

EFFICACY OF LOCALLY DELIVERED TEA TREE OIL GEL AS AN ADJUNCT TO NON-SURGICAL PERIODONTAL MANAGEMENT; A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

Objective: The aim of this controlled randomized clinical trial is to assess the clinical impact of intra pocket application of Tea Tree Oil (TTO) gel.

Methods and materials: Twenty-two patients, both genders, aged 20 to 50, were diagnosed with moderate to severe periodontitis. Two groups were selected: the test group, which included eleven patients who received both nonsurgical periodontal therapy (NSPT) and locally delivered TTO gel, and the control group, which included eleven patients who received only NSPT. The following parameters were considered clinically at baseline and three months after NSPT: plaque index (PI), modified sulcular bleeding index (MSBI), probing depth (PD), and clinical attachment level (CAL). Patient Satisfaction Questionnaire Short Form (PSQ-18) was assessed postoperatively in both groups.

Results: Three months postoperatively, the clinical data shows better improvement in test group than in control group. PSQ-18 showed improvement in patient satisfaction in both groups.

Conclusion: Adjunctive local delivery of TTO gel together with NSPT in severe periodontitis has better effect clinically than that of NSPT alone.

KEYWORDS: Local drug delivery, Tea tree oil Gel, Non-surgical Periodontal Therapy, Clinical Attachment Level.

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INTRODUCTION

Periodontitis is a condition that causes inflammation of the teeth's supporting tissues caused by specific microbes or groups of microorganisms that contributes to gradual deterioration of the periodontal ligament and alveolar bone, leading to periodontal pockets, gingival recession, or both ^[1].

Periodontitis is generally known to be caused by the continuous destruction of the surrounding periodontium by complexly organized bacterial communities that colonizes the tooth surface, gingival margin, and subgingival area in the form of dental plaque biofilm ^[2].

Research suggests that the treatment of periodontal disease relies on the management of the residual mass of periodontal microbes ^[3]. Therefore, it is proposed that non-surgical therapy is regarded as the initial treatment of periodontitis, which includes mechanical therapy. Chemical therapy could supplement the non-surgical mechanical therapy, including antimicrobials that can be systemically or locally delivered ^[1].

Conventional non-surgical treatment methods for periodontitis cannot ensure remission, and the use of antibiotics systemically is restricted due to elevated dosage and micro-organisms resistance. Additionally, the superior architecture and characteristics of subgingival biofilm make antibiotics inactive or ineffective. For nearly 30 years, drug structures like antibiotics and antiseptics have been advanced for direct subgingival management as locally delivered drugs. ^[4]

Contrary to systemic administration, local drug delivery (LDD) provides higher therapeutic concentrations of antibiotics at site of infection, and it is independent of the patient's adherence ^[5]. Moreover, the benefit of LDD is its attention after usage considerably surpass the minimal inhibitory concentration (MIC) and persists for as much as numerous weeks. They can be utilized in numerous forms as

irrigations, fibers, films, microparticles, compacts, strips, gels, vesicular liposomes, injectable, and nanoparticle systems ^[6,7].

Natural products have long been an important source of medications, with natural ingredients accounting for almost half of all pharmaceuticals currently in use. Oriental medicines have been studied for their antibacterial and anti-inflammatory properties, as well as periodontal tissue regeneration, in the management of periodontal condition. TTO, denoting an example of one of these natural products, is obtained from paper bark tea tree ^[8].

Tea tree oil is an essential oil obtained largely from Australian native plant *Melaleuca alternifolia*. It is extracted through the process of hot distillation, which involves the leaves and terminal branches of the plant. This plant is a member of the Myrtaceae family, which includes Australian arboreal plants. It is known as "nature's most versatile healer" among the native populations ^[9].

TTO components reduce the levels of Tumor Necrosis Factor Alpha (TNF- α), interleukin IL-1beta (IL-1 β), IL-8, IL-10, and Prostaglandin E2 (PGE2) through lipopolysaccharide activated human monocytes, proving TTO's anti-inflammatory action ^[10].

TTO's major active components are 1,8-cineole and Terpinen-4-ol, and it has been shown that 1,8-cineole possesses anti-inflammatory characteristics and may permeate human skin. Terpinen-4-ol not only has anti-inflammatory characteristics like 1,8-cineol, but it has anti-bacterial capabilities. TTO has the same antibacterial effect as chlorhexidine (CHX), however the mode of action is different. Antibacterial, antiviral, and antifungal activities are all present ^[10].

TTO is capable of lowering both inflammatory mediators and periodontal pathogens, which in turn reduces the stimulation of inflammatory cytokines, allowing periodontal tissues to repair when applied locally in periodontal pockets ^[10].

Although the use of tea tree oil in the management of periodontitis has been discussed, additional research is essential to substantiate the anti-inflammatory effects of TTO in patients with periodontitis. Consequently, this study aims to assess the impact of applying TTO gel locally as supplementary treatment for severe periodontitis, focusing on clinical outcomes and patient satisfaction.

MATERIALS AND METHODS

Clinical trial design and sample size calculation

Twenty-two patients diagnosed with severe periodontitis were chosen from the outpatient clinic of Oral Medicine, Periodontology, Oral Diagnosis department, Faculty of Dentistry, Ain Shams University, Egypt. Research Ethics Committee (ID: FDASU-Rec IM 1045) approved this study. The research was conducted in accordance with Ain Shams University's research standards. Participants were given a thorough explanation of the process and signed an informed consent form before starting the treatment.

This study was designed to be a randomized, controlled, comparative, two parallel arms, double blinded, clinical trial. The study consists of two groups, each containing 11 patients. The patients were randomly allocated to one of the two groups; test group (received both NSPT and locally delivered TTO gel) and control group (received only NSPT) using computer generated random tables. Patients were blinded to the type of the intervention and the whole-time frame of the study will be 3 months.

The following were the periodontal parameters of the cases: Outpatients diagnosed to have severe periodontitis (Interdental CAL at site of greatest depth ≥ 5 mm, bleeding on probing (BOP), and probing depth ≥ 6 mm).^[11] Patients that suffered from any systemic disease or were under any medication did not participate in this study. Smokers, patients with a history of allergy to one of the components of tea tree oil, pregnant women or lactating mothers,

and asthmatic patients^[12] were eliminated from the study.

Preparation of the gel^[10]:

The preparation of tea tree oil 5% gel (Germany, Sigma Aldrich® Steinheim) for sub-gingival application was laboratory prepared by NAWAH (NAWAH Scientific, Research institute, Egypt). The gelling agent, Carbopol 940, was soaked in distilled water for 2 hours before mixing with TTO and propylene glycol. A preservative, 0.2% w/v methyl paraben, was added. The mixture was magnetically stirred for 30 minutes, and the pH was adjusted by adding 1 mol NaOH. The gel was autoclaved at 110°C for almost half an hour. The gel was loaded in syringes with 3 ml each for easy administration to periodontal pockets.

Treatment Protocol:

Clinical parameters (PI, MSBI, PD, and CAL) were measured at 6 areas for each tooth using University of Michigan O' probe with William's markings. These readings were taken twice: first at baseline (after the NSPT) and again three months later. Full mouth one-stage debridement was performed using ultrasonic scalers, manual scalers, and curettes.^[5]

The cases were called back three months later for a follow-up consultation and asked to complete the Patient Satisfaction Questionnaire Short Form (PSQ-18) to assess their approval with the therapy.^[13]

Application of the gel

TTO Gel was gently administered in the deepest pocket by syringe with blunt tip, and the syringe will be removed slowly to avoid injuring the tissues after phase I therapy by two weeks^[14].

Patients are advised to brush their teeth three times daily with a soft toothbrush and floss regularly. Patients were guided to have soft diet, brush close to the treated area, or use interdental products. Regular check-ups were conducted every two weeks to ensure proper oral hygiene and remove supragingival plaque^[15].

Statistical Analysis

The study analyzed categorical and ordinal data using Fisher's exact test, mean and standard deviation, and Shapiro-Wilk's test. Parametric data was analyzed using independent and paired t-tests, while non-parametric numerical and ordinal data were analyzed using Mann-Whitney U test and signed rank test. The significance level was set at $p \leq 0.05$. Statistical analysis was performed using R statistical software version 4.3.0 for Windows.^[16]

RESULTS

The study involved 22 patients (i.e., 11 cases each), which were distributed evenly and randomly among the groups under study. There were 6 (54.5%) males in the test group and 5 (45.5%) females. While in the control group, there were 5 (45.5%) males and 6 (54.5%) females. The mean age of the cases in the test group was (34.69 ± 3.12) years while in the control group it was (35.17 ± 5.23) years. Regarding gender ($p=1$) and age ($p=0.806$), the dissimilarity between the two groups did not show meaningful statistical distinction. Both sex

and age are illustrated in table 1.

Table 2 shows that all clinical measurements that showed an overall significant improvement from baseline to 3 months after therapy while Table 3 shows the intergroup comparison between the two groups.

With regards to the plaque index (PI), both groups showed no difference at either baseline or three months ($P=1.64 \pm 0.67$, $P=1.45 \pm 0.82$). (Table 2)

Modified sulcular bleeding index (MSBI) showed reduction of bleeding during the treatment phase with significant decrease in test group than control group. ($P=0.027^*$). (Table 3)

Regarding the probing depth (PD) and clinical attachment level (CAL), measured in mm, both groups in the current research revealed a significant decrease in PD and improvement in the CAL after follow up when compared to baseline (Table 2), as well as a statistically significant difference when compared to each other. ($P < 0.001^*$). (Table 3)

Questionnaire responses are summarized in Table 4.

TABLE (1)

Parameter	Value	Test	Control	p-value
Gender	Male	n	6	5
		%	54.5%	45.5%
	Female	n	5	6
		%	45.5%	54.5%
Age	(Mean \pm SD) years	34.69 \pm 3.12	35.17 \pm 5.23	0.806ns

*; significant ($p \leq 0.05$) ns; non-significant ($p > 0.05$)

TABLE (2)

(Mean \pm SD)	Test group			Control group		
	Baseline	3months	P-value	Baseline	3months	P-value
1- Plaque index (PI)	2.64 \pm 0.50	1.00 \pm 0.77	<0.001*	2.73 \pm 0.47	1.27 \pm 0.79	<0.001*
2- Modified sulcular bleeding index (MSBI)	2.64 \pm 0.50	0.36 \pm 0.50	<0.001*	2.64 \pm 0.50	1.18 \pm 0.75	<0.001*
3- Probing depth (PD)	7.18 \pm 0.75	4.29 \pm 0.46	<0.001*	7.09 \pm 0.83	5.45 \pm 1.04	<0.001*
4- Clinical attachment loss (CAL)	7.27 \pm 1.10	3.82 \pm 0.75	<0.001*	6.73 \pm 1.19	5.18 \pm 1.17	<0.001*

*; significant ($p \leq 0.05$) ns; non-significant ($p > 0.05$)

TABLE (3)

(Mean±SD)	Test group	Control group	P-value
1- Plaque index (PI) difference	1.64±0.67	1.45±0.82	0.390ns
2- Modified sulcular bleeding index (MSBI) difference	2.27±0.65	1.45±0.93	0.027*
3- Probing depth (PD) difference	2.89±0.57	1.64±0.92	0.006*
4- Clinical attachment loss (CAL) difference	3.45±0.52	1.55±1.21	<0.001*

*, significant ($p \leq 0.05$) ns; non-significant ($p > 0.05$)

TABLE (4)

Domain	Answer	Test		Control		p-value
		n	%	n	%	
General Satisfaction	Strongly Agree	16	59.3%	12	23.1%	<0.001*
	Agree	6	22.2%	10	19.2%	
	Uncertain	1	3.7%	10	19.2%	
	Disagree	2	7.4%	10	19.2%	
	Strongly Disagree	2	7.4%	10	19.2%	
Technical Quality	Strongly Agree	20	43.5%	9	13.8%	0.169ns
	Agree	2	4.3%	7	10.8%	
	Uncertain	0	0.0%	13	20.0%	
	Disagree	7	15.2%	13	20.0%	
Financial Aspects	Strongly Disagree	17	37.0%	23	35.4%	1ns
	Strongly Agree	11	50.0%	11	50.0%	
	Agree	0	0.0%	0	0.0%	
	Uncertain	0	0.0%	0	0.0%	
	Disagree	0	0.0%	0	0.0%	
Interpersonal Manner	Strongly Disagree	11	50.0%	11	50.0%	0.032*
	Strongly Agree	19	79.2%	18	52.9%	
	Agree	3	12.5%	4	11.8%	
	Uncertain	0	0.0%	4	11.8%	
Time Spent with Doctor	Disagree	1	4.2%	4	11.8%	0.475ns
	Strongly Disagree	1	4.2%	4	11.8%	
	Strongly Agree	4	10.5%	2	4.7%	
Communication	Agree	11	28.9%	7	16.3%	0.005*
	Uncertain	3	7.9%	11	25.6%	
	Disagree	10	26.3%	12	27.9%	
	Strongly Disagree	10	26.3%	11	25.6%	
	Strongly Agree	0	0.0%	0	0.0%	
Accessibility and Convenience	Agree	0	0.0%	0	0.0%	0.799ns
	Strongly Agree	0	0.0%	5	22.7%	
	Uncertain	0	0.0%	5	22.7%	
	Disagree	2	9.1%	5	22.7%	
Overall	Strongly Disagree	20	90.9%	12	54.5%	<0.001*
	Strongly Agree	0	0.0%	4	5.0%	
	Agree	17	31.5%	12	15.0%	
	Uncertain	11	20.4%	24	30.0%	
	Disagree	9	16.7%	19	23.7%	
Overall	Strongly Disagree	17	31.5%	21	26.2%	<0.001*
	Strongly Agree	70	30.0%	56	17.6%	
	Agree	39	16.7%	40	12.6%	
	Uncertain	15	6.4%	67	21.1%	
	Disagree	31	13.3%	63	19.8%	
	Strongly Disagree	78	33.5%	92	28.9%	

*, significant ($p \leq 0.05$) ns; non-significant ($p > 0.05$)

DISCUSSION

This study proves TTO gel's effectiveness as an adjuvant to NSPT in severe periodontitis. During trial period, the patients experienced no problems regarding the therapy. The only problem was the unpleasant flavor of the used gel.

TTO is believed to have powerful immunomodulatory impacts on inflammatory response. TTO, which is made up of terpinen-4-ol, -terpineol, and 1,8-cineole, prevented lipopolysaccharide-activated monocytes from producing TNF- α , IL-1, IL-8, IL-10, and prostaglandin E2. The water-soluble portions of TTO, terpinen-4-ol, and α -terpineol also reduced superoxide production by agonist-stimulated monocytes. Therefore, this clearly explains the improvement of clinical parameters in our study.^[17, 18]

Variable forms of TTO were used for the treatment of gingivitis and periodontitis that includes toothpaste (0.5%), gels (2.5%, 5%), and solutions (0.2%, 1.5%)^[19].

A systematic review performed by Casarin et al., 2017 found that 5% TTO gel significantly reduced PD and CAL in chronic periodontitis [18]. Therefore, similar to Taalab et al., 2021 this study used 5% TTO gel.^[20]

No significant discrepancy was found in plaque index (PI) between groups at baseline or 3 months ($P=0.390$ ns). PI decreased in both groups following therapy. Patients were kept under strict maintenance programs, ensuring minimal plaque accumulation. This allowed for an accurate assessment of therapy alternatives and patient compliance to oral hygiene instructions.

The results of plaque index were agreed with Abdel Aziz et al., 2022 who found reduction in plaque accumulation in both groups^[21]. Additionally, the clinical outcomes published by Soukoulis & Hirsh, that accomplished a double-blind, long-term study for assessing impact of using toothbrushes with TTO gel (2.5%) applied twice daily were

consistent with our findings^[22]. They discovered that the plaque index was not lowered by TTO.

Modified sulcus bleeding index (MSBI) showed a significant decline in the groups after treatment ($P < 0.001$) with a statistical difference between the two groups after three months follow up ($P=0.027$). These results are a reflection of healing from inflammation and decline in proinflammatory markers.^[23]

Our findings were consistent with those of Taalab et al., 2021 who found that NSPT in combination with tea tree oil can significantly reduce clinical symptoms of inflammation in individuals with periodontitis.^[20]

PD decreased and CAL improved in the test group, owing to the resolution of inflammation caused by changes in the subgingival bacteria^[24]. Furthermore, reducing local variables by scaling may promote a local and systemic host response, hence stimulating healing^[25].

The outcomes reported were consistent with those of Elgendy et al., 2013 who stated that there was a major decrease in PD and CAL in (SRP plus TTO gel) compared to (SRP only).^[26]

Also, the current study's findings were in accordance with the findings of other studies such as Arweiler et al., 2000; Saxer et al., 2003; Soukoulis & Hirsch 2004, which all stated that TTO acts efficiently in lowering oral microorganisms, and it has lipophilic characteristics that aid in its diffusion through the epithelium^[22, 27, 28]. TTO would be a unique, harmless medication that might supplement the current chemotherapeutic periodontal therapy alternatives.

In addition, Thayaparan & Mahdi, 2013 stated that Patient Satisfaction Questionnaire Short Form (PSQ-18) is a valid, reproducible questionnaire that has the potential to be used in a variety of situations, as well as being well appreciated by patients due to its brevity^[29].

Regarding patient satisfaction the results follows that of Liss et al.,2021 which concluded that regardless of treatment strategy, the patient's experiences of being involved in therapeutic decisions appear to be very important for patient satisfaction and adherence to self-performed periodontal infection control^[30].

The limitations of this present study include its narrow focus on a single form of periodontitis, a brief follow-up duration, and a small participant pool. Future investigations, featuring a larger sample size and an extended follow-up period during the maintenance phase, are needed to validate these findings and offer a more comprehensive understanding of the role of TTO in treating periodontitis.

CONCLUSION

According to the findings of this study, integrating TTO alongside NSPT yielded superior therapeutic benefits compared to using NSPT alone. Furthermore, it highlights the effectiveness of TTO as anti-inflammatory agent, which mitigates pro-inflammatory processes and promotes the healing of periodontal tissues.

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Conflict of interest

In this work, the authors confirm the absence of any conflicts of interest.

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