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Original Article

Formulation and Evaluation of Clindamycin Loaded Biodegradable Dental Cones for Sustained Drug Release in Post-Extraction Management

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ABSTRACT

Objectives: Dental diseases affect nearly 70% of the global population, often leading to extractions due to periodontitis, caries, or trauma. Post-extraction complications such as bacterial infections, pain, inflammation, and bleeding hinder healing. This study aims to develop clindamycin-loaded dental cones as a localized drug delivery system to manage post-extraction complications effectively. **Materials and Methods:** Dental cones were prepared using gelatin and agar-agar via the mold-filling method. The formulations were evaluated for *in vitro* drug release, antibacterial efficacy, swelling index, and stability. Drug release kinetics were analyzed using zero-order, first-order, Higuchi, and Korsmeyer-Peppas models. Antibacterial activity was tested against Staphylococcus aureus and *Escherichia coli* using the agar disc diffusion method. Stability was assessed under refrigeration for one month. **Results:** *In vitro* drug release studies demonstrated a gradual and controlled release over five days, with the F8 formulation exhibiting the highest cumulative release. Drug release in formulations F7 and F8 ranged from 2.97% to 82.06% and 2.17% to 86.53%, respectively. Antibacterial studies confirmed the effectiveness of these formulations against *Staphylococcus aureus* and *Escherichia coli*, highlighting their potential for infection control. Swelling index analysis showed that F8 exhibited the highest swelling (43%), correlating with sustained drug release. Kinetic modeling indicated that drug release followed the Higuchi model and zero-order kinetics, suggesting a controlled diffusion mechanism. Stability evaluations indicated that refrigeration maintained the integrity and effectiveness of the cones over time. **Conclusion:** The biodegradable clindamycin dental cones provide sustained drug release, infection control, and reduced inflammation, offering an alternative to conventional post-extraction treatments while minimizing systemic side effects. Their stability and therapeutic efficacy make them a promising advancement in dental therapeutics.

Keywords: Dental cones, Post-extraction management, Local drug delivery, Clindamycin, Sustained release, Antibacterial efficacy, Dental therapeutics.

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INTRODUCTION

Globally, around 70% of the population experiences dental issues, necessitating various dental procedures, including extractions. The frequency of tooth extractions varies across different regions, with distinctions observed between Western and non-Western countries (Broers *et al.*, 2022). The rate of extractions is often considered an indicator of a country's oral health status and socioeconomic conditions. Several factors contribute to the need for permanent tooth extractions, including dental caries, periodontal diseases, orthodontic issues, failed dental treatments, prosthetic needs, impacted teeth, and other underlying conditions. Understanding the causes behind extractions is essential for improving oral healthcare strategies. Various cross-sectional studies across different nations have analyzed the primary reasons for tooth loss. Some studies suggest that periodontal disease is the leading cause, whereas others report that dental caries remains the predominant factor. However, certain research

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findings indicate that periodontal disease accounts for a higher proportion of extractions in specific populations (Jafarian and Etebarian, 2013).

Following a tooth extraction, complications may arise, some of which can be severe or even life-threatening if not managed appropriately. Early identification and intervention by dental professionals are crucial in minimizing risks. Several factors contribute to post-extraction complications, including inadequate administration of local anesthesia, incomplete extraction, tooth or root fractures, alveolar bone fractures (such as maxillary tuberosity fracture), oro-antral communication, accidental displacement of a tooth/root into surrounding tissues, aspiration of tooth fragments, damage to adjacent soft tissues, excessive bleeding, temporomandibular joint dislocation, nerve injury, thermal burns, and mandibular fractures. It is imperative that patients receive detailed postoperative care instructions to mitigate these risks and promote smooth recovery (Goswami *et al.*, 2020).

Common post-extraction complications include pain, swelling, haemorrhage, trismus, dry socket, and infections. Managing these complications typically involves systemic and local therapies. However, conventional systemic treatments present significant drawbacks, such as insufficient antibiotic concentrations at the periodontal site, rapid decline of plasma drug levels below therapeutic efficacy, increased bacterial resistance, and potential adverse effects due to high peak plasma concentrations (Jain *et al.*, 2008).

Local drug delivery has been explored as an alternative to systemic therapy. Various methods, such as subgingival irrigation with antibiotic solutions or gels, have been used. However, these agents are quickly eliminated by gingival fluid, reducing their effectiveness (M, 1989). Other localized treatment options include biodegradable membranes, Platelet-Rich Fibrin (PRF), and bone graft materials, but these come with limitations such as handling difficulties, inconsistent therapeutic effects, and high costs (Sasaki *et al.*, 2021; Ahmed *et al.*, 2019). To address these challenges and enhance treatment effectiveness, dental cones have emerged as a preferred approach for post-extraction care (Hiwe *et al.*, 2022). Dental cones are solid, cone-shaped formulations designed to be inserted into the tooth socket following extraction (Advankar *et al.*, 2019). These cones deliver sustained antibacterial effects and help control post-extraction complications, such as infections and excessive bleeding (Lachman *et al.*, 1987). The primary advantages of dental cones include precise localized drug delivery, controlled drug release, reduced systemic side effects, and improved stability of medications that degrade in the gastrointestinal tract or undergo extensive first-pass metabolism (Advankar *et al.*, 2019). By providing sustained drug release directly at the extraction site, dental cones present a promising alternative to conventional therapies for post-extraction complications.

MATERIALS AND METHODS

Materials

Clindamycin phosphate, (gift sample from Bhavani Pharmaceuticals Hubli) gelatin, agar-agar, PEG 400, glutaraldehyde 25%, sodium benzoate, di-sodium hydrogen ortho phosphate, potassium di-hydrogen phosphate, etc.

Methods

Drug Compatibility Studies - FTIR Spectroscopy

The compatibility of the Active Pharmaceutical Ingredient (API) with excipients was assessed using Fourier Transform Infrared (FTIR) Spectroscopy, an essential pre-formulation study for predicting the stability and shelf-life of the dosage form. A 1:1 ratio of the pure drug and excipients was mixed uniformly to create a physical mixture, which was then subjected to FTIR spectral analysis to evaluate any potential chemical interactions between the drug and excipients. The obtained infrared spectra were analyzed for any significant shifts or alterations in characteristic peaks.

Design of dental mould

A custom dental mould was fabricated using anti-corrosive brass material to ensure durability and precision. The mould was manufactured at M/s Patil Workshop, Shiggaon and designed specifically for preparing dental cones. To achieve the required frustum shape, grooves were drilled into the brass block using a drilling machine with Beat No. 12. The groove dimensions were selected based on the desired cone structure, with an upper diameter of 12 mm, a lower diameter of 9 mm, and a total length of 16 mm.

Design of dental cone

The dimensions of the dental cones were determined based on the anatomical size of the alveolar socket. Resorba Medical GmbH, 2021. Illustrates the dimensions of commercially available PARASORB® cones, which are widely utilized to minimize alveolar ridge atrophy following tooth extraction. Table 1 presents the average dimensions of molar tooth sockets, which served as a reference for formulating the design specifications of the dental cones developed in this study.

Since the cones developed in this study were specifically designed for molar tooth sockets, their dimensions were tailored accordingly. Additionally, as the prepared cones follow a matrix-based structure, they can be further adjusted by trimming to achieve the required size.

Preparation of dental cones

The dental cones were formulated using biodegradable natural polymers to ensure biocompatibility and sustained drug release. Initially, a weighed quantity of gelatin was dispersed in an

adequate amount of distilled water and allowed to hydrate for 30 min. The hydrated gelatin solution was then continuously stirred in a water bath maintained at 60±5°C until complete dissolution. Once the gelatin was fully dissolved, the co-polymer agar-agar was added, followed by glutaraldehyde as a crosslinking agent and PEG 400 as a plasticizer, solubility enhancer, and stabilizer. Continuous stirring ensured uniform consistency. In a separate step, the drug and preservative were dissolved in a small volume of water before being incorporated into the polymeric solution to achieve a homogeneous mixture. The final mixture was then slowly poured into a pre-glycerinated and cooled dental mould, ensuring even distribution. The solution was left undisturbed for 5 min, after which the mould was placed in an ice bath for 30 min to facilitate solidification. Once the cones had set, they were carefully removed and stored at 4°C in a refrigerator until further use. Each dental cone contained 26 mg of clindamycin phosphate, ensuring localized and sustained drug release at the site of application (Hiwe *et al.*, 2022). Table 2 outlines the formulation details of the dental cones used in this study.

UV Estimation

A stock solution of clindamycin phosphate (100 µg/mL) was prepared using phosphate-buffered saline (pH 6.8). Appropriate aliquots from the stock solution were pipetted into separate 10 mL volumetric flasks and diluted with the same buffer. The working standard solutions were scanned within the UV range of 200-400 nm using a Shimadzu UV-1900 spectrophotometer (Smith *et al.*, 2019).

In vitro Flux Determination of Clindamycin Phosphate Drug

The Franz diffusion apparatus was used for the study. A dialysis membrane, pre-soaked for 24 hr, was secured to the donor compartment with a rubber band. A 20 mg/mL drug solution was prepared in phosphate buffer (pH 6.8) and added to the donor compartment, while the receptor compartment contained phosphate buffer. At specific time intervals over 24 hr, samples were withdrawn from the receptor compartment and analyzed using a UV spectrophotometer. The drug flux was calculated using the formula J = m / A t. (Jones and White, 2020).

Surface pH

To assess potential irritation in the oral cavity, the surface pH of the dental cones was evaluated. The cones were allowed to swell in 5 mL of phosphate buffer (pH 6.8±0.05) for a short period. A combined glass electrode was placed on the cone surface and allowed to equilibrate for 1 min to measure pH. Since acidic or alkaline pH can cause mucosal irritation, efforts were made to maintain a surface pH close to neutral (Kumar *et al.*, 2018).

Hardness

The hardness of the dental cones was tested at room temperature using a Monsanto hardness tester. Three cones from each batch were selected for hardness testing (Lee *et al.*, 2017).

Swelling Index

Dental cones were weighed initially (Wo) and immersed in simulated gingival fluid (pH 6.8, 37±0.5°C) on a petri dish for 30 min. After removing excess buffer with filter paper, the swollen cones were re-weighed (Wt). The swelling index was calculated using the formula (Rajendran and Gupta, 2021).

$$S.I = (wt\text{-}w0) \times 100/w0$$

Drug Content Estimation

To determine drug content uniformity, each dental cone was dissolved in 100 mL of phosphate buffer (pH 6.8) and kept for 1 hr with intermittent shaking. The solution was then filtered using Whatman filter paper, and 10 mL of the filtrate was analyzed using a UV spectrophotometer at 207 nm (Shimadzu 1900, Japan; Verma *et al.*, 2018).

In vitro Dissolution

Dental cones were placed in 10 mL vials containing 8 mL of pre-warmed phosphate buffer (pH 6.8) at 37°C. The setup was kept in an incubator at 37°C without agitation to simulate the stagnant intrapocket condition. At predetermined intervals (1, 3, 5, 24, 48, 72, 96, and 120 hr), aliquots were withdrawn, replaced with an equal volume of fresh buffer, and analyzed using a UV spectrophotometer. Placebo dental cones were used as blanks to eliminate polymer interference (Sharma and Patel, 2019; Gupta and Singh, 2020).

In vitro Antibacterial Study

Nutrient agar medium (50 mL) was prepared and sterilized at 15 lb pressure for 20 min in an autoclave. Under aseptic conditions, 20 mL of sterile nutrient agar was poured into petri plates. Once solidified, 0.1 mL of microbial suspension containing *E. coli* and *S. aureus* was spread onto the media. Sterile discs (6 mm diameter, 5 mm thickness) containing the optimized dental cones (F7 and F8) and a standard drug solution were placed on the agar surface. The plates were incubated at 37°C for 24 hr, after which the zone of inhibition was measured and compared (Rao *et al.*, 2018).

Stability Studies

The most effective formulations, F7 and F8, were selected for stability studies. The dental cones were stored at 2-8°C for one month, and their stability was evaluated at the end of the storage period (Singh and Yadav, 2017).

Kinetic Data Analysis and Drug Release Models

The data obtained from the *in vitro* drug release studies were analyzed using various mathematical models, including the zero-order, first-order, Higuchi model, and Korsmeyer-Peppas model, to determine the release kinetics and mechanism of drug release from the dental cones. The most suitable model was selected based on the best-fit analysis (Patel and Kumar, 2020).

RESULTS

UV Estimation of Clindamycin Phosphate

The stock solution of clindamycin phosphate was analyzed within the wavelength range of 200 nm to 400 nm, and the maximum absorbance was observed at 207 nm (Figure 1) in a phosphate buffer with a pH of 6.8.

Standard Calibration Curve of Clindamycin

The standard calibration curve of the pure drug demonstrated good linearity, with a regression coefficient (R^2) of 0.9766. The drug followed Beer's law within the concentration range of 20 to 120 µg/mL in phosphate buffer at pH 6.8. The equation derived from the calibration curve was y = 0.0042x+0.00526, which was utilized for calculating the drug content and *in vitro* drug release studies.

Compatibility studies: FTIR Studies of clindamycin phosphate and dental cone

The samples were scanned in the region of 4000-400 cm^{-h} for FTIR studies. Pure clindamycin phosphate showed characteristic peaks.

The FTIR analysis was conducted by scanning the samples in the range of 4000-400 cm^{-1}. as shown in Figures 2 and 3 Pure clindamycin phosphate exhibited characteristic peaks at 2978 cm^{-1} (N-H stretching), 1640 cm^{-1} (C=O stretching), 1450 cm^{-1} (C-H bending), 1248 cm^{-1} (C-O stretching), and 1182 cm^{-1} (C-O tertiary alcohol). The FTIR spectra of the drug-polymer mixture displayed peaks at 2951 cm^{-1} (N-H stretching), 1688 cm^{-1} (C=O stretching), 1467 cm^{-1} (C-H bending), 1254 cm^{-1} (C-O stretching), and 1155 cm^{-1} (C-O tertiary alcohol). The FTIR spectrum of the pure drug was comparable to the reference standard clindamycin spectrum found in the IP Pharmacopoeia. A drug compatibility study with polymers was performed, confirming that all characteristic peaks of clindamycin phosphate remained unchanged in the polymer mixture. This demonstrated that there was no interaction between the drug and excipients, indicating that the selected excipients were suitable as drug carriers.

In vitro flux determination of clindamycin phosphate

In vitro flux studies of clindamycin phosphate API were conducted over 24 hr using a modified Franz diffusion apparatus, resulting in a flux of 2.69 µg/cm^2/hr.

Table 1: Dimension of molar tooth socket.

Molar	Crown width (M-D)	Root width at CEJ (M-D)	Root width at CEJ (B-L)	Root length	Trunk length
Max first	10.4 mm	7.9 mm	10.7 mm	13 mm	4.1 mm
Max second	9.8 mm	7.6 mm	10.7 mm	12.8 mm	4.2 mm
Mand first	11.4 mm	9.2 mm	9.0 mm	13.5 mm	3.27 mm
Mand second	10.8 mm	9.1 mm	8.8 mm	13.5 mm	3.28 mm

M-D = mesiodistal; B-L = buccolingual; max = maxillary; mand = mandibular.

Table 2: Formulation of dental cones.

Sl. No.	Ingredients (%w/v)	F1	F2	F3	F4	F5	F6	F7	F8
1	Clindamycin phosphate	2%	2%	2%	2%	2%	2%	2%	2%
2	Gelatin	7.5%	15%	7.5%	15%	7.5%	15%	7.5%	15%
3	Agar Agar	2%	2%	5%	5%	2%	2%	5%	5%
4	PEG (400)	20%	20%	20%	20%	30%	30%	30%	30%
5	Glutaraldehyde (25%)	0.l%	0.l%	0.l%	0.l%	0.l%	0.l%	0.l%	0.l%
6	Sodium benzoate	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
7	Distilled water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

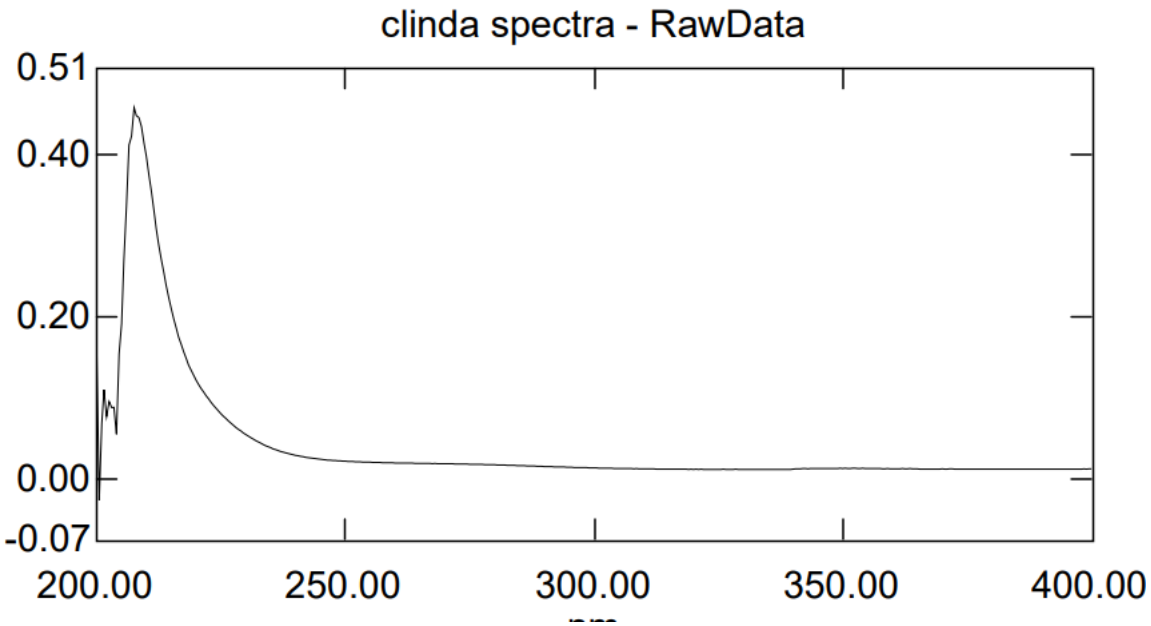

Figure 1: λ_{max} of clindamycin phosphate.

Evaluation of Dental Cones

Surface pH

The surface pH of all formulations was within the gingival pH range of 6.1 to 6.74, with values recorded between 6.1 and 6.4 for the prepared batches. The detailed values are provided in Table 3.

Swelling index

The swelling index was determined based on the percentage of water absorbed at room temperature. Formulation batches F1 to F8 exhibited varying swelling indices. Among them, formulation F8 displayed the highest swelling, reaching 21.87±0.25%.

Drug content

The drug content across formulations ranged from 95.8±3.2% to 100.97±4.9%, indicating efficient drug loading and uniform distribution. The detailed values for all batches are listed in Table 3.

Hardness

The hardness of the dental cones varied between 2.6±0.47 to 5.3±0.47 kg/cm², demonstrating good compressibility, ensuring they can withstand movements within the buccal cavity.

In vitro drug Release

The *in vitro* drug release for each batch was calculated. The drug release in the F7 & F8 batch was determined to be between 2.97 to 82.06 and 2.17 to 86.53% respectively. The details of data are given in Table 3.

Antibacterial Study

The diameter of zone of inhibition was measured and the value was shown in the Table 4. The diameter of the zone of inhibition was measured after 24 hr of incubation and compared to the reference drug diameter. Over that microbial agent, it has stronger antibacterial activity. By using the agar disc diffusion method, the zone of inhibition of the standard and test samples at 10 µg/mL concentrations was assessed as shown in the following.

Stability studies

The stability studies of the optimized formulations F7 and F8 were conducted over a period of one month under refrigerated conditions (2°-8°C). Throughout the study period, there were no observable changes in physical appearance, with both formulations retaining their original color and consistency. Minor reductions in surface pH and drug content were noted; however, these changes were within acceptable limits, indicating no significant degradation. Specifically, formulation F7 maintained a surface pH of 6.2±0.047 and drug content of 97.2±0.25%, while formulation F8 exhibited a surface pH of 6.1±0.047 and drug content of 98.7±0.49%. These results confirmed that both F7 and F8 formulations remained physically and chemically stable over the one-month evaluation period.

Pharmacokinetic models

The in vitro drug release kinetics of the optimized formulations F7 and F8 were evaluated using various mathematical models, namely Zero-order, First-order, Higuchi, and Korsmeyer-Peppas, as illustrated in Figure 4. The goodness of fit for each model was determined using the correlation coefficient (R^2) values. For formulation F7, the R^2 values were 0.9813 for the Zero-order

Table 3: Evaluation of dental cones.

Sl. No.	Formulations	Surface pH	Swelling Index (%)	Drug Content Estimation (%)	Hardness (compressibility) kg/cm^2	*In vitro* Release for 120 hr
1	F1	6.4±0.047	6.7±1.39	99.8±3.3	4.3±0.47	61.62
2	F2	6.4±0.047	11.6±4.4	99.1±5.8	4.3±0.47	85.72
3	F3	6.2±0.047	19.7±0.2	98.9±5.7	2.6±0.47	74.29
4	F4	6.4±0.081	22.5±4.2	99.8±6.6	3±0	85.37
5	F5	6.2±0.047	28.3±4.5	95.8±3.2	4.3±0.47	70.71
6	F6	6.2±0.047	34.6±1.1	97.58±5.9	5±0	80.88
7	F7	6.1±0.047	39.8±3.8	98.8±2.5	4.3±0.94	82.06
8	F8	6.1±0.047	43.0±4.1	100.97±4.9	5.3±0.47	86.53

Table 4: Antibacterial Study.

Bacterial strains	Samples	Concentration (mcg/mL)	Zone of inhibition (mm)
E. coli	Clindamycin std	10 mcg/mL	18 mm
	F7	10 mcg/mL	17 mm
	F8	10 mcg/mL	15 mm
S. aureus	Clindamycin std	10 mcg/mL	21 mm
	F7	10 mcg/mL	19 mm
	F8	10 mcg/mL	16 mm

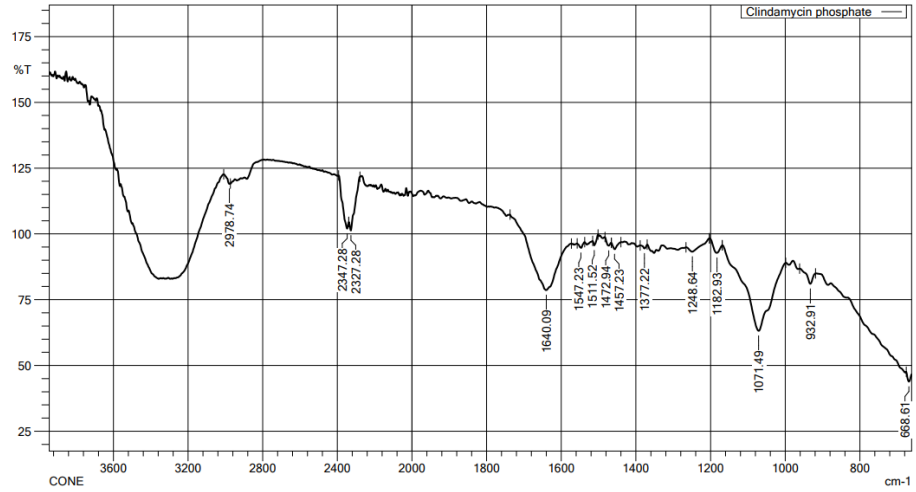

Figure 2: FTIR graph of clindamycin phosphate.

model, 0.9091 for the First-order model, 0.9813 for the Higuchi model, and 0.8816 for the Korsmeyer-Peppas model. Similarly, formulation F8 showed R^2 values of 0.9771 (Zero-order), 0.903 (First-order), 0.9771 (Higuchi), and 0.8573 (Korsmeyer-Peppas). These findings indicate that both formulations followed Zero-order and Higuchi release kinetics predominantly, suggesting a diffusion-controlled drug release mechanism with a consistent release rate over time.

Based on the kinetic analysis, it was observed that the drug release from both formulations F7 and F8 followed the Higuchi model most closely, indicating that the drug release was primarily diffusion-controlled. Furthermore, the high correlation with the Zero-order model also suggested that the release from the dental cones was sustained and independent of drug concentration. The Korsmeyer-Peppas model analysis revealed that the release mechanism followed anomalous (non-Fickian) diffusion, suggesting a combination of both diffusion and erosion mechanisms contributing to the drug release from the biodegradable dental cones.

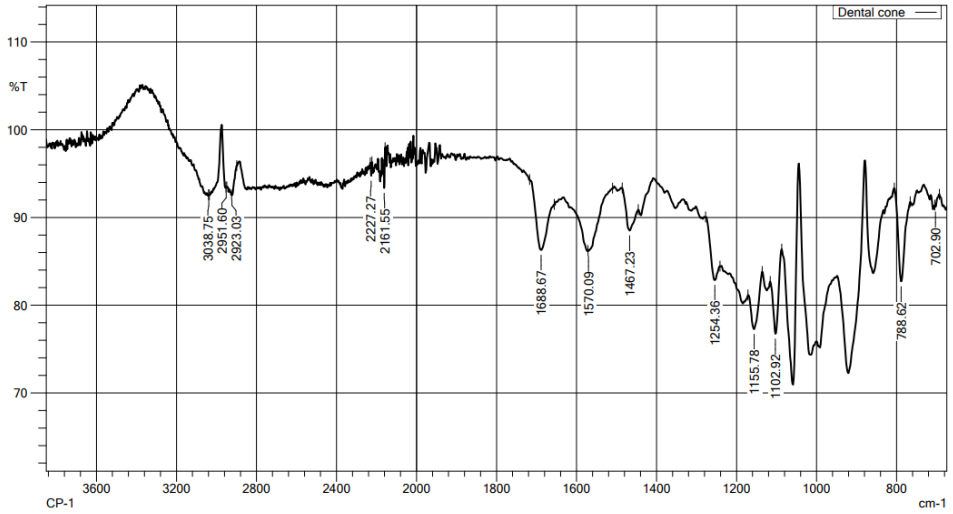

Figure 3: FTIR graph of polymers and drug mixture.

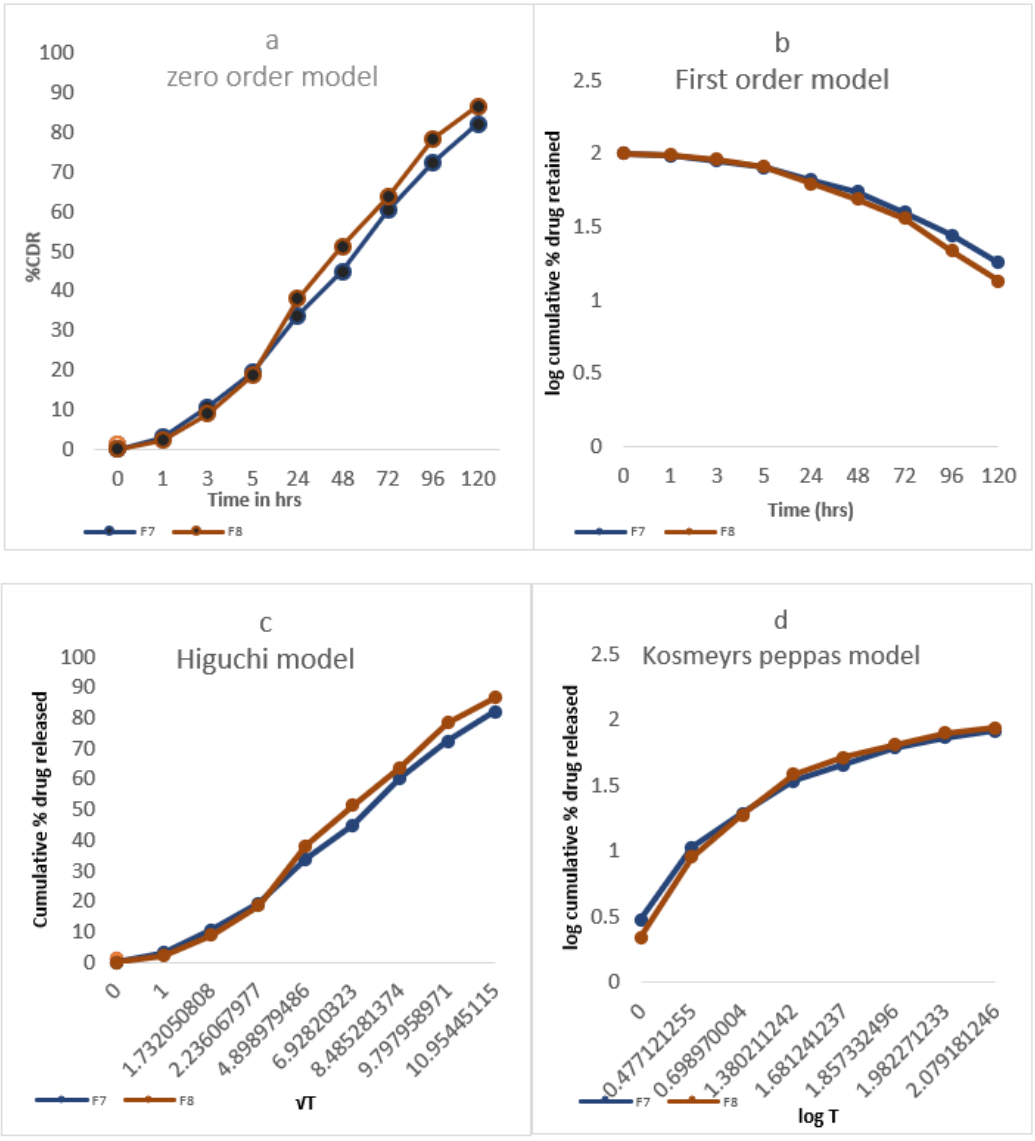

Figure 4: *In vitro* drug release kinetics of the optimised formulation F7 and F8 analyzed using different mathematical models: a) zero order model b) First order model c) Higuchi model d) Kosmeyrs peppas model.

DISCUSSION

At least 70% of the population worldwide experiences dental issues. Dental extractions are necessary for several conditions include severe periodontitis, tooth decay, and trauma. Issues following tooth extractions, such as bacterial infections, swelling, discomfort, and so on. One of the cutting-edge treatments for the period following tooth extraction is dental cones. More effective local therapeutic dose forms include dental cones. Dental cones are used to reduce pain, bleeding, inflammation, and bacterial infections. Clindamycin dental cones were prepared by mould filling method using gelatin as main polymer and agar-agar as a copolymer in different ratios. The standard calibration curve of the pure drug exhibits good linearity with regression of coefficient R2 = 0.9766, and the drug exhibits beer law in concentration ranges of 20, to 120 µg/mL in phosphate buffer pH 6.8. *In vitro* flux studies of clindamycin phosphate API performed for 24 hr using modified franz diffusion apparatus and dialysis membrane out of 20,000 µg/mL drug solution at the end of study flux was found to be 2.69 µg/cm2/hr. FTIR studies confirmed the absence of chemical interaction between the drug and the polymers. The physical evaluation data indicates that all the prepared cones are cream white in colour and hardness of the cones ranges from 2.6 to 5.3 kg/cm^2.The physicochemical evaluation data indicates that all the dental cones have surface pH very close to gingival pH in the range of 6.1 to 6.4, indicate negligible irritation to the gingiva. The swelling index was low at minimum concentrations of polymers where as it was higher at maximum concentrations. All the three polymers are responsible for swelling property combined mixture of these polymers with glutaraldehyde as a crosslinking agent binds covalently between the polymers to form strong matrix network internally due to this swelling was observed more up to 43% in F8 formulation. The drug content studies showed uniform and homogenous distribution in the range of 95% to 100% of drug. The *in vitro* drug release studies showed that the cones of F2, F4, F6 were busted in the time interval 24 hr to 48 hr so there was a sudden dose dumping observed, whereas in case of F1, F3, F5 the drug release observed was less compared to F8 formulation, F7 and F8 showed slow, controlled and linear release of the drug 82% and 86% respectively, above the MIC level for 5 days. Since the dental cones remains immobile in the gingival socket, a static dissolution model was adopted in this work. Slow and controlled drug release was seen up to 5 days cumulative drug release was greater in F8 formulation. Dental cones of F7 & F8 formulations confirmed good anti-bacterial activity against *E. coli* and *S. aureus*. Stability studies revealed that cones of F7 & F8 was stable at refrigerator temperature. The kinetic data analysis of optimized formulations F7&F8 showed that the drug release from dental cones best fit to higuchi model, whereas drug release kinetics from dental cones fits to zero order release kinetics. From korsmeyer -peppas plot, it was concluded that the mechanism of drug release from the film followed anomalous (non-Fickian) diffusion.

CONCLUSION

This study aimed to develop dental cones containing an antibacterial agent for post tooth extraction treatment. The formulated cones showed satisfactory drug release. Compatibility between the drug and polymers was confirmed through FTIR analysis. The optimized formulation (F7 & F8) using gelatin and agar-agar exhibited better results in terms of *in vitro* drug release, swelling, drug content, and antibacterial property. These biodegradable dental cones offer a promising alternative to conventional drug delivery for post tooth extraction management.

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ABBREVIATIONS

FTIR: Fourier Transform Infrared Spectroscopy; **UV-vis:** Ultraviolet-visible Spectroscopy; **PEG 400:** Polyethylene Glycol 400; **CEJ:** Cementoenamel Junction; **S.I.:** Swelling Index; **Wo:** Initial Weight; **Wt:** Weight after Swelling; **J:** Drug Flux**; *E. coli*:** *Escherichia coli*; ***S. aureus*:** *Staphylococcus aureus*.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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