Intrigue Versus Risk: Clinic-based 3D Printing of Prosthetic Devices

By Barry Hand and Michael Lavezzo, CPO, CTP

As the popularity of 3D printing gains momentum in the prosthetics industry, some O&P professionals have considered purchasing a 3D printer to print their own custom-fitted sockets. While 3D-printed sockets can save time and money, and provide a quality product, it can be risky and difficult to operate these printers without constant access to someone with professional experience and knowledge on the subject.

In-house Versus Outsourcing

3D-printed sockets are less expensive, require less fabrication time, and can combine flexibility with strength and stiffness, in comparison to those made using traditional methods. The materials used in 3D-printed sockets can be reformed and reshaped after being fabricated, benefiting the clinician who may otherwise have to make a new socket. But individuals using 3D printers are finding that they get frustrated with their results.

Stratasys, one of the pioneers in 3D printing, has identified four considerations when choosing between buying a 3D printer versus outsourcing:

1. ***Advanced equipment and materials:*** Companies who specialize in 3D printing offer a broad scope of technologies and materials. By utilizing their services, you can explore new 3D-printing solutions that might not otherwise be available.
2. ***Investment risk:*** Buying a 3D printer can be a significant capital expense. Additionally, it often involves staff resources to set up software, provide maintenance, and purchase material and other items used in the printing process.
3. ***Manufacturing ability:*** Many parts of a prosthesis are complex and require special build styles or specific materials. In-house operations may not be able to achieve the desired look, feel, or function.
4. ***Additive manufacturing expertise:*** Expertise is the differentiating factor in creating a quality part or product. 3D-printing technologies require knowledge of what is required to finish a part and the equipment used to accomplish that.

"Some of the issues I have with the process of 3D printing are all the types of filaments that can be used and the applications for each filament," says Josh Wiley, BOCP, Floyd Brace Company, Charleston, South Carolina. "I've printed various items, including an above-elbow socket and a mechanism for a prosthetic socket. Each one of the items have been printed more than a couple of times to make sure print quality is good and to make sure they will work before using a more expensive filament."

Numerous Variables

The properties necessary to print an adequate prosthesis can often only be achieved through a specific combination of printer configuration, careful material selection, and rigorous process and environmental controls. The most commonly available materials used in 3D printing are brittle and not designed to be used in products for patient use. Extremiti3D uses a proprietary polymer engineered for durability, dimensional stability, and strength. Such polymers ensure the quality and integrity of the finished product. The specific printer configuration associated with a given product is a complex combination of a long list of important variables. They include, but are not limited to, the factors listed in the table below.

A miscalculation of any of these settings can ruin the end product. Even professional additive manufacturing companies struggle to optimize so many variables. Simplify3D, a 3D-printing software company, identifies over 25 common issues encountered during printing, including the material not sticking to the print bed, under-extrusion, over-extrusion, gaps, stringing and oozing, overheating,

Nozzle size	Nozzle temperature	Feed rate	Print speed	Bead width	Bead height
Use of supports	Support material	Humidity and temperature	Print bed temperature	Print bed angle	Post processing
Curing	Power stability	Wall thickness	Infill pattern	Infill percentage	Material preparation

layer shifting, and a clogged extruder. A particular concern in prosthetics applications is layer separation, which is the main cause of socket failure due to breakage.

"Another issue I have would be the time involved with making sure the print comes out correct," says Wiley. "I've spent a lot of time looking at the prints for their first hour to make sure that I have good layer adhesion and to make sure it sticks to the printer bed; and you really don't know if it's going to stick to the bed until you are about one to two hours into the print if it's a large print. This is probably the main frustration."

Software and Printer Issues

Printing sockets without the right expertise is not just risky, it is inconvenient and an inefficient use of time. Choosing a printer that can print the right materials, which must be configured correctly, can depend on dozens of variables based on specific user needs. Maintenance of that printer can take up precious time and become costly. In addition, it is critical to have a backup printer to mitigate any down-time due to equipment failure.

Optimizing data quality is also a serious inconvenience in printing. 3D-model resolution (the number of facets making up the surface of a CAD model) is controlled in the software when it is created and affects the quality of a print. The ability to repair a broken STL file is critical to data integrity and a successful print. Also, when repairing resolution problems, it takes familiarity with the software to maintain dimensional accuracy for final print accuracy. Changing and modifying data, adding features or components, or embossing enhance the ability of the product to save the customer time and money. Specialized techniques in software manipulation allow companies such as Extremiti3D to create physical, 3D-printable features that fit closely to existing prosthetics components.

Figure 1
A 3D-printed socket that failed mid-print.

Figure 2
A well-designed, complex 3D-printed socket.

It's More Than the Socket

The sum of the parts must be compatible. 3D-printing experts can provide an efficient and effective solution that is not simply a uniformly thick replica of a limb scan. Sockets must be able to work with the entire prosthesis, not

just fit the patient well. With 3D printing, pyramids and other interfaces can fit snugly, shuttle locks can be nested, total contact surfaces can be printed and inserted, and windows can be created and printed directly into the part without the need for modification afterward. With clinical input, specific areas that need to be stiffened or made more flexible can be identified and modified directly into the printed object. These features can be achieved by adding or removing material, but often this takes engineering knowledge to apply the right geometry.

Weighing Your Options

While it is true that 3D-printed sockets save time and money for customers and end users, it is a complex and complicated process that requires extensive knowledge and experience to ensure a high-quality, safe product. The conveniences advertised by vendors of 3D printers are heavily outweighed by the inconveniences, as well as risks, associated with buying and using a printer in-house rather than going through a central fabrication company that offers 3D printing. Outsourcing printing efforts ensures that parts are fabricated using the correct materials, on a correctly configured printer, in a controlled environment to produce the highest quality possible for the end user. Central fabrication facilities offer clinical expertise and customer relationships that are important in helping prosthetists design the best possible 3D-printed socket. Plus, having a close working relationship with 3D-printing engineers ensures the designs are communicated properly to produce the final socket.

Buying a 3D printer is a big decision and involves a significant learning curve. You should plan to dedicate a person to run and maintain the machine, stay informed of the variables and issues that can (and will) occur, maintain a quality control process, and have a backup printer available. Patient care, diagnostics, and treatment planning require a certified prosthetist's expertise and time, but outsourcing 3D printing can produce a superior outcome by combining a prosthetist's clinical knowledge with an engineer's expertise in 3D printing. **O&P EDGE**

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