

Clinical and Maker Perspectives on the Design of Assistive Technology with Rapid Prototyping Technologies

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A: The RIT E-NABLE Lab is representative of many maker spaces, including tools like consumer 3D printers. The designs that come from e-NABLE are characterized by bright colors and mechanical simplicity similar to toys and puppet hands, such as this Raptor Reloaded hand.

B: University of Pittsburgh Prosthetists use this state of the art lamination room to build professional prosthetic sockets. The shown prosthetic is the Michelangelo Arm, an advanced myoelectric arm by Ottobock, a prior employer of an attending prosthetist.

Figure 1. We compare the experiences of clinicians and researchers (A) to those of the e-NABLE community (B). One clear contrast is the level of fabrication technology used by both communities, and this impacts the complexity of the produced devices. This is shown by contrasting the products of attending institutions, a Raptor Reloaded Arm from e-NABLE and a Michelangelo Arm from the prosthetic company Ottobock.

ABSTRACT

In this experience report, we describe the experiences of volunteer assistive device designers, clinicians, and human computer interaction and fabrication researchers who met at a summit on Do-It-Yourself Assistive Technology. From the perspectives of these stakeholders, we elucidate significant challenges of introducing rapid prototyping to the design of professional assistive technology, and opportunities for advancing assistive technology. We describe these challenges and opportunities in the context of an emerging gap between clinical and volunteer assistive device design. Whereas clinical process is fully led by the question, “will this do harm”, while volunteers chaotically pursue the lofty goal of providing assistive technology to all. While all stakeholders hold the same core goals, there are many practical limitations to collaboration and development.

Keywords

Assistive technology, clinical practice, clinician, design, do no harm, experience report, prosthetic, prosthetist, prototyping, rapid fabrication, regulation, safety, 3D printing, 3D scanning

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1. INTRODUCTION

3D printed and non-professional assistive technology design has stimulated new questions about the future while presenting unique challenges for collaboration among volunteers and clinicians. What technologies and practices will be appropriate for creating effective and safe assistive devices as rapid prototyping technology becomes ubiquitous? What role should clinicians have when non-professionals can create assistive technology in the home? What assurances can we make that Do-It-Yourself assistive technology (DIY-AT) is safe, and works properly? We address these questions from the perspectives of several stakeholders in the design of rapidly fabricated prosthetic devices (volunteers, clinicians, and technologists).

In this experience report, we document challenges and opportunities with introducing rapid prototyping technologies into the field of assistive technology. These findings are the result of a summit on DIY-AT, focusing on the future of 3D printed prosthetics, such as devices created by the e-NABLE Community of volunteers. The summit brought together: Enable Community Foundation leaders and volunteers (e-NABLErs); human computer interaction/fabrication researchers; rehabilitation scientists and engineers; and clinicians (occupational therapists, orthotists, and prosthetists) (Figure 1). We describe their shared experiences of using rapid prototyping technology such as 3D printers and 3D scanners in the design and life cycle of assistive technology, primarily focusing on upper limb prosthetics.

During the summit, we identified two main perspectives on the introduction of rapid prototyping to assistive technology design. First is the perspective of the clinicians, which revealed an

unmet role in the research, development, and release of open-source and 3D printed devices. Second is the perspective of makers and their role: to create DIY designs that provide a wider population of users access to assistive technology.

Clinicians' concerns centered on their obligation to "do no harm" and whether volunteers can design and support safe devices without the expertise and experience of clinicians. Clinicians also wondered how to safely contribute to DIY devices within the current structure of volunteer organizations. The attending clinicians identified many aspects of their research process that was missing from e-NABLE's practices, and argued that pre-patient device testing and more validation measures would produce improved designs. Clinicians acknowledged the important role of rapid prototyping in their practice: as a tool to create highly customized devices and to advance clinical research.

E-NABLErs, in turn, noted that many of their developments could improve professional practice. For example, DIY-AT can help to provide highly customized and easy to produce terminal devices for standard prosthetics, and has brought inexpensive upper limb prosthetics to children and other underserved populations for whom traditional medical prosthetics are less practical or accessible. These developments, they argue, are the result of a rapid and somewhat chaotic "maker" approach to design. They pointed to successes in creating a wide variety of customized terminal devices and an international impact by supporting people without access to professional prosthetics. They see their role as filling in the gaps where clinicians cannot support all users, all the time.

While this summit brought together a large group of diverse perspectives and stakeholders in the design of assistive technology, we limit the scope of this report to perspectives of professionals and experienced volunteers who primarily create prosthetic devices. The focus of many of the summit attendees is in the design of upper limb prosthetic devices, or other assistive technology for people with limb differences, such as gripping aids or orthotics. Further, we note that none of the authors of this paper use prosthetic devices. We limit the scope of this report to our multi-stakeholder perspective on the experience of designing assistive technology and the rapid prototyping technologies that support and disrupt the design process. We do not focus on the utility of prosthetics or any other assistive technology.

2. BACKGROUND

The first amateur-buildable 3D printed prosthetic-like device was created in 2011, and since then the e-NABLE network of volunteers has grown into an international movement creating and distributing 3D printed prosthetic-like devices [22]. The story has gained massive popularity as it introduced a new aspect of 3D printing and assistive technology to the public at large [12, 13, 27]. E-NABLE has the potential to make inexpensive prosthetic-like devices available to underserved populations, such as: children who outgrow traditional prosthetics [9], or people in countries with developing health care systems where access to prosthetics and the clinicians who create them may be limited [18].

2.1 A CLINICAL PERSPECTIVE

Since the 1990s, 3D printing has been a topic of interest in the professional prosthetics world [25]. From the use of 3D printing as a rapid prototyping method, to studies investigating its viability and usage in socket fabrication, and the release of cosmetic prosthetic attachments, 3D printing has made its mark on the professional field and will continue to do so [14, 19].

One possible value of rapid prototyping is in follow up. It is difficult to study assistive technology in the wild and most literature documenting abandonment rates use surveys [3, 23]—improved sensor integration could change this, as it has with wheelchairs [26] (which provide an easy platform for sensor deployment).

Among clinicians, there appear to be conflicting opinions and ambivalence. Clinicians may embrace 3D printing technology or becoming defensive or resistant against it [30]. Perceived job insecurity may also make clinicians hesitant to encourage or participate in research and development of 3D printing technologies for use in the professional world [20].

2.2 A MAKER'S PERSPECTIVE

DIY-AT and 3D printing have been studied in many assistive technology domains [4, 7, 8, 15]. DIY-AT can improve user relationships with devices [2, 17], by allowing for cost effective customization of devices [7, 8, 9] which may reduce abandonment rates [16, 23, 24]. Further, digital fabrication technologies supports sharing these designs online, providing opportunities for collaboration which produces improved designs [29]. However, with respect to sharing assistive technology online, few designers report having a disability or designing for themselves, and few designers have clinical expertise [5]. 3D modeling tools are also being created to support different aspects of device design [10, 21] for assistive technology in particular [1, 4, 7, 11, 28].

3. DIY-AT SUMMIT

It is difficult to bridge the gap between clinical and non-professional assistive technology designers. Clinicians have safety regulations that limit what they create to assure patient safety. Non-professionals may circumvent many of these regulations and constraints. For example, e-NABLE can circumvent medical device requirements by referring to their prosthetic-like devices as toys. This allows them to produce a wide variety of designs rapidly. However, the e-NABLE community has few formal mechanisms for assuring safety and quality. These regulatory factors and cultural differences impede collaboration between clinical and non-professional assistive technology designers.

This report is the result of a two-day summit of e-NABLE volunteers, Enable Community Foundation representatives, clinicians (prosthetists, orthotists, and occupational therapists), and human computer interaction and fabrication researchers. The goal of this summit was to discuss the value of 3D printing and rapid prototyping technology, and identify the challenges to introducing the technology to clinical and volunteer practices. Many stakeholders in the domain of prosthetic design attended, in hopes of sharing their experiences and learning from designers on either side of the clinical / non-professional gap.

Table 1. Presenters, affiliation, and presentation titles for the presentations that set discussion topics for the DIY-AT Summit

Presenter	Affiliation	Presentation title
Jon Schull	MAGIC ACT, Rochester Institute of Technology; Enable Community Foundation	The status of e-NABLE: volunteers printing prosthetic-like devices
Andrea Hess	Independent Prosthetist	Clinical research goals regarding rapid prototyping
Ben Salatin	Clinical Rehabilitation Engineer for the Albuquerque Veterans Medical Center	Clinical concerns regarding 3D printed prosthetic-like devices
Scott Hudson	Human Computer Interaction Institute of Carnegie Mellon University	A technical perspective of rapid prototyping assistive technology
Jeffery Bigham	Human Computer Interaction Institute of Carnegie Mellon University	A technical perspective of behavioral science and assistive technology
Skip Meetze	e-NABLE Volunteer	Recent technical advances for 3D printed prosthetic-like devices

This summit began with six presentations of differing perspectives on rapid prototyping and its role in the creation and design of prosthetic devices. These presentations titles, presenters, and affiliations are in Table 1.

Following these presentations, attendees broke out into groups to discuss current research and experiences regarding different topics. These topics were broken into three categories, which bridged different stakeholder’s expertise, including augmenting clinical expertise among makers; improving tools for clinicians and makers; and advancing 3D printed prosthetics. Finally, the groups reconvened to discuss the greater challenges to introducing rapid prototyping technology into the design and creation of prosthetics. These discussions elucidate various challenges to introducing rapid prototyping technology into the practices of different stakeholders. This introduces opportunities for new research, invention, and innovation.

4. BRING “DO NO HARM” TO DIY-AT

The core concern of clinicians, when presented with DIY-AT, was how to enforce a clinician’s Hippocratic Oath to “Do No Harm”¹. From one perspective, clinicians can support the design of better open source assistive technology by applying the validation methods used in their practice, and supporting patient follow-up on devices already in use. From another perspective, a clinician’s involvement in the design of open source assistive technology gives them liability if the designs fail, both legally and morally. Finally, clinicians were concerned by the response of regulators and insurance companies, and how this may limit users’ access to professional devices.

4.1 The Design Phase

Clinicians train to identify safety and biomechanical flaws at each stage of the design process. For example, prosthetists are the product of rigorous education in clinical decision-making, techniques for assessing the appropriate application of assistive technology, and the design of safe devices. Attending clinicians described their research as a highly structured process that ensures they fully validate devices before a patient ever tests one. They worried that communities of volunteers lack the training and insight needed to validate open source designs.

The US Food and Drug Administration (FDA) classifies prosthetics as low risk devices. Because prosthetists are the only licensed professionals who can provide a medically certified prosthetic, the FDA enables them to produce prosthetics with

¹ “Do No Harm” refers to the Hippocratic Oath taken by many clinicians in western cultures. The concept refers to a clinician’s job: first, do no harm to a patient, and then help the patient.

little interference on a case-by-case basis. More regulation is required for the manufacturers of prosthetic parts; the FDA ultimately holds these manufacturers responsible for any malfunction and injury resulting from a flawed design. However, makers act as both manufacturer and prosthetists. An attending e-NABLEr described the lack of regulation as one of the factors that contributes to their diversity of devices; however, he thought that the regulatory environment might change as the community develops advanced devices (e.g., myoelectric prosthetics).

The attending e-NABLErs characterize their “maker” perspective as a drive to invent new, creative solutions with “down and dirty” iteration cycles and rapid prototyping. Maker culture has no barrier to entry. Makers are self-trained and unregulated. They build on the diversity of experiences provided by novice and expert creators. The e-NABLErs described their methodology as trial-and-error based, with little structure, follow-up, or feedback methods; they argue this allows them to conduct collaborative, large-scale, open-sourced research and development. The attending e-NABLErs preached caution, however: There are no formal mechanisms for enforcement of best practices, or suspension of dangerous activities.

Whereas traditional clinical research methodologies intend to reduce risk to patients, attendees from both groups were concerned about the research methodology of makers. Both groups acknowledged that unregulated processes pose potential risk to users, as failures found in testing often happen during use. The clinicians believe that, by bringing a clinical perspective, they could obtain evidence as to whether or not a method, fabrication technique, or device is truly beneficial to the user. The e-NABLErs recognized the importance of clinicians, and often encourage recipients to seek professional support. However, in general e-NABLE cannot and will not require access to clinicians. In fact, much of the population they support cannot access clinicians due to location or cost. Further, clinicians, when approached by patients who are seeking support with an e-NABLE device, may fall into the “do no harm” conflict: Supporting an unknown device could put the patient at risk, but turning them away could result in no treatment or unregulated treatment by volunteers.

4.2 Follow Up

One clinician noted that the most important role she provides to patients is to follow up on a device after she releases it. This reflects her clinical knowledge regarding the importance of education in patient care and the long-term effects of devices. The clinician cited how she adjusts devices to fit a growing patient, and how she recognizes that a device is injuring the

patient through use. It may be damaging the skin or requiring an awkward, straining motion. She specifically commented on the awkward grasping motion in e-NABLE devices. To close the fingers, a user must bend his wrist, which she says would cause strain and could eventually cause a repetitive strain injury. The clinicians thought that their understanding of biomechanics might have prevented this design flaw.

Clinical practice provides a system to support follow up in the form of regular medical appointments. The e-NABLEers recognized the value of this, as there is no current formal expectation for recipients to follow up with their assigned volunteer. However, e-NABLEers rebutted that the prohibitive financial and time costs of meeting clinicians were as disruptive as seeking out their volunteer. Both groups wished to find a balance between the expertise of clinicians and the access to the crowd of supportive and invested volunteers e-NABLE can provide.

4.3 Device Access

There is another challenge regarding open source designs: how do these designs affect an individual's access to assistive technology? From the e-NABLE perspective, designers without clinical training or engineering experience may be able to collect assistive technology designs from the Internet. Shared designs remove the need for design expertise with rapid prototyping technology. However, there was a prevailing concern among the attending clinicians that these freely available designs could do harm to the populations they support because people may lose access to professional devices.

One presenter remarked that a colleague of hers was in court because a medical insurance company no longer considered his devices medically necessary. The company argued that 3D printed trans-radial prosthetics became exceedingly popular because the media misreported and presented them out of context. This caused the company to recognize the devices as a widely appropriate assistive technology, so they are denying claims on more expensive, but medically valuable, advanced devices. For the populations that e-NABLE supports, this is less of an issue, because many cannot currently access advanced devices through a medical practitioner. From e-NABLEers perspective, any hand is better than no hand. This was a main point of contention at the summit.

5. MOVING BEYOND MAKING HANDS

In general, the clinicians encouraged the advancement of 3D printed prosthetics and pushed the attending e-NABLEers to iterate on terminal devices rather than the gauntlets and hands they currently release. This meets the clinical need for safety regulations at the level of the prosthetic socket, and still leverages the value of 3D printed devices. With current modeling practices, it is much easier to create a custom terminal device than a form fitting socket [15]. From the perspective of e-NABLEers, this may be a more exciting task as it allows for the creation of a plethora of task-specific devices. It builds on the strengths of maker communities to create unique designs and to iterate and customize these designs for individuals.

Clinicians felt that there are not enough professionals able to create and support the current populations of prosthetic users who require task-specific terminal devices. Communities like e-NABLE may be able to fill this void. However, clinicians raised specific concerns regarding potentially dangerous activities—*i.e.*

steering wheel and bike attachments that a user cannot quickly detach in an emergency, or swimming equipment that could increase drowning risk. One prosthetist described her experience building a terminal device for a surfer; she was extremely worried that if the design failed to float or broke, it could lead to the death of her patient. She wondered if communities like e-NABLE could limit themselves to safer activities.

Concerning how devices connect to users, clinicians believed that research of rapid fabrication technology and socket fitting should remain a topic for professional practice. The prosthetists argued that this was the most complex part of their craft, and that it posed the greatest risk to patients. As they see it, if digital rapid prototyping technology could support the ambiguity and freedom of their craft, it would be a valuable asset because it enables the reproduction of a crafted design. However, current systems are limited. One prosthetist referred to 3D scanning technology's ability to produce a rigid representation of an amputated limb; however, this did not reflect the malleability of flesh. The more standard practice of constructing casts of a limb includes a prosthetist fitting around unseen structures in the limb, such as malleable muscle groups and non-standard bone structures. He worried that 3D scanning and printing cannot express the complex relationship between a socket and a patient's physiology.

Rapid fabrication tools may support customizing devices to fit to a user in another way. It may be possible that 3D scanning could support reproducing previously fitted designs. One attendee was an engineer for the US Department of Veterans Affairs (VA) who prototypes 3D printed assistive technology for occupational therapists (OTs) in the VA's hospital system. The attendee had been working with thermo-forming and scanning techniques for creating reproducible arm splints. In his case, he took the common orthotist practice of creating a thermoformed orthotic and 3D scanning it. The e-NABLEers drew comparisons to their practice of creating thermoformed gauntlets with 3D printed PLA sheets. Both groups remarked that these techniques could allow clinicians and users to reproduce devices by sharing 3D model files. In the VA, OTs could reproduce the scanned version and mail it to patients if the original were broken. For e-NABLE device users, they can reprint a gauntlet and reform it in the home with some support from a volunteer or friend.

6. "ENABLING THE FUTURE" OF AT WITH RAPID PROTOTYPING

Rapid prototyping technology is valuable because it supports design innovation. This leads to many new directions for clinicians to explore when supporting a patient with unique needs. An attendee representing the VA had expertise in rapid fabrication as well as clinical design. This afforded him unique opportunities to negotiate the high standards of clinical practice while introducing the customization and innovation benefits of rapid prototyping. However, he can only support a small number of OTs, and most clinicians do not have the expertise needed to include rapid prototyping in their practice. He believes this is because of lack of training or access to the technology. Without a full understanding of the potential of the technology, the extra time required to learn 3D modeling or to scan a device before sending it out seems prohibitive to many of his OT collaborators.

Some clinicians raised another concern for integrating rapid prototyping into their practice; under current systems: it may be difficult to compensate clinicians for the time-spent prototyping. For example, an OT's primary income is for time spent with patients. If clinicians must prototype outside of a care session, it is not clear that medical insurance companies will compensate them for their time. In the case of prosthetists, their income is from the sale of devices. The amount of money reimbursed by insurance companies to a prosthetist is dependent on the original cost of the materials, the estimate on time and labor required for the job, and the time the prosthetist will spend seeing the patient for evaluation, delivery, and subsequent maintenance and follow up visits. Due to this billing structure, prosthetists may not be as interested in creating rapid prototype items: The time they spend designing, modeling, and printing may not be covered for insurance reimbursement. In addition, medical insurance companies are likely to tie reimbursement to FDA approval of the devices a clinician produces and getting approval for every custom device is not feasible.

Cost was less of a concern for e-NABLEers, as the volunteer community had not needed to work with medical insurance companies or the FDA. Rather, rapid prototyping excited them because it could remove some of the costs of creating devices, and some of the barriers to accessing clinicians for devices and maintenance. From their perspective, the cost or location of a practitioner can inhibit many people from accessing professional assistive devices. For instance, it may be difficult for children to get prosthetics covered by insurance because they outgrow them. Further, they argue, it can be difficult to get professional care for a device at a moment's notice. Since the e-NABLE devices are "do-it-yourself" and made by non-professionals, it should be easier to fix a device when it breaks, or adjust it to the user's particular needs. However, many of the clinicians were skeptical of this benefit in e-NABLE's current practice. One prosthetist argued that someone without a hand could not construct the devices, and that scheduling time with a volunteer is less reliable than scheduling time with clinicians.

Many clinicians saw the role of rapid prototyping as furthering research in the prosthetics field. One clear example was how rapid prototyping technology could support embedding custom data collection sensors into prosthetics. They described the value of these sensors for studying device use in the wild. This may support research on usage and abandonment. One clinician compared this to tracking location data on wheelchairs; this data supports research into wheelchair accessibility and usage. It is currently difficult to collect sensor data on prosthetic devices, because of prohibitive cost and difficulty integrating new sensors into standard prosthetics. The clinicians believed that rapid fabrication could make it easier to use sensors by embedding them in devices. This requires further research into rapid manufacturing techniques that support sensor integration. The data collected from these devices could benefit many fields of research. It could support the testing of new devices, or lead to discoveries on the causes of device abandonment.

7. DISCUSSION

Both the attending clinicians and e-NABLEers recognized a common goal: for people with limb differences to access devices that improve their quality of life. However, the backgrounds each group led to a constant tension between the clinicians' cautious optimism and the unqualified exuberance of volunteers.

Out of this tension, we elucidate many potential avenues of research that could bridge the gap between these communities as well as advance each individually.

"Do no harm" is central to clinical practice, and is relevant to every portion of the life cycle of DIY-AT. This poses major challenges to volunteer groups and is a unique area of interest for researchers investigating multiple stakeholder collaboration. How can we regulate large groups of people, without tying their hands to legal and bureaucratic systems that delay design iteration? The systems used by professionals assure that devices are safe and properly maintained, however the lack of oversight on groups like e-NABLE allows for rapid and unhindered growth, in both positive and negative directions.

One method for supporting collaboration may be to separate the domains of each group. There seemed to be consensus that each group could support research on different portions of the prosthetic: the sockets that connect the prosthetic-like device to a user, and the terminal devices that allow users to interact with the environment. Clinicians considered the design of sockets to be one of the most difficult and technically challenging portions of their craft; they encouraged the e-NABLE community to avoid this area of design. However, terminal devices may cover a larger variety of tasks, many of which are relatively safe. Focusing design efforts on these devices may allow e-NABLE's resource of thousands of designers to create a huge repository of customizable designs. Advances in rapid prototyping technology and 3D modeling technology support both these goals. 3D modeling software should better support clinical practice by integrating into the crafting style of socket design, while software for volunteers should support the design of validatable devices with minimal expertise.

Finally, clinicians perceive the current state of rapid prototyping technology as prohibitive to them and their patients, making it difficult to access many of the benefits reaped by e-NABLE. It is important that users can easily alter their assistive devices or have an accessible support system for maintaining them. Researchers should explore how volunteers, clinicians, and patients can collaborate over the life cycle of a design. This includes validation of designs, tools for adjusting designs during use, and techniques for conducting research that leverages the capabilities of rapidly prototyped devices.

8. CONCLUSION

Currently, there is a large divide between clinical practice and the work of volunteer assistive device designers. Both groups provide value: clinicians produce safe and robust devices, while e-NABLE produces a large quantity of unique and customized designs. There seems to be a consensus that rapid prototyping technology can play a significant role in the future of assistive technology. However, if we do not overcome the challenges of these conflicting methodologies the gap may persist and worsen in the years to come. Clinicians may continue to have difficulty leveraging rapid prototyping in their practice, while e-NABLE will produce more devices that they cannot validate and fully support. To bridge this gap, there must be new ways for clinicians to share their expertise with volunteer communities, and volunteers must support a collaborative design process that provides clinicians and assistive technology users access to a wide variety of validatable designs.

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