

COMPARATIVE EVALUATION OF FLAX SEED AND CHLORHEXIDINE MOUTHWASH IN THE TREATMENT OF GINGIVITIS – A CLINICO-IMMUNOLOGICAL STUDY***Dr. Georgina George Ettiyil, Dr. Harsha Mysore Babu, Dr. Vivekananda M. R., Dr. Shivaprasad D., Dr. S. Ravindra**

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ABSTRACT

Background and Objectives: One of the noteworthy developments in this age of dentistry is that the dental practice is based on preventive measures and the surfacing of a philosophy. Chemical agents have been advocated as adjuncts to mechanical methods to augment the plaque control. Flax seed is known for its anti-inflammatory action. Studies evaluating its effects on gingivitis are scarce. Hence, the present study was aimed to compare and evaluate the efficacy of Flax seed as an anti-inflammatory agent with chlorhexidine gluconate in the treatment of plaque induced gingivitis. **Materials and Methods:** In this randomized controlled clinical trial, 30 subjects were randomly assigned to two groups with 15 subjects in each group, Group A received Scaling+ Flax seed mouthwash and Group B received Scaling + Chlorhexidine mouthwash. Clinical parameters like Plaque index (PI), Gingival index (GI), Sulcular Bleeding Index (PBI) and immunological parameters i.e., Interleukin-6 (IL-6) levels were assessed at baseline and at one month. Statistical analysis was carried out using SPSS software 2.0. **Results:** The results of the current study showed that the mean scores of PI, GI, SBI and the levels of IL-6 at baseline and at one month had consistently decreased to lower values in both Group A (7.586 ± 4.04) and Group B (11.716 ± 8.19) which was statistically significant on intragroup analysis. The results from baseline to one month were comparable on intergroup analysis with no statistically significant difference. **Conclusion:** Flax seed mouthwash was found to be equally effective as chlorhexidine gluconate in treating chronic generalized gingivitis.

KEYWORDS: Flax seed, Mouthwash, Gingivitis, Chlorhexidine Gluconate, Interleukin-6.**INTRODUCTION**

Gingivitis is an inflammatory process limited to the epithelial tissues surrounding the coronal portion of the teeth and it is one of the most common diseases of the oral cavity which is mostly induced by microbial plaque. The etiological factors are mostly due to higher accumulation of plaque in the cervical area of the teeth.^[1] Inflammation is a natural defensive mechanism that protects the host from bacterial infection and other noxious challenges.^[2]

Mouthwashes are being used as an adjunct to mechanical plaque control therapy to get better results. Mouthwashes of herbal origin may offer noteworthy recompenses over the chemical ones like listerine and chlorhexidine.^[3] In the field of Periodontal disease prevention, herbal products have shown to be good substitutes to synthetic substances and an outsized proportion of the population prefers herbal origin products.^[4] Among these phytotherapeutic preparations, flax seed plays a essential role due to its effective anti-inflammatory and anti-oxidant properties which are contributed to by omega-3

fatty acid present as a major element.^[5] Simopoulos et al, documented that systemic consumption of omega-3 polyunsaturated fatty acids downregulates the production of inflammatory mediators (PGE2 and leukotrienes) and inflammatory cytokines.^[6] Similarly, dietary supplements that contain omega-3 fatty acids have also been reported as a chief effector on reactive oxygen species thereby promoting the anti-oxidant effect.^[7]

Flax seed, 'Linum usitatissimum', in latin translates to "very useful". Flax seed is an imperative functional food component, abundant in omega-3,6 and 9 polyunsaturated fatty acids (PUFA), alpha-linolenic acid (ALA), lignans and fibre. Diminution of cardiovascular disease, atherosclerosis, arthritis, osteoporosis, diabetes, cancer, autoimmune and neurological disorders are some of the inherent health benefits Flax seeds.^[8,9] Essential fatty acids such as polyunsaturated fatty acids, linoleic acid (LA), and the essential omega-3 fatty acid, omega-6 fatty acid are the prime constituents of Flax seed. The plant derived sources of omega-3 fatty acids are scarce and Flax seeds and flax oil is a promising option for

vegan or vegetarian diet followers.^[10] Adequate dietary consumption of omega-3 polyunsaturated fatty acids (n-3 PUFAs) on a regular routine increases tissue levels of fatty acids that downregulate inflammation.^[11]

In chemical plaque control, Chlorhexidine is regarded as the 'gold standard',^[12] but there are a few demerits allied with the prolonged usage such as alteration in taste perception and discoloration of teeth to name a few. Also, it has been reported that few oral bacteria develop opposition to the antibacterial activity of chlorhexidine.^[13] These limitations of chlorhexidine have led to the expansion of naturally occurring oral hygiene products.

There is a need for a long term, natural and economical remedy for routine plaque control. As there is paucity in literature regarding therapeutic benefits of Flax seed, this study was conducted to evaluate the anti-inflammatory property of flax seed extract incorporated in a mouthwash formulation for the management of patients diagnosed with chronic generalized gingivitis in comparison to chlorhexidine.

MATERIAL AND METHODOLOGY

Study population: This study was a randomized controlled clinical trial carried out at, Dept of Periodontics, Sri Hasanamba Dental College and Hospital, Hassan, India. The study protocol was approved by the ethical committee of the institution. The patients were explained about the study and a written informed consent was obtained from all the patients prior to the intervention.

Study design: A total of 47 patients were assessed for eligibility for the study, out of which 11 patients were excluded (7 did not meet inclusion criteria and 4 were not willing to participate in the study). Thus, 36 patients were included in the study. They were divided into two groups randomly using the chit method- Group A received Scaling and Flax seed mouthwash (test group) and Group B received Scaling and Chlorhexidine mouthwash (control group). (Figure 1).

The inclusion criteria for the study were patients aged between 18-35 years, diagnosed with Chronic generalized gingivitis, full mouth bleeding score ≥ 1 , who had not undergone dental treatment for the past three months and who had not taken any antibiotic or anti-inflammatory drug therapy in the preceding 6 months were included in the study. Participants with any systemic diseases/ conditions or fibrotic gingival enlargement or if allergic to flax seed were excluded from the study. Also, participants who were smokers, pregnant or lactating women were excluded from the study.

At the baseline, standardized oral hygiene procedures were performed on all patients. The patients were provided with the mouthwashes of their respective

group. Same set of oral hygiene maintenance instructions were given to the patients. The patients were recalled after 30 days from baseline. The clinical parameters, Plaque index^[14], Gingival index^[15] and Sulcular bleeding index^[16] were recorded at baseline and on 30th day. The GCF samples were collected at baseline and on 30th day for analysis of Interleukin -6 levels using Human IL-6 ELISA kit (Fine Test®, EH0201).

STATISTICAL ANALYSIS

Statistical analysis was done using SPSS software version 20 and Microsoft excel version 2007. Independent student t test was used to compare PI, GI, SBI and IL-6 levels between two groups at different time intervals. Student paired 't' test was used to compare the mean PI, GI, SBI and IL-6 levels between different time intervals within each study group. The level of significance (P- value) was set at $p < 0.05$.

RESULTS

The values of Plaque index (PI), Gingival index (GI) and Sulcular bleeding index (SBI) are depicted in Table 1 at baseline and at one month time interval. Independent student t test was performed to compare the mean value of the indices at baseline and at one month period between group A and group B. The test results revealed that there was no statistically significant difference demonstrated between group A and group B at baseline and at one month for PI and GI.

At one month, Group A showed statistically significant lesser mean SBI score 0.5358 ± 0.14945 than Group B (0.6788 ± 0.15524) at $p=0.016$. However the mean PI and GI score did not significantly differ between the two groups. Hence, from this tabular data, we can infer that Group A was significantly effective in reducing the Sulcular bleeding score compared to Group B.

The mean Interleukin-6 (IL-6) levels at baseline and at one month are depicted in Table 2. Unpaired t test was performed to compare the mean IL-6 levels at baseline and at one month between group A and group B. The test results revealed that, even though there was marked reduction in IL-6 levels from baseline to one month, there was no statistically significant difference demonstrated between group A and group B at baseline and at one month interval.

The intragroup comparison of the mean scores are depicted in Table 3 at baseline and at one month interval. Student paired t test was performed to compare the mean PI, SBI, GI and IL-6 levels between baseline and one month within group A and group B. The test results demonstrated a statistically significant lesser mean PI, SBI, GI and IL-6 levels in the post intervention period compared to the baseline period in both group A and group B at $P < 0.001$. Hence, we can infer that both Flax seed mouthwash and Chlorhexidine is equally potent in significantly reducing the clinical and immunological parameters during one month period of the study.

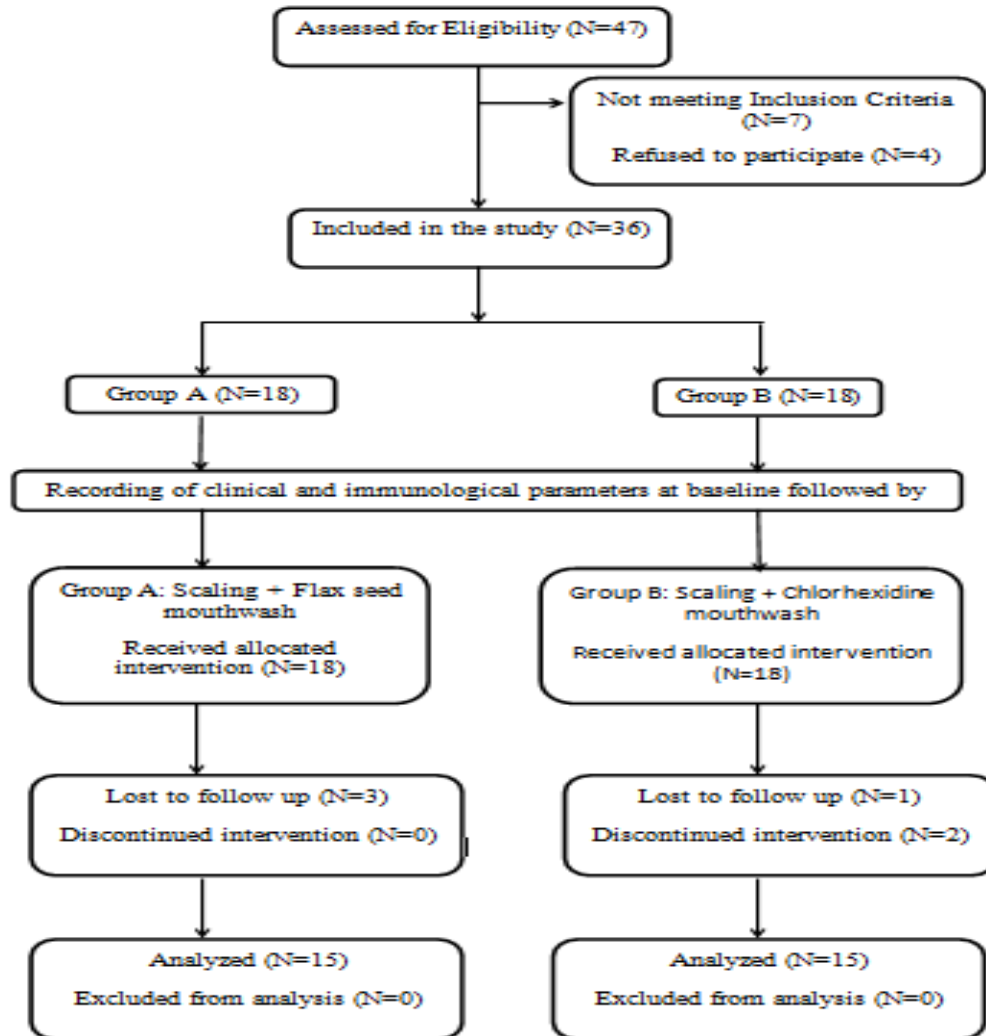


Figure 1: Study design flowchart.

Table 1: Comparison of mean scores of PI, GI, SBI between two study groups at baseline and at one month.

TIME	PARAMETER	GROUP	N	MEAN	SD	P VALUE
BASELINE	PI	GROUP A	15	1.3759	0.19825	0.363
		GROUP B	15	1.316	0.15366	
	GI	GROUP A	15	1.3445	0.20212	0.056
		GROUP B	15	1.2312	0.0881	
	SBI	GROUP A	15	1.3657	0.1538	0.037*
		GROUP B	15	1.2373	0.16692	
AT ONE MONTH	PI	GROUP A	15	0.6137	0.16778	0.373
		GROUP B	15	0.6663	0.15048	
	GI	GROUP A	15	0.5462	0.16833	0.19
		GROUP B	15	0.6295	0.17186	
	SBI	GROUP A	15	0.5358	0.14945	0.016*
		GROUP B	15	0.6788	0.15524	

PI- Plaque index, GI- Gingival index, SBI- Sulcular bleeding index, SD- Standard deviation

*P value: level of significance at $p < 0.05$ was considered statistically significant

Table 2: Comparison of mean Interleukin -6 levels between two study groups at baseline and at one month.

GROUPS	PARAMETER	N	MEAN DIFFERENCE from BL to 1M	SD	P VALUE
GROUP A	PI	15	0.76227	0.2257	<0.001
	SBI		0.82987	0.21672	<0.001
	GI		0.79833	0.27092	<0.001
	IL-6		7.586	4.04	<0.001
GROUP B	PI	15	0.64967	0.24635	<0.001
	SBI		0.55853	0.22392	<0.001
	GI		0.60167	0.188	<0.001
	IL-6		11.716	8.19	<0.001

PI- Plaque index, GI- Gingival index, SBI- Sulcular bleeding index, SD- Standard deviation
*P value: level of significance at $p < 0.05$ was considered statistically significant

Table 3: Intragroup comparison of mean scores of PI, SBI, GI and IL-6 levels at baseline and at one month within each study group using Student paired t test.

TIME	Group	N	Mean	S. D	P value
BASELINE	GROUP A	15	12.053	4.013	0.182
	GROUP B	15	15.63	9.294	
AT ONE MONTH	GROUP A	15	4.466	3.165	0.608
	GROUP B	15	3.913	2.649	

PI- Plaque index, GI- Gingival index, SBI- Sulcular bleeding index, SD- Standard deviation
P value: level of significance at $p < 0.05$ was considered statistically significant



Figure 2: Armamentarium for IL-6 levels testing using ELISA kit.

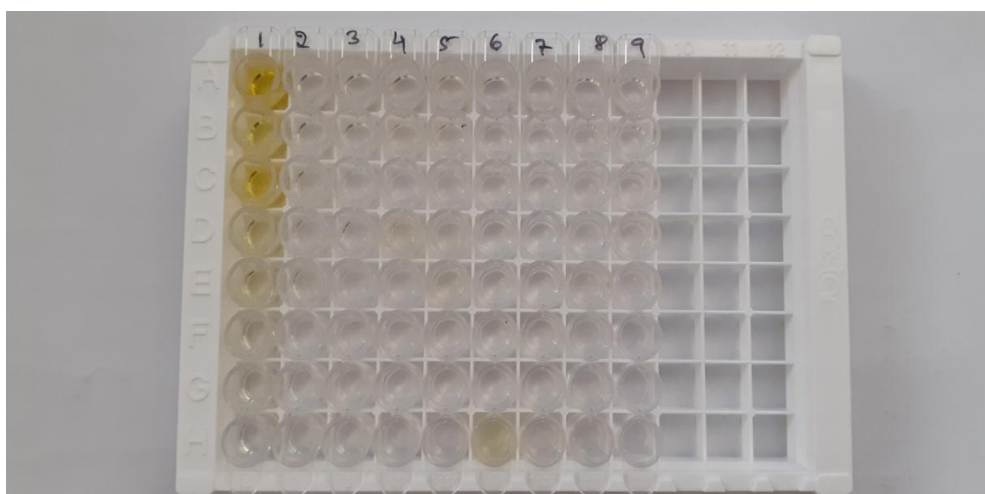


Figure 3: Final reading taken post addition of stop solution.**DISCUSSION**

There are multiple risk and vulnerability factors which have been proposed to explain the commencement and succession for the periodontal diseases which are multifactorial in nature.^[17] The primary etiologic factor to initiate periodontal disease is considered to be the bacterial plaque.^[18] Multiple species of microorganisms co-exist in the form of a biofilm on the tooth surface and are associated with the plaque maturation.

Regular plaque control is key factor in preventing and arresting the progression of the disease. More emphasis is laid on oral hygiene measures for plaque control. Mechanical plaque control is considered to be the gold standard of periodontal therapy.^[19] It includes toothbrush, interdental floss, interdental brushes and woodsticks.^[20]

The efficiency of mechanical plaque control by the patient depends upon dexterity and motivation level of the patient, hence the mechanical plaque control might not always be sufficient completely.^[19] Thus, mechanical agents are supported with adjuvant action of chemical plaque control measures which include mouthwashes. A mouthwash is a premedicated fluid which is supposed to be held and swished by the action of perioral musculature to eradicate the oral pathogens.^[21] The mouthwashes provide a means of depositing an active material for slow release in the mouth and contribute to the anti-inflammatory and antiplaque result for a long phase of time.^[17]

Herbal medicine is both defensive and protective in its approach. The naturally occurring active components in these herbal materials offer a mild and lasting way of restoration of health in a most dependable and least detrimental way.^[22] India is known for its rich source of natural herbal produce which have shown to be effective both topically and systemically. The relatively safe nature and cost-effectiveness of herbal extracts have led to a resurgent interest in their utility as therapeutic agents. The advantages of Herbal mouthwashes are that they do not contain any baleful ingredients or added sugars or harmful preservatives. This fact gives the herbal mouthwashes an additional edge over chlorhexidine mouthwashes.^[22] The current study has attempted to evaluate the efficacy of one such herbal mouthwash which was composed of Flax seed extract in comparison to Chlorhexidine gluconate mouthwash.

Flax seed (*Linum usitatissimum*) is a fibrous crop which originated from India and was domesticated in the Middle East. It belongs to the family Linaceae, and is rich in the omega-3 fatty acid alpha-linolenic acid.^[23] Flax seed is used as food; the seeds are usually roasted, ground added to grain/legume stew (shiro wot).^[9] It is also consumed in the form of porridge. Limited amounts are also pressed locally for its edible oil. In ancient medicine remedies, flaxseed was taken per oral as a

home remedy for diarrhoea, constipation, ulcerative colitis, enteritis and several other gastrointestinal diseases. Flax seeds have high antioxidant activity that could treat the symptoms of diabetes, acne, high cholesterol, cardiovascular disease, and other heart conditions. It is also believed to be functional for certain cancers and psychological disorders.^[24]

The results of the current study have shown that the mean scores of PI, SBI, GI and IL-6 levels at baseline and at one month had consistently decreased to lower values in both Group A (Flax seed mouthwash) and Group B (Chlorhexidine mouthwash) which was statistically significant on intragroup analysis. The results from baseline to one month were comparable on intergroup analysis which showed improvement on clinical parameters but not statistically significant.

There have been reports of the flax seed herbal mouthwash showing positive beneficial effects on the clinical parameters. The results of our study were similar to the findings of **Deepika A** who compared the efficacy of CHX and the flax seed (oil pulling therapy) mouthwash. The test group used flaxseed oil (as oil pulling) every morning before brushing and the control group had used chlorhexidine mouth rinse. Re-evaluation of the indices was done post 30 days in both the groups. It was concluded that flaxseed oil is an effective adjuvant in reducing plaque-induced gingivitis.^[25]

The results of this study is in conjugation to the findings of **Apoorva B B et al** who conducted an in vitro study to evaluate antimicrobial activity of flaxseed extract against periodontal pathogens. It was concluded that, the study demonstrated bactericidal role of flaxseed against *P. gingivalis*, a key periodontal pathogen and can be an adjunct to periodontal therapy.^[26] In another study, **Pappu R et al** evaluated the efficacy of an indigenously formulated flax seed extract in the form of biodegradable gel, as an adjunct in the treatment of chronic periodontitis. The results of the study demonstrated that the flax seed extract gel could be equally associated to the effectiveness of flurbiprofen gel, at the end of three months.^[27]

CONCLUSION

The results showed that the test group showed a statistically significant improvement in the clinical and immunological parameters and a statistically significant difference was observed. It was found that Flax seed mouthwash had a comparable efficacy with chlorhexidine. Based on these results, the present study indicates that 33.3% Flax seed mouthwash can be used as an adjunct to scaling in the treatment of chronic generalised gingivitis. However, larger and more robust clinical trials for longer duration are required to verify these findings and corroborate its use as an adjunctive therapy for the management of plaque induced gingivitis.

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