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Review Article

A Review on Mucoadhesive Buccal Tablets

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ABSTRACT

Mucoadhesive buccal tablets are a novel and patient-friendly drug delivery technology that adheres to the buccal mucosa, prolongs extended residence duration, and regulates drug release. The principles, advantages, challenges, and most recent developments in the field of mucoadhesive buccal medication administration are highlighted in this study. It discusses the anatomy and physiology of the buccal cavity, mechanisms of mucoadhesion and various natural and synthetic polymers employed to enhance adhesion and drug permeation.

INTRODUCTION

Over the past two decades, mucoadhesion research has experienced significant growth, driven by its potential to improve targeted and systemic drug delivery. Although oral administration is often preferred, it has drawbacks, including liver metabolism and enzyme degradation, which limit the oral delivery of peptide and protein-based medications.[1] Transmucosal delivery of drug offers advantages over oral administration. Mucoadhesion uses bioadhesive polymers to target drugs to specific body regions for extended periods.[2] Transmucosal drug delivery can occur through various mucosal linings, with oral mucosa being a convenient and preferred route.[3] Buccal mucosa, lining the inner cheek, is utilized for both systemic and local medication delivery. The buccal route serves as suitable for oligonucleotides, proteins and conventional small molecules. Bioadhesive formulations increase drug concentration, improving bioavailability, and reducing dose requirements and side effects.[4] Drugs with partition coefficients (40-20,000) and pKa values (2-10) are optimal for buccal delivery.[5]

Structure of the Oral Cavity: [7,8,9,10,11,12]

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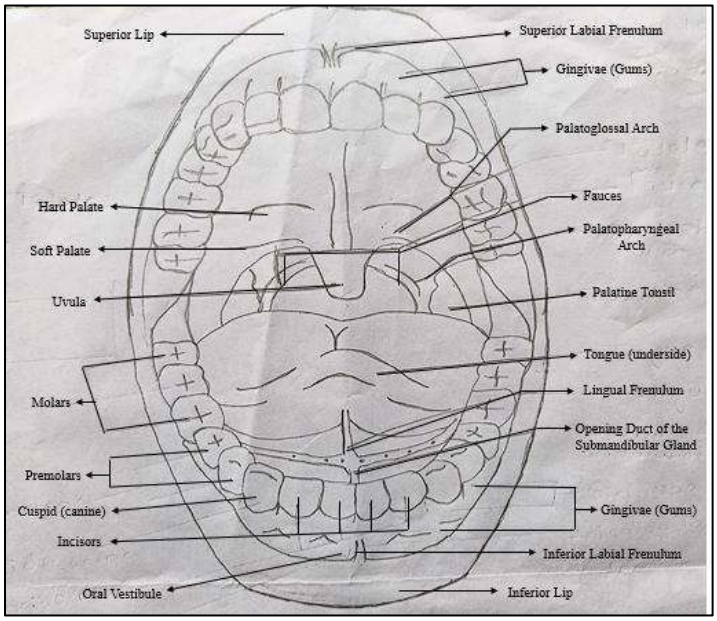

Fig. 1 Structure of the Oral Cavity [6]

The Buccal Cavity: The buccal cavity is made up of the tonsils, floor of the oral cavity, both soft and hard palates, cheeks and the lips that enclose to the vestibule outside the mouth. A multilayered, highly vascularized mucous membrane that is rather thick and dense lines the oral cavity. Drugs are entering the systemic circulation through a network of capillaries and arties underneath the mucosal membrane. The phrase "buccal drug delivery" describes the release of a medication that can happen when the form of dosage is positioned within the external vestibule situated between the gingival and buccal mucosa, which is the membrane covering the cheeks.

Summary of Oral Mucosa: The buccal mucosa consists of dual layers: connective, basement membrane and epithelium tissue.

A) **Epithelium:** Epithelium protects the tissue and acts as a barrier to foreign particles. The thickness ranges from 500 to 800 µm, with 40-50 layers of stratified square epithelial cells.

B) **Connective Tissue and Basement Membrane:** The basal layer of epithelium is demarcated from the connective tissue by the basement membrane. It is composed of extracellular components. The bulk of connective tissue is responsible for the tissue's resistance to deformation, extensibility, and mechanical stability.

The Mucosal Layer: Mucus is a clear, thick, and sticky liquid that adheres to the mucosal epithelial surface and resembles a delicate, continuous gel coating. In humans, this layer's thickness varies between 50 and 450 µm. Goblet cells in the epithelial lining, or specialized exocrine glands, produce and secrete mucus. Although the exact nature of the mucus layer's composition differs significantly across species, locations, and health conditions, it generally consists of the following typical components:

Water	95%
Lipids and Glycoproteins	0.5 to 5%
Mineral salts	0.5 to 1%
Free Proteins	0.5 to 1%

Physiological factors influencing Buccal absorption

1. **Epithelial Permeability:** The epithelial layer serves as a selective barrier, regulating absorption and influencing permeability. Notably, the sublingual mucosa is more porous than the buccal mucosa, facilitating greater drug absorption.

2. **Epithelial Thickness:** Buccal mucosa thickness ranges from 500 to 800 µm. And the thickness varies across the mouth cavity.

3. **Blood supply:** The buccal mucosa's rich blood supply, with a flow rate of 2.4 ml/min/cm, facilitates rapid bioavailability of a drug molecules into the systemic circulation, aided by the lymphatic network in the lamina propria.

4. **Activity of metabolism:** Because the medicine is administered straight to the bloodstream, there is no need for first-pass processing at the liver or gut wall. This method is used to deliver enzymatically labile medicines, such as proteins and peptides.

5. **Saliva and mucus:** On a regular basis, the salivary gland secretes 0.5-2L of saliva, which consistently washes the mouth mucosa. The presence of abundant saliva in the sublingual region accelerates drug absorption by rapidly dissolving medications.

6. **Retention Capability:** The ability of the buccal cavity to retain drug delivery systems, such as tablets or patches, for an extended period, allowing for prolonged drug release and absorption.

7. **Transport Pathways and Mechanisms:** Drugs can get through the epithelial barrier in two differen ways:

- The Paracellular pathway, which runs between neighbouring epithelial cells.• The Transcellular route: drug transfer across epithelial cells via mechanisms that include carrier-mediated transport, passive diffusion, and endocytic processes.

Table 1: Oral epithelium characteristics [13]

Tissue	Structure	Epithelial Thickness (µm)	Permeability	Residence Time	Blood (ml/min/cm^2)
Buccal	Non keratinized	500-600	Intermediate	Intermediate	2.4
Sublingual	Non keratinized	100-200	Very good	Poor	0.97
Gingival	Keratinized	200	Poor	Intermediate	1.47
Palatal	Keratinized	250	Poor	Very good	0.89

Introduction to the Oral Mucosal Tissue [14,15,16]

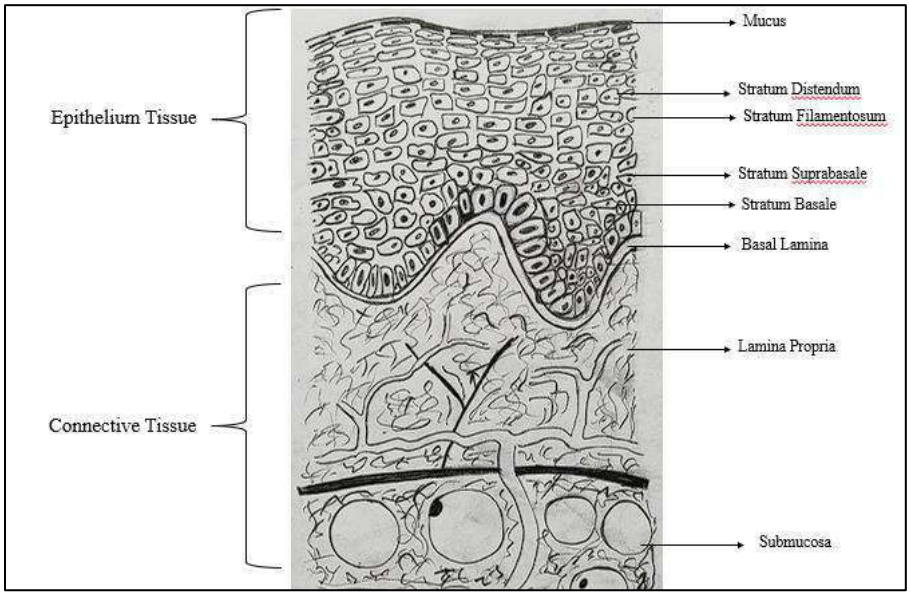

Fig.2: Anatomy of Buccal Mucosa

A stratified squamous epithelial layer forms the outer surface of the oral mucosa, coated by mucous, which provides mechanical protection to underlying tissues. Beneath this layer lies the lamina propria and submucosa. The oral mucosa has varying degrees of keratinization, with non-keratinized regions (e.g., buccal mucosa) being more permeable than keratinized areas (e.g., gingiva and hard palate). The oral mucosa's structure and composition enable it to serve as a primary site for absorption of the drug in the oral cavity.

Mucoadhesion

"Fixing" of surfaces that are attached to one another is the simplest definition of adhesion.[17] In a biological context, bioadhesion is the adherence of an organic or synthetic polymers to a biological substrate; if this adhesion takes place on mucosal membranes or a mucus layer, it is referred to as mucoadhesion. Mucoadhesive drug delivery systems take advantage of the sticky properties of specific polymers to target specific areas of the body, enhancing drug delivery and prolonging release. While oral administration is common, some medications are susceptible to acidic stomach conditions and first-pass metabolism, reducing bioavailability. To overcome these limitations, mucoadhesive systems are being developed for non-oral routes, such as buccal, nasal, and vaginal delivery. Research is ongoing, and mucoadhesive systems are being used to develop various medications, including those for hypertension, angina, inflammation, pain, ophthalmic conditions, and hormonal therapies.[18]

Mechanism of Mucoadhesion

The exact mechanism of bioadhesion between macromolecules and mucosal tissue remains unclear. For effective mucoadhesion, The adhesive should be capable of spreading across the entire surface area, facilitating intimate contact and promoting chain diffusion within the mucus. This process involves a balance of attractive and repulsive forces, with the attractive forces needing to dominate for successful mucoadhesion.[19] Hence, the mucoadhesion mechanism is separated into two stages: contact and consolidation (Fig. 3).

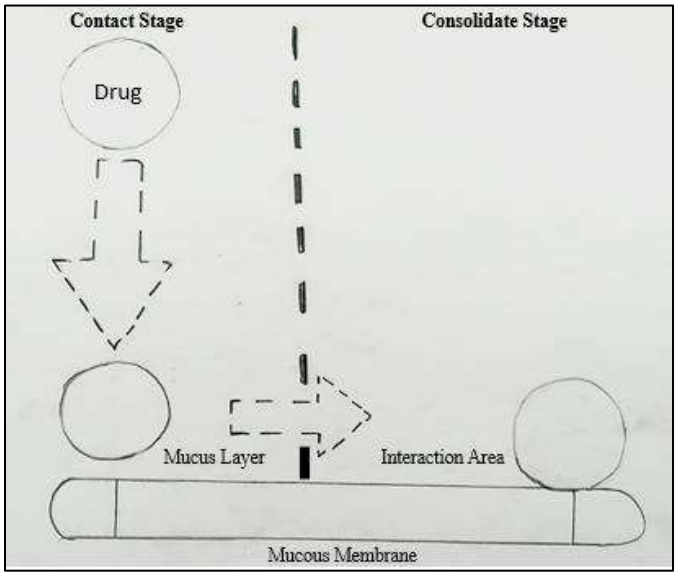

Fig.3: Phases of the Mucoadhesion Mechanism [20]

Stage 1: The initial stage of mucoadhesion begins with contact between the mucoadhesive and the mucous membrane, followed by spreading and expansion to form a close bond with the mucus layer. The contact is mechanically facilitated in vaginal or ocular formulations, while nasal delivery relies on aerodynamic forces for deposition. In the gastrointestinal tract, direct adhesion is challenging, but peristaltic motion and oesophageal adhesion can aid in establishing contact.[21]

Stage 2: The consolidation stage is the second condition, where mucoadhesive molecules are activated by moisture, allowing them to relax and form bonds through weakened hydrogen and van der Waals interactions. There are two ideas that explain this phase: dehydration theory and diffusion theory. Diffusion theories implies mucoadhesive compounds and mucus glycoproteins engage by entangling their chains as well as forming supplementary bonds, creating a mixture that prolongs time of contact with the mucousal membrane. In contrast, theory of dehydration is less relevant for formulations that are solid or extremely hydrated.[22]

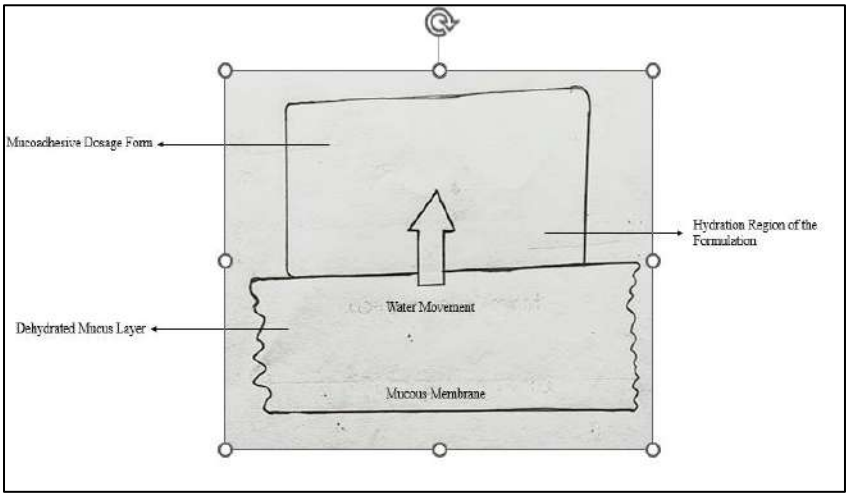

Fig. 4: Theory of Mucoadhesion for Dehydration [23]

Theories of Mucoadhesion: [24,25,26]

1. **Electronic Theory:** This concept relies on the opposing electrical charges between the mucoadhesive and biological surface. Upon contact, electron transfer occurs, creating a dual electric layer, and the forces of attraction between these layers dictate the mucoadhesional strength.

2. **Adsorption Theory:** This theory proposes that mucoadhesive substances bind to mucus via secondary chemical bonds, specifically:

- Van der Waals forces
- Hydrogen bonds
- Electrostatic attraction
- Hydrophobic interactions

3. **Wetting Theory:** This concept applies to liquid systems that exhibit surface tension, enabling them to spread through a surface. The contact angle is a key metric used to assess the affinity, with smaller contact angles indicating greater affinity. For optimal spreadability, the contact angle should be close to zero. The spreadability coefficient is calculated as the differential between the surface energy (γB) and interfacial energy (γA), providing a quantitative measure of a liquid's ability to spread over a surface. The equation should be:

$$SAB = \gamma_B - \gamma_A - \gamma_{AB}$$

The adhesion work (WA), which represents the energy needed to separate two phases, increases as the interfacial energy exceeds the individual surface energies.

$$WA = \gamma A + \gamma B - \gamma AB$$

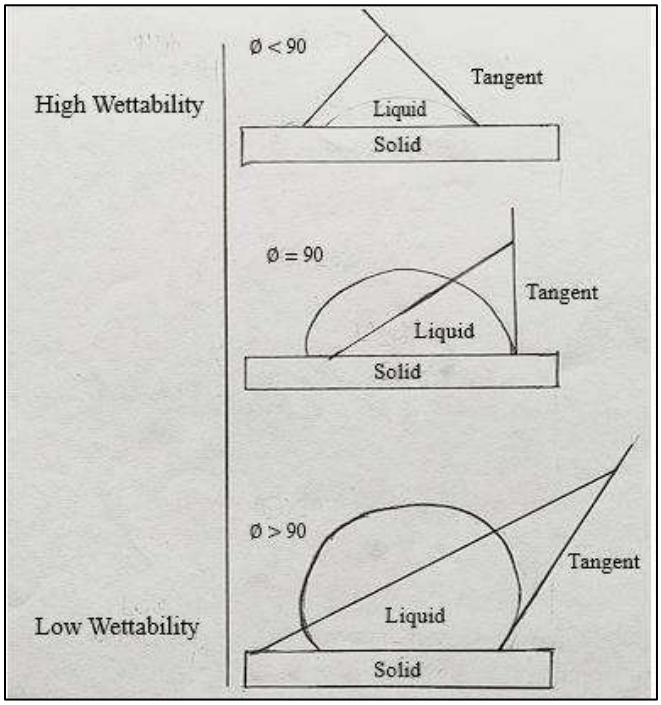

Fig.5: Schematic Representation showing effect of contact angle on Bioadhesion. [27]

4. **Diffusion theory:** This concept proposes that mucoadhesion occurs when mucin and polymer chains intermingle, forming a semi-permanent bond. The extent of interpenetration depends on factors such as diffusion coefficient, chain flexibility, and contact duration. Effective bioadhesion requires an

interpenetration depth of 0.2-0.5 µm. Additionally, good relative solubility between components is necessary for diffusion to occur. The mucoadhesive bond is strengthened by structural similarities between the bioadhesive and mucus.

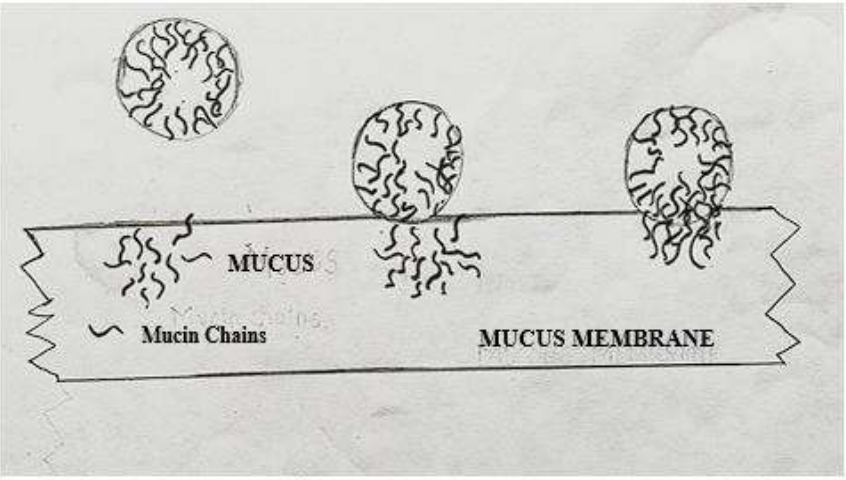

Fig.6: Secondary interactions resulting from inter-diffusion of polymer chains of bioadhesive device and of mucus. [28]

5. **Fracture theory:** This widely accepted explanation, supported by mechanical measurements, describes the relationship between the forces required to detach polymers from mucus and the resilience of their adhesive bonds. Research shows that a decrease in cross-linking degree or an increase in network strand length results in a higher work of fracture, indicating stronger mucoadhesion.

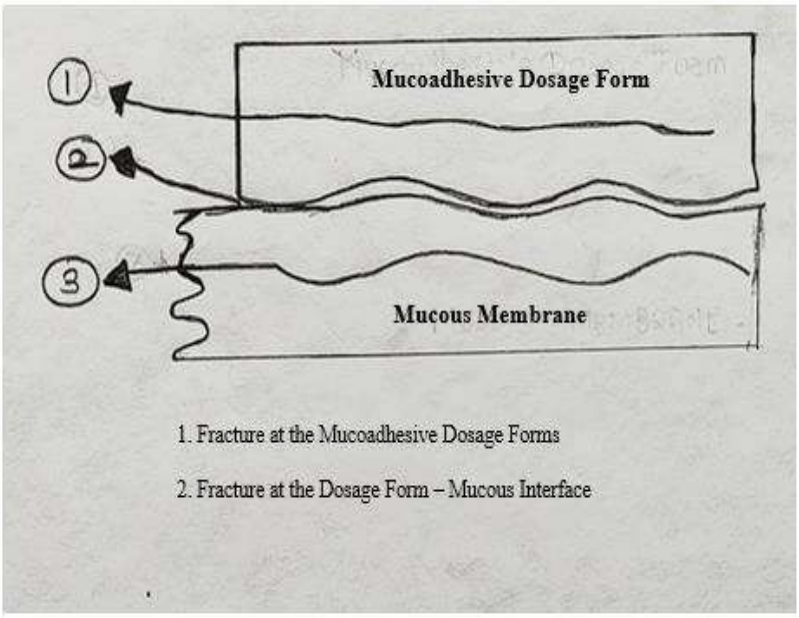

Fig.7: Possible sites of Mucoadhesive bond failure [29]

6. **Mechanical theory:** This theory suggests that adhesion occurs when a mucoadhesive liquid fills microscopic surface irregularities, creating a strong bond. The increased surface

area allows for more interactions, facilitating energy dissipation. Since mucoadhesion varies across situations, no single theory fully explains the phenomenon. However, understanding these mechanisms aids in developing new mucoadhesive products.

Buccal drug delivery system: [30]

Drug delivery through buccal cavity membranes may be categorized as follows:

1. Buccal Drug Delivery

Delivery by the buccal mucosa (inner lining of the cheek)

2. Sublingual Drug Delivery

Delivery through the mucous membrane under the tongue.

3. Transmucosal Drug Delivery

Delivery through other mucous membranes in the mouth, such as the gums or palate.

Advantages of Oral Cavity Drug Delivery: [31]

1. **Convenient administration**: Easy to administer and terminate therapy.
2. **Prolonged localized delivery**: Allows for sustained release of drugs in the oral cavity.
3. **Suitable for unconscious patients**: Can be administered to patients who are unconscious or have difficulty swallowing.
4. **Improved bioavailability**: Provides an alternative route for systemic drug delivery, bypassing first-pass metabolism for certain drugs.
5. **Reduced dose and side effects**: Enables significant dose reduction, minimizing dose-dependent side effects.
6. **Ideal for sensitive drugs**: Suitable for drugs unstable in acidic or alkaline environments or destroyed by enzymes.
7. **No activation required**: Does not require activation for absorption.
8. **Enhanced tissue permeability:** Enables localized modification of tissue permeability and protease inhibition.
9. **Suitable for patients with nausea or swallowing difficulties**: Can be utilized by individuals who are experiencing nausea, vomiting, or difficulty swallowing.
10. **Adequate drug dissolution**: The presence of saliva guarantees that there is enough water to dissolve the medication.

Limitations of Buccal Drug Delivery: [32]

1. **Mucosal irritation and unpleasant taste/odour**: Drugs causing irritation or having unpleasant characteristics are unsuitable.
2. **pH instability**: Drugs unstable at buccal pH cannot be administered via this route.
3. **Dose limitations**: Only drugs requiring small doses can be delivered bucally.
4. **Limited absorption mechanisms**: Only drugs absorbed through passive diffusion can be administered bucally.
5. **Practical challenges**: Eating and drinking may be restricted, and tablets may be swallowed accidentally.

6. **Variable bioavailability**: Buccal delivery can result in unpredictable bioavailability due to low permeability for most drugs.

CONCLUSION

Buccal Mucoadhesive drug delivery is a promising research arena, offering a gentle route for the systemic delivery of poorly absorbed oral drug and potent peptide/protein molecules. Advancing buccal drug delivery requires the development of safe and effective permeation enhancers. To optimize treatment outcomes, predicting, monitoring, and controlling delivery rates, biodegradation, and site-specific targeting are essential. The buccal mucosa provides a viable alternative route for delivering drugs vulnerable to gastric pH, intestinal enzymes, or hepatic first-pass effect. As new pharmaceuticals emerge, mucoadhesive systems will likely play a crucial role in innovative drug delivery solutions.

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