

Formulation and *In Vitro* Evaluation of Dental Gel by Using *Melaleuca alternifolia* Oil

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ABSTRACT

The study was aimed to develop and evaluate Dental Gel containing *Melaleuca alternifolia* oil as the chief constituent for the treatment of Dental Caries. It has a wide spectrum of antibacterial activity against a number of Dental Caries pathogens, hence it is selected for the treatment of Dental Caries. The gel is formulated by using carbopol 934 as gelling agent, *Melaleuca alternifolia* oil as medicinal agent, polyethylene glycol as co-solvent, methyl paraben as preservative, Glycerine as sweetening agent, and required quantity of distilled water as vehicle. The gel was evaluated for physical parameters like appearance, viscosity and it shown satisfactory results. The prepared gel was evaluated for various properties such as antimicrobial activity, pH, spreadability, extrudability, homogeneity, diffusion study, drug content etc. *In-Vitro* experiments demonstrated that the formulation F4 is an optimized and all results observed the pH 6.9, viscosity 45844, spreadability 3cm, homogeneity -Very Good, extrudability 95.2, drug content 97, diffusion Study 92.15, gel showed the zone of inhibition about 18 ± 0.04 mm.

Keywords: *Melaleuca alternifolia* oil, Carbopol 934, Diffusion Study, Zone of Inhibition.

INTRODUCTION

Dental gel is an oral care product typically used for oral hygiene purposes. It's a gel-like substance applied to the teeth and gums for various purposes, such as cleaning, freshening breath, reducing plaque buildup, soothing gum irritation, or delivering active ingredients like fluoride desensitizing agents. Dental gels come in different formulations to specific needs, such as whitening gels, fluoride gels, or gels for sensitive teeth. They are often recommended by dentists as part of a daily oral hygiene routine. Gels are semisolid organic or inorganic colloids rich in liquid, consisting of hydrated threads or granules of the dispersed phase intimately associated with the dispersion medium.¹

Tea tree oil, essential oil derived from the tea tree (*Melaleuca alternifolia*), a species of tall

shrub or tree in the myrtle family (Myrtaceae) originally native to the Bungawalbin Valley in New South Wales, eastern Australia. Tea tree oil historically was used by Australian Aboriginal peoples in herbal remedies. Today, it is commonly used as an over-the-counter topical agent to treat acne, dandruff, athlete's foot, and various other skin and oral conditions. Tea tree oil (TTO), an essential oil obtained by steam distillation of aerial parts of *Melaleuca alternifolia* has claims for analgesic, antimicrobial, antiseptic, and anti-inflammatory activity.

The potential benefits of tea tree oil, which is extracted from the leaves of *Melaleuca alternifolia* tea trees, have been studied in relation to the treatment of periodontal disease. The oil is of interest in the field of

oral health because of its well-known antibacterial and anti-inflammatory qualities. The following are some methods that tea tree oil's potential for treating periodontal disease has been investigated.

Advantages:

- ❖ It has several benefits, including increasing tooth resistance to germs and plaque, re-mineralizing decayed teeth.
- ❖ Reducing sensitivity and discomfort by plugging exposed dentin tubules.
- ❖ It can be easy to use and affordable when compared to other fluoride treatments.

Disadvantages:

- It can produce nausea, vomiting, diarrhea, and stomach discomfort if used in high quantities.
- It can induce dental fluorosis, a disorder that alters the look of teeth, if used excessively or incorrectly in children under the age of six.
- It may have poor dimensional stability and low tear strength, which compromise the accuracy and longevity of dental impressions.
- It may be inefficient or hazardous if used with incompatible toothpastes, mouthwashes, or whitening agents.²

MATERIALS AND METHODS

Chemicals and Reagents

Essential oil

Melaleuca alternifolia essential oil was procured from-Shree Narayan Agro industries, India. Carbopol 934 was obtained as gift sample from Emcure Pharmaceuticals, Pune, India. Methyl paraben, Propyl paraben, glycerin, propylene glycol was obtained from Merck Pvt. Ltd.

Collection of samples

A total of 41 swabs samples from patients with oral infections like periodontal abscess, periapical abscess, chronic periodontitis, periapical granuloma, dental caries, root caries attending the Owaisi Hospital, Hyderabad, India was collected by trained personnel. Cotton swabs were first prepared

and dipped in Cary and Blair transport medium in small tubes. Then, swabs along with medium in tubes were sterilized and then used for collection of samples. The swabs were gently pressed on the portion of teeth with caries and rotated 2-3 times. Then swabs were immediately dipped in the tube with sterile transport medium. The tubes were brought to Microbiology Laboratory of the Department of Microbiology, Owaisi Hospital, Hyderabad, India for microbiological analysis. The method of Cheesbrough (2000) was used for the microbiological analysis. A loopful of each sample was inoculated on Blood agar, Macconkeys agar and MRS lactobacilli agar, Mutans Sanguis agar, KF Streptococcal agar at 37°C for 24 – 48 h aerobically except for KF Streptococcal agar and Mutans Sanguis agar in which the plates were incubated anaerobically. After incubation, macroscopic and microscopic examinations of colonies were carried out, sub-cultured on appropriate slants and stored at 37°C for biochemical and culture characterization for identification (Table 2).

Identification of bacteria

Isolated bacterial colonies were identified by using appropriate microscopic and macroscopic methods. The colony morphology and biochemical characteristics of the bacterial isolates were studied carefully (Cheesbrough (2000)). Gram staining was performed by preparing a thin homogenous bacterial smear on a clean glass slide from the bacterial culture grown on specific agar, air-dried and heat-fixed. The smear was stained with crystal violet for 1 minute, washed with distilled water and flooded with Gram's iodine solution for 1 minute. The slide was again washed with water and decolorized with absolute alcohol until no violet color came off. The smear was counter stained with safranin for 30 sec, washed with water, blot-dried and observed under Microscope using oil immersion objective.

Preparation of microbiological culture media

The ampoule of the freeze-dried culture of bacterial strain was procured. The surface of ampoule was disinfected and appropriate precautions were taken during ampoule handling. The ampoule was broken carefully and 2 ml of isotonic solution was added to microbiological culture media. Serial dilutions were prepared from the undiluted solution.

Preparation of mueller hinton agar media

Media (38 g) was suspended in 1000 ml of distilled water and heated to boil until it gets dissolved completely. Then, it was sterilized by autoclaving at 15 lbs pressure, 121 °C for 15 min and cooled to 45-50 °C, mixed thoroughly and poured into sterile petri plates.³

Determination of antimicrobial activity

The disc diffusion method was used to screen the antimicrobial activity of Melaleuca alternifolia oil extract on the bacterial strain of Streptococcus mutans.⁴ In vitro antimicrobial activity was screened by using Mueller Hinton agar media. After sterilization, the media was transferred to

sterilized petri plates aseptically and allowed to stand for 20 min. One ml of bacterial culture (610 CFU/ml, 9th serial dilution) was spread on the surface of agar plates using sterile glass spreader after solidification of agar plates. Sterile discs of Whatman filter papers were used for an antibacterial study. The discs were impregnated with Melaleuca alternifolia oil extract (2%, 2.5%, 3%, 3.5%, 4%, 4.5% and 5% w/v)⁵, ethanol as a blank and then carefully placed on the surface of prepared agar plates. The plates were kept for incubation for 24 h at 37 °C. Zones of inhibition formed around the disc were measured by a transparent scale (in mm) at the end of incubation.

Preparation of gel formulation

Three gel formulations were prepared with different concentrations of carbopol. Initially, methylparaben solution was prepared in water and then carbopol 934 was soaked in the water for 24 h for preparation of gel. Solutions of a measured quantity of extracts of drug were prepared in 5 ml of ethanol and added to the gel and then required the quantity of polyethylene glycol (PEG 400) was added.⁶ Composition of the mucoadhesive gel is shown in table 1.

Table No:1 Preparation of Dental gel containing melaleuca alternifolia oil

S.NO.	INGREDIENTS	F1	F2	F3	F4
1.	Melaleuca alternifolia oil [ml]	0.5	1	1.5	2
2.	Carbopol [g]	0.2	0.4	0.6	0.8
3.	Poly ethylene glycol [ml]	2.5	5	7.5	10
4.	Methyl paraben [g]	0.1	0.1	0.1	0.1
5.	Glycerine [g]	0.2	0.2	0.2	0.2
6.	Ethanol [ml]	2	2	2	2
7.	Distilled water [ml]	14.5	11.3	8.1	4.9

EVALUATION OF DENTAL GEL

All prepared gel formulations were evaluated for physical appearance, pH, viscosity, spreadability, stability study, drug content, diffusion study, extrudability, Homogeneity, Anti microbial activity.

Physical appearance:

Colour: The color of the formulation was checked out against a light background.

Odor: The odor of the gels was checked by mixing the gel in distilled water and taking the smell.

Determination of pH: The pH of the gel was check using digital pH meter by dipping the glass electrode completely into the gel system.⁷

Determination of viscosity: Viscosities of the formulated gels was check using Brooke field viscometer, spindle no. 7 and spindle speed 50rpm at 20°C was used for gels, the

corresponding dial reading on the viscometer was noted ⁸ Table No.2

Determination of spreadability:

Spreadability was formed by change picked block and glass slide equipment. The equipment consisted of a picked block with a fixed glass slide and a pulley ⁹. A pan was attached to another glass slide (move) with the help of a string ¹⁰⁻¹³. For the determination of spreadability measured amount of gel was placed in the fixed glass slide, the movable glass slide with a pan attached to it, was placed on the fixed glass slide such that the gel slide with a pan attached to it, was placed on the fixed glass slide such that the gel was sandwiched between the two slides for 5 minutes. Now about 50 grams of weight was added to the pan ¹⁴⁻¹⁶. The time duration for the slides to separate was noted.

Spreadability was determined using the following formula.

$$S = M.L/T$$

- Where, S = Spreadability.
- M = Weight in the pan (tied to the upper slide).
- L = Length moved by the glass slide.
- T = Time (in sec.) taken to separate the upper slide from the ground slide.

Where S is the spreadability in grams.cm/sec, M is the mass in grams: T is the time in seconds.

Determination of extrudability: It was determined by employing a tube crammed with the gel, having a tip of five mm gap and by activity, the quantity of gel that extruded

through the tip once pressure was applied on the tube was noted down.

Determination of homogeneity: All the developed gels were tested for homogeneity by visual inspection after the gels have been set in the container ¹⁷⁻¹⁸. They were tested for their look and appearance and presence of any aggregates.

Determination of drug content: The drug content of the gel formulations makes up my mind by dissolving Associate in Nursing an accurately weighed amount one g of gel in 100 metric capacity unit of solvent. The solutions were kept for shaking for 4 hr and then kept for 6 hr for the complete dissolution of the formulations ¹⁹. Then the solutions were filtered through 0.45 mm membrane filters and proper dilutions were made and solutions were subjected to the spectrophotometric analysis ²⁰. The drug content was calculated from the simple regression equation obtained from the standardization information.

Determination of antimicrobial activity:

Agar cup plate method was used for screening of antimicrobial activity of melaleuca alternifolia Oil gel. All formulations of melaleuca alternifolia Oil gel of about 2% were placed aseptically in cups of agar plate which was previously inoculated with the culture. The plates were left at ambient temperature for 30 mins before to incubation at 37°C for 24 hrs. The broad-spectrum antibiotic i.e., Doxycycline was used as a positive control for obtaining comparative results. Plates were observed after 24-48 hrs incubation for the appearance of the zone of inhibition



Fig. No 1: Preparation of culture media

Zone Of Inhibition: The antibacterial activity was performed by agar well diffusion method. The plates were evaluated after incubation at 37°C for 24 hours after which the zone of inhibition around each was measured by using scale in millimetres

(mm). The ratio between the diameter of inhibition zone produced by plant extracts and the inhibition zone around the well with formulation was used to express antibacterial activity.²¹

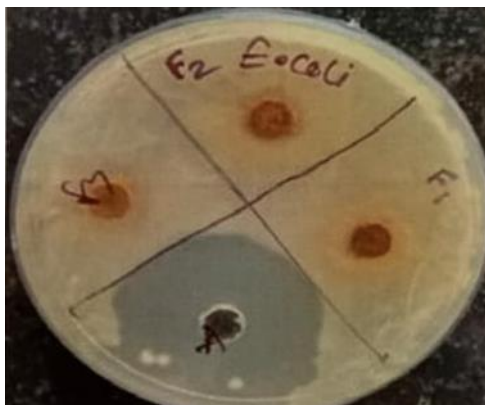


Fig. No 2: Zone of Inhibition

RESULT AND DISCUSSION

Table No: 2 Evaluation parameters of Dental Gel

S. No	Parameters	F1	F2	F3	F4
1	Colour	White	White	White	White
2	Odour	Pleasant	Pleasant	Pleasant	Pleasant
3	Ph	6.7	6.5	6.4	6.9
4	Viscosity	44295	38674	40546	45844
5	Spreadability (cm)	2	2.3	2.5	3
6	Extrudability	92.1	86.3	89.2	95.2
7	Homogeneity	Very Good	Good	Good	Very Good
8	Drug Content (%)	89	92	94	97
9	Diffusion Study (%)	76	79	84.05	92.15
10	Anti-Microbial Activity (Zone of Inhibition) (mm)	11	12	15	18

Table No: 3 Table of Stability Studies for optimized formulation F4

S No	Parameters	Results Obtained
1	Colour	White
2	Odour	Pleasant
3	pH	6.9
4	Viscosity	45844
5	Spreadability (cm)	3
6	Extrudability	95.2
7	Homogeneity	Very Good
8	Drug Content (%)	97
9	Diffusion Study (%)	92.15
10	Anti-Microbial Activity (Zone of Inhibition) (mm)	18

CONCLUSION

The tea tree oil was found to have antibacterial activity against Streptococcus

salivarius, Streptococcus sanguis and Lactobacilli acidophilus. The formulations developed from tea tree oil showed

significant results so it can be further used commercially to develop dental gels after conducting clinical trials on human beings. Nevertheless, further research is still needed in order to determine if they efficiently could substitute the synthetic antibiotics or used in combination.

CONFLICT OF INTERESTS: Declared none.

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