+TUO project: low cost 3D printers as helpful tool for small communities with rheumatic diseases

Francesca Ostuzzi
The Chemistry, Material and Chemical Engineering Department, Politecnico di Milano, Milano, Italy and Department of Industrial System and Product Design, University of Gent, Gent, Belgium
Valentina Rognoli
The Chemistry, Material and Chemical Engineering Department, Politecnico di Milano, Milano, Italy
Jelle Saldien
Department of Industrial System and Product Design Ghent, University of Ghent, Ghent, Belgium, and
Marinella Levi
The Chemistry, Material and Chemical Engineering Department, Politecnico di Milano, Milano, Italy

Corresponding author

Francesca Ostuzzi can be contacted at: Francesca.Ostuzzi@ugent.be

Introduction

In recent years 3D printing (3DP) technologies have spread because of increased accessibility, cost reduction and media hype. A high number of low-cost 3DP systems, especially fused deposition modelling (FDM), were introduced in the market. These systems target entry-level users, mainly for personal use. However a high impact on industrial design is recognized, especially for enabling rapid prototyping (RP) and manufacturing of products previously thought to be impossible to produce. This innovation addresses former industrial design issues typical of traditional mass production techniques such as: geometrical freedom, economical scalability and products variety. Currently also, the accessibility is drastically increasing through the creation of

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low-cost, open-source FDM machines that are implemented and distributed through Fab Labs and other makerspaces (Campbell *et al.*, 2012; Levy, 2003). The scholars defined this phenomenon like democratization of technologies (Tanenbaum *et al.*, 2013) or also democratization of manufacturing (Mota, 2011) that implies a significant cultural shift in how people engage with technology. While industrial and high-cost additive manufacturing (AM) technologies find applications in several fields like automotive, aerospace and medical, low-cost systems, as FDM ones, remain mainly linked with production of gadgets, small items, prototypes, etc. These applications do not always value the potential of the technology, leading to statements such as "It's a toy, not a tool" (Moilanen and Vadén, 2013). Nowadays though, low-cost and entry-level 3DPs are finally being applied to more functional and end-use contexts, e.g. for the creation of health-related devices, as design tools in small enterprises or in relation with DIY craftsmanship. Despite this, the process of democratization of technologies is challenging the dominant paradigm in which the user is perceived and considered only as a consumer, a passive receptor of products coming from industrial mass production. Thanks to this manufacturing revolution on desktops (Gershenfeld, 2005), an alternative vision of users is shaping, they become more like *creative appropriators*, hackers, tinkerers, artists and even co-designers or co-engineers. Nowadays a growing number of persons have access to production tools and to the knowledge needed to fabricate objects with these technologies. Some examples of applications are listed in the section "Case studies of AM applications".

This research starts from the analysis of current applications to explore the feasibility, advantages and disadvantages of introducing 3DP low-cost machines as RP and manufacturing tools during co-creation processes with people that have specific product needs. Health care is recognized as a domain that requires an approach close to mass customization, mainly because every person's body is different (Igoe and Mota, 2011).

In our design case, we selected to focus on users suffering from rheumatic diseases (RDs), which limit certain movements and actions because of pain and stiffness in patients' articulations. This is particularly a concern for these people because it affects their daily occupations, jeopardizing their well-being and their feeling of empowerment (White *et al.*, 2013; Schneider *et al.*, 2008; Ottenvall Hammar and Hakansson, 2013). Assistive devices support daily activities and facilitate patients' occupation. Our research involves people facing a hindrance on some specific daily activity and focuses the attention on the design and production phase of assistive devices, outlying here the main problematic areas. In fact, industrial mass production cannot always fulfil everyone's needs, particularly when dealing with persons with specific diseases, characterized by different, individual progressions. Industrial mass production in general seeks for a high level of standardization, often following the model one size fits all. Furthermore, according to previous studies, psychological factors related to self-confidence and device perception may be the more important factors that cause the non-acceptance, non-use or rejection of assistive devices (Rogers *et al.*, 2002), which puts greater pressure on understanding the actual individual needs of the end user. In fact, if aesthetics and usability of devices are important, to actively involve the end user in the selection process of the assistive devices is evenly important to decrease the degree of a non-use scenario (Wessels *et al.*, 2003). Additionally, this study investigates the willingness of participants to use new technologies (3DP in this case) to co-design and personalize assistive devices that could help them in their daily lives.

This paper reports on the pilot project +TUO, a case study conducted together with a Regional Association of patients with RDs, named ALOMAR (www.alomar.it) and XXX (XXX.it), an academic AM Lab. The study involved a group of patients with a range of different RDs in Milano, Italy. It represents the first step of a bigger process-oriented research that aims to innovate idea generation and production by adopting low-cost 3DP in a co-generative process shared with different stakeholders. A broader purpose of the research is to provide also new insights on social inclusion through the use of new technologies.

State of the art

Here following, a brief description of + TUO's theoretical background, divided into: low-cost 3DP, RD, user involvement and case studies of AM applications. These four main areas are, in certain cases, already connected, as it can be noted in the following paragraphs.

Low-cost 3DP

The number of innovations on materials, processes and accessibility related to low-cost and entry-level 3DP technologies has been increasing rapidly in recent times. We decided within this study to focus on the use of FDM 3DP, a technology that is based on a polymeric filament extrusion on a build platform. This specific kind of 3DP is highly diffused in low-cost and entry-level contexts. It is not limited to RP, but can also be used to produce functional final products. The main advantages of the low-cost FDM technology and its use are based on the layer-to-layer building approach (Campbell *et al.*, 2012; Evans and Campbell, 2003; Gebhardt, 2011; Lopez and Wright, 2002; Tucka *et al.*, 2008) and can be synthetized as:

- *High geometrical complexity achievable in products and components*.
- *Production flexibility*: This leads to higher products differentiation. This allows overtaking the mass customization approach, getting closer to a full industrial personalization.
- *Rapidity*: This is referred to design rapidity from idea to production (while on the other hand the production process itself can be highly time-consuming).
- *Accessibility*: These technologies are already spread around in different places, such as local Fabrication Labs (Fab Labs). These realities grow on the assumption that "giving people the ability to make things for themselves can be the fastest way to solve their problems" (Mandavilli, 2006).

Among these advantages, we note also some design-related values; for example, the possibility to develop fit-to-one product, to personalize each product aesthetically and geometrically and to improve functionality whilst increasing design complexity. The main limits of the technology are: production speed, accuracy, nonlinearity (i.e. different resolutions for XYZ axes), narrow commercial material choice so far and the possibility to achieve only relatively small dimensions (Campbell *et al.*, 2012). When dealing with low volumes (or one-piece-manufacturing), the comparison between rapid manufacturing (RM) technologies and workshop-based technologies (Evans and Campbell, 2003) might prove interesting.

Studies focused on future uses of 3DP in private contexts just began (Shewdbridge *et al.*, 2014); first, results show how the adoption of fabrication tools such as 3D printers may sustain the creation of physical representations of product ideas/concepts. The term "everyday making" was introduced to describe the process, related to everyday design, of creating physical representations of ideas using fabrication tools. Other studies focused more on the idea that users might be more engaged with objects able to produce themselves thanks to 3DP processes (Khot *et al.*, 2014).

Rheumatic diseases

In Italy alone, more than five million people (around 1 person every 12 persons) are affected by RD. In total, 734.000 of them are affected by chronic illnesses such as rheumatoid arthritis or spondyloarthropathies (www.anmar.it). In general, RDs are chronic inflammatory joint diseases and are characterised by pain, stiffness and fatigue that limit activities of daily living (ADLs). Some consequences (Schneider *et al.*, 2008; Bury, 1982; White *et al.*, 2013) of such conditions are:

- abandonment of work and social life;
- decrease in life quality and health perception;
- feeling of premature ageing and loss of self-confidence; and
- increased dependency on others (with consequent sorrow and distress).

Previous studies revealed that occupation could empower people with ongoing health conditions through four main dynamics: revealing, explaining, managing and overcoming health conditions (White *et al.*, 2013). In fact, while the experience of ongoing illness and its treatment has caused profound disruption to patients' lives and self-confidence, new occupations can help them to overcome their conditions by introducing new meaning in their lives and providing a renewed sense of purpose (White, *et al.*,2013; Wilcock, 1999; Ottenvall Hammar and Hakansson, 2013; Steultjens *et al.*, 2002). The importance of ADLs and involvement linked to a disability is also the main feature of the theoretical model of the International Classification of Functioning, Disability and Health (ICF), created by The World Health Organization (WHO).

The use of assistive devices is often crucial to support daily occupations. These devices are frequently prescribed to patients with RD to compensate physical limitations, limit their pain and protect their joints. Previous studies were developed to better understand how to design assistive devices for people with RDs (Yen, 2013; Rogers *et al.*, 2002). Often, the market supplies mass products that do not fit with the needs of a single patient (functional and/or aesthetical); moreover, often, the end user cannot actively participate during the design and supply processes, while it is shown that involving the user in the selection process has a positive impact on the use and perception of the device. Another reason for non-use can also be found in the length of the delivery period: the sooner the end user receives the assistive devices, the less likely he will abandon it (Wessels *et al.*, 2003). Previous studies and our own experience confirm that existing devices are often adapted by the end user to create new products that fit his/her specific needs. "These self-made artefacts can deliver profound happiness, even if they are not as functional or aesthetically defined as the industrial ones" (De Couvreur *et al.*, 2013; Ottenvall Hammar and Hakansson, 2013; de Boer *et al.*, 2009). This shows the need for specific geometrical and functional personalization that classic mass production cannot deliver.

As previous studies have shown, involving the end user in the creation process of an assistive device to support ADLs can be extremely valuable. The co-creation with the user improves an understanding of the user's needs and wishes, and it actively engages all the stakeholders in a community-based process (De Couvreur and Goessens, 2011; De Couvreur *et al.*, 2013). The same community-based approach is central for the functioning of Fab Labs and other makerspaces. Moreover, it is complicated for a person with RD to be active in a co-design and/or co-production process using the traditional DIY crafting methods because of pain, consequent loss of handcrafting abilities, discretion, etc. In this context, the introduction of 3DP was of interest, also because it does not imply any specific physical effort or manual skill, and it can be easily accessed by citizens.

User involvement

The involvement of end users during the design process is a consolidated approach that can be developed at different levels: from a more passive contribution (user as subject), typical of user-0centred design methods, to more active ways of participation (user as partner), typical of participatory design methods (Sanders and Stappers, 2008).

This study is based on the importance of the end users' occupation and engagement in the design process of their own assistive devices, and thus, focused on the idea of developing a co-design (and co-production) process to create unique and personalized assistive devices. Co-design is a specific expression of co-creation; "with co-design we indicate collective creativity as it is applied across the whole span of a design process" (Sanders and Stappers, 2008). A co-design process starts from the belief that all people are creative and that the end user is the expert in his/her own experience of use (Sanders and Stappers, 2008; De Couvreur *et al.*, 2013). Co-design traditionally takes place during the *front end* of the design process to collect information and inspire further exploration. It generates new insights and concepts (Sanders and Stappers, 2008; Kwok-leung Ho, 2011). Co-design processes often use toolkits to enhance creativity and facilitate the communication between different actors.

In our opinion, thanks to spreading digital technologies and, in particular, of entry-level and low-cost FDM technologies, we can really start talking about participation during the actual product generation (what we call co-production) that is the product manufacturing itself: making together is a powerful method that provides pleasure and meets meaningful goals, leading engaging agents to new sources of profound happiness. To some extent, this technology plays a role in our research between a proper production tool and a toolkit useful to stimulate creativity and participation.

Some studies are already exploring and building on this process of communities' involvement during different design phases, specifically in association with the use of 3DP technologies (Hermans, 2014; enablingthefuture.org, ucodo.com). In general, this hands-on approach allows end users to "adapt their assumptions through the engagement with design activities within their own local environment" (De Couvreur *et al.*, 2013; Mugge *et al.*, 2009). In co-design, traditional roles get mixed up, and the creation of a multidisciplinary team is often important: in this study, we defined a cross-functional development team, following the team definition as described in the study D4E1 (Design for Everyone; De Couvreur *et al.*, 2013):

1 *End User*: Is an expert in his/her experience.
2 *Designer*: The designer generates tools and settings, supporting the end users' needs and following the making process.
3 *Occupational therapist (OT)*: The OT validates ideas and final products, with a particular focus on damages limitation.

To these three actors we added:

- *Researcher*: The researcher facilitate the communication between actors and observe the dynamics of the workshop.

Case studies of AM applications

To support and augment our research, we identified various applications of AM technologies in different contexts. Here is following a brief selection of some contexts that integrate well with RP technologies to solve a specific problem related with individual end users. Examples are sub-grouped in: medical applications, prosthesis applications and assistive devices production moving, respectively, from high-cost technologies to low-cost ones, from low user involvement (user as subject) to high user involvement (user as partner) and from RP to real RM.

In the *medical and health-care fields*, the adoption of AM technologies is well-established. Since decades, AM technologies triggered interest in the medical and health-care fields, one of the main reasons being that these technologies can be easily associated with the use of traditional medical 3D data like magnetic resonance (Giannatsis and Dedoussis, 2009; Beyers, 2010; Hermans, 2014). Exploring this specific context during our research was helpful because we share the focus on *including* the patient on different levels (starting from the phase of collecting input data), and we both face a health condition that is unique and hard to solve using only standard methods and tools. Giannatsis developed a categorization for RP technologies used in the medical field that is extremely similar to what is the traditional categorization of all RP technologies (Gebhardt, 2011) as follows:

1 Direct methods:
   - *RP*: biomodelling, the use of RP technology for creating prototypes to be used for surgery planning or testing.
   - *RM*: fabrication of implants and porous implants. Drug delivery and micro-scale medical devices.
2 Indirect methods:
   - *Rapid tooling*: Fabrication of specific surgical aids and tools, mould for tissue engineering.

These sets of technologies are used in the medical field as aiming to support diagnosis, planning, communication, problem prediction and dealing with unique geometrical configuration. In general, stereolithography is the most frequent and intensively used AM technology. The reasons behind this choice are the level of accuracy, precision and control on geometries, tolerances, the option of transparency and possible use of biocompatible resins in the field of implants production (Melchels *et al.*, 2010; Petzold *et al.*, 1999). FDM mainly dispenses liquids and pastes (e.g. bio-ceramic or polymer materials) and is adopted for the direct fabrication of bone tissues and tissue fabrication of biocompatible cellular scaffolds (Liu Tsang and Bhatia, 2004; Melchels *et al.*, 2012). It is chosen because it is less expensive and less time-consuming, and it is often selected also for the fabrication of biomodels for surgery planning to evaluate the complexity of the surgery itself. This technology is defined as office-friendly, and it has the ability to process biocompatible materials with some minor modifications (Giannatsis and Dedoussis, 2009). For this field of application, professional 3DP technologies are usually adopted compared to low-cost FDM systems due to the limits that have been explored in the previous section.

Commercial examples linked with prosthesis application, mainly focusing on the aesthetical aspects are *Be Spoke Innovation* (bespokeinnovations.com) and *Unyq* (unyq.com), companies that produce covers surrounding existing prosthetic legs. Their example is interesting because: first, they value aesthetics and second, there is an active involvement of the user in the design process. Through active involvement, the design reaches a level of actual personalization rather than just customization. Even in this case, the technologies used are expensive and top-of-line such as 3D scan/measuring of parameters and 3DP of polymers (although presence of metal components is also reported sometimes), with different finishing effects such as leather, metals (chromo), different levels of glossiness and textures (i.e. *tattoo* on leather).

On the other hand, low-cost, entry-level, open-source 3DP technologies count an increasing number of similar applications, where 3DP, and specifically FDM, plays a central role together with the co-creation process and the virtual sharing of results and of the design process itself. Media and platforms able to sustain these phenomena are both virtual and physical. On the physical side, we see Fab Labs, Living Labs and other kind of makerspaces; on the virtual side, we have a number of platforms, such as *Instructables* and *Thingiverse* (thingiverse.com). A good example of a project in this scenario is "Enabling The Future" (enablingthefuture.org), where we see a network of passionate volunteers using 3DP to give the World a "Helping Hand" with reference to 3D-printed hands and arms for those in need of assistance all over the world. This is a *bottom-up* approach with high involvement of the end user. Enabling the Future uses low-cost FDM 3DP and open-shares insights on the specific products, but to realize one of their products, medium/high specialized skills are still needed. This last approach is the closet to our study because of the central role played by communities its bottom-up approach and the low-cost 3DPs.

Building on this theoretical scenario and these assumptions, the present paper describes a pilot study where 3DP was introduced as a tool for co-designing and co-producing assistive devices for (and with) a small community of persons with RD.

Research methodology

+TUO uses a mixed methods approach, mainly based on qualitative research methods to explore the actual end users' needs in terms of assistive devices and to explore the possibility to satisfy those needs using low-cost FDM. In this study, low-cost 3DP technology was involved at all stages of the iterative generative session (idealization, prototype, test, final co-production; for details, see Figure 3).

The +TUO Project overall structure is the following (Table I):

1 Questionnaire:
   - Questionnaire analysis; and
   - Participants recruitment.
2 Design of reference products.
3 Activation stage.
4 Generative session:
   - Co-design stage (eventually reiterated); and
   - Co-production stage (eventually reiterated).

A brief premise about specific terms adopted from now on is important. When we use the term "assistive device", we mainly refer to small, non-medical devices, that help the end users during the execution of small daily activities, such as opening a bottle or a jar, writing a letter, cooking at home, etc. When we use the term "actor", we refer to whoever actively participated to one or more +TUO Stages. We can also refer to them as "co-designers" as long as everybody in such a context is considered playing an active role in the design process. All actors: end users, designers, OTs and researchers together form the cross-functional "team" that is the operational unit of each generative session.

When we use terms such as: "end user", "user" or "participant", we always refer to selected persons affected by RDs: they are the persons who are going to use the assistive device on their daily routine. They are expert of their own condition and novice users (in our case) of the technology and often have already hacked some assistive devices on their own. Similarly, when we use the term "designer", we specifically refer to design professionals. They are experts in the use of the technology and in the design process, but have minimal knowledge (again, in our case) of the specific RDs condition. With OT, we refer to the third group of actors: occupational therapists. They are expert users with respect to the design process, materials and solutions selections, but novice users of the technology. Finally, "researchers" also participate to the process: their main role is to facilitate the communication and to observe the dynamics at each stage. It can be noted that everybody can be an expert and a novice user, depending on the point of view. This is also the reason why we define these as cross-functional teams, meaning they combine different expertise and focus on a shared goal. A summary of the +TUO participants and the roles of the different actors at each stage can be found in Table II.

Questionnaire and participants recruitment

Through a questionnaire with 136 respondents, researchers obtained a first overview on patients' daily activities, needs and desires with particular focus on specific assistive devices. In total, 85 per cent of the whole group answered that they had to limit their daily activities since the RDs' uprising. Participants had to list all the assistive devices already used, underlying pros and cons for each one. Participants had also to list all the assistive devices they needed but did not adopt yet, explaining why they did not have them already. Reasons were generally related with high price, low availability and with the low suitability from functional and aesthetical points of view.

Finally, participants were asked to express their willingness to actively participate to the further steps of our +TUO study: 81 respondents confirmed their availability. For this pilot study, ten participants (out of these 81) were recruited – eight women and two men. The selection is consistent with previous studies, as the disease affects women with a percentage four times higher than men (Bury, 1982; www.alomar.it). The age ranged from 30 to 70 years, with each participant having one or more ongoing RDs. Table III lists all the participants detail.

Design of reference products

As stated previously, the questionnaire helped researchers to better understand end users' needs, wishes and demands related to particular activities/actions and specific assistive devices. Many activities (and the related products) were listed as problematic, such as: walk up the stairs, dress up, open bottles or jars, close shoes, conduct general sport activity, put-on make up, gardening, maintain social activities, cook, etc. Two main activities were recurring more often than others: to open bottles and to close dresses or bags. Designers of XXX, an AM

Table I +TUO process: overview on stages, sub stages and physical outputs

No.	Stage	Sub-stage	Physical outputs
1	Questionnaire	Insights from 136 participants Recruitment of 10 participants	
2	Design of reference products		Two reference products, see Figure 1
3	Activation	Self introduction among actors Introduction to Occupational Therapy and to 3D Printing Co-design Practical exercise	Development (iterations) on the Reference Product "Zip-Aid", see Figures 6 and 8
4	Generative session	Co-design stage (ideation-prototype-test) Co-production stage see Figure 3	New products and iterations on the reference product "Bottle opener", see Figures 7 and 8

Table II +TUO process: overview on stages, actors and their role in each stage

No.	Stage	Actors*	Role
1	Questionnaire	E, R	E: 126 end users answered to the questionnaire E: 10 end users were selected to participate to the next stages of +TUO R: Researchers analyzed the results, grouping them and obtaining the first highlights
2	Design of reference products	D, R	R: Researchers transferred important highlights to the designers D: Three designers designed two reference products based on questionnaire highlights (Figure 1)
3	Activation	D, E, OT, R	Three teams each one counting: three E, one OT, one D and one R R: Introduces the schedule of the day, listing the goals for the specific stage. Facilitates the communication and observes the dynamics E: Introduces his/her own daily condition D: Introduces design and 3DP OT: Introduces assistive devices and occupational therapy
4(a)	Generative session Co-design	D, E, OT, R	Nine teams were formed: one E, one OT, one D and one R R: Introduces the schedule of the day, listing the goals for the specific stage. Facilitates the communication and observes the dynamics E: Gives continuously inputs on his/her wishes and needs in terms of functionality; tests prototypes; determines the moment when a prototype can become a final product (Figure 3) D: Sustains the idea generation with brainstorming, sketches and generates 3D printed prototypes OT: Focuses on technical aspects of assistive devices related with RDs; evaluates the product during the test phase
4(b)	Generative session Co-production	D, E, R	The previous nine teams continue the work without OT R: Introduces the schedule of the day, listing the goals for the specific stage. Facilitates the communication and observes the dynamics E: Gives inputs on his/her wishes and needs in terms of aesthetics D: Finalizes the detailed design and optimizes the printing process

Notes: *E: End user; D: Designer; OT: Occupational therapist; R: Researcher

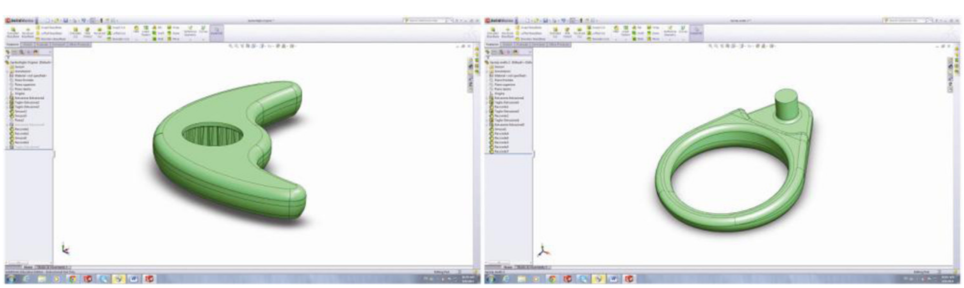
Table III Participants demographics and information linked to the disease and the relation with objects

Name	Age group (years)	gender	RD	Onset of the disease (years)	Limitations on daily activities	Limitations linked with specific objects
s.	30-50	f	Rheumatoid arthritis	10-20	yes	yes
v.	30-50	f	Rheumatoid arthritis	10-20	no	no
mg.	50-70	f	Lupus erythematosus	> 30	yes	yes
n.	50-70	f	Rheumatoid arthritis	2-5	no	no
a.	50-70	m	Rheumatoid arthritis	2-5	yes	yes
l.	30-50	f	Fibromyalgia, with Sjogren's disease	1	yes	yes
f.	50-70	m	Rheumatoid arthritis	20-30	yes	no
r.	30-50	f	Rheumatoid arthritis	20-30	yes	yes
mp.	50-70	f	Rheumatoid arthritis	20-30	yes	yes
m.	30-50	f	Rheumatoid arthritis	> 30	yes	yes

laboratory of XXX, designed then the two reference products: bottle opener and zip-aid, as depicted in Figure 1.

The design was developed with 3D computer-aided design (CAD) Software SolidWorks, a software useful to create solid models thanks to a simple interface, that helps designers to make quick changes if and when needed. In general, this process was developed by designers not actively involving with the end users or the OTs. Designers

Figure 1 Reference products designed by XXX, a bottle opener and a zip-aid



tried to imagine and address the users' needs developing benchmarks, using their own personal experience and conducting online researches. There are two reasons as to why we developed these reference products:

1 To use them as example during the Activation stage to better describe the 3DP technology to participants.
2 To check after the Generative session potential differences between products developed by the designers alone and by multidisciplinary teams.

Activation stage

The activation stage is a first collective meeting, where all the stakeholders meet for the first time. The main focus is to introduce 3DP low-cost FDM technology, in this case, using the WASP Project machine (www.wasproject.it). This first workshop is based on the belief that occupation-based practice uses occupation both as a therapeutic medium and as a goal of the therapy (White *et al.*, 2013). The activation stage aims to:

- create a sense of community;
- engage end users and involve them in a social activity;
- raise their awareness about the illness through comparison with other patients; and
- explain the functioning, advantages and disadvantages of low-cost 3DP.

As emerged from the questionnaire, patients affected with RDs tend to loose their hand capabilities, which implies difficult active participation during the creation of models and mock ups made with more traditional prototyping techniques (i.e. hand modelling with simple materials). In this scenario, the adoption of 3DP for the prototyping stage was useful to overcome this barrier, as it required little manual skills. Furthermore, we used this first approach with end users to understand their opinion about the low-cost 3DP and their ideas for possible applications, and un-lock the potentialities of this technology to the end users.

Three groups were formed, each one with three end users (one absence), one OT, one designer and one researcher. This team composition allows and stimulates the communication between novice and expert users, where each team member is both novice and expert of a particular expertise. As outlined before, end users are experts in their own needs and conditions related to RDs, while OTs are experts in assistive devices, the dynamics of *proper* gestures (with a focus on limiting damages of articulations) and the designers are experts in the design process and in the production technology. Communication is fundamental in this kind of team: in our case, it was sustained and facilitated, thanks to the researchers, who acted as mediators among the actors. Furthermore, 3DP as a technology, but also as *toolkit* stimulating creativity, helps to engage *laypersons* in the design process (i.e. in this context: end users and OTs), and can be compared to a digital–physical toolkits (Hermans, 2014).

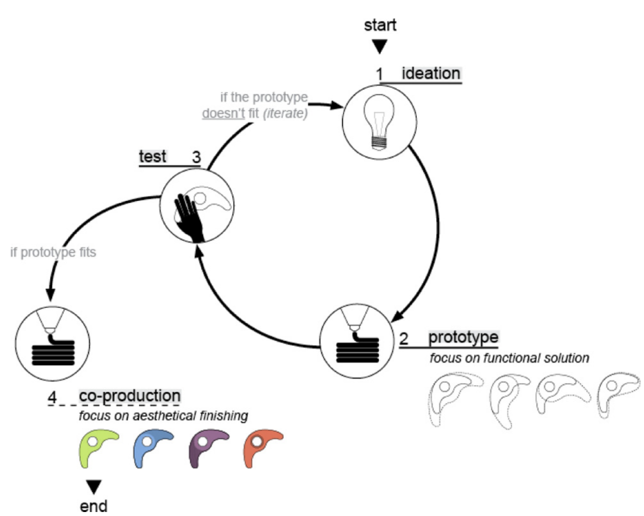
After obtaining an informed consent agreement, a practical co-design exercise with 3D printers took place, and was conducted by the designers. This introduced the technology to all participants, showing them a simple case study. We have chosen the zip-aid (see above) as a *reference product* (Figure 1). We made this choice because the questionnaire revealed that such a device answers a common need for patients with RDs, and because it is simple and fast to produce (because of its small dimensions). Each participant was then asked to talk to the team members to change this *reference product*, to make it more personal and functional. Together, end users, OTs and designers modified geometrical, dimensional and aesthetical aspects to achieve a product completely personalized. At this point, the designer modelled the personalized zip-aid, sharing the process with all the other actors until the file was ready to be 3D printed. The printing machine was visible in the middle of the room together with sample products and other design tools as depicted in Figure 2. The entire process lasted around 2 hours. Specific outputs are listed in the section "Results of the activation stage".

Generative session

During the generative session, which represents the core of +TUO, the assistive devices are realized from concept to production. This session is divided into two main stages (Figure 3): co-design and co-production. The co-design is an iterative process of ideation–prototype–test that has to be repeated as many times as needed to obtain a satisfactory product for all the

Figure 2 Setting for the activation stage

Figure 3 Generative stage overview: from the iterative co-design process "ideation - prototype - test" to the co-production stage



stakeholders, especially end users. In general, during the co-design stage, the main goal is to define the functional aspects of the device such as: geometry, dimensions, proportions, weight, etc. The second phase of the generative session is the co-production stage. During this stage, after the tested prototypes are ready to be produced, the focus is on defining aesthetical variables like: colour, texture, small decorations, considering also all the variables related with the printing process (printing speed, object orientation, etc.). The whole dynamic of the generative session is represented in Figure 3; further details are reported in the next paragraphs.

Co-design stage
This is the stage where the product is designed, with a particular focus on its functional requirements. The teams are comprehensive of: one user, one designer, OT and one researcher. The working environment was set up in XXX, paying attention to find available infrastructures suitable for persons with RDs. This stage took place two weeks after the Activation stage. In this *bridging* period, as a preparation, end users had to focus carefully on their personal struggles with specific products while conducting their usual ADLs. End users indeed arrived to the co-design stage with lists of potentially needed products (i.e. a mouse aid for computer, a toothpaste squeezer, a key holder, etc.). The approach was to focus on the most useful one, chosen together with the specific help and advice of OTs. At this point, the process was mainly to identify possible designs together with the other team members, following the iterative process of *ideation–prototyping–test*:

- *Ideation*: First, we identify wishes and demands and highlight limits linked to the pathology, as well as technical/technological limitations linked to 3DP. Each team naturally adopted the tools/techniques considered more suitable and well-known by the designer. In general, a brainstorm was followed by rapid idea visualization using sketches on paper or tablet. This way, each team generated concepts, validated some ideas and then outlined potential solutions.
- *Prototyping*: These solutions were rapid-prototyped by the designers using low-cost 3DP or sometimes traditional workshop prototyping materials (Figure 5).
- *Test*: All the prototypes were tested by the end user, under the guidance of the OTs to avoid dynamics potentially harmful for end users' articulations (see Figure 4).

We tried to keep the approach as similar as possible to the one adopted from D4E1 (Design for every(one); De Couvreur *et al.*, 2013) where all the stakeholders communicate using:

> Tangible, physical prototypes, keeping an open mind to observe unexpected interactions, creating a social setting (with groups rather than one on one meetings), using a research method as spontaneous as possible.

Figure 4 Test with prototypes during the co-design session

This way we aim also to reach and share a wellness feeling among the participants, a purpose of the research that goes beyond the product itself:

> By sequentially asking why one prototype is better than another triggers the participants to examine their responses. Non-designers often have problems with the notion of creativity. We invite them to suggest new ideas through the process of copying, transforming and combining elements from the several user-prototype interactions (De Couvreur *et al.*, 2013).

This co-design process (ideation–prototype–test) lasted a maximum of 4 hours each time and was iterated many times (in this pilot test up to three times); sometimes, only small details were changed to reach a *high fit-to-one* level "till the identification of a detailed final design, then followed by the manufacturing stage (co-production stage)".

The same co-design process was also developed on the second *reference product*, the bottle opener, for each End User. In this case, as with the zip aid, changes were done on an already existing design by XXX. Without creating a completely new design each time, it was possible to focus on actions like replication or transformation of the reference product for every end user. This implied a deeper focus on smaller variables and details, and thanks to the iteration by different teams on the same product, we could reach a level of knowledge and a set of ideas and options that are useful for other generative sessions. Specific outputs of this stage are listed in the section "results of the generative session".

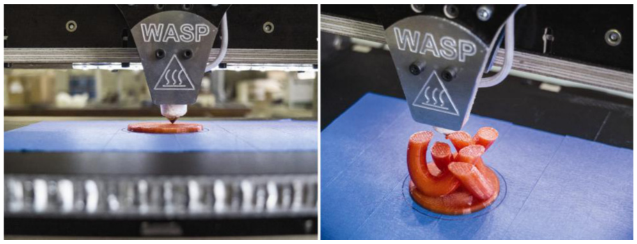
As described in Figure 3, when the prototype does not fit completely the user's functional needs, the iterative process starts again; only when the prototype fits all the functional needs we proceed to the final stage: the co-production stage.

Co-production stage
When the test reveals that a prototype is *good enough*, the team can start with the production of the final product for the end user (Figure 3). It is important to highlight that the production and the prototyping processes are in fact developed by the exact same machine. What, in our, opinion makes the difference between the "prototype" and the "final product" is that for the latter the printing process and aesthetic are optimized. On the contrary, technical and functional aspects (as geometry, dimensions, weight, etc.) are identical. Therefore during the co-production the designer pays attention to small geometrical, material and technical variables to reach a high printing quality (i.e. printing speed, layer thickness, product orientation, etc.), while the end user is invited to focus on aesthetical aspects, such as colour choice, small decorations, texture, etc.

As in Figure 3, OTs are not present at this stage, as long as the product is already defined in its functional features.

Basically, to print an object with 3DP technology, a virtual 3D model in .STL file format is needed. This file is produced by Designers with 3D CAD software e.g. SolidWorks. The .STL file is then processed by software to make it suitable for print, modelling the product layer by layer. The prototyping process from concept to final product can be very fast (in our context, in less than one day a new product design could be realized from scratch). All the products manufactured during + TUO were produced using WASP 3Dprinter (www.wasproject.it) in XXX an Italian made FDM (Fused Deposition Modelling) machine, Figure 5.

Figure 5 WASP Project, printing a sample product



The end user was present during this last stage, so that he/she was also involved during the creation of the .STL file and the launch of the printing process. In this case, users were involved more as spectators and rarely were they able to actively participate in the technical steps (for example, using SolidWorks or activating the 3DPrinter). The software is in fact quite complex and a medium–high level of expertise is required to use it.

Results

The following results, divided into the sequential stages of +TUO, summarize all the achieved physical outputs and the insights we collected from our approach.

Results of the activation stage

To explain the functioning of the FDM technology, we used a comparison with normal desk printers. This appeared to be clear enough even to participants without any specific technological knowledge in informatics or materials. The designers' vocabulary was pre-discussed and some rules were applied, i.e. using the word "plastic" instead of "polymer, PLA, ABS, etc."; "virtual drawing" instead of "3D model"; "heated head" instead of "extruder"; "horizontal width (and depth) and vertical height" instead of referring to "x, y, z axis". Such details were fundamental changes in our everyday lexicon and proved right not to lose attention simply because the technology was not understood. None of the participants (end users) had seen a 3D printer before, and seven out of nine participants showed high interest, asking questions and staying longer than planned to see the machine actually printing. It appears clear that this approach could be done just because of the low-cost machine itself; other industrial machines of the same technology could be not so accessible, light and transportable. In fact, it was crucial to put the WASP on the table, as it appeared simple and not too "technological".

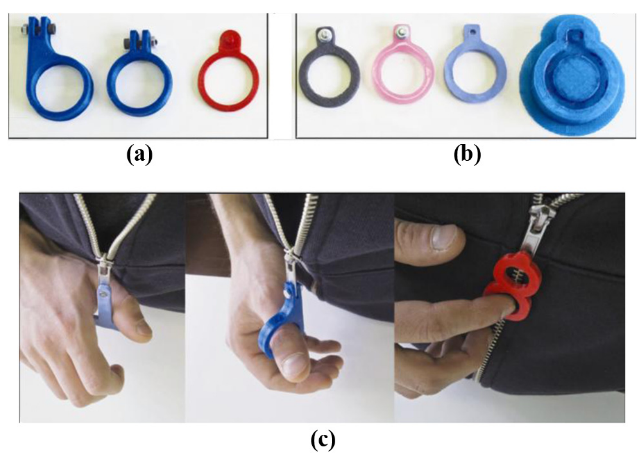
At this stage, we started a brief co-generative exercise focusing on the reference product zip-aid. OTs, designers and end users worked together to personalise the device. This aid was selected because of its print rapidity (that takes around 20 minutes). In this way, the whole process (introduction to Occupational Therapy, introduction to 3DP and brief co-generative exercise) was developed during the same day and also in the same location. From the design output, some variables were analyzed and explored (see next paragraph and Figure 8 for further details). While the product architecture remained the same for every end user (when compared with the reference product), other variables like colour, dimensions, geometry, proportions and connections were changed by and for each end user. Some examples are visible in Figure 8. Here are following some conclusions. The material choice is too small; some end users reported the need of a softer and more flexible material in comparison with PLA. We tried with thermoplastic polyurethane (TPU), but the result was still too rigid. We solved the problem using the 3DP to build a mould for casting silicon (in Figure 6b); the need raised from the user's perspective, was confirmed by the OTs and the suggested technique was determined by the designers' experience. In our opinion, the activation stage was a first meaningful moment of teamwork and community creation thanks to the technology and the cross-disciplinary team. It helped from the very beginning to show the role of each actor and to identify each specific expertise.

Results of the generative session

During this session, as anticipated before, we developed one product for each participant. In detail: toothpaste squeezer, vegetable holder, various zip aids, assistive devices for using a mouse, cutting board aid, medicine bottle opener; all products are visible in Figure 7. These ideas of products rose thanks to the participants' self-observation that took place between the activation stage and the generative session, and thanks to the communication between different stakeholders during the first phase of the co-design process: the *ideation phase*. Here are following the results from the co-design and co-production stages (they are often merged). Particular attention is given to the obtained artefacts.

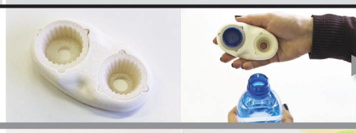
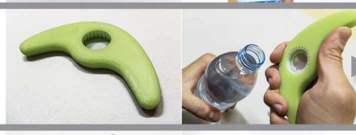
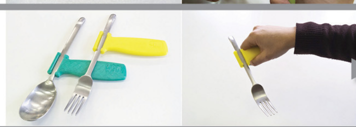
Final products were eight instead of nine because one participant had a need specifically linked with flexible materials such as textiles, making 3DP unsuitable. Much more ideas were raised, and were rapidly prototyped and tested, but here we decided to focus on the ones that from prototypes became final products. Problems occurred when objects needed were too big, too small or too detailed. It was difficult at the beginning to explain to the actors all limitations and advantages of the technology, especially when linked with technical solutions. Another limit that was raised concerned the material: often this polymeric material (PLA) was

Figure 6 Results of the first co-design session on zip aids



Notes: (a) Zips in PLA; (b) zips in silicon, with mould in PLA; (c) gestures; modifications are obtained thanks to a collective design and are different for each user. See also Figure. 8

Figure 7 Output products: specific devices performed by and for each end user, together with the whole team

Name	Product	Description
v.		Bottle and other jar opener
s.		Bottle opener
m.		Piece of cutlery holder
l.		Cutting board aid
mp.		Mouse aid
r.		Zip opener
a.		Zip opener mold
v.		Toothpaste squeezer

perceived as poor, cheap and not resistant enough; on the other hand, the availability, grand amount of bright colours and its light weight were appreciated.

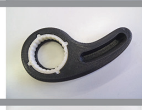
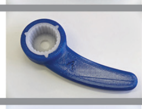
The iterative co-design stage was mainly focused on functional aspects and helped all the involved actors to discover or better understand real needs in terms of shapes, dimensions, gestures, etc. After the *ideation phase*, were main ideas coming from the end user were listed, and the first design was collectively developed, there was the *prototyping phase* finally followed by the *test phase* on the 3DP prototypes. In each phase of the iterative process (*ideation–prototyping–test*), each actor played a different and fundamental role. For example, during *ideation*, a central role was given to end users because of their deep knowledge about their own daily condition. During the same phase, designers were sustaining the process using tools and methods such as brainstorming, sketching and rapid materializations of small mock-ups, while OTs were sharing more technical insights pointing out clearly pros and cons of different solutions in terms of safety for articulations.

The *prototyping phase* was lead by designers because of their prototyping skills, particularly related in this case with 3DP and virtual modelling; as mentioned also OT and end users were participating during this phase and demonstrated enthusiasm and curiosity but adopted a mainly observing role due to lack of technical knowledge on 3DP. A central role was adopted by OTs during the *test phase* together with end users: in fact end users sometimes expressed appreciation for specific prototypes that were not suitable according to OTs who were able to provide a solid vision of possible articulation damages at a later stage. Thanks to this interaction between actors some prototypes apparently good were discarded to limit damages in time. During this *testing phase*, the designer had an observing role, due to lack of specific knowledge and experience about the disease and its specific assistive devices. The second stage of the generative session, the co-production stage, was mainly developed by end users and designers, both focused on the optimization of the product, under the aesthetical and the production point of views. These roles were neither strictly nor explicitly defined; thus, we observed that naturally each different actor covered a leading role during one stage, continuing to participate during all the other stages. Often at the end of the whole co-design process actors expressed the fascination for other actors' skills and sometimes actors also expressed the desire to learn more about specific issues (i.e. end users about 3DP, designers about occupational therapy, etc.). Probably also the presence of the researcher as a facilitator helped to enhance the sense of community and the possibility for everyone to participate.

Particular attention should be given to the exercises involved in a personalized redesign of the two reference products developed by XXX. In fact, while products in Figure 7 are mainly unique expressions able to solve a specific need and were developed involving just one team, the work made on the reference products was iterated by each team in sequential way. The goal was indeed, starting from the same design (the reference product) to iterate as much as possible thanks to the opinion and participation of all teams. This iteration led to the creation of a small series of unique versions of the same starting idea (the reference product). As shown in Figure 8, bottle openers and zip aids were developed in nine unique ways thanks to different combinations of shape, colour, dimension, geometry, etc. Thanks to the analysis of these artefacts, the difference between modifications appeared clearly: some were specifically related to the participant (for example: favourite colour, dimension of the hand, orientation of the handle), while other modifications made by one user were suddenly improving the product in a way that was helping everybody and thus sequentially adopted in all variations.

One example of this kind of variation can be further described. The first end user (S.) found the bottle opener already good enough, and no changes were made on the reference design. The second end user (MG.) could not open any bottles because the action required too much strength, and the grip between device and lid was not sufficient. As shown in Figure 9(a), the grip part in the reference product was only geometrically different (a small corrugation in the surface), obtained directly with the 3DP process. Thanks to the test made by MG., it was clear the design needed some improvements. The OT proposed to use an "anti-slippery"

Figure 8 Iterations on bottle opener and zip aid

Name	Bottle opener	Zip aid	Changes
s.			• No change *(bottle opener)* • New shape in order to use two fingers *(zip aid)*
mg.			• New shape in order to use one hand *(bottle opener)* • Bigger dimension *(zip aid)*
n.			• New shape in order to use one hand *(bottle opener)* • New *softer* material *(zip aid)*
a.			• New shape in order to use one hand *(bottle opener)* • New *softer* material *(zip aid)*
l.			• Thinner handles in order to improve the grasp *(bottle opener)* • No change *(zip aid)*
r.			• Thinner handles in order to improve the grasp *(bottle opener)* • Rotation of the axis of 90° in order to use the thumb *(zip aid)*
mp.			• New shape in order to use one hand *(bottle opener)* • New shape *(zip aid)*
m.			• New shape in order to use one hand *(bottle opener)* • New shape *(zip aid)*
v.			• New shape in order to use it also for other jars *(bottle opener)* • New *softer* material *(zip aid)*

Note: The two reference products initially designed by XXX were replicated by and for each end user

Figure 9 Detail of the bottle opener

(a) (b)

Notes: (a) Grip design in the Reference product; (b) grip design (in TPU) made thanks to the Co-design stage

material and the designer explored coherent options obtainable with 3D printers. The solution was to print an inner ring, see Figure 9(b), with the same corrugated surface, in TPU. This ring is printed separately from the main body and than inserted without the need for glue or other connections. A similar example can also be seen in Figure 6 concerning the other reference product, zip-aid.

These collective experiments allowed us to:

- Underline the importance of a cross-functional team thanks to which not obvious solutions were found.
- Highlight the importance of a collective and iterative co-design experience to achieve modifications on two levels: personalized features and modifications that represent incremental innovations (meaning with this that some modification become the *new reference item*).

See how the technology (being rapid, low-cost and accessible) really facilitates the continuous materialization of ideas into prototypes. This ease of having functional prototypes sustained and accelerated the decisional process, that in this product development process is often difficult and can eventually lead to weak choices.

Discussion

The +TUO pilot study provided to participants with RDs, designers, OTs and researchers a real opportunity for social interaction and communication. Furthermore the study showed the potential of co-design and co-production for personalized assistive devices using an AM technology in its low-cost, entry-level user version. +TUO pilot study proved that the adoption of low-cost 3DP FDM technologies in such a context is feasible and greatly advantageous, though some limitations were identified.

Interesting conclusions of the study can be grouped under two main categories:

1. The first side focuses on *technological issues*, such as the role of 3DP technology in +TUO contexts and the main pros and cons linked to differences between the low-cost version and the industrial ones.
2. The second side focuses on *social and user interaction dynamics*, mainly represented by the +TUO process, with core in the generative session.

First, *under the technology-oriented point of view*, we can state as in addition to already validated advantages of low-cost 3DP (as described in the *State of the Art*), we found other main values that are mainly related with low-cost 3DP usability and accessibility. This new low-cost and open-course version of AM technologies encourages the process of "making together" thanks to its simplicity, small dimensions and low costs. Furthermore, low-cost 3DP are usually installed in friendly contexts as, in our case XXX, Fab Labs or other kind of makerspaces, this collocation also encourages the process of "making together" and the creation of small communities around it. In +TUO, we adopted a specific low-cost machine, WASP Project, that presents also other additional values related with its specific design, as verified by users' comments: for example, the use of natural material (wood) for the shell of the printer recalls other well-known contexts, the process is intuitive in its fundamental principles, the printing plate is accessible and fully visible, simplifying the comprehension; the wooden frame also hides all the electronic components that might appear as too complex; the rapidity in going from idea generation to production start, avoids misunderstandings during the process.

The previously described advantages are rather general and applicable to different contexts. In the +TUO context, we see some additional and specific advantages:

- *Possibility for End Users with RDs to actively participate thanks to low physical effort*: Patients with RDs cannot apply those traditional prototyping and low-volume manufacturing technologies that require high manual skills. In general, we found that the use of 3DP is simpler under the physical point of view because only few passages require manual strength (the change of filament reel, the extraction of the piece from the printing board). In this way, the participation during the production process does not enhance the distance or deepen a sense of exclusion of end users from designers and OTs. Furthermore, with simplified software or with the transferring of technical knowledge, it could be possible also for end users to reach a higher level of involvement.
- *Same sensorial and mechanical qualities between prototype and final product*: In a traditional product development, the prototype is different (in shape, colours, materials but also geometry, weight, etc.) from the final product. In +TUO, the difference between the final product and the prototype is limited to small aesthetical details: in this study, dirty mock-ups, prototypes and final products are mainly the same in terms of production technology and materials. This means that when the *test phase* is developed the uncertainty related with the success of the end result is almost not existent.
- *Fast delivery period of the assistive device*: Traditionally, in acquisition processes, especially when dealing with a selection of a customized mass industrialized items, the time that goes from the definition of features to the delivery can be quite long. In +TUO, thanks to the use of RM 3DP, it was possible to deliver a final product within a few hours after defining the product's features.
- *New aesthetics and functions linked with material and geometrical possibilities*: Products created with such a technology have a strong aesthetical character and appearance. The material choice is limited to a small selection, in this project, mainly PLA was used (it is easier to control during the printing, it is cheaper and easier to be found in different colours). Though from the participants' feedback, we found that this polymeric material can be perceived as cheap and not durable enough. On the other hand, it is a very light material, and, thanks to a careful design of the filling geometry and density, a good relation between weight and resistance was reached. The lightweight is of great value in the scenario of RDs and it is linked to the technology itself, which allows producing geometries previously impossible (i.e. filling patterns were before impossible to be made). The bottle opener for example is solid enough to carry out its function and still almost empty on the inside: a small grid constitutes the structure, keeping the final weight very low. An arguable disadvantage of the low-cost technology is that it is clearly less accurate than industrial ones (both AM technologies and traditional technologies, such as injection moulding). Examples are the visible layers on the finished product. A reduction of this imperfection can be obtained mainly through several iterations (trial and error approach, iterated by the Designers), but they cannot be completely avoided. Though, if, on one hand, this new aesthetic can be perceived as "defective", on the other, it can be interpreted as something characteristic and thus re-evaluated. These small imperfections and the high level of personalization can lead to unique products, possibly characterized by a greater attachment between user and product. Last advantage of +TUO final products is that they are made with the same process and material as the testing prototypes: in this way, we never face a differences between the two, especially under the functional and structural point of view.
- *Transition from the customization to the personalization approach*: At this stage of the research, end users could define the needed products starting from zero. This allowed the team to achieve completely unique products, where each feature was a free choice (with the exception of the technology used to produce them). In this context, we state that the co-design with 3DP technology allows to go beyond customization to product personalization.

Various disadvantages have been described in the paper, especially linked with the material perception and the medium–high level of technical skills required to actively take part during the printing process. In addition to these, another important fact needs to be underlined: in the +TUO pilot project, we decided arbitrarily to focus just on the 3DP technology. In future works, we foresee the possibility of printing just those parts or components that are subject to *contextual* modifications (for example, in the reference product bottle opener the handle) while other parts, more *predictable*, can be produced with more traditional technologies (for example, the rubber insert can be an extruded profile suitable for different kind of bottles).

Under the *user-oriented point of view*, we can observe, as in +TUO pilot study, that a small community composed by all our actors was created, thanks to the active participation of everyone involved (end users, designers, OTs and researchers). This community-based approach is, in our perception, one of the variables that made +TUO feasible and repeatable in the future in other places and with other unknown actors. The possibility of adopting a "making together" approach, that was rapid and local, was sustained by the choice for low-cost, entry-level, open-source FDM 3D printers, in comparison with more industrial or high cost versions. With this approach, the presence of each actor was meaningful, and everybody found his/her role during different stages in a spontaneous and natural way. Furthermore, as shown some specific choices (functional, aesthetical, technical, etc.) were difficult – if not impossible – without the presence of a cross-functional team. With focus on the end user, it is important to note that +TUO and particularly the generative process represents a meaningful activity both under the occupational point of view (+TUO is already an occupation, social and creative) and under the assistive devices design point of view. To personalize a product provokes on users a higher emotional link with it, adding value and even opening chances for innovative applications (Mugge *et al.*, 2009). In fact, as seen in the state-of-the-art section, we have shown that if end users' opinions are considered during the selection of the device (or in this case its creation) a reduced degree of non-use can be achieved (Wessels *et al.*, 2003). End users were then asked about the option of sharing the emerged ideas in the future, within the community of people with RDs: none of them showed uncertainties and all of them offered their personal help on engaging and explaining to other *new actors* the work done till that point.

Future studies will focus on the next iterations of the physical outputs of the + TUO pilot study. These studies will investigate the possibility for sharing the products with communities based in other regions and other contexts. Explorations will focus on how to communicate the project to different contexts and users easily (e.g. with different machines/technologies to people with different needs/pathologies). These explorations will be based on the same insights from maker, open-source communities and DIY (Dalton *et al.*, 2014).

Conclusions and future works

The goal of the + TUO pilot study was to explore the advantages and limitations of introducing low-cost 3DP to co-design and co-produce assistive devices, together with and for persons with RDs. The main focus was the creation and validation of the + TUO design process (Table I), together with the interpretation of the first physical outputs obtained. The adoption of low-cost 3DP in such a context was positive both from the physical and the occupational points of view. In fact the collective generative process supported by the technology itself and investigated with + TUO, helped end users to become part of a small community, to share ideas, problems and to materialize personalized solutions in a rapid dynamic and local environment. Different stakeholders were involved in + TUO, and we were able to formalize with them explicitly *how* and *why* their personal skills and expertise, and the collaborative dynamic of the project, were helpful to reach functional solutions. In this context, a real example of social inclusion also during the manufacturing process was explored. The end user is not giving input for a new and/or personalized design anymore, but is taking part in the whole process, becoming a key player in defining when a prototype can become a final product.

Finally we have highlighted some aspects that need a deeper investigation. Further explorations could be focused on the understanding of: what is the new material experience related with 3D printed products? Can we design processes able to realize different finishing on 3DP parts (to change mechanical and aesthetical aspects)? How can we design devices that are able to change thanks to the context of realization and to the specific users' needs? How can we transfer the knowledge gained from this experience to other contexts and users? Also, follow-up and checking the end users' satisfactions of the obtained assistive devices are planned. In addition, it is important to highlight that no economical considerations were investigated in this study. A cost analysis is going to be part of planned future studies where the main focus will be moving from designing and testing the +TUO feasibility to its scale-up, to achieve small series of unique assistive devices.

To conclude: +TUO pilot study explored a new application for the 3DP low-cost and entry-level technology and the reasons supporting this choice. Starting from these first results, we can build new scenarios, where + TUO can be scaled-up and replicated in different places, for example with the support of solid and diffused networks such as Fab Lab, able to reach and involve different and unknown end users. In our vision, this process does not have to be limited to 3DP, but to an entire set of technologies that with low-cost, entry-level and open-source 3DP share advantages related with the production flexibility and the accessibility (i.e. laser cutters and CNC machines). To make this scenario feasible, it is also important to deal also with the *openness* of our product designs, meaning with this not only the easy or free availability of projects but also the facility of changes generation and the possibility to build on someone else's contribution to reach a real series of unique products able to satisfy both common needs, shared by an entire community and specific and unique needs peculiar of each single user.

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