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The Case For Broad-Range Outcome Assessment Across Upper Limb Device Classes

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PROFESSIONAL OPINION

THE CASE FOR BROAD-RANGE OUTCOME ASSESSMENT ACROSS UPPER LIMB DEVICE CLASSES

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The emergence of 3D-printed upper limb prosthetic devices a couple of years ago, spearheaded substantially by the e-NABLE community,[1, 2] has triggered a variety of reactions, ranging from euphoric press coverage predicting a new age of low-cost universally obtainable prosthetic solutions to anxious reluctance by clinicians fearing the demise of high-quality professional health care provision.[3,4] The circumstance that untrained volunteers produce e-NABLE devices on their hobby-grade 3D-printers[5] was both hailed as a revolutionary paradigm shift suited to address a host of current challenges in health care economics, and derided as inappropriate intrusion into long-standing training and certification standards of a well-regulated profession. That many of the early generation e-NABLE devices targeted young patients with partial hand amputation[6] was interpreted by proponents as finally offering this neglected population long-desired solutions, whereas skeptics felt that many of the recipients of such devices would traditionally have been deemed to have a residual functional enough to be a contra-indication for a prosthesis.[7]

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So, how valuable are those 3D-printed devices really for their users, and – be extension – for society at large? Most reasonable people may feel that the truth, as for so many contested questions, is somewhere in the middle. The confidence boost from having a 3D printed superhero hand can be very real for a young patient, even if it is used only for short times. Affordable customizations tailored to special tasks, such as holding a musical instrument,[8] can make a big difference for young users, even if there is little utility beyond that. Meanwhile, the e-NABLE community has progressed to be about more than mere device fabrication and distribution, with EnablewebCentral having become a sophisticated platform for tracking cases, recruiting follow up feedback, and even providing referrals to and coaching from Prosthetists. That devices produced by hobbyists would be able to outright replace much more expensive commercial prostheses is no longer being claimed by representatives of the e-NABLE community. Instead, a mutually beneficial collaboration between the 3D-printing community and Prosthetics and Orthotics (P&O) professionals has been proposed.[9]

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News stories on the topic have recently become fewer and less sensationalist. On the other side, many prosthetics clinicians have come to realize that 3D-printing technology does have the potential to substantially change fabrication methods in the field, and that there is good reason to embrace the associated technological progress. It can be argued that the development already has brought some benefits for the field:

- The publicity, even if partly unwarranted, may have triggered a greater interest in the P&O profession, attracting more talented students, and motivating new research opportunities.

- Some of the young patients who have been introduced to prosthetics through an, even unnecessary, e-NABLE device may be more likely to accept and use prostheses later on.

- Limb loss management being the first prominent area of using crowd intelligence to address healthcare challenges,[10] an approach that promises wide applicability in the future,[11,12] gives our field once more a pioneering role within the allied health sciences.

Still, while it may be easy to intuitively agree with many of those points, there is very little actual evidence on the underlying question of how effective 3D-printed upper extremity devices are in achieving their intended purposes. Most of the research that has been published on the topic to date is limited to technical description and basic function testing of devices. There appears to be no pertinent outcome data of any kind for 3D-printed e-NABLE devices, let alone data that would allow comparison to conventional prosthetics.

This gap can be addressed. The field of P&O has come a long way in establishing evidence based decision making. As new technology has been introduced in increasing frequency over recent decades, the necessity to demonstrate its benefits have yielded more and better research studies. Outcome assessment, as a key component of Evidence Based Practice, has rightfully become more and more important in the field over the past years. A great many different tools have been developed and are now available to allow for reliable data on most any conceivable assessment criterion. Much important work has been - and continues to be – done to determine validity of the various tools in different populations.[13] While the availability of specialized outcome assessment tools is a benefit for the primary clinical purposes of documenting and monitoring individual patients' rehabilitation progress, the respective data can – with limitations – also be useful to compare different interventions. Certainly, this falls short of the scientific rigor of a prospective study with randomized group allocation, but, with a sufficiently large response rate, can deliver relevant descriptions of real-life outcomes to allow fact-based answers to our question and to inform future work.

A group of researchers and clinicians led by Jen Mankoff (University of Washington) and Jon Schull (e-NABLE) is pursuing this approach. Having devised a comprehensive online questionnaire, efforts are currently focused on collecting a sufficient number of responses from both users of e-NABLE devices and conventional upper limb prostheses.[14] This will allow a detailed, evidence-based, comparison between those device groups on a shared scale. As is common in prosthetics research in general, and in particular if targeting an upper limb loss population, it is a major challenge to obtain a large enough sample size to allow for generalizable conclusions. To address this issue, the survey has been translated into several foreign languages and is being advertised through a number of online and offline media.

If it generates sound evidence on the effective differences between upper limb device classes, the respective discussion will become less biased and more constructive. Given the recent developments in the field and the expanding device options for people with limb loss, it would be dangerous to assume that nothing new can be learned from such data. Knowing what today's patients want (or don't want) and knowing what works (or doesn't work) for them is important, not just for makers of 3D-printed devices but for trained prosthetists as well. Clearly, data-based innovation in prosthetic care is accelerating. With the participation of traditional clinicians, professional prosthetic services could both benefit and contribute.

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Dr. Jon Schull, Founder of e-NABLE: Volunteers designing and delivering free 3D-printed prosthetics worldwide. A biological psychologist, inventor, entrepreneur, human-computer interaction researcher, and digital community organizer, Dr. Jon Schull is the creator of e-NABLE, an online philanthropic community that designs, customizes and fabricates open-sourced affordable 3D-printed prosthetic hands and arms for children and adults with upper limb differences. In past lives, Schull was founder of SoftLock.com aka DigitalGoods (NASDAQ:DIGS) a seminal digital rights management company, professor and former director of the Center for Student Innovation at Rochester Institute of Technology. His current base of operations is the Rochester Enable Lab at Vertus High School.

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