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Review

Three-Dimensional Printing Technologies in Oral Films Manufacturing—A Minireview

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Abstract: The interest in buccal drug delivery is under consideration due to some distinct properties compared to the traditional pharmaceutical formulations for oral administration: significantly higher bioavailability, a faster absorption rate of the drug, and substantial compliance for special needs patients. Oral films are obtained through various technologies, from conventional tools to 3D and 4D printing approaches. This minireview aims to describe the current additive manufacturing technologies in oral film fabrication, display their advantages and limitations, and discuss various formulation strategies. It also provides advanced data regarding synthetic and natural polymers used in 3D printing technologies for oral films. Moreover, it shows the most recent studies with 3D-printed orodispersible films and mucoadhesive buccal films manufactured through previously analyzed methods. Finally, conclusions and future perspectives are also briefly summarized.

Keywords: buccal drug delivery; active pharmaceutical ingredients; oral films; 3D inkjet printing; extrusion-based 3D printing methods; liquid crystal display 3D printing; polymers; personalized medicine

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1. Introduction

Oral administration is most widely used because of the low cost of therapy, convenience, and self-medication. Due to high patient compliance, over 70% of commercially available drugs are formulated for oral administration. A relatively new formulation consists of oral films (OF) adapted for buccal drug administration, avoiding gastric pH, first-pass metabolism, and enzymatic degradation of active pharmaceutical ingredients (API), and providing effective therapy for patients with special needs [1–3]. Oral films are novel drug delivery systems containing active ingredients in water-soluble polymer matrixes [4]. They release the drug when placed in the oral cavity by dissolving or adhering to the buccal mucosa [5]. Their action can be topical [6–8] or systemic [9–11]. The variety of active ingredients contained in OF is wide: plant extracts [12–15], herbal compounds [16–18], nutraceuticals [19], conventional drugs [20–26], antibiotics [27], antivirals [28,29], vaccines [30], insulin [31], and other proteins [32].

Oral films can be orodispersible films (fast-dissolving oral films or oral dissolving films—ODF) [33–45] and mucoadhesive buccal films (MBF) [46–53]. The ODFs are formulated for rapid drug release and subsequent absorption in the oral cavity or digestive tract [54–56]. MBFs are designed for prolonged drug release [57–59]. Due to their properties, OFs are considered patient-centered pharmaceutical formulations [60]. Oral film formulations ensure high patient compliance due to accessibility, application/removal, retention, and analgesia [6]. They are usually prepared by classical methods (solvent and semisolid casting methods, melt extrusion, solid dispersion extrusion, and rolling) [33,61]. Currently, the most advanced tools use 3D printing technology and classical methods [62,63].

This review aims to describe in detail the 3D printing methods used to fabricate OFs. We used two databases (Google Scholar and PubMed) and Mendeley software for open-access articles/reviews published between 2013 and 2023. The following keywords were used: 3D printed oral patches/films, 3D printed buccal films, 3D printed orodispersible films, and 3D printed fast-dissolving oral films. The last search was conducted on 15 July 2023.

2. Oral Films as Innovative Dosage Forms

The main constituents of oral films are polymers, plasticizers, and API. To increase their acceptability, they could also contain other components: taste correctors, disintegration promoters, flavors, salivary secretion stimulants, and coloring agents [64,65].

Film-forming polymers provide rapid disintegration in the oral cavity and mechanical strength.

Plasticizers are responsible for the flexibility of the film, lowering the melting temperature during hot melt extrusion, increasing the film-forming ability of the polymers, and other mechanical properties. They can significantly affect the solubility and absorption of active ingredients and can be used as solubility and absorption enhancers.

Mucoadhesive polymers are required to provide optimal adherence to the buccal mucosa. The most commonly used ones are Methyl Cellulose (MC), Carboxymethyl Cellulose (CMC), Ethyl Cellulose (EC), Hydroxyethyl Cellulose (HEC), Hydroxypropyl Methyl Cellulose (HPMC), Hydroxypropyl Cellulose (HPC), Polyvinyl Alcohol (PVA), and Polyvinyl Pyrrolidone (PVP) [1,4,63,66].

Oral films' evaluation regards multiple aspects like physicochemical and pharmacotechnical properties. In addition, oral films containing API are compared with placebo.

Physicochemical investigations are assessed using specific methods. FT-IR spectrophotometry allows the examination of the infrared spectra of all formulation components; thus, unwanted interactions between them and pure API could be detected. Oral film morphology is examined using SEM. The X-ray diffraction analysis helps to determine the crystallized or amorphous nature of the oral films' constituents. Differential scan calorimetry (DSC) analysis determines if the API is compatible with auxiliary substances.

The pharmacotechnical evaluation measures moisture absorption capacity, tensile strength, elongation, thickness folding endurance, pH value, swelling degree, disintegration time, dissolution rate, and release kinetics. Table 1 displays the principal drugs that could be used as APIs for oral films and their solubility:

Table 1. Solubility of the most common drugs used as APIs for oral films.

Top Researched	Active Substance	Solubility in pH 6.5 Buffer (mg/mL)
1	Paracetamol	Approximately 20
2	Ibuprofen	Approximately 30
3	Metformin	Approximately 25
4	Aspirin	Approximately 5
5	Propranolol	Approximately 4
6	Ondansetron	Approximately 8
7	Phenytoin	Approximately 10
8	Captopril	Approximately 5
9	Nifedipine	Approximately 15
10	Amlodipine	Approximately 8

The ideal characteristics of oral films are shown in Figure 1. The most important aspects that should be considered include good taste for better patient acceptance, high moisture resistance and a suitable tension surface to withstand the stresses of moisture and mouth movement, good solubility in saliva, the ability to be ionized in the oral cavity, and the ability to penetrate the oral mucosa to ensure a rapid therapeutic effect.

Figure 1. The ideal features of oral films, adapted from [67].

Figure 2 shows the advantages of oral films as a pharmaceutical formulation for drug administration, which can increase patient compliance. Key aspects resulting from the literature search highlight the following: not requiring water at the disposal, no risk of suffocation, increased stability compared with liquid form, ease of application for the patient, and suitability for patients with mental disorders, dysphagia, and swallowing disorders. From the active dosage and bioavailability standpoint, oral films provide increased API bioavailability, a low dosage, ease of dosing, a high absorption rate, and are more practical.

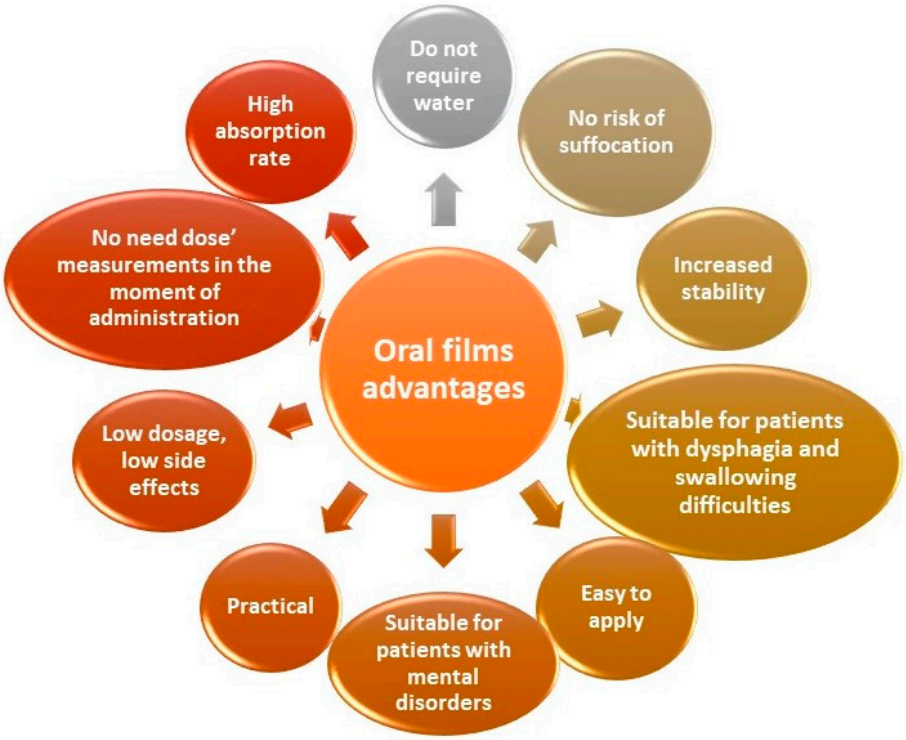


Figure 2. The advantages of using oral films for drug administration, adapted from [67,68].

The significant limitations of drug formulation as oral films are displayed in Figure 3.

Figure 3. Oral film limits in drug administration, adapted from [67,68].

These limitations could be diminished by the current innovative manufacturing methods for OFs through 3D printing technology.

3. Three-Dimensional Printing Technologies for Oral Films

Three-dimensional printing [69–79] can solve the formulation problems of producing OFs. Currently, buccal dosage forms are reserved for potent agents due to the limited capacity of drug incorporation. Three-dimensional printing techniques could be used to superimpose the layers of OF to accommodate more active ingredients per unit area. They also consider the mucosal surface's limited area for drug absorption and may provide a potential solution for incompatible ingredients by compartmentalizing the buccal film layers [2]. In addition, 3D printing could provide a platform for controlled drug release over longer periods, reducing the frequency of administration.

The printing techniques [80] used for oral film fabrication are presented in Figure 4.

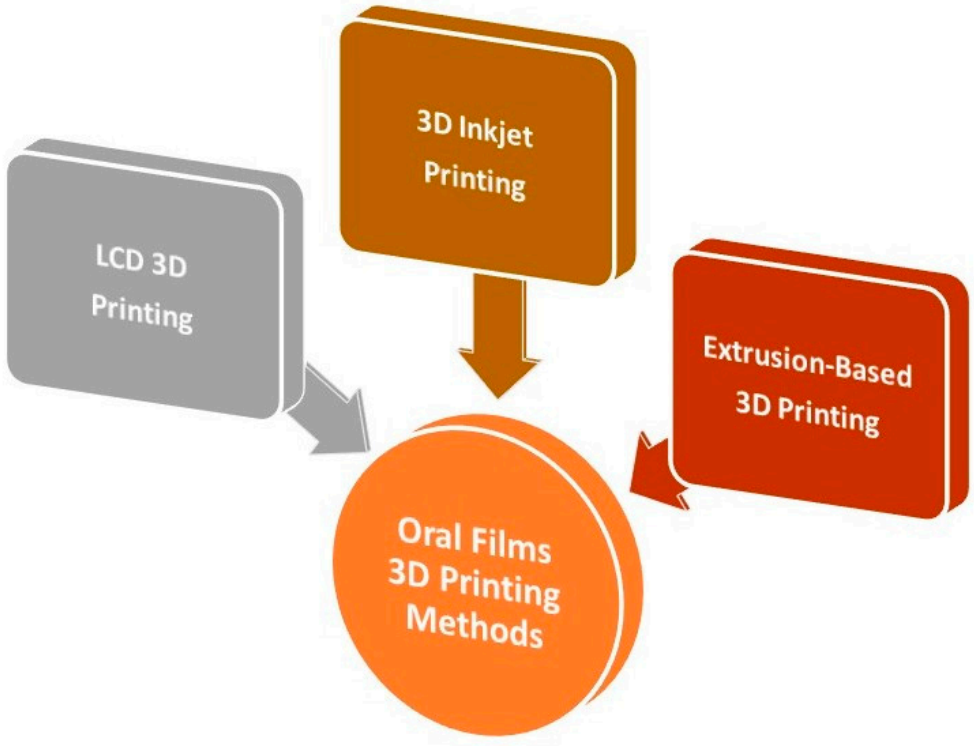


Figure 4. Three-dimensional printing methods for oral films; adapted from [67,68,80].

3.1. Three-dimensional Inkjet Printing

Three-dimensional inkjet printing is an extension of conventional inkjet printing limited to a single-layer coating [3,80–82]. Three-dimensional inkjet printing (material jetting) enables multilayer buildup in the vertical direction using a layer-by-layer printing tool [83]. A computer-aided design (CAD) of the 3D structural system emphasizes the printing instructions; the size of each layer is automatically generated by easy-to-use software algorithms [83].

Thus, multilayer OFs achieve all the characteristics of inkjet printing: good printing resolution and a wide range of liquids or suspensions that can be used as ink materials.

Each layer must be cured before the subsequent inks are applied. The type of ink applied has a significant effect on the curing stages. Low-temperature curing by IR lamps or UV/Vis light is the most commonly used mechanism in 3D inkjet printing processes. They can be quickly set up during 3D inkjet printer setup [84].

- Advantages

Three-dimensional inkjet printing represents a suitable method for personalized OFs.

The complexity of the structured layers did not significantly affect the manufacturing time compared to the overall size of the printed object. Manufacturing costs are very predictable and are limited to the necessary materials to be printed, each layer's curing

time, and the inkjet printer's energy consumption. The production time can be significantly reduced (e.g., from a few days to a few hours). In addition, this method can be used to combine very different liquid inks (with different viscosities and solubilities) [83].

- Limitations

The cure time limits the 3D inkjet's potential to obtain fast-printed complex 3D structures. The layer thickness is also limited.

The solvents used to print the top layers could influence the underlying layers. Their properties (adhesion and delamination) could affect the entire printed structure [83].

3.2. Extrusion-Based 3D Printing Methods

3.2.1. Fused Deposition Modeling

Fused Deposition Modeling (FDM) is one of the most popular techniques in 3D printing. By depositing thermoplastic filaments layer by layer and extruding them through a nozzle (either melted or softened), the 3DP structure is created, following a CAD geometry. The material is heated above its melting point in the head of the 3D printer (hot melt extrusion, or HME); then, the mixture of polymer and agent melts and deposits layer by layer as fine filaments [85]. They solidify quickly and produce the desired 3D structure. FDM enables mold reproducibility and uniformity of active ingredient concentration [86].

- Advantages

FDM allows a wide range of filaments: Polylactic acid (PLA), Polyethylene Terephthalate Glycol (PETG), Polyvinylalcohol (PVA), Polycaprolactone (PCL), Acrylonitrile Butadiene Styrene (ABS), Polyphenylsulphone (PPSF), Acrylonitrile Styrene Acrylate (ASA) [85,87]. It represents a significant advantage, according to various 3D-printed structures' destinations. Due to the FDM 3D printing technique, they cannot be easily contaminated. FDM also offers appreciable mechanical strength for 3D-printed structures [88]. It can obtain different release profiles for the printed dosage forms by changing the formulation's 3D model design, infill percentage, or surface area [85,89].

- Limitations

FDM is a multistep process involving prior filament preparation by HME. During processing, the repeated thermal stress led to the potential degradation of heat-sensitive drugs/polymers [90]. Even if FDM can print many details, the finest ones are limited [85,87] by the nozzle size, layer thickness, and polymer type. The final 3D-printed product's stability and strength depend on the mechanical properties of the filaments [91]. Polymers that harden faster (with a more significant difference between TG and melting point) in the cooling step give sharper detail levels.

3.2.2. Pressure-Assisted Microsyringe (PAM)/Semisolid Extrusion (SSE)

The PAM/SSE technique uses viscous and semisolid materials for microsyringes [91–93]. It uses compressed air to extrude the semisolid material, leading to 3D-printed microstructures. In the PAM/SSE process, the starting material's viscosity is highly significant and must be adjusted. If the viscosity is high, the material can clog the nozzle; if the viscosity is low, the 3D structure will not have mechanical stability during the layer formation, and the nozzle will drip. The desired 3D model structure is generated using CAD software and converted to a .stl file. After that, it is loaded into the 3D printer equipment. The CAD file changes allow the required transformations of the final 3D-printed object [91].

- Advantages

Compared to FDM, PAM/SSE ensures continuous 3D-printed form fabrication at room temperature. The filament prior preparation through HME is unnecessary [92,94]; thus, PAM/SSE is suitable for thermo-labile drugs. The 3D printing process is computer-controlled; production time, manual labor, and costs are diminished [91] compared to conventional techniques.

- Limitations

Incorporating solvents raises concerns about safety and stability during manufacturing and drying [92]. Optimizing the initial viscosity affects the integrity of the 3D-printed product. Nose plugging can occur during the 3D printing process. Printing optimization is essential to ensuring the mechanical uniformity and durability of the 3D-printed structure. Only aqueous solvents are suitable for the PAM /SSE technique [92].

3.2.3. Direct Powder Extrusion (DPE)

As SSE, DPE avoids the initial filament fabrication by HME. Thus, the production cost is significantly reduced, the formulation development is accelerated, and attention is moved to the single 3DP process [91].

- Advantages

Thermal stresses are avoided, so the mechanical stability of the filaments is not a problem for manufacturing, unlike the FDM process. Single-step printing is a convenient and more practical method for on-site fabrication in hospitals and pharmacies [91].

- Limitations

The final product has surface roughness and variable weight. If the melt residence time in the heating zone of the extruder is long, the rheological properties of the drug/excipients could be affected, and the risk of API's thermal degradation could be substantial. Due to pneumatic pressure, material oxidation before printing can occur [91].

3.3. Liquid Crystal Display 3D Printing

Liquid crystal display (LCD) 3D printing is an emerging technology with low-cost equipment [95]. It is one of the three currently available photocuring three-dimensional printing technologies. LCD 3D printers are based on UV wavelengths. The UV light comes from an array of light-emitting diodes (LEDs) that shine through the LCD [96], used as an imaging system. As control parameters, the exposure time and scanning speed correspond to varying degrees of polymerization, influencing the light density in the projection process and the scan type. The most critical parameters in LCD 3DP are exposure time, wavelength, and amount of power supply [97]. Unlike UV light, visible light-induced photopolymerization is safe for the human body and ensures high light penetrability. Developments of photosensitive systems that can operate in visible light has attracted great interest recently and is strongly supported by LED development. Three-dimensional printers using such LED technology (e.g., LED projectors) have recently been introduced on the market [98]. With the printing process in visible light, there are many possibilities for developing new resin formulations [68] with safer photoinitiators and polymers.

- Advantages

LCD machines have good resolution and are low-cost. Currently, the LCD 3D photocuring machine is applied in dentistry, jewelry, toys, etc.

- Limitations

LCDs have a short functioning life and need to be periodically replaced; only 10% of the light can penetrate the LCD screen, while the rest of it is absorbed. The partial light leakage could lead to the exposure of photosensitive resin at the bottom. The liquid tank needs to be cleaned regularly. The adhesions of the printed part to the screen can determine failed prints.

As an overview, the advantages and limitations of all methods previously discussed are summarized in Table 2.

Table 2. Advantages and limitations of 3D printing technologies in oral film manufacturing.

Printing Technique	Advantages	Limitations
3D Inkjet Printing	- Suitable for personalized oral films	- Cure time limits fast-printed complex structures
	- Complexity of structured layers does not significantly impact manufacturing time	- Solvents used for top layers can affect underlying layers
	- Predictable fabrication costs	
Extrusion-Based 3D Printing Methods	- Wide range of filaments available	- Thermal stress may lead to the potential degradation of heat-sensitive drugs/polymers
	- Shapes' reproducibility and API concentrations' uniformity	- Limitations on achieving fine details due to nozzle size, layer thickness, and polymer type
	- Different release profiles are achievable by changing the 3D model design, infill percentage, or surface area	- Final product stability and strength depend on the mechanical properties of the filaments
Pressure-Assisted Microsyringe (PAM)	- Continuous 3D printing at room temperature	- Concerns regarding safety and stability during solvent incorporation and drying processes
	- Suitable for thermo-labile drugs	- Nozzle clogging may occur during the printing process
Semisolid Extrusion (SSE)	- Computer-controlled process with reduced production time, manual labor, and costs	- Optimization of printing pressure is essential for mechanical uniformity and durability
		- Only aqueous solvents are appropriate
Direct Powder Extrusion (DPE)	- Significantly reduced production cost	- Surface roughness and variable weight in the final product
	- Accelerated formulation development	- Risk of thermal degradation of API due to melting residence time and potential material oxidation
Liquid Crystal Display 3D Printing	- Good resolution and low cost	- Short functioning life of LCDs and the need for periodic replacement
	- Safe visible light-induced photopolymerization	- Light leakage from LCDs and exposure of the photosensitive resin
		- Liquid tank requires regular cleaning
		- Adhesion issues between printed parts and screen

4. Polymers for 3D Printing Technologies

Polymers play an essential role in fabricating 3D-printed OFs [47,99,100]. Therefore, selecting a suitable polymer is crucial for a high-quality OF. Figure 5 shows the ideal polymer properties for 3D-printed OFs.

The synthetic polymers commonly used in 3D printing [101,102], which are characterized by high printability and mechanical strength, are polycaprolactone (PCL) [103–105], polylactic acid (PLA) [106], and poly(lactic-co-glycolic acid) (PLGA) [107], polyvinylpyrrolidone (PVP) [108], polyvinyl alcohol (PVA) [109], and novel binary and ternary polymer blends based on ABS [110], HPMC [111], and carboxymethylcellulose (CMC) [112,113].

A high printing temperature and an organic solvent are required to produce the ink containing these materials; these conditions limit their applications for drug delivery.

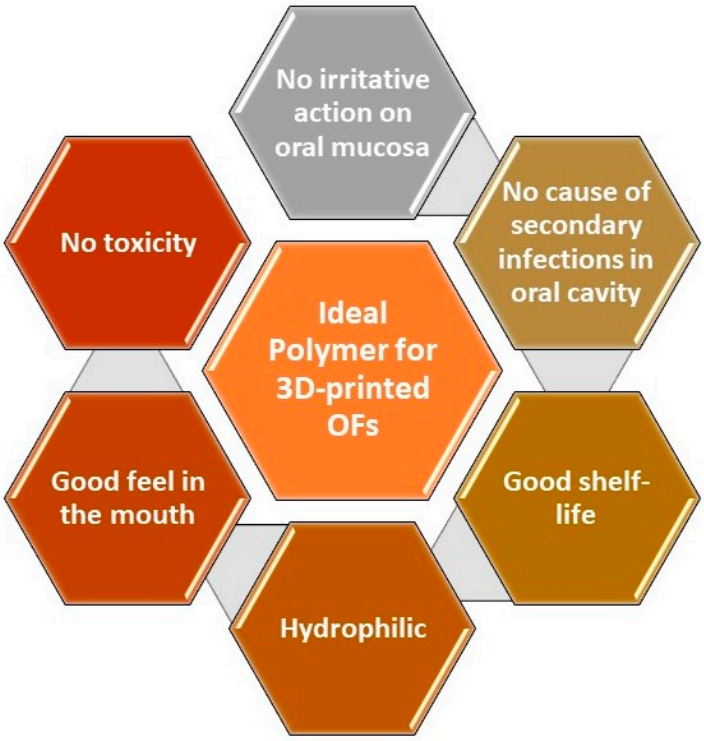


Figure 5. Ideal polymer features for 3D-printed oral films; adapted from [67,68,80].

Three-dimensional inkjet printing requires inks with low viscosity (10–20 mPa s) and surface tension (28–42 mNm^{-1}) for appropriate droplet generation [84,114]. Therefore, the nature and type of inks that can be employed are minimal, thereby diminishing the number of active materials that could be printed [114,115]. Karjalainen et al. [115] reported a method to synthesize materials derived from highly viscous or even solid monomers with the potential to be integrated into 3D inkjet printing processes. It uses polymerizable ionic liquid precursors, applying deposition and polymerization, followed sequentially by quaternization and anion metathesis of the films. They developed a control technique to verify the mechanical and superficial properties of the inkjet-printable polymeric films of neutral and cationic nature by post-polymerization reactions [115].

Natural materials such as collagen [116,117], alginate [118], cellulose [119], starch [120], gelatin [121], hyaluronic acid [122], and chitosan [123] are more similar to body structures and have lower toxicity. However, in their native form, they do not have suitable mechanical strength or high durability. Therefore, numerous studies have focused on developing suitable hydrogels for 3D printing that meet biological requirements and can be printed satisfactorily by selected technologies [120,123–125].

The essential ink properties of extrusion-based 3D printing methods are shear thinning behavior and viscosity. The 3D printing tools and the mechanisms of gel formation have an intrinsic connection; thus, the hydrogel ink needs to be crosslinked during and after 3D printing. If crosslinking occurs before 3D printing, the risk of nozzle clogging increases; if crosslinking is produced after 3D printing, the final structure's resolution decreases [123]. Melocchi et al. [126] produced different filaments based on various polymers. These filaments were insoluble (ethylcellulose, Eudragit1 RL), promptly soluble (polyethylene oxide, Kollicoat1 IR), enteric soluble (Eudragit1 L, HPMC acetate succinate), and swellable/erodible (PVA, hydrophilic cellulose derivatives, Soluplus1) by using a twin-screw extruder. Moreover, they demonstrated the possibility of employing these filaments to print 600 mm-thick disks through the FDM method [126].

On the other hand, compatibility with lithographic processes is requested for the hydrogel inks suitable for light-based 3DP [123]. Xu et al. [127] investigated 3D-printed OFs based on LCD, examining their printability and quality, and establishing the factors influencing

these parameters. They used HPMC, Polyethylene (glycol) Diacrylate (PEGDA), tartrazine, diphenyl (2,4,6-trimethyl benzoyl) phosphine oxide (TPO), and PEG [128]. Four printed formulations were obtained, and the influence of photoinitiator (TPO), photoabsorbent (Tartrazine), and HPMC as polymer forming agents was evaluated on OF's printability.

5. Three-dimensionally Printed Oral Films Using Different 3D Printing Methods—Literature Data

Cader et al. [129] prepared an oral pharmaceutical formulation through water-based 3D inkjet printing. They used PVP with Mw ~ 10,000 as a film-forming polymer, thiamine HCl (purity > 99%), polysorbate 20 (TWEEN20), and glycerol (as a plasticizer to avoid cracking during the drying process) mixed with deionized water to formulate ink solutions for 3D printed oral multilayer films.

Jamroz et al. [130] fabricated ODFs with aripiprazole through the FDM method. First, they prepared a mixture of aripiprazole and polyvinyl alcohol (PVA) using ethanol as a wetting agent. The mixture was dried at (70 °C) and extruded at a temperature of 172 °C to obtain filaments of drug-loaded PVA, wherein the drug was in amorphous form during the extrusion process. ODFs of 6 cm^2 with a disintegration time of 43 s were obtained from drug-loaded PVA filaments. Through FDM, they ensured reproducibility in shape and uniformity of drug content. The authors also compared the 3D-printed ODFs with those prepared by solvent casting (SCM) and found their mechanical characteristics were similar. Additionally, the results showed that PVA acted as a stabilizing agent by maintaining the amorphous nature of aripiprazole in 3DP ODFs [130].

Elkanayati et al. [131] coupled HME with FDM for 3D-printed MBFs for xerostomia therapy. They used adipic acid as an API, polyethylene oxide N80 as a carrier polymer, and xylitol as a saliva secretion stimulant.

FDM has also been used to produce MBFs with unidirectional drug release. For example, Eleftheriadis et al. [132] prepared PVA-based OFs containing a hydrophilic drug (diclofenac sodium). Xylitol was introduced into the polymer blend as a plasticizer. Polymeric filaments and buccal films were formulated in the absence or presence of chitosan to investigate the effect of the natural polymer on mucoadhesion and drug permeation in OF. The potential of FDM printing was exploited by developing multilayer films. A back layer was fabricated to modify the drug release properties.

Another type of MBF containing ketoprofen and lidocaine was manufactured through FDM 3D printing and combined with inkjet printing [133]. HPMC-based films containing ketoprofen were fabricated using FDM technology. An ethyl cellulose-based backing layer ensured unidirectional release properties; the second step involved depositing lidocaine hydrochloride and l-menthol (as a permeation enhancer) onto the film. Physicochemical analysis showed that the films' alteration led to changes in the mucoadhesive and mechanical properties due to the substrate's ink deposition [133]. Eleftheriadis et al. [134] also developed an automated digital design for 3D-printed individualized therapies.

Similarly, Ehtezazi et al. [135] aimed to obtain 3DP single-layered and multilayered oral films using the FDM method. The selected polymers were polyethylene oxide (PEO) and PVA. Paracetamol and ibuprofen were model drugs. Hence, filaments of PEO with ibuprofen and PVA with paracetamol were prepared by the hot-melt extrusion method (60 °C for PEO and 130 °C for PVA). Through 3DP FDM, they processed these filaments to obtain both ODFs of ibuprofen and paracetamol. Notably, the authors have printed taste masking layers at lower temperatures (130 °C) to assess the ODFs' acceptability and, thereby, patient compliance. Higher disintegration times were observed for both ODFs, probably due to high-molecular-weight polymers.

For syringe extrusion 3D printing, the polymers' selection is performed according to several characteristics. The most important are rheological properties, nozzle extrudability, drying conditions, flow consistency, and reproducibility of 3D printing formulations [136]. However, only a few studies describe 3D-printed ODF fabrication using SSE. Consequently, we aimed to investigate and identify the best printing materials for this method, which can

be used for 3D-printed ODF fabrication and other essential pharmaceutical applications such as prolonged and immediate-release drug delivery systems.

Recently, SSE has been used for prolonged-release MBFs loaded with propranolol hydrochloride (PRH). It is well known that this drug undergoes extensive hepatic first pass metabolism [137]. Hence, Jovanovic et al. [137] incorporated PRH in MBFs based on gelatin-PVP and gelatin-PVA. They aimed to evaluate the effects of PVP and PVA on gelatin-based films' properties. They revealed that both polymers led to PRH-loaded MBFs with suitable mechanical and mucoadhesive properties and a prolonged drug release time [137].

Elbl et al. [138] included an in-process drying step in an SSE 3D printer and demonstrated the feasibility of this apparatus through benzydamine hydrochloride incorporation in multilayered ODFs. The films were dried before the subsequent layers' printing to reduce development time. They also improved the drug uniformity and mechanical properties of the films. Moreover, they studied the effects of various drying times on the ODF's properties (Figure 6) [139].

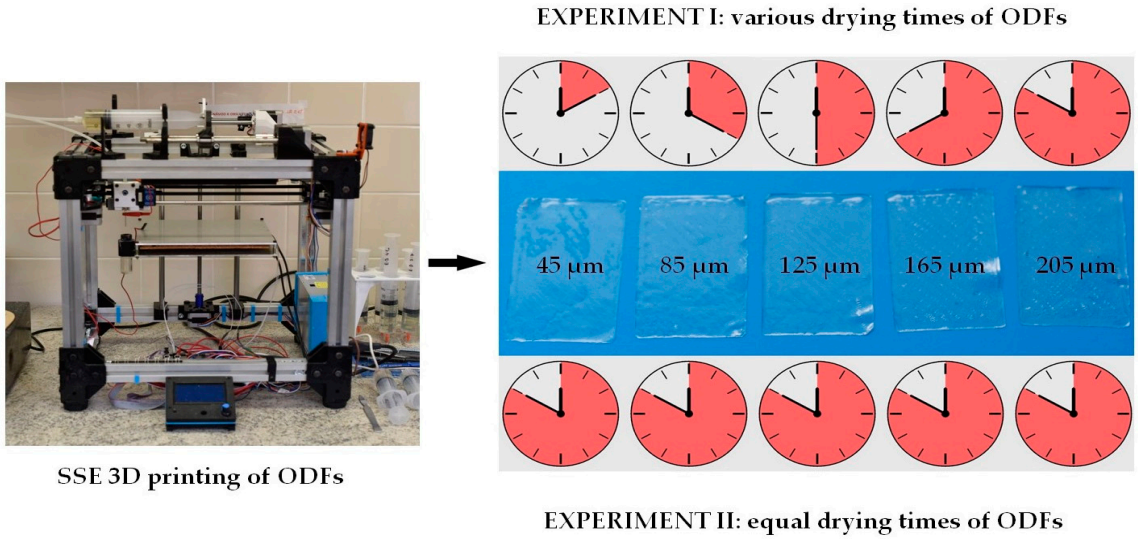


Figure 6. Preparation and drying time influence the evaluation of 3D-printed orodispersible film properties. Reproduction with permission from [139].

Concomitantly, a porous structure was conferred to 3D-printed multilayered ODFs for potential use as a substrate for inkjet printing [140].

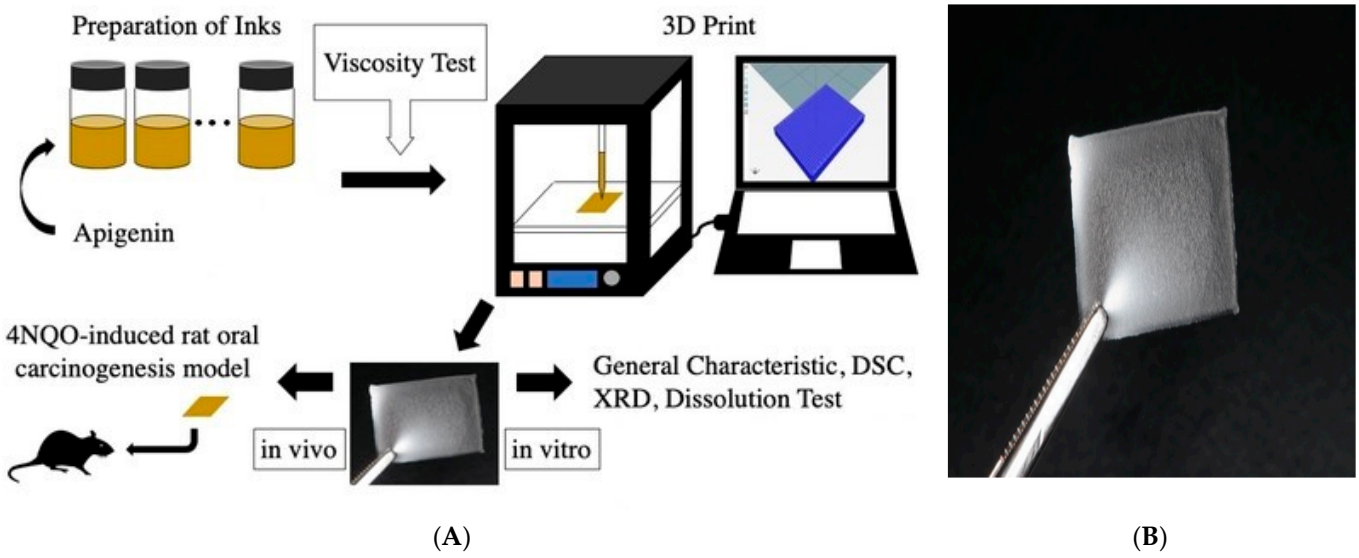
Additionally, Tagami et al. produced 3D-printed mucoadhesive films loaded with catechin to treat mouth ulcers [93]. They used HPMC inks and obtained MBFs in various macroscopic geometries.

More recently, Elbadawi et al. [141] incorporated caffeine in oral films based on pullulan and HPMC. Then they studied the design type's influence on patch mechanics.

He et al. [142] manufactured stretchable oromucosal patches for saquinavir-programmable delivery. For this purpose, three ink types were requested. The backing membrane ink was obtained using methanol for Nile red, MC, and glycerol solubilization at 60–65 °C. Saquinavir mesylate, malic acid, and glycerol were dissolved in water at 70–75 °C for saquinavir ink's achievement. Then, HPMC K100 LV was gradually added, forming a white HPMC-saquinavir suspension that was cooled down to 4–6 °C until it became transparent ink. Finally, in water at 70–75 °C, sodium carbonate, HPMC K200 M, and glycerol were dissolved for the alkaline ink's assessment.

Using apigenin as an API, Takashima et al. obtained 3D-printed MBFs for oral leucoplakia, proving their chemopreventive effects on oral cancer in vivo on rats [143]. The semisolid extrusion-type 3D printer was the platform, and apigenin was formulated as printer ink. The MBFs contain polymers (HPMC, CARBOPOL, and Poloxamer), water,

and ethanol for apigenin solubilization. The printer ink's suitable viscosity was adjusted, leading to the thriving manufacturing of the 3D-printed oral mucoadhesive films (Figure 7).



(**A**) (**B**)

Figure 7. (**A**). Overview of preparation, physicochemical, pharmacotechnical, and anticancer properties of 3D-printed mucoadhesive buccal films with apigenin. (**B**). Three-dimensional printed apigenin-loaded film—reproduction with permission from [143].

Using the LCD technique, Xu et al. [127] obtained 3D-printed bilayer mucoadhesive films for oral mucosal delivery of dexamethasone acetate (Figure 8).

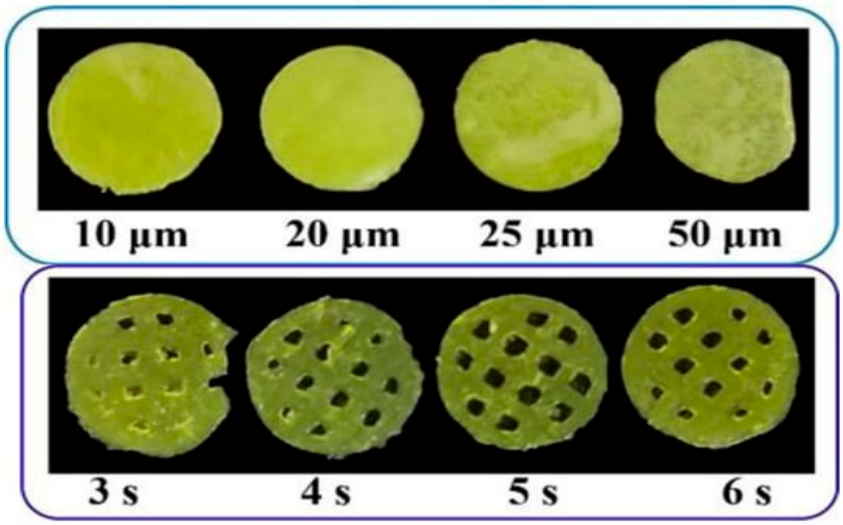


Figure 8. Three-dimensional printed bilayer oral films through the LCD method with different printing parameters: layer height (10–50 µm) and exposure time (3–6 s). Reproduction with permission from [127].

Moreover, the authors performed an in vivo evaluation of the 3D-printed oral film's effectiveness in treating oral ulcers.

It is important to note that 3D printing in oral films is still relatively new, and comprehensive quantitative data may be limited at this stage. Due to the early stage of development and the complexity of the 3D printing process, obtaining precise quantitative data regarding the advantages and limitations can be challenging. Researchers actively explore and refine these techniques, but extensive quantitative data may not be readily available.

It is worth mentioning that the advantages and limitations mentioned in the study are based on the existing literature, expert opinions, and observations from the field. While specific quantitative data may be scarce, these qualitative insights provide valuable information about the potential benefits and challenges of 3D printing in oral films. As the field continues to evolve, more quantitative studies are expected to be conducted, providing researchers with concrete data on the performance and characteristics of 3D-printed oral films. As technology matures, it will be possible to gather and present more robust quantitative data to support the advantages and limitations of these methods.

In conclusion, while the importance of quantitative data must be acknowledged, it must be emphasized that the current state limits the availability of extensive quantitative information.

6. Conclusions

The most recent advances in oral films, including formulation strategies using natural and synthetic polymers, fabrication technologies, and intensive studies regarding their optimization, represent substantial progress for their therapeutical applications. Three-dimensional printing tools are extensively used in the pharmaceutical field for personalized medicine for patients with special needs. Compared to conventional methods, 3D printing enables the development and production of complex oral adhesive films with complex shapes and functions. These techniques, unconstrained by batch manufacturing and the extensive pharmaceutical equipment required, have great potential to become the gold standard for research and development departments and patient-tailored medicine. They significantly increase manufacturing speed while improving cost efficiency. This way, significant and helpful changes in traditional drug formulations and manufacturing techniques will gradually occur, so corresponding official regulations and industrial applications can be expected.

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