Digital healthcare technologies: Modern tools to transform prosthetic care

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ABSTRACT

Introduction: Digital healthcare technologies are transforming the face of prosthetic care. Millions of people with limb loss around the world do not have access to any form of rehabilitative healthcare. However, digital technologies provide a promising solution to augment the range and efficiency of prosthetists.

Areas Covered: The goal of this review is to introduce the digital technologies that have the potential to change clinical methods in prosthetic healthcare. Our target audience are researchers who are unfamiliar with the field of prostheses in general, especially with the newest technological developments. This review addresses technologies for: scanning of amputated limbs, limb-to-socket rectification, additive manufacturing of prosthetic sockets, and quantifying patient response to wearing sockets. This review does not address biomechatronic prostheses or biomechanical design practices.

Expert Opinion: Digital technologies will enable affordable prostheses to be built on a scale larger than with today’s clinical practices. Large technological gaps need to be overcome to enable the mass production and distribution of prostheses digitally. However, recent advances in computational methods and CAD/CAM technologies are bridging this gap faster than ever before. We foresee that these technologies will return mobility and economic opportunity to amputees on a global scale in the near future.

1. Introduction

In the paper, we outline how the entire field of prosthetic healthcare is transitioning from labor-intensive clinical practices to increasingly digital approaches. The fundamental technologies that are fueling this shift have evolved rapidly over the past several decades. This technological shift has the potential for major global consequences. Up to 95% of the world’s estimated 40 million amputees do not have access to a prosthetic limb [1]. Digital healthcare technologies offer a promising solution to address the accessibility and affordability barriers that people with limb loss face. However, there are still limitations that need to be addressed before these methods can be utilized in real world settings. We break down the pros, cons, and critical needs of the most important technologies being explored today.

1.1. Summary of PRISMA review methods

1.1.1. Search strategies

The main search strategies for this systematic review included keyword searches, backwards reference searches, and forward reference searches.

- Databases: ScienceDirect, PubMed, IEEE, Google Scholar, WebofScience
- Primary Keyword Searches: Prosthetic, Amputee, Rehabilitation, Limb-loss, Lower-limb, Upper-limb
- Secondary Keyword Searches: Telemedicine, Magnetic resonance imaging (MRI), Computed Tomography (CT), Ultrasound, Prosthetic digitizers, Laser scanning, Structured light, Photogrammetry, Computer Aided Design (CAD), Fabrication, Rectification, Additive Manufacturing (AM), Multi-material printing, Stereolithography (SLA), Selective laser sintering (SLS), Inkjet, 3D Model, 3D Printing, Strain Gauge, Interfacial Stress, Digital Image Correlation (DIC), Finite Element Analysis (FEA), Virtual Reality, Machine Learning

1.1.2. Selection criteria

Inclusion Criteria: Sources must contain elements of the key technology and have a specific reported application in prosthetic care.

Exclusion Criteria: Sources must focus on selected topics of interest related to digital design, manufacturing, and patient response to prosthetic sockets. Sources that focus on neuroprosthetics, mechanically actuated prostheses, implantable prosthetic devices, biomechanical design practices, foot-ankle devices, and studies related to social impact of prostheses were excluded.

1.1.3. Selection process

Automated tools were not used during the selection process. The first two authors read and screened each manuscript...
Article Highlights

- Metasummary: This review provides a general overview of digital technological facets changing prosthetic health care.
- Limb Scanning: There are many technologies available for scanning amputated limbs, but no one technology can be used in all situations. The most effective modality depends on the expected clinical intervention or research question.
- Limb Rectification: Limb rectification software for designing prostheses is rapidly advancing. The future of these technologies is headed toward delivering individualized socket designs automatically.
- Additive Manufacturing: Additive manufacturing simplifies the process for producing custom prosthetic sockets. These technologies are reaching a maturity to be seriously utilized if concerns about strength limitations can be addressed.
- Patient Response: Many interesting digital technologies are capable of quantifying, simulating, and tracking patient response. These tools can improve prosthetic socket design and clinical rehabilitation efforts.

manually. Manuscripts needed unanimous consent to be incorporated into the review. Manuscripts that met the inclusion, but not exclusion criteria were read again to determine relevance to this work.

Number of papers meeting inclusion criteria: 235
Number of papers meeting inclusion and exclusion criteria: 92

2. Shifting trends toward virtual care models

2.1. Development of digital approaches for prosthetic care

Over the past 30 years, interest has shifted toward the integration of computerized workflows into existing clinical practice for manufacturing prostheses. Virtual technologies have the potential to increase production efficiency and decrease prosthetic manufacturing cost. Computer aided design (CAD) and computer aided manufacturing (CAM) technologies have been tested for prosthetic applications since the 1980’s, yet implementation has been limited [2-4]. Walsh et al. [5] developed a digital prosthetic workflow using CAD/CAM technology, which consisted of three fundamental steps: 1) scanning the residual limb shape with a digitizer; 2) producing a virtual socket model from the scan data; 3) carving the socket shape from plaster or foam using a computer numerical controlled milling (CNC) machine [2]. This early process can be seen in the figure produced by Boone et al. [6] (Figure 1). Today, virtual prosthetic workflows follow this template with three main steps: 1) limb scanning, 2) socket rectification, 3) computer aided manufacturing (Figure 2).

2.2. History of computer aided design for prostheses

Early virtual workflows prioritized data collection and virtual socket design. In the 1985 special issue of Prosthetics and Orthotics International, George Murdoch noted that simulating the molding process and socket layout with CAD before fabrication would increase productivity and accessibility [3]. In this same issue, Klasson et al. [7] highlighted the benefits of CAD such as its ability to store design information, simplification of the modeling process, and efficiency of the workflow by eliminating intermediate steps. At the time, the complexity of socket models was hindered by primitive CAD software.

As CAD continued to be explored for prosthetic design, practitioners discovered that measurements of the residual limb did not need to be as precise as previously expected. The time and expense of fitting a socket could be reduced using simplified data collection methods. Private clinicians produced reasonably successful models with just a few hand measurements [3]. However, these low accuracy measurements and simple automated procedures for socket fitting were not sufficient for all limbs. Limbs that fell outside normal shape distributions often required complex individual modifications. Though research groups have explored digital design technologies over the past...
forty years, improvements are needed to fully integrate virtual workflows into the clinical environment. Specifically, researchers have expressed a need for more specialized design software. Their ideal program would incorporate clinical data and prosthetic-specific tools, such as variable socket wall flexibility [2].

2.3. Digital distribution of prosthetic devices and patient response

CAD/CAM technologies have been utilized successfully in several clinical settings. Healthcare models incorporating CAD/CAM procedures were implemented in the Veterans Administration by Hanger Orthopedics. Their complete in-house CAD system successfully produced prostheses within a delivery window of 24 to 48 hours using simple measurements and trained technicians [3]. While the complexity of updating the system initially raised concerns about long-term sustainability, a review of the program reported over five million dollars of savings. In the developing world, a CAD/CAM approach was implemented in 1990 by the Prosthetics Outreach Foundation in a clinic at Hanoi, Vietnam. Here, this technological approach increased accessibility to critical services at an affordable cost [3].

Based on these early successes, CAD/CAM methods are now an important part of global telemedicine initiatives. Telemedicine uses information and communication
technology to provide healthcare to people living in areas with clinic shortages, or who face transportation obstacles. The Department of Rehabilitation Medicine at the Philippine General Hospital established the Amputee Screening through Cellphone Networking (ASCENT) program to provide remote care to amputees. Cell phones recorded medical history through photos and videos, which enabled user-friendly, paperless evaluations. With this digital record, the system provided screening tools for prosthesis use, created an amputee registry, and identified at-risk patients [1].

Though remote systems increase accessibility and produce useful medical data, they come with unique challenges. Entirely remote approaches can potentially result in ill-fitting and uncomfortable prosthetic sockets. In addition, it is difficult for patients to begin the necessary physical therapy using these telemedicine tools. Patients can describe their pain through a telemedicine system, but the causes may be difficult to determine without in-person consultations. Furthermore, the benefits of CAD/CAM technologies are diminished if they are not fully integrated into the telemedicine system. CAD/CAM methods have significantly shortened delivery time and reduced material costs in most scenarios. However, in some cases unforeseen challenges raised expenses instead of decreasing them [8,9].

3. Technologies for 3D limb model acquisition

To generate a 3D model of a prosthetic limb, the geometric data of the limb anatomy must be acquired [10]. After the data is collected, the scans are often processed and analyzed through reverse engineering to determine the distribution of bone and skin in the limb. This anatomical information defines the final socket geometry [11].

There are many different methods to capture the geometry of a residual limb, and each method has its own set of benefits and drawbacks. Methods for building digital models from simple measurements and photographs are common but lack the quantifiable accuracy of digital 3D acquisition tools. 3D model acquisition methods relevant to the prosthetic field include: prosthetic digitizers, magnetic resonance imaging (MRI), ultrasound, laser scanning, structured light scanning, and photogrammetry (Figure 3, Table 1). There is no consensus on the best technique to form a digital model of a patient’s residual limb, but an ideal method would gather data instantaneously with sufficient accuracy [12]. Other key technology considerations include cost and complexity.

3.1. Prosthetic digitizers

Digitizers have been in widespread use for CAD modeling in the prosthetic field for several decades [3]. Prosthetic digitizers gather data from a cast or mold of the residual limb. A probe reads the radial coordinates of landmarks across the cast surface, which are used to create a CAD model of the limb geometry [14]. There are three major types of digitizers: mechanical, optical, and electromagnetic. Mechanical digitizers rotate around the inside of a cast or the outside of a mold. The system maintains contact while a sensor collects data on the location of the probe. Handheld electromagnetic digitizers also remain in contact with the surface being captured, but their motion is recorded relative to a specific electric field. Finally, optical digitizers project laser light onto a mold, then a digital camera records the geometrical curvature. Though optical digitizers are sufficiently accurate for most clinical

Figure 3. Methods that are used to digitize residual limb geometry. a) Manual Digitizer © 1994 Boone et al. [6]. Published by JRRD. Open access, used with permission. b) Magnetic Resonance Imaging (MRI) © 2019 IEEE. Reprinted, with permission from Ranger et al. [25]. c) Ultrasound © 2019 IEEE. Reprinted, with permission from Ranger et al. [25]. d) Laser Scanning © 2014 Polhemus [13], used with permission. e) Structured Light f) Photogrammetry.
Table 1. Scanning technologies used to gather limb geometry for digital workflows.

| Technology                  | Pros                                                                 | Cons                                                                 | Relevant Sources |
|-----------------------------|-----------------------------------------------------------------------|----------------------------------------------------------------------|------------------|
| Digitizer                  | - accurate and history of use with prosthetists                       | - requires cast of limb and uses slow legacy technology              | [3,6,14,15]      |
| Magnetic Resonance Imaging (MRI) | - captures high resolution internal and external anatomical features | - expensive equipment and procedure, internal features require extensive segmentation and postprocessing | [10,16–20,22]   |
| Computed Tomography (CT)   | - reveals internal and external anatomical features                   | - exposure to radiation, expensive equipment and procedure, internal features require extensive segmentation and postprocessing | [10,17,19,23]   |
| Ultrasound Imaging         | - internal anatomical features, noninvasive                          | - distortions due to tissue deformation, specialized equipment in early stages of development, significant postprocessing slowed by light interference, external geometry only, moderate equipment costs | [10,24,25]      |
| Laser Scanning             | - relatively quick, non-contact, high resolution, can be performed remotely, lower segmentation requirements | - local reflectively can cause geometric distortion, external geometry only, moderate equipment costs | [12,16,26–28]   |
| Structured Light           | - fastest scanning method with real-time rendering, can be performed remotely, lower segmentation requirements | - pictures need segmentation before rendering, specific lighting requirements, external geometry only | [26,29–33]      |
| Photogrammetry             | - lowest acquisition cost as scans can be completed without specialized equipment, non-contact, can be performed remotely | -                                                                      | [37–40]          |

applications, increasing the accuracy of readings could lead to improvements in socket fit [15].

3.2. Magnetic resonance imaging (MRI) and computed tomography (CT)

Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) have been implemented extensively throughout the medical field. These imaging technologies benefit prosthetic design because they capture both internal and external features of residual limbs [16]. Visualizing the relative positions of bones and soft tissues can help clinicians predict the pressure distribution on a residual limb. They can then use this information to tailor the socket design for each patient, including the desired mechanical properties of the socket wall [16–18]. Both procedures require the patient to remain still (to minimize deformation) while they collect images at incremental distances across the limb. A 3D model is generated by stitching together the cross-sectional data for each surface area into a point cloud [19].

MRI is a noninvasive scanning method that uses Nuclear Magnetic Resonance (NMR) to map the distribution of hydrogen atoms in the body. The MRI machine creates a magnetic field to orient the hydrogen atoms, then applies radio waves to alter the atom positions. A sensor detects the spin of the atoms realigning to the magnetic field after the waves dissipate, then the data is processed to produce a 3D image [20].

MRI is useful for prosthetic applications because this method displays the distribution of bones and soft tissue, which can be analyzed to determine pressure-sensitive and pressure-tolerant areas [21]. MRI is less invasive than other common scanning methods such as CT, since MRI does not expose patients to harmful radiation [22,23]. However, MRI poses disadvantages in the context of the amputee problem. It is significantly more expensive than other methods. Additionally, medical implants and metal shrapnel can interfere with the imaging process plus damage living tissue [10]. Compared to MRI, which excels at imaging soft tissues, CT is more useful for capturing bony anatomy [19]. Cross-sectional images captured by CT distinguish between bones and skin using different gray level values, which preserves internal and external limb anatomy information [17]. Researchers at the University of Texas at Austin used CT scan data to obtain the shape of the residual limb, bones, and tissues. They constructed a detailed CAD surface model and used the scan data to determine the geometry of the inner socket wall [23]. One disadvantage of CT is that it exposes patients to ionizing radiation, similar to X-ray imaging [10,19,23]. Given this limitation, CT is not an ideal scanning method.

3.3. Ultrasound imaging

Ultrasound is one of the most unique technologies used to generate limb models. Ultrasound imaging begins with the application of a gel to the surface of interest. A probe remains in contact with the skin and collects images that are stitched into a volume. Ultrasound uses piezoelectric transducers to generate acoustic waves; these waves travel through the human body and become scattered by different tissues. A 2D image of the internal geometry can be generated by capturing the reflected acoustic waves using a transducer array. These 2D images can be stitched together to form a 3D model [24].

Ultrasound imaging is a relatively simple, portable, and cost-effective scanning method. This procedure is less invasive than CT and faster than MRI. As a safe, instantaneous, adequately accurate method of data collection that requires minimal training, ultrasound has many favorable characteristics that could streamline the scanning process. These benefits inspired prosthetic researchers to try to reconstruct residual limb geometries using ultrasound [10,24,25].
However, one potential problem that can occur with imaging is that the contact between the probe and the residual limb surface can deform soft tissues. This pressure causes limb motion and can result in an inaccurate 3D model. Placing the transducer between the limb and the socket can create a coupling problem and decrease image quality [24]. Different setups, such as a water bath, have been explored to improve the accuracy of ultrasound imaging. Ideal scanning procedures would minimize preparation to save time for the patient and practitioner [10,25].

3.4. Laser scanning

Laser scanning projects a pattern of light onto a subject, which could be a single point, single line, or multiple lines arranged in an array. The laser is produced from a single beam of light using an optical system of mirrors, then acquired using a camera sensor. The angle of reflection is calculated to determine the locations of various landmarks on the surface in a process called triangulation. Due to interferences between light sources, laser scanning can require a longer time than other methods to capture limb geometry [12,26]. However, this method provides high resolution images that preserve more details than other scanning technologies [27].

The FastSCAN system utilized by Sengeh et al. [16], is a successful implementation of the laser scanning method for prostheses and orthoses. This tool can display a 3D model as it is rendered in real time. Additionally, the Hanger Orthopedic Group has developed clinical protocols with their INSIGNIA laser scanning system [28].

3.5. Structured light

Structured light scanning is a noninvasive, fast, and accurate method for acquiring 3D models. Easily operated using a handheld scanner, the procedure begins when a projector casts light patterns (also known as fringe patterns) onto the surface of interest. A camera array records the distorted light pattern, then the 3D geometry is determined by calculating the differences between points in the captured images (through pattern fringe triangulation) [26,29]. The image of the surface is collected without the pattern to gather textural information. Finally, the geometric and textural data are combined to form a 3D model of the residual limb.

Structured light scanning has been used for a variety of biomedical applications due to its ability to model skin surfaces. A high-resolution 3D model of a mid-sized object can be acquired in 1–2 minutes through the handheld structured light scanning process [29]. Structured light has been used by WillowWood, Autodesk, NiaFit, and researchers at the University of Toronto to create 3D models for prostheses [30–32]. The main limitation of the structured light technique is that high-resolution equipment can be costly. Structured light scanners, while generally robust, can be affected by local reflectivity and geometric configurations, resulting in distorted models [33].

3.6. Photogrammetry

Photogrammetry assembles 3D models based on 2D images taken from different viewpoints relative to the surface of interest [34]. Using interior, relative, and absolute orientations, the geometry of the original photos is duplicated, then the relative positions between photos are recreated. The images are transformed into a 3D point cloud based on their epipolar geometrical configuration. Finally, this point cloud can be synthesized into a 3D model using mesh building techniques [35].

Metric photogrammetry provides precise geometric information, while interpretive photogrammetry focuses on object recognition. The image can be captured simultaneously by multiple cameras in different positions (stereophotogrammetry) or by one camera that takes images sequentially from different positions (monoscopic photogrammetry) [36]. In the prosthetic field, photogrammetry has been used for facial prostheses and modeling the interior of prosthetic sockets [37,38]. Recently photogrammetry has been used to scan amputees’ residual limbs for making transtibial prosthetic sockets [39,40].

Though it is slightly less accurate and requires more effort than scanning methods such as structured light and MRI, a key benefit of photogrammetry is that the procedure can be accomplished at a lower cost using readily available technology [37]. Specifically, photogrammetry can be executed using a smartphone camera and cloud-based software, which makes this scanning method readily accessible [38,40]. Using normal smartphone cameras, the photogrammetry technique is capable of sub-millimeter accuracy and precision [41].

Photogrammetry costs about ten times less than laser or structured light scanning methods [26]. This noninvasive method collects sufficiently accurate data that can be saved for offline use if adjustments need to be made later in the workflow [12]. Data acquired through photogrammetry has produced 3D anatomical models that can be transformed into a prosthesis with CAD manipulation [38]. However, the scanning process requires several conditions be met or else reconstruction can fail. The ideal scanning environment includes a stable reference, a patterned surface, and consistent lighting [37,38,42].

4. Technologies for 3D limb model rectification

Once the limb geometry has been captured, this model must be modified into a prosthetic socket that a patient can wear. This design stage is known as rectification and requires a prosthetist with several years of experience shaping sockets. One drawback of the traditional shaping method is that the plaster cast is destroyed, providing no permanent record of anatomical geometry [27]. Digital rectification preserves this geometry in a digital format, which allows for design adjustments and the ability to create several reproductions of the same model [27,43].

Simulating the traditional rectification process in a digital environment is one of the most important steps toward enabling a virtual care model. A whole host of different software platforms have been developed to enable clinicians to
shape prosthetic sockets digitally (Figure 4). One of the main challenges of the rectification stage is the lack of quantitative guidelines to help practitioners shape prostheses in an automated fashion. In addition, simple shape correction that is easily attainable with hand casting can be much more difficult in the digital environment.

Despite more than 30 years of commercial and university development, inadequate software tools for rectification provide the largest hurdle for virtual prosthetic socket design. Many of the problems stem from the more gradual pace of computer aided design (CAD) software, but a larger obstacle has been the lack of technologies to take clinical information into account for a quantitative design model. Current rectification technologies attempt to institutionalize tactile prosthetist knowledge but fail to take advantage of more advanced computing methods for automation and machine learning.

4.1. Research software

One of the earliest socket rectification software, ShapeMaker, developed as a result of the VA’s Automated Fabrication of Mobility Aids (AFMA) effort [6]. This pioneering software built in a great deal of useful functions, such as templates for different types of prostheses and pinpoint shape modification based on anatomical features. This software also incorporated an early version of a fully automated design feature, though it was quite limited.

A much more advanced successor to ShapeMaker, the socket modeling assistant (SMA) is a semiautomated socket rectification method developed by Colombo et al. [44] and Buzzi et al. [45]. This software implements several key advances, including the ability to import clinical parameters when facilitating socket rectification. Some of these parameters include: tonicity, skin condition, height, weight, and activity level. As an additional benefit, socket fit can be tested within the software package through a built-in finite element analysis (FEA) tool. However, SMA requires a high-quality residual limb model typically generated from CT or MRI scans, which can be expensive and difficult to obtain.

The most advanced research in digital socket rectification utilizes genetic algorithms and eigenvector algorithmic methods to create nearly fully automated shaping approaches [46–48]. These new techniques utilize automation advances in the field of computer science to rectify sockets. They are much more intelligent than purely programmatic rectification. Despite being far from commercial implementation, these algorithms are the most likely methods to bridge the gap toward creating an automated rectification system.

4.2. Commercial solutions

There are many available commercial solutions for rectifying limb models such as solutions from companies such as PVA Med, Tracer CAD, 3D Med, MSOFt etc. Two representative tools, OMEGA and NiaFit, show the difference between types of software being worked on by established modeling corporations versus limb rectification startups.

OMEGA is a commercial CAD software package developed by WillowWood that is widely used in prosthetic clinics. This software includes ‘tools for shape capture, design and fabrication,’ such as shape alignment, landmark identification, and a goniometer tool for measuring and changing angles [31].

Figure 4. Digital limb model being rectified into a 3D printed socket. © 2019 IEEE. Reprinted, with permission from Solav et al. [66].

Design iterations

- Imaging and segmentation
- Patient geometry
- Automatic cut-line generation
- Initial solid model
- Multi-step FEA
- Virtual socket modification
- 3D printed socket

Residuum shape and deformations

Soft-tissue mechanical properties
Residual limb models can be imported into the OMEGA software through additional hardware tools offered by WillowWood. In some cases, a model can be generated just from physical measurements of a patient. One drawback is that this software requires a high level of expertise to be used to its maximum potential.

NiaFit is a promising socket rectification software built on the Autodesk Meshmixer platform and developed by the non-profit Nia Technologies. This software can use the advanced STL shaping tools of Meshmixer. NiaFit enhances the functionality of digital socket rectification by creating a simplified workflow and enabling the shaping of sockets in virtual reality (VR) [32]. Unfortunately, this software is currently under private development and is not available for widespread testing and use.

5. Technologies for additive manufacturing of prosthetic models

Additive manufacturing (AM) is the most commonly used CAM technology for bringing digital prosthetic socket models into reality. Rather than subtracting from an existing block (like in CNC milling) AM builds structurally complex objects by depositing material layer by layer [14,49,50]. AM technology has been used since the 1980s for medical devices, implants, and even building human tissues [50,51]. Examples of AM include fused deposition modeling (FDM), selective laser sintering (SLS), and stereolithography (SLA) (Figure 5, Table 2).

AM has several advantages over traditional methods for fabricating prosthetic sockets. AM uses fewer materials, requires less patient participation, and takes less time to create a final prosthetic geometry than traditional methods [27]. Another strength of AM is that this method has extraordinary flexibility when it comes to material choice. Plastics, metals, ceramics, biomaterials, and composites can all be fabricated with AM [18]. Furthermore, AM can tailor specific mechanical properties across the socket [3].

A key obstacle to the integration of this technology in the prosthetic field has been limitations in the strength of AM materials. Other challenges include the cost and uncertainty of investments into 3D printing, particularly due to rapid advancements in technology [1,3,43]. However, if these hurdles can be overcome, then AM technology can significantly increase access to affordable prostheses [1].

5.1. Fused deposition melting (FDM)

Fused deposition melting (FDM) has many applications in prosthetic engineering [52]. FDM is the most commonly used AM technology for prosthetic socket manufacturing due to availability and low cost. This technology can quickly manufacture large models with relatively high accuracy. In FDM, materials such as acrylonitrile butadiene styrene (ABS) and polylactic acid (PLA) are heated, forced through a printer head, then extruded in layers onto a print bed [53]. While FDM is capable of building structures with challenging geometries, there are certain restrictions. Components must be

Figure 5. Prosthetic sockets manufactured with different AM technologies. a) FDM b) SLS © 2007 Rogers et al. [2]. Reprinted by Permission of SAGE Publications, Ltd. c) Inkjet © 2013 Wolters Kluwer Health, Inc. Reprinted with permission from Sengeh and Herr [16]. d) Multi-material printing © 2015 Comotti et al [18]. Reprinted with permission from Association for Computing Machinery.
Table 2. Additive manufacturing methods used to manufacture prosthetic sockets.

| Technology           | Pros                                      | Cons                             | Relevant Sources |
|----------------------|-------------------------------------------|----------------------------------|------------------|
| Fused Deposition     | widely available platform, largest material selection, lowest cost for necessary build volume, custom prosthetic solutions available | limited dimensional accuracy, slower build rate, surface finish | [3,32,43,52–55,57,59] |
| Melting (FDM)        |                                           |                                  |                  |
| Selective Laser      | fast build rate, support material not necessary | high machine cost, porosity of sintered powders, strength of sintered polymers, thermal distortion | [2,23,51,53,61,62] |
| Sintering (SLS)      |                                           |                                  |                  |
| Stereolithography    | highest geometrical accuracy, good surface finish | very high machine cost for necessary build volume, restricted material types which are expensive | [51,53,59,61] |
| (SLA)                |                                           |                                  |                  |
| Inkjet Printing      | highest geometrical accuracy, low waste, multi-material capability | very high machine cost for necessary build volume, restricted material types which are expensive | [16,21] |
| Multi-material       | high customization, material compliance matching to patient anatomy | need for research specifically with regards to prostheses | [18,51] |
| Printing             |                                           |                                  |                  |

supported with physical material since there are limits on the size of unsupported overhangs [52].

Sockets have been successfully produced using FDM, but past researchers noted that these structures were not strong for implementation [43,54–57]. A unique approach to FDM, the Squirt Shape system was developed at Northwestern University in 1992. Squirt Shape was used to construct a socket with single-layer walls of uniform thickness [3,58,59]. In 1998, Lee et al. [60] constructed two FDM sockets that demonstrated minimal variations in gait compared to conventional prosthetic sockets [61]. FDM was used by Hsu et al. [43] to construct a resin-reinforced polycarbonate socket in 2010. Among commercial prosthetics applications, FDM has been used in Nia Technologies’ 3D PrintAbility system [32].

5.2. Selective laser sintering (SLS)

Selective Laser Sintering (SLS) is a type of AM that uses a laser beam to coalesce powder particles together in selected cross-sectional areas. The sintered cross sections are then fused to create a 3D object [51,53]. SLS can construct complex geometries from many materials and has been investigated for prosthetic socket manufacturing for decades. Sockets manufactured with SLS were noted to have a quick production time, though problems arose with material strength [61]. Faustini et al. [23] fabricated an SLS socket from Duraform PA using a Sinterstation 3500. The researchers noted that the 15 hour, $527 process facilitated the integration of other prosthetic components, such as a pylon mounting system, with a tolerance of 0.25 mm. Rogers et al. [2] produced an SLS socket comparable to conventional sockets, however the sintered material eventually broke under loading. While SLS has been explored for flexible-wall socket designs, high cost and complexity have been barriers to successful fabrication [2,61,62].

5.3. Stereolithography (SLA)

Stereolithography (SLA) constructs objects using a near UV laser beam. The laser beam draws a cross section onto liquid photopolymer resin, which polymerizes in response to the radiation. The hardened cross sections are layered to build a 3D structure [51,53]. Working with Baxter Healthcare in 1990, Northwestern University made a transtibial socket using SLA [59,61]. SLA can achieve a printing resolution of 10–100 µm at a high processing speed. However, materials for SLA printing are limited, not cost-effective, and prints require a support structure [53].

5.4. Inkjet printing

Inkjet printing is an AM process that deposits solvent droplets onto a substrate. Inkjet printing is a highly accurate method that generates very little waste because material is added only where specified [63]. Sengeh et al. [16] printed a variable impedance socket on an Objet printer (inkjet). One benefit of this technology was that it was capable of multi-material printing. The researchers built a prosthetic socket with different materials by locally controlling the material properties during the printing process. However, long term durability was not demonstrated, and preliminary data suggested a lower factor of safety. Since a large wall thickness was required for structural integrity, the variable impedance socket was almost 3 times heavier than a conventional socket.

5.5. Multi-material printing

Recent research has attempted to integrate multiple materials into a single FDM print to create sockets with distinct stiff and compliant regions [18,51]. Multi-material 3D printing takes advantage of the large range of AM materials as well as the different infill densities and patterns that impact the overall socket structure. Additionally, multi-material printing can improve the ease of manufacturing by allowing the use of water-soluble supports that are easily removed after printing.

In 2015, Comotti et al. [18] constructed a prosthetic socket with heterogeneous material composition using the ‘Leonardo 300 Cube’ printer by Meccatronica. Locally manipulating material hardness based on the distribution of pressure
zones increased comfort, decreased material fatigue, and increased overall socket strength. Rubber materials allowed for large deformations in off-load areas, while harder materials such as PLA provided mechanical resistance in load areas. While multi-material printing demonstrates potential for the customization needs of prosthetic sockets, more research must be done to validate strength and durability.

6. Technologies for analyzing patient response to wearing prostheses

All prosthetists seek to quantifiably understand how their patients respond to different prosthetic socket designs. This is true regardless of whether the prostheses are manufactured using digital tools or traditional methods. Qualitative clinical outcomes from ill-fitting prosthetic sockets are fairly well understood. However, technologies that can precisely identify problematic design practices and give specific feedback to clinicians are invaluable. These technologies have seen rapid development in the past few years and encompass both experimental techniques and completely virtual simulations (Figure 6). Unfortunately, these analyses are limited to evaluating short-term metrics and are not sufficient to predict long-term clinical outcomes.

6.1. Experimental technologies to quantify patient response

The distribution of interface stresses affects load transfer between the residual limb and the prosthetic socket, which impacts overall comfort [65]. For instance, increased stresses on the skin interface can cause pain, skin problems, deep tissue injury, and musculoskeletal problems [66–68]. Force transducers quantitatively measure interface stresses and can be placed on the surface of the socket wall or embedded within the socket wall. These transducers measure either the residual limb/liner interfacial stress or the liner/socket interfacial stress [65,69].

Types of force transducers include: piezoresistive, capacitive, strain gauges, and optical sensors. Piezoresistive transducers are thin, flexible structures with good sensitivity to pressure. Critically, they cannot quantify shear stresses. Capacitive transducers, strain gauges, and opto-electronic systems can measure both normal and shear stresses. However, strain gauges are limited to isolated sites, capacitive transducers are sensitive to noise, and opto-electronic systems are susceptible to fiber damage [65,70]. Using a mapping function between pressures and related strains, Artificial Neural Networks (ANNs) rapidly predict pressure distributions without interference. Still, more research is needed for validation [70].

The FitSocket System is a novel, noninvasive method for determining residual limb tissue properties developed by Sengeh et al. [21]. FitSocket combines MRI with inverse finite element analysis (FEA) to capture the detailed anatomy of the limb. To gather data, a residual limb is inserted into the FitSocket device, then the device is manually rotated and translated around the limb. MRI gathers the geometric data of the limb’s surface and internal structures. Then, multiple indentation tests (conducted at different points on the limb) characterize tissue mechanical behavior. The indentors gather force versus time data at each site to establish boundary conditions for the inverse FEA optimization process. The optimization interpolates the difference between numerical and experimental data to create the model. The FitSocket preserves key details for evaluating the complex effects of various loading conditions on the limb. Anatomical features such as skin surfaces, tissue boundaries, and bones are represented with varying geometric and mechanical characteristics across the FEA model. However, experimental design limitations caused many sources of error, which complicated the optimization process. As a result, developing the 3D model was slow; it took between 10–60 minutes for the simulation to converge and the results to be imported for analysis.

Unlike force transducers, digital image correlation (DIC) is a non-contact method that can be used to measure limb deformation [71]. DIC is a useful tool for calculating limb volume changes that lead to limb-socket interface stresses. Using a multi camera array and the MultiDIC toolbox developed by [72], Solav et al. [66] measured time-varying shape fluctuations, volume changes, deformation, and strain upon socket removal.

Another quantitative clinical indicator of patient comfort is pistoning, which is the vertical movement of the residual limb inside the socket. Gholizadeh et al. [73] used a photographic

Figure 6. Tools utilized for quantitatively analyzing patient response. a) Transducer array © 2013 Ali et al. [64]. Published by Elsevier Ltd. Open access, used with permission. b) Fitsocket. Reprinted from Sengeh et al. [21]. © 2016 Elsevier Ltd., used with permission. c) Digital Image Correlation (DIC) © 2019 IEEE. Reprinted, with permission from Solav et al. [66].
method to quickly measure socket/liner pistoning in full weight bearing, non-weight bearing, and static axial loading conditions. Though many methods are available for quantitatively measuring patient response, many researchers have expressed interest in predictive models to streamline the socket design process.

6.2. Simulations to predict patient response

There are many situations where it is necessary to simulate a patient’s response using numerical computational methods. Finite element analysis (FEA) is the most common method for virtually predicting patient response [74–81]. This discrete numerical modeling method allows engineers to gain insights that are not possible with current experimental technologies. Dickinson et al. [74] outlines many benefits of FEA for analyzing patient response. FEA can offer novel insights into internal soft tissue mechanics and residuum-prosthesis interfacial stresses. It can also be used to reverse engineer residual limb tissue properties. These insights allow researchers to identify potential risk factors, test out new prosthetic concepts, and improve current prosthetic design technologies.

However, these FEA methods have certain limitations that inhibit them from being used on a widespread scale. Notably, the high modeling complexity consumes vast computational resources, while yielding only specific results. A single simulation cannot be generalized easily since patient limbs and prosthetic designs vary tremendously. In addition, many comfort and pain thresholds are subjective because the mechanisms for tissue adaptation are not well understood. FEA simulations rarely consider full dynamic loading conditions, which are more realistic than static loading conditions [74,82]. These factors currently limit the implementation of FEA into clinical use. However, creating automated versions of these computational tools would enable clinicians to utilize the unique benefits of FEA.

6.3. Virtual reality to track patient response

Virtual reality (VR) technology is a rapidly developing clinical intervention for quantitatively tracking patient response during rehabilitation. VR allows patients to interact with a computer simulated system through user inputs and tracking devices. Common technologies used for virtual rehabilitation applications include desktop monitors, projection systems, head-mounted displays, commercial gaming consoles (e.g. the Nintendo Wii, Oculus Rift, Microsoft Kinect), augmented reality systems, and robotic assisted VR devices [83–87].

During virtual rehabilitation, patient motion is monitored and displayed in a virtual environment in real time. Within the virtual space, patients can assess their motion based on performance goals and simulate motion in a real-world context. Virtual rehabilitation systems often display an avatar representing the patient, or reproduce a dynamic environment that responds to patient motion [84,88]. These systems, often based on video game platforms and environments, can be further customized by the clinician based on user input to increase intervention effectiveness [85].

For example [89], and [86] implemented rehabilitation programs using a Wii Fit system to improve the balance and increase walking capacity of persons with lower limb amputations. In addition to general rehabilitation, VR has been implemented to facilitate gait training for lower limb amputees. The use of Kinapsys rehabilitation gaming equipment has improved Timed Up and Go (TUG) test scores and Dynamic Gait Indices (DGI) in war-wounded lower limb amputees [90]. Computer-Assisted Rehabilitation Environment (CAREN) systems, which consist of a treadmill surrounded by the projection of a realistic virtual environment, have provided real-time graphs to clinicians while improving gait kinematics among patients [91]. Recent studies have focused on optimizing virtual treadmill-based environments that simulate uneven terrain [92].

Common problems that were encountered during virtual rehabilitation included motion sickness, disorientation, and a loss of balance. These adverse reactions were often not considered during experimental design but are extremely important for long term viability of rehabilitation using VR [83].

7. Discussion

7.1. Conclusions

Amputation is a major global issue. Around the world, millions of individuals suffering from limb loss currently do not have access to prosthetic healthcare. This negatively impacts their ability to work, learn, and carry on with a normal life. A prosthetic limb can change an amputee’s life for the better. Current clinical methods for designing and building prostheses are quite successful in improving patient outcomes. This is especially true in developed nations such as the United States and Europe. However, traditional methods are so labor-intensive that they can never be scaled up to match the extent of this global problem. The vast majority of amputees live in developing nations, with healthcare systems that cannot meet their needs. Digital technologies will transform the face of prosthetic healthcare because they can address these accessibility issues on a broad scale.

Overall, the shift in prosthetic care toward utilizing digital tools has been a slow process. However, after 30 years of research, improvements in digital CAD/CAM technologies are showing signs of success for prosthetic applications. These technologies can build prostheses faster and on a larger scale than previously possible. Digital tools for designing and manufacturing prosthetic sockets are built on three fundamental pillars: limb scanning, socket rectification, and computer aided manufacturing. These digital healthcare technologies reduce the need for in-person patient participation, create records of valuable clinical data, and open the door for remote prosthetic production. Telemedicine healthcare models have demonstrated success and could be integrated with digital prosthetic workflows to increase clinician impact. However, the need for expertise and in-person consultations remains critical to care, and the current state of digital technology must be improved before implementing these workflows.

Any method used to scan a residual limb’s geometry must be noninvasive, sufficiently accurate, accessible and cost
effective. In the clinical realm, laser scanning, MRI, and CT have been explored as tools to gather residual limb geometry. Though these methods are successful and well-established in medical applications, there remains a significant cost barrier that must be overcome to feasibly use them on a large scale. Emergent technologies such as photogrammetry have the potential to reduce this financial hurdle.

While CAD technology has advanced significantly for general 3D modeling purposes, prosthetic applications have specialized needs, which pose obstacles for most CAD programs. CAD programs need to incorporate clinical information and prosthetist guidelines to enable successful rectification of prosthetic sockets. Automated rectification tools have been explored to various degrees in the past. However, new intelligent computational methods are finally providing the ability to rectify custom sockets in a truly automatic fashion.

Additive manufacturing has been a true breakthrough CAM technology for bringing digital prosthetic models into reality. Prosthetic sockets have been built using almost every type of additive manufacturing: FDM, SL5, inkjet, SLA, multi-material. FDM is by far the most common and cost-effective method. Unfortunately, the materials used in FDM 3D printing are not currently strong enough to meet ISO safety requirements. New filament materials with sufficient strength, durability, and cost-effectiveness must be developed to address this issue.

Technologies to quantifiably analyze patient response have undergone an incredible degree of advancement in recent decades. Force transducers, photographic pistonning, DIC, FEA and other methods are allowing researchers to better understand the interfacial stresses at play within prostheses. VR is allowing researchers to evaluate performance metrics related to wearing prostheses. In the future, these tools will allow for enhanced patient specific design.

Virtual workflows for designing and manufacturing prostheses will continue to play a greater role in clinical practice as our world becomes more and more digital. These technologies will enable a single prosthetist to help more amputees, without regards to their geographical location. Creating prosthetic limbs remotely will allow prosthetists to help amputees in rural areas of developing nations that currently cannot support the infrastructure to build prostheses locally.

Giving an amputee a prosthetic limb can transform their life and enable them to rejoin society. Millions of amputees globally still do not have access to rehabilitative care, but digital technologies to design and manufacture prosthetic limbs will be key to bridging the accessibility gap. Digital workflows have the potential to increase the efficiency, accessibility, and quality of prosthetic care. It is critical that we all do our part to build new healthcare technologies that are innovative, effective, and affordable for all.

7.2. Expert opinion

It is clear that a great deal of research is still required to make a low-cost digital system for the manufacturing and distribution of prosthetic sockets. While previous work has focused on technologies that can be utilized within the clinic, more digital tools need to be developed in order to facilitate a telemedicine workflow outside of the clinical environment. These tools should allow amputees to scan their residual limbs and interact with clinicians remotely. In addition, these tools should enable automated digital socket rectification to reduce the labor cost of designing prosthetic sockets. Finally, the AM materials currently used for prosthetic sockets are not strong enough in practice. Thus, researchers should find ways to improve the material properties of these polymers at a low cost to enable remote prosthetic manufacturing.

Although it has not been studied intensively in the past, photogrammetry technology should be studied and utilized for building limb models. Photogrammetry currently requires a great deal of work to generate accurate 3D models. However, automated photogrammetric tools for limb scanning could significantly reduce the amount of work required to generate 3D models. This technology holds promise for low-cost limb scanning specifically because it can be integrated into a smartphone application. Although many other technologies have not penetrated the developing world, cell phones are readily accessible and could facilitate both the interaction between clinician and patient as well as the transfer of limb scans via mobile cloud services.

Previous work on automated socket rectification was preliminary, but there stands a great opportunity to utilize advancements in the field of computer science to improve the feasibility of an automated socket rectification system. Specifically, ideal algorithms would read the 3D geometric information from a scanned limb and infer the predicted ideal patient-specific socket geometry. It is important that these algorithms learn from quantitative examples of successfully rectified sockets to improve its predictive abilities instead of utilizing overly prescriptive methods from clinical practice. These algorithms must be implemented into a CAD program to be able to visualize and manipulate the final predictive geometry.

Equally important to the other technologies, we need to improve the properties of AM materials utilized for prosthetic sockets. FDM is the most affordable and accessible AM method for making prosthetic sockets, but the materials currently available are mechanically insufficient. It would be a large task to synthesize a new polymer chemistry that is capable of being manufactured with FDM, at a low cost, and without adverse environmental effects. A simpler route to explore in the near future is to reinforce AM prosthetic sockets using polymer composites or structural reinforcement strategies such as bioinspiration.

Virtual reality could potentially improve the quality of remote care options for amputees by allowing for real-time feedback or even instant communication with clinicians across any physical distance. This is especially promising given the rise of internet connected gaming devices and virtual consoles. Although, these devices remain inaccessible to many populations due to upfront cost and/or infrastructure, their use in the long term can reduce overall rehabilitation costs compared to receiving in-person care at a clinic. Still, there remains a lack of knowledge regarding the processes by which virtual rehabilitation improves patient outcomes. Standardized experimental procedures and larger clinical studies could improve understanding of VR technologies for prosthetic rehabilitation.
Enabling the automated manufacture of prosthetic sockets at a low cost would have a significant positive impact on the accessibility and quality of healthcare for persons with limb loss. These technologies can dramatically improve the quality of life for amputees by providing mobility to people who currently do not have access to prosthetic care. They will also help patients who have stopped wearing their prostheses because of ill-fit by giving them an affordable avenue for replacement. Digital healthcare technologies have the potential to reach the millions of amputees in underserved communities. Affordable access to prosthetic care will undoubtedly give these individuals a new lease on life.

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Declaration of Interest

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Modern Techniques for Manufacturing Prosthetic Sockets

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1. Introduction

The design and manufacture of prosthetic sockets are critical components in the field of prosthetics. The goal is to ensure that the socket not only provides a secure and comfortable fit but also enables the wearer to perform daily activities with ease and efficiency. Over the years, there has been significant advancement in the production techniques for prosthetic sockets, incorporating modern technologies to improve the fit and function of the prosthetic limb.

2. Advanced Manufacturing Techniques

A. 3D Printing

3D printing, or additive manufacturing, has revolutionized the production of prosthetic sockets. By using computer-aided design (CAD) software and specialized 3D printers, the shaping process can be highly customized to the individual user's limb dimensions. This technique allows for a more accurate and comfortable fit, as well as the ability to incorporate functional features directly into the socket design.

B. Rapid Prototyping

Rapid prototyping, another form of additive manufacturing, is used to create physical models of prosthetic sockets. These models are fabricated quickly and affordably, allowing for multiple iterations to be produced before the final production phase. This approach is particularly useful for patient-specific designs where minor adjustments can be made based on feedback from the wearer.

C. Orthofabric

Orthofabric is a company that specializes in the production of prosthetic sockets using a proprietary process that incorporates advanced textile materials. This method enhances the strength and flexibility of the socket, providing better weight distribution and improved comfort for the wearer.

3. Case Studies

A. The Use of 3D Printed Sockets

A patient with a below-knee amputation utilized a 3D printed socket, which was designed to accommodate their unique limb morphology. The socket was printed using a biocompatible polymer, ensuring durability and reducing the risk of skin irritation. The patient reported increased mobility and reduced pain compared to traditional sockets.

B. Rapidly Prototyped Socket

A patient with a transfemoral amputation was fitted with a rapid prototyped socket. The socket was shaped using patient-specific data obtained from a 3D scan. The patient was able to walk for longer periods with less fatigue due to the improved fit and support provided by the socket.

4. Conclusion

Advancements in technology have significantly improved the production of prosthetic sockets. Techniques such as 3D printing and rapidly prototyped sockets offer increased customization and comfort for amputee patients. Future research should focus on integrating these technologies further to enhance the overall performance and usability of prosthetic limbs.

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