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A parametric 3D printed assistive device for people with cerebral palsy – assessment of outcomes and comparison with a commercial counterpart

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ABSTRACT

This paper presents the use of a parametric design platform and 3D printing to create personalized assistive devices (ADs) for individuals with cerebral palsy, specifically a fork/spoon holder. Five subjects participated in the study, each receiving a customized device to fit their dominant hand, and they tested both the 3D printed device and a commercially available one. The devices were evaluated based on functionality and satisfaction using two standard clinical questionnaires (IPPA and QUEST 2.0). The results showed that neither the 3D printed nor the commercial device provided substantial benefits, but the questionnaires provided valuable feedback on areas for improvement. The study highlights the need for highly personalized solutions in ADs, which could be addressed by 3D printing. A configurator for generating production files from a parametric model could facilitate personalization, but a large number of model versions should be available to meet individual needs. Future research could explore clinical evaluations and guide the development of efficient and effective frameworks for digital fabrication in terms of clinically feasible AD model sourcing.

Implication for rehabilitation

- * 3D printing can be a method of creating assistive devices with dimensions fitting the user.
- * Standard questionnaires for measuring the effectiveness and satisfaction may efficiently identify shortcomings and suggest improvements.
- * Each person may have individual requirements, which calls for a large database of solutions in order to meet the person's needs.

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KEYWORDS

assistive technology; digital fabrication; occupational therapy; rehabilitation

Introduction

Assistive devices (AD) are supposed to help people with disabilities in participating in daily living. Typical examples are devices for increasing autonomy during meals. Most prescribable ADs are mass produced. They are indexed and ISO 9999 classified (2011) in gateways like the EASTIN database (www.eastin.eu) (Andrich, 2011; Gower et al., 2012). However, standardized items, designed for the majority groups, may not fit all (Federici & Borsci, 2016; Scherer & Craddock, 2002).

Healthcare professionals may make or modify AD to fit the individual needs. This is often the case in spinal units (Bromley, 2006). Some carers may be creative and employ their artisan skills to produce personalized devices (Gibson et al., 2019). Comparison is difficult as the provider's skills, methods, and ingenuity are difficult to standardize, replicate, and compare with mainstream AD provision.

Digital Fabrication is a design and production process in which computer-controlled machinery builds a physical object from a three-dimensional (3D) model. The process starts by creating a 3D representation of a physical object in a computer aided design (CAD) program.

A popular digital fabrication tool, the 3D printer, extrudes a fused plastic filament onto a build plate and

then on top of previously extruded material in order to gradually build up the object. The CAD generates a stereolithography (STL) file that is then converted by a process called slicing to a "g-code" file, which controls the 3D printing process. This is a very economical digital fabrication method because there are free versions of the software and the 3D printing machines themselves have become available to the public at affordable prices. Iterations can be made, and the models can be shared worldwide via the internet. Many 3D models are released under open-source licenses, free to copy, modify, and use (as long as the original author is cited) by the do-it-yourself movements nowadays known as makers.

There are several sites like Thingiverse (www.thingiverse.com) containing 3D models ready to print. Although Thingiverse with 2 million models (mid-2021 data) are among the largest repositories, it contains relatively few ADs. These are ad-hoc classified (not using ISO classification) and thus difficult to find by clinicians. Most rehabilitation research using 3D printing is focused on orthotics and prosthetics (Schwartz et al., 2020). The latter often demonstrate the possibility of digital fabrication to enhance comfort, fit, and solve special individual issues. Finding or designing AD for digital fabrication requires specific knowledge

and may be a daunting task for most people typically involved in the AD provision.

One of the critical issues for employing digital fabrication in clinical use is the lack of best practice descriptions (Schwartz et al., 2020; Thorsen et al., 2019). There is a need to establish efficient workflows that can be pragmatically implemented for 3D printing of assistive devices, preferably compatible with the existing paradigm of AD supply and prescription. This study aims to contribute by describing and evaluating a possible procedure based on customizing existing designs through a dedicated internet service.

Methods

The present study documents some results of a larger project called Grippos, which aimed to test an online configurator platform for creating personalized 3D printed assistive devices for people with neurological disorders (Parametric online configurator, 2022).

Our institution's task within the Grippos project was to test the feasibility of the platform for fitting the ADs to adults with cerebral palsy (CP), a chronic condition often involving arm and hand impairments. We added questionnaires and comparison with an existing device to the project task to obtain empirical data.

The staff involved in the AD creation process were the authors: MR (physician) – patient selection, anthropometric measurements, and model configuration; DC (Occupational Therapist – OT) – fitting the AD with the participants as well as assisting in using the AD during mealtimes, administering questionnaires, and collecting data; RT (engineer) – 3D printing devices.

The workflow is illustrated in Figure 1.

Participants

Participants were a convenience sample of people with cerebral palsy, having impairments of the upper limbs. All lived in the residential nursing care of our rehabilitation center. All interactions with the participants were in accordance with current clinical practice of standard AD provision and compliant with the rules of the local ethics commission. All participants pro-

vided written informed consent prior to enrollment in the study.

Outcome measures

Effectiveness and satisfaction of the ADs were evaluated using, respectively, the Individually Prioritised Problem Assessment (IPPA) (Wessels et al., 2002) and the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) (Demers et al., 2002). In the first part of the IPPA, the participating user is asked to list up to seven of the most important issues the AD is supposed to solve for him or her. Each issue is given a score of importance and a score of difficulty from 1 (very little) to 5 (very much). The mean product of importance and difficulty is the partial IPPA score before AD provision. Once the participant has used the AD, he/she is asked to score the difficulties that he/she experienced, when using the AD for each of the same items. The importance scores are kept unchanged, and the second partial IPPA score is again computed as the mean of the importance scores times difficulty scores. Thus, the IPPA score is a change score ranging from -20 to 20. A negative score indicates that the AD worsens the problems, whereas a positive score means that the AD facilitates the activities. It measures how the AD meets the user requirements or expectations. The user can additionally provide a general comment to the score.

Regarding satisfaction, we employed the device subscale of QUEST in which the participant is asked to score, from 1 (very little) to 5 (very much), each of eight satisfaction items (Q1 – Dimensions, Q2 – Weight, Q3 – Adjustments, Q4 – Safety, Q5 – Durability, Q6 – Ease of use, Q7 – Comfort, and Q8 – Effectiveness). The QUEST score is the mean. An item scoring below 3 indicates a problematic issue. Each of the eight items can be accompanied by a specific comment explaining the problem.

Results from the IPPA and QUEST questionnaires were paraphrased as general statements to allow grouping in common issue categories.

AD provision and evaluation

The Grippos platform features two models of assistive devices (the ConfAD and a cup holder) that can be configured to the user's anthropometric measurements. The ConfAD is config-

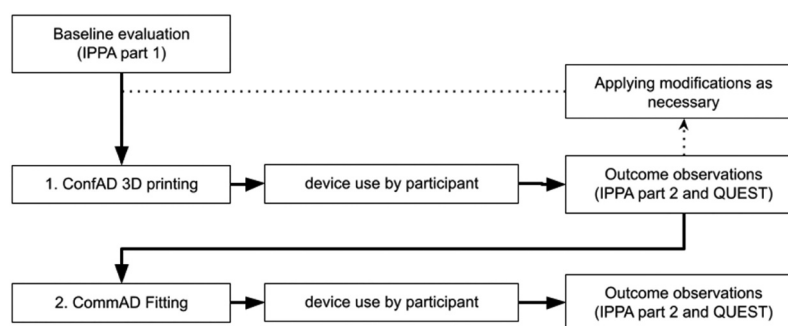


Figure 1. Schematic description of the stages of the study.

ured by inserting three measures: breadth and thickness of the palm together with the desired width of the device, see [Figure 2](#) and reference (Parametric online configurator, 2022). An STL file can be downloaded, and the device can be fabricated on a desktop 3D printer following detailed instructions provided on the platform.

In a plenary session, after provisional testing of both solutions, it was decided that the cutlery handling was the most appropriate solution for the participants. Thus, we selected the (fork/spoon) holder (ConfAD) and a commercial device (CommAD) with similar functions for evaluation and comparison. The ConfAD is designed as a handle in which a spoon or a fork can be inserted, uniting a so-called “buildup handle” with a strap around the hand (cuff), see [Figure 2](#). It falls into the ISO 9999-15.09 classification of “Assistive products for eating and drinking” (2011).

In the same category (ISO 15.09.13) we selected a customizable commercial counterpart (CommAD) as a reference. This is a two-part concept where one part is attached to the hand using a strap system and the other part is one of several “magnetized” objects (knife, spoon, fork, etc.) that can attach to the first part (The Tactee Cutlery System® – www.tactee.it) (Veneziano et al., 2015). The system was pragmatically selected as readily available yet flexible commercially available ADs resembling the characteristics of the ConfAD as it is fixed to the hand in a similar manner with a cuff to which the tool could be attached. These tools (fork, knife, spoon, and more) were part of the CommAD kit, whereas the ConfAD was designed to allow any flatware supplied by the hospital food service.

For each participant, three hand measurements were taken using a caliper: the palm width (second to fifth metacarpal head), the thickness (at the third metacarpal head), and the space between the index and thumb fold (see [Figure 2](#)). These were inserted into the online platform by the physician (MR). Then, the STL was downloaded and sent to the engineer (RT), who would proceed with the 3D printing on our institution’s 3D printer (Ultimaker S5, Ultimaker BV, The Netherlands, www.ultimaker.com). This is a dual extrusion high-end entry level fused deposition modeling machine. This type of machine works by extruding layers of melted material in a certain path on a build plate or on top of previously extruded material. An open-source software called Cura (Ultimaker Cura 4.11, Ultimaker BV, The Netherlands, www.ultimaker.com) was used for slicing (converting the STL to g-code for the 3D printing process). We used thermoplastic polyurethane

(TPU95), a smooth rubber-like food, and dishwasher safe material, which is generally considered suited for objects involving skin contact.

The OT administered the first part of the IPPA questionnaire (baseline assessment) as described in the IPPA questionnaire. Then, each participant had a ConfAD made and the OT fitted the ConfAD, discussed the proper use with each participant, and assisted while they were using the tool for eating during lunch. After the participant had gained experience with the use, the therapist administered the QUEST and the second part of the IPPA questionnaire.

At a subsequent lunch, in which the OT was assisting, the participant had the CommAD fitted and the use was explained by the OT. As with the ConfAD, the participant used the device for eating, whereafter the QUEST and second part of IPPA were administered by the OT. Both times, the participant was encouraged to try to put on/take off the device as well as experimenting with the best use.

Results

Five subjects participated in the study: four were affected by cerebral palsy and one by non-progressive congenital ataxia (see [Table 1](#)).

Digital AD manufacturing

The ConfAD was made using the settings given by the configurator: 0.4-mm nozzle and default Cura Ultimaker White TPU 95A fine profile with 25% infill, 0.1 mm layer height, 0.76 mm wall thickness, and no support (for full specifications, please see the settings in the freely downloadable software). The production time was 6 h (± 30 min).

The configuration platform was still in its development phase, and there was some unclear terminology in fitting instructions. Design terminology rather than medical terminology leads to misunderstandings of dimensional measures. The width of the palm was described as the length, as this was referring to the length of the device and not the anatomical measurement. Furthermore, this involved an uncertainty about whether a gap between hand size and device size should be added to the measurements.

There were scaling and other technical issues (non-manifold model) of the STL files that had to be repaired. For these reasons, measurement and production processes had to

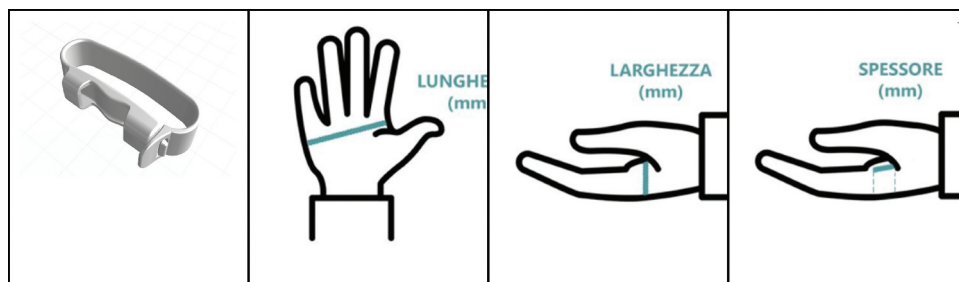


Figure 2. The 3D model of the configurable AD (ConfAD) and the measurement instructions. The cuff can be opened and closed to fix the handle to the hand using a hook located on the ulnar side.

Table 1. The IPPA/QUEST scores for the participants. CP – Cerebral palsy, NPCA – Non-progressive congenital ataxia. ConfAD – 3D printed configurable assistive device, CommAD – Commercial assistive device.

ID	Age	Disorder	IPPA ConfAD	IPPA CommAD	QUEST ConfAD	QUEST CommAD
ID1	45	CP	1.0	0	2.8	2.8
ID2	47	NPCA	-4.3	2.0	2.6	4
ID3	48	CP	-0.5	-0.5	3.6	3.1
ID4	48	CP	0.0	-1.5	2.6	2.0
ID5	45	CP	0.0	0.0	3.1	2.6
<i>Mean</i>	<i>47</i>	<i>CP</i>	<i>-0.8</i>	<i>0.0</i>	<i>2.9</i>	<i>2.9</i>

be repeated in three of the five devices before they could actually be used by the participants.

Outcomes

Common problematic issues prioritized by the participants at the IPPA interview were paraphrased as follows: need to improve the grasp of the tool; increase independence, both within and outside the care unit; self-esteem; and the problem of picking up the last part of the meal. Subject ID2 was only eating with a spoon as her clinical condition implied homogenized food only. She, as most adult spoon users, would normally use a clenched grip, thumb and middle finger pinch, to hold the spoon and not a transverse palmar grasp as the ConfAD would require (Figure 3).

Participants ID2, ID3, and ID4 mentioned spoon and fork handling as the principal problems, whereas ID1 and ID5 handled these tools satisfactorily, but wanted to use a knife during meals. The IPPA and QUEST scores are listed in Table 1.

As of Table 1, the CommAD only proved convenient for ID2 who was the only person to score it positively on IPPA despite mentioning issues with usability and effectiveness in the QUEST evaluation. In general, neither ConfAD nor CommAD was adequate as ADs for spoon use since they did not match the participants' needs and shared many issues according to QUEST items Q1–Q8. Most participants gave both the ConfAD and the CommAD a low score (<3) on the QUEST and commented on a number of issues that are summarized below:

The dimension (Q1) was a problem for all participants. Though the size of both ADs was matching their hands, there were problems with the shape. The ConfAD was too thick for three participants whereas the CommAD was of excessive size for 4 participants. The weight (Q2) of ConfAD was acceptable by all. The CommAD, which was more than twice the weight, was perceived as too heavy by all. The ConfAD had adjustment issues (Q3); the closing mechanism

could not be operated by any participant. Inserting and maintaining the cutlery in position was problematic. CommAD also had issues with donning (putting it onto the hand) and all participants needed help in donning/doffing. Safety (Q4) and Durability (Q5) were not commented on. Most importantly, none of the devices were perceived as apt for purpose (Q6) because they were difficult to put on and did not match the users' impairment problem. In particular, the CommAD required assistance to fit the strapping system, which defeated the objective of providing independence for the user. The ConfAD had problems related to rigidity and sharp corners (a problem that could be solved by adequate post processing after 3D printing). One participant suggested adding a soft padding to the ConfAD to improve comfort. Only two participants felt that the CommAD was comfortable (Q7).

The most important issue was the effectiveness (Q8). Neither ConfAD nor the CommAD was useful for eating except for participant ID2 who had some advantages and disadvantages with the CommAD. A common disadvantage of both devices was that they imposed a palmar grip. This grip caused her to dip her hand into the soup when picking up the food from the plate.

To summarize, neither of these two solutions met functional requirements for our participants.

Discussion

We tested a workflow for personalized AD provision using an experimental platform of AD models that could be configured to fit the user's hands and then 3D printed (Parametric online configurator, 2022). In the following, we discuss the shortcomings of this pilot study and suggestions for further investigations.

3D printing implications

Digital fabrication such as 3D printing opens new possibilities for providing assistive devices in a more flexible way, taking into



Figure 3. A participant (ID2) eating with the ConfAD (a) and with the CommAD (b).

account personal needs. Promoters of 3D printing often claim that it is inexpensive (Schwartz et al., 2020). However, it must be acknowledged that it takes a long time for the machine to build each device, it is difficult to get perfect solid results and requires experienced persons to set up and supervise. Hence, it calls for a substantial amount of man-machine time to get one specialized result. Though commercial build-up handles are available from 5€ (foam tube style) to 300€ (CommAD), digital fabrication gives the possibility of iterating the design until it fits the user by addressing matching issues (Federici & Borsci, 2016; Scherer & Craddock, 2002). However, the fitting process needed refinement as evinced by the QUEST and the design issues mentioned in “Results” is just one example that shows the importance of a tight collaboration between AT provider and designer in which a common language must be established. Technical issues have arisen calling for engineering competencies to solve the issue. The advantage of digital fabrication lies in its ability to facilitate small iterations in the design, which can be made to accommodate technical solutions and adjustments to size. The issues of the 3D printed CommAD, as evinced by the QUEST comments, like the shape and rigidity depends both on the original design, but also on the printing (slicing) settings and furthermore by eventually post-processing (cutting away edges, reheating, reshaping, etc.) the objects. As the final device can be improved via intervening on these factors, they also contribute to the complexity of the fabrication process and its documentation requirements. Further studies could look into adequate strategies for tweaking these factors to maximize user satisfaction.

Appropriateness of the devices

Two different AD solutions were available on the online platform: a cup holder and a spoon/fork holder (ConfAD). Being a pragmatic study, having to choose from the two solutions, the latter was chosen as most appropriate for the participants, though this solution is more typically used by people with spinal cord injury rather than people with CP (Bromley, 2006). Besides that, the cup holder was not appropriate for our participants and the design had technical issues. Normally, the participants’ needs would dictate which AD to propose and not vice versa. The results of IPPA and QUEST showed that the devices were not appropriate. It may be considered that, having lifelong chronic conditions, participants were accustomed to their situation and, on one hand, did not have a particular need for AD nor an initial request for being autonomous at eating. Eating style, methods, and habits were very individual. Both devices were using a concept imposing the palmar grip for holding cutlery that did not match the user’s normal eating posture (e.g. the clenched grip). The problem of cutlery handling for people with CP may be more related to a combination of impaired coordination and control of proximal joints and not just the problem of holding the cutlery. Besides these conceptual issues, the ConfAD had issues with retaining the spoon; this would require modification of the design concept itself. Comfort problems could be solved by user-specific shaping of the handle.

Thus, configuring an AD by size only, may be too simplistic and adding the possibility of a conceptual redesign (CAD design)

to the online platform may expand the versatility but may also increase complexity calling for specific design skills of the platform users. Alternatively, one could envisage a large searchable database of different ADs for different needs, from which an individual configurable solution could be selected to match the user, as in the case of commercial ADs that can be found in the EASTIN database (Andrich, 2011; Gower et al., 2012).

Evaluation methods

Identifying needs, shortcomings, and possible improvements is essential for efficient and effective AD provision. The questionnaires used in this study were suitable to that end, but rarely used in the context of 3D printing (Schwartz et al., 2020; Thorsen et al., 2019). They identified issues in the AD design and engaged the users in proposing improvements. We found it advantageous and practical to actively involve people with cerebral palsy in the evaluation and exploration of their needs and abilities. Particularly, the possibility in the questionnaire of adding comments to the ratings appeared to give a sense of empowerment to the participants, besides being potentially useful for design iterations. An open question remains as to how much a person should use a device to gain sufficient experience for providing meaningful responses to the effectiveness and satisfaction of the AD. In our case, devices were used only once as questionnaires revealed both devices to be inappropriate for continuous use, though we cannot exclude that longer training would result in different outcomes.

Clinical feasibility

As a research project, the provision model was feasible because the technical part (3D printing etc.) was fully taken care of by the engineer and evaluations could fit into the OTs work plan. The time spent on fabrication would be accounted for in clinical practice and would add to the cost of AD provision. In some contexts, the added time may not be compatible with existing public healthcare provision plans. However, 3D printing may provide the client with a highly personalized solution that cannot be found elsewhere.

The involvement of the people with disability in a collaboration structured around the evaluations was seen as constructive. Ideas from both parties regarding how to improve the AD to be useful and satisfactory emerged from the QUEST comments and opens up for the possibility of end-users to participate actively in their personal device production (Thorsen et al., 2023). The therapeutic effect of “doing” together is acknowledged as an important component in OT activity (Piergrossi, 2013). Besides the functional value of the AD, there may therefore be important rehabilitation aspects that should be investigated further.

Digital fabrication such as 3D printing may be feasible, but a cost-benefit analysis with respect to buying standardized ADs is warranted. Is it compatible with current clinical practice? What are the possible therapeutic benefits? How can a viable database of reference designs be established? Will it foster innovations of AD devices and provision paradigms? Finally, how much does involvement in AD design empower the users as a therapeutic benefit?

Conclusion

We tested an online platform for generating parametric models for 3D printing assistive devices. This allows for a non-designer, e.g. a physician, to produce the design file matching anthropometric data of the client, without having to learn to use a CAD program first. However, this approach is complex and resource consuming compared to the provision of off-the-shelf commercial assistive devices.

Applying a proposed AD solution to possible users led to a mismatch between their needs and the solution, a problem also seen in mass-produced devices. The functionality and user satisfaction were similar to a conceptually similar commercial device. This could be addressed by increasing the number of possible device models in the configurator to better meet individual needs.

Clinical questionnaires, routinely used for standard AT provision, are instrumental in assessing the devices functionality and shortcomings. Outcome scores can be used to compare functionality and satisfaction of solutions and the comments provided by the users can provide the designer with insight into what actions should be taken to improve the design.

To bring digital fabrication, such as 3D printing, into clinical practice so that clinicians can effectively personalize appropriate ADs, a large selection of models to select from is needed. We must define what kind of configurability or changeability of shape they should have to accommodate typical needs. Finally, the technology should be readily accessible for clinicians.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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