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Narrative Review

Innovations With 3-Dimensional Printing in Physical Medicine and Rehabilitation: A Review of the Literature

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Abstract

Created more than 30 years ago, 3-dimensional printing (3DP) has recently seen a meteoric rise in interest within medicine, and the field of Physical Medicine and Rehabilitation is no exception. Also called additive manufacturing (AM), the recent increase in the use of 3DP is likely due to lower-cost printers as well as breakthroughs in techniques and processing. This thematic narrative review serves to introduce the rehabilitation professional to 3DP technology and how it is being applied to orthoses, prostheses, and assistive technology (AT). The basics of the technology, as well as the benefits and challenges of using it within the rehabilitation framework, are described. Proponents of the technology suggest that 3DP offers not only a better way to make devices, but a better way to make improved devices. However, the strength of this claim has not been properly tested by the current literature. This narrative review evaluates the evidence and provides a discussion of possible implications for the rehabilitation professional.

Introduction

Three-dimensional printing (3DP) technology has existed for more than 30 years, but has only recently garnered increased attention among scientists, engineers, and the public [1]. The rise of 3DP is attributed to the availability of lower-cost printers and breakthroughs in techniques and processing. Researchers are discovering many medical and dental applications including devices and implants [2-4]. Work is also being done to print biosynthetic and hybrid human tissues including skin, cartilage, and bone [5-8]. For the field of physical medicine and rehabilitation (PM&R), 3DP has the potential to provide unique solutions to common obstacles related to the fabrication and delivery of orthoses, prostheses, and assistive technology (AT).

The term "3-dimensional printing" is one of many processes that are referred to collectively as additive manufacturing (AM); although imprecise, these terms are often used interchangeably. AM is defined as: "The fabrication of objects through the deposition of [thin layers of] material using a print head, nozzle, or other printer technology" [9]. The process is also categorized as a type of computer-aided manufacturing (CAM), which is an umbrella term for the use of computer software to control machinery in manufacturing. The definition of AM covers numerous manufacturing technologies, and many proprietary terms are used for these processes for marketing purposes. However, all current AM technologies can be grouped into 7 categories, which are explained in Table 1 [9]. Each of these technologies is associated with specific materials, accuracies, speed of print, and cost, which are beyond the scope of this review. However, all 3DP technologies share a similar concept: a virtual 3-dimensional (3D) model of the object is created by computer-aided design (CAD), often with the use of 3D scanning. The model is then "sliced" into discrete two-dimensional layers, in which the geometry becomes digital code that the printer uses to "build" the object layer by layer. Depending on the technology, post processing may be needed to remove support material, to improve surface finish, or to cure unfused material. In some cases, the 3D printed object may serve as a mold from which the final object is cast.

In addition to a range of processes, 3D printers come in a wide range of sizes of various levels of production quality [13]. Printers can be loosely classified into 2

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Table 1
Types of additive manufacturing

- *Binder jetting*—Liquid bonding agent is selectively deposited and immediately cured to join powdered materials.
- *Directed energy deposition*— Focused thermal energy (ie, laser or electron beam) is used to fuse materials by melting as they are being deposited.
- *Material extrusion*—Material is melted and selectively dispensed through a nozzle or orifice (eg, Fused Deposition Modeling [FDM]).
- *Material jetting*—Droplets of light-activated liquid photopolymer (resin) are selectively deposited and instantly cured by ultraviolet light (eg, PolyJet).
- *Powder bed fusion*—Thermal energy (ie, laser or electron beam) selectively fuses regions of a powder bed (eg, selective laser sintering [SLS], direct metal laser sintering [DMLS]).
- *Sheet lamination*—Sheets of material are cut to shape and bonded to form an object.
- *Vat photopolymerization*—Light-activated liquid photopolymer (resin) in a vat is selectively cured by ultraviolet laser or Digital Light Projector chip (Texas Instruments) (eg, Stereolithography [SLA]).

Adapted from references [9-12].

production quality types: industrial and personal. All industrial printers are designed to produce consistently high-quality parts, at a high level of throughput, and often have advanced software for controlling various aspects of the software files, which command the creation of the object. Personal printers are becoming more widely available, at lower prices, making it possible for individuals to design and build objects themselves.

This article explores the current and future roles of 3DP in rehabilitation medicine, with the goal of providing rehabilitation professionals with a base of knowledge about 3DP techniques and their applications. A secondary aim is to discuss future implications of the use of 3DP in the field of physical medicine and rehabilitation.

Literature Search Strategy

Literature was identified for this review by searching PubMed for the following key terms: 3D printing/3DP, additive manufacturing, stereolithography, fused deposition modeling, selective laser sintering, and rapid prototyping. Other secondary terms (rehabilitation, prosthesis, orthosis, wheelchair, durable medical equipment, assistive technology, and assistive device) were used alone and in combination with key terms. Some articles were also identified by searching the cited references of the articles found on PubMed. Finally, additional references were also found using a Google Scholar search of the same terms as used in PubMed. Articles from all search methods were included if they used 3DP either directly or indirectly for rehabilitation applications. Articles were excluded if 3DP was used for surgical techniques, were related to organic matter (eg, bone, stem cells, and other tissues), or 3DP references were older or less detailed than another included article. The search identified 20 articles. Table 2 describes all 20 articles and assigns Levels of Evidence according to the standards of the Evidence Committee of the American Academy of Physical Medicine and Rehabilitation [34,35]. Articles describing projects in which 3DP was used were classified into the domains of orthoses, prostheses, and assistive technology.

Evidence: Applications to PM&R

Orthoses

In the rehabilitation literature, many articles detail the use of 3DP to manufacture various types of lower limb devices, including ankle-foot orthoses (AFOs). The most common traditional method of fabrication involves an orthotist creating a positive mold of the body area in question from which to vacuum form an orthosis from thermoplastic sheeting or thermosetting fiberglass and resin [36,37]. When cured, this sheet must be processed, including the removal of excess material and the addition of shaping or secondary features (eg, flaring or foam padding). Alternatively, the positive mold may be sent to a central fabrication facility for actual device creation, but when the device returns to the orthotist, more modifications may still be needed to ensure good fit on the patient. This process, along with waiting for insurance authorization and coordinating patient appointments, takes 8 business days at best with one prominent national company, but can sometimes take much longer due to logistics and trying to avoid the patient returning before the device has been returned [38]. Researchers highlight how 3D printing an orthosis allows for complete customization, rapid manufacturing time, and the use of a variety of inexpensive but durable materials. However, insurance authorization could be a rate-limiting step, no matter how the orthosis is made. Using a powder-bed fusion process, Faustini et al studied the biomechanical properties of 3 materials used for 3D printing in the production of a "passive dynamic AFO" [14]. According to the authors, passive dynamic orthoses are "designs that rely on characteristics such as material properties, component thickness, AFO shape, springs, and fluid pressure dynamics, to establish bending or rotational stiffness characteristics and to regulate the storage and return of mechanical energy [...] to achieve smooth efficient walking by providing a variable level of support and mechanical energy return to the ankle during stance in gait" [14]. Although there were no participants in this study, the authors noted that one 3DP material (Rilsan D80) did offer the most desirable profile, but it did not improve upon the carbon fiber model used as the control [14]. Mavroidis et al also compared two 3DP materials in the production of AFOs and captured gait analysis of a participant without a disability [16]. The results showed performance of the 3DP devices similar to that of the commercially available one. Schrank et al developed a novel

Table 2
Evidence articles for 3DP in PM&R*

First Author, Year [Ref]	Device/Object	Participants/Intervention	Outcomes/Results	Classification and Level
Orthoses				
Faustini, 2008 [14]	3D printed AFO	No participants. 3D printed AFOs were produced with 3 material types (Rilsan D80, DuraForm PA, and DuraForm GF) and compared to a control (carbon fiber AFO). All 4 were laboratory tested to evaluate desired biomechanical properties.	Rilsan D80 exhibited the least amount of energy dissipation through mechanical damping and was the only material to withstand destructive testing, but damping was still significantly higher (36%) than the carbon fiber AFO. Authors note that the freedom to alter designs to achieve customized devices may outweigh this property difference.	Process/product development with controlled trial, Level II
Harper, 2014 [15]	3D printed AFO	13 Participants with different diagnoses trialed a control (carbon fiber AFO) as well as two 3D printed AFOs (20% more compliant and 20% more stiff than control). 3D kinematic and kinetic data and electromyographic data were collected during walking at self-selected and controlled velocities.	As orthosis stiffness decreased, ankle range of motion and medial gastrocnemius activity increased and the knee became more extended throughout stance. Minimal changes in other gait analysis parameters were observed, although authors did find evidence that the control of frontal plane balance may be influenced by AFO stiffness.	Crossover controlled trial, Level II
Mavroidis, 2011 [16]	3D printed AFO	1 Healthy participant trialed 2 3D printed AFOs compared to a control prefabricated AFO and shod. The two 3D printed AFOs were fabricated with Accura 40 resin (more rigid) and DSM Somos 9120 Epoxy Photopolymer (more flexible). Motion capture and force plates were used to evaluate 10 walking trials.	Authors measured kinematics and kinetics of the hip, knee, and ankle of each leg in the sagittal plane. Findings included that the 3D printed AFO performed similarly in terms of controlling ankle kinematics and kinetics compared to control. Authors highlight how devices were customized and rapidly produced, leading to decreased orthosis fabrication cost and time.	Process development with controlled trial, Level II
Pallari, 2010 [17]	Additive manufactured customized foot orthoses	7 Participants with rheumatoid arthritis walked barefoot, with traditionally made orthoses, and 3D printed orthoses at self-selected walking speeds on a pressure sensor gait analysis device. Each participant walked 3 times for each condition, with the average of the 3 measurements used for analysis.	No significant difference in stride length, walking velocity, cadence (steps/min), and cycle time (time for a full gait cycle) noted. Also recorded was self-reported pain and orthotic comfort and fit using 100-mm visual analogue scales. No statistically significant difference for these measurements.	Feasibility trial with device development report, Level II
Paterson, 2014 [18]	Computer-aided design program allowing for 3D printing of wrist orthoses for end-users	10 Practitioners with no previous CAD experience trialed newly developed software to make 3D printed orthoses.	Semi-structured interviews were recorded and coded to establish qualitative trends and areas of future research. All users were able to use the software and noted potential improvements in modeling complex orthoses.	Feasibility trial without control, Level IV
Paterson, 2015 [19]	Evaluated different 3DP processes to make 3D printed wrist orthoses	1 Healthy participant. Authors fabricated 6 different wrist orthoses using 4 different AM processes. A healthy participant was used to model the devices.	All processes except 1 were viable for upper limb orthoses. Authors noted the need for further research and development into AM processes, materials and orthosis design optimization.	Technical report with case study, Level IV
Salles, 2012 [20]	3D printed foot orthoses	26 Runners (13 pairings) completed 4 data acquisition sessions over 3 months while using either a 3D printed custom FO or a control FO. Authors measured gait analysis and qualitative discomfort measure on 150-mm visual analogue scale. Participants were encouraged to run in the devices between evaluations.	Kinematics of the knee and ankle, the vertical component of a ground reaction force, plantar pressure distribution, and discomfort ratings were recorded. Authors found that the 3D printed FO had lower values for ankle dorsiflexion at foot-strike, maximum ankle eversion, and peak mean pressure under the heel. These findings suggest reduced injury risk. Lower discomfort ratings were also reported for the 3D printed FO.	Single-blind paired-samples experimental design, Level I

(*continued on next page*)

Table 2 (*continued*)

First Author, Year [Ref]	Device/Object	Participants/Intervention	Outcomes/Results	Classification and Level
Schrank, 2011 [21]	3D printed AFO with a new fit customization and manufacturing framework	2 Healthy participants trialed 3D printed AFOs created with a new customization process developed to improve dimensional accuracy of the 3DP process itself. Post production measurements and 1-hour walk test were used.	Postproduction dimensional accuracy data were all within acceptable intra- and intercomponent dimensional accuracy tolerances. The 1-hour walk test also resulted in no skin irritation in the participants.	Process development with case studies, Level IV
Telfer, 2012 [22]	Parts of end product for a novel FO and AFO design using AM	1 Participant underwent 3D gait analysis shod and wearing 3D printed FOs and AFOs with adjustable elements. The elements adjusted included changing pressure under metatarsal head (for FO) and ankle joint stiffness (for AFO).	Gait and pressure data revealed a significant decrease in reduced pressure under target metatarsals for the FO and distinct effects on ankle kinematics, which could be varied by adjusting the stiffness level of the AFO.	Pilot case study with 2 devices, Level IV
Telfer, 2013 [23]	3D printed foot orthoses	12 Participants with symptomatic pronated foot type and 12 matched controls trialed 9 versions of 3D printed FOs, Each participant had a custom set of FOs with incrementally increased rearfoot post angles. 3D gait analysis was used to evaluate gait.	Authors reported a linear mechanical response of the rearfoot and knee joint when the rearfoot post angles were incrementally increased for both cohorts. Authors note that this finding could be leveraged to treat a pronated foot.	Device development with controlled trial, Level II
Telfer, 2014 [24]	3D printed foot orthoses with embedded temperature sensors	10 Healthy participants wore 3D printed foot orthoses with embedded sensors and their activity was monitored. Temperature and activity data were then correlated and checked for validity.	A threshold-based algorithm was developed and validated to identify time periods of high activity from foot temperature data. The authors highlight how this can facilitate future research.	Device development and validation, Level IV
Prostheses				
Fey, 2011 [25]	3D printed prosthetic feet of varying keel and heel stiffness	12 Unilateral below-knee amputees walked at 1.2 m/s wearing three 3D printed prosthetic feet of varying keel and heel stiffness. The participants were evaluated with gait analysis.	Gait kinematics, kinetics, muscle activity, prosthetic energy storage and return, and mechanical efficiency were measured. Decreasing foot stiffness increased prosthesis range of motion, mid-stance energy storage and late-stance energy return. The net contributions to forward propulsion and swing initiation was limited due to the additional muscle activity needed to provide body support.	Crossover RCT with 3 arms; Level II
Gretsch, 2015 [26]	3D printed robotic transradial prosthesis	1 Teenage participant with a transradial amputation tested a device in a nonstructured manner.	No structured outcomes. Participant highlighted the use of individual thumb movement and cited the new prosthesis as improved over a traditional, externally powered prosthesis in terms of less weight and lower costs.	Device development with case study, Level IV
Herbert, 2005 [27]	3D printed prosthetic transtibial and transradial sockets	2 Participants with amputations (1 transtibial and 1 transradial) underwent 3D scanning of residual limb. Then a 3D printed socket was produced and trialed.	No structured outcomes. Participants noted that the 3D printed sockets were as comfortable as their own sockets made by traditional methods.	Technical report with case studies, Level IV
Hsu, 2010 [28]	Resin enforced 3D printed socket	1 Participant with a unilateral below-the-knee amputation trialed a resin-reinforced 3D printed prosthesis compared to 3 of his own prostheses measuring local pressure distribution between the residual limb and socket interface. Patient walked 10 m 5 times at a comfortable walking speed.	Statistical analysis of pressure data was similar between the 3D printed socket compared to other baseline sockets. Authors highlight the ability to bypass the time-intensive traditional methods and yield a noninferior device.	Device development with controlled trial, Level II

Laszczak, 2015 [29]	3D printed sensor designed for monitoring mechanical stresses at the stump–socket interface	No participants. Sensor design and fabrication was described, as well as the evaluation process.	Authors built and validated a low-cost pressure sensor. Results showed excellent linearities for both pressure and shear signals, which were comparable to those of commercial systems. Authors developed a signal processing model to separate pressure and shear data for independent calibrations for future prosthetic applications.	Device development with validation, Level IV
Sengeh, 2013[30]	3D printed transtibial socket	1 Bilateral transtibial male amputee walked with conventional and 3D printed sockets on walkway at self-selected speeds while ground reaction forces, motion capture data, and socket-residual limb interface pressures were measured.	No statistically significant differences were reported, although there was a reduction in peak contact pressures at the fibular head and tibial plateau. A 16% increase in the self-selected walking speed was noted with the 3D printed socket.	Case study with device development report, Level IV
Zuniga, 2015 [31]	3D printed transcarpal prosthesis	9 Children and adolescents (age range 3-16 y) were measured and fitted for a 3D printed hand. Authors compared measurements taken directly from participants to measurements taken from photographs of the participants. A qualitative survey was also conducted.	Authors found no significant difference in anthropometric measurements taken directly compared to those taken from photographs, suggesting that a remote fitting protocol could be viable. On the survey, all but 1 participant reported an increase in quality of life with the device.	Device development with controlled trial, Level II
Assistive Technology				
Brown, 2012 [32]	Development of new software to produce 3D printed tactile visualizations of data plots for persons with visual deficits	2 Groups of 3 visually impaired participants participated in a user-centered design process to develop and evaluate custom printed tactile graphs. Group 1 had a mathematical background and provided device feedback that was implemented before testing with group 2.	Multiple iterations of device development were described and evaluated but without structured outcomes. Qualitative responses were used to improve successive iterations. Users reported significant benefits of this process and graphs compared to Braille embossers.	Process/Product case studies, Level IV
Medola, 2012 [33]	3D printed prototype for casting of new ergonomic wheelchair pushrims	6 Independent wheelchair users performed wheelchair activities to test propulsion, braking and maneuvering with a control and a 3D printed pushrim.	A nonvalidated survey showed that 67% of participants believed that the 3D printed devices had better appearance, and all participants thought that the devices made overall locomotion easier. Of the participants, 67% reported that locomotion was "very easy," and 33% reported it "somewhat easier" than compared to standard pushrims.	Low-powered, nonblinde crossover RCT, Level II

Ref = reference; 3D = 3-dimensional; 3DP = 3-dimensional printing; RCT = randomized controlled trial; AFO = ankle–foot orthosis; CAD = computer-aided design; AM = additive manufacturing; FO = foot orthosis.

* Presented in alphabetical order by first author within each domain.

framework for the fabrication of a passive-dynamic AFO and demonstrated that the dimensional accuracy of the product was within acceptable measurement parameters [21]. Proof of accuracy of the process from design to finished product is important, as this had not been established in the use of older 3DP processes [39].

Whereas some groups studied 3DP materials and processes in the production of devices similar to those currently available, other groups developed novel types of orthoses using 3DP. Telfer et al published a single case study on an "adjustable stiffness AFO," which is adjustable for various functional activities [22]. For example, a patient might prefer a stiffer device for walking on flat surfaces and more flexibility when navigating stairs. Harper et al [15] used 3DP to test the relationship between AFO stiffness and gait parameters. A cohort of 13 participants with a variety of diagnoses and requiring carbon fiber AFOs were provided with 2 new 3DP devices (one 20% more stiff and one 20% less stiff) and underwent gait analysis. The stiffness did not have a significant impact on gait [15].

In addition to AFOs, other researchers evaluated 3D printed foot orthoses (FO). Telfer et al established the dose-response relationship of changing the shape of an orthosis on biomechanical data taken from gait analysis [23]. The study design required 24 participants to each have 9 different FOs with incrementally increased rearfoot posting [23]. Creating a study design that required 216 orthoses was in part possible due to the use of 3DP to cut down on the time and costs associated with so many devices. In another study by Telfer et al, 3DP was used to make a novel FO with embedded temperature sensors that were used to track periods of high activity levels [24]. Pallari et al have also published on the feasibility of mass customization of FOs for persons with rheumatoid arthritis with pain related to their inflammatory joint disease [17]. Mass customization is a term that represents the availability of low-cost units that are highly customizable. Pallari et al evaluated gait parameters including velocity, cadence, cycle time, and stride length as well as 100-mm visual analogue scale (VAS) scores in the outcome assessment. However, the outcomes for traditional FO versus 3D printed FO were not statistically different. Salles et al compared 3D printed orthoses to generic control orthoses in a cohort of runners. Using gait analysis over a 3-month observation period, they found that when wearing 3D printed orthoses, participants had significantly lower values for ankle dorsiflexion at foot-strike, maximum ankle eversion, and peak mean pressure under the heel. This may offer a decreased risk of injury [20].

Upper limb orthoses have also been created with 3DP. Paterson et al reported the development of a specialized CAD software that enabled orthosis fabrication professionals who were not familiar with CAD to design and print individualized upper limb orthoses [18]. This process-based research design addressed how 3DP may change the whole device workflow paradigm and help make devices more efficiently. However, this study's qualitative approach did not provide strong recommendations for current practice but, rather, explored areas for future research. Other work by Paterson et al also compared the strengths and weaknesses of 4 different 3DP processes in producing upper limb orthoses [19]. The results were that the technologies using selective laser sintering (SLS), stereolithography (SLA), and PolyJet material jetting are currently viable for clinical use, whereas fused deposition modeling (FDM) was less favorable due to needed improvements in surface quality [19]. These studies highlight the need for research into materials that are more suitable for long-term exposure to skin as well as ongoing cost analysis and viability of the 3DP process [19]. Paterson et al noted that the next logical step is conducting clinical trials to evaluate devices with end-users. It was posited that 3DP printed devices could improve upon currently available models in that they could be easier to put on and take off, be more aesthetically pleasing, and be better tolerated because of a lattice design that allowed improved ventilation [18]. The devices described had "elastomer regions" that effectively expanded and contracted to suit the motion of the user in certain planes where motion was allowable without compromising the overall goal of stability [18].

Prostheses

In the traditional fabrication method for prostheses, the highly unique geometry of a person's residual limb requires manual molding techniques using casting materials such as fiberglass or plaster [27,28,40]. Hsu et al provided a visual comparison of traditional versus CAD/CAM prosthetic fabrication processes [28]. With traditional techniques, up to 95% of amputees experience socket discomfort at least some of the time [27]. However, prosthetics researchers are evaluating how prosthetic devices and fabrication methods can be improved with 3DP.

Herbert et al incorporated new 3DP processes in a feasibility experiment using 3D printed sockets in preliminary prosthetic fittings [27]. The authors detailed the process for how they created 3D printed sockets for both a transtibial and a transradial amputee. The study highlighted that the 3DP of a socket for a residual limb required 3D scanning, the benefits of which include the ability to store the 3D anatomical reconstruction of the participant's limb as data; such data are not available when only plaster molds are used and discarded [39,41-43]. Serial 3D scanned data can be saved and reviewed to follow changes in a participant's anatomy over time and can also be pooled with other participants' data for research. More recently, Hsu et al developed a resin-reinforced 3D printed socket and showed that it was similar to standard sockets when testing pressure data during gait [28]. Sengeh et al used more advanced printing techniques to create multi-material 3D printed prosthetic sockets that were shown to reduce the contact pressures over the bony prominences of the residual limb as well as to increase the self-selected walking speed of one participant [30]. Expanding beyond prosthetic sockets, Fey et al explored the use of 3DP to make prosthetic feet of varying keel and heel stiffness in differing planes to study the effects of these changes on gait mechanics [25]. Using robust gait analysis and a cohort of 12 participants, the authors showed improvements in mid-stance energy storage and late-stance energy return at statistically significant levels for their 3D printed feet by varying the heel stiffness [25]. In another study, Laszczak et al developed and validated a low-cost 3D printed prosthetic pressure sensor that offers innovative ways to obtain pressure data [29].

Complete upper limb prostheses have also been produced with 3DP. Such devices, like the Robohand device pictured in Figure 1, are not as high-technology as commercially available alternatives, but for persons who do not have access to a state-of-the-art prosthesis, a printed functional prosthesis could be life changing. This is made possible, in part, because the makers of the Robohand freely distribute their design files online. Gretsch et al discussed their process of developing a separate device that improves upon the Robohand design [26]. Specifically, the authors described how the Robohand requires functional wrist flexion to cause voluntary closure of the terminal device, although it offers only simultaneous closing of all fingers, whereas their new design was shoulder powered, adapted to be used without wrist function, and still offered individual finger (including thumb) flexion of the terminal device [26]. This technical case study lacked a controlled trial of the process or product, which would be a logical next step. The study by Gretsch et al had one participant, a 13-year-old girl, and the authors highlighted that their design could be easily scaled to accommodate growth. For children and adolescents who need prostheses, accommodating the rapid growth of a residual limb or easily replacing a lost or broken prosthesis highlights the economic upside of 3DP in rehabilitation.

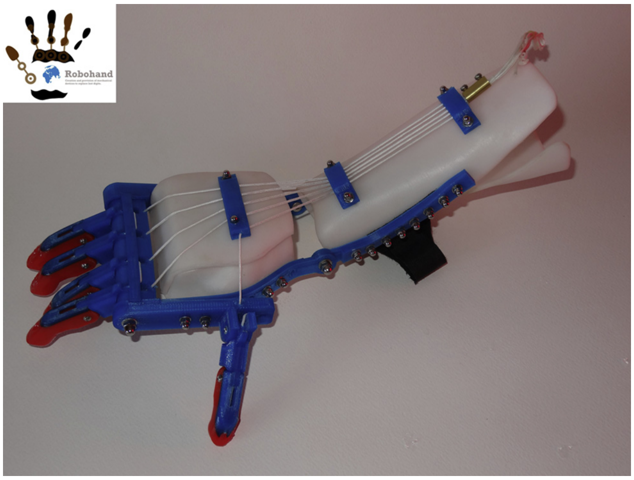

Figure 1. Robohand device. Copyright: www.Robohand.net. Permission granted.

Zuniga et al also developed a 3D printed prosthetic hand [31]. Like the Robohand, the Zuniga "Cyborg Beast" requires wrist function that flexes the prosthetic fingers and thumb in unison. The researchers trialed a controlled protocol for fitting and scaling based on anthropometric measurements taken directly versus those taken from photographs of 11 participants. They found that there were no significant differences in these measurements, suggesting that a novel remote-fitting procedure for persons in rural (or globally remote) areas may be viable. The authors described the plethora of other variables that would need to be addressed by future studies, including functionality, validity, durability, benefits, and rejection [31]. The perceived benefits of such printed upper limb prostheses are the option to have multiple devices for different purposes and the ability to change or adjust devices frequently with lower associated cost. The Zuniga device costs US $50 compared to as much as US $4000 for a wrist-controlled prosthetic hand, and the Gretsch device costs US $300 worth of materials compared to US $25,000 for a robotic shoulder-controlled device [26,31].

Assistive Technology

Using 3DP, researchers have been developing some devices that help promote independence in activities of daily living and mobility. Brown et al described the development and provided a case study of 3D printed tactile displays of graphs for persons with visual impairments (Figure 2) [32]. The study detailed the development of a device that was novel and fills a gap in the available technology for persons with visual impairments. The device was qualitatively well received by end-users in this study [32]. In the realm of wheeled mobility, Medola et al used 3DP to develop a new type of wheelchair pushrim and then trialed it in a cohort of 6 participants [33]. All participants thought that the new pushrim improved ease of locomotion. Two-thirds appreciated its esthetics, which might increase the potential for device acceptance [33].

Discussion

General Advantages and Challenges of 3DP

The National Additive Manufacturing Innovation Institute, now called America Makes, lists the advantages of 3DP as allowing shorter lead times, mass customization, reduced parts count, more complex shapes, parts on demand, less material waste, and

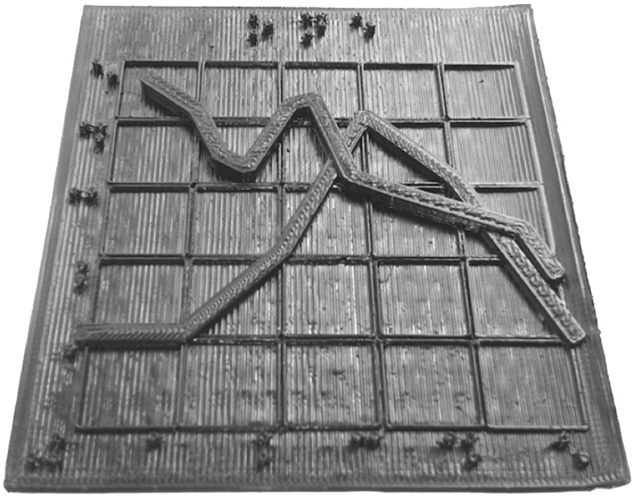

Figure 2. Three-dimensional printed Textile Graph for the visually impaired. Copyright: The Prototyping and Design Lab, University of Maryland Baltimore County. Reprinted with permission from [32].

lower life-cycle energy use [44]. However to fully appreciate these benefits, one must understand traditional manufacturing methods. The 2 most popular traditional manufacturing methods are injection molding, a process of injecting into a mold a melted material that then hardens into the object, and machining, a process of carving the object from a block of material. Injection molding is a widely used process for mass manufacturing because of its low cost per product. However, it is a poor choice for producing prototypes or customized products because of the time and cost of creating a new mold. 3DP excels in cost savings for prototypes and customization, because a new mold is not needed for each product version.

Machining processes allow for some customization, but can be wasteful because the material carved off is often discarded. The cost of this waste adds up quickly. The Department of Energy estimates that 3DP can save 50% in energy cost and 90% in material cost compared to machining [45]. Another unique way that 3DP saves on material costs is by "filling" the inner volume of an object with a lattice that reduces the amount of material used but maintains comparable strength. Neither injection molding nor machining could achieve the design of a material-saving inner lattice. The time needed to produce devices with 3DP versus traditional fabrication methods in rehabilitation may be an advantage or challenge, depending on the specific device and delivery protocol. Whereas it may take only minutes for a person to undergo casting for an orthosis, it takes a least 8 business days for the device to be manufactured by a third party and delivered by the current methods [38]. A clinical research laboratory with 3D scanning and printing capabilities may be able to deliver a device much more quickly. However, this is dependent on the specific device and process, as the production times with 3DP vary greatly depending on the type of machine, type of material, and level of resolution (layer thickness) of the object.

General challenges of 3DP are often related to the cost of the 3D printer, CAD software, maintenance, and training users [39]. As the costs of CAD/CAM processes go down, the upfront investment is less of an obstacle [39]. Interestingly, 3DP equipment costs have gone down due to expired patents for proprietary techniques [46,47]. Software for CAD has seen less of a price decrease than 3D printers themselves and can also require a high level of expertise, because raw data from 3D scanning must be manipulated to make a build file. Hopefully, these programs will become more user-friendly over time. Paterson et al explored the development of user-friendly CAD software for use by therapists to 3D print custom wrist orthoses [18]. However, regardless of how user-friendly CAD software becomes, significant training may be required for individuals to use such programs in rehabilitation endeavors [46,48].

The techniques of 3DP have also been criticized in the past due to the lack of a variety of materials compatible with the process. Plastics are the most often used material in 3DP. Warping and brittleness are 2 problems with many of the currently available plastics [40,49]. Such characteristics are not desirable in the fabrication of devices for persons with disabilities. However, the technology has become more sophisticated, and new processes are available. New materials, processes, and machines have allowed researchers to use a variety of desired properties, such as varying levels of stiffness as discussed in some of the literature presented above [15,22]. Another potential drawback is that 3DP was previously not considered an option for mass manufacturing because the process has not been time efficient. However, 3DP allows for mass customization, which offers the potential for customized products at relatively low prices [50]. The ability to have a base digital design and to quickly change the design without changing the fabrication process gives 3DP the potential to make mass customization possible. For rehabilitation, mass customization could be used to modify adaptive equipment of set sizes for further customization based on clinical examination measurements or a 3D scan overlay.

Other 3DP techniques and breakthroughs are being refined at a rapid pace, but the effects of these advances on rehabilitation are yet to be seen. Metal additive manufacturing, such as direct metal laser sintering (DMLS), removes the need for an intermediate step in the process of making metal 3D printed products [51]. Because some patents have not yet expired, this process is still very expensive. However, strong metal devices with intricate customization options would be a great benefit in the realm of adaptive medical equipment. Metal 3DP opens many potential avenues for projects in rehabilitation, including direct printing of prosthetic pylons and custom adaptive sports equipment, as well as reducing the complexity of power wheelchair designs.

Evaluating the Evidence for 3DP in Rehabilitation

The current literature shows many avenues of potential impact for 3DP in PM&R. However, given the evolving nature of this manufacturing technique in conjunction with the evolving nature of the field of rehabilitation, the literature has been limited in both scope and quality. Many of the studies would have benefited from stronger study designs, including larger numbers of subjects, case-control comparisons, and blinding of investigators. Although many novel designs and processes were introduced, they were often not subjected to controlled trials using validated outcome measures. Many of the studies in support of 3DP in PM&R were case-control or case series. In addition, most of those studies that did have more robust designs either reported no statistically significant differences or findings were of limited clinical significance. However for some studies, the goal was to show that 3D printed products were as efficacious as controls, because the 3DP process was described as an improvement over the traditional fabrication method. Translating the current evidence of the articles in support of 3DP to a strength or grade of recommendation would yield a Grade D recommendation for 3DP printing in PM&R [52]. However, this recommendation does not seem to reflect the true value that lies in exploring future applications of 3DP in PM&R.

One of the most striking findings is the general lack of peer-reviewed evidence addressing 3D printed assistive technology. Other groups of engineers have created custom 3D printed assistive technology, such as a rotating mount to change the orientation of a smartphone or tablet without needing hand function, mouth stick holders, custom wheelchair device mounts, a specialized hygiene mirror for self-catheterization, and an iPad keyguard for users with hand tremors [53-55]. However, this work has not yet been submitted for publication in peer-reviewed literature. The field stands to benefit if researchers aim to more rigorously evaluate and publish such work.

Implications of 3DP for the Rehabilitation Professional

Drawing general conclusions about the application of 3DP to PM&R requires recognition of the complexity of this phenomenon. Proponents of 3DP in PM&R say that it is not just a better way to make the same device, but a better way to make a better device. This approach of identifying the *process* as separately valuable from the *product* can help to clarify what parameters or outcomes should be measured in future research. In studies that do not address 3DP processes or products as separate aims, it is difficult to control the variables so as to draw clear conclusions. By improving research designs to truly capture improvements in the process and the resulting products, future recommendations could be more specific and much stronger. A number of improvements in study design should be considered, including blinding when possible, the use of “standard of practice” controls for devices, and well-powered cohorts of age-matched controls for patient studies. No matter the study design, use of validated outcomes with high clinical impact is necessary.

The implications of 3DP for the rehabilitation professional will be determined by the amount of exposure that each clinician seeks. Those clinicians who wish to stay up to date on the use of 3DP in rehabilitation will need to review multiple areas of research including, but not limited to, prosthetics and orthotics, rehabilitation engineering, and assistive technology. In addition, clinicians should consider reviewing the abstracts from organizational conferences outside of their standard clinical practice, for example the American Academy of Orthotists & Prosthetists, the Rehabilitation Engineering and Assistive Technology Society of North America, or the International Seating Symposium. The coverage of 3DP at such conferences may be variable, but likely to increase over time.

A few centers are fabricating durable medical equipment for clinical research purposes with the use of in-house 3DP capabilities. This work may ultimately help to evaluate whether it would be advantageous to have immediate 3DP capabilities in a rehabilitation setting, but the research does not yet support the practice. Outside of these centers, researchers could also access 3DP technology without as much upfront cost by using a 3DP service bureau [56,57]. A service bureau allows a customer to submit a build file, and the company prints and mails the object to the customer [56,57]. These companies offer 3DP technology without the costs of purchasing and maintaining the actual machine.

Given that 3DP is largely restricted to research in rehabilitation at this time, a reimbursement model has not been developed for devices fabricated with 3DP. This out-of-pocket expense is certainly an obstacle to future growth of the process in rehabilitation. For a reimbursement model to be developed, the research literature will need to demonstrate the benefits of the 3DP process and/or its products. In addition, regulatory concerns would arise with the sale of 3D printed medical devices, including quality control, risk management, and liability, all of which would require further inquiry. The expansion of 3DP technology has also driven a Do-It-Yourself (DYI) movement created by hobbyists with supportive online communities [58]. This movement can be attributed to the low costs of personal 3D printers and a growing number of rehabilitation-associated projects found on the Internet. Thingiverse.com is an online space dedicated to the sharing of user-created digital designs, and it already has many AT designs available [10]. However, despite the rise of this DIY approach to AT, little to no literature exists to direct the clinician on how to respond, and clinicians should remain critical of this approach. The low-cost personal printers tend to produce inconsistent, lower-quality parts, and, when using higher quality printers, the costs quickly rise. The appropriateness of a DIY approach depends on the device being printed. Since 3DP designs are not necessarily designed by or with rehabilitation professionals, they may not meet acceptable standards. As such, printing a replacement cane grip may be more appropriate than a wheelchair part. Finally, the benefits of multidisciplinary team involvement are lost with the DIY approach.

Unfortunately, the current evidence is insufficient to guide the rehabilitation professional on how to assess the current role of 3DP for persons with disabilities. The majority of the evidence is found in orthoses and prostheses, but the strength of research would benefit if researchers evaluate 3DP processes and products separately. Material property, consistency, and overall quality may be issues that need to be specifically evaluated. Service bureaus may be the path of least resistance for persons looking to obtain 3D printed devices, and the physiatrist may be asked to comment on such devices. Given the rehabilitation professional's oath to "first, do no harm," he or she must be critical of the assertion that 3DP devices are improvements upon standard equipment and should caution the patient to be critical as well. Even if research determines that 3DP is a better way to make a better device, the community would still need to address regulation, liability, and reimbursement.

Future Research and Limitations

Future research on 3DP in PM&R should continue to examine both the *process* itself as well as its *products*. In terms of the process, more research is needed on CAD/CAM program usability, material variability/availability, and costs of 3DP for rehabilitation-related endeavors. As the usability of 3DP improves, research should help to evaluate which rehabilitation professionals should be directly using the technology. Rehabilitation engineers and orthotists/prosthetists may be best suited; however, there may be advantages to having therapists and physicians directly involved with 3DP endeavors, as these providers are frequently the first ones to identify new clinical needs requiring equipment that is not currently available. Clinical providers with a good working knowledge of 3DP may be the best source of new innovative ideas for the use of 3DP in rehabilitation equipment. In addition, it would be helpful for 3D scanning and reconstruction modeling to be closely compared with casting, as passive manual positioning of a limb is not allowed in the scanning process.

With regard to 3DP products, research should first focus on evaluating products that are already available. Reports in non—peer-reviewed manuscripts have highlighted how 3D printed prostheses with different functional abilities can be an area of further research [59]. An example of a commercially available 3D printed rehabilitation product is an ergonomic joystick handle for powered wheelchairs users; such products are designed to be more functional for the user, as they are printed to fit the person's anatomy [60]. Research to demonstrate the potential improvement in function and/or esthetics of such a device would help to establish the benefit of 3DP in rehabilitation. Quality control of 3DP objects is another area of potential research.

Assistive technology abandonment is another way to compare 3DP. AT abandonment research has already established that devices are abandoned, at large costs to society, for reasons such as lack of user involvement in device selection, poor esthetics, lack of customization, and difficulty of procurement [58,61,62]. Evaluating whether 3DP devices affect any or all of these causes of abandonment could also be important to the evaluation process [58,61].

Long-term studies with sufficient power will be needed to establish clinical effectiveness and efficiency, patient acceptance, and device durability. Studies of clinical effectiveness should use validated outcome measures. In studies of lower limb orthoses and prostheses, measures might include one of the multiple variations of walk tests (10 Meter, 2 Minute, 6 Minute Walk), the Berg Balance Scale, the Functional Independence Measure (FIM), the Goal Attainment Scale (GAS), or the History of Falls Questionnaire Outpatient Physical Therapy Improvement in Movement Assessment Log (OPTIMAL). These outcome measures are a very small sample of possible measures to consider. For studies of relative efficiency of the 3DP process versus standard fabrication, measures such as time to delivery, times that a device needs to be re-fabricated or modified to achieve adequate fit, cost of fabrication, or mean time until device failure could be considered.

Conclusion

The field of PM&R is constantly evolving, and 3DP has many potential applications in PM&R to innovatively help individuals with disabilities to improve function and quality of life. Applications of 3DP in prosthetics, orthotics, and assistive technologies may offer more efficient or effective ways to address clinical needs in rehabilitation. The process of 3DP can help to maximize the creative effort that goes in to device development, and many of the reasons that patients abandon devices may be able to be addressed by 3DP. Future research will benefit from clearly addressing how the 3DP *processes* improve upon traditional fabrication methods and/or showing how 3DP *products* are improved compared to traditional devices.

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