International Journal of Recent Development in Engineering and Technology
Website: www.ijrdet.com (ISSN 2347-6435(Online) Volume 15, Issue 01, January 2026)

3D Printing in Pharmaceutical Sciences: Transforming Drug Manufacturing

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Abstract-- **Three-dimensional (3D) printing and modelling are being used more and more in surgical settings. Among the applications for this technology are patient education and counselling, inter-team communication, and preoperative surgical planning. The majority of research on 3D technology has been done on adult populations, and it has been demonstrated to be a useful teaching tool for patients in a variety of surgical specialties. Due to the unique congenital characteristics of young patients and the complexity of compact anatomy, pediatric surgery is a rare instance that requires a distinct approach. Surgeons must make decisions that consider children's evolving requirements as they mature in addition to urgent issues. Three-dimensional (3D) printing has emerged as a helpful technique for providing a tailored medicinal approach. This paper's initial section discusses the principles of 3D printing and modelling. We then examine the transformative potential of 3D printing in pediatric surgery, outlining its applications, benefits, and limitations. The paper concludes with a discussion of the prospective uses of 3D printing in the future, such as improved patient outcomes, customized treatment regimens, and the technology's further advancement as an essential instrument in the field of pediatric surgery.**

Keywords-- **counselling, pediatric surgery, 3D printing.**

I. Introduction

Additive manufacturing, also known as 3D printing, was first used in the 1980s. (1) Shortly after the automotive and aerospace industries realized the potential of rapid prototyping, the medical field did too. (2) The ability to turn digital 3D models into real, patient-specific objects has opened up new avenues for personalized medicine. Surgeons who specialize in pediatric frequently encounter complex surgical situations that are uncommon in adult populations. Pediatric surgery presents unique challenges such as congenital defects, growth-related changes, and the need for minimally invasive but effective procedures. (3) The recently created technology known as three-dimensional printing (3DP), which prints each patient's unique anatomy for patient-specific models, enables this level of customisation. Its applications include patient education and intraoperative surgical usage. (4) Most clinical 3D items are made via additive manufacturing, which creates the desired product by modifying a digital 3D model and printing it in layers.(4–7)

The broad term "additive manufacturing" encompasses a wide range of advanced processes, such as stereolithography, selective laser sintering, and fused deposition modelling, which may form a variety of materials into the needed shape.(8) Pre-operative surgical planning, inter-team communication, and patient education and counselling have all benefited from the use of 3D technology. Nonetheless, adult populations have been the focus of the majority of 3D technology research. Previous studies on adult populations have shown the usefulness of 3D-printed models such a preoperative counselling tool for patients [9]. In example, Pugliese et al. found that adult patients undergoing laparoscopic splenectomy, nephrectomy, or pancreatectomy reported a higher level of awareness of the treatment plan when a 3D model was used during a consultation with the surgical team [9].The data that is now available shows that 3DP is a useful tool that enhances clinical care; however, previous evaluations were primarily limited to adult therapy in a specific surgical specialism.(10).

II. Methods

Criteria for inclusion and exclusion

The use of three-dimensional printing (3DP) in pediatric patient-specific. This systematic study's primary focus is care. Additive manufacturing, which deposits material in precisely layered amounts to form the needed shape, was used to create the study's 3DP products.

Inclusion Criteria required that studies:

1) use additive manufacturing to manufacture 3DP items
2) use a patient-specific 3DP object in a patient's clinical care, either directly or indirectly
3) Provide primary data
4) Focus on the pediatric population, which is defined as patients who are under the age of eighteen. Studies assessing qualitative data from adults about pediatric patients (e.g., a parent's understanding of his or her child's sickness) were included as long as the patients themselves were children. Both case studies and case series were present.

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The following were the exclusion criteria:

1) method papers, reviews, editorials, technique articles, book chapters, and fragmentary pieces (e.g., only abstracts available)
2) Articles that aren't available in English
3) articles in which patient care was neither directly or indirectly impacted by the 3DP object
4) products created via methods other than additive manufacturing, like subtractive manufacturing, computer numerical control milling, and prototype machining
5) studies with participants who were at least 19 years old
6) 3DP items that were not patient-specific, i.e., multiple patients received the same treatment
7) cadaver experiments
8) animal studies
9) proof-of-concept or purely in vitro tissue engineering studies. (11)

III. Overview Of 3D Modeling And Materials

Over the past 40 years, 3D printing has undergone enormous evolution. Figure 1 provides an overview of the steps involved in creating 3D-printed implants or models. (12) The first 3D-printed object was produced in the 1980s when stereo lithography (SLA) was developed for the aerospace sector. (13, 14) SLA is based on a constructive method that creates a model by layering plastic with an ultraviolet light.

Preoperative Planning with 3D Models:

Accuracy and planning are crucial when it comes to pediatric surgery. Surgeons have an unparalleled perspective thanks to 3D models, which are made from each patient's unique anatomical data. Unlike 2D images from CT scans or MRIs, 3D models offer a tangible, three-dimensional representation of the patient's anatomy, enabling a more comprehensive understanding of the surgical site.

Surgical Guides:

The rapidly evolving field of surgery has entered a new era of precision and personalization with the advent of 3D printing. Customized surgical guidelines that are tailored to the unique anatomy of each patient have become highly popular and practical tools. In a systematic evaluation of 3D printing uses in medicine, surgical guides were the most frequently mentioned use. (16) In contrast to general guidance, these specialized tools provide accurate implant placement or tissue removal.

Drug-eluting implant 3D printing:

Recent developments in 3D printing have led to the development of medicine-eluting implants, which offer focused, localized medication therapy over extended periods of time. These implants tailored to each patient are being studied in several medical fields, including implants, oral medication, and transdermal systems. The materials and procedures utilized in 3D printing take into account certain characteristics such as form, surface roughness, microstructure, and drug release behaviour (15).

Patient Education and Communication:

The relationship between a patient and a doctor is the foundation of healthcare. Effective communication is the cornerstone of this connection, and 3D models are becoming indispensable tools for this. (16) Applying medical three-dimensional pictures Experts may describe surgical procedures intuitively. Patients and their families can feel less nervous and make better decisions if they can see a 3D model of their anatomy and understand the surgical procedure. (17).

Training and Simulation:

Due to the high stakes and little margin for error, the medical field necessitates extensive training. Conventional methods often make use of cadavers or simple simulations. However, a more moral and dynamic alternative are reproducible 3D-printed models that replicate real-world surgical situations. Novice surgeons can refine their skills in a risk-free environment by using these models. (16) Loke et al. contrasted the use of traditional 2D drawings and 3D physical models of the Fallot tetralogy.

Regulatory and Ethical Considerations:

A great deal of power comes with a great deal of responsibility. Strict control is now required due to the use of 3D printing in medicine. The Food and Drug Administration (FDA) is one of the regulatory bodies. The United States has taken the lead in developing regulations that ensure patient safety. These suggestions address a variety of subjects, such as software approval, material biocompatibility, printing process quality control, and sterilization methods. Consequently, only a small number of software systems are available (17).

IV. Difficulties And Limitations

Every positive aspect of 3D printing is accompanied by a cloud, and medical 3D printing is no exception. Technology has numerous advantages, but it also has disadvantages.

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Technical issues could result from things like print limitations on resolution, limitations on materials, and integrating multiple materials into a single print. There are noticeable scaling effects when more implants are produced each year using 3D modelling tools and modern technology. (15).

V. 3D Printer Types

1. Fused Filament (FF):

Fused Filament Fused Deposition Modelling, or FF for short, is a method in which a molten. Thermoplastic filament is applied to a form plate in layers that solidify quickly after being extruded through a temperature exit or a narrow nozzle (18). This modern method drives certain quantities of thermoplastic polymer thin filament onto the liquefier plate or heater using a pinch system and torque. The fixed temperature of the liquefier block is influenced by the type of filament, its melting point, and the glass transition temperature. Consequently, the molten filament is extruded using the heated nozzle and hardens onto the deposit on the Buildup plate.

The nozzle regulates the polymer's flow, and the orifice's diameter determines the material's extrusion diameter.

One or more nozzles may be used to print an item with fused filament. Two or more polymers containing various pharmaceuticals can be printed simultaneously to construct drug delivery systems with several medications. Layer thickness, angle, and spacing factors are included in the software of the 3D printer. Diagrammatic representation (1) offers a basic depiction of FF (19).

Fused filament is the most popular 3D printing technology, according to 20 reports. No FF printer has yet been developed specifically for use in pharmaceutical or medical contexts (21). However, FF has recently been used in the production of tablets and implants employing filaments created by hot liquefying and extruding a range of drug-polymer combinations (42). Additionally, FF has demonstrated progress in the pharmaceutical industry because to lower printing costs and high quality (23). The capacity to precisely make different dosage forms, such as tablets or capsules, and build a variety of devices with organized and quick drug release capabilities are just two advantages of employing FF printing technologies (24).

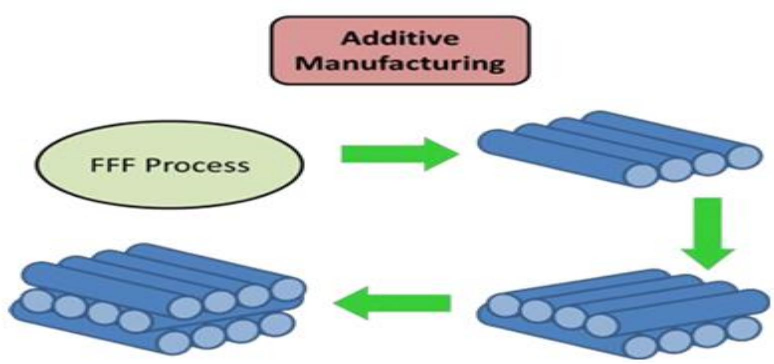

Fig no.1 Beads are deposited side by side in the fused filament fabrication process until a layer is finished. The layers that are deposited make up the final portion.

In order to create platforms and implants, a range of polymer materials have been investigated. However, the use of polymers in drug delivery systems is somewhat limited. The most popular polymers used in FF printing are acetate, poly (lactic acid) (PLA), poly (vinyl alcohol), and ethylene vinyl (PVA). (EVA), polymethylmethacrylate (PMMA), acrylonitrile butadiene styrene (ABS), and polycapro lactone (PCL). However, the rheology and heat transmission characteristics of the filament are the most crucial considerations when selecting the materials for this kind of application. Consequently, FF Printing identified a number of limitations, such as insufficient polymers and slow and insufficient drug release.

2. Stereolithography (SLA):

SLA is a vat polymerization technique. Applying ultraviolet (UV) light to fluid layers in a container with selective solidification can be used to describe the fundamental steps of the SLA processes. Within UV light and stronger irradiations react with the generated resin, a photo initiator molecule (PI). The chemical polymerization reaction functions as a local stimulant only in the open area. In that process, a newly made resin superfine film is carefully inserted after the first layer has been improved (25). As a result, the product gradually expands layer by layer.

This technique can be categorized according to the mode of irradiation or the direction of the incident light beam. In order to solidify the resin, UV was applied either above in the free surface method or below via a diaphanous Color vat in the controlled worked surface technique.

There are two approaches to apply radiation technology: either project the full pixelated drawing onto a thin layer in digital light ray processing (DLP)-SLA, or use a laser beam to scan every single point in the selected cross-section. A chemical reaction occurs when the compounds are exposed to UV or Project DLP. known as gelation occurs (26, 27). The device will release light in a certain pattern during the manufacturing process, causing the polymers to get in line with the conventional design.

Before the first layer is printed, a supporting framework is required to hold the product.

After being exposed to light, the first layer will rapidly solidify, enabling the subsequent layer to adhere to the surface. When printing is complete, excess liquid materials and the supporting skeleton are removed. On the other hand, the SLA is considered slow printing (28). Based on the findings of the current research, photo. In a single print cycle, curable polymerization can generate up to 28 distinct dosage forms (29). Micro-SLA based diode laser curing can be used to create platforms loaded with acetylsalicylic acid (30).

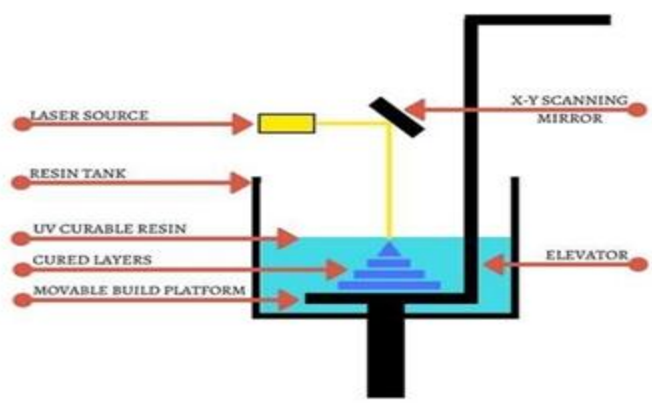

Fig no.2 Stereo lithography (SLA)

3. SLS, or selective laser sintering:

This technique operates using laser beams, just like SLA. The powder is spread out in a thin layer on a platform inside the chamber. The laser raises the temperature of the particle to precisely lower or reach the sing a cross-section made from the 3D geometry model to determine the powdered material's melting point.

A single, solid piece was created by the mechanical bonding of the material's particles. There is no need for specialized support structures because the portion in printing Span is supported by the leftover powder. A recoater puts a new layer of powder on top of the single layer that the build work platform deposits into the working chamber, which is usually between 50 and 200 microns.

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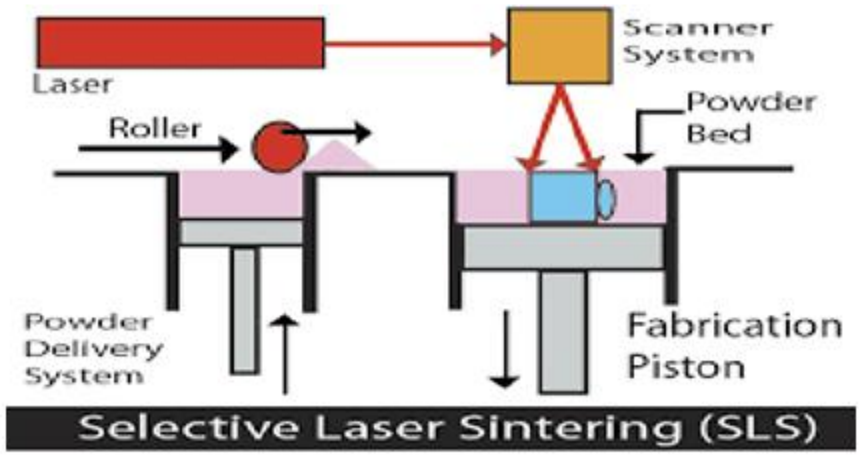

Fig no.3. Selective laser sintering

The laser then starts scanning the next form cross-section. This process is repeated for each layer until the geometry is complete, at which point the finished portion is allowed to cool gradually inside the apparatus. After the components have cooled, the worker takes the build chamber out of the laser printer and moves it to a cleaning area, where they separate the printed components and remove any excess powder (30). This method has many advantages, including quick production, high precision and resolution, no need for supporting structures, and highly controllable internal microstructures. Nevertheless, there are a number of drawbacks, including as the high expense and post-processing SLS used in anticancer delivery systems. SLS used several laser powers to create implantable polycaprolactone/fluorouracil tablets. settings. Initially, tablets provided a regulated release after a quick release of a high concentration of the drug at the specific cancer site (31).

4. Digital light ray processing (DLP):

This technique, which makes 3D printing possible, uses projected light to polymerize specific materials and get the desired outcome. This apparatus has shown notable benefits in terms of enhancing product features and printing efficiency and quality. The need for certain supporting structures, the scarcity of resources, the potential for material toxicity, the requirement for post-processing, and the costly equipment involved are some of its disadvantages. DLP uses an optical semiconductor called a Digital Micro Mirror Device (DMD); the image is produced by capturing reflected light using aluminium mirrors.

The DMD is frequently referred to as the DLP chip. With a dimension of less than 15 µm, each mirror on this chip may contain more than two million of them. Similar to a photo mosaic, these mirrors are stacked in a matrix arrangement, with each mirror acting as a pixel and each area holding a small, square picture. A photo gets blended together to form a single, large image when it moves away from the mosaic. The screen size is determined on the number of mirrors (32). Additionally, the resolution and reproducibility of 3D printing processes can be affected by the equipment, software, and materials used (33). More than two million pixels create a broadly accessible Factual 1920x1080p clear resolution when using the DLP 1080p method (34). Medical geometries have both mechanical and physical properties and are well-formed. The absence of substantial shear stress, temperature, or pressure is caused by tiny nozzles made to provide printing advancements appropriate for living tissues with minor cell injury. DLP technology allows for faster output than laser-assisted 3D printing, which confines the light spot to the object. This method rapidly prints the entire layer by exposing the precise resin to light. The ingredients used in DLP printing are certain types of polymers that cause photosensitive liquid lead to solidify when exposed to light. The printed tablets are mechanically strong, have a small brow, swell ability, weight fluctuation, and suitable medication release patterns. were produced after adjustments were made to the UV intensity, exposure time, material concentration, and layer thickness. Overall, evidence demonstrates that DLP-3DP is an appropriate platform for creating oral tablets with various shapes and release patterns (35).

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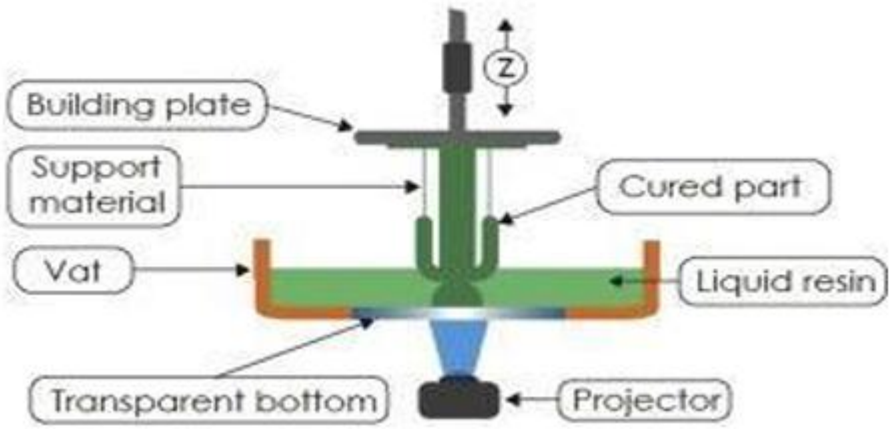

Fig no. 4 Schematic representation of the digital light processing vat polymerization process, in a bottom-up configuration.

5. Drop On Demand (DOD):

A material jetting printer has two print jets: one is used to deposit construction raw materials, and the other is used to jet a specific, dissolvable support material. To create the exact cross-sectional zone of a part, the DOD printers work by depositing material along a predetermined track in a point-by-point fashion.

These printers feature a fly-cutter that skims the Build working area after each layer to ensure a completely level and smooth surface before creating the next layer. DOD equipment is commonly used to create wax-like patterns for lost-wax casting, investment casting, and Mold-making applications through indirect 3D printing (36).

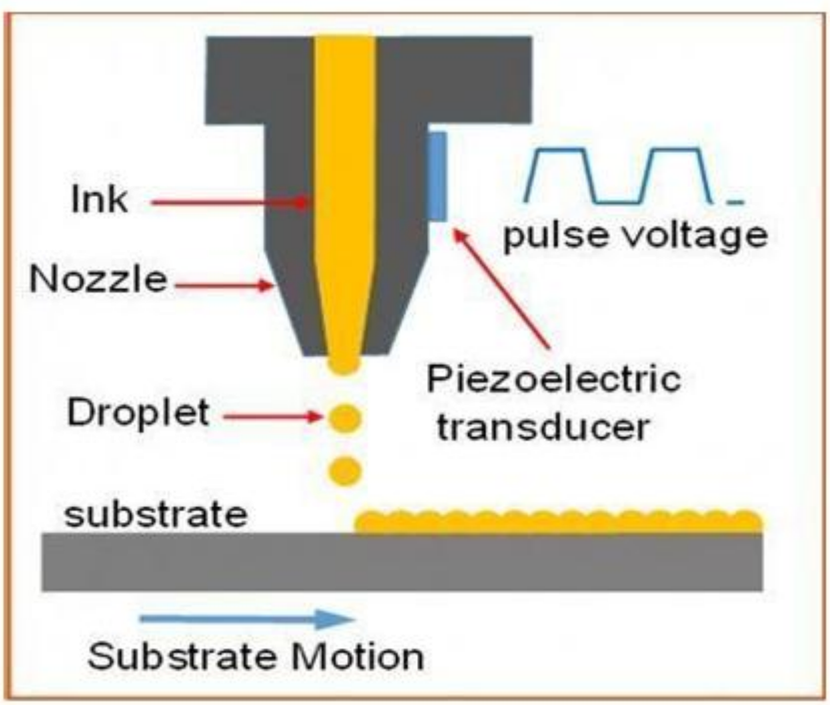

Fig no.5. Drop On Demand

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VI. Conclusion

However, current research suggests that 3D technology can be a useful supplement for improving communication between patients, their families, and the surgical team. Furthermore, by utilizing this technology, one can better understand the intended surgical procedure and the patient's unique anatomy. Further research is needed to assess the usefulness of 3D printing and modelling for patient education and counselling in pediatric populations. The objectives of these studies should be larger sample sizes and an attempt to take response bias into consideration.

3D printing makes it feasible to provide individualized care, better outcomes, and ongoing progress. Despite challenges, 3D printing in medicine promises a transformative era that will bring in personalized and patient-centered care.

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