Prototyping Approaches for Rehabilitation Devices: From Product Embodiment to Data Management

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Abstract. This paper will present two research cases, both of which have similar objectives within upper-limb rehabilitation, which have utilized prototyping as a broad tool to explore the design solution space. Prototyping is a fundamental component of a large array of design work, with a multitude of techniques now available to designers of product embodiments and functions. PRIME-VR2 and ReHyb are two large European research projects focusing on efforts to reinvent medical rehabilitation through engagement with new technological advances to develop unique biomedical devices. PRIME-VR2 is focused on the development of a bespoke virtual reality gaming controller that can recreate therapeutic motions, while ReHyb aims to create rehabilitation aiding assistive exoskeletons. Prototyping has been a critical tool in the development of the design solutions, notably PRIME-VR2 has explored a range of novel additive manufacturing strategies such as a complex phased printing procedure and the ReHyb project has made innovative use of Lego Technic components in prototypes developed for human-robot interactions. Starting by examining the principles of prototyping within a bespoke device context, the two case studies are subsequently presented. Both are explored from the point of view of key prototyping practices and the data management and design generation tools. Lastly, the two projects are compared considering the strengths and weaknesses of both design approaches with a discussion focusing on the implications for future design projects that may have similar objectives in rehabilitative medicine.

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1 INTRODUCTION

Prototyping is a vital element in the process of designing new products successfully and allows designers to visualize and interact with a developing product embodiment as it becomes more fully established. Interactive digital tools that consolidate different forms of data are rapidly becoming more widely used and integrated into product development processes and often articulate with prototyping practices in a variety of ways. This work will consider two cases in which prototyping tools have a distinct relationship with novel digital tools influence the design procedures at large, particularly in terms of data management.

The critical question of this research is how the use and management of data influences prototyping practices and by extension, design of products at large? Furthermore, we want to examine to what extent are these novel tools useful in the creation of bespoke rehabilitation devices. Firstly, an overview of prototyping will be provided in order to elucidate the current tools that designers use. Furthermore, this section will consider the theoretical status of prototypes within the context of modern design and how these may articulate with current practices of data analysis. Secondly, we will then introduce the case studies which are the key focus of the paper. Each case will be summed up in terms of its critical goals and how each is approaching the key design problems. This will be supplemented with an exploration of the most important prototyping practices for each project; in the case of PRIME-VR2, additive manufacturing is the key area of focus and ReHyb focuses on tools to create prototypes supporting the exploration of human-exoskeleton, crucially Lego. Each case is then reviewed from the point of view of data management. The way the data is utilized and managed with respect to the key prototyping work is an interesting point of analysis and the key contribution of this work. Lastly, we will summarize the main differences between the two cases and examine the strengths and weaknesses of each of the approaches taken to both prototyping and the use of data. Additionally, we will offer insights into how the various approaches may be used by designers working within different contexts.

2 PRINCIPLES OF PROTOTYPING: CRITICAL PRACTICES FOR DESIGN OF REHAB DEVICES

2.1 Key Theoretical Overview and Categorization of Prototypes

Design methods consist of structured processes which facilitate the conception, evaluation and development of design ideas. Prototyping is regarded as one of the most prominent design methods through being established as an integral aspect of product development which can foster innovation. In essence, prototypes are early versions or iterations of a design concept or solution. Definitions in literature have defined them based on the level of approximation of their features to the final product [20] as well as based on their roles i.e. representations of information [19] or iterative tools that improve communication, enable learning and inform design decisions [6]. Prototypes can take either physical or digital forms, can encompass multiple characteristics and be made using a wide range of technologies and materials, as seen in Figure 1. Prototype taxonomies have also tried to classify them according to a wider range of different measures and are considered beneficial for designers by acting as decision-support and common language tools.

2.2 Prototyping Roles in Engineering Design

Prototypes can increase the value of the overall design process by having a range of different roles and purposes [3, 11, 16], as defining an explicit purpose to be achieved by a prototype can lead to higher quality design outcomes and better inform design decisions. In engineering and product design, prototypes are applied to reinforce designers' learning and tacit knowledge by answering functionality-related questions or validating the design prior to production, by identifying key features and ensuring integration of parts and sub-systems and, consequently, refine the overall design [11]. They are also regarded as efficient communication tools that transfer information to all stakeholders for demonstrating and testing concepts [6]. However, as opposed to prototypes being commonly considered as functionality verification/validation tools in traditional engineering design, the roles of prototyping have also been proved particularly beneficial during the early design process stages of problem definition, research, ideation and conceptualization in modern design practice.

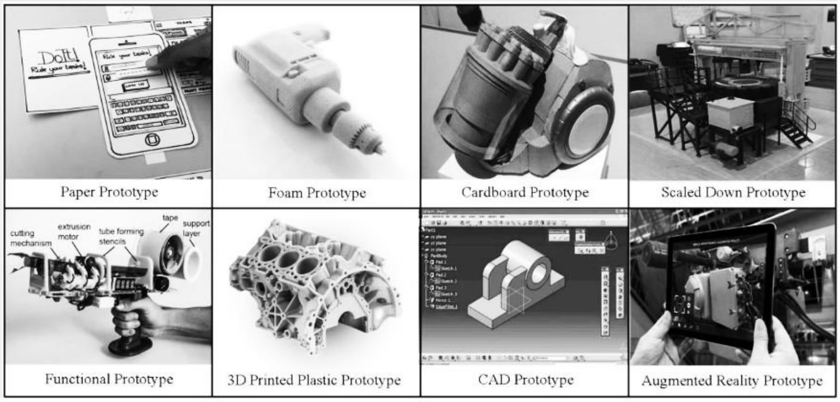

Figure 1: Examples of different types of prototypes basic and complex in different media.

With prototyping being at the core of emergent design approaches and methods such as Design Thinking and Human-Centered Design (HCD), it can facilitate the exploration of the design space and mapping to potential solutions, stimulate imagination, enhance concept ideation and evaluation through divergence and convergence and therefore, enable accurate and continuous refinement of concepts through iterative strategies [11, 5]. Design Thinking in particular concentrates on the insights gained through the actual process of creating a prototype, apart from the final prototyping outcome as well as the cognitive benefits offered to designers via learning by reflection, learning by thinking and learning by making [16]. As a result, prototyping can minimize the uncertainty existing in the fuzzy front end of design projects; but most importantly, assist in the early involvement of end users and the elicitation of their requirements. This a vital part of HCD approaches and design for rehabilitation in particular, an area in which users' effective interaction with the final product is of great significance to its success.

2.2.1 Prototyping's Role in Addressing User Requirements

The particular role of prototypes in requirement elicitation is a topic that has been explored in relevant research, due to the importance of verifying product desirability since the early design stages, at least to a significant extent. Apart from utilizing prototypes to verify already known information about user requirements, application of prototyping can also result in the acquisition of new, unknown data in relation to users' needs by unveiling unpredicted phenomena [5] and also due to users using prototypes in different ways than intended by the designers [14]. Users' interaction with prototypes strongly contributes to design iterations by enabling them to provide feedback and consequently reinforcing the process of translating user requirements into design features. Additionally, in design projects of abstract nature, user-prototype interactions can lead to defining target audience and the product's alignment with the design problem or opportunity. According to experts, users experiencing early prototypes can generate a positive first impression of the product and makes them feel more valued as well as maintain a high level of user acceptance since their subjective quality demands need to be satisfied [6]. In such cases, besides prototypes being visually attractive, evaluation of their subjective quality can also be influenced by the application of modern prototyping technologies such as 3D Printing/Scanning, Virtual or Augmented Reality and Generative Design which can have either a positive or negative effect. Finally, prompting end users to actively participate in design or prototyping exercises can result in direct, honest and constant feedback.

2.2.2 Prototyping and the Use of Design Data

Nevertheless, the question of comprehensively implementing data from user testing into prototypes in a systematic manner has been fostering research in the related fields. This is even more evident in an era where digital, big-data is becoming a key part of design processes and designers have to discover novel ways of directly incorporating data findings into prototype or final product features. The development of prototyping-based frameworks and tools have tried to tackle these issues by enabling data-driven design decisions through user-testing cycles; therefore, aiming to reduce designers' uncertainty and maximize the added value to end users beyond simply designing functional products [1]. Providing that the 3 main elements/conditions for a data-driven design process are data collection, data evaluation and data application, there have been several efforts to plan, structure the prototyping process and provide support regarding the utilization of learnt insights based on Design Thinking and HCD principles. Some of the developed tools concentrate on the documentation of existing, known user data as well as ways of data collection and implementation of learnt lessons [10], whereas other prototyping-based guides focus on user data collection through the planning of purposeful prototyping and focused testing, along with encouraging prototyping iterations based on the evaluation of the quality/applicability of acquired data [15, 2]. Finally, another research area which can support the managing of data within design and prototyping processes is the digital twin. Although digital twin is a growing, promising technology which is widely used in a wide range of industries, its application in product design is still limited [10] and mainly focused on production and manufacturing stages. We can now turn to two important case studies in which we can examine the status of prototyping within product development more closely from two different perspectives.

3 CASE STUDIES OVERVIEW

3.1 PRIME-VR2

PRIME-VR2 (https://prime-vr2.eu/) is an EU Horizon 2020 project that aims to deliver a unique upper limb rehabilitation ecosystem utilizing virtual-reality gaming and bespoke gaming controllers that recreate therapeutic motions. The patients will enter a virtual gaming environment designed around their rehabilitation needs and use an especially configured controller to engage with the game and the virtual environment. Figure 2 below shows a CAD rendering of the bespoke controller that is being created utilizing real patient data acquired through the involvement of three Living Labs. One lab specializes in sports injury rehabilitation, another in stroke recovery and another in the treatment of hyperkinetic movement disorders, notably dystonia. Each of these use cases presents unique design challenges so a large amount of iterative prototyping has been carried out.

The key goal of the project is to successfully develop a bespoke controller or one patient from each Living Lab. The key question here is how a unique profile is developed. PRIME-VR2 has aimed to use a trio of methods in which to analyze the biomechanics of each patient involved with the project. Firstly, a scanning procedure using a series of RealSense 3D scanning cameras acquires the critical ergonomic data that defines the boundaries of the design domain; Secondly, a motion capture procedure is performed utilizing a Leap motion scanner which defines the range of motion that the patient is capable of performing with the limb in question; Thirdly, a set of force analysis tests are performed to provide insight into the extant of muscle strength in the hand that can be used to provide baseline measurement for the therapies. As will be discussed in section 4.2, this data forms the backbone of the generative design workflow that has been developed in order to create the bespoke controller designs. For this reason, the relationships between the acquired data, the CAD development data and the prototypes is highly sensitive.

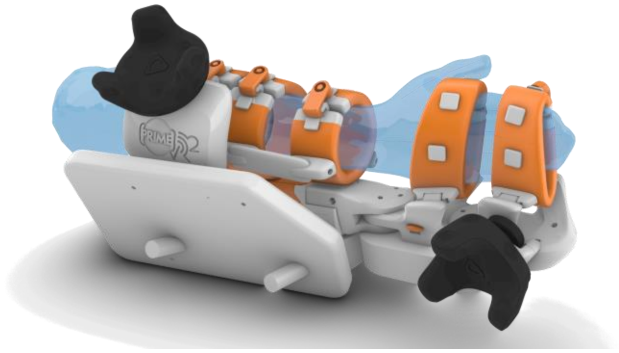

Figure 2: CAD visualization of PRIME-VR2 bespoke controller.

3.1.1 Design and Prototyping Practices

A wide variety of prototyping practices have been explored throughout the PRIME-VR2 project. While many have tended towards "conventional" approaches such as cardboard mockups or small mechanical assemblies, most extensive area of exploration has been in additive manufacturing, of which the project is aiming to innovate significantly. As each prototype has a unique form, it was critical that the additive approaches were mastered and thoroughly explored. An Ultimaker S3 is the principle prototyping tool, critically facilitating the creation of multi-material prints. The exploration of this domain has allowed the project to develop a range of interesting mechanical forms, notably the use of auxetics, snap fittings and embedded flexible sections resulting in the creation of compliant structures that have embedded functionality. Some of this is shown below in Figure 3.

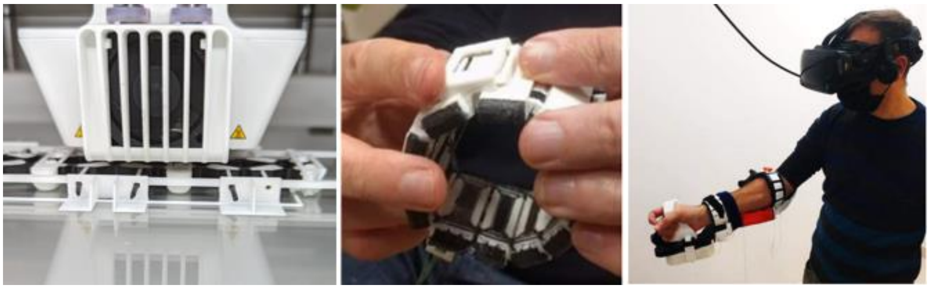

Figure 3: Prototyping and user testing practices.

The rapid prototyping work has proved critical to the development of a workable design solution that delivers on the key aim of being bespoke. Furthermore, the ability to explore different iterations of the proposed designs quickly has proved vital in the detailing of the final embodiment and has allowed PRIME-VR2 to conduct differ series of user tests with the different prototype iterations, with feedback from the users directly feeding back into future prototyping approaches through the adjustment of machine settings. As the controller is intended to be operational with a wider suite of devices, the flexibility of additive processes allowed the project to rapidly react to emergent problems with assembly, weight or fit.

3.2 ReHyb

ReHyb (https://rehyb.eu) is also an EU Horizon 2020 project with clinical, technical, and research partners. The aim is to develop a hybrid upper-limb exoskeleton for at-home stroke rehabilitation with sensing and actuation capabilities managed by a digital patient twin. Project researchers are responsible for the design and development of the interfaces for stroke patients to conduct rehabilitation with serious games and for therapist to monitor the progress of the patient. Other ReHyb project partners are responsible for the development of the actual exoskeleton.

3.2.1 Design and Prototyping Practices

A Lego Technic exoskeleton was the first prototype explored as Lego Technic blocks allow for quick building and testing, it has a large maker community to support it, and it is affordable (Fig 4). This early prototype provided connectivity to test Unity modules for patient interface ideas and easy configuration of data management using Python [8]. A key limitation of the Lego prototype being the strength of the assembly as bricks have broken off during studies due to limited flexibility and inability for rapid adaptability to participants having different size arms. Another limitation is the Lego motors lacking sufficient power to move a participant's arm during studies. However, beyond these limitations, multiple student design sprint projects have shown that the Technic bricks are a valuable resource for early prototyping of human-exoskeleton interaction. We have been investigating the translation of exoskeletons movements into the movement of an avatar in serious games. For instance, researchers investigated the Lego exoskeleton used by a child with cerebral palsy to control a fish avatar capturing stars for points. In another prototype we used the gaze interaction with a HTC Vive Pro Eye virtual reality headset explore new ways of controlling the exoskeleton during exercises.

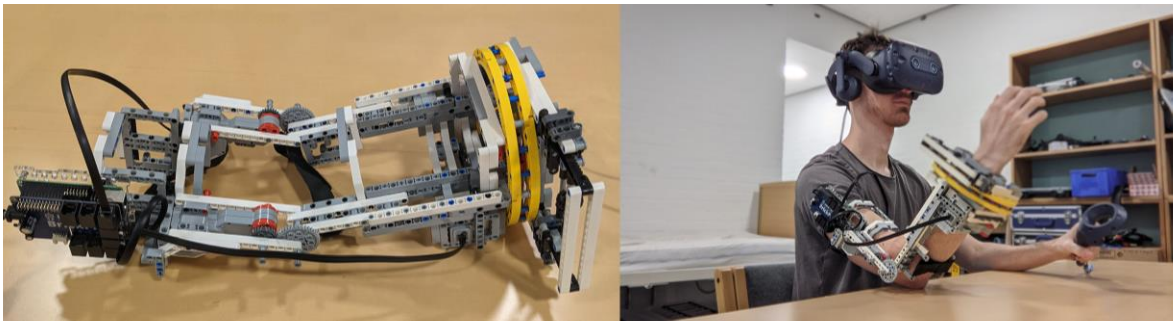

Figure 4: Lego exoskeleton featuring four motors, two for bending of the elbow and two for the rotation of the wrist.

We also compared a variety of virtual and augmented reality headsets and their hand motion trackers. While a HoloLens 2 provided clear sight with holograms placed in the actual environment, its field of view of only 52 degrees was very limiting when trying to play serious games. The Vive Pro Eye's 110 degrees provided double the size of the screen which is beneficial for stroke patients as many also have vision problems. However, the Vive Pro Eye is tethered to a large, powerful computer and weighs around 550g similar to the HoloLens 2 at 566g. Weight is important as stroke patients typically have motoric deficiencies and would be wearing a headset for 20-30-minute rehabilitation sessions. Recently we have begun testing and prototyping on the newer Pico Neo 3 Pro Eye with hand tracking, which provides standalone functionality, a wide field of view, and is relatively lightweight.

4 DATA MANGEMENT

The use of data is central to both projects and ultimately allows both to conform to the unique design demands of patient needs. In this section we will explore further the key data management tools of each project. PRIME-VR2 utilizes data sets that are amalgamated into a user-friendly graphical interface, whereas ReHyb has focused on the development of a Digital Twin tool for prototype simulation and monitoring.

4.1 User Data Toolkit and Generative Design Workflows – PRIME-VR2

Part of developing a clear biomechanical profile of the user involves understanding conceptually how the data acquired from the scans described earlier can be utilized. With respect to this requirement, a "User Data Toolkit" (UDTK) has been proposed that will function as a mediator between the raw data acquired from the scans and somebody interested in using the data i.e., a designer for the purposes of product development or someone involved in the procurement of medical devices for individual patients with singular needs. Furthermore, technology has been central in the advancement of the medical industry, including software products that improve clinicians' mode of work by enabling them to do a better diagnosis whilst focusing more on providing a tailored recovery program. Data collected from a range of sources is often abstract to the naked eye. Moreover, this data often exists in different formats due to the different instruments used, making diagnosis a very time-consuming activity. The complexity of such an activity can be simplified through visualisations methods where abstract information from multiple sources can be gathered and represented in intuitive ways through specifically designed software tools. This has been the goal of the toolkit, to present the processed data in a simplified and accessible format in order for designers or clinicians using the systems to easily interact with it. The toolkit can be split into three layers:

- ***Data collection layer***: Data is initially collected from the three scanning methods that include 3D scanning, motion capturing and force assessment and is tied to a patient profile. This data, after acquisitions, initially exists in an unprocessed form
- ***Data storage and processing layer:*** The data is then processed. The 3D scanning point cloud data is processed to that a complete closed CAD mesh is created that represents a close approximation of the anthropometric data of the patient. The motion capture data is consolidated into a JSON format, tying the measured range of movement to a skeletal frame and the force data is consolidated into an Excel spreadsheet that calculates the mean forces measured during the assessments.
- ***User interface (UI):*** All three data types are then consolidated into the User Profile Toolkit (Fig 5) which allows the user to set up patient profiles by starting a new controller design. The acquired data can then be uploaded and explored within the GUI.

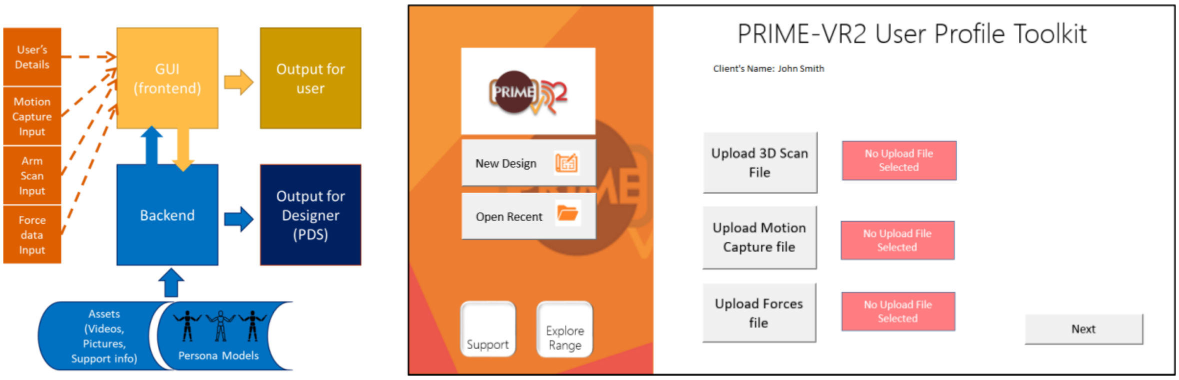

Figure 5: Dataflows within PRIME-VR2 and initial mockup of the GUI of the User Profile Toolkit.

4.2 Links to Generative Design Workflow

The UDTK directly links to the design workflow within PRIME-VR2. This project has made extensive use of generative design tools, notably a Rhino-Grasshopper visual programming workflow that has allowed for the embedding of discrete data sets into the design solution space. Of critical importance is the 3D scan data that creates a mesh representation of the patient's arm and hand geometry. This data is fed into the algorithmic workflow and facilitates the generation of bespoke controller forms, notably the controller straps, each of which has a unique diameter (Fig 6). This form finding process, also articulates closely with the build strategy of the Ultimaker printers in a kind of positive feedback loop of design information. A more complete overview of the algorithmic design logic is explored in another article by the authors (see [21]).

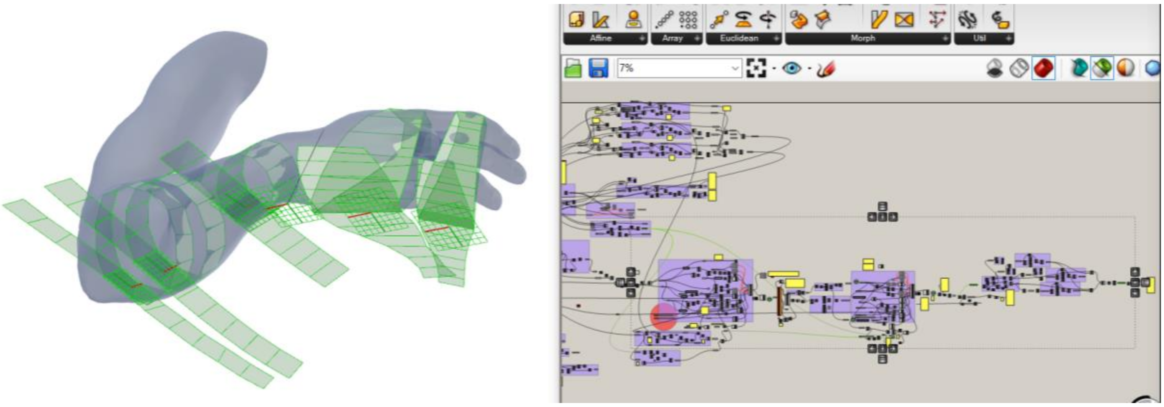

Figure 6: Preview of generative design workflow within Rhino-Grasshopper.

4.3 Digital Twins – ReHyb

The digital patient twin serves as the central data backbone for the rehabilitation system (Fig 7). The ultimate goal is to tailor the system's decision making to the patient's current state, rehabilitation behavior and needs. The ReHyb digital twin consists of three layers:

- ***Data collection layer*:** Collects data about the patient's physiological and cognitive state using medical records, sensor data and manual data input. Pre-defined patient profiles containing general information such as name, age, date of stroke and affected body areas are combined with data from sensors such as EMG sensors, eye-tracking sensors and exoskeleton data, performance data from the serious games and therapist input based on manual assessments.
- ***Data storage and processing layer:*** Aggregates raw sensor data to variables describing the patient's physiological and cognitive state using Machine Learning algorithms and stores them in a database. We differentiate between online variables needed for real-time adjustments and feedback during the training sessions and aggregated state variables describing the overall state of the patient. Both online and state data is fed into a cognitive architecture responsible for decision-making and controlling the system's components.
- ***User interface (UI):*** Visualizes important information obtained from the digital twin and supports interaction with the users, which can be the patients, therapists as well as other stakeholders such as caregivers. Apart from conventional data visualization techniques such as graphs, we embodied the digital twin into patient avatars. Such embodiment holds great potential for triggering body-ownership and the patient's identification with their digital twin, which could not only promote the patient's understanding of and trust in the HDT system, but also positively affect their therapy engagement and motivation [7, 9, 13].

Prototyping a digital twin for rehabilitation is a challenge. Firstly, the digital twin needs to map all data streams and their correlations, resulting in a highly complex system that should be drafted as a comprehensive yet understandable architecture. Secondly, the lack of medical real-world data during prototyping raises various challenges. Machine learning models rely on large quantities of diverse data, thus depending on the availability of real-world-like data.

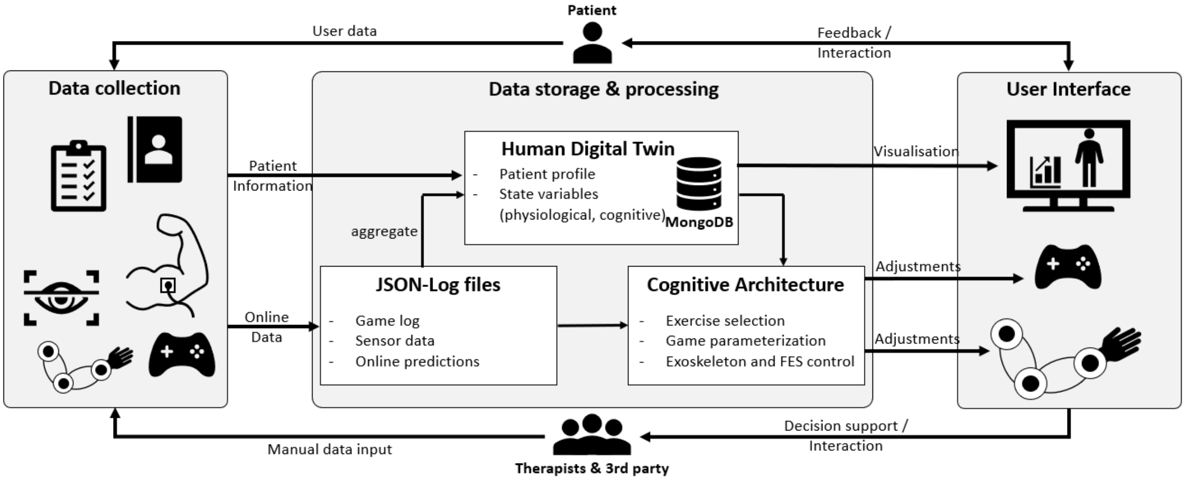

Figure 7: Human Digital Twin-framework as it is used within the ReHyb project. The system consists of three layers – the data collection layer, the data storage and processing layer and the user interface – and represents the data backbone for the rehabilitation system.

To face these challenges, we made use of several digital prototyping tools popular in other domains. For designing the digital twin architecture, we used Miro (https://miro.com) – a digital collaborative whiteboard with common design tools such as sticky notes, boxes, arrows, etc. Different components of the digital twin architecture can be clustered, and data streams can be visualized using connective arrows.

For implementing the digital twin prototype, we use Node-RED (https://nodered.org) – a node-based visual programming tool structuring specific parts of the program inside functional boxes (i.e. nodes) and implementing the program logic by connecting these nodes via visual input-output-wires. Finally, we compensated for the lack of real-world medical data using mocking-data as well as synthetically generated data. With Node-RED we created random (or pre-defined) values and feed them into simple value-mapping nodes representing future prediction modules. This way, in combination with the debug-nodes provided by Node-RED, we are able to evaluate and adjust the overall system behavior. Further, Generative Adverserial Networks (GANs) can be used to extend datasets with limited amount of data by generating data with similar properties and distributions [18].

5 DISCUSSION

It is clear from the two case studies that there is much to be gleaned in terms of design and prototyping strategies and how this may interact with key design information. In this section, we will consider this further by directly comparing the two approaches, considering their key differences, their strengths, and potential weaknesses. Additionally, we will explore the implications of this – what the projects may learn from one another and what wider design practice may take from it.

5.1 Key Similarities and Differences in Approaches

While both projects are creating rehabilitation tools, the nature of these tools is quite different leading to distinct design challenges. As we have already discussed, the principal tools for PRIME-VR2 were additive manufacturing methods of prototyping and for ReHyb it was the construction of functional Lego models. With reference back to our initial discussion on prototyping, the nature of rehabilitation poses unique design challenges; understanding the domain specific "problem space" in which the therapies must be performed, understanding of functional requirements and user ergonomics to ensure fit and comfort. Each case study had different approaches to address the problem space thus for the benefit of the reader we present Table 1 summarizing the key strengths, weaknesses and articulations between the two project's prototyping and data management practices.

	PRIME-VR2	ReHyb
Prototype design	BESPOKE VR CONTROLLER	LEGO EXOSKELETON
Purpose	Creation of a VR gaming controller with a bespoke design that can recreate therapeutic motions when used	Functional prototype to test devices and interfaces for human-exoskeleton interaction through user testing
Tools	Additive manufacturing materials - mostly TPU and PLA	Lego Technic, VR and AR headsets, Unity
Strengths	Adaptability of prototypes, conformity to ergonomic and functional requirements	Fast construction, modular, low-cost, maker-community support
Weaknesses	Resource expensive	Fragile, bulky, insufficient motor power
Dissemination	Deliverables, research papers, design development documentation including photographs, videos, CAD modeling and simulation	Open-source, deliverables, research papers, CAD modelling, building instructions
Data management	USER PROFILE TOOLKIT	DIGITAL TWIN
Purpose	Development of a GUI containing a biomechanical profile of patient data	Development of a system architecture for a digital patient twin
Tools	Unity, Excel	Miro, Node-RED, Python, Unity, MongoDB, JSON
Strengths	Fast development, amalgamation of key data sets	Fast development, expandable, developer-community support
Weaknesses	Only tested on emulated or synthetic data, data limited in scope	Only tested on emulated or synthetic data
Dissemination	Prototype interface, deliverables	Prototype interface, deliverables, research papers

Table 1: Summary of PRIME-VR2 and ReHyb prototyping and data management strategies.

5.2 Implications for Future Design Projects

But what can these project tell us about design work at large? There is a large body of work that explores different design approaches; the benefits and drawback of different methodologies or making methods (see [17] for example). It is clear from the discussion in the previous section that the distinct strategies of prototyping and data management offer distinct kinds of advantages that aid design outcomes. First and foremost, the tight coupling between physical prototypes and digital layers must be considered in detail for the development of rehabilitation devices. While this coupling has not been in the forefront of previous engineering taxonomies of physical prototypes (Figure 1) our approaches demonstrated the feasibility of integration by use of common digital tools like Unity, Python, Rhino-Grasshopper, Node-RED and MongoDB. In each of the two cases, dynamic interaction between user movement and device was mandatory. Whereas the look-and-feel (e.g., sound and color), were not considered important at this stage of development. The PRIME-VR2 had a sharp focus on details of the prototype mounting (Figure 3) while this issue has been ignored in the Lego Exoskeleton approach that only dealt with the interaction aspects.

PRIME-VR2 is distinct in utilizing discrete data sets in order to inform the design development work. With respect to rehabilitation, this is an important element in the developmental process due to the close consideration of ergonomic fit and functionality required for a medical device, such as conforming to ISO Standards such as BS EN 12182 [4] and BS EN ISO 14971 [5]. The articulations between the various data types and the prototyping information culminated in a complex workflow requiring multiple levels of iteration and assessment. The benefits here are manifest in facilitating a rigorous design workflow in which ergonomic and functional requirements are tested against a clear target profile. Furthermore, thinking in terms of abstract layers of functional architecture allows for the parsing of distinct design envelopes, enabling a generative design workflow which was critical to providing a set of practical solutions to the "domain problem" of the rehab therapy motion which the controller had to mimic. The key drawback here is resource requirements. PRIME-VR2 is a large research project that can marshal a wide variety of equipment and personnel. Similar project may only be able to implement similar workflows with large project budgets. However, smaller scale projects may benefit by seeking to implement simplified versions of the project architectures and consider widely available and more affordable prototyping tools such as Makerbots.

Though the case studies present different design contexts, there are elements that can both opportunities for learning and improvement. ReHyb's interesting use of Lego components presents a compelling challenge to the PRIME-VR2 approach as Lego allows for the assembly of discrete blocks of material, the design domain is more bounded and a solution space can be more easily reached. On the other hand, the "openness" of the PRIME-VR2 approach has revealed possibilities in manufacturing innovation and facilitated the exploration of complex additive production methods.

6 CONCLUSIONS

This paper has outlined a series of novel approaches to prototyping by exploring two unique case studies from industry-focused academic research. Firstly, we presented the two case studies of PRIME-VR2 and ReHyb and made plain the critical aims, approaches, similarities and differences between the two projects. From here, we focused in on the question of prototyping and categorization of how prototyping has been utilized in the two settings. By reviewing the experiences of the two project teams, we illustrated the practical benefits of prototyping and demonstrate how particular methods may work best in specific contexts. Furthermore, we considered how the use of specific data sets has informed the design and prototyping work by examining how the two distinct project methodologies have acquired and processed user data, with PRIME-VR2 constructing a "User Profile Toolkit" that can be utilized by both designers and clinicians and ReHyb developing a Digital Twin by which user data can be presented for patients, therapists and other stakeholders. It is clear from our analysis that both of these systems have unique ways of organizing data with distinct articulations with the surrounding design and user data. Furthermore, we offered insights into the design of biomedical devices by comparing the two project approaches directly and establishing strategies that may help other researchers or designers harness the full potential of prototyping within the challenging settings of biomedical engineering or rehabilitative medicine.

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REFERENCES

[1] Ali, H.; Lande, M.: Data-Driven Decisions in Prototyping and Product Development: A Framework for Uncertainty and Decision-Making, Proceedings of the ASME 2019 International Mechanical Engineering Congress and Exposition. Volume 14: Design, Systems, and Complexity. Salt Lake City, Utah, USA. November 11–14, 2019. V014T14A039. ASME. https://doi.org/10.1115/IMECE2019-11671

[2] Arndt Hansen, C.; Eifler, T.; Deininger, M.: Effects of Structured Prototyping Support on Novice Designers' Prototyping Plans, Proceedings of the ASME 2021 International Design Engineering Technical Conferences and Computers and Information in Engineering Conference. Volume 6: 33rd International Conference on Design Theory and Methodology (DTM). Virtual, Online. August 17–19, 2021. V006T06A017. ASME. https://doi.org/10.1115/DETC2021-71057

[3] Bohmer, A. I.; Kayser, L.; Sheppard, S.; Lindemann, U.: Prototyping as a Thinking approach in Design: Insights of Problem-Solving Activities While Designing a Product, 2017 International Conference on Engineering, Technology and Innovation (ICE/ITMC), 955–963. https://doi.org/10.1109/ICE.2017.8279985

[4] BS EN 12182 available at: https://knowledge.bsigroup.com/products/assistive-products-for-persons-with-disability-general-requirements-and-test-methods/standard

[5] BS EN ISO 14971 available at: https://www.bsigroup.com/en-GB/medical-devices/our-services/iso-14971/

[6] Buker, T.; Endress, F.; Miehling, J.; Wartzack, S.: The Interplay of Subjective Quality Evaluation, Prototyping Technologies and the User's Technology Acceptance, Proceedings of the Design Society, 2, 2022, 2077-2086. https://doi.org/10.1017/pds.2022.210

[7] Genay, C. S.; Lecuyer, A.; Hachet, M.: Being an Avatar "for Real": a Survey on Virtual Embodiment in Augmented Reality, IEEE Transactions on Visualization and Computer Graphics, 2021, https://doi.org/10.1109/tvcg.2021.3099290

[8] Homola, B. I.; Sheldon, S.; Ago, S.; Mariani, M.; Hansen J. P.: Prototyping Exoskeleton Interaction for Game-based Rehabilitation, in CHI EA '22: Extended Abstracts of the 2022 CHI Conference on Human Factors in Computing Systems, New York, 2022. https://doi.org/10.1145/3491101.3503566

[9] Hooi, R.; Cho, H.: Being immersed: avatar similarity and self-awareness, in Proceedings of the 24th Australian Computer-Human Interaction Conference, New York, NY, USA, 2012. http://doi.org/10.1145/2414536.2414576

[10] Jensen, M. B.; Elverum, C. W.; Steinert, M.: Eliciting unknown unknowns with prototypes: introducing prototrials and prototrial-driven cultures, Design Studies 49; 2017 https://doi.org/10.1016/j.destud.2016.12.002. 5

[11] Kronsbein, T.; Müller, R. M.: Data Thinking: A Canvas for Data-Driven Ideation Workshops, HICSS. 12, 2019. https://doi.org/10.24251/HICSS.2019.069

[12] Lauff, C. A.; Kotys-Schwartz, D.; Rentschler, M. E.: What is a prototype? What are the roles of prototypes in companies? Journal of Mechanical Design 140(6), 2018; https://doi.org/10.1115/1.4039340.3

[13] Lo, C. K.; Chen, C. H.; Zhong, R. Y.: A review of digital twin in product design and development, Adv Eng Inform, 48, 101297, 2021; https://doi.org/10.1016/j.aei.2021.101297

[14] Petrakis K.; Wodehouse A.; Hird A.: Prototyping-Driven Entrepreneurship: Towards a Prototyping Support Tool Based on Design Thinking Principles, The Design Journal, 24(5), 2021, 761-781, https://doi.org/10.1080/14606925.2021.1957531

[15] Petrakis, K.; Wodehouse, A.; Grierson, H.; Coutts, E.; Liikkanen, J.; Parkkamäki, H.: The Application of a Prototyping Support Tool in a Student Design, DS 117: Proceedings of the 24th International Conference on Engineering and Product Design Education (E&PDE 2022), London South Bank University in London, UK. 8th - 9th September 2022, https://doi.org/10.35199/EPDE.2022.65

[16] Petrakis, K.; Hird, A.; Wodehouse, A.: The concept of purposeful prototyping: Towards a new kind of taxonomic classification, In Proceedings of the Design Society: International Conference on Engineering Design, Vol. 1, Cambridge University Press, 2019, 1643–1652, https://doi.org/10.1017/dsi.2019.170
[17] Pugh, S.: Engineering Design—Unscrambling the Research Issues, Journal of Engineering Design, 1(1), 1990, 65-72, https://doi.org/10.1080/09544829008901644
[18] Poudevigne-Durance, T.; Jones, O. D.; and Qin, Y.: MaWGAN: A Generative Adversarial Network to Create Synthetic Data from Datasets with Missing Data, Electronics 11(6), 837, 2022, https://doi.org/10.3390/electronics11060837
[19] Ullman, D. G.: The mechanical design process, McGraw-Hill New York, NY, 2002
[20] Ulrich, K. T.; Eppinger, S. D.: Product Design and Development, (5th ed.), McGraw-Hill/Irwin, New York, NY, 2012
[21] Urquhart, L.; Wodehouse, A.; Loudon, B.; Fingland, C.: The Application of Generative Algorithms in Human-Centered Product Development, Applied Sciences. 12(7), 3682, 2022 http://doi.org/10.3390/app12073682