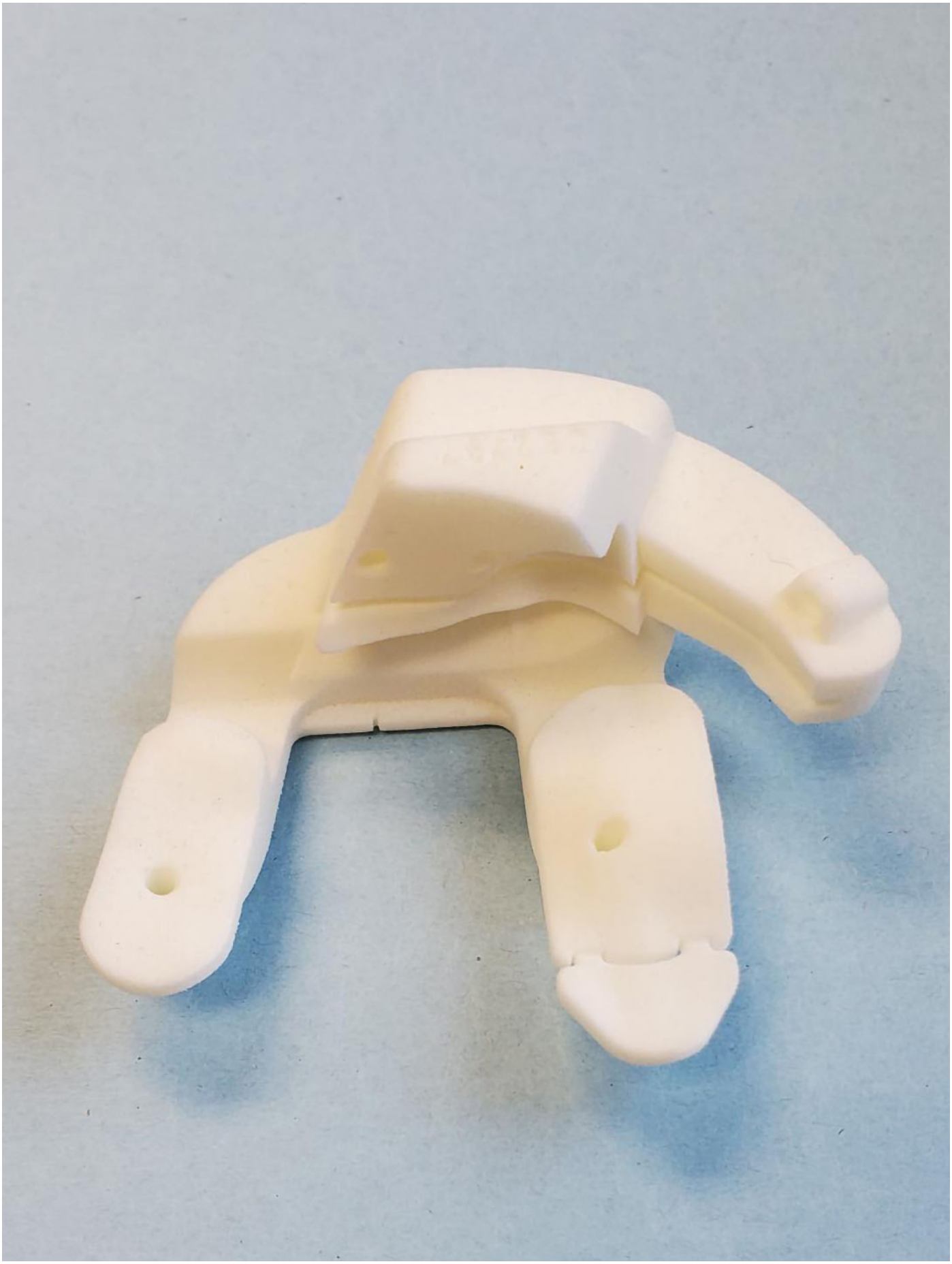

Challenges and Considerations for Processing 3D-Printed Medical Devices

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LEARNING OBJECTIVES

1. Understand the current technology used to develop custom medical devices
2. Analyze the risks posed by newer devices
3. Identify current and future challenges of 3D-printed devices for the Sterile Processing department

Many who watched *Star Trek: The Next Generation* were amazed by the incredibly futuristic technology it presented, including superfast space travel, amazing medical procedures and remarkable industrial replicators that could create almost anything from tools to human organs to warp engine parts. Although we are not quite there yet with these types of inventions, we are living in a time where a technology can create things from houses to medical devices: 3D printing.

As early as 1971, the initial iterations of 3D printers were available, and by 1987, the first patent was issued. Since then, the technology advanced dramatically: Precise engineering components managed by more powerful computers improved the use of the material "printed" on a substrate. Advanced organic chemistry delivered more suitable "plastics," including some synthesized from corn that make them biodegradable. Further, advanced software enabled the design of complex shapes and precise control over the depositing of materials at specific temperatures. On top of that, the cost of the printers has reduced dramatically, which makes the use of 3D printing technology more accessible—from its use in creating anatomic models, organ scaffolding systems, and more.

Objective 1: Understand the current technology used to develop custom medical devices

3D printing is the most common way to refer to a process called additive manufacturing (AM), which is the mechanism used to build models or devices. A three-axis "printer" deposits the additive over a substrate, building layer by layer to the shape and size programmed. The additive is often

a polymer or resin; however, metal powders and bioinks mixed with living cells are also currently available.[1,2]

Polymers and resins are melted and deposited in an extremely precise fashion to build an object or device. There are numerous materials available for this process, including a great variety of mechanical properties and colors and even some with antimicrobial properties. These materials are often used to create anatomical models to assist complex surgical procedures, where the model is developed based on information collected by the patient's computed tomography (CT) or magnetic resonance imaging (MRI) scans. Once these models are complete, they should be sterilized because, although they will not be implanted, they are often used close to the sterile area in the Operating Room. Depending on the material of the 3D-printed device, steam or vaporized hydrogen peroxide (VH_2O_2) can be used.

Metal 3D printing works in a similar way, but the metal in powder form is completely or partially melted to form a solid mass.[2] Once completed, several steps are needed to finish the device before it can be decontaminated, evaluated and finally sterilized. As metal implants are usually printed in industrial settings (not at healthcare facilities), the manufacturer often sterilizes the implants using ethylene oxide (EO) or irradiation (e.g., gamma radiation or electron-beam processing).

On the polymer and resin side, anatomical models are used to plan for and assist with complex neurosurgical procedures, while metal powders can create custom implants to fit patient needs. The use of bioinks is still in the developmental stages, yet it has the potential to revolutionize the development of replacement organs and tissues.[1] Of these three additives and 3D-printing applications, resin anatomical models and metal implants have the biggest influences on the Sterile Processing (SP) environment.

Objective 2: Analyze the risks posed by newer devices

As SP professionals know, there are inherent risks associated with the use of virtually any medical device. In the U.S., we are fortunate to have a very robust regulatory framework, which classifies devices based on their risks.[3] 3D-printed devices usually fall under the U.S. Food and Drug Administration's (FDA's) Class II (moderate to high risk) or Class III (high risk) categories. Within this framework, 3D-printed medical devices, such as patients' anatomical models or patient-specific instruments, fall under Class II, while implants may fall under Class II or III.

From an external perspective, and as with any medical device, the manufacturer must thoroughly assess the potential risks posed by the device to obtain approval for commercialization. Although some 3D-printed medical devices, particularly metal implants, arrive sterile from the manufacturer, many devices, including those printed at the healthcare facility, will need to be processed in the Sterile Processing department (SPD).[4]

To address the challenges these devices will pose to the facility and SPD, the risks must be evaluated before the devices come into or are printed by the facility. General risk assessments include having access to updated information about device processing and understanding specific aspects of the processing such as warnings provided by the manufacturer and the device's instructions for use (IFU). Specific risk assessments must ensure that the necessary accessories, supplies and equipment are available.[5]

The conventional approach of risk management also applies to the adoption of new technologies, which generally includes:

1. Identifying the risk, in this case the processing of the new medical device
2. Quantifying or assessing the risk
3. Prioritizing the list of risks assessed
4. Developing a mitigation plan
5. Performing ongoing monitoring

Hansson and Aven developed a five-step model linking facts and value in risk management.[6] The first step uses specific information based on evidence, which may be related to the use of cleaning chemicals, disinfectants, washer-disinfectors, ultrasonic cleaners, and sterilization technologies.

The second step involves collecting the information needed to use and process the device. This specific knowledge includes information gathered from experience, manufacturers' IFU, internal standard operating procedures (SOPs) and other sources. This step is critical and emphasizes the importance of the expertise within the SPD. *Note: This part of the assessment should be free of preconceived ideas and experiences, as they will be considered in the next step.*

The third step is the risk evaluation, where evidence and knowledge are evaluated through a risk discussion and include the perspective of experts (SP professionals) and decision makers (hospital administration). This step relies heavily on scientific evidence and information provided by the manufacturer; however, experiences about potential failure modes are also important.

The fourth step is reviewing all the gathered information by the decision maker to determine the risks and the approach the organization will take to manage those risks.

The fifth and final step involves documenting actual and potential risks, how the risks will be managed, and how monitoring will take place. This step ends with effective communication. Those involved in the risk management process and all internal stakeholders will need access to the information and training on the new processes.

Objective 3: Identify current and future challenges of 3D-printed devices for the Sterile Processing department

With the rapid advancement of 3D-printing technologies, healthcare facilities will continue to encounter challenges related to staff expertise, equipment, accessories and supplies. This includes new equipment, such as sterilizers or washer-disinfectors with specific cycles (e.g., temperature, time or chemical agents), and the need for adequate staff training and documented competencies. For those working in large acute-care hospitals, this may not seem like a problem, but for those in smaller facilities or departments with limited resources, acquiring new equipment and supplies and developing a robust training program can be challenging. Another concern relates to the time needed to process new devices. This is similar to challenges SP professionals may experience with loaned devices: if the devices arrive late, surgical delays can result.

It is important to understand that 3D-printing technology is not new and can be used by virtually anyone with basic computer skills. This technology is readily available, easy-to-use, and generally low-cost, with prices ranging from $100 to thousands of dollars for a final product. These factors present minimal barriers to healthcare facilities wanting to manufacture 3D-printed devices. The opportunity is appealing, and facilities can begin with simple anatomical models and progress from there. Although the materials and technology are widely available, perhaps the biggest challenge relates to the regulatory and quality aspects of such devices. Due to the rapid evolution of this technology, regulatory requirements will continue develop. Therefore, manufacturers and healthcare settings will need to quickly adapt to ensure the safety and effectiveness of future 3D-printed medical devices.

Medical device manufacturing is thoroughly regulated, leading to limited or controlled risks, limited contamination, and ongoing process monitoring. The most common standard for quality management systems (QMS) used today is the Association for the Advancement of Medical Instrumentation's ANSI/AAMI/ISO 13485:2016/(R)2019 *Medical devices—Quality management systems—Requirements for regulatory purposes*.[7] This quality management framework covers all critical aspects, including the requirements for a QMS, quality policy, resource management, product aspects including design and development, procurement, continuous measurement, and analysis improvement, among many others. QMS for medical device manufacturers are largely focused on highly standardized processes and predictable outcomes through process control and validations.

Quality management in hospital settings is equally or even more thorough but has a different focus. Healthcare quality performance indicators are closely related to safe, effective, patient-centered care. When healthcare systems create their own 3D-printed medical devices, they assume the role and responsibilities of the device manufacturer, which include creating and validating processing instructions for those medical devices. Since this falls outside the expertise of most facilities, consultants or labs may be hired to develop and validate these processes.

Conclusion

The emergence of 3D-printing technology and its ability to create many different types of devices brings tremendous opportunities to the medical device industry as well as significant challenges to device processing and sterilization professionals and regulatory authorities.

3D-printing technology is making tremendous strides—both in the increased complexity in what can be created and the rapidly growing level of adoption. SP professionals must be aware that there is ongoing research for the use of newer materials, including biocompatible matrices used in combination with living cells, that will soon revolutionize the way healthcare facilities provide care. Biocompatibility tests for biomaterials are currently being performed, which has the potential to become common in SPDs.

Current medical device regulations focus largely on conventional manufacturing processes, but that is certain to change in the future. The more companies and healthcare facilities adopt the technology to create custom-developed medical devices and the more universities and institutes continue developing newer applications, the more regulations will be required to address new ways of developing and manufacturing devices.

Some interesting experiences come from abroad, with some European countries already implementing regulations that require hospitals looking to develop medical devices onsite to have a manufacturing QMS in place, much like ANSI/AAMI/ISO 13485.[7] Although this oversight may