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" Effectiveness of Chlorhexidine Gel And Ozonated Oil In Treatment of Plaque Induced Gingivitis – A Randomized Controlled Clinical Study"

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Abstract
Aim: *To compare the clinical effectiveness of chlorhexidine gel and ozonated oil in the treatment of plaque induced gingivitis patients.*
Methods: *A total of 20 subjects aged from 16 to 65 years suffering from plaque induced gingivitis were selected for this study. Subjects were randomly divided into group I (control) and group II (test) with 10 subjects in each group. Subjects were advised to apply chlorhexidine gel/ ozonated oil twice daily onto buccal and lingual surfaces of marginal gingiva for 3 weeks. PI, GI and BI was assessed at baseline, 7th, 14th and 21st day.*
Results: *PI, GI and BI in group I and group II showed statistically significant reduction from baseline to 21st day, whereas there was no statistically significant difference between the groups from baseline to 21st day.*
Conclusion: *Gingival application of ozonated oil can be an effective alternative to chlorhexidine gel to combat plaque induced gingivitis.*
Key words: *Plaque induced gingivitis, ozonated oil, chlorhexidine gel.*
Abbreviations: *PI- plaque index; GI- gingival index; BI – bleeding index.*

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I. Introduction

Plaque-induced gingivitis is an inflammatory process, limited to the gingiva, resulting from bacteria located at the gingival margin. To prevent gingivitis and its progression to periodontitis, daily and effective supra-gingival plaque controls are considered the most effective methods to regain and maintain dental and periodontal health.[1]

Various plaque control agents have been introduced to combat gingival inflammation. Ozonated preparations are one among them as they are highly effective in killing bacteria present in different forms [2].

The main use of ozone in dentistry relies on its antimicrobial properties. It is proved to be effective against both Gram-positive and Gram-negative bacteria, viruses and fungi.[3]

In periodontology, ozone has been used in various forms , such as ozonated water,ozonized oil and gaseous ozone and it has been used in the treatment of gingivitis, periodontitis, peri-implantitis, surgical cuts, prophylaxis.[1]

Its known actions on human body are antimicrobial, analgesic, immunostimulating, antihypoxic and detoxicating[2].

Composition of Medical grade ozone is mixture of pure oxygen and pure ozone in the ratio of 0.05-5% of O_3 and 95-99.95% of O_2.

O3-Oil has also been proven to be effective against these eight periodontal putative pathogens Aggregatibacter actinomycetemcomitans, Campylobacter rectus, Eikenella corrodens, Fusobacterium nucleatum, Porphyromonas gingivalis, Prevotella intermedia, Treponema denticola, and Tannerella forsythia, as assayed by multiplex PCR method.[5]

Chlorhexidine gluconate has been referred to as a gold standard for treatment of plaque induced gingivitis and as an effective chemical plaque control aid. Chlorhexidine is supplied as mouthwash, topical gel and biodegradable chips for local drug delivery in the periodontal pocket. Chlorhexidine gluconate is an efficient broad spectrum antimicrobial agent. It is a cationic molecule that causes bacterial cell wall lysis and rupture. Cationic molecules bind to the negatively charged surfaces such as teeth surface, dental pellicle and bacterial cell wall. Chlorhexidine has a substantivity of 12 h and hence is used twice daily. Various studies have quoted the significant reduction in gingivitis by use of chlorhexidine gluconate gel on topical application.[4]

Therefore, the purpose of this study was to compare the clinical effects of chlorhexidine gel and ozonated oil in the treatment of plaque induced gingivitis patients.

II. Materials And Methods

This study was a randomized, controlled, parallel group clinical study. It was conducted at Yenepoya Dental College and Hospital, Mangalore from february 2019 to april 2019. The clinical trial was approved by the Institutional Ethics Committee (2019/03, february).Voluntary informed consent was obtained from each of the subjects after providing them with detailed information brochure about the study. By obtaining informed consent, we adhered to the principles of Helsinki declaration that are outlined when human subjects are involved.

Sample size

The sample size was calculated effect size of 1.5 and power of 80%.

Participants

Twenty systemically healthy subjects aged 16 to 54 years, suffering from plaque induced gingivitis were recruited. The subjects' inclusion was based on the following criteria; Subjects exhibiting no evidence of clinical attachment loss and teeth having probing depth of <3mm ; Subjects who are willing to give the consent. Subjects possessing at least 20 natural teeth; Subjects with plaque score 1.0-1.9 (fair) and gingival score 1.1-2.0 (moderate inflammation).Subjects who are negative for any systemic diseases .Subjects who have undergone surgical or non surgical periodontal treatment three months prior to the commencement of the study. Subjects with history of systemic antibiotic administration and/or anti inflammatory drugs within three to six months prior to the study, pregnancy and lactating mothers and subjects with the habit of smoking were excluded from the study.

Armamentarium

1.Mouth mirror, Willams periodontal probe, Explorer , Gloves, Mouth mask, Alpha Plac
2. Ozonated oil
(ozonated refined vegetable oil-Ozone forum of India)

3.Chlorhexidine gluconate gel(1.0%W/W)
(Hexigel-15gm ,ICPA health care products ltd)

Study design

This was a randomized, single-blinded, controlled, parallel clinical study. The clinical study was divided into screening, treatment and post-treatment phases. Figure 1 describes the study design.

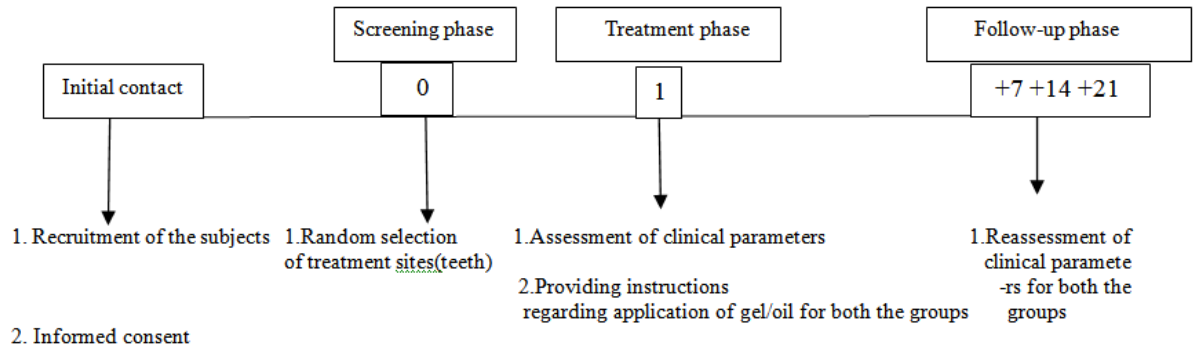


Figure 1 – Study design

Screening phase

The subjects indicated for application of chlorhexidine gel (group I) and ozonated oil (group II) were recruited for the study. The importance of maintaining oral hygiene was reinforced by the same operator. Those subjects who sufficed the inclusion criteria were randomly selected by using computerized randomization method.

Treatment phase

At baseline, the recruited subjects belonging to both the groups were assessed for gingival disease in terms of plaque index, gingival index, and bleeding index and instructions on how to apply the chlorhexidine gel and ozonated oil was conveyed and medicaments were given to the subjects belonging to both the groups by principal investigator of the study. Subjects were instructed to dispense one peanut size drop of gel /oil ie., chlorhexidine gel/ozonated oil respectively, onto their index finger and application of the same topically onto the buccal and lingual surfaces of marginal gingiva twice daily ie.,morning and night after 30 minutes of

consumption of food and subjects were advised not to eat or drink ,at least half an hour following the application .

Follow up phase

On day 7th, 14th and 21st day the subjects with both control and the test groups were recalled for the reassessment of the same clinical parameters which was done by a calibrated examiner who is not the part of the study.

Outcome measurements

The principal investigator (PI) and calibrated examiner conducted all clinical examinations. The calibrated examiner was blinded to the treatment modality that has been provided to each subject.

The primary outcome was assessment of plaque index (Turesky-Gilmore-Glickman modification of Quigely Hein index,1970), gingival index (Loe and Silness 1963), bleeding index (Modified sulcular bleeding index by A.Mombelli 1987) for all the subjects. The secondary outcome was assessment of the same clinical parameters for all the subjects at 7th,14th, and 21st day of the study.

Examiner calibration

All measurements of clinical parameters were performed by principal investigator and a calibrated examiner. At baseline the clinical parameters were assessed by principal investigator whereas, at day 7,14 and 21 clinical parameters were assessed by calibrated examiner who is not the part of study in order to avoid bias.

Statistical analysis:

Collected data was analyzed by both descriptive and inferential methods. Descriptive methods such as mean and standard deviation were computed to summarize the data. Inferential method such as Independent t test and Paired sample t test were used to compare the parameters across different time periods between the two groups and within the groups respectively. And for multiple comparisons between the groups Bonferroni test was used. Value of <0.05 was considered as statistically significant, P value of < 0.002 is considered as high statistical significance and P value of <0.001 is considered as very high statistical significance.

Level of significance in the present study was 5%.Data was subjected to statistical analysis with the statistical package for social science software (SPSS, version 22.0)

AGE:

In group 1, the mean value of age was 27.800±6.844 and group 2 was 21.100±2.282 the mean value of age is with t value of 2.939 and p value of 0.009, which denotes that, there is statistically significant difference between the groups. **(Table 1)**

Age

group	N	Mean	Std. Deviation	T
Chlorhexidine	10	27.80	6.84	2.939
Ozone	10	21.10	2.28	P=0.009 hs

Clinical parameters

In the intragroup comparison, the mean values of PI,GI, and BI in group I and group II from baseline to 21st days showed statistically significant difference with p < 0.001 (**Table 2,3 and 4**)

In group I the mean difference in PI from baseline to 14th day is 0.340, 14th day to 21st day is 0.290 and baseline to 21st day is 0.630. On comparing these values there is statistically significant difference between the follow up with p value <0.001 (**Table 5**)

The mean difference in terms of PI in group II from baseline to 14th day is 0.430 and 14th day to 21st day is 0.290 and baseline to 21st day is 0.720.On comparison, there is reduction in mean plaque index score between the follow up which is statistically significant with p value <0.001 (**Table 5**)

The mean difference in GI score in group I from baseline to 14th day is 0.390, baseline to 21st day is 0.610 and the difference statistically significant with p value <0.001, whereas, the mean difference between 14th to 21st day is 0.220 with p value 0.010 which implies that there is no statistically significant difference (**Table 5)**

BI score was reduced in group I and group II from baseline to 14th day and baseline to 21st day with p value <0.001, but there is no statistically significant reduction in the GI score from 14th to 21st group I and group II with p value >0.001(**Table 6)**

On intergroup comparison, there is no statistically significant difference between the groups from baseline to 21st day in terms of PI,GI, and BI with p value >0.001 (**Table 7**)

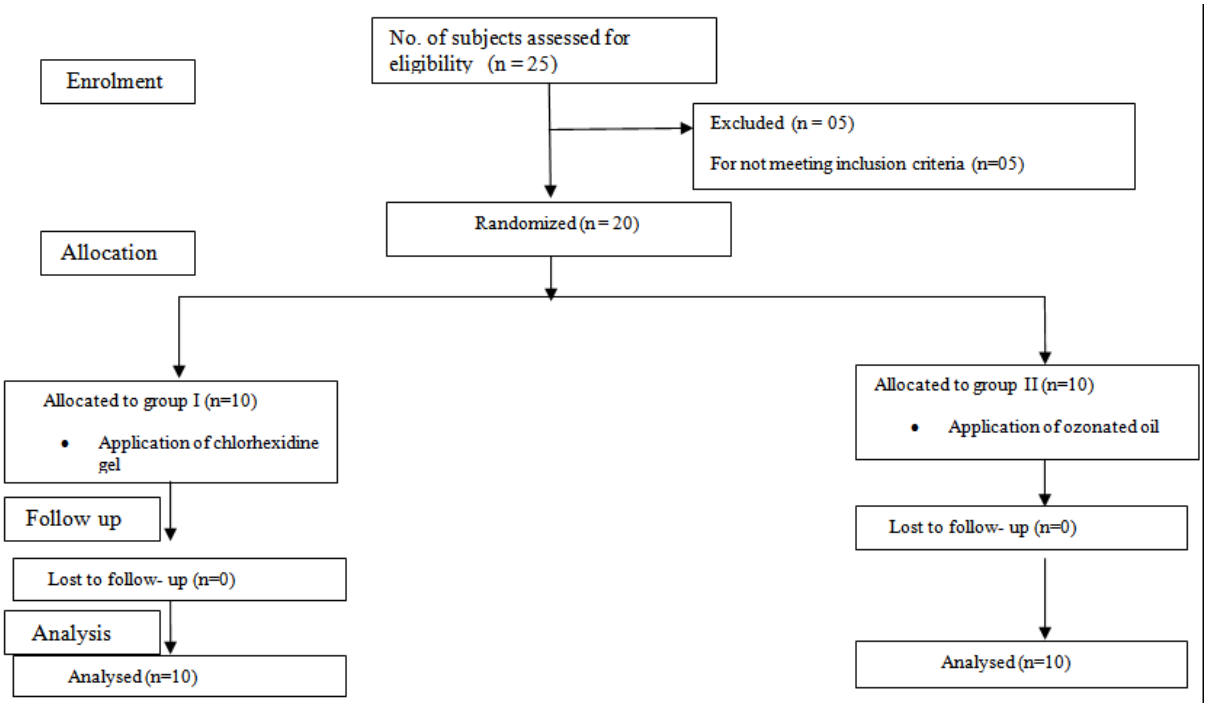


Fig. 2 CONSORT study flow chart of various phases of clinical study.

III. Discussion

Plaque-induced gingivitis is an inflammatory process, limited to the gingiva, resulting due to bacterial insult at the gingival margin. To prevent gingivitis and its progression to periodontitis, effective supra-gingival plaque control measures are considered the most effective methods to regain and maintain dental and periodontal health.[1]

The addition of a chemical agent as an adjunct to conventional plaque control methods has been suggested to improvise the effectiveness of plaque control.

Chlorhexidine gluconate is an efficient broad spectrum antimicrobial agent with its effects on gram positive and gram negative bacteria, viruses, and fungi [3]. However, due to its undesirable effects such as brownish discolouration of teeth, dorsum of tongue and taste alteration after prolonged use, several other alternatives to chlorhexidine have been investigated [6].

Ozonated preparations are one among them as they are highly effective in killing bacteria present in different forms. The main use of ozone in dentistry relies on its antimicrobial properties. Ozonated oils are obtained from the chemical reaction between ozone and unsatured fatty acids of vegetables oils.[7,8] They are gaining importance due to its excellent curative results, simple application, long-term effects, and nontoxic nature.[6]

The aim of the present study was to compare the clinical effectiveness of chlorhexidine gel and ozonated oil in the treatment of plaque induced gingivitis patients.

The results indicated that, both group I and group II from baseline to 21st day showed statistically significant reduction in terms of PI, GI, and BI, but there is no statistically significant reduction between the groups from baseline to 21st day after the application of chlorhexidine gel/ozone oil.

The results of the present study is in accordance to the study conducted by Indurkar MS, Verma [1], who assessed the efficacy of the same products which were used in our study, but assessment of clinical parameters on 14th day was not carried out in their study.

Group		N	Mean	Std. Deviation	F	P
	Baseline	10	1.250	.165		
Group I	14th day	10	.910	.099		
	21st day	10	.620	.181	42.614	.000
	Baseline	10	1.350	.165		
Group II	14th day	10	.920	.079		
	21st day	10	.630	.134	76.695	.000

Table 1-comparison of plaque index in group I and group II from baseline to 21st day

Group		N	Mean	Std. Deviation	F	P
Group I	Baseline	10	1.240	.143	40.900	.000
	14th day	10	.850	.151		
	21st day	10	.630	.164		
Group II	Baseline	10	1.290	.145	47.010	.000
	14th day	10	.910	.137		
	21st day	10	.610	.185		

Table 2-comparison of gingival index in group I and group II from baseline to 21st day

Group		N	Mean	Std. Deviation	F	P
Group I	Baseline	10	1.160	.207	27.749	.000
	14th day	10	.750	.158		
	21st day	10	.580	.169		
Group II	Baseline	10	1.240	.246	36.995	.000
	14th day	10	.800	.105		
	21st day	10	.560	.158		

Table 3-comparison of bleeding index in group I and group II from baseline to 21st day

Group	Dependent Variable	(I) Duration	(J) Duration	Mean Difference (I-J)	P
Group I	Plaque index	Baseline	14th day	.340	.000
			21st day	.630	.000
		14th day	21st day	.290	.001
Group II	Plaque index	Baseline	14th day	.430	.000
			21st day	.720	.000
		14th day	21st day	.290	.000

Table 4-comparison of plaque index in group I and group II from baseline to 14th day, 21st day 14th and 21st day

Group	Dependent Variable	(I) Duration	(J) Duration	Mean Difference (I-J)	P
Group I	Gingival Index	Baseline	14th day	.390	.000
			21st day	.610	.000
		14th day	21st day	.220	.010
Group II	Gingival Index	Baseline	14th day	.380	.000
			21st day	.680	.000
		14th day	21st day	.300	.001

Table 5-comparison of gingival index in group I and group II from baseline to 14th day, 21st day 14th and 21st day

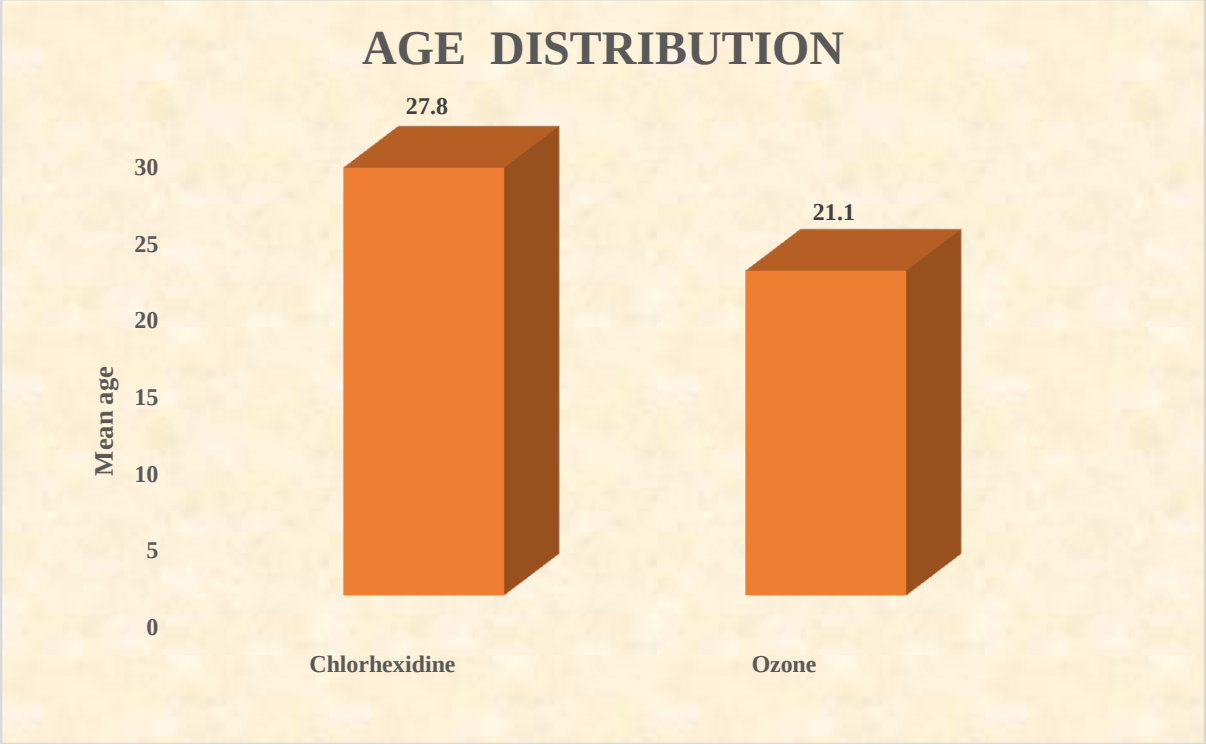
Group	Dependent Variable	(I) Duration	(J) Duration	Mean Difference (I-J)	P
Group I	Bleeding index	Baseline	14th day	.410	.000
			21st day	.580	.000
		14th day	21st day	.170	.129
Group II	Bleeding index	Baseline	14th day	.440	.000
			21st day	.680	.000
		14th day	21st day	.240	.018

Table 6-comparison of bleeding index in group I and group II from baseline to 14th day, 21st day 14th and 21st day

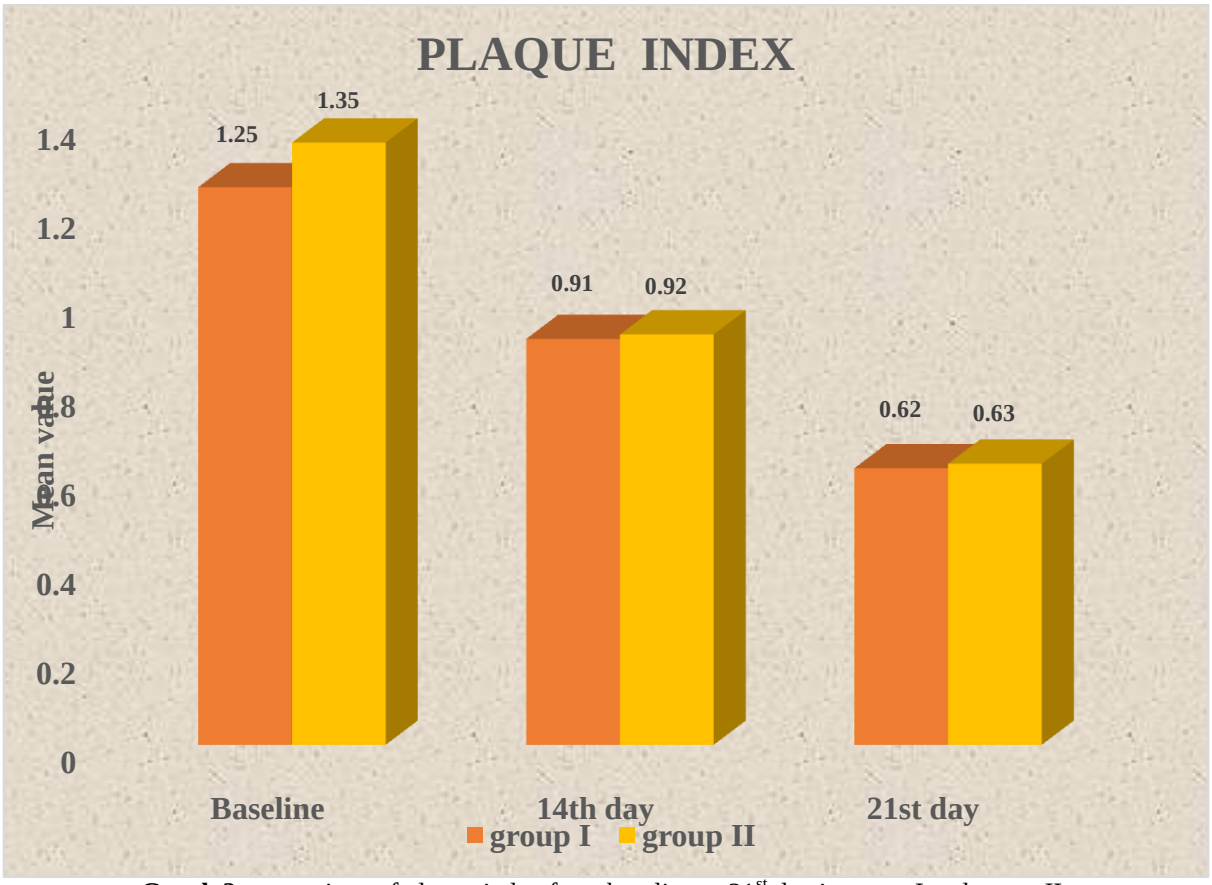
Plaque index	Duration	Group	N	Mean	Std.Deviation	T	
	Baseline	Group I	10	1.250	.165	1.355	
		Group II	10	1.350	.165	p=0.192 ns	
	14th day	Group I	10	.910	.099	.249	
		Group II	10	.920	.079	p=0.806 ns	
	21st day	Group I	10	.620	.181	.140	
		Group II	10	.630	.134	p=0.892 ns	
Gingival index	baseline	Group I	10	1.240	.143	.777	
		Group II	10	1.290	.145	p=0.477 ns	
	14th day	Group I	10	.850	.151	.931	
		Group II	10	.910	.137	p=0.364 ns	

	21st day	Group I	10	.630	.164	.256
		Group II	10	.610	.185	p=0.801 ns
Bleeding index	Baseline	Group I	10	1.160	.207	.788
		Group II	10	1.240	.246	p=0.441 ns
	14th day	Group I	10	.750	.158	.831
		Group II	10	.800	.105	p=0.416 ns
	21st day	Group I	10	.580	.169	.274
		Group II	10	.560	.158	p=0.787 ns

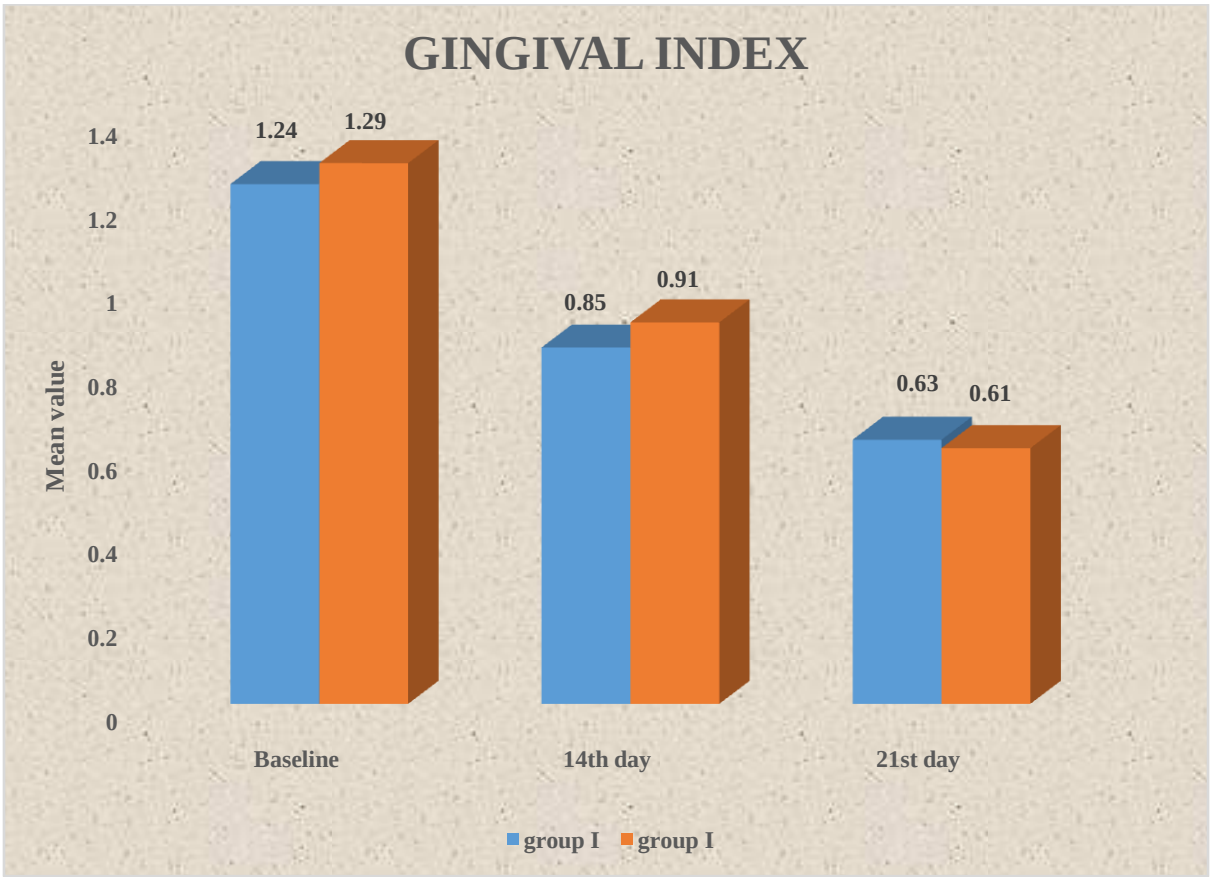
Table 7-comparison of plaque index, gingival index and bleeding index on baseline, 14th day, and 21st day between the group I and group II



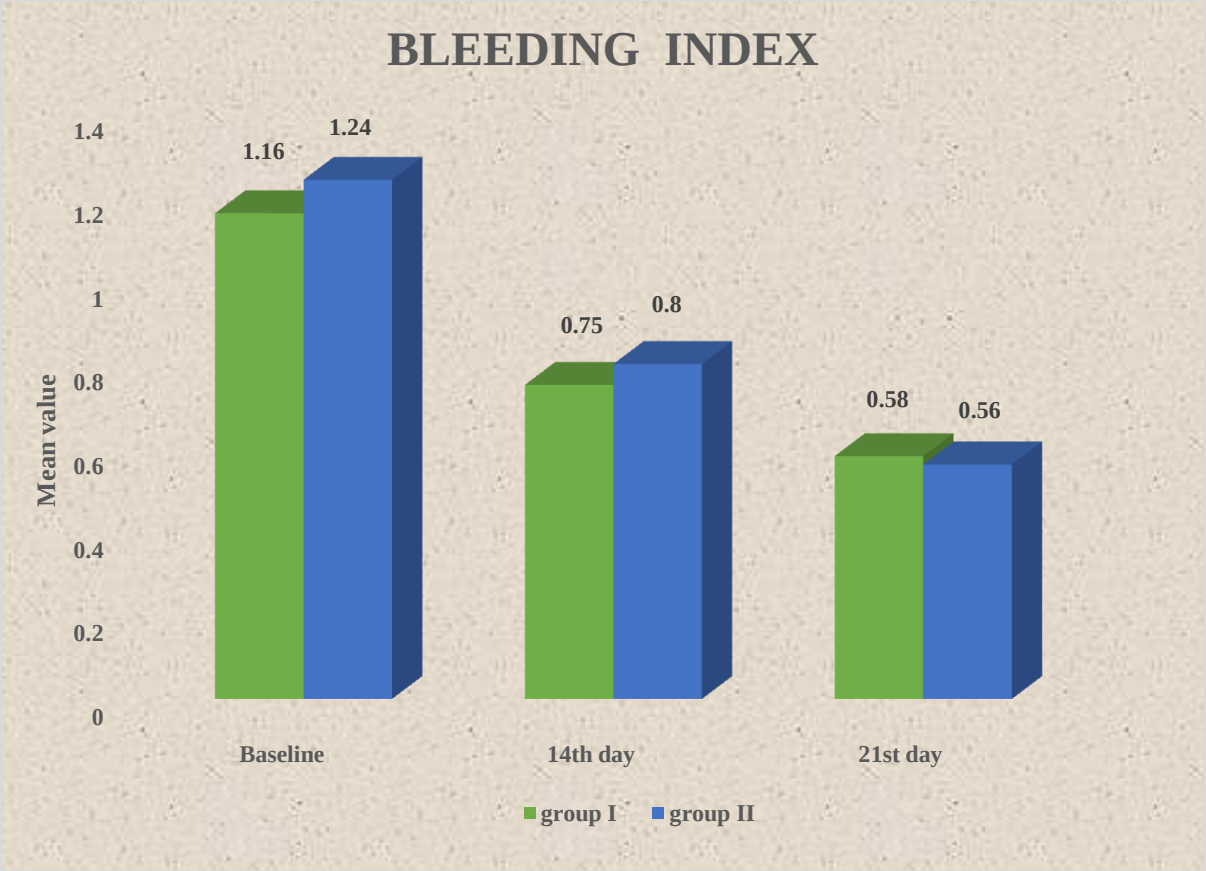
Graph 1-comparison of age between group I and group II



Graph 2-comparison of plaque index from baseline to 21st day in group I and group II



Graph 3-comparison of gingival index from baseline to 21st day in group I and group II



Graph 4-comparison of bleeding index from baseline to 21st day in group I and group II

The possible explanations that can attribute to the results of our study are as follows:

- Antimicrobials like chlorhexidine and ozonated oil are used for the treatment of plaque induced gingivitis.
- The application of these antimicrobials on the tooth surface causes disruption of biofilm, which inhibits bacterial adhesion and plaque co-aggregation at the gingival margins, thus improving the gingival health as stated by indurkar, Verma [1]
- Chlorhexidine gluconate has been referred to as a gold standard for treatment of plaque induced gingivitis and as an effective chemical plaque control aid. It is an efficient broad spectrum antimicrobial agent. Cationic molecules of chlorhexidine binds to the negatively charged surfaces such as teeth surface, dental pellicle and bacterial cell wall causing bacterial cell lysis. Chlorhexidine has a substantivity of 12 h and hence it is used twice daily, which was followed in our study.
- Hirschfield [9] demonstrated the significant reduction in gingivitis by use of chlorhexidine gluconate gel on topical application, which is in accordance to our study.
- O3-Oil has also been proven to be effective against these eight periodontal putative pathogens aggregatibacter actinomycetemcomitans, campylobacter rectus, eikenella corrodens, fusobacterium nucleatum, porphyromonas gingivalis, prevotella intermedia, treponema denticola, and tannerella forsythia, as assayed by multiplex PCR method.[5] This can be attributable to the reduction in the bleeding on probing which was observed in our study from baseline to 21st day after the application of ozonated oil.
- O_3-Oil showed significantly greater diameters of growth inhibition ($p<0.01$) than chlorhexidine digluconate and PVP-1 in all dilutions for both staphylococcus aureus (Sa) and porphyromonas gingivalis (Pg) strains[9]. This can be attributable to the reduction in gingival index score from baseline to 21st day in our study.
- Other possible mechanisms might be that, the saponification that occurs as a result of alkali hydrolysis of fat, when oils are acted upon by salivary alkalis such as bicarbonates, soap making process will be initiated. Soaps are known to be good cleansing agents because they are emulsifiers. Emulsification greatly enhances the surface area of the oil, thereby increasing its cleansing action.[10]

Observations made this study are as follows:

- In our study, there was an inclusion of 14th day follow up from baseline, which helped in obtaining comprehensive data on clinical parameters. We observed there was no statistically significant difference

between 14th to 21st day in group I in terms of GI and in group I, group II in terms of BI. In other similar studies this particular follow up has not been included.

- In our study, BI was recorded to assess the presence of the active disease, which was not recorded in the study conducted by Indhurkar and Verma.
- There is no bias in the obtained results as there was incorporation of blinding in the study design and also there is no inclusion of any other therapy to improve oral hygiene.

Limitations of the present study are as follows:

- The groups were unsupervised in the application of therapeutic agents, as it was not professional application.
- Smaller sample size was used in our study, so obtained results has to be validated with larger sample size.
- Lack of microbial assessment.

Results of the present study demonstrated that, there is statistically significant reduction in terms of PI, GI and BI from baseline to 21st day within group I and group II. Furthermore longitudinal, randomized, microbial and controlled clinical trials with larger sample size are necessary to adequately test the potential benefits of ozonated oil over chlorhexidine gel and other antimicrobial agents.

IV. Conclusion

Gingival application of ozonated oil can be effective alternative to chlorhexidine gel to combat plaque induced gingivitis.

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