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THE FUTURE: 3D MANUFACTURING OF MEDICAL DEVICES

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Abstract—Three-dimensional (3D) printing is the future in the manufacturing world; its applications are widely applicable from the construction industry, engine components, replacement parts, oil and fuel tanks, welding, and manufacturing medical devices. It allows transforming designs in the digital environment into physical objects using layers manufacturing methods. Specifically, in the medical segment, 3D manufacturing is spreading faster since it will enable the unique customization to meet the patient's needs, such as heart valve design, and for physicians such as a unique ergonomic surgical tool to increase useability, thus positively impacting patient outcome. Various 3D manufacturing technologies depending upon the material have made it possible to achieve a variety of applications and provide a competitive cost advantage. However, like any other new technology, 3D printing is no different in facing the challenges in its adoption. It is imperative to take a deeper dive to discuss 3D manufacturing in the medical device industry, current 3D printer technology, its applications in the medical industry, and finally, the manufacturing and product design challenges

Keywords: 3D Printing, Additive Manufacturing, Medical Devices, Technology, 3D Printing Materials, Applications, Challenges, Regulations.

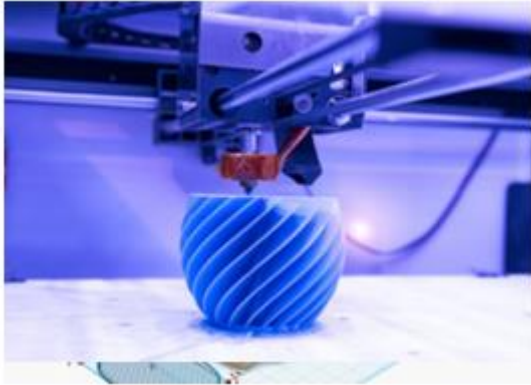
I. INTRODUCTION

3D printing is an innovative technology in the medical device industry. 3D printing (also known as additive manufacturing) takes digital 3D models and creates 3-dimensional solid objects from those CAD files using a 3D printer^[8]. Unlike subtractive manufacturing, such as milling or CNC routing, 3D printing builds objects with thin layers to produce 3-dimensional parts. 3D printing can make anything from concept models, prototypes, and surgical instruments. 3D printing has the potential to create devices faster and more cost-effectively than traditional methods. 3D printing of implants has already begun, but 3D printed medical devices are still mainly in the research and development stages. 3D printing is handy for small-batch production or low-demand items because 3D printers can produce a one-off object without costly production runs. 3D

printing is also cost-effective for medical devices. It is because a 3D printer can make a small number of products and not waste any materials. It uses only the amount of material necessary to complete that product. The FDA has even said that 3D printed parts can be more reliable, safer, cheaper, and more easily customized than 3D printed medical devices^[6]. Printed products show promise in a variety of medical applications, including prosthetics, orthotics, diagnostics, patient-specific implants (e.g., pacemaker), drug delivery technologies (e.g., 3D printed pills), tissue engineering scaffolds, surgical tools, and imaging techniques.

II. TECHNOLOGY

3D printing is a new innovative technology that is making its way through almost every industry. Someone new might think it is scary and straight out of a sci-fi movie, but anyone can understand it. In simple terms, 3D printing is a process through which 3D objects are built up layer-by-layer from digital 3D models. 3D printers vary in their technological sophistication and capability, often printing by depositing or solidifying a fluid or powder material combined with other raw materials to form the 3-dimensional object desired. 3D printers create 3d objects of any shape or geometry digitally and much faster than any traditional machining process. 3D printing technology is easy to learn for anyone with 3d modeling software experience; 3D printer manufacturers often also supply free 3D printer files upon request. 3D printers come in various shapes and sizes, and each differs in its applications. Since humans have begun creating things, we have been taking more extensive material and cutting it down to create a specific part. In the modern days, we know them as CNC machines and laser cutters, but this isn't additive manufacturing and is known as subtractive manufacturing because of its way of subtracting the material from the more prominent material to create a part. 3D printing is different because it builds parts from scratch using a CAD drawing. Generally, for 3D printing, we need a 3D printer, an STL file, or CAD software such as Solidworks to design a new STL part, a 3D slicer software, and material either resin or a filament.



An example of 3D Printing Machine shown in the image above and 3D printed glasses).

There are several types of 3D printers and technologies available. Each differs in size, type of material printed, and use case. For example, some can print medical-grade products, while hobbyists can use others at home. Let's dive deeper into the primary types of 3D printers available today in Plastics and Metal Manufacturing^[9].

1. Plastics 3D printer

a. Resin 3D printers: SLA:

SLA or stereolithography is the first type of 3D printing technology ever invented, and it works using a light source via a process known as photo-polymerization. In other words, SLA printers scan every area of the resin material layer by layer, creating part one layer at a time and moving the build area one layer height, and the process continues until the final part completes. Once printed, parts require hardening by UV light before being ready for use^[16]. However, these parts are more delicate than many other types of 3D printed parts and must stay away from direct sunlight, or they start to degrade and becomes no longer of use. Examples of SLA printers are Formlabs Form 3^[17] (shown in the image in the previous page), Flashforge Hunter, etc.

b. SLS 3D printers (Selective Laser Sintering)

Selective laser sintering is an additive layer manufacturing process. The mechanism spreads the polymer powder over a surface, and then a laser sintering head moves back and forth over the bed and fuses small sections of the polymer material to build up a complex object. This technology differs from fused deposition modeling 3D printers that build objects with extruded continuous strands of filament.



These printers, unlike FDM printers, don't work fast (approx 20-100mm/hour) but have a high resolution!^[14] I know what you're going to say; it's not as good as FDM. You're right. But it makes up for it in other areas (light materials and resolution). Some examples of SLS 3D printers are Nexa3D QLS350 and Farsoon eForm, image of SLS 3d printer is shown above.



2. PolyJet (Material Jetting)

Polyjet or Material Jetting works by projecting a stream of material from an inkjet style print head in multiple colors to build up a 3D object layer by layer^[13]. The layer-by-layer approach has been used in 3D printing for years and is common with the more well-known additive manufacturing technologies. Polyjet technology differs from other additive manufacturing processes because it uses liquid resins and powders instead of powdered resins or waxes (such as stereolithography or selective laser sintering printers, see an example of the machine above).

These 3D printers are one of the most advanced 3D printing methods on the market today. The machines use this combination of layers and color to create the printed object, see color human brain anatomy in the image above. This method allows for some very realistic prints by providing a very detailed texture.



the design, such as stainless steel, aluminum, titanium, and cobalt-chromium alloys.



3. Metal 3D printer

a. Direct Metal Laser Sintering

Direct metal laser sintering (DMLS) is the most widely used type of high-performance 3D printer for metals, alloys, and superalloys. DMLS was conceived in the early nineties at the Massachusetts Institute of Technology (MIT) by Dr. Carl Deckard and Dr. Donald Mossman while enhancing the technology behind direct metal deposition for tooling applications^[12].



It can produce multi-functional parts with unprecedented accuracy. Images of equipment and tools are shown above and below. The process involves using a computer-aided design (CAD) model to make a thin layer of powder on a support structure, which high-powered lasers will sinter. Afterward, through vibration, the remaining powder flushes out. The next thin layer of powder is spread on top, adhered to the previous layer, and hardened with lasers anew. Various powders are used, depending on the metal used for

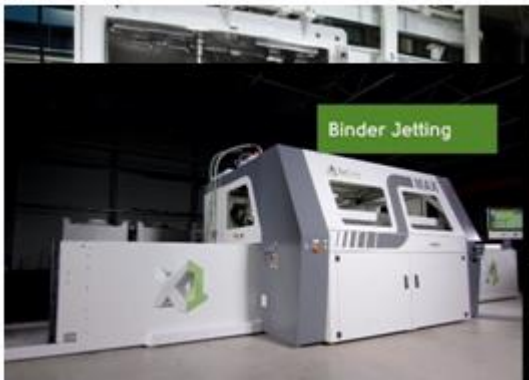
b. Electron Beam Melting (EBM)

Electron beam melting has been around for a long time. Electron beam melting (EBM) or electron beam additive manufacturing (EBAM), as it is sometimes called, is a 3D printing technology that was invented and patented by Dr. Carl Deckard with the University of Texas in 1981^[10]. With an idea and some trial and error with early EBM systems, Dr. Deckard produced many identical parts with those created by conventional means like casting or machining. Once the technology improved, EBM systems could make very high-quality metal parts, but those parts were limited to those that required complex geometries; thus, the technology didn't immediately gain steam as a contender in the big 3D^[11].

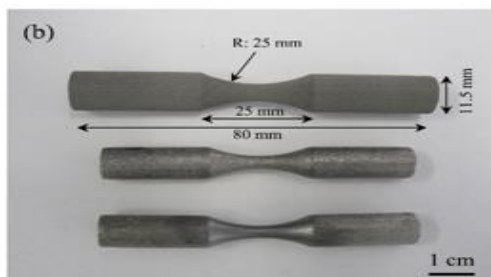
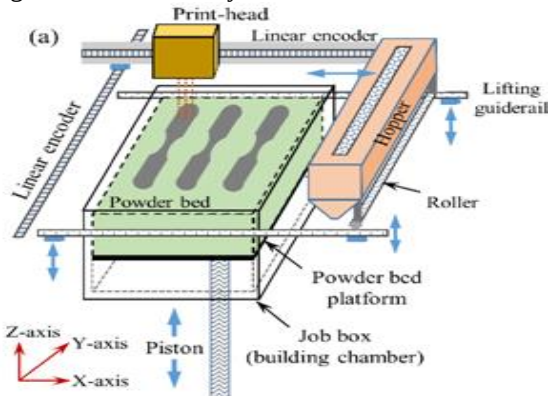
Electron Beam Melting (also known as Electron Beam Direct Metal Deposition) is a 3D printing technology that allows metals to be melted and deposited in layers, just like Fused Deposition Modeling (FDM),^[15] so you can print 3D objects, see below image for visualization. But EBM 3D printers are different from FDM printers in the way they melt their material. They do it by using an electron beam to heat metal powder into a solid form.

c. Binder Jetting

When it comes to Binder Jetting technology, most people have never even heard of it, but more and more companies are adopting the technology for several printing applications. One of the main selling points of Binder Jetting 3D printers is their versatility from being used from one application to another.



Binder jetting refers to a technology for 3D printing where the thermoplastic powder is heated and then shot into an air stream that cools it and helps to bind and solidify this into a net shape of the desired object ^[19]. A Binder jetting equipment is shown above, and the process is stated in the image on left side. The binder jetting 3D printers rely on the thermoplastic powder, supplied in a pliable, low-density condition and heated by an array of warmers within the supply hopper. The hot material flows from the supply hopper, then through the heel of the printer, where you add powdered material on your 3D printer, and then it comes out through nozzles on its way out on the build area.



III. APPLICATIONS

3D printing is a new dynamic trend that has been adopted quickly by the medical community. 3D printing technology is being utilized in many different applications, such as 3D printed organ replicas and 3D printed bones for studying bone structure^[2]. The use of 3D printing in medicine is

highly convenient, as it allows doctors to print 3D models of organs and bones from CT scans or MRIs. This application enables surgeons to practice surgeries before they even perform on actual patients. Let's dive into the specific medical applications currently being produced using additive manufacturing technology along with the future aspects of it.

1. Surgical Instruments:

The less complex medical accessories such as needle drivers, hemostats, scalpel handles, forceps, retractors are currently 3D printed. Given the straightforward design of these tools and less critical application and its impact on the patient, these tools supply a suitable candidate for 3D manufacturing. The regulations around these have been less complex and give rapid process for approval. As tools are considered the best friend of a surgeon, 3D manufacturing innovation supplies easy customization based on their use. Compared to the traditional manufacturing process of surgical instruments, the design iteration process using 3D technology is quick ^[18]. Typical tools used during the surgery are shown in the image below.



Customization to the needs has improved the possibility to make a positive impact on patient lives. Widespread use of technology can drive surgical instrument innovation and specifically improve the operating techniques.

Another example would be medical trays or other dedicated spaces explicitly created for holding implantable devices used in minimally invasive or endoscopic surgery. Using traditional manufacturing techniques would take a long time and multiple iterations before you get the correct fit from injection molding and expensive tooling costs per unit manufactured, making it impractical. 3D printing can quickly and cheaply iterate the designs allowing the surgeon to focus on what is more important, patient care.

2. Dental Implants:

3D printing in dental application is an innovative technology to reproduce a tooth in one dentist visit. The extensive application includes a crown, bridge replacements; fillings currently bring 3D printed. The 3D process does not just expedite the process compared to traditional channels but also provides customization to the intricate details using computer-aided design and manufacturing (CAD/CAM), shown in the 3D image below. This technology creates a digital 3D image of the patient's mouth transferred to the 3D printing machines to manufacture the implant. The entire process, including additive manufacturing, focuses on to great details of the design and provides appealing aesthetic output. It allows the dentist to plan and complete the surgery precisely and ensure patient safety by avoiding nerves.

A 3-year follow-up clinical study conducted ^[3] on titanium dental implants showed a 94.5% overall implant survival rate. The study aimed to evaluate the additive manufactured dental implants after three years of loading, clinical, radiographic, and prosthetic parameters and concluded that the 3DP/AM titanium dental implants represent a successful clinical option for the rehabilitation of single tooth gaps in both jaws.

3. Orthopedic Implants:

Joint replacement, hips, knees, ankles, parts of the spine, bones, or damaged bones have felt the benefits of 3D printing. A study done by ^[1] concluded that 3d-printed hip implants had similar long-term performance compared to traditional hip replacements, but with several advantages: including reduced risk of dislocation and lower revision rates.

The orthopedic area needs customization due to the complex shapes and structures requiring proper materials for the best output. 3D print allows customization ^[7] and the choice of the right materials and resulting imperfectly fitted devices, see below an image of orthopedic implants and its complexity. In addition, and like the other applications, we can print these implants directly on-site and much faster for urgent needs. The complications that arise from traditional orthopedic implants, such as hip implants, could be minimized, including faster post-surgery recoveries.



3D-printed bone replicas have also helped physicians in figuring out the successful technique for orthopedic trauma surgeries. 3D printing can simulate the surgery to determine the method or equipment to make the surgery more successful. It helps physicians evaluate what is happening with the fracture and prevents prolonged chronic pain. 3D printing has revolutionized surgical methods and in improving patient lives.

4. Prosthetics:

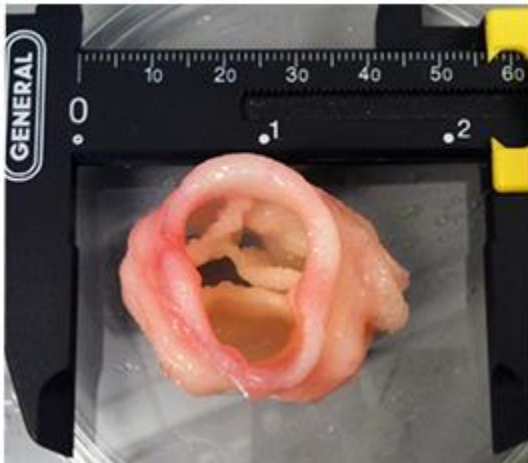
3D printing is changing lives with patient-specific anatomic printed prosthetics. Much like additive manufacturing advantages, prosthetic benefits using the 3D computer-aided design model rather than relying on the 2-dimensional traditional scans or using the existing prosthetics to fit the wearer's needs. The new technology brought radical changes, which could print exact 1:1 model of patient hand as shown in the figure. According to American Orthotics and Prosthetics Association, the average cost is \$1,500 to \$8,000, which insurance doesn't cover. The 3D printed prosthetic could cost as little as \$50. Thus, the most significant advantage is the subsequently lower cost of the 3D printed arm compared to the traditionally manufactured prosthetic arm. In addition, traditional prosthetics is very time-consuming and does not allow modifications as it will require destroying the original molds. Image below demonstrate the structure and complexity involved in prosthetics.

Currently, about 95% of the 40 million amputees do not have access to the prosthetic device, thus leading to an urgent need to bridge the gap. The main difference in the material used between traditional vs. 3D printing is the amount of

plastic. 3D printed prosthetics are composed of plastics; however, the new development allows other materials such as lightweight titanium^[20] to be used in 3D printing to increase durability and strength.

5. Heart Valve and Bioprinting organs:

3D printing of heart valve came into existence by Butcher from Cornell University^[4], see image on below. Heart valve possessed the same anatomical architecture and used a combination of cells and biomaterials to control the valve's stiffness. This advancement in tissue engineering and the biomedical community could transform the need for organs transplant.



With that, 3D-printed organs and research have been consistently growing for safe transplantation in human beings. Currently, liver tissues have been printed successfully to create an entire miniature human kidney. Moreover, synthetic skin development is also in the works to help patients who suffer burn injuries and other skin issues.

Simple use of additive manufacturing techniques such as 3D printing creates customized hearing aids for individual patients. There is a growing elderly population that has an increased need for such devices to compensate for ears that are increasingly sensitive to loud noises. Traditionally these hearing aids are mass-produced as there is not enough market volume to warrant custom-designed models. However, the increasing use of 3D printing would be more practical, allowing individualized hearing aid designs explicitly tailored to the patient's ear shape and size.



6. Medical Equipment:

Printing 3D production of medical equipment is a game-changer. Such a kit includes personal protective equipment. During the Covid-19, it made a drastic difference in saving lives at the hospital.

Similarly, it would be helpful for companies to start producing components in-house for medical devices utilizing additive manufacturing. It wouldn't just significantly reduce the manufacturing cost but also increase the volume of finished medical devices due to efficient processes, less scrap, and improved quality standards. The opportunity also lies in fully automating the 3D manufacturing of less risky devices such as Class I medical devices.

7. Surgical Planning and Educational Purposes:

3D printing shows much promise in the medical community and has many potential applications. 3D printing in medicine will likely be used as a surgical practice tool or for creating 3d models from CT scans for educational purposes. 3D printing of models from MRIs could also be a possibility that 3D printing could have a 3d printed organ replica is that 3d printers can 3D print organic tissues.

Regarding medical research, 3D printing is helping develop organ models for patient education and pre-operation planning for surgeons for critical and complex surgeries. It prevents risk, identifies obstacles pre-surgery, and thus improves patient outcomes.

Another application is the 3D printed models of cancerous tumors^[5] to identify the new anti-cancer drug. Also, understand how tumors develop and spread.

Regulations

In the USA, 3D printing for medical devices is regulated by Food and Drug Administration (FDA) Center for Devices and Radiological Health. Like any other medical device, 3D printed medical devices must be maintained through a quality management system (QMS) and categorized based on their risk classification into three regulatory categories. Class I, Class II, and Class III device regulatory scrutiny increases as risk classification increases. Manufacturers of



3D printers should establish and maintain a quality management system to ensure that the devices meet specified requirements and are safe for the intended use. The manufacturer guarantees that all devices on the market comply with the quality system (QS) regulation. QS regulation requires manufacturers to document their quality system and all aspects of pre-production, production, and postproduction activities in written procedures that indicate responsibility for their implementation. Quality control includes both testing and monitoring devices and ensuring continued safety and effectiveness through routine quality audits.

To meet the requirements of the FDA, 3D printer manufacturers must also ensure their products are tested and validated as per cGMPs^[6] (current Good Manufacturing Practice) regulations. For example, they must clear premarket review by demonstrating the safety and effectiveness or substantial equivalence to another device before being introduced into interstate commerce. Manufacturers and importers of these devices are required to register their establishments with the FDA, and they must list their products in a database called the MAUDE (Medical Device Unique Device Experience) system.

Like the USA, 3d printed medical device in Europe falls within Medical Devices Directive 93/42/EEC until the new EU Medical Device Regulation 2017/745 (EU MDR) enters the entire application. Manufacturers must carry out the conformity assessment procedures, compose a technical file to ensure health and safety before placing them on the EU market. In addition, the manufacturer must conduct a risk assessment of the 3D printer to ensure patient safety assessment and the risks accounted for before designing and constructing the machinery. The machinery directive 2006/42/EC lists essential requirements on the products' health, safety, and performance. Products manufactured according to the specified directive can freely move throughout the internal market and EU member states.

IV. CHALLENGES

3D printing technology has been in use for years in industrial applications, but its use in medical devices is still recent and thus brings several regulatory challenges related to this technology.

One challenge that has already presented itself due to 3D printing is ensuring compliance with Good Manufacturing Practice (GMP) regulations and quality standards for design. 3D printers are helpful in their ability to create complex geometries that potentially would be more difficult to machine, such as cooling channels into a medical device. However, 3D printing also enables small batch and low-volume production. It can result in smaller production lots and introduce variability during the manufacturing of medical devices, which could pose a problem with 3D printed product qualification and long-term product

reliability. It is not practical to test each product to ensure reliability, thus demanding a creative way to evaluate the product.

Another challenge related to 3D printing is related to the quality of the print itself. 3D printers use different materials for producing the part, including plastics, polymers, metals, and biomaterials, etc. But these materials may vary in properties and safety profiles when used in medicine depending on the additive method, material composition, 3D printer operating conditions (e.g., print speed, operating temperature), 3D printed device design (e.g., 3-dimensional structure, overhang, and surface roughness), and 3D printer build parameters (including nozzle and layer widths, feedstock composition, and geometry of the additive process on the substrate). Understanding these variables is necessary to ensure product quality from a medical device safety perspective.

Finally, 3D printing's application in implantable medical devices may require long-term stability studies to ensure safety and efficacy for regulatory approval. It also introduces challenges related to providing the effectiveness of 3D prints in in-vivo studies since post-processing methods must remove products without damage.

V. CONCLUSION

3D printing is an emerging technology that can change medical care and health outcomes for patients. However, it must take time before we fully understand how this new way of manufacturing products can improve our healthcare system and positively improve patient lives at a lower cost. While there are many challenges in designing with 3D printers, including FDA regulations on what materials you can use, as well as limitations due to current designs and models available for manufacturers, future advances in these areas may help overcome some of those hurdles. For now, though, be aware that while innovations like 3d-printed drug delivery systems could benefit your customers' quality of life by improving treatment options or reducing side effects from pharmaceuticals they are taking; they might also delay necessary treatments when a patient needs surgery because their traditional medical implants are not 3D printable yet.

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