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Exemplifying Prototype-Driven Development through Concepts for Medical Training Simulators

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Abstract

This paper attempts to exemplify prototype-driven development in the early stages of product development, the stages before requirements and specifications are fixed. This pre-requirement phase provides opportunities and uncertainties for the design team to explore, and this paper shows how this could be (and has been) done through extensive use of explorative prototyping. Prototyping, in this context, is the activity building and experimenting with various concepts with the aim of producing tangible insights as fast as possible. In prototyping, prototypes are tangible artifacts built to answer specific questions, in order to explore and gain new insights as the project requirements emerge. The context for this article is product development of patient simulators used in medical training, referred to as 'Mannequins'. Mannequins are widely used in medical training to enable practice of treatment for conditions too rare or dangerous to perform on real patients. From this context, specific examples on prototype-driven development are shown through two case projects; Development of a chest for the training of cardiopulmonary resuscitation, and a fractured leg in order to train on realigning and stabilizing displaced fractures. These projects are user-centered design challenges within the medical education field. This paper shows how a prototype-driven development approach could be utilized on a project level and provides insights on prototyping to gain answers, learning and inform decisions. The paper argues that before requirements and specifications are fixed, a more exploratory and prototype-driven approach is needed, in order to provide more informed requirements and specifications. This way, prototypes are the drivers of the development and the iterations impact the direction of the ongoing development. Specific aspects of prototype-driven development such as user-interaction, prototype resolution, evaluation and testing are also discussed in this paper.

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Keywords: Prototyping; Prototype-Driven Development; User-Centered Design; Emerging Requirements

1. Introduction

When exploring new opportunities within a product domain, the ambiguity and lack of constraints can lead development teams into doing premature decisions in projects. This could result in costly rework and products failing due to not meeting the targeted users' requirements or needs [1]. In this pre-requirement phase of product development, the uncertainty and opportunities facing the design teams are important to explore in order to do informed decisions. Upcoming challenges and opportunities remain hidden unless elicited or made explicit in the ongoing development [2,3]. Hence, how to leverage unknown opportunities and accommodate future challenges is not evident—yet important—in product development [4].

By presenting two case projects we exemplify how prototyping have been utilized to explore and gain answers before requirements and specifications are made tangible or fixed. The cases are gathered from two early stage development projects focusing on development of medical training simulators further referred to as *mannequins*. In these projects, the design teams set out with no fixed or predetermined product requirements, and the goal was to investigate needs and corresponding opportunities for mannequins to improve or introduce new functionality for medical training and simulation.

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1.1. Research Question

Prototypes serve various purposes in product development and the importance of prototypes is frequently highlighted in research [5,6]. Schrage [7] propose that in order to create better products, organizational cultures must learn to create better prototypes. Further, it is discussed how companies should derive their product requirements from prototypes as a contrast to requirement driven prototyping [7]. While these statements are based on interviews with industry actors, there is a call for empirical data to support the statements. This paper will contribute to how prototypes could be utilized to explore and establish product requirements on a project level. By presenting examples and findings on the use of prototypes from two case projects, we will answer the following research question; *How can prototypes be used to explore and establish informed requirements as opposed to using prototypes for meeting set requirements?*

1.2. Research scope

This research article provides examples and insights on the use of prototype-driven development on a project level. Hence how prototyping could be utilized for exploring and gaining answers in product development projects. Prototypes are an important aspect of research on early stage product development, product development methodology and managerial frameworks in this context [1,8]. This paper will, however, focus on how prototypes could be developed and utilized to provide designers and developers with examples for tackling the uncertainty of projects before product requirements and specifications have been made tangible.

1.3. Prototyping and Roles of Prototypes

The use of prototypes in different settings, disciplines, and stages of development has resulted in several frameworks for defining prototypes and their purposes [9]. While some see prototypes as product approximations or tools for testing and verifying early designs, the generative role of prototypes and prototyping activities is of interest when exploring potentials in the early phases of product development. From case studies, [10] have derived three roles of prototypes within companies, where they present how prototypes serve as tools for communicating, learning and for informing decision making.

As roles of prototypes and how prototypes are utilized in projects are described, prototyping is often explained as the creation and utilization of such artifacts [11]. The authors argue that the importance of prototyping ranges further than just the activity of creating prototypes. In this paper we define prototyping as the designing, building and testing of new concepts and ideas. Hence prototyping is considered a learning activity, cognitive and physical, and can enable new insights and generate knowledge when exploring a solution space [12]. The outcome of prototyping is therefore generated knowledge and prototypes, tangible artifacts embodying this either explicit or tacit knowledge [13].

1.4. Answering Design Questions

As prototyping is a tool for acquiring new insights, prototypes are built and tested to answer questions [5]. Hence, the prototyping medium is determined by the questions that need answering and both, physical, digital and analytical models can serve the purpose as prototypes [7]. The importance of prototypes is not how they are created or their closeness to a final product, but rather how they are utilized to gain answers to important open design questions [14].

In the context of this paper—i. e. products designed for interaction with users—many design questions require external feedback to be answered. An example is prototyping to answer how a product would serve a role in a user's life or how the interaction is perceived by the look and feel of an artifact [14]. Prototypes are a mode of communication and they enable interactions and design teams to explain concepts in a tangible matter and gain feedback [10]. As boundary objects, prototypes can be used to establish a common ground for this communication to happen by bridging both disciplinary and knowledge gaps.

1.5. Prototyping Strategies

In product development, the generative role of prototyping is effective when trying to come up with novel ideas and multiple alternatives for exploring a solution space. This concept generation is a divergent approach seeking out the potential solutions before converging down on one or multiple concepts to develop further. Eris [15] propose that divergent and convergent thinking could be achieved by subsequently asking generative design questions and deep reasoning questions in development projects. Generative design questions are open-ended, seeking to identify multiple possibilities not tied to the logical nature of the problem, while deep reasoning questions could measure the applicability of revealed alternatives and sort out unfeasible solutions or concepts [15].

In the early (i.e. pre-requirement) phase of product development, designers could benefit from using low-resolution prototypes to gain rapid answers and insights. We consider the resolution of prototypes as the level of detail. Note that this is often differentiated from fidelity, as the latter is considered the closeness to the eventual (final) design [14]. Utilizing low-resolution prototypes their rough construction and unfinished attributes allows playing with the ideas, possibilities, and potentials rather than verifying design [7]. Also, using a lower resolution makes it easier to get inspiration and change or generate concepts from the gained insights, all which could prohibit designers from prematurely fixating on design solutions [16].

When investigating the potentials of ideas and proposed concepts, a higher resolution might be necessary in order to gain unbiased or unclouded feedback, as many questions require external answering in the design process. Designers must be aware and reflective what prototypes they present, and to what audience, as prototype attributes and intent not necessarily is communicated by the artifact itself [14].

2. Case Projects

The development projects used as cases for this article were requested by a medical company and performed by two teams of graduate students. The first project is the development of a mannequin chest for training of cardiopulmonary resuscitation (CPR) and the second; the development of a leg for training of displaced bone fracture realignment. Mannequins are widely used in both skill training and education of health care providers. The aims of these projects were to create safe and repetitive training environments, that would appear realistic enough to enable users to transfer skill and knowledge into real-world medical scenarios.

2.1. Case 1: Resuscitation Mannequins

Resuscitation mannequins are no recent invention and commercially available products for training medical personnel and laypeople in CPR have existed for decades. The mannequins are most often human-like dummies, as seen in Fig. 1, that allow for chest compressions and artificial ventilation, as one would perform on a person suffering from sudden cardiac arrest. The project was proposed as; to rethink and develop a new chest concept for resuscitation mannequins to closer resemble the human chest and enable a more realistic chest compression experience for users in training. This was considered a response to the lack of realism found in currently used mannequins [17]. This project was carried out over a period of 9 months. During this period, a total of 84 prototypes was developed for a new mannequin chest concept.

Fig. 1. Example of one commercially available resuscitation mannequin. This uses a linear compression spring mechanism to enable chest compressions.

2.2. Case 2: Displaced Leg Fracture Task Trainer

Advances in emergency care training and patient simulators, various tasks are now being taught using human-like mannequins. The second project was requested to explore the need for a mannequin-based trainer for realignment of a displaced leg fracture and subsequently the requirements for this functionality. Displaced fractures are common as well as challenging to treat for emergency responders, as these fractures could cause circulation issues and potential damages to tissue and vessels. The procedure of realignment and stabilization of fractures are taught both in theory and by using human markers. Human markers (i.e. actors) are used for training in securing and stabilizing the leg by fixing it using splints but does not enable training of the actual repositioning.

Mannequins are products designed to prepare users for procedures and interactions too dangerous or rare to be trained on real patients or human markers. Hence lack of realism, by their ability to include functionality as found in the human body, could leave users insufficiently prepared for interactions with patients. Therefore, in the design of mannequins, it is a desire to approximate the physiological aspects required to perform a given task, but at the same time avoid introducing aspects not found in human patients. Such aspects could interfere with the simulation, sense of immersion, and potentially introduce sources of false learning.

This development project of a new leg for mannequins was carried out over 4 months and resulted in more than 15 conceptual prototypes.

The following subsections show how prototyping has been extensively used to drive the development of the two projects and to identify and explore revealed product opportunities.

2.3. Exploring Opportunities for Case 1

In Case 1, the starting point for the project was to rethink and create a new chest concept for resuscitation mannequins. A chest would have to have the ability to be compressed and recoil as a human chest would do, to enable users to practice routine and motor skills for CPR. Already existing solutions for CPR training varies by concept, but there is a consensus about their lack of realism and simplified characteristics as compared to a human chest. This being the background for the project, the developers aimed to create a concept with functionalities closer resembling the human body, leaving users better prepared for an eventual real encounter of a cardiac arrest patient in need of chest compressions.

Initial steps of the development consisted of simultaneous explorative prototyping and research in order to create rough prototypes of aspects of the human chest to investigate. Identified characteristics where split into two areas of interest; 1: Whether patients ribs fracture during CPR and how this affects the rescuer? 2: How a chest deforms when compressed and how it feels to perform compressions? Generative low-resolution prototyping resulted in three conceptual prototypes attempting to answer the two questions above.

The first prototype, shown in Fig. 2, attempted to simulate ribs fracturing from excessive loading, while the two

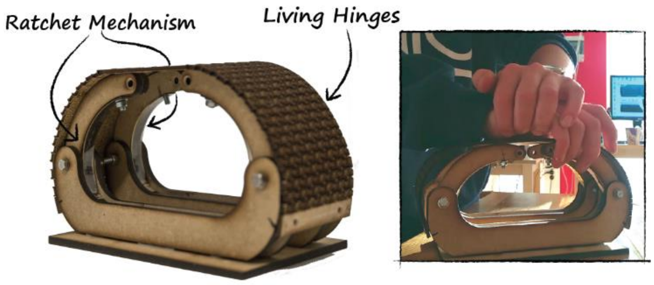

Fig. 2. Rib fracturing model with mechanical features to the left and testing of the prototype shown on the right.

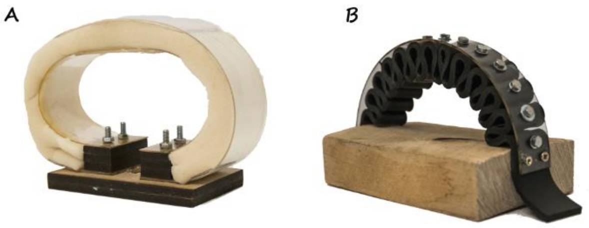

Fig. 3. Spring configurations using (A) foam and (B) rubber for increased resistance and stability.

prototypes, in Fig. 3, were using different spring configurations to simulate the tactility and deformation of a chest. While the questions concerned real-world interactions with patients, the team wanted to expose the prototypes to "users" with prior clinical CPR experience and allow them to test and discuss the characteristics and functionalities of the prototypes.

Experience as in inherited knowledge by the users is, however, not always explicit and articulated. More so, users from the field of medicine possess knowledge from their education, training, and work experience, making the disciplinary knowledge gap between medical personnel and design engineers vast.

Prototyping showed potential in bridging this gap, as the users interacting and testing the prototypes could articulate their experiences by comparing them to the physical characteristics of the artifact. More importantly, this experience and tacit features were made tangible to the development team through the prototypes. Jargon and complex sensory experiences were translated into a physical/technical context that was able to influence future development.

The testing and interaction resulted in new insights and unknown aspects of patient CPR identified as opportunities for the team to investigate. The insights were made explicit as the following points:

- The patient ribs fracture almost every time, and that this is easily sensed. It could be compared to breaking thin branches under a thick carpet as opposed to the brittle clicks provided by the presented prototype.
- Chest compressions are not like compressing on the spring-like prototypes, but more like a hard couch pillow. It becomes harder by the depth of the compression and is considered less responsive than a spring.
- The stiffness of a chest is not constant, as it would reduce in stiffness and responsiveness after many compression cycles.

2.4. Exploring Opportunities for Case 2

Like the previous example, the team in Case 2 (developing a mannequin leg for repositioning training) developed low-resolution prototypes to investigate the context of leg fracture and repositioning. Here, the procedure and interactions when first responders come to aid a patient suffering from a displaced fracture. In this project it was observed how the team used prototyping and physical interaction with prototypes to understand and make their problem tangible. This is exemplified by the prototype, as seen in Fig. 4, that was made to accommodate their initial findings from research, that repositioning is important to relieve pain and ensure circulation to the distal part of the fractured leg. Open design questions were at this point how repositioning a leg is experienced from a rescuer's perspective and what tactile experience and challenges it might impose. In order to explore this interaction, the prototype was strapped to one of the team members legs, as seen in Fig. 5, and was then attempted repositioned by paramedics at the hospital.

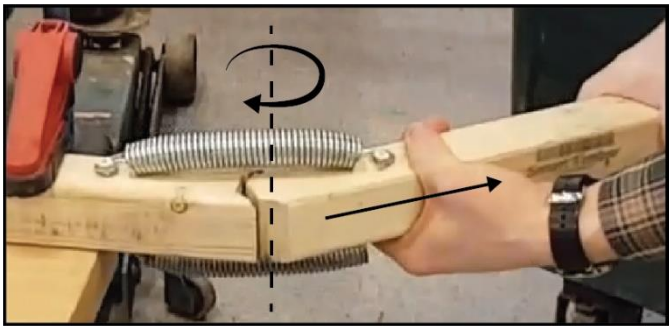

Fig. 4. Broken leg model suspended by springs with arrows indicating the pull and rotate movement.

During realignment, the paramedics pointed out how the procedure is usually very painful, and that the patient must be given sedatives for them to perform it. Swelling and muscle tensioning around the fracture would also constrain the movement, and both sedatives and physical fatigue of the muscles is often necessary to realign the fracture. The paramedics reenacted the procedure and showed how repositioning requires the rescuers stretch the patient's leg by leaning back. Using his or her own body weight, as well as another person holding the patient, could be necessary in order to gradually elongate the muscles and reposition the fracture.

Based on this feedback, simulating tiring and sedated muscles became a new feature to investigate. This had not been identified earlier by the team but was made apparent by users testing and interacting with the rough prototype.

Fig. 5. Paramedics attempting to reposition the broken leg model strapped to one of the team members.

2.5. Generating and Evaluating Concepts for Case 1

From investigating the mannequin chest development, it became evident that the development team used prototyping to generate concepts that could adapt the feedback and insights revealed from the earlier testing and interactions with users. As prototypes were created, they were tested and iterated upon to reveal a potential for answering the identified opportunities. The team prototyped extensively within two domains, namely the chest deformation and characteristics, and rib fractures by haptic and audible response.

The prototyping outcome, in form of prototypes, is illustrated in Fig. 6. In the figure, it is noticeable how different concepts were first evaluated on a rough principle level before being either discarded or further developed through concept iterations. As the team developed prototypes along two distinct paths of interest, each concept had the opportunity to be tested and compared to alternative solutions along that path. Having multiple prototypes to compare, decisions could be made based on relative performance measures.

One example of this prototype evaluation is found along path A in Fig. 6. Concepts A3, A4, A5, and A6, were tested and compared, revealing strengths and weaknesses of the different concepts. As prototype, and concept, potentials were made apparent, the team got empowered to select which concepts to develop further by new prototype iterations. Concepts deemed promising based on the prototype's performance was developed further to investigate the potential and for meeting the targeted form and force characteristics for an adult chest.

In this project it was observed how this iterative and selective approach, discarded unfeasible solutions before landing on one concept for each domain. Here, one was simulating the shape and deformation of the chest when compressed (A6.3), and one was simulating the tactile feeling of ribs being fractured from excessive loading (B9.2). As these prototypes had undergone several rounds of changes and testing, and the team deemed these as good approximations of the functionalities elicited from the medical personnel. As functional prototypes, they were tested by medical personnel to enable feedback and evaluation of the proposed concept and the included functionality. Hence, these could provide answers to if, and how, a product could be realized and the corresponding requirements for the future product.

2.6. Generating and Evaluating Concepts for Case 2

The team investigating repositioning of displaced leg fractures had identified how muscles constraining the fracture played a crucial role in creating a realistic simulator. Hence, investigating the solution space for mimicking the biomechanics of a contracted muscle became a core objective.

During the development of the broken leg simulator, generative design questions enabled widening the solution space and testing multiple alternative concepts through prototyping. Asking "how many ways they could create a linear actuation mechanism constraining a fracture" resulted in the generation of low-resolution prototypes to be tested. The prototypes investigated different physical principles for constraining a simulated leg, and how these principles could be actuated and controlled in order to simulate the elongation of muscles.

Electromagnets, mechanical springs, hydraulics, pneumatics, air-muscles, and muscle-wire were investigated and tested resulting in multiple promising concept proposals. From internal testing, the team noted strengths and weaknesses of their concepts before deciding on which to develop further. The team identified that ease of control for many of their prototypes, compromised the tactile feeling of a muscle as

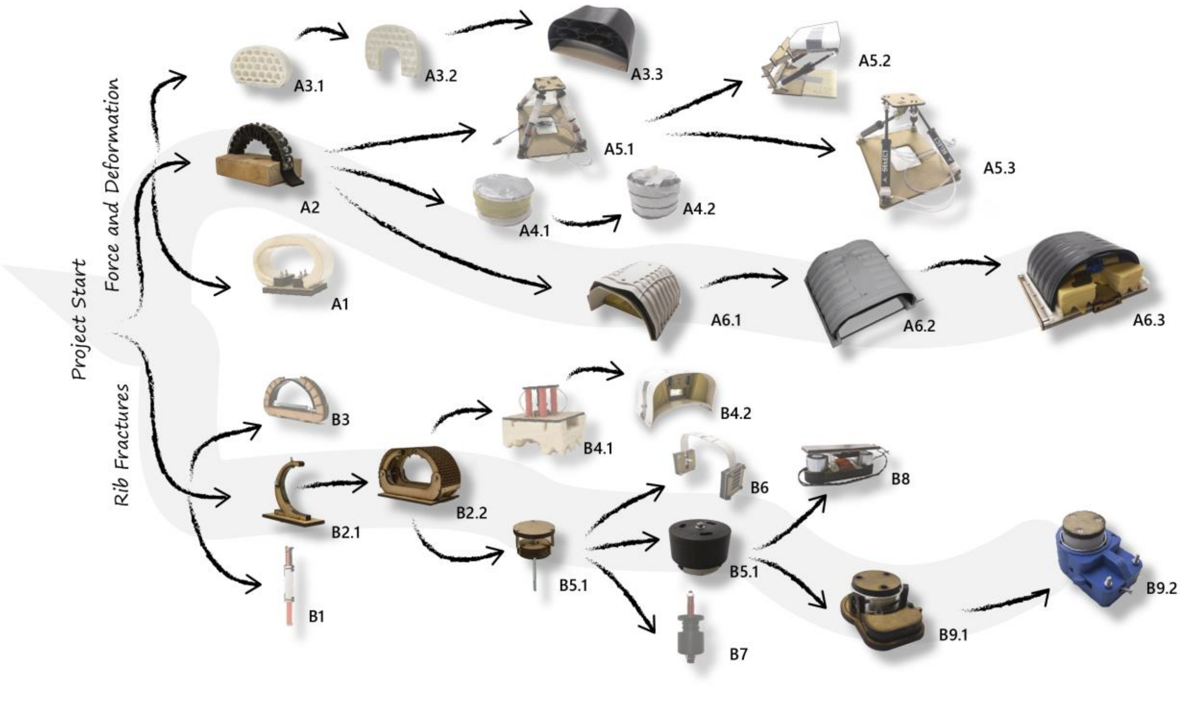

Fig. 6. Retrospective mapping of the most influential prototypes developed throughout the timeline of the mannequin chest project. Path A investigating concepts for chest deformation and tactility and path B concepts for simulating ribs fracturing from compressions.

described by the paramedics. By evaluating the alternative concepts by prototypes, the team decided on moving forward using a pneumatic system. Pneumatic cylinders were evaluated as a robust and controllable principle, which also provided an "organic tactile experience" as the air being compressed in the system allowed for subtle movements.

Investigating how pneumatics could be integrated in a mannequin leg, the team developed a proof-of-concept prototype to experiment with different pressures and connections constraining the leg as seen in Fig. 7. With this prototype, the team tried to answer questions concerning integration of the earlier revealed functionality.

To gain answers to the usability, tactile experience and training procedure, the team further developed the leg model by hiding the mechanisms and replicating a rough look and feel of a human leg, as seen in Fig. 8. This prototype was tested with paramedics to gain feedback on how the proposed concept could aid users in training, and if the captured functionality was accurate.

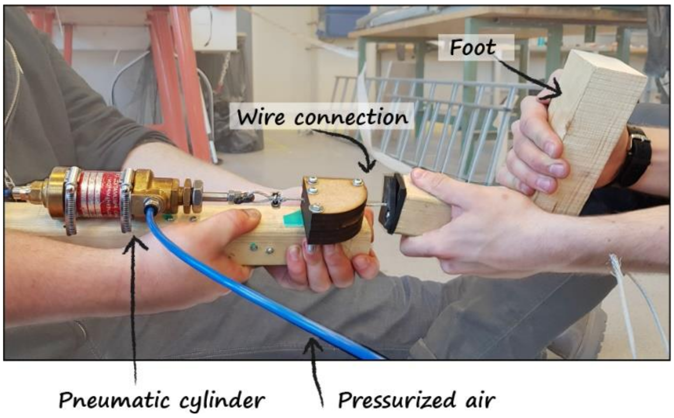

Fig. 7. Proposed concept prototype of a broken leg for mannequins.

Fig. 8. Testing of proposed conceptual prototype with paramedics.

2.7. Selected Concepts and Emerging Requirements

Prototyping was utilized to translate the vision and ideas of the design teams back to users and the physical world and context of medical simulation. By proposing a concept prototype, the teams could gain important answers to if their earlier findings were substantial and accurate for the context of a new product. Hence both development teams utilized higher resolution prototypes to manifest their insights as requirements for future products.

In Case 1, this process consisted of both internal testing, measuring the characteristics of the proposed prototype, and external testing with medical personnel at the hospital. Internal testing and measurements were carried out to quantify prototype characteristics and compare this to the feedback as well as physiology data found in research [18]. These efforts in testing and evaluating the proposed concepts were performed to settle the emerging requirements and manifest the opportunities as features to include in a product. The learning from this process provided suggestions to incremental design changes, as well as affirming the elicited functionality.

In Case 2, the team integrated their proposed concept with an existing simulator enabling paramedics to attempt repositioning on a full-scale mannequin, as shown in Fig. 8. This enabled a realistic scenario for them to reenact the procedure and give feedback to the functionality and tactile experience of performing the procedure. In this process, the emerging requirements from prior testing and concept generation was made apparent and confirmed. For example, the slight movement and play of the pneumatic cylinder was considered a good approximation of the tactility of the tense muscles constraining the fractured leg.

The results from this testing, confirmed the elicited functionalities in both projects. Additionally, it provided new insights for the teams to bring forward in the continuation of the projects. Based on how the presented prototypes performed and their evaluation from medical personnel, the teams could establish and communicate requirements for the future products to be realized.

3. Discussion

In the two presented cases, prototypes enabled a discussion with expert users on needed functionality and aspects important keep on the radar for the development teams. It is, however, worth questioning if similar insights would have been accessible by investing enough resources on upfront research. This would have required looking into, e.g. analytical simulations of the human body, research on biomechanical behavior of human physiology and in-depth interviews with stakeholders. While using a systematic method of establishing upfront requirements could have led to meaningful specifications and functionalities to include, using prototypes quickly made these insights, not only available but also tangible. Prototyping enabled eliciting sensory experiences from trained medical personnel and provided a common understanding of how this was either represented or lacking in the presented prototypes. As the identified functionalities were described and reenacted by using the prototypes, it is not evident that this tacit knowledge could have been accessed through interviews and research alone.

The prototyping carried out by the two teams lead to the generation of multiple concepts and prototypes to be tested and evaluated in parallel. This was made possible by fast low-resolution prototyping in both projects. The identified functionalities and tacit features were attempted realized as multiple conceptual prototypes providing the teams with critical answers informing the development.

Concept generation through generative design questions was proven useful in covering a wider area of the solution space. Hence, having a better chance of finding a suitable concept for the specific design challenge. Further, the generation and testing of multiple concepts and ideas by prototyping avoided prematurely fixating on solutions. This is especially important when approximating aspects of the human body, as designing by the inspiration of physiology and copying human attributes could become a fixating element.

By being able to test often and adapt concepts as requirements emerged and shifted, the development teams could do informed decisions and quickly launch "proof-of-concept" prototypes to gain feedback. The identified functionalities for the two new products could hereby be tested and evaluated before being deemed ready for further development. This is a clear benefit of extensive prototyping as gaining answers fast and aligning development to fit users' needs and specifications is vital for eventually launching a successful product.

The examples from the presented cases have shown the importance of prototyping when moving into and exploring a new product context. However, it is worth noting the limitations of only relying on prototypes and prototype driven methods. Prototyping is but one tool in the toolbox of design engineers and is complementary rather than opposing to other working modes in the early stage of product development. As requirements and product plans are being solidified, new questions arise for product developers to address. Hence, this would require different prototyping strategies, as well as the utilization of diverse engineering tools to gain answers.

We propose this extensive use of prototyping as one way of accommodating the uncertainty of the pre-requirement phase of projects and using prototyping for learning to elicit and explore emerging requirements for new products.

4. Conclusion

The main contribution of this paper, and answer to the research question ("*How can prototypes be used to explore and establish informed requirements as opposed to using prototypes for meeting set requirements?*") has been to give two concrete case examples of how to drive development and establish informed requirements using prototyping.

By studying two case examples on prototype-driven development, it has been identified how prototyping activities for learning are important for eliciting and exploring functionalities and corresponding requirements for new products. In this context, prototyping has been observed to enable design teams to explore product potentials, communicate with users, and doing informed decisions by generation and evaluation of concepts. This paper has shown how prototype-driven development could be done to accommodate the uncertainty before requirements are made fixed or tangible. By this, prototyping is proposed as a complementary tool to be utilized for exploring and establishing informed requirements in the pre-requirement phase of product development projects.

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