

## A Review on Formulation and Evaluation of Dental Cones

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### ABSTRACT:-

Dental cones, particularly those formulated with biodegradable polymers and azithromycin dihydrate, offer a promising solution for localized drug delivery in periodontal therapy. These cones are designed to be inserted into periodontal pockets, providing a controlled release of medication to target bacteria and promote healing after tooth extractions. Periodontal diseases, such as periodontitis and gingivitis, destroy tooth-supporting tissues if left untreated. Traditional treatments like scaling, root planning, and systemic antibiotics have limitations, including bacterial resistance and incomplete treatment outcomes. Dental cones present a novel, effective approach to managing periodontal disease by delivering targeted antibacterial action and aiding tissue regeneration, potentially reducing the risk of severe periodontitis and tooth loss.

**KEYWORDS:** Dental cones, biodegradable polymers, azithromycin dihydrate, localized drug delivery, periodontal therapy, and periodontitis tissue regeneration.

### I. INTRODUCTION:-

The word "peri" means surrounding, "odont" means tooth, and "itis" means inflammation are the root words of the word "periodontitis"[1]. Infections affecting the gums, periodontal ligament, and alveolar bone that surround teeth are referred to as periodontal

disorders [2]. Periodontal illnesses include necrotizing periodontitis, aggressive periodontitis, systemic problems associated with periodontitis, and chronic periodontitis [3]. Among other reasons, these for a long time oral inflammatory diseases may impact infective endocarditis, diabetes, and cardiovascular disease [4]. A region termed "pockets" forms between the gums and teeth when periodontal disease is present. This area offers the perfect environment for the growth and multiplication of anaerobic pathogenic bacteria. Clinically speaking, as the disease progresses, the periodontal pocket—which is already marginally deeper than the sulcus of a healthy tooth—deepens and causes more harm to the tooth's supporting tissues as well as, frequently, tooth loss. The primary etiological reason for the development of inflammation and tissue damage is bacterial colonization of the subgingival region [5]. Modern periodontal therapy uses mechanical cleaning techniques like scaling and root planning (SRP) and systemic or local administration of antimicrobial drugs to treat inflamed tissue, reduce the amount of pathogenic bacteria, stop bone resorption, and eliminate the depth of diseased pockets [6]. Systemic antibiotic therapy is helpful, but it requires high oral doses to reach the gingival crevicular fluid (GCF) at optimal concentrations, and prolonged dosing can cause resistance. Mouthwashes, gels, and toothpastes solely address dental plaque and mucosal infections; they don't

address other conditions. Furthermore, such local delivery techniques require multiple injections and a high initial concentration to achieve efficacy [7]. Controlled release devices have been suggested for intrapocket injection to circumvent the drawbacks of both localized and systemic medication delivery [8]. The germs that are growing in the pockets can be specifically targeted by these devices. All of these treatments, nevertheless, are helpful in treating and preventing infection during the early stages of the illness. Reaching these therapeutic objectives may be challenging in other situations, such as severe periodontitis, where periodontal therapy alone may not be sufficient to restore the health and function of the teeth. In these situations, periodontal disease-affected teeth ought to be removed [9].

A bioresorbable material is needed to repair the surrounding tissues and stop bacterial infection after infected teeth are extracted. An attempt has been made to create a biodegradable polymer that can be used to fill an empty socket with dental cones. Dental cones are used to treat the affected area and prevent bacteria from growing around the teeth. Dry socket conditions can also benefit from these cones. The formulation of dental cones was chosen to include azithromycin dihydrate. Among the new class of antibiotics called azalides, which is used to treat aerobes and anaerobes discovered in the periodontal pocket, azithromycin is the first and most significant member. When certain circumstances are met, azithromycin is frequently used to treat a broad range of mild-to-moderate bacterial infections brought on by susceptible strains of the listed pathogens, such as *Streptococcus pneumoniae*, *Moraxella catarrhalis*, and *Haemophilus influenzae*[10].

By preventing the creation of bacterial proteins, it has bacteriostatic action. Because of their strong post-antibiotic effects, tissue concentrations of azithromycin can be 100–1000

times higher than blood levels and last for a considerable amount of time after blood levels have dropped. Azithromycin's tissue concentration may surpass the microorganism's minimum inhibitory concentration (MIC) for a duration of 2 to 10 days, with an elimination half-life of 4 days in abscesses. Saliva, GCF, and periodontal tissues all have high concentrations of it. Advanced, persistent, or aggressive periodontitis can be treated with it [11].

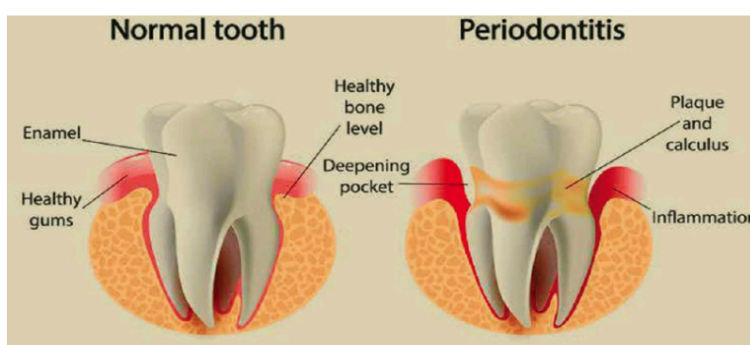
In a physiological setting, gelatin—a naturally occurring protein produced by the hydrolysis of collagen—is very friendly and biodegradable. Gelatin is used as a topical hemostatic in dentistry formulations to assist in accelerating and stabilising the formation of clots in wounds and bleeding areas. Owing to its porosity, flexibility, and biocompatibility, it can be used as a scaffold or a drug carrier inside wounds with osseous defects to encourage bone mending and expedite the healing process. [12]

Dental problems are a serious public health concern in every country, affecting people of all periods, races, and genders. In recent times the frequency of oral illness has regions dramatically. Dental diseases affect over 70 of the population. Major oral diseases such as tooth caries, dental decay, periodontal infections, and dry sockets impact the mortal population. Periodontitis is a localized inflammation response caused by bacterial infection of a periodontal pocket associated with a subgingival shrine. It's an infection of periodontium. Periodontal complaint is a general term encompassing a group of inflammation pathology that substantially includes gingivitis and periodontitis. The periodontium is itself a marquee term that comprises a number of different structures. In the periodontal complaint, there's a confirmation of a gap between epoxies and teeth called 'pockets'. This fund provides an ideal niche for anaerobic pathogenic bacteria to develop and multiply. Clinically, the periodontal fund which is slightly deeper than the sulcus of a healthy tooth

deepens as the condition advances resulting in additional damage of the tooth's supporting towel and, In numerous cases, tooth loss. Periodontal ligament, alveolar bone cementum. According to who it's extensively spreadable habitual complaint around the world.it begins with the accumulation of shrines around teeth which form a microbial biofilm with bacterial followed by localized inflammation of gingiva [13].

The inflammation in the periodontal towel is initiated by microbial shrines and bacterial infection. In the periodontal fund, the bacteria form

a largely structured and complex biofilm. As this continues, the biofilm reaches for subgingival, and it becomes difficult for the case to 1 reach it during oral hygiene practices. Traditional treatment options for similar conditions include mechanical debridement aimed at removing the subgingival foliage and furnishing a clean, smooth and compatible root face. But, in several cases, the complex deconstruction of the root and the position of the lesion may hinder the treatment and help sufficient 2 reduction of the bacterial cargo. [13,14,15]

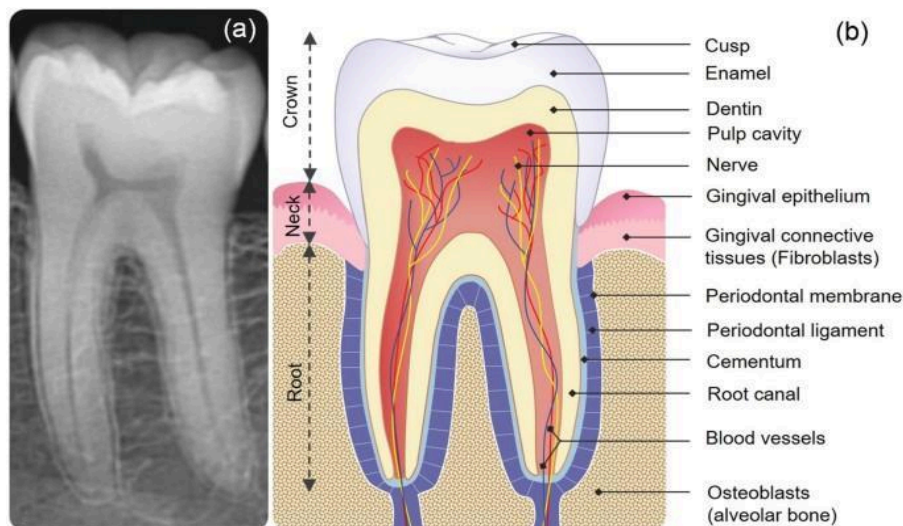


**Fig 1: Difference between the healthy tooth and infected tooth [14]**

Periodontitis is an infection-driven seditious complaint in tooth-supportingnapkins [ i.e., the periodontium]. also, genetics and environmental and behavioural factors are involved in the development of the complaint, the exposure of susceptible individualities to its inauguration, and the speed of progression. The structure of the periodontium is different; it's composed of the gingiva, the underpinning connective towel, cement on the root face, alveolar bone, and the periodontal ligament between the cementum and alveolar bone. The junctional epithelium of the gingiva is a unique structure, located at the bottom of the gingival sulcus, which controls the constant presence of

bacteria at this point. The most characteristic point of periodontitis is the activation of osteoclast birth and the destruction of alveolar bone as its consequence, which is unrecoverable and leads to loss of tooth support [15,16]

The complex structure of the periodontal biofilm, conforming of multiple bacterial communities abiding in a glycocalyx matrix, has been well described by Marsh [14]. It has been demonstrated that formerly bacteria attach to a tooth face and live within a mature biofilm structure, they've reduced vulnerability to antimicrobials compared with planktonic or free-floating bacteria [15].



**Fig. 2 Structure of periodontium [16]**

Thus, mechanical debridement is considered critical to disrupting the biofilm when using systemic antibiotics to treat periodontitis. The explanation for the use of spare systemic antimicrobials is to further reduce the bacterial cargo, enabling resolution of the inflammation in the periodontal pocket antibiotics may be specified for periodontal cases who don't respond to conventional mechanical remedies, for cases with acute periodontal infections associated with systemic instantiations, for prophylaxis in medically compromised cases, and as an adjunct to surgical and non-surgical periodontal remedy. operation of antibiotic periodontal remedy focuses on the pathogenic microbiota, the case, and the choice of medicine [16,17,18]

## II. STAGES:-

There are substantially four stages in periodontal conditions which include different clinical sign & symptoms and radiological webbing is given as follows:-

2.1. Gingivitis It's the only stage when periodontitis can be reversible. At this stage the sanctum conformation around teeth occurs. There are

mainly numerous royal symptoms seen at this stage analogous as bad breath, blown sanguine bonds and bleeding while brushing and flossing. It can be reversed by maintaining good oral hygiene and regular checks. Generally, 1- 2 mm clinical attachment loss, lower than 15 of bone loss around root, probing depth 4 mm or lower occurs.

2.2. Early stage It's the alternate stage of the periodontal complaint. It's manageable by oral hygiene but not reversible. At this stage, the infection starts spreading to girding napkins and starts slighting it. Symptoms at this stage include inflammation of bonds, severe bad breath, and bleeding during brushing or flossing, distance between teeth becomes apparent and will gradually increase. also, 3- 4 mm clinical attachment loss, lower than 15- 33 of bone loss around the root, probing depth 5 mm or lower occurs(18,19).

2.3. Moderate stage Like the alternate stage, the moderate stage can't be reversed. The same symptoms as the moderate stage occur but space between teeth and recessions of bonds are more apparent. Treatment like deep cleaning, scaling and distraction surgeries can be done at this stage.



Around 5 mm or farther clinical attachment loss, 33 of tooth loss of four teeth or lower, with complex issues analogous as probing depth 6 mm or further, Class II-III furcations and moderate crest scars.

2.4. Advanced position 50 – 90 of periodontal napkins are lost during the final stage of the periodontal complaint. fresh symptoms include pus-filled, swollen epoxies, loosening of the teeth, perceptivity to cold, painful chewing, and severe

halitosis. More voids or gaps between teeth and epoxies, goo recession, patient needling dentures, and other potentially worse health issues are affected by not treating it. Treatment for periodontitis can include routine examinations, cleanings, and upholding proper dental hygiene. lower than 20 teeth(10 opposing dyads) remain after secondary occlusal trauma, significant crest abnormalities, suck collapse, and pathologic migration of teeth.

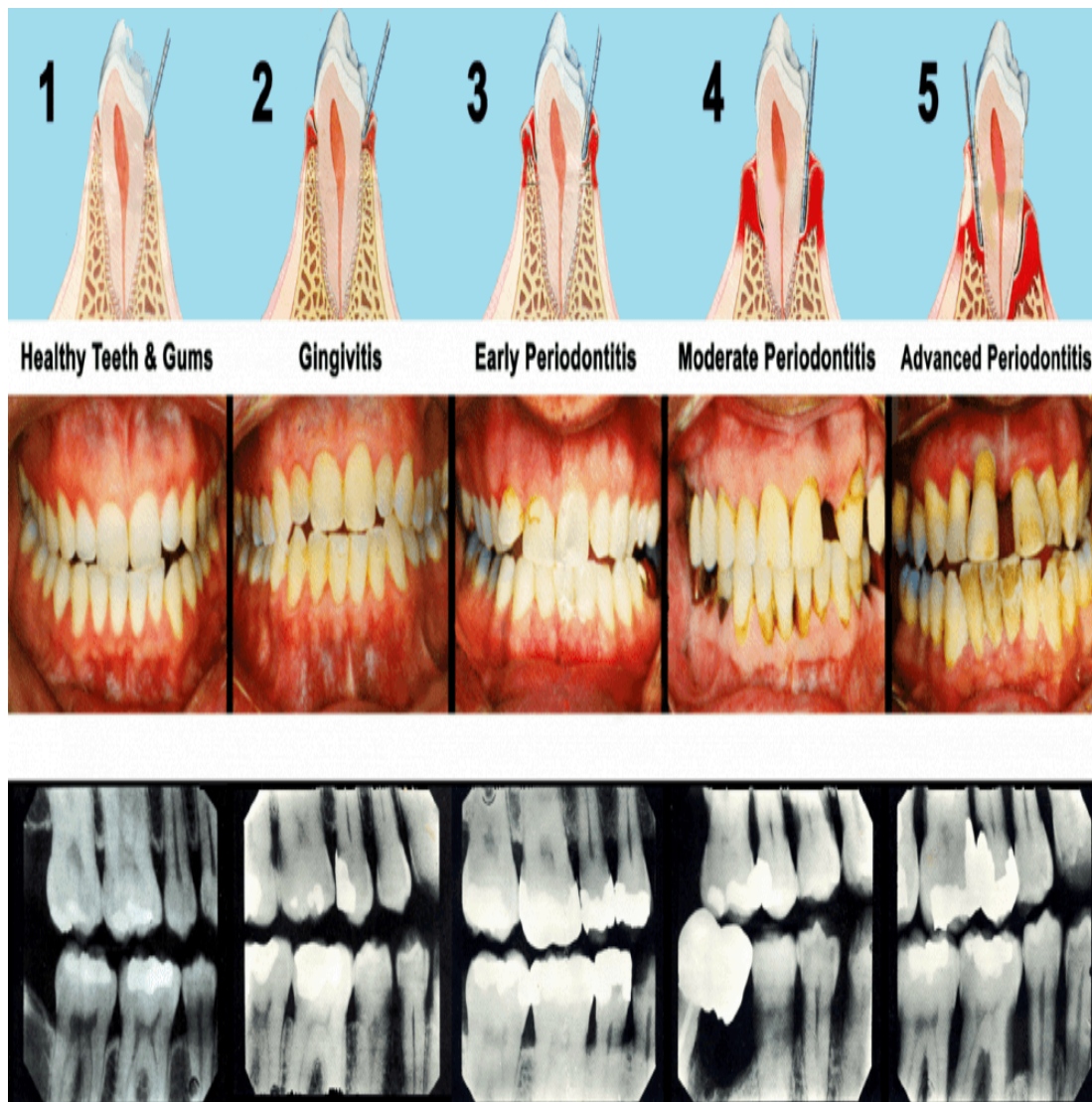


Fig 3: Various phases of periodontitis [21]

### Treatments:

1. Use mechanical techniques such as root planning and scaling.
2. Systemic antibiotics are utilized in antimicrobial therapy
3. Local drug distribution systems (LDDS models)

### 2. Types of Periodontitis

The pathophysiology and etiology of periodontal disease

**2.1. Gingivitis:-** Gingivitis, as preliminarily mentioned, is an inflammation of the epoxies that can be averted by rehearsing good oral hygiene.(19,20)

**2.2. habitual periodontitis:-** This periodontal complaint can beget severe bad breath, bleeding when brushing or flossing, and patient goo vexation. loss of bone, ligaments, and epithelium that can notbe reversed(20)

**2.3. Aggressive periodontitis:-** This early-onset habitual periodontal seditious complaint generally appears between puberty and the morning of the third decade of life. It can be localized or generalized. The same symptoms as habitual periodontitis are present.(21)

**2.4. Necrotizing ulcerative gingivitis:-** HIV, immunosuppressants, and malnutrition are the main causes of this condition. Necrosis is the death of a live towel or cell. It generally happens as a result of shy food requirements.(22).

**2.4.1. Peri-implant mucositis:-** This condition is characterized by soft towel inflammation around dental implants without any substantiation of bone loss. Red or sore epoxies around implants and bleeding after brushing were among the symptoms(23).

**2.5. Systemic habitual periodontitis:-** Cases with systemic pattern are susceptible to this kind of habitual periodontal complaint. Goo inflammation is a result of systemic ails similar diabetes, heart complaint, and respiratory diseases.

### III. ETIOLOGY AND PATHOGENESIS OF PERIODONTAL DISEASE

The term "periodontic disease" describes the inflammatory reactions that bacteria, or dental plaque, leave on teeth, causing damage to the tissues around the teeth. The body reacts to the bacterial accumulations by becoming inflamed. Alveolar bone loss and tissue adhesion to the teeth are caused by a persistent and progressive bacterial infection of the gums. There are several phases or states of periodontal disease, from mild gingivitis that is easily treated to severe periodontitis that is incurable. A number of risk factors, including smoking cigarettes, systemic disorders, prescription drugs for cancer therapy,antiepilepsy,steroids, and ill-fitting bridges, misaligned teeth and loose fillings, pregnancy, and usage of oral

contraceptives, enhance the risk of periodontal disease.

Apart from these factors, any medical condition like HIV infection, diabetes, or diseases involving neutrophils, which activate the host's antibacterial defenses, will probably exacerbate periodontal disease. Gingivitis, a moderate form of periodontal disease, is the most common type. Seventy-five percent of adults in the US have

gingivitis, which is characterized by gum irritation, redness, swelling, and frequent bleeding. Advanced types of periodontitis are also common, impacting over 30% of adults in the US with moderate disease and 10% with advanced disease. Though the symptoms are similar to those of gingivitis, they are more severe because of increased bacterial accumulations and heightened inflammatory reactions. [23,24]

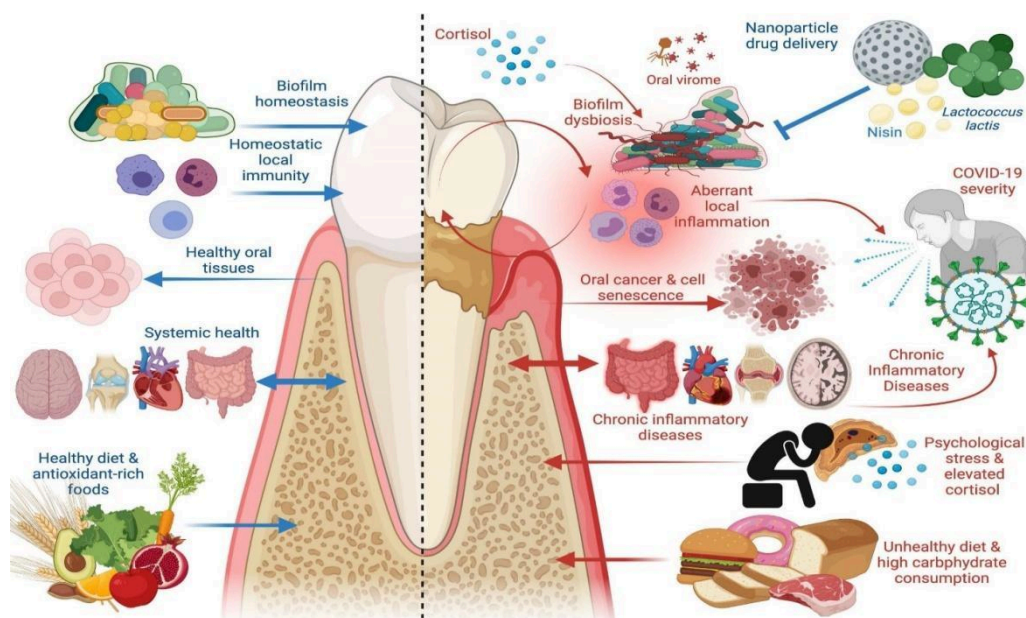


Fig No.4 Etiology and pathogenesis of periodontal disease [22]

Healthy dietary components, homeostatic immunity in gingival and periodontal tissues, supra- and subgingival biofilm homeostasis, and the absence of chronic inflammatory illness at distant locations are all elements that support periodontal health. In turn, healthy periodontal tissues lower the risk of oral carcinogenesis and have a reciprocal effect on systemic health, lowering the risk of chronic inflammatory diseases.

The right panel shows the elements that lead to periodontal disease: biofilm dysbiosis; unchecked gingival and periodontal inflammatory reactions; psychological stress accompanied by increased cortisol release; and poor diets with a

high carbohydrate content. In addition to its negative effects on oral tissue health, periodontal disease also increases the risk of oral carcinoma, causes healthy cells to undergo cell senescence, aggravates systemic inflammation, and increases the risk of chronic inflammatory diseases such as inflammatory bowel disease (IBD), cardiovascular disease, autoimmune disorders, and Alzheimer's disease.

The severity of COVID-19 and unfavorable outcomes have been linked to periodontal disease and other systemic chronic inflammatory illnesses. Novel approaches to therapy have surfaced, including the use of

nanoparticle drug delivery systems in conjunction with bacteriocins like nisin and oral probiotics like *Lactobacillus acidophilus*, which can restore biofilm homeostasis and reduce aberrant inflammation.

The probing depth is a useful tool for determining the amount of periodontal disease and how far along the illness is. The periodontal pocket is less than 2 mm deep and there is no loss of epithelial attachment or pocket formation in a healthy periodontium. Periodontal pockets have a maximum length of 12 mm. Clinically, periodontitis is diagnosed in patients with periodontal pockets that are four millimeters or larger. Individuals with advanced or severe periodontitis are diagnosed with periodontal pockets measuring six millimeters or more. Many people fail to treat gingival bleeding and attachment loss because of their mild symptoms. If gingivitis is not treated, it can develop into permanent periodontitis and cause tooth loss [24,25].

Most periodontal disorders are successfully treatable once they are diagnosed. The first step in treating periodontal disease is to change or eradicate the source of the bacteria and associated risk factors. This will stop the disease from getting worse and keep the periodontium in a healthy state. Second, it's important to stop periodontitis from returning. Ultimately, in extreme situations, an attempt at periodontal attachment regeneration must be made. Scaling and root planning are two specific cleaning procedures that are part of the first nonsurgical stage. An antiseptic mouthwash and medication may be used as additional treatments, either to speed up the healing process or to manage the bacterial infection.

Antibiotics are frequently used, and they might be a useful substitute for scaling and root planing. To eradicate a wide variety of bacteria, tetracycline or a mix of metronidazole and amoxicillin can be utilized. Overuse of these

substances, though, could prevent the germs from dying. Because there are so many different species living in the plaque, another disadvantage of antibiotic therapy is how hard it is to pinpoint and eliminate a particular infection. Patients with periodontal disease may potentially benefit from surgical treatment in addition to antibiotic medication. Surgery is obviously required to try to stop tooth loss if the periodontal pockets are not reduced or if more alveolar bone loss is seen [26].

A periodontist's surgical approach to treating periodontal disease involves excising inflammatory tissues to lessen the harm done to the alveolar bone surrounding the infection site. Moreover, surgery gives dentists access to places where plaque and tartar are impossible to remove with scaling and root planning. In order to lessen pockets, bacterial accumulations must be removed in order to promote bone and tissue regeneration. Bone grafts and other operations aim to promote bone growth and regeneration. In order to prevent additional gum recession and bone loss if the periodontal disease has resulted in an excessive loss of gum tissue, soft-tissue grafts may be necessary. [27]

The oral cavity is an open system that is in contact with the outside world. Moreover, the likelihood of foreign material entering the system through the oral cavity is increased because food and beverages are constantly consumed through the mouth. Through the activation of host defense cells, which in turn manufacture and release mediators that drive the effectors of connective tissue breakdown, the presence of vast numbers of bacteria can indirectly cause tissue damage. Microbial plaque constituents have the ability to trigger the first wave of inflammatory cell infiltration, involving lymphocytes, macrophages, and polymorphonuclear leukocytes (PMNs). [27]

#### IV. MATERIAL AND METHODS: -



Dental cones are used in endodontic procedures to fill the area inside a tooth's root after it has been cleaned and shaped. They are also referred to as root canal cones or gutta-percha cones. These dental cones can be made using a variety of techniques and materials, but the main kinds are as follows:-

### 1. Gutta-Percha Cones

**Material:**Gutta-percha, a natural rubber-like material, is the most commonly used material.

**Formulation:**Gutta-percha is formulated with zinc oxide, waxes, resins, and other materials to improve its handling characteristics. The cones are made by heating the gutta-percha mixture, shaping it into the desired cone shape, and then cooling it.

### 2. Resilon Cones

**Material:**Resilon, a thermoplastic synthetic polymer-based material.

**Formulation:**Resilon is combined with bioactive glass and other fillers. The cones are manufactured by extruding the Resilon mixture and then cutting it into the required shape.

### 3. Calcium Silicate-Based Cones

**Material:**Calcium silicate, a bioceramic material.

**Formulation:**These cones are formulated with calcium silicate cement, providing bioactive properties that promote healing and sealing. The material is molded into cone shapes.

### 4. Hydrophilic Polymer Cones

**Material:**Hydrophilic polymers, which absorb moisture and expand.

**Formulation:**These cones are made by combining hydrophilic polymers with other materials that expand upon contact with fluids, ensuring a tight seal within the root canal.

### 5. Custom-Made Cones

**Material:**Typically, gutta-percha or bioceramic.

**Formulation:**Custom-made cones are tailored to the specific anatomy of the patient's root canal. This involves heating and adapting the material to the canal shape for a more precise fit.

### 6. Silver Point Cones (Historical)

**Material:**Pure silver.

**Formulation:**Historically, silver was used to create cones by cutting and shaping silver points to fit into the root canal. However, this method is largely outdated due to corrosion issues and is not commonly used today.

These methods vary depending on the desired properties such as biocompatibility, sealing ability, and ease of use. Each type of cone has its own advantages and specific clinical applications. [28]

#### 4.1 Marketed Formulations of Dental Cones Based on Types -

##### 1. Gutta Percha Cones

**Product Name** -Waldent Gutta Percha Points 4% #20

**Product Description** - Waldent Gutta Percha Points 2% is a Early root Canal filling material. It is a thermoplastic filling material that is heated and compressed into the canal(s) of the tooth which is then sealed with adhesive cement.

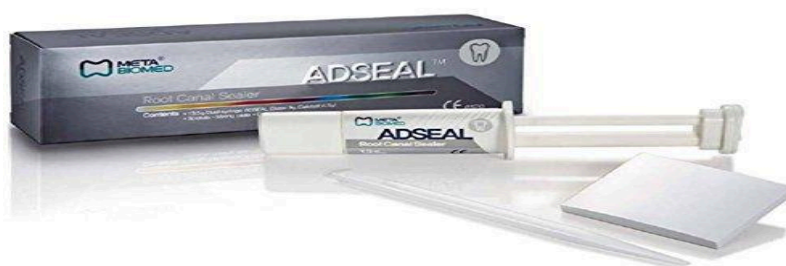


**Advantages** -Made from the Finest Gutta Percha Uniformly Hand Rolled.  
 Stiff but flexible to provide ideal working qualities.  
 Uniform and non-distorting crimp.  
 Radiopacity.  
 Long shelf life and freshness assured [29]

## 2. Resilon Based Root Canal Sealer

**Product Name** -Meta Adseal (Resin Based RC Sealer)

**Product Description** - ADSEAL is a epoxy resin based root canal sealer which is a paste - paste type of dual syringe. It had a outstanding chemical and physical property including extremely excellent sealing property and biocompatibility.



**Advantages** –

Easy to mix paste.  
 Hermetic sealing ability.  
 Non staining to teeth.  
 Excellent biocompatibility [30]

## 3. Calcium Silicate-Based Cones

**Product Name** –CeraSeal Calcium Silicate – Based Bioceramic Root Canal Sealer.

**Product Description** –Meta CerasealRc Sealer is the second generation of bioceramic sealers, which has extraordinary insulator capabilities.



#### Advantages –

- Excellent sealing ability.
- It prevents from propagation of the bacteria.
- Ceraseal never shrinks and expands in root canal.
- It prevents from odontoclasia by keeping its stable volume.
- Prevents from wash - out phenomenon.[31]

#### 4. Calcium Hydroxide Cones

**Product Name** - Dentsply Dycal Calcium Hydroxide

**Product description** - Dentsply Dycal Ivory Calcium Hydroxide Composition is a rigid, self-setting material useful in pulp-capping, and as a protective base/liner under dental filling materials. It will not inhibit the polymerization of acrylic and composite restorations.



**Advantages –**

Strong at critical time of condensation.  
 Easy to place, with ability to flow where needed while it stays in place when necessary.  
 Shown to protect the pulp and promote the formation of secondary dentine to engender confidence in performance. [32]

**6. Evaluation of dental formulations**

**Surface pH Measurement:-**

**Purpose:-**

To determine the pH of the dental cone's surface when it comes in contact with a moist environment (like oral conditions). This is crucial as the pH can affect the local environment in the mouth and the potential for irritation or damage to surrounding tissues.

**Procedure:** -A small sample of the dental cone is placed in distilled water, and the surface pH is measured using a pH meter or pH paper after a specific time interval (usually 2-4 hours). The pH

should ideally be close to neutral (around 7) to avoid irritation.

**2.Swelling Index :-**

**Purpose:-** To measure the ability of the dental cone to swell upon contact with moisture. This is particularly important for drug delivery systems where swelling can affect drug release kinetics.

**Procedure:** The initial weight of the dental cone is recorded. It is then immersed in a medium (e.g., phosphate buffer solution) for a predetermined time period. After immersion, excess water is removed, and the swollen sample is weighed. The swelling index is calculated using the formula:  

$$\text{Swelling Index (\%)} = \frac{(W_t - W_0)}{W_0} \times 100$$
 where (W<sub>t</sub>) is the weight at time (t), and (W<sub>0</sub>) is the initial weight.

**3. Drug Content Estimation:-**



**Purpose:** To quantify the amount of drug present in the dental cone. This test ensures that the dosage is consistent and within the therapeutic range.

**Procedure:** The dental cone is dissolved or extracted in a suitable solvent, and the solution is analyzed using techniques like UV-Vis spectroscopy, High-Performance Liquid Chromatography (HPLC), or other suitable analytical methods. The drug content is calculated by comparing it with a standard calibration curve of the pure drug.

#### 4. In Vitro Drug Release Study

**Purpose:** To determine the rate and extent of drug release from the dental cone over time. This test is crucial to predict the performance of the dental cone in delivering the drug at a controlled rate.

**Procedure:** The dental cone is immersed in a dissolution medium (such as phosphate buffer saline, pH 7.4) and maintained at a temperature that mimics physiological conditions (usually 37°C). At specific time intervals, samples are withdrawn and replaced with fresh medium to maintain sink conditions. The amount of drug released is then measured using appropriate analytical techniques (like UV-Vis spectroscopy or HPLC). The cumulative release is plotted against time to obtain the release profile.

**5. Other Potential Tests Sterility Testing:** To ensure the dental cones are free of microbial contamination.

**Mechanical Strength Testing:** To evaluate the cone's ability to withstand the forces experienced during application.

**Biocompatibility Testing:** To assess the safety of the material in contact with tissues. [33]

#### V. CONCLUSION:-

Dental cones formulated with biodegradable polymers and azithromycin offer a

promising advancement in the treatment of periodontal diseases, particularly periodontitis. These cones provide a localized, controlled release of antibiotics directly into periodontal pockets, effectively targeting bacterial infections and promoting tissue healing. This novel approach overcomes many of the limitations associated with traditional therapies, such as systemic antibiotic resistance and incomplete bacterial eradication. By enhancing localized antibacterial action and supporting tissue regeneration, dental cones represent a significant step forward in managing periodontal disease and improving post-extraction recovery. Further research and clinical trials could expand their use and optimize their efficacy, particularly in severe periodontal cases.

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