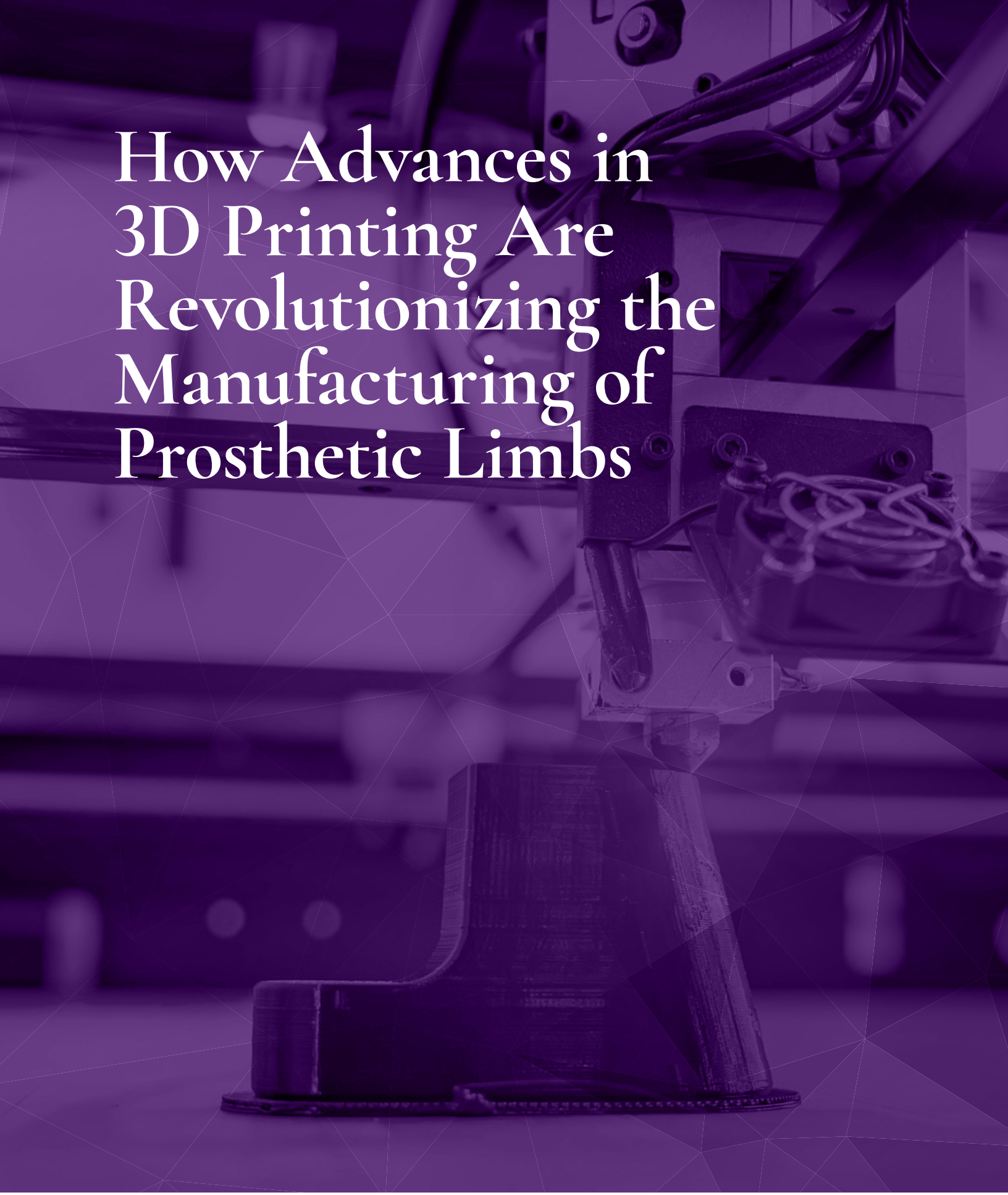

How Advances in 3D Printing Are Revolutionizing the Manufacturing of Prosthetic Limbs

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Introduction

Approximately one out of every 190 Americans is living with limb loss. That translates to roughly 2 million people. If the current trend continues, this number could double by 2050.[1] The WHO estimates that, worldwide, 35-40 million people are in need of a prosthesis.[2]

Traditional manufacturing methods simply can't keep up with the growing demand for prosthetic devices. Fortunately, over the pasts few decades, additive manufacturing, otherwise known as 3D printing, has helped to reduce the time of production, lowered cost barriers, and improved the overall usability of prosthetic devices.

Recent advances in 3D printing technology have revolutionized the manufacturing of prosthetic limbs, so that manufacturers are able to reduce costs as well as production times, while simultaneously improving the customization of prosthetic limbs for enhanced wearer satisfaction.

Limitations of traditional methods

The traditional process for manufacturing protheses begins with creating a foam, plaster, or fiberglass mold of the patient's residual limb to create an artificial socket. Using measurements based upon the mold, the manufacturer relies on a computerized numerical control (CNC) or a milling machine to create a thermoset polyurethane prototype of the mold.

Over a series of visits, the practitioner adjusts the prototype to better fit the wearer. When the wearer has approved the fit, the socket is manufactured. The process is typically lengthy, taking up to four weeks.

The prosthesis is then chosen from an already-existing line of devices, with considerations such as socket fit and the patient's lifestyle and needs taken into account. The pylons that attach the socket to the device are typically customized, but with only a limited choice in available materials.

In addition to a limited choice in materials and lengthy production, the CNC and milling process used to manufacture sockets and prostheses has limitations. The machines are not able to reproduce complex surface designs or to create parts with different thickness, which can hinder socket fit and limit the number of prosthetic designs available to the wearer.

An ill-fitting artificial limb can greatly reduce quality of life by causing painful areas of rubbing, resulting in ulcers, lesions, and poor circulation. This is likely to result in lowered device utility, problems with gait and range-of-motion, and general discomfort. Too often, wearers abandon the prosthesis altogether.

The traditional manufacturing process is more expensive as well. Average device costs can range from $6,500 to $35,000, making them cost prohibitive for many patients, especially those with no or inadequate insurance coverage.[3]

Out with the old, in the new

Additive manufacturing began in the early 1980s when a Japanese researcher pioneered the technique. In 1981, Charles Hull invented stereolithography, a process similar to the modern 3D printing technique. The 3D printing method has continually evolved through the years, and now, companies like Airbus and Ford print parts used on their planes and vehicles.

Approximately 5 years ago, medical device makers and, in some cases, medical providers began printing prosthetic limbs. Printing was done on everything from home-built 3D printers to industry-grade machines. The process gradually improved over the past decade.

Now, advances in additive manufacturing technology and workflow have resulted in a virtual renaissance for manufacturers of prostheses.

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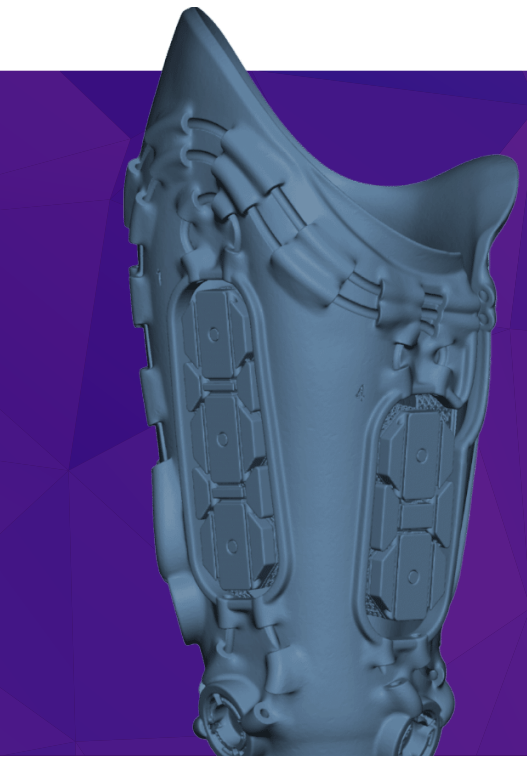

Case Study: Prosthetic manufacturer transitions to 3D printing

Two years ago, Quorum Prosthetics of Windsor, CO began testing 3D printing of its Quatro Prosthetic Sockets, which had previously been produced through a traditional resin lamination process. The Quatro socket gives wearers the ability to adjust volume, suspension and compression with a simple dial. Quorum also wanted to 3D print the liner that surrounds the socket.

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Outsourcing as an option

Before making an up-front investment in its own 3D printing devices, Quorum wanted to test the additive manufacturing method, so it chose to outsource its production to a service bureau with experience and expertise in medical device manufacturing.

The service bureau printed the socket or liner from the digital files Quorum provided and quickly sent back the printed device.

"With the digital workflow of 3D printing, you can send files across the country, get them printed, and have the parts sent right back to you," says Sean McClure, lead engineer at Quorum.

The value of a digital map

Quorum saves the CAD file for each client stored within its system and can quickly replicate a patient's existing 3D-printed socket when needed. This allows Quorum to efficiently produce additional sockets if desired by patients without the need for a refit. If, over time, the patient needs a modification, the original CAD file can be easily updated.

To recreate an existing socket, Quorum can take measurements from the patient's traditional resin-produced device, recreate it within a CAD design, make updates to optimize the design, and print it for the patient.

"With small changes to the fit, 3D printing is really an advantage because the patient doesn't have to start from square one," McClure says. "We make a minor adjustment and can print a new socket instead of having them come in, see a practitioner and be refitted for a whole new socket."

Faster production times

Formerly, Quorum spent many hours making multiple laminations of a socket using the traditional resin-casting method of production. Using 3D printing, the highly detailed digital design is sent to the printer and quickly produced.

McClure reports that additive manufacturing has allowed the company to produce up to four prosthetic sockets in the time it previously took to traditionally manufacture a single device using its traditional resin-molding process.

New materials bring more benefits

Quorum now prints its Quatro socket using Nylon 12, which maintains a solid structure that resists breaking but that can be printed in variable thicknesses in areas that may not need reinforcement.

The components on the socket, such as the raised feature to which the BOA is attached, is printed from thermoplastic polyurethane, which is soft and flexible and is often used to create flexible joints such as prosthetic fingers and as the liners for prosthetic sockets.

Further, the thermoplastic polyurethane material can be designed to be flexible or rigid, depending on the patient's needs.

Bringing 3D manufacturing in house

Because of the clear advantages offered by additive manufacturing, Quorum made the decision to bring the manufacturing of its prosthetic devices back in house and invest in its own 3D printers.

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The 4 benefits of using 3D printing

1. Better fit, enhanced comfort

With the 3D printing process, prostheses are uniquely designed for the patient through parametric modeling, which relies on magnetic resonance imaging (MRI) or computer tomography (CT) scans to map the patient's body. For children who are still growing, volumetric scaling uses the original digital map to scale the device for the patient's growth.

Digital maps and attendant measurements are used to design a device that will fit an individual patient more precisely. The result is a computer-aided design (CAD) model of the socket or limb. In a process called digital prototyping, the digital design can be digitally tested for exact fit, using finite element analysis (FEA) software.[4] Changes to the design are made as necessary and, once approved, the digital file is ready to be printed.

All of this work is done before the device is printed, avoiding the lengthy trial-and-error process necessary with traditional manufacturing methods. The software then sends the digitally rendered model to the 3D printer to manufacture the customized prosthetic limb.

3D printing can also be used to produce and improve inner liners. Sometimes the liner that fits over the residual limb can become uncomfortable if pressure is not evenly distributed. Introducing a softer inner liner made from 3D printed materials can provide more effective cushioning and support, thus improving comfort for the user. Because 3D printing can create complex shapes, a mesh-like structure can be printed and customized to the patient, which allows even airflow throughout the socket. This ventilation is necessary because moisture build-up can cause problems ranging from constant discomfort to lesions and infection.

The manufactured device, digitally customized for the patient, results in much higher patient satisfaction levels and, therefore, greater utility.

2. Faster manufacturing process

As with traditional methods, the additive manufacturing process utilizes prototyping before the final product is manufactured. But unlike traditional methods, adjustments can be quickly made in the software based upon patient and physician feedback to produce the patient's prosthetic limb.

With 3D printing, this process takes minutes, compared with the time-consuming, back-and-forth method of creating the multiple physical prototypes necessary with traditional prosthetics production.

3D printing methods can substantially cut production time and increase capacity for manufactures, thereby allowing medical providers to treat more patients. According to Sean McClure, lead engineer at Quorum Prosthetics, 3D printing cut the organization's production time by nearly 400% in some cases. *[See pg 4 for a case study for Quorum Prosthetics' experience with 3D printing.]*

3. More materials, greater functionality

Through the additive manufacturing process, artificial limbs can now be made from a wider variety of materials. Some manufactures have machines that can print over 190 materials, from carbon fibers to polythermals and metals, allowing physicians and manufacturers to consider weight, strength, and durability when choosing the material from which the prosthetic will be made. These materials can be soft, flexible, and even bendable. Some materials are now UL GREENGUARD certified for use in medical and pharmaceutical devices.

Traditional manufacturers had little control over device thickness when casting in resin. But the additive method maintains uniform thickness, for better fit. The result is a more customized fit and greater functionality for patients. Some patients report that the additively manufactured limb feels more like an actual part of their body.

4. Lower costs, increased profits

One of the most important benefits of manufacturing prosthetic limbs through 3D printing technology is the dramatically lower cost of production. This is truly groundbreaking when you consider that the cost to manufacture some advanced prosthetic limbs can be as high as $50,000 through traditional manufacturing methods.5

What's more, manufacturers can reduce the costs of making prosthetic limbs even as they shorten print times. While the design process allows for greater precision in customization, the manufacturer can print multiple customized pieces in each run.

Also, compared with conventional manufacturing, additive manufacturing virtually eliminates material waste, shortens the fabrication period, and eliminates the need for most skill-based manual operations.

Welcome to the revolution

Recent advances in additive manufacturing have ushered in a virtual renaissance for manufacturers of prosthetic devices. 3D printing enables manufacturers to create better fitting, lighter, stronger, more flexible, and more comfortable prosthetic limbs than ever before – and in less time.

The printing process creates the prosthetic limb or socket by building it up layer by layer based on customized instructions from specialized software. Devices can be printed using a much wider variety of materials, creating a more natural-feeling device than those made with traditional materials.

The new and improved technology is driving greater demand, which, when combined with the lower costs and faster production times afforded by 3D printing, is resulting in higher profits for manufacturers adopting the technology.

About Westwind

Westwind provides comprehensive, integrated IT and emerging technology solutions to government and commercial agencies. As one of its emerging technology solutions, Westwind delivers additive manufacturing and prototyping systems for a range of industries including aerospace, healthcare, military, and automotive. With decades of additive manufacturing sales and production experience, Westwind helps customers select the right solution for their needs. Westwind participates in numerous contract vehicles and has several Small Business (SB) certifications, including Minority, Woman-Owned, and HUBZone designations.

Westwind's subsidiary, Roadrunner 3D, provides a digital manufacturing center featuring advanced 3D print technologies. With deep engineering and additive manufacturing talent, Roadrunner 3D's print specialists can fabricate products and parts for one-off or ongoing needs – from quick-turn prototypes to repeatable, production-grade manufacturing for end-use parts.

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Contact

Westwind

Address:
5655 Jefferson NE Suite B
Albuquerque, NM 87109
United States

Contact:
P: 866-345-4720
E: info@wwcpinc.com

www.wwcpinc.com