

Original Article**Comparative Evaluation of Oral Irrigator and Dental Floss as an adjunct to Tooth Brushing on Reduction of Plaque and Gingivitis- A Randomized, Single Blind Clinical Study of Rural Patients****P.K. Sasikumar¹, Shankar Shanmugam², Sakthi Saranya Devi³, M.Kirthika⁴**¹Reader, Dept of Periodontics, ²Reader, Dept of Public Health Dentistry, J.K.K.N Dental College and Hospital, Kumarapalayam, Namakkal^{3,4}Dept. of Oral Medicine and Radiology, Dept of Pedodontics, Vinayaka Mission Sankarachariyar Dental College & Hospital, Salem.

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ABSTRACT

Aim: The purpose of this short-term, randomized trial was to assess the efficacy of the addition of daily oral irrigation and dental floss to manual tooth brushing and also compared to determine which regimen had the greatest effect on the reduction of plaque and gingivitis. **Material and methods:** A parallel clinical study of 70 subjects was performed over a period of four weeks. The subjects in the first group (OIS) were trained in the correct use of oral irrigator, once per day in the evening and the second group (DF) were trained to brush their teeth two times per day, in the morning and evening, with uses of standard dental floss. Pre-scaling baseline data was recorded; subjects were re-evaluated after the scaling regarding their oral hygiene and gingival status in the 2nd and 4th week follow-up. **Results:** After four weeks, subjects who used oral irrigator associated regular tooth brushing demonstrated that significant decreases ($p < 0.001$) in papillary bleeding, of 16.80%, with an initial mean PBI value of 0.93 (± 0.15) and a final mean PBI value of 0.59 (± 0.25). **Conclusion:** These results supported the clinical efficacy of oral irrigator for the removal of bacterial plaque from proximal tooth areas. When combined with manual tooth brushing the daily use of an oral irrigator with standard jet tip, is significantly more effective in reducing gingival bleeding scores than is the use of dental floss, as determined within the limits of this 4-week study design

Introduction

Dental plaque is a host-associated biofilm which are matrix-enclosed bacterial populations that are firmly adherent to each other and to the surface. Dental plaque is the primary aetiological factor for the exacerbation of periodontal diseases and caries formation¹. They cannot easily dislodged and consist of an estimated 400 to 1,000 species of bacteria². The products of biofilm bacteria are known to initiate a chain of reactions leading to *host* protection, and also to tissue destruction. Haffajee et al.³ demonstrated that meticulous supragingival plaque removal reduces inflammation and gingival crevicular fluid (GCF). This alters the subgingival environment and modifies both the quantity and composition of subgingival plaque.

Periodontal diseases are multifactorial oral conditions, consisting of a diverse family of pathological conditions affecting the periodontium which commonly occur in the population (Mariotti 1999)⁴. In 1999, Periodontal diseases classified into gingival diseases and periodontal diseases. Gingival diseases were sub classified as dental plaque induced and non-plaque induced⁵. The effective removal of dental plaque is essential for the prevention of periodontal disease and dental caries. In UK Adult Dental Health Survey 1998 showed that 72% of subjects had visible plaque on at least one tooth, with little difference between the groups of respondents, stratified by age, gender and social class⁶.

* Corresponding author : Dr. Sasikumar Karuppanan, Reader, Dept of Periodontics, J.K.K.N Dental College and Hospitals, Kumarapalayam, Namakkal Dist, Tamilnadu., Email: sasikumar@jkkn.org

Original Article

Plaque Index		N	Mean	SD	t	p
Plaque Index	Baseline	32	1.638	0.276	44.54	< 0.001**
	4 weeks	32	1.438	0.269		
P.Bleeding Index	Baseline	32	1.438	0.269	17.36	< 0.001**
	4 weeks	32	1.172	0.253		
Gingival Index	Baseline	32	1.638	0.276	28.11	< 0.001**
	4 weeks	32	1.172	0.253		
t-Test using for Group B (Oral Irrigator)						
Plaque Index	Baseline	32	0.859	0.238	14.41	< 0.001**
	4 weeks	32	0.716	0.199		
P.Bleeding Index	Baseline	32	0.716	0.199	12.90	< 0.001**
	4 weeks	32	0.563	0.170		
Gingival Index	Baseline	32	0.859	0.238	16.80	< 0.001**
	4 weeks	32	0.563	0.170		

Table 1: Comparison of Intra Group of A and B using Independent t-Test at Baseline, 2 and 4th week

This survey did not record specific information about methods of plaque removal used but only frequency of tooth cleaning.

Debridement of calculus and disruption of the oral biofilm by oral healthcare professionals has been shown to be effective for reducing the clinical parameters of gingival bleeding and mean pocket depths by shifting the proportions of the species during recolonization and by modifying the habitat (Haffajee 2001)⁷. Over 3 months there is a gradual shift back to pathogenesis if patients do not have meticulous, frequent removal of supragingival dental plaque. The recolonisation of periopathogens occur when supragingival dental plaque is allowed to accumulate, triggering the inflammatory response, allowing bacteria to extend subgingivally, and establishing an environment that favours pathogen regrowth (Haffajee 2006).

Various studies showed that most of the individuals remove only about 40% to 50% of plaque by tooth brushing. The results of those studies indicated that most subjects are not

brushing effectively, even though they brush

once every day. There is no single oral hygiene method that is correct for all patients due to differences in the morphology of the dentition, oral health/disease status, and/or the individual's manual dexterity⁸. The Oral Irrigator (OI) was introduced to the dental profession in 1962 and has been studied extensively for the past decades. Clinical studies demonstrate that an Oral Irrigator is safe and can significantly reduce bleeding and gingivitis in a variety of cohorts (Flemmig et al., 1990; Brownstein et al., 1990)⁹. Although it is universally recognized that interproximal cleansing is essential for controlling periodontal disease (Løe, 1979), many people have difficulty accomplishing this with traditional dental floss (Asadoorian, 2006). Thus, compliance with floss is low (Warren and Chater, 1996)¹⁰, and various adjuncts for interdental cleaning have been studied. The aim of this clinical randomized trial was to assess the efficacy of the addition of daily oral irrigation (OI) and dental floss (DF) to manual

* Corresponding author : Dr. Sasikumar Karuppanan, Reader, Dept of Periodontics, J.K.K.N Dental College and Hospitals, Kumarapalayam, Namakkal Dist, Tamilnadu., Email: sasikumar@jkkn.org

tooth brushing and also compared to manual tooth brushing and also compared to determine

		Group	N	Mean	SD	t	p
Plaque	Baseline	A	32	1.638	0.276	12.09	< 0.001**
		B	32	0.859	0.238		
	4 weeks	A	32	1.172	0.253	11.31	< 0.001**
		B	32	0.563	0.170		
P. Bleeding Index							
Index	Baseline	A	32	1.822	0.203	20.35	< 0.001**
		B	32	0.934	0.141		
	4 weeks	A	32	1.363	0.188	20.24	< 0.001**
		B	32	0.591	0.106		
Gingival Index							
Index	Baseline	A	32	2.903	0.419	15.22	< 0.001**
		B	32	1.572	0.264		
	4 weeks	A	32	2.419	0.404	15.64	< 0.001**
		B	32	1.119	0.242		

** Highly Significant (Significant at 1 %)

Table 2: Independent t-Test using for Comparison of Group A(DF) and Group B(OI) at Baseline, 2nd & 4th week

reduction of plaque and gingivitis.

Materials and Methods:

The present study was designed to carry out in the Department of Periodontics and Public Health Dentistry, JKKN Dental College and Hospitals, Komarapalayam, India. It included a total of 70 patients who were complaining of bad breath and bleeding gums (32 males and 38 females, in the age range of 18 to 25 years). The ethical clearance for the study was availed from the ethical committee of the institution (Under the Tamilnadu Dr.MGR Medical University, Chennai), and informed consent was taken from all the participants of the study.

Each subject was to have a minimum of 18 scorable teeth (excluding third molars, teeth with orthodontic appliances, bridges, crowns or implants) to be included in the study, the subjects were required to have at least mild to moderate gingivitis with the age of 25 to 38

yrs. Subjects were required to fulfil the

following criteria: ≥ 18 years of age, a minimum of five evaluable teeth in each quadrant (with no partial dentures, orthodontic banding or wires); moderate gingivitis (50% bleeding on marginal probing, Galgut et al., 1998)

The exclusion were; presence of aggressive periodontitis, presence of severe periodontitis, that is, clinical attachment loss of ≥ 5 mm, any physical limitations that might compromise the normal tooth brushing technique, evidence of neglected oral hygiene or major hard or soft tissue lesions or trauma, gross caries or the other hard tissue pathology, heavy calculus, orthodontics, prosthodontics, and oral piercings, a medical condition with a requirement of prophylactic antibiotic coverage before dental treatment, use of antibiotic therapy or anti-inflammatory medications in the previous 28 days, use of anticoagulants,

steroid therapy, and smoking status

Group A		N	Mean	SD	ANOVA	P
Plaque Index	Base line	32	1.638	0.276	24.70	< 0.001**
	2 Weeks	32	1.438	0.269		
	4 Weeks	32	1.172	0.253		
	Total	96	1.416	0.326		
P. Bleeding	Base line	32	1.822	0.203	44.91	< 0.001**
	2 Weeks	32	1.613	0.191		
	4 Weeks	32	1.363	0.188		
	Total	96	1.599	0.269		
Gingival Index	Base line	32	2.903	0.419	11.32	< 0.001**
	2 Weeks	32	2.697	0.404		
	4 Weeks	32	2.419	0.404		
	Total	96	2.673	0.451		
Group B						
Plaque Index	Base line	32	0.859	0.238	16.93	< 0.001**
	2 Weeks	32	0.716	0.199		
	4 Weeks	32	0.563	0.170		
	Total	96	0.713	0.236		
P. Bleeding	Base line	32	0.934	0.141	58.74	< 0.001**
	2 Weeks	32	0.775	0.132		
	4 Weeks	32	0.591	0.106		
	Total	96	0.767	0.189		
Gingival Index	Base line	32	1.572	0.264	24.96	< 0.001**
	2 Weeks	32	1.369	0.264		
	4 Weeks	32	1.119	0.242		
	Total	96	1.353	0.315		

** Highly Significant (Significant at 1 %)

Table 3: The intra group comparison between A (Dental Floss) and Group B (Oral Irrigator) using ANOVA at Baseline, 2nd week and 4th week.

which regimen had the greatest effect on the Diabetes, rheumatic fever, hepatic or renal disease and other transmissible diseases, were each also a basis for exclusion.

Study products

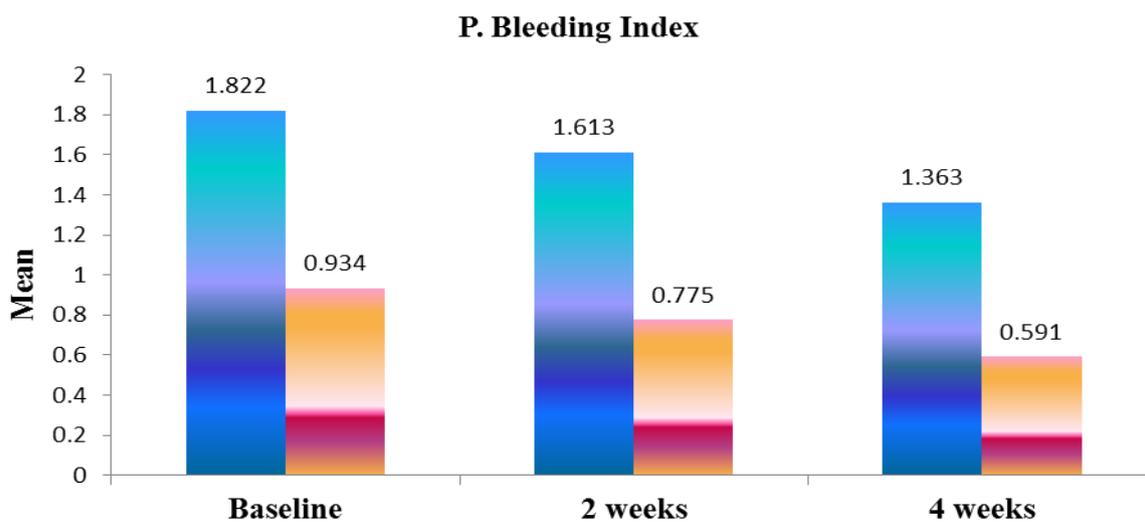
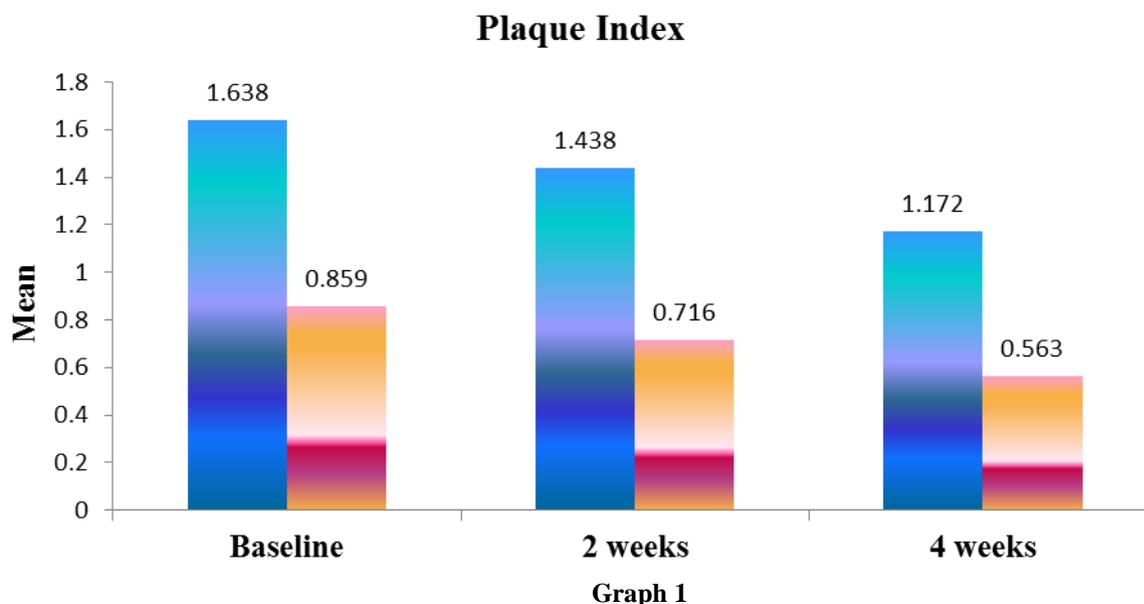
Two different interdental products were tested in this study, one product per group, with 35 subjects enrolled in each group. All subjects received a standard toothbrush (Oral-B Indicator 35) and Standard fluoride dentifrice (Colgate Private Ltd, India). In addition,

subjects were randomized (see below for

details) into one of two groups for assignment of an interdental cleaning device:

Group A (OIS): OI (Waterpik® Ultra Water Flosser, USA) with a standard jet tip (Figure 1, Hussein et al., 2008)¹¹.

Group B (DF): Standard waxed floss (Oramint^R) (Figure 2).



Graph 1& 2 showing the comparison of Plaque and P.Bleeding Index of Group A (DF) and Group B respectively (Blue colour denotes – Dental Floss (DF), Pinkish Orange denotes - .Oral Irrigator (OI) Group)

Procedure;¹¹

During the four week of experimental phase, supra and subgingival gingival irrigation was done with standard jet tip (different type of

waterpik Tips available and showed in figure

3). All the subjects were professionally irrigated with Oral Irrigator once a day in the evening with warm tap water and were

instructed to finish one container of 500 ml at each visit.



Figure 1: Water Flosser Used for the Study



Figure 2: Water Flosser with Different type of Tips



Figure 3: Standard Dental Floss Used for this Study

Subjects in the B group (DF) used standard waxed dental floss once a day in the evening. At the baseline visit (First visit), immediately following the baseline assessment, subjects used their allocated product for the first time. Clinical assessment¹¹

Clinical parameters were assessed at baseline (First visit), 2nd week (second visit), and week 4 (Third visit). After disclosing plaque, baseline plaque scores were brought to zero by professional scaling and polishing with rubber cups and an abrasive paste. First the Gingival Index and then plaque was scored.

The teeth were dyed using a new cotton swab with fresh disclosing solution (Mira-2-Ton®, Germany) for each quadrant in order to disclose the plaque. Subsequently, the absence or presence of plaque was recorded on a 6-point scale (0-5, 0 = no plaque, 5 = plaque covering more than two-thirds of the tooth surface).

Gingivitis was assessed as the primary outcome using the bleeding on marginal probing index (BOMP) as described by Van der Weijden et al¹². (1994) and Lie et al. (1998). In short, the gingival margin is probed at an angle of approximately 60° to the longitudinal axis of the tooth and the absence or presence of bleeding is scored within 30 seconds of probing on a scale 0 – 2 (0 = no bleeding, 1 = pinpoint bleeding, 2 = excessive bleeding).

Statistical analysis:

The preferred statistical analysis when two treatments are being compared is a comparison of mean scores by the independent sample t-test. An analysis of covariance, using the baseline scores as the covariate, must be done whenever the comparison between more than

two values is required. The means were calculated for the plaque and gingival index scores at 0, 14, and 28 days for both (Group A & B) groups.

Results:

A total of 70, among which 35 were randomly allotted for the group A and the remaining 35 for Group B. Six patients (two females, four males) were lost to follow up of whom five patients discontinued the initial scaling and one patient did not comply with the oral hygiene instructions given. Hence, only 64 patients (28 males and 36 females) available for statistical analysis, among which 32 were Group A and 32 were Group B. The statistical analysis conducted was per-protocol analysis, as the data from patients lost to follow up was not utilized. The results showed that there was a significant reduction in plaque scores, gingival scores, and gingival bleeding index scores both in the Group A and the Group B following scaling as represented in Table 1, Graph 1 (plaque index scores), Table 2 (Gingival index scores), Graph 2, Table 3 (Gingival bleeding index scores).

The means and standard deviations on the bleeding index, gingival index, and plaque index are provided in Table 3. The mean values for the bleeding index, gingival index, and plaque index were reduced from baseline at both 2nd and 3rd follow-up times, on facial and lingual sites, for each of the groups. The gingival health measures of the bleeding index and gingival index showed a statistically significant percentage reduction in each group at each follow-up time. Percentage reduction in plaque index was statistically significant in Group A (OI) compared with Group B at all follow-up times. In that case, the mean, percentage reduction in plaque index was not significantly greater than zero.

Bleeding Index for Surfaces:

The percent reduction in the bleeding index on the surfaces (Table 2) was greater in Group B (0.77) than Group A (1.61) at 14th day ($p = < 0.001$). At 28th day, the Group B percent reduction (1.36) was also significantly greater than that for Group A (0.59) at $p = < 0.001$. For Group B, the facial percent reduction in bleeding index was 58.74 at 14th day, which were significantly greater than 44.91 for Group A. At 28th day for Group B, the facial percent reduction in bleeding index was 12.90 for Group B versus 17.36 for Group A, a significant statistical difference at $p = < 0.0072$.

Plaque Index for the Surfaces:

The mean percentage reductions in the plaque index at 2nd week, for Groups A and B, surfaces (Table 1,2) were 1.43, and 0.72 respectively. Group B was not significantly different from Group A on this measure. The mean percentage reductions in the plaque index at 28th day, for Groups A and B on surfaces were 1.17 and 0.56, respectively. Group A was not significantly different from Group B, but was significantly less than Group B at $p = 0.0109$. Table 3 summarizes the group comparisons on facial surfaces by expressing the ratio of the percent reduction of each index in Group B compared to Group A. It can be seen from Table 3 that the gingival health measures of bleeding index and gingival index range between 1.15 and 1.93 across the two follow-up times. Plaque index ratios were much more variable due to fluctuations in both numerator and denominator values.

Gingival Index for Surfaces:

The percent reduction in the gingival index on the surfaces (Table 2, 3) was greater in Group B (1.36) than Group A (2.69) at 14th day ($p = 0.001$). At 28th day, the Group B percent reduction (1.35) was also significantly greater than that for Group A (2.41) at $p = < 0.001$. For Group B, the facial percent

reduction in gingival index was 24.96 at 28th day, which were significantly greater than 11.32 of Group B. At 28th day for Group B, the facial percent reduction in bleeding index was 16.80 versus 28.11 for Group A, a significant statistical difference at $p = <0.0172$.

Discussion:

Maintenance of good oral hygiene is the key to prevention of oro-dental diseases. The primary etiological factor for dental diseases is dental plaque. The formation of plaque on the teeth is characterized by a progression from a limited number of bacteria to the complex flora of mature dental plaque, which involves initial adherence of bacteria to the salivary pellicle and subsequent accumulation by growth.¹³

This study shows that the addition of oral irrigation and Dental Floss to manual tooth brushing provides significant benefits to oral health through greater reductions in bleeding and gingivitis over traditional brushing and flossing, notably with a near twofold increase in the percent reduction in bleeding in Group A compared to Group B. This finding may be important to individuals who do not irrigate/floss, or have significant difficulties in flossing. Based on these results, it appears that the manual tooth brushing, plus the use of an oral irrigation device once daily with plain water, is as effective as a traditional brushing and flossing routine, and in some cases may provide superior results for reducing bleeding and gingivitis.

The present study focussed on the ability to reduce gingival inflammation in a population of young individuals with moderate gingivitis using an OI. The OI works through the direct application of a pulsed stream of water or other solution. The study duration of four weeks was chosen to monitor the changes in the bleeding index, which meets the ADA guidelines on OI's for studies assessing the effects of adjunctive therapies on reduction of gingivitis (ADA, 2008)¹¹. In the present study, an attempt

was made to evaluate and compare the effectiveness of professional subgingival irrigation and dental floss, with scaling in gingivitis patients. The clinical parameters such as PI, BI, GI, were compared between baseline, 2 weeks and 4th week.

In this present study both Oral Irrigator and Floss groups did show statistically significant improvements after four weeks. At the end of the study both groups show a significant 15 - 17% reduction of the bleeding index as compared to baseline. For the DF group this difference was not observed. Comparisons among groups showed a significant difference at four weeks between the DF group and OI groups. The absolute difference of 11% at four weeks for OI groups as compared to the floss group reveals a relative effect of oral Irrigation.

In consideration of the ADA guidelines for oral irrigators, the results of the present study do not reach the lower limit of superiority of 20% as estimated proportionate reduction related to clinical relevance as compared to standard oral hygiene procedures (ADA, 2008). However, the ADA also has guidelines on adjunctive dental therapies (ADA, 1997). In those guidelines a lower limit of 15% is applied. The study outcomes of the present study do comply with this guideline, indicating a potential beneficial effect for the oral Irrigator in Indian Population.

In the present study, the mean reduction of plaque score from baseline to 4th week was 15.9% in Dental Floss group, which was statistically non-significant. This was consistent with the findings of Eros S. Chaves et al.¹⁴ This improvement observed from baseline to 4th week may be due to adequate maintenance of oral hygiene, while instruction was given to each patient. In group A, the mean reduction in plaque score from baseline to 28th day was 17.4%, which was significant ($P = 0.03$). This finding was similar to that of study done by Badersten et al.¹⁵

Barnes CM et al (2005)¹⁶ studied the

effect of Oral Irrigation and Dental Floss on gingival bleeding, gingivitis and showed that oral irrigation was an effective alternative to manual tooth brushing and dental floss. Goyal CR et al. (2012)¹⁷ found that the mean reduction in plaque score from baseline was 22.2%, which was highly significant ($P < 0.001$); this finding is similar to that of observation made by this study. In 2002, Al-Mubarak, et al.¹⁸ found that twice daily water irrigation via a soft subgingival tip (Pik Pocket® subgingival irrigation tip, Waterpik Technologies) reduced both traditional clinical measures of periodontitis and serum measures of IL- α and PGE2 in individuals living with diabetes better than tooth brushing alone. This concurrent with present study that reduced inflammation was there when using oral irrigation compared with dental floss.

Oral irrigation has a long history of reducing bleeding and gingivitis independent of plaque removal. A recent systematic review (Husseini et al., 2008)¹⁹ reported no statistically significant reduction in plaque when the OI was used as an adjunct to tooth brushing when compared to tooth brushing. A consistent finding in previous research is that the use of an oral irrigator improves bleeding and gingivitis without a direct correlation to a reduction in the amount of plaque, suggesting the disruption of plaque and subsequent removal of endotoxins weakens the pathogenicity of the plaque. This is agreed with present study that had significant of 10% reduction of bleeding and Plaque formation when using Oral Irrigation at once daily in the evening time. The mechanisms of actions underlying these clinical changes for the bleeding index in the absence of a clear effect on plaque are not understood, although different hypotheses have been put forward (Husseini et al., 2008). One of the hypotheses is that supragingival irrigation alters the population of key pathogens, reducing gingival inflammation (Flemming et al., 1995). Another

hypothesis is that the water-pulsation may alter the specific host-microbial interaction in the subgingival environment (Chaves et al., 1994).

The absence of an effect for DF at four weeks may also seem surprising. A transient effect of 7% Bleeding Index reduction was observed at two weeks. However, a recent systematic review supports this finding that dental floss has no significant effect on plaque or bleeding indices (Berchier et al., 2008)²⁰. Interestingly, the reduction in bleeding could not be linked to plaque removal. This is similar to data presented by Flemmig et al. (1990) showing no change in plaque scores for either the brushing group or the brushing and irrigation group from baseline to 6 months, but a significant difference in bleeding on probing and gingival index scores in favour of the irrigation group. Likewise, Flemmig et al. (1995)²¹ and Husseini et al (2008) reviewed and reported that an adjunct to brushing, the oral irrigator does not have a beneficial effect in reducing visible plaque. However, there is a positive trend in favour of oral irrigation improving gingival health over regular oral hygiene or tooth brushing. Also in this study there were no statistically significant differences detected in plaque scores among the groups.

There is also the possibility that the beneficial action of an OI is at least partly because of the removal of loosely adherent soft deposits interfering with plaque maturation and stimulation of the immune response (Fracella et al., 2000)²². Other explanations could be a mechanical stimulation of the gingiva or a combination of the above-mentioned factors (Fracella et al., 2000; Flemmig et al., 1990). Furthermore, irrigation may reduce the thickness of the plaque, which may not be easily detectable using 2-dimensional scoring systems (Jolkovsky et al., 1990)²³. Based upon the findings in this study, further research on the long-term effects of irrigation regimens is warranted to detect efficacy in Indian

Population.

Conclusion:

Within the limits of this clinical study, it may be concluded that the Oral Irrigator and Dental Floss were effective in controlling plaque and gingivitis in patients from rural area of Kumarapalayam, Tamilnadu, India. The Waterpik Water Flosser paired with a manual toothbrush is significantly more effective than Dental floss for removing plaque. Specifically, the group utilizing the Water Flosser had 9%–10% better plaque removal. Further, clinical and in vitro studies are required to clarify and broaden our understanding of the role of this supra and subgingival removal of plaque in periodontal disease.

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