities (Dopp et al., 2020). This often results in a considerable number of patient safety incidents related to medical devices because manufacturers fail to understand the context of product use due to the lack of considerations of user expectations in design (Tase et al., 2021). Designers commonly regard regulatory requirements as a barrier towards innovation and creativity in the design of medical device products. Complying and observing the applicable ISO and industry standards, together with product certification, is frequently regarded as a challenging and restricting task in design. Substantial time and budget are exhausted on verification and validation testing (VVT) of medical devices (Balzan et al., 2021). The introduction of ISO 14971:2019 and ISO 13485:2016 has put designers under huge pressure to amend their design processes, whilst placing a barrier to innovation. Additionally, it is a very common occurrence for manufacturers to

resolve regulatory issues very late in the design process (Guerra Bretaña and Flórez-Rendón, 2018). Consequently, designers end up conducting rework to verify that devices are compliant. In this regard, there exists a clear need for a framework which addresses usability and regulatory requirements within MDD processes, with a particular focus on medical devices for therapeutic purposes. The research question being addressed in this paper seeks to acquire an understanding of the collective user requirements in view of patients, clinicians and designers. These requirements assist in the creation of a user-centred framework which supports the development of an adequate strategy for regulatory approval whilst maintaining user experience (UX) central to design.

Based on this introduction, the structure of this paper is organised as follows: *Section 2* discusses related work which led to the identification of a research gap. *Section 3* describes a mixed-methods methodology adopted to identify requirements for therapeutic devices from the patients', clinicians' and designers' perspective. *Section 4* presents the key findings of this study whilst *Section 5* presents a novel framework architecture which addresses the identified requirements. *Section 6* and *Section 7* discuss the overall findings and draws relevant conclusions respectively.

2. Related Work

Liberman-Pincu and Bitan (2021) developed a novel user-centered product design methodology which targets medical device functionality, usability and aesthetics. The aim was to put the user at the centre of the design process in the design of autonomous medical devices. While the study did not target therapeutic medical products, the devised methodology provided tools which support the designer in selecting the most efficient design solution, making subjective design decisions and reducing bias when designing devices with high affordance and usability. The study did not address the relevance of compliance and the significance of adopting an adequate regulatory strategy which supports product functionality and usability. Similarly, Shah et al. (2009) proposed a theoretical framework for user-involvement within the medical device development process. Their research suggested a robust method for engaging patients and healthcare professionals in design, however there was no consideration of regulatory implications. The latter is a crucial step and is in the designer's and the manufacturer's interest to conduct user research for regulatory compliance as part of the product development process. This was addressed in the study by Dunn et al. (2019), which highlights the value of compromising between product aesthetics and regulatory considerations. The authors proposed a framework for human-centred design innovation in the field of MDD through acknowledging the need to consider the requirements of patients. The framework proposed bridges the gap between business, technological and human considerations, however it was only validated through two case studies with no specific mention of therapeutic device applications. Additionally, regulatory requirements did not form part of the proposed solution. The patient is the main actor of the framework whereby clinician requirements were regarded as secondary to the approach, whilst designer requirements were not considered. Santos (2013) developed a methodology intended at addressing medical device development within a regulatory and a business domain was proposed. The methodology focused on addressing holistic aspects of process optimisation within the medical industry and is intended to assist designers in developing relevant solutions within a New-Product Development (NPD) environment. The framework comprises a set of guidelines implemented through subdividing existing industrial product development processes into different stages and assisting in the identification and optimisation of the elements driving the product development process. The framework is also a flexible one and may be implemented in the design of any medical device (Santos, 2013). Nevertheless, the methodology adopted was not a user-centred one and consequently has not been applied in the design of a new medical device. The elicitation of user requirements with respect to the different stakeholders concerned in NPD was not sufficiently integrated in Santos's methodology; for instance, UX considerations are only considered as a sub-process of the methodology, with no reference to user-product interaction or elicited emotions during product use.

This review amply demonstrates the need for a framework which provides design support merging regulatory compliance and UX through a UCD approach. A thorough literature review did not show any comprehensive consideration of the collective requirements pertaining to patients, clinicians, and designers as a common practice in the field of MDD. This indicates that there is a gap in adopting a

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UCD approach in the creation of a MDD framework which guides designers to design safe and clinically effective products which deliver improved interactions with the product.

3. Methodology

The Design Research Methodology (DRM) by Blessing and Chakrabarti (2009) was selected as a basis to develop the proposed MDD framework. The DRM was selected since it aims to support designers during product design and development and is thus an ideal frame of reference for this study. It also provides the opportunity to perform multiple iterations between the different stages of research and therefore does not restrict the designer to execute research in a linear fashion. The adopted study methodology, based on the DRM, is shown in Figure 1. Within the *Descriptive Study* (DS), an effort is made to identify patient, clinician, designer, and market requirements. This was achieved by conducting three separate investigations with the different medical device users. The approach of involving the user directly within the UCD approach assists the designers in designing safe and reliable products to their customers. A mixed-method approach was chosen for considering both qualitative and quantitative user perspectives. This approach is regarded as the best practice to contextualise patient experiences within a clinically meaningful design framework (Regnault et al., 2018).

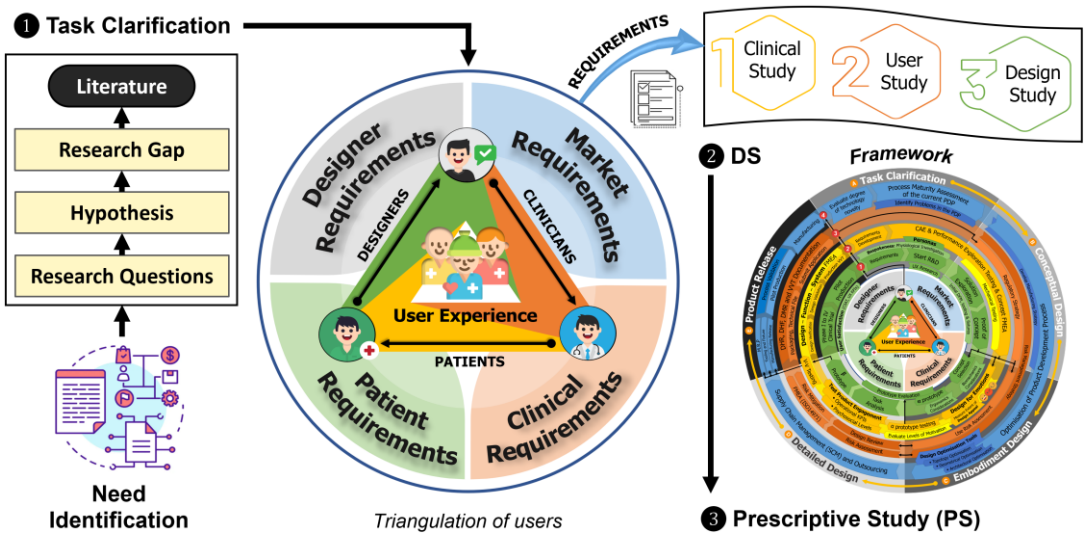

Figure 1. Study methodology for conducting research

In the study conducted by Abela et al. (2021), a total of 16 clinicians were interviewed to identify a set of clinician requirements in the design of therapeutic products (Study 1 in Figure 1). Recruited clinicians were mainly engaged to work in physiotherapy, stroke rehabilitation, occupational and neurological physical therapy. In the second study, which is presented in this paper, the aim was to understand patient's ($n=24$) preferences regarding product properties by using a selected set of rehabilitation devices (Study 2 in Figure 1; corresponding outcomes presented in *Section 4.1*). Participants involved mainly patients with stroke, neurological and musculoskeletal conditions. The chosen mixed-methods approach facilitated the interpretation of UX during therapy which provided a better understanding of the applicable design considerations to be included in the framework. Six different devices were provided to the participants who correlated their preferences and experiences with the structure and design of the product. This facilitated the identification of patient requirements which helps to maintain the end-user central to the framework. Devices were restricted to hand and finger rehabilitation products. All patients were interviewed by means of an interview script which involved open discussions in line with a set of questions formulated from literature addressing the topic. The first set of questions were analysed using the PrEmo emotional response tool (Desmet, 2018), which is a non-verbal assessment tool to measure positive and negative emotions such as desire, joy, fascination, disgust, dissatisfaction, and boredom. This facilitated the appraisal of user emotions without the patients having to verbalise their feelings and sentiments regarding the product used. The rest of the questions involved ratings on a five-point Likert scale regarding personal views on product properties and their influence on the ongoing therapy. Properties included: *Size*, *Portability*, *Surface Finish*,

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Comfort, User-friendliness, Aesthetics and *Functionality*. Patients were asked to rate their experience from the point of view of product design, product complexity and level of independence during use. All questions were orally presented and interviews lasted around 30 minutes each. Data was analysed on IBM SPSS 26.0 statistical software and a set of identified requirements were developed (*Section 4.1*). Inter-rater Reliability (IRR) was used to assess the consistency and replicability of the qualitative analysis. Random sampling to recruit participants was also used to eliminate sampling bias.

The third study, also presented in this paper, was carried out with 15 designers (Table 1) who were subjected to a semi-structured questionnaire (Study 3 in Figure 1; corresponding outcomes presented in *Section 4.2*). The investigation was carried out to understand the areas where designers require guidance and support to implement applicable industry standards and medical device regulations and efficiently develop safe and reliable medical devices, particularly ones which offer high-quality UX intended as user-centred products. Due to challenges in recruiting designers employed in the field of bespoke therapeutic product design, designers working in other fields of MDD were also recruited.

Table 1. Overview of recruited participants for data collection (Y: Years of Experience*)**

Ref.	*Y**	*Background*	*Ref.*	*Y**	*Background*
P1	25	Interaction Design, Innovation	P9	13	Kinesiology, Rehabilitation
P2	16	CAD Modelling, Reverse Engineering,	P10	7	3D Modelling, Assistive Technology
P3	16	Medical Equipment, Surgical Devices,	P11	20	Product Design, Systems Engineering
P4	21	CAD Modelling, User Centred Design	P12	30	Biomedical Research, Medical Devices
P5	11	Engineering Design, Creativity	P13	4	Product Design, Development
P6	5	Product Design Engineering	P14	15	Complex Systems Engineering
P7	8	Industrial Design, Materials	P15	30	Accessibility, Rehabilitation Design
P8	11	User-Centred Design, Product Design,			

A mixed-methods approach was adopted to facilitate the elicitation of designer requirements which complements the different user requirements presented in *Section 1*. The designers' experience varied between 4 and 30 years (Mean = 15.5 years, Std. Dev. = 8.1 years). Participants worked within medical device companies in the design and manufacture of Class I through Class III medical devices. Out of all participants, 60% of designers were previously involved in academic medical device research whilst 80% of the designers had a background in engineering. All participants were involved in the design of bespoke medical devices, whilst 47% of designers stated that they were also involved in designing generic devices. All semi-structured interviews were conducted using an online video conferencing tool and lasted an average of 60 minutes. Interviews were recorded and transcribed verbatim and were divided into three parts; the first part collected information about the designer, their key responsibilities, and roles within MDD. The second part dealt with understanding the current industry design practices together with a thorough consideration of the designer's interaction with other stakeholders (such as healthcare professionals and patients), the designer's involvement in regulatory affairs, product requirements for bespoke and generic medical devices, and a general qualitative assessment with regard to product safety and design reliability. The third part focused on gathering designer's thoughts with regards to (i) improvements on existing design frameworks and (ii) recommendations for a framework which adopts a user-centred design approach and merges elements of UX, medical device regulations and product VVT at the centre of the framework. A thematic analysis based on the guidelines by Braun and Clarke (2006) was conducted based on the relevant themes that emerged from the transcripts. IRR was used to evaluate both the consistency and the replicability of the analysis, whilst Intra-Class Correlation (ICC) was used to evaluate the validity of the mixed-methods approach.

4. Requirements for a Novel Framework Architecture

This section presents the identified requirements essential to develop a framework which is suitable to support designers in the design and development of user-centred medical device products from the perspective of the three stakeholders in this study. As described in previous work, a set of six requirements emerged with what regards the needs of clinicians when making use of therapeutic products in a clinical setting (Abela et al., 2021). These will be amalgamated with the below sets of elicited requirements concerning patients and designers respectively.

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4.1. Patient Requirements

.P1 **Functionality and Usability.** The solution should provide ways to support the designer in generating prototypes which can continuously be validated for form, fit and function.

.P2 **Product Engagement and Appeal.** The study showed that the right design considerations in view of UX will result in products which are engaging, attractive and enjoyable. The emotional design of a product is highly relevant to patients as these often opt to use devices which induce positive feelings and intrigue. The solution should support in the design of useful, interactive and easy-to-use devices, and which are considered fun and engaging.

.P3 **Identifying Elements of User-Experience.** Participants remarked that properties such as portability, comfort of use, colour, aesthetics, surface finish and material selection all have a direct influence on the UX to the medical device user. Generating personas to inform certain design decisions helps in reflecting patient needs, actions and behaviour.

.P4 **Bespoke Product Design and Customisability.** The study has shown that a correlation exists between customisability and usability since in general patients prefer products which address their own physiology. The solution should guide designers in classifying the nature of data collected and suggest considerations based on patient physiology, anthropometry and anatomy.

4.2. Designer Requirements

.D1 **Communication with the End-User.** The solution should facilitate adequate communication between the designer and the end-user. One participant remarked that "*During the whole design process, the opinion of the patients is the one that matters the most*" implying that guidance is generally required to specify the intended purpose of the product. The solution should focus on delivering comprehensive information and on building trust with the framework itself.

.D2 **Translating Regulations into Design Implications.** The solution should provide tangible guidelines to the designer in view of regulatory compliance. This could be in the form of an access database with checklists, gates, forms and digital/analog templates which suggest design considerations at different stages of the design process in view of the applicable risks and market regulatory legislation.

.D3 **Elicitation of Critical User-Requirements.** The solution should aim at identifying critical user requirements and translate these into critical design specifications. The designer's experience in conjunction with the framework is fundamental in generating critical product specifications.

.D4 **Integrating Key Aspects of UX.** The framework should provide suggestions to integrate all UX aspects in the design with regards to user requirements. One designer suggested that "*A tool to support the designer in thinking about UX would be helpful since this is missed out on many occasions*". The framework should support in capturing the UX of users in relation to other soft requirements and in view of device functionality and usability.

.D5 **Support in Design Process Optimisation.** The solution should assist in reducing the time from problem definition to solution generation, resulting in a more efficient process with less time re-iterating during design. Designers suggested that the framework should provide support through yielding relevant information for selected design parameters. The framework should provide a virtual plan to help increase process efficiency and reduce the possibility of having to revisit design ideas at more advanced stages.

.D6 **Enhancing Design Innovation and Creativity.** The solution should deliver stage-base information by being aware of the stage that the designer is currently at. All participants agreed that the tool should not be too prescriptive since this can have a bad influence on MDD. The framework should not provide a direct solution to the existing design problem; however, it should inform the designer about certain design decisions to be made.

5. *MEDPRO*: A User-Centred Framework for Medical Devices

A systematic framework architecture is being proposed based on the identified requirements defined in *Section 4*. The purpose of the **MED**ical Device **PRO**duct Development (MEDPRO) framework is to provide design support to the MDD process by bridging the gaps between UX, medical device regulation

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and product development. The proposed architecture (Figure 2) serves as a model for a computer-based support tool to be generated which can further provide proactive assistance to designers dealing with medical devices. The framework is an outcome of two domains which form the basis of its structure. Primarily the architecture is a result of the integration of the identified patient, clinician and designer requirements outlined in *Section 4*. Secondly the framework is also founded on literature which is critical to the formulation of different stages and layers outlining its structure.

The arrows in black highlight the interaction between the various layers at different stages of the product development process. This indicates the non-linearity of the process where all components affect the rest of the architecture such that a change in any one of them can potentially affect the outcome.

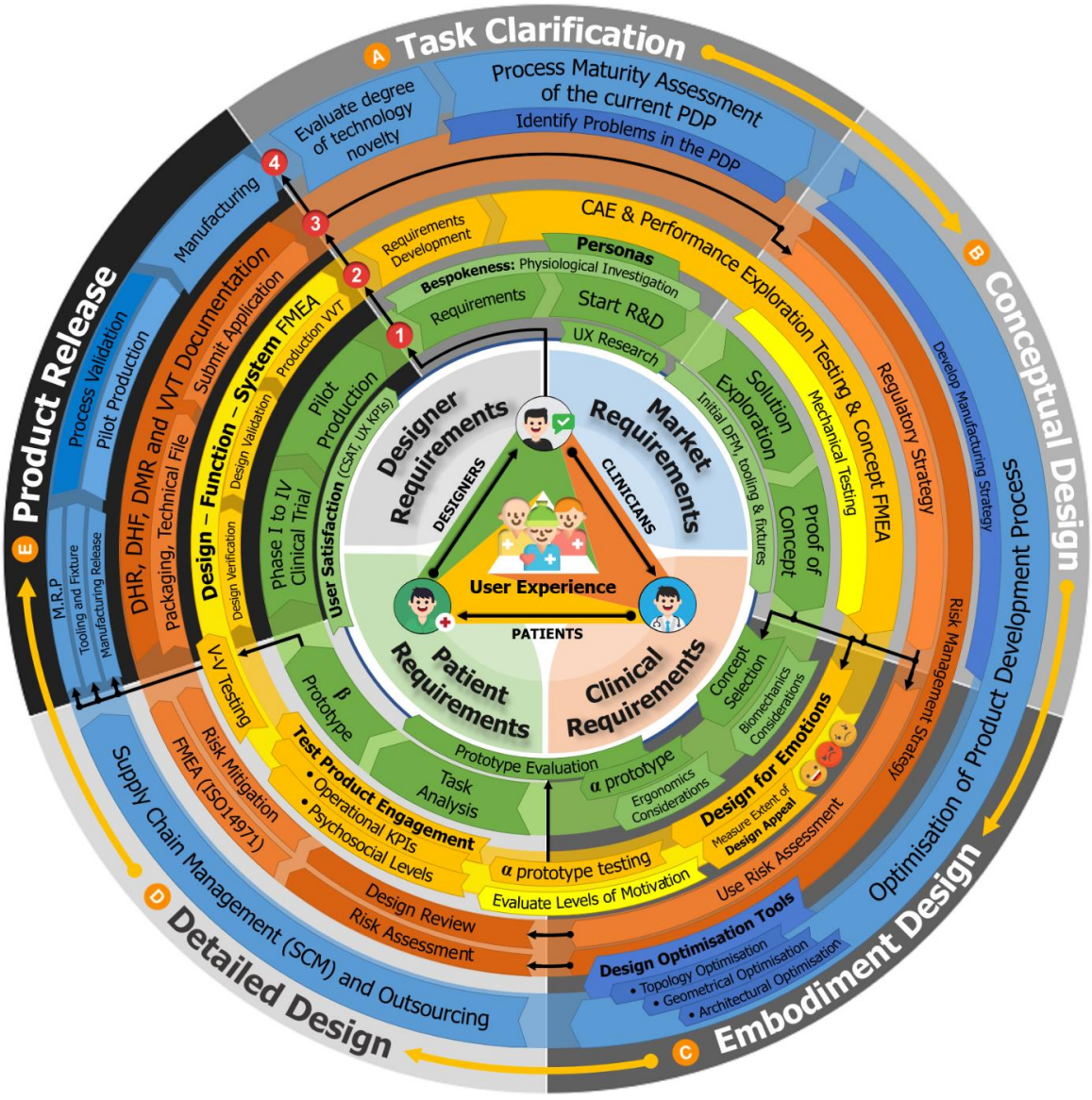

Figure 2. The MEDPRO framework architecture for MDD

5.1. Stages of the MEDPRO Framework

There are five stages within the MEDPRO framework: (A) *Task Clarification (TC)*, (B) *Conceptual Design (CD)*, (C) *Embodiment Design (ED)*, (D) *Detailed Design (DD)*, and (E) *Product Release (PR)*. Within the *Task Clarification* stage, the designer is expected to define the problem whilst identifying the user needs pertaining to users utilising the device. In this stage, the designer establishes the fundamental user requirements and generates the specification document as a reflection of his understanding of the identified requirement and as an output of TC. The second stage is the *Conceptual Design* stage, where the designer

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is focused on generating and evaluating potential solutions in view of the design problem in hand. Concept generation often involves functional analysis to assist in the generation of potential solutions. Functional analysis could however feed into the TC stage as it creates a way to understand and articulate any given problem without the need to specify a solution. This is made possible by supporting designers in capturing all user requirements in view of each product function defined. Within the *Embodiment Design* stage, the nominated solution is elaborated and evaluated in terms of product structure, form, and layout. This implies that the selected design concept is developed in view of all regulations but also with particular attention to technical and financial criteria which are a prerequisite for detailed design and production. Within *Detailed Design* the designer's work is mainly aimed at refining and confirming product details such as material selection and product dimensions. The last stage of the framework is *Product Release* which implicates the process of launching the product within the chosen market. This means that the product would have reached the final version making it adequately suitable for production and stable manufacturing.

5.2. Layers in the MEDPRO Framework

The framework is composed of four collateral layers (Figure 2). These are ① Product Design, ② Medical Device Testing, ③ Regulatory Approval, and ④ Product Development Process. The circled numbers indicate the information flow between layers.

5.2.1. Product Design

From the third study (Section 3), 80% of designers agree that product design should be a central element of the framework developed. This integrated layer involves a process which constitutes a formal approach towards the development of medical devices classified in different ways and in-line with MDR or FDA requirements (for EU or US markets). This process includes a set of design activities all of which require formal documentation which represent the procedures followed to design medical devices with the adequate safety and efficacy in view. The layer involves a formal methodology to conduct product development, starting from requirements revelopment and user needs, towards pilot production and manufacturing. This process is generally regulated under FDA and EU MDR regulations.

5.2.2. Medical Device Testing

The second layer involves a series of sub-processes required to demonstrate both the reliability and safety of the medical device. This constitutes a vital element within the framework as it involves early performance testing exploration with the associated risk analysis, extensive verification and validation testing (VVT), together with clinical trials at later stages of design. VVT might include elements of performance testing, analysis of biocompatibility or toxicity and usability testing. In later stages of the design, this will involve dimensional and functional testing together with production and packaging verification.

5.2.3. Regulatory Approval

It was observed that 87% of the recruited designers highly agree that guidance on the implementation of the right standards and regulations is useful for MDD. This layer is crucial in assisting the designer with interpreting rules and devising the most adequate regulatory strategy in view of the medical device being designed. The regulatory process starts from the *Conceptual Design* stage by defining a regulatory and risk management strategy. This layer guides the designer in assessing and mitigating existing risks through suitable design reviews but also assists in creating a Technical File and in generating the Design History File (DHF), Device Master Record (DMR) and the Device History Record (DHR) in line with Regulation 2017/745 for the EU and in line with the FDA for the US.

5.2.4. Product Development Process

The final layer of the MEDPRO framework is essential in facilitating the transition from the conceptual design stage towards product release. The importance of this layer lies in bringing medical products to market in an efficient and effective manner and helps manufacturers balance cost factors when innovating. The designer is guided in following specific stages throughout the entire product development cycle, from selecting the most appropriate manufacturing processes, towards fabrication

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and production. The designer is guided in assessing concurrent development processes and optimising process flaws early in product development. This layer also guides designers in validating the designated manufacturing process and in providing support in Design for Manufacturing (DFM).

6. Case study: Design of a bespoke VR controller for specialised rehabilitation

To explain further the main underlying principles of the framework, a case study for the design of a therapeutic medical device is being considered. The idea behind this task is that instead of using an off-the-shelf device for serious gaming activities, one can use a VR controller which is purposely designed according to the person's needs for rehabilitation purposes. The case study forms part of a Horizon 2020 project titled "Personalised Recovery Through a Multi-User Environment: Virtual Reality for Rehabilitation" (Prime-VR2). A therapeutic tailor-made wearable controller was consequently designed for three distinct target user groups in-line with the design workflow proposed by the MEDPRO framework. The target groups involved persons with a range of sports injuries, post-stroke patients, and children with dystonia experiencing involuntary upper-limb movements.

6.1. Design Development

In harmony with Stage A of the MEDPRO framework, various sets of requirements were identified from patients to map these into functional product design implications. Specific therapeutic exercises were then identified with respect to the different user groups. The scope was to replicate these exercises through the device which was being developed. Design development was spread out over the course of several months, starting from the analysis of therapies, the distillation of key mechanical principles in which these therapies could be captured, the development of appropriate spatial mappings and the fundamental form generation. During Stages B and C of the MEDPRO framework (conceptualisation and embodiment), a strategy was adopted to synthesise different factors including the various therapies the device had to recreate, the anatomy and biomechanics of the users, the core functionalities including the sensors and other electrical componentry and its articulation with the VR environments. The proposed recommendations of the framework were deemed highly beneficial since all of these factors created a very complex design task. *Solution Exploration* provided good grounds to understand the core spatial requirements with respect to human anatomy. Crucially it included exploring potential topologies and connectivities between functional and structural elements whilst leaving the design open to technical embodiments and the specifics of the individual user (Figure 3). The wrist was an important component in the therapeutic practises for all users, hence different concepts were explored around it (Figure 3).

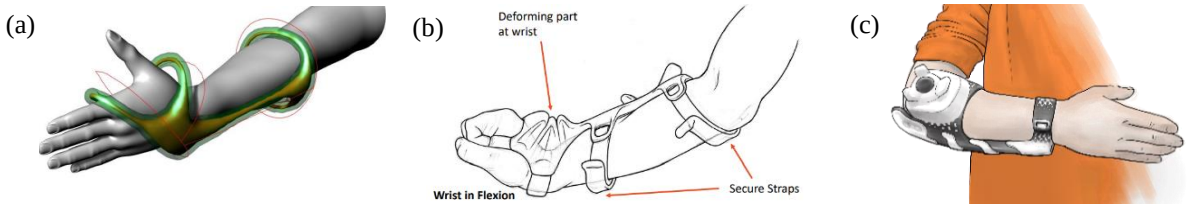

Figure 3. (a) Initial exploration of space envelopes; (b), (c) Initial wrist concepts

Following through Stage D, a functional design was established in CAD (Figure 4a). Additionally, as proposed by the framework, a Beta-prototype which captures all the functionality to be included in the bespoke device for evaluation with patients during therapy was developed. The MEDPRO framework facilitated the interface between different design activities whilst it provided an architecture for the design workflow. This involves suggestions for the inclusion of several rounds of testing, simulation and analysis that have informed product design as part of DFM. The developed upper-limb rehabilitation device (Figure 4b) was integrated within a range of VR environments (Figure 4c) and accommodates for all the mechatronic requirements necessary to sense and actuate through the product experience. As indicated by the framework, feedback will be gathered from users through the developed prototype. This formal

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evaluation will be conducted in the upcoming stages of the case study as the project progresses into Stage E of development involving design verification and validation together with clinical trialing.

(a) (b) (c)

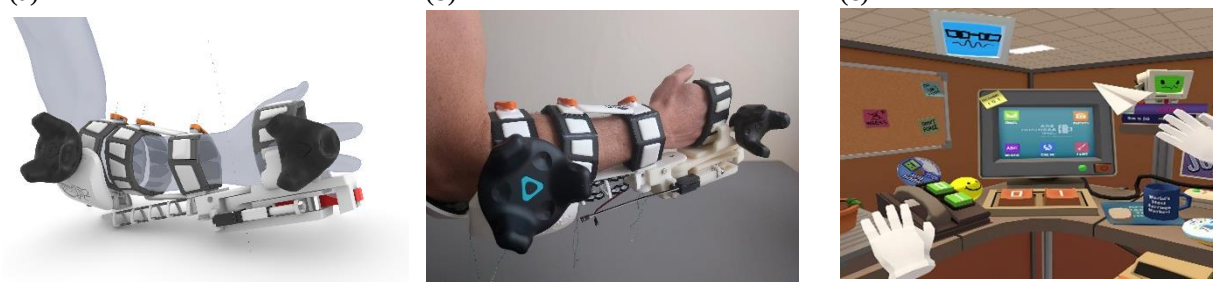

Figure 4. (a) The established model in CAD; (b) Creation of the initial prototype; (c) "Job Simulator" setting integrated within the VR environment for use during therapy

7. Discussion

Adopting a mixed-methods approach in data collection enabled a better elicitation and understanding of requirements in view of different medical device users which are involved in the therapeutic field of healthcare. The nature of the research study methodology selected therefore facilitated requirements identification from patients, clinicians and designers and hence the formulation of a user-centred MDD framework targeting aspects of UX within a highly regulated industry. The data collection phase of the investigation was hence validated through the mixed-methods approach. This study has shown that designers typically only consider regulatory issues at very advanced stages of the design process, often with the result of having to go back to the drawing board in order to augment the chosen regulatory strategy. This causes a number of redundant design reiterations which can be avoided through the proposed framework, whereby the designer is guided in tackling the necessary activities in an efficient manner thus yielding a cost-effective and streamlined product development. The framework also places the UX central to the architecture. This follows from the observations made in the study, which implicate the importance of considering the UX of patients and clinicians at the different stages of the MDD process. Literature complements the latter by suggesting that the application of both functional and ergonomic design principles often results in the production of cost-effective medical devices, significant reduction in risks, coupled with higher-quality experience during product use (Bitkina et al., 2020; Abela et al., 2021). The MEDPRO framework is still subject to a thorough evaluation with medical device designers. However, through its application within a case study, the framework was observed to assist the designer in taking the required design decisions with respect to usability, ergonomics and accessibility through a holistic evaluation of user needs and wants. The framework's potential in complying with regulatory requirements is yet to be explored and validated. Meanwhile, designers suggested that economic considerations for financial planning also plays a vital role in product development. However, this does not form part of the proposed framework. Another constraint of the framework is the sector of product design being addressed, which is limited to medical devices for therapeutic purposes. Even though this restriction was not imposed in data collection when recruiting participants, the elicitation of user requirements in view of medical devices other than therapeutic products such as implants, software, In-Vitro Diagnostics (IVD), medical imaging or surgical products, would yield an alternative construct of the proposed framework.

8. Conclusion

This study investigates the elicitation of requirements for therapeutic medical devices from user groups pertaining to patients, clinicians, and designers. The main contribution lies in the integration of the three sets of requirements into a novel framework architecture for the holistic design of medical devices. The framework forms the basis for the development of a computer-based software tool which assists in the design of safe and effective products in-line with the applicable regulations and placing the user as a central contributor towards MDD. The case study considered demonstrates various ways in which the framework can provide insights and transform the design of rehabilitation devices. Future work will endeavor in evaluating and validating the MEDPRO framework with designers employed in the medical device industry.

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