From Patient to Maker - a case study of co-designing an assistive device using 3D printing

Rune Thorsen PhD[1)], Federico Bortot MA[2)], Antonio Caracciolo PT[1)]

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or

contact: rthorsen (at) dongnocchi.it

Abstract

Commercially available assistive devices (AD) may not always match the individual needs of the patient. Sometimes substantial customizations or a new design is needed. New ideas, arising by involving the patient, could help many, but product development and marketing is hard.

We hypothesize that digital fabrication (DF), e.g. 3D printing, may be an opportunity to involve patients in the process of custom design and creation of personalized ADs. As DF is minimizing the requirement for manual activities, DF has the potential to enable people in creating ADs for personal use, despite physical limitations. However, co-design and the use of DF in AD provision is still in its infancy and scarcely reported in scientific literature.

We studied the literature, performed a mini survey and then conducted a case story of a person with severe upper extremity impairment who became a maker of her personal AD using 3D printing.

Implications of using DF as a key enabling technology empowering patients with physical limits to become active in personal AD provision are discussed.

We conclude that this topic merits a proper scientific investigation of systematically engaging patients as competent participants in the development and realization of assistive devices and technologies.

Keywords: Activities of Daily Living, Emerging trends, Ergonomics and Anthropometry, Instrumentation, Usability, Outcomes, Service Delivery, Universal Design

Introduction and Background

The inclusion and empowerment of patients with physical disabilities is a continuing challenge for the provision of sustainable healthcare. Progress in digital manufacturing enables us to develop assistive devices (AD) for activities of daily living (ADL) and may also provide new ways to transfer novel technologies into practical use.

Using our hands is fundamental to most activities of daily living, but our hands may become impaired due to different causes like; spinal cord injury (Thorsen et al., 2014), multiple sclerosis (Leray et al., 2016) or amputations (Dillingham 1998). These are cases where people may be proactive in searching for AD that can help them in everyday life.

Provision of assistive technology and devices

Healthcare professionals may prescribe various AD to help their patients compensate for limitations in manual dexterity, but the challenge of the prescriber is to be aware of the vast range of assistive solutions (Roelands, et al., 2002); ranging from simple assistive devices for eating (Levine, 1989) to advanced and expensive robotic arms (Maheu et al., 2011). Mass-produced (off the shelf) ADs may not be available in a version fitting specific needs of the patient (Johnston et al., 2014). Besides this, an often underestimated issue in AD provision, is the abandonment or non-use (Verza et al. 2006; Harris 2010). As patients may not give feedback on reasons for abandonment to the provider (Phillips & Zhao, 1993; Cruz et al., 2016), the AD designs may suffer from lack of development and adaptation to the users specific needs (Scherer, 1996; Biddiss & Chau, 2007; Harris, 2010). There are other complications in supplying the patient with an adequate device (Wessels et al., 2003); problematic procurement, lacking information, technical support etc. (Andrich & Caracciolo, 2007) and users needs and priorities may change (Phillips & Zhao, 1993; Andrich & Caracciolo, 2007; Dijcks et al., 2006).

The obvious solution is to involve the patient directly in the design and production of her/his personal assistive device. This is the case when therapists are creating or customizing ADs for their clients in the orthopedic workshop (Bromley, 2006, Weiss & Prinz, 2013). This is where digital fabrication may present new opportunities.

Patient-Maker hypothesis

Digital fabrication (DF) techniques, where a computerized toolchain is used to realize physical objects, has become accessible to the common man and is widely adopted by people calling themselves '**Makers'** (Bussy, 2017). They use computer-controlled machines for realizing objects in so called makerspaces or fablabs. The term most often relates to 3D printing, but may also include computer controlled laser cutting, knitting or online prototyping services like for electronic circuits. Makers are coming from many walks of life and use DF to produce products for themselves out of curiosity or necessity. As machines realize the physical product, the need for manual ability is minimal. As the Makers say: "if you can imagine it you can make it".

The Maker approach to producing objects for personal use, could present an opportunity for a paradigm shift in rehabilitation thinking - a change of role of the patient from being a passive receiver of care to become an active participant in creating specialized solutions (Chen et al., 2016). Reportedly one in ten chronic patients are creating innovative solutions for personal use (Canhao et al., 2016).

Most innovations, whether originating by patients, professionals or researchers are never crossing the 'valley of death' to become commercialized (Leahy et al., 1996), though they potentially could be useful for relieving a number of disabilities. As advancements in DF makes prototyping of mechanical parts and electronic devices available and affordable, people with special needs may start to 'homebrew' AD solutions (Day & Riley, 2017).

Motivation for the study

Within an ongoing project of developing an open source neuroprosthesis for rehabilitation of the hand (Thorsen et al., 2013), we investigate the potential of engaging patients as producers and consumers of assistive technology. This paper is propaedeutic for further research on the following question: are patients interested in becoming active in making assistive devices for themselves using digital fabrication and can they become Makers of personal AD? To address this question we performed a literature study, a questionnaire and a case study.

Methods

The context of this study is the current AD provision service at our rehabilitation institute and a project for participatory engagement in redesigning care services (OpenCare). As participative design in healthcare is scientifically uncharted grounds this account is reporting results from preliminary action research based activities: reviewing the literature, understanding patients interest in co-design and a feasibility case study of a co-designing a relatively simple AD (Sharp 1998).

Literature study

Mass media and the internet report about innovating patients making solutions for themselves. Some textbooks are giving ideas for simple aids that can help a person become more independent. These aids can be constructed together with family, friends and rehabilitation workers (Werner 1987).

To find prior research in co-designing AD with DF, we searched for scientific literature describing people with disabilities who actively had engaged in producing assistive devices using digital fabrication. We used the following search terms: (“assistive technology” OR “assistive device”) AND (co-design OR fablab OR makerspace) AND (rehabilitation OR disability OR impairment OR patient) AND (“3D printing” OR “additive manufacturing” OR “digital manufacturing” OR “ digital fabrication” OR “fused filament fabrication” OR “rapid prototyping”).

Searching the major scientific databases: PubMed and Scopus yielded no peer reviewed papers pertinent to the topic. The same search on Google Scholar revealed 14 reports; mostly proceeding papers. A few accounts actually involved the end users in the creation process (Watanabe et al. 2015; Kanstrup et al. 2015, De Couvreur et al. 2013, Hofmann et al. 2016).

Many articles from the mass media are available on the internet with showcases of people engaging in AD development for themselves; “The Internet is full of stories about amputees creating entire prosthetic limbs in their homes” (Travis and Andrews 2013). Scientific literature on progress in rehabilitation engineering reports on 'expert-patients', involved in the development of advanced technologies like paraplegic cycling (Fitzwater, 2002) or artificial legs (Williams et al., 2016), where the researchers are patients themselves. A review of AD solutions on ‘thingiverse’ (a major site for sharing designs for 3D printing), concludes that the majority of designers have little or no experience with AD; inventors are neither disabled neither having specific training in healthcare (Buehler et al., 2015). Apparently there is a gap between clinical practice and amateur AD designers using DF (Buehler et al., 2015; Hofmann et al., 2016). These findings are confirmed by a literature review in the field of physical medicine and rehabilitation; no clinical studies are addressing co-design (Lunsford et al., 2016). Thus, we observe that there is a void in peer reviewed scientific work regarding AD co-design and that Co-designing AD using digital manufacturing remains to be explored.

Pilot survey

An open question is to what extent patients are interested in investing time and energy in co-designing AD. We attended a series of conferences and events on the topic of co-designing solutions for people living with multiple sclerosis (MS); one in particular was involving many people living with MS (HackAMSterdam, 2016). This presented an opportunity to conduct a structured interview of people with MS related disability.

We formed two questions: 1. Would you be interested in self-producing ADs in a makerspace (Y/N) ?; 2 How much time would you eventually invest (<1 hour, 10 hours, 50 hours or more) ?.

Nine people with MS related motor impairment, responded to the questionnaire; 7 out of 9 would engage in create their own assistive device or technology in a makerspace of those; one would have invested more than 50 hours, four would have invested approximately 10 hours and the remaining two would spend about an hour.

Case story

Based upon the literature findings and the survey we decided to perform a case study. The local AD counseling service (SIVA) had a client that was requesting a specialized solution to her needs. Thus together with this client, we formed an ad-hoc workgroup including facilitators: the therapist from SIVA, a biomedical engineer, design students and the local makerspace (www/wemake.cc/).

Digital fabrication

For the case story we selected inexpensive 3D printing (fused filament fabrication) as our DF tool. Computer aided design (CAD) software is integral to the DF tool chain. We reviewed a number of solid modeling CAD program which were free to use so it would not incur cost to the collaborators. Clearly it should be possible to learn for a non-professional and since multiple persons should collaborate, we selected an online collaborative solution that runs on a browser, without the need of installation on specific computers. In this way 3D models could be shared to enable collaborators to see, copy and modify a the model.

Evaluation of assistive devices

The outcome of the co-design process was evaluated by the Individually Prioritised Problem Assessment (IPPA) questionnaire (Wessels et al. 2002). This tool is used for assessing the satisfaction and effectiveness of AD provision in clinical settings as well as for reporting results in scientific literature. The evaluee is identifying activities causing problems in ADL; activities, which the AD should facilitate.

For each problem the importance and difficulty is rated on a 1-5 point likert scale; 1 = minimal and 5 = maximal importance/difficulty. After the AD provision the person is asked to rate the difficulties of the same activities again. The IPPA score is calculated as the difference in means of importance rating by difficulty rating. The IPPA score ranges from -20 to 20. A positive score indicates that one or more activities have become easier to accomplish. See Wessels et al. 2002, for a full description.

The participant

Our participant, a mid-aged woman, had amputations of the phalanges of both hands and the lower legs. Both elbow joints were surgically blocked at approximately 20° flexion for some years, see figure 1. Her chronic condition required a full time carer helping in all activities of daily living (ADL). To become more autonomous she was looking for a variety of solutions for dressing, personal care, feeding etc.

Figure 1. Left: Right hand of the participant. Grasping is limited to a lateral grip between thumb and metacarpal hand. Right: Maximal elbow flexion while holding a combing device.

The therapist had proposed a large selection of existing assistive devices and technologies ranging from special cutlery to robotic arms. Her evaluation of the latter did not meet her expectations and the simpler ADs could not compensate for the limited range of movement of the elbow joint and lack of fingers. The participant therefore decided to engage in this pilot co-design process.

At the first meeting we explained about co-design, possibilities of digital fabrication and the participant illustrated her impairments and the challenges in daily living that they pose. She had made a list of ADL tasks for which she would have liked to become autonomous. The list was divided into categories: dressing, personal care and self feeding. Together we chose to start addressing an AD for eating. We settled for a device that she could hold with the metacarpal part of the hand, grasping with her thumb considering the lack of the four fingers (see figure 1). A fork should be attachable to the other end of the device, enabling her to fork food on a plate and bring it to her mouth, thus compensating the blocked elbow joint. Furthermore it should also be stowable in a bag when not used.

Co-design of an assistive device

We did not find a reference design on the internet and drafted a solution from scratch as the simplest viable solution; a four piece modular device that the participant could assemble into a ‘fork holder’ AD (version 0). It was 3D printed in house as a demonstrational mock-up for the participant to evaluate, see figure 2. The design files are available on https://goo.gl/GQyMRE.

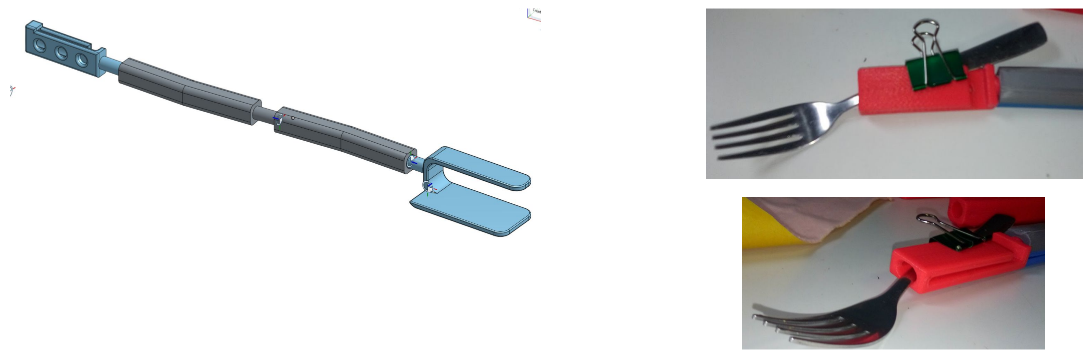

Figure 2. The first CAD version of the 'fork holder' (left) with a photo of the 3D printed result (right).

At the following meeting, the participant evaluated the solution together with her personal carer. After some ad-hoc modifications the primary objective was reached; it was possible for the participant to grasp and hold the device, simulating forking something on a plate and bring it to her mouth.

The participant proposed some minor modifications, which we applied to a branch of the original design as the first functional device (version 1).

At the third meeting the result was critically evaluated by the participant; the concept proved feasible though difficult to use. The personal career and the participant proposed several improvements: a) redesigning the handle to be more ergonomically designed for the metacarpal stump and enabling a firmer grip considering the thumb as the only finger; b) a modification of the cutlery attachment piece balancing the attachment; c) a more aesthetic design making the device smoothly curved and other smaller modifications, but keeping the concept. Then these revisions were applied to the CAD drawings for the final devices which the participant would use for the DF manufacturing process.

At that point the first part of the IPPA questionnaire was administered, see table 1. The participant was introduced to the makerspace where she was assisted in going through the process of downloading the CAD files and converting (slicing) them to a suitable format (g-code) for the 3D printer. To reach the objective of enabling the participant to master the entire fabrication, the design student provided lessons in CAD design. Despite activity limitations, the participant was able to use a computer and became able to make revisions to the design. However help was needed in mounting filament and preparing the process and the machine was left to work overnight. During that time there was a power outage so the production failed. A facilitator had to restart the machine, collected the final object, post processed it lightly by removing grates and supports and brought it to the participants home.

At that point the participant had constructed her first prototype, see figure 3,weighing 54g of (PLA) plastic with a cost of 12€/kg yielding a total material cost of 0.65 € for the device. The final design is available at https://goo.gl/hD9NTT.

 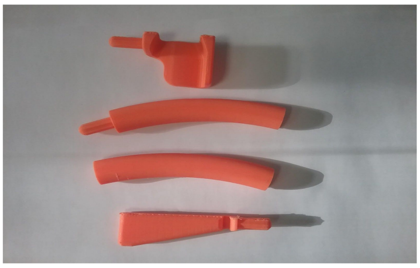

Figure 3. The final version of the assistive device (left) that can be disassembled (right) can be found on www.OnShape.com (https://goo.gl/hD9NTT) with the name 'DIY_ausilio_2.0'.

Evaluation

Before making the final device we administered the first part of IPPA. Our participant indicated seven 7 (maximum) issues of different aspects of daily living, each being very important and very difficult (if not impossible) for her to accomplish. The AD co-design was only addressing one of the seven issues; feeding. After 6 months we conducted a follow up interview administering the second part of the IPPA questionnaire (see Table 1). It shows int the follow up column, that a number of issues, including feeding, had become less difficult. She did however, not find it worthwhile using the AD she had been creating and due to logistic problems and technical issues with computer & Internet connection, she was not able to evolve the design further. As she had her personal assistant 24/7 anyway for other ADL, she found the device too rudimentary in its present form to be effective in confrontation to being fed by the assistant.

There is however an interesting improvement of 3.8 in the total IPPA score from 17.9 to 14.1 can be observed; some ADL issues have become easier. From the interview emerged that she increasingly started using everyday objects such as coat hangers, kitchen tongs etc. to solve her needs in daily living.

Problem	Importance	Before AD creation		At follow up	
		Difficulty	Score	Difficulty	Score
Dressing	4	5	17.9	5	14.1
Feeding	4	4		3	
Personal hygiene	5	4		4	
Toilet visit	3	3		1	
Access public places	4	5		4	
Blow the nose	4	5		5	
Scratching	4	5		2	

Table 1. Results of the IPPA questionnaire with priorities and difficulties before AD making on the left. Right columns show the difficulties and score at the follow up interview. We see that feeding is one of the highest prioritized issues after personal hygiene. The IPPA Change score was 3.8 meaning less perceived difficulty.

The entire process took place over a year of which the first half was dedicated to the creation and the second half to reflection over the AD. In the first month we had 3 meetings with discussions of issues and possible solutions, then followed a month of three co-design cycles where we realized a design proposal, followed by a meeting with the participant for evaluation of the device. Then we had the first interview followed by the participant producing the AD at the makerspace.

Time consumption

The 3D printing time of the final device was around 14 hours. During the period 3 prototypes plus the final version was produced. Various issues may arise during 3D printing and failures were encountered. We estimate that we totalled more approximately 100 hours of machining time. Seven meetings of co-design were held and 12 hours (3 sessions of 4 hours) were invested in teaching CAD the participant, who had no previous experience.

Discussion

Our literature search revealed a scarcity of scientific works on co-designing assistive devices with digital fabrication (DF). DF is, however, proposed as a viable method of AD provision in journalistic publications and conference proceedings. The void of research has been corroborated in the retrieved literature (Buehler et al., 2015; Hofmann et al., 2016; Lunsford et al., 2016).

We found some showcases of codesigning advanced assistive technology (Travis and Andrews 2013; Fitzwater 2002; Williams 2016). In these stories the participants with disabilities are academically trained people already involved in research and development. They are probably not be representative for the clinical reality (Roulstone 2000; Shier 2009). The literature study and an ad-hoc questionnaire lead us to think that some people with special needs would and could participate in innovation and making of solutions for themselves using DF, specifically leveraging 3D printing as a manufacturing method.

Our case study illustrates that despite severe impairment of the hands, a person can manufacture an AD using 3D printing. In this specific case the impairment was finger amputations and elbow stiffening following secondary complications of an infection, but we believe that causes like spinal cord lesion and multiple sclerosis, which often affects people's physical abilities in a young age, may be candidates for co-designing as well.

Therefore we propose further investigation in a model: where healthcare professionals and technicians who traditionally are deciding on the patient needs, rather vest a role as facilitators in a process where the patient becomes a participant in the design process rather than a passive receiver of AD. The participants have special needs for AD and are experts on expectations, limits and needs whereas facilitators have the knowledge about possibilities, products, and processes that may be applied.

In such a paradigm the resources for digital fabrication must be readily available. We think that Makerspaces (or fablabs) may provide such resources, as in our case, and clear the way for developing such a healthcare co-design framework where patients can become makers in collaboration with facilitators. The maker culture may be a role model for sharing and disseminating reference designs and knowledge.

Our participant had prepared a list of ADL issues and how she would like to see them solved, which turned out to be effective for the inception of the co-design process as it catalyzed a user centered and proactive investigation of solutions feasible for 3D printing. We learned that co-design implies openly discussing physical health and private matters as well as being willing to commit to a trial and error process.

We found that instructing a participant in the maker skills requires substantial time and energy of the involved parties. Though 3D printing is a rapid prototyping process, it should be recognized that the entire manufacturing cycle (from CAD drawing to postprocessing the object) may take days and several appointments were made. In our case story, months of iterating the design passed before the final device was ready. Meantime the participants priorities may change. We partly attribute this and the time lag to the lack of use of the final device. A shorter cycle together with a better design may have had a more positive outcome. Therefore we conclude that time must be kept short from inception to final product, which calls for an effective infrastructure, a swift identification of feasible models and immediate availability of facilitators and manufacturing facilities.

An improvement in the IPPA score lead us to hypothesize that the co-design process may be useful for the participant to engage in innovative activities. The participant became engaged in a personal innovative process; starting to deploy everyday objects as assistive devices. As also reported by De Couvreur et al. 2013, the end result of co-designing may differ entirely from the initial concept.

The IPPA questionnaire was used to evaluate to which extend problems identified by the individual participating in AD co-design was diminished. Being generic and identifying the priorities of the person, it appears not only time effective and useful as a measure of the results, but may also be a structured means of prioritize where co-design effort should be centered. The issues identified were closely related to the list of ADL issues that the participant initially prepared, which we assume is a sign of consistency. Looking at the problems list one may say that a ‘scratching device’ could have been more appropriate and easy to construct, whereas ‘access public places’ is difficult to solve by a maker solution, but rather an environment related accessibility issue.

This extended use of the IPPA instrument warrants further investigation on a larger scale to assess consistency and validity.

Using an online CAD program turned out to be effective in showing and altering the design during the codesign events. It was immediately available on any computer with an internet connection; during meetings, in the makerspace and at the participants’ home. Thus participant and facilitators could instantly share ideas and modifications without dealing with program installations, file copying and version control issues.

Most of the work was carried out by volunteers and by ad-hoc organization, which is clearly reflected by the quality and quantity of the results. Clearly the ‘maker way’ is incompatible with standardized procedures of today’s busy and quantity optimized rehabilitation institutions workflow. Therefore we envisage many complications in implementing such a paradigm in modern health care, as it’s not readily governed by today’s regulations. We need to clarify quality, safety, sustainability issues as well as changing mindsets towards sharing and caring.

This leads us to highlight what we believe would be the most important issues and opportunities of co-design for digital fabrication.

Issues of codesign

* Efficiency in synthesizing a design is imperative. This calls for database of validated reference designs; searchable for the specific needs for AD retrieval (Coakley et al., 2014).

* Digital fabrication may be inexpensive in material cost but time consuming, machine-time and iterations may make the process more lengthy and costly than expected.

* Though machines are doing the manufacturing there will be some manual operations involved in preparation and finishing, so it's not an entirely ‘hands-free’ manufacturing process.

Opportunities

* Co-design using DF opens new possibilities for designing and creating assistive devices in which the user has been responsible and owns the entire process providing the user with the opportunity to personalize and adapt the AD to specific needs and changes.

* Novel databases like ‘Thingiverse’ and online CAD programs may provide reference designs and facilitate collaboration between facilitators and participants.

* Participative web tools like wikis (e.g. wikipedia), repositories (e.g. thingyverse), rating sites (e.g. hospital compare) and sharing economy sites (e.g. shapeways) may be inspirational for further development of collaborative AD design frameworks.

Conclusions

Digital fabrication may be an opportunity for future health care providers to implement patient-makerspaces and change perceptions from being ‘disabled’ into a being ‘skillful’ people. There are many issues to yet to investigate. First of all we need to understand how many AD users would be interested and able to acquire the technical skills involved in participative digital manufacturing of AD. Costs, time and efforts should be confronted with outcome measurements of the added value for the patients (Andrich & Caracciolo, 2007) and we need to know how to harvest, validate and disseminate knowledge accumulated in co-design of AD?

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Bionotes

Rune Thorsen M.Sc. electrical engineering. Pursued postdoctoral studies at The University of Twente, The Netherlands (1998); Politecnico di Milano, Italy (1999); Salisbury District Hospital and University College London, England (2000). He is full researcher at Fondazione Don Gnocchi, Via Capecelatro 66, 20148 Milano, Italy

Federico Bortot has graduated at Politecnico in Milan in "Design & Engineering" Master Course. He's passionate about interaction design and is focusing his studies in interface and experience design. He likes studying multiple subjects, among which communication, interpretation and semiotics. He's working as freelance UI designer in Milan.

Antonio Caracciolo is a rehabilitation therapist and logopedist. He is the coordinator of the DAT (Domotica, Ausili, Terapia Occupazionale) at the IRCCS S. Maria Nascente -Fondazione Don Carlo Gnocchi. He is a Adjunct professor at three universities in the city area of Milan.

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