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Recent advances in Mucoadhesive Oral Suspensions: Design Principles, In-vitro Assessment, and Clinical Potential

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Abstract

Mucoadhesive oral suspensions are novel approach to overcome the limitations of traditional oral drug delivery system including rapid salivary washout, enzymatic degradation, low solubility, and extensive first pass metabolism. These formulations significantly expand mucosal residence time, increase local and systemic absorption, by forming strong interactions between therapeutic polymers and mucin glycoproteins, and hence increase the overall therapeutic efficacy. The basic design parameters in these systems include the rational choice of mucoadhesive polymers, the ability to control viscosity, tuning of drug polymer compatibility, particle size, and fining of pH, ionic balance, and diffusion, erosion, and swelling based release. Evaluation methods based on in vitro studies such as mucoadhesive strength tests, detachment force tests, plate methods of Wilhelmy, wash off tests, ex vivo residence tests, and the overall stability profiling give predictive indication of the desired behavior of such suspensions in-vivo. The recent developments in the discipline, including the introduction of nanoparticles of systems, combo systems of polymer, hybrid suspension gel technologies and 3D print constructions highlight the growing versatility and predictivity of these delivery modes, culminating in an anticipated pivotal role in future accurate oral therapeutics.

Keywords: Mucoadhesive Suspensions; Oral Drug Delivery; Controlled Release

Introduction

Oral drug delivery system is a widely preferred route of drug delivery, due to its convenience, safety, and the ability to be mixed with a wide range of pharmaceuticals. However, traditional oral dosing types are often faced with rapid elimination from the oral cavity, enzymatic degradation as well as extreme first pass metabolism, which reduces systemic drug exposure and efficacy [1]. These restrictions are especially high when it comes to agents with disproportionate aqueous solubility, limited physicochemical stability, and narrow windows of absorption; hence, there is a need for innovative delivery technologies [2].

Mucoadhesive drug delivery systems have gained importance as an alternative to overcome these barriers by increasing the residence time of the formulation on the mucosal surface. The process of mucoadhesion is mediated by continuous interactions between the selective polymers and mucin glycoproteins, such as hydrogen bonding, electrostatic attraction, van der Waals interaction, and physical interpenetration of polymer chains. Such interactions impart resistance to salivary washout and mouth motility, thus maintaining the balance of the drug in the target locality and appropriate systems to promote triumphant absorption [3, 4].

Mucoadhesive drug delivery systems have been identified as a systematic topical approach to reducing the level of physiological barriers by increasing the residence time of therapeutic formulations at the interfaces of the mucosal surface. Mucoadhesion is also a phenomenon that is based on a series of physicochemical interactions between the designed polymeric matrices and the mucin glycoproteins and the physical interpenetration of polymer strands. The effects of these complex interactions include protection against salivary clearance and oral motility, which, in turn, prolongs the presence of the drug in the target membrane and allows the development of augmented absorption in the suitable mucosal environment [5-7].

Mucoadhesive drug delivery systems have become a novel method to overcome these physiological barriers by increasing the period of interaction between the formulation and the mucosal surface. Mucoadhesion between polymers and mucin glycoproteins is achieved by interactions between certain polymers and the glycoproteins of mucin. These interactions assist the mucosal delivery to counter the salivary washout and oral motions to achieve prolonged drug residence in the site of application and, if required, increased the systemic absorption [8-10]. Mucoadhesive oral suspensions provide a versatile and patient friendly drug delivery system that can be used to deliver hydrophilic and hydrophobic medications. This preparation involves being easily swallowed, its applicability to both geriatrics and pediatrics, and the ability to offer controlled release of drug [11-13]. Additionally, by using mucoadhesive polymers that are incorporated into suspensions, it is possible to protect the thermolabile drugs, deliver them to the oral cavity and have a better therapeutic result whether it is local or systemic therapy [14, 15].

The recent developments in the polymers and formulation science have resulted in the production of suspensions that have superior stability, lower viscosity and better adhesive capabilities. These inventions have increased their clinical application, especially in the treatment of oral lesions, infections, inflammation, and administration of drugs that are vulnerable to first pass metabolism. However, there are still problems of tradeoffs between viscosity and palatability, consistent dispersion of drugs, and inconsistency in mucosal adhesion. These limitations can be overcome by a thorough investigation of polymer mucin interactions and reliable in vitro assessment strategies [16-18]. This review provides a complex set of designing principles, in vitro evaluation methods, and clinical prospects of the mucoadhesive oral suspensions with specific attention given to the latest scientific developments that have highlighted their increasing applicability in oral drug delivery [19].

Mechanism of Mucoadhesion

Mucoadhesion is the property of a substance, the ability of drug substance to attached to the mucosal surface over a long duration. The process is usually taken through two main stages, which are the wetting and contact process followed by the interpenetration and consolidation stage. First stage includes, the mucoadhesive polymer is hydrated under saliva and allows the close contact with the mucosal surface [20-22]. This wetting enables the polymer chains to disperse and align them in such a way that they get the most contact with the mucin network. Polymer flexibility, molecular weight, and surface energy are among some of the factors that play a major role in determining the level of wetting and surface interaction. At this phase, physical forces like van der Waals forces and hydrogen

bonding starts to become adhesive [23-25].

The second phase involves, the interpenetration and consolidation, is whereby the polymer chains are diffused into the network of glycoprotein mucin of the mucosal surface. This entanglement provides a well developed interlocking mechanism that is reinforced by other forces such as hydrogen bonding, electrostatic forces and hydrophobic interactions. The intensity and length of time of mucoadhesion is determined by the length of the polymer chain, the density of cross linking, and the concentration of active groups that can be bonded with mucin. The adhesion process is also influenced by the environmental factors, including pH, ionic strength and the turnover rate of the mucus layer. This is because knowledge on these mechanisms will help in optimizing mucoadhesive formulation to attain longer drug retention, slower release and enhanced therapeutic effect [26]. The figure.1 depicts the mechanism of mucoadhesion in a visual manner.

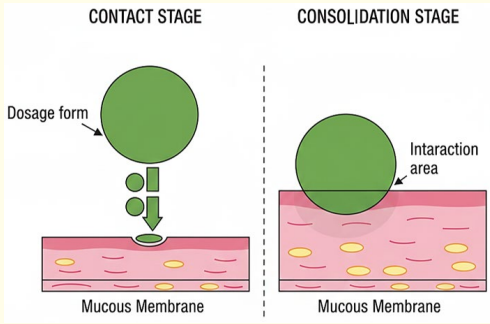

Figure 1: Mechanism of Mucoadhesion.

Design Principles of Mucoadhesive Oral Suspensions

Mucoadhesive oral suspensions are advanced types of drug delivery systems that are designed to increase the time of retention of drug in the oral cavity to increase therapeutic efficacy by the local absorption or systemic absorption. The figure.2 shows the overview of design principles involved in the mucoadhesive oral suspension. Physicochemical, biological and formulation related parameters have to be taken into serious consideration to aid the design of these systems to facilitate optimum adhesion, stability, and drug release [27].

Selection of Drug Candidate

The selection of polymer is one of the underlying factors in the development of an effective mucoadhesive oral suspension. Polymers should form a strong binding with mucin layer of the oral mucosa by hydrogen, electrostatic bond, or van der Waals force. Polymers that are frequently used are Natural Polymers includes, the chitosan, alginate, pectin and guar gum are naturally biocompatible, biodegradable, and strong mucoadhesive polymers [28]. The Synthetic Polymers includes, Carbopol, polycarbophil, hydroxypropyl methylcellulose (HPMC), and polyvinyl alcohol offer controlled viscosity and reproducible adhesive characteristics. The functional groups, concentration and the molecular weight of the polymer play a profound impact on the strength as well as the time of adhesion. These parameters need to be well balanced in of practice and this yields the desired therapeutic outcome.

Viscosity Optimization

Viscosity is a determining factor in the development of mucoadhesive suspension. Mucosal retention can be enhanced by high viscosity, counteracting clearance by the salivary flow, but resisting patient acceptability by giving an unpleasant mouthfeel or difficult to swallow the suspension [29]. Low viscosity preparations on the other hand, are easily washed out thus minimizing contact time with

the mucosa. As a result, the recommended balance between the adhesive strength and rheological properties is essential to make the desired pharmaceutical product.

Drug-Polymer Compatibility

The stability, bioavailability as well as sustained release is based on chemical as well as physical compatibility between the drug and polymer. In preformulation investigations, the use of analytical methods like Fourier-transform infrared spectroscopy (FTIR) or differential scanning calorimetry (DSC) tends to be frequently applied in order to discover potential interaction effects between drugs and polymers, which might pose a risk to therapeutic activity [30, 31].

Particle Size and Surface Area

The size of drug particles that have a direct influence on the suspension stability, rate of sedimentation and the mucoadhesive performance. Smaller size particles give more surface area upon which the polymer and mucosal layer interactions which improves adhesion and release control [32, 33]. However, particles that are overly fine will pull out aggregation or sedimentation issues, and thus resolve the integration of appropriately chosen suspending agents.

pH and Ionic Strength

The aqueous suspension should have a pH in the physiological range of the oral cavity (typically pH 6.2-7.4) to exclude mucosal irritation as well as maintain the functionality of the polymeric network. Besides, polymer swelling kinetics and mucoadhesive processes are regulated by the ionic strength of a specific medium; in particular, the divalent cations can be used to strengthen the viscoelastic properties of the alginate-based gels [34].

Drug Release Mechanisms

Mucoadhesive suspensions are designed to provide regulated or prolonged effects of drugs at the point of delivery. The main modes of release include Diffusion-controlled release, this process involves the drug permeating the polymer matrix, Erosion-controlled release, where the polymer is dissolved gradually releasing the medicament contained within; Swelling-controlled release; where the polymer swells as it comes in contact with the saliva allowing slow diffusion of the drug inside the polymer. The pharmacokinetic profile can be customized by combining these mechanisms, results in the targeted therapeutic effects [35].

Stability Considerations

Stability of mucoadhesive suspensions on long-term basis is a critical issue, since it incorporates the chemical stability of the active drug ingredient as well as the physical stability of the colloidal suspension. The critical attributes such as sedimentation, flocculation, microbial growth and viscosity changes should be as much as possible diminished. Based on this, judicious use of suitable preservation agents, careful modification of the pH and additions of rheological modifiers are common in achieving product shelf-life and uniform performance [36, 37].

Palatability and Patient Acceptability

Since oral suspensions have to be administered directly into the mouth, sensory properties such as taste masking, flavouring agents and judicious use of the colorants have a decisive role in influencing patient compliance. As a result, the formulation should be organoleptically palatable and at the same time maintain the mucoadhesive qualities and the drug release kinetics which form the basis of therapeutic activity [38].

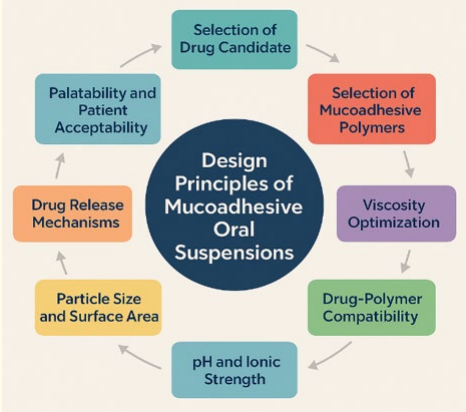

Figure 2: Overview of Design Principles of Mucoadhesion Oral Suspensions.

In-vitro Assessment of Mucoadhesive Oral Suspensions

Invitro assessment of mucoadhesive oral suspensions is a process that focuses on systematic testing of the mucoadhesive strength, in which detachment force testing, or mucoadhesive strength testing are most frequently used to determine the complex interaction process of polymers with mucin, which forms the basis of adhesive behavior. At the same time, microscopic analyses of viscosity, particle size distribution and zeta potential are conducted in order to explain the suspension stability and retention in simulated oral conditions. Complementary drug release studies, executed by using simulated diffusion systems or simulated saliva, provide information on release kinetics that cannot be predicted correctly without providing insights on complementary in vivo performance. Collectively, these parameters create an inclusive structure, which has optimizing adhesion effects, pits the formulation as well as strengthening the therapeutic effectiveness before the clinical review [39, 40].

Mucoadhesive Strength Evaluation

Mucoadhesive strength is a crucial area of determining the degree of the interaction between the formulation and the mucosal surfaces hence predicting the ability of the suspension to be confined in the oral cavity. This test is used to measure the force of detachment, adhesion work and bonding forces through the use of a mucin or other biological relevant substrate [41]. It is a measure of interpenetration of polymer chains and their behavior under hydration, where a high value is associated with a long residence time and good delivery of a therapeutic agent.

Drug Release Studies

The drug release studies evaluate the rate at which the active ingredient releases out of the mucoadhesive matrix into the surrounding media, and it can provide important prediction of in vivo release kinetics and therapeutic duration [42, 43]. These systems are used the tools like Franz diffusion cells or dialysis procedures, to produce diffusion profiles that have been analyzed using classical models, like Higuchi and zero-order kinetics, to obtain the drug diffusion studies. The resultant data provided whether the formulation works to achieve the sustained or controlled release at the mucosal interface so as to verify its clinical potential.

Wilhelmy's Method

The Wilhelmy method measures mucoadhesion interactions by measuring the forces applied to a platter with a polymer coating, when immersed in mucin. This technique provides an early and high screening evaluation of the phenomena associated with interfacial adhesion. By measuring the change in weight when they are immersed and withdrawn, it is possible to get a direct measure of

adhesive forces. Complementary measurements of the contact angle offer information on wetting properties and the balance of hydrophilic & hydrophobic interactions. Collectively, these data help to identify polymers that have surface energies favorable for optimum mucosal adhesion [44].

Detachment Force Measurement

This technique is used to quantify the mechanical force required to separate the formulation from mucosal tissue to provide a very direct measure of the adhesive strength. Experiments using texture analysers provide force versus distance curves that give information about the typical rupture behavior of the polymer - mucin complex [45]. High levels of detachment forces indicate strong polymer mucins interpenetration and consequent bonding. Consequently, this technique has proven to reliably predict in vivo retention under the shear stress levels in the oral cavity.

Recording of Adherence

It uses either of two methods for analyzing the temporal adhesion of a suspension adhering to mucosal surfaces: visual or instrumental analysis. This approach provides both qualitative descriptions and quantitative measurement of adhesive behavior, taking account of loss of mass, surface coverage or opacity under the controlled hydration regimes. Such variations reflect the dynamic nature between polymer hydration as well as erosion kinetics and resistance to dislodgement, and thus offer a firm basis for comparison between persistence profiles for multiple formulations [46].

Falling Sphere Method

The Falling sphere method evaluates the mucoadhesion by measuring the resistance of a sphere moving through the mucinous medium, it can be estimated that strong the polymer-mucin interactions by, the higher a sphere is slowed down in a mucinous medium, the longer its time of fall and, the higher the viscosity, the greater the entanglement of the polymer chains or the more intense binding at the interface. This technique is especially good at identifying small variations of adhesive strength between formulations and is therefore a very valuable tool for preliminary screening [47].

Rotating Cylinder Method

The rotating cylinder method is used to measure the mucoadhesive formulation wash from the mucosal tissue mounted on the rotating cylinder. It mimics the mechanical stresses similar to the oral physiological movements and also the associated with the salivary flow. Retention time as recorded under these conditions is used as an index of adhesion strength, erosion resistance and polymer cohesion. By varying the rotational speed, it can provide an assessment of stability of the formulation thereby gaining a dynamic evaluation of the mucoadhesive stability of the formulation that mimics the real world oral environment [48].

Falling Liquid Film Technique

The Falling Liquid Film Technique simulates the constant exposure of fluid to the mucosal surface by the ability to put the simulated saliva into flow on an inclined plane coated with the formulation. The time it takes the formulation to be washed off, which is in fact the wash off time, is a measurable indication of cohesive strength and the hydration dynamics of the polymers. Systems with strong mucoadhesion properties display structural integrity in the presence of prolonged fluid flow, an attribute of special interest to oral dosage forms which are subjected to constant salivary clearance [49].

Ex-vivo Residence Time

Ex vivo Residence Time is used to determine the longevity of a formulation's attachment to the excised mucosal tissue. By exposing the tissue to controlled agitation or fluid flow while monitoring retention, to recreate the biological conditions without the need for in vivo testing. The resulting residence time depends on the swelling of the polymer, the interpenetration of polymer chains, and muco-protein bonding which higher values are correlated with better in vivo persistence and thus provide predictive information on

clinical performance [50].

In-vitro Wash-off Test

The in vitro wash off test assesses the resistance of a formulation to being washed off by the simulated saliva and therefore provides direct evidence for adhesion endurance. Here mucosa tissue in which the test formulation has been pre-coated is violently agitated in a buffer solution simulating oral clearance. The residual mass or percentage left after the wash off is measured, providing a good quantitative measure of the wash resistance and the possibility to identify formulations able to maintain a long term mucosal residency [51].

Stability Studies

Stability Studies are carried out in a way to ensure that mucoadhesive oral suspensions maintain their physicochemical integrity, efficacy, and safety over their projected shelf life. Such studies not only predict the robustness of formulations under a range of storage conditions but also includes accelerated and real-time testing protocols in order to monitor improvements or changes of viscosity fluctuations, mucoadhesive strength, particle size distribution, and active drug content. Furthermore, interactions of polymer and drug, sedimentation behavior, pH changes and potential microbial degradation pathways are tracked carefully to assure quality of product and safety for the patient over the period of time [52].

Clinical Potential and Applications

Local Therapy

Local therapeutic strategies using mucoadhesive oral suspensions aims at binding the active pharmaceutical ingredient at the anatomical site of action for prolonged periods of time in the oral cavity. Accordingly, this has increased the effect of drug presence volume, thus enhancing the drug activity in the oral and oropharyngeal pathologies [53, 54]. The mucoadhesive matrix maintains the contact with the mucosal surfaces for improved permeation of the drug to the local tissues. Consequently, such treatment strategy is efficacious in the treatment of oral ulcers, candidiasis, gingivitis, and periodontal infections, Reduced wash off by saliva ensures sustained drug availability and minimizes dosing frequency.

Systemic Therapy

Systemic administration of mucoadhesive suspensions has the advantage of rapid mucosal absorption, by pass the first pass hepatic metabolism. The increased contact time provided by the mucoadhesive formulation favors the transmucosal uptake. Adhesion strength further promotes drug permeability across buccal and sublingual tissues and thus potentially very advantageous for agents with inherently low oral bioavailability. As a result, analgesics, antihypertensives and peptide therapeutics which require a rapid systemic onset can be administered via this pathway. Moreover, this strategy is an alternative in patients with dysphagia or gastrointestinal intolerance [55-57].

Advantages

Mucoadhesive oral suspensions offer a numerous advantage, such as extended mucosal contact time, as well as decreased dosing frequency and enhanced therapeutic results. Their non-invasive nature improves patient compliance as well as patient comfort. The ability of these formulations to release the drug for extended periods, or under control, results in increased drug bioavailability and local drug retention, and higher drug therapeutic efficiency compared with conventional oral liquids. Furthermore, the compatibility of the formulation with a wide range of drugs and polymers allows lot of flexibility in design and optimization.

Challenges

Notwithstanding these benefits, formulation and performance challenges associated with mucoadhesive oral suspensions may pose problems for the translation into the clinic. Such problems have their origin in the very dynamic setting in the mouth, with its fast turnover of saliva, its degradation by enzymes, and its mechanical disturbances that can destroy adhesion and reduce residence time.

Additionally, effective taste masking, long term stability and degree of variation in polymer-mucin interactions are challenging in formulation refinement. Regulatory oversight and patient acceptability are the additional reasons for the barriers to widespread adoption [58-60].

Recent Advances

Nanoparticle-based Suspensions

Nanoparticle and mucoadhesive suspension is a place where nanotechnologies and polymer sciences come together, in which the nanoscale carriers are intentionally added into mucoadhesive matrices to enhance the drug retention and mucosal penetration. Such systems are characterized by significantly higher therapeutic efficiency both for local and for systemic delivery. Their large surface area encourages strong PCR-mucin interactions which enhance adhesion. Moreover, they serve the purpose of controlled or stimulus responsive drug release, which translates into improved bioavailability. In more recent investigations, lipid, polymeric and metallic nanoparticles have been successfully used to be incorporated in mucoadhesive formulations aimed at a target application on oral therapy [61-63].

3D-Printed Oral Suspensions

3D printing offers the possibility of designing personalized mucoadhesive oral suspensions with controlled drug loading, rheology and polymer architecture. As a technology, patient specific dosing and adhesion profile optimization are supported. Advance in modalities of printing makes it possible for the fabrication of structured mucoadhesive matrices on which residence time and release kinetic can be modulated. Mucosal compatibility of printable hydrogels and biopolymers can be designed. In turn, this new and emerging platform holds great promise for customized therapeutics and pediatric forms [64, 65].

Combination Polymers

Combination polymers involve the deliberate mixing of two or more mucoadhesive materials to provide synergistic properties such as increased adhesion, increased stability and controlled release properties. The combination of these two polymers in a hybrid system is preferable because it overcomes the inherent limitations of single polymers. They promote better hydration, chain interpenetration and mechanical strength, from which better mucosal retention is derived. Functionalized polymers having thiol, acrylic or ionic groups additionally increase binding with mucin. Such combinations are responsible for strong and long acting formulations that can be used for both local and systemic therapy [66-68].

Emerging Clinical Studies

Contemporary clinical investigations are investigating the therapeutic potential of mucoadhesive oral suspensions in disease states which requires localized or rapid systemic drug delivery. These studies provide proof of safety, effectiveness and patient acceptability. Clinical trials have proven better results in the area of oral infections, pain control, and chronic inflammatory disorders by using adhesive suspensions. Enhanced bioavailability as well as reduced dosing frequency represent the practical benefit. Ongoing research aims to standardize evaluation protocols and bring clinical translation closer [69].

Innovation Category	*Description*	*Key Advantages*	*Research/Clinical Relevance*
Stimuli-Responsive Mucoadhesive Suspensions	Formulations that react to pH variation, temperature or ionic variation in saliva and so changes the adhesion or drug release characteristics.	Provide on-demand release of drugs and enhance treatment.	Provide specific utility for conditions which require variable or site specific dosing.
Thiolated and Functionalized Polymers	Incorporation of thiol, carboxyl or cation group to enhance the covalent or electrostatic interactions with the mucin.	Cause strong and durable adhesion and improve the permeability.	Generate enthusiastic interest for systemic delivery of drug by buccal and sublingual routes.
Bioinspired Mucoadhesive Materials	Adhesives based on the proteins of mussels, glycans or mucus - mimetic polymers.	Have a high degree of biocompatibility, high wet adhesion, and little irritation.	Representation of a new concept in oral mucosal advanced therapy.
Hybrid Suspension–Gel Systems	Formulations that make a transition from a suspension to in situ microgels networks on contact with saliva.	Improves retention, minimizes wash off and allows controlled drug diffusion.	Ideal for long term chronic oral situations where it is necessary to have a local delivery for an extended period of time.
Pharmaco-engineered Release Platforms	Mathematical and mechanistic models are coupled with the design of formulations in order to optimize the release kinetics	Produce predictable drug delivery profiles, which are also tunable, with enhanced reliability.	Support advanced formulation development and approval of the regulatory process.

Table 1: Recent Innovations in Mucoadhesive Oral Suspensions [70-74].

Conclusion

Mucoadhesive oral suspensions have become a refined medium linking the most basic of polymer science to the most sophisticated of oral drug delivery requirements. By providing the property of prolonged mucosal residence, increased stability and control over the drug release, these systems overcome the inherent shortcomings of regular oral formulations. The combination of principles of rational design and thorough in vitro evaluation and their understanding of polymer-mucin interactions have strengthened their aspects of translation into local and systemic therapies. Recent innovations such as nanoparticle integrated suspensions, hybrid polymer networks and new 3D printed dosage formats point towards a definite and decisive shift towards precision engineered patient tailored solutions. Ongoing research is leaning towards bio responsive polymers, smart mucoadhesive that can be triggered by pH or temperature, as well as clinically validated models that are more accurate predictors of in vivo performance. As these technologies mature, mucoadhesive oral suspensions are set to play an important role in the future development of oral therapeutics as they can provide safer, more effective and patient centric drug delivery options.

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