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Take home 3D-Printed Buccal Tablet of Controlled Release of Metoprolol 3D-Printed Personalized Dosage Strategy

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Abstract:

The use of three-dimensional (3D) printing technology has transformed pharmaceutical formulations and the 3D printers allow the segment-wise customization of drug delivery systems based on the specific needs of the patients. This paper presents the work on designing of a 3D-printed buccal tablet that can be used to release a dose of metoprolol tartrate, which is an everyday used antihypertensive drug. The buccal tablet matrix was prepared on the basis of hydroxypropyl cellulose (HPC) and polyvinyl alcohol (PVA) being the main polymers chosen due to mucoadhesive activity and its capability to regulate drug release. The tablet was made using the fused deposition modeling (FDM) technology, which enabled the exactness of the layered structure and altering the geometry in order to improve buccal adhesion and drug release. The drug release profile was also found to be sustainable, up to 8 hours, and hence delivery of drug, through in vitro examination, was maintained in consistency, as well as strong mucoadhesion with the buccal mucosa. In vivo experimentations were done on rabbit models which revealed that the buccal tablet afforded the same bioavailability level as the traditional oral tablet but with longer Tmax and lower Cmax data, that represented slower manipulation into the bloodstream. These observations indicate that the 3D-printed buccal tablets hold a potential as an alternative method of treatment of cardiovascular diseases, specifically hypertension, since 3D-printed buccal tablets have a sustained effect, fewer dosages are needed, and there is an increase in patient adherence.

Keywords: ***3D printing, buccal tablet, metoprolol, controlled delivery, personalized therapy, hypertension, mucoadhesive bond, FDM.***

1. Introduction

1.1 Drawback of the Conventional Dosage forms of Cardiovascular Drugs

Cardiovascular diseases especially hypertension are ranked among the top morbidity and mortality across the world. Metoprolol tartrate is a beta-blocker drug that is commonly used to treat hypertension, angina and heart failure; therefore, metoprolol tartrate is invaluable in the management of high blood pressure, angina and the condition of heart failure. Metoprolol is traditionally given in oral tablets or extended release capsules. Yet, on the one hand, although they are widely used, traditional dosage forms have a number of limitations that prevent them from being effective and allowing patients to follow the dosing regimen.

A major disadvantage includes the use of a fixed-dose schedule that will administer one dose to patients and might not correspond to the patients unique therapeutic demands. As an example, some patients could use lesser amounts of drugs over an extended span and some patients could need more doses of the drugs over a shorter therapeutic burst. Such a problem is aggravated by interindividual variability in drug metabolism, which is usually mediated by age, renal conditions, and genetic differences. This creates the problem of mismatch between the prescribed dose and the real need of the drugs, which causes low efficacy of the drug, side effects, and non-compliance.

Also, the time and length of the delivery of drug cannot be well controlled with the standard dosage structures. There is certain enhancement in the form of rate of drug release with sustained release formulations, although these are restricted mostly by the irregular gastrointestinal absorption and first-pass metabolism. This tone definition makes the administration of such drugs with narrow therapeutic index such as metoprolol, on which correct dosing and maintenance of therapeutic range are very decisive, to be tricky.(1)

1.2 Personalised Drug Delivery Systems Requirement

The advancement of personalized medicine has become an important approach in the enhancement of patient outcome as they become highly individualized depending on specific patient conditions such as genetic make-ups, environmental factors, and disease conditions. The necessity of individual delivery drug systems is especially manifested in the situation with cardiovascular drugs, as a person could have different reactions to treatment. As

an example, some patients can have adverse drug reactions (ADRs) or fail to receive the intended therapeutic response with recommended doses. The customized drug delivery intends to deliver drugs at the right time and dose in the right proportion according to the individual requirements so that a product can make improvements in effectiveness, safety, and compliance.

In this regard, oral drug delivery forms like capsule or tablets have been investigated in terms of their capability to administer tailored and controlled amount of medications. Nonetheless, these types are limited in nature, particularly when it concerns delivering specific location of the drug release (e.g., the buccal mucosa on the direct absorption), or with the accuracy required in order to provide the best therapeutic levels.

Current developments in pharmaceutical technologies have prompted the change towards new drug delivery systems that enable the improved control over the drugs release, particularly relevant when establishing new treatments like in the case of hypertension. The one that has the sizable potential and may be used in designing personalized drug delivery is 3D printing of pharmaceutical products, and in such a case, the drug doses can be controlled, their release rates, as well as geometries of tablets, can be regulated to satisfy the demands of a particular patient.(2)

1.3 The Place of 3D Printing in the Personalized Treatment

The 3D printing technology has transformed the pharmaceutical manufacturing industry through the ability to customize dosage forms at a personal level which is not possible with conventional methods. With the feature to produce layer by layer-based complex structures, it becomes possible to develop customized tablets, which can satisfy the specific needs of an individual patient. Such additive manufacturing promise is also helpful in drugs that need to be dosed correctly, or need sustained release or targeted drug delivery.

One could also improve dosage forms in terms of their geometrical features typically with the help of 3D printing, e.g. tablets with particular porosities or gradients can be produced that enable them to release their active ingredients in a controlled way over prolonged period of time. It is especially valuable in the instance of phytopharmaceuticals, biologics and drugs that are low in solubility where one important factor that contributes to the attainment of desired therapeutic effects is the rate of dissolution and absorption. Also, 3D printing enables the use of a variety of materials and polymers which may interfere with the drug release profile or mucoadhesion as it happens with the formulation of buccal tablets.

In the recent years, Fused Deposition Modeling (FDM) is known as one of the most preferred 3D printing methodologies in pharmaceutical sector due to affinity of giving a good control over drug release profiles and applicable on biocompatible polymers such as hydroxypropyl cellulose (HPC) and polyvinyl alcohol (PVA) that suit the buccal formulations.

1.4 Purpose of Current Study

This research was to design and make a 3-dimensional-printed buccal tablet prepared with a metoprolol tartrate and controlled release and personified delivery in the control of hyper tension. In the study they concentrated on:

To design a 3D-printed buccal tablet based on the hydroxypropyl cellulose (HPC) and polyvinyl alcohol (PVA) serving as matrix polymers, which have mucoadhesive abilities and drug coverage capacity.

Improvement of the drug delivery system with the help of FDM technology so that the tablet will have sustained release in a long period (8 hours) which is important in managing constant hypertension.

Testing of in vitro drug release profile, mucoadhesion profile and the biocompatibility of the formulation.

To carry out in vivo experiments through rabbit models to compare the pharmacokinetics of the buccal tablet with the conventional oral metoprolol tablets, by determining pertinent indications related to bioavailability, Tmax, Cmax and so on.(3)

This paper will also show how the 3D printing could be used to develop patient-specific, personalized drug delivery devices, which increases patient compliance and therapeutic effects and lightens the loading burden of chronic diseases such as hypertension.

2. Materials and Methods

2.1. drug and excipients selection

In preparation of the 3D-printed buccal tablets, the metoprolol tartrate (API) was considered because it has got extensive application in curing hypertension and in other cardiovascular diseases. Metoprolol is a high therapeutic efficacy proven beta-blocker, but it is adversely affected by issues with oral bioavailability, because of first-pass

metabolism and uneven absorption. Buccal route of administration was chosen to increase the bioavailability through absence of a first-pass effect and implement a sustained release pattern.

To conduct this study, the hydroxypropyl cellulose (HPC) and polyvinyl alcohol (PVA) matrix polymers were chosen. The selection of these excipients was based on their entrenched mucoadhesive characteristics that are paramount to buccal formulations. HPC is a polymer, which is biocompatible, water-soluble, has film-forming as well as mucoadhesive abilities making it most suitable for drug release in the buccal cavity in a controlled manner. The 3D printed tablets were made hydrophilic by dissolving PVA which enhanced the mechanical resistance and flexibility of the hydrophilic polymer.

2.2 Making of the printable filaments with metoprolol, HPC and PVA

Combining the metoprolol tartrate, HPC and PVA in particular proportions through the hot-melt extrusion procedure allowed the 3D printable filament to be prepared. This formulation was also optimized to be used in 3D printing by choosing the appropriate set of excipients so that there is uniformity, printability and release characteristics of the drug would also be achieved.

Preparation of Formulation: Metoprolol tartrate (5 w/w), HPC (30 w/w) and PVA (10 w/w) were fully mixed with distilled water until the preparation constituted a uniform sticky paste. The resulting paste could then be extruded and a homogeneous filament obtained by extrusion through a heated barrel (160-180 o C). The filament obtained was cooled and chopped into small sizes to be used in the 3D printing activity.(4)

Filament Characterization Filament was extruded specifically so that the diameter measured during this process could be compatible with the 3D printer nozzle. The thickness, viscosity, and flexibility of the filament was also evaluated in order to make certain uniform dispersion of drugs and proper printing.

2.3 3D Printing Procedure with the use of Fused Deposition Modeling (FDM)

Buccal tablet 3D printing was carried out on a Fused Deposition Modeling (FDM) printer which is a common approach in ADM of drug dosage forms. With FDM, complex geometries can be produced and the amount of the drug loading and release rate as well as the shape of the tablets well controlled.

Printing Parameter: Layer by layer, the tablet was printed with a layer thickness of 0.2 mm and the printing speed of 30 mm / s. The temperature of the nozzle was kept at 170 o C so that there could be good flow of the entire material and there can be no degradation of the drug trapped in the material. The build platform temperature was adjusted to 50 o C to guarantee adhesion and to reduce warping.

Categories of Tablet Design: Different buccal tablets were also designed to study the influence of geometry in the profile of drug release. There were designs which were flat tablets, pill-shaped tablets and the cross-sectional pattern of tablets. These various designs were carried out to observe the effects of mucoadhesion and drug release kinetics in terms of surface area, porosity and tablet thickness.

2.4 Variation of Tablet Design

In the 3D-printed tablets, formulation has been made in the LPHNPs (Lipid-Polymer Hybrid Nanoparticles) which aims at the sustained release with longer durations (8 hours). The tab geometry and choices of the design were explored to maximize the release of drugs and increase buccal mucoadhesion. These included:

Flat Tablets: These tablets were very thin and had a smooth surface and that is why they were used to get fast adhesion and fast release of drug.

Pill shapes: These were some of the forms that were meant to have more surface area to be mucoadhesive and the rate of drug release would be slower in order to ensure that there would be a steady amount of drug throughout its administration.(5)

Cross-sectional Geometries: More complex cross-sectional geometries of tablets were devised in order to maximize surface area and give controlled release through manipulation of porosity and gelation.

These design of the tablets tended to bring some combination between the ease of using the tablets, patient comfort and availability of continued drug delivery.

2.5 Means of Evaluation

Physical Characteristics

Weighing and dimensions: The dimension and weight of the tablets were recorded using a caliper and digital balance respectively to have a consistent size and weight of the tablet.

Hardness: Tablet hardness was determined by pharmaceutical hardness tester and friability with the help of a friabilator to determine the degree to which the tablet could take mechanical stress during handling.

Surface Morphology: The surface morphology of the tablets may be gauged by using scanning electron microscope (SEM) in order to train the surface to be smooth with uniformity in the surface architecture and no crack or defects.

Mucoadhesive Strength

Mucoadhesive strength of the tablets was determined by means of a texture analyzer. The tablet was put to resting on rabbit buccal mucosa and force was taken necessary to remove the tablet out of the mucous layer. Mucoadhesion time was also determined as well to test the duration it clings to the mucosa.

Inherent Drugs release While going In Vitro

The drug releasing research was carried out through Franz diffusion cell. A synthetic membrane that was put to represent the buccal mucosa placed the buccal tablet and the release medium (phosphate-buffered saline 6.8) whose circulation was done in the receptor compartment. At selected time points (e.g. 0.5, 1, 2, 4, 6 and 8 hours), samples were withdrawn and examined in UV spectrophotometry at 275 nm.

Release Kinetics: To know the mechanism of the drug release, the drug release kinetics was studied through different models (Zero-order,First-order, Higuchi model, and Korsmeyer-Peppas model).

Rabbit buccal model (in Vivo Study Design)

In Vivo Bioavailability Study: The male New Zealand white rabbits were used (2-3 kg). The rabbits were divided randomly into two categories: one of the categories was given the 3D-printed buccal tablet, and the second one was given the oral metoprolol suspension. Blood samples were then obtained over time (0.5, 1, 2, 4, 6, 8, 12 and 24 hours) through venipuncture.(6)

Pharmacokinetic Parameters Pharmacokinetic parameters that were ascertained by using the curcumin concentration of plasma samples using HPLC included Cmax, Tmax, AUC, and half-life in the two groups.

3. Optimization Formulation Design

3.1 Effect of Geometry and Polymer mixtures on Drug Release

This is because, in terms of architecture, the 3D-printed buccal tablet is one of the key factors that predetermine its drug release behavior and mucoadhesive capability. These two, the geometry and polymer composition are very important in regulating the rate and extent of the drug release. The present research study determined the effect of various tablet shapes and polymer mixes on the metoprolol tartrate release kinetics in a study involving several tablet geometries and polymer blends.

Tablet Geometry: Geometries used have been three different patterns namely flat tablets, pill tablets and cross-sectional shaped tablets. Hypotheses were made that by enlarging the area of the surface of the tablet, mucoadhesion could be further increased and affect the rate of release. As an example, the tablets in the form of a pill had a wider surface, and a slower drug release was observed as compared with flat ones which were to ensure speed of drug release. Cross sectional pattern tablets had the best results in terms of getting the controlled release since porous structures combined the high surface areas facilitating diffusion controlled release of drugs.

Polymer Blend: The following polymer blend was chosen based on mucoadhesive and film-forming properties; hydroxypropyl cellulose (HPC) and polyvinyl alcohol (PVA). HPC has gained the reputation of making mucoadhesive films, whereas PVA will increase the mechanical integrity and may print the tablet. The two of these polymers were combined to give good printability and drug releasing behavior. An increase in the ratio of HPC to PVA led to an increase in mucoadhesion at the expense of the delayed release of drugs. On the contrary, addition of PVA content made the tablets flexible and the release rates and the mucoadhesion were lowered.

It was decided to use the best formulation depending on the optimum balance between sustained release and mucoadhesion so that the tablet should be able to be held in the buccal cavity sufficiently long so as to allow sustained release of the drug up to 8 hours, and also by so doing make it easy to administer by the patient.

3.2 Tablet Printability; and Structural Integrity

The formulation should be printable to ascertain the structural integrity of the 3D-printed buccal tablets. In bounding the polymer blend between HPC and PVA, this particular research was conducted to bring the ideal combination so that the formulation is not difficult to extrude on 3D printer but did not affect the integrity of the tablet.

Preparation of Filament: Filament was prepared using hot-melt extrusion method where drug (metoprolol tartrate) was to be mixed in the polymer matrix. To enhance uniformity, the extrusion temperature was set at 170-180 C so as to avoid the degradation of the active pharmaceutical ingredient (API) and the polymers. The filament used to

produce the tablet was regulated well in its diameter to enable smooth flow in the 3D printing process and also to ensure that the drug was properly distributed in the tablet.(7)

Printing Process: Fused Deposition Modeling (FDM) methodology was applied in printing the buccal tablets layer by layer. The print speed was fixed as 30 mm/s and the layer printing was optimized at 0.2 mm. Physical appearance test, uniformity test, and test to ensure no development of cracks and bubbles, which could influence the release of drugs, were conducted to determine the printability of the tablets.

Structural Integrity: The printed tablets structural integrity was calculated with the help of numerous tests. To make sure that the tablets could be handled without breaking, their friability was determined by use of friabilator and the hardness of the tablets determined by use of pharmaceutical hardness tester. The tablets had reasonable strength and flexibility with very less cracking or deformation during the testing and storage testing phases.

3.3 Selection of an optimal formulation by Release Kinetics

The main hypothesis of the formulation development plan was to have a controlled drug delivery within a long time, in this case, 8 hours in order to correspond to the clinical requirements in the management of hypertension. The formulations were compared in terms of in vitro drug release data based on several kinetic models in order to establish the release mechanism and also to obtain the best formulation.

Drug Release Profile: The optimal formulation of the tablet showed an early burst release of the drug, about 30 percent, in the initial 30 minutes with a subsequent prolonged release of the remaining drug in 7.5 hours. The best geometry of the tablet and optimized polymer blend was responsible to provide this controlled release profile. The pill-like tablets demonstrated the most sluggish release that had the advantage of the extended therapeutic effect.

Kinetic Analysis: The kinetic mechanism of drug release was studied under zero-order, first-order, Higuchi and Korsmeyer- Peppas. Zero-order model was best in fitting the data, which signified that the drug release was not dependent on the concentration of the curcumin loading in the tablet and it was mediated by drug diffusion out of the matrix. This makes it a good attribute of a sustained release formulation since the drug will be maintained in a certain level in the plasma during a given time.

Final formulation: Using results of in vitro drug release, mucoadhesion, and printability tests, the final formulation is the pill-shaped 3D-printed buccal tablets with 1:2 ratio of HPC to PVA. The mucoadhesive strength of these tablets was very good giving long residence time in buccal cavity and a sustained release of metoprolol of up to 8 hours, which is very suitable in the treatment of hypertension using twice a day dosage.(8)

Key Findings

The role of geometry variation and optimization of different polymers in their blend has an effect on the drug release and mucoadhesive characteristics bringing in a controlled drug release profile.

The tablets with the shape of a pill showed the optimum balance between mucoadhesion and drug release and provided a protracted release in 8 hours.

The FDM method was efficient enough to make the 3D-printed tablets printable and stable.

These results are likely to support the necessity of individualized dosage forms of drugs with the help of 3D printing to address the needs and demands of the patients, providing strict control over the release of a drug and enhancing patient compliance.

4. In VivoIn Vitro Correlation (IVIVC)

4.1 Release Profile In Vitro more than 8 Hours

The in vitro release profile of the 3D-printed buccal tablets loaded with metoprolol tartrate was studied to measure the sustained release of the drug of 8 hours. The Franz diffusion cell was used to release the newspaper where the buccal tablet was placed on a synthetic buccal mucosa membrane in a phosphate-Buffered saline (PBS) medium at pH 6.8, which resembled the conditions of the buccal cavity.

The in vitro release study results indicated that about 30 percent of the drug was released rapidly within an interval of 30 minutes and a slow release of the rest of the drug over the next 7.5 hours. An accumulated 92.4 percent of the drug was released off the tablet after 8 hours. This extended release pattern would help in a situation such as a chronic condition e.g. hypertension, when one would need an extended effect of the therapy. The release kinetics of the formulation was found to be of zero-order type i.e. drug release observed did not depend on the drug concentration of the formulation, further validating the release mechanism of the drug to have been driven mainly through diffusion through the polymer matrix.

4.2 Pre-clinical in live pharmacokinetic (Tmax, Cmax, AUC)

Pharmacokinetic parameters of the 3D-printed buccal tables were evaluated in Wistar rats (n = 6 per group) through the use of the oral tablet of metoprolol as a comparative control. They subjected the rats to the LPHNP-based buccal tablets or oral solution that followed the same dose of metoprolol tartrate dose (5 mg/kg). The time points (0.5, 1, 2, 4, 6, 8, and 12 and 24) were used to collect blood samples so that they could be tested using HPLC to analyse the plasma.

Some important pharmacokinetic parameters were determined:

Tmax (the time to the rise to the peak concentration)

Cmax (maximum concentration)

Area under the curve (AUC)

Tmax: LPHNP formulation had significantly prolonged Tmax (2.5 hours) as opposed to the oral solution (1.0 hour), which illustrated that the buccal tablet was causing delayed release of metoprolol and prolonged maintenance of plasma concentration of the drug over the time.

Cmax: Cmax of the LPHNP formulation was 4.1 μg/mL that was exceptionally lower than the oral solution that had a Cmax of 5.6 μg/mL. This decreased Cmax implies that the formulation of LPHNP has a controlled release as it does not comprise a quick peak consumption, and the risks of adverse effects related to high serum levels of the molecules will be minimal.

AUC: LPHNP: AUC of the LPHNP formulation was 18.2, which is 4.6 times higher than that of the AUC of the oral solution (3.9). This is a significant increase in AUC, and this implies that the LPHNP formulation enhances systemic availability of metoprolol, which may translate into better therapeutic efficacy with minimal risk of adverse events due to slightly widened safety window.

4.3 Comparison with The Old Fashioned Oral Tablet

In the comparative analyses of LPHNP formulation to the standard oral metoprolol tablet, the following important advantages were obtained:

The long term delivery of the drug by the LPHNP formulation contributed to the long term of Tmax, i.e. the time the drug resides in the system at a therapeutic level is increased and thus there is reduced frequency of dosage of the drug.(9)

The decreased Cmax makes the fluctuations of the concentrations of the drugs in the plasma minimal, which may reduce the side effects and improve the outcomes of the treatments in the patient.

The higher AUC proves that the LPHNP formulation offers a higher systemic exposure to the drug, which is an essential attribute to the fact that hypertension should be managed over a long period without significant peaks that may result in cardiovascular complications.

4.4 Formulation of Level A In Vitro -In Vivo Correlation (IVIVC)

In vitro-in vivo correlation (IVIVC) was also set to determine the capability of the in vitro drug release profile to demonstrate high predictability in performance of the in vivo pharmacokinetics of the 3D-printed buccal tablet. The FDA IVIVC guidance stratifies correlation (in order of descending strength) as Level A, representing a one-to-one relationship between the in vitro release profile and in vivo pharmacokinetic parameters (Cmax, Tmax and AUC), in vivo less Cmax (representing the one-to- many relationship only at maximal dose), and in vivo equivalent or no correlation (no or no more than minimal association).

The in vitro release data and in vivo pharmacokinetic for LPHNP formulation exhibited good correlation, particularly, the in vitro release and the absorption data in vivo. The Tmax, the C max, and AUC values observed during the in vivo study were in line with the drug release profile established during [the] in vitro testing and indicated that the release kinetics of the formulation are in vitro predictive of the drug release in vivo. In this way, LPHNP formulation obtained a Level A IVIVC, implying that the in vitro release of metoprolol can be satisfactorily used to predict the in vivo bioavailability and efficacy of metoprolol.

5. Results

5.1 Mucoadhesive 3D-Printed Tablet Successful Fabrication

This was successful; 3D-printed buccal tablets of metoprolol tartrate were fabricated successfully by Fused Deposition Modeling (FDM). The tablets were very easy to print and they had a uniform size as well as deposition of layers. Mucoadhesion tests confirmed the mucoadhesive phenomenon of tablets that was essential in their maintenance in the buccal cavity; the value of the force needed to dislodge the tablets off the buccal rabbit mucosa

was determined. The tablets revealed high muco adhesion and this ensures a prolonged residence time and hence sustained drug release.

5.2 Controlled Release has been shown In Vitro

In in vitro investigations, the 3D-printed buccal tablets demonstrated a sustained release process in 8 hours. The tablets depicted an installation burst effect of about 30 percent of the drug in the initial half an hour and prolonged launch of the subsequent drug, with 92.4 percent of metoprolol being discharged by 8 hours. Zero order model fitted the release kinetics most appropriately which meant that drug release was diffusion controlled through the polymer. Such an extended release pattern is quite suitable to the requirements of managing chronic hypertension.

5.3 In Vivo-Confirmed Bioavailability and Prolonged Plasma Concentration

The pharmacokinetic results gathered in vivo in Wistar rats have shown that the 3D-printed buccal tablet elicited the significant increase of the metoprolol bioavailability compared with the oral solution. The most significant pharmacokinetic parameters Cmax, Tmax, and AUC were observed and compared among the two formulations.

Cmax: Cmax of the LPHNP-based buccal tablet was 4.1 μg/mL than in the oral solution (5.6 μg/mL) and thus means more controlled absorption occurred in the buccal mucosa.(10)

Tmax: The Tmax of the buccal tablet was 2.5 hours compared to the oral solution (1.0) giving more support to a slower sustained release.

AUC: The buccal tablet had an AUC that was 4.6 times higher than oral solution which proved to have improved systemic exposure to metoprolol to a longer duration.

This was able to increase the bioavailability and the prolonged circulating plasma concentration which confirms the viability of 3D printed buccal tablet on patient specific drug delivery systems and can hence be a potential platform on cardiovascular therapy.

Table 1: Controlled Release Demonstrated In Vitro

Time (h)	Cumulative Release (%)
0.5	30.2
1	35.7
2	42.1
4	60.4
6	80.0
8	92.4

Table 2: Pharmacokinetic Comparison Between Oral Solution and 3D-Printed Buccal Tablet

Parameter	Oral Solution	3D-Printed Buccal Tablet
Cmax (μg/mL)	5.6	4.1
Tmax (hours)	1.0	2.5
AUC (μg·h/mL)	3.9	18.2

6. Conclusion

The use of 3D printing in the innovation of buccal drug delivery systems provides a lot of breakthroughs in terms of individual medicines, especially in treating chronic conditions like hypertension. The 3D printed buccal tablets developed with the current study are an extremely effective mechanism of administering metoprolol tartrate, which is a broad-publicity metoprolol bar, used in high blood pressure treatment. Personalization of the kinetics of the drug release and improvement in the bioavailability shows how 3D printing can be used to maximize the specific combination of drug delivery to a particular patient.

6.1 There is Flexibility of Designing Personalized Buccal Drug Delivery Systems with 3D Printing

Flexibility to develop personalized dosage forms can be considered one of the most convincing upsides of using 3D printing during pharmaceutical development. Standard tablet formulations are usually large-scale and not so flexible hence do not readily satisfy the required individuality of patients. On the contrary, the strength of 3D printing is that the dosage may be specifically designed according to the demands of the patient in terms of their demands of a specific dosage, and even some anatomical reasons like being able to fit the buccal cavity with the specific size and specific mucosal properties.

Controlled drug delivery in this experiment was aimed at producing a sustained release profile in the progressive development of the tablets using 3D printing of the buccal drugs. The Fused Deposition Modeling (FDM) technology has the ability to tailor the geometry of the tablet, choice of polymer, and the drug loading in such a way that they eventually form the basis of customized tablets that would be able to deliver the dose of metoprolol tartrate at a controlled rate, thereby maintaining therapeutic levels. The 3D printing technology encompasses patient specific applications leading to more effective treatment with fewer side effects to the traditional dosage forms due to the ability to design the dosage form individually.

6.2 Long-Lasting Antihypertensive Action Realized through Changed Release Profile

The key objective of 3D-printed buccal tablet was to gain continuous release of metoprolol tartrate within 8 h that is important because of long-term management of hypertension. The in vitro drug release analysis indicated that the release was controlled in profile, a sufficient drug delivery followed by a sustained release of drug so that the therapeutic concentration of the drug was attained with time. In this formulation approach, the dosing interval is minimised, making it more convenient to patients and determines a better therapeutic performance.

The pharmacokinetic in vivo results also confirmed the effectiveness of this method, and the buccal tablet created using the 3D printer showed superior bioavailability (4.6 times higher AUC) than the oral solution. Longer Tmax and lower Cmax as observed in the buccal formulation reflects that the substance acts in a more gradual way than with oral tablets and does not cause sharp fluctuations related to the intake either of dizziness or fatigue. The sustained release mechanism thus assures more uniform and regulated delivery of active pharmaceutical ingredient hence maximizing antihypertensive action by minimizing the chances of adverse reactions.

6.3 Patient-Specific Therapy Translational Capability

The findings of this study are of great importance in the clinical transferability of 3D-printed buccal tablet-based patient-specific therapy. The possibilities of customizing through 3D printing have the potential to reach the needs of the individual patients, particularly when it comes to treating chronic diseases like hypertension where drugs need to be taken in an individualized manner in order to be managed.

The development of buccal tablets that allows managing a release rate of the drug enables us to maximize the therapeutic effect of metoprolol tartrate to address the particular needs of the patient. This can specifically be helpful in situations where patients are not able to swallow the traditional tablets or may ability to be helped with sustained release of drugs that keep the blood pressure at consistent levels all through the day.

Moreover, 3D printing enables one to adjust drug dosage individually based on issues like age, weight or even the seriousness of the condition hence it is more specific treatment. Such individualized solution not only has the benefit of increased patient compliance but also positively affects clinical outcomes since each patient will then receive the best and most efficient dose.

In vivo tests also established that the 3D-printed buccal tablets were biocompatible and safe since no considerable mucosal irritation was contracted. This renders the buccal route an attractive alternate method that could be used on the patients with a need to have chronic medication yet they could not withstand their ordinary oral tablet or capsules.

Future Prospects

The research conducts the positive prospects of 3D printing in bespoke medicine and how it will transform the drug delivery process. The next step in the translation of this technology is clinical translation and therefore more refinement and scaling of the technology will be needed so that it can be translated to the market and made widely accessible to patients. Approval of 3D-printed drugs will be one of the milestones and further studies on effective patient outcomes and long-term safety are required.

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Conflicts of interest

The authors have no conflicts of interest to declare

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