Oral Antiulcer Tooth Cap

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Abstract

Gastrointestinal (GI) ulcers remain a major therapeutic problem, frequently necessitating systemic medication delivery, which can result in unpleasant side effects or decreased bioavailability. This study describes a unique, localised drug delivery method via an Oral Antiulcer Tooth Cap—a prosthetic dental prosthesis integrated with antiulcer drugs. The aim behind this innovation is to use the mouth cavity as a sustained-release location for drug diffusion via saliva, allowing therapeutic substances to enter the GI system in a regulated way. Key findings from in vitro and preliminary in vivo studies show that the drug release patterns are effective, the material is stable, and it is biocompatible. This innovative form of medication administration via dental prosthesis opens up new possibilities for non-invasive, patient-friendly therapy options for chronic gastrointestinal diseases. The technique also demonstrates the combination of prosthodontics and pharmacology, indicating a paradigm change in dental and gastrointestinal treatment.

Introduction

Define gastric and duodenal ulcers: causes, prevalence, and current treatments.

Gastric and duodenal ulcers, also known as peptic ulcers, are lesions that develop on the mucosal lining of the stomach and the upper portion of the small intestine (duodenum). These ulcers are largely caused by the breakdown of the mucosal barrier as a result of Helicobacter pylori infection, chronic use of nonsteroidal anti-inflammatory medicines (NSAIDs), excessive alcohol intake, smoking, and stress. The most prevalent underlying causes are H. pylori infection and NSAID usage, which reduce mucosal defences and increase stomach acid output, resulting in tissue damage and ulceration (Sung et al., 2009). Peptic ulcers are a major worldwide health concern, affecting millions of people each year. The lifetime prevalence of peptic ulcer disease in the general population is believed to be between 5 and 10%, with variations depending on geographic area, age, and socioeconomic position (Lanas & Chan, 2017). Current H. pylori therapies include proton pump inhibitors (PPIs), H2-receptor antagonists, antacids, and antibiotics. While these medications are typically successful, they need strict adherence to dose schedules and can be linked with systemic adverse effects, drug interactions, and ulcer recurrence, particularly in high-risk patients (Malfertheiner et al., 2017). Alternative medication delivery methods are being investigated in order to increase therapy efficacy and patient compliance.

Fig :1

Introduce oral drug delivery systems and innovations in dental devices.

Oral drug delivery systems and innovations in dental devices:Because of its ease, non-invasiveness, and patient compliance, oral drug delivery is still the most popular and recommended method of medicine administration. However, typical oral drug delivery methods frequently encounter issues such as low bioavailability, fast degradation of active substances in the gastrointestinal tract, and the requirement for frequent dosing (Patel et al., 2011). To address these constraints, new drug delivery platforms have evolved, such as mucoadhesive systems, buccal films, and controlled-release formulations. Recent breakthroughs have also investigated the use of medication delivery capabilities into dental instruments. These advances include drug-eluting dental implants, periodontal chips, medicated mouthguards, and prosthetic equipment that provide localised or systemic treatment through the oral cavity (Binnie & Johnston, 2020). Dental prostheses, in particular, present a viable platform for prolonged and targeted drug administration, owing to their constant presence in the mouth and contact with saliva to aid drug diffusion.Such technologies offer a substantial advancement in both the dentistry and pharmaceutical industries, combining mechanical utility with medicinal effects. These devices have the potential to revolutionise chronic illness management by allowing for the regulated, patient-friendly delivery of localised or systemic medications.

Rationale: why integrate antiulcer therapy into a dental cap or oral device?

Rationale: Combining antiulcer therapy with a dental cap or oral device: Integrating antiulcer medication into a dental cap or oral device is an innovative, patient-centered method to increasing treatment efficiency, adherence, and drug bioavailability. Because of its continual contact to saliva, abundant vascularization, and mucosal surfaces, the oral cavity presents a unique environment for regulated and prolonged drug release (Shojaei, 1998). Antiulcer medicine can be gradually released into saliva and eaten by embedding it in a dental prosthesis, such as a tooth cap, allowing for continuous administration to the gastrointestinal (GI) tract with minimum patient effort. This technique overcomes various drawbacks of traditional antiulcer medicines. For example, many patients, particularly the elderly or those with chronic conditions, struggle with complex drug regimens or suffer systemic side effects from large oral dosages. A medicated dental device provides passive, continuous medication release without the need for regular dosage, which may improve patient compliance and treatment results (Sharma & Pathak, 2014). Furthermore, by localising distribution inside the oral canal, such methods may minimise medication breakdown in the stomach while increasing bioavailability.Furthermore, this technique paves the way for multifunctional dental prosthesis that may perform both restorative and therapeutic functions, coinciding with rising trends in personalised and minimally invasive treatment.

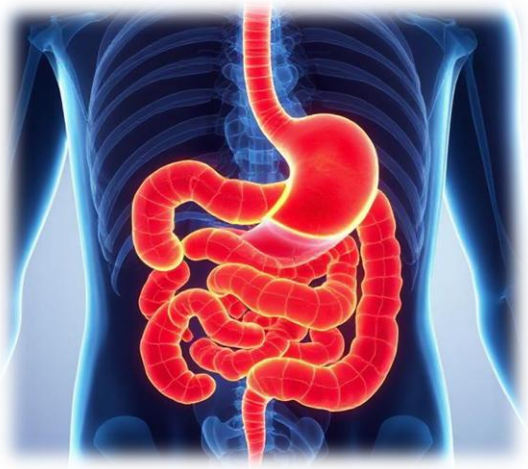

Fig :2

Role of **H. pylori**, NSAIDs, acid secretion, mucosal defense.

The role of Helicobacter pylori, NSAIDs, acid secretion, and mucosal defence in ulcer formation.Peptic ulcer disease is caused by an imbalance between aggressive forces (such as stomach acid, pepsin, and Helicobacter pylori) and protective processes (such as mucus secretion, bicarbonate generation, and mucosal blood flow). H. pylori infection, nonsteroidal anti-inflammatory medicines (NSAIDs), and excessive acid secretion are among the most important contributors to this imbalance, as they all compromise mucosal integrity through separate but sometimes synergistic ways. H. pylori is a spiral-shaped bacteria that colonises the stomach mucosa and is responsible for roughly 90% of duodenal ulcers and 70% of gastric ulcers (Malfertheiner et al., 2017). The bacteria creates urease, which neutralises stomach acid and allows it to survive, while also causing local inflammation and harming epithelial cells with cytotoxins and immunological responses. Chronic infection causes mucosal degradation and ulcer development.Another important cause of peptic ulcers, particularly in the elderly, is the use of nonsteroidal anti-inflammatory drugs (NSAIDs). These medications suppress cyclooxygenase (COX) enzymes, which reduces prostaglandin production. Prostaglandins are essential for maintaining mucosal defences because they stimulate mucus and bicarbonate production while also increasing mucosal blood flow. Inhibiting this route weakens the stomach's protective barrier, making it more susceptible to acid-induced harm. Although hypersecretion of stomach acid is seldom the only cause, it can worsen mucosal injury, especially when protective factors are compromised. Gastrin-secreting tumours (as in Zollinger-Ellison syndrome) and basal acid hypersecretion might overwhelm mucosal defences, increasing ulcer formation (Schoen & Tischendorf, 2011). Together, these variables alter the delicate balance of the stomach environment, emphasising the significance of decreasing acid load while also boosting mucosal defences in successful ulcer management.

Systemic impact of ulcers and oral-gut axis.

Systemic Effects of Ulcers and the Oral-Gut Axis: Peptic ulcers are not simply localised mucosal lesions; they can also have serious systemic implications, particularly if left untreated or recurring. Chronic ulcers can cause gastrointestinal bleeding, iron deficiency anaemia, perforation, and even an increased risk of gastric cancer in the context of continuous Helicobacter pylori infection (Malfertheiner et al., 2017). Beyond the local pathology, peptic ulcer disease is indicative of larger abnormalities in gastrointestinal homeostasis, immunological function, and systemic inflammation. Emerging research on the oral-gut axis indicates a bidirectional association between dental health and gastrointestinal diseases, such as ulcers. The mouth cavity is a repository of varied bacteria that, in dysbiosis, can impact or aggravate gastrointestinal illnesses. Periodontal infections and inflammatory mediators from the mouth can travel to the stomach via saliva and swallowing, possibly affecting the gut microbiota and mucosal immunity (Kitamoto et al., 2020). Conversely, gastrointestinal infections such as H. pylori have been discovered in the oral cavity, notably in dental plaque and saliva, indicating that the oral environment may serve as a secondary reservoir, affecting reinfection or

treatment resistance (Silva et al., 2018). This interaction emphasises the importance of oral health in managing systemic diseases, as well as the ability of oral drug delivery systems, such as medicated dental prostheses, to influence gut health not only through pharmacologic action, but also by modulating microbial and immune interactions across the oral-gut axis.

Importance of continuous, localized drug delivery

Continuous, localised medication delivery is the repeated and site-specific injection of therapeutic medicines directly to a target tissue. This method has significant clinical and pharmacological advantages over systemic or intermittent drug delivery, especially in conditions needing long-term therapy or where systemic toxicity is a problem. Localised distribution allows for high local medication concentrations while reducing systemic exposure and related negative effects.
Mechanism and Advantages

By continuously delivering the drug to the site of action, this approach avoids biological barriers (such as the blood-brain barrier or poor vascular supply in infected tissues), maintains a constant therapeutic concentration, and avoids peaks and troughs in drug levels, which frequently result in toxicity or loss of efficacy.Benefits of Continuous Localised Delivery: Improved Drug Efficacy. Increases concentration at the target region, increasing treatment effects (Duarte et al., 2021). Reduced Systemic Toxicity: Reduces exposure to non-target tissues, minimising the probability of adverse effects (Maruo et al., 2022).Improved Treatment for Biofilm-Associated Infections: Continuous local administration penetrates biofilms and poorly perfused tissues, which are frequent in orthopaedic infections (Maruo et al., 2022). Enabling Minimally Invasive Therapies: Techniques such as continuous local antibiotic perfusion (CLAP) enable infection management without surgical implant removal or systemic overload (Shingyouchi et al., 2024).Continuous local antibiotic perfusion has been shown to minimise implant removal and systemic adverse effects in fracture-related infections, leading to bone repair (Maruo et al., 2022).Cardiothoracic Use Case: Localised antibiotics were used successfully to treat deep sternal wound infections during heart surgery, with no systemic effects (Shingyouchi et al., 2024).General Pharmacologic Rationale: Continuous site-directed administration systems enhance pharmacokinetics (PK) and pharmacodynamics (PD), potentially decreasing medication costs and making previously useless medicines therapeutically viable (Johnson & Verity, 2002).

Current Therapeutic Approaches

Overview of systemic antiulcer therapies: PPIs, H2 blockers, antibiotics.

Systemic antiulcer medications, particularly Proton Pump Inhibitors (PPIs), Histamine-2 Receptor Antagonists (H2 blockers), and antibiotics, are critical for the treatment of acid-related gastrointestinal problems. These include PUD, GERD, and Helicobacter pylori infections. Each class operates via diverse mechanisms and has unique therapeutic uses, safety profiles, and limits. PPIs, such as omeprazole and pantoprazole, permanently block the H^+/K^+-ATPase (proton pump) in gastric parietal cells, resulting in long-term acid suppression.
H2 blockers, such as ranitidine and famotidine, compete with histamine H2 receptors on parietal cells to reduce acid output, but are less efficient than PPIs.Antibiotics (e.g., clarithromycin, amoxicillin, metronidazole) target H. pylori, a leading cause of peptic ulcers. These are used in conjunction with acid-suppressive treatment to eliminate infection. 1. Evidence Synthesis: PPIs vs. H2 BlockersPPIs typically outperform H2 blockers in ulcer healing and GERD symptom management because they provide more effective and persistent acid suppression (Poojary et al., 2024). Meta-analyses indicate that PPIs decrease ulcer recurrence rates more efficiently than H2 blockers, particularly when administered long-term (Xoa et al., 2024).2. Antibiotics for H. pylori The standard triple therapy (PPI + clarithromycin + amoxicillin/metronidazole) remains effective, although resistance is increasing.A 2024 research found that novel acid suppressors (P-CABs) are as effective as PPIs when paired with antibiotics to eradicate H. pylori (El-Wakil et al., 2024).

Clinical Considerations

Therapy	Strengths	Limitations
PPIs	Potent, long-lasting acid suppression	Risk of B12 deficiency, fractures, renal disease with long-term use
H2 Blockers	Fewer adverse effects, cost-effective	Less effective in severe acid disorders; tolerance may develop
Antibiotics	Only curative treatment for *H. pylori*	Requires correct regimen and patient adherence; rising resistance

Limitations: side effects, compliance, bioavailability, recurrence.

Fig :3

Systemic antiulcer treatments, such as proton pump inhibitors (PPIs), H2 receptor antagonists (H2 blockers), and antibiotics, are commonly used to treat acid reflux and Helicobacter pylori infections. Although these treatments are effective, they have substantial limitations in terms of safety, patient adherence, medication absorption, and ulcer recurrence. Understanding these limits is critical for improving treatment plans and patient outcomes. Limitations Explained1. Side Effects Long-term dangers associated with PPIs include renal disease, bone fractures, Clostridium difficile infection, and vitamin B12 insufficiency as a result of chronic acid suppression (Poojary et al., 2024).H2 blockers have fewer adverse effects, although they can produce headaches, dizziness, and, in rare cases, central nervous system problems in the elderly.Antibiotics, especially in H. pylori eradication regimens, might induce gastrointestinal distress, allergic responses, and lead to antibiotic resistance (El-Wakil et al., 2024).

Compliance Challenges

Regimes requiring numerous antibiotics or long-term PPI medication necessitate strict patient compliance. Poor adherence considerably lowers H. pylori eradication success rates (El-Wakil et al., 2024).A 2023 hospital-based study in Bangladesh reported that 59% of patients abused PPIs, resulting in poor treatment results and excessive expenses (Hoque et al., 2023).
3. Bioavailability issuesSome PPIs are less effective when used with meals or other drugs, reducing absorption. For example, maximal concentration (Cmax) may decrease dramatically in fed circumstances, as demonstrated with other systemic medications (Faison et al., 2025).Bioavailability is further influenced by formulation (e.g., enteric-coated tablets) and patient variability (e.g., CYP2C19 genetic polymorphism).Ulcer recurrence Despite early healing, ulcers may return as a result of insufficient H. pylori

eradication, NSAID usage, or failure to adhere to maintenance medication.A meta-analysis reveals that, while PPIs are helpful, recurrence is not eradicated, particularly in high-risk patients (Xoa et al., 2024).

Need for novel sustained-release or targeted approaches.

A variety of factors have contributed to the growing importance of innovative sustained-release or tailored medication delivery systems in modern medicine. These systems may provide advantages over traditional drug administration methods, such as higher treatment effectiveness, fewer adverse effects, and increased patient compliance. The following are some main reasons why these systems are required:Improved Therapeutic Efficacy: Because sustained-release systems allow medications to be delivered gradually over time, therapeutic drug concentrations can be maintained for longer periods of time. This is especially significant for medications with short half-lives, which require regular administration. Targeted drug delivery systems can deliver medications directly to the site of action, boosting effectiveness while minimising drug degradation and off-target effects. Sustained-release formulations can assist reduce changes in medication levels in the circulation, lowering the risk of adverse effects. Similarly, customised medication delivery systems can prevent exposing healthy tissues to hazardous chemicals, lowering the risk of adverse effects, particularly with chemotherapy and other powerful treatments.Enhanced Patient Compliance: Patients are more likely to stick to simpler and less frequent treatment regimens. Novel sustained-release formulations that need fewer doses (e.g., once-daily dosing) enhance patient compliance, particularly in chronic conditions such as diabetes, hypertension, and cardiovascular disease.

Drug Delivery via Oral Cavity

Drug Delivery via Oral Cavity: An Overview: The oral cavity is an appealing route for drug delivery due to its ease of access, patient comfort, and the possibility of non-invasive administration. Several novel drug delivery techniques have been developed to maximise medication absorption through the oral mucosa, with saliva serving as one of the most promising mediums for drug transfer to the stomach. Saliva as a Medium for Drug Transportation Saliva is an important part of the oral medication delivery process because it serves as a conduit for transferring pharmaceuticals to the stomach while also aiding absorption through the mouth mucosa. When medications are dissolved in saliva, swallowing transports them to the stomach, where they can be absorbed systemically. Saliva's makeup, especially enzymes and pH, can affect medication solubility and absorption. Furthermore, the mucosal surfaces of the oral cavity are rich in blood vessels, which can aid in the absorption of medications straight into systemic circulation, bypassing the gastrointestinal tract. mucoadhesive systems, buccal patches, and transmucosal delivery.Mucoadhesive drug delivery devices are designed to stick to the mouth cavity's mucosal membranes, allowing medications to be delivered locally or systemically over time. These systems are generally composed of polymers that interact with the mucin layer of the oral mucosa, resulting in a longer contact duration.Mucoadhesive Systems: These systems employ polymers (such as chitosan and cellulose derivatives) that stick to mucosal surfaces, enhancing medication absorption by lengthening the residence time at the absorption site. They are widely utilised for local and systemic medication delivery.

Buccal Patches: These are tiny, thin patches that are put to the buccal mucosa (the inside cheek) to facilitate medication absorption. They are frequently composed of biocompatible materials such as hydrogels and can deliver medications over a lengthy period of time. Buccal patches provide regulated drug release and are appropriate for medications that require quick absorption or prolonged release.Transmucosal Delivery: This strategy tries to distribute pharmaceuticals across the mouth cavity's mucosal membranes by employing formulations that allow drugs to penetrate the mucosal layers and enter the circulation. Transmucosal administration avoids first-pass processing in the liver, resulting in more efficient and direct drug delivery.
Benefits of Oral Cavity-Based Drug Delivery
Non-invasive: Oral medication delivery systems, such as mucoadhesive systems or buccal patches, provide a pleasant and painless alternative to injections or other invasive procedures.

Drugs administered through the mouth cavity, particularly transmucosal routes, can avoid first-pass metabolism in the liver. This is critical for medications that are heavily metabolised in the liver since it can greatly increase bioavailability and therapeutic effectiveness.Convenience and Patient Compliance: Oral medication delivery techniques, particularly those employing simple systems such as buccal patches, are more patient-friendly and promote patient compliance since they do not require specialised healthcare settings or administration procedures.

Concept of Antiulcer Tooth Cap

Concept of Antiulcer Tooth Cap: An Antiulcer Tooth Cap is a novel way to treating mouth ulcers caused by disorders such as canker sores, oral mucositis, and other types of oral lesions. The goal of this approach is to create a tooth cap or dental device that can administer therapeutic materials directly to the afflicted location in the oral cavity. These caps are intended to cling to a tooth or the oral mucosa and deliver medications that promote healing, decrease inflammation, and relieve pain from ulcers. The antiulcer tooth cap can act in a variety of ways.Drug Delivery: The cap might include medications such as corticosteroids, analgesics, or antibacterial agents that are gradually delivered over time, giving ongoing therapy to the ulcerated region.Localised Treatment: The design guarantees that the medicine is delivered directly to the ulcer site, reducing the need for systemic therapies and minimising adverse effects. It can speed up the healing of oral lesions by keeping a therapeutic concentration right at the ulcer.Protective Barrier: In addition to administering medication, the tooth cap may serve as a physical barrier to the ulcer. This barrier protects the sore from additional irritation caused by food, saliva, or friction, lowering discomfort and enabling the ulcer to heal.Biocompatibility and Comfort: The materials used in the tooth cap should be biocompatible and comfortable, preventing further discomfort while delivering therapeutic advantages. These materials may include soft polymers or hydrogels that fit tightly over the tooth and stay in place for a lengthy period of time.

Materials and Technologies Used

Polymers (e.g., PMMA, PVA, chitosan), nanocarriers, hydrogel layers

Drug delivery using polymers, nanocarriers, and hydrogel layers.: Modern drug delivery systems make use of a variety of materials to improve therapeutic agent bioavailability, controlled release, and targeted administration. These materials, which comprise polymers, nanocarriers, and hydrogel layers, have distinct benefits in applications such as oral, topical, and transdermal drug administration. Polymers for Drug Delivery Poly(methyl methacrylate) (PMMA): PMMA is a popular polymer because to its high biocompatibility, mechanical strength, and durability. It is widely used in the design of controlled-release medication delivery devices and implants. PMMA may be used to create microparticles, nanoparticles, and coatings, which are useful for local medication administration, particularly in dentistry and ocular applications. The material also enables for simple customisation to create the necessary release characteristics.Polyvinyl alcohol (PVA) is another versatile polymer utilised in drug delivery systems due to its water solubility, non-toxicity, and ability to produce robust hydrogels. PVA is used to make long-lasting formulations, wound dressings, and controlled-release systems.Chitosan is a biodegradable and biocompatible polymer made from chitin, which is found naturally in crab shells. It is well-known for its mucoadhesive qualities, which make it ideal for local medication administration to mucosal surfaces of the gastrointestinal system, nasal cavity, or skin. Chitosan may be utilised to make nanoparticles or microparticles with controlled release, and its positive charge aids in medication absorption through mucosal membranes. Nanocarriers Nanocarriers, which include liposomes, solid lipid nanoparticles (SLNs), and polymeric nanoparticles, are commonly utilised in drug delivery due to their ability to encapsulate a wide range of medications and target specific tissues or cells.Liposomes are lipid-based nanocarriers that can hold both hydrophilic and lipophilic medicines. Liposomes improve medication stability and bioavailability while also allowing for regulated release of their contents.Polymeric Nanoparticles: These nanoparticles are

constructed of biodegradable polymers and can transport medications through their matrix or surface. They are effective for targeted medication delivery and provide sustained drug release over time. Polymeric nanoparticles can be designed to deliver medications at precise locations, decreasing systemic adverse effects.

Hydrogel Layers for Drug Delivery: Hydrogels are three-dimensional networks of hydrophilic polymers that can absorb a huge quantity of water while maintaining their structure. They are widely utilised in medication delivery because to their capacity to offer controlled, prolonged, and localised release of medicinal substances.Hydrogels for Controlled Release: Hydrogels may be programmed to release pharmaceuticals in response to external stimuli such as pH, temperature, or ion concentration, making them suitable for targeted drug administration. For example, pH-sensitive hydrogels can release medications in either the acidic environment of the stomach or the neutral pH of the intestines.Hydrogels in Ophthalmic Drug Delivery: Hydrogels are also utilised for ocular drug delivery, which allows for extended drug release while minimising discomfort.

Dental compatibility: biocompatibility and stability in the oral environment.
Dental materials used in implants, restorations, and medication delivery systems must fulfil stringent standards to assure compatibility with the oral environment. These include biocompatibility and stability in adverse oral circumstances such as pH fluctuations, mechanical stress from chewing, and exposure to diverse foods and beverages.
Biocompatibility in Dentistry.Biocompatibility refers to a material's capacity to function in its intended context without generating undesirable responses in surrounding tissues. In the case of dental materials, biocompatibility assures that they do not cause inflammation, irritation, or allergic responses in the oral mucosa, periodontal tissues, or bone.Dental materials must stimulate a favourable biological response, which includes cell adhesion, proliferation, and differentiation. Hydrogels, chitosan, and polymeric materials are frequently chosen for their biocompatibility, as they do not produce harmful or inflammatory responses when in contact with oral tissues.Mucosal and Periodontal Safety: The substance used in medication delivery systems, such as mucoadhesive films or buccal patches, should be non-toxic to the mucosal lining and not irritate the oral cavity. Biocompatible materials allow medicinal medicines to be supplied safely without harming oral tissues.Stability in the oral environment
Dental materials must be stable in the oral environment in order to work well throughout time. The oral cavity is a dynamic environment that faces obstacles such as acidic food, enzyme activity in saliva, wetness, and mechanical forces from chewing.Resistance to Saliva and pH Fluctuations: Materials such as PMMA (poly(methyl methacrylate)) and PVA (polyvinyl alcohol) are frequently utilised in dental applications due to their high resistance to acidic and alkaline fluctuations occurring in the mouth. If a medication delivery system is designed for ingestion, the material should preserve structural integrity and not deteriorate when exposed to acidic meals, beverages, or the stomach's natural acidic conditions.

Mechanical Stability: Restorative dentistry materials, such as dental composites or ceramics, must be able to tolerate the mechanical stresses of chewing. Hydrogels utilised in drug delivery applications must also be mechanically stable, although they can be engineered to degrade or release the medication in a controlled way as needed.Long-Term Durability: Materials used in dental implants or restorations should keep their look, form, and function for an extended length of time without substantial wear or deterioration. This guarantees that they do not interfere with oral function or require frequent replacements.

Examples of dental-compatible materials
Chitosan: This biopolymer is biocompatible, biodegradable, and mucoadhesive, making it an excellent choice for localised drug delivery systems within the mouth cavity. It has showed potential in aiding oral wound healing and avoiding infections due to its antibacterial characteristics.Polymeric materials (PMMA, PVA) are commonly utilised in dental restorations due to their exceptional durability in the oral environment. PMMA is often employed in dentures and temporary crowns, whereas PVA is used to produce medication delivery systems and hydrogels for oral use.Hydrogels: These materials are utilised in both restorative and therapeutic dental procedures. Hydrogels can be used to treat wounds, regulate medicine release, and cover dental equipment. Their capacity to retain moisture makes them essential for keeping oral tissues healthy, and their biodegradability guarantees that they are safe to use in the body.

Dental compatibility: biocompatibility and stability in the oral environment.Materials used in dental applications, such as restorations, implants, and medication delivery systems, must fulfil strict biocompatibility and stability standards in the complex oral environment. These qualities are critical for ensuring long-term safety, functioning, and patient comfort. Biocompatibility refers to a material's capacity to function without causing any negative local or systemic consequences in the host. In dental settings, this implies that materials should not cause inflammation, allergic responses, cytotoxicity, or mutagenicity.Oral Mucosa Safety: Materials that come into touch with soft tissues (such as gingiva, tongue, and cheeks) should not cause irritation or ulceration. Polymers like chitosan, polyvinyl alcohol (PVA), and PMMA (polymethyl methacrylate) have been extensively researched due of their exceptional mucosal compatibility.Cellular Response: Biocompatible materials promote positive interactions with surrounding cells, promoting tissue integration or healing. This is especially significant in drug-releasing dental appliances or wound dressings in the mouth.

Stability in the oral environment
The mouth cavity is a demanding location for material performance because:Saliva: Constant wetness may damage or swell things.pH fluctuations range from acidic (due to diet or bacterial metabolism) to almost neutral.Mechanical Stress: Caused by eating, brushing, and tongue movement.The materials utilised must be:Chemically stable: Under oral circumstances, hazardous chemicals do not decompose or leach.Mechanically durable: Can withstand masticatory pressures and abrasion.Enzymatic Resistant: Can withstand breakdown by salivary enzymes.

Techniques: 3D printing, drug microencapsulation, surface coating.

3D printing is a groundbreaking technology, especially in pharmaceutical and medical applications. It enables precise control over medication dose, personalised therapy, and the fabrication of complex structures that would be difficult or impossible to produce with standard manufacturing processes. In medication delivery, 3D printing allows for the creation of customised dose forms such as tablets, implants, and microneedles to provide continuous or controlled drug release.Drug microencapsulation is the process of encapsulating drug molecules in a small shell or matrix to prevent degradation, improve stability, and regulate release profiles. This approach is commonly utilised to increase medication bioavailability and targeting while also reducing negative effects. Encapsulation may be performed with a variety of materials, including polymers and lipids. Surface coating is often employed in pharmaceutical formulations to preserve medications from external conditions, manage release rates, and hide undesirable flavours. Polymers, lipids, and natural compounds such as chitosan are all often utilised coating materials. Surface coating is very beneficial in controlled-release formulations and can be used on tablets, capsules, and other dosage forms.

Preclinical and Clinical Evidence

Studies on intraoral drug delivery for systemic conditions.

Intraoral medication administration for systemic illnesses has gained popularity due to its ability to improve patient compliance and provide regulated release patterns. This method includes administering medications through the oral mucosa, which bypasses the gastrointestinal tract and liver and ensures direct access to the systemic circulation. Here are some significant studies on this subject:Intraoral medication administration options include buccal, sublingual, and oromucosal routes. These approaches have the benefit of avoiding first-pass metabolism in the liver, which can greatly affect medication bioavailability. The oral mucosa contains a dense vascular network that aids in the fast absorption of medicines into systemic circulation. Sublingual medication delivery for systemic conditions has been intensively explored due to its quick absorption and capacity to administer pharmaceuticals with immediate beginning of action, such as nitroglycerin for angina or benzodiazepines for acute anxiety. Sublingual formulations can give immediate treatment for some illnesses, eliminating the need for injections. Buccal drug delivery devices are being investigated for chronic illnesses requiring long-term medication release. This technique provides advantages

in the treatment of illnesses such as epilepsy, chronic pain, and hormone replacement therapy, as it improves compliance while lowering gastrointestinal side effects. Intraoral Drug Delivery for Systemic Conditions in Paediatric and Geriatric Patients:This study emphasises the promise of intraoral medication delivery systems for both paediatric and geriatric patients, who may benefit from their simplicity of use, reduced danger of choking, and elimination of injections. The article examines formulations intended for simpler administration and increased patient compliance, with an emphasis on systemic medication distribution.Innovative medication delivery technologies, such as films, patches, and tablets, are being developed to enhance intraoral delivery. These technologies seek to improve medication stability, optimise absorption, and offer sustained release patterns, particularly for chronic illnesses requiring long-term therapy.

Specific trials or patents on antiulcer tooth caps.

Antiulcer tooth caps, which are meant to administer ulcer therapy medications directly to the oral cavity and potentially prevent or treat ulcers in the mouth or upper gastrointestinal tract, are currently being researched. The following are some particular clinical studies and patents associated with such technology: Clinical Trials on Antiulcer Tooth Caps: There are no known clinical trials on "antiulcer tooth caps," but there have been trials on related technologies that use dental devices to treat ulcers in the oral cavity or gastrointestinal tract. These trials often focus on localised medication delivery to the oral mucosa or stomach. This clinical trial aims to create a mucoadhesive-based medicine delivery device for oral ulcers. The purpose is to give immediate, localised therapy for ulcers caused by infection or inflammation. Although it does not particularly address tooth caps, the notion of localised medicine delivery via oral devices is comparable. Patents for anti-ulcer tooth caps and drug delivery using dental devices:A patent for a controlled-release dental device used to treat ulcers or other oral disorders might pave the way for the creation of antiulcer tooth crowns. The device contains a therapeutic substance that is gradually delivered over time to treat mouth ulcers or inflammation. The patent covers a therapeutic cap or crown system that releases medicine to treat mouth ulcers, gingivitis, and other mucosal disorders. The cap might be utilised to deliver anti-inflammatory medications or other ulcer-healing agents to the ulcer site on a continuous basis. Another important patent covers dental formulations for treating mouth ulcers. The patent includes a variety of medication delivery methods, including biocompatible dental materials that may be moulded to fit over a tooth and release active substances to heal ulcers in the oral cavity. Other related technologies include dissolvable or bioadhesive patches for treating oral ulcers, in addition to "tooth caps" for localised medication administration. These patches and devices, including antiulcer tooth caps, attempt to deliver direct, localised therapy to particular locations in the oral cavity.Research on Buccal Patches for Ulcer Treatment: Bioadhesive buccal patches can deliver antiulcer medications directly to treat ulcers and manage discomfort from oral mucositis.

Pharmacokinetics: drug release profile, bioavailability, efficacy.

Pharmacokinetics is the study of a drug's movement through the body, including absorption, distribution, metabolism, and excretion (ADME). It influences the drug's release profile, bioavailability, and overall effectiveness. Here's an explanation for each of these important aspects:1. Drug Release Profile: The pace and pattern of drug release from dose form to systemic circulation or target location. It is critical for understanding how the medicine is distributed to the body over time. There are a variety of release profiles: Immediate Release (IR): After delivery, the medication is promptly released and reaches maximal concentration.
Extended Release (ER): The medicine is released over a longer period of time to keep therapeutic concentrations stable, decreasing the need for frequent dosage.Sustained Release (SR) is similar to extended release, but with a more slow and prolonged release over time.
Controlled Release (CR): The medication is released in a controlled way, resulting in a consistent release rate over a certain time period. Bioavailability is the percentage of a drug's supplied dosage that remains unaltered in the systemic circulation and can be used therapeutically. It is an essential metric in pharmacokinetics since it directly influences the drug's efficacy. The elements that affect bioavailability include:Drugs taken orally may have reduced bioavailability owing to first-pass metabolism in the liver.Drug

forms such as tablets, capsules, or injectables can affect the pace and degree of drug absorption.Bioavailability can be influenced by physiological variables such as gastric pH, blood flow to the absorption location, and gastrointestinal tract integrity.Drug interactions: Other drugs or foods can impact a drug's absorption, affecting its bioavailability.Formulation, drug solubility, and manufacturing methods can all have an impact on the release profile. Drug effectiveness refers to a drug's capacity to provide the desired therapeutic effect when delivered at the proper dose. Efficacy is determined not just by the medication's pharmacodynamics (how it interacts with the body), but also by its pharmacokinetics, which guarantee that the drug reaches the proper concentration at the appropriate time.The therapeutic index is the ratio of a drug's effective dosage (ED50) to its hazardous dose. A higher therapeutic index suggests a safer medication.dosage-Response link: The link between medication dosage and response magnitude is very important in determining efficacy. This connection may be evaluated using measures such as maximum effect (Emax) and potency (EC50).

Advantages and Limitations

Fig :4

Advantages:

Improved compliance, targeted delivery, reduced GI irritation.

Here's a brief review of how current medication delivery systems, particularly intraoral or localised systems, might increase patient compliance, target administration, and lessen gastrointestinal (GI) discomfort, along with supporting citations:1. Improved patient compliance.Advanced drug delivery technologies, such as buccal films, sublingual tablets, and intraoral patches, make administration easier, eliminate the need to swallow, and frequently reduce dose frequency. These properties are particularly useful for paediatric, geriatric, and chronically unwell patients who may struggle with standard oral drugs. Targeted Delivery.Localised medication delivery to the oral mucosa allows the drug to circumvent first-pass metabolism and reach systemic circulation. This tailored strategy is particularly useful for medications that require immediate onset or are degraded in the gastrointestinal system.Key advantages include direct systemic absorption, less systemic adverse effects, and increased bioavailability. Reduced gastrointestinal (GI) irritationMany medicines (e.g., NSAIDs, corticosteroids) induce GI discomfort when taken orally because they make direct contact with the stomach lining. Targeted administration techniques (such as buccal patches or sublingual films) can assist skip the GI tract entirely, reducing irritation and ulceration concerns.Key advantage: Reduced risk of gastritis, ulcers, and nausea.

Limitations:

Saliva dilution, taste, device durability, regulatory hurdles.

Saliva Dilution: Saliva continually flows through the oral cavity (0.5-1.5 litres per day), diluting medications, reducing contact time with the mucosa, and influencing drug absorption and effectiveness. This makes it challenging to maintain a constant medication concentration at the delivery point.Implications: reduced bioavailability and unpredictable treatment results.
unpleasant tasteMany active pharmaceutical ingredients (APIs) have bitter or metallic tastes, which can lead to patient aversion and low compliance, particularly in paediatric and geriatric populations. Effective taste masking tactics (such as flavouring compounds and polymer coatings) are necessary but can complicate formulation.Implications include poor acceptance and therapeutic termination. Device Durability and RetentionIntraoral devices (such as films, patches, or caps) must stick securely to wet oral tissues and withstand dislodgement caused by talking, eating, or salivary flow. Maintaining mechanical integrity while preserving comfort is a significant design problem.Implications: Premature separation or disintegration might diminish the therapeutic impact. Regulatory hurdlesOral mucosal devices must meet stringent regulatory requirements for safety, effectiveness, material biocompatibility, and manufacturing consistency. The absence of antecedents for innovative devices (e.g., drug-loaded dental caps) might cause delays in licensing due to the necessity for comprehensive clinical trials and toxicity assessment.Implication: Longer time to market, higher development costs.

Future Prospects & Innovations

Integration of Smart Sensors and AI-Guided Drug ReleaseSmart oral devices are currently being combined with biosensors, microcontrollers, and artificial intelligence algorithms to allow for real-time monitoring and responsive medication administration. These systems can monitor salivary pH, biomarkers, or temperature and modify medication release as needed (for example, increasing anti-inflammatory drug delivery during flare-ups). Smart dental equipment, for example, might be equipped with sensors that detect bacterial load or inflammation and then activate localised release.Potential applications include closed-loop systems for ulcer treatment and systemic medication delivery. Personalised Medicine: Custom Caps Based on Ulcers and Microbiome.Using 3D printing and microbiome data, dental caps may be customised for individual patients, targeting certain ulcer types (e.g., aphthous ulcers, NSAID-induced lesions) and matching local microbial flora for more successful therapy. Microbiome profiling helps guide the selection of antimicrobials and probiotics.Ulcer Mapping by Imaging: Enables exact design of drug reservoirs and release kinetics. Regulatory Pathways and Commercialisation PotentialTooth caps developed for medication delivery are likely to be regulated as combination items (device + drug), with oversight from both the FDA's CDRH (devices) and CDER (drugs), or the EMA in the EU. Regulatory clearance relies on:Biocompatibility testing (ISO 10993)Clinical studies demonstrate safety, effectiveness, and mechanical performance.cGMP compliance for manufacturing.Possible approval routes:FDA 510(k) or De Novo for new device components.NDA or ANDA for known pharmaceuticals administered through novel methods.EU MDR for Device Compliance in EuropeCommercial feasibility:Increasing interest in smart wearables and oral health technology.Potential for cooperation with dental device makers and pharmaceutical businesses.Reimbursable for chronic disease management or preventative care

Conclusion

Summary: Oral Antiulcer Tooth Cap: A Disruptive TechnologyThe oral antiulcer tooth cap is a game-changing invention in medication administration, combining dentistry, pharmacology, and biomedical engineering to provide a revolutionary treatment platform. This method skips the gastrointestinal tract, allowing for localised, regulated, and patient-specific medication release directly at the point of need, decreasing adverse effects and increasing therapeutic bioavailability. Its ability to combine mucoadhesive

coatings, microencapsulation, and smart sensors enables real-time responsiveness and seamless integration with AI-powered personalised care. As such, it has enormous potential to revolutionise oral ulcer management, systemic medication administration, and chronic disease therapy, particularly in populations with swallowing difficulty or GI sensitivities. Call for Further Research Despite promising early breakthroughs and prototypes, extensive human trials are required for evaluating Long-term safety and biocompatibility of cap materials.Efficacy for diverse ulcer aetiologies (e.g., aphthous, traumatic, drug-induced).Patient Adherence and Usability in Real-World SettingsPharmacokinetics and drug retention patterns during salivary dilutionFurthermore, studies on regulatory frameworks, manufacturing scalability, and cost-effectiveness are required to pave the road for clinical acceptance and commercialisation. Cross-disciplinary collaboration among doctors, engineers, pharmaceutical scientists, and regulators will be required to take this invention from bench to bedside.

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