Co-creating a 3D Printed Prosthesis Design using an Intersectionality Lens

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Abstract. The ongoing project PROTEA1 aims to improve the fit and acceptance of lower leg prostheses by optimizing the prosthetic design using 3D printing and integrating sensors to monitor pressure distribution of the residual limb to identify and localize potential problems, such as pressure or chafing points, in advance. This goal is pursued since 2022 with a human-centred, gender- and diversity-sensitive, participatory technology design. For this, a transdisciplinary team comprising engineering, physical therapy, orthopaedic technology, psychology, movement sciences and gender studies regularly meets and co-creates knowledge in online and face-to-face settings. The gender-sensitive, continuous and iterative involvement of stakeholders and potential users is the base for technology development and influences decisions regarding specific designs. The intersectional perspective of the gender approach of PROTEA became most visible in a use case decision workshop, where the team decided on which user group they would like to focus on. For this co-creation workshop, empirical results of user and stakeholder interviews and focus groups as well as literature analysis were translated into diverse conditions and challenges of respective target groups, and questions around potential ethical and societal consequences were raised.
In this paper we will present the sociotechnical framework of PROTEA, comprising a detailed requirement analysis which led to the development of personas and a set of

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technical and user-driven requirements. These results are being used by engineers who are currently working on a 3D-printed outer and inner socket of a lower leg prosthesis and the placing of pressure sensors within the inner shaft.

1. Introduction

The prostheses research project follows a human-centered design approach, which supports the development of appropriate technologies in an iterative process with relevant stakeholders by using qualitative methods (e.g. focus groups, interviews and personas) to put human needs, abilities and behaviour at the heart of developments and results in user-friendly technologies (Norman 2013). The first step of this approach is to develop a general understanding of the context of use of the application to be developed, and in the second step, the specific requirements of the users are specified. Since the project received funding for specifically integrating gender knowledge and expertise into the research (Thaler 2022), the entire process of PROTEA is gender- and diversity-sensitive, building on theories of mutual shaping of technology and use (van Oost 2003; Rohracher 2005).

The understanding of sex and gender in the project is intersectional, which means that relevant social and identity markers are used along with experiences of inequity and (potential) discrimination in order to analyse usage contexts and prepare them for technology development (Winker 2009, Winker & Degele 2011, Walgenbach 2012).

The integration of gender researchers and their knowledge already started at the proposal writing phase and led to a project design, in which scientific gender knowledge (Wetterer 2009) was included as crosscutting issue in all phases and all work packages of the project. At the kick-off meeting a first workshop was held for the transdisciplinary project team about gendered innovations (Schiebinger et al. 2011) and especially raising awareness on the concept of "configuring the user as 'everybody' and the use of the 'I-methodology'" (Oudshoorn et al. 2004, p.30). I-methodology is a technology design practice without any involvement of actual users, in which designers and engineers construct a general idea of a user (an 'everybody') and try to answer research questions by putting themselves in the role of the users (Thaler 2022). This problem was addressed by PROTEA's approach of a human-centred design approach, deriving user requirements and needs from empirical data and not those of the designers.

Already during the kick-off meeting beside gender and intersectionality, also responsible research and innovation (RRI) was seen as highly relevant, including not only ethical, wider societal and environmental aspects, but also process values of reflexivity, responsiveness, anticipation and deliberation (Stilgoe et al. 2013).

2. Methodology

The methodology of PROTEA has two levels. The first one is the immediate level of gender-sensitive human-centered technology design, using stakeholder mapping, focus groups, interviews, personas, user workshops etc. The second – or meta-level – comprises methods of knowledge co-creation within the transdisciplinary project team and advisors. The motivation to co-create knowledge respectively co-design technology within the transdisciplinary team comprising engineering, physical therapy, orthopaedic technology, psychology, movement sciences and gender studies was that: "… scientific knowledge, in particular, is not a transcendent mirror of reality. It both embeds and is embedded in social practices, identities, norms, conventions, discourses, instruments and institutions – in short, in all the building blocks of what we term the social. The same can be said even more forcefully of technology." (Jasanoff 2004, S. 3)

The co-creation and co-design approach need flexibility, systemic thinking and good facilitation (Greenhalgh et al. 2016), and a "shared understanding of others experience is key in the early stages of building trust between diverse stakeholders and helps banish myths that constrain contextually sensitive solutions being developed." (Langley et al. 2018, p. 5).

In PROTEA the knowledge co-creation is not only aiming at the prostheses design but also at gender knowledge (Thaler et al. 2022). In **Fig. 1** the methods and co-creation process is presented in a timeline from July 2022 to June 2024.

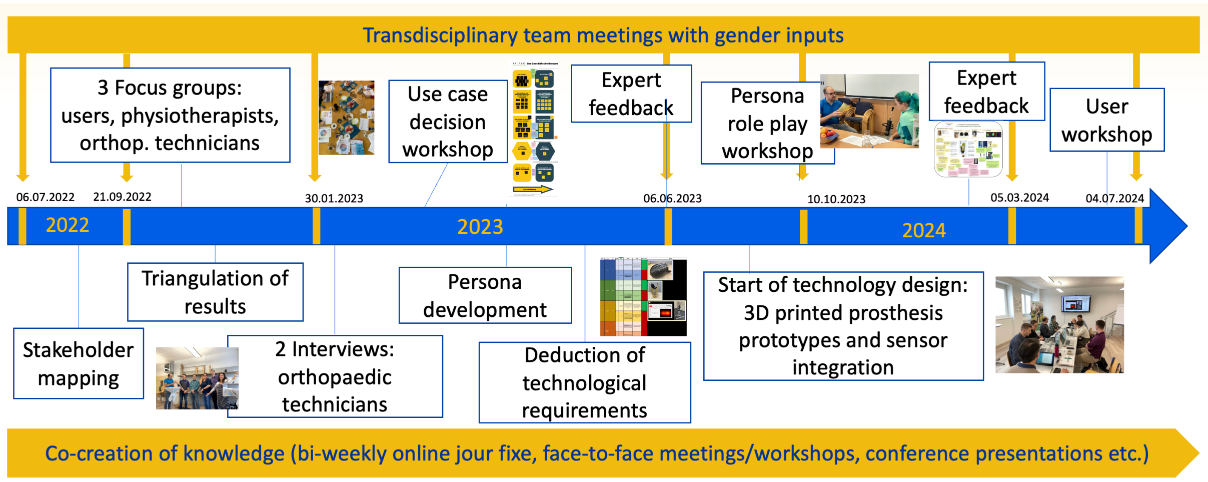

Figure 1. Overview of the context of use and requirements analysis in PROTEA

In the initial project year, a total of three focus groups and two interviews were conducted with three relevant stakeholder groups, namely users with prostheses (contacted via a self-help group), orthopaedic technicians, and physical therapists. The focus was on analysing the problem areas of using prostheses in everyday life and the solutions proposed by different stakeholders from their specific expertise and perspective. In order to ensure the saturation of the results, two interviews were conducted with prosthetists and orthotists based on the results of the focus groups.

As part of the co-creation process, team-internal meetings (including gender inputs) and a workshop were held to triangulate the results, define the target group and develop personas. The results were further consolidated by involving advisors with orthopaedic and healthcare expertise, and with co-creation workshops at three consortium meetings between September 2022 and June 2023. The knowledge co-creation always took place within the whole transdisciplinary team, in order to generate a corresponding common understanding on the one hand and to create a robust catalogue of requirements for the human-centered technology design.

The integration of gender and intersectionality in PROTEA's human-centered technology development (the first level of methodology) took place firstly, in the gender-balanced selection of interview and focus group participants and the use of gender-balanced teams on the part of the interviewers and evaluators; secondly, gender-sensitive addressing of participants and design of guidelines (e.g. using gender-sensitive language and avoiding gender stereotyping), and thirdly, in the evaluation and interpretation of the results, as well as presentation and dissemination of preliminary results within and outside the PROTEA team. The necessary gender competences were introduced in the context of consortium meetings through the implementation of specific gender workshops, using inputs and interactive methods, such as the wheel of privileges exercise (Thaler & Karner 2023).

One key method and moment of knowledge co-creation was the team-internal use case decision workshop, which was conducted online using a virtual whiteboard. The workshop began with an input including background literature (Greitemann et al. 2016) and results from PROTEA's focus groups and interviews. All team members contributed to a discussion on different usage contexts and discussed potential users and use cases in an interactive setting. Two fundamentally distinct user groups were initially identified (based on amputation history and activity level of those affected) and their specific needs were substantiated with data from literature and empirical results. Subsequently, the respective technical solution concepts and design ideas for each user group were outlined, and the respective user-specific challenges and problems were defined. Finally, social and ethical considerations for the respective user group were added, and both use cases were discussed.

From the engineers' perspective in the team, the workshop was a necessary step, as it became clear that there are sometimes major differences within the group of the affected people and the resulting requirements. The different mobility classes and a closer look at the everyday situation showed that not all needs can be met universally and that the adaptations to the prosthesis need to be designed more specifically. The decision was essential for the technical concepts, which could be defined more precisely.

Consequently, the joint decision in the team for a specific user group (“the user as somebody”) instead of “configuring the user as everybody” (Thaler 2022, p. 5) was made, and led to the derivation of personas. Personas are not actual users, but hypothetical archetypes (Hartson and Pyla op. 2012). Personas are an effective method for placing the wishes and needs of users at the centre of development and for developing scenarios that are as close to reality as possible. The advantages of this method are an understanding of the (primary) users for the whole transdisciplinary team, with their needs and behaviours, which can counteract stereotypes based from the personal environment (“I-Methodology”), lead to more empathy with users, and puts needs and goals of these users in the centre of all decision-making. In reflection meetings, the gender-sensitive design of the personas was discussed in particular in order to avoid gender stereotypes (Marsden et al. 2015).

In the second year the knowledge co-creation process was employed to transfer the identified user problems, as well as the needs and requirements of various stakeholders into technological tasks. The first technical concepts and developments comprised various elastic 3D printing materials, which were tested for their suitability for the soft socket and compared with material samples from conventional production. Simplified geometries were then created to test the sensor placement on a curved surface. A method had to be found for integrating the sensors into the soft socket, therefore a door system was integrated into the geometry into which the sensors were inserted. The next step was to implement these concepts into the real geometry. The entire process was continuously evaluated and adapted through regular exchanges with the whole project team. This exchange with colleagues as well as interviews with stakeholders and experts and their feedback were an important factor in the technical conceptualization and implementation. Through this knowledge co-creation, PROTEA’s engineers were able to very quickly supplement the existing design with the new findings.

This process involved several meetings and the ongoing exchange of empirical results. A key method of knowledge co-creation used role play as an intervention. Based on the developed personas, engineers of the project team received distinct items and basic instructions to “try walking in my shoes”, as the exercise was called. The role plays always included two active players, one personating a specific user based on the developed personas, the other playing themselves as engineers explaining their 3D printed prosthesis prototype asking for feedback.

Furthermore, technical solution ideas and sketches were constantly discussed in bi-weekly online meetings, and through team-internal existing expertise, including that pertaining to orthopaedic technology, physiotherapy, and so forth. Initial technical concepts were discussed in face-to-face meetings, including one with advisors from medicine and physiotherapy, as well as an affected person with expertise in orthopaedic technology.

During another face-to-face meeting two users were invited to assess their needs for an upcoming user workshop, which took place at the end of year two. In this workshop with four users the newest 3D printed prototypes were presented, and potential sensor integration and data issues discussed.

At the time of the submission of this paper another face-to-face meeting is planned, including advisors to specifically address arisen gender-specific and medical questions concerning the implementation of sensor technology. The further development of the technology and answering of gender related question will be in the focus of the third project year.

3. Results

The main focus of PROTEA activities – of the first methodological level – was the empirically sound conduction of the context of use and requirements analysis based on the verbalized wishes and needs of relevant users and involved stakeholders. Affected persons reported that it is crucial to put the prosthesis on properly in the morning. Otherwise pressure and friction points may occur or walking and standing on the prosthesis may become unsafe. From the therapists' perspective, a primary objective of the therapy is to develop the independence of those affected and to achieve safe handling of the prosthesis in the respective living environment. For the therapists, the possibility of a before-and-after comparison would be particularly helpful for future prostheses in order to better map the therapy process. Relevant data for this would be parameters of the gait pattern, movement behaviour in everyday life and prosthesis use. Biofeedback for patients using pressure sensors in the soles or on the residual limb would also be useful, possibly with live data transmission to a tablet.

In the perception of orthopaedic technicians, they mostly work with people who suffer from peripheral arterial occlusive disease (PAD) and belong to a lower social class. From their point of view, it would be beneficial if sensors could be positioned between the liner and socket and the sensors could focus on pressure (tibia, popliteal fossa), temperature (popliteal fossa, end of residual limb) and blood flow (circular on the residual limb). It would also be important that the sensors are suitable for documentation and also function as a biofeedback system so that users of the system can be shown what the actual pressure situation looks like, for example. With regard to the visualization of the data, it was noted that valid threshold values are needed in order to be able to handle the data accordingly.

On the second or meta-level of knowledge co-creation within the transdisciplinary team, one important event was the use case decision workshop, which was held in order to determine the characteristics, problems, needs and proposed solutions based on the aforementioned requirements. Based on roughly two different reasons for amputation (trauma vs. disease-related; see Greitemann et al. 2016) and the different age and activity structure of those affected, two user groups were distinguished, supplemented by the different needs from a social, (physio)therapeutic and (orthopaedic) technical perspective based on the empirical results. The engineering teams described technical solutions for the two use cases complemented by social and ethical dimensions. Finally, a decision was made in favour of focusing on users with multiple morbidities and health impairments who tend to have a low socio-economic status. This group of people tends to be inactive and moves mainly indoors and to a limited extent outdoors. In accordance with the classification of mobility classes after amputation (Greitemann et al. 2002) this corresponds with mobility class 1 (indoor walker) and mobility class 2 (limited outdoor walker). This group of people is also characterized by muscular weaknesses and advanced age. The issues that arise for this target group include poor stability when walking, difficulties with rolling while walking, problems when putting on and taking off the prosthesis to limited mobility in general or a severely impaired 'healthy' foot.

The final decision on the user group paved the path for further steps, and based on the description of the user group three personas were set up. The personas include a description of the living situation, social environment, their health status, aids, background of the amputation, medical care, their daily challenges and their personal requirements for the prosthesis.

In the second year, the focus was transferring this knowledge into the development of prototypes. In a first step, the prototypes developed to this date were discussed in the form of a moderated role play. PROTEA's engineers assumed the role of the personas created and attempted to comprehend the daily challenges from the perspective of those affected and to reflect on the prototypes created to this date. As a consequence, the technicians gained an understanding of the situation of those affected and user-centred questions such as "Is the material easy to clean?" came to mind. In addition to the moderated discussion, two interviews were conducted with orthopaedic technicians to answer gained questions like "Do you need markings on the outer and inner socket to put the prosthesis on quickly and easily?" and to gain a better understanding of state-of-the-art prosthesis production. The results of these iterative discussions led to the identification of three objectives for the further development of the prototypes:

- Development of a breathable prosthesis
- Reduction of the number of parts where possible
- Determination of the ideal sensor positioning

To address these issues in detail a fabric structure should be investigated for the 3D-printed prosthesis that allows temperature regulation and offers appropriate comfort in order to avoid pressure points. With regard to the sensor technology, a pressure point detection and monitoring system is desired. Furthermore, a solution that allows for quick and easy donning would be desirable. The sensor technology, outer wall, and inner wall were developed as prototypes, which were discussed together with users in a workshop. In this workshop, four retired males with amputated lower legs (due to chronical diseases) – generally assessed the current prototype very positively. They regarded the optics as satisfying, the perforations in the prosthesis prototype for air ventilation as clever, but the weight as too heavy for now. About integrating pressure sensors, the group had diverse attitudes for various reasons, reaching from a general technology aversion (which led to a principal refusal of all digital solutions) to a hope for exactly this sensor technology to avoid undetected pressure wounds. The perception of three users was that pressure points can be detected easily by themselves, and a sensor technology would not be needed for them. But if sensors would be integrated and then send data, they all agreed that their orthopaedic technicians were their most trusted experts, which they would feel comfortable sharing their personal sensor data with.

Now, the next engineering steps towards a sensor integration were taken. Different elastic printing materials got tested for their behaviour and properties. First simplified geometric parts were produced to test the sensor behaviour on a curved surface. Therefore, a system was created being both a sensorized prosthesis demonstrator and a test bench for the soft socket. This system is a mechanical part simulating the interaction between patients and their prostheses. It is able to display a real-time mapping of the forces within a soft 3D-printed half sphere representing the soft socket. A mobile mass consisting of a steel cylinder with a handle mimics the movement while walking. Flexiforce[2] sensors and an Arduino Nano[3] are used, the data is read out via an USB interface. The visualization is done in real time through a Matlab[4] interface by using a colour map and two graphs for force and voltage monitoring. Furthermore, a first prototype of the soft socket was printed. It includes a door system for the sensor integration and is perforated to improve the temperature of the residual limb. In the third and final project year the sensors will be implemented and tested on the printed socket.

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[2] https://www.tekscan.com/force-sensors

[3] https://www.arduino.cc/

[4] https://www.mathworks.com/products/matlab.html

4. Discussion and outlook

The gender-sensitive human-centered design approach applied in PROTEA focuses on the participatory development of 3D-printed prostheses with sensor technology. This process is carried out iteratively as co-creation of knowledge and co-design of technology with the project team, users and relevant stakeholders. The human needs, abilities and behaviours from a diversity perspective are at the centre of the developments and the result are user-friendly technologies according to the 'Gendered Innovations' concept (Schiebinger et al. 2011) and the avoidance of the so-called 'I-Methodology' (Oudshoorn et al. 2004).

The gender-sensitive knowledge co-creation was conducted in coordination with the entire transdisciplinary team in order to generate a corresponding shared understanding on the one hand and to create the broadest possible catalogue of requirements on the other (Thaler 2022). A use case decision workshop was held in the overall consortium in order to arrive at personas and requirements based on the empirical results. Starting with two user groups, the different needs of the respective target groups were first described from a social, (physio)therapeutic and (orthopaedic) technical perspective based on the empirical results and technical solution approaches for the two use cases. Possible problems and challenges as well as social and ethical dimensions were then discussed for both user groups. Finally, a consensus was reached focussing on multimorbid and health-impaired users with a rather low socio-economic status. In accordance with the classification of mobility classes after amputation (Greitemann et al. 2002), this group can be categorised as mobility class 1 and mobility class 2. People in mobility class 1 tend to be inactive and move mainly indoors. In contrast, mobility class 2 is characterised by greater mobility and a tendency to move around in limited outdoor areas This group of people is also characterized by muscular weaknesses and advanced age.

The aspect of gender sensitivity of PROTEA was firstly evident in the gender-balanced selection of interview and focus group participants and the use of gender-balanced teams of interviewers and evaluators; secondly, it was evident in the manner in which the participants were addressed and the design of the guidelines; thirdly, it was evident in the evaluation and interpretation of the results, as well as their presentation in joint knowledge production settings within and outside the PROTEA team (e.g. with advisors). The fourth step involved the translation of empirical results into the previously mentioned use case decision workshop, which was guided by the concept of intersectionality (Winker & Degele 2011; Walgenbach 2012; consideration of gender, age, socio-economic status). This requirements analysis derived from the empirical surveys, co-creative processes and the use case decision workshop led to the development of gender-sensitive personas (Marsden et al. 2005), which were later used for a role play ‘try walking in my shoes’, one of the interventions aiming at gender-reflexive knowledge co-creation and technology co-design.

At the end of the second year, the project is well on track, the results from human-centred design and gender research methods are well integrated in technology development of PROTEA, the bi-weekly online meetings, and regular face-to-face-meetings as well as gender workshops and meetings with advisors and users can be seen as successful instruments of a transdisciplinary knowledge co-creation.

For the last and third project year two major tasks lie ahead, on the technology design level the integration of sensors and the algorithmic model to make use of gained data. And from an intersectional perspective – which connects to the technology design – more data are needed to answer questions, which arose from the latest user workshop: Did we invite the right target group, and if so, are they really not needing sensors or may they not be aware of the benefits of sensor technology like orthopaedic technicians suggested? And finally, how can we better include under-represented users potentially facing discrimination because of intersecting identity markers (elder women, less mobile users, multi-morbid users living in care facilities, etc.)?

Co-creation and co-design are no guarantee that we will get everything right from the start, but they help us to detect conceptual errors in early stages and lead us to designs and technologies, which are robust, because they are more likely to be accepted by our target group.

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