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Mini Review Article

3D Printing In Pharmacotherapy: Transitioning From Batch Manufacturing To Personalized Dosing

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ABSTRACT

Traditional mass manufacturing relies on a “one-size-fits-all” approach, which frequently leads to adverse reactions or incorrect dosing for unique patient demographics. This review evaluates the transition from batch manufacturing to personalized dosing using three-dimensional (3D) printing technologies, specifically focusing on Fused Deposition Modeling (FDM), Selective Laser Sintering (SLS), and Inkjet printing. Current literature demonstrates that 3D printing enables the fabrication of highly customized dosage forms, including multi-drug polypills for geriatric patients, flavored chewables for pediatrics, and complex geometric matrices that manipulate drug release kinetics on demand. Despite its massive clinical potential to decentralize pharmacy practice, the widespread integration of 3D-printed pharmacotherapy remains hindered by a lack of medical-grade excipients, thermal degradation risks, and the absence of standardized regulatory guidelines for point-of-care manufacturing.

INTRODUCTION

For decades, the pharmaceutical industry has relied on conventional mass-manufacturing techniques that follow a “one-size-fits-all” paradigm. (1) (2) While cost-effective for large-scale production, this generalized approach fails to account for individual patient differences in genetics, age, weight, and disease state, frequently

resulting in adverse drug reactions or sub-therapeutic efficacy.

To mitigate the clinical risks associated with standardized dosing, the healthcare sector is rapidly transitioning toward personalized medicine. Precision pharmacotherapy aims to tailor medication regimens to the unique physiological and genomic profiles of individual patients, maximizing therapeutic outcomes while

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minimizing side effects. (1) (2) (3) This customized approach is particularly critical for vulnerable demographics, such as pediatric and geriatric populations, who require highly specific dosage adjustments and combination therapies to improve medication adherence.

The advent of three-dimensional (3D) printing, or additive manufacturing, has emerged as a revolutionary tool to facilitate this paradigm shift. (1) By utilizing computer-aided design (CAD) software, 3D printing enables the layer-by-layer fabrication of complex, patient-specific pharmaceutical dosage forms on demand. (2) The clinical viability of this technology was cemented in 2015 with the U.S. Food and Drug Administration (FDA) approval of Spritam (levetiracetam), a rapidly disintegrating anti-epileptic tablet produced via binder jet printing. (3)

Therefore, the aim of this review article is to evaluate the role of 3D printing technologies in advancing personalized pharmacotherapy. This paper will explore core printing mechanics, their specific clinical applications in developing complex drug delivery systems, and the current regulatory and technical bottlenecks preventing their widespread integration in pharmacy practice.

2. Core 3D Printing Technologies in Pharmaceutics

The transition from conceptual design to a physical pharmaceutical product relies on several distinct additive manufacturing platforms. (1) The selection of a specific 3D printing technology depends entirely on the physicochemical properties of the active pharmaceutical ingredient (API) and the desired drug release profile. (2) The most widely researched platforms in drug delivery are material extrusion, vat photopolymerization, powder bed fusion, and jet printing. (3)

3.1. Material Extrusion: Fused Deposition Modeling (FDM) Fused Deposition Modeling (FDM) is currently the most extensively utilized 3D printing technique in the pharmaceutical sector due to its cost-effectiveness and scalability. FDM operates by feeding a drug-loaded thermoplastic polymeric filament through a heated nozzle, which extrudes the melted material layer-by-layer onto a build platform. The primary advantage of FDM is its solvent-free process, which yields mechanically robust solid dosage forms. However, because the process relies on high temperatures to melt the polymers, FDM is strictly limited to thermally stable drugs; heat-sensitive APIs are at a high risk of thermal degradation during printing. (1) (2) (3)

3.2. Vat Photopolymerization: Stereolithography (SLA)

Stereolithography (SLA) constructs 3D objects by curing a liquid photosensitive resin using an ultraviolet (UV) laser. As the laser traces the computer-aided design, the liquid polymerizes and hardens layer-by-layer. (1) SLA provides exceptionally high printing resolution and precision, making it highly suitable for fabricating complex micro-structures, such as drug-loaded microneedle arrays for transdermal delivery. (2) Despite its precision, its clinical application is currently hindered by a lack of biocompatible, Generally Recognized as Safe (GRAS) photopolymers. Furthermore, residual photoinitiators trapped within the printed matrix pose potential risks of cytotoxicity. (3)

3.3. Powder Bed Fusion: Selective Laser Sintering (SLS)

Selective Laser Sintering (SLS) employs a high-energy laser to selectively fuse powder particles together on a powder bed. Once a layer is sintered, a roller distributes a new layer of powder, and the



process repeats. Because SLS utilizes loose powder without the need for liquid binders, it naturally produces highly porous dosage forms. This high porosity allows rapid fluid penetration, making SLS an ideal technology for fabricating fast-dissolving and orally disintegrating tablets. Like FDM, the primary limitation of SLS is the potential degradation of the API caused by the high-energy laser beams during the sintering process. (1) (2) (3)

3.4. Droplet-Based Systems: Jet Printing

Jet printing platforms, including binder jetting and inkjet printing, utilize pattern-generating nozzles to deposit tiny, digitally controlled droplets onto a substrate or powder bed. In binder jetting, a liquid binding agent is deposited onto a bed of API and excipient powder, cementing the particles together at room temperature. This room-temperature processing completely bypasses the thermal degradation risks associated with FDM and SLS. (1) The highly porous structures created by binder jetting enable near-instantaneous disintegration, which was the core mechanic behind the FDA-approved epilepsy drug, Spritam. However, the high porosity often results in highly fragile dosage forms that require post-fabrication drying steps. (2)

5. Clinical Applications and Patient-Centric Design

The primary advantage of 3D printing over traditional manufacturing is its ability to transition pharmacotherapy from a mass-produced standard to a highly individualized patient experience. By manipulating the digital design and material composition, pharmacists can target the unique physiological and sensory needs of specific patient demographics. (1) (3) (2)

3.1. Pediatric and Geriatric Customization

Pediatric patients present a unique clinical challenge due to their constant physiological changes and frequent rejection of medications based on texture, taste, or appearance. (3) 3D printing circumvents these barriers by allowing the point-of-care fabrication of chewable, fast-dissolving tablets that can be customized with specific flavors, colors, and precise weight-based dosages, significantly improving pediatric medication adherence. (2) (4) Conversely, the geriatric population frequently suffers from polypharmacy, a condition where patients must manage complex regimens of multiple daily medications, which increases the risk of missed doses and drug-drug interactions. 3D printing addresses this through the creation of the “polypill”. (1) (2) Additive manufacturing enables the consolidation of several active pharmaceutical ingredients into a single, multi-compartment tablet. For example, customized polypills can combine immediate-release and sustained-release compartments in a single dosage form, simplifying a patient’s regimen and improving therapeutic compliance. (5)

3.2. Accessibility for the Visually Impaired

Visual impairment significantly affects medication management, often leading to poor adherence and dangerous dosing errors. 3D printing offers a groundbreaking solution by allowing the surface modification of dosage forms. (1) Using Selective Laser Sintering (SLS), researchers have successfully fabricated orally disintegrating printlets that feature embossed Braille and Moon patterns. These tactile modifications enable visually challenged patients to safely and independently identify their specific medications. (2)

3.3. Regenerative Medicine and Bioprinting



The application of 3D printing extends far beyond oral solid dosage forms, crossing into the realm of tissue engineering and regenerative medicine. 3D bioprinting utilizes “bioinks”—formulations composed of biocompatible polymers and living cells—to construct functional tissue scaffolds, implants, and biological wound dressings. (3) These bioprinted constructs can be engineered to release therapeutic agents, such as localized antibiotics or growth factors, directly at the site of a surgical wound or bone defect. Furthermore, 3D bioprinting holds the long-term potential to fabricate patient-specific tissues and organs from the patient’s own genetic material, mitigating the risk of transplant rejection and addressing the global shortage of donor organs. (4)

5. Challenges and Regulatory Hurdles

Despite the significant clinical potential of 3D printing, widespread implementation is currently stalled by several technical, material, and regulatory obstacles. A primary challenge is the current lack of global standardization for the design, fabrication, and quality control of 3D-printed pharmaceuticals. While regulatory bodies like the FDA have issued guidance regarding 3D-printed medical devices, comprehensive frameworks specifically governing decentralized pharmaceutical manufacturing—such as production within local pharmacies or hospital clinics—remain underdeveloped. Technical limitations also create substantial barriers. The most common printing method, FDM, often requires high temperatures to melt polymer filaments; these conditions can cause thermal degradation of heat-sensitive active pharmaceutical ingredients (APIs), rendering them ineffective. Furthermore, there is a severe shortage of biocompatible, medical-grade polymer excipients that are proven safe for long-term clinical use. Safety is a major concern in

decentralized settings, where the risk of cross-contamination in extrusion nozzles—when different drugs are printed using the same hardware—poses a significant patient safety risk. Finally, the inherent nature of additive manufacturing limits its scalability. While industrial pharmaceutical presses can mass-produce hundreds of thousands of tablets per hour, 3D printing relies on slow, layer-by-layer construction. (3) (4) This throughput limitation suggests that 3D printing will likely remain a specialized solution for small-batch, personalized medicine, rather than a replacement for high-volume conventional drug production.

5. CONCLUSION

The integration of three-dimensional printing into the pharmaceutical sciences represents a monumental shift away from the traditional, rigid “one-size-fits-all” model of mass manufacturing. Additive manufacturing offers unprecedented flexibility, enabling the on-demand fabrication of patient-specific dosage forms that feature complex geometries, precise release kinetics, and customized dosing. This technology holds exceptional promise for vulnerable demographics, offering tailored solutions such as multi-drug polypills to combat geriatric polypharmacy and flavor-customized, rapidly disintegrating tablets to improve pediatric adherence.

However, the transition from experimental research to widespread clinical application remains hindered by significant bottlenecks. The absence of standardized regulatory frameworks for decentralized, point-of-care compounding poses a major hurdle. Furthermore, the limited availability of safe, medical-grade printable polymers and the inherent risks of thermal degradation during extrusion currently restrict the scalability of the technology. Despite these challenges, as material sciences advance and regulatory agencies establish



comprehensive guidelines, 3D printing is poised to fundamentally revolutionize pharmacotherapy, cementing personalized medicine as the new standard of clinical care.

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